Sensor-Instrumented Modular Head for Measuring Soft-Tissue Tension During Total Hip Arthroplasty

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[INTRODUCTION] Dislocation continues to be a common complication of total hip arthroplasty (THA). Many factors affect the prevalence of dislocation after THA, including soft-tissue laxity, surgical approach, component position, patient factors, and component design [1]. Restoration of soft-tissue tension around the hip joint has been thought to be a crucial factor in preventing dislocation after THA, and recent studies have suggested the dislocation mechanisms without prosthetic or bony impingements and the soft-tissue might play an important role for dislocation after THA [2,3]. There are several intraoperative maneuvers that can be employed to assess both soft-tissue tension and limb lengths, including the shuck test. However, there have been no clinically useful objective means of testing soft-tissue tension after THA, so we developed a sensor-instrumented modular femoral head to measure soft-tissue tension and force direction during surgery. The objectives of this study were to investigate the accuracy of the sensor-instrumented modular head, and to confirm this head could work in vivo.

[MATERIALS AND METHODS] The sensor-instrumented modular head that we developed was composed of two metal parts made of stainless steel with four pressure sensors (FlexiForce A201-100, Tekscan Inc., South Boston, MA). This 26mm head was designed to measure the resultant hip force dynamically (Fig.1,2). The head is attached to the neck of the femoral stem, instead of real femoral head or trial femoral head during surgery. Sensors were placed on the faces of a cube-shaped recess, so that three mutually perpendicular load components could be measured: for example, #4 sensor measures $\theta=0^\circ$, $\phi=0^\circ$ component of an applied load. For calibration study, the sensor-instrumented modular head was fixed with a custom jig and mounted on a testing machine (Instron4204, INSTRON, Norwood, MA). Sensor output voltage ($V_i$) was found to respond linearly to the applied load components ($F_i$) when $F_i$ was perpendicular to the sensor surface. 100N load was applied to the head through hemispherical polyethylene from the various directions ($30^\circ<\phi<90^\circ$, $0^\circ<\theta<45^\circ$, 15 increments) three times and $V_i$ was recorded. If an arbitrary load $F$ ($F_1$, $F_2$, $F_3$) was applied, each theoretical $F_i$ was described as follows;

$$F_1=|F|\sin\theta \cdot \sin\phi$$
$$F_2=|F|\cos\theta \cdot \sin\phi$$
$$F_3=|F|\cos\theta \cdot \cos\phi$$

From $V_i$ from each sensor, the applied load can be measured and calculated. The magnitude and the angle of the applied loads were compared with those measured by the head.

Next, the sensor-instrumented modular femoral head was applied in vivo. The patient was a 77 year old female (136cm height, 40kg weight), receiving left THA due to RA. The patient provided written informed consent and the study protocol was approved by the institutional review board. The patient was operated using a posterolateral approach without trochanteric osteotomy, and was provided hybrid THA (4-U: Nakashima Medical, Okayama, Japan [4]). After all components except the real femoral head were placed, the sensor-instrumented head was attached to the neck of the femoral stem. The soft-tissue tension and direction was measured from full hip extension to $90^\circ$ flexion three times. After measurements, the head was replaced to the final 26mm metal femoral head.

[RESULTS] In the calibration study, external loads were applied from 19 different directions three times. Calculated errors of force magnitudes were between -8.24 to 2.52N, and angular errors were between $0^\circ$ to $3.79^\circ$. Mean absolute errors of force magnitude were 2.87%, and mean absolute angular errors were 1.44%.

In vivo measurement, dynamic soft-tissue tension and direction was successfully measured during surgery (Fig.3). The hip position was changed from full extension to $90^\circ$ flexion, and this was done three times. During three cycles of measurement, the general pattern and the magnitudes of the measured load components were similar (Fig.3). The relative variability of the resultant hip force at $90^\circ$ flexion was 12%. The postoperative course of the patient was uneventful.

[DISCUSSION] We developed the sensor-instrumented modular femoral head for measuring the soft-tissue tension and direction during surgery [5]. The sensor can be fabricated with head diameters between 22mm to around 32mm for commonly used femoral head sizes – a sensor of 26mm diameter was used in this study.

From the results of the calibration study, mean absolute errors of force magnitude were 2.87%, and mean absolute angular errors were 1.44%. In vivo use of this device demonstrated feasibility for surgical application in a sterile field.

Little information has been available for objective soft-tissue tension and direction around hip joint during and after THA. With this modular head sensor, the soft-tissue tension and direction can be measured objectively during THA surgery. We believe this will be useful for enhanced understanding the dislocation mechanisms, to permit optimized intraoperative soft-tissue balance, and ultimately decrease the incidence of dislocation after THA.