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Title page

Micro-invasive ultrasound guided carpal tunnel release using a novel retractable needle mounted blade, a cadaveric study.

Short title

Ultrasound guided micro-invasive carpal tunnel release in cadavers with a novel blade

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Summary

Ultrasound guided micro-invasive procedures are defined as those performed via needles without significant scarring. Ten cadaver hands underwent micro-invasive ultrasound guided carpal tunnel release using a novel needle based tool, the “micro i-Blade”. An ultrasound imaged landmark, the inflexion point of the ligaments distal to the hook of the hamate, was used to position the distal extent of the cut. The transverse carpal ligament was successfully released in all hands without damage to nerves or arteries. In 3 specimens the fascia between the thenar and hypothenar muscles was partly preserved while the palmar aponeurosis was partly cut in one specimen. The “micro i-Blade” with the cutting knife retracted was also useful as a probe palpated through the palm of the cadaver hand, to test the release of the transverse carpal ligament and to guide the procedure.

Key words, Ultrasound, carpal tunnel release, ultrasound guidance.

Introduction

Ultrasound guided carpal tunnel release of the transverse carpal ligament (TCL) was first described in 1997, initially with a 1.0 to 1.5cm skin incision and subsequent ultrasound guidance (1). Subsequent “ultra-minimally invasive” techniques have been described using ultrasound to guide endoscope sheaths and blades(2,3), unprotected endoscopic blades (4), hook knives (5,6) and purpose built instruments (7), these have all required small incisions and dissection to position the tools.

To be described as micro-invasive a procedure needs to be carried out without incisions, that is with 14 gauge (2.1 mm) or smaller needle sized instruments that will not leave a significant scar. Micro-invasive approaches to cutting the TCL have been described including an abrading saw with entry and exit holes (8) and a cutting thread or wire, threaded through a needle from the palm to a wrist exit hole and then back again to encircle and cut the transverse carpal ligament while preserving the palmar aponeurosis (9). Simple repeated needle fenestration of the TCL has also been described (10).

The TCL is a tough ligamentous structure creating the roof of the carpal tunnel between the scaphoid and trapezium bones on the radial side, and the pisiform and hamate bones on the ulnar side. Traditionally the TCL was considered to include all the collagenous connective tissue deep to the palmar aponeurosis which is a strong layer bound to the skin of the palm and which receives the insertion of the palmaris longus muscle. Modern anatomists however have recognized there is a separate superficial layer (11,12). The deep layer of the TCL is composed of firm densely packed transversely orientated collagen fibres and comprises the TCL proper, enclosing the carpal tunnel with free edges both proximally and distally. It is normally 1.3 to 3.6mm thick although it can be up to 6mm thick in some cases of carpal tunnel syndrome (13). The superficial layer, adherent to the deep TCL in the centre of the carpus, blends proximally with the deep fascia of the forearm and gives origin to and encloses the thenar and hypothenar muscles. It contains many nerve fibres and looser irregularly directed bundles of collagen fibres (10). The fibrous and well innervated palmar aponeurosis into which the palmaris longus muscle inserts covers this separate superficial fascia which in turn is covered by subcutaneous fat and skin.

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One of the authors (PH) has been developing a multi-purpose micro-invasive instrument consisting of a needle with a retractable cutting blade deployed from the tip. Marketed as the “micro i-Blade” (Summit Medical Ltd, Sandy, Utah. USA http://microi-tool.com), it has been designed specifically for use under ultrasound guidance.

Figure1 here.

The purpose of this study was to perform ultrasound guided carpal tunnel release in 10 cadaver hands using the micro i-Blade, with subsequent dissection to verify the release of the TCL and evaluate damage to other structures. We planned to correlate the anatomy seen on ultrasound imaging with the subsequent dissection and gain insights into the surgical technique and landmarks needed to perform and verify release of the transverse carpal ligament using the micro i-Blade.

