2012

A comparison between minimally invasive and traditional surgical approaches to total knee arthroplasties in improving functional outcomes and reducing pain levels in adult patients

Heather Robinson
Pacific University

John Eng
Pacific University

A comparison between minimally invasive and traditional surgical approaches to total knee arthroplasties in improving functional outcomes and reducing pain levels in adult patients

Title: A comparison between minimally invasive and traditional surgical approaches to total knee arthroplasties in improving functional outcomes and reducing pain levels in adult patients

Clinical Question: Do minimally invasive surgical approaches to total knee arthroplasties (TKA) result in improved functional outcomes and less pain in patients with degenerative knee osteoarthritis (OA) when compared to a traditional surgical approach?

Clinical Scenario: We are Doctor of Physical Therapy students who are providing physical therapy to patients post-TKA in the acute care setting. We were able to observe both a minimally invasive and a traditional surgical approach. During the immediate post-surgical rehabilitation, we observed that the patient who had undergone the minimally invasive surgery displayed an improved level of function compared to the patient who had undergone the traditional TKA. A variety of health care practitioners we spoke with considered the minimally invasive approach superior to the traditional approach in terms of functional outcomes and pain. We are interested in determining whether the minimally invasive approach is indeed superior to the traditional approach in these regards and believe that this information will help us to prepare more specific plans of care for our future patients post-TKA.

Clinical PICO:
P: Adults with degenerative knee OA immediately post-TKA
I: Minimally invasive quadriceps sparing surgical approach for a TKA
C: Traditional medial parapatellar surgical approach for a TKA
O: Knee Society Score, amount of post-operative pain, ability to walk community distances and climb stairs

Overall Clinical Bottom Line: Based on the results of the outcomes from Varela *et al.*[i], Wulker *et al.*[ii], and Tashiro *et al.*[iii], there appears to be insufficient data to strongly support or negate the ability of the MIS TKA approach to reduce pain and improve functional KSS in adults with knee OA who opt for a TKA. Pain and function were measured by validated outcomes (pain medication usage, visual analog pain scale, and Functional KSS[iv]). Varela *et al*. and Tashiro *et al.* found clinically significant mean improvements between groups in pain at 24 hours and 1 week after surgery, respectively. We would anticipate that the type and quality of post-surgical pain between 24 hours and 1 week after the operation are different. The time points for assessment of pain were closer for Wulker *et al.* and Tashiro *et al.* (8 days and 1 week, respectively); however, in Wulker *et al.,* no clinically significant differences between groups were found. Although we do not know of a reported MCID for the functional KSS, a score of 10 points can move a subject from a subjective category of poor to fair, fair to good, or good to excellent.[v] Thus, mean improvements over 10 points appear to be clinically meaningful. Varela *et al.* and Tashiro *et al.* found clinically significant mean improvements in the MIS group in function measured by the Functional KSS, when compared to the Standard TKA group. The time points were closer: Varela *et al.* looked at KSS at 1 and 3 months

post-surgery and Tashiro *et al.* looked at it at 3 weeks post surgery. Wulker *et al.* looked at KSS much sooner (8 days post op) and found no difference between the groups. The MIS approaches were also different between the studies. Varela *et al.* used the subvastus MIS, whereas Wulker *et al.* and Tashiro *et al.* used the midvastus MIS. It is possible that the type of MIS approach may have altered the reported outcomes. The internal validity of all three studies was good (PEDro scores ranging from 6-7/10). The external validity was compromised. All 3 studies were completed in foreign countries (Spain, Europe, and Japan) where the average length of hospital stay after a joint replacement surgery far exceeds the average in the USA. Furthermore, Varela *et al*. and Wulker *et al.* excluded obese patients, which limits the applicability of the study results to the USA where obesity is prevalent and a contributor to knee osteoarthritis.[vi] Further studies must be done in the USA healthcare system in order to determine whether there are earlier post-operative differences in pain or function between the two surgical approaches.

Search Terms:
Total knee arthroplasty, pain, minimally invasive, ambulation

Appraised By:
Heather Robinson, SPT
School of Physical Therapy
College of Health Professions
Pacific University
Hillsboro, OR 97123
robi2135@pacificu.edu

Jonathan Eng, SPT
School of Physical Therapy
College of Health Professions
Pacific University
Hillsboro, OR 97123
joneng@pacificu.edu

Rationale for chosen articles: The articles chosen for appraisal were selected based on the similarity of the article PICO to our clinical PICO, how well our clinical question was addressed, year of publication, level of evidence based on Physiotherapy Evidence Database (PEDro) scores, and the use of comparable measures of pain (VAS and/or pharmaceutical use) and functional outcomes (Knee Society Score). We determined the PEDro scores using the PEDro criteria.[vii] We found five articles that met our criteria and three of these were selected for appraisal based on how close the article PICO resembled our clinical PICO and the article's level of evidence. Any differences noted between our selected articles were not considered to be significant enough to affect our overall clinical bottom line.

- Varela-Egocheaga, J., Suarez-Suarez, M., Fernandez-Villan, M., Gonzalez-Sastre, V., Varela-Gomez, J., Rodriguez-Merchan, C. Minimally invasive subvastus approach: Improving the results of total knee arthroplasty: a prospective, randomized trial. *Clinical Orthopaedics and Related Research*. 2010;468:1200-1208.

  PEDro Score: 7/10
  P: 100 adults with degenerative knee OA
  I: Minimally invasive subvastus TKA
  C: Conventional, parapatellar TKA

O: Knee ROM and Knee Society scores, perioperative pain and blood loss, length of hospital stay, operative time, radiographic measurements, mean blood loss, and complications

- Wulker, N., Lambermont, J., Sacchetti L., Lazaro, J., Nardi, J. A prospective randomized study of minimally invasive total knee arthroplasty compared with conventional surgery. *The Journal of Bone and Joint Surgery*. 2012;92(7): 1584-1590.

