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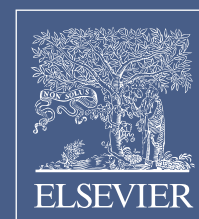
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JOURNAL OF ARTHROSCOPY AND JOINT SURGERY

JAJ S

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Journal of Arthroscopy and Joint Surgery (JAJS) is committed to bring forth scientific manuscripts in the form of original research articles, current concept reviews, meta-analyses, case reports and letters to the editor. The focus of the Journal is to present wide-ranging, multi-disciplinary perspectives on the problems of the joints that are amenable with Arthroscopy and Arthroplasty. Though Arthroscopy and Arthroplasty entail surgical procedures, the Journal shall not restrict itself to these purely surgical procedures and will also encompass pharmacological, rehabilitative and physical measures that can prevent or postpone the execution of a surgical procedure. The Journal will also publish scientific research related to tissues other than joints that would ultimately have an effect on the joint function.

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5. The MCh course is at the Edge Hill University and although most of the payment for the course can be made along the way in installments over the 2 years, there would be an initial Commitment of £8,000 to be made to secure the place before the formalities with Royal colleges and GMC are commenced at this End. The salary scales are detailed with the information sheet as well.
6. There will be two posts per year as the "Wrightington - ISKSAA MCh Fellowship". There would be an **assured Wrightington placement** during the 2-year UK rotation via this stream . **Only ISKSAA Life Members can apply for these posts** .
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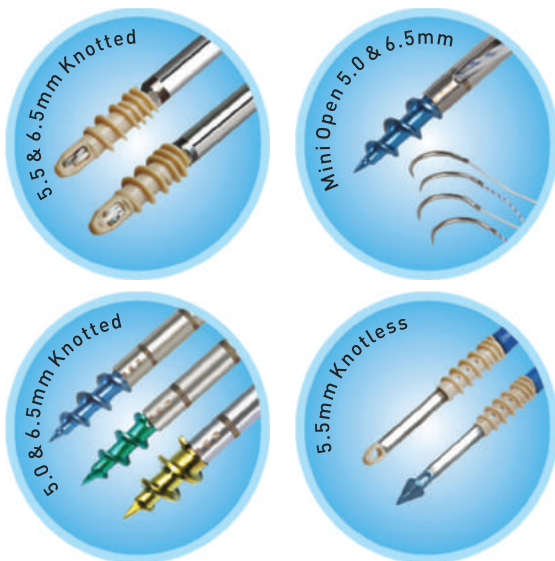


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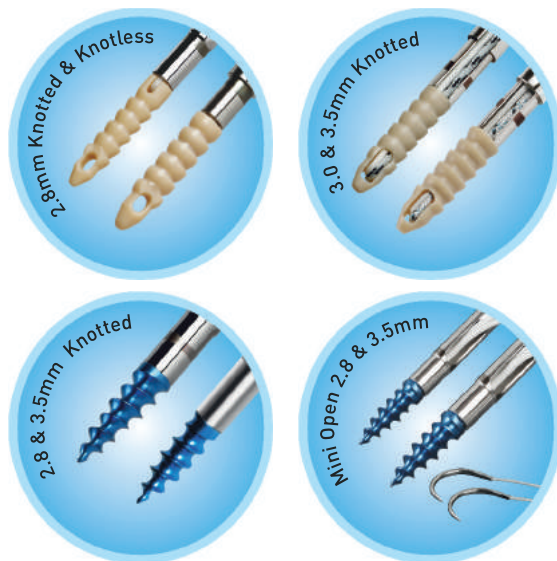
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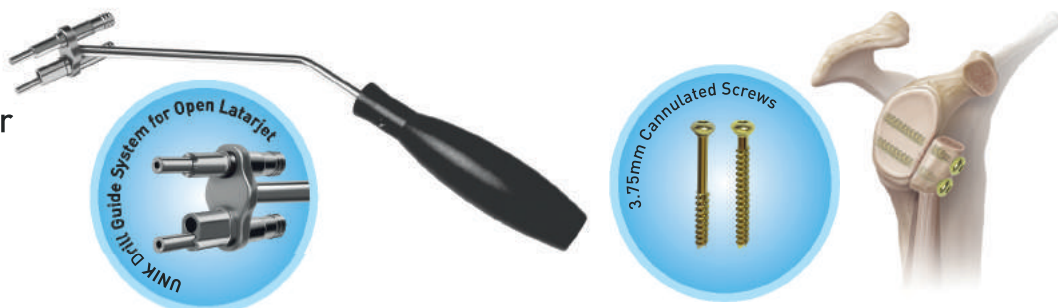


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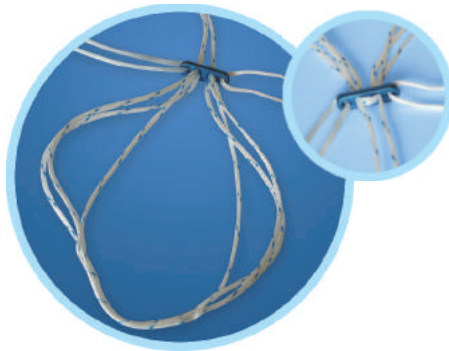
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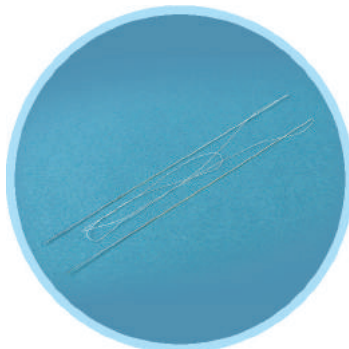


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Review article

Orthopaedic operating room considerations in covid-19 pandemic: A systematic review

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ABSTRACT

Purpose: Worldwide COVID 19 has affected the medical practices and Orthopaedics is not any different. Despite risk, the surgeons cannot deny the surgical procedure on patients with suspected or confirmed COVID 19 infection. The purpose of this manuscript is to review various operating room measures which are recommended and being followed to carry out orthopaedic surgeries in the current scenario of COVID 19 pandemic. The information would be useful for orthopaedic surgeons to carry out safe surgical practice for reducing the transmission of COVID 19 infection.

Method: ology: A systematic literature search was performed using search engines- PubMed, Google Scholar and Scopus from January to August 2020 for relevant research articles. The keywords utilized for systematic literature search were “COVID 19”, “Corona virus” and “Operating room”, “Orthopaedic procedure” in 4 combinations. Duplicates were excluded. Further sorting was done according to the pre-set inclusion and exclusion criteria. Original articles pertaining to orthopaedic surgery and operating room in COVID 19 and available in English language were included. Editorials, case reports, other speciality articles were excluded.

Results: 16 articles were finally included in review after screening for titles, abstracts and full texts. The information obtained is presented as a narrative review.

Conclusion: Various important recommendations include use of negative pressure OR, HEPA filters, dedicated separate OR for COVID positive and suspected patients with well defined separate corridors for transport, avoid AGP wherever possible, minimize the number of assistants and staff and follow strict sanitation protocols after each surgery. A well planned systematic approach is warranted to mitigate the risk of transmission of COVID 19 while carrying out orthopaedic surgeries.

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1. Introduction

Covid-19 or SARS-CoV-2 is an infectious disease that has spread rapidly over the entire world.^{1,2} The outbreak was started from Wuhan province, China in December 2019, and World Health Organisation (WHO) has declared it as pandemic in March 2020.³

Covid-19 has heavily affected the healthcare system. Elective orthopaedic procedures were postponed in order to reduce the

burden on health system. As the number of cases are now decreasing, the elective surgeries may have to be resumed. While operating on covid suspected or positive patient, there is high probability of getting infection to surgeons and other staff in operating room, it must be ensured that all surgeries be done safely, without exposing patients or health-care providers to infection.⁴

The purpose of this systematic review is to look at the current literature on methods required for conducting safe orthopaedic surgeries during COVID-19 pandemic and formulate practical recommendations on desired changes in the operating room while performing orthopaedic procedure on a covid-19 suspected or positive patient.

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2. Material and methods

A systematic literature search was performed using PubMed, Google scholar and Scopus. The electronic database was screened of all the articles published between January 2020 to August 2020. The search was conducted using following keywords- “COVID 19”, “coronavirus”, “orthopaedic procedures” and “operating room” in different combinations. The selected articles were sorted in an excel sheet and the duplicate articles were removed. Original articles pertaining to orthopaedic surgeries in COVID patients available in English language were included in the review. Case reports and editorials were excluded from the study. The selected articles were initial screened through titles and thereafter by abstract reading and final list were prepared after full text reading.

3. Results

After removing the duplicate articles, we obtained 630 articles from our electronic search using the combinations of keywords. These 630 articles were screened using our exclusion criterion and 229 articles were obtained.

A second screening of these 229 articles was conducted by going through the titles. One hundred seven articles were excluded and 122 articles were selected. When conducting the second screening of 122 articles on the basis of abstract reading, 106 articles were removed. The final list of 16 articles was made (Fig. 1). These 16 articles were randomly distributed amongst 4 authors for full text reading. These 16 articles are listed in Table 1.

As the data was heterogenous, it was not possible to perform a systematic review and the obtained information is provided as a narrative review.

4. Discussion

The data extracted from the included articles is discussed under the following headings for simplification.

4.1. Screening

It has become a practice to screen each patient requiring surgery for COVID 19. Screening includes history of contact, symptoms of COVID and tests including rapid antigen test, RT-PCR as well as CT chest.⁹ Although there is risk of infection, it is impossible for surgeons to avoid operating in all suspected or COVID positive patients. Surgeons require to decide whether to operate or not on the basis of patient’s clinical status, indication of surgery (urgent/emergency/non-urgent) and available resources.⁹

4.2. Operating room (OR) ventilation

Usually, the direction of airflow in the operating room complex is from the OR towards the surrounding area (positive pressure).²⁴ A positive pressure OR is one in which the air pressure inside the OR exceeds that of the surrounding adjacent areas and hence restricts contamination of surgical field by contaminants from surrounding environment. A negative pressure OR on the other hand is one which maintains lesser air pressure inside than the surrounding environment and hence restricts any dissemination from within the OR. Positive pressure environment is utilized to reduce the risk of surgical site infection by contamination; however, it will not restrict the dissemination of infectious particles from inside the OR to outside environment. Hence, a negative pressure OR with separate ventilation system and HEPA filter is desirable for performing surgery on COVID 19 positive/suspected patient to mitigate the risk of cross transmission amongst patients and staffs. Twelve

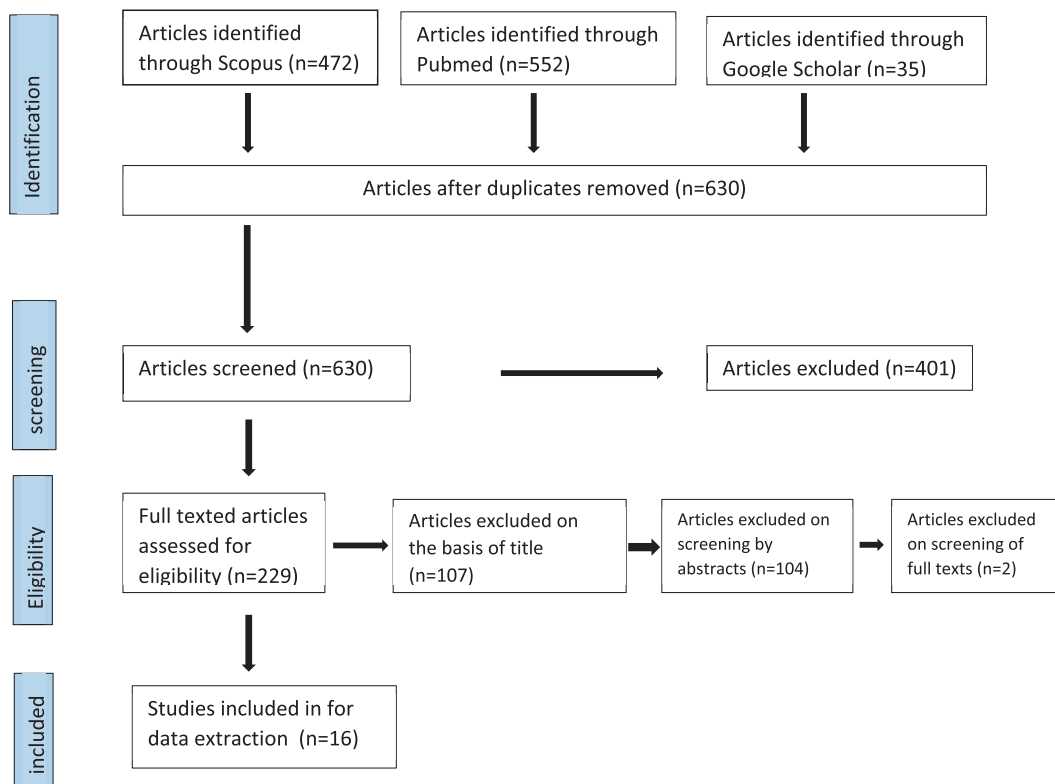


Fig. 1. Prisma Flow diagram showing the flow of information in the systematic review.

Table 1
Summary of total articles reviewed.

Sr. No.	Author	Article	OR environment				Separate OR for COVID
			Negative pressure OR	HEPA Filter	Laminar airflow	AC	
1	Abdelnasser MK et al. ⁵	COVID-19. An update for orthopaedic surgeons	Yes, with separate ventilation system	Recommends to add HEPA filters to positive pressure room if negative pressure not available,	N.A	No	Yes
2	Ambrosio L et al. ⁶	The role of the orthopaedic surgeon in the COVID-19 era: cautions and perspectives	Yes; If not available, turn off positive pressure and use HEPA filter	HEPA filter with frequent air exchange to be used In case of positive pressure OR	N.A	N.A	Yes
3	Barry TWL et al. ⁷	In the Extraordinary Times of Coronavirus Disease 2019: Clinical Strategies for Performing Spinal Surgery	Yes; 6–12 cycles of air change per hour	N.A	N.A	N.A	Yes, with specific access corridors
4	Casiraghi A et al. ⁸	Operational strategies of a trauma hub in early coronavirus disease 2019 pandemic	N.A	N.A	N.A	N.A	Yes
5	de Caro F et al. ⁹	Returning to orthopaedic business as usual after COVID-19: strategies and options	Yes	N.A	N.A	N.A	N.A
6	Ding BTK et al. ¹⁰	Operating in a Pandemic: Lessons and Strategies from an Orthopaedic Unit at the Epicenter of COVID-19 in Singapore	Yes	Minimum 15 air changes per hour through HEPA filter	NA	NA	NA
7	Geevarughese NM and Ul-Haq R ¹¹	Aerosol generating procedures in orthopaedics and recommended protective gear	Negative pressure OR with minimum 12 air changes per hour for AGPs	Exhaust air is filtered through HEPA	NA	NA	NA
8	Hirschmann MT et al. ¹²	COVID-19 coronavirus: recommended personal protective equipment for the orthopaedic and trauma surgeon	N.A	N.A	N.A	N.A	N.A
9	Kenanidis E et al. ¹³	Organizing an Orthopaedic Department During COVID-19 Pandemic to Mitigate In-Hospital Transmission: Experience From Greece	Negative pressure OR	Yes	N.A	N.A	Yes
10	Mi B et al. ¹⁴	COVID-19 Orthopaedic Safe Care Toolset: Guidelines for the Diagnosis and Management of Patients with Fracture and COVID-19	Negative pressure OR/Independent airflow system	N.A	Laminar airflow to be switched off immediately after surgery	N.A	N.A
11	Parvizi J et al. ¹⁵	Resuming Elective Orthopaedic Surgery During the COVID-19 Pandemic: Guidelines Developed by the International Consensus Group (ICM)	Ventilation system with minimum 20 air changes per hour. Normal positive pressure OR for elective procedures. No need of negative pressure; Though in room air filters, negative pressure ante chamber can be used.	Yes	N.A	N.A	N.A
12	Sadigale O et al. ¹⁶	Resuming arthroplasty: A well aligned and a balanced approach in the COVID-19 era	Negative pressure OR with 20 air changes per hour is recommended; Avoid positive pressure OR	N.A	Yes	N.A	N.A
13	Service BC et al. ¹⁷	Medically Necessary Orthopaedic Surgery During the COVID-19 Pandemic: Safe Surgical Practices and a Classification to Guide Treatment	Yes	N.A	N.A	N.A	N.A
14	Verma V et al. ¹⁸	Adapting Policy Guidelines for Spine Surgeries During COVID-19 Pandemic in View of Evolving Evidences: An Early Experience From a Tertiary Care Teaching Hospital Recommendations of protective measures for orthopaedic surgeons during COVID-19 pandemic	N.A	Individual OR having separate ventilation system and HEPA filters	N.A	N.A	N.A
15	Wang Y et al. ¹⁹	Recommendations of protective measures for orthopaedic surgeons during COVID-19 pandemic	Negative pressure OR (- 5 Pa)	Hepa filter must be used	N.A	N.A	Yes
16	Stinner DJ et al. ²⁰	The Orthopaedic Trauma Service and COVID-19: Practice Considerations to Optimize Outcomes and Limit Exposure	Negative pressure OR	N.A	N.A	N.A	Yes

out of 16 articles recommend use of a negative pressure OR, whereas one article¹⁵ mentions that there is no need of negative pressure OR and a positive pressure OR with minimum 20 air changes per hour and in-room air filter and negative pressure antechamber can be used for elective surgeries. Since positive-pressure ORs are usually utilized to reduce the risk of surgical contamination,^{6,24} there conversion to negative pressure OR in the wake of this COVID pandemic should be planned carefully and will

require OR maintenance. Some hospitals have ORs with reversible ventilation mode, while others also have positive-pressure ORs with a negative pressure anteroom.²⁰ If it is not feasible to have a negative pressure OR, positive pressure should be turned off and a HEPA filter with frequent air changes should be used.²³ One article mentions about air conditioner in OR and recommend that AC should be switched off during the surgery.⁵ One article on resuming arthroplasty surgeries recommends use of laminar air flow in a

negative pressure OR.¹⁶ Only one article mentions the value of recommended pressure in negative pressure OR to be -5 Pa .¹⁹ Recommended air changes per hour in OR ventilation is variable in different articles. Barry TWL et al.⁷ recommend 6–12 air change per hour for aerosol generating procedures; Geevarughese NM and Ul-Haq R¹¹ recommend minimum 12 air changes per hour, whereas Sadigale O et al.¹⁶ recommend minimum 20 air changes per hour in arthroplasty surgeries.

4.3. HEPA filter

HEPA filters are high efficiency air filtration systems that restrict the passing particles by diffusion, interception, and inertial impaction.²¹ The filtration effectiveness of HEPA filters is around 99.97% of 0.3 μm particles.²² The size of aerosol droplets is 1–5 μm .²¹ Orthopaedic surgeries often involve multiple aerosol generating procedures and HEPA filters with frequent air changes per hour should be helpful by filtering out the aerosol particles from the air. Eight articles recommend use of HEPA filters to reduce the risk of COVID 19 transmission. Ding BTK et al.¹⁰ recommends HEPA filter with minimum 15 air changes per hour. Abdelnasser MK et al.⁵ and Ambrosio et al.⁶ also recommend to add HEPA filters to positive pressure room if negative pressure is not available.

4.4. Separate OR for COVID patients

Seven articles^{5–8,13,19,20} mention and recommend about having separate designated OR for COVID positive or suspected patients. Hospitals should also designate separate specific corridors/walkways for transfer of COVID positive or suspected patients to OR.¹⁰ The pathways to OR should be well defined and proper labelling of corridors is necessary to avoid any confusion. A unidirectional flow of OR staff should be maintained with minimum door opening.

4.5. Surgical team and OR staff management

Twelve out of 16 articles recommend that minimum number of staff members should be kept inside the OR for any surgical procedure.^{5–7,10,11,13–16,18–20,25} Less number of staff will facilitate the implementation of social distancing and also reduce the PPE demand.¹⁸ It is advised that experienced surgeon with highest skill should perform the procedure to avoid prolonged surgical duration and hence exposure time.^{5,7,13,14,16,18} Sadigale O et al.¹⁶ recommend maximum of 8 persons in surgical team with carefully selected personnel based on their experience and familiarity to the procedure. Trained staff and personnel for specific surgeries should be incorporated in the team. Unnecessary movement in the OR complex should be strictly discouraged.⁶ Sales representatives should also not be allowed in OR until strictly needed.^{5,6,14,19,20} Verma V et al.¹⁸ utilized a surgical team including chief surgeon, senior resident, junior resident, and scrub nurse. Barry TWL et al.⁷ utilized minimal personnel in spine surgeries which consisted of the spine surgeon, a resident, one scrub nurse, and one circulating nurse. It is advised to do daily screening and close monitoring of peri-operative teams with temperature assessment to identify early disease.¹⁷ Service BC et al.¹⁷ recommend using surgical teams separated physically performing work on alternate weeks to avoid exposure of the entire staff. If patient is to be operated under GA and intubated, surgical team should not be present inside the OR during intubation and around 20 min after that depending on the air change frequency as intubation is an aerosol generating procedure.^{7,14,16,18}

4.6. Use of personal protective equipment (PPE)

Each article recommends proper use of PPE in operating rooms. The PPE should include surgical gowns, surgical hood (to cover head and neck), facemasks (N95/FFP2) with a face shield/goggles or Powered Air-Purifying Respirator (PAPR) and fluid resistant shoes or boots.^{5,6,26} Association of Advancement of Medical Instrumentation (AAMI) grading classifies surgical gowns on the basis of liquid barrier capacity. Personnel in operating room should use AAMI level III surgical gown. Proper hand hygiene and donning and doffing technique are necessary. Personnel should be vigilant to avoid self-contamination during PPE doffing. N95 or FFP 2 masks have 95% filtration efficiency for particles of size 0.3 μm . N95/FFP2 use is essential when operating a suspected or positive patient as routine surgical masks do not provide good protection against aerosols in high risk aerosol generating procedures.¹² A simple surgical mask can however be worn over N-95 to prevent gross contamination. N95 respirator must be checked for not being soiled or damaged before reuse. Full face shield is preferred to protective eye goggles. Multiple surgical masks should also not be used as alternative to N95/FFP2 as it also fails to filter virus loaded particles.⁸ In addition to the type of masks used, the fitting and sizing of the mask is of utmost importance. Only a perfect-sized and well-fitted mask leads to efficient sealing of the respiratory tract. PAPR respirator filters out contaminants from air using a battery powered unit. Ding BTK et al. advise to use PAPR for prolonged surgeries (>4 h) in COVID 19 patients.⁶ However, PAPR's higher cost, reduced visual field, regular requirement of maintenance, difficulties in hearing etc are its disadvantage.

4.7. Aerosol generating procedures (AGPs)

Orthopaedic surgeries involve multiple procedures which generate aerosol. These include use of power drill, oscillating saw, harmonic scalpel, pulse lavage, burr, cautery, reaming etc which are very often utilized. Nogler et al. demonstrated that aerosols spread in up to 6–8 m are generated by high-speed cutters during revision hip arthroplasty.²⁷ Electro-cautery should be used minimally and in minimum setting possible along with a smoke evacuator.^{5,6,13,15,17–19,26} Power devices like drills, saws, reamers and burr should also be used minimally and the power settings should be as low as possible.^{5–7,9,11,12,15–19} Considering using a Gigli saw, sharp osteotomes, and manual reaming whenever possible.^{15,18} Use of negative pressure OR, HEPA filter and proper PPE is imperative to attenuate cross-infection.¹¹

5. Conclusion

Recommendations include use of negative pressure OR, HEPA filters, dedicated separate OR for COVID positive and suspected patients with well defined separate corridors for transport, avoid aerosol generating procedures wherever possible, minimize the number of assistants and staff and follow strict sanitation protocols after each surgery.

Declaration of competing interest

None.

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Review article

Surgical complications of total knee replacement after solid organ transplant: A systematic review of the literature



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ABSTRACT

Background: Since the mid-twentieth century, solid organ transplantation has become established worldwide and conferred immense benefit to hundreds of thousands of patients. Comorbidities associated with end stage organ failure and the use of immunosuppressive treatment result in solid organ transplant patients (SOTP) commonly developing bone disease necessitating joint replacement. The increasing life span of SOTPs has also resulted in an increase in age related osteoarthritis. The aim of this literature review was to summarise the evidence available on outcomes following total knee replacements (TKR) in SOTP's.

Methods: A systematic search of the literature was performed by authors using PRISMA guidelines. A total of 10 papers were reviewed for this article. Data was extracted from the papers regarding complications specifically related to TKR.

Results: SOTP's are more susceptible to post-operative complications following TKR. Infection was the most common post-operative complication encountered (6.99%). Overall complication rate reported was 22.58%. Renal transplant patients have shown to have a higher infection rate when compared to liver patients. Mortality rate is increased in this patient group (5.91%). Post-operative knee scores show good to excellent clinical results.

Conclusion: This review of the literature has highlighted from the limited data that there is an increased risk of post-operative complications following TKR in SOTP's. Further data is required to more accurately quantify this risk. Despite this, the benefit to be gained from TKR may outweigh the proven increased risk.

Implications: When counselling solid organ transplant patients for TKR, information regarding the increased post-operative risk should be discussed. This may become a more common scenario as life expectancy following SOT increases.

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1. Introduction

The number of solid organ transplants (SOT) carried out is on the rise. The Global Observatory on Donation and Transplantation reported that in 2017, 139,024 organs were transplanted worldwide, representing an increase of 7.25% from 2015.¹ Patient life expectancy after SOT has also increased over time, with a mean of 4.3 years of life saved per transplant.² Patients with a kidney transplant have a median survival of 12.4 years, with similar median survival rates of 11.1 years and 9.4 years for liver and heart

transplants respectively.³ The increased life expectancy is due to advancement in surgical techniques, perioperative care and pharmacological (immunosuppressive) treatment. A greater number of transplants and improved survival rates means there will be an increasing population of patients with SOT who are more likely to reach old age and therefore more likely to suffer from degenerative joint disease. (see Figs. 1–6)

Skeletal complications post-SOT are well described in the literature.⁴ The main cause of these complications is lifelong immunosuppressive medication post-SOT, though pre transplant comorbidities almost certainly play a role. Pharmacological advances such as the use of tacrolimus and mycophenolate have allowed lower doses of corticosteroids to be used, but these medications are also known to cause osteoporosis and osteonecrosis.

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- 1) Did not contain long term follow up data of over 1 year
- 2) Meeting abstracts.
- 3) Complication rates were not reported.
- 4) Single case studies.
- 5) Those which reported outcomes from multiple types of joint arthroplasty but did not include outcome data specifically related to total knee replacement.
- 6) Revision arthroplasty procedures.
- 7) Data extracted from national database

Fig. 1. Exclusion criteria for systematic search.

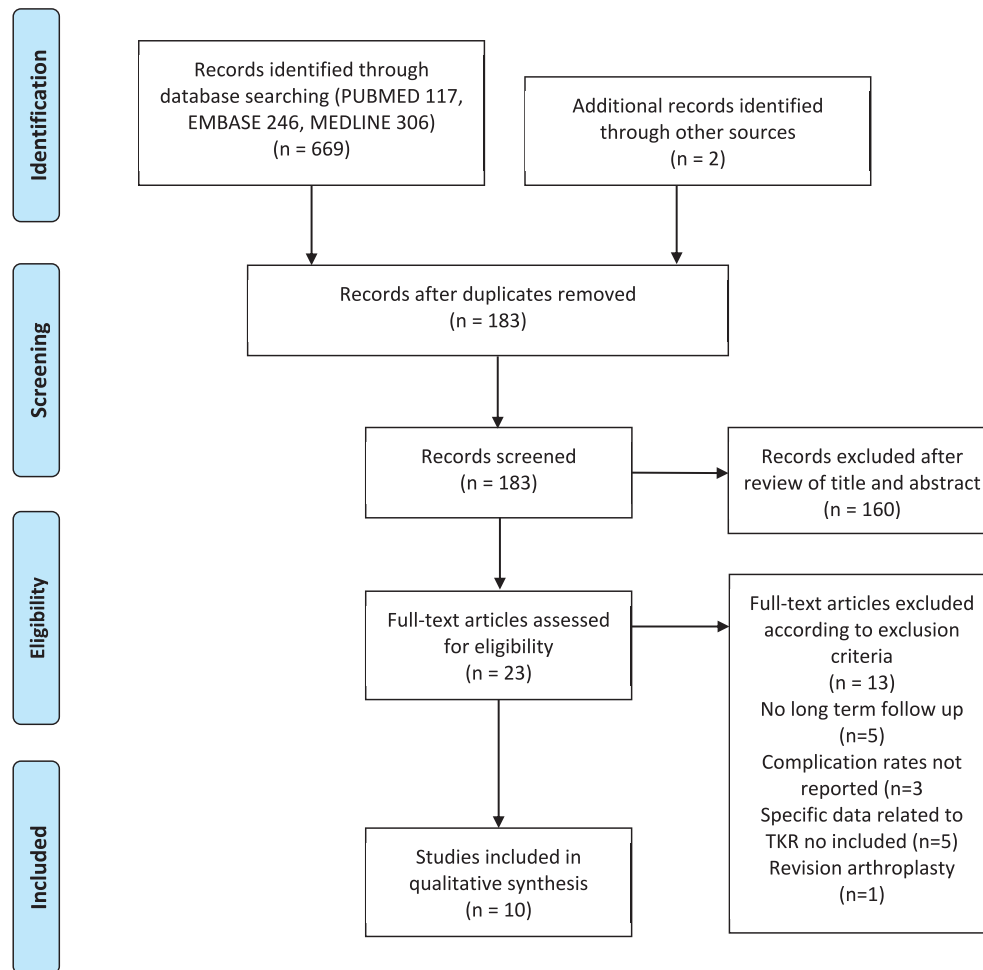


Fig. 2. Prisma flow diagram highlight study selection process.

Osteoporosis, in theory, is likely to increase the risk of peri-prosthetic fractures both intra and post operatively. Osteonecrosis is more common in the hip but cases in the knee, ankle and shoulder have all been described post-SOT and is a common indication for joint replacement surgery. Immunosuppressive treatment also raises concerns over the risk of superficial and deep infections after joint replacement surgery.

The increasing life expectancy of patients with SOT and the associated skeletal complications will result in increased demand in arthroplasty procedures. There is little evidence analysing the surgical complications associated with total knee replacement (TKR) in SOT patients. It is important that surgeons are aware of the

potential complications and are able to provide an accurate risk profile to patients with SOT who are contemplating having a TKR. The aim of this systematic review is to analyse the data that has been reported to better understand the risks associated when performing a TKR in SOT patients.

2. Materials and methods

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2009 guidelines and checklist were utilised in when performing this systematic review.

A systematic search using the key terms and Boolean operators

Complication	Risk (%)
PJI	6.99
Extensor mechanism failure	0.54
Fracture	3.76
death	5.91
arthrofibrosis	2.15
other	3.23
Overall complication risk	22.58

Fig. 3. Overall complication rates associated with TKR in SOT.

“total knee replacement” OR “total knee arthroplasty” AND “organ transplant” OR “organ transplantation” was performed. The search strategy was applied to the article title and abstract, with no limit regarding the year of publication. The search strategy was limited to studies in English. The following databases were accessed on July 11, 2020; Medline, PubMed and EMBASE using the criteria set above. After review of articles included in the qualitative synthesis, references were reviewed to capture additional studies that may have fulfilled the inclusion criteria. One reviewer performed the initial literature search and screening. The assessment and critical appraisal of studies included in the systematic review were jointly performed by two reviewers. The level of evidence of each study was recorded independently by the two reviewers using the U.S Preventive Services Task Force Grade Definitions.⁵ Data was

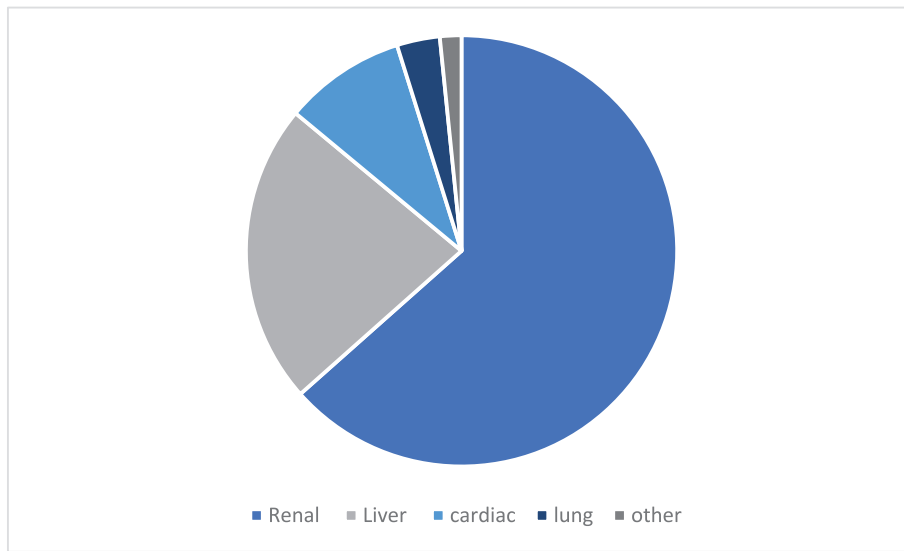


Fig. 4. Distribution by organ transplant type.

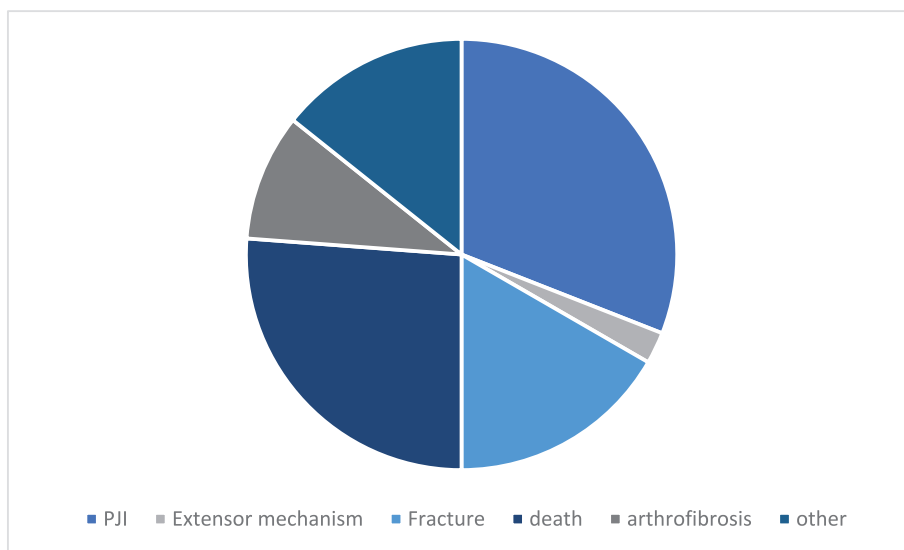


Fig. 5. Complications reported.

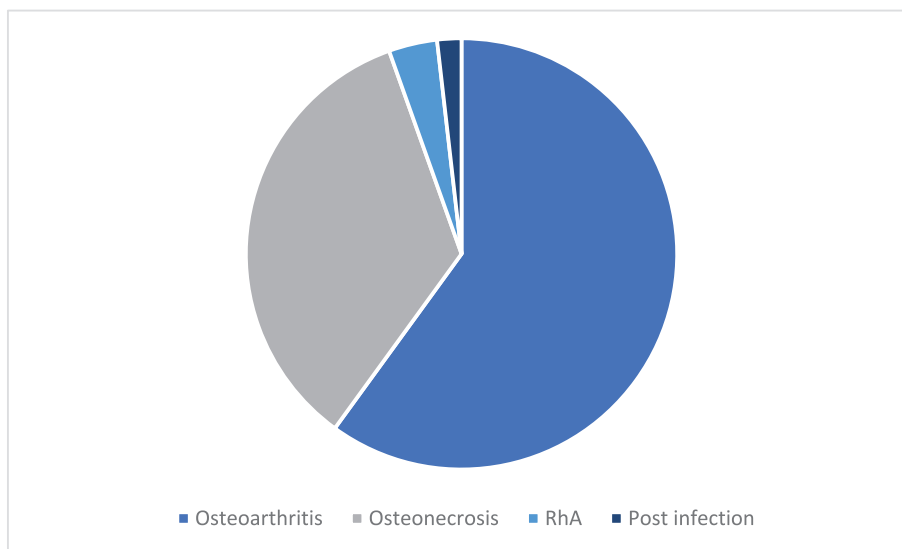


Fig. 6. Indications for TKR

extracted from the studies related to complications encountered specifically related to total knee replacements in SOT patients and combined.

3. Results

All studies included in the quantitative assessment were level 4 low quality cohort studies and agreement was achieved by both reviewers. There was low risk of bias within these studies when using the 'Cochrane Tool to Assess Risk of Bias in Cohort Studies'.⁶ A summary of study characteristics are presented in Table 1.

There was an almost equal number performed in men and women (60:61). The most common transplant type was kidney (63%) followed by liver (22.5%), heart (9.15%) and lung (3.2%). The most common indications for TKR were osteoarthritis (60%) and osteonecrosis (34.5%). Other indications reported were rheumatoid arthritis and post-infection. The mean follow-up time post TKR ranged between 3 months and 208 months. The mean time between organ transplantation and arthroplasty surgery was 90.3 months (range 10–271.2). A weighted average complication rate was calculated taking into account the number of patients in different studies. Prosthetic joint infection was the most common complication reported (31%), followed by death (26.2%), fracture (16.7%) and arthrofibrosis (9.5%). The overall complication risk was 22.58%. The revision rate was 3.8% over the follow up periods.

4. Discussion

Most authors acknowledge the theoretical risk of periprosthetic infection and perioperative complications due to inherent comorbidities of solid organ transplant patients. Cohort studies analysed in this paper reported varying rates of complications, infectious or otherwise, in patients undergoing knee arthroplasty after different types of solid organ transplantation. It is difficult to differentiate the reasons for the varied complication rates between the studies. Co-morbidities, severity of the underlying disease, immunosuppressive regimes, variability within implants and surgical technique are likely to play a part, but were not described in detail. It is therefore difficult to draw conclusions on specific risk factors for complications. In most of the studies, infective complications were the commonest complication which often necessitated revision

surgery. Each paper did report low numbers of patients that had TKR and THR was the most common arthroplasty performed in the studies.

Papagelopoulos et al. described that two patients undergoing total knee arthroplasty (TKA) for osteonecrosis and post-traumatic arthritis after orthotopic liver transplant had an improved KSS from an average of 45.5 pre-operatively to 94 post-operatively with clinical results classed as excellent.¹¹ In twelve renal transplant recipients undergoing sixteen total knee arthroplasties to treat osteonecrosis,⁷ osteoarthritis⁷ and rheumatoid arthritis,² the mean KSS after surgery was 97.1 and the mean functional score was 87.7 representing an excellent clinical outcome.⁷ In a further 21 patients undergoing TKA after solid organ transplantation (12 kidney, 4 liver and 5 lung), KSS rose from an average of 53.6–90.7, demonstrating no significant difference between the clinical outcomes in transplant patients and in non-transplant patients. These clinical outcomes make a strong case for the provision of knee arthroplasty in transplant patients, though complications due to comorbidities associated with transplant may outweigh the clinical benefits. Factors that may impact outcome from TKR have not been described in the literature and would be an area of further research.

Given the overwhelmingly positive outcomes reported in knee arthroplasty patients following transplant, the authors of the aforementioned small case control studies who reported complications still supported the use of TKA to treat bone disorders in transplant recipients. However, many of the authors recognised the limitations of their reports given the small cohort sizes. Larger studies using national statistics databases have been carried out.

A study extracting data from the Medicare database in the USA identified 3339 patients who underwent TKA after transplant (2321 kidney, 772 liver, 129 lung, 412 heart and 167 pancreas). Transplant patients were younger when getting TKA, significantly more likely to be male and significantly more likely to have more comorbidities. The study reported an increase in post-operative medical complications and an increase in overall periprosthetic infection, periprosthetic fracture and TKA revision. They reported a revision rate of 3.9% (similar to that found in this systematic review) and PJI rate of 5.4% and 1.5% for periprosthetic fractures. However, this study emphasised that not all individual transplants have a similar complication profiles, and special consideration should be given to renal and liver transplant patients as they are more at risk. Heart

Table 1
Summary of study characteristic.

	No. of TKR	No. of Patients	Gender M:F	Transplant Organ type	Mean Age	Indications	Follow-up (months)	Timing of TKR Post-Transplant	Complications	Revision Rate	KSS objective	KSS functional
Bouquet et al. ⁷	16	12	6:6	Renal	45 (27–57)	OA (n = 7) Osteonecrosis (n = 7) RhA (n = 2)	65 (25–107)	132 (10–294)	6.25% (n = 1) • Scar necrosis (n = 1)	0	97.1 (93–100)	87.7 (60–100)
Klatt et al. ⁸	23	19	9:10	Renal (n = 11) Liver (n = 7) Heart (n = 4) Lung (n = 1) Renal and liver (n = 1)	60 (48–68)	OA (n = 12) Osteonecrosis (n = 5) Post infection (n = 1)	85 (27–208)	3.8 years (1.2–22.6 years)	39% (n = 9) • Infection 17.3% (n = 4) • Chronic pain and swelling (n = 1) • Quadriceps tendon rupture (n = 1) • Arthrofibrosis requiring open debridement (n = 1) • Femoral stress fracture (n = 1) • Haemarthrosis requiring return to theatre (n = 1)	13% (n = 3)	–	–
Ledford et al. ⁹	5	4	1:3	Lung	62 (52–71)	OA (n = 3) Osteonecrosis (n = 2)	–	42.8 (17–63)	MCL sleeve avulsion (n = 1) Death (n = 1) – unrelated to procedure PJI (n = 1) Death (13.2%) – 5 years Infection (3.2%) Arthrofibrosis 2.1% (n = 2) Periprosthetic 5.2% fracture (n = 5) Re-operation 4.2% (n = 4) Peroneal nerve palsy (n = 2) MCL laxity (n = 1)	20% (n = 1)	92 (81–95)	92 (81–95)
Ledford et al. ¹⁰	96	76	38:38	Kidney (n = 59) Liver (n = 26) Heart (n = 9) Renal-Pancreas (n = 2)	66 (35–81)	–	52 (4–161)	–	Death (13.2%) – 5 years Infection (3.2%) Arthrofibrosis 2.1% (n = 2) Periprosthetic 5.2% fracture (n = 5) Re-operation 4.2% (n = 4) Peroneal nerve palsy (n = 2) MCL laxity (n = 1)	4.2%	77.8 (±24.7)	64.4 ± 27.0
Leonard et al. ¹⁹	4	4	3:1	Cardiac (n = 4)	60	–	54 (26–111)	12 years	Arthrofibrosis (n = 1)	–	89	79
Levitsky et al. ²⁰	8	5	–	Liver	49 (39–59)	OA (n = 5) Osteonecrosis (n = 3)	50 median (3–114)	–	None	0	–	–
McCleery et al. ²¹	22	22	–	Kidney	–	–	–	–	Late infection 9.09% (n = 2)	–	–	–
Palmisano et al. ²²	7	5	3:3	Kidney (n = 5) Liver (n = 1)	58.1	OA (n = 6) Osteonecrosis (n = 1)	31.6	7.29 years	Infection (n = 3)	42.9% (n = 3)	–	–
Maguire et al. ²³	5	5	–	Kidney	–	Osteonecrosis	–	–	None	0	–	–
Papagelopoulos et al. ¹¹	2	2	–	Liver	–	Osteonecrosis	54	43.5 months	None	0	94 (93–95)	–

and Lung transplants carried the fewest medical and surgical complications at the 30-day time point.¹² A review of Nationwide Inpatient Sample in the USA examined and compared early (inpatients) post-operative outcomes of primary TKR after SOT to patients without SOT. They confirmed an increasing percentage of TKR patients with a history of SOT from 0.069% to 0.103% during their study period (1998–2011). The study showed patients with SOT to be younger at the time of surgery and more likely to have associated co-morbidities. The length of stay was higher in SOT patients (4.16 vs 3.65 days). Early post-operative complications were higher in the SOT patient group with statistically higher rates of infection and need for transfusion products. The overall complication rate was shown to be 1.43 times more likely in SOT patients (95% CI 1.19–1.72; P = 0.0002).¹³

Studies comparing patients on dialysis treatment with SOT recipients (kidney) when receiving joint arthroplasty procedures show a reduced risk profile associated with renal transplant. The authors of this paper suggest that renal transplantation is considered in patients with end stage disease prior to arthroplasty surgery given the lower complication rate.^{14,15} Duplantier et al. reports a

comparative study between matched SOT and non SOT arthroplasty patients which showed a increased complications rates between the SOT cohort.¹⁶

Outcomes and complications after revision arthroplasty were not included in this study but have been reviewed. A case control study focusing on the outcomes of revision TKA in transplant recipients reported on nine patients (4 renal transplants, 3 liver, 1 cardiac and 1 renal-pancreas). 56% of the revision TKAs were required after prosthetic joint infection. The KSS of the patients improved significantly after revision surgery (from an average of 68.5–92.8) but there were notable complications. Two patients required reoperation after the revision surgery (both due to prosthetic joint infection) and estimated survivorship free from mortality at 5 and 10 years after revision was low at 71% and 60% respectively, with five patients having died by the time of final follow up.¹⁷ The study concluded that despite the clinical improvement, the high mortality rate contraindicated revision knee arthroplasty. However, this study made use of a limited sample size and aggregated separate conclusions for each organ type into one take-home message. A larger retrospective review of

the Medicare Database from 2005 to 2014 analysed 359 renal transplant recipients undergoing revision TKA and reported that compared to non-transplant patients, the length of stay, the rate of septicaemia, and the mortality of the patients was significantly increased.¹⁸ Understandably the complication rate associated with revision surgery is higher.

Immunosuppressive treatment was not withheld in patients perioperatively in any of the studies due to the risk of organ rejection. Various immunosuppressive treatment regimens were in place at the time of surgery. Most patients were also on corticosteroid treatment. In one paper (Klatt et al.) a patient was not on immunosuppressive treatment due to organ transplant failure and did not incur any post-operative complications. However, no statistical significance could be drawn from this as this was only a single case. Complication rates associated with the specific immunosuppressive regimes could not be determined in this study and represents an area where further research should be carried out. The authors of this paper suggest the close involvement of the transplant team in managing perioperative immunosuppressive treatment.

5. Conclusion

Comorbidities associated with solid organ transplant predispose patients to bone disease necessitating surgical intervention. Complication rates post joint arthroplasty are increased in transplant patients when compared to non-transplant patients. Of particular concern in this cohort of immunosuppressed patients is the increased risk of infection after arthroplasty. Some papers appear to show a higher risk of infection in transplant recipients undergoing knee arthroplasty as opposed to hip arthroplasty, and this represents an area of potential research. Additionally, the literature seems to suggest that there is a higher risk of infection post TKA in renal transplant recipients as compared to non-renal transplant recipients, though further data is required to clarify this link. Despite the complications faced by the patient cohort, the clinical outcomes of knee arthroplasty are excellent, and thus patients with symptomatic osteoarthritis or osteonecrosis should be considered for TKA and counselled on the increased risk of post-surgical complications. We recommend a thorough pre-operative work-up including the input from transplant physicians. However, we recommend caution should be taken when considering revision TKA after primary failure, as although the clinical outcomes are again excellent, the mortality rate is increased.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Review article

Pre-operative opioid use negatively impacts the outcomes of hip and knee arthroplasty: A systematic review

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ABSTRACT

Introduction: There is increasing evidence that pre-operative administration of opioid analgesia in the management of hip and knee osteoarthritis pain negatively impacts post-operative outcomes. This article provides a literature review of the effects of pre-operative use of opioid analgesia on outcomes following hip and knee arthroplasty including patient reported outcome measures (PROMs), rate of infection, rate of revision surgery, length of hospital stay and readmission.

Methods: A systematic literature review of Medline, Embase and Cochrane CENTRAL was performed up until September 2020 according to PRISMA guidelines. Studies reporting post-operative outcomes in opioid using patients compared to non-opioid using patients undergoing total hip or knee arthroplasty were included.

Results: 21 studies of the 703 studies identified from the initial search were included. The evidence suggests that pre-operative use of opioid analgesia confers worse post-operative outcomes including inferior PROMs, increased rates of revision, infection and readmission, and prolonged hospital stay.

Conclusion: Whilst more large-scale data is required to ascertain the full effect of pre-operative opioid use and to determine effective strategies of cessation, pre-operative opioid use should be considered an independently modifiable risk factor for worse post-operative outcomes, and efforts should be made to either taper or cease usage prior to major joint arthroplasty.

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1. Introduction

Osteoarthritis (OA) is one of the most common musculoskeletal disorders in the United Kingdom (UK). Opioid analgesia is frequently used in the management of osteoarthritic pain, with arthroplasty the last resort after other therapeutic measures have been exhausted. In 2018, 92,874 primary total hip arthroplasties (THAs) and 99,093 primary total knee arthroplasties (TKAs) were recorded in the UK's National Joint Registry (NJR).¹ THA and TKA are both clinically and cost effective in the treatment of severe joint disease; cost per Quality Adjusted Life Year (QALY) is estimated at £1372 for THA and £2101 for TKA, both substantially less than the £20,000 cost per QALY threshold used to define a procedure as cost-

effective.² Whilst these figures are averages that already incorporate the risk of revision surgery, the individual cost of revision procedures is high. With the established risks of major surgical procedures and the potential for increased morbidity and health-care costs as a result of adverse outcomes, any modifiable factor with the potential to adversely influence post-operative outcomes must be addressed and optimised pre-operatively.

The term 'opioid' is used to describe both natural and synthetic versions of opiate-based analgesics. Opioids have been used for hundreds of years and remain the most potent and reliable analgesics available.³ Their mechanism of action is through one of a family of opioid G-protein coupled receptors, with agonists of the μ -opioid receptor producing the most potent analgesic effects.⁴ Opioids occupy the top two tiers of the World Health Organisation (WHO) analgesic ladder, with weak and strong opioids succeeding paracetamol and NSAIDs in the escalation of pain management. Commonly used opioid medications include the

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weak opioids codeine, dihydrocodeine and meptazinol. Stronger opioids include tramadol, oxycodone, morphine and fentanyl. While opioid analgesics provide excellent short-term pain relief, their prolonged use remains controversial due to their associated side effects, concerns about long-term efficacy, poorer functional outcomes, and the potential risk for addiction and abuse.^{5–8}

There is growing evidence that pre-operative use of opioid analgesia in the management of OA pain negatively impacts post-operative outcomes following major joint arthroplasty. This systematic review provides a summary of the evidence concerning the effects of pre-operative opioid use on the outcomes of hip and knee arthroplasty.

2. Methods

This systematic review was performed in accordance with the Preferred Reporting Items for Systematic reviews and Meta Analyses (PRISMA) statement.⁹ Electronic databases Medline, Embase and Cochrane CENTRAL were searched from inception up to September 2020. Search terms included ‘opiate’, ‘opioid’, ‘preoperative’, ‘arthroplasty’, ‘TJA’ ‘joint replacement’, ‘outcome’, and ‘PROM’. Studies reporting post-operative outcomes in opioid using patients compared to non-opioid using adult (age >18 years) patients undergoing total hip or knee arthroplasty were included. No restrictions were placed on the date of publication or study design. Non-English language studies were excluded. Bibliographies of eligible studies were examined for further suitable studies for

inclusion. Randomised controlled trials (RCTs), non-randomised controlled trials, prospective cohort studies, and retrospective case series were included. Non-clinical (e.g., laboratory or biomechanics), non-human (e.g., animal or predictive models), conference abstracts, and expert opinions were excluded.

Three reviewers (TK, SE, KK) independently screened paper titles and abstracts for inclusion. In cases where the title and abstract were not detailed enough to make a decision regarding inclusion, the full text was reviewed. Inclusion decisions were discussed among all authors, with the senior author (HP) assisting in case of any selection conflict. The full texts of articles meeting the eligibility criteria were included, with data extracted independently by the same three reviewers. Extracted data included study design, sample size, procedure, duration and dose of pre-operative opioid (morphine equivalent dose), follow up, patient reported outcome measure (PROM), and outcome.

