An Evaluation of the Mechanical Performance of Kyphon Xpander™ II Inflatable Bone Tamp compared to Stryker SpineJack™ Device

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All authors were employees of Medtronic PLC during this testing.

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KEY POINTS

Kyphon Xpander™ II IBT generated 1200 N vertical lift force during inflation in foam block simulating osteoporotic bone, compared to 200 N vertical lift force during deployment of the SpineJack™ device.

Kyphon Xpander™ II IBT generated 8 mm of vertical displacement in a pair of foam blocks under a 350 N compressive load, compared to no measurable vertical displacement during deployment of the SpineJack™ device.

Deployment of the SpineJack™ device was observed to result in subsidence into foam blocks under a 350 N compressive load due to a smaller surface area, rather than effectively registering a lift force.

The SpineJack™ device generated a concentrated stress measuring 900% (1860 psi) compared to a Kyphon Xpander™ II IBT (205.8 psi) when inflated to a volume observed in a study that measured balloon inflation volumes during BKP procedures.[1] (3.155 cc ± 0.14 cc).

INTRODUCTION

Balloon Kyphoplasty (BKP) is a widely used treatment option for vertebral compression fractures (VCF) due to osteoporosis, cancer, or benign lesion. The procedure involves the inflation of an inflatable bone tamp (IBT) within a fractured vertebral body, which exerts a vertical lifting force attempting to restore the height of the fractured vertebral body to its anatomic height. The IBT is then deflated and removed, leaving behind a void that is filled with bone cement to serve as an internal cast, stabilizing the bone. IBTs have been used for the reduction of fractures and creation of a void in cancellous bone since 1998.[2]

The SpineJack™ Implantable Fracture Reduction System is a device designed to reduce vertebral compression fractures.[3] The SpineJack™ device is an implant with a fixed footprint and a ranging in diameter of 4.2 mm, 5.0 mm and 5.8 mm.[3] The procedure involves the irreversible expansion of a titanium implant by pulling the ends of the implant toward each other, allowing the device to expand.[4] Per the surgical technique, caution should be taken to ensure that the desired orientation is achieved before expanding the device.[4] If properly placed within the vertebral body, the longitudinal compression results in the implant opening in the cranio-caudal direction, allowing it to exert a vertical lifting force.[5] The expanded device is left in place, and bone cement is injected through the center of the implant to serve as an internal cast, stabilizing the vertebral body.[4]

STUDY OBJECTIVES

The purpose of the bench testing documented in this white paper was to compare the mechanical performance of the Kyphon Xpander™ II IBT and SpineJack™ device.

METHODS

FIXTURE PREPARATION

Foam blocks of density 10 pcf (0.16 g/cm^3) mimicking osteoporotic cadaver bone[6] were used as a testbed. A pilot hole was drilled into each cube before sectioning in two and potting each half in liquid plastic to allow mounting onto an Instron load frame. Each device was placed on a lower half, and the corresponding upper half was lowered onto it until a 5 N pre-load was registered on the Instron load cell.

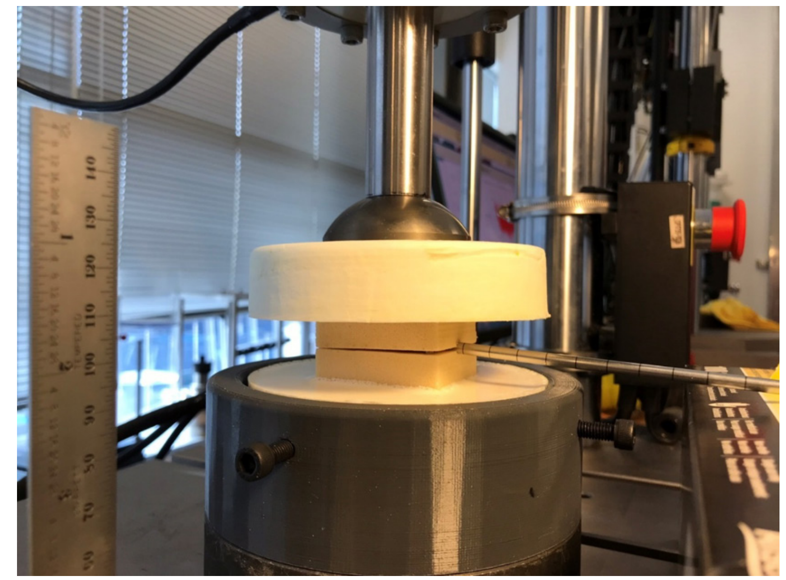


Figure 1. Photograph illustrating experimental set-up. The foam block is cut in half and potted in liquid plastic to allow it to be mounted on an Instron servo-hydraulic load frame, able to measure the force during deployment of a device (either SpineJack™ or Xpander™ II IBT) within this "sandwich."

