In-vivo ultrasound observations of the surgically repaired flexor digitorum profundus tendon: a case series

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ABSTRACT

In-vivo ultrasound observations of the surgically repaired flexor digitorum profundus tendon – a case series

There are few assessment tools available to objectively measure in-vivo flexor tendon healing in the hand. Ultrasound properties of echogenicity and tendon thickness, which indicate structural properties of the healing tendon, have previously been used to evaluate healing of the surgically repaired Achilles tendon in humans, and various animal tendons. In the past, tendon excursion has been measured invasively by radiographic measurement of implanted metal markers, however a non-invasive alternative is to measure the distance moved by tendon-suture material, which is rendered visible by ultrasound imaging. Gapping of the tendon ends has also been previously measured ultrasonographically, as has margination (definition of tissue borders), which indicates tendon adhesions. In addition, power Doppler ultrasound is a sensitive measure of tendon vascularity and is able to detect change in tendinopathy lesions and inflammatory conditions.

However, it is not known if the ultrasound properties (of echogenicity, thickness, excursion, gap, margination and vascularity) can usefully detect change in the surgically repaired intra-synovial flexor digitorum profundus (FDP) tendon of the hand. Therefore, this study was designed to: 1) document longitudinal change in grey-scale and power Doppler ultrasound measurements of echogenicity, vascularity, thickness and excursion of the surgically repaired intra-synovial FDP tendon during the first eighteen weeks post-operative; 2) document thickness of the corresponding uninjured contra-lateral tendon; 3) record concurrent clinical outcomes at twelve weeks post-operative.

Three male participants aged between 33 and 59 years who had undergone surgical repair of the FDP tendon within the digital sheath consented to take part in the study. Repeated estimates of echogenicity and power Doppler signal levels as well as measurements of tendon thickness and excursion were determined using a linear array 13 MHz ultrasound transducer. Measurements were made on five occasions between two weeks and four
months post-surgery on each subject. Three sites on the injured digit were assessed: the mid-repair site, 1 cm proximal and 1 cm distal to the surgical repair, along with measurements from the corresponding contra-lateral digit, which served as a control. A radiologist rated the echogenicity, power Doppler signal levels and margination of the transverse area of each site on 0 to 4, 0 to 3, and 1 to 4 scales, respectively, before measuring tendon thickness (mm), defect length (mm), and excursion (mm) using on-screen calipers. Tendon excursion was measured on both passive and active DIP joint motion using suture material as a marker.

The standardised protocol of ultrasound evaluations detected a pattern of incremental change in echogenicity scores (4 to between 1 and 3) and power Doppler score (PDS) (no registration to 1 or 2) at the mid-tendon repair site over the sixteen-week period of investigation. Tendon-thickness measurements increased between weeks two and four, then trended downward, averaging 194 to 122 percent of the corresponding uninjured contra-lateral tendon. Excursion of the FDP tendon induced by 30 degrees passive distal interphalangeal (DIP) joint flexion ranged between 1.4 mm and 2.2 mm at 2 weeks, trending upward to between 0.8 mm and 3.6 mm at eighteen weeks post-surgery. Active DIP joint flexion of 30 degrees induced FDP tendon excursions of between 0.8 mm and 1.9 mm at six weeks after surgery, and 1.3 mm to 3.2 mm by eighteen weeks. Dynamic change in the ultrasound variables was most remarkable at the mid-repair site. A greater reduction in echogenicity levels, less variation in tendon thickness and greater tendon excursion were documented in the two participants with good or excellent clinical outcomes (Strickland-Glogovac criteria).

For the first time, longitudinal measurement of ultrasound properties of echogenicity, vascularity, thickness, defect length and suture excursion of the surgically repaired intra-synovial FDP tendon has been investigated *in-vivo* in the human hand. Although the measurement properties of the ultrasound variables are yet to be determined, the ease of measurement and documented change suggest that these variables offer a non-invasive tool for evaluating tendon healing. Future applications include evaluating and validating a range of physical, biological and pharmacological interventions to modulate healing of the intra-synovial digital flexor tendon in the human hand.
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Finally, thanks are due to the participants and this study is dedicated to them, the users of our health system and my ultimate employers. It is a privilege to work in public health and a double privilege to be able to contribute, through research, to better health outcomes for working people.
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<table>
<thead>
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<th>Description</th>
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<tr>
<td>3D</td>
<td>three dimensional</td>
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<tr>
<td>AP</td>
<td>anterior-posterior</td>
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<tr>
<td>cm</td>
<td>centimetre</td>
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<tr>
<td>CSA</td>
<td>cross-sectional area</td>
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<tr>
<td>DICOM</td>
<td>Digital Imaging and Communication in Medicine</td>
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<tr>
<td>DIP</td>
<td>distal interphalangeal</td>
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<td>Dr</td>
<td>doctor</td>
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<tr>
<td>FDP</td>
<td>flexor digitorum profundus</td>
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<td>FDS</td>
<td>flexor digitorum superficialis</td>
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<tr>
<td>GJ</td>
<td>Gill Johnson</td>
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<td>GM</td>
<td>Grant Meikle</td>
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<td>ICC</td>
<td>Intraclass correlation coefficient</td>
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<td>IP</td>
<td>interphalangeal</td>
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<td>kgF</td>
<td>kilogrammes of force</td>
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<td>MB</td>
<td>Miranda Bühler</td>
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<tr>
<td>MCP</td>
<td>metacarpophalangeal</td>
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<td>ML</td>
<td>medial-lateral</td>
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<td>mm</td>
<td>millimetre</td>
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<tr>
<td>MHz</td>
<td>megaHertz</td>
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<tr>
<td>MRI</td>
<td>magnetic resonance imaging</td>
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<td>number</td>
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<tr>
<td>PACS</td>
<td>picture archiving and communication system</td>
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<td>PDS</td>
<td>power Doppler score</td>
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PIP  proximal interphalangeal
RTUS  real-time ultrasound
SD  standard deviation
sec  second
TAROM  total active range of motion
TPROM  total passive range of motion
VBP  vinculum brevis profundus
VBS  vinculum brevis superficialis
VLP  vinculum longus profundus
VLS  vinculum longus superficialis
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1.0 INTRODUCTION

Approximately 250 cases of digital flexor tendon laceration occur in New Zealand each year, often resulting in long-term functional limitations associated with stiffness and poor tendon gliding. The associated cost of workers’ compensation alone amounts to NZ$1.5 million annually (1). Due to their complex anatomy, poor healing, and propensity for adhesion formation, the lacerated intra-synovial digital flexor tendon is notoriously difficult to repair and rehabilitate (2, 3). Further investigation of the process of adhesion formation and the specific effects of treatment methods in modulating tendon healing are research priorities for orthopaedic and rehabilitation research programmes (3-7).

Over the past 50 years, laboratory based-biomechanical and anatomical investigations have been instrumental in improving our understanding of the response of the flexor tendons to surgical repair (8-10). Additional studies using invasive in-vivo techniques have examined dynamic function of the tendon following repair (11-13). Knowledge gained from these two groups of studies forms the basis of post-operative rehabilitation protocols. However, scar formation and subsequent adhesion of the flexor tendons are common problems that frequently interfere with normal tendon gliding and cause variable functional outcomes following surgical repair, particularly where injury occurs within the digital sheath (14-18). It remains difficult to tell from a clinical perspective if the tendon is healing or if tendon gliding is occurring.

The early stages of tendon healing following surgical repair involve proliferation and activation of fibroblasts either from within (intrinsic healing) or alternatively, around the tendon (extrinsic healing). Cellular activity is sustained by a combination of existing/repairing or substitute blood vessels, and synovial diffusion (19). The in-growth of a substitute blood supply associated with extrinsic healing is thought to be responsible for random collagen deposition and resultant tendon adhesion (20).

Ultrasound is a non-invasive and easily accessible investigative modality that may have application in investigating tendon healing in-vivo in the human hand. Ultrasonographic images are produced by the reflection of sound waves at structural interfaces within the
tissues. The properties of ultrasound imaging attractive to tendon research include echogenicity (image brightness), representative of the alignment and density of structural units within the tendon (21-23), spatial measurements of tendon thickness and gap formation, along with margination (definition of tissue margins) which may denote adhesions formed between the repaired tendon and its surrounding tissues (24-26). Suture material visible on ultrasound has potential in direct measurement of tendon excursion. The addition of power Doppler, a sensitive measure of blood flow (27, 28), may enable concurrent tracking of vascular changes in relation to structural changes.

The potential role of ultrasonography as a viable approach in evaluating outcomes of flexor tendon repair and rehabilitation has been suggested (25, 29-31). However the ability of real-time and Doppler ultrasonography to document temporal changes in connective tissue structure, motion and vascularity in the healing flexor tendons of the human hand has not yet been fully examined. Potential areas for investigation include, the rate of change in structural properties at specific locations in the healing tendon; the precise amplitude of early tendon excursion occurring at the repair site; and the location and temporal relationships of any new blood vessels detectable by power Doppler.

Therefore, this study aims to explore the feasibility of documenting change in tendon healing properties using ultrasound imaging technology. The properties of interest are those of collagen fibre density and alignment, gap formation, spatial dimensions, tendon excursion and vascularity, as measured by change in ultrasound properties of echogenicity, linear measurements and power Doppler score in the healing FDP tendon of the human hand over the first two to eighteen weeks post-operatively.
2.0 LITERATURE REVIEW

This literature review was undertaken in order to describe the anatomical features of the healthy flexor digitorum profundus (FDP) tendon along with the cellular events and vascular status of the healing tendon, as a basis for interpreting ultrasound imaging of the FDP tendon in the finger following sharp laceration and surgical repair. The literature describing the use of ultrasound as a measurement tool in the context of tendon healing is also explored, with the aim of defining the ultrasound variables most likely to measure change in the healing tendon over time.

2.1 Healthy tendon

2.1.1 Tendon structure and function
Knowledge of the anatomy of the flexor tendon apparatus, well-defined by cadaveric and animal studies and intra-operative observations, is central to understanding the functional demands of the healing tendon and interpreting ultrasound imaging. The long flexor tendons of the hand control prehension and power grip of the fingers and enable the fine digital motion that serve to give and receive tactile information and enhance interpersonal communication. The long flexor tendons originate proximally in the forearm from the muscles of flexor digitorum superficialis (FDS) and FDP, both of which give rise to four tendons each, the two sets of which maintain a complex relationship as they traverse the hand and digits (32). The FDP tendons lie deep to those of the FDS as each pair enter the confined space of the fibro-osseous digital sheaths at the level just proximal to the metacarpophalangeal (MCP) joint in the hand (32). At the level of the proximal phalanx, the FDS tendon bifurcates and is penetrated by the FDP tendon. The FDP tendon, now superficial, goes on to attach distally at the base of the distal phalanx, while the FDS tendon rejoins in a decussation (termed ‘Campers chiasma’) before forming two slips, which attach along the sides of the middle phalanx (Figure 2.1).
Figure 2.1 The complex relationship between the two flexor tendons, flexor digitorum profundus (FDP) (1) and flexor digitorum superficialis (FDS) (2) involves the bifurcation of the FDS then reunion deep to the FDP tendon at Camper’s chiasma (3). Maintenance of smooth gliding surfaces between these surfaces is critical for function. Image from Yu & Chase (2004) (32).

The FDP acts to flex both the distal (DIP) and proximal (PIP) interphalangeal joints of each digit, while the FDS flexes the PIP joint only. The synovial-lined fibro-osseous digital sheaths, reinforced by a complex arrangement of five annular and three cruciform pulleys, serve to prevent bowstringing and maximise joint range of motion and facilitate smooth tendon gliding (32, 33).

A key function of the FDP tendons is to resist tensile loads and transmit forces generated by muscle. To do this effectively the combination of a large amplitude of excursion and high tensile strength is required. Cadaver studies have found the actual amount of excursion in the uninjured FDP tendon within the digital sheath varies according to the degree of finger flexion; this ranges from 2mm at approximately 20 degrees of DIP joint flexion (34) through to 16-20 mm on composite MCP, PIP and DIP joint flexion (35-38). However, limited published research is available on tendon excursion in vivo in the human hand.

Like all tendons, the tensile strength of the long flexor tendons is conferred by their molecular composition and hierarchical stress-aligned architecture within its collagenous structure. Biochemically the FDP tendons are composed of up to 80% fibrous type I collagen.
by dry weight, with the remaining matrix comprising water, proteoglycan (ground substance), elastin and cells (tenocytes) (22, 39-42). Within the digital sheath itself, fibrocartilaginous regions are present in response to compressive load and shear forces behind the soft tissue pulleys.

Architecturally, tendons are characterised by a fibrillar network of densely packed parallel-aligned collagen fibres. The basic protein subunit, tropocollagen, is arranged in a staggered array structure, stabilised by hydrogen and covalent bonds to form primary tendon bundles (fibrils), which, along with proteoglycans and elastin, combine to form secondary tendon bundles (fascicles) (43). Fascicles are invested by the endotenon, which serves as a conduit for vessels and nerve fibres, to form tertiary tendon bundles (fibres) (21). The epitenon, which is continuous with the endotenon, envelopes the tendon fibres to provide the smooth gliding surface necessary for resistance-free excursion (42). The molecular composition and architectural arrangement of tendon tissue confers not only its biomechanical properties but also the tendon’s appearance on ultrasound imaging.

Tendons are a hypo-cellular connective tissue with low metabolic requirements (44-47). This low metabolic rate is necessary to avoid ischaemia with load-bearing but results in a much slower rate of healing compared with other tissues. While we have a good understanding of anatomy and tensile strength, tendon nutrition is more contentious and may play a role in outcomes following surgical repair.

2.1.2. Tendon nutrition
Cellular activity of the healthy tendon is sustained by both vascular perfusion and synovial diffusion. The vascular supply to the FDP tendon, as determined by dye injection studies of human cadaver and animal studies, is characterised by a segmental arrangement. The proximal system originates in the palm and continues with vessels from the synovial folds of the proximal reflections of the tendon sheath before terminating at the level of the proximal phalanx (48). An intermediate vascular supply originates from the vinculum longus to the FDP via branches of the vinculum brevis to the FDS at the level of the PIP joint (33, 48-51).
Distally, small blood vessels arise from the vinculum brevis to the FDP, and the bony insertion supplied by branches of the digital arteries (32, 50, 52-54) (Figure 2.2).

Figure 2.2 The flexor digitorum profundus (FDP) and flexor digitorum superficialis (FDS) tendons as they traverse the digit within the fibro-osseous sheath. Tendon blood supply includes the long (VLS) and short (VBS) vincula to the flexor digitorum superficialis, and the long (VLP) and short (VSP) vincula to the flexor digitorum profundus, originating from the digital artery. The star denotes flexor digitorum profundus tendon blood supply from the distal bony insertion. Image from Yu & Chase (2004) (32).

Tendon nutrition via synovial diffusion occurs by the process of imbibition whereby synovial fluid is forced into the interstitial spaces of the tendon. The significance of this process was demonstrated first by Lundborg (1976, 1978) (10, 55) who documented the continued repair activity of isolated flexor tendon segments placed in the synovial knee joints of a rabbit; and later by Manske (1978a, 1978b) (56, 57) who demonstrated the greater efficiency of synovial diffusion as compared with vascular perfusion during repair by measuring the relative uptake of titrated proline in various experimental animals. Imbibition of synovial fluid within the fibro-osseous sheath is enhanced by the compressive and shear forces provided by the fibrous pulleys and the unique spiral configuration of the FDS around the FDP (33).

The intra-synovial FDP tendon itself is relatively hypo-vascular when compared to the extra-synovial tendon (49, 58). Blood vessels are found predominantly dorsally within the epitenon and endotenon layers, but interestingly, not within the substance of the collagen bundles themselves (9, 48) (Figure 2.3). The volar one-third to half the tendon is often reported to be avascular and devoid of capillary loops with regions over the proximal and
middle phalanx (under the 2\textsuperscript{nd} and 4\textsuperscript{th} annular pulleys respectively) noted to be particularly avascular (41, 49, 54, 58) although more recently it has been demonstrated that there are no truly avascular zones (59). Diffusion is thought to play the greatest role in regions of high pressure (and low vascularity) such as those behind the pulleys; between the proximal sources of vascularisation and the long vinculum; and between the long and short vincula (49, 58).

![Figure 2.3 Blood vessels are found predominantly in the dorsal aspect of the tendon. Image from Strickland (2005) (2).]

The intra-synovial FDP tendon has dual nutrient pathways that support normal cellular processes. While the relative importance of each pathway is somewhat understood in the healthy and healing (animal) tendon, the role of perfusion versus diffusion in the surgically repaired tendon of the human hand is far less clear.

2.2. Healing tendon

Tendon healing following sharp laceration and surgical repair of the FDP tendon involves cellular events and re-establishment of nutritional pathways. The following sections describe key aspects of these events and highlight factors relevant to the formation of adhesions that may be amenable to investigation using ultrasound imaging technology.

2.2.1. Cellular events
Like most connective tissues, the surgically repaired intra-synovial flexor tendon undergoes three identifiable phases of healing: inflammation, fibroplasia (repair) and finally, remodeling and maturation in overlapping but widely accepted time-frames of 72 hours, five to 28 days, and three weeks up to one year, respectively (60). However, as described by
Peacock (1965) (61), the demands of the healing FDP tendon are complex and include, “long amplitudes of motion where a central segment of scar tissue is required to develop unyielding tensile strength for conduction of muscular power while peripheral segments of the same scar are expected to develop elasticity or elongation.” In addition, sharp laceration and surgical repair of the intra-synovial FDP tendon often involves direct injury to the segmental vascular system and dissipation of pressure and fluid from a violated digital sheath, disrupting the nutritional pathways necessary to sustain the repair process. Consequently the source of viable cells and nutritional supply for the healing tendon has caused considerable debate.

For the greater part of last century, the theory of flexor tendon healing was that of extrinsic healing based on the assumption that tendons were a-cellular, metabolically inert and ‘virtually dead’. Clinically, this belief formed the basis of immobilisation as the necessary component of treatment for the first three to six weeks post-operatively. In this model, the repair process was solely dependent on a substitute blood supply and cells migrating from the tendon sheath and surrounding tissues (62-64). In more recent times an intrinsic process of tendon healing is supported based on the finding that, inflammatory cells and tenoblasts or fibroblasts do in fact emanate from both the epitenon and endotenon, as well as from extrinsic tissues to participate in the healing process (10, 39, 47, 56, 57, 65-67). Cellular activity is sustained most importantly by diffusion, but also by re-establishment of the intra-tendinous blood supply and the vincula system, providing an intrinsic capacity for digital flexor tendon healing in the absence of vascular ingrowth (10, 47, 55-57). Clinically these findings provide the scientific basis for primary repair and post-operative mobilisation programmes without fear of tendon necrosis due to disrupted nutritional pathways.

While the two mechanisms of tendon healing are not mutually exclusive, it is the extrinsic mechanism of healing that is held responsible for the formation of problematic adhesions. The factors determining the predominance of one mode of healing over another are not completely understood, but include: the degree of tendon trauma, sheath disruption, repair-site attenuation (gap), suture material, immobilisation, and ischaemia (2, 9, 19, 47, 50, 68).
Immobilisation is a key factor in adhesion formation and impaired tendon biomechanical properties. Early mobilisation has been shown to effect a more rapid gain in tendon strength and gliding properties during the repair phase of healing (9, 69, 70). Significantly, the mobilised tendon repair has been shown to maintain a breaking strength of over 2000 gm during the first three weeks post-operative, whereas the immobilised tendon experiences an intervening drop in tensile strength to a minimum of 900 gm at around 10 days (60, 71, 72). Interestingly, while mobilisation has been shown to have a significant impact on the rate and quality of post-surgical tendon healing, an increase in force alone does not appear to hasten collagen concentration and repair-site maturation (69, 73, 74). During remodeling and maturation the tendon repair regains tensile strength and gliding properties via increasing density and parallel alignment of collagen fibres (due to fibrillar thickening and cross linking) (75). While the positive effects of early mobilisation have been clearly demonstrated in animal models, limited research has been undertaken to confirm these events in-vivo in the human flexor tendon.

2.2.2. Revascularisation and diffusion

The degree of vascular availability (either from within the tendon itself or new substitute pathways from the surrounding soft tissues) impacts on the mode of tendon healing.