3. Results

703 studies were initially identified. After screening, removal of 274 duplicate studies and studies that did not fit the inclusion criteria took place, 21 studies were included as eligible based upon our agreed protocol (Fig. 1).

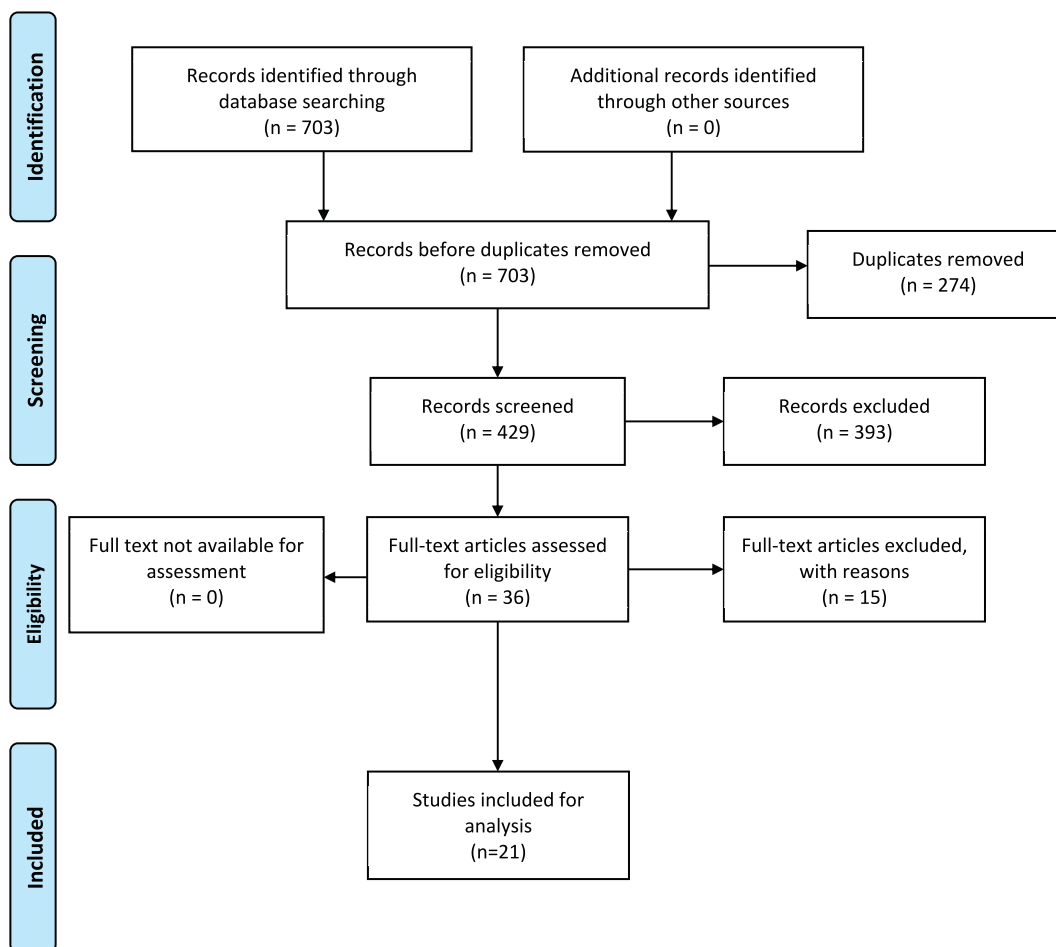


Fig. 1. Prisma flowchart.

Table 1
Summary of studies reporting impact of pre-operative opioid use on post-operative PROMs.

Ref no:	Author(s) & Year	Study Design	Sample size (n)	Procedure	Duration and dose of pre-operative opioid (morphine equivalent dose)	Follow up	PROM	Outcome
11	Franklin et al. (2010)	Retrospective Cohort	6346 patients	TKA	At least one opioid prescription – duration and dose not specified	12 months	KSS	<p>Opioid using group: Mean post-operative KSS: 81.3 Mean improvement: 46.5</p> <p>Opioid naive group: Mean post-operative KSS: 86 Mean improvement: 48.9</p>
12	Zywiell et al. (2011)	Retrospective Cohort	98 joints	TKA	Minimum 6 weeks pre-op >20 mg/day 58 mg/day (mean)	36 months (mean)	KSS ^a	<p>Opioid using group: Mean post-operative KSS: 79 (p < 0.001) Mean improvement: 41</p> <p>Opioid naive group: Mean post-operative KSS: 92 (p < 0.001) Mean improvement: 55</p>
13	Pivec et al. (2014)	Retrospective Cohort	124 joints	THA	Minimum 6 weeks pre-op >30 mg/day	58 months (mean)	HHS ^b	<p>Opioid using group: Mean post-operative HHS: 84 (p = 0.002) Mean improvement: 41</p> <p>Opioid naive group: Mean post-operative HHS: 91 (p = 0.002) Mean improvement: 46</p>
14	Goesling et al. (2016)	Prospective Cohort	574 patients	THA, TKA	Current opioid use on day of surgery – any dose, duration not given	6 months	WOMAC ^c	<p>Opioid using group: Mean post-operative WOMAC score: 80.8 Mean improvement: 41.5</p> <p>Opioid naive group: Mean post-operative WOMAC score: 85.5 Mean improvement: 36.1</p>
15	Nguyen et al. (2016)	Retrospective Cohort	82	THA, TKA	Continuous use at least 4 weeks pre-op <30 mg/day (34%) 31–60 mg/day (17%) 61–120 mg/day (15%) >120 mg/day (34%)	6–12 months	WOMAC ^c	<p>Opioid using group: -Mean improvement in WOMAC score: 17.8 (p < 0.01)</p> <p>Opioid naive group: -Mean improvement in WOMAC score: 39.0 (p < 0.01)</p>
16	Smith et al. (2017)	Retrospective Cohort	156 patients	TKA	Within 2 years pre-op At least one opioid prescription – dose not specified.	6 months	WOMAC ^c	<p>Opioid using group: Mean improvement in WOMAC score: 27 (p = 0.008)</p> <p>Opioid naive group: Mean improvement in WOMAC score: 33.6 (p = 0.008)</p>
17	Manalo et al. (2018)	Retrospective Cohort	67 patients	TKA	At least one opioid prescription – duration and dose not specified.	12–17 months	EQ-VAS ^d	<p>Opioid using group: Mean post-operative VAS score: 71.3 (p = 0.007)</p> <p>Opioid naive group: Mean post-operative VAS score: 77.9 (p = 0.007)</p>
18	Hernandez et al. (2019)	Retrospective Cohort	159 patients	TKA	3 years (mean) 48 mg/day (mean)	28.8 months (mean)	KSS ^a	<p>Opioid using group: Mean post-operative KSS: 85 (p = 0.01) Mean improvement: 32 (p = 0.3)</p> <p>Opioid naive group: Mean post-operative KSS: 90 (p = 0.01) Mean improvement: 29 (p = 0.3)</p>
19	Bonner et al. (2019)	Retrospective Cohort	389	THA	Active opioid prescription at time of surgery 48.7–49.4 mg/day (mean)	7.5 months (mean)	HOOS-PS ^e , PROMIS Global-10 ^f SF10A ^g PROM	<p>Opioid using group: Mean post-operative PROM scores: HOOS-PS 75.6 (p = 0.05) PROMIS Physical: 45.4 (p < 0.0001) PROMIS Mental: 49.8 (p = 0.001) SF10A: 41.3 (p = 0.021)</p> <p>Opioid naive group: Mean post-operative PROM scores: HOOS-PS 79.2 (p = 0.05) PROMIS Physical: 50.1 (p < 0.0001) PROMIS Mental: 54.3 (p = 0.001) SF10A: 43.9 (p = 0.021)</p>

^a Knee Society Scores.

^b Harris Hip Scores.

^c Western Ontario and McMaster Universities Arthritis Index.

^d EQ VAS general health scores.

^e Hip Disability and Osteoarthritis Outcome Score–Physical Function Short Form.

^f Patient-Reported Outcomes Measurement Information System Global-10.

^g Physical Function Short Form.

3.1. Pre-operative opioid use adversely impacts patient reported outcome measures (PROMs) post-hip and knee arthroplasty

PROMs are frequently used in THA and TKA to quantify subjective improvement in patient status following surgery. One meta-analysis of six studies reporting PROMs following THA and TKA in opioid users versus opioid naive patients concluded that opioid users had worse absolute post-operative PROMs compared to opioid naive patients (SMD -0.53, 95% CI -0.75, -0.32, $p < 0.0001$).¹⁰ However, there was a similar relative improvement in PROMs from pre-to post-operatively in opioid users compared to non-opioid users, suggesting that opioid users do still benefit from arthroplasty. A summary of studies reporting PROMs following THA and TKR in opioid-using compared to opioid naive patients can be found in Table 1.^{11–19} All studies report either worse absolute PROMs or reduced improvement in PROMs in patients using opioids pre-operatively compared to those not using pre-operative opioids.

Nguyen et al. showed greater improvement in post-operative PROMs in opioid-naïve compared to opioid-using patients (39.0 vs 17.8 respectively, $p < 0.01$). This study also included an intervention group in which opioid-using patients reduced their pre-operative opioid use by at least 50%. By tapering their pre-operative opioid use, this group achieved greater changes in PROMs than the opioid-using group (75.7 vs 65.3 respectively, $p < 0.02$).¹⁵

3.2. Pre-operative opioid use is associated with increased infection risk

Several studies have demonstrated that pre-operative opioid use is associated with a higher risk of post-operative infection. In one series comparing 15,901 opioid-using patients with over 9,000,000 non-opioid patients undergoing major joint arthroplasty (hip, knee, shoulder) or spinal fusion, opioid dependent patients were found to have an increased risk of surgical site infection (OR 2.5, 95% CI 2.0–3.0 [$p < 0.001$]).²⁰ Bell et al. studied a cohort of 23,754 patients, of which 5051 (21.3%) had used opioids prior to total joint arthroplasty. In both univariate and multivariate analyses, pre-operative opioid use was found to be a significant independent predictor of prosthetic joint infection within two years of the index procedure (OR 1.63 and 1.53 respectively $p = 0.005$).²¹ Similarly, Peratikos et al. reported higher risk of 90-day surgical site infection (OR 1.35, $p < 0.001$) in pre-operative opioid-users and Cancienne et al. reported increased risk of peri-prosthetic joint infection at 1 year (OR 1.16, $p < 0.0001$) in pre-operative opioid-users.^{22,23} This study also showed that prolonged post-operative opioid use was associated with higher risk of periprosthetic joint infection (OR 1.33, $p < 0.0001$).

3.3. Pre-operative opioid use is associated with increased risk of revision surgery

Multiple large studies showed that pre-operative use of opioid analgesia is a risk factor for early revision. Weick et al. examined the association between pre-operative use of opioids and 30 day readmission as well as the rate of early revision surgery in patients undergoing THA and TKA.²⁴ With 324,154 and 159,822 patients in

the 1- and 3-year follow-up groups respectively, opioid-naïve patients in both groups demonstrated lower rates of revision than patients using opioids for more than 60 days pre-operatively. For TKA, the rate of revision for opioid-using patients was 2.14% at 1 year and 5% at 3 years, compared to 1.07% and 2.58% for opioid-naïve patients ($p < 0.001$). For THA, the 1- and 3-year revision rates for opioid-using patients was 1.10% and 2.99% respectively, compared to 0.38% and 1.24% for opioid-naïve patients ($p < 0.001$). Although the indication for revision was not specified, pre-operative use of opioid analgesia was nonetheless shown to be an independent risk factor for early revision surgery.

A large study of 32,636 American war veterans undergoing TKA showed that opioid use for more than three months in the year prior to TKA was associated with an increased risk of revision surgery in the first year post-operatively (OR 1.40; 95% CI 1.19 to 1.64; $p < 0.005$).²⁵ Again, no association between the pre-operative use of opioids and the aetiology of revision surgery was reported.

Finally, a study of 34,792 patients undergoing THR, TKR or shoulder arthroplasty found that the risk of revision in the 18 months post-operatively was 36% higher among pre-operative opioid users (HR 1.36, 95% CI = 1.15 to 1.62, $p < 0.001$).²²

3.4. Use of pre-operative opioids is associated with prolonged hospital stay and increased risk of readmission after hip or knee arthroplasty

Several studies reported both increased length of stay (LOS) and higher readmission rates following arthroplasty in patients taking opioids pre-operatively compared to opioid-naïve patients. Menendez et al. reported that patients undergoing THA, TKA, total shoulder arthroplasty or spinal fusion, and coded via ICD-9-CM as being opioid 'dependent' or 'abusers', had a prolonged LOS - defined as a LOS in the 75th percentile - compared to patients without opioid dependency (OR 2.6, $p < 0.001$).²⁰ Rozell et al. studied 802 patients undergoing primary THA or TKA, reporting that pre-operative use of opioids was the strongest predictor of increased post-operative opioid requirement, defined as the need for post-operative IV 'rescue' opioids.²⁶ Requirement of post-operative rescue opioids was, in turn, associated with a LOS greater than 3 days (OR 1.59, $p = 0.025$). Similar findings were reported by Cozowicz et al. with higher perioperative opioid prescription (>370 mg/day morphine equivalent) associated with a 12% increase in LOS for patients following lower limb arthroplasty ($p < 0.001$).²⁷

Weick et al. considered the association between pre-operative opioid use and the risk of readmission within 30 days post procedure. For TKA patients with more than 60 days of pre-operative opioid use, the 30 day readmission rate was 6.17%, compared to 4.82% in opioid-naïve patients ($p < 0.001$).²⁴ For THA, the figures were 5.85% and 3.71%, respectively ($p < 0.001$). Specific reasons for readmission were not given.

3.5. Other complications

A number of studies reported rates of other post-operative complications to be higher in patients using opioid analgesia pre-operatively. Menendez et al. reported an association with respiratory depression and failure, pneumonia, myocardial infarction,

post-operative ileus and mental disorder.²⁰ Sing et al. found that use of long acting opioid analgesia pre-operatively independently predicted complications within 90 days (OR: 6.15 $p = 0.013$).²⁸ Similarly, Rozell et al. reported that pre-operative opioid use was a significant predictor of increased post-operative opioid requirements. In addition, higher overall rates of in-hospital complications were observed in this group (OR 1.92 (95% CI 1.34–2.76, $p < 0.001$)).²⁶

4. Discussion

Despite known limitations regarding their efficacy in non-malignant chronic pain management, opioid analgesics are commonly used in the treatment of musculoskeletal pain.²⁹ A recent US-based study of more than 300,000 patients undergoing TKA observed that 58.2% patients were either intermittent or continuous opioid users in the year preceding their operation.³⁰ The evidence reviewed demonstrates an association between pre-operative use of opioid analgesia and multiple adverse outcomes following total joint arthroplasty, including inferior PROMs, increased rates of infection, revision, prolonged hospital stays, and readmission.

Inferior post-operative outcome scores seen in patients using pre-operative opioid analgesia are likely to be multifactorial. Worse scores may be attributable in part to the condition of opioid-induced hyperalgesia (OIH), a state of nociceptive sensitization in which long-term opioid use paradoxically leads to increased sensitivity to pain.^{10,12,13,15} Although the mechanism of OIH is not yet fully understood, acknowledgement that opioid use can result in hyperalgesia may go some way towards explaining why pre-operative opioid use appears to be an independent risk factor for worse post-operative pain scores. On the other hand, worse PROMs in opioid users may not necessarily be the direct result of opioid use; patients with more severe pre-operative symptoms are more likely to have worse absolute post-operative outcome scores, whilst concurrently being more likely to be prescribed opioids for pain management.³¹ Poorer pre-operative scores may therefore themselves be predictors of worse post-operative scores, independent of opioid use. Furthermore, more severe pre-operative pain can be the result of 'central sensitization'; an abnormal state of increased responsiveness of nociceptors in the central nervous system, which results in increased severity of both acute and chronic pain. Central sensitization can develop independently of opioid use and itself has been shown to result in increased pain and analgesia requirements post-TKA, whilst simultaneously increasing the likelihood of pre-operative opioid use.^{32–34} Further confounding factors exist; patients may be using opioid analgesia to manage pain from other body regions, including joints other than the joint undergoing arthroplasty, and psychological factors such as pain catastrophising may increase the likelihood of pre-operative opioid use as well as predisposing patients to worse post-operative outcomes. Further research into the precise mechanisms of the adverse affect of opioid use on post-operative outcomes is therefore required.

None of the reviewed studies correlate type or amount of opioid used prior to joint arthroplasty with post-operative outcomes. Although Zywił et al. and Pivec et al. defined opioid use as >20 mg/day and >30 mg/day morphine equivalent dose respectively, other studies did not define lower limits.^{12,13} Duration of pre-operative use was clearly defined in each of the studies, but varied considerably from 'at least one opioid prescription within two years pre-op' to 'continuous use at least four weeks pre-op'. Clearly distinctions must be drawn between infrequent, weak opioid use and frequent strong opioid use. At present, this information is not available and warrants further investigation.

Although there is no consensus in the literature regarding the

optimal strategy for cessation or reduction of opioid use prior to surgery, based on the available evidence, frequent or continuous use should be considered a modifiable risk factor prior to arthroplasty and attempts should be made to taper or cease usage pre-operatively. One large study showed that whilst over 6 months of opioid use prior to arthroplasty or lumbar fusion was associated with an increased risk of adverse events, a period of 3 months opioid-free mitigated this risk and resulted in a significant reduction in adverse outcomes.³⁵ A further series found that a reduction in morphine equivalent dose of 50% prior to total joint arthroplasty led to a statistically significant improvement in PROMs at 6 and 12 months post op when compared to opioid users who did not wear opioid use, with results similar to those in the non-opioid using group.¹⁵ Although these studies employ different methodologies to reduce opioid use pre-operatively, both support the hypothesis that reducing opioid use prior to surgery helps to reduce the risk of adverse outcomes. A systematic review comparing non-steroidal anti-inflammatory drugs (NSAIDs) with opioids for the management of knee OA found no difference in effectiveness between the drug classes.³⁶ This supports the use of alternative analgesia in place of opioids pre-operatively in an attempt to minimise the risk of inferior post-operative outcomes.

Whether adverse outcomes can be minimised by performing joint arthroplasty prior to the development of symptoms severe enough to warrant opioid analgesia is another area that remains unclear. There is, however, some evidence to suggest that there is a greater improvement between pre- and post-operative scores (particularly for TKA) in those with more severe disease prior to arthroplasty. Therefore, there is clearly a balance to be struck regarding the optimal timing of surgery and the need to maximise patient outcomes.³⁷

Formal data collection on opioid use in joint registries may help provide useful information and contribute to large scale analysis of the effect of opioid use on outcomes in arthroplasty. Provided reliable information is obtained, this could in turn be incorporated into outcome calculators, thereby helping to better advise patients and clinicians as to expected outcomes of surgery. If this data collection proves impracticable, careful documentation of opioid prescription prior to arthroplasty would at the very least serve as a useful starting point in discussions with patients regarding their role as a potential risk factor, particularly in the event of an unfavourable post-operative outcome.

There are a number of limitations associated with the studies reviewed. All were retrospective cohort studies with heterogeneous groups of patients. A variety of different outcome scores were used that were not always directly comparable. Although several of the studies expressed the quantity of opioid use in 'morphine-equivalent dose', the definition of 'opioid-using' varied between studies, as did the duration of use considered relevant. In studies that relied on the presence of a prescription for opioids as a marker of opioid use, it cannot necessarily be assumed that in all cases patients will be actively taking those prescriptions at the frequencies and doses prescribed. Finally, follow up duration differed significantly between the studies, as did the sample sizes which ranged from >6000 patients in one study to just 67 in another.

5. Conclusion

Pre-operative use of opioid analgesia has been shown by multiple studies to confer worse post-operative outcomes following total joint arthroplasty, including inferior PROMs, increased risk of infection and revision surgery, longer length of stay, and increased risk of readmission. Whilst more large-scale data is required to ascertain the full effect of pre-operative opioid use, the available evidence shows that its use should be considered an independently

modifiable risk factor for inferior outcomes and efforts should be made to either taper or cease use prior to major joint arthroplasty.

Key messages

- Evidence shows an association between the pre-operative use of opioid analgesia and worse post-operative outcomes following total joint arthroplasty, including inferior PROMs, increased rates of infection, revision, prolonged LOS, higher readmission rates and other complications.
- Pre-operative use of opioid analgesia should be considered an independently modifiable risk factor and cessation or dose reduction pre-operatively may reduce the risk of inferior post-operative outcomes.
- Further research is needed into the precise mechanism by which pre-operative opioid use yields adverse post-operative outcomes, as well as the optimal strategy for reduction of opioid use prior to surgery.
- Prospective data collection on pre-operative opioid use via arthroplasty registries is recommended to enable better quality, large scale association studies.

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Author contributions

TK, SE, KK (Conceptualization; Data curation; Formal analysis; Methodology; Supervision; Roles/Writing - original draft; Writing - review editing); HP (Conceptualization; Methodology; Supervision; Writing - review & editing).

Declaration of competing interest

All authors declare that they have no conflicts of interest.

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Review article

Flexible reamers for primary anatomical ACL reconstruction- a systematic review



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ABSTRACT

Introduction: Surgery for ACL reconstruction has evolved a lot. To fulfil the ever increasing patient demand and to lower the failure rates, emphasis is now being laid on reproducing the anatomic origins of ACL during reconstruction. Use of conventional rigid reamers does address this concern; however, it has its own pitfalls and difficulties. Of late, flexible reamers systems are increasingly being used for drilling of femoral tunnels and are becoming a popular alternative to the rigid systems. The aim of this systematic review is to summarize the data published on the use of flexible ACL reamer systems for ACL reconstruction.

Method: A systematic search of literature was performed on PubMed, Cochrane Library and DOAJ using the keywords 'flexible ACL' and 'flexible cruciate'. Data was analysed and compiled.

Results: A total of 17 studies met the inclusion criteria. We incorporated original studies (cadaveric as well as patient based) on "primary Anatomical ACL reconstruction using flexible reamer".

Conclusion: Flexible reamer system can be used as an alternative to the conventional rigid reamers as they avoid the need for hyperflexion of knee without compromising the tunnel length. Even though flexible reamers do have lower risk of injury to the posterior structures and produce minor variations in the tunnel characteristics, its impact on clinical outcomes needs to be further investigated.

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1. Introduction

Over the years, since 1895, when the first suture repair of ACL and PCL was done by A.W. Mayo Robson,¹ the surgical treatment of ACL injury has evolved significantly. These injuries have been an area of keen interest for researchers. This has improved our understanding of risk factors for injury and have also addressed various technical issues aimed at improving overall outcomes like graft selection, graft placement, tensioning, methods of graft fixation and rehabilitation protocols. The current gold standard of treatment for a skeletally mature patient with a symptomatic ACL injury is ACL reconstruction (ACLR) with a free tendon graft, placed through tunnels in the distal femur and proximal tibia and anchored at both sides.²

With improved understanding of native ACL anatomy, knee kinetics and biomechanics coupled with the technological

advancements over the last few decades, more emphasis is now being laid for 'more' anatomic ACL reconstructions.³ In fact, nonanatomic or aberrant placement of femoral tunnels is reported to be one of the most common and preventable causes of failure of ACL reconstruction.⁴ The conventional transtibial technique results in a non-anatomically placed femoral tunnel which is suboptimal and located anterior and vertical relative to the native footprint.⁵ Such a vertically oriented graft tends to be stable in anterior-posterior plane but does not resist rotational forces.^{6,7} Attempts have been made to address the issues of persistent rotational instability by reproducing the double bundle (anteromedial and posterolateral) pattern of ACL or drilling the femoral tunnel 'down the clock face' which produces an ACL which courses horizontally like the native ACL and thus improves rotational stability. However, some argue that technical complexities associated with drilling of 4 tunnels in a double bundle reconstruction makes the procedure complicated without much additional improvements in functional outcome⁸ and if using the transtibial technique to establish anatomic tunnels by drilling 'down the clock', it was observed that one can capture the native tibial and femoral footprints only if a

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tibial starting point, prohibitively close to tibial plateau, is used; resulting into short tibial tunnel and its associated complications.⁹

Over time, a variety of techniques have been described by the researchers to assist in anatomic placement of femoral tunnel e.g. drilling of femoral tunnel through accessory medial portal (called transportal technique), outside-in femoral drilling, wide notch-plasty, hyperflexing the knee, use of 70° arthroscope for improved visualization etc. In the transportal technique, femoral and tibial tunnels are drilled independent of each other. Drilling of the tibial tunnel is similar to that of transtibial technique and has a number of references to identify the exit point for drilling including centre of footprint, intraarticular landmarks like tibial spine, horns of lateral meniscus and PCL. The femoral tunnel is then placed through a separate medial portal. The contemporary transportal technique using rigid guide wires and reaming system offers several advantages over the conventional transtibial technique like anatomic placement of femoral tunnel which reduces the strain on the graft.¹⁰ This procedure however can be technically challenging and has its own shortcomings like shorter femoral tunnel as compared to the transtibial technique, risk of damage to medial femoral condyle articular surface, need for hyperflexion of knee >120° during the entire process of drilling and subsequent difficulty in visualization, need for an assistant to keep the knee hyperflexed, exit point of guide wire being close to peroneal nerve risking its injury, oblong shape of the femoral aperture and posterior blow out.

To address the shortfalls of above systems, flexible reamers and guide wires for transportal technique have been developed for drilling of femoral tunnels in ACL surgery. It has several theoretical advantages over the rigid system namely.

1. More circular cross-section of the tunnel; as it can be drilled through a more medial accessory medial portal, leading to more perpendicular drilling of the lateral femoral cortex that too without compromising on the length of the tunnel (Fig. 1). This is contrary to the rigid reaming systems in which an attempt to go more perpendicular to the lateral femoral cortex, to produce a more circular aperture, by positioning accessory anteromedial portal more medially leads to compromised femoral tunnel length¹¹ (Fig. 2); flexible system has been given an inbuilt curve to the femoral jig in the range of 40–45°, that permits more medial entry portal without compromising the femoral tunnel length (Fig. 3).
2. Low risk of iatrogenic injury to medial femoral condyle as reasonable amount of “play” is there with the flexible system; this concept stands true even with more medial portal drilling with the flexible system.
3. Avoids the need for hyperflexing the knee, thus not impair the visualization while drilling. Hyperflexing the knee impedes the visualization by
 - a) Stasis of saline into the knee
 - b) Pushing of fat pad posteriorly into the field of vision
 - c) Some difficulty in identifying certain landmarks like posterior horn of lateral meniscus that can be used as a guide for anatomical placement of femoral tunnel.¹²
4. Lower chances of injury to the peroneal nerve (Figs. 4-7).

Though studies highlighting the complications associated with the use of flexible reamer systems like breaking of reamers have also been reported,¹³ there appears to be a dearth of higher level of evidence on use of flexible reamers in ACL reconstruction.

In this systematic review we aim to summarize the evidence available on use of flexible reamers for anatomic ACL reconstruction.



Fig. 1. Perpendicular drilling of wall (1a) and oblique drilling of wall (1b) - appreciate the change in intended aperture shape-circular with perpendicular drilling and elliptical with oblique drilling.

2. Material and methods

A systematic search of literature was performed on PubMed, Cochrane Library and DOAJ using the keywords ‘flexible ACL’ and ‘flexible cruciate’. References from primary and review articles and major orthopaedic texts were cross-referenced to identify any additional articles that met the inclusion criteria and were not located in the original search. All articles published up to October 20, 2020 were included, including articles published online.

Inclusion Criteria:

1. Original articles on Primary (anatomic) ACL reconstruction (single bundle as well as double bundle) using a flexible ACL reamer system.
2. Both cadaveric and patient studies

Exclusion criteria.

1. Multiple Ligament Injured knee with ACL reconstruction with flexible system
2. Revision surgeries

2.1. Data extraction and analysis

The articles included in the study were reviewed separately by two independent authors. One reviewer extracted the following data which was reviewed by the second author. Data was also extracted independently and reviewed. Disagreements were resolved before moving further; if no agreement reached, by the



Fig. 2. Appreciate that more medial portal drilling with rigid pin leads to less length of femoral tunnel. a: Rigid guide pin through not so medial anteromedial portal, b: Rigid guide pin through not so medial anteromedial portal-tunnel length, c: Rigid guide pin through more medial anteromedial portal, d: Rigid guide pin through more medial anteromedial portal, note shorter tunnel length.

third author.

3. Results

A comprehensive search of literature on PubMed, Cochrane Library and DOAJ with keywords “flexible ACL” and “flexible cruciate” revealed a total of 147 and 138 articles in PubMed, 18 and 24 articles in Cochrane Library and 5 and 2 articles in DOAJ respectively. This included original articles (cadaveric as well as patient), systematic review, narrative review, editorial commentary, technical notes, letter to editors and case reports. The total number of articles from the literature search was 334. The above search results were screened for relevance to the selected topic, duplicates/reviews/technical notes/editorials/letter to editors removed and 17 original studies meeting the inclusion criteria were included for the purpose of this study (Flowchart 1). Evidence was evaluated on the following terms:

1. Knee Flexion required during surgery
2. Femoral tunnel length achieved
3. Tunnel Position

4. Footprint Replication and exit point
5. Femoral tunnel aperture morphology
6. Graft bending angle
7. Posterior cortex damage and damage to posterolateral structures
8. Iatrogenic Injury to Medial Femoral condyle

Flowchart 1: DATA extraction.

Total articles in results (n = 164).

Electronic database search: PubMed, Cochrane Library, DOAJ using keywords ‘flexible cruciate’

Included.

Eligibility.

Screening.

Identification.

Electronic database search: PubMed, Cochrane Library, DOAJ using keywords ‘flexible ACL’

Total articles in results (n = 170).

Original studies related to the topic selected (n = 36).

Articles screened and duplicates removed.

17 articles meeting the inclusion criteria selected.

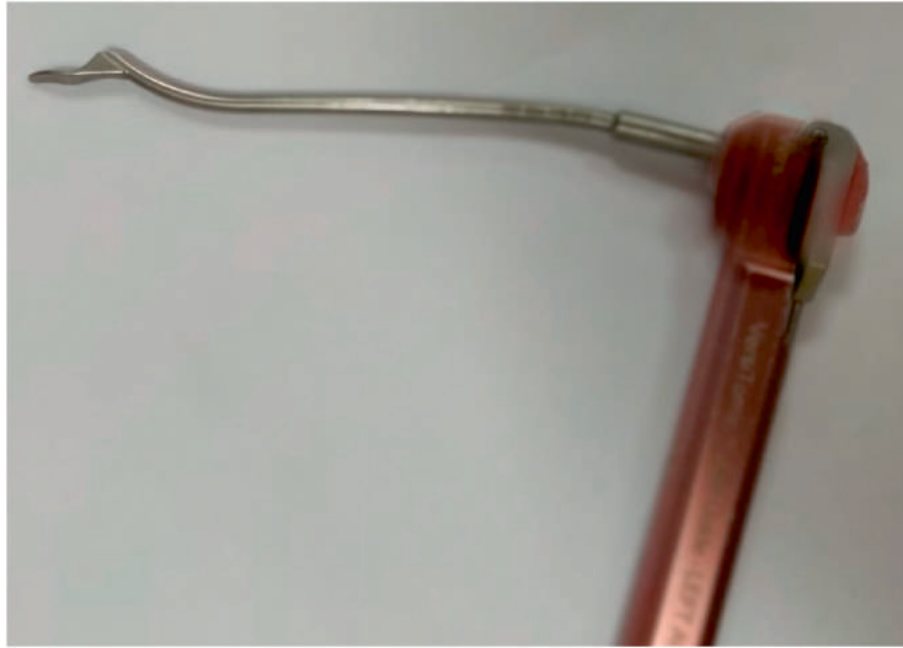


Fig. 3. Femoral jig for flexible guide wire with an inbuilt upward curvature near the offset site.



Fig. 4. Risk to posterolateral structure if rigid guide pin is used at lesser flexion angles.



Fig. 5. Rigid pin with knee hyperflexed avoid damage to posterolateral structures.

4. Discussion

ACL injuries are one of the most commonly researched injuries in the field of orthopaedics with over 27800 articles in PubMed database until October 2020. A primary ACLR is expected to restore anatomic as well as physiological stability of knee if the anatomic origins of the femoral and tibial footprints are reproduced.³ An equally important factor at play for improved long term outcomes is graft bone incorporation. Successful long term clinical outcomes after ACLR requires incorporation of tendinous graft into the bony tunnel at least at the orifice. Use of conventional rigid reamer systems through anteromedial portal allows for anatomic placement of the femoral tunnel but it comes with its own set of possible complications viz. short tunnel length, damage to medial femoral condyle, non-circular femoral aperture, graft bending and the need for hyperflexion of knee.¹⁴ Hyperflexion is essential to obtain a

good length of the tunnel and to prevent the guide wire from exiting posteriorly which increases the risk of injury to the common peroneal nerve. Hyperflexing the knee is associated several technical limitations:

1. Not all the operative set ups have operation theatre (OT) table that can break. Most of the places use the gravity assisted inflation of the knee by keeping 3 L Normal Saline bottles at a height and by keeping OT table at a lower level. We postulate that in such a scenario, where the limb has to be brought to the side of the OT table and dangled in order to achieve complete flexion of the knee; which in combination with low height of OT table, has to potential to unsterile the operative field.
2. When limb has to be dangled to the side of OT table, to insert the guide pin from accessory medial portal, hip has to be maximally abducted which may prove to be difficult in some patients.

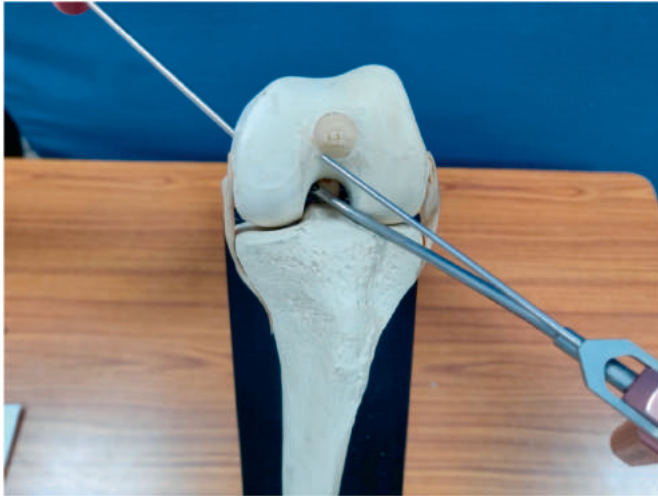


Fig. 6. Adequate length of femoral tunnel and more ventral exit point of guide wire even with less knee flexion with flexible reaming system.

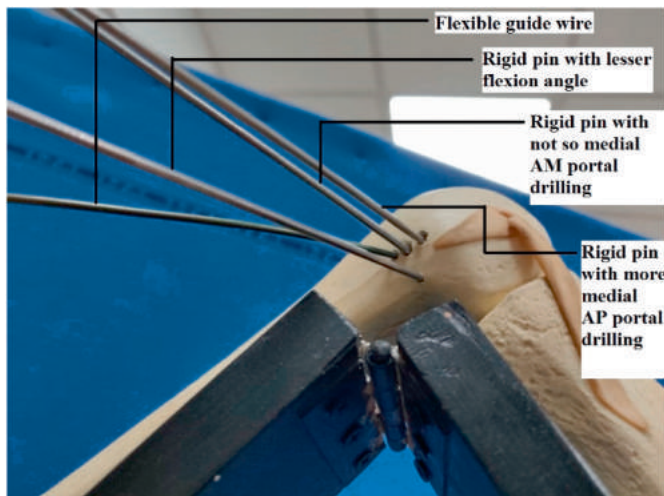


Fig. 7. Exit point of different guide wires with same femoral entry point.

3. If the limb is hyperflexed without dangling it on the side of the table, keeping it on the OT table pushes the tibia upwards which compromises the arthroscopic field making the identification of intra-articular landmarks like posterior horn of lateral meniscus¹² more difficult.
4. In obese patients and those with pre-existing knee stiffness, adequate tunnel length can be difficult to obtain with a rigid reaming system.

Flexible reamers systems were first propagated by Cain and Clancy.¹⁵ These systems are becoming increasingly popular option among the surgeons today as it offers several theoretical advantages like:

1. Allows more perpendicular drilling at the medial wall of lateral femoral condyle leading to a circular aperture as we can go more medial without the risk of small tunnel length¹¹
2. Adequate tunnel length without the need for hyperflexion
3. Deep and down footprint replication due to more freedom in placing femoral tunnel

4. Avoids the need for hyperflexion of knee without compromising on the length of the tunnel.
5. Can be comfortably done keeping the limb on the table as maximal flexion is not needed thereby not impairing the arthroscopic vision
6. No stress to assistant of maintaining complete knee flexion
7. Decreased risk of CPN injury and posterior blowout as the exit point of guide wire is more ventral due to inbuilt 45° angulation in femoral jig
8. Decreased risk of medial femoral condyle cartilage damage as there is more “play” in the system and

As the flexible reamers continues to be used for ACLR, literature is being continuously being updated which has also shed light upon possible pitfalls which may be associated with the use of such reaming systems. These include.

1. Risk of breakage of flexible reamers¹⁶ and the consequent difficulties in retrieving them
2. Anterior femoral tunnel exit point lead to increased abrasive and bending forces which can lead to aperture widening and loosening of bone-graft junction.

We have pragmatized this systematic review into different surgically relevant points; that are as follows:

1. Knee Flexion and Femoral tunnel length

During the procedure, flexion of knee is a variable which affects the visibility as well as placement of tunnels. The degree of knee flexion determines the length of the femoral tunnel, distance of the exit point from posterolateral structures at risk and the chances of posterior cortex blow-out. Kadija et al.¹⁷ demonstrated that increasing the angle of knee flexion while using the rigid reamers from 110 to 125–130° was associated with statistically significant increase in tunnel length (p-value 0.017). Increase in the femoral tunnel length by increasing the degree of knee flexion, irrespective of the type of reamer used, has also been demonstrated in cadaveric studies (Forsythe et al.,¹⁸ Dave et al.¹⁹).

Kalra et al.²⁰ studied the effect of various degrees of knee flexion (70°, 90°, and 120° of flexion) on tunnel length while drilling with a flexible reamer in a series of 10 cadaveric knees and demonstrated a trend for progressively increasing tunnel length with an increase in knee flexion. They found that adequate femoral tunnel length can be achieved with knee at 90° of flexion without the need for hyperflexing the knee. Dave et al.¹⁹ also found that use of a flexible reamer system and 120° of knee flexion can independently decrease the likelihood of posterior cortex blow out.

Tunnel length is one of the most important factors governing the outcomes of ACLR.²¹ In a study conducted by Kadija et al.¹⁷ on 125 patients who had undergone primary anatomic ACL reconstruction, the length of femoral tunnel was compared among two groups of patients: those who underwent reconstruction using flexible reamers and those where rigid reamers were used. It was observed that the length of the femoral tunnel was statistically significantly longer with the use of flexible reamers when compared with rigid reamers (p-value<0.01). Similar trends were also observed in studies done by Kim et al.,²² Yoon et al.,²³ Kosy et al.²⁴ and Wein et al.²⁵ where patients undergoing ACLR using flexible reamers were retrospectively analysed for the tunnel length and compared with a control group where rigid reamers were used. Even the cadaveric studies (Silver et al.²⁶; Steiner & Smart,²⁷ Dave et al.¹⁹) presented a similar picture where longer tunnels were achieved using a flexible reamer through a medial portal when compared with rigid reamers through the same portal.

The relative gain in the length of intraosseous tunnel is possible with the flexible reamers because it tends to exit anteriorly on the lateral femoral cortex compared to the rigid reamer which exits close to the posterior femoral cortex. This finding was confirmed by the cadaveric study done by Steiner et al.²⁷

However, in a study done by Larson et al.,²⁸ where they compared tunnel length using four different techniques of femoral tunnel drilling (transtibial, transportal with rigid reamers, transportal through flexible reamers and outside-in technique) in a total of 20 cadaveric knees, similar findings were not reproduced. It was seen that drilling through the tibial tunnel produced the longest but non-anatomical tunnel and use of transportal technique produced anatomically placed tunnel but they were shorter. The tunnels were found to be longer in the rigid group as compared to the flexible group (p-value 0.039). They postulated that use of flexible reamers may not work with some suspensory fixation devices as the mean tunnel length in this group was found to be less than 30 mm and considering the fact that at least 15–20 mm of graft must be placed in the tunnel.

2. Tunnel Position

With improvements in technology, there has been an evolution of tools that are used in assessing the exact location and study the morphology of the intraosseous tunnel. In the study done by Muller et al.,²⁹ postoperative antero-posterior radiographs were used to determine the femoral tunnel angle (using a method described by Illingworth et al.³⁰). It was described as the angle between anatomical axis of femur and the line bisecting the femoral tunnel on the radiograph (which was used as a surrogate for femoral tunnel position); higher angles were associated with a graft which is more horizontal. Although the mean femoral tunnel angle in the patients who underwent ACLR using flexible drills was higher than in those where rigid drill was used, this difference was found to be statistically insignificant on analysis. This study was found to have some limitations; the tunnel position was only assessed in 2 dimensional planes and the method described by Illingworth et al.³⁰ was studied only for ACLR using a rigid drill thus raising questions about its accuracy in predicting the position of tunnel in real time.

In 2015, Kadija et al.¹⁷ used the postoperative antero-posterior as well as lateral x rays to indirectly determine the position of femoral tunnel in frontal and sagittal plane and compared the results of two groups of patients (one undergoing ACLR using rigid reamer and the other using flexible reamer). They found that the angle in the sagittal plane did not differ in the two groups significantly. However in the frontal plane, the angle of the tunnel was statistically significantly lower with flexible reamers when compared to the tunnel drilled with rigid reamer (p-value<0.01).

Jamsher et al.³¹ used MRI to measure sagittal and coronal graft inclination angles following ACLR using flexible and rigid reamers via anteromedial portal and used patients with intact ACL as controls. In the flexible group, they found the inclination of graft to be similar to the native ACL in both sagittal and coronal planes. However in the rigid group, even though no difference was observed in coronal inclination when compared to the control group, they did find an increase in sagittal angulation as compared to the native ACL. They postulated that the inclination angle depends upon the positioning of the femoral offset in the rigid system which is further impacted upon by the low angle imposed by the AAM portal. However, with flexible reamers it is possible to select the angle, often around 45° to the epicondylar axis, following the course of the native ACL.

3-Dimensional CT scan is now considered as the most accurate method for postoperative determination of tunnel position.³² Kim

et al.,²² in a series of 54 patients (twenty seven undergoing ACLR with rigid reamer and other 27 using a flexible one) demonstrated no statistically significant difference in the tunnel position using 3-D CT scans in two groups of patients undergoing anatomic double bundle ACLR. Similar findings were observed in a recent study done by Kosy et al.²⁴

In a cadaveric study done by Larson et al.,²⁸ the mean angle of femoral tunnel in the coronal plane was identified using a 3-D CT, which demonstrated a more horizontal graft when flexible reamers were used as compared to the rigid group. The findings were found to be statistically significant (p-value 0.007).

3. Footprint Replication and exit point

Restoration of the native ACL obliquity, origin and insertion has been found to be associated with improved outcomes. One of the methods used to quantify the location of aperture of femoral tunnel is the quadrant method described by Bernard et al.³³ using a lateral roentgenogram. The position of the aperture is described in terms of percentage of distance from highest point of intercondylar notch (vertical) and posterior wall (horizontal). A systematic review on the centre of native ACL footprint done by Piefer et al.³⁴ showed the average distance in terms of percentage from both the highest point of intercondylar notch and the posterior wall to the centre of AM bundle footprint to be 23.1% and 21.5% respectively and for centre of PL bundle footprint to be 48.8% and 32% respectively. The anatomic centre of the ACL femoral footprint is 43% of the proximal-to- distal length of the lateral, femoral intercondylar notch wall and r+2.5 mm anterior to the posterior articular margin, where r represents ACL femoral socket radius.

In the study done by Kosy et al.,²⁴ no statistically significant difference was found in the position of the aperture when either of the two reaming systems was used. Study done by Tashiro et al.³⁵ had similar findings in the two groups (one undergoing ACLR using flexible reamers and other using rigid reamers) although they found that the femoral tunnel exit point was significantly located more anteriorly in the flexible group (p-value<0.001). This was also demonstrated in the cadaveric study done by Steiner and Smart²⁷ where they found the exit point to be located anteriorly in the flexible group (p value < 0.01). Yoon et al.²³ in their study also tried to determine the location of the aperture in a total of 30 patients undergoing ACLR using flexible reamers. They however did not include a control group in their study. Their findings revealed that the centre of footprint of reconstructed ACL was within anatomic range but was closer to the footprint of the AM bundle. Similar findings were observed in a study done by Kim et al.²² comparing the results of double bundle ACL reconstruction using flexible and rigid reamers. The difference in mean position of aperture from the centre of anatomic footprint was <5% which was found to be insignificant on statistical analysis.

4. Femoral tunnel aperture morphology

Another important aspect of ACLR is the morphology of the apertures of the tunnel. A more circular aperture is presumably associated with maximum contact and thus it will promote healing at bone graft interface particularly at the orifice. However a more ellipsoid femoral tunnel can cover a greater area of ACL footprint.¹¹ Kim et al.²² found that the mean height: width ratio of both the AM and PL femoral tunnel was larger when rigid reamers were used as compared to the flexible group. The resultant apertures were thus elliptical with rigid reamers. This can be attributed to near perpendicular drilling with flexible reamers producing a more circular tunnel whereas rigid reamers drill the medial surface of lateral femoral condyle at an angle thus producing a more elliptical

tunnel. This is in contrast to the study done by Kosy et al.,²⁴ who found no difference in the aperture shape between the flexible and the rigid group. In the cadaveric study done by Forsythe et al.,¹⁸ they examined the effect of various degrees of knee flexion on tunnel characteristics using flexible and straight guides. They found no significant difference in the area of aperture covered between the flexible and straight guide for all flexion angles. Although they did however found that the flexible system achieved greatest aperture area at 90° of flexion and which then decreased with increased flexion. The same for the rigid group was 110° of flexion beyond which the area of aperture began to decrease. Similarly no difference in aperture morphology was observed in the cadaveric study done by Larson et al.²⁸

5. Graft bending angle

Changes in the values of graft bending angle can affect the stress at the junction of graft and the bony aperture and thus can be a reason for graft failure. The graft changes direction at the femoral tunnel aperture, redirecting forces or abrasive forces may be created and they could cause a localized area of increased graft stress at the sharp aperture edge, potentially contributing to graft damage and widening of the bone tunnel aperture.³⁶

Kim et al.²² in their study found the graft bending angle at the orifice of femoral tunnel of both AM and PL bundles significantly more acute in the reconstructions using rigid reamers (i.e. the graft bending angle is low) as compared to the flexible reamers; the same has been reported in the studies done by Tashiro et al.³⁵ and Yoon et al.²³ Kim et al.²² postulated this to be a result of less degree of knee flexion when flexible reamers are used and because of the 42° curved guide tip used in flexible systems which changes the reaming trajectory.

Tashiro et al.³⁵ studied the effect of two femoral tunnel drilling techniques on graft bending angle and correlated the angle to tunnel widening post operatively. In their study found greater widening of femoral tunnels at the end of 6 months in patients who had a higher graft bending angle i.e. the flexible reamer group. They postulated that the more anterior exit point of femoral tunnel in patients who underwent ACLR using flexible reamers increases the stress due to increased anterior bending of graft leading to aperture widening and recommended further investigations into its clinical implications.

6. Posterior cortex damage and damage to posterolateral structures

Violation of the posterior femoral cortex is one of the complications that can happen while drilling a femoral tunnel. Although it's incidence with use of rigid reamers has been investigated, the literature reporting the incidence when using flexible reamers is sparse. The risk is higher when using the rigid system as even though the entry of the femoral tunnel may be the same, the exit point of the femoral tunnel tends to be anterior in case of flexible reamers. The risk is further compounded in cases of knees with restricted flexion as one possible way to avoid such complications is to hyperflex the knee before drilling. But, no significant differences in the rates of posterior blowouts were observed in either groups in the studies done by Kadija et al.,¹⁷ Kim et al.²² and Kosy et al.²⁴

In a cadaveric study done by Silver et al.,²⁶ they observed the distance between guide pin and common peroneal nerve as well as femoral origin of LCL was higher when using flexible system compared to the flexible system, but only the latter difference was found to be statistically significant (p-value 0.003).

7. Iatrogenic Injury to Medial Femoral condyle

Use of rigid reamers over the beath pin is associated with the risk of iatrogenic injury to the articular surface of the medial femoral condyle.¹⁴ To prevent this during the surgery, hyperflexion (>110°) of the knee is necessary¹⁴ which has its own set of problems. This, however, may not be possible in all patients' especially bulky ones. Flexible reamers do seem to address this pitfall of the rigid reamers as they curve over the medial condyle and the system and reamers are flexible and can be manipulated away from the medial femoral condyle. In 2019, a study was done by Yoon et al.²³ in a total of 30 patients who underwent ACLR using a two portal technique with the help of flexible reamer systems. they found no cases of medial femoral condyle injury during the operation.

5. Conclusion

Flexible reamer system can be used as an alternative to the conventional rigid reamers and avoids the need for hyperflexion of knee without compromising the tunnel length. Even though flexible reamers do have lower risk of injury to the posterior structures and cartilage of medial femoral condyle and produce minor variations in the tunnel characteristics, there is lack of consensus on the anatomical characteristics of femoral tunnel. Overall, its impact on clinical outcomes and the dissection of tunnel physiognomies needs to be further investigated.

Declaration of competing interest

None.

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Research paper

Evaluation of the pathological anatomy of posteromedial corner in varus osteoarthritic knees using magnetic resonance imaging

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ABSTRACT

Background: Understanding the pathological changes in varus osteoarthritic knees will help the surgeon to correct the deformity while performing total knee arthroplasty. The currently available MRI resolution allows us to recognize the anatomical details of the posteromedial corner and the changes associated with osteoarthritic knees. The study aims to assess the pathological changes of the varus osteoarthritic knees on MRI and to compare it to non-arthritic knees.

Methods: MRI of 26 patients with varus osteoarthritic knees (Kellgren and Lawrence grade 4) scheduled for total knee arthroplasty were reviewed and compared to MRI of 10 other patients without knee arthritis. The superficial Medial Collateral Ligament (sMCL) was assessed in terms of medial and posterior bowing, and the posteromedial corner (PMC) was evaluated in terms of thickness and signal integrity. **Results:** The superficial Medial Collateral Ligament (sMCL) was medially and posteriorly displaced in all severely varus arthritic knees compared to its position in non-arthritic knees, in addition to significant increase in posteromedial corner thickness with heterogenous appearance indicating scarring in the posteromedial corner (PMC). (p-value lower than 0.05).

Conclusion: The apparent tightness of the superficial Medial Collateral Ligament can be secondary to the pathology that affects the posteromedial corner (scarring) where sMCL is retracted and bowed posteriorly and medially, not simply contracted and shortened. Understanding the pathological changes of severely varus osteoarthritic knees on MRI can lead to a better algorithm to perform soft tissue balance during Total knee replacement surgery without releasing sMCL and subsequent knee instability.

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1. Introduction

Soft tissue balancing is a crucial step in correcting a varus deformity during total knee arthroplasty. This step typically consists of incremental medial releases that may ultimately necessitate release of the superficial medial collateral ligament (sMCL) in severe varus deformity, creating instability and thus the need for more constrained implants.

Posteromedial corner complex as well as sMCL changes were recognized in osteoarthritic varus knee and probably representing a key point for varus correction at Total knee Arthroplasty (TKR). The field of joint imaging, and particularly magnetic resonance imaging (MRI), has evolved rapidly owing to technical advances and the application of these to the field of clinical research. The resolution of the currently available MRI allows us to recognize the anatomical details of the posteromedial corner structures and the changes associated with the osteoarthritis and varus deformity.

The components of the posteromedial complex include the semimembranosus tendon and its expansions, posterior oblique ligament, oblique popliteal ligament, posterior horn of medial meniscus, and posteromedial aspect of the joint capsule. The superficial and deep components of the MCL are in close relation with

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the posteromedial complex anatomically and functionally.

