Tampere University

LASSE LINNANMÄKI

The Biomechanical Properties of Flexor Tendon Repairs

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ACADEMIC DISSERTATION
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PunaMusta Oy
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To Anniina, Veera, and Alvar

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Lasse Linnanmäki

ABSTRACT

During the last decades, an increasing number of finger flexor tendon repair studies have been published. Yet, there is still no established study design. Both static and, more recently, cyclic testing methods have been used. The outcomes of these studies vary significantly between cyclic testing studies and lead to difficulty in comparing different study results. Additionally, the variation-causing factors of the experimentally studied flexor tendon repairs (testing methodology, tendon material, surgeon performance, and inter-surgeon variation) are often ignored in the literature, and instead studies are focused on comparing the different mean values of biomechanical outcomes (yield load and ultimate load).

This dissertation examined the relationship between static and cyclic testing methods. The aim was to develop an objective failure-determining method. Static loading derived yield load predicted well the ability of flexor tendon repair to preserve intact during repetitive loading and unloading. However, the yield load was correlated with the 50% probability to fail during repetitive loading (critical load) and safe load that corresponds to 2.3% probability to fail (−2 SD probability to fail) better represented the clinically acceptable situation.

In addition to mathematical methods, time-extension curves of cyclic testing were analysed visually. If there was a manifestation of sudden extension increase at the time-extension curve (fatigue point) during repetitive loading and even minimal gapping, the tested flexor tendon repair failed. This highlights the harmfulness of gapping on flexor tendon repair. The significance of gapping has remained controversial in the literature.

When variation causing factors of the flexor tendon repair were inspected, no factor exceeded any of the others. Tendon material properties were rendered inferior to the execution of the repair. However, inter-surgeon related variation consisted of only one tenth of the total variation. Surgeons can lower the probability of failure by producing more consistent repairs. Performing repairs as presented in the literature may help with this objective but, nevertheless, modifications of the performed repairs did not strengthen or weaken the performed repairs.

Thus, based on the findings of this dissertation, cyclic testing is still the recommended method for comparing different flexor tendon repairs. Gapping of

the repair predicted well the forthcoming failure of the repair. Based on variation causing factors, failure probability of flexor tendon repairs can be lowered with a more meticulous surgical technique.

TIIVISTELMÄ

Sormen koukistajajännekorjauksia on tutkittu viime vuosikymmeninä enenevissä määrin. Tästä huolimatta yhtenäistä tutkimusasetelmaa eri tutkimusten välillä ei ole olemassa. Korjauksia on tutkittu sekä staattisella että sittemmin myös syklisellä menetelmällä. Syklisellä menetelmällä tehtyjen tutkimusten päätemuuttujatkin vaihtelevat huomattavasti, mikä aiheuttaa suuria haasteita vertailtaessa eri tutkimusten tuloksia. Aiemmissa tutkimuksissa ei ole huomioitu tekijöitä, jotka aiheuttavat vaihtelua kokeellisessa mallissa korjattujen koukistajajänteiden biomekaanisiin päätemuuttujiin (myötövoima ja maksimivoima). Tällaisia tekijöitä, joita tässä väitöskirjassa kutsutaan hajontatekijöiksi, ovat testausmenetelmä, jännekudos, jännekorjauksen suorittamiseen liittyvä hajonta sekä kirurgien välinen hajonta. Hajontatekijöiden sijaan kirjallisuudessa on enimmäkseen keskitytty edellä mainittujen päätemuuttujien vertailemiseen keskiarvoja käyttäen.

Tässä väitöskirjassa tutkittiin staattisen ja syklisen menetelmän suhdetta toisiinsa. Tavoitteena oli kehittää objektiivinen menetelmä, jolla korjauksen hajoamista voidaan ennakoida. Mallin perusteella selvisi, että staattisista koestuksista saatava myötövoima ennakoi hyvin jännekorjauksen todennäköisyyttä selviytyä toistuvasta edestakaisesta kuormituksesta. On kuitenkin huomioitava, että myötövoima vastasi 50 %:n hajoamistodennäköisyyttä (kriittinen voima). Näin kehittämämme raja-arvo varmuusvoima, joka tarkoittaa koukistajajännekorjauksen 2,3 %:n hajoamistodennäköisyyttä (hajoamistodennäköisyys −2 keskihajonnan kohdalla), kuvaa paremmin kliinisesti hyväksyttävää tilannetta.

Matemaattisten mallien lisäksi syklisten koestusten aika-venymäkäyriä analysoitiin visuaalisesti. Jos käyrällä esiintyi kohta, jossa venymä alkoi voimakkaammin lisääntyä (väsymispiste), ja korjaukseen ilmaantui raottumaa, johti tämä lopulta korjauksen hajoamiseen. Tämä korostaa entisestään kirjallisuudessa ristiriitaisesti kuvatun raottuman haitallisuutta korjauksen kestävyyden kannalta.

Jännekorjauksen hajontatekijöistä yksikään ei noussut selvästi muita merkittävämmäksi. Jännemateriaalin merkitys kuvautui korjauksen suorittamista merkityksettömämpänä. Eri kirurgien välisen hajonnan lisä korjauksen kokonaishajontaan oli suhteellisen pieni, vain yksi kymmenesosa. Kirurgi voikin vähentää korjauksen hajoamisen todennäköisyyttä pyrkimällä keskenään

mahdollisimman yhdenmukaisiin jännekorjauksiin. Toistettavuuden näkökulmasta kirjallisuudessa esitettyjen korjausten tekeminen sellaisenaan on yksi keino yhdenmukaistaan korjauksia, mutta korjauksen muokkaaminen ei väitöskirjan perusteella heikennä tai vahvista tehtyjä korjauksia.

Väitöskirjan perusteella on suositeltavaa käyttää syklistä koestusmenetelmää sormen koukistajajännekorjausten vertailuun. Koukistajajännekorjauksen raottuma ilmeni olevan merkki korjauksen hajoamisesta. Hajontatekijöiden perusteella mahdollisimman yhtenäisillä korjauksilla voidaan vähentää korjauksen hajoamistodennäköisyyttä.

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ABBREVIATIONS

A1–A5	Annular pulleys 1–5
ANOVA	Analysis of variance
Av	Variable annular pulley
C1–C3	Cruciform pulleys 1–3
CoV	Coefficient of variation
DIP	Distal interphalangeal joint
ECM	Extracellular matrix
FDP	Flexor digitorum profundus
FDP-II	Second ray of flexor digitorum profundus
FDS	Flexor digitorum superficialis
FPL	Flexor pollicis longus
IHM	Interlocking-horizontal mattress
IP	Interphalangeal joint
MCP	Metacarpophalangeal joint
MFSS	Multifilament stainless steel
MLE	Maximum likelihood estimation
O	Oblique pulley
PIP	Proximal interphalangeal joint
PLDLA	Bioabsorbable poly-L/D-lactide
SD	Standard deviation
UHMWPE	Ultra-high molecular weight polyethylene
USP	United States Pharmacopeia
VBP	Vinculum brevis profundus
VBS	Vinculum brevis superficialis
VLP	Vinculum longus profundus
VLS	Vinculum longus superficialis
μ	Mean
p	Probability of failure
σ	Standard deviation
ω	Expectation value

ORIGINAL PUBLICATIONS

This dissertation is based on the following articles, which are referred to in the text by their Roman numerals.

Publication I	Linnanmäki L, Göransson H, Havulinna J, Sippola P, Karjalainen T, Leppänen OV. Validity of Parameters in Static Linear Testing of Flexor Tendon Repair. J Biomech. 2016 Sep 6;49(13):2785–2790. Copyright © 2016 the American Society for Surgery of the Hand. DOI: 10.1016/j.jbiomech.2016.06.022
Publication II	Linnanmäki L, Göransson H, Havulinna J, Sippola P, Karjalainen T, Leppänen OV. Gap Formation During Cyclic Testing of Flexor Tendon Repair. J Hand Surg Am. 2018 Jun;43(6):570.e1–570.e8. Copyright © 2018 the American Society for Surgery of the Hand. DOI: 10.1016/j.jhsa.2017.12.005
Publication III	Linnanmäki L, Göransson H, Havulinna J, Karjalainen T, Leppänen OV. Factors Accounting for Variation in the Biomechanical Properties of Flexor Tendon Repairs. J Hand Surg Am. 2018 Dec;43(12):1073–1080.e2. Copyright © 2018 the American Society for Surgery of the Hand. DOI: 10.1016/j.jhsa.2018.08.012
Publication IV	Leppänen OV, Linnanmäki L, Havulinna J, Göransson H. Suture configurations and biomechanical properties of flexor tendon repairs by 16 hand surgeons in Finland. J Hand Surg Eur Vol. 2016 Oct;41(8):831–7. Copyright © SAGE Publications. DOI: 10.1177/1753193416641624

1 INTRODUCTION

A 30-year-old man arrives at the hospital emergency department after suffering a knife wound to his non-dominant hand. This is a typical situation where flexor tendon injury occurs. An incidence of 4.8 to 33/100 000 person-years for finger flexor tendon injuries has been reported. (Clayton and Court-Brown, 2008; de Jong et al., 2014; Manninen et al., 2017) The incidence of flexor tendon injuries is, however, decreasing due to the increased safety and automatization of industrial processes (de Jong et al., 2014; Manninen et al., 2017). In flexor tendon injuries, damage to digital nerves often requires microsurgical skills to be repaired (Manninen et al., 2017), and this increases the total cost of the repair process (Rosberg et al., 2003). Moreover, it has been estimated that all hand and wrist traumas are more expensive to treat than, among other things, lower limb and hip fractures. Costs are high both in terms of health care (e.g., intensive care and rehabilitation) and as a result of productivity losses due to absenteeism. (de Putter et al., 2012)

When a finger flexor tendon is injured, the main function of the tendon – to transmit the contraction of the muscle to the flexion of the finger – is impaired. In a typical situation, cut tendon ends are treated with an end-to-end suture repair. There are numerous alternative repair methods (Viinikainen et al., 2008), but the basic principles of repair configurations remain mostly the same: central portions of the lacerated tendon ends are approximated with a core repair and the surface of the tendon is finished with a peripheral repair. This combination creates a biomechanical composition that has been studied a great deal during recent decades. The purpose of these studies has been to create a repair method that preserves tendon healing, tendon gliding, the biomechanics of the tendon, and, finally, withstands the selected rehabilitation program. (Strickland, 2005)

In experimental studies, load-to-failure testing is commonly used to test different flexor tendon repairs (Pruitt et al., 1991). Based on the single pull, ultimate load, gapping loads, and, less frequently, yield load have been reported for the selected repair method (Viinikainen, 2008). Since the 1990s, a more physiological cyclic testing method has been used for the testing of flexor tendon repair (Pruitt et al., 1991), but the method is still relatively uncommon. Furthermore, there is still a lack of consistency in biomechanical testing setups in the literature that hampers the comparison of the results of different studies (Hausmann et al., 2009). Additionally, there have been no studies that demonstrate how the aforementioned static testing measures are related to cyclic testing.

During the last decades, at least partial active rehabilitation programs have taken over from passive rehabilitation programs after tendon repair (Tang et al., 2013). However, active rehabilitation subjects the repaired tendon to higher tension loads compared with passive methods (Sapienza et al., 2013). Too high a tension on the repaired tendon leads to gapping and rupture of the repair. Estimations about acceptable gapping have varied between 1 mm and 10 mm (Ejeskär and Irstam, 1981; Gelberman et al., 1999; Sanders et al., 1997; Seradge, 1983; Silfverskiöld et al., 1992), and the significance of gapping has therefore remained controversial.

As previously mentioned, flexor tendon injuries are relatively rare (Clayton and Court-Brown, 2008; de Jong et al., 2014; Manninen et al., 2017), and this emphasises the significance that surgeons should make repairs that are as consistent as possible to avoid repair ruptures during rehabilitation. Regardless of the huge number of experimental tendon repair studies in the literature (Strickland, 2005), to date, no study has paid attention to the variation within flexor tendon repairs and their components.

The major aim of the series of experimental studies described in this dissertation was to assess the relation between static and cyclic testing methods and to develop an objective testing setting for the comparison of repair methods. Related to testing methodology, a second aim was to better understand the significance of gapping. A further aim was to identify the variation factors in flexor tendon repair. The following literature review accounts for the present view of the biomechanical properties of finger flexor tendon repairs in adults.

2 REVIEW OF THE LITERATURE

2.1 Characteristics of flexor tendon

2.1.1 Anatomy and histology of flexor tendons

2.1.1.1 Anatomy of flexor tendons

The flexor tendons of the fingers originate from muscles that are attached to the forearm (extrinsic) and to areas of the hand (intrinsic). The muscles of extrinsic tendons, the main interest in the context of flexor tendon repairs, are responsible for producing grip force. The extrinsic tendons include the flexor digitorum superficialis (FDS), the flexor digitorum profundus (FDP), and the flexor pollicis longus (FPL). Their muscles originate from the medial epicondyle of the humerus and the inner surface of the deep fascia of the forearm. There is an inelastic connective tissue fascia between the muscle bellies that separates the whole flexor system in three layers: superficial, intermediate, and deep. The superficial layer comprises other flexors of the hand, while the FDS belongs to the intermediate layer and the FPL and the FDP to the deep layer.

The FDS muscle mass is composed of four tendons (FDS II–V) in the antebrachium. Sometimes, the FDS tendon of little finger may be extremely small or absent.

Individual FDP tendons to the II–V fingers are separated from each other proximal to the wrist. There may be interconnections between the FPL and FDP II tendons (Bogumill, 2002). Additionally, the FDP tendons of the fingers III–V may share the same muscle belly and have interconnections. Blocking the flexion movement of one of these tendons leads to less strength in the interconnected neighbouring flexor (Horton et al., 2007). This phenomenon is termed quadriga (Verdan, 1960a).

Deep fascia surrounds the tendons of the extrinsic muscles in the region of the wrist. Extension of the fascia forms the volar part of the carpal tunnel (flexor retinaculum) and prevents the extrinsic muscles from bowstringing at the wrist. The FDP tendons lie deep in the carpal tunnel, and the FDS tendons are situated in a more volar position. Tendons pass through the carpal tunnel with the median nerve that is located between the flexor tendons and the flexor retinaculum.

In the carpal tunnel, tenosynovium (ulnar bursa) envelopes the extrinsic tendons of the fingers II–V. The tenosynovium continues distally as tendon sheath to the little finger. On the radial side of the carpal tunnel, there is a sheath for the FPL (radial bursa) that continues distally to the thumb. Sometimes, these two bursas are connected. In the fingers III–V, individual tendon sheaths begin at the level of the distal palmar skin crease and continue proximally to the level of the distal interphalangeal joint (DIP). Tendon sheaths 1) provide nutrition for the tendons, 2) serve as a slick surface for the tendons to glide smoothly on, and 3) are part of the supporting system of the tendons to hold them to the bony plane in volar direction and to prevent the tendons from bowstringing during finger flexion. To fulfil the supporting function of the tendon, parts of the sheaths are composed of thickened parts called pulleys. The pulley system comprises five annular (circular, A1–A5) and three cruciform (cross-shaped, C1–C3) pulleys in the II–V fingers (Doyle, 1989; Doyle and Blythe, 1975) (Figure 1). The most important pulleys are considered to be A2 and A4 (Rispler et al., 1996) due to the lack of full active flexion of fingers II–V without them. The A2 and A4 pulleys originate from bone and appear between joints, whereas the other annular pulleys originate from the volar plates. The thin cruciform pulleys allow flexion of the finger joints. In the thumb, there are only three or four pulleys: two annular (A1 and A2), one oblique (O) between the metacarpophalangeal joint (MCP) and the interphalangeal joint (IP), and usually a variable annular pulley (Av) that is transverse, oblique, or fused with the A1 pulley (Schubert et al., 2012).

At the level of the A2-pulleys of fingers II–V, the FDS tendons divide and the FDP tendons pass between the slips of the FDS tendon (Camper's chiasm). The FDPs insert to the distal phalanges of the fingers while the two slips of the FDSs connect and then separate again to two longitudinal slips that insert on both sides of the middle phalanges.

The primary function of the FDP is to flex the DIP while the FDS flexes the proximal interphalangeal joint (PIP). A secondly function of the FDP is to flex the PIP and the MCP, and the FDS also flexes the MCP.

In fingers II–V, the synovial tunnel is especially tight from the level of the distal palmar crease to the middle of the middle phalanx because both the FDS and FDP travel through the synovial tunnel in this region, and the FDS and FDP change their position relative to each another. This region has become known as "No Man's Land" (Bunnell, 1948; Newmeyer and Manske, 2004) due to the occasional unacceptable results of primary flexor tendon repairs in this area. Previously, only skin closure was advised in this area and secondary repair was performed with a graft (Verdan, 1960b). Based on the anatomical characteristics and results of tendon repairs, the hand has been divided into five zones with "No Man's Land" corresponding to Zone II (Figure 1) (Kleinert et al., 1981). After the development of tendon repair techniques and rehabilitation programs, this area has now become known as "Some Man's Land" (Kleinert et al., 1995) pinpointing the possibility of performing primary flexor tendon repairs in this region by surgeons who are familiar with flexor tendon repair procedures.

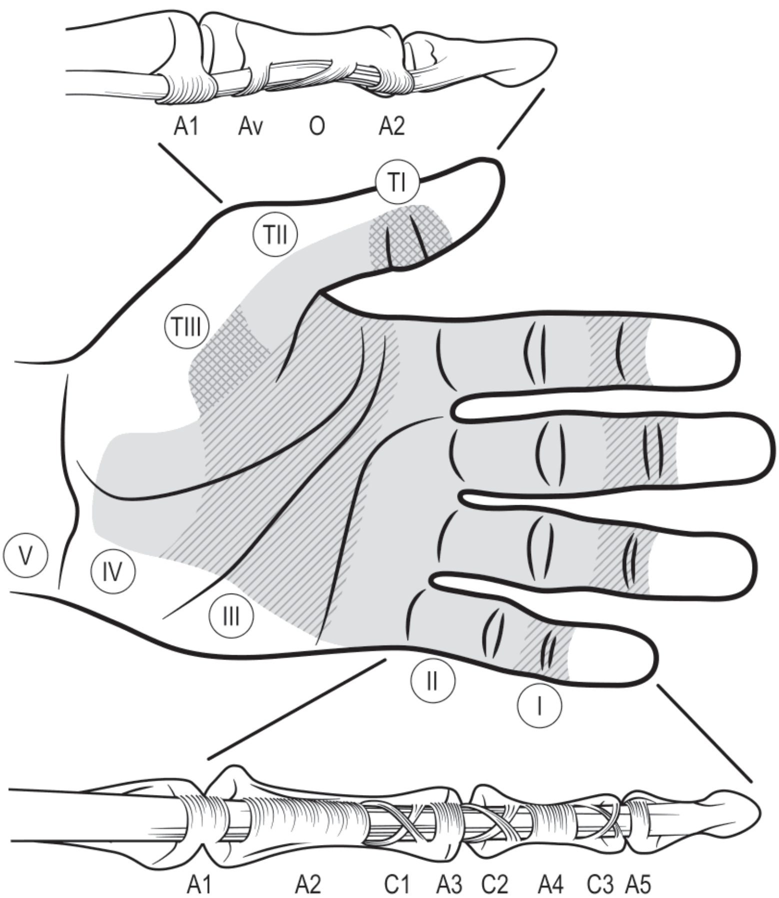

Figure 1. Organization of the pulley system and the clinical classification of flexor tendon injuries.

2.1.1.2 Tendon and tendon sheath histology

Tendons are primarily composed of parallel bunches of collagen fibrils (mostly type I) and elastic fibres embedded in a water-proteoglycan matrix (Kannus, 2000). Further, the collagen fibrils are composed of triple helixes of collagen polypeptides. Between the collagen helixes, there are intermolecular cross-links that increase the tensile strength of the tendon. (James et al., 2008) Between the collagen fibrils lie fibroblast-like cells (tenocytes) in a row arrangement. They are spindle-shaped cells and are the main component of the cellular matrix of the tendon. Tenocytes are responsible for the production of collagen and the reorganization of the extracellular matrix (ECM). Along with collagen fibrils (65% to 80% of the dry weight of the tendon), the ECM comprises ground substance (mainly proteoglycans), elastic fibres (1% to 2% of the dry weight), and inorganic components (less than 0.2% of the dry weight) (Kannus, 2000). The purpose of the ECM is twofold: mechanical and biological. Small variations in the composition of the ECM can lead to a significant difference in sliding between fibrils or fascicles. Additionally, the ECM provides a healthy microenvironment for the tendon. (Screen et al., 2015)

The histology of the insertion of the tendon to the bone varies significantly from the other tendon tissues, and there appears to be a fibrocartilaginous transition zone between tendon and bone (Thomopoulos et al., 2003). The biomechanical environment causes differences in the microstructure of the tendon. The dorsal side of the tendon has greater strength, less collagen crosslinking, and a larger single bundle cross-sectional area than the palmar side of the tendon (Soejima et al., 2003). Furthermore, in the pressure-bearing areas, such as at the site of the pulleys, the tendon has fibrocartilage-like organization and a high concentration of glycosaminoglycans (Merrilees and Flint, 1980).

The tendon is sheathed by epitenon (Figure 2). In this layer, the collagen fibrils (type III) are not highly arranged. Furthermore, there is an endotenon-called connective tissue extension of the epitenon that divides the tendon into fascicles (Figure 2). This structure brings vasculature and innervation to the tendon.

Finally, the tendon sheath works as a membrane that ultrafiltrates plasma and produces synovial fluid. In the friction zones of the sheath (pulleys), cells are like chondrocytes and analogous with the cartilages of the joints. (Lundborg and Myrhage, 1977)

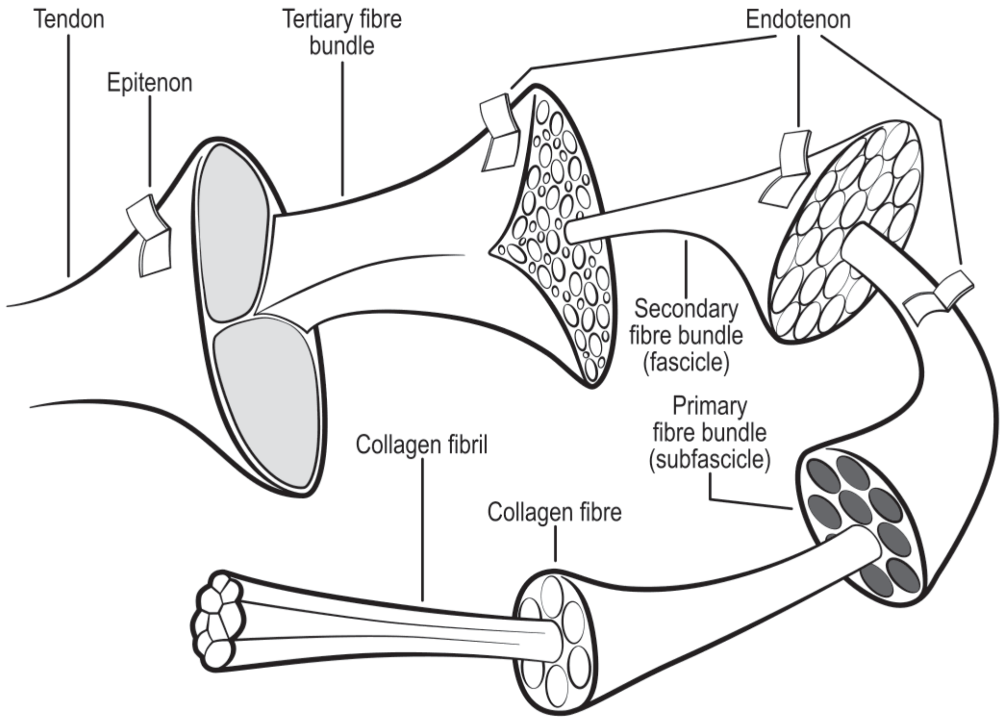

Figure 2. Microanatomy of the tendon (Adopted from Kannus, 2000).

2.1.1.3 Vascularisation of flexor tendon

Separate connective tissue structures (vincula) bring vasculature from digital vessels to the longitudinal intrinsic vessels of the flexor tendons. In addition, the blood supply is provided from the palm and from the junction of the tendon and bone. The intrinsic vessels of the tendon mainly run at the dorsal side of the flexor tendon and leave the volar side more hypovascular. Due to the segmental blood supply, some parts of the flexor tendons are left avascular. (Lundborg et al., 1977) At the friction surface of the pulleys, vasculature is absent. However, the microscopical structure of the pulleys allows perfusion in the synovial membrane to continue despite elevated pressures. (Lundborg and Myrhage, 1977)

There are both long and short vinculum for the FDS and the FDP. The structures of the different vincula and their relation to each other varies considerably. Usually, vinculum longus superficialis (VLS) starts from the base of the proximal phalanx and extends to the FDS. Vinculum brevis superficialis (VBS) comprises several arteries and originates from the membranous part of the volar plate of the PIP to the FDS. Vinculum longus profundus (VLP) originates from the distal part of the proximal phalanx to the FDP. Vinculum brevis profundus (VBP) originates from the distal part of the middle phalanx to the FDP. (Ochiai et al., 1979) Vincula must be preserved during repair so as not to diminish the vasculature of the tendon. Due to interconnections between vincula, dissection of the FDS tendon during repair of the FDP tendon can lead to diminished perfusion in the FDP tendon. (Lundborg et al., 1977)

2.1.1.4 Nutrition of flexor tendon

Both vasculature (Ochiai et al., 1979) and diffusion (Lundborg and Rank, 1978) feed the flexor tendons. The most important nutrition pathway, however, is the diffusion of synovial fluid. The synovial membrane has been proposed to be essential for optimal diffusion. (Lundborg et al., 1980) However, even without synovial contact and vasculature, all segments of the tendon are perfused in 60 minutes (Manske and Lesker, 1982). During active mobilisation of intact fingers, the avascular zones of the tendons may be better nourished when compared with passive mobilisation (Lundborg et al., 1980).

2.1.2 Biomechanics of flexor tendon

Tendon insertions (tendon-bone junctions) are about two-fold weaker than the tendon itself. The weakest points of the FDS and FDP tendons are at the Campers' chiasm and at the attachment to the distal and medial phalanx. The FDS and FDP tendons bear maximum forces ranging from 212 N to 1252 N and 623 N to 1182 N, respectively, depending on the tested finger. (Pring et al., 1985) A tendon behaves differently when loading and unloading during the testing cycle. First, during loading, the tendon resists elongation. Second, during unloading, the tendon is prevented from recovering back to its original length. The elongation is most obvious during the first cycles. (Goodman and Choueka, 2005)

Muscle training strengthens tendons, whereas immobilisation weakens them (Kannus et al., 1997). Too strong a loading of the tendons can, however, change the effect from beneficial to degenerative (Shepherd and Screen, 2013). Ageing decreases the maximum load and yield load of the tendon potentially via impaired healing. In a study with mice, homeostasis of the tendon was not altered. (Ackerman et al., 2017) Furthermore, diabetes impairs the structure of tendons (Shi et al., 2015).

