Treatment of 2-Part Proximal Humeral Fractures in Osteoporotic Patients With Medial Calcar Instability Using a PHILOS Plate Plus an Allogeneic Fibula Inserted Obliquely – A Retrospective Study

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Abstract

Introduction: To date, there is little research assessing the efficacy of a proximal humeral internal locking system (PHILOS) plate plus an allogeneic fibula inserted obliquely in the treatment of 2-part proximal humerus fractures (PHFs) with calcar comminution in patients >60 years old with severe osteoporosis. The aim of this study was to retrospectively evaluate the outcomes of elderly patients with osteoporotic 2-part PHFs combined with medial column (calcar) instability or disruption who experienced a PHILOS plate plus an allogeneic fibula inserted obliquely. Materials and Methods: One hundred and twelve consecutive elderly patients with severe osteoporotic 2-part PHFs combined with calcar instability or disruption who were treated with a PHILOS plate plus an allogeneic fibula inserted obliquely were retrospectively identified from 3 tertiary medical centres during 2014–2019. The primary outcomes were the Constant scores and American Shoulder and Elbow Surgeons (ASES) scores; secondary outcome was the rate of key orthopaedic complications. Results: Median follow-up was 24 (15.3–27.6) months. Significant improvements in the median Constant scores were observed (39 [26–58 points] prior to surgery vs 81 [67–95 points] at final follow-up). The median ASES scores improved from 43 (26–64 points) prior to surgery to 83 (65–96 points) at final follow-up. The percentage of key orthopaedic complications was 25.6% (22/86). Four (4.7%) cases had loss of reduction, 4 (4.7%) experienced aseptic loosening, 1 (.8%) had non-union, 4 (4.7%) suffered a periprosthetic fracture, 3 (3.5%) experienced a revision surgery, 1 (.8%) had a dislocation and 5 (5.8%) suffered an unbearable shoulder pain. Conclusion: For elderly patients with
osteoporotic 2-part PHFs combined with calcar instability or disruption, PHILOS plate combined with an allogeneic fibula inserted obliquely might have recognisable advantages in decreasing the loss of fixation and preventing medial calcar collapse.

Keywords
proximal humerus fractures, calcar, allogeneic fibula, loss of reduction, varus collapse

Introduction
The classification of 2-part proximal humerus fractures (PHFs) is based on a 4-segment theory.1-3 The majority of 2-part PHFs involve medial support (calcar) disruption, which is associated with an increased risk of loss of reduction or varus collapse.4-6 Treatment of PHFs with proximal humeral internal locking system (PHILOS) plates is becoming increasingly common in China.5 However, the efficacy of treating 2-part PHFs with calcar comminution in patients >60 years old with severe osteoporosis remains unclear.7,8 Furthermore, there is no acknowledged management algorithm or guideline in treating these 2-part PHFs.9,10 Early enthusiasm has been tempered by the results of several recent studies11,12 that have shown a higher-than-expected rate of PHILOS-related complications. Reported complications have mostly involved loss of reduction, varus collapse, plate breakage and screw cut-out.13,14 Concurrently, the use of PHILOS plates has frequently been conditioned by local cortical density.9,15 Failures secondary to the medial calcar have been acknowledged.4,6 To achieve the restoration of the medial calcar and a reduction of the stresses, a host of authors have used the allogeneic fibula filling technique,7,16-18 although there are statements against the use of intramedullary fibula allograft that are not sustained with references.5,19

We executed a retrospective review to assess the outcomes of elderly individuals with severe osteoporotic 2-part PHFs combined with medial column (calcar) instability or disruption who were treated with a PHILOS plate combined with a humeral calcar inserted obliquely using an allogeneic fibula at an angle of 120° to the longitudinal axis of the humerus shaft (an angled allogeneic fibula insertion technique) for maintaining this reduction.