We have also found the distal TCL can be difficult to distinguish under ultrasound imaging from the overlying palmar aponeurosis particularly in the location near the hamate bone. The palmar aponeurosis contains many nerve endings and cutting this structure during carpal tunnel release may contribute to persisting pain (11). One of the key surgical landmarks in releasing the TCL is the small pad of fat superficial to the median nerve which often wraps around the distal margin of the TCL, the surgical exposure of which is commonly used to establish the distal extent of the release (13). During previous imaging and dissections we believed this fat pad and distal margin of the TCL are located at the inflexion point at which the fascial structures in the palm change angle, approximately 5mm distal to the distal part of the hook of the hamate. We planned to section the TCL from just distal to this point using the micro i-blade and correlate that with our dissection of the hand.

Figure 2 here.

Methods

The study was performed at the Macquarie University Faculty of Medicine Surgical Skills and Anatomy Centre in Sydney Australia which provided institutional review and approval. The cadaveric specimens were preserved frozen and thawed before the study. A Sonosite “Edge” ultrasound system with a linear 6 to 13mHz 38mm (HFL 38) probe with a plastic cover was used for imaging (Sonosite Inc, Bothell, WA, USA).

Figure3 here.

The hands were supported in a dorsiflexed position over a bolster and secured to a plate with elastic bands. An initial ultrasound scan was performed and the median nerve was imaged to its distal division particularly noting the most ulnar sided branches. Also identified were the ulnar artery and nerve including the distal branches of the nerve and the formation of the superficial palmar arterial arch. In the final 6 specimens the following positions were also marked.

1. The point at which the median nerve emerges from deep to the flexor digitorum superficialis muscle to lay directly under the deep fascia of the forearm.
2. The midpoint of the pisiform bone
3. The proximal extent of the hook of the hamate
4. The distal extent of the hook of the hamate
5. The inflexion point of the TCL/palmar aponeurosis

The micro i-Blade was inserted through the skin, just proximal and to the ulnar side of the emergence of the median nerve from deep to flexor digitorum superficialis. Under transverse (short axis) ultrasound guidance the tool was passed immediately deep to the TCL on the ulnar side of the median nerve and close to the hook of the hamate. When the tip was distal to the hamate the probe was rotated to the longitudinal imaging plane, lined up with the tool and the tip positioned just distal to the inflexion point which we propose marks the distal TCL.

As the micro i-Blade is activated it passes distally and at an angle from the body of the tool, this was imaged in the longitudinal scan, After checking the blade position was distal to the inflexion point the cutting stroke was commenced by withdrawing the i-blade back towards the wrist, lifting the tip while maintaining external pressure from the skin on the cutting surface. This process was repeated until the ligament was determined to have been cut.

Figure 4 here.

Full sectioning of the ligament was determined using 3 techniques, firstly by imaging the probing retracted micro i-Blade, we knew from previous experience this was feasible but slow. Secondly we planned to use the retracted micro i-Blade as a probe without imaging to feel the deep surface of the TCL. In our pilot releases prior to the study however the texture of the palmar aponeurosis on probing was found to be similar to the partially cut TCL, varying in the firmness of the tissue while having a similar rough feel to the probing tool. Finally we assessed palpation of the tip of the retracted micro i-Blade through the skin to determine if we could feel the difference between the cut and uncut TCL.

Results

The inflexion point of the ligament was easily imaged in all specimens at a mean distance of 6.5mm distal to the hook of the hamate.

Table 1 here

In all ten specimens there was complete section of the TCL proper as evidenced by wide separation of the cut edges along the entire length of the ligament. In three of the ten specimens a small number of softer strands of the superficial TCL remained uncut. The overlying palmar aponeurosis was partially sectioned in one specimen. There was no damage to the median nerve, ulnar nerve or artery or the superficial palmar arch.

Figure 5 here.

Figure 6 here.

