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Effects of implant precoating and fat contamination on the stability of the tibial baseplate



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ABSTRACT

Background: Approximately 5% of primary total knee arthroplasty patients require revision within 10 years, often due to distal component loosening. Application of a thin layer of PMMA cement as precoating on the tibial component aims to prevent aseptic loosening. This study investigates the impact of precoating and fat contamination on tibial baseplate stability.

Methods: Two groups of NexGen[®] stemmed tibial implants (size 4) were studied: Option implants (N = 12) and PMMA Precoat implants (N = 12). Each implant design was divided into two subgroups, (N = 6), with one subgroup featuring bone marrow fat at the implant-cement interface and the other without contamination. In a mechanical testing machine, the implants underwent uniaxial loading for 20,000 cycles, while recording vertical micromotion and migration of the tibial baseplates. Subsequently, a push-out test assessed fixation strength at the cement interfaces. Results were compared using non-parametric statistics and presented as median and min-to-max ranges.

Results: Option implants exhibited higher micromotion in dry conditions compared to precoated implants (p = 0.03). Under contamination, both designs demonstrated similar micromotion values. Fixation strength did not significantly differ between designs under dry, uncontaminated conditions (p > 0.99). However, under contaminated conditions, the failure load for the non-coated Option implant was nearly half that of the uncontaminated counterparts (3517 N, 2603–4367 N vs 7531 N, 5163–9000 N; p = 0.002). Precoat implants displayed less susceptibility to fat contamination (p = 0.30).

Conclusion: NexGen[®] implant PMMA precoating might reduce the risk of aseptic loosening and revision surgery in case of eventual bone-marrow fat contamination.

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1. Introduction

Total knee arthroplasty (TKA) is an orthopaedic procedure used to address severe degenerative joint illness, namely osteoarthritis, by the substitution of impaired surfaces with synthetic prostheses. This operation reduces pain, restores

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the joint functions, and improves patient mobility, boasting a success rate of up to 95% thanks to developments in implant design and surgical procedures [1,2]. Revision operations, although rare, present a significant challenge for both medical professionals and patients due to reduced prosthesis survival rates [1,3].

Understanding the reasons for primary TKA failure is crucial for improving the implant's survival outcomes and reducing healthcare costs. Several variables can contribute to the failure of a knee implant, among them instability, inappropriate insertion of the implant, and the occurrence of aseptic loosening of the components. These issues may be linked to surgical techniques adopted during the operation, such as variations in the cementing technique or contamination of the interfaces.

According to the Norwegian Arthroplasty Register (NAR), aseptic loosening of the distal component is the third most common cause of TKA failure, following instability and pain, accounting for approximately 11% of all revisions between 2016 and 2022. This marks a slight decrease from the 15% reported between 2005 and 2015 [1,2]. Several factors have been associated with aseptic loosening of the tibial baseplate, including wear particle exposure, implant alignment, cement mantle thickness, patellar resurfacing, and implant design [4].

Studies have shown that procedures with an average migration of 1 mm the first year after surgery have a significantly higher risk of failure and are more likely to require revision surgery within the following 5 years [5]. Many theories have been proposed to explain the causes of implant failure. For this project, the emphasis will be on the implant's mechanical stability and its binding strength, which are heavily influenced by the implant's design and its relationship to the cementation conditions of the surgery.

Recent advancements in specialised coating technologies, such as hydroxyapatite (HA), have made uncemented implants increasingly popular. Yet, their adoption remains limited mainly due to a lack of conclusive results on the long-term survival of implants and patient outcomes. Still, studies have shown an increase in the survival rate for patients implanted in the last decade, with 10-year Kaplan-Meier survivorship rates between 1.5–2.0% below those of cemented types [1,6,7].

The Zimmer Biomet NexGen[®] implant has been the main brand for TKA in Norway since 2014, capturing a market share of 44% of all cemented primary TKAs in the period between 2016–2022. Out of this group, approximately 62% consisted of the Precoat stemmed version vs 36% for the Option version (NexGen[®] Complete Knee Solution—Precoat) [1]. This phasing out of the Option variant is followed by other national agencies after an increased risk of tibial loosening was detected when implanted in conjunction with LPS implants [8,9].

Coating techniques with polymethylmethacrylate (PMMA) and increased roughness are used to improve the mechanical grip of cemented implants [10]. First proposed in 1982, coating titanium alloy with a thin film of PMMA allowed the increase of the implant bone-cement interface strength to levels similar to that of bone cement [11]. However, assessing the direct effect of PMMA pre-coating on the tibial baseplate's stability is challenging, which leads to a lack of current studies supporting its use over cheaper, non-coated variants [12]. Studies have shown conflicting results, with some indicating a higher risk of revision and others suggesting a lower risk associated with said PMMA coating [12–14].

The presence of contaminants, such as bone marrow fat or blood, can interfere with the bonding between the implant and the bone, potentially reducing its stability [15]. It is theorised that migration of residual bone marrow fat to the implant-cement interface during early joint flexion may significantly reduce its bonding strength [16].

This study aims to examine how pre-coating tibial baseplates with PMMA affect implant stability in dry and fatcontaminated conditions. By studying how fixation conditions affect implant survival, valuable insights can be gained about the factors that lead to their failure.

