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VALIDATION OF A NOVEL 3D-PRINTED INSTRUMENTED SPATIAL LINKAGE THAT MEASURES CHANGES IN THE ROTATIONAL AXES OF THE TIBIOFEMORAL JOINT

Daniel P Bonny [1], S. M. Howell [1,2], M. L. Hull [1,2,3]

[1] Biomedical Engineering Graduate Group
University of California, Davis
Davis, California, 95616
USA

[2] Department of Mechanical Engineering
University of California, Davis
Davis, California, 95616
USA

[3] Department of Biomedical Engineering
University of California, Davis
Davis, California, 95616
USA

INTRODUCTION

The two kinematic axes of the tibiofemoral joint, the flexion-extension (F-E) and longitudinal rotation (LR) axes [1], are unrelated to the anatomic landmarks often used to align prostheses during total knee arthroplasty (TKA) [1, 2]. As a result, conventional TKA changes the position and orientation of the joint line, thus changing the position and orientation of the F-E and LR axes and consequently the kinematics of the knee. However, the extent to which TKA changes these axes is unknown. An instrument that can measure the locations of and any changes to these axes is an instrumented spatial linkage (ISL), a series of six instrumented revolute joints that can measure the six degrees of freedom of motion (DOF) between two rigid bodies without constraining motion. Previously, we computationally determined how best to design and use an ISL such that rotational and translational errors in locating the F-E and LR axes were minimized [3]. However, this ISL was not constructed and therefore its ability to measure changes in the axes has not been validated. Therefore the objective was to construct the ISL and quantify the errors in measuring changes in position and orientation of the F-E axis.

METHODS

An ISL (Figure 1) was constructed specifically to locate the axes of rotation of the tibiofemoral joint. The links of the ISL were fabricated using a high-accuracy rapid prototyping machine (Eden260V, Objet Geometries Inc., Billerica, MA) with an in-plane print resolution of 0.042 mm, an out-of-plane print resolution of 0.016 mm, and a print accuracy of 0.02-0.20 mm. Six digital absolute encoders (DS-25-16, Netzer Precision Motion Sensors Ltd, D.N. Misgav, Israel) were installed, each with a maximum absolute error of 0.025°.

A fixture consisting of two fixed axes was developed that allowed for controlled adjustments of the positions and orientations of the ISL relative to the F-E axis of the fixture (Figure 1). The fixture adjusted the attachment of the ISL relative to the F-E axis in four DOF: the anterior-posterior (A-P) and proximal-distal (P-D) positions as well as

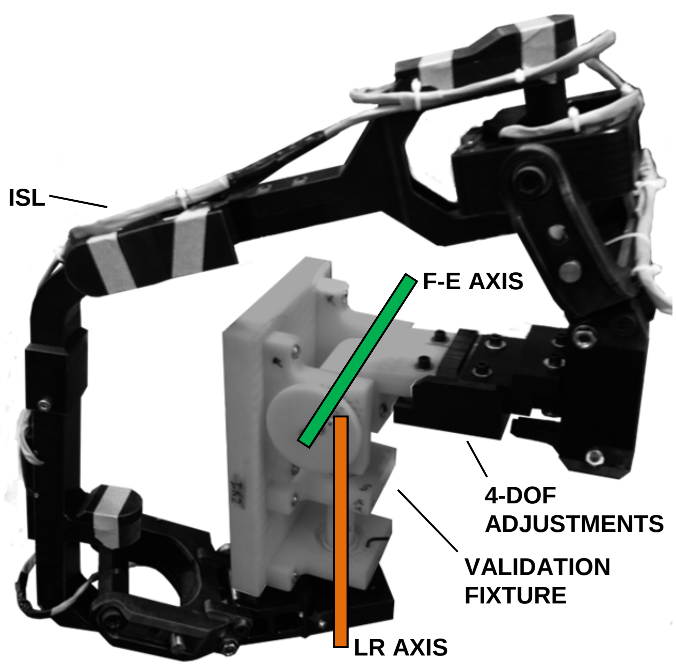

FIGURE 1. THE 3-D PRINTED ISL, ATTACHED TO THE VALIDATION FIXTURE

the varus-valgus (V-V) and internal-external (I-E) orientations. The reference P-D and A-P surfaces of the fixture to which the ISL attached were parallel to the F-E axis so that all adjustment directions for the two translations were known. Adjustments to the P-D and A-P positions of the fixture (ΔPD and ΔAP respectively) were 2.87, 5.08, and 9.74 mm for both positions. Adjustments to the I-E and V-V orientations of the fixture, ΔIE and ΔVV respectively, were -3.0°, 0.0°, and +3.0° for both I-E rotation and V-V rotation. Thus 81 possible combinations, three each of ΔAP, ΔPD, ΔVV, and ΔIE, were available. The reference configuration was 0.0° for ΔIE, 0.0° for ΔIE, and 2.87 mm for both ΔPD and ΔAP.

