Fracture Fixation Using Shape-Memory (Ninitol) Staples

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KEYWORDS

• Ninitol • Shape memory • Implants • Staples • Fracture fixation

KEY POINTS

- Shape-memory alloy (SMA) staples have been used successfully for osteotomies, arthrodesis, and fracture fixation, especially in small bones.
- SMA staples have inherent compressive properties that create a stable fracture environment that promotes primary bone healing, most effective for transverse fracture patterns.
- Current literature evaluating the indications for staple use, their biomechanical properties, comparison to alternative implants, and functional outcomes is limited.
- Understanding where SMA staple compression can be optimized and using proper indications are important factors for achieving consistent widespread success and minimizing failures.
- SMA staples are not a substitute for lag screw fixation or traditional plate and screw constructs, but are simply another tool that can be used for effective fracture fixation.

INTRODUCTION

Nitinol is a shape memory alloy (SMA) composed of nickel and titanium. The use of nitinol is ubiquitous in endovascular stents and has proven both safe and effective. The alloy is not new to orthopedic fracture surgery, as there have been descriptions of usage dating back to the 1980's. However there has been a resurgence in the use of nitinol orthopaedic implants primarily in foot and ankle as well as hand surgery. Currently, SMA staples are used as standalone implants for interfragmentary compression across osteotomies, arthrodeses, as well as for fracture fixation. Recent reports of orthopaedic use of staple fixation have included first metatarsophalangeal joint arthrodesis,[1] scaphoid fractures,[2] intercarpal fusion,[3] and patellar fractures.[4] They also have been used for ligament fixation, facial fractures and reconstructions, and spinal procedures.[5] Successful growth modulation with SMA staples has been reported in animal models.[6]

HISTORY OF SHAPE-MEMORY ALLOY STAPLE FIXATION

NITINOL is an acronym derived from the alloy's elemental composition as well as its place of discovery: Nickel titanium–Naval Ordinance Laboratory. The alloy was discovered in 1959 by William J Buehler and Frederick Wang who were given the task of developing a better alloy for the U.S. Navy Polaris re-entry vehicle.[7,8] When they mixed nickel and titanium and roughly equal anatomic percentages, they discovered an alloy that behaved completely dissimilar to other known alloys. It took about 20 years for science to catch up with this discovery and explain its material properties and inner

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workings. Nitinol has two unique properties that make it attractive for fracture surgery: pseudoelasticity (or super-elasticity) and shape memory.

Pseudoelasticity is an elastic response to an applied stress that is caused by a phase transformation. A pseudoelastic alloy is able to constantly unload stress over high strains to regain its original shape, much like a spring or rubber band. Common orthopedic alloys such as titanium and 316 L stainless steel can tolerate strain of about 0.25% to 0.5% before plastic deformation occurs. Nitinol on the other hand can absorb up to 8% strain before it enters the plastic deformation slope on the stress-strain curve.[9] Therefore, nitinol is 16 to 32 times more elastic than other alloys used in orthopaedic surgery and demonstrates tremendous endurance.[9]

Shape memory is the ability to undergo reversible deformation with changes in temperature. Nitinol can exist in 1 of 2 solid-state phases, martensite and austenite. Below the transition temperature (martensitic phase), nitinol exhibits extremely elastic properties. Somewhat paradoxically, above the transition temperature (austenitic phase), nitinol releases energy causing it to return to a more stable conformation and become more rigid. The ability of nitinol to readily deform at cooler temperature and then recover its original shape and become more rigid upon warming is a unique material property of this alloy.

The transition temperature can be modified by altering the ratio of nickel and titanium. As a result, most SMA nitinol staple implants are manufactured to have a transition temperature just below body temperature. The resting shape of SMA staples is manufactured to have the bridge and tines in the closed position. The implant is then cooled to its martinsitic phase which makes it flexible. The staple is opened without plastically deformation, and then it is loaded onto and retained by the insertion tool and the open, active position. The tines of the staple are perpendicular to the transverse limb of the staple after loading, facilitating insertion. the ambient body temperature releases the potential energy stored in the implant causing it to return to its original, stable configuration causing the tines to close toward the center of implant. When energy stored in the implant is released to the bone, the work performed is continuous interfragmentary compression. The SMA staple will exert continuous compressive forces across the fracture site until the implant has fully returned to the resting shape. This property differentiates SMA staples from conventional staples that lack these compressive properties.[10,11]

