


## CLINICAL ARTICLE

# Comparison of the Effects of Proximal Humeral Internal Locking System (PHILOS) Alone and PHILOS Combined with Fibular Allograft in the Treatment of Neer Three- or Four-part Proximal Humerus Fractures in the Elderly

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**Objective:** To compare and analyze the clinical outcomes of the proximal humeral internal locking system (PHILOS) alone and the PHILOS combined with fibular allograft in the treatment of Neer three- and four-part proximal humerus fractures (PHF) in the elderly.

**Methods:** From January 2014 to January 2018, a total of 42 elderly patients with Neer three- or four-part PHF admitted to our hospital were randomly divided into observation group and control group, with 21 patients in each group. The observation group was treated with the PHILOS combined with fibular allograft. The control group was treated with the PHILOS alone. Perioperative parameters and fracture classification were recorded in the two groups. Function results were assessed by Visual Analog Scale (VAS), Constant-Murley score (CMS), American Shoulder and Elbow Surgeons (ASES) score, and the Disability of Arm-Shoulder-Hand (DASH) score. Radiological results were evaluated using the neck-shaft angle (NSA) and humeral head height (HHH), and complications were also recorded in each group.

**Results:** There were no significant differences between the two groups in terms of preoperative status, age, gender, cause of trauma, fracture site, and fracture classification. The average follow-up time was 12 months. At the last follow-up, the VAS and DASH observation groups were lower than the control group, and there was significant difference between the two groups ( $P < 0.05$ ). The CMS and ASES were higher in the observation group than the control group, and there was significant difference between the two groups ( $P < 0.05$ ). The mean difference in the NSA and HHH were lower in the observation group than the control group, and there was a significant difference between the two groups ( $P < 0.05$ ). There was one postoperative complication in the observation group, which was humeral head avascular necrosis (AVN). There were seven postoperative complications in the control group, including three cases of humeral head collapse and three cases of screw cutout and one case of humeral head AVN. The incidence of postoperative complications in the observation group was significantly lower than the control group ( $P < 0.05$ ), there was a significant difference between the two groups.

**Conclusions:** For Neer three- or four-part PHF in the elderly patients, PHILOS fixation with fibular allograft shows satisfactory short-term results with respect to humeral head support and maintenance of reduction, and may reduce the incidence of complications associated with fixation using a PHILOS alone.

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## Introduction

Proximal humeral fractures (PHF) account for 4%–5% of the whole body bone fractures<sup>1</sup>, and the incidence of PHF is increasing due to a high number of elderly osteoporotic patients<sup>2</sup>, making PHF the third most common injury among older people<sup>3</sup>. It has been reported that more than 80% of patients with minimally displaced PHF can be managed by non-operation<sup>4</sup>, but approximately 20% of patients with displaced and comminuted fractures require surgery<sup>5</sup>. These fractures are difficult to treat, as it is unpredictable whether they will achieve stable fixation that maintains intra-operative reduction. Operative management of PHF still remains challenging for orthopedic surgeons in the world<sup>6</sup>.

Although various surgical techniques have been described for the unstable PHF, proximal humeral internal locking systems (PHILOS) are increasingly popular for treating these fractures because they offer improved biomechanical properties by providing divergent and convergent fixed-angle screws that improve fixation and pullout strength in osteoporotic bone<sup>7</sup>. It is also known to be clinically and biomechanically effective in elderly patients with PHF<sup>8</sup>. However, it is difficult to obtain stable fixation in osteoporotic patients even with PHILOS<sup>9</sup>. Some authors have also reported some complications, such as avascular necrosis (AVN), screw cutout, implant failure, plate impingement, head collapse, and infection<sup>10,11</sup>. Good outcomes have been reported following the use of an associated intramedullary allograft<sup>9,12</sup>. However, most previous studies are case series, and no comparative study has evaluated the clinical and radiological outcomes of PHILOS with and without an associated fibular allograft in elderly patients.

The aim of this study was to compare and analyze the clinical outcomes of the PHILOS alone and the PHILOS combined with fibular allograft in the treatment of Neer three- or four-part PHF in the elderly. The hypothesis was

that patients treated using the PHILOS combined with fibular allograft would have better clinical and radiological outcomes with lower complication rates than those treated using only the PHILOS alone.

## Patients and Methods

This research was a retrospective study and was approved by the Ethics Committee of Nanjing First Hospital, Nanjing Medical University. Written informed consents were obtained from all enrolled patients.

