CHAPTER 38

THE OSSTAPLE™

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The object of this presentation is to introduce the podiatric community to the OSStaple™ system. Staples are generally simple U-shaped implants that come in multiple sizes with variable width or bridge distance and leg length. Like most staples, simple U-shaped implants are available in this system as well as several other implant designs. This is a new product for bone fixation utilizing staples fabricated from nitinol; an alloy of 50% titanium and 50% nickel. The staples, due to the physical properties of the alloy possess thermoplastic properties. Case presentations will demonstrate their usefulness of application for various types of surgical foot procedures.

THE STAPLE SYSTEM

The OSStaple™ system is marketed through BioMedical Enterprises, Inc (San Antonio, TX) and consists of an assortment of staple sizes and configurations as well as instrumentation for insertion and heating of the staple, the "Warmsystem"™. The staples vary from small monocortical staples with short legs to larger sizes intended for bicortical application. Larger epiphyseal staples that are designed for fixation of larger bones are also available. The system includes the OSStaple™ 4-prong design or mini-plate as well as a staple for ligament fixation (Figure 1).

Traditionally, staple fixation has been limited in application due to difficulties in placement with traditional manual insertion or the limited stability achieved. Staples were traditionally viewed as a technique of appositional fixation within the bone fragments once they were brought into contact. Classically, the fragments were stabilized with the insertion of the legged staple. Application has usually been in epiphyseal and metaphyseal areas of cancellous bone due to the manual techniques of insertion.

The OSStaple™ features a rectangular shaped leg that is smooth. The bridge is an S-shaped design with somewhat rounded corners connecting the legs. The OSStaple™ is unique in that is designed to provide interfragmentary compression of bone fragments. This is accomplished through the application of heat to the staple once it is inserted. The nitinol staple is manufactured with the legs pointing towards each other in its "closed position." It is then straightened after heating the staple to 500°C and holding it in this position for a period of time. The staple is then quenched in ice water that rapidly freezes its position. Actually nitinol exists in two crystal phases, a martensitic phase and a stronger austenitic one. With the ice water quenching, there is a phase transformation to the martensitic state and the structure remains there until heating following surgical implantation.

The staples are packaged sterile in individual boxes in a polyethylene holder that prevent it from returning to its original shape prior to use. Following insertion, the staple is designed to return to its original configuration with heating. This is done with the "Warmsystem"™ that applies electrical current for two seconds to heat the staple through the joule effect. This resistive heating, with passage of a current though the staple, is controlled to be below the temperature and time threshold required to cause thermal necrosis of bone. This converts the nitinol staple to its austenitic phase where it is stable and stronger with regard to its tensile yield strength and comparable to 316L stainless steel.

The OSStaple™ system includes instrumentation for the precise location of drill holes at the appropriate distance equivalent to the bridge of each

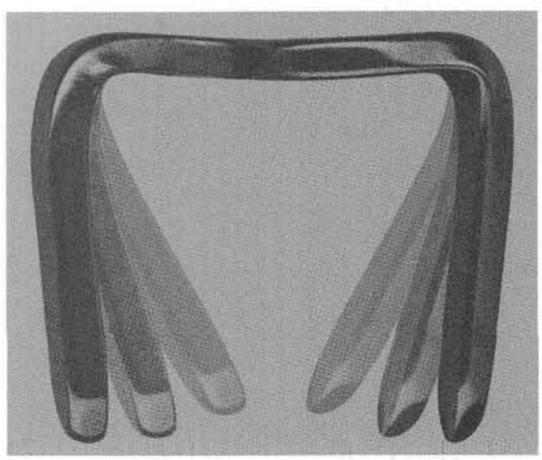

Figure 1. The OSStaple™.

staple. Little manual pressure is required during insertion of the staple. Once inserted, interfragmentary compression of the fragments is achieved with passage of a current through the staple utilizing the Memograph® Warmsystem™. The handpiece for the Warmsystem™ is touched at each shoulder of the staple in alternating fashion until satisfactory compression is achieved, usually 1 to 4 heating applications depending upon the size of the OSStaple™ or OSSplate™. Heating of the staple results in closure of the legs of the staple exerting an interfragmentary compressive force of 7 lbs with the smaller staples and up to 13 pounds force may be achieved with the larger epiphyseal versions. The OSStaple™ is an expedient method for the fixation of bone with a simple device that allows for stability of the osseous fragments through interfragmentary compression.

