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Randomized Controlled Trial of Irrigation-Coupled Bipolar Electrocautery Versus Tourniquet in Total Knee Arthroplasty

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ABSTRACT

Background: Recovery from total knee arthroplasty remains arduous for some patients, prompting interest in perioperative management. While tourniquet use is not associated with longer-term outcomes, its effect on quadriceps strength in the immediate postoperative window is unknown.

Methods: A single-center, double-blind, randomized controlled trial of 66 patients undergoing primary total knee arthroplasty from 2019 to 2022 was performed to compare the use of an irrigation-coupled bipolar device (ICBD) and no tourniquet (ICBD group, N = 34) to tourniquet use with no ICBD (tourniquet group, N = 32). Groups were similar with respect to age, sex, and obesity. The primary outcome was quadriceps strength at 2 weeks, measured using a handheld dynamometer and standardized to the contralateral side. Knee Injury and Osteoarthritis Outcome Score for Joint Replacement was measured with the difference from baseline serving as a secondary outcome. Comparisons were performed using the Student's t-test.

Results: Only 28 patients, 14 in each group, had primary outcome data. At 2-weeks, quadriceps strength was higher in the ICBD group compared to the tourniquet group (83% vs 70%), though not statistically significant ($P = .16$). There was no difference between the ICBD and tourniquet groups in Knee Injury and Osteoarthritis Outcome Score for Joint Replacement changed at 2-weeks (13 vs 10, $P = .37$) or 6-weeks (16 vs 17, $P = .76$).

Conclusions: Tourniquet use was associated with a small but not statistically significant difference in quadriceps strength at 2 weeks that may justify further study given the loss of power here. There can be limitations to conducting randomized controlled trials that are important for early-career investigators to consider and that were magnified due to COVID-related restrictions in the present study, which we discuss.

Level of Evidence: Level II.

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Introduction

The volume of total knee arthroplasties (TKAs) performed in the United States is projected to increase with the aging population. [1] While most patients are eventually satisfied following TKA, recovery can be slower and more arduous than many patients expect, and a small proportion of patients remain dissatisfied. [2] In addition, there has been a large shift to same-day discharge following TKA, which was only hastened by COVID-19 pandemic-era

restrictions. [3,4] Given patient interest in accelerating recovery and pressures to facilitate quicker discharges, factors affecting early postoperative function are of increasing interest. [5] One practice frequently studied is tourniquet use.

A pneumatic tourniquet is commonly used in TKA to limit perioperative blood loss, enhance surgeon visualization, and maximize cement penetration, though it can lead to ischemic damage and even reperfusion injury. [6,7] The extent to which such changes actually lead to clinically significant differences in patient outcomes has been frequently studied with inconclusive findings. [8–10] While there may or may not be a difference in acute pain early on, differences in pain or function after 6 weeks appear minimal. [11–16] Little is known regarding quadriceps strength in

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the subacute period and whether this may be associated with early patient reported outcomes.

We conducted a double-blind, randomized controlled trial (RCT) comparing isometric quadriceps strength at 2 weeks following TKA in patients randomized to either a standard TKA protocol with tourniquet use or no tourniquet with an irrigation-coupled bipolar device (ICBD). We hypothesized that participant isometric quadriceps strength at 2 weeks postoperation would be greater in the ICBD group compared to standard tourniquet use. Patient-reported outcome measures were also collected at 2 and 6 weeks. The trial was led by an early-career arthroplasty surgeon and conducted during the COVID-19 pandemic, which likely exacerbated some of the challenges normally encountered. Given this, we also include a discussion of this experience with the hopes of helping other early-career arthroplasty surgeons consider conducting an RCT.

Material and methods

This was a prospective, randomized, controlled trial with blinding of patients and outcome assessors but not the surgeon. The study was approved by the academic center’s Institutional

Review Board, and the trial was registered at [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04016285) (NCT04016285). Patients at a large, academic hospital clinic seen in the practice of an early-career, fellowship-trained arthroplasty surgeon were screened for enrollment from 2019-2022. Patients who were between 18 and 85 years of age, scheduled for unilateral elective primary TKA, competent to provide informed consent, and able to participate in the required testing and questionnaires at follow-up appointments were invited. Patients undergoing revision TKA or unicompartmental arthroplasty were excluded. Informed consent was obtained from all patients considered for enrollment by an approved member of the study team.

