TECHNIQUES

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TRANSVERSE PLANE SHEAR TEST FIXTURE FOR TOTAL KNEE SYSTEM

Reliable test methods for determining the stiffness, strength, and durability of total knee replacements are required for the evaluation of new designs and materials. It is very important in testing to evaluate the designs under conditions that closely resemble physiological conditions and conform to established testing standards. Physiological loading on the knee comprises axial compression, anteroposterior shear, mediolateral shear, and internal-external torque. A variety of test fixtures have been developed that can simulate this complex loading environment experienced by knees. However, in practice, the tests do not need all the degrees of freedom for quality assessment and inspection. The acceptance of any test method or fixture by the industry depends on its ease of use and cost of implementation. In this paper we present a new test fixture designed for anteroposterior shear (and also mediolateral shear) that is simple yet effective. The test fixture developed is for use in a uniaxial tension-compression material testing system that is readily available in all materials testing laboratories.

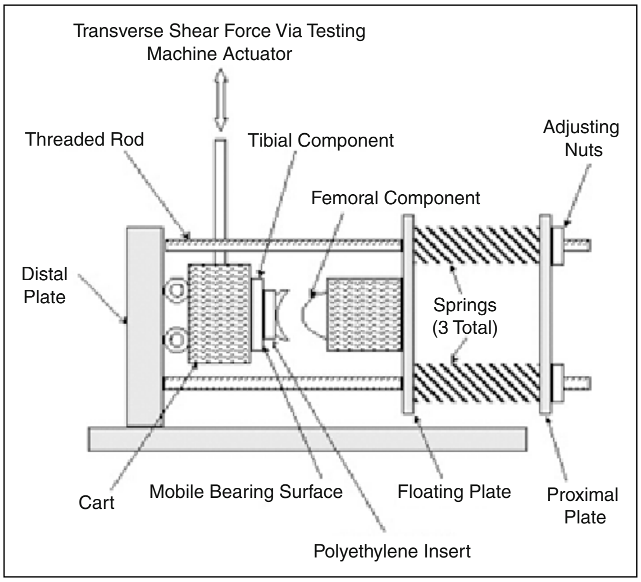

Fig. 1: Schematic of the transverse shear knee joint test fixture

Anteroposterior and mediolateral (transverse plane) shear is a loading mode recommended as a standard test for total knee replacement systems.[1] Transverse plane shear tests require a biaxial testing machine because a compressive force that simulates body weight must be applied in addition to the shear force on the knee. Examples of test fixtures capable of multiple degrees of motion and force actuation to reproduce complex load environments in knees are presented by Walker et al.[5] and Woo et al.[6] The equipment developed by Walker et al.[5] was capable of three degrees of translation motion that can provide axial compression, anteroposterior shear, and mediolateral shear, and one rotational freedom that provides the torque loading. Woo et al.[6] presented a six degree of freedom robotic and universal force-moment sensor testing system. These devices while very sophisticated have limited use in an industrial testing and quality assessment program due to the complexity and cost of implementing such a system.

More tailored test methods and fixtures that can perform a particular test using already available test equipment are highly desirable. Heim et al.[2] developed such a testing machine with biaxial actuators to perform anteroposterior shear tests on knee joints. The test fixture of Heim et al.[2] used an electromechanical actuator on a uniaxial materials testing machine for application of anteroposterior shear displacement and a separate pneumatic actuator for application of compressive joint displacement. In line load cells were used to measure reaction forces. Their testing machine, though simpler than the devices of Walker et al.[5] and Woo et al.[6] still required two force actuation systems. Here, we present a simpler test fixture that can be used to test total knee replacement in anteroposterior or mediolateral shear with the simultaneous application of an axial compression force. The details of the design and fabrication are discussed and demonstrated by an anteroposterior shear test of a commercially available knee replacement system.

MATERIALS AND METHODS

Fixture Description

The fundamental idea was to use the actuator of an existing servohydraulic materials testing machine to apply a controlled anteroposterior shear force and a set of compression springs (McMaster Carr; Chicago, IL) to apply a constant joint compression force. A schematic diagram of our fixture is shown in Fig. 1. A photographic image of the fixture as installed in the testing machine is provided in Fig. 2. The tibial and femoral bone shafts are replaced by pine wood blocks into which the knee components are mounted. The tibial end is mounted to a “cart” equipped with an anterior and a posterior axle, upon each are mounted two “wheels” (bearings). The cart wheels ride within two parallel tracks machined into the fixed distal plate. The testing machine actuator is connected to the cart through a load cell. The distal plate is mounted securely to the horizontal platen of the materials testing machine. The simulated femur is mounted securely to the floating plate. Between the floating plate and the proximal plate are three compression springs. The simulated femur is mounted so that an axis through the centroid of the three springs passes approximately through the joint center. Three longitudinal threaded rods connect the distal and proximal plates and pass through the floating plate. In this way, the springs impart a compressive force

