New Horizons in Spine Treatment

SPRING 2013
The Annual Meeting of the North American Spine Society has always provided the perfect backdrop for original ideas and novel products, and supported a forum for creative exchange. This past year’s NASS meeting in Dallas, TX did not disappoint those looking for innovation. One product in particular that garnered a lot of attention was the 4WEB Spinal Truss System. The cage was conceived by Jessee Hunt and initially developed as a device that would provide structural support for interbody fusion. Its open configuration was designed to sustain strength without impeding or restricting the potential for bone to grow into and through the implant. It is believed that by doing so, this new device would enable greater bone formation and fusion without compromising initial healing or mechanical support (Figure 1). Modeled from a truss structure, the inherent design goal was to extend the strain to the margins of the construct and reduce the concentration of forces at the surface of the implant in contact with the bony endplates—essentially dissipating load broadly across the entire surface (Figure 2).

It has been known for some time that distribution and dissipation of stress are the hallmarks of bone remodeling. In that light, this device represents a unique foray into applied design that integrates the strength inherent to truss geometry, the architecture of static distribution force, and the dynamics of bone remodeling as a fresh therapeutic approach to spine surgery. Recent advances in engineering technology (additive fabrication in particular) have aligned, and a new potential for complex and intricate designs and structures previously unavailable to medical manufacturing has emerged. The 4WEB Truss Implant Technology represents a first opportunity to view that technology in a clinical application. A final design was evaluated and optimized by Lisa Ferrara, Ph.D. (OrthoKinetic Technologies, LLC, Southport, NC) that would effectively minimize the material and maximize the distribution of strain—her guidance defining lateralization of force and reduction of subsidence risk as an integrated facet of the process. The 4WEB truss was fabricated from medical grade titanium alloy using Electron Beam Welding, conferring a rigid truss structure that was subsequently validated for strength, stress, and strain distribution.

The 4WEB Spinal Truss System was subjected to a number of rigorous tests including finite element analysis, subsidence and mechanical performance evaluation, as well as a 12-month large animal study. Even with the greatest confidence in product design, sometimes it is not possible to anticipate the serendip-
ity of biologic translation. Working with Peggy Lalor, Ph.D. (Histion, Inc., Everett, WA), a respected authority of bone pathology, Jessee was on pins and needles waiting for the histology results. Her remark of never having seen such profuse filling of an interbody spine fusion device filled with autograft at 3-months increased the excitement surrounding this technology. Several additional independent reviews and positive clinical reception from all physicians who have had the chance to interpret the histology, and an expedited review and clearance by FDA of the devices for clinical use as an ALIF for lumbar spine fusion, and more recently as a cervical fusion device validate the animal study results.

Assessments of the bone histology from the preclinical model offered insight into bone remodeling that under-anticipated the implications of the design. In an effort to lessen stress shielding, the 4WEB Spinal Truss System accentuated load sharing while hastening structural bone constructs that interfaced and accepted the truss load. Unprecedented amounts of bone were deposited throughout the cage that resulted in an integrated fusion mass throughout the cage.

The 4WEB Spinal Truss System—Load Transfer Design

The open web design increases volume for bone deposition, and at the same time, provides tensile struts that facilitate apposition. These effects were collaterally efficient, assuring biomechanical support analogous to rebar in cement and stimulating an osteogenic response via a load transfer mechanism. Wolf’s Law describes the nature in which bone remodels, stating that bone in a healthy person or animal will adapt to the loads it is placed under to reduce strain. If loading on a particular bone increases, the bone will remodel over time to resist strain associated with loading and translate the force in tension.