CLINICAL USE OF SHAPE-MEMORY ALLOY STAPLES

The popularity of SMA staples has increased in recent years, and currently multiple sizes and configurations exist including various staple widths, lengths of the transverse limb or legs, and the number of legs on each staple. To date, these implants have been marketed and designed for use in the wrist, hand, and foot and currently available staple sizes and geometries are best suited for those anatomic locations. Despite the current popularity of these implants, few studies exist that examine the biomechanical performance of these implants.[12,13] However, a recent biomechanical study demonstrated that nitinol staple lengths that were 2 mm short of the far cortex resulted in the same compression as a bicortical staple, supporting the idea that bicortical placement is not necessary to obtain adequate compression.[14] The same study found that troughing of bone, to minimize implant prominence, did not weaken the biomechanical properties of the construct and that double staple constructs doubled the compressive force and increased bending strength by greater than 90%.

Although the clinical uses of SMA staples are varied and include use as compressive devices for fixation of osteotomies, small bone arthrodesis, and fracture fixation, clinical studies are limited. The current literature describing indications of SMA staple fixation includes metatarsophalangeal joint arthrodesis,[1] scaphoid fractures,[2] and intercarpal fusion,[3] however, the majority of these publications are limited to cadaver or animal models. In 1987, Yang and colleagues[15] reported the earliest clinical review of fracture fixation using nitinol staples, documenting 51 procedures for fractures and arthrodeses, most of which were in the foot and ankle. The study also reported staple use in fractures of the patella, olecranon, wrist, and metacarpal/phalanges. A later study reported outcomes of 158 intra-articular fractures stabilized with nitinol staples.[16] In that study, satisfactory treatment of fractures of the medial and lateral malleoli, tibial plateau, and lateral humeral condyle were also described.

Indications for Staple Fixation

Indications for SMA staple use are still being determined. These implants are useful for generating continuous interfragmentary compression with the goal being primary bone healing. Traditional orthopaedic implants composed of stainless steel or titanium have limited capacity to store or release energy; hence, these alloys can create only static interfragmentary compression from an exogenous energy source (interfragmentary compression screws, compression plate osteosynthesis). Nitinol staples are a useful adjunct for fracture patterns in which traditional techniques for interfragmentary compression are less effective or difficult to employ. These implants are particularly useful for transverse diaphyseal fractures and can be utilized throughout the body including the clavicle, scapula, long bones of the upper and lower extremity, as well as the pelvis and acetabulum. Advantages include improved accuracy and efficiency in translating provisional fracture reductions into definitive fixation constructs, as well as ease and reproducibility of application. The nascent techniques described here are consistent with AO principles-the only difference being the mode of generating interfragmentary compression. Potential contraindications of SMA staple use include severely osteoporotic bone, absent or poor cortical bone quality, and fractures with significant comminution resulting in small-sized fragments.

How nitinol staples fit in with traditional fracture fixation?

Minimax fracture fixation was popularized by the influential Bernhard Weber.[17] Adjunct SMA staple constructs are an extrapolation of his minimax fracture fixation concept: smaller problem focused implants used to do a specific job (provisional reduction, interfragmentary compression) that are then supported by a more robust fracture neutralization construct, such as a plate, medullary based implant, or an external fixation frame.

Shape memory alloy staples are most useful in appendicular skeletal fracture patterns that are not readily amenable to conventional interfragmentary compression techniques such as leg screws, compression plate osteosynthesis, or the usage of an articulated tensioning device or some variation thereof. Compression plate osteosynthesis can be challenging and time consuming to execute correctly and is dependent on a perfect plate contour and on adequate bone stock to generate sufficient friction between the plate and bone.