Within the surgically repaired and subsequently immobilised animal tendon, studies have demonstrated that an ordered sequence of revascularisation takes place involving the ingrowth of granulation tissue. In the canine model, revascularisation begins with small blood vessels appearing in the tendon stumps by one week post-surgery and between the tendon ends by four weeks (63, 75). Subsequently, vascularity declines, although blood vessels remain in communication between the tendon and sheath for up to eighteen weeks (63). Vessels emerging from the surrounding soft tissues enter the tendon dorsally and extend volarwards on the surface of the tendon, similar to the internal vascular patterns seen in the healthy uninjured tendon. Importantly, disruption of the immobilised tendon’s segmental blood supply has been observed to lead to tendon necrosis (63, 64).
In contrast, early mobilisation has been shown to hasten repair site revascularisation, with new vessels originating intra-tendinously from proximal vessels extending through previously avascular zones (52), and without the ingrowth of peripheral adhesions seen in the immobilised tendon (9, 52). Stump approximation has been observed to impact on the rate of revascularisation, causing a delay of 5-7 days where gaps are larger (9, 52, 56, 57).

While vascularisation of the intra-synovial FDP tendon repair site has been shown to occur in animal models, the relative significance of revascularisation or neo-vascularisation in the nutritional support of the surgically repaired human FDP tendon is not well understood (52, 59). An ongoing debate also exists regarding the benefits of repairing the digital sheath. Some authors advocate sheath closure to aid synovial diffusion, maintain biomechanical efficiency, enhance smooth gliding and act as a barrier to adhesions (2), while others argue that full closure of the pulleys and/or sheath may restrict gliding of the newly repaired tendon and limit functional recovery (38). An ability to visualise the re-establishment of tendon vessels following surgical repair in-vivo in the human hand would help researchers understand the relative role of post-operative nutritional pathways and determine the effects of various surgical and rehabilitation treatments on tendon vascularity.

2.2.3. Adhesion formation
Despite the developing knowledge of ultra-structural and biological events associated with tendon healing, adhesions continue to be the most frequent complicating factor in postsurgical flexor tendon healing. They are also difficult to confirm clinically.

Adhesion formation is thought to be initiated in the inflammatory phase of tendon healing with coagulation and fibrin deposition. Gradual maturation of the clot occurs following infiltration by granulation tissue and transition into a vascularised, mesothelium-covered fibrous band often containing nodules of calcification (19). Adhesions tether the tendon to the surrounding soft or bony tissues, preventing the tendon excursion necessary for function. The adhesion may manifest clinically as a plateau in progress with a significant difference between passive (full) and active (limited) finger joint flexion and often with a concomitant limitation in passive finger joint extension (76, 77).
A variety of pharmacological and non-pharmacological products have been trialed experimentally with the aim of reducing adhesions, including introducing stem cells, regulating growth factors, and using barriers such as silicone-coated tubes or hyaluronic acid (3, 78-82). Mechanisms of mechanical modulation of tendon healing and homeostatic response have been further elucidated with the recent discovery of primary cilia – the connective tissues' “cellular cybernetic probe”. This organelle is postulated to have a key role in cell-signaling and response to loading (83-88), and also has a high concentration of integrin receptors, thought to be important in early angiogenesis (89). While a range of interventions for reducing post-operative adhesions have been suggested, early mobilisation remains the only clinically justified means to modulate the quality of post-surgical tendon healing (3).

However, the mechanisms by which different rehabilitation approaches modulate intra-synovial repair site collagen synthesis and extracellular matrix maturation are not yet fully understood (69). A better understanding of the conditions (precise early mobilisation parameters) under which intrinsic healing mechanisms predominate and adhesion formation is minimised is required. The dependence on in-vitro and animal studies is a limiting factor in progressing knowledge of tendon healing in the human hand. Further investigation is required to understand the factors influencing the incidence and development of postsurgical adhesions. One important variable related to success or failure of the tendon repair and modulation of tendon healing is that of excursion of the repaired tendon induced by either passive or active exercises.

2.2.4. Excursion of the healing flexor digitorum profundus tendon
The clinical and biological benefits of tendon excursion or early mobilisation are well documented in human and animal studies. However, the actual tendon excursion necessary to prevent adhesion of the surgically repaired FDP tendon is not yet confirmed, and neither the amount of excursion that actually occurs at the repair site during the rehabilitative period nor the safest and most effective method to elicit the required excursion have been agreed upon (77, 90).
Clinical studies have established the positive benefits of early mobilisation of the hand following surgical repair of the flexor tendons. With the introduction of early controlled mobilisation, the incidence of ‘poor’ results with post-operative immobilisation has been shown to reduce from 44 percent down to 24 percent (91). Even more significantly, combined passive and active motion has, in some instances, further reduced the incidence of poor results to zero (92) with the associated number of ‘good or excellent’ outcomes increasing to over 90 percent (12, 93, 94).

As described in Section 2.2.1, the initial loss of flexor tendon repair-strength frequently seen in the first 10 to 14 days following immobilisation can be eliminated by early controlled passive mobilisation (60, 72), thereby supporting the idea that a precise, immediate mobilisation programme improves the quality of tendon health and function during healing. Information about the amount of tendon excursion at the repair site during the rehabilitation period is of critical importance for refining rehabilitation programmes so as to optimise the biological repair response and minimise adhesion formation following flexor tendon suture within the digital sheath.

This section of the literature review examines the methodologies (radiographic and ultrasound imaging techniques, and direct measurement) previously used to investigate tendon excursion in both in-vivo and laboratory models. Published findings are tabled and discussed. Clinically important findings are highlighted and gaps in the knowledge are identified.

2.2.4.1. Radiographic studies
Standard radiographs permit estimation of the degree of tendon excursion in vivo either statically, when the hand is registered in two different positions, or dynamically, using video fluoroscopy. Aside from the usual problems of the radiation dose imparted to participants, the need to insert metal markers, which have been known to move or dislocate, detracts from using this method (95-97). The estimated error of radiographic measurement of tendon excursion is between 3 mm and 5 mm (98), and although three-dimensional
methods (radiostereography) report a much lower rate of error (0.02 mm) (95), this method is complex and requires additional equipment.

2.2.4.2. Colour Doppler studies
Colour Doppler ultrasonography has been employed alongside a tailor-made data-acquisition programme to derive tendon-excision values using the Doppler formula (based on the speed of moving structures within the tissue as the propagation medium) (99, 100). While this method is non-invasive, the intra-rater reliability is variable – acceptable at ten days and three months post-operative (ICC 0.88 and 0.94; SEM 1.1 mm and 1.2 mm, respectively) but not at six weeks (ICC 0.58, SEM 2.0 mm), with an overall measurement error of around 10 percent (101). Further limitations of the colour Doppler method include the high number of repeated measures required to reach acceptable levels of reliability (two series of 25 flexion/extension movements at each session) and its tendency to underestimate excursion due to a dependence on perfect parallel positioning of the transducer in relation to the tendon.

2.2.4.3. Speckle tracking studies
Speckle tracking, or cross correlation of grey-scale images, uses ultrasound imaging alongside digital software to mark and track speckles on serial images. This method demonstrates a stronger correlation with the joint angle when compared with colour Doppler (ICC 0.377 and 0.642, respectively) although Doppler measurement provides greater precision than speckle tracking when measuring tendon excursion calculated from joint angle (mean differences 0.44 cm and 1.07 cm, respectively) (102). To date, speckle tracking and colour Doppler have only been used to measure tendon excursion at the level of the wrist and they may not be sensitive enough to evaluate the smaller amplitudes of tendon excursion found at the repair site in zone II of the hand.

2.2.4.4. Cadaveric studies
Cadaveric studies investigating biomechanical and kinematic properties of tendon excursion in the human hand were located as part of this research strategy (103, 104). However, the marked variation in findings of these studies, attributed to disrupted physiology, differences
in limb temperature, cadaveric rigidity, unknown trauma and/or degenerative pathologies, detracts from their applicability for the purposes of this review (104).

2.2.4.5. Biomechanical modeling
Biomechanical modelling is frequently employed in kinematic studies (103, 105). However, these models do not accurately reflect the alterations in tendon excursion and length of the moment arm associated with post-operative oedema and pulley or sheath disruption in the surgically repaired flexor tendon. Putting these limitations aside, the literature reveals surprising similarity between values found in the actively mobilised surgically repaired tendon and those derived from biomechanical modelling (16.6 mm on 160 degrees combined PIP and DIP joint motion (12, 106).

2.2.4.6. Animal studies
Anatomically the canine flexor apparatus is similar to that of humans, with comparable tendon excursion relative to sheath in the zone II region (34, 107), and a number of studies have investigated intra-synovial digital flexor tendon excursion in the canine model (74, 108, 109). While providing reliable information, there are differences between human and animal anatomy that limit applicability of these findings. These differences include the absence of cruciate pulleys; the hyper-extended position of the canine DIP joint; and propensity for scar formation (3).

2.2.4.7. Intra-operative in-vivo human studies
Two studies report intra-operative measurement of post-operative intra-synovial flexor tendon excursion (93, 110). Although this approach does not lend itself to repeated measurement, it is useful for calibrating radiographic measurements.

2.2.4.8. Published findings and clinical applications
Opinions on the relationship between in-vivo tendon excursion during the rehabilitation period and functional range of motion outcomes are based on a small number of human and animal studies which vary in quality. An often-cited case series (n=34) comparing intra-operative observations and three-month post-operative functional outcome concluded that, “3 mm to 5 mm of extension motion of the tendon anastomosis in a passive exercise programme is sufficient to prevent firm adherence of a repaired flexor tendon...” (110).
However, the observations made in this latter case series took place only on one occasion and whether or not the amount of excursion was maintained post-operatively still needs to be confirmed. Researchers carrying out a subsequent animal study similarly concluded that 3 mm to 4 mm tendon excursion was required to stimulate the intrinsic repair process during the early repair period (9). These two studies are relatively unique in that they use hand exercises involving both passive flexion and passive extension; hence the findings may be due to the specific quality of excursion produced on passive extension. Further research is required to confirm this.

Four *in-vivo* radiographic studies examine the relationship between repair-site tendon excursion in various post-operative exercises and outcome following surgical repair within the human hand. An initial radiographic study found only a weak correlation (r=0.35) between tendon excursion during the rehabilitative period and the total active range of motion or active DIP joint motion at the four-month follow-up (95). However, investigators in a later study determined that tendon excursion at the level of the proximal phalanx induced by dynamic traction of the DIP and PIP significantly influenced subsequent total active DIP and PIP joint range of motion at the six-week and one-year follow-ups (96). The addition of passive over-pressure to maximise interphalangeal (IP) joint flexion and the inclusion of all four digits in dynamic traction resulted in even greater overall excursion, particularly in the case of DIP joint motion (11). The addition of early active flexion effected a further increase in tendon excursion and additional benefit for DIP joint active motion outcome (12). This apparent association between actual tendon excursions occurring during the rehabilitative period and the active range of motion outcomes suggests that greater tendon excursion reduces the formation of restrictive adhesions. The maximum excursion measured by the radiographic studies was 6 mm to 9 mm and the authors determined that this was the point at which adhesions would be prevented following tendon repair within the digital sheath, and beyond which no further benefit would be conferred (11, 12).

The summary data from relevant radiographic and intra-operative studies for the actual *in-vivo* excursion of the surgically repaired intra-synovial FDP tendon in the human hand during
different rehabilitative regimes to date are detailed in Table 2.1. The lower overall magnitude of tendon excursion over the middle phalanx as compared to that over the proximal phalanx is explained by the slack within the tendon being taken up by motion proximally at the PIP joint.

Investigators in a number of studies have noted a relative reduction in tendon excursion during the early post-operative period (74, 97, 108, 111, 112) implying that temporal changes in the ability of the tendon to undergo excursion may be a common feature of the post-operative healing process.

From Table 2.1, larger passive IP joint ranges of motion are associated with correspondingly greater amplitudes of tendon excursion (11, 12) and active joint motion generates the greatest amplitude of tendon excursion (12, 95, 100). However, findings are somewhat variable between studies.

Investigation of FDP tendon excursion in human in-vivo and cadaver studies has led to a number of clinically important observations. For example, mobilisation of the (IP) joint distal to the repair site is necessary to achieve adequate excursion (34), and passive flexion initiated at the MCP rather than IP joints effects a small but significant increase in FDP tendon excursion with DIP joint motion (113). However, passive flexion of the MCP joint alone produces no detectable excursion of the FDP tendon over the proximal phalanx (37). Measurement of tendon excursion at the wrist level has determined that active flexion of the distal and proximal IP joints while maintaining the MCP joints in extensions produces the greatest differential gliding between the FDS and FDP tendons, and active composite flexion produces the greatest overall FDP tendon excursion (13).

Based on observations made in a canine model, 3 mm to 4 mm of tendon excursion is recommended following repair of FDP tendon lacerations over the middle phalanx, achieved by mobilising the DIP joint passively through a range of at least 35 degrees. For lacerations of both the FDP and FDS tendons over the proximal phalanx, it is recommended that the PIP joint be mobilised 30 degrees and the DIP joint 30 degrees to 40 degrees (37, 114).
However, whether or not these recommendations based on animal studies have application to the human hand is yet to be confirmed.

In both the human hand and canine model, excursion values are higher with the addition of synergistic wrist motion and lower when the wrist is maintained in flexion (35, 97, 114). The finding in some instances of negative excursion on passive finger flexion when the wrist is positioned in flexion suggests the tendon may be prevented from translating proximally by an increase in gliding resistance during more traditional passive flexion regimes, with potential for a vicious cycle of more adhesion and less excursion leading to more adhesion (107, 115).
Table 2.1 *In-vivo* flexor digitorum profundus tendon excursion at the proximal and middle phalanx following surgical repair in zone II of the human hand

<table>
<thead>
<tr>
<th>Investigator/s</th>
<th>Excursion (proximal phalanx)</th>
<th>Excursion (middle phalanx)</th>
<th>Method</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duran 1975 (110)</td>
<td>3 mm to 5 mm</td>
<td>3 mm to 5 mm</td>
<td>Intra-operative measurement with callipers (mm)</td>
<td>Isolated passive extension of the PIP joint and DIP joint through an individually tailored joint range of motion.</td>
</tr>
<tr>
<td>Brüser 1981 (115)</td>
<td>7.4 mm</td>
<td>2.5 mm</td>
<td>Radiographic imaging and measurement using millimetre paper</td>
<td>Passive flexion Measured at two weeks post primary repair, delayed repair (&lt;ten days) or tendon graft of the FDP and/or FDP tendon.</td>
</tr>
<tr>
<td>Hagberg 1991 (95)</td>
<td>9 mm†</td>
<td>2 mm‡</td>
<td>3D Radiographic imaging with computer analyses (stereophotogrammetry)</td>
<td>Active composite fist and extension within a dorsal blocking splint †Average over five week period ‡Maximum over five week period</td>
</tr>
<tr>
<td>Silfverskiold 1992 (96)</td>
<td>5.6 mm† (SD3.5)</td>
<td>0.9 mm‡ (SD1.0)</td>
<td>Radiographic imaging and measurement using a micrometre</td>
<td>†Passive DIP and PIP flexion 71 degrees/active extension Weeks one and three post-op following a dynamic traction protocol ‡Passive DIP joint flexion 30 degrees/active extension Week one post-op □Passive DIP joint flexion 30 degrees/active extension Week three post-op</td>
</tr>
<tr>
<td>Study</td>
<td>Week dimension</td>
<td>Flexion/Extension</td>
<td>Radiographic Details</td>
<td></td>
</tr>
<tr>
<td>---------------------</td>
<td>----------------</td>
<td>-------------------</td>
<td>--------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Silfverskiold 1993</td>
<td>11.7 mm†</td>
<td>2.3 mm‡</td>
<td>†Passive DIP and PIP flexion 132 degrees/active extension</td>
<td></td>
</tr>
<tr>
<td></td>
<td>11.7 mm†</td>
<td>2.3 mm‡</td>
<td>‡Passive DIP flexion 57 degrees/active extension</td>
<td></td>
</tr>
<tr>
<td></td>
<td>19.2 mm§</td>
<td>5.3 mm§</td>
<td>†DIP and PIP passive flexion/active extension 132 degrees</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>‡DIP passive flexion/active extension 57 degrees</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>‡DIP and PIP active flexion/extension 153 degrees</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>§DIP active flexion/extension 65 degrees</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Week three post-op early active exercises</td>
<td></td>
</tr>
</tbody>
</table>

*Note: The numbers in parentheses represent the reference numbers.*
The optimal magnitude of tendon excursion and the key factors influencing tendon excursion remain unclear. Resistance to tendon excursion resulting from bulging of the repair site, early adhesion, oedema and ensuing engorgement of the healing tendon as it is pushed rather than pulled proximally contrive to ensure that passive motion of a digital joint does not always equate to simultaneous excursion of the underlying flexor tendon (36, 95, 96, 111, 115, 116). The need for a large IP joint range of motion to be established soon after the operation before restrictive adhesions form (thought to be well within a week) has been emphasised (11, 12, 96). Wrist position and the sequential mobilisation of joints may also have important roles to play. Issues of frequency and intensity of post-operative exercise require consideration. The status of the surrounding soft tissues (for example pulley disruption) also has an undetermined impact on the in-vivo tendon excursion during the post-op period.

Further studies are needed to confirm the critical amount of tendon mobility and the role of specific hand exercises during the rehabilitative period.

2.2.5. Gap formation
Elongation (gap formation) at the repair site is implicated in adhesion formation and poor functional outcomes after repair of the flexor tendons (56, 57, 62, 72, 117, 118). Gap formation has been investigated in-vivo by radiographic means and ex-vivo in animal and cadaver models macroscopically.

Early mobilisation techniques aiming to restore the gliding surface of the surgically repaired tendon have always been cautious about maintaining the integrity of the repair site. Inadequate post-operative immobilisation has been shown to lead to an increase in callus size and adhesion formation in the divided and repaired chicken tendon (117) and is a key factor in gap formation in the human tendon.

Surgically repaired tendons are known to undergo deformation on some occasions (62, 95, 96, 98, 117). The deformation can be minor (for example, a slight thinning of the tendon), or major, leading to separation of the tendon ends by several millimetres or more. The degree
to which deformation occurs and the response of the healing tendon depends on the circumstances in which the repaired tendon is healing. Gaps of less than 3 mm appear to be taken care of by intrinsic healing mechanisms and don’t interfere with function, while those greater than 3 mm may (re)instigate the extrinsic tendon healing response, with subsequent adhesion formation (50, 56, 57, 107). A definitive relationship between gap formation and functional outcome has yet to be established (95, 96, 98).

2.2.6. Tendon thickness
The spatial dimensions of the healing tendon are relevant to structural properties of collagen fibre content and alignment, bulk and attenuation of the surgically repaired intra-synovial flexor tendon. However, objective measurements of tendon thickness in the surgically repaired intra-synovial flexor tendon of the human hand have not yet been documented. Researchers undertaking in-vivo ultrasonographic studies of healthy FDP tendon thickness report anterior-posterior (AP) diameters ranging from 1.2 mm to 3.7 mm and medial-lateral (ML) dimensions of 5.0 mm to 8.0 mm in the region of the fibro-osseous sheath (119-123).

Qualitative observations of changes in thickness of the in-vivo divided and repaired human FDP tendon have identified both thinning in conjunction with “gapping”, and also thickening along with collagen fibre disorganisation (124). However, it remains unclear whether tendon thickening or, conversely, tendon thinning is a part of the natural history or healing process in either acute or chronic tendon injury. Increasing cross-sectional area (CSA) is suggested as one way in which the equine healing tendon becomes stronger in response to greater tensile load (24, 125). Paradoxically, tendons with higher mean CSA were also shown to be weaker (125). Tendon thickness is a measureable parameter that may provide useful information about the rate or quality of healing of the surgically repaired FDP tendon in the hand. An in-vivo method for measuring thickness of the healing FDP tendon is needed.

2.3. Ultrasound imaging as an investigative tool
Ultrasound is a non-invasive and easily accessible investigative modality that may have application in investigating tendon healing in-vivo in the human hand. Ultrasonographic images produced by the reflection of sound waves at structural interfaces within tissues
create grey-scale images, while the reflection of sound waves by moving tissues allows the detection of (blood) flow by Doppler ultrasonography. Preliminary studies using ultrasonography to investigate connective tissue changes in healing tendons have been carried out with promising results in equine and rabbit models (24, 26, 126-131), in the human Achilles tendon (132-141), and various other tendons (142, 143). Power Doppler ultrasonography also has a growing role in diagnosis and monitoring tendon vascularity in rheumatic diseases (27, 144, 145).

