Fracture Treatment Using TiNi Shape Memory Alloy Bone Fixater (BRM-SH System) *

Seung-Baik Kang1, Kang-Sup Yoon1, Tae-Hyun Nam2, Ji-Soon Kim3 and Victor E. Gjunter4

1Department of Orthopaedic Surgery, Seoul National University College of Medicine and Seoul Municipal Boramae Hospital, 395 Shindaejangdong, Dongdaemun-gu, Seoul 156-012, Korea
2Department of Material Science & Engineering, Gyeongsang National University, 900 Ganzwadong, Chinju, Gyeongnam 660-701, Korea
3School of Materials and Metallurgical Engineering, University of Ulsan, San 29, Mugeodong, Namku, Ulsan 680-749, Korea
4Institute of Medical Materials and Shape Memory Implants, 634034 Ul.19 Gvardeyskoy Divizji-17, Tomsk, Russia

Titanium–Nickel shape memory alloy (TiNi SMA) has great potential as a biomaterial in orthopaedic applications due to its unique thermal shape memory effects, superelasticity and high damping properties. We designed and manufactured bone fixaters using newly developed TiNi SMA wire (Af, 35±2°C). Two bone fixater designs (single and double ring) were prepared for the treatment of bone fracture in twenty patients (6 distal femur, 5 distal fibular, 4 distal tibia, 2 metacarpal bone, 2 periprosthetic fracture and 1 subtrochanter of femur). Serial radiographs, complete blood count (CBC) and urine analysis were performed postoperatively. Radiological union was achieved without complications in approximate eight weeks after operation. There were no abnormal findings on follow-up CBC or urine analysis. On a subjective level, use and application of the TiNi SMA fixater was not as demanding as conventional fixation methods, such as cerclage or the Dall-Miles technique. The efficacy of SMA bone fixater in this study is very excellent as demonstrated in this clinical study. It gives the new armament to orthopedic surgeon.

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1. Introduction

Titanium–Nickel shape memory alloy (TiNi SMA) has unique thermal shape memory effects, superelasticity, good corrosion resistance and high damping properties. First developed and introduced in the early 1960’s, it was expected to be widely used in all fields of medicine. However, due to lack of sufficient evidence demonstrating the biocompatibility of TiNi SMA, as well as concerns over nickel toxicity, medical applications of this material were largely overlooked. Recently the biocompatibility of TiNi SMA is clarified.1–4)

The unique properties of TiNi SMA lend to diverse technological applications in the medical and dental industries. These applications have included everything from surgical tools to permanent implants, including implants within the bloodstream. Among such applications, TiNi SMA bone fixaters present a useful alternative to conventional materials currently used in the treatment of fractures.

We developed TiNi SMA with optimal transformation temperature (Af = 35±2°C) for human applications.5) Using this material, we designed and manufactured bone fixater system (SH-BRM system, Bio-Smart, Ulsan, Korea). Our clinical experience with the SH-BRM system is present in this study.

2. Materials and Methods

A ring type bone fixater made of TiNi SMA was first designed in our laboratory. The ring type fixater system is expected to replace conventional cerclage (circumferential wire fixation). Single and double-ring bone fixaters were developed based on analysis of the computerized tomography (CT) transverse section data of human bones. The inner diameters of bone fixaters were 15, 20, 25, 30 mm in double ring and 7, 10, 12, 15, 20 mm in single ring. Double ring bone fixaters were developed for the treatment of long bone fractures, while single ring fixater were used for the treatment of short bone fracture (Fig. 1).

The SH-BRM system was studied in accordance with Korea Food and Drug Administration regulations. Approval for clinical investigation of the material and system was obtained from the Korea Food and Drug Administration and Institute Review Board of Seoul Municipal Borame Hospital. The indications of this bone fixater were limited to the oblique/spiral type bone fracture and periprosthetic fracture. Twenty patients were treated with this system from June 1999 to May 2000. An informed consent was obtained from all pa-

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tients. Serial radiographs, complete blood count (CBC), and urine analysis were performed at 1, 4, 8 and 12 weeks postoperatively. The safety and effectiveness of SH-BRM system were evaluated by analysis of follow-up data. When fracture union was established definitely, the fixater and surrounding tissue were removed for histological examination.