2.1.2.1 Forces and kinematics of the flexor tendon

The FDP muscle is essential for finger flexion, and on its own it can cause movement in all three finger joints (MCP, PIP, and DIP). The more force is used, the more the FDS muscle participates in the kinematics (Goodman and Choueka, 2005), and it plays a significant role in sustaining finger movements together with the FDP (Li and Zhang, 2010). In *in vivo* measurements, the force of the FDP tendon increases constantly during finger flexion achieving forces of 1.3 N to 4.0 N (Kursa et al., 2006; Nikanjam et al., 2007). Flexion of the wrist does not affect this pattern (Kursa et al., 2006). Conversely, the force in the FDS tendon remains constant during finger flexion when the wrist is in a neutral posture. However, when the wrist is at 30° flexion, the force increases during the flexion. Generally, forces in the FDS tendon are between 1.3 N and 8.5 N. Peak loads in the FDP and FDS are below 20 N and 40 N, respectively. Thus, if it is desired to keep forces in the tendons low – for example, during the rehabilitation of the repaired tendon – it is recommended that finger flexion is performed with either the wrist in a neutral posture or the flexion of the finger restricted during flexion of the wrist. (Kursa et al., 2006) Moreover, the extension of the wrist seems to increase forces in the tendon during different finger movements even more than flexion of the wrist (Lieber et al., 1996).

It is controversial how forces in flexor tendons change during passive (finger is moved by other hand) or active (patients move the finger themselves) mobilisation. The difference in the forces has been stated to be significant (Sapienza et al., 2013; Schuind et al., 1992). Moreover, forces of up to 35 N in the FDP tendon have been reported if the fingers have been actively mobilised. During passive movements, however, forces remained at 9 N (Schuind et al., 1992). Conversely, Powell and Trail (2004) observed that there is no significant difference between active and passive mobilisation: forces in the FDP tendon remained at 6 N regardless of active or passive finger flexion. Lately, Edsfeldt et al. (2015) noted that flexion of all fingers causes a force of 6 N, whereas isolated flexion of a finger can cause a peak load of up to 26 N if the wrist is in a neutral posture (Table 1). Furthermore, movements more complex than simple finger flexion increase forces in the FDP tendon, significantly (Powell and Trail, 2004; Schuind et al., 1992).

Table 1. Forces in tendons of the hand during activity.

Reference	Studied tendon	Activity	Force (N)			
			Mean	SD	Min	Max
Schuind et al. (1992)	Isolated FDP	Unresisted DIP flexion	19	16	1	28
	Isolated FDP	Unresisted PIP flexion	1	1	0	2
	Isolated FDS	Unresisted DIP flexion	0.2	0.4	0	1
	Isolated FDS	Unresisted PIP flexion	9	5	3	13
	Isolated FPL	Unresisted thumb IP flexion	18	11	4	35
Edsfeldt et al. (2015)	FDP	Isolated FDP flexion	26	20		74
	FDS	Isolated FDS flexion	13	6		24
Urbaniak et al. (1975)	FDP	Active flexion against slight resistance				9
Powell and Trail (2004)	FDP and FDS	Active FDS and FDP flexion	6*		1	27
Kursa et al. (2006)	FDP	Active FDS and FDP flexion	5	4	1	15
	FDS	Active FDS and FDP flexion	3	3	1	13
Edsfeldt et al. (2015)	FDP	Active FDS and FDP flexion	7	5		17
	FDS	Active FDS and FDP flexion	3	7		26

FDP, flexor digitorum profundus; DIP, distal interphalangeal joint; FDS, flexor digitorum superficialis; PIP, proximal interphalangeal joint; FPL, flexor pollicis longus; IP, interphalangeal joint
*Median value reported.

2.1.2.2 Excursion of flexor tendon

The gliding distance of the tendon during finger movements is called excursion. In addition to the movements of the finger joints, movements of the wrist also affect the amount of excursion (Kociolek and Keir, 2016; Wehbé and Hunter, 1985). The excursion of the FDP is 32 mm if the finger is fully flexed and the wrist is in neutral posture when measured at the level of the carpal tunnel. However, there is 56% increase in excursion to 50 mm if the wrist is fully extended during finger extension and fully flexed during finger flexion. For the FDS, the corresponding excursion increases by 104% (from 24 mm to 49 mm). (Wehbé and Hunter, 1985) If only one finger is tested in an experimental study setting, the excursion of the FDP is 8.8 mm at the MCP and 1.3 mm at the PIP if only the MCP is flexed. The corresponding values are 9.2 mm and 6.0 mm during PIP flexion and 2.4 mm and 2.2 mm during DIP flexion, respectively. Thus, the most effective excursion is achieved with PIP flexion when only one joint is moved. (Horibe et al., 1990)

To avoid excursion decrease after flexor tendon repair, there should be movement of the tendon instead of immobilisation to prevent any ominous adhesion formation (Gelberman et al., 1986). McGrouther and Ahmed (1981) observed that the movement between the FDS and FDP tendons is minimal at zone II. If adhesions limit the movement between the FDS and FDP tendons, there is a further risk of adhesions between the FDS tendon and its sheath. Maximal excursion of both the FDS and FDP tendons and between the tendons can be achieved with fingers in a hook posture; while the MCP is in a neutral posture, and the PIP and DIP are in 90 degrees of flexion (Sapienza et al., 2013; Wehbe and Hunter, 1985). Active movements of the hand have been proven to cause generally larger excursion compared with passive movements (Korstanje et al., 2010; Panchal et al., 1997; Sapienza et al., 2013), even though study design differences between studies have hampered the comparability of excursion values (Korstanje et al., 2010).

2.2 Rupture of the flexor tendon

2.2.1 History of flexor tendon repair

In the ancient world, the tendon was not recognized as an individual tissue, but instead it was thought to be a neuronal tissue and called "neuron". However, ancient Roman physician Galen (129 AD to c. 210 AD) understood the difference between tendons and nerves and performed simple tendon repairs on gladiators with a suture. That said, he had advised other physicians not to perform repairs due to his conclusion that tendons and nerves are fused together, and thus tendons are sensitive to pricking. (Manske, 2005)

Nearly 1 000 years later, Avicenna, the great Muslim physician (c. 980 AD to 1037 AD), recommended performing tendon repairs and his concepts spread to Europe. From the 14^{th} to the 16^{th} centuries, several European surgeons performed successful tenorrhaphies. However, tendon repairs were not commonly acknowledged. (Manske, 2005)

The first scientific experimental flexor tendon studies were made in the 18^{th} century (Manske, 2005). In the beginning of the 20^{th} century, primary flexor tendon repairs at zone II were avoided due to infections, scarring, and imperfect surgery leading to flexion contractures. Hence, grafting was preferred. Sterling Bunnel coined the phrase: "No Man's land" for zone II based on terms used in World War I. From the 1950s onwards, encouraging results of primary repair were published. (Newmeyer and Manske, 2004) In 1967, Kleinert et al. (1967) published excellent results on the primary repair of zone II lacerated flexor tendons. The published results aroused intense debate among hand surgeons. Little by little, however, primary tendon repair became a standard procedure. (Newmeyer and Manske, 2004)

Additionally, in 1973, Bruner (1973) demonstrated zig-zag incisions for the primary repair of flexor tendons, and this method is still widely used today.

Initially until the 1980s, studies focused on the healing process and the significance of adhesion formation. After the conclusion that the tendon has intrinsic capacity to heal was made, studies looked forward to the development of more durable repair methods that could withstand the post-surgical mobilisation of the tendon. (Manske, 2005) After the introduction of the first passive mobilisation protocols, the development of rehabilitation protocols changed drastically in the 1970s (Starr et al., 2013).

Numerous suture configurations have been developed and studied in the past years (Myer and Fowler, 2016; Strickland, 1995). The evolution to current multi-strand core sutures has, however, taken a long time. In the 1980s and 1990s, four- and six-strand repair methods were developed. During the last decades, these methods have been simplified to achieve better ultimate loads and cause fewer friction forces. (Wu and Tang, 2014a)

2.2.2 Basic principles

Most tendon injuries are caused by laceration and occur in 20 to 29-year-old males. In such injuries, only a single tendon, most often the extensor tendon, is usually affected. The FDP tendon is most commonly injured in zone II of the index finger. (de Jong et al., 2014)

The injured finger is examined clinically to make a preoperative assessment of the tendon and any other possible injuries (e.g., nerve damage) and to make the decision whether to operate or not. In the last decades, tendon injuries have been repaired as an emergency. However, it has been noted that delaying the operation to office hours may result in better outcomes. Hence, nowadays, the majority of tendon repairs are done within a week of the injury. (Lalonde, 2011; Neumeister et al., 2014) If there is large soft tissue destruction, severe wound contamination, infection, or joint destruction, repair of the tendon should be delayed until the conditions for healing are better (Mehling et al., 2014). A delayed one- or two-stage reconstruction is regarded as an excellent option in such situations (Freilich and Chhabra, 2007).

General or block anaesthesia is usually used during the operation (Lalonde, 2011). However, wide-awake local anaesthesia using a local injection of lidocaine mixed with adrenaline is considered to be an option (Lalonde, 2011; Mehling et al., 2014; Neumeister et al., 2014; Tang, 2015). The advantage of the wide-awake method is that the patient can co-operate during the operation, and the repair can be evaluated intraoperatively (Neumeister et al., 2014).

A partial FDP tendon injury over 80% of its diameter should be repaired as a total laceration (Mehling et al., 2014). No one knows if the FDS should be repaired or resected, and different surgeons treat the lacerated FDS in different ways (Henry, 2011). There is a risk of increased adhesions and gliding resistance if both the FDS and FDP tendons are repaired (Xu and Tang, 2003).

Strickland (2005) listed the ideal characteristics for optimal tendon repair as follows: 1) sutures are easily placed in the tendon; 2) knots are secure; 3) the juncture of tendon ends is smooth; 4) gapping persevere minimal at the repair site; 5) there is minimal repair interference with tendon vascularity, and 6) the repair is of sufficient strength throughout the healing process to permit the application of early motion stress to the tendon. In the hand and wrist, the tendon is usually repaired in an end-to-end fashion. However, in zone I, the tendon is usually reinserted into the bone if the distal stump is less than 1 cm long.

2.2.3 Biomechanical testing of flexor tendon repair

To ensure that the repair fulfils the requirements of mobilisation procedures after tendon repair, the repair methods are evaluated using biomechanical testing. It is crucial that the repair withstands the selected rehabilitation program. The spectrum of study methods of flexor tendon repairs is wide: there have been *in vivo* and *ex vivo* studies and the outcomes of these have not yet been established (Strickland, 2005). Goodman and Choueka (2005) divided testing methods into two types: 1) linear testing and 2) curvilinear testing. Linear testing is further divided into static and cyclic testing methods.

2.2.3.1 Linear static testing

Traditionally, linear tests have been carried out using the principle of load-to-failure. Here, the tendon is attached between the clamps of an appropriate testing machine and the ends of the tendon are pulled apart at a constant speed (linear static testing). Thus, while the rate of pull is static, the load in the repair increases leading to deformation (i.e., elongation), and finally the repair ruptures. The linear load-deformation curve has typically three regions: 1) toe, 2) linear, and 3) failure (Goodman and Choueka, 2005) (Figure 3). In the toe region, the repair adapts to the load. In the linear region, the load and elongation are linearly proportional. After the proportional upper limit is reached, the slope of the curve is reduced. This is the point on the load-deformation curve that is called the yield point. The yield point is considered to be the beginning of irreversible deformation (Viinikainen et al., 2004). The highest peak of the load-deformation curve is termed the ultimate load, and it usually occurs at the end of the failure region. The stiffness of the structure is the load required to elongate the repair a given amount. It is the same thing as the slope of the curve, and it is measured within the linear region.

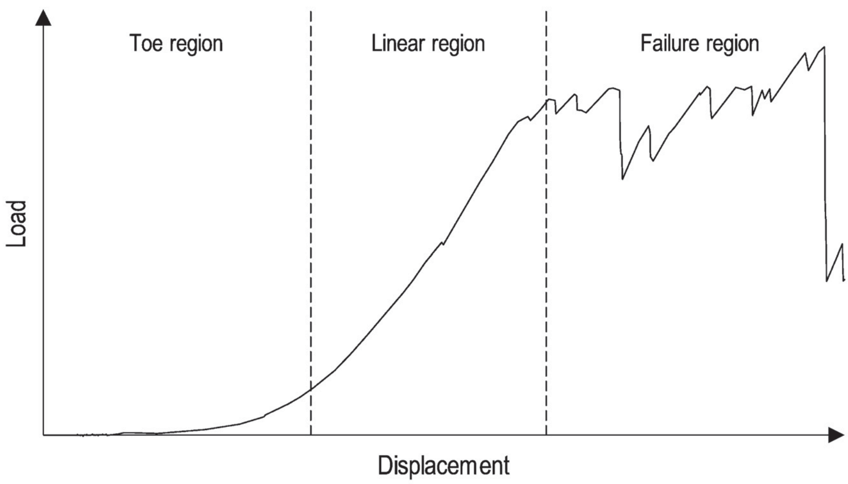

Figure 3. Typical load-deformation curve of static testing.

Load-to-failure static testing has been the primary method used to compare different suture configurations (Goodman and Choueka, 2005). Typically, gap values (e.g., the load needed to create a 2 mm gap between the ends of the repaired tendon) and the ultimate load of the repair method are reported (Viinikainen, 2008). Even though the yield load presents the last point of the intact repair, yield loads are rarely reported in the literature. Additionally, yield load has to be determined visually or by computer program, and thus it is more laborious to determine than ultimate load.

There are some parameters that must be defined within static testing. Distraction rate, which is commonly 20 mm to 40 mm/min (Hausmann et al., 2009), is the velocity between the clamps of the testing machine. An increase in the distraction rate results in an increase in both the ultimate load and the stiffness of the repair (Parimi et al., 2012). Preload is a pre-tension load that is achieved before testing, usually being 1 N to 2 N (Hausmann et al., 2009). However, variations in these settings reported by different studies and the number of different suture techniques used complicates the comparability of the results.

2.2.3.2 Linear cyclic testing

The linear cyclic testing method is a more recently introduced method to implement linear loading (Pruitt et al., 1991). During cyclic testing, the tendon repair is stretched repetitively (Figure 4) on the contrary to the only one traction used in static testing. Cyclic testing better resembles the rehabilitation of flexor tendon repair more physiologically than simple static loading. It renders gap formation with significantly lower loads compared with static testing (Pruitt et al., 1991; Viinikainen et al., 2009). Additionally, cyclic testing decreases the ultimate strength of the tested tendon (Gibbons et al., 2009). However, the cyclic testing method suffers from a lack of consensus on testing methodology.

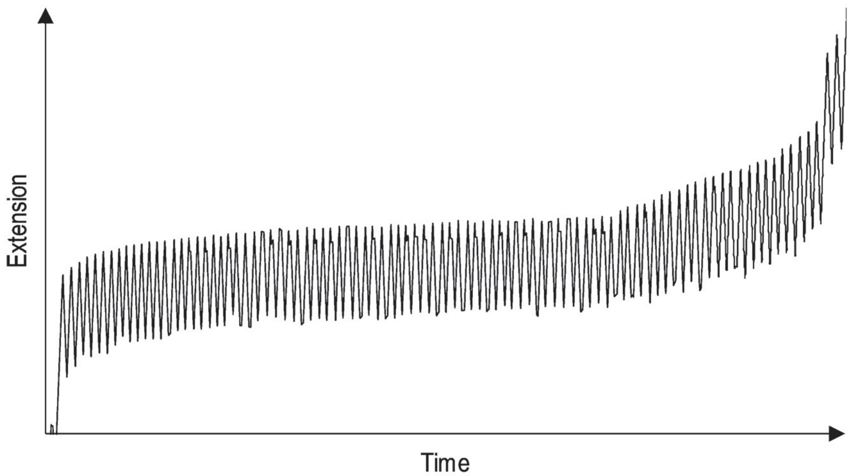

Figure 4. Typical time-extension curve of the cyclic test.

Two primary methods have been established to perform cyclic testing. The use of only one peak load at every cycle (Aoki et al., 1994; Bhatia et al., 1992; Corradi et al., 2010; Ditsios et al., 2002; Gibbons et al., 2009; Haddad et al., 2010a, 2010b; Hausmann et al., 2009; Mishra et al., 2003; Peltz et al., 2014; Pruitt et al., 1996b, 1991; Tahmassebi et al., 2015; Tran et al., 2002; Wieskötter et al., 2018; Wu and Tang, 2014b) (Table 2), or at a specific threshold, incrementally increasing load (Barrie et al., 2001, 2000a; Corradi et al., 2010; Gil et al., 2016; Jordan et al., 2015b, 2015c, 2015a; Kang et al., 2018; Kozono et al., 2017, 2016; Matheson et al., 2005; Sanders et al., 1997; Takeuchi et al., 2017, 2011, 2010; Viinikainen et al., 2009; Williams and Amis, 1995; Wit et al., 2013; Wolfe et al., 2007) (Table 3). In many studies with one peak load, testing has been completed with static load-to-failure testing after a specific number of cycles (Bhatia et al., 1992; Ditsios et al., 2002; Gibbons et al., 2009; Haddad et al., 2010b; Hausmann et al., 2009; Mishra et al., 2003; Peltz et al., 2014; Tahmassebi et al., 2015; Wieskötter et al., 2018; Wu and Tang, 2014b). This method is in the minority within studies using incremental loads (Jordan et al., 2015a; Wolfe et al., 2007). However, tendons usually undergo cyclic testing until a specific cycle count, until failure, or until a specific gapping amount (Aoki et al., 1994; Barrie et al., 2001, 2000a; Corradi et al., 2010; Gil et al., 2016; Haddad et al., 2010a; Jordan et al., 2015c, 2015b; Kang et al., 2018; Kozono et al., 2016, 2017; Matheson et al., 2005; Pruitt et al., 1996b, 1991; Sanders et al., 1997; Takeuchi et al., 2017, 2011, 2010; Tran et al., 2002; Viinikainen et al., 2009; Williams and Amis, 1995).

There are almost as many testing setups as there are studies. Thus, it is essential to know some attributes according to the testing setup. The distraction rate can be determined as the frequency of the peak loads or as actual speed. If frequency is used, the gauge length (distance between the grips in which the tendon is placed) determines the actual distraction rate. Usually, preload is used to simulate static forces in tendon material. Moreover, peak load and cycle count are essential attributes during testing.

The gauge length used has only been reported in recent studies, and it varies between 30 mm and 60 mm (Haddad et al., 2010b, 2010a; Hausmann et al., 2009; Jordan et al., 2015a, 2015c, 2015b, Kozono et al., 2017, 2016; Peltz et al., 2014; Tahmassebi et al., 2015; Takeuchi et al., 2017, 2011; Viinikainen et al., 2009; Wieskötter et al., 2018; Wit et al., 2013; Wu and Tang, 2014b), with the exception of Takeuchi et al's (2010) 120 mm. The frequency of the peak loads has been reported in most of the studies, and it varies from 0.2 Hz to 2 Hz (Aoki et al., 1994; Barrie et al., 2001, 2000a; Corradi et al., 2010; Ditsios et al., 2002; Gil et al., 2016; Haddad et al., 2010b, 2010a; Kang et al., 2018; Matheson et al., 2005; Mishra et al., 2003; Peltz et al., 2014; Pruitt et al., 1996b, 1991; Sanders et al., 1997; Tahmassebi et al., 2015; Tran et al., 2002; Wolfe et al., 2007). In other studies, the distraction rate has been determined to be from 20 mm to 300 mm/min (Bhatia et al., 1992; Hausmann et al., 2009; Jordan et al., 2015a, 2015c, 2015b, Kozono et al., 2017, 2016, Takeuchi et al., 2017, 2011, 2010; Viinikainen et al., 2009; Wieskötter et al., 2018; Williams and Amis, 1995; Wu and Tang, 2014b). When the frequency is determined, both FDP flexion amplitude (11.8 mm, Sapienza et al. (2013)) and finger flexion time (empirically two seconds) should be considered.

The applied preload has been reported to be 0.5 N to 5 N (Barrie et al., 2001, 2000a; Corradi et al., 2010; Ditsios et al., 2002; Gibbons et al., 2009; Gil et al., 2016; Haddad et al., 2010b, 2010a; Hausmann et al., 2009; Jordan et al., 2015b, 2015a; Kang et al., 2018; Kozono et al., 2017, 2016; Matheson et al., 2005; Mishra et al., 2003; Peltz et al., 2014; Sanders et al., 1997; Tahmassebi et al., 2015; Takeuchi et al., 2017, 2011, 2010; Wieskötter et al., 2018; Wit et al., 2013; Wolfe et al., 2007; Wu and Tang, 2014b). In some studies, the preload has been stated to be 0 N, or it has not been reported (Aoki et al., 1994; Bhatia et al., 1992; Gibbons et al., 2009; Jordan et al., 2015c; Pruitt et al., 1996b, 1991; Tran et al., 2002; Viinikainen et al., 2009; Williams and Amis, 1995).

In studies with a single peak load, the load has varied between 2.5 N and 78.4 N (Aoki et al., 1994; Bhatia et al., 1992; Corradi et al., 2010; Ditsios et al., 2002; Gibbons et al., 2009; Haddad et al., 2010a, 2010b; Hausmann et al., 2009; Mishra et al., 2003; Peltz et al., 2014; Pruitt et al., 1996b, 1991; Tahmassebi et al., 2015; Tran et al., 2002; Wieskötter et al., 2018; Wu and Tang, 2014b). However, the peak load has usually been 30 N or less. In these studies, the cycle count has been between 250 and 6 000 with some exceptions of below 20 and 40 000 or until failure.

If the study was performed using incremental loads, the initial load has varied between 5 N and 40 N (Barrie et al., 2001, 2000a; Corradi et al., 2010; Gil et al., 2016; Jordan et al., 2015c, 2015a, 2015b; Kang et al., 2018; Kozono et al., 2017, 2016; Matheson et al., 2005; Sanders et al., 1997; Takeuchi et al., 2017, 2011, 2010; Viinikainen et al., 2009; Williams and Amis, 1995; Wit et al., 2013; Wolfe et al., 2007). The variation in cycle number with initial load is huge ranging from 5 up to 8 000 cycles. However, a typical count is 400 or more. In some of these studies, the number of increments has not been restricted in the study design (Kozono et al., 2017, 2016; Sanders et al., 1997; Takeuchi et al., 2017, 2011, 2010; Viinikainen et al., 2009; Williams and Amis, 1995; Wit et al., 2013), whereas elsewhere the final load has varied between 33 N and 90 N (Barrie et al., 2001, 2000a; Corradi et al., 2010; Gil et al., 2016; Jordan et al., 2015c, 2015a, 2015b; Kang et al., 2018; Matheson et al., 2005; Wolfe et al., 2007). Typically, increments of 5 N to 10 N have been used. The cycle count of the increments mostly varies between 400 and 4 000 cycles. In one study, the amount of increment and the cycle count were designed to be more or less uneven (Corradi et al., 2010).

In summary, the study designs for linear cyclic studies are anything but established. This concern was already being articulated nearly ten years ago (Hausmann et al., 2009), but a lack of consistency remains.

Due to it being a more complex testing method, there are no objective parameters to define at the cycle-displacement curves, such as the stiffness, yield load, and ultimate load for the load-displacement curve of static testing. Haddad et al. (2010a) observed a significant correlation between actual gap and the cycle-displacement curve, especially within 10 to 10 000 cycles. During the first 10 cycles, there was a huge increase in deformation despite the absence of a gap. Additionally, 90% of gapping occurred during the first 200 or 500 cycles for core repair or core and peripheral repair, respectively. They concluded, however, that the direct detection of gap, e.g., from recorded video, remained preferable.

Only in a proportion of cyclic studies have gaps been measured using recorded video (Kang et al., 2018; Kozono et al., 2017, 2016; Mishra et al., 2003; Takeuchi et al., 2017, 2011, 2010; Tran et al., 2002; Viinikainen et al., 2009; Wit et al., 2013; Wu and Tang, 2014b) or photographs taken during testing (Haddad et al., 2010a, 2010b; Peltz et al., 2014; Tahmassebi et al., 2015; Wolfe et al., 2007). In many studies, a strain gauge displacement sensor has been used (Aoki et al., 1994; Barrie et al., 2000a; Corradi et al., 2010; Pruitt et al., 1996b, 1991; Sanders et al., 1997). Ditsios et al. (2002) used glued markers and an infrared camera, and some researchers paused testing to measure the gap (Hausmann et al., 2009; Matheson et al., 2005; Williams and Amis, 1995). Nevertheless, the measuring method is an important factor when evaluating if gap values are comparable or not. Moreover, only some of the studies considered the morphology of gap formation (e.g., partial and total gap) (Haddad et al., 2010b; Tahmassebi et al., 2015; Viinikainen et al., 2009; Wu and Tang, 2014b), and usually only the largest part of the gap was measured.

The essential limitation of static and cyclic testing methods is that they do not consider adjacent tissues, such as tendon sheath and pulleys, not to mention biological healing. However, due to the good availability of surrogate animal tendons and the ease of execution, it is easy to test newly-developed suture materials or repair configurations and to compare existing repairs.

Table 2. Linear cyclic testing studies made with a single peak load.

