Biomechanical Test Data of the AXIS Beaming System for Charcot Foot Reconstruction: Improved Strength, Fatigue Resistance and Compression Using a Novel Implant

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Introduction

Charcot foot disease is a common and debilitating condition affecting millions of individuals worldwide. It is most commonly associated with diabetic neuropathy, but can occur with almost any neuropathic condition that causes the limb to become insensate. Conservative management including control of associated medical co-morbidities, glycemic control and appropriate patient education concerning daily foot care and shoe wear are the mainstay of treatment.[1]

Foot deformity will progress if the condition is neglected. Some patients with advanced neuropathy will develop severe deformities even with diligent medical attention and treatment. The patient with progressive Charcot disease that has failed conservative treatment (ie: boots, casting, antibiotics) may present with a rocker-bottom deformity of the midfoot with or without ulcerations requiring restoration of the plantar arch and anatomical position of the mid-foot (Figure 1).

Figure 1

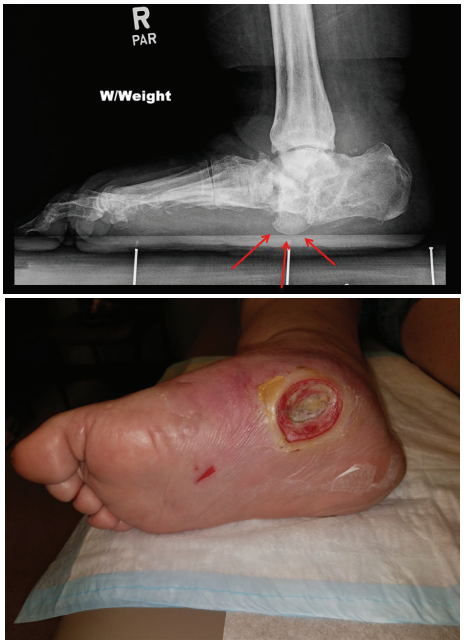

Figure 1: Lateral radiograph (top) showing evidence of rocker-bottom deformity and clinical image (bottom) of the plantar surface exhibiting rocker-bottom deformity and ulceration of the mid-foot plantar surface.

Neuropathic dislocation of the midfoot or ankle often leads to dislocation and subsequent infection. A perfect storm of medical comorbidities in diabetic patients make the condition extremely difficult to treat once osteomyelitis develops. Amputation of the leg often ensues.[2]

The Development of "Superconstruct" Techniques and Implants

Traditionally, surgery in the diabetic foot was limited to simple exostosis removal in attempts to treat bony prominence and infection.[3] While a stable plantigrade foot that ulcerates due to bony prominence may do well with this technique, some deformities are simply too unstable or too deformed for this to be effective. Studies done in the last 20 years have questioned the effectiveness of indefinite treatment of severe and worsening deformities with elaborate bracing and offloading devices.[4-6] Poor functional results, recurrent ulceration and progression of deformity have been noted in studies where non-surgical management has been used alone.[7]

The Charcot foot presents an unusual set of problems for the surgeon. Severe, rigid deformity combined with osteoporosis and bone that has often become fragmented and avascular due to the Charcot process is inherently difficult to treat. The term "Superconstruct" was coined to describe advanced surgical techniques needed for successful limb salvage in these complex cases.[8]

In this type of surgery, the zone of Charcot bone deformity is bridged with either long plates or screws to achieve fixation outside of the injury of osteoporotic and fragmented bone. Axial fixation using multiple screws or "beaming" was introduced in 2009 and has become the method of choice for internal fixation in cases requiring a "superconstruct".[9] This technique applies the fixation intraosseously with long screws spanning the intramedullary canals of the metatarsals to the talus and calcaneus (in most cases). These "beaming" techniques offer powerful deformity correction and exceptional stability.[10] In addition, the surgery can be done through limited incisions with lower morbidity than plates, screws and other techniques.

This technique changed expectations for what could be accomplished through surgical correction of the rocker bottom foot and near normal anatomic relationships can be restored with the procedure.[11-13]

As the technique was first developed, standard orthopaedic bone screws were used. These first-generation devices were originally developed to be mechanically optimized for pull out strength and often proved inadequate in fatigue strength under bending loads to allow for complete healing of the fusions when applied as beams for the Charcot patient. Cannulated hip screws in diameters up to 8mm were used, but also suffered from implant breakage. (Fig 2b, c, d) Smaller diameter screws necessary for the lesser metatarsals suffered from fatigue failure as well, and were simply not long enough to span the distances required. First generation implants also suffered from the inability to achieve adequate compression at the fusion site due to the significant osteoporosis associated with Charcot foot disease.

The shortcomings of the standard orthopedic beams have led to the development of several next generation implants. These implant systems carry an FDA clearance for use specifically in the Charcot patient. While they have evolved to provide increased lengths, the necessary design features to prevent critical fatigue failure of the implant are still less than optimal. [1, 14]

Non-cannulated implants were developed in order to try to improve strength, but are technically demanding to use since they do not allow for provisional fixation of the deformity prior to application of the device. In addition, removal of these non-cannulated implants after failure can lead to massive bone destruction if infection develops.

