Arthroplasty Today 32 (2025) 101621

Contents lists available at ScienceDirect

Arthroplasty Today

journal homepage: http://www.arthroplastytoday.org/

Original Research

Revision Rates for Aseptic Loosening in the Obese Patient: A Comparison Between Stemmed, Uncemented, and Unstemmed Tibial Total Knee Arthroplasty Components

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A R T I C L E I N F O

Article history:
Received 15 August 2024
Received in revised form
18 December 2024
Accepted 5 January 2025
Available online 22 February 2025

Keywords:
Total knee arthroplasty
Obesity
BMI
Cementless
Loosening
Revision

A B S T R A C T

Background: Total knee arthroplasty (TKA) is an effective treatment option for high body mass index (BMI) patients achieving similar outcomes to nonobese patients. However, increased rates of aseptic loosening in patients with a high BMI have been reported. Component fixation is a concern when performing TKA in the obese patient. To address this concern in cemented TKA, extended tibial stems have been used. Uncemented implants that take advantage of biologic osseointegration have also been advocated. This retrospective study examined the use of and revision rates of extended cemented tibial stems and uncemented implants compared with conventional cemented implants in our high BMI patient population.

Methods: We retrospectively reviewed a prospectively maintained database of 3239 primary Attune TKAs (Depuy, Warsaw, Indiana). All obese patients (BMI > 30 kg/m^2) with > 30 months of follow-up were included in our analysis. Those who underwent cemented TKA using a tibial stem extension (Group 1) (n = 145) and those where cementless implants were used (Group 2) (n = 100) were compared to a control group (n = 1243) using a standard cemented implant. Primary outcome measures were all-cause revision, revision for aseptic loosening, and revision for tibial loosening. Kaplan-Meier survival analysis and Cox regression models were used to compare the primary outcomes between groups.

Results: In total, there were 1512 knees that met the inclusion criteria. The mean follow-up was 6.8, 5.1, and 5.3 years for cemented, stemmed, and cementless groups, respectively. There were 37 all-cause revisions identified. Seven were for aseptic loosening (2 tibial, 1 femoral, and 4 involving both components); all of these were in the standard cemented implant group. There were no revisions in the stemmed or cementless implant groups. Survival analysis did not show any significant differences between groups for either all-cause revision or for aseptic loosening.

Conclusions: This retrospective analysis showed that there were no revisions required for aseptic loosening when a cemented, stemmed, or uncemented implant was used in obese patients. These findings show that cementless and extended stem implants are a reasonable option in obese patients.

Level of evidence: Level III.

Introduction

Obesity is increasingly prevalent. Nearly one-third of the world's population is classified as obese [1]. Obesity is defined as a body mass index (BMI) of > 30 kg/m^2. The World Health Organization

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https://doi.org/10.1016/j.artd.2025.101621

subdivides this into 3 categories: class I (30.0-34.9 kg/m^2), class II (35.0-39.9 kg/m^2), and class III (> 40.0 kg/m^2) [2].

Total knee arthroplasty (TKA) in obese patients is challenging; however, it remains an effective treatment option. High BMI patients achieve similar outcomes to nonobese patients [3-5]. It has been reported that there is an increased rate of aseptic loosening in patients with a high BMI [6]. In patients with high BMI, increased forces are placed across the implant fixation interfaces. As such, component fixation and the potential for aseptic loosening has been a concern when performing TKA in the obese patient.

To address this, some arthroplasty surgeons have advocated the use of extended tibial stems [4,7-11] in cemented implants and, more recently, the use of cementless fixation [12-15]. Extended tibial stems increase the surface area for cemented fixation, distribute this force over a larger area, and are therefore thought to improve implant stability. This reduces the micromotion between interfaces and consequently should reduce the risk of aseptic loosening. Uncemented implants, once biologic fixation is achieved, integrate into bone creating a transitional zone and effectively eliminating an interface.

This study aimed to evaluate implant survival for extended tibial stem implants and cementless implants in comparison to conventional cemented implants in high BMI patients.

