



Outcomes of total knee replacement with the use of a NexGen MIS Tibial Component (Mini-keel) : a systematic review

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NexGen MIS Tibial Component (Mini-keel) is a tibial component specially developed for minimally invasive surgery in total knee replacement (TKR), and the size limitations of its design and the modular system could affect tibial fixation strength, however, this has not been precisely evaluated thus far. This study aimed to systematically review the literature describing the outcome following TKR with the use of a Mini-keel.

Electronic searches of databases were undertaken in July 2019 by two experienced orthopaedic surgeons according to the PRISMA guidelines for literature describing the outcomes of TKR with the use of a Mini-keel. Quality of studies was assessed using the Joanna Briggs Institute Critical Appraisal Checklist. The initial search found a total of 623 studies from all the databases. Seven studies met all the inclusion criteria and were eligible for critical appraisal and quality assessment. In total, 2,198 cases were included in the systematic review.

Thirty-five revision cases due to aseptic loosening were found from the systematic review. Two studies were negative about using a Mini-keel and three studies were positive about it, while the other two studies did not judge the quality of a Mini-keel. There have been conflicting conclusions among studies for the use of a Mini-keel.

There remains a paucity of prospective cohort studies between TKRs with the use of a Mini-keel and those with the use of a conventional implant, which makes it difficult to determine the usefulness and reliability of this implant. **Keywords** : knee ; total knee replacement ; minimally invasive surgery ; NexGen MIS Tibial Component ; systematic review.

INTRODUCTION

Total knee replacement (TKR) is a successful and technically well-established procedure in the treatment of end-stage degenerative joint disease or deformity of the knee with a rate of survival of more than 90% after 15 years of follow-up (*1-3*). It is becoming increasingly popular among people of working age as there is a trend among working

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 - [®] 2021, Acta Orthopædica Belgica.

No benefits or funds were received in support of this study. None of the authors have a conflict of interest.

adults choosing to delay retirement (4), and a less invasive approach have become more demanding expectations (5). At its birth in 2003, minimally invasive surgery (MIS) in TKR (MIS-TKR) started with the purpose of reducing the size of the incisions and the damages to the soft tissues (6-8). MIS-TKR is believed to be helpful for short skin incision, smaller soft tissue dissection, reduced postoperative pain, decreased use of painkillers, shorter recovery and hospitalisation periods, fast recovery of the range of motion as well as the muscular strength, reduced need for postoperative manipulation, lower cost, and fewer postoperative aesthetics (9-11). However, in MIS-TKR, the risks of malpositioning of the prosthesis and wound problems with inadequate visualisation of the operative field could be increased because compared with conventional techniques, it involves a smaller exposed surgical site (12). Moreover, with this technique, the tibial implant must be inserted without tibiofemoral dislocation, which cannot be easily conducted with the use of standard components. To overcome these problems, a lot of efforts have been made to reduce the size of the instruments to make them fit through smaller incisions, and also to improve the components in order to make the implanting technique easier through small approaches and limited exposures (13). The NexGen MIS Tibial Component (Mini-keel) (Zimmer Inc., Warsaw, IN, USA) (Fig. 1) is one of the inventions that can be inserted into the knee without anterior dislocation of the knee joint due to the presence of a minimised keel (14). It is made of two parts : the plate with a keel underneath and a modular stem ("drop-down" stem extension). The size limitations of its design and the modular system could affect tibial fixation strength, however, this has not been precisely evaluated in a clinical setting. Currently, there is a lack of evidence in the literature that provides knee surgeons with evidence-based recommendations on the use of a Mini-keel for TKR, and no systematic review has been published in this arena so far. The aim of this systematic review, therefore, was to provide the reader with the related outcomes for MIS-TKR with the use of a Mini-keel based on the best available evidence



Fig. 1. — NexGen MIS Tibial Component (Mini-keel) ; Zimmer Biomet Inc., Warsaw, IN, USA.

