

Nitinol dynamic disc as an adjunct for continuous compressive force generation during bone healing

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A novel concept for screw dynamization and fully dynamic constructs

Orthopaedic implants made from shape memory alloys (SMAs), such as Nitinol, have steadily risen in popularity and clinical acceptance due to their strength, efficiency, ease of use and continuous compression. The most commonly used Nitinol implants in foot and ankle surgery are staples, primarily used for arthrodesis. In practice, surgeons utilizing Nitinol staples often rely on hybrid constructs, adding static devices—such as locking plates or screws—to provide added fixation and stability across the same joint where a Nitinol staple is intended to provide continuous compression. Certain manufacturers market hybrid constructs consisting of both Nitinol and static titanium implants. A key limitation of such hybrid constructs is the inherent neutralization of compression caused by the addition of static devices such as locking plate screws and cannulated screws. To address the clinical need for more robust fixation and stability than a Nitinol staple may provide in isolation, without neutralizing its continuous compression, a Nitinol disc (REFLEX[™] Dynamic Disc, Medline Industries, LP, Northfield, IL) is proposed to transform a traditional static lag screw (headed cannulated screw) into a dynamic construct that provides continuous compression and gap recovery.

Transform a traditional static lag screw (headed cannulated screw) into a dynamic construct that provides continuous compression

Nitinol—Smart memory alloy

Nitinol is a metallic alloy created from equal parts of titanium and nickel. Nitinol and nickel titanium (NiTi) based alloys, belong to a group of materials colloquially referred to as “smart functional materials” or “shape memory alloys” given that they exhibit excellent thermal shape memory effects as well as superelastic properties.¹ The thermal based properties provide the alloy with the ability to recover its original shape after heating above a specific temperature (Af).¹ The superelastic behavior allows the alloy to recover to its original shape after deformation to tensile strains as high as 8%.¹ This provides an elastic modulus that closely resembles that of bone, especially evident among the more porous Nitinol implants.^{2,3}

Wolff's Law

Long-term complications from resultant instability are of major concern when intraoperative anatomical reduction isn't achieved, such as arthritis when joint involvement occurs, or non-union following an arthrodesis procedure. It's crucial for the fracture surface environment to be correctly reduced, providing a site that is conducive to bone healing by granting strain transduction during therapeutic loading.⁴ This is the basic principle of Wolff's Law, whereby bone will remodel in response to the loads it's placed under.⁴ If the loading of bone is decreased, the bone becomes less dense and weaker as no stimulus is provided for the continued remodeling that's necessary to maintain bone mass.⁴

When there's a reduction in bone density (osteopenia) caused by the removal of typical stress from the bone by an implant, it's referred to as stress shielding.⁵ Minimizing stress shielding on the bone through an implant that permits continued bone growth and remodeling may be accomplished through implants that provide for uniform strain delivery along the fracture surface.⁵ In turn, a constant mechanotransduced signal for osteocytes and osteoblasts may persist.^{6,7}

Modes of bone healing, bone resorption/bone remodeling, and importance of compression

Stability dictates the type of healing that will occur. The mechanical stability governs the mechanical strain and when the strain is <2%, primary bone healing (contact healing) will occur.^{7,8} When the strain is between 2% and 10%, secondary bone healing will occur.⁷ Strain is dependent on both the displacement as well as the gap width. Small gaps produce high strain, whereas, for the same amount of displacement in larger gaps the strain is much smaller, demonstrating an inverse relationship.^{6,9}

Primary bone healing requires direct reduction and absolute stability in a low strain (<2%) environment and undergoes intramembranous healing, which is accomplished via Haversian remodeling without the formation of a bony callus.⁸ This type of healing occurs with absolute stability constructs that involve visualization, anatomic reduction and stable fixations. Examples of such constructs include lag screws and compression plating.⁸

Secondary bone healing requires indirect reduction and relative stability. This type of healing occurs when the strain is between 2–10%, involves responses in the periosteum and external soft tissues and is accomplished via endochondral/intramembranous ossification, whereby the callus/cartilage become mineralized and replaced by bone.^{7,8} Relative stability involves indirect reduction and fixation. The goal is to restore axial, angular and rotational alignment while preserving the biological environment of the fracture.⁸ Examples of such constructs include intramedullary rods, bridge plating, external fixators and casting.⁸

No single method of treatment or healing pattern is best on its own. For any given situation, the goal is to recover the function of the bone, limb and patient as early as possible through the optimal choice of the surgical procedure and implant.⁹ In practice, most fixation involves components of both types of healing, giving rise to newer implant technologies and hybrid constructs that employ both static and dynamic elements.⁸ Examples of these hybrid constructs include titanium plates and intramedullary (IM) nails that provide absolute stability with Nitinol elements that provide continuous compression.