Early fatigue failure leading to non-union, loss of correction and recurrence of deformity (Figure 2a) continues to be a concern with many of the currently available systems. The implant systems designed for the Charcot patient population must address the healing limitations these patients experience: osteoporotic bone, fragmented or avascular bone, as well delayed healing co-morbidities. Compression with these devices continues to be an issue and is often minimal. Hardware migration remains a common occurrence.

Figure 2a

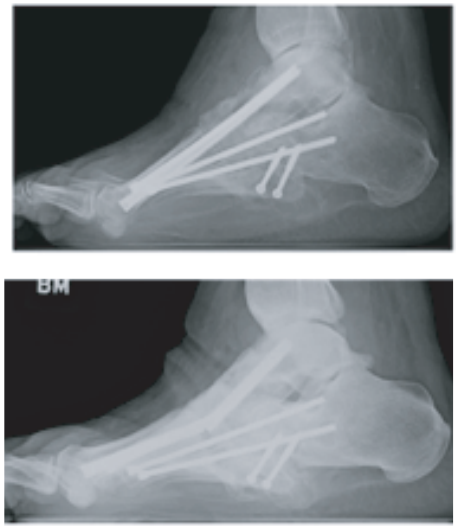

Figure 2a: Fatigue failure of a competitive beaming device 2 months after weight bearing initiated. Eventual loss of correction led to revision fixation and bone grafting.

Figure 2b

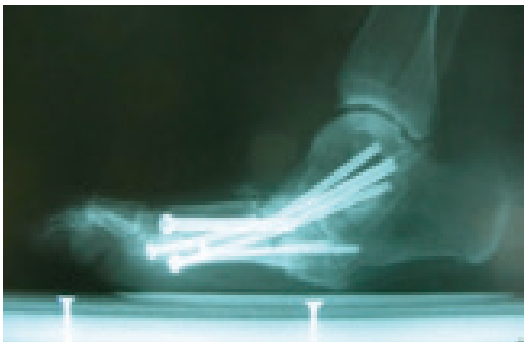

Figure 2c

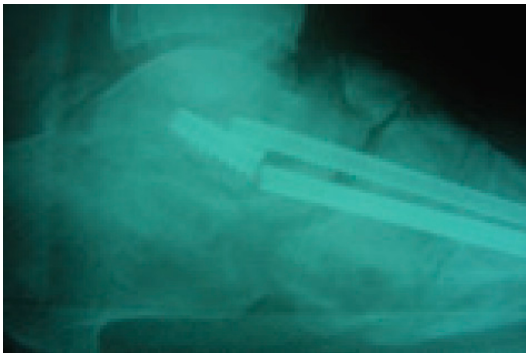

Figure 2d

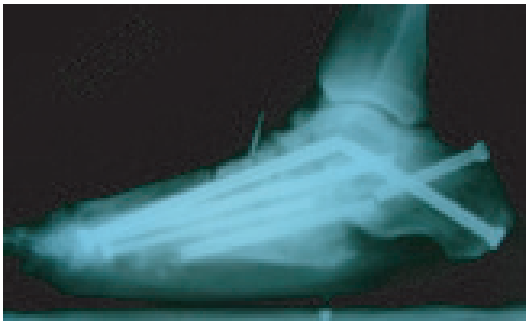

Figure 2b, c & d: Examples of 1st generation beaming screws that have failed though cyclic loading prior to complete arthrodesis.

A Novel Design for Real World Tasks.

The Axis system was developed to address the strength, compression, and hardware migration issues of the earlier generation beams. This comprehensive beaming system is characterized by the following features:

1. The implants are designed to resolve stress risers found in earlier devices which improve strength and fatigue resistance to a bending moment.
2. The implants are designed to offer rigid compression of the fusion site to promote osseous healing.
3. The implants are designed to prevent migration.
4. Specialized instrumentation is available to facilitate reduction and implant application through smaller exposures.
5. Specialized removal instrumentation is available to facilitate hardware removal when necessary.

AXIS Beam and X-Clip Design Rationale

X-Clip designed to add compression and prevent implant migration

The X-Clip device was created to address two critical issues for clinical success in achieving arthrodesis using a beaming construct – the inability to achieve adequate compression at the fusion site due to the significant osteoporosis associated with Charcot foot disease, and hardware migration. Hardware migration has proven to be a common source of failure for these procedures for all previous generation devices using this technique and can result in serious consequences. (Figure 3)

Figure 3

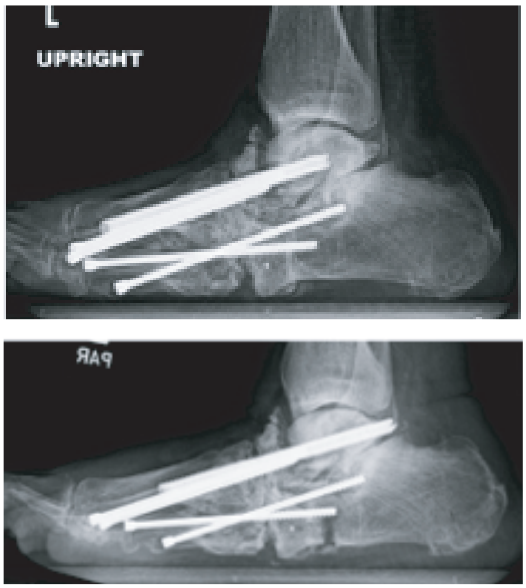

Figure 3: Post-operative radiographs at 3 and 5 months showing the migration of fully threaded cannulated screw in medial column posteriorly into the retrotalar space. Impingement of neurovascular structures is of concern in this area.