MATERIAL AND METHODS

The PICOS tool was adopted to formulate the research question and modified since no comparators were sought in this study (15). Two reviewers searched the online databases (MED-LINE, PubMed, Cochrane Central Register of Controlled Trials and Cochrane Database of Systematic Reviews) for literature describing the outcomes of TKR with the use of a Mini-keel. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were used for designing this study (16). Database search was conducted on 1st, July 2019 and retrieved articles from the databases since inception to the search date. The electronic search citation algorithm used was : ((TKR OR TKA OR (total knee replacement) OR (total knee arthroplasty)) AND (low-profile OR modular OR mini-keel* OR short-keel* OR MIS OR (minimally invasive surgery)) AND tibia* (Title/Abstract)). The search also included the yet to be printed search results. Results were pooled and exported to EndnoteX6 software (Thomson Reuters, USA) and duplicates were removed electronically and manually. The two reviewers independently reviewed all the titles and abstracts. The remaining search results were divided equally between the two reviewers and reviewed in duplicate applying the inclusion and exclusion criteria. Any discrepancies at the title and abstract stage as well as the full-text stage were resolved by consensus between the two reviewers and the third more senior author. This process led to 100% agreement between the authors.

Levels 1, 2, 3, 4, and 5 evidence (according to the Oxford Centre for Evidence-Based Medicine)

clusion criteria
All levels of evidence
Written in the English language
Studies on humans
Studies reporting the outcome of total knee replacement using NexGen MIS Tibial Component (Mini-keel)
Operative procedure consisted solely of total knee replacement
Total knee replacement irrespective of any pathology
clusion criteria
Studies describing trial protocols without any results
Total knee replacement not using the mini-keel modular tibial implant
Total knee replacement without describing details of used implants
Revision total knee replacement
Unicompartmental knee replacement
Patellofemoral knee replacement
Animal studies
Basic science studies (e.g. cadaveric studies)
Diagnostic studies without any description of treatments
Technical notes without any results
Reviews, systematic reviews

Table I. - Inclusion and exclusion criteria applied to articles identified in the literature

English-language studies were eligible for inclusion in the systematic review. We excluded duplicate subject publications within separate unique studies. Both electronically published articles and print journal were included for this review. Clinical outcome studies, prospective case series, retrospective case series and case reports that described the outcomes of TKR with the use of a Mini-keel irrespective of any pathology were included. Studies describing the results of unicompartmental knee replacement, patellofemoral knee replacement, and revision TKR were excluded. Studies on animal models and basic science studies (e.g. cadaveric studies), studies describing trial protocols without any results, diagnostic studies without any description of treatments, technical notes without any results, and review articles were also excluded. The detailed inclusion and exclusion criteria are shown in Table I.

Both the reviewers independently extracted the relevant study data from the final pool of included articles and recorded this data on a spreadsheet designed *a priori* in Microsoft Excel 2013 (Microsoft Corporation, Redmond, Washington, USA). Participant-specific demographics extracted from each study included the number of cases and patients, gender distribution, mean age with range (years), original disease, surgical approach, mean

operation time, details of stem extension, type of femoral component, cementing technique, final outcome, and specific notes (if any). Study-specific demographics extracted from each study included the level of evidence according to the simplified evidence level table from the Centre for Evidence-Based Medicine, Oxford, country where the study was conducted and the year of publication. Studies were then analysed and assessed using the Joanna Briggs Institute Critical Appraisal Checklist (JBICAC) for case series and case-control studies. A scoring system was implemented based on the findings from the studies. JBICAC scores the answers to its questions as yes, no, unclear or not applicable. We then allocated numbers to each answer where domains answering with yes gets 2 points, unclear gets 1 and no gets 0. A scoring of 20 indicated the maximum points of both case series and case-control studies. The extracted data was then analysed using Microsoft Excel 2013. Statistical analyses in this study focused on descriptive statistics.

RESULTS

The initial search found a total of 623 studies from all the databases. The search process led to 100% agreement among authors. Duplicates found