From January 2014 to January 2018, a total of 42 elderly patients with Neer three- or four-part PHF admitted to Nanjing First Hospital were randomly divided into observation group and control group, with 21 patients in each group. The observation group was treated with the PHILOS combined with fibular allograft. The control group was treated with the PHILOS alone. Perioperative parameters and fracture classification were recorded in the two groups. The demographic characteristics of the patients in the two groups are shown in Table 1.

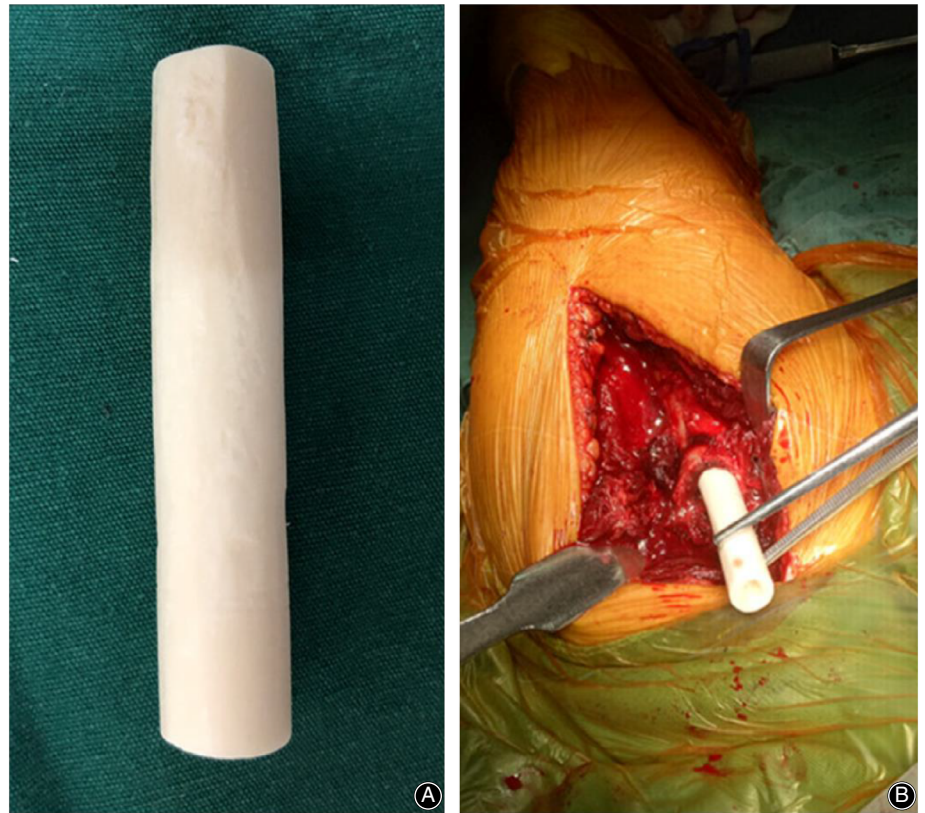
Inclusion criteria were as follows: (i) patients over 60 years of age; (ii) unilateral acute shift of Neer classification<sup>13</sup> of three- or four-part of the proximal humerus fracture; (iii) patient's fragments were either displaced more than 1.0 cm or angulated more than 45° and were preoperatively conformed by radiograph or computed tomography (CT) with three-dimensional (3D) reconstructions; and (iv) there were no obvious surgical contraindications.

Exclusion criteria were as follows: (i) a history of shoulder surgery or chronic bone nonunion, there was severe soft tissue injury at the surgical site or systemic or local infection; (ii) pathological fracture or open fracture; (iii) complications of serious nervous or vascular injury; (iv) hypertensive patients with poor blood pressure control and diabetic patients with poor

