Biomechanical evaluation of a modified proximal humeral locking plate application for distal extra-articular diaphyseal humeral fractures

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Directed by Professor Hwan-Mo Lee

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My mother and father, my mother-in-law, my father-in-law always supported me. Above all, I am grateful to my beloved wife, Kwon Ji-hye. I also express my love to my two daughters, Hyorim and Yurim. I dedicate this thesis to my family.

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ABSTRACT

Biomechanical evaluation of a modified proximal humeral locking plate application for distal extra-articular diaphyseal humeral fractures

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Introduction: The upside-down use of a proximal humerus internal locking system (PHILOS) plate is suggested as an alternative option for distal extra-articular diaphyseal humeral fracture fixation without biomechanical evidence, while extra-articular distal humerus locking plate (EADHP) is widely used. The purpose of this study was to compare the biomechanical performance between two different fixation methods: a modified use of the PHILOS plate on the anterior cortex versus conventional use of an EADHP on the posterior cortex.

Methods: Twelve pairs of fresh-frozen cadaveric humeri were used and 7mm gap osteotomy was performed at 50mm proximal to the lateral epicondyle to simulate a fracture model. Single load to failure was measured after five stiffness tests of the plate-bone constructs in anterior/posterior bending stiffness, internal/external torsional stiffness, and axial compressional stiffness.

Results: There were no significant differences in metrics between the two groups, except for the load to failure in posterior bending, which was significantly higher for PHILOS (1589.3 ± 234.5N) compared to EADHP (1430.1 ± 188.6 N) ($p<0.023$).

Conclusion: The modified use of PHILOS plate showed comparable biomechanical performance compared to the conventional EADHP. The new fixation method offers the potential clinical advantages, considering the patient's position and surgical approach at the time of surgery as well as postoperative soft tissue irritation. Therefore, this could be an option for distal humeral extra-articular diaphyseal fracture fixation when the use of EADHP is not suitable or preferred.

Keywords : distal humeral fracture, locking plate fixation, EADHP, PHILOS plate, biomechanical testing

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I. INTRODUCTION

Diaphyseal humeral fractures are known to account for about 2% of all adult fractures[1,2] and 11% to 35% of humeral shaft fractures located at distal one third.[3] In recent randomized controlled trials, operative management showed better outcomes compared to functional bracing in the treatment of humeral diaphyeal fractures including distal one third humeral shaft fractures.[4,5] To address the surgical treatment of distal diaphyseal humeral fractures, several approaches can be used[6-10], depending on the fracture features or status of the patient. If the fracture line is extended to or over the metaphysis, limited bone stock would be available for sufficient screw fixation via a conventional anterolateral approach. Thus, to achieve a solid fixation, the posterior approach is typically preferred to utilize the lateral column of the metaphysis for plate fixation.[11,12]

Extra-articular distal humerus locking plate (EADHP, DePuy Synthes, Oberdorf, Switzerland) is a precontoured design for use in distal extra-articular humeral fractures, and it has shown low hardware failure rate (0% to 2.2%) in previous clinical studies.[13-15] In addition, EADHP showed sufficient performance in previous distal humeral biomechanical study when double plate fixation was not required. [16] Therefore, single EADHP fixation is widely used as a treatment option for distal extra-articular diaphyseal humeral fractures. However, surgical treatment using EADHP is likely to be associated with skin prominence (Fig. 1) by the plate itself and subsequent discomfort in activities of daily living, which can cause discomforts as to require implant removal.[15,17] Furthermore, in many cases, the plate is inevitably placed beneath the radial nerve. Therefore, despite meticulous adhesion release, the nerve is constantly at risk of iatrogenic injury during implant removal. Additionally, an anterolateral approach is inevitably used if the initial status of the patient does not allow a prone position or a lateral decubitus position for the posterior approach, due to concomitant injuries associated with trauma.

Figure 1. Skin protrusion after conventional extra-articular distal humeral plate application.