  PEDro Score: 6/10
  P: 134 adults (mean age 70.1 years) with degenerative knee OA
  I: Minimally invasive midvastus TKA without the use of computer navigation
  C: Conventional TKA approach
  O: Knee ROM, Knee Society total and function scores, VAS for pain and ADLs, operative time, radiographic measurements, mean blood loss, and complications

- Tashiro, Y., Miura, H., Matsuda, S., Okazaki, K., Iwanmoto, Y. Minimally invasive versus standard approach in total knee arthroplasty. *Clinical Orthopaedics and Related Research*. 2007;463: 144-150.

  PEDro Score: 6/10
  P: 41 adults with degenerative knee OA immediately post-TKA
  I: Minimally invasive TKA
  C: Standard medial parapatellar TKA
  O: Knee extensor and flexor torque, visual analog scale, pace of rehabilitation, Knee Society scores, radiographic findings, operative time, and complications

Table 1. Comparison of PEDro Scores

	Tashiro *et al.*	Wulker *et al.*	Varela-Egocheaga *et al.*
Random	1	1	1
Concealed Allocation	0	0	1
Baseline Comparability	1	1	1
Blind Subjects	0	0	0
Blind Therapists	0	0	0
Blind Assessors	0	0	0
Adequate Follow-up	1	1	1
Intention to Treat	1	1	1
Between Group	1	1	1
Point Estimates & Variability	1	1	1
Total Score	6/10	6/10	7/10

Article 1: Varela-Egocheaga *et al*., Minimally invasive subvastus approach: Improving the results of total knee arthroplasty: a prospective, randomized trial. *Clin Ortho Relat Res* (2010) 468:1200-1208.

Clinical Bottom Line: Based on this prospective, randomly controlled study of 100 adults with knee OA, subjects who received a minimally invasive subvastus TKA approach (MIS group; n= 50) statistically and clinically significantly consumed less pain medication at 24 hours following surgery and demonstrated a statistically and clinically significant improvement in Functional Knee Society scores (KSS) at 1 month and 3 months following surgery compared to the standard TKA group (control group; n =50). All patients were similar at baseline with regards to prognostic variables and outcome measures. At 24 hours post-surgery, the number needed to treat (NNT; 95% CI) for decreasing the amount of pain medication usage was 2 (1.60-3.10), indicating that 2 additional patients would need to be treated with the MIS surgery in order prevent one additional occurrence of pain medication use at 24 hours. At 48 hours, the NNT increased to 16.67 with an infinite upper limit of the 95% CI. Statistically significant improvements in functional KSS were found between groups at 1 and 3 months after surgery. The MIS group scored an average of roughly 19 and 15 points higher than the standard TKA group at 1 and 3 months, respectively. A mean improvement of 10 points appears to be clinically meaningful. The effect size at 1 month was 1.04 (0.62-1.46) and at 3 months was 0.93 (0.52-1.34). The internal validity of this study is good (PEDro score 8/10). The results are applicable to the majority of Spanish candidates for TKA with the exception of patients with a BMI > 40. The average hospital length of stay (LOS) in this study was 8 days; in the USA, the average LOS following TKA is 3.5 days. Based on this article, we would recommend that adults seeking a TKA in Spain choose the MIS TKA approach over the Standard TKA because it provided an immediate benefit to MIS subjects by reducing the amount of pain medication needed within 24 hours of surgery and provided a statistically and clinically significant improvement in function for the initial 3 months following surgery when compared to patients who received the traditional TKA. Further studies must be done in the USA healthcare system in order to determine whether there are earlier post-operative differences in pain or function between the two surgical approaches.

Article PICO
P: 100 adults with knee osteoarthritis and willingness to participate in the trial
I: Total knee arthroplasty (TKA) using minimally invasive subvastus approach
C: TKA using traditional parapatellar approach
O: Post-operative pain, time to start walking, and Knee Society total and function scores (KSS)

Blinding: The authors did not mention whether the subjects were blinded. All procedures were performed by the same surgeon who could not be blinded. The authors did not mention blinding of assessors, however all assessors performed identical objective post-operative testing protocols. We feel that it was not important to blind the subjects to obtain unbiased pain ratings because pain was objectively measured by the use of analgesic medications. The authors did not state how or who administered the KSS

assessments and therefore we do not know if blinding of assessors could have influenced the KSS scores.

Controls: The control group (standard TKA group) consisted of 50 subjects who received a TKA using the conventional medial parapatellar surgical approach. The experimental group (MIS group) consisted of 50 subjects who received a TKA using the minimally invasive subvastus surgical approach. All surgical procedures were done by the same surgeon who followed well-described operative protocols for each of these approaches. All subjects received the same deep venous and infection prophylaxis prior to surgery and followed identical postoperative protocols. We feel that any differences in outcome measures between the MIS and Control groups can be attributed to the surgical intervention (the independent variable).

Randomization: The authors stated that 100 subjects were randomly divided into two groups of 50 each using a table of randomized numbers. All subjects met the inclusion criteria and were shown to be similar at baseline related to the following preoperative parameters: age, gender, weight, BMI, Knee Society score, functional score, and preoperative knee ROM. The authors showed that the above parameters were statistically similar using the Student's t-test and the Mann-Whitney U test.

Study: This study was a prospective, randomized trial that compared the conventional TKA medial parapatellar approach to the minimally invasive TKA subvastus approach. Inclusion criteria included knee osteoarthritis and willingness to participate in the trial. Exclusion criteria included knee flexion contracture > 10 degrees, varus > 20 degrees, valgus > 15 degrees, BMI > 40kg/m2 or those who previously had knee surgery. 100 subjects were included and because the authors did not state it, we assumed no subjects were lost.

Outcome measures: The two outcome measures we are interested in are post-operative knee function and pain. Knee Society scores (KSS) were used to score functional and global recovery. Knee function was measured by a questionnaire called the Knee Society Score. The Global KSS is split into 2 different sections: (1) an objective section that regards pain with activity, range of motion, and several aspects of joint alignment, and (2) a functional section that asks about the patient's ability to walk a specified distance and climb stairs with or without the use of an assistive device. The function section of the KSS (the component of the Global KSS that we are interested in) is rated on a scale of 0 to 100. A score from 80-100 grades a patient's functional ability as excellent; 70-79 is considered good; 60-69 is considered fair; below 60 is considered poor.[viii] Although we do not know of a reported MCID for this outcome measure, a score of 10 points on the functional KSS can move a subject from a subjective category of poor to fair, fair to good, or good to excellent. Thus, mean improvements over 10 points appear to be clinically meaningful. Functional KSS were collected at 1 month, 3 months, 1 year and 3 years. The authors did not state whether the KSS was verbally administered by a clinician involved in the study, or if the questionnaire was entirely performed by self-report. The authors measured post-operative pain by quantifying the amount and type of analgesic medication taken in the hospital at 24 and 48 hours post-surgery. Although this method of

measuring pain is not commonly used, the authors stated that they used this measure instead of the Visual Analog Scale (VAS) to mitigate any confusion in recording pain ratings in relation to pain medication intake. This method does appear to have face validity.

