Orthopedic Research and Reviews

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ORIGINAL RESEARCH

Effects of Surgical Approach and Tourniquet Use on Patient-Reported Outcomes Following Total Knee Arthroplasty: A Pilot Randomized Clinical Trial

Olawale A Sogbein[1,2], Bryn O Zomar[1,3], Dianne M Bryant[3], James L Howard[1], Jacquelyn D Marsh[1], Brent A Lanting[1]

[1]London Health Sciences Centre – University Hospital, Division of Orthopaedic Surgery, Department of Surgery, London, Ontario, Canada; [2]Schulich School of Medicine & Dentistry, Western University, London, Ontario, Canada; [3]Faculty of Health and Rehabilitation Sciences, Western University, London, Ontario, Canada

Correspondence: Olawale A Sogbein, Tel +1 519-476-1151, Email olsogbein@nosm.ca

Introduction: Total knee arthroplasty (TKA) is one of the most successful procedures for the treatment of severe knee osteoarthritis. Various surgical approaches have been investigated in the hopes of improving postoperative outcomes. Two include the medial parapatellar (standard) and midvastus. As the midvastus approach does not disrupt the extensor mechanism, it may be advantageous for functional recovery, however length of stay and long-term function are similar between approaches. Tourniquet use during TKA has conflicting results in the literature. We hypothesized that a future trial comparing outpatient versus standard TKA could appropriately use either surgical approach with or without a tourniquet. Therefore, the objective of this pilot randomized trial was to compare postoperative pain, function, quality of life, and satisfaction between patients who underwent a medial parapatellar or midvastus approach for TKA ± tourniquet use.

Methods: We conducted a randomized trial with a two-by-two factorial design to compare the medial parapatellar to the midvastus surgical approach for TKA ± tourniquet use. The Short Form-12 (SF-12), Western Ontario McMaster Osteoarthritis Index (WOMAC), and Knee Society Score (KSS) were collected at baseline, postoperatively at two, six, 12 weeks, and one year.

Results: Eighty-three patients were included. Postoperative WOMAC scores were statistically but not clinically higher at six weeks and three months in favour of no tourniquet use. There were no differences in postoperative WOMAC scores between approaches. Short Form-12 and KSS scores increased in both groups with no significant differences postoperatively ($p > 0.05$).

Conclusion: There were no clinically significant differences in postoperative pain, function, quality of life, or satisfaction between surgical approaches or whether a tourniquet was used. As such, both surgical approaches ± tourniquet use are safe and reliable. We believe a future larger randomized trial could likely incorporate either surgical approach or tourniquet preferences without significant impact on patient reported outcomes.

Keywords: total knee arthroplasty, midvastus, medial parapatellar, tourniquet

Introduction

Total knee arthroplasty (TKA) is one of the most successful surgical procedures for the treatment of severe knee osteoarthritis with the ability to restore a patient's function and alleviate pain once nonoperative modalities have been exhausted.[1] With increasing pressure on hospitals to reduce healthcare costs and develop enhanced recovery protocols, there has been a larger interest in implementing fast track outpatient (same day discharge) TKA pathways.[2] The influence of different surgical approaches and tourniquet use on improving postoperative pain and function has been investigated.

Received: 11 July 2022
Accepted: 1 November 2022
Published: 15 November 2022

The medial parapatellar (standard) approach is the most common approach providing excellent exposure to the joint, however, with the disruption of the quadriceps extensor mechanism and patellar blood supply. The midvastus approach is viewed as an appropriate middle ground between the medial parapatellar and subvastus approaches for primary TKA with its arthrotomy preserving the quadriceps tendon as well. Multiple meta-analyses have reported decreased pain and improved range of motion within two weeks postoperatively in favour of the midvastus approach compared to the medial parapatellar; however, the midvastus approach requires longer operative time.[3–5] Though it was proposed that this would promote accelerated rehabilitation, there is no consensus for this in the literature currently. Length of stay and long-term functional outcomes have also been shown to be similar between approaches; therefore, both techniques are currently viewed as reliable and safe.[3–6]

The use of a tourniquet during TKA is still controversial with conflicting results in the literature and as a consequence, practices vary amongst arthroplasty surgeons. Studies supporting tourniquet use report improved intraoperative visualization, decreased blood loss, and no early postoperative functional differences,[7–9] whereas others have reported tourniquet use hindering early postoperative rehabilitation exercises and quadriceps strength following TKA.[10–13] Therefore, it is possible that quadriceps insult from tourniquet use could potentially interfere with an outpatient TKA pathway, although this has yet to be investigated.