In total, 73 patients were enrolled and randomized, though only 66 progressed to surgery during the study period (Fig. 1). Participants were randomized to either a standard TKA protocol with pneumatic tourniquet use or to a no-tourniquet protocol utilizing the ICBD. The ICBD was chosen for use in the no-tourniquet group based on the primary surgeon’s past experience with the device. In cases where blood pressure control was not optimal, the ICBD was helpful in achieving improved hemostasis. Participants were allocated to the two groups using the block randomization method. A study team member independent of data collection provided the

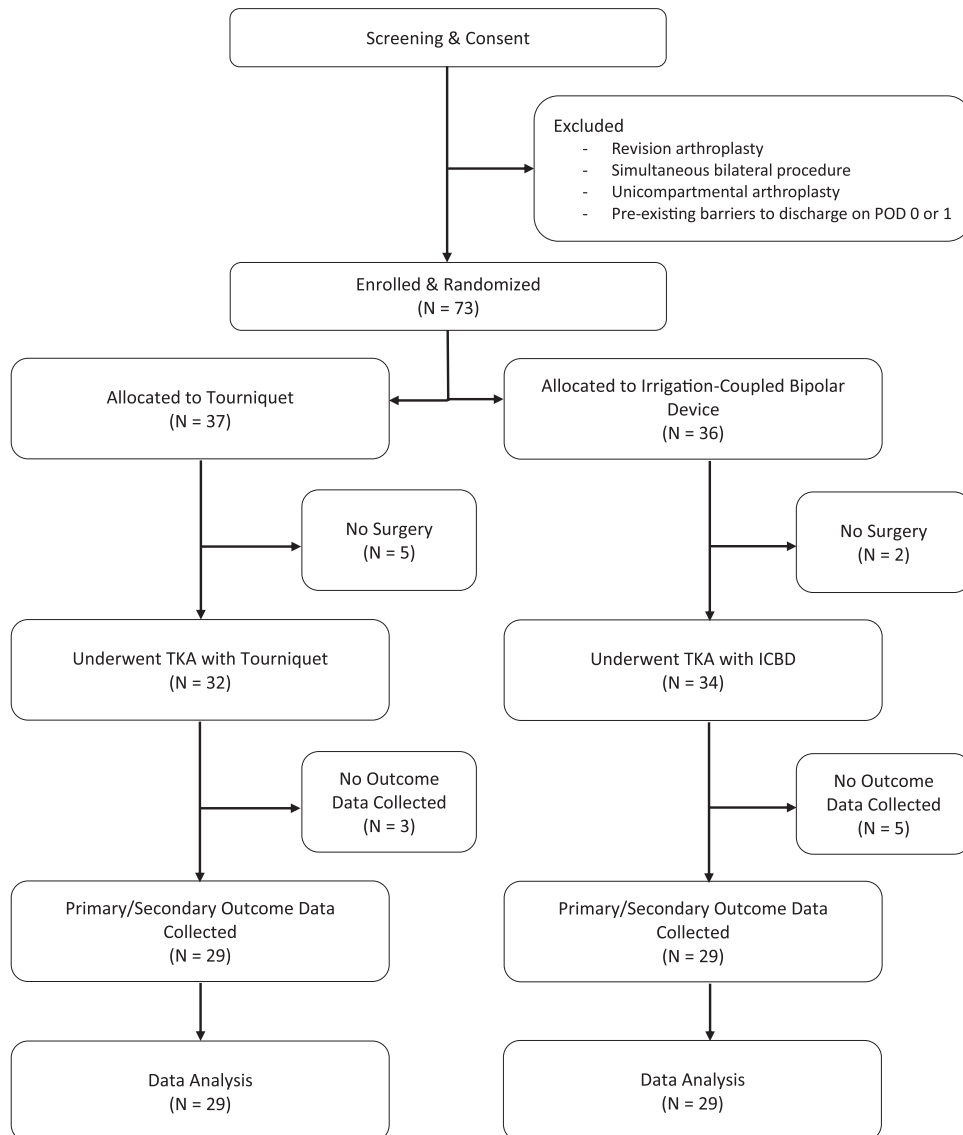


Figure 1. Consolidated Standards of Reporting Trials diagram for patient selection and enrollment in this study.

