

Nitinol Compression Staples for Bone Fixation in Foot Surgery

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We reviewed the use of compression staples made of the memory metal alloy nitinol for fixation in foot surgery. A retrospective study was performed of 31 feet in 27 patients who underwent arthrodesis or an osteotomy fixated using compression staples. OSStaples (BME, San Antonio, Texas) were used in 18 feet, and Memodyn staples (Telos Medical, Fallston, Maryland) were used in 13 feet. A total of 48 compression staples were implanted. The following procedures were performed and fixated using compression staples: 15 Akin osteotomies, 2 first metatarsal base epiphysiodeses, 3 first metatarsal–cuneiform fusions, 2 naviculocuneiform fusions, 3 calcaneocuboid fusions, 4 talonavicular fusions, 3 subtalar joint fusions, and 2 Evans osteotomies. In our clinical experience, compression staples provide an adequate source of internal fixation in foot surgery. Good bone apposition and stabilization and compression of the bone surfaces before staple fixation are important when using staple fixation to promote an optimal environment for bone healing. (J Am Podiatr Med Assoc 96(2): 102-106, 2006)

Bone staples have been used in the United States for a variety of foot and ankle procedures since 1906,^{1,4} including triple arthrodesis, calcaneal osteotomy, forefoot and midfoot fusions, lesser-metatarsal osteotomy, and epiphysiodesis.^{4,10} The advantages of staple fixation may include good approximation of fragments, dynamic compression, avoidance of pin-tract infections from exposed hardware, and technically less operating time compared with bone screws.^{3, 8, 9, 11} Compression staple application is a four-step technique: temporarily fixate, pre-drill holes, implant and seat staple, and apply heat for compression. In the past, traditional bone staples have maintained alignment of the bone, and the only compression afforded was that applied by other means. Traditional bone staples have demonstrated an inconsistent quality of fixation, a tendency to loosen, a lack of compression, and bulkiness.^{1-4, 12}

Studies have shown^{2-4, 12-14} that the stability of staple fixation depends on leg length and width, cross-

section geometry, angle of insertion, bone density, and power- *versus* hand-driven technique. Most studies have investigated the pullout strength of the staples, with the logic that greater pullout strength leads to more secure fixation, quicker bony union, and a lower incidence of nonunion.¹³ Staple variations have increased the stability in bone. Barbed staples were developed to prevent loss of fixation.^{2, 4} The powered 3M Staplizer (3M, St Paul, Minnesota) introduced in 1986 had several advantages over manually driven staples. Ostgaard et al¹⁵ found a 33% decrease in operating time when using power-driven staples for internal fixation of ankle fractures compared with pin-and-screw placement. The greater pullout force of power-driven *versus* hand-driven staples has been demonstrated in several studies.^{3, 4, 12, 14}

Currently, metal composition is being used to improve staple fixation and stability. *Nitinol* is an acronym that stands for nickel (Ni), titanium (Ti), and Naval Ordnance Laboratory (NOL) (where the alloy was discovered in the early 1960s). Nitinol (NiTi) is a nickel-titanium metal alloy whose shape and stiffness can be controlled by temperature.^{16, 17}

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knee observed in patients with PFPS because increased rearfoot eversion may lead to an increase in tibial internal rotation and tibial abduction relative to the femur. Nevertheless, further research is required to investigate the causal relationship because it remains unclear whether rearfoot eversion instigates medial collapse of the knee. Further research may also be directed toward investigation of the rearfoot and knee frontal plane motion simultaneously to better understand the contribution of the rearfoot segment to the medial collapse.

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Nitinol belongs to a class of materials called "shape memory alloys." Shape memory alloys have interesting mechanical properties. Nitinol, for example, contracts when heated, which is the opposite of what standard metals do when heated (expand). Not only does NiTi contract, but it produces a 100-times-greater thermal movement (expansion and contraction) than standard metals. Another interesting property of shape memory alloys is the shaped memory effect. This alloy can be heat-treated to "remember" a particular shape. Afterwards, if the shape is bent and distorted, the alloy may be heated to regain its original shape. Nitinol has a two-shape memory effect, allowing it to transition from one predefined shape to another.¹⁸

Nitinol has been shown to be a safe implant and to be comparable to a fixation device made of stainless steel and titanium.^{16, 17} The NiTi compression staple was introduced in China and was first used in a human body in 1981.¹⁶ The staple functions by the prongs of the staple deflecting into the bone on application of a heating current below the level of thermal necrosis to the surrounding tissues (Fig. 1). The transition temperature for NiTi is 42° to 52° C. A study by Tang et al of 36 metatarsal osteotomies for hallux valgus fixated using NiTi staples showed shortened bone healing time.^{16, 17}

BME (San Antonio, Texas) was the first company in the United States to have NiTi implants available and US Food and Drug Administration approval. The OSStaple (BME) is available in 13 designs with a 12-component instrument set, including an electronic

bipolar current source to compress the staple.¹¹ The OSStaple has been shown to provide 4 to 14 pounds of compression.

