

Uniquely Braided Polymer that enhances Screw Fixation in OrthoGeriatric Patients receiving Treatment for Fractures



Ilana Odess
Chief Executive Officer

“At Woven, we believe we are in the perfect place at the perfect time. We are focused on treating the aging, Orthogeriatric population while also addressing the shifting economics that affect the entire healthcare industry as a whole.”- Ilana Odess

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CEOCFO: Ms. Odess, would you tell us the focus at Woven Orthopedic Technologies?

Ms. Odess: Woven Orthopedics is focused on treating orthopedic conditions in the rapidly growing, aging population around the world. We call these patients, “Orthogeriatric” patients. Specifically, we enhance screw fixation in fracture treatment surgery performed on patients with compromised bone.

CEOCFO: What are you looking to provide?

Ms. Odess: We are a company that specializes in enhancing orthopedic screw fixation in compromised / poor quality bones. Today, fractures treated with surgery are treated using bone screws. Orthogeriatric patients, who typically have compromised / low-quality bone experience high rates of complications with those bone screws. Our purpose is to reduce the complications.

CEOCFO: How do you do this?

Ms. Odess: We have a specific braided material used to enhance the interface between a bone screw and bone much like a wall anchor enhances a screw’s ability to hold a screw inside of a wall in your house. After an individual fractures his bone, a patient may go into the hospital and receive surgery to fix the fracture. When the surgeon uses screws and plates, they would also use a Woven device to enhance the interface between the screw and the bone.

CEOCFO: *Are there other types of interfaces in use today or is this a novel concept?*

Ms. Odess: This is a novel concept. When surgeons operate on patients with compromised bone today, surgeons are forced to improvise and use ad-hoc solutions that may not be approved for that specific use, or carry larger risks and lead to other comorbidities. There are many limitations.

CEOCFO: *How does this interface work?*

Ms. Odess: The interface works in both the short term and long term by enhancing the surface area contact between the screw and the bone and by affecting the exchange of load between the screw and bone interface after surgery.

The first concept is rather simple but to help understand the importance of load exchange, you can think about the practice of using braces to straighten teeth in orthodontics. By exerting pressure on teeth in a certain direction, the boney tooth actually resorbs (dissolves) at one end and then remodels at the other end, effectively “moving” the tooth to an adjacent location. While that process is great for straightening teeth, it’s not so good if you’re trying to heal a fracture. In fracture treatment, screws and plates are implanted to create a stable environment so that bone can remodel in the same place and heal. Unfortunately, screws apply pressure to bone just like braces do to teeth. In many cases, bone will move away from the screws leading to potential pain and/or an unstable healing environment. Our device helps transfer load/pressure so that bone does not resorb away.

While the concepts are simple, the properties needed to create the correct interface between the screw and bone are very complex. The device must be durable enough to withstand human motion, safe to implant in bone, and flexible enough to provide the right pressure exchange, among other things. We believe we have achieved the optimal properties for both short-term and long-term efficacy. More specifically, we create an elastic, mechanical wedging, a three-dimensional interface, an elastic buffer, and a porous environment that promotes bone in-growth. Our animal studies show the effects. They’re even visible in histology and micro CT.

CEOCFO: *How did you decide to develop it for an interface in the way you describe?*

Ms. Odess: The idea came from a spine surgeon. While performing surgery one night, the surgeon was operating on an elderly patient and was unable to achieve fixation between screws and bone. Since it is very difficult to get a fracture to heal when you do not achieve screw fixation, the surgeon needed to find a way to help the patient. He came up with the novel idea, filed a patent, and then approached us to help start a business. The company was formed because we saw that this was a technology that could address a large unmet clinical need.

CEOCFO: *Where are you in the process of development and commercialization?*

Ms. Odess: We have finished the design phase, completed mechanical testing, and recently completed pre-clinical, animal studies. Our next milestone is to submit this to a European notified body and to the FDA for regulatory clearances. We anticipate submission in the second half of this year.

CEOCFO: *Would this come in different sizes, or what form will you eventually be selling?*

Ms. Odess: The device will be offered in 3 diameter sizes that fit most of the screw sizes available in the market. The devices will be sold in a kit that will include an inserter as well.

CEOCFO: *What have you learned so far in the testing?*

Ms. Oden: The test results for our device support the mechanism of action I described earlier and prove our effectiveness. The mechanical and animal tests show enhanced short-term strength, long-term strength, and bone ingrowth in a few different ways. The animal tests also demonstrate safety and functionality.

CEOCFO: *Is the Woven polymer permanently in the body or does it dissolve at some point?*

Ms. Odess: The polymer that we are using for our first generation device stays in the body. We don't want it to dissolve because it has characteristics that allow for bone-ingrowth. If it dissolved, we may risk losing that element.

CEOCFO: *How far will your July funding take you?*

Ms. Odess: We originally raised \$6.6 million but were over-subscribed. As a result, the board decided to increase the round by up to \$2 million last summer. The total Series A raise is \$8.6 million. Overall, the raise has funded us since 2013 and will take us through the summer of 2016.

CEOCFO: *What has been the reception from the medical community?*

Ms. Odess: We've had a phenomenal amount of support from the medical community so far. Before starting the business, we knew that to be successful, we would need to attract the people who knew the most about the clinical need. We spoke with surgeons who perform fracture fixation procedures, distributors who sell fixation devices, and suppliers who manufacture products in our industry. While we are not approved for sale yet, we have had these parties invest in our businesses which is a great testament to what we're trying to do.

The industry understands that loss of screw engagement is a problem. They also understand that in today's environment with Obamacare, we are moving towards a "treat for performance" model that would create an environment that not only affects patients but also physicians and hospitals for poor clinical outcomes. There has been a lot of understanding and a lot of support from surgeons and the industry thus far.

CEOCFO: *How will you be handling the business side?*

Ms. Odess: We are preparing to launch in Europe at the end of this year. We plan to sell the product by leveraging distributors as well as some of our internal staff on the ground. There is also a possibility that we will work with partners to commercialize. Unlike typical medical device companies, we believe we have an opportunity to partner with entities in three different verticals: manufacturers, suppliers, and/or distributors. What will be important at the beginning, as a stand-alone company, is to show strong penetration and adoption rates. By proving that surgeons will use our device, use it consistently, and use it in more and more cases, we hope to benefit the entire fixation process for patients.

In the first year, we plan to implement a controlled launch in Europe since we will have the regulatory CE Mark in Europe before FDA clearance in the US. We have selected three countries to start and will expand as adoption grows.

CEOFCO: *Why is Woven Orthopedic Technologies noteworthy?*

Ms. Odess: The aging population is a rapidly growing segment of our population. One out of five citizens in the US will be over 65 years old 2030. In countries like Japan, one out of three people are over the age of sixty. In the US, 10,000 people are enrolling in Medicare per day. With the incidence of compromised bone growing just as fast as the elderly population, the number of fractures and patients who need surgery to repair those fractures are going to explode. Right now, there are no solutions designed specifically for these patients. We are the first to offer an OrthoGeriatric-specific solution. In addition, the passing of Obamacare is transforming our industry model from a “pay-per-procedure” to a “pay for performance” model. Our solution helps patients, physicians, and providers provide better care and helps providers and policy makers avoid penalties and loss of reimbursement for reoperations and potential readmissions.

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Interview conducted by: Lynn Fosse, Senior Editor, CEOFCO Magazine

