Cadaver Study Examining Safety Profile of TenJet® Percutaneous Tenotomy System

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Abstract

Our aim was to establish that using focused water jet technology for debridement and aspiration of degenerative tissue associated with chronic tendinopathy is tissue discriminating and has minimal effect on healthy tendon. The reported incidence of tendinopathy in the general population ranges from 1-4% with significantly higher rates associated with overuse in athletes and workers, leading to prolonged chronic pain, loss of work days, and disability[1,2]. Conservative methods for treating the pain associated with chronic tendinosis are in fact limited, and consist of relative rest, disuse, physical therapy for strengthening the tendon, injections of either corticosteroids or platelet rich plasma[3], (or) another type of percutaneous procedure that utilizes ultrasonic energy. Our aim was to examine the effect of various settings of TenJet, a focused hydrojet technology, on healthy tendon.

Need For Improved Percutaneous Tenotomy Technology

The clinical acceptance of any new technology is dependent on its ability to demonstrate improvement over an already accepted mode of treatment. Current options for debriding diseased tendon include open or arthroscopic surgical procedures performed under general anesthesia, or a percutaneous tenotomy procedure using ultrasonic energy to emulsify and aspirate diseased tissue. Shortcomings of percutaneous tenotomy using ultrasound energy include a high grade of subcutaneous edema that develops at the incision site due to high volumes of saline being injected into the tissue during the procedure. Intraoperatively this edema can impede visualization of diseased tissue and postoperatively can take time to resolve. Furthermore, the instrument itself is limited in size, and thus access to deeper tissues can be difficult or impossible.

Shortcomings of open or arthroscopic surgical procedures include costs and risks generally associated with open surgery or arthroscopy, including the need for general anesthesia.

Percutaneous Hydrotenotomy

The TenJet hydrotenotomy system, developed by Hydrocision® Inc., North Billerica, MA, seeks to provide the benefits associated with surgical debridement of a diseased tendon tissue in a minimally invasive procedure that can be performed in 15 minutes under ultrasound guidance and a local anesthetic. The TenJet system is able to provide selective debridement by discriminating between different tissue consistencies.

The TenJet hydrotenotomy system includes a power console that delivers high-pressure sterile saline through a miniaturized tube to a distal-end nozzle of a hand piece from which it is delivered across a small window, less than 3 mm in size, as a fine, high pressure jet stream. The velocity of the saline, controlled through settings 1 to 10 on the console, creates its own Venturi suction effectively pulling tissue into the cutting window where the jet and suction act simultaneously to cut and remove targeted tissue. Debrided tissue and waste saline then travel through a second evacuation tube to a waste container. The pressure and nozzle parameters built into the system make it possible for the device to selectively debride diseased tissue, which is more gelatinous in composition, while leaving the healthy surrounding, fibrous tendon tissue intact.

TenJet handpiece with a 3”12 gauge needle tip.

HydroCision Power Console

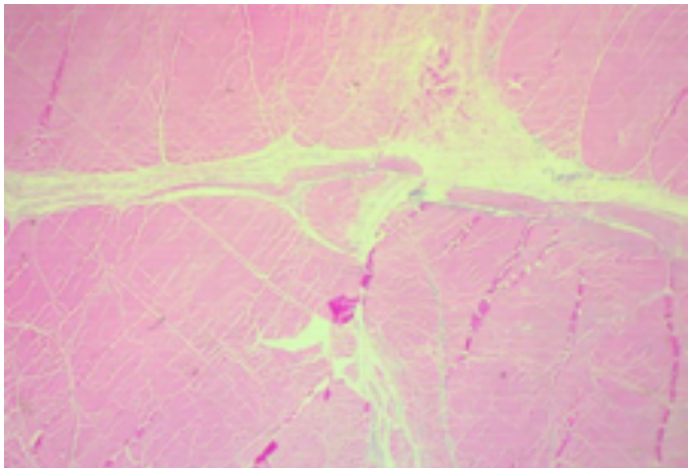
Cadaver Experiments

In order to establish safety parameters, we chose to examine the effect of various water jet pressures on healthy tendon tissue integrity. One patella tendon, one Achilles tendon, one extensor tendon mass, fresh, unpreserved, 24hrs after deceased time were obtained.

