

# Sustained Dynamic Compression Device Provides Continuous Compression in the Setting of Bone Resorption Following Arthrodesis in an Ovine Model

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**INTRODUCTION:** Charcot neuroarthropathy (CN) is an often painless, progressive, inflammatory, destructive degenerative disease of the midfoot and ankle characterized by joint dislocations and fractures, eventually leading to deformities of the foot. Currently, surgical intervention for CN involves placing intramedullary (IM) devices (solid or cannulated bolts or screws) from the metatarsals to the hindfoot in a technique called “beaming” of the medial and lateral columns to apply compression, stabilize, and realign the foot. Unfortunately, during weight bearing, these beaming screws undergo repetitive and significant compressive, tensile, and bending loading, resulting in loss of compression and failure in 25-60% of implanted devices. To improve surgical outcomes in these challenging patient populations, a device capable of applying sustained dynamic compression (SDC) for use in midfoot fusion was designed. The device described in this work utilizes a superelastic material, NiTiNOL, to enable sustained dynamic compression of bony segments when challenged with bone resorption and/or joint settling. Specifically, the NiTiNOL element used in this device is inserted in a “stretched” condition and is capable of adapting to ~4mm of bone change. While similar devices have been implemented clinically in tibiotalar calcaneal fusion and shown quicker time to fusion and increased success rates in challenging patients, the mechanobiological process of resulting fusion aided by these devices in CN patients remains to be determined. Here, the authors first explore biomechanical performance of novel NiTiNOL-containing device that maintains sustained dynamic compression (SDC) when challenged with resorption, a feature intended to effectively stabilize the foot and thus preserve limbs in the diabetic CN population. Then preliminary results of a large animal model were conducted to explore the healing process using the dynamic device. This study aims to analyze the biomechanical performance of dynamic IM devices compared to static IM devices for midfoot arthrodesis and investigate the ability of a dynamic compression IM nail to stimulate fusion across tarsal joints in an ovine model.

**METHODS:** A total of 32 skeletally mature Rambouillet Cross ewes were evenly split into four groups: (1) reduced bone quality treated with static device, (2) reduced bone quality treated with SDC device, (3) standard bone quality treated with static device, and (4) standard bone quality treated with SDC device. In the half of the sheep that were allocated to the reduced bone quality group, a previously established model of reduced bone quality was implemented by applying an external fixator to one hindlimb for four weeks prior to arthrodesis procedure. This fixator allowed the unloading of the calcaneus-tarsus-metatarsus bony segments, which has previously demonstrated 29% reduction in bone mineral density. The midfoot fusion procedure was performed on all sheep, with 100mm IM devices placed through the calcaneus, tarsus, and metatarsus bones per device manufacturer’s instructions. Serial radiographs were taken in vivo every four weeks to track bone resorption and/or joint settling as indicated by distance the SDC device had retracted. Animals were sacrificed at 8-months (n=8/group) following device implantation under Colorado State University Animal Care and Use Committee – Approval No. #1199). Following euthanasia and fine dissection, calcaneus-tarsus-metatarsus constructs containing the device underwent four-point bending testing, microCT analysis, and both static and dynamic histomorphometry analyses.

**RESULTS SECTION:** The simulated resorption distance of the static device (0.54±0.07mm) was significantly lower than the simulated resorption distance of the dynamic device (6.8±0.44mm) (p<0.01). In vivo radiographic assessment of bone resorption/joint settling revealed no significant differences in resorption distances between bone quality across all timepoints (p≥.40). Specifically, 63.3% (0.99 mm) and 52.3% (1.14 mm) of total bone resorption / joint settling occurred in the first two months following implantation in the reduced and standard bone quality groups, respectively. At the end of the 8-month study period, the normal and depleted bone quality samples exhibited 2.2 and 1.6 mm of total resorption, respectively (p=.40). Biomechanical four point bending of treated calcaneus-tarsus-metatarsus constructs did not reveal significant differences in construct stiffnesses between static and SDC devices (p=0.21) or bone quality (0.25). MicroCT assessments revealed a significant increase in arthrodesis bone volume fraction (p=.036) and mean density bone volume (p=.041) in the SDC group as compared to the static group across both surgical models.

**DISCUSSION:** These data illustrate that even if initial joint compression during arthrodesis procedures is adequately applied, bone resorption of less than 1 mm will eliminate all compressive force when using static fixation hardware. As sufficient and continued interfragmentary compression is requisite for positive joint fusion outcomes, these data highlight the benefit of this SDC device to apply continued compression in this clinically challenging situation. This capability was confirmed by the in vivo measurements of SDC device movement, which again illustrated the ability of the SDC device to apply continued compression when challenged with bone resorption/joint settling. Furthermore, the calcaneus-tarsus-metatarsus-device constructs treated with SDC and traditional static devices exhibited similar biomechanical stiffness values, confirming the SDC device can produce the requisite immediate postoperative structural properties. Furthermore, the benefit of continuous compression on multiple segment arthrodesis is illustrated by these microCT data. These benchtop and preliminary data highlight the capability of a SDC device to compensate for bony resorption/joint settling in a multiple segment arthrodesis procedure for patients with both good and poor bone quality.

**SIGNIFICANCE/CLINICAL RELEVANCE:** This novel device provides a much-needed solution to treat CN in at-risk diabetic patients, positively impacting patient mobility and quality of life.

