A Review of Bipolar Sealer Use in Modern Total Joint Arthroplasty

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INTRODUCTION

Due to the rich vascularity of the hip and knee joints, total hip arthroplasty (THA) and total knee arthroplasty (TKA) have an inherent risk of substantial intra- and perioperative blood loss. Effective hemostasis is therefore imperative during the course of the procedure to prevent numerous potential complications. It is well reported that postoperative anemia is of significant concern to surgeons given the increased morbidity, length of hospital stay, and mortality associated with it [1]. With regards to the hip, reports have stated that primary THA averages 1000 to 2000 mL of intraoperative blood loss, and transfusion requirements have ranged from 3% to 50% [2-5]. Some reports have stated a rate of one serious homologous blood transfusion-related complication for every 67,000 transfused [6]. Consequent concerns about safety of allogeneic blood transfusions after intra- and postoperative blood loss from total hip and knee arthroplasty procedures have led to a general emphasis on efforts to develop techniques aimed at decreasing blood loss. Such techniques include autologous donation and transfusion, perioperative blood salvage, controlled hypotension, fibrin sealants on exposed bone and soft tissue surfaces, antifibrinolytic treatment, erythropoietin therapy, intraoperative cell savers, hemodilution, pharmacological devices, and bipolar sealers [7,8]. Secure hemostasis is valuable during any surgery to prevent both local and systemic morbidity as well as mortality. Bipolar sealers can be used intraoperatively to control active bleeding with spot coagulation of vessels in an effort to both decrease blood loss and improve surgeon visualization, and can additionally be used to pre-treat areas that will likely bleed during the course of the operation [9]. The device in this manner can broadly “paint” over surfaces that may bleed after closure of soft tissues [10]. Some of the proposed advantages of electrothermal bipolar vessel sealers include diminished thermal injuries, reduced charring, less tissue necrosis, reduced time of operation, ease of visualization of vessels being sealed, no systemic morbidity risks (as may be seen with certain pharmacologic strategies), and the absence of foreign material left at the surgical site. However, the disadvantages include the cost of the device and the risk of thermal spread. Some studies comparing bipolar sealers to standard monopolar devices have reported superior results in reducing blood loss and transfusion risk, while other reports have shown equivocal outcomes, leading to questions regarding the cost-effectiveness of the technology.

Abstract

The rich vascularity of the hip and knee joints provides a substantial source of blood loss intra- and perioperatively during total knee or hip arthroplasty procedures. Due to concerns over postoperative anemia and the subsequent risks of transfusion of blood products, a push has been made in the Orthopedic and other surgical fields toward developing technology to provide superior intraoperative hemostasis. Standard unipolar electrocautery has been utilized for many years, but at the detriment of local tissue damage through charring and possibility of eschar detachment postoperatively and consequent repeat bleeding. Bipolar sealer devices were developed to produce hemostasis with radiofrequency energy in combination with continuously-flowing saline irrigation at the electrode tip to denature the vessel wall’s elastin and collagen and cause contraction of vascular collagen, occlusion of blood flow, coagulation and subsequent soft tissue sealing at a much lower temperature (< 100ºC) than with standard electrocautery. The advantage of electrothermal bipolar vessel sealers include diminished thermal injuries, reduced charring, less tissue necrosis, reduced time of operation, ease of visualization of vessels being sealed, no systemic morbidity risks (as may be seen with certain pharmacologic strategies), and the absence of foreign material left at the surgical site. However, the disadvantages include the cost of the device and the risk of thermal spread. Some studies comparing bipolar sealers to standard monopolar devices have reported superior results in reducing blood loss and transfusion risk, while other reports have shown equivocal outcomes, leading to questions regarding the cost-effectiveness of the technology.

