Saline-Coupled Bipolar Sealing in Revision Total Knee Arthroplasty for Infection

Peter B. Derman, MD, MBA, Atul F. Kamath, MD, and Gwo-Chin Lee, MD

Abstract

Blood conservation with saline-coupled bipolar sealing devices in primary total knee arthroplasty (TKA) has had mixed results. Moreover, investigators have not studied these devices in infected TKA cases in which conventional methods of blood management cannot be used.

We conducted a single-surgeon, case–control study to evaluate how the choice of an electrocautery device affects total blood loss, transfusion requirements, and total cost in revision TKA for infection. Each of the 80 patients in the study had an infected TKA and underwent surgery that involved the use of a saline-coupled bipolar sealing device at our institution. Results were compared with those of a control group of 40 patients immediately predating use of this device. Groups were matched for age, body mass index, American Society of Anesthesiologists (ASA) classification, and surgery type. We then compared the groups on multiple variables, including total blood loss, transfusion requirements, operative time, and hemoglobin decrease.

The groups did not differ with respect to blood loss or transfusion requirements. However, operative time was significantly lower in the bipolar sealer group. This difference translated to an average net additional cost of about $70 per case.

Given the results of this study, use of a saline-coupled bipolar sealing device in patients with infected TKAs is not clinically or economically justified.

The issue of blood management in total joint arthroplasty has generated significant research, innovation, and controversy. Allogeneic blood transfusions for intraoperative or postoperative blood loss are often necessary in revision total knee arthroplasty (TKA) and total hip arthroplasty (THA).[1,2] However, transfusions are costly and carry the risks of disease transmission and transfusion reactions.[2,3] Alternative methods for replacing blood or minimizing its loss include fibrin sealants,[4,5] antifibrinolytic treatment,[6-10] erythropoietin therapy,[11] controlled hypotension,[12] hemodilution,[13-15] cell salvage,[16-18] and preoperative autologous blood donation.[13,19,20] Each of these techniques, however, comes with its own set of limitations and associated costs.

Saline-coupled bipolar sealing, an emerging United States Food and Drug Administration (FDA)–approved strategy for reducing perioperative blood loss, combines bipolar radiofrequency energy with continuously flowing saline at the electrode tip. The saline distributes energy over a larger surface to more evenly seal vessels and to cool tissue temperatures below 100°C.[21] This temperature is sufficiently high to cause contraction of vascular collagen and occlusion of blood flow.[22] In contrast, conventional monopolar electrocautery devices produce tissue temperatures higher than 300°C, which results in tissue charring and postoperative bleeding, which in turn result from eschar detachment. By generating lower tissue temperatures and spreading radiofrequency energy more broadly, saline-coupled bipolar sealers may minimize tissue damage and improve hemostatic control.[20] The technology can be used to pretreat areas of expected bleeding or to control active bleeding to improve visualization and decrease blood loss.[23]

Blood conservation with saline-coupled bipolar sealing devices in primary TKA and THA has had mixed results. Although some authors have reported positive results in primary THA[24] and TKA,[21,25-27] others have found no significant reduction in transfusions in comparisons with conventional electrocautery.[20,28] In a recent series of 71 patients who each underwent 2 primary THAs with a saline-coupled bipolar sealer system as an alternative to reduce blood loss, Barsoum and colleagues[28] reported no significant difference in blood profiles between this group and a group of patients who had THA with conventional electrocautery. However, researchers have not evaluated the role of these devices in the revision of an infected TKA or THA. Proponents of this technology claim that it is ideally suited to revision arthroplasty, particularly in the setting of infection when a conventional blood conservation method, such as cell salvage, is not an option.[23] However, in today's cost-conscious environment, in addition to being safe and clinically effective, new devices or technologies need to be cost-effective to gain widespread use.

Authors' Disclosure Statement: Dr. Kamath and Dr. Lee have received funding from Covidien, DePuy, and Elsevier. Dr. Derman reports no actual or potential conflict of interest in relation to this article.