Using the retracted micro i-Blade as a probe under ultrasound imaging allowed a high degree of confidence that the TCL was cut by imaging the tool passing between the cut edges of the ligament from inside the carpal tunnel to the superficial tissues. However it is important to identify and maintain imaging at the tip of the tool in making this assessment, which makes it a relatively slow process repeatedly moving and imaging the tip. Using the retracted micro i-Blade as a probe allows the tip to feel the intact portions of the TCL as a surgeon would probing during an open release. The overlying tissues of the palmar aponeurosis however have a similar rough feel to the partly cut TCL, slightly catching the tip of the retracted blade. The firmer quality of the TCL can be difficult to distinguish from the palmar aponeurosis. In our early experience prior to the study it was found that cutting all the fibrous tissues found overlying the carpal tunnel on probing with the micro i-Blade tip usually included the palmar aponeurosis. Palpation of the tip of the retracted micro i-Blade through the skin provided a quicker means of establishing the release, as the feeling of the tip deep to the TCL was distinctly different after release of the ligament. While the TCL is intact the firm fibres mean the tip cannot be clearly felt through the skin. This was found to be the quickest and most definite way of ensuring the complete division of the TCL while minimising the sectioning of the soft overlying palmar aponeurosis. After the first one or two passes of the micro i-Blade a distinct loosening of the TCL and a passage formed along the cut of the tool was apparent. This also aided the subsequent positioning of the micro i-Blade for further cutting passes.

We did not record the number of passes of the blade or the time taken to perform the procedure as we were also evaluating the methods to ascertain the release. There was however a learning effect evident with the procedure taking around 15 minutes in the later releases.

There was no deterioration in the quality of imaging from introduction of air during the repetitive cuts made in the TCL.

Discussion

This study establishes the feasibility of using the micro i-Blade to perform carpal tunnel release. The tool was able to be positioned accurately under ultrasound guidance and the blade deployed with enough force to cut the ligament. Rojo-Manaute (5) described a “ducks beak” appearance of the distal TCL which they included in the distal part of their release. In the accompanying figures the indication of the distal part of the “duck’s beak” shows a short tapered end which is unclear in the accompanying ultrasound image. Guo (9) subsequently defined their concept of the “duck’s beak” with an elongated distal segment superficial to the fat pad enclosing the distal TCL, describing this as the blending of the TCL with the palmar aponeurosis. The subsequent diagram of the position of their cutting thread excludes this elongated distal segment which represents palmar aponeurosis alone. The inflexion point we used probably represents the initial narrowing of the short “duck’s beak” described by Rojo-Manaute. The identification of the inflexion point of the ligaments on ultrasound imaging and subsequent positioning just distal to this point ensured the tool cut the entire TCL. In addition the blade of the micro i-Blade protrudes 2 mm beyond the tip of the needle when deployed so that the cut actually started 4 to 5 mm beyond the inflexion point.

During our experience of the micro i-Blade it has become apparent that the blade is not as sharp as a surgical scalpel. While this has slowed the sectioning of the TCL it has also been apparent that softer tissues have tended to slide off the blade. A deliberate attempt to cut the ulnar nerve in our pilot experience showed an incomplete section after over 10 cutting passes of the micro i-Blade using firm counter-pressure. According to the manufacturers there is no recognised engineering standard for sharpness and the sharpness of the blade is currently determined and limited by the manufacturing process. Limited sharpness of the blade is a possible advantage in carpal tunnel release as although it requires extra passes of the cutting blade it may also reduce the risk of inadvertent damage to nerves and arteries. In some other applications the inability to easily cut softer tissues may prove a disadvantage to the use of the micro i-Blade.

Preservation of the palmar aponeurosis was complete in 9 specimens and largely intact in the tenth as the cutting was able to be stopped when the tip of the retracted tool was palpable through the skin and the very firm fibres of the TCL impalpable with the tip of the tool. Further experience with the micro i-Blade and clinical studies may allow users to accurately cut just the TCL while leaving the overlying fascia and palmar aponeurosis intact. Compared to just probing with the retracted blade, the addition of palpation of the tip of the tool through the skin appeared to be the optimal method of assessing the adequacy of the cut. The final assessment of the completeness of the cut of the TCL should also be done using ultrasound of the tip of the retracted micro i-Blade. The softness of the tissues overlying the probe in the carpal tunnel may also be a useful functional test of the decompression required as the entire constraining ligament can be assumed to be parted when the blade tip is clearly palpable through the skin. The area between the inflexion point and the more distal superficial palmar arch should also be palpated from the skin to the inserted retracted micro i-blade to ensure there are no restricting distal bands of ligament. We found the proximal TCL to be the part most easily sectioned as the thickest part of the TCL is the mid-section adjacent to the hook of the hamate. After one or two complete length cutting passes sectioned the proximal TCL the micro i-Blade could then be worked more distally in the thicker ligament feeling the edge where thick parts of the tight unyielding ligament were still intact.

