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Saline-Coupled Bipolar Sealing in Simultaneous Bilateral Total Knee Arthroplasty

Atul F. Kamath, MD, Daniel C. Austin, BA*, Peter B. Derman, MD†, R. Carter Clement, MD‡, Jonathan P. Garino, MD§, Gwo-Chin Lee, MD‖

Department of Orthopedic Surgery, Mayo Clinic, Rochester, MN,
**Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA,*
†Department of Orthopedic Surgery, Hospital for Special Surgery, New York, NY,
‡Department of Orthopedic Surgery, University of North Carolina, Chapel Hill, NC,
§Department of Orthopedic Surgery, Lankenau Institute for Medical Research and Pennsylvania Orthopedic Center, Exton, PA,
‖Department of Orthopedic Surgery, Penn Presbyterian Medical Center, University of Pennsylvania, Philadelphia, PA, USA

Background: The efficacy of saline-coupled bipolar sealing devices in joint arthroplasty is uncertain, and the utility in simultaneous bilateral total knee arthroplasty (TKA) has not been reported.

Methods: This study compares the use of bipolar sealing and conventional electrocautery in 71 consecutive patients. The experimental and control groups were matched for age, sex, body mass index, American Society of Anesthesiologists (ASA) classification, and preoperative hemoglobin. Variables of interest included blood loss, transfusion requirements, and operative characteristics.

Results: In comparison to patients treated with conventional electrocautery, those treated with the bipolar sealer were 35% less likely to require transfusion. The median number of transfusions per case was also significantly lower in the experimental group. Hemoglobin change, total blood loss, and length of stay were not significantly different between the groups. The experimental group had longer operative times.

Conclusions: Bipolar sealing shows promise as a blood loss reduction tool in simultaneous bilateral TKA. The marginal savings attributed to reduced transfusion rates with use of the bipolar sealer did not exceed the additional per-case expense of using the device. The decision to use the device with the goal of less blood loss must come with the additional expense associated with its use.

Keywords: *Knee, Arthroplasty, Equipment and supplies, Surgical hemostasis, Blood transfusion*

The number of simultaneous bilateral total knee arthroplasties has been increasing despite increased risks of complications compared to unilateral total knee arthroplasty (TKA).[1,2] Bilateral arthroplasty has potential benefits, such as reduced rehabilitation time and cost savings, but blood transfusion requirements have been as high as seventeen-fold greater in bilateral TKA,[3] with the procedure ranking second only to revision total hip arthroplasty (THA) in terms of orthopedic transfusion requirements.[4]

While allogeneic blood transfusions are often necessary in major surgery, these transfusions are costly, expose patients to risks including exposure to pathogens and transfusion reactions,[5,6] and may be a significant risk factor for postoperative bacterial infection[4] and immune suppression.[6] Much of the morbidity associated with simultaneous bilateral TKA, including increased risk of cardiopulmonary complications, delirium, and intensive care unit admission, may be indirectly related to perioperative blood loss.

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Correspondence to: Atul F. Kamath, MD
Department of Orthopedic Surgery, Mayo Clinic, 200 First St SW, Gonda 14-Rm 130, Rochester, MN 55905, USA
Tel: +1-267-250-0773, Fax: +1-507-266-4234
E-mail: akamath@post.harvard.edu

To reduce these morbidities, a necessary goal of safe bilateral TKA becomes the minimization of blood loss. A variety of blood management strategies have been used in the peri-operative period. Interventions including pharmacological agents,[7] the anti-fibrinolytic agent tranexamic acid,[8] fibrin sealants,[9] and predonation of autologous blood have all demonstrated utility in orthopedic procedures.[4,10] Perioperative blood salvage and cell salvage/re-transfusion have shown to be effective for reducing transfusion requirements,[11] but results in TKA have been mixed.[12,13]

