OrthoTec

Q&A

Interview with Jeff Koslosky, director of technology and product development at Secant Medical

Forming Technology with a Twist

Instead of using metals, some manufacturers are turning to biomedical textiles for permanent implants.

MARIA FONTANAZZA

Finding the ideal material for an orthopaedic implant isn't always a straightforward process. As manufacturers look for more effective and less invasive technologies, Secant Medical LLC (Perkasie, PA) has stepped up to the plate in working with customers, not just to develop a customized technology, but also to understand their specific needs. The company prides itself on anticipating what it must do as a supplier to serve device manufacturers that are part of a constantly evolving industry.

Koslosky

In this month's Q&A, Jeff Koslosky, director of technology and product development in Secant Medical's Advanced Technology and Materials group, discusses where biomedical textiles are being used in orthopaedic devices, their future potential, and how the company is attracting metal loyalists.

OrthoTec: Let's start with the basics. What is a biomedical textile?

Jeff Koslosky: Fundamentally, a biomedical textile is either a knitted, woven, braided, or nonwoven textile geometry that is designed for permanent implantation in the body. It is typically composed of raw materials that are either polymeric or metallic in nature. Generally, they are biomaterials that have a track record for being implanted inside the body and used in medical devices to repair a particular disease or disease state.

Specifically from the orthopaedics side, we don't tend to focus on one forming technology or any one raw material. I think that's one of the advantages of the technology that we have—we can truly mix and match to customize a biomedical textile to our client's need.

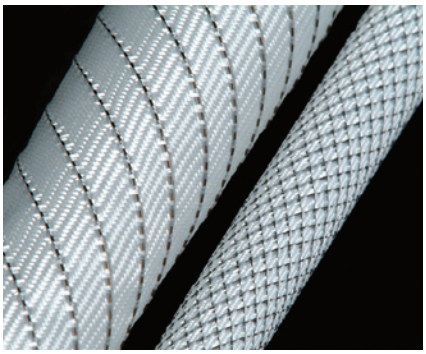
One of the approaches that we take in design methodology is that we try to understand as much as possible about what the actual device design is looking to accomplish. [Then we] go into our toolbox with the various forming technologies and raw materials that we have access to and leverage their properties to truly create a custom solution for our client's device application.

ORT: What technologies are being used in orthopaedics?

Koslosky: We have a lot of technology fit and overlap with motion preservation [devices]. Textiles, by definition, are flexible and compliant but can be strong or stiff in one direction. The ability to have [materials] that are in line with motion preservation is one of our advantages. In addition, minimally invasive delivery techniques are other orthopaedic areas where we've been able to carve out a niche for our technology. For the same reason, textiles are compliant and can be compacted to small delivery through a cannula or a trocar, and expanded or shape transformed once they're put into a particular space.

We've seen some really good fit and placement with containment applications. Whether they are containing hydrogels, bone cements, or other types of fluids being injected, you can envision almost a vessel that we can weave, knit, or braid out of polymeric or metallic filaments to contain or direct the flow of that material.

We've also seen [applications] in soft tissue—an abundance of ligaments, tendons, and joints—because many textiles have that feel of being long and strong in the axial direction. We overlap quite well in joint repair, rotator cuff technologies, and various therapies in the sports medicine side of orthopaedics, which continues to be a match for our technologies.