The mechanical effect of compression eliminates mobility of the bone fragments in relation to each other by preloading, as long as the compression exceeds the traction produced, i.e. through bending.^{6,9} The forces produced through compression also produce friction. Shear displacement through torque is suppressed as long as the friction exceeds the shear load.^{6,9}

As tissue deformation within the gap is increased through the reduction of mobility, the width of the gap due to surface resorption increases.⁹ Especially in small gaps, tissue deformation can be lowered by increasing gap width.⁹ As healing takes place and the gap becomes filled with woven bone, further resorption begins to take place, reducing the gap size.⁹ During the reduction of gap width, it's crucial for the implant to maintain compressive forces across the fusion site as the gap recovers.

Orthopaedic hardware made from Nitinol has been extensively studied. Literature utilizing the SMA reports well cited fusion rates with low complications and non-unions when bone segments are anatomically reduced, ensuring maximum bone apposition. These studies highlight scenarios where the reduction necessitates greater degrees of compression, as compared to bone healing where relative stability and secondary healing are primarily taking place. *See Clinical evidence: Applications of Nitinol.*

Most fixation involves components of both types of healing, giving rise to newer implant technologies and hybrid constructs that employ both static and dynamic elements⁸

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In vitro performance: REFLEX™ Dynamic Disc²³

Study objective

In order to determine the compressive force at various gap distances, an analysis of simulated bone resorption on the compressive performance of the dynamic disc was performed.

Test methods

Healthy dense bone was simulated using 40 PCF synthetic solid foam blocks (Sawbones®, A Pacific Research Company, Vashon Island, WA). Lag screws of four varying sizes (4.0 mm, 4.5 mm, 5.5 mm, and 7.0 mm) along with their corresponding dynamic disc (REFLEX Dynamic Disc, Medline Industries, LP Northfield, IL) made from Nitinol were positioned into the Sawbone using the manufacturer's instructions and instrumentation. For all construct types, except the 7.0 mm screw without washer, the pilot hole in the top block was modified using the provided countersink. If applicable, the dynamic disc or washer was placed under the screw head. The screw was inserted through the top block and into the bottom block until all threads were inserted into the bottom block. The top and bottom blocks were placed in the loading fixtures. The loading fixtures were attached to the axial load cell and load frame actuator (*Figure 1*). A single lag screw without a disc and a screw with a washer was also implanted (7.0 mm size) (*Figure 2*). The construct was loaded until the dynamic disc was fully compressed. The displacement at full compression was maintained for 30 seconds. The construct was then unloaded until the dynamic disc was fully uncompressed. For the 7.0 mm screw with and without a washer, the construct was loaded to the same force required to fully compress the 7.0 mm dynamic disc with the 7.0 mm screw. The displacement at this force was maintained for 30 seconds, at which point the construct was then unloaded. The compressive force at various gap distance was recorded at 0.5 mm increments to a simulated 4.0 mm gap for the four implants with the dynamic disc and 0.1 mm increments for the single screw and washer. The maximum gap recovery was recorded for each sample (*Table 1*).

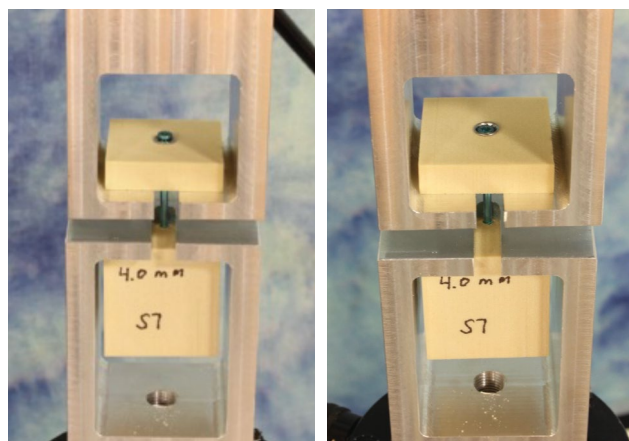


Figure 1: 4.0 mm screw and dynamic disc attached to the axial load cell and load frame actuator. The figure on the left displays the screw prior to loading and the figure on the right displays the disc in its fully compressed state. Notice the biconvex (*left*) and biconcave (*right*) shape of the dynamic disc before and after it has been fully compressed.

