Background: Extra-articular distal humerus locking plates (EADHPs) are precontoured anatomical plates widely used to repair distal humeral extra-articular diaphyseal fractures. However, EADHPs frequently cause distal protrusion and resulting skin discomfort. The purpose of this study was to predict the occurrence of anatomic fit mismatch. We hypothesized that the smaller the humerus size, the greater the anatomic fit mismatch with EADHP.

Methods: Twenty humeri were analyzed in this study. Humeral length and distal humeral width were used as parameters of humeral size. Plate protrusion was measured between the EADHP distal tip and the distal humerus. We set the level of unacceptable EADHP anatomic fit mismatch as ≥10 mm plate protrusion.

Results: A significant negative linear correlation was also confirmed between humeral size and plate protrusion, with a coefficient of determination of 0.477 for humeral length and 0.814 for distal humeral width. The cutoff value of humeral length to avoid ≥10 mm plate protrusion was 293.6 mm (sensitivity, 88.9%; specificity, 81.8%) and for distal humeral width was 60.5 mm (sensitivity, 100%; specificity, 81.8%).

Conclusions: Anatomic fit mismatch in distal humeral fractures after EADHP fixation has a negative linear correlation with humeral length and distal humeral width. For patients with a distal humeral width <60.5 mm, ≥10 mm plate protrusion will occur when an EADHP is used, and an alternative implant or approach should be considered.

Keywords: Bone plates; Humeral fractures; Prostheses and implants; Humerus

INTRODUCTION

Distal-third humeral fractures account for up to 2% of all adult fractures [1], and they are challenging to surgically correct [2-4]. Various anatomical precontoured locking plates have recently been developed and are used for surgical treatment of distal humerus fractures [5-7]. Extra-articular distal humerus locking plates (EADHPs; DePuy Synthes, Oberdorf, Switzerland) are anatomical precontoured plates widely used in distal humeral extra-articular diaphyseal fractures [8-12]. The posterolateral elbow column is used to fix the EADHP with a posterior approach. Despite the distally tapered design of the plate, it causes plate protrusion and skin discomfort after surgery (Fig. 1). Implant prominence after EADHP fixation was
noted in up to 59.5% of cases [13]. This problem requires implant removal after fracture union [11,12]. However, in most distal humeral fracture cases, EADHPs should be placed beneath the radial nerve (Fig. 2). Thus, iatrogenic radial nerve palsy is likely to result from EADHP removal surgery.

Zhou et al. [14] reported that EADHP caused approximately 8° of anatomic fit mismatch in the shafts of adult Chinese bodies in a cadaveric humeri study, which can be resolved by bending the plate. However, anatomic fit mismatch with plate protrusion occurring at the EADHP distal tip is likely to occur when the humerus is small, and anatomic fit mismatch is difficult to resolve through plate bending. Therefore, it is necessary to predict the plate protrusion occurrence and resulting skin discomfort that leads to risk of iatrogenic radial nerve palsy to better inform treatment planning and implant selection. However, the humeral size at which EADHP distal tip protrusion occurs due to anatomic fit mismatch has not been established.

The purpose of this study was to determine the humeral size cutoff for plate protrusion despite proper plate positioning through a cadaveric study. We hypothesized that the smaller the size of the humerus, the greater the anatomic fit mismatch of EADHP that would occur, and that the relationship between humeral size and mismatch will have a negative linear correlation.

**METHODS**

Because this study is a cadaveric study, there is no Institutional Review Board approval and informed consent for this study.

