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Tourniquet application does not affect the periprosthetic bone cement penetration in total knee arthroplasty

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Abstract

Purpose Poor scientific evidence exists on the issue of tourniquet application during total knee arthroplasty (TKA). It has been suggested that tourniquet application might improve interdigitation of the cement into the periprosthetic bones due to relatively dry surgical field. The hypothesis of the present study was that tourniquet use did not affect the periprosthetic bone cement penetration.

Methods The single-centre, randomized, controlled trial included 86 patients undergoing primary TKA (Clinical-Trials.gov NCT02475603). All patients meeting the inclusion criteria were randomly assigned to the tourniquet ($n=43$) or non-tourniquet ($n=43$) group after obtaining a written informed consent. The cumulative bone cement penetration was radiologically measured in AP (seven zones) and lateral views (three zones) as defined by Knee Society Scoring System. Further parameters such as perioperative blood loss, soft tissue swelling, pain level/analgesic consumption, operative time, length of hospital stay (LOS) and complication rate were statistically compared between the groups.

Results The cumulative bone cement penetration averaged 28.5 ± 1.7 mm in tourniquet versus 26.6 ± 1.6 mm in non-tourniquet groups (n.s.). The mean intraoperative blood loss was 250 ml higher in the non-tourniquet group ($p=0.0001$). Patient-reported pre- to 6th-day post-operative reduction of the pain level was significantly higher in the non-tourniquet group ($p=0.003$). The Morphine Equivalent Dose was higher in the Tourniquet group at discharge day ($p=0.02$). Parameters such as total blood loss, soft tissue swelling, surgical time, LOS, and complication rates revealed similar results between the groups.

Conclusions Tourniquet application did not influence the bone cement penetration significantly. Even though the intraoperative blood loss was reduced, the total blood loss was not affected significantly by tourniquet use. There was a tendency of higher post-operative pain and opioid analgesic requirement in the tourniquet group.

Level of evidence I.

Keywords TKA · Tourniquet · Bone cement penetration · Blood loss · Soft tissue swelling · Pain · Surgical time

Introduction

The results of a recent practice survey among members of American Association of Hip and Knee Surgeons [3] demonstrated a common tourniquet use during the implantation of knee arthroplasties. Proponents of tourniquet application during primary TKA put forward the advantages of blood-poor operative field due to reduced intraoperative bleeding [37]. Currently, available data on numerous outcome parameters, such as blood loss [35], soft tissue swelling [14], pain [15, 18], surgical time [15], length of hospital stay [15] and complication rates [15, 24] did not provide a solid scientific base regarding the issue of tourniquet application during primary TKA.

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Even though excellent long-term clinical results were achieved with cemented primary TKA [2, 10], aseptic loosening of the tibial component is one of the most frequent causes of revision surgeries [30]. Increased periprosthetic bone cement penetration improved implant stability and survival in previous works [4, 26, 34]. With respect to the use of tourniquet during the cement setting, it has been suggested that tourniquet application might improve interdigitation of the cement into the periprosthetic bones [27]. It remained unclear whether the relatively dry operative field achieved with the use of a tourniquet increases tibial bone cement penetration, which in turn might enhance implant stability and long-term survival [4, 26, 34]. Pfitzner et al. [27] found in primary TKA with the use of tourniquet and a different implant design/bone cement manufacturer (Nexgen LPS, Zimmer, Warsaw, IN, USA / Palacos R®) an increase of the mean cumulative (six zones) tibial cement mantle thickness of 1.2 mm (0.2 mm in each zone). Vertullo et al. [32] reported in a total of 40 randomized cases that tourniquet inflation during cementation did not improve tibial cement penetration (Nexgen LPS, Zimmer, Warsaw, IN, USA / Palacos R®).

To our knowledge, the present study is the first randomized clinical trial analyzing the tibial bone cement penetration with and without tourniquet application in primary TKA using the following implant design/bone cement manufacturer (PFC® SIGMA® prosthesis/SmartSet Bone cement, DePuySynthes, Warsaw, IN, USA).

Furthermore, the influence of tourniquet use on perioperative blood loss, soft tissue swelling, pain, operative time, length of hospital stay and complication rates should be quantified.

The hypothesis of the present study was that the use of a tourniquet did not effect the tibial bone cement penetration in primary TKA.