were 76 articles and were removed A total of 547 articles were then identified for title screening. Three hundred and sixty-seven articles were excluded based on the inclusion criteria leaving 180 articles for abstract screening. Eighty-seven articles were then excluded and 93 articles were included for full-text review. Eventually, seven studies (four case-control studies and three case series) met all the inclusion criteria and were eligible for critical appraisal, quality assessment and included in the study. One study was a comparative study between Mini-keel and standard tibial implant (Kajetanek et al (17)), and others were studies describing the outcomes of Mini-keel only (The other three casecontrol studies focused on other factors (type of femoral component (18), obesity (19) and varus deformity (20)) and did not compare Mini-keel with standard components.). The oldest study included in this review was published in 2011. In total, 2,198 TKRs in 1,922 patients were included in the systematic review. Of the participants, 20.6% were male and 79.4% were female (data availability : 67.3%). Mean age of the participants was 68.3 years (range, 48 to 88 years). Of the seven studies finally included in this systematic review, two studies (Foran (21) and Kajetanek (17)) were negative about using a Mini-keel and three studies (Benazzo (14), Yoo (22) and Yang (18)) were positive about it, while the other two studies (Yoo (19) and Yoo (20)) did not judge the quality of a Mini-keel. Thirty-five revision cases due to aseptic loosening were found from the systematic review. Other than revisions, five complications (three cases of rupture of the medial collateral ligament, one case of detachment of the cortex from the medial femoral condyle, and one case of periprosthetic tibial fracture) were reported.

The flow chart of the literature search algorithm is shown in Fig. 2. Due to the lack of homogeneity in studies, a meta-analysis was deemed unsuitable for this study. Detailed data extracted from all the studies is shown in Table II. The outcomes of quality assessment using JBICAC were shown in Table III.

DISCUSSION

MIS-TKR, which has become popular in the past 15 years thanks to advances in surgical techniques and instrumentation, involves minimum damage to the suprapatellar pouch without patellar eversion and tibiofemoral joint dislocation, which aimed to minimise damage and tension in the soft tissue. Using downsized guiding tools and cutting zigs have made reducing the length of skin incision and damage to the underlying structures possible in MIS-TKR. Reported advantages of MIS-TKR such as the faster recovery of muscle strength, less blood loss, and shortened hospital stay have encouraged knee surgeons to use this technique for patients (23),

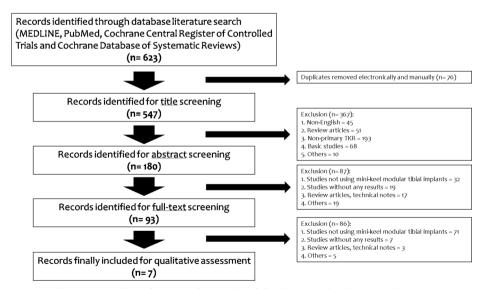


Fig. 2. —PRISMA flowchart for results of the literature database search.

while it still requires an experienced surgeon and takes time to obtain the necessary surgical skills.

While MIS-TKR can be performed through a small incision, it can be challenging if the field of view is extremely limited (12,13). The tibial resection surface should be sufficiently anteriorly dislocated with the knee flexed when conventional tibial components are used. If the length of the incision is small, complications may occur by excessive tension on the adjacent tissue. Mini-keel is designed to facilitate insertion and manipulation of prostheses in the smaller surgical fields to overcome these disadvantages. It is made of titanium alloy and composed of a tibial plate with a minimised keel and a 45 mm- or 75 mm-long modular drop-down stem extension. Thanks to its short keel length (range, 17 to 19 mm), it prevents tension on the surrounding tissue and additional soft tissue resection when it is inserted. In addition, it provides a 5.20% wider contact surface than normal tibial component, which contributes to the stability of the knee. Although there have been a small number of clinical studies of Mini-keel, there has been no systematic review in this arena thus far.

This systematic review finally found seven studies, two of which were negative about using a Mini-keel and three of which were positive about it, while the other two focused on patient's factors and did not comment on the quality of a Mini-keel. Both of the two negative studies opposed to the use of a Mini-keel because of the high revision rate due to aseptic loosening and no studies reported inferior clinical outcomes of this implant such as HSS score, Knee Society Score and knee range of motion. In the result of the quality assessment of the seven included studies using JBICAC tool, the study of Benazzo et al¹⁴ and that of Yang et al. (18) showed higher quality than other studies in the category of case series and case-control studies, respectively, and both of the two studies are positive about the use of a Mini-keel. Potential advantages of this implant, i.e. faster recovery following TKR or less postoperative pain thanks to smaller approaches and limited exposures, have not been researched or judged in any studies.