Study losses: 100 subjects were included and because the authors did not state it, we assumed no subjects were lost.

Summary of internal validity: This article has good internal validity. It was not included in the Physiotherapy Evidence Database (PEDro); however, we used the PEDro criteria to evaluate the internal validity and scored it 7/10. No major threats of internal validity were present in this study. We identified 2 minor threats. First, the authors did not specify whether the subjects and/or assessors were blinded. If no blinding occurred, threats such as rater bias were possibly present. Rater bias may have compromised the validity of the KSS values. The surgeon was not blinded to group assignment, however it would be impossible to do this. We do not feel that this particular lack of blinding could significantly affect the KSS outcome measure, as it is not likely that the surgeon administered the actual KSS evaluation. Second, the authors selected a non-validated outcome measure to record pain; however, we feel that tracking pain medication intake was an appropriate and objective measurement of pain. The use of the VAS in the acute care setting can be problematic because it does not take into account the influence of pain medication on the score, and so pain medication intake may be a more reliable choice for measuring pain in this setting.

Evidence: We want to evaluate the differences in post-operative pain medication intake and KSS between the MIS and standard TKA groups at 24 and 48 hours post-surgery. As physical therapists, we evaluate and treat within this 48-hour period. Since pain is frequently the primary limiting factor to our interventions, understanding the typical expected pain timelines for particular procedures is crucial to better designing and implementing treatment plans for these patients.

The authors reported that at 24 hours status/post TKA, 24 subjects in the MIS group consumed analgesics compared to 35 subjects in the standard TKA group. The authors calculated this difference to be statistically significant ($p=0.002$). Also at 24 hours, 2 subjects in the MIS group consumed opioids compared to 11 subjects in the standard TKA group. The authors calculated this difference to be statistically significant ($p=0.007$). At 48 hours post-operatively, 41 subjects in the MIS group consumed analgesics as compared to 36 in the standard TKA group. The authors calculated this difference to statistically insignificant ($p=0.307$). However, also at 48 hours post-operatively, 1 subject in the MIS group consumed opioids compared to 9 in the standard TKA group. This was calculated as statistically significant ($p=0.007$). For the purpose of more closely examining the difference between the two groups regarding pain medication usage, we combined analgesics and opioids use into total analgesic medication use and used categorical statistics (Tables 2-4).

Table 2. 2x2 Table of subjects taking and not taking analgesics at 24hrs post-TKA			
Group	Pain medication used	No pain medication used	Total subjects
MIS Group	**22**	**28**	50
Standard TKA Group	**46**	**4**	50
Totals	68	32	100

Table 3. 2x2 Table of subjects taking and not taking opioids at 48hrs post-TKA.			
Group	Pain medication used	No pain medication used	Total subjects
MIS Group	**42**	**8**	50
Standard TKA Group	**45**	**5**	50
Totals	87	13	100

Table 4. Categorical Statistics for pain medication usage				
	24 hours post-operation		48 hours post-operation	
Statistic	Estimate	95% CI	Estimate	95% CI
CER	0.92		0.90	
EER	0.44		0.84	
ARR	0.48	0.32-0.64	0.06	-0.07-0.19
RRR	0.52	0.34-0.65	0.07	-0.09-0.20
NNT	2.08	1.6-3.1	16.67	5.2-(-14.0)
RR	0.48	0.35-0.66	0.93	0.80-1.09

The calculated controlled event rate (CER), absolute risk reduction (ARR), and relative risk reduction (RRR) indicate that the MIS TKA was superior to the standard TKA in reducing subjects' need of pain medication at 24 hours and 48 hours post-operation. The CER measures how often pain medication usage occurred in the standard TKA group. The 24-hour and 48-hour CERs of 0.92 and 0.90 respectively, means that 92% of the standard TKA subjects experienced pain that required medication use after 24 hours and 90% after 48 hours. This is a high percentage and indicates that standard TKA is not clinically successful in preventing pain medication usage to mediate pain. In comparison, the EER measures how often pain medication usage occurred in the MIS group. The EER of 0.44 means that 44% of the MIS group used pain medications in the first 24 hours post operation. Thus, pain medication usage at 24 hours was 48% less in the MIS group compared to the standard group (92%- 44%). After 48 hours, 84% of the MIS group used pain medications, which was only 6% less than the standard TKA group. The ARR is the percent by which the risk of pain medication usage was reduced by receiving the MIS TKA. The 24-hour and 48-hour ARRs of 0.48 and 0.06 respectively, means that the MIS group was 48% less likely than the standard group to use pain medications after 24 hours and 6% less likely after 48 hours. The 24-hour risk reduction was a substantial reduction and the confidence interval (CI) of 0.32-0.64 is narrow. The 48-hour ARR of only 6% is not substantial and indicates that the MIS TKA was not

necessarily the superior operation if the goal is to reduce pain at the 48-hour mark. The RRR is the percent by which the risk of pain medication use would be reduced if all 100 subjects had received the MIS TKA. The 24-hour RRR of 0.52 means that if all subjects had received the MIS intervention, the total risk for analgesic use would have been reduced by 52%. This is a considerable risk reduction but the confidence interval of 0.34-0.65 is relatively broad. The 48-hour RRR is only 0.07 and indicates that there is only a 7% risk reduction at the 48-hour mark; this further suggests that there may not be a difference between the two TKA approaches in terms of pain experienced 48 hours post operation.