Table I. **Patient Characteristics**

Demographic	Conventional Electrocautery (N = 40)	Bipolar Sealer (N = 40)	P
Age, mean (SD) y	64.2 (13.1)	59.9 (10.6)	.112
Female sex, no. (%) patients	18 (69%)	8 (31%)	.017
Body mass index, mean (SD)	31.7 (8.4)	31.5 (5.6)	.888
ASA classification, mean (SD)	2.9 (0.6)	2.8 (0.6)	.711
Surgery Type, no. (%) patients			.597
ROH + spacer implantation	15 (38%)	16 (40%)	
I&D + polyethylene exchange	9 (23%)	12 (30%)	
Hardware replantation	16 (40%)	12 (30%)	

Abbreviations: ASA, American Society of Anesthesiology; I&D, irrigation and debridement; ROH, removal of hardware.

We therefore investigated how the choice of electrocautery device affects total blood loss, transfusion requirements, and total cost in revision TKA for infection.

Materials and Methods

We conducted a cohort study of 80 patients with infected TKA managed by a single fellowship-trained arthroplasty surgeon at our institution between 2007 and 2010. This study was approved by our institutional review board. Applicable procedures included removal of the prosthesis and placement of an antibiotic spacer, irrigation and debridement with synovectomy and polyethylene exchange, and reimplantation TKA.

The switch from conventional electrocautery alone to the addition of the saline-coupled bipolar sealer (Aquamantys System; Medtronic Inc, Minneapolis, Minnesota) was made in May 2009. The 40 eligible patients who predated this transition were placed in the conventional electrocautery group (control), and the 40 eligible patients who postdated the transition were placed in the bipolar sealant group (experimental). The patients in the cohorts were matched on age, body mass index, ASA classification, and types of surgery performed (**Table I**). Patient characteristics were comparable across the groups, with the only significant difference being a higher proportion of women in the control group than in the bipolar group (69% vs 31%; P = .017).

Demographic and prognostic values were collected from patient charts. The primary outcomes of interest were total blood loss and transfusion requirements. Total blood loss was the sum of operative blood loss and postoperative drain output. Secondary outcomes were operative time, total tourniquet time, discharge hemoglobin (Hb), preoperative-to-postoperative change in Hb (ΔHb), and complications. Eighty-two consecutive patients were examined for eligibility; 2 patients (1 from each study arm) received muscle flaps during knee surgery and were excluded from the study. Four other patients, from the experimental group, required multiple procedures during the same hospitalization. These patients were excluded from the ΔHb calculations, but their operative data were included in the analysis of total blood loss, operative time, and total tourniquet time. In the control group, 1 patient was missing operative time data, and 8 were missing tourniquet time data; in the experimental group, 6 patients were missing tourniquet time data. All other data were available. Missing data were excluded from our calculation of averages.

A tourniquet was used in all cases, but the leg was not exsanguinated before inflation. For each knee, a standard medial parapatellar approach was used, and a complete synovectomy was performed. The prosthesis was carefully removed, the femoral and tibial canals were reamed, and all exposed surfaces were aggressively debrided. The bipolar sealing device was used to pretreat the posterior, posterolateral, and posteromedial capsule of the knee before insertion of the knee prosthesis or antibiotic cement spacer. In each case, the tourniquet was deflated before wound closure, and hemostasis was achieved by treating visible areas of bleeding with a conventional monopolar electrocautery device or, when available, the bipolar sealer. Each knee received a medium-size drain and was placed in a long leg posterior splint with a knee immobilizer.

Deep vein thrombosis prophylaxis consisted of enoxaparin 30 mg injected subcutaneously twice daily for 10 days beginning 24 hours after surgery, then aspirin 325 mg taken twice daily for 5 weeks. After March 1, 2010, prophylaxis consisted of dalteparin 5000 units injected subcutaneously for 10 days, then aspirin for the balance of 6 weeks after surgery. Twenty-one (3 control, 18 experimental) patients were on chronic anticoagulation and required warfarin therapy after surgery. The first dose of warfarin was given the night of surgery. The goal international normalized ratio for these patients was between 1.8 and 2.2. Two control patients were on chronic clopidogrel therapy, which was continued with other anticoagulation methods. Patients received allogeneic blood transfusions only when symptoms (lethargy, diaphoresis, tachycardia, hypotension) warranted, and not by predetermined transfusion triggers.

