DEVELOPMENT OF HUMERAL INTRAMEDULLARY FIXATION NAIL (HIFN) BASED ON KOREAN CADAVERIC TESTS

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INTRODUCTION

Due to a wide range of motions and frequent movements of the upper arm, there is a high incidence rate of humeral fractures in human skeleton. Using a humeral intramedullary fixation nail (HIFN) for humeral fractures is one of effective MIS (Minimally Invasive Surgery) methods, and this kind of surgery can usually provide the patient with an early recovery [1,2]. Most of the HIFNs shown in Korea are mainly foreign-made ones developed by the anatomical information of foreigners, reporting that they are not suitable for Koreans [3]. This study developed a HIFN based on Korean cadaveric tests referring to the anatomical features of the Korean humerus. Biomechanical stability was also compared and analyzed with that of a foreign-made product. The convenience and safety of humeral surgery was simultaneously verified through clinical tests.

METHODS

Total 72 humeral bones were collected from Korean cadavers (Male: 66, Female: 6) to obtain morphological information from the CT images of Korean humeral bones. CT scans were taken after separating the humeral bones from the cadavers, and the Korean humeral model was created by reconstructing 3D cadaveric CT images (Fig. 1). Based on the reconstructed Korean humeral model, design parameters necessary for developing a HIFN such as total dimension (TD) of the medulla, proximal bending angle (PBA), proximal epiphysis diameter (PED), diaphysis diameter (DD), and distal epiphysis diameter (DED) were selected. Also, the measurement values from the 3D reconstruction FE model were analyzed to define a HIFN suitable for Koreans (Fig. 2).

The HIFN prototype (Ti-6Al-4V, 10.0mm×180mm) was developed by applying the measured values of the design parameters. The foreign-made HIFN (Ti-6Al-4V, 11.0mm×200mm, Polarus, ACUMED™, USA) was selected for biomechanical comparison and analysis. Mechanical tests were conducted using the MTS 858 Table Top System, USA. A static 4-point bending test with a loading rate 1 mm/sec and a static torsional with a loading rate 5°/min were carried out based on the ASTM F1264-03 (Fig. 3).
RESULTS AND DISCUSSION

According to the static 4-point bending test results, the bending stiffness of the prototype was equivalent to the Polarus, and the maximum fracture load of the prototype resulted to be approximately 83% of the Polarus. On the other hand, static torsional test results showed that the torsional stiffness of the prototype was approximately 140% of the Polarus, and the maximum torsional fracture load of the prototype was approximately 350% of the Polarus, securing excellent performance.

To verify the convenience and safety of the developed HIFN prototype during the humeral surgery, clinical tests using the Korean cadavers were conducted. From the tests, nerve damage due to the interference with the Axillary Nerve was found near the two holes located in the proximal part of the HIFN prototype, when the fixing screws were inserted inside the holes (Fig. 4). As a countermeasure for this, design modification was carried out for the location and inserting direction of the screw holes (Fig. 5), and the stability of the fixation nail was finally secured.

CONCLUSIONS

In this study, a 3D Korean humeral model was constructed based on the CT images of the Korean cadavers. The HIFN prototype suitable for Koreans was developed referring to the anatomical and morphological information. Static 4-point bending and torsional tests were conducted on the developed prototype, showing that the prototype had the almost equal or superior mechanical performance compared to the foreign-made one. The results of the clinical tests using Korean cadavers also showed the possibility of Axillary Nerve damage in the proximal part of the humerus. It was possible to secure the performance of the HIFN prototype by modifying the design specifications of the screw holes.

REFERENCES


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