Use of a Bipolar Blood-Sealing System During Total Joint Arthroplasty

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educational objectives

As a result of reading this article, physicians should be able to:

1. Discuss the available blood-saving strategies for patients treated with total joint arthroplasty (TJA).
2. State the potential strengths and limitations of using monopolar and bipolar sealer in TJA.
3. Describe the available evidence regarding monopolar and bipolar sealer use in TJA.
4. Describe the best situation for use of a bipolar sealer in TJA.

ABSTRACT

The goal of the clinical use of a bipolar blood-sealing system is to reduce perioperative blood loss in total joint arthroplasty (TJA). This study was performed to determine whether a bipolar sealer is safe and effective in TJA and whether there are any advantages over monopolar sealers. The authors searched electronic databases and reference lists of relevant articles; retrieved all published randomized, controlled trials concerning the subject; and then performed a meta-analysis. Nine clinical trials involving 871 patients were...
included. The results of the meta-analysis indicate that using a bipolar sealer in TJA could reduce total measured blood loss, intraoperative blood loss, and operative time, which was especially observed in revision TJA for infection and primary total knee arthroplasty without tourniquet use. However, there was no significant difference between the 2 groups in terms of calculated blood loss, hemoglobin decrease, transfusion requirements, length of stay, and complications. The results of the comparison between bipolar and monopolar sealers used in TJA indicate that the routine use of a bipolar sealer for TJA may be of limited benefit except in revision TJA and primary total knee arthroplasty without tourniquet use. In the future, more high-quality randomized, controlled trials are needed to provide robust evidence and confirm the best option. [Orthopedics. 2015; 38(12):757-763.]

Total joint arthroplasty (TJA) is a common orthopedic procedure used to treat end-stage knee and hip diseases. It is well tolerated, and, in correctly selected patients, a high percentage of results are satisfactory. Although a patient’s recovery may be promising, significant intraoperative and postoperative blood loss can occur. Thus, alternative strategies, including tourniquets, local hemostatic agents, reinfusion drains, and, more recently, bipolar sealing have been used to minimize blood loss.

Although using bipolar sealing represents a novel approach to reducing blood loss in TJA, it has already been used in many other surgeries, including oncological procedures and spine and joint reconstructive procedures. Because it creates a broader and drier surgical field, the device is believed to be able to reduce intraoperative bleeding and allow the surgeon to work more quickly. Compared with the monopolar sealer, which chars tissue by generating a temperature higher than 300°C, the flowing saline used in bipolar sealing theoretically keeps temperatures below 100°C, which causes vascular contraction, occludes blood flow, and minimizes host-tissue damage.

There have been several clinical trials comparing the use of the 2 devices in TJA. In initial studies, reduced blood loss and transfusion requirements were seen. However, several recent studies have cast doubt on the efficacy of the device used in this population. In addition, to the current authors’ knowledge, no systematic study has investigated the efficacy of bipolar sealing used in this population. To determine whether reduced blood loss and transfusion requirements occurred in the bipolar group, the current authors conducted a systematic review and meta-analysis to compare the use of bipolar and monopolar sealers in TJA.

**Materials and Methods**

**Search Strategy**

The authors performed a systematic search of the PubMed, Embase, Cochrane, and Google Scholar databases for all peer-reviewed studies published between 1990 and 2014 to find all clinical trials comparing bipolar and monopolar sealers in TJA. Medical Subject Headings (MeSH) arthroplasty, replacement, joint, and bipolar sealer were used as to identify studies from these databases. There was no limitation on language or publication status. The “Related Articles” feature was used in PubMed to broaden the search, with the latest date being May 30, 2014.

**Selection Criteria**

Studies were included if they were clinical trials comparing the 2 devices used in TJA with adequately reported data. The meta-analysis was not confined to randomized, controlled trials (RCTs); nonrandomized trials were also included. After exclusion of duplicates, 1 reviewer (Z.H.) performed an initial title and abstract screening of articles to discard those that were apparently ineligible. Then 2 reviewers (J.M., B.S.) independently examined the full articles to assess the trials for eligibility and inclusion, and disagreements between reviewers were resolved by consensus after discussion. Citations that were clearly irrelevant or not clinical trials were not reviewed in full. If necessary, attempts were made to contact the articles’ authors to obtain further details.

**Validity Assessment**

Two reviewers (J.Y., Z.Z.) independently rated the quality of the eligible studies. Study quality was judged using the Modified Jadad Quality Scale for RCTs and the Newcastle-Ottawa Quality Assessment Scale for other studies. Randomized, controlled trials achieving 4 or more points (from a maximum of 8) were considered to be of high quality. The Newcastle-Ottawa Quality Assessment Scale evaluated the qualities of studies based on 3 aspects: the selection of study groups (0 to 4 points), the comparability of the groups (0 to 2 points), and the ascertainment of either the exposure or outcome of interest (0 to 3 points). Studies achieving 5 or more points (from a maximum of 9) were considered to be of high quality. Discrepancies were resolved by consensus after discussion, and a third reviewer (P.K.) was consulted if necessary.

