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Exec Chat: Miach Orthopaedics Bullish On BEAR For Repairing, Not Replacing, Torn ACLs

by Marion Webb

Medtech Insight spoke with Martha Shadan, CEO of Miach Orthopaedics, about the company's marketing efforts for its US FDA-cleared BEAR implant for treating anterior cruciate ligament (ACL) tears, ongoing clinical trials, plans for the rest of the year, and highlights from the AAOS 2022 event.

Miach Orthopaedics' CEO Martha Shadan expressed excitement about surgeons' uptake of its now commercially available bio-engineered Bridge-Enhanced ACL Restoration, BEAR implant, designed to get patients with anterior cruciate ligament tears back on their feet and back to their sports faster post-surgery compared with standard ACL reconstruction.

Since Miach launched the BEAR implant this January, after receiving US Food and Drug Administration *de novo clearance* in December 2020, it significantly exceeded revenue expectations. Miach's revenues were up 400% in the first quarter compared with the prior quarter, and more than 300% above expected first-quarter revenues, Shadan told *Medtech Insight*. She declined to give revenue figures.

"What I can say is, we budget a certain number of physician users and were significantly above what we budgeted, as well as the repeat usage by surgeons is much higher than we had expected for the initial quarter," Shadan said.

Capt. Raquel Peat, director for the FDA's Center for Devices and Radiological Health's Office of Orthopedic Devices, noted at the time of the de novo clearance, "Torn ACLs are among the most common knee injuries in the US, but for years, treatment has been limited to ACL reconstruction, which can be quite invasive and typically requires using tendon or a combination of tendon and bone from other parts of the body, or obtained from a tissue bank, to complete the reconstruction." (Also see "*Start-Up Spotlight: Miach's BEAR Implant Helps Body Repair Torn*

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ACL" - Medtech Insight, 9 Oct, 2019.)

Unlike ACL reconstruction, which uses allograft, autograft or suture-only repair, the BEAR Implant is a resorbable implant made from bovine collagen and is secured via suture to bridge the gap between the torn ends of a patient's ACL. The patient's own blood is injected into the implant during the surgical implantation to form a device-protected clot that allows the body to heal. Within about eight weeks, the BEAR Implant is absorbed and replaced by the body's own tissue, the FDA said.

Source: Miach Orthopedics

The de novo clearance was based on a study of 65 patients receiving the BEAR Implant and a 35-member control group that was treated with ACL reconstruction using their own tendon from another part of the body. At two-year follow-up, patients who received the BEAR implant reported an average score of 88.6 and the control group reported an average score of 84.6 using the International Knee Documentation Committee (IKDC) Subjective Score, a questionnaire where patients rate symptoms including pain, stiffness, knee function and sports activity.

Shadan declined to give an exact number for how many patients have been implanted using the BEAR technique, but said it has been used in "several hundred" surgical procedures, including clinical study participants.

The BEAR Implant is currently being evaluated in two clinical studies: The *BEAR III study* will enroll 250 participants and aims to determine if age is a risk factor for a worse outcome after a bridge-enhanced ACL restoration as defined by an 11.5 point difference on the IKDC subjective score at two years post-surgery; the *BEAR Moon* study will enroll 200 participants and compare the BEAR procedure against ACL reconstruction using a bone-patellar tendon-bone graft.

To date, the privately held Westborough, MA-based company has raised $32m -- $22.5m in a series A financing and $9.5m in a bridge loan from insiders, Shadan said. Shadan hopes to raise another $30m in a series B financing round, which would carry the company to break even.

Shadan discusses below more details on the continued evaluation of the BEAR implant, their marketing plans for the US and beyond, and the rising role of digital technologies in orthopedics.

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MARTHA SHADAN, CEO OF MIACH ORTHOPAEDICS *Miach Orthopaedics*

[Shadan's answers have been slightly edited in the interest of length and clarity].

Medtech Insight: **What are the main objectives for the BEAR III trial and the BEAR Moon trial?**

Shadan: The BEAR Moon trial is a level one study that was initiated by a group of Moon facilities to further study the BEAR [procedure] against standard of care, and that's an NIH grant study. We are not involved in the day-to-day running [of the study], but as the manufacturer, we have responsibility to report to the FDA on safety. It's pretty much being run by the [six] Moon sites.

They don't normally do a comparison like this with a product, but there's high interest on their part in terms of the promise for BEAR compared to standard of care. All of our studies, except for the BEAR Moon study, we extended the follow-ups to six to 10 years. The two-year follow-up for BEAR III is expected in March of 2026 [which is] the same for the BEAR Moon study. We are six years out on BEAR I – those assessments are in process and six-year assessments in BEAR II are starting in April of this year. So, we have a long-term follow-up. The next assessment after the six will be 10 years. The BEAR Moon is only a two-year follow-up study. All BEAR studies have the two-year endpoint, six-year assessments and 10-year assessments. (Also see "*AAOS Results Recap: Stryker's Knee-Surgery Robot And Miach's New ACL Scaffold*" - Medtech Insight, 15 Mar, 2019.)