Materials and methods

Ethics approval

The present study was carried out in accordance with the Declaration of Helsinki. The protocol was approved by the Institutional Ethics Committee (File reference 2012-334N-MA). The clinical trial was registered at ClinicalTrials.gov (NCT02475603). The patients were included corresponding to the Consolidated Standards of Reporting Trials (CONSORT) (Fig. 1). The first author approached the patients on admission day and written consent was obtained after informing each patient about the study protocol.

Patients

This single-centre prospective randomized controlled study involved 86 patients who underwent primary unilateral TKA due to a severe symptomatic osteoarthritis of the knee. Inclusion and exclusion criteria are visualized in Table 1. Patients were randomized to receive TKA performed with ($n = 43$) or without tourniquet ($n = 43$). This assignment was accomplished by a patient management nurse, who was not involved in patient care, using a computer generated randomization list. The pre-operative characteristics of the patients are shown in Table 2. The physical status of patients was analyzed with the Physical Status Classification System of the American Society of Anesthesiologists (ASA) [1] and Charlson comorbidity score [6]. The Kellgren and Lawrence score [16] was used to radiologically assess the degree of knee osteoarthritis (Table 3).

Surgical procedure

All TKAs were performed according to a standard protocol. Standard medial parapatellar approach and femur first surgical technique were performed. A cemented PFC® SIGMA® prosthesis (DePuySynthes, Warsaw, IN, USA) was implanted. For the cementation, 40 g of bone cement (SmartSet Bone cement, DePuySynthes, Warsaw, IN, USA) was applied.

The cementation was performed according to manufacturer instructions.

The bone surface was routinely lavaged by pressing wet surgical sponges on the bone under continuous suction to remove loose bone, blood, fat and marrow. The bone and implant were dried prior to cement application. In its dough state, the cement was applied manually to the cleaned and dried prepared tibial plateau, tibial stem and to the undersurface of the tibial base. Once the implant has been seated, an impactor was applied to help further pressurize the cement.

In the tourniquet group, a pneumatic tourniquet (balbina™, Ulrich medical, Ulm, Germany) was placed on the proximal thigh following anaesthesia introduction. Spinal anaesthesia was predominantly performed in both groups. Hypotensive anaesthesia was usually not necessary.

Additionally, an ultrasound-guided continuous femoralis nerve block (FNB) was placed immediately prior to TKA; the catheter was routinely removed at third post-operative day. Intraoperative/intraarticular injections to reduce post-operative pain and blood loss were not applied.

After accomplishment of standardized sterilization, the tourniquet was inflated to 360 mmHg (immediately