Only one study has reported ultrasound observations of the healing surgically repaired intra-synovial FDP tendon (29). While the authors of this study give definitions for the ultrasonographic variables on static and dynamic assessment, they use a ‘prognostic score’ that is poorly defined and variables are not comparable with those used by the small number of studies that have used ultrasound to investigate other surgically repaired tendons (25, 30). A problematic feature of ultrasound literature is the diverse range of ultrasound and tendon properties that have been examined and the multiplicity of operational definitions for any one property or scale. For the purposes of this study, rather than adopting a composite ultrasound scale of tendon healing, individual ultrasound properties of the healing tendon are evaluated on their own merits.

This next section reviews ultrasound imaging of the digital flexor tendons, and explores ultrasound variables suitable for the repeated measurement of structural, vascular and gliding properties of the healing tendon, namely echogenicity, linear measurement, evaluation of discreet tissue margins, and power Doppler signal. The aim of the review is to determine methods most suitable for repeated ultrasonographic measurement of tendon properties in the recently repaired human FDP tendon.

2.3.1. Digital flexor tendon imaging
The digital ultrasound appearance of the normal anatomical characteristics of the healthy uninjured FDP and FDS tendons, the digital sheath and pulley system, as well as the changing relationship of the two tendons has been well described (31, 146, 147) and is illustrated in Figure 2.4 and Figure 2.5.
Abnormal sonographic findings, along with clinical signs, have been validated for the purposes of diagnosing partial or full rupture and adhesions of the digital flexor tendons in-vivo in the human hand, as confirmed macroscopically at surgery (25, 30, 124, 146, 148-152).

Of interest, visualisation of the suture material can be distinguished at the repair site in the surgically repaired tendon for at least one year post-operative (22, 30, 146).
2.3.2. Echogenicity
The ultrasound property of echogenicity is widely used to investigate the cellular and structural status of tendons. A review of relevant literature has identified a number of studies that have described the echogenic features associated with both healthy and healing tendons.

2.3.2.1. Healthy tendon
The ultrasound property of echogenicity is directly related to the amount of B-mode ultrasound echoes that are reflected back to the ultrasound probe from the tissues. The more reflective the tissue becomes, the brighter or more ‘echoic’ is the image. Conversely, minimally reflective or hypo-echoic tissues result in minimally bright images, and non-reflective or anechoic regions such as fluid clefts in tendons and fluid in sheaths are displayed as black.

When healthy tendon tissue is scanned perpendicular to its long axis with a linear-array transducer it is significantly more echogenic than other tissues, such as skeletal muscle (23). A number of factors contribute to the highly echoic nature of normal tendon tissue. The densely packed parallel alignment of collagen fibres and fascicles reflect echoes directly back to the ultrasound transducer and the abundance of reflective acoustic interfaces produced by the hierarchical architecture of the individual collagen filaments also contributes to the echoic nature of healthy tendon tissue (21-23, 153).

Although healthy tendons present a typically fibrillar pattern in the longitudinal plane and a homogeneously punctate pattern in the transverse plane, the individual parallel or punctate echoes from the ultrasound head are unlikely to all be directly representative of individual fibres or fascicles. Rather, while some of the echogenicity may be due to ‘true’ structural echoes, other waves are formed by interference from cumulative tissue interface reflections (131, 135). Overall, echogenicity provides an overview of general tendon structure. Because the average diameter of a tendon fibril is similar to the resolution of high frequency (13 MHz) ultrasound, some interference is inevitable when imaging tendinous structures (23).
Tendon fascicles on the other hand are larger than axial resolution and therefore are the main producers of structural echoes (131).

The reflectivity of the normal tendon is highly dependent on the incident angle of the ultrasound beam due to its highly ordered internal structure. If the angle of incidence of the ultrasound beam is less than orthogonal, the image will falsely appear hypoechoic, resulting in a phenomenon known as anisotropy (154, 155). Anisotropy is more likely to occur where the tendon follows a curvilinear path (classic examples being supraspinatus and tibialis posterior around the malleolus) or a when non-linear array transducer is used (22, 124).

2.3.2.2. Tendon pathology
Disruption of normal, healthy tendon architecture following a pathological process results in reduced reflectivity of the tendon tissue (or increased scattering of the ultrasound beam), with a consequent reduction in image brightness (21, 26, 155, 156). Regions of abnormally high concentrations of ground substance preferentially absorb ultrasound and so appear hypoechoic (157) with on-going hypoechogenicity attributed at least in part to the high cell-to-matrix ratio of the injured tissue (158).

A number of changes in echogenicity associated with structural change within the pathologic tendon have been defined. The definition of ‘uniform degrees of whiteness’ refers to ‘normo-echoic (isoechoic)’ regions whereas a ‘lack of whiteness’ is termed ‘hypoechoic’ (159). In the latter case, infiltration of the collagen fibre pattern by inflammatory fluid (oedema), haemorrhage and/or immature fibroplasia may be implied. ‘Hyper-echoic’ refers to an increased whiteness and is associated with either infiltration of fibrous (scar) or calcified tissue in or around the collagen fibres or alternatively, the presence of foreign bodies such as sutures. ‘Anechoic’ refers to a total lack of whiteness and represents relatively simple (that is not proteinaceous) fluid (for example urine in the bladder). These terms can be used in an absolute sense or a relative sense (for example comparing the tendon to the surrounding tissues) (155).

The cellular processes of healing lead to changes in tendon collagen content and density. The acoustic impedance of tendon tissue increases accordingly and the tendon changes are
presumed to be reflected in echogenicity levels after injury (131, 158). The validity of imaging variables in measuring structural changes in tendon tissue can be evaluated against the gold standard of histology. While a small number of authors have investigated the correlation between histology and ultrasound findings in healing surgically repaired animal tendons (128, 129), no investigators have examined changes in echogenicity levels in the surgically repaired digital flexor tendon during the post-operative period.

In surgically repaired animal tendons, it has been found that poor internal echo structure is associated with histologically immature granulation tissue and, conversely, that an increase in echogenity is associated with maturation of scar tissue (128). In the same animal model, histological evidence of fibrosis, adhesion and irregular arrangement of collagen fibres appears less echogenic on sonography (129).

In more chronic Achilles tendon lesions, abnormal tendinous tissues (most commonly hypoechoic areas), have been identified sonographically and verified histologically (135, 160). In the common extensor tendon of the forearm of patients with tennis elbow focal hypoechoogenicity has been found to demonstrate collagen fibre disorganisation and degeneration and fibroblastic proliferation at histology, with the severity of histologic change correlating with changes in grey-scale imaging levels (142). Similar correlations have been established between ultrasonographic observations of injured and normal tendons and their histopathologic appearance in equine models of core tendon lesions (126).

2.3.2.3. Classification systems
A review of studies characterising echogenicity during healing in surgically repaired tendons and tendon pathologies reveals a number of methods of quantifying echogenicity and the degree of change demonstrable in tendon tissue. The majority of classification systems aim to quantify subjective estimations of image brightness, while others use digital grey-scale analysis. The classification systems are detailed in the following tables, along with findings in the surgically repaired Achilles tendon in-vivo in humans (Table 2.2) and surgically repaired Achilles tendon in-vivo and ex-vivo in animals (Table 2.3). Classification systems used to investigate closed partial lesions (tendinopathy) in humans are outlined in Table 2.4, and
those used to investigate similar lesions *in-vivo* and *ex-vivo* in animal models are described in Table 2.5.
### Table 2.2 In-vivo assessment of echogenicity in the surgically repaired human Achilles tendon

<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Finding</th>
<th>Classification system</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thermann 1989 (132)</td>
<td>Majority classified as belonging to grade 3 or 4.</td>
<td>1 = normal echotexture; 2 = shorter, thinner and more distant internal echoes; 3 = single, parallel internal echoes with little direction; 4 = undirected, more spotted internal echoes ‘salt and pepper’.</td>
<td>Six months after surgery</td>
</tr>
<tr>
<td>Burchardt 1991 (133)</td>
<td>Most classified as 2 or 3, implying proximity to normal echotexture structure.</td>
<td>As above (Thermann 1989)</td>
<td>One to ten years after surgery</td>
</tr>
<tr>
<td>Martinoli 1993 (135)</td>
<td>Normal echotexture replaced by disorganised pattern without clear structure; reduced echogenicity.</td>
<td>Qualitative analysis</td>
<td>15 patients two to eighteen months after surgery</td>
</tr>
<tr>
<td>Rupp 1995 (136)</td>
<td>Hypoechochogenicity was a frequent finding; only four patients demonstrated return to normal echogenicity.</td>
<td>Hypoechochogenic; focal hypoechochogenicity &lt;5 mm; focal hyperechochogenicity; focal hyperechochogenicity with dispersion of longitudinally oriented texture.</td>
<td>60 patients followed up at a mean of eleven years post-operative.</td>
</tr>
<tr>
<td>Karjalainen 1996 (137)</td>
<td>Both increased and decreased echogenic areas seen at one year. Poor clinical outcome associated with more irregular hypoechoic areas.</td>
<td>Qualitative analysis</td>
<td>13 tendons one to three years post surgical repair</td>
</tr>
<tr>
<td>Reference</td>
<td>Summary</td>
<td>Grade</td>
<td>Patients</td>
</tr>
<tr>
<td>-------------------</td>
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</tr>
<tr>
<td>Merk 1997 (138)</td>
<td>Over 90% graded 2 or 3. Only 3 patients graded 1 (normal).</td>
<td>As above (Thermann 1989)</td>
<td>54 patients at an average of four years five months after surgery</td>
</tr>
<tr>
<td>Rominger 1998 (134)</td>
<td>Structural changes regressed partially; none returned to normal fibre structure.</td>
<td>As above (Thermann 1989)</td>
<td>60 patients examined at six to seventy-eight months after surgical repair</td>
</tr>
<tr>
<td>Moller 2002 (139)</td>
<td>Heterogeneity was a common finding at one year post injury.</td>
<td>0 = (fairly) homogeneous (minimal intratendinous echo changes); 1 = mildly (moderately) heterogeneous (localised hypoechoic and/or hyperechoic areas interspersed in the tendon, or severe heterogeneity with generalised hypoechoic and/or hyperechoic areas in the tendon); 2 = (severely) heterogeneous (generalised hypoechoic and/or hyperechoic areas in the tendon).</td>
<td>58 patients examined at six, twelve, and twenty-four months after surgical or nonsurgical treatment.</td>
</tr>
<tr>
<td>Author(s)</td>
<td>Finding</td>
<td>Classification system</td>
<td>Conditions</td>
</tr>
<tr>
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</tr>
<tr>
<td>Thermann 2002 (128)</td>
<td>Poor internal echo structures at 2 weeks and an increase in short and non-direct parallel echo structures at four weeks. Increasing echogenicity and a more parallel pattern by eight weeks. Almost intact tendon tissue by twelve weeks.</td>
<td>Qualitative analysis</td>
<td>105 rabbit tendons after operative therapy with tendon suture or non-operative treatment with fibrin glue.</td>
</tr>
<tr>
<td>Jann 2003 (24)</td>
<td>Dehescence and adhesion following insufficient immobilisation</td>
<td>Qualitative analysis of relative echogenicity by comparison with surrounding tissues.</td>
<td>Deep flexor tenorrhaphy in 5 mature horses</td>
</tr>
<tr>
<td>Gideroglu 2009 (129)</td>
<td>Low echogenicity at three weeks; broader and more longitudinally-aligned echoes at six weeks.</td>
<td>Qualitative analysis</td>
<td>Surgically lengthened rabbit tendon at three and six weeks post-operative.</td>
</tr>
<tr>
<td>Author(s)</td>
<td>Finding</td>
<td>Classification system</td>
<td>Conditions</td>
</tr>
<tr>
<td>-----------</td>
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</tr>
<tr>
<td>Zanetti 2003 (161)</td>
<td>Increased homogeneity at three and six months and was the only ultrasound finding to predict a significant difference in outcome.</td>
<td>Homogenous or in-homogenous</td>
<td>47 patients with Achillodynia lasting more than four weeks treated according to standardised protocol.</td>
</tr>
<tr>
<td>O’Connor 2004 (162)</td>
<td>Grade 1 tendinopathic changes were classified in twelve of 66 ‘normal’ tendons.</td>
<td>0 = normal tendon, uniform normal striated echo pattern throughout the tendon; 1 = area of reduced reflectivity occupying up to 25% of the transverse area of the tendon; 2 = 25-50%; 3 = 50-75%; 4 = more than 75%.</td>
<td>Evaluated reproducibility of quantitative and semi-quantitative measures of various healthy ‘normal’ tendons on ultrasound.</td>
</tr>
<tr>
<td>Ohberg 2004 (163)</td>
<td>Normalised tendon structure following twelve week eccentric training regime.</td>
<td>Normal or abnormal structure</td>
<td>25 patients with mid-portion painful chronic Achilles tendinosis</td>
</tr>
<tr>
<td>Malliaras 2010, 2011 (143, 164)</td>
<td>Along with measurements of AP diameter, findings support a proposed continuum of tendon pathology.</td>
<td>Normal, diffuse or focal (pathology)</td>
<td>Prospective repeated measures study of ‘dysrepair’ changes in volleyball players.</td>
</tr>
</tbody>
</table>
### Table 2.5 *In-vivo* and *ex-vivo* ultrasound assessment of echogenicity in tendinopathy in the animal model

<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Finding</th>
<th>Classification system</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genovese 1985 (159)</td>
<td>Classification of echogenicity useful for quantifying the severity of tendon injury and prognosticating return to racing.</td>
<td>Type I = hypoechoic, white areas predominating over black or anechoic areas; Type II = hypoechoic, normoechoic and anechoic of equal intensity; Type III = hypoechoic, anechoic areas predominate over normoechoic areas; Type IV = totally anechoic lesion.</td>
<td><em>In-vivo</em> equine superficial flexor tendon in lame racehorses.</td>
</tr>
<tr>
<td>Genovese 1990 (130)</td>
<td>Normalisation of echogenicity, improved density of fibre pattern, and evidence of lengthening of the linearly arranged fibres over a three month period.</td>
<td>Type-rated scale of 0 to 4, indicating the diminished sonographic intensity of a lesion. 1 = minimal loss of echogenicity; 4 = totally anechoic, with no apparent tendon fibers present.</td>
<td>Equine superficial flexor tendon lesions</td>
</tr>
<tr>
<td>Reef 1996 (165)</td>
<td>Improved from 3 to 0 or 1 by sixteen weeks; marked improvement in treatment group as compared with placebo controls.</td>
<td>0 = normal to near normal echogenicity; 1 = mostly echogenic; 2 = 50% anechoic and 50% echogenic; 3 = mostly anechoic.</td>
<td>Over 200 horses with a recent injury to the superficial flexor tendon, treated with intralesional BetaAPN-F ten days to four months or longer following the tendon injury.</td>
</tr>
<tr>
<td>Tsukiyama 1999 (166)</td>
<td>Higher value in normal tendons than in diseased tendons (p&lt;0.01). Mean value in acute lesions was lower than in early fibrosis or healed lesions (p&lt;0.01). Mean value increased as healing progressed.</td>
<td>Computerised histogram (grey-scale) value</td>
<td>Equine model of tendon lesion <em>Sonography just prior to euthanasia and histology just after.</em></td>
</tr>
</tbody>
</table>

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32
<table>
<thead>
<tr>
<th>Reference</th>
<th>Description</th>
<th>Methodology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perkins 2004</td>
<td>Treatment had no effect on echogenicity (p=0.43).</td>
<td>Grey-scale analysis</td>
</tr>
<tr>
<td>Avella 2009</td>
<td>Echogenicity increasing from hypoechoic to near normal over several months.</td>
<td>Qualitative analysis</td>
</tr>
<tr>
<td>Waguespack 2011</td>
<td>Significant increase in echogenicity between three and six weeks in treatment group.</td>
<td>As above (Reef 1996)</td>
</tr>
</tbody>
</table>
2.3.2.4. Measurement of echogenicity

Several scales for estimating echogenicity have been developed (129, 132, 139). The most frequently used is that described by Thermann (1989) (132), which rates echogenicity levels on a 1 to 4 scale, where: 1 = normal echotexture structure; 2 = shorter, thinner and more distant internal echoes; 3 = single, parallel internal echoes with little direction; 4 = undirected, more spotted internal echoes ‘salt and pepper’ (132-135). The main finding of studies that used Thermann’s scale in the surgically repaired Achilles tendon was persistent abnormalities of the surgically repaired Achilles tendon even years after surgery. Computerised grey-scale analysis has been used measure echogenicity to grade the severity of equine tendon pathology (166) and determine the treatment effect of a training programme (125). Although quantitative digital measurements of grey-levels are attractive, they have also been demonstrated to be highly susceptible to instrument variables and transducer handling and therefore may have rather poor reproducibility (131).

O’Connor (2004) (162) and Genovese (1985) (159) used five-point scales (0 to 4) to classify echogenicity in the normal human tendon and pathologic equine tendon, respectively. The scale described by Genovese (1985) (159) has successfully demonstrated change in tendon structure over time. The scale described by O’Connor (2004) (162) has largely been used on healthy tendons and has been shown to be more specific to the transverse plane – the plane of orientation recommended in preference to the longitudinal plane for ultrasound assessment of tendon structure (23, 131).

The reliability of ultrasound measurement of echogenicity may be poor. For instance, the reliability of ultrasound assessment is often associated with operator experience; however, years of experience is an inadequate indicator of reliability (142). One study of tennis elbow examined inter and intra-rater reliability and reported low ICC values for most variables (142). However other investigators reported very good inter and intra-rater reliability (162, 168). For the purposes of a longitudinal study, reliability of echogenicity measurement is likely to be better if undertaken by a single investigator.
In summary, there is some evidence that the ultrasound variable of echogenicity can detect change in structural properties of the healing tendon, although it is not known if this measurement of echogenicity is feasible or useful in the surgically repaired digital flexor tendon. There is no one standard way to measure echogenicity however a five-point rating scale may be most suitable for semi-quantitative assessment of echogenicity of the FDP tendon in the transverse plane.

2.3.3. Thickness
The only published method for in-vivo measurement of FDP tendon thickness to date is real-time grey-scale ultrasound. Previously published dimensions recorded in healthy individuals are given in Section 2.2.6.

The reliability of tendon thickness measurement appears good. Intra-tester reliability for measurement of the normal, uninjured flexor tendon thickness demonstrating strong correlation coefficients (r) between 0.43 and 0.81 and ICC values ranging from 0.76 to 0.99 depending on the level and orientation of the measurement (121, 122). In-vivo ultrasound measurement of other human tendons has also shown high intra-observer reliability with mean test-retest difference of 0.22 mm (95% limits of agreement +/- 0.35 mm (169) and 0.14 mm (140)). Other authors also found reproducibility to be excellent (ICC 0.99) (139) and inter-observer reliability to be high (P>=0.175) (170).

However, while O'Connor (2004) (162) found in-vivo intra-subject and intra-visit measurements of tendon thickness measurements to be reproducible for a range of tendons, inter-observer variation was found to be a source of error. Pickersgill (2001) (171) also identified differences in image analysis between observers as a source of error in ultrasound measurement of equine tendon dimensions. It has therefore been recommended that the same observer undertakes serial ultrasound examination of tendon dimensions (162, 171).

Validity of ultrasound measurement of tendon thickness has been supported by close correlation with histological examination of cadaveric specimens (r²=0.94) (122). Minimal difference between ultrasound and post-mortem measurement (on average less than 5%)
has been reported (172) as well as a strong correlation \((r=0.87, \ p=0.001)\) between ultrasound and MRI measurement in the AP dimension of previously repaired Achilles tendon thickness (137). However, in the latter study, the ML dimension correlated less strongly \((r=0.58, \ p=0.06)\) (137), suggesting that AP dimension is a more valid and reliable measure of tendon spatial dimensions.

Studies of normal in-vivo FDP tendon thickness indicate no significant difference in tendon thickness between left and right but gender differences have been identified, with tendons found to be larger in men than in women (121, 169).

2.3.4. Excursion
The ability of grey-scale ultrasound to visualise suture material at the tendon repair site for at least one year post-operative presents an opportunity to measure tendon excursion (at the repair site) using the suture material as a marker, and an adjacent bone or joint prominence as a landmark. Such a method has not previously been reported, but would be similar to that described by radiographic studies in which displacement of an implanted metal marker is measured against a bony landmark (11, 12, 95, 96).