2. Materials and methods

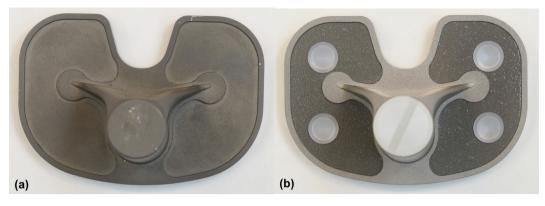
The methodology described in this section is inspired by the experimental designs of previous studies, particularly those presented in the works of Kelly et al. (2021) and Crook et al. (2017) [15,17].

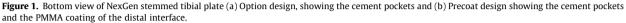
2.1. Implants

Two versions of the NexGen[®] (Zimmer Biomet, Warsaw, Indiana, USA) tibial baseplate were included in this study: Nex-Gen[®] Option (NexGen Complete Knee Solution, Figure 1a, N = 12) and the NexGen[®] Precoat (NexGen Complete Knee Solution–Precoat, Figure 1b, N = 12). Both variants include a triangular tibial stem that is 37.7 mm long. Their composition consists of a titanium grade five alloy (90%), alumina (6%), and vanadium (4%) known as Tivanium[®] Ti-6AI-4 V Alloy.

These implants are appropriate for cruciate-retaining surgeries and are equipped with cement pockets on their surface to improve the adherence of cement [18,19]. Ten different sizes of implants are available, and for this project, a size four base-plate was selected due to its compatibility with the Sawbone tibial model. The Precoat implants share the same geometry as the Option variant, but differ in having a PMMA coating layer on the distal interface, polyethylene (PE) covered holes for augment fixation, and the option to add a modular stem.

Both baseplates were tested using an ultra-high-molecular-weight polyethylene (UHMWPE) 14 mm plastic insert. The PE-inserts were reused between tests, with one insert per testing group.





2.2. Bone model and bone preparation

Composite bone models, as depicted in Figure 2, were used to represent the in vivo anatomy of the tibia, while minimising inter-specimen variability. Current "4th generation" bone composites are capable of faithfully reproducing human bone biomechanical properties and have been validated for biomechanical studies [20,21].

To prepare the bone, surgical instruments by Zimmer Biomet[®] were positioned and fixed with surgical nails onto the tibia surface (Figure 3). The implant was positioned to ensure adequate cortical support for both the anterior side and rear condyles. In addition, the guide was used to secure the drilling guide and followed the same instructions as in the operating theatre. The drilling was done with a surgical bit that had a mark indicating the drilling depth. Finally, the bone impactor is forcefully inserted into the drilled hole by hammering. This creates enough space in the bone to accommodate the implant stem and its wings. Both the implant and the bone model were weighed before and after cementation to determine their respective masses.

2.3. Bone cement and cementation procedure

Palacos[®] R + G (Heraeus Medical LLC, Warsaw, Indiana) bone cement stored in a 3 °C fridge was used to perform full cementation (FC) with cement also placed into the stem canal. The choice of cement type was made due to its high adoption in the Norwegian market [1]. The preparation was carried out according to the manufacturer's instructions using a Palamix[®] vacuum mixer to get a bubble-free cement dough.

The bone cement preparation began with the combination of the liquid and powder constituents, subjected to a vacuum, and then mixed. After 2 min, cement was applied, first on the implant and subsequently on the bone surface and in the prepared cavity. The bone cement was administered via a Palamix[®] cement gun. The implant was then inserted into the bone model and secured to some extent using a hammer just after the cement was applied. A 50 N force was applied to the specimen 4 min after cement preparation began and maintained until the 13-minute mark from the beginning of the cement mixing. This stage is analogous to the "extension under compression" procedure used in the operating theatre. Finally, the specimen was put in a heating cabinet set at the physiological temperature of 37 °C for 30 min to secure a successful curing of the cement.

2.4. Bone marrow fat contamination

Each implant design was divided into two subgroups (N = 6) with and without contamination of the implant-cement interface. For the contaminated groups, 0.15 ml of bone marrow fat was placed around the edges of the distal interface of the tibial implant before cementing. The fat was collected from a calf bone and was stored frozen at -23 °C. At the moment of application, the content was heated to 70 °C.

2.5. Stability test

The model was subjected to a compressive cyclic load 24 h after the cementation of the implant using servo-hydraulic biaxial mechanical testing equipment (MTS Model 858 Mini Bionix II[®]) without the use of any lubricant at the bearing site. The load curve was captured from a real person weighing 75 kg performing level walking [22]. Each baseplate was loaded axially for 20,000 cycles with a minimum load of 100 N, peak load of 1.76 kN and loading frequency of 1 Hz (Figure 4).

Three linear variable differential transformers (LVDT; Solartron Metrology[®], Leicestershire – United Kingdom; model: AX/1.5/S) were fixed to the baseplate with custom made holders at an angle of approximately 120° to measure the vertical



Figure 2. The Sawbone[®] models, (Pacific Research Laboratories Inc. Vashon, WA, USA) were made using firm polyurethane foam. The density of the foam is 12.5 lb per cubic foot (PCF) for simulating cancellous bone and 40 PCF for simulating the outer cortical shell (product reference: 1522-912). As per the manufacturer, both materials comply with the ASTM F1839-08 material standard. The model has a rectangular base of approximately 5.7 cm in width, 7.6 cm in length, and 7.6 cm in height. The proximal end has been shaped to correspond to the tibia, measuring 46.2 × 75.3 mm.