The NNT is the number of patients that would need to have the MIS as compared to the standard TKA approach in order to have one additional successful outcome. The NNT of 2.08 indicates that 2 people would need to receive the MIS TKA in order to prevent one additional occurrence of pain medication use after 24 hours. The NNT has a narrow CI of 1.60-3.10. At 48-hours post-surgery, the NNT was 16.67 and the 95% CI upper limit was infinite. The RR is a ratio of the probability of pain medication use in the MIS group versus the standard TKA group. The RR of 0.48 indicates that the MIS group had a 48% occurrence of pain medication use compared to the standard group after 24 hours. This RR is substantial and suggests that the MIS TKA was of considerable benefit 24 hours post operation. The 48-hour RR indicates that 93% of the MIS group used pain medications 48 hours post operation. These statistics reveal that the MIS TKA was clinically effective at reducing pain post-TKA up to 24 hours, but not at 48 hours after the surgery.

We are only interested in the functional section of the Knee Society Scores (KSS) because knee alignment is more of a concern to a medical doctor than to a physical therapist and the pain scores were measured by use of pain medications (also included in the global KSS) during the hospital stay. The authors reported that they found KSS scores to be statistically significantly higher in the MIS group when compared to the standard TKA group in regards to functional KSS at 1 month and 3 months post-operation. We chose these time points because we are primarily concerned with the therapy implications immediately following TKA and these time frames most closely fit our clinical PICO. We were able to calculate 95% CIs for the differences between group means (Table 5). The MIS group scored an average of roughly 19 points and 15 points higher than the standard TKA group at 1 and 3 months, respectively. Although we do not know of a reported MCID for this outcome measure, a score of 10 points on the functional KSS can move a subject from a subjective category of poor to fair, fair to good, or good to excellent. Thus, mean improvements over 10 points appear to be clinically meaningful. We calculated the effect size at 1 month (1.04 with 95%CI of 0.62-1.46) and 3 months (0.93 with 95%CI of 0.52-1.34). Because the mean improvements appear to be able to move subjects to an improved category on the functional KSS and the effect sizes are large, it is clear that the difference in KSS between the groups is clinically significant.

Table 5. Between-group mean differences and effect sizes at 1 and 3 months post-surgery in KSS scores		
Time Post-operative	Mean Difference	Effect Size
1 month	18.74 (11.10-26.38)	1.04 (0.62-1.46)
3 months	15.14 (8.22-22.06)	0.93 (0.52-1.34)

*95% confidence intervals (CI) are in parentheses

Applicability of study results:
Benefits vs. Costs: In terms of our clinical question, based on the findings of this article the MIS TKA provided an immediate benefit to subjects by reducing the amount of pain medication needed within 24 hours of surgery and providing a statistically and clinically significant improvement in function for the initial 3 months following surgery when compared to patients who received the traditional TKA. The authors did not mention a cost difference between the two surgical procedures, however reducing the amount of pain medication needed post-operatively may decrease the likelihood of patients experiencing adverse drug reactions from unnecessary medication use. The authors noted there was no difference between average surgical time, length of hospital stay, or incidence of complication, however they did mention that the experience level of the surgeon is an important factor in the success of MIS procedures. Access to an experienced surgeon may be difficult for patients residing in rural areas. The MIS TKA approach reduced the amount of pain medication needed by patients and improved immediate functional capacity. It does not reduce the length of hospital stay, significantly change the cost associated with the procedure, or reduce the incidence of complications.

Feasibility of treatment: The findings of this study are clinically relevant to physical therapists practicing within inpatient rehabilitation settings and will help to provide a better understanding for how to plan treatment sessions and set appropriate goals when working with patients following a TKA. As an example, the authors defined "walking start day" as the day the patient was able to walk 20 meters and climb two stairs. Based on the findings of this study, it is reasonable to adjust goals following an MIS TKA procedure to walk 50-100 feet on the first post-op day (POD 1) and attempt stairs POD 3-4.

Summary of external validity: Due to the fact that on average, Spanish patients status/post TKA have an 8-day length of stay,[ix] the findings of this study are not externally valid beyond the Spanish healthcare system. In comparison, the Agency for Healthcare Research and Quality, the average length of stay in the USA for patients with major joint replacements was 3.4 days in 2009.[x] The surgeon must be experienced and have already ascended the steep learning curve required of the MIS procedure in order for the findings of this study to be considered valid. Subjects with a BMI > 40 were excluded and therefore the findings are unable to be applied to the bariatric community.

Article 2: Wulker *et al*., A prospective randomized study of minimally invasive total knee arthroplasty compared with conventional surgery. *Journal of Bone and Joint Surgery*. 2012; 92(7): 1584-1590.

Clinical Bottom Line: Based on this prospective, randomized controlled study of 162 older adults with knee osteoarthritis (OA), there were no statistically significant differences in visual analog scale (VAS) pain ratings and functional Knee Society Score (KSS) between the minimally invasive midvastus approach (MIS; n=66)) and the standard traditional parapatellar standard total knee arthroplasty group (Standard; n=68)) at hospital discharge on post-operative day 8. All subjects followed identical postoperative protocols and were similar at baseline with regards to prognostic variables and outcome measures. This study had good internal validity (PEDro 6/10) with no major threats identified. This study was conducted in the European healthcare system where the average length of stay following TKA is greater than 8 days. In the USA, the average length of stay following TKA is 3.5 days, therefore, it is difficult to extrapolate these data to our population. Based on this study, we would not recommend that adults seeking TKA choose the MIS approach over the standard TKA approach, as there appears to be no benefit. Further studies must be done in the United States healthcare system in order to determine whether there are earlier post-operative differences in pain or function between the two surgical approaches.

Article PICO:
P: 134 adults (mean age 70.1 years) with degenerative knee OA
I: Minimally invasive midvastus TKA
C: Conventional TKA approach
O: Knee ROM, Knee Society total and function scores, VAS for pain and ADLs, operative time, radiographic measurements, mean blood loss, and complications

Blinding: The authors did not mention whether the subjects were blinded; however, subjects agreed to random assignment prior to participation. Although it is possible that not blinding the subjects may have resulted in biased pain ratings on the VAS, we feel that this is unlikely and not a major threat to the study. Procedures were performed at 5 separate medical centers by 5 different surgeons who could not be blinded. The authors did not mention blinding of assessors, however all assessors performed identical post-operative testing protocols. The authors did not state how or who administered the KSS assessments and therefore we do not know if blinding of assessors could have influenced the KSS scores.