2.3.5. Gap
A number of studies report ultrasound visualisation of stump ends and a perceivable 'gap' in the surgically repaired digital flexor tendon that may or may not be separated by a hypoechoic scar (25, 29, 30, 119, 124, 151, 152). Appreciation of a 'well-defined hypoechoic gap' that went on to fill with amorphous hypoechoic tissue has been reported in surgically repaired animal tendons (24, 128). While the nature of the 'gap' may be somewhat variable, these studies suggest ultrasound imaging would allow appreciation of the stump ends and measurement of the distance between them.

A small number of studies report ultrasound measurement of gap in millimetres using onscreen calipers (29), while others report gap as present or absent (124). For the purposes of this study, on-screen calipers were deemed most appropriate.
2.3.6. Margination
Margination, or the demarcation of adjacent tissue borders, has been used as an ultrasonographic sign of the quality of tendon healing and gliding properties and the presence or absence of post-surgical adhesions in a range of tendons (24-26).

Jann (2003) (24) reports a well-defined four-point scale for the evaluation of margination of tendon tissue visualised in the transverse view: grade 1 (margins well defined \[normal\]); grade 2 (slightly less definition between borders \[good\]); grade 3 (margins irregular \[fair\]); grade 4 (borders blend \[poor\]). This scale was considered suitable for the purposes of the current study.

2.3.7. Power Doppler
Power Doppler sonography is a widely used approach for the in-vivo measurement of blood flow and neo-vascularisation in soft tissues (27, 28). For the purposes of this study, the principles of Doppler assessment and its relationship to the anatomical detail of healthy and abnormal tendon vasculature were examined. Methods of evaluating and quantifying the power Doppler signal were also reviewed.

2.3.7.1. Definition
Power Doppler sonography as a means of non-invasive measurements of blood flow is based on the principle of the effect of motion on sound, whereby a change in the frequency of a sound wave as a result of the movement of either the source or receiver can be detected – the “Doppler effect” (145).

Power Doppler sonography detects the volume of blood present within tissue and is sensitive to low-velocity flow in small vessels at the microvascular level (145, 173, 174). The ability to detect the presence of blood flow at relatively low flow rates is particularly useful for identifying vascular changes in joints and in soft tissues as a consequence of inflammation (142, 145, 173).

2.3.7.2. Normal tendon
Under ideal conditions, power Doppler is able to detect flow velocities as low as 0.04 cm/sec to 0.06 cm/sec in a 3 mm tube, but is three to four times less sensitive in tubes with smaller
diameters (0.30 mm and 0.05 mm) (175) (flow velocities in peripheral tissues such as the capillaries of the nail fold range between 0.03 - 0.08 cm/sec). In the healthy digital flexor tendon power Doppler is normally unable to detect flow signals due to the small diameters of their vessels (42, 162). However, the digital arteries are normally visible, with thin vessels running adjacent to tendons also visible on occasion – probably synovial sheath or peri-tendon vessels (42).

Image artefacts relating to movement of the transducer or patient, brightness of the bone cortex or occlusion by pressure from the transducer or tissue tension may interfere with image interpretation. Artefacts can be minimised by optimising machine settings, using a fixed mould for the area to be examined, keeping vessels un-occluded by using a standoff pad or ample gel and maintaining tissues at a relaxed length and constant temperature (145, 176).

2.3.7.3. Tendon pathology
In inflammatory states, intra-tendinous flow becomes visible due to increased velocities and reduction in impedance of the tendon vasculature (22). Power Doppler sonography can identify and quantify vascularity in chronic tendon pathology (142, 162), and differentiate hyperaemic synovial inflammation from a static fluid collection or oedema (173, 177, 178). The validity of power Doppler sonography in clinical practice is supported by the strong correlation between power Doppler and histological findings in synovial tissue (174) and Achilles tendinopathy (160). However studies investigating neo-vascularity (angioblastic hyperplasia) in non-inflammatory Achilles tendinopathy using power Doppler and symptom-severity have had variable results (161, 173, 176, 179-182). The developing role of Doppler imaging in aiding understanding of therapeutic mechanisms and evaluating the efficacy of specific treatment modalities has been illustrated by its ability to demonstrate a change in flow rate following low frequency therapeutic ultrasound treatment in a collagenase-induced mouse model of Achilles tendinitis (183).

2.3.7.4. Classification systems
The nature of the changes taking place within the microcirculation of the surgically repaired intra-synovial digital flexor tendon that can be detected with power Doppler sonography is
not known. Information regarding findings and classification systems of power Doppler investigations are therefore based on studies of other tendon pathologies. Ultrasound investigations of non-inflammatory tendinopathies in humans and the animal model using power Doppler are presented in Table 2.6 and Table 2.7, respectively. Power Doppler studies of tendons and joints in the inflammatory arthritides are presented in Table 2.8.

Several scoring systems to quantify power Doppler signal have been used; one system makes a distinction between the presence or absence of neo-vascularisation (161, 176, 179, 184, 185) while others are based on a Likert grading scale (27, 162, 163, 174, 176, 178, 181, 185-191). Other methods used to quantify power Doppler images include the surface measurement of digital coloured pixels (182, 186, 190) and vessel-counting (180).
<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Finding</th>
<th>Classification system</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>O’Connor 2004</td>
<td>Three assessments showed minor vascularity on one or two occasions.</td>
<td>Semi-quantitative four-point scale (normal, mild, moderate and severe).</td>
<td>Variety of tendons in 11 normal healthy subjects.</td>
</tr>
<tr>
<td></td>
<td>All other assessments were normal.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peers 2003</td>
<td>Not strictly related to symptoms but rather to functionality and chronicity.</td>
<td>Estimation of flow quantification (mm²) performed through computerised surface measurement of coloured pixels.</td>
<td>25 patients with symptomatic Achilles tendinopathy lasting more than three months.</td>
</tr>
<tr>
<td>Zanetti 2003</td>
<td>Did not predict clinical outcome after conservative treatment.</td>
<td>Flow pattern and distribution as determined by spectral analysis.</td>
<td>40 patients with Achillodynia lasting more than four weeks.</td>
</tr>
<tr>
<td>Silvestri 2003</td>
<td>Flow present in all cases of tendonitis and active tenosynovitis; absent in stenosing tenosynovitis and controls.</td>
<td>Flow pattern and distribution as determined by spectral analysis.</td>
<td>49 patients with tendonitis (patellar, Achilles, rotator cuff), 47 patients with tenosynovitis (acute or stenosing) and 6 healthy controls.</td>
</tr>
<tr>
<td>Reiter 2004</td>
<td>Specificity of 100% and sensitivity of 50%; presence of flow associated with more severe symptoms.</td>
<td>Flow detected or not detected</td>
<td>28 symptomatic Achilles tendons</td>
</tr>
<tr>
<td>de Vos 2007</td>
<td>63% symptomatic tendons demonstrated neo-vessels at baseline; no correlation with symptom severity; did not predict clinical outcome after conservative treatment.</td>
<td>Modified Ohberg score: 0 = no vessels visible; 1+ = one vessel, mostly anterior to the tendon; 2+ = one or two vessels throughout the tendon; 3+ = three vessels throughout the tendon; 4+ = more than three vessels throughout the tendon.</td>
<td>63 symptomatic Achilles tendons at baseline and twelve weeks.</td>
</tr>
<tr>
<td>Author(s)</td>
<td>Finding</td>
<td>Classification system</td>
<td>Conditions</td>
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</tr>
<tr>
<td>Knobloch 2007 (179)</td>
<td>Immediate resolution of neo-vascularisation on power Doppler; complete resolution of pain after a twelve week training programme.</td>
<td>Presence or absence of neo-vascularisation.</td>
<td>Single case study flexor carpi ulnaris tendinopathy treated with sclerosing therapy and eccentric training.</td>
</tr>
<tr>
<td>Guerini 2008 (184)</td>
<td>Hyper-vascularisation was noted in 91% of trigger fingers but was never found in the healthy control group.</td>
<td>Hyper-vascularisation noted or not noted.</td>
<td>A1 annular pulleys, tendons and tendon sheaths in 33 trigger fingers.</td>
</tr>
<tr>
<td>Sengkerij 2009 (188)</td>
<td>Excellent inter-observer reliability (ICC 0.85); neo-vessels present in majority of cases; no correlation with symptom severity.</td>
<td>Modified Ohberg as above (de Vos 2007)</td>
<td>33 symptomatic Achilles tendons</td>
</tr>
<tr>
<td>Richards 2010 (180)</td>
<td>Reduction in number of vessels on PD, followed by morphological improvements and a reduction in size, preceded by symptom improvement.</td>
<td>Site and number of vessels</td>
<td>11 participants with conservatively managed Achilles tendinopathy at two, six, twelve and fifty-two weeks from baseline.</td>
</tr>
</tbody>
</table>

Table 2.7 *In-vivo* power Doppler ultrasound assessment of non-inflammatory tendinopathy in the animal model

<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Finding</th>
<th>Classification system</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yeh 2009 (183)</td>
<td>Increase in micro-circulation observed after low-frequency ultrasound treatment.</td>
<td>Doppler power energy and blood flow rate within the peritendinous space using “swept scan” technique.</td>
<td>Collagenase-induced mouse model of Achilles tendinitis.</td>
</tr>
</tbody>
</table>
### Table 2.8 *In-vivo* power Doppler assessment of tendons and joints in the inflammatory arthritides

<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Finding</th>
<th>Classification system</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Newman 1996 (178)</td>
<td>Demonstrated therapeutic response of decrease in soft-tissue hyperemia (synovial perfusion) (reduction in mean score from 3.9 to 1.8).</td>
<td>1 = normal or minimal vascularity; 2 = mild hyperemia; 3 = moderate hyperemia; 4 = marked hyperemia.</td>
<td>Steroid injection treatment of synovitis in 8 knee joints.</td>
</tr>
<tr>
<td>Walther 2001 (174)</td>
<td>Good correlation between histopathology results and power Doppler (0.89 by Spearman’s p; P&lt;0.01); correlation between digital image analysis and qualitative grading of 0.89 by Spearman’s p (P&lt;0.01).</td>
<td>As above (Newman 1996)</td>
<td>Synovial hypertrophy in 23 knee joints with rheumatoid arthritis or osteoarthritis undergoing arthroplasty</td>
</tr>
<tr>
<td>Weidekamm 2003 (177)</td>
<td>Results were correlated with benchmarks of the clinical and radiology investigations.</td>
<td>Power Doppler score: 0 = no vascularisation; 1 = small vascularisation; 2 = moderate vascularisation.</td>
<td>Hand and finger joints in 47 patients with rheumatoid arthritis.</td>
</tr>
<tr>
<td>Milosavljevic 2005 (27)</td>
<td>Measures correlated significantly to the number of swollen joints, but not to other clinical or laboratory measurements of disease activity.</td>
<td>0 = no detectable PD signal; 1 = mild vascularity (&lt;=30% of synovial proliferations area); 2 = moderate vascularity (&lt;=60% of synovial proliferations area); 3 = severe vascularity (&gt;60% of synovial proliferations area).</td>
<td>Tendon and synovial tendon sheath tissue vascularity in tenosynovitis of flexor and extensor tendons in psoriatic arthritis, measured on longitudinal and transverse scans.</td>
</tr>
<tr>
<td>Koski 2006 (189)</td>
<td>Good or excellent agreement (mean k value intra-reader 0.72, inter-reader 0.57).</td>
<td>0 = no detectable Doppler signal inside the synovium of the joint bursa or tenosynovium; 1 = mild but clear; 2 = moderate; 3 = substantial increase in Doppler signal.</td>
<td>41 patients with monoarthritis or polyarthritis in 41 synovial sites.</td>
</tr>
</tbody>
</table>
Treatment response shown by power Doppler by week two \((P<0.01)\); good to excellent inter-observer reliability \((ICC>=0.8)\).

0 = no Doppler signal/no blood flow; 1 = single Doppler signals/mild blood flow; 2 = various, confluent Doppler signals/moderate blood flow; 3 = confluent Doppler signals with more than half of the visible synovium showing Doppler signals/intense blood flow.

Digital counting of coloured pixels from saved images.

24 patients with active arthritis treated with TNF-\(\alpha\) inhibitor adlimumab.

Ultrasound evaluation of synovitis is an outcome measure at least as relevant as physical examination.

0 = absence of signal, no intra-articular flow; 1 = mild, one or two vessels (including one confluent vessel) for small joints and two or three signals for large joints (including two confluent vessels); 2 = moderate confluent vessels (>grade 1) and less than 50% of normal area; 3 = marked vessels signal in more than half the area.

Synovitis in the joints of patients with rheumatoid arthritis (multi-centre trial).

Significant reduction in vascularity detected in all tendons.

0 = none; 1 = minor; 2 = moderate; 3 = major presence of vascularisation.

Tenosynovitis at the wrist and ankles in 20 patients with rheumatoid arthritis taking biological medication at baseline, one, three, six and twelve months.
2.3.7.5. Measurement properties of power Doppler scales
The ability to quantify power Doppler sonography is clearly desirable, particularly to allow observations over time. At present, most researchers favour a semi-quantitative score of the maximum area of enhancement. Digital analysis software is available (145) but digital techniques are plagued by technical artefacts and therefore cannot automatically be assumed to be more accurate than semi-quantitative analytical methods (174).

Five-point power Doppler scales have been most commonly used in studies of Achilles tendinopathy (163, 186, 187) while four-point scales predominate in the rheumatology literature (177, 178). Good and excellent inter and intra-observer agreement of four-point power Doppler rating scales has been reported for assessment of synovial tissue vascularity in psoriatic arthritic hands by Milosavjevic (2005) (27) (correlation on simple kappa estimation 98.8-99.2 and 98.7-98.9), Albrecht (2008) (190) (ICC >0.8) and Koski (2006) (189) (mean $k$ value 0.57-0.72).

Power Doppler sonography has well-established construct validity in the evaluation of disease status in rheumatoid arthritis, but there is less evidence of criterion validity (145). There is little information available on the reliability of power Doppler ultrasound image acquisition and image reading or evidence of sensitivity to change.

In summary, power Doppler sonosgraphy appears to provide a reliable and accurate method for visualising blood flow in a number of soft tissues. Based on the findings of this literature review a four-point power Doppler rating scale is an appropriate tool to investigate change in the vascularity of the healing post-operative digital flexor tendon over time.

2.3.8. Individual factors in tendon imaging
Individual factors that may cause variability in making in-vivo ultrasound observations of human digital flexor tendons include sex, tendon pathology including inflammatory conditions or tendinosis, age and repetitive high loads. Studies of tendon thickness consistently find tendon thickness to be greater in men as compared to women (169). Focal or diffuse thickening is known to occur in patients with rheumatoid arthritis or tendovaginitis (122). General thickening has been found in patients with metabolic disease such as hypercholesterolemia and adaptive thickening has been documented in sport
climbers (122). Tendon disease resulting from adaptive and micro-trauma processes alters tendon structure and cellular activity producing thickening, hypoechoogenicity and vascularisation of the affected tendon (162, 165). However hypoechoic zones within tendons have been reported even in asymptomatic subjects, particularly if they have a high level of physical activity (169). Physical activity prior to imaging has also been found to increase vascularity on imaging (167), although in contrast Sharma (2006) summarises findings of previous studies that report tendon blood supply in general decreases with mechanical loading down to 20% of capacity at peak exercise (193). Tendon blood supply is reported to reduce with age, as are other tendon properties such as tensile strength; the latter as a result of loss of collagen and its cross-linking and an increase in stiffness (193).

Locally applied corticosteroid can cause morphologic changes to tendon evident on ultrasound imaging (165). Lesions such ganglia or cysts will also alter tendon image (194). Obesity is known to alter the depth of rotator cuff and other tendons from the skin (169). Obesity, fluid shift or a history of manual work (and associated callus formation) may alter the depth of the flexor tendons from the skin in the digits. Individual differences in ultrasound measurements of tendon thickness between sides have been shown to be small, suggesting that hand dominance does not have a significant impact on this variable (121, 169).

2.3.9. Justification of present study
In summary, considerable knowledge has been gained regarding the process of tendon healing from both animal and in-vitro studies. Positive clinical benefits of early mobilisation have been associated with more rapid acquisition of collagen fibre density and longitudinal alignment; early mobilization is possibly associated with the re-establishment of an intra-tendinous blood supply and/or synovial diffusion. However, post-surgical adhesions remain a frequent complication in intra-synovial FDP tendon healing.

Some of the temporal and location-specific changes in structural, gliding and vascular properties that may provide more information about factors and conditions contributing to the development of post-surgical adhesions in the human hand include: the rate of accrual of structural properties that give the healing tendon tensile; whether or not vascularisation
of the repair site takes place in the surgically repaired human tendon; and whether or not it is associated with good (intrinsic) or poor quality (extrinsic) healing. Currently, investigation of post-surgical adhesion formation in the human hand is limited by a lack of non-invasive measurement tools. The precise amplitude of early repair site tendon excursion necessary to prevent adhesion formation, and how this is to best be achieved, requires further study, as does the relationship between gap formation and functional outcome; and whether tendon thickening or conversely tendon thinning is a part of the natural healing process following tendon injury.

The applicability of results from animal studies for humans is limited, due to animals’ faster rates of healing, more prolific formation of granulation tissue, and lesser propensity for dense scarring, as well as anatomical differences (3). Most approaches to investigating the properties of the healing tendon, (with the exception of measurement of tendon thickness) are invasive and present ethical barriers. Different approaches are needed that allow investigation of the healing human digital flexor tendon in-vivo.

Ultrasound is a non-invasive and easily accessible imaging modality that allows repeated measurements to be taken. The grey-scale ultrasound property of echogenicity reveals important information about the structural status of tendons, while power Doppler ultrasound is a sensitive measure of blood flow. On-screen calipers allow accurate linear measurement of tissue dimensions and real-time ultrasound enables capture of tendon movement.

From the review of the literature, six specific ultrasound properties of the healing tendon have been identified that may be useful for the purposes of non-invasive longitudinal investigation of key aspects of tendon healing in the surgically repaired FDP tendon. These are:

Echogenicity (scale 0 to 4) (162), and thickness (mm) as viewed at specific locations in the transverse plane, representative of cellular activity/events and the structural properties of the healing tendon.
Margination (scale 1 to 4) (24) - the definition of tissue margins as viewed in the transverse plane, representative of the presence of adhesions.

Tendon excursion (mm), measured in the longitudinal plane using tendon suture material as a marker landmarked against an adjacent bony prominence.

Repair site 'gap' (mm) as measured between the identified ends of the tendon stumps.

Power Doppler assessment (scale 0 to 3) (27, 177) in the transverse plane for estimation of neo-vascularity in the healing tendon complex.

A pilot study was carried out to test the feasibility of carrying out measurement of the ultrasound variables. Following this a main study was designed to gain preliminary information about temporal change in the ultrasound properties at specific locations and about the feasibility of undertaking repeated measurements in a population of tendon-repaired participants over the first two to eighteen weeks after surgical repair.
3.0 METHODS

This study aimed to explore the feasibility of documenting change in the ultrasound properties of echogenicity, linear measurements, and power Doppler signal in the healing flexor digitorum profundus (FDP) tendon of the human hand over the first two to eighteen weeks after surgical repair.

In order to determine the feasibility of documenting these ultrasound properties, a two stage pilot study was carried out. The objective of the first stage was to 1) define optimal image-acquisition parameters, and 2) test the feasibility of registering the ultrasound variables of echogenicity, thickness, margination and power Doppler signal using B-mode grey-scale ultrasound and power Doppler ultrasound in the healthy uninjured hand. The objective of the second stage of the pilot study was to test the feasibility of measuring tendon excursion and gapping, in addition to the measurements above, in a subject with a tendon repaired hand.

The main study was carried out in a case series of patients who fulfilled specific tendon-repaired criteria, using the imaging protocol and operational definitions determined in the pilot study.

Approval was obtained from the Lower South Island Regional Ethics Committee (Appendix 1). The participant information sheet and consent form are given in Appendix 2. All participants signed written informed consent before entering into the study.

3.1. Pilot study stage 1

The specific aims of the first stage of the pilot study were

To establish optimal machine settings and transducer-couplant set-up for ultrasound examination of the healthy intra-synovial FDP tendon.

To become familiar with the ultrasound appearance of tendon echogenicity, thickness, margination and power Doppler signal in the healthy tendon.
To identify facilities for collection and storage of digital data.

3.1.1. Methods

3.1.1.1. Participants
A series of images were acquired from the uninjured digits of two of the investigators (MB and GJ).