The proximal humerus internal locking system (PHILOS, DePuy Synthes, Oberdorf, Switzerland) plate was originally designed to fix the proximal humerus fractures, allowing multiple screw fixation at its proximal part. Although the PHILOS plate is anatomically contoured to fit the proximal humerus, we can use the plate for distal humeral diaphyseal fracture fixation characterized by small distal fragment on the anterior cortex with a modified (upside-down) application. Therefore, in the current study, the proximal part of the plate is used for fixation of the distal fragment, allowing a sufficient number of screws.[18] Nonetheless, to date, no study has been performed to evaluate whether this modified use would have comparable biomechanical performance to the conventional EADHP fixed on the posterior cortex.

The purpose of this study was to compare the biomechanical performance between the two different fixation sites and plate configuration for distal humeral diaphyseal fracture: upside-down application of a PHILOS plate on the anterior cortex versus conventional use of EADHP on the posterior cortex. We hypothesized that the modified use of PHILOS plate would have comparable biomechanical performance to that of EADHP.

II. MATERIALS AND METHODS

1. *Specimen preparation*

Twelve pairs of fresh-frozen cadaveric humeri (24 specimens) were used in this study, and the subjects' ages ranged from 53 to 85 years old (mean ± SD : 73.4 ± 11.3). There were 8 male and 4 female specimens. None of the humeri had either gross deformities or a history of injury or operation. All specimens were kept frozen at -20°C and then they were thawed at room temperature for 24 hours before use. The humeri were cut 22 cm from the distal end of the humerus, and all soft tissues were removed.

To access the humeral bone strength, we measured the cortical surface area (CSA, in mm^2) using the axial image of computed tomography (CT)

(SOMATOM Definition AS, Siemens Medical Systems, Erlangen, Germany) at 50 mm proximal to the lateral epicondyle. After the CT, each pair was assigned to either upside-down use of the PHILOS plate on the anterior cortex (Group A) or conventional use of EADHP on the posterior cortex (Group B). The group assignment was determined by the block randomization, and each group was assigned 6 right and 6 left sides. Osteotomy was performed at 50 mms proximal to the lateral epicondyle at a setting of a 7 mm gap to simulate the unstable distal extra-articular diaphyseal humeral fracture – AO (Arbeitsgemeinschaft für Osteosynthesefragen) classification 12 C1.3.

In Group A, the 6-hole PHILOS plate was used upside-down and bent adequately to fit the contour of the anterior cortex of the distal humerus. At the distal fragment, the plate was placed distally enough to allow three bicortical screws fixation, but without encroaching the coronoid fossa (Fig. 2a). In Group B, the 6-hole EADHP was placed distally according to the plate design and positioned laterally enough not to affect the olecranon fossa (Fig. 2b). The number of screws required to fix either side of the fracture is still remains controversial, but at least six cortical holds per fragment are typically required for stable plate fixation. Therefore, three bicortical screws were inserted into each proximal and distal fragment in both groups.

