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Laboratory Test Apparatus

The test apparatus is shown in Figs. E-1A, E-1B, and E-2. A steel cable tensioned by a linear hydraulic actuator (A591-4; Instron, Norwood, Massachusetts) applied compression. The steel cable was looped around a groove in the foot plate and was connected through pulleys and adjustable cable guides to the actuator. The foot plate provided a mounting location for the fixture block of the apparatus that was distal to the center of rotation of the ankle. The arm and counterbalance system enabled the application of a pure moment to the foot plate with minimal forces and off-axis moments. A servomotor (D50R10-0243; Designatronics, New Hyde Park, New York) with feedback from a rotary encoder (H32R85-L0306, SDP; Designatronics) and torque cell (TRT-200; Transducer Techniques, Temecula, California) applied torque at a constant rate of rotation (2°/sec).

Detailed Test Results

Relative Tibial Component Motion

There were no significant differences in tibial component motion in plantar flexion-dorsiflexion (main effects: $p = 0.100$ for implant type and $p = 0.078$ for compression; interaction: $p = 0.551$). Although the difference between the Agility and STAR in this direction was not significant, it was the only instance in which the mean magnitude of the relative motion of the STAR exceeded that of the Agility. Compression increased the mean motion magnitudes for each implant, but neither difference reached significance.

The only significant difference in inversion-eversion was between the relative motion magnitude of the Agility (mean for the two preloads, 268 μm [95% CI, 183 to 353 μm]) and that of the STAR (139 μm [95% CI, 111 to 167 μm]) (main effects: $p = 0.037$ for implant type and $p = 0.850$ for compression; interaction: $p = 0.278$).

In internal-external rotation, application of a compressive load resulted in a significant decrease in motion, from a mean of 293 μm (95% CI, 210 to 375 μm) for the two implants in the uncompressed state to 195 μm (95% CI, 109 to 281 μm). In addition, the effect of implant type nearly reached significance, with motion being greater for the Agility (main effects: $p = 0.052$ for implant type and $p = 0.044$ for compression; interaction: $p = 0.770$).

Talar Component Relative Motion

Applying a compressive load decreased the mean motion of the Agility implants in the three loading directions from 1307 μm (95% CI, 1025 to 1588 μm) to 884 μm (95% CI, 634 to 1133 μm) but had varying effects on the STAR (which averaged 624 μm [95% CI, 352 to 897 μm] in the uncompressed state and 578 μm [95% CI, 336 to 819 μm] in the compressed state). Additionally, the loading direction had a significant effect on the relative motion ($p = 0.009$), with plantar flexion-dorsiflexion tests showing the greatest motions overall, followed by inversion-eversion and internal-external rotation.

No significant effects were found in plantar flexion-dorsiflexion (main effects: $p = 0.106$ for implant type and $p = 0.470$ for compression; interaction: $p = 0.131$), even though the mean relative motion magnitude for the Agility (1424 μm [95% CI, 884 to 1963 μm]) exceeded that for the STAR (816 μm [95% CI, 276 to 1356 μm]) by 608 μm. The inclusion of a compressive load in this test decreased the amount of motion for the Agility and increased the motion for the STAR, but neither change was significant.

No significant effects were found in inversion-eversion (main effects: $p = 0.100$ for implant type and $p = 0.247$ for compression; interaction: $p = 0.316$), although mean relative motion was greater for the Agility than for the STAR.

In internal-external rotation, significant differences due to both effects and to their interaction were found (main effects: $p = 0.039$ for implant type and $p < 0.0001$ for compression; interaction: $p = 0.001$). Compression decreased the motion of both implants; however, the difference was significant for the Agility ($p = 0.002$) but not for the STAR ($p = 0.083$).

Displacement Directions

The motion of the tibial component of the Agility was greatest along the Z axis when loaded in plantar flexion-dorsiflexion and in inversion-eversion; motion was more evenly divided among all three directions when loaded in internal-external rotation. The majority of the motion of the Agility talar component was along the Y axis in plantar flexion-dorsiflexion and along the Z axis in inversion-eversion; the majority of the motion produced by loading in the internal-external rotation direction consisted of components along the X and Z axes.

The motion of the STAR tibial component was primarily along the Z axis during plantar flexion-dorsiflexion and inversion-eversion loading, but the Z component was favored only slightly during the internal-external rotation tests. The STAR talar component generally had the least amount of motion along the Y axis. It also favored motion along the Z axis during plantar flexion-dorsiflexion loading and along the X axis during internal-external rotation. In inversion-eversion, the majority of the motion was split between the X and Z axis directions.