For surgical planning for TKR in osteoarthritic varus knee to ensure post-surgery satisfactory stability, the recognition of the posteromedial complex MRI changes could be helpful for the target achievement. The study aimed to assess the surgically significant pathological changes of the severely varus osteoarthritic knees on MRI and to compare it to non-arthritic knees. Our hypothesis is that these changes are indicating that the sMCL is retracted by its adjacent posteromedial scarred tissues and not shortened, thus just freeing the sMCL -not releasing it-will be enough for restoring its length and obtaining proper soft tissue balance while performing total knee arthroplasty in severely varus osteoarthritic knees.

2. Materials and methods

MRI of 26 patients with varus osteoarthritic knees (Kellgren and Lawrence grade 4) scheduled for total knee arthroplasty in a high-volume arthroplasty institution,¹ were reviewed and compared to MRI of Ten age-matched patients with knee pain but without a history of acute trauma or radiographic evidence of osteoarthritis, referred for MR imaging of the knee during the same period in the same institution. The varus deformity was defined as a hip-knee-ankle angle less than 180°. Only patients with primary osteoarthritis were included in this study.

All images were performed using a closed MRI system 1.5 T (Philips, Ingenia) and dedicated knee coil 16 channels. Multiple sequences in different planes were performed including:

- 1 Proton density with fat suppression in sagittal and coronal planes with 3 mm slice thickness and 3 mm gap. (Field of view is 160 × 160, TE 30, TR 3000, 24 slice, ETL -21, Matrix 288 × 208, Nex 2)
- 2 STIR sequences in axial and coronal planes. (Fov 160 × 160, Slice thickness 3 mm and 3 mm gap, TE 30, TR 4200, slice 30, Matrix-264 × 216, ETL -12, Nex 2)
- 3 T2 weighted in axial and sagittal planes. (Fov 160 × 160, TE 100, TR 5400, Slice thickness 3 mm and gap 3 mm, Slice 27, Matrix 324 × 260, ETL 13, Nex 2)

The superficial MCL was assessed in terms of medial and posterior bowing, and the posteromedial corner was evaluated in terms of its thickness and integrity. Measurements were performed on coronal, axial, and sagittal views in T2-weighted and PD-weighted VISTA sequences for all patients. Patients were classified into two groups: arthritic and non-arthritic group (see Figs. 1–4).

Medial bowing of MCL was evaluated in coronal views in T2-weighted and PD-weighted VISTA sequences by measuring the distance from a line through the medial edges of the medial femoral and tibial condyles at the level of the medial meniscus to the inner aspect of the MCL excluding the marginal osteophytes and the extruded medial meniscus.

The superficial MCL posterior distance was determined in axial views in T2-weighted and PD-weighted VISTA sequences by measuring the line originating from the posterior margin of the superficial MCL and perpendicular to the posterior condylar axis, at the most superior level of the femoral notch.

Measuring of the thickness of the posteromedial complex on all patients was performed on axial views in T2-weighted and PD-weighted VISTA sequences. Posteromedial corner was measured by drawing its' borders as described by Lundquist et al. at the level of the meniscus.² The software automatically calculated the mean thickness of the entire posteromedial complex area.

All measurements were done digitally by two physicians, a senior musculoskeletal consultant radiologist and an experienced orthopedic surgeon specializing in knee arthroplasty, using Philips Intellispace Pacs Enterprise software version 4.4.

Interobserver variations in interpretation of Kellgren grade, sMCL posterior and medial bowing, and posteromedial corner thickness and signal alteration were recorded in both groups of patients, and then discrepancies were resolved by consensus. We performed the statistical analysis using SPSS (Statistical Package for the Social Sciences) version 16. Using independent sample T test, we considered significant difference between the two groups when the P value was lower than 0.05. This study was approved by the institutional review board at our hospital, and informed consent was obtained from all potential candidates before performing the MRI study.

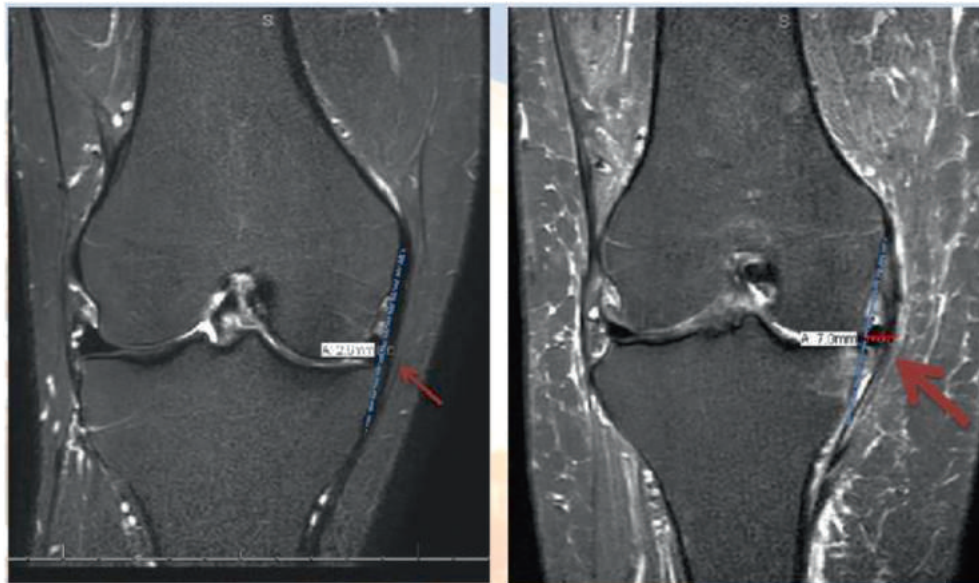


Fig. 1. a,b Coronal proton-density fat-saturated images through MCL and both menisci level in nonarthritic knee (a), and arthritic knee (b). Normal alignment of MCL is noted in the non-arthritic knee with distance between medial condylar line and MCL measures 2.5 mm while in the arthritic knee measures 7 mm with significant medial bowing.

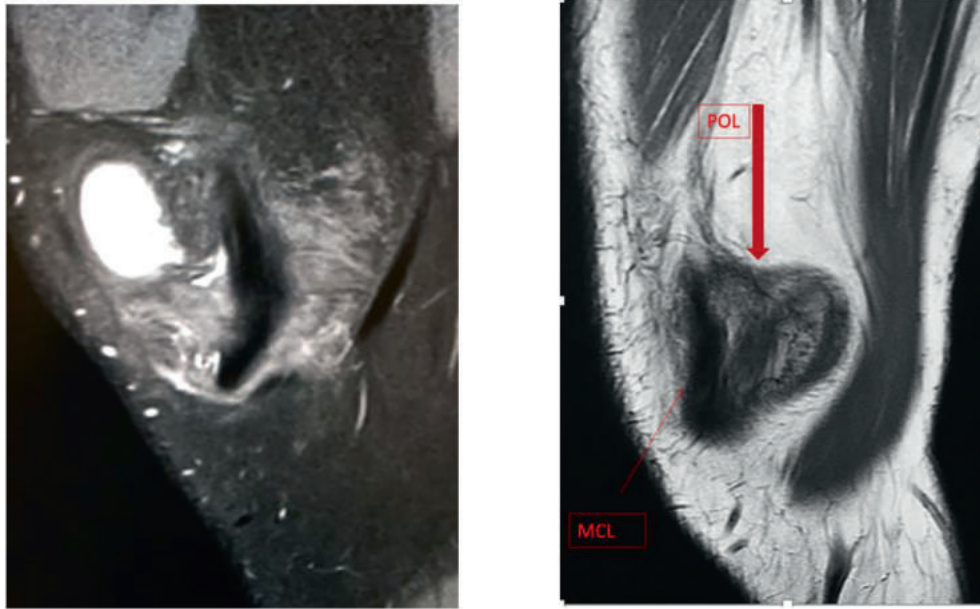


Fig. 2. Sagittal sequences through an arthritic knee at the level of MCL, Significant posterior bowing of MCL clearly seen in proton-density fat-saturated VISTA sagittal sequence with background of suppressed fat and surrounded soft tissue edema. Posterior bowing of POL is also noted in T2W sagittal image.

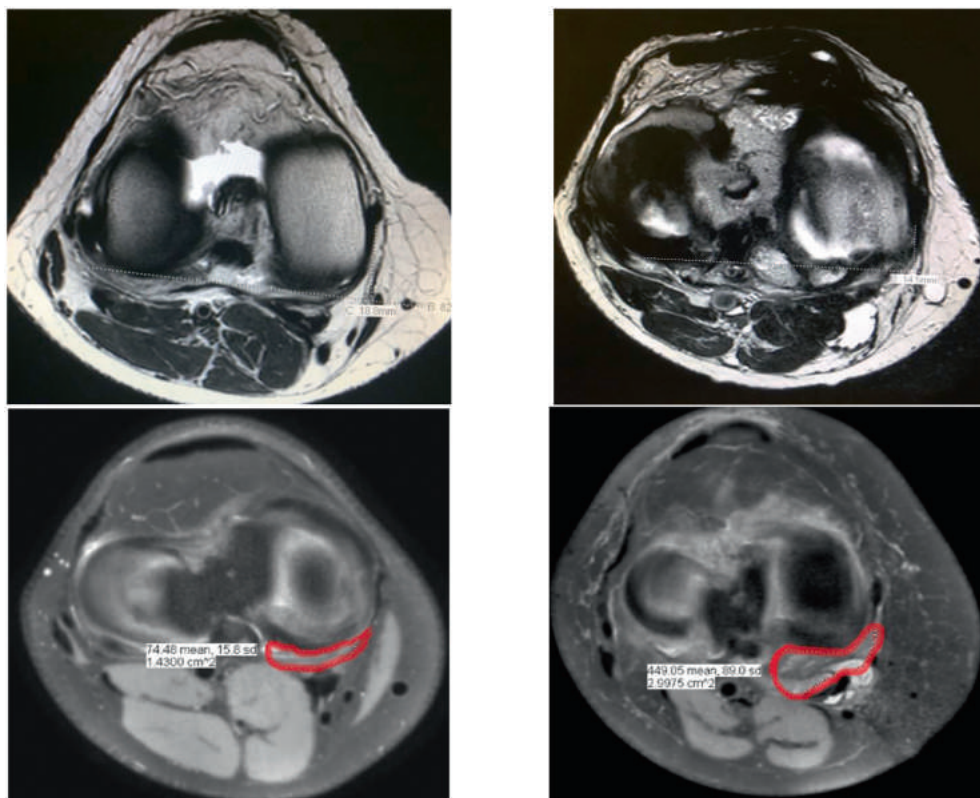


Fig. 3. Axial T2W and Fat suppressed images through menisci level of non-arthritic (left) and arthritic knees (right). Significant posterior bowing of MCL is noted in arthritic knee, measured by reduction of distance between mid-aspect of MCL to the posterior meniscal line associated (14.5 mm versus 18.8 mm) with significant thickening of posterior medial complex in comparison to normal alignment of MCL and normal thickness of posterior medial complex in the non-arthritic knee.

3. Results

The superficial Medial Collateral Ligament (sMCL) was medially and posteriorly displaced in all severely varus arthritic knees

compared to its position in non-arthritic knees, in addition to significant increase in posteromedial corner thickness with altered signal denoting scarring in the PMC complex. (p-value lower than 0.05). The involvement of the posterior oblique ligament was seen

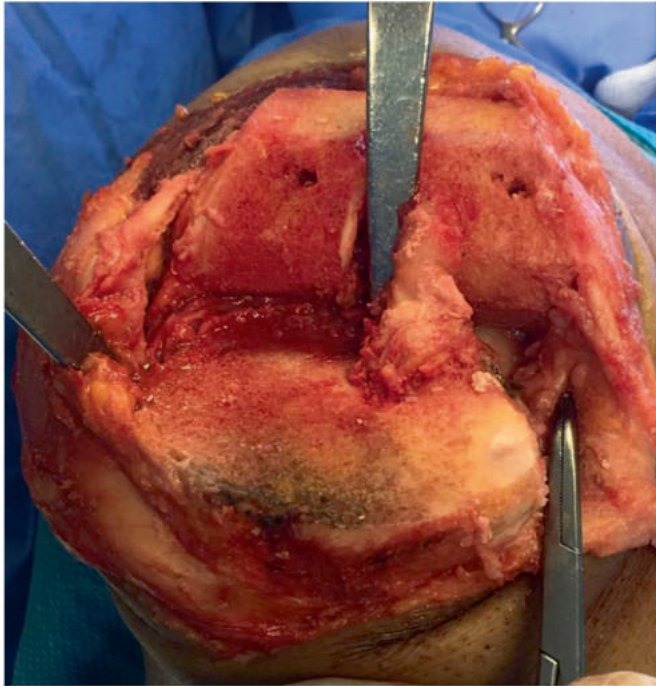


Fig. 4. The superficial Medial collateral ligament after being cleared from scarred posterior tissues while performing cruciate retaining TKR (Forceps pointing to sMCL).

in all cases with variable degrees of heterogeneous appearance of the ligament and loss of the normal signal within the posteromedial complex. The mean age of the arthritic group was 55years, and the mean age of the non-arthritic group was 49 years.

3.1. Statistical findings

There were significant differences between the two groups in sMCL medial displacement, posterior displacement and distance, and PMC complex thickness (p-value < 0.05). The mean and standard deviations of sMCL medial displacement in the arthritic group versus the non-arthritic were 7.68 ± 1.85 and 2.4 ± 0.87 mm respectively. The mean and standard deviations of sMCL posterior distance in the arthritic group versus the non-arthritic group were 13.16 ± 2.86 and 18.67 ± 2.66 mm respectively. The mean and standard deviations of PMC complex thickness in the arthritic group versus non arthritic were 7.98 ± 1.49 and 4.11 ± 0.71 mm respectively. (Mean value and standard deviations of medial displacement, posterior distance, and PMC complex thickness are shown in Table 1).

4. Discussion

Our study demonstrated significant radiologically confirmed pathological changes in the posteromedial corner of the severely

arthritic varus knees in the form of thickening and scarring of the posterior oblique ligament and posteromedial corner with subsequent posterior and medial bowing and retraction of the sMCL in comparison to non-arthritic knees, thus supporting our hypothesis that just clearing the sMCL from these scarred structures will help it to return to its normal position and restore its normal length and function without any need to pie crust or disinsert or release it neither fully nor partially unlike what is traditionally mentioned in literature about surgical medial release of fixed varus knee deformities while performing total knee arthroplasty.³

Kaneyama et al. mentioned that contracture of the posterior capsule pulls the MCL backward and prevents full extension of the knee because full elongation of the MCL is limited. He reported that posteromedial vertical capsulotomy selectively increases the extension gap by separating the sMCL from the contracted posterior capsule thus allowing the sMCL to move freely anteriorly and sufficiently to allow full knee extension.⁴

Masuda et al. found that the selective increase of the extension gap by this capsulotomy was about 2.7 mm in Posterior stabilized TKA. His explanation was that cutting the contracted posteromedial joint capsule behind the sMCL can restore the excessive tension of the sMCL to its normal state, in addition to inserting a tight spacer block opening the extension gap by tearing the posterior medial joint capsule furtherly.⁵ This is, however more or less close to our explanation which is based mainly on freeing the sMCL from the contracted capsule and posterior oblique ligament not just tearing the posteromedial capsule.

While there are several OA grading systems based on radiography,^{6,7} Kellgren and Lawrence grading is a system that is most widely used for screening purposes of patients being enrolled onto OA research studies and clinical trials.¹ Understanding and recognizing the MR imaging appearances of osteoarthritis has consequently become of considerable importance. Several studies reported various radiological findings in advanced osteoarthritis, many of them focused on cartilage,^{8,9} bone marrow lesions,^{10–12} and meniscal extrusion.^{13,14} However, in this study our concern was focused on changes with clinical significance for the surgical technique while balancing severely varus knees as this is a still a debatable subject with many surgeons still performing pie crusting or partial disinsertion of distal end of sMCL with subsequent knee instability hazards. This concern brought us to the changes occurring in posteromedial corner and its contents.

To our knowledge, there is a paucity of literature focusing on the medial side of the knee specifically the posteromedial corner (PMC), with some authors labeling it “the neglected corner.”² The normal anatomic components of the PMC are difficult to visualize with standard imaging technology; With modern MRI technology, the major anatomic structures comprising the PMC can be readily identified. As treatment and operative management techniques evolve, understanding the correct application of these advancements in MRI of the knee is very beneficial in improvement of surgical techniques and maturation of clinical practice.

The PMC lies between the posterior margin of the longitudinal fibers of the superficial medial collateral ligament (sMCL) and the

Table 1
Statistical Data (mean values and standard deviations of medial displacement, posterior distance, and PMC complex thickness).

	Group	Mean value (mm)	Std. Deviation
sMCL medial displacement	Arthritic knees	7.6846	1.84796
	Non arthritic knees	2.4200	0.87152
sMCL posterior distance	Arthritic knees	13.1692	2.85892
	Non arthritic knees	18.6700	2.65625
PMC complex thickness	Arthritic knees	7.9846	1.49283
	Non arthritic knees	4.1100	0.70781

medial border of the posterior cruciate ligament (PCL). With its five major components: the semimembranosus tendon and its expansions, the oblique popliteal ligament (OPL), the posterior oblique ligament (POL), the posteromedial joint capsule, and the posterior horn of the medial meniscus, The PMC structures are relaxed when the knee is flexed and tight when the knee is extended. The superficial and deep portions of the MCL occupy the middle third of the medial side of the knee, and although they function in close association with the structures of the PMC, they are not typically considered part of it.² The delicate nature of the ligaments makes the different parts of the posteromedial corner (PMC) of the knee more difficult to separate from each other than the sMCL and the deep portion of MCL.¹⁵

Although earlier articles considered the POL a posterior part of the sMCL,^{16,17} more recent studies prove this to be a discrete separate ligament.^{18–20} POL originates just distal and posterior to the adductor tubercle, giving it an origin distinct from that of the sMCL, which originates just proximal and posterior to the medial femoral epicondyle.^{20–22} Distally, the POL has three arms: the superficial, central, and capsular arms. The central, arm is the largest and thickest of the three arms and forms the main portion of the POL. It merges distally with and reinforces the posteromedial joint capsule, adhering to the posteromedial aspect of the medial meniscus and the adjacent aspect of the tibia at the posterior articular surface.²⁰ The natural tendency of the POL is to be relaxed when the knee is flexed and tight when the knee is extended. With increasing flexion, the posteromedial capsule becomes relaxed and folds upon itself.²

These anatomical findings –being also supported by the radiological findings in this study–showing that the POL has close relation with the posterior capsule and deep MCL without any clear attachment with the sMCL, are supporting our hypothesis that the changes affecting the sMCL in varus arthritic knees are likely to be secondary to the changes involving the posteromedial complex in addition to the effect of marginal osteophytes. The scarred tissue in the PMC and the adhesions are acting as ‘softphytes’ tensioning and deforming the ligament and the posterior capsule. The oblique ligament forces the sMCL to bow posteriorly.

Understanding the exact pathology in the PMC may allow for improved soft tissue balancing leading ultimately to improved functional outcome. While medial release is the standard intraoperative mode of balancing, the correct intraoperative sequence, extent and magnitude of releases required remains ill-defined with the classic extensive medial release leading to unnecessary instability and abnormal knee kinematics.²³

In severe arthritis the posteromedial capsule with its attaching structures are thickened scarred and fibrosed or contracted, unlike the sMCL which does not contract even in severe varus deformities and is only affected secondary to these changes in addition to nearby osteophytes, as a result separating it from all these interconnected structures with removal of bony osteophytes will help restoring its normal length, tension and position and thus restoring soft tissue balance in the medial side of the knee.

The current study has several limitations. Firstly, due to the lack of similar studies in the current literature, it was impossible for us to calculate the Sample Size and Power of the study. As a result, the sample size might be small, nevertheless, the prevalence of these changes in all of the varus arthritic knees, it seems unlikely that a larger population would have significantly altered the observation. Secondly, utilization of a 3.0 T MRI or higher could have provided better data. Derby et al. described a relatively low accuracy for the diagnosis of posterolateral corner injuries when using a 1.5 T MRI.²⁴ However, we found no studies in the current literature to compare the accuracy rates between 1.5 and 3 T MRI in posteromedial corner injuries. Moreover, in the current literature, we

found no data regarding the intraobserver variability of the measurements performed in our study, therefore their accuracy can be a limitation of our study. Thirdly, the effect of bony osteophytes as well as meniscal extrusion should be evaluated together with the capsular and posteromedial scarring. Furthermore, histological specimens from sMCL and other PMC structures should be evaluated in other studies to support the radiological findings in this study. Finally, anatomic variability between individuals regarding sex and patient morphology has not been taken into account during this study.

5. Conclusion

In severely varus arthritic knees, the sMCL is deformed due pathological changes in the posteromedial corner. Clearing the superficial MCL from these surrounding pathological tissues –not releasing it–will help restore its normal shape, length, and position, allowing us to balance varus knees intraoperatively without creating instability.

Credit author statement

Samih Tarabichi, Mohamed Elkabbani: Conceptualization, Methodology, Software, Mohamed Elkabbani, Mohamed Helaly: Data curation, Writing – original draft., Amr Osman: Visualization, Investigation., Samih Tarabichi: Supervision. Amr Khater: Software, Validation. Mohamed Elkabbani: Writing- Reviewing and Editing

Declaration of competing interest

The authors declare that they have no conflict of interest.

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Research paper

Lateral epicondyle osteotomy for correction of valgus deformity during total knee arthroplasty: Surgical technique and clinical outcomes



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ABSTRACT

Background: Lateral epicondyle osteotomy is one of the surgical choices when seeking a proper equalization and balance of the flexion and extension gaps during the correction of a valgus knee deformity, when performing a total knee arthroplasty (TKA). However, its use is not frequent, and the reports described in literature are scarce. The aim of this study was to describe the clinical outcomes of the patients in which lateral epicondyle osteotomy was performed during TKA in a consecutive group of patients with valgus deformity.

Methods: Retrospective study of 18 patients with valgus deformity, who had lateral epicondyle osteotomy during TKA, from January 2016 to December 2018. The type of valgus deformity was assessed with Ranawat's classification. The femorotibial angle was measured with a panoramic leg standing X-rays before and after the TKA; The function was evaluated with the Knee Society Score-KSS and Oxford Knee Score scale.

Results: The average age was 71.8 ± 6.1 years and 13 cases were women. According to Ranawat's classification, 11 knees had Grade III ($>20^\circ$) valgus deformity. The mean preoperative and postoperative femorotibial angles were $25.8^\circ \pm 9.9^\circ$ and $7.1^\circ \pm 1.8^\circ$, respectively. Functional improvement was observed through the KSS and Oxford scales, with an average increase of 37.4 ± 13.4 and 32.4 ± 6.7 points compared to preoperative. No evidence of intraoperative or postoperative complications associated with the procedure was found.

Conclusion: In these patients, the osteotomy of the lateral epicondyle proved to be an effective surgical option for the correction of valgus deformity during TKA, allowing proper alignment of the limb with good functional results.

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Author's contribution

FB, AC, JP and EC made the design of the study. FB, TR and WP collected the data from the clinical records. EC, AE and JP helped with the statistical analysis. The interpretation of the results and the draft of the manuscript were made by all authors. All authors

read and approved the final manuscript.

1. Introduction

The valgus knee is considered a complex deformity involving bone and soft tissue abnormalities and its correction represents a challenging task for the orthopedic surgeon. Valgus deformity is present in up to 15% of patients undergoing total knee replacement (TKA) and has been found associated with less favorable functional

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results compared to varus knees.^{1–4}

Traditionally it has been taught that the iliotibial band (IB), lateral collateral ligament (LCL), popliteus muscle tendon (PT), posterolateral capsule (PLC) and lateral head of gastrocnemius are the soft tissues mainly contracted in valgus knees. To achieve a correct balance and equalization of the flexion and extension gaps, a stable joint and an appropriate alignment of the extremity, various release sequences during the TKA have been proposed.^{2,3,5–8}

Despite the rational and sequential release of soft tissues, in some cases with severe deformities it is not possible to achieve an adequate balance and equalization of the gaps, especially in knees with rigid valgus or associated with flexion deformities.^{2,9} In these knees, but not exclusively, the osteotomy of the lateral epicondyle plays an important role and has been proposed as a solution. It was initially described by Scuderi & Insall in 1995¹⁰ and reproduced by other authors as part of the sequential releases of the soft tissues involved in the deformity, with good results in terms of joint balance, mobility and function.^{7,11–14}

This procedure allows simultaneous release of the LCL and the popliteus tendon (PT), which are part of the structures that, in some cases, need to be released to complete an appropriate correction of the deformity, because they are attached to the bone fragment of the epicondyle (naturally). After performing the osteotomy, the epicondyle finds the best position in flexion and extension, allowing adequate balance, equalization of the gaps, joint stability and extremity alignment. However, its use is limited due to the risk of possible complications inherent to the procedure such as pseudarthrosis, pain at the site of osteotomy and residual instability. In addition, up to this point in time, the number of articles that describe the surgical technique and clinical results of an epicondyle osteotomy without fixation, are scarce. The aim of this study was to describe the clinical outcomes of the patients in which lateral epicondyle osteotomy was performed during TKA in a consecutive group of patients with valgus deformity. In this study, the epicondylar osteotomy surgical technique without the use of fixation is described, with clear references of where and how to perform the osteotomy in three specific scenarios.

2. Materials and methods

This study was approved by institutional review board and conducted under the principles of the Helsinki Declaration. A retrospective review was performed using the following inclusion criteria: (1) patients who were diagnosed with knee osteoarthritis and preoperative valgus deformity of the knee (Ranawat classification Grade II-III), and (2) patients who required a femoral lateral epicondyle osteotomy for correction of valgus deformity during primary TKA from January 2016 to December 2018. All eighteen cases were identified from our institutional arthroplasty registry and signed the informed consent form. No cases were excluded.

2.1. Description of our surgical technique

With the patient under neuraxial conductive anesthesia in the supine position, a standard anterior midline skin incision is done, and then a medial parapatellar arthrotomy is performed. Subsequently, the meniscus and the posterior and anterior cruciate ligaments are resected. It is important to release the medial soft tissues as minimal as possible during the procedure.

Using an intramedullary rod in the femur, with a valgus angle between 3 and 5°, the distal femoral cutting guide is placed and the cut is made. This valgus position depends on the preoperative planning, and its goals are to 1) obtain the most neutral knee possible, without excessive residual valgus and 2) to restore the

mechanical axis of the extremity, taking in to consideration that every case has to be individualized, in case of coexisting deformities, and/or femoral metaphyseal remodeling, which are present in many of these cases. Then the size of the femoral component is defined. After that, the multi-cut (4 in 1) femoral guide is positioned, being careful to place it in an appropriate external rotation with respect to the transepicondylar axis and the Whiteside line. Our recommendation is for you to avoid using de posterior condyles as reference for the external rotation of the component, and more if you have a valgus knee case because of the big possibility of leaving the component in internal rotation. After the position is defined, the multi-cuts (4 in 1) femoral guide is fixed, and the anterior, posterior and oblique cuts are made. Then, the femoral box is made depending of the implant that was defined since the preoperative planning.

Afterwards, using an extramedullary rod, the tibial cut is made at a posterior slope of 3° and 90° (neutral of varus-valgus) with respect to the center of the ankle (mortise joint). The anterior, posterior, medial and lateral osteophytes are then resected completely. If after that we end with an asymmetrical lateral space gap in extension and/or flexion, the process of sequential soft tissue release begins considering that LCL, IB and PLC play a major role in extension, while PT, LCL and PLC play a leading role in knee flexion.

With the previous information as reference, we initially release the IB and/or PLC depending on which space is asymmetric. Even in the cases in which a liberation of the LCL and/or TP seem to be required, we don't do this directly, but rather proceed with the epicondyle osteotomy because, with doing so, both of these structures are liberated due to the fact that they (LCL and TP) remain naturally attached to the bone fragment of the osteotomized epicondyle. We indicate the osteotomy in the following three scenarios: 1) when there is an asymmetrical lateral space gap in extension after releasing IB and after the release of PLC from the tibia and femur, 2) when an asymmetrical lateral space gap in flexion persists, after releasing PLC from the femur and tibia, and 3) when an asymmetric lateral space gap persists in flexion and extension after the release of IB and after the release of PLC from the femur and tibia.

When doing the epicondyle osteotomy, the first thing to do is to position the knee in a 90° angle. Then, a straight line is projected from the supracondylar lateral cortex of the femur, through the epicondyle towards distal. (Fig. 1). The osteotomy is started with an oscillating saw in the distal portion of this projected line in the epicondyle, from distal to proximal (Fig. 2), achieving with this a precise and uniform cut. Proximally, the osteotomy is finished with an osteotome and not with the oscillating saw. Invasion of the lateral cortical of the femur must be avoided. It's important, as long as its possible, to leave the epicondylar bone fragment adhered to the proximal soft tissues, that are, in this moment, loose proximally due to the osteotomy, and also trying to preserve the bone fragment's and femur's periosteum. (Fig. 3). Finally, a bone fragment that is solid, unique with good width and completely mobile is obtained, which makes it easier for it to find its own location distally and posteriorly, depending on what the equalization and balance of the flexion and extension gaps require. Keeping the bone fragment adhered to the proximal soft tissues, and preserving the periosteum are no limitations for the fragment to be able to move voluntarily, but they do advantage stability and consolidation. Then, the balance and equalization of the gaps are done by increasing, progressively, the gap measuring blocks in flexion and extension, which helps the movement of the epicondyle towards posterior and distal until it finds an optimal position in a stable, balanced, and aligned joint. No fixation is used for the osteotomy, and the postoperative follow-up and the physical rehabilitation process is not modified because of the procedure. X-rays before and

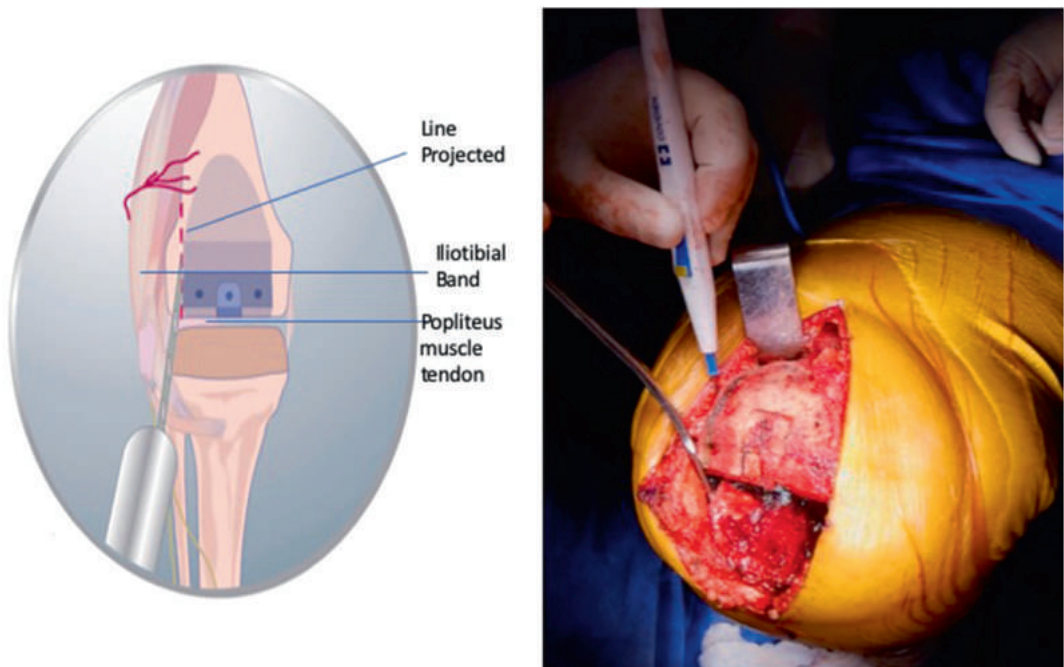


Fig. 1. A) Illustration and intraoperative photo describing the line projected from the lateral cortical of the femur in order not to invade the lateral cortical and obtain a suitable bone fragment.

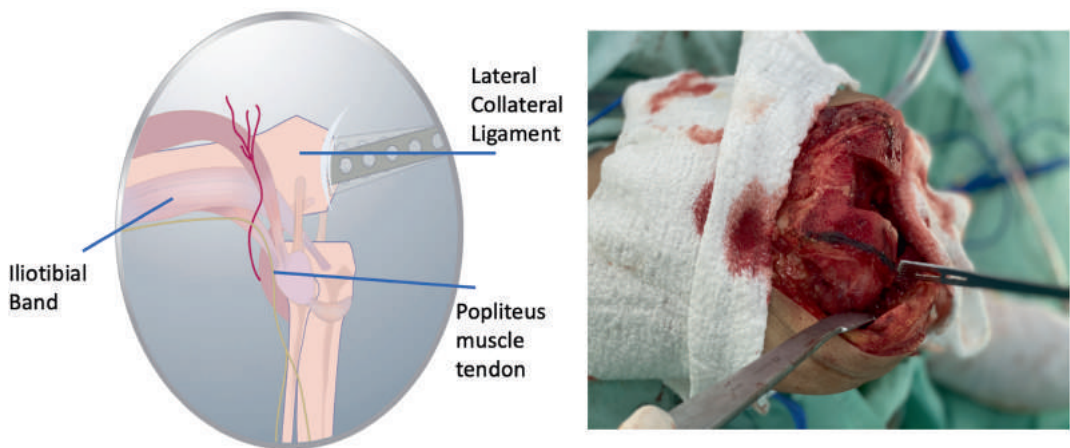


Fig. 2. Illustration and intraoperative photo showing the onset of lateral epicondyle osteotomy with oscillating saw.

after TKA in one case are shown in Fig. 4.

2.2. Implant decision

Stabilized-posterior (PS) or constricted condylar (CCK) type implants were used. The choice of the implant was not conditioned by the severity of the deformity and the decision was made according to the clinical characteristics of each patient (e.g. presence of rheumatoid arthritis, poor bone quality, among others).

2.3. Postoperative follow-up

All patients started the rehabilitation program the same or next day post-surgery, which included full weight bearing as tolerated and active and passive range of motion exercises. All of them stay hospitalized 2 days after surgery, including surgery day.

The routine follow-up visits were performed as follow: stitch removal visit, 1 month postoperative, 3 months postoperative, 6 months postoperative, 1 year postoperative and then each year. During follow-up, at each clinic visit, a comprehensive physical examination was performed, in conjunction with functional scales (KSS and Oxford) and evaluation of possible complications. Instability was evaluated clinically with stress maneuvers, as well as patellofemoral tracking.

2.4. Data collection

The main outcome of the osteotomy was the change between preoperative and postoperative measurement on the femorotibial angle. The knee was evaluated in a plain AP and Lateral X-ray, and the alignment of the extremities was assessed in a panoramic anteroposterior (AP) standing view of the lower extremities. The

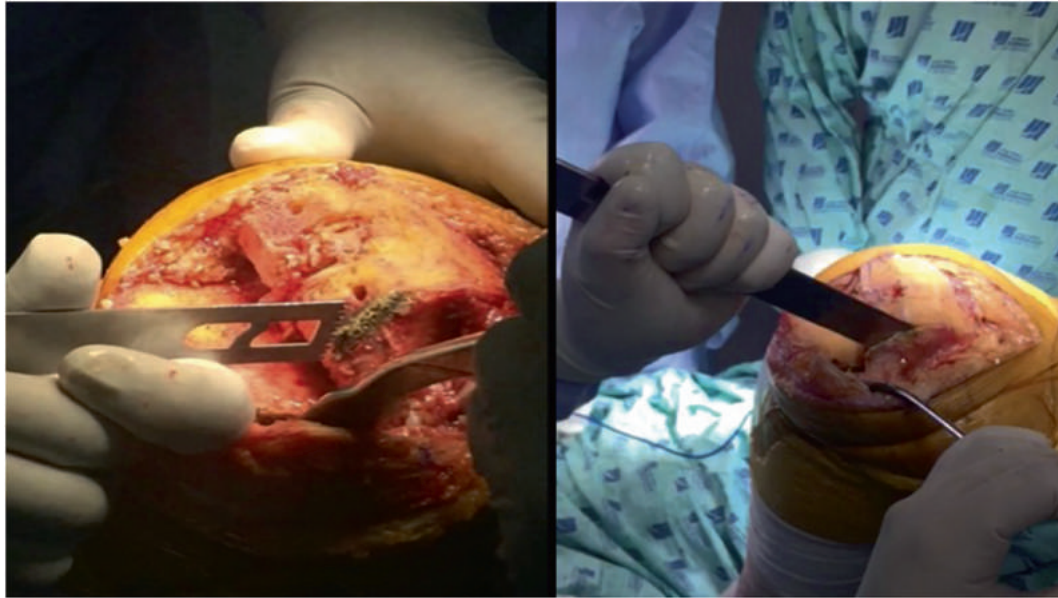


Fig. 3. Intraoperative photos of epicondyle osteotomy completed with osteotomy.



Fig. 4. Preoperative and postoperative x-ray of a left knee with valgus deformity Grade II intervened with PS prostheses.

magnitude of the deformity was assessed according to Ranawat classification.¹ The functional outcomes were measured with the Knee Society Score-KSS and Oxford Knee Score scales before and after TKA. Complications associated with osteotomy such as fracture, pseudoarthrosis and instability were documented. All

information was taken from clinical records.

2.5. Statistical analysis

A descriptive analysis was carried out using Stata 13®

(StataCorp, College Station, Texas, USA). The quantitative variables were summarized with mean ± standard deviation or median (interquartile range). Frequencies were reported for categorical variables. The normality assumption was tested using the Shapiro Wilk test. Paired sample *t*-test was used to assess the differences in function score before and after surgery.

3. Results

Eighteen patients who underwent TKA and required lateral epicondyle osteotomy for correction of valgus deformity were analyzed. The average age was 71.8 ± 6.1 years and 13 cases were women with a median follow-up time of 20 months (Interquartile Range-IQR Range: 17–28 months). Seven left knees and 11 right knees were included. At the time of the surgery, the body mass index (BMI) was 31.2 ± 4.7 kg/m². In three knees, that had very poor bone quality secondary to RA, CCK implants (Optetrak Revision Knee System, Exactech) were used, and in 15 knees, PS type implants (Attune: Johnson & Johnson; Optetrak: Exactech; Geminis SL: Link) were used.

According to Ranawat’s classification, seven knees had a grade II valgus (10°–20°) and 11 knees a grade III (>20°). Eight knees had a deformity associated with a flexion contracture between 5° and 10°. There were no patients with medial collateral ligament incompetence in this series of patients. After TKA, in all cases the alignment was improved with a mean post-operative femorotibial angle of 7.1 ± 1.8°. Functional improvement was observed through KSS and Oxford scales, with an average increase of 37.4 ± 13.4 (*p* < 0.001) and 32.4 ± 6.7 (*p* < 0.001) points compared to preoperative, respectively (Table 1). After 1-year of follow-up, all patients reported excellent function with the KSS scale (≥80 points). Using the Oxford scale, six patients reported moderate functional outcomes (30–39 points), and 12 patients’ satisfactory function (40–48 points).

At the end of follow-up, no evidence of intra or postoperative complications associated with the procedure was found. Radiological follow-up showed that the bone fragment of the epicondyle remained stable and in the same position as the beginning in all cases.

4. Discussion

The principal finding of this study suggests that in patients with an average valgus deformity of 25.8° ± 9.9° undergoing TKA, the lateral epicondyle osteotomy, for the correction of valgus knee deformity, offers satisfactory functional results and no associated complications at the end of follow-up. Since the 1970s different authors have studied and proposed various rational soft tissue release sequences to achieve an adequate balance during TKA in knees with valgus deformity.¹⁵ However, currently, there is no consensus among orthopedic surgeons about what is the best release sequence.

In 1979, Chitranjan Ranawat described a release sequence, which he improved in 1985 because the use of constrained implants was not necessary.^{16,17} Mihalko et al., demonstrated in cadaveric models that with the release of LCL, PT, IB and lateral gastrocnemius without sacrificing the posterior cruciate ligament (PCL), it obtained less than 5° of correction, but if these structures were released and the sacrifice of PCL was performed, it could correct up to 9° of deformity.⁶ Scuder and Insall in 1995, described the osteotomy of the lateral epicondyle to achieve an adequate knee balance in knees with valgus deformity >20°. ¹⁰ But it was until 2002, when Brilhaut et al., described a series of 13 patients, reporting good to excellent functional results with the KSS scale.¹³

In the literature, good functional results in patients with valgus deformity have been described with the lateral epicondyle osteotomy. These findings suggest that this procedure can be considered as a safe option to achieve a proper balance of soft tissue (Table 2). However, there still exists a barrier towards its realization because of fear of the possibility of developing a pseudarthrosis. So far, only one case in study by Scior et al.¹⁸ has been reported, who required revision surgery due to displacement of the osteotomized fragment.

Some authors such as Brilhautl et al.,¹³ Hadjicostas et al.,⁵ Mullaji and Shetty¹¹ and Li et al.¹² have described the osteotomy of the lateral epicondyle with the use of screw fixation to promote the consolidation and prevent the displacement of the bone fragment. On the contrary, Conjeski et al.⁷ and Raut et al.,¹⁴ like us, choose not to use internal fixation. This decision is because during our clinical practice we have seen that the bone fragment displaces and

Table 1
Radiological and functional results from 18 patients with valgus deformity.

Case	Age (Years)	Sex	Tibiofemoral angle (°)		KSS		Oxford	
			Preoperative	Postoperative	Preoperative	Postoperative	Preoperative	Postoperative
1	83	F	25	10	72	87	10	45
2	79	F	15	8	70	93	8	43
3	72	F	15	4	58	92	11	34
4	66	F	20	5	75	80	8	45
5	67	F	19	10	72	84	10	47
6	79	M	30	8	74	90	13	35
7	70	F	15	10	79	88	18	39
8	81	M	12	8	55	97	6	35
9	68	F	10	8	46	90	11	30
10	78	F	28	6	46	89	9	40
11	64	F	35	5	48	87	8	42
12	68	F	35	7	50	90	8	45
13	70	M	32	7	45	91	10	45
14	78	F	40	6	46	90	8	48
15	65	F	35	7	43	92	12	47
16	69	M	28	5	62	95	12	47
17	68	F	27	6	54	92	10	48
18	68	M	43	8	42	96	8	48
Total	71.8 ± 6.1		25.8 ± 9.9	7.1 ± 1.8	57.6 ± 12.8	95.0 ± 8.5	10.0 ± 2.7	42.4 ± 5.6

KSS: Knee Society Score, Oxford: Oxford Knee Score, F: Female, M: Male, Mean ± standard deviation.

Table 2

Results reported in the literature on corrected knees with lateral epicondyle osteotomy.

Author (Year)	Fixed Knees	Follow-up	Valgus Deformity	Complications associated with osteotomy	Functional Results	
Brilhault et al. (2002)[12]	Y	13	56 Months (12–78)	>10°	None	KSS: Mean preoperative: 32 Mean postoperative: 88. Satisfactory alignment.
Hadjicostas et al. [5]	Y	15	28 Months (24–60)	Range: 17° to 27°	None	KSS: Mean preoperative: 37 (30–44) Mean postoperative: 90 (86–94). No reported scales. Satisfactory alignment.
Mullaji and Shetty. (2010) [10]	Y	10	20 Months (14–31)	Range: 10° to 36.5°	None	No reported scales. Satisfactory alignment.
Conjeski et al. (2018)[7]	N	12	34.7 Months (4–109)	Range: 12° to 26°	None	KSS (Functional Activity): Mean preoperative: 30 (12–47) Mean postoperative: 64 (18–80). Satisfactory alignment.
Scior et al. (2018)[16]	Y	98	4.5 years ±2.1	Range: 10° to 20°	1 case of displacement of osteotomy fragment	KSS: Mean preoperative: 35.9 ± 19.0. Mean postoperative: 84.9 ± 18.0.
Li et al. (2019)[11]	Y	25	3.3 years (1.5–7.9)	>20°	None	KSS: Mean preoperative: 36.5 ± 4.3. Mean postoperative: 89.1 ± 2.5.
Raut et al.(2020)[13]	N	25	5 years (1–15)	Range: 13° to 30°	None	Oxford Knee Score: Postoperative: 43.3 ± 2.7
This study	N	18	20 months (17 a 28)	Range: 10° to 43°	None	KSS: Mean preoperative: 57.6 ± 12.8 Mean postoperative: 95.0 ± 8.5. Satisfactory alignment.

Y: Yes, N: No; KSS: Knee society score; Mean ± standard deviation.

stabilizes by itself, allowing a proper balance.

Unlike other authors, we project a line from the supracondylar lateral cortex of the femur to the distal part of the epicondyle with two objectives: first to avoid invading the lateral cortical of the femur, and second, so that it serves as a consistent reference to perform an accurate cut that gives us a bone fragment that has enough width to minimize the risk of fracture. Additionally, when starting the cut of the fragment with the oscillating saw and finishing it with osteotome, we believe that there is a greater chance of ensuring that a single and smooth cut is obtained. From our experience, the osteotomy of lateral epicondyle without fixation is a simple technique that allows the correction of knees with valgus deformity, without modifying the postoperative evolution of patients and without requiring any immobilization.

4.1. Limitations

This study has limitations. First, the number of cases and follow-up time can be considered as limited to evaluate the results of a surgical technique. However, in the literature there are few reported cases performed without fixation of the epicondyle. Second, although the data described in the study was recorded from a prospective institutional registry, and the radiological images were reviewed by the authors, this study has the disadvantages of retrospective designs. Third, Merchant X-Ray view were not performed to assess the patellofemoral alignment in these patients because, by institutional protocol, this view is only requested in patients in which a misalignment is suspected during the physical examination and no patients with abnormal alignment were identified. Fourth, the patients in this study had advanced osteoarthritis and valgus deformity Ranawat II and III. However, the specific etiology of the valgus deformity could not be established because radiological follow-up was not available during the disease progression over time.

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5. Conclusion

In these patients, the osteotomy of the lateral epicondyle proved to be an effective surgical option for the correction of valgus deformity during TKA, allowing proper alignment of the limb with good functional results.

Declaration of competing interest

None.

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Research paper

Component asymmetry in bilateral total knee arthroplasty in the middle eastern population[☆]Raghavan Sivaram^a, Atul Bandi^b, Saseendar Shanmugasundaram^{a,*}, Ahmed Tarek Hafez^b, Ahsan Javed Butt^c, Hesham Al Khateeb^d^a Consultant, Apollo Hospital, Muscat, Sultanate of Oman, Oman^b Department of Orthopedics, King Hamad University Hospital, Bahrain^c Consultant and Head of Department of Trauma and Orthopedics, King Hamad University Hospital, Bahrain^d Consultant, Mediclinic City Hospital, Dubai, United Arab Emirates

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ABSTRACT

Purpose: Proper sizing of the femoral and tibial components is an important step in total knee replacement (TKA). When performing bilateral TKA, there is often an opinion that the same size prosthesis as the opposite side will suffice, even though there are reports of anatomical differences between sides. In this study, we quantify the incidence of asymmetry in femoral and tibial component sizes in staged bilateral TKA in a Middle East population.

Methods: This is a retrospective observational study of all patients who underwent uncomplicated bilateral TKA with the same type of prosthesis by two surgeons at the same institute, between January 2013 and January 2019.

Results: There were 123 patients, femoral and tibial component size variations were present in 42 patients (34.1%) and 30 patients (24.4%) respectively. The variation was evident in both posterior substituting (PS) and cruciate retaining (CR) designs. The femoral components had a higher variation in size between the sides for both PS and CR designs than the tibial components for both designs. The percentage variation in the size of the femoral component was similar for PS and CR subgroups (32.7% and 33.3% respectively). However, for the tibial component, the size variation was higher for PS design (24.5%) than for CR design (18.7%). 7.3% had a side-to-side variation by 2 or more sizes in both femoral and tibial components.

Conclusion: Variations in the size of the femoral and tibial components is common in patients undergoing bilateral TKA. Contralateral component size should not be used as the determinant of component sizes on the other side.

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Level of evidence: IV.

1. Introduction

TKA is one of the most commonly performed elective orthopedic procedures. One of the important factors in determining good outcome in TKA patients is proper sizing of both femur and tibial

components.¹ Using femoral components sizes larger than the desirable is known to cause increased in patellofemoral contact pressures, irrespective of standard or gender specific design types and also decrease the flexion gap as the jigs are modular and the cuts depend on whether an anterior or posterior referencing is being used.² Mahoney et al., in their study of femoral component sizes that were chosen using a joint space tensioning system, reported that a femoral component overhang of 3 mm or more from increased component size was associated with increased post-operative knee pain.³

Painful knee conditions such as osteoarthritis and rheumatoid arthritis requiring TKA are quite prevalent in Middle Eastern population and thus the incidence of bilateral TKA has been on the rise.^{4,5,6} To our knowledge, there are few reports^{7,8,9} about

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component asymmetry in bilateral TKA, and none for the Middle Eastern population. Hence, the present study was planned to quantify asymmetry in femoral and tibial component sizes in staged uncomplicated bilateral TKA in the Middle Eastern population. The assessment was done for both PS and CR subgroups. Comparison was also made with available data from literature.

2. Methods

The records of all patients who underwent staged, uncomplicated bilateral TKA by two different surgeons (AJB and HAK) at King Hamad University Hospital, Bahrain between January 2013 and January 2019 were collected. Data was collected retrospectively using the hospital information system (HOPE) and was cross-verified with the implant registry from the operating theatre. Depuy PFC Sigma (Warsaw, IN, USA) was the implant being used at the centre for both PS and CR designs.

Inclusion criteria included availability of implant data for both knees and both knees in each patient being operated by the same surgeon. For uniformity of comparison, patients with implant designs other than PFC sigma (Depuy) were excluded. Patients for whom each knee was operated by a different surgeon, were also excluded, in order to avoid variations in subjective preferences between surgeons. All knees were operated in a staged manner. Parameters studied included age, gender, body mass index (BMI), the type of implant and component sizes in the femur and the tibia. Percentages were used to assess the incidence of asymmetry in various categories of the patients. A convenient sample size, that included all available records of patients who had undergone bilateral knee replacement in the institute, was chosen.

Patients underwent standard blood work-up, radiographs and pre-operative work-up before the procedure. Additionally all patients underwent MRSA screening with nasal, axilla and groin swabs.

The surgery was performed under tourniquet control and spinal anaesthesia, through a standard medial parapatellar approach with eversion of patella. Both the surgeons performed femoral sizing using posterior referencing jigs fixed in 3° external rotation. In case of mid-liners, the larger size was opted for to prevent anterior femoral notching.^{10,11} For the tibial component sizing, extra-medullary jigs were used with standard anatomical landmarks of the shin of the tibia and in line with the second toe of the foot. Overhanging osteophytes were removed circumferentially from proximal tibial surface such as to avoid both anteroposterior and mediolateral overhang. External rotation was fixed relative to the tibial tuberosity position, by eyeballing. Patella resurfacing was not performed for any of the patients. The cementing technique included vacuum mixing (Optivac Mixing Accessories Biomet, Warsaw, IN, USA) with application of cement (Smartset GMV-Endurance, Depuy, Warsaw, IN, USA) by using finger packing on the tibial surface along with application of cement on tibial base plate and femoral components.¹² No drains were placed in any of the operated knees.

Post-operatively all patients received three doses of first generation cephalosporin, two weeks of subcutaneous Enoxaparin (Clexane, Sanofi-aventis, Gentilly, France) for deep venous thrombosis, prophylaxis. All patients were mobilized on the first post-operative day with a walking Zimmer frame support and underwent rehabilitation as per the enhanced recovery programme.^{13,14} Radiographs were done in the immediate postoperative period to assess the component position and knee alignment. Patients were discharged between third to fourth post-operative days.

3. Results

A total of 123 patients satisfied the inclusion and exclusion criteria. Of these, 34(27.6%) were males and 89(72.4%) were females. The age of the patients was between 50 and 92 years with a mean age of 66.6±7.6 years. The body mass index (BMI) ranged from 19.3 to 51.5 kg/m² with a mean BMI of 35.6±6.3 kg/m².