The issue of how much of the TCL needs to be sectioned has been debated with some authors suggesting only the deeper part of the ligament needs to be released (13, 15). In 3 of our specimens several strands of the softer superficial part of the TCL were intact with oblique fibres evident. The deep ligament edges were separated by several millimetres indicating these remaining fibres were part of the fascia which invests the thenar and hypothenar muscles and continues over the superficial aspect of the TCL proper. Preservation of these fibres are unlikely to lead to failure of the procedure as the TCL had retracted back leaving a gap of 3 to 5mm between the cut edges with a likely effective decompression of the contents. Palpation of the retracted blade tip through the skin did not distinguish these fibres from the surrounding soft tissues showing there was no impediment to the protrusion of contents of the carpal tunnel. In open surgery the general recommendation is to cut the whole ligament, this takes account of the likelihood that the deep part of the ligament is the most likely to be missed with the open approach. In describing 12702 cases of endoscopic carpal tunnel release Pajardi (15) opined that there is an advantage in subsequent grip strength of leaving superficial fibres in the TCL even though these narrowed the final distance between the two cut edges of the ligament. Luria (16) and Nazarani (17) noted the sign of parallel retraction of the cut edges (railroad sign) to signify transection of the TCL on endoscopic release, this condition would have been met in our specimens as the superficial fibres only slightly reduce retraction of the deep ligament when cut.

Although the tip of the cutting blade can be imaged during cutting (figure 4) the most important part of the procedure is the initial positioning of the tool avoiding the median nerve, ulnar artery and superficial palmar arch. If scanning in the transverse view, the tip of the blade can be imaged as it passes through the ultrasound beam while in the longitudinal view the movement of tissue around the blade is more obvious than the blade itself. As there is compression of the overlying tissues during cutting the dynamic view was most useful to continually assess the position with respect to the median nerve. After several passes sectioning the deep TCL the blade created a passage that made it subsequently easier to re-insert, requiring just the ultrasound transverse scan to check the position prior to the next cut.

One concern with repetitive passage of an instrument or blade under ultrasound guidance is the possibility of introducing air into the tissues which will degrade the imaging through artefact. The micro i-Blade can be disassembled into 2 components, an outer needle with a handle and an inner rod which has the cutting blade on the tip. It can either be inserted assembled or the outer needle may be filled with fluid so that the inner blade can be inserted once the device is in position. In this study the blade was inserted assembled without problems of introducing air into the tissues during use.

The practice of ultrasound guided micro-invasive procedures currently sits between specialties, the first author and designer of the micro i-Blade (PH) is an anesthesiologist with an interest in ultrasound guidance, innovation, pain and musculo-skeletal procedures. Carpal tunnel release is a procedure traditionally done by surgeons however most surgeons have little experience in ultrasound guided procedures. The literature of ultrasound guided carpal tunnel release describes the procedure performed by surgeons, radiologists, rheumatologists and physiatrists (1-10). In performing ultrasound guided micro-invasive procedures the key skills are ultrasound interpretation and instrument guidance. These are increasingly generic across many specialties where point of care ultrasound is becoming widespread. Coupled with a detailed knowledge of the relevant anatomy, clinical skills in diagnosis and procedure specific knowledge, advanced ultrasound guided micro-invasive procedures will continue to be approached from a number of specialties in the future.

