Duramesh: MSI’s Novel Suturable Mesh

In an interview with SmartTRAK, Mesh Suture, Inc. (MSI) Founder Gregory Dumanian MD, discusses the Company and its novel suturable mesh that has the potential to change how hernias and other conditions are treated.

By Doug Devens | Product Director/Senior Analyst - Wound

MSI is commercializing a novel suturable mesh that combines a mesh’s ability to distribute forces and support tissue with the precise placement and minimal foreign body presence of a suture. In a time when patients and physicians are rethinking how mesh is used in hernia treatment, MSI’s Duramesh offers the potential of retaining the durability of mesh repair with less foreign body presence. Today, the Company is running clinical trials and building evidence to support regulatory clearance in the United States. To find out more about the Company and its operation, SmartTRAK talked with Gregory Dumanian, MD, Chief of Plastic Surgery at Northwestern University’s Feinberg School of Medicine, Founder & Medical Officer of MSI and the inventor of the new technology.

Click on the following video or visit https://vimeo.com/651799429 to listen to SmartTRAK Senior Analyst Doug Devens’ interview with Dr. Dumanian, which was recorded via Zoom audio (24: 35 min). A transcript of the interview is also provided below.
SmartTRAK: Dr. Dumanian, welcome. Can you briefly describe the inspiration and history of MSI?

Gregory Dumanian MD: I think the easiest thing is to start with adding color that it all started during my days as a general surgery resident at Mass General in Boston. There was a very famous surgeon and he used to do this thing called the Superman Closure. His name was Dr. Ron Malt and the Superman Closure used a number five nylon suture that you would sew in a certain way, and no matter what the tension, you were going to get that abdomen closed. The residents all knew that when you did a Superman Closure, you had to triple glove. We would put three layers of gloves on because that suture, under all that tension, would cut through an intact glove and cut our finger, called your posting finger. In fact, even to this day, whenever I see a surgeon with a cut on their index finger, their posting finger from tying knots under too much tension, I take a picture. I have a collection of surgeons with cut fingers.

And it always bothered me that, if that suture's cutting our finger, what's happening to the tissues that are being encircled by that suture loop? It was 2002 and we had a visiting professor at Northwestern in plastic surgery and I was trying to convince the residents to investigate this issue of suture cutting. And they thought it was a stupid idea, so we didn't proceed. I went from general surgery to plastic surgery and hand surgery. And hand surgery has all of these intricate suturing techniques for finger tendons. Why? The collagen of the finger tendons is very linear and so the stitches would cut through the finger tendons. And so you do these fancy suturing patterns to prevent the problem of suture pull-through or the sutures cutting.

So in general surgery, I know sutures cut. In hand surgery, we have all this fancy stitching so that the stitches don't pull through. I became a hernia surgeon over time, and we use meshes and the meshes distribute forces to prevent suture pull-through or sutures cutting. And then one day I was driving my daughter to horseback riding and it just flashed—a suture with mesh-like characteristics to limit the problem of suture pull-through.

And since that time, that was about 2010, we submitted our patents in 2011 and it's been a full 10-year journey to bring this product to market. It's exciting because sutures have been around for 3000 years, they have mummies who were closed with sutures in ancient Egypt. Braided sutures came about 40 years ago, barbed sutures to avoid the problems of knots, little hooks on the suture, that was 30 years ago. And then, this is the first new design of a suture since barbed sutures 30 years ago. So that's the inspiration and the history of Mesh Suture.

That's fascinating. That's a great story. I like how you tie everything together. Let's talk a little bit more about your product. Some of the problem is the cut-through. Can you go
more into what will differentiate it from meshes and maybe talk a little bit more about why Duramesh instead of meshes that they've been using for decades now?

GD: Yeah. Since the 60s. So just think about hanging a heavy picture on a wall. Do you use a nail that unfortunately can pull through the drywall, or do you use a molly? A molly, that's what we call them in Chicago, those pieces of plastic. You put a drill hole- that expands out.

GD: So you want something bigger to distribute forces. The problem is when you use something bigger, the knots become unacceptably large and then you have problems with the knots. So you need a physically bigger suture than what is currently available by the USP, the United States Pharmacopeia, which only goes up to one millimeter for the very largest sutures. You need something with lots of air so that the filaments collapse.

So that's one issue. But number two, the whole idea of tissue incorporation. Tissue incorporation has two strong benefits. Number one, if an implant is incorporated, it doesn't become infected. And number two, all that foreign body reaction, the scar, the microencapsulation of those filaments would tend to increase the strength of the suture tissue interface. So tissue incorporation leads to less infections, and by our data, a stronger repair. So those are the intellectual underpinnings of a mesh suture.

