



# Blood loss reduction: effect of different knee prosthesis designs and use of tranexamic acid—a randomized controlled trial

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## Abstract

**Purpose** In regard to blood loss in total knee arthroplasty (TKA), the effect of either knee prosthesis designs or bone preparation is still unclear. While the benefit of using tranexamic acid (TXA) is well demonstrated, our study aims to determine the effect of different knee prosthesis designs uses and efficacy of blood loss reduction by different routes of TXA administration.

**Methods** The 228 patients undergone primary TKA were randomized to determine between open-box and closed-box prosthesis. Among each group, a second randomization was applied to categorize the patients into (1) no use of TXA (No-TXA), (2) intra-articular TXA use (IA-TXA) and (3) intravenous TXA use (IV-TXA). The calculated blood loss (CBL), drain volume (DV) and an average number of units of blood transfused (ANUBT) were blindly evaluated.

**Results** The open-box TKA had 85.60 and 63.29 ml ( $p=0.02$  and  $p<0.01$ ) more CBL and DV compared to closed-box TKA. The IA-TXA and IV-TXA significantly reduced CBL by 190.75 and 162.01 ml ( $p<0.01$  and  $p<0.01$ ) and reduced DV by 129.07 and 61.04 ml ( $p<0.01$  and  $p=0.01$ ), respectively, when compared to No-TXA. Patients who received IA and IV-TXA had ANUBT of 0.21 and 0.23 unit, which was significantly lower than 0.42 unit of No-TXA group ( $p=0.03$ ).

**Conclusions** Use of the different prosthesis designs could significantly affect CBL and DV following TKA. However, the use of either design resulted in a comparable ANUBT. Regardless of prosthetic type, either IA- or IV-TXA could significantly reduce the CBL and ANUBT when compared to No-TXA.

**Keywords** Tranexamic acid · Blood loss reduction · Open-box knee prosthesis · Closed-box knee prosthesis · Total knee arthroplasty

## Introduction

Total knee arthroplasty (TKA) is one of the most successful procedures for an end-stage osteoarthritic knee. However, TKA can lead to substantial blood loss because of the deep soft tissue dissection and several bone cuts during the operation [1–3]. Among various blood-conserving strategies, tranexamic acid (TXA) is one of the most widely used methods for reducing blood loss without increasing the risk

of a thromboembolic event [4, 5]. Many studies in the literature have reported the benefits of using TXA in TKA but an ideal dose regimen and route of administration are still inconclusive [6–10]. Accordingly, age, gender, body mass index and operative time that have been reported as potential determinants affecting blood loss may also have influence on efficacy of TXA [11–13].

The venous sinus of the trimmed bone has been proposed as another possible source of bleeding following TKA. The previous study demonstrated a direct association between blood loss and area of uncovered bone cuts caused by a different bone preparation of two prosthetic designs [14]. At our institution, we have experience in implanting posterior-stabilized (PS) fixed-bearing (FB) TKA with two different femoral component designs, closed-box and open-box (Fig. 1). The closed-box femoral component is designed to cover the cancellous bone of the distal femoral housing while the open-box implant leaves the housing area

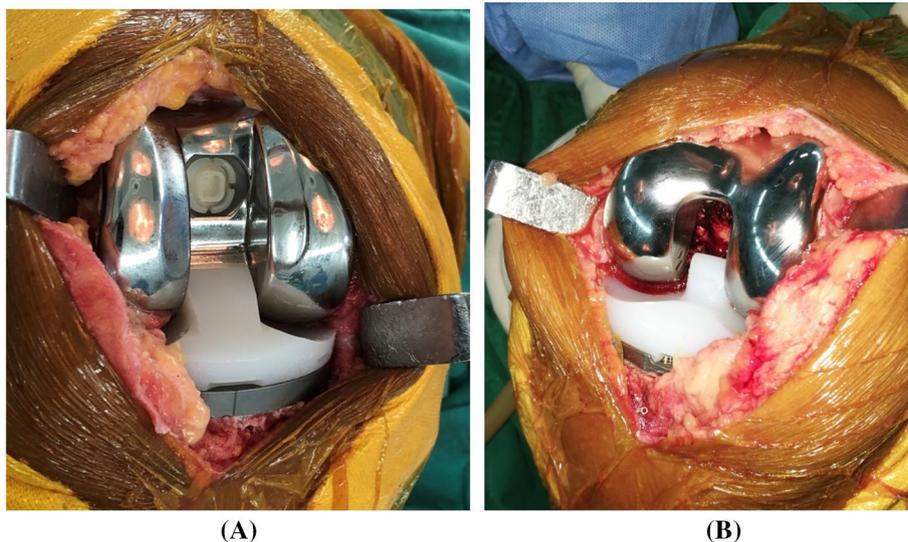
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**Fig. 1** **a** Closed-box prosthesis covers the whole area of cancellous bone at the distal femoral housing. The central plastic plug of the femoral component could be removed if insertion of the retrograded nail is required to treat periprosthetic fracture of the femur. **b** Demonstration of inevitable blood loss from the trimmed cancellous surface in an open-box prosthesis that may be a source of significant blood loss