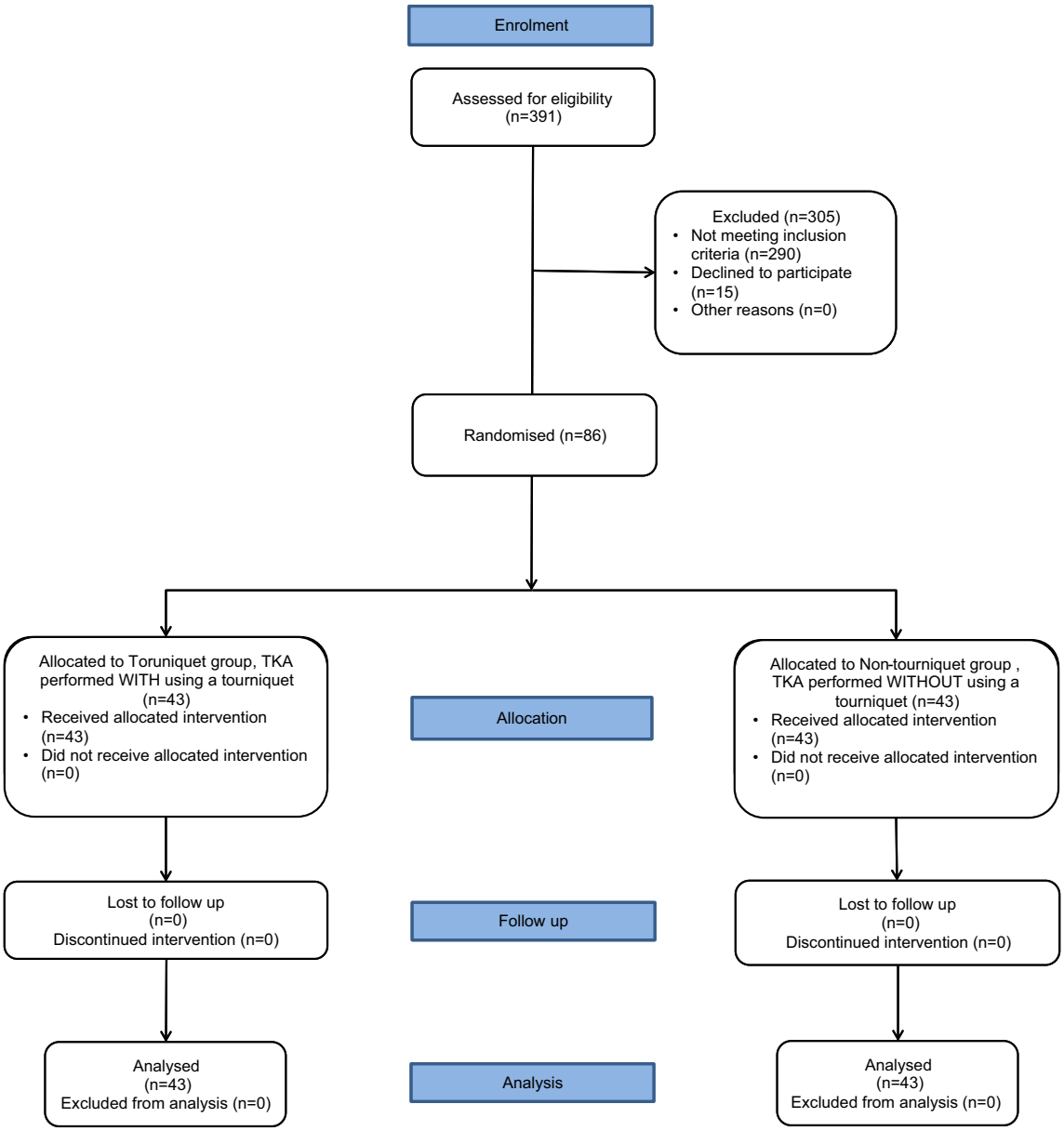

Fig. 1 Flow diagram visualizing the study design

prior to skin incision). All patients had an intraarticular drain placed at completion of surgery, which was routinely removed at second post-operative day. After skin closure and application of an elastic-compressive bandage, the tourniquet was released (Table 3).

Outcome parameters

Bone cement penetration

Second-day standardized digital radiographs were used to assess the cement penetration according to criteria defined by the Knee Society Scoring System [9]. Seven zones on AP and three zones on lateral view radiographs were systematically analyzed (Fig. 2). First, the tibial plateau height was determined with the ruler provided by the software (Syngo, Siemens Healthineers) to calculate the magnification factor on AP and lateral view radiographs. At all measurement sites (ten zones), the bone cement penetration depth was measured after identification of the bone to cement transition as described previously [27] and illustrated (Fig. 2). The cumulative cement penetration depth was calculated and expressed as the sum of all measurement sites.

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Age 55–85 years	Age < 55 years or > 85 years
Osteoarthritis Kellgren and Lawrence score III or IV	Osteoarthritis Kellgren and Lawrence score I or II
Physical status ASA score I or II	Physical status ASA III or IV
BMI < 45 kg/m^2	BMI > 45 kg/m^2
Written consent	Unable to provide written consent
Implant design (PFC sigma, Depuy)	Other implant designs
	Malignant disease
	Rheumatoid disease
	Infectious disease
	Coronary heart disease
	Neurological dysfunction
	Immobility
	Liver insufficiency
	Coagulation disorder
	Glucocorticoids, Aspirin, Heparin, Cumardine, Warfarin
	History of DVT or pulmonary embolism

Table 2 Demographics

Characteristics	Tourniquet ($n=43$)	Non-tourniquet ($n=43$)	p value
Gender (n)			n.s
Male	16	16	
Female	27	27	
Age (years)	70 ± 6.8	71 ± 6.8	n.s
Side (n)			n.s
Right	18	26	
Left	25	17	
Handedness (n)			n.s
Right	41	41	
Left	2	2	
BMI (kg/m^2)	31.9 ± 5.7	31.9 ± 5.7	n.s
ASA score			n.s
I	27	32	
II	16	11	
III	0	0	
IV	0	0	
Comorbidity score			n.s
0	27	30	
I	14	10	
II	2	3	

To improve the accuracy of the measurements, contrast and zooming tools of the software (Syngo, Siemens Healthineers) were utilized. Inter- and Intraobserver reliability was calculated by repeated measuring in 15 cases at different time points (Cronbachs alpha > 0.8).

Blood loss

The intraoperative blood loss was recorded by the end of the surgery and documented in the intraoperative anaesthesia protocol. The volume of liquid in the suction bottle minus the volume of irrigation fluid used during surgery was considered for accurate calculation of the blood loss.

