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Design and Clinical Application of Proximal Humerus Memory Connector

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Treatment for comminuted proximal humerus fractures and nonunions are a substantial challenge for orthopedic surgeons. Plate and screw fixation does not provide enough stability to allow patients to begin functional exercises early after surgery. Using shape memory material nickel titanium alloy, we designed a new device for treating severe comminuted proximal humerus fractures that accommodates for the anatomical features of the proximal humerus. Twenty-two cases of comminuted fracture, malunion, and nonunion of the proximal humerus were treated with the proximal humeral memory connector (PHMC). No external fixation was needed after the operation and patients began active shoulder exercises an average of 8 days after the operation. Follow-up evaluation (mean 18.5 months) revealed that bone healing with lamellar bone formation occurred an average of 3.6 months after surgery for the fracture cases and 4.5 months after surgery for the nonunion cases. Average shoulder function was 88.5 according to the criteria of Michael Reese. PHMC is an effective new device to treat comminuted proximal humerus fractures and nonunions. The use of this device may reduce the need for shoulder joint arthroplasty.

Keywords humeral fractures, proximal humerus memory connector, shoulder fractures

1. Introduction

Fractures of the proximal humerus account for 4-5% of all reported fractures (Ref 1, 2). In cases of displaced proximal humerus comminuted fractures, stable fixation is not always possible, leading to nonunion at the fracture site and ischemic necrosis at the humeral head (Ref 1, 3). In these fractures, conservative treatment is not an option and external fixation is a lengthy process that is associated with pain and varying amounts of disability (Ref 4, 5). The only remaining option is artificial joint replacement, which is not desired by many patients (Ref 6). Using shape memory material nickel titanium alloy (Ref 7), we designed a new device for treating severe comminuted proximal humerus fractures that accommodates for the anatomical features of the proximal humerus. The purpose of this report was to evaluate this device, named the proximal humeral memory connector (PHMC), in patients who sustained comminuted humeral fractures and associated non- or malunions.

2. Experimental and Clinical Procedure

2.1 Structure Design

The PHMC consisted of a 2-2.5 mm thick nitinol plate comprised of 50-53% nickel (Fig. 1). The humeral head portion of the PHMC consisted of a humeral head guiding fixation branch and anatomical neck half-ring bone-holding branches. The humeral body portion consisted of plates and bone-holding wings, as well as a compressive branch. The device was heat treated for a one way memory effect and the reverting temperature was 33 ± 2 °C. The PHMC was designed to be suitable for many different clinical applications.

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2.2 Principle of PHMC Fracture Fixation

The PHMC was placed in ice water and flattened prior to placement on the proximal humerus. After insertion, body heat increased the temperature of the PHMC and caused it to revert to its original shape. When closure of the PHMC was stopped by the bone, the fracture was automatically fixated. The humeral head portion of the PHMC stabilized the fractured humeral head via the humeral head guiding fixation branch and anatomical neck half-ring bone-holding branches. The humeral body portion of the PHMC interacted with the proximal humeral tubular bone and produced multi-point fixation. The compressive branch of the PHMC produced the longitudinal compressive force after being placed in the drilled opening.

2.3 Patients Characteristics

Between August of 2000 and September of 2003, 22 patients were treated for proximal humeral comminuted fractures, nonunions or malunions with the PHMC. Thirteen patients suffered the fracture between the anatomical neck and surgical neck of humerus. Four cases were malunion and five cases were nonunions. Fifteen patients were male and seven were female. The age ranged between 13 and 69 years with an average age of 41.7 years. The Michael Reese system was used to evaluate shoulder joint function after surgery for all patients.