A transverse fracture plane can be anatomically reduced with orthogonal linear compression clamps, such as a Weber tenaculum. The transition of this provisional fracture reduction into definitive fixation can be done accurately and efficiently with the use of SMA staples. The staple can be located on the bony surface immediately adjacent to the proposed neutralization implant. Once anatomic reduction is obtained, the transverse limb of the staple is measured (bridge size) to adequately span the fracture and any potential nondisplaced comminution such as a butterfly fragment. Some systems have multiple staple sizes from miniature to robust and have a guide for determining the appropriate bridge length. A drill guide is used for accurate placement. The first hole is drilled in the desired location through the far cortex, and a pull-pin is placed through the guide and the hole. Adjustments can be made by rotating the guide with the pull-pin acting as the center of rotation. The second hole is then drilled, which will set the definitive position of the staple. The length of each staple leg is measured using a depth gauge. The longest acceptable length for the legs of the staple should be chosen to allow the SMA staple to compress both the near cortex and far cortex along the length of the limb, providing adequate stability and compression across the entire fracture site.[11,14]

SMA staples are implanted with an inserting device that keeps the bridge and legs in the open activated conformation. The tips of the legs are aligned with the drill holes, and the staple is partially inserted by hand. The inserters have a quick release that disengages the staple, and then the staple is fully inserted with a tamp. In circumstances where impacting the staple is not desired, the staple can by gently seated using a lobster claw clamp between the staple bridge and the far cortex. This is preferable to impacting one leg at a time, which can cause the staple to be inserted off axis. Interfragmentary compression occurs immediately once the insertion device is released and continues until the fracture gap is limited by fracture apposition. Multiple staples can be placed orthogonal about the fracture if it requires compression from various vectors. Double-staple constructs were shown to have better bending stiffness than a single-staple construct, regardless of the plane of the deforming load.[12,14,18]

The Hueter-Volkmann Law states that compressive forces on bone lead to resorption. Resorption at a fracture surface under static compression can potentially lead to destabilization of the construct and loss of interfragmentary compression. With SMA staple constructs, bone resorption or fracture settling will not disrupt the interfragmentary compression so long as the bridge and legs of the staple have not retained the resting or closed position. In our experience, most SMA staples remain in open activated position through bony union indicating that the fracture surfaces are under continuous interfragmentary compression throughout the healing phase.

Efficiency of the adjunct SMA staple fracture fixation constructs

Once the fracture is reduced, application of the SMA staple for interfragmentary compression is both efficient and reproducible. The procedure takes only a few minutes to prepare the staple insertion site and apply the implant. Efficiency of this technique is further improved during the application of the neutralization construct. Translation of the provisional fracture reduction into the definitive fixation construct can then be efficiently achieved with a neutralization plate. The plates' purpose is to protect the reduction and interfragmentary compression achieved with the SMA implant.

A locked plate can be applied to the bone as an internal fixator which is often less time consuming and less dependent on a perfect plate contour compared to a compression plate construct.

OUTCOMES OF SHAPE-MEMORY ALLOY STAPLES USED FOR FRACTURE FIXATION

Only two publications have reported nitinol staple fixation of fractures. In 1987, Yang and colleagues[15] reported 10 ankle fractures, 2 patellar fractures, 2 olecranon fractures, and 7 metacarpal and phalangeal fractures with isolated staple fixation without any neutralization construct. Other uses of SMA staples in their series included wrist, foot and hip arthrodesis, osteotomies of various bones and re-attachment of the peroneus longus tendon and medial collateral ligament. All fractures healed satisfactorily, with full range of motion of joints, except for 2 ankle fractures in which 5 to 10 degrees of