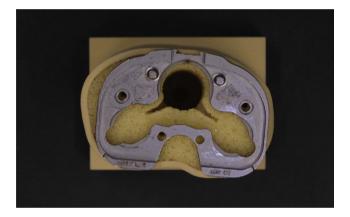


Figure 3. Top view of the prepared bone model showing the surgical guide used during the process, the drilled stem hole and the broach for the cruciate stem.

displacement at the anterior, posterolateral, and posteromedial positions of the implant (referred to as anterior, lateral, and medial, respectively). These LVDTs were supported by a metallic plateau attached to the bone model walls approximately 8 mm under the lower edge of the baseplate, following the same distribution of the holders as illustrated in Figure 5. The LVDTs are graded for a measurement range of ± 1.5 mm with an accuracy of 1.5 μ m.

This step, in which the load was placed in a slightly medial distribution (Figure 6), also functioned as a "preconditioning" for the subsequent adhesion test [16].

Raw stability data were collected using a Digital to Analog Converter (DAC) unit, the Fylde micro ANALOGUE 2, from Fylde Electronic Laboratories. Five columns containing time stamps, force values, and three LVDT data points were recorded with a sampling rate of 100 samples per second. Matlab was used to extract motion curves, implant migration and micromotion at the end of the cyclical load for each measured LVDT position.

2.6. Adhesion test

A push-out test was conducted to measure the adhesion strength between the tibial implant and the bone cement. To reinforce the construct, specimens were embedded in self-polymerising denture resin (Meliodent[®] Heat Cure – Rapid Repair, Kulzer – Mitsui Chemicals Group, France). The model was placed in a metallic cylinder and secured with six screws for fix-ation and levelled positioning (see Figure 7). Around 450 ml of the resin that had been prepared was poured into the mould, ensuring that it entirely covered the Sawbone but left the cement mantle and implant exposed.

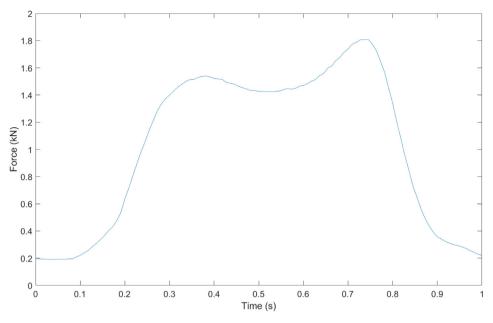


Figure 4. Representation of one cycle (s) of the load curve (kN).

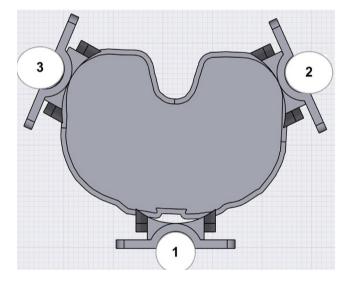


Figure 5. LVDT positioning with numeric identification, (1) anterior, (2) lateral, and (3) medial.

Axial push-out strength was measured using an Instron 5966 universal testing machine equipped with a 10,000 N uniaxial load cell, an Instron[®] digital controller, and Bluehill[®] 3 (version 3.76) software. A 10 mm drill was drilled into the rigid base of the tibia bone models to reach the distal end of the tibial baseplate. The tests utilised a standard configuration with a displacement control rate of 0.05 mm/s. The maximum load endured before failure and the respective failure modes were recorded for each sample. Failures were categorised as: no-failure, bone failure, implant debonding, or failure between the bone and cement. This test was set up similarly to existing literature [23].

2.7. Statistical methods

All data were analysed using non-parametric tests due to the small sample size using GraphPad Prism 10 (GraphPad[®] Software). Results are shown in median values, with their maximum and minimum range represented in parentheses. A Kruskal-Wallis test, in conjunction with Dunn's multiple comparisons, was used to evaluate the impact of implant type and the presence of bone marrow fat in the four comparison groups. Mann-Whitney *U* test was used to assess the differences

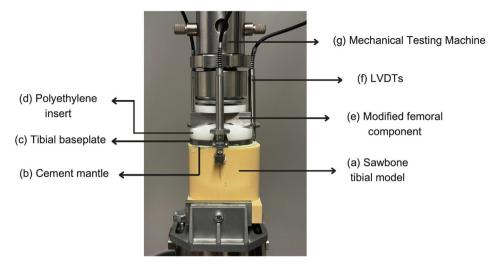


Figure 6. The stability testing rig with the mechanical testing system medially displaced. The system includes: the implanted bone model – sawbone tibial model (a), cement mantle (b), tibial baseplate (c), PE insert (d), modified femoral components (e) –, the LVDTs (f), and the mechanical testing machine (g).

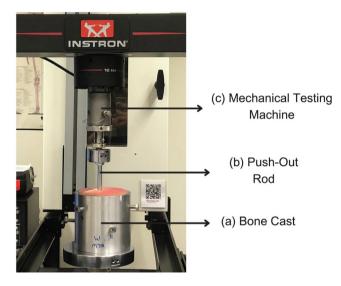


Figure 7. Components of the adhesion test: (a) the casted model, (b) the push-out rod, and (c) the mechanical testing machine.

in baseplate motion between the uncontaminated Option and Precoat groups. Spearman correlation was used to investigate the relationship between implant motion, cement thickness, and push-out force for all groups. Tests with a p-value equal to or lower than 0.05 were defined as statistically significant. Graphs are displayed as box plots with whiskers representing min-to-max intervals.

2.8. Variable definition

Inducible micromotion was calculated using the difference between the loading peak and the subsequent unloading phase, or the amplitude of the oscillatory motion recorded by the LVDTs. Permanent migration was assessed by calculating how much the implant had moved from its original position at the end of the stability test. To better display the tibial base-plate's movement trajectory, migration findings were also split into subsidence and lift-off values.

