Shape memory Ni-Ti alloy swan-like bone connector for treatment of humeral shaft nonunion

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Abstract From August 1990 to December 2007, 156 patients with humeral shaft nonunion were treated with our patented Ni-Ti shape memory alloy swan-like memory pressure connector (SMC). The SMC device cooled with ice before implantation was warmed to 40–50°C after implantation to produce balanced axial and compression forces to stabilise the fracture three-dimensionally. This combined with autologous bone grafting achieved bone tissue regeneration in the fracture and promoted smooth recovery of joint function, with a nonunion healing rate of 98.7% after a single SMC implantation. Failure of nonunion healing occurred in only two cases but was successfully managed by a further operation. Complications were not found in any of these patients apart from four with pre-existing radial nerve injuries. These results demonstrate the effectiveness of the SMC device for the management of humeral shaft nonunion. The device provides continuous compression of the fracture with minimal trauma to the local blood supply.

Résumé D’août 1990 à décembre 2007, 156 patients présentant une pseudarthrose de la diaphyse humérale ont été traités avec notre appareil breveté en alliage de titane à mémoire de forme (SMC). Cet appareillage est refroidi par la glace avant son implantation puis réchauffé à 40–50° après implantation de façon à entraîner une compression axiale et stabiliser la fracture de façon tridimensionnelle. La combinaison d’une greffe autologue améliore encore le

processus de régénération osseuse dans ces fractures et permet de retrouver une meilleure fonction articulaire et un taux de guérison de la pseudarthrose de 98,7% après une simple implantation de l’appareil (SMC). Un échec et une absence de consolidation ne sont survenus que dans deux cas et ont été traités avec succès après une deuxième intervention. Nous n’avons observé aucune complication secondaire à cet appareillage exceptés 4 patients présentant des lésions préexistantes du nerf radial. Ces résultats démontrent que cet appareillage est efficace dans le traitement des pseudarthroses de la diaphyse humérale et permet d’avoir une compression continue du foyer de fracture en minimisant au maximum les troubles de la vascularisation sanguine locale.

Introduction

Humeral shaft fracture, a commonly seen fracture type of long bones, gives rise to rather high rates of nonunion. It was reported that the incidence of nonunion of humeral shaft fracture was 2–10% when managed conservatively and was around 15% when managed by open reduction and internal fixation [8, 20, 23]. The treatment of humeral shaft nonunion is often complex and technically demanding. The last decade has witnessed much technical improvement in various internal fixation devices and surgical approaches for the treatment of humeral shaft nonunion, including the application of cancellous bone grafting plus dynamic compression plate, intramedullary nails, external fixation frames and transplantation of vascularised bone graft [1, 2, 5, 17, 19].

Ni-Ti shape memory alloy possesses excellent properties of wear and corrosion resistance and good biocompatibility. Simon et al. [21] designed a vena cava filter using Ti-Ni alloy, which demonstrated excellent efficacy in a multi-

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centre clinical trial involving 147 cases from 19 vascular centres. Shape memory alloys have been widely used in clinical practice for manufacturing new instruments and devices [11, 25]

The incidence of fracture nonunion is closely associated with the stresses around the fracture fragments. Humeral bone bears weight under normal circumstances, and re-establishment of normal conditions, in addition to proper fracture fixation to resist shear stress, bending and rotation, may greatly promote nonunion healing. We designed a Ti-Ni shape memory alloy device for treatment of humeral shaft nonunion based on the anatomy of humeral bones (Chinese Patent No. ZL 013444218.X). As the shape of this device bears a rough resemblance to a swan, we call it a swan-like memory pressure connector, or SMC for short [25].

From August 1990 to December 2007, 156 cases of humeral shaft nonunion were treated using this device, yielding a success rate as high as 98.7%. In this article, we present our experience with this device for treatment of humeral shaft nonunion in these cases.

Patients and methods

Patients

From August 1990 to December 2007, 156 patients with humeral shaft nonunion were treated using the SMC in our hospital, including 84 men and 72 women with a median age of 43 years (range: 28–71 years). The patients had sustained their primary fractures due to traffic accidents (109 cases), falling (33 cases), sports activities (9 cases) or

other causes (5 cases). The fractures included transverse fracture (71 cases), spiral or oblique fracture (62 cases) and comminuted fracture (23 cases); 132 patients had closed fractures and 24 had open fractures. Of these patients, 137 were treated surgically for the primary fractures, and the diagnosis of fracture nonunion was established by the presence of pain at the fracture site, abnormal bone movement and arm dysfunction six months following the surgery. Radiography of the fractures identified hypertrophic nonunion in 63 cases, atrophic nonunion in 74 cases and nonunion of another nature in 29 cases. The period between the primary fracture and the secondary surgery for fracture nonunion averaged 11.2 months (range: 6–36 months), and 19 patients underwent at least two operations after the fracture, and occasionally, as many as three operations were performed. Table 1 presents the detailed clinical data of these patients.

