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Tibial cement mantle thickness is not affected by tourniquetless total knee arthroplasty when performed with tranexamic acid

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Abstract

Purpose Evidence exists that tourniquet use leads to increased cement penetration in total knee arthroplasty (TKA) due to decreased blood and fat in the bone during cementation. The use of tranexamic acid (TXA) has led to decreased blood loss and transfusion rates. The purpose of this study was to determine if the use of a tourniquet while utilising modern TXA protocols affects the tibial cement mantle penetration.

Methods 140 patients who underwent primary TKA with and without a tourniquet (70 in each group) were retrospectively reviewed. All patients received a standard TXA protocol. The primary outcome measure was cumulative depth of cement mantle penetration of the tibial plateau on post-operative radiographs. Secondary outcome measures included post-operative change in haemoglobin and hematocrit levels, blood loss, and transfusion rates.

Results There was no significant difference in age, sex, or pre-operative haemoglobin or hematocrit levels between groups. Tourniquet use resulted in significantly lower blood loss (100.0 mL versus 154.7 mL, $p < 0.001$), and significantly reduced drop in haemoglobin (1.8 g/dL vs 2.5 g/dL, $p < 0.001$) and hematocrit (5.7% vs 7.4%, $p = 0.04$) levels. However, depth of tibial cement mantle penetration did not differ between the tourniquet group (15.3 mm) and non-tourniquet group (15.0 mm, p value n.s.). No patient in either group required a blood transfusion.

Conclusions Tourniquet use in primary TKA results in decreased blood loss and less change in pre-operative vs post-operative haemoglobin and hematocrit levels. However, with the use of TXA, not using a tourniquet resulted in similar cement mantle penetration around the tibial component as with a tourniquet.

Keywords Total knee arthroplasty · Total knee replacement · Tranexamic acid · Tourniquet · Cementation · Cement penetration

Abbreviations

TKA	Total knee arthroplasty
TXA	Tranexamic acid
IRB	Institutional review board
Hg	Haemoglobin
Hct	Hematocrit
T	Tourniquet
NT	No tourniquet
CI	Confidence interval

Introduction

The use of a tourniquet during total knee arthroplasty (TKA) is routinely employed to allow for decreased blood loss and better surgical visualization during the procedure [14, 23, 25]. In addition to these potential advantages, some studies have found that tourniquet use leads to increased cement penetration because of decreased blood and fat in the cancellous bone during cementing [16, 26]. This can potentially have significant effects on long-term implant fixation. However, tourniquet use is not without potential disadvantages, with a number of studies showing increased thromboembolic events, increased thigh pain, increased swelling, delayed bleeding, and decreased early functional scores compared to performing the procedure without a tourniquet [17, 23, 26].

Cement mantle penetration is critical to a successful primary TKA. Increased cement mantle thickness has been shown to confer increased implant survival and stability

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[2, 15, 22], as aseptic loosening is a devastating complication that usually occurs at the bone–cement interface [11]. Therefore, meticulous preparation of the bone surface prior to cementation is essential to avoid residual blood at the bony surface [18], which can decrease the cement mantle penetration depth and adhesive/tensile strength by up to 50% [1, 3, 7, 10, 12]. Historically, one benefit of tourniquet use was to aid in the preparation of the bone surface for cementation by reducing the blood in the field.

In recent years, increasing utilisation of tranexamic acid (TXA), an anti-fibrinolytic agent that inhibits plasmin from degrading fibrin, has led to a significant decrease in blood loss and transfusion rates during TKA [24]. Both intravenous and topical forms have demonstrated significant benefits in minimising blood loss, and have brought transfusion rates following primary TKA extremely low [6, 19]. In addition, even in high-risk groups, TXA has not demonstrated an increase in adverse events associated with pro-coagulants [5]. Therefore, its use in primary TKA has become widespread. Given the demonstrated anti-fibrinolytic properties of TXA in TKA, it is theorised that the use of TXA may mimic the beneficial effects of tourniquet use [8].

