Tarsometatarsal Arthrodesis using a Novel Orthopedic Staple

Robert B. Weinstein, DPM, FACFAS
Dharmesh Bhakta, DPM, FACFAS

Abstract:

Arthrodesis of joints in the foot are commonly performed procedures in the field of orthopedic surgery. Many devices have been successfully employed to stabilize bone segments during the healing process including screws, pins, plates, rods and staples. A variety of orthopedic staples exist, broadly characterized as either conventional or shape memory (Nitinol), based on their material properties and structure. The use of a particular type of staple may be dictated by regional anatomy, bone quality, desire for compression, and likelihood of post-recovery local or systemic irritation. We present a case series of midfoot arthrodesis procedures using the novel low profile titanium alloy Orbitum™ staple that is designed to achieve the compressive effects of superelastic Nitinol while retaining the mechanical attributes of conventional staples.

Introduction:

Arthrodesis of joints by the compression method, first described by Key in 1932 and later popularized by Charnley in the late 1940's and early 1950's, is a well known technique in orthopedic and specifically foot surgery (1-3). It was proposed and later proven that compression leads to earlier union of segments (4,5). This method has subsequently been applied universally when performing joint arthrodesis since the 1960's and is considered standard operating procedure, except in certain cases where compression would be detrimental (e.g. compression fractures, across growth plates, etc.)

A variety of surgical implants have been utilized to either maintain compressed bone segments or to deliver an intersegmental compressive force. The most commonly employed method involves screws, since this device is well suited to be used in rigid tissue. Fundamentally, a screw transmits force by conversion of rotation to axial motions (torque converted to linear force.) When placed between bone ends, this effectively compresses the two segments together. Screws are often selected for fixation in foot surgery since the osseous segments are generally of sufficient mass and density. Local anatomical factors in the surgical approach allow for placement of screws at a variety of angles and configurations to sufficiently compress joints in fusion constructs. However, there are occasions when a bone screw could potentially be problematic. For example, certain joints in the midfoot require steep approach angles for screw entry. This may lead to insufficient compressive force, inadequate bone purchase, or fracture of the proximal bone segment from the severely oblique entry angle. Another issue with screws that is encountered in this region is the prominence of the screw head, which can present in the post operative state as prominent or irritating in shoe gear.

Plates have also been used in compression constructs, illustrated in great detail early on by the Swiss AO group (6). When properly affixed across an arthrodesis site some interfragmentary compression is possible. Generally speaking, these devices are used in place of screws in arthrodesing procedures of the foot when there is bone compromise in the area of fusion. Conditions such as osteopenia, segmental bone loss, and simply avoiding the dangers of screw insertion outlined above would be indications for use of a bone plate. Despite these benefits, plate insertion involves disturbing additional anatomy for placement of these larger objects, increased operative time to insert, prominence of the device, and limited compression delivered.

Bone staples have played a role in orthopedic surgery probably since the introduction of the steel pins by Martin Kirschner in 1909. Roux-Lane's bent wire and Schede's plain steel staple are early examples of such devices. These devices have taken on a variety of configurations and designs that reflect local anatomy, procedure type, bone size and density. Two, three and even four prong staples such as Lambotte's gold plated bone spikes were developed to cross fracture lines (7). Conventionally, staples are configured with a bridge and two legs, although there may be more than two legs. They are made from biocompatible and sturdy materials such as stainless steel or titanium. Staple configurations have historically been for static placement to hold approximated or compressed bone ends together. This design has been used in orthopedic surgery for many decades and well documented in Charnley's early papers among others (2,8). Staples have the advantage over screws and plates in that they are lower profile, rapidly inserted, and can be used in bone of poor density. Due to the smaller diameter and geometries of their legs there are also more options for placement compared to other forms of fixation.

