

Clinical effect of using MultiLoc[®] nails to treat four-part proximal humeral fractures

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Abstract

Objective: This study was performed to evaluate the clinical effect of MultiLoc[®] nails (DePuy Synthes, Raynham, MA, USA) on the treatment of four-part proximal humeral fractures (PHFs).

Methods: From January 2014 to January 2018, 32 patients with four-part PHFs were treated with intramedullary MultiLoc[®] nails in our hospital. The operation time, bleeding volume, post-operative X-ray findings, and fracture healing status were recorded and analyzed. At the end of follow-up, the clinical outcome was evaluated based on the visual analog scale (VAS) score, American Shoulder and Elbow Surgeons (ASES) shoulder score, Constant–Murley score (CMS), and occurrence of any complications.

Results: Among all patients, the average operation time was 124.5 minutes (range, 91–152 minutes), the average amount of bleeding was 90 mL (range, 55–150 mL), and the fracture healing rate was 100%. At the end of follow-up, the mean VAS score was 1.6 ± 0.4 , mean ASES score was 84.4 ± 6.3 , and mean CMS was 70.3 ± 6.1 ; no serious complications had occurred; and the patients exhibited good recovery of shoulder function.

Conclusions: MultiLoc nails[®] can be applied to the treatment of four-part PHFs. This surgical fixation method has no obvious complications and helps to restore shoulder function.

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Keywords

Proximal humeral fractures, MultiLoc® nails, Neer four-part fractures, treatment outcome, fracture healing, complications, shoulder function

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Introduction

Proximal humeral fractures (PHFs) account for about 45% of humeral fractures and 5.7% of whole-body bone fractures. In recent years, an increase in injuries resulting from traffic accidents and the aging of the population have contributed to rapidly increasing rates of PHFs, and the incidence rate of PHFs currently ranks third behind distal radial fractures and hip fractures.¹ The severity of fracture comminution and displacement has also increased in recent years, and the proportion of displaced fractures has increased by nearly 50%. Complex four-part fractures of the classic Neer classification occur frequently.^{2,3} Such fractures are often difficult to treat because of the poor fracture condition and severe comminution. At present, the main surgical treatments are angular stable plate fixation and shoulder arthroplasty, including hemi-shoulder, total shoulder, and reverse shoulder arthroplasty.^{4,5}

Increasing numbers of publications are reporting that the outcome of reverse shoulder replacement is better than that of plate fixation and shoulder hemiarthroplasty in elderly patients with PHFs. Nevertheless, the main surgical methods for treating PHFs at present are open reduction and locking plate fixation, intramedullary nail fixation, and shoulder replacement.^{6,7} Notably, however, the application of reverse shoulder replacement is greatly limited by its high cost. A large case study showed that open reduction and internal fixation has several advantages over

one-stage shoulder replacement.⁸ Therefore, locking plates are still frequently used for the treatment of four-part PHFs.^{9,10} Many types of internal fixation are available, and the application of PHILOS® plates (DePuy Synthes, Raynham, MA, USA) and intramedullary nails can be of substantial benefit in the treatment of complex PHFs.¹¹ However, no single type of internal fixation is suitable for all types of humeral fractures. For example, locking plates have an associated failure rate when used for internal fixation and can pose a risk of complications.¹²

Sproul et al.¹³ retrospectively analyzed PHFs treated with locking plates in 514 adult patients. They found that the incidence of complications approached 49% of patients analyzed, and 14% of patients required a second operation. In their report, the most common complications were varus deformity (16% of complications), humeral head necrosis (10%), screw penetration (8%), subacromial impact (6%), and infection (4%). All of these complications occurred frequently in elderly patients with osteoporosis, patients with poor reduction and/or residual bone defects, and patients lacking support in the proximal and medial humerus. These types of complications limit the utility of locking plates, and they are the consequences of using the locking plate technique, which has several shortcomings. First, the humeral locking plate provides decentered arm fixation, which results in difficulty resisting varus stress caused by rotator cuff traction and thus produces focused local stress on the plate with subsequent failure of the internal

fixation device. Second, the direction of the screw action is parallel to the rotator cuff force; this makes it difficult to fix the large nodule, resulting in a high incidence of malunion. Third, during the operation, peeling of soft tissue aggravates damage to the blood supply at the fracture end, leading to a high rate of ischemic necrosis of the humeral head.

