CHAPTER **32**

AN IN VITRO COMPARATIVE STUDY OF SCREW AND NITINOL STAPLE COMPRESSION: A Model Showing Active Dynamic Compression

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INTRODUCTION

Cortical screws, cancellous screws, and Nitinol staples have been used successfully in clinical practice as a means of fixation for osteotomies and fusions of the foot and ankle.

In this study, application of these devices was at the first metatarsocuneiform joint. The typical approach for a Lapidus arthrodesis is to place a screw dorsal-proximal to plantar-distal across the first metatarsocuneiform joint. A second screw is then placed dorsal-distal to plantar-proximal across the fusion interface. Once the screws are tightened, the compressive environment created by the crossed screws is static.

The screws should be applied so that maximum compression is achieved. There should be optimal bone-to-bone contact across any arthrodesis site. Movement or gapping of the site may occur for several reasons. From a cellular level, there is bone resorption as the process of neo-osteogenesis occurs. In situations with absolute stability and no micro-movement at the reduced fracture osteotomy site, resorption is expected to be minimal or none. However, other forms of gapping can occur and result in relative motion. There must be strict nonweightbearing (patient compliance) during this period to avoid the increased potential for movement across the interface which can result in non-union or pseudoarthrosis. This potential increases with surgeon error, over or under compression (osteopenic bone), irregular joint surfaces, inadvertent early weight-bearing or in the presence of iatrogenic bone graft.

In contrast, Nitinol compression staples are placed plantar-medial at the fusion site, to reduce plantar gapping and maximize stability and plantar compression at the tension side of the fusion interface. A second staple is placed dorsally for additional compression and to impart rotational stability. Nitinol is an implant material that has temperature dependent shape change memory and super-elasticity. When heated with an electrical controller (the OSSforce) the Nitinol implants attempt to return to their memorized (original) shape, creating a dynamic or residual compressive force across the fusion interface. This dynamic force can adjust over time to any potential gapping as a result of the surface vagaries, osteopenic bone, surgeon application, premature weightbearing or the presence of bone grafting material.

METHODS

A test model of the Lapidus procedure was created by starting with a Sawbones (Pacific Research Laboratories, Vashon, WA) forefoot bone model, and cutting out a section containing the navicular, medial and middle cuneiform, and first metatarsal bones. This segment of 4 bones was further prepared by grinding the dorsal and plantar surfaces of the navicular flat, drilling a vertical mounting hole through the navicular with a template, shortening the metatarsal by cutting it mid-shaft, and drilling an axial mounting hole in the metatarsal. Figure 1 shows the original Sawbones model and the resulting test specimen.

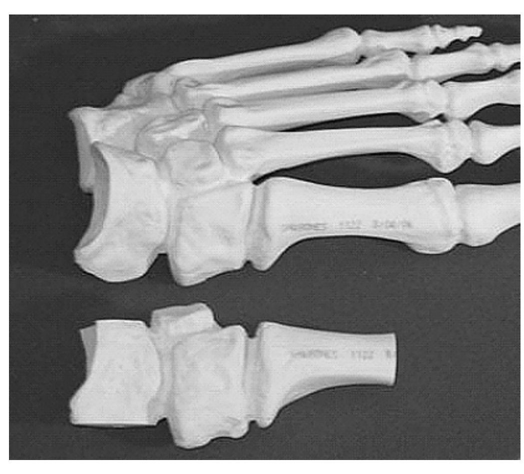

Figure 1. Sawbones specimen prepared for testing.

A custom mechanical test jig was fabricated which consisted of 3 main components: an aluminum base plate and angle mount, a linear micrometer slide (Parker Instrumentation), and a load cell with digital display unit (Mark-10 model BGI). The linear micrometer slide consisted of a stationary base portion that was mounted to the aluminum plate and a moveable top portion with integral metric micrometer that slid on ball bearings with minimal friction. The micrometer allowed the exact linear travel of the moveable section to be measured to an accuracy of 0.01-mm. The load cell was securely mounted to the aluminum angle. The force-deflection characteristics of the jig were measured by inserting a rigid aluminum rod and testing the system. Figure 2 shows the resulting force-deflection characteristics of the jig.