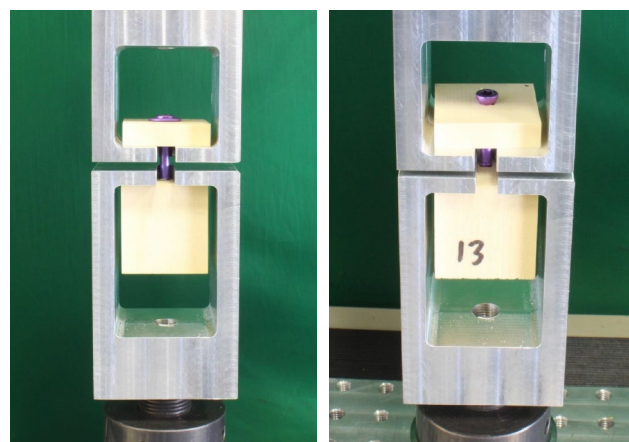


Figure 2: Left, 7.0 mm screw with a traditional washer attached and Right, 7.0 mm screw with no washer, attached to the axial load cell and load frame actuator.

Results²³

Max compressive force (N) and max recovery (mm) with REFLEX™ Dynamic Disc and with traditional static lag screw with and without a washer

Screw Size	Disc/ Washer Size	Max Compressive Force	Max Gap Recovery	Compressive Force (N) at Various Gap Distances (mm)							
				0.5 mm	1.0 mm	1.5 mm	2.0 mm	2.5 mm	3.0 mm	3.5 mm	4.0 mm
4.0 mm	REFLEX Disc	196 N	2.5 mm	26 N	16 N	12 N	4 N	<1 N	-	-	-
4.5 mm	REFLEX Disc	347 N	3.0 mm	58 N	43 N	23 N	9 N	2 N	<1 N	-	-
5.5 mm	REFLEX Disc	508 N	3.0 mm	173 N	86 N	46 N	27 N	3 N	<1 N	-	-
7.0 mm	REFLEX Disc	503 N	4.0 mm	168 N	140 N	94 N	67 N	56 N	47 N	24 N	<1 N
7.0 mm	Washer	570 N	0.4 mm	-	-	-	-	-	-	-	-
7.0 mm	-	531 N	<1.0 mm	5 N	-	-	-	-	-	-	-

Table 1: The mean compressive force values at various incremental axial displacements for each of the combined screw and disc sizes implanted.

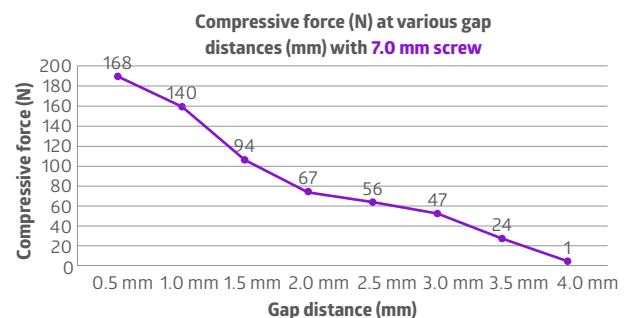
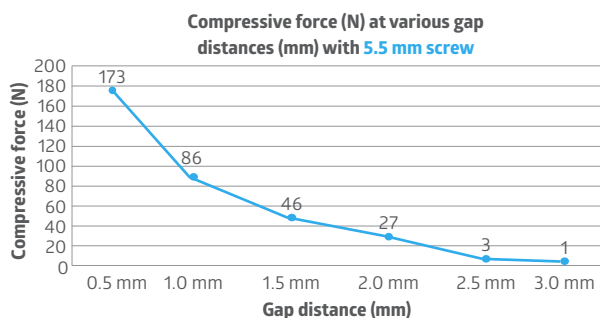
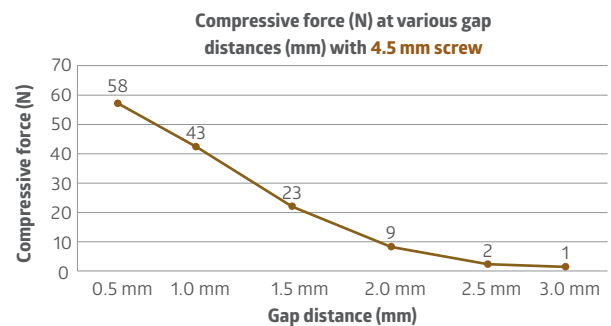
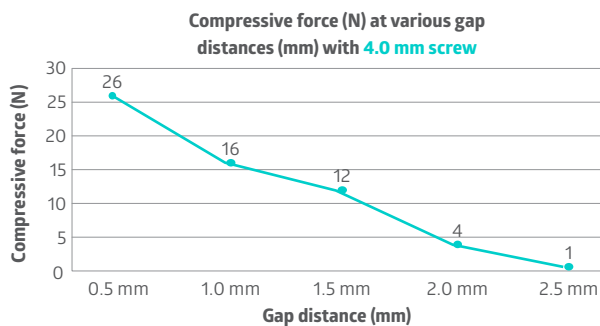
The dynamic disc was able to sustain compressive force up to 4.0 mm of axial displacement implanted in combination with the 7.0 mm lag screw. A sustainable declining force is evident up to 4.0 mm of displacement, as seen with the 7.0 mm combination. This same compressive force was not evident in the single screw implant or in the washer test, as both implants were not able to sustain a compressive force even for 1.0 mm of gap simulation.