The X-Clip was designed as an intra-osseous open-ended "nut." (Figure 4) It engages the screw threads allowing a metal on metal interface, thus dramatically increasing the compressive forces generated by the screw along its length. In addition, by engaging the screw threads, additional and more rigid points of bone contact are created, decreasing the tendency of loosening and migration of the device. An additional benefit is a decreased cut-out potential when the screw placement is near the cortex of a bone, since the X-Clip contains the screw within the bone on three sides.

Figure 4

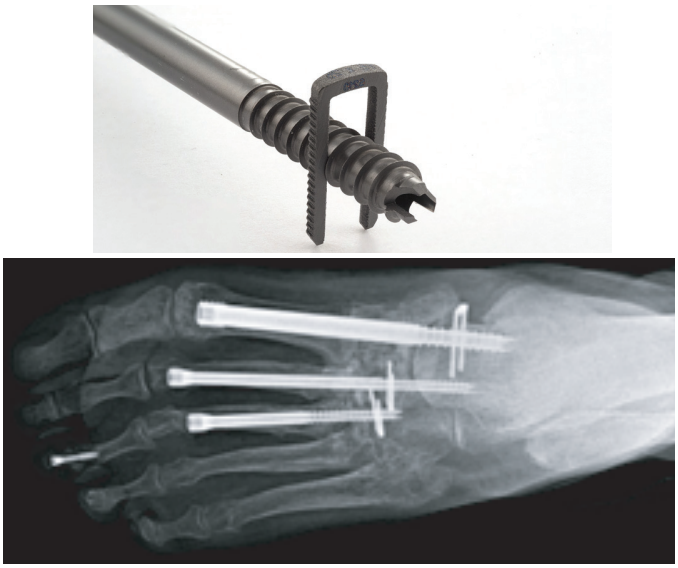

Figure 4: The X-Clip fixes to the distal end of the AXIS beam with the smooth inner tines measured to the inner diameter of the beam and the outer serrated edges designed to rigidly fix within bone.

Greater Beam Strength

One approach to improve beam strength has been to use a non-cannulated device. For any given diameter, a solid beam would have higher bending yield and ultimate loads compared to a cannulated beam due to the increased bending moment of inertia. Cannulated beam systems, however, dramatically improve the surgeon's ability to achieve the alignment goals necessary for a successful outcome. Charcot foot deformity correction surgeries are technically demanding, and the use of guide wires allows the surgeon to provisionally fix and check the alignment of each column during reduction of the deformity, which in turn reduces surgical time and improves success rates. Cannulated devices are also critical for use in mini-incision and percutaneous techniques that are now commonly performed. The AXIS beam was designed to maintain implant strength without sacrificing the functionality of cannulation. This was done by modifying the geometry (thread and shank) of the AXIS beam in a way to ensure its strength and fatigue resistance to bending moments.

In the clinical use of early devices, we noted a high rate of failure of the beams at the thread shank interface, and hypothesized that the transition zone from the screw shank created a stress riser that was prone to fatigue and ultimately device breakage. (Figure 5) Finite element analysis of existing competitive implants was used to evaluate surface von Mises stresses which verified this stress riser existed. (Figure 6a) The design of AXIS sought to eliminate this stress riser by modifying the thread transition zone.

Figure 5

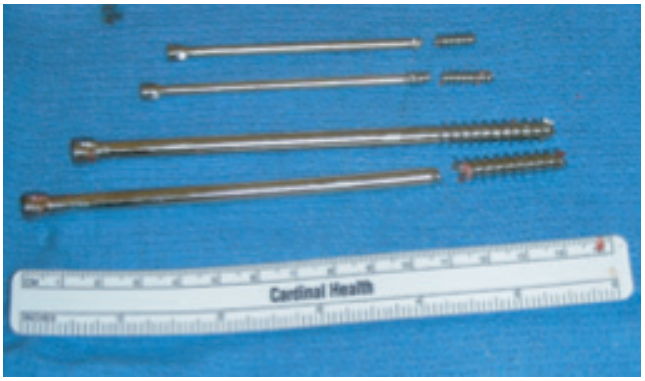

Figure 5: Broken Competitive headless compression screws retrieved from a patient with non-union and recurrence of deformity following beaming. Note that the three broken screws failed at the predicted stress riser near the thread transition from the shaft

To eliminate this critical stress riser, two proprietary design modifications are used:

1. A transition zone for the inner diameter of the beam threads was tapered from the start point of the threads to the tip. This taper allows for added beam wall thickness in the zone where stresses are highest without sacrificing bolt thread length.
2. A parabolic thread pattern was created which increases the amount of metal on the leading edge of the screw thread, effectively adding additional wall diameter between threads. (Figure 6 & 6a)