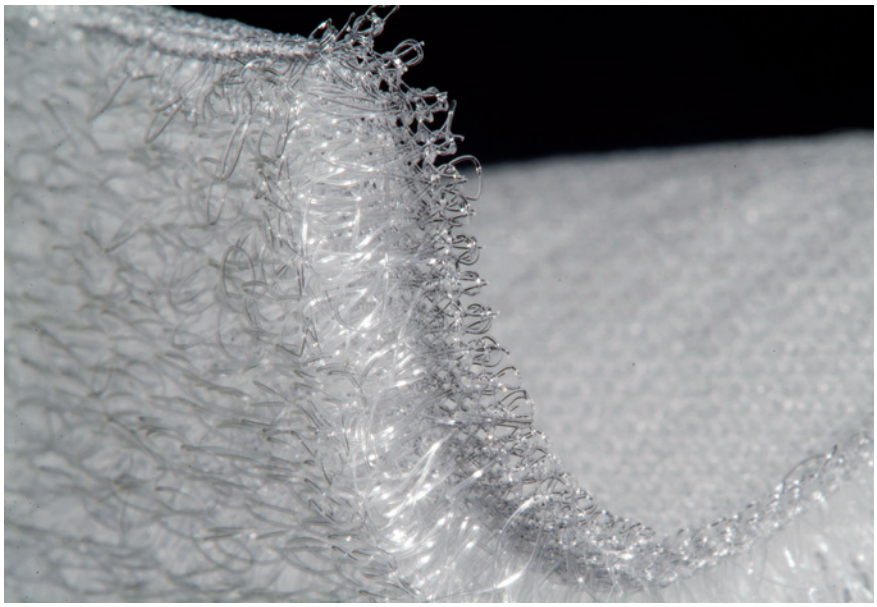


Tubular containment structures with radially oriented metallic reinforcement filaments.

Image courtesy of SECANT MEDICAL

ORT: When and where did Secant Medical first become involved in orthopaedics?

Koslosky: Much of our orthopaedics background started in the late 1980s and early 1990s with some work in anterior cruciate ligament (ACL) replacement. We still see that as a large area of interest right now. There are people who are focused on engineering structures containing synthetic or synthetic-biologic combinations for ACLs and PCLs [posterior cruciate ligaments]. If you track back, the majority of our company originates more on the cardiovascular side as well as in soft tissue support for hernia mesh applications. One of the things that we like to do is take some [of our] techniques in cardiovascular or hernia repair and bring what we've learned from those industries over to the orthopaedics side.



A multilayered osteoconductive scaffold structure can be used for engineered tissue response.

ORT: How do you generate interest in biomedical textiles, especially when approaching companies that have traditionally worked with metals?

Koslosky: Much of the challenge that we face is an awareness issue. We've seen an increase in the number of devices on the market that are made from more flexible materials. When you come into an industry where there is a plethora of very rigid, machined rods, screws, and plates and you hand them a flexible fabric, it often raises some eyebrows and leads to questions insofar as, how can it be something that works? There are questions about mechanics and long-term durability of the flexible structures relative to the gold standard products. If you look at the overarching trends with minimally invasive technologies—the shape transformation abilities and the ability to have more dynamic types of systems—you can see more people who are particularly receptive to working with our technologies.

[Biomedical textiles] aren't a replacement [for metals]. There's still a need for screws and plates and hip stems. But, the ability to offer another way to solve those problems, or help to facilitate healing where some rigid plastic or metals don't [work], this is the space that we try to go after. [We] try to make our potential clients aware and educate the market the best that we can.

Some of the excitement for us in the ability to take biologic materials on their own merit and process them with our same forming technologies of weaving, knitting, and braiding.

ORT: What are some areas of innovation?

Koslosky: We're seeing interest in many exciting areas. One important point to clarify is that the concepts and product ideas generally originate with our clients. It's up to us to bridge the gap between what their concept is and how to make a plausible textile structure out of that [idea]. The new and interesting areas that are starting to become more of a focus for our technologies in orthopaedics are on the orthobiologics side. A good number of device designers are starting to incorporate biologics in one form or another into their device designs and concepts. But, what they find is that many tissues on their own merit aren't strong enough to bear load instantaneously, so they're looking for short-term mechanical performance and long-term healing. We've carved out a niche for ourselves in orthobiologics as far as strengthening or [creating] a composite between a textile and a tissue-based product, or even down the road, providing a 100% biologic repair [product]. I'd say tissue engineering, tissue scaffolding, and orthobiologics are some of the new and emerging areas where we're seeing some of our clients leverage our technologies.

ORT: What are some joint treatment applications for biomedical textiles?

Koslosky: Applications such as [those for] the shoulder, including rotator cuff repair, the knee—including meniscus tears, and extremity joints—have garnered ample attention. It's an area where we have a number of people interested in leveraging our technologies both in concert with tissue products or by themselves as load-bearing members or as scaffolds. We also see some interest in leveraging our technologies in the spine, whether they are for facet joint repair, annulus repair, or anywhere you have soft tissue involved. Generally that tends

to be an area where we can leverage some of our technologies as scaffolds, support materials, or adjuncts to just putting in a biologic material.

ORT: Do customers raise proprietary technology or intellectual property (IP) concerns when you're working with them?