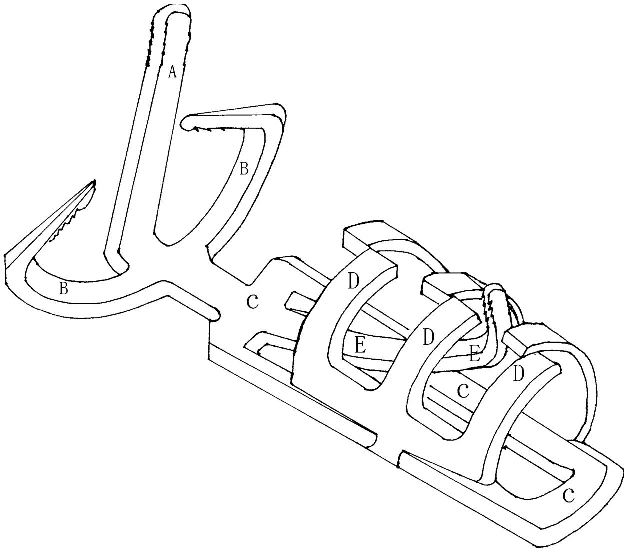

Fig. 1 Schematic of proximal humerus memory connector (PHMC) (A) humeral head guiding fixation branch; (B) anatomical neck half-ring bone-holding branches; (C) plates; (D) bone-holding wings; (E) compressive branch

2.4 Surgical Method

After adequate brachial plexus or general anesthesia, patients were seated in a beach-chair posture and a deltopectoral approach was used to expose the humerus. For fractures located between anatomical neck of humerus and the surgical neck, a hole was drilled with a diameter of 0.4-0.6 cm, 0.5-1.0 cm below the apex of the greater tubercles of humerus. This hole was oriented toward the center of the humeral head, but did not penetrate articular face of humeral head. Then the humeral head guiding fixation branch that had been spread in ice water was inserted into the hole, and the anatomical neck half-ring bone-holding branches were inserted into the corresponding points in the same fashion. A hole was also drilled for the compressive branch of the PHMC and this portion was inserted into the cavity. The PHMC was heated and the fracture site was appropriately fixated. If the fracture extended to the upper 1/3 of the humerus diaphysis, the diaphysis fracture was first fixated with shape memory fracture staples (Ref 8). It should also be noted that the half-ring bone-holding branches of PHMC can be used for anchorpile for the suture of joint capsule and shoulder-sleeve. Severe comminuted and compressed fractures in this region also required autogeneous ilium grafting. The grafted bone was trimmed to pad the area of bone deficiency and support the humeral head.

For nonunions of the surgical neck of the humerus, scar, and dead bone tissue were removed. The medullary cavity was drilled and the humeral nonunion was fixated with the PHMC. Homogeneous ilium was harvested for bone grafting. The grafted ilium was trimmed to three fundamental shapes: the block shape for padding, the slat shape for splinting the nonunion site (along with the humeral body portion of the PHMC) and the chipping shape comprised of spongy bone for filling the gap at the nonunion site.

2.5 Post-operative Management

Drainage was left in place for 24-48 h. The arm was suspended with scarf bandage for one week. Active motion of the elbow and wrist began on post-operative day 1. Shoulder active range of motion was encouraged after 7-12 days after operation.

Fig. 2 (a) AP x-ray of the shoulder joint of a 15-year-old female patient (30 days after injury). Image shows fracture from anatomical neck to surgical neck, and dislocation of the humeral head. (b) Following treatment with PHMC and bone grafting, the obsolete fracture healed very well and the patient regained normal function

3. Results

All patients were followed-up between 6 and 37 months, with an average follow-up time of 18.5 months. Osseous healing occurred an average of 3.6 months after the operation for the fracture group and 4.5 months for the nonunion group. The fracture and nonunion sites were connected by plate bone; no disorder wave bone was seen. External fixation was not required for any patient after the operation. After allowing 7-12 days for wound healing, all patients actively exercised their shoulder joints. Averaged shoulder score was 88.5 according to Michael Reese system at the last follow-up. Typical cases treated with PHMC are shown in Fig. 2 to 5.

4. Discussion

The goal of open reduction and internal fixation (ORIF) is to restore proximal humeral anatomy with enough stability to permit the fracture to heal, while still allowing for early motion to avoid stiffness or subsequent avascular necrosis (AVN). Prosthetic replacement is often used in place of ORIF to provide early stability for the more comminuted or complicated proximal humeral fractures (Ref 9, 10). However, prosthetic replacement is not a desirable method for a younger population.

