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MED TECH OUTLOOK

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EDITION

Ronald Berenson, MD,
President and CEO

KitoTech Medical

A Revolution in Wound Closure

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MEDTECH OUTLOOK TOP 10
MEDTECH DEVICES
STARTUPS - 2019

KitoTech Medical

A Revolution in Wound Closure

By Alex D'souza

In today's challenging health care environment, it is refreshing to see a product come to market that provides a new and better way to address a procedure that has changed very little in over 50 years. The combined skillsets of Seattle-based KitoTech Medical's President and CEO, Ronald Berenson, a physician, and Paul Leung, an engineer and the company's VP of Operations, led to the creation of an innovative product, which has the potential to change the way physicians close wounds, one of the most common medical procedures.

Reimagining Wound Closure

Imagine a busy emergency room (ER) where physicians see many patients with lacerations during each shift. Treating these lacerations usually requires physicians, significant resources, and takes up valuable time in the ER. The wound is most often closed with sutures and staples, and also requires a vial of anesthetic, other supplies, and often an assistant to perform the procedure. It is time consuming given the need to inject the anesthetic and wait 15-20 minutes for it to numb the area, which is then followed by the actual wound closure. Well over a half hour goes by before the procedure is completed and even more time when treating children. Valuable resources and time that adds up to hundreds


Paul Leung, PE,
VP of Operations

of dollars in ER costs and that could be allocated to more seriously ill patients. Closing wounds with sutures and staples also has a number of other problems, which include scarring, inconsistent results, and risks of infections and needle sticks. In addition, patients need to return to the hospital or clinic to have the sutures or staples removed, which is inconvenient and adds costs. Until recently, however, doctors and patients did not have a choice.

Enter microMend®

Nestled in the heart of Seattle, the team at KitoTech is equipping doctors with microMend® – an innovative next-generation wound closure product. It is designed like a butterfly bandage, but incorporates two arrays of miniature staples that the company calls Microstaples. These anchor the device to the skin with the holding strength of a suture. microMend is as easy and rapid to apply as a bandage and can be used to close a broad range of wounds, including lacerations, skin tears, and surgical incisions and port sites, which previously required sutures and staples.

"We knew there was strong resistance for physicians to adopt a new product if it altered the way they closed wounds. Consequently, from the beginning, our goal was to develop a device that could securely close wounds, and could be applied like a bandage – painlessly, easily, and rapidly," says Berenson. microMend was developed with this in mind so that it could be applied without the need for local anesthesia and be used by a broad range of medical personnel thus freeing up doctors' time to perform other higher value procedures. It is currently being used in a broad range of medical specialties, including emergency medicine, surgery, orthopedics, plastics, and dermatology. It can also be used outside hospitals and clinics by the military, first responders such as ambulances, nursing homes, and occupational health clinics.

microMend has a number of features that make it an ideal wound closure product. Paul Leung, who is the brain behind the design of microMend, explains, "First, Microstaples have been designed so that they are painless when inserted into the skin. Second, an array of angled Microstaples is placed at each end of the device, which creates a wedging effect and mechanical anchoring to the skin that achieves secure wound closure." In addition, the Microstaples are fixed at short distances from one another. Consequently, when microMend is applied, consistent and reproducible wound closure is achieved with a tight seal that prevents bacteria from entering the wound. In contrast, staples and sutures are placed at larger distances from one another along the wound length resulting in wound gaps through which bacteria can enter and lead to infection.

In contrast to sutures and staples, microMend is straightforward to use and thus achieves consistent results that are independent of surgical skills. Leung also emphasizes that their product does not require suture needles and thus eliminates the risk to doctors and other health care providers of transmissible infections. Finally, in contrast to sutures and staples, microMend is designed so that it can be easily removed by the patient and thus does not require a return clinic visit for their removal.