Recent advances in applied bone biomechanics define optimal structural cues that encourage or escort bone remodeling. Insight emerging from this field addresses the eventuality of material evolution and the appearance of structural synergy with load bearing, strain energy density, and resultant bone formation. The innovation of the 4WEB geometric design incorporates unique engineering concepts that integrate truss resolution from global loading potentials resulting in augmented bone formation with unique reciprocity and reliance on trajectory driven loading (Figure 3). Impressive about bone formation around the construct is that bone that formed both inside and outside the 4WEB Spinal Truss System is matched (Figures 4a and 4b). The bone image inside the cage has been rendered at higher magnification to demonstrate the lamellar bone structure on both sides of the truss.

**Figure 3.** Bone formation utilizing the 4WEB Spinal Truss System. Image courtesy of 4WEB, Inc.
The 4WEB Spinal Truss System—
Surface Topology

The additive fabrication process used to manufacture the intricate 4WEB design results in a fully fused solid that has a micro texture surface topology/energy that has been shown to guide mesenchymal stem cells toward an osteogenic lineage. Presented at the AAOS, and later published in *The Spine Journal*, an evaluation of acid-etched titanium alloy surfaces was reported to guide stem cell osteogenic differentiation. While the concept of surface topology triggering cell recognition and tissue differentiation is not a new concept, the 4WEB design maximizes this mechanical asset by providing the microstructure to all of the struts that run throughout the bone implant construct rather than restricting the surface topology to select contact surfaces seen in predicate devices.

Summary

The 4WEB Spinal Truss System utilizes the geometric distribution provided in a truss design to redistribute axial loading vectors and exploit the generation of shear forces that accentuate bone formation. This bone formation is highly organized, stable, and hastens the deposition of structural lamellar bone in a very short time. Histopathological assessment did not reveal any evidence of hypertrophic cartilage formation, suggest instability, or provide any evidence of inflammatory changes in the marrow that might resonate with chronic reactive bone.

Finite element analysis shored up a basis for stress distribution that would minimize the likelihood of subsidence while accentuating the open structure that would allow bone to pass throughout the construct and integrate with the two adjacent cranial and caudal vertebral bodies. Topologic surface features of titanium struts mirrored roughness assessments that have been shown to actively promote osteoblast phenotype and reduce surface proliferation. The added enhancement of the additive fabrication technology contributed and correlated with the impressive quality and substantial quantity of bone that was seen within the devices tested in the large animal model.

Although the 4WEB Spinal Truss System has only recently received FDA clearance for ALIF and ACDF procedures, available clinical data suggests that reduced pain, accelerated return to function, and demonstrated bone production are hallmarks of the success of the device. The robust response demonstrated radiographically at 4 months provides confidence that fusion is accelerated and that the open structure of the system does not hamper clinical evaluation (Figure 5). Given the accelerated forma-
tion of bone and reduction of pain attendant to use of the 4Web geometry, perhaps the next consideration is then furthered by optimization of intent to achieve better clinical outcome, lessened patient morbidity, and demonstrated improvement in quality of life. Offering relief of pain, enhanced bone formation, and return to function, the 4WEB Spinal Truss System represents a tool affording a unique strategy for securing a stable fusion in treating degenerative disc disease.

**REFERENCE**


**Figure 5.** Radiographic evidence of fusion at 4 months after the cage was implanted. Images courtesy of 4WEB, Inc.

**Timothy Gainey, Ph.D.**

Tim Gainey is Director of Orthopaedic Research and Technology Development at the Atlanta Medical Center. He is also the recent President of co.don Tissue Engineering, a subsidiary of co.don AG. He has been published extensively in peer review journals and a lecturer at a variety of scientific meetings both domestically and overseas. Tim holds a B.S./B.A. degree at the University of Illinois and a Ph.D. degree at the University of South Florida. He is a member of eleven professional societies including the Orthopaedic Research Society and the American Association for the Advancement of the Sciences. He has also been honored by various professional and business organizations, most recently as the 2000 winner of the Outstanding Research Award, Sofamor-Danek Award, Australian Spine Society. Further, Tim is an Editorial Reviewer for industry publications including BioDrugs, Journal of Pediatric Orthopaedics, Tissue Engineering, Journal of Shoulder and Elbow Surgery.