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Treatment of Clavicular Nonunions with Shape Memory Ni-Ti Alloy Swan-Like Bone Connector

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Disability caused by nonunited fracture of the clavicle is a rare condition that is expressed by local pain. This condition is usually treated by reduction of the fracture and stable fixation with augmentation by autogenous bone graft. This is a retrospective study to assess outcome of the treatment of clavicular nonunion with a novel shape memory Ni-Ti alloy swan-like bone connector (SMC). August, 2003 to December, 2006, 5 consecutive patients with clavicular nonunion were treated using SMC in our hospital. The SMC device was cooled with ice before implantation and then warmed to 40-50 °C after implantation, to produce balanced axial and compression forces that would stabilize the fracture. We have used cancellous bone grafting in all our cases to obtain solid healing. Average follow-up was 37 months (range 25-58). In all patients, satisfactory osseous union was achieved. There was no complication from the hardware. The average Constant score which is for evaluating function of injured shoulder after operation was 86 points (average Constant score for the unaffected shoulder was 95). All patients were very satisfied with the treatment and outcome. The SMC provides a new effective method for fracture fixation and treatment of bone nonunion for clavicle.

Keywords clavicle, constant score, Ni-Ti alloy, nonuion, shape memory

1. Introduction

Clavicle fractures occur commonly, accounting for 5 to 10% of all fractures (Ref 1, 2). Most of these fractures can be treated nonoperatively and will heal without surgical intervention (Ref 3). Some may be susceptible to nonunion, with age, gender, location and nature of the fracture (amount of displacement), soft-tissue damage, inadequate immobilization (Ref 4), and primary operative treatment (Ref 5) suggested as contributing factors. The incidence of nonunion of clavicle fractures ranges from 1 to 15% (Ref 6, 7). The objective of treatment in patients with clavicular nonunion is to restore the normal anatomic configuration of the clavicle and induce solid union of the fracture. In nearly all reported series, autogenous bone graft is usually recommended as a necessary adjunct to the healing process (Ref 8).

Ni-Ti shape memory alloy possesses excellent properties of wear and corrosion resistance and good biocompatibility. In as early as 1990, this alloy was approved for medical use by FDA of the US. With the rapid development of its medical applications, the Ni-Ti shape memory alloy is considered to represent a major discovery in research of medical material science and recognized as a valuable biomaterial that ''remembers''. Simon et al. (Ref 9) designed a vena cava filter using Ti-Ni alloy, which demonstrated excellent efficacy in a multicenter clinical trial involving 147 cases from 19 vascular centers. By now shape-memory alloys have been widely used in clinical practices for manufacturing new instruments and devices (Ref 10, 11).

The occurrence of fracture nonunion is closely associated with the stress condition around the bone fracture fragments. Clavicular bone bears no weight under normal condition, so reestablishment of the biomechanical condition around the bone fracture mimicking the normal anatomical and physiological environment for the bones, in addition to proper fracture fixation against shear stress, bending and rotation, may greatly promote nonunion healing. Based on intensive investigations on physical, chemical, and mechanical properties of the Ti-Ni alloy, we designed a Ti-Ni shape-memory alloy device for treatment of clavicular shaft nonunion according to the anatomy of clavicular bones (Chinese Patent No. ZL 013444218.X). As the shape of this device bears a rough resemblance of a swan, we call it Swan-like Memory-pressure Connector, or SMC for short).

From August 2003 to December 2006, 5 cases of clavicular shaft nonunion were treated using this device, yielding a success rate as high as 100%. In this article, we present our experience with this device for treatment of clavicular nonunion in these cases.

2. Patients and Methods

2.1 Patients

From August 2003 to December 2006, 5 patients with clavicular nonunion were treated using SMC in our hospital,

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Table 1 Clinical details of patients

No.	Sex/age	Mechanism of injury	Side	Location of fracture	Complications	Follow-up, months	Constant score (affected/control shoulder)
1	M/21	Traffic accidents	L	Midshaft		25	87/99
2	M/35	Falling	R	Midshaft		58	83/89
3	M/45	Falling	R	Midshaft		28	86/97
4	F/27	Sports activities	L	Midshaft	Pain in donor site	32	87/93
5	F/50	Traffic accidents	R	Midshaft		42	89/96