As Easy as a Bandage, As Strong as a Suture

The ease of use and rapid application are microMend's strongest suits. In addition, the post-op care is identical to that of wounds closed with sutures and staples further adding to the device's appeal for doctors and patients. "We have conducted clinical studies that demonstrate outstanding clinical results with microMend," Berenson states. In a clinical study directly comparing microMend to sutures in surgery, 85% of doctors and nurses rated microMend superior, while 90% of patients rated cosmetic results better with microMend. In another study in dermatology, microMend achieved excellent clinical outcomes in closing wounds associated with skin excisions and Mohs surgeries. microMend has also demonstrated great results in other specialties, including emergency medicine, plastics, vascular surgery, and orthopedics. "We are excited to see the outstanding clinical outcomes with microMend, and are continuing to conduct clinical studies to document its efficacy in a variety of medical specialties," extols Berenson.

> microMend products are truly revolutionary. They have noticeably decreased our throughput times for laceration repairs in the Emergency Department.

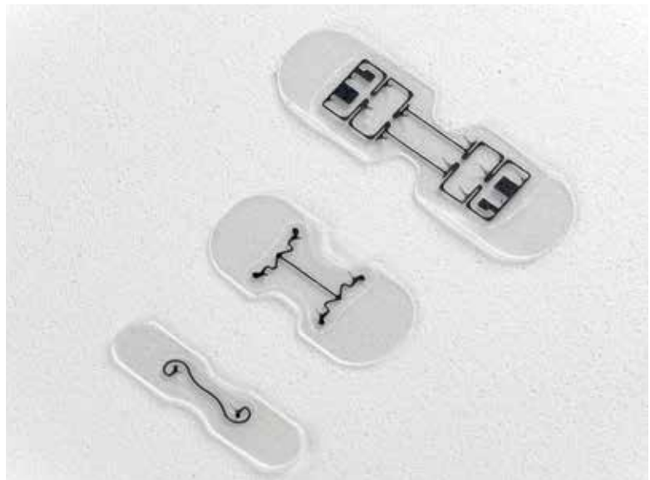
microMend's gentle application has a distinct advantage in closing wounds in the fragile skin of elderly and chronically ill patients where sutures cannot be used because they often rip right through their skin. In addition, these patients often experience minor injuries that tear their skin. These skin tears cannot be closed with any of the current wound closure products due to the fragility of these wounds. microMend has been documented to have the unique ability to effectively treat these tears.

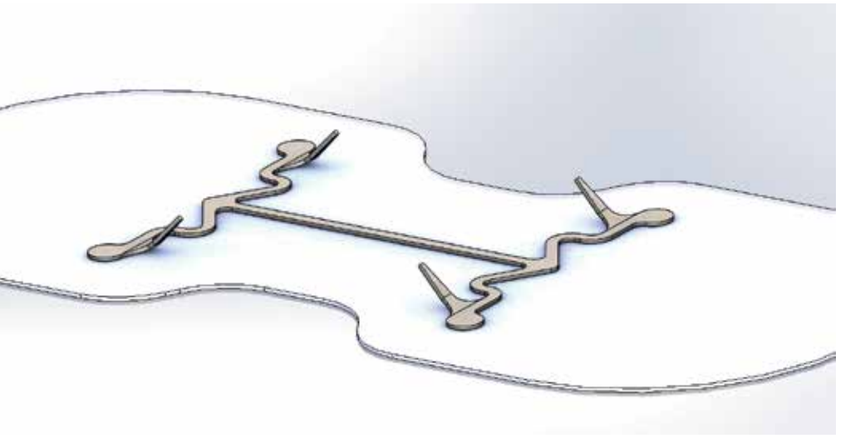
microMend also provides significant cost savings. It is priced at about half of the cost of the supplies required to close lacerations with sutures. Clinical studies have demonstrated that microMend is 7x faster than sutures in closing wounds. A laceration can be closed in seconds. Contrast this to the over 30 minutes required for suturing when you add up the time to inject local anesthetic, wait for it to take effect, and then perform the time-consuming suturing. With ERs costing $15-20 per minute, savings using microMend add up to hundreds of dollars per patient. In the operating room (OR), microMend reduces the time required for closing surgical incisions by several minutes. This translates into significant savings given that ORs cost about $50 per minute. Finally, patients can easily remove microMend devices avoiding the return hospital or clinic visit required for suture and staple removal that is often not reimbursed.

