# Patient specific instrumentation versus standard of care in total knee arthroplasty: a randomized trial in an obese population.

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INTRODUCTION:

Successful total knee arthroplasty (TKA) depends on knee alignment, soft tissue balancing, and appropriate component position. Patient specific instrumentation (PSI) has been introduced in TKA with the goal of increased accuracy of component positioning by creating custom fit cutting guides to match the patient's bony anatomy. Increased accuracy in component positioning has the potential to improve outcomes in all patient populations. Obese patients in particular present increased technical challenges associated with proper exposure and determining appropriate alignment. Thus, techniques to improve accuracy in this cohort could have particular benefit. We have previously shown that PSI was more costly and less effective than standard of care in the early term from a health care payer perspective in this cohort. Longer term clinical and radiographic outcomes in this obese cohort should be considered. The present study aims to compare PSI to standard of care (SOC) in obese patients undergoing primary TKA at 5 years postoperatively.

METHODS: A single center randomized trial was completed with patients undergoing surgery between January 2015 and January 2018 by one of five fellowship trained arthroplasty surgeons at a tertiary academic center. Patients between the ages of 20 and 70 years, with body mass index (BMI) greater than 30 and osteoarthritis undergoing primary TKA were randomized to SOC or PSI. Patients were excluded if they previously had open knee surgery, infection, or history of trauma to the affected knee, were scheduled to under simultaneous bilateral TKA, had underlying dementia or cognitive delay, inflammatory arthritis, chronic pain syndrome or fibromyalgia. All participants were evaluated at baseline, 6 weeks, 3, 6 and 9 month, 1 year and 5 years post-operatively. Participants had radiographs taken and completed patient reported outcome measures, including the Short Form 12 survey (SF-12) and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). Surgeons evaluated participants using the Knee Society Score (KSS). Medical and surgical adverse events were recorded.

RESULTS:

At 5 years, 158 participants were available for analysis. (Figure 1) There were 80 in the PSI group and 78 in the SOC group. Demographics including age, sex, BMI were similar between groups. There was no difference in baseline SF-12, WOMAC or KSS between groups. There was no significant difference in these outcomes between PSI and SOC at 5 year post-operative. Mean total WOMAC score for PSI and SOC were 82.5 ± 19.3 and 83.2 ± 15.9, respectively (p=0.83). Rates of adverse events were similar between groups. There were five (6.3%) revisions in the PSI group and two (2.6%) revisions in the SOC group (p=0.44).

DISCUSSION AND CONCLUSION:

Our results suggest there is no significant difference in patient reported outcomes, function or adverse events at five years of follow-up in obese patients undergoing primary TKA with PSI or SOC. Participants will continue to be followed for longer term evaluation of this technique.