3.1.1.2. Procedure
Scans were performed on either a DP-6600 Shenzhen Mindray ultrasound machine (Shenzhen Mindray Bio-Medical Electronics Co., Ltd., Shenzhen, China) using a 10 MHz Linear Array probe, or an Antares Premium Edition ultrasound machine (Siemens, Hamburg, Germany) using a VF 13-5 MHz Linear Array probe. Technical decisions regarding probe orientation and optimal resting position were made based on information regarding ultrasound image capture of tendons from published literature (121, 147) and in discussion with the radiologist (GM). Key points with regard to methodology were recorded as field notes.

3.1.2. Results

3.1.2.1. Machine settings and transducer-couplant set-up
From this preliminary work it was found that the real-time B-mode grey-scale imaging with the tissue specific settings of “General” and the exam mode “Small parts” visualised the FDP tendon clearly. The high frequency 13 MHz ultrasound machine with a linear transducer was selected over the 10 MHz for its optimal image resolution and concentration of the ultrasound beam in the more superficial and relatively small region occupied by the flexor tendons. It was found that a transducer-couplant set-up using ample gel (Aquasonic 100 Ultrasound Transmission gel, Parker Laborotories Inc, New Jersey, USA) minimised near-field artifact while at the same time allowing 30 degrees DIP joint motion.

3.1.2.2. Power Doppler calibration
Colour gain was set at a level just below the disappearance of colour noise deep to the cortical bone (27).
3.1.2.3. **Ultrasound appearance of healthy tendon**

The normal uninjured tendon appeared echogenic compared to the surrounding soft tissues in the transverse plane with a regular longitudinally-aligned fibrillar pattern in the sagittal plane, as previously described (22). Tendon margins could be identified in both the sagittal and transverse planes for measurement of tendon thickness. Power Doppler registered no flow within the healthy tendon however the two digital arteries supplying the flexor tendon complex were clearly visible.

3.1.2.4. **Data collection and storage**

For all variables, image analysis was carried out by the radiologist (GM) on-screen at the time of acquisition from frozen static images, chosen by freezing the picture at the area required. Outcome data was simultaneously recorded on the draft Data Collection Form by the hand therapist (MB).

Images with and without measurements as well as cine clips were saved as DICOM (Digital Imaging and Communication in Medicine) files on the Dunedin Hospital PACS (picture archiving and communication system) (Sectra IDS5, Version 11.1P3, Teknikringen 20, SE-583 30 Linköping, Sweden) and then downloaded to disc along with PACS viewer software. Files were copied and saved to a secure server at the School of Physiotherapy, University of Otago. Image data were re-opened for viewing and cataloging with the ClearCanvas viewing workstation (Toronto, Canada) version 1.3. These facilities were confirmed to be a safe and effective means for the collection and storage of digital data.

3.1.2.5. **Conclusion**

From this work, the optimal machine settings and transducer-couplant set-up for visualising the healthy intra-synovial FDP tendon were established and the scale of the on-screen measurements was verified. Data-collection and storage methods were deemed safe and effective for the purposes of the study.

3.2. **Pilot study stage II**

Having established the optimal parameters for ultrasound-imaging of the healthy intra-synovial FDP tendon, the purpose of stage II of the pilot study was to establish the feasibility
of collecting these same data, as well as tendon excursion and gap, in participants with surgically repaired flexor tendons at three pertinent sites along the repaired tendon.

The aims of stage II of the pilot study were

To finalise the operating procedure for ultrasound-imaging.

To document the ultrasound variables of echogenicity, thickness, excursion, gap, margination, and power Doppler signal in the healing tendon.

To finalise the rating scales and data collection form.

3.2.1. Methods

3.2.1.1. Participants
One participant (female, age 48 years) who had undergone FDP tendon repair (Appendix 3) consented to attend one 45-minute scanning session at six weeks post-surgery. Data was collected on the surgically repaired digit and on the corresponding contra-lateral healthy digit.

3.2.1.2. Set-up
For the purposes of the study, the operational resting position of the forearm was supination, with the hand and digits supported in a thermoplastic dorsal blocking splint. The dorsal blocking splint maintained the wrist in approximately 20 degrees flexion and the metacarpophalangeal (MCP) joints in 50-60 degrees flexion. The interphalangeal (IP) joints were positioned in maximum comfortable extension. The contra-lateral uninjured hand was maintained in the same position as the injured hand (Figure 3.1).

3.2.1.3. Procedure
Image-acquisition and interpretation were performed by the radiologist (GM) using an Antares Premium Edition ultrasound machine (Siemens, Hamburg, Germany) with a VF 13-5 MHz Linear Array probe and ample gel (Aquasonic 100 Ultrasound Transmission gel, Parker Laborotories Inc, Fairfield, New Jersey 07004, USA) on the volar aspect of the injured digit. Registration (measurement or estimation) of the ultrasound variables was undertaken on the injured and, where relevant, uninjured digit(s) of the trial participant.
A variety of image-acquisition and data-collection methods for the ultrasound outcome variables were trialed, discussed and agreed upon by the radiologist (GM) and hand therapist (MB). Operational definitions were determined for the six ultrasound variables to be used in the study. Participant data was recorded on the draft Data Collection Form (Appendix 4).

Figure 3.1 Participant set-up with the injured and uninjured hands supported in thermoplastic dorsal blocking splints; wrist 20 degrees flexion, metacarpophalangeal joints 50-60 degrees flexion; interphalangeal joints in maximum comfortable extension.

Figure 3.2 Locating the proximal data collection site (a.) relative to the mid-tendon repair site (b.) using a centimeter ruler placed adjacent to the injured digit (171).

3.2.2. Results

3.2.2.1. Tendon data collection sites
From this pilot study, suture material and tendon abnormalities occupying a region of approximately 2 cm in length were observed with the ultrasound. This region was defined as the tendon-repair region. The tendon data collection sites were defined as follows: a. the proximal end of the tendon-repair region, b. the midpoint of the tendon repair, and c. the distal point of the tendon-repair region (Figure 3.3). Data collection sites a. and c. were located 1 cm either side of site b.
Figure 3.3 Location of the three data collection sites in the surgically repaired tendon of the hand; a. (1 cm proximal), b. (mid-tendon repair site), c. (1 cm distal), viewed in the transverse plane. Image modified from Strickland (2005) (2) and Khalegian (1984) (31).

Site b. was identified in the sagittal plane as the point at which the tendon was most hypoechoic, with maximal disruption of fibre pattern and visible suture material. In order to image site b. in the transverse plane, the transducer head of the ultrasound probe was manipulated from the longitudinal to the transverse orientation using a ‘spin on the spot’ technique about a reference point on the side of the transducer.

Sites a. and c. were then located relative to site b. using the method described by Pickersgill (2001) (171). Accordingly, a small mark on the end of the hand-held probe (held in the transverse orientation) was lined up against a ruler held parallel to the study digit (Figure 3.2). The probe was moved either proximal or distal while the hand therapist (MB) sighted the distance along the ruler and verbally relayed the correct location to the radiologist (GM). This method has been shown to produce no significant difference in cross-sectional area (CSA) values measured on repeated occasions by the same operator at predetermined levels in the equine limb (suggestive of a high degree of intra-operator reliability) (171). However the accuracy and repeatability of the method of level location with the aid of a ruler against the limb has not in itself been directly evaluated.
On the uninjured contra-lateral finger, the tendon was evaluated at the corresponding level of the mid-tendon repair site (b.). Measurement site b. was landmarked to the nearest joint on the injured digit, and then identified by measuring from the same the bony landmark on the uninjured digit.

3.2.2.2. Echogenicity
For the purpose of this study, the ultrasound variable of echogenicity was rated according to the scale described by O’Connor (2004) (162), where: grade 0 (normal tendon); grade 1 (reduced reflectivity up to 25% of the transverse area of the tendon); grade 2 (reduced reflectivity 25-50% of the transverse area of the tendon); grade 3 (reduced reflectivity 50-75% of the transverse area of the tendon); grade 4 (reduced reflectivity 75-100% of the transverse area of the tendon). Echogenicity levels were estimated in the transverse view of the repaired tendon at each of the three data collection sites a., b., and c. giving a total of three registrations for each participant.

3.2.2.3. Tendon thickness
Six measurements of tendon thickness (0.0 mm) on the injured digit and two on the corresponding contra-lateral uninjured digit were made by the radiologist using on-screen calipers. Simple linear measurements of the AP and ML dimensions were taken in the transverse view at the three sites (a., b. and c.) on the injured digit, and at the equivalent of site b. on the uninjured hand. This gave a total of six measurements on the injured hand and two on the uninjured hand.

3.2.2.4. Tendon excursion
Tendon excursion was visualised in the longitudinal plane and defined as the distance that the suture material moved from when the DIP joint was in full comfortable extension to 30 degrees flexion. The distance was calculated as the distance (0.0 mm) from an identified tendon suture to the nearest joint line with the DIP joint in extension, minus the distance from the identified suture to the same joint line following approximately 30 degrees DIP joint flexion as measured using on-screen calipers. Tendon excursion was measured under conditions of both passive (weeks two to eighteen) and active (weeks twelve and eighteen) DIP joint motion. Distal interphalangeal joint motion of approximately 30 degrees was guided by the hand therapist following practice with a finger goniometer.
3.2.2.5. Tendon gap
The ultrasound variable of ‘tendon gap’ could not be identified due to poorly defined tendon ends and a consequent inability to determine whether a gap existed or not. However a region of healing tendon, or ‘tendon defect’ was appreciable. The ‘defect size’ was defined as the distance (0.0 mm) between the discernible borders of the hypo-echoic region of healing tendon and adjacent normo-echoic tendon, and was measured by the radiologist using on-screen calipers.

3.2.2.6. Margination
Margination, or definition of tissue margins of the involved tendon 1) relative to the adjacent tendon and 2) relative to the surrounding soft tissues was visualised in the transverse plane at each of the three sites and scored according to the following scale: grade 1 (margins well-defined [normal]); grade 2 (slightly less definition between borders [good]); grade 3 (margins irregular [fair]); grade 4 (borders blend [poor]) (24).

3.2.2.7. Power Doppler score
Power Doppler score (PDS) of 1) the involved tendon and 2) the surrounding soft tissues was estimated using power Doppler mode in the transverse plane. Assessments were made at each of the three sites and scored according to the following scale: grade 0 (no detectable power Doppler signal); grade 1 (mild vascularity <= 30% of transverse area); grade 2 (moderate vascularity <=60% transverse area); grade 3 (severe vascularity >60% of transverse area) (27, 177). A total of six estimates of power Doppler signal were recorded for the participant.

Higher levels of power Doppler signal were observed in the repaired FDP tendon and surrounding soft tissues compared to the uninjured digit. The power Doppler calibration method described in section 3.1.1.4 was therefore deemed satisfactory for detecting change in power Doppler signal.

3.2.2.8. Conclusion
The Data Collection Form, Operating Definitions for Ultrasound Variables (echogenicity, margination and PDS), and Operating Procedure for Ultrasound Imaging were then finalised (Appendix 4). Based on this work, the radiologist, hand therapist and supervising investigator were satisfied that the collection of ultrasound outcome variables of tendon
echogenicity, thickness, excursion, defect size, margination and PDS in the surgically repaired intra-synovial FDP tendon was feasible.

3.3. Methods: main study

The objective of this study was to document change in six ultrasound variables between two and eighteen weeks post-operatively. The variables of interest were echogenicity, thickness, excursion, defect size, margination and PDS in the healing FDP tendon. A further aim was to compare concurrent functional outcomes at twelve weeks after surgery.

3.3.1. Study design

A longitudinal observational study over the duration of the eighteen-week post-operative phase of tendon healing was carried out in four participants with sharp laceration and surgical repair of the intra-synovial FDP tendon complex of the hand using high frequency real-time ultrasound (RTUS) and power Doppler ultrasound. Repeat registrations using the ultrasound scanning protocol in the pilot study took place fortnightly from ten to fourteen days until six weeks post-operatively followed by two additional scans at twelve and eighteen weeks after surgery. Five sets of ultrasound data were collected for each participant. Each scanning session lasted approximately 30 minutes.

3.3.2. Participants

Four patients meeting the study criteria were recruited by their treating hand therapist from the Dunedin Hospital Hand Clinic. Potential participants included patients admitted to the Dunedin Hospital with a primary injury of a sharp laceration of the FDP tendon within the digital sheath of one or more digits; less than two weeks post-surgical repair at the time of entry into the study; aged between 18-60 years; and able to provide written informed consent. Exclusion criteria included coexisting medical conditions (rheumatoid arthritis, diabetes mellitus, or immune deficiency states) or a previous tendon injury to the involved digit(s) on the injured or uninjured hand.

Participants were screened for these inclusion and exclusion criteria using a standardised interview template (Appendix 4). Confounding variables gathered from the initial screening interview or surgical and hand therapy notes included relevant medical history; mechanism
of injury, initial management, delay in surgical repair, post-op positioning; surgical technique, suture material, any difficulties or complications; age, sex, and occupation/sport.

Post-operative rehabilitation followed the normal Dunedin Hospital Modified Duran Protocol (early passive flexion and active extension) (91).

3.3.3. Ultrasound imaging protocol
The participant set-up was standardised for all participants, as described in section 3.2.2.1. Assessment of the ultrasound variables in the injured hand took place at the three predetermined sites on the repaired tendon and at a single level on the contra-lateral and corresponding uninjured digit as described in section 3.2.2.2.

All scans were performed on a Siemens Antares Premium Edition ultrasound machine (Siemens, Hamburg, Germany) using a VF 13-5 MHz Linear Array probe with optimal depth and power settings. Registrations of the ultrasound variables, with the exception of PDS, were undertaken in B-mode RTUS. Power Doppler mode was set at the “low flow” standard setting (867Hz) and calibrated as described in section 3.1.1.4.

Ultrasound image-acquisition was carried out by the same experienced radiologist (GM) on each occasion for all participants according to the operating procedure described in section 3.2.2. Registrations of the six ultrasound variables were made according to the operational definitions given in section 3.2.3 and recorded on the Data Collection Form (Appendix 4) by the hand therapist. The radiologist was blinded to previous measures and the hand therapist was present on all occasions.

3.3.4. Functional outcome measures
The functional outcome measures of total active range of motion (TAROM) (degrees) and total passive range of motion (TPROM) (degrees) at the PIP and DIP joints were collected retrospectively from the clinical notes of each participant at four, six and twelve weeks after surgery. In addition, TAROM was classified according to the original Strickland-Glogovac criteria (91) (Table 3.1). The Quick Disabilities of the Arm Shoulder and Hand (QuickDASH) outcome measure (score/100) (195, 196) was collected at six and twelve weeks; grip strength on a Jamar dynometer (percentage of contra-lateral uninjured hand) at twelve
weeks; return to work and/or leisure (days post-op); and failure or complication at any point in time.

Table 3.1 Original Strickland-Glogovac criteria

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Excellent (85-100% of motion)</th>
<th>Good (70-84% of motion)</th>
<th>Fair (50-69% of motion)</th>
<th>Poor (less than 50% of motion)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net active range of motion at the distal and proximal</td>
<td>&gt;149°</td>
<td>125-149°</td>
<td>90-124°</td>
<td>&lt;90°</td>
</tr>
<tr>
<td>interphalangeal joints</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Strickland & Glogovac (1980) (91)

3.3.5. Data Analysis

Data sets collected from each participant were entered on an Excel spreadsheet (Microsoft Office Excel 2007). Given the results for echogenicity and PDS were on visual scale dimensions it was deemed appropriate and informative to illustrate the results for each of the three sites graphically in colour-density gradient plots with colour-pixel opacity based on each participant’s score values (Adobe Illustrator CS5 version 15.1.0). Measurements of tendon excursion, tendon thickness and defect size for each participant were plotted graphically. Percentage-change analysis was carried out to compare key ultrasound variables at each of the three measurement sites. Tendon thickness measurements were calculated as mean values and compared to the group-mean uninjured contra-lateral tendon thickness at each measurement occasion. Case-by-case comparison was made between key ultrasound variables and clinical outcomes at twelve weeks after surgery.
4.0 RESULTS

4.1. The participants

Four male participants with surgical repair of the FDP tendon within zone II of the digital sheath on the palmar surface of the hand consented to participate in the study. Participant #4 presented clinically with re-rupture of the FDP tendon repair in the fifth post-operative week, confirmed by ultrasound-imaging at week twelve. Consequently, data collected from participant #4 is not included in this study.

The participants’ demographic details are summarised in Table 4.1. The age range of the participants was between 33 and 59 years. All participants identified as New Zealanders of European descent and were employed in moderate to heavy manual work.

Table 4.1 Age, occupation, smoking status, digit lacerated and dominance of the involved hand for each study participant.

<table>
<thead>
<tr>
<th>Participant number</th>
<th>Age</th>
<th>Occupation</th>
<th>Smoker</th>
<th>Injured Finger</th>
<th>Injured Hand</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>33y</td>
<td>Welder</td>
<td>Yes</td>
<td>Little</td>
<td>Dominant</td>
</tr>
<tr>
<td>2</td>
<td>38y</td>
<td>Butcher</td>
<td>No</td>
<td>Index</td>
<td>Non-dominant</td>
</tr>
<tr>
<td>3</td>
<td>59y</td>
<td>Engineer</td>
<td>No</td>
<td>Ring</td>
<td>Non-dominant</td>
</tr>
</tbody>
</table>

4.1.1. The injuries

The injuries sustained by the participants to their FDP tendons were all confined to a single digit, though in a different digit in each case. Of the three injuries, two were located distal to the PIP joint and one at the level of the PIP joint (Figure 4.1).
The details of the FDP tendon suture repair technique and suture material as well as concomitant neurovascular involvement gained from the orthopaedic surgeons’ operation notes are outlined in Table 4.2.

Table 4.2 Concomitant neurovascular involvement and details of the flexor digitorum profundus tendon surgical repair for each study participant.

<table>
<thead>
<tr>
<th>Participant number</th>
<th>Concurrent flexor digitorum superficialis laceration</th>
<th>Digital nerve laceration</th>
<th>Digital artery laceration</th>
<th>Suture technique</th>
<th>Suture material</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No</td>
<td>Ulna</td>
<td>No</td>
<td>Not available</td>
<td>Not available</td>
</tr>
<tr>
<td>2</td>
<td>Ulna slip</td>
<td>Ulna</td>
<td>Ulna</td>
<td>6 core over sewn</td>
<td>4-0 supramid nylon</td>
</tr>
<tr>
<td>3</td>
<td>Radial and ulna slips</td>
<td>Radial</td>
<td>Radial</td>
<td>Kessler over sewn</td>
<td>2-0 and prolene</td>
</tr>
</tbody>
</table>

Further information regarding the status of the fibro-osseous sheath and surrounding soft tissues was available from the operation notes of participants #2 and #3. In participant #2, “the sheath was divided at two locations – proximal to the A2 pulley in the digit and proximal to the A1 pulley in the palm; the sheath was not repaired”. In participant #3, “the A2 pulley was intact”. The operation notes for participants #2 and #3 reported, “skin closure with 4-0 nylon”.

Figure 4.1 Location of the flexor digitorum profundus tendon (FDP) mid-repair site for each study participant (P1 – participant #1, P2 – participant #2, P3 – participant #3, FDS – flexor digitorum superficialis). (Image modified from Yu & Chase 2004) (32).
4.2. Descriptive results of ultrasound variables

Selected results for each of the three study participants is presented in numeric form or graphically to illustrate trends. Complete sets of raw data are presented in Appendix 5.

4.2.1. Echogenicity (0-4)

An incremental pattern of increasing echogenicity (becoming less hypo-echoic over time) was detected at the mid-tendon repair site (b.) (Figure 4.3).

The temporal change in individual participant’s regional echogenicity score, along with the AP and ML dimensions of tendon thickness, are depicted in colour-density plots (Figure 4.2, Figure 4.3 and Figure 4.4). The dynamic change in tendon echogenicity scores seen at site b. is in contrast to the relatively static pattern perceived in the distal tendon site (c.) (Figure 4.4) and the inconsistent pattern detected in the 1 cm proximal region (a.) (Figure 4.2).

![Colour density plots of individual participant’s tendon echogenicity scores and anterior-posterior and medial-lateral spatial dimensions at site a. (1 cm proximal). (P1 – participant #1; P2 – participant #2; P3 – participant #3).](image)

Figure 4.2 Colour density plots of individual participant’s tendon echogenicity scores and anterior-posterior and medial-lateral spatial dimensions at site a. (1 cm proximal). (P1 – participant #1; P2 – participant #2; P3 – participant #3).
Figure 4.3 Colour density plots of individual participant’s tendon echogenicity scores and anterior-posterior and medial-lateral spatial dimensions at site b. (mid-repair site). (P1 – participant #1; P2 – participant #2; P3 – participant #3).