Now, there are a lot of other things too, because meshes we know distribute forces, going back to Dr. Jeekel, who is a friend who did the famous trial in the New England Journal showing that a mesh repair of a hernia does better than a suture repair. But the problem is putting in a mesh you have to elevate soft tissue flaps to put in a mesh and meshes are a lot of foreign material. So you want to have a big mesh so you distribute forces, but at the same time, you want to limit the foreign material so you have less wound complications and less tissue elevation. So a suturable mesh like Duramesh allows you to accurately place this implant with the aid of a needle-like suture, the simplicity of a suture, but with the characteristics of a mesh.

So, those are the intellectual underpinnings of why we think that Duramesh suturable mesh has favorable characteristics over sutures, less pull-through, stronger earlier repair and favorable characteristics compared to a mesh, less soft tissue dissection, less total foreign material.

What do you see as the economic advantages that would accrue to this for the healthcare system, for whomever, on a bigger picture? So we've got the advantages, better repair, less foreign body. What do you see as the potential economic advantages?

GD: There's a huge body of data about the economics of a mesh augmentation of a standard laparotomy incision. We know, from very well-done studies, that even a three-centimeter
incision for a laparoscopy port at the umbilicus has over a 30% hernia rate. That's just unbelievable. We know that for any incisional hernia, depending on how you measure it whether clinically or by ultrasound, there is an 8% to 23% incisional hernia rate. And all those people coming back to the operating room for repeat repairs, well the direct costs of an incisional hernia and then there's the lost wages and time off of work and suffering. And the cycle of sometimes a hernia repair doesn’t work and you need an even bigger operation. So from the abdominal wall point of view, John Fischer from Penn has shown what the advantages would be to the healthcare system of putting in a sheet of mesh at the time of any laparotomy.

But the problems with putting in a sheet of mesh, as we discussed, are people don't want that and there's soft tissue elevation and there are wound complications that happen from sheets of mesh. So the healthcare system potentially could avoid the billions of dollars that are spent on incisional hernia repair by getting it right the first time. In orthopedics, you have to use splints and casts for soft tissue repairs to protect the repair. In Achilles tendon repairs, my son's tennis coach wore a boot for three months so that the stitches wouldn't cut through the Achilles. Well, if you have a stronger earlier repair that would allow for earlier mobilization and prevent issues of stiff joints or stuck tendons because you can't move the tendon repair, a faster, earlier, stronger, better repair.

So, orthopedic (surgeons) don't use mesh because they don't have the ability to place a mesh, there are no soft tissues to put it in. But a suturable mesh for orthopedics would have unique characteristics that would, we believe, significantly improve outcomes.

**Now you talk about incisional hernia prevention in addition to the orthopedic market, but it would also be hernia repair. This would be used for hernia repair too, is that right?**

GD: Once we get Duramesh into people's hands, we're going to see how they use it, but I have two ways to answer your question. Number one, for just a simple umbilical hernia repair, the Americas Hernia Society and the European Hernia Society have a joint paper saying that any umbilical hernia over a centimeter in size should have a planar mesh placed. So that's the guideline. And yet at the European Hernia Society that I was just at in Copenhagen, 70% of umbilical hernias are repaired with just stitches. So sutures are being used, but they have failure rates, but because of their simplicity, that is what doctors are still using, despite the recommendations. So I fully expect with a new product, that there are going to be adopters of suturable mesh for an umbilical hernia repair and/or an inguinal hernia repair. So the Shouldice techniques where surgeons are just using sutures, well maybe they're going to adapt the suturable mesh for their soft tissue repairs in the inguinal area.
But let's talk about incisional hernias of the anterior abdomen, like an ostomy take-down site where there's a hesitation to use a planar mesh because of the contamination that's present. Well, for a non-clean, non-sterile abdominal wall incision where there's a hesitation to use a sheet of mesh, maybe something more than a suture will have some advantages. There's this thing at Northwestern that we call mesh strips, where, because Duramesh is not available, we take a sheet of mesh and cut it into strips and use it as sutures. This idea has caught on and literally is being done around the United States and even is reported around the world. So, until Duramesh is available, people are doing this technique and one of the places they're using it is when there's mild contamination. So, we'll see how smart surgeons use this product to help solve their own problems.

I didn't mention this, but hiatal hernia is a very interesting issue where, at Northwestern, which is my institution, I don't do hiatal hernias because I'm a plastic surgeon, half of the hiatal hernias, the surgeons tell me they use a bio-absorbable product to help augment the repair where stitches tend to cut through the crura. Those absorbable meshes are pretty expensive, it takes more time to put them in and there is one study, only one randomized clinical trial that I'm aware of that used a bioprosthetic mesh. At five years, both the suture group and the bioprosthetic group had a 58% five-year recurrence rate. So, we need something new for these problems that are just not going away and maybe a suturable mesh, better than a suture, accurate placement of a mesh, with less downsides than a planar mesh, may solve people's problems.