Relatively minimally invasive techniques, such as the use of intramedullary nails, are also available for treating these fractures. However, intramedullary nails are rarely used because the initial design of the intramedullary nail at the proximal humerus cannot fully correct the complex fracture block at the metaphysis, and patients can easily develop complications such as a rotator cuff injury and acromion impact. Intramedullary antegrade nailing for proximal humeral fractures and humeral shaft fractures has several criticisms, such as the above-mentioned disadvantages and loss of shoulder range of motion.¹⁴

The AO Foundation recently developed a MultiLoc[®] nail (DePuy Synthes) for the treatment of PHFs. The “screw-in-screw” technique and ascending calcar screw can significantly improve anti-rotation and bending functions, enhance axial and shear stability, and prevent development of humeral head varus deformity or greater tuberosity displacement.^{15,16}

This study was performed to evaluate the clinical results of MultiLoc[®] nails on the treatment of complex four-part PHFs. We herein report our results together with a detailed description of the surgical procedure, fracture healing state, degree of functional recovery, and related complications.

Materials and methods

Ethics statement

This retrospective study was approved by the Ethics Committee of Shenzhen

People’s Hospital at Jinan University and was conducted in accordance with the Helsinki Declaration. All patients participated in the study on a voluntary basis and provided informed consent prior to participating.

General information

Considering the advantages of MultiLoc[®] nails, we applied this approach to 32 patients with four-part PHFs in our department from January 2014 to January 2018. We collected and analyzed the operation duration, amount of blood loss during surgery, postoperative X-ray results, and fracture healing status.

The inclusion criteria were an age of ≤ 70 years; clinical manifestations and corresponding physical signs of four-part PHFs, with the fracture status confirmed by X-ray and computed tomography according to the Neer criteria³; and limitation of the surgical intervention to closed reduction with internal fixation using MultiLoc[®] intramedullary nails.

The exclusion criteria were open fractures; other fractures, vascular or nerve injury, or severe skin/soft tissue injury in the ipsilateral limb; pathological fractures; humeral head-splitting fractures; and the performance of open reduction with plate internal fixation and artificial joint replacement.

Surgical technique

While under brachial plexus block or general anesthesia, the patient was placed in the beach chair position with his or her trunk at an angle of 30° to 45° to the floor. All fractures were first treated with indirect closed reduction by manual traction. An approximately 3-cm longitudinal incision was then made at the anterior angle of the acromion, and the humeral head was exposed via blunt separation of



Figure 1. The patient was placed in the beach chair position at a 30° to 45° elevation, and the transdeltoid incision was marked.

muscle fibers in the anterior middle third of the deltoid (Figure 1).

An indirect reduction technique using upper arm traction, a suture traction nodule, a Kirschner wire, a pry rod, and direct reduction using a bone hook and stripper pry/pull technique were applied for reduction and temporary fixation of the Kirschner wire. Posterior extension, adduction, and anterior displacement were then conducted to expose the humeral head. The insertion point of the guide needle was 1.0 to 1.5 cm inside of the groove between the posterolateral side of the biceps tendon, the greater tuberosity, and the humeral head. The insertion point was located at the top of the humeral head as confirmed by X-ray based on the positive position of the shoulder joint and the exit position of the supraspinatus muscle. A longitudinal incision was made in the supraspinatus muscle belly to pull and protect the muscle. A groove was then created along the hollow drill of the guide wire, and the

medullary cavity was reamed to a 9-mm diameter. An 8-mm-diameter MultiLoc® intramedullary master nail was inserted, and X-ray imaging was performed to confirm that the proximal height of the intramedullary nail was correct. With the aid of an aiming arm, two to four locking screws with a diameter of 4.5 mm (greater tuberosity A/B/D, lesser tuberosity C) and one to three nails in the middle with a diameter of 3.5 mm were placed according to the fracture type. A 4-mm calcar screw was also inserted from 135° in the lateral direction to support the anteromedial humeral head if necessary. One or two 4-mm screws were used to fix the distal end. Tail caps of appropriate height were used. After these interventions, the shoulder joint activity was tested to ensure that space was present under the acromion to avoid impact. The final alignment of the fracture was evaluated by intraoperative anteroposterior and lateral images of the shoulder (Figure 2).