Core technique	Str	Core suture	Peripheral technique	Peripheral suture	S. no	Surrogate	Gauge length (mm)	Freq (Hz)	Distraction rate (mm/min)	Pre-load (N)	Peak load (N)	Target cycles	Number of ruptured	Achieved cycles Mean	Achieved cycles SD	Gap (mm) At (cycles)	Gap (mm) Mean	Gap (mm) SD	Load-to-failure
Aoki et al., 1994																			
modified Kessler	2	4-0 bpe	simple running	6-0 pp	7	cadaver	N/A	0.67	-	N/A	9.8	40000	3	37282	17318	40000	0.8	0.1	No
Becker	-	6-0 pp	-	-	6	cadaver	N/A	0.67	-	N/A	9.8	40000	1	36552	17710	40000	0.8	0.4	No
Savage	6	4-0 bpe	simple running	6-0 pp	6	cadaver	N/A	0.67	-	N/A	9.8	40000	0	43538	1851	40000	0.7	0.3	No
tendon splint (internal)	-	4-0 bpe	simple running	6-0 pp	7	cadaver	N/A	0.67	-	N/A	9.8	40000	0	45434	4559	40000	0.8	0.3	No
tendon splint (dorsal)	-	4-0 bpe	simple running	6-0 pp	6	cadaver	N/A	0.67	-	N/A	9.8	40000	0	45866	2852	40000	0.7	0.1	No
Bhatia et al., 1992																			
Kessler	2	4-0 bpe	-	-	7	cad. (fresh)	N/A	-	60	N/A	20	10	N/A	N/A	N/A	N/A	N/A	N/A	Yes
Kessler	2	4-0 bpe	-	-	5	cad. (frozen)	N/A	-	60	N/A	20	10	N/A	N/A	N/A	N/A	N/A	N/A	Yes
Kessler	2	2-0 bpe	-	-	5	cad. (fresh)	N/A	-	60	N/A	20	10	N/A	N/A	N/A	N/A	N/A	N/A	Yes
Kirchmayr	2	4-0 bpe	-	-	10	cad. (frozen)	N/A	-	60	N/A	20	10	N/A	N/A	N/A	N/A	N/A	N/A	Yes
Kirchmayr	2	4-0 bpe	-	-	4	cad. (fresh)	N/A	-	60	N/A	20	10	N/A	N/A	N/A	N/A	N/A	N/A	Yes
Kirchmayr	2	2-0 bpe	-	-	4	cad. (frozen)	N/A	-	60	N/A	20	10	N/A	N/A	N/A	N/A	N/A	N/A	Yes
Corradi et al., 2010																			
Staggered	4	3-0 pa	simple running	5-0 pa	10	cadaver	N/A	0.5	-	2	40	2500	0	2500	0	2500	1.37	0.09	No
Ditsios et al., 2002																			
modified Kessler	4	4-0 pa	simple running	6-0 pp	16	dog	N/A	2	-	0.5	5	6000	0	6000	0	N/A	0	0	Yes
modified Kessler	4	4-0 pa	simple running	6-0 pp	16	dog	N/A	2	-	0.5	17	6000	0	6000	0	N/A	0	0	Yes
Gibbons et al., 2009																			
Adelaide	4	3-0 bpe	-	-	15	porcine	N/A	N/A	N/A	1	10	10	0	10	0	-	N/A	N/A	Yes
Haddad et al., 2010a																			
modified Kessler	2	4-0 bpe+c	simple running	6-0 pp	4	sheep	35	0.4	-	2	20	1000	0	1000	0	1000	1.67	0.78	No
modified Kessler	2	4-0 bpe+c	-	-	4	sheep	35	0.4	-	2	20	1000	1	824	353	1000	10	1.99	No
Adelaide	4	4-0 bpe+c	simple running	6-0 pp	4	sheep	35	0.4	-	3	30	1000	0	1000	0	1000	1.91	0.2	No
Adelaide	4	4-0 bpe+c	-	-	4	sheep	35	0.4	-	3	30	1000	0	1000	0	1000	6.61	1.87	No

Str, Strand number; S. no, Sample number; Freq, Frequency; mod., modified; s., simple; cad., cadaver; p.lac., partially lacerated; N/A, Not available

Suture materials: bpe, braided polyester; pp, monofilament polypropylene; pa, polyamide; bpe+c, silicone coated braided polyester; bgc, barbed glycolic carbonate; s, silk; pds, polydioxanone

Table 2 (continued). Linear cyclic testing studies made with a single peak load.

Core technique	Str	Core suture	Peripheral technique	Peripheral suture	S. no	Surrogate	Gauge length (mm)	Freq (Hz)	Distraction rate (mm/min)	Pre-load (N)	Peak load (N)	Target cycles	Number of ruptured	Achieved cycles Mean	Achieved cycles SD	Gap (mm) At (cycles)	Gap (mm) Mean	Gap (mm) SD	Load-to-failure
Haddad et al., 2010b																			
-	-	-	simple running	6-0 pp	8	sheep (p.lac.)	35	0.2	-	3	30	500	N/A	N/A	N/A	500	1.0	0.41	Yes
modified Kessler	2	4-0 bpe+c	simple running	6-0 pp	8	sheep (p.lac.)	35	0.2	-	3	30	500	N/A	N/A	N/A	500	1.0	0.12	Yes
Hausmann et al., 2009																			
modified Kessler 2	2	3-0 bpe+c	-	-	10	sheep	50	-	60	1	15	3000	0	3000	0	3000	7.42	1.57	Yes
modified Kessler 2	2	3-0 bpe+c	-	-	10	calf	50	-	60	1	15	3000	0	3000	0	3000	7.16	1.66	Yes
modified Kessler 2	2	3-0 bpe+c	-	-	10	pig	50	-	60	1	15	3000	0	3000	0	3000	4.94	2.11	Yes
modified Kessler 2	2	3-0 bpe+c	-	-	10	cadaver	50	-	60	1	15	3000	0	3000	0	3000	7.4	2.22	Yes
-	-	-	deep running	5-0 pa	10	sheep	50	-	60	1	15	3000	0	3000	0	3000	0.15	0.34	Yes
-	-	-	deep running	5-0 pa	10	calf	50	-	60	1	15	3000	0	3000	0	3000	0.65	0.97	Yes
-	-	-	deep running	5-0 pa	10	pig	50	-	60	1	15	3000	0	3000	0	3000	0.3	0.42	Yes
-	-	-	deep running	5-0 pa	10	cadaver	50	-	60	1	15	3000	0	3000	0	3000	0.25	0.35	Yes
Mishra et al., 2003																			
Kessler	2	3-0 pa	simple running	6-0 pa	5	pig	N/A	1	-	2	20	3000	3	N/A	N/A	3000	0.5	N/A	Yes
Kessler	2	3-0 pa	cross-stitch	6-0 pa	5	pig	N/A	1	-	2	20	3000	1	N/A	N/A	3000	0.8	N/A	Yes
Kessler	2	3-0 pa	Halsted	6-0 pa	5	pig	N/A	1	-	2	20	3000	2	N/A	N/A	3000	0.3	N/A	Yes
Kessler	2	3-0 bpe	simple running	6-0 pa	5	pig	N/A	1	-	2	20	3000	0	3000	0	3000	1	N/A	Yes
Kessler	2	3-0 bpe	cross-stitch	6-0 pa	5	pig	N/A	1	-	2	20	3000	0	3000	0	3000	0.4	N/A	Yes
Kessler	2	3-0 bpe	Halsted	6-0 pa	5	pig	N/A	1	-	2	20	3000	0	3000	0	3000	0.4	N/A	Yes
Peltz et al., 2014																			
authors own	4	3-0 bgc	-	-	15	sheep	40	1		3	30	250	N/A	N/A	N/A	102.5	2	-	Yes
Adelaide	4	3-0 bpe+c	-	-	15	sheep	40	1		3	30	250	N/A	N/A	N/A	24.4	2	-	Yes
authors own	4	3-0 bpe+c	-	-	10	sheep	40	1		3	30	250	N/A	N/A	N/A	4.7	2	-	Yes
Pruitt et al., 1991																			
Bunnell	2	3-0 s	-	-	2	cadaver	N/A	0.67	-	N/A	4.9	40000	0	N/A	N/A	40000	3.1	1.2	No
Bunnell	2	3-0 s	simple running	6-0 pp	3	cadaver	N/A	0.67	-	N/A	4.9	40000	0	N/A	N/A	40000	0.7	0.1	No
Tsuge	2	3-0 s	-	-	3	cadaver	N/A	0.67	-	N/A	4.9	40000	0	N/A	N/A	40000	3.2	0.2	No
Tsuge	2	3-0 s	simple running	6-0 pp	3	cadaver	N/A	0.67	-	N/A	4.9	40000	0	N/A	N/A	40000	0.9	0.2	No
modified Kessler	2	3-0 s	-	-	2	cadaver	N/A	0.67	-	N/A	4.9	40000	0	N/A	N/A	40000	1.9	0.5	No
modified Kessler	2	3-0 s	simple running	6-0 pp	3	cadaver	N/A	0.67	-	N/A	4.9	40000	0	N/A	N/A	40000	0.5	0.1	No

Ketchum	2	3-0 s	-	-	2	cadaver	N/A	0.67	-	N/A	4.9	40000	0	N/A	N/A	40000	3.2	0.1	No
Ketchum	2	3-0 s	simple running	6-0 pp	3	cadaver	N/A	0.67	-	N/A	4.9	40000	0	N/A	N/A	40000	0.5	0.2	No
Bunnell	2	3-0 s	-	-	4	cadaver	N/A	0.67	-	N/A	9.81	40000	0	N/A	N/A	40000	3.5	1.1	No
Bunnell	2	3-0 s	simple running	6-0 pp	3	cadaver	N/A	0.67	-	N/A	9.81	40000	0	N/A	N/A	40000	1.2	0.4	No
Tsuge	2	3-0 s	-	-	3	cadaver	N/A	0.67	-	N/A	9.81	40000	0	N/A	N/A	40000	3.6	0.8	No
Tsuge	2	3-0 s	simple running	6-0 pp	3	cadaver	N/A	0.67	-	N/A	9.81	40000	0	N/A	N/A	40000	1.0	0.2	No
modified Kessler	2	3-0 s	-	-	6	cadaver	N/A	0.67	-	N/A	9.81	40000	0	N/A	N/A	40000	1.8	1	No
modified Kessler	2	3-0 s	simple running	6-0 pp	5	cadaver	N/A	0.67	-	N/A	9.81	40000	0	N/A	N/A	40000	1.1	0.6	No
Ketchum	2	3-0 s	-	-	3	cadaver	N/A	0.67	-	N/A	9.81	40000	0	N/A	N/A	40000	3.4	1.2	No
Ketchum	2	3-0 s	simple running	6-0 pp	3	cadaver	N/A	0.67	-	N/A	9.81	40000	0	N/A	N/A	40000	0.3	0.3	No
Pruitt et al., 1996b																			
modified Kessler	2	4-0 bpe+c	simple running	7-0 pp	55	dog	N/A	0.67	-	N/A	2.5	40000	N/A	N/A	N/A	40000	0.75	0.17	No
Tahmassebi et al., 2015																			
Adelaide	4	3-0 bpe+c	-	-	12	sheep	40	1	-	3	30	250	N/A	N/A	N/A	250	3.95	N/A	Yes
interlocking Adelaide	4	3-0 bpe+c	-	-	12	sheep	40	1	-	3	30	250	N/A	N/A	N/A	250	3.8	N/A	Yes
Tran et al., 2002																			
Tajima	2	3-0 bpe	locking running	6-0 pp	7	cadaver	N/A	0.25	-	N/A	78.4	5000	7	2	2	N/A	N/A	N/A	No
Tajima	2	3-0 bpe	Silfverskiöld	6-0 pp	7	cadaver	N/A	0.25	-	N/A	78.4	5000	7	560	987	N/A	N/A	N/A	No
Tajima (horiz. mattress)	4	3-0 bpe	locking running	6-0 pp	7	cadaver	N/A	0.25	-	N/A	78.4	5000	7	304	249	N/A	N/A	N/A	No
Tajima (horiz. mattress)	4	3-0 bpe	Silfverskiöld	6-0 pp	7	cadaver	N/A	0.25	-	N/A	78.4	5000	0	5000	0	N/A	N/A	N/A	No
Wieskötter et al., 2018																			
-	-	-	s. running (1 mm)	6-0 pds	12	porcine	30	-	25	1	5	1000	3	N/A	N/A	N/A	N/A	N/A	Yes
-	-	-	s. running (2 mm)	6-0 pds	12	porcine	30	-	25	1	5	1000	2	N/A	N/A	N/A	N/A	N/A	Yes
-	-	-	s. running (3 mm)	6-0 pds	12	porcine	30	-	25	1	5	1000	2	N/A	N/A	N/A	N/A	N/A	Yes
-	-	-	locking running	6-0 pds	12	porcine	30	-	25	1	5	1000	3	N/A	N/A	N/A	N/A	N/A	Yes
-	-	-	Lembert-mattress	6-0 pds	12	porcine	30	-	25	1	5	1000	0	N/A	N/A	N/A	N/A	N/A	Yes
-	-	-	Halsted	6-0 pds	12	porcine	30	-	25	1	5	1000	0	N/A	N/A	N/A	N/A	N/A	Yes
-	-	-	Silfverskiöld	6-0 pds	12	porcine	30	-	25	1	5	1000	0	N/A	N/A	N/A	N/A	N/A	Yes
-	-	-	lin-locking	6-0 pds	12	porcine	30	-	25	1	5	1000	1	N/A	N/A	N/A	N/A	N/A	Yes
Wu and Tang, 2014																			
mod. Kessler (10 mm)	4	4-0 pa	simple running	6-0 pa	18	porcine	50	-	25	1	15	20	N/A	N/A	N/A	N/A	N/A	N/A	Yes
mod. Kessler (asymm.)	4	4-0 pa	simple running	6-0 pa	18	porcine	50	-	25	1	15	20	N/A	N/A	N/A	N/A	N/A	N/A	Yes
mod. Kessler (12 mm)	4	4-0 pa	simple running	6-0 pa	18	porcine	50	-	25	1	15	20	N/A	N/A	N/A	N/A	N/A	N/A	Yes

Str, Strand number; S. no, Sample number; Freq, Frequency; mod., modified; s., simple; cad., cadaver; p.lac., partially lacerated; N/A, Not available

Suture materials: bpe, braided polyester; pp, monofilament polypropylene; pa, polyamide; bpe+c, silicone coated braided polyester; bgc, barbed glycolic carbonate; s, silk; pds, polydioxanone

Table 3. Linear cyclic testing studies made with incremental loads.

Core technique	Str	Core suture	Peripheral technique	Periph. suture	S. no	Surrogate	Gaug. length (mm)	Freq (Hz)	Distr. r. (mm/min)	Pre-load (N)	Initial load (N)	Cycl.	Increments (N)	Cycles/increment	Last load (N)	Rupture no	Achieved load (N) Mean	SD	Achieved cycles Mean	SD	Load (N) x cycles x 10E3 Mean	SD	Gapping (mm) At (c.)	Mean	SD	Load-to-failure
Barrie et al., 2000a																										
not specified (nonl.	4	4-0 bpe	l. running	6-0 pa	10	cadaver	N/A	0.5	-	3	25	8000	10	4000	65	10	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	No
not specified (lock)	4	4-0 bpe	l. running	6-0 pa	10	cadaver	N/A	0.5	-	3	25	8000	10	4000	65	10	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	No
not specified (nonl.	8	4-0 bpe	l. running	6-0 pa	10	cadaver	N/A	0.5	-	3	25	8000	10	4000	65	10	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	No
not specified (lock)	8	4-0 bpe	l. running	6-0 pa	10	cadaver	N/A	0.5	-	3	25	8000	10	4000	65	6	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	No
Barrie et al., 2001																										
m. Kessler (lock)	2	3-0 bpe	l. running	6-0 pa	10	cadaver	N/A	0.5	-	3	25	8000	10	4000	85	10	48	8	13793	3195	429	146	N/A	N/A	N/A	No
m. Kessler (lock)	2	4-0 bpe	l. running	6-0 pa	10	cadaver	N/A	0.5	-	3	25	8000	10	4000	85	10	32	9	6283	5675	177	169	N/A	N/A	N/A	No
m. Kessler (nonl.)	2	3-0 bpe	l. running	6-0 pa	10	cadaver	N/A	0.5	-	3	25	8000	10	4000	85	10	47	6	13925	2840	433	122	N/A	N/A	N/A	No
m. Kessler (nonl.)	2	4-0 bpe	l. running	6-0 pa	10	cadaver	N/A	0.5	-	3	25	8000	10	4000	85	10	31	7	4872	4790	128	129	N/A	N/A	N/A	No
m. Kessler (cr-l.)	2	3-0 bpe	l. running	6-0 pa	10	cadaver	N/A	0.5	-	3	25	8000	10	4000	85	10	50	7	14629	2992	466	148	N/A	N/A	N/A	No
m. Kessler (cr-l.)	2	4-0 bpe	l. running	6-0 pa	10	cadaver	N/A	0.5	-	3	25	8000	10	4000	85	10	29	7	5256	3919	136	108	N/A	N/A	N/A	No
Cruciate (lock)	4	3-0 bpe	l. running	6-0 pa	10	cadaver	N/A	0.5	-	3	25	8000	10	4000	85	10	65	11	21182	4141	834	251	N/A	N/A	N/A	No
Cruciate (lock)	4	4-0 bpe	l. running	6-0 pa	10	cadaver	N/A	0.5	-	3	25	8000	10	4000	85	10	49	13	14578	5361	486	270	N/A	N/A	N/A	No
Cruciate (nonlock)	4	3-0 bpe	l. running	6-0 pa	10	cadaver	N/A	0.5	-	3	25	8000	10	4000	85	10	65	8	20938	3190	811	196	N/A	N/A	N/A	No
Cruciate (nonlock)	4	4-0 bpe	l. running	6-0 pa	10	cadaver	N/A	0.5	-	3	25	8000	10	4000	85	10	46	12	13767	5169	447	220	N/A	N/A	N/A	No
Cruciate (cr-l.)	4	3-0 bpe	l. running	6-0 pa	10	cadaver	N/A	0.5	-	3	25	8000	10	4000	85	10	78	5	27131	1942	124	150	N/A	N/A	N/A	No
Cruciate (cr-l.)	4	4-0 bpe	l. running	6-0 pa	10	cadaver	N/A	0.5	-	3	25	8000	10	4000	85	10	50	8	14888	3188	480	153	N/A	N/A	N/A	No
Corradi et al., 2010																										
Staggered	4	3-0 pa	s. running	5-0 pa	10	cadaver	N/A	0.5	-	2	40	1000	15-23-12	250-250-300	90	N/A	N/A	N/A	N/A	N/A	N/A	N/A	1800	5.6	0.08	No
Gil et al., 2016																										
modified Kessler (1-knot)	4	3-0 lpa	-	-	7	cadaver	N/A	1	-	2	22	100	11	100	55	7	31	5	135	66	N/A	N/A	N/A	N/A	N/A	No
modified Kessler (2-knot)	4	3-0 lpa	-	-	8	cadaver	N/A	1	-	2	22	100	11	100	55	8	33	29	94	107	N/A	N/A	N/A	N/A	N/A	No
Jordan et al., 2015a																										
m. Kessler (knot)	4	3-0 pds	-	-	10	porcine	30	-	20	3	15	15	5	500	20	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Yes

Bunnell (knot)	4	3-0 pds	-	-	10	porcine	30	-	20	3	15	15	5	500	20	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Yes
Bunnell (knotless)	4	3-0 bpds	-	-	10	porcine	30	-	20	3	15	15	5	500	20	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Yes
Bunnell (knotless)	4	3-0 bpds	not spec.	4-0 bpds	10	porcine	30	-	20	3	15	15	5	500	20	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Yes
Jordan et al., 2015b																										
Kessler (locking)	4	3-0 pds	s. running	5-0 pds	10	porcine	30	-	20	3	10	400	10	400	30	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	No
Kessler (locking)	4	3-0 pds	glue	bds-ga	10	porcine	30	-	20	3	10	400	10	400	30	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	No
Kessler (locking)	4	3-0 pds	s. running + glue	5-0 pds + bds-ga	10	porcine	30	-	20	3	10	400	10	400	30	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	No
Jordan et al., 2015c																										
modified Kessler	4	3-0 pds	l. running	5-0 pds	12	porcine	30	-	20	N/A	10	400	10	400	30	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	No
Lahey	4	3-0 pds	l. running	5-0 pds	12	porcine	30	-	20	N/A	10	400	10	400	30	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	No
Adelaide	4	3-0 pds	l. running	5-0 pds	12	porcine	30	-	20	N/A	10	400	10	400	30	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	No
Becker/MGH	4	3-0 pds	l. running	5-0 pds	12	porcine	30	-	20	N/A	10	400	10	400	30	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	No
Kang et al., 2018																										
Lim-Tsai	6	4-0 lpa	s. running	6-0 pa	10	porcine	30	1	-	2	20	500	13	500	33	10	N/A	N/A	N/A	N/A	N/A	N/A	1000	4.15	N/A	No
Tang	6	4-0 lpa	s. running	6-0 pa	10	porcine	30	1	-	2	20	500	13	500	33	2	N/A	N/A	N/A	N/A	N/A	N/A	1000	1.09	N/A	No
Kozono et al., 2016																										
modified Kessler (symm.)	6	4-0 pp	IHM	6-0 pp	10	dental roll	60	-	300	2	10	500	5	500	-	10	N/A	N/A	N/A	N/A	N/A	N/A	1500	1.9	0.3	No
modified Kessler (asymm. 1 mm)	6	4-0 pp	IHM	6-0 pp	10	dental roll	60	-	300	2	10	500	5	500	-	10	N/A	N/A	N/A	N/A	N/A	N/A	1500	1.8	0.2	No
modified Kessler (asymm. 2 mm)	6	4-0 pp	IHM	6-0 pp	10	dental roll	60	-	300	2	10	500	5	500	-	10	N/A	N/A	N/A	N/A	N/A	N/A	1500	1.6	0.3	No
modified Kessler (asymm. 3 mm)	6	4-0 pp	IHM	6-0 pp	10	dental roll	60	-	300	2	10	500	5	500	-	10	N/A	N/A	N/A	N/A	N/A	N/A	1500	1.4	0.2	No
modified Kessler (asymm. 4 mm)	6	4-0 pp	IHM	6-0 pp	10	dental roll	60	-	300	2	10	500	5	500	-	10	N/A	N/A	N/A	N/A	N/A	N/A	1500	1.5	0.2	No
modified Kessler (asymm. 5 mm)	6	4-0 pp	IHM	6-0 pp	10	dental roll	60	-	300	2	10	500	5	500	-	10	N/A	N/A	N/A	N/A	N/A	N/A	1500	1.4	0.2	No

Str, Strand number; Periph., Peripheral; S. no, Sample number; Gaug., Gauge; Freq, Frequency; Distr. r., Distraction rate; Cycl., c., Cycles; nonl., non-lock; cr-l., cross-lock; m., modified; symm., symmetric; asymm., asymmetric; l., locking; s., simple; not spec., not specified; N/A, Not available

Suture materials: bpe, braided polyester; pa, polyamide; lpa, looped polyamide; pds, polydioxanone; bpds, barbed polydioxanone; pp, polypropylene; pldla, copolymer of L/D lactid acid; bpe+c, silicone coated braided polyester; bds-ga, purified bovine serum albumin and glutaraldehyde glue

Table 3 (continued). Linear cyclic testing studies made with incremental loads.

Core technique	Str	Core suture	Peripheral technique	Periph. suture	S. no	Surrogate	Gaug. length (mm)	Freq (Hz)	Distr. r. (mm/min)	Pre-load (N)	Initial load (N)	Cycl.	Increments (N)	Cycles/increment	Last load (N)	Rupture no	Achieved load (N) Mean	SD	Achieved cycles Mean	SD	Load (N) x cycles x 10E3 Mean	SD	Gapping (mm) At (c.)	Mean	SD	Load-to-failure
modified Kessler (asymm. 1 mm)	6	4-0 pp	IHM	6-0 pp	10	porcine	40	-	300	2	10	500	5	500	-	10	N/A	N/A	N/A	N/A	N/A	N/A	6500	6.6	1.0	No
modified Kessler (asymm. 3 mm)	6	4-0 pp	IHM	6-0 pp	10	porcine	40	-	300	2	10	500	5	500	-	10	N/A	N/A	N/A	N/A	N/A	N/A	6500	5.1	0.8	No
modified Kessler (asymm. 5 mm)	6	4-0 pp	IHM	6-0 pp	10	porcine	40	-	300	2	10	500	5	500	-	10	N/A	N/A	N/A	N/A	N/A	N/A	6500	4.9	1.0	No
Kozono et al., 2017																										
modified Kessler (symm.)	6	4-0 pp	IHM	6-0 pp	10	porcine	40	-	300	2	10	500	5	500	-	10	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	No
modified Kessler (asymm. 1 mm)	6	4-0 pp	IHM	6-0 pp	10	porcine	40	-	300	2	10	500	5	500	-	10	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	No
modified Kessler (asymm. 2 mm)	6	4-0 pp	IHM	6-0 pp	10	porcine	40	-	300	2	10	500	5	500	-	10	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	No
modified Kessler (asymm. 3 mm)	6	4-0 pp	IHM	6-0 pp	10	porcine	40	-	300	2	10	500	5	500	-	10	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	No
modified Kessler (asymm. 4 mm)	6	4-0 pp	IHM	6-0 pp	10	porcine	40	-	300	2	10	500	5	500	-	10	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	No
modified Kessler (asymm. 5 mm)	6	4-0 pp	IHM	6-0 pp	10	porcine	40	-	300	2	10	500	5	500	-	10	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	No
Matheson et al., 2005																										
modified Kessler	2	4-0 pp	s. running	6-0 pp	10	cadaver	N/A	0.1	-	2	20	500	13	500	33	1	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	No
modified Kessler	2	4-0 pp	Silfverskiöld	6-0 pp	10	cadaver	N/A	0.1	-	2	20	500	13	500	33	9	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	No
Savage	4	4-0 pp	s. running	6-0 pp	10	cadaver	N/A	0.1	-	2	20	500	13	500	33	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	No
Sanders et al., 1997																										
modified Kessler	2	4-0 bpe	s. running	6-0 pa	10	cadaver	N/A	1	-	5	25	4000	10	4000	-	10	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	No
modified Kessler	2	4-0 bpe	Halsted	6-0 pa	10	cadaver	N/A	1	-	5	25	4000	10	4000	-	10	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	No
Savage	6	4-0 bpe	s. running	6-0 pa	10	cadaver	N/A	1	-	5	25	4000	10	4000	-	3	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	No
modified Kessler	2	4-0 bpe	Silfverskiöld	6-0 pa	10	cadaver	N/A	1	-	5	25	4000	10	4000	-	10	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	No

Takeuchi et al., 2010																										
-	-	-	s. running	6-0 pp	10	dental roll	120	1	60	2	5	500	5	500	-	10	N/A	N/A	N/A	N/A	9	2	1500	2.6	0.3	No
-	-	-	Silfverskiöld	6-0 pp	10	dental roll	120	1	60	2	5	500	5	500	-	10	N/A	N/A	N/A	N/A	1	2	1500	2.8	0.2	No
-	-	-	IHM	6-0 pp	10	dental roll	120	1	60	2	5	500	5	500	-	10	N/A	N/A	N/A	N/A	19	4	1500	2.6	0.1	No
Takeuchi et al., 2011																										
Pennington mod. Kessler	6	4-0 pp	s. running	6-0 pp	10	artificial roll	60	-	300	2	10	500	5	500	-	10	N/A	N/A	2008	410	36	11	N/A	N/A	N/A	No
Pennington mod. Kessler	6	4-0 pp	IHM 1/2	6-0 pp	10	artificial roll	60	-	300	2	10	500	5	500	-	10	N/A	N/A	2041	367	37	10	N/A	N/A	N/A	No
Pennington mod. Kessler	6	4-0 pp	IHM 3/4	6-0 pp	10	artificial roll	60	-	300	2	10	500	5	500	-	10	N/A	N/A	2464	251	49	8	N/A	N/A	N/A	No
Pennington mod. Kessler	6	4-0 pp	IHM 3/4 + s. running	6-0 pp	10	artificial roll	60	-	300	2	10	500	5	500	-	10	N/A	N/A	2612	283	54	10	N/A	N/A	N/A	No
Pennington mod. Kessler	6	4-0 pp	IHM	6-0 pp	10	artificial roll	60	-	300	2	10	500	5	500	-	10	N/A	N/A	2682	268	57	9	N/A	N/A	N/A	No
Taukechi et al., 2017																										
-	-	-	s. running	6-0 pa	12	porcine	40	-	300	2	10	500	10	500	-	12	N/A	N/A	1336	322	24	9	1500	2.0	0.8	No
-	-	-	asymm. running 1	6-0 pa	12	porcine	40	-	300	2	10	500	10	500	-	12	N/A	N/A	909	331	13	8	1500	1.5	0.4	No
-	-	-	asymm. running 2	6-0 pa	12	porcine	40	-	300	2	10	500	10	500	-	12	N/A	N/A	767	250	10	5	1500	2.5	0.7	No
Viinikainen et al., 2009																										
Pennington mod. Kessler	6	pldla	s. running	6-0 pp	10	porcine	35	-	90-120-135-135	0	35	4000	10	4000	3 mm gap	N/A	N/A	N/A	N/A	N/A	374	N/A	N/A	N/A	N/A	No
Savage	6	4-0 bpe+c	simple running	6-0 pp	10	porcine	35	-	90-120-135-135	0	35	4000	10	4000	3 mm gap	N/A	N/A	N/A	N/A	N/A	241	N/A	N/A	N/A	N/A	No
Williams and Amis, 1995																										
-	-	-	deep biting	5-0 pp	10	cadaver	N/A	-	20	N/A	10	10	5-10	10	-	10	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	No
modified Kessler	2	4-0 pp	deep biting	5-0 pp	10	cadaver	N/A	-	20	N/A	10	10	5-10	10	-	10	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	No

Str, Strand number; Periph., Peripheral; S. no, Sample number; Gaug., Gauge; Freq, Frequency; Distr. r., Distraction rate; Cycl., c., Cycles; nonl., non-lock; cr-l., cross-lock; m., modified; symm., symmetric; asymm., asymmetric; l., locking; s., simple; not spec., not specified; N/A, Not available

Suture materials: bpe, braided polyester; pa, polyamide; lpa, looped polyamide; pds, polydioxanone; bpds, barbed polydioxanone; pp, polypropylene; pldla, copolymer of L/D lactid acid; bpe+c, silicone coated braided polyester; bds-ga, purified bovine serum albumin and glutaraldehyde glue

Table 3 (continued). Linear cyclic testing studies made with incremental loads.