The overall movement of the tibial component was determined by averaging measurements taken at three different LVDT positions, resulting in relative micromotion and relative migration values.

3. Results

3.1. Implant stability

Both versions of tibial baseplates demonstrated stable fixation throughout the stability testing, with no instances of loosening or debonding noted.

I. Vertical micromotion of the tibial baseplate

The median relative micromotion was 14.1 μ m (11.1–18.6 μ m) for the Option design and 10.6 μ m (7.7–11.8 μ m) for the Precoat design in the non-contaminated groups. Contamination caused micromotion values to slightly change: 11.5 μ m (10.4–15.3 μ m) for the Option group and 10.2 μ m (9.3–12.3 μ m) for the Precoat group.

The groups were statistically different (Kruskal-Wallis p = 0.03), particularly when comparing the Option dry and Precoat dry designs (Figure 8) (Mann-Whitney p-value: 0.03).

II. Direction of motion

During cyclic loading, 15 baseplates exhibited maximum subsidence medially, 7 laterally, and 1 anteriorly. There was no significant difference in the relative migration of the tibial baseplate between the four groups (Figure 9)(p = 0.91). Lift-off mainly occurred anteriorly in 3 out of 4 groups. There was a significant difference in movement between the anterior and medial points in the Option dry group (Kruskal-Wallis p-value: 0.01; Dunn's p-value: 0.04), more detailed information on the specific motion behaviour of each measured LVDT position can be seen in Figure 10.

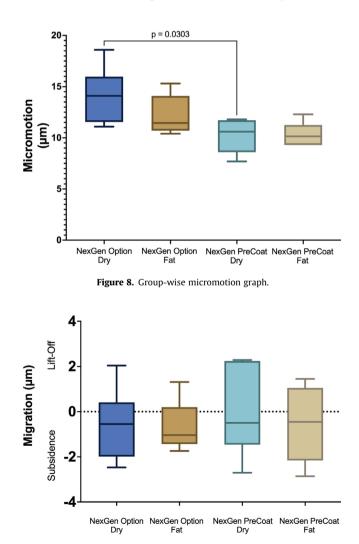


Figure 9. Boxplot showing relative migration for all test groups (N = 6). Negative migration is defined as subsidence and positive values as lift-off.

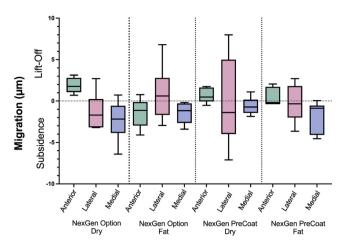


Figure 10. The graph shows migration for all the LVDT positions (anterior, lateral and medial) and for all tested groups.

3.2. Adhesion

Under contaminated conditions, the failure load for the Option implants was nearly half (3517 N, 2603–4367 N) that of their uncontaminated counterparts (7531 N, 5163–9000 N) (Dunn's = 0.002). Precoat implant fixation was less affected by fat contamination (4606 N, 2573–6231 N vs. 6116 N, 4832–7000 N; p = 0.30) compared to Option implants. When assessing both designs under non-contaminated conditions, no differences in fixation were observed (p > 0.99). Groupwise comparisons are shown in Figure 11. Implant debonding was much more prevalent in the contaminated groups than in the dry groups (10 out of 12 vs 4 out of 12). Bone-cement failure often happened due to implant debonding in the stem region (Figure 12).

3.3. Cross-factors influence

I. Cement thickness:

The cement thickness was consistent across all groups, with median measurements ranging from 1.35 to 1.69 mm. No correlation between implant micromotion and cement mantle thickness was found (Spear man's r = 0.18; p = 0.40). Migration decreased as cement-mantle thickness increased (Spearman's r = -0.63; p = 0.03) particularly in non-contaminated samples, as shown in Figure 13.

Cement mantle thickness did not affect push-out force overall (p = 0.81). However, there was a trend (Spearman's r = 0.44; p = 0.15) for stronger push-out forces on samples with thicker mantles, particularly within dry groups, regardless

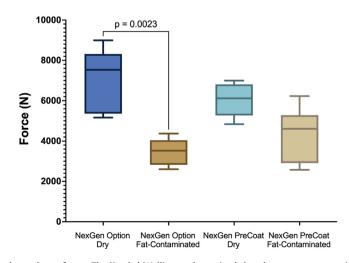


Figure 11. Group-wise graph for the push-out forces. The Kruskal-Wallis test determined that the groups were statistically distinct (p < 0.01), and the subsequent Dunn's multiple comparison test revealed differences between the Option dry and Option contaminated groups (p = 0.002).

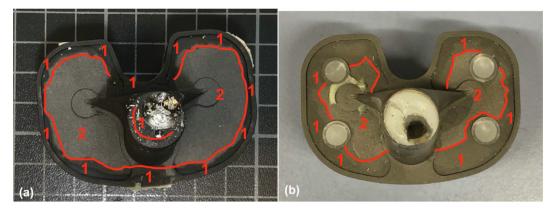


Figure 12. Spreading of the fat content on the distal side of tibial baseplate: (a) Option and (b) Precoat after the cyclical load and push-out test. Areas with the number 1 indicated the contaminated area and number 2, the dry portion of the implant.