The test specimen was mounted on the jig such that the metatarsal and the flattened plantar portion of the navicular were located horizontally. The metatarsal was mounted to the shaft of the load cell and the navicular was bolted to the moveable section of the linear slide. A uniform vertical osteotomy of the first metatarso-medial cuneiform joint was then created in each test specimen using a coping saw. Figure 3 shows the test jig with a Sawbones Lapidus model mounted and ready for testing.

The 2 bone fragments were then separated using the linear slide so that there was a gap of 2.0-mm between the medial cuneiform and metatarsal. The slide was locked in place to insure no movement of bone fragments. The joint was then fixated using 1 of 3 methods, cortical screws, cancellous screws, or Nitinol staples (BioMedical Enterprises, San Antonio, TX) in a classic Lapidus procedure, shown in Table 1.

Figure 4 shows the resulting forces acting on the bone fragments and test jig. The compressive force at the joint created by the screws or Nitinol staples creates equal and opposite reactive forces at the load cell and micrometer-slide interface. Thus, by measuring the tensile force at the load cell we are also measuring the compressive force created at the metatarso-cuneiform joint by the fixation. The linear slide with attached micrometer allows us to simulate bone resorption in a controlled manner. By moving the micrometer a known amount, the moveable portion of the slide is permitted to slide toward the fixed load cell by the fixation device.

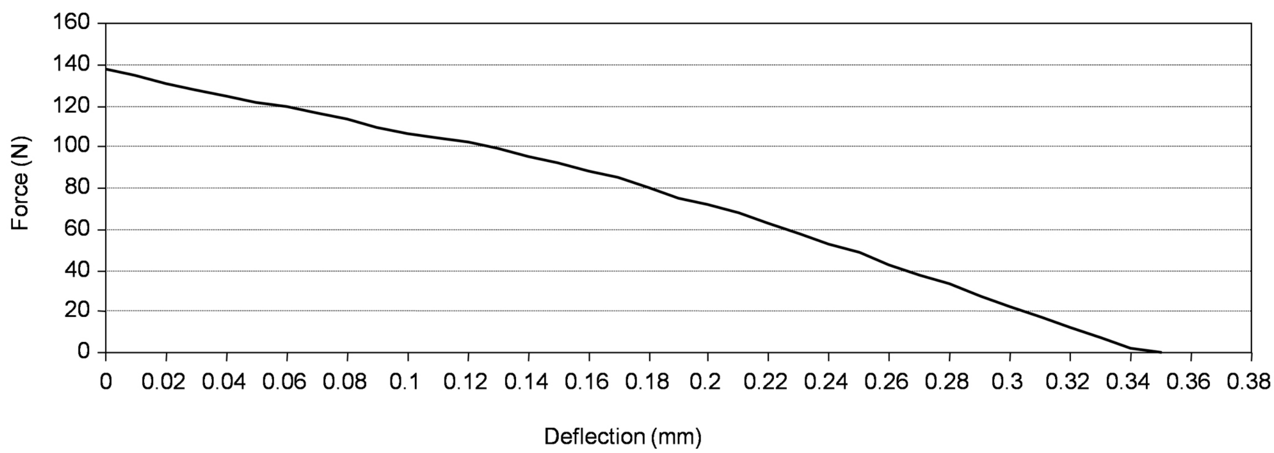

Figure 2. Force-deflection of the jig with a solid rod in place.

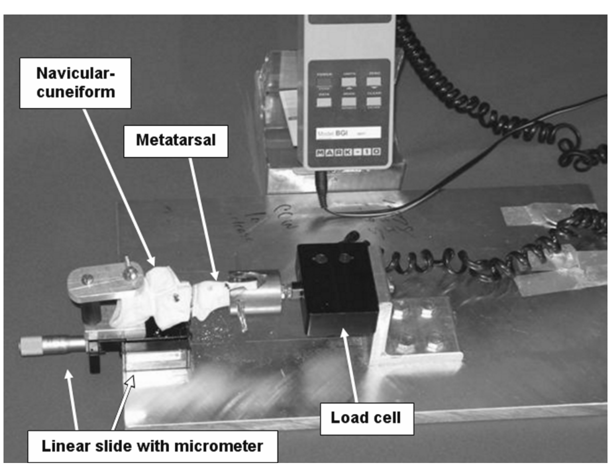

Figure 3. Test jig with test specimen in place.

