TenJet™

HydroCision™

Clinical Case Report Compendium

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   Orthopedic Associates of Muskegon, Muskegon, MI

The TenJet System

The TenJet Tenotomy System, developed by HydroCision™ Inc., North Billerica, MA is designed to provide the benefits associated with surgical debridement of a diseased tendon tissue using a minimally invasive, ultrasound guided technique for precise diseased tissue resection.

The technology utilizes a two channel, 12-gauge needle specifically engineered to deliver a pressurized high velocity jet of saline for resecting tissue. TenJet's patented design uses the principles of flow dynamics to create an in-line Venturi suction effect to pull in degenerative tendinopathic tissue into a 1.5 mm window while leaving the healthy tendon fibers unharmed providing physicians with a safe and effective option to treat patients with chronic tendinopathy.

Case 1

Treatment of a Fifty-five-year-old Female with Lateral Epicondylitis

Reginald W Kapteyn, DO, MA, BA
Orthopedic Associates of Muskegon, Muskegon, MI

Patient History

A 55-year-old female with persistent symptoms for 3 years had undergone extensive conservative treatment that included activity modification, nonsteroidal anti-inflammatory drugs (NSAIDs), elbow straps, and three to four steroid injections.

Treatment

The patient consented to an ultrasound-guided tenotomy treatment using the TenJet™ device instead of open or arthroscopic surgery. After identifying the defect on ultrasound, the pathology was accessed using a minimally invasive 3 mm incision. The TenJet device was advanced through the tendon sheath to the hypoechoic area and the intra-tendinous calcifications. Using the foot pedal, the system was activated and under continuous ultrasound guidance, the procedure was performed for 4 minutes at setting 8 until a uniform isoechoic appearance was observed.

Follow Up

The patient was instructed to start physical therapy with eccentric loading after the 2-week follow-up visit for a period of 4 weeks.

Visual Analog Scale (VAS) pain scores improved from 5 (baseline) to 2 at 2 weeks, and 0 at 6 weeks. The patient remained pain-free at 6 months.

Patient Reported Elbow Evaluation (PREE) function scores improved by 43% at 2 weeks, 99% at 6 weeks, and 100% at 6 months.

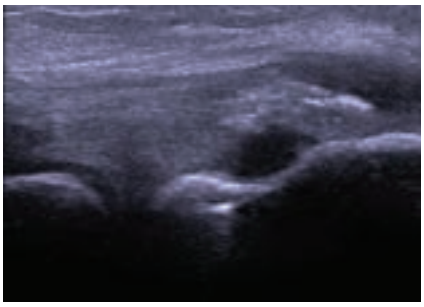

Figure 1.

Pre-procedure diagnostic ultrasound imaging shows an extensive area of tendon with calcifications and necrotic tissue.

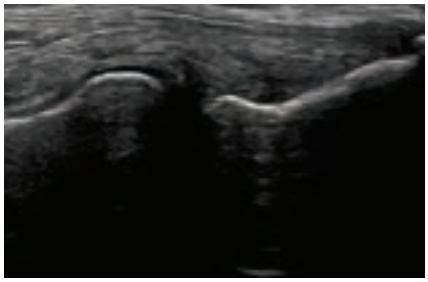

Figure 2.

Six-month follow-up ultrasound shows complete resolution of the calcific debris, with reduced hypoechoic appearance.

Case 2

Treatment of a 42-year-old female tennis player with calcific rotator cuff tendinosis

Michael Dakkak, DO, MBA
Cleveland Clinic Florida, Weston, FL

Patient History

A 42-year-old recreational right hand dominant tennis player with no significant past medical history presents with chronic shoulder pain for 2 years. She denies any trauma and reports the pain has been progressive where she now experiences pain with overhead activities, reaching, and ADLs. Her pain was reported as a constant dull ache and rated an 8/10 at baseline and a 10/10 with activity. She reports that pain worsens while sleeping. Previous treatments have included ice/heat, NSAIDs, physical therapy, and both oral steroids and a subacromial corticosteroid injection, which successfully provided short-term relief.