Material and methods

We retrospectively reviewed a prospectively maintained database of 3239 primary Attune TKAs (Depuy, Warsaw, Indiana). All obese patients (BMI > 30 kg/m^2) with a minimum of follow-up of 30 months were included in our analysis. Those who underwent cemented TKA using a tibial stem extension (stemmed) (n = 150) and those where uncemented implants were used (cementless) (n = 101) were compared to a control group (n = 1261) using a standard cemented implant (Fig. 1). Internal review board approval was obtained. All operations were performed by or under the direct supervision of specialist arthroplasty surgeons.

Data included the patients' age, gender, American Society of Anesthesiologists (ASA) grade, and the indication for surgery. Revisions and reoperations were identified using our own database, review of clinical notes, and cross-checked against the National Joint Registry. In the case of the patient's death, general practioner records were requested. The primary outcomes were revision for any cause (all-cause revision) and revision for aseptic loosening. We defined revision as removal or exchange of any component. This included isolated bearing exchange for infection as part of a debridement, antibiotics, and implant retention procedure and secondary patellar resurfacing.

Statistical analysis

Continuous descriptive statistics used means, median values, ranges, and 95% confidence intervals where appropriate. Where categorical variables were compared, *Pearson chi-square test* was used and *t-test/Mann-Whitney U* tests were used for continuous variables.

Survival analysis was undertaken to compare the outcomes of the stemmed tibial component and cementless groups to the control group of cemented primary implants. Kaplan-Meier curves were used to model survival for each group with endpoints being all-cause revision and revision for tibial loosening. A log-rank test was used to determine whether there were significant differences in the fitted survival distributions.

A Cox proportional hazard regression analysis was performed to compare adjusted revision rates between the 3 groups. Adjustments were made for age at surgery, gender (male, female), primary diagnosis (osteoarthritis (OA), post-traumatic OA, avascular necrosis, inflammatory arthropathy, and other), ASA score (I, II, III, and IV), and meniscal constraint (fixed bearing cruciate retaining, posterior stabilized, and rotating platform). The level of significance was taken to be $P < .05$ and RStudio (version 2022.02.2) was used to perform the analyses.

Results

In total, there were 1512 knees that met the inclusion criteria. An overview of the age, gender, ASA, indications, cement type, and implant constraints is given in Table 1. The mean follow-up was 6.8, 5.1, and 5.3 years for cemented, stemmed, and cementless groups, respectively. There were significant differences in age and gender distributions between the standard cemented implant control group and the comparator groups (Table 1).

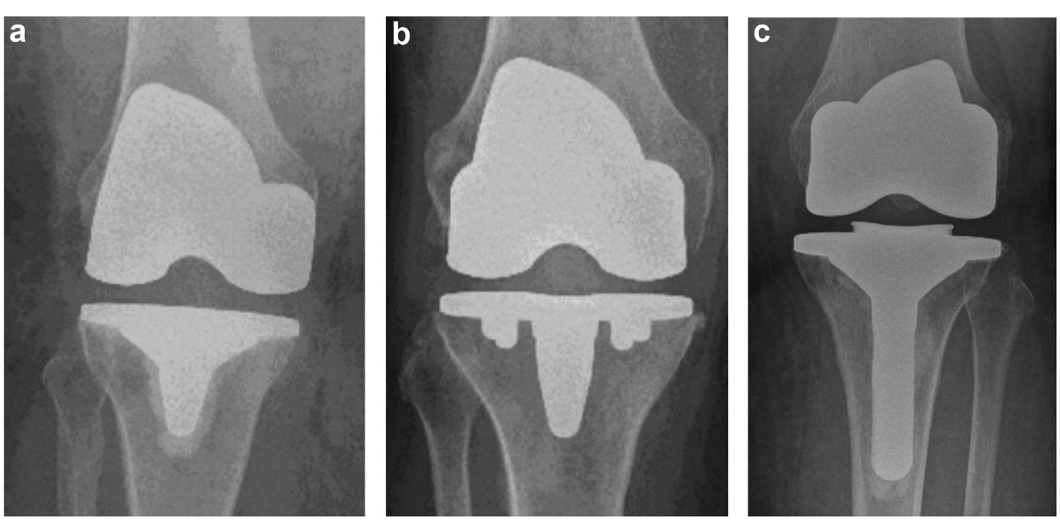

Figure 1. (a-c) Shown are AP radiographs of a standard (a) cemented TKA, (b) cementless TKA, and (c) a stemmed TKA. TKA, total knee arthroplasty.