Keywords

- Bipolar sealer
- Aquamantys©
- Electrocautery
- Hemostasis
- Arthroplasty

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cost of the device and the risk of thermal spread with coagulation [11]. Some studies have demonstrated that bipolar sealers have the ability to reduce smoke production, tissue damage, blood loss and transfusion requirements during intraoperative hemostasis as compared with the standard electrosurgery, which has led to further evaluation of the value of this relatively new technology [12,13]. However, as new surgical devices are created, and as the volume of joint replacement procedures continues to increase rapidly, the importance of cost and efficacy of intraoperative techniques is paramount, and a single bipolar sealer device costs about 50-times more than a standard monopolar device.

THE BASIC SCIENCE AND USE OF Bipolar SEALERS

The most recent iteration of this technology genre, the Aquamantys® System is a bipolar sealing device (BPS 6.0-VT Tissue Link Medical, Dover, NH), which combines a bipolar electrosurgical generator with a rotary peristaltic saline pump [14]. The current hand-held device has both the aforementioned combined into a single unit. Electrosurgical bipolar vessel sealers produce a hemostatic seal by applying radiofrequency energy in combination with continuously-flowing saline irrigation at the electrode tip directed at a vessel, therein denaturing the vessel wall's elastin and collagen and causing contraction of vascular collagen, occlusion of blood flow, coagulation and subsequent soft tissue sealing at a much lower temperature (<100°C) than occurs with standard electrosurgery [15-17]. The saline flow serves to cool tissue temperatures, and serves as a conductive fluid to distribute energy over a larger, more even surface of the vessel while sealing [7,12]. Typically, the depth of penetration of these saline-coupled bipolar sealing technologies is only 2mm or less [9]. By contrast, conventional monopolar electrocautery risks producing an eschar and tissue charring from temperatures exceeding 300°C, and thereby poses a risk of subsequent postoperative bleeding with eschar breakage or detachment [7].

Basic science research aimed at delineating the physiologic effects bipolar sealers has used animal model studies predominantly in the General Surgery literature because of the role that bipolar sealers have played in advancing the potential of complicated laparoscopic procedures. However, the results are generic and applicable to the device’s function within orthopedic procedures as well. An animal study on New Zealand white rabbits was performed to better understand the mechanical, histological and biomechanical differences among several different hemostatic techniques, including bipolar sealers [17]. The researchers ligated the 2-mm-sized short gastric vessels with the LigaSure electrothermal bipolar vessel sealer (LigaSure, Valleylab, Boulder, CO) as well as comparisons with metal clip, plastic clip, Harmonic Ace and tie ligation, and three days later through a reoperation harvested the vessels for analysis. Interestingly, they found that the Liga Sure bipolar sealer had significantly lower bursting pressures in arteries than the other aforementioned techniques. This electrocautery technique additionally showed significantly lower expression of inducible and endothelial nitric oxide synthase (iNOS and eNOS) mRNA expressions, which they hypothesized, was due to thermal injuries of the whole vessel wall from the device causing more full-thickness tissue damage than the other techniques. Perivascular fibrosis and inflammation were frequently observed in the sites proximal to the ligation, which was not unlike any of the other evaluated hemostatic devices. Harold [18] determined that electrothermal bipolar vessel sealer use in pig arteries secured vessels up to 7 mm in diameter with burst strengths of at least three times that of physiologic burst strength, indicating that it adequately seals the majority of vessels that a surgeon may encounter. They also reported a mean thermal spread for any vessel size of 2.57 mm, indicating that there is some spread of coagulating effects from the device to the nearby vessel wall, but that the risk to surrounding soft tissues is minimal. Similar results of bursting pressures and thermal spread were described in a comparable pig study by Carbonell [19].

In TKA, bipolar sealers can be used to treat the soft tissue and exposed bone after bone cuts and trial components have been placed, prior to the actual implantation of components. Transected branches of the inferior geniculate arteries at the posterolateral and medial joint corners are sources of bleeding that can be cauterized with the device. Spot treatment of bone surfaces not covered by implanted components is also recommended. In THA, pretreatment of areas expected to bleed is as important as coagulating large open muscle and bone beds from the femoral canal or extended trochanteric osteotomy sections. Of note, it is imperative in these procedures to avoid contact with skin edges, subcutaneous tissues, tendons and ligaments with the bipolar sealing devices due to potential harm from their shrinking effect on collagen [9].

