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Influence of the tourniquet on tibial cement mantle thickness in primary total knee arthroplasty

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Abstract
Purpose The purpose of the study was whether the use of a tourniquet increases cement mantle thickness in primary total knee arthroplasty and influences the calculated blood loss and postoperative pain.
Methods Ninety patients with a primary total knee arthroplasty (TKA) were enroled in this prospective randomised trial and divided into a group with ($n = 45$) and without tourniquet ($n = 45$). The radiological tibial cement mantle thickness was evaluated postoperatively in four zones on anteroposterior and two zones on lateral radiographs, and values were cumulated. Additionally, the calculated blood loss and postoperative pain levels were recorded.
Results There was a median cumulative cement mantle thickness of 13 mm (range 8–19 mm) without tourniquet and of 14.2 mm (range 9–18 mm) with tourniquet ($p = 0.009$). The median calculated blood loss was 0.6 L (range 0.2–2.0 L) without and 0.9 L (range 0.3–1.5 L) ($p = 0.02$) with tourniquet. Patient-reported postoperative pain levels were significantly higher in the tourniquet group during mobilisation ($p = 0.01$) and at rest ($p = 0.001$).
Conclusions The use of a tourniquet in primary TKA increased the tibial cement mantle thickness but also increased the postoperative calculated blood loss and postoperative pain. Surgeons might take this into consideration for decision-making whether to use a tourniquet during TKA.
Level of evidence II.

Keywords Total knee arthroplasty · Tourniquet · Cement mantle thickness · Blood loss · Cementing technique

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Introduction

Cemented implants in primary total knee arthroplasty (TKA) have demonstrated excellent results and long-term implant survival [4, 14]. However, aseptic loosening is still one of the most frequent causes of implant failure [33]. The tourniquet, which is commonly used by many surgeons during TKA, has the proposed benefits of creating clean and blood-poor surfaces and improved visualisation due to reduced bleeding [41]. However, considerations for cementing techniques are based on assumptions from total hip arthroplasty. Therefore, it is still unknown if this reduced bleeding, caused by the tourniquet, also increases cement penetration into the trabecular bone and consequently implant stability. In two recent studies, the tourniquet showed no effect on early micromotion measured by radiostereometric analysis (RSA) between the tibial component and the tibia, but it remains unknown if this method is valid to predict long-term implant stability [23, 29]. In contrast, implant stability was found to be dependent on cement mantle thickness [8, 30, 38]. However, to the author's knowledge, this is the first study investigating the influence of the tourniquet on cement mantle thickness in TKA. Regarding the perioperative blood loss, the literature is still inconsistent, caused by the inhomogeneity of the surgical and perioperative protocol of the studies [3, 24, 25, 36, 40]. The hypothesis of this study was that the use of a tourniquet results in an increased cement mantle thickness at the tibial component in primary TKA. Therefore, the cement mantle thickness of the tibial component with and without the use of a tourniquet during TKA was determined. Secondary goals were an evaluation of the perioperative blood loss and postoperative pain levels.

Materials and methods

A randomised clinical trial was performed in which 90 patients with primary end-stage osteoarthritis received a unilateral total knee arthroplasty (TKA). Patients were excluded if they received any anticoagulation prior to surgery (e.g., acetylsalycylic acid, phenprocoumon, warfarin, clopidogrel, dabigatran, rivaroxaban and low molecular weight heparin) and had the diagnosis of liver dysfunction/coagulation dysfunction or a history of peripheral arterial obstructive disease or thromboembolic events. A total of 114 patients with primary end-stage osteoarthritis were identified for this study, and 94 patients met the inclusion criteria. Four patients declined participation. Finally, 90 knees (90 patients) undergoing cemented TKA were randomised into two groups: use of a tourniquet (Group 1, $n = 45$) and no use of a tourniquet (Group 2, $n = 45$) (Fig. 1). Patients were assigned to the two branches of the study at the start of the operation, by opening a sealed envelope. All operations were performed in a single centre by a single senior surgeon (RH) who had completed more than 1,000 primary TKAs.

