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No Additional Benefit With Use of a Fibrin Sealant to Decrease Peri-Operative Blood Loss During Primary Total Knee Arthroplasty

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ABSTRACT

Blood loss remains a substantial problem associated TKA. This study evaluated the efficacy of a fibrin sealant on: (1) blood loss; (2) blood transfusions; and (3) length of stay. We evaluated the records of 113 consecutive patients with sealant and 70 without sealant. There was no significant difference in the hemoglobin levels (all 9.5–10 g/dL) on each of three postoperative days. There was also no significant difference in the intraoperative blood loss, postoperative blood loss or the total perioperative blood loss in both groups. The mean requirement in each patient was 2.5 ± 2.4 units in the fibrin sealant group compared to 2.0 ± 0.8 units in the non-fibrin sealant group. We have stopped using fibrin sealant based on this study.

Perioperative blood loss remains a substantial problem associated with total knee arthroplasty (TKA) [1–3]. Although the blood transfusion rate is highly variable (6%–69%) [4,5], the mean transfusion rate has been reported to be between 20 and 45%, with typically a mean of two units of blood transfused per patient [2,6–8]. The use of autologous blood (either pre-donated or re-infused), as an alternative to allogeneic blood transfusions has been evaluated, but its routine use remains controversial [9–11]. Furthermore, all types of transfusions have been associated with varying increases in hospital cost, length of stay, or transfusion-related medical complications [7,12–15].

Consequently, there has been an increased emphasis on minimizing peri-operative blood loss and several techniques have been utilized [8]. These include pre-operative pharmacologic therapy (e.g. tranexamic acid, ε-aminocaproic acid, or erythropoietin) [16–19], intra-operative techniques such as electrocautery or bipolar sealers [20], tourniquet use [21], hypotensive regional anesthesia [22,23], acute normovolemic hemodilution (ANH) [24], shorter operative times [7], post-operative measures such as drain clamping and early drain removal [25,26], reinfusion drains [27], and post-operative erythropoietin [28]. Another recent development has been the intra-operative use of fibrin sealants which enhance coagulation and theoretically should help decrease post-operative blood loss [25]. However, reports are conflicting about differences in blood loss and transfusion rates in patients who have received a fibrin sealant compared to those who have not during total knee arthroplasty [25,29]. Furthermore, the use of a fibrin sealant may add substantial costs of up to $500 to the surgical procedure [7]. Thus, it is important to determine the clinical and economical efficacy of using this treatment modality.

Due to the conflicting reports about the outcomes of fibrin sealant use in TKA, the purpose of this study was to evaluate the efficacy of a fibrin sealant on: (1) peri-operative blood loss; (2) blood transfusion requirements; and (3) length of hospital stay.

Methods

The medical records of all consecutive patients who underwent a primary TKA by a single fellowship trained surgeon (VJR) at a single teaching institute between 2004 and 2011 were retrospectively reviewed following Institutional Review Board approval. Patients prior to July, 2006 did not receive a fibrin sealant while all patients after this date received fibrin sealant intra-operatively. Exclusion criteria included patients younger than 18 years of age, patients with severe medical comorbidities (American Society of Anesthesiologists [ASA] grade 4 or higher) [30], patients with known bleeding/clotting disorders, bilateral TKA during the single hospital stay and patients with known allergy to fibrin sealant. One additional patient was later excluded from the fibrin sealant group due to a clerical error in the number of units that were transfused.

A total of 113 patients (16 males, 97 females) were identified who underwent a primary total knee arthroplasty and received a fibrin sealant intra-operatively. This cohort was compared to 70 patients (21 males, 49 females) who underwent the same procedure by the same

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surgeon, but did not receive fibrin sealant. The two groups were similar in baseline preoperative demographic variables including age, gender, body-mass index (BMI), diagnosis, American Society of Anesthesiologists (ASA) grades, hemoglobin (Hb) and hematocrit (Hct), and Knee Society Scores (KSS) [31] (Table 1).

Data Extraction

The data on each patient were extracted from their medical charts. The Hb and Hct values were recorded preoperatively, immediately after surgery and during each morning for the entire hospital stay. The perioperative blood loss was recorded and included intraoperative blood loss and postoperative blood loss. The intraoperative blood loss was calculated from the amount of blood in the suction canister after subtraction of the irrigation fluid that was used during the case and combining this to the number of soaked lap sponges (estimated as 100 mL of blood per sponge) [32]. The post-operative blood loss was calculated from the sum of drain output that was recorded for each eight hour shift by the nursing staff on the floor. We also recorded the number of patients requiring a blood transfusion, the mean number of transfusions (units of blood) that were given in each group, and the length of hospital stay.

Fibrin Sealant and Surgical Technique

The fibrin sealant used in this study (Evicel, Ethicon, Somerville, New Jersey) is a plasma-based product consisting primarily of fibrinogen, thrombin, and other proteins involved in the terminal clotting cascade [33]. The mechanism of action of fibrin sealants is to augment the final steps of the coagulation cascade where thrombin converts fibrinogen into fibrin.