BIPOLAR SEALER USE BEYOND JOINT REPLACEMENT SURGERY

The general surgical fields have seen great advances with use of the bipolar sealer device for hemostasis. Through randomized controlled trials, bipolar vessel sealers have been demonstrated in laparoscopic colorectal resection to be faster and more cost-efficient than surgical clips and vascular staplers for vascular control and operative time [20,21]. This technology has additionally been safe and successful with laparoscopic cholecystectomy, [22] liver surgery, [23] and in the field of endoscopic gynecological surgery [24]. The electrothermal bipolar vessel sealer device was reported as safe and effective for intestinal resections and hemostasis in the setting of acute trauma, with substantial shortening of valuable operative time [25].

In Orthopedics, the excessive blood loss encountered in spinal reconstructive surgery – particularly during surgical correction of adolescent idiopathic scoliosis – and the risks and limitations that often preclude the transfusion of blood products has led to the use of the bipolar sealer intraoperatively. A comparison study by Mankin [26] reported a significant reduction in blood loss by 57% after the introduction of the Aquamantys® bipolar sealer as compared to a control group of patients treated with hypotensive anesthesia, thrombin-soaked sponges, and intraoperative blood salvage (435±192 mL vs 1009±392 mL). Complication rates between the cohorts were similar, and none of the 100 patients treated with the bipolar sealer required blood transfusions in contrast to 5 of the 76 control group patients. Gordon [27] additionally noted the effectiveness of the Aquamantys® bipolar sealer device in pediatric patients with adolescent idiopathic scoliosis undergoing posterior spinal fusion and segmental spinal fusion.
Table 1: Outcome studies of bipolar sealer use for hemostasis in total joint arthroplasty.

