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Swan-like Memory Compressive Connector

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Nonunion is a common complication after fractures of the diaphysis of the upper extremity. Conventional internal fixation cannot provide compressive stress at the fracture site, which is critical for fracture repair in nonweight-bearing bones. In order to overcome this problem, we developed a novel nitinol device that provides initial and continuous compression and three dimensional fixation, the swan-like memory compressive connector (SMC). A total of 188 cases (243 bones) of fractures and nonunions were treated by SMC over the course of 16 years. At follow-up, the nonunion sites were bridged by plate-like bone in 92 cases (106 bones) at an average of 3.8 months after surgery. In the fracture group, the fracture sites were bridged by plate-like bone in 93 cases (134 bones) at an average of 2.6 months after surgery. No infection or re-fracture occurred after removal of the SMC. There was no persistent joint dysfunction caused by the SMC.

Keywords connector, fracture, multipoint axial fixation, nonunion, upper limb diaphysis

1. Introduction

Fracture healing is highly dependent on the stress that exists within the region (Ref 1, 2). Providing compressive stress at the fracture site of nonweight-bearing bones of the upper extremity via fixation, while minimizing shear, torsion, and bending has been a long-standing problem in the biomedical community. In order to overcome these challenges, we developed a nitinol shape memory alloy device in 1990 (Ref 3, 4). This device, called the swan-like memory compressive device (SMC), provides compression during fracture healing in the upper extremity. The purpose of this study was to evaluate the clinical outcomes from a sample of patients in whom the device was implanted.

2. Experimental and Clinical Procedure

2.1 Subjects

Between August 1990 and August 2006, a total of 188 cases and 243 bones had been treated by SMC. These included clavicular, humeral, ulnar, and radial shaft fractures and nonunions. The nonunion group was composed of 93 cases: 107 bones with 60 males and 33 females. Age ranged from 10 to 80 years, with an average of 37.6 years. The nonunion sites and previous treatment are described in Table 1. The fracture group consisted of 95 cases, 136 bones with 72 males and 23 females. Average age was 35.9 years with a range from 14 to 76 years. Distribution of the fracture sites are described in Table 2.

2.2 Design

The SMC was a 1.5-2.5 mm thick nitinol plate that contained 50-53% nickel. The SMC consisted of three parts: a swan body bone-connecting plate, a swan neck axially compressive portion, and a swan wing bone holding portion (Fig. 1). The SMC was treated for a one-way memory effect, with a reverting temperature of 33 ± 2 °C.

Prior to implantation, the SMC was flattened in ice water. After implanting the device into the region of interest, the body heat increased the temperature of the SMC, causing it to revert to its original shape. The bone resisted the bending of the components and compressive forces were continually produced secondary to the inherent properties of the memory device. The swan neck axial portion provided continuous axial compression, the swing portion produced continual holding or fixation forces, and the combination of these produced multi-direction three-dimensional fixation (Fig. 2). Previous biomechanical evaluation of the SMC using the electrometric method, photoelasticity method, and three-dimensional finite element analysis (ANSYS 5.4) revealed that holding force in the humerus was 98.40-125.05 N and compressive force was 152-196 N (Ref 5, 6).

2.3 Operative Methods

Before operation, a sterilized SMC was placed into an ice box. Then, 500 mL 40-50 °C saline water was prepared. The fractured bone was reduced, and the SMC was flattened in the ice condition. The SMC was placed around the fractured bone, and the hook of swan-neck was placed into a pre-drilled hole. The SMC was reverted to its original memory shape by the application of 40-50 °C saline solution, and the fracture fixation was complete.

When treating the nonunion sites, sclerotic bone was removed (attention was paid to preserve or reconstruct the

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Table 1 Ninety-three cases (107 bones) of upper limb nonunion sites and previous fixation methods

	Fixation methods							
Site	Common plate	Compressive plate	Common & Ender nail	Interlocking nail	External fixation bracement	Circle connector	Plaster fixation	Total
Humerus	15	10	18	2	1	1	3	50
Ulna & radius	6	4	12				6	28
Ulna	2	1	7		1		3	14
Radius	3	2	5				1	11
Clavicle	1		1				2	4
Total	27	17	43	2	2	1	15	107
Percentage	25.23	15.88	40.18	1.86	1.86	0.93	14.01	100