The purpose of this study was to determine whether tourniquet use influences cement mantle penetration in TKA with the use of intravenous TXA. The hypothesis was that with the use of TXA, there will be no difference in depth of cement mantle penetration between TKA performed with a tourniquet and TKA performed without a tourniquet.

Methods

In this retrospective cohort study, 70 patients (70 knees) who underwent TKA with a tourniquet (T group) were compared to a cohort of 70 years aged and sex-matched patients (70 knees) who underwent TKA without a tourniquet (NT group). There were no differences in baseline patient characteristics (Table 1). The local institutional review board (IRB) approved the study prior to collecting data (IRB number AAAS1860). The primary outcome was the depth of cement mantle penetration about the tibial component based on post-operative radiographs. Through a retrospective chart review, data were also collected on pre-operative demographics, pre-operative haemoglobin and hematocrit (Hg/Hct) levels, estimated blood loss (EBL) during surgery as described in the operative note, and post-operative outcomes including transfusion rates, and post-operative Hg/Hct levels.

Table 1 Patient characteristics

	Tourniquet	No tourniquet	*p* value
Patients	70	70	
Male	28	26	
Female	42	44	
% Male	40.0%	37.1%	n.s
Age (years)	67.0 (9.2)	67.5 (8.3)	n.s

Mean (SD)

Statistical significance ($p < 0.05$)

The senior surgeon (HJC) on this study switched from tourniquet use to no tourniquet use in TKA on June 25, 2018. Once the surgeon switched to surgery without tourniquet, there was no crossover. Therefore, the two natural cohorts of tourniquet (T Group) and no tourniquet (NT Group) were created based on date of surgery (T: October 2017 through June 2018, NT: June through November 2018). For convenience, we used consecutive patients undergoing unilateral primary TKA with the senior surgeon (HJC) before and after June 25, 2018 to choose patients. In the tourniquet group, the inflation pressure when tourniquet was used was set to 250 mmHg, and was in place from incision until final closure. In the no tourniquet (NT) group, no tourniquet was inflated or even applied in a deflated state at any point during the case. No other changes to operative technique or post-operative protocols were made during this short time period. All patients received 10 mg/kg of intravenous tranexamic acid immediately prior to surgery, and an equivalent second dose during wound closure. The primary outcome measure was depth of cement mantle penetration on the tibia. Secondary outcomes were blood loss, transfusion rates, and change in haemoglobin and hematocrit levels.

All patients received one of three implants: Zimmer Persona (Zimmer-Biomet, Warsaw, IN, USA), ConforMIS iTotal (Conformis, Billerica, MA, USA), Smith and Nephew Journey II (Smith & Nephew Orthopedics, Memphis, TN, USA). A total amount of 80 g of polymethyl methacrylate (PMMA) bone cement [Simplex (Stryker, Kalamazoo, MI, USA) with Tobramycin] was utilised for each patient. Cement technique for each case consisted of full exposure of the plateau, pulsatile lavage of the exposed bone with saline, drying the bone with lap sponges and suction, followed by meticulous manual pressurisation of the cement onto the tibial plateau and within the canal using a spatula and digital pressurisation. Finally, the undersurface of the tibial implant was coated with PMMA bone cement, inserted onto the tibia, and then impacted. Femoral and patellar impacting was performed next.

Depth of cement mantle penetration was calculated based on the protocol outlined by Pfitzner et al., utilising the anteroposterior and lateral knee radiograph at the 4–6-week post-operative visit [16]. These radiographs were done in the office, with patients standing erect with the knee in full extension, by trained radiology technicians in a standard format. In brief, measurements were performed in six zones of the tibial plateau based on the Knee

Society scoring system [4]. There were four zones based of the anteroposterior view and two zones based on the lateral view (Fig. 1). Cement mantle measurements were only performed at the baseplate, because of the significant variability in stem design between implants. Cement depth was measured utilising the measurement tool in the picture archiving and communication system (PACS). The thickness of all six zones was cumulated and compared between groups. Images were reviewed by the two authors (CLH and MJG) who were blinded to cohort group, and then reviewed again at an interval of at least 2 weeks to determine inter- and intraobserver reliability.