Of the total 246 knees in 123 patients, 122 were CR designs and 124 were PS designs. Of 123 patients, 97 had same type of implants (PS or CR) in both knees (group B), 49 being bilateral PS and 48 being bilateral CR designs, while the remaining 26 patients (group A) had CR on one side and PS on the other (Figs. 2 and 3).

In the bilateral PS knee subgroup of 49 patients, the femoral components were different in 16 patients (32.7%), while the tibial components were different in 12 patients (24.5%). In the bilateral CR knee subgroup of 48 patients, the femoral component sizes were different in 16 patients (33.3%) and the tibial component sizes were different in 9 patients (18.7%)(Fig. 4).

The femoral component varied in size between the sides in 42 out of 123 patients (34.1%), of which 9 patients (7.3% of 123 patients) had a size variation by 2 or more. Similarly, the tibial component varied in size between the sides in 30 out of 123 patients (24.4%), of which 9 patients (7.3% of 123 patients) had a variation by 2 or more sizes (Fig. 1).

Of the Group A patients, femoral component size variation was present in 10 out of 26 patients (38.5%), of which 1 (3.8%) had size variability by 2 or more, and tibial component size variation was present in 9 out of 26 patients (34.6%), of which 1(3.8%) had size variability by 2 or more. In 97 patients in Group B, femoral component size variation was present in 32 out of 97 patients (32.9%), of which 8 (8.2%) had size variation by 2 or more sizes, while tibial component size variation was present in 21 out of 97 patients (21.6%), of which 8 (8.2%) had size variation by 2 or more sizes.

4. Discussion

Cemented TKA is an effective operative procedure, with good or excellent outcome in patients with osteoarthritis of the knee joint.^{15,16} Primary TKA as per our department protocol is performed as a sequential unilateral procedure, staged with a minimum of three months interval between the two sides. This protocol has been formulated based on the study by Parvezi et al. which has shown decreased perioperative mortality in unilateral TKR as compared to simultaneous single staged bilateral TKR.¹⁷

Clinically and radiologically, it may appear that component sizing is likely to be the same for a patient undergoing bilateral TKA. However, it should not be presumed to be so. We found a difference in the sizing of components in both femur and tibia in both CR and PS knees of PFC sigma(Depuy). In comparison to the previous studies^{7,8,9} wherein lower variation in the component mismatch was reported, our study proved otherwise.

Anthropometric measurement has been studied intra-operatively duringTKA,^{18,19} however few studies have explored implant asymmetry in bilateral TKA^{7,8,9}, furthermore to our knowledge no study has been performed on the middle eastern population. Brown et al.⁷ reported asymmetry rates of 6.7% and 1.1% of femoral and tibial components respectively, while Capeci et al.⁸ reported variation of 8.7% and 6.7% for femur and tibial components respectively, both in American populations. Reddy et al.,⁹ in an assessment of an Indian population, reported component mismatch of 10.4% and 7.46% for the femur and tibia respectively in PFC Sigma knees. Whereas, our study showed a higher variation in

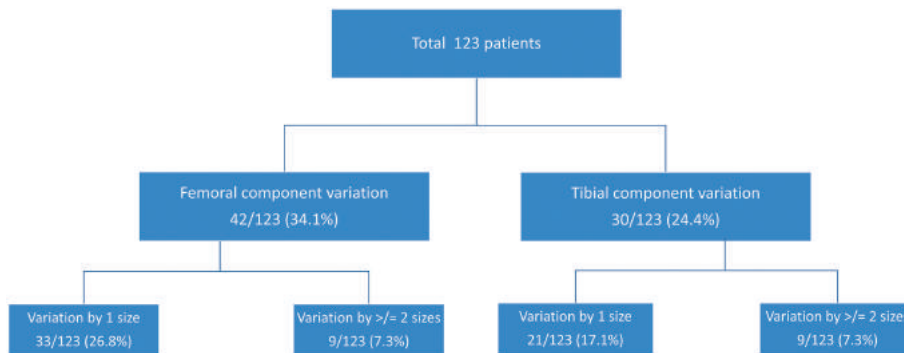


Fig. 1. Femoral and tibial component variations based on sizes.



Fig. 2. Anteroposterior radiographs of patient who underwent TKA with PS design on the left and CR design on the right.

the component sizes of femur and tibia. The femoral components had a higher variation in size between the sides for both PS and CR designs. While, the percentage of variation in PS and CR subgroups was almost similar for the femur (32.7% and 33.3%), there was difference in the incidence in the tibia (24.5% vs 18.7% respectively). This could be due to a combination of reasons – anthropometric differences, differences in the disease process and also differences arising from instrumentation and available implant sizes. Interestingly, 7.3% of all patients had a variation by 2 or more sizes in femoral and tibial components between the sides.

Meticulous sizing of individual components in TKA is of utmost importance, since use of inappropriate sizes can result in flexion-extension gap discrepancy. An oversized femoral component can produce decreased in flexion gap resulting in lower postoperative knee bending and increased patellofemoral joint forces, whereas an undersized component size can lead to a higher flexion space and hence instability. Similarly, an oversized tibial component can cause improper rotational alignment and can increase posterolateral corner impingement.

One weakness of this study is that sizing of components can be subjective and based on the individual surgeon's observation. Though, the institute follows standard guidelines established for sizing the components, any such subjective variation is reflective of the subjective variability in the general population. Also, this is a retrospective study and hence we did not attempt to assess the preoperative and postoperative functional knee scores. Similarly, the intraoperative morphometry of the femur and the tibia was not available as it is not general practice to measure the same.

5. Conclusion

This happens to be first study of this kind in the Middle Eastern population that throws light on component asymmetry in TKA. The results help to prime the surgeon not to rely solely on previously used component sizes and to independently size the femur and tibia. Going forward, a larger sample size needs to be studied to make a more concrete statement, and a correlation could be made with intraoperative morphometric measurement of the knee.



Fig. 3. Lateral radiographs of patient who underwent TKA with PS design on the left and CR design on the right.

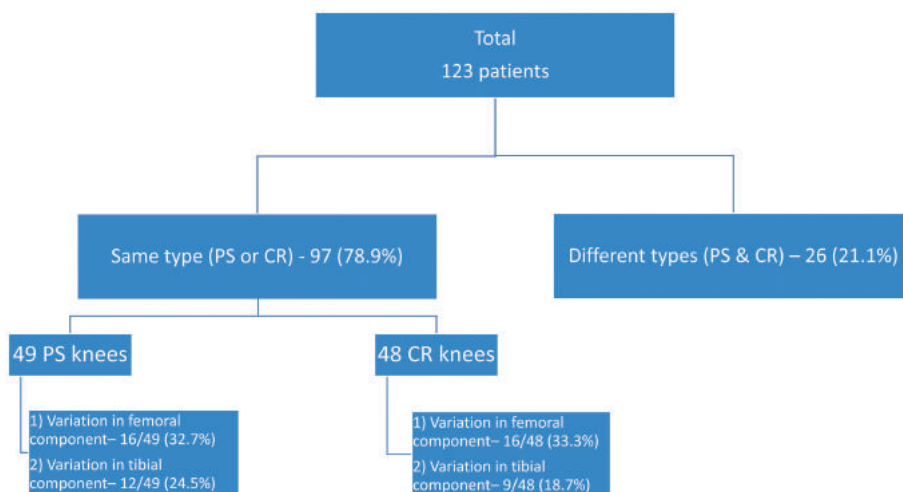


Fig. 4. Distribution of PS and CR design types and component variations under PS and CR design subgroups.

Declarations

Ethics approval and consent to participate

Ethics committee approval was obtained for the study; consent to participate was not needed as it was a retrospective study of surgical records and radiographs; no patient identifiable records were revealed during the study or in the manuscript.

Consent for publication

Consent for publication was not needed as no patient identifiable records have been revealed in the manuscript.

Availability of data and material

The datasets during and/or analysed during the current study

available from the corresponding author on reasonable request.

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Authors' contributions

Raghavan Sivaram. Conceptualization, Data curation, Formal analysis, Methodology, Supervision, Writing – original draft. Atul Bandi. Conceptualization, Data curation, Formal analysis, Methodology, Writing – original draft. Saseendar Shanmugasundaram. Critical review. Ahmed Tarek Hafez. Data curation, Formal analysis, Methodology. Ahsan Javed Butt. Supervision, Critical review. Hesham Al Khateeb: Conceptualization, Supervision, Critical review.

Declaration of competing interest

The authors declare that they have no competing interests.

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Research paper

Efficacy of combined use of intravenous and intra-articular versus intra-articular tranexemic acid in blood loss in primary total knee arthroplasty: A randomized controlled study

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Total knee arthroplasty

ABSTRACT

Purpose/objectives: This study was conducted to compare the efficacy of preoperative intravenous (IV) and intraoperative topical administration of tranexamic acid versus intraoperative topical administration of tranexamic acid along in reducing blood loss in primary total knee arthroplasty (TKA) subjects. The hypothesis of this study was the combined use of intravenous and Intra-articular injection of Tranexamic acid will be more efficacious than intra-articular administration alone in reducing blood loss in Primary Total Knee Arthroplasty.

Materials and method: A total of 31 subjects were selected and randomized into intervention and control group. The intervention group received both intravenous and intra articular tranexamic acid i.e. Trenexamic acid 1 gm IV injection 15 min before skin incision and Trenexamic acid 1 gm intra articular application intraoperatively after joint capsule closure. Subjects in the control group received only intra articular tranexamic acid i.e. Trenexamic acid 1 gm in 20 ml normal saline using intra articular application after joint capsule closure. Outcome measurements included postoperative surgical site drain output, drop in haemoglobin levels and transfusion rate. Ethics approval was taken from the Medical Research Unit, Armed Forces Medical College, Pune.

Results: The mean total blood (drain output) in the intervention group was 354.5 (± 208.22) ml vs. 397.65 (± 125.00) ml in the control group. T-test between the two groups on the volume drained post-operatively was not significant ($p = 0.482$). No subjects in the intervention group required post-operative blood transfusion but one subject from the control group required blood transfusion.

Conclusion: Combined use of intravenous and intraarticular injection tranexamic acid had lesser surgical site bleeding compared to only topical administration, however this was not statistically significant.

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1. Introduction

Total knee arthroplasty (TKA) is a commonly performed orthopaedic procedure which provides significant pain relief and improves the quality of life of the patients suffering from arthritic disorders of the knee.^{1,2} One of the common problems needing attention during arthroplasty is blood loss due to surgery, accounting for nearly 40% of transfusions in orthopaedic patients.³ Blood losses following TKA range from 800 to 1800 ml.⁴ To reduce blood loss and the need for blood transfusions in

orthopaedic surgery, the use of pharmacologic approaches have become more popular in recent years.^{5,6} The use of tranexamic acid has been reported to reduce blood loss in TKA patients by reversible blockade of lysine binding sites on plasminogen molecules to exert its antifibrinolytic action.^{7–9} The recommended dosage in total knee replacement surgery is 10–15 mg/kg intravenous over 30 min before inflation of tourniquet and second dose 3 h after first dose.¹⁰

Topical application of tranexamic acid to bleeding wound surfaces also helps in reducing the blood loss in patients undergoing some major surgeries and does not cause systemic complications.⁸ Combined intravenous and intra-articular usage of tranexamic appears to be more effective than single dose local application in reducing blood loss and transfusion rate without any complications as reported in other studies.^{11–13} However, whether combined

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topical and intravenous administration of tranexamic acid is better than intravenous administration alone is not known.

The study was conducted to compare the combined efficacy of intravenous and intra-articular injection of tranexamic acid versus intra articular administration alone in reducing blood loss among subjects undergoing TKA in a tertiary care centre in India. Our hypothesis was that synergistic effect of intravenous and intra-articular injection of tranexamic acid would be more efficacious than single topical administration in the reduction of surgery-related blood loss.

2. Materials and method

Study design.

This was randomized controlled clinical trial.

Study setting.

This study was conducted in a tertiary care centre in western India between June 2018 and September 2019.

2.1. Study population

Subjects undergoing unilateral primary total knee replacement at the tertiary care centre were invited to participate in this study. Those who provided written consent were recruited. Subjects were then screened for exclusion criteria: those subjects allergic to tranexamic acid, known history of thromboembolic diseases, cardiovascular diseases (myocardial infarction or angina), cerebrovascular disease (stroke), pre-operative significant renal dysfunction and pre-operative haemoglobin less than 10 g/dl.

2.2. Sample size

Sample size has been calculated based on following study¹⁴ that reported mean drain output of 110.9 ± 61.3 ml in intervention group and 56.8 ± 34.6 ml in control group. Sample size for hypothesis testing about difference between means (two tailed test).

μ_1 : 110.90 μ_2 : (Topical) mean 1
 μ_2 : 56.8 μ_2 : (Combined) mean 2
 SD1: 61.30 SD1= (Topical)
 SD2: 34.60 SD2= (Combined)
 N: 13 Sample size from each group

As per this study sample size is 13 in each group and total of 26.

2.3. Randomization

The subjects were randomly divided into two groups using a lottery system. Group A was designated "intervention arm" and Group B "control arm".

2.4. Allocation concealment

This was a single-blinded study with all subjects being blinded. The patient and the nursing staff during the process of obtaining consent for surgery were only told that tranexamic acid will be while the exact allocation was not revealed.

2.5. Intervention

Patients in Group A (intervention group) received both intravenous and intra-articular tranexamic acid: Tranexamic acid 1 gm of I.V. injection 15 min before giving skin incision and Tranexamic acid 1 gm intra articular application after the closure of the joint capsule. Patients under Group B (control group) received only intra-

articular tranexamic acid: Tranexamic acid 1 gm intra-articular after joint capsule closure.

2.6. Outcome assessment

Following the surgery, both groups had suction drains in situ. The drains were kept clamped opened by the surgeon after 2 h after the completion. The drain was kept for 24 h after surgery and output noted. The patients who required blood transfusion was noted.

All the surgeries were performed under tourniquet and intra-operative loss of blood was considered negligible.⁴ The post-operative haemoglobin levels were checked on the first, third, fifth and fourteen day post operatively.

2.7. Surgical steps

All the patients were operated under spinal anaesthesia and each patient was given prophylactic antibiotics (Cefotaxime and Amikacin) 15 min before skin incision. Patients in the intervention group received intravenous tranexamic acid 15 min prior to inflation of tourniquet. Pneumatic tourniquet was used throughout the duration of the surgery in all patients. All the patients underwent surgery using standard medial parapatellar approach.

2.8. Post-operative care

Apart from the routine post-operative care, transfusion of blood was given to patients whose haemoglobin levels were <8.0 g/dl or to patients with haemoglobin level <9.0 g/dl with the symptoms of anaemia like increase in heart rates (tachycardia), light headedness, shortness of breath. Thromboprophylaxis with Enoxaparin 40 mg SC OD was prescribed for all patient after 12 h post-surgery. No subjects from both the group had complication like deep vein thrombosis.

2.9. Data collection, data entry and analysis

The data collected in the paper-based form were entered into Microsoft Excel 2014. Data were cleaned and imported to STATA. All analyses were performed in STATA 13.1/MP (StataCorp. 2016. Stata Statistical Software: College Station, TX: StataCorp LP USA). Continuous variables are presented as mean (\pm standard deviation) or median (interquartile range) wherever applicable. Categorical variables are presented as frequencies and percentages. The data were found to be within normal distribution. The mean amount of drain output between intervention and control was tested using paired *t*-test. Categorical variables were compared with chi-squared test. P values < 0.05 were considered significant.

2.10. Ethics considerations

Ethics approval was obtained from the Medical Research Unit, the institutional review board at the Armed Forces Medical College, Pune via letter no: JEC/OCT/2017, dated November 12, 2017. This study was registered with the Clinical Trials Registry of India via registry number CTRI/2018/05/014106, dated May 25, 2018. This study was conducted after taking informed written consent from the participants as per the consent from approved by the ethics board.

3. Results

Of a total of 37 patients who were screened, five were excluded reason being one patient pre-op Hb level was 9.3 mg/dl, two

patients had renal dysfunctions and other two had history of CVA in the past. Out of final 31 patients included in this study, 11 males and 3 females were in the intervention group and 9 males and 8 females were in the control group. The outcomes of 31 subjects were analysed as the outcome of one patient could not be assessed because the surgical site drain was blocked. The consort diagram showing the screening and randomization of subjects for this study is given in Fig. 1.

The mean age was 66.4 (± 5.27) years in the intervention group and 66.28 (± 5.67) years in the control group. T-test of mean age between the two groups was not significant ($p = 0.949$). The main indication for TKA was osteoarthritis. Both in intervention and control group had one patient each who underwent TKA due to rheumatoid arthritis. All the subjects in both the groups underwent unilateral primary TKA performed by two senior surgeons in single institution. The baseline characteristics and underwent the same surgery as shown in Table 1.

Two types of surgeries, posterior stabilized and cruciate retaining were performed to all patients by two surgeons in single institution with both surgeons having experience of more than 10 years. In the intervention group, 8 underwent cruciate retaining surgeries while 6 underwent posterior stabilized surgeries. In the control group, 9 underwent cruciate retaining and 8 underwent posterior stabilized surgeries. The details are shown in Table 1.

4. Study outcome

In the post-operative period, the mean drain output in the interventional arm was 354.5 (± 208.22) ml and was 397.65 (± 125.00) ml in the control arm as shown in Fig. 2. T-test between the two groups on the volume drained post-operatively was however not significant ($p = 0.482$).

In serial measurements of post-operative Hb level monitoring only one patient required transfusion (transfused 2 units of PRBC)

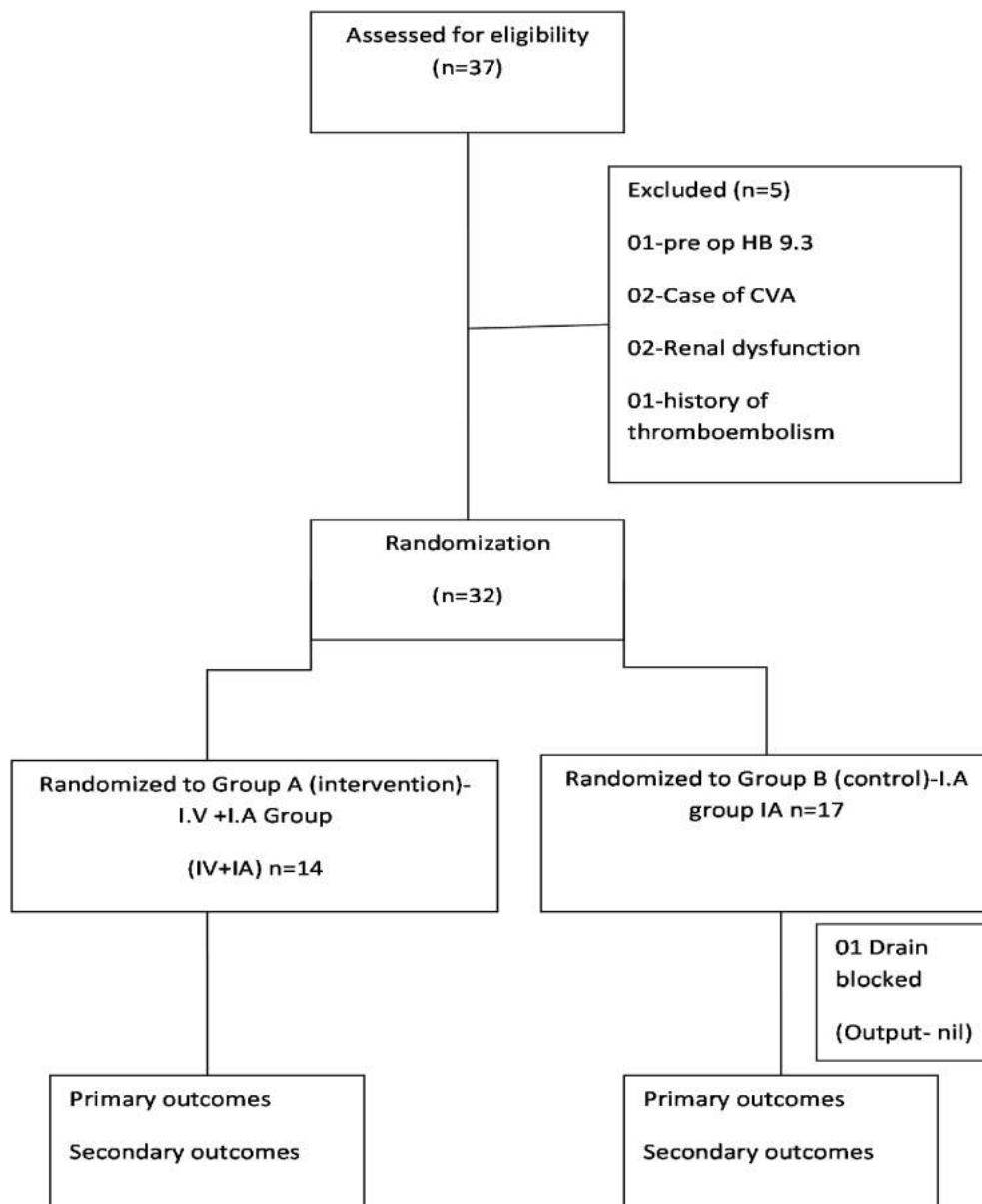


Fig. 1. CONSORT diagram of patients who were randomized for intervention (intravenous + intra-articular tranexamic acid) vs control (intravenous tranexamic acid) while undergoing total knee replacement surgery at a tertiary care centre in Western India, 2018–2019.

Table 1
Basic characteristics of the patients who underwent unilateral total knee arthroplasty are given in table below.

	I-V + IA Group		IA Group	
	n	(%)	N	(%)
Total	14	(45.16)	17	(54.84)
Age (mean ± SD) years	66.28	(±5.67)	66.4	±5.27
Sex				
Male	11	78.57	9	(52.94)
Female	3	21.43	8	(47.06)
Indication				
Osteoarthritis	14	(45.16)	17	(54.84)
Rheumatoid arthritis	1	7.14	1	5.88
Knee joint				
Right knee TKA	8	57.14	9	52.94
Left knee TKA	6	42.86	8	47.06
Type of implant				
Dual pivot (DJO)	7	50.00	9	52.94
Smith & Nephew	7	50.00	8	47.06
Type of surgery				
Cruciate retaining	8	57.14	9	52.94
Posterior stabilized	6	42.86	8	47.06
Drain output (mean ± SD) ml	354.5	±208.22	397.65	±125.00
Haemoglobin postoperative day 1				
<8.0 mg/dl	0	(0.00)	0	(0.00)
≥8.0 mg/dl	14	100.00	17	100.00
Haemoglobin postoperative day 3				
<8.0 mg/dl	0	(0.00)		
≥8.0 mg/dl	14	100.00		
Haemoglobin postoperative day 5				
<8.0 mg/dl	0	(0.00)	1	5.88
≥8.0 mg/dl	14	100.00	16	94.12
Haemoglobin postoperative day 14				
<8.0 mg/dl	0	(0.00)	0	(0.00)
≥8.0 mg/dl	14	100.00	17	100.00

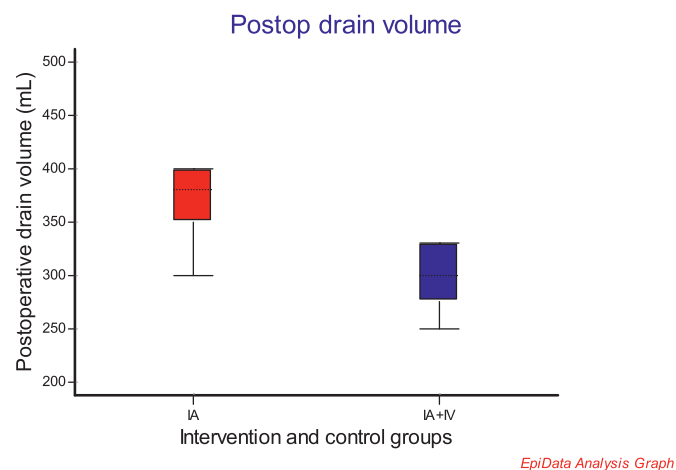


Fig. 2. Total drain output (ml).

in control group on 5th post op period (Hb on 5th day was 7.8 mg/dl). One patient from control group developed complication of superficial wound dehiscence on 15th post op day, managed with debridement and antibiotics; swab culture from infected site showed sterile. The details of the postoperative outcomes are shown in Table 1.

5. Discussion

The findings show that the post-operative blood loss was similar among groups receiving both intravenous and intraarticular tranexamic acid and those receiving only intraarticular tranexamic

acid during TKA surgeries. The mean drain output was lesser in the intervention group. The requirement of post-operative blood transfusion was zero among the intervention group while one subject in the control group required blood transfusion. Though our findings did not detect difference in post-operative blood loss, it could have been because of the small sample size.

Sung-Yen Lin et al.¹⁴ however reported significant differences in the postoperative Hb level, Hb drop, total drain amount and total blood loss. The study showed mean postoperative Hb levels on both postoperative day 1 and day 3 were significantly higher in the combined group than in the topical group (P value = 0.017 and 0.016, respectively) or the control group (P value b 0.001 for both). The Hb drop was also significantly less in the combined group compared to the topical and control groups on the first and third days after operation. Likewise, total drain amount was significantly lower in the combined group compared to the other 2 groups (P value b 0.001 for both). The mean values of total blood loss in the topical and combined, and control groups were 705.1 ± 213.9, 578.7 ± 246.9, and 948.8 ± 278.5 ml, respectively, with a significant inter group difference (P value b 0.001).

In another study by Chen et al., in 2016¹⁵ among 100 patients undergoing primary TKA, compared between, combined IV and IA administration of TXA has a synergic effect, leading to higher postoperative Hb levels without influencing drug safety in TKA patients.

In a randomized control trial¹⁶ has not seen any significant difference between the IV TXA and IA TXA groups concerning blood loss, and concluded IA TXA is equally safe and effective as its IV infusion concerning decreased blood loss and adverse effects. Intraoperative Intravenous and Intra-Articular Plus Postoperative Intravenous Tranexamic Acid in Total Knee Arthroplasty,¹⁷ double blinded study was concluded to study if repeated dose of post operative IV TXA has additive effect of controlling blood loss, and found no additive effect with respect to blood loss when a repeated postoperative dose of intravenous TXA administration was combined with intraoperative intravenous and intra-articular TXA administration.

There are two limitations in our study. First, the case numbers are not powered to detect the differences in total blood loss and transfusion rate between the 2 studies groups as the volume of TKA performed in our centre was relatively less, hence warrant larger sample size study is needed to reach a more citable and extendable conclusion for larger populations. Second, there were two different surgical techniques CR/PS used which might affect the amount of blood loss.

6. Conclusion

Combined administration of intravenous and intraarticular tranexamic during total knee arthroplasty showed a reduction in post-operative drain volume as compared to only intraarticular tranexamic acid though not statistically significant.

Author contribution

All authors have contributed equally in conception and design of this study, acquisition of data, data entry and analysis, initial drafting of manuscript, critical revision and final approval of the manuscript for publication.

Credit author statement

All authors were involved in conception, designing of study. Dr Yeshe Dorji collected and analysed the data and wrote the manuscript. All authors were involved in critical review of this

manuscript. All authors have approved this manuscript for publication.

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Declaration of competing interest

This article is the author's original work and is not under consideration for publication elsewhere. There were no conflicts of interests declared by the authors.

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Attune total knee arthroplasty: is there evidence of early tibial component de-bonding? A prospective cohort study with a minimum two year follow-up



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ABSTRACT

New TKA are designed to optimize patient outcomes and improve implant longevity such as the Attune TKA. Concerns have been raised regarding a potentially high rate of early de-bonding at the implant–cement interface of the tibial component. Our study aimed to prospectively assess the clinical outcomes and radiographs of a consecutive series of patients undergoing either Attune TKA or another modern TKA for OA to establish failure rates and compare radiological abnormalities.

96 Attune TKA performed by three surgeons at our local center were matched to 96 control TKA (PFC/Vanguard) performed between 2015 and 2017. Day one, one year and two year post surgery radiographs were analyzed by two independent, blinded assessors. Clinical outcome was assessed using the Oxford Knee Score and survival of the implant recorded. Patients were contacted two years from surgery, 93 Attune and 92 control TKAs attended for clinical and radiological assessment by the same independent assessors.

No TKA in either group were revised. No significant radiolucencies (≥ 2 mm) at the cement–bone or implant–cement interfaces were encountered in either group. The incidence of radiolucencies (< 2 mm) across both interfaces was similar between both groups and did not affect clinical outcome. There was no significant difference between the incidence, progression and extent of radiolucencies at two years follow-up in either of the groups as compared with one year. No clinically relevant adverse radiographic features were found in this prospective cohort study comparing a consecutive series of Attune TKA with a matched group of established, modern TKA designs.

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1. Introduction

Total Knee Arthroplasty (TKA) is a financially and clinically effective treatment for managing symptomatic end-stage knee arthritis. TKA demand is expected to increase significantly over the coming years with an estimated increase of up to 637% between

2005 and 2030 in the USA.^{1,2} This is due to a combination of factors including an ageing population, changing patient expectations and increasing population BMI.^{1,3} TKA's popularity is due to its association with improvement in mobility and better quality of life,⁴ although the improvement is not uniform and many patients report residual symptoms. A study of 10,000 patients included in the England and Wales National Joint Registry (NJR), found that a significant proportion had on-going issues: 57% had problems with kneeling, 20% had persistent pain and 17% had pain on walking.⁵ Less than 10% of patients reported no knee problems following TKA. Nearly 20% of patients were not satisfied with the outcome of their surgery and similar findings in other studies have driven the

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push for further development of TKA systems.^{6,7}

The Attune TKA system was developed by DePuy, (DePuy Synthes, Raynham, Massachusetts, United States) with changes to the tibial base, femoral radius, polyethylene formulation, and patella-femoral articulation. The developments were aimed to improve the performance of the knee in deep flexion, optimize patella tracking and enhance implant longevity. There have been positive reports in the literature reflecting improved performance of Attune TKA system. Carey and Harty found that more Attune knees achieved the minimum clinically important difference in Patient Related Outcome Measure (PROM) score compared with control implants in the contralateral knee of the same patient.⁸ Webb et al. described a reduced incidence of lateral release in Attune TKA as compared with the Press-Fit Condylar (PFC) and Sigma knees,⁹ and Whittaker et al. showed that learning curve had no effect on PROM whilst using the Attune system.¹⁰ However, concerns have been raised of high rates of early tibial loosening. Bonutti et al. published a case series of 15 knees revised in three community hospitals due to early aseptic loosening of the tibial component at the implant-cement interface.¹¹ Most presented with anterior knee pain, with pain on weight bearing, a knee effusion and decreased range of motion. The average time to revision was 19 months (range, 1–34 months) and in each case at the time of revision surgery a loose tibial implant devoid of cement was found. The authors suggested that adaptations in the Attune TKA system resulted in inferior outcomes, a cause for concern for implanting surgeons. Although the authors did not provide an actual incidence of tibial loosening, such early failures are worrying and this has caused apprehensions amongst arthroplasty surgeons across the world. The work of Deen et al. who have reported an incidence of proximal tibial resorption of 35% as soon as 6.9 months following implantation of the Attune TKA,¹² added to concerns about the long term implant survival. As have Cerquiglini et al. who found no evidence of any cement attachment on any of the 11 tibial trays they retrieved,¹³ yet the majority of retrieved PFC trays were also found to be devoid of cement attachment in their study. Some centers have stopped using the Attune system whilst others have embarked on a prospective audit of their patient cohort to establish clinical outcomes, with an RCT comparing the Attune TKA to Sigma PFC TKA run through the Leiden University, Netherlands, predicted to take until mid 2023 for results to be available.¹⁴

Incidence of early component loosening needing revision is typically low and therefore surrogate measures such as change in patient symptoms and/or changes in radiographic appearance are used to establish the incidence. To understand if a particular implant is associated with higher incidence of residual clinical symptoms and/or have abnormal radiographic findings, it is important to compare the data of the implant under scrutiny with a well-established implant. Clinical and radiological outcomes depend upon many factors including patient demographics, surgical technique, implant used and post-operative regime. It is important to minimize the bias by ensuring that patient demographics, surgical technique and post-operative regime are similar between the two groups.

The aim of this cohort study is to compare the occurrence of aseptic loosening as determined by revision rates, clinical outcomes and radiological evidence in a consecutive series of Attune TKA matched with a cohort of patients who underwent TKA using established TKA systems implanted by the same surgeon.

2. Material and methods

To investigate the incidence of early tibial aseptic loosening and the overall clinical performance of the Attune TKA at our local center, a prospective, cohort study was designed with formal

approval from our local clinical governance department.

200 primary cemented TKAs were performed between 2015 and 2017 by three consultant arthroplasty surgeons. A consecutive series of 100 primary Attune TKA were paired with 100 primary non-Attune TKAs [Sigma PFC (DePuy Synthes, Raynham, Massachusetts, USA) or Vanguard, (Zimmer Biomet, Warsaw, Indiana, USA)] each performed by the same surgeon, at our local center. It should be made clear to avoid confusion that the Attune TKA in our study were all original Attune baseplates and not the Attune S+ baseplates, a later development. Pre-operative diagnosis, extent of deformity, BMI, ASA status, patient's age and gender were recorded, as was the type of implant, extent of constraint (CR vs PS), size of each component, component alignment and whether the patella was resurfaced or not.

All cases underwent same pre-operative work up, pre-operative counseling and templating, surgical steps, post-operative regime including the same DVT prophylaxis, standardized physiotherapy and similar analgesia. All surgeries were performed under tourniquet with a midline incision and medial parapatellar arthrotomy. Measured resection technique was used to achieve a balanced knee which could be fully extended and flexed to at least 120° without any component lift off. Bony surfaces were prepared as per standard surgical technique and irrigated with 0.9% saline using a pulstatile high-pressure lavage system (JetLavage, Endocon, Heidelberg, Germany) for at least 1 min (flow rate 1200 ml/min). After irrigation, preparation of bone cement was initialized according to the manufacturer's specifications. All TKAs were fully cemented using 80 g of high-viscosity bone cement. The bone cement was prepared using a vacuum mixing system (Palamix, Heraeus Medical, Wehrheim, Germany). The bone surface was dried, and the mixed bone cement applied to the tibial bone surface, tibial keel canal and on the implant surface. Implantation of tibial and femoral components was performed in a single step from a single mix. The leg was then held in full extension with axial compression until the cement was set. There were no differences in cementing technique between the two groups. Tourniquet was released prior to closure to ensure adequate haemostasis and the wound closed in layers. All patients received the same standard postoperative care. They were encouraged to mobilize as tolerated on the day of surgery. On day one post-surgery, anterior-posterior (AP) and lateral standing radiographs of the operative knee were obtained. Patients typically stayed in the hospital until the wound was dry, there were no peri-operative complications, pain was well controlled, and patients were considered safe for discharge. A standard post-discharge protocol was used. All patients were contacted on day 30 of surgery to establish whether they had needed any readmission, or any hospital visit, and reasons recorded. All patients were seen in a consultant-led outpatient clinic at 12 weeks, one year and two years post-surgery when patient reported Oxford Knee Score (OKS)¹⁵ and an up to date weight bearing AP and lateral standing radiographs of the operated knee were obtained. OKS was used from 0 to 48 with 0 being the worst outcome and 48 the best.¹⁶

The one day, one-year and two-year post-operative radiographs were analyzed according to the 'Knee Society Reporting Protocol'¹⁷ to identify radiolucency either at implant-cement or cement-bone interface and standardize their reported location (diagram 1). In addition, any adverse features such as fracture, component malposition, retained loose body (cement or bone) were recorded. The radiographs were reviewed by two independent orthopedic surgeons who were blinded to the clinical outcome. The assessment was recorded on a standardized form and in case of a discrepancy, the radiographs were reviewed by the senior author (who was not involved in any of the surgeries) and consensus reached. In addition, 35% of the radiographs were re-examined independently by each reviewer and data compared to establish

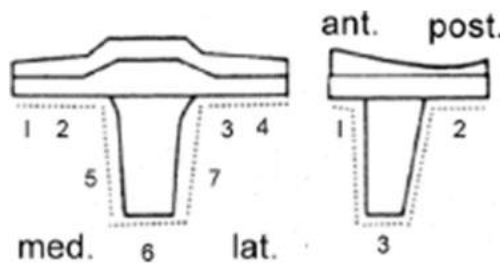


Diagram 1. The Knee Society total knee arthroplasty roentgenographic evaluation and scoring system.

inter and intra-observer reliability. Thickness of the tibial baseplate was used as reference to establish magnification and thereby quantify the thickness of radiolucencies.

Aseptic loosening necessitating revision was recorded as our primary end point. Incidence of significant radiolucency on either the post-operative or one-year post-operative radiographs was compared between the two groups as a secondary end point. A radiolucency (either at implant-cement or at cement-bone interface) was considered significant if it was 2 mm or more in depth or progressive. Non-significant radiolucencies (less than 2 mm) were also recorded for analysis. The location of radiolucencies was documented according to the Knee society reporting protocol in AP zones 1–7 and lateral zones 1–3.¹⁷ Two-year post-operative radiographs were used to monitor for progression of radiolucencies.

Statistical analysis was performed on RStudio (RStudio, Inc., Boston, Massachusetts, USA). Pre-operative data, patient demographics, surgical parameters were compared to identify any differences in the baseline data. Wilcoxon rank-sum test were used for all non-parametric data analysis and the significance for all analyses was set at $p < 0.05$, with 95% confidence intervals (CIs) as appropriate.

3. Results

Of the 100 Attune TKA, 96 cases were available with complete data for analysis including one-year radiograph and OKS. These cases were matched to 96 control TKA (Sigma PFC $n = 41$, Vanguard $n = 55$). From this cohort, 93 Attune TKAs and 92 control TKAs (Sigma PFC $n = 40$, Vanguard $n = 52$) were available for clinical and radiological follow-up at two years.

All pre-operative characteristics, except gender, were well

matched across the two arms with regard to age, gender, ASA, number of patella re-surfacings and pre-operative deformity (Table 1). Inter-observer reliability was 96% whilst intra-observer reproducibility was 97%.

3.1. Clinical outcomes

No patient died or needed readmission during the follow-up period. None of the patients underwent further surgery in either of the groups. No patient was lost to follow up at one year, although 4 patients in the Attune arm did not complete OKS at their review, their radiographs did not exhibit any concerning features but as their data remained incomplete they were not included in the analysis. None of the patients in either groups had noticed significant knee effusion or suffered from increasing knee pain and/or loss of knee flexion at the time of their annual review. At two years, 3 further patients in the Attune arm and 4 patients on the control arm were not available for full follow-up, but had not died, been re-admitted or undergone further surgery on their operative knees.

Median OKS at one-year post-surgery was 36 (IQR 25.75–43) in the Attune arm and 36.5 (IQR 26–44) in the control arm. This difference was not statistically significant, $p = 0.61$. The distribution in different subgroups¹⁸ based on OKS was also not statistically significant, (Table 2A). Median OKS at two-year post-surgery was 37 (IQR 26–44) in the Attune arm and 37.5 (IQR 27–44.5) in the control arm. This difference was not statistically significant, $p = 0.62$. The distribution in different subgroups¹⁸ based on OKS was also not statistically significant, (Table 2B).

Table 1
Characteristics across the study arms.

	Attune	Control	SMD	Significance
Age (median [IQR])	70.6 [61.56–77.47]	68.11 [62.83–77.53]	0.036	$p = 0.88$
Gender n (%)				
Male	51(53.1)	34 (35.4)		
Female	45 (46.9)	62 (64.6)		
Laterality n (%)			0.021	$p = 0.36$
Left	59 (61.5)	42 (43.8)		
Right	37 (38.5)	54 (56.2)		
Patella resurfacing n (%)			0.19	$p = 0.22$
Yes	37 (38.5)	28 (29.2)		
No	59 (61.5)	68 (70.8)		
Varus (number of cases)	89	83		
Mean	7.2	6.5		
Standard deviation	5.2	5.0		
Varus (deg) (median [IQR])	10.00 [0.00, 10.00]	10.00 [0.00, 10.00]	0.14	$p = 0.52$
Valgus (number of cases)	7	13		
Mean	0.6	2.0		
Standard deviation	2.3	5.7		
Valgus (deg) (median [IQR])	0.00 [0.00, 0.00]	0.00 [0.00, 0.00]	0.32	$p = 0.12$

3.2. Radiographic evaluation and clinical correlation

None of the cases in either group exhibited implant loosening. There were no cases of significant radiolucency either at the implant-cement or cement-bone interfaces in either groups on the post-operative radiographs. There were no cases of significant radiolucency either at implant-cement or cement-bone interfaces in either groups on one-year and two-year radiographs. There was no significant difference between the two groups when component alignment was compared (Table 3). None of the radiolucencies at implant-cement or cement-bone interfaces in either groups seen on the one-year radiographs progressed on the two-year radiographs.

3.3. Radiolucencies at the cement-bone interface

The overall incidence of TKAs with radiolucencies <2 mm observed at the cement-bone interface between the two groups not significantly different (34 in the Attune arm and 28 in the control arm; $p = 0.51$). 44 radiolucencies (all <2 mm) were observed at the cement-bone interface in 34 knees in the Attune group, the median OKS at one-year follow up for this cohort was 36.5 (IQR 27.25–42.5). The presence of radiolucencies at the cement-bone interface in the Attune TKA did not affect performance when compared to Attune TKAs without radiolucency at the cement-bone interface. The median OKS at one-year follow up for this cohort (no radiolucency at cement-bone interface at one-year) was 34.5 (IQR 23.5–43.0). The difference between the two groups was not statistically significant ($p = 0.69$). 35 radiolucencies (all < 2 mm) were observed in 28 knees at the cement-bone interface in the control group. The median OKS at one-year follow up for this cohort was 38.5 (IQR 26.0–46.0). The presence of radiolucencies at the cement-bone interface in the control group did not affect performance when compared to control TKAs without radiolucency at the cement-bone interface. The median OKS at one-year follow up for this cohort (no radiolucency at cement-bone interface at one-year) was 35.5 (IQR 26.0–43.25). The difference between the two groups was not statistically significant ($p = 0.37$). Graph 1 displays the position of the cement-bone

lucencies across both groups. Similar results were observed at the two-year follow-up. Fig. 1 and 2

3.4. Radiolucency at the implant-cement interface

The frequency of TKAs with radiolucencies <2 mm observed at the implant-cement interface between the two groups was not statistically significant with 26 in the Attune arm, 20 in the control arm; ($p = 0.42$).

Radiolucencies were present on the post-operative radiograph at the implant-cement interface in both the groups, yet none were significant (>2 mm) and none of these progressed. 28 radiolucencies (all <2 mm) were observed at the implant-cement interface in 26 knees in the Attune group, the median OKS at one-year follow up for this cohort was 31.5 (IQR 21.0–40.0). The presence of radiolucencies at the implant-cement interface in the Attune TKA did not affect performance when compared to Attune TKAs without radiolucency at the implant-cement interface. The median OKS at one-year follow up for this cohort (no radiolucency at implant-cement interface at one-year) was 37 (IQR 26.25–43.75). The difference between the two groups was not statistically significant ($p = 0.11$). 29 radiolucencies (all < 2 mm) were observed in 20 knees at the implant-cement interface in the control group. The median OKS at one-year follow up for this cohort was 36.5 (IQR 26.0–40.25). The presence of radiolucencies at the implant-cement interface in the control group did not affect performance when compared to TKAs without radiolucency at the implant-cement interface. The median OKS at one-year follow up for this cohort (no radiolucency at implant-cement interface at one-year) was 36.5 (IQR 26.0–44.0). The difference between the two groups was not statistically significant ($p = 0.52$). Details of the location of lucencies seen at the implant-cement interfaces are shown in graph 2. Similar results were observed at the two-year follow-up. Fig. 3 – 6

Of note, lateral zone 3 in the Attune TKA had notably more lucencies than the control arm. 57% ($n = 16$) of radiolucencies seen at the implant-cement interface in the Attune group were seen in lateral zone three, anterior to the keel; their median OKS was 32.5, (IQR 26.75–40). There was no statistically significant difference in OKS between those Attune TKAs where there was lucency anterior to the keel at the implant-cement interface and those where it was absent, median 36.0, (IQR 25–43.25) ($p = 0.51$).

Table 2a
Stratification of Oxford Knee Score (OKS) at one year.

	Attune	Control	Significance
Poor (OKS <27)	27	28	$p = 0.50$
Fair (OKS 27–33)	20	13	$p = 0.78$
Excellent (OKS ≥34)	49	55	$p = 0.81$

Table 2b
Stratification of Oxford Knee Score (OKS) at two years.

	Attune	Control	Significance
Poor (OKS <27)	26	27	$p = 0.52$
Fair (OKS 27–33)	20	12	$p = 0.80$
Excellent (OKS ≥34)	47	53	$p = 0.82$

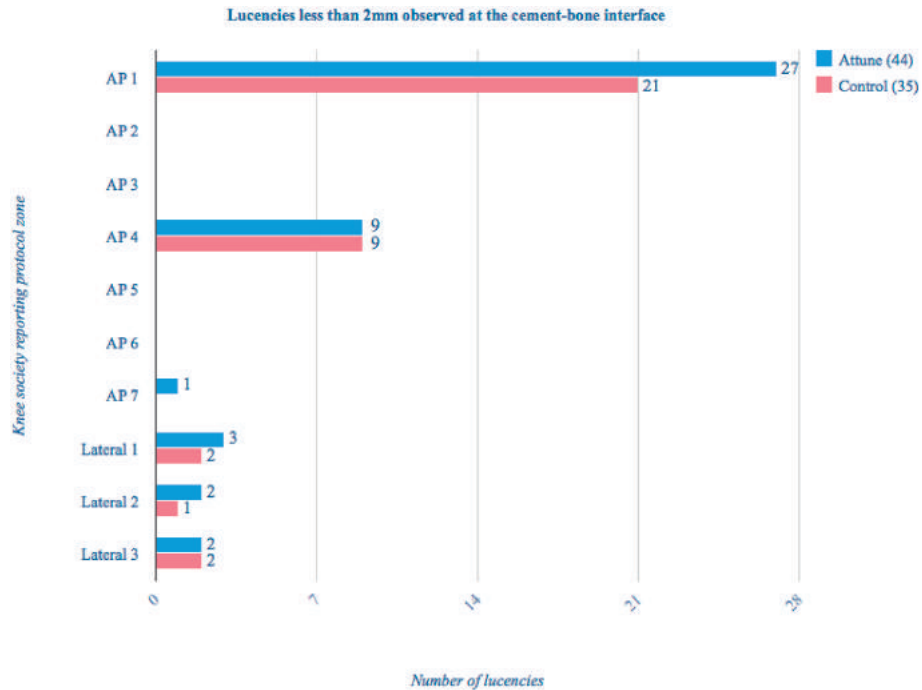
Table 3
Comparison of component alignment.

	Attune	Control
Femoral flexion degrees Median (IQR)	1 (0–2.5)	1 (0–2)
Femoral valgus degrees Median (IQR)	5 (5–5)	5 (5–6)
Tibial slope degrees Median (IQR)	6 (5–7)	5 (4–6)
Tibial valgus degrees Median (QIR)	0 (0–0)	0 (0–0)
Tibial varus degrees Median (IQR)	0 (0–1)	0 (0–1)

4. Discussion

This cohort study confirms that patients with Attune TKA have similar outcomes at two-year follow up as compared to Sigma PFC or Vanguard TKA. No difference was found in the incidence of radiolucency occurrence at either cement-bone or implant-cement interface between the two cohorts and patient reported outcome measures were similar between the two groups. Reassuringly, no evidence of increased aseptic loosening was found in this study either clinically, radiographically or as an indication for revision in the Attune cohort as compared with established TKA systems. Non-significant radiolucencies (<2 mm) occurred with similar frequency in both the cohorts and these had no effect on clinical outcomes.

Developments in TKA systems focus on improving patient satisfaction, implant survival and surgical efficiency. Some developments in TKA system designs have previously been reported to lead to increased incidence of tibial component aseptic loosening. Foran et al. studied 529 TKAs using the Nexgen Tibial Component developed for minimally invasive surgery in 460 patients implanted by a single surgeon over the course of 18 months.¹⁹ Eight patients initially experienced a pain-free postoperative period, then developed pain on weight-bearing with a clinical



Graph 1. Lucencies less than 2 mm observed at the cement-bone interface.

effusion and radiographical findings indicative of loosening. Other authors have noted aseptic loosening in tibial component developed for minimally invasive surgery, the majority at the implant-cement interface,^{20,21} while further reports disagree and find no increased rates of loosening.²²

Tibial loosening generally presents with symptoms and/or with radiological evidence of implant loosening.¹¹ Symptoms of loosening are identified at clinical review, and clinical deterioration objectively quantified by use of Patient Reported Outcome Measures (PROMs). OKS is a popular and validated PROM and is routinely used by NJR of England and Wales. OKS generally reaches a postoperative peak followed by a plateau at one year. Although a

gradual decline following this has been observed in the literature, no statistically significant difference is usually seen within the first five years.²³ We therefore used OKS at one-year as a benchmark to assess clinical outcome. In addition, we followed the patients up at two years to ensure there was no deterioration in PROMS, as well as no new adverse features identified on the radiological review.

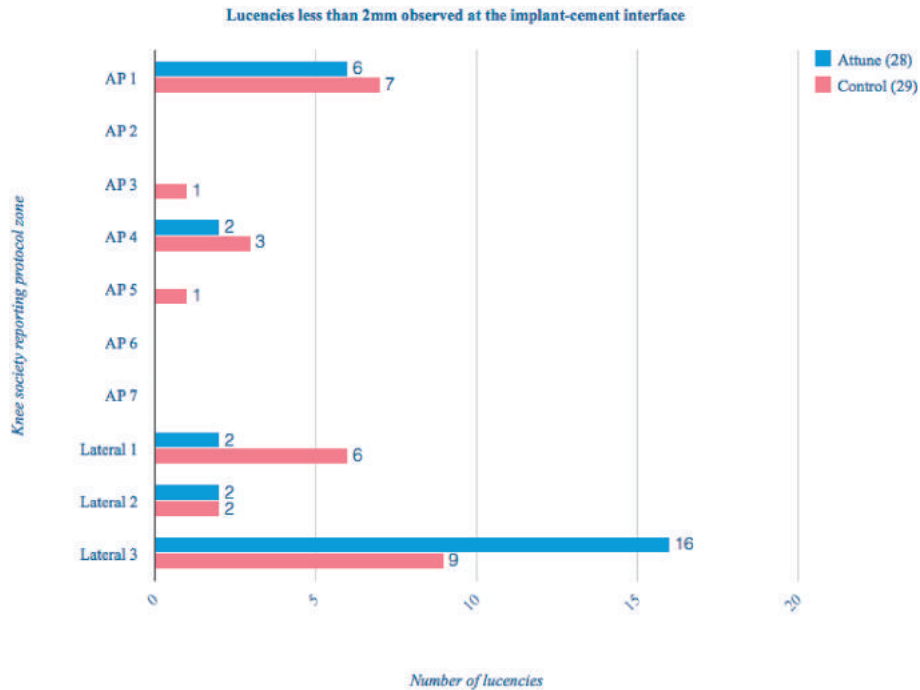
Implants can loosen at either the implant-cement or cement-bone interface. Presence of a radiolucency at either of these interfaces can be suggestive of loosening provided it meets certain criteria. Goodfellow et al. suggested that the pathological



Fig. 1. Attune radiograph showing lucency at the cement-bone interface in AP zone 1.



Fig. 2. Control (Vanguard) radiograph showing lucency at the cement-bone interface in AP zone 1.



Graph 2. Lucencies less than 2 mm observed at the implant-cement interface.

radiolucencies i.e. those which are abnormal and typically associated with infection or aseptic loosening are progressive, poorly defined and over 2 mm thick, while physiological radiolucencies (i.e. a normal finding) develop within the first post-operative year, become stable thereafter and are no more than 2 mm.^{24,25} The latter are thought to indicate suboptimal fixation and represent a layer of fibrocartilage which develops at the cement-bone interface.²⁶ These physiological radiolucencies have been shown to have no correlation with clinical outcome, are typically seen with cemented rather than cementless implants and are at the cement-bone interface.²⁷

Radiographical appearances, particularly the implant-cement and cement-bone interfaces can be influenced by cementing technique. There is a lack of consensus in the literature and orthopedic community with respect to the accepted method of cementing. Cement viscosity, application time and application method have all been shown to influence cement penetration and degree of radiolucency, and all may vary between surgeons.^{28–30} To achieve clinically relevant conclusions, it is necessary to compare clinical and radiological data with another TKA system which has a proven track record with long-term clinical data confirming its safety and efficacy and has been implanted by the same surgeon. We therefore conducted this study comparing radiographs of Attune TKA with well-established TKA systems implanted by the same group of arthroplasty surgeons in patients with similar characteristics and all joint replacements performed with a standardized surgical technique.