Given the increased emphasis on developing outpatient TKA, we hypothesized that a future randomized clinical trial comparing outpatient versus standard TKA could appropriately use either surgical approach (standard or midvastus), with or without a tourniquet. Therefore, the objective of this randomized pilot trial was to compare postoperative patient-reported pain, function, quality of life, and satisfaction between patients who underwent a medial parapatellar or midvastus approach with and without the use of a tourniquet following TKA.

Materials and Methods

We conducted a randomized trial with a two-by-two factorial design to compare the medial parapatellar surgical approach to the midvastus surgical approach for TKA with and without the use of a tourniquet. All participants underwent surgery between August 2017 and February 2020. This study was conducted at a single institution among patients of two fellowship trained arthroplasty surgeons and was approved by the Health Sciences Research Ethics Board for Research Involving Human Subjects and registered at clinicaltrials.gov (NCT03081663). Our study complies with the Declaration of Helsinki.

Inclusion Criteria

Patients scheduled to undergo primary TKA who were willing and able to comply with follow-up requirements, self-evaluations, and provide informed consent were included. Inclusion criteria also included English fluency, varus knee alignment, diagnosis of osteoarthritis, American Society of Anesthetists (ASA) I, II, or III, and access to a home or cell phone.

Exclusion Criteria

Patients, who were diagnosed with inflammatory arthritis, had a body mass index (BMI) greater than 40, age less than 18, skeletally immature, had an active or suspected latent infection in or about the joint, had inadequate bone stock for fixation of the prosthesis, prior hardware precluding intramedullary instrumentation, or prior osteotomies of the femur or tibia were excluded. We also excluded patients with cognitive or neuromotor conditions, chronic pain management issues, or had a family history of anaesthesia-related complications (eg, malignant hypothermia, pseudocholinesterase deficiency, airway difficulties, obstructive sleep apnea).

Randomization

Patients were enrolled at their preadmission visit at up to three months prior to their surgery. Patients were allocated to one of the four treatment groups via a web-based randomization system using block randomization, stratified by surgeon. We randomly allocated patients in a 1:1:1:1 ratio to receive their TKA with either the medial parapatellar (standard) or midvastus surgical approach as well as with or without a tourniquet. Patients and outcome assessors were blinded to group allocation.

Interventions

Both surgical approaches were completed using a straight midline incision. The medial parapatellar arthrotomy was performed by making an incision approximately 8 to 10 centimeters proximal to the superior pole of the patella. A small sleeve of the medial quadriceps tendon is incorporated to displace the vastus medialis medially and extensor mechanism with the patella laterally. The medial arthrotomy is continued distally along the medial edge of the patella tendon adjacent to the tibial tubercle. Five millimeters of tendon was left medially to enable closure after the TKA was performed. Finally, the arthrotomy is continued distally along the medial edge of the patella tendon adjacent to the tibial tubercle.[14]

The midvastus surgical approach was performed by identifying the superior medial corner of the patella. Distally the arthrotomy was the same as the medial parapatellar approach, skirting the patella and proceeding adjacent to the patellar tendon at the tibial tubercle. The arthrotomy is extended proximally to the insertion of the vastus medialis obliquus (VMO) at the superior medial patellar border. The incision is continued parallel with the fibers of the VMO directed from the superior medial border of the patella into and along the muscle fibers.[15]

An intramedullary femoral guide and extramedullary tibial guide were utilized during surgery in the standard of care group, while computer assisted navigation was utilized for the midvastus group. All other aspects of the surgery were kept the same between the groups and all participants had a cemented Stryker Triathlon implant used for their surgery. For patients randomized to tourniquet inflation, the tourniquet was inflated at the start of the procedure and deflated after surgical closure. The pneumatic tourniquet was inflated to either 225 or 300 mmHg depending on surgeon preference. In the no tourniquet group, the tourniquet was inflated for cementation at the surgeon's discretion.