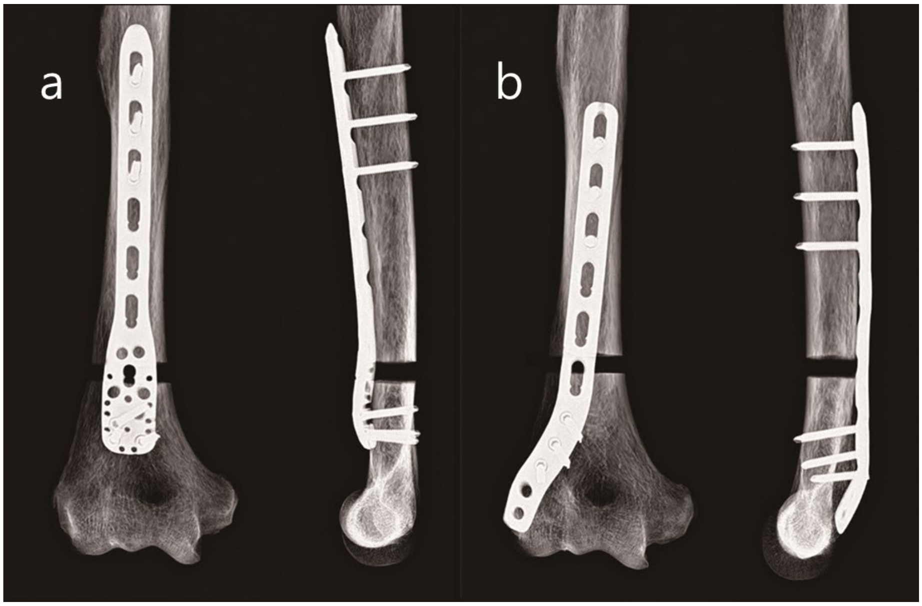

Figure 2. Radiographs of bone and plate constructs with a 7 mm osteotomy gap. (a) PHILOS plate fixed on the anterior cortex with three bicortical screws per fragment. (b) Conventional extra-articular distal humeral plate fixed on the posterior cortex with three bicortical screws per fragment.

The specimen was secured at a customized cuboid jig of 6.5 cm in width and 7.5 cm in height with the proximal and distal parts using unsaturated polyester resin (EC-304, AEKYUNG CHEMICAL, Seoul, Korea). The translucent resin properties were used to confirm that the humerus had proper axis. The medial epicondyle was partially removed when the medial-lateral width of the humerus was more than 6.5 cm. Prior to securing with resin, the plate and screw head and tip were covered with silicon to ensure the absence of extra-support on the plate and screw. [19]

2. *Biomechanical testing*

The biomechanical performance tests consisted of a single load to failure after a total of five stiffness tests (anterior bending stiffness, posterior bending stiffness, internal torsional stiffness, external torsional stiffness and axial compressional stiffness).

Rotational stiffness was measured using a torsional stiffness tester (DPTST; DYPHI, Daejeon, Korea). Other stiffness tests and single load to failure test were measured using an electrohydraulic materials test system (model 3366; Instron, Canton, MA).

Anterior and posterior bending stiffness tests were conducted in a 4-point bending setup, with a supporting span of 21 cm, a loading span of 12 cm, and a bending moment of 4.5 Nm at a rate of 0.75 Nm per second (Fig. 3a). After the 4-point bending test, the stiffness test under torsional loading was performed in the order of internal rotation and external rotation, and 1.6 Nm was applied with 0.2 Nm torque per second (Fig. 3b). Axial compression was performed under a load of 250 N and a loading rate of 17 N per second was applied (Fig. 3c). The stiffness value was evaluated as the slope of linear region in the force/displacement graph at the fifth cycle. Single load to failure was measured in the posterior bending setup, and the point of failure was determined when a sudden change occurred due to loss of fixation in the force / displacement curve.

The anterior bending stiffness test setup simulated a loading condition on distal humerus during elbow flexion, while the posterior bending stiffness test simulated the humerus during elbow extension. The chosen levels of load in this study were based on those of previous studies that were known to be near-physiological loading conditions on distal humerus during elbow motion.[20] Also, the chosen loads were known to not cause plastic deformation in plate and bone constructs in previous study.[21,22]