Methods
Study Population
This retrospective study was reviewed and approved by the Investigational Review Boards of the Jinshan Hospital, Fudan University, the Affiliated Hospital of Jiangnan University, and the First Affiliated Hospital, Sun Yat-sen University, and an exemption for informed consent was obtained from these review boards. One hundred and twelve consecutive elderly individuals sustaining severe osteoporotic 2-part PHFs combined with medial column (calcar) instability or disruption were identified from 3 tertiary medical centres from January 2014 to December 2019. Inclusion criteria: patients aged ≥60 years old; a 2-part PHF combined with medial column (calcar) instability or disruption; patients undergoing a PHILOS plate (Synthes, Solothurn, Switzerland) with a humeral calcar inserted obliquely using an allogeneic fibula at an angle of 120° to the longitudinal axis of the humerus shaft; bone mineral density (BMD) < −3.2. Major exclusion criteria: open PHF; lacking follow-up data; patients who were treated with minimally invasive surgical techniques; a PHF with tuberosity fractures; great vessels and major nerve damage; affected shoulder dysfunction prior to surgery; pathological PHF; neurovascular dementia; psychosis; hypoparathyroids; severe infectious diseases (i.e. severe infectious disease and acquired immune deficiency syndrome) and an American Society of Anaesthesiologists (ASA) score of IV or V.

Follow-ups occurred at 3 months, 6 months and 12 months after surgery and yearly thereafter. The percentage of follow-up at each time point after surgery (3 months, 6 months, 12 months, 15 months, 18 months, 24 months and final follow-up) were 97%, 95%, 93%, 91%, 89%, 86% and 86%, respectively. The primary outcomes were the Constant and ASES scores which were routinely collected via outpatient follow-up or telephone follow-up by 2 experienced surgeons (WY and XSZ) and were recorded according to the follow-up schedule. Patients who failed to attend the follow-up were excluded from the analysis. The secondary outcomes were the rates of major orthopaedic complications including loss of reduction, varus collapse, aseptic loosening, intolerable shoulder pain, deep infection and bone-related issues (non-union, refracture, dislocation and necrosis).

Surgical Technique
After general anaesthesia, the patient was placed in a semi-supine position with a small triangular pad under the affected shoulder, and the C-arm machine was placed on the
patient’s head to ensure intraoperative lateral perspective of the shoulder. After the temporary fixation with the Kirschner wire, the cortex in the attachment area of the PHILOS plate was fenestrated, and allogeneic fibula was inserted (Figure 1A). The allogeneic fibula was produced using a 4–6 mm diameter hollow drill (the size of the diameter was chosen based on the degree of osteoporosis), ejector rod and pliers from the knee reconstruction kit (Figure 1B).

We adopted an anterolateral approach of the shoulder with an incision length of approximately 10 cm. We exposed the fracture site along the muscular space between the deltoid muscle and the pectoralis major muscle and identified the intertubercular groove of the humerus. With a C-arm machine, we used sutures to pull apart the tendon-bone portion of the rotator cuff, pried the fracture blocks with the assistance of 2 2.5-mm Kirschner wires and corrected the varus and retroversion displacement of the fractures. After satisfactory reduction, the fracture blocks were temporarily fixed using two 2.5-mm Kirschner wires through the inner cortex of the intertubercular groove, and the position of the Kirschner wires avoided obstructing the position of the bone marrow tunnel. We used the PHILOS plate as a template to determine the entry point of the lateral cortex of the bone marrow tunnel. This entry point is approximately at the proximal edge of the screw hole on the medial calcar (Figure 1C) or is on the fracture line. Under the monitoring of the C-arm machine, a 2.5-mm Kirschner wire was drilled into the attachment site of the PHILOS plate lateral to the intertubercular groove. On the anteroposterior X-ray photograph, the insertion point of the Kirschner wire was set at the medial and downward 1/3 of the humerus head. On the lateral X-ray photograph, the Kirschner wire was located in the backward and downward 1/3 of the humeral head, and the length reached approximately 5 mm below the cartilage. The length of the Kirschner wire in the bone tissue was measured to be 48 mm which might change with the patient size. The Kirschner wire was used as a guide pin, and a hollow drill with a diameter of 4–6 mm was used to penetrate the lateral cortex. Then, the 4–6-mm diameter rod was slowly driven into the bone tunnel to a depth of approximately 45 mm (Figure 1D). The allogeneic fibula was made into a cylindrical shape with a diameter of 4–6 mm and a length of 50 mm (Figure 1E and F), and it was implanted along the bone marrow tunnel to ensure that 2 mm remained outside the cortex. The PHILOS plate was placed on the back of the greater tuberosity of the humerus, 5 to 10 mm from the intertubercular groove, to ensure that the plate was accurately positioned and completely covered the tail of the allogeneic fibula. The humeral head was fixed using 5 locking screws plus 1 calcar support screw to ensure that