This study has limitations as the procedure was only performed on cadavers without clinical follow up. Differences that may be found in a clinical situation include bleeding into the tissues during the procedure and the difference in the ultrasound imaging quality and tissue texture between cryopreserved cadavers and living patients. It is also not known whether any of the cadavers had clinical carpal tunnel syndrome before death which may change the feasibility of the procedure.

Acknowledgements and financial disclosures

Associate Professor Peter Hebbard has a royalty agreement with Summit Medical, the manufacturer of the micro i-Blade

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Mid-pisiform	proximal hamate (hook)	Distal hamate (hook)	Inflexion point of ligaments	Distal hamate hook to inflexion point
19 (4)	31 (3.9)	41 (5)	47 (6)	6.5 (2.3)

Table 1 Mean distance in mm (SD) from the emergence of the median nerve from deep to flexor digitorum superficialis and distance from the distal hamate hook to the ligament inflexion point

Legends

Figure 1. Micro i-Blade with blade retracted (A) and blade activated (B), close up of tip showing deployed blade (C).

Figure 2. Longitudinal ultrasound images of the proximal palm showing the characteristic inflexion point and the relation to the hamate. Proximal is on the right corresponding to the imaging orientation when the micro i-Blade is operated in the right hand. Frame A curved arrow indicates hamate. Frames B and C are positioned progressively to the radial side of the hamate. Small arrows indicate the superficial surface of the TCL, curved arrow indicates the inflexion point and the dashed arrow the fat pad deep to the distal part of the TCL. Frame D indicates the position of the micro i-Blade at the commencement of the procedure.

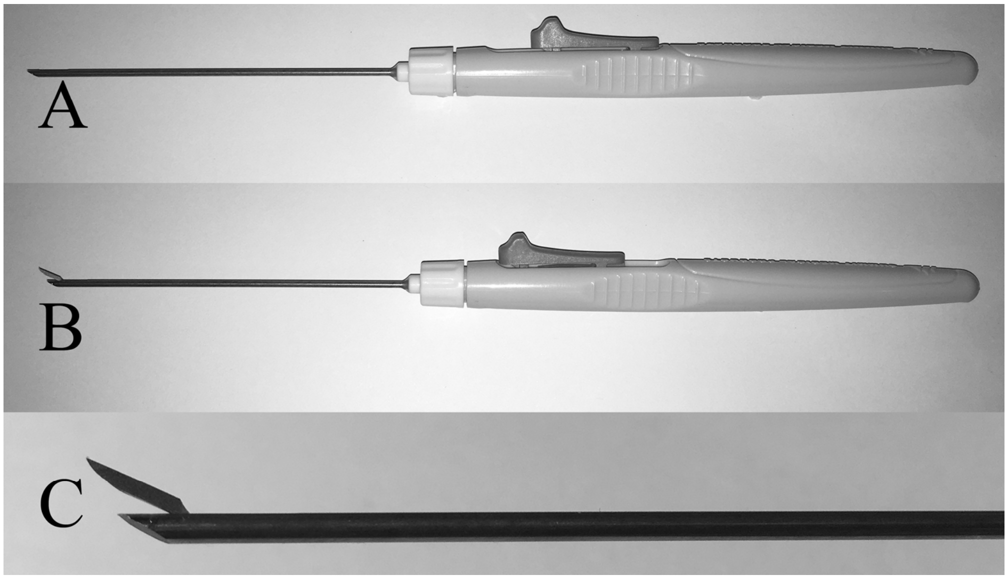
Figure 3. Hand positioned for micro-invasive carpal tunnel release with the micro i-Blade inserted.

Figure 4. Ultrasound image of the micro i-Blade extended in transverse (upper) and longitudinal (lower panel) view. Curved arrow indicates tip of cutting edge, small arrows the body of the micro i-Blade and the dashed arrow the median nerve. The position of the blade in the upper panel is more proximal than the lower panel which is at the level of the hook of the hamate.

Figure 5. Complete section of the superficial and deep portions of the TCL, the distal TCL is held in forceps with the free end indicated by the curved arrow. The fat pad under the distal TCL is indicated with the straight white arrow and the position of the hook of the hamate with a black arrow.

