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# Is the rod necessary? Biomechanical comparison of static knee spacers during axial loading

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# ABSTRACT

*Background:* Knee Spacers are required in two-stage revision surgery of periprosthetic joint infection of the knee. Extended bone and ligamentous defects are often temporarily arthrodised via a static spacer. Regarding their weight-bearing potential and construction, there is no current consent. Our aim was to evaluate three individual static spacer variants with regard to their axial loading capacity.

*Methods:* The static spacer variants were tested in a cadaver model. One after the other, a spacer with metalreinforced rods, a spacer without metal reinforcement and a rod-less spacer were implanted and tested up to an axial loading of 1000 Newton. Target parameters were plastic deformation, stiffness and spacer movement at both the femoral and tibial surface. Loading was applied up to 1000 Newton. Radiological controls of the bone substance were performed.

*Findings:* The spacer variants did not differ regarding deformation, stiffness or spacer movement. However, deformation increased significantly with the axial load in all spacer variants. Radiographs showed no fracture or spacer-dislocation resulting from testing.

*Interpretation:* While the spacer reinforcement or the sheer presence of a rod did not influence the axial loading capacity in this in vitro study, weightbearing should be discouraged to limit further bone erosion.

# 1. Introduction

Total joint arthroplasty is among the most successful surgical procedures in orthopaedic surgery, as it can provide a patient suffering from osteoarthritis with a significant reduction in pain, improved quality of life and increase in mobility (Canovas and Dagneaux, 2018; Meftah et al., 2016). However, complications after artificial joint replacement are a major challenge for the patient and treating physician. In particular, periprosthetic joint infection (PJI) should be mentioned with an incidence between 0.9% to 2.8% (Kheir et al., 2021; Kim et al., 2020). PJI is one of the most common causes leading to surgical revision of total knee arthroplasty (TKA) (Bozic et al., 2010). Chronic infections usually require prosthesis removal or replacement to sanitise the infection. This is often performed in two stages, i.e., the infected prosthesis is first removed with aggressive debridement and a temporary, antibioticreleasing spacer inserted, after which a prosthesis is reinstalled in a follow-up surgery.

Prefabricated spacer models are available for purchase, but these are often associated with a high cost and cannot always be optimally adapted to the anatomical conditions of the affected joint.

Alternatively, individual spacers can be manufactured intraoperatively from bone cement (PMMA) with an antibiotic additive, which can be fixed/used as either mobile (i.e., with the possibility that the joint can be moved in the prosthesis-free interval) or static (as temporary arthrodesis). Particularly in the case of poor soft tissue conditions including ligamentous defects of the medial and/or lateral collateral ligament and bony defects, a static spacer is often unavoidable. Since defect sizes often vary broadly in these patients, commercially available models are often unsuited. Therefore, individually moulded spacers are required.

In general, there are three ways to cast an individual static knee spacer. The first option is to solely mould a cement block into the joint

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cavity. This block can additionally be fixated by adding an intramedullary rod which is either fabricated from PMMA or a metal core encased in PMMA.

Since the authors' standard operating procedure requires static spacer patients to keep their leg in an extension orthosis, the knee is mainly exposed to axial force.

The aim of this study was therefore to evaluate the three outlined spacer variants regarding their axial loading capacity.

# 2. Methods

# 2.1. Specimen data

Surgical preparations and testing were performed in 4 fresh frozen specimens (4 female) with a mean age at death of 87.5 years. After being stored at -20 °C, specimens were thawed at room temperature for 24 h before dissection and testing. Bone quality was assessed via CT-imaging using Hounsfield units (HU). Specimens averaged 150.9 HU (± 27.2), representing a healthy bone mass.

The specimens included the knee joint with the distal third of the femur, the proximal third of the tibia, patella and skin, as well as the intact soft tissue envelope. The preparation and implantation of the spacers were performed by a single specialised surgeon (COL). During testing, the specimens were kept moist with 0.9% saline solution.

To fabricate the spacers, 60 g polymethyl methylacrylate (PMMA) mixed with 0.83 g Gentamicin (Optipac® 60, Zimmer Biomet, BIOMET France, France) and 80 g PMMA mixed with 0.98 g Gentamicin (Optipac® 80, Zimmer Biomet, BIOMET France, France) were used, partially supplemented with metallic rods. For the metallic reinforced rod-variant, two titanium rods (diameter 5.5 mm, length: 120 mm; CD HORIZON® Spinal System Lined pre-bent rod, Medtronik Sofamor Danek USA, Inc., USA) were used.