Figure 6

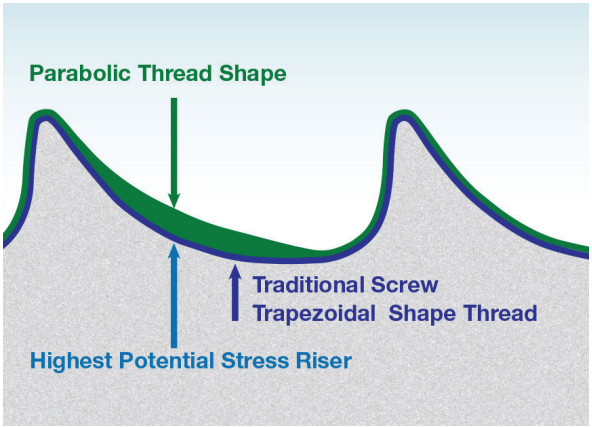

Figure 6: AXIS parabolic thread shape compared to traditional, third generation beam thread pattern. More material is present in the leading edge of the thread reinforcing the area where the greatest stress occurs.

Figure 6a

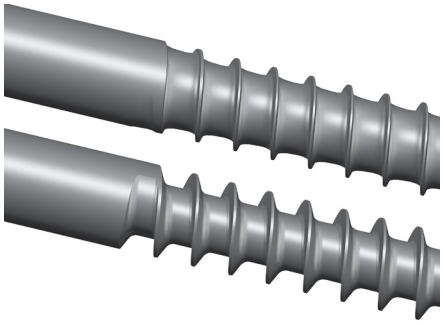

Figure 6a: Images of the AXIS 6.5mm cannulated implant (top) and the leading competitor 6.5mm solid bolt (bottom) illustrate the differences between inner and outer diameters of the threaded portion and the shank-thread transition zone.

Mechanical Performance Test Methods*

The comparison of medical devices requires rigid adherence to federal guidelines for mechanical testing (ASTM testing methods are based on device intent) as well as other benchtop investigations with which to determine the performance characteristics of devices that may also include additional components. For the current evaluation of the Extremity Medical AXIS 6.5 mm cannulated beam and the 7.0 mm cannulated testing beam from a leading competitor, the ASTM Standard ASTM F382-17 for static (single load to failure) and dynamic (cyclic loading to cycle survival [runout]) was followed for 4-point bending.

For static loading tests, beams for each type of implant were loaded in displacement control at 25.4mm/min until plastic deformation of the implant. Three samples (n=3) were tested during static loading for each type of implant, analyzing mechanical performance for such variables as yield bending strength (N-m), ultimate bending strength (N-m), bending stiffness (N/mm), bending structural stiffness (N-mm2), yield load (N) and ultimate load (N). The static performance testing for yield and ultimate load further dictate subsequent testing and the initial loading start point for dynamic testing per the ASTM standard.

For dynamic loading tests, sinusoidal loading curves were applied to each construct at 5Hz with a load ratio of 10 (i.e.: max load = 250N, min load = 25N). Constructs were loaded at varying load ratios to understand the life cycle survivability of each implant at greater and greater loads. Three samples (n=3) were tested during dynamic loading for each construct until structural failure or a fatigue run out criteria of 1,000,000 cycles were reached (per ASTM F382-17). Data were collected for load ratio input under load control (N), number of cycles completed (cycles) and failure characterization. A finite element analysis (FEA) was also conducted between the AXIS 6.5mm cannulated beam and competitive 6.5mm solid beam to better characterize the surface von Mises stresses (mPa) associated with each implant under identical loading scenarios with specific emphasis placed on the shank to

**Data on file at Extremity Medical*

thread transition zone. The surface von Mises stresses were calculated utilizing the ANSYS structural analysis package for strength analysis (ANSYS Co, Canonsburg, PA). The maximum von Mises stresses were then compared as a percentage of maximum of the competitive 6.5mm solid beam to the AXIS 6.5mm cannulated beam (competitive Stressmax/AXIS Beam Stressmax). Structural analyses were also completed on the bending moment of inertia for AXIS and a leading competitive device with a Charcot indication.

Finally, comparative tests were conducted between constructs instrumented with the AXIS beam alone and the AXIS beam with the X-Clip engaged for fixation. The construct setup involved a 5pcf foam block (representing osteoporotic bone, per Sawbones, Inc, Vashon Island, WA) to represent the proximal fixation area and a pre-drilled polyethylene cylinder to represent the distal anatomy containing the beam shank.

During insertion for both constructs, devices were passed through a compression only donut load cell (Futek Inc, Irvine, CA) to capture compressive loading while the implants were delivered between the two block constructs. In addition, the insertion torque during implant delivery was captured with a Mark-10 torque insertion meter (Mark-10, Copiague, NY). Data was collected at 10Hz for device compression (N) during torsional insertion and maximum insertion torque (N-m) when inserted with the AXIS beam alone and when supplemented with the X-Clip. These data were compared with a one-way ANOVA ($p<0.05$). In addition, the pullout strength (N) between both types of implant techniques was also evaluated using a single, ramped displacement test to failure utilizing a Pullout Gauge Fixture (Mark-10, Copiague, NY). Pullout forces (N) for each type of implant were compared using a one-way ANOVA ($p<0.05$).