Before the application of SH-BRM system, the fixater was prepared by cooling the TiNi SMA alloy in ice-cold saline. The reduction in temperature initiated a conversion into a martensitic phase state. Once cooled, the fixater was malleable and easy to deform (Fig. 2). The fixater size was determined either preoperatively from radiological film or intraoperatively by direct measurement. An appropriately sized bone fixater was selected and applied to the reduced fracture site (Fig. 3). Immediately thereafter, warm saline was irrigated over the TiNi SMA fixater, causing a contraction of the fixater to its original shape. Fastening of the fracture site was enhanced.

Ten men and ten women with a mean age of 55 years (range, 22 to 82) participated in this study. Fracture types according to the anatomic location included distal femur (6), distal fibular (5), distal tibia (4), metacarpal bone (2), femur shaft (periprosthetic fracture, 2) and subtrochanter of femur (1).

3. Results and Discussion

No major and minor post-operative complications arose in this clinical investigation. In all patients, the postoperative courses were uneventful. Radiological union was achieved in all patients approximately eight weeks following the procedure date. There were no abnormal findings on the follow-up CBC and urine analysis.

At present, TiNi SMA is clinically used in several orthodontic, orthopedic and cardiovascular applications.6) Thus far, no adverse tissue or allergic reactions to these implants have been reported. The nickel in TiNi SMA is chemically joined to the titanium in a strong intermetallic bond, hence the risk of reaction, even in patients with nickel-sensitivity, is extremely low. Recently, the biocompatibility of the TiNi SMA has been detailed in several studies.1, 3, 7–9) There is currently no published data demonstrating that the use of this TiNi SMA in the human body has any negative effect, and several medical devices used as permanent implant have been approved for their safety and efficacy and now on the market. Bone fixaters in seven cases achieved the bony union were retrieved for analysis of the surrounding tissue. There was no evidence of metallosis, which is frequently observed in tissue surrounding titanium-base alloy (Ti6Al4V) implant. Furthermore, the fixater was covered by new bone by a greater degree than has been observed for stainless steels plate (Fig. 4).

As a biomaterial, TiNi SMA exhibit excellent mechanical reliability, shape memory effect, superelasticity and damping capacity, good corrosion resistance, biofunctionability, and biocompatibility. These qualities lend to the development of potential limitless medical applications, particularly in orthopaedics. Among the newest devices currently being tested or employed is the ring shaped bone fixater described in this study, which may eventually replace circumferential wiring system such as wire cerclage and Dall-Miles cable system (Stryker® Howmedica, Allendale, NJ, USA).
The cerclage with wire has been a valuable part of the orthopedic armamentarium. Cerclage is used as an adjunct to intramedullary nailing, to treat fractures in the vicinity of a hip prosthesis or femoral component of total joint. The Dall-Miles cables have recently been introduced as an alternative to cerclage, with widespread acceptance. Both fixation methods (Dall-Miles cable and wire cerclage) are complex and demanding with regard to technical skill. In contrast, the application methods for the SH-BRM system were relatively simple and easy. Functionally, SH-BRM may represent an improvement over the current, conventional systems based on superelastic properties, which allow a constant, stabilizing force to be applied on the bone surface.

The double ring fixater was developed for the treatment of long bone fracture such as femur, tibia, and humerus. In this study, the fixater was applied to six distal femur fracture, combined with supracondylar intramedullary nail (Fig. 5). It is very difficult to obtain satisfactory results for the management of distal femur fractures. Currently, the supracondylar nail system is best device for the treatment of distal femur fractures. Anatomical reduction and its maintenance is not attainable by supracondylar nailing alone. When combined with the double ring fixater, however, union was obtained uneventfully and the alignment of distal femur was anatomical in all six cases of this study.

4. Conclusions

The TiNi shape memory alloy bone fixater (BRM-SH system) demonstrated excellent efficacy for fracture treatment. TiNi SMA was biocompatible and showed no adverse reactions in clinical observations. Subjectively, the application techniques of BRM-SH system were not as demanding and complicating relative to conventional methods such as the Dall-Miles cable system or cerclage. Advances in this system will enable the development of improved, more effective, and variable designs, which will increase the number of tools available for the practicing physician. Patient benefit can only improve with these advances. Now, we are devising and developing the various bone staplers using TiNi shape memory alloy.

REFERENCES


Fig. 5 A, B: Preoperative radiograph of distal femur fracture. C, D: Postoperative radiograph showing the well fixed with double ring fixater with supracondylar nail.