Table 1
Overview of demographics preoperative characteristics and implant characteristics.

	Control (cemented primary Attune)		Cementless (Attune primary cementless)		Stemmed (Attune revision tray + 50x14mm stem)	
Total No.	2407		220		157	
BMI > 30	1243	52%	100	45%	145	92%
BMI > 35	537	22%	37	17%	125	80%
BMI > 40	178	7%	8	4%	75	48%
Included in analysis: BMI > 30						
Total Prosthesis Years	8529		545		768	
Mean Follow Up (SD) {years}	6.99		5.29		5.26	
Range {years}	2.6-12.7		2.6-7.9		2.6-7.2	
Median (IQR) {years}	7.0 (5.2-8.6)		5.5.(4.2-6.6)		5.4(4.7-6.2)	
Female	797	64%	41	41%	122	84%
Age {years}						
<65	434	35%	60	60%	79	54%
65-74	501	40%	33	33%	44	30%
>=75	308	25%	7	7%	22	15%
ASA						
I	55	4%	8	8%	2	1%
II	862	69%	82	82%	65	45%
III	319	26%	10	10%	77	53%
IV	7	1%	0	0%	1	1%
V	0	0%	0	0%	0	0%
Indication						
OA	1213	98%	98	98%	140	97%
Inflammatory Arthropathy	18	1%	1	1%	3	2%
AVN	2	0%	0	0%	0	0%
Trauma	8	1%	0	0%	1	1%
Other	2	0%	1	1%	1	1%
Cement						
Palacos R+G	369	30%	n/a		4	3%
Smartset GHV	874	70%	n/a		141	97%
Meniscal Constraint						
CR Mobile	747	60%	81	81%	10	7%
CR Fixed	378	30%	0	0%	67	46%
PS mobile	93	7%	19	19%	5	3%
PS Fixed	25	2%	0	0%	63	43%

ASA, American Society of Anesthesiologists; BMI, body mass index; CR, cruciate retaining; IQR, interquartile range; n/a, not applicable; PS, posterior stabilized; SD, standard deviation; AVN, avascular necrosis.

Revisions

Across the entire patient cohort (3239 knees), there were 66 all-cause revisions identified. Of the 1488 knees performed in patients with BMI in excess of 30, there were 37 all-cause revisions, of which 7 were for aseptic loosening (2 tibial, 1 femoral, and 4 involving both components). These were all within the standard cemented implant group with no revisions observed in either the stemmed or uncemented implant groups. There were no significant differences when the standard cemented group was compared to the stemmed tibia or cementless groups. The remaining revisions were undertaken for the following recorded reasons: infection [14], progressive OA/patella resurfacing [6], periprosthetic fracture [1], instability [2], malalignment [1], stiffness [4], and other [1] (Table 2).

An overview of BMI and tibial component alignment for the 6 implants revised where there was tibial loosening is reported in Table 3. There was no gross malalignment noted for the tibial components in these knees.

Table 2
Overview of revisions and indications for revision for all patients with detail of specified cause for patients with BMI > 30 kg/m^2.