Park and Dickerson[29] estimated the cost of operative time at

$20 per minute, excluding physician fees. At our institution, use of the saline-coupled bipolar sealing system incurs a cost of about $500 per case. The cost-effectiveness analysis was performed by calculating the difference in average operative time between the control and experimental groups. This figure was then multiplied by its corresponding per-minute cost to determine gross financial savings. Net savings were then derived by subtracting the cost of using the bipolar sealing system.

Chi-square tests were used to analyze categorical variables, and unpaired Student t-tests and analyses of variance were used to compare continuous variables. A 2-tailed alternative hypothesis was used for all statistical analyses, and $P<.05$ was considered significant. All statistics were calculated with SPSS version 15.0 (SPSS, Chicago, Illinois).

Results

The bipolar sealer did not have any significant effects on blood loss. Mean (SD) total blood loss was 865.6 (707.3) mL for the conventional electrocautery group and 747.6 (577.6) mL for the bipolar sealer group ($P = .416$) (**Table II**). The trend toward lower blood loss in the experimental group remained when blood loss was subdivided into operative and postoperative categories, but in both cases this trend did not achieve statistical significance.

There was no significant difference in transfusion requirements between cohorts. Patients in the conventional electrocautery group received a mean (SD) of 1.8 (1.7) units of packed red blood cells, and patients in the bipolar sealer group received 1.4 (1.3) units; the difference was not statistically significant ($P = .296$). The proportion of patients who required transfusion was approximately the same for the 2 groups: conventional (63%) and bipolar sealer (68%) ($P = .639$). The strongest trend involving transfusions was that control patients tended to be more likely to require more than 2 units of blood (33% vs 15%); but this trend did not reach statistical significance ($P = .066$).

Overall cost was about equal for the 2 groups, as savings from reductions in operative time offset much of the added cost of the bipolar sealer. Mean (SD) operative time was 140.2 (45.7) minutes in the bipolar sealing group and 161.6 (47.3) minutes in the control group, or 21.4 minutes shorter per case in the bipolar sealing group ($P = .044$). This corresponds to a savings of about $430 per case. Accounting for the cost of the device, this results in a net increase of $70 per case in this series.

Four patients in the conventional electrocautery group had adverse events. One had a pulmonary embolism; 1 had pleuritic chest pain and an episode of hypotension but a negative workup for thromboembolism; 1 had a right upper extremity deep vein thrombosis; and 1 had difficulty weaning from the ventilator and developed ascites (after receiving blood products) and acute urinary retention. All 4 patients recovered without further complication. There were no adverse events in the bipolar sealer cohort.

Discussion

As reported in the literature, saline-coupled bipolar sealing has produced mixed results. Some authors have described reductions in blood loss and transfusion requirements in primary TKA[21,25-27] and THA,[24] whereas others have reported no significant difference in blood requirements in comparison with conventional techniques.[20,28] These devices have not been evaluated in revision or infected joint arthroplasty. Nevertheless, proponents of this technology claim that it is ideally suited for revision arthroplasty, particularly in the setting of infection when use of a conventional blood conservation method, such as cell salvage, is unavailable.[23] We therefore investigated the effect of a saline-coupled bipolar sealer on total blood loss, transfusion requirements, and total cost in revision TKA for infection.

