Does bone cement influence soft tissue balancing in total knee arthroplasty?

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ABSTRACT

Background: Soft tissue tension significantly affects the function of total knee arthroplasties. This study aims to evaluate if there is a difference in soft tissue tension, comparing trails to cemented definitive components in TKA.
Methods: We prospectively compared femorotibial compartment pressures before and after cement fixation of the components in 40 primary TKA. Femorotibial pressures were measured in the medial and lateral compartment with the knee in 10°, 45°, and 90° of flexion (six measurements per TKA), and the difference in pressure between both compartments was calculated in the three positions.
Results: The median femorotibial pressures were not significantly different following cement fixation. There was, however, a change in the difference between medial and lateral compartment pressures after cement fixation. The difference between both compartment pressures decreases after cement fixation. This difference is statistically significant only with the knee in 10° of flexion; mean (IQR) pressures change from 8.5 (five to 14) pounds to six (2.25–10) pounds (P = 0.01).
Conclusion: Compartment pressures in TKA do not significantly change after cement fixation. The number of TKA that qualifies as 'balanced' increases after cement fixation, predominantly because the differences between the medial and lateral compartment pressures decrease.

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1. Introduction

Total knee arthroplasties (TKA) to treat patients with end-stage knee osteoarthritis are used in more than 500,000 new patients in the United States each year [1,2]. Unfortunately around 20% of these patients report to be dissatisfied [3,4]. One factor leading to dissatisfaction in TKA and that can ultimately be a reason for revision surgery is soft tissue imbalance. In the USA, 35% of the early TKA revisions are attributed to soft tissue imbalance, manifesting as instability or stiffness, and femorotibial incongruency, which could lead to subsequent component loosening [5,6].

Soft tissue balancing refers to ligamentous tension throughout the range of motion (ROM) that is intra-operatively determined by the surgeon [7]. Once the balance is found to be adequate with a trial implant, the definite TKA is inserted. In the majority of

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cases in Australia (50.9%) and the UK (89.5%), fixation of the definite TKA relies on bone cement [8,9]. It is however unknown whether the cement mantle between the prosthesis and the bone affects the contact pressures between the femur and tibia. After cement fixation of the prosthesis, the surgeon may or may not reassess the soft tissue balance with a trial liner before the definitive liner is inserted.

In the pursuit of improving the outcome of TKA, a wireless microelectric device has been developed, in design identical to the tibial liner that measures the compartment pressures in the femorotibial joint [10–12]. Pressures exceeding 40 pounds in the medial or lateral compartment, or a difference between both compartments exceeding 15 pounds correlate with poorer functional outcome [10,12]. The sensor has a moderate to good reliability in 83% of the measurements when the examiner is blinded for the result in an identical setup [13].

We hypothesized that femorotibial pressures increase after cement fixation of the TKA, as a result of the cement mantle. The aim of this study is to evaluate if cement used for fixation during TKA implantation affects femorotibial compartment pressures.

2. Material and methods

2.1. Patients

We prospectively evaluated the femorotibial compartment pressures before and after cement fixation of the components in 37 patients with 40 TKA (three patients received a bilateral TKA). The only difference between both measurements is the presence of bone cement. The mean (standard deviation [SD]) age was 64.3 (8.9) years the mean body mass index was 32.0 (6.6). Twenty-five TKA were implanted in right knees, 15 in left knees. There were 21 TKA implanted in female patients, 19 in male patients. Thirty-one knees had a preoperative varus alignment; nine knees had a valgus alignment.

All patients were diagnosed with osteoarthritis, rheumatoid, or other inflammatory arthritis. Eligible patients were aged 50 to 80 years. Patients that required a constrained or revision TKA and patients that received a hemi- or unicompartmental TKA were excluded. Ethical approval was obtained from our local Ethics committee.

