INTRODUCTION:

Hinge knee systems are used to treat gross knee instability resulting from loss of collateral ligament function, femoral and/or tibial bone loss including the insertions of the collateral ligaments or patellar tendon, or comminuted fractures of the proximal tibia or distal femur. Failure of the link and/or hyperextension mechanisms were common issues associated with previous hinge knee systems. A new hinge knee system (LEGION HINGE, Smith & Nephew, Inc.) was designed to address these issues. The knee system is composed of several functional mating parts including both metal and polyethylene components and is offered with an insert that guides the motion of the implant for kinematic improvement (Figure 1).

The purpose of this study was to evaluate the kinematic, fatigue and wear performance of this novel hinge knee replacement system.

METHODS:

Kinematic study: Kinematics and kinetics of the LEGION HINGE Guided Motion (GM) knee system were assessed for a deep knee bend using a numerical lower leg simulator (LifeMOD, San Clemente, CA). Measurements of anterior-posterior (A-P) and internal-external (I-E) rotation and translations over the flexion range were compared to 3D MRI data of healthy weight bearing knees [1], and measurements of medial-lateral (M-L) patella shear forces were measured to a standard primary knee implant.

Fatigue study: Five knee systems were tested to evaluate the construct fatigue performance. The tibial base was cemented to a fixture at 30° of simulated flexion. The femoral component was attached to a linear translator to allow free A-P motion. A sinusoidal compressive load of 80/800 lbf (355.86/3558.58 N) at 1 Hz frequency was applied.

Another five knee systems were tested to specifically evaluate the characteristics of the hyperextension stop mechanism, with the whole assembly during hyperextension and varus-valgus (V-V) loading. The tibial tray was cemented to a fixture that has a built-in angle of 5° hyperextension which is the maximum allowed. The tibial tray was tilted by 2° using a step block to induce the maximum V-V moment. A sinusoidal compressive load of 60/600 lbf (266.89/2668.93 N) at a frequency of 10 Hz was applied. The sleeve taper pull-off force was measured at the end of the both tests.

Wear study: Three knee systems were tested for wear performance. All metal components were fabricated from cobalt chrome except for the Ti-6Al-4V insert locking screw. All plastic components were fabricated from UHMWPE. Wear testing was conducted on an AMTI 6-station force controlled knee simulator at 1 Hz frequency for approximately 5 million cycles under ISO 14243-1 load/motion profiles and soft tissue constraints. 50% Alpha calf bovine serum (average protein concentration: 20 g/l) was used as lubricant and was replaced every 0.5 million cycles. Gravimetric measurements of all polyethylene parts and metal parts except axle plugs, femur and tibial tray were made at the beginning and end of the experiment only as disassembling the constructs weekly would compromise the integrity of the press-fit bushings, taper lock, post bolt and axle plugs. Soak controls of each polyethylene component were used to correct for fluid absorption. Mass measurements were divided by their corresponding densities (UHMWPE: 0.93 g/cm³, CoCr: 8.28 g/cm³, Ti-6Al-4V: 4.42 g/cm³) to obtain volumetric wear. The results of the test all of the components were inspected for any damage and wear patterns.

RESULTS:

Kinematic performance: Simulation results showed that up to 130° of flexion the A-P translation and I-E rotation followed a similar path over the flexion range compared to the MRI data (Figure 2). The magnitude of A-P translation at 130° was 9.5 mm for the GM design compared to 15.7 mm for the MRI data. The magnitude of I-E rotation at 130° was 18° for the GM design compared to 20.8° for the MRI data.

Fatigue performance: All constructs successfully completed 10 million cycles of fatigue testing. After testing the hinge knee was fully functional with no signs of damage to the hyperextension stop or any of the polyethylene components. No significant fretting was seen on the post-bolt or on the inner and outer diameters of the post sleeve. Axes showed small areas of fretting at the ends due to loading with the femoral component. The average sleeve taper pull-off forces after the 30° flexion and hyperextension fatigue tests were 543.96 ± 115.07 lbf (2419.65 ± 511.86 N) and 416.94 ± 167.90 lbf (1854.64 ± 746.86 N), respectively.

Wear performance: All constructs successfully completed wear testing and were fully functional with no issues of binding of the mating parts. All polyethylene components showed only burningish on the articulating surfaces. The volumetric wear rate of polyethylene components was 17.54±1.24 mm³/Mcycle. The volumetric wear rate of the metal components (excluding femoral and tibial tray) was 0.045±0.01 mm³/Mcycle.

DISCUSSION:

Kinematic analysis showed the GM design has A-P and I-E kinematics that are similar to those seen in a normal healthy knee and good patella tracking as evidenced by the low M-L patella shear forces. Fatigue testing revealed no signs of damage to the hyperextension stop or any of the components. The wear rate of the polyethylene parts was within the range of wear rates published in the literature for primary knee designs (up to 35.8 mm³/Mcycle). The low metal wear rate indicates that fretting and corrosion of the components was minimal.

The GM design has been shown to closely replicate the kinematics of the natural knee without compromising the fatigue and wear characteristics, which could lead to better outcomes for the patient population that requires a hinge knee implant.

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