An a priori power analysis using a small sample of data revealed that 70 patients per group were sufficient to detect a 1.2 mm difference or more in cumulative cement mantle penetration, with $\beta = 0.8$. The difference seen in the Pfitzner et al. study was 1.2 mm, which is what we defined as clinically relevant [16]. Continuous measures such as estimated blood loss (EBL) and cement mantle depth were compared using unpaired *t* tests. Categorical comparisons such as gender percentage were calculated using Chi-square analysis. Statistical significance was defined a priori as p value < 0.05.

Results

There was not a statistically significant difference in cumulative cement mantle penetration on post-operative X-rays comparing the T group (mean 15.3 mm, range 6.5–30.8 mm) vs the NT group (mean 15.0 mm, range 8.3–26.5 mm) (p value n.s.) (Table 2, Fig. 2). The mean correlation coefficient of the interobserver reliability was 0.92 [95% confidence interval (CI) 0.89–0.96], and the correlation of the intraobserver reliability was 0.91 (95% CI 0.87–0.95).

Length of surgery was found to be longer in the T group (mean 108.8 min, range 56.0–150.0 min) versus the NT group (mean 98.7 min, range 30.0–160.0 min) (p value = 0.006). Mean estimated blood loss (EBL) was found to be lower in the T group (100.0 mL) versus the NT group (154.7 mL) (p value < 0.001) (Table 3).

Mean pre-operative Hg and Hct levels were not statistically significantly different between the T group (13.2 g/dL and 34.4%) and NT groups (13.4 g/dL and 40.7%) (Table 3). Mean post-operative Hg and Hct levels were likewise not statistically significantly different between the two groups (11.4 g/dL/34.4% vs 11.0 g/dL/33.3% respectively). There was a significant difference between the T and NT groups in the post-operative haemoglobin drop (1.8 g/dL versus 2.5 g/dL, p value < 0.001) and hematocrit drop (5.7% versus 7.4%,

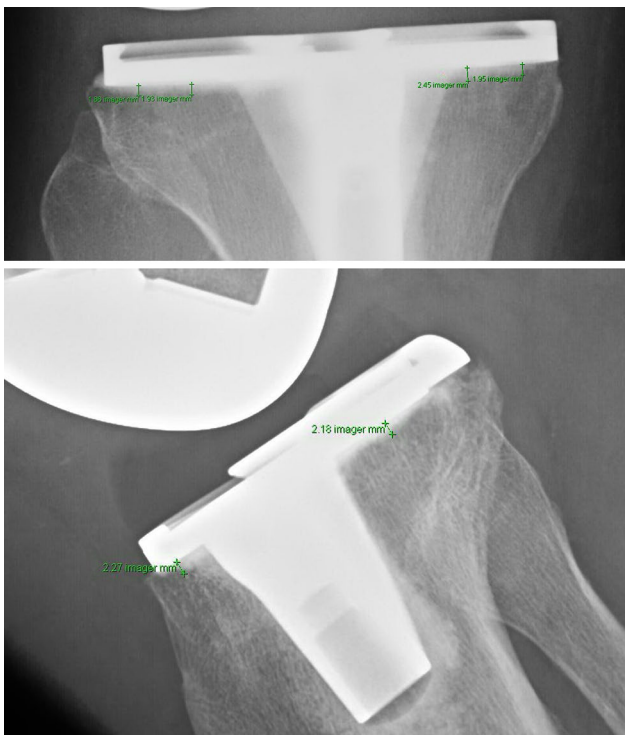

Fig. 1 Anteroposterior and lateral radiographs with six zone cement mantle measurements