Figure 6. Partial preservation of oblique strands (black arrowheads) of the superficial part of the TCL.

The extent of the distal TCL is indicated with a curved arrow.



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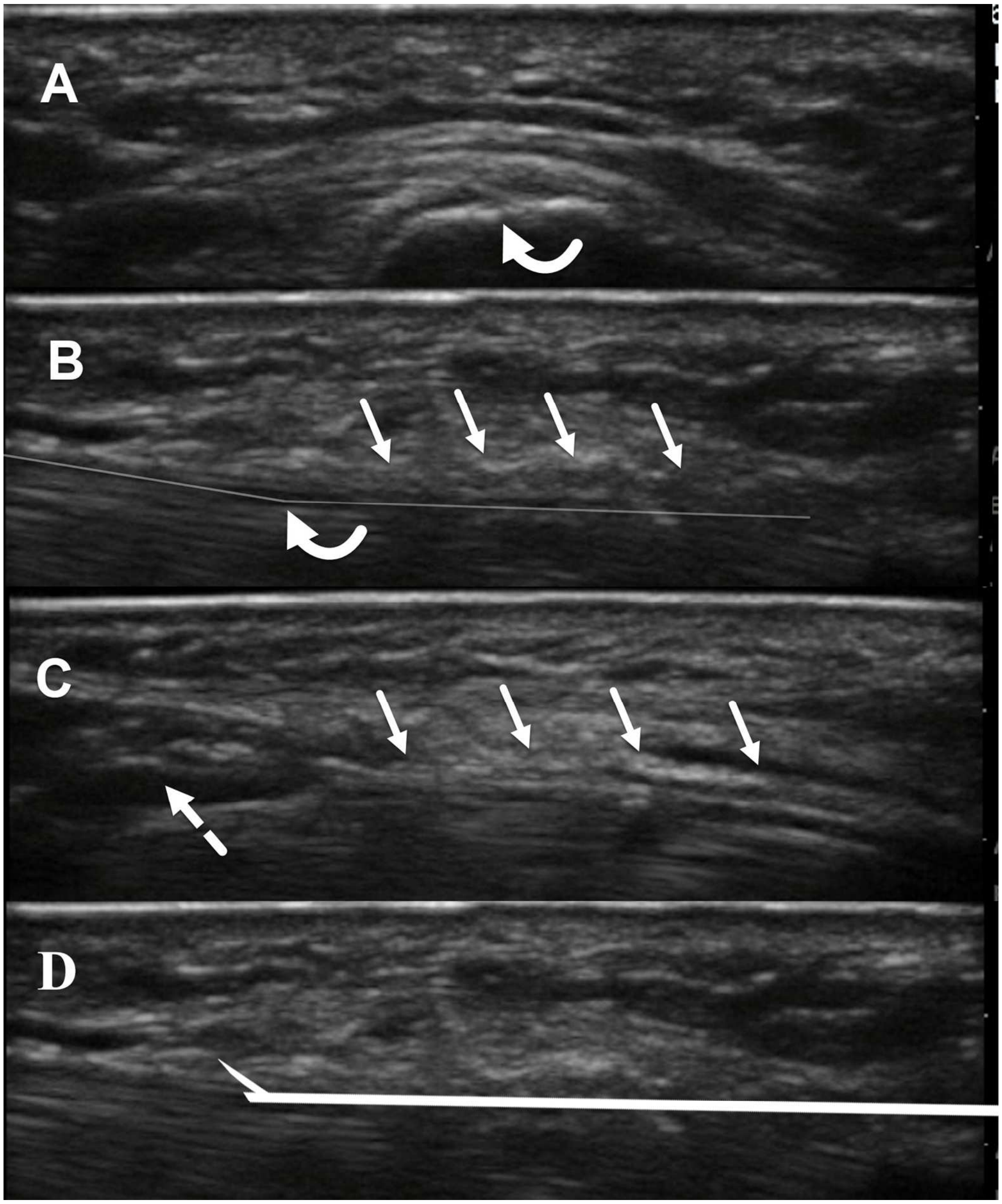

