

Note from the Editor: The “FAQ on Innovations” series represents a specific type of article in The Journal of Orthopaedic Experience & Innovation. The articles in this series are originated by the Senior Editorial Board who develop the questions. The Senior Editorial Board reviews the accuracy of the articles although “FAQ on Innovation” and “Blogs” are the only articles that are not peer-reviewed in the same way that all other articles in the journal are.

The Anatomy of an Innovation- Ziptek for Tissue Repair

The Founder: William Bennett, M.D.

Orthopedic Surgeon- Sportsmedicine

Sarasota, Florida

Q: What were the origins of Ziptek?

A: “When I was working with companies on bone anchors and sutures for minimally invasive repairs, I did have a bit of an epiphany in 1996, thinking, ‘Sutures have been around for roughly 2,000 years and not much has changed.’ As a field we have largely failed to investigate other potential ways of approaching tissue repair and attachment. Suture is string and it can only hold a tissue repair in a loop. If you use suture to pull tendon to tissue, ligament to ligament, etc., you are relying on the width of the suture to experience all the forces and hold the tissue together. So I thought, ‘What if I could make an anchor with good holding power and then put some type of expansile disc over the tissue...something with an increased surface area that locks onto the anchor in the bone?’”

“Some plastic, general and orthopedic surgeons recognize that using a type of button in repairs—whether under or on top of the skin—is helpful because it releases some of the pressure of the repair system/suture strand to a larger surface area. I recall doing a rotator cuff repair on a subscapularis tendon and some of the suture repair loop system wasn’t working well on the subscapularis. So, I was motivated to figure out how to do a loop suture repair that could hold a big footprint, which resulted in moving away from suture loop technology.”

Q: What did you believe was lacking in the tissue repair systems that were already on the market?

A: “All of the existing devices are load-sharing and stress shielded. If you have a tissue repair system that never releases the pressure on that tissue, then the tissue never experiences normal stress, i.e., compressive, tensile and shear forces that are needed to create a normal tendon or ligament through remodeling. Our system, which is revolutionary not evolutionary, works such that the loop suture technology is not utilized. Resorbable button tissue repair technology is a technology whose biomechanics is completely different than suture loop technology. There are two ends to a suture and our technology utilizes two buttons on the end and does not require that the suture complete the circle to create the fixation. Most suture loop technology is a circle or ellipse of some sort that is vertical or horizontal or cruciate and with tension applied to it, the circle becomes an ellipse, or the ellipse becomes thinner. This allows the tissue to pull away from the fixation site- this is called gap formation.”

“With our technology any longitudinal tension creates a direct downward compressive force, and the tissue doesn’t move or gap. The buttons are on-lay locking discs- “captures”, meaning they run down the suture over bumps in one direction only, like a Zip Tie.”

“The button material is resorbable and releases over time, meaning that it results in good remodeling. The tissue repair goes through the inflammatory phase, repair phase, and the remodeling phase, so our device transfers loads to the healing tissue over time.”

“The fact is that if bone doesn’t have the right types of stress/load, then you are likely to get a nonunion, this is true for soft-tissue but instead of a non-union you get incomplete remodeling or scar tissue repair. Stem cells, including adult stem cells and adult tissue cells always respond to stress-shielding in this fashion. The difference between scar repair and maturation to a true ligament/tendon is less ultimate tensile strength and less elasticity and the cells require full and normal compressive, tensile and shear loads in order to remodel. In addition, the discs, in a repair situation pushes more tissue down onto the bone for increased surface area healing.”

“In summary, a tissue repair device must transfer its load sharing ability to the tissue fully at some point to get true remodeling. Our resorbable button material is “sync’d” to tissue healing to do so.”

Q: Give us some information about the patent and FDA journey.

A: “Ziptek owns 25 patents and in 10 countries. We have done more than 1,500 implants in the US with extremely low and minimal adverse clinical effects, mild tissue irritation in three instances and zero revision surgeries. The material has been tested for biocompatibility ISO 10993 with 3 implantation studies and 12 other tissue safety studies with irritation being less than some of the most inert suture materials on the market.”

“The company was incorporated in 2012—but I had been funding patents and the design for ten years prior to its incorporation. The FDA approved Ziptek for 24 indications in March 2017. We entered the market in late 2018 and did it for only \$3 million...the typical cost of getting this kind of device cleared by the FDA is \$25 million!” We were building momentum when Covid hit and basically sidelined us for 2 years. 2022 has started with a surge of national interest.