Structure and working principle of the SMC device

The SMC device was designed based on full consideration of the humeral bone anatomy and biomechanics and manufactured with 2-mm-thick Ti-Ni shape memory alloy plate (with Ni content of 50–53%) by Huzhou Swine-shape Memory Co. Ltd. (Fig. 1). The device, processed with one-way heat treatment and a reversion temperature of $33\pm 2^{\circ}\text{C}$, consisted of compression hooks and embracing arms connected to the main plate, with an inner diameter of 6–23 mm and a diameter/axial length ratio of around 1:6. Before use the device was immersed in ice-cold water at $0\text{--}4^{\circ}\text{C}$, in which the alloy had good plasticity to allow extension of the embracing arm to a length greater than the diameter of the fractured bone to be fixed. The compression hook at the “neck” of the SMC was extended dorsally and

Table 1 Clinical data of the patients and their treatments before SMC implantation

Treatment approach	<i>n</i>	Age (years)	Male/female	Transverse/spiral/comminuted fractures	Open/closed fractures	Follow-up duration	Time to nonunion (postoperative months)
Conservative treatment							
Plaster external fixation	6	47	2/4	2/3/1	0/6	6.4	4.8
Abduction splint fixation	13	56	5/8	1/7/5	2/11	7.3	5.7
Surgical treatment							
Internal fixation							
Interlocking intramedullary nails	7	38	5/2	3/4/0	0/7	6.5	5
Intramedullary nails	32	42	21/11	22/10/0	0/32	7	4.9
Stainless steel plate	27	35	17/10	13/6/8	2/25	6.3	5.3
Compression plate	35	51	21/14	17/12/6	4/31	6	5.2
SMC	1	36	1/0	1/0/0	0/1	6	6
External fixation							
Single-arm frame	21	39	8/13	8/13/0	11/10	6.7	4.8
Circular frame	14	43	4/10	4/7/3	5/9	7.2	6.5
Total	156	43	84/72	71/62/23	24/132	6.6	5.4

Fig. 1 **a** Schematic diagram of the SMC structure. **b** Schematic diagram of application of the SMC for humeral shaft fixation. The arrows indicate the direction of pressure

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 in the humerus 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 into contact with the humerus. The anterior compression hook was then inserted into the hole, and the SMC was heated with warm water to 40–50°C to cause recovery of the preset shape, during which process the device produced sufficient force to stabilise the fracture. At normal body temperature, the embracing arms of the implanted SMC recovered their remembered shape and securely embraced the humeral 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 humeral shaft. The balanced forces generated by the embracing arms and the compression hooks (head and tail hooks) thus allowed three-dimensional stabilisation of the humeral shaft. The implantation process of the device is illustrated in Fig. 2.

Surgical procedures

An anterolateral approach was adopted for the surgery. After clearance of the scar tissues and the necrotic bone

debris, the medullary cavity was cleared and restored. In the case of malunion due to hypertrophic callus growth, osteotomy according to the original anatomy of the humeral bone was performed. When extensive humeral bone sclerosis has occurred, caution should be taken during osteotomy to avoid excessive tissue removal and the consequent obvious reduction of the limb length. Preferentially, holes 3–6 mm in diameter were drilled in the sclerotic bones for later autologous bone grafting. The fixation of the SMC is described above. When bone grafting was necessary, the iliac crest or the fibular bone could be the preferred donor site. For bone grafting, a slot measuring 20–25 mm in length, 7–10 mm in width and 2–5 mm in depth at the midpoint of the SMC was made, spanning an appropriate length over the nonunion area. The embracing arms near the midpoint were opened by 3–7 mm at 4°C, through which the cortical bone grafts with roughened surface were inserted along with the cancellous bone grafts. The embracing arms were then warmed to tighten the bone graft strips. Around the fractured ends of the humeral shaft, crusts of cancellous bone graft with a thickness of matchsticks were stuffed into the free space between the humeral bone and SMC and in the holes previously drilled in the sclerotic bone. Removal of the SMC was easy. After routine exposure of the fractured area, ice was applied to the SMC for 3 min, and the SMC could be easily opened for removal. The SMC was removed in 46 patients six months after the implantation, and follow-up of the patients did not reveal evidence of refracture in the fixed area.