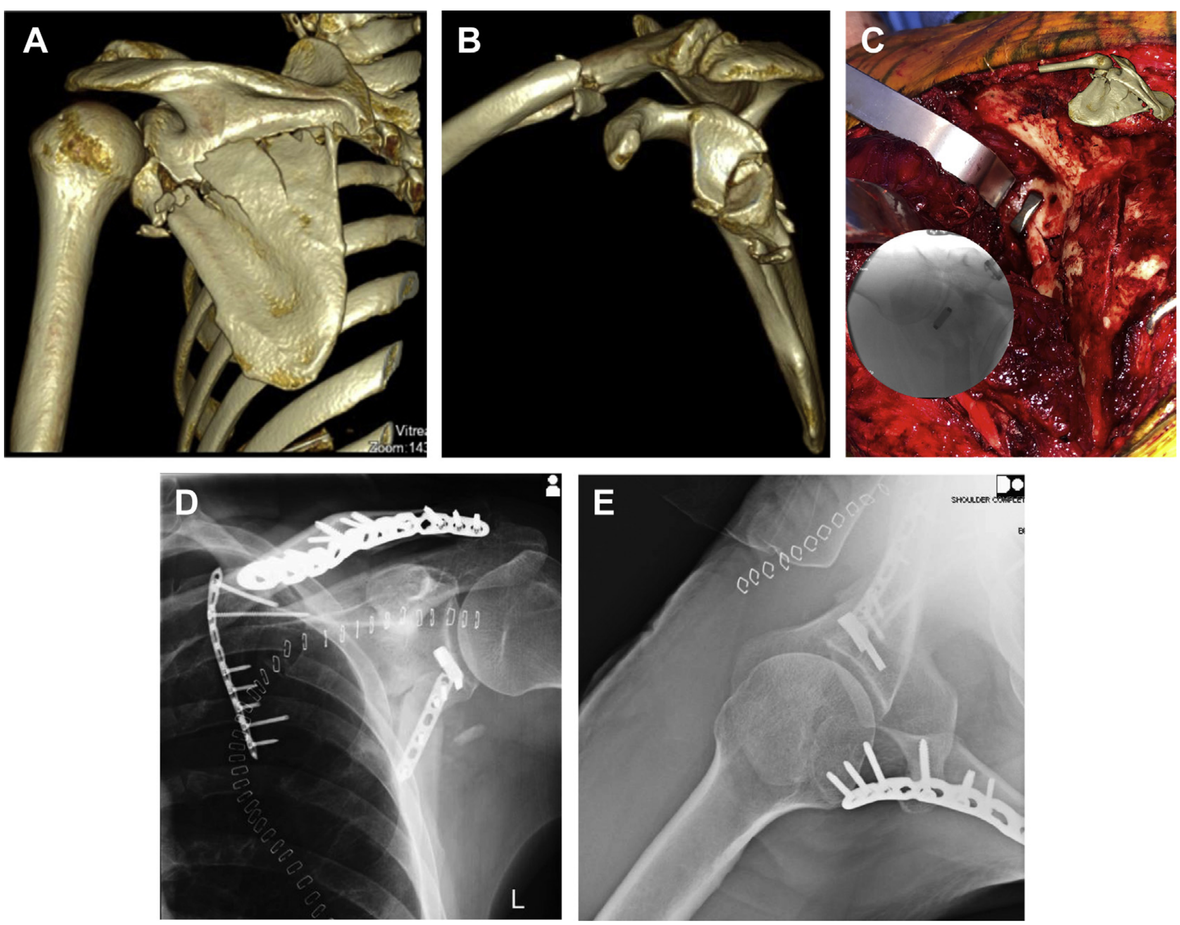

Fig. 1. (*A–E*) A 42-year-old man sustained a floating shoulder, distal third clavicle fracture and associated large inferior glenoid fracture extending transversely into the scapular body. An SMA staple was used for preliminary fixation to secure the large inferior glenoid fragment. Insertion of a lag screw perpendicular to the fracture would have been technically difficult due to soft tissue obstruction within the axilla. A neutralization plate was then applied along the lateral border of the scapula, and a plate was used medially to stabilize the remaining scapular body.

functional deficit remained. In patients who had follow-up of longer than 2 years, no signs of inflammation or tenderness were noted over the surgical site, and no radiographic evidence of staple loosening or bone absorption was seen. Eight patients had their staples removed (range 3–26 months after the initial procedure), and histologic evaluation found few inflammatory cells in the tissue surrounding the staples, supporting the idea that nitinol is highly biologically compatible.

In 1993, Dai and colleagues[16] reviewed 132 intra-articular fractures treated with only nitinol staples, without any additional neutralization fixation. Staples were used in 69 patellar, 43 malleolar (ankle), 15 olecranon, 4 lateral condylar and capitellar, and 1 tibial plateau fracture. All fractures were healed by 2 months. In 93 patients with follow-up of at least 1 year, none demonstrated clinical signs of late infection, local foreign body reaction, or radiographic evidence of staple pullout, breakage, or loosening. Nearly all (93.5%) of these patients reported excellent or good results. Seven patients had staple removal after fracture union, 4 because of articular protrusion, and 3 because of patient preference.