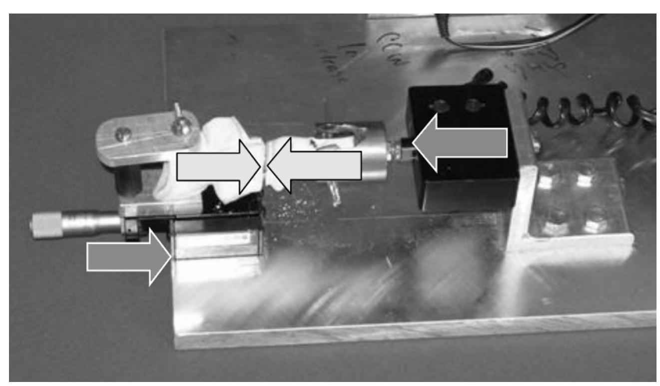

Figure 4. Force diagram of jig and specimen.

Table 1

METHODS OF FIXATION FOR THE FIRST METATARSO-CUNEIFORM JOINT.

Method	Procedure
Cortex screw	1. A 3.5 mm x 45 mm self-tapping fully-threaded cortical screw was placed dorsal-distal on the metatarsal to plantar-proximal on the medial cuneiform. The insertion point on the metatarsal was 25-mm from the joint. 2. A 3.5 mm x 34 mm self-tapping fully-threaded cortical screw was placed dorsal central on the cuneiform and directed distal plantar and lateral. Insertion into the cuneiform was 13 mm from the joint. 3. Countersink both holes. 4. Ream out the proximal portion of the hole for both screws. 5. Tighten both screws, starting with the 45 mm screw and then the 34 mm screw.
Cancellous screw	1. A 4.0 mm x 44 mm short thread cannulated screw was placed dorsal-distal on the metatarsal to plantar-proximal on the medial cuneiform. The insertion point on the metatarsal was 25 mm from the joint. 2. A 4.0 mm x 34 mm short thread cannulated screw was placed dorsal central on the cuneiform and directed distal plantar and lateral. Insertion into the cuneiform was 13 mm from the joint. 3. Countersink both holes. 4. Tighten both screws, starting with the 44 mm screw and then the 34 mm screw.
Nitinol staple	1. Preheat a laboratory oven to 37° C (body temperature). 2. Drill holes per manufacturer's instructions for a 20 mm bridge, 20 mm leg Nitinol staple (OS 2020 W2x3, BioMedical Enterprises, Inc. San Antonio TX). The staple was placed dorsally on the metatarsal and cuneiform. 3. Drill holes for an 18 mm bridge, and 18/15 mm leg Nitinol staple (OS 181815W2, BioMedical Enterprises). This staple was placed medially at the midline of the metatarsal. 4. Active the Nitinol staples using the manufacturer's electrical heating unit at the recommended settings and then immediately place the jig with test specimen in the oven.

Screw Compressive Force Tests

After mounting the bone fragments and placing the 2 cancellous or cortical screws, the force-deflection characteristics of the system were tested. The screws were tightened as described in Table 1. The locking mechanism on the linear slide was released and the initial compressive force recorded. The micrometer was then turned to allow the moveable slide to move 0.01-mm toward the load cell and the resultant compressive force recorded again. This process was continued until the compressive force fell to zero or reached a constant level due to friction in the slide.

Nitinol Staple Compressive Force Tests

Similar to the screw compressive tests, the force-deflection characteristics of the bone fragments fixated by Nitinol staples was measured. After preparing the specimen as described in Table 1, the compressive force was recorded. The micrometer was loosened by reaching into the oven and allowing the slide to move in 0.05-mm increments, with compressive force recorded at each step.