Sample Size

As the main purpose of this study was to inform the surgical protocol of a future randomized clinical trial, we aimed to include 40 patients per group for a total of 80 participants. Therefore, all four groups comprised 20 patients, group 1 (midvastus approach with tourniquet), group 2 (midvastus approach without tourniquet), group 3 (medial parapatellar approach with tourniquet), and group 4 (medial parapatellar approach without tourniquet).

Outcome Assessments

Outcomes we assessed were self-reported postoperative pain, function, satisfaction, and quality of life. The Short Form-12 (SF-12) assessed quality of life,[16] Western Ontario McMaster Osteoarthritis Index (WOMAC)[17] assessed pain, stiffness, and physical function, and the Knee Society Score (KSS) assessed satisfaction, pain and function.[18] Outcome measures were collected at baseline, as well as at standard follow-up visits to the surgeon at two, six, 12 weeks, and one year postoperative. The SF-12, KSS Symptoms, and KSS Expectations were assessed at all time points. The full KSS was assessed only at baseline, three months, and one year. The WOMAC was assessed at baseline, six weeks, three months, and one year.

Statistical Analysis

We used descriptive statistics to present the demographic and surgical characteristics of the groups using means with standard deviations for continuous variables and proportions for categorical variables. We compared surgical characteristics between the groups using Student's *t*-tests and results were presented with mean differences and 95% confidence intervals. We used longitudinal mixed-effects models for between-group comparisons with time treated as a categorical variable. The models included group (surgical approach or use of a tourniquet), time, baseline scores, BMI and sex as fixed covariates as well as group by time interactions. We included random intercepts for participants to account for the repeated measurements of the outcomes. Between-group comparisons at each time point were estimated with the appropriate contrasts from the longitudinal model and presented as the mean differences and 95% confidence intervals. Statistical significance was determined using an a priori alpha level of 0.05. We conducted all analyses according to the intention-to-treat principle using *Stata/IC version 16.1* (StataCorp LLC 2019).

Results

From August 2017 to February 2020, 352 patients met the eligibility criteria, of which 91 patients consented to take part in the study. Five patients were withdrawn prior to randomization; two were withdrawn by their treating surgeon as a cementless implant was chosen, two were included incorrectly as they were found to have a BMI >40, lastly one patient had their surgery moved up before randomization could occur. A total of 86 patients were randomized. Seven participants crossed over from the midvastus group and two from the standard group (Figure 1). To address this, we performed our primary analysis according to the