Controls: The control group consisted of 68 subjects who received a TKA using the conventional medial parapatellar surgical approach (Standard Group). The experimental group consisted of 66 subjects who received a TKA using the minimally invasive midvastus surgical approach (MIS Group). All surgeons followed well-described operative protocols for each approach. All subjects followed identical postoperative protocols. Any differences between the MIS and standard groups can likely be attributed to the surgical intervention.

Randomization: The authors stated that 162 subjects were randomly divided into two groups. All subjects met the inclusion criteria and were statistically similar at baseline related to the following preoperative parameters: age, sex, BMI, total KSS, functional

KSS, VAS pain score, VAS pain score for activities of daily living, and/or primary diagnosis.

Study: This study was a prospective, randomized trial that compared the conventional TKA medial parapatellar approach to the minimally invasive TKA midvastus approach. Inclusion criteria included requirement of either a primary unilateral or bilateral TKA, age between 18 and 80 years, informed consent, and stable health (free of conditions or not receiving treatment that would pose operative risk). Exclusion criteria included insufficient femoral or tibial bone stock, BMI >35kg/m², failed total or unicondylar replacement of affected knee, active infection, collateral ligament insufficiency, knee flexion <90 degrees, fixed flexion deformity >15 degrees, varus or valgus > 20 degrees, or having an immunosuppressive disorder (except inflammatory arthritis). An intention to treat analysis was performed in order to account for a total loss of 28 subjects from the study. The authors described that each surgical procedure utilized the same brand of knee replacement instruments, began with an anterior femoral cut and used spacer blocks to confirm ligament balancing in flexion and extension. The MIS was defined as requiring a skin incision of <15cm. Post-operative care included pain management and continuous passive motion, which was started on the first postoperative day. Patients began full weight bearing with the use of an assistive device on the first postoperative day.

Outcome Measures: The two outcome measures we are interested in are post-operative pain as measured by the VAS and knee function as measured by the Function score of the KSS. The authors measured post-operative pain using 0-100mm VAS. The VAS is a validated outcome measure and has been reported to have an MCID of a 19-30 mm change from baseline for outpatients with hip and knee OA[xi,xii] and 13-30mm change for adult patients with acute pain starting within 24-72 hours prior to admission to emergency department.[xiii,xiv] We could not find MCIDs for patients in inpatient care and/or patients status/post TKA in the literature. We feel that our patient population is somewhere between emergency and outpatient OA care. The Functional KSS was thoroughly discussed in the Varela *et al.* CAP. Functional KSS scores were collected preoperatively, at discharge (8 days post-op), 4-6 weeks post-operative, and 1-year post-operative. The authors did not clarify whether the KSS outcome measure was given by a clinician involved in the study, or if the KSS was entirely performed by self-report.

Study Losses: The authors provided a clear flow diagram of the study participants throughout the study. 162 subjects were randomized into the MIS (n=79) and standard TKA (n=83). Two subjects were lost to the standard group due to being operated on by another surgeon. At 4-6 weeks post-operation, 5 subjects were lost from the MIS group and 5 from the Standard Group due to missed visits. After 1 year, 66 subjects were valid for analysis in the MIS group and 68 in the standard group; 6 and 5 subjects withdrew from the MIS and standard groups respectively and 2 and 3 were lost due to missed visits, respectively. There was a 1% total dropout rate at discharge, 7% at 4-6 weeks and 17% at 1 year. The dropout rates between the groups were roughly equal. A blinded statistician preformed an intention-to-treat analysis, although the authors did not explain how the ITT was performed.

Summary of Internal Validity: This article has good internal validity. It was not included in the Physiotherapy Evidence Database (PEDro); however, we used the PEDro criteria to evaluate the internal validity and scored it 6/10. No major threats of internal validity were identified. However, we identified 3 minor threats. First, the authors did not specify whether the subjects and/or assessors were blinded. If no blinding occurred, threats such as rater bias were possibly present. Rater bias may have compromised the validity of the study when obtaining KSS values. The surgeon was not blinded to group assignment; however, it would be impossible to do this. We do not feel that this particular lack of blinding would have significantly affected the KSS outcome measure because it is not likely that the surgeon performed the actual KSS evaluation him or herself. Second, the use of the VAS in the acute care setting can be problematic as it does not take into account the influence of pain medication on the score. However, Williamson *et al*.[xv] has shown the VAS to have good validity and reliability in the acute setting, and high sensitivity. Based on this information, we have chosen to consider pain medication influence on score as a minor threat. Third, the authors admitted that their study was underpowered and this may have altered the significance or lack thereof when comparing outcome measures.

Evidence: We want to evaluate the differences in post-operative pain and KSS between the MIS and Standard TKA groups at discharge (8 days post-surgery). We chose this time point because we are primarily concerned with the therapy implications immediately following TKA and this time frame most closely fits our clinical PICO. The authors reported that no statistically significant differences were found between groups in regards to mean VAS pain ratings and functional KSS at discharge. However, the authors did not report in the article on whether there was a significant difference in reduction of pain on the VAS from baseline. It is possible that the authors may have presented these data in the article Appendix, but we did not have access to this information through our database. The mean VAS rating preoperatively and at discharge was 56.7mm and 29.1mm, respectively, for the MIS group (27.6 mm reduction) and 53.4mm and 28.5mm, respectively, for the standard TKA group (24.9 mm reduction). Thus, the between-group difference in mean pain reduction from pre-operative to discharge was 2.7mm. While we do not know if this was statistically significant, the MCID for pain measured on a 0-100mm VAS is a 19-30mm change from baseline for patients with hip and knee OA in outpatient care, or a change from baseline of 13-30 mm for adults in the emergency department with recent acute pain. When evaluating the within group changes from pre-operative to hospital discharge, both the MIS group and the Standard TKA group satisfied the MCID range for VAS for both emergency department and outpatient OA patients. The mean difference in reduction between groups fails to satisfy either MCID range. When compared to the Standard TKA group, it appears that the MIS subjects did not have a clinically significant reduction in pain on the VAS 1 week after surgery.