Surgical technique

All patients received a cemented, posterior-stabilised primary TKA (Nexgen LPS Flex, Zimmer, Warsaw, IN, USA) with a fixed bearing design without patella resurfacing. A total amount of 40 g of bone–cement (Palacos R®, Heraeus, Hanau, Germany) was used with a fourth-generation cementing technique including pulsatile lavage, vacuum mixture, double cementing technique and cement gun pressurisation. The tibial component was cemented first, and so independently from the used implant size, always the same amount/thickness of cement was applied to the implant and to the bony surface. A medial mini-midvastus approach was used in all patients [17]. According to the randomisation, a pneumatic tourniquet was applied prior surgery at

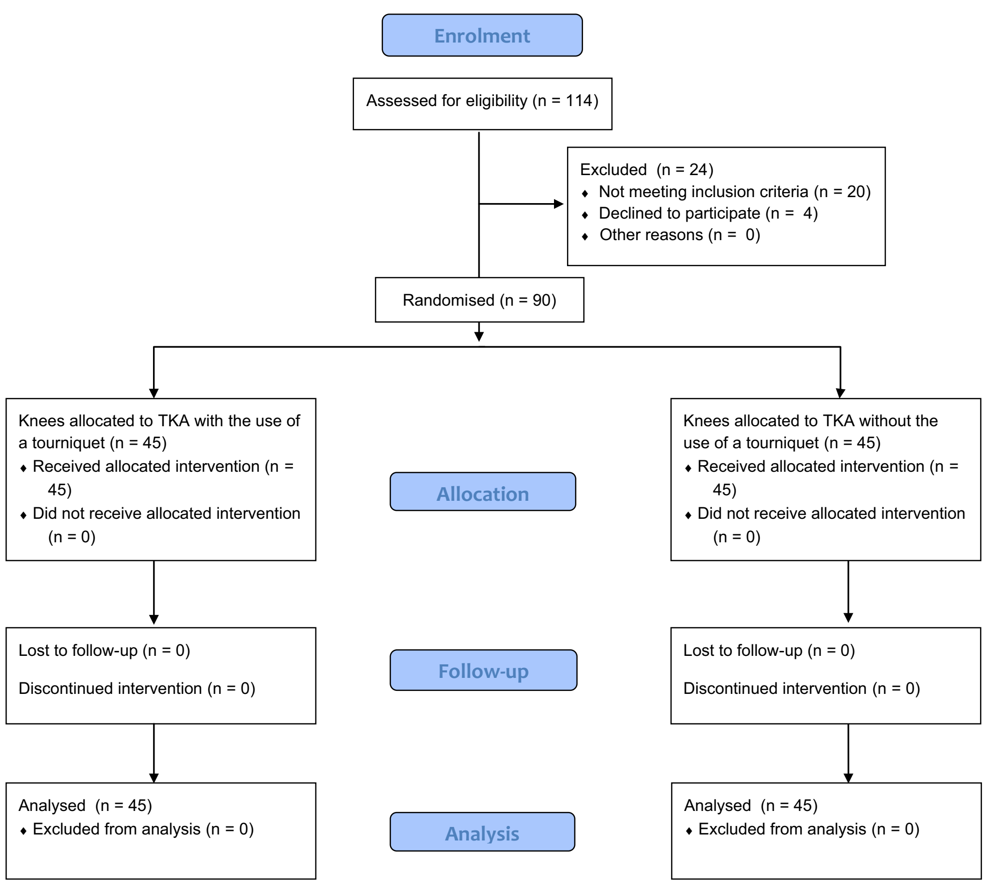

Fig. 1 Flow diagram illustrating patient enrolment, allocation, follow-up and analysis [28]

the proximal thigh and inflated from skin incision until skin closure without the use of an esmarch bandage for exsanguination of the leg before inflation. The inflation pressure was 350 mmHg in the respective cases. An intra-articular drainage was used in every patient and removed after 24 h. Every patient received the same standardised postoperative pain medication protocol.