Clinical outcome evaluation

Rehabilitation started immediately after recovery from anaesthesia; the patients were instructed to perform gentle flexion and extension of the elbow joint and practise fist clenching and release. At two weeks and one, two, three, six, 12, 24 and 36 months after SMC implantation, respectively, lateral radiographs of the fractured upper arm were taken, and Neer and Morrey scores were used to evaluate functional recovery of the shoulder and elbow joints.

Results

The operation time averaged 107 min for SMC implantation (range: 90–160 min), and the patients were followed up for two to six years (mean: 3.7 years). In 69 of the cases, the newly generated bony tissues resembling bone plates occurred in the nonunion area within an average of 3.8 months. One patient sustained a refracture due to a fall and refused further treatment. In 74 of the cases, the SMC was removed six months to two years after the implantation and no refracture or episodes of infection occurred. Apart from the four patients

Fig. 2 Intraoperative photographs illustrating the implantation of the SMC. **a** The selected connector was immersed in ice-cold water at 0–4°C to allow extension of the embracing arms and the compression hook. **b** To maintain the extension of the connector, ice was applied to cover the connector during the implanting process. **c** The two ends of the fracture nonunion were fixed with the embracing arms and hot

water was applied to restore their original shape and secure the two ends. **d** Two holes were drilled at the optimal sites in which the compression hooks were anchored. **e** Hot water was applied to the compression hooks to restore their original shape, in which process an axial compressing force was imposed on the nonunion fracture to promote the healing

with pre-existing symptoms of radial nerve injury before the operation, none of the patients suffered radial nerve injuries associated with the operation. In most of the patients over 65 years old, who were generally in poor general condition, the SMC was not removed to avoid a secondary surgery, based on the consideration that the device did not noticeably affect their daily activity. Failure of nonunion healing occurred only in two of these cases after the operation, and after a second SMC implantation with autologous bone grafting, the fracture healed satisfactorily. The total cure rate of nonunion reached 98.7% in these cases after treatment with the SMC.

Typical case 1 A 40-year-old man sustaining a humeral shaft fracture in the middle segment received a primary Kuntscher nail fixation, but reported fracture site pain, abnormal bone movement and upper limb dysfunction 1.2 years after the operation. Radiography revealed obvious loosening of the intramedullary nail within the medullary cavity and a gap between the fractured ends, and the diagnosis of hypertrophic nonunion was established. A second internal fixation with intramedullary nail plus autologous iliac bone grafting was performed. But 1.3 years later, radiography demonstrated no evidence of fracture healing. The patient then underwent a third operation with

SMC implantation in addition to autologous iliac bone grafting. The radiographs taken four months later revealed fracture healing and growth of bone plate-like tissues at the nonunion. The patient was followed up for 55 months, and showed satisfactory recovery of the shoulder and elbow joints, with a Neer score of 67 and a Morrey score of 93 (Fig. 3).

Typical case 2 The 30-year-old male patient had a humeral shaft fracture in the middle segment. Ten months after internal fixation with intramedullary nail, no evidence of fracture healing was observed and the patient complained of right upper arm pain and arm dysfunction, and the diagnosis of nonunion was established. The patient received a second operation with SMC implantation plus autologous iliac bone grafting. Four months after the operation, the fracture was healed as shown by radiography. Forty-six months after the operation, the patient had a Neer score of 94 and a Morrey score of 100 (Fig. 4).

Typical case 3 The 55-year-old male patient suffered humeral shaft fracture at the upper segment in a traffic accident. Six months after internal fixation with a dynamic compression steel plate, screw breakage occurred and caused humeral shaft nonunion. SMC implantation with

Fig. 3 **a** Humeral shaft nonunion in a 40-year-old male patient 1.2 years after internal fixation of the fracture using a Kuntscher nail. **b** In the same patient, a second fixation using an interlocking intramedullary nail with autologous bone grafting was performed, but nonunion occurred again 1.3 years after the operation. **c** Four months after SMC implantation and autologous bone grafting, growth of bone plate-like tissues occurred at the nonunion suggesting fracture healing

autologous iliac bone grafting was subsequently performed and radiographs taken four months after the operation demonstrated healing of the nonunion. At the follow-up 46 months after the second operation, the patient had a Neer score of 92 and a Morrey score of 98 (Fig. 5).