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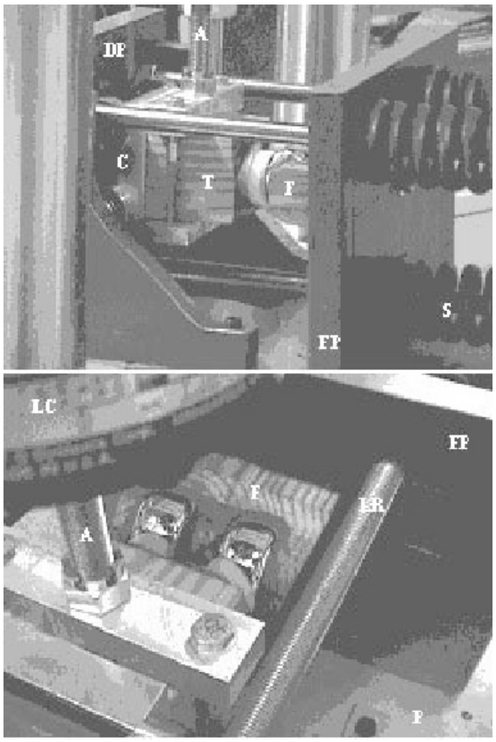

Fig. 2: Oblique mediolateral (top) and anteroposterior (bottom) views of test fixture used to perform anteroposterior shear testing of knee implants. The springs (S) supply a constant compression force based on their deflection. The simulated tibia (T) is attached to a cart (C) attached to the load cell (LC) and the actuator (A) of a materials testing machine. The cart rolls anteroposteriorly or mediolaterally (vertically) on bearings in tracks machined within the distal plate (DP), which is attached to the platen (P) of a materials testing machine. The load cell is mounted to the actuator to supply load feedback. The simulated femur (F) is attached to the floating plate (FP). Longitudinal rods (LR) pass through the floating plate and attach to a proximal plate (not shown).

across the knee joint. The floating plate “floats” on polytetrafluoroethylene (PTFE or Teflon®) bearings fitted between the plate and the longitudinal connecting rods. The proximal plate can be positioned and secured with nuts on the threaded rod for any desired compressive force using predetermined calibration data. Anteroposterior shear force is applied by the vertical actuator of the testing machine. The embodiment of the design imposes external constraints on all rotations and shears except that which is being tested (anteroposterior shear *or* mediolateral shear) but does not impose motion constraints on internal components.

Calibration Tests

Calibration between joint compressive force and floating plate position with respect to the proximal plate position was accomplished by mounting the floating plate-spring-proximal plate assembly (we call this the “spring pack”) vertically within the operating theater of the materials testing machine. This calibration was performed before and after the knee testing. A 5 kN load cell was mounted to the testing machine actuator and aligned with the centroid of the three springs. The compressive reaction force was recorded as the actuator was displaced downward at a constant quasistatic rate. The before test calibration constant (675 N/mm) indicated how much spring compression was required to impart a specific joint compressive force. The after test calibration constant (679 N/mm) indicated little change in calibration occurs after performing tests (less than 0.6% change).

Demonstration Tests Methods

A knee implant system was obtained from an orthopedic implant manufacturer (Encore Orthopedics; Austin, TX) to demonstrate the shear fixture. The implant is a mobile bearing design. The underside of the ultra high molecular weight polyethylene (UHMWPE) tibial insert has an elongated anteroposterior slot which snaps onto a post on the tibial baseplate. The slot allows the insert to move relative to the baseplate during knee joint motion. Thus, evaluating this system with anteroposterior shear loading is important, as concerns exist with regard to slot elongation during cyclic loading as well as joint dislocation. Other specific details of the system are not disclosed for proprietary reasons and are not required for the purposes of describing the test fixture. The tibial baseplate component was cemented with poly methyl methacrylate (PMMA) into a closely fitting cavity within a pine wood block. One of two tibial inserts then was installed upon the baseplate. The femoral component was cemented similarly onto a machined wood block. Each was mounted as described previously to form a joint flexion angle of 0°, although any joint flexion angle can be produced. A compressive force of 2,890 N was applied by positioning of the proximal platen. This force represents the joint compressive force for a 720 N person during the walking gait when the anteroposterior shear force is a maximum.[3,4] A drip and recovery system was set up so that the contact surfaces would be continuously lubricated with bovine serum (Pel Freeze Biologicals; Rogers, AR), to simulate a total knee replacement postoperative intracapsular environment.