surgeon with the randomization group prior to surgery. Due to staffing changes and the COVID-19 pandemic, this process was changed, and the surgeon was provided the randomization table directly. The blinded study coordinator would notify the surgeon of any upcoming surgeries, and the surgeon would reference the randomization table for group allocation. Participants were blinded to their assigned study group, as were the study personnel performing follow-up and statistical analysis of our data.

With the exception of tourniquet and ICBD use, all participants received similar TKA procedures and postoperative care. All cases were performed by the same fellowship-trained arthroplasty surgeon utilizing a mid-vastus approach. All patients received 1 gram of tranexamic acid prior to tourniquet inflation and an additional 1 gram at the conclusion of the procedure. For the tourniquet group, the tourniquet was inflated to 300 mmHg prior to incision and remained inflated until cementing of the components was complete. This cuff pressure was chosen based on the surgeon's experience with the patient population in our area. At the time this RCT was conducted, this reflected the surgeon's typical practice. For the ICBD group, a tourniquet was still placed on the operative thigh. For all cases in this group, the tourniquet was inflated for no more than 5 minutes while the approach was completed with the knee in extension. Once the knee was flexed, the tourniquet was then deflated for the remainder of the procedure. Handheld accelerometer-based navigation to the femur and tibia was utilized in all cases to avoid instrumenting the canals and precipitating hemarthrosis. All patients received cemented bicruciate-substituting implants with patellar resurfacing. All participants were discharged either on the day of surgery or on postoperative day one.

Demographic and clinical characteristics of the study population are described using the absolute number of participants in each group as well as the percentage of the respective study group each category represents. Age was categorized into 10-year age groups for all analyses so that its effect would not be forced linear. Body mass index was categorized across thresholds of 18.5, 25, 35, and 40 kg/m². These thresholds were selected as they allowed for an adequate sample size and appropriate precision of association estimates. The functional outcome examined was isometric quadriceps strength at 2 weeks postoperation, expressed as a percent of the contralateral extremity.

Isometric quadriceps strength was tested for the operative and contralateral extremities of each participant at the 2-week follow-up appointment. With each participant seated in a chair, a dynamometer was attached to the anterior aspect of the distal tibia and to a fixed point behind the participant's leg. Participants were asked to slowly kick the foot out into the dynamometer pad with as much force as possible. Following one practice trial, this procedure was repeated 3 times for each extremity.

The "Knee Injury and Osteoarthritis Outcome Score for Joint Replacement" survey (KOOS, JR) is a validated measure of knee health in osteoarthritis patients undergoing TKA. The survey was administered to participants preoperatively at the time of their informed consent and invitation to the trial, and again at the 2-week and 6-week follow-up appointments. Participant responses were scored according to the survey's rubric.

An a priori power analysis, using an alpha level of 0.05, determined that a study population of 70 participants would be 80% powered to detect clinically important differences in our primary outcome. This was based on a previously reported standard deviation and minimal clinically important difference in isometric quadriceps strength of 0.22 Nm/kg and 0.15 Nm/kg, respectively. [17] The decision was made to enroll an additional 3 patients to account for anticipated dropout, for a total study population of 73 participants.

Demographic and clinical characteristics were summarized using descriptive statistics. Comparisons of baseline characteristics between groups should be evaluated by considering the absolute differences and not through hypothesis testing. Quadriceps strength of the operative limb was standardized using the contralateral limb and expressed as a percentage. KOOS, JR scores were standardized relative to baseline as the absolute difference. Boxplots were used to visually compare outcomes across treatment groups. Given the close to normal distributions of the outcome variables, comparisons between groups were evaluated empirically using two-sample T-tests. Statistical analyses were performed using STATA 17.0 (STATA Corp; College Station, TX). An alpha threshold of 0.05 was used to define statistical significance of the primary outcome as well as to assess secondary outcomes [18].

