Hemostasis Using a Bipolar Sealer in Primary Unilateral Total Knee Arthroplasty

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Abstract

Previous studies have shown that, compared with standard electrocautery, a bipolar sealer reduces tissue damage and smoke production during surgery.

We conducted a multicenter, prospective, randomized study to compare a bipolar sealer with standard electrocautery for hemostasis. Sixty-nine primary total knee arthroplasties were performed. Cohorts were evaluated for intraoperative and postoperative blood loss, blood transfusion requirements, postoperative hemoglobin and pain levels, length of hospital stay, range of motion, and Knee Society scores.

Amount of blood loss and decrease in postoperative hemoglobin were significantly lower in the bipolar sealer group than in the standard electrocautery group. Need for autologous blood transfusions was decreased in the bipolar sealer group compared with the electrocautery group. There were no between-groups differences in clinical knee scores.

The bipolar sealer was an effective coagulation alternative for total knee arthroplasties in reducing blood loss and transfusion requirements without affecting clinical outcome.

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Am J Orthop. 2009;38(12):E179-E183.

Total knee arthroplasty (TKA) is often associated with extensive bleeding and a need for intraoperative and postoperative blood transfusions.[1-3] Complications of blood transfusions have been studied from medical, ethical, technical, and financial standpoints.[4-6] Patients' and surgeons' awareness of problems associated with administration of blood products has encouraged use of new technologies and strategies to reduce the incidence of perioperative blood loss and transfusions.

One way to control how many transfusions are required after TKA is to limit intraoperative bleeding. Meticulous operative technique and use of surgical devices have not always reduced blood loss satisfactorily. Standard electrocautery is the method most commonly used to obtain intraoperative hemostasis. However, widespread use of standard electrocautery has been accompanied by reports of severe patient burns, operating room fires, viruses and carcinogens in the smoke produced by the device during surgery, and severe tissue necrosis.[7-10] In other studies, investigators who found that electrocautery remarkably delays skin incision

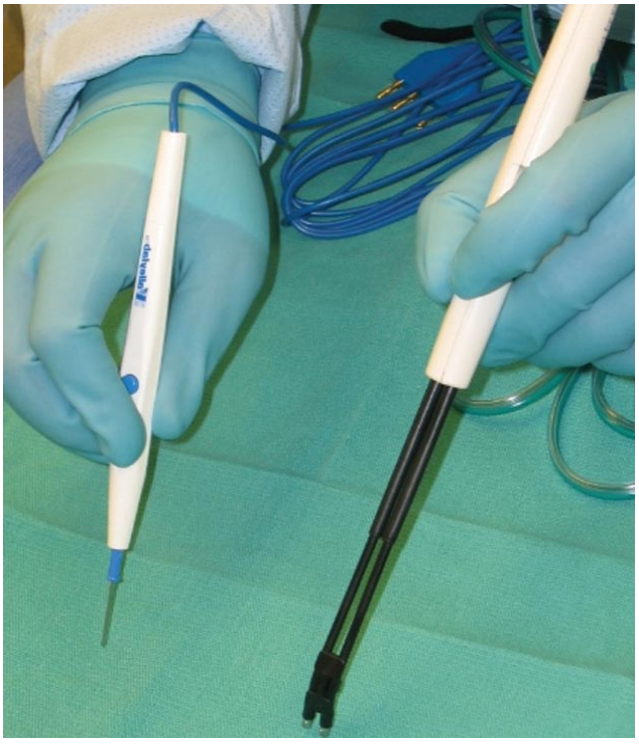

Figure. Bipolar sealer and standard electrocautery.

Table I. Sample Demographic and Preoperative Data

Clinical Outcome Measure	Group	
	Standard Electrocautery	Bipolar Sealer
All patients[a]	34	35
Men[a]	11 (32%)	13 (37%)
Women[a]	23 (68%)	22 (63%)
Age[b] (y)	66±10.5	66±11.1
<75[a]	26 (76%)	27 (77%)
≥75[a]	8 (24%)	8 (23%)
Body mass index (BMI)[b]	30±4.8	31±7.6
BMI <30[a]	18 (53%)	16 (46%)
BMI ≥30[a]	16 (47%)	19 (54%)
Hypertension[a]	4 (12%)	6 (17%)
Degenerative joint disease[a]	4 (12%)	5 (14%)
Diabetes[a]	2 (6%)	2 (6%)
Knee circumference[b] (in)	16.4±1.1	16.6±1.6
Range of motion[b] (°)	103±17	104±17
Knee score[b]	44±19	49±22
Function score[b]	50±14	55±19
Predonated blood[a] (hematocrit)	28 (82%)	24 (69%)
Estimated blood volume[b] (mL)	4954±950	4844±795
Baseline hemoglobin[b] (g/dL)	12.7±1.9	12.8±1.5
Baseline hemoglobin[a] <12 g/dL	11 (32%)	9 (26%)