Saline-coupled bipolar sealing provides an alternative option for achieving hemostasis. Radiofrequency energy conducted at temperatures below 100°C[14] allows for collagen contraction and hemostasis without excessive thermal tissue damage.[14,15] The use of the bipolar sealer to reduce blood loss in unilateral TKA has been explored with mixed results.[14,16-18] Similarly, the efficacy of the device remains unclear in THA procedures, with past research showing promising results,[15] but with more recent studies raising doubts about the efficacy of the device in THA.[19,20] Of note, a randomized, double-blind study in THA reported no significant differences in transfusion requirements, units of blood transfused, or hemoglobin changes.[20]

The ability of bipolar sealing to reduce blood loss in joint arthroplasty remains uncertain, and this device has not yet been evaluated in bilateral TKA. While the overall economic efficiencies of simultaneous TKA may be supported, the tools associated with reducing peri-operative blood loss need further analysis. Therefore, we sought to study the effectiveness and utility of bipolar sealing in simultaneous bilateral primary TKA.

METHODS

We performed a single surgeon case-control study of 71 consecutive patients undergoing simultaneous bilateral TKA from 2007 to 2009. The study was carried out according to a protocol approved by our institution's ethical review board. The 29 experimental cases were performed with the use of a commercially-available saline-coupled bipolar sealer (Aquamantys System, Salient Surgical, Portsmouth, NH, USA). The control group of 42 patients received conventional electrocautery alone for hemostasis. One bilateral TKA patient received a blood transfusion immediately prior to the start of surgery and had to be excluded from the study.

Standard surgical technique, extremity tourniquets, implants, and postoperative rehabilitation protocols were used in all patients. In the experimental group, additional treatment using the saline-coupled bipolar sealer was performed during surgical exposure and before final component implantation. This included pretreatment of the posterior capsule prior to fixation of the prosthetic components. The tourniquet was let down for final hemostasis in all procedures. All patients received aspirin or warfarin postoperatively for prophylaxis. Exceptions to this protocol included two patients in the experimental group who received both aspirin and warfarin, a single patient in the control group who also received clopidogrel postoperatively, and a single patient in the control group with no postoperative prophylaxis data available. Of the 29 patients in the experimental cohort, 22 received aspirin, and five were anticoagulated with warfarin; while of the 42 patients in the control group, 35 received aspirin, and five were anticoagulated with warfarin. The need for blood transfusions was determined by the primary surgeon and medical co-management team based upon pertinent medical co-morbidities (e.g., strong cardiac disease history), clinical symptoms such as lethargy, and hemodynamic parameters such as tachycardia and/or hypotension refractory to initial fluid resuscitation. In general, patients without cardiac history were not transfused for a hemoglobin level greater than 8 g/dL. This is the standard protocol at our institution for determining the need for a blood transfusion in patients recovering from joint arthroplasty. Fixed, predetermined transfusion triggers were not employed. This protocol of transfusing patients based upon relevant symptoms was identical between the groups and remained consistent throughout the course of the study.

Demographic variables included age, gender, body mass index (BMI), American Society of Anesthesiologists (ASA) classification, and preoperative hemoglobin level. Common co-morbidities requiring an ASA classification of III in our patient population included chronic liver disease, coronary artery disease, and stable congestive heart failure. All patients were deemed medically optimized for bilateral arthroplasty surgery. In addition to demographic data, a number of other outcome variables were recorded and compared between treatment groups: initial hemoglobin, discharge hemoglobin, in-hospital hemoglobin nadir (i.e., the lowest hemoglobin level during hospitalization), units of autologous blood transfused, units of allogeneic blood transfused, operative time, tourniquet time, intraoperative blood loss, and length of stay. Coagulation studies including prothrombin time (PT), partial thromboplastin time (PTT), and international normalized ratio (INR) where not retrospectively captured. Tourniquet time was the sum of the number of minutes that the tourniquet was inflated during the surgeries on the right and left knees. Hemo-

globin change was calculated based upon the difference between the preadmission testing hemoglobin level and the hemoglobin nadir obtained during the hospital stay. Estimated blood loss was used as a surrogate for total intra-operative blood loss because drains were not routinely used. Estimated blood loss was an approximation agreed upon by the surgeon, anesthesiologist, and circulator nurse at the end of the case based upon the amount of blood within the suction container and on the sponges used during the case. The primary outcome of interest in the study was the need for blood transfusion as it provided an overall measure of both visible and hidden blood losses that proved clinically important. This analysis of transfusion requirements was carried out based on the total number of units transfused to an individual, regardless of whether they were autogenic or allogeneic. Only nine of 71 patients predonated blood (seven in the control group and two in the experimental group), and the immediate preoperative hemoglobin levels did not differ significantly from predonation values.