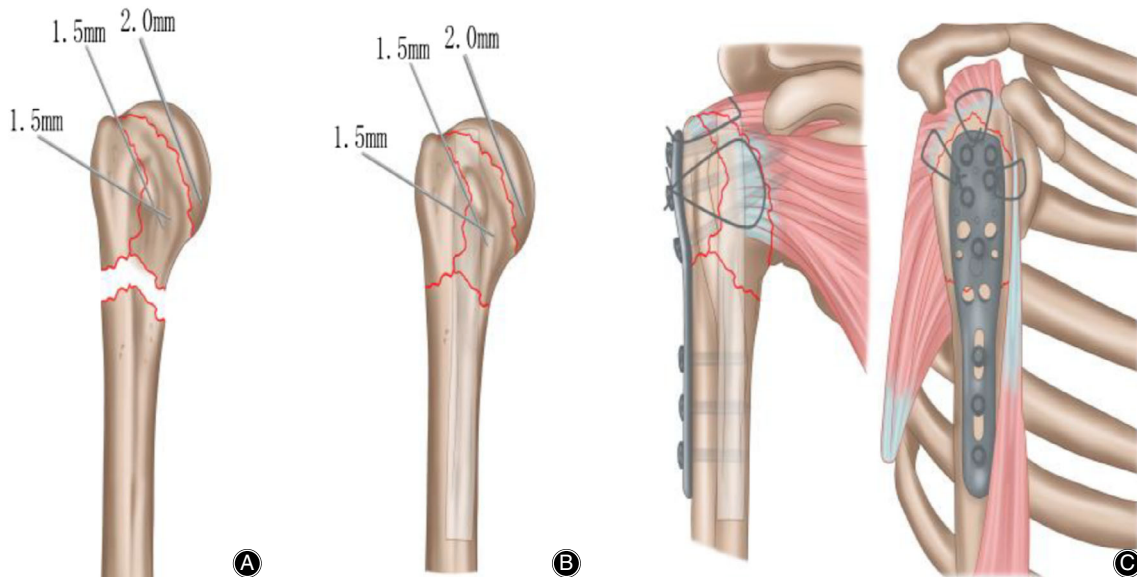
**TABLE 1** Comparison of general data between the two groups of patients

Variables	Observation group(n = 21)	Control group(n = 21)	$\chi^2/t$ -value	P-value
Gender	Male	11	0.096	0.757
	Female	12		
Mean age	68.8 ± 6.3	69.0 ± 7.2	0.114	0.901
Preoperative time (days)	4.2 ± 1.1	4.3 ± 1.2	0.281	0.780
Mechanism of injury	F	15	0.525	0.469
	TA	6		
Fracture site	Left	9	0.382	0.537
	Right	12		
Neer classification	Neer 3	14	0.111	0.739
	Neer 4	7		

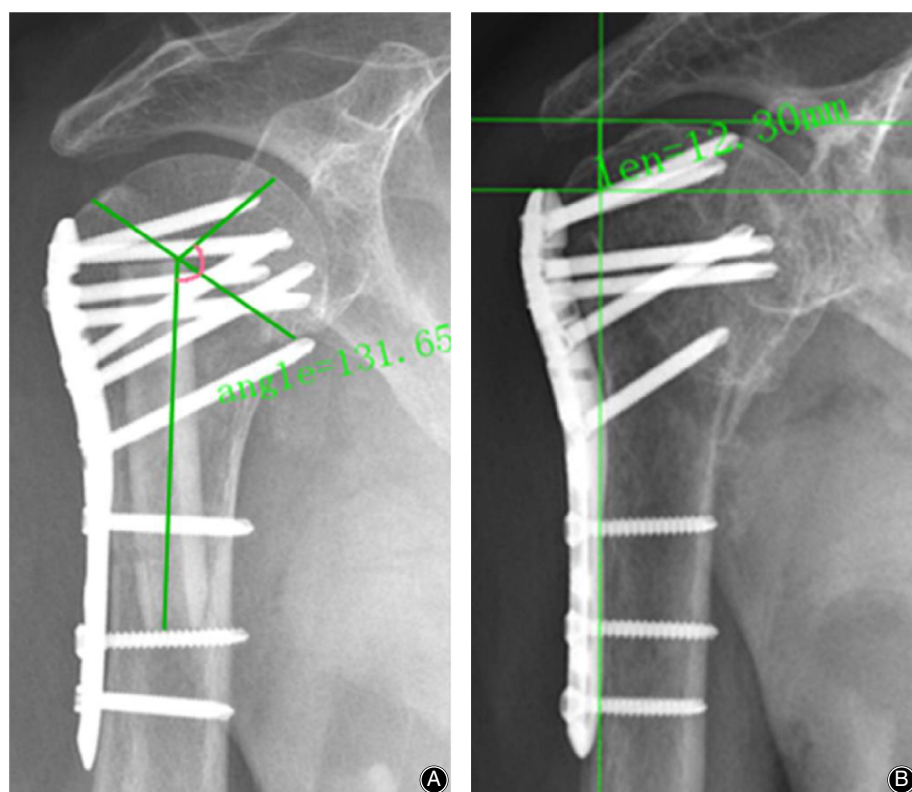
Observation group: PHILOS combined with fibular allograft; Control group: PHILOS alone.



