

ORTHOPAEDIC APPLICATIONS OF SHAPE MEMORY STAPLES

Haluk YETKİN, M.D.,
Erdal CİLA, M.D.,

Ulunay KANATLI, M.D.,
Aykın ŞİMŞEK, M.D.

Alpaslan ŞENKÖYLÜ, M.D.,

Gazi University, Faculty of Medicine, Department of Orthopaedics and Traumatology, Ankara,
Turkey.

Gazi Medical Journal 1999; 10 : 153-155

SUMMARY

Purpose: Equiatomic nickel and titanium alloy has been a recent introduction as an implant in orthopaedic surgery. This alloy has a reversible thermoelastic martensitic transformation property. Our purpose is to present our clinical experience in orthopaedic applications of shape memory staples. **Methods:** From 1995 to 1997, we used shape memory staples as implants for internal fixation in 23 patients who have been followed up for at least two years. **Results:** Infection and nonunion was observed in only one patient (4.3%). The osteotomies in all the other patients healed uneventfully. **Conclusion:** Shape memory staples are suitable materials for bone fixation. The main disadvantage has been the relatively high cost of these implants, compared to alternative implants.

Key Words: Nitinol, Biocompatible Materials, Alloys, Surgical Stapling, Fracture Fixation.

INTRODUCTION

The interest in applications of shape memory alloys as an implant in orthopaedic surgery is increasing (1). Equiatomic nickel and titanium (Ni 49.9% and Ti 50.1%) alloy has been used for this purpose. This alloy has a potential to display two different phase properties according to environmental heat. The first phase is the martensitic phase that can be seen at low temperatures and the second is the austenite phase that occurs at biologic temperatures. At the martensitic phase, the alloy can be deformed and its shape can be altered. When heated to

biological temperatures, it enters the austenite phase and regains its initial shape. Deformations even up to 8% strain can be completely recovered. This property is known as "Reversible Thermoelastic Martensitic Transformation." Shape memory alloy takes this transformation property from its crystallographic structure (1,2,4,5,6).

These properties of the alloy were first described by Buehler and Wang in 1963 (4). In 1981, Dai et al. were the first to use this alloy on a human subject, fixing a patellar fracture with shape memory staple (2). There is controversy on the biocompatibility of the NiTi alloy because of the toxic and allergic effects of nickel. However,

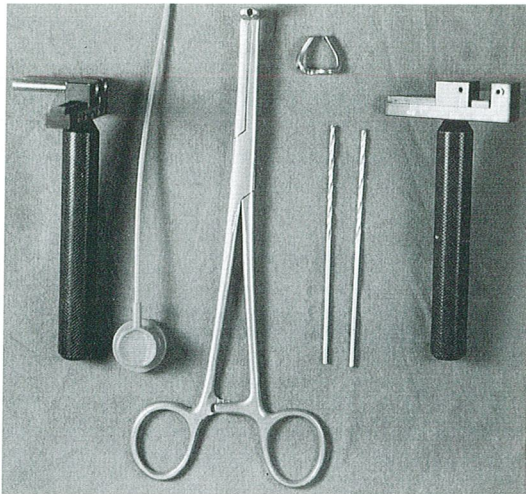


Fig - 1: Shape memory staple and its inserting instruments. *in vivo* and *in vitro* studies revealed that biocompatibility of NiTi alloy is similar to that of titanium (1,3).

In this study, we presented our clinical experience on orthopaedic applications of shape memory staples made of NiTi alloy (Nitinol).

MATERIAL AND METHOD

Between 1995-1997, we have used shape memory staples (b.r.i., La Seyne, France) in twenty-three patients at Gazi University Medical School, Orthopaedics and Traumatology Department. One patient was treated for fibular fracture, two for metacarpal fractures, one for carpo-metacarpal joint degenerative arthritis and nineteen patients for hallux valgus. The "U" shaped Nitinol has two straight legs, named the insertion segments and a wavy horizontal segment, connecting the two legs, named the compressive segment (Fig. 1). There is a seventy degrees angle between the insertion and compressive segments at the austenite phase. After cooling the staples to minus 15°C by ethylene chloride, the legs of the staple can be deformed to fit the pre-drilled holes. When the staples are inserted, they are influenced by body heat and the staples regain their original shapes and exert compression between the two fragments. In order to increase the stability, at least two shape memory staples have been used at different planes (Fig. 2A-2B).