Core technique	Str	Core suture	Peripheral technique	Periph. suture	S. no	Surro-gate	Gaug. length (mm)	Freq (Hz)	Distr. r. (mm/min)	Pre-load (N)	Initial load (N)	Cycl.	Incre-ments (N)	Cycles/incre-ment	Last load (N)	Rup-ture no	Achieved load (N)		Achieved cycles		Load (N) x cycles x 10E3		Gapping (mm)			Load-to-failure
																	Mean	SD	Mean	SD	Mean	SD	At (c.)	Mean	SD	
simple square	2	4-0 pp	deep biting	5-0 pp	10	cadaver	N/A	-	20	N/A	10	10	5-10	10	-	10	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	No
modified Kessler	2	4-0 pp	s. running	5-0 pp	10	cadaver	N/A	-	20	N/A	10	10	5-10	10	-	10	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	No
Wit et al., 2013																										
modified Kessler	2	3-0 pa	-	-	8	porcine	50	N/A	N/A	0.2	15	5	15	5	-	8	28.6	6.5	N/A	N/A	N/A	N/A	5	6.6	3.1	No
modified Kessler	4	3-0 pa	-	-	8	porcine	50	N/A	N/A	0.2	15	5	15	5	-	8	36.7	12	N/A	N/A	N/A	N/A	5	2.2	2.0	No
Cruciate	4	3-0 pa	-	-	8	porcine	50	N/A	N/A	0.2	15	5	15	5	-	8	45.5	13	N/A	N/A	N/A	N/A	5	1.0	0.3	No
modified Kessler	2	3-0 pa	s. running	5-0 pp	8	porcine	50	N/A	N/A	0.2	15	5	15	5	-	8	38.1	9.3	N/A	N/A	N/A	N/A	5	0.1	0.3	No
modified Kessler	4	3-0 pa	s. running	5-0 pp	8	porcine	50	N/A	N/A	0.2	15	5	15	5	-	8	57.9	7.4	N/A	N/A	N/A	N/A	5	0.0	0.0	No
Cruciate	4	3-0 pa	s. running	5-0 pp	8	porcine	50	N/A	N/A	0.2	15	5	15	5	-	8	56.3	15	N/A	N/A	N/A	N/A	5	0.0	0.0	No
Wolfe et al., 2007																										
Cruciate (locked)	4	3-0 bpe	s. running	6-0 pa	10	cadaver	N/A	2	-	2	25	8000	10	4000	65	3	N/A	N/A	N/A	N/A	790	250	N/A	N/A	N/A	Yes
modified Kessler	2	3-0 bpe	s. running	6-0 pa	10	cadaver	N/A	2	-	2	25	8000	10	4000	65	10	N/A	N/A	N/A	N/A	330	100	N/A	N/A	N/A	Yes
internal tendon repair device	-	-	s. running	6-0 pa	10	cadaver	N/A	2	-	2	25	8000	10	4000	65	10	N/A	N/A	N/A	N/A	370	130	N/A	N/A	N/A	Yes

Str, Strand number; Periph., Peripheral; S. no, Sample number; Gaug., Gauge; Freq, Frequency; Distr. r., Distraction rate; Cycl., c., Cycles; nonl., non-lock; cr-l., cross-lock; m., modified; symm., symmetric; asymm., asymmetric; l., locking; s., simple; not spec., not specified; N/A, Not available

Suture materials: bpe, braided polyester; pa, polyamide; lpa, looped polyamide; pds, polydioxanone; bpds, barbed polydioxanone; pp, polypropylene; pldla, copolymer of L/D lactid acid; bpe+c, silicone coated braided polyester; bds-ga, purified bovine serum albumin and glutaraldehyde glue

2.2.3.3 Curvilinear testing

In curvilinear testing, flexor tendons are not harvested but tested in their natural context. As with linear testing, curvilinear testing can also be accomplished with either static (Angeles et al., 2002; Barrie et al., 2000b; Komanduri et al., 1996; Stein et al., 1998) or cyclic loading (Alavanja et al., 2005; Angeles et al., 2002; Choueka et al., 2000; Moriya et al., 2010; Thurman et al., 1998). The main benefit of curvilinear testing is that adjacent tissues have an influence on the tendon repair during testing. For example, friction forces, caused by the bulk of the repair, and pinch forces can be measured. Additionally, curvilinear testing creates an excellent experimental environment for the comparison of repair methods. However, tendon healing and antagonistic muscle activity cannot be modelled.

2.2.4 Surrogates of human flexor tendons in experimental studies

Ideally, biomechanical testing of the flexor tendon repairs should be performed with human tendons. There are, however, availability and ethical problems in using human cadaver hands. Thus, tendons of many animals, such as pig, dog, sheep, calf, chicken, and rabbit, have been used as a surrogate. Mostly, porcine tendons have been used (Hausmann et al., 2009; Havulinna et al., 2011) because they have been evaluated to resemble human tendons sufficiently well (Cao et al., 2009; Havulinna et al., 2011; Mao et al., 2011; Smith et al., 2005). First, the anatomical structures of porcine tendons are similar (Mao et al., 2011; Smith et al., 2005). Second, biomechanical performance is also similar (Havulinna et al., 2011; Mao et al., 2011). Especially, the FDP-II tendon of porcine is observed to be a suitable surrogate despite its slightly smaller diameter (Havulinna et al., 2011). However, the diameter of the tendon has no remarkable effect on ultimate load or gapping within the tendons of human, pig, or sheep (Hausmann et al., 2009).

The tendons of sheep have been recommended instead of pig due to the higher gap resistance of pig tendon (Hausmann et al., 2009). Furthermore, the tendon of the hind-leg of rabbit has been recommended for use as an experimental model due to its similar vascularisation with human tendon (Jones et al., 2000).

Dental rolls have been recommended to be used in the training of new flexor repair techniques (Tare, 2004). Dental rolls have also been used as a surrogate material for human tendon in some experimental studies (Kozono et al., 2016; Takeuchi et al., 2011, 2010). The advantage of artificial material is its uniformity: it is easier to place stitches in a standardized manner (Takeuchi et al., 2011). Within tendons, there is always a biological variation between each sample.

2.2.5 Flexor tendon repair

A typical repair method comprises two parts: a thicker suture in the middle of the tendon ends that acts as a core suture and a thinner suture along the tendon surface between tendon ends acting as a peripheral suture. Globally, the spectrum of different repair methods is vast.

Lotz et al. (1998) created a biomechanical spring analogy to model tendon repair. They concluded that the biomechanical performance of the tendon repair comprises the sum of individual forces of the core and the peripheral suture. Based on their model, the core suture fails immediately after rupture of the peripheral suture due to the transfer of the total force to the core suture. Thus, it is significant that there is a balance in load-sharing between the core and the peripheral sutures.

In general, a repair should be strong enough to withstand the selected mobilisation program. In the FDP, forces of up to 10.6 N and 17.8 N can be achieved during passive and active rehabilitation movements, respectively, if all fingers are moved together (Edsfeldt et al., 2015). However, due to wound and oedema of the adjacent tissue, the safe load needed to keep the repair intact is unknown. Both core and peripheral suture material and calibre affect the strength of the repair. Furthermore, configuration of the repair is essential because the number of strands, placement of the repair and knot, shape of the repair, purchases of core and peripheral suture, and the locks used affect whether the repair withstands the rehabilitation (Wu and Tang, 2014a).

2.2.5.1 Core suture

In the basic procedure, tendon ends are placed against the core suture to make healing and scar formation possible. At present, there is no agreement as to whether some of the developed sutures are superior to others (Viinikainen et al., 2008). Furthermore, even the most popular configurations have been repeatedly modified, re-modified, and misnamed (Sebastin et al., 2013).

Also, experimental repair methods have been introduced. Gordon et al. (1998) developed a stainless steel internal anchor that had promising results with its high tensile strength. Additionally, a single-strand multifilament stainless steel device

(Teno Fix) has been evaluated as a substitute for the core suture (Su et al., 2005). However, the modern multi-strand core suture has remained the primary method.

Tang et al. (2013) collected information about current practice from several hand surgeon units in the United States, Canada, Switzerland, Italy, the United Kingdom, and China. They found that 4-strand, 6-strand, and 8-strand core sutures along with 3–0 or 4–0 threads were usually performed. The Kessler configuration and its modifications (Figure 5 (A)) were the most commonly used as core suture in addition to the Adelaide repair (Figure 5 (B)). Among peripheral sutures, the simple running suture was the most commonly used with 6–0 suture.

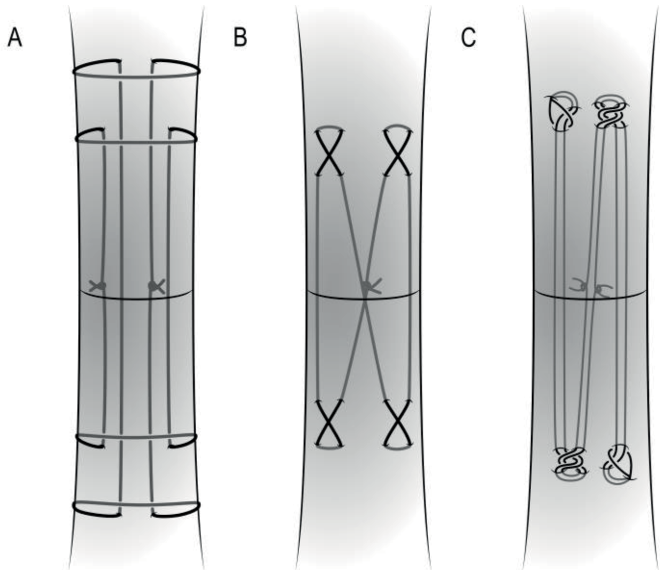

Figure 5. Commonly used core suture methods. A. Double modified Kessler. B. Adelaide (aka cross-locked cruciate). C. Lim-Tsai core repair is used in Switzerland.

Healy et al. (2007) collected corresponding information within the Irish Hand Surgeon Society. In Ireland, most of the hand surgeons used 2-strand modified Kessler. Also, the double modified Kessler (Figure 5 (A)), and the Adelaide (Figure 5 (B)) repairs were popular. In Israel, 2-strand modified Kessler has remained the main method (Sarig et al., 2013). Australian hand surgeons used 4-strand core repairs and preferred the Adelaide repair over the double modified Kessler (Tolerton et al., 2014).

2.2.5.2 Suture calibre

Usually, increasing the suture calibre also increases the tensile strength of the repair. Using a braided polyester suture and different 2-strand techniques (modified Kessler, modified Bunnell, and double-grasping), repairs with 4–0 suture were 66% stronger than with 5–0 suture, repairs with 3–0 suture were 52% stronger than with 4–0 suture, and repairs with 2–0 suture were 51% stronger than with 3–0 suture (Taras et al., 2001). Additionally, the use of 3–0 suture with 4-strand repairs (volar or dorsal cruciate and Adelaide) led to 2- to 3-fold fatigue strength when compared with 4–0 suture with the same repair (Barrie et al., 2001). However, Alavanja et al. (2005) queried these findings by their cadaver model. They did not find a significant difference between strengths and in the work of flexion of the Adelaide repair with 3–0 and 4–0 braided polyester sutures. Only an increase in suture calibre from 4–0 to 2–0 increased the maximum tensile strength but also the work of flexion increased. Thus, they concluded that both 4–0 and 3–0 sutures used with the Adelaide repair are adequate to withstand active postoperative rehabilitation protocols.

Taras et al. (2001) reported that there is no difference between the mean tensile strengths of several 2-strand repairs (modified Kessler, modified Bunnell, and double-grasping) with 5–0 and 4–0 braided polyester sutures. Furthermore, the difference between repair methods only becomes visible with 2–0 and 3–0 braided polyester sutures. However, a 4–0 polyfilament caprolactam double-stranded suture in 8-strand double modified Kessler repair was 43% stronger than 3–0 single-stranded suture in 4-strand double modified Kessler repair (Osei et al., 2014).

In 2-strand and 4-strand repair configurations, repairs are mainly disrupted by suture rupture when 4–0 or 5–0 sutures are used (Barrie et al., 2001; Osei et al., 2014; Taras et al., 2001; Viinikainen et al., 2004). However, suture pullout is more common with 2–0 and 3–0 sutures (Taras et al., 2001; Viinikainen et al., 2004). It is therefore recommended that a stronger suture material is used if the repair is disrupted by suture rupture (Haimovici et al., 2012). It is also important to pay attention to the number of strands. An increased amount of suture material (stronger material or number of strands), however, may lead to increased work of flexion because of bulking (Alavanja et al., 2005).

Gap formation during cyclic testing in a cadaver model was not dependent on suture calibre: there was only 0.3 mm to 0.5 mm gapping after 1 000 cycles of 3.9 N pulp pinch loads in Adelaide repairs with 2–0, 3–0, and 4–0 braided polyester sutures (Alavanja et al., 2005). However, an 8-strand double modified Kessler repair with 4–

0 suture withstood gapping significantly better than a 4-strand double modified Kessler repair with 3–0 suture during linear static loading (Osei et al., 2014). Similarly, a 4-strand double Pennington repair with 4–0 polyethylene had higher visible gap force than the corresponding 2-strand Pennington repair with 2–0 polyethylene (Haimovici et al., 2012).

2.2.5.3 Suture material

Typically, 3–0 and 4–0 braided polyester sutures (Tang et al., 2013) and monofilament polypropylene sutures (Lawrence and Davis, 2005) are used for core suture. A braided polyethylene suture is also recommended (Lawrence and Davis, 2005). Furthermore, there has been developments in new suture materials, such as mono- and multifilament nickel-titanium shape memory alloy (Karjalainen et al., 2012a, 2010) and bioabsorbable poly-L/D-lactide (PLDLA) (Viinikainen et al., 2009, 2006).

Lawrence and Davis (2005) performed linear static loadings with typical 4–0 suture materials. They observed that a suture made of strands of ultra-high molecular weight polyethylene (UHMWPE), a core with a braided jacket of polyester (Fiberwire®), and a stainless-steel suture were significantly stronger than other suture types with ultimate loads of 37.4 N and 36.2 N, respectively. A monofilament polypropylene suture (Prolene®) and a braided polyester suture (Ethibond®) reached similar ultimate loads of 24.8 N and 25.4 N, respectively. However, polyester showed better stiffness when compared with polypropylene. Nylon sutures had the worst biomechanical performance with an ultimate load of 21.9 N. The order of the suture materials to resist gap formation with a 4-strand repair was similar to the ultimate loads (from the best to the worst, stainless steel 87.4 N, braided polyethylene 80.5 N, braided polyester 65.6 N, monofilament polypropylene 63.4 N, and nylon 46.7 N).

McDonald et al. (2011) introduced a multifilament stainless steel (MFSS) 4–0 suture that had an ultimate load of 39.9 N. Additionally, elongation of the MFSS was the least when compared with polyethylene and polyester sutures. Karjalainen et al. (2010) introduced nickel–titanium shape memory alloy suture with an ultimate force of 26.0 N to 46.5 N depending on size (150 μm vs 200 μm). However, in vivo studies are still needed (Wu and Tang, 2014a).

A knotless barbed suture has also been evaluated in flexor tendon repair with a cadaver model, but no significant advances were observed when compared with the braided polyethylene suture (Nayak et al., 2015). Instead, Maddox et al. (2015)

discovered more ruptures postoperatively than with conventional repair methods in their chicken model. Barbed sutures have, however, been proposed to be competitive in terms of both maximum and gap formation forces when compared with conventional suture materials (Shin et al., 2016) even though conflicting results have been reported (Ben-Amotz et al., 2015).

Ideally, bioabsorbable materials would be excellent for flexor tendon repair due to their gradual absorption from the tissue. Viinikainen et al. (2006) found that there is no significant difference between the ultimate loads of a braided polyester suture (Ticron®) and a bioabsorbable PLDLA suture (28.2 N and 26.4 N, respectively). Moreover, the knots of the PLDLA suture were significantly smaller and the initial stiffness of the PLDLA was higher. The PLDLA suture has been observed to withstand active mobilisation (Viinikainen et al., 2009) and even corresponds to the endurance properties of the braided polyester suture during healing in a rabbit model (Viinikainen et al., 2014). Additionally, the PLDLA material had mainly degraded after 52 weeks of healing, whereas the silicone coated braided polyester suture still bulked the repair site (Viinikainen et al., 2014).

Although only rarely noted, there is a temperature change when a suture is removed from its package and stitched to the tendon. Vizesi et al. (2008) pointed out that the braided polyester suture retained its stiffness, but both the monofilament polypropylene suture and a monofilament polyamide nylon (Ethilon®) lost their biomechanical viscoelasticity when placed at body temperature. Furthermore, it is notable that when comparing different suture materials, the cross-sectional areas of the same numeric size category may differ regardless of the materials having the same United States Pharmacopeia (USP) classification. For example, the 4–0 braided polyethylene suture is even larger than the 3–0 silicone coated braided polyester or the monofilament polypropylene sutures (Scherman et al., 2010).

2.2.5.4 Number of core repair strands

An increase in the number of core repair strands has been widely accepted to significantly increase the strength of the repair (Barrie et al., 2000a; Wu and Tang, 2014a). The use of 4-strands leads to significant greater fatigue strength when compared with 2-strand repair (Barrie et al., 2001), and, similarly, 8-strand repair is superior to 4-strand repair (Barrie et al., 2000a). However, the effect of strand number on gap formation is not similar. For example, an 8-strand repair does not resist gap any better than a 4-strand repair (Barrie et al., 2000a). Nevertheless, a 2-strand repair withstands gapping significantly worse than 4- and 6-strand repairs, whereas gliding resistance increases slightly but not significantly when using more strands (Thurman et al., 1998). Lee et al. (2015) achieved promising results with their own 10-strand modification of the Lim-Tsai repair. Resistance for 2 mm gap was significantly better than with repairs of up to 8 strands. Ultimate load was higher with the 10-strand repair than with 2-, 4-, or 6-strand repairs. However, the need for the common use of the 10-strand repair is doubted due to the increased bulkiness of the repair site (Wu and Tang, 2015).

Haimovici et al. (2012) observed that the double Pennington repair with the braided polyethylene suture sustained significantly greater loads than the single Pennington repair with double stranded braided polyethylene thread in spite of the same number of four grips, number of strands, and the same suture material. They concluded that it is not the number of strands that is significant, but how the sutures are passed through the repair site. Calfee et al. (2015) made the same observation with 3–0 single stranded thread when compared with a looped thread. A 3–0 single-stranded double modified Kessler repair with 4 strands (four grips) had 41% higher ultimate load and 78% higher load to resist gap formation than a 3–0 looped repair with 4-strand modified Kessler (two grips). Nevertheless, the longitudinal orientation of strands or the distance between each strand has no influence on suture strength (Dogramaci et al., 2008; Wu et al., 2011). Thus, Osei et al. (2014) emphasised the importance of strand number over an increase in suture calibre. However, equal load sharing and the number of knots should be considered because the repair disrupts from its weakest strand.

Adhesion formation or gliding resistance did not differ significantly when 2- and 4-strand Kessler repairs in a chicken model were compared. Thus, it is permitted to increase the number of strands without any concern of worsened healing. (Strick et al., 2004) This conclusion is supported by the results of clinical studies. There have been great results with 4-strand repairs in children under four years of age (Navali and Rouhani, 2008) and even with 6-strand repairs (three separate "figure of eight" sutures) in children under two years of age (Al-Qattan, 2011). However, children's flexor tendon repairs are typically performed with 6-strand or 4-strand repairs in adolescents or younger children, respectively (Nietosvaara et al., 2007).

2.2.5.5 Placement of the repair

Soejima et al. (1995) studied the placement of the repair and noted that a dorsally placed 2-strand suture had a 26.5% greater failure load than a suture that is placed in the palmar side. They found that the dorsal side of the tendon has 58.3% greater strength than the palmar side. Komanduri et al. (1996) demonstrated with 2-stranded sutures that dorsally placed repairs have 58.5% to 80.7% greater ultimate loads than palmar placed sutures depending on the configuration. Both the larger in diameter collagen bundles at the dorsal side than the palmar side of the FDP (Soejima et al., 1995) and an advantageous biomechanical environment (e.g., higher friction forces of the palmar side than the dorsal side of the tendon) (Komanduri et al., 1996) may explain the previous findings. Furthermore, Cao et al. (2002) showed that dorsal-enhanced 6-strand repair has a 73% greater ultimate load and a 2 mm gap formation load than a centrally placed 4-strand repair. However, the different number of strands was partially responsible for the better biomechanical competence.

Nevertheless, even though dorsal placed sutures were thought to obstruct vascularisation of the tendon, there is no evidence to corroborate this finding. Thus, the strength of repair could rightly be prioritized. (Neumeister et al., 2014)

2.2.5.6 Purchase of core suture

There are several studies that have shown the significant effect of modifying the core suture purchase length on the durability of the repair. Tang et al. (2005) observed that the ultimate load and gap resistance of the repair increased along with the length of the core suture purchase when 2- and 4-strand repair methods were used. The authors recommended an optimal purchase length of 7 mm to 10 mm. Cao et al.'s (2006) observations supported the previous finding with their study of several 4-stranded repair methods. However, even though Kim et al. (2009) demonstrated the same correlation between the purchase length and the ultimate load, they concluded that the increased load cannot be attributed to the better grip of the repair but to the characteristics of the suture material. There was a tendency that the longer the purchase the more probable suture failures by breakage.

Recently, Lee et al. (2010) found that the optimal placement of the Adelaide (cross-locked cruciate) repair is 10 mm from the tendon cut edge. When compared with the placement of 7 mm, the ultimate load was 17%, and the 2 mm gapping load was 42% higher. Additionally, with the 10 mm placement, an increase of the work of flexion was the lowest (5.2%) among their results.

2.2.5.7 Suture locking

The interface between tendon and core suture is classified into two types: locking loops (Figures 6 (A) and 6 (B)) and grasping loops (Figures 6 (C) and 6 (D)). The locking suture tightens a bundle of tendon fibres inside it and the grasping suture pulls through the fibre bundles when tensile forces are applied (Figure 6 (D)). (Hotokezaka and Manske, 1997) Additionally, while tension of the sutures is in the same direction (Figure 6 (E))), a simple locking loop does not tighten a bundle of fibres but deforms and pulls out (Figure 6 (F)) (Karjalainen et al., 2012b). The significance of locking and grasping loops has been controversial, partially due to nomenclature (Hotokezaka and Manske, 1997).

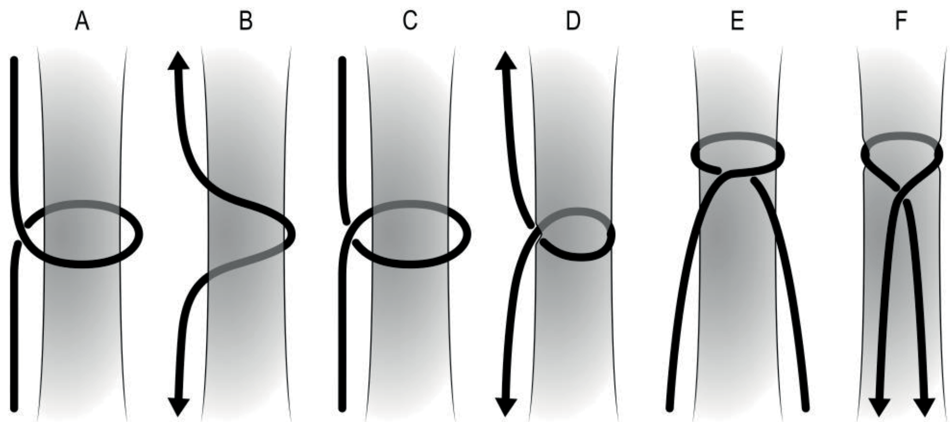

Figure 6. The simple grasping loop does not tighten around the tendon but slips during bidirectional pull (A and B). The simple locking loop grips during bidirectional tension (C and B) but deforms during unidirectional tension (E and F). Figure adopted from Karjalainen et al. (2012b) and Hotokezaka and Manske (1997).