[a]Number (%) of patients. [b]Mean±SD.

healing concluded that its application should be minimized to reduce the possibility of postoperative complications.[11]

A new device, the bipolar sealer, provides hemostasis at 100°C or less—temperatures lower than those of conventional electrocautery. The bipolar sealer, which does not char or burn tissue or produce smoke, delivers radiofrequency energy to saline for hemostatic sealing and coagulation of soft tissue and is used in hepatic transplantations, cirrhotic liver resections, cholecystectomies, and oncology surgery with favorable results.[2]

In the study reported here, we wanted to determine whether patients who underwent unilateral TKA with the bipolar sealer experienced less total blood loss than patients who underwent unilateral TKA with standard electrocautery. Secondary outcome variables were divided into 2 groups. Blood-specific variables included requirements for blood transfusions (number of units), decrease in postoperative hemoglobin (Hg) levels, amount of postoperative drainage, and incidence of hematoma formation. Outcome-specific variables included assessments of postoperative pain scores, length of hospital stay, and knee range of motion (ROM).

Materials and Methods

Sixty-nine patients were prospectively enrolled from 5 medical centers between June 23, 2003, and January 15, 2005, in a study comparing a bipolar sealer with standard electrocautery, used for hemostasis in primary TKAs. Thirty-five patients were randomized to the bipolar sealer group, and 34 patients were assigned to the standard electrocautery group. The study group was treated with a bipolar sealer (Salient Surgical Technologies, Dover, NH), and the matching group was treated with standard electrocautery (Electrosurgical Pencil; Valleylab, Boulder, Colo) (Figure). The study protocol was reviewed and approved by the institutional review board of each participating institution.

Patients who had a diagnosis of osteoarthritis and were candidates for primary unilateral TKA were included in this study if they were older than 21 and had a body mass index (BMI) of less than 40. Patients were excluded from the study if they had a preoperative platelet count of less than 150,000 platelets per microliter or if they had a history of prior arthrotomy or alcohol or other drug abuse. Patients with known bleeding disorders (hemophilia, factor deficiencies, severe cardiac condition) were also excluded.

During surgery, patients were randomized (1:1 ratio) to bipolar sealer treatment or standard electrocautery treatment. The randomization schedule was computer-generated using a randomized block design. Each investigative center received a separate randomization scheme. Treatment assignments were provided in individually sealed envelopes and opened by study personnel in the operating room once the eligibility criteria had been confirmed. A patient was considered enrolled in the study at time of randomization. A strict intraoperative treatment algorithm was followed by each surgeon. Complete preoperative demographic variables and the surgical treatment algorithm are described in detail in Tables I and II.

Hemoglobin and hematocrit were recorded at baseline as well as daily after surgery. Hg decrease (change) was calculated by subtracting the lowest measured Hg level (postoperative Hg nadir) from the baseline measured Hg level.

Transfusion rate and number of units transfused were reported for each group. The transfusion rate is the per-

Table II. Surgical Treatment Algorithm

Treatment Area	Procedure Timing	Treatment Time (seconds)
Lateral posterior corner (lateral inferior genicular artery)	Before implant insertion	30-45
Medial posterior corner (medial inferior genicular artery)	Before implant insertion	30-45
Quadriceps area—cut muscles and tendon	Before tourniquet release	45-90
Bone—cut surfaces not covered by implant	Before tourniquet release	30-45
Remaining bleeding areas (synovium, suprapatellar pouch)	After tourniquet release	30-90
Skin and subcutaneous tissue	Not applicable	Not recommended

centage of patients from each group who received a blood transfusion of packed red blood cells, autologous donation, whole blood, cell saver blood, fresh-frozen plasma, or platelets. Number of units transfused is reported only for patients who received blood. Any transfused amount was reported as total blood volume given.