Radiological evaluation

On the fourth postoperative day, a standardised digital anteroposterior and lateral radiograph of the operated knee was taken. All radiographs were analysed independently by two investigators (NV, PvR). Measurements were performed two times with an interval of 2 weeks within the local picture archiving and communication system (PACS) blinded whether a tourniquet was used. Despite the high accuracy of the PACS, the thickness of the cement mantle was analysed in millimetres with one decimal because of the decreased reliability and doubtful clinical relevance of more than one decimal. Measurements were performed in six zones based on the Knee Society scoring system and according to the technique of Kopec et al. [13, 19]. After standard magnification of the radiograph and identification of the bone–cement interface with the contrast tool, four zones at the tibial baseplate on the anteroposterior view and two zones on the lateral view were measured (Fig. 2). Cement mantle measurements were only performed at the tibial baseplate (Fig. 3), because of the ongoing discussion about full tibial stem cementation and the inconsistent recommendations from implant manufacturers [15]. The penetration of cement is following a random distribution affected by the individual structure of the host bone. To reduce bias in single measurements due to these individual variations within the cement mantle, the thickness of the six zones was cumulated and compared between the groups.

Blood loss and pain level

On the second postoperative day, the pain at rest on a visual analogue scale (VAS) was documented [9, 12]. On the fourth postoperative day, the pain at rest and during mobilisation was again documented on a VAS. To determine the overall blood loss, peripheral blood was taken preoperatively and on the first postoperative day. Total blood loss was calculated using the method of Bourke and Smith [10] to take both obvious and hidden blood loss into account. The study was approved by the institutional review board (Charité-Universitätsmedizin Berlin; ID-Number: EA1/078/11), and informed consent was obtained from every participant.

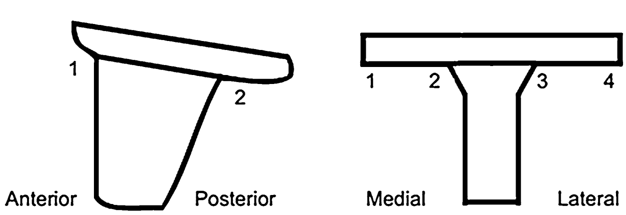

Fig. 2 Localisation of the six zones at the tibial baseplate for measurement of the cement mantle thickness

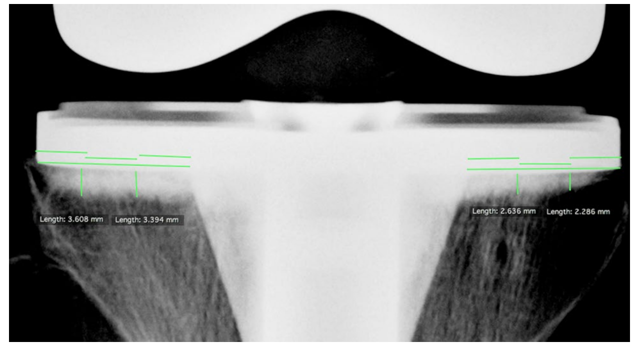

Fig. 3 Anteroposterior radiograph showing the measurement of the cement mantle thickness with the width measurement tool in the local picture archiving and communication system (PACS). The medial and lateral tibial plateau was separated in thirds in every radiograph to define the location for measurements

Statistical analysis

An a priori power analysis was performed to calculate the sample size. Based on a power of 0.80 ($1-\beta$) with $\alpha = 0.05$ to detect a difference of 1 mm between two groups, a total required sample size of $n = 88$ was identified. An overall study sample size of $n = 90$ was assumed as appropriate to include possible study dropout with this short follow-up. Data were not-normally distributed and presented as median with ranges. A nonparametric approach was used to compare the cement mantle thickness. Significant differences between the groups were evaluated by the Mann–Whitney *U* test for independent samples. Inter- and intraobserver reliability testing was performed by calculation of the intraclass correlation coefficients. For statistical analysis SPSS® (version 19; IBM Corp; Somers, NY, USA) was used. The level of significance was set with an alpha of 0.05.

Results

The study sample included 32 men and 58 women, with a median age of 70 years (range 47–90 years). The groups were comparable with regards to age, gender and BMI (Table 1).

Table 1 Patient demographics

Variable	Group 1 (tourniquet) ($n = 45$)	Group 2 (without tourniquet) ($n = 45$)	p value
Sex (male:female) (number of patients)	21:24	11:34	n.s.
Age (years)*	69.3 (47–85)	70.5 (50–90)	n.s.
BMI (kg/m^2)*	27.8 (18.5–38.1)	26 (18.5–33.9)	n.s.