There have been questions in the past with regard to the use of nickel in orthopedic implants particularly concerning nickel sensitivity. Nickel is an essential trace element that binds with a carrier protein in the skin to act as a hapten capable of cell-mediated immune reactions. When implanted, nitinol shows excellent biocompatibility with regard to corrosion resistance. No appreciable leaching of nickel ions occurs. There is no inflammatory response and behavior is similar to Ti-V-Al.

CASE PRESENTATIONS

Case 1

DKP is a 50-year-old female who presented with symptomatic acquired hallux varus with hallux malleus and hammertoe deformities 2,3,4 in the right foot. She was 4 years postoperative from a McBride-type bunionectomy (Figure 2A). On 10-25-2000, she underwent surgical repair, specifically hallux varus repair with EHL tenoplasty, hallux IPJ fusion, and hammertoe repair 2,3,4. The hallux fusion was performed in conjunction with a complete first metatarsophalangeal (MTP) joint release and EHL tendon transfer. The fusion was fixated with an axial 0.062 inch Kirschner-wire flanked on either side with two 11x8 mm OSStaple™ (Figure 2B). Excellent position was achieved and correction of the preoperative deformity (Figures 2C, 2D). The patient was followed and last evaluated at 8 months postoperative and bony union was evident.

Figure 2A. Case 1, initial presentation.

Figure 2B. Case 1, immediate postoperative radiograph.

Figure 2C. Case 1, 6 week postoperative view.

Figure 2D. Case 1, 6 months postoperative view.

Case 2

EW a 65-year-old female with pes cavus deformity was seen with initial complaints of a long-standing ulcer at the great toe IPJ and pain due to walking with pressure on the tips of her toes.

The preoperative diagnosis was a pes cavus deformity with heel varus and contracture of the plantar fascia, hammertoe deformities 2, 3, 4, 5 with MTP joint & extensor tendon contractures, and hallux malleus.

On 12-15-2000, she underwent surgical repair, specifically, calcaneal osteotomy, peroneus longus and EHL tendon lengthening, MTP joint, extensor and flexor tendon releases, hallux IPJ fusion, digital fusions 2,3,4, hammertoe repair 5, and a plantar release. The hallux fusion was performed through a converging semielliptical dorsal transverse incisional approach with internal fixation. The osteosynthesis consisted of an axial 0.062 inch K-wire flanked on either side with 11x8 mm OSStaple™. The calcaneal osteotomy was a lateral based closing wedge with posterior displacement. This was fixated with a solitary 20x20 OSStaple™. Full bony consolidation was noted without resorption or displacement.

Figure 3A. Case 2, initial presentation.

Figure 3B. Case 2, postoperative view of the hallux repair.

Figure 3C. Case 2, initial presentation, lateral view.

Figure 3D. Case 2, postoperative view of calcaneal osteotomy.

Case 3.

SW is a 47-year-old female with AODM. She presented with chronic pain in the first MTP joint of the right foot of several years duration. She had a history of multiple prior surgeries with a postoperative infection and poor skin and subcutaneous tissues from multiple surgical procedures. The hallux was short with medial deviation and lack of toe purchase.

She was initially treated with reduced activities, rocker sole shoes, and electrical bone growth stimulation. Due to continued symptoms she underwent surgical repair on 1-10-2001. The procedures included first MTP joint fusion with autogenous bone graft. The fusion was performed with limited exposure of the first MTP joint through two small incisions. Fixation was with an axial 0.062 inch K-wire and a single 20x20 mm OSStaple™, although the distal leg was shortened due to the smaller height of the proximal phalanx versus the first metatarsal.