<table>
<thead>
<tr>
<th>Author</th>
<th>No. Total patients (N)</th>
<th>Procedure</th>
<th>Type of Study</th>
<th>Results</th>
<th>Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>[13]</td>
<td>50</td>
<td>Primary THA</td>
<td>Prospective, blinded, randomized, comparison bipolar sealer vs standard electrocautery</td>
<td>Total blood loss in bipolar sealer group decreased by 40% Transfusions decreased in bipolar sealer group by 73% Significant intraoperative blood loss reduction (p = 0.002) Significant postoperative blood loss reduction (p = 0.001) No difference in modified Harris hip scores Reduced tissue damage and smoke production with bipolar sealers</td>
<td>Bipolar sealer is an effective means of hemostasis in total hip arthroplasty as an alternative to standard electrocautery</td>
</tr>
<tr>
<td>[12]</td>
<td>50</td>
<td>Primary TKA</td>
<td>Prospective, randomized comparison bipolar sealer vs standard electrocautery</td>
<td>Significant reduction in postoperative blood loss (p = 0.05) with bipolar sealer Significant reduction in total blood loss (p = 0.02) with bipolar sealer No tissue charring or smoke production with bipolar sealer No difference in knee scores between cohorts</td>
<td>Bipolar sealer is as effective or more effective than standard electrocautery to reduce blood loss, tissue damage and smoke production in TKA</td>
</tr>
<tr>
<td>[31]</td>
<td>100</td>
<td>Primary anterior supine intermuscular THA</td>
<td>Retrospective consecutive series bipolar sealer (Aquamantys) vs standard electrocautery (first 50 cases) vs traditional electrocautery (second 50 cases)</td>
<td>No significant differences with length of hospitalization, intraoperative blood loss, postoperative hemoglobin levels, operative times Lower rate of intraoperative and postoperative transfusions with bipolar sealer use</td>
<td>Bipolar sealer is as effective as standard electrocautery for hemostasis in THA, with a lower rate of transfusion</td>
</tr>
<tr>
<td>[5]</td>
<td>200</td>
<td>Primary anterior supine intermuscular THA</td>
<td>Double-blinded prospective study bipolar sealer (Aquamantys) vs standard monopolar electrocautery</td>
<td>Similar transfusion rates between cohorts (6% and 4%) Actual blood loss and change in hemoglobin were identical (1.35 and 3.3g) Estimated intraoperative blood loss was significantly greater with bipolar sealer use (140.0 vs 127.5, p = 0.034)</td>
<td>The use of bipolar sealer was not found to provide increased hemostasis, and the cost was 50-fold higher ($500 to $10) than standard electrocautery The team's practice has stopped use of bipolar sealer in this procedure</td>
</tr>
<tr>
<td>[30]</td>
<td>40</td>
<td>Primary TKA</td>
<td>Prospective matched-pair analysis bipolar sealer (Aquamantys) vs standard electrocautery</td>
<td>Significant reduction of 28.4% total visible blood loss in bipolar sealer group (1130 vs 1580 mL, p &lt; 0.003) Reduced probability for allogeneic transfusion by a factor of 5 and for overall transfusion of stored blood from 39% to 5% No complications No reoperations</td>
<td>Bipolar sealer devices are recommended for use in TKA to potentially decrease blood loss and risk of transfusion at no additional morbidity to the patient</td>
</tr>
<tr>
<td>[29]</td>
<td>95</td>
<td>Primary THA</td>
<td>Prospective, randomized controlled trial bipolar sealer (Aquamantys) vs fibrin spray vs standard electrocautery</td>
<td>Bipolar sealer group compared to control group with blood savings at 6 hours (96mL), 24 hours (129 mL), 48 hours (296 mL), and 72 hours (121 mL) Significance compared to standard electrocautery only at 48 hours postop Fibrin spray group had superior performance in blood loss prevention No adverse events</td>
<td>Bipolar sealer is effective with minimal risk to the patient Fibrin spray is superior to bipolar sealer, and standard electrocautery</td>
</tr>
<tr>
<td>[7]</td>
<td>80</td>
<td>Revision for infected TKA</td>
<td>Case-Control Study bipolar sealer (Aquamantys) vs standard electrocautery</td>
<td>Mean total blood loss was 846.6±707.3mL for conventional electrocautery group and 747.6±577.6mL for the bipolar sealer group (p = .416) Transfusion requirement was mean 1.8±1.7 units rRBCs vs 1.4±1.3 units (p = .296) Proportion of patients who required transfusion was 63% vs 69% (p = .639) Control patients tended to be more likely to require 2+ units rRBCs (33% vs 15%) (p = .066) Mean operative time was 140.2±45.7min vs 161±47.3min (p = .044) Net increase $70 per case No adverse events with bipolar sealers vs 4 with conventional</td>
<td>Although the operative time was significantly less in the bipolar sealer group, this did not offset the high cost of the device itself and the device did not significantly alter blood loss or need for transfusion Saline-coupled bipolar sealing device is not efficacious in patients with infected TKA</td>
</tr>
<tr>
<td>[10]</td>
<td>111</td>
<td>Primary TKA</td>
<td>Prospective, randomized controlled trial bipolar sealer (Aquamantys) vs standard unipolar electrocautery</td>
<td>No significant differences in mean postoperative drain output (unipolar: 77.6±334.0mL vs bipolar: 77.8±31.1mL, p = .97) No significant differences in postop day 1 thru 3 hemoglobin level (p = .2-6) or hematocrit (p = .17-46) No significant difference in transfusion needs (36% vs 40%, p = .67) No significant differences in mean hemoglobin nadir (9.2±1.1g/dL vs 9.3±1.1g/dL, p = .81) No significant difference in mean change in hematocrit (11.1±3.5g/dL vs 10.6±2.7g/dL, p = .42)</td>
<td>Unipolar and bipolar sealer efficacy are equivocal with no significant differences in terms of drain output, transfusion rates or postoperative hemoglobin nadir</td>
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AquaMantys® bipolar sealer was used in a cohort of 50 patients and demonstrated significant reductions in intraoperative estimated blood loss, total perioperative blood loss, volume of blood products transfused, and overall transfusion rate in comparison with the 50 control group patients using traditional electrocautery. The technology has been used in orthopedic oncology as well with comparable decreases in overall transfusion risk [28].