Postoperative treatment

Patients with rotator cuff injuries were provided with a shoulder joint abductor for 4 weeks, whereas patients without a rotator cuff injury were given an upper limb fixation band for 4 weeks. Intentional motion of the affected elbow and wrist joints was initiated on the first day postoperatively, and pendulum motion assisted by the healthy limb was initiated with the affected shoulder at the second week postoperatively. Intentional motion was initiated with the affected shoulder at the third week. Motion was limited to 60° within 2 weeks postoperatively and to 90° within 2 to 4 weeks postoperatively. Unrestricted activity against gravity was allowed 6 weeks postoperatively, and weight-bearing activities and exercise were introduced 12 weeks postoperatively.

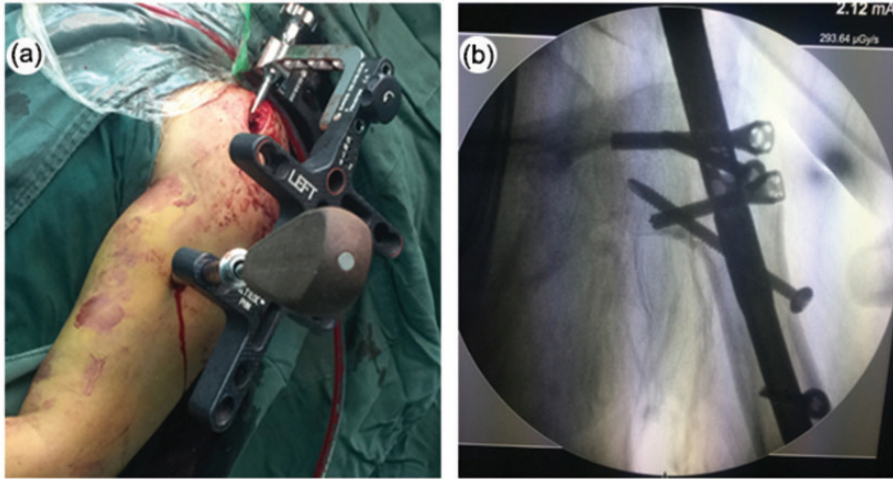


Figure 2. The intraoperative performance and fluoroscopy images indicated the proper positioning of the intramedullary nails for treating a four-part fracture. (a) Satisfactory reduction of a proximal humeral fracture was achieved. A proximal intramedullary nail (MultiLoc[®]) was inserted after proximal reanimation from the humeral head opening. An additional anterior aiming arm was installed, and a screw was fixed at the distal end of the fracture. (b) Intraoperative fluoroscopy imaging provides an example of proximal humeral nailing with good fracture reduction and MultiLoc[®] fixation.

Evaluation indicators

The patients' age; sex; pathogenesis; operation time; blood loss; postoperative X-ray results at 1, 3, 6, and 9 months; and fracture healing status were recorded. Radiographs included both the posteroanterior and laterolateral views to evaluate the bony union and incidence of complications. All radiological results were evaluated by experienced radiologists and orthopedic surgeons. At the end of the follow-up period, a visual analog scale (VAS) was used to evaluate the pain level, and the American Shoulder and Elbow Surgeons (ASES) shoulder score and the Constant–Murley score (CMS) were used to evaluate recovery of proper shoulder function.