Dynamic disc was able to sustain compressive force up to 4.0 mm of axial displacement implanted in combination with the 7.0 mm lag screw

Statistical analysis

Utilizing an analysis of variance (ANOVA) test on the four different screw sizes in combination with their corresponding Nitinol Dynamic Disc, it was evident that the mean peak force significantly differed by screw size ($p < .00$).

In an analysis accounting for triplicate measures, the ANOVA showed a significant mean difference in force across all gap groupings, for all screw sizes in combination with the Nitinol Dynamic Disc ($p < .0051$ for all measures). A Mann-Whitney U test was run comparing only the 7.0 mm screw with standard washer and no washer, which found no significant median differences in force at gap distances less than 0.1 mm ($p < .1226$).



Discussion and advantages of washer use

In an in vitro biomechanical analysis of washer load in combination with a cannulated screw fixation, screws inserted with a washer generated approximately 2.5 times more compressive force before screw intrusion than those inserted without washers.¹⁰ The intrusion of the screw during union may result in the loss of compressive forces, further compromising fixation quality. Washers provide an advantage as they allow more compressive force to be generated, especially during scenarios in which creating compression is important to the stability of fracture reduction and subsequent healing or there is a concern for perforating a thin bone cortex or impingement on surrounding structures.¹⁰

This was also evident within our data set, as in the analysis comparing the 7.0 mm lag screw in combination with a standard washer versus no washer at all, the standard washer generated a greater median difference in peak force owing to an overall greater compression found with use of a static, standard washer. However, these generated forces were statistically greater at larger gap distances with the use of the Nitinol dynamic disc as compared to the standard, static washer.

Conclusion

The addition of a Nitinol SMA Alloy disc to the static screw allows dynamic compression to take place while the bone undergoes remodeling. The findings show that a traditional lag screw does not provide continuous compression during bone resorption and remodeling, as was evident with the use of the dynamic disc in combination with the static lag screw. The use of an SMA implant as a washer allows for a significant distribution of force as the gap width changes ($p < .00$). The addition of a dynamic disc to a static construct, made from a material that allows dynamic motion to take place, contributes to the generation of higher compressive force across a given area.

Screws inserted with a washer generated approximately 2.5 times more compressive force

Forces were statistically greater at larger gap distances with the use of the Nitinol dynamic disc as compared to the standard, static washer

The addition of a Nitinol SMA Alloy disc to the static screw allows dynamic compression to take place while the bone undergoes remodeling

In Vitro Performance Testing: Bone Resorption Gap Recovery Simulation using REFLEX® Dynamic Disc²³

Study objective

The purpose of this study was to visualize and assess the REFLEX Nitinol Dynamic Disc's ability for gap recovery during a simulated bone resorption.

Test methods

Thin ice sheets were placed between two 40 PCF synthetic foam blocks (Sawbones®, A Pacific Research Company, Vashon Island, WA). The ice sheets placed between the blocks were allowed to melt until a simulated even gap distance of approximately 4mm was measured. A standard cannulated technique and countersinking was performed according the manufacturer's instructions. Parallel 7.0mm UNITE® titanium partially threaded cannulated screws, each pre-loaded with a 7.0mm REFLEX disc, were inserted and tightened until fully seated. Following screw insertion, the ice sheets were left to melt in order to simulate the bone resorption that may occur during the post-operative healing phase. Following screw insertion, the entire construct including screws, discs, and blocks were left alone without being disturbed. Images were captured until the ice was fully melted (Figures A-G).