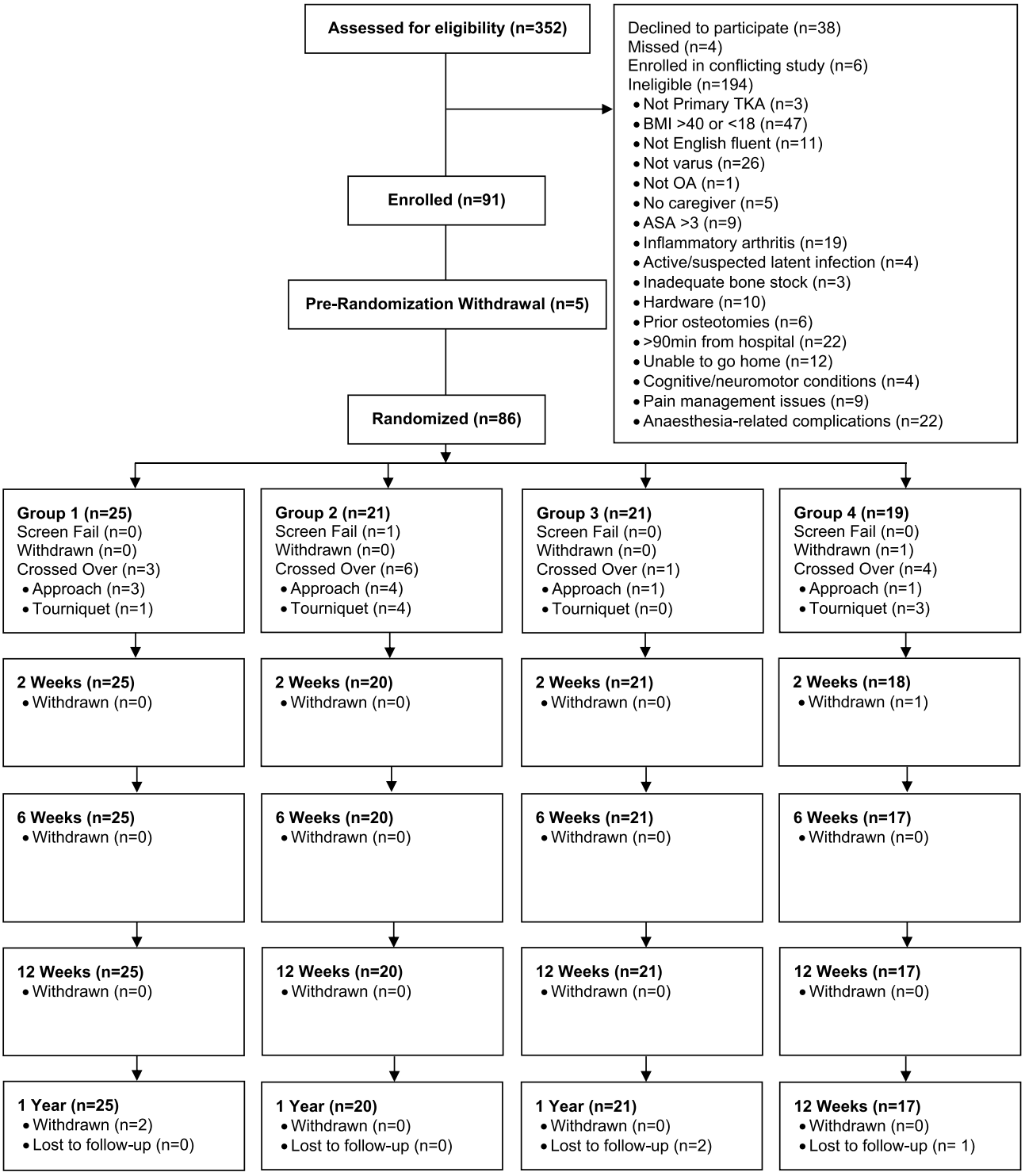

Figure 1 Participant flow through the study. Some patients were ineligible for >1 reason.

intention-to-treat principle and performed an as-treated analysis finding no changes to our results. Baseline characteristics and comorbidities were similar between groups (Table 1). Operative parameters were similar between groups (Tables 2 and 3).

Surgical Approach

There were statistically but not clinically significant differences at baseline in WOMAC and baseline KSS symptoms, expectations, and function between groups ($p < 0.05$). WOMAC scores increased in all domains postoperatively. There were no significant differences in total WOMAC scores at any time point postoperatively between surgical approaches (Table 4). Short Form-12 and KSS scores also increased in both groups from baseline to one year postoperatively. Furthermore, there were no statistical differences between groups for SF-12 and KSS scores at any time points postoperatively (Table 4).

Table 1 Baseline Demographics of Patients Undergoing Total Knee Arthroplasty with Either the Standard or Midvastus Surgical Approaches and Either Tourniquet Use or Not

Characteristic	Standard (n=39)	Midvastus (n=45)	Tourniquet (n=46)	No Tourniquet (n=38)
BMI (Range), kg/m^2	32.4 (4.1)	30.1 (4.5)	30.5 (4.0)	32.0 (4.8)
Age (Range), y	67.1 (7.7)	69.8 (7.3)	66.5 (7.4)	70.9 (7.1)
Sex (Male), n (%)	21 (54)	18 (40)	19 (41)	20 (53)
Contralateral Knee Symptoms, n (%)	27 (69)	29 (64)	31 (67)	25 (66)
Contralateral TKA, n (%)	11 (28)	9 (20)	16 (36)	16 (42)
Smokers, n (%)	4 (10)	3 (7)	5 (11)	2 (5)
ASA Score, n (%)				
1	1 (3)	0	1 (2)	0
2	17 (44)	17 (38)	21 (46)	13 (35)
3	21 (54)	28 (62)	24 (52)	24 (65)
Charlson Comorbidity Index, n (%)				
0	25 (64)	29 (64)	34 (74)	20 (53)
1	11 (28)	7 (16)	8 (17)	10 (26)
2	3 (8)	8 (18)	4 (9)	7 (18)
3	0	1 (2)	0	1 (3)

Abbreviations: BMI, body mass index; ASA, American Society of Anesthesiologists physical status classification system.