Each specimen was evaluated before testing using plain radiography in anterorior posterior (ap) and lateral view to rule out fractures, bone abnormalities or previous surgery.

Ethics approval was granted by the ethics committee of local institutions (proj. nr. 21–1560).

#### 2.2. Spacer implantation

After defrosting, knees were dismantled from skin and subcutaneous tissue. The proximal femur and distal tibia were embedded in aluminium cylinders using a two-component resin (Technovit 4004, Kulzer GmbH, Hanau, Germany). The physiological valgus of 6° was respected and maintained during embedding.

Using the standard prosthetic approach (medial arthrotomy of the knee joint), all subjects were prepared for implantation of a regular knee prosthesis by means of conventional cutting blocks. Medial and lateral collateral ligaments were transected to best mimic the usual situs after infection-related prosthesis explantation. After tibial and femoral bone resection, a central defect in the proximal tibia as well as the distal femur was created, simulating erosion after removal of the cemented TKA using a defect-size-sample.

One after another SP1, SP2 and SP3 were each implanted, tested and carefully removed. Rods were freshly moulded before implantation in each specimen. All spacer variants were implanted, keeping the leg in an extended position. Radiography ensured correct spacer-implantation.

The spacer variants were implanted as follows (Fig. 1):

- Plain rod spacer (SP1)

By filling the cement application tubes, cylindric PMMA cement rods (length = 12 cm; diameter = 9 mm) were cast. The rods were pushed into the femoral and tibial medullary cavity, leaving at least 2 cm inside the joints to overlap. They were moulded together by a fresh pack of Optipac® 60 bone cement in the extended knee position while simultaneously applying tension to the limb. Hereby, the joint cavity was filled with cement.

- Titanium rod spacer (SP2)

In contrast to SP1, the SP2 rods were moulded containing a titanium rod, which was placed inside the application-tube before injection of the cement. As previously performed in SP1, the rods were placed medullary before moulding the surrounding spacer and filling up the joint space using Optipac® 60 bone cement.



Fig. 1. Spacer variants: SP1 with cemented main core and rods (\*), SP2 with additional metal rod-enforcement (orange) and SP3 with a single main core and defect filling (#).

- Rod-less spacer (SP3)

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For SP3, medullary cavities were neither sealed nor filled. While keeping the joint in extended position and applying tension, the joint space gap as well as the defect areas were filled using a larger amount of bone cement (Optipac® 80) to compensate for the difference in volume resulting from the exclusion of rods.

#### 2.3. Measurements

Testing was performed by a biomechanical testing machine (Z010; Zwick/Roell, Ulm, Germany). The testing machine's charts were used for statistical analysis. Movements of the femur, spacer and tibia were recorded by a motion capture system (Optotrak Certus, Northern Digital Inc., Waterloo, Ontario, Canada). A sensor was each mounted to the femur and tibia and likewise to the spacer with screw-in pins (Fig. 2). The spacer's pin was placed at the level of the joint line in the medial part of the spacer while hardening and replaced during spacer change while the other pins remained in situ. Radiography ensured that there was no contact between the pins and the rods (Fig. 3).

Motion capture measurements were performed with a 100 Hz rate.

#### 2.4. Testing protocol

Each spacer was loaded with a baseline of 30 N. Cyclic loading was performed at 4 levels, each consisting of 1000 cycles applied with a loading rate of 100 mm/min: 30–400 N, 30–600 N, 30–800 N and 30–1000 N. Before and after each step of 1000 cycles, a single cycle with the loading-level was performed. The pre-cycle measurement was called M1, while the post-cycle measurement was called M2. The single measurements M1 and M2 were performed with a loading rate of 10 mm/min.

The cyclic loading protocol is within the range of previous studies simulating loading during a rehabilitation period (Brinkman et al.,



**Fig. 2.** Testing setup within the testing machine and with mounted motion capture sensors. Femoral fixation (+), tibial fixation (++), motion capture sensors (#).



**Fig. 3.** Radiography of the SP2 spacer after testing showing the spacer's core (\*), femoral (+) and tibial (++) enforced rods and screw-in pins (#) to mount the motion capture sensors.

2011; Chong et al., 2019; Markolf et al., 2003; Weimann et al., 2013). The loading frequency was adapted to avoid exceeding the physiological range of loading (Fuss, 1991; Pape et al., 2010), however it granted accurate measurements of the testing machine. During M1 and M2, measurements were performed using the testing machine as well as the motion capture system.

# 2.5. Data analysis

Our aim was to compare the stiffness of spacer variants during increased loading. Stiffness was defined as linear region's gradient of the load-displacement curves of the maximum (1000N) loading level's post-cyclic measurement (M2). The linear region gradient was determined from the least-squares fitting (Fig. 4).