The drain output was measured at 12 and 24 hours and at time of drain removal, or a mean of approximately 48 hours (SD, 4 hours) after surgery. Postoperative drainage was reported for each group along with a 1-tailed 95% confidence interval (CI) for the difference between the 2 groups. Knee circumference at proximal pole of patella, passive ROM, and Knee Society Objective and Function scores were reported for each group at baseline, before discharge, and at 1- and 3-month follow-up.

The primary outcome measure, the difference in total blood loss between the 2 patient cohorts who underwent TKA, was calculated on the basis of the patient's total blood volume (estimated), preoperative Hg level, postoperative Hg levels, and number and type of red blood cell units transfused. The derived variables' unadjusted blood loss (UBL) and adjusted blood loss (ABL) were used to assess differences in blood loss between the 2 treatment groups. UBL is amount of blood loss based on percentage of change in patient's Hg level relative to patient's estimated blood volume (EBV), calculated by multiplying total blood volume of each patient by maximum change in Hg or hematocrit, and ABL is amount of blood loss based on change in Hg plus total amount of blood given back to patient.

The demographic and prognostic variables analyzed for their effect on the primary outcome of blood loss were sex, age, BMI, baseline Hg, hypertension (as a comorbidity), and allogeneic blood exposure. Dependent variables analyzed include intraoperative and postoperative drainage, Hg change, UBL, ABL, and restored blood volume.

Chi-square tests were used for the analysis of categorical variables between the 2 cohorts. Student *t* test and analysis of variance were used for comparison of continuous variables. Unless otherwise stated, data were expressed as means and SDs, as medians with interquartile ranges, or as frequencies and percentages with 95% CIs. All statistical testing was conducted with a significance level of .05 and a 2-tailed alternative hypothesis. Variables associated with the primary outcome measure were tested with a significance level of .05 and a 1-tailed alternative hypothesis. These variables include UBL, ABL, EBV given, and Hg decrease. Statistical analysis was performed with SAS software (Cary, NC).

Results

Blood loss was significantly lower for patients treated with the bipolar sealer than for patients treated with standard electrocautery (see Table III). The difference in UBL between the 2 groups was 299 mL (95% CI, –3 to 600; $P = .03$). In addition, postoperative Hg levels were higher for the bipolar sealer group (mean, 9.9 g/dL; SD, 1.2 g/dL) than for the standard electrocautery group (mean, 9.3 g/dL; SD, 1.5 g/dL), and the postoperative Hg decreases were 2.9 g/dL and 3.5 g/dL, respectively ($P = .04$).

More blood transfusions were done in the standard electrocautery group (16 patients, 47%) than in the bipolar sealer group (10 patients, 29%). Four patients in the bipolar sealer group and 12 in the standard electrocautery group received autologous blood transfusions ($P = .0186$).

There was significantly less ABL in the bipolar sealer group (mean, 1686 mL; SD, 1081 mL) than in the standard electrocautery group (mean, 2447 mL; SD, 1425 mL). The difference in ABL between the 2 groups was 531 mL (95% CI, 88-974; $P = .0098$).

There were no significant differences in the clinical and functional variables assessed. At 3-month follow-up, mean Knee Society scores were 69 (SD, 16) for the standard electrocautery group and 78 (SD, 7) for the bipolar sealer group ($P>.05$). Results for knee circumference, ROM, and other functional scores are summarized in Table IV.

The sex distribution and mean age of the 2 groups were similar; additional demographic variables are listed in Table I. Sex, age, BMI, and hypertension showed no significant effect on the primary outcome or its associated variables ($P>.05$). More blood was received by patients 75 or older (mean, 2040 mL; SD, 1223 mL) than by patients younger than 75 (mean, 1448 mL; SD, 910 mL), but the difference (592 mL) was not statistically significant. There was a mean of 135 mL more total drainage ($P>.05$) for patients with BMI of more than 30 (mean, 621 mL; SD, 308 mL) than for patients with BMI of 30 or less (mean, 486 mL; SD, 295 mL). There was more postoperative drainage for patients who received allogeneic blood (n = 17; mean, 638 mL; SD, 374 mL) than for patients who did not receive this transfusion (n = 16; mean, 521 mL; SD, 277 mL), but the difference (117 mL) was not statistically significant ($P>.05$). UBL was higher for hypertensive patients (n = 10; mean, 1717 mL; SD, 776 mL) than for normotensive patients (n = 59; mean, 1348 mL; SD, 606 mL), but the difference (369 mL) was not statistically significant ($P>.05$). In addition, more blood ($P>.05$) was received by hypertensive patients (mean,