All surgeries were performed by a similar technique in a similar perioperative setting. A standard medial parapatellar approach was used in all cases along with posteriorly stabilized cemented components. Routine intra-operative hemostatic procedures used included a tourniquet and standard electrocautery. After the final components were cemented in place, the surgical site was thoroughly irrigated and all excess saline was suctioned away to have a clean, dry field. With the tourniquet still inflated, 5 mL of fibrin sealant was placed diffusely into the joint with the manufacturer-provided syringe. The tourniquet was deflated once the sealant reached a gel like consistency, which is a visual cue that hemostasis has been achieved. The tourniquet was then inflated again and the closure was done in layers over a suction drain. However no suction was applied and the drain was set to gravity. No clamping of the drain was done.

Post-Operative Regiment and Venous Thromboprophylaxis

All patients were mobilized post-operatively with physical therapy and continuous passive motion devices on the first post-operative day. The drains were removed on the first postoperative day, unless the output was more than 50 cc in the last 8 hours shift. For venous thromboprophylaxis, all patients received 5 mg of warfarin the day of surgery, which was titrated to International Normalization Ratio (INR) of 1.8–2.2 post-operatively along with a pneumatic calf compression device. Indications for blood transfusion were symptomatic anemia or if there were low Hb (<7 g/dL) and Hct (<21%) values. Symptoms were defined as tachycardia (HR >100 BPM), orthostatic hypotension (>20 mm Hg drop systolic pressure when standing), sustained light-headedness, dizziness, or syncope, and inability to partake in physical therapy. Patients were planned to be discharged on post-operative day three unless they had not met their physical therapy milestones as determined by the physical therapist.

Table 1
Pre-Operative Patient Demographics.

	Fibrin Sealant	Non-Fibrin Sealant	*P* Value
Gender (M:F)	16:97	21:49	0.01
Mean age (range)	64 (39–84)	62 (44–80)	0.09
Mean BMI (range)	34.7 (19.9–51.6)	32.1 (20.3–52)	0.13
KSS objective (range)	43 (22–65)	44 (12–77)	0.53
KSS function (range)	43 (5–80)	40 (0–90)	0.46
Hemoglobin (g/dL)	11.2	11.5	0.13
Hematocrit (%)	34.2	34.6	0.56

KSS: Knee Society Score [31].

Data Analysis

All patient data were extracted to and organized using a standard spreadsheet (Excel, Microsoft, Redmond, Washington). All statistical analysis was performed using dedicated statistical software (SPSS 17.0, IBM, Chicago, IL). A *post hoc* power analysis was performed to determine the study power needed to detect a significant difference of at least 5% in the hemoglobin concentration between the two study groups. Based on the observed effect size, 61 patients would have been required in the each group to achieve a power (1-β) of 0.80. The calculated actual power of this study was 0.83 based on the observed effect size.

A Student's T-test was utilized for analysis of continuous variables and a Fisher's exact test was used for categorical variables. The level of statistical significant was set at $\alpha = 0.05$. Within each study group (fibrin sealant and no-fibrin sealant), the mean hemoglobin levels on each post-operative day were analyzed using an analysis of variance (ANOVA). Graphical representation of the post-operative hemoglobin levels for each group was calculated at the 95% confidence interval.

Results

There was no significant difference in the hemoglobin and hematocrit levels on each postoperative day. There was also no significant difference in the intraoperative blood loss, postoperative blood loss or the total perioperative blood loss in both groups (Fig. 1, Table 2). When each group was analyzed individually, an analysis of variance (ANOVA) demonstrated no significant difference in the mean hemoglobin level only on post-operative day ($P = 0.1$–0.9).

Within the fibrin sealant group 48 patients (43%) required transfusions, while 21 patients (30%) in the non-fibrin sealant group were given transfusions, which was not statistically significant ($P = 0.12$). For patients who required a transfusion (range 1–4 units), the

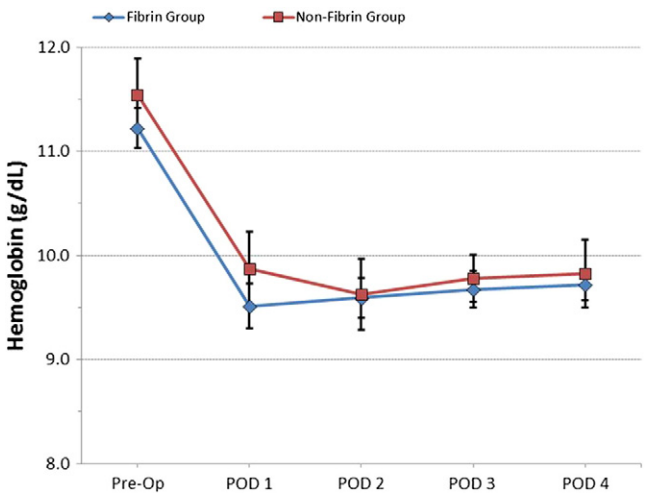

Fig. 1. Mean hemoglobin levels (mg/dL) for the fibrin sealant group and the non-fibrin sealant group on day prior to the procedure and for four subsequent post-operative days (POD). Vertical error bars represent the 95% confidence interval for each group.