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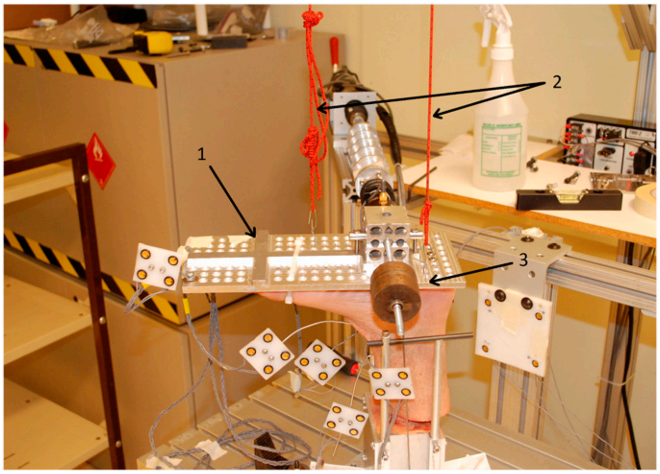

Fig. E-1A

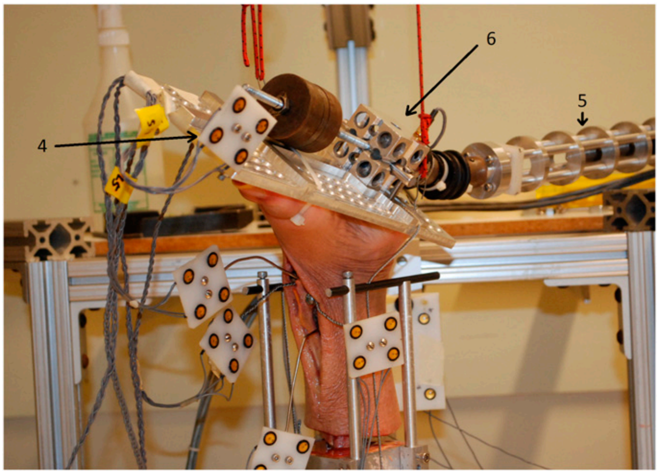

Fig. E-1B

Figs. E-1A and E-1B The ankle loading apparatus displaying the foot plate (1), pulley counterweight (2), disc counterweight (3), marker carrier with four infrared LED markers (4), moment applicator (5), and fixture block (6). **Fig. E-1A** Viewed in the plantar flexion-dorsiflexion loading direction. **Fig. E-1B** Viewed in the inversion-eversion loading direction.

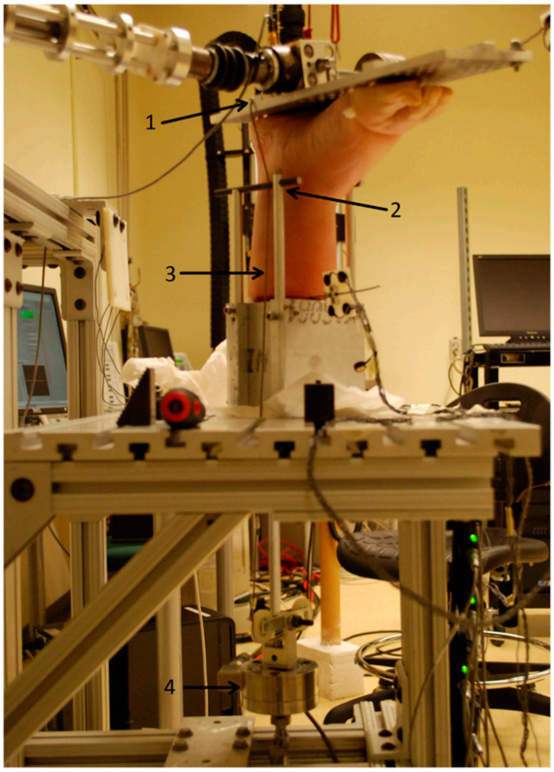

Fig. E-2
The ankle loading apparatus viewed in the plantar flexion-dorsiflexion loading direction showing the compressive load application components: foot plate cable groove (1), adjustable cable guides (2), cable supplying the compressive load (3), and hydraulic actuator with pulley attachment (4).