Results

Patient enrollment concluded after 3 years, with 37 patients having been allocated to the tourniquet group and 36 to the ICBD group. Despite small populations, the study groups were well-balanced with similar distributions of measured demographic characteristics including age, sex, and body mass index (Table 1) [19,20].

While there was a slightly higher average quadriceps strength at 2 weeks postoperation in the ICBD group (83% of contralateral) compared to the tourniquet group (70% of contralateral), this difference did not reach statistical significance ($P = .16$) (Fig. 2). Additionally, there was no significant difference in change in KOOS, JR scores at 2 weeks (13 in ICBD vs 10 in Tourniquet, $P = .37$) and 6 weeks (16 in ICBD vs 17 in Tourniquet, $P = .76$) following surgery (Fig. 3).

Discussion

This RCT of patients undergoing primary TKA found that tourniquet use was associated with a nonstatistically significant decrease in knee extension strength at 2 weeks but no difference in patient-reported outcome measures at 2 or 6 weeks. The comparisons were limited by a loss of follow-up but suggest there could be a short-term effect associated with tourniquet use that may warrant further investigation given increasing interest in optimizing

Table 1
Demographics of TKA patients undergoing tourniquet ("Tourniquet") or no-tourniquet ("ICBD") protocol.

Characteristic	Tourniquet (N%)	ICBD (N%)
Gender		
Man	15 (47%)	13 (38%)
Woman	17 (53%)	21 (62%)
Age, years		
44-54	7 (22%)	4 (12%)
55-64	13 (41%)	17 (50%)
65-74	9 (28%)	9 (26%)
≥75	3 (9%)	4 (12%)
Race/ethnicity		
White, non-Hispanic	30 (94%)	25 (73%)
Black, non-Hispanic	1 (3%)	5 (15%)
Asian	0 (0%)	1 (3%)
Hispanic	1 (3%)	0 (0%)
Other	0 (0%)	3 (9%)
Body mass index		
<18.5	0 (0%)	1 (3%)
18.5-24.9	2 (6%)	3 (9%)
25-29.9	18 (56%)	17 (50%)
35-39.9	5 (16%)	6 (18%)
≥40	7 (22%)	7 (20%)

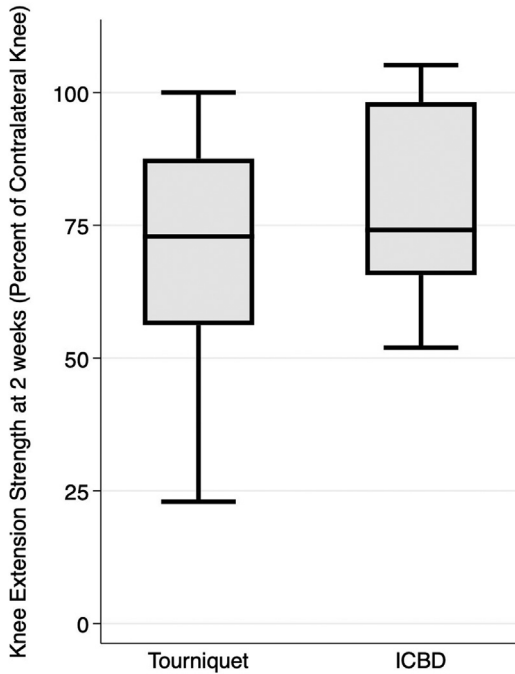


Figure 2. Two-week postoperative isometric quadriceps strength as percentage of contralateral extremity.

recovery times following TKA, even if there is not a longer-term benefit associated with avoiding tourniquet use.