Table III. Blood Loss and Postoperative Data

Clinical Outcome Measure	Group		Difference (95% CI)[a]	P[a]
	Standard Electrocautery	Bipolar Sealer		
Patients[b]	34	35	—	NS
Transfusion[b]	16 (47%)	10 (29%)	—	NS
Allogeneic[b]	9 (26%)	8 (23%)	—	NS
Autologous[b]	12 (35%)	4 (11%)	—	.0186
Units transfused[c]	2.4±1.1	2.1±1.0	—	NS
Postoperative hemoglobin nadir[c] (g/dL)	9.3±1.5	9.9±1.2	0.6 (–1.3 to –0.05)	NS
Hemoglobin decrease[c] (g/dL)	3.5±1.3	2.9±1.2	0.6 (–0.07 to 1.1)	.0417
Unadjusted blood loss[c] (mL)	1553±704	1254±543	299 (–3 to 600)	.0262
Unadjusted blood loss[c,d] (mL)	1439±546	1208±476	231 (–21 to 482)	.0359
Estimated blood volume given[c] (mL)	1901±1177	1338±789	563 (–246 to 1372)	.1647
Estimated blood volume given[c,e] (mL)	1535±658	1338±789	197 (–247 to 933)	NS
Adjusted blood loss[c] (mL)	2447±1425	1686±1081	761 (155 to 1368)	.0073
Adjusted blood loss[c,f] (mL)	2106±917	1575±871	531 (88 to 974)	.0098
Postoperative drainage[c] (mL)	598±311	512±302	86 (–98 to 271)	NS
Length of stay[c] (d)	3.6±1.1	3.6±1.0	—	—

Abbreviations: CI, confidence interval; NS, not significant.
[a]1-tailed 95% CI and 1-sided *t* test for significance. [b]Number (%) of patients. [c]Mean±SD.
[d]Excludes 2 outliers from standard electrocautery group (3220 mL, 3530 mL) and 1 from bipolar sealer group (2861 mL).
[e]Excludes 2 outliers (from standard electrocautery group) who received 4223 mL and 4706 mL of blood.
[f]Excludes 3 outliers from standard electrocautery group (5258 mL, 6176 mL, 6491 mL) and 1 outlier from bipolar sealer group (5464 mL).

Table IV. Postoperative Physiologic Clinical Data

	Mean±SD					
	Discharge		1-Month Follow-Up		3-Month Follow-Up	
	SE	BS	SE	BS	SE	BS
Knee circumference (in)	18.3±1.8[a]	17.7±2.1	17.4±1.1[a]	17.5±1.9	17.6±1.3	17.8±1.9
Passive range of motion (°)	68±22	68±23	96±11	100±16	106±10	109±12
Knee score	ND	ND	67±18	66±21	69±16	78±7
Function score	ND	ND	47±14	42±19	73±18	70±20

Abbreviations: SE, standard electrocautery group; BS, bipolar sealer group; ND, not done.
[a]Excludes 1 outlier (at discharge and 1-month follow-up) with knee circumference of 50 inches.

1845 mL; SD, 1029 mL) than by normotensive patients (mean, 1609 mL; SD, 1074 mL).

Baseline Hg was the only prognostic factor that showed a significant effect on the primary outcome. UBL was lower for patients with a baseline Hg lower than 12 g/dL (n = 20; mean, 1004 mL; SD, 724 mL) than for patients with a baseline Hg of 12 g/dL or higher (n = 49; mean, 1563 mL; SD, 530 mL). The difference between the 2 groups was 559 mL (95% CI, 246-872; $P = .0007$).

Two patients in the bipolar sealer group experienced severe adverse events that appeared not to be related to cautery device. One of these patients had a pulmonary embolism after surgery and was treated with systemic anticoagulation. This patient, who subsequently developed a moderate coagulation disorder that required numerous blood transfusions, was excluded from the secondary efficacy analysis. One day after surgery, the other patient presented with severe delirium that responded to medical management. Four weeks after surgery, this patient had a severe syncopal event and abraded the surgical wound site in a fall. This patient was hospitalized with a severe wound dehiscence and was treated with surgical débridement. The wound eventually healed without a flap. Additional adverse events in the bipolar sealer group were deep venous thrombosis (3 patients), urinary tract infection (1), atrial fibrillation (1), arthrofibrosis (2), and infection of the right ankle in the nonoperative extremity (1).