Memodyn staples (Telos Medical, Fallston, Maryland) have been used in Europe since 1990 and were approved by the US Food and Drug Administration in 2001.¹⁹ Memodyn staples come in two- and four-leg designs with a lower profile and can be compressed by applying either a bovie or handheld electrocautery. Memodyn staples have been shown to withstand a compression force of 6 to 11 pounds. The Memodyn staple has been tested using handheld high-temperature cautery (Bovie AA03; Aaron Medical, St Petersburg, Florida) and a normal hospital bovie. The bovie was set at 45 W, bipolar, and was used on the orthocut setting. The average temperature after heat application did not exceed 43.2°C. We sought to review the use of NiTi compression staples to determine whether they are comparable to other methods of fixation.

Materials and Methods

A retrospective study was performed of 31 feet in 27 patients who underwent either arthrodesis or an osteotomy fixated using compression staples. OSStaples, which were the first staples available at our institution, were used in 18 feet, and Memodyn staples were used in 13 feet. A total of 48 compression staples were implanted. The osteotomy or arthrodesis was temporarily fixated using a Kirschner wire or manual compression. An adjustable drill guide was used to determine staple size and placement, appropriate pilot holes were drilled, and the staple was tapped in using the impaction device and mallet. All OSStaples were stimulated using the electronic bipolar current source. All Memodyn staples were stimulated using the hospital bovie at 45 W on the orthocut setting. Compression either was visualized across the joint or osteotomy or was seen on intraoperative fluoroscopy. Plain film radiographs and office notes were reviewed to compile information about patient age, sex, surgical history, staple size and quantity, and complications. Minimum follow-up was 3 months.

As mentioned previously, the drill guide is used to help determine staple size. There are also templates to help determine the size of the staple for the particular procedure. When determining the size of the staple, bridge distance in relation to the fusion or osteotomy is critical. We suggest 4 to 6 mm on each side of the osteotomy or fusion site. A second important factor in determining the appropriate staple is arm length. Arm length should be as great as possible to purchase all cortices, when attainable. By applying these concepts regarding bridge distance and arm

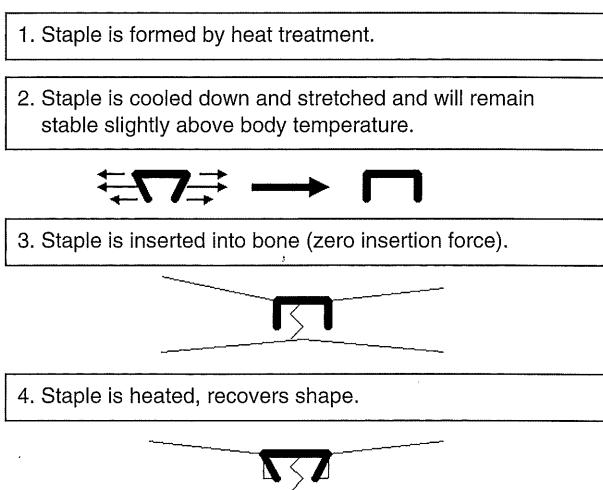


Figure 1. Formation, insertion, and compression seen in the bone with NiTi compression staples.

length, the overall stability of the fixation is improved, as is the uniformity of compression across the osteotomy or fusion site.

Results

Akin Osteotomy

Fifteen proximal Akin osteotomies were performed, eight using the OSStaple and seven using the Memodyn staple (Fig. 2). In all cases, a sagittal bone saw was used to make an osteotomy in the proximal aspect of the proximal phalanx, with care taken to leave the lateral cortex intact. Osteotomies were fixated using either a single OSStaple (in seven cases) or two (in one case) or a single Memodyn staple (in seven cases). In two cases, with the OSStaple, the lateral cortex fractured 6 and 10 weeks after surgery. Both patients remained free of pain, and the fixation appeared to be radiographically stable and healed at 9 and 14 weeks. In two cases using the Memodyn sta-