Success through Collaboration and Dedication

When physicians and others see microMend, their first reaction is that it seems so obvious. They ask why it was not thought of before. Well, like all breakthroughs, it takes more than a good idea to create a product. It takes a great team and tremendous effort to transform the idea into an innovative product. This is why it is important to highlight how the duo of Berenson and Leung created and developed microMend to appreciate their dedication and their journey. Berenson had a strong academic career in medicine before he was attracted to the life sciences industry 30 years ago. He became a serial entrepreneur founding and leading several companies that have developed innovative medical products. Two of the companies he founded were NASDAQ-listed. Following his entrepreneurial streak and penchant for transformation, he set up KitoTech in 2013.

The ingenious idea of microMend was conceived while Berenson was serving as an entrepreneur-in-residence at the University of Washington. Berenson tells the story: "It was at UW that I met Marco Rolandi, a professor in the Materials





Science department, who was working on making miniature needles known as microneedles. Many groups and companies had been working on developing microneedles for drug delivery. This has proved challenging in practice, and so we focused on other potential medical applications." Dr. Rolandi was using a common biopolymer, known as chitosan to make the microneedles. Chitosan has powerful wound healing properties, which led Berenson to the idea of incorporating the microneedles into a device to close wounds. Dr. Rolandi was able to come up with a basic design for the wound closure device and the concept was validated in their early studies. However, chitosan as well as other polymers proved difficult to work with to make reproducible Microstaples that could securely close wounds without breaking.

Paul Leung then entered the picture when he was recruited to KitoTech by Berenson. Leung is an outstanding mechanical engineer with a strong track record of developing medical products. Leung proposed to design an inexpensive, easy-to-make and reproducible device. He suggested that the Microstaples be made out of the stainless steel metal found in medical staples today. He then worked with an outside group to demonstrate that stainless steel Microstaples could be reproducibly made using a low cost manufacturing process. With the strength of metal, they were proved to be unbreakable and an array of the Microstaples was shown to have similar holding strength to sutures.

"From there, it was a team effort to develop the product. I translated Ron's vision of the wound closure device into reality," recalls Leung. After a series of engineering, stress and finite element analysis, and fine-tuning every single characteristic and dimension, the duo finally produced the first generation of the product, which worked well in pigs. However, they discovered that it was irritating to human skin when they applied it to themselves and their colleagues.

After a number of unsuccessful attempts to solve this problem, Leung suggested that Berenson study the medical literature to look for an answer. Berenson discovered an old paper that reported that stiff and inelastic bandages cause shear on skin that results in irritation. They concluded that they had to give the device the capacity to stretch. "Unlike a piece of tape that can be made stretchable with the right material, giving a Microstaple array made out of metal the ability to stretch was a challenge. We came up with novel cantilever springs along the base of the Microstaple array that solved the problem," informs Leung.

Although the journey to the final product did not stop there, the invention of the spring was the breakthrough needed to make a device that was suitable for clinical use. After further optimization, the final microMend product made it to the market earlier this year. It falls under the FDA classification of a Class 1 510(k) exempt medical device, which allows a rapid and straightforward regulatory process. microMend's technology is protected by two pending patents on the Microstaple technology, device design and mechanics and its clinical applications.

KitoTech has developed a straightforward, reproducible, and low-cost manufacturing process, which uses readily available and inexpensive FDA-grade materials. The Microstaples are produced by a leading manufacturer of miniature metal products, including components of medical devices. The final assembly and packaging are performed by an outside manufacturer with extensive experience in producing wound care and closure products. All materials are sourced in the US, and the manufacturing of the Microstaples and final product is performed in the US.

In the future, KitoTech will be developing new products based on its Microstaples. Berenson states: "Our Microstaple technology platform can act as an enabling technology to improve current medical devices by allowing them to securely attach to the skin. Now that we have developed our core technology, it is straightforward to develop these products." Leung adds, "Wound care is the next frontier we will be focusing on in which Microstaples will be used to enable more secure attachment of wound dressings, skin substitutes and grafts to the skin. In addition, Microstaples will also be incorporated into a variety of appliances and devices, including ostomy bags, surgical drains, catheters, EKG monitors, glucose monitors, insulin pumps, and more."