**Fig. 1** (A) Fibular allograft (12 mmx60 mm);  
(B) Insertion of fibular allograft.



**Fig. 2** (A) (The illustration of the PHILOS combined with fibular allograft technology): A 2.0 mm Kirschner-wire (K-wire) was inserted into the humeral head to control rotation, and a periosteal elevator was used as a joystick at the fracture site to obtain reduction. After reduction of the greater tuberosity and humeral head, one or two 1.5 mm K-wires were used for temporary fixation ; (B) The allograft humerus is placed in the distal medullary cavity of the fracture, and the medial support is used to prevent the deformity and collapse of the humeral head in the long term; (C) Rotator cuff sutures were passed through the proximal humeral locking plate, and this was then slid from proximal to distal along the lateral aspect of the shaft, under the axillary nerve. The rotator cuff sutures were tied into place through eyelets on the plate, fixation was then obtained with screws and the wound was closed.



**Fig. 3** (A) The humeral neck-shaft angle (NSA) was defined as the angle between a line that is perpendicular to the articular segment or atomic neck of the humerus and a line that bisects the humeral shaft; (B) The humeral head height (HHH) was defined as the distance between uppermost edge of the plate and the uppermost part of the humeral head.

**TABLE 2** Radiological outcomes of the two groups

Outcomes	Observation group (n = 21)	Control group (n = 21)	t-value	P-value
Mean difference of NSA (°)	3.42 ± 0.71	9.82 ± 1.02	23.599	<0.001
Mean difference of HHH (mm)	2.14 ± 0.33	4.54 ± 0.42	2.429	<0.001

Observation group: PHILOS combined with fibular allograft; Control group: PHILOS alone; NSA, neck-shaft angle; HHH, humeral head height.

glycemic control; and (v) patients who refused to participate or failed to cooperate during the trial.

### Surgical Technique

A proximal humeral locking plate (PHILOS; DePuy Synthes, Pennsylvania, America) was used in all

patients. A fibular allograft (Datsing, Beijing, China) was used in the observation group.

Step 1: All patients were placed in the beach chair position on a radiolucent operating table followed by cervical plexus anesthesia.

Step 2: A deltopectoral approach was performed for all patients. An approximate 15 cm skin incision was made. The

**TABLE 3** Clinical outcomes in the two groups

Outcomes	Observation group (n = 21)	Control group (n = 21)	$\chi^2$ /t-value	P-value
VAS	1.14 ± 0.96	1.25 ± 1.12	0.342	0.734
CMS	86.00 ± 7.56	79.71 ± 9.14	2.429	0.020
ASES	87.76 ± 7.15	81.62 ± 9.62	2.349	0.024
DASH	17.95 ± 7.47	28.14 ± 8.27	4.190	<0.001
Complications	1	7	3.860	0.018

Observation group: PHILOS combined with fibular allograft; Control group: PHILOS alone; VAS, Visual Analog Scale; CMS, Constant-Murley score; ASES, American Shoulder and Elbow Surgeons; DASH, Disability of Arm-Shoulder-Hand score.

insertion of the deltoid muscle was one-half detached posteriorly subperiosteally.

Step 3: Non-absorbable sutures were passed through the junction of the greater tuberosity and the rotator cuff to promote mobilization and reduce fragmented tuberosities. A 2.0 mm Kirschner-wire (K-wire) was inserted into the humeral head to control rotation, and a periosteal elevator was used as a joystick at the fracture site to obtain reduction. After reduction of the greater tuberosity and humeral head, one or two 1.5 mm K-wires were used for temporary fixation. The plate was placed in a position that did not impinge on the acromion. Indirect reduction was performed by inserting a cortical screw into the humeral shaft following the shape of the plate. In the observation group, fibular allograft (12 mm × 60 mm, Fig. 1) was inserted into the intramedullary canal distal to fracture site and was then driven back to the proximal humeral bone. Intramedullary fibular allograft was pushed onto the medial calcar to support the humeral head for prevention of varus displacement and deformity of the humeral head. The position varied depending on the configuration of the fracture. The graft was positioned vertically in valgus fractures and at a slightly oblique angle along the inferior cortex in the varus fractures. If anatomical reduction was achieved, locking screws were

placed through the fibula into the humeral head and shaft to secure its position. Rotator cuff sutures were passed through the proximal humeral locking plate, and this was then slid from proximal to distal along the lateral aspect of the shaft, under the axillary nerve. The rotator cuff sutures were tied into place through eyelets on the plate, fixation was then obtained with screws and the wound was closed (Fig. 2).