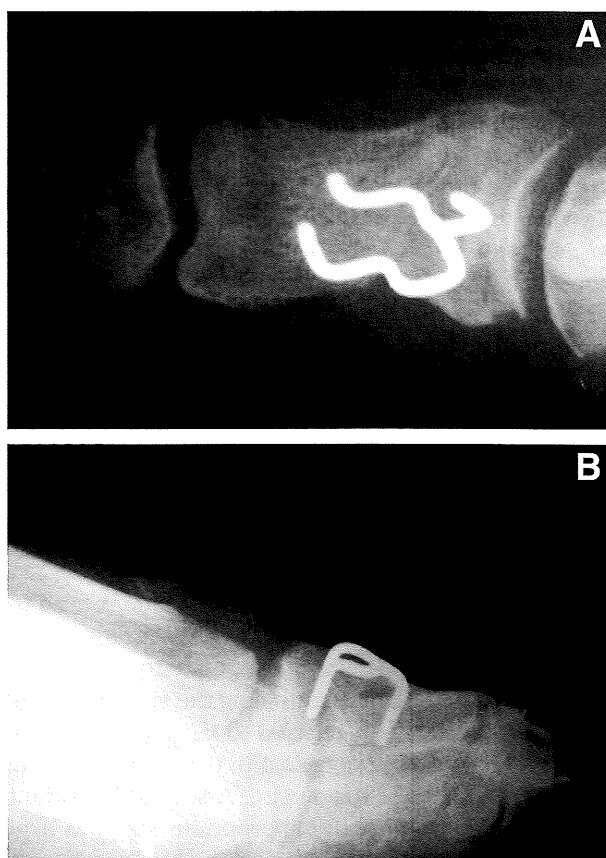


Figure 2. Anteroposterior (A) and lateral (B) radiographs of Akin osteotomy with Memodyn staple fixation.

ple there was malposition of the osteotomy unrelated to the fixation that was noted to be stable. One of these Akin osteotomies was a revision procedure performed 5 weeks after the original operation. Three months after surgery, this patient remained free of pain, with the fixation intact, but continued to have a 1-mm medial gap of the osteotomy. There was also one additional proximal phalanx shortening osteotomy performed and fixated using two OSStaples that healed uneventfully. Epiphysiodesis of the first metatarsal base was performed on one patient bilaterally using OSStaples.

Midfoot Arthrodesis

Twelve midfoot fusions were performed: four in talonavicular joints, three in calcaneocuboid joints, two in naviculocuneiform joints, and three in first metatarsal-cuneiform joints (Fig. 3). In one case, the talonavicular joint had been fused as part of a triple arthrodesis procedure in a diabetic patient with neuropathy; 5 months after surgery, a radiographic evaluation showed an asymptomatic broken 25 × 22-mm OSStaple at the talonavicular joint (Fig. 4).

Rearfoot Arthrodesis

Two Evans and three subtalar joint fusions were performed. In the Evans osteotomy using the Memodyn quad staple, the surgeon had difficulty removing the staple after inappropriate placement (Fig. 5). One leg

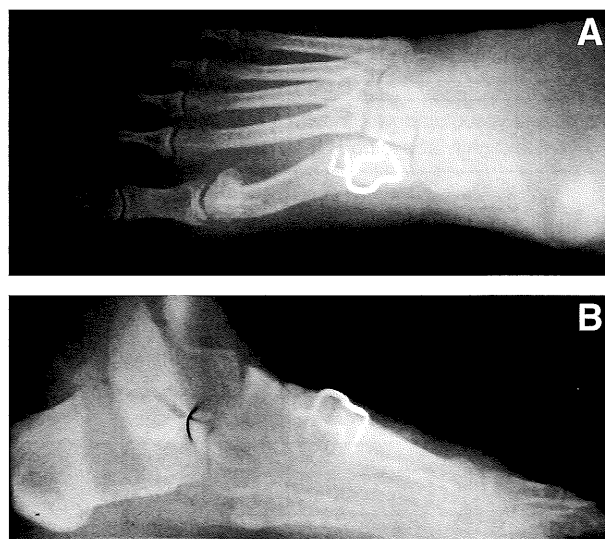


Figure 3. Anteroposterior (A) and lateral (B) radiographs of Lapidus fusion with Memodyn staple fixation.