Nitinol Staple Long Term Tests

The dynamic nature of the Nitinol staples was tested in 2 long term tests. In the first test, the jig with test specimen was placed in the oven, and the micrometer was used to create a simulated bone gap in 0.1-mm increments. After each 0.1-mm increment, the compressive force was recorded and then 45 minutes allowed to elapse before recording the compressive force again. At the 0.5-mm gap, the time was increased to 60 hours to study the long term effect of heat on the staples.

In the second test, the test jig with specimen was placed in the oven and the micrometer was used to introduce a simulated bone resorption gap of 2-mm. The bone fragments and staples were then allowed to sit in the oven for 12 hours to study the effect on compressive force.

RESULTS

Ten test iterations of each type of screw and 5 iterations of the Nitinol staples were conducted to show the resulting compressive force as a function of bone resorption gapping. The results of the cortical and cancellous screw tests are shown in Figures 5 and 6. The mean responses of the cortical and cancellous screws were calculated and are shown compared with the Nitinol staples in Figure 7.

Since the jig itself was subject to small deflections under load, the simulated bone gap was corrected for the deflection of the jig using the curve of Figure 2. Both types of screws revealed a rapid loss in compressive force with gapping. All 20 of the screws lost all of their compressive force within the first 0.16-mm of simulated bone gapping/movement. The cannulated screws exhibited higher initial compressive force than the cortical screws, probably due to their larger threads. The Nitinol staples, on the other hand, had a much more gradual loss in compressive force as a gap was introduced to the model. Force was present up to and over 1-mm in gapping. In this test, the Nitinol staples were not allowed to stand at body temperature to regain their compressive force – the results of long term tests at body temperature are described below.

The ability of the Nitinol staples to dynamically increase compressive force over time is shown in Figures 8 and 9. Figure 8 shows that standing at body temperature (37 °C) for 60 hours resulted in a 45% increase in compressive force for the Nitinol staple construct, from 22 to 32 N. Similarly, Figure 9 shows that a Lapidus construct with no compressive force recovered to 10 N after 12 hours at body temperature.

DISCUSSION

Screws have long been accepted as the gold standard for providing compression stability to a fixation construct. The authors use screws routinely in all areas of the foot and ankle. There are no claims stating screws are inferior to