#### Postoperative Rehabilitation

The shoulders were immobilized in functional brace for between 4 and 6 weeks postoperatively. Patients received passive exercises immediately after the operation. About 4 weeks and 6 weeks later, active exercises including external and internal rotation were performed by/on all patients.

#### Clinical and Radiological Evaluation

##### Radiological Measurements

Radiological evaluation was performed immediately after the operation and at the final follow-up by measuring the neck-shaft angle (NSA) and humeral head height (HHH) on antero-posterior views (Fig. 3).

The humeral neck-shaft angle (NSA) was defined as the angle between a line that is perpendicular to the articular



**Fig. 4** PHILOS fixation alone in a 65-year-old male patient with a four-part proximal humeral fracture on the right side. (A) X-ray film before surgery; (B) CT before surgery; (C) 3D CT before surgery; (D) X-ray film after surgery; (E) X-ray film 3 months after surgery; (F-J) Function of patient's upper arm at the last follow-up.



**Fig. 5** PHILOS fixation with fibular allograft in a 76-year-old male patient with a four-part proximal humeral fracture on the right side. (A) X-ray film before surgery; (B) CT before surgery; (C) 3D CT before surgery; (D) X-ray film after surgery; (E) X-ray film 3 months after surgery; (F–J) Function of patient's upper arm at the last follow-up.

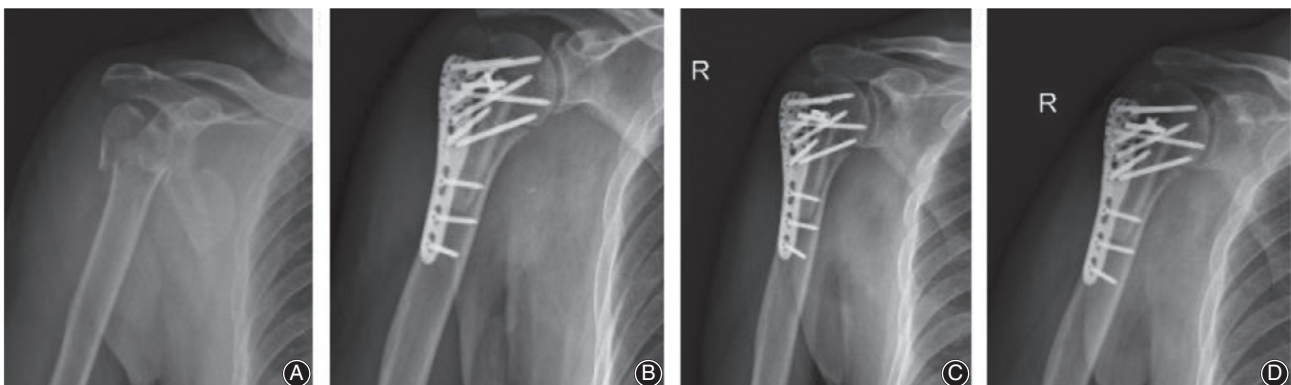
segment or atomic neck of the humerus and a line that bisects the humeral shaft by the measurement tools of the hospital's PACS system. The change in NSA was measured to assess whether the humerus had varus deformity.

HHH was defined as the distance between the upper end of the plate and the upper end of the humeral head by the measurement tools of the hospital's PACS system. The change in HHH was measured to assess the collapse of the humeral head. Comparing the immediate postoperative

