Implant Migration and Peri-prosthetic Bone Quality of Uncemented Tibial Base Plates with or without Screw Fixation
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INTRODUCTION:
The foam foam backed Advance BioFoam total knee arthroplasty components utilize a porous titanium coating on the underside of the tibial baseplate, intended to promote bone in-growth and provide a more robust bone-implant interface without cement. There is also a version of the Biofoam Advance that incorporates screwed fixation that allows for augmented fixation with four titanium screws; however, it is not clear that this augmentation is necessary. In addition, the presence of screws may have an impact on the quality of the bone surrounding the tibial component. The objective of this study was to employ radiostereometric analysis (RSA) to compare implant migration and dual energy x-ray absorptiometry (DEXA) to compare bone mineral density in a randomized controlled trial of this implant design with or without screw fixation.

METHODS:
Fifty-one subjects were randomized to receive a BioFoam total knee replacement (Weight Medical) with or without screw fixation. This study was approved by the local Research Ethics Board and informed consent was obtained from each subject before enrollment. During surgery, eight tantalum markers, one millimetre in diameter, were inserted into the proximal tibia. Using a calibration box, stereo RSA radiographs were taken post-operatively and then again at six weeks and three, six, 12 and 24 months following surgery. Model Based RSA was used with 3D models of the tibial component to measure migration.

Bone density of seven regions of the proximal tibia (medial, lateral, anterior, and posterior to the stem; and three regions below implant tip) was measured with DEXA pre-operatively and post-operatively at two and six weeks, and three, six, 12 and 24 months.

Health outcome questionnaires (Womac and Oxford Knee Score) were used to capture self-reported health status before surgery and at each follow-up interval.

Functional assessments of gait were made pre- and post-operatively using the Walkabout Portable Gait Monitor (WPGM), a light-weight belt, consisting of three, tri-axially arranged, accelerometers applied at the lumbar region of the spine during level walking. It measures the user’s acceleration in x, y and z directions and records data at 200 Hz for 20 seconds. Custom software converts the accelerations to velocities and displacements in the three-dimensional coordinate system and calculates the following gait characteristics: stride frequency, envelope, surge, lurch and functional leg length discrepancy.

RESULTS:
The with screw fixation and without screw fixation groups did not differ in age (with screws: 69±5.2 years, without screws: 68.9±6.7 years; p value = 0.964) or BMI (with screws: 30.6±4.2 kg/m², without screws: 30.0±4.6 kg/m²; p value = 0.655).

The migration results were calculated as maximum total point motions (MTPM), or the motion of the standardized point on the implant that moved the most, and were compared between groups using a repeated measures ANOVA. MTPM results at one year were 1.34±0.88 mm for screw fixation and 1.59±1.44 mm without screw fixation (p value = 0.204). The clinical precision of the MTPM metric is 0.34 mm, calculated as the standard deviation of measurements made from double exams of all patients. For the migration about the individual anatomical axes, a difference between groups was seen only for tilt about the medial-lateral axis (with screws: posterior tilt of 0.17±1.08 degrees; without screws: posterior tilt of 0.74±1.31 degrees; p-value = 0.041).

The bone mineral density was not significantly different between groups pre-operatively. Post-operatively, there was a statistically significant difference between groups only for one region of interest: the lateral region in the anterior-posterior view. At one year the group with screw fixation had an increase in bone mineral density of 0.234 g/mm² compared to pre-operative bone mineral density, while without screw fixation, the change in bone mineral density was 0.069 g/mm² (p-value = 0.001).

Health outcome questionnaire results were not statistically significant between groups for any metric pre- or post-operatively.

There were no significant differences between groups for any of the gait parameters.

DISCUSSION:
The migration results at one year indicate that the addition of screws does not significantly impact implant fixation in the short term. At one year, the changes in bone mineral density are equivalent between groups for six out of seven regions of interest. Longer term monitoring of the migration and peri-prosthetic bone mineral density changes for these two implant groups will continue. Although higher than the migration seen with cemented tibial components, the amount of migration is comparable to other uncemented designs.

SIGNIFICANCE:
The evaluation of new uncemented total knee arthroplasty components is important to prove sufficient fixation. In addition, the selection of augments to enhance fixation is typically up to the discretion of the surgeon and this study provides evidence the addition of screws is not necessary for adequate fixation.