Improved Percutaneous Tenotomy device using a novel mechanically oscillating stainless steel cutter for Tendon Debridement and Fragmentation

Clinical Study White Paper

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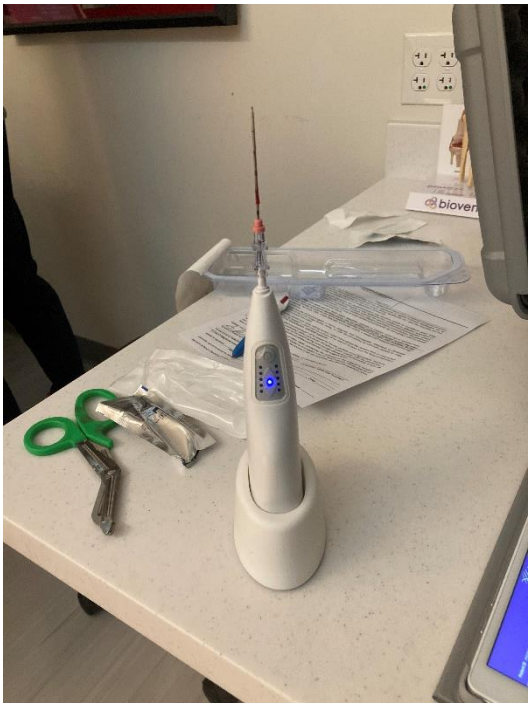
Background:

Tendinopathy is a common clinical condition due to an improper healing response in the setting of recurring stresses applied on the tendon,[1,2] resulting in disorganization of collagen fibrils, neovascularization, and degeneration of tenocytes,[3] which leads to decreased mechanical integrity without a proper healing response.[1,2] Treatment of tendinopathy is challenging secondary to heterogenicity in the presentations and degree of tendinopathy, and the recovery process is rather lengthy often requiring multiple modalities.[4] When conservative management fails, more invasive treatment modalities can be considered, which includes ultrasonic tenotomy, percutaneous needle tenotomy, and open surgical or arthroscopic debridement.[5,6]

Currently available percutaneous treatment devices include the Ocelot Nano (recently cleared by the FDA for fragmentation and debridement), Tenex and TenJet. The Ocelot Nano is a portable, handheld, battery-powered device that consists of a reusable drive unit, a charging station, a sterile disposable unit that houses the cutting tool assembly, and an optional tablet/mobile application that displays real-time operating data. The Ocelot Nano functions by rapidly oscillating a stainless-steel needle to mechanically debride and fragment irregular tendon tissue; this well-established procedure breaks up scar tissue and releases growth factors. Tenjet breaks down the damaged tissue and debrides the area using a high-pressure stream of fluid under ultrasound image guidance. With Tenex, abnormal tendon tissue identified under ultrasound undergoes emulsification through a small incision via a handheld instrument, where small-

amplitude, high-frequency oscillations emulsify necrotic tissue, and a tube-within-a-tube irrigation system aspirates the debris.[7,8] Although these devices can be utilized for management of tendinopathy refractory to more conservative management, there is no evidence in the literature suggesting tissue removal is essential in expediating recovery. TenJet uses a high-pressure saline stream to debride tissue.

Both Ocelot Nano and Tenex are handheld devices capable of performing soft tissue fragmentation or debridement; however, there are some technological differences between the two devices. The Ocelot Nano device mechanically oscillates the cutting tip while the Tenex device ultrasonically oscillates the cutting tip to perform fragmentation or debridement of soft tissue. Another difference is that the Ocelot Nano does not require irrigation to cool the cutting tip but allows clinicians to manually irrigate and aspirate if needed using a syringe attached to the cannula. On the other hand, Tenex utilizes irrigation to maintain the ultrasonic tip at the proper temperature, which can remove the naturally occurring substances from the procedure and anything that might be injected at the target site pre/post procedures. With the Ocelot Nano, the cannula can be left at the target site, creating a safe port for the targeted delivery of biologic agents such as platelet-rich plasma (PRP) without inserting another needle separately. The Ocelot device also has a longer needle tip, providing reach as far as 80+ mm, which is often required to perform procedures around deeper structures. Another advantage and novel technology of the Ocelot Nano device includes the ability to send data to a device application, showing the force required to puncture the tissue in real time, which allows the user to evaluate the tissue condition during the procedure.