Table 2 Ninety-five cases (136 bones) of upper limb diaphysis fractures distribution data

Site	Cases	Bones	Open	Close
Homolateral multi-segment humerus/ulna/radius	12	38	17	21
Homolateral humerus/clavicle	3	6	1	5
Humerus	54	54	19	35
Homolateral ulna/radius	12	24	5	19
Ulna	5	5	0	5
Radius	2	2	0	2
Clavicle	7	7	0	7
Total	95	136	42	94
Percentage			30.8	69.1

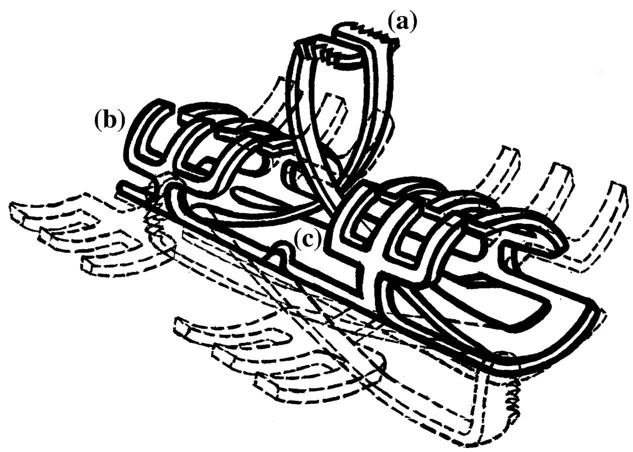

Fig. 1 Schematic diagram of SMC (A) Swan neck axially compressive portion; (B) Swan wing bone holding portion; and (C) Swan body bone-connecting plate

bone fulcrum). The SMC was placed around the bone as previously described, and bone grafting was performed as needed.

2.4 Post-Operative Treatment

For the fracture cases, post-operative drains were used depending on the extent of the injury and degree of soft tissue damage. For the nonunion cases, 24-48 h of drainage was applied. Typically, a triangular bandage was used as an arm

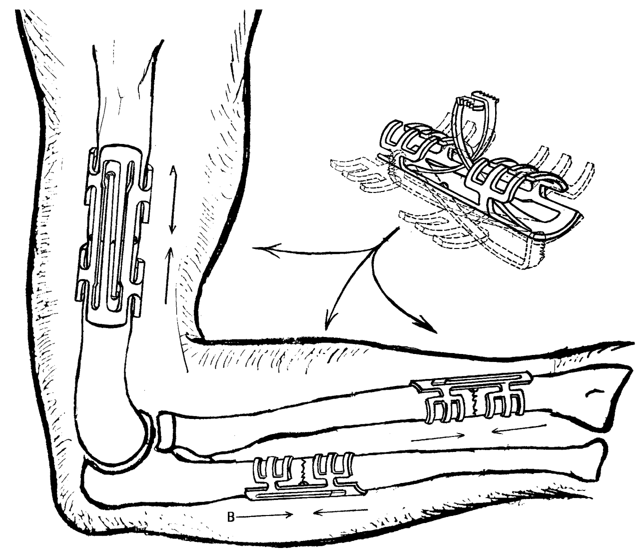

Fig. 2 Schematic diagram of SMC fixation in the upper limb diaphysis

sling for 1 week. For cases in which there was severe damage to the soft tissue, the arm was immobilized with a plaster cast for 2 weeks. Cases that required substantial reconstruction required up to 4 weeks of immobilization. Functional exercises began 10 days after operation and included a gradual progression of lifting, extension, and flexion of the injured limb. The SMC was removed 6-10 months after the operation, if the bone was well healed.

3. Results

Follow-ups ranging from 5.5 months to 6 years (average 2.25 years) after surgery were performed. In the nonunion group, 92 cases (106 bones), were healed, and the nonunion site was bridged by plate-like bone. This occurred an average of 3.8 months after operation. One case (one bone), a humeral nonunion, sustained a fall 1.5 months after operation. This patient refused re-operation and was lost at follow-up. In the fracture group, 93 cases (134 bones) were healed, and the fracture site was bridged by plate-like bone at an average of 2.6 months after surgery. Two cases (2 bones), both humeral fractures, became nonunions secondary to excessive exercising. This was treated and cured by SMC plus autogenous iliac graft. There were no incidences of infection or re-fracture after removing the SMC. No permanent joint disability occurred as a result of the SMC application. The typical cases are shown in Fig. 3-5.