Patients were operated in supine position and received prophylactic antibiotics as well as tranexamic acid. The setup included a side support on the thigh and bolster under the heel to allow flexion. Access to the knee joint was obtained through a standard medial para-patellar approach. The femur and tibia were prepared for a posterior stabilized TKA with patella resurfacing using intramedullary guidance (Legion® Oxinium™, Smith & Nephew, Memphis, TN). Rotation of the femur was applied by assessing the epicondylar axis and the Whiteside's line. Rotation of the tibia was applied by placing the tibial tray on the midmedial third of the tuberosity as anatomical landmark, by evaluating the patella tracking and if necessary with extramedullary guidance.

After removal of osteophytes, the soft tissue balance was traditionally trialed by applying varus- and valgus stress with an uncemented trial implant and a trial liner. Once the soft tissue balance was deemed adequate by the surgeon, the femorotibial pressures were measured with the wireless tibial sensor (VERASENSE Knee System; OrthoSensor, Inc., Dania Beach, FL) whose design is identical to a normal liner. Femorotibial pressures were measured with the patella relocated in the trochlear groove, with arthrotomy provisionally closed using two towel clips or temporary sutures; one proximal and one distal to the patella. Additional releases were performed if required to obtain a well-balanced TKA [10,12,13]. When the surgeon was satisfied, contact pressures were documented again (TRIAL).

The trial components were then removed and superficial 2.5-mm diameter holes were drilled to serve as additional cement anchors in case of sclerotic bone. The bone was then extensively washed with pulse lavage and then dried before the final TKA was implanted with bone cement (Palacos R + G pro, Heraeus Kulzer GmbH, Germany).

Cement was inserted with a cement gun to allow pressurization before the tibial, femur, and patellar component were inserted simultaneously. To maintain constant pressurization of the prosthesis bone interface while the PMMA was setting, a two-millimeter thicker trial liner was inserted while the knee was held in full extension. Local intra articular anesthesia was applied while the cement hardened and after which care was taken to remove redundant cement.

The same size sensor that was used for the TRIAL measurement was then inserted to measure the femorotibial pressures in exactly the same way. These pressures were also documented (FINAL). The subsequent measurements are illustrated in Figure 1. Finally, the wound was washed and closed.

All procedures were performed by a dedicated hip-and-knee surgeon with more than 20 years of surgical experience.

Femorotibial pressures were measured in two compartments (medial compartment and lateral compartment) through three positions (10°, 45°, and 90° of flexion), resulting in six pressures that were observed and recorded per patient.

Furthermore, we calculated the difference (DIFFERENCE) in pressure between the medial and lateral compartment throughout all three positions.

Finally, the total femorotibial pressure (TOTAL) was calculated for each patient by adding the medial to the lateral compartment pressure throughout all three positions. The reason being is that considerable changes in compartment pressures were incidentally observed, possibly as a result of unintended varus or valgus stress. By adding the relatively high pressure on the loaded compartment to the lower pressures on the unloaded opposite compartment, we tried to compensate for these possible errors.

Overall, differences in 12 pressures (six observed and six calculated) were assessed per TKA, both with the TRIAL and with the FINAL implant.

To detect an effect size of 0.5 between pairs, with a power of 80% and a level of significance of five percent (two sided), 34 TKA were required [14]. When anticipating a dropout rate of 10% in case of failed measurements, we aimed to include 41 TKA.
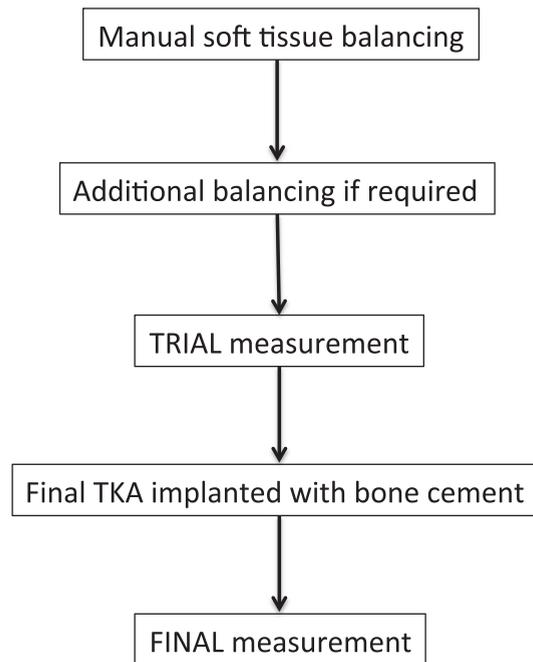
Manual soft tissue balancing

↓

Additional balancing if required

↓

TRIAL measurement

↓

Final TKA implanted with bone cement

↓

FINAL measurement

Figure 1. Flowchart representing the subsequent measurements.