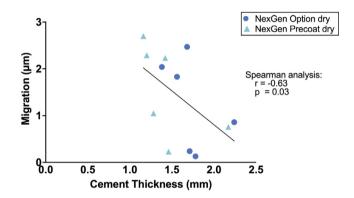


Figure 13. Spearman's correlation between implant migration (µm) in absolute value, and cement thickness (mm) for dry samples.

of implant design. High absolute migration values resulted in significantly lower push-out forces (Spearman's r = -0.69; p = 0.01) for dry implants, regardless of the chosen design (Figure 14).

4. Discussion

The stability of two different tibial baseplates by the same company was measured using cyclical loading and adhesion tests with the aim to better assess the effect of the PMMA coating. When non-contaminated, we found no differences between both designs neither in micromotion pattern nor in adhesion strength. Micromotion was consistently observed

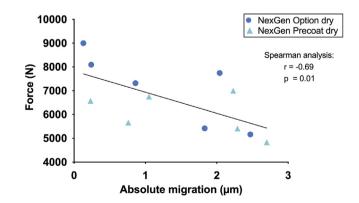


Figure 14. Spearman's correlation between push-out force (N) and absolute migration (µm) for dry samples.

in all tested groups, indicating uniformity in the implantation procedure despite design differences and potential contamination. Both subsidence and lift-off values are small, well within the "excellent fixation" range [24]. For most of the samples, lift-off occurred on the anterior point, suggesting a posteromedial loading of the samples, while medial and lateral points tended to subside. Non-coated Option samples had slightly higher push-out forces than Precoat ones. Contamination of the implant-cement interface with bone marrow fat reduced bonding for non-coated implants with their median pushout strength reduced by 45% compared to the dry counterpart. Precoat samples, on the other hand, were not significantly impacted, showing a lower reduction by 25%.

Under this specific regime of cyclical loading, the measured baseplate micromotion values varying between 10.2 μ m and 14.1 μ m, are similar to those documented in other in vitro studies [24–27]. The relative migration results in this study are considerably lower than the millimetre-scale values reported in standard RSA investigations along the Y-axis, which typically ranges from 0.2 mm to 2.1 mm [5,28,29]. To compare our migration values to maximum total point motions (MTPM) often reported for RSA studies at 2 years follow up, (with 0.2 mm precision) is not straightforward.

The highest recorded migration value after the 20,000 load cycles was 8.4 µm, which is equivalent to around 3 months of walking [17]. So, in 1 year, the cumulative displacement is estimated to be below 0.1 mm. Laende et al. [30], compared RSA values from different implant designs, including NexGen[®], regarding differences in the migration of cemented and uncemented implants at 1 and 2 years post-surgery [30]. Our estimated migration is below the range of the reported MTPM for the cemented NexGen[®] design at the 1-year mark (median: 0.38 mm; range: 0.14–1.66 mm). In a meta-analysis, Pijls et. al. [31] concluded that a mean MTPM at 1 year mark less than 0.5 mm was considered at an "acceptable" risk for early aseptic loosening [31]. The estimated migration aligns with the good implant survival rate for both NexGen[®] designs as shown in the Norwegian arthroplasty register, despite the challenge of comparing in vitro testing to patient data [1].

The push-out force ranges of precoated and uncoated samples were comparable, indicating that the PMMA coating did not offer a significant bonding strength advantage. This is consistent with the available literature. Bini S.A. et al. [14] investigated the relation between PMMA coating of TKA tibial baseplates and implant survival in patients also using NexGen[®] implants and found no protective effect related to the coating, with revision surgeries uncommon for both designs [14]. Using a pull-out test, Martin et al. [32] compared the adhesion strength of four implant designs in cadaveric bones with and without motion during the curing phase of the cement, to reproduce lipid infiltration on the implant-cement interface and assess its impact on the pull-out values of the implants. Both non-coated Option and Precoat NexGen[®] implants in our study exhibit adhesion strength comparable to that of the Attune S+ (DePuy[®]; mean: 7230 N +- 1557 N), the Persona (Zimmer[®]; mean: 5806 N +- 2323 N) and the Triathlon (Stryker[®]; mean: 5325 N +- 1944 N) in the non-motion (dry) cohort. When contaminated, the Precoat implant performed similarly to their Triathlon (Stryker[®]; mean: 4054 N +- 889 N) cohort group, while the Option implant outperformed their Vanguard[®] samples (Stryker[®]; mean: 2196 N +- 1342 N) [32].

Kelly et al. [15] used a similar pull-out setup to explore the impact of fat contamination on first and second-generation Attune (DePuy[®]) and the PFC Sigma (DePuy[®]) tibial baseplate on bone models. Both Option and Precoat designs performed better than the 1st gen Attune and the PFC Sigma when implanted in dry conditions, demonstrating push-out values very comparable to their Attune S. Furthermore, even when contaminated, the Precoat design in our study outperformed their results for the PFC Sigma in dry conditions [15].

Implants with the Option design showed both high relative median micromotion and good adhesion in dry conditions. We found no correlation between the implant's relative micromotion and push-out values. However, an increase in (absolute) migration within the group resulted in a decrease in the force required to push-out the tibial baseplate from the implanted bone. Additionally, the presence of thicker cement mantles was found to reduce the absolute migration of the baseplate. Both these findings are supported by the literature, suggesting a correlation between higher implant motion to early implant failure [31]. Surprisingly, the relationship between cement mantle and push-out force was not statistically significant. However, there was a tendency indicating that samples with thicker cement mantles tended to have greater push-out values.