**Data Extraction**

Two authors (B.S., F.P.) independently extracted the data, including general information (eg, authors, publication year), patient demographics, indications for TJA, device used, clinical outcomes, and complications. Postoperative blood loss was defined as the blood measured in the negative-suction wound drains postoperatively. Total measured blood loss was defined as the sum of the intraoperative and postoperative blood loss. Calculated blood loss was estimated with methods described by Bourke and Smith and Gross, based on the maximum decrease in hemoglobin concentration normalized.
to the patient’s weight and height. Complications such as superficial wound infection, deep infection, and deep venous thrombosis were also compared between the 2 groups. Discrepancies were resolved by consensus after discussion, and a third reviewer was consulted if necessary.

Statistical Analysis
The authors performed their meta-analysis according to the guidelines of the Cochrane Collaboration and the quality of meta-analysis reporting. For continuous outcome data, such as total measured blood loss and calculated blood loss, means and SDs were used to calculate a mean difference (MD) and 95% confidence interval (CI). For dichotomous outcomes, such as intraoperative and postoperative complications, the risk ratio (RR) and 95% CI were calculated as summary statistics. The authors checked all results for clinical and statistical heterogeneity. Clinical heterogeneity was evaluated based on the study populations and interventions, definition of outcome measures, concomitant treatment, and perioperative management. Heterogeneity was determined by chi-square test. A $P$ value of .05 was considered to be statistically significant, and $I^2$ values were used for the evaluation of statistical heterogeneity ($I^2$ of 50% or more indicated the presence of heterogeneity). A fixed-effects model was used to synthesize data when heterogeneity was absent; otherwise a random-effects model was used. Data were presented as a forest plot. Analyses were conducted using Review Manager version 5.0 statistical software (The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark).

RESULTS
Study Characteristics
Figure 1 shows the details of study identification, inclusion, and exclusion. The search strategy yielded 152 studies after titles and abstracts were examined and full texts were read; 9 of these met the predefined inclusion criteria.$^5,9-16$ A total of 871 patients were included in the 9 trials: 145 knees and 284 hips in the bipolar group and 155 knees and 287 hips in the monopolar group. Of these 9 trials, 6 were RCTs$^5,9,11,12,14,15$ and 3 were retrospective cohort studies (RCSs).$^{10,13,16}$ Table 1 summarizes the baseline characteristics of the included trials.

Table 1: Data on Included Studies and Methodology Assessment Score

<table>
<thead>
<tr>
<th>Study</th>
<th>No. of Patients</th>
<th>Mean Age (SD), y</th>
<th>No. of M/F Patients</th>
<th>Quality Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfeiffer et al$^{10}$</td>
<td>20</td>
<td>72</td>
<td>7/13</td>
<td>Primary TKA</td>
</tr>
<tr>
<td>Marulanda et al$^5$</td>
<td>25</td>
<td>57</td>
<td>14/11</td>
<td>Primary THA</td>
</tr>
<tr>
<td>Marulanda et al$^{11}$</td>
<td>35</td>
<td>66 (11.1)</td>
<td>11/23</td>
<td>Primary TKA</td>
</tr>
<tr>
<td>Zeh et al$^9$</td>
<td>50</td>
<td>68.3 (11.5)</td>
<td>20/30</td>
<td>Primary THA</td>
</tr>
<tr>
<td>Barsoum et al$^{12}$</td>
<td>71</td>
<td>55.4 (10.9)</td>
<td>36/35</td>
<td>Primary THA</td>
</tr>
<tr>
<td>Clement et al$^{11}$</td>
<td>38</td>
<td>61.2</td>
<td>11/19</td>
<td>Revision THA</td>
</tr>
<tr>
<td>Plymale et al$^{14}$</td>
<td>50</td>
<td>64.9 (0.4)</td>
<td>12/38</td>
<td>Primary TKA</td>
</tr>
<tr>
<td>Derman et al$^{16}$</td>
<td>40</td>
<td>59.9 (10.6)</td>
<td>22/18</td>
<td>Revision TKA</td>
</tr>
<tr>
<td>Morris et al$^{15}$</td>
<td>100</td>
<td>63.5 (10.8)</td>
<td>48/52</td>
<td>Primary TKA</td>
</tr>
</tbody>
</table>

Abbreviations: F, female; M, male; RCS, retrospective cohort study; RCT, randomized, controlled trial; THA, total hip arthroplasty; TKA, total knee arthroplasty.