One of the negative studies (Foran et al²¹) did not use drop-down stem extensions and it might result in a high revision rate due to aseptic loosening. In an attempt to obtain further stability by increasing the interface between the implant and the tibia, additional use of a drop-down stem extension has been strongly recommended by the manufacturer since June 2010. In fact, the study by Kajetanek et al¹⁷ showed higher revision rate of the cases without a stem extension (33.3%) compared with those with a 45 mm stem extension (4.9 %) and those with a 75 mm stem extension (16.7 %), while no statistical differences among them were described. Foran et al also mentioned that another possibility of their poor results could be unfavorable design features of a Mini-keel, and it is possible that the geometry of a Mini-keel may lead to unfavorable stress shielding in vivo and weakening of the underlying bone, which increases susceptibility to bone loss as well as osteolysis (21). Kajetanek et al mentioned that the design of this implant involves an additional interface between the plate and the keel, which also could be a source of loosening (17).

The quality of the cement technique may also have contributed to the result in each study. An optimal cement amount and distribution with good pressurisation is very important for secure fixation and long-term durability of TKRs, and even more critical for tibial components with short keels like a Mini-keel The manufacturer released a document in July 2009 detailing proper cement technique for a Mini-keel and described that "The MIS Tibial Component is designed for cemented use. The instrumentation prepares a cement mantle around the keel with a line-to-line fit at the ends of the fins. For this reason, cement must be applied within the tibial medullary canal as well on the proximal tibial surface, under the tibial plate and around the keel". Benazzo et al. (14) emphasised the importance of cementing techniques through analysing cement volume, distribution, and penetration from followup radiographs, while they did not document the correlation of radiolucency. It was reported that a safe cement penetration should be between 3 and 4 mm, and the pattern of distribution of the cement is coherent with the design of the implant and the cementing technique used (24).

From this systematic review, 5 complications (3 cases of rupture of the medial collateral ligament,

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Author	Year	Country	Type of the study	Nur	nber of pa	tients	Number of TKRs	Follow-up period	Age	(years)
				Male	Female	Total			Mean	Range
Foran [21]	2011	USA	Case series	NA	NA	460	529	NA	61	56-73
Benazzo [14]	2012	Italy	Case series	139	36	175	200	3 years (mean)	69	52-88
Yoo [22]	2014	Korea	Case series	NA	NA	168	168	6 years and 1 month (mean)	68.8	53-80
Kajetanek [17]	2016	France	Case control	47	165	212	212	59.4 months (mean)	73.2	47.4-88.5
Yoo [20]	2016	Korea	Case control	30	415	445	627	5 months (mean)	71.8	NA
Yoo [19]	2018	Korea	Case control	26	345	371	371	Minimum 5 years	69.3	53-80
Yang [18]	2018	Taiwan	Case control	25	66	91	91	Minimum 5 years	69.4	48-85
Author	Cementin	g					1		1	
Foran [21]	enhance c		ation. Palacos (Zimmer) a			high-press	ure, high-volume pulsat	ile lavage and then dried. Cement	was then fing	er-packed to
Benazzo [14]								ut pressurization of the cement. T tibial plate, then impacting it.	he cementing	technique
Yoo [22]	Cemented	(Details are a	not described)							
Kajetanek [17]	-		-	-	-			the keel. The cancellous femoral d under the base plate with a ceme		
Yoo [20]	Not descri	bed (TKRs ir	n Figures seem to be cem	ented)						
Yoo [19]	Not descri	bed (TKRs ir	n Figures seem to be cem	ented)						
Yang [18]	The fully of	cemented tecl	hnique with pressurizatio	n was use	d.					

Table II. — Details of 7 studies included in the systematic review

TKR, total knee replacement ; OA, osteoarthritis ; RA, rheumatoid arthritis ; ON, osteonecrosis ; BMI, body mass index.