VAS visual analogue scale

* Values are expressed as median, with range in parentheses

Table 2 Results of cement mantle thickness, blood loss and pain between tourniquet and nontourniquet group

Variable	Group 1 (tourniquet) ($n = 45$)	Group 2 (without tourniquet) ($n = 45$)	p value
Tibial cumulated cement mantle thickness (mm)*	14.2 (9–18)	13.0 (8–19)	0.009
Calculated blood loss (L)*	0.9 (0.3–1.5)	0.6 (0.2–2.0)	0.02
Pain (points on VAS)			
At rest @ preoperative day*	3 (0–8)	2 (0–8)	n.s.
At rest @ second postoperative day*	3 (0–7)	3 (1–8)	n.s.
At rest @ fourth postoperative day*	2 (0–6)	1 (0–3)	0.001
At mobilisation @ fourth postoperative day*	3 (0–7)	2 (0–4)	0.01

VAS visual analogue scale

* Values are expressed as median, with range in parentheses

The mean correlation coefficient of the interobserver reliability was 0.93 [95 % confidence interval (CI) 0.89–0.97], and the correlation of the intraobserver reliability was 0.96 (95 % CI 0.94–0.99) and 0.94 (95 % CI 0.90–0.97). The cumulative cement mantle thickness was 14.2 mm (range 9–18 mm) with the use of a tourniquet and 13 mm (range 8–19 mm) without the use of a tourniquet ($p = 0.009$) (Table 2) (Fig. 4).

The calculated blood loss was 0.9 L (range 0.3–1.5 L) with the use of a tourniquet and 0.6 L (range 0.2–2.0 L) without the use of a tourniquet (Table 2). Comparing both groups, the use of the tourniquet showed an increased calculated total blood loss ($p = 0.02$).

In the tourniquet group (Group 1), the preoperative pain level at rest on the VAS was 3 points (0–8 points) compared to 2 points (0–8 points) without a tourniquet (Group 2) (n.s.). On the second postoperative day, the pain at rest was 3 points (0–7 points) on the VAS in Group 1 and 3 points (1–8 points) in Group 2 (n.s.). Looking at the pain at rest on the fourth postoperative day, Group 1 showed a decrease to 2 points (0–6 points) on the VAS and Group 2 to 1 points (0–3 points) ($p = 0.001$). The pain during mobilisation on the fourth postoperative day was 3 points (0–7 points) on the VAS in Group 1 and 2 points (0–4 points) in Group 2 ($p = 0.01$) (Table 2).

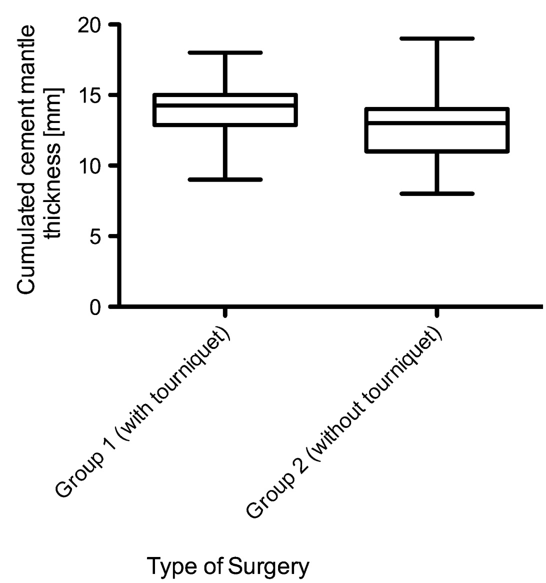

Fig. 4 *Boxplot* of the cumulative cement mantle thickness in both groups is shown. Cement mantle thickness is greater in the tourniquet group than the nontourniquet group. *Horizontal line* = median; *box* = upper and lower quartile; *Whisker* = minimum and maximum

Discussion

The most important findings of the present study were that the use of a tourniquet increased the cement mantle thickness at the tibial component in primary TKA. Furthermore, the use of a tourniquet showed an increased total blood loss and increased postoperative pain. To our knowledge, this prospective study is the first to investigate the influence of the tourniquet on the cement mantle thickness in TKA.