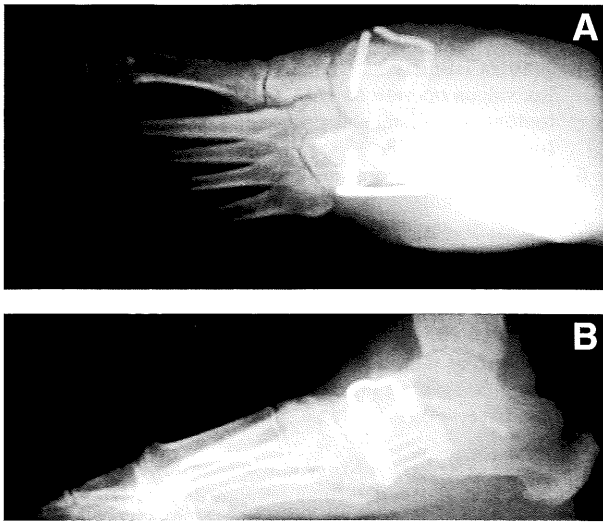


Figure 4. Anteroposterior (A) and lateral (B) radiographs showing fracture of OSStaple at the talonavicular joint 5 months after surgery.

of the quad staple in this case was removed using wire cutters. Also noted in this case, 9 weeks after surgery a medial gap was seen radiographically, but staple fixation was stable. Two of the three subtalar joint fusions were performed as triple arthrodeses.

Discussion

As technology advances, many attempts have been made to improve bone fixation. Bone staples were introduced into orthopedic surgery with the benefits of internal fixation and decreased operating time. Stan-



Figure 5. Evans osteotomy fixated using a Memodyn quad staple.

ard staples have varied in the quality of fixation, have lacked compression, and have had a tendency to back out. Chiodo et al²⁰ wrote that although screw fixation is known to be superior to standard staples in resisting bending moments, staples across an arthrodesis site are believed to neutralize rotational forces. They stated that using two staples yields the largest proportional increase in torsional stability. In our study, 12 of the 34 procedures performed used two staples. The staples were used as primary fixation in all but one arthrodesis. Two staples were used more often in the midfoot and rearfoot than in the forefoot. With the development of NiTi, a memory alloy controlled by temperature, staples have evolved to provide compression for improved fixation and holding power.²⁰

Nitinol is a material with many exciting possibilities. It is being used in many medical devices, including endoluminal stents, distraction rods for scoliosis correction, and mesh expanding prostheses for laparoscopic hernioplasty. The only NiTi-containing orthopedic implant widely used is the Mitek G2 suture anchor (DePuy Mitek Inc, Johnson & Johnson Co, Norwood, Massachusetts).¹⁶ For a product to become popular, it must be proved to be better than what is already available. Currently there are no comparative clinical studies that scientifically prove that compression staples are comparable to other forms of fixation in widespread use, such as screws, Kirschner wires, and cerclage wire.

In this preliminary study, one of 31 cases had hardware-related adverse outcomes. In this case, on the 5-month postoperative radiograph, an OSStaple for a talonavicular fusion was seen to be broken in a patient known to have diabetic neuropathy who had undergone a triple arthrodesis. In two Akin procedures using the OSStaple, postoperative radiographs at 6 and 10 weeks revealed a fractured lateral cortex of the osteotomy. In both of these cases a single staple was inserted from medial to lateral, engaging only the medial cortex. Both of these patients remained asymptomatic, without clinical or radiographic loss of fixation, and healed uneventfully at 9 and 10 weeks. One nonunion of a revision Akin osteotomy can be attributed to improper closure of the osteotomy.

This study has several weaknesses as a retrospective analysis of compression staples. Data were assessed from three different surgeons who used compression staples. Owing to the variability between postoperative radiographs and documentation in the office notes, fusion rates could not be accurately assessed. Additional data on patient comorbidities, including smoking history and diabetes, would be useful in assessing fusion rates.

In our clinical experience, compression staples provide an excellent source of internal fixation to add to the podiatric surgeon's armamentarium. Our experience corroborates the advantages of staples as described in the literature, including good approximation of bone fragments, technically easy application with fewer steps than an AO applied screw, and the benefits of internal fixation in avoiding pin-tract infections. The preliminary findings of this study suggest that NiTi compression staples provide comparable fixation for arthrodeses and osteotomies of the foot. Good bone apposition in fusions and osteotomies is important to optimize compression staple fixation. Stabilization and compression of the bone surfaces before staple fixation encourages compression and stability to promote bone healing. Fixation effectiveness is known to be increased by a greater number of staples. To decrease rotational forces, more than one staple is recommended. Comparing the two types of compression staples, Memodyn has the benefits of using a bovie or hand cautery *versus* having the electronic bipolar current source brought in. Memodyn staples have a lower profile. Follow-up for the Memodyn staples in our study is shorter than that for the OSStaple, and continued tracking of these patients is warranted for a more parallel comparison. The OSStaple and Memodyn staples, both made of NiTi, seem to be effective as a primary or secondary mode of fixation in osteotomies or arthrodesis procedures in the foot. Further studies need to focus on the fusion rate and a longer follow-up period.

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