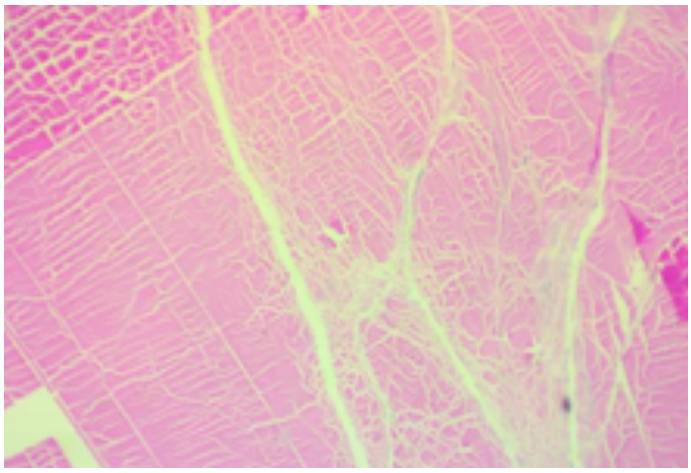
Two pilot experiments were conducted to establish the technique for the safety study. For the first pilot, the cutting end of the TenJet hand piece was placed on the surface of the superficial fascial tendon of the Achilles myotendinous region, and the hydrojet stream was applied at a pressure setting of "3" for 30 seconds and then for 3 minutes. At thirty seconds, the surface appearance of the tendon was then examined under standard analog microscope which revealed no disruption of the superficial fibers over the portion of the tendon. At 3 minutes, a slight disruption of superficial fibers was noted. This was confirmed under 40x standard microscopy. This was repeated at pressure setting of "10" for 3 minutes. At a setting of "10" for 3 minutes, some visual and microscopic disruption of superficial tissue was observed without any evidence of dissection of the tendon.

The second pilot experiment was conducted on a patella tendon to establish, under ultrasound guidance, the technique of intratendon placement along the longitudinal orientation of the fibers. We thus commenced establishing a control channel, where the instrument was advanced along the longitudinal orientation of the fibers for a channel of approximately 2cm's, again confirming intratendon placement throughout under ultrasound visualization.

We then utilized the distal portion of Achilles tendon to examine a more prolonged and practical effect of utilizing the TenJet hydrotenotomy system on the healthy tendon.Settings of "3", "5", and "7" were utilized, and the handpiece was placed into the tissue for three minutes time at each setting. The handpiece was moved forward and backward to simulate debridement of diseased tissue during this time. These sections were further analyzed under 40x standard microscopy[4].



Histology of healthy tendon treated with TenJet at setting "5" for 3 minutes. Histological analysis demonstrates bundles that are varied in size and shape with most of the bundles being large. The bundles of tendon are surrounded by skeletal muscle tissue, connective tissue stroma and sections of vessels. All of the tissue has a normal histologic appearance. Nuclear characteristics are preserved in the tissue around and within the tendon.



Histology of healthy tendon treated with TenJet at setting "7" for 3 minutes. Histological analysis demonstrates large collagen bundles associated with connective tissue stroma and skeletal muscle tissue. The skeletal muscle tissue and connective tissue stroma demonstrate normal characteristics. Vascular structures are observed and are within normal limits. There is no suggestion of alteration of the tendon or the superficial tissue. On one surface, there is a thin layer of connective tissue stroma in the peritendon region.

Conclusions

Our conclusions were that, at pressure settings between "3" and "7", the TenJet hydrotenotomy device provoked miniscule gross disruption to the cadaver tissue[4]. This was confirmed under 40x standard microscopy. There was no continuous residual channel visualized with ultrasound at any of the settings which would otherwise suggest a region of "cut" tissue. The settings of "3", "5", and "7" appeared to show increased possibilities for debridement, without damage to otherwise relatively "healthy" cadaver tendon.

References

[1] Sanders T et. al., The Epidemiology and healthcare burden of tennis elbow, American Journal of Sports Medicine, 2015 May, 43 (5): 1066-1071

[2] Hopkins C et. al., Critical review on the socio-economic impact of tendinopathy, Asia Pacific Journal of Sports Medicine, Arthroscopy, Rehabilitation and Technology 4 (2016) 9-20

[3] Andres B et. al., Clinical orthopedics and related research, (2008) 466: 1539-1554

[4] Data on file

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