Tourniquet use remains a frequently studied aspect of TKA. Despite this, much of the work published on this topic is inconclusive as to whether the benefits of tourniquet use outweigh the potential risks. 8 Previously documented advantages of tourniquet use include decreased intraoperative blood loss, lower rates of postoperative blood transfusions, and decreased total operative time. [21] Conversely, increased total blood loss, increased postoperative pain, reperfusion injuries, neuromuscular injuries, and delayed rehabilitation have also been reported with tourniquet use [22].

The metabolic changes that occur in tissues both underlying and distal to a tourniquet, particularly when certain critical time thresholds are crossed, are well known. In one seminal canine study, tourniquet times of 1, 2, and 3 hours, as well as 3 hours with hourly tourniquet release, were studied for the changes in tissue oxygenation, acidity, inflammatory response, et cetera in the exposed limb. That study reported increased levels of lactic acid and creatine phosphokinase in muscle tissue following tourniquet exposure of 2 hours or greater with no interval deflation. [23] Human studies have also reported elevations in creatinine kinase following tourniquet exposure in TKA that are detectable for multiple days postoperatively [24,25].

These results are not without limitations. While the RCT study design is the favored method to estimate treatment effects given that random allocation of the treatment should balance it across study groups with respect to both known and unknown confounders, the design can be challenging to execute. Some of these challenges may be especially relevant to early-career surgeons and were likely magnified in the present study by the COVID-19 pandemic. Here we will discuss some of these limitations to hopefully aid early career arthroplasty surgeons in their review of existing literature and the planning and execution of their own RCTs.

An initial limitation was a loss of follow-up prior to the intervention. While 73 patients were enrolled in the study and randomized, only 66 progressed to TKA. This loss of follow-up appeared to be random, which would be consistent with patient blinding and unlikely to lead to selection bias, but it does highlight that performing randomization as close as possible to the time of surgery is preferable. Once patients are randomized to a group, it is ideal to analyze them in these groups regardless of compliance with treatment protocols, referred to as intention-to-treat analysis. [26] Per-protocol analysis can also be performed, but may reflect selection bias introduced by the lack of adherence. The loss of follow-up we experienced contributed to the reduced power of this study.

This also underscores the importance of promoting follow-up among patients. Reminders were sent to patients, and they were also compensated for their time. Personalized reminders and engagement are strategies that have been shown to be effective in promoting follow-up, and they may be especially helpful in studies

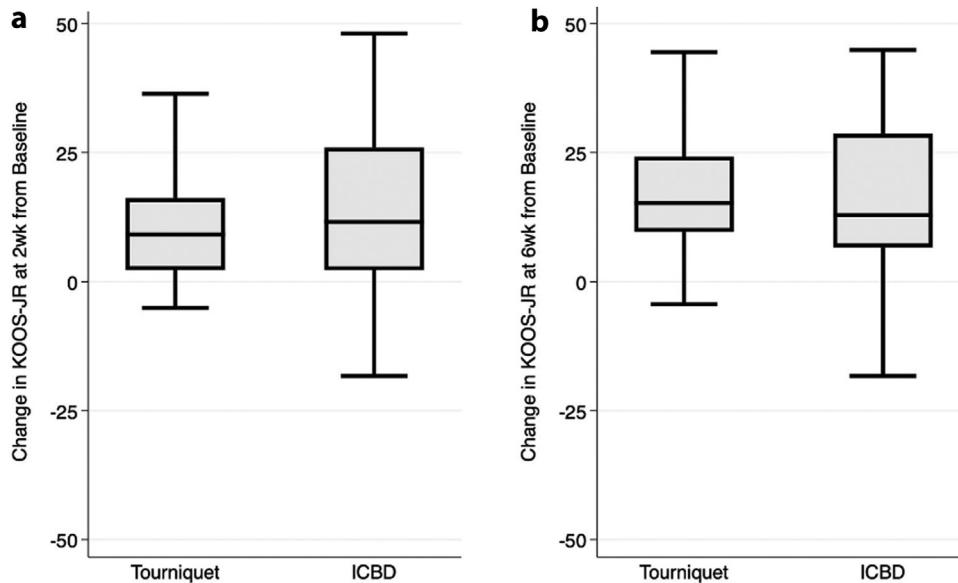


Figure 3. Change in 2- and 6-week postoperative KOOS, JR scores.

with outcome measurements further removed from the time of intervention [27,28].