ADVANTAGES OF STAPLE FIXATION

There are many advantages of SMA staple fixation. These implants can be used to generate interfragmentary compression across fractures when traditional techniques are difficult or not possible. The posterior column acetabular and the glenoid fractures shown (Figures 1 and Figure 4) have transverse fracture planes with respect to the surgical exposures. Orthogonal interfragmentary screw fixation across these fractures would require accessory percutaneous approaches that can be technically demanding. The SMA staples used for interfragmentary compression were applied through the same surgical approach and required only one c-arm fluoroscopy shot during insertion to prove the implants were in satisfactory position.

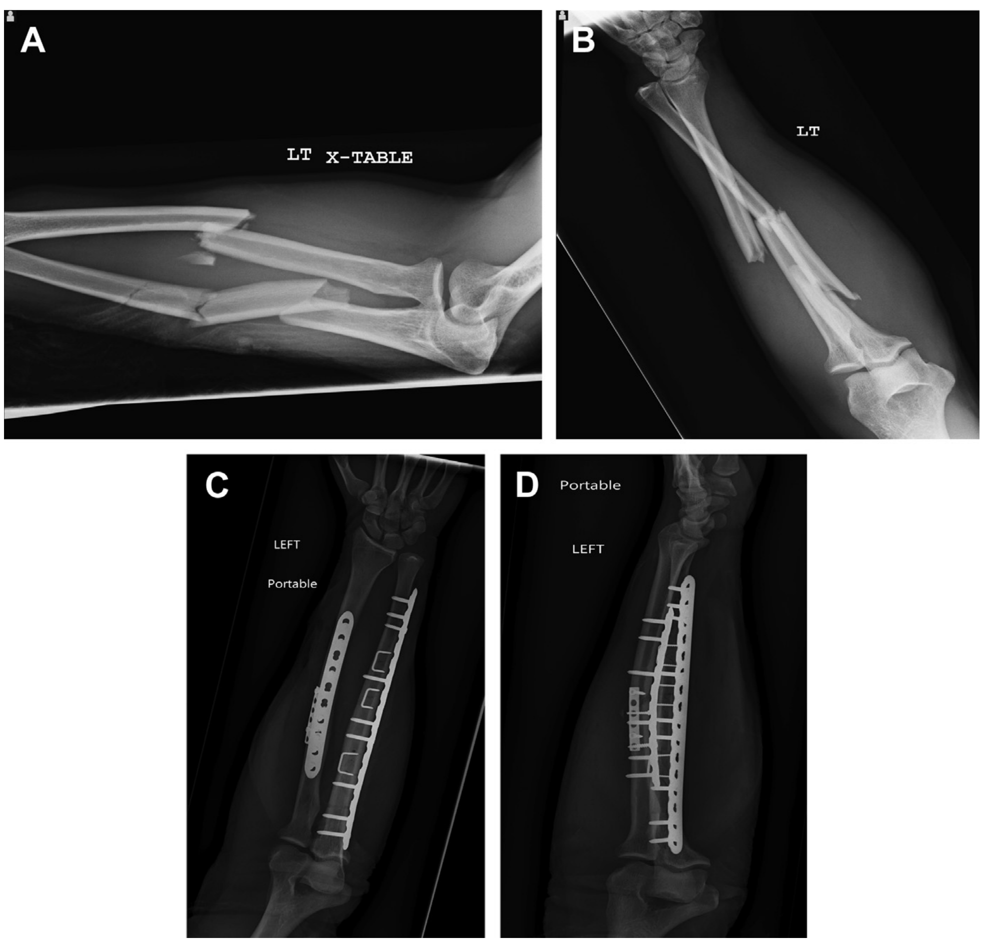

Fig. 2. (*A–D*) A 40-year-old man sustained an open Gustilo-Anderson type I segmental ulnar fracture, a transverse comminuted radial shaft fracture, and a distal radioulnar joint injury. After radial shaft fixation, the ulnar fracture fragments were sequentially held together with bone reduction forceps, and SMA staples were placed for provisional reduction and interfragmentary compression.

