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Protocol and Statistical Plan

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The purpose of this study was to determine patellar kinematics in TKA patients with medialized dome and medialized anatomic patellae during a seated knee extension and a weight-bearing lunge activity using high-speed stereo radiography (HSSR). Flexion of the patella in the sagittal plane was reported relative to the femur and with respect to the long axis of the tibia to enable comparison to prior reports that utilize each of these anatomic references. Based on prior computational evaluation, we hypothesized that patients with anatomic patellar implants would exhibit greater patellar flexion relative to the femur and less external rotation, greater knee extension strength, and improved patient-reported outcomes compared to patients with dome patellar implants.

Twenty-seven subjects with posterior-stabilized, rotating-platform total knee arthroplasty (ATTUNE Knee, DePuy Synthes Products, Warsaw, IN) were recruited for this study after the approval of the Institutional Review Board of the University of Denver and registration on www.clinicialtrials.gov (NCT02532933). All subjects signed informed consents. A power analysis (90%) using an effect size of 8 degrees resulted in a sample size of 16 subjects per group [10]. Subjects were required to be at least nine months post-operation and with no reported concomitant orthopaedic conditions or neurologic disorders that hindered normal movement. All subjects were patients of the surgeon co-authors, Drs. Dennis and Haas, and each surgeon contributed patients from both the dome and the anatomic groups. Surgeons performed TKA using a femur-first gap-balancing operative technique [12]. Patient selection criteria for dome v. anatomic patellae was not considered, as the focus of this study was solely on differences due to implant design.

Postoperatively, at the time of testing, subjects completed *Part 2 – Function* of the Knee Society Score (KSS) questionnaire, the Knee injury and Osteoarthritis Outcome Score (KOOS), and the Patient's Knee Implant Performance (PKIP) Questionnaire [13–16]. Because the completion of specific activities of daily living were required for this study, only participants scoring good or excellent (>69) on the KSS were

included in the study. Height, weight, and leg dominance were recorded. Maximum isometric flexor and extensor strength were evaluated at 60° knee flexion and normalized to body weight. (Cybex, Medway, MA).

Subjects performed a non-weight-bearing seated knee extension and a weight-bearing lunge activity while conventional marker-based motion capture (Vicon Motion Systems, Ltd., Oxford, UK) recorded whole-body motion and HSSR captured x-ray images of the knee joint in two planes (50 Hz, Figure 1). Femur, tibial tray, and patellar component CAD geometries for each subject were obtained from the manufacturer. The femoral and tibial tray geometries were used to track the motion of the respective implants (Autoscoper, Brown University, Providence, RI) [17]. Accuracy of the HSSR is 0.2±0.1 mm in translation and 0.4±0.3 degrees in rotation, comparable to those measured in other stereo radiography systems [11,18,19]. Because the patellar component is radiolucent, it was not visible in the x-ray images. Thus, images of four static poses of each subject's patella were recorded with the HSSR and used to derive the 3D patellar bone geometry of each subject using a previously-developed statistical shape model (SSM) [20]. The resection plane of the implant was assessed based on the radiographic images and the patellar component model fit on the posterior surface of the SSM developed for each subject (Figure 2).

Sagittal plane patellar flexion was reported with respect to a medial-lateral axis on the femur (PF flexion), PF tilt was reported with respect to the inferior-superior axis of the patella, and medial-lateral translation was described along the medial-lateral axis of the femur. In addition, patellar sagittal plane flexion was reported with respect to the long axis of the tibia (patellotibial (PT) flexion) [21] for comparison to prior work that uses PT flexion as the convention. In general, higher PF flexion is associated with lower PT flexion. The maximum knee flexion achieved during each activity was measured from marker-based motion capture [22].

Unpaired, two-tailed Student's t-tests ($p<0.05$) were used to compare kinematic measurements between the dome and anatomic groups, and paired, two-tailed t-tests ($p<0.05$) were used to compare kinematic measurements between the knee extension and lunge activities. Pearson's correlation coefficients between measurements were calculated.

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