

ORTHOPEDICS

Woven Orthopedic Technologies LLC

Biotextile strengthens screw fixation in compromised bone

One of the biggest challenges with orthopedic screws is inadequate fixation in poor quality bone, whereby screws and bone lose their fixation together. In fact, the revision rate of requiring a second surgery for loss of screw engagement is 15%. **Woven Orthopedic Technologies LLC** hopes to significantly reduce that rate with its braided polymer. Similar to placing a foot in a sock, the sleeve-like device is first placed into a screw hole with a screw subsequently inserted inside the polymer. The porosity of the weave and the various polymer elements allow for different configurations that create both some flexibility to adapt to the environment within the hole and good fixation within the entire bone.

In the short term, the Woven device increases the contact between the screw and the bone (radial surface area contact) by forging a three-dimensional interface. “Essentially, we produce enhanced friction, for more grip, and more contact points,” says company CEO Ilana Odess. This is in contrast to traditional screw placement, where the threads are the only part of the screw in contact with the bone, leaving valleys of open space. “We close those valleys with a uniquely manufactured woven polymer, so there is much more surface area and a better environment between the screw and the bone,” Odess explains. As a result, the fixation is more uniform, secure, stable and strong, and less susceptible to screw loosening.

Long term, the sleeve evenly distributes pressure (load) and enables positive remodeling, unlike standard screw technology that experiences bone resorption over time (bone migrates away from the screw). “Recent *in vivo* data of our polymer show extremely promising results in that the bone actually moves closer to the screw and grows within the construct,” Odess states.

Woven Orthopedics is targeting the aging population, those over the age of 50, initially for spine and trauma. “There are no

other technologies that are orthogeriatric specific,” Odess says. These patients tend to have compromised bone. Of the roughly 12 million spine and trauma fracture fixations performed globally each year, 5 million of them (40%) involve orthogeriatric patients, for an annual market opportunity of over \$4 billion for the device. CE mark is expected late 2016, followed by 510(k) De Novo in the second half of 2017.

The company’s technology is based on the intellectual property of Alexander Jones, founding member of the Denver Spine Institute in Colorado and now retired chief resident of orthopedic surgery at Johns Hopkins University. In the late 1990s, while an orthopedic surgeon with Denver Orthopedic Specialists, Jones performed emergency fracture fixation on a patient’s ankle, and experienced the common occurrence of poor screw engagement. Frustrated that there was not a readily available solution, Jones defined, planned and invented an interface to help protect screws from loosening during and after implantation. He created something for fixating the screw and the bone similar to wall anchors found in hardware stores.

“Dr. Jones envisioned using a fabric that wrapped around the screw to help achieve fixation in bone,” Odess recounts. However, he needed to find a group of business experts to help him build a company. That was left to Viscogliosi Brothers LLC, an orthopedic-specialty investment firm, which brought in Odess and Brandon Bendes, vice president of strategy and finance. Previously, Odess was co-founder and general manager of medical devices for Johnson & Johnson in Israel (1996–1999), held executive positions at Johnson & Johnson (1999–2002) and was president of Advanced Stent Technologies Inc. (2002–2005) until it was acquired by Boston Scientific Corp.

Woven has four issued and 17 pending patents, and will not be sharing any royalties/revenues with another entity.

The company’s simple solution adds

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Contact: Ilana Odess, CEO
Business: Braided polymer enhances screw engagement in orthogeriatric patients
Founded: March 2013
Founders: Viscogliosi Brothers LLC; Ilana Odess
Employees: 11
Financing To Date: \$7.8 million
Investors: Viscogliosi Brothers; Medical Screw Distributors; Orthopedic surgeons; Keiretsu Forum; Tech Coast Angels; Astia Angels; Private individuals
Board Of Directors: Anthony Viscogliosi (Viscogliosi Brothers); John Viscogliosi (Viscogliosi Brothers); J. Douglas Craft (Medicraft Inc.); David Helfet, MD (Hospital for Special Surgery [HSS], New York); Frank Cammisa Jr., MD (HSS); Ilana Odess

only one minor step to a typical fracture fixation procedure and takes a few seconds to implant per designated pilot hole. The surgeon still uses existing hardware (screws and plates). After the plate is applied over the fracture, the pilot holes are drilled to usual size. The Woven sleeve is then placed on an insertion mechanism, which is placed in the pilot hole to guide the surgeon in positioning the sleeve along the walls of the hole. The final step is the normal insertion of the screw in the hole.

The sleeve will be available in three diameter sizes: 2.5 mm, 3.5 mm and 6.5 mm, all in the same length that can be customized with a special cutting device. A surgeon may choose to use a separate sleeve with each screw, or with only select screws, depending on the quality of the bone, the anatomy and the decision of the surgeon. “Bone quality is extremely variable and surgeons can use our device in a customized range of applications,” says Bendes, a former strategic and mergers and acquisitions specialist in the health care space at Huron Consulting Group in the 2000s. He also worked at Viscogliosi Brothers from 2010 to 2013.

The Woven sleeve is a permanent implant, but the inserter may be disposable. Odess says there are no other products specifically designed to enhance screw fixation in compromised bone. “However, in cer-

tain cases, surgeons can improvise with ad hoc techniques like rescue screws or grafts (match-stick trick) that may improve fixation in certain cases,” she notes. “But these techniques are associated with significant risks, including additional fracture and high long-term loosening rates.”

Another advantage of the sleeve is that surgeons and hospitals do not need to go through a rigorous certification or training and education process, “so this helps

substantially shorten our time to market,” Odess says. Sales of the sleeve are expected to commence in Europe in late 2016 via a direct sales/distributor hybrid model. The selling price should be in the low hundreds of dollars and reimbursement will be covered under fixation codes in many countries. US sales should begin in late 2017, again using a hybrid sales model, perhaps in partnership with a manufacturer, distributor or supplier.

The company, one of *START-UP*'s picks for the 2015 A-List, has raised \$7.8 million to date through an ongoing Series A round that is expected to close by the end of 2015. (See “*The A-List: The Trend-Shaping Series A Financings Of 2015*” — *START-UP, January 2016.*) **SU**

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- Bob Kronemyer

An excerpt from “*The A-List: The Trend-Shaping Series A Financings Of 2015*” – *START-UP, January 2016.*

WOVEN ORTHOPEDIC TECHNOLOGIES

\$6.6m
INVESTORS:
 Viscoqliosi Bros.,
 Astia Angels, Keiretsu
 Forum, others

Innovations in orthopedic screw design frequently involve machining of the screw threads themselves, which means making a separate set of changes for each type and size screw. But when fixation problems arise in the operating room due to an irregular fit between fastener and bone, little can be done. March 2013 start-up Woven Orthopedic has taken a universal approach to this problem. It has created a biopolymer-based mesh-like cage that is inserted around screws during fixation procedures. The design features woven cross-sectional geometric patterns that enhance fixation properties by adapting to the combination of bone density at the bone surface and the shape of the fastener. By increasing surface area contact between the bone and screw, the device distributes load transfer to reduce loss of screw engagement and help with bone healing and remodeling.