Jaeger et al. [16] conducted a study comparing the relative motion to the bone of Attune and Attune S + tibia components under various loads and flexion points using cadaveric bones. Their findings revealed that bone marrow fat infiltrated the implant-cement interface through small defects in the cement mantle [16]. Building upon these findings, our research suggests that the formation of unnoticed defects in the cement layer, such as cracks or unfilled spaces, may contribute to certain unexplained cases of aseptic loosening. Additionally, other studies propose that the process of bone resorption around the cement mantle significantly compromises the cement-bone bond, potentially leading to the development or expansion of these defects over time. Consequently, this could result in increased fat infiltration, thereby weakening the implant's stability [33,34].

These findings suggest that using PMMA to pre-coat the tibial baseplate helps reduce the negative effects of fat contamination on bonding strength. Which, in turn, could offer a more forgiving system for use in the operating theatre. Further investigation of the relation between cement viscosity and micro-gaps when in vivo in the cement mantle could advance our comprehension of how bone marrow fat infiltration contributes to aseptic loosening and how common of a problem fat contamination of the implant-cement interface really is. Currently, the topic of low vs high-viscosity bone cements is still in debate. Dinh et. al. [35] investigated the differences in cement mantle depth between two high viscosity bone-cement applied with two different techniques using cadaveric bones [35]. When using a finger packing method, the lower viscosity bone-cement allowed deeper cement penetration, closer to the ideal 3–4 mm range proposed by literature. Silverman et. al. [36], on the other hand, proposes that the higher cement penetration observed in low viscosity cements is not present on in vivo TKAs due to the squeeze bearing effect, with lower viscosity cement escaping from under the tibial baseplate during the compression period [36].

In addition to implant design and surgical factors, other elements may also contribute to the loosening of the tibial baseplate. A well-established link exists between polyethylene wear and aseptic loosening. Recent findings indicate that this effect is not limited to the articulating surface but also involves backside deformation of the PE-insert [37]. This was evident in NexGen[®] PS inserts but to a lesser extent for CR inserts [37].

There were some limitations in the research methodology. Between each mounting of the specimens in the mechanical testing rig, we aimed to find the same contact point between the ball and the modified femoral component (Figure 6). A slight variation in the contact point might have caused a small deviation in the loading distribution to the baseplate and could explain the variance in migration measurements [38,39].

Due to physical constraints, measurements were also limited to three positions: anterior; lateral; and medial. Employing optical methods could enhance the collection of data points around the implant, facilitating a more comprehensive understanding of the tibial component's movement. Although cement thickness consistently measured below the recommended 3 mm in all groups examined, which might be explained by the lack of interconnectivity within the Sawbone[®] bone's porous structure, stability tests indicated no increase in micromotion. Comparing the effect of fat-contamination and other physiological contaminants on the adhesion strength of other implant designs may also yield valuable insights into the best alternative for hospitals and patients.

5. Conclusion

Bone marrow fat contamination greatly affects push-out forces, particularly in the non-coated Option implants. The Precoat implants, on the other hand, exhibit greater resilience in fat-contaminated conditions. Tibial baseplate stability tests showed no loosening or debonding. In non-contaminated groups, the Option design showed a 33% higher median relative micromotion compared to the Precoat design, still, the four groups had similar tibial baseplate movement patterns. Dry samples with thicker cement mantle tended to have lower absolute migration and higher push-out force.

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Declaration of Generative AI and AI-assisted technologies in the writing process

During the preparation of this work, the author(s) used Quillbot AI in order to clarify and proofread the text. After using this tool/service, the author(s) reviewed and edited the content as needed and take(s) full responsibility for the content of the publication.

CRediT authorship contribution statement

Maya Maya Barbosa Silva: Writing – review & editing, Writing – original draft, Investigation, Formal analysis, Data curation. Jan-Erik Gjertsen: Writing – review & editing, Funding acquisition. Irene Ohlen Moldestad: Writing – review & editing, Methodology, Data curation. Ove Nord Furnes: Writing – review & editing, Supervision, Conceptualization. Michelle Khan: Writing – review & editing, Investigation, Data curation. Paul Johan Høl: Writing – review & editing, Supervision, Project administration, Methodology, Formal analysis, Conceptualization.

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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References

^[1] Furnes O, Gjertsen JE, Hallan G, Inderhaug E, Gundersen T, Hole R, et al.. Yearly Report Norwegian National Advisory Unit on Arthroplasty and Hip Fractures Norwegian Arthroplasty Register Norwegian Cruciate Ligament Register Norwegian Hip Fracture Register Norwegian Paediatric Hip Register Report 2023; 2023. Available from: https://www.helse-bergen.no/4ad4ab/contentassets/ 9f19d57711ee4e60815d6b89e8e8472b/report2023.pdf.