Lift Force

To measure vertical lift force, the Instron was programmed under displacement control, with the position of the platens holding the foam testbed held in a fixed position. The vertical lift force was recorded continuously during deployment of a device.

Each Kyphon Xpander™ II IBT (size 15/3, n= 3) was prepped with water and inflated using a Kyphon inflation syringe within the foam blocks. Inflation was performed in 0.5 cc steps, and the system was allowed to settle into a steady state for 20 seconds between each inflation increment. The peak pressure after each 0.5 cc inflation increment was noted. Inflation continued in this manner until the rated maximum inflation volume (MIV) of 5.0 cc was reached.

The SpineJack™ device (size 4.2 mm, n= 2) was deployed within the foam blocks. The handle was turned one full revolution at a time, with a rest period of 20 seconds between each revolution, until the handle could no longer be turned.

Height Restoration

To measure height restoration, the Instron was programmed under force control, with the platens programmed to maintain a constant compressive load of 350 N. This load was selected to correspond to one-half bodyweight, such as would be experienced in the spine of a patient lying prone. The resulting position of the foam testbed in response to the device deployment was recorded continuously.

The Xpander™ II IBT (size 15/3, n=1) was prepped with water and inflated using a Kyphon Inflation Syringe within the foam blocks. Inflation was performed in 0.5 cc steps, and the system was allowed to settle into a steady state for 20 seconds between each inflation increment. The peak pressure after each 0.5 cc inflation increment was noted. Inflation continued in this manner until the rated maximum inflation volume (MIV) of 5.0 cc was reached.

The SpineJack™ device (size 4.2 mm, n= 2) was deployed within the foam blocks. The handle was turned one full revolution at a time, with a rest period of 20 seconds between each revolution, until the handle could no longer be turned.

Stress Concentration

A custom test fixture (designed by Pressure Profile Systems (PPS)) was used to measure the stress concentration. The fixture was designed to pivot on a fixed point under a constant spring load to simulate a collapsed vertebral body. A pressure sensor plate located on the inferior surface captures force and stress data from devices placed within the fixture.

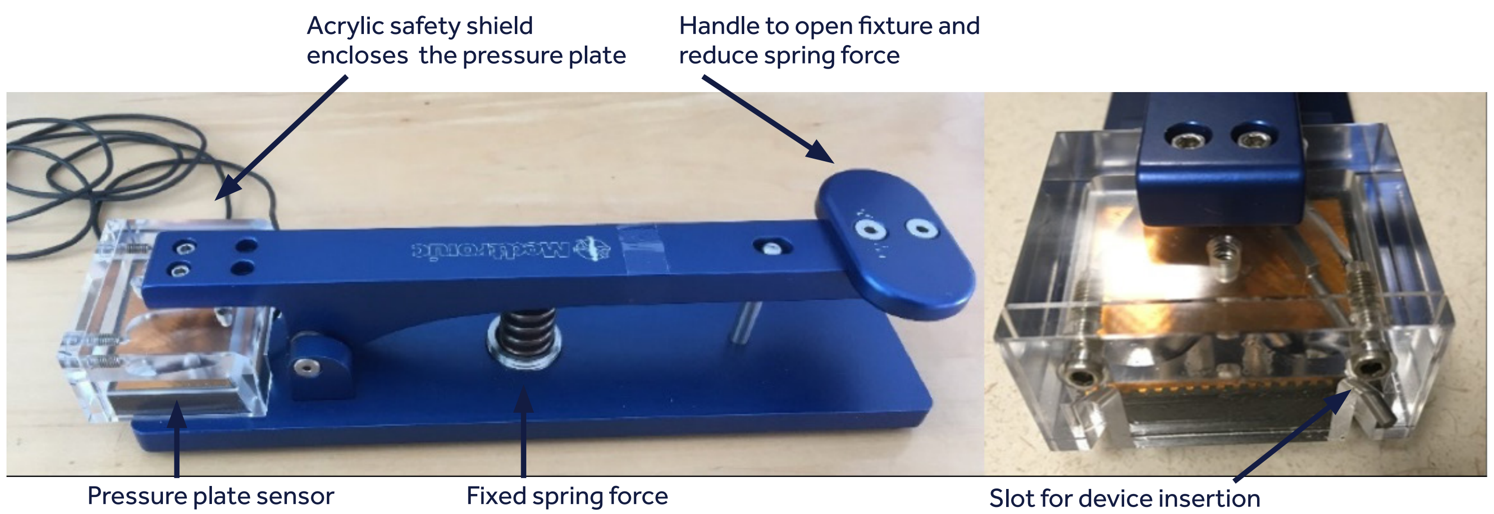


Figure 2: PPS custom test fixture with pressure plate to simulate an endplate under a constant load

Due to limited number of available test samples, a titanium mockup of the SpineJack™ device (size 4.2 mm) replicating the device geometry was used during the testing. The pressure sensor secured by the custom fixture was connected via USB port to PPS- Chameleon Software for data capture continuously through the procedure steps.

