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Does A Mobile-Bearing Vs. Fixed-Bearing Total Knee Replacement Affect Post-Operative Knee Pain at One Year?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

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Abstract

OBJECTIVE: The objective of this selective EBM review is to determine whether or not a mobile-bearing vs. fixed-bearing total knee replacement affects post-operative knee pain at one year.

STUDY DESIGN: Review of three English language primary studies, published between 2008 and 2012.

DATA SOURCES: Three randomized controlled trials published after 2008 comparing post-operative knee pain in mobile vs. fixed-bearing total knee replacements using PubMed and Cochrane databases.

OUTCOMES MEASURED: Knee pain, reported by patients post-operatively using various professional questionnaires, was the primary outcome measured. Subjects reported pain experienced during specific provoking activities on the EuroQol, Western Ontario & McMaster Universities OA Index, Knee Society Score, visual analog scales, Oxford 12-item Questionnaire, and SF-36. Results were then compared one year post-operatively. The tool used to assess significance of outcomes measured was p-value.

RESULTS: One year post-operatively, Lampe et al showed no significant difference in post-operative knee pain in mobile vs. fixed-bearing knee replacements. Breugem et al demonstrated less knee pain when using the mobile-bearing implant. Jolles et al showed significantly less pain in the fixed-bearing knee implants in two of the questionnaires, but no difference in the three other evaluation methods, consequently deeming the study inconclusive.

CONCLUSIONS: The results of the RCTs are inconclusive in determining whether or not type of implant affects post-operative knee pain one year after a total knee replacement. Further research may identify one of the implants as more effective in a particular gender or race.

KEY WORDS: TKR, mobile-bearing implant, fixed-bearing implant, post-operative pain

INTRODUCTION

When learning of a new or worsening medical condition, among the patient's immediate thoughts is, "how does this change my life?" Pain is of the utmost concern on a patient's mind when considering treatment options. Total knee replacement surgery is quickly becoming a necessary step in order for many Americans to maintain their demanding lifestyles. A mobile-bearing prosthesis is an implant in which the polyethylene tibial insert rotates inside the metal tibial tray. As opposed to a fixed-bearing prosthesis, in which the polyethylene tibial insert is firmly attached to the inferior metal tibial tray. Although fixed-bearing prostheses are the traditional implant option, many orthopedists believe that the newer, mobile-bearing implant is more successful due to its unique additional pivot point, which is thought to more closely mimic the human knee. This paper evaluates three double-blind randomized controlled trials (RCTs) comparing post-operative knee pain following a TKR for treatment of osteoarthritis.

Obesity rates and the population of 45-64 year-olds rising in the United States (among other factors) is dramatically increasing the demand for total knee replacements.[1] From 1999 to 2008, 134% more total knee replacements were performed in the United States.[1] It has been proven that TKRs are a cost-effective way to extend the quality of life for a patient's remaining years.[2] Today's dispute centers around which knee implant provides the most benefit to the patient. Benefit, here, is measured in post-operative pain. The average cost of a total knee replacement in the United States is $49,500.[3] In 2010 there were 719,000 TKRs performed in the United States.[4] With daunting figures like these and America's current healthcare uncertainty, a procedure of this magnitude should

cause the patient minimal post-operative pain in order to yield the most successful rehabilitation.

The most common reason for total knee replacement is to repair damage to a joint from osteoarthritis or rheumatoid arthritis.[5] Candidates for knee replacement are those who have failed non-surgical treatments such as NSAIDs, intra-articular injections, exercise regimens, and weight loss plans. The initial treatment regimen for osteoarthritis includes Acetaminophen and weight reduction, accompanied by a low-impact exercise program, such as swimming. The next step is typically an intra-articular injection of hyaluronic acid, which acts to lubricate the joint.

For rheumatoid arthritis, the best treatment is to start a DMARD (methotrexate) or glucocorticoids early in the disease[6]. Most rheumatoid patients find the best results with combination DMARD therapy. The gold standard treatments for osteoarthritis and rheumatoid arthritis are, respectively, anti-inflammatories (Acetaminophen) and a DMARD, such as methotrexate[6].

TKR is the most invasive, but only effective, treatment for many arthritic joints. Even when the surgery is performed with no immediate sequelae, most patients require the procedure again within five to ten years.[5] This short life of a knee implant necessitates a quick, painless recovery in order to be of value to an aging patient with a growing list of other critical medical conditions.

OBJECTIVE

The objective of this selective EBM review is to determine whether or not a mobile-bearing vs. a fixed-bearing total knee replacement affects post-operative knee pain at one year.

METHODS

Studies chosen must meet certain criteria to be used in this selective EBM review. The control group for these studies is the fixed-bearing implant, the traditional knee replacement. The newer, revised mobile-bearing implant will be the experimental group. The outcome measured is post-operative knee pain at 1 year.