- [2] Dyrhovden GS, Lygre SHL, Badawy M, Gøthesen Ø, Furnes O. Have the causes of revision for total and unicompartmental knee arthroplasties changed during the past two decades? Clin Orthop Relat Res 2017;7(475):1874.
- [3] Greidanus NV, Peterson RC, Masri BA, Garbuz DS. Quality of life outcomes in revision versus primary total knee arthroplasty. J Arthroplasty 2011;6 (26):615–20.
- [4] Kutzner I, Hallan G, Høl PJ, Furnes O, Gøthesen Ø, Figved W, et al. Early aseptic loosening of a mobile-bearing total knee replacement Available from:. Acta Orthop 2018;1(89):77–83. https://www.tandfonline.com/doi/abs/10.1080/17453674.2017.1398012.
- [5] Ryd L, Albrektsson BEJ, Carlsson L, Dansgard F, Herberts P, Lind strand A, et al. Roentgen stereophotogrammetric analysis as a predictor of mechanical loosening of knee prostheses. https://doiorg/101302/0301- 620X77B37744919. 1995 5;77:377-83. Available from: https://online. boneandjoint.org. uk/doi/abs/10.1302/0301-620X77B37744919.
- [6] Irmola T, Ponkilainen V, Mäkelä KT, Robertsson O, W-Dahl A, Furnes O, et al. Association between fixation type and revision risk in total knee arthroplasty patients aged 65 years and older: a cohort study of 265,877 patients from the Nordic Arthroplasty Register Association 2000–2016 Available from:. Acta Orthop 2021;92:90–5. https://actaorthop.org/actao/article/view/763.
- [7] Niemeläinen MJ, Mäkelä KT, Robertsson O, WDahl A, Furnes O, Fenstad AM, et al. The effect of fixation type on the survivorship of con temporary total knee arthroplasty in patients younger than 65 years of age: a register-based study of 115,177 knees in the Nordic Arthroplasty Register Association (NARA) 2000–2016 Available from:. Acta Orthop 2020;1(91):184–90. https://actaorthop.org/actao/ article/view/484.
- [8] Wilton T, Skinner JA, Haddad FS. Camouflage uncovered: what should happen next? The bone & joint journal. 2023 3;105-B:221-6. Available from: https://pubmed.ncbi.nlm.nih.gov/36854320/.
- Keohane D, Sheridan GA, Masterson E. High rate of tibial debonding and failure in a popular knee replacement : a follow-up review Available from:. Bone Joint open 2022;6(3):495–501. https://pubmed.ncbi.nlm.nih.gov/35698801/.
- [10] Pittman GT, Peters CL, Hines JL, Bachus KN. Mechanical bond strength of the cement-tibial component interface in total knee arthroplasty. J Arthroplasty 2006;9(21):883–8.
- [11] Raab S, Ahmed AM, Provan JW. Thin film PMMA precoating for improved implant bone-cement fixation Available from: J Biomed Mater Res 1982 (16):679-704. https://pubmed.ncbi.nlm. nih.gov/7130220/.
- [12] Keohane D, Power F, Cullen E, O'Neill A, Masterson E. High rate of tibial debonding and failure in a popular knee replacement: A cause for concern Available from:. Knee 2020;3(27):459-68. https:// pubmed.ncbi.nlm.nih.gov/31883858/.
- [13] Brown M, Ramasubbu R, Jenkinson M, Doonan J, Blyth M, Jones B. Significant differences in rates of aseptic loosening between two variations of a popular total knee arthroplasty design. International Orthopaedics. 2021 11;45:2859. Available from: /pmc/articles/ PMC8560675//pmc/articles/ PMC8560675/?report=abstracthttps: //www.ncbi.nlm.nih.gov/pmc/articles/PMC8560675/.
- [14] Bini SA, Chen Y, Khatod M, Paxton EW. Does pre-coating total knee tibial implants affect the risk of aseptic revision? J Bone Joint Surg Ser B 2013;3(95 B):367–70.
- [15] Kelly BC, Owen JR, Shah SC, Johnson AJ, Golladay GJ, Kates SL. A biomechanical comparison of the effect of baseplate design and bone marrow fat infiltration on tibial baseplate pullout strength Available from:. J Arthroplasty 2021;1(36):356–61. https://pubmed.ncbi.nlm.nih.gov/32829970/.
- [16] Jaeger S, Eissler M, Schwarze M, Schonhoff M, Kretzer JP, Bitsch RG. Does tibial design modification improve implant stability for total knee arthroplasty? An experimental cadaver study. Bone & Joint Research. 2022 4;11:229. Available from: /pmc/articles/ PMC9057524//pmc/articles/ PMC9057524/?report=abstracthttps: //www.ncbi.nlm.nih.gov/pmc/articles/PMC9057524/.
- [17] Crook PD, Owen JR, Hess SR, Al-Humadi SM, Wayne JS, Jiranek WA. Initial stability of cemented vs cementless tibial components under cyclic load Available from. J Arthroplasty 2017;8(32):2556–62. https://pubmed.ncbi.nlm.nih.gov/28433426/.
- [18] Shanbhag AS, Bailey HO, Hwang DS, Cha CW, Eror NG, Rubash HE. Quantitative analysis of ultrahigh molecular weight polyethylene (UHMWPE) wear debris associated with total knee replacements. J Biomed Mater Res 2000.
- [19] Bonutti PM, Khlopas A, Chughtai M, Cole C, Gwam CU, Har win SF, et al. Unusually high rate of early failure of tibial component in ATTUNE total knee arthroplasty system at implant-cement interface Available from:. J Knee Surg 2017;6(30):435–9. http://www.thieme-connect. com/products/ ejournals/html/10.1055/s-0037-1603756.
- [20] Elfar J, Menorca RMG, Reed JD, Stanbury S. Composite bone models in orthopaedic surgery research and education; 2014.
- [21] Zdero R, Brzozowski P, Schemitsch EH. Biomechanical properties of artificial bones made by Sawbones: A review Available from:. Med Eng Phys 2023;8:118. https://pubmed.ncbi.nlm.nih. gov/37536838/.
- [22] Kutzner I, Heinlein B, Graichen F, Bender A, Rohlmann A, Halder A, et al. Loading of the knee joint during activities of daily living measured in vivo in five subjects Available from. J Biomech 2010;8(43):2164–73. https://pubmed.ncbi.nlm.nih.gov/20537336/.
- [23] Billi F, Kavanaugh A, Schmalzried H, Schmalzried TP. Techniques for improving the initial strength of the tibial tray-cement interface bond Available from:. Bone Joint J 2019;1(101-B):53-8. https://pubmed.ncbi.nlm.nih.gov/30648489/.
- [24] Bert JM, McShane M. Is it necessary to cement the tibial stem in cemented total knee arthroplasty? Available from: Clin Orthop Relat Res 1998;356:73-8. https://pubmed.ncbi.nlm. nih.gov/9917670/.
- [25] Peters CL, Craig MA, Mohr RA, Bachus KN. Tibial component fixation with cement: full-versus surface-cementation techniques Available from:. Clin Orthop Relat Res 2003;4(409):158–68. https://journals.lww.com/clinorthop/Fulltext/2003/ 04000/Tibial_Component_Fixation_With_Cement_Full_. 21.aspx.
- [26] Alipit V, Kirk A, Scholl D, Schmidig G, Springer BD, Lee GC. Micromotion analysis of various tibial constructs in moderate tibial defects in revision total knee arthroplasty Available from: | Arthroplasty 2021;1(36):362–367.e1. https://pubmed.ncbi.nlm.nih.gov/ 32798182/.
- [27] Jaeger S, Rieger JS, Bruckner T, Kretzer JP, Clarius M, Bitsch RG. The protective effect of pulsed lavage against implant subsidence and micro motion for cemented tibial unicompartmental knee components: an experimental cadaver study Available from. J Arthroplasty 2014;29:727–32. https:// pubmed.ncbi.nlm.nih.gov/24184324/.
- [28] Molt M, Ryd L, Toksvig-Larsen S. A randomized RSA study concentrating especially on continuous migration Available from:. Acta Orthop 2016;5 (87):262-7. https://pubmed.ncbi.nlm.nih.gov/ 27088580/.
- [29] Ryd L, Lindstrand A, Rosenquist R, Selvik G. Micromotion of conventionally cemented all-polyethylene tibial components in total knee replacements. A roentgen stereophotogrammetric analysis of migration and inducible displacement. Archives of orthopaedic and traumatic surgery Archiv fur orthopadische und Unfall-Chirurgie. 1987 2;106:82-8. Available from: https://pubmed.ncbi.nlm.nih.gov/3566511/.
- [30] Laende EK, Wilson JLA, Flemming JM, Valstar ER, Richardson CG, Dunbar MJ. Equivalent 2-year stabilization of uncemented tibial component migration despite higher early migration compared with cemented fixation: an RSA study on 360 total knee arthroplasties Available from:. Acta Orthop 2019;3 (90):172–8. https://www.tandfonline.com/doi/abs/10.1080/17453674.2018.1562633.
- [31] Pijls BG, Valstar ER, Nouta KA, Plevier JWM, Fiocco M, Middel dorp S, et al. Early migration of tibial components is associated with late revision: a systematic review and meta-analysis of 21,000 knee arthroplasties Available from:. Acta Orthop 2012;83:614–24. https://pubmed.ncbi.nlm.nih.gov/ 23140091/.
- [32] Martin JR, Wronski PT, Schilkowsky RM, Orfanos AV, Fehring TK, Mason JB, Chitranjan S. Ranawat award: motion during total knee cementing significantly decreases tibial implant fixation strength Available from: J Arthroplasty 2022;6(37):S12–8. https://pubmed.ncbi.nlm.nih.gov/35231563/
- [33] Miller MA, Goodheart JR, Izant TH, Rimnac CM, Cleary RJ, Mann KA. Loss of cement-bone interlock in retrieved tibial components from total knee arthroplasties basic research. Clin Orthop Relat Res 2014;472:304–13.
- [34] Miller MA, Terbush MJ, Goodheart JR, Izant TH, Mann KA. Increased initial cement-bone interlock correlates with reduced total knee arthroplasty micro-motion following in vivo service. J Biomech 2014;7(47):2460–6.