Comparative Mechanical Performance Test Results

Static Testing

The complete tabulated data from the static performance testing per ASTM238-17 are shown below in Table 1. All measured data points for construct mechanical strength were found to be statistically greater for the AXIS system beam than for the predicate (all values $p<0.0001$). Failures modes for both implant types were permanent deformation of the beam. Load-displacement curves for each beam are shown in Figure 7.

Table 1

TABLE 1: MECHANICAL TESTING PERFORMANCE PER ASTM 238-17 BETWEEN A COMPETITIVE BEAM AND AXIS BEAM						
	Yield Bending Strength (N-m)	Ultimate Bending Strength (N-m)	Bending Stifness (N-m)	Bending Structural Stifness (N-m)	Yield Load (N)	Ultimate Load (N)
Competitive 7.0 mm cannulated beam						
Mean	10.10	18.51	91.67	2446390.67	505.00	925.33
SD	0.50	0.66	0.58	15687.17	25.36	32.81
AXIS 6.5mm cannulated beam						
Mean	29.22	46.21	315.00	8394044.00	1461.00	2310.67
SD	0.03	1.01	1.00	20724.58	1.73	50.50
ANOVA Result ($p<0.05$)	0.00	0.00	0.00	0.00	0.00	0.00

Figure 7: Load Displacement

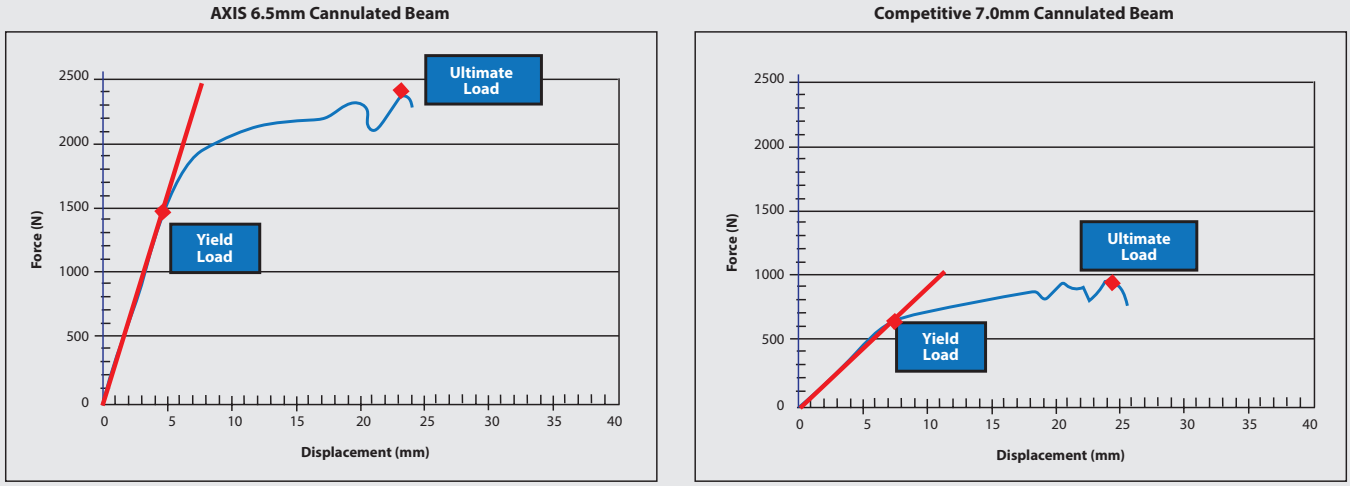

Figure 7: The red line represents the calculated stiffness (N/mm). Note: the 6.5mm Axis beam has a 182% increased yield load, and 150% increased ultimate load over the 7.0mm competitive beam.

Dynamic Testing

Data for dynamic (cyclic) testing at increasing 4-point bending loads demonstrated complete full cycle (1 million cycles per ASTM238-17) for the AXIS system with loads beginning at 750N and ending at 1,150N (Table 2 & Figure 8). For the competitive system, cyclical load testing began at a lower input load (450N) than for the Axis beams per the ASTM standard for initiating dynamic loads based on its lower static testing performance. Construct failure in the competitive beam was observed at 750N after 21,000 cycles. This 750N load was the starting cyclic load limit for the AXIS system based on its own static testing performance results. Examples of dynamic failure modes are shown in Figure 9.

Table 2

TABLE 2: DYNAMIC MECHANICAL TESTING PERFORMANCE BETWEEN A COMPETITIVE BEAM AND AXIS BEAM		
Competitive 7.0 mm cannulated beam	4pt Bending Load (N)	Cycle Count (n)
Sample 1	450	1,000,000
Sample 2	500	1,000,000
Sample 3	750	Failure @ 21,002
AXIS 6.5 MM cannulated beam	4pt Bending Load (N)	Cycle Count (n)
Sample 1	750	1,000,000
Sample 2	950	1,000,000
Sample 3	1150	1,000,000

Note that the starting load for the AXIS 6.5mm beam is equal to the failure load for the competitive 7.0mm Beam

Figure 8: Cyclic Loading (4 Point Bend)