Results



Figure A: Implanted screw with Dynamic Disc in position



Figure B: Implant in place with ice melting



Figure C



Figure D



Figure E



Figure F



Figure G: Ice completely melted with no visible gap remaining

The test displays ice melting between the sawbones, simulating bone resorption that occurs during healing. As demonstrated, the screw is adequately seated with the Dynamic Disc, Figure A. The ice then slowly melts, Figures B-F. Once the ice has completely melted, there is no visible gap remaining between the two blocks in Figure G.

Conclusion

The simulated test visually demonstrates the capability of the Dynamic Disc's SMA properties to recover gaps from bone resorption.

Clinical evidence: Applications of Nitinol

The following is a compendium of scholarly articles using Nitinol implants in orthopaedic foot and ankle surgery followed by upper extremity applications.

Author and Title	Methods	Results	Conclusion
Mereau, T.M. and Ford, T.C. 2006. <i>Nitinol Compression Staples for Bone Fixation in Foot Surgery</i> ¹¹	Retrospective study of 31 feet in 27 patients undergoing either arthrodesis or an osteotomy fixated using compression staples. Forty-eight compression staples made of Nitinol were implanted.	Akin Osteotomy: All 15 patients remained free of pain with the appearance of radiographically stable fixation. Midfoot Arthrodesis: All 12 fusions showed radiographic evidence of stable fixation with one asymptomatic broken staple at the talonavicular joint. Rearfoot Arthrodesis: Four out of five fixations were radiographically stable with a medial gap evident in one case. However, the staple fixation in this case was stable.	The preliminary findings of this study suggest that Nitinol compression staples provide comparable fixation for arthrodesis and osteotomies of the foot.
Sandhu, J.S. <i>et al.</i> , 2013. Digital Arthrodesis with a One-Piece Memory Nitinol Intramedullary Fixation Device ¹²	Evaluation of 35 patients who underwent surgical correction of hammertoes via arthrodesis of the proximal interphalangeal joint (PIPJ) with a 1-piece memory Nitinol intramedullary fixation device.	There were 65 implants in 35 patients included in this study. Overall, a 93.8% fusion rate was noted. Complications were noted in four patients (6.1%): one asymptomatic nonunion, two hardware failures, and one implant displacement.	Using a one-piece memory Nitinol intramedullary fixation device for PIPJ arthrodesis provided a successful fusion rate. Despite the low complication rate, none of the patients required a second procedure or removal of hardware, to date.
Hsu, A.R. <i>et al.</i> , 2015. Tibiotalocalcaneal Arthrodesis Using a Nitinol Intramedullary Hindfoot Nail ¹³	A case report of a 26-year-old woman who presented following a motor vehicle collision and sustained a combined open bimalleolar ankle fracture-dislocation and ipsilateral calcaneus fracture. Use of a tensioned Nitinol compressive element within an intramedullary nail was employed during a revision ankle arthrodesis following nonunion and end-stage subtalar arthritis from the initial procedure.	A computed tomography scan at three months demonstrated successful union across the ankle and subtalar joints. At 18-month follow up, the patient was wearing normal shoes without a brace and had no residual pain or other symptoms.	This preliminary clinical experience showed that the internal Nitinol compression element was able to apply stained compression across the joints as seen on serial radiographs.
Aiyer, A. <i>et al.</i> , 2016. <i>The Impact of Nitinol Staples on the compressive Forces, Contact Area, and Mechanical Properties in Comparison to a Claw Plate and Crossed Screws for the First Tarsometatarsal Arthrodesis</i> ¹⁴	Twenty identical sawbones were randomly assigned to one of four treatment groups (n=5 per group), consisting of either a single NiTi staple, two NiTi staples, a cross cannulated lag screw, or a compression plate.	Contact Force and Area: There was a significantly greater ($p<.05$) contact force and contact area in both NiTi staple groups compared to the claw plate and crossed screw groups at time zero, following 1 mm and 2 mm of displacement. There was a significant ($p=.049$) 57% reduction in contact area in the claw plate group following 2 mm displacement. Plantar Gapping and Recovery: A non-recoverable plantar gap of 0.11 mm in the crossed screw group and 0.96 mm in the claw plate group ($p<.01$) was evident. Following the 3 mm test, a similar trend was observed, with both SMA staple groups recovering their plantar gap following unloading. Conversely, there was a permanent plantar gap in the crossed screw group and claw plate group, which increased to 0.72 mm and 5.3 mm ($p<.001$), respectively.	The dynamic nature of the SMA staples was evident in the complete recovery of the plantar gap following the mechanical test.