The animation of the technique in the link below is for a Haglund-Achille tendon reattachment. The steps are the same for any tissue repair. To date the device has been used for repair in the shoulder, knee , elbow and foot and ankle

Animation of the innovation

<https://youtu.be/-XZ7vhaNcs0>

The Researcher: Dr. Michell Ruiz-Suárez-

Orthopedic Surgeon- Shoulder and Trauma

Mexico City, Mexico

Q: Tell us about the research process of the innovation.

A: “My background as a shoulder and elbow surgeon was what led Ziptek to reach out to me. They asked me to conduct an animal model study, so I obtained ten goats and recreated a

degenerated rotator cuff repair. The use of goats in such work is backed up by the scientific literature as the size of the tendon is similar to that of a human.”

Q: Could you outline the research process?

A: “We created an injury of the infraspinatus muscle and then left it alone for two weeks. (European studies have found that this is the approximate time frame that it takes for the acute inflammatory phase to ‘wash out.’) We randomized such that one side of the goat was experimental and the other was the control (no procedure). After two weeks we went to the OR and repaired the tendons using two metallic suture anchors and four Ziptek devices in order to recreate a transosseous equivalent construct. We then began sacrificing the goats at 3, 6, 9, and 12 months (two goats per sacrifice). We lost two goats during the process, but our power study calculations determined that eight goats were sufficient to see significant differences.”

Q: We were your most important findings?

A: “To our surprise, the orientation of the collagen matrix at the site of the repair proved very similar to the native one starting at six months. Up until then we found no significant difference in scarring but after six months there was significant remodeling of the tissue. Our control group (contralateral side) was repaired using a Mason-Allen repair stitch. This group exhibited disarrayed collagen matrix resembling fibrovascular tissue similar to a scar.”

***The engineer: Ramses Galaz, Ph.D.,
Biomedical Engineer- Professor
Hermosillo, Sonora Mexico***

Q: What was your early involvement in developing this innovation?

A: “When I first met Bill Bennett in 2009 he said, ‘You know how when you put down a carpet you use tacks instead of nails? I want to develop a rotator cuff device like that.’ Something just clicked for me. If we could make a knotless device then surgeons wouldn’t have to lose time tying, thus you would have a rapid learning curve—and you would standardize the amount of force you use in surgery. Surgeon A’s knot often has different mechanical behavior than that of surgeon B. One is tight and the other not so tight—we have no reference as to which is better and why.”

Q: Can you walk us through the science?

A: “The traditional tendon or ligament repair where you put an anchor and screw into the bone with a couple of sutures passing through the tendon has not changed in 30 years! You have a thin strand of suture passing through a muscle, tendon, or ligament and you are creating a lot of force that is interacting with what is essentially a thin thread...it will try to rip it off, thus damaging the tissue.”

“Thin is ‘out’ and simple is ‘in.’ With traditional repairs you can have up to 86% of tissue re-tears occurring at the suture site, which renders the tissue useless for any future repair. Bill Bennett’s zip tie idea made sense from an engineering perspective because it would mean that you create a larger area across which you could distribute the pressure that is pushing against the tissue. Thus, the idea of a button. Instead of a knot, the Ziptek method offers a simpler alternative—a button—that spreads out the forces more evenly. Our suture has beads that act as a

locking mechanism—it's essentially like a resorbable zip tie.”

“The button pushes downwards against the tissue, and as demonstrated in our finite element analysis and experimental results, is easily able to withstand the amount of pressure/forces interacting with the tendon and suture. For tissue to heal, it needs to be touching the bone, which creates a collagen bridge between the tendon and bone. In addition, the two pieces should not move relative to each other...you want minimum relative displacement of tissue against bone. You must have gentle pressure in order to keep the tissue in place...then nature does the rest. The resorbable button will lose its holding power and transfer the responsibility to the tissue gradually but mainly over the ensuing 10-12 weeks.”

***The foot and ankle surgeon: Peter Mangone, M.D.
Orthopedic Surgeon Foot and Ankle
Asheville, North Carolina***

Q: What got you interested in this technology?