The size of the locking loop has been observed to be essential to the strength of the repair. In an experimental study, increasing the size of the loop from 10% to 50% of cross-sectional area of the tendon resulted in a linear 23% increase in ultimate tensile strength. (Hatanaka and Manske, 1999) Actually, the size of the loop being 25% of the width has been proposed to be the optimal size for a simple locking loop in terms of the ultimate load, the 2-mm gap resistance, and the stiffness (Dona et al., 2004). The width of the circle-lock (Figure 7 (A)) and the cross-lock (Figure 7 (B)) loops should be at least 2 mm to achieve an appropriate locking strength (Peltz et al., 2011; Xie et al., 2005). The type of locking loop is essential (Wu et al., 2011). The cross-lock loop fails more frequently as a result of suture rupture than the simple locked loop. Thus, the cross-lock loop has a considerably better holding capacity because the failure mode is more dependent on suture strength. (Barrie et al., 2001) However, the cross-lock loop seems to be equal to the circle-lock loop with its biomechanical properties (Xie and Tang, 2005). Additionally, if there is a transverse component in a loop to prevent unwinding or an additional anchoring loop, the locking loop could be strained with significantly greater loads to pull out (Karjalainen et al., 2012b).

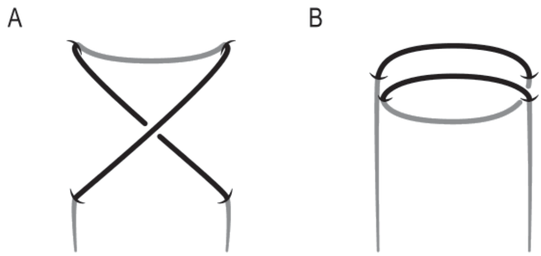

Figure 7. Schematic illustration of the cross-lock (A) and the circle-lock (B).

The grasping loop provides less tensile strength than the locking loop and usually fails by pulling out of the tendon (Wada et al., 2000). However, the difference in biomechanical competence between the grasping loop and the simple locking loop is negligible. With a 2-strand repair, using a locking loop increased gap resistance slightly but there was no difference in ultimate loads when compared with grasping locks. (Wu and Tang, 2011) Nevertheless, insertion of a grasping loop into a normal flexor tendon has been observed to lead to biomechanical changes in the tendon and a decrease in tensile strength (McDowell et al., 2002). Moreover, adding two grasping loops in a row leads to a propensity for gapping (Hatanaka and Manske, 1999). Al-Qattan et al. (2011) demonstrated that adding "a three figure of eight" grasping loops to a cross-lock 4-strand repair leads to a significant increase in both the ultimate and 2 mm gapping loads. However, a repair with ten strands can suffer from an increase of bulk in the repair site and should be clinically evaluated.

Finally, Wu and Tang (2014a) concluded that even though there is evidence on the superiority of locking repair, this evidence should not be overvalued. Adding locks to a repair is as important as other properties, such as strand number and the purchase length of the repair.

2.2.5.8 Knots

In their experimental model, Aoki et al. (1995) showed that locating knots outside of the repair site increases the tensile strength and the gap resistance of the repair. Due to their study methodology, however, they did not pay attention to the friction forces that can increase because of the outside-lying knot. Nevertheless, Pruitt et al. (1996a) had similar findings in their *in vivo* study in a canine model. Even though knots-outside repairs had initially a greater tensile strength than knots-inside repairs, there was no difference after six weeks. Moreover, during the six weeks of healing, relative tensile strength increased 67% for knots-inside repairs versus only 20% for knots-outside repairs.

Subsequently, it has been proposed that a knot that is buried in the tendon is an optimal place for a side-locking repair. When a braided polyethylene suture was used, the repair had higher gap resistance and ultimate load than a repair with a knot between tendon ends. (Komatsu et al., 2007) This would solve two important problems: knots do not shear the tendon sheath causing friction forces and tensile strain is not directed straight to the knot. The latter is significant because "a suture is only as strong as its knot" (Savage, 1985). Moreover, 4-strand and 6-strand repair with a single knot has a higher tensile strength and gap resistance than a similar repair with two knots (Aoki et al., 1995; Rees et al., 2009). It has been suggested that the higher tensile strength and gap resistance are the result of more equal load bearing between strands when the whole repair is made with only one thread. (Rees et al., 2009)

Trail et al. (1989) reported that 3–5 knot throws should be enough to prevent the repair from slippage using conventional nylon and polyester sutures. However, the increase in strength of suture materials may lead to an increase in knot throws. It has been noted that the braided polyethylene suture suffers from an exceptionally high amount of knot unravelling during tensile testing (Moriya et al., 2012; Waitayawinyu et al., 2008). Thus, Le et al. (2012) ended up suggesting six throws with the braided polyethylene suture to prevent knot unravelling.

2.2.5.9 Significance of peripheral suture

Initially, a peripheral suture was only thought to tidy up the repair site. Later, it was shown to be an essential structure for the strength of flexor tendon repair (Bhatia et al., 1992) and has significance in resisting gap formation (Pruitt et al., 1991). Typically, a 5–0 or 6–0 monofilament suture is selected to perform the peripheral repair. The most common peripheral suture technique is a simple running over-and-over suture (Figure 8 (A)). (Tang et al., 2013) There are also some other common peripheral repair methods, such as Halsted (Wade et al., 1989) (Figure 8 (B)), an interlocking technique (Silfverskiöld and Andersson, 1993) (Figure 8 (C)), and an interlocking-horizontal mattress (IHM) technique (Dona et al., 2003) (Figure 8 (D)).

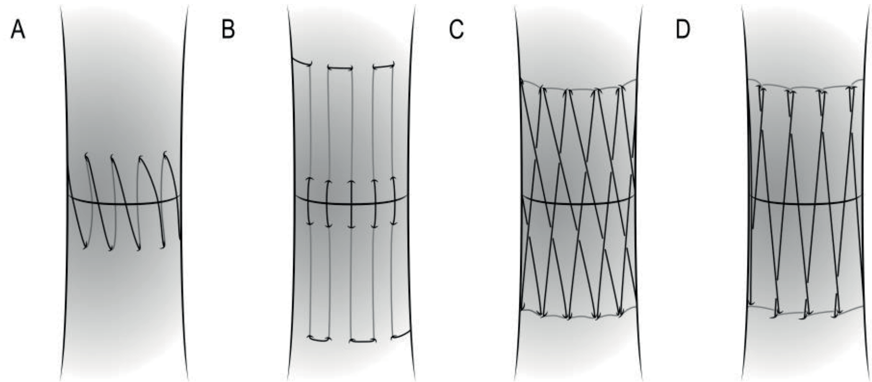

Figure 8. Typical peripheral repair methods drawn with purchase lengths introduced in the literature: A. Simple running. B. Halsted repair. C. Silfverskiöld. D. IHM.

The number of peripheral repair strands crossing the repair site increases the tensile strength, whereas there is no correlation between strand number and increased work of flexion (Kubota et al., 1996). It is recommended that the stitches of the peripheral suture penetrate to half the depth to the centre of the tendon. As a result, there is an 80% increase in tensile strength when compared with more superficially penetrated stitches. Due to the higher stiffness of the more deeply placed sutures, they fail abruptly with quickly increased gap formation. (Diao et al., 1996) For the simple running peripheral suture, a purchase length of 2 mm from the end of the tendon seems to be optimal in terms of ultimate load and gap formation (Merrell et al., 2003). Furthermore, increasing the strand number from 10 to 18 increases tensile strength from 11.6 N to 22.1 N (Kubota et al., 1996).

As with the core sutures, there are differences between different peripheral sutures. Originally, a horizontal mattress (Halsted) configuration was demonstrated to have 89% more tensile strength and needing 93% more load to produce a visible gap when compared with a conventional circumferential running suture (Wade et al., 1989). Moreover, a repair with a cross-stitch peripheral suture was found to have 31% or even 245% higher ultimate load and later gap initiation when compared with a repair with a simple running suture (Kim et al., 1996; Silfverskiöld and Andersson, 1993). Thus, the weakness of the simple running peripheral suture compared with more complex repairs has been proven (Mishra et al., 2003).

However, the simple running circumferential suture is very simple to accomplish. This is crucial in the clinical situations where there is lack of space at the repair site. Adding the peripheral suture on the repair site increases the gliding resistance between the tendon and its sheath (Yaseen et al., 2015). However, another advantage of the simple running peripheral suture is a low increase in work of flexion when compared with Halsted or cross-stitch sutures (Kubota et al., 1996).

Dona et al. (2003) developed the IHM suture that has 71% greater ultimate load and 14% greater 2 mm gapping load than the simple running suture and, moreover, it is easy to execute. Takeuchi et al. (2010) observed that the IHM suture has 36% and 113% greater fatigue strength during cyclic loading when compared with the cross-stitch suture and the simple running suture, respectively. Additionally, the IHM suture has significantly lower gliding resistance than the simple running suture (Moriya et al., 2010).

Stitching even half of the circumference with the simple running suture or with the Silfverskiöld suture leads to a significant decrease in gapping. This is significant to know in situations when the lacerated tendon lies, e.g., underneath the pulleys. Naturally, the gap resistance is greater when the whole circumference was repaired. (Ansari et al., 2009) However, Takeuchi et al. (2011) disputed the partial circumferential repair and recommended the use of the IHM suture combined with the simple running suture when it is impossible to have the IHM suture along the entire circumference.

2.2.5.10 Gliding resistance

To work properly, a tendon sheath should be slick enough for movements of the tendons, especially at the pulleys. Interestingly, intrasynovial tendons (e.g., FDS and FDP) have less friction between the pulleys and surface of the tendon compared with the extrasynovial tendons (Nishida et al., 1998a). In addition, if the A2 pulley has been replaced with a tendon graft, there will be increased friction forces (Nishida et al., 1998b). Furthermore, removing the A3 pulley – one of the minor pulleys – leads to a significant increase in gliding resistance (Zhao et al., 2000). Thus, the system of flexor and pulleys is highly specialised to minimise friction forces in its intact state.

Repairing the tendon with suture materials leads to increased bulk in the site of the repair and causes a 4-fold increase in gliding resistance (Zhao et al., 2001b). By using repair methods with a minimal gliding resistance, it is possible to prevent the occurrence of a rupture during rehabilitation (Amadio, 2005). Sanders et al. (2001) demonstrated with their cadaver model that a 6-strand Tajima repair increased repair site bulk by 55%, but a 2-strand Savage repair increased repair site bulk by only 20%. However, there was no difference in gliding function between the 2-strand and 6-strand repairs. On the contrary, suture configuration had a significant effect on the gliding function of 2- and 4-strand repairs in the study of a canine model. The authors concluded that the more loops were outside at the tendon surface the higher the gliding resistance was. Additionally, knots outside the repair site are thought to have a negative effect on the gliding function. (Zhao et al., 2001a) These conclusions have since been verified with human tendons (Zhao et al., 2001b), though it seems that locking loops do not have an adverse effect on the gliding resistance (Tanaka et al., 2004). Additionally, the suture material of the core suture does not have an influence on the gliding forces, even if there is a difference between the gliding properties of the suture materials themselves (Silva et al., 2009).

The peripheral suture improves the gliding function significantly: angular rotations are higher in the PIP and the DIP with the 2-strand repair combined with the simple running peripheral suture when compared with core-only repair (Sanders et al., 2001). As stated earlier in Chapter 2.2.5.9, the type of peripheral suture is associated with the amount of frictional force (Moriya et al., 2010). Moreover, as lower gapping of the repair is associated with the use of the peripheral repair (Pruitt et al., 1991), it is notable that increased gapping leads to increased gliding resistance. Zhao et al. (2004) observed that gapping of 3 mm or more increases the risk of the repair site getting stuck in the A2 pulley and even the presence of a 2 mm gap caused a significant increase in gliding resistance. In fact, the increase in the peak gliding resistance was 6.4-fold.

Gliding function is decreased when the tendon sheath is closed during tendon repair (Sanders et al., 2001). Furthermore, venting the proximal tendon sheath and the A2 pulley decrease the gliding resistance by 31% when compared with the intact sheath (Bunata et al., 2009). Based on animal (Tang et al., 2007; Xu and Tang, 2003) and cadaver (Tang et al., 2003a; Zhao et al., 2002) studies, it has been concluded that repairing both the FDS tendon and the A2 pulley will increase the risk of rupture of the repair due to increased gliding resistance. Resection of one slip of the FDS tendon during the FDP tendon repair seems to increase the work of flexion by 9% which is significantly less than the repair of the FDP tendon and both slips of the FDS tendon (51%). However, suture material does not have an effect on the work of flexion. (Hwang et al., 2009) Clinical studies, however, have not addressed the represented problem with the repair or resection of the FDS tendon (Henry, 2011).

Finally, in their chicken model, Xie et al. (2008) observed that gliding resistance increases for the first five days after tendon repair: force to resist tendon mobilisation at day 4 and day 5 was about twice that of day 0. Additionally, work of flexion increased gradually during that time. They concluded that rehabilitation programs should not begin earlier than after three days of healing to avoid the period when gliding resistance is increasing. Cao and Tang (2006) made a similar recommendation of beginning rehabilitation from the fourth to the seventh day postoperatively.

2.2.5.11 Gap between tendon ends

After flexor tendon repair, gapping of the repair site is associated with harmful effects during recovery. Not only does the gliding resistance of the repaired tendon increase but also the gap between tendon ends increases (Zhao et al., 2004) (Chapter 2.2.5.10). In addition, the strength of the repair may also be threatened. Ketchum et al. (1977) emphasised the harmfulness of any gap between tendon ends in their canine model. This concern was affirmed in Seradge's (1983) clinical study in which a gap of 1 mm to 3 mm – depending on the repair method – was directly correlated with the need for tenolysis. Moreover, Sanders et al. (1997) detected a point of inflection at the cycle-displacement curve of cyclically tested samples near the gap of 2 mm and, after that, repairs ruptured. Additionally, repairs that have gapped 3 mm or more do not strengthen normally during the healing process. In a canine model, repairs with gap of at least 3 mm did not have normal tendency to gain the ultimate load and rigidity during forty days of healing. However, there was no increase in the adhesion formation within the repairs with a gap of as much as seven millimetres. (Gelberman et al., 1999)

Conversely, even though Ejeskär and Irstam's (1981) study confirmed the correlation between gapping and poor outcome, it was only a gap of 5 mm that implied suture rupture or knot unravel. They concluded that even a 10 mm gap between intratendinous markers can be concluded to be the maximum compatible with an acceptable result. Also, Silfverskiöld et al. (1992) reported that gaps of up to 10 mm would be compatible with a good clinical result. However, they regarded the gapping as a poor predictor of clinical result. In recent studies, gap formation of 2 or 3 mm has been considered as a critical threshold value (Jordan et al., 2015c; Matheson et al., 2005; Sanders et al., 1997; Wolfe et al., 2007; Wu and Tang, 2014b) but there is no unambiguous basis for this.

However, minimizing the gapping between tendon ends is desirable. The peripheral suture has been accepted to be the key factor in resisting early gapping of the repair (Pruitt et al., 1991; Silfverskiöld and Andersson, 1993; Wade et al., 1986). However, de Wit et al. (2013) demonstrated that the benefit of the peripheral suture is highly dependent on the core suture. When a cruciate core repair was combined with the simple running peripheral suture, there was only a 15% reduction of gap at the failure load when compared with core-only repair. Reductions for the Kessler and double Kessler repairs were 42% and 87%, respectively. The authors explained these results with the load sharing between core and peripheral repairs. Additionally, they regarded the transverse segment of the Kessler repair to explain the initial gap formation of the repair.

The core suture configuration is another key factor in resisting gap formation (Corradi et al., 2010; Jordan et al., 2015c; Kuwata et al., 2007; Sanders et al., 1997). There can be more than a ten-fold risk reduction of gap formation between typical core suture configurations (Matheson et al., 2005). A 3 mm asymmetric placement of 6-strand core suture purchases can enhance the resistance to gap formation (Kozono et al., 2017, 2016). Even asymmetric suture purchases within a 2-strand core suture seems to increase the gapping resistance of the repair (Wu and Tang, 2014b). Conversely, a symmetric peripheral suture seems to improve the strength of the repair when compared with an asymmetric peripheral suture (Takeuchi et al., 2017). However, Uslu et al. (2014) demonstrated that if the surface area of the core suture material was equal at the repair site between multi-strand repairs, the load needed to form a 2 mm gap could be equal regardless of the strand number. A 2-strand repair with thicker sutures had as high 2 mm gap resistance as an 8-strand repair with thinner sutures. Al-Qattan et al. (2013) observed significantly higher initial gap load with 6 mm suture purchase compared even to 5 mm suture purchase in a 2-strand suture, but emphasised the challenge of performing optimal repairs in a clinical situation, at least with children. Usually with adults, core suture purchases of 7 mm to 10 mm are recommended in terms of initial gap formation and 2 mm gap resistance (Cao et al., 2006; Lee et al., 2010; Nelson et al., 2012; Tang et al., 2005). Also, deeper peripheral suture purchases up to 2 mm using the simple running suture provide more gap resistance for the repair (Nelson et al., 2012).

The type of loops of the core repair has been reported to affect gap formation (Tahmassebi et al., 2015; Tanaka et al., 2004). Wu et al. (2011) found a circle lock to be the most gap resistant followed by the cross-lock and the simple locking loop, respectively. Albeit, it seems that pre-tensioning cross-lock and simple locking loop repairs unifies the difference in gap resistance (Jordan et al., 2015c). Generally, Vanhees et al. (2013) recommended the pretension of the suture-tendon interface before knot tying with 10 N to 15 N for better gap resistance of the core suture. Wu and Tang (2012) tensioned core sutures by producing a shortening of the suture segment during repair and observed 10% shortening to be optimal in terms of gap formation and bulkiness of the repair site.

The core suture material must also be considered. For example, PLDLA suture materials have been shown to have greater gap resistance than conventional suture materials (Viinikainen et al., 2009). Some studies also support similar results in terms of barbed suture material (Peltz et al., 2014; Sato et al., 2014), but opposite views exist (Ben-Amotz et al., 2015). Jordan et al. (2015a) achieved equal gap resistance with conventional and barbed suture materials when different repair methods were used. Nayak et al. (2015) observed higher 1 mm gap resistance with the barbed suture but, considering the cost increase, did not recommend the barbed suture over conventional materials.

2.2.5.12 Pulleys

In terms of biomechanics, the main purpose of the pulleys is to minimize the required moment arm to accomplish finger flexion. The significance of the short moment arm is twofold: on the one hand it makes the motion of the fingers more precise but on the other it lessens the available force to flexion. Injury and lack of pulleys cause bowstringing of tendons and leads to a loss of joint mobility. (Goodman and Choueka, 2005)

The significance of the reconstruction of pulleys and the tendon sheath during tendon repair has been controversial. Previously, it was recommended that at least the A2 and A4 pulleys remained intact (Elliot and Giesen, 2013). The A4 is considered to be the most important of the pulleys. Mitsionis et al. (1999) observed that releasing it led to a significantly larger loss of excursion efficiency than dissecting the second most important pulley the A2. However, even a 25% excision of the A2, A4, or A2 and A4 pulleys combined was possible without loss of work of flexion or a significant decrease in angular rotation.

Conversely, Franko et al. (2011) showed that although the excursion of the repaired tendon increased gradually by 0.7% to 8.2%, depending on the extent of the A4 pulley and proximal sheath release, the increase in the work of flexion was smaller the larger the part of the pulley was released (11.5% with intact A4 vs 0.83% to 3.25% released A4). In the same way, flexion lag (distance from the fingertip to the palmar skin when the tendon is pulled to the predefined marker) increased from under 1 mm to over 4 mm, depending on the release rate. Thus, the authors of the study concluded that A4 pulley release is justifiable if necessary, due to its low influence on clinical outcomes.

Similarly, release of the A1 pulley after flexor tendon repair has been reported to decrease the work of flexion by 7% to 30%, depending on the finger. There was, however, no flexion lag after the pulley release, unlike with the release of the A4 pulley. (Buonocore et al., 2012) Barthel et al. (2016) found that releasing the A4 pulley seems to be less effective in terms of the size of the digital channel than releasing the A2 pulley. Furthermore, in their chicken model, Cao and Tang (2009) found that the strength of the tendon repair is 30% to 60% lower when the A2 pulley is left intact. Additionally, the presence of volar oedematous subcutaneous tissue increases work of flexion even more. However, an intact A2 pulley plays a greater role in work of flexion increase (Wu et al., 2012). Furthermore, release of the whole A1 pulley and half of the A2 pulley does not significantly decrease the excursion efficiency of the FDP tendon (Lu et al., 2015).

If one of the A1, A3, and A5 pulleys or the palmar aponeurosis alone are dissected, there is no significant loss of efficiency or excursion (Phillips and Mass, 1996; Rispler et al., 1996; Tang and Xie, 2001). Conversely, the loss of the A1, A3, and A5 pulleys decreases the flexion efficiency significantly (Rispler et al., 1996). Additionally, the adjacent tendon sheath of the A3 pulley may play a significant role in preventing bowstringing (Tang and Xie, 2001).

Pulleys not only keep the tendon near the bone, which is significant for the gliding resistance of the bone, but also change the direction of the tendon. Tension direction has a significant effect on the strength of the tendon repair, and the forces to form a gap or to rupture decrease, while the angle of tension increases. For example, pull at 90° decreases the 2 mm gapping load by 36% and the ultimate load by 24%. (Tang et al., 2001) Additionally, the curvature of tendon motion arcs has an influence on the repair strength. A decrease in the arc leads to lower 2 mm gap formation load and ultimate load. Consequently, preserving the pulley-sheath system can prevent the weakening of the tendon repair caused by an increased degree of direction and a decreased tendon motion arc. (Tang et al., 2003b)

Finally, based on a clinical study, there is evidence that releasing the A3, C3, or A4 pulleys will not lead to bowstringing. During 5 to 12 months follow up, there were good and excellent outcomes with 20 of 22 fingers. Thus, the authors recommended helping the surgery by releasing these pulleys, if necessary. (Moriya et al., 2015) Therefore, the venting and partial release of pulleys is nowadays thought to be acceptable alongside leaving the tendon sheath open without suturing (Elliot and Giesen, 2013; Lee, 2012; Neumeister et al., 2014; Tang et al., 2013).

2.2.6 Tendon healing

Tendons heal by scar formation (Potenza, 1962). There are three phases in tendon healing: inflammatory, fibroblastic, and remodelling (Gelberman et al., 1985). During the first week after tendon repair, cells from adjacent tissues form a clot of proinflammatory cells over fibrinous bridges at the repair site (Beredjiklian, 2003; Gelberman et al., 1985). There are, however, no such clots at the areas of larger gaps. In 14 days, epitenon cells have begun to proliferate, especially at the site of a moderate gap between the tendon ends. (Gelberman et al., 1985) The fibrin clot is solely responsible for the strength of the repair during the inflammatory phase (Branford et al., 2014).

However, the strength of the repair is increased during the fibroblast phase by the synthesis of the extracellular matrix (Branford et al., 2014). The secretion of fibroblasts initiates some days after wounding, and the number of fibroblasts increases for three weeks. The fibroblasts proliferate rapidly and secrete immature unorganized type III collagen. (Stadelmann et al., 1998) During the repair process, the diameter of the collagen is smaller, and thus the tensile strength is reduced (Ehrlich et al., 2005). For the first weeks, neovascularisation of once-avascular areas of the tendon and the traversing of intrinsic blood vessels nourishes the healing process (Gelberman et al., 1991). Overall, the combination of type III collagen and new vessels produce scar formation with the tendon.

The remodelling phase initiates three weeks after the tendon repair and takes up to two years. During this period, the collagen network becomes longitudinally organized, type I collagen replaces type III, and the tensile strength of the wound increases. However, the wound never exceeds the normal strength of the tendon. (Stadelmann et al., 1998)

The tendon healing process has been divided into extrinsic and intrinsic healing. In extrinsic healing, sheath tissue is thought to supply the healing process (Potenza, 1962). In intrinsic healing, it has been observed that granulation tissue and adhesion formation form without a sheath (Matthews and Richards, 1976). Overall, tendon healing has been considered a combination of both extrinsic and intrinsic mechanisms. Earlier, it was presumed that tendon adhesions were formed by migrating cells from adjacent tissues. Nevertheless, tendon cells were also observed to migrate out of the tendon and contribute to adhesion formation. (Manske, 1988) Lately, it has been observed that there is a basement membrane at the surface of the tendon that prevents adhesion formation. Thus, adhesion formation is induced by cells that migrate from the injured zones of the tendon. (Taylor et al., 2011)

It is thought that cells of the tendon sheath contribute to adhesion formation when fingers are immobilised, and intrinsic cells are favoured during mobilisation. Adhesive cells (collagen type I and fibronectin) have poorer attachments during immobilisation, and therefore they are more capable of migrating. Mobilisation leads to increased cellular activity and higher collagen and glycosaminoglycan content in mobilised tendons, whereas there is increased collagen degradation in immobilised tendons. (Branford et al., 2012)

Thus, it is natural that mobilised tendons have double the ultimate load than immobilised tendons after three weeks of rehabilitation (Gelberman et al., 1982), while the strength of immobilised tendons will have decreased during the same period (Hitchcock et al., 1987). Mobilisation prevents adhesion formation and keeps the gliding surface smooth (Gelberman et al., 1983). Additionally, mobilisation advances the reorientation of blood vessels to a normal pattern, whereas immobilisation leads to the persistence of a random pattern (Gelberman et al., 1981).

2.2.7 Rehabilitation of flexor tendon repair

After tendon injury and repair, fingers are rehabilitated with one of three basic protocols: 1) immobilisation, 2) controlled passive motion, or 3) early active motion (Neumeister et al., 2014). In addition to noncompliant adults, the immobilisation protocol was previously only used with children younger than ten years (Havenhill and Birnie, 2005). However, active motion programs have been proven to provide good outcomes in children (Nietosvaara et al., 2007) and a recent study also encourages using the early active motion protocol with children irrespective of age (Singer et al., 2017).

Naturally, the repaired tendon is totally immobilised during the immobilisation protocol. During the active and controlled passive protocols, a dorsal splint is usually used. Here, a plaster hood extends beyond the fingertips to limit finger extension. If the controlled passive motion protocol is used, finger flexion is accomplished with rubber bands or with the other hand and, conversely, the active motion protocol comprises active finger movements.

Chesney et al. (2011) wrote a systematic review on the flexor tendon rehabilitation protocols in 2011. They compared the early active motion protocol with the passive motion protocol which could be only passive flexion (Duran type), passive flexion combined with active extension (Kleinert type), or a combination of Duran and Kleinert types. The authors concluded that there is weak evidence to recommend either the early active motion protocol or the combined Duran and Kleinert type protocol. There were rupture rates of 4.1% and 2.3% and excellent or good results of 94% and 73% with the early active motion protocol and the Duran and Kleinert type protocol, respectively. Conversely, a rupture rate of 7.1% and an excellent or good result of 67% with the Kleinert protocol were achieved.

In 2013, Starr et al. (2013) presented another systematic review of the rehabilitation protocols used over a period of 25 years. Combining the Duran and Kleinert type protocols into a single passive motion protocol group, they reported that there were significantly fewer ruptures (4% vs 5%) but a higher decrease in motion (9% vs 6%) when the passive motion protocols were compared with the early active motion protocols. During the last decades, however, there has been a decrease in overall rupture rates with the development of better rehabilitation protocols and improved suture techniques and materials. The authors concluded that the early active motion protocol was applicable to improve range of motion.