Figure 4.4 Colour density plots of individual participant’s tendon echogenicity scores and anterior-posterior and medial-lateral spatial dimensions at site c. (1 cm distal). (P1 – participant #1; P2 – participant #2; P3 – participant #3).

Figure 4.5 illustrates the increasing echogenicity of the initially hypoechoic profundus tendon at site b. in participant #1.
Figure 4.5 Ultrasound images in the transverse view illustrating change in echogenicity at the mid-repair site in participant #1 at a. two weeks, b. six weeks and c. eighteen weeks after surgery. The flexor digitorum profundus tendon is located in the centre of each image (long arrow) with the two slips of the flexor digitorum superficialis tendon located below (short arrows).

4.2.2. Excursion (mm)
Measurement of tendon excursion on both active and passive digital movement indicated an upward trend in excursion amplitude between six and eighteen weeks after surgery (Figure 4.6).

Passive tendon excursion amplitudes increased from between 1.4 mm and 2.2 mm at two weeks to between 0.8 mm and 3.6 mm by eighteen weeks post-surgery. Values were similar for active excursion which increased from between 0.8 mm and 1.9 mm at six weeks post-surgery to between 1.3 mm and 3.2 mm at week eighteen.

Figure 4.6 Ultrasound measurement of flexor digitorum profundus tendon excursion (mm) induced by controlled distal interphalangeal (DIP) joint motion of A, isolated passive DIP joint flexion/active extension of 30 degrees and B, isolated active DIP joint flexion/active extension of 30 degrees. (P1 – participant #1; P2 – participant #2; P3 – participant #3).
4.2.3. **Power Doppler score (0-3)**

A remarkably consistent increase in power Doppler score (PDS) of the FDP tendons was evident at location b. over the rehabilitative period from zero registration of the PDS at week two to 2 or 1 in all three participants by week eighteen (Figure 4.8). Power Doppler detected no blood flow in region a. until week eighteen post-operation (Figure 4.7), while in region c. PDS increased slightly from zero registration at week two to 1 in two participants at week eighteen (Figure 4.9).

The temporal changes in individual participant’s regional PDS along with changes in the spatial dimensions of AP and ML tendon diameter are depicted by colour-density plots (Figure 4.7, Figure 4.8 and Figure 4.9).

![Figure 4.7 Colour density plots of individual participant’s power Doppler scores and anterior-posterior and medial-lateral spatial dimensions at site a. (1 cm proximal). (P1 – participant #1; P2 – participant #2; P3 – participant #3).](image-url)
Figure 4.8 Colour density plots of individual participant’s power Doppler scores and anterior-posterior and medial-lateral spatial dimensions at site b. (mid-repair site). (P1 – participant #1; P2 – participant #2; P3 – participant #3).

Figure 4.9 Colour density plots of individual participant’s power Doppler scores and anterior-posterior and medial-lateral spatial dimensions at site c. (1 cm distal). (P1 – participant #1; P2 – participant #2; P3 – participant #3).

The sheath and surrounding soft tissues demonstrated fluctuating PDS at each of the three sites a., b. and c. (Appendix 5).

Power Doppler assessment detected no blood-flow in the uninjured contra-lateral tendons.
4.2.4. Thickness (mm)
Flexor digitorum profundus tendon thickness at the mid-repair site (b.) (Figure 4.11) trended downward slightly over the sixteen-week period of observation from between 2.7mm and 4.8 mm to between 2.2mm and 3.8 mm in the anterior-posterior (AP) dimension and from between 3.7mm and 8.3 mm to between 4.3mm and 6.2 mm in the medial-lateral (ML) dimension (Figure 4.11). Tendon thickness measurements for each individual participant at the 1 cm proximal site (a.) (Figure 4.10), mid-repair site (b.) (Figure 4.11) and 1 cm distal site (c.) (Figure 4.12) are presented in the graphs below.

Figure 4.10 Tendon thickness measurements (mm) at site a. (1 cm proximal). A, anterior-posterior dimensions. B, medial-lateral dimensions. (P1 – participant #1; P2 – participant #2; P3 – participant #3)

Figure 4.11 Tendon thickness measurements (mm) at site b. (mid-repair site). A, anterior-posterior dimensions. B, medial-lateral dimensions. (P1 – participant #1; P2 – participant #2; P3 – participant #3)
4.2.5. Defect size (mm) and margination (1-4)

A downward trend in defect size was observed over the sixteen-week period of investigation from between 6.5 mm and 8 mm to between 2.1 mm and 8.2 mm (Figure 4.13). Margination demonstrated a less clear pattern of change compared to the other ultrasound variables (Appendix 5).

Figure 4.12 Tendon thickness measurements (mm) at site c. (1 cm distal). A, anterior-posterior dimensions. B, medial-lateral dimensions. (P1 – participant #1; P2 – participant #2; P3 – participant #3).

Figure 4.13 Defect size (mm) for each participant at two to eighteen weeks post-surgery. (P1 – participant #1; P2 – participant #2; P3 – participant #3).
4.3. Clinical outcomes

Clinical outcomes of joint range of motion, grip strength and self-reported disability were measured and recorded by each participant’s hand therapist. One therapist treated participants #1 and #3 while a second therapist treated participant #2. Clinical data were drawn from the participants’ clinical notes for the purposes of this study. A complete set of data for all clinical outcome measures for all participants was available for the twelve-weeks post-operative stage and this is reported in Table 4.3. The remaining full set of incomplete data is given in Appendix 5.

Table 4.3 Clinical outcomes for each study participant at twelve weeks post surgery.

<table>
<thead>
<tr>
<th>Participant number</th>
<th>Total composite proximal and distal interphalangeal joint range of motion flexion-extension (degrees)</th>
<th>Strickland/Glogovac classification of active joint range of motion</th>
<th>Grip strength as percentage of contra-lateral uninjured hand (%)</th>
<th>Quick-DASH functional outcome score where 0 = no disability and 100 = maximum disability</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Passive: 160, Active: 155</td>
<td>Excellent</td>
<td>75</td>
<td>2.27</td>
</tr>
<tr>
<td>2</td>
<td>Passive: 165, Active: 85</td>
<td>Poor</td>
<td>29</td>
<td>70.45</td>
</tr>
<tr>
<td>3</td>
<td>Passive: Not available, Active: 125</td>
<td>Good</td>
<td>34</td>
<td>18.18</td>
</tr>
</tbody>
</table>

Passive joint range of motion was available at week six but not week twelve for participant #3. TPROM for participant #3 at week six was 145 degrees.

Information pertaining to the participant’s work status was not systematically recorded by the treating therapists, although it was noted that all participants had made at least a partial return to their normal employment by twelve weeks post-operatively.

4.4. Analysis of ultrasound variables over time

Results were analysed by percentage-change in ultrasound variables as a way of drawing comparisons between the key ultrasound variables of echogenicity, AP tendon thickness and PDS at each of the three sites, 1 cm proximal (a.) (Figure 4.14), mid-repair (b.) (Figure 4.15) and 1 cm distal (c.) (Figure 4.16).

Dynamic change in the ultrasound variables of echogenicity and PDS was most remarkable at site b. over the eighteen-week period of investigation (Figure 4.15). The AP tendon
diameter underwent change at the mid-repair site over the first four weeks after surgery but less so during the subsequent period of observation (Figure 4.15). A notable change in PDS was observed at regions a. and c. at eighteen weeks post-operative (Figure 4.14 and Figure 4.16). Change in echogenicity occurred to a lesser extent at region a. and not at all in region c. (Figure 4.14 and Figure 4.16).

**Figure 4.14** Graph of individual participants' percentage-change in echogenicity, AP thickness and power Doppler score between weeks two and eighteen post-surgery at site a. (1 cm proximal). (P1 – participant #1; P2 – participant #2; P3 – participant #3).
Figure 4.15 Graph of individual participants’ percentage-change in echogenicity, AP thickness and power Doppler score between weeks two and eighteen post-surgery at site b. (mid-repair site). (P1 – participant #1; P2 – participant #2; P3 – participant #3).

Figure 4.16 Graph of individual participants’ percentage-change in echogenicity, AP thickness and power Doppler score between weeks two and eighteen post-surgery at site c. (1 cm distal). (P1 – participant #1; P2 – participant #2; P3 – participant #3).
4.5. Analysis of tendon thickness between injured and non-injured hands

Comparison was made between mean thickness at site b. of the injured FDP tendon and that of the corresponding location on the contra-lateral uninjured tendon.

The surgically repaired FDP tendon was found to be larger in both AP and ML tendon diameter compared to the uninjured contra-lateral digit throughout the rehabilitative period. The AP diameter of the surgically repaired tendon was 122-194 percent and ML diameter 117-157 percent that of the uninjured contra-lateral tendon during the sixteen-week investigation (Table 4.4).

<table>
<thead>
<tr>
<th>Dimension and plane of measurement</th>
<th>Mean tendon diameter (mm) (n=3) and % contra-lateral</th>
<th>Contra-lateral (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior-posterior tendon thickness at the mid repair site (transverse plane)</td>
<td>Week 2</td>
<td>Week 4</td>
</tr>
<tr>
<td></td>
<td>3.5</td>
<td>2.2</td>
</tr>
<tr>
<td></td>
<td>(194%)</td>
<td>(122%)</td>
</tr>
<tr>
<td>Medial-lateral tendon thickness at the mid repair site (transverse plane)</td>
<td>6.2</td>
<td>6.6</td>
</tr>
<tr>
<td></td>
<td>(148%)</td>
<td>(157%)</td>
</tr>
</tbody>
</table>

Contra-lateral dimensions are the mean for each of the three participants over the five data collection points.

4.6. Case-by-case comparisons of ultrasound variables and functional outcomes

4.6.1. Summary of week twelve
A summary of key ultrasound variables and functional outcome at twelve weeks after surgery is given in Table 4.5. Lower echogenicity scores and smaller AP thickness were documented in the participants demonstrating good or excellent functional outcomes (participants #3 and #1, respectively). Power Doppler score was the same for all three participants (Table 4.5).
Table 4.5 Twelve-week functional outcomes and key ultrasound variables of echogenicity, anterior-posterior (AP) thickness and tendon power Doppler score at site b. (mid-repair).

<table>
<thead>
<tr>
<th>Participant</th>
<th>TAROM (degrees)</th>
<th>Functional outcome (Strickland criteria)</th>
<th>Echogenicity score</th>
<th>AP thickness (proportion of contra-lateral)</th>
<th>Power Doppler score</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1</td>
<td>155</td>
<td>Excellent</td>
<td>1</td>
<td>100%</td>
<td>1</td>
</tr>
<tr>
<td>#2</td>
<td>85</td>
<td>Poor</td>
<td>4</td>
<td>246%</td>
<td>1</td>
</tr>
<tr>
<td>#3</td>
<td>125</td>
<td>Good</td>
<td>1</td>
<td>140%</td>
<td>1</td>
</tr>
</tbody>
</table>

TAROM = total active range of motion

4.6.2. Tendon excursion and total active range of motion outcome
The ultrasound variable of tendon excursion induced by passive DIP joint flexion of 30 degrees was compared with the functional outcome of total active range of motion (TAROM) and is depicted graphically in Figure 4.17. Better TAROM was documented in the two participants (#1 and #3) demonstrating greater tendon excursion on passive DIP joint motion of 30 degrees at all five measurement occasions (Figure 4.17).

![Figure 4.17](image)

Figure 4.17 Comparison of change over time between A, tendon excursion induced by passive distal interphalangeal joint motion of 30 degrees and B, total active range of motion, for each participant. (P1 – participant #1; P2 – participant #2; P3 – participant #3).

4.6.3. Power Doppler score sheath and surrounding soft tissues
Early elevated PDS of the sheath and surrounding soft tissues at site b. was documented in the participant #2 who had a poor functional outcome (Appendix 5).
5.0 DISCUSSION

The applicability of ultrasound imaging properties in monitoring healing of the surgically repaired intra-synovial flexor tendon has not previously been investigated. The present study documented change in five sonographic properties of the surgically repaired flexor digitorum profundus (FDP) tendon within the digital sheath of three participants, supporting the feasibility of the role for ultrasound imaging in monitoring in-vivo healing of the human FDP tendon.

Further, this study provides new information regarding the specific rate of change in those ultrasound properties that are indicative of the structural status of the healing tendon, the amplitude of tendon excursion at the repair site, neo-vascularisation of the tendon repair site and spatial dimensions of the healing tendon.

Over the duration of the post-operative week two to eighteen period of investigation, the key findings were: 1) an increase in the ultrasound echogenicity scores and tendon excursion, 2) a corresponding increase in power Doppler scores (PDS) and reduction in defect size, and 3) a reduction in tendon thickness at the mid-tendon repair site. In general, better functional outcomes were found in the participants who demonstrated greater change in echogenicity and tendon gliding and less variation in tendon thickness. Therefore, we found that ultrasound is able to document change in ultrasound variables suggestive of progressive change in tendon healing and gliding properties.

5.1. Change in echogenicity score

As expected, the present study documented incremental changes in echogenicity at the mid-tendon site b. (Figure 4.3). This progressive change implies restoration of the architecture and composition of the healing tendon, namely an increase in the density and longitudinal alignment of collagen fibres and reduction in the amount of ground substance, characteristics that confers tensile strength and gliding properties to the tendon.

The incremental change in tendon structural status documented in the current study mirrors the findings of previous histology studies that report increasing collagen fibre
density and alignment in the first two to eighteen weeks following surgical repair (9, 63, 69, 73).

Although the incremental pattern of healing found in the present study is in keeping with previous studies of animal and human ultrasound observations of post-surgical tendon healing (128, 129, 133-139), the rate of change in the FDP tendon differs from that found in other tendons. Change in the intra-synovial FDP tendon is slower compared to the healing rabbit tendon (Table 2.3) yet faster than the surgically repaired human Achilles tendon (Table 2.2), although the echogenicity rating scales are not directly comparable. The faster rate of change in echogenicity levels in the FDP tendon compared to the Achilles tendon is rather surprising as the human intra-synovial flexor tendon is widely considered to heal slower when compared with other tendons (7). One possible explanation for the more rapid change is that the FDP tendon is subject to the tensile and directional loads of early controlled-movement exercises within the first three to five days post-operative, whereas the Achilles tendon is typically immobilised for a minimum of three weeks (137, 139). More work needs to be done to evaluate the different rates of healing in different tendons and under different conditions.

In this study, when the proximal, mid- and distal sites (a., b., and c.) were compared, the rates of change in echogenicity varied. The location found to undergo the most consistent change in the present study was the mid-tendon repair site (b.) (Figure 4.3). In comparison, the 1 cm distal site (c.) demonstrated near-normal echogenicity levels throughout the period of investigation, whereas the 1 cm proximal site (a.) demonstrated inconsistent change (Figure 4.2 and Figure 4.4). The apparent non-response of the distal tendon stump in the healing process may be explained by relatively little trauma incurred distal to the surgical lesion. The mid-repair and the more proximal regions may have undergone greater trauma, related to the retrieval of a retracted stump and/or the requirement to open the sheath for tendon retrieval or to allow gliding of a bulky repaired tendon repair.

Change in echogenicity also varied in relation to functional outcome. On a case-by-case basis, a greater reduction in mean echogenicity score at site b. over the first 12 weeks was documented in participants who demonstrated good or excellent functional outcomes (Table 4.5). This finding, although not examined statistically, suggests a positive relationship
between these two variables. However, while echogenicity and clinical parameters have been correlated in the surgically repaired human Achilles tendon (133, 134), this is not a consistent observation (136, 138, 139). Possibly, a greater reduction in echogenicity score as seen in the present study may signify activation of the more organised intrinsic mode of healing.

The incremental change in echogenicity levels documented in this study supports the use of the ultrasound variable of 'echogenicity' (as estimated on the five-point echogenicity scale) to register change in tendon structural properties during the healing process. As a research tool, echogenicity could help evaluate the effect of specific early-movement exercise parameters and dosage on the quality and rate of tendon healing, and help evaluate other biological and pharmacological treatments for tendon healing.

5.2. Excursion

Real-time ultrasound (RTUS) was useful in measuring excursion of the healing tendon, a key factor in the success of post-operative rehabilitation protocols and long-term clinical outcomes. Specific benefits of the method of ultrasound measurement of tendon excursion using suture material as a marker include the ease of measurement, the ability to undertake repeated measurements at regular intervals, and the non-invasive nature of the procedure.

Excursion amplitudes measured in our study sample were comparable to previous findings with some notable exceptions. The repair-site FDP tendon excursions induced by 30 degrees passive and 30 degrees active DIP joint flexion were found to be similar to those reported in previous radiographic studies using greater ranges of joint motion (11, 95, 115) and considerably larger than one investigation in which the researchers used the same amount of joint motion (96) (Table 2.1). However, the excursions documented in the present study are somewhat smaller than that reported by Silfverskiold (1994) (12), who used a greater active range of joint motion and subjected participants to early active exercises throughout the rehabilitation period, as compared to the early passive exercises carried out by the participants in the present study.

The overall greater values of tendon excursion per degree of joint range of motion documented in the present study suggest that radiographic studies may underestimate the
amount of tendon excursion occurring in-vivo at the repair site. Conversely, ultrasound measurement using the suture as a marker may overestimate the degree of tendon excursion. An alternative explanation is that the amount of excursion is more dependent on the type of exercises the tendon has been subjected to during the course of healing, rather than the method used to measure excursion. Interestingly the excursions documented in the present study are similar to that previously reported for the healthy uninjured tendon on a similar range of joint motion (34).

On a case-by-case basis, greater excursion measured on passive DIP joint motion in the early post-operative period was mirrored by good or excellent functional outcomes at the twelve weeks post-operative mark (Figure 4.17). This finding concurs with a number of previous studies that have shown a significant link between early tendon excursion and clinical outcomes (11, 12, 96). Together with the results of the current study, preliminary evidence is provided for ultrasound measurement of early tendon excursion as a prognostic indicator of functional outcome. Such a clinical tool could help evaluate tendon function in the early post-operative period.

The methodology of the present study could assist in clarifying the critical amount of tendon-repair-site excursion necessary to prevent functionally limiting tendon adhesions. The measurement of tendon excursion using suture material as a marker may also offer a criterion standard for evaluating the 'flexor lag test', used by clinicians to determine causes of poor active finger flexion during the rehabilitative period (77).

**5.3. Change in power Doppler score**

Based on histology and ultrasound studies, and knowledge of ultrasound mechanics, PDS is a sensitive measure of tissue vascularity (22, 160, 174, 175). The finding in this study of an increasing PDS at site b. provides preliminary evidence that neo-vascularisation of the tendon repair site does indeed take place. The observation of an increasing PDS at the mid-repair site is a new finding in a surgically repaired tendon. The early and increasing neo-vascularisation of the tendon repair site observed by the present study is supported by similar observations in histology studies of surgically repaired and subsequently mobilised intra-synovial canine tendons (52, 75). One study investigating healing of the non-
operatively managed Achilles tendon rupture (n=11) observed a mild increase in flow on colour Doppler sonography in some cases both at the acute and late repair stage (197).

The detection of Doppler signal depicting the presence of neo-vessels within the repaired FDP tendons in the present study suggests vascularisation of the repair site may have a significant role in FDP tendon healing in the first 18 weeks post-operative. However, it raises a second important question, namely, from where did these vessels arise? The finding of lower levels of power Doppler signal distally at site c. but no power Doppler signal until eighteen weeks proximally at site a. (Figure 4.9 and Figure 4.7) suggests neo-vascularisation at the mid-repair site may have been sourced from vessels originating distally, possibly supplied by vessels of the vinculum brevis or bony tendon insertion. In contrast, canine studies suggest new vessels in the healing tendon arise from more proximal vessels and extend through normally hypo- or avascular regions, including the volar regions of the tendon (52). The more pronounced vascularity detected at the mid-repair location in the present study concurs with the concentration of vessels within 2 mm of the repair site observed in surgically repaired canine tendons (75).

It is possible that in the present study, intra-tendinous vessels contributing to the repair site from proximal or distal were of a calibre smaller than that detectable by power Doppler. Alternatively neo-vessels may have entered the tendon from the surrounding soft tissues. This scenario is most likely in participant #2 where PDS in the surrounding soft tissues was observed to be higher in the early post-operative period (Appendix 5). The suture technique employed for participant #2 (six-strand technique) involves placement of suture material in the more vascular dorsal aspect of the tendon and may have had an impact on vascularity due to the constriction of the more dorsally located intra-tendinous vessels by suture material.