Formal statistical analysis was used to compare the data between the experimental and control groups. No previous studies analyzing the effects of bipolar sealing in bilateral TKA had been published to provide appropriate effect sizes to use in our power analysis calculations. Therefore a large Cohen's *d* effect size was assumed for the study, and patient group numbers met prestudy power analysis suggesting that at least 26 patients per group would be necessary for use of the Student *t*-test with a Cohen's effect size (*d*) of 0.8, an alpha of 0.05, and a power of 0.80. Continuous data sets with normal distributions were compared using the two-tailed Student *t*-test and reported as a mean ± 95% confidence interval (CI). Continuous data sets with non-normal distributions were compared using the Mann-Whitney *U*-test and reported as a median with interquartile range (IQR). Normality for the data sets was determined using the Kolmogorov-Smirnov test. Chi-square analysis was used to compare categorical data. Statistical analysis was completed using Microsoft Excel (Redmond, WA, USA) and the VassarStats Statistical Software Package.[21] In all analyses, a two-tailed alternative hypothesis was used, and a *p*-value of less than 0.05 was considered significant.

RESULTS

The cases and controls were matched for all demographic variables, including age, sex, BMI, ASA classification, and preoperative hemoglobin (Table 1). Patients treated with the saline-coupled bipolar sealer during TKA had significantly lower blood transfusion requirements than those managed with conventional electrocautery (Table 2). Fifty-five percent of patients in the experimental cohort required a blood transfusion, while 83% of the control group required blood postoperatively ($p = 0.01$). Similarly, the number of units of blood transfused in the bipolar sealer treatment group (median of 1 unit; IQR 0–2) was significantly lower than the electrocautery group (median of 2 units, IQR 2–2; $p = 0.006$). Additionally, relatively fewer individuals in the experimental group required greater than two units of blood (6.9%) compared to the control group (19%). However, this trend did not reach statistical significance ($p = 0.148$).

Median (IQR) blood loss was 100 mL (range, 75 to 200 mL) in the bipolar sealer group, and 100 mL (range, 42.5 to 150 mL) in the electrocautery group ($p = 0.246$). Median hemoglobin levels at discharge were not significantly different between the two groups: 9.1 g/dL (range, 8.7 to 9.4 g/dL) in the experimental group versus 9.4 g/dL (range, 8.7 to 10.1 g/dL) in the control group ($p = 0.197$). The mean (± 95% CI) hemoglobin drop observed in the

Table 1. Preoperative Patient Characteristics

Variable	Conventional electrocautery (control group; n = 42)	Bipolar sealer (experimental group; n = 29)	*p*-value
Age (yr)*	63.4 ± 17.9	59.1 ± 4.1	0.120
Body mass index (kg/m^2)†	32.4 (29.2–38.9)	35.0 (31.4–42.9)	0.267
ASA classification‡	2.58 ± 0.55	2.59 ± 0.5	0.89
Male gender§	16 (38)	14 (48)	0.393
Preadmission hemoglobin (g/dL)*	13.3 ± 0.5	13.5 ± 0.4	0.432

ASA: American Society of Anesthesiologists.
*Student *t*-test expressed as mean ± 95% confidence interval. †Mann-Whitney *U*-test expressed as median (interquartile range). ‡Students *t*-test expressed as mean ± standard deviation for respective treatment groups presented; note that values were not normally distributed. §Chi-square test expressed as number of patients (%).