The patient continued with the electrical bone growth stimulation postoperatively and 6 weeks of non-weight bearing. Excellent position was achieved and correction of the preoperative deformity. The patient was followed and last evaluated at 8 months postoperative with bony union evident.

Figure 4A. Case 3, initial presentation.

Figure 4B. Case 3, postoperative view, 1st MPJ joint fusion.

Figure 4C. Case 3, postoperative lateral view.

Figure 4D. Case 3, postoperative view.

Case 4.

CJ is a 70-year-old female who presented with a severe luxatory hallux valgus deformity of the right foot. She was treated for recurrent ulceration lateral at the IPJ of the great toe and chronic pain. On 10-25-2000, she underwent a first MTP fusion with an axial 0.062" K-wire and a dorsal based OSStaple™. A mini-plate 4 prong 15x8 staple was used. Excellent position and correction of the preoperative deformity were achieved. The patient was followed and last evaluated at 6 months postoperative with bony union evident.

Figure 5A. Case 4, initial presentation.

Figure 5B. Case 4, postoperative view.

Figure 5C.Case 4, 6 month postoperative view.

Figure 5D. Case 4, 6 month postoperative lateral view.

Case 5.

LT, an 81-year-old female presented with chronic hindfoot pain secondary to severe collapsing pronatory deformity of the left foot. She exhibited recurrent sinus tarsiitis with poor response to nonsteroidal antiinflammatory drugs and supportive measures. On 3-28-2001, she underwent a triple arthrodesis of the left foot. The calcaneocuboid and talonavicular fusion sites were each fixated with two OSStaples™ placed oblique to each other. Staples were 20x20 and 25x22 so that the legs would avoid each other.

Excellent position and correction of the pre-operative deformity were achieved. The patient was placed in a below-knee cast for 8 weeks with limited weight-bearing. Excellent position was noted at radiographic exam at 6 weeks but some loss of correction was noted at the 9th week and 12th week postoperative radiographic exams.

Figure 6A. Case 5, initial presentation.

Figure 6B. Case 5, postoperative view, triple arthrodesis.

Figure 6C. Case 5, 9 week postoperative view.

Figure 6D. Case 5, 12 week postoperative view.

Case 6.

RS is a 77-year-old female with chronic sub pain of the first MTP joint of the right foot. She was 5 years postoperative of a first MTP joint fusion. Clinically, she was in 55° of extension at the fusion site with symptoms consistent with chronic tibial sesamoiditis as well as pain at the great toe nail. The toe was well-aligned in the transverse plane. She had a positive cardiovascular history and had been on coumadin for the past three years due to atrial fibrillation.

On 5-16-2001, she underwent a revisionary first MTP joint fusion, excision of tibial sesamoid, and EHL tendon lengthening. The 1st MTP joint fusion was fixated with two OSStaples™, a 13x10 mm and a 15x12 placed perpendicular to each other dorsal and medial. She was treated postoperatively with restricted weight-bearing in a below-knee walker for 7 weeks. Preoperative symptoms resolved but she did have a postoperative complication with a second metatarsal stress fracture at $2^1/_2$ months postoperative. The patient was followed and last evaluated at 3 months postoperative with bony union evident.

Figure 7A. Case 6, initial presentation.

Figure 7B. Case 6, Postoperative view.

Figure 7C. Case 6, Postoperative view at 2 1/2 months.

Figure 7D. Case 6, three months postoperative.

SUMMARY

The OSStaple™ system has been used in numerous situations predominantly in older individuals for joint fusions. The staple provides good stability even in cases of overt osteopenia and poor bone stock. Of particular usefulness and simplicity is the technique for fusion of the great toe IPJ and MTP joints. The staple comes in a variety of sizes and so it has been found useful from the small great toe IPJ to fusions of large joints such as the talonavicular and calcaneocuboid joints. The OSStaple™ is a method of achieving stability through interfragmentary compression even in bones too soft for traditional methods of interfragmentary compression, for example, screws. OSStaple™ system has been shown to be effective and should be considered for osteosynthesis of pedal arthrodesis and cancellous bone osteotomies.