This study had several limitations. First, we included patients with infected TKA treated with various procedures. Al-

Table II. Operative and Postoperative Data[a]

Outcome	Conventional Electrocautery (N=40)	Bipolar Sealer (N = 40)	P
Operative time, min	161.6 (47.3)	140.2 (45.7)	.044
Tourniquet time, min	99.3 (36.2)	91.2 (42.8)	.414
Total blood loss, mL	865.6 (707.3)	747.6 (577.6)	.416
Operative blood loss, mL	267.5 (193.4)	209.4 (166.5)	.154
Postoperative blood loss, mL	598.1 (678.1)	538.2 (486.2)	.651
Transfusion, no. (%) patients	25 (63%)	27 (68%)	.639
Units transfused	1.8 (1.7)	1.4 (1.3)	.296
>2 units transfused, no. (%) patients	13 (33%)	6 (15%)	.066
Hemoglobin decrease, g/dL	2.6 (2.0)	2.3 (1.7)	.543

[a]All data are mean (SD), except where noted otherwise.

though the groups had similar case mixes, it is impossible to standardize the degree of difficulty or blood loss for each type of case. Because this is a single-surgeon series, however, surgical technique and device treatment time were standardized across patient groups. Furthermore, irrigation and debridement with polyethylene exchange can lead to blood loss comparable to that of other included procedures because complete synovectomy and aggressive debridement of all surfaces result in significant tissue inflammation.

Second, though the groups' demographics were similar, the control group had a significantly higher proportion of female patients. The difference may have skewed results in favor of the experimental group because, on average, Hb levels are lower in women than in men. To counteract this bias, we compared ΔHb of patients in each group.

Third, in the absence of an exhaustive analysis of operating room expenses and surgical flow, we assumed that all costs of running an operating room are variable. In reality, some costs are fixed, and others are step-costs that do not decline linearly. In addition, other surgical flow bottlenecks may prevent the effects of reduced operative time from being fully manifested. Therefore, linear estimation of cost savings from reductions in operative time in this study likely produced larger savings figures than would be immediately realized; more detailed analysis would be beneficial in future studies.

Fourth, though we powered this study to allow us to make inferences about the efficacy of the bipolar sealer in the setting of infected TKA, a larger, prospective, randomized study can give a more discriminating perspective across the various parameters.

In this study, saline-coupled bipolar sealing did not produce a statistically significant reduction in blood loss in patients being treated for infected TKA. In contrast, Marulanda and colleagues[21] compared this technology with conventional electrocautery in a prospective randomized study of 50 primary TKAs and found a significant (P = .02) reduction in total blood loss (bipolar sealer, 424.5 mL; conventional electrocautery, 296 mL) but no difference in postoperative rates of allogeneic blood transfusions.

There are several potential explanations for the findings discrepancy. First, patients with infected TKA often have multiple comorbidities (eg, anemia of chronic disease, medications) that can affect Hb levels, and the heterogeneity and the complexity of our patient population may have prevented trends toward reduced blood loss from achieving statistical significance. Second, though bipolar sealing devices allow for pretreatment and broader treatment areas, the technique for achieving hemostasis is essentially unchanged. The tourniquet was deflated before closure in each procedure, and hemostasis was achieved using the bipolar sealer or conventional electrocautery. As the only significant difference in surgical technique was posterior capsule pretreatment using the bipolar sealer, substantial differences are not expected.[8] Surgical technique modification (proactive treatment of each cut surface) could potentially produce different results.

In this study, average transfusion requirements tended to be lower in the experimental group (1.4 units) than in the control group (1.8 units), but these trends did not reach statistical significance (P = .296). Weeden and colleagues[27] conducted a retrospective, single-surgeon, case-matched series of 100 patients undergoing TKA and reported that bipolar sealer use resulted in a 64% decrease in transfusion incidence (P<.001). These positive results have been disputed, however. Zeh and colleagues[20] and Barsoum and colleagues[28] both conducted prospective randomized trials of patients undergoing primary THA with and without saline-coupled bipolar sealing and found no statistically significant differences in blood profiles between the groups. Again, lack of significance in our study may stem from the heterogeneity and the complexity of the patient population in revision TKA for infection.

Cost-effectiveness of a new technology is another important component of evaluation. Although our results showed that bipolar sealing did not significantly reduce blood loss or blood transfusions, there were significant reductions in operative time in comparison with controls. Wounds in the experimental group were generally drier after tourniquet deflation than wounds in the control group and required less time for hemostasis. This may explain the modest but statistically significant reduction in operative time; larger differences would not be expected, as operative technique was largely unchanged. Deducting per-case device cost from estimated savings generated by shorter operative time results in added per-case cost of approximately $70. Therefore, reduction in surgical time nearly made up for device costs.