Table 2 Cumulative cement mantle penetration tourniquet vs no tourniquet group

	Tourniquet	No tourniquet	p value
Cumulative cement mantle penetration (mm)	15.3 (4.6)	15.0 (3.5)	n.s

Mean (SD)

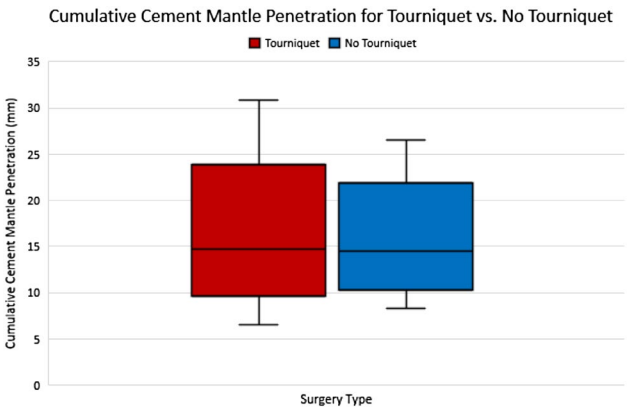

Fig. 2 Box and whisker plot of cumulative cement mantle. Whiskers represent range, boxes represent 25th and 75th percentile, line represents median

Table 3 Secondary outcomes

	Tourniquet	No tourniquet	*p* value
Length of surgery (min)	108.8 (20.3)	98.7 (22.3)	0.006*
Estimated blood loss (mL)	100.0 (0)	154.7 (92.8)	< 0.001*
Preop Hg (g/dL)	13.2 (1.5)	13.4 (1.5)	n.s
Preop Hct (%)	34.4 (3.9)	40.7 (3.9)	n.s
Postop Hg (g/dL)	11.4 (1.5)	11.0 (1.2)	n.s
Postop Hct (%)	34.4 (4.0)	33.3 (3.5)	n.s
Change in Hg (g/dL)	1.8 (0.9)	2.5 (0.9)	< 0.001*
Change in Hct (%)	5.7 (2.8)	7.4 (2.8)	0.006*
Patients requiring transfusion	0	0	

Mean (SD)

*Statistical significance ($p < 0.05$)

p value = 0.005). Despite these differences, no patients in either cohort required a blood transfusion in the perioperative period.

Discussion

The most important finding of the present study was that, when using intravenous TXA, there was no difference in cement mantle penetration of the tibial component in primary TKA in patients who underwent surgery without a tourniquet when compared to patients who underwent TKA with one. Tourniquet use was associated with less EBL and less change in Hg and Hct post-operatively when compared to pre-operative baseline, but this was not a clinically significant difference.

In a previous randomised, prospective clinical trial, Pfitzner et al. evaluated the effect of the cement mantle about the tibial component in patients undergoing primary TKA with and without a tourniquet, without the use of TXA [16]. They concluded that cumulative cement mantle penetration using a tourniquet was superior to no tourniquet (13 mm vs 14.2 mm; *p* value = 0.009), but also noted that patients who underwent TKA with tourniquet had increased calculated blood loss and post-operative pain. Several other studies have corroborated the fact that tourniquet use in primary TKA can lead to more post-operative pain and dysfunction than patients who had no tourniquet used during their procedure [9, 25]. With the advent of modern TXA protocols such as the one utilised at our institution, the risk of haemorrhage and large-volume blood loss has drastically decreased, potentially allowing for decreased risks of surgery without a tourniquet [5, 6, 19, 24].

One critique of performing TKA without the use of a tourniquet may be that of greater cement penetration with one [16, 20]. However, there are also studies that suggest that tourniquet use does not affect cement mantle penetration [9, 13, 21], further clouding the issue. However, these studies are limited. This study is the first to our knowledge to evaluate cement penetration in primary TKA using a modern TXA protocol without a tourniquet. These results suggest that in addition to the possible benefits of doing primary TKA without a tourniquet in terms of post-operative function and pain, provided TXA is used, there may be no difference in cement mantle penetration comparing knees performed with and without a tourniquet, further validating performing primary TKA without one.