	Overview of revisions		Stemmed (attune revision tray + 50 × 14 mm stem)
	Control (cemented primary attune)	Cementless (attune primary cementless)	
Total no. of revisions	66	0 (0%)	4
BMI > 30	34	0 (0%)	3
BMI > 35	11	0 (0%)	1
BMI > 40	5	0 (0%)	2
Included in analysis: BMI > 30			
Infection	11	-	3
Aseptic loosening (All)	7	-	-
Loosening tibia	6	-	-
Loosening femur	5	-	-
Loosening patella	2	-	-
Periprosthetic fracture	1	-	-
Implant wear/fracture	1	-	-
Instability	2	-	-
Malalignment	1	-	-
Stiffness	4	-	-
Progressive OA	6	-	-
Other	1	-	-

BMI, body mass index.

Table 3
Data on 6 patients with tibial loosening.

	BMI (kg/m^2)	AP alignment tibial component (°)	Sagittal alignment (slope) tibial component (°)	Time to revision (y)
Patient 1	36	90.6 (0.6 valgus)	5.0	2.2
Patient 2	44	88.1 (1.9 varus)	4.0	2.2
Patient 3	35	91.0 (1.0 valgus)	2.7	3.7
Patient 4	31	88.6 (1.4 varus)	5.3	4.4
Patient 5	32	87.4 (2.6 varus)	4.8	4.5
Patient 6	34	89.4 (0.6 varus)	5.0	6.7

BMI, body mass index; AP, antero posterior.

Table 4
Overview of published studies comparing cementless and stemmed tibial components to standard tibial components

Study	Study type	BMI	Implant	Mean follow-up control/cohort	n		All-cause revision		Aseptic loosening tibia		Conclusions
					Cemented	Cementless	Cemented	Cementless	Cemented	Cementless	
Bagsby et al., 2016	Multicenter retrospective cohort study	BMI > 40	Triathlon/Scorpio (Stryker)	73/43	154	149	20	1	9	0	Significantly lower all-cause revision and aseptic loosening in cementless cohort
Boyle et al., 2018	Retrospective cohort	BMI > 30	Triathlon (Stryker)	61/62	171	154	3	3	1	1	No significant difference between groups
Sincrope, 2018	Retrospective cohort	BMI > 40	Triathlon/Scorpio (Stryker)	100/72	85	108	5	22	10	1	Significantly lower all-cause revision and aseptic loosening in cementless cohort
					Standard	Stemmed	Standard	Stemmed	Standard	Stemmed	
Elcock et al., 2023	Retrospective cohort	BMI > 40	Triathlon (Stryker)	61/55	57	54	1	2	1	0	No significant differences in 5-year survival
Elzohairy et al., 2020	Randomized control trial	BMI > 35	NexGen LPS Flex (Zimmer)	91	88	92	-	-	13	3	No significant differences in aseptic loosening but noted significant difference in revision for instability
Parratte et al., 2016	Randomized control trial	BMI > 30	NexGen LPS Flex (Zimmer)	36	60	60	1	1	1	0	No significant difference in revisions
Fournier et al., 2020	Retrospective matched cohort	BMI > 30	HLS (Wright-Tornier-Corin)	50/52	105	35	11	5	7	0	Stemmed TKA for obese patients significantly decreased tibial loosening rate
Garceau et al., 2022	Retrospective matched cohort	BMI > 40	Persona (Zimmer-Biomet)	37/36	74	162	-	-	4	0	Stemmed tibia significantly improved survival for aseptic loosening
Steere et al., 2018	Retrospective cohort	BMI > 35	Persona (Zimmer-Biomet), Genesis II (Smith & Nephew)	32	128	50	6	2	0	0	No significant differences

BMI, body mass index; TKA, total knee arthroplasty.