In conclusion, operative time was significantly improved in the bipolar sealer group compared with the similar group of patients treated solely with conventional electrocautery. This reduction offset much of the added cost of the bipolar sealer, making its use nearly cost-neutral. However, use of the saline-coupled bipolar sealer did not significantly decrease total[9] blood loss or transfusion requirements of patients with infected TKA. In light of the additional expenditure and lack of robust clinical benefit, this study suggests that a saline-coupled bipolar sealing device is not justified in patients with infected TKAs.[10]

Dr. Derman is Resident, Department of Orthopaedic Surgery, Hospital for Special Surgery, New York, New York. Dr. Kamath is Fellow, Department of Orthopaedic Surgery, Mayo Clinic, Rochester, Minnesota. Dr. Lee is Assistant Professor, Department of Orthopaedic Surgery, Hospital of the University of Pennsylvania, Philadelphia.

Address correspondence to: Gwo-Chin Lee, MD, Department of Orthopaedic Surgery, University of Pennsylvania, Penn Presbyterian Medical Center, Cupp 1, 39th St & Market St, Philadelphia, PA 19104 (tel, 215-593-0612; fax, 215-349-5128; e-mail, gwo-chin.lee@uphs.upenn.edu).

Am J Orthop. 2013;42(9):407-411.

References

1. Bierbaum BE, Callaghan JJ, Galante JO, Rubash HE, Tooms RE, Welch RB. An analysis of blood management in patients having a total hip or knee arthroplasty. *J Bone Joint Surg Am*. 1999;81(1):2-10.
2. Blanchette CM, Wang PF, Joshi AV, Kruse P, Asmussen M, Saunders W. Resource utilization and costs of blood management services associated