Discussion

Currently debate about the best internal fixation methods for management of humeral shaft continues. Use of a long compression plate and autologous iliac bone graft, for

Fig. 4 **a** Humeral shaft nonunion in a 30-year-old male patient 10 months after fracture fixation with an intramedullary nail. **b** SMC implantation and autologous bone grafting were performed, and growth of bone plate-like tissues occurred at the nonunion 4.5 months after the operation

Fig. 5 **a** In a 55-year-old male patient with humeral shaft fracture, nonunion occurred 6 months after internal fixation using a dynamic compression plate due to screw breakage. **b** Four months after SMC implantation and autologous bone grafting, the nonunion healed with growth of bone plate-like tissues at the nonunion

instance, requires extensive tissue stripping in the upper arm causing massive blood supply loss, with a high risk of radial nerve injuries [3, 14]. Intramedullary nails better preserve the blood supply and require less soft tissue stripping, also allowing homogeneous elastic stress distribution over the bone tissues and the nails, good resistance to rotation and compression, and excellent performance in fracture stabilisation. Intramedullary nails also provide good internal fixation stability in cases of bone defect when plating is impossible. But problems such as limited range of motion of the shoulder joint and screw displacement may arise following intramedullary nailing. In patients with a narrow medullary cavity, cavity expansion operations may commonly cause perforation of the cortical bones [6, 9, 24]. Lin et al. [12] reported their experience with 41 humeral shaft nonunion cases managed with intramedullary nailing and autologous bone grafting, and success was achieved in 39 cases. According to Einhorn et al. [4], intramedullary nails can be used with assured success in the treatment of tibial nonunion, but for humeral shaft nonunion, failure frequently occurs due the absence of axial compression of the fracture. Humeral shaft nonunion can also be managed with external fixation frames, but the potential risk of infections, pin loosening and patient discomfort limits their application [2, 9]. Patel et al. [16] used an Ilizarov external fixation frame for treating 16 humeral shaft nonunion cases without bone grafting, and successful bone healing was achieved in 15 cases.

Compared with the other fixation methods, SMC implantation results in less perfusion changes in the cortical bone [7] and does not functionally compromise the shoulder, elbow or wrist joint, therefore allowing early functional training to promote recovery. In our patients treated with the SMC, healing of nonunion was achieved in four months on average after the operation, slightly faster than that with other fixation methods. A nonunion healing rate as high as 98.7% was achieved in these patients, suggesting the advantages of this device over the various other internal fixation methods [23]. In our early clinical trial, failure of bone healing occurred in two of these cases, largely due to inappropriate size of the device and omission of bone grafting. Revision SMC implantation and autologous iliac bone grafting were subsequently performed, and the patients recovered satisfactorily.

The manipulation and implantation of the SMC requires the following precautions. Before implantation, the SMC device is immersed in ice-cold water at 0–4°C, and after reduction of the fracture, the SMC is implanted and warmed with water at a temperature of 40–50°C. Ideally, fixation of the fracture with the 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, only warm

water above 40°C can be used to wash the device. 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.

Radial nerve injury is a major concern in the treatment of humeral shaft nonunion [13]. According to some reports, the incidence of radial nerve injury in nonunion management may reach 8% with open reduction and plate fixation [10, 15, 18, 22]. In the nine cases treated by McKnee et al. [15], radial nerve injury was found in two cases. In our study, radial nerve injuries were observed in none of these cases except for the four cases with pre-existing injuries. Typically, radial nerve injuries occur in the initial stage of humeral fracture, especially one in the lower segment of the humerus. Obvious displacement of the fractured ends is very likely to cause radial nerve injuries. In our experience, the local soft tissue at the site of humeral fracture is often in poor condition, and during the operation, the radial nerve does not need to be fully freed as long as the operative field is sufficient for operations on the fracture ends and SMC fixation.

Conflict of interest The authors Jia-can Su, Xin-wei Liu, Bao-qing Yu, Zhuo-dong Li, Ming LI, Chun-cai Zhang disclose no conflict of interest either financially or personally with other people or organisations that may inappropriately influence the work.