Figure 2. Longitudinal ultrasound images of the proximal palm showing the characteristic inflexion point and the relation to the hamate. Proximal is on the right corresponding to the imaging orientation when the micro i-Blade is operated in the right hand. Frame A curved arrow indicates hamate. Frames B and C are positioned progressively to the radial side of the hamate. Small arrows indicate the superficial surface of the TCL, curved arrow indicates the inflexion point and the dashed arrow the fat pad deep to the distal part of the TCL. Frame D indicates the position of the micro i-Blade at the commencement of the procedure.

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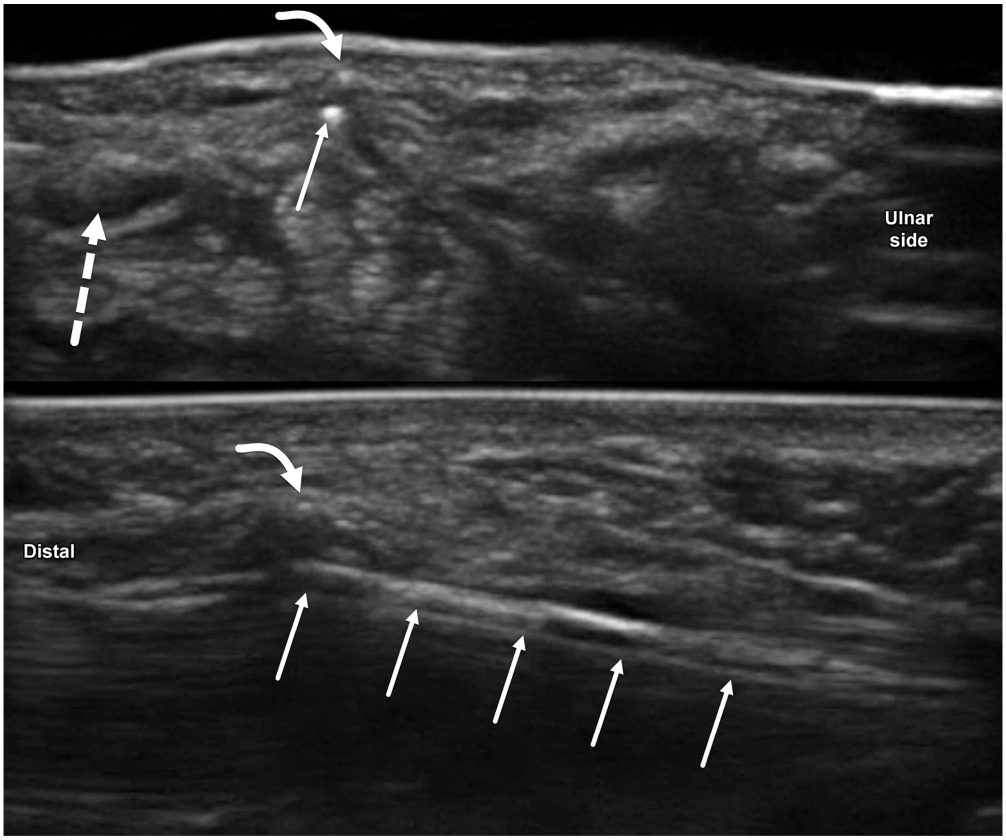