We are only interested in the functional section of the KSS because knee alignment is more of a concern to a medical doctor than to a physical therapist. The authors reported that at discharge there was no statistical difference in functional KSS between the MIS group and standard TKA group. The authors calculated both the mean functional KSS and the differences in mean functional KSS. The mean functional KSS at discharge was 38.7 with a 95% CI of 34.6-42.8 for the MIS group, and 36.8 with a 95%

CI of 32.7-40.9 for the standard TKA group. The difference in mean function score at discharge was 1.87 (95% CI, -3.12-6.87). The CI crosses zero, further supporting that the difference in mean function score is not significant.

Applicability of study results:
Benefits vs. Costs: Based on the findings of this article, the MIS TKA did not provide an immediate benefit to subjects in terms of pain reduction or functional improvement by the time of discharge. The authors did not mention a cost difference between the two surgical procedures and noted that there was no significant difference between average surgical times. The MIS TKA approach requires a more experienced surgeon. Costs associated with the education and training of surgeons in the MIS approach as well as with a patient's ability to access such a surgeon may be a limiting factor for patients interested in pursuing the MIS TKA.

Feasibility of treatment: The findings are clinically relevant to physical therapists practicing within the inpatient rehabilitation setting. According to this study, no difference in pain or function existed between the MIS TKA approach and the standard approach up to one year. Therefore, no change in treatment protocol should be enacted if a patient post-MIS TKA should present to the acute rehabilitation department.

Summary of external validity: Due to the fact that these European subjects were discharged on post-operative day 8,[8] the findings are not externally valid beyond the European healthcare system. In comparison, according to the Agency for Healthcare Research and Quality, the average length of stay in the USA for patients with major joint replacements was 3.4 days in 2009.[9] No VAS or Functional KSS scores were recorded before day 8 in this study and therefore we cannot know if there was a significant difference in pain and/or functional KSS scores between the groups during this period. We therefore also cannot know whether or not therapy can be modified for MIS TKA patients before day 8. The surgeon must be experienced in the MIS procedure in order for the findings of this study to be considered valid. Subjects with a BMI>35 were excluded and therefore the findings are unable to be applied to the bariatric community.

Article 3: Tashiro *et al*., Minimally invasive versus standard approach in total knee arthroplasty. *Clin Ortho Relat Res* (2007) 463:144-150.

Clinical Bottom Line: Based on this prospective, randomized controlled study of 41 adults with knee OA, subjects who received the MIS TKA (n=20 subjects; 24 knees) experienced significantly less pain at 1 week following surgery and demonstrated significantly improved Functional KSS at 3 weeks following surgery compared to the standard TKA group (n= 21 subjects; 25 knees). All patients were similar at baseline with regards to prognostic variables and outcome measures. The MIS group had statistically significant improvements in VAS pain ratings at 1 week and functional KSS at 3 weeks, compared to the standard TKA group. The MIS group satisfied the MCID (19-30mm reduction for patients with OA in outpatient care; 13-30 mm for general patients in the emergency department) for the VAS from baseline to post intervention; however, the standard TKA group did not. The mean difference between groups was also clinically significant. At 3 weeks status/post knee surgery, the mean difference between groups on the functional KSS was 9 points (95% CI 1.85-16.15. Although we do not know of a reported MCID for this outcome measure, a score of 10 points or more on the functional KSS appears to be clinically significant. Because the mean improvements appear to be just shy of being able to move subjects to an improved category on the functional KSS and the effect sizes are medium (0.62, 95%CI 0.12-1.12), it is unclear whether the difference in KSS between the groups was clinically significant. The internal validity of the study was good (6/10 using PEDro criteria). These results are applicable to the majority of candidates for TKA in Japan. Further studies must be done in the United States healthcare system in order to determine whether there are earlier post-operative differences in pain or function between the two surgical approaches.

Article PICO
P: 41 adults with degenerative knee OA
I: Minimally invasive TKA
C: Standard medial parapatellar TKA
O: Knee extensor and flexor torque, visual analog scale for pain, pace of rehabilitation (measured by active straight leg raising, 90 degree knee flexion, and T-cane gait), Knee Society scores, radiographic findings, operative time, and complications

Blinding: The authors did not mention whether the subjects were blinded; however, subjects agreed to random assignment prior to participation. Although it is possible that not blinding the subjects may have resulted in biased pain ratings on the VAS, we feel that this is unlikely and not a major threat to the study. The number of surgeons involved in this study was not mentioned; blinding of surgeon(s) would be impossible. The authors did not mention blinding of assessors, or state how or who administered the KSS assessments and therefore we do not know if blinding of assessors could have influenced the KSS scores.

Controls: The control group consisted of 21 subjects (25 knees) who received a TKA using the conventional medial parapatellar surgical approach (standard TKA group). The experimental group consisted of 20 subjects (24 knees) who received a TKA using the

minimally invasive surgical approach (MIS group). Surgeon(s) followed well-described operative protocols for each approach. On the second postoperative day, subjects started continuous passive motion and weight bearing was permitted as tolerated. Any differences between the MIS and standard groups can likely be attributed to the surgical intervention.

Randomization: 20 subjects were randomly selected for the MIS group unless they previously had an osteotomy or had severe osteoporosis. 21 subjects were selected during the same 19-month period for the control group. The authors stated that subjects were similar at baseline with respect to: age, gender, weight, height, preoperative ROM, KSS, functional KSS, and radiographic stage. The authors did not perform statistical calculations to show that the above parameters were statistically similar. However, by examining the data table, this did appear to be accurate.

Study: This study was a prospective, randomized trial that compared the conventional TKA medial parapatellar approach to the minimally invasive TKA approach. The only inclusion criterion was knee osteoarthritis. Exclusion criteria for the MIS group included previous osteotomy or severe osteoporosis. 41 subjects were included and because the authors did not state it, we assumed no subjects were lost. The authors described the MIS surgical procedure clearly. The medial parapatellar retinaculum was cut and a capsular incision was made that ran proximally to the insertion of the VMO. The authors did not describe the standard TKA surgical approach. Post-operative care included epidural anesthesia that was removed on the second post-operative day, and continuous passive motion, which was started on the second post-operative day. Patients began weight bearing as tolerated as soon as possible. No descriptions were given for post-operative rehabilitation.