All chosen studies are double-blind randomized controlled trials in order to ensure the exclusion of patient or researcher bias. Articles were selected using multiple criteria. All articles are primary literature published after 1996. Each trial used a mobile and fixed-bearing implant produced by the same manufacturer, to reduce outstanding variables. A large, heterogeneous population is desired to be able to accurately generalize results of the study to the greater population receiving this treatment. Randomization is more likely to achieve external validity.[7] Additionally, identical anesthesia type, procedure, discharge criteria, post-operative medications and rehabilitation programs must be performed between control and experimental groups of each study. Lastly, pain must be quantified by the patient, in order to qualify as a POEM.

In selecting studies, the key words “mobile-bearing TKR”, “fixed-bearing TKR” and “pain” were used in PubMed and the Cochrane Database of Systematic Reviews. All three articles were found written in the English language, although one was written in Sweden, one in Germany, the other in Amsterdam. All three articles are published in three different orthopedic journals. Jolles et al[8] and Lampe et al[9] are written by a compilation of scientists and researchers working in a team. Breugem et al[10] is compiled from a team of five MD, PhD scholars and one Master of Science researcher.

Inclusion criteria for article selection include studies that are controlled, randomized, double-blind, similar demographics between controlled and experimental groups, and recent publication. Exclusion criteria include studies that solely provide pre-operative pain measurement, did not include both fixed and mobile-bearing knee implants, small study population, or a high withdrawal/drop out rate. Although the studies used multiple questionnaires and blinded, objective observers to determine efficacy of each implant, statistical techniques utilized here to measure outcomes include only those that are subjective reports of the patient's knee pain. All three studies used p-values to analyze the results and determine clinical significance.

OUTCOMES MEASURED

The outcome measured in all three studies is post-operative knee pain, a POEM (Patient Oriented Evidence that Matters). The knee pain was measured as continuous data using multiple questionnaires, range of motion measurements, and gait analyses. However, since POEMs are concerned solely with the patient's interpretation of his or her post-operative pain, this review analyzes only the patient's account of the pain. The questionnaires used for this review had a statement and the patient chose which category applied to them, ex. mild pain, intermittent pain, etc. These responses were then scored. The entire questionnaire received one numeric score inside a range of possible scores--Ex. 83 on a scale of 0-100.

For Jolles et al[8], each patient completed the EuroQol questionnaire, Western Ontario & McMaster Universities osteoarthritis index, Knee Society score, and visual analog scales.

Table 1- Demographics & Characteristics of Inlcuded Studies

Study	Type	# Pts	Age (yrs)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Jolles[8]	Double blind RCT	55	Any age, mean age 68.6	u/l OA of the knee awaiting a TKR	Pts with OA of hip and/or neurological sx	1	Mobile-bearing (n=26) or fixed-bearing (n=25) prostheses of the same design
Breugem[10]	Double blind RCT	103	>21	Otherwise good health	Revision or u/l knee arthroplasty, patellectomy, fixed varus or valgus deformity >20 degrees, skeletal immaturity, Charcot joints, non-cooperative to follow-up, life expectancy <5 yrs, no signed informed consent	1	Posterior-Stabilized Fixed Prosthesis (n=55) or Posterior-Stabilized Mobile Prosthesis (n=48)
Lampe[9]	Double-blind RCT	100	70 +/- 8 (52-84)	Informed consent, OA of knee, failed non-operative tx, uni-compartmental implants not an option, age 40-90 yrs, ASA pre-op classification grade 1-3, no deformity >20 degrees varus or 15 degrees valgus, no previous bone surgery to index knee, no previous joint replacement at index leg, no post-op infection or thrombosis in follow-up period	None stated	4	Fixed-bearing prosthesis (n=52) or mobile bearing version (n=48) of same implant

Breugem et al[10] assessed one year post-operative pain using Visual Analog Scales, Oxford 12-item questionnaire, and SF-36. Lampe et al[9] compared Oxford, Knee Society and Knee Society Functional scores at one year post-TKR.

All of the questionnaires are filled out by the patient and administered by an uninvolved person double-blinded to the study. Each questionnaire raises its own unique set of questions to determine the patient's direct level of pain as well as the effects of this pain on his or her daily functionality. An example question from the Knee Society Score is, "For how long are you able to walk before the pain in your knee becomes severe?"[11] The Visual Analog Scale works similarly but differs in the fact that it allows a more accurate depiction of the patient's pain by allowing the patient to mark their pain at any location on a 10-centimeter line. This allows pain to rate as a 5.6 instead of either a 5 or a 6, for example.

RESULTS

Three studies compared post-operative knee pain at 1 year between the fixed-bearing and mobile-bearing total knee replacement. The evaluation methods were not identical but all questionnaires shared similar features. The data from all three studies contained continuous data that could not be converted to dichotomous data. Therefore, the analysis of risk reduction (RRR), absolute risk reduction (ARR), and numbers needed to treat (NNT) could not be calculated.