Bonutti et al. suggested a concerning possibility of increased rates of aseptic loosening in Attune TKA systems in their case series but there are significant limitations to their study.¹¹ All revision cases reported were following primary TKAs referred from other institutions and the authors were therefore unable to provide a rate of aseptic loosening. In addition, the retrospective nature of the study prevented the authors from being able to account for confounding factors such as patient demographics, individual surgeon technique, post-operative care and institutional differences, or

compare with control cases. Our study has tried to overcome this limitation by comparing two cohorts with identical surgical techniques as well as standardized post-operative care. We have not seen a single case of aseptic loosening in this study in either of the cohorts and none of the patients have undergone revision surgery or are awaiting revision. A recent independent report based on UK National Joint Registry data found no difference in overall revision rate in Attune TKA systems as compared with all other TKAs, or in revision rate specifically for aseptic tibial loosening.^{31,28}

In a study similar to ours, Staats et al. investigated 276 Attune TKA systems and found a significantly increased frequency of radiolucencies as compared with PFC controls (35.1% of Attune TKA vs 7.5% of PFC TKA).³² The authors also noted that the majority of the radiolucencies occurred at the implant-cement interface in the Attune group. Their study did not record patient-reported clinical outcomes, although survival analysis found no difference in revision-free survival or revision rate at the time of last follow-up. The authors found the largest proportion of radiolucencies at the cement-implant interface anterior to the keel (in zone 3 on lateral radiograph) at 12 months. They advised close monitoring and clinical correlation in these patients. Contrary to their observations, we did not find a significant difference in incidence of radiolucencies at cement-bone or implant-cement interface in the Attune group as compared with controls at two-year follow-up. In addition, we also assessed patient-reported clinical outcomes at one and two years; this was similar in both groups. It is not possible to explain the differences between our results and those reported by Staats, with reference to the incidence of radiolucency. The two studies are quite similar in the study design as well as methodology. Our sample size is smaller, but we have looked at PROM and it does confirm that these radiolucencies have no impact on the clinical outcome, at least in the short term.

Our findings and possibly more importantly data from the UK registry provide some assurance that early tibial loosening does not seem to be an issue with the Attune TKA system as suggested by the study by Bonutti et al. Aseptic tibial loosening is a rare event and



Fig. 3. Attune radiograph showing lucency at the implant-cement interface in AP zone 1.

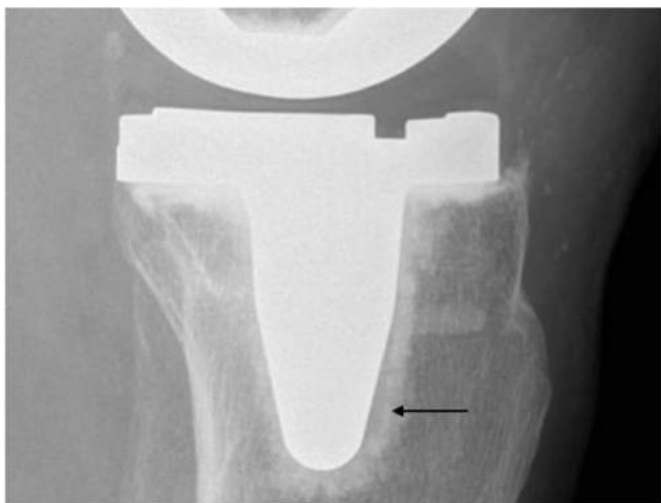


Fig. 4. Attune radiograph showing lucency at the implant-cement interface in lateral zone 3.

can occur at any time frame post-arthroplasty. New tibial implants tend to have shorter keels, increased conformity and are possibly less forgiving than conventional TKA systems. Since the start of our study DePuy have launched an alternative option; the Attune S+ tibial tray. This offers increased surface roughness, 45° undercut pockets to enhance mechanical fixation and the ability to use a rotating platform. None of the TKA in our study used the Attune S+ tibial base plate. Attention to detail in cementing as well as surgical technique is likely to be more critical with the newer designs than with the conventional systems. Restoration of native tibial slope, meticulous preparation of the bony surfaces prior to cementing, adequate application of bone cement on both the cancellous bone as well as the under surface of the implant are some of the key steps in achieving a stable bond between implant-cement and cement-bone interface. A standardized cementing technique needs to be



Fig. 5. Control (PFC) radiograph showing lucency at the implant-cement interface in AP zone 1.



Fig. 6. Control (PFC) radiograph showing lucency at the implant-cement interface in lateral zone 3.

followed to ensure stable fixations. In spite of following all the key steps in cementing, our cohorts did show occurrence of radiolucency at both implant-cement as well as cement-bone interfaces. The former is likely to be associated with the surgical technique whilst the latter are physiological with no clinical relevance. The importance of the presence of a small (<2 mm) radiolucencies at the implant-cement interface, which does not progress, is not known but is likely to be of little consequence.

There are some limitations to this study. Pre-operative OKS were not available. The relative change in PROM score therefore cannot be compared between Attune and control arms. The study cannot determine rate of aseptic loosening with certainty as no cases were revised for aseptic loosening. We used clinical and radiological outcomes as surrogate measures of loosening in this study.

However, clinical outcomes quantified by PROM scores are subjective, and aseptic loosening is not always evident radiologically.¹¹ Similarly, aseptic loosening may occur before symptoms become apparent.²⁹ These surrogate measures may therefore be relatively crude. For more rigorous assessment of the incidence of aseptic loosening in Attune knee systems, a longer follow-up period with greater sample size is required.

5. Conclusion

In conclusion our prospective cohort study of 100 consecutive Attune TKA has demonstrated a reassuring incidence of early tibial component loosening and de-bonding with no cases seen at 2 years; performing in line with established modern TKA designs. We hope our study will be of interests to implanting surgeons worldwide who had concerns regarding the potential high early failure rate suggested previously in the literature.

Credit statement

Tom Robinson: Methodology, investigation, data curation, formal analysis, writing of all drafts of the manuscript. **Samuel King:** Formal analysis and writing of all drafts of the manuscript. **Richard Pilling:** Investigation and data curation. **Johnathon Lamb:** Formal analysis. **Hemant Pandit:** Conceptualization and supervision. All other co-authors have contributed equally to the editing and production of the final manuscript.

Declaration of competing interest

HP receives funding from Zimmer Biomet, Depuy Synthes, Medcata International, Meril Life and Kennedy's Law for work separate to this study. JL has received an educational grant from AO & DePu Synthes for an unrelated PhD project. All other authors declare that they have no conflict of interest regarding the publication of this manuscript.

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Research paper

Custom-made 3D printed patient specific guides (PSG) improves component axial alignment in total knee arthroplasty (TKA)

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WOMAC

ABSTRACT

Background: Usage of Patient Specific Instrumentation (PSI) or Patient Specific Guides (PSG) in TKA has evolved rapidly in the past decade. Restoration of Mechanical axis in TKA is vital to achieve good functional outcome and long term implant survival. We carried out a comparative study to assess the efficacy of PSG in achieving neutral axial alignment and its impact on early functional outcomes compared to Conventional Instrumentation (CI).

Methods: Patients eligible as per study design ($n = 100$) undergoing TKA were randomized and divided in two equal groups which were matched in baseline demographics and clinical profile. All the patients in the PSG group ($n = 50$) and conventional instrumentation (CI) group ($n = 50$) underwent TKA with same implant. Pre-operative CT scans done as per specified protocol to acquire image data for 3D printing PSG. Duration of surgery and post-operative Hip-Knee-Ankle (HKA) angles achieved in the two groups was compared. Post-operative functional outcomes were assessed using WOMAC scores.

Results: There was statistically significant difference in the mean post-operative axial alignment achieved between the two groups ($p = 0.041$). Outliers (180 ± 3 deg) of HKA angle were more in the CI Group ($p = 0.007$). There was no difference in functional outcomes between the two groups at one year. Duration of surgery was significantly less in PSG Group ($p < 0.001$).

Conclusion: 3D printed PSG are superior in achieving neutral HKA axis as compared to CI in TKA. Better axial alignment of TKA components does not correlate with better patient reported functional outcomes. PSG use significantly reduces surgical time.

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1. Introduction

Incidence of TKA surgery has increased exponentially over the last two decades, improved function, high survivorship and enhanced ability of patients in performing the Activities of Daily Living has led to a significant rise in the number of younger patients undergoing TKA.^{1,2} Sharkey PF, Hozack WJ et al. highlighted polyethylene wear, infection, instability and mal-alignment as the leading causes of failure of TKA³; clearly there is a need for high performance implants, to improve surgical technique, and use high precision tools to achieve alignment in TKA surgery.

Restoration of a neutral mechanical axis is a key determinant for survivorship and success of primary total knee arthroplasty.^{4,5} The

mechanical axis of the lower limb, by definition, is a line drawn from the center of the femoral head to the center of the ankle joint, and passes through the center of the knee just medial to the tibial spine in the coronal plane (HKA Angle). Failure to achieve a post-operative alignment within an acceptable range of $180^\circ \pm 3^\circ$ of the mechanical axis has been associated with early failure of TKA^{3,4}; due to higher risk of loosening and early polyethylene wear due to eccentric loading,^{6–8} instability and osteolysis.^{9,10}

Conventional Instrumentation (CI) in TKA utilizes an intramedullary guide for distal femoral resection and an extramedullary or intramedullary guide for the tibial bone to achieve alignment. The intramedullary femoral guide requires a snug fit of the rod in the femoral canal which may not be obtained due to differences in canal diameters or femoral deformity. The distal femoral cut also depends on the position of the entry point in the femur made by the surgeon and can significantly change the distal femoral cut thereby affecting the femoral component axial

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alignment and the HKA axis. Most conventional instrumentation systems also do not factor the femoral bow which can significantly alter the femoral component placement in the sagittal plane. Achieving a proximal tibial cut perpendicular to tibial axis using extra medullary tibial cut alignment guides are fraught with a high error rate due to variations in patient native tibial anatomy, surgical skill learning curve and observer error. Cumulative impact of variations in the patient's femoral and tibial anatomy, errors in surgical technique and judgment can lead to mal-alignment of components in the sagittal, coronal and rotational planes.

Computer-Assisted surgery (CAS) in TKA surgery is a high precision dynamic tool to achieve lower-limb alignment and positioning of the components while maintaining soft tissue balance in the entire range of motion of the replaced knee; overall reducing the outliers in axial alignment beyond acceptable limits compared to CI¹¹; high initial cost of set up, recurring cost of consumables, steep learning curve, increased surgical time and procedure-specific complications restrict the usage of CAS in developing countries.^{12,13}

Patient-specific instrumentation (PSI) in TKA surgery is uniquely poised to fill this lacuna between CAS and conventional instrumentation (CI) surgery in TKA. PSI has significant potential to address some of the vital issues in TKA such as component alignment, implant sizing and implant positioning and at the same time not burden the patients or health system with very high costs.¹⁴ PSI uses CT/MRI based three-dimensional (3D) imaging to capture the native anatomy of an individual's knee and enables the creation of a virtual 3-dimensional model of the distal femur and proximal tibia. Various reports in the literature report advantages of PSI, to reduce surgery time,^{15,16} reduce blood loss¹⁷ reduce intramedullary instrumentation thereby reducing chances of fat embolism, and also having high accuracy in predicting component size thereby reducing instruments and implants inventory in the operating room.¹⁶

A prospective observational study was undertaken at our center with the primary aim to study the accuracy of 3 D printed patient specific guides (PSG) in achieving postoperative coronal plane axial alignment in TKA compared to conventional instrumentation (CI). The study also evaluated the correlation between postoperative HKA axis achieved and its impact on functional outcomes. Secondary aim of the study was to evaluate the impact of PSG usage on the duration of surgery.

2. Methods

A prospective interventional comparative study was carried out to compare outcomes in patients undergoing TKA with PSG and CI at a large orthopedic referral center of a tertiary care hospital between October 2017 and June 2019. The subjects were veteran or serving military personnel and their dependents presenting with end stage knee arthritis. The study was conducted after obtaining necessary approval from the hospital Ethics Committee. **Inclusion Criteria:** Correctable varus/valgus deformity less than 20°, Body mass index (BMI) less than 35 kg/m² (as per the existing hospital protocol), ASA Grade (*American Society of Anesthesiologists*) III or less, quadriceps strength 5/5, bi-compartmental disease; **Exclusion Criteria:** patients who had previous distal femoral or proximal tibial osteotomies, severe bone defects in the proximal tibial condyles, previous knee surgery, post-traumatic arthritis, extra-articular deformity, flexion less than 90°, flexion deformity more than 30°, peripheral neuropathy, valgus knee, ligamentous laxity, retained metal hardware at the hip, knee or ankle.

100 patients of end stage arthritis presenting to the outpatient department with considerable pain and functional disability were enrolled for the study. Baseline demographic data of the patients

like age, gender, body mass index (BMI), comorbid medical and surgical history, preoperative deformity in sagittal and coronal plane, ligament laxity, ROM, quadriceps power and functional assessment using the WOMAC scoring system were matched. The patients were explained in detail about the study and a written informed consent with an option to quit obtained from the patients. Patients were selected randomly for both groups.

All patients in PSG group underwent CT scan of their lower limbs as per a specified protocol (Fig. 1). The CT scan data was loaded on a compact disc and sent to the 3D image processing platform where the data was processed to produce a virtual 3 D model of the patients knee and the HKA axis of the arthritic knee (Fig. 2), the distal femoral cut and the proximal tibial cut were planned and customized to the patient specific anatomy to achieve a neutral HKA axis of 180 deg (Fig. 3). Pin fixation slots were built in the design as per the pre-set template of the planned TKA implant Scorpio NRG, USA. The patient specific distal femoral cutting and proximal tibial cutting guides were 3D printed using medical grade PLA (Polyactic-Acid). The Guides were delivered on an average turnover time of 07–10 days from the day data was received by the 3D printing platform. Guides with serial number specific to the patient when delivered were sterilized with ETO (Ethylene Oxide) to avoid any deformation of the 3D printed guides. All the surgeries were performed by a single surgeon. Both groups were followed up post operatively at 06 weeks, 3 months, and 06 months 01 year.

All patients included in the study underwent TKA surgery by standard medial para-patellar approach and measured resection technique by a single surgeon and were implanted with a single radius posterior stabilized (PS) implant Scorpio NRG (*Stryker Co., Kalamazoo, USA*). In PSG group the patient specific guides were used to execute the distal femoral and the tibial cut only (Fig. 4); in the CI group standard instrumentation technique was utilized to make the distal femoral cut using intramedullary alignment rod and extra medullary alignment jig for the proximal tibial cut.

Tourniquet was inflated without exsanguination prior to incision and deflated after skin closure. Surgery duration using the PSG and CI was recorded from the time of incision to skin closure. All the patients included in the study were treated with the same post-operative protocol in terms of DVT prophylaxis (LMWH 5000 i.u. subcutaneous once a day started 6 h after surgery up to day 05 post-operative followed by tab aspirin 325 mg twice a day up to 14th post-operative day), sequential compression device usage for 05 days postoperative and early mobilization from bed and full weight bearing ambulation from the following day. Post-operative analgesia (PCM 650 mg infusion IV BD, tab etoricoxib 90 mg OD and Inj tramadol 100 mg BD) up to 48 h post-operative followed by tab PCM 1 gm 6hrly, tab tramadol 100 mg 8hrly, tab etoricoxib 90 mg, tab pregablin 75 mg orally up to day 05 post surgery; at discharge the patients continued with oral medication up to 03 weeks (by tab PCM 1 gm 8hrly, tab tramadol 50 mg 12hrly, tab etoricoxib 90 mg once a day, tab pregablin 75 OD orally. Preoperative antibiotics (Inj Cefperazone 2 gm IV + Inj gentamycin 80 mg IV) stat dose given 60 min prior to inflation of the tourniquet, post-operative antibiotics two doses (Inj Cefperazone 2 gm. IV) at 12 hrly interval; wound check and de-bulking of the compression dressings was done at 5th post-operative day. Patients were discharged when they were ambulant with support of a walker, on oral pain relief medication and when at least 90° flexion was achieved; all patients were provided standard discharge counseling as per protocol of the center.

All patients included in the study were assessed for functional outcomes and radiographic evaluation done in the outpatient clinic at scheduled post-operative follow up visits at 06 weeks, 06 months and 01 year from the date of surgery. Staples were removed on the scheduled visit at 03 weeks in the clinic.

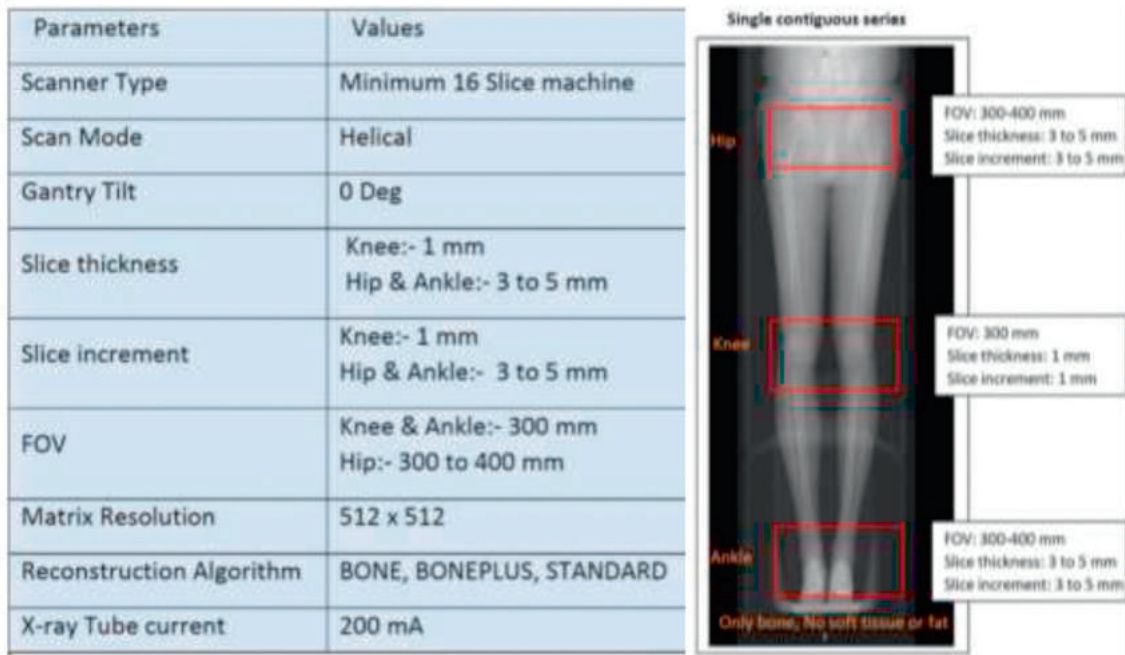


Fig. 1. CT Scan Protocol for scan configuration.

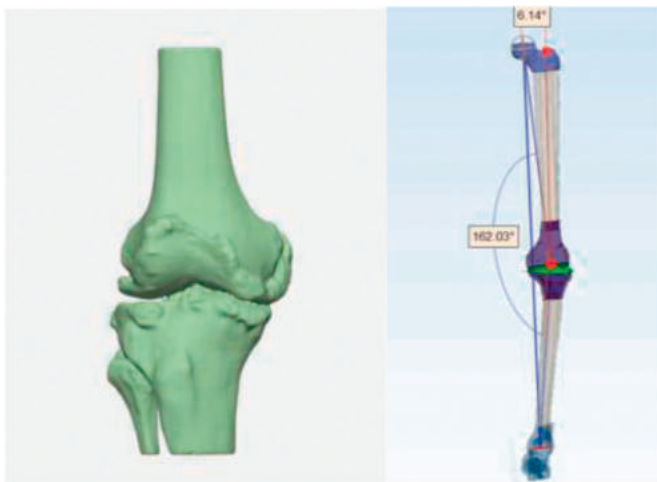


Fig. 2. Generated 3D image of the patient's knee and alignment for planning distal femoral and proximal tibial cuts.

Radiographs obtained at the follow up visits in clinic at 06 weeks, 06 months and 01 year as per the “Knee Society Total Knee Arthroplasty Roentgenographic Evaluation and Scoring System” and were evaluated using the Knee Society protocol for radiolucency at the bone–cement interfaces around the tibial and femoral components, any change in the position of the components, femoral–tibial alignment in the coronal plane, and osteolysis. Any collateral ligament laxity, subluxation of tibia, presence of osteophytes, any bone defects in the tibia and femur, and the quality of bone were also assessed. Mechanical alignment was noted using standing long-leg antero–posterior radiographs in the pre op period and at 6 weeks post op 06 months and 01 year (Fig. 5). There was no patient lost to follow up in the study.

2.1. Statistical analysis

The data collected was subjected to statistical analysis using SPSS (Statistical Package for Social Sciences) Version 15.0 statistical Analysis Software. For categorical data chi-square test was used, for continuous data independent samples and paired t-test was used and for ordinal/scalar data Mann-Whitney U test and Wilcoxon signed rank test was used. The values were represented in Number (%) and Mean ± SD. The level of significance “P” value thus assessed determined the significance of observation [p = 0.05(Not significant); p < 0.05(significant); p < 0.01(Highly significant); p < 0.001(Very highly significant)].

3. Results

Mean age of the patients in the study was 63.42 yrs (47–80 yrs) and comparable in groups, 64.08 ± 7.36 yrs in PSG Group and 62.76 ± 7.14 yrs in CI Group (p = 0.365); 39 patients in PSG group (76%) and 43 in CI group (82%) were aged between 51 and 70 yrs. There were 11 (22%) in PSG Group and 7 (14%) in CI Group in the age group of 71–80 years. In PSG group 1 (2%) and 2 (4%) patients in CI Group was aged ≤50 yrs (Table 1). Gender profile in the study was stratified, there were more females (n = 54) in the study compared to males (n = 46). In PSG Group females were higher (n = 28; 56%) as compared to the CI Group (n = 26; 52%) the variation in gender variation in the study was statistically not significant (p = 0.688). Mean BMI of the patients in the study was 26.73 kg/m²(23.08–31.69 kg/m²). Mean BMI in both groups was comparable 26.69 ± 2.15 kg/m² in PSG Group and 26.78 ± 1.63 kg/m² in CI Group and statistically not significant (p = 0.799). 74% of patients were in the BMI range of 25.0–29.9 kg/m². 03 patients in the PSG group were of BMI >30 kg/m². There was 01(2%) patient in PSG Group and 3 (6%) patients in CI Group who underwent TKA surgery for end stage arthritis secondary to rheumatoid arthritis, all the

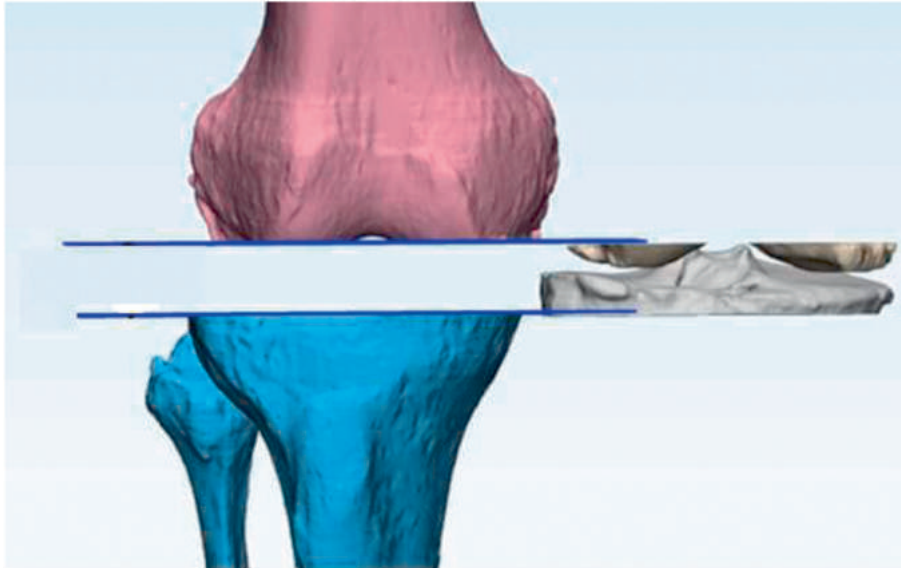


Fig. 3. Distal femoral and proximal tibial cuts planned on software to restore a neutral HKA axis.



Fig. 4. 3D printed PSG being used in TKA for distal distal femoral and tibial cuts.

others were diagnosed cases of osteoarthritis. Statistically, there was no significant difference between two groups with respect to diagnosis ($p = 0.307$). In the study 55 patients were operated in left knee and 45 patients on right knee. 31(62%) in PSG group and 24(48%) in CI group were left side and 19(38%) in PSG group and 26(52%) in CI group were right sided.

Mean duration of surgery in PSG Group was 60.26 ± 4.30 min (52–71 min) and 88.94 ± 2.47 min (84–96 min) in CI Group: the difference between two groups was statistically highly significant ($p < 0.001$) (Fig. 6).

3.1. Mechanical parameter

Mean pre-operative HKA in both PSG Group (162.04 ± 4.02 deg) and CI Group (163.23 ± 4.27 deg) was comparable ($p = 0.154$). At follow up in both the groups there was a significant change in the mean HKA however the change was more prominent in PSG group 16.33 ± 3.32 deg (10.1%) compared to CI Group 13.41 ± 3.11 deg (8.3%). Post-operatively mean HKA in PSG group was (178.36 ± 3.52 deg) and (176.64 ± 4.74 deg) in CI Group, statistically the difference was significant ($p = 0.041$), post-operative mechanical alignment achieved in PSG group was closer to neutral alignment compared to the CI group (Table 2).

3.2. Outliers

Outliers in the assessment of post-operative HKA axis in TKA are defined as $180 \pm 3^\circ$ (177–183 deg), TKA component alignment beyond the range of acceptable limit are known to adversely affect outcomes, and implant longevity. In PSG Group number of patients with restoration of HKA to 177–183 deg range was 84% whereas in CI Group this proportion was only 58%. In PSG Group there were 8 (16%) patients with HKA angle lesser than the lower acceptable limit (177 deg) whereas in CI Group, there were 16(32%). In CI Group, there were 5 (10%) patients with HKA more than the high acceptable limit (183deg) and no patient in PSG group. Thus, the proportion of outliers was significantly higher in CI Group as compared to that in PSG Group which was statistically highly significant ($p = 0.007$) (Table 3).

3.3. Functional parameters

In PSG Group the mean baseline WOMAC score were comparable was 60.96 ± 6.27 in PSG group and 60.12 ± 5.85 in CI Group ($p > 0.05$). There was a comparable linear decline in WOMAC scores in both groups assessed at 06 weeks PSG group (34.36 ± 4.43) and CI group (34.82 ± 3.98); 06 months PSG group (18.46 ± 3.84) and CI group (17.82 ± 3.50); and 01 year PSG group (14.08) and CI group

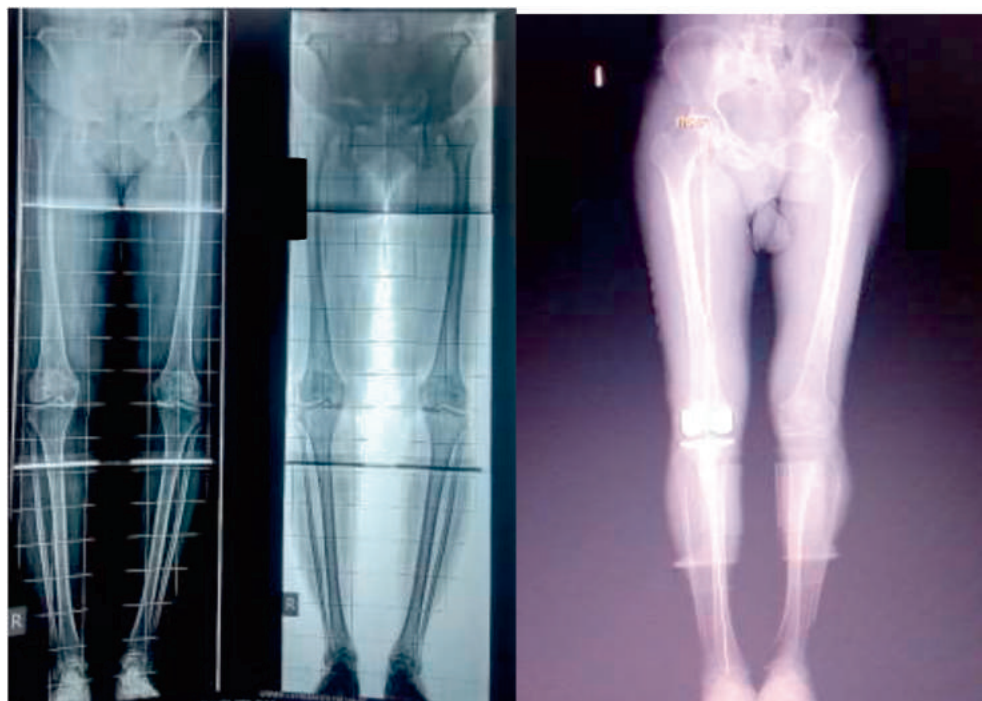


Fig. 5. Depicts long lower limb radiographs and measurement of mechanical axis Pre Operative and Post operative.

Table 1
Comparison of age profile of patients in two groups.

SN	Age Group	PSG Group		CI Group	
		No.	Percent	No.	Percent
1.	≤50 Years	1	2%	2	4%
2.	51–60 Years	19	38%	20	40%
3.	61–70 Years	19	38%	21	42%
4.	71–80 Years	11	22%	7	14%
Mean Age±SD (Range) in years		64.08 ± 7.36 (49–79)		62.76 ± 7.14 (47–80)	

't' = 0.910; p = 0.365.

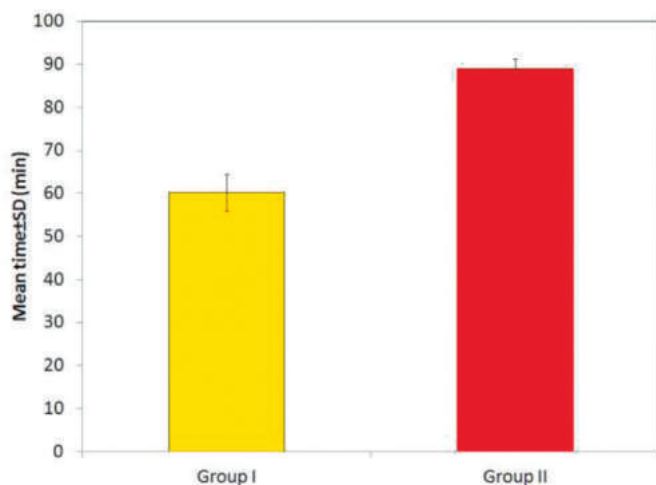


Fig. 6. Comparison of mean duration of surgery between two groups.

(15.60) Statistically there was no significant difference between two groups at any of the time intervals ($p > 0.05$) (Fig. 7). Mean

Table 2
Comparison of Pre- and Post-operative HKA Angle between two groups.

SN	Time	PSG Group (n = 50)		CI Group (n = 50)		Statistical significance	
		Mean	SD	Mean	SD	't'	'p'
1.	Pre-surgery	162.04	4.02	163.23	4.27	1.436	0.154
2.	Post-surgery	178.36	3.52	176.64	4.74	2.068	0.041
Change in HKA		16.33	3.32	13.41	3.11		
't' (Paired 't'-test)		34.81		30.47			
'p'		<0.001		<0.001			

Table 3
Comparison of Post-Operative HKA angle (outliers) between two groups.

SN	HKA Range	PSG Group (n = 50)		CI Group (n = 50)	
		No.	Percent	No.	Percent
1.	≤177°	8	16%	16	32%
2.	177–183°	42	84%	29	58%
3.	>183°	0	0	5	10.0

$\chi^2 = 10.047$ (df = 2); $p = 0.007$.

percent improvement in the WOMAC scores from pre-operative baseline to 06 weeks was 43.68% in PSG group and 42.08% in CI group; in the post-operative 06 weeks to 06 months period the change in scores was 46.27% in PSG group and 48.82% in CI group (Table 4).

3.4. Complications

02 patients in PSG Group and 03 patients in CI group had delayed wound healing. Two patients in each group had superficial infections which responded to oral antibiotic therapy for 05 days and one dressing change. None of the cases required revision surgery another patient developed bullous pemphigoid reaction around the operated knee scar and was managed conservatively by

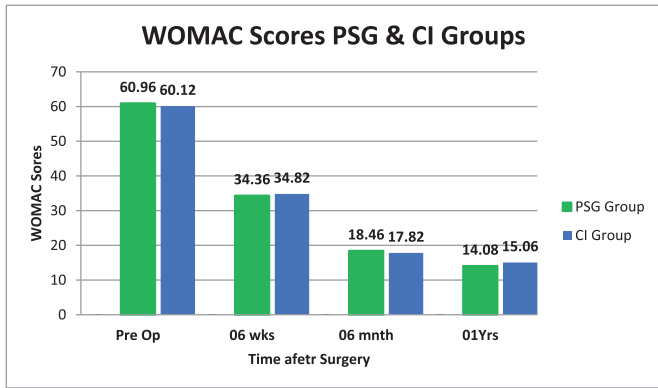


Fig. 7. Comparison of WOMAC scores between two groups at different time intervals.

Table 4
Evaluation of within Group change in WOMAC scores by 06 months.

SN	Time	Mean change	SD of change	Percent change in Mean score(%)	Statistical significance (Wilcoxon signed rank test)	
					'z'	'p'
PSG Group						
1.	Baseline to 6 weeks	-26.60	5.64	43.68%	6.159	<0.001
2.	6 weeks to 6 months	-15.90	3.37	46.27%	6.168	<0.001
CI Group						
1.	Baseline to 6 weeks	-25.30	6.18	42.08%	6.157	<0.001
2.	6 weeks to 6 months	-17.00	2.48	48.82%	6.172	<0.001

application of local steroid ointment locally and settled in 01 week time. None of the patients developed fat embolism or pulmonary embolism.

4. Discussion

There are many known and unknown variables for a successful outcome and long term survivorship of TKA. The surgical flow in TKA surgery entails a dynamic equilibrium between restoration of neutral mechanical alignment and optimal rotational positioning of components while achieving ligament balance throughout the range of motion. A neutrally aligned well-balanced TKA with accurate positioning of the femoral and tibial components in all planes will restore tibio-femoral and patella-femoral kinematics thereby improving outcomes and survivorship.¹⁻³ The cost effectiveness and turnover time to manufacture PSI have been of some concern in the past restricting the usage of PSI or PSG as a popular tool for use in TKA ever-since it was introduced; in our center most of these aspects of PSI were negated due to close collaboration with a locally based medical devices 3D printing company to manufacture the PSG at a low cost and a turnover time of less than 10 days. Our study was focused primarily to assess the axial alignment achieved by using PSG compared to conventional TKA instrumentation; other aspects of TKA surgery reported in the literature to be directly linked to PSI usage in TKA, like duration of surgery and functional outcomes were also assessed.

Various studies in the literature Sharkey et al.³ Ritter MA, Faris PM et al.,⁴ Lotke et al.⁵ have highlighted the role of mechanical axial alignment in survivorship of TKA and functional outcomes. Ritter MA, Davis KE et al. in a study on 6070 knees in 3992 patients concluded that post-operative limb axial alignment remains a crucial factor that causes a knee to fail in the long term.⁹ However, achievement of an acceptable axial alignment (180deg ±3 deg) is

likely to be highly inconsistent with conventional methods due to inherent short comings in the conventional instruments, faulty or difficult assessment of anatomical landmarks per-operatively, surgeons learning curve and large variations in the native anatomy of the knee, variations in the femoral bow, wide femoral intramedullary canal, ankle and foot deformities and tibial bowing to name a few. Newer techniques like computer navigation, robotic surgery and PSI are highly precise tools to achieve neutral alignment apart from the other objectives of TKA surgery.

Many studies in the literature by Noble et al.,¹⁴ Daniilidis K et al.,¹⁶ Ng VY et al.,¹⁷ and Boonen B et al.¹⁸ report lower rates in the number of outliers of HKA Axis by using PSI. In our study patients in PSG group with restoration of HKA to 180 ± 3 deg was 84% whereas in CI Group this proportion was only 58% the proportion of outliers was significantly higher in CI Group as compared to that in PSG

Group (p = 0.007). Thienpont E et al. in a systematic review and meta-analysis of 44 studies which included 2866 knees that underwent surgery with PSI and 2956 knees that underwent surgery with standard instrumentation; noted that the risk of mechanical axis mal-alignment was significantly lower for PSI, with a pooled relative risk of 0.79 (p = 0.013).¹⁹ Similar findings are reported by Lin Y, Cai W, Xu B et al. in a meta-analysis of RCT's.²⁰

Mean duration of surgery in our study in the PSG group was 60 min and 88 min in the CI group (p < 0.001). Sassoon A, Nam D et al. reported similar results in a systematic review.²¹ Significant reduction in the duration of surgery in PSI is due to reduction in the number of surgical steps for axial alignment, and sizing of femoral and tibial components. The technique used by us for PSG was useful in preoperatively planning the distal femoral cut, axial alignment of the femoral component and sagittal plane positioning of the femoral component. On the tibial side it was designed for preoperatively deciding the tibial cut, tibial slope and axial alignment of the tibial component. Conflicting results were reported by Hamilton WG, Parks NL et al.²² in a RCT where they found no significant decrease in surgical time compared to conventional instrumentation.

Patients in both groups reported improved quality of life, pain, stiffness and disability There was no significant difference in clinical outcomes between two groups up to 01 year (p > 0.05). Mean WOMAC scores in both groups reduced in a linear fashion measured at 06 weeks, 06 months and 01 year. Results of our study is in line with the findings reported by Tarun Goyal, Sujit K et al. in a systematic review and meta-analysis and in a multi-centric double blind RCT by Boonen B, Schotanus MG.^{23,24}

Many conflicting studies report no benefit of PSI in TKA. Mannan et al.²⁵ in their systemic review of 26 studies which included 1792 knees concluded that no demonstrable benefit of PSI could be ascertained in comparison to conventional instrumentation. In

their Systematic review of Patient specific Instrumentation in total knee arthroplasty Adam Sassoon et al.²¹ reviewed more than 30 studies from Embase and Medline data base and concluded that there was no clear-cut benefit of PSI over conventional instrumentation. Similar conclusions suggestive of inefficiency of PSI have been made by several high quality randomized controlled studies prominently by workers like Justin A M J Leeuwen et al.²⁶ A study performed by Chen JY et al.²⁷ who showed more outliers with PSI. These findings are most likely due to the steep learning curve in using PSI, inaccuracy in collection of CT scan data, noise at the time of data input, failure to incorporate the patients clinical findings and variables in the plan, long turnover time to manufacture PSI guides, deformation of guides during sterilization process; most the initial challenges in processing, manufacturing and using PSI have been addressed by advancements in software, 3D printing hardware, medical grade printing materials, drastic reduction manufacturing time and costs of 3D printed guides and overall better understanding of the process.

Our study had some limitation of this study is that the study was focused on studying the HKA axis and alignment in coronal plane. Rotational alignment and sagittal alignment of components which have a bearing on overall knee function and longevity both in short and long term could not be evaluated as the present generation of PSG used in the study were designed for axial alignment only. The follow up period was for 01 year in order to determine whether TKA done using PSG have an effect survivorship and failure, long term follow up studies coupled with a much larger sample size would be required in future for a definite comment on effect of neutral mechanical axis alignment on implant survival.

5. Conclusion

Patient specific guides (PSG) significantly reduce the outliers in HKA axis compared to conventional instrumentation. PSG usage reduces duration of surgery and as the surgeons become familiar with the PSG guides usage the surgical time is further expected to reduce. Better radiological outcomes, however, did not translate into better clinical outcomes, at least, in the short term. We feel in the long-term PSG may have a significant impact of the failure rate in TKA surgery as precise axial alignment components is an important determinant of longer term survivorship of TKA. With increase in the volumes the design and production costs of PSG for TKA surgery are further likely to reduce significantly. In future PSG usage in TKA may emerge as a useful and cost effective tool with increasing availability of open source 3D modeling software and Point of Care (PoC) desktop 3D printing units.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Research paper

Cemented medial mobile-bearing Unicompartmental Knee Arthroplasty: Effects of compliance with current indications on functional outcomes and long-term survival rates



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ABSTRACT

Background: Unicompartmental knee arthroplasty (UKA) is a surgical option for patients with medial compartment osteoarthritis (OA). The objective of this study was to describe the functional outcomes and long-term survival rates of cemented medial mobile-bearing UKA according to the compliance with current indications.

Methods: Retrospective study of 78 patients with medial unicompartmental knee OA treated with mobile-bearing cemented UKA (Oxford phase-III) between 2002 and 2012, with an average follow-up of 10.4 ± 3.4 years. Preoperative radiographs and clinical records were reviewed to assess the compliance with current indications (isolated medial compartment OA, flexion $\geq 90^\circ$, integrity of all ligaments, varus deformity $< 15^\circ$). Patients who met all criteria were classified with appropriate indication. The function was measured using the knee society score (KSS).

Results: Nineteen (24.3%) patients did not meet the current indications for UKA. Non-isolated OA of the medial compartment was the most frequent inappropriate indication (16 patients), followed by range of flexion $< 90^\circ$ (2 patients) and lack of integrity of the ligaments (1 patient). A significant improvement was found on the KSS after surgery [preoperative KSS: 50.0 (Interquartile range-IQR: (35.0–60.0)); post-operative KSS: 70.0 (IQR:60.0–70.0), $p < 0.05$]. Survival after 15 years of follow-up in cases without and with appropriate indication was 55.8% and 89.7%, respectively. A higher risk of revision surgery was found in cases with inappropriate indication (hazard ratio: 4.87, 95% Confidence Interval: 1.54–15.38, $p:0.007$).

Conclusion: When proper patient selection is carried out, cemented medial mobile-bearing UKA offers good functional outcomes with a survival rate of 89.7% at 15 years of follow-up.

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Level of Evidence: IV, case series;

1. Introduction

Unicompartmental knee arthroplasty (UKA) and total knee

arthroplasty (TKA) are effective treatment options for patients with medial unicompartmental osteoarthritis (OA).¹ Although TKA is the most commonly used approach by surgeons,² it has been described that UKA replicates more closely the native knee kinematics, because it preserves the anatomy of the lateral and patellofemoral compartments and cruciate ligaments, which translates into a higher degree of patient satisfaction. Compared to TKA, UKA is a less invasive procedure that offers several advantages, such as less

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blood loss, fewer analgesic requirements, lower complication rate, shorter hospital stay and faster recovery.^{1,2}

With current implant designs, short and medium term outcomes have revealed similar functional outcomes between patients treated with TKA and UKA.^{1,3} However, several studies have described higher revision rates in cases treated with UKA, which has led some surgeons not to consider it as a viable treatment option and ignore its advantages over TKA.⁴ Although the indications for UKA have changed over the years, the success of the procedure has been mainly attributed to proper patient selection.² Current indications for medial UKA implantation are: 1) isolated symptomatic medial unicompartmental OA, 2) range of flexion $\geq 90^\circ$, 3) correctable varus deformity of less than 15° , 4) intact anterior and posterior cruciate and collateral ligaments, and 5) absence of inflammatory joint disease.^{2,5}

Recently, long-term results have been described from specialized centers with good clinical results in the functional scales and survival rates above 90% at 10 years and 88.6% at 15 years of follow-up.^{6,7} However, there are still few studies describing long-term outcomes (greater than 10 years) related to UKA in patients with medial unicompartmental OA. Therefore, the objective of this study was to describe functional outcomes and long-term survival of cemented medial mobile-bearing UKA according to the compliance with current indications.

2. Methods

Retrospective study on a cohort of consecutive patients with medial unicompartmental OA treated with cemented medial mobile-bearing UKA between January 2002 and May 2012 in a single center in Cali, Colombia. Eighty-five consecutive UKAs were performed during the study period; Seven cases were lost to follow-up without availability for a clinical and radiological follow-up. Finally, 78 patients with UKAs were included with a range of follow-up from 7 to 17 years. This study was approved by the Institutional Review Board and was conducted in accordance with the guidelines of the Helsinki Declaration.

2.1. Surgical procedure

A medial parapatellar skin incision was carried out from the medial patellar margin until 3 cm distal to the joint line, just medial to the tibial tubercle. This incision was deepened through the joint capsule to explore the lateral and patellofemoral compartments. The stability of the cruciate ligaments was then assessed, and the medial and intercondylar osteophytes were removed. In all cases, a cemented, mobile-bearing Oxford Phase III medial UKA (Biomet Ltd, Bridgend, UK) was implanted using an extramedullary tibial guide, an intramedullary femoral guide, and the corresponding cutting guides. Postoperative rehabilitation protocol included isometric quadriceps exercises with knee flexo-extension from the first post-operative day. From the second post-operative day, walking was allowed with the use of a walker.

2.2. Data collection

Data was gathered from institutional clinical records; all information was collected during patient follow-up as part of the institutional protocol. The following variables were included: age, sex, associated comorbidities, body mass index (BMI) and ASA (American Society of Anesthesiologists) classification. In all cases, compliance with the current indications for UKA was retrospectively verified: 1) isolated symptomatic unicompartmental OA of the medial compartment, 2) range of flexion $\geq 90^\circ$, 3) varus angular deformities amenable to correction of less than 15° , 4) intact

anterior cruciate and collateral ligaments, and 5) absence of inflammatory joint disease.^{2,5} Preoperative radiographs were reviewed to assess if there was evidence of OA in a compartment other than the medial one at the moment of surgery. Indications 2 to 5 were verified based on the clinical records. Cases who met all criteria were classified with appropriate indication. Primary outcome measures were prosthesis survival and functional outcomes. Revision was defined as the replacement or removal of any component implanted in the primary surgery. The function was evaluated before surgery and at final follow-up using Knee Society Score (KSS).

2.3. Statistical analysis

All analyses were performed using Stata 16.0 (StataCorp. College Station, TX, USA). Continuous variables were summarized using mean \pm standard deviation or median (interquartile range-IQR). Shapiro-Wilk test was used to evaluate the assumption of normality. Categorical variables were described with absolute frequencies and percentages. Differences in the KSS score before and after surgery were tested with use of the Wilcoxon signed-rank test.

The sample was divided into two groups: revision group vs non-revision group. Chi-squared test or Fisher's test were used to compare the distribution of the categorical variables between groups. Continuous variables were compared by Mann-Whitney *U* test or Student's *t*-test.

Survival time was defined as the time between UKA and revision surgery. Patients who did not require revision or who died during follow-up were considered as censored. Survivorship analysis was performed with the Kaplan-Meier method. The Cox regression model was used to assess differences in implant survival between cases with and without appropriate indication according to current indications for UKA. The hazard ratio (HR) was reported with its respective 95% confidence interval (CI). *P* values < 0.05 were considered as statistically significant.

3. Results

3.1. Patient characteristics

A total of 78 patients were included in the analysis, with a mean follow-up of 10.4 ± 3.4 years. Fourteen patients (17.9%) died without need for revision surgery with a time of follow-up of 9.4 ± 3.8 years after UKA. At the time of surgery, the mean age was 65.2 ± 8.4 years, and 75.6% (59) were women. High blood pressure and diabetes mellitus were presented in 57.5% (45) and 16.7% (13) of the cases, respectively. According to ASA classification, 15.4% (12) had ASA I, 67.9% (53) had ASA II, and 16.7% (13) had ASA III. Around 52.6% (41) were overweight (BMI 25.0–29.9 kg/m²), and 16.7% (13) were obese (BMI ≥ 30 kg/m²). Twenty-six (33.3%) patients had undergone previous surgery to treat meniscal injuries (23 cases treated with arthroscopy and 3 with open surgery).

According to the clinical description reported by the surgeon, 19 of the 78 patients undergoing surgery were identified with an inappropriate indication for UKA. The presence of OA in a compartment other than the medial one was the most frequent contraindication (16 patients), followed by range of flexion $< 90^\circ$ (2 patients) and loss of ligament integrity (1 patients).

3.2. Function

Patients showed significantly higher postoperative KSS scores in the clinical and function component compared to the baseline ($p < 0.05$). A significant improvement in the KSS clinical score from

44.0 (IQR: 33.2–50.0) to 95.0 points (IQR: 83.0–95.0) was observed at the end of the follow-up ($p < 0.001$). Similar findings were observed in the KSS function score, with a preoperative score from 50.0 (IQR: 35.0–60.0) to 70.0 points (IQR: 60.0–70.0) at the end of the follow-up. Postoperative improvement in KSS scores did not differ between patients with and without appropriate indication (KSS function: inappropriate indication group: 10 (IQR: 10–25), appropriate indication group: 20 (IQR: 0–30), $p: 0.996$).

3.3. Revision

Revision surgery was required in 12 (15.4%) patients, and the most common indication for revision surgery was progression of OA, followed by aseptic loosening and polyethylene failure (Table 1). Of the patients undergoing revision surgery, 7 patients did not meet the current UKA indications and were classified with inappropriate indication. Survival rate at 5 years, 10 years, and 15 years of follow-up in the entire cohort was 94.8% (95% CI: 86.9–98.0), 86.6% (95% CI: 76.5–92.6), and 80.5% (95% CI: 66.4–89.1), respectively.

At baseline, no significant differences were found between revision and non-revision groups concerning age, sex, obesity, ASA scale, and history of previous surgery ($p > 0.05$). Inappropriate indication for UKA was identified as a risk factor for revision surgery (HR 4.87, 95% CI: 1.54–15.38, P value: 0.007) (Table 2). Survivorship curves according to the compliance with current indications for UKA are shown in Fig. 1. At 15 years of follow-up, survival rate in cases with appropriate indication was higher compared to cases with inappropriate indication at the moment of the UKA (89.7% vs 55.8%). In both, non-revision and revision groups, the most frequent contraindication for UKA was non-isolated medial OA.

4. Discussion

The main finding of the study showed that Cemented Medial Mobile-Bearing UKA is a surgical procedure that offers good long-term functional outcomes in patients with medial uni-compartmental OA. Although functional results were comparable between knees with and without an appropriate indication, an elevated risk of revision surgery was found for patients who were classified as an inappropriate indication for UKA. Progression of OA was the most common cause for revision surgery, followed by aseptic loosening, results similar to those described in previous publications.^{4,8,9} Polyethylene dislocation occurred in one patient, a complication that has been reported in patients treated with mobile-bearing UKA.¹⁰

In the present study, a statistically significant improvement in the KSS score was observed in patients treated with UKA and is similar to those previously reported.^{7,11–14} In addition, previous studies have shown that older age is not a determining factor in functional outcomes of UKA,^{15,16} which has allowed older adults with unicompartmental OA not to be deprived of the benefits of UKA. Even authors like Burn et al. have shown that UKA offers

better functional outcomes compared to TKA after adjusting for age.¹⁷

Although the overall survival rate (86.6%) at 10 years of follow-up was within the range of the publications of the last 5 years (84.4% and 97.1%). This rate was lower compared to other studies.^{4,8,9,11,12} However, when discriminating our results according to compliance with current indications for UKA, the 10-year survival rate increased to 92.8%, comparable to that reported by Walker et al. who described a survival of 92.4% in 113 patients with medial OA treated with Oxford phase III UKA.⁷ A similar tendency was observed at 15 years of follow-up, with a higher implant survival probability in cases with an appropriate indication for UKA (89.7% vs the entire cohort: 80.5%). Compared to TKA, the reported survival rates for UKA are consistently lower, as revealed by Wilson et al. in a meta-analysis published in 2019, where an increased risk of revision in cases with UKA at 5 and 10 years of follow-up was found.¹

In this study, non-compliance with the current indications for UKA had a negative effect on survival rate and was identified as a risk factor for revision surgery. Patients with an inappropriate indication were 5 times more likely to require revision surgery. The main contraindication identified was the non-identification of OA in the patellofemoral or lateral compartment prior to UKA, which correlates with the reported causes for revision surgery. Similar results were described by authors such as Winnock de Grave et al.¹³ and Seth et al.,¹⁸ who reported case series of revision surgery with evidence of OA in the lateral compartment before the primary UKA. Consequently, it is important for surgeons to perform a thorough evaluation of preoperative radiographic images (anteroposterior, lateral, and axial projections of the patella) to achieve an optimal surgical result and reduce the risk of revision.