In addition to that, we will be initiating a registry called the Bridge registry, and that gets started in about a month to two months and that'll be 30 sites, 750 patients. The registry will track patient satisfaction, time back to driving, time back to work, time back to sport, time back to same level of sport. We will track pain scores, rate of contralateral tears and improvement in quality of life. Those are some of the bigger ones.

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Q **How does the BEAR procedure compare to currently available surgical treatment options?**

A Shadan: There is nothing like the BEAR [technique]. We are the first to clinically demonstrate that we can restore the patient's own ACL rather than replacing it. All the other technologies, even some that are emerging, they still rely on replacing the ACL, and we're the only one that restores the ACL for the broad majority of tear indications.

Q **What kind of education does the BEAR technique require versus using traditional ACL reconstruction?**

A Shadan: The procedure itself is very intuitive and straight-forward. The time to do the procedure is less than it would be to do an ACL reconstruction. And generally speaking, they [surgeons] rate it as being easier than what they're currently doing. And we're tracking that to make sure that what we're doing is helping the surgeon.

Q **What is the market opportunity for the BEAR implant?**

A Shadan: There are about 400,000 ACL injuries a year in the US and about 200,000 ACL reconstructions. We believe that we can treat any patient where ACL reconstruction is being used – both with autografts and allografts. In addition to that, we think that there's upside with the patients who aren't currently getting surgically treated where BEAR may potentially be used.

Q **How many patients with an ACL surgery choose not to get surgery?**

A Shadan: About 200,000. We believe about 50% of those could potentially be our patients. I think that they either don't want to get an allograft from a deceased donor, or they don't want to have a tendon harvested from one of their legs. And we don't require either of those. I think that has strong appeal. I think it's attractive to think about regenerating your own tissue rather than replacing it.

Q **A common consequence of ACL reconstruction surgery is premature**

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osteoarthritis (OA) of the knee. What is the outlook with the BEAR implant?

A Shadan: That's a great question. It is way too early for us to declare or to promote anything. We did have some promising results in animals, and that is the reason why we are following our patients six to 10 years to see if there is any [correlation] in humans. About 70% of patients who have had ACL reconstruction develop premature osteoarthritis ... it's very high. They don't develop the OA until many years later, but if you're 15 and you tear your ACL, by the time you're 35, you could have OA in that knee.

Q **What are your company plans for the rest of this year?**

A Shadan: We will be expanding our sales organization [from 11 reps to about two dozen reps], adding additional territories to cover some of the higher volume territories in the US. We're primarily on the East Coast, east of the Mississippi, and we'll be expanding west of the Mississippi as well as adding more reps on the East Coast, down into Florida. We're going to stay laser-focused on the US on that top-line revenue growth. We are also looking at a potential CE mark. We have plans to start the process. And we will look at other ways to enhance adoption of the BEAR [technique]. [Editor's Note: The company also plans an outreach campaign to patients to create awareness for the BEAR implant.]

Q **The digital ecosystem was a major focus at the recent annual American Academy of Orthopedic Surgeons meeting in Chicago. What is your perspective on that?**

A Shadan: I am an advisor to a group in Massachusetts called MassMEDIC and we have a group of emerging companies that have asked individuals (CEOs and professionals) to mentor them, and probably 50% of them have some type of digital component to their technology. I'm also on the board of AdvaMed and we are seeing a very significant uptick in membership from companies with some kind of digital component, either wearables for sensors or combinations. (Also see "*AAOS 2022 Roundup: Stryker, Zimmer Biomet, J&J's DePuy Synthes, Canary Medical*" - Medtech

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Insight, 29 Mar, 2022.)

Q **Is the digitization of surgery the future in orthopedic surgery?**

A Shadan: I think it is. I think there is lots to figure out. I think that this data collection for the sake of data collection doesn't help anyone unless it is converted to information that can be used to manage the health of individuals. There is a trend to try to integrate systems. There are regulatory issues to figure out with those products. (Also see "*AAOS 2021: Digital Tools In Surgical Ecosystem, Software-Enabled Tech, Robots, Wearables, Sensors*" - Medtech Insight, 9 Sep, 2021.)

[On use of virtual reality, augmented reality and mixed reality] my son is a second-year orthopedic resident and he's using it. In terms of training these kids, it's really helpful to get them proficient faster. I also think it's going to elevate the ability of surgeons across the board, whether it gives them more confidence, there's more precision, they can do it faster, better.

Q **Do you think that medical device reps will have a physical presence in the operating room of the future?**

A Shadan: With COVID, we had to things differently. Access to the OR was restricted and companies pivoted and started using software that allowed them to remotely proctor cases. I thought that was going to be adopted at a much higher rate. It seems to me that we're falling back to having reps in the OR in every case proctoring cases. I thought there was going to be a hybrid. I'm not seeing it yet and that's disappointing to me. Not that I don't think reps have their place – I've got direct reps – but I do think that there's a more efficient way to support cases than having to be in the OR for every single case. I would like to think there's an evolving opportunity for us to be able to leverage technology to create more efficiency across the board.

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