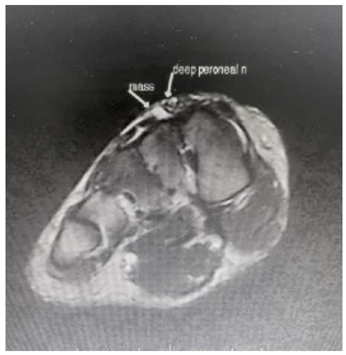
Relatively recent to the market are staples configured from 'shape memory' metal alloys (Nickel-titanium alloy, 'Nitinol'), which by design will elastically return to a configuration set in manufacturing due to its superelasticity (9). It's usefulness in compression constructs is obvious since the staple can be applied across an arthrodesis site in a 'loaded' configuration, and upon release of an insertion tool will spring back together and carry the affixed bone segments along with the legs effecting interfragmentary compression. Consequently, these devices must be pre-loaded prior to insertion and cannot be reinserted after deployment. Once the unsprung configuration is realized it cannot be undone in the operative setting. Additionally, the compressive effect may crush bone with insufficient density, and the inserter tool often leaves the staple bridge protruding some distance from the cortex after the device is released. To remedy this situation the surgeon will attempt to tamp the staple further into the bone which could compromise bone material underneath or in very dense bone can be unsuccessful. Another consideration is the material itself. Nitinol is roughly 50% each of nickel and titanium making this material unacceptable for use in cases where nickel allergy is a concern.

The Nitinol designs are configured to 'self compress,' that is the legs converge towards each other carrying the bone ends closer together, and certain physical characteristics come into play. During insertion methods, a drill is generally used to remove bone substance and allow entry of the device. This weakens the friction fit of the already smooth metal. Another issue is seen after deployment, where it is very often the case that unless the staple is bicortical, gapping will be seen on the far side of the fusion site.

A new orthopedic staple (Orbitum™, Fuse Medical, Richardson, TX) has been developed to achieve interfragmentary compression in a manner that is distinctly different from the superelastic method. The staple design involves a multitude of sharp tines beveled along their tips and length so as to diverge upon implantation into hard materials. This design also creates a compressive effect by elastic deformation although very different from the Nitinol designs. The insertion sequence often requires no drilling, and since the implant is made from titanium alloy and has an extremely low profile it is ideal for midfoot arthrodesis. We present a series of cases demonstrating the Orbitum™ staple application and outcomes.

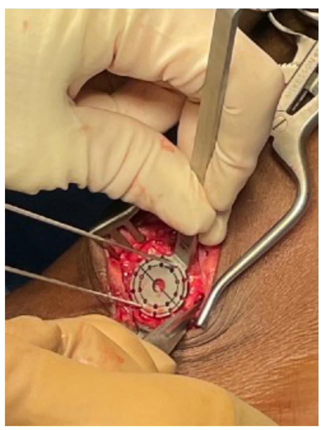
Case 1:

A 46 year old obese diabetic female was treated for longstanding pain in the midfoot with occasional swelling on top of her foot (Fig. 1). Conservative treatments included NSAIDs, steroid injections, and periodic rest or immobilization. MR imaging revealed degenerative changes of the second tarsometatarsal joint with joint effusion and periarticular spurring (Figs. 2 and 3). The diagnosis of isolated osteoarthritis of the joint was made and the patient elected arthrodesis for definitive treatment.



Figs. 2,3 Fig.1

The joint was approached dorsally with a longitudinal incision just lateral to the extensor hallucis longus tendon. After careful dissection to avoid the dorsal cutaneous nerves and dorsalis pedis artery, a linear periosteal-capsular incision was made for tarsometatarsal



Figs. 4,5 Figs. 6,7

joint exposure. Synovitis (identified on preoperative MR as capsolosynovial cyst) was appreciated and removed. All spurs were removed with a rongeur. Interosseous ligaments connecting the proximal second metatarsal with the first and third metatarsals were sectioned (Fig. 4). A saggital saw using a narrow blade was used to remove cartilage and subchondral plate on adjacent sides of the joint under cold saline irrigation. The joint was held in approximation, while a drill guide for an appropriate sized compression staple was used to template placement. Cortical punctures were made through the guide with a 1.6mm K-wire (Fig. 5). A 16mm 6-leg Orbitum™ staple was then brought to the corresponding hole pattern and tamped into place (Fig. 6 and 7). Complete approximation of the joint was appreciated top to bottom and confirmed with orthogonal images using a portable C-arm. Layered closure was then carried out over the staple beginning with the deep fascia, then subcutaneous layer and skin. A soft dressing was applied along with a well-padded posterior splint.

The patient was seen for her first post operative appointment 10 days after surgery where a hard cast was placed and non-weight bearing status was continued. 6 weeks later the patient was converted to a fracture boot and begun progressive weight bearing over a three week span. Serial radiographs were taken throughout the post operative period. The patient was converted to regular shoe gear in week 11 post operatively.