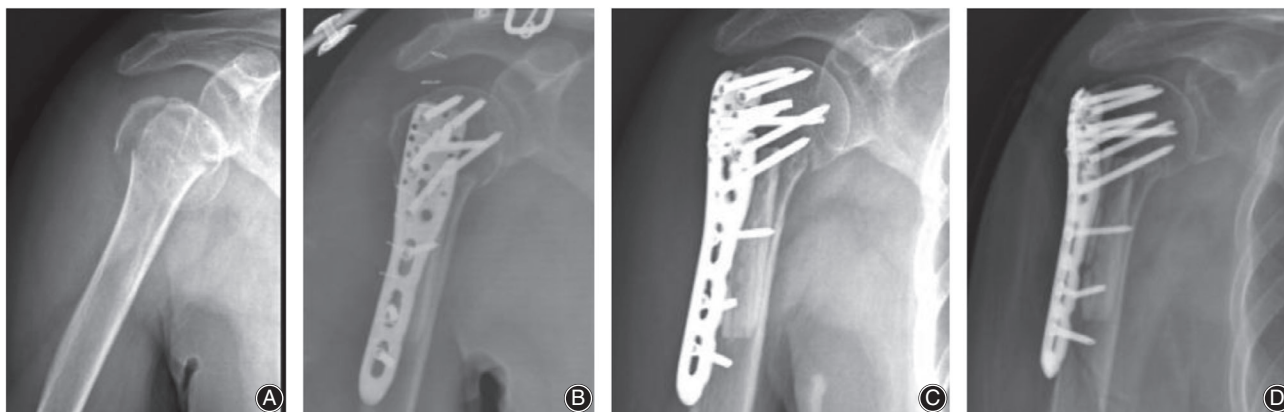
radiological findings with those at the final follow-up, loss of fixation was defined if the varus NSA change was  $>5^\circ$  or if HHH change was  $>3$  mm<sup>14,15</sup>.

#### Postoperative Patient Follow-Up

Clinical evaluation was assessed at the final follow-up using a Visual Analog Scale (VAS)<sup>16</sup> score for pain, Constant-Murley score (CMS)<sup>17</sup>, American Shoulder and Elbow



**Fig. 6** PHILOS fixation with fibular allograft in three patients with a four-part proximal humeral fracture on the right side. (A) X-ray film before surgery; (B) X-ray film after surgery; (C) X-ray film 1 month after surgery; (D) X-ray film 3 months after surgery.



**Fig. 7** PHILOS fixation with fibular allograft in three patients with a four-part proximal humeral fracture on the right side. (A) X-ray film before surgery; (B) X-ray film after surgery; (C) X-ray film 1 month after surgery; (D) X-ray film 3 months after surgery.

Surgeons (ASES) score<sup>18</sup>, and Disability of Arm-Shoulder-Hand (DASH)<sup>19</sup> score.

The VAS was used to assess the pain of the shoulder joint of the subject. The VAS total score is 10 points, with zero points indicating no pain and 10 points indicating unbearable pain.

The CMS score was 100 points, which consisted of pain (15 points), muscle strength (25 points), functional activity (20 points), and shoulder mobility (40 points). Higher scores indicate better functionality. Among them, objective evaluation indicators included shoulder mobility and muscle strength (65 points), and subjective evaluation indicators included pain and functional activities (35 points).

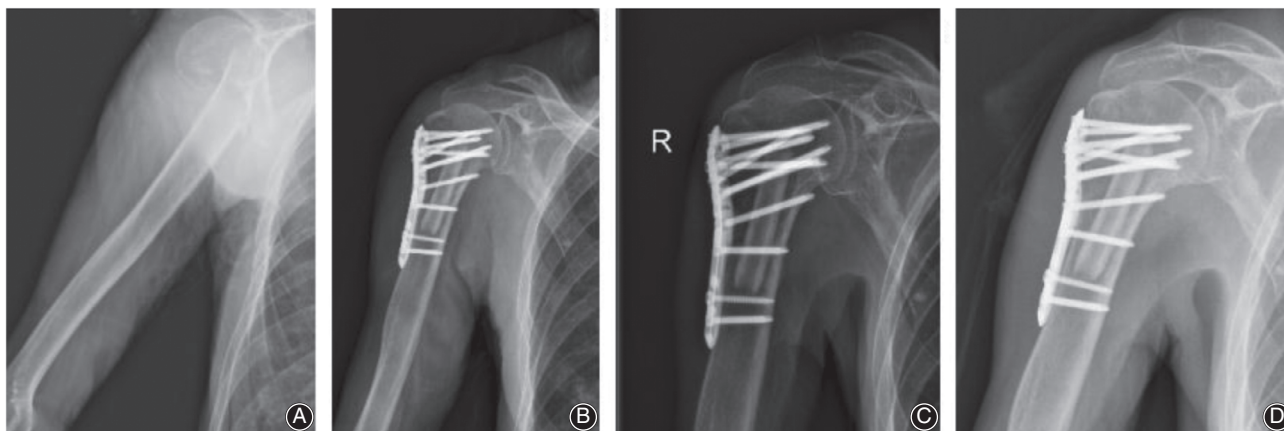
The rating scale of the ASES, which includes pain (50%) and life function (50%), is 100 points. The higher the score, the better the shoulder function.

