Shape Match Derived Kinematic Alignment versus Conventional Alignment using Computer Navigation for Total Knee Arthroplasty in a Randomized Trial using Radiostereometric Analysis

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Introduction: Surgical techniques for implant alignment in total knee arthroplasty (TKA) has expanded recently as multiple manufacturers introduce patient-specific cutting blocks derived from 3D reconstructions of pre-operative imaging, commonly MRI or CT. The patient-specific OtisMed system uses a detailed MRI scan of the knee for 3D reconstruction plus a full leg scan to estimate the kinematic axis, dictating the cutting planes in the custom-fit cutting blocks that are machined for each patient. The resulting planned alignment can vary greatly from a neutral mechanical axis. The purpose of this study was to evaluate the early fixation of components in subjects randomized to receive shape match derived kinematic alignment or conventional alignment using computer navigation. A subset of patients were evaluated post-operatively with gait analysis.

Methods: Thirty-eight patients were randomized to receive cruciate retaining cemented TKA (Triathlon, Stryker) using computer navigation aiming for neutral mechanical axis (standard of care) or patient-specific cutting blocks (OtisMed custom-fit blocks, Stryker) derived from pre-operatively MRI scans. Radiostereometric analysis (RSA) exams and health outcome questionnaires were performed post-operatively at 6 weeks, 3 months, 6 months, and 1 year. A subset (9 subjects) of the patient-specific group underwent gait analysis (Optotrak TM, AMTI force platforms) one year post-TKA, capturing three dimensional (3D) knee joint angles and moments. Principal component analysis (PCA) was applied to the 3D gait angles and moments of the subjects. Angle and moment patterns were compared to a case-matched control group who also had standard computer navigated surgery.

Results: Five MRI scans for surgical planning were not useable due to motion artifacts, with 2 successfully re-scanned. The patient-specific planned overall alignments ranged from 4 degrees valgus to 9 degrees varus. Ligament releases were performed in 62% of navigation cases and 32% of patient-specific cases. One patient-specific case was revised for failure of the cruciate ligament, resulting in a polyethylene liner exchange for a thicker, cruciate substituting insert. Implant migration at 1 year was not different between groups, 0.44±0.29 mm for the patient-specific group and 0.37±0.20 mm for the navigation group (maximum total point motions; t-test P =0.46; 95% confidence interval from double exams = 0.14 mm). EQ-5D and Oxford Knee scores, satisfaction, pain, and range of motion were not different between groups at any follow-up including the polyethylene liner exchange case. During one-year post-operative gait, the patient-specific group had a lower early stance phase flexion moment magnitude in the than the computer navigated recipients, bringing patterns further away from asymptomatic characteristics (P = 0.02).

Discussion: Implant migration was not different between groups at 1 year despite differences in planned implant alignment. Both groups have implant migration of less than 0.5 mm at 1 year, categorizing them as “safe” according to Pijls et al (2012). Subject function and satisfaction were also not different between groups, despite significantly fewer ligament releases in the patient-specific group. However, gait analysis of a subgroup has not shown an improvement towards restoring asymptomatic gait, and in fact showed a move further from asymptomatic in terms of the magnitude of early stance phase flexion moment. It should be acknowledged that the production of patient-specific cutting blocks may not be possible for all patients due to the MRI scanning requirements. Continued evaluation with RSA and gait to 2 years will be performed to monitor these subjects over the longer term.

Significance: The data show that deviation from neutral mechanical alignment in total knee arthroplasty does not have a detrimental effect on implant fixation to 1 year.

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