Pain scoring prior to surgery was 9/10. Upon conversion to shoe gear the patient was 2/10, and was 0/10 at 20 weeks and patient was subsequently discharged.

Figs 8 and 9: Post-operative radiographs showing staple placement.

Case Report 2:

A 64 year old female with no significant comorbidities presented with longstanding midfoot pain of approximately 3 years who failed conservative care. Isolated midfoot arthritis was identified in preoperative radiographs. Election was made to perform second and third tarsometatarsal arthrodesis.

Midline incision was used, and anatomic dissection was used to reach the periosteal plane over the mid tarsus, with care to avoid the deep peroneal neurovascular bundle. Saw resection was used to remove articular cartilage to subchondral bone on adjacent sides of the second and third metatarsal cuneiform joints. Once brought into approximation, demineralized bone matrix was used to fill any deficits and the joints were fixated with the 16mm hourglass Orbitum™ staple (Figs 10 and 11.)

Figs. 10, 11

Of particular note, the staple creates significant plantar compression. The design of the staple permits unicortical costructs, and more compression occurs as distance increases from the bridge. The result is that the metatarsal declination parabola is maintained, a problem that can occur with multiple tarsometatarsal arthrodesis.

The patient was noted to have 10/10 pain prior to surgery. At approximately 5 weeks post op she was converted from non weight bearing to weight bearing in a protective boot. At 8 weeks post surgery she related 1-2/10 pain and was started in physical therapy. By 10 weeks out she was wearing a tennis shoe and related no appreciable pain at the surgical site.

Case Report 3:

A 47 year old obese female presented with extensive post-traumatic midfoot arthritis subsequent to a lisfranc fracture dislocation injury (Fig 12.) Pertinent medical history included hypothyroidism. She had prior ORIF with removal of hardware prior to definitive surgery. The hardware had been removed 10 years prior to presentation in the treating surgeons office. Due to continued pain in the joint, election was made to fuse the medial lisfranc joint.

Fig. 12

Anatomic dissection was carried out in two incisions, one medial and one dorsal, avoiding neuromuscular structures. Standard joint take down and curettage was performed through the subchondral plate exposing bleeding cancellous bone. Demineralized bone matrix was used to fill any defects, and 20mm hourglass Orbitum™ staples were used in a delta configuration medially, and 16mm hourglass were used dorsally over the central metatarsals. Decompression of the metatarsal segments allowed for relocation of the lesser metatarsophalangeal joints (Figs 13 and 14.)

When performing multiple adjacent joint fusions, real estate for hardware placement can often become an issue. The Orbitum™ staple was used in lieu of long plates and multiple screws.

Figs. 13, 14

Upon initial presentation, the patient related a pain score of 6/10. At 6 weeks she rated her pain at 2/10 and was converted from non weight bearing to weight bearing in surgical boot. She was covered to full weight bearing in shoes at 10 weeks and at 5 months was 0/10 pain score with resolved edema and no concerns with her surgical site.

Fig. 15

Case Report 4:

A 28 year obese old female presented with longstanding midfoot pain. Pertinent medical history included depression and anxiety disorder. Central tarsometatarsal (TMT) arthritis was diagnosed as a result of biomechanical abnormality (metatarsus adductus) and election was made to proceed with fusion of her second and third TMT joints after exhaustion of conservative care (Fig 15.)

Standard midline approach and joint take down was carried out. Demineralized bone matrix was used to fill any defects and a 16mm hourglass Orbitum™ staple was used to secure each tarsometatarsal joint (Figs 16 and 17.)