uncovered. However, the potential advantage of the closed-box femoral component was still unknown. Therefore, the aims of this study were: (1) to determine whether use of the open-box and closed-box femoral prosthesis has effects on blood loss, drain volume (DV) and average number of units of blood transfusion (ANUBT) and (2) to compare the efficacy of blood loss reduction by different routes of TXA administration in the different knee prosthesis designs.

## Materials and methods

We conducted a double-blinded, prospective randomized controlled trial (RCT) of patients undergoing primary unilateral TKA in a single institution. All patients with the diagnosis of primary osteoarthritis of the knee scheduled for primary unilateral TKA during January 2015–January 2016 were enrolled after being assessed for eligibility. Patients with preoperative hemoglobin of less than 10 g/dL, previous history of a thromboembolic event, renal insufficiency, cardiovascular disease or cerebrovascular accident were excluded. Patients with a bleeding disorder and patients requiring anticoagulant therapy were also excluded. The study was approved by the Institutional Review Board, and written informed consent was obtained from every patient.

Participating patients were randomized into two groups at the beginning of the procedure by computer-generated blocks of four: group I (closed-box), using a fixed-bearing (FB), posterior-stabilized (PS) TKA prosthesis with the closed-box femoral component (PFC Sigma, DePuy Synthes, Warsaw, IN, USA); and group II (open-box), using a FB, PS TKA prosthesis with the open-box femoral component (NexGen LPS, Zimmer Biomet, Warsaw, IN, USA). Consolidated Standards of Reporting Trials (CONSORT) flow diagram is shown in Fig. 2.

Identical surgical technique was performed for all patients by a single surgeon, and the similar perioperative protocol was followed. A standard medial parapatellar approach was performed under regional anesthesia and a single injection of femoral nerve block. A tourniquet control at 250 mmHg was used in all patients for a bloodless operative field. The distal femoral cut was prepared with a conventional instrument via an intramedullary reference while an extramedullary reference was applied for the proximal tibial cut. The cutting block that matched the size of the femoral component was applied, and femoral box preparation was finished. Thus, the bone plug was applied to occlude the opening of the femoral medullary canal. All the knee prostheses were implanted with polymethyl methacrylate (PMMA), but spare some area of femoral box preparation, unless the closed-box prosthesis was used (Fig. 1). The patella was resurfaced in all cases of the closed-box group but in none of the cases of the open-box group.

Following placement of a drainage tube into the knee joint, second randomization was performed by computer-generated blocks of six to assign which route the TXA would be administered. The control (No-TXA) group received routine hemostasis without administration of TXA. The intra-articular TXA (IA-TXA) group received 15 mg/kg of TXA applied directly into the joint before closure of the arthrotomy; the TXA was maintained for 3 h until the vacuum drain was activated. The IV-TXA group received a single dose of intravenous TXA (10 mg/kg) before the closure of the arthrotomy wound. Hence, all patients would undergo an identical surgical technique until the TXA was applied.

Following the closure of the arthrotomy, a compressive dressing was applied before deflation of the tourniquet. All drains were temporarily clamped for 3 h and removed at 24 h after the surgery. During the first 48 h, intravenous patient-controlled analgesia (PCA) morphine was set to