In addition, Hamilton et al.,¹⁹ who investigated the long-term outcome in 805 knees treated with medial mobile-bearing UKA, reported no significant difference in implant survival and overall function in patients with and without damage to the lateral side of the patellofemoral joint. However, they reported that cases with cartilage loss on the lateral compartment reported having slight difficulty descending stairs. Regarding the impact of the degree of angular deformity as a contraindication to UKA, Seng et al.,²⁰ reported similar functional outcomes on the KSS scale in patients with severe flexion deformity 15° or varus deformity 15° compared to patients with minor deformities. However, the survival rate in the study performed by Seng et al. was only evaluated at a minimum of 5 years and for this reason, conclusions cannot yet be made regarding the impact on the implant survival.²⁰

In the present study, no statistically significant differences were found between revision and non-revision group respect to age, sex, obesity, ASA classification and previous surgery. There are contradictory results in the literature on the relationship between age and the implant survival. Although some studies have found no difference in the implant survival rate according to age,^{16,21} authors such as Alnachoukati et al.,⁶ reported better survival rates in younger patients. Whilst Price et al.,²² and Vander der List et al.,²³ described that a younger age (<60 years) is associated with a decreased likelihood of survivorship.

The role of the BMI has also been debated as an indication criterion for UKA. Although there is evidence to support the use of UKA in obese patients,²³ authors such as Kandil et al.,²⁴ have described that obese patients double the risk of revision surgery during the first 90 days. At 2-year follow-up, in a study by Polat et al.,²⁵ a greater number of revisions and lower functional scores were described in obese and morbidly obese patients, mainly attributed to implant loosening. Similarly, Nettrour et al.,²⁶ reported that the risk of aseptic revision is up to 5 times higher in obese patients. Xu et al.,²⁷ in their series of 184 knees, reported a

Table 1
Description of the causes for revision surgery.

Causes for revision	N = 12
Progression of OA	6
Progression of OA and polyethylene failure	2
Aseptic loosening	2
Dislocation	1
Periprosthetic joint infection	1

OA: Osteoarthritis.

Table 2
Comparison of clinical characteristics of patients according to the requirement of revision surgery.

Variable	Revision group (N = 12)	Non-revision group (N = 66)	P value
Age ^a			
Mean (SD)	64.8 (7.9)	65.3 (8.6)	0.856
Sex, n (%)			
Female	9 (75.0)	50 (75.8)	1.000
Male	3 (25.0)	16 (24.2)	
ASA classification, n (%)			
I	3 (25.0)	9 (10.2)	0.383
II-II	9 (75.0)	57 (86.4)	
Previous surgery, n (%)			
No	6 (50.0)	46 (69.7)	0.200
Yes	6 (50.0)	20 (30.3)	
BMI Status, n (%)			
Normal (kg/m ²)	3 (25.0)	21 (31.8)	0.745
Overweight (kg/m ²)	9 (75.0)	45 (68.2)	
Femorotibial angle (°)			
Median (IQR)	183.0 (183.0–189.0)	183.0 (182.7–184.0)	0.141
Inappropriate indication for UKA, n (%)			
No	5 (41.7)	54 (81.8)	0.007
Yes	7 (58.3)	12 (18.2)	
Type of Inappropriate indication			
Non-isolated medial OA	6	10	–
Flexion < 90°	0	2	
Loss of ligament integrity	1	0	

^a At the time of surgery; BMI: Body Mass Index; CI: Confidence Interval; HR: Hazard Ratio; SD: Standard Deviation; IQR: Interquartile Range; UKA: Unicompartmental Knee Arthroplasty.

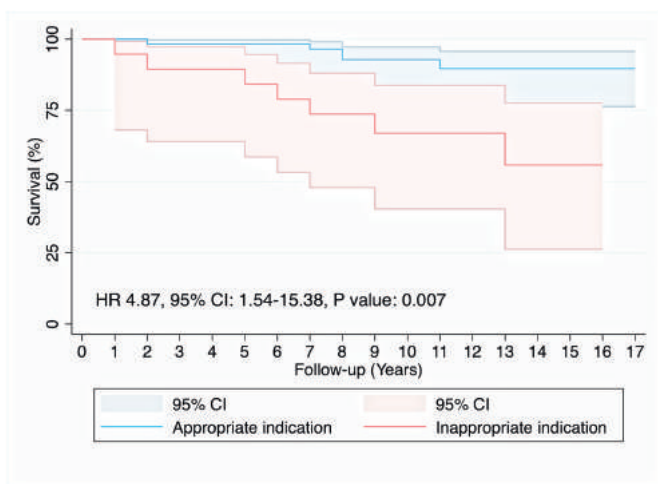


Fig. 1. Survivorship curves with 95% confidence intervals (CI) in cases with and without appropriate indications for UKA.

10-year survival in non-obese and obese patients of 98% and 88%, respectively.

In this cohort, no evidence was found to restrict the use of UKA according to the ASA classification. In the recent literature, there are few studies comparing the relationship between subjective assessment of the patient's overall health using the ASA score and the risk of revision. Like us, Liddle et al.,²¹ did not find a relationship between the ASA classification and implant survival time. However, in another study from the same author,²⁸ a higher probability of survival was reported in patients with ASA I-II compared with patients categorized as ASA III-V. Furthermore, Nettrour et al.,²⁶ described an increased risk of revision in cases classified as ASA III-IV, but this association was attributed to obesity in the multivariate analysis.

This study has shown that careful selection of patients for

medial UKA is therefore crucial to guarantee the effectiveness of the surgical procedure and a longer survival of the prosthesis. It is important to remember that medial UKA should not be indicated in patients with evidence of OA in other compartments. In particular, the ideal patient for UKA is the one with no history of inflammatory disease with isolated unicompartmental OA limited to the medial compartment, with a range of flexion of at least 90° and a varus deformity lower than 15° (amenable to correction). All published studies reiterate that the success of the UKA depends firstly on adequate patient selection, and secondly on the experience of the surgeon in performing the surgical.² No differences in terms of functional outcomes or survival have been found according to the type of prosthesis design (mobile- or fixed-bearing),²⁹ so the selection depends on the surgeon's preferences.

Limitations of this study include the retrospective nature of the data collected from the surgical notes and institutional clinical records. On the other hand, postoperative images were not reviewed in this study, so femorotibial angles and mechanical alignment, and their relationship to early loosening of the prosthesis, were not assessed. Another drawback is the small sample size, which may not have sufficient statistical power to detect a difference between the groups and for example, the non-significant difference in KSS function score between the patients with or without appropriate indication must be interpreted in light of this limitation. However, the long-term follow-up and retrospective verification of compliance with current indications for UKA and their effect on implant survival may be considered as a strength of the research.

5. Conclusion

In conclusion, when proper patient selection is carried out, cemented medial mobile-bearing UKA offers good functional outcomes with a survival rate of 89.7% at 15 years of follow-up.

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Author's contribution

LB, AC, JP and MM made the design of the study. LB, AE and WS collected the data from the clinical records. EC, AE, MM and JP helped with the statistical analysis. The interpretation of the results and the draft of the manuscript were made by all authors. All authors read and approved the final manuscript.

Declaration of competing interest

None.

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Research paper

Intermittent adductor canal block for post-operative pain management and faster rehabilitation following unilateral total knee replacement



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ABSTRACT

Background: Total knee arthroplasty (TKA) is usually associated with intense, early postoperative pain thereby interfering with patient's sleep and rehabilitation activities. To control the post-operative pain various traditional analgesic techniques have been recommended. But due to various systemic side effects, adductor canal blocks (ACBs) have emerged as a newer modality with effective postoperative analgesia and aids in faster rehabilitation. We retrospectively analysed the outcomes of USG guided intermittent adductor canal block in patients undergoing Unilateral TKA as a better mode for pain relief with fast track recovery.

Material and methods: A total of 51 patients underwent Unilateral TKA for arthritic knee were included in the study. Post-operatively all patients underwent an USG guided ACB with indwelling catheter. All patients received a standardized multimodal analgesic regimen (unless contraindicated) and intermittent 8th hourly 0.25% 8 ml bupivacaine through ACB catheter. Post-operative VAS score reading was noted twice in a day (morning and evening) on post-operative day 1, 2 and day 3 (morning). The readings were recorded in 2 ways-Without movement of knee (at rest) and with passive movement of knee (slight flexion). Post-operative rehabilitation was evaluated in terms of Quadriceps power, ambulation ability with walker or cane, climbing stairs and duration of hospital stay.

Results: VAS score statistically reduced from POD1 to POD2 and POD1 to POD3 both at rest and during movement and post-operative pain management was successful using ACB in 88% patients without any opioid supplementation.

Conclusion: In our study we recommend intermittent ACB as a very good modality for post-operative pain management, preserving quadriceps strength, early rehabilitation and short hospital stay with minimal or no bupivacaine related side effects in patients undergoing unilateral total knee replacement.

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1. Introduction

Total knee arthroplasty (TKA) is a highly successful routinely done procedure worldwide for treating advanced osteoarthritis (OA). However, the main drawback of TKA is having intense, early postoperative pain thereby interfering with patient's sleep and rehabilitation activities. Thus, effective analgesia post TKA is utmost paramount to aid better rehabilitation and fast track

recovery of the patient.¹

Various traditional analgesia techniques have been recommended to control the post-operative pain following TKA such as patient-controlled analgesia (PCA), intravenous opioids, continuous epidural analgesia (CEA), peri-articular infiltrations (PAI), Lumbar plexus block (LPB) and femoral nerve blocks (FNBs) but due to various side effects their use has been controversial. Peripheral nerve blocks now have become the optimal pain relief modalities. Their usage has been increasingly preferred in patients undergoing various orthopaedic surgical procedures. Furthermore, in literature peripheral nerve blocks are found to be superior over intravenous patient-controlled analgesia or epidural analgesia in terms of shorten functional recovery and quality of pain control with

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minimal side effects.^{2–4}

PCA using intravenous opioids and CEA pose the risk of various systemic side effects while LPBs is technically demanding and requires advanced skills and FNBS leads to quadriceps weakness thus increases the risk of inpatient falls and delays the rehabilitation recovery.^{1,5,6} In contrast, adductor canal blocks (ACBs) have become popular as they are able to preserve quadriceps strength along with similar postoperative analgesia to the traditional FNBS. One drawback to ACBs is that they do not provide analgesia to the posterior aspect of the knee. Single shot ACB has relatively poor efficacy when compared to continuous ACB but continuous ACB needs more cost and constant monitoring of patients in view of anaesthetic agent related toxicity which becomes difficult at a high-volume centre.

An ideal analgesia should facilitate early recovery, less side effects, full satisfaction of the patient and short hospital stay. Therefore, regional anaesthesia with nerve blockade that preserves the muscle function are more preferable pain relief modality in maintaining the fast track recovery of the patient. Thus, this study was conducted to assess the effective post-operative pain relief, early functional recovery in terms of ambulation ability, hospital stay duration and to look for side effects if any by choosing a middle path of giving intermittent injection via an indwelling catheter in adductor canal.

2. Methodology

Total of 51 patients who underwent elective primary unilateral TKA at our institute from January 2017 to June 2018 were included in the study after informed consent and approval from ethical and scientific committee. Patients with inability to cooperate or any psychiatric illness, allergic to local anaesthetic agents and those operated under general anaesthesia were excluded from the study. The sample size was calculated using the reference study of Jaeger et al.⁷

3. Technique of adductor canal block

All patients underwent TKA by using standard medial Parapatellar approach under spinal anaesthesia using a tourniquet. Intraoperatively, as per standard TKA protocol - a 100 ml of cocktail was infiltrated in the peripheral tissue and posterior joint capsule of the knee joint in every patient.

- Patient with normal kidney function:- Cocktail of 20 ml bupivacaine 0.5% (100 mg) + 0.5 ml adrenaline (500mcg) + 1 ml amikacin (250 mg) + 0.5 ml clonidine(75mcg) + 78 ml Normal saline = 100 ml was used.
- Patient with Diabetes mellitus or abnormal kidney function:- Cocktail of 20 ml bupivacaine 0.5% (100 mg) + 0.5 ml adrenaline (500mcg) + 0.5 ml clonidine(75mcg) + 79 ml Normal saline = 100 ml (no amikacin or nephrotoxic drugs) was used.

Post-operatively all the patients were shifted to recovery room where they underwent ultrasound guided adductor canal block. Patients were laid in supine position with thigh abducted and externally rotated. Adductor canal was visualized using a high-frequency linear ultrasound (US) transducer (10 MHz linear probe of USG machine ESOATE EUROPE BV MODEL 8100, S.no- 91251183) placed antero-medially at a mid-point between inguinal crease and medial condyle (Fig. 1). The femoral artery lies just under the sartorius within the adductor canal (Fig. 2). Once the femoral artery was identified using colour Doppler scan a 100 mm 19G short bevel needle was inserted by the single senior anaesthetist and after the needle tip was visualized anterolateral to artery and just deep to the



Fig. 1. Showing placement of USG transducer and needle insertion point.

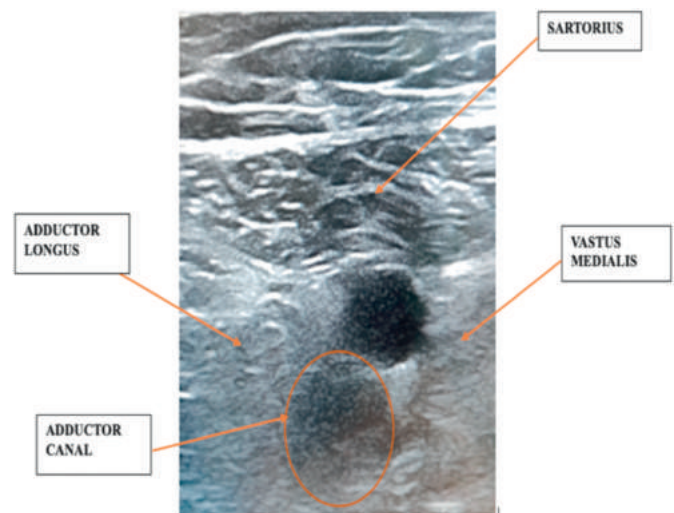


Fig. 2. The adductor canal beneath sartorius.

posterior fascia of the Sartorius muscle 1–2 ml of normal saline was injected first after careful aspiration to prevent intra-arterial injection. After ensuring that the normal saline passes without any resistance, catheter was inserted through the needle following which needle was removed and sterile dressing was done. 0.25% Bupivacaine 8 ml was injected immediately (Fig. 3) and after that 8th hourly was given as intermittently on day of surgery, POD1, POD2 and POD3. Post-operative all patients received a standardized multimodal analgesic regimen (unless contraindicated) as followed:

- Post-operatively- Inj Acetaminophen 1gm three times a day, Inj Lornoxicam 8 mg IV two times a day, Tab Etoricoxib 60 mg two times a day, Tab Pregabalin 75 mg one in night and I-V antibiotics.

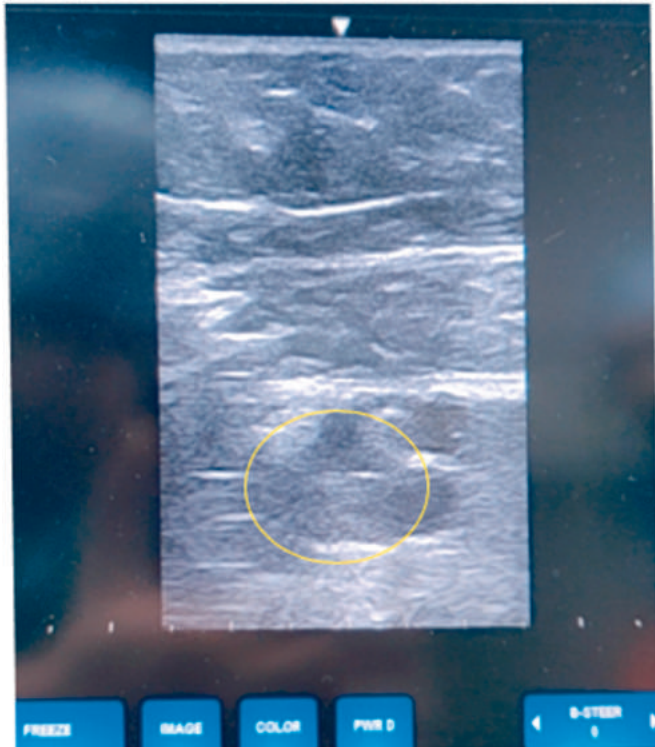


Fig. 3. Local anaesthetic spreading under sartorius within adductor canal.

(ii) For breakthrough pain additional dose of 0.25% bupivacaine injection was given through the catheter and if the pain persisted rescue analgesia was started-Fentanyl at 10-25mcg/hour by infusion pump.

On post-operative day one (POD1), all patients were encouraged to stand up and walk full weight bearing with the help of walker and knee range of motion was started. On POD2, patients were encouraged to walk with support of cane and try climbing stairs. On POD3, Adductor Canal Block Catheter were removed and patients were trained to climb stairs and discharged subsequently. Patients were evaluated twice a day for pain on basis of VAS (visual analogue score) Pain Score which were recorded in 2 ways:- (i) without movement of knee (at rest) and (ii)with passive movement of knee (slight flexion). Post-operative rehabilitation was evaluated in terms of BMI grading in different age groups, Quadriceps power based on MRC grading, ease of ambulation with walker or cane, climbing stairs and duration of hospital stay. We also looked for block complications like catheter leakage, block failure, hematoma formation, infection at catheter site, quadriceps palsy, intravascular injection, bupivacaine related toxicity (anxiety, visual or auditory disturbances, drowsiness, convulsion, respiratory depression, ar-rest) etc.

4. Statistics

The quantitative variables were expressed as mean ± sd and compared using paired t-test. A p-value < 0.05 was considered statistically significant. Statistical Package for Social sciences (SPSS) version 16.0 was used for statistical analysis.

5. Results

Out of 51 patients there were 9 males and 42 females. The mean

Table 1
Percentage reduction in VAS score.

	Percentage reduction in VAS		
	Day 1 vs. Day 2		Day 1 vs Day 3
	D1-D2-Morning	D1-D2-Evening	D1-D3-Morning
Without Movement	32.93%	37.91%	64.35%
With Movement	28.64%	34.36%	59.30%

age of the study group was 63.12 years with mean age of males being 64.67 years and females being 62.79 years respectively. The mean BMI (body mass index) of the group was 31 with mean BMI of males being 28.89 and females being 31.56 respectively.

VAS score of total population showed a decreasing trend from POD1 to POD3but there was no statistically significant difference in the morning and evening VAS score (with movement/without movement) between males and females (p value > 0.05). There was statistically significant drop in VAS score (with/without movement) on POD3 as compared to POD1 and POD2 as the p value was <0.05 (Table 1 and Fig. 4). VAS scores in Diabetes mellitus and hypertensive patients on POD1, POD2, POD3 (morning-without movement) were found to be higher as compared to patients without DM/HTN but was not statistically significant. The average quadriceps power was calculated on scale of 5 based on MRC grading and the results showed that there was improvement from POD1 to POD3 respectively (Fig. 5).

Ambulation was started according to pain tolerance, in 48 patients (94.11%) on POD1 and 3 patients (5.8%) on POD2 initially with help of walker. Then 38 patients (74.5%) were shifted to ambulate with cane on POD2. 43 patients (84.3%) were ambulated

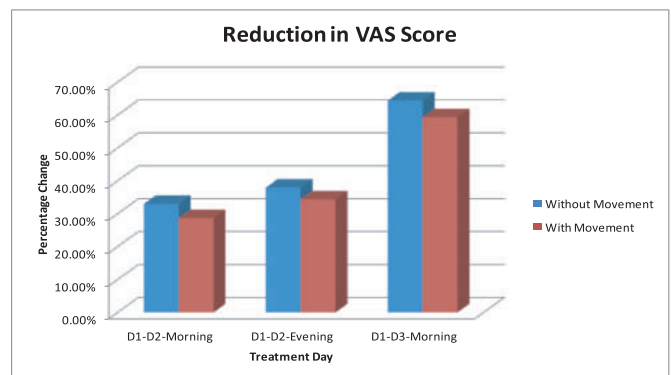


Fig. 4. Percentage reduction in VAS score.

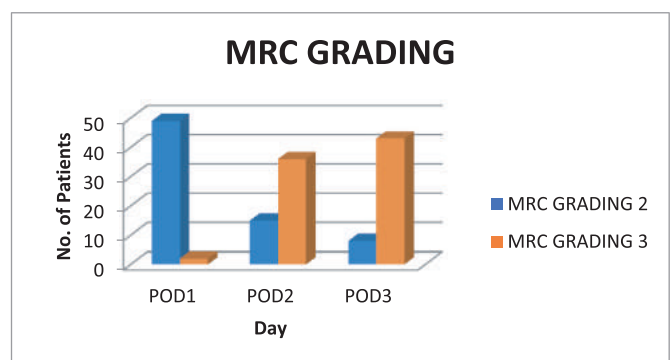


Fig. 5. Quadriceps power based on MRC grading.

Table 2
Ambulatory status of patients.

	NO. OF PATIENTS			
	POD1	POD2	POD3	POD4
Started Ambulating	48	3		
Ambulating with Walker	48	13	8	
Ambulating with Cane		38	43	
Stairs		4	41	6

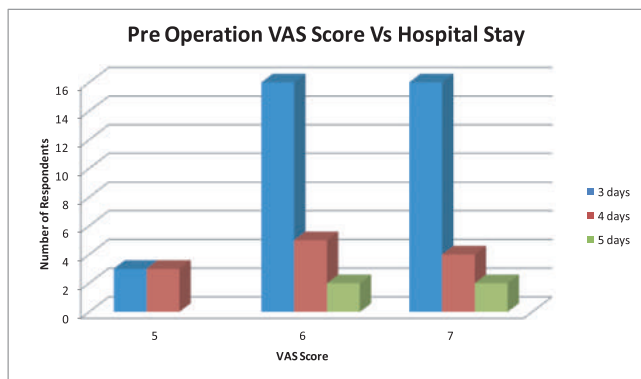


Fig. 6. Duration of hospital stay vs Pre-op VAS score.

comfortably with cane on POD3 (Table 2). 8 patients (15.6%) could not be ambulated using cane because of complications like catheter leakage and block failure that may have not given the adequate analgesia. 45 patients (88.2%) were discharged on POD3 after the stairs training; remaining 6 patients were trained to climb stairs on POD4 and then subsequently discharged. There was no statistically significant difference between males/females in terms post-operative functional recovery and duration of hospital stay. There was no statically significant difference between the duration of hospital stay and pre-operative VAS score of the patients (patients with more pre-op deformity of the knee had higher pre-op VAS score) (Fig. 6).

The block failure was seen in 6 out of 51 patients i.e. 11.76%. Out of 6 patients there were 2 cases of catheter leakage and 4 cases of block failure. None of the patients had infection at the catheter site nor an arterial puncture during the procedure. Neither did any of the patients suffered from quadriceps palsy or hematoma formation or any other bupivacaine related side effects as mentioned earlier (Fig. 7). The mean hospital stay in case of block failure was 3.83 days. The mean hospital stay in block successful patients was

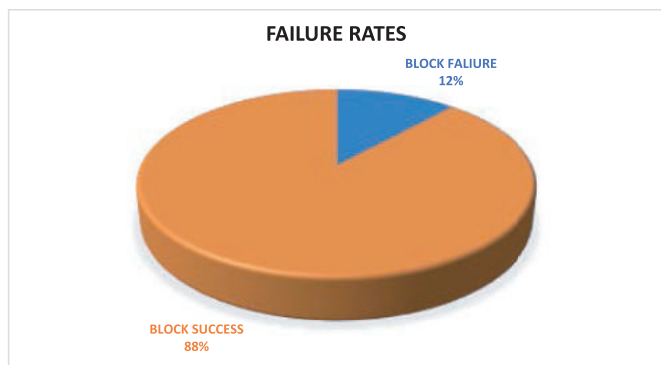


Fig. 7. Block failure rates.

3.33 days which was statistically significant as the t-value was 1.85567 and p-value was 0.03476.

6. Discussion

The primary objective of elective TKA surgery is functional and painless restoration of knee range of motion. Postoperative pain is the rate limiting factor that causes knee stiffness, poor functional outcomes and patient dissatisfaction with the procedure.⁸ Adequate pain relief in the immediate post-operative period is a keyhole of an optimal regional analgesic technique. Continuous FNB has ability in controlling the postoperative pain effectively however it leads to poor muscle strength thus hinders in early functional recovery of the patient and may also increases the risk of inpatient fall. While Continuous ACB is almost a pure sensory nerve blockade that reduces quadriceps strength by 8% as suggested by jaeger et al.⁷ Moreover, continuous ACB needs more cost and constant close monitoring of the patients in view of anaesthetic drug related side effects (drowsiness, visual impairment, respiratory distress) that makes the procedure little cumbersome at high volume centres and single shot ACB is found to be less effective in post op pain relief. Thus, present study was conducted to determine the effectiveness of middle path regimen that is intermittent injection via indwelling catheter in adductor canal in terms of pain relief, functional recovery, drug related side effects and duration of hospital stay.

Our findings were found to be comparable with the previous studies that intermittent ACB is an effective modality in terms of post op pain control, ambulation ability and early functional recovery. Moreover, intermittent ACB further reduces the percentage of quadriceps strength loss, requires less monitoring, minimal or no bupivacaine related side effects and more cost effective. A Combination of Acetaminophen, COX 2 inhibitors, NSAIDS, Gabapentoids and Corticosteroids (in non-diabetic patients) work as an adjunct for pain control in post-operative period⁹ as a part of multimodal analgesia. Other modalities like Epidural analgesia, although an effective technique but causes motor blockade and bladder/bowel dysfunction that limit early rehabilitation especially in the setting of fast-track protocols in present time. To overcome the disadvantages associated with epidural analgesia; Peri Articular Infiltrations and Nerve blocks are gaining popularity because they are associated with less motor blockade and no bladder/bowel dysfunction than systemic regimens.¹⁰ Femoral nerve blocks, in single shot or continuous infusion, which are a great alternative to Oral/IV analgesics but since it causes quadriceps weakness which hinders patient rehabilitation its use needs to be reconsidered.

In the current study 51 patients were included and all of them underwent unilateral TKA. All the patients were treated on the basis of multimodal analgesia protocol as discussed before and all of them underwent an USG guided adductor canal block infiltration for post-operative pain management as the primary source for pain control and for breakthrough pain as well. There were 9 males (18%) and 42 females (82%) respectively enrolled in the study with mean age being 63.12 years which gave an interference that osteoarthritis is a disease of old age and more common in females compared to males. The similar results have been shown in a study conducted by Singh J et al.¹¹ The mean BMI (body mass index) of the group was 31.30. Mean BMI of females was more than males but was statistically insignificant but patients with BMI of >30 develop early osteoarthritis and may need early total knee arthroplasty. This has been shown by Kulkarni et al.¹² in their study respectively. Another point to consider is that BMI has no influence on the functional outcome of the patients which has been shown by O'Neill et al.¹³

Outcomes were compared using the VAS score for pain and MRC grade for quadriceps power. There was a statistically significant

reduction in VAS score on POD3 as compared to POD1. Morning VAS score (without movement) which was 3.31 on POD1 was brought down to 1.18 on POD3 (64% reduction). Morning VAS score (with movement) which was 3.98 on POD1 was brought down to 1.62 on POD3 (59% reduction). Similarly, comparison was also made between POD3 and POD2 and the results were statistically significant with p value < 0.05 and a VAS score of 2.22 (33% reduction without movement) and 2.84 (29% reduction with movement) on POD2. Thus, the interference achieved through the results obtained was that 8th hourly intermittent injection of 0.25% bupivacaine through Adductor canal block is a very efficient means for controlling post-operative pain and reducing opioid consumption in patients undergoing unilateral TKA. In our study it was observed that there were only 6 patients in whom opioid (fentanyl infusion as a rescue drug) was used to control post-operative pain due to block related complications-catheter leakage and block failure (88% patients without any opioid supplementation). Similar results were also observed in the study conducted by other authors like Hanson et al.,¹⁴ Jenstrup et al.¹⁵ and Grevstad et al.¹⁶ Pre-Op VAS score was not statistically significant in respect to duration of hospital stay of patients. VAS score was not statistically different with regard to different age groups, gender, BMI and co-morbidities.

ACB preserved quadriceps strength thus aiding in early ambulation and rehabilitation. In our study, major shift was seen in the translation of the patients with MRC Grade 3 (quadriceps power) on POD2 from POD1 which was 34 patients (67%). Additional, 7 patients (14%) showed improvement in quadriceps power with MRC grade 3 on POD3 from POD2. 94% patients (48) were ambulated on POD1. 75% patients (38) were ambulated with cane on POD2 and 84% patients (43) were ambulated with cane on POD3. 15% patients (8) could not be ambulated using cane because of complications as mentioned in the results. 88% patients (45) were discharged on POD3 after the stairs training. The results in our study are conclusive that ACB spares quadriceps muscle thereby maintaining its strength, faster rehabilitation, early ambulation and short hospital stay. The findings are comparable with results found in other similar studies conducted by Kwofie et al.,¹⁷ Grevstad U et al.¹⁸ and Donghai Li et al.¹⁹

Since USG guided adductor canal block is a technically demanding procedure 88% patients (45) had successful block and 12% patients (6) had block complications (catheter leakage & block failure) in our study. While none of the patient had bupivacaine related side effects. Catheter leakage indicated that the in-situ catheter was blocked and therefore the medicine could not be pushed into the catheter and similarly block failure indicated that the in-situ catheter is either not in the right place or has migrated from its original site due to some manipulation. In both the scenario's, the rescue analgesia that was given to the patient was fentanyl infusion at 20mcg/hour initially which was gradually decreased and then stopped. The mean hospital stay in cases of block failure was 3.83 days whereas in block successful cases was 3.33 days which showed that patients who had block complications took more time for complete pain control and thus their rehabilitation was delayed.

Several limitations were noted in our study: Firstly, the sample size is small and predominant of women with more elderly age patients which may alter the pain perception ability and thus influence the result of pain control measures. Therefore, the result of the study cannot be implemented over entire population. Secondly, in addition to nerve blockade all patients received adjuvant IV and oral analgesic drugs as per standard TKA protocols at our institute that can mask the effect of nerve block and cannot be avoided for the study group (Analgesics alone per say cannot control the post-operative pain and is always a part of any multimodal analgesia regime). Thirdly, we did not use the specific devices to measure side

effects of Bupivacaine drug toxicity, instead patients were monitored clinically and dose were given intermittently i.e. 8hourly to reduce the drug toxicity as compared to continuous dosage given in various studies. However, no patients in our study developed anaesthetic agent related toxicity or complications.

7. Conclusion

To conclude, intermittent ACB is a very effective modality for post-operative pain management, preserving quadriceps strength, early rehabilitation and short hospital stay in patients undergoing unilateral total knee replacement and if placed correctly there are minimal chances of complications. Furthermore, intermittent regimen that we followed in our study was found to be more cost effective, less toxic or no drug related side effects and less cumbersome. Since it is a non-comparative study and technically demanding procedure future studies using intermittent ACB as primary modality of pain control can further confirm or refute this modality as standard of care to post-operative pain in patients undergoing unilateral total knee replacement. Hence, our study prompts for future studies with larger sample size and comparative cohort trials on further acceptance of this modality as a primary line of pain management.

Declaration of competing interest

The authors of the study have no conflict of interest.

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The work is original and can be considered for the publication.

List of Abbreviations

TKA	Total Knee Arthroplasty
ACB	Adductor Canal Block
VAS	Visual analogue score
PAI's	Peri-Articular Infiltrations
POD	Post operative day
Inj	Injection
MOR	Morning
EVE	Evening
BMI	Body mass index
Pre-Op	Pre-operative vas score
DM	Diabetes mellitus
HTN	Hypertension

Credit author statement

Prateek Garg: Conceptualization, Investigation, Writing – original draft, Writing- Review & Editing, Visualization, Project administration Nikhil Verma: Supervision, Writing- Review and editing Anuj Jain: Supervision, Project administration Simon Thomas: Supervision, Project administration Shekhar Agarwal: Conceptualization, Methodology, Validation, Resources

Ethical approval and consent to participate

Ethical approval has been taken and all patients were included in the study only after their written consent form.

Consent for publication

All authors give their full approval for the study to be published in the concern journal & the work is original and not under

publication process with any other journal.

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Author's contributions

All authors have contributed in the study.

Author's information

All authors are well informed that the study is going to be submitted with the journal for the publication purpose.

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Does drain matter in primary total knee replacement surgeries?

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ABSTRACT

Background: Drains has traditionally been used in primary total knee replacement (TKR) surgeries, but its use still controversial. Recent trends in total knee replacement has inclined towards operating without the use of drains. Drains decreases tension over the incision ultimately decreasing pain, ecchymosis and need for change of dressings. However, tamponade effect does not occur at surgical site increasing bleeding which in turn increases requirement of post-operative blood transfusion and transfusion related complications. It also increases chances of retrograde infection. Therefore this study was undertaken to clarify and compare the role of drainage system in total knee replacement surgeries.

Material and method: 62 randomly allocated patients undergoing unilateral or bilateral primary TKR surgeries has been studied in two groups of 31 patients each viz without drain and with drain with respect to percentage drop of haemoglobin, requirement of blood transfusion and wound complication as wound dehiscence, necrosis of wound margin, wound infection (superficial/deep) within one month of primary TKR surgeries.

Result: The difference of mean drop of hemoglobin, required post-op blood transfusion, mean unit of blood transfusion, mean hospital stay was statistically insignificant. In group without drain 3.2% had wound margin necrosis and superficial wound infection treated with oral antibiotics, rest all thirty patient did well; while in group with drain, none of the patient had wound margin necrosis. No significant association was seen between the percentage of the patients having wound dehiscence and wound margin necrosis, superficial or deep infections in the two groups.

Conclusion: The use of drains confer no added benefits or harm in primary TKR surgeries and their use should be individualised depending upon Surgeons preferences, experiences and set ups.

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1. Introduction

Total Knee Replacement (TKR) is one of the most lucrative

orthopedic surgical advances of the twentieth century. It is widely used in the treatment of osteoarthritis and moderate/severe rheumatoid arthritis.

Primary total knee replacement can result in a considerable amount of blood loss which often requires post-operative blood transfusion.^{1–3} In some studies, transfusion of blood after total knee replacement has been reported to be as high as 30%.⁴ Allogenic blood transfusion carries the risk of immunological and non-immunological adverse effects like increased rate of postoperative infections, disease transmission and high medical cost.

Various methods have been suggested to reduce blood loss following TKR, such as pre-operative erythropoietin and iron

Abbreviations: TKR, Total Knee Replacement; TKA, Total Knee Arthroplasty; NSAIDS, Non-steroidal anti-inflammatory drugs; Hb, Haemoglobin; Post-op, Post Operative; Pre-op, Pre Operative.

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supplementation, auto transfusion,^{5,6} post-operative blood salvage,⁷ hypotensive anesthesia,⁸ tranexamic acid administration,⁹ intra-articular epinephrine injection,¹⁰ thrombin based hemostatic agents¹¹ and temporary drain clamping.^{12,13}

Closed suction drain is being used widely in different surgical specialties, with orthopedics not being an exception.¹⁴ The use of suction drain has been practiced routinely, ever since the era of Hippocrates. Advanced sterility techniques and decreased infection rate has made use of drain in primary TKR as a matter of controversy and discussion over the past few decades. There are different schools of thought regarding the use of vacuum drainage after TKA; each concept having its own pros and cons.

Merits of use of drain is that it prevents hematoma formation at surgical site by evacuating blood from joint space, which is one of the factors responsible for colonization by bacteria causing superficial as well as deep-seated infection. Drains decreases tension over the incision (which consequently decreases pain), reduces ecchymosis and the need for change of dressings, reduces delayed wound healing and also reduces risk of infection.^{15,16} However, demerits of use of drainage system is that it increases bleeding because the tamponade effect does not occur at surgical site increasing requirement of post-operative blood transfusion which in turn increases transfusion related complications.¹⁹ It can also cause retrograde infection^{14,17,18} by transfer of bacteria through drain lumen.

Though some studies have shown that drainage after TKA is not necessary^{19–21} it is still widely used in current practice in Indian setup. There are limited Indian literature suggesting no added benefits of drain used in TKR but that is also inconclusive. Many studies have compared blood loss and infection rates between drained and non-drained groups in order to elucidate effect of drainage method on prognosis of TKA surgeries. However, the results have been contradictory, necessitating more studies to untangle same problem. So this study was done to clarify the role of drainage system after total knee arthroplasty by comparing the percentage drop of haemoglobin, requirement of blood transfusion and wound complication as wound dehiscence, necrosis of wound margin, wound infection (superficial/deep) within one month of the patients undergoing primary TKR surgeries with drain or without drain to provide practical information for orthopedic surgeons and medical care givers.

2. Material and methods

This prospective comparative study was carried out at tertiary health centre of a metro city for a duration of one year on 62 randomly selected patient. Study population comprised of both male and female undergoing unilateral or bilateral primary total knee replacement surgeries which was divided in two groups viz; group 1 without drain and group 2 with drain. Patient allocation was done by simple randomization in two groups by using a sealed envelope technique. The study has been conducted as per CONSORT guidelines.

2.1. Sample size with justification (answer to query raised by reviewer#-3)

A sample size of 31 patients per group (i.e. total 62 patients undergoing TKR) was needed to detect a difference of 45% in amount of blood transfused between the group of non-drained patients and drained patients (0.54 units) with 80% power, using a two-sample *t*-test and assuming a (two-sided) of 0.05, a mean amount of blood transfused was 0.98 and a SD of 0.6 units in the non-drained patients group.

2.2. Formula for sample size estimation

Sample size was determined by using the effect sizes from the previously published study from Indian Journal of Orthopaedics²⁵ and with the help of following formula:

$$n (\text{Per Group}) = 2 \left[\frac{(Z_{\alpha/2} + Z_{\beta})\sigma}{\Delta} \right]^2$$

where n = Sample size (per group).

$Z_{\alpha/2}$ = (1.96) for 95% confidence (i.e. α = 0.05). = 1.96.

Z_{β} = Cut-off value for Power (1 - β). = 0.8416

σ = Common Standard Deviation (SD) of both the groups. = 1.62 g % (post-op Hb).

Δ = Mean difference to be detected (minimum difference) = 1.15 g% (post-op Hb).

Δ / σ = Effect size in SD units. = 0.71

$$n (\text{Per Group}) = 2 \left[\frac{(1.96 + 0.8416) \times 1.62}{1.15} \right]^2 = 31.14$$

Thus sample size according to this formula is 31.14 \approx 31 (Minimum Per Group) i.e. Total 62 (Minimum).

Patients with infective pathology, revision TKR, previous operated cases for fractures or deformities around the knee, any coagulative disorder, recent history of thrombo-embolic episode, Uni-compartmental knee replacement and medically unfit patient were excluded from the study.

Patients were explained about the nature of the study in their vernacular language and informed consent was taken. Study has been approved by institutional ethical and scientific committee. Full confidentiality of the patient has been maintained throughout the study duration.

2.2.1. Preoperative protocol

All the drugs containing salicylates and non-steroidal anti-inflammatory drugs (NSAIDS) was stopped 7 days prior to surgery. Pre-operative haematological assessment included haemoglobin, platelet count and other blood parameters were noted.

2.2.2. Surgical procedure

Under spinal or general anesthesia (as per patient's requirement) in supine position with a pneumatic tourniquet on the thigh with pressure 100–150 mm of Hg above the systolic blood pressure knee was opened through standard midline anterior approach and medial parapatellar arthrotomy done. All the necessary soft tissue releases and bony cuts are taken All components were implanted using cement palacos RG. Joint was thoroughly washed with normal saline. Patellar resurfacing was not done in any of the cases. Posterior capsule, medial collateral ligament, lateral collateral ligament, quadriceps tendon, patellar tendon, periosteum was infiltrated with local infiltration. Tourniquet was released after cement setting and haemostasis achieved. In cases of use of drain, wound was closed after putting suction drain in lateral gutter (intra-articular) of knee (Fig. 1). Drain used in group 2 (with drain) was 12 number Romo Vac (Romsons, India) (Fig. 2). After properly washing, wound was closed in standard layers and sterile dressing applied. All the surgeries were carried out by same surgical team and component of a single company only has been implanted in all the patients.

Local infiltration formula for unilateral TKR.

Age <70 years >70 years.

Ropivacaine (0.75%) 40 ml 54 ml.

Clonidine 0.6 ml 0.8 ml.

Adrenaline 0.3 ml 0.3 ml.

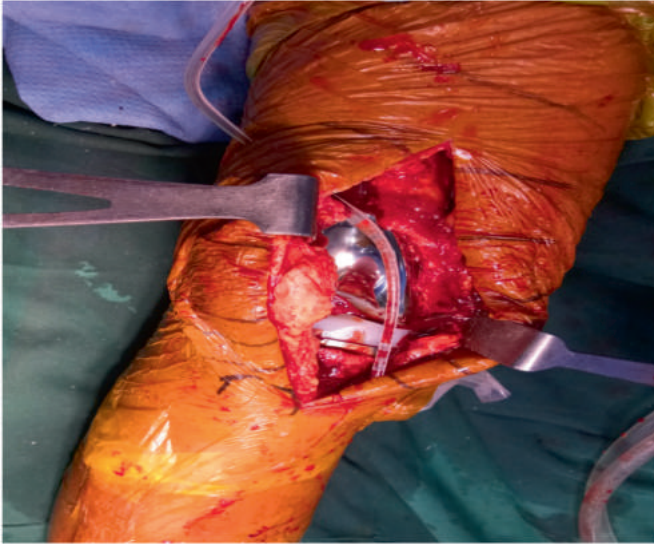


Fig. 1. Intraoperative photograph showing drain in situ.



Fig. 2. Romovac drain number 12.

Ketorolac 1 ml 1 ml.
 Normal saline 19 ml 25 ml.
 Total 60 ml 80 ml.
 Local infiltration formula for bilateral TKR.
 Age <70 >70.
 Ropivacaine (0.75%) 40 ml 54 ml.
 Clonidine 0.6 ml 0.8 ml.
 Adrenaline 0.3 ml 0.3 ml.
 Ketorolac 2 ml 2 ml.
 Normal saline 58 ml 64 ml.
 Total 100 ml 120 ml.

2.2.3. Postoperative protocol

Postoperative haemogram was done on day 1 and day 3. The percentage drop of haemoglobin postoperatively was calculated and compared with preoperative values. Postoperative drain output volume was measured daily. Blood transfusion was

considered if: Drain collection of ≥ 500 ml (possible ongoing loss) in 24 h with haemoglobin drop of ≥ 4 gm/dl or if total haemoglobin of patient drops to < 8 gm/dl. Total number of unit transfusion required were noted. The drain was removed after 48 h of surgery or < 50 ml drain whichever was earlier. Dressing was done on day 2 of each patient or earlier if soakage was present. Second dressing was done before discharge usually on day 4–6. Wound was examined at the time of dressings. Follow up was done on day 14 and day 30. In case of any wound complication, more follow up were done accordingly. On first follow up staple removal was done. On each follow up wound was examined for dehiscence, margin necrosis and infection (superficial/deep) up to 30 days postoperatively.

Quadriceps strengthening and ankle pump exercises was instructed postoperatively. Patient was mobilized full weight bearing with the help of a walker on day 1 in both group of patients. Three doses of intravenous antibiotics (Cefuroxime 1.5 gm) was given to patients of each group. First dose was given 30 min before incision, 2nd and 3rd dose was given after 12 h and 24 h of surgery. Intravenous analgesics and fluids were also given postoperatively.

2.2.4. Statistical analysis

Statistical analysis was carried out with the help of SPSS (version 20) for Windows package (SPSS Science, Chicago, IL, USA). The description of the data was done in form of mean \pm SD for quantitative data while in the form of % proportion for qualitative (categorical) data. P-values of < 0.05 was considered significant. For quantitative data, unpaired Student's t-test was used to test statistical significance of difference between two independent group means. For comparison of categorical variables (i.e to examine the associations between qualitative/quantitative variables), chi-square test was used if the number of elements in each cell were 5 or higher and Fisher's exact test, otherwise. To compare proportions between two groups Z test of proportions was used.

3. Observation and results

Of 62 patients in total, 31 were included in Group one in whom drain was not used and rest 31 were in group two in whom drain was used. Mean age of patients in group without and with drain were 65.9 and 65.39 years respectively. In group 1, 71% of patients were female and 29% male. In group 2, 64.5% of patients were female and 34.5% were male. Out of 62 patients, 20 (32.3%) patients were males and 42 (67.7%) were females, showing female preponderance.

While studying the distribution according to side of the surgery between two groups ($n = 31$), in group without drain, 7 (22.6%) patients underwent right TKR, 6 (19.4%) underwent left TKR and 18(58.1%) patients underwent bilateral TKR. In group with drain, 12 (38.7%) patients underwent right TKR, 12 (38.7%) underwent left TKR and 7(22.6%) patients underwent bilateral TKR. No significant association was seen between the sides operated in the two groups.

While considering mean preoperative hemoglobin, it was found that 12.242 gm/dl was the observed value in group without drain and 12.100 gm/dl was the average observed value in group with drain. The difference was statistically insignificant(Table-1).

Post op day one and day three hemoglobin were measured and compared, it was found that, in group without drain the average value on day one was 10.532 gm/dl and in group with drain it was 10.694 gm/dl. While on day three, the values were 9.787 gm/dl and 9.787 gm/dl respectively. Average day one and three hemoglobin levels were found to be similar in both groups when tested using independent t-test(Table-1).

The mean drop of hemoglobin was 2.571 gm/dl (20.913% of pre-op value) in group without drain while in group 2, drop was

Table-1
Comparison of various parameters in two groups (p < 0.05 significant).

Drain		n	Mean	SD	SE	T	P
Hb preop	Yes	31	12.100	1.4601	.2622	-.382	.704
	No	31	12.242	1.4660	.2633		
Hb day 1	Yes	31	10.694	1.5665	.2814	.380	.705
	No	31	10.532	1.7660	.3172		
Hb day 3	Yes	31	9.787	1.2701	.2281	.000	1.000
	No	31	9.787	1.7291	.3106		
Drop of Hb	Yes	31	2.339	1.4233	.2556	-.657	.514
	No	31	2.571	1.3602	.2443		
% Drop of Hb	Yes	31	18.700	9.8784	1.7742	-.871	.387
	No	31	20.913	10.1271	1.8189		

2.339 gm/dl (18.7% of pre-op value) which is slightly lower, but the difference is statistically insignificant (Table-1).

In both the groups, 3 patients each (9.7%) required post-op blood transfusion and average unit of blood transfusion required was also same (1.33 unit in both groups).

In group without drain, only one patient (3.2%) (Figure-3) had wound margin necrosis rest all thirty patient did well; while in group with drain, none of the patient had wound margin necrosis. With respect to wound dehiscence, none of the patient had wound dehiscence among both the groups. No significant association was seen between the percentage of the patients having wound dehiscence and wound margin necrosis in the two groups.

In our study, in group without drain only one patient (3.2%) had



Fig. 3. Wound margin necrosis of a patient in the group without drain.

superficial wound infection and in group with drain, none of the patient had wound infection. None of the patient of any group developed deep wound infection. No significant association was found between the % patients having wound infection in the two groups.

Mean hospital stay (days) in both groups was also comparable, 5.65 days and 6.03 days in group without drain and with drain respectively. But again the difference found was statistically insignificant when compared using independent t-test.

4. Discussion

Drains have traditionally been used in total knee replacement but its use is controversial. Intra articular suction drains during TKR has its own pros and cons. Recent trends in total knee replacement has inclined towards operating without the use of drains. For sure, this method has its advantage like it decreases requirement of blood transfusion and transfusion related complications but at the same time can increase the risk of wound dehiscence.

There are limited Indian literature suggesting that, there are no added benefits of drain use in TKR. Whatever data available from literature about same is confusing and inconclusive. In this study, we tried to fulfil this lacunae in Indian literature.

4.1. Age distribution

The mean age of the patients who underwent TKR in our study was found to be 65 years which is compared with the available studies as shown in Table 2.

Our findings are comparable with study of Keska R et al.²² while studies of Aalberth G et al.²⁰ and Sharma GM et al.²³ had higher mean age compared to our study.

4.2. Mean preop and post-op b

In the study conducted by Shah N et al.²⁴ and Sharma GM et al.,²³ mean pre-op Hb was 12.01 and 12.17 gm/dl respectively. These findings are comparable with our findings. While in study of Adalberth G et al.,²⁰ mean pre-op Hb was 14.2 gm/dl in group without drain and 14.3 gm/dl in group with drain. Thus, differing from mean Hb of our study by being on the higher side.

In the study conducted by Adalberth G et al.,²⁰ mean post-op Hb

Table 2
Comparison of age and number of patient of our study with other studies.

Study	No. of Patient	Mean Age (year)
Adalberth G et al²⁰	90	71
Sharma GM et al²³	120	72
Keska R et al²²	108	68
Present Study	62	65

on day 1 and 3 in group without drain was 11.6 gm/dl was 10.9 gm/dl while in group with drain it was 11.6 gm/dl and 11 gm/dl respectively. They concluded that there was no statistically significant difference between their study groups (p value = 0.8). This finding is comparable to our study.

Reilly et al.,¹⁹ in their study concluded that drop of Hb in group without drain was 2.6 gm/dl and in group with drain was 2.33 gm/dl. This co-relates with our study too. While in study of Shah N et al.,²⁴ drop of Hb was 1.61 gm/dl in patients having no drain, which was slightly lower than our study. This might be because they used tranexamic acid locally apart from other local infiltration.

4.3. Percentage of patient who required blood transfusion

In our study, 9.7% patients in both group required blood transfusion and average unit of blood transfused was 1.33 units. This might be because we used local infiltration in both the patient groups and did meticulous haemostasis on deflation of tourniquet after implantation of femoral and tibial component.

In the studies of Reilly TJ et al.¹⁹ and Keska R et al.²² requirement of blood transfusion was 16% & 39% in patients without drain and 39% & 53% in patients with drain respectively. These results differs from our finding being on much higher side in their studies.

4.4. Wound complications

In our study, in group without drain, one patient had wound margin necrosis in distal part of the wound which was noted on day 5 postoperatively and treated conservatively by repeated dressing and oral antibiotic (Cefuroxime for 10 days). Improvement was noted after 1 week of staple removal with complete healing. While in group with drain, all patients had healthy wound margin without any evidence of necrosis.

None of the patient of any group had wound dehiscence in our study.

In group without drain, we had one patient (3.2%) with superficial infection presented with localized pustular swelling near wound margin on day 7 postoperatively without any active discharge and without any history of fever. Blood investigations were done and total leukocyte count, erythrocyte sedimentation rate and c-reactive protein were found to be within normal limit. No growth of organism was found in swab culture. The patient was treated with minor debridement and oral antibiotics (cefuroxime) for 10 days following which it healed completely. While in group with drain, no patient developed superficial or deep infection. There was no statistical difference in wound infection between the two groups.

There was no case of deep infection in our study.

Sharma GM et al.²³ and Reilly TJ et al.¹⁹ noted 1.69% & 3% incidence of superficial wound infection in their study group without drain. Whereas values for the same becomes 1.63% & 5.8% in group with drain. Our study findings were comparable to them.

4.5. Duration of hospital stay

In our study, the mean duration of hospital stay for group without drain and with drain were 5.65 and 6.03 days. Study conducted by Sharma GM et al.²³ reported average length of hospital stay of 5.12 days and 6.21 days respectively. In their study there was a significant difference between the study groups with respect to average duration of hospital stay while our study shows no difference in both the study groups. They stated that the presence of drain interferes with post-operative physiotherapy thus delaying mobilization and increasing the duration of hospital stay.