The post-operative blood loss was routinely documented by staff nurses as the liquid in the Redon drain (B. BRAUN). The intraarticular drain was removed at 48 h (h) post-operatively. The methods applied to calculate the total blood loss until the 5th post-operative day (d) are listed in Table 4. The total blood loss was calculated with Ward's formula [36] and with the haemoglobin balance method [11, 13, 21, 25], which previously was found to be the most reliable for estimating total blood loss after TKA [12].

Pain assessment and analgesic consumption

Pain intensity was evaluated with the visual analogue scale (VAS) (rating 0–10) pre-operatively and at 6th post-operative day during full weight-bearing mobilization of the patients. The reduction of the pain level between pre- to 6th post-operative day was calculated.

A standardized post-operative pain management protocol was followed: the opioid analgesic consumption was recorded pre- and post-operatively (at discharge day) by assessing the Morphine Equivalent Dose (MED) expressed in mg/day. The amount of the non-opioid medication

Table 3 Degree of osteoarthritis, leg alignment, surgery-related parameters

Characteristics	Tourniquet ($n=43$)	Non-tourniquet ($n=43$)	p value
Kellgren and Lawrence Score			n.s
I	0	0	
II	0	0	
III	17	18	
IV	26	25	
Pre-op mechanical leg alignment (°)	7 ± 5	8 ± 5	n.s
Surgical time (min)	79 ± 23	85 ± 20	n.s
Tourniquet time (min)	82.3 ± 20	0	0.0001
Tourniquet pressure (mmHg)	360 ± 20	0	0.0001
Surgeons			n.s
I	15	15	
II	9	12	
III	8	3	
IV	11	13	
Femoralis nerve block (FNB)			n.s
Yes (n)	41	34	
No (n)	2	9	
Patella resurfacing			n.s
Yes (n)	5	5	
No (n)	38	38	
Prosthesis design			n.s
Fixed bearing (n)	25	26	
Mobile bearing (n)	18	17	

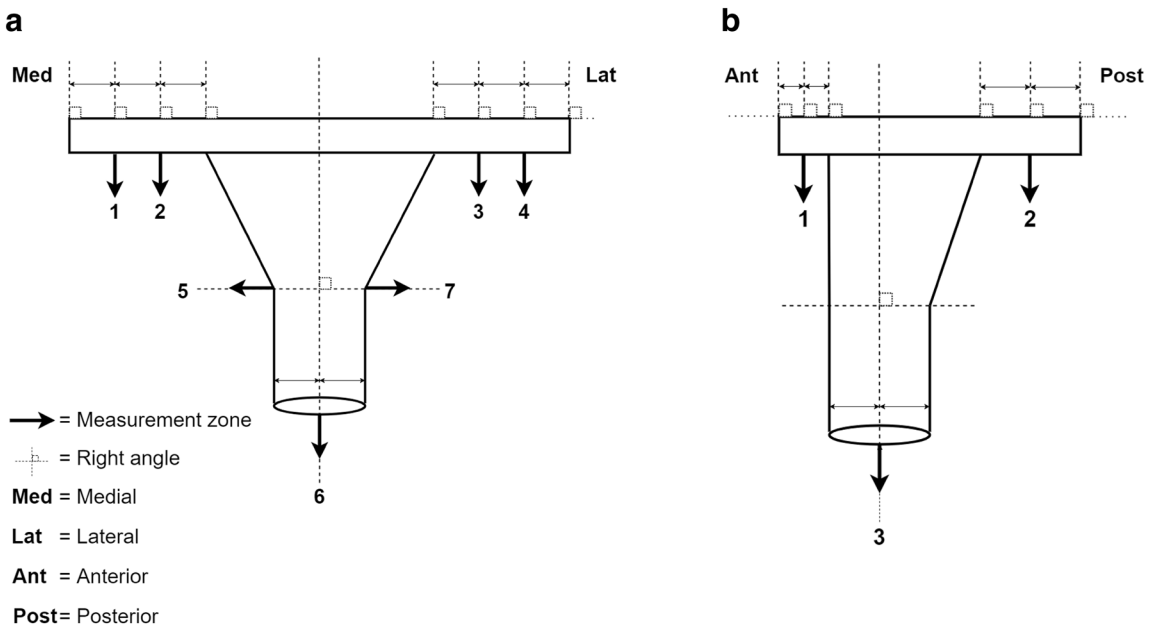

Fig. 2 Measurement method of bone cement penetration **a** AP view; **b** lateral view