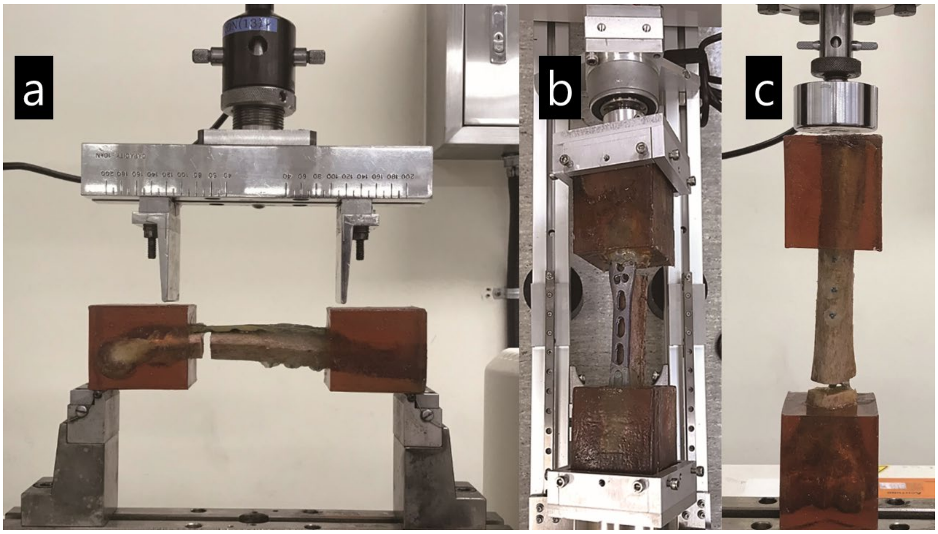

Figure 3. Secured customized cuboid jig using unsaturated polyester resin. (a) Four-point bending setup for posterior bending setup. (b) Torsional testing setup. (c) Axial compressional testing setup.

3. *Statistical analysis*

Since no study has been published on this topic to date, a pilot study was performed using three paired humeri (6 specimens) and the sample size was calculated using the posterior bending stiffness value. The mean (±standard deviation) value for each group in the pilot study was 128.8 ± 20.5 N/mm for group A and 103.9 ± 13.3 N/mm for group B. Based on these data, we found that 24 specimens (12 per group) were required to provide 80% power at an α level of 0.05. The Wilcoxon Signed-Rank test was used to compare significant differences in CSA and mechanical performance values between the two groups. A statistical significance was set as $p < 0.05$. Statistical analyses were performed using IBM SPSS Statistics for Windows (version 25.0; IBM, Armonk, NY).

III. RESULTS

In group A (PHILOS), the mean cortical CSA was 226.8 ± 61.8 mm^2, mean anterior bending stiffness was 107.8 ± 22.0 N/mm, mean posterior bending stiffness was 138.1 ± 34.7 N/mm, mean stiffness value in the internal torsion was 0.504 ± 0.076 N/deg, mean stiffness value in external torsion was 0.498 ± 0.088 N/deg, mean axial compressional stiffness was 1113.9 ± 279.8 N/mm, and the mean single load to failure (N) was 1589.3 ± 234.5. In group B (EADHP), the mean cortical CSA was 228.5 ± 64.9 mm^2, mean anterior bending stiffness was 124.6 ± 23.2 N/mm, mean posterior bending stiffness was 127.9 ± 22.9 N/mm, mean stiffness value in internal torsion was 0.526 ± 0.054 N/deg, mean stiffness value in external torsion was 0.507 ± 0.106 N/deg, mean axial compressional stiffness was 1064.2 ± 242.4 N/mm, and the mean single load to failure (N) was 1430.1 ± 188.6. However, there were no significant differences in measured values between the two groups, except for the single load to failure (posterior bending setup) (p=0.023) (Table. 1) (Figure. 4).

Table 1. Comparative results of the cortical cross-sectional area and biomechanics between the two groups.

	Group A(n=12)	Group B(n=12)	*p* value
Cortical CSA (mm^2)	226.8 ± 61.8	228.5 ± 64.9	0.695
Stiffness in anterior bending (N/mm)	107.8 ± 22.0	124.6 ± 23.2	0.084
Stiffness in posterior bending (N/mm)	138.1 ± 34.7	127.9 ± 22.9	0.239
Stiffness in internal torsion (N/deg)	0.504 ± 0.076	0.526 ± 0.054	0.117
Stiffness in external torsion (N/deg)	0.498 ± 0.088	0.507 ± 0.106	0.480
Stiffness in axial compression (N/mm)	1113.9 ± 279.8	1064.2 ± 242.4	0.638
Single load to failure (N)	1589.3 ± 234.5	1430.1 ± 188.6	**0.023**

Group A: modified use of PHILOS plate on the anterior cortex. Group B: conventional extra-articular distal humeral plate on the posterior cortex. The values are given as the mean and standard deviation.