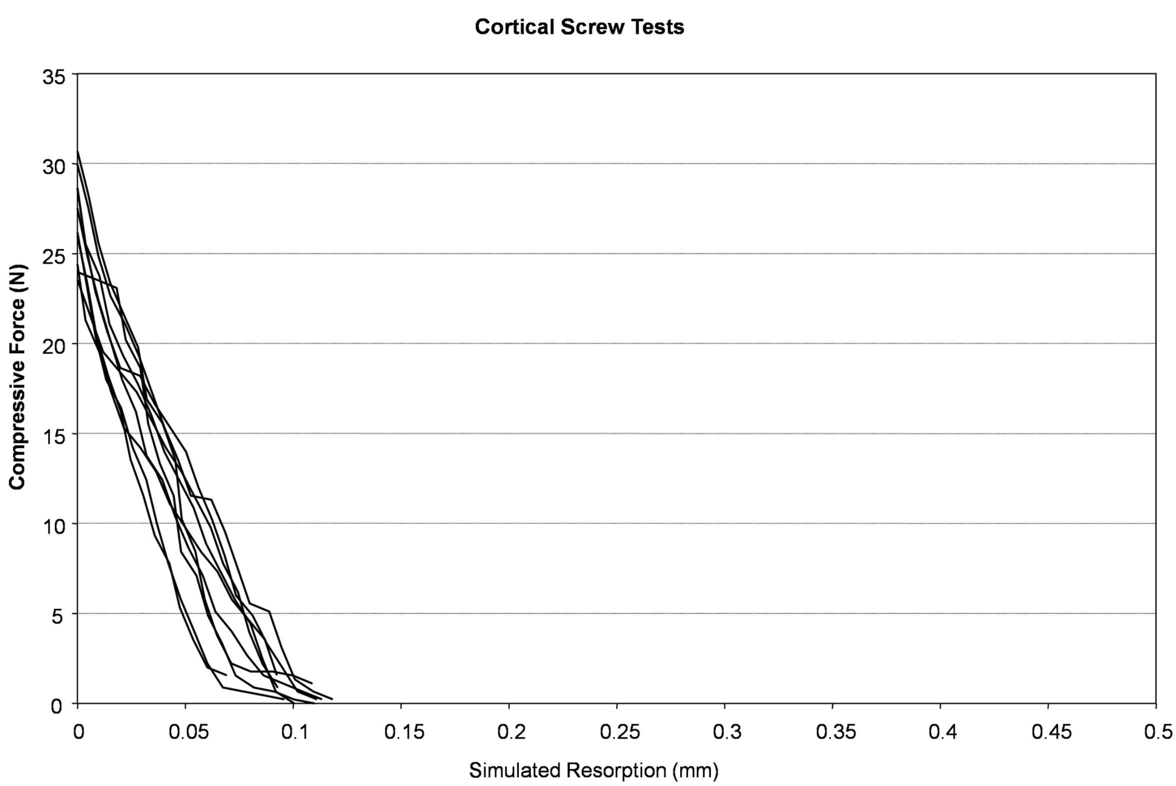

Figure 5. Compressive force for cortical screw tests for different simulated bone resorption.

staples with proper application at the fusion site. Although the compressive force from a screw placement is dynamic during its application, once the screw is tightened down, it functions as a static device. The stability from screw compression may also be affected by several factors such as bone density, bone resorption, and fixation orientation.

As the Lapidus procedure has become more popular over the past several years, many have adapted a crossing screw construct. The compressive force provided with this construct is highly dependent on the initial tightening of the first screw. This may be either the screw from the cuneiform and/or the metatarsal. During this study, we discovered that placing the second screw will not enhance the compressive forces generated by the construct as believed, but may actually counteract the compressive forces of the first screw by shear and oblique forces directed 90 degrees to the original orientation. In fact some surgeons may not place both screws under interfragmentary compression but in fact place a fully threaded screw simply as a stabilizing or supporting element of the osteosynthesis and not overdrill the near fragment.

In the experimental model, it was shown that compressive forces placed across the arthrodesis site essentially drops to zero when the surfaces are brought together by 0.1-mm. This may be clinically reproduced by screw loosening, a minimal amount of bone resorption, or patient non-compliance. Other published research has highlighted similar experiments to show the difference between static and dynamic compression. The compression recorded from the Nitinol staples are shown to have less dramatic decrease with simulated osseous resorption. Even more impressive is the return of compressive forces, approximately 45% in our tests, due to the inherent dynamic compressive activity of the staples. In fact, when the staple is left for one week at body temperature, it is shown to continue in its compressive forces as the staple attempts to return to its original memory shape.

The answer to the age-old question of how much compression is required for primary bone healing is unknown. It is understood that stability is the most important tenet for providing primary bone healing and clearly compression forces can enhance stability. Nitinol staples represent a fixation device that can provide active compression over a period of time to a fixation construct. This is exciting, as the forces applied to the bone surfaces will not only increase over time, but also have the ability to adapt to subtle changes that may occur with bone gapping/movement/resorption as well. Both of these were shown to occur in the Sawbones models and will be followed up in cadaver specimens in the near future.