To compare the irreversible reaction of the spacer variants and evaluate durability, plastic deformation of the specimen was observed. Deformation was defined as the difference in displacement at the minimum load of 30 N (*dtm*). Each spacer's initial *dtm* measurement (M1, 400 N) was compared with *dtm* after cyclic loading at the other levels (M2 of loading level).

To evaluate movements between the femur and spacer (dFS) as well as the tibia and spacer (dTS), distances between motion capture sensors were compared at the M2 of each level. Hereby, we aimed to evaluate not only the relation between dFS and dTS, but also whether movement increased depending on the loading level.

#### 2.6. Statistical analysis

For statistical analysis, the Wilcoxon signed-rank test was applied to compare measurements at different loading levels. Therefore, each spacer variant was observed separately. To compare spacer variants, the Related-Samples Friedman's Two-Way Analysis of Variance by Ranks (Friedman test) was used. The level of significance was each set at P = 0.05.

Power analysis was performed expecting a nonspheric correction ( $\epsilon = 1$ ), assuming a large eta squared ( $\eta 2 = 0.14$ ) (Cohen, 1995) and correlation of 0.9, resulting in a total sample size of 3 with an actual power of 0.801. Calculation of power analysis was performed using G\* Power Version 3.1.9.6 (Erdfelder et al., 2009).



Fig. 4. Example load-displacement curve (blue) of an SP1 measurement during loading with 1000 N; stiffness was measured as the slope of the linear regression, graphed as the red line. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

Stiffness calculations were performed using MATLAB (Version R2021b, The MathWorks, Inc., Natick, MA, USA). Statistical testing was performed using SPSS 28.0 (IBM SPSS Statistics, Chicago, IL, USA).

#### 3. Results

#### 3.1. Defect creation

Measurements of created defect sizes showed satisfactory homogeneity of defect sizes among specimens (average\_{femoral} = 20.1 cm<sup>3</sup>  $\pm$  3.8 cm<sup>3</sup>; average\_{tibial} = 29.9 cm<sup>3</sup>  $\pm$  7.5 cm<sup>3</sup>). The width of the joint space gap was 2.9 cm ( $\pm$  0.4 cm) on average.

## 3.2. Deformation

Deformation was significantly larger after cyclic loading with 1000 N than with 400 N for all spacer variants ( $P_{SP1} = 0.006$ ;  $P_{SP2} = 0.006$ ;  $P_{SP3} = 0.006$ ). Overall, the average difference between deformation after 400 N (0.31 mm) and after 1000 N (1.09 mm) was 0.77 mm. Comparison of the other loading levels did not show further significant differences. Average deformations are shown in Table 1.

#### Table 1

Average deformation values and standard deviation  $(\pm)$  of spacer variants (Millimetre, mm) after 1000 cycles (M2), including the level of significance (Friedman-Test).

	400 N	600 N	800 N	1000 N
SP1	$0.40\pm0.5$	$0.59\pm0.6$	$\textbf{0.77} \pm \textbf{0.7}$	$1.02\pm0.8$
SP2	$0.47\pm0.3$	$0.70\pm0.5$	$\textbf{0.85}\pm\textbf{0.6}$	$0.98\pm0.7$
SP3	$0.07 \pm 0.5$	$0.33\pm0.8$	$\textbf{0.75} \pm \textbf{1.0}$	$1.26 \pm 1.4$
Sig. (P)	0.282	0.282	0.779	1.000

# 3.3. Stiffness

Post-cyclic measurements (M2) of stiffness after 1000 N were drafted to compare the weightbearing capability of spacer variants. Average stiffness did not differ significantly between SP1 (1167.5 N/mm  $\pm$  312.2), SP2 (1075.8 N/mm  $\pm$  173.5) and SP3 (1087.6 N/mm  $\pm$  209.9) (P = 0.779).

# 3.4. Motion capture

Analysis of motion capture revealed larger movement at the femurspacer-surface (dFS) than at the tibia-spacer-surface (dTS) in spacer variants SP1 and SP2 (Fig. 5). dTS was larger than dFS in SP3. Regardless of the spacer variant, differences between both measurements did not differ significantly at any loading level (Table 2). Comparing dFS and dTS of all spacer variants via Friedman-Test did not show significant differences at any loading level (p > 0.05) (Table 2).

#### 3.5. Radiological analysis

Plain radiography of the spacers prior and after testing showed no lucency around the rods as signs of loosening. However, lucency was visible at the femoral and tibial contact areas in all variants and specimens after testing. The measured thickness was below 1 mm at both the femur and the tibia. We detected no fractures and the spacers did not dislocate.