Table 4 Methods used to calculating total blood loss

Methods	Formula	Index
Ward's formula [36]	TBL = EBV × ln(Hctpost/Hct0)	TBL = calculated total blood loss (mL) EBV = estimated blood volume (mL) Hctpost = haematocrit on first post-op day Hct0 = haematocrit pre-op
Haemoglobin balance [11–14, 21, 25]	Hbtotal = EBV × (Hb0 − Hbfinal) × 0.001 + Hbbloodtrans TBL = 1000 × Hbtotal × Hbtotal/Hb0 1 U banked blood is considered to contain 52 ± 54 g Hb [21]	Hbtotal = the loss volume of haemoglobin (g) Hb0 = haemoglobin pre-operatively (g/L) Hbfinal = haemoglobin on 5th post-op day (g/L) Hbbloodtrans = the total volume of blood transfusion (g)

such as Paracetamol, Ibuprofen, Novaminsulfon was also recorded. The number of patients with opioid analgesic consumption was evaluated.

Soft tissue swelling

The circumference of the limb was measured on three sites; on the midpoint of the patella, 20 cm proximal and 15 cm distal to the midpoint of the patella. Repeated measurements were performed by the same investigator on admission day and 6 days post-operatively. The post- to pre-operative change of the limb circumference was calculated.

Complications

Complications such as post-operative hematoma, delayed wound healing, surgical site infection, deep vein thrombosis (DVT), pulmonary embolism, vascular injury as well as nerve lesion were recorded for all cases.

Statistical analysis

Microsoft Excel software (version 2010) was used for the documentation of the data. GPower (version 3.1.9.2) and SPSS (version 22) were used for all statistical analysis. Mean and standard deviation (SD) or (SEM) were calculated for normally distributed data, median and range for non-parameteric data. Student's *T* test for parametric and chi-squared test for non-parametric data were calculated. The power analysis (a priori) was performed based on previously published data [27]. The power analysis (post hoc) considered an effect size of 0.5. For a power of 0.8, a total sample size of 86 (43 for each group) was required to detect significant differences. Statistical significant was set at a p value of < 0.05.

Results

Demographics

There were no statistically significant difference between the defined groups with regard to parameters such as age, gender, side, handedness, BMI, ASA score, comorbidity score. (Table 2).

Surgical procedure-related parameters

The degree of knee osteoarthritis and the pre-operative mechanical leg alignment revealed homogenous results between the groups. The mean surgical time was 6 min lower in the tourniquet group, without reaching statistical significance. Similar results were found with regard to surgery-related parameters: surgeons, femoral nerve block, patella resurfacing and prosthesis design (PFC® SIGMA®; DePuySynthes, Warsaw, IN, USA) (Table 3).

Bone cement penetration

The cumulative bone cement penetration of all zones (sum of zones 1–10) averaged 28.5 ± 1.7 mm for the tourniquet and 26.6 ± 1.6 mm for the non-tourniquet group (n.s.) (Fig. 3a–c). The bone cement penetration in each of the zones is illustrated (Fig. 3d, e). At the most distal point of the stem (Zone 6 AP, Zone 3 lateral), a higher bone cement penetration was found in the tourniquet group ($p < 0.05$).

Blood loss

The mean intraoperative blood loss was 250 ml higher in the non-tourniquet group ($p = 0.0001$) (Fig. 4). However, the total blood loss measured with two different methods until the 5th post-operative day did not show significant differences between the groups. The bleeding index was