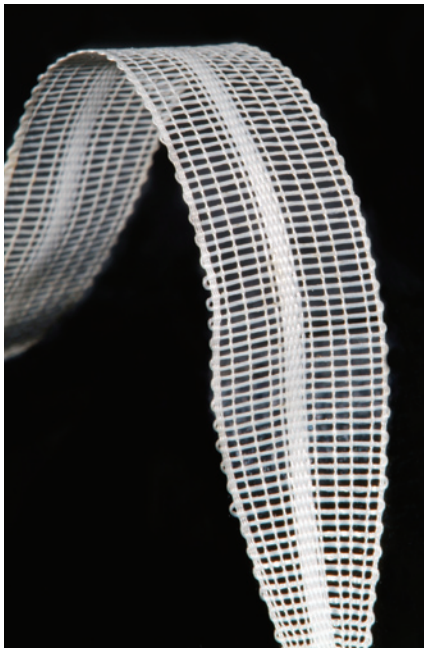
Koslosky: I think these are always concerns when working with a client. One of our most important jobs here at Secant Medical is to maintain the confidentiality of every client's program. It is, first and foremost, the most important thing that we do on the development side—to make sure we have an open and trusting relationship with our clients, that they feel that they can disclose their concepts to us, and that we won't be moving that [information] forward to other potential clients.

There are also arrangements that we get into as a company where exclusivities are part of the business relationship. More often than not, our clients put a good deal of IP around their concepts. Secant Medical has a policy where we have no interest in owning any device or product, IP, or patents. All of that is completely and totally the property of our client. Sometimes some of our engineers are coinventors, but at the end of the day, we are a component supplier and textile manufacturer to the industry. That's our strong suit and we don't want to be the device company. The IP truly belongs to our clients and we work hard to make sure that we strengthen their technology to the point that they can create barriers of entry for all of their competition.

ORT: How does Secant Medical maintain its edge in innovation?

Koslosky: We are in a very unique position in that there isn't a great deal of direct competition. There's a very small group of people that work in medical implantable textile structures. Some of our clients and some medical device companies have chosen to vertically integrate in some segments. The disadvantage here is that a development team becomes myopic in their vision of what is possible. A broad perspective on medical devices in general combined with an unmatched expertise in textile forming and biomaterials keeps us at the forefront.

What also sets us apart is that we continue to invest strongly in having new technology available for clients. We try to go out and educate ourselves at events like NASS [North American Spine Society], AAOS [American Academy of Orthopaedic Surgeons], and other surgeon conferences so we can be right there alongside some of our clients and potential clients in understanding what are the trends in orthopaedics and the market, and putting the technologies in place today to anticipate the needs of this market one year, two years, or three years down the road. Our goal is to have technology in place for our clients to leverage at the time that they need it.



Shown here is a woven fabric substrate to be used with a xenograft for joint repair.

In addition, our company has formed some strategic partnerships with some biomaterials providers. These [partnerships] have given us the ability to offer solutions to our clients of which they may not have otherwise been aware or didn't have access to. We truly see ourselves in the lead position in the market and are making investments back in our technology as well as trying to stay on top of changing trends in the industry to keep our position at the forefront.

ORT: Do you work with doctors when developing technologies?

Koslosky: Occasionally we've had a surgeon inventor who has approached us, but that is very rare. It's more typical that the medical device companies are the ones developing the design, funding it, and have the ability to put [in place] the regulatory personnel to get the device approved. We've sat in on meetings with clients and their surgeon advisors. We've been involved with cadaver and animal labs to learn firsthand alongside the surgeon and the client we're working with. More often than not, we tend to work directly with a medical device client.

ORT: Where do you see the market for biomedical textiles heading?

Koslosky: I think it's an exciting field right now. We continue to see an increased interest in biologics. Some of the excitement for us is the ability to take biologic materials on their own merit and process them with our same forming technologies of weaving, knitting, and braiding. It gives us access to an entirely new type of biomaterial that we can put into the structures that we make. Instead of using a synthetic material that the body recognizes as being a foreign substance and treating it from a cellular standpoint very differently, it's exciting to leverage collagen or other materials of a biologic nature and process them into the structure that more closely replicates the tissue that is damaged or destroyed.

It is a very early-stage technology at this point and one of the developments that we're excited about. You can envision, if you put collagen materials into an ordered structure and place them inside the body and the body recognizes [them] as a building block with which it is more familiar, the amount of time it takes to facilitate healing significantly decreases.

We're working with not only clients as they move forward on a biologics side, but we've also explored university partnerships to develop new technologies, especially on the biologics side, and marry them with our ability to form structures.