with knee and hip surgeries in US hospitals. *Adv Ther*. 2006;23(1):54-67.
3. Goodnough LT, Brecher ME, Kanter MH, AuBuchon JP. Transfusion medicine. First of two parts—blood transfusion. *N Engl J Med*. 1999;340(6):438-447.
4. Mawatari M, Higo T, Tsutsumi Y, Shigematsu M, Hotokebuchi T. Effectiveness of autologous fibrin tissue adhesive in reducing postoperative blood loss during total hip arthroplasty: a prospective randomised study of 100 cases. *J Orthop Surg*. 2006;14(2):117-121.
5. Wang G-J, Goldthwaite CA Jr, Burks S, Crawford R, Spotnitz WD; Orthopaedic Investigators Group. Fibrin sealant reduces perioperative blood loss in total hip replacement. *J Long Term Eff Med Implants*. 2003;13(5):399-411.
6. Camarasa MA, Ollé G, Serra-Prat M, et al. Efficacy of aminocaproic, tranexamic acids in the control of bleeding during total knee replacement: a randomized clinical trial. *Br J Anaesth*. 2006;96(5):576-582.
7. Colwell CW Jr, Chelly JE, Murkin JM, et al. Randomized study of aprotinin effect on transfusions and blood loss in primary THA. *Clin Orthop*. 2007;(465):189-195.
8. Eubanks JD. Antifibrinolytics in major orthopaedic surgery. *J Am Acad Orthop Surg*. 2010;18(3):132-138.
9. Gill JB, Rosenstein A. The use of antifibrinolytic agents in total hip arthroplasty: a meta-analysis. *J Arthroplasty*. 2006;21(6):869-873.
10. Ralley FE, Berta D, Binns V, Howard J, Naudie DD. One intraoperative dose of tranexamic acid for patients having primary hip or knee arthroplasty. *Clin Orthop*. 2010;468(7):1905-1911.
11. Bezwada HP, Nazarian DG, Henry DH, Booth RE Jr. Preoperative use of recombinant human erythropoietin before total joint arthroplasty. *J Bone Joint Surg Am*. 2003;85(9):1795-1800.
12. Nelson CL, Fontenot HJ. Ten strategies to reduce blood loss in orthopedic surgery. *Am J Surg*. 1995;170(6A suppl):64S-68S.
13. Goodnough LT, Monk TG, Despotis GJ, Merkel K. A randomized trial of acute normovolemic hemodilution compared to preoperative autologous blood donation in total knee arthroplasty. *Vox Sang*. 1999;77(1):11-16.
14. Ness PM, Bourke DL, Walsh PC. A randomized trial of perioperative hemodilution versus transfusion of preoperatively deposited autologous blood in elective surgery. *Transfusion*. 1992;32(3):226-230.
15. Segal JB, Blasco-Colmenares E, Norris EJ, Guallar E. Preoperative acute normovolemic hemodilution: a meta-analysis. *Transfusion*. 2004;44(5):632-644.
16. Sinclair KC, Clarke HD, Noble BN. Blood management in total knee arthroplasty: a comparison of techniques. *Orthopedics*. 2009;32(1):19.
17. Bridgens JP, Evans CR, Dobson PMS, Hamer AJ. Intraoperative red blood-cell salvage in revision hip surgery. A case-matched study. *J Bone Joint Surg Am*. 2007;89(2):270-275.
18. Brown CV, Foulkrod KH, Sadler HT, et al. Autologous blood transfusion during emergency trauma operations. *Arch Surg*. 2010;145(7):690-694.
19. Friederichs MG, Mariani EM, Bourne MH. Perioperative blood salvage as an alternative to predonating blood for primary total knee and hip arthroplasty. *J Arthroplasty*. 2002;17(3):298-303.
20. Zeh A, Messer J, Davis J, Vasarhelyi A, Wohlrab D. The Aquamantys system—an alternative to reduce blood loss in primary total hip arthroplasty? *J Arthroplasty*. 2010;25(7):1072-1077.
21. Marulanda GA, Ragland PS, Seyler TM, Mont MA. Reductions in blood loss with use of a bipolar sealer for hemostasis in primary total knee arthroplasty. *Surg Technol Int*. 2005;14:281-286.
22. Samdani AF, Torre-Healy A, Asghar J, Herlich AM, Betz RR. Strategies to reduce blood loss during posterior spinal fusion for neuromuscular scoliosis: a review of current techniques and experience with a unique bipolar electrocautery device. *Surg Technol Int*. 2008;17:243-248.
23. Rosenberg AG. Reducing blood loss in total joint surgery with a saline-coupled bipolar sealing technology. *J Arthroplasty*. 2007;22(4 suppl 1):82-85.
24. Marulanda GA, Ulrich SD, Seyler TM, Delanois RE, Mont MA. Reductions in blood loss with a bipolar sealer in total hip arthroplasty. *Expert Rev Med Devices*. 2008;5(2):125-131.
25. Marulanda GA, Krebs VE, Bierbaum BE, et al. Hemostasis using a bipolar sealer in primary unilateral total knee arthroplasty. *Am J Orthop*. 2009;38(12):E179-E183.
26. Pfeiffer M, Bräutigam H, Draws D, Sigg A. A new bipolar blood sealing system embedded in perioperative strategies vs. a conventional regimen for total knee arthroplasty: results of a matched-pair study. *Ger Med Sci*. 2005;13:3:Doc10.
27. Weeden SH, Schmidt RH, Isabell G. Hemostatic efficacy of a bipolar sealing device in minimally invasive total knee arthroplasty. *J Bone Joint Surg Br*. 2009;91(suppl 1):45.
28. Barsoum WK, Klika AK, Murray TG, Higuera C, Lee HH, Krebs VE. Prospective randomized evaluation of the need for blood transfusion during primary total hip arthroplasty with use of a bipolar sealer. *J Bone Joint Surg Am*. 2011;93(6):513-518.
29. Park KW, Dickerson C. Can efficient supply management in the operating room save millions? *Curr Opin Anaesthesiol*. 2009;22(2):242-248.

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