To our knowledge, the device we present has not been described in the scientific literature. Here, we present results from the use of this new ultrasound-guided percutaneous tenotomy device, the Ocelot Nano, for treatment of recalcitrant chronic tendinopathy.

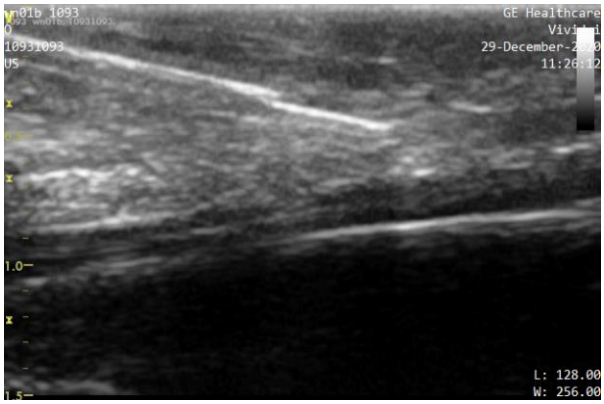
Studies:

Animal Model Study

For the initial investigation of this device, we used the Achilles tendon of 12 rabbits. To induce tendinopathy, the central medial gastrocnemius portion, approximately 1cm superior to the calcaneal tuberosity, of the right Achilles tendon were injected with collagenase. Additionally, half of the rabbits had collagenase injected into the left Achilles tendons. Only the right Achilles tendon of each animal was treated with the Ocelot device 3 weeks following the injection. The probe was inserted percutaneously into the tendinopathic portion of the tendon under ultrasound guidance to debride the damaged tissue. Six weeks following the debridement, samples of treated, normal, and abnormal tissues of the Achilles tendons were collected and sent for processing and microscopic evaluation of longitudinal sections to assess the impact of the treatment and the degree of tendon recovery.

Result:

In the animal model study, we found that all tendons demonstrated healing over time without adverse events. Minor difference was anecdotally observed between the treated and untreated legs with the untreated Achilles tendons being distinctively enlarged, which was confirmed by the pathologist. In the human cadaver study, of the 5 tendons treated with the Ocelot Nano device, 1 showed partial, 2 showed near complete, and 2 showed complete debridement. Of the tendons treated with the



Tenex device, 3 showed partial, 1 showed near complete, and 1 showed complete debridement. Both devices showed similar degree of collagen disruption at impact site.

Animal Model Discussion:

In the animal model study, rabbits were chosen given the fragility and smaller size of the Achilles tendon, especially when compared to a human Achilles tendon, to assess the safety of the Ocelot Nano device. There were some limitations to the study. Our intention for the collagenase injections was to induce a chronic tendon injury that would not recover without intervention. However, all tendons healed by 9 weeks post injection regardless of intervention status. Despite this fact, there were no complications (i.e., nerve damage, infection, tendon rupture, etc.) during the study, and the result clearly illustrated the safety of the device and its utility where the small tendon was debrided with ease.

The Cadaver Study

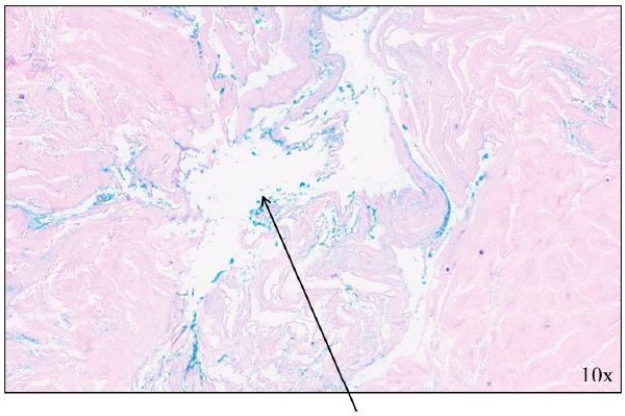
Following the animal study, a cadaver study was conducted where Achilles tendons of 10 fresh-frozen cadavers were injected with collagenase and treated with the new device and Tenex device side by side.