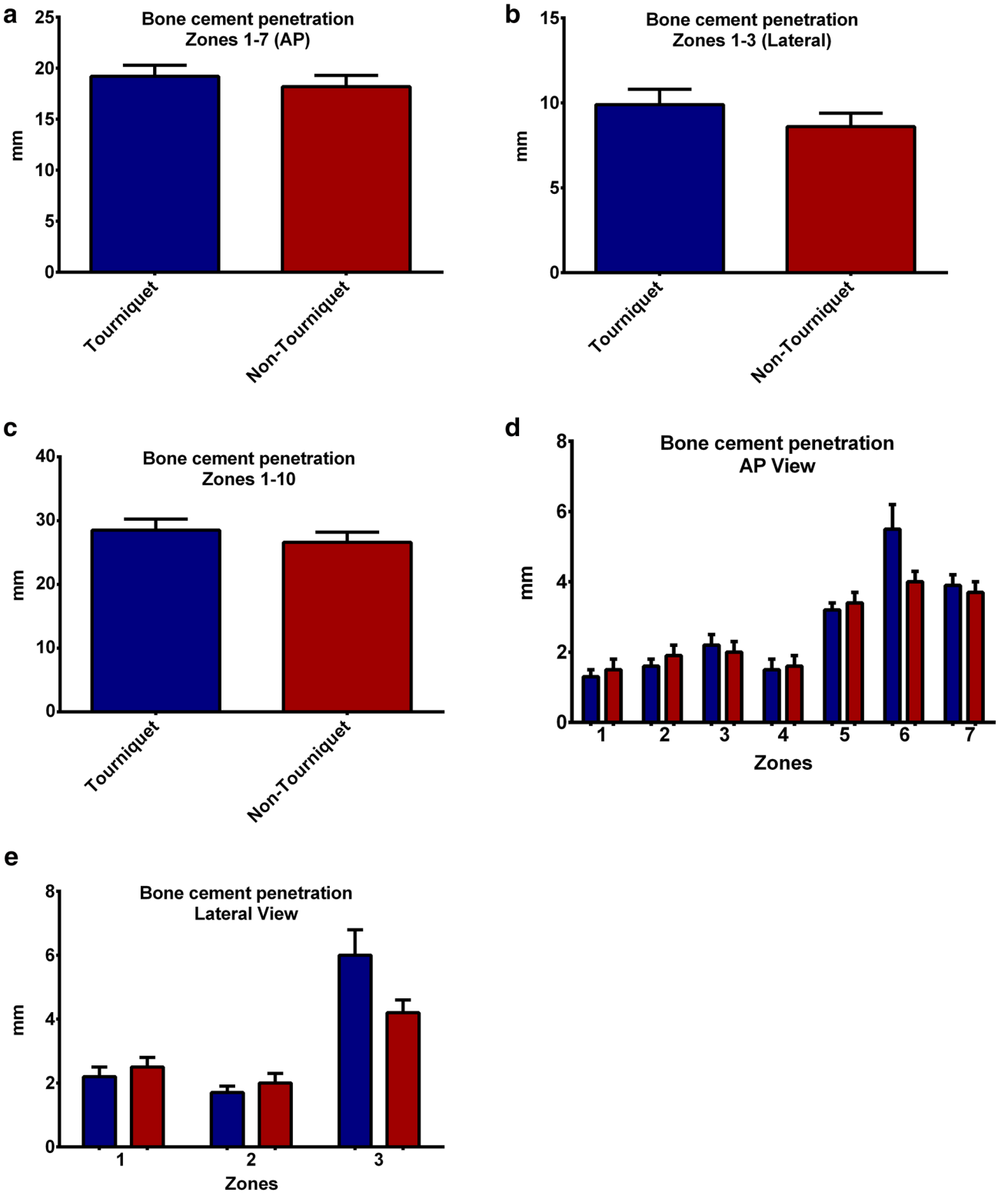

Fig. 3 **a** Mean ± SEM cumulative bone cement penetration on AP view (zones 1–7); **b** mean ± SEM cumulative bone cement penetration on lateral view (zones 1–3); **c** mean ± SEM cumulative bone cement penetration AP and lateral (zones 1–10); **d** mean ± SEM bone cement penetration in each zone (AP); **e** mean ± SEM bone cement penetration in each zone (lateral)

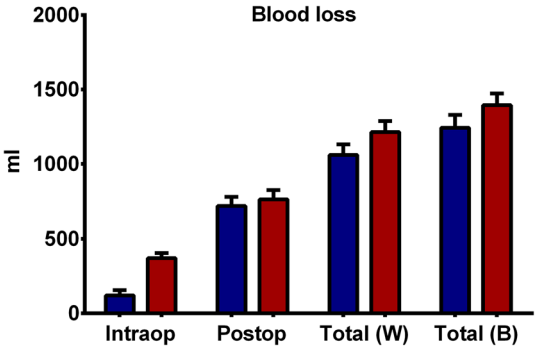

Fig. 4 Blue column indicates the tourniquet and red column the non-tourniquet group. Mean ± SEM intraoperative blood loss ($p = 0.0001$); mean ± SEM post-op blood loss (n.s.); mean ± SEM total blood loss calculated with Ward's formula (based on 1st post-op day data) and haemoglobin balance (based on 5th post-op day data)