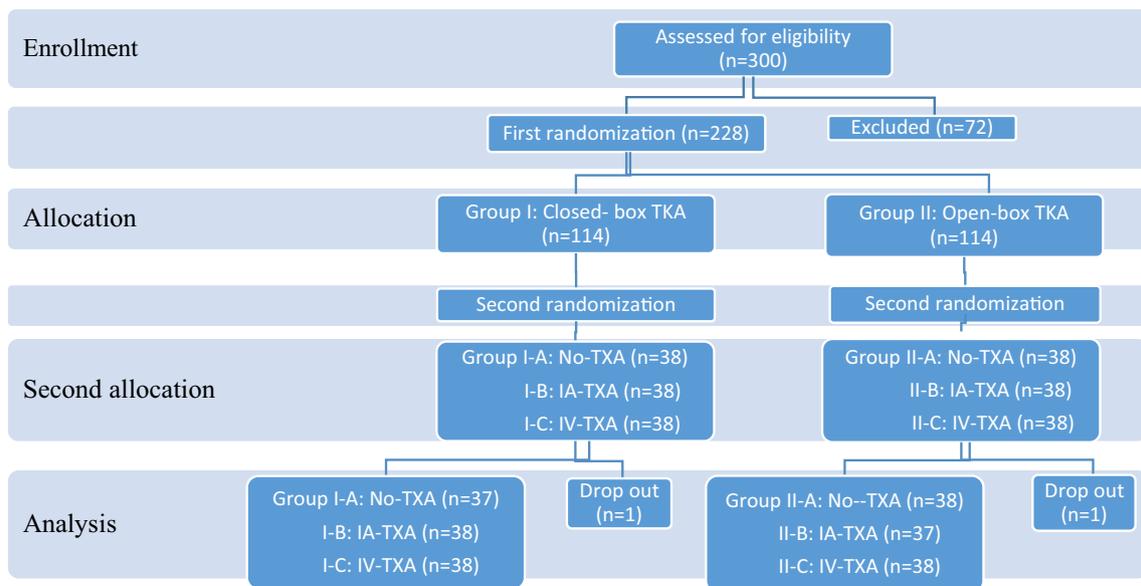


Fig. 2 CONSORT flow diagram of this study protocol

inject an on-demand bolus in conjunction with 30 mg of ketorolac being given intravenously every 8 h. Afterward, the morphine PCA, ketorolac, antibiotics, intravenous fluid and Foley’s catheter were discontinued. Low molecular weight heparin was injected subcutaneously at 24 h after the operation, and 10 days of oral warfarin was initiated for all patients as postoperative thromboembolic prophylaxis. Every patient was encouraged to attempt early mobilization with an identical postoperative physiotherapy protocol beginning on the day after surgery. There was no routine screening test for thromboembolic events. Only symptomatic deep vein thrombosis patients were evaluated with ultrasonography.

The outcomes of our study were calculated: blood loss (CBL), drain volume (DV) and an average number of units of blood transfused (ANUBT). The patients’ total blood volume was calculated using the equation of Nadler et al. [15], and the calculated blood loss was assessed from the difference between preoperative and 24-h postoperative Hb by using the hemoglobin balance method (Table 1) [8].

Our institution’s blood transfusion protocol is implemented when serum Hb level drops below 9.0 g/dl. All of these outcomes were recorded by the same group of

independent investigators, and the investigators and patients were blinded to the treatment protocol.

### Statistical analysis

Descriptive statistics, Chi-square test, Student’s *t* test and analysis of variance (ANOVA) were used as appropriate. A multivariate regression analysis, controlling for age, gender, BMI, operative time and TXA groups, was used to compare the differential effects of the two knee prosthesis types and between the three TXA groups on CBL and DV. Student’s *t* test was used for comparative analysis of the ANUBT between the two knee prosthesis types, while the ANOVA was applied to determine the ANUBT between the different routes of TXA.

According to the previously estimated CBL from PS and cruciate-retaining TKA [14], 114 patients in each group were expected to achieve 80.245% of power to detect an 80-ml difference of CBL with a standard deviation of 214 ml and a significance level (alpha) of 0.05 using a two-sided two-sample equal-variance *t* test. STATA/MP 14.2 (Stata-Corp) was used for all statistical analysis. Statistical significance was defined as  $p < 0.05$ .

Table 1 Calculated blood loss and total body volume formulation

Parameter	Formulation
Male: TBV (ml)	$(0.0003669 \times \text{height}^3 [\text{cm}]) + (32.19 \times \text{body weight} [\text{kg}]) + 604$
Female: TBV (ml)	$(0.0003561 \times \text{height}^3 [\text{cm}]) + (33.08 \times \text{body weight} [\text{kg}]) + 183$
Calculated blood loss (ml)	$\text{TBV} [\text{ml}] \times (\text{Hbi} - \text{Hbe}) / \text{Hbi} + \text{sum of blood products transfused} [\text{ml}]$

TBV, total body volume; Hb<sub>i</sub> [g/dl], preoperative hemoglobin; Hb<sub>e</sub> [g/dl], postoperative hemoglobin

## Results

Of the 300 potential candidates, 34 met the exclusion criteria, 38 declined to participate in the study, no one dropped out because of any intra-operative complication, two dropped out due to patients declining to complete the protocol, and therefore, a total of 228 patients (189 females and 39 males) remained for analysis. There were no significant differences between the six groups in all demographic and perioperative parameters (Table 2).