Pre-clinical results, you were presenting on that in Copenhagen. Could you describe, summarize your pre-clinical results as to how it works so far?

GD: What I presented in Copenhagen was a study that was doing laparotomy incisions in large pigs. So not a Yucatán 30-kilogram pig, these are 75-kilogram pigs to mimic the forces that would on the human abdominal wall. They actually grew at the time of sacrifice to be 320 pounds. So, if you can close an abdomen in a 320-pound animal that's on four legs where all the forces are inferior on the abdominal wall, you're doing okay. I had three groups and there were five animals per group, randomized per group, (the) Number One Duramesh and the 0 Duramesh. The Number One is 3.4 millimeters. The 0 is two millimeters in size. And then we compared (these two groups) to a Number One (USP) polypropylene. So, standard of care, running monofilament, 15-centimeter incisions and the results were just very gratifying.

Fewest hernias in the Number One Duramesh. Most in the Number One polypropylene. So all of the Number One polypropylene had hernias while three of the five Number One Durameshes were perfect. And the 0 Duramesh was in between. So more filaments, better repair. And this was without adhesions in the Number One Duramesh. So the foreign body reaction that we
were trying to place did not extend anywhere unexpected, like to the bowel. And the biocompatibility was identical to the polypropylene standard suture so (you’re) literally getting something for nothing. Same biocompatibility, but a better tissue hold and without adhesions.

I am familiar that you are starting a trial on clinicaltrials.gov at Walter Reed. Now, can you give us a little bit of about that and maybe other human clinical trials that you are planning or in the process of running?

GD: The Walter Reed trial unfortunately is on hold just because of some financial issues from the government granting agency. And we hope to get it going, but at this point, there is no active push at Walter Reed. We had set things all up and then it, unfortunately, didn’t happen. And I asked, "Should we take it off of clinicaltrials.gov," but we just left it there as not accruing patients. So that's what you found.

I see.

GD: We do have some exciting clinical trials that are just starting to get underway in Europe and in Mexico and all for abdominal wall--both for varied uses, including just varying types of abdominal wall incisions and their closure, and specifically at umbilical hernia repair in comparison to sutures and standard meshes. So all I could say for that is, stay tuned.

The clinical trial that has been completed was all in orthopedics and that was in a center that just worked on children with cerebral palsy where their tendons were under very high-tension loads and standard sutures tend to fail and break down. And that trial did beautifully. So we did 53 patients, 80 implantations and the only complication was a palpable knot that was taken out in the office. So the early clinical results are also just very exciting.

I didn’t mention one other preclinical trial, which is a study in Achilles's tendons in rabbits. And I’m going to plug plastic surgery again. When we were trying to figure out a model that the bunnies were just jumping around and tearing every type of suture. So I said, 'Why don't we just get some Botox from the office? We'll Botox their leg so they won't hop as hard.' So we started Botoxing these animals and then doing their Achilles tendon repair and then the early results, the Duramesh suturable meshes had less pull-through and less gapping in comparison to a standard suture. So it was the marriage of plastic surgery and other in a better suture and we actually were able to create a surgical model.

That’s a really funny story about how you got there.
GD: Yeah. We, unfortunately, hurt a few bunnies to get to that place, but there's no good small animal tendon model to actually test this stuff because it's a new suture. We had to create surgical models to test it.

And that can be a slow and expensive process, but you seem to have made it through it.

GD: Yeah.

Okay. Now, I am aware that you are not available commercially in the United States. You don’t have FDA clearance. Are you available commercially internationally anywhere? Or based on maybe the result of the completed trial, a pediatric trial that you had run for the orthopedic application?

GD: Yes. We’re excited to say that Duramesh is available with full CE marking. So anywhere that a CE mark allows a product to be used, we will try and enter that market. Currently, we are working to establish distributors in multiple countries around the world, including the UK, the Benelux countries, the Middle East, Mexico. So we’re working to bring this new device into surgeon's hands.

That sounds like really good progress. That’s exciting. Do you have a timeline for FDA approval when you would be available here in the US if I may ask?

GD: Of course. We're working and in communication with the FDA. There are meetings that are scheduled that are on the books. COVID has really put a damper on things. Without getting into strong details, something that by the FDA internet site is supposed to take three weeks, it’s taken us over four to five months to get on the books for a meeting, but we're working with them. They're smart people and we're going to work together to try and bring this to market in the United States.

It sounds like there’s a plan, but yeah, I think COVID-19 has upended a lot of plans. Where do you see the Company, say in five years or 10 years? Where do you see MSI out that far?