Physical Examination

There were no overlying skin changes, swelling, or deformity on the right shoulder. Patient did not have bony tenderness but did have tenderness to palpation of the posterior distal insertion over the greater tuberosity. She had full range of motion both actively and passively, however with pain. She had 5/5 strength in her upper extremities but with reproducible pain during empty can testing of the supraspinatus. Hawkins and Neer Test were positive.

Ultrasound Evaluation

A high frequency linear transducer was used to perform a musculoskeletal ultrasound examination in short and long-axis. A mild amount of tendinosis was present with a calcium deposit measuring 0.98 cm x 0.32 cm x 0.46 cm (Figure 2). The calcification had well-defined borders with posterior acoustic shadowing present and appeared to be mature.

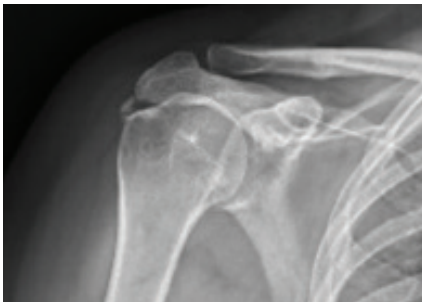

Figure 1.

Initial X-ray

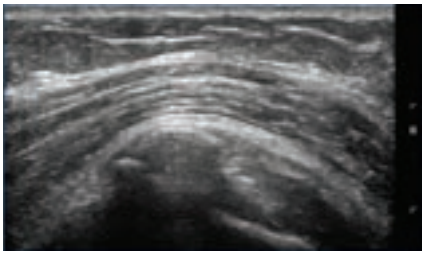

Figure 2.

Initial Diagnostic Ultrasound

Ultrasound-guided Tenotomy and Removal of Calcific Debris

The calcific portion of the supraspinatus tendon was identified using ultrasound. The patient was draped sterile and then had local anesthesia administered to the tendon. An incision was made with an # 11 blade down to the tendon to create a track and advance the TenJet needle into the tendon. Using the needle, and the pressurized saline jet at the tip of the needle, the calcium deposit was broken up and extracted (Figure 3). The tendon was viewed both in short and long axis to ensure as close to complete removal of the calcium deposit. The total time the device was used for approximately 7 minutes.

Post-Procedure Follow-up, and Activity Progression

After the procedure, the patient was placed in a sling for 2 days. She was instructed to start range of motion pendulum exercises after 2 days. At her 10-day follow-up office visit, a wound check was performed, which showed no signs of infection. A repeat X-ray (Figure 4) and ultrasound (Figure 5) were obtained. The patient reported having 80% improvement in her symptoms.

The patient was instructed to start physical therapy with progressive range of motion and strength training exercises once a week for the following 6 weeks. At her 2 month follow-up appointment, she no longer reported pain and was cleared to start a return to sport rehabilitation program. At 3 months, she resumed playing recreational tennis without pain.

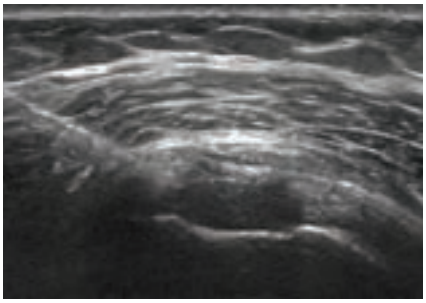

Figure 3.

Ultrsound showing the TenJet needle during the procedure

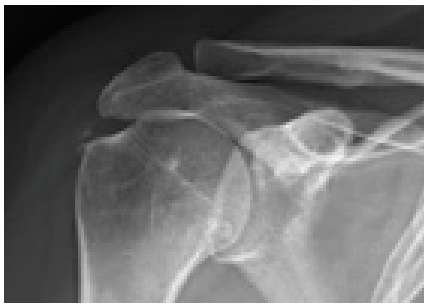

Figure 4.