Table 5 Perioperative blood loss

Variables	Tourniquet ($n = 43$)		Non-tourniquet ($n = 43$)		p value
Hb pre-op day (g/dl)	13.8	± 1.3	13.9	± 1.3	n.s
Hb 5th post-op day (g/dl)	10.3	± 1.1	10.2	± 1.1	n.s
Bleeding Index	3.5	± 1.4	3.9	± 1.2	n.s
Blood transfusion (n) %	1	2	4	9	n.s

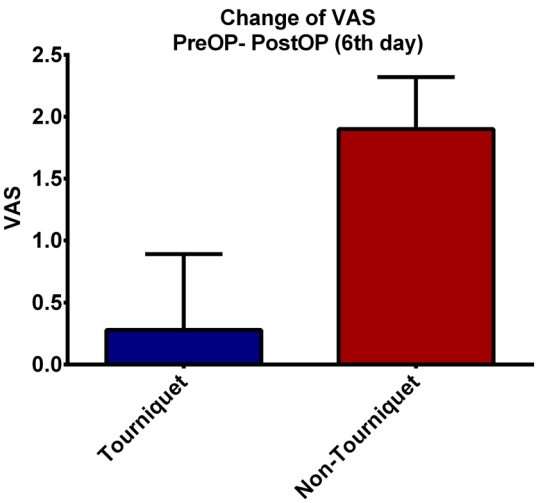

Fig. 5 Relative reduction of pain intensity quantified with VAS and calculated by pre-op minus 6th post-op day values

similar between the groups. A total of five (6%) patients received post-operative blood transfusions due to anaemia-related symptoms (Table 5).

Pain assessment and analgesic consumption

There was no significant difference in VAS pre-operatively between both groups. The post-operative pain relief was significantly higher ($p = 0.003$) in the non-tourniquet group; which was quantified by VAS changes between pre- to 6th post-operative day (Fig. 5). The number of cases with opioid requirement at the discharge day and the Morphine Equivalent Dose were significantly lower in the non-tourniquet group ($p = 0.02$) (Table 6).

Soft tissue swelling

The pre- to post-operative differences of the soft tissue circumference of the limb are listed in Table 6. Patients of the tourniquet group showed a similar post-operative soft tissue swelling on all measured sites (n.s.).

Surgical time, length of hospital stay and complications

The surgical time was 6 min shorter in the tourniquet group ($p = 0.05$) and the length of hospital stay revealed similar results between the groups (n.s.) (Table 6).

In the tourniquet group, one patient was diagnosed with deep vein thrombosis and one other patient underwent a revision surgery due to surgical site infection. In the non-tourniquet group, one patient had a delayed wound healing without a need for revision surgery (Table 6).

Discussion

The principal findings of the present study were that the cumulative bone cement penetration measured in ten zones increased by 1.9 mm in the tourniquet group, however, without revealing statistical significant differences between the groups. Pfitzner et al. [27] measured with a similar method in six zones a mean cumulative increase of tibial cement mantle thickness of 1.2 mm, when tourniquet was used. The findings of the present study are, therefore, in line with the previously published study by Pfitzner et al. [27] using a different implant design and bone cement manufacturer.

Scientific evidence is lacking on the issue whether the application of tourniquet improves the cemented tibia component fixation and long-term survival. The effect of tourniquet use on implant fixation in cemented tibial components was assessed recently with radiosteriometric analysis (RSA) and revealed no difference between the groups [19, 23]. Ryd et al. [28] reported for mostly non-cemented tibia components that micromotion as determined by RSA to be a risk factor for implant loosening. However, it remains unclear whether RSA was reliable to

Table 6 Pain intensity, analgesic consumption, soft tissue swelling, surgical time, hospital stay and complications

Variables	Tourniquet ($n=43$)		Non-tourniquet ($n=43$)		p value
Pain (VAS) mean ± SD					
Pre-op	4.5	±2.9	5.5	±2.7	n.s
Post-op	4.2	±2.1	3.7	±2.3	n.s
Difference between pre-op and post-op at 6th day	0.3	±3.7	1.9	±2.7	0.003
Number of cases with opioids at discharge (n) %	21	49	16	37	0.02
Morphine Equivalent Dosage at discharge (mg/day) mean ± SD	35	±8	22	±7	0.02
Number of cases with non-opioids at discharge (n) %	43	100	43	100	n.s
Ibuprofen at discharge (mg/day) mean ± SD	850	150	890	140	n.s
Diclofenac at discharge (mg/day) mean ± SD	60	5	50	5	n.s
Paracetamol at discharge (mg/day) mean ± SD	840	180	630	150	n.s
Novaminsulfon at discharge (mg/day) mean ± SD	1700	140	1650	120	n.s
Change of soft tissue circumference (Post-op – Pre-op)					
Thigh (20 cm proximal to patella) (mm) mean ± SD	24	±26	16	±19	n.s
Knee (midpoint of patella) (mm) mean ± SD	33	±15	30	±14	n.s
Gastrocnemius (15 cm distal to patella) (mm) mean ± SD	5	±21	5	±10	n.s
Surgical time (min) mean ± SD	79.1	±23	85.3	±20	0.05
Length of hospital stay (day) mean ± SD	11.2	±3.1	10.6	±3.9	n.s
Complications					n.s
Nerve lesion (n)	0		0		
DVT (n)	1		0		
Pulmonary embolism (n)	0		0		
Delayed wound healing (n)	0		1		
Surgical site infection (n)	1		0		