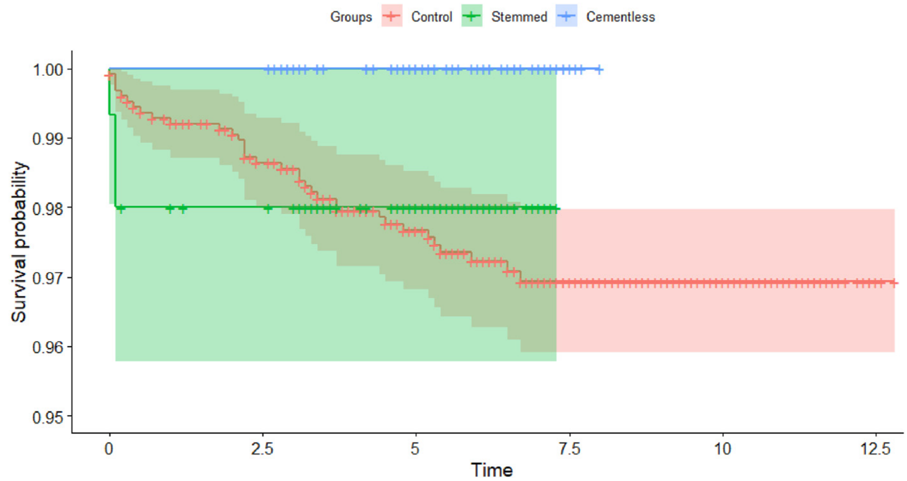

Figure 2. Kaplan-Meier survival chart comparing cemented, cementless, and stemmed groups for all-cause revision.

Survival analysis

Survival analysis did not show any significant differences between the 3 groups for all all-cause revision (Fig. 2) (log rank test: $P = .53$ and $P = .55$ for stemmed and cemented groups, respectively). Similarly, survival analysis with revision for aseptic loosening of the tibia as endpoint showed no significant difference in the stemmed and cementless group when compared to the control group (Fig. 3) (log rank test: $P = .62$ and $P = .89$ for stemmed and cemented groups, respectively).

Cox regression analysis for all-cause revision adjusting for, gender, primary diagnosis, ASA score, and meniscal constraint found no significantly increased risk of revision associated with any parameter. Cox regression analysis for tibial loosening did not show any significant differences in proportion hazard ratio for any of the adjusted parameters.

Discussion

This study found no incidence of tibial component loosening when cementless or stemmed tibial components were used in obese patients. With follow-up periods in excess of 5 years across all groups, this suggests favorable early to mid-term outcomes for both. Survival analysis comparing these to a cohort of standard cemented tibial components showed no significant difference in all-cause revision or revision for tibial component loosening.

An overview of current literature comparing the use of cementless and stemmed tibial components to standard cemented tibial components is detailed in Table 4. Variations of implant designs have been explored. To our knowledge, this is the first study comparing the results of the ATTUNE (Depuy, Warsaw, IN, USA) stemmed and cementless options to standard cemented tibial trays in obese patients.

We report early to mid-term outcomes with mean follow-up of 6.8, 5.1, and 5.3 years for cemented, stemmed, and cementless groups, respectively (minimum 2.5 years from operation). Although loosening is most commonly observed as a late complication, on average requiring revision at 5.5 years (range: 0.03-24.2 years) [16], obesity is shown to increase the risk of early failures [5,17]. Le et al. report 40% of aseptic loosening in obese patients occurred within the first 2 years after surgery [18]. All except 1 case of tibial loosening in our control cohort occurred within the first 5 years. Similarly, most all-cause revisions occurred in the first 5 years. Although it is important to explore early failures, mid-term to long-term follow-up will be required to detect any differences between implants [4].