The simulated SpineJack™ device (size 4.2 mm, n= 5) was placed within the fixture on the pressure sensor by pressing the handle to reduce the spring force, and then the handle was released to allow the compressive force from the spring to stabilize in the loaded position. The compressive force (SpineJack™ baseline) and peak pressure were recorded from the software, and a screenshot was captured to show the sensor output.

The Xpander™ II IBT (size 15/3, n= 5) was prepped with water and placed within the fixture on the pressure sensor by pressing the handle to reduce the spring force, and then the handle was released to allow the compressive force from the spring to stabilize in the default position; the IBT was unloaded in this configuration. The IBT was then inflated at 0.5 cc increments every 30 seconds until the force measurement matched the SpineJack™ baseline compressive force (41–46 lb). The compressive force and peak pressure were recorded from the software, and a screenshot was captured to show the sensor output.

RESULTS

Lift Force

During inflation of Kyphon Xpander™ II IBTs, the maximum peak pressure noted was approximately 600 psi. There were no balloon ruptures observed. Under fixed displacement control, the average maximum lift force recorded was 1200 N (n= 3). The force waveform pattern showed progressively higher individual force peaks with each inflation increment, as the balloon gradually expanded in volume, and thus area, thereby increasing the vertical lift force (Figure 3).

During deployment of SpineJack™ device, the waveform pattern recorded indicated an initial deployment force with turns 1-2 and then settling into a pattern during later turns where a rise and settle was noted with each turn, with no further increase in the maximum lift force. The maximum force recorded was 200 N (Figure 3).

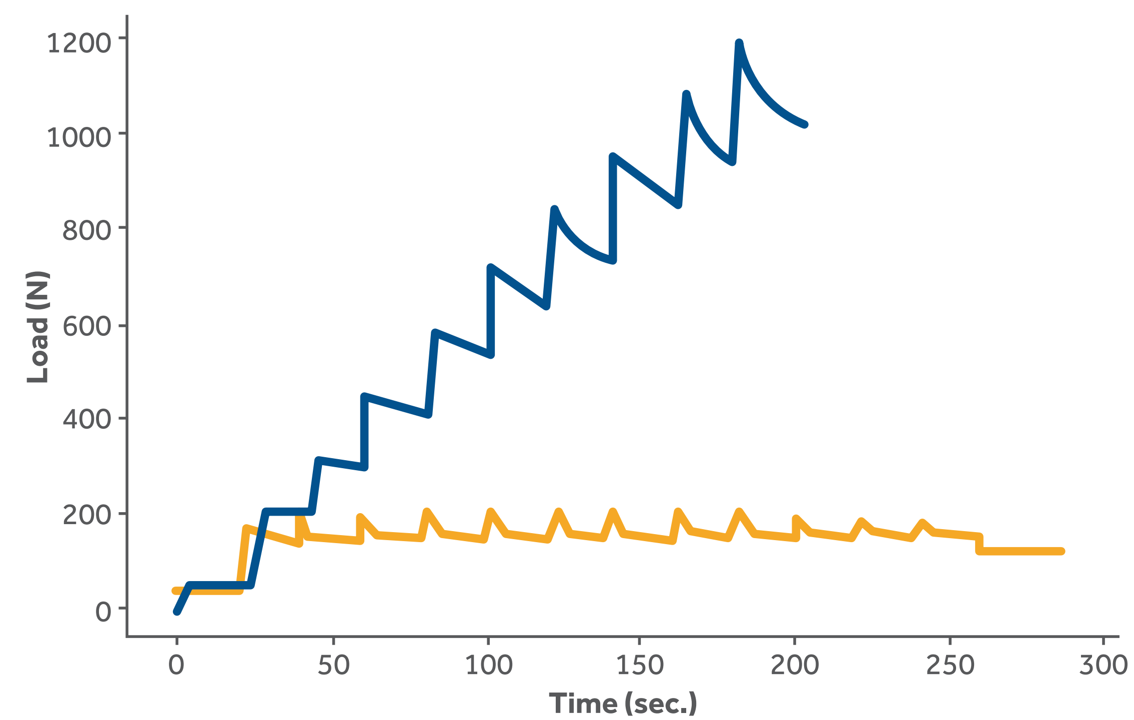


Figure 3. Graph plotting vertical lift force recorded by Instron while operating under displacement control during inflation of Kyphon Xpander™ II IBT (blue) and SpineJack™ (yellow). Inflation in 0.5 cc increments to a maximum inflation volume of 5.0 cc for Xpander™ II IBT resulted in a maximum vertical lift force of 1200 N. Incremental deployment of SpineJack™ device reached a maximum vertical lift force of 200 N.