The VAS score ranged from 0 to 10, with 0 being painless and 10 being excruciating pain. The ASES shoulder score was composed of two quantum tables, namely life function and pain, each occupying 50%. The highest possible ASES shoulder score

was 100, with a higher score indicating better shoulder joint function. The CMS was composed of four quantum tables, with pain contributing 15 points, shoulder joint activity contributing 40 points, functional activity contributing 20 points, and muscle strength contributing 25 points. As with the ASES shoulder score, a higher CMS indicated better shoulder joint function.

Results

Thirty-two patients were included in our study. Their average age was 50.7 years (range, 26–70 years), and they comprised 11 (34.4%) men and 21 (65.6%) women. The PHF in 15 (46.9%) patients was the result of a traffic accident, that in 11 (34.3%) patients was the result of a fall from a significant height, and that in 6 (18.8%) patients was the result of a fall at ground level. The fracture site was located in the left shoulder in 18 (56.3%) patients

Table 1. Patients' demographic characteristics.

Number of patients	32
Sex, male/female	11/21
Age, years	50.7 (26–70)
Interval between injury and surgery, days	4.2 (1–10)
Fracture mechanism, accidental fall/traffic accident	19 (59.4)/13 (40.6)
Neer classification (four-part)	32
Duration of operation, minutes	124.5 (91–152)
Bleeding volume, mL	90 (55–150)
Duration of follow-up, months	14.6 (10–18)

Data are presented as average (range), n, or n (%).

and in the right shoulder 14 (43.7%) patients. All patients presented with four-part Neer fractures. The average time from injury to the operation was 4.2 days (range, 1–10 days). The average operation time was 124.5 minutes (range, 91–152). The average intraoperative blood loss was 90 mL (range, 55–150 mL), and the average follow-up period was 14.6 months (range, 10–20 months) (Table 1).

Clinical efficacy evaluation

At the end of the follow-up period, antero-posterior and lateral X-ray views of the proximal humerus indicated that all fractures had undergone osseous union (Figure 3) with good recovery of shoulder joint function. No patients developed malunion in our study. No evidence of rotator cuff injury was found in any patients.

The mean VAS score was 1.6 ± 0.4 points, the mean ASES shoulder score was 84.4 ± 6.3 points, and the mean CMS was 70.3 ± 6.1 points.

We also tested the range of motion of the recovered shoulder joint. The mean forward bending angle was $142.5^\circ \pm 21.6^\circ$, the mean abduction angle was $139.2^\circ \pm 26.3^\circ$, the

mean external rotation angle was $60.1^\circ \pm 11.7^\circ$, and the mean internal rotation angle was $58.4^\circ \pm 13.8^\circ$ ($P < 0.05$) (Table 2). Typical cases are shown in Figure 4.

Complications

At the end of the follow-up period, we detected no infection at the incision site and no iatrogenic nerve or vascular injury in any patients. One patient had an acromion impact from a high tail cap, which recovered well after removal of the internal fixation device. Two patients experienced occasional subacromial pain. Another patient had stiffness in the ipsilateral elbow, possibly resulting from inadequate rehabilitation therapy. One other patient had calcar screw displacement, but without accompanying shoulder dysfunction. Therefore, the total incidence rate of complications in this study was 13.3% (4/30).

Discussion

PHF is a common osteoporotic fracture seen in elderly patients and is often caused by an indirect blunt force, such as landing on a hand or elbow when falling. The force is conducted through the forearm or elbow, leading to development of a fracture. Elderly patients are at risk of serious comminuted fractures as a result of minor accidents because such patients often have serious osteoporosis. In recent years, the incidence rates of PHF have increased with increases in high-energy injuries, such as those caused by traffic accidents.^{17,18}

Most of the patients included in this study were young, and their fractures were severely comminuted as is commonly seen in patients with fractures resulting from high-energy injuries. Many of these patients also had a seriously damaged blood supply. Nonsurgical treatment of such fractures can easily result in fracture malunion or non-union, humeral head necrosis, traumatic