Loss of synovial diffusion may have been a factor in neo-vascularisation of the healing tendon. Disruption of the digital sheath was documented in the surgical notes of two of the study participants (#2 and #3) and it was assumed that surgical digital sheath disruption also took place in the third participant (#1). However, it is not clear whether the PDS findings of the present study suggest extrinsic or intrinsic modes of healing. Interestingly, the PDS documented at the distal site were generally accompanied by a concurrent increase in
echogenicity (becoming less hypo-echoic) (Figure 4.9, Figure 4.4 and Figure 4.16), possibly implying that the vessels identified in the distal region were part of a healthy, good quality 'intrinsic' healing process. The possibility that new vascularity within the tendon may indeed be a part of a progressive healing process challenges the currently dominant theory that neo-vascularisation represents a process of tendon degeneration or failed healing (160, 163, 176, 182).

In summary, PDS appears to be a feasible method for gaining temporal and location-specific information that can contribute to an understanding of the nutritional pathways to the healing tendon. This information can help to: determine the suture techniques that avoid compromise of new blood vessels; understand the impact of digital sheath repair (or pulley resection) on neo-vascularisation of the healing tendon; evaluate the suitability of various extra-synovial tendons for intra-synovial tendon grafting with respect to neo-vascularisation; examine the effect of specific early-movement exercise interventions and other pharmacological and non-pharmacological treatments on tendon neo-vascularisation.

5.4. Change in tendon thickness

Post-operative FDP tendon-thickness measurements found in the present study tended to increase between the second and fourth post-operative week and then trend downward (Figure 4.11, Figure 4.11 and Figure 4.12). Tendon thickness is indicative of structural properties of the healing tendon, although may it be related to more than one factor. The finding of a reduction in thickness but concomitant increase in echogenicity, particularly at the mid-repair site (b.) (Figure 4.8 and Figure 4.15) suggests a progressive tendon remodelling process both in terms of diameter change and internal structural formation.

Change in post-operative human digital flexor tendon thickness has not previously been reported; however, long-term follow-up of surgically repaired human Achilles tendon reveals an increase in tendon thickness at both the acute stage of repair (132) and for up to 10 years post-operatively (134, 136, 137, 139). The pattern of change documented in the present study is similar to that of Thermann (2002) (128), who reported peak thickness in ultrasound measurement of tendon thickness in the surgically repaired rabbit Achilles tendon at four weeks and values still significantly greater than the uninjured tendon at
twelve weeks. There is some indication that peak tendon thickness may represent a peak in cellular proliferation and repair activity in the tendon, based on studies in the surgically repaired rabbit tendon and human patella tendinopathy (129, 143).

In the present study, tendon thickness was found to be greater in the healing tendon compared to the contra-lateral uninjured tendon throughout the post-operative period (Table 4.4). The documented anterior-posterior (AP) and medial-lateral (ML) tendon dimensions suggest the mid-repair sites (b.) may have encountered significant resistance within the digital sheath. Tendon dimensions derived from ultrasound-imaging studies may help determine the need to increase intra-thecal space (for example, pulley resection) to allow greater ease of tendon gliding and reduce the work of flexion.

Tendon-thickness measurements varied in relation to functional outcome. On a case-by-case basis, the present study found a much greater variation in healing tendon thickness in the participant with a poor functional outcome compared with the participants with good and excellent functional outcomes (Figure 4.11, Table 4.5). Based on observations made in patella tendinopathy it has been suggested that variability in thickness may indicate interrupted or delayed healing. This might explain the observations made in the present study (143, 164).

5.5. Change in defect size and margination

Tendon defect size documented in the present study demonstrated an interesting pattern of change. However, the ultrasound property of margination was more variable and was deemed not to be a useful property to measure.

Tendon defect size demonstrated a downward trend (Figure 4.13), mirroring the change in echogenicity levels and supporting the impression of a progressive remodelling of the tendon-repair region. The defect sizes documented in the present study are somewhat greater than the 3 mm ‘gap’ reported to be conducive to functional tendon healing (50, 56, 57, 107). However, defect size does not necessarily denote a separation of the tendon ends. The relevance of defect size (as measured by ultrasound) to tendon gapping requires further investigation.
The ultrasound variable of margination requires further definition or discounting of its applicability in the context of the study aims.

5.6. Limitations and strengths of the study

The work carried out as part of this thesis represents the first attempt to measure longitudinal change in ultrasound properties of echogenicity, vascularity, tendon thickness and gliding properties *in-vivo* in the healing surgically-repaired intra-synovial human digital flexor tendon. Further, the temporal change documented in Doppler signal represents the first series of such observations within any surgically repaired tendon. Having demonstrated that quantification of ultrasound variables of echogenicity, vascularity, tendon thickness, excursion, and defect size is a feasible method of investigation in a clinical population, the next step in the research pathway would be to explore the reliability of the ultrasound variables.

Error is introduced into ultrasound-imaging by varying skill levels of the operator, the influence of the imaging protocol, and subjectivity in image interpretation (142). In the present study, the same experienced radiologist performed all imaging, obviating inter-observer error. The radiologist had the advantage of quantifying image properties from on-screen images at the time of imaging. However a limitation of this study is that the reliability of the Radiologist with respect to repeatability of his estimation and measurement of the ultrasound variables could not be quantified.

The use of previously described four and five-point scales for vascularity, echogenicity and margination eliminated variability associated with the use of dichotomous outcomes for classifying properties that are not 'black and white'. The use of a standardised image acquisition and interpretation protocol minimised the impact of these known sources of variability.

Attempts were made to reduce the impact of bias on the results. Although the radiologist in this study was aware of the purpose of the study and had a working knowledge of the condition under investigation, he was blinded to each of the participant’s previous scan’s results. Furthermore the minimum of two weeks between each scan provided a washout
period, thereby reducing the risk of data-acquisition bias. The radiologist was also blinded to the participants’ clinical outcomes.

While the number of participants for the purposes of data collection and analysis of this study was limited to three, the demographic and injury details of the participants were relatively similar (Table 4.1 and Table 4.2), thereby reducing the impact of confounding issues such as age-related variation in tendon-healing responses. Ultrasound is non-invasive and allows for repeated measurements over time. The longitudinal design of the present study compensates in part for the small number of participants, allowing individuals to be their own control subjects by imaging the corresponding healthy contra-lateral digit to that of the surgically repaired one.

Other benefits of ultrasonographic investigation of tendon healing in the digital flexor tendons include higher image resolution compared with other tendons because of their superficial location, mandating the use of higher frequency ultrasound probes. Recruitment of participants with such a clear diagnosis originating from a defined event has advantages over much of the ultrasound literature of tendon healing (which largely addresses tendinopathy, a condition that faces uncertainty in terms of precise diagnosis of participants) (142).

**5.7. Future directions**

Future research is required to address the measurement properties of real-time and power Doppler ultrasonography, including reliability and sensitivity to change. Results from the current study may be useful as a basis for power calculations to establish participant numbers and study design for future studies. A larger cohort of tendon-repaired participants is needed to confirm the patterns of change detected in the present study and may clarify the significance of PDS findings. Further ultrasound and histology studies in animal models may serve to strengthen the validity of the observations made in this present study.
Documentation of longer term change in ultrasound properties of the healing tendon would help categorise complicated versus uncomplicated tendon healing, and clarify the relationship between each of the ultrasound variables and the clinical outcome. Development of a composite scale of tendon healing would improve sensitivity and specificity when quantifying change in the healing tendon (142). A composite scale would help to provide an ultrasound model of acute tendon healing, which could in turn help us better understand cumulative trauma disorders such as tendinopathy. If the ultrasound variables used in the current study prove reliable then ultrasound imaging can be applied in rehabilitation research into the effects of specific early movement exercise parameters and dosage on tendon healing, optimal surgical techniques, and other treatments not yet in clinical practice.
5.8. Conclusions
To date, experience in evaluating changes in the surgically repaired FDP tendon with ultrasonography is limited. Previous studies have used a multiplicity of operational definitions. While using ultrasound as a tool to monitor flexor tendon healing has been suggested, very little research has been done on longitudinal change in specific ultrasound properties of the surgically repaired intra-synovial FDP tendon. The present study used a standardised protocol to prospectively document change in ultrasound characteristics of the healing flexor tendon over the first two to eighteen weeks following surgical repair. Based on the serial observations of three participants, the following points are offered as concluding remarks:

- Temporal and location-specific changes in echogenicity can provide information about the relative rate and location of change in tendon structural properties. The rate of change in the human FDP tendon was faster than expected. While tendon structural properties in the distal tendon stump appear to be relatively unaffected by the injury and surgical procedure, new blood vessels were detectable in this region and it is therefore postulated that neo-vascularisation is a part of the healing process in the surgically repaired human FDP tendon; however, the significance of this is not clear.

- Anterior-posterior thickness of the healing surgically repaired FDP tendon appears to increase early on and then gradually decrease. Peak thickness and variation in thickness are variables that warrant future investigation. Ultrasound measurement of excursion of the healing tendon using suture material as a marker is a feasible non-invasive method that allows repeated in-vivo measures of this important variable. The amplitude of tendon-repair site excursion as documented on RTUS was relatively greater than that recorded by other radiological methods but values for passive and active tendon excursion were similar to each other, possibly relating to the early passive-movement exercises carried out by the present study population. The methodology used in the present study may offer further information about the critical amount of repair-site excursion and the early-movement exercises most
suitable to achieve this. Overall, a greater reduction in echogenicity levels, less variation in tendon thickness and greater tendon excursion appear to bear some relation to better clinical outcomes.

Ultrasound imaging presents a new non-invasive tool for investigating the surgically repaired flexor tendon in the hand. Quantification of ultrasound properties during the healing of surgically repaired digital flexor tendon lesions in-vivo has potential for significant medical and economic impact in rehabilitation and orthopaedic medicine. As a first step, this study demonstrated that real-time and power Doppler ultrasonography were able to document dynamic change in structural properties, vascularity and gliding properties of the healing intra-synovial FDP tendon during the first four months post-surgical repair, with the mid-repair site being the focal region of dynamic change.
REFERENCES


88


85. Donnelly E, Ascenzi MG, Farnum C. Primary cilia are highly oriented with respect to collagen direction and long axis of extensor tendon. J Orthop Res. 2010;28:77-82.


APPENDIX 1: ETHICAL APPROVAL

1/02/2010
Dr Grant Meikle
Radiology, DPH

Dear Grant

REF: A study of flexor tendon healing in the hand

I am writing on behalf of the combined Otago District Health Board and Dunedin School of Medicine, Research Advisory Group (RAG) to confirm that the project mentioned above has been granted approval to proceed.

According to my records:
- This project is due to commence: 1/02/2010
- It is due to be completed by: 31/08/2011

If you have any questions with regards to this project please contact me quoting the project ID shown above.

Yours sincerely

Ruth Sharpe
CLINICAL RESEARCH ADVISOR

cc Sonya Dillon, ODHB
Miranda Buhler, SCHOOL OF PHYSIOTHERAPY
# Locality Assessment by Locality Organisation – Otago DHB

Refer to pages 13–15 of Guidelines for Completion of the National Application Form for Ethical Approval of a Research Project (NAFG-2009-v1).

## Locality organisation sign off

Ethics committees review whether investigators have ensured their studies would meet established ethical standards if conducted at appropriate localities. Each locality organisation is asked to use the locality assessment form to check that the investigator has also made the appropriate local study arrangements.

Ethics approval for study conduct at each site is conditional on favourable locality assessment at that locality.

Please note that the locality organisation may have additional requirements to be met before a study may commence at that locality.

## Part One: General

To be completed by the principal investigator for this locality.

<table>
<thead>
<tr>
<th>Full project title:</th>
<th>Healing characteristics of the flexor tendons of the hand - a pilot study using real-time ultrasound and Doppler scanning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short project title:</td>
<td>A study of flexor tendon healing in the hand</td>
</tr>
<tr>
<td>Locality to be assessed:</td>
<td>Dunedin Hospital</td>
</tr>
<tr>
<td>Brief outline of study:</td>
<td>This pilot study aims to evaluate whether real-time and Doppler ultrasound imaging have clinical application in detecting changes during the rehabilitative stage of healing flexor tendons after surgical repair. Eight participants admitted to Dunedin Hospital for flexor tendon repair will be recruited. Repeated ultrasound imaging will be undertaken fortnightly until 6 weeks post-operatively, at 12 weeks and at 18 weeks.</td>
</tr>
<tr>
<td>Principal investigator (for this locality):</td>
<td>Dr Grant Meikle, Consultant Radiologist</td>
</tr>
<tr>
<td>Contact details:</td>
<td>Radiology Department, Dunedin Hospital Ext 8588</td>
</tr>
<tr>
<td>Other local investigators (list all at this site):</td>
<td>Miranda Buhler, Senior Physiotherapist/Hand therapist</td>
</tr>
<tr>
<td>Contact details:</td>
<td>Physiotherapy Outpatient Department, Dunedin Hospital Ext 8808</td>
</tr>
</tbody>
</table>
Part Two: Locality Issues

To be completed by the principal investigator for this locality and signed by the authorised locality representative. (See the Guidelines (NAFG-2009-v1) (pages 13–15) for more information and examples.) Identify any local issues and specify how these issues will be addressed.

1. Suitability of local researcher
   For example, are all roles for the investigator(s) at the local site appropriate (for example, has any conflict the investigator might have between her or his local roles in research and in patient care been adequately resolved)?
   x Yes    No

2. Suitability of the local research environment
   a) Are all the resources (other than funding that is conditional on ethical approval) and/or facilities that the study requires appropriate and available (for example, is staffing adequate? Is this site accessible for mobility-impaired people where necessary)?
   x Yes    No
   b) Have all potentially affected managers of resources such as patient records or laboratory managers been notified?
   x Yes    No

3. Have issues such as cultural issues specific to this locality or to people being recruited at this locality been addressed?
   x Yes    No

4. Have the local investigator contact details and other important contact details been provided to the locality organisation for checking?
   x Yes    No

Part Three: Declaration by locality organisation

I am authorised to complete locality approval on behalf of this locality organisation. I understand that I may withdraw locality approval if any significant local concerns arise. I agree to advise the principal investigator and then the relevant ethics committee should this occur.

(Questions 1–4 at Part Two above must be completed prior to signing.)

I confirm the organisation has sufficient indemnity insurance to compensate participants for harm that does not qualify for compensation under the Injury Prevention, Rehabilitation and Compensation Act 2001.

Signature: [Signature]          Date: [Date]
Name: Vivian Blake            Position: Chief Operating Officer
Contact details: Private Bag 1921, DUNEDIN

ODHB 53621 V1 Issued 03/12/2009
Locality Assessment by Locality Organisation

Refer to pages 13–15 of Guidelines for Completion of the National Application Form for Ethical Approval of a Research Project (NAFG-2009-v1).

Locality organisation sign off

Ethics committees review whether investigators have ensured their studies would meet established ethical standards if conducted at appropriate localities. Each locality organisation is asked to use the locality assessment form to check that the investigator has also made the appropriate local study arrangements.

Ethics approval for study conduct at each site is conditional on favourable locality assessment at that locality.

Please note that the locality organisation may have additional requirements to be met before a study may commence at that locality.

Part One: General

To be completed by the principal investigator for this locality.

<table>
<thead>
<tr>
<th>Full project title:</th>
<th>Healing characteristics of the flexor tendons of the hand - a pilot study using real-time ultrasound and Doppler scanning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short project title:</td>
<td>A study of flexor tendon healing in the hand</td>
</tr>
<tr>
<td>Locality to be assessed:</td>
<td>School of Physiotherapy, University of Otago</td>
</tr>
<tr>
<td>Brief outline of study:</td>
<td>This pilot study aims to evaluate whether real-time and Doppler ultrasound imaging have clinical application in detecting changes during the rehabilitative stage of healing flexor tendons after surgical repair. Eight participants admitted to Dunedin Hospital for flexor tendon repair will be recruited. Repeated ultrasound imaging will be undertaken fortnightly until 6 weeks post operatively, at 12 weeks and at 18 weeks.</td>
</tr>
<tr>
<td>Principal investigator (for this locality):</td>
<td>Dr Gillian Johnson, Senior Lecturer</td>
</tr>
<tr>
<td>Contact details:</td>
<td>School of Physiotherapy, University of Otago, 122 Great King Street, Dunedin 9054 Tel 03 479 5425</td>
</tr>
<tr>
<td>Other local investigators (list all at this site):</td>
<td>Miranda Bühl, Masters Candidate Grant Mekle, Radiologist, DPH</td>
</tr>
<tr>
<td>Contact details:</td>
<td>03 474 5424</td>
</tr>
</tbody>
</table>
Part Two: Locality Issues

To be completed by the principal investigator for this locality and signed by the authorised locality representative. (See the Guidelines (NAFG-2009-v1) (pages 15-15) for more information and examples.) Identify any local issues and specify how these issues will be addressed.

1. Suitability of local researcher
   For example, are all roles for the investigator(s) at the local site appropriate for her/his local roles in research and in patient care been adequately resolved?
   - Yes

2. Suitability of the local research environment
   a) Are all resources (other than funding that is conditional on ethical approval) and/or facilities that the study requires adequately available (for example, is staff in place? Is this site accessible for mobility-impaired people where necessary)?
   - Yes
   b) Have all potentially affected managers of resources such as patient records or laboratory managers been notified?
   - Yes

3. Have issues such as cultural issues specific to this locality or to people being recruited at this locality been addressed?
   - Yes

4. Have the local investigator contact details and other important contact details been provided to the locality organisation for checking?
   - Yes

Part Three: Declaration by locality organisation

I am authorised to complete locality approval on behalf of the locality organisation. I understand that I may withdraw locality approval if any significant concerns arise. I agree to advise the principal investigator and then the relevant ethics committee should this occur.

(Questions 1-4 at Part Two above must be completed prior to signing.)

I confirm the organisation has sufficient indemnity insurance to compensate participants for harm that does not qualify for compensation under the Injury Prevention, Rehabilitation and Compensation Act 2001.

Signature: [Signature]
Date: 18/01/10

Name: Dr Gillian Johnson
Position: Senior Lecturer, School of Physiotherapy, University of Otago

Contact details: 03 479 5424 Fax 03 4795414 Email gill.johnson@otago.ac.nz
Title: Healing characteristics of the flexor tendons of the hand - a preliminary study using real-time and colour Doppler ultrasound.

The Ngāi Tahu Research Consultation Committee (The Committee) met on Tuesday, 17 November 2009 to discuss your research proposition.

By way of introduction, this response from the Committee is provided as part of the Memorandum of Understanding between Te Rūnanga o Ngāi Tahu and the University. In the statement of principles of the memorandum, it states "Ngāi Tahu acknowledges that the consultation process outlined in this policy provides no power of veto by Ngāi Tahu to research undertaken at the University of Otago". As such, this response is not "approval" or "mandate" for the research, rather it is a mandated response from a Ngāi Tahu appointed committee. This process is part of a number of requirements for researchers to undertake and does not cover other issues relating to ethics, including methodology; they are separate requirements with other committees, for example the Human Ethics Committee, etc.

The Committee considers the research to be of importance to Māori health.

The Committee notes the researchers have identified that, “a percentage of participants are likely to identify as Māori”, and so as this study involves human participants, the Committee strongly encourages that ethnicity data be collected as part of the research project. That is the questions on self-identified ethnicity and descent, these questions are contained in the 2006 census.

The Committee commends the researchers on their intention that “ODHB Tikaka Best Practice guidelines will be observed”.

The Committee suggests dissemination of the research findings to relevant Māori health organisations regarding this study, including Taeora Tinana, Māori Physiotherapists within the New Zealand Society of Physiotherapists.

We wish you every success in your research and the Committee also requests a copy of the research findings.

The recommendations and suggestions above are provided on your proposal submitted through the consultation website process. These recommendations and suggestions do not necessarily relate to ethical issues with the research, including methodology. Other committees may also provide feedback in these areas.