Jolles et al[8] (Table 2) shows that VAS and WOMAC demonstrated significantly less pain in the fixed-bearing implants ($p \leq 0.05$), yet EuroQuol, Knee Society Score, and Knee Society Function showed no difference (p-value >0.05). Thus, this study is inconclusive

Table 2 – One Year Post-Operative Knee Pain Questionnaire Scores (Jolles et al[8])

	Fixed-Bearing	Mobile-Bearing	P-Value
EuroQuol	79.6	82.9	0.67
Visual Analog Score	1.4	2.4	0.02
WOMAC*	13.4	22.8	0.019
Knee Society Score	78.6	73.3	0.34
Knee Society Function	82.4	86.4	0.71

*WOMAC: Western Ontario & McMaster Universities Osteoarthritis Index

At the one-year follow-up for Breugem et al[10] (Table 3), less anterior knee pain was experienced in the patients that received the mobile-bearing implants. With a p-value = 0.03, these results are significant. Additionally, the patients with anterior knee pain reported a decreased quality of life.[10]

Table 3 – One Year Post-Operative Knee Pain Questionnaire Scores (Breugem et al[10])

	Fixed-Bearing	Mobile-Bearing
Knee Society Score	82.7 (95% CI: 77-88.4)	83.2 (95% CI: 77.5-88.8)
Knee Society Function	65 (95% CI: 56-74)	60.8 (95% CI: 49.1-72.4)
Visual Analog Score	21.9 (95% CI: 13.2-29)	19.2 (95% CI: 12.2-26.2)
Oxford Knee Score	24.2 (95% CI: 21.2-27.2)	26.1 (95% CI: 22.3-29.8)
SF-36 Q7 (Pain)	25.9	24.6

The Study conducted by Lampe et al[9] (Table 4) clearly shows no statistically significant difference between the fixed-bearing control group and mobile-bearing experimental group, with all three p-values greater than 0.05.

Compliance within the studies overall was very high. Jolles et al[8] kept all participants except one, excluded for post-surgical varus laxity. Breugem et al[10] lost only one participant due to post-surgical cardiac events causing his demise. Lampe et al[8] went from 100 to 96 at the 12 month follow-up due to patient withdrawal.

Table 4 – One Year Post-Operative Knee Pain Questionnaire Scores (Lampe et al[9])

	Fixed-Bearing	Mobile-Bearing	P-Value
Knee Society Score-Functional	88 +/- 13 (CI: 45-100)	87 +/- 13 (CI: 50-100)	0.694
Knee Scale	85 +/- 14 (CI: 41-100)	88 +/- 12 (CI: 40-100)	0.328
Oxford Knee Score	21 +/- 9 (CI: 12-52)	20 +/- 8 (CI: 12-43)	0.434

DISCUSSION

The theoretical advantage of the mobile-bearing prosthesis is the ability to self-align and therefore to accommodate small mismatches, which could lead to a decrease in the incidence of anterior knee pain.[10] Breugem et al[10] concluded that the mobile-bearing implant ultimately yields less knee pain one year after replacement. Lampe et al[9] clearly found that there is no difference in post-operative knee pain between implant designs. Jolles et al[8] was inconclusive, as two questionnaires demonstrated $p \leq 0.05$, while the other three indicated a $p > 0.05$. The analysis of these three studies yields an inconclusive answer to the originally posed question of whether or not the type of prosthesis influences post-operative knee pain.

Although Breugem et al[10] reported that the mobile-bearing implant showed significantly less anterior knee pain in the first four weeks following the procedure ($p = 0.001$), the reported pain at the one year mark was still less, but the gap was closing between the two implant types. This could potentially have important future implications. If it can be proven that one implant promises an easier short-term recovery, it may appeal to many patients. A study to elaborate on this would be determining the most important outcome to a patient. If post-operative range of motion is more important to patients, then

they will most likely choose their implant based upon that, instead of post-operative pain. This could have major implications for manufacturer marketing.

TKR complications are rare but serious. As with any other major surgery, there is a possibility of infection, post-operative embolism, or MI. With wear and tear, the knee replacement erodes the plastic spacer, leading to increased pain. Commonly, scarring of the knee occurs, further limiting the possible post-operative ROM.[12] Additionally, most surgeons advise against strenuous physical activity, such as running and jumping for the remainder of the patient's life.

A significant limitation of all three studies is the subjectivity of the responses. Arguably the best way to conduct a study, yet not humane to the patient, in order to accurately evaluate knee implants would be a bilateral knee replacement with one fixed and one mobile implant in each knee. This would enable the patient to compare, instead of having only one new knee with no reference point besides the damaged pre-operative knee. However, the intense TKR recovery does not allow for this type of treatment in most patients. Another pitfall is that each study used the same brand implant. So these results have been proven for only three different brands of implants and cannot be generalized to all manufacturers.

CONCLUSIONS

Analysis of these three studies shows inconclusive evidence on whether or not a mobile-bearing versus fixed-bearing total knee replacement affects post-operative knee pain. A limitation of these three studies is testing the best implant relative to gender or race. The gender-specific knee replacement is on the market, but a further reach of this study would be to test its true efficacy in the increased angle of female knees.

Future studies are also warranted to determine the benefit of a mobile-bearing knee replacement. Numerous products in all facets of life are created and marketed as different in a minute detail from the standard product. Whether or not this slight difference makes an actual difference in the consumer's quality of life must be determined. Studies to determine factors that increase the life of an implant are also essential due to the long post-operative recovery and short life of a TKR.

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