Height Restoration

To mimic height restoration in a mechanical setting, separation of the foam blocks was measured against the inflation of the Kyphon Xpander™ IBT versus the expansion of the SpineJack™ device. During inflation of Kyphon Xpander™ II IBTs, the maximum peak pressure noted was approximately 600 psi. There were no balloon ruptures observed. Under a constant 350 N force control, inflation of the Kyphon Xpander™ II IBT resulted in movement of the upper foam block by 8 mm (n=1). Thus, the Kyphon Xpander™ II IBT inflation was able to generate a lift force exceeding 350 N, which resulted in the observation of the upper foam block moving upwards to maintain the prescribed constant force of 350 N.

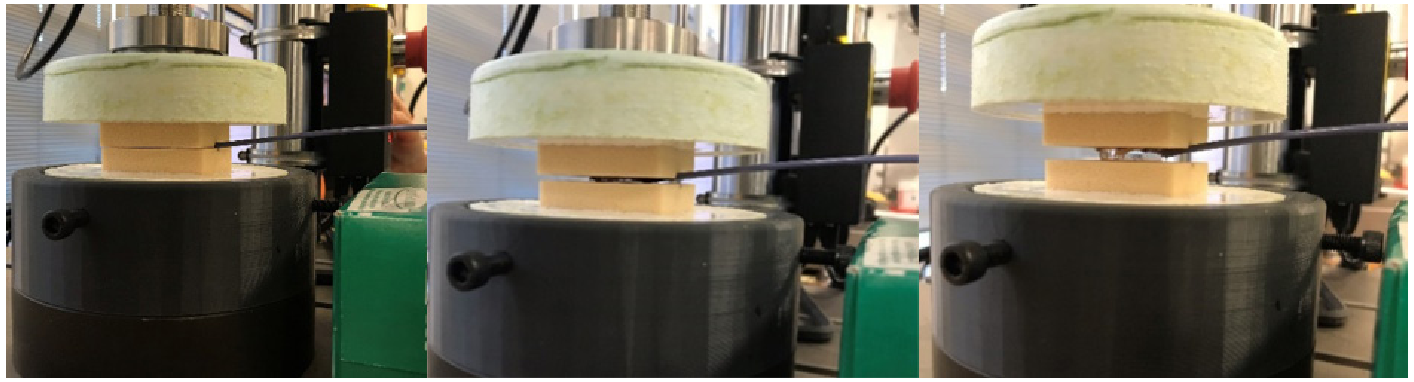


Figure 4. This sequence of images illustrates the movement of the upper foam block in response to inflation of Kyphon Xpander™ II in order to maintain a constant compressive load of 350 N. This represents the ability of the balloon to exert a lifting force to overcome a half-bodyweight load, as might be encountered by a spine in the prone position, to restore the height of a fractured vertebra.