Staple fixation is also highly versatile, having small footprint instrumentation so these implants can be applied in spaces limited by soft tissues, bone reduction clamps, and other implants. This increases their appeal during the provisional reduction and fixation of fractures. These implants do not crowd bony corridors and can be applied quickly and reproducibly.

SMA staples obtains continuous interfragmentary compression and provides strong preliminary fixation with immediate continuous compression. This is in contrast to lag screw fixation, which is a static compressive construct that trends toward entropy.[18,19] SMA staple constructs may lead to greater stability, as these implants have the potential to maintain interfragmentary compression across the fracture throughout healing, despite fracture settling and bony resorption. As a result, SMA staple fixation may be biomechanically stronger than more traditional implants, especially when multiple staples are utilized[14,18,20] Furthermore, they can obtain uniform fracture compression even without purchase in the far cortex.[14]

LIMITATIONS OF STAPLE FIXATION

Despite the promise that these implants hold, there are several limitations to use of SMA staples. These include osteoporotic bone and highly comminuted fractures. Also, galvanic corrosion a concern when dissimilar metals are used in the same fixation construct. Lastly, these implants are currently associated with an increased cost when compared to traditional implants.

FUTURE DIRECTIONS AND CONCLUSIONS

Although the use of SMA staples as an adjunct in fracture fixation constructs is in its infancy, the implants hold promise due to the ease of application and simplicity of the technique, while facilitating and maintaining continuous interfragmentary compression. Cost-effective considerations, understanding where SMA staple compression can be optimized, and using proper indications are important factors for achieving consistent widespread success and minimizing failures. The use of nitinol staple implants will not likely not supplant traditional