**Specimens**

A total of 20 humeri of various sizes were used. All soft tissue was removed, and the lack of any gross deformities of the humerus was confirmed. Humeral length and distal humeral width were used as parameters of humeral size. Humeral length was measured along the anatomical axis, and the distance between the humeral head tip and the trochlear tip with a perpendicular line on the axis was measured using digital tape (BL-DM; Bluetec, Daejeon, Korea). Distal humeral width was measured as the medial-to-lateral length between the medial and lateral epicondyles along the perpendicular plane of the anatomical axis using a digital caliper (SD500-150PRO; Sincon, Busan, Korea) (Fig. 3).
Measurement of Anatomic Fit Mismatch
A six-hole EADHP was positioned sufficiently laterally to not encroach on the olecranon fossa. EADHP mismatch caused by humeral posterior angulation in the shaft area as well as in the distal part was due to the plate’s distal five holes being longer than that of the distal humeral posterolateral column. The shaft mismatch could be resolved through proper EADHP bending \[14\], so the middle portion of the EADHP was bent using a plate bending press (Plate Bending Press 329.3; DePuy Synthes) to fit the contour of posterior angulation of the humerus. Additionally, mismatch occurring at the plate distal tip may be improved by proximal plate positioning, but in such cases, plate-bone mismatches occurred at the posterolateral column even if the plate was modified by the plate bending press. Therefore, we first fitted the EADHP to the posterolateral column, the mismatch occurring in the humeral shaft was resolved by the plate bending press, and the mismatch occurring in the plate distal tip was measured. The amount of mismatch between the plate and distal humerus was assessed by measuring the distance between the center point of the EADHP distal tip and the distal humeral bone point. The distal humeral bone point was set as a perpendicular line drawn from the plate distal tip center point to the humeral bone (Fig. 4).

There have been no previous studies of EADHP anatomic fit mismatch and symptom occurrence. We defined unacceptable EADHP anatomic fit mismatch as plate protrusion ≥ 10 mm.

Statistical Analysis
Simple linear regression was performed to estimate how humeral length and humeral width predicted protrusion distance. Receiver operating characteristic curve analysis was used to determine the appropriate cutoff value for plate protrusion, and the value with the largest Youden index (J) was defined as the optimal cutoff value \[15\]. Statistical power was set to 0.9 and the threshold for significance was set to \(p \geq 0.05\). All statistical analyses and tests were performed using IBM SPSS ver. 25.0 (IBM Corp., Armonk, NY, USA).

RESULTS
Mean humeral length was 301.13 ± 23.3 mm and mean distal humeral width was 60.9 ± 5.0 mm. Mean plate protrusion distance was 9.1 ± 2.7 mm. In total, 45% (9/20) of humeri showed ≥10 mm plate protrusion. A significant linear correlation was observed between humeral length and plate protrusion (\(p = 0.001\)) and the coefficient of determination value (\(R^2\)) was 0.477. The best-fit linear equation was \(Y = 32.85 - 0.08X\) (Fig. 5A). A significant linear correlation was also confirmed between distal humeral width and plate protrusion (\(p < 0.001\)), and the \(R^2\) was 0.814 and the best-fit linear equation was \(Y = 38.57 - 0.48X\) (Fig. 5B).

The area under the curve for humeral length was 0.879 and for distal humeral width was 0.944. The maximal J value for humeral length was 0.707; thus, the cutoff value for humeral length to avoid ≥10 mm plate protrusion was 293.6 mm (sensitivity,

Fig. 4. The distal humeral bone point was set based on a perpendicular line drawn from the center point of the extra-articular distal humerus locking plate (EADHP) tip to the humeral bone. Plate protrusion was measured between the center point of the EADHP distal tip and the distal humeral bone point.

Fig. 5. (A) Scattergram of distal plate protrusion for humeral length: the best-fit linear equation is calculated as \(Y=32.85-0.08X\), where \(Y\) represents the protrusion and \(X\) represents the humeral length. (B) Scattergram of distal plate protrusion for distal humeral width: the best-fit linear equation is calculated as \(Y=38.57-0.48X\), where \(Y\) represents the protrusion and \(X\) represents the distal humeral width.
eters for humeral size in this study. Distal humeral width was the primary measure for anatomic fit mismatch at the distal tip of the plate. If the gap between the bone and plate is more than 5mm, biomechanical stability is significantly decreased. When the three bicortical screws are supposed to be fixed, if the gap between the bone and plate occurs at the lateral column and two unicortical screws at the end to match at the distal tip of the plate can be reduced to some degree, but a gap occurs at the lateral column and two unicortical screws at the end to match at the distal tip of the plate. Therefore, these mismatches should be considered in preoperative planning.