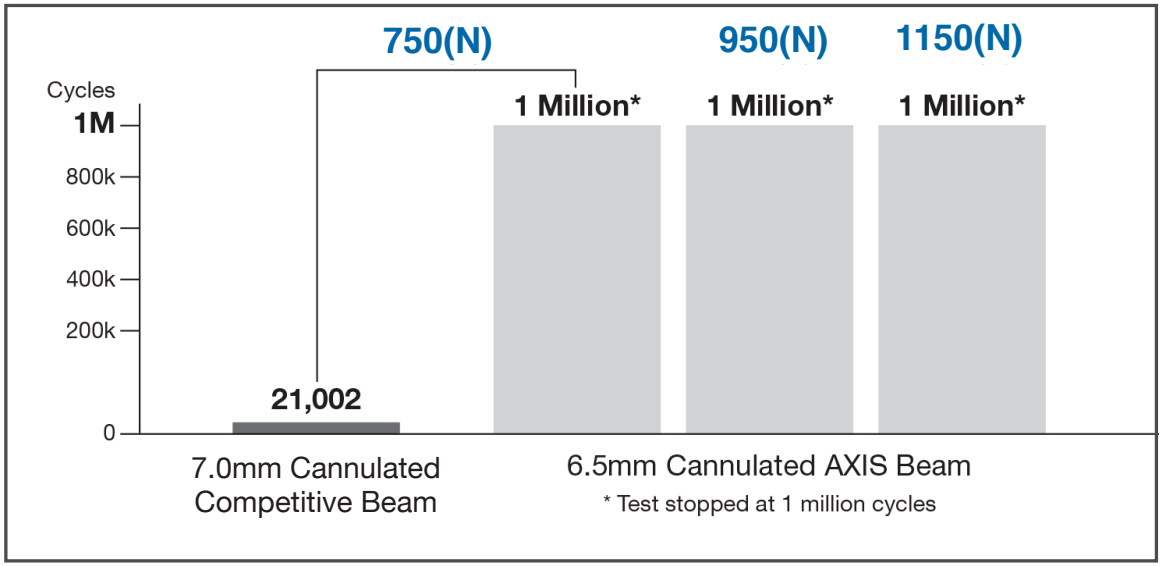

Figure 8: The AXIS beams demonstrated forty-seven times more the fatigue life than the competitive beams at 750(N). The AXIS beams also survived 1,000,000 cycle runouts at higher loads: 950 (N), and 1,150 (N).

Figure 9

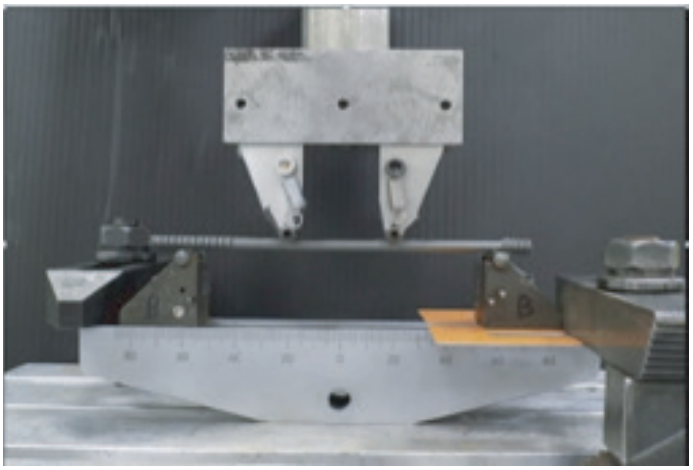

Figure 9: Example of the 4-point bending apparatus utilized for both static and dynamic bending tests between the AXIS system and the competitive system. Dimensions for inner loading distances and outer support distances are consistent with ASTM F382-17.

Figure 9a

Figure 9a: Example of fatigue fracture of 7.0mm competitive beam @ 21,000 cycles (750 N).

Figure 9b

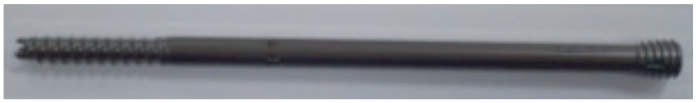

Figure 9b: Example of a complete run out of 1,000,000 cycles for the 6.5mm AXIS beam (750 N).

Computational Evaluation

From the FEA evaluation, the AXIS system was found to have a 39% reduction in maximum surface von Mises stress (MPa) compared to the competitive implant. This 39% reduction in surface stress would indicate a lower likelihood of fatigue fracture. The maximum stress risers for both implants were located at the shank to thread transition zone. The maximum von Mises stresses were found to be on the tensile aspect for each type of implant. (Figure 10).

For clarity in identifying this computational comparison, the von Mises stress legend indicates that higher stresses are depicted from going from blue (low) to red (high). The computational comparison demonstrates the differences in magnitude of stresses as well as the location within which these stresses occur.