Clinical evidence: Applications of Nitinol (continued)

Author and Title	Methods	Results	Conclusion
Schipper, O.N. <i>et al.</i> , 2018. <i>Radiographic Results of Nitinol Compression Staples for Hindfoot and Midfoot Arthrodeses</i> ¹⁵	Retrospective chart review of 149 joints in 96 patients who underwent hindfoot or midfoot arthrodesis using a Nitinol staple construct or Nitinol staple and partially threaded screw construct for end-stage arthritis, coalition, trauma, neuromuscular hindfoot imbalance or deformity with a minimum 3-month follow-up.	Overall, 92.7% (89/96) of patients and 95.3% (142/149) of joints had evidence of radiographic union at final follow-up. In the staple and screw group, 90.6% (29/32) of patients and 95.7% (44/46) of joints had radiographic evidence of union at the time of final follow up.	Midfoot and hindfoot arthrodesis using Nitinol staples were a safe and effective treatment for painful degenerative or post-traumatic hindfoot and midfoot conditions, facilitating bony union with limited complications. The addition of a partially threaded compression screw did no improve or hinder arthrodesis.
Obrador, C. <i>et al.</i> , 2018. <i>Comparative Study of Intramedullary Hammertoe Fixation</i> ¹⁶	Retrospective review of operative hammertoe correction in 96 patients, 27 patients (28.1% were treated with a Kirschner wire (K-wire) fixation, 54 patients (56.3%) with Nitinol staple implants, and 15 patients (15.6% with sterile autograft implants.	Toes treated with a K-wire showed the highest incidence of nonunion, with 35.4% nonunions vs. 3.2% for the Nitinol implant and 3.7% with autograft implant. Both the Nitinol implant as well as the autograft implant provided statistically significant higher fusion and stable pseudoarthrosis outcomes than the K-wire ($p=.00$ in both cases for the k-wire vs autologous implant comparison and $p=.003$ and $p=.002$, respectively for the K-wire vs Nitinol implant comparison).	No statistically significant difference by type of fixation in any of the validated scoring systems (VAS, SF-36, and FFI) was evident, although statistical significant differences were found in favor of the Nitinol and autograft implants in terms of satisfaction rates.
Schipper, O.N. and Ellington, J.K. 2019. <i>Nitinol Compression Staples in Foot and Ankle Surgery</i> ¹⁷	Systematic review of literature/review of case series and surgical technique on the use of Nitinol compression implants in the application of foot and ankle surgery.	Nitinol compression implants are quick and easy to insert and have a high radiographic union rate for midfoot and hindfoot arthrodesis. The talonavicular and naviculocuneiform joints had the highest nonunion rate; therefore, the authors recommend a minimum of two to three staples for arthrodesis of these joints.	Nitinol staples are able to recover plantar gapping and contact surface area after cyclical loading.
Payo-Ollero, J., <i>et al.</i> , 2019. <i>The efficacy of an intramedullary Nitinol implant in the correction of claw toe or hammertoe deformities</i> ¹⁸	Prospective analysis of 36 patients with claw or hammertoe, treated with an intramedullary Nitinol implant.	The Nitinol implant was able to correct the lesser toe deformities and there was a progressive increase in the distal interphalangeal joint flexion and a decrease in the metatarsophalangeal joint extension during follow-up. The correcting in the proximal interphalangeal joint remain, with 2.4 (range 1–57) years as the average follow up.	The implant was able to demonstrate good alignment of the toe and a high rate of joint fusion with few complications.
Mansoor, M.A. and Siddiqui, M.E. 2020. <i>First Metatarsophalangeal Joint Arthrodesis Using Flat Cut Technique and Fixing With Staples: A Review of Outcome</i> ¹⁹	Retrospective review of 37 feet, two with bilateral foot surgery, underwent first metatarsophalangeal joint (MTPJ) arthrodesis for primary osteoarthritis of the first MTPJ using two shape memory Nitinol staples.	Union occurred in 33 cases including three cases of delayed union. Four cases developed non-union. Of these, one case was infective non-union. Average American Orthopaedic Foot and Ankle Surgeons (AOFAS) Foot and Hallux scores was 45 (range, 23-70). Forty-two (70%) of patients rated their outcome as Excellent, 14 (20%) as good, two (5%) as fair and two (5%) as poor.	Use of the shape memory Nitinol staples resulted in 89% union rate. Patients had an average improvement of 44 points on the AOFAS score and 90% rated good to excellent satisfaction.