X-ray at 10-day post-procedure appointment

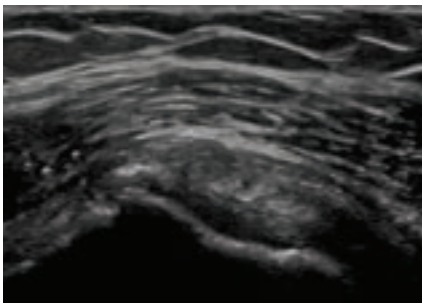

Figure 5.

Ultrasound at 10-day post-procedure appointment

Case 3

Treatment of a Thirty-one-year-old Male Soccer Player with Patella Tendinosis

Joseph J. Ruane, DO
Ohio Health, Columbus, OH
Head Team Physician, NHL Columbus Blue Jackets

Patient History

A 31-year-old, high-level recreational soccer player presented with a history of anterior knee pain, and no comorbid conditions. He began developing intermittent pain 4 years ago but was able to play through the discomfort. Six months ago, pain progressed to a point where it not only inhibited participation, but made it difficult to perform simple tasks such as playing with his young children and carrying objects up the stairs. Daily average pain was 3-4/10, and up to 7/10 with activity.

Prior treatments had consisted of three separate rounds of physical therapy, the last involving an aggressive eccentric protocol. The patient had taken multiple anti-inflammatory drugs and two rounds of oral corticosteroids, which, initially, alleviated his symptoms enough to allow exercise but recently stopped providing any benefit.

Physical Examination

The gross examination of the knee revealed no abnormalities. There was no joint effusion, ligaments were stable, and there was no joint line tenderness.

The patient's gait was not demonstrably antalgic. On seated examination, the right knee showed a degree of fullness in the infrapatellar region compared to the left. There was tenderness of the patella tendon upon palpation, but no significant soft tissue crepitus. There was no erythema or warmth. Quadriceps strength was adequate although the tone and bulk was noted to be less on the affected side than on the unaffected side.

Ultrasound Evaluation

Musculoskeletal ultrasound evaluation using a high frequency linear probe was obtained (Figure 1). Longitudinal view revealed considerable diffuse thickening of the proximal tendon, with scattered areas of hypoechoic change and loss of normal fibular continuity. An

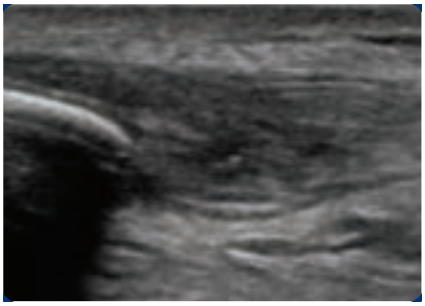

Figure 1.

Pre-procedure ultrasound in longitudinal view of the patella tendon. Note diffuse hypoechoic proximal thickening with intra-substance tearing.

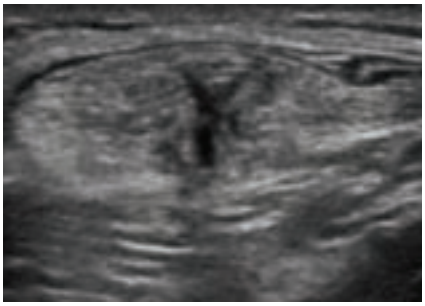

Figure 2.

Pre-procedure ultrasound in transverse view. Note central anechoic lesion.

irregular, central contiguous area of anechoic signal was observed, suggesting intra- substance tear. In the transverse plane (Figure 2), extensive intra-substance changes, tendon thickening, and a central anechoic lesion were observed. There were no significant calcifications noted, and the bony acoustic signal from the inferior pole of the patella was unremarkable. There were no demonstrable changes in the Hoffa's fat pad.

Ultrasound-guided Tenotomy

The rationale, relative risks and benefits, and realistic expectations of ultrasound-guided tenotomy were described, and the patient consented to undergo the procedure. In the procedure room, after sterile preparation and application of sterile gel, a 3 mm incision was made 2 cm below the inferior pole of the patella. The TenJet™ handpiece was inserted, and the tip was observed under direct visualization until it contacted the inferior pole of the patella. Sweeps were made from cranial-to-caudal as well as medial-to-lateral while gently rotating the probe to thoroughly explore the lesion. Short axis views were utilized to ensure adequate medial to lateral debridement.