4. Discussion

An appropriate internal fixation device should (1) be stable enough to prevent shearing, bending, torsion, and distraction; (2) permit early functional exercises; (3) allow for multi-point

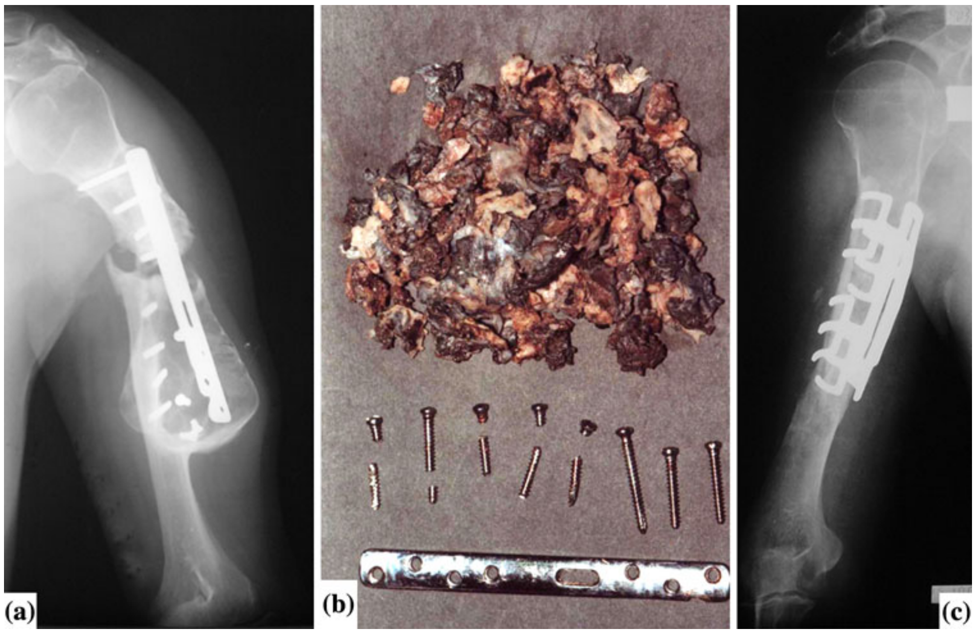

Fig. 3 (a) Nonunion of humerus, 6 years after dynamic compressive plate fixation; (b) Plate, fractured screws, and abnormal tissues removed from the nonunion site; (c) The nonunion was healed 5 months after treatment by SMC and bone grafting

Fig. 4 (a) Nonunion of humerus treated by Kuntsher Nail; (b) Re-nonunion after second operation of an interlocking medullary nail; (c) Nonunion was healed after third operation with SMC (4 months after operation)

Fig. 5 (a) Fracture of the upper limb diaphysis (humerus, radius, and ulna); (b) Fracture healed 2 months after operation; (c) x-ray after SMC removal showing no bone atrophy

fixation, while allowing adequate blood supply; and (4) provide compressive stress at fracture site without a stress shielding effect. The SMC meets these requirements, and the results from the 188 cases highlight the functional success of the SMC device.

The compressive distance of the swan neck is 1-5 cm, so the compression does not disappear with the absorption of fracture line; the compression is initial and continuous. This is an important characteristic of the device and is reliant on the inherent properties of the memory method of fabrication. In addition, the swan wing provides multi-point fixation, which benefits the blood supply in the bone. The three dimensional shape of the SMC and the characteristics of the shape memory alloy, result in stable three dimensional fixation that may not be possible by plate and screw fixation alone.

Two months after SMC fixation, the fracture sites were bridged by "anatomic type" plate bone (Fig. 5c). No bone atrophy was seen, as is the case with rigid fixation. This distinct bone healing phenomenon may be specifically related to the shape memory alloy (Ref 7), and the initial compression at fracture site. Furthermore, the phenomenon may be a separate type of bone healing type (Ref 8) which requires further study.

5. Conclusion

SMC is a new and effective technique for the treatment of fractures and nonunions of upper limb diaphysis. This technique allows us to combine multipoint holding with longitudinal compression of the fractured bone, a problem that cannot be tackled by conventional methods.

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