Normally distributed data are presented in mean (SD) values, not normally distributed data in median (interquartile range [IQR]) values. Differences between the TRIAL and FINAL pressures are assessed using the Wilcoxon signed-rank test for comparing median values in not normally distributed data within a single sample. We used a significance level of 0.05. Statistical analysis was performed using SPSS version 22.

3. Results

Comparisons between median (IQR) pressures that were measured with the TRIAL and FINAL implant are summarized in Table 1 and illustrated in the Boxplot in Figure 2. Only pressures in the lateral compartment with the knee held in 45° and 90° of flexion increased with the FINAL implant, all other pressures decreased. None of these changes were statistically significant.

Table 1
The femorotibial pressures before and after cementing with median (IQR) values (n = 40).

	TRIAL Pressure (lb)	FINAL Pressure (lb)	P-value
MEDIAL			
10° flexion	13 (10–17.75)	12 (9–18.75)	0.94
45° flexion	14 (10–19.75)	13 (9.25–18.75)	0.64
90° flexion	15 (10.25–20)	14.5 (10.25–18.75)	0.26
LATERAL			
10° flexion	20 (16–23)	19 (13–25)	0.63
45° flexion	16 (13–24)	16.5 (13.25–23.75)	0.18
90° flexion	14 (10–17.75)	16 (11–21.50)	0.11
TOTAL			
10° flexion	34 (26.74–44)	31.5 (24.25–42.5)	0.80
45° flexion	31 (25.25–42.25)	29 (25–41.75)	0.90
90° flexion	29 (23.25–37.25)	28 (23–37.75)	0.54
DIFFERENCE			
10° flexion	8.5 (5–14)	6 (2.25–10)	**0.01**
45° flexion	7 (3.5–13)	5 (2–9)	0.06
90° flexion	6 (3–9.75)	6 (3–11)	0.54

MEDIAL = the pressure in the medial compartment.
LATERAL = the pressure in the lateral compartment.
TOTAL = total pressure in both compartments combined.
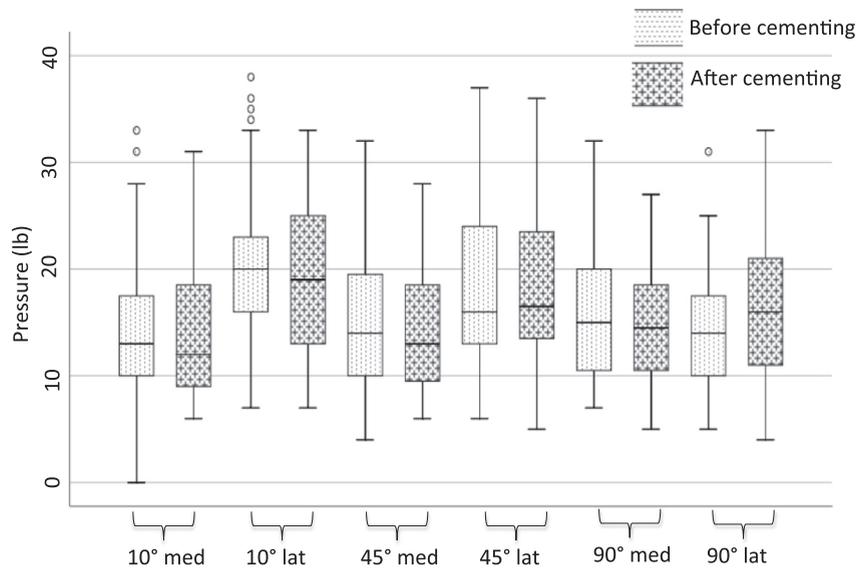DIFFERENCE = difference in pressure between the medial and lateral compartment.