Methodological Quality Assessment
The 6 included RCTs were assessed as high quality (4 or more points), with a minimum of 5 points and a maximum of 8 points. According to the Newcastle-Ottawa Quality Assessment Scale, 3 RCSs$^{13,14,16}$ and 2 RCTs$^{14,16}$ scored 8 points and 1 RCT$^{13}$ scored 7 points, indicating that they were all of high quality.

Meta-Analysis
Blood Loss. Combining the results of the 6 studies$^{5,10,12,13,15,16}$ in which to-
tal blood loss was measured properly, the meta-analysis found that total measured blood loss significantly increased in patients in the monopolar group (MD, -222.90; 95% CI, -379.02 to -66.77; \(P=.03\); \(I^2=66.6\%\)) (Figure 2), but subgroup analysis showed significantly decreased total measured blood loss in patients undergoing primary total knee arthroplasty (TKA) and revision surgery for infection (Figure 2). A pooling of the data for calculated blood loss in 2 studies\(^5,11\) showed no significant difference between the 2 groups (MD, -283.05; 95% CI, -719.40 to 153.30; \(P=.008\); \(I^2=66\%\)) (Table 2). Four of the included studies\(^5,9,13,16\) provided data on intraoperative blood loss, and the meta-analysis showed a significant decrease in intraoperative blood loss in the bipolar group (MD, -165.66; 95% CI, -301.42 to -29.89; \(P<.0001\); \(I^2=88\%\)) (Table 2). A pooling of the data for postoperative blood loss in 6 studies\(^5,9,11,13,14,16\) showed no significant difference between the 2 groups (MD, -113.17; 95% CI, -295.41 to -69.07; \(P=.0001\); \(I^2=92\%\)) (Table 2).

### Highest Hemoglobin Decrease

Data for highest hemoglobin decrease were provided in 6 trials\(^5,11-14,16\). No significant difference was found between the groups as to the highest hemoglobin decrease (MD, -0.21; 95% CI, -0.45 to -0.03; \(P=.10\); \(I^2=46\%\)) (Figure 3).

### Number of Transfusions per Patient

Data on the number of transfusions per patient were available in 5 studies\(^5,11-13,16\). No significant difference was found between the 2 groups in terms of the number of transfusions per patient (MD, -0.26; 95% CI, -0.69 to 0.18; \(P=.02\); \(I^2=67\%\)) (Figure 4).

### Number of Patients Needing Transfusions

Seven of the included studies\(^5,11-16\) provided data on the number of patients needing transfusions. The meta-analysis indicated that no significant difference existed between the 2 groups (Figure 5).

### Operative Time

A pooling of the data for operative time in 4 studies\(^9,12,13,16\) showed a significantly reduced operative time in the bipolar group (Table 2).

### Length of Stay

Data on the length of stay were provided in 5 trials\(^5,9,11-13\). No significant difference was detected between the 2 groups (Table 2).

### Complications

Based on the available data, complications were divided into superficial wound infection, deep infection, and deep venous thrombosis. The meta-analysis detected no significant differences between the 2 groups (Table 3).

### Discussion

Total joint arthroplasty is an effective intervention for advanced osteoarthritis. The current focus of the procedure is to lower or eliminate the risks of complications associated with it. Blood loss conservation is a major concern.\(^1\) It has been proven that unilateral primary total hip arthroplasty (THA) or TKA is associated with a tremendous amount of blood loss.\(^20\) The percentage of blood loss associated with unilateral revision THA or TKA for infection is even greater. Postoperative anemia has an adverse effect on morbidity.
and mortality of affected patients. Morbidities associated with severe anemia, especially in the older population, include fatigue, tachycardia, hypotension, dyspnea, and impaired levels of consciousness.\(^{21,22}\) In addition, it has been reported that lower postoperative hemoglobin levels will lead to less participation in rehabilitation programs and resultant increased lengths of stay.\(^{23}\)

Driven by the increased morbidity and mortality associated with large blood loss, the orthopedic community has invested in research to assuage the problem.\(^{24}\) Techniques to decrease perioperative blood loss, such as red blood cell salvage, tourniquet use, hypotensive regional anesthesia, and fibrin sealant, have been studied.\(^{1,3,4}\)

Recently, the bipolar sealer has been used as a novel approach to reducing intraoperative blood loss in lower extremity TJA.\(^{5}\) Initial reports demonstrated promising results in reduced blood loss and transfusion requirements in both THA\(^{5}\) and TKA.\(^{10,11,25}\) However, more recent studies have cast doubt on its efficacy.\(^{9,12}\)

The current study indicates that using a bipolar sealer in TJA can reduce total measured blood loss, intraoperative blood loss, and operative time, which was especially observed in revision surgeries for infection and primary TKA without tourniquet use. However, no significant difference was detected between the 2 groups in terms of calculated blood loss, hemoglobin decrease, and transfusion requirements, which are more meaningful measures to represent blood loss due to surgery. Regarding length of stay and complications, which are well recognized parameters for rehabilitation, no significant difference was detected.