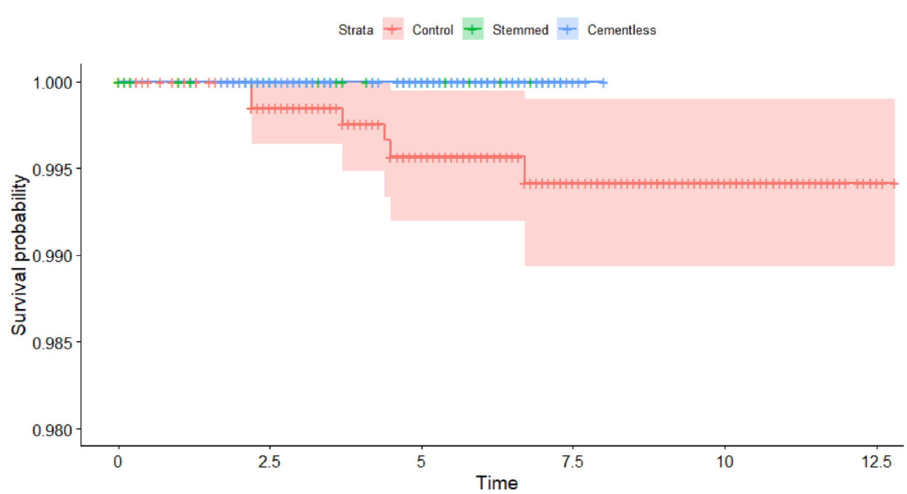

Figure 3. Kaplan-Meier survival chart comparing cemented, cementless, and stemmed groups for revision for tibial loosening.

The cementless cohort in this study showed a 100% survival at a mean of 5.3 years. Other studies have looked at the use of cementless implants in obese patients [12,13,15] (Table 4). King et al. [14] reported a 98% survival of cementless total knee replacements in a cohort of patients with a BMI > 40 kg/m^2. Similarly, Goh et al. [19] reported survival of 97.1% for all-cause revision and 99.0% for aseptic failure for a cohort of 1408 patients with cementless total knee replacements at 7 years. Cox regression across the same cohort did not show an association of increased BMI with increased revision rates, suggesting an improved biological fixation. A further 4 studies [12-15] compared the survival of cementless implants to a control group of cemented implants. They however reported mixed results. Two studies [12,13] reported a significantly lower incidence of all-cause revision as well as revision for aseptic loosening in the cementless implant group. In contrast, Boyle et al. [15], similar to our findings, reported no statistically significant difference between cohorts either for aseptic loosening of the tibia or all-cause revision.

As with the cementless cohort, the group with a stemmed tibial tray had a 100% survival rate at a mean of 5.1 years (2.6-7.3 years). This was also found in other studies reporting the use of stemmed tibial trays in the obese patient [9,10]. The majority of studies identified in the literature comparing stemmed to unstemmed tibial trays in obese patients did not find a significant difference in survival/revision rates [4,7,8,11]. However, 2 studies did report a significantly improved survival for aseptic loosening with the use of an extended tibial stem [9,10].

Overall, many studies comparing strategies to mitigate risk of fixation failure in high BMI patients showed no significant difference, as was the case with this study. Although not significant, all the studies identified did show a lower revision rate for aseptic loosening in obese patients for either cementless or stemmed tibia fixation (Table 4). Notably, in contrast to studies showing a significantly improved survival, no studies showed an increased revision rate for aseptic loosening. This implies that there is no disadvantage to using cementless or stemmed tibial components in obese patients. On balance, it appears that our findings of a lower revision risk for aseptic loosening when using either a cementless fixation or stemmed tibia in obese patients, although not statistically significant, is in line with the findings of other reports in the literature.

In considering which of the 2 enhanced fixation strategies is best in obese patients, other implant-related factors may need to be taken into account. The use of an extended stem with this implant necessitates a reduced tibial slope to avoid an anterior cortical breach. The ATTUNE revision tibial tray which allows a stem to be attached has a built-in 2° tibial slope. This usually necessitates the use of a posterior stabilized implant and in our hands would also be an indication for primary patella resurfacing. When using a cruciate-retaining implant, we would take a more selective approach to the patella. We observed a single intraoperative cortical breach when using an extended tibial stem resulting in cement extrusion. This did not require revision. The risk of this would be reduced when using a standard cementless tibial component. Similarly, the possibility of future revision is also a consideration. The increased magnitude of the resulting bone defect post extraction with extended tibial stems may compromise future revision options [20].

We acknowledge the limitations of this retrospective cohort study. Perfectly matched cohorts could not be achieved given the number of patients available; as such, the proportion of high BMI patients in cemented and cementless groups were not the same as in the stemmed group. This results from high BMI being the primary indication in our institution for using a stemmed tibia and other indications being rare. The follow-up periods are shorter for the stemmed and cementless groups in comparison to the control group. However, none of the 6 failures in the control group occurred after the mean follow-up period.