Another limitation, which was also simultaneously a strength, was the use of an objective measure of quadriceps strength as the primary outcome. While this measurement is reproducible and has clinical meaning, it is completed physically in the office and cannot be done over the telephone or electronically. Given the process of data collection, it is not possible to address a lack of actual follow-up in the clinic. The COVID-19 pandemic, with its associated clinic restrictions and patient preferences for social distancing and reduced person-to-person contact, obviously magnified this issue in the present study. Nevertheless, it underscores the potential value of a primary outcome that could be collected even in the absence of physical follow-up with the patient.

Regarding the measurement of quadriceps strength at the 2-week follow-up appointment, we did not specifically document whether the nonoperative limb was affected at baseline by any comorbidities. This could have been interesting information. However, we believe that our reporting of the change in quadriceps strength as a percentage of the nonoperative side helped control for this. Contralateral limb pathology seems only likely to bias the results if the pathology occurred during the study, which seems unlikely. Still, it would have been ideal to record this systematically.

Staff training was another issue that arose and was magnified during the COVID-19 pandemic. A number of patients who attended their 2-week follow-up appointment only had quadriceps strength measured on the operative side, with no measurement of the contralateral side for standardization. This oversight occurred during a turnover in research staff. It would have been ideal to have an overlap in staffing with observed training; however, given the pandemic-era workplace restrictions in effect at the time, this was simply not possible. In hindsight, closer observation in the collection of primary outcome data would have been helpful, but it was only after several patients had progressed further in their postoperative course that this lapse in protocol was appreciated. As a corollary to this, a plan for interim data review at predetermined enrollment benchmarks would have brought some of the issues with data collection to our attention sooner. Had this been our practice, we perhaps could have made adjustments to our follow-up visit protocol to mitigate some of the limitations we have discussed here.

Conclusions

In summary, we found no difference in quadriceps strength at 2 weeks following TKA between the standard tourniquet group and the ICBD group. We also found no difference in the postoperative patient-reported KOOS, JR scores at 2 and 6 weeks. Future trials investigating the short-term postoperative consequences of tourniquet use would likely be free of many of the pandemic-era limitations we have discussed.

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Conflicts of interest

S. Duncan receives research support from Medtronic; is a paid consultant for Smith and Nephew, BoneSupport, and OrthAlign;

receives research support from Smith and Nephew, Zimmer/Biomet, Stryker, BoneSupport, and Medtronic; is an editorial board member of Journal of Arthroplasty, JAAOS, J Hip Surgery, and J Knee Surgery; and is a board/committee member of BOC. D. Landy is a speaker bureau of Smith and Nephew; is an editorial board member of Am J Sports Med; and is a board/committee member of AAHKS YAG. C. Conley is a speaker bureau and paid consultant of Smith and Nephew, OrthAlign, and BoneSupport; has stock options in MiCare and ROMTech; receives research support from Smith and Nephew, Medtronic, BoneSupport, Stryker, and Zimmer/Biomet; is an editorial board member of JAAOS, JOA, The Knee, Journal of Hip Surgery, CORR, AJS, and HSS Journal; and is a board/committee member of BOC and AAHKS YAG. All other authors declare no potential conflicts of interest.

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CRediT authorship contribution statement

David C. Landy: Writing – review & editing, Writing – original draft, Validation, Supervision, Software, Formal analysis, Data curation. **Samuel D. Mounce:** Writing – review & editing, Writing – original draft, Validation, Project administration, Data curation. **Franco M. Sabatini:** Writing – review & editing, Writing – original draft, Supervision, Project administration, Investigation, Data curation. **Jeffrey A. Chapek:** Writing – review & editing, Writing – original draft, Supervision, Resources, Project administration. **Caitlin E. Conley:** Writing – review & editing, Writing – original draft, Validation, Supervision, Project administration, Investigation, Formal analysis, Data curation. **Stephen T. Duncan:** Writing – review & editing, Writing – original draft, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Data curation, Conceptualization.

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