BMI TKR, total knee replacement; OA, osteoarthritis; RA, rheuma- toid arthritis; ON, osteonecrosis; BMI, body mass index. (kg/m²)	Mean Operation time	Drop-down stem (length)	Femoral component	Disease	Approach
NA	NA	Not used	CR	OA	Subvastus approach or midvastus approach
NA	90 min	45 mm	PS (LPS-Flex)	OA: 178 cases, Post- trauma: 22 cases	Mini-midvastus approach: 172 cases, mini-trivector approach 35 cases
27±3.7 (mean ±SD)	87.5 min	45 mm	PS (LPS-Flex)	OA: 165 cases, RA: 2 cases, ON: 1 case	Mini-midvastus approach
28.73 (mean)	NA	Not used: 3 cases, 45 mm: 203 cases, 70 mm: 6 cases	PS (LPS-Flex)	OA: 206 cases, Others: 6 cases	Medial trans- quadricipital parapatell approach
27.2 (mean)	85.3 min	45 mm	PS (LPS-Flex)	OA: 622 cases, RA: 3 cases, ON: 2 cases	Mini-midvastus approach
27.1 (mean)	86.7 min	NA	PS (LPS-Flex)	OA: 367 cases, RA: 4 cases	Mini-midvastus approach
27.5 (mean)	164.3 min	45 mm	CR (CR-Flex): 46 cases, PS (LPS- Flex): 45 cases	Not described	Not described
Outcomes			Notes		
Eight cases were revised for early aseptic loosening of the tibial compone concerning radiographic signs of pending failure. The mean time from pr months (range, 9-31 months).		-		n all revised cases, more devoid of cement and fa crylate.	
Three cases underwent revision. HSS score increased from a median value score increased from a median value of 31 points in the Knee and 45 points 83–100) and 94 (range: 81–100), respectively. The survival rate at 5 years interval. The mean survival rate per Kaplan-Meier analysis was 99.4% at 6.1 years	nts in the Function s s was 97.9 % with a	core to 95 (range: 95 % confidence			
revision. The mean postoperative outcomes were: knee range of motion, femorotibial angle, 5.2 degrees valgus; tibial component alignment angle posterior inclination, 4.8 degrees; the percentage of cases with tibial component (4.8×10^{-6}) , where the two provides the two pr	, 90.2 degrees; tibial ponent alignment ar	l component ngle of 90±3 degrees,			
Compared with cases using standard components (standard group), the ra was significantly higher in the Mini-keel group with 12 cases (5.7 %) and = 0.036). The use of Mini-keel appears to be a prognostic factor for surgi- 11.88), $P = 0.02$) but not for the development of a radiolucent line (HR =	4 cases in the stand cal revision (hazard	dard group (1.6 %) (P ratio = 3.86 (1.23–	months) in the Mi months) in the sta postoperative alig	nment were not prognos	
The average postoperative outcomes were: knee range of motion, 127.8 d score, 92.5; KSS Function score, 76.7; femorotibial angle, 5.0 degrees va 90.2 degrees; tibial component posterior inclination, 4.6 degrees; the percalignment angle of 90 \pm 3 degrees, 96.5 %; the percentage of cases with th valgus, 83.6 %.	lgus; tibial compone entage of cases with	ent alignment angle, h tibial component	The accuracy of the in severe cases of outcomes and sho	preoperative varus defo	ent was slightly reduced rmity. Radiological vere satisfactory regardle
The average postoperative outcomes were: knee range of motion, 133.4 d femorotibial angle, 5.7 degrees valgus; tibial component alignment angle, with tibial component alignment angle of 90 ± 3 degrees, 95.6 %; the perce of 6 ± 3 degrees valgus, 93.5 %.	, 90.5 degrees; the p	percentage of cases	case of detachmen occurred. Compar		medial femoral condyle s, obese patients showed
KSS Function score at 5-year follow-up averaged 81.67 and 80.12 in the $(p = 0.29)$. The femorotibial angle averaged 5.85 degrees and 5.85 degree respectively $(p = 0.60)$. The average tibial component angle was 0.46 deg CR and PS groups, respectively $(p = 0.30)$. The average posterior inclinat degrees in the CR and PS groups, respectively $(p = 0.51)$. Radiolucency v and in 9 zones of the PS group $(p = 0.24)$. Three TKRs required further su periprosthetic tibial fracture (PS group) and two revision TKRs (one CR is urrival rate at 5.7 years was 97.8% with a 95 % confidence interval.	s valgus in the CR a rees and 0.61 degre ion averaged 2.28 d vas noted in 17 zone urgery: one locking	and PS groups, es varus in the legrees and 1.93 es of the CR group plate fixation for a	in the PS group. N showed good relia	No significant difference	n the CR group and 8.7 was identified. Mini-kee oth CR and PS prosthes

Table II. — Details of 7 studies included in the systematic review

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	Y00 [22]	0	2	2	0	0	0	0	2	2	0	8/20