Figure 10

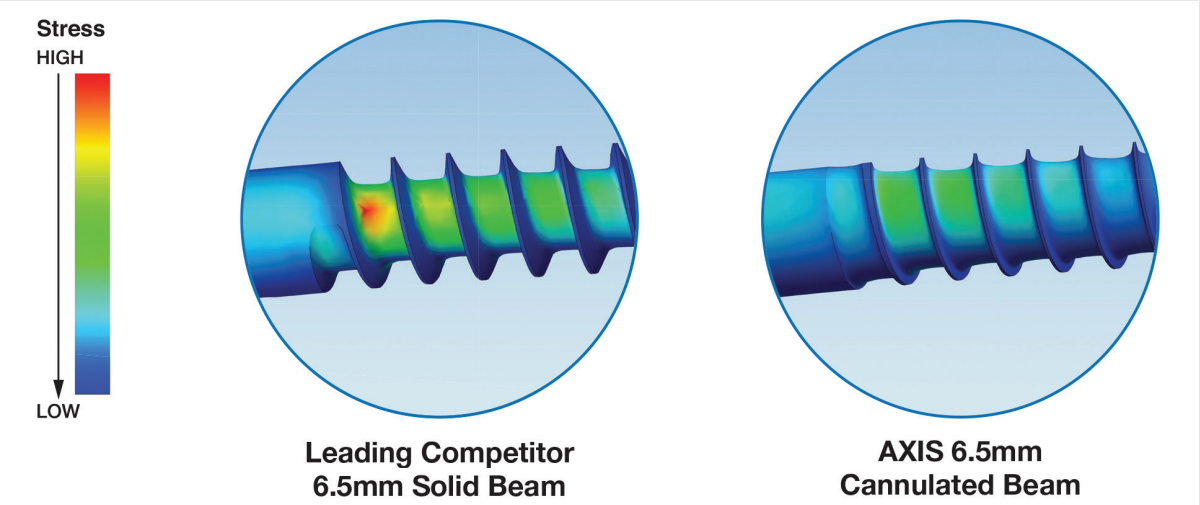

Figure 10: Finite element analysis of AXIS 6.5mm cannulated implant and the competitive 6.5mm solid implant showed a significant reduction in surface stress for the AXIS cannulated beam. Red indicates area of a potential stress riser at the thread transition from the shaft.

Pullout Testing

The mechanical results from the pullout testing of the AXIS beam when used with and without the X-Clip demonstrated a significantly greater axial pullout strength ($p<0.004$) when the X-Clip was utilized (Figure 11).

Figure 11

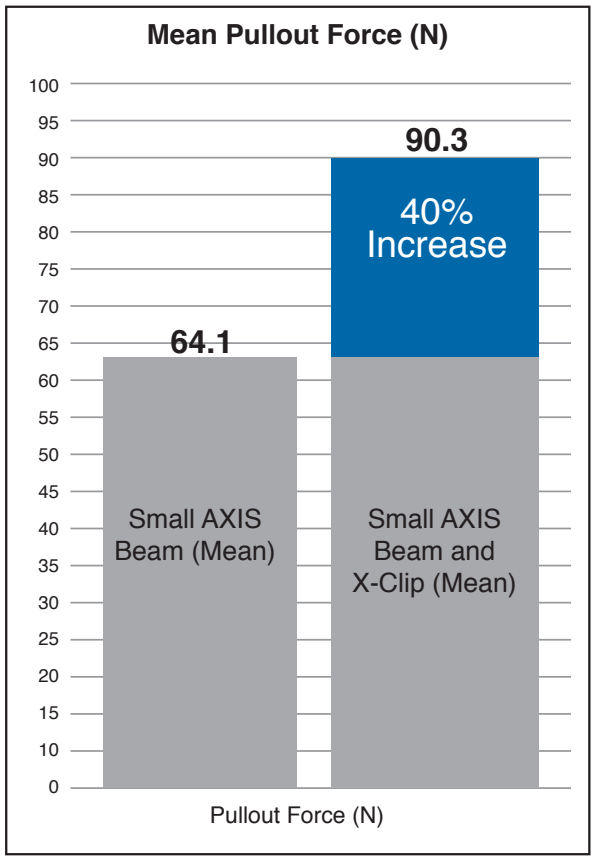

Figure 11: Axial pullout forces for the AXIS beam system when used with and without the X-Clip supplementary fixation device. Note: The AXIS beam/ X-Clip construct provided 40% additional pull-out strength versus the beam alone

Insertion Torque

Data for maximum axial compression and insertion torque when delivering the AXIS beam implant with and without the optional X-Clip are shown in Figure 12. The beam/ X-Clip construct provided greater maximum compression and torque during insertion when compared to the beam only. It also demonstrated the ability to maintain compression force as the screw was advanced past its maximum insertion torque.

Figure 12

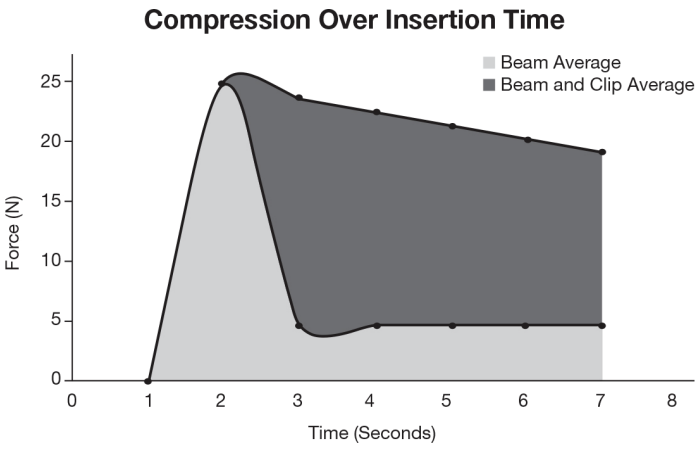

Figure 12: Illustrates the X-Clips ability to maintain compression with the advancement of the beam. The AXIS beam/X-Clip construct essentially acts as a "nut & bolt" and limits screw strip-out.