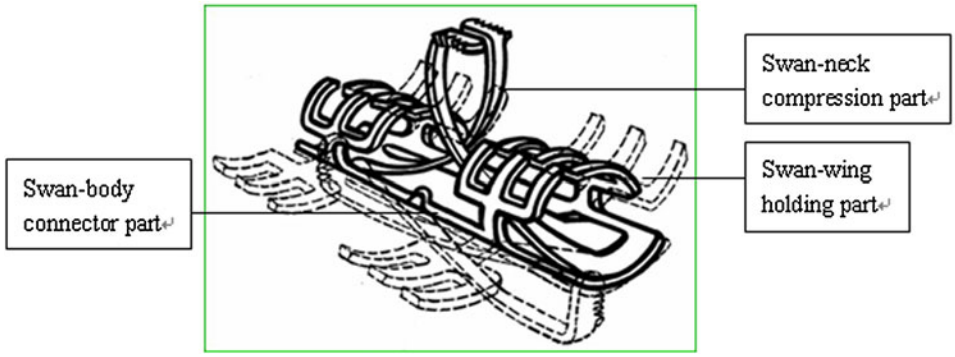

Fig. 1 Schematic diagram of SMC

including 3 men and 2 women with a median age of 36 years (range 21-50 years) (Table 1). The patients had their primary fractures due to road accidents (2 cases), falling (2 cases), sports activities (1 cases). The fractures included transverse fracture (1 cases), spiral or oblique fracture (2 cases), and comminuted fracture (2 cases). All the patients had closed fractures and were treated conservatively for the primary fractures, and the diagnosis of fracture nonunion was established for the presence of pain at the fracture site, abnormal bone movement, and arm dysfunction 6 months following the conservative treatment. Radiograph of the fractures identified hypertrophic nonunion in 3 cases, atrophic nonunion in 2 cases. The period between initial fracture and our surgery for fracture nonunion averaged 13.5 months (range 8-32 months).

2.2 Structure and Working Principle of the SMC Device

The SMC device (Huzhou Swan Biological Memory Medical Devices Co., Ltd., Zhejiang, China) was designed based on full consideration of the clavicular anatomy, and manufactured with 2 mm thick Ti-Ni shape memory alloy plate (with Ni content of 50-53 at.%). The device (Fig. 1), processed with one-way heat treatment and a reversion temperature of 33 ± 2 °C, consisted of compression arms (head and tail hooks) and embracing arms connected to the main plate, with an inner diameter of 10-30 mm and a diameter/axial length ratio of around 1:6. Before use the device was immersed in ice-cold water at 0-4°°C, in which the alloy had good plasticity to allow extension of the embracing arm to a length larger than the diameter of the fractured bone to be fixed. The compression hook at the ''neck'' of SMC was extended dorsally and temporarily secured on the back of the main plate. The midpoint of the plate was then positioned to overlap with the point of the fracture, and a hole was drilled on the clavicle proximal to the fracture, where the ''tail hook'' was anchored. After careful reduction of the fracture, the SMC was fixed and a hole was drilled in the cortical bone at the point where the extended compression hook at the neck of the device came in contact with the clavicle. The anterior compression hook was then inserted into the hole, and the SMC was heated with warm water to 40 to 50 °C to cause recovery of the preset shape, during which process the device produced sufficient force to stabilize the fracture. At normal body temperature, the embracing arms of the implanted SMC recovered their remembered shape and securely embraced the clavicular shaft. In a similar fashion, the anterior compression hook also underwent shape conversion and produced a force to resist the pulling by the tail hook, thus imposing an axial compression along the clavicular shaft. The balanced forces generated by the embracing arms and the compression arms (head and tail hooks) thus allowed 3-dimensional stabilization of the clavicular shaft.

2.3 Surgical Procedures

All procedures were carried out by the corresponding author (Shuo-gui Xu) (Fig. 2) and all the patients signed informed consent for their operation and application of internal fixation of SMC. Although we are aware that most hypertrophic nonunions do heal, once a stable rigid fixation was obtained, we performed bone grafting in all patients to give them the best possible conditions for healing. Cancellous bone was harvested from the ipsilateral iliac crest. In the hypertrophic nonunions the superficial part of the excessive bone was removed. Then the fracture was reduced and fixed with SMC. The site was packed with the cancellous bone graft in the defects and around the fracture site. The fixation of the SMC has been described above. The embracing arms near the midpoint were opened by 3-7 mm at 0-4 °C, through which cancellous bone grafts were inserted in close contact with the rough cortical bones. The embracing arms were then warmed to tighten the bone. Around the fractured ends of the clavicular shaft, crusts of cancellous bone graft with thickness of matchsticks were stuffed into the