The open-box TKA resulted in 85.60 ml (95% CI 15.18–156.01;  $p=0.02$ ) higher CBL and 63.29 ml (95% CI 21.99–104.59;  $p<0.01$ ) higher DV than that of the closed-box group. The IA-TXA and IV-TXA reduced CBL by 190.75 ml (95% CI – 288.46 to – 93.04;  $p<0.01$ ) and 162.01 ml (95% CI – 257.88 to – 66.14;  $p<0.01$ ) and DV by 129.07 ml (95% CI – 176.94 to – 81.20;  $p<0.01$ ) and 61.04 ml (95% CI – 107.93 to – 14.15;  $p=0.01$ ) in comparison with the No-TXA group, respectively.

The ANUBT of the open-box TKA were 0.32 unit (95% CI 0.22, 0.42) which was higher than 0.24 unit (95% CI 0.14, 0.34) of the closed-box TKA ( $p=0.28$ ). The IA-TXA and IV-TXA had ANUBT of 0.21 unit (95% CI 0.10, 0.31) and 0.23 unit (95% CI 0.12, 0.33), respectively, which were significantly lower than 0.42 unit (95% CI 0.27, 0.58) of the patients who did not receive TXA ( $p=0.03$ ). The ANUBT of closed-box with No-TXA, IA-TXA and IV-TXA were 0.41 unit (95% CI 0.18, 0.63), 0.19 unit (95% CI 0.06, 0.32) and 0.13 unit (95% CI -0.01, 0.27), and those of open-box with No-TXA, IA-TXA and IV-TXA were 0.42 unit (95% CI 0.21, 0.63), 0.24 unit (95% CI 0.08, 0.41) and 0.29 unit (95% CI 0.13, 0.45), respectively. There was no statistical significance in ANUBT among the six study groups ( $p=0.11$ ).

## Discussion

The procedure for TKA involves multiple bone cuts, and thus, the bleeding from the venous sinus of the trimmed bone may be one of the major sources of blood loss following this procedure. The closed-box femoral component was designed to cover the exposed surface of cancellous bone cutting in the PS TKA. However, the closed-box design may hinder subsequent insertion of a retrograde femoral nail in the treatment of a periprosthetic fracture of the distal femur. Therefore, surgeons considering the use of closed-box designs should weight the risk of increased difficulty in managing periprosthetic fracture against the benefit of decreased blood loss.

Cankaya et al. [16] compared 50 cruciate-retained (CR) TKA and 50 posterior-stabilized (PS) TKA. They found that the CR TKA had 43 ml and 74 ml less DV and CBL, respectively, but this difference did not reach statistical significance. Comparatively, Mahringer-Kunz et al. [14] reported on a series of 473 patients who underwent a cruciate-retained (CR) or posterior-stabilized (PS) TKA. They found that the CR TKA significantly reduced the CBL by 46 ml, compared to the PS TKA, and proposed that the area of uncovered bone cuts by different knee prosthesis designs might lead to significant blood loss. With the multivariate regression model adjusted for age, gender, BMI operative time and the use of TXA, we found the closed-box TKA had 63.29 ml less DV compared to open-box TKA. This amount might be mainly attributed to 85.6 ml reduction of CBL by the closed-box TKA. Hence, having less CBL in the closed-box TKA might be explained by the reduction in an intra-articular blood loss. In accordance with the aforementioned studies, we assumed that the dissimilarity in bone preparation of each prosthetic design could result in a significant difference in DV and CBL. Nevertheless, this factor did not have an effect on blood transfusion requirement.

**Table 2** Demographic and perioperative characteristics

Characteristics	Overall	Closed-box TKA			Open-box TKA		
		No-TXA	IA-TXA	IV-TXA	No-TXA	IA-TXA	IV-TXA
Age (years)	64.23 ± 7.61	64.41 ± 7.12	65.53 ± 8.36	63.38 ± 8.43	63.38 ± 7.13	63.95 ± 7.70	64.83 ± 6.97
Female:male	186:42	31:7	33:5	34:4	29:9	30:8	32:6
BMI (kg/m <sup>2</sup> )	27.43 ± 4.36	27.02 ± 3.41	26.99 ± 3.83	27.96 ± 5.25	27.15 ± 3.94	28.03 ± 4.51	27.49 ± 5.20
ASA 1:2:3 (N)	32:143:53	4:28:6	7:21:10	3:24:11	8:22:8	6:22:10	4:26:8
Hb (mg/dl)	12.32 ± 1.27	12.04 ± 1.02	11.78 ± 1.15	12.31 ± 1.25	12.53 ± 1.45	12.56 ± 1.32	12.09 ± 1.26
Operative time (min)	75.68 ± 14.99	77.57 ± 19.82	75.31 ± 14.10	75.39 ± 14.01	77.10 ± 17.55	78.09 ± 13.54	73.49 ± 12.87
Right:left	115:113	20:18	20:18	18:20	18:20	19:19	20:18
Length of stay (days)	6.47 ± 0.99	6.47 ± 0.99	6.39 ± 0.90	6.30 ± 0.78	6.49 ± 0.99	6.39 ± 0.84	6.71 ± 1.35