Table 2. Operative, Postoperative, and Hemodynamic Values

Variable	Conventional electrocautery (control group; n = 42)	Bipolar sealer (experimental group; n = 29)	*p*-value
Transfusion required*	35 (83)	16 (55)	0.010
Units of blood transfused†	2.0 (2.0–2.0)	1.0 (0.0–2.0)	0.006
> 2 Units of blood transfused*	8 (19)	2 (6.9)	0.148
Estimated blood loss (mL)†	100 (42.5–150)	100 (75–200)	0.246
Discharge hemoglobin (g/dL)†	9.4 (8.7–10.1)	9.1 (8.7–9.4)	0.197
Hemoglobin decline (g/dL)‡	4.2 ± 0.5	4.8 ± 0.4	0.139
Operative time (min)‡	174 ± 8.7	196 ± 15.5	0.012
Length of stay (day)†	3.0 (3.0–4.0)	3.0 (3.0–3.0)	0.660

The median number of transfusions per case was significantly lower in the experimental group. Hemoglobin change, total blood loss, and length of stay were not significantly different between the groups. The experimental group had significantly longer operative times.
*Chi-square test expressed as number of patients (%). †Mann-Whitney *U*-test expressed as median (interquartile range). ‡Student *t*-test expressed as mean ± 95% confidence interval.

bipolar sealer group (4.8 ± 0.4 g/dL) was larger than that of the electrocautery group (4.2 ± 0.5 g/dL), but this difference failed to reach significance ($p = 0.139$).

The mean total operative time in the experimental group (196 ± 15.5 minutes) was significantly longer than that observed in the control group (174 ± 8.7 minutes; $p = 0.012$). The length of inpatient stay after surgery was similar between the treatment groups, with a median of three days in the bipolar sealer cohort and three days in the electrocautery group ($p = 0.660$). There were no device-related complications, and there were no wound complications in either the control or experimental groups.

DISCUSSION

The number of simultaneous bilateral TKAs has been increasing[1] despite increased complications associated with the procedure.[2] Conventional electrocautery may not effectively coagulate bleeding from non-point sources, and certain areas may prove difficult to treat with standard electrocautery because of charring and potential risks to nearby vital structures.[22] With reduction in blood loss a primary goal in simultaneous bilateral TKA, we sought to examine the utility and effectiveness of bipolar sealing as an alternative despite the increased cost of the technology.

The literature to date on saline-coupled bipolar sealing has shown conflicting results in terms of the efficacy of the device in reducing blood loss. Prior work has shown blood loss reductions and lower transfusion requirements when using the bipolar sealer in THA.[15] However, more recent studies have failed to show significant differences in blood loss parameters when comparing the bipolar sealer to traditional electrocautery in THA.[19,20] A randomized, double-blind study of blood loss in THA that compared the use of the bipolar sealer to conventional electrocautery reported no significant differences in transfusion requirements, units of blood transfused, or hemoglobin change.[20] Research focusing on bipolar sealer use in TKA has suggested that the device reduces blood loss in surgery,[14,16] minimizes hemoglobin drops,[14,16,18] and decreases the need for blood transfusions by up to 64%.[18] Marulanda et al.[14] conducted a prospective randomized study of the device in unilateral TKA and found a significant decrease in hemoglobin drop and adjusted blood loss but did not find significant differences in transfusion requirements.[14]

In our study, blood transfusion rates were 33% lower in our experimental bilateral group than in our control group; this is less than the 64% reduction observed in unilateral TKA study by Weeden et al.[18] The transfusion rate in our control group of 83% (median 2 units) was similar to the 84% transfusion rate (mean 2.2 units) reported by Bong et al.[10] for patients undergoing bilateral TKA who did not predonate blood. We did not observe significant differences in perioperative blood loss or hemoglobin declines as has been seen in other studies. Interestingly, these previous unilateral TKA studies demonstrated significant differences in hemoglobin changes but failed to show significantly blood transfusion differences.[14,16] In bilateral TKA studies, transfusion rates can be up to twice those seen in unilateral TKA studies.[4,10,14] These higher rates may affect the baseline comparative hemoglobin profiles of bilateral TKA cohorts. While not directly observed, significant blood loss reductions might be inferred from reduced transfusion requirements, as was seen in our study.