An additional factor to consider when deciding whether or not to use a tourniquet for TKA is delayed bleeding. This has been noted in previous meta-analyses as a possible explanation for increased wound complications when the tourniquet is used and inflated throughout the case all the way through final closure, as its release after the wound is closed can create a buildup of blood products and increased pressure on the deep surface of a healing wound [17]. This factor was not specifically evaluated in this study, but the results suggest that the use of a tourniquet with intravenous TXA does not affect cement mantle penetration, and if surgeons choose to not use a tourniquet, this complication can be mitigated.

Although blood loss was higher in the NT group vs the T group, the clinical significance of this difference (54.7 mL) is unknown at this time, and beyond the scope of this study. Similarly, the difference in drop of Hg and Hct of the T vs the NT group, although statistically significant, may lack clinical significance (0.7 g/dL/1.7%). Additionally, the fact that no patient in either cohort required a perioperative blood transfusion suggests that these differences were certainly not clinically significant enough to change post-operative medical management. No formulae for calculating total body blood volume was performed.

This study has several limitations. First of all, as with all retrospective studies, there are risks of confounding factors that may influence outcome measures between the groups, although these confounders are minimised by the fact that the study cohort consists of a consecutive group of patients undergoing TKA with one surgeon. In addition, only the cement mantle of the tibial component was analysed, as the femoral component cement mantle depth can only be assessed on a perfect fluoroscopic lateral radiograph to avoid overlay of the medial and lateral condyles, and not on an anteroposterior radiograph, thereby limiting the ability to assess femoral cement mantle fixation. However, as both tibia and femur were prepared in similar fashion intraoperatively and cemented simultaneously, analysis of the tibial component alone is sufficient. Further, bone mineral density was not evaluated in these cohorts. Although there are no differences in sex and age between the groups, there could have been slight differences in

bone density, which could affect cement penetration. Another limitation of the study is that a single-surgeon series may introduce a form of inherent bias, as other types of cement and surgeon idiosyncrasies in cement technique might have differing results. However, bony preparation and cement preparation, application, and implantation were consistent throughout both cohorts. Further, the use of different implants in the study groups may be a confounder, but both groups had the same three implants, and this likely does not have any influence on the results. In addition, the senior surgeon was not blinded to the use of tourniquet vs no tourniquet, as that would be impossible to achieve. Lastly, this study only evaluates cement mantle depth, and does not claim to extrapolate its findings to TKA implant survivorship or longevity. Although it has been shown that increased cement mantle thickness improved implant stability, further studies evaluating the association of this depth with TKA implant that long-term outcomes are necessary [7, 12].

Conclusions

With the use of current TXA protocols, foregoing a tourniquet while performing primary TKA was associated with no change in cement mantle penetration of the tibial component when compared to TKA performed with a tourniquet. We also found that tourniquet use in primary TKA resulted in decreased blood loss and less change in preoperative vs post-operative haemoglobin and hematocrit levels, but these values were small. Surgeons may choose to consider these data as another factor when deciding whether or not to use a tourniquet when performing primary TKA.

Author contributions CLH devised the study, did the data collection, analysis, and wrote the manuscript. MJG devised the study, did the data collection, analysis, and wrote the manuscript. NOS did the data collection, analysis and wrote the manuscript. RPS edited the manuscript and provided guidance with the study. JAG edited the manuscript and provided guidance with the study. HJC provided patient data, devised the study, and edited the manuscript. All the authors have read and approve of the final manuscript.

Compliance with ethical standards

Conflict of interest All authors report no relevant conflicts of interest in this study.

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Ethical approval This article does not contain any studies with human participants or animals performed by any of the authors.

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