Age and gender distribution of the groups differed. Younger patients receive stemmed or cementless implants more frequently compared to the standard cemented implant group. In the cementless group, the majority were male. This was not the case in the other 2 groups. These differences between the groups reflect surgeon choice. These choices are taken in specific at-risk cohorts (high BMI, active) in an attempt to mitigate the increased demand on implant fixation. However, a Cox proportional hazards regression analysis did not reveal any difference between groups associated with significant change in revision rate in this study cohort. Smoking has also been associated with an increased risk of aseptic loosening [21]. In our cohort, none of the patients who underwent revision for aseptic loosening were smokers, nor at the time of their index arthroplasty or at the time of their revision.

The cemented group had longer mean follow-up of 6.8 years compared to 5.3 and 5.1 years in the cementless and stemmed groups, respectively. Although aseptic loosening is considered a late complication, there is an increased early risk of failure observed in the obese patient population [4,5,17] and 40% of aseptic loosening is seen within the first 2 years [18].

Within the context of the National Health Service in the United Kingdom, the cost of a treatment should also be taken into consideration when comparing equivalent treatments. Extended stemmed tibial implants (which require the use of a revision implant tray with an additional stem) cost more than a standard cementless implant. In our institution, taking the cost of components and cement into account, the cementless implant represents a 21% and the stemmed a 69% premium over a standard cemented implant. The cost of revision surgery and any perceived or actual theater time saving or expense are more challenging to factor into a detailed cost analysis, which is beyond the scope of our study.

Conclusions

With short to mid-term follow-up, we did not observe any revisions for aseptic loosening when a cemented, stemmed, or cementless implant was used. These findings are in line with other studies showing that cementless fixation or extended stem implants are not inferior in obese patients who represent an increasing cohort of patients requiring and undergoing knee arthroplasty. However, although both options appear to be effective in reducing the risk of aseptic loosening, the use of a stemmed tibia may have disadvantages, such as an increased risk of cortical breach intraoperatively, given the difficulties associated with alignment in obese patients [22], and increased difficulty of revision.

Although no statistically significant differences of mid-term survival were found between the 3 groups at this point in time, long-term follow-up is required. One group may become more clearly preferable with continued follow-up. At this stage, we cannot draw a strong conclusion in support of either cementless or extended stem tibial components. Our preference, all other things being equal, would be for cementless fixation given potential disadvantages of intraoperative difficulty, difficult revision, and additional expense.

Conflicts of interest

Bernard H. van Duren received research support from Medacta International as a Principal Investigator. Reshid Berber is a paid consultant for DePuy Synthes J&J; received research support from DePuy Synthes J&J as a Principal Investigator. Benjamin Bloch is a paid consultant for DePuy Synthes, Zimmer Biomet, and Ethicon; received research support from DePuy Synthes as a Principal

Investigator; received royalties, financial or material support from Springer Nature (Revision Knee Arthroplasty – A Practical Guide textbook); and is in the Medical/Orthopaedic publications editorial/governing board of Bone & Joint 360. Peter James received royalties from DePuy Synthes; is a paid consultant for DePuy Synthes; and received royalties, financial or material support from Springer Nature (Revision Knee Arthroplasty – A Practical Guide textbook). All other authors declare no potential conflicts of interest.

For full disclosure statements refer to https://doi.org/10.1016/j.artd.2025.101621.

CRediT authorship contribution statement

Bernard H. van Duren: Writing – original draft, Formal analysis, Data curation, Conceptualization. **Amy M. Firth:** Writing – review & editing, Data curation. **Reshid Berber:** Writing – review & editing, Formal analysis, Conceptualization. **Hosam E. Matar:** Writing – review & editing, Formal analysis, Conceptualization. **Peter J. James:** Writing – review & editing, Conceptualization. **Benjamin V. Bloch:** Writing – review & editing, Formal analysis, Conceptualization.

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