predict implant survival in cemented prosthesis design. Therefore, Ledin et al. [19] acknowledged the method of RSA for the detection of micromotion as a major limitation of their investigation. Increased cement penetration depth improved implant stability and survival after TKA [4, 26, 34]. According to a biomechanical study [4] with synthetic tibias, a significant micromotion occured with a 1-mm cement mantle under the tibial tray. However, if the cement mantle beneath the tibial baseplate was increased to 3 mm, excellent stability of the implant was seen [4]. Peters et al. [26] applied eccentric load, simulating three times body weight for 6000 cycles and concluded that the stability of tibial components may be related to the depth of cement penetration. Walker et al. [34] described an inverse relation between the development of radiolucency and initial cement penetration. The radiolucency hypothetically occurred due to low cement penetration, which resulted in cement-to-bone micromotion with high local stresses at the bone trabeculae increasing the resorption [34]. Based on their findings, an ideal depth of cement penetration is 3–4 mm [34].

However, there are no data supporting the hypothesis that the increased cumulative (ten zones) cement penetration depth of 1.9 mm affects the long-term tibia component survival positively.

To our knowledge, a clinically meaningful difference of bone cement depth is not consistently defined in the literature.

Concerning the ideal bone surface preparation and the cement application techniques, there are discussions ongoing [17, 22, 29]. The findings reported by Kopec et al. [17] suggest that continued use of the hand-packing technique for cementation may be warranted. On the other hand, a statistically significant positive effect of cement gun as well as cement syringe use on the tibial cement penetration was demonstrated by Lutz et al. [22]. An in vitro study [29] tested whether pressurized cement application with a cement gun can compensate the use of jet lavage for bone surface preparation. The conclusion was that the use of jet lavage could not be compensated by cement application technique.

The present study included some limitations to be acknowledged. It was a prospective randomized trial, which indicates a high validity. Solid inclusion and exclusion criteria were defined to obtain a homogeneous study population. The TKAs were performed by four different surgeons, which suggest minor differences in the standard surgical technique. However, the number of procedures performed by each surgeon in each group was similarly distributed. All surgeons were intraoperatively not blinded to the performed intervention. To reduce bias, the bone surface preparation, cement application,

pressurization and implantation of the components were standardized in both groups.

Due to differences in study setting and implant design/cement manufacturer, it is indeed difficult to compare the above-mentioned results with the findings of the present study.

Concerning the perioperative blood loss, comparable findings have been recently reported [15, 20].

Ejaz et al. [8] found a faster recovery, and less post-operative pain and analgesic consumption without the use of tourniquet in TKA. Higher soft tissue swelling may occur after tourniquet application [14, 15, 33, 35]. A tendency of increased incidence of deep vein thrombosis [5, 31, 37] and hypoxia-induced wound complications [7] were observed if tourniquet was applied. Jiang et al. [15] reported a significant reduction of the operative time by 9.9 min with tourniquet application.

Conclusion

The application of the tourniquet does not affect the depth of the periprosthetic tibial bone cement penetration. However, tourniquet could reduce intraoperative blood loss and operative time without clinical relevance. Intraoperative tourniquet use is associated with higher post-operative pain intensity and increased need for opioid analgesics. The indication for use of the tourniquet should be a subject of thorough evaluation. Available data do not support a routine tourniquet application during TKA and might justify a change of the clinical pathway.

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Compliance with ethical standards

Conflict of interest The authors declare that there were no conflicts of interest.

Ethical approval The present study was approved by our Institutional Ethics Committee (File reference 2012-334N-MA) and was carried out in accordance with the Declaration of Helsinki.

Informed consent Researchers approached the patients on admission day and written consent was obtained.

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