5. Limitation

Use of local infiltration {ropivacaine (0.75%), clonidine, adrenaline, ketorolac and normal saline} can reduce the postoperative blood loss in both the study groups and thus, can act as a confounding factor.

It was a single centre study with small sample size and short duration of follow up done under a single consultant, including only those patients who has given informed written consent. **(Answer to query raised by reviewer#-4).**

6. Conclusion

To conclude, inclusion of drain in primarily TKR surgeries has no significant difference in terms of drop of Haemoglobin, requirement of blood transfusion, wound complications and average amount of hospital stay when compared to TKR done without drains.

Thus, the use of drains confer no added benefits or harm in primary TKR surgeries and their use should be individualised depending upon Surgeons preferences, experiences and set up.

Funding

Study have been approved by the appropriate ethical committee and have been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki. Informed consent has been obtained from patients and full confidentiality has been maintained.

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Credit author statement

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Declaration of competing interest

None.

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Accuracy of magnetic resonance imaging of the knee for intra-articular pathology in children: A comparison of 3T versus 1.5T imaging[☆]



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ABSTRACT

Background: Magnetic resonance imaging (MRI) is an essential tool in assessment of knee pathology in children. Published values demonstrate variable accuracy of MRI, lower accuracy in younger patients, and none compare 3T–1.5T. We aim to assess the accuracy of MRI for anterior cruciate ligament, meniscal, osteochondral and chondral abnormality; and to compare 3T–1.5T MRI.

Methods: Arthroscopy findings and pre-operative MRI reports were reviewed retrospectively. Agreement between MRI report and arthroscopic findings were assessed, using arthroscopy as the gold standard. Sensitivity, specificity, positive predictive value, negative predictive value and accuracy were calculated for all pathologies, and both magnet strengths.

Results: Of 439 patients there were 109 exclusions, 330 patients remained for review. Average time from MRI to arthroscopy was 120 days, with mean age 13.6. Sensitivity for medial meniscal pathology was 78.7%, lateral meniscal pathology 60.4%, ACL rupture 92.5%, OCD 94.2% and chondral change 23.1%. The only significant difference was sensitivity for ACL injury (1.5T: 96.7%, 3T 83.3%, $p = 0.02$), suggesting no disadvantage of 1.5T imaging.

Conclusion: MRI of the knee gives relatively lower sensitivity and accuracy for lateral meniscal tear compared to medial meniscal tear and has poor sensitivity for chondral pathology in children. There is no clear disadvantage of 1.5T imaging compared to 3T.

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1. Introduction

Childhood sports participation is common and sports related knee injuries, particularly anterior cruciate ligament (ACL) and meniscal injuries, are increasing.^{1–4} A history of mechanism and ongoing symptoms are essential for diagnosis, but clinical diagnosis can be more challenging in children. They are often unable to provide a detailed injury mechanism and can be less compliant

with examination. Children tend to have more laxity and therefore clinical findings, such as in ACL injury, can be more difficult to interpret. Imaging is important in supporting a clinical diagnosis and planning treatment. As such, knowledge of the chosen imaging modality is important for a treating surgeon.

Magnetic Resonance Imaging (MRI) is the mainstay of investigation of intra-articular knee injuries. There have been numerous publications on the accuracy of MRI of the paediatric knee (Table 1). Sensitivities for meniscal pathology vary, with a range of 45.5–93% for lateral meniscus, and 50–100% for medial meniscus.^{4–14} There is a relatively uniform finding of a lower sensitivity for lateral meniscal injury than medial meniscal injury, and a finding of generally higher sensitivity for meniscal tear in studies utilising 3T imaging to those using 1.5T or lower. Sensitivity for ACL injury varies between 64% and 95%.^{4–14} The largest series of these studies assessed meniscal injury with 3T MRI, but did not address other

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Table 1

Comparison of previous study results for accuracy of meniscal and ACL injuries and OCD (osteochondritis dissecans) [where meniscal injuries were not separated into medial and lateral, cells are merged showing medial and lateral together].

Reference	Magnet (Tesla)	Slice thickness (mm)	No. of limbs	Medial meniscus (%)		Lateral meniscus (%)		ACL (%)		OCD (%)	
				Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity
King et al 1996 ⁵	0.5	3	26	Sensitivity 100*		Specificity 89*		Not assessed		Not assessed	
Stanitski 1998 ⁶	1–1.5	Not described	28	Sensitivity 50*		Specificity 45.5*		75	100	Not assessed	
Zobel et al 1994 ⁷	1.5	5	30	85	88	80	100	64	94	Not assessed	
McDermott et al 1998 ⁸	1.5	Not described	53	NA†–83‡	65†–80‡	50†–67‡	78†–88‡	87.5	100	Not assessed	
Major et al 2003 ¹⁵	1.5	4	59	92	87	93	95	92	87	Not assessed	
Kocher et al 2001 ⁴	1.5	3 or 4	118	79.3	92.0	66.7	82.8	76	94.1	90.9	97.9
		Not separated									
Lee et al 1999 ⁹	1.5	4	43	Not assessed		Not assessed		95	88	Not assessed	
Sampson et al 2008 ¹⁰	3	Not described	61	91	93	77	93	100	100	Not assessed	
Jung et al 2009 ¹¹	3	Not described	85	100	99	88.5	90	98.5	98	Not assessed	
Kijowski et al 2009 ¹²	3	Not described	100	97	66	80	79	100	98.4	Not assessed	
Magee and Williams 2006 ¹³	3	2	100	Sensitivity 96*		Specificity 97*		Not assessed		Not assessed	
Kijowski et al 2012 ¹⁴	3	1.5	250	95	74	85	82	Not assessed		Not assessed	

* Combined medial and lateral.

† Paediatric patients.

‡ Adolescent patients.

intra-articular pathology.¹⁴

Multiple studies report on MRI appearances and accuracy values for chondral abnormalities in the knee,^{16–18} more recently demonstrating higher sensitivity for more significant abnormalities (8.8% for grade I to 83.3% for grade IV using Outerbridge classification),¹⁹ and also report on specific sequences that may improve sensitivity.²⁰ However, none of these involve assessment in children. There has been one report on accuracy of MRI for chondral change in the paediatric population⁶ from 1998 reporting 0% sensitivity for articular damage in a series of 28 patients. A recent publication reported a high sensitivity for chondral defects, but not chondral damage in general.²¹

Advantages of 3T imaging over 1.5T for imaging the knee are reported^{22–24} but the only direct comparison included only 19 patients with arthroscopy to confirm findings, and all were adults.²⁵ As 1.5T is standard within most UK centres, and 3T imaging is currently only available at our tertiary referral centre for our patients, comparison is valuable to assess whether all imaging should be performed centrally, and/or all utilising 3T modality.

We therefore aim to assess the accuracy of MRI for intra-articular knee injuries, including meniscal and cruciate injuries, osteochondritis dissecans (OCD), and chondral change; and to compare 1.5T and 3T MRI to determine any difference in sensitivity, specificity, negative predictive value (NPV), positive predictive value (PPV), and accuracy in a group aged under 18. The null hypothesis is that there is no significant difference for these values between the different magnet strengths.

2. Methods

Patients having undergone arthroscopy of the knee performed by the senior author were identified through interrogation of theatre management software for the period 1st May 2015 to 30th April 2020 (selected to cover all cases performed by senior author). Electronic patient record review for MRI report (reported by one of two paediatric radiologists with a musculoskeletal subspecialisation for centrally performed scans) and full diagnostic arthroscopy findings, which was used as the gold-standard, and recorded fully for each patient, was performed retrospectively. MRI performed in peripheral hospitals were reported by their local radiologist with subspecialty musculoskeletal interest, and these reports were assessed. The following patients were excluded: age over 18, no pre-operative MRI, second arthroscopy with previous intra-

articular intervention, and any arthroscopy occurring more than 1 year from the time of MRI. This time period was allowed as, although it is possible that meniscal injury can occur due to instability following ACL injury, this concept is controversial, and more likely occurs at time of injury on current evidence.²⁶ Local departmental approval was granted for medical note review.

The following data was recorded: patient age, date of MRI, magnet strength (both 1.5T and 3T scans performed centrally, 1.5T only in peripheral hospitals), date of surgery, MRI report and arthroscopy findings. True and false positive, and true and false negatives were recorded in order to calculate sensitivity, specificity, PPV, NPV, and accuracy. The purpose of this study was to produce clinically applicable data rather than inter-rater and intra-rater reliability, therefore radiologists were aware of clinical details, and a single report was reviewed.

Imaging within our unit was performed on either 1.5T GE Optima (General Electric Healthcare, Chicago, Illinois, USA) or 3T Philips Ingenia (Philips Healthcare, Amsterdam, Netherlands) MRI scanners with both transmit and receive extremity knee coils. The standard protocol was to utilise a 3 mm slice thickness and 0.3 mm interslice spacing, performing axial proton density (PD) fat saturation (FS) from above the patella to the tibial tuberosity, coronal PDFS angled parallel to the posterior femoral condyles, and sagittal T1, T2FS, and T2 gradient echo sequences angled perpendicular to the posterior femoral condyles.

Pathological abnormalities assessed were: medial meniscal tear, lateral meniscal tear, ACL tear/absence, OCD, and chondral change (Outerbridge classification at arthroscopy²⁷ and modified Outerbridge classification on MRI report¹⁹).

Comparisons between MRI report and arthroscopy findings were interpreted as follows where areas of ambiguity could be expected:

- True positive: Same pathology found at arthroscopy as on MRI (similar findings were accepted as a true positive; for example, a posterior meniscal horn tear reported as 'horizontal' on MRI, was accepted to be correct if it was a radial tear, but not if it was in a different location)
- False negative: An MRI report being completely normal and pathology identified at arthroscopy, or a pathology identified at MRI but this was in a different area/significance to the arthroscopy findings (for example, a meniscal tear reported as posterior horn which was found to be in the anterior horn)

In order to perform a comparison with published data, as all previous publications have either used the presence and absence of abnormality^{6,12,14} on both MRI and arthroscopy, or have not described the method used,^{4,10,15,21,22} we will assess our data in this manner in addition.

Statistical analysis was performed using SPSS 23.0 software (IBM Corporation), using a Z-test to compare sensitivity/specificity/PPV/NPV/accuracy for 3T and 1.5T MRI. A 2-sample T-test was performed, after performing a Kolmogorov-Smirnov test for normal distribution, to compare time to surgery in patients.

3. Results

During the studied period, 439 arthroscopies were performed. 109 were excluded for the reasons demonstrated in Fig. 1. 330 procedures remained with preceding MRI for review. 240 MRIs were performed centrally and 90 performed in peripheral hospitals. 125 3T and 205 1.5T scans were performed.

Mean age at time of MRI was 13.5 (range 2.3–17.2), and mean time to surgery from MRI 120 days (range 4–364 days). In the 3T group these values were 13.9 (5.1–17.2) and 117 days (4–364 days), and in the 1.5T group 13.4 (2.3–16.8) and 122 days (6–353 days) respectively. Time from MRI to surgery for both groups were normally distributed and not significantly different ($p = 0.229$) and were therefore comparable. Incidence of the pathologies assessed within the study group is demonstrated in Table 2.

A summary of results is provided in Table 3. These results are for

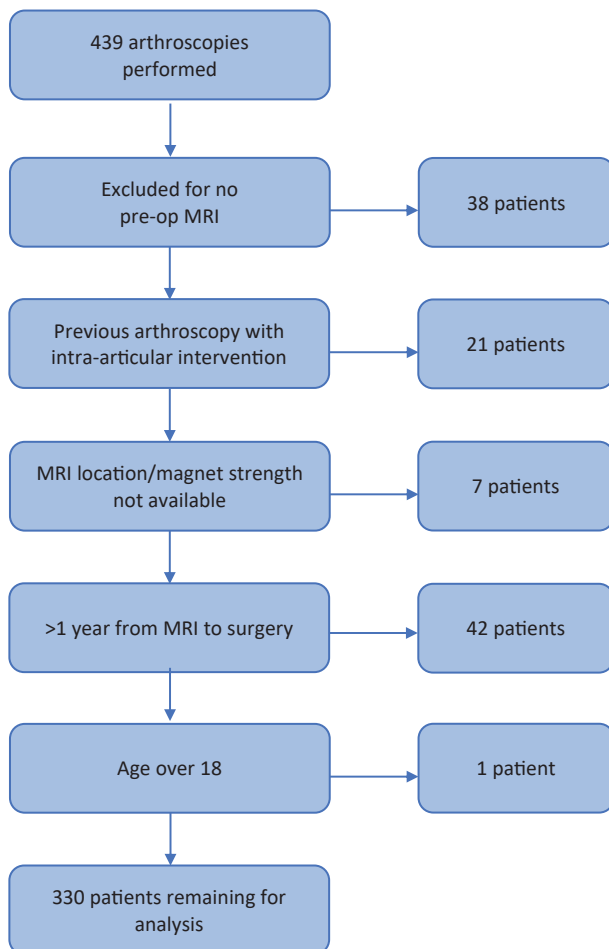


Fig. 1. Flow of participants for inclusion/exclusion.

Table 2
Incidence of pathology within study group, n = 330.

Pathology	Number found at arthroscopy
Medial meniscal tear	47
Lateral meniscal tear	91
ACL rupture	93
OCD	52
Patellofemoral chondral change	75
Tibiofemoral chondral change	51

Table 3
A summary of findings in all patients, 3T only, 1.5T only.

Category	All patients	3T	1.5T
Medial meniscus			
Sensitivity	78.7%	71.4%	81.8%
Specificity	95.8%	96.4%	95.4%
PPV	75.5%	71.4%	77.1%
NPV	96%	96%	96%
Accuracy	93.3%	93.6%	93.2%
Lateral meniscus			
Sensitivity	60.4%	54.3%	64.3%
Specificity	97.1%	96.7%	97.3%
PPV	88.7%	86.4%	90%
NPV	86%	84%	88%
Accuracy	86.9%	84.8%	88.2%
ACL			
Sensitivity	92.5%	83.3%	96.8%
Specificity	99.6%	100%	99.3%
PPV	98.9%	100%	98.4%
NPV	97%	95%	99%
Accuracy	97.6%	96%	98.5%
OCD			
Sensitivity	94.2%	96%	92.6%
Specificity	95.2%	93.8%	96%
PPV	79%	80%	78.1%
NPV	98.9%	98.9%	98.9%
Accuracy	95%	94.25%	95.5%
Chondral change			
Sensitivity	23.1%	25%	21.9%
Specificity	96.5%	96.5%	96.5%
PPV	75%	76.9%	73.7%
NPV	73.2%	73.2%	73.1%
Accuracy	73.3%	73.6%	73.2%

specific injury characterisation. The only significant difference found was for ACL sensitivity ($p = 0.02$), with higher sensitivity in the 1.5T group.

Table 4 demonstrates the results when considering only the presence or absence of pathology, with no significant differences found between 3T and 1.5T for any value (ACL and OCD are not included in this table as the values did not change from Table 3).

Table 4
A summary of findings when only presence or absence of pathology is considered for meniscal injury, comparing 3T and 1.5T imaging.

Category	All patients	3T	1.5T
Medial meniscus			
Sensitivity	84.8%	84.6%	84.9%
Specificity	96.1%	96.4%	95.9%
PPV	78%	73.3%	80%
NPV	98%	98%	97%
Accuracy	94.5%	95.2%	94.2%
Lateral meniscus			
Sensitivity	67.8%	67.7%	67.9%
Specificity	97.5%	96.7%	97.9%
PPV	91%	88.5%	92.7%
NPV	89%	89%	89%
Accuracy	89.3%	88.8%	89.7%

Table 5

Sensitivity for chondral pathology comparing Outerbridge classification at arthroscopy to modified Outerbridge classification on MRI, p value comparing 3T and 1.5T MRI.

Outerbridge grade	All patients	3T	1.5T	P
I (n = 46)	6.52%	8.7%	4.35%	0.597
II (n = 61)	9.84%	14.3%	7.5%	0.846
III (n = 29)	51.72%	58.3%	47.1%	0.598
IV (n = 19)	78.95%	60%	100%	0.032

Sensitivity for ACL tear was 92.5%. There were 7 false negative results. However, 4 of these patients had evidence of partial tear at arthroscopy with no symptoms or signs of instability, and no intervention required. If these patients were to be excluded, sensitivity improves to 96.6%, and NPV to 98.7%. Results of MRI for ACL injury therefore is highly reliable, especially in the presence of no signs of instability on examination.

Considering chondral damage for all grades of pathology, sensitivity is very low at 23.1%. A subgroup analysis comparing patellofemoral abnormality to tibiofemoral abnormality demonstrates these groups to have a sensitivity of 26.7% and 15.7% respectively. Assessing specifically for correlation of the Outerbridge (arthroscopy) and modified Outerbridge (MRI) gradings, has sensitivities demonstrated in Table 5.

There is a trend towards higher sensitivity for higher grade lesions, but no significant difference found between 1.5T and 3T imaging for any grade of abnormality.

4. Discussion

We report the sensitivity, specificity, PPV, NPV and accuracy for MRI assessment of meniscal tear, ACL injury, OCD, and chondral change in children, both for all MRIs performed in our patients, and comparing 3T and 1.5T MRI. We believe this is the largest reported data set of this nature in the literature.

4.1. Overall values

We report the findings in Table 3 as our true values for all of the pathologies assessed, due to the methods used for these results rather than simply the presence or absence of any pathology. Due to methods used in published evidence, however, we have to use Table 4 for comparison in meniscal injury. Sensitivity is comparable in our group to previous data,^{4–14} specifically the finding of relative high sensitivity for medial meniscal tear, and lower sensitivity for lateral meniscal tear.

The interval between MRI and arthroscopy is a mean 120 days for all cases. This is longer than in other publications, despite some of these papers having the same range of data,^{10,14,22} and reflects a fully state funded healthcare system. Change in findings due to the interval to surgery may be expected, for example, in ACL injury where ongoing instability may cause cumulative meniscal damage.^{28,29} However, although delayed surgery has been linked to meniscal tears,³⁰ progression of tears is not yet proven.²⁶ Within our data, no differences in sensitivity for meniscal injury were demonstrated when comparing patients with ACL injury to the whole patient group.

OCD is another pathology where there can be potential change in appearance with time from MRI to surgery. The ROCK (Research in Osteochondritis of the Knee) group recently reported that many MRI features of OCD are unreliable with respect to interrater reliability and more work is required to predict instability and prognosis.³¹ However, we found high sensitivity, specificity and accuracy for OCD, where location, size and stability were assessed,

despite the relatively long interval in comparison to other similar studies. The timing of MRI in the treatment of OCD, and the treatment protocol undertaken, has the potential to affect these values.

The accuracy data we report for all pathologies is relevant for healthcare systems where shorter intervals between MRI and arthroscopy cannot be achieved.

4.2. Chondral abnormality

The accuracy for assessment of chondral change is poor at 73.2% (sensitivity 21.2%, NPV 73.2%) for 1.5T and 73.6% (sensitivity 25%, NPV 73.2%) for 3T MRI, with no significant difference between the two modalities. Comparing for Outerbridge grades, sensitivity is lower for all grades as compared to reported values for the knee in adults,¹⁹ with very low sensitivity for grade I and II abnormality. Assessment of chondral damage on MRI has not been previously evaluated in this way for children and is a valuable finding for consideration in paediatric knee surgery. Our results demonstrate higher values for the patellofemoral joint compared to the tibiofemoral joint when assessed independently, but values are still very low. This may be explained by more difficulty visualising the thinner and more curved chondral surfaces of the tibiofemoral articulation, compared to the patellofemoral joint.

A large proportion of local paediatric knee surgery relates to management of patellofemoral instability. It is essential to assess the patellofemoral joint for chondral change prior to stabilisation procedures, due to the potential to increase pain by increasing patellofemoral contact pressure in procedures such as isolated MPFL reconstruction. Consideration should be given to concomitant arthroscopy in all patients undergoing patella stabilisation procedures on the basis of low accuracy and sensitivity, both to guide prognosis and surgical management. Regarding the tibiofemoral articulation, pre-operative screening for alignment and stability is important as chondral abnormalities may be discovered at arthroscopy which were not expected, and treatment without addressing abnormalities will lead to a higher likelihood of failure.^{32,33} Values also guide consent for adjuvant procedures that should be discussed with the patient prior to surgery, as the need for additional procedures and the effect upon postoperative rehabilitation cannot be predicted from MRI.

4.3. 3T v 1.5T

The main focus of this study was to compare 3T–1.5T MRI. 3T imaging did not demonstrate any significant benefits for any pathology assessed. We therefore accept the null hypothesis of no significant difference between 1.5T and 3T MRI and conclude there is no clear benefit of centralised scanning in order to mandate 3T or reporting of these images by a specialist paediatric musculoskeletal radiologist.

MRI remains the best non-invasive investigation for evaluation of intra-articular knee pathology, and in a patient group who are mostly adolescent and therefore rarely require sedation or anaesthetic, remains an essential diagnostic tool. The orthopaedic surgeon managing paediatric patients with knee pathology must be aware of the values reported in order to accurately evaluate and inform patients.

On the basis of our findings of relatively low sensitivity in areas such as lateral meniscal and chondral pathology, we also support the use of arthroscopy as a diagnostic tool, in select cases, on the basis of clinical findings. In paediatric patients a clinical diagnosis can be more difficult an MRI with questionable accuracy in conjunction, can lead to difficulty formulating a management plan for patients. Diagnostic arthroscopy remains a valuable tool, providing the patient is adequately counselled regards

complications and rehabilitation in the instance of no identifiable pathology. Diagnostic arthroscopy is also supported by an International Olympic Committee statement on the management of paediatric ACL injury for meniscal tear.³⁴

Limitations include the retrospective methodology and also that values can only be calculated from patients who subsequently require arthroscopy. As a result, specificity and NPV values are likely lower than true values, as findings in patients without significant clinical concern and a negative MRI who do not require arthroscopy cannot be verified. Arthroscopy is, however, the gold standard comparison with no better means of determining values.

5. Conclusion

MRI of the knee for assessment of intra-articular pathology is a useful diagnostic tool in a population for whom diagnosis can be difficult. There are limitations with MRI assessment, particularly in lateral meniscal tear and assessment of chondral abnormality. There is no clear advantage of using 3T as compared to 1.5T MRI, and as such no absolute need to perform all scans in a centre with 3T MRI available. The orthopaedic surgeon should be aware of the data on accuracy of MRI and its implications, specifically in surgical planning and the value of arthroscopy in unclear cases.

Credit author statement

Graeme Hancock: Conceptualization, Methodology, Formal analysis, Investigation, Data curation, Writing – original draft, Writing – review & editing, Project administration. Matthew Hampton: Investigation, Writing – review & editing. Penny Broadley: Verification, Resources, Writing – review & editing, Supervision. Fazal Ali: Verification, Resources, Writing – review & editing, Supervision. Nicolas Nicolaou: Conceptualization, Methodology, verification, Resources Writing – review & editing, Project administration, Supervision

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Research paper

Functional outcomes of paediatric medial patellofemoral ligament (MPFL) reconstruction surgery with or without patella distalisation and medialisation for recurrent patella instability

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ABSTRACT

Background: No studies to date have compared the outcome of isolated medial patellofemoral ligament reconstruction (MPFLR) surgery with MPFLR plus re-alignment procedures (MPFLR+) in the paediatric population, making it unclear when additional re-alignment procedures are required.

By retrospectively reviewing and comparing our MPFLR patient cohorts' we aim to generate guidance to aid surgical planning.

Methods: University of Salford ethical approval was secured and theatre records were retrospectively reviewed, identifying all patients less than 18 years-of-age who received MPFLR surgery between October 01, 2015 and October 01, 2019.

All patients were contacted for documented consent. Pre-operative and post-operative outcome questionnaires were reviewed in conjunction with patient's medical records and radiological imaging.

Results: A total of 75 MPFLR surgeries were identified and 33 patients (40 knees) consented for inclusion in the study; 23 MPFLR and 17 MPFLR+. Mean improvement in outcome scores achieved statistical significance ($P < 0.05$) in almost all questionnaire subtypes for both groups. A greater improvement in Quality of life (QoL) correlated with an increased tibial tuberosity–trochlear groove distance (TT-TG) in the MPFLR group 0.557 ($P = 0.025$) and a lower Patellotrochlear index (PTI) - 0.549 ($P = 0.034$) in the MPFLR + group.

Increased Body Mass Index (BMI) correlated with worse outcomes in numerous questionnaire subtypes ($P = 0.05$ and $P = 0.01$) for the MPFLR + group.

Increased Trochlear dysplasia correlated - 0.541 ($P = 0.03$) with less improvement in symptoms following MPFLR + surgery and an increased need for revision surgery 0.312 ($P = 0.053$) in both groups.

Conclusions: Both groups achieved good outcomes and statistically significant improvements in almost all mean outcome scores following MPFLR surgery, suggesting that our current described selection criteria are appropriate. While we were unable to identify any absolute radiological cut off figures in this diverse population with changing anatomy, we recommend additional procedures be considered for high TT-TG distances and or significant patella alta.

Patients with a high BMI should be supported in losing weight prior to surgery and patients with trochlear dysplasia need counselling with regard to potential lesser improvements in symptoms, a higher risk of failure and need for revision surgery. Additional realignment procedures did not appear to offer any improved outcome in the presence of trochlear dysplasia.

Level of Evidence IV: Case series.

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1. Introduction

First time patella dislocation is relatively common, with an estimated annual incidence of 5.8 per 100,000 people, increasing to

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29 per 100,000 in patients aged 10–17 years.¹ It is thought to account for up to 16% of all acute knee trauma in young athletes presenting with haemarthrosis,² and the return to pre-injury levels of sporting activities has been found to be just two thirds with or without surgery.³ Initial treatment is largely conservative but remains controversial with no evidence-based consensus to guide decision making.^{4,5} Re-dislocation rates of up to 71% have been reported,^{6–8} and a long term follow-up study of 100 patella dislocations managed conservatively concluded that re-dislocation rates were too high and not acceptable.⁶

Numerous risk factors for recurrent patella dislocation have been suggested in the literature including younger age of first dislocation, open physes, sports-related injuries, patella alta, trochlear dysplasia, increased tibial tuberosity–trochlear groove (TT-TG) distance, rotational deformity and lateral insertions of the patellar tendon (increased Q angle).^{6,9–11} While it is recommended that all these factors should be considered in operative planning, specific guidance is lacking in the literature.

Medial patellofemoral ligament reconstruction (MPFLR) is commonly recommended,¹² with or without extensor realignment “as needed” in paediatric and adolescent patients⁵ but again guidance is lacking as to when these additional surgical procedures are required. Longo et al.¹³ found no studies to date that have compared the outcome of combined procedures with those of isolated procedures.

We aim to address this by retrospectively reviewing and comparing our patient cohorts that have received isolated MPFLR surgery or MPFLR plus additional re-alignment procedures (MPFLR+) over the last 4 years for recurrent patella instability. By analysing the outcome scores and revision rates in conjunction with the patients pre-operative radiological parameters we aim to generate guidance to aid surgical planning and help achieve successful outcomes.

2. Materials and methods

University of Salford ethical approval was secured prior to the commencement of this study and it was also registered with the Quality and Standards Department at Sheffield Children’s Hospital (SCH).

A retrospective review of the Bluespier Theatre Management system¹⁴ was undertaken identifying all paediatric patients (<18 years of age) who had undergone MPFLR surgery in isolation or with additional re-alignment procedures under the senior surgeons care between the dates October 01, 2015 and October 01, 2019. All identified patients and their parents or guardians were then contacted via post with a request for documented consent for their data to be used in this study.

As part of the senior surgeons routine practice all patients undergoing MPFLR surgery are asked to complete both pre-operative and 6 month post-operative knee outcome score questionnaires, including the Knee Injury and Osteoarthritis Outcome Score for Children (KOOS-Child)¹⁵ and The Pediatric International Knee Documentation Committee (Pedi-IKDC) Subjective Knee Evaluation Form.¹⁶ Both of which have been validated for the use in knee disorders in children.^{15–19} All patients aged 16 years-of-age are asked to complete adult IKDC and KOOS questionnaires, the scores of which are then converted to allow for direct comparison. Tegner activity levels are also routinely collected pre and post operatively.^{20,21}

Reviewing the medical records including the operative note, intraoperative arthroscopic photos, degree of chondral damage, clinic letters and patients’ past medical history; failure of procedure or need for revision surgery were identified and documented. Failure was defined as ongoing or recurrent instability symptoms

and or further dislocation following surgery.

Relevant existing pre-operative radiographs and Magnetic Resonance Imaging (MRI) studies were also reviewed and the following radiological markers were calculated and documented: The tibial tuberosity–trochlear groove (TT-TG) distance as a marker of malalignment,^{22,23,24} the patellochlear index (PTI) described by Biedert²⁵ for the assessment of patellofemoral joint articular correlation and patellar height, and the Dejour classification for grading of trochlear dysplasia.²⁶

All patient data was anonymised and collated in a password protected Microsoft Excel spreadsheet.²⁷ IBM® SPSS® Statistics software²⁸ was then used to analyse the data. Paired student t-tests were used to compare pre and post-operative questionnaire results for statistical significance, while independent t-tests were undertaken to look for statistical significant differences in outcome by side, gender and age. Pearson’s and Spearman’s correlations were then calculated comparing continuous and ordinal variables respectively, with the change in outcome scores between the pre- and post-operative questionnaires.

A preliminary power calculation utilising the pathological threshold value of TT-TG being 20 mm or more²² and a mean TT-TG of 12.2 mm in children with instability symptoms²⁹ estimated that a minimum of 23 operated knees would be required in each group in order to detect a statistically significant difference.

3. Results

3.1. Overview

Between October 01, 2015 and October 01, 2019 a total of 75 MPFLR surgeries were identified as being performed under the senior surgeons care for recurrent patella instability, in patients less than 18 years-of-age; 44 (71%) of the patients were Female (54 knees) and 18 Male (21 knees). Isolated MPFLR was performed in 48 patients (52 knees) and 18 patients (23 knees) received MPFLR+.

All patients had an arthroscopy and all MPFLR surgeries were performed utilising a free hamstring autograft and an anatomic reconstruction technique, similar to that described by Ladenhauf et al.³⁰ Whereby the 2 free ends of the graft are secured in the superior-medial border of the patella using 4.75 mm Arthrex Bio-composite SwiveLock anchors and the double bundled end of the graft is fixed in the distal femur at Schottle’s point with a 6 × 23 mm Biocomposite interference screw following radiological and clinical isometry testing.

The additional re-alignment procedures consisted of 18 Fulkerson Osteotomies, 4 Grammont patella tendon realignment surgeries and 1 Roux-Goldthwait procedure. These enabled medialisation to address high TT-TG distances and distalisation for a low PTI. Medialisation was performed in 20 of the 23 cases, with correction ranging from 5 to 15 mm, with 10 mm being the most frequent performed medialisation distance. Distalisation was performed in 9 cases, with distalisation ranging from 6 to 9 mm as part of 8 Fulkerson osteotomies and 1 skeletally immature patient received 5 mm of distalisation as part of a Grammont procedure. The decision to include distalisation as part of the realignment procedure was made on the combined findings of the clinical examination under anaesthetic and the PTI measurements, all of which measured equal to or less than 0.32.

An additional lateral release was deemed necessary and performed in 3 of the isolated MPFLR cases and 5 of the MPFLR+. This has not been considered separately or deemed a re-alignment procedure as it is utilised for soft tissue balancing and frequently performed at the operating surgeons’ discretion.

A total of 33 patients provided formal written consent to complete follow up questionnaires and be involved in the study,

accounting for 40 primary MPFLR surgeries; 23 of these received an isolated MPFLR and 17 underwent MPFLR+ (See Table 1 for patient demographics).

The mean age at the time of surgery for the consented patients was 13 years and 7 months (range: 10 years 5 months–16 years 2 months) in the isolated MPFLR group and 15 years and 11 months (range: 12 years 3 months–17 years 7 months) in the MPFLR + group.

Radiological parameters were recorded for all patients apart from two, one in each group. The pre-operative imaging for one patient, performed in another hospital was unavailable, and one patient had a Computerised Tomography (CT) scan rather than an MRI resulting in an inability to calculate the PTI. Complete questionnaire data was available for all 17 knees in the MPFLR + group but only 16 knees in the MPFLR group.

Comparing the pre- and post-operative questionnaires, both groups achieved statistically significant ($P < 0.05$) improvement in their mean outcomes for all questionnaires, apart from the KOOS Child Pain subscale in the MPFLR + group ($P = 0.058$). The largest and most statistically significant improvements were seen in the KOOS Child Quality of Life (QoL) subset and the Pedi-IKDC for both groups ($P = 0.000$) (see Table 2).

3.2. Differences in outcome

Comparing the mean outcome differences for the KOOS Child questionnaire between the 2 groups, the isolated MPFLR demonstrated greater improvements in all subsets apart from QoL which was higher for the MPFLR + group. However these differences were not found to be statistically significantly different (see Table 3).

PTI was lower in the MPFLR + group in keeping with a higher degree of patella alta, but didn't reach statistical significance ($P = 0.092$). The only statistically significant difference was in the mean TT-TG measurements ($P = 0.021$) being 15.56 mm in the MPFLR group and 19.13 mm in the MPFLR + group.

3.3. Correlations

3.3.1. Isolated MPFLR group

TT-TG was found to positively correlate with the KOOS child subset for QoL; Pearson Correlation 0.557 ($P = 0.025$), indicating that a higher TT-TG is associated with a greater improvement in a patients QoL following isolated MPFLR surgery (see Table 4). The highest TT-TG for which an isolated MPFLR was performed in our series was 23 mm.

No other statistically significant correlations were identified in the MPFLR group.

3.3.2. MPFLR + group

PTI had a negative Pearson Correlation of - 0.549 ($P = 0.034$) with the KOOS child subset for QoL indicating that a smaller index (greater tendency towards patella alta) is associated with a greater improvement in a patients QoL following MPFLR+ (see Table 5).

Trochlear dysplasia had a negative Spearman's correlation of - 0.541 ($P = 0.03$) with the KOOS child subset for Symptoms, demonstrating that patient's with a higher degree of Trochlear

Table 1
Numbers of operated knees (Consent – 38% of Males / 59.3% Females).

	Female		Male	
	Total	Consented	Total	Consented
MPFLR	36	19	16	4
MPFLR +	18	13	5	4

Table 2

Paired t-test's comparing pre and post operative questionnaires* Correlation is significant at the 0.01 level (2-tailed).** Correlation is significant at the 0.05 level (2-tailed).

Questionnaire's	MPFLR		MPFLR+	
	Mean	Significance	Mean	Significance
<u>KOOS – Child</u>				
Symptoms	-26.000	0.001**	-15.588	0.013*
Pain	-25.187	0.009**	-12.294	0.058
ADL	-27.125	0.003**	-15.706	0.020*
Sport	-35.733	0.003**	-21.187	0.007**
QOL	-26.812	0.000**	-35.529	0.000**
<u>Pedi-IKDC</u>				
Tegner	-30.22000	0.000**	-23.91353	0.000**
	-1.812	0.037*	-1.471	0.010**

** Correlation is significant at the 0.01 level (2-tailed).

* Correlation is significant at the 0.05 level (2-tailed).

Table 3

Paired t-test's comparing continuous variables between both groups.

Measured Differences	Mean	Significance
<u>KOOS – Child</u>		
Symptoms	11.438	0.234
Pain	14.813	0.209
ADL	13.813	0.186
Sport	21.214	0.097
QOL	-7.125	0.412
<u>Pedi-IKDC</u>	9.31250	0.267
<u>Tegner</u>	0.500	0.665
<u>TT-TG</u>	-3.562	0.021*
<u>Biedert PTI</u>	0.09200	0.092
<u>Trochlear dysplasia</u>	0.063	0.843
<u>BMI</u>	-5.235	0.638

** Correlation is significant at the 0.01 level (2-tailed).

* Correlation is significant at the 0.05 level (2-tailed).

Dysplasia achieve less improvement in symptoms following MPFLR + surgery.

The outcomes for patients with Dejour grade A trochlear dysplasia were worse but comparable to those of patients with no dysplasia, while patients with grade B trochlear dysplasia showed less improvement than grade A patients. Grade C trochlear dysplasia patients actually demonstrated a negative improvement in all KOOS outcome scores, suggesting they were worse post-operatively than prior to surgery.

Table 5 demonstrates how an increase in BMI from healthy to overweight and subsequently obese is statistically significantly correlated with a worse outcome in KOOS child subtypes Pain, ADL and Sport ($P = 0.05$), and Pedi-IKDC ($P = 0.01$) following MPFLR + surgery.

No further statistically significant correlations were identified.

3.4. Revision surgery

To date 5 of our patients have encountered failure of their primary MPFLR surgery, experiencing either recurrent instability symptoms and or further dislocation. While the results of the patients who chose not to consent for the study have not formally been included, their records were reviewed and no further failures were identified.

All 5 patients have undergone revision MPFLR surgery, giving us a revision rate of 6.66%, towards the lower end of revision rates reported in the literature for MPFLR in skeletally immature patients, with 13.8% being the pooled average in a recent systematic review and meta-analysis of 21 studies (range 0–38%).³¹

Of the patients requiring revision surgery 3 were female; 2 had undergone isolated MPFLR and 1 had received MPFLR plus a

Table 4
Significant correlations for the MPFLR Group.

		KOOS - Child						
Pearson's		Symptoms	Pain	ADL	Sport	QOL	Pedi-IKDC	Tegner
<u>TT-TG</u>	Correlation Coefficient	0.429	0.362	0.283	0.401	0.557*	0.405	0.160
	Sig. (2-tailed)	0.098	0.169	0.288	0.139	0.025	0.119	0.555
	N	16	16	16	15	16	16	16

** Correlation is significant at the 0.01 level (2-tailed).* Correlation is significant at the 0.01 level (2-tailed).
* Correlation is significant at the 0.05 level (2-tailed).** Correlation is significant at the 0.05 level (2-tailed).

Table 5
Significant correlations for the MPFLR + Group.

		KOOS - Child							
Pearson's		Symptoms	Pain	ADL	Sport	QOL	Pedi-IKDC	Tegner	
<u>PTI</u>	Correlation Coefficient	-0.312	-0.416	-0.371	-0.307	-0.549*	-0.377	-0.213	
	Sig. (2-tailed)	0.258	0.123	0.173	0.286	0.034*	0.167	0.445	
	N	15	15	15	14	15	15	15	
Spearman's									
<u>Trochlear Dysplasia</u>	Correlation Coefficient	-0.541*	-0.398	-0.357	-0.369	-0.485	-0.315	0.366	
	Sig. (2-tailed)	0.030	0.127	0.175	0.176	0.057	0.235	0.163	
	N	16	16	16	15	16	16	16	
<u>BMI Category</u>	Correlation Coefficient	-0.374	-0.508*	-0.517*	-0.507*	-0.480	-0.632**	-0.218	
	Sig. (2-tailed)	0.139	0.037*	0.033*	0.045*	0.051	0.007**	0.400	
	N	17	17	17	16	17	17	17	

** Correlation is significant at the 0.01 level (2-tailed).* Correlation is significant at the 0.01 level (2-tailed).
* Correlation is significant at the 0.05 level (2-tailed).** Correlation is significant at the 0.05 level (2-tailed).

Fulkerson's osteotomy. The other 2 patients were male, 1 had undergone isolated MPFLR while the other had received MPFLR plus a Roux-Goldthwait procedure. Trochlear dysplasia was documented in 4 of the 5 patients; 1 was Dejour grade A, 1 was grade B and 2 were grade C. Hypermobility was recorded for 2 patients and 3 were obese according to their Body Mass Index (BMI).

An additional female patient with hypermobility has undergone a lateral patella-femoral ligament reconstruction as a secondary procedure due to symptoms of medial instability, the MPFLR was found to be intact at the time of surgery.

It would appear that hypermobility and obesity may be associated with an increased risk of failure of the primary surgery; however no statistically significant correlation was found between any of the patient factors analysed and the need for revision surgery. There was a weak correlation (0.312) with increased trochlear dysplasia; but this did not reach statistical significance (P = 0.053).

4. Discussion

By comparing the outcomes of patients who have undergone MPFLR and MPFLR + surgery in our centre it is clear to see that both groups did well; with all mean improvements in outcome scores being above the suggested MCID's and reaching statistical significance (P < 0.05) in all but the KOOS Child Pain subscale for the MPFLR + group (P = 0.058).

While research is ongoing to define the minimal clinically important difference (MCID; the smallest change in score needed for the effect to be considered clinically relevant) for the KOOS Child, Pedi-IKDC and Tegner questionnaires; the KOOS website³² suggests that a change of 8–10 is considered appropriate based on the work by Roos and Lohmander.³³ While the IKDC MCID has previously been reported to be 6.3, 6 months following surgery³⁴ and 9.8 more recently.³⁵ We opted to use the higher end of these ranges when comparing our data and were able to demonstrate high percentages achieving the MCID (see Table 6). All mean improvements in outcome (Table 2) were greater than the upper end

Table 6
Percentage of cases achieving the Minimal Clinically Important Difference (MCID).

Questionnaire	MPFLR	MPFLR +
<u>KOOS - Child</u>	%	%
Symptoms	62.50	58.82
Pain	81.25	41.17
ADL	81.25	41.17
Sport	81.25	52.94
QOL	81.25	82.35
<u>Pedi-IKDC</u>	75.00	70.58

of these suggested MCID's.

It is encouraging and rewarding to see that the largest and most statistically significant improvements were seen in the KOOS Child QoL subset and the Pedi-IKDC for both groups (P = 0.000).

The fact that both groups did well suggests that our current selection criteria for when to undertake additional procedures is appropriate. These are commonly performed for an elevated TT-TG of ≥20 mm in isolation in a skeletally mature patient, or ≥17 mm in a small or skeletally immature patient. Additional procedures are also considered for lower TT-TG distances if significant patella alta and or trochlea dysplasia is present.

However the decision process is often more multi-factorial than this and takes in to account patients' individual anatomy, examination findings and past medical history such as the degree of hypermobility. Some patients and their parents may also opt for isolated MPFLR surgery due to the increased potential complications and the longer rehabilitation time associated with additional realignment surgery. A number of recent papers have also shown that isolated MPFLR can provide a reduction in patellar height measurements potentially avoiding the need for more invasive distalisation procedures.³⁶ However the mean improvements seen are relatively small, and may be more of a consideration in mild cases rather than patients with severe patella alta.

Comparing the 2 groups, the isolated MPFLR demonstrated greater improvements in all subsets apart from QoL which was

higher for the MPFLR + group. However, these differences were not found to be statistically significantly different (see Table 3). The only statistically significant difference was the mean TT-TG measurements ($P = 0.021$) being 15.56 mm (range: 5–23) in the MPFLR group and 19.13 mm (range 12–32) in the MPFLR + group which demonstrates the application of our selection criteria in practice. There was however quite a lot of overlap between the two groups and it is difficult to define a set cut off figure due to the degree of concurrent clinical patella alta and other patient factors as mentioned above.

This is very much mirrored in the literature where there appears to be no real clear consensus on what value is indicative of an elevated TT-TG distance in the paediatric population.¹³ The ‘normal’ TT-TG has actually been demonstrated to increase with age in a recent MRI study,²⁹ although over the age of 11 years (the majority of our patients) there is little increase in the mean value, ranging from 9.1 to 10.7 mm. This is comparable to the reported normal value in adults (9.4 mm)³⁷ so of little help in aiding surgical decision making. They did also show an increased median TT-TG of 12.1 mm in patients with instability, however the TT-TG is greater than this in the majority of our patients and therefore also of little benefit.²⁹ This may however be an area to be explored further in future studies when sub-analysis of sufficient numbers of patients at different developmental stages may provide further insights.

The mean PTI was lower (higher degree of patella alta) in the MPFLR + group as again would be expected, being 0.28 (range: 0.1–0.48) compared to 0.34 (range: 0.09–0.60) but there was also considerable overlap and this didn’t quite reach statistical significance ($P = 0.092$) as an independent variable. Interestingly Lewallen et al.⁹ identified patella alta to be associated with an increased risk of recurrent instability following first time patella dislocation in one study but later found it not to be a significant risk factor in a separate sub analysis of paediatric and adolescent patients.¹⁰ This may suggest there are developmental changes in the normal patellar height from childhood into adolescence and subsequently adulthood, again making it difficult to truly identify any set cut off parameters. There is however little in the literature that documents this. One study that measured and compared the Insall-Salvati index on adolescent and adult knee radiographs did notice a difference, with adults having a higher ratio (more patella alta) than adolescents. However, the difference was not found to be statistically significant.³⁸ Similarly reviewing our data demonstrated no correlation between age and patella height (PTI).

As both groups did well following these selection criteria we recommend that MPFLR + should be considered for an elevated TT-TG of ≥ 20 mm in the skeletally mature and for ≥ 17 mm in the skeletally immature. Additional procedures should also be considered for lower TT-TG distances if significant patella alta is present. This is also supported by the fact that patients with a greater degree of patella alta achieved a statistically significant greater improvement in the KOOS Child QoL subset following MPFLR+ ($P = 0.034$).

While there was no significant difference in BMI between the 2 groups and there was no correlation found with BMI and outcomes in the MPFLR group, this was not the case with the MPFLR + group. Here an increased BMI category (healthy/overweight/obese) statistically significantly correlated with a worse outcome in KOOS child subtypes Pain, ADL and Sport ($P = 0.05$), and the Pedi-IKDC ($P = 0.01$). The reasons for this are likely to be multi-factorial, however the additional procedures undertaken in the MPFLR + surgery often leave patients in more discomfort post-operatively compared to an isolated MPFLR, potentially leading to a delay in post-operative mobilisation. This may be compounded in overweight and obese children due to the increased forces being placed across the operated knee, which are said to be 2 to 3 times

body weight in normal gait, increasing further in knee specific activities.³⁹

It has also been shown that impaired mobility is more prevalent in overweight children and adolescents⁴⁰ who typically display a slower, more tentative walking pattern⁴¹ associated with altered lower limb joint kinematics and kinetics⁴² during normal gait. This is likely to worsen further during the post-operative period potentially resulting in the reduced outcome scores in these patients. We therefore recommend that weight loss should be encouraged in overweight and obese patients, especially prior to MPFLR + surgery. This should be delivered in a multi-disciplinary approach, ideally involving a dietician as this has been shown to be important in helping make new nutritional habits more sustainable.⁴³

There was also less improvement in the KOOS Child Symptoms subset for patients undergoing MPFLR+ with an increased severity of Trochlear dysplasia ($P = 0.03$), with Dejour grade B having lesser improvements in outcomes than type A, and type C scoring worse postoperatively than prior to surgery. While not statistically significant, increased trochlear dysplasia also correlated 0.312 ($P = 0.053$) with a higher risk of failure and need for revision surgery in both groups. Additional realignment procedures did not appear to offer any improved outcome in the presence of trochlear dysplasia.

Trochlear dysplasia has also been previously reported to be associated with an increased risk of recurrent instability following first time patellar dislocation⁹ which makes clinical decision making even more difficult in these patients. We recommend appropriate counselling prior to surgery so that patients and their families are fully aware of the increased risks.

4.1. Limitations

A preliminary power calculation estimated that a minimum of 23 operated knees would be required in both the isolated MPFLR and the MPFLR + groups in order to detect a statistically significant difference. Unfortunately the response to a request for formal written consent to be involved in the study was poorer than we would have hoped, resulting in our numbers being lower than predicted. This may have limited the degree of significance of our findings particularly in regard to the TT-TG, PTI and degree of trochlear dysplasia which were almost statistically significant.

With regard to revision rates however, we did review the notes of all operated patients and didn’t pick up any further failures than those presented here. Due to the lack of formal consent and incomplete functional scores the data for these patients has not been formally included.

The retrospective nature of this study may also have limited our numbers and resulted in less availability of complete patient data and or imaging. While we don’t feel this was a significant problem, it is likely our uptake of written consent would have been higher if collected prospectively.

While the Tegner activity levels were also collected pre- and post operatively these have not been validated in the paediatric population and in fact have been reported to be difficult to use and confusing for children.⁴⁴ The scores added little to this study and we would be unlikely to collect them in any future paediatric studies.

5. Conclusion

Both groups did well and achieved statistically significant improvements in almost all mean outcome scores following MPFLR surgery, indicating it is a good treatment option for recurrent patella instability in the paediatric population. We were unable to

identify any absolute radiological cut off figures in this diverse population with changing anatomy. However greater improvements in KOOS QoL were seen with higher TT-TG distances (up to 23 mm) in our MPFLR group, and with higher degrees of patella alta in the MPFLR + group. Both of which support our current and recommended criteria for the consideration of additional procedures; an elevated TT-TG of ≥ 20 mm in isolation in a skeletally mature patient, or ≥ 17 mm in a small or skeletally immature patient. Additional procedures should also be considered for lower TT-TG distances if significant patella alta is present.

Additional realignment procedures did not appear to offer any improved outcome in the presence of trochlear dysplasia and patients with more severe dysplasia (grades B and C) had worse outcomes following MPFLR + surgery. Patients with trochlear dysplasia were also found to have a higher risk of failure and be more likely to require revision surgery in both groups. These patients will require appropriate counselling prior to surgery. Patients with a high BMI category (overweight and obese) had worse outcomes with MPFLR + surgery and should be supported in losing weight prior to surgery.

5.1. Take home messages

MPFLR surgery is a good treatment option for paediatric patients with recurrent patellofemoral instability. However a thorough pre-operative work-up is required with detailed imaging in the form of an MRI scan and patients with an increased TT-TG distance and/or patella alta are more likely to benefit from addition realignment procedures.

Poorer outcomes are more likely with both MPFLR and MPFLR + for patients with trochlear dysplasia and patients with an elevated BMI. Appropriate counselling is required and weight loss support should be offered prior to surgery.

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Review article

Management of recurrent patellofemoral instability with patella alta in the skeletally immature



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ABSTRACT

A significant contributing factor to recurrent patella instability in the skeletally immature child is patella alta. Tibial tubercle transfer is contraindicated in the skeletally immature child due to the significant risk of anterior tibial growth arrest. In this review article, we explore the clinical findings, investigations and the past and present treatments used to manage patella alta in the skeletally immature child. We also explore the use of medial patella femoral ligament reconstruction and future considerations in this field.

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1. Introduction

The aetiology of recurrent patella instability in the skeletally immature child is multifactorial.^{1–3} One significant contributing factor is the height of the patella.⁴ A high riding patella (patella alta) is common. It is reported to be present in 50–60% of patients with a first time dislocation⁵ and in approximately 30% of patients with recurrent patella dislocations.⁶ Abnormally high patella height results in decreased resistance to lateral translation of the patella due to limited contact within the femoral trochlea.^{7,8} Recurrent patellar instability persists in approximately 50% of adolescent patients who present with a first-time patella dislocation^{9,10} and the presence of patella alta increases the likelihood of this recurrence along with other factors such as the presence of trochlea dysplasia and abnormal Tibial Tubercle-Trochlea Groove (TT-TG) distance.¹¹ Recurrent instability will often require surgical stabilisation which presents specific challenges in the skeletally immature child due to the presence of an open proximal tibial physis.