Previous studies have illustrated that calculated blood loss is more accurate than measured obvious blood loss and can be more than twice the obvious blood loss.\(^{18,19}\) Many studies attribute it to so-called hidden blood loss postoperatively.\(^{26}\) The current meta-analysis found that significantly reduced total measured blood loss and intraoperative blood loss existed in the bipolar group. Subgroup analysis found significantly reduced total measured blood loss in the bipolar group.

### Table 3

<table>
<thead>
<tr>
<th>Event</th>
<th>Pooled Incidence in Bipolar Group (No./ Total No.)</th>
<th>Pooled Incidence in Monopolar Group (No./ Total No.)</th>
<th>Risk Ratio (95% Confidence Interval)</th>
<th>P</th>
<th>P Value(^a)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Superficial wound infection</td>
<td>3.3% (2/60)</td>
<td>3.4% (2/59)</td>
<td>0.98 (0.18 to 5.47)</td>
<td>.36</td>
<td>0%</td>
</tr>
<tr>
<td>Deep infection</td>
<td>0% (0/131)</td>
<td>0.8% (1/128)</td>
<td>0.32 (0.01 to 7.97)</td>
<td>.49</td>
<td>NA</td>
</tr>
<tr>
<td>Deep venous thrombosis</td>
<td>2.6% (5/196)</td>
<td>2.0% (4/204)</td>
<td>1.26 (0.36 to 4.46)</td>
<td>.72</td>
<td>0%</td>
</tr>
</tbody>
</table>

Abbreviation: NA, not available.

\(^a\) Test of heterogeneity. To calculate the weighted mean differences, a fixed-effects model was used if I\(^2\) was < 50% and a random-effects model was used if I\(^2\) was > 50%.
One of the theoretical benefits of the bipolar sealer lies in reduced operative time. Although most authors reporting on the bipolar sealer have not included this metric, a study investigating the bipolar sealer in pediatric spine surgery reported a 50% decrease in operative time per level of the vertebral column fused.29 The current authors compared operative times between the bipolar and monopolar sealer groups. The results suggested that operative times were reduced in the bipolar group. Of 4 included studies,3,12,13,16 2 studies that reported reduced operative time in the bipolar group focused on revision surgeries for infection.13,16 In which intraoperative blood loss makes up a majority part of total perioperative blood loss, whereas the other studies concentrated on primary THA. This finding coincides with that regarding blood loss; that is, only when intraoperative blood loss makes up a large part of the total perioperative blood loss does the benefit of using a bipolar sealer appear. Many studies have evaluated the relationship between operative time and cost.13,16,30 However, due to a lack of adequate data, the current authors did not analyze the cost-effectiveness of bipolar vs monopolar sealing.

Although proponents claim that the bipolar sealer can minimize host-tissue damage,7,9 the current meta-analysis found no significant difference between the 2 groups in terms of length of stay, which is a well-defined indirect gauge of tissue damage. No compelling evidence was found to draw conclusions about whether the bipolar sealer had a beneficial or detrimental effect in terms of tissue damage.

Many joint surgeons use tranexamic acid (TXA) to reduce blood loss. The results have been promising.31,32 By using TXA, total blood loss and the rate of transfusion requirements in TJA can be significantly decreased. Tranexamic acid is so effective that it makes the other methods seem ineffective. Compared with the cost of bipolar devices, using TXA in TJA has advantages,32 especially in an environment that tends toward decreased reimbursement.

This meta-analysis has some limitations. First, the patients in the included studies were very different, and heterogeneity was high. The random-effects model was used when heterogeneity was present. Second, 3 non-RCT studies10,13,16 were included, which may have produced bias. Third, some of the studies reported continuous data, such as postoperative joint scores without SDs. Although study authors were contacted for more information, the missing data were not obtained; thus, these data could not be fully used. Finally, the manufacturers of the devices were different in the included studies, which may contribute to bias.

**Conclusion**

The results of this meta-analysis indicate that using a bipolar sealer in primary TJA does not lead to decreased blood loss, transfusion requirements, or highest hemoglobin decrease. However, in revision TJA for infection and TKA with no tourniquet use, in which intraoperative blood loss may occur, using a bipolar sealer can significantly reduce intraoperative blood loss, total measured blood loss, and operative time. Based on the available data, the authors do not recommend using a bipolar sealer routinely in TJA other than in revision surgery or TKA without a tourniquet. More high-quality studies with a larger number of patients are needed to evaluate the efficacy of using a bipolar sealer in TJA.

**References**

3. Levy O, Martinowitz U, Oran A, Tauber C, Horoszowski H. The use of fibrin tissue...