Post-procedure Instructions

Due to the size of this lesion, the patient was placed in a double hinge brace locked out at 30 degrees while awake for the first 2 weeks. Toe touch weight bearing with crutches was allowed for the first three days, then as tolerated until the recheck visit. A small supply of Tramadol was provided, which the patient stated he took twice on the 1st day, then OTC analgesics were sufficient.

Follow-up and Activity Progression

At the two-week follow up visit, there was the expected amount of local tenderness at the treatment sight, and the wound healed well with no local swelling. The patient was not using crutches and was tolerating full weight bearing with little discomfort. He had discontinued OTC analgesics. Pain was rated at 2-3/10. Progressive range of motion and strengthening plan was prescribed to follow over 4 weeks.

At the 8-week follow up visit, the patient was tolerating load-bearing exercise but had not yet started impact activity. Activity-related pain was reported to be 1-2/10. A progressive return-to-sport plan was initiated, with light jogging allowed.

At 12 weeks the patient began a gradual return to recreational soccer.

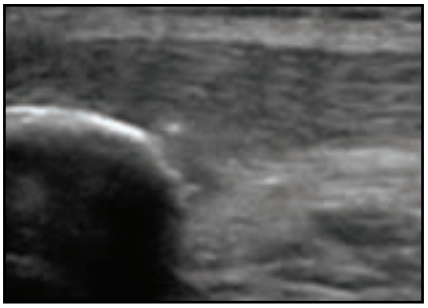

Figure 3.

Twelve-week ultrasound in longitudinal view demonstrates improved morphology with a more normal linear fibrillar pattern.

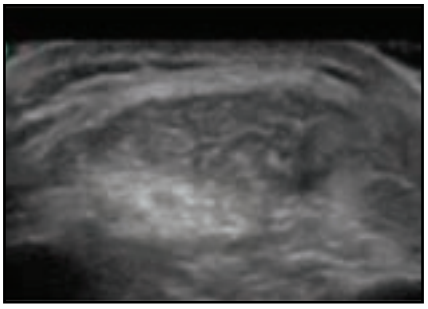

Figure 4.

Twelve-week ultrasound in transverse view illustrates an increased signal density and a decrease in the overall size of the intra-substance tear.

Case 4

Treatment of a 54-year-old male runner with chronic plantar fasciosis

Michael Dakkak, DO, MBA
Cleveland Clinic Florida, Weston, FL

Patient History

A 54-year-old male with no significant prior medical history presents with chronic left plantar heel pain. He denies any trauma and reports that the pain is worse in the morning for the first hour upon awakening with gradual improvement throughout the day. His pain is reported as an intermittent sharp ache at a baseline pain level of 6/10, which is 9/10 at its worst. He was previously seen by a foot specialist where he was placed in a CAM walking boot, sent to physical therapy, and given multiple corticosteroid injections; with each injection providing relief for about 1 month. An MRI showed focal nodular thickening of the medial cord plantar fascia in the forefoot measuring up to 0.8 x 0.6 cm. He proceeded to obtain a second opinion from sports medicine for minimally invasive treatment options.

Physical Examination

There were no overlying skin changes, swelling, or deformity on the left foot. He did not have bony tenderness but did have tenderness to palpation over the left medial calcaneus and at the origin of the plantar fascia. The patient was noted to have full range of motion both actively and passively. He had 5/5 strength. Special testing was positive for Windlass. Calcaneal squeeze and single leg hop testing was normal.

Ultrasound Evaluation

A high frequency linear transducer was used to perform a musculoskeletal ultrasound examination in short and long-axis. There was a severe amount of fasciosis measuring 0.85 cm at its thickest point in both short and long axis on ultrasound (Figure 1). No hyperemia was present. There were intra-fascial hypoechoic regions likely representing degenerative tearing and severe fasciosis.