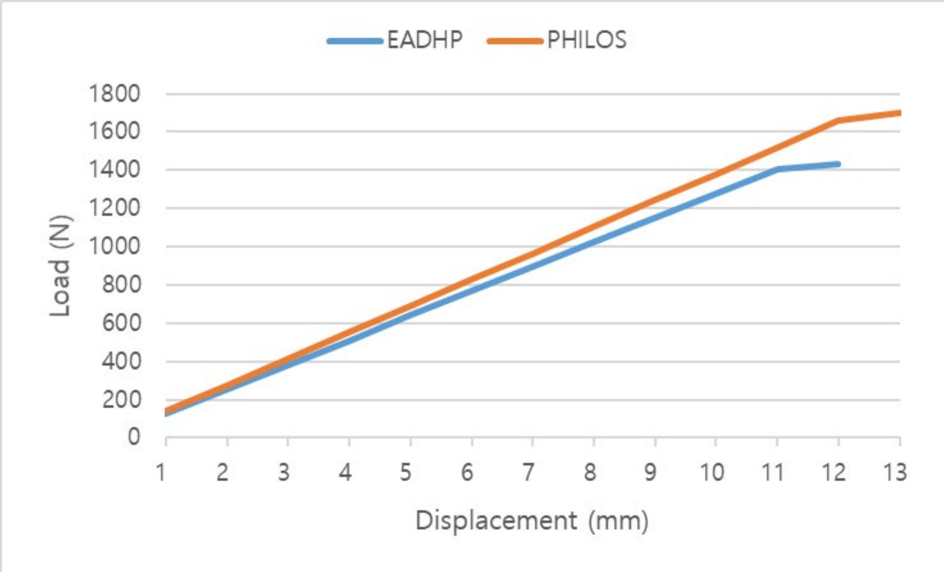

Figure 4. Schematic graph of load to failure (N) in posterior bending setup. The point of failure was determined when a sudden change occurred due to loss of fixation in the force / displacement curve.

IV. DISCUSSION

The purpose of this study was to compare the biomechanical performance of the two different fixation sites and the plate configurations for distal humeral diaphyseal fracture: modified use of the PHILOS plate on the anterior cortex versus the conventional use of EADHP on the posterior cortex. We hypothesized that the modified use of the PHILOS plate would show comparable biomechanical performances (anterior and posterior bending stiffness, external and internal torsional stiffness, and axial compressional stiffness) compared with the conventional use of EADHP, which was confirmed by the results. Interestingly, a single load to failure of the PHILOS plate was higher than that of EADHP.

For comparison of the two different approaches and plate configurations for distal extra-articular diaphyseal fracture, we had to assure that the paired distal humeri had similar bone strength, although we used the paired humeri harvested in the same cadaver for each setup. While previous researchers reported that cortical bone thickness could more reliably predict bone strength than BMD in the proximal humerus[23,24], no method has been established for quantitative assessment of bone quality for distal humerus.[25] Meanwhile, Siu *et al*. reported that the measurement of diaphyseal cortical CSA is significantly related to the long bone strength.[26] Therefore, we measured the CSA to access the humeral bone strength. In addition, the lateral epicondyle was used as an anatomical landmark in this study due to its clarity when compared to the olecranon fossa which is commonly used as a landmark.

Unlike the anterior portion of the distal humerus, which was placed in the muscles, there was a lack of muscle around the posterolateral column of the distal humerus where thick EADHP could result in protrusion underneath the skin, which could lead to discomfort and pain in daily living activities and increase the likelihood for implant removal. In addition, the radial nerve has always been an issue in application as well as for removing the implant placed in the distal humerus. In previous cadaveric studies, the radial nerve traversed 12.7-15.8 cm above the lateral epicondyle.[27] Therefore, if the fracture line has a proximal extension, it is necessary to apply the plate under the radial nerve in the posterior approach, and several studies reported an incidence of iatrogenic radial nerve palsy of up to 15%.[28-31] Since the PHILOS plate yielded a comparable biomechanical performance to that of EADHP, it is expected that the use of PHILOS plates in distal humeral diaphyseal fractures may reduce iatrogenic radial nerve injuries.