Yes = $2 / \text{Unclear} = 1 / \text{No} = 0$	ar = 1 / No =	0										
Study	1. Were	2. Were cases	3. Were the 4. Was	4. Was	5. Was	6. Were	7. Were	8. Were	9. Was the	10. Was	Total- %	%
	the groups	the groups and controls	same criteria	exposure	exposure	confounding	strategies	outcomes	exposure	appropriate	score	
	comparable matched	matched	used for	measured in a	measured in factors	factors	to deal with	assessed in	period of	statistical		
	other	appropriately?	identification	standard, valid the same way identified?	the same way	identified?	confounding	a standard,	interest long	analysis		
	than the		of cases and	and reliable	for cases and		factors	valid and	enough to be	used?		
	presence of		controls?	way?	controls?		stated?	reliable	meaningful?			
	disease in							way for				
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	absence of							controls?				
	disease in											
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Kajetanek	0	0	5	2	2	0	0	2	2	2	2 12/20	60
[17]												
Y00 [20]	0	0	2	2	2	0	0	2	0	2	2 10/20	50
Y00 [19]	0	0	2	2	2	0	0	0	0	2	8/20	40
Yang [18]	2	5	5	2	5	0	0	0	2	2	2 14/20	70

40

50

70

%

1 case of detachment of the cortex from the medial femoral condyle, and 1 case of periprosthetic tibial fracture) were reported in total. These complications may occur in MIS-TKR regardless of the use of a Mini-keel, as they might happen by excessive tension on the adjacent tissue when the tibial component was inserted with the knee extended. Mini-keel is designed to facilitate insertion of prostheses in the smaller surgical fields, however, care still should be taken to prevent tension on the surrounding tissue when it is inserted.

This systematic review found only one retrospective study which compared outcomes following TKR with the use of a Mini-keel and that with the use of a standard keel component, and no prospective (cohort) study or randomised-controlled trial was found. Kajetanek et al performed a casecontrol study in 459 consecutive TKRs (212 Minikeel and 247 standard components) and analysed the rate of revision for aseptic tibial loosening and identification of a radiolucent line after a median follow-up of 5 years. As a result, the rate of revision for tibial aseptic loosing was significantly higher in the Mini-keel group with 12 cases (5.7%) and 4 cases in the standard group (1.6%) (P = 0.036), while the decision to perform surgical revision was subjective, based on the patient's symptoms, X-ray interpretation, and the surgeon's experience. The use of a Mini-keel appeared to be a prognostic factor for surgical revision (hazard ratio (HR) = 3.86 (1.23-11.88), P = 0.02) but not for the development of a radiolucent line (HR = 1.75 (0.9-3.4), P = 0.097). They concluded that the use of a Mini-keel was associated with a greater risk of revision for tibial component loosening. Note that the choice of the prosthesis was decided by the availability of components in the operating room and not by randomisation, which can be a limitation of this study.

Yoo et al. (19) showed MIS-TKR with the use of a Mini-keel in obese patients showed satisfactory clinical and radiological results. Yang et al. (18) described MIS-TKR with the use of a Mini-keel with both CR and PS prostheses showed good reliability. Yoo et al. (20) showed that satisfactory component alignment was achieved in MIS-TKR with the use of a Mini-keel regardless of the degree of varus deformity.

The strengths of this systematic review include the pursuit of knowledge in a new and important arena that has scarce published information and remains a topical subject for knee surgeons. The methodology is sound and encompasses a broadbased and comprehensive systematic literature search of multiple databases with multiple reviewers allowed for a very inclusive approach to capturing the vast majority of existing literature. In addition, the included studies were critically appraised using a validated quality measurement tool (JBICAC). Nonetheless, there are limitations which include the inclusion of English only studies and the overall low level of evidence available in the included studies on this topic. Non-prospective designs are prone to data inaccuracy as well as missing information, which subjects them to selection and source bias. Publication bias should also be recognised, and they may diminish the accuracy of the data collected and therefore limits the quality of a systematic review without a doubt

CONCLUSION

Although over half of the studies found from this systematic review reported good and satisfying outcomes following MIS-TKR with the use of a Mini-keel, there still have been controversies among studies on this subject. There, unfortunately, remains a paucity of prospective comparative studies, which makes it difficult to perform a meaningful assessment of the use of a Mini-keel for MIS-TKR. To make any specific recommendations for knee surgeons with regard to the use of this implant for MIS-TKR, adequately powered longterm prospective cohort studies comparing MIS-TKRs with the use of a Mini-keel and those with the use of a conventional implant need to be conducted in the future.

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