The ISL was used to locate the F-E axis of the fixture in its reference configuration. A "sequential discrete" pattern of applied motion [3] was used with an I-E rotation range of ±15° and a total flexion range of 110°; both I-E rotation and flexion were applied in 5° increments. The F-E axis was described by two positions (A-P and P-D) and two orientations (I-E and V-V) [3].

The F-E axis was located after each adjustment using the same pattern of applied motion originally used to locate the F-E axis of the validation fixture in its reference configuration. The 110° range of flexion was broken into four 60° flexion arcs, with initial flexion angles of 20°, 30°, 40°, and 50°. The starting flexion angles of 0° and 10° were not included because the ISL will be used to locate the axes in knees with implanted total knee arthroplasty components that have a different radius from 0° to 10° than from 10° and beyond which may change the position and orientation of the F-E axis [2]. The 110° flexion limit was chosen to prevent collision of the ISL with the fixture.

The actual changes in the F-E axis were determined analytically using the geometric relationships between each part of the validation fixture, which required knowledge of six quantities. In the reference configuration of the fixture, the axis about which ΔVV was adjusted was of known perpendicular distance L to the F-E axis and the axis about which ΔIE was adjusted was of known perpendicular distance D to the F-E axis. The actual P-D and A-P changes in the measured F-E axis were defined analytically as a function of ΔAP, ΔPD, ΔVV, ΔIE, L, and D. Changes in the position of the ISL relative to the F-E axis would not change either of the measured orientations of the F-E axis, thus the actual V-V and I-E changes were equal to ΔVV and ΔIE respectively.

The measurement error of the ISL was quantified by computing the difference between the actual and measured changes in the two positions and two orientations of the F-E axis. Of the 80 possible validation combinations (81 minus the reference combination), 20 were used to validate the ISL. Of the 20 combinations, 8 were chosen such that the actual change of only one variable was non-zero, and the other 12 were randomly chosen from the remaining 72 combinations. The bias, precision, and root-mean-square error (RMSE) of the differences between the actual and measured changes between the reference F-E axis and adjusted F-E axis were calculated for each flexion arc.

RESULTS

The differences between the actual and measured changes in the F-E axis showed little variation across each of the four starting flexion angles (Figure 2). The largest differences were in measuring the A-P change, though the RMSE was always below 1 mm (maximum 0.83 mm). The maximum difference in the P-D direction was 0.48 mm. The maximum differences in orientations were 0.32° and 0.45° for V-V and I-E respectively. The largest bias error in position (-0.33 mm) was in the difference between the changes in the P-D direction at a starting flexion angle of 40°; while the largest bias error in orientation (-0.37°) was in the difference between the changes in the I-E orientation at a starting flexion angle of 50°.

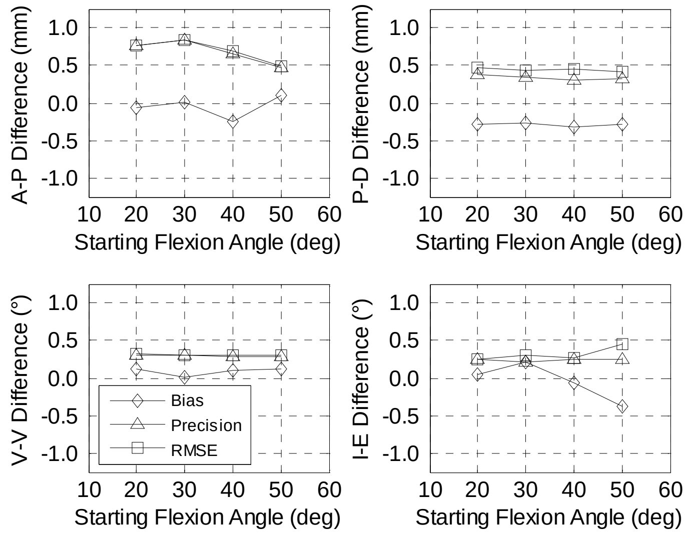

FIGURE 2. BIAS, PRECISION, AND RMSE OF THE DIFFERENCES BETWEEN THE ACTUAL AND MEASURED CHANGES IN THE F-E AXIS

DISCUSSION

This study demonstrated that our 3-D printed ISL is capable of measuring both a change in position and a change in orientation of a fixed F-E axis with minimal error. Possible sources of error during validation include error in assembly of the fixture between trials, errors in calibration of the ISL, and deflection of the ISL links during validation.

There were several limitations in this study. This validation was performed on a fixture with two fixed axes, thus it does not validate the ISL to measure the change in a non-fixed axis (i.e. an axis that translates and/or rotates throughout flexion). In addition, the ability to measure a change in the LR axis could not be validated because it was necessary to attach the ISL close to one of the bearings defining the LR axis; the limited space was not adequate to adjust the attachment of the ISL relative to the LR axis in multiple degrees of freedom. However, this should not be considered a serious limitation because the F-E axis is the dominant axis of the tibiofemoral joint [1] and therefore has a greater effect on tibiofemoral kinematics than the LR axis.

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