A: “A lot of people have the mindset of, ‘I have always done xyz and it’s worked just fine...it’s good enough.’ My motto is: ‘Good enough can be better.’ When I saw Bill Bennett’s LinkedIn post regarding a soft tissue fixation method that holds in place, but doesn’t strangulate the tissue, I was intrigued.”

Q: What has been your experience with the device thus far?

A: “To date I have done approximately 55 cases using Ziptek with no complications. These have primarily been Achilles tendon reattachments, Haglund’s procedure, as well as lateral and medial ligament reconstructions. The histological data indicate that this device spreads the forces over a larger area and thus allows for better microvascularity. And since you are not tying the tissue, you are not strangulating it...and if you have better circulation then you get better ingrowth. It’s also faster because there is no necrotic tissue resulting from knot tying.”

Q: What would you say to surgeons considering Ziptek?

A: “It checks all the boxes. It reapproximates the tissue you are trying to fix while providing adequate strength. It’s the ideal soft tissue device because it allows for early range of motion as the tendons heal better and early weight bearing is feasible. One of the most debilitating aspects of foot and ankle surgery is when patients cannot bear weight. Functionally and emotionally, it takes a lot out of them. Ziptek allows for an earlier, safer return to function whether it’s work or sports.”

Q: What can you tell us about the learning curve?

A: “Surgery using Ziptek doesn’t take any longer than what I did before. I would say that after 5-10 cases, surgeons should feel comfortable with this procedure.

***The shoulder surgeon: Aaron Schachter, M.D.
Orthopedic Surgeon, Shoulder
Milford, Connecticut***

Q: When you first encountered Ziptek, what did you think?

A: “Many of the issues we have with soft tissue fixation are related to biology. We have already ‘checked the box’ as far as stronger anchors, but we need to improve the biology of healing. We have seen a lot of research on improving the biology of healing via cell manipulation and biochemical means. Ziptek stood out for me because their animal study in Mexico demonstrated that it improves things not only mechanically, but biologically. You can have the strongest construct in the world, but if the tendon-bone interface doesn’t improve then you are at your limit of what is possible.”

Q: What were you impressed with?

A: “I could tell that the thought process behind Ziptek was different. In a rotator cuff repair—the most common surgery where we are trying to attach soft tissue onto bone—traditional repair doesn’t have uniform coverage because you are dealing with sutures. So Ziptek is a different way of thinking...you are compressing something instead of yoking it down with sutures. For me, the greatest draw was the histologic data from their animal study showing more normal microscopic transition from tendon to the bone. It’s the first device I’ve seen where we don’t end up with organized scar following repair.”

Q: What has it been like to use this device?

A: To date, I have used Ziptek in closing subscapularis repairs in shoulder arthroplasty. I’ve found that it’s had a substantial impact on function, survivability and whether you do a tenotomy or osteotomy. Ziptek gives me the immediate security and is tissue friendly.”