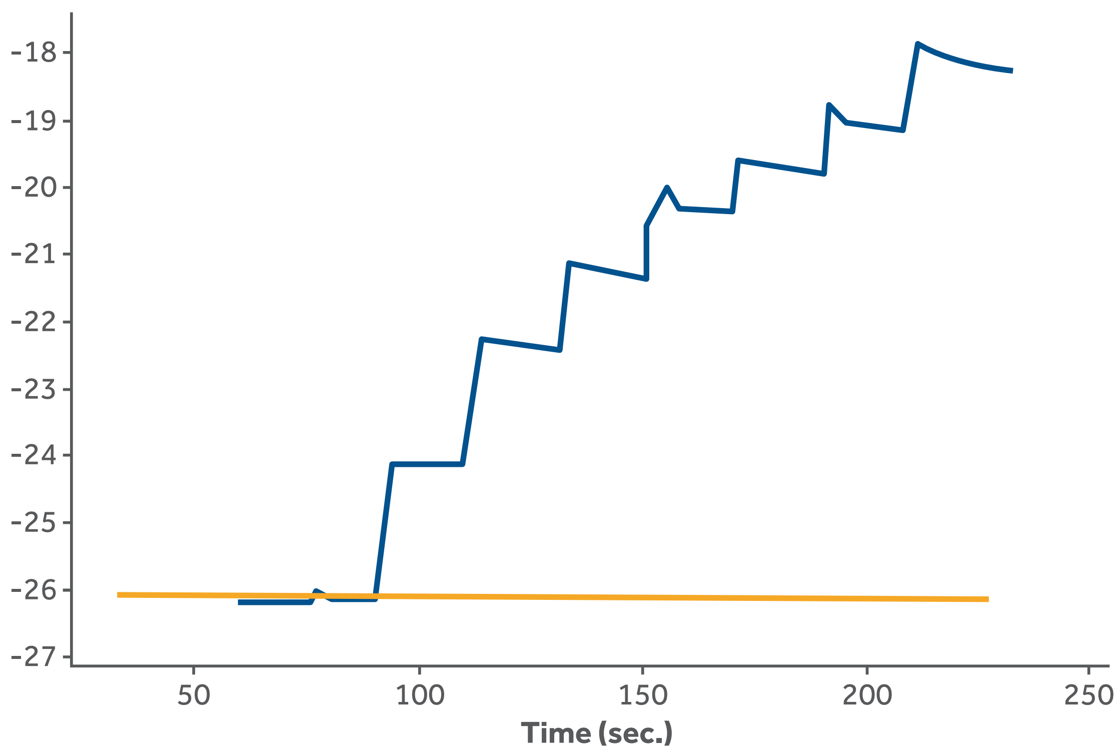


Figure 5. Graph plotting displacement position recorded by Instron while maintaining a constant 350 N force control during inflation of Kyphon Xpander™ II IBT (blue) and SpineJack (yellow). Inflation in 0.5 cc increments to a maximum inflation volume of 5.0 cc for Xpander™ II IBT resulted in a change in displacement of 8 mm. Incremental deployment of SpineJack™ device resulted in no change in displacement position.

During deployment of SpineJack™, no displacement of the foam blocks was observed in response. This indicates that SpineJack™ deployment did not result in a vertical force exceeding 350 N, and so no movement of the foam blocks was required to maintain this constant compressive load.

Subsidence

The characteristic subsidence patterns in the foam block testbed is shown below for each device. The Kyphon Xpander™ II subsidence pattern (Figure 6) shows the larger surface area resulting from omnidirectional inflation to a volume of 5.0 cc, providing a broad surface across which to effectively apply a lift force. In contrast, the SpineJack™ subsidence pattern (Figure 7) shows the smaller surface area left behind from deployment of this fixed-footprint geometry. This smaller impression left behind suggests that most of the deployment energy was expended in cutting into the foam block, rather than registering a lift force on the load cell through the block.

Figure 6. Photograph illustrating the subsidence pattern within the foam block from inflation of a Kyphon Xpander™ II IBT to a volume of 5.0 cc.

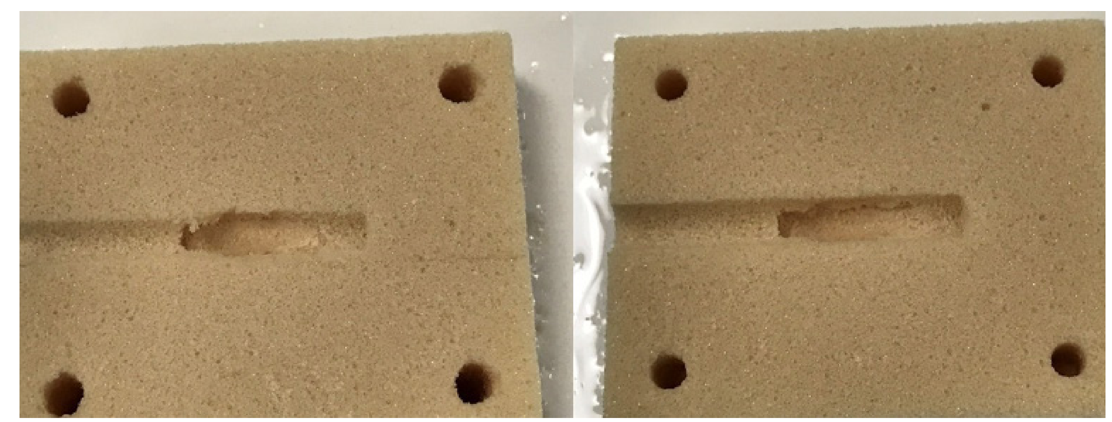


Figure 7. Photographs illustrating the subsidence pattern within the foam block from expansion of a SpineJack™ device.

The final maximum dimension of the SpineJack was ~0.6". Both test samples used during this test showed deformation, and one broke, indicating an inability to fully deploy in this testbed.