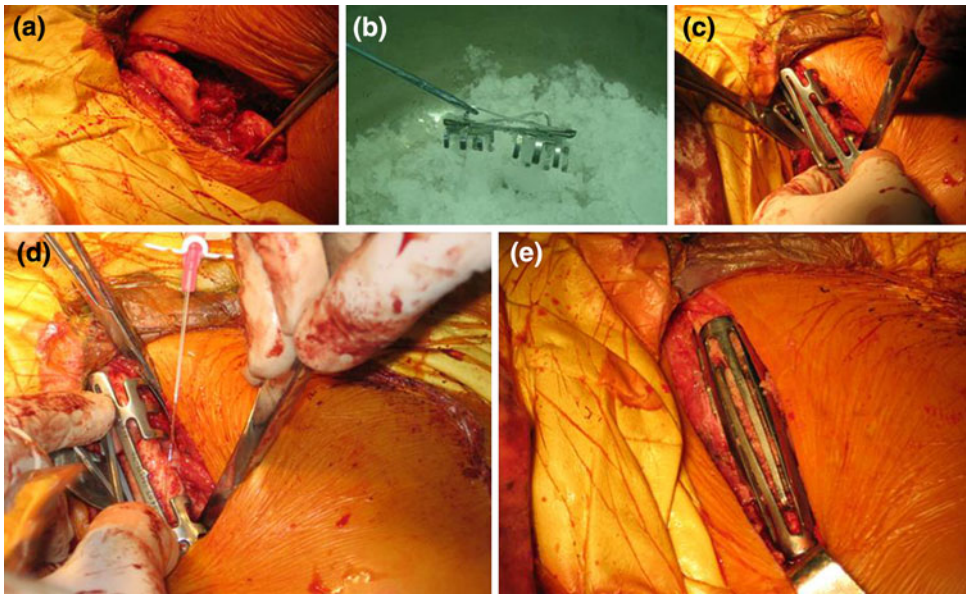

Fig. 2 (a) Clearance of the scar tissues and the necrotic bone debris. (b) Extend the selected SMC in the mixture of ice and water, unfold the arms in sequence. (c) The fracture was reduced and fixed with SMC. (d) Spray hot water on the memory alloy to allow morphological recovery, make sure that the recovery stress has an influence on the non-continuous end of the bone. (e) Finished application of SMC and cancellous bone grafting

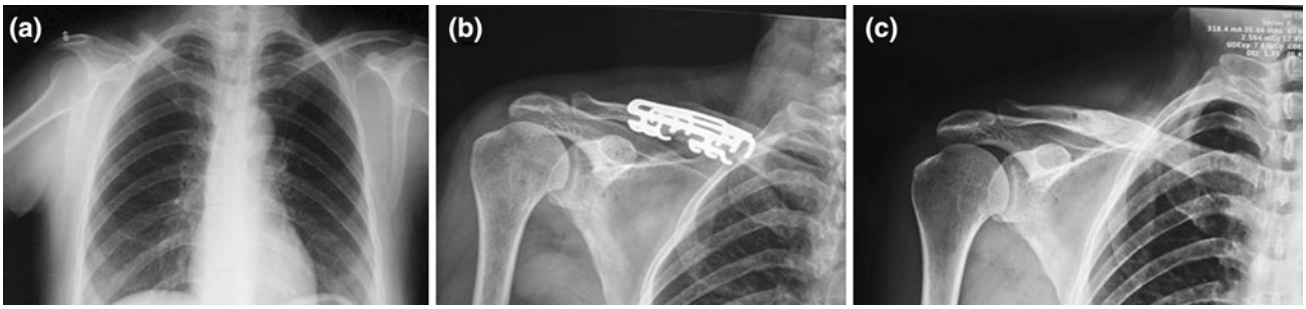

Fig. 3 Typical case: a 50-year-old woman sustaining clavicular midshaft fracture following a traffic accident. (a) Preoperative x-ray film showing hypertrophic nonunion. (b) Postoperative x-ray film showing fixation of the nonunion with SMC supplemented with iliac crest bone graft. (c) Thirteen months later, removal of the SMC

free space between the clavicle bone and SMC and in the holes previously drilled in the sclerotic bone. Removal of the SMC was convenient. After routine exposure of the fractured area, ices were applied to the SMC for 3 min, and SMC could be easily opened for removal.

2.4 Clinical Outcome Evaluation

Rehabilitation exercise was administered in all the cases. The extremity was placed in a sling for immobilization, and active motion was restricted for 3 weeks. The next 3 weeks the patients were gradually allowed to move the arm to 90° of flexion and abduction. Six weeks after surgery the patients were allowed to move the shoulder freely. Full use was allowed after 3 months, but contact sports were discouraged for the first 6 months. All the patients had the SMC removed at an average of 13 months (range 8-23 months) later after primary operation. Patients available for clinical follow-up had a follow-up x-ray at 2 weeks and 1, 2, 3, 6, 12, 24, and 36 months after SMC implantation, respectively, and the functional outcome was scored by the Constant score (Ref 11, 12). This score includes subjective pain evaluation by the patient, functional ability in activities of daily living, and objective measures of range of movement and muscle strength.