#### 4. Discussion

According to our data, we conclude that the increased axial loading up to 1000 N leads to significantly increased osseus deformation, while the presence and constitution of an enforcing rod does not influence deformation.

In general, the use of static knee spacers is well established as part of a two stage revision surgery following septic periprosthetic joint



□ dTS 400N ■ dTS 1000N □ dFS 400N ■ dFS 1000N

Fig. 5. Average distance of the spacer to the tibia (dTS) and to the femur (dFS). Distances are given during minimum (400 N) and maximum (1000 N) loading. Both distances increase with loading level in every spacer variant.

Table 2
Average distances and standard deviation (±) between motion capture sensors of femur and spacer (dFS) and tibia and spacer (dTS); Levels of significance (p) are given
by the Wilcoxon rank test (1) for pairwise comparison of dTS and dFS and by Friedman test (2) for comparison of each spacers' dTS and dFS at the same loading level

	SP1			SP2		SP3			Comparison of spacer variants		
	dTS	dFS	Sig. (P) (1)	dTS	dFS	Sig. (p) (1)	dTS	dFS	Sig. (P) (1)	Sig. (P) (dTS) (2)	Sig. (P) (dFS) (2)
400 N	$\begin{array}{c} 0.150 \pm \\ 0.10 \end{array}$	$\begin{array}{c}\textbf{0.320} \pm \\ \textbf{0,49} \end{array}$	0.715	$\begin{array}{c}\textbf{0.111} \pm \\ \textbf{0,08} \end{array}$	$\begin{array}{c}\textbf{0.333} \pm \\ \textbf{0,38}\end{array}$	0.144	0.509 ± 0,50	$\begin{array}{c}\textbf{0,205} \pm \\ \textbf{0,10}\end{array}$	0,465	0.105	0.779
600 N	$\begin{array}{c}\textbf{0.220} \pm \\ \textbf{0,09} \end{array}$	$\begin{array}{c}\textbf{0.424} \pm \\ \textbf{0,57}\end{array}$	1.000	$\begin{array}{c}\textbf{0.243} \pm \\ \textbf{0,18}\end{array}$	$0.518 \pm 0,34$	0.109	$0.555 \pm 0,59$	$\begin{array}{c}\textbf{0,263} \pm \\ \textbf{0,16}\end{array}$	0,715	0.472	0.779
800 N	$\begin{array}{c}\textbf{0.276} \pm \\ \textbf{0,17}\end{array}$	0.487 ± 0,60	0.715	$\begin{array}{c}\textbf{0.300} \pm \\ \textbf{0,18}\end{array}$	$\begin{array}{c} 0.632 \pm \\ 0,45 \end{array}$	0.109	$0.739 \pm 0,82$	$\begin{array}{c}\textbf{0,293} \pm \\ \textbf{0,20}\end{array}$	0,465	0.472	0.779
1000 N	$\begin{array}{c} \textbf{0.366} \pm \\ \textbf{0,30} \end{array}$	$\begin{array}{c}\textbf{0.556} \pm \\ \textbf{0,62} \end{array}$	0.715	$\begin{array}{c}\textbf{0.228} \pm \\ \textbf{0,17} \end{array}$	$\begin{array}{c}\textbf{0.772} \pm \\ \textbf{0,59} \end{array}$	0.109	$\begin{array}{c}\textbf{0.932} \pm \\ \textbf{0,91} \end{array}$	$0,315 \pm 0,23$	0,144	0.368	0.472

infection, especially in the presence of large bone defects (Lo Presti et al., 2021; Pfitzner et al., 2015a). Although the majority of previously described static spacers contain an intramedullary rod with a metal core, heterogeneous techniques have been described. Some authors recommend the use of steel fixateur rods, connected by a tube-to-tube connector and surrounded by cement in the joint space (Hipfl et al., 2019; Röhner et al., 2016). This concept leaves the rods vulnerable to bacterial coating (biofilm) and is therefore not favourable. Kotwal et al. suggested the use of a slotted titanium reconstruction femoral nail bridging the joint space. The length should be appropriate to guarantee a minimum of 6 in. within the femur and tibia (Kotwal et al., 2012). Their technique implies retrograde femoral nailing before antegrade tibial threading. Although promising great stability, the technique raises two concerns. First, this technique also does not imply coating of the metal inside the medullary canal. Second, the femoral medullary canal is further compromised than being filled by the nail, creating not only a cavity but also potentially spreading infection on a large scale.