Figure 1. Schematic representation of allogeneic fibula implantation (A). Tools for making and implanting allogeneic fibulas (B). Bone tunnel entrance marker (C). Intraoperative fluoroscopy of the bone tunnel position (D). Production of allogeneic fibula (E). Allogeneic fibula implanted along the bone tunnel (F). Postoperative X-ray photographs of the proximal humerus (G). Postoperative CT scan of the proximal humerus (H).
the plate fit tightly with the lateral cortex. The diaphyseal screws were placed after the head screws.

After successfully completing the above procedures, we used the C-arm machine to confirm that the positions of plate, screws and allogeneic fibula were adequate. No abnormalities were detected in passively moving the shoulder joint. Finally, we rinsed the incision and closed it in layers. A negative pressure drain was placed and removed after 2 days. The postoperative X-ray and CT were shown in Figure 1G and H.

**Results**

Of 112 patients, 26 (23.2%) were excluded according to the present criteria, as presented in Figure 2. Leaving 86 eligible patients from whom all relevant information was available met the inclusion and exclusion criteria. There were 39 men and 47 women. Mean age was 68.8 (± 5.2) years. Bone mineral density (BMD) was −3.5 (±.3). Prior to surgery, median Constant and ASES scores were 39 (26–58) and 43 (26–64), respectively. Median follow-up was 24 (15.3–27.6) months. Baseline data were shown in Table 1.

Table 2 exhibited the median Constant and ASES scores. At the last analysis, significant improvements in the median Constant scores were observed (39 [26–58 points] prior to surgery vs 81 [67–95 points] at final follow-up). The median ASES scores improved from 43 (26–64 points) prior to surgery to 83 (65–96 points) at final follow-up.

Table 3 presented the major orthopaedic complications. The percentage of major orthopaedic complications were 25.6% (22/86). Of these complications, 4 (4.7%) individuals had loss of reduction, 4 (4.7%) experienced postoperative loosening, 1 (1.2%) had non-union, 4 (4.7%) suffered a periprosthetic fracture, 3 (3.5%) experienced a revision surgery which was mainly attributed to postoperative loosening and dislocation, 1 (1.2%) had a dislocation related to a malreduction and 5 (5.8%) suffered an unbearable shoulder pain. Revision was mostly attributed to periprosthetic fractures. One case was revised with a reverse total shoulder arthroplasty (Zimmer, Warsaw, IN, USA); 2 cases underwent a semi-shoulder joint replacement (Trabecular Metal; Zimmer, Warsaw, IN, USA).

**Discussion**

Our analysis provides evidence that PHILOS plate combined with an allogeneic fibula inserted obliquely might be a reliable surgical option in decreasing the loss of fixation and preventing medai calcar collapse for elderly patients with osteoporotic 2-part PHFs combined with calcar instability or disruption. Furthermore, the retrospective study was conducted with data from a cohort representative of the ‘real world’ practice.