Figs. 16, 17

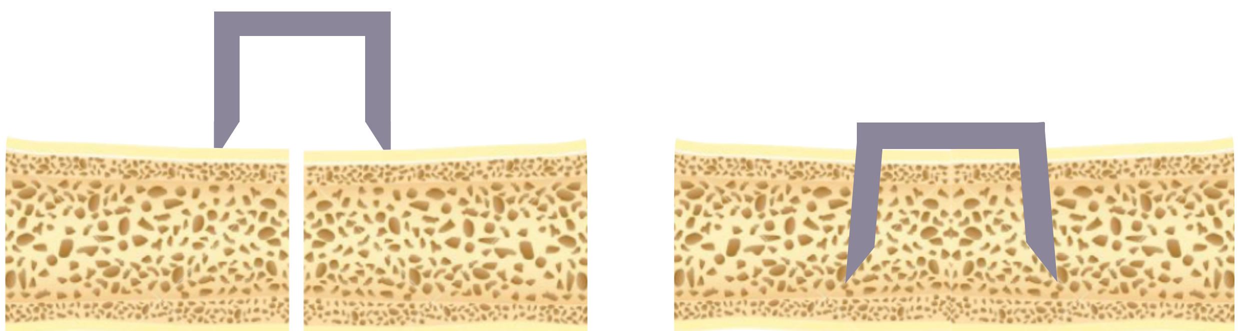
In the lead author’s experience, cases of isolated tarsometatarsal arthrodesis in the presence of metatarsus adductus present a particular challenge due to the extremely difficult angle of insertion. Consequently, staples are often preferential over screws, since they can capture the most bone mass and placement can be directly perpendicular to the compression axis. Very long incisions are also avoidable with this method, rather than the traditional screw throw that would originate from the mid shaft of the metatarsal.

Upon initial presentation, the patient rated her pain a 6/10. She was moved from non weight bearing post operatively to weight bearing in a boot at 8 weeks post operative and was in shoes at 12 weeks rating her pain as "mild." At 4 months post op she related only minimal pain when weight bearing.

Discussion:

The choice of any fixation device depends on the needs of the local anatomy. Large bones that can accommodate one or more screws in a configuration closest to perpendicular to the fusion direction is an ideal situation. However, the midfoot and hindfoot can prove challenging to have this set up. Most of the joints are flat or planar and arranged in the sagittal plane. Some of the bones are small and made yet smaller after joint preparation. This scenario presents an ideal setting for implantation of a bone staple.

The attributes of a mechanical staple were historically straightforward. The mechanism of action could best be described as splintage; that is, maintaining apposition of bone ends as well as the surgeon could place them together. Attempts have been made to improve on their action by bridge modification and this has improved the compressive effort (10). In the novel Orbitum™ staple configuration presented in this series, the legs are by their design forced into divergence upon implantation into hard material. While this seems to be contrary direction of leg travel to all nitinol staples currently on the market, it appears to follow the laws of physics. As the leg diverges from the bridge into the bone substance, the bone pushes back on the staple with equivalent force. Since the staple itself is stationary while the bone is not, the force underneath the bridge translates to movement of the bone ends towards each other.



Effect of resilient elastic divergent leg deformation on bone ends. As the staple leg enters the bone, the leg is 'steered' outward while the bone reacts by 'pushing' in the opposite direction.

The effect of compression is seen throughout the fusion site and is greatest where there is the most deflection, specifically the ends of the legs.

The design of the Orbitum™ staple introduces the concept of 'resilient elasticity' to bone stapling. The legs are configured to be thin and long and have an internal bevel that steers the legs outward from the central axis of the staple bridge. Despite being made of a ductile material (titanium alloy), the stress applied to the legs in typical bone can deform the leg without reaching the fracture point; in fact it appears that the stress of implantation may reach the elastic limit without plastic deformation. This was apparent in explantation of some devices in the case series due to preference for a different size staple.

The effect of this resilient elasticity is clearly illustrated by increased travel (compression) the further away from the bridge the fusion mass is. In other words, the trans face of a fusion site demonstrates the compressive effect more than the cis face. Since it is often the case that compression in less visualized areas such as a far cortex cannot easily be appreciated, it is desirable to have this compression mechanism exerting its effect due to the physical properties of the bone-staple construct. By eliciting a compressive force within the bone, rather than within the staple, the staple can be placed unicortical while creating bicortical compression. This advantage gives mechanical superiority in regions where bicortical placement would be problematic, or where visualization of the far cortex is obscured. A classic example of this in foot surgery is presented here in the tarsometatarsal articulations.

Conclusion:

Bone staple use in foot and ankle surgery has a long history due to the ideal nature of this fixation method for procedures commonly performed in this region. This case series of tarsometatarsal arthrodesis presents a novel staple design and its application as a compressive device that relies on the physical interaction of metal deformation by divergence rather than convergence within a bone to bone construct to achieve interfragmental compression and ultimately fusion.

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