TXA, tranexamic acid; BMI, body mass index; kg/m<sup>2</sup>, kilogram/meter<sup>2</sup>; ASA, American Society of Anesthesiologists; N, number; Hb, hemoglobin; mg/dL, milligram/deciliter

Generally, using the bone plug to occlude the femoral opening hole is widely accepted as a simple technique to reduce blood loss, but Torres-Claramunt et al. [17] demonstrated an insignificant difference between occlusion and non-occlusion group in terms of blood loss and transfusion. Moo et al. [18] recently demonstrated significant blood loss reduction following TKA by applying bone wax to the exposed cancellous surface. The blood loss of the bone wax and control group was 987.9 and 1183.5 ml, and postoperative Hb level drop was 2.7 and 3.6 g/dL, respectively, even though there was insignificant difference in blood transfusion. Therefore, prosthetic design, canal occlusion or application of sealant to the trimmed cancellous surface may minimize blood loss following TKA.

In comparison between IA-TXA and IV-TXA, the results varied among previous studies. Nevertheless, meta-analyses and systematic reviews demonstrated that IA-TXA was equal to IV-TXA in terms of perioperative blood loss reduction, but the transfusion rate was still inconclusive [8–10]. Recently, Stowers et al. [19] reported their multicentered, randomized controlled trial comparing IA- and IV-TXA use in elective TKA surgery. They found no significant difference between single-dose 1.5 g IA-TXA and 1.5 g IV-TXA regarding blood loss reduction. Latest network meta-analysis by Fillingham et al. [20] revealed a superior effect of IA-, IV- and oral-TXA on blood loss and blood transfusion reduction when compared to placebo. Furthermore, comparable efficacy was identified among these routes of TXA administration. In our findings, both routes of the single-dose TXA administration were sufficient to result in significantly less CBL, DV and ANUBT across knee prosthesis types, compared to the No-TXA group. While the IA-TXA reduced DV and CBL by 129.07 and 190.75 ml, respectively, the IV-TXA could reduce DV and CBL by 61.04 and 162.01 ml, respectively, when compared to No-TXA group. These findings might support a theoretical superiority of intra-articular bleeding control by the topical TXA [21–23], whereas the IV-TXA seemed to better reduce hidden blood loss [24].

According to our findings, the patients who received the TXA require significantly less ANUBT. Interestingly, the ANUBT was lowest when the IV-TXA was administered in conjunction with the closed-box TKA (0.132 unit). We hypothesize that this group might benefit from a synergic effect of controlling the blood loss through a local and systemic action of the closed-box TKA and IV-TXA, respectively. If so, the IV-TXA may be considered as an interesting option when we perform the closed-box TKA. In the same way, Jain et al. [25] also reported that using the IA combined with IV-TXA provided better reduction in blood loss than a single-route administration of TXA. However, further investigation on a synergic effect obtained from knee prosthesis design combined with the most appropriate route of TXA may be conducted with a larger cohort study.

This prospective RCT study has some limitations. First, different patellar management in both groups may affect our result, even though blood loss from patellar resurfacing was not well documented. Although both PFC and NexGen knee prostheses had a similar 10–15-year survivorship (94–96%) [26], evidence showed that there is approximately 10% of painful patellar clunk in the PFC Sigma system [27, 28], but it is significantly lower in the NexGen LPS system [29]. Hence, we prefer to resurface the patella in the closed-box TKA to avoid this complication. Despite this different protocol between groups, the closed-box TKA significantly reduced the CBL and DV compared to the open-box TKA. Second, our comparison between only two prosthetic types performed by a single surgeon should be recognized as another limitation. Lastly, a difference in blood transfusion protocol among institutions may cause a variation of ANUBT.

## Conclusions

Use of the different prosthesis designs could significantly affect the calculated blood loss (CBL) and drain volume (DV) following TKA. However, the use of either design resulted in a comparable average number of units of blood transfused (ANUBT). Regardless of prosthetic type, either IA- or IV-TXA could significantly reduce the CBL and ANUBT when compared to No-TXA.

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## Compliance with ethical standards

**Conflict of interest** The authors have no competing interests related to the study design, data collection and results interpretation of this manuscript.

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