Two adverse events in the standard electrocautery group were reported as possibly related to the treatment regimen. Both events occurred in the same patient. The patient presented with a moderate wound infection 1 day after surgery and then with a deep venous thrombosis on the operative leg 2 days after the procedure. The patient was treated with intravenous antibiotics and systemic anticoagulation with complete resolution of symptoms. Additional adverse events in the standard electrocautery group were deep venous thrombosis (1 patient), joint pain (2), arthrofibrosis and/or decreased ROM (2), wound hematoma (1), hemarthrosis (1), and superficial wound infection (1).

Discussion

Numerous studies have demonstrated that TKAs are associated with major perioperative blood loss.[12-15] Similarly, many studies have found a high incidence of blood transfusions (autologous and allogeneic) after TKA.[5,6,16-18] Sehat and colleagues[3,19] calculated visible and hidden blood loss in TKA

patients and reported that the proportion of hidden (unaccounted) blood loss is 50% of total blood loss. Thus, visible blood loss, ordinarily taken to represent net loss, is in fact only half the true total blood loss. Other investigators have noted similar results using mathematical models that calculate blood loss based on the relationship between hematocrit and EBV.[20-22] Devices that afford the surgeon more control over active bleeding sites during surgery might help significantly reduce visible and hidden blood loss, which in turn can reduce the need for blood transfusion and additional morbidity. In this study, a bipolar sealer for TKAs was investigated and found to be an effective blood management technique in comparison with standard electrocautery.

Orthopedic surgeons have adopted a variety of blood conservation strategies, including predonation of autologous blood,[6] intraoperative and postoperative salvage and reinfusion of blood,[16,23] and acute normovolemic hemodilution.[24] Although reasonable and proven, these strategies are not directed to the more desirable target—reduction in amount of expected perioperative blood loss associated with TKA. In this study, we examined a novel use of available technology to reduce blood loss after TKA. This device, a bipolar sealer, was designed to coagulate and seal the likely sources of soft-tissue and bony bleeding during major orthopedic procedures. After adjustments were made for Hg levels, weight, and age, the group treated with the bipolar sealer had a mean of 531 mL less blood loss.

Callaghan and colleagues[4,17] found that patients younger than 65 and with Hg higher than 13.5 g/dL had only a 3% risk for transfusion. This finding is consistent with one of ours—that patients 75 or older and with Hg lower than 12 g/dL had more blood loss and more blood transfusions than the other patients. Of note regarding these 2 variables is that Hg levels reached statistical significance ($P = .0007$) only in our series.

Our study had several limitations. Although a strict treatment algorithm was implemented, every surgery is unique, and various operator-dependent modifications (in duration and location of device use) might have had an effect on surgical outcomes. We did not measure blood loss directly but instead used the decline in Hg coupled with drain output and blood products transfused to calculate ABL. Nevertheless, we believe that this is the most direct and realistic measurement possible. The calculation revealed a significant ($P = .007$) 761-mL difference in blood loss between the 2 cohorts.

In summary, use of a bipolar sealer (vs standard electrocautery) resulted in a significant reduction in blood loss in primary TKA. The results of this multicenter, randomized study are similar to those found with other applications of the bipolar sealer.[25] Widespread use of bipolar electrosurgery in other surgical specialties corroborates the principle of implementing this novel technology to increase safety and reduce procedure-related morbidity. We believe that the blood-related effects of this device, along with absence of smoke, intraoperative appearance of healthy sealed tissue (without excessive charring and burning of healthy surrounding zones), and short learning curve, further support use of this device in unilateral TKAs.

Authors' Disclosure Statement

Dr. Goldberg wishes to note that he holds stock options in, has received consulting fees from, and has spoken for Salient Surgical Technologies. Dr. Marulanda wishes to note that he receives ongoing research support from Salient Surgical Technologies. The other authors report no actual or potential conflict of interest in relation to this article.

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This paper will be judged for the Resident Writer's Award.