Patients have been clinically and radiologically followed for at least two years

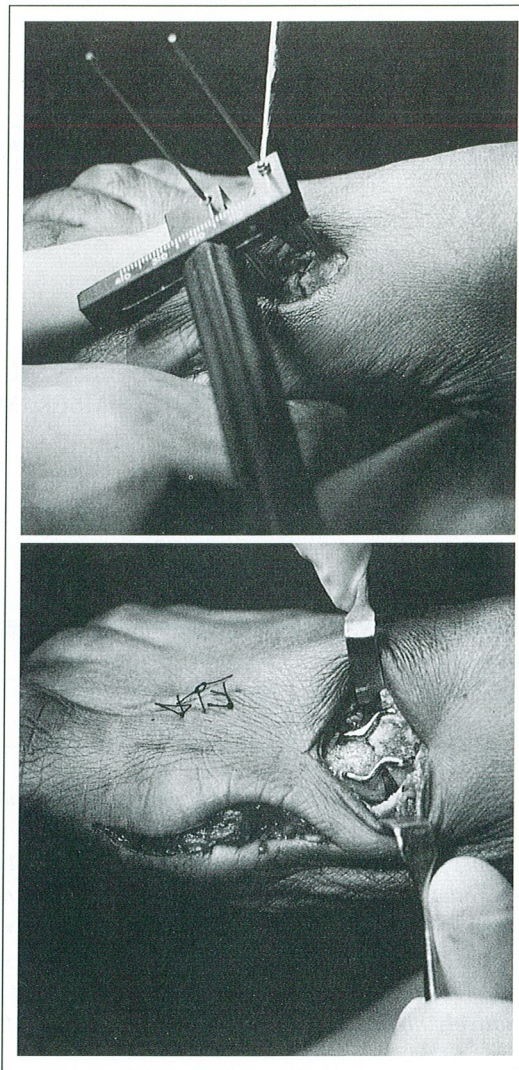


Fig - 2 : (A) Application of the shape memory staple to the proximal metatarsal osteotomy of a hallux valgus patient. (B) The view after insertion of the staple.

(24-36 months).

RESULTS

During follow-up, one patient surgically treated for hallux valgus developed a *Staphylococcus aureus* infection at the metatarsal osteotomy which and resulted with nonunion. This patient was treated by removal of the implant, curettage and grafting. In all the other patients, we observed fracture healing in the normal expected period of three to six weeks. We have not experienced systemic or local allergic reactions, metal intoxication or implant failure in our patients.

DISCUSSION

Shape memory alloy implants have numerous indications in orthopaedic surgery (1,6,7). Despite the adverse reactions that have been described for nickel, in vivo and in vitro studies revealed that the NiTi alloy is biocompatible (1,3,5). This biocompatibility is believed to be the result of the passive film layer which covers the alloy (5).

It is well known that stable fixation and compression are the two main factors in obtaining union between two bony fragments. Due to the pseudoelastic property of shape memory staples, even when resorption occurs between the two fragments, the implant maintains its compressive effect, which has a positive influence on fracture healing (3).

In the literature, nonunion was not reported in surgeries for small bones or intra-articular fractures where at least two staples were used at different anatomical planes (2,3). Musialek et al. (2) reported four nonunions in twelve patients treated with only one staple. In our study, we used at least two staples and observed only one nonunion (3).

For the transformation to the austenite phase, different heating methods have been described (1,2). In our study we observed that body heat is adequate for this transformation.

Shape memory staples are suitable materials for bone fixation because of their biocompatibility, continuous compression effect (pseudoelasticity) and ease of application. On the other hand, their high cost is the main disadvantage of this alloy.

Correspondence to: Dr.Haluk Yetkin
Gazi Üniversitesi Tıp Fakültesi
Ortopedi ve Travmatoloji
Anabilim Dalı
Beşevler
06510 Ankara-TÜRKİYE
Phone: (90)312-2121400 / 5529
Fax : (90)312-2129008

REFERENCES

1. Wever DJ, Veldhuizen AG, Sanders MM, Schakenraad JM, van Horn JR. Cytotoxic, allergic and genotoxic activity of a nickel-titanium alloy. *Biomaterials* 1997; 18 : 1115-1120.
2. Dai KR, Hou XK, Sun YH, Tang RG, Qui SJ, Ni C. Treatment of intra-articular fractures with shape memory compression staples. *Injury* 1993; 24 : 651-655.
3. Musialek J, Filip P, Nieslanik J. Titanium-nickel shape memory clamps in small bone surgery. *Arch Orthop Trauma Surg* 1998; 117 : 341-344.
4. Putters JLM, Sukul DMKS, de Zeeuw GR, Bijma A, Besselink PA. Comparative cell culture effects of shape memory metal (nitinol), nickel and titanium: A biocompatibility estimation. *Eur Surg Res* 1992; 24:378-382.
5. Rondelli G. Corrosion resistance tests on NiTi shape memory alloy. *Biomaterials* 1996; 17 : 2003-2008.
6. Şimşek A, Atik OŞ, Yetkin H, Şener E, Takka S: Şekil hafızalı "U" çivisi ve klinik uygulamalarımız (Erken bildiri). *Artroplastî Artroskopik Cerrahi* 1995; 6 : 32.
7. Yetkin H, Kanath U, Şimşek A, Cila E, Güzel V. Clinical application of shape memory staples: Technique tip. *Foot Ankle Int* 1998; 19 : 571-572.