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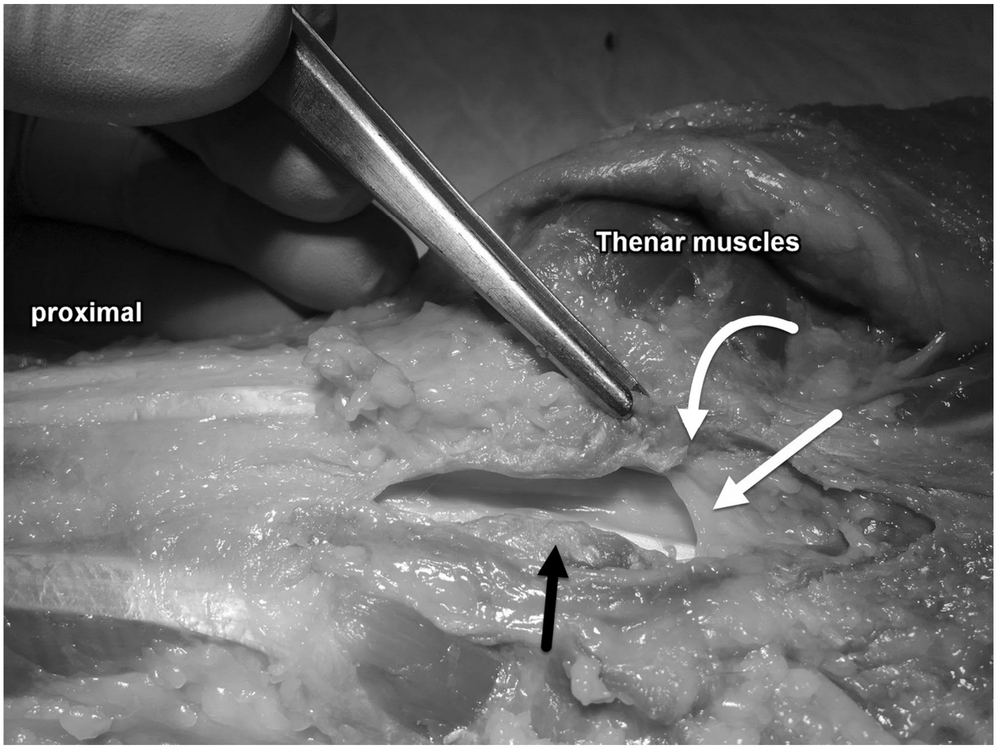

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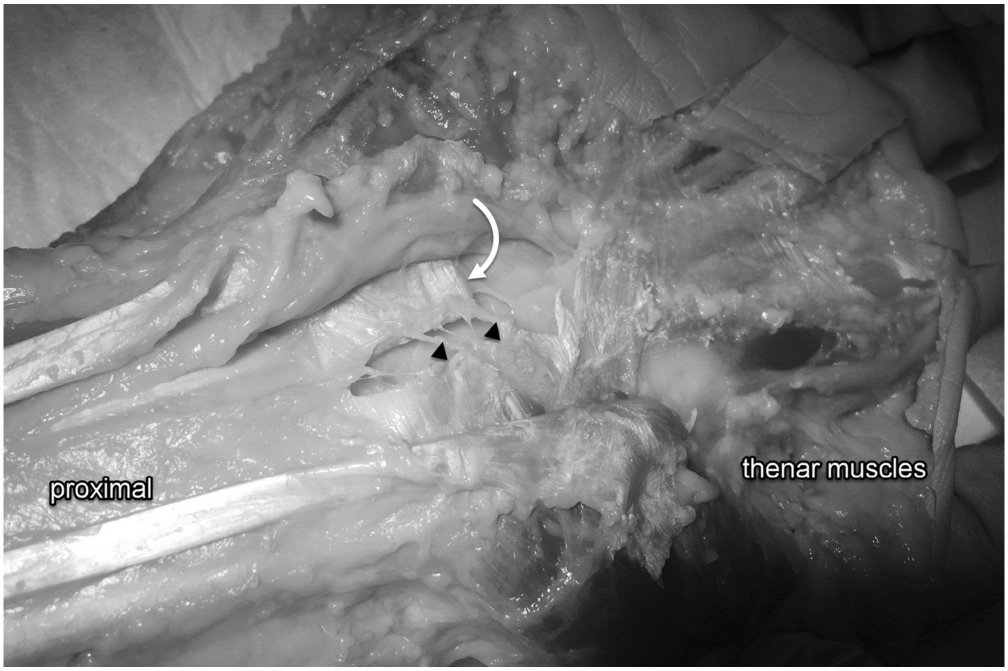

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