A monotonic test to failure was performed first with a single tibial insert, followed by a cyclic fatigue test with another insert. Test control and data acquisition were accomplished with custom virtual instrumentation on a desktop computer. The monotonic test was performed so that the simulated tibia displaced posteriorly until the femoral component dislocated anteriorly. The cyclic fatigue test was performed in sinusoidal load control at a frequency of 1 Hz with a peak posterior shear force of 1,450 N (tibia translates posteriorly) and a peak anterior shear force of 725 N. These shear forces represent the peak shear forces for a 720 N person during the walking gait.[3,4] A digital caliper was used to measure the growth in the anteroposterior dimension of the elongated slot on the tibial insert after each logarithmic decade of loading (1 cycle, 10 cycles, 100 cycles, . . .). This dimensional growth was interpreted to represent the increase in the anteroposterior range of motion for the knee system.

RESULTS

Demonstration Tests

The femoral component did dislocate anteriorly in the monotonic test as the tibial component was displaced posteriorly.

The compression springs are sized so that very little motion of the fixture floating plate occurs upon complete knee dislocation, meaning that the dislocation event within the fixture is quite subdued and nowhere near the violent event one might imagine. In the cyclic fatigue test, this particular knee design suffered an anterior dislocation of the femoral component upon the tibial insert, similar to the monotonic test, after several thousand cycles. Typical anteroposterior shear force and displacement data are provided (Fig. 3). For proprietary reasons, the shear forces (as measured by the load cell) and tibial displacements (as measured by the materials testing machine) have been normalized: each value is divided by the peak anterior or posterior shear force or displacement, respectively. The growth in the range of motion for this knee system indicated relatively monotonic growth up to failure (Fig. 4). Again for proprietary reasons, the results are presented in a normalized manner: the change in the range of motion is divided by the maximum change, and the number of cycles of loading have been divided by the (maximum) number of cycles to failure.

DISCUSSION

A test fixture has been designed, fabricated, and demonstrated which should prove useful in the evaluation of total knee systems with respect to their anteroposterior and mediolateral shear mechanical behavior. The two shears are tested separately as the fixture constrains all external rotations and translations except the one being tested. However, rotations and translations internal to the implant system remain unconstrained. The fixture is simple to construct and integrate within a standard mechanical testing system. It consistently provides any normal physiologic joint compressive force during the application of a simultaneous transverse plane shear force. The fixture should be considered as a practical solution to the problem of applying this type of combined loading when evaluating total knee systems.

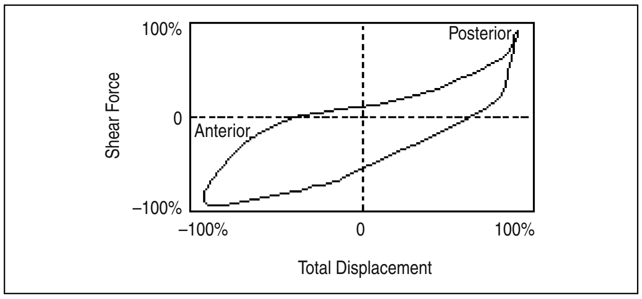

Fig. 3: Anteroposterior shear force versus tibial displacement after several thousand cycles of loading. The shear forces and displacements have been normalized by the maximum anterior and posterior shear forces and displacements, respectively. Posterior refers to posterior tibial translation.

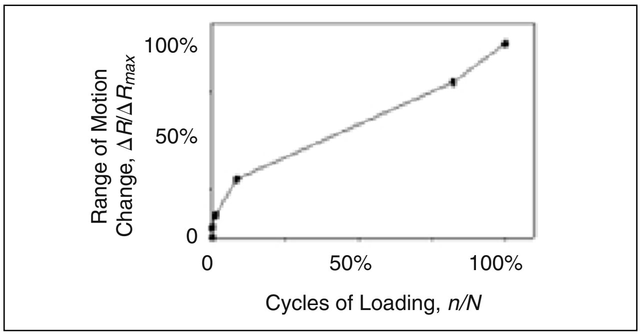

Fig. 4: Change (growth) in anteroposterior range of motion versus number of cycles of loading. The range of motion change (ΔR_{max}) has been normalized by the maximum change (ΔR_{max}). The cycles of loading (n) have been normalized by the cycles to failure (N).

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