Legends-

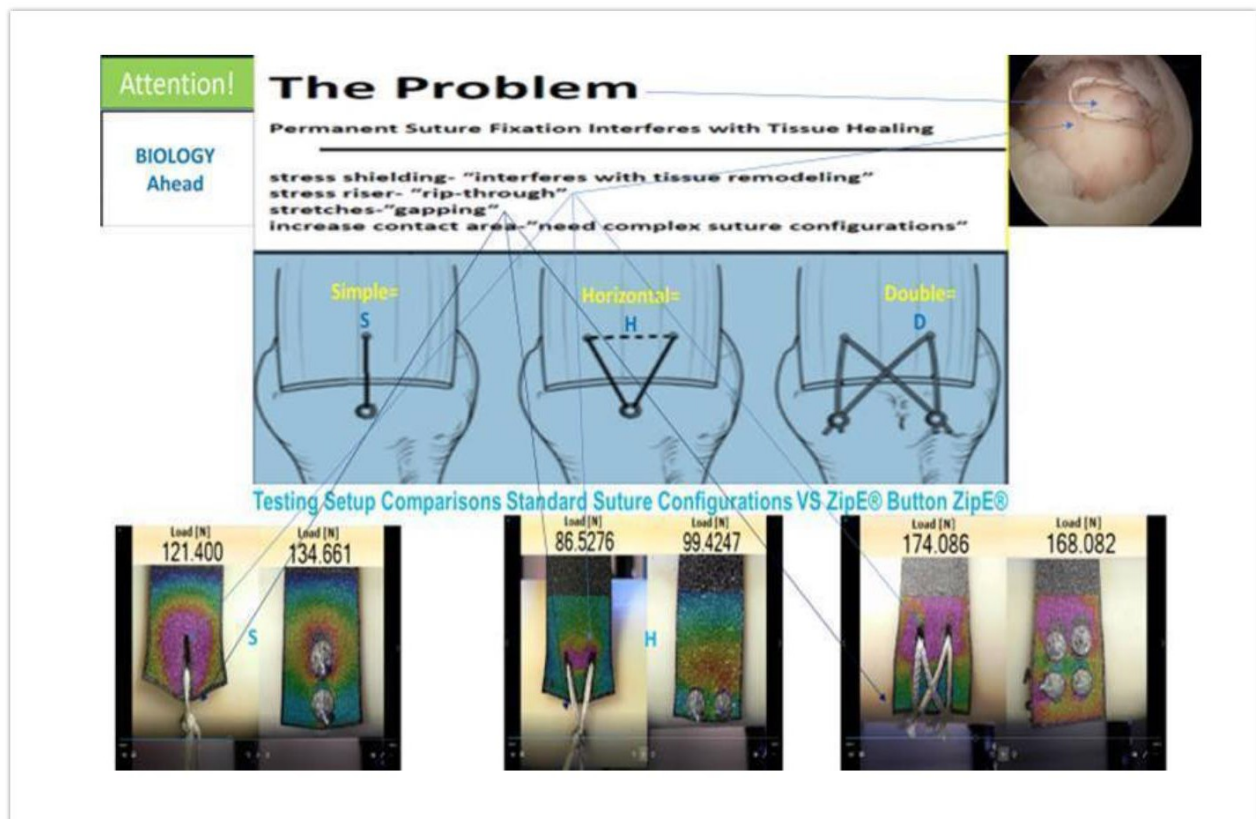
1.) Biomechanical Testing-

The main failure mode with tissue repair especially in rotator cuff tears is the suture ripping through the tissue. This occurs because of high strain at the suture site and the inherent “yoking” technique utilized for various suture loop configurations. Additionally, suture loop fixation is prone to gapping, both deficits contribute to failures of tissue repair.

Ziptek’s ZipE® Zipoplasty™ resorbable on-lay pressure dissipating suture locking discs offer superior resistance to rip through, gapping and decrease strain.

The following photo depicts the three various suture configurations that were tested using and Instron with an increasing tensile force against various ZipE® Zipoplasty configurations: a simple suture loop, horizontal row, double row versus a Vertical ZipE® parallel, a Horizontal ZipE® parallel and a double parallel. Notably, the ZipE® double parallel uses two anchors versus the suture double row, which uses four.

The ZipE® outperforms all configurations for resistance to rip through and gapping. Please click on link below to visualize dynamic testing and the superior outcomes of the zipoplasty approach.



https://youtu.be/_kA3ClkWXuQ

2.) Haglund Repair with ZipE® Zipoplasty-
Pete Mangone MD- Asheville, NC

This ZipE® double parallel configuration requires only two anchors for the 4 points of fixation that are 6.5mm circular and create nearly a 4-cm squared surface contact area. Click on the link below to visualize intra-operative immediate range of motion – notice no gapping and no rip-through.



<https://youtu.be/Ysdo80QL0Io>

3.) Brostrom Repair with ZipE ® Zipoplasty™-
Samuel Adams MD- Foot and Ankle Surgeon- Duke
two anchors, 4 ZipE® onlay suture locking discs-



4. Arthroscopic Rotator Cuff Repair with ZipE® Zipoplasty Transosseous Technique-
William F Bennett MD
Sarasota, Florida

This technique uses the Tensor Tunneler system to create a double row repair with locking ZipE® discs medially and laterally at the exit tunnel and a vertical loop suture for both tunnels.

Click on link below to see video illustration



<https://youtu.be/dAP-rzclgJw>

5.) Arthroscopic Rotator Cuff Repair with ZipE® Zipoplasty Bone Anchor Technique-
William F Bennett MD
Sarasota, Florida

Immediate range of motion following repair with no movement of the tissue can be seen in the video. There is one anchor for 2 ZipE® discs.

Click on link below to see video illustration



<https://youtu.be/LXeD4dH9T3Y>