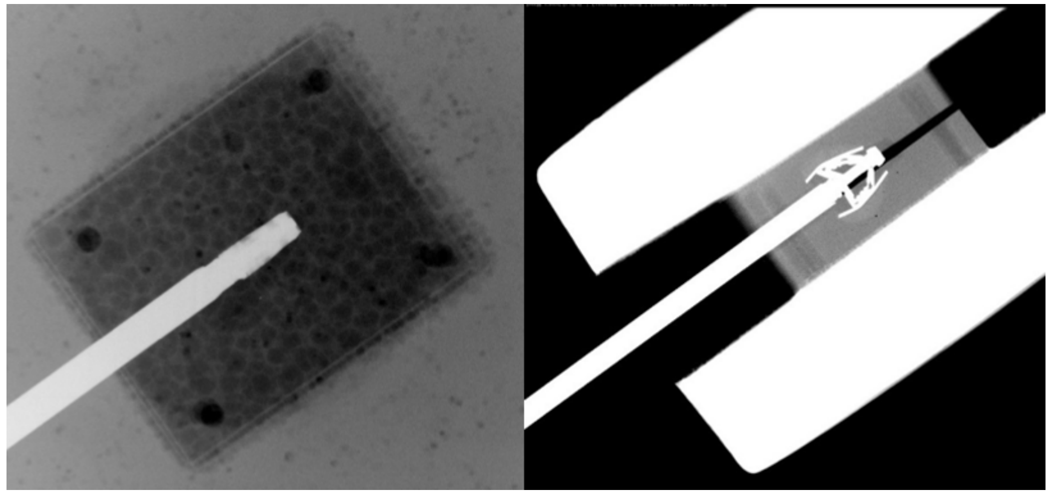


Figure 8. X-ray images illustrating the expanded SpineJack™ device (top view at left; side view at right) within the foam blocks.

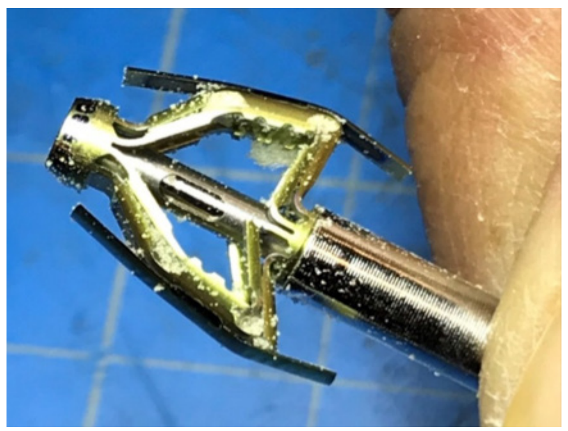


Figure 9. Photograph illustrating the SpineJack™ device after deployment in 10 pcf foam blocks. Note the asymmetrical and broken tine, indicating an inability to be fully deployed.

Stress Concentration

Placement of the SpineJack™ insert into the fixture resulted in an average compressive force of 43.2 ± 1.92 lb, with an average maximum pressure recorded of 1860 ± 394.6 psi.

Kyphon Xpander™ II IBTs were inflated until an average compressive force of 42.2 ± 1.09 lb, with an average maximum pressure recorded of 205.8 ± 18.1 psi. The IBTs had an average maximum inflation pressure of 232.8 psi and a maximum volume of 3.15 cc. There were no ruptures observed.

Both the Kyphon Xpander™ II IBTs and the SpineJack™ insert demonstrated similar force outputs on the fixture measuring 42.2 ± 1.09lbs and 43.2 ± 1.92 lbs, respectively.