The functional outcomes in patients included in the present study experiencing a PHILOS plate plus an allogeneic fibula inserted obliquely, and reasons for exclusion. PHF: proximal humerus fractures.
patients were painless with a well-functioning shoulder at the lasted follow-up. Similar functional outcomes have been reported in a previous study assessing the clinical outcomes in 18 patients with 2-part PHFs experiencing osteosynthesis with a PHILOS plate demonstrated the median Constant shoulder score was 83 (79–87) and the median Disabilities of Arm, Shoulder and Hand Outcome Measure (DASH) score was 25 (24–27). In a retrospective study involving 8 patients with 2-part PHFs treated with a PHILOS plate, the Constant score was 64 (56–72). A prospective study of 13 patients with osteoporotic 2-part PHFs showed that the mean Shoulder Function Index score was 73.2 (64–77). The results of the 4 studies confirmed that PHILOS plate is associated with good functional outcomes. However, evidence-based studies have indicated that the mechanical performance of PHILOS is inconstant. In patients with loss of medial column mechanical support, long-term functional outcomes tend to be poor, indicating that the restoration of the mechanical support of the medial column in PHF fixation may be the key factor for improving functional outcomes.

Frequently reported complications related to the implant mainly involved both loss of reduction and varus collapse. In the current study, the rate of the loss of reduction was 4.7% (4/86) and the varus collapse failed to be detected. There is, as far as we know, only 1 prior study involving an allogeneic fibula inserted obliquely, this study evaluating the outcomes according to the Constant and ASES scores and the rate of key orthopaedic complications in 112 patients with 2-part PHFs treated with a PHILOS plate plus oblique insertion of autologous fibula reported that the rate of loss of reduction was 2.6% (3/112), which is consistent with our result. A retrospective study of 36 patients with unstable PHFs with medial column disruption reported a 5.6% rate of varus collapse. However, a previous retrospective evaluation of 72 patients with acute PHFs who experienced PHILOS plate fixation showed that 26.4% (19/72) patients had a varus collapse. Furthermore, other reports have demonstrated disasteful results, with implant-related complications ranging from 9 to 36%, including high rates of varus collapse or screw penetration, particularly in fractures with medial column disruption. The high rate of varus collapse may be primarily explained by the medial calcar instability or loss of medial column mechanical support.

To enhance the stability of the medial calcar and improve the defect of the humeral head, an intramedullary

### Table 1. Patient Demographics.

| Variable                      | N = 86 |
|-------------------------------|--------|
| Gender, M/F                   | 39/47  |
| Age, years                    | 68.8 ± 5.2 |
| BMI, kg/m²                    | 27.7 ± 3.8 |
| BMD                           | −3.5 ± 0.3 |
| Side, left/right               | 41/45  |
| Interval to surgery from admission | 6.8 (1 day–12 days) |
| Comorbidities, no%            |        |
| Hypertension                  | 23 (26.7) |
| Diabetes mellitus             | 25 (29.1) |
| Pulmonary                     | 11 (12.8) |
| Cerebrovascular accident      | 13 (15.1) |
| Other                         | 7 (8.1) |
| Mechanism of injury           |        |
| Traffic                       | 20 (23.3) |
| Falling                       | 54 (62.8) |
| Other                         | 12 (13.9) |
| ASA index, no.%               |        |
| I                             | 16 (18.6) |
| II                            | 25 (29.1) |
| III                           | 45 (52.3) |
| Constant scores prior to surgery | 39 (26-58) |
| ASES scores prior to surgery  | 43 (26-64) |
| Follow-up time (months)       | 24 (15.3-27.6) |

BMI: body mass index; BMD: bone mineral density; ASA: American Society of Anaesthesiologists; ASES: American Shoulder and Elbow Surgeons.

### Table 2. Functional Outcomes at Each Follow-Up.

| Time, month(s) after Surgery | Percentage of Follow-Up, No.% | Constant Scores | ASES Scores |
|------------------------------|--------------------------------|-----------------|-------------|
| 3                            | 97                             | 73 (54–87)      | 76 (58–82)  |
| 6                            | 95                             | 76 (57–89)      | 77 (64–86)  |
| 12                           | 93                             | 77 (64–88)      | 82 (62–90)  |
| 15                           | 91                             | 78 (65–90)      | 84 (67–92)  |
| 18                           | 89                             | 82 (68–94)      | 83 (66–95)  |
| 24                           | 86                             | 81 (66–96)      | 84 (65–97)  |
| Final follow-up              | 86                             | 81 (67–95)      | 83 (65–96)  |

ASES: American Shoulder and Elbow Surgeons.