**OUTCOMES OF Bipolar SEALER HEMOSTASIS IN ARTHROPLASTY**

Falez [29] compared the AquaMantys® bipolar sealer use to both fibrin spray and standard electrocautery in a prospective, randomized trial of 95 patients who underwent primary THA. They determined that at 6-, 24-, 48- and 72-hours postoperatively, those patients treated with bipolar sealer and fibrin spray had lower mean blood losses than with standard electrocautery, although differences were more substantial with the fibrin spray. Significant mean blood savings were seen with the bipolar sealer only at the 48-hour postoperative time.

Marulanda [4] conducted a multicenter, prospective, randomized study to compare standard electrocautery with a bipolar sealer for hemostasis in primary unilateral TKA. Of the total 69 patients, they reported a significantly lower amount of blood loss and decrease in postoperative hemoglobin for those in the bipolar sealer cohort, in addition to lower trends for the need of autologous transfusion of blood products. They found no difference in clinical outcomes when compared to standard electrocautery, concluding that bipolar sealers are effective alternatives in primary unilateral knee arthroplasty without adversely affecting the clinical outcome.
Marulanda [12] reported on 50 primary TKAs comparing bipolar sealer to conventional electrocautery for hemostasis in a prospective, randomized study. They demonstrated a significant reduction in postoperative (p = 0.05) and total (p = 0.02) blood loss, as well as an absence of smoke production and tissue charring with bipolar sealer use. Similar to the aforementioned studies, there were no clinical outcome differences per Knee Society scores, suggesting that bipolar sealing devices are at least as effective as the standard electrocautery option without affecting patient knee clinical outcomes.

A prospective matched-pair analysis of 40 patients by Pfeiffer [30] concluded that the Aquamantys® bipolar sealer use for electrocoagulation in TKA is superior to conventional hemostasis. They reported a reduced total visible blood loss of more than 28% compared to the control patients, and a reduction of blood transfusions by a factor of five. There were no associated complications with its use, and no requirement for reoperation.

Despite these studies demonstrating the value of the bipolar sealer in lowering intraoperative and postoperative blood loss and decreasing transfusion needs, some other reports have failed to show any significant improvements with the bipolar sealer in arthroplasty. A retrospective review of 100 consecutive anterior supine THAs was evaluated, with the first 50 cases using traditional electrocautery for hemostasis and the subsequent 50 cases utilizing an Aquamantys® bipolar sealer device. They reported a lower intraoperative and postoperative transfusion rate with the bipolar sealer group, but no significant differences between the cohorts with respect to length of hospitalization, intraoperative blood loss, postoperative hemoglobin levels, or operative times [31]. As a continuation of this 100-patient retrospective pilot study, the team performed a double-blinded prospective study to compare Aquamantys® bipolar sealer to standard monopolar electrocautery in reducing blood loss after anterior supine intermuscular THA [5]. Surprisingly, this trial’s data was contrary to some of the results of their previous research and the results of others, in that the use of the bipolar sealer did not account for a significant difference in postoperative hemoglobin, change in hemoglobin, or a decrease in transfusion requirements. They reported a significantly higher estimated blood loss of about 15 mL with the patients who had bipolar sealer use, but reported that this was likely anomalous given the identical hemoglobin changes in both cohorts. They proposed that the use of bipolar sealer technology may be more efficient in surgeons early in their training when a greater volume of intraoperative blood loss may be at risk.