The major downside of saline-coupled bipolar sealing observed in our study was the significantly increased operative time when the device was used. It is likely that this notable increase represents a learning curve from when the device was first adopted and that the magnitude of this gap may decrease over time. Nevertheless, the observed 13% increase in operating time could be clinically relevant if it leads to increased costs, infections, or anesthesia complications and should be further investigated in future studies. A previous report has raised the possibility of increased rates of peri-prosthetic femoral condyle fracture after bipolar sealing in knee arthroplasty, a complication that should also be considered.[23]

When considering future use of the saline-coupled bipolar sealer in bilateral TKA, cost effectiveness must be a consideration. Length of stay, a major factor in the cost of surgical procedures, did not differ significantly between the groups. In contrast, use of the bipolar sealer in our study was associated with one fewer unit of blood transfused and would reduce the overall procedure cost by US $761, the average cost of a blood transfusion.[24] However, the per-case cost of the bipolar sealer at our institution is US $500. In sum, use of the saline-coupled bipolar sealing device resulted in a net expense of US $139 to US $1,059 per case, when including associated operative time costs.[25,26] It is important to consider that this cost-benefit analysis uses US dollars and that conclusions may be different in other institutions or countries where cost and currency adjustments might produce a more or less favorable expense profile.

This study has limitations inherent in any retrospective analysis. Patients were not randomized to the experimental or control treatments. However, the similar preoperative baseline profiles of the groups suggest that this has not influenced the data and that meaningful conclusions can still be made. Additionally, this study did not compare or present coagulation profiles of patients in either group. The study was modeled on previous studies evaluating bipolar sealing technology, such as that by Marulanda et al.,[14] that did not routinely present coagulation profiles. Although the groups were well-matched, the surgeon and staff managing these patients were not blinded to the use of the bipolar sealing device and patients were transfused based upon clinical symptoms, thereby allowing for the possibility of bias to occur in the decision making process. However, the criteria of transfusing symptomatic patients was used consistently and may still provide important trends with respect to transfusion rates in our experimental (bipolar sealing) group. The use of tourniquets and the lack of vacuum drainage minimized measurable blood loss, making it difficult to observe differences in total blood loss as noted in previous studies. The slight variability in deep venous thrombosis (DVT) prophylaxis between groups could be an unaccounted for confounder within the study. However, this is unlikely as the differences are small, with 76% of patients in the experimental group and 83% of patients in the control group receiving aspirin. Differences in prophylaxis were based upon unique patient characteristics, such as history of DVT or chronic anticoagulation, and not based upon whether or not the patient had been treated with the bipolar sealer. Additionally, while the study was adequately powered to observe a large Cohen's *d* effect size, it was underpowered to detect a moderate effect size as observed for hemoglobin drop by Marulanda et al.[14] (Cohen's $d = 0.48$) in their study of bipolar sealing in unilateral TKA. While the results of our study suggested no significant differences in the hemoglobin changes between the groups, there was a trend toward a larger mean hemoglobin decline in the experimental group than the control group (4.8 ± 0.4 g/dL vs. 4.2 ± 0.5 g/dL). This greater decline in the experimental group calls into question whether the relatively fewer blood transfusions seen in the experimental group is attributed to a discrepancy in total blood loss calculations. Further research of saline-coupled bipolar sealer use in bilateral TKA is necessary to confirm the blood conservation benefits seen in our study. Similarly, additional studies are necessary to confirm our observations in larger groups of patients and in a prospective fashion, as this is an initial investigation of bipolar sealing in bilateral TKA.

In conclusion, our results indicate that use of a saline-coupled bipolar sealer likely reduces blood loss in simultaneous bilateral TKA. Patients in the bipolar sealer group were 35% less likely to require a blood transfusion. The median number of units of blood transfused per patient was significantly lower in the experimental group as well. The measured hemoglobin declines and length of patient stay were equivalent between the two groups, but operative time was longer in the bipolar sealer group. While our study provides promising evidence for the clinical advantages of using saline-coupled bipolar sealing in bilateral TKA, the decision to use the device with the goal of less blood loss must come with the additional expense associated with its use. Future randomized prospective studies are necessary to confirm these observations.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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