Frueh et al. (2014) performed a retrospective analysis of their primary flexor tendon repairs over a period of six years. They compared the early active motion protocol with the Kleinert type passive motion protocol. They reported that the early active motion protocol performed better due to a higher total active motion rate at four weeks and a lower rupture rate (5% vs 7% with Kleinert type protocol). However, there was no significant difference in total active motion rates at 12 weeks after tendon repair.

The full early active motion protocol is still rarely used in clinical situations. Globally, combined protocols of the active and passive motions dominate. However, some rehabilitation programs have started to include a halfway active motion protocol. (Tang et al., 2013)

3 AIMS OF THE STUDY

The present dissertation intends to develop better methods for the comparison of flexor tendon repairs. The detailed objectives of the study were as follows:

1. To assess the relationship of biomechanical parameters between the static and cyclic testing of flexor tendon repairs. (I)

2. To develop an objective method to determine the load at which irreversible deformations begin in cyclical loading (I)

3. To examine the harmfulness of gapping in flexor tendon repairs. (II)

4. To assess those factors that cause variation in the biomechanical properties of flexor tendon repairs. (III)

5. To investigate the significance of modifying established flexor tendon repair techniques. (IV)

4 MATERIALS AND METHODS

4.1 Samples

Thawed fresh frozen porcine FDP tendons from a local abattoir were used. The tendons were dissected and then measured using callipers. The cross-sectional areas of the tendons were calculated ($A = \pi * ab$, where *a* is the semi-minor axis and *b* the semi-major axis). After measuring, the tendons were transected with a sharp surgical scalpel and immediately repaired.

In Studies I–III, a tendon of second ray (FDP-II) was used. The same samples were also used in Studies I and II. A total of 55 tendons was used in Studies I and II. Of these, only 35 cyclically tested tendons were considered in Study II. In Study III, 50 tendons were used.

Additionally, 16 porcine tendons from ray three or four were used in Study IV. A different ray was selected to enable execution of the repair without the magnification of loupes. These tendons were revealed in the trotter and cut. The repairs were done *in situ* apart from pulley venting, where necessary. The tendons were dissected after the repair and measured. The repaired tendons from all studies were kept moist wrapped in a saline soaked gauze.

Fifty absorbent sticks (BD Visisorb™, Beaver-Visitec International, Inc., Waltham, Massachusetts, United States) were used in Study III. The sticks are homogenous, soft-woven cylinders with a diameter of 5 mm and are similar to previously used dental rolls (Kozono et al., 2016; Takeuchi et al., 2011, 2010). The sticks were used to mimic tendons but also to minimize biological variation. The variation of the sticks model was assumed to be negligible, and all variation was caused by testing methodology or surgical performance.

The samples of Studies I-IV are presented in Table 4.

Table 4. Samples, suture configurations, and testing settings.

Study	Core technique	Strand no	Core suture	Peripheral technique	Peripheral suture	Sample no	Surgeons	Material	Testing method	Preload (N)	Distraction rate (mm/min)
I*	Pennington modified double Kessler	4	4-0 bpe	simple running	6-0 pa	35	single	FDP-II tendon	cyclic	0	300
	Pennington modified double Kessler	4	4-0 bpe	simple running	6-0 pa	20	single	FDP-II tendon	static	0.5	20
II*	Pennington modified double Kessler	4	4-0 bpe	simple running	6-0 pa	35	single	FDP-II tendon	cyclic	0	300
III	simple loop (jig)	2	3-0 bpe	-	-	10	single	absorbable stick	static	0.5	20
	simple loop (free)	2	3-0 bpe	-	-	10	single	absorbable stick	static	0.5	20
	simple loop (free)	2	3-0 bpe	-	-	10	single	FDP-II tendon	static	0.5	20
	Adelaide repair	4	3-0 bpe	-	-	10	single	absorbable stick	static	0.5	20
	Adelaide repair	4	3-0 bpe	-	-	10	single	FDP-II tendon	static	0.5	20
	-	-	-	simple running	5-0 pa	10	single	absorbable stick	static	0.5	20
	-	-	-	simple running	5-0 pa	10	single	FDP-II tendon	static	0.5	20
	Adelaide repair	4	3-0 bpe	simple running	5-0 pa	10	single	absorbable stick	static	0.5	20
	Adelaide repair	4	3-0 bpe	simple running	5-0 pa	10	single	FDP-II tendon	static	0.5	20
	Adelaide repair	4	3-0 bpe	simple running	5-0 pa	10	several	FDP-II tendon	static	0.5	20
IV	surgeon's typically used	varied	3-0 lbpe	surgeon's typically used	5-0 pa	16	several	FDP-III or -IV tendon	static	0.5	20

*The same samples of 35 cyclically tested tendons were used both in Study I and Study II.

Suture materials: bpe, braided polyester; lbpe, looped braided polyester; pa, polyamide

4.2 Surgeons

The same investigator performed all the repairs in Studies I–III with the exception of ten repairs in Study III. The repairs were performed by ten hand surgeons (seven specialists and three residents) at Tampere University Hospital.

In Study IV, the repairs were performed during a national symposium on flexor tendon repair that was held in Tampere, Finland, on 24 April 2015. Delegates from the six largest hand surgery units in Finland participated in the symposium. Sixteen hand surgeons (eight specialists and eight residents) took part, and each surgeon performed a single repair.

4.3 Repair methods

In Studies I and II, the repair method used was the same for all the samples. Two Pennington modified Kessler repairs (Pennington, 1979) with 4–0 braided polyester suture (Ethibond Excel®, Ethicon, San Lorenzo, Puerto Rico, United States) (Figure 9 (A)) were used as a core suture and the repair was completed with nine loops of circumferential running peripheral repair with 6–0 polyamide suture (Ethilon®, Ethicon, San Lorenzo, Puerto Rico, United States) (Figure 9 (D)).

In Study III, the repair methods varied between different groups to determine variation-causing factors. 1) Ten absorbent sticks were repaired to define the methodological variation related to testing procedure (baseline variation). The repairs were done using a custom-made jig (Figures 10 (A) and 10 (B)) and the method used a simple loop with 3–0 braided polyester thread (Ethibond Excel®, Ethicon, San Lorenzo, Puerto Rico, United States) (Figure 9 (B)). The jig was used to minimize surgical-performance-derived variation. The baseline variation was subtracted from the total variations of repairs to measure the variation caused by surgical performance and tendon material.

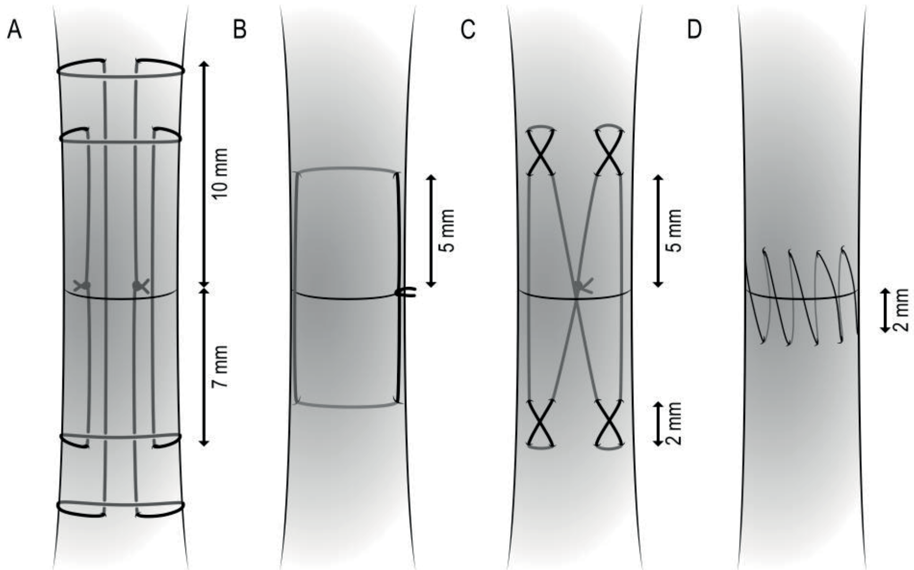

Figure 9. Schematic illustration of repair methods used. A. Modified Kessler repair. B. Loop repair. C. Adelaide repair. D. Simple running peripheral repair.

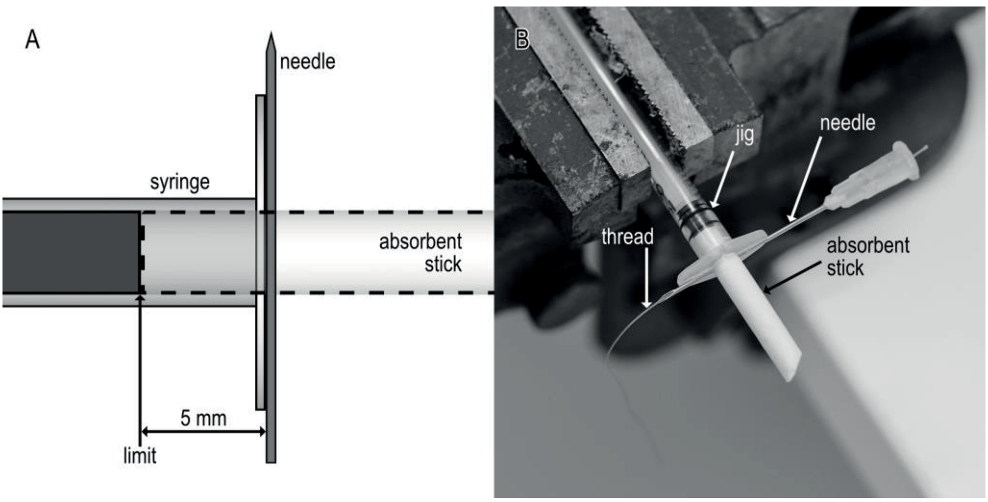

Figure 10. A custom-made jig was used to maximize the reproducibility of the simple loop in the absorbent sticks. A trail was sewn onto the top plate of a 1 ml syringe. The piston from the syringe was cut to a specific length to limit the stitch to 5 mm from the cut end of the absorbent stick. The piston was used as the limit in the syringe. The absorbent stick (dashed line) was pushed into the syringe against the limit. A 20G needle was pushed through the absorbent stick. A 3–0 braided polyester thread was driven by the needle through the absorbent stick along the trail. This procedure was repeated in both halves of the repair.

2) Ten sticks were repaired with the objective of performing similar simple, free-handed loop repairs (Figure 9 (B)). Therefore, the variation of these samples was assumed to be caused by surgical performance and testing methodology only – there was no variation caused by tendon material. 3) A four-strand Adelaide core suture (Sandow and McMahon, 2011) (Figure 9 (C)) with the same 3–0 braided polyester thread was performed on another ten sticks, and 4) a nine-purchase simple running peripheral suture (Figure 9 (D)) with 5–0 polyamide monofilament (Ethilon®, Ethicon, San Lorenzo, Puerto Rico, United States) was used on a further ten sticks. 5) A combination of the previously described core (Adelaide) and peripheral (simple running) repair methods were used to perform another ten repairs.

In study III, the porcine tendons were used to measure the effect of the tendon substance on the variation of the biomechanical properties. The same repair methods used with the absorbent stick repairs were used, i.e., the simple loop (free-handed), the Adelaide repair, the simple running peripheral repair, and the combined repair (Adelaide + peripheral).

The order of repair of these 50 absorbent sticks and 40 tendon samples were randomized to minimize the bias arising from the learning curve. Finally, ten hand surgeons repaired one FDP-II tendon with the same combined repair. The surgeons were provided with the schematic illustrations shown in Figures 9 (C) and 9 (D). The surgeons were unfamiliar with the Adelaide repair despite being experienced in tendon surgery. Consequently, the effect of experience in a specific repair technique was minimized.

In study IV, all surgeons were asked to name and draw the core and peripheral repairs and to report the suture materials that they use in everyday practice. Thereafter, they performed the same repair on the tendon *in situ*. A looped 3–0 braided polyester thread (Tendo Loop®, B. Braun Surgical GmbH, Melsungen, Germany) was provided with an option to cut the loop if necessary to use as a single thread. For the circumferential suture, 5–0 polyamide monofilament (Dafilon®, B. Braun Surgical GmbH, Melsungen, Germany) was used. After the repair, dissection, and measuring, the number of purchases of the peripheral suture was counted and the tendons were photographed (Fujifilm X-T1, Fujifilm Holdings Corporation, Tokyo, Japan). Then, the lengths of the core and peripheral suture purchases were measured from the calibrated photographs.

4.4 Biomechanical testing

All the samples of the study were tested with linear static or cyclic loading. A material testing machine (LR 5 K Lloyd Instruments Ltd, Hampshire, United Kingdom) was used to perform the biomechanical tests. NEXYGEN computer software (Lloyd Materials Testing, AMETEK, Inc., Berwyn, Pennsylvania, United States) was used to gather data from the machine. The gauge between the clamps that secured the samples to the machine was 30 mm.

Biomechanical tests were filmed with two diametrically placed cameras (Canon EOS 550D and Canon EOS M, Tokyo, Japan). The diameter scale was set to videos based on still photographs that were taken before testing.

4.4.1 Linear static loading

Linear static loading was used in Studies I, III, and IV. In Study I, twenty out of a total of 55 repaired tendons were loaded in a static manner. In Studies III and IV, all of the 116 samples were tested with static loading. For all static tests, 0.5 N was used as preload and the distraction rate was 20 mm/min. Based on load-deformation curves, the ultimate load and the yield load were determined. A custom MATLAB-based computer software (MATLAB R2015b, MathWorks, Natick, Massachusetts, United States) was used to assess the yield load with a 0.1 mm offset method (Lotz et al., 1998). The offset line was drawn 0.1 mm under the steepest slope of the load-deformation curve. The yield load was the intersection of the offset line and the load-deformation curve (Figure 11).

Additionally, in Study IV, the stiffness was determined from a linear regression in a moving cell fashion for all data points (Lotz et al., 1998). Determination was started from the beginning of the load-deformation curve and continued until the peak load (25 data points/second). The linear regression line that best represented the slope of the load–deformation curve in its most linear region was sought.

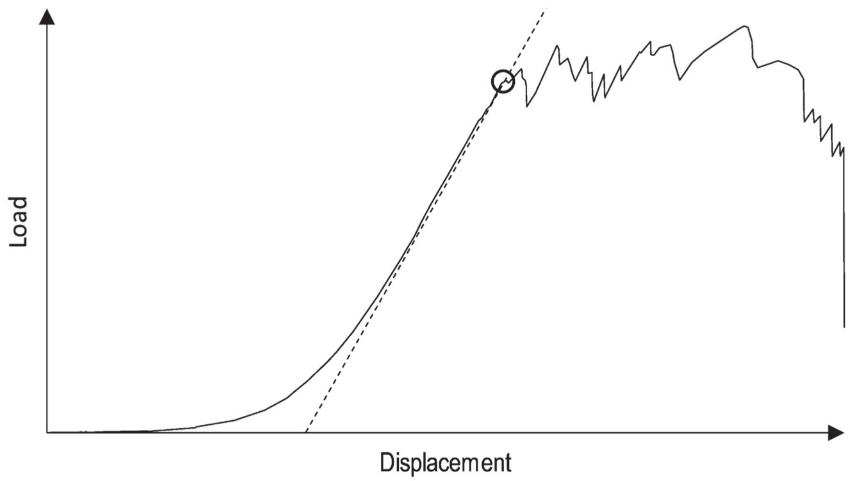

Figure 11. Determination of the yield load. The intersection of the offset line and the load-deformation curve is marked as a circle.

4.4.2 Linear cyclic loading

The remaining 35 tendons of Studies I and II were tested using the cyclic method. The maximum count of cycles was 500 for all the tests. The 500 cycles correspond to 5 to 10 days of active rehabilitation, and according to an animal model, the biological strengthening only starts thereafter (Gelberman et al., 1999). Additionally, 500 cycles have been proven to be sufficient to indicate the possible failure of the repair in a similar testing setting (Haddad et al., 2010a). The distraction rate was set to 300 mm/min: the excursion of the FDP tendon in its sheath during normal finger flexion (11.8 mm) (Sapienza et al., 2013) and finger flexion time during rehabilitation correspond to this rate. The lower limit for the load was 0 N during all tests.

The constant upper limit for the load was randomly adjusted for each specimen so that the loads of the cyclically tested samples would cover the whole range of loads both under and over the yield load based on the static tests of Study I. Each specimen was tested using only a constant upper limit for the load: the load changed repeatedly between 0 N (resting phase) and the chosen upper limit (peak phase) during testing. Thus, the specimens either sustained all the 500 cycles – after which the testing ended – or failed during the testing. Failure modes – suture break, suture pull-out, or knot unravel – were assessed afterwards.

4.5 Analysis

The parameters of static and cyclic testing were compared in Study I. Based on cyclic tests with different peak loads, a custom MATLAB-based computer software derived estimate curve was reconstructed to measure failure probabilities (Chapter 4.5.1). Static loading-based measures (gap loads, yield load, and ultimate load) were compared with these failure probabilities. Using the specific failure probability, new estimate measures – critical and safe load – were assessed (Chapter 4.5.2).

In Study II, a mathematical model was used to examine common features of the time-extension curves of repairs that fail or sustain during testing. Thus, it was determined whether there is a threshold that predicts failing (Chapter 4.5.3).

In Study III, tendon repair methodology was broken down into parts. Variations of the results were normalised by their means and standard deviations and these normalised variations (coefficient of variations) were used to subtract and sum up, resulting in specific clinically interesting variations (Chapter 4.5.4).

Finally, basic statistical methods were used to examine if there was a difference between standard and modified repair methods in Study IV (Chapters 4.5.6 and 4.6).

4.5.1 Estimate curve

In Study I, methodology was developed in collaboration with a graduate engineer. Maximum likelihood estimation (MLE) – that is often used to estimate parameters of a statistical model – was used to estimate the probability of failure for cyclically loaded specimens (Figure 16 (A) and 16 (D)). Thus, it was possible to perceive the successes and failures of tendon repairs in terms of probability.

Let θ be a vector that includes the parameters of likelihood function and $x = \{x_1, x_2, \dots, x_n\}$ be an observed sample. The likelihood of parameters θ with observations x equals the probability of observations x with parameter values θ: $\mathcal{L}(\theta|x) = P(x|\theta)$. For independent and identically distributed observations, the joint probability of observations x is a product of the probabilities. Thus, for a continuous probability distribution $\mathcal{L}(\theta|x) = \prod_{i=1}^{n} f_\theta(x_i)$, in which f_θ is probability density function with parameters θ. The best likelihood is obtained by maximizing this result.

Let $I_f(i)$ be an indicator function in which i is an index of an observation. The value of the indicator function is 1 if the specimen fails, and 0 if the specimen sustains all 500 cycles. For convenience, these two possible outcomes are called success (0) and failure (1).

Let $p_\theta\ (x)$ be the probability of failure, in which x is a peak load used in the cyclic tests and θ includes parameters of the probability distribution. If load x_i corresponds to observation i, probability of failure is $p_\theta\ (x_i)$ and probability of success is $1 - p_\theta\ (x_i)$. Utilising the indicator function, the probability is $\left|p_\theta\ (x_i) + I_f(i) - 1\right|$ in both cases. So, the function to be maximized is $\prod_{i=1}^{n}\left|p_\theta\ (x_i) + I_f(i) - 1\right|$.

It can be assumed that the peak load the repaired tendon barely sustains during cyclic testing is normally distributed. The probability of failure at the given peak load equals the probability that the load which the tendon repair withstands is less than the load used. Thus, the probability of failure is obtained from cumulative distribution function of the normal distribution: $p_{\omega,\sigma}(x) = \frac{1}{2}\left[1 + \mathrm{erf}\left(\frac{x-\omega}{\sqrt{2\sigma^2}}\right)\right]$, in which parameters to estimate are expectation value ω and standard deviation σ. The curve resulting from this function is called the estimate curve.

4.5.2 Critical load and safe load

Based on the estimate curve, a custom MATLAB-based computer software was used to specify the estimate parameters in Study I. The steepest slope of the estimate curve represents the average point at which irreversible plastic deformation begins to cumulate (termed critical load). However, the critical load is not directly applicable to a clinically safe threshold due to a failure rate of 50% (Figure 12). Thus, point $p_{\mu,\sigma}(-2\sigma)$ – that is twice the standard deviation under mean of the critical load and corresponds to a 2.3% failure probability – is termed safe load (Figure 12). Safe load takes into account the effect of variation within the sample and can be regarded as a more clinically relevant parameter than critical load.

The main purpose of Study I was to assess the relationship between the parameters of static and cyclic testing. Thus, probabilities of failure were evaluated for each static testing derived parameter (ultimate load, yield load, and 1 and 2 mm partial and total gapping loads): probability of failure (%) $= y_1 * 100\%$, in which y_1 represents the probability to failure (y-axis) at the point where load (x-axis) equals the mean of each statically derived parameter (Figures 16 (B) and 16 (C)).

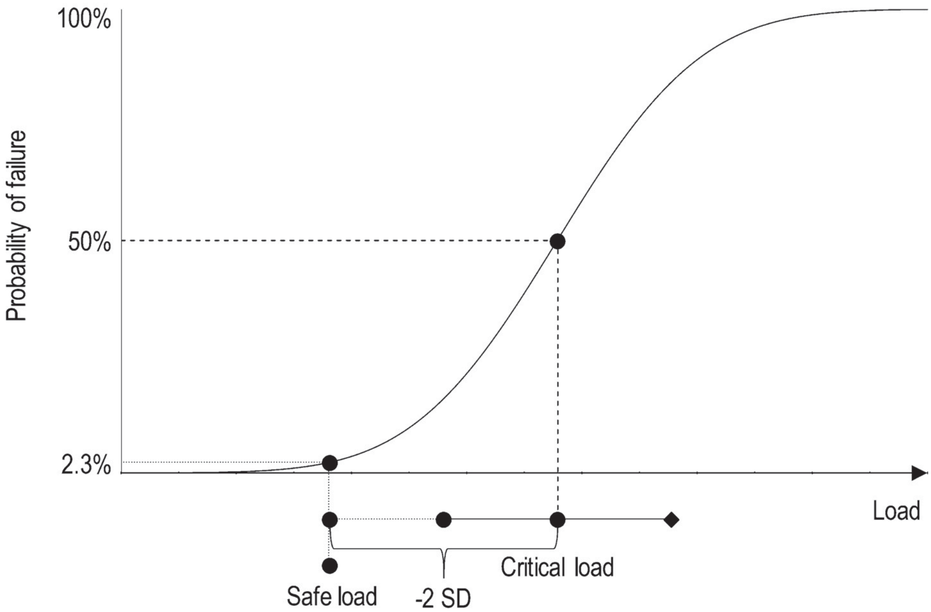

Figure 12. The critical load represents 50% probability of failure. Twice the standard deviation under the critical load is the safe load. The probability of failure is only 2.3% at the safe load.

4.5.3 Fatigue point

In Study II, the biomechanical behaviour of the cyclically tested tendons was evaluated, and time-extension graphs were formed for each specimen. These graphs were used to examine whether there are common features between sustained or failed repairs. If the specimen sustained the first 50 cycles, there was a power law obeying shape in the graph: the extension of the sample built up rapidly during the first cycles but eventually levelled off. Among the tests, there were specimens in which a sudden increase in the total extension was observed during repetitive loading. After this point of the change, the extension increased linearly until the failure of the repair. That point was termed fatigue point.

The fatigue point can be determined mathematically by fitting a piecewise-defined function to the minimal extensions $x(t)$ of test. Let the first part of the function follow the power law and the latter part be linear:

$$x(t) = \begin{cases} k_1 t^b + c, \ t < t_0 \\ k_2(t - t_0) + k_1 t_0^b + c, \ t \geq t_0 \end{cases}, \tag{1}$$

where t and t_0 are time and the fatigue point, respectively. Additionally, k_1, k_2, b, and c are parameters of the curve fitting. To determine the difference in the change, the angle of the slope of the linear part of the function was subtracted from the angle of the slope of the tangent of the power function at the fatigue point, and the fatigue point was considered legitimate only if the change in the angle of the slope was greater than 0.3 degrees.

Concerning the shape of the time-extension graph, the samples were classified into three groups: Sustained, Fatigued, and Disrupted (Figure 18). The following were of special interest: 1) repairs that sustained all 500 cycles (Sustained) and 2) repairs that sustained the first 50 loading cycles, but eventually fatigued (expressed the criterion meeting the fatigue point) and then failed (Fatigued). Specimens that failed before 50 cycles or failed later without the fatigue point were allocated to the Disrupted group.

4.5.4 Variations

In Study III, specific tendon repair properties were of interest, and the coefficients of variation (CoVs) were calculated to examine their importance. CoV is a standardized measure of dispersion, and it is also known as a relative standard deviation. CoV can be used to compare variations of data that have different magnitudes, such as the loads of combined repair (Adelaide + peripheral) and simple loop repair. Standard deviation is dependent on the magnitude of absolute measurements: the higher the mean, the higher the SD. Thus, it was not possible to use SD in the analysis.

Means (μ) and standard deviations (σ) of yield and ultimate loads were calculated for each group and, based on these, CoVs were calculated by $CoV = \frac{\sigma}{\mu} * 100\%$. Each percentage value that handles these variations is a relative measure and not an absolute portion of some total variation.

In order to isolate the variations of specific factors, the following equation was used: $CoV_A = \sqrt{CoV_{(A+B)}{}^2 - CoV_B{}^2}$ (Figure 13). In the formula, CoV_A is the main factor to be calculated. $CoV_{(A+B)}$ equals the overall variation within the group including two variation-inducing factors: CoV_A and CoV_B. CoV_B equals the overall variation within another group in which the same variation-inducing factors are present, except for the variation CoV_A. The CoV_A is the main variation inducing factor to be calculated. For example, the variation due to heterogeneity in the pull-out resisting properties of porcine tendons can be isolated by comparing simple loop repairs between tendons and sticks (Table 10). However, the sum of specific variations cannot exceed the variation of tendon repairs because the aim of Study III was to investigate clinically significant variation within the biological tissue (the tendon). Subsequently, if the value in the equation to be squared was negative (i.e., the subtrahend is larger than the minuend) the calculation could not be fulfilled. Thus, the variation of the specific factor was assumed to equal the overall variation.

The overall variation of the combined repair was calculated with two methods: with the prescribed method and by the sum of the overall variation of the core repair and the overall variation of the peripheral repair.

To isolate the variation caused by tendon substance, the variations of stick repairs were subtracted from the variations of the corresponding tendon repairs. Thus, it was assumed that the difference in the variations between groups was caused by tendon substance and the variation caused by surgical performance and testing methodology remained equal (Table 10).