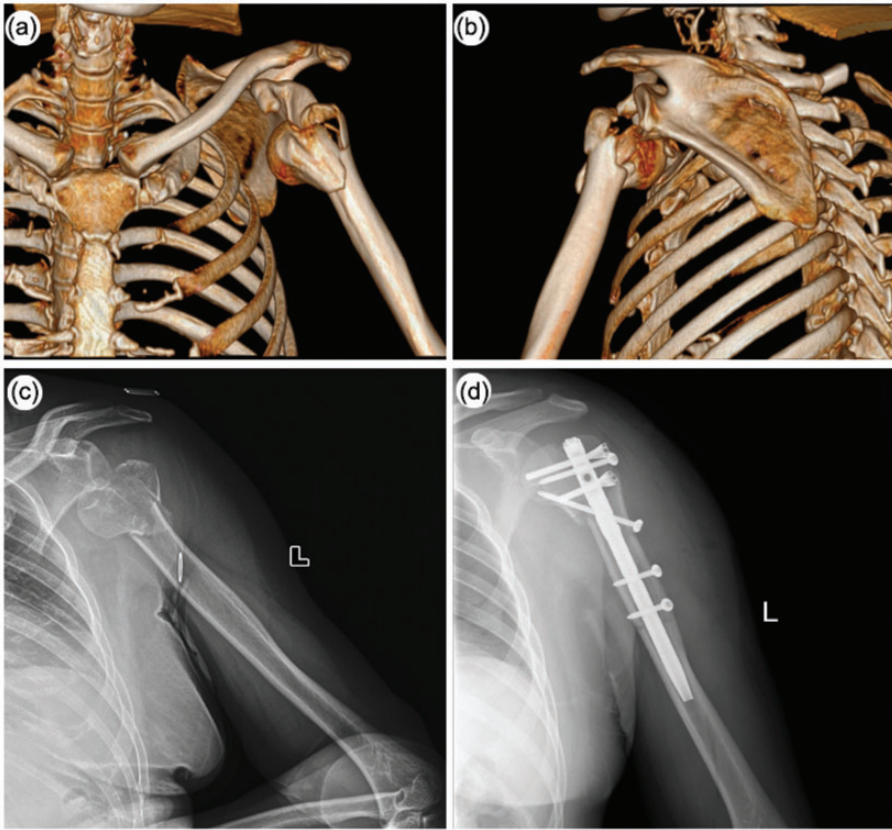


Figure 3. Recovery as shown by computed tomography scans and X-ray images of a 48-year-old woman with a four-part PHF. (a, b) Computed tomography scans showing the anterolateral and posteromedial views of the tridimensional reconstruction. (c) Preoperative X-ray image. (d) X-ray image after the intramedullary nailing procedure, indicating that the initial postoperative alignment of the fracture and the position of the MultiLoc[®] nails were satisfactory.

Table 2. Evaluation of recovery after 12 months.

VAS score	1.6 ± 0.4
ASES shoulder score	84.4 ± 6.3
Constant–Murley score	70.3 ± 6.1
Range of motion	
Forward flexion	$142.5^\circ \pm 21.6^\circ$
Abduction	$139.2^\circ \pm 26.3^\circ$
External rotation	$60.1^\circ \pm 11.7^\circ$
Internal rotation	$58.4^\circ \pm 13.8^\circ$

Data are presented as mean \pm standard deviation. VAS, visual analog scale; ASES, American Shoulder and Elbow Surgeons.

arthritis, and other serious complications, which can cause pain and seriously limited limb function. Most scholars have therefore suggested surgical treatment to restore shoulder function for these patients.