Both remarks can be solved with a two-rod technique, in which both rods are introduced to the tibia and femur separately after being coated with cement. The advantage of usage of titanium spine rods as a metal core is that they are easy to coat and lengthen. This technique has been described by other authors as well (Ghanem et al., 2016). The rods are then connected by filling the joint space with antibiotic-impregnated cement. Thus, antibiotics are released all around the spacer while also combatting biofilm adhesion (Klinder et al., 2018).

Although the concept of a rod is almost unanimously proclaimed for

static knee spacers, no recommendations have yet been made regarding their weight-bearing potential. The aim of this study was to shine light on this topic. The spacer variant without the rod served as the control group.

General recommendations regarding postoperative weightbearing of static knee spacers are limited. Some authors suggested full weight bearing if possible (Hipfl et al., 2019; Kotwal et al., 2012; Pfitzner et al., 2015b). In contrast, Yoo et al. suggested only toe-touching loading, similar to our clinical routine(Yoo et al., 2011). In our study, irreversible deformation differed significantly depending on the loading level in all spacer variants. Overall deformation was 1.08 mm after cyclic loading with 1000 N, which is relatively small (<2 mm). We identified areas of lucency only at the contact surfaces around the joint but not around the rods. This can be interpreted as an additional sign that the rods play no crucial role in axial loading capacity. However, prolonged testing, especially at higher loads, may lead to further deformation as a result of creep behaviour. Creep describes the deformation of the trabecular bone under continuous long-term exposure to mechanical stress, which can lead to larger permanent deformation (Novitskaya et al., 2014).

To put our study's loading into perspective, according to Taylor et al., the maximum applied force of 1000 N represents half of the bodyweight load of an average weight patient (Taylor et al., 2004). Bergmann et al. reported axial forces of >3000 N during daily activities (Bergmann et al., 2014). Therefore, the results of the present study led us to the conclusion that weightbearing should be discouraged.

There were no significant differences in the measurements between

spacer variants when comparing their stiffness or deformation. Motion capture showed no significant differences between femoral (dFS) and tibial movement at the spacer surfaces (dTS). We conclude that the implication or constitution of a rod does not influence the axial loading capacity of a spacer. However, since the spacer variants did not differ during our tests, we cannot rule out a type II error.

We are aware that our setup solely evaluates axial compression withdrawal without active muscular and ligamentous forces. However, side loading forces are regularly smaller than axial ones (Bergmann et al., 2014) and patients' knees are also supported with a stiff orthosis to limit forces other than axial loading to a minimum. To minimise inconsistency in defect creation, as well spacer casting and implantation, all surgical aspects were performed by one surgeon (COL). The main limitation of our study is the small number of specimens (n = 4). Although fulfilling the requirements of the given power analysis, correlation and effect size were assumed due to the lack of comparable literature. The studies power could be further increased by adjusting these two factors, which would potentially result in an increased actual power. While this study gives valuable orienting results, we suggest increasing the number of specimens to confirm the results.

Keeping the described limitations of our study in mind, our results do not allow us to recommend completely abandoning rod use in static knee spacers, since rotational or horizontal forces were not tested in a similar manner. We rather suggest limiting the rod lengths to a minimum to spare the unharmed medullary cavity, if the knee is supported by an extension orthosis. It seems likely that metal reinforcement of the rods is unnecessary. Future studies should evaluate the importance of reinforcements to horizontal and rotational resistance. Interestingly, no rod-less spacers dislocated during our testing.

On the one hand, perforation of the medullary cavity in a septic environment can create additional room for infection as well as mechanical bone erosion and limit future prosthetic options. Therefore, the omission of an intramedullary rod is tempting.

On the other hand, an intramedullary extension allows for better anchorage, reducing dislocation rates and bone loss (Calton et al., 1997). Commonly, the rods are cast with a metal core (Zahar and Sarungi, 2021). Although no studies have described rods without a metal core, metal reinforcement seems plausible as being superficial compared to pure cement rods. On the downside, the metal core makes them potentially more expensive. To the best of our knowledge, no study has evaluated the stability of rod-containing static spacers solely cast from antibiotic-impregnated cement, neither in vivo nor in vitro.

#### 5. Conclusion

Static spacer variants did not differ in deformation nor stiffness when exposed to axial cyclic loading, regardless of metal rod-reinforcement or the complete absence of rods. The rods themselves therefore do not seem to be relevant for axial loading capacity. However, loading with 1000 N significantly deformed knees among all spacer variants, leading to the conclusion that weightbearing should be discouraged to spare healthy bone for future prostheses.

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## **Declaration of Competing Interest**

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

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