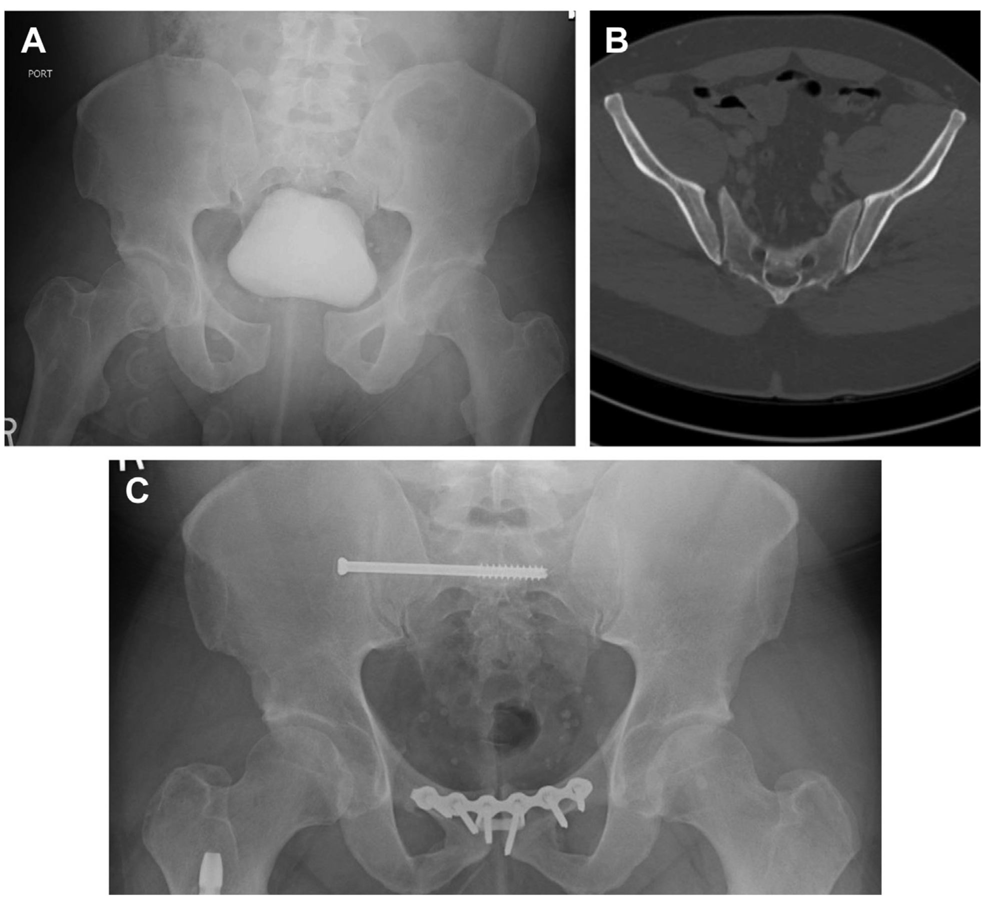

Fig. 3. (*A–C*) A 40-year-old man sustained an open-book pelvic injury resulting in pubic symphysis diastasis (type 2) and disruption of the right sacroiliac joint. An SMA staple was used as preliminary fixation to maintain compression and reduction while allowing reduction clamp removal, thereby permitting unobstructed plate application.

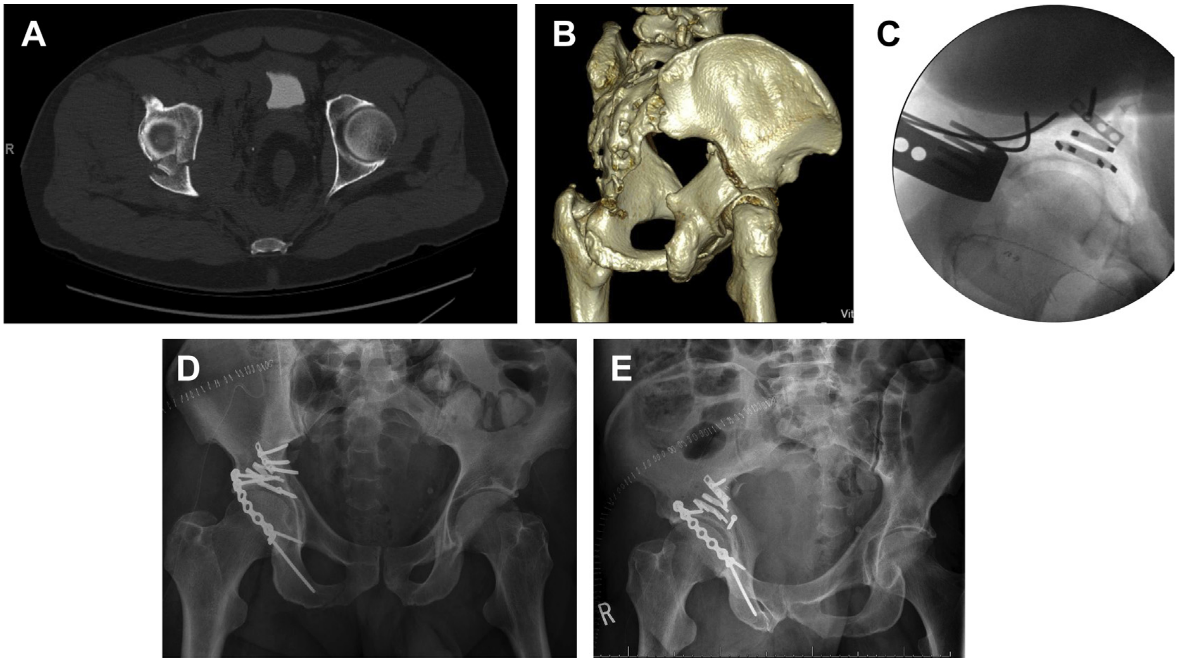

Fig. 4. (*A–E*) A 55-year-old man sustained a right posterior column fracture with an associated right hip dislocation. A posterior approach was used to expose the fracture, and SMA staples were used to compress and stabilize the fracture site with the aid of a buttress tubular plate to prevent shear during compression.

techniques for interfragmentary compression, however they may prove to be effective as another tool to the armamentarium in treating certain challenging fracture patterns.

CASE EXAMPLES

Case examples include

- Glenoid fracture (Fig. 1).
- Both-bone forearm fractures (Fig. 2).
- Pubic symphysis (Fig. 3).
- Posterior acetabular column (Fig. 4).

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