Zeh [14] compared the Aquamantys® bipolar sealer device with standard electrocautery in primary THA via a prospective randomized trial of 105 patients. The 50 patients in the standard electrocautery cohort and the 55 patients in the bipolar sealer hemostasis cohort showed no difference in terms of mean operating time, mean hospital stay, mean drain fluid, mean total blood loss, mean intraoperative blood loss, or calculated postoperative blood loss. There was no statistical difference in mean serum myoglobin between groups indicating that conventional electrocautery was not traumatizing the surrounding skeletal musculature to any greater a degree than the Aquamantys® or vice versa. Significance was found only with the mean time to suction drain removal, which was lower in the standard electrocautery patients.

Another prospective, single-center, randomized, double-blinded study by Barsoum [15] failed to show efficacy of the bipolar sealer in use with uncomplicated primary THA. They reported on 140 patients receiving primary THA with either the Aquamantys® 6.0 bipolar sealer (N = 71) or a standard Bovie electrocautery (N = 69). The mean number of blood units transfused and proportion of patients requiring transfusion were similar in the two cohorts. There were additionally no significant differences in estimated blood loss, postoperative hemoglobin levels, perioperative narcotic usage, length of stay in hospital, or postoperative clinical outcome scores (pain, Harris hip, Short Form-12).

Bipolar sealing technology with the Aquamantys® was additionally reported by Plymale [10] in a consecutive, randomized trial in comparison with standard unipolar electrocautery during primary TKA. In a final cohort of 50 patients undergoing the procedure with bipolar sealer use and 61 patients with the standard unipolar device, they reported no statistically significant difference in mean postoperative drain output, proportion of patients requiring packed red blood cell transfusion, or mean auto-transfusion amounts. There were similarly no significant differences between mean postoperative hemoglobin nadirs in either group. Mean hemoglobin level difference and mean change in hematocrit were also not significantly different between cohorts.

The use of the Aquamantys® bipolar sealing in revision TKA was analyzed by Derman [7] in a case-controlled study of 80 patients with infected TKA. The 40 patients who used conventional electrocautery underwent either removal of hardware with spacer implantation (15, 38%), I&D with polyethylene exchange (9, 23%) or hardware reimplantation, with the 40 patients using bipolar sealer respectively undergoing 16 (40%), 12 (30%) and 12 (30%), respectively. While the bipolar sealer group did have lower total blood loss it was not statistically significant. There were additionally no significant differences in transfusion of packed red blood cells or proportion of patients requiring transfusion. Of particular note, although patients in the bipolar sealing group had a significantly lower operative time (161.6 vs 140.2 min, p = .044) accounting for savings of $430 per case, this did not offset the $500 cost of the device itself (net increase of $70 per operation).

CONCLUSION

Proposed benefits from this technology include prevention of substantial blood loss intraoperatively and postoperatively, improved visualization intraoperatively, decreased morbidity to surrounding tissues and reduced risk for transfusion [9]. These goals are founded in the results of several of the aforementioned studies, yet many still find no difference when compared to standard monopolar electrocautery. Additionally, the theoretical benefits of reduced pain and swelling from decreased postoperative hematoma formation are as of yet unfounded, given the lack of significant clinical outcome differences when comparing bipolar sealers to the conventional hemostasis techniques. Since bipolar sealer devices initially

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add substantial additional costs to arthroplasty procedures, it is imperative that their use be of considerable benefit to the patient in order to offset this cost via less blood loss and lower transfusion risks for the patient. Further evaluation of bipolar sealer use in more complicated arthroplasty cases, including revision hip and knee arthroplasty surgery, and other orthopedic procedures is necessary before definitive conclusions about its indications and limitations can be defined. Specific patient subsets including those with vascular abnormalities or elevated bleeding risks can be further evaluated in the context of bipolar sealer use to determine its utility in these situations as well. Perhaps further use in complex revision cases, patients with coagulation defects, may find a superior niche for the technology and its potential for decreasing overall blood loss and operative time [9]. In addition, a large cost-effectiveness analysis should be completed to determine expense, bleeding-related complications and patient morbidity associated with the use of bipolar sealer, and in comparison to standard electrocautery and various other hemostasis or blood-sparing technologies.

REFERENCES