Discussion

Management of Charcot deformities represents a complex array of issues raging from diabetes, obesity and non-compliance to therapeutic efforts. Surgical reconstruction of the foot combined with arthrodesis has become more successful as new techniques and implants are developed to address the problems associated with surgery in these patients. Axial fixation or "beaming" of these deformities has evolved to become one of the more successful techniques; however, fatigue failure of the devices, migration of implants and poor compression in osteoporotic bone still make non-union and loss of correction problematic long term.

Implant fatigue resistance is of critical importance. Bolts, screws and beams not specifically engineered to handle the loading demands specific to the Charcot patient population are prone to failure. Many surgical cases require the beam to be passed from the metatarsals to the calcaneus and talus. Beams spanning the entire medial column historically have a high failure rate. The AXIS beams were specifically designed to improve fatigue resistance and to eliminate the stress risers associated with existing Charcot products. The smallest diameter medial column AXIS beam (6.5mm) was compared to a large diameter competitive beam (7.0mm) to ensure that the improved strength was not simply related to a larger diameter device.

It is clear from the mechanical testing done in this study that the design modifications in the AXIS beam geometry have created a much stronger device. Static testing showed the 6.5mm AXIS beam to have a Yield Strength and Yield Load which were both 2.89 times the value of the larger 7.0mm competitive beam. In addition, the 6.5mm AXIS beam was much stiffer and stronger than the 7.0mm competitive beam: both the Bending Structural Stiffness and the Ultimate

Bending Strength were 3.4 times greater for the AXIS beam than for the larger diameter competitive device. The ultimate load of the AXIS beam was 2.50 times that of the competitive beam tested.

Metal implants must support the patient during the period of bone healing or they will fail. As shown above, the cyclic loading of both beams at 750N (approximating a ~170-pound individual) indicate a better stabilization method using AXIS compared to competitive beams which failed early in the cyclic testing (~21k cycle).

It should be further noted that the runout testing for the AXIS system at 1150N (approximating a person of nearly 270 pounds) achieved more than 1 million cycles without signs of fatigue fracture or other structural changes. This data implies that for a person weighing 170lbs, and walking 2,500 steps per day per foot, that the larger diameter competitive beam (7.0mm) would be predicted to fail in only 8.4 days, as compared to the smallest medial column beam in the AXIS system (6.5mm) which would be predicted to last at least 410 days in a person weighing 270lbs.

Compression across bone fusion sites improves fixation, stability and encourages osseous healing by eliminating motion through the fusion site and by creating direct bone to bone contact for primary healing. Compression using beaming devices techniques relies on thread purchase in bone. In good quality bone, simple screw and bolt threads may be all that are needed. Charcot foot disease, however, is associated with poor quality bone that is osteoporotic, fibrotic and avascular. Compressive forces generated through screw thread / bone interface in this compromised bone is often minimal and often inadequate to achieve the desired stability. The X-Clip (intraosseous nut) was shown to improve the fusion construct by achieving thread purchase directly though metal on metal contact. The X-Clip essentially converts the AXIS beam into an intra-osseous "nut and bolt" construct. The X-Clip engages the screw threads directly and spreads the compressive force across a much larger surface area of bone. In this study, the addition of the X-Clip significantly increased both pull out strength and compressive force at the model fusion site. The significant increase in torque during compression demonstrates the improvement in thread engagement created by the metal on metal interface. Clinically, the X-Clip may also act to contain the beam within the bone, preventing implant cut out which can occur with osteoporosis. We also hypothesize that implant migration will be diminished in the clinical setting with the tapered thread design of the bolt as it engages the X-Clip. It is worth noting that in addition to the improved material properties, the AXIS system includes instruments designed to improve the surgeon's ability to accurately apply the beams and X-Clip devices. These instruments also facilitate percutaneous reduction of deformity. Cannulated awls for guide wires are useful for application of the guide wires into the metatarsal shafts and into the posterior talus. The X-Clip targeting guide allows for accurate percutaneous application of the X-Clip. In the event a beam needs to be removed, the heads of the beams are captured and can be threaded into the removal driver to facilitate extraction.

Conclusion

The AXIS beams are designed for improved strength which is achieved through thread design, shaft thread transitioning, and shaft size. Improved strength was verified through computer analysis using finite element analysis and through both static and fatigue mechanical testing comparing the beam to a comparable device of larger diameter. The proprietary X-Clip significantly improves mechanical performance in an osteoporotic bone model, essentially creating an intra-osseous "nut and bolt" construct that is capable of creating high compressive forces and significantly improving pull out resistance. These improvements are designed to address the primary modes of failure of predicate devices used in beaming techniques for Charcot foot reconstruction.

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