There is a lack of data available in the literature whether the use of a tourniquet increases implant fixation and survival in TKA. The only studies investigating the influence of the tourniquet on implant fixation in TKA using radiostereometric analysis (RSA) found no difference between the groups [23, 29]. However, there is little evidence whether this technique predicts implant survival. Ledin et al. [23] mentioned that the capability of the RSA method to predict loosening is mostly based on beliefs and theoretical reasoning. The only study supporting this found early micromotion with RSA to be a risk factor for loosening mostly in noncemented tibial components [32]. Accordingly, Ledin et al. [23] referred the weakness of the RSA method to predict clinical outcomes as major limitation of their study. In contrast, an increased cement mantle thickness was found to increase implant stability and survival [8, 30, 38]. Aseptic loosening is mostly localised at the bone–cement interface [25]. Preparation of the bone surface is therefore most important [31]. Pulsatile lavage such as use of "low-viscosity" cement showed an increased cement penetration depth [11, 20]. Residual blood at the bony interface reduces the adhesive/tensile strength by up to 50 % [6, 16, 26]. In the comparative study of Vandenbussche et al. [37], no difference in radiological signs of loosening was observed at 3-month follow-up between TKAs performed with or without tourniquet. However, the short follow-up does not allow an evaluation of differences in implant longevity.

In addition, the calculated total blood loss was found to be increased with the use of a tourniquet. This is in line with other prospective studies that showed an increased blood loss with the use of a tourniquet [24, 34, 36]. Causes are an increased "hidden blood loss" by using a tourniquet due to an increased haemolysis [24] and postischaemic activated fibrinolysis [2, 18], such as hyperperfusion after deflation [5, 22]. In contrast, the blood loss was reduced with the use of a tourniquet in other studies [3, 24, 36, 40]. These different results might be caused by the different methods of blood loss calculation used, such as the different protocols of tourniquet application and duration of inflation (whole procedure vs. only during cementation) [21, 35]. Alcelik et al. [3] mentioned this inconsistent use of the tourniquet in the included studies as major shortcoming of their meta-analysis. Furthermore, the early postoperative pain was increased in the tourniquet group. There is distinct evidence that the use of the tourniquet increases postoperative pain and impairs function [1, 23, 37]. Causes are the greater hidden blood loss with postischaemic swelling of the soft tissue envelope and the direct trauma of the tourniquet to nerval structures and soft tissues [1, 24, 37, 42]. This is supported by the data, which show that a lower inflation pressure and a shorter tourniquet time result in reduced postoperative pain [7, 27, 39].

This study has limitations. Only the cement mantle thickness of the tibial component was analysed. Evaluation of the femoral cement mantle thickness is only possible on lateral radiographs with potential inaccuracy due to overlay of the medial and lateral condyle. Moreover, a posterior stabilised design was used in every case. A measurement of the cement mantle thickness at the most relevant parts of the femur is not possible with the intercondylar box. Second, bone mineral density was not measured in the study patients, but groups were equal regarding age, gender and BMI. However, this might affect cement penetration, even if there is no evidence that osteoporosis is a risk factor for loosening in cemented TKA. Third, the surgeon was not blinded. It seems to be impossible to blind a surgeon whether a tourniquet is inflated during surgery or not. To reduce possible bias, the application of the cement, pressurisation and implantation of the component was performed in a standardised way in every patient.

Even if an increased cement mantle thickness was found to improve implant stability [8, 30, 38], there is no evidence in the literature if an increase of 1 mm in cement mantle thickness or the use of a tourniquet improves long-term implant survival. The differences of tibial cement mantle thickness between the tourniquet and nontourniquet group in this study were statistically identifiable but small and therefore of questionable clinical relevance. Further prospective studies are necessary to evaluate the influence of the tourniquet and cement mantle thickness on long-term implant survival.

Conclusion

The use of a tourniquet in primary TKA increased the tibial cement mantle thickness but also increased the postoperative calculated blood loss and postoperative pain. Surgeons might take this into consideration for decision-making whether to use a tourniquet during TKA.

Conflict of interest Tilman Pfitzner, Philipp von Roth, Ninja Voerkelius, Hermann Mayr and Carsten Perka declare that they have no conflicts of interest. Robert Hube is a consultant for Zimmer.

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