Fig. 3 (a) Malunion of surgical neck of a 13-year-old male patient. The humeral head is positioned at 100 degrees of varus. (b) Six months after bone rectification and fixation by PHMC, the deformity was corrected and the bone healed

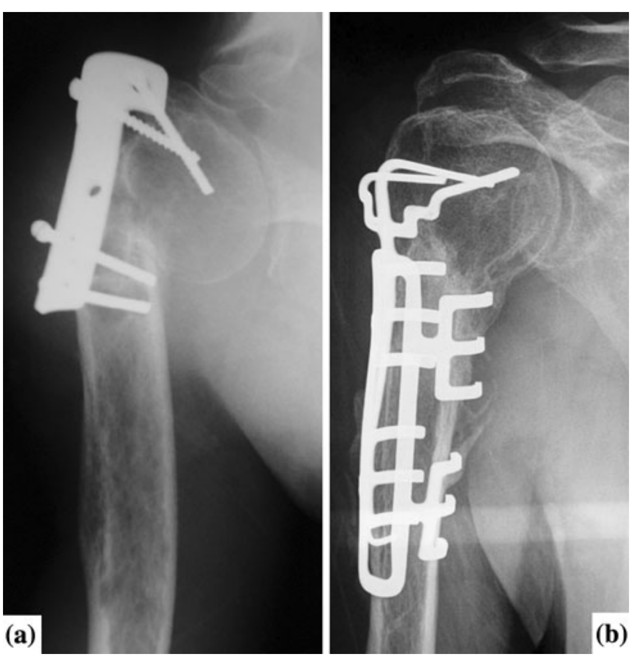

Fig. 4 (a) A 37-year-old male patient, 11 months after fixation with plate and screws (displaced fracture and nonunion are visible). (b) After treatment with PHMC, the nonunion was healed

Currently, there have been no other options for severely comminuted fractures. The PHMC is a new ORIF technique that restores the stability in comminuted fractures. The results of

Fig. 5 (a) Comminuted fractures from the anatomical neck to the proximal ¼ of humerus in a 44-year-old male patient. The diaphysis fractures were fixated with shape memory staples and then fixated with PHMC. (b) Five months after operation, transthoracic lateral projection (Cahoon) x-ray revealed substantial fracture healing

our study showed that the PHMC method was effective in all of the patients. No patients developed AVN, even in fractures in which the integrity of the humeral head was jeopardized (Fig. 2, 4, 5). The chance for AVN may be reduced by the continuously compressive stress that is inherent in the PHMC design.

During fixation, the humeral head portion of the PHMC and the compressive branch of the PHMC produced compression at the fracture site. This compression persisted even after absorption of the bone besides the fracture line. Additionally, the humeral body portion of the PHMC produced multi-point three-dimensional fixation, which is important for the humerus, which experiences multiplanar forces. The shape memory alloy is slightly elastic, which permits small amounts of movement within the three-dimensional constraints of the PHMC. These ‘‘micro-movements’’ occur with muscle contraction and allow for effective nonrigid and nontraditional elastic fixation.

The PHMC is effective for fractures and nonunions of the proximal humerus below anatomical neck. Comminuted fractures in this region are usually accompanied by bone deficiency because secondary to compression of cancellous bone tissue. Additionally, the cortex bone of surgical neck is very thin, making adequate fixation extremely difficult. To overcome these problems during surgery, autogeneous ilium grafts were used to overcome loss of bone stock and to support the humeral head. The amount of the graft was dependent on the bone deficiency, but typically a segment of the ilium 3-4 cm long and 3 cm wide was removed. One end of the graft was trimmed for to contact the humeral head and the other end was inserted into the humeral medullary cavity. If deficiency in humeral bone still existed below the humeral head, a blend of shattered ilium pieces and artificial bone (e.g., MIIG X3) were used to fill the gap. An additional trimmed ilium graft could also be used to splint or bridge the site of the nonunion or comminuted fracture.

While PHMC appears to be a clinically valuable method to repair fractures and nonunions of the proximal humerus below anatomical neck, it is not indicated for comminuted fractures above anatomical neck. Further research is needed to develop alternative methods to repair more proximal fractures, while avoiding prosthetic replacement. Further longitudinal studies are also needed to evaluate long-term outcomes after surgical fixation using the PHMC.

5. Conclusion

PHMC proved to be an efficacious method to treat fractures and nonunions of the regions of the humerus ranging from the anatomical neck to the diaphysis. Moreover, this new method of treatment may reduce the rate of prostheses displacement in the humerus, and reduce the need for shoulder joint arthroplasty.

Acknowledgment

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