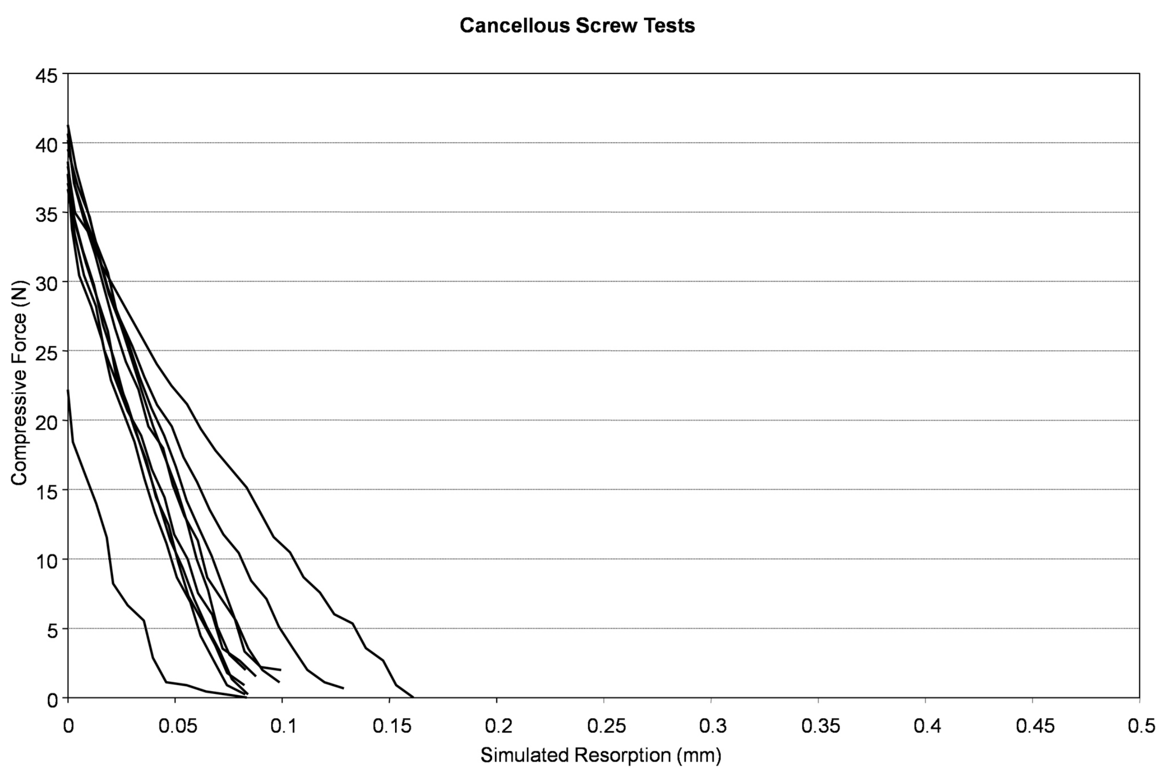

Figure 6. Compressive force for cancellous screw tests for different simulated bone resorption.

CONCLUSION

The concept of dynamic compression has been used to describe fixation devices for many years. It has been used for fixation plates (DCP, LC-DCP) as well as screw designs. These are dynamically compressive upon application, but do not truly define this term once tightened. It is also described for tension band environments in the body, as soft tissues (tendons/ligaments) impart forces across the fusion sites. The shape memory designed into the Nitinol staples studied show the ability to produce an actively dynamic compressive force – a compressive force that will recover from minimal bone gapping and can increase in time with the application of heat, something the other devices do not. The benefits of this type of device can provide unlimited options for repair of osteotomies, arthrodesis and fractures. This is an exciting area for further research.

BIBLIOGRAPHY

Blitz NM, Ray RG. Feature: How to handle Lapidus complications. *Podiatry Today.* Volume 16, September 2003.

Brodke DS, Klimo P, Bachus KN, Braun JT, Dailey AT. Anterior cervical fixation: analysis of load-sharing and stability with use of static and dynamic plates. *J Bone Joint Surg* 2006;88:1566-73.

Hansen ST. Functional reconstruction of the foot and ankle. Philadelphia: Lippincott Williams & Wilkins; 2000.

Mardjetko S. Anterior surgery in the management of scoliosis. *Cont Spine Surg* 2005;V6:N2.

Payette CR, Sage RA, Gonzalez JV, Sartori M, Patwardhan A, Vrbos L. Triple athrodesis stabilization: a quantitative analysis of screw vs staple fixation in fresh cadaveric matched-pair specimens. Scientific Seminar of the American College of Foot and Ankle Surgeons, Annual Meeting N 54, New Orleans, March 1996.

Shaw JA. A Biomechanical comparison of scaphoid screws. *J Hand Surg* 1987;12:347-53.