To isolate variation caused by surgical performance, the variation of testing methodology was subtracted from the variations of stick repairs. Thus, material substance variation was assumed to be negligible, and all the variation was caused by the surgeon (Table 10).

To isolate inter-surgeon variation, variation caused by a single surgeon was subtracted from the variation caused by multiple surgeons (Table 10). To compare variations between datasets, inter-surgeon variation in Study IV was also calculated using the preceding method.

If necessary, proportions of the CoVs were also calculated. For example, the inter-surgeon variation proportion of the total variation was calculated with the following equation: $\frac{CoV(several\ surgeons)}{CoV(several\ surgeons) - CoV(combined\ repairs)}$.

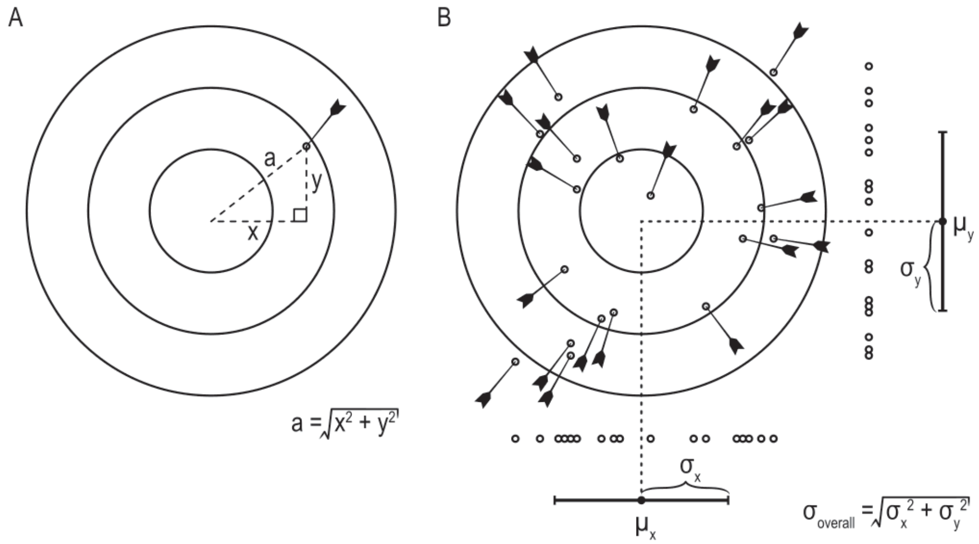

Figure 13. The mathematical model used in Study II can be simplified in the following way: hit of the arrow to the target depends on the accuracy of the archer (vertical variation) and environmental conditions (e.g., wind, horizontal variation). A) If the archer shoots a single arrow, the total distance from the assumed aiming point can be calculated using the Pythagoras' theorem. B) When the archer has shot several arrows, the total variation can be calculated based on the standard deviations (σ) of the horizontal and the vertical variations. μ = mean.

4.5.5 Gap analysis

In Study I and IV, the gap values (1 mm and 2 mm partial and total) were determined from the recorded videos of the static tests. A diameter scale derived from a still photograph taken prior to testing was added to the videos. The gap was considered partial when the maximum opening of the repair site reached a certain measurement (1 mm or 2 mm). Conversely, the gap was considered total 1 mm or 2 mm when the minimum opening of the repair site was more than the previous measurements. Two investigators determined the gapping values individually and the mean of their interpretations was considered legitimate. The interobserver coefficient of variation was then determined.

In Study II, the gap values were determined from still images derived from the recorded videos of the cyclic tests. The images were taken at the resting state of the cycle 1) at the fatigue point and 2) at the last sustained cycle. If the sample resisted all the 500 cycles, the final gap was determined during the 500^{th} cycle. ImageJ 1.50i computer software (W. Rasband, http://imagej.nih.gov/ij/) was used and the gap was measured by pixels at the largest and smallest sections of the gap using a digital ruler. The distance was then converted to millimetres. The longest distance between tendon ends at the specific moment was regarded as the largest section and, conversely, the shortest distance as the smallest section (Figure 14). If both sections were greater than 1 mm or 2 mm, the gap was determined to be a 1 mm or 2 mm total gap, respectively. If only the largest section was greater than 1 mm or 2 mm, the gap was determined to be a 1 mm or 2 mm partial gap, respectively.

In Study III, gapping values were not assessed.

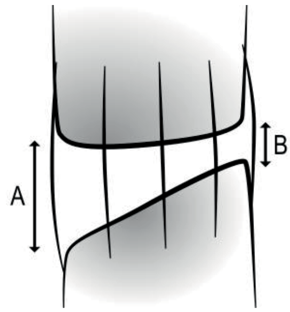

Figure 14. An illustration of a gap measurement image. Gaps were determined by measuring the longest (A; the largest section of the gap) and the shortest (B; the smallest section of the gap) distance of the tendon ends.

4.5.6 Suture modifications

In Study IV, both the drawings of the tendon repairs and the images taken from the tendon repairs were evaluated and compared with the literature. The ratio between standard core suture configurations and their unique modifications was the primary outcome. Suture configuration was regarded as unique if it had not been previously described in an academic publication, either journal or book. For example, the Pennington modified Kessler (Pennington, 1979) and the Gan modified Lim-Tsai (Gan et al., 2012) were regarded as standard repair methods. Differences in the biomechanical properties between groups was the secondary outcome.

4.6 Statistical analysis

An alpha level of 0.05 was considered statistically significant in all studies. In Study I, the relationship between the parameters obtained from static testing and the cross-sectional areas of the tendons were assessed with Pearson's correlation coefficient. Unpaired T-test was used to compare cross-sectional areas of the tendons between static and cyclic tested samples and the parameters of the static tests (ultimate load, yield load, and gapping load) with the critical load.

A one-way ANOVA was used to assess the differences in the cross-sectional areas of the tendons between groups in both Study II and Study III. In Study III, Spearman's correlation was used to calculate the correlation between the cross-sectional areas of the tendons and the yield loads.

In Study IV, differences between groups were assessed with a two-way ANOVA. An *a priori* power calculation for the ultimate load was based on the following assumptions on a two-sided level: difference between the groups 25%, standard deviation 15%, power $(1-\beta)$ set at 0.80 and $\alpha = 0.05$. Thus, a minimum of six samples was required. As in Study I, Pearson's correlation coefficient was used to compare the cross-sectional areas of the tendons with the biomechanical outcomes. Fisher's exact test was used to compare the modification tendency between senior and resident hand surgeons.

5 RESULTS

5.1 Cross-sectional areas of tendons

In Studies I–IV, the mean of cross-sectional areas of the tendons were 5.8 mm^2 (SD 1.2), 5.9 mm^2 (SD 1.0), 6.1 mm^2 (SD 0.8), and 40 mm^2 (SD 9), respectively. No Study had significant differences in the cross-sectional areas of the tendons between the groups ($p = 0.494$, $p = 0.466$, and $p = 0.698$ for Studies I–III, respectively).

In Study I, the ultimate loads of statically tested tendons did not relate to the cross-sectional areas of the tendons ($R = 0.130$; $p = 0.585$). Moreover, the effect was similar in Study IV: the cross-sectional areas of the repaired tendons did not correlate with the biomechanical properties of the repaired tendons.

5.2 Interrater coefficient of variation for gap determination

As previously stated, two investigators determined the gap values in Studies I and IV. In Study I, the interrater coefficient of variation for determination of gapping loads were 7.7%, 4.2%, 3.2%, and 2.3% for 1 mm partial, 2 mm partial, 1 mm total, and 2 mm total gaps, respectively. In Study IV, the corresponding values were 11.4%, 6.8%, 4.6%, and 2.0%.

5.3 Failure modes

In Studies I and II, failure of the peripheral suture preceded core suture failure in all tests except for one cyclically tested sample. All the core sutures failed by suture rupture in Studies I, II, and IV. Conversely, in Study III, the main failure mode of the core suture was suture pull-out: only one core suture within absorbent sticks and three core sutures within inter-surgeon repairs failed by suture rupture. Also, all the peripheral repairs in Study III failed by suture pull-out with the exception of three inter-surgeon repairs failing by suture rupture. Failure modes are presented in Table 5, and a typical failure mode during cyclic testing is demonstrated in Figure 15.

Table 5. Failure modes of repairs.

Study	Group	Core suture		Peripheral suture	
		Break	Pull-out	Break	Pull-out
I	Static	20	0	5	15
	Cyclic	16	0	10	6
II	Fatigued	6	0	4	2
	Disrupted	10	0	6	4
III	Absorbent stick	1	49	0	50
	Tendon	3	47	3	47
IV	Original repair	7	0	3	4
	Modified repair	9	0	0	9

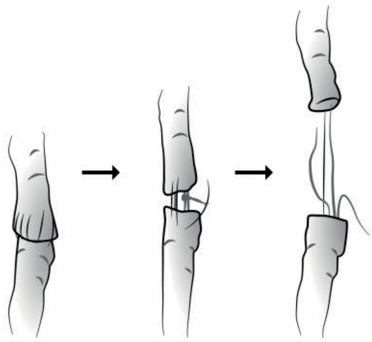

Figure 15. Usually, during cyclic tests, tendon repair ruptures were initiated by rupture of the peripheral suture, and after that the core suture ruptured. See also Table 5.

5.4 Relation of parameters of static testing to cyclic testing (Study I)

5.4.1 Linear static tests

In Study I, twenty Pennington modified double Kessler repairs accomplished with simple running peripheral repairs were tested in a linear static manner to assess the basic biomechanical parameters. The samples had the ultimate load of 46.2 N (SD 11.3) and the yield load of 38.1 N (SD 13.5). The other biomechanical parameters are summarized in Table 6 and Figures 16 (B) and 16 (C).

Table 6. Biomechanical properties of the statically tested tendon repairs of Study I. All parameters are expressed in Newtons.

Parameter	Mean (SD)
Ultimate load	46.2 (11.3)
Yield load	38.1 (13.5)
1 mm partial gapping load	31.1 (10.0)
2 mm partial gapping load	39.3 (10.2)
1 mm total gapping load	41.3 (12.0)
2 mm total gapping load	44.5 (11.9)

5.4.2 Linear cyclic tests

An additional 35 repairs with the same configuration were tested using the cyclic method and sixteen of them failed before 500 cycles (Figure 16A). The samples were divided into successes and fails, and the estimate curve was built. The critical load (failure rate of 50%) was 37.8 N (SD 9.9), and the safe load (failure rate of 2.3%) was 18 N. Two of the repairs were tested under the safe load and both survived all 500 cycles.

The critical load differed significantly from the ultimate ($p = 0.009$), 1 mm partial gap ($p = 0.019$), and 2 mm total gap loads ($p = 0.040$). There was no significant difference between the critical load and the yield, 2 mm partial gap, or 1 mm total gap loads. The safe load was lower than the mean of any static test derived parameter.

5.4.3 Probability to fail

When the biomechanical parameters of the static testing were set to the estimate curve, all of the parameters had a higher probability to fail than the safe load (Figures 16 (B) and 16 (C) and Table 7). The probabilities are dependent on the variation within the present samples.

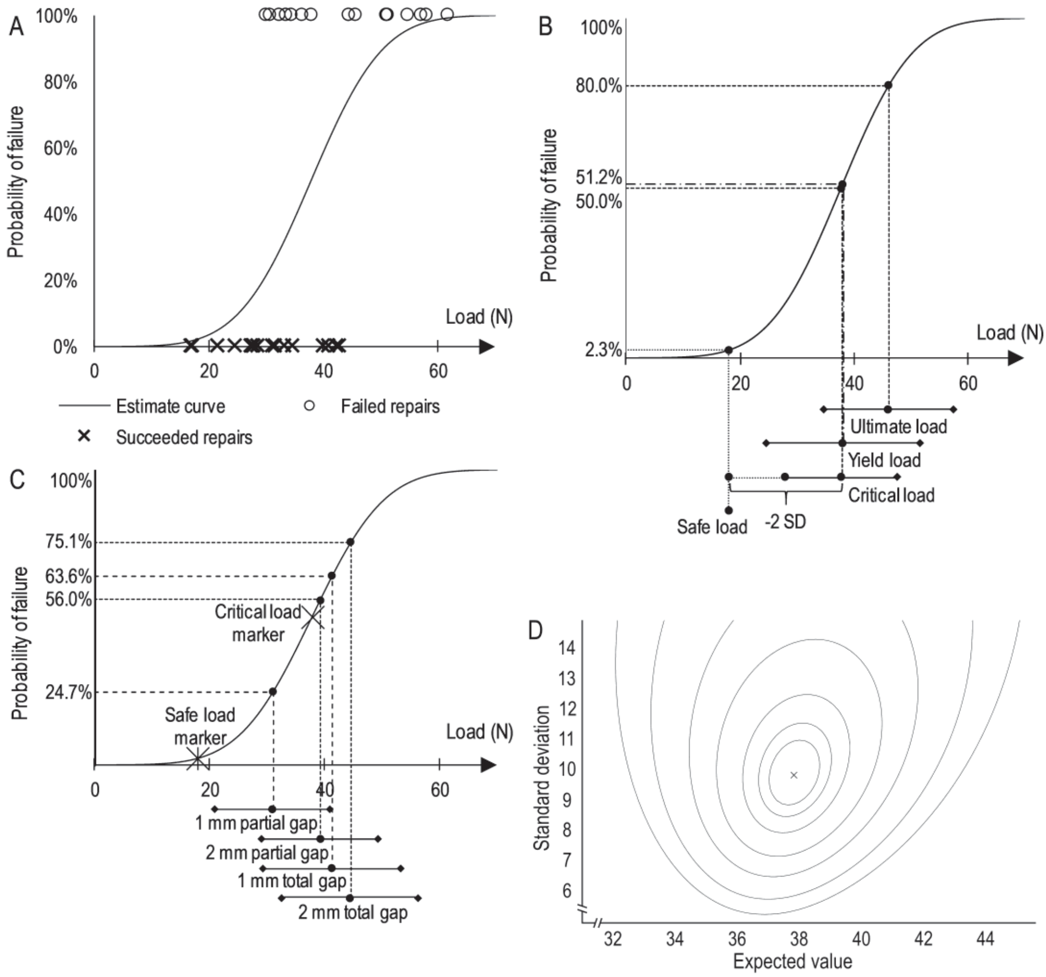

Figure 16. Estimate curve based on cyclic testing of 35 repaired tendons and the determination of the probability of repair failure. A) The relation between peak load during cyclic testing (x-axis) and the probability of failure (y-axis). Each cross or circle represents a single tendon repair. B–C) Probabilities of repair failure during repetitive loading related to the use of the mean of each statically derived parameter or critical load as a peak load. Whiskers represent the standard deviation. The critical load (dashed line, cross, X) is determined as a point where the probability of failure (solid line) is 50%. The safe load (dot line, star, *) is assigned as twice the standard deviation under the critical load (see Chapter 4.5.2). D) Graphical presentation of the MLE function. Beginning from the farthest, solid lines represent 95, 90, 80, 60, 40, and 20% relative likelihoods. Maximum likelihood (critical load) is marked as X.

Table 7. Estimated probabilities of repair failure during cyclic loading for mean of each statically-derived parameter serving as peak load. See also Figure 16.

Parameter	Probability of failure (%)	Probability at −2 SD (%)
Ultimate load	80.0	7.4
Yield load	51.2	0.4
Critical load	50.0	2.3
Safe load	2.3	
1 mm partial gapping	24.6	0.3
2 mm partial gapping	56.0	2.9
1 mm total gapping	63.6	1.9
2 mm total gapping	75.1	4.1

5.5 Gap formation during cyclic testing (Study II)

5.5.1 Biomechanical behaviour

In Study II, time-extension curves were inspected during the cyclic testing and three biomechanical patterns were observed (Figures 17 and 18): 1) Nineteen specimens that sustained all 500 cycles and did not manifest the fatigue point were classified into Sustained group (load range 17.0 N to 42.8 N). 2) Six specimens that sustained the first fifty cycles but later manifested the fatigue point, gapped, and failed were classified into Fatigued group (load range 30.1 N to 51.1 N). 3) Ten specimens that failed during the initial fifty cycles or did not manifest a proper fatigue point were classified into Disrupted group (load range 30.8 N to 61.9 N). It was intended to load one specimen up to 78.0 N. However, the specimen broke during the very first cycle and was therefore omitted from the gap analysis.

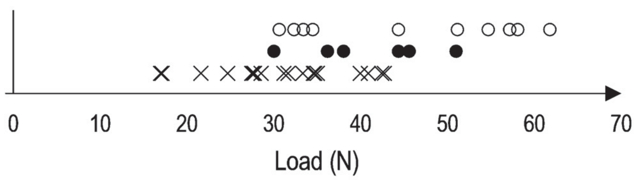

Figure 17. The loads used classified by group. There was a significant difference between the peak loads in the Sustained (cross), Fatigued (black circle), and Disrupted (white circle) groups ($p = 0.006$). Each symbol represents each single sample.

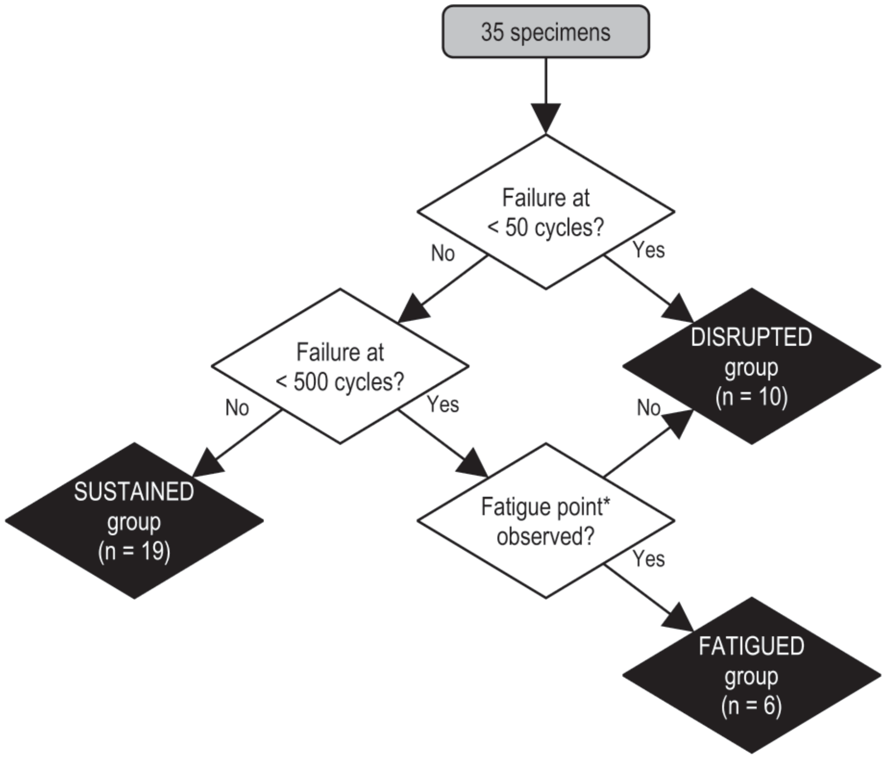

Figure 18. Group allocation of Study II. *The criterion for the fatigue point was a change in angle of the slope greater than 0.3 degrees.

For the Sustained and Fatigued groups, the median changes in the angles of the slopes of the time-extension curves were 0.00 degree (range -7.51 to 0.26) and 3.00 degrees (range 0.42 to 13.13), respectively. There was a significant difference between the two groups ($p < 0.001$). The typical time-extension curves of the specimens in the Sustained, Fatigued, and Disrupted groups are presented in Figure 19.

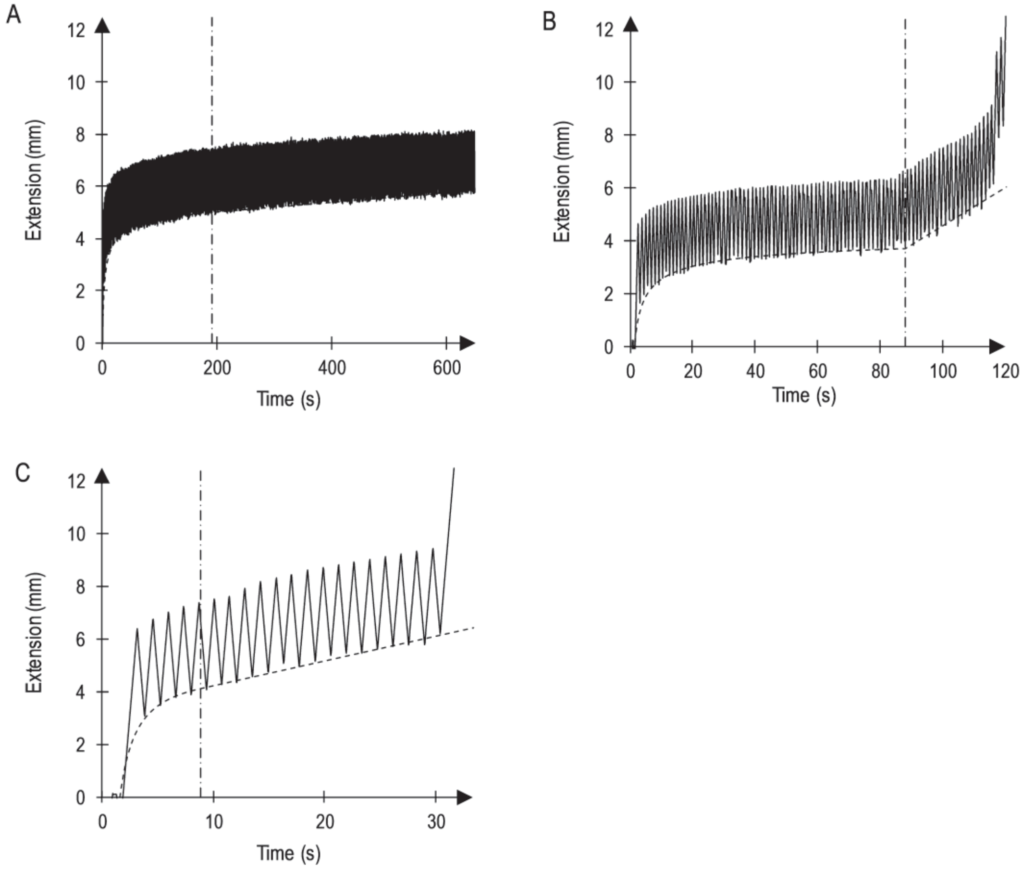

Figure 19. Examples of specimens in the Sustained (A), Fatigued (B), and Disrupted (C) groups. The fitting function (dashed line) and fatigue point (semi-dotted line) are presented in the figure.

5.5.2 Gap formation

For the gap analysis, the main task was to differentiate those repairs that sustain (Sustained group) from those repairs that barely fail (Fatigued group). Thus, it is appropriate to compare gap difference at the biomechanical junction moments. Hence, the final gap of the Sustained specimens was compared with the gap of the Fatigued specimens at the fatigue point. When the medians of the largest sections of the gaps were compared, the gap at the fatigue point was larger in the Fatigue group than the final gap in the Sustained group (1.2 mm vs 0.3 mm, respectively). The smallest sections did not, however, differ between these two groups (Figure 20).

The measurements of the gap at the fatigue point and the final gap are presented in Table 8 and Figure 20. There were no gaps larger than a 2 mm partial gap in the Sustained group (Table 9). Only those specimens that were to fail during the very next cycle expressed a total gap of over 1 mm.

Table 8. Descriptive data and gap measurements of Study II.

Group	n	Cross-sectional area (mm^2)		Load (N)		Section of repair	Gap at fatigue point (mm)		Final gap (mm)	
		Mean	95% CI	Mean	95% CI		Median	Min–Max	Median	Min-Max
Sustained	19	5.8	5.2–6.3	31.1	27.4–34.8	Smallest			0.0	0.0–0.3
						Largest			0.3	0.0–2.0
Fatigued	6	6.4	5.2–7.6	41.0	33.0–48.9	Smallest	0.0	0.0–0.8	1.6	0.9–3.7
						Largest	1.2	1.1–1.6	3.3	2.0–5.5
Disrupted*	10	5.7	5.1–6.3	45.9	37.2–54.6	Smallest			0.3	0.0–3.2
						Largest			1.2	0.0–6.5

n, number of samples; CI, confidence interval; Min, minimum value; Max, maximum value
* One repair failed during the first cycle and was omitted from the gap analysis.

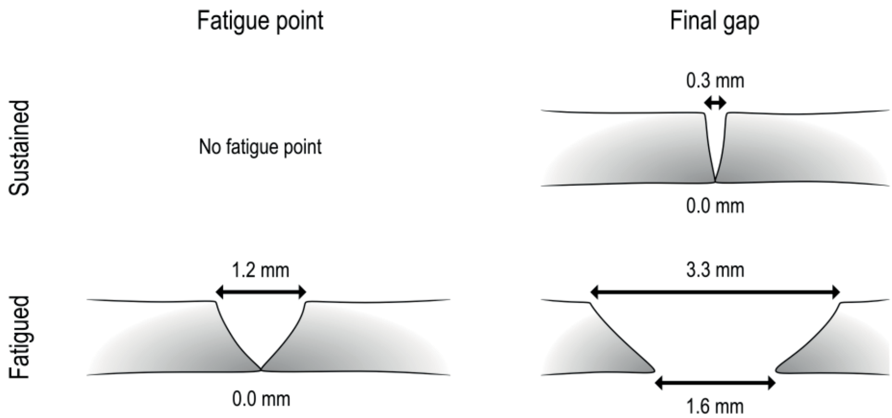

Figure 20. Gapping values. Each panel provides the medians of the smallest and the largest sections of the gap. For the ranges, see Table 7.

Table 9. Number of repairs in each group classified according to the magnitude of final gap formation.

Parameter	Sustained	Fatigued	Disrupted*
Under 1 mm partial gapping	15	0	3
1 mm partial gapping	3	0	2
2 mm partial gapping	1	1	1
1 mm total gapping	0	3	1
2 mm total gapping	0	2	2

*One repair failed during the first cycle and was excluded from this table.

5.6 Variation accounting factors of tendon biomechanics (Study III)

The need to evaluate variations both at the ultimate load and at the yield load arises from two aspects: due to the historical state of the ultimate load, it has been the most reported parameter. Additionally, the yield load is more significant in terms of clinical competence. Generally, the specimens in Study III had consistently smaller variations within ultimate loads than the variations within the yield loads. The means, standard deviations, and the coefficients of variation (CoV) of each group are presented in Tables 10 and 11.

Table 10. Calculated factor-specific variations.