Clinical evidence: Applications of Nitinol (continued)

Author and Title	Methods	Results	Conclusion
Xia, D., et al., 2020. <i>Combination of mini locking plate and Nitinol arched shape-memory connector for purely lateral malleolus fractures: technique and clinical results</i> ²⁰	Retrospective review of 21 patients with simple lateral malleolus fracture, Type A or B (Weber AO Classification) treated operatively with a Nitinol arched shape-memory connector (ASC).	<p>Based on postoperative radiographic assessment, the articular reduction of the lateral malleolus fractures was classified as anatomical (17 cases), acceptable (2 mm step, 4 cases) or poor (>2 mm, 0 cases).</p> <p>None of the patients showed postoperative articular gap or step >2 mm.</p> <p>No patients showed loss of reduction, and all of the lateral malleolus fractures healed after an average of 12.6±1.5 weeks (range, 10–16 weeks).</p> <p>The rate of complications in this study was 5/21 (23.8%), including numbness after the procedure and traumatic arthritis and hardware irritation.</p> <p>No severe complications such as fracture, secondary loss of reduction, delayed/non-union, or wound infection were noted.</p>	The Nitinol arched shape-memory connector is not only an effective rigid device for multi-fragmented comminuted fracture with rare hardware irritation but it also provides continuous concentrated compression to accelerate osseous healing.
Use of Nitinol in upper extremity orthopaedic surgery			
Xia, D. et al., 2020. <i>Application of a novel shape-memory alloy concentrator in displaced olecranon fractures: a report of the technique and mid-term clinical results</i> ²¹	Prospective analysis of 57 patients undergoing surgical repair of Mayo type II and type III olecranon fractures using an arched shape memory connector during fixation.	<p>Postoperative radiographic measurements demonstrated an anatomical or nearly anatomical reduction of olecranon fractures in all patients.</p> <p>None of the patients showed a postoperative articular gap of more than 2 mm.</p> <p>The patients were followed up for 44 months on average (range, 31 to 56 months).</p> <p>No loss of anatomical reduction was observed in the patients.</p> <p>All of the olecranon fractures healed after an average of 15 weeks (range, 10 to 34 weeks)</p>	In the treatment of olecranon fractures, the Nitinol arched shape memory connector may not only serve as a favorable device for multi-fragmented fractures with rare hardware irritation but also provide a continuous compression to accelerate osseous healing, thereby aiding the restoration and permitting an early rehabilitation with a low incident of postoperative complications.
McKnight, R.R., et al. 2021. <i>Retrospective Comparison of Capitulate Arthrodesis using Headless Compression Screw Versus Nitinol Memory Staples for SLAC and SNAC Wrist: Radiographic Functional, and Patient-Reported Outcomes</i> ²²	<p>Retrospective review of 41 patients undergoing capitulate arthrodesis (CLA) for scaphoid nonunion advanced collapse (SNAC) and scapholunate advanced collapse (SLAC) wrist using either screws or Nitinol staples.</p> <p>Thirty-one patients were included in the staple group and nine patients in the screw group.</p>	<p>There was an 89% union rate for the screw group and a 97% union rate for the staple group.</p> <p>Two patients had screws back out, one who went onto union after screw removal and the other who went onto nonunion after hardware removal.</p> <p>There were two (6.5%) hardware related complications in the staple group. One patient had staple loosening requiring revision and the other, dorsal impingement requiring staple removal after radiographic union. In all subsequent cases, the staples were countersunk with no impingement.</p>	<p>The Nitinol memory staples represent a safe and effective alternative to compression screws for capitulate arthrodesis.</p> <p>Countersinking the staples may reduce the risk of impingement on surrounding structures.</p>