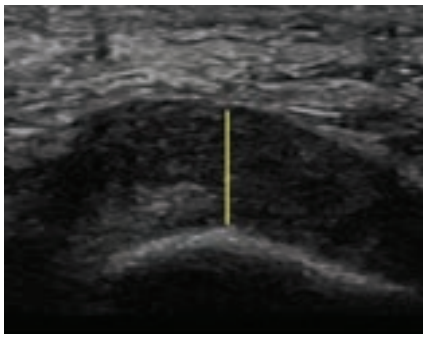

Figure 1.

Pre-procedure ultrasound of plantar fascia

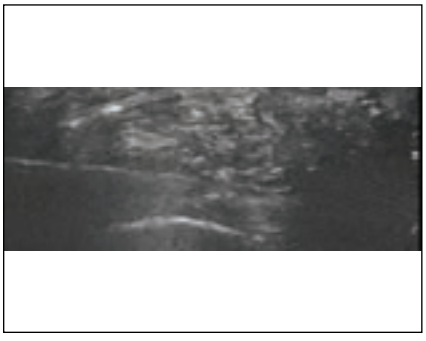

Figure 2.

Image of TenJet device during procedure

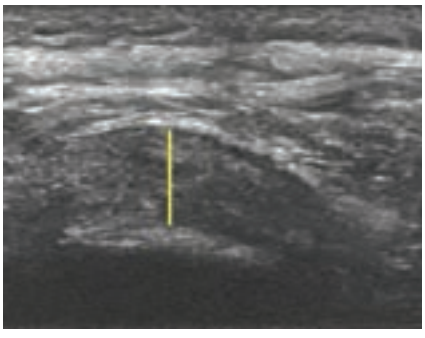

Figure 3.

Post-procedure ultrasound of plantar fascia at 3 months

Ultrasound-guided Tenotomy

The plantar fascia was identified using ultrasound. The patient was draped sterile and then had local anesthesia administered to both perifascial and intrafascial tissues. An incision was made with an #11 blade down to the fascia and a track was created for advancing the instrument. The TenJet needle was visualized on ultrasound and advanced into the area of severe fasciosis where the tissue was excised using the pressured saline jet at the tip of the needle. The fascia was viewed both in short and long axis during the procedure to excise the diseased tissue in the hypoechoic region. The device was used for approximately 5 minutes.

Post-Procedure Follow-up and Activity Progression

The patient was placed in a CAM boot for 2 weeks after the procedure with instructions to leave it on at all times except while showering and sleeping. At his initial 10-day follow-up visit in the office, a wound check was performed, which showed no signs of infection. He reported experiencing about 40% improvement from his baseline symptoms.

He was then instructed to wean out of the boot and start physical therapy once a week over the next 6 weeks. Exercises with a focus on progressive range of motion, ankle joint mobility, gastrocnemius and soleus flexibility, and intrinsic foot muscular strengthening exercises were recommended.

At his 3-month follow-up appointment, he no longer reported pain and was cleared to start a return to run program. A repeat musculoskeletal ultrasound was performed at his 3-month follow-up appointment, which showed improved fascia architecture with fewer regions of hypoechoic tissue. Fascial thickening improved, measuring 0.71cm at its widest point (representing ~16% decrease in thickness). The patient no longer reported symptoms and successfully went on to complete a 5k race within the next 8 weeks.

Discussion Points

This case demonstrates that the TenJet device is effective in treating severe plantar fasciosis. It should be noted that while the overall thickness of the plantar fascia had reduced at the 3-month follow-up, it was still thickened compared to acceptable normal limits at its widest point. However, the overall fascia architecture showed considerable improvement and the patient had a successful recovery with resolution of pain and return to running.