### Table 3. The key Orthopaedic Complications.

| Variable                                | No. %     |
|-----------------------------------------|-----------|
| Total complications                     | 22 (25.6) |
| Patients affected                       | 18 (20.9) |
| Loss of reduction                       | 4 (4.7)   |
| Varus collapse                          | 0 (0)     |
| Avascular necrosis of the humeral head  | 0 (0)     |
| Aseptic loosening                       | 4 (4.7)   |
| Non-union                               | 1 (1.2)   |
| Periprosthetic fracture                 | 4 (4.7)   |
| Revision                                | 3 (3.5)   |
| Dislocation                             | 1 (1.2)   |
| Deep infection                          | 0 (0)     |
| Unbearable shoulder pain                | 5 (5.8)   |

ASES: American Shoulder and Elbow Surgeons.
fibular allograft has been used in the reconstruction of medial support, although there are statements against the use of intramedullary fibula allograft that are not sustained with references. A biomechanical study of locking plate plus an intramedullary fibular allograft in the management of unstable PHFs showed that intramedullary fibular allograft markedly increases both the maximum failure load and the initial stiffness of this construct when compared to a plate alone. The initial stiffness at the fracture interface was increased by 3.84 times when an intramedullary fibular allograft is used to support a medial calcar. Using the fibular allograft as oblique post may have more advantages compared with using the fibular allograft as a vertical medial strut. A vertically inserted fibula may have difficulty reaching the medial calcar and therefore has limited effect on dispersing the varus stress. Although this surgical regimen can enhance the stability of the medial calcar and improve defects of the humeral head, the 2 points need to be mentioned during surgery. First, minimally invasive techniques were adopted to make full use of Kirschner wire poking reduction combined with sutures to pull humerus tuberosities. Kirschner wires were driven into the inside of the intertubercular groove to avoid affecting the placement of the PHILOS plate. Second, the ideal allogeneic fibula is placed proximally below the humeral head cortex and distally against the medial calcar, parallel to the calcar tangent. The insertion point of the allogeneic fibula was placed on the proximal edge of the hole of the calcar screw. When determining the fibula insertion point during surgery, we should first place the PHILOS plate in a satisfactory position and then determine the position of the hole of the calcar screw under fluoroscopic guidance. A 2.5-mm Kirschner wire was used as a guide wire to drill a hole at the proximal end of the hole of the calcar screw in the direction of the medial calcar to the lower part of the humeral head cortex. The guide wire should be inserted in multi-angle perspectives to ensure that it is located in the humeral head and parallel to the calcar tangent. After the insertion of the guide wire, a 6-mm hollow drill is used to make the hole. The hole should not be too deep as it is sufficient to simply penetrate the humerus cortex. Then, we can gently tap the length of the allogeneic fibula into place with a 6-mm diameter ejector rod, the depth of which is determined by fluoroscopy.

The current study has certain limitations. This is a retrospective study, and information bias and loss of follow-up bias cannot be avoided, which makes our conclusions less reliable. Another is that selection bias seems to exist because the inclusion and exclusion criteria are artificially set. We have achieved encouraging results using a PHILOS plate along with an oblique insertion of allogeneic fibula for complex PHFs with medial calcar disruption. The intramedullary fibula for severe calcar disruption can restore the medial cortex while providing stability. In such cases, the oblique technique could fail. Furthermore, given the short application time, absence of a large sample size and lack of long-term follow-up, is this technique enough to provide stability in severe medial calcar disruption? Other limitations are cost and disease transmission risk from allograft. Limitations and indications of the technique need to be further clarified. In addition, the effect of optimal diameter and sagittal orientation of an allogeneic fibula on prognosis also needs further exploration.

Conclusion
The results reported in this study demonstrated that a PHILOS plate combined with an oblique insertion of an allogeneic fibula as a primary procedure might be associated with significant advantages in clinical outcomes, along with favourable Constant and ASES scores as well as accepted orthopaedic complications at final follow-up, and might provide a targeted treatment option for osteoporotic 2-part PHFs with medial calcar instability or disruption in elderly individuals.

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