The proximal humeral nail MultiLoc[®], a representative third-generation proximal humeral intramedullary nail, has achieved good clinical outcomes in recent years.¹⁵ We performed 32 cases of closed reduction and internal fixation with MultiLoc[®] nails for the treatment of four-part PHFs in the present study. All 32 patients achieved

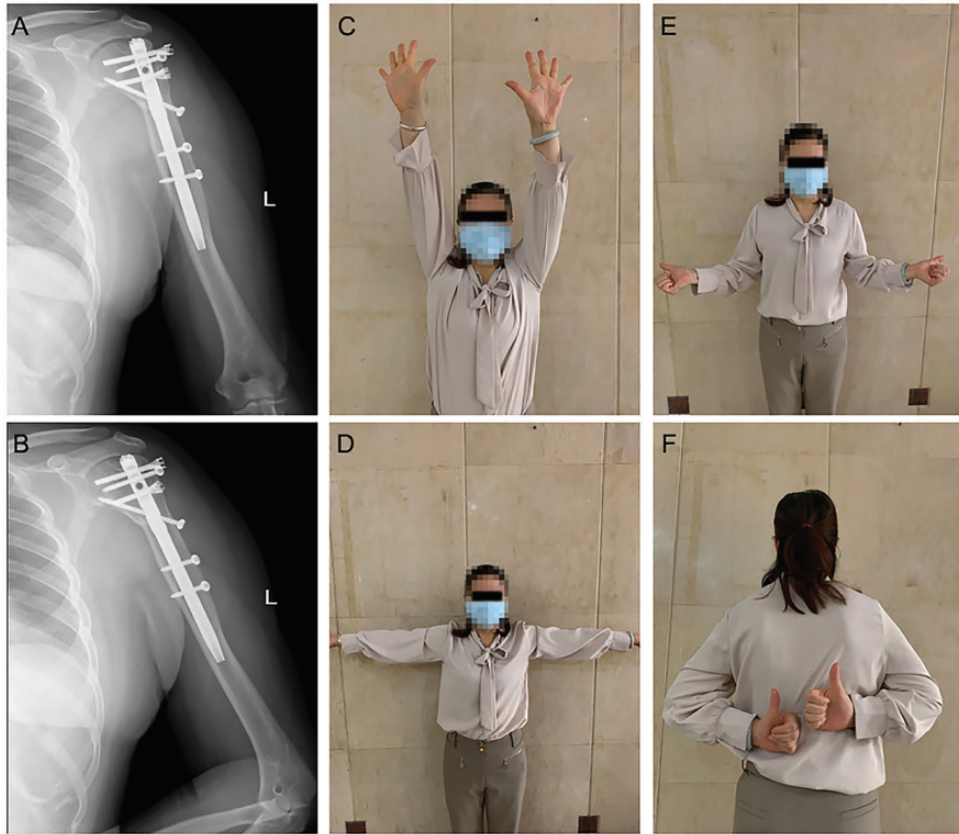


Figure 4. Clinical outcome 12 months postoperatively as shown by radiographs. (a) Anteroposterior and (b) lateral radiographs showing complete fracture union of the left shoulder at 12 months postoperatively. (c–f) The same patient demonstrated good functional outcomes for the left shoulder 12 months postoperatively. (c) Forward flexion. (d) Abduction. (e) External rotation. (f) Internal rotation posteriorly.

successful bone healing and had excellent scores during the clinical evaluation phase of the study. At the end of the follow-up period, the mean VAS score was 1.6 ± 0.4 , the mean ASES shoulder score was 84.4 ± 6.3 , and the mean CMS was 70.3 ± 6.1 . The incidence of complications was low at 13%. The excellent clinical outcomes and low complication rate associated with this approach in the present study further demonstrate the superiority of MultiLoc[®] nails for the treatment of four-part PHFs.

The MultiLoc[®] nail has several advantages in terms of its structural design and biodynamics.^{19,20} First, the MultiLoc[®]

proximal humerus nail is a fixation device that distributes the load centrally and separately. The type and extent of proximal locking can be adapted to the fracture type and to the specific biomechanical requirements. Distal locking with two screws in different planes avoids toggling and provides better stability with an improved bone–implant interface. A central polyethylene sleeve provides angle-stable fixation of the proximal locking screws in the nail and prevents unintended backing-out of screws during functional after-treatment. In addition, the nail locks the proximal and distal humerus in place,