References

- 1.** Es-Souni M, Es-Souni M, Fischer-Brandies H. *Assessing the biocompatibility of NiTi shape memory alloys used for medical applications*. *Anal Bioanal Chem* 2005;381(3):557-67. DOI: 10.1007/s00216-004-2888-3.
- 2.** Wadood A. Brief Overview on Nitinol as Biomaterial. *Advances in Materials Science and Engineering* 2016;2016:1-9. DOI: 10.1155/2016/4173138.
- 3.** Geetha M, Singh AK, Asokamani R, Gogia AK. Ti based biomaterials, the ultimate choice for orthopaedic implants—A review. *Progress in Materials Science* 2009;54:397-425.
- 4.** Stock JT. Wolff's law (bone functional adaptation). *The International Encyclopedia of Biological Anthropology* 2018:1-2.
- 5.** Al-Tamimi AA, Peach C, Fernandes PR, Cseke A, Bartolo PJD. Topology Optimization to Reduce the Stress Shielding Effect for Orthopedic Applications. *Procedia CIRP* 2017;65:202-206. DOI: 10.1016/j.procir.2017.04.032.
- 6.** Ito K, Perren SM. Biology and biomechanics in bone healing. In: Foundation A, ed. *AO philosophy and basic principles*: AO Foundation; 2018.
- 7.** Marsell R, Einhorn TA. The biology of fracture healing. *Injury* 2011;42(6):551-5. DOI: 10.1016/j.injury.2011.03.031.
- 8.** Calafi LA. Basic Principles and Techniques of Internal Fixation of Fractures. In: Foundation A, ed. 2014.
- 9.** Perren SM. Fracture Healing: Fracture Healing Understood as the Result of a Fascinating Cascade of Physical and Biological Interaction. Part I. An Attempt to Integrate observations from 30 years AO Research, Davos. *Acta Chirurgiae Orthopaedicae Et Traumatologiae Cechoslovaca* 2014;81:355-364.
- 10.** Bishop JA, Behn AW, Castillo TN. The biomechanical significance of washer use with screw fixation. *J Orthop Trauma* 2014;28:114-117.
- 11.** Mereau TM, Ford TC. Nitinol Compression Stables for Bone Fixation in Foot Surgery. *J Am Podiatr Med Assoc* 2006;96(2):102-106.
- 12.** Sandhu JS, DeCarbo WT, Hofbauer MH. Digital arthrodesis with a one-piece memory nitinol intramedullary fixation device: a retrospective review. *Foot Ankle Spec* 2013;6(5):364-6. DOI: 10.1177/1938640013496458.
- 13.** Hsu AR, Ellington JK, Adams SB, Jr. Tibiotalocalcaneal Arthrodesis Using a Nitinol Intramedullary Hindfoot Nail. *Foot Ankle Spec* 2015;8(5):389-96. DOI: 10.1177/1938640015598838.
- 14.** Aiyyer A, Russell NA, Pelletier MH, Myerson M, Walsh WR. The Impact of Nitinol Staples on the Compressive Forces, Contact Area, and Mechanical Properties in Comparison to a Claw Plate and Crossed Screws for the First Tarsometatarsal Arthrodesis. *Foot Ankle Spec* 2016;9(3):232-40. DOI: 10.1177/1938640015620655.
- 15.** Schipper ON, Ford SE, Moody PW, Van Doren B, Ellington JK. Radiographic Results of Nitinol Compression Staples for Hindfoot and Midfoot Arthrodeses. *Foot Ankle Int* 2018;39(2):172-179. DOI: 10.1177/1071100717737740.
- 16.** Obrador C, Losa-Iglesias M, Becerro-de-Bengoa-Vallejo R, Kabbash CA. Comparative Study of Intramedullary Hammertoe Fixation. *Foot Ankle Int* 2018;39(4):415-425. DOI: 10.1177/1071100717745854.
- 17.** Schipper ON, Ellington JK. Nitinol Compression Staples in Foot and Ankle Surgery. *Orthop Clin North Am* 2019;50(3):391-399. DOI: 10.1016/j.jocl.2019.02.003.
- 18.** Payo-Ollero J, Casajus-Ortega A, Llombart-Blanco R, Villas C, Alfonso M. The efficacy of an intramedullary nitinol implant in the correction of claw toe or hammertoe deformities. *Arch Orthop Trauma Surg* 2019;139(12):1681-1690. DOI: 10.1007/s00402-019-03203-w.
- 19.** Mansoor MA, Siddiqui ME. First Metatarsophalangeal Joint Arthrodesis Using Flat Cut Technique and Fixing With Staples A Review of Outcome. *Med Forum* 2020;31(6):35-39.
- 20.** Xia D, Zhang Y, Ou T, et al. Combination of mini locking plate and nitinol arched shape-memory connector for purely lateral malleolus fractures: technique and clinical results. *Ann Transl Med* 2020;8(23):1573. DOI: 10.21037/atm-20-4055.
- 21.** Xia D, Zhou P, Li L, et al. Application of a novel shape-memory alloy concentrator in displaced olecranon fractures: a report of the technique and mid-term clinical results. *J Orthop Surg Res* 2020;15(1):453. DOI: 10.1186/s13018-020-01982-2.
- 22.** McKnight RR, Tait MA, Bracey JW, Odum SM, Lewis DR, Gaston RG. Retrospective Comparison of Capitulum Arthrodesis Using Headless Compression Screws Versus Nitinol Memory Staples for SLAC and SNAC Wrist: Radiographic, Functional, and Patient-Reported Outcomes. *Hand (N Y)* 2021;1558944721999732. DOI: 10.1177/1558944721999732.
- 23.** Data on File.