- [35] Dinh NL, Chong AC, Walden JK, Adrian SC, Cusick RP. Intrusion characteristics of high viscosity bone cements for the tibial component of a total knee arthroplasty using negative pressure intrusion cementing technique Available from. Iowa Orthop J 2016;36:161-6. https://pubmed.ncbi.nlm.nih.gov/ 27528854/
- [36] Silverman EJ, Landy DC, Massel DH, Kaimrajh DN, Latta LL, Robin son RP. The effect of viscosity on cement penetration in total knee arthroplasty, an application of the squeeze film effect. J Arthroplasty 2014;10(29):2039-42.
- [37] Bhalekar RM, Wells SR, Nargol MM, Shariatpanahi S, Nargol AVF, Waller S, et al. Aseptic loosening of the option stemmed tibial tray in the Zimmer
- [37] Blackar KN, Wens SK, Pargor KNY, Sharacpanan S, Pargor KYY, Waler S, et al. Abeptic lossening of the option scenario using the planter of stem versus hybrid fixation Available from:. Arch Orthop Trauma Surg 2006;1(126):45-8. https://link. springer.com/article/10.1007/s00402-005-0082-5.
- [39] Zhang J, Chen Z, Wang L, Li D, Jin Z. Load application for the contact mechanics analysis and wear prediction of total knee replacement Available from:. Proc Inst Mech Eng Part H J Eng Med 2017;5(231):444–54. https://pubmed.ncbi.nlm.nih.gov/28427318/.