> We have conducted studies that demonstrate the proficiency of our product with regard to the cosmetic outcomes and confirm that wounds can be closed seven times faster with microMend compared to sutures

Ready to Revolutionize – A Unique Approach

With a small and dynamic group, folks at KitoTech are fueled just as much by their passion for the company as they are for the technology that is about to transform the way wound closure is performed. It is truly a team effort comprising KitoTech's employees as well as its many collaborators including key advisors and consultants, manufacturers, physicians, and the distributors of microMend.

KitoTech's first market is emergency medicine, including ERs and urgent care centers, where the ability to use medical products rapidly and easily is of major importance. Since its recent introduction, microMend has achieved rapid market uptake and currently has an 80% repeat order rate, which is well above the industry average. The high reorder rate speaks volumes about its potential for the future. "microMend products are truly revolutionary. They have noticeably decreased our throughput times for laceration repairs in the Emergency Department. Moreover, patients love them because there are no needles involved. Additionally, the cosmetic results are fantastic. These products are especially useful for laceration repairs in children," sums up Dan Wahl, DO, one of KitoTech Medical's many happy customers. KitoTech is beginning to explore opportunities in the OR, where microMend has demonstrated excellent results in closing surgical incisions and port sites associated with laparoscopic and robotic surgeries.

The opportunities for microMend reach beyond physicians and hospitals. In contrast to sutures and staples, microMend does not require skilled medical personnel to use them. It can be used by a broad range of health care personnel, including paramedics, PAs, nurse practitioners, nurses, nursing assistants, medical assistants, and others. This opens up opportunities outside of the hospital for microMend, where wounds are common, but physicians and other skilled personnel are rarely present to close them. microMend is currently being used in several of these markets including the military, first responders (ambulances, fire, police), home health care, and prisons. It also has the potential to be used in nursing homes, occupational health, schools, and athletics. Ease of use as well as the speed of microMend closure are especially beneficial in all of these settings. These are very large markets amounting to millions of patients and require a sales channel with the broad reach to access them. KitoTech is working with Henry Schein, the largest distributor of medical products outside the hospital in the US, to sell into these markets.

"Someday we expect the average person will be able to purchase microMend for use at home, in the wilderness, and many other settings where cuts, lacerations, and skin tears occur," he adds.

The future is bright for KitoTech. Growing numbers of physicians and other health care providers are becoming fans of microMend. Its applications outside of hospitals and clinics create a number of additional opportunities for utilizing our product. In addition, the Microstaple technology is a platform that can be used to improve the function of existing medical devices, which will lead to many new products. A "small" idea can have a big impact with the right team to make it a reality.

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COMPANY:

KitoTech Medical

WEBSITE:

kitotechmedical.com &
micromendskinclosure.com

KEY PERSON:

Ronald Berenson,
president and CEO,
Paul Leung,
VP of Operations

DESCRIPTION:

KitoTech Medical has devised microMend—an excellent, painless alternative to the conventional wound closure methods like sutures, surgical glues, and common adhesive strips

TOP 10 MEDTECH DEVICES STARTUPS - 2019

Portable medical devices have revolutionized the way in which physicians monitor and determine a patient's health. Smart glucose monitoring devices are being used to measure the glucose levels in a patient's blood on the go. These smart devices can be connected to a Smartphone in order to monitor sugar levels and take necessary actions quickly. In addition, latest automated insulin pumps have been developed to continuously monitor glucose levels and adjust insulin levels with no or little input from the user.

A rising number of people with lower-limb disorders are bolstering the need or mobility aid and assistive medical devices across the world. The growing morbidity and health burden of complications such as cerebral embolisms and spinal cord injuries are driving the demand for the medical exoskeleton. Advanced exoskeletons are being developed to enable people with paraplegia, amputees, and stroke and spinal cord injury sufferers to get back on their feet sooner. Such advancements in instrumentation and video imaging are allowing physicians to renovate several procedures in various surgical specialties starting from open to endoscopic surgeries.

This edition of MedTech Outlook features companies such as KitoTech Medical, a Seattle-based medical device company that has developed microMend, a unique wound closure device that provides safe, secure, and very rapid skin closure for a variety of incisions. MedTech Outlook's editorial board has assessed and shortlisted some of the most prominent organizations in the industry that solve challenges by implementing the current technological trends in the space. Through this special edition, we present to you "Top 10 MedTech Devices Startups - 2019."