The DASH scoring system consists of 30 items. Each of the five options corresponds to one to five points. When there are more than three missing items, the score is not calculated. The better the activity, the lower the score.

In addition, complications, such as AVN, screw cutout, implant failure, plate impingement, head collapse, and infection, were also recorded.

#### Statistical Analysis

Statistical analysis was performed using SPSS v. 19.0 (SPSS Inc., Chicago, Illinois, US). Continuous variables, presented as the mean and standard deviation (SD), were compared by the Student *t* test to detect the group differences. Qualitative data of groups was compared by the  $\chi^2$  test. *P* value <0.05 was considered as significant difference.



**Fig. 8** PHILOS fixation with fibular allograft in three patients with a four-part proximal humeral fracture on the right side. (A) X-ray film before surgery; (B) X-ray film after surgery; (C) X-ray film 1 month after surgery; (D) X-ray film 3 months after surgery.

## Results

### Intraoperative Radiological Outcomes

The radiological outcomes are shown in Table 2. The average NSA immediately postoperatively in the observation group was  $138.9^\circ$  ( $118.9^\circ$ – $156.6^\circ$ ), the average NSA at the last follow-up was  $135.8^\circ$  ( $118.4^\circ$ – $155.5^\circ$ ), and the mean difference in the NSA was  $3.42 \pm 0.71^\circ$ . The average NSA immediately postoperatively in the control group was  $135.4^\circ$  ( $109.0^\circ$ – $155.8^\circ$ ), the average NSA at the last follow-up was  $125.8^\circ$  ( $97.0^\circ$ – $149.7^\circ$ ), and the mean difference in the NSA was  $9.82 \pm 1.02^\circ$ . The mean difference in the NSA between the values immediately postoperatively and those at the final follow-up were significantly greater in the control group ( $P = 0.000$ ).

The average HHH immediately postoperatively in the observation group was 12.3 mm (6.7 mm–15.7 mm), the average HHH at the last follow-up was 10.2 mm (6.5 mm–13.5 mm), and the mean difference in the HHH was  $2.14 \pm 0.33$  mm. The average HHH immediately postoperatively in the observation group was 12.2 mm (7.0 mm–18.5 mm), the average HHH at the last follow-up was 9.0 mm (1 mm–15.1 mm), and the mean difference in the HHH was  $4.54 \pm 0.42$  mm. The mean difference in the HHH between the values immediately postoperatively and those at the final follow-up were significantly greater in the control group ( $P = 0.000$ ).

### Follow-up Results

The clinical outcomes are shown in Table 3. No patients were lost to follow-up. The average follow-up time was 12 months. All fractures healed clinically and radiologically. The VAS ( $P = 0.734$ ) score was not significantly different between the two groups. The CMS ( $P = 0.020$ ) score, ASES ( $P = 0.024$ ) score, and DASH ( $P = 0.023$ ) score were significantly different between the two groups at the final follow-up.

### Complications

There were seven postoperative complications in the control group (Fig. 4), including three cases of humeral head collapse, three cases of screw cutout, and one case of humeral head AVN. There was one postoperative complication in the observation group (Fig. 5–8), which was AVN.

## Discussion

PHF has been ranked as the third most frequent fracture and has a strong correlation with osteoporosis<sup>20</sup>. The management of these fractures depends on the vascular status, bone quality, fracture pattern, degree of comminution, and patient factors. Non-operative management is preferred for elderly patients and those with major comorbidities and for undisplaced fractures<sup>21</sup>. However, treating these fractures using non-operative method requires a high level of patient compliance and it is associated with complications, like stiff shoulder and Sudeck's osteodystrophy<sup>22</sup>.