The most common surgery to stabilise the patella in skeletally immature children is an anatomic reconstruction of the medial patellar femoral ligament (MPFL) used in isolation, but there are

concerns that this does not always address the underlying causative pathology.¹² Failure to address patella alta when identified pre-operatively can increase the risk of failure of surgical stabilisation procedures.¹³ In addition, the presence of patella alta affects the isometry of MPFL reconstruction.¹⁴

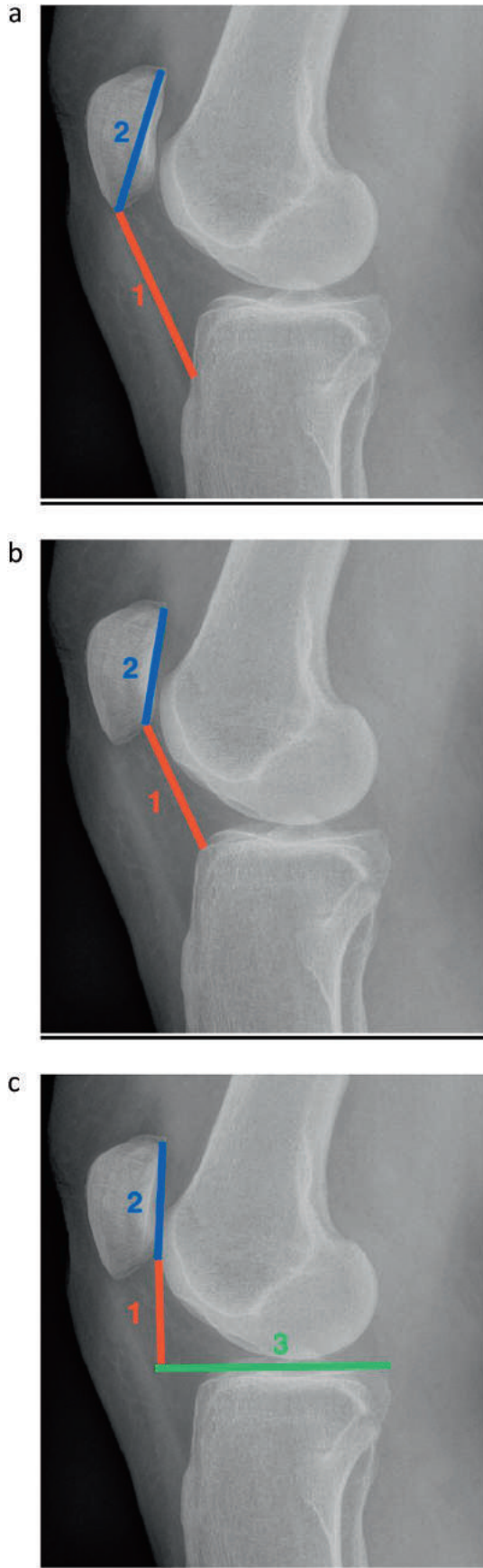
The objective of surgery to treat patella alta is to reduce the height of the patella. In the skeletally mature patient this can be effectively achieved by performing a distalising osteotomy of the proximal tibial tubercle.^{15,16} However, this technique is contraindicated in patients with an open proximal tibial physis due to the significant risk of physeal growth arrest and secondary recurvatum deformity.¹⁷ Reducing patella height in the skeletally immature child therefore commonly involves surgery to directly reduce the length of the patella tendon.

The aim of this review article is to explore both the clinical and radiological methods used to identify patella alta, the surgical methods which can be utilised to distalise the patella in the skeletally immature child and a comparison of these methods with isolated reconstruction of the MPFL.

2. Clinical examination and identification of patella alta

A thorough systematic clinical assessment is required in children presenting with patella instability. The clinical examination begins with an assessment of generalised laxity. The Beighton score

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Is a validated score to measure this with a score greater than 5/9 representing a diagnosis of hyperlaxity in adults.^{18–20} Controversy exists about the exact Beighton score that should be used to diagnose hyperlaxity in children. Some studies suggest that the cut off should be lower, with a Beighton score of 4 possibly representing hypermobility in children.¹⁹

Lower limb coronal and sagittal malalignment can be assessed with the child standing and during gait. Torsional malalignment should be suspected by excessive foot or patella progression angles during gait. A formal rotational profile should then be undertaken to identify any femoral or tibial torsional malalignment issues.

Patella tracking is an important aspect of the clinical assessment. This is best achieved with the child sat over the edge of the clinical examination table while observing tracking with active flexion and extension of the leg.

The 'J-sign' is an observed lateral translation of the patella during leg extension, indicating disengagement of the patella from the femoral trochlea. It can be associated with both patella alta and/or trochlea dysplasia.

Patella translation should be tested in both extension and 30° of flexion when the patella should be engaged in the trochlea.²¹ Excessive translation of greater than 2 quadrants would be indicative of excessive patella mobility and could suggest patella alta. With continued passive lateral translation of the patella the knee can slowly be flexed, whilst observing the patient for signs of apprehension. Apprehension in deeper flexion also can suggest the presence of trochlea dysplasia and/or patella alta.²²

Identification of excessive patella height can be challenging to ascertain on clinical examination alone and it is therefore important to arrange further diagnostic imaging to identify and quantify patella alta.

2.1. Imaging for patella alta

Patella alta can be primarily identified from plain radiographs. Anterior-posterior (AP), lateral and skyline views should be arranged. The lateral radiograph is the most important radiograph to quantify the severity of patella alta and should be taken with the knee in 30° of flexion with overlapping of the femoral condyles to allow accurate and reproducible measurements between patients.

There are multiple methods described to assess the patella height on the lateral radiograph in adults. The most commonly described methods are the Insall-Salvati ratio,²³ Blackburne-Peel ratio²⁴ and the Caton-Deschamps index (CDI).²⁵ (Fig. 1a–c).

Both the lack of ossification around the knee and expected skeletal growth in a child means patella height ratios described in skeletally mature patients should be used with caution in children.

Micheli et al.²⁶ recognised this in 1987 and described a new technique specific to children. Based on the AP radiographs, they calculated the patella length using the difference between the inferior pole of the patella and the tibial plateau. Measurements were recorded on serial radiographs during skeletal growth. They highlighted that the measurements of patella height are dependent on skeletal growth and patella alta can become acquired during growth.

This theory is supported by Walker et al.²⁷ who showed that the Insall-Salvati ratio is consistently high in young children and this ratio gradually decreases with age. They suggest that the Insall-Salvati ratio could be applied to girls at approximately 10 years of age and boys at 12 years.

Fig. 1. a–c: Radiographic measurements to identify and quantify patella alta. The Caton-Deschamps index is the most reliable measurement in the skeletally immature patient.

Another measurement specific to children was described by Koshino and Sugimoto.²⁸ They also found that the Insall-Salvati method is unreliable and significantly over diagnoses patella alta in children. They found patella alta to be present in 3.4% of patients in their cohort. This number increased to 67% when applying the Insall-Salvati ratio to the same cohort. The described method uses the midpoints of the femoral and tibial physis to calculate a ratio between the patellotibial distance and the tibiofemoral distance. This technique is unique and suitable for the growing child as it eliminates the need to adjust for epiphyseal ossification and can be applied to knee flexion angles between 30 and 90°.

Although specific to the growing child Koshino and Sugimoto's method was found to be less reproducible than the Caton-Deschamps ratio in children, with a lower inter-observer reliability.²⁹ While originally described in skeletally mature patients the Caton-Deschamps ratio has been validated for use in children with excellent inter and intra-observer reliability.^{30,31} It is crucial that the Caton-Deschamps ratio is correlated closely with the patient's age as the patella length changes significantly as the child grows. The normal age-based Caton-Deschamps values should be used on an individualised case by case basis.

In 2006 Biedert and Albrecht³² introduced a new method to measure patella height using sagittal MRI. This patellochlear index creates a ratio between the true articular cartilage overlapping the patella and the trochlea (Fig. 2). The normal range in patients without patellofemoral pathology was 0.12–0.80 with values less than 0.12 indicating patella alta. Use of MRI has advantages in the standardised methods by which the limb is positioned for imaging and avoids the common error of lateral radiographs being performed in varying degrees of knee flexion.

2.2. Is there a role for tibial tubercle osteotomy?

A tibial tubercle osteotomy is a powerful and commonly utilised tool to treat patella alta in the presence of recurrent patellar

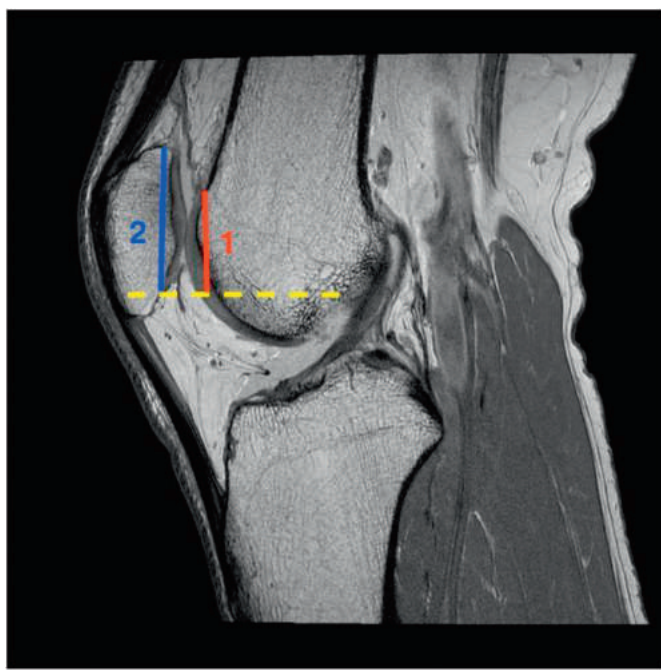


Fig. 2. The patellochlear index (PTI) is calculated from the sagittal MRI slice with the maximum patellar cartilage thickness and the maximal craniocaudal diameter of the patella. Line 1 is divided by line 2 to create a ratio. Normal range is 0.12–0.50 with less than 0.12 representing patella alta.

instability. The tubercle can be effectively distalised to reduce the patella height while also addressing an increased TT-TG measurement with concomitant medialisation of the tubercle and anteriorisation to offload lateral and central patella chondral damage.^{33,34} Unfortunately, osteotomy of the tibial tubercle is contraindicated in the growing child with an open proximal tibial physis due to the significant risk of anterior tibial growth arrest.^{35,36} The proximal tibial physis is sensitive to growth arrest which can occur following trauma, surgery and excessive plaster cast treatment.

The sequelae of anterior tibial growth arrest include recurvatum and typically valgus deformity of the proximal tibia producing leg length discrepancy, pain, instability and osteoarthritis. The resultant deformity may require extensive surgical treatment with epiphysiolysis, guided growth, corrective osteotomies and potentially limb lengthening procedures.^{37–39}

Due to the expected concerns regarding iatrogenic growth arrest there are few published outcomes of tubercle transfers in the growing child. Harrison et al.⁴⁰ suggests it is safe to perform tubercle transfers in children aged greater than 14 years, but this was only a small series of 27 knees in 1955. This is further supported by Crosby and Insall's series who also observed growth arrest in patients aged under 14 years.⁴¹ The resultant deformity in both series was recurvatum. Neither of these studies effectively assessed deformity parameters. If considering a tibial tubercle osteotomy in a child approaching skeletal maturity it is important to ensure accurate measurements of bone age are performed with close follow up and careful assessments of alignment, in particular tibial slope. However, tibial tubercle osteotomy in the skeletally immature cannot be recommended based on the current available evidence.

It is also common for skeletally immature patients with patella alta and abnormal TT-TG measurements to be 'left' due to the concerns of performing additional realignment procedures, or simply overlooking the pathology. In such cases, the concern is not only ongoing symptoms, but the risk of chondral damage and subsequent osteoarthritis that may arise from repeated episodes of instability.

2.3. Techniques and outcomes of patella distalisation in the skeletally immature

Patella alta in the skeletally immature child can be surgically treated to directly reduce the height of the patella whilst preserving the proximal tibial physis. This has commonly been attempted using varied techniques: The Roux-Goldthwait procedure, patella tendon shortening procedures^{42,43} and the Grammont procedure (Table 1).

The Roux-Goldthwait procedure was originally described in 1888 by Roux⁴⁴ with a further modification by Goldthwait⁴⁵ in 1895. It is described as a hemi-patellar tendon transfer to be performed in patients with recurrent patellar dislocations. The patellar tendon is split vertically with the lateral half of the tendon transferred beneath the remaining medial half of the tendon and secured to the periosteum of the tibia. The procedure has commonly been combined with either open or arthroscopic lateral retinacular release.^{46,47} The procedure has respectable success with an average re-dislocation rate of 6.6% across multiple small retrospective studies.^{48–50} Despite the low re-dislocation rates patients appear to remain apprehensive following the procedure with 18.2–61% of patients having persistent positive apprehension tests following surgery.^{51,52} The Roux-Goldthwait procedure does not appear to effectively reduce patella height as desired. Aarima et al.⁵¹ report the greatest reduction in patella height with a mean reduction in patella tendon length of 7% following surgery, with reduction in the Insall-Salvati ratio from 1.15 to 1.07 following

Table 1

Table illustrating the pros and cons of the different distalising procedures.

	Pros	Cons
Roux-Goldthwait	<ul style="list-style-type: none"> • Avoids disruption of the tibial tubercle • Re-dislocation rate of 6.6% when combined with lateral retinacular release • Unlikely to cause growth arrest 	<ul style="list-style-type: none"> • Patients remain apprehensive following surgery • Patella height is not reduced by the procedure • Higher re-dislocation rate compared to other distalising procedures • Concerns about patellofemoral OA • 82% recurrent dislocation rate in long term follow up • Further procedures to stabilise patella likely required
Galeazzi	<ul style="list-style-type: none"> • Avoids disruption of the tibial tubercle • Early re-dislocation rate less than 10% • Does not cause growth arrest 	<ul style="list-style-type: none"> • Growth disturbance possible. Alterations in tibial slope has been reported in 10% of cases • Concerns about patellofemoral OA • Understanding of the changing relationship between the femoral MPFL insertion and the distal femoral physis is vital • No long term follow up data of this procedure • 16.7% complication rate, often due to surgical technique and post-operative rehabilitation
Grammont	<ul style="list-style-type: none"> • Allows distalisation and medialisation and can be combined with MPFL reconstruction 5.9% re-dislocation rate 	<ul style="list-style-type: none"> • Growth disturbance possible. Alterations in tibial slope has been reported in 10% of cases • Concerns about patellofemoral OA • Understanding of the changing relationship between the femoral MPFL insertion and the distal femoral physis is vital • No long term follow up data of this procedure • 16.7% complication rate, often due to surgical technique and post-operative rehabilitation
MPFL	<ul style="list-style-type: none"> • Ability to perform safely in all age groups with anatomic and non-anatomic techniques • Lowest reported re-dislocation rate, less than 5% • Can cause growth disturbance • Can be combined with MPTL and/or MQTFL reconstructions in cases of patella alta • Appears to reduce patella height in the growing child • Should be considered the new gold standard 	<ul style="list-style-type: none"> • Contraindicated with open physis due to significant risk of growth arrest. Not recommended in the skeletally immature • Non-union associated with distalisation
Tibial tubercle transfer	<ul style="list-style-type: none"> • Allows for accurate distalisation of patella • Able to correct a raised TT-TG distance as well as alta • Good outcomes and can be combined with MPFL reconstruction for patella alta 	<ul style="list-style-type: none"> • Contraindicated with open physis due to significant risk of growth arrest. Not recommended in the skeletally immature • Non-union associated with distalisation

surgery. Both Malecki et al.⁵² and Sillanpaa et al.⁵³ reported persistently raised Caton-Deschamps index and Insall-Salvati ratios respectively. Early post-operative complications are rarely encountered and importantly there are no reports of growth arrest following this procedure. The success of the Roux-Goldthwait may represent the non-anatomical reconstruction of the Medial Patellofemoral Ligament (MPTL) as opposed to dealing with patella height. A review of 35 patients with a mean follow up of 8 years at our own unit found a re-operation rate of 30% with mean post-operative Kujala score of 68.0 and Lysholm-Tegner score of 69.6. Patella alta was the main risk factor identified for re-operation. Often performed with other surgical procedures, it is difficult to tease out the contribution of the Roux-Goldthwait as an isolated procedure,⁴⁸ but it is no longer used at our centre.

Galeazzi described a tenodesis technique in 1922,⁵⁴ the semitendinosus tendon is harvested and left attached at the pes anserinus, it is then fixed to the patella in an oblique manner. Early results using this technique were promising with both Letts et al. and Hall et al. reporting good to excellent results with a re-dislocation rate less than 10%. Despite early reported success, Grannatt et al.⁵⁵, with a longer term follow up study failed to replicate the early promise seen. In the 34 patients included in the study 38 (82%) had recurrent patella instability with 41% of those patients requiring further surgery to stabilise the patella-femoral joint. This is again a non-anatomical form of MPFL reconstruction.

In 1985 Grammont⁵⁶ described another procedure proposed to alter both the patella height and the mechanics of the patella tendon without disrupting the tibial tuberosity. Here the deep patella tendon fibres are peeled off the cartilaginous tibial tuberosity, while maintaining the distal tendon attachment to the periosteum. This allows both distalisation and medialisation of the patella tendon. Kraus et al.⁵⁷ reported good long term outcomes using the Grammont procedure in 65 knees. They saw improvement in functional outcome scores and reported 11 post-operative re-dislocations (8 early, 3 late dislocations) for the procedure performed in isolation. There were no reports of growth disturbance in their series. Despite the results of this study there are concerns regarding both growth disturbance and extensor mechanism failures when using this technique. In a large series of 50 knees treated with the Grammont procedure Garin et al.⁵⁸ reported a high (10%)

incidence of changes in the tibial slope, greater than 5°. This may be partly due to the surgical technique employed to peel the tendon off the sensitive tibial tuberosity, whilst also suggested to be caused by vascular disruption.⁵⁸ (Fig. 3a and b).

Patellofemoral osteoarthritis (OA) has been reported in long term follow up studies of both the Roux-Goldthwait and the Grammont procedure, seen in up to 25% of patients.⁵⁹ It is not known if it is the nature of recurrent patellar instability that causes the increase risk of OA or the procedures themselves. The presence of chondral damage sustained due to patella dislocation is thought to be the main cause of arthritis following patellofemoral instability.⁶⁰

Due to the perceived unacceptably high re-dislocation rates, disruption to the extensor mechanism and possible risks of secondary OA these procedures have until recently been largely superseded by isolated reconstruction of the MPFL.

2.4. Isolated MPFL reconstruction in patella alta

Reconstruction of the MPFL is the most commonly performed procedure for recurrent patella instability in the skeletally immature. In a child with considerable remaining growth a non-anatomic extra-osseous reconstruction is utilised by some due to the close relationship the femoral MPFL origin shares with the distal femoral physis and concerns of growth disturbance.^{61,62} Surprisingly, anatomic studies suggest the relationship to the physis and perichondral ring of the native MPFL is closer in adolescents.^{63,64} An anatomic reconstruction can be safely performed in the skeletally immature patient, although care must be taken if bone tunnels or sockets are used for the femoral fixation, aiming distally and anteriorly to avoid the femoral notch, articular surface of the lateral femoral condyle as well as the physis.⁶⁵ Epiphyseal fixation and anatomic reconstructions are likely to improve isometry and long term survival of the reconstructed ligament.⁶⁶

Despite the success reported with MPFL reconstruction there is still concern that underlying pathology is not addressed, specifically patella alta, lateralised extensor mechanism and trochlea dysplasia. Patella alta will also affect the isometry of the reconstructed MPFL,^{67,68} and the more severe the alta the less likely it is that this will work both in terms of isometry and longevity.



MPFL reconstruction in skeletally immature children reduces re-dislocation rates when compared to the traditional distal realignment procedures. In a systematic review by Shamrock et al.⁶⁹ the re-dislocation rate of MPFL reconstruction was less than 5% in 132 skeletally immature knees. Parikh et al.⁷⁰ reported the outcomes of 179 consecutive cases of MPFL reconstructions performed in children and adolescents, with a 4.5% re-dislocation rate at average 16.2 months follow up. Note that in all of these studies the follow up period is short.

A systematic review by Bartsch et al.⁷¹ reviewing isolated MPFL reconstructions concluded that additional distalisation procedures are not required for patients with a pre-operative CDI of 1.2–1.4 with no difference in outcomes observed when compared to patients with normal pre-operative patellar height. Interestingly isolated MPFL reconstruction has been observed to reduce the patellar height in patients with patella alta.⁷² Lykissas et al.⁷³ and Fabricant et al.⁷⁴ both observed significant reductions in patella height measurements in patients with pre-operative patella alta treated with MPFL reconstruction alone, a trend also identified in adults.⁷⁵

It appears that MPFL reconstruction is a powerful tool in the management of recurrent instability in the skeletally immature child. Although the concerns about growth arrest can be avoided with MPFL reconstruction it isn't without potential complications. Parikh et al.⁷⁰ reported a 16.7% complications rate including stiffness, re-dislocation and patella fractures. There are also concerns with cases of severe patella alta, often encountered in the very young, that isolated reconstruction will not suffice in preventing recurrence, and may lead to pain and early failure due the reconstructions anisometric nature (Fig. 4a – 4d).

2.5. Patella alta and failure rates with isolated MPFL

Multiple risk factors have been associated with failed isolated MPFL reconstruction, and in older cohorts the role of patella alta is well described.⁷⁶ Success of reconstruction is limited to short term studies, with long term outcome data lacking.⁷⁷ Patella alta often co-exists with trochlea dysplasia and a lateralised extensor mechanism, and so it is at present evident that in mild cases MPFL reconstruction may suffice, but this is yet to be proved in the medium to long term. The contribution of patella alta in failure is difficult at present to determine. When performing an isolated MPFL reconstruction in the skeletally immature, it is always important to consider all other potential contributing factors to the instability. The success of the MPFL reconstruction undoubtedly depends on the ability to correct the driving underlying mechanics behind the patella instability.

2.6. Future developments

A better understanding of the anatomy of the soft tissue constraints to lateral patellofemoral dislocation has led to modified reconstruction procedures that may evolve to play a role in those skeletally immature patients with multiple risk factors.⁷⁸

In patients with severe patella alta an MPFL reconstruction can be augmented with reconstruction of the MPTL. Yang and Zhang⁷⁹ reported excellent outcome scores, with no post-operative dislocations and significant reductions in patellar height ratios in 58

Fig. 3. a: Modified Grammont procedure in a 11-year-old with recurrent patellofemoral instability. The patella tendon has been elevated from the tibial tuberosity, medialised, advanced and fixed using two all suture anchors. **b:** The same clinical case, partial thickness central quadriceps autograft harvested. The guidewire is placed at the upper third of the medial patella, and the graft passed under the vastus medialis before fixation to the patella, and then to the femur.



Fig. 4. a and b: AP and lateral radiographs of the same 11 year old skeletally immature girl presenting with recurrent patella instability. Radiographs identify the presence of significant patella alta. Subsequent MRI revealed a concomitant raised TT-TG distance. **c and d:** Post-operative AP and lateral radiographs of the same 11 year old girl. Patella stabilisation surgery involved a quadriceps autograft MPFL reconstruction, combined with a distalising and medialising modified Grammont procedure.

patients treated with this combined technique for recurrent instability in the presence of severe patella alta. The current difficulty in assessing the success of this technique when combined with MPFL is the heterogeneity of techniques used.⁸⁰

The medial quadriceps tendon femoral ligament (MQTFL) is also a possible important contributing part of the MPFL and reconstruction of this is increasing in popularity.^{81,82} The dynamic elements of this reconstruction due to the insertion on the quadriceps tendon may improve dynamic stability. Originally this technique was utilised to reduce the associated risk of patella fracture that occurred with patella fixation in the early era of MPFL reconstruction,⁸³ but as understanding increases of the anatomy, it is likely that combined techniques of MPFL, MPTL and MQTFL will develop for the at risk paediatric cohort.

By treating instability at a young age, the potential for realignment of the patella may lead to a resultant improvement in the development of trochlea anatomy. Historical studies have identified that remodelling does occur, although many studies are limited to congenital and habitual patella dislocation.^{84–86} More contemporary evidence suggests that remodelling of the trochlea does not occur in the older paediatric cohort beyond 10–11 years of age.^{87–89} If this is the case, intervening earlier in symptomatic recurrent dislocation in cases with multiple morphological abnormalities may potentially improve long term outcomes.

Combining correction of alta and lateralised extensor mechanism in the skeletally immature may therefore improve the one factor that cannot safely be corrected in all but those who are at the cusp of maturity, that is trochlea dysplasia.^{90,91}

3. Summary

Recurrent patella instability in the presence of patella alta is a challenging problem encountered in the skeletally immature. The CDI is the most reliable radiographic measurement for diagnosing and quantifying patella alta but must correlated with the patients age. The presence of patella alta can be confirmed on the MRI scan by using the patellochlear index. Traditionally patella alta was treated using distal re-alignment techniques to avoid inadvertent damage to the proximal tibial physis when performing tibial tubercle transfer. Long term results of distal re-alignment procedures have highlighted high rates of patellofemoral OA, re-dislocations and in some cases growth arrest. These techniques are now largely superseded by reconstruction of the MPFL. Results suggest good short-term outcomes with low re-dislocations rates and improvements in patella height ratios in some studies when performed in patients with patella alta. In patients with mild patella alta MPFL reconstruction can be augmented with MPTL or MQTFL reconstruction with good results, although further studies are needed to identify if isolated soft tissue procedures perform well in the medium to long-term, especially where the patella alta is significant.

Author credentials

Matthew Hampton, Specialist orthopaedic registrar, MBChB, MRCS. Contribution: Study design, wrote manuscript, manuscript preparation. Fazal Ali, Consultant Orthopaedic surgeon, MBBS, FRCE (Eng), FRCS, (Tr&Orth). Contribution: Study design, manuscript preparation. Nicolas Nicolaou, Consultant Orthopaedic surgeon, Bsc (Hons), MBBS, MRCS (eng), MSC, FRCS (Tr&Orth). Contribution: Principal investigator, study design, manuscript preparation.

Declaration of competing interest

None.

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Research paper

Return to work after medial opening wedge high tibial osteotomy

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ABSTRACT

Background: High tibial osteotomy (HTO) is frequently performed in young and physically active patients with knee medial compartment osteoarthritis and varus deformity. There is however, limited evidence on the function of patients after returning to work following HTO. The main objective of this study was to evaluate the return to work following medial opening-wedge HTO in our institution.

Methods: Patients who underwent medial opening wedge HTO were identified and sent a questionnaire to assess their type of employment, as well as their return to work and function at work following surgery. Work related outcomes were assessed using the Workplace Activity Limitations Scale (WALS), whilst quality of life and satisfaction with surgery was assessed using the EQ-5D and Visual Analogue Scales (VAS).

Results: There were 42 patients identified in the study. The mean time to return to work was 2.6 months, with 79% of patients returning to work by 3 months. The mean WALS score was 5.4 and the mean EQ-5D was 0.77. The mean VAS for quality of life was 77.9 and mean VAS for satisfaction with surgery was 58.3. In patients with light intensity physical jobs, however, mean satisfaction with surgery increased to 86. Survivorship of HTO was 93% in this series.

Conclusions: Medial opening-wedge HTO is an effective treatment method for patients who are still in active employment. The majority of patients return to work within 3 months of surgery and demonstrate good function at work. Patient satisfaction with surgery, however, is higher in less physically demanding jobs.

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1. Introduction

Osteoarthritis of the knee is a common condition causing pain and loss of function.¹ High tibial osteotomy (HTO) is a treatment option for patients with a varus deformity and medial compartment osteoarthritis of the knee.² The objective of HTO is to realign the mechanical axis thereby unloading the medial compartment, reducing pain and delaying joint replacement surgery.^{2–5}

In comparison to a lateral closing wedge HTO, a medial opening wedge HTO is inherently less stable.² However the reported advantages include a reduced risk of neurovascular injury, less soft tissue stripping, non-disruption of the proximal tibio-fibular joint and more accurate angular correction.¹ Development of new, robust fixation technologies which enable a stable osteotomy and early weight bearing in the postoperative period has contributed to the

increasing use of this procedure.^{2,6,7} Significant improvements in pain and functional scores have been reported following HTO with five to ten year survivorship ranging from 74% to 92%.^{1,5,6,8,9}

HTO is performed in young and active patients, with return to work an important functional outcome.^{2,8} However, there are limited studies in the current literature evaluating return to work following HTO. A recent review article noted that majority of the published studies lacked systematic evaluation of return to work.⁵ Furthermore there is no consistent criteria for return to work following HTO.⁷

Hence the main objective of this study was to evaluate the return to work following medial open wedge HTO in our institution.

2. Methods

2.1. Subjects

Following institutional approval for the study, all medial opening wedge HTO procedures, which were performed in our

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department, between 2004 and 2016, were identified using an electronic patient database.

Inclusion criteria for the study were radiographic evidence of medial compartment knee osteoarthritis, medial joint pain, and varus malalignment. Exclusion criteria included severe obesity (body mass index (BMI) > 40), symptomatic osteoarthritis of the lateral compartment, rheumatoid arthritis, extension deficit >15° and severe ligamentous deficiencies.

Case notes were reviewed to obtain demographic details, operation notes and functional outcomes. Pre and postoperative radiographs including long leg alignment views were reviewed and the mechanical axis was measured using Picture Archiving and Communication System (Philips, Netherlands).

2.2. Surgical technique

All patients underwent an arthroscopy either prior to or at the time of HTO and the osteoarthritis grade in the medial compartment was documented.¹⁰ All operations were performed by a single surgeon (HSG) using the medial opening wedge HTO technique described by the AO expert group.^{11,12} Implants used included the Puddu plate (Arthrex; Naples, Florida) and subsequently the TomoFix plate (Synthes GmbH, Oberdorf, Switzerland). Bone graft was not routinely used, unless a large correction was performed. Postoperatively patients underwent routine rehabilitation and were allowed to weight bear as tolerated.

2.3. Outcome assessment

Patients received a questionnaire to assess work related function, overall quality of life and satisfaction with surgery by reporting how likely they would be to undergo the operation again (Fig. 1). Function at work was assessed using the Workplace Activity Limitations Scale (WALS), which evaluates function at work across 12 domains, total score 0–36, with a lower score indicating better function.¹³ Quality of life was assessed using a visual analogue scale (VAS) and the EuroQoL-5D (EQ-5D), which assess quality of life across five domains, total score 0–1, with a higher score indicating better quality of life.^{14,15}

Additionally, the questionnaire included information about their type of employment and their return to work postoperatively. Employment types were broadly categorised into high work intensity (lifting and wearing of a burden greater than 15 kg, climbing stairs or ladders with load, work in constrained postures like shoveling or digging); moderate work intensity (lifting and wearing of a burden of 10–15 kg), and low work intensity (working in a sitting position, handling light work objects, walking or standing), as has been reported by previous authors.⁶

2.4. Statistical analysis

Data was collated and analysed using Excel (2013, Microsoft, USA) and SPSS (v20, IBM, USA). Normality was assessed using the Shapiro-Wilks test.

3. Results

3.1. Demographics

In total 46 procedures (42 patients) were identified and 29 patient questionnaires were obtained (69% follow up). Patients completed the outcome questionnaires at mean time of 47.4 months (range 6–100) from the time of surgery.

The mean patient age was 46 years (range 33–63), 37 (88%) patients were male, mean grade of American Society of

Anaesthesiologists physical status classification system was 1.3 (range 1–3), and mean BMI was 29 (range 20.3–36.8). The mean grade of osteoarthritis (Kellgren-Lawrence) in the medial compartment was 2.7 (range 1–4), with 83% of patients having grade 3 or 4 osteoarthritis.

The Tomofix plate was used in 36 procedures and the Puddu plate in 10 procedures. The mean varus deformity pre-operatively was 7.6° (range 1–19) and the mean amount of valgus correction achieved post-operatively was 7.2° (range 4–18). The mean length of stay post-operatively was 2.3 days (range 1–7).

3.2. Employment type

Of the total cohort of patients, 12 were employed in high intensity work, 16 in moderate intensity and 14 in low intensity. Of the 29 patients who completed the work questionnaire, 28 were in full time employment post-operatively and one was in part-time employment. One patient was unable to return to work post-operatively but the remainder all returned to work at the same level and did not have to change their employment type.

3.3. Functional outcomes

The mean time taken to return to work was 2.6 months (range 0.25–6) and 22 (79%) patients had returned to work by 3 months post-operatively.

The mean WALS score was 5.4 (range 0–16) and mean EQ-5D was 0.77 (range 0.16–1). The mean VAS score for overall quality of life was 77.9 (range 35–97) and the mean patient satisfaction with surgery was 58.3 (0–100). No correlation was identified when quality of life VAS, EQ5D, WALS score or satisfaction with surgery VAS were compared to patient age, grade of osteoarthritis or use of bone graft, for both the overall cohort and individual work intensity subgroups. There was, however, a positive correlation between increased pre-operative deformity and post-operative WALS score outcome ($R = 0.49$, $p < 0.01$); and a weak negative correlation between increasing deformity and post-operative satisfaction scores ($R = -0.33$, $p = 0.08$).

When comparing patients in different work intensities, the patients in high intensity work took significantly longer to return to employment post-operatively (mean 3.6 months), compared to the moderate and low intensity workers (2.2 and 2.1 months respectively; $p = 0.039$) (Table 1). Function at work and overall quality of life was however, worst in the moderate intensity group and best in the low intensity group (Table 1, Figs. 2 and 3). The low intensity group also demonstrated significantly higher satisfaction with surgery (mean 86), compared to the high and moderate intensity workers (mean 48.8, and 43.2 respectively; $p = 0.01$).

3.4. Complications and survivorship

Three patients subsequently underwent knee arthroplasty (one total knee arthroplasty and two unicompartmental knee arthroplasties). Two of these patients were in moderate intensity employment and one was in low intensity. These revision procedures occurred at a mean 3.9 years (range 3–4.8 years) after the index HTO. This resulted in a 93% survival rate for our series.

There were 11 patients (24%) who subsequently underwent removal of metalwork due to soft tissue irritation. Other complications included superficial wound infection (5) which responded to oral antibiotics; deep wound infection (1) which required removal of metalwork and application of a circular external fixator; non-union (1) which required revision HTO and bone graft. One patient sustained a pulmonary embolism postoperatively which was treated with anti-coagulation. Excluding removal of

Employment questionnaire:

1. Prior to your operation were you in employment?

FULL TIME (> 35 hrs / week)	PART TIME (< 35 hrs/ week)
UNEMPLOYED	RETIRED
2. What type of work was this?
3. What was your job title?
4. Did you have to change your job after the operation?

YES	NO
------------	-----------
5. Currently are you in employment?

FULL TIME	PART TIME	UNEMPLOYED	RETIRED
------------------	------------------	-------------------	----------------
6. What type of work is this?
7. What is your current job title?
8. How long did you take off work following your operation?

Fig. 1. Patient questionnaire.

metalwork, the complication rate in this study was 15%. There was no difference in complication rates between patients treated with the Tomofix or Puddu plates.

4. Discussion

The mean time to return to work in this study was 2.6 months, with 79% having returned to work by 3 months. This represents a faster return to employment than reported in other studies in the current literature.^{6,8} This may have been influenced by the fact that many of the patients in this study were self-employed individuals and therefore could only take a limited time off work. Additionally, we encouraged full weight bearing of all patients in the immediate postoperative period, thereby optimizing the rehabilitation process. As has been reported in other literature, patients with the highest intensity employment, took the longest time to return to work.^{8,16}

Whilst previous literature has reported return to work following medial opening wedge HTO, this study is the first to attempt to quantify patient function at work. In this study, function at work as assessed by the WALSS score, was better than has been reported in previous studies for patients undergoing total knee arthroplasty, which suggests that work related function of patients was as good as if not better than if they had undergone joint replacement surgery.¹³

Function at work, and quality of life indices were closely related to the intensity of employment, with patients in low intensity work demonstrating the best outcome scores. It was notable that of the

four patients who underwent bilateral procedures, over the course of the study period, three were employed in low intensity work. Additionally, the one patient who was unable to return to work following surgery was engaged in high intensity work. There were also correlations identified between increasing pre-operative deformity and worse subsequent function at work, as well as reduced post-operative satisfaction, suggesting that patients with greater deformities may have worse outcomes following surgery, possibly related to a more difficult post-operative recovery and thereby greater difficulty with returning to normal function.

Interestingly functional outcomes, quality of life and patient satisfaction was worse in the moderate intensity group than in the high intensity group. This may have been related to patient expectations, as these patients still had relatively physical jobs but may not have been expecting the same impact on their work function, whereas patients in the high intensity group were more likely to be counselled about this in advance. In addition, these patients returned to work more quickly and this may also have impacted on their overall post-operative recovery.

The grade of osteoarthritis in the medial compartment was 3 or 4 in the majority of patients, which is consistent with previous studies.¹⁸ Although this represents a significant degree of degenerative disease, this also reflects the fact that many of these patients are still young and still physically very active, making arthroplasty less appropriate. In addition, the grade of osteoarthritis was not correlated with functional outcomes irrespective of work intensity, both in this study and in previous literature, and this therefore supports the fact that grade of osteoarthritis alone, should not be

Please state how much difficulty you have carrying out each activity '**without** any help from another person or without the help of a special gadget or piece of equipment'

0 = no difficulty, **1** = some difficult, **2** = lot of difficulty, **3** = unable to perform

(If not applicable to your work please score as **N/A**)

1. Getting to and from your work place:	0	1	2	3	N/A
2. Getting around the workplace:	0	1	2	3	N/A
3. Sitting for long periods of time at work	0	1	2	3	N/A
4. Standing for long periods of time at work	0	1	2	3	N/A
5. Lifting, carrying or moving objects:	0	1	2	3	N/A
6. Working with your hands (e.g. writing, grasping small objects, typing):	0	1	2	3	N/A
7. Crouching, bending, kneeling or working in awkward positions:	0	1	2	3	N/A
8. Reaching for objects:	0	1	2	3	N/A
9. The schedule and hours that your job requires:	0	1	2	3	N/A
10. Pace of work that your job requires:	0	1	2	3	N/A
11. Meeting your current job demands:	0	1	2	3	N/A
12. Concentrating or keeping your mind on work	0	1	2	3	N/A

Fig. 1. (continued).

Quality of Life Questionnaire

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility:

- I have no problems in walking about
- I have some problems in walking about
- I am confined to bed

Self-Care:

- I have no problems with self-care
- I have some problems washing or dressing myself
- I am unable to wash or dress myself

Usual Activities: (e.g. work, study, housework, family or leisure activities)

- I have no problems with performing my usual activities
- I have some problems with performing my usual activities
- I am unable to perform my usual activities

Pain/Discomfort:

- I have no pain or discomfort
- I have moderate pain or discomfort
- I have extreme pain or discomfort

Anxiety/Depression:

- I am not anxious or depressed
- I am moderately anxious or depressed
- I am extremely anxious or depressed

Fig. 1. (continued).

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a cross at whichever point on the scale indicates how good or bad your health state is today.

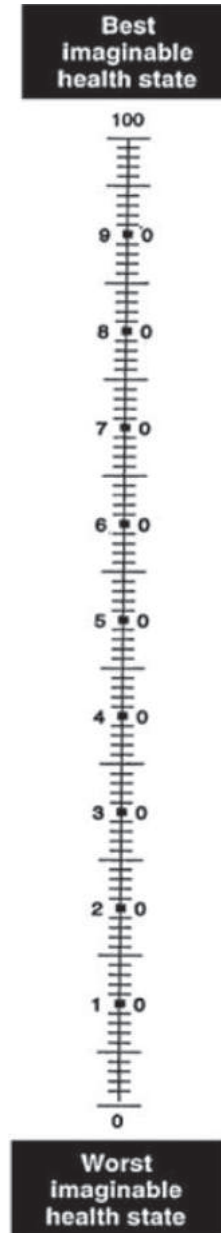


Fig. 1. (continued).

Please also indicate on this scale how likely you would be to **undergo this operation again:**

Very likely to undergo surgery again



Very unlikely to undergo surgery again

Fig. 1. (continued).

used as a criterion to assess patient eligibility for medial opening wedge HTO.¹⁸

The overall mean patient satisfaction with surgery was not as high in this study as has previously been reported, particularly in the heavy and moderate intensity work groups, of whom a large proportion indicated that they would not want to undergo the surgery again.⁶ This may again be related to the relatively heavy nature of their work, making the recovery process more difficult. It is however, worth considering that this cohort of patients do potentially stand to gain the most from surgery, particularly if it can delay the need for knee arthroplasty.

The overall complication rate in our study was 15%, which is similar to that reported in other literature.^{1,5,15} The most common complication in our study was superficial wound infection which responded to a course of oral antibiotics. This may be related to the bulky nature of the TomoFix implant and the relatively thin soft tissue cover of the medial proximal tibia.¹⁷ This probably also impacts on the number of patients who subsequently required implant removal (24%), which again is consistent with the

published literature.¹

A survival rate of 93% over a mean of^{3,8} years was noted in our series which is consistent with other studies in the literature, with five-year survival rates between 80 and 97%.^{3,8} This suggests that medial opening wedge HTO can be reliably performed in patients of working age and thereby delay the need for knee arthroplasty.

The strengths of this study, include that it is the first to attempt to quantify function at work following medial opening wedge HTO and has demonstrated that this is closely related to intensity of work. This should guide surgeons performing medial opening wedge HTO, with regards to the importance of proper counselling of patients pre-operatively, ensuring that they have realistic expectations of post-operative function. Whilst timely return to work is important, it is also essential that patients have sufficient time off post-operatively to enable a full recovery. Limitations of this study include its retrospective nature and particularly the lack of pre-operative function and quality of life scores, which makes it more difficult to accurately assess the impact of surgery. Additionally, in some patients there was extensive time in between completion of

Table 1
Baseline characteristics and functional outcomes in relation to work intensity.

	Heavy intensity	Moderate intensity	Low intensity
Number	12	16	14
Age	43 (range 36–58)	49 (range 38–63)	45 (range 33–63)
Osteoarthritis grade	3.2 (range 2–4)	2.5 (range 1–4)	2.9 (range 1–4)
Deformity (degrees)	8.2 (range 2–13)	8 (range 2–12)	6.6 (range 2–19)
Mean time to return to work (months)	3.6 (range 1–6)	2.2 (range 0.25–4)	2.1 (range 0.25–6)
WALS	5 (range 5–12)	7.8 (range 0–16)	3.1 (range 0–8)
EQ5D	0.79 (range 0.69–1.0)	0.73 (range 0.16–1.0)	0.84 (range 0.62–1.0)
Quality of life VAS	82 (range 50–97)	67 (range 35–96)	84 (range 65–98)
Operation satisfaction VAS	49 (range 0–100)	43 (range 0–100)	86 (range 16–100)

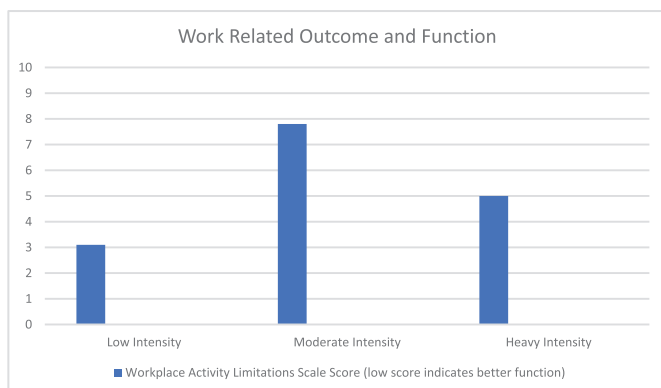


Fig. 2. Work related outcome and function.

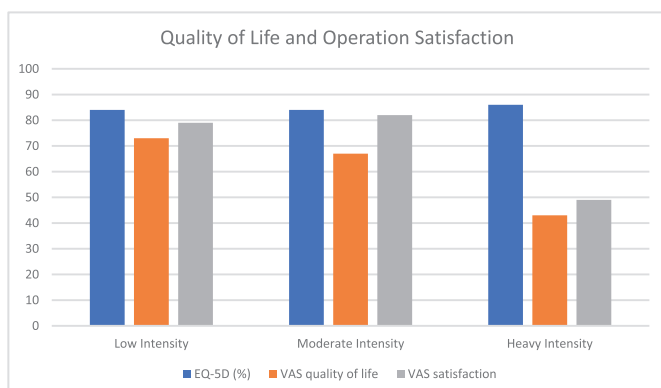


Fig. 3. Quality of life and operation satisfaction.

the questionnaires and the surgery itself, which may have introduced some recall bias.

5. Conclusion

The current study has demonstrated that medial opening wedge HTO is a successful procedure for patients who are at work and want to return to full time employment post procedure. The results indicate that majority of patients can return to work within three months of HTO and that function at work is good to excellent. Function at work and satisfaction with surgery is however, closely related to physical intensity of work, with patients with low intensity work obtaining the best functional and quality of life outcomes and reporting the highest satisfaction with surgery.

CRedit author statement

Cezary Kociałkowski: conceptualization, collection of data, data analysis, writing of manuscript. Darshan Angadi: data analysis, writing of manuscript. Alexander Dodds: conceptualization, reviewing of manuscript. Harminder Gosal: conceptualization, reviewing of manuscript.

Declaration of competing interest

None.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jajs.2021.03.001>.

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Technical note

Flipcutter® breakage during All-inside ACL reconstruction: Possible technical errors and tips to avoid misadventure



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ABSTRACT

All inside ACL reconstruction is a refashioned technique which offers the advantage of being less invasive, more bone stock and tendon preservation. The advent of retractable retrocutting devices like Flipcutter® has made the technique simple and reliable with reproducible results. However complications with this new technique and instruments are yet to unravel. We present two cases where Flipcutter® broke inside the joint during the procedure. We report this infrequent complication and discuss the possible events leading to breakage, further management and technical tips to avoid this misadventure.

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1. Introduction

The all-inside technique is a popular technique of ACL reconstruction being less invasive, more bone and tendon preserving surgery. It also allows better graft positioning, fixation and early rehabilitation.¹ Although the technique was originally described over twenty year ago but technical difficulties and intraoperative complications related to creation of tibial socket limited its use.² Later, the technique was simplified with the advent of second generation retractable retrocutting devices (Flipcutter®, Arthrex) and adjustable cortical suspensory devices.³ However, the All-inside technique still remained elusive to general public coming to government setup with ACL deficiency as flipcutter® is a single-time use and very expensive device. To provide the advantages of All-inside technique to the non-affording population, we tend to reuse the flipcutter after proper sterilization techniques. Breaking of flipcutter during the procedure increases the surgical duration and procedural cost. In this article, we share the complication of breakage of Flipcutter®, with a focus on technicalities and possible

causes leading to breakage.

2. Material and method

We have done over 60 ACL reconstruction surgeries in last 3 years in our centre using All-Inside technique. In this article we are sharing our experience of handling flipcutter and two cases where flipcutter broke intra-operatively. In both the cases, the Flipcutter® blade broke while initiating the retro reaming of tibial tunnel (Fig. 1).

Case 1: 18 years old female kabbadi player suffered complete ACL tear while playing. The patient belonged to low socioeconomic family and could not afford the Flipcutter®. The patient was taken for All-Inside ACL reconstruction using a reprocessed ethylene oxide (ETO) sterilized Flipcutter® after due consenting and explaining the pros and cons of procedure. Unfortunately the flipcutter broke inside the joint. Once the Flipcutter® blade was noted to break, the retro-reaming was stopped and the fluid flow was halted to prevent migration of the broken piece. Using a grasper, the broken piece was removed from medial portal (Fig. 2). The knee was checked under C-arm for any other metallic broken piece in the knee before proceeding further. The procedure was completed by converting it into outside-in technique by transtibial drilling.

Case 2: 40 years old male patient with complete ACL tear secondary to domestic fall while dancing. He was planned for All-

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Fig. 1. Broken tip of Flipcutter.

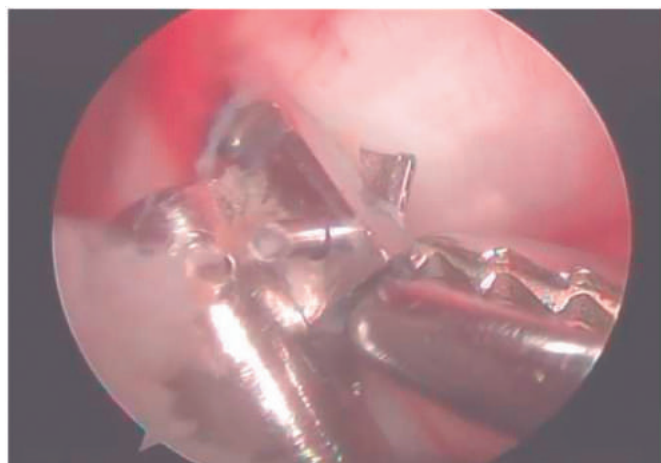


Fig. 2. Arthroscopic retrieving of broken part.

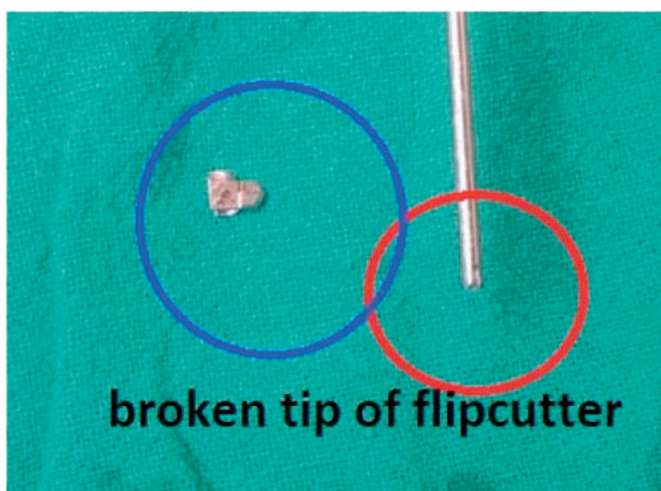


Fig. 3. Flipcutter blade with sleeve assembly.

Inside ACL reconstruction after due work-up. Here a new flipcutter was used which broke during the procedure. The broken pieces were retrieved as mentioned earlier (Fig. 3). The ACL reconstruction procedure was completed by using a new Flipcutter® with due caution. Both patients followed routine rehabilitative protocol and achieved good results.

3. Discussion

Instrument breakage is a disheartening complication, especially in arthroscopy. Because of the fragile design, inappropriate instrument usage and little maneuvering space in the knee joint, the complication of broken instruments is not uncommon in ACL reconstruction.⁴ It ranges from 0.11% to 0.81% in various arthroscopy studies.^{4,5} However we do not have much literature related breakage of Flipcutter®.

The possible reasons which could have lead to breakage of Flipcutter® can be varied.

1. While tibial reaming there could be mismatch between two perpendicular forces, the axial pulling force and rotatory cutting force. This causes increase in the shear forces at flip joint and proximal end can give way and break. This can be prevented by pulling the device carefully and slowly and avoid unwarranted force in case of resistance.
2. There could be increase in wobbling motion while applying retrograde force and improper cutting and thereby increasing tendency of breakage. This can be reduced by proper use of graduated stepped guide.³ The graduated sleeve should be advanced into tibial cortex 7 mm mark with mallet and it should be firmly held in place at proper angle while reaming and should not be removed until the socket preparation is complete.
3. The medial tibial spine has strong bone; the Flipcutter® may break if an incompletely flipped blade hits on this bone. This can be prevented by first, keeping the proper alignment of tibial jig; second, the gradual introduction of the Flipcutter® into joint cavity more proximal to bony surface and stay within foot-print; third, gradually flipping the blade under vision from antero-lateral portal and carefully receding the blade to engage properly over the bone and reaming with forward drilling with optimum pull. Special care should be taken in cases of narrow foot-print.
4. Use of reprocessed Flipcutter® possibly increases the chances of instrument failure.⁶ This may be due to inadequate locking of flipped blade chiefly because of two reasons. First, bone and soft tissue debris get accumulated at proximal end with each use which is hard to remove. Second, there is possibility of some misalignment of locking system with repeated use and increased probability of dislodgment of blade from its tip. Reuse also lead to loss of sharpness of blade which may require an increased retrograde pulling force. Hence it is suggested that if a Flipcutter® is to be reused for any reason, it should be assessed for proper flipping, adequacy and smoothness of locking prior to procedure. This decreases intra-operative misadventure.

4. Conclusion

The advent of flipcutter has made All-inside technique return to field of ACL reconstruction with reproducible results. However, it is a very costly instrument and flimsy enough to break if proper technique is not used. The breaking of flipcutter will lead to financial loss, increased surgical time, compromised patient rehabilitation and also bring disrepute to surgeon. Also it is recommended not to use reprocessed flipcutter on a regular basis. Young

arthroscopic surgeons can prevent this misadventure by taking a note of above-mentioned technical aspects. More refined observations and constant technical modifications are needed to reduce other complications.

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Credit author statement

KESHAVE SINGH – writing-original draft preparation, visualisation, SAURABH DUTT – writing-original draft preparation, Project administration, RAKESH SEHRAWAT – editing, DHANANJAYA SABAT – writing –review and editing, VINOD KUMAR – Conceptualization, Methodology, Investigation, PRITISH SINGH – writing-review and editing

Declarations of competing interest

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