With real-time ultrasound guidance, percutaneous tenotomy with the Ocelot Nano device was performed on 5 cadavers with the probe passing through each tendon 10 times as the standard procedure. The same procedure was performed on the other 5 cadavers with the Tenex device. The procedure was performed and observed by fellowship-trained Sports Medicine physicians as well as a fellowship-trained musculoskeletal radiologist. The tissues were then hematoxylin and eosin stained and histologically analyzed by a pathologist to evaluate for collagen disruption and degree of debridement of the disorganized collagen in accordance with histological analysis performed by Wong et al.[9]

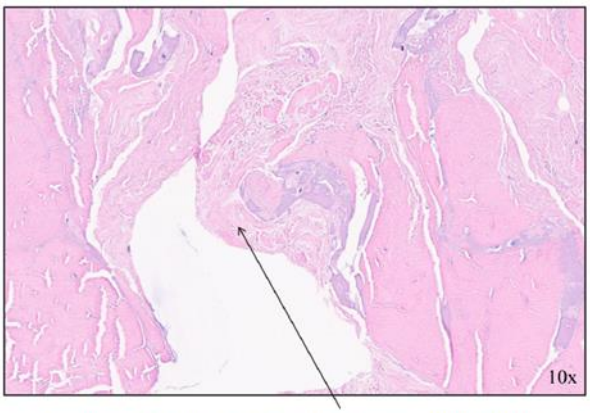
The purpose of this preclinical cadaver study was to assess the performance of the Ocelot Nano in human tissue for debridement and fragmentation of soft tissue under simulated treatment conditions and compare it to the performance of the Tenex TX1 device under the same conditions, with the goal of establishing substantial equivalence in effect of this ultrasound-guided percutaneous tenotomy device for the treatment of chronic tendinopathy.

There were no significant differences found between the 2 devices in terms of degree of collagen disruption at impact site. Device B showed better debridement of affected collagen compared to Device A. No significant differences were found with the transverse pass between the devices. Post-assessment information confirmed that Device B was the Ocelot Nano. The laboratory report noted that the extent of collagen disruption and amount of debridement of collagen may vary according to the thickness of a tendon and duration of application for each device.

Samples	Device	Histologic Findings	
		Collagen Disruption	Debridement
RLUI204205A	A	Moderate	Partial
RLUI204206A	B	Mild	Near Complete
RLUI204205C	A	Moderate	Complete
RLUI204206C	B	Moderate	Complete
RLUI206205A	A	Moderate	Near Complete
RLUI206206A	B	Moderate	Complete
RLUI207205V	A	Moderate	Partial
RLUI207206V	B	Mild	Near Complete
RLUI208205A	A	Moderate	Partial
RLUI208206A	B	Moderate	Partial



Treatment Pass with moderate collagen disruption at impact site
Complete debridement of affected collagen



Treatment Pass with moderate collagen disruption at impact site
Complete debridement of affected collagen

The cadaver study demonstrated that the Ocelot Nano (device B) was as effective as the Tenex device regarding debridement. In fact, the Ocelot Nano device showed better debridement of affected tendon tissue compared to the Tenex device without significant differences in the disruption of the collagen fiber following the procedure.

Human Clinical Study

Eighteen patients underwent a percutaneous tenotomy procedure with the Ocelot Nano device for chronic tendinopathy in various anatomical sites with either Kenneth Mautner, MD or Rob Bowers, MD at the Department of Physical Medicine and Rehabilitation and the Department of Orthopedic Surgery at Emory University in Atlanta, GA . A total of 9 male and 9 female patients with a mean age of 52.8 years have undergone the procedure. Conditions treated include medial or lateral epicondylopathy, gluteus medius tendinopathy, distal quadriceps tendinopathy, patellar tendinopathy, Achilles tendinopathy, and plantar fasciopathy. There was no procedure- or device-related adverse events. Fifteen of the 18 patients, greater than 90 days from their procedure, reported on their improvement. Seven rated their improvement as excellent (>75% improvement) and six rated as good (50-75% improvement). Two patients felt the outcome was poor (<25% improvement). Overall, 13 of 15 patients (87%) had a good to excellent outcome following Ocelot. Among those 15 patients, five patients who rated their outcome as good were also treated with PRP injections concurrently after the initial tenotomy procedure had been completed. While the findings of this preliminary clinical data need a larger sample and longer-term follow up to further evaluate the safety and effectiveness of this novel device, the results are promising.