Although there are many surgical options available, PHILOS have consistently demonstrated biomechanical

superiority over other forms of fixation in osteoporotic bone<sup>23,24</sup>. Proponents of PHILOS fixation often cite better fixation, early mobilization, head preservation, restoration of range of motion, and satisfactory function as some of the major advantages of PHILOS construct<sup>25</sup>. But multiple studies have reported on the implant-related complications associated with PHILOS fixation, most commonly, intra-articular screw penetration, postoperative fracture displacement, and AVN<sup>26–28</sup>. A meta-analysis of 12 studies with a total of 514 proximal humerus fractures treated with PHILOS fixation showed an overall complication rate of 49% and a 13.8% reoperation rate. The most common indication for reoperation involved intra-articular screw perforation. The most common complications were varus malunion (16%), osteonecrosis (10%), intra-articular screw penetration (8%), subacromial impingement (6%), and infection (4%)<sup>29</sup>.

The importance of reducing and maintaining the medial calcar to provide biomechanical support for a laterally placed plate has been recognized<sup>30–32</sup>. Researchers concluded that medial support screws played a key role in PHILOS fixation of displaced PHF, but a biomechanical study showed the addition of medial support screws had no effect on the stiffness of the medial cortex in cases with varus malunion<sup>33</sup>. In addition, a clinical study demonstrated that the place of calcar screws might lead to a high risk of humeral head necrosis<sup>34</sup>. Some investigators tried to use bone cement to strengthen the stability of PHILOS in PHF, and the data showed that a good clinical result with a decreasing complication rate<sup>35</sup>, but cement-related heat injuries may exist<sup>36</sup>. Autologous bone grafting might be an alternative method for overcoming varus collapse. However, autologous bone grafting harvested from the patients themselves has some complications, such as vascular or neurologic injuries, deep infections at the donor site, and deep hematoma formation<sup>37</sup>.

Use of an endosteal strut allograft can re-establish medial support, even in the comminuted osteoporotic bone commonly found in these patients. We considered that the fibula might be the most suitable donor bone for reconstructing the medial support in these types of fractures. Its length, geometrical shape, and mechanical strength might also be appropriate for these fractures. The cortical bone of the fibula provides immediate structural continuity and stability at the fracture site. When used as an intramedullary bone graft, it also has some osteogenic potential in addition to acting like a strut across the fracture site. Allograft is cancellous or corticocancellous chips or tricortical graft used as osteoconductive filler for metaphyseal defects. The fibular strut allograft may also minimize postoperative osteonecrosis by increasing the biomechanical strength of the construct and resisting a loss of reduction. Maintenance of reduction may permit revascularization of head pieces rendered ischemic at the time of injury. An important finding of this study is that the rate of varus malalignment and loss of HHH was significantly less when plate fixation was accompanied by a strut allograft.



The similarly good clinical outcomes in our study might be related with some factors. Fibular allograft used as volumetric filling in the bone void formed after reduction of humeral neck-shaft angle could push the humeral head resistance to the force from the scapular fossa along with the screws, preventing the screw penetrating into the articular surface. Besides, this medial strut could prevent the varus placement of the head to diminish humeral head varus collapse and reduce the incidence of malunion. Anatomical medial strut with allograft bone has more potential to prevent humeral head varus displacement compared with the isolated fibula allograft. Anatomical allograft should be modified into a specific shape to fill the bone void according to the intramedullary geometry of the proximal humerus through computer virtual design with Pro-E software. This kind of structural allograft provides enough medial stability and allows the formation of osteogenic tissue across a fracture site along with the surface of the allograft followed by bone formation. In addition, faster fracture healing could minimize articular segment AVN or collapse. Anatomical allograft is a plane contacted with the humeral head, and the support position could be pushed to the inferior medial point. However, isolated fibula was just a point-to-point support of the humeral head, and the support point is just at the line of extension of the intramedullary canal direction.

This study has several limitations. Firstly, it is not a randomized trial because the two techniques were performed

at different times. Secondly, the study was limited by its retrospective design, which could introduce selection bias and the potential for confounding. Thirdly, although a large number of patients were included, this study had relatively low power to detect differences in forward elevation between the two groups. Subtle differences between the groups may not be identified in a single-center study. A large-scale, multicenter study would be required to investigate these clinical outcomes further.

### Conclusions

In conclusion, the present results showed that that patients treated by PHILOS combined with fibular allograft had a better functional outcome and a lower complication rate compared to patients treated by PHILOS alone. Suitable void filler in the proximal humerus for supporting the head fragment, medial cortical bone and greater tuberosity might play a key role in reducing the incidence of complications in elderly patients, especially with osteoporosis.

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