References

1. Changulani M, Jain UK, Keswani T (2007) Comparison of the use of the humerus intramedullary nail and dynamic compression plate for the management of diaphyseal fractures of the humerus. A randomised controlled study. *Int Orthop* 31(3):391–395
2. Chapman JR, Henley MB, Agel J, Benca PJ (2000) Randomized prospective study of humeral shaft fracture fixation: intramedullary nails versus plates. *J Orthop Trauma* 14:162–166
3. Dujardin FH, Mazirt N, Tobenas AC, Duparc F, Thomine JM (2000) Failure of locked centro-medullary nailing in pseudarthrosis of the humeral diaphysis (in French). *Rev Chir Orthop Reparatrice Appar Mot* 86(8):773–780
4. Einhorn TA (1995) Enhancement of fracture-healing. *J Bone Joint Surg Am* 77:940–956
5. Hornicek FJ, Zych GA, Hutson JJ, Malinin TI (2001) Salvage of humeral nonunions with onlay bone plate allograft augmentation. *Clin Orthop* 386:203–209
6. Ilyas I, Younge DA (2003) Locked intramedullary nailing for difficult nonunions of the humeral diaphysis. *Int Orthop* 27(5):278–281
7. Kang QL, Zhang CC, Gao TC, Hou TS, Li M (2004) Perfusion changes of cortical bone beneath swan-like memory connector fixation in rabbit fracture models. *Chin J Clin Anat* 22(03):286–289
8. King AR, Moran SL, Steinmann SP (2007) Humeral nonunion. *Hand Clin* 23:449–456
9. Kocaoğlu M, Eralp L, Tomak Y (2001) Treatment of humeral shaft non-unions by the Ilizarov method. *Int Orthop* 25:396–400

10. Lau TW, Leung F, Chan CF, Chow SP (2007) Minimally invasive plate osteosynthesis in the treatment of proximal humeral fracture. *Int Orthop* 31(5):657–664
11. Levi DS, Kusnezov N, Carman GP (2008) Smart materials applications for pediatric cardiovascular devices. *Pediatr Res* 63(5):552–558
12. Lin J, Hou SM, Hang YS (2000) Treatment of humeral shaft delayed unions and nonunions with humeral locked nails. *J Trauma* 48(4):695–703
13. Livani B, Belangero W, Andrade K, Zuiani G, Pratali R (2008) Is MIPO in humeral shaft fractures really safe? Postoperative ultrasonographic evaluation. *Int Orthop* [Epub ahead of print] doi:10.1007/s00264-006-0200-1
14. Martinez AA, Cuenca J, Herrera A (2004) Treatment of humeral shaft nonunions: nailing versus plating. *Arch Orthop Trauma Surg* 124(2):92–95
15. McKee MD, Miranda MA, Riemer BL, Blasier RB, Redmond BJ, Sims SH, Waddell JP, Jupiter JB (1996) Management of humeral nonunion after the failure of locking intramedullary nails. *J Orthop Trauma* 10(7):492–499
16. Patel VR, Menon DK, Pool RD, Simonis RB (2000) Nonunion of the humerus after failure of surgical treatment. Management using Ilizarov circular fixator. *J Bone Joint Surg Br* 82:977–983
17. Pullen C, Manzotti A, Catagni MA, Guerreschi F (2003) Treatment of post-traumatic humeral diaphyseal nonunion with bone loss. *J Shoulder Elbow Surg* 12:436–441
18. Ring D, Jupiter JP, Quintero J et al (2000) Atrophic ununited diaphyseal fractures of the humerus with a bony defect: treatment by wave-plate osteosynthesis. *J Bone Joint Surg Br* 82(6):867–871
19. Rubel IF, Kloen P, Campbell D, Schwartz M, Liew A, Myers E, Helfet DL (2002) Open reduction and internal fixation of humeral nonunions: a biomechanical and clinical study. *J Bone Joint Surg Am* 84:1315–1322
20. Sarmiento A, Zagorski JB, Zych GA, Latta LL, Capps CA (2000) Functional bracing for the treatment of fractures of the humeral diaphysis. *J Bone Joint Surg Am* 82:478–486
21. Simon M, Kaplow R, Salzman E, Freiman D (1977) A vena cava filter using thermal shape memory alloy. Experimental aspects. *Radiology* 125(1):87–94
22. te Velde EA, van der Werken C (2001) Plate osteosynthesis for pseudarthrosis of the humeral shaft. *Injury* 32(8):621–624
23. Tomić S, Bumbasirević M, Lesić A, Mitković M, Atkinson HD (2007) Ilizarov frame fixation without bone graft for atrophic humeral shaft nonunion: 28 patients with a minimum 2-year follow-up. *J Orthop Trauma* 21:549–556
24. Van Houwelingen AP, McKee MD (2005) Treatment of osteopenic humeral shaft nonunion with compression plating, humeral cortical allograft struts, and bone grafting. *J Orthop Trauma* 19:36–42
25. Zhang CC, Gao JZ, Cheng TY (1990) An arcuate shape memory automated compressor. The State Patent Office of the People's Republic of China (Patent No. 38606) 8821780.3;3:28