In fracture fixation using a locking plate, an appropriate working length considering the fracture pattern should be applied. Furthermore, plate material selection, screw placement, and bone-plate offset should be carefully chosen.[32] Also, Strom *et al*. suggested that the bending stiffness value increases as the plate thickness increases.[16] These factors should be considered in the biomechanical study of locking plate. In the current study, we controlled the overall plate length, overall bone-plate offset, numbers of screws, and plate material. Although EADHP had a 4.2 mm thickness and PHILOS plate had a thickness of 3.8 mm, the current study showed no significant difference between the anterior and posterior bending stiffness between the two groups. Rather, the single load to failure test showed a significantly higher value in the PHILOS group compared to the EADHP group.

This study had several limitations. First, the plate location and the plate working length were different. Second, there was inevitable change in the effective bending length during anterior/posterior stiffness test, including the single load to failure test. However, such change would have been relatively insignificant in the torsional stiffness test. Third, single load to failure had another limitation due to the polyester resin surrounding the plate-bone construct, which should be considered when interpreting the results.

V. CONCLUSION

Modified use of the PHILOS plate on the anterior cortex of the humerus showed comparable biomechanical performance, compared to conventional EADHP on the posterior cortex for distal extra-articular diaphyseal humeral fractures. Therefore, this may be an option for distal humeral extra-articular diaphyseal fractures where the use of EADHP is not suitable or preferred, considering the patient's position, surgical approach at the time of surgery as well as postoperative soft tissue irritation. The results provide additional considerations for treatment approaches for patients.

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ABSTRACT(IN KOREAN)

원위 상완골 관절 외 골간부 골절에서 PHILOS 금속판의 변형 적용

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연세대학교 대학원 의학과

임준열

연구 배경 및 목적: 근위 상완골용 잠김금속판을 원위 상완골의 관절 외 골간부 골절에서 역적용 하는 것이 고식적으로 사용되는 잠김 금속판을 이용해 고정하는 것에 대안적인 치료법이 될 수 있다고 제시되고 있으나 이에 대한 생역학적 근거가 부족하다. 본 연구의 목적은 접근법이 다른 두 가지의 잠김 금속판의 생역학적 성능을 비교하는 것으로 원위 상완골 전방에 변형 적용하는 근위 상완골 잠김 금속판군과, 고식적 후방 고정 잠김금속판군을 비교 분석하였다.

연구 재료 및 방법: 12구의 카데바 상완골 좌, 우 대응표본을 대상으로 하였으며 외상과 근위부 50mm 위치에 7mm 골간격 골절 모형을 생성하였다. 전/후방 굽힘 강성, 내/외회전 비틀림 강성 및 축 압축 강성을 측정한 후 단회 항복 강도을 측정 하였다.

연구 결과: 단회 항복 강도(뉴턴)는 변형 적용된 근위 상완골 잠김 금속판군 (1589.3 ± 234.0) 에서 고식적 잠김 금속판군 (1430.0 ± 188.6) 에 비해 통계적으로 유의미한 차이를 보였고 ($p < 0.023$), 그 이외의 측정값들에서는 두 군간 유의미한 차이를 보지 않았다.

결론: 원위 상완골의 관절 외 골간부 골절모형에서 근위 상관골 잠김 금속판 변형 적용군은 고식적 잠김 금속판 고정군과 비교할만한 생역학적 성능을 보였다. 새로운 잠김 금속판 변형 적용법은 전방 접근을 통해 양와위로 수술이 가능하며, 수술 후 내고정물 자극이 적₩다는 임상적 장점이 있다. 따라서 상완골 원위부 관절외 관절외 골간부 골절에서 고식적인 후방 접근 잠김 금속판의 사용이 적합하지 않거나 선호되지 않을 경우에, 근위 상완골 잠김 금속판 변형 적용하는 수술방법이 대안이 될 수 있다.

핵심되는 말: 원위 상관골 골절, 잠김 금속판 고정, 원위 상완골 관절 외 골절 잠김 금속판, 근위 상완골 잠김금속판, 생역학 실험