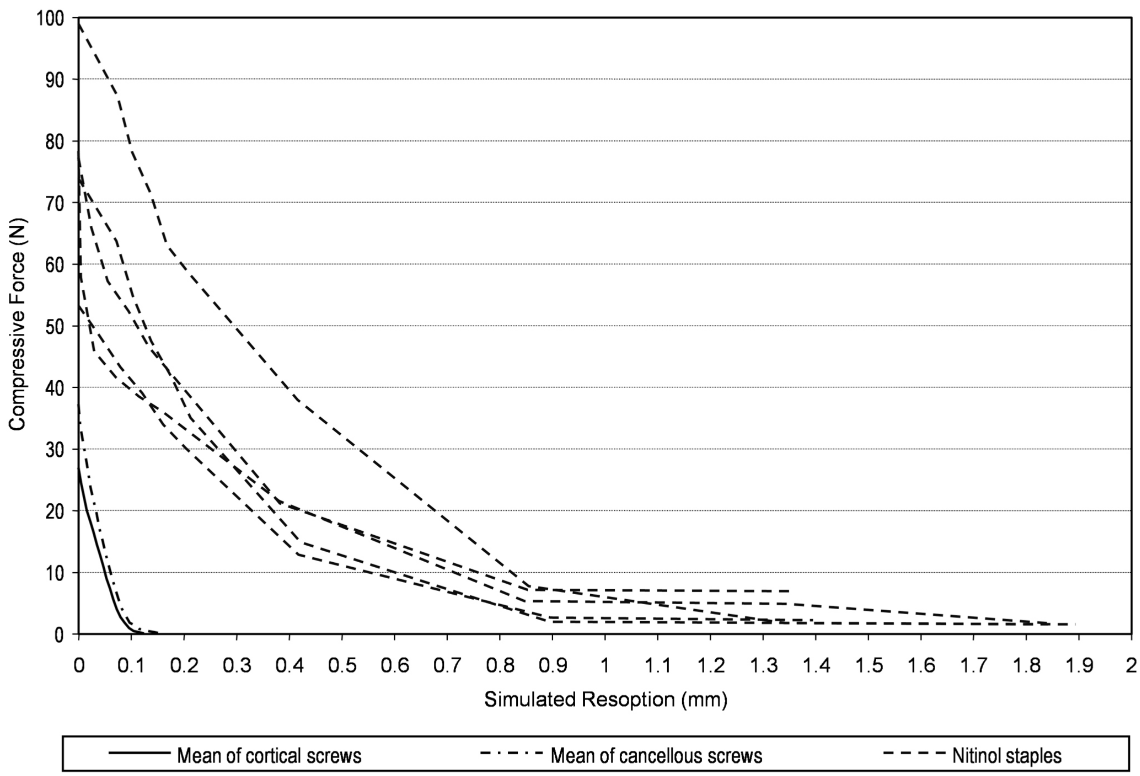

Figure 7. Comparison of compressive force for mean cancellous screw, mean cortical screw, and 5 Nitinol staples for different simulated bone resorption.