Factor		Formula	Coefficient of variation (%)	
			Yield load	Ultimate load
Testing procedure		Simple loop on stick with jig (baseline)	14	11
Surgical performance	Simple loop	Simple loop on stick – baseline	21	15
	Core repair	Core on stick – baseline	16	15
	Peripheral repair	Peripheral on stick – baseline	30	23
	Combined repair	Combined on stick – baseline	18	14
	Inter-surgeon	10 surgeons – 1 surgeon	14	N/A
Tendon	Simple loop	Simple loop on tendon – simple loop on stick	31	23
	Core repair	Core on tendon – core on stick	9	N/A
	Peripheral repair	Peripheral on tendon – peripheral on stick	N/A	N/A
	Combined repair	Combined on tendon – combined on stick	17	N/A
Surgical performance and tendon combined	Simple loop	Simple loop on tendon – baseline	38	27
	Core repair	Core on tendon – baseline	18	6
	Peripheral repair	Peripheral on tendon – baseline	14	13
	Combined repair	Combined on tendon – baseline	25	13

N/A, Value not available (negative result of the subtraction)

Table 11. Measured loads, standard deviations and coefficients of variation. Each group comprised ten samples.

Material	Repair	Yield load (N)			Ultimate load (N)		
		Mean	SD	CoV (%)	Mean	SD	CoV (%)
Absorbent stick	Simple loop (jig)	21.2	2.9	14	23.8	2.6	11
Absorbent stick	Simple loop (free)	24.2	6.0	25	27.8	5.2	19
Absorbent stick	Adelaide repair	28.1	5.8	21	32.6	6.1	19
Absorbent stick	Peripheral repair	26.6	8.8	33	36.1	9.0	25
Absorbent stick	Combined repair	43.2	9.9	23	51.1	9.1	18
Tendon	Simple loop (free)	8.9	3.6	40	14.2	4.2	29
Tendon	Adelaide repair	30.0	6.8	23	45.1	5.6	12
Tendon	Peripheral repair	23.5	4.6	20	32.7	5.7	17
Tendon	Combined repair	53.5	15.4	29	74.6	12.7	17
Tendon	Several surgeons	45.2	14.4	32	60.4	8.0	13

5.6.1 Yield load

The overall variation of the combined repair showed up to be the sum of its components: core repair and peripheral repair (Figure 21). Both caused half of the total variation. Furthermore, the overall variation of the combined repair divided evenly to surgical performance and tendon substance. In the core only repairs, corresponding proportions were 2/3 and 1/3. In the peripheral only repairs, technical performance caused all the variation. Within simple loop repairs, the variations seemed to be much higher (Figure 21).

Surgical performance caused comparable variations in all core, peripheral, and combined repairs. However, surgical variation caused a higher portion of the overall variation in the peripheral repairs (Table 10). Inter-surgeon variation only explained a tenth of the total variation.

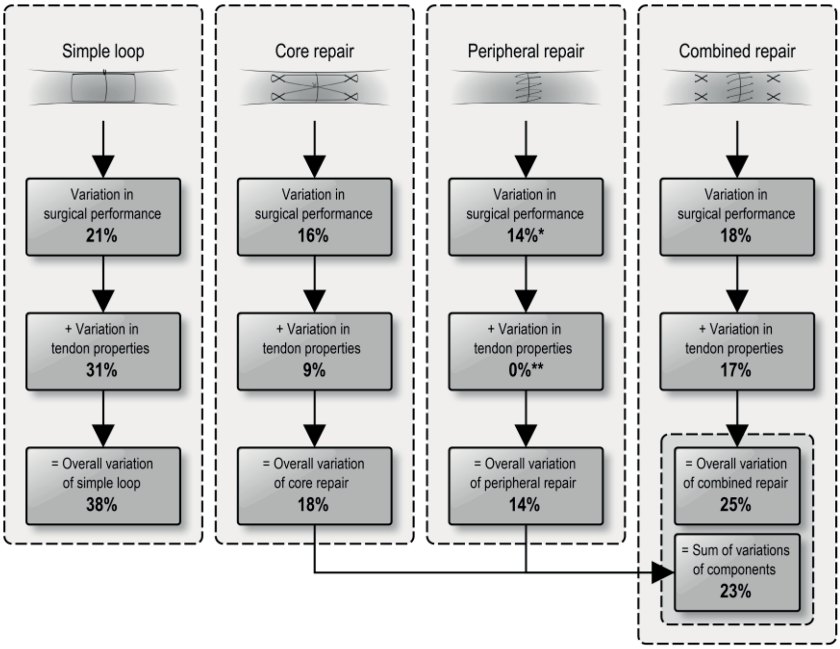

Figure 21. Flow chart of the variations for specific factors in yield load. See also Table 10 for the context of formulas. *The variation for a specific factor outweighed the overall variation and was thus assumed to be equal to it. **The variation for a specific factor was overpowered by the variation of the preceding group.

5.6.2 Ultimate load

The CoVs in ultimate load were consistently lower compared with the corresponding variations in yield load (Table 11). Variation caused by tendon substance was negligible in all repair methods except simple loops (Figure 22). Thus, the total variation was the result of surgical performance. However, the magnitude of surgical performance CoVs were comparable with the corresponding CoVs in yield load (Table 10). The inter-surgeon variation in ultimate load was also negligible (Table 10 and Figure 23).

The variation of the combined repairs in ultimate load was also the sum of its components. In ultimate load, however, the core repair was responsible for 1/3 and the peripheral repair for 2/3 of the overall variation.

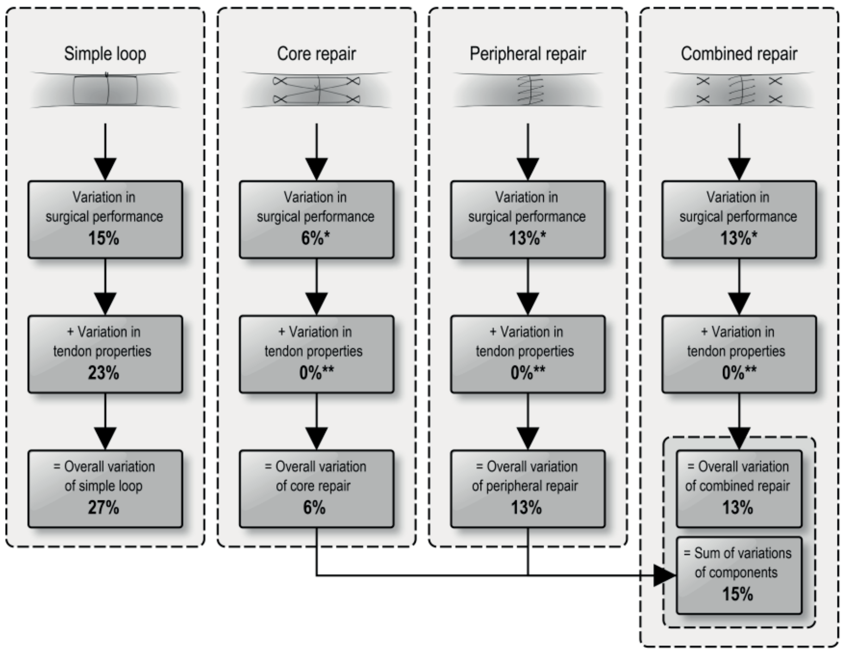

Figure 22. Flow chart of the variations for specific factors in ultimate load. See also Table 10 for the context of formulas. *The variation for a specific factor outweighed the overall variation and was thus assumed to be equal to it. **The variation for a specific factor was overpowered by the variation of the preceding group.

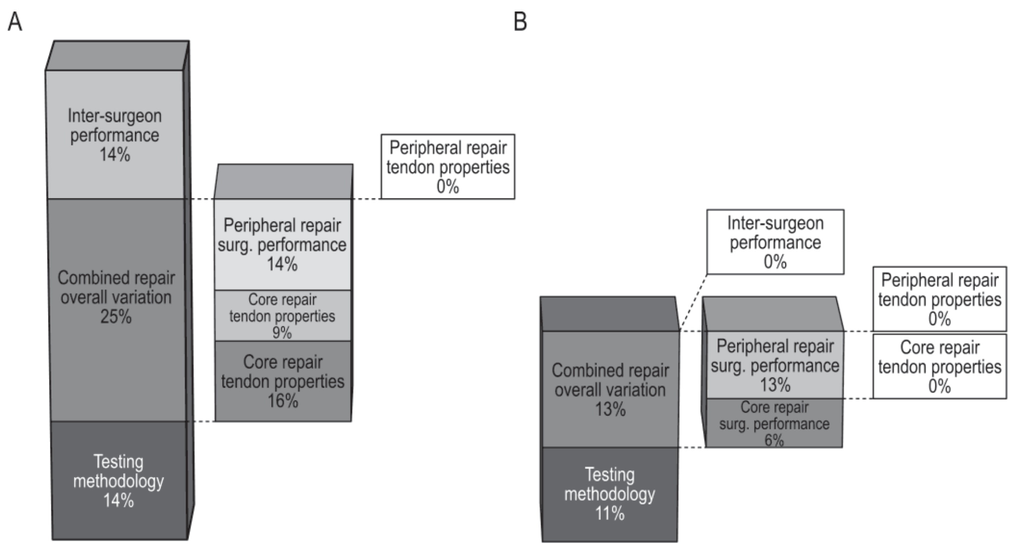

Figure 23. Variations of specific factors in yield load (A) and ultimate load (B) shown presented in a box model. The variation of the combined repair seems to be a product of the independent partial variations of the core and peripheral repairs.

5.7 Modification of suture configuration (Study IV)

5.7.1 Suture configuration

Within the repairs performed in the national tendon symposium, seven of the sixteen surgeons used a standard core suture configuration. The Lim-Tsai (Lim and Tsai, 1996) (Figure 24 (A)) was the most frequently used standard core suture configuration as performed by three of the surgeons. The other suture configurations used were the Pennington modified Kessler (Pennington, 1979), Adelaide (Sandow and McMahon, 2011), and the Gan modified Lim-Tsai (Gan et al., 2012) (Table 12).

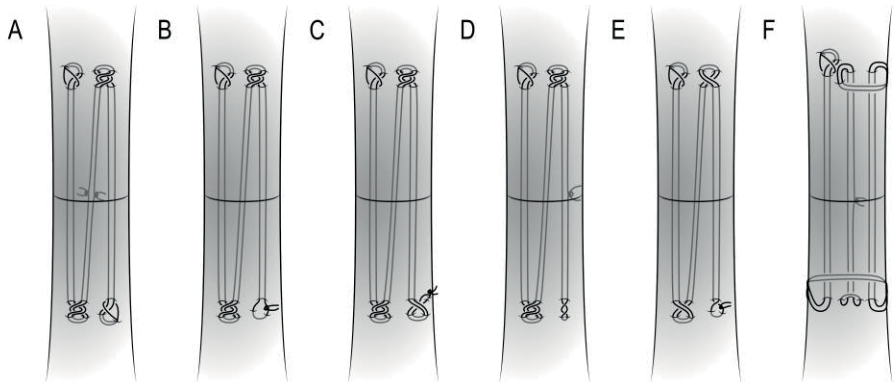

Figure 24. Schematic drawings of typical core suture configurations in Study IV. (A) Lim-Tsai (standard suture configuration). (B) Gan modified Lim-Tsai (standard suture configuration). (C) Modified Lim-Tsai with one looped thread, with knot outside the tendon surface. (D) Modified Lim-Tsai with one looped suture, with knot between the tendon ends. (E) Modified Lim-Tsai with one looped thread, with Tsuge locks changed to simple loops. (F) Modified Lim-Tsai with one looped thread, with Tsuge loops changed to Pennington locks. Note that different modifications had some minor differences within groups.

The remaining nine surgeons used unique core suture configurations that had not been previously described. One of the surgeons misnamed the configuration incorrectly as the original one. The Lim-Tsai and its modified configurations are presented in Figure 24. There was no correlation in the tendency to make modifications between senior and resident hand surgeons (four of eight seniors and five of eight residents, p = 1.000).

Table 12. Core suture configurations used by the individual participants (n = 16).

Suture configuration as named by participant	Suture configuration used	Details
Adelaide (4-strand)	Adelaide (4-strand)	Correctly named and done
Lim-Tsai (6-strand)	Lim-Tsai (6-strand)	Correctly named and done, Figure 24 (A)
Lim-Tsai (6-strand)	Lim-Tsai (6-strand)	Correctly named and done, Figure 24 (A)
Lim-Tsai (6-strand)	Lim-Tsai (6-strand)	Correctly named and done, Figure 24 (A)
Lim-Tsai (6-strand)	Unique modification (6-strand)	Misnamed, Figure 24 (E)
Modified Kessler (4-strand)	Pennington modified Kessler (4-strand)	Misnamed, correctly done
Modified Kessler (6-strand)	Unique modification (6-strand)	Figure 24 (F)
Modified Lim [sic] (6-strand)	Modified Lim-Tsai (Gan modification) (6-strand)	Misnamed, correctly done, Figure 24 (B)
Modified Lim-Tsai (6-strand)	Modified Lim-Tsai (Gan modification) (6-strand)	Correctly named and done
Modified Lim-Tsai (6-strand)	Unique modification (6-strand)	Figure 24 (C)
Modified Lim-Tsai (6-strand)	Unique modification (6-strand)	Figure 24 (C)
Modified Lim-Tsai (6-strand)	Unique modification (6-strand)	Figure 24 (C)
Modified Lim-Tsai (6-strand)	Unique modification (6-strand)	Figure 24 (D)
Modified Lim-Tsai (6-strand)	Unique modification (6-strand)	Figure 24 (F)
Modified Tsuge (6-strand)	Unique modification (6-strand)	Figure 24 (D)
Modified Tsuge (6-strand)	Unique modification (6-strand)	Figure 24 (F)

The peripheral repairs were very similar: fourteen were simple running sutures. Two were the Silfverskiöld repairs (Silfverskiöld and Andersson, 1993) either all the way around the repair or to the anterior part of the repair (completing it with a simple over-and-over repair).

The actual repairs and surgeon drawings were compared and there were no statistical differences in terms of suture configuration, number of knots, or length of suture purchases. The suture materials used by the surgeons in everyday practice are summarized in Tables 13 and 14.

Table 13. The core suture materials that the surgeons reported using in everyday practice.

Core suture material	Number of surgeons using the core suture material
FiberLoop® 4–0[a]	6
FiberLoop® 3–0[b]	1
Braided polyester loop 3–0	7
Simple braided polyester 3–0	2

[a]Arthrex, Inc., Naples, Florida, United States
[b]FiberLoop® 3–0 is not commercially available

Table 14. Peripheral suture materials that the surgeons reported using in everyday practice.

Peripheral suture material	Number of surgeons using the peripheral suture material
Polyamide monofilament 5–0	1
Polypropylene monofilament 6–0	7
Polypropylene monofilament 5–0	8

5.7.2 Biomechanical properties

The biomechanical properties between the original and modified core suture configurations did not differ significantly from each other (Figure 25). The properties are summarised in Table 15. Misnaming the repair or the experience of the surgeon did not have an influence on the biomechanical competence of the repair.

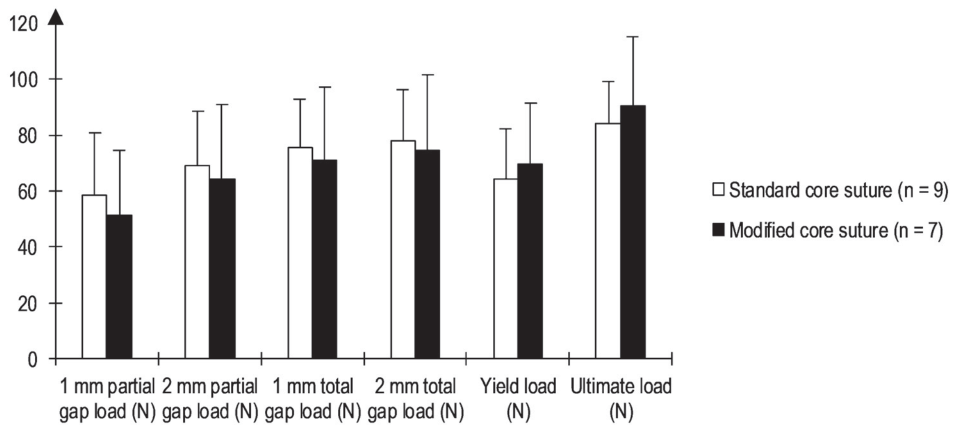

Figure 25. Early gapping values, ultimate load and yield load categorized according to whether original or modified suture configuration was used. There were no statistically significant differences. The error bars represent standard deviations.

The ultimate load, the load at the yield point, and the stiffness were correlated with the number of peripheral suture purchases ($R = 0.709$, $p = 0.002$; $R = 0.834$, $p < 0.001$; and $R = 0.554$, $p = 0.024$, respectively). The repairs in which the knot of the core suture was left outside the repair site were stronger, the ultimate load being 102 N (SD 22), compared with 80 N (SD 16) for the repairs in which the knot was placed between the tendon ends ($p = 0.043$). Repairs using the Silfverskiöld peripheral suture yielded higher ultimate and yield loads compared with repairs using the simple running peripheral suture (125 N (SD 22) vs 82 N (SD 14), $p = 0.002$; and 115 N (SD 7) vs 64 N (SD 14), $p < 0.001$, respectively).

All gapping loads were correlated with the number of peripheral suture purchases ($R = 0.804$–0.852; $p < 0.001$). The Silfverskiöld peripheral suture configuration was superior to the simple running peripheral in terms of gapping loads: the load needed to produce a 1 mm partial gap was 124% higher for the Silfverskiöld technique. The other differences were 102%, 82%, and 79% for 2 mm partial, 1 mm total, and 2 mm total gapping loads, respectively ($p < 0.001$ for all gapping loads). Additionally, the purchase length of the peripheral suture was correlated with the load needed to create a 1 mm partial gap ($R = 0.569$; $p = 0.021$). Otherwise, the length of the purchases of either the core or peripheral sutures had no effect on the biomechanical properties of the repairs.

Inter-surgeon coefficients of variation were 23% in ultimate load and 29% in yield load. In a subgroup analysis, corresponding values were 27% and 31% in original core sutures and 18% and 27% in modified core sutures.

Table 15. Biomechanical data and measurements of the repaired tendons and drawings. All parameters are expressed as mean (SD).

Parameter	All		Standard core SCs		Modified core SCs	
Ultimate load (N)	88	(20)	84	(15)	91	(24)
Load at yield point (N)	68	(22)	64	(18)	70	(22)
Load at 1 mm partial gap (N)	55	(22)	59	(22)	52	(23)
Load at 2 mm partial gap (N)	67	(23)	69	(19)	64	(27)
Load at 1 mm total gap (N)	73	(22)	75	(18)	71	(26)
Load at 2 mm total gap (N)	76	(23)	78	(18)	75	(27)
Stiffness (N/mm)	12	(2)	12	(2)	13	(2)
Cross-sectional area (mm^2)	40	(9)	40	(9)	41	(10)
Number of peripheral suture purchases	13	(3)	14	(5)	13	(3)
Length of core suture purchases in drawing (mm)	9.0	(2.0)	9.6	(1.2)	8.4	(2.3)
Length of core suture purchases in tendon (mm)	8.1	(2.0)	8.3	(2.2)	8.0	(2.0)
Length of peripheral suture purchases in drawing (mm)	1.6	(1.9)	1.9	(2.3)	1.4	(1.6)
Length of peripheral suture purchases in tendon (mm)	1.7	(0.7)	1.8	(1.1)	1.6	(0.2)

There were no significant differences between groups.
N, newtons; SC, suture configuration.

6 DISCUSSION

6.1 Enhancing testing methodology to compare repair techniques

The management of tendon repairs is one of the most studied subjects within the field of hand surgery. There has also been a noteworthy number of experimental studies on the subject. The reasons for this are possibly because studies on tendon repairs are relatively straightforward to execute and also because of innovations within repair techniques and suture materials. Consequently, there is a need to comprehend the results of the experimental studies from a clinical point of view. There are two principles that should be assimilated when examining the parameters of flexor tendon studies. Firstly, the parameters must be precise enough to respond to the clinical situation. Due to the cyclical manner of clinical flexor tendon rehabilitation, it should be possible to contrast the outcomes of static tests with cyclic tests. Secondly, a mean value of outcome represents only the average of a group. The average does not reflect the fact that, for example, half of the repairs have lower ultimate load and several repairs would possibly fail in relatively low loads (Figure 27). The clinical decision should therefore be made with full knowledge of the weakest repairs, and hence the variation within outcomes should be known.

The results of cyclic tests can be surveyed in two ways: by examining which samples failed during testing (Study I) or by inspecting the load-cycle curve after testing (Study II). In Study I, an objective method to compare repair methods was developed. The point where half of the tested samples had failed was assigned and named the critical load. On average, irreversible failures begin to cumulate cycle after cycle at critical load. However, from a clinical point of view, the critical load is just an average and has the impractical failure rate of 50%. Thus, the point – that is twice standard deviations (Mean – 2 SD) under critical load – was calculated and named the safe load. In other words, the safe load is the point where even the weakest individuals are subtracted from the critical load. Thus, the variation of properties within samples is considered. The safe load has a failure rate of 2.3% and may be the most practical outcome in terms of safety. If the safe load was determined to correspond to Mean – 1 SD, as much as 16% of samples would fail during repetitive loading. However, the safe load is applicable only if the present variation within the samples is assumed to be similar to the variation in clinical practice.

The linear static method is very straightforward to perform: the test yields outcomes, such as ultimate load and yield load, that are easy to understand and compare. With the linear cyclic method, outcomes are more complex. Many studies compare cycle counts and the ultimate loads in load-to-failure tests measured after the cyclic test. Additionally, gap amounts have been measured. This is, however, problematic due to a high investigator-dependent variation. For example, in Studies I and IV, there was interrater coefficient of variation of 7.7% and 11.4% in the smallest partial 1 mm gap, respectively. In Study I, a method to presume Newton-based outcomes with cyclic testing was developed. When each sample has individual peak loads, it is possible to model the estimate curve that provides information not only from both loads that the repair withstands but also from the probabilities to failure at certain loads. However, this method also suffers from some weaknesses. For example, it requires *a priori* assumption about the vicinity of the biomechanical competence in order to adjust the suitable peak load distribution profile. Additionally, the required sample size is greater than what is needed for simpler approaches.

In Study II, the cycle-extension curves of the samples were analysed, and three patterns were observed. First, repairs that sustained 500 cycles did not manifest a fatigue point or substantial gapping (Sustained), whereas the failed tendon repairs either fatigued, gapped, and eventually failed before the end of the test (Fatigued) or disrupted very early without a fatigue point (Disrupted). If there existed the described fatigue point at the curve of the sample, the repair was on the verge of inevitable fail during repetitive cycling. The fatigue point, moreover, correlated with the initial gap formation. Thus, it can be judged that the fatigue point denotes a transition from the elastic phase to the plastic phase similar to the yield point that can be detected with static testing. The harmfulness of gap formation in clinical settings is evident (Seradge, 1983). Fatigue of the repair may damage the repair, especially during the early phase of rehabilitation of the repaired tendon. According to an animal model, the biological strengthening of the tendon repair begins 5 to 10 days after surgery with postoperative mobilisation (Gelberman et al., 1999). The healing is probably the same with humans even though the schedule may differ. With time and rehabilitation, the strength of the tendon increases and the repair can withstand greater loads compared with the first weeks (Gelberman et al., 1982).

Some decades ago, it was observed that although early rehabilitation produces great clinical results, it may also lead to rupture of the repair (Kessler and Nissim, 1969). Thus, a need for biomechanical testing arose and numerous biomechanical studies have assessed the biomechanical properties of different repair techniques using static linear tensile testing. The ultimate force of the repair was regarded as the most relevant outcome in early studies. According to Study I, the mean of the ultimate load was 46.2 N and the critical load was 37.8 N. This statistically significant difference is in accordance with the previous findings that tendons subjected to cyclic loading rupture at lower loads than implied by the results of static testing (Sanders et al., 1997). Later, it was argued that the plain average cannot be regarded as a proper threshold and percentile adjustments were proposed. One study suggested an 18% deduction due to the possible decrease in repair strength during the first three weeks after surgery and, moreover, an additional 30% deduction from the ultimate strength, rationalising it by avoiding gapping greater than 2 mm. They assessed that the gapping occurs at approximately 70% of the ultimate repair strength. (Edsfeldt et al., 2015) Also, another guide recommended a safety margin of 50% (Strickland, 1999). Based on the smaller safety factor of 50%, the safe level of loading would be 23.1 N (50% of the ultimate load of 46.2 N), resulting in an estimated probability of repair failure of 6.8%. This still remains over the safe load of Study I and has a greater risk to fail. However, the validity of any deduction has not been clinically verified.

As previously mentioned, the yield load is stated to be the beginning of irreversible deformations, and it has been suggested to be the best outcome with which to compare repair methods (Viinikainen et al., 2004). In Study I, the yield load and the critical load were virtually equal (38.1 N and 37.8 N, respectively) still having failure probabilities of 51.2% and 50%, respectively. This supports the proposal that the critical load also represents the beginning of the permanent failure. Nevertheless, the failure probability of the yield load remains clinically intolerable. Even the 1 mm partial gapping (probability of failure 24.7%) is a very risky outcome from a clinical point of view. Moreover, the gap values are usually measured during the resting phase of the test. If the measures were done during the peak phase, the gap value would be markedly higher and would manifest earlier (Figure 26).

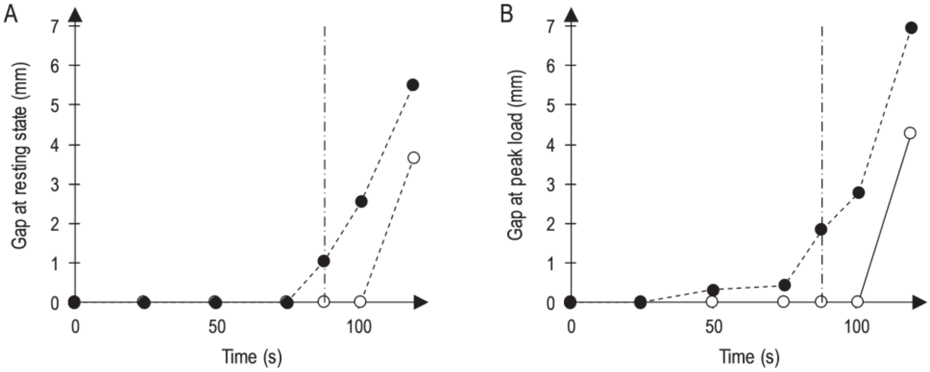

Figure 26. Example of gaps measured during the resting (A) and the peak (B) phase of a sample in Fatigued group. In particular, the largest section of the gap (dash line) was substantial at the fatigue point (dot-dash line) when measured at the peak load.

According to the gap formation in Study II, it was noted that any gap formation will lead to an inevitable rupture of the repair. The harmful effects of the gap formation – e.g., adhesion formation (Seradge, 1983), increased gliding resistance (Zhao et al., 2004), and the disadvantageous effect on the strength accrual of the repair (Gelberman et al., 1999) – are well known. However, there is clinical evidence that, possibly due to the healing ability of the living tendon to regenerate over the gap (Aoki et al., 1997