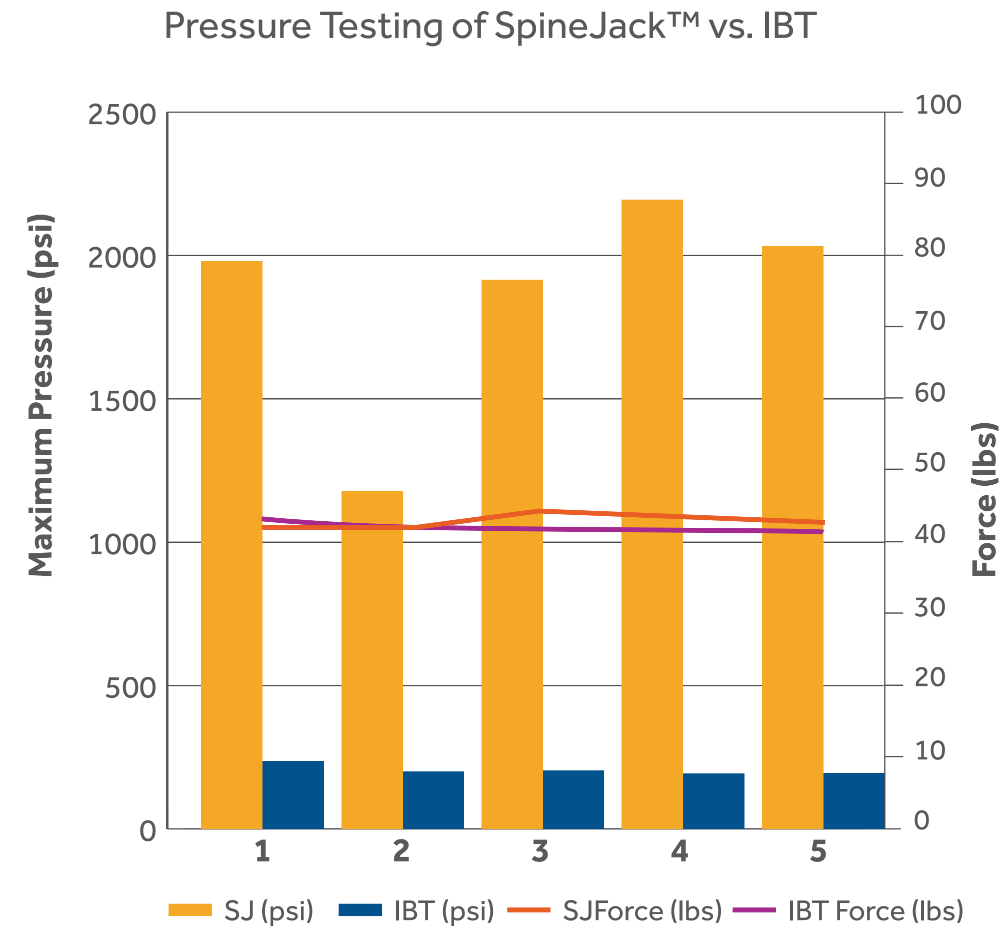


Figure 10. Plot showing the SpineJack™ and Kyphon Xpander™ II sample maximum pressure and force exerted during testing.

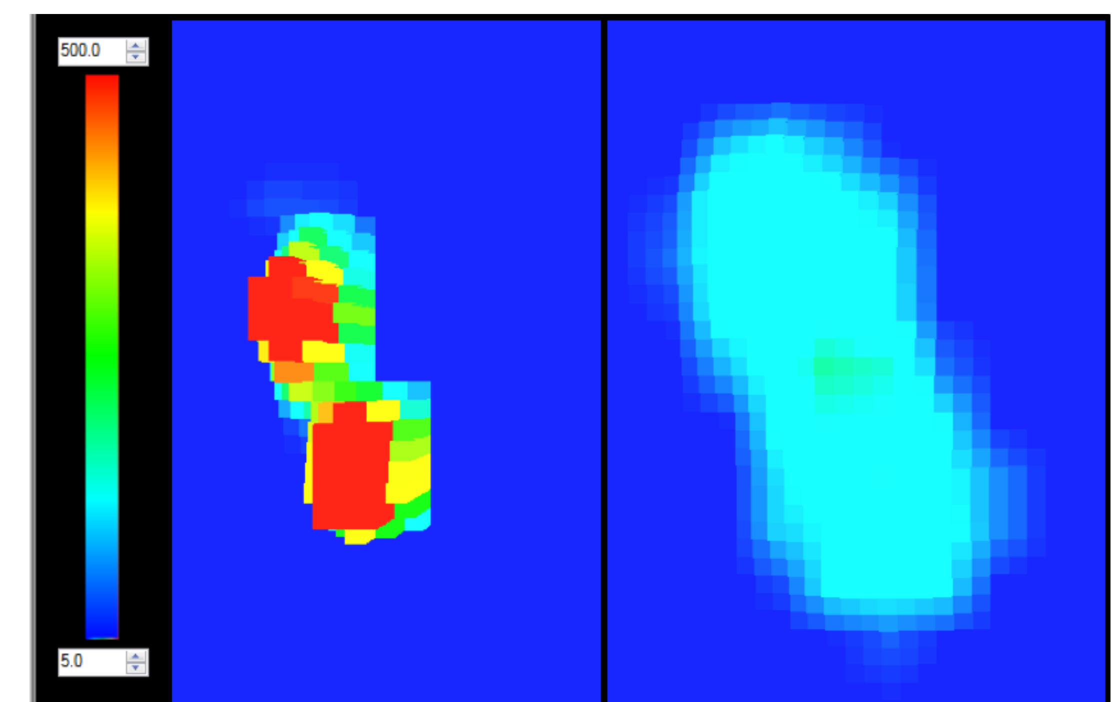


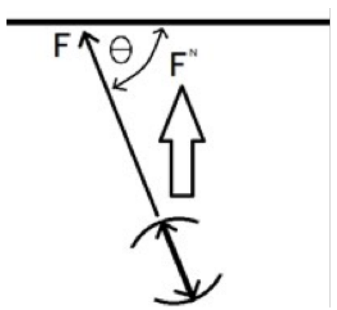
Figure 11. Pressure sensor visual output showing surface area and stress concentration areas of SpineJack™(left) and Kyphon Xpander™ II IBT(right).