Figure 2. This boxplot represents the mean (IQR) pressures between the femur and tibia in pounds on the Y-axis, before and after cement fixation of the implants with the knee held in different degrees (°) of flexion.

The TOTAL pressure of both compartments combined decreased in all three positions. The difference in pressure between the medial and lateral compartment decreased in 10° (statistically significant) and 45° of flexion and remained unchanged in 90° of flexion.

Before cementation (TRIAL) 70% (28/40) of the TKA qualified as 'balanced'. After cementation (FINAL), this improved to 85% of the TKA (34/40). All TKA that did not qualify as 'balanced', had a difference between both compartments that exceeded 15 pounds.

4. Discussion

Regarding the femorotibial compartment pressures, two findings should be noted.

First, cement fixation does not (statistically significant) increase these pressures. Moreover, these pressures actually decreased in seven out of nine measurements following cement fixation, among those are the combined (TOTAL) pressures. This was in contrary to our hypothesis that a cement mantle increases contact pressures, and is possibly caused by the fact that the sample size is too small in contrast to the power analysis. Another explanation could be that a thicker liner was used to compress the cement during the cementing phase. The thicker liner could have stretched the ligaments, resulting in lower pressures once measured with the original size sensor. Another explanation could be plasticity of the sensor, as was suggested by Nodzo et al. [15]. If that theory is correct, lower pressures could be observed in consecutive measurements with the same sensor.

Second, the difference in pressure between both compartments becomes smaller after cement fixation. Although this is difficult to explain, one reason could be that the bone cement hardens with the knee at rest in full extension. Any small and unintended bumps on the bony cuts are subsequently filled with cement while the prosthesis 'settles' in its optimal position with regard to femorotibial pressures. This improves the congruency and decreases differences in pressures between the medial and lateral compartment. In this study, six TKA (15%) that were 'unbalanced' due to excessive pressure differences between both compartments, normalized and became 'balanced' after cement fixation.

It was furthermore noted that especially in 10° and 45° of flexion, both the TRIAL and FINAL implant resulted in higher pressures in the lateral compartment compared to those in the medial compartment (Boxplot in Figure 2). This might be attributed to the side support that could have acted as a buttress during the measurements. Ideally, the leg should be held in such a position that it does not touch the side support, to avoid unintended valgus stress and subsequent lateral compartment overload, when performing the measurements.

Previously, a similar study was performed by Chow et al. who described that 44% of the knees that were 'balanced' prior to final fixation, exhibited 'imbalance' after cementation. However, in this study it is suggested that the sensor was used as a guide to position the components, rather than a measurement tool to evaluate the final pressures. In 'imbalanced' knees, either the tibial baseplate or femoral component was further impacted if required based on the pressures that were measured. To our impression, 'imbalance' was defined as the state when the cement had not hardened [16]. In our study, 85% of the knees were balanced after cementation.

There are some weak points to this study. First, the sample size is too small in contrast to the power calculation. Moreover, small sample size reduces the chance of detecting a true effect and reduces the likelihood that a statistically significant result reflects a true effect [17].

Second, it is difficult to extrapolate these findings to the general practice, because it remains controversial whether different cementing techniques and implants result in different outcomes [18–20]. Moreover, the use of a tourniquet could influence the tibial cement mantle thickness and subsequently result in increased the femorotibial pressures [21].

Finally, while the cement hardened local intra-articular anesthetics (LIA) were applied in the joint capsule. The fluid might cause the capsule to bulge with an increased joint capsule tension and femorotibial pressure as a result. Although unlikely, this might have influenced our findings.

Future studies should elaborate on clinical relevance of femorotibial compartment pressures. Furthermore, they should evaluate TRIAL and FINAL contact pressures in uncemented TKA.

5. Conclusion

Femorotibial pressures do not increase after cement fixation in TKA. The number of TKA that qualifies as 'balanced' increases after cement fixation, predominantly because the differences between the medial and lateral compartment pressures decrease.

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