Table 2 Operative Parameters of Patients Undergoing Total Knee Arthroplasty with Either the Standard or Midvastus Surgical Approaches

Parameters	Standard Mean (SD)	Midvastus Mean (SD)	Mean Difference (95% CI)	*p*-value
Change in Haemoglobin, mmHg	−24.0 (7.1)	−24.2 (7.1)	−0.2 (−3.4, 3.0)	0.90
Operative Time, min	55.0 (8.8)	58.2 (8.9)	3.2 (−0.7, 7.1)	0.10
Tourniquet Time, min	33.2 (24.5)	38.4 (25.3)	5.2 (−5.7, 16.1)	0.35
Length of Stay, hrs*	44.5 (IQR 26.50)	44 (IQR 26.48)	−13.8 (−34.4, 6.9)	0.19
Anaesthesia, n (%)				
Spinal	36 (92)	43 (96)		
General	3 (8)	2 (4)		

Note: *Presented as median and range.

Table 3 Operative Parameters of Patients Undergoing Total Knee Arthroplasty with Either Tourniquet Use or Not

Parameters	Tourniquet Mean (SD)	No Tourniquet Mean (SD)	Mean Difference (95% CI)	*p*-value
Change in Haemoglobin, mmHg	−23.8 (7.3)	−24.5 (6.8)	0.7 (−2.5, 3.8)	0.68
Operative Time, min	55.3 (8.6)	58.5 (9.2)	−3.2 (−7.0, 0.7)	0.11
Length of Stay, hrs*	44 (IQR 26.50)	45 (IQR 25.48)	5.1 (−15.8, 26.0)	0.63
Anaesthesia, n (%) Spinal General	 43 (93) 3 (7)	 36 (95) 2 (5)		

Note: *Presented as median and range.

Table 4 Outcome Measures of Patients Undergoing Total Knee Arthroplasty with Either Midvastus or Standard Approach

Questionnaire	Time Point	Midvastus (n=45) Mean (SD)	Standard (n=39) Mean (SD)	Mean Difference (95% CI)
WOMAC	Baseline	83.7 (6.1)	81.9 (6.4)	−1.7 (−3.1, −0.3)
	6 Weeks	89.2 (4.9)	87.8 (6.8)	−0.7 (−3.0, 1.7)
	3 Months	93.1 (4.2)	90.6 (6.4)	−1.0 (−3.3, 1.3)
	1 Year	95.5 (4.8)	93.5 (5.1)	−1.0 (−3.4, 1.3)
SF12 MCS	Baseline	54.7 (9.6)	55.0 (10.4)	0.2 (−2.0, 2.5)
	2 Weeks	50.5 (10.4)	51.5 (11.0)	0.7 (−3.4, 4.9)
	6 Weeks	53.9 (8.9)	54.1 (10.0)	−0.8 (−4.8, 3.3)
	3 Months	56.0 (7.0)	56.7 (8.9)	0.7 (−3.4, 4.7)
	1 Year	55.7 (8.5)	55.8 (7.4)	−0.8 (−4.9, 3.3)
SF-12 PCS	Baseline	33.5 (8.6)	30.6 (7.9)	−3.4 (−5.3, −1.6)
	2 Weeks	31.3 (8.2)	29.7 (8.5)	−0.1 (−4.0, 4.0)
	6 Weeks	37.6 (8.8)	34.9 (9.5)	−1.5 (−5.5, 2.4)
	3 Months	43.8 (8.2)	41.1 (8.3)	−1.9 (−5.8, 2.0)
	1 Year	48.3 (8.3)	43.7 (11.0)	−3.2 (−7.1, 0.8)
KSS Symptoms	Baseline	9.0 (5.1)	7.6 (4.7)	−1.7 (−2.8, −0.6)*
	3 Months	19.7 (3.7)	18.4 (5.1)	−0.4 (−2.6, 1.7)
	1 Year	21.1 (4.3)	20.3 (4.8)	−0.4 (−2.6, 1.8)
KSS Satisfaction	Baseline	14.9 (7.7)	16.1 (7.9)	0.2 (−1.5, 1.9)
	2 Weeks	16.6 (3.9)	16.6 (4.2)	0.4 (−2.2, 3.0)
	6 Weeks	17.8 (3.8)	17.9 (3.8)	<-0.1 (−2.6, 2.5)
	3 Months	29.8 (8.2)	29.1 (7.5)	−0.7 (−3.3, 1.9)
	1 Year	34.5 (6.0)	32.8 (7.2)	−1.7 (−4.3, 0.9)

(*Continued*)

Table 4 (Continued).