3. Results

All patients achieved union. Union was solid at an average of 9 weeks (range 6-13 weeks). All the patients were followed up for 25 to 58 months (mean 37 months). No refractures or infection were seen. The overall Constant score was 86 points in the affected shoulder and 95 points in the control shoulder (Table 1). Five patients in this study had a Constant score more than 70 points, rated as good or excellent. One patient (case 4) had recurrent pain at the site of harvest of bone graft at the iliac crest when sleeping on that side. We observed no other complications.

3.1 Typical Case

A 50-year-old woman sustaining clavicular midshaft fracture following a traffic accident received a primary conservative treatment, but reported fracture site pain, abnormal bone movement, and upper limb dysfunction 1 year after the conservative treatment. Radiography revealed the presence of space between the fractured ends, and the diagnosis of hypertrophic nonunion was established (Fig. 3). The patient then underwent a second operation with SMC implantation in addition to autologous iliac bone grafting. The radiographs taken 3 months later revealed fracture healing. The patient was followed up for 42 months, which showed satisfactory recovery of the shoulder joints, with a Constant score of 89 and 96 points in the control shoulder.

4. Discussion

Most of the clavicular fractures occur in the middle third (Ref 13). The clavicular fractures have a great healing potential and nonunion is a relatively uncommon complication after clavicle fracture. Predisposing factors for nonunion are severe displacement, comminution, additional soft-tissue trauma, soft-tissue interposition, and inadequate initial immobilization. We had two fractures with comminution related to high energy trauma. Anatomic restoration is usually achieved by an osteotomy of the nonunion site and its realignment (Ref 14). Currently, debate remains over the various fixation methods for management of clavicular nonunion for their respective limitations. Various authors have described open reduction and internal fixation (ORIF) with plates and screws (Ref 7, 15) and intramedullary fixation with Steinmann (Ref 16), Knowles (Ref 15), modified Hagie (Ref 17), and Rush pins (Ref 18), as well as Kirschner wires (Ref 19) and external fixators (Ref 4), to treat clavicular nonunions, with little consensus as to which is the optimal method of fixation. We have used cancellous bone grafting in all our cases to obtain solid healing, although hypertrophic nonunions usually heal when rigid stabilization is obtained. One patient had symptoms from the donor site, so the procedure of bone grafting in all cases of nonunion may not be necessary, but we still find it necessary in the atrophic cases.

The SMC device used in our patients was designed based on full consideration of such risk factors for clavicular shaft nonunion as instability of the fractured ends, bone mass loss, and local blood supply impairment. After massive experimental study in animals, the patented device was officially approved for clinical use in China. Due to the inherent property of shape-memory alloy, the compression arms at the neck of the device yielded evenly distributed compression forces at multiple sites at the interval of 3-5 mm. These forces provide continuous axial compression on the fractured ends, which can be transmitted across the fracture to ensure the stable biomechanical environment that allows smooth healing of the nonunion. The SMC device has direct contact with the clavicular bone surface at multiple points to establish a 3-dimensional stabilization of the fracture. This 3-dimensional fixation confers strong resistance on the fracture against rotation and shearing stress, and also protects the blood supply crucial for the bone healing. In addition, the main plate of the device bridging the fracture offers optimal sites for bone graft implantation.

Compared with the other fixation methods, SMC implantation does not functionally compromise the shoulder joint, and therefore allows early functional training to promote recovery. In our patients treated using SMC, nonunion healing was achieved in 9 weeks on average after the operation, similar with other fixation methods (Ref 2, 3, 13). A nonunion healing rate as high as 100% was achieved in these patients, suggesting the advantages of this device.

Due to the nature of shape memory alloys, the manipulation and implantation of SMC must proceed with the following precautions. Before implantation, the SMC device is immersed in ice-cold water at 0-4 °C, and after reduction of the fracture, SMC is implanted and warmed with water of 40-50 °C. Most preferentially, fixation of the fracture with SMC is performed in a single attempt, and repeated cooling and warming of the device, once implanted, must be totally avoided. In all the subsequent procedures after SMC implantation, the device has to be washed, when necessary, with warm water above 40 °C. Ice-cold water or water below 40 °C should never be used for washing the implanted device, or the fixation performance of the device can be lowered.

Using the SMC device, we have achieved high rate of bone healing with low incidence of the complications. Healing of the nonunion promotes the functional recovery of the compromised arm. The advantages of SMC in the treatment of clavicular shaft nonunion, as we presume, lie mainly in the continuous compression of the fracture, stable biomechanical environment due to 3-dimensional fixation.

5. Conclusions

This series suggests that the treatment with a SMC device allows gradual mobilization and exercises, which give the patient the opportunity to achieve a good functional result. Based on the encouraging results of our clinical trials, we believe that SMC can serve as an effective means for management of clavicular nonunion and a lager number of patients is required to endorse wider generalization of the results.

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