SUMMARY

Lift Force / Height Restoration

The results of the comparative mechanical testing in this study show that, within a testbed of foam blocks simulating osteoporotic cadaveric bone[6], the deployment of SpineJack™ generated a maximum 200 N lift force, compared to 1200 N during inflation of Kyphon Xpander II™ Inflatable Bone Tamps. Comparing the ability to vertically displace loaded foam blocks, to replicate vertebral body height restoration, inflation of Kyphon Xpander II™ IBTs was able to overcome a constant compressive force of 350 N (corresponding to half-bodyweight) and resulted in displacement of 8 mm. The expansive strength of the SpineJack™ device was unable to overcome a 350 N load and resulted in no displacement of the foam blocks.

According to the surgical technique, the SpineJack™ is designed to expand in the cranio-caudal orientation. The surgical technique cautions the user to ensure the desired orientation is achieved prior to expansion, as this is irreversible.[4] Incorrect orientation will result in decreased vertical lift force performance. For example, misorientation at a 45° angle results in only approximately 71% of the maximum force potential of a normal force (Figure 12). In contrast, the inflation of an IBT is in the radial direction, and therefore is not sensitive to radial orientation during inflation.



$$F^N = F(\sin\theta)$$
$$90° \text{ Angle: } F(\sin 90) = F(1) = 100\% \text{ Force Exerted}$$
$$45° \text{ Angle: } F(\sin 45) = F(0.707) = \sim 71\% \text{ Force Exerted}$$

Figure 12. Rotational effects on a normal force.

Stress Concentration

The purpose of this test was to measure the pressure differences between a Kyphon Xpander™ II IBT and simulated 4.2 mm SpineJack™ footprint under a constant load by targeting a similar force output. The compressive loads of 43.2 lb for SpineJack™ vs. 42.2 lb for Xpander II were not statistically different. The SpineJack™ footprint had a statistically higher mean peak pressure of 1860 psi compared to the Xpander™ II IBT of 205.8 psi. The concentration of force demonstrated by the SpineJack's higher peak stress (904% of the peak stress induced by Xpander™ II IBTs) was also seen with its movement within the bone foam while reviewing the device imprint patterns in the bone foam fixture. While testing for stress concentration under similar force conditions, the maximum stress induced by the IBT was demonstrated to be lower than the SpineJack™ insert, which resulted in higher induced stress in the direction of expansion.

A simulated SpineJack™ device representing the 4.2 mm implant footprint was used to perform the stress concentration test. The surgical technique details that "SpineJack™ blades have been designed to allow for plastic deformations in order to adapt to the patient-specific bone conditions and vertebral endplate shape."[4] Deformation of the blades would reduce the representative surface area available to be used during deployment, and so the solid footprint of the simulated device represents a best-case scenario given the entire surface was used in capturing the pressure against the sensor.

The average maximum inflation volume of the single IBTs during testing was 3.15 cc ± 0.14 cc representing a clinical setting when compared to inflation volume of two balloons @ 6.0 mL ± 2.8 mL seen in a bi-lateral randomized trial comparing inflation volumes and height restoration.[1]

This study was subject to common limitations of simulated bone testing. The results from this study may not be representative of in vivo performance.

Indications and Risks for Kyphon Balloon Kyphoplasty

Please see package insert for complete list of indications, warnings, precautions, and other important medical information.

Risks of acrylic bone cements include cement leakage, which may cause tissue damage, nerve or circulatory problems, and other serious adverse events, such as cardiac arrest, cerebrovascular accident, myocardial infarction, pulmonary embolism, or cardiac embolism.

Kyphon Xpander™ II and Kyphon Express™ II Inflatable Bone Tamp (IBT) is intended to be used as a conventional bone tamp for the reduction of fractures and/or creation of a void in cancellous bone in the spine (including use during a balloon kyphoplasty procedure with a legally marketed PMMA-based bone cement that is cleared for use in kyphoplasty procedures), hand, tibia, radius, and calcaneus.

References

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5. Medtronic Data on File: ETR 31101176.
6. O'Neill F, Condon F, McGloughlin T, et. al. Validity of synthetic bone as a substitute for osteoporotic cadaveric femoral heads in mechanical testing. *Bone Joint Res.* 2012;1(4): 50–55.
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