The Ngāi Tahu Research Consultation Committee has membership from:

Te Rūnanga o Ōtākou Incorporated
Kāti Huirapa Rūnaka ki Puketereaki
Te Rūnanga o Moeraki
Ngāi Tahu Research Consultation Committee
Te Komiti Rakahau ki Kāi Tahu

Nāhaku noa, nā

Mark Brunton
Kaïtakawaenga Rangahau Māori
Facilitator Research Māori
Research Division
Te Whare Wānanga o Otago
Ph: +64 3 479 8738
email: mark.brunton@otago.ac.nz
Web: www.otago.ac.nz

The Ngāi Tahu Research Consultation Committee has membership from:
Te Rūnanga o Ōtākou Incorporated
Kāti Huirapa Rūnaka ki Puketeraki
Te Rūnanga o Moeraki
22 January 2010

Dr Gillian Johnson  
School of Physiotherapy  
University of Otago  
PO Box 56  
Dunedin

Dear Gillian

Ethics ref: LRS/09/11/653  
Study title: Healing characteristics of the flexor tendons of the hand - a pilot study using real-time ultrasound and Doppler scanning

Investigators: Dr Gillian Johnson, Ms Miranda Buhler, Dr Grant Meikle

Localities: School of Physiotherapy, Dunedin Hospital

The above study has been given ethical approval by the Lower South Regional Ethics Committee. Please note the correct ethics reference number.

Approved Documents
Amended Information Sheet for Participants version 2 15 January 2010
Amended Consent Form version 2 15 January 2010
Amended Initial Screening Interview Template
Evidence of consultation with Ngāi Tahu research Consultation Committee
Locality Assessment from School of Physiotherapy
Locality Assessment from Dunedin Hospital

Certification
The Committee is satisfied that this study is not being conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is being carried out.

Accreditation
The Committee involved in the approval of this study is accredited by the Health Research Council and is constituted and operates in accordance with the Operational Standard for Ethics Committees, April 2006.

Progress Reports
The study is approved until 31 August 2011. The Committee will review the approved application annually and notify the Principal Investigator if it withdraws approval. It is the Principal Investigator’s responsibility to forward a progress report covering all sites prior to ethical review of the project by 31 January 2011. The report form is available on http://www.ethicscommittees.health.govt.nz. Please note that failure to provide a progress report may result in the withdrawal of ethical approval. A final report is also required at the conclusion of the study.

Requirements for SAE Reporting
The Principal Investigator will inform the Committee as soon as possible of the following:
- Any related study in another country that has stopped due to serious or unexpected adverse events
Lower South Regional Ethics Committee
Ministry of Health
229 Moray Place
PO Box 5949
Dunedin
Phone (03) 474 8562
Fax (03) 474 8090
Email: lowersouth_ethicscommittee@moh.govt.nz

- withdrawal from the market for any reason
- all serious adverse events occurring during the study in New Zealand which result in the
  investigator breaking the blinding code at the time of the SAE or which result in hospitalisation or
death.
- all serious adverse events occurring during the study worldwide which are considered related to
  the study medicine. Where there is a data safety monitoring board in place, serious adverse
  events occurring outside New Zealand may be reported quarterly.

All SAE reports must be signed by the Principal Investigator and include a comment on whether
he/she considers there are any ethical issues relating to this study continuing due to this adverse
event. It is assumed by signing the report, the Principal Investigator has undertaken to ensure that all
New Zealand investigators are made aware of the event.

Amendments
All amendments to the study must be advised to the Committee prior to their implementation, except in
the case where immediate implementation is required for reasons of safety. In such cases the
Committee must be notified as soon as possible of the change.

Please quote the above ethics committee reference number in all correspondence.

The Principal Investigator is responsible for advising any other study sites of approvals and all other
 correspondence with the Ethics Committee.

It should be noted that Ethics Committee approval does not imply any resource commitment or
 administrative facilitation by any healthcare provider within whose facility the research is to be carried
out. Where applicable, authority for this must be obtained separately from the appropriate manager
 within the organisation.

We wish you well with your study.

Yours sincerely

Anna Paris
Lower South Regional Ethics Committee Administrator
dd (03) 474 8562
fax (03) 474 8090
Email: anna_paris@moh.govt.nz
13 September 2011

Dr Gillian Johnson
University of Otago - School of Physiotherapy
School of Physiotherapy
University of Otago
PO Box 56
Dunedin

Dear Dr Johnson -

Ethics ref: LRS/09/11/053 (please quote in all correspondence)
Study title: Healing characteristics of the flexor tendons of the hand - a pilot study using real-time ultrasound and Doppler scanning

Thank you for your email dated the 1st September 2011 enclosing the final progress report relating to the above named study. This documentation has been reviewed and approved by the Chairperson of the Lower South Regional Ethics Committee under delegated authority.

Approved Documents

- Final Progress report – signed and dated 1 September 2011 by Dr Gill Johnson

As this is the final report, the file has now been archived.

Please do not hesitate to contact me should you have any queries.
APPENDIX 2: PARTICIPANT INFORMATION AND CONSENT FORMS

A study of tendon healing in the hand

INFORMATION SHEET FOR PARTICIPANTS

Thank you for showing an interest in this project. Please read this information sheet carefully before deciding whether or not you want to participate. If you decide to participate we thank you. If you decide you do not take part there will be no disadvantage to you of any kind and we thank you for considering our request.

Aim of the Project

The aim of the project is to investigate the use of ultrasound imaging in detecting changes of the healing tendons in the hand following their surgical repair. The study is being conducted as part of the thesis requirements for a Masters of Physiotherapy degree.

What type of Participants are being sought?

Individuals aged between 18 and 60 years who have very recently undergone surgery for repair of their injured flexor tendon in their hand.

You will not be able to participate in the study if you have one or more of the following conditions:

- Rheumatoid arthritis
- Diabetes mellitus
- Immune deficiency condition
- Individuals who have previously injured either hand

What Participants will be asked to do?

Should you agree to take part in this project, you will then be required to attend an interview held at the Physiotherapy Outpatient Department in which you will be asked for information about your hand injury, your normal activities, your general health and any previous injuries. The interview will last approximately 20 minutes.

The investigators will access your medical and physiotherapy records for information regarding your tendon surgery and outcomes, with your permission.

Ultrasound imaging of the healing tendons of the hand
Version 3 14 April 2010
Once the wound on the surface of your hand is sufficiently healed (your Hand Therapist, Doctor or Nurse will inform us when this has happened) you will be required to attend four to six real-time and Doppler ultrasound imaging sessions to be held in the Radiology Department at Dunedin Hospital.

Each session will take approximately 30 minutes and will involve scanning the tendon wound site with ultrasound. Your hand and fingers will be positioned in order to best visualise the state of the repaired tendon. A radiologist will undertake the ultrasound imaging along with the assistance of one of the investigators who is a registered Hand Therapist. The tendons of your non-injured hand will also be scanned to serve as a comparison.

It may be possible to book your session at a time that fits in with your normal hospital appointments. However in some cases you may need to make extra trips in to the hospital.

**Benefits of the study**

A $10 petrol voucher will be issued to you on your attendance at each of the scanning sessions. You may also be interested in seeing the tendon at the different stages of your rehabilitation, with feedback from the Radiologist and Hand Therapist.

The information gained from the study is hoped to lead to more effective rehabilitation programmes for individuals who have suffered traumatic hand injuries.

**Risks of the study**

The study involves ultrasound imaging of the tendons of your hand. Ultrasound imaging (also called ultrasound scanning or sonography) involves exposing part of the body to high-frequency sound waves to produce pictures of the inside of the body.

Ultrasound imaging is non-invasive and does not use ionising radiation (as used in X-rays). Your hand will remain in a protected position according to the normal treatment protocol for tendon repair. Participation in this study will be discontinued should any harmful effects appear or if your doctor feels it is not in your best interests to continue.

**Can Participants Change their Mind and Withdraw from the Project?**

You may withdraw from participation in the project at any time and without any disadvantage to yourself of any kind.

**What Data or Information will be Collected and What Use will be Made of it?**

Data regarding the tendon healing process such as the thickness of the tendon and the gap between the injured and healing tendon will be gathered from the ultrasound images. Information regarding your age and sex, the location of your tendon injury and the type of surgical repair will be gathered to fully describe the participants involved in the study.

Only the research investigators will have access to this information. The results of the project may be published but every attempt will be made to preserve your anonymity. You are most welcome to request a copy of the results of the project should you wish.
The data collected will be securely stored in such a way that only those mentioned above will be able to gain access to it. At the end of the project any personal information will be destroyed immediately except that, as required by the University’s research policy, any raw data on which the results of the project depend will be retained in secure storage for ten years, after which it will be destroyed.

If I need an interpreter, can one be provided?
An interpreter can be provided if you need one. Please indicate this on the consent form. You may have a friend, family or whānau support to help you understand the risks and/or benefits of this study and any other explanation you may require.

If you have any queries or concerns regarding your rights as a participant in this study, you may wish to contact a Health and Disability Services Consumer Advocate, telephone: (03) 479 0265 or free phone: 0800 37 77 66 or free fax: 0800 2787 7678 (0800 2 SUPPORT) or email: advocate@hdc.org.nz.

If there is a specific Māori issue/concern please contact Linda Grennell at 0800 377 766.

Compensation
In the unlikely event of a physical injury as a result of your participation in this study, you will be covered by the accident compensation legislation with its limitations. If you have any questions about ACC please feel free to ask the researcher for more information before you agree to take part in this trial.

Where can I get more information about the study?

Miranda Bühler (Co-investigator)
Physiotherapist/Hand therapist &
Masters candidate
Physiotherapy Outpatient Department
Dunedin Hospital
Tel (wk) 03 474 7945 (mob) 027 299 3979
Email buhmi484@student.otago.ac.nz

Dr Gill Johnson (Principle Investigator)
Senior Lecturer, School of Physiotherapy
University of Otago
325 Great King Street
Dunedin
Tel (Wk) 03 479 5424
Email gill.johnson@otago.ac.nz

Statement of approval
This study has received ethical approval from the Lower South Regional Ethics Committee, Ethics reference number LRS/09/11/053.

If you would like to take part, please contact me at:

Miranda Bühler
Physiotherapy Outpatient Department
Dunedin Hospital
Tel (wk) 03 474 7945 (mob) 027 299 3979
Email buhmi484@student.otago.ac.nz

Ultrasound imaging of the healing tendons of the hand
Version 3 14 April 2010
A study of tendon healing in the hand

CONSENT FORM

<table>
<thead>
<tr>
<th>Language</th>
<th>Description</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>English</td>
<td>I wish to have an interpreter</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deaf</td>
<td>I wish to have a NZ sign language interpreter</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Māori</td>
<td>E hiaia ana ahau ki tetahi kaiwhaka Māori/kaiwhaka pakeha korero</td>
<td>Ae</td>
<td>Kao</td>
</tr>
<tr>
<td>Cook Island Māori</td>
<td>Ka inangaro au i teti tangata uri reo</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fijian</td>
<td>Au gadreva me dua e vakadewa vosa vei au</td>
<td>Io</td>
<td>Sega</td>
</tr>
<tr>
<td>Niuean</td>
<td>Fia manako au ke fakaosa e taha tagata fakahokohoko kupu</td>
<td></td>
<td>Nakai</td>
</tr>
<tr>
<td>Sāmoan</td>
<td>Ou te mana’o ia i ai se fa’amatata upu</td>
<td></td>
<td>Leai</td>
</tr>
<tr>
<td>Tokelauan</td>
<td>Ko au e fosou ki he tino ke fakaliliu te gagana Peletania ki na gagana o na motu o te Pahefika</td>
<td></td>
<td>Leai</td>
</tr>
<tr>
<td>Tongan</td>
<td>Oku ou fsena’u ha fakatouneas</td>
<td>Io</td>
<td>Ikai</td>
</tr>
</tbody>
</table>

I have read and I understand the information sheet dated 15th January 2010 for volunteers taking part in the study designed to investigate tendon healing in the hand using ultrasound images. I have had the opportunity to discuss this study. I am satisfied with the answers I have been given.

I have had the opportunity to use whānau support or a friend to help me ask questions and understand the study.

I understand that

1) taking part in this study is voluntary (my choice), and that I may withdraw from the study at any time, and this will in no way affect my continuing health care.

2) my participation in this study is confidential and that no material that could identify me will be used in any reports on this study.

3) the treatment, or investigation, will be stopped if it should appear harmful to me.

I consent to investigators accessing my medical and physiotherapy records.

I understand that I will receive a $10 petrol voucher on attendance at each of the scanning sessions.

Version 3  14 April 2010  1
I understand the compensation provisions for this study.

I have had time to consider whether to take part in the study.

I know who to contact if I have any side effects from the study.

I know who to contact if I have any questions about the study in general

I wish to receive a copy of the results [ ] Yes [ ] No

I agree to my current health care provider(s) being informed of my participation in this study/the results of my participation in this study

I .................................................. (full name) hereby consent to take part in this study.

Date: 

Signature: 

Full names of researchers: Dr Gill Johnson
Ms Miranda Buhler
Dr Grant Meikle

Contact phone number for researchers: 03 474 7945

Project explained by: 

Project role: 

Signature: 

Date: 

Version 3 14 April 2010 2
## APPENDIX 3: PILOT STUDY PARTICIPANT

Trial participant details:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>48</td>
</tr>
<tr>
<td>Sex</td>
<td>female</td>
</tr>
<tr>
<td>Injured hand</td>
<td>right</td>
</tr>
<tr>
<td>Mechanism</td>
<td>glass laceration</td>
</tr>
<tr>
<td>Digit</td>
<td>ring &amp; little</td>
</tr>
<tr>
<td>Tendon(s)</td>
<td>FDS &amp; FDP</td>
</tr>
<tr>
<td>%Lac</td>
<td>100% &amp; 60%</td>
</tr>
<tr>
<td>Location</td>
<td>MCP joint</td>
</tr>
<tr>
<td>Material</td>
<td>4-0 looped supramid</td>
</tr>
<tr>
<td>Occup</td>
<td>Administrative</td>
</tr>
</tbody>
</table>

A study of tendon healing in the hand

Initial screening interview template

<table>
<thead>
<tr>
<th>Date</th>
<th>Study ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Sex</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>Descent</td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
<td>Yes</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>Yes</td>
</tr>
<tr>
<td>Immune deficiency condition</td>
<td>Yes</td>
</tr>
<tr>
<td>Previous injury to involved hand</td>
<td>Yes</td>
</tr>
<tr>
<td>Previous injury to the uninvolved hand</td>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Injured hand</th>
<th>Preferred hand</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of injury</td>
<td>Date of surgery</td>
</tr>
</tbody>
</table>

Mechanism of injury

<table>
<thead>
<tr>
<th>Digits involved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location of injury</td>
</tr>
<tr>
<td>Initial treatment</td>
</tr>
</tbody>
</table>

Difficulties or complications

General health

Medications

Work/sport/leisure

Interview template Version 2 15 March 2010
# A study of tendon healing in the hand

## Data Collection Form

<table>
<thead>
<tr>
<th>Date</th>
<th>Study ID</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Medical History

### Injured hand

### Mechanism of injury

<table>
<thead>
<tr>
<th>Digits involved</th>
<th>Tendons involved</th>
<th>Percentage laceration</th>
<th>Location</th>
<th>Surgical technique</th>
<th>Suture material</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Other structures injured

### Difficulties/complications

### Functional Outcomes

<table>
<thead>
<tr>
<th>Functional Outcomes</th>
<th>4 weeks</th>
<th>6 weeks</th>
<th>12 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROM <em>each digit</em></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AROM <em>each digit</em></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contralateral</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>QuickDASH</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grip strength</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Contra-lateral</em></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RTW/leisure</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Difficulties/complications

### Adverse events

---

Data Collection Form Version 3 31 March 2010
<table>
<thead>
<tr>
<th>Injured hand/Involved digit</th>
<th>Study ID</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tendon thickness (mm)</strong></td>
<td><strong>Week post operative (date)</strong></td>
</tr>
<tr>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Mid repair *Save</td>
<td>FDS longitudinal short axis</td>
</tr>
<tr>
<td>*Save</td>
<td>FDP longitudinal short axis</td>
</tr>
<tr>
<td></td>
<td>FDS transverse short axis</td>
</tr>
<tr>
<td></td>
<td>transverse long axis</td>
</tr>
<tr>
<td></td>
<td>FDP transverse short axis</td>
</tr>
<tr>
<td>1 cm proximal *Save</td>
<td>FDS longitudinal short axis</td>
</tr>
<tr>
<td>*Save</td>
<td>FDP longitudinal short axis</td>
</tr>
<tr>
<td></td>
<td>FDS transverse short axis</td>
</tr>
<tr>
<td></td>
<td>transverse long axis</td>
</tr>
<tr>
<td></td>
<td>FDP transverse short axis</td>
</tr>
<tr>
<td>1 cm distal *Save</td>
<td>FDS longitudinal short axis</td>
</tr>
<tr>
<td>*Save</td>
<td>FDP longitudinal short axis</td>
</tr>
<tr>
<td></td>
<td>FDS transverse short axis</td>
</tr>
<tr>
<td></td>
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Data Collection Form   Version 3   31 March 2010
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<tr>
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<td>0°</td>
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<td><strong>Total excursion</strong></td>
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<td>FDP relative to FDS (differential glide)</td>
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<td>30°</td>
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<td>Measure thickness</td>
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<td>Sheath and surrounding soft tissues</td>
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<td>Comments</td>
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<tr>
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<td>FDS</td>
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Operating Definitions for Ultrasound Outcome Variables - Rating Scales

Echogenicity

0  Normal tendon
1  Reduced reflectivity occupying up to 25% of the transverse area of the tendon
2  Reduced reflectivity occupying 25-50% of the transverse area of the tendon
3  Reduced reflectivity occupying 50-75% of the transverse area of the tendon
4  Reduced reflectivity occupying 75-100% of the transverse area of the tendon

Margination

1  Margins well defined (normal)
2  Slightly less definition between borders (good)
3  Margins irregular (fair)
4  Borders blend (poor)

Power Doppler signal scale

0  No detectable power Doppler signal
1  Mild vascularity \(\leq 30\% \text{ of transverse area}\)
2  Moderate vascularity \(\leq 60\% \text{ transverse area}\)
3  Severe vascularity \(> 60\% \text{ of transverse area}\)

Operating definitions ultrasound outcome variables - rating scales
Version 2 31 March 2010
Operating Procedure for Ultrasound Imaging

Injured hand

- Landmark mid repair site
- Mid repair
  - Longitudinal
    - Measure short axis FDS & FDP
    - Measure length of region of healing tendon
    - Comment echo-texture
    - Measure excursion
  - Transverse
    - Measure short and long axis FDS & FDP
    - Rate echogenicity
    - Rate margination
- 1 cm Proximal
  - Longitudinal
    - Measure short axis FDS & FDP
    - Comment echo-texture
  - Transverse
    - Measure short and long axis FDS & FDP
    - Rate echogenicity
    - Rate margination
- 1 cm Distal
  - Longitudinal
    - Measure short axis FDS & FDP
    - Comment echo-texture
  - Transverse
    - Measure short and long axis FDS & FDP
    - Rate echogenicity
    - Rate margination

Uninjured hand

- Landmark
- Mid repair
  - Longitudinal
    - Measure short axis FDS & FDP
    - Comment echo-texture
  - Transverse
    - Measure short and long axis FDS & FDP
    - Calibrate power Doppler
Injured hand

- Mid repair
  - Longitudinal
    - Comment power Doppler
  - Transverse
    - Rate power Doppler scale
- 1 cm Proximal
  - Longitudinal
    - Comment power Doppler
  - Transverse
    - Rate power Doppler scale
- 1 cm Distal
  - Longitudinal
    - Comment power Doppler
  - Transverse
    - Rate power Doppler scale
## APPENDIX 5: RAW DATA SETS

### Ultrasound variables

<table>
<thead>
<tr>
<th>Location</th>
<th>Participant</th>
<th>Week 2</th>
<th>Week 4</th>
<th>Week 6</th>
<th>Week 12</th>
<th>Week 18</th>
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### 30 degrees DIP joint flexion

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### Power Doppler score (0-3) FDP tendon

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### Tendon thickness anterior-posterior (millimetres)

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### Tendon thickness medial-lateral (millimetres)

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<td>Week 2</td>
<td>Week 4</td>
<td>Week 6</td>
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<th>Week 6</th>
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### Functional Outcomes

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<th>Week 6</th>
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<th>Participant</th>
<th>QuickDASH score 6 weeks</th>
<th>QuickDASH score 12 weeks</th>
<th>Grip strength (kgF)</th>
<th>Contra-lateral grip strength (Kgf)</th>
<th>RTW (weeks post-op)</th>
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Comparison Power Doppler score (sheath/surrounding soft tissues) and Strickland-Glovac score

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<th>TAROM (Strickland-Glovac criteria)</th>
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<tbody>
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