which helps to effectively resist axial, torsional, and bending loads. Second, compared with the curved nail with a decentered angle, the design of the straight nail has the advantage of a more internal needle point, which can help reduce rotator cuff damage. This design diminishes the likelihood of a varus deformity because the nail direction is consistent with the mechanical axis of the humeral shaft. This technique can also significantly increase the fixation stability because the nail entry position has excellent bone mass and the humeral head is surrounded by the relatively intact bone ring. Third, the intramedullary nail is more flexible than the locking plate and screw fixation approach because it can lock in multiple directions and angles at the proximal end, which can be perpendicular to the fracture line. Fourth, the distal locking pin can be locked in multiple directions under an external force. Finally, the proximal locking pin hole is threaded, which provides a stable angle and stable locking. This design can prevent the screw from puncturing and dropping out postoperatively.¹⁵

The vast majority of the patients in the present study achieved a good ASES shoulder score and CMS. Nevertheless, the mean forward elevation range of the recovered shoulder joint was $142.5^{\circ} \pm 21.6^{\circ}$, resulting in anterior flexion loss. During the operation, the tail of the MultiLoc[®] nail was definitely below the osteochondral surface, which was assisted by direct vision from the incision and intraoperative fluoroscopy. Additionally, an X-ray image was taken to confirm that the proximal height of the intramedullary nail was appropriate. This prevented rotator cuff impingement. Moreover, an approximately 3-cm longitudinal incision was made at the anterior angle of the acromion, and the humeral head was exposed via blunt separation of muscle fibers in the anterior middle third of the deltoid. This prevented damage to the rotator cuff. Finally, no evidence of

rotator cuff injury was found in any patients. We believe that the partial loss of anterior flexion resulted from adhesion of the scar tissue in the surgical area and the absence of postoperative functional exercise in some patients.^{21,22}

Hessmann et al.¹⁵ performed a prospective multicenter study on the treatment of PHF with MultiLoc[®] nails in 17 patients. At 6 months postoperatively, the mean CMS was 66. Lopiz et al.²³ reported the use of MultiLoc[®] nails for the treatment of PHFs in elderly patients. The average angle of the cervical axis was 135° at the end of the follow-up period, the mean CMS was 83.3 ± 16.7 , the reoperation rate was 11.5%, and the incidence of rotator cuff complications was 34.6% (9/26). Hao and Huat et al.²⁴ performed a prospective study of 22 patients with 2-, 3- and 4-part PHFs treated with MultiLoc[®] nails. The authors found that after 12 months, the mean CMS and ASES shoulder score were 75.5 ± 12.1 and 81.7 ± 6.2 , respectively, and the mean VAS score was 1.7 ± 0.8 . This satisfactory outcome and low complication rate were comparable with those observed in our study. Therefore, we believe that the MultiLoc[®] nail is well suited for the treatment of Neer four-part PHFs.

Our study had several limitations. First, the present study only represented the experience of the surgeon involved because the surgical approach was determined by the fracture type and the surgeon's preferences. Second, few reports have focused on the application of MultiLoc[®] intramedullary nails for such complex fractures, and we only had a small group of patients with no control group. Third, we do not believe that the follow-up time was long enough to accurately evaluate the occurrence of traumatic osteoarthritis.

In conclusion, as a result of their unique biomechanical advantages and improved design, MultiLoc[®] nails can obtain better clinical outcomes when used to treat

complex Neer four-part PHFs than those obtained using other existing techniques. However, the use of MultiLoc® nails has a significant learning curve. The surgeon should choose the appropriate indications, standardize the operation, and work to avoid complications caused by improper technique. In addition, because of the short follow-up period in this study, a larger study with randomized and control cases is needed to reach a more comprehensive conclusion. We plan to perform a study with randomized and control cases, increased sample size, and extended follow-up time.

Authors' contributions

ZFJ performed the surgery, collected and analyzed the data, drafted the manuscript, and carried out the patient follow-up. GHL supervised the project and reviewed the manuscript. CLL, JDL, and QSL conceived of the study, participated in its design and coordination, and helped to draft the manuscript. XJH was responsible for the whole project and designed and supervised the study. All authors read and approved the final manuscript.

Declaration of conflicting interest


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