Case 5

Treatment of Painful Right Achilles Calcific Tendinosis

Reginald W Kapteyn, DO, MA, BA
Orthopedic Associates of Muskegon, Muskegon, MI

Patient History

A 60-year-old, male patient presented with right Achilles pain that had worsened over a period of nine months without any inciting event. The pain was at the posterior calcaneus, with or without weight bearing, but worse while standing and walking. He had undergone four weeks of physical therapy, had tried shoe inserts and a stretching program.

Examination

On physical examination, the patient had tenderness at the insertion of the right Achilles tendon; dorsiflexion was 12 degrees. Lateral radiographs showed three linear calcific densities through the mid-Achilles tendon, and numerous calcific densities at the distal Achilles. The patient noted pain at both the mid-Achilles and distal Achilles with ultrasonographic palpation. Ultrasound examination confirmed the calcifications both at the mid- and the distal Achilles combined with a hypoechoic tendon appearance.

Treatment with the TenJet™ device was ultimately recommended to treat the numerous calcifications using a minimally invasive approach.

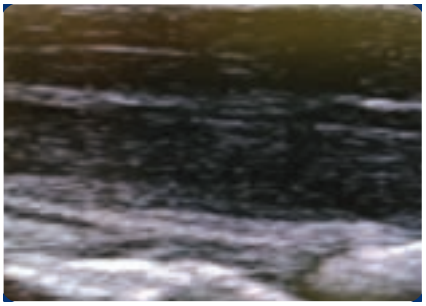

Figure 1.

Pre-procedure ultrasound

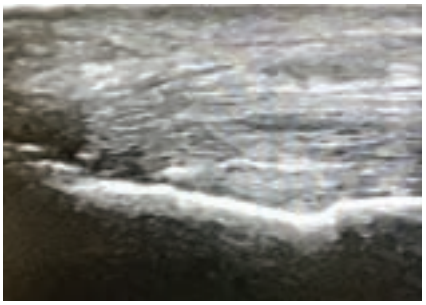

Figure 2.

6 Month follow-up ultrasound

Ultrasound-guided Tenotomy

The diseased portions of the tendon were identified using ultrasound imaging and marked. After delivery of local anesthetic, three incisions were made to access the calcifications and the entirety of the hypoechoic tissue.

The TenJet needle was placed within the calcific bands, longitudinal and parallel to the tendon fibers. Using the TenJet device for approximately 2 minutes, the mixed hyper- and hypoechoic areas were removed, leaving an isoechoic and healthy appearance to the mid-tendon. The distal Achilles was then treated, and after approximately 3 minutes run time, it was estimated that 75% of the diseased tendon had been removed. Some calcific debris remained, but the procedure was stopped because additional incisions would have been necessary to provide access, which seemed excessive in a high stress area. The patient was instructed to use a walking boot until the 2-week follow up visit.

Post-Procedure Follow-Up

The patient was non-compliant and stopped wearing the walking boot 7 days post-procedure since his pain had begun to improve. As such, he presented at the 2-week follow up visit up with a pain rating of 7/10, the same as prior to the procedure. One of the incision sites was noted to have slight drainage and slough. This was debrided in the office, and Steri-strips™ were re-applied. The patient was prescribed Keflex 500 mg QID for seven days, and was instructed to continue wearing the boot until the next follow--up visit. The patient was instructed to begin an eccentric strengthening program once he was pain-free at rest.

Follow-Up

The patient was seen again at 3 weeks post-procedure and doing quite well. He was pain-free at rest, and had minimal discomfort in the right heel when standing. The wound had healed, and the infection had resolved.

At the 4-week post-procedure visit, the patient was pain-free with static standing. He had a dull ache with a few degrees of stretch at the insertion of the Achilles. However, the pain had improved to 3/10 compared to 7/10 pre-procedure. He was off prescription pain medication, and had just begun the eccentric physical therapy program of two weekly sessions for four weeks. His walking boot had been discontinued.

At the 3-month post-procedure visit, the patient had completed physical therapy and returned to work. He reported no pain at rest, a dull ache with few hours of standing, and little pain while walking.

6-month post-procedure ultrasound demonstrated complete healing of the entire tendon without any residual calcifications.

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