Outcome measures: The two outcome measures we are interested in are post-operative pain as measured by the VAS and knee function as measured by the Function score of the KSS. The authors measured post-operative pain at 1 and 2 weeks post-surgery, using a 100-point VAS. The VAS is a validated outcome measure and has an MCID of a 19-30mm reduction for outpatient OA care and 13-30mm for patients in the emergency department.[10,11,12,13] The Functional KSS is thoroughly discussed in the Varela *et al*. CAP. The authors measured Functional KSS at 3 weeks and 3 months post-operative. The authors did not clarify whether this outcome measure was administered by a clinician involved in the study, or if the KSS was entirely performed by self-report.

Study losses: Because the authors did not state it, we assumed no subjects were lost.

Summary of internal validity: This article has good internal validity. It was not included in the Physiotherapy Evidence Database (PEDro); however, we used the PEDro criteria to evaluate the internal validity and scored it 6/10. No major threats were present. We identified 2 minor threats. First, the authors did not specify whether the subjects and/or assessors were blinded. If no blinding occurred, rater bias could have been present. Rater bias may have compromised the validity of KSS values. The surgeon was not blinded to group assignment; however it would be impossible to do this. We do not feel

that this particular lack of blinding could significantly affect the KSS outcome measure because it is not likely that the surgeon administered the actual KSS evaluation him or herself. Second, the use of the VAS in the acute care setting can be problematic as it does not take into account the influence of pain medication on the score. Based on this information, we have chosen to consider pain medication influence on score as a minor threat. However, Williamson *et al*.[14] has shown the VAS to have good validity and reliability in the acute setting, and high sensitivity.

Evidence: We want to evaluate the differences between the MIS and standard groups in post-operative VAS pain ratings at 1 week and Functional KSS at 3 weeks. We chose these time points because we are primarily concerned with the therapy implications immediately following TKA and these time frames most closely fit our clinical PICO. As physical therapists, we evaluate and treat within this post-operative time frame. Since pain is frequently the primary limiting factor to our interventions, understanding the typical expected pain timelines for particular procedures is crucial to better designing and implementing treatment plans for these patients. The authors reported that at 1-week status/post TKA, the MIS group had significantly lower scores on the VAS pain scale than did the standard group ($p< 0.05$). The estimated mean VAS ratings (numbers were estimated from a graph) preoperatively and at 1 week were 67mm and 25mm for the MIS group (42 mm within-group pain reduction) and 57mm and 45mm for the standard TKA group (12mm within-group pain reduction). At 1 week post-surgery, the difference between group means was 20mm. The MCID of the for pain on the 100 mm-VAS has been reported as a 19-30mm reduction from baseline for patients with OA in outpatient care, or a reduction from baseline of 13-30 mm for general patients in the emergency department. No MCIDs for patients in inpatient care and/or patients' status post-TKA could be found in the literature. We feel that our patient population is somewhere between emergency and outpatient OA care. The MIS group satisfied the MCID range for VAS for both emergency department and outpatient OA patients (42mm > 30mm); however, the mean difference for the standard TKA group did not meet the MCID (12mm < 19mm or 13mm). The mean difference (42mm MIS – 12mm Standard = 30mm) satisfies the MCID range of the VAS for both emergency and outpatient OA care. We do not know the standard deviations for these data and therefore we are cautiously optimistic that on average, the MIS subjects had a clinically significant reduction in pain on the VAS 1 week after surgery and that, on average, the standard group did not.

We are only interested in the functional section of the Knee Society Scores (KSS) because knee alignment is more of a concern to a medical doctor than to a physical therapist. The authors reported that at 3 weeks status/post TKA, the MIS group scored significantly higher on the functional KSS than did the standard group ($p<0.05$). We were able to calculate 95% CIs for the differences between group means (Table 6). The MIS group scored an average of roughly 9 points higher than the standard group at 3 weeks. Although we do not know of a reported MCID for this outcome measure, a score of 10 points on the functional KSS can move a subject from a subjective category of poor to fair, fair to good, or good to excellent. Thus, mean improvements over 10 appear to be clinically meaningful. Although the mean difference of 9 points would not have been clinically significant, the 95% CI of 1.85-16.15 completely straddles the MCID of 10 points and so we can expect that a portion of the population would have clinically

meaningful improvements. However, we must also consider the low end of the 95% CI (1.85) which would result in a portion of the population not having clinically meaningful improvements. We calculated the effect size at 3 weeks (0.62, 95%CI 0.12-1.12) which is a medium effect size and further supports our conclusion that the MIS approach is sometimes clinically significant in regards to improvement on the Functional KSS. Overall, we feel that this evidence moderately suggests that the MIS approach resulted in clinically significant improvements in the Functional KSS.

Table 6. Between-group mean differences and effect sizes at 3 weeks post-surgery for Functional KSS

Time Post-operative	Mean Difference	Effect Size
3 weeks	9 (1.85-16.15)	0.62(0.12-1.12)

95% confidence intervals (CI) are in parentheses

Applicability of study results:

Benefits vs. Costs: Based on the findings of this article, the MIS TKA provided an immediate benefit to subjects in terms of pain reduction by 1 week and functional improvement by 3 weeks status post-TKA. The authors did not mention a cost difference between the two surgical procedures, but noted that the average operative time for the MIS group was significantly longer than the standard TKA group by a mean of ~ 1 hour ($p<0.001$). There was no mention of a difference in length of hospital stay. The MIS TKA approach requires a more experienced surgeon. Costs associated with the education and training of surgeons in the MIS approach as well as with a patient's ability to access such a surgeon may be a limiting factor for patients interested in pursuing the MIS TKA.

Feasibility of treatment: The findings of this study are clinically relevant to physical therapists practicing within inpatient rehabilitation settings and will help to provide a better understanding for how to plan treatment sessions and set appropriate goals when working with patients following a TKA.