GD: Five years from now, I want MSI to have global regulatory approval to bring this device into the hands of any early adopter in all the various fields, general surgery, orthopedics, urology, gynecology, even neurosurgery, where they work on back closures and things. So I want this available and with the knowledge base to surgeons that this product exists. So education and availability. Ten years from now, I want the data in long-term studies to show the efficacy of this new device. And we'll see what the data shows. I mean, is it totally ubiquitous to be used in any high tension internal closure? Or are there places where the advantages don't really outweigh
the disadvantages? So I have a five-year plan, have it available worldwide. Ten-year plan, have the data to back up all the things that we’re talking about today.

As you are aware from the EHS Congress, right now is a difficult time for the hernia market and the regulations are changing based on the legal environment, et cetera. How do you think MSI, Duramesh in particular, will avoid some of that? Do you see it really affecting you or do you see that you’re different enough that it’s just something happening over on the side? And then maybe as part of that, I’m wondering, do you see yourself as replacing meshes in general, at least for prophylactic use, but also it sounds like for other indications? Or do you see it really replacing a subset of mesh use? So that’s kind of two questions. How do you see the changes in the market going right now and how do they affect MSI and Duramesh? And then, given the trouble that mesh has, do you see yourself replacing all meshes or really only for specific indications?

GD: That's actually a four-part question, but-

Yeah. Okay.

GD: ... I'll try.

All right. Well, answer it as you go.

GD: I'll try and see as I can. There is a general desire in the market to avoid sheets of mesh. And there is greater regulation of meshes with meshes in certain areas going from class two to class three and biologic meshes, bioabsorbable meshes so that that foreign body response is not maintained for the life of the patient. I think Duramesh completely plays into the desire of the market for a smaller foreign body implantation, for a midline incisional hernia where 1,200 square centimeters of mesh are routinely placed in abdomens from one side of the abdominal wall to the other. Duramesh, if the data shows that a Duramesh closure is effective for a midline incisional hernia repair, would represent 0.3% of the total foreign body of a large sheet of mesh that's used routinely in the operating room.

So I think we play very well into the market of less mesh is probably a better idea, but the data shows we need more than a suture. So it's got to be better than a suture, but less than a large planar sheet of mesh. In terms of what would be in the future, we do recognize the desire to have something that holds early on and then goes away. For a midline incisional hernia, if you have gapping of more than 15 millimeters at 30 days, that is predictive of an incisional hernia.
So maybe all that's needed is that reduction of tissue tearing and suture pull-through in the first month. So an absorbable Duramesh, again, would go along with the way surgeons and the market think are the important characteristics of tissue approximation. Do I see it replacing all sheets of mesh? No, I see it being a complementary agent, either avoiding the need for a sheet of mesh at a later time and/or limiting the amount of mesh at the time of a large incisional hernia repair. So I do not see it replacing sheets of mesh, but I do see it as another arrow in surgeons' quivers to care for patients.

There was a question about indications, but you've already kind of touched on that, that certainly you're looking at orthopedic indications. Do you see anything outside of orthopedic indications and hernia, of course, for Duramesh?

GD: Urology and especially gynecology, all the trocar sites. So a trocar site closure sounds like a small, unimportant thing, but boy, there are a lot of trocar site hernias that I see and having a kit or a system to close a small abdominal wall defect, robots for instance, all of those things, that is I think, an important adjunct. If we're spending so much money on the robot to minimize the damage of the abdominal wall, well at least you want your robot closure to be as good as the rest of the abdominal wall.

But a key issue would be putting a bone anchor on the end of the suturable mesh so that Achilles, when they're ruptured off of the calcaneus, or especially for shoulders where you need a specific type of bone anchor to not pull through the very gentle humerus. And so you can do a rotator cuff more effectively and with better long-term outcomes, there are a lot of rotator cuffs that are done in the United States and the needles that we've chosen all go through these trocars so we're planning how best to deploy the devices with minimally invasive techniques.

So my last question is, is there anything else you'd like us to know about MSI and Duramesh? Is there anything that I didn't ask you that you were hoping you could talk about?

GD: I do like to point out that this is a doctor-led company, or a surgeon-led company. And this is a product that is designed to solve my problems and I'll say our, the collective surgeon, our problems. And the word of mouth and how the idea has flowed throughout the surgical community, has actually been really exciting, especially with social media. There's the International Hernia Collaboration, and I've shown some Duramesh and people around the world are asking, 'Hey, when is this thing going to be available?'

So, there are devices that are company-generated. Like, 'We're going to get you this really fancy mesh with all of these peptides on it so that we can get you this X and Y and Z,' as opposed to a
more simple, ‘I know how to hang a picture on a wall and I know what works and I know what doesn't work, and I need something more than a suture and I'm going to think about how I do things at home to make things better in the operating room.’ So I think surgeons get that and as a doctor-led company, maybe that's going to reverberate and push its usage in a different kind of way.

Well, thank you very much, Dr. Dumanian, for your time. I really appreciate it.

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