Conclusion:

Here, we have demonstrated safety and early efficacy of a novel, percutaneous, ultrasound-guided tenotomy device, the Ocelot Nano. These data indicate that the Ocelot Nano is equivalent to Tenex, with several unique features to aid in the management of tendinopathy. While more samples are required to accurately assess its effectiveness and safety, we find that the Ocelot Nano holds significant potential in the management of tendinopathy and can provide a safe, minimally invasive, highly cost-effective alternative approach to other minimally invasive or surgical procedures.

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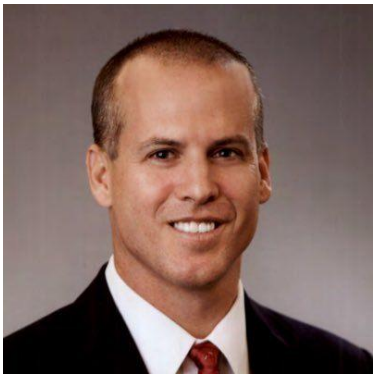

Kenneth Mautner, MD

Dr. Ken Mautner is an Associate Professor in the Department of Physical Medicine and Rehabilitation and the Department of Orthopedic Surgery at Emory University in Atlanta, GA. He is board certified in PM&R with a subspecialty certification in Sports Medicine. He is the Director of Primary Care Sports Medicine and Fellowship Director for the ACGME accredited Primary Care Sports Medicine Fellowship. Dr. Mautner is co-editor of the *Atlas of Interventional Musculoskeletal Ultrasound* as well *Musculoskeletal Physical Examination: An Evidence Based Physical Approach.* He has been using Musculoskeletal Ultrasound in his practice since 2007 and has been teaching courses around the country since 2009. Dr. Mautner is considered a leader in the field of Orthobiologics treatment for chronic soft tissue and joint disorders including Platelet Rich Plasma and Stem Cell injections. Dr. Mautner is the head team physician for the Atlanta Hawks, team physician for the Atlanta Braves, Emory University, Agnes Scott College, and Pace Academy, and serves as a consulting physician for Georgia Tech Athletes.

Robert Bowers, DO, PhD

Currently, Dr. Bowers is director of the Emory Baseball Medicine Program, which is designed to treat baseball and throwing-related injuries, prevent further injury and enhance athlete performance. As a former Division 1 college athlete himself, he brings a unique understanding of sports-related injuries to his patients. His perspective, experience and expertise allow him to serve as team physician for the Atlanta Braves and the Georgia Tech baseball team. He is also the head team physician for the College Park Skyhawks, the G League affiliate of the Atlanta Hawks, and Woodward Ac

Haruki Ishii, MD

Haruki Ishii, MD, completed his internal medicine internship at Medical College of Georgia and his residency in Physical Medicine and Rehabilitation at New York University (NYU). During his residency at NYU, Dr. Ishii was a three-time recipient of the Howard Rusk Award for Academic Excellence and Teaching. He then completed his Sports Medicine Fellowship at NYU and moved to Atlanta to continue his training. Dr. Ishii currently serves as a Primary Care Sports Medicine Chief Fellow at the Emory University and provides sideline coverages for Morehouse University as well as Oglethorpe University athletic teams.

Jonathan Shaw, DPT, OCS

Jonathan Shaw received his Doctorate of Physical Therapy in 2007, and became a board-certified Orthopedic Clinical Specialist in 2010. He practiced at Emory Physical Therapy from 2008-2014. While there, he primarily focused on orthopedic and soft tissue disorders, including chronic tendon injuries. Dr. Shaw left clinical practice in 2014 and focused on commercializing disruptive medical devices. Dr. Shaw is the Co-Founder and Secretary of the Board of Directors at TendoNova and the Sales Director at OXOS Medical.

Financial Disclosure: Jonathan Shaw is a founder so TendoNova and has a substantial financial interest. Ken Mautner, MD is an advisor to TendoNova and a co-inventor with a moderate financial interest.