Summary of external validity: Due to the fact that Japanese patients have an average 9-day length of stay in the hospital for a TKA, the findings in this study are not externally valid beyond the Japanese healthcare system.[xvi] In comparison, according to the Agency for Healthcare Research and Quality, the average length of stay in the USA for patients with major joint replacements was 3.4 days in 2009. In this study, no VAS or Functional KSS measurements were taken before 1 week and 3 weeks, respectively. We therefore cannot know if there was a significant difference in pain and/or functional KSS between the groups during this period. We also cannot know whether or not therapy should be modified for MIS TKA patients before 1 week. Lastly, the surgeon must also be experienced in the MIS procedure in order for the findings of this study to be considered externally valid.

Synthesis/Discussion: The original purpose of our critically appraised topic was to determine whether MIS TKA or standard TKA was most effective for generating improved functional outcomes and less pain in patients with degenerative knee OA. We were unable to definitively answer our question for six reasons. First all of the studies

were completed in countries in which the average hospital length of stay is longer compared to the USA. Second, one of the studies (Wulker *et al*.) had low statistical power. Third, two of the studies excluded patients with a BMI that would place them into an obese category (Varela *et al.*: BMI>35 and Wulker *et al*.: BMI>40). Obesity is prevalent in USA and contributes to knee OA (Zhang 2008). Fourth, Varela *et al.* and Tashiro *et al*. found clinically significant improvements in pain; however, Varela *et al.* looked at pain 24 hours after surgery and Tashiro *et al.* looked at pain 1 week after surgery. We would anticipate a significant difference in the type and quality of post-surgical pain between 24 hours and 1 week after the operation. The time points for assessment of pain were closer for Wulker *et al.* and Tashiro *et al.* (8 days and 1 week, respectively); however, in Wulker *et al.,* no clinically significant differences between groups were found. Fifth, Varela *et al.* and Tashiro *et al.* found clinically significant improvements in function measured by the Functional KSS, in the MIS group when compared to the Standard TKA group. The time points were closer but still different: Varela *et al*. looked at KSS at 1 and 3 months post surgery and Tashiro et al. looked at the KSS 3 weeks post-surgery. Wulker *et al.* looked at KSS much sooner (8 days status post operation) and found no difference between the groups. Last, the MIS approaches were different among the studies. Varela *et al.* used the subvastus MIS, and Wulker et al. and Tashiro *et al*. used the midvastus MIS. It is possible that the type of MIS approach may have altered the reported outcomes. Overall, the MIS TKA approach may be a promising surgical intervention for knee OA. We look forward to reviewing more research on the matter in order to determine whether or not modifications to the physical therapy protocol are warranted for patients who have undergone the MIS TKA.

References:

[i] Varela-Egocheaga, J., Suarez-Suarez, M., Fernandez-Villan, M., Gonzalez-Sastre, V., Varela-Gomez, J., Rodriguez-Merchan, C. Minimally invasive subvastus approach: Improving the results of total knee arthroplasty: a prospective, randomized trial. *Clinical Orthopaedics and Related Research*. 2010; 468: 1200-1208.

[ii] Wulker, N., Lambermont, J., Sacchetti L., Lazaro, J., Nardi, J. A prospective randomized study of minimally invasive total knee arthroplasty compared with conventional surgery. *The Journal of Bone and Joint Surgery*. 2012; 92(7): 1584-1590.

[iii] Tashiro, Y., Miura, H., Matsuda, S., Okazaki, K., Iwanmoto, Y. Minimally invasive versus standard approach in total knee arthroplasty. *Clinical Orthopaedics and Related Research*. 2007; 463: 144-150.

[iv] Lingard EA, Katz JN, Wright RJ, Wright EA, Sledge CB. Validity and responsiveness of the Knee Society Clinical Rating System in comparison with the SF-36 and WOMAC. *J Bone Joint Surg Am*. 2001; 12:1856-64.

[v] Orthopaedic Scores Web site. Available at: http://www.orthopaedicscore.com/scorepages/knee_society_score.html. Accessed January 31, 2012.

[vi] Zhang Y and Jordan JM. Epidemiology of Osteoarthritis. *Rheum Dis Clin N Am*. 2008; 34:515-29.

[vii] Physiotherapy Evidence Database. The George Institute for Global Health. Available at: www.pedro.org.au. Accessed on November 4, 2011.

[viii] Orthopaedic Scores Web site. Available at: http://www.orthopaedicscore.com/scorepages/knee_society_score.html. Accessed January 31, 2012.

[ix] Organization for Economic Cooperation and Development. OECD statistics database. Available at: http://stats.oecd.org/index.aspx?DataSetCode=HEALTH_STAT. Accessed on February 26, 2012.

[x] Agency for Healthcare Research and Quality. U.S. Department of Health and Human Services national statistics on all hospital length of stays. Available at: http://hcupnet.ahrq.gov/. Accessed on January 31, 2012.

[xi] Tubach F, Baron G, Falissard B, Logeart I, Bellamy N, Bombardier C, Felson D, Hochberg M, van der Heijde D, Dougados M. Extended report: Evaluation of clinically relevant changes in patient reported outcomes in knee and hip osteoarthritis: the minimal clinically important improvement. *Ann Rheum Dis* 2005; 64:29-33.

[xii] Quintana JM, Escobar A, Bilbao A, Arostegui I, Lafuente I, Vidaurreta I. Responsiveness and clinically important differences for the WOMAC and SF-36 after hip joint replacement. *Osteoarthritis Cartilage.* 2005; 12:1076-83.

[xiii] Gallagher EJ, Liebman M, Bijur PE. Prospective validation of clinically important changes in pain severity measured on a visual analog scale. *Annals of Emergency Medicine*. 2001; 38(6):633-38.

[xiv] Lee JS, Hobden E, Stiell IG, Wells GA. Clinically important change in the visual analog scale after adequate pain control. *Academic Emergency Medicine*. 2003; 10 (10): 1128-30.

[xv] Williamson A, Hoggart B. Pain: a review of three commonly used pain rating scales. *Journal of Clinical Nursing*. 2005; 14:798-804.

[xvi] Wei-Che T, Hao-Yun K, Yuan-Kun T, Herng-Chia C, King-Teh L, Hon-Yi S. A population-based study of prevalence and hospital charges in total hip and knee replacement. *International Orthopaedics*. 2009; 33(4):949-54.