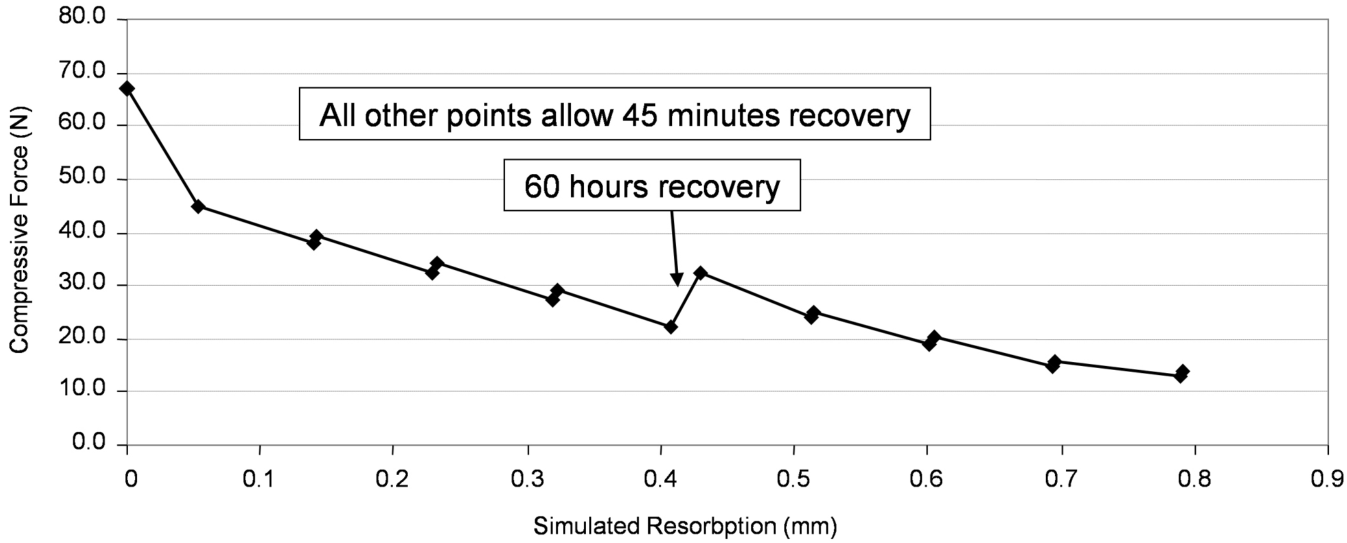

Figure 8. Compressive force for Nitinol staples with recovery time at each step.

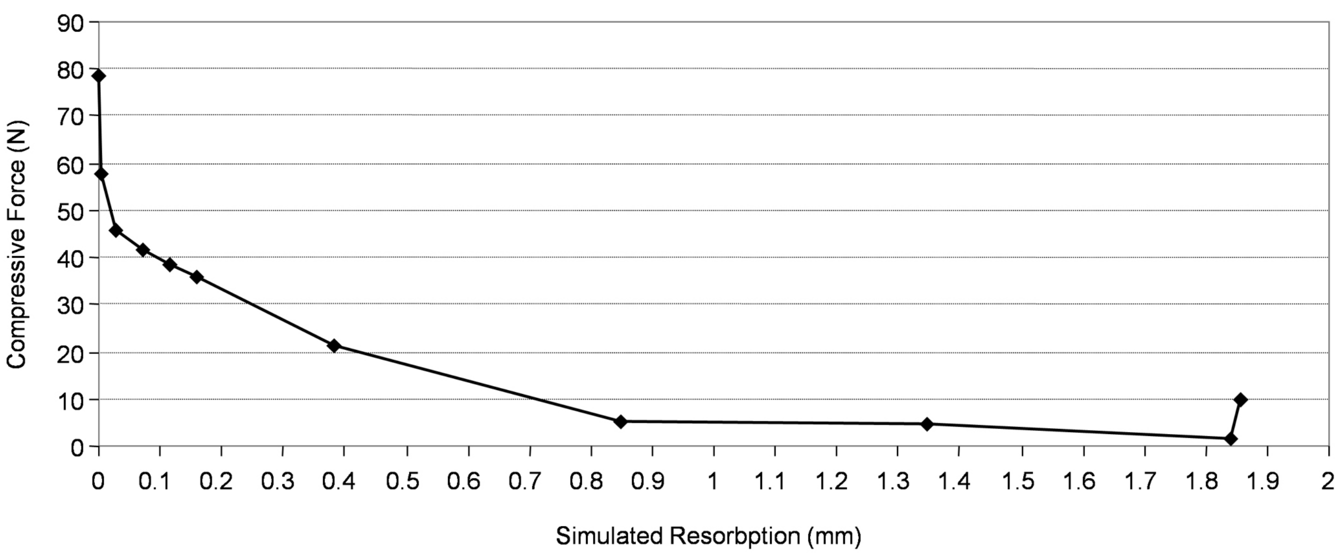

Figure 9. Compressive force for Nitinol staples with 12 hours recovery time.