Questionnaire	Time Point	Midvastus (n=45) Mean (SD)	Standard (n=39) Mean (SD)	Mean Difference (95% CI)
KSS Expectations	Baseline	13.7 (1.7)	14.1 (1.3)	0.5 (0.2, 0.9)*
	2 Weeks	8.0 (2.3)	8.5 (2.4)	0.9 (−0.4, 2.1)
	6 Weeks	8.3 (2.6)	8.5 (2.8)	0.3 (−0.9, 1.5)
	3 Months	9.0 (2.9)	8.5 (2.7)	−0.2 (−1.4, 1.1)
	1 Year	9.9 (2.8)	9.3 (2.7)	−0.3 (−1.6, 1.1)
KSS Function	Baseline	42.3 (14.5)	39.3 (13.7)	−3.5 (−6.7, −0.2)*
	3 Months	66.2 (13.3)	61.6 (18.2)	−3.2 (−10.7, 4.4)
	1 Year	75.2 (15.7)	70.8 (16.9)	−2.5 (−10.0, 5.1)

Note: *Significant result.
Abbreviations: WOMAC, Western Ontario McMaster Osteoarthritis Index; SF-12, Short Form 12; KSS, Knee Society Score.

Tourniquet Use

There were statistically but not clinically significant differences at baseline SF-12 MCS, SF-12 PCS, KSS satisfaction, and KSS function ($p < 0.05$). WOMAC scores increased in all domains postoperatively from baseline. There were statistically but not clinically significant differences in total WOMAC scores at 6 weeks and 3 months in favour of tourniquet use ($p < 0.05$) (Table 5). The SF-12 and KSS scores also increased in both groups from baseline to one year postoperatively. Furthermore, there were no significant differences between groups for SF-12 and KSS scores at any time points postoperatively (Table 5).

Table 5 Outcome Measures of Patients Undergoing Total Knee Arthroplasty with Either Tourniquet Use or Not

Outcomes	Time Point	Tourniquet (n=46) Mean (SD)	No Tourniquet (n=38) Mean (SD)	Mean Difference (95% CI)
WOMAC	Baseline	83.2 (6.3)	82.5 (6.3)	−0.6 (−2.0, 0.8)
	6 Weeks	87.9 (5.4)	89.4 (6.3)	2.5 (0.3, 4.7)*
	3 Months	91.3 (5.4)	92.8 (5.4)	2.8 (0.5, 5.0)*
	1 Year	94.7 (5.4)	94.6 (4.6)	1.7 (−0.6, 4.0)
SF-12 MCS	Baseline	53.3 (10.2)	56.5 (9.4)	3.3 (1.1, 5.5)*
	2 Weeks	51.0 (10.3)	50.9 (11.1)	−0.7 (−4.8, 3.4)
	6 Weeks	53.9 (9.5)	54.1 (9.3)	−0.5 (−4.6, 3.6)
	3 Months	55.1 (7.9)	57.6 (7.7)	1.6 (−2.4, 5.7)
	1 Year	54.2 (8.3)	57.6 (7.2)	2.5 (−1.6, 6.5)
SF-12 PCS	Baseline	33.7 (8.5)	30.2 (7.9)	−3.8 (−5.6, −2.0)*
	2 Weeks	30.9 (7.2)	30.3 (9.6)	1.3 (−2.7, 5.3)
	6 Weeks	36.0 (8.2)	36.8 (10.4)	2.5 (−1.5, 6.4)
	3 Months	41.8 (7.8)	43.3 (8.9)	2.5 (−1.4, 6.4)
	1 Year	47.0 (9.8)	45.4 (10.0)	0.5 (−3.5, 4.4)

(*Continued*)

Table 5 (Continued).

Outcomes	Time Point	Tourniquet (n=46) Mean (SD)	No Tourniquet (n=38) Mean (SD)	Mean Difference (95% CI)
KSS Symptoms	Baseline	8.6 (4.7)	8.1 (5.3)	−0.7 (−1.8, 0.4)
	3 Months	18.8 (4.5)	19.5 (4.3)	1.0 (−1.1, 3.2)
	1 Year	20.7 (4.7)	20.8 (4.3)	0.6 (−1.5, 2.8)
KSS Satisfaction	Baseline	14.0 (7.2)	17.3 (8.1)	2.4 (0.8, 4.1)*
	2 Weeks	16.0 (3.5)	17.4 (4.5)	1.1 (−1.5, 3.7)
	6 Weeks	17.1 (3.7)	18.8 (3.7)	1.6 (−0.9, 4.2)
	3 Months	28.4 (7.4)	30.7 (8.2)	1.8 (−0.8, 4.4)
	1 Year	33.1 (6.4)	34.4 (6.8)	1.6 (−1.0, 4.2)
KSS Expectations	Baseline	14.0 (1.4)	13.8 (1.6)	<-0.1 (−0.4, 0.3)
	2 Weeks	8.3 (2.2)	8.0 (2.5)	−0.3 (−1.5, 0.9)
	6 Weeks	8.3 (2.3)	8.5 (3.1)	0.4 (−0.8, 1.7)
	3 Months	8.8 (2.5)	8.6 (3.1)	−0.1 (−1.3, 1.2)
	1 Year	9.5 (2.7)	9.7 (2.9)	0.7 (−0.6, 1.9)
KSS Function	Baseline	42.3 (14.1)	38.9 (14.0)	−3.8 (−7.0, −0.6)*
	3 Months	62.7 (15.5)	65.8 (16.1)	5.8 (−1.7, 13.2)
	1 Year	73.5 (16.9)	72.9 (15.7)	3.4 (−4.0, 10.9)

Note: *Statistically significant result at p<0.05.
Abbreviations: WOMAC, Western Ontario McMaster Osteoarthritis Index; SF-12, Short Form 12; KSS, Knee Society Score.

Discussion

Our goal was to determine whether a future large randomized clinical trial investigating outpatient TKA could include either surgical approach (standard or midvastus) and with or without intraoperative tourniquet use. Overall, patient-reported postoperative pain, function, quality of life, and satisfaction did not significantly differ clinically between groups up to one year postoperative.

Over the last two decades, there has been a continual trend of decreased hospital length of stay following most surgical procedures. Furthermore, in Canada 2018–2019 saw a 22.5% volume increase in knee replacements performed compared to five years earlier as the demand for this intervention continually grows.[1,19] With increasing economic pressures and associated healthcare expenditures, the emphasis has shifted towards the development and implementation of outpatient TKA.[2] Previous studies have compared patient-reported outcomes and costs between early discharge and standard length of stay following TKA reporting increased costs in the latter, no differences in patient-reported outcomes, and similar complications.[2,20,21] Contrarily, others have reported increased complications and readmissions following outpatient TKA (length of stay zero days) with the consensus of cost savings maintained.[22–24] Therefore, a large blinded randomized control trial to assess safety, postoperative outcomes, the ideal surgical candidate for outpatient TKA, and with a full economic evaluation would address the current gap in the literature. However, prior to undertaking this, we sought to first evaluate the influence of surgical approach and tourniquet use as a potential confounder on patient-reported outcomes (PROMs) following TKA.

We did not find any significant differences in PROMs between the medial parapatellar or midvastus surgical approaches up to one year postoperative. Presently, both approaches are viewed as safe and reliable with numerous

studies reporting similar findings. Alcelik et al performed a meta-analysis of 18 randomized and quasi-randomized controlled trials involving 1040 patients comparing functional outcomes of these two approaches. Postoperative KSS scores did not differ between groups at 6 and 12 weeks, however using the midvastus approach led to significant improvement in flexion and pain in the first week postoperatively.[3] It was theorized that this improved flexion in the early postoperative phase could promote earlier rehabilitation, but length of stay and days to straight leg raise did not differ between surgical approaches. Similarly, Liu et al investigated the postoperative clinical outcomes between these two surgical approaches including a total of 32 randomized clinical trials (RCTs) with 2451 TKAs in their meta-analysis.[4] No significant differences were found between groups in KSS scores up to one year postoperative but range of motion (ROM) was significantly higher at postoperative one week favouring the midvastus group. This difference in ROM was not present at six weeks postoperative. They concluded that the midvastus approach provided significant benefits in short-term pain and ROM but with no differences in patient-reported outcomes. Given the findings in the previous studies, it is possible that the quadriceps sparing nature of the midvastus approach would facilitate earlier rehabilitation; however, overall length of stay was similar between groups. Given that length of stay and PROMs did not differ significantly between approaches, we believe that a future clinical trial investigating outpatient TKA could appropriately incorporate both interventions without leading to differences in PROMs up to one year.

Our current analysis found no clinically significant differences in patient-reported postoperative function, quality of life, or satisfaction when comparing tourniquet use following TKA in our pilot trial. Currently, tourniquet use varies amongst surgeons with conflicting results in the literature regarding pain, blood loss, and functional outcomes.[8–10,13,25] A common cited concern for tourniquet use is the intraoperative pressure applied to muscles, nerves, and blood vessels possibly causing neuromuscular damage and subsequently contributing to poorer postoperative functional outcomes.[26] We sought to investigate its possible influence on longer term PROMs as much of the non-conclusive literature has focused on early postoperative and short-term outcomes. Similar to our trial, Goel et al compared postoperative PROMs with or without tourniquet use following TKA as part of their randomized blinded trial. They reported no significant differences in KOOS or SF-12 scores between groups at six to eight months postoperative, concluding that tourniquet inflation did not compromise functional outcomes or increase pain in their trial.[8] Jawhar et al found no differences in WOMAC, EQ-5D, or satisfaction between tourniquet use following TKA at six months in their randomized trial.[9] Furthermore, Guler et al evaluated WOMAC and KSS scores up to one-year postoperative following TKA with or without tourniquet use. They reported significantly higher WOMAC scores from one to six months postoperative in their tourniquet group; however, this difference disappeared at one year between groups. Contrarily, KSS scores were significantly higher in the no tourniquet group from one to six months postoperatively with no differences at one year.[13] Though retrospective in nature, they reported decreased quadriceps volume in patients who had the intervention but overall similar PROMs at one year regardless of tourniquet use.

The factorial randomized design of our pilot trial was beneficial as it allowed us to investigate two interventions (surgical approach and tourniquet use) and include all patients in both analyses optimizing efficiency and trial-related costs. Additionally, we did not find a significant interaction between surgical approach and tourniquet use in our analysis. Our study does have certain limitations. The small sample size of our trial is evident; however, our aim was to inform the surgical protocol of a future large, randomized trial. Therefore, we included the number of patients we deemed feasible to recruit within a two-year time frame to obtain a preliminary understanding of postoperative PROMs. This did lead us to be underpowered to report the subscales for some of our outcome measures. As described earlier, the crossover occurred involving surgical approach with seven participants crossing over from the midvastus group and two from the standard group. To address this, we performed our primary analysis according to the intention-to-treat principle and performed an as-treated analysis finding no changes to our results. Furthermore, in planning for a future larger trial to improve the crossover rate, we will incorporate an additional unblinded research coordinator. They would have the sole responsibility of randomizing participants and notifying surgeons again preoperatively. There were significant baseline differences between some of our patient reported outcomes (Tables 4 and 5); however, these did not reach clinical significance. In addition, baseline scores were used as covariates in our analysis. Finally, some patients in our no tourniquet group still had the tourniquet inflated during cementation as is the preference of one of our surgeons. This led to a mean tourniquet

time of eleven minutes in this group. Given this small time frame combined with the lack of consensus in the literature, it is unclear if this had any impact on our findings.

Conclusion

This randomized pilot trial showed that there were no differences in postoperative patient-reported pain, function, satisfaction, or quality of life between the medial parapatellar or midvastus surgical approaches. Furthermore, whether or not an intraoperative tourniquet was used during TKA also did not lead to differences in postoperative PROMs up to one year either. As such, we believe a future larger randomized trial could likely incorporate either surgical approach or tourniquet preferences without significant impact on PROMs.

Data Sharing Statement

No further data will be shared.

Funding

This trial was funded by Stryker Canada through an investigator-initiated study grant.

Disclosure

Dr James L Howard reports grants, personal fees from DePuy, Stryker, and Smith and Nephew for Institutional Research Support, personal fees from Intellijoint and Sanofi, outside the submitted work. Dr Brent A Lanting reports grants, personal fees from Stryker for institutional support, during the conduct of the study; grants, personal fees from DePuy and Smith and Nephew for institutional support, outside the submitted work. The authors report no other conflicts of interest in this work.

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