Humerus length and distal humeral width were used as parameters for humeral size in this study. Distal humeral width was the most relevant measure, and it had approximately twice the R² value of humerus length. In a previous cadaveric humeral estimation study, the R² between the distance from the olecranon fossa upper margin to the trochlear tip and humeral length was 0.47 [17]. This R² suggests that humeral length is not highly predictive of the size of the humeral region. Additionally, the R² between humeral length and plate protrusion as measured in this study was 0.477, which was similar to previous values observed between the distal humerus region and humeral length.

Interestingly, the R² between distal humeral width and protrusion was 0.814, suggesting that distal humeral width is a better predictor of plate protrusion than humeral length.

Zhou et al. [14] reported a mismatch issue for EADHPs in the distal humerus posterolateral column and shaft in a Chinese cadaveric study. They found that 75% (33/44) of humeri were longer than 293.6 mm, which is the cutoff value for plate protrusion in this study. However, they focused on mismatch at the shaft, not at the distal tip of the EADHP. Furthermore, plate-bone mismatch due to angulation of the shaft area can be resolved through plate bending, but distal plate protrusion is difficult to resolve, so it is necessary to predict whether the patient is an EADHP candidate before surgery.

EADHP anatomic fit mismatch should be predicted preoperatively to prevent implant removal and potential iatrogenic radial nerve damage. Trikha et al. [13] reported that approximately 59.5% (22/37) of patients treated using an EADHP exhibited prominence on the elbow posterolateral side. Among them, only one patient underwent implant removal. Although implant mismatch occurred, not all patients developed skin discomfort requiring implant removal. However, in the majority of cases, the EADHP is placed beneath the radial nerve in a posterior approach to distal humeral fractures, and no matter how cautious we are, iatrogenic radial nerve palsy can occur during implant removal. Thus, when skin protrusion due to EADHP anatomic fit mismatch at the distal tip and resulting discomfort are expected, alternative treatments should be considered.

As an alternative treatment, a lower profile plate for the distal medial tibia can be employed for distal humerus fractures through the same posterior approach [18]. This locking plate does not use the posterolateral column of the distal humerus and seems to be less affected by protrusion; however, whether the biomechanical properties of the plate are comparable to conventional EADHPs should be investigated. As another alternative, a locking compression plate used for the proximal humerus was suggested via an anterolateral approach [19,20]. A previous biomechanical study showed that modified use of a proximal humeral locking plate has comparable mechanical stability com-
pared to EADHP [21]. Yin et al. [22] suggested both an antero-
lateral approach and a lateral approach to distal humeral ex-
tra-articular fractures as alternative surgical methods. Unlike
EADHP, plate irritation was not reported in the clinical outcomes
of the anterolateral approach or the lateral approach.

There are several limitations to this study. First, cadaveric stud-
ies have some important differences from in vivo studies. In this
cadaveric research, the soft tissue was completely removed, but
soft tissue dissection is limited during in vivo surgery. Second,
the definition or threshold value for EADHP anatomic fit mis-
mismatch leading to skin protrusion and related discomfort was
determined arbitrarily, because research on this topic is sparse. The
threshold leading to protrusion and discomfort in patients may
not be consistent with this value. Third, the sample size was
small.

In conclusion, anatomic fit mismatch in distal humeral frac-
tures after EADHP fixation has a negative linear correlation with
humeral length and distal humeral width. In particular, for pa-
patients whose distal humeral width is less than 60.5 mm, 10 mm
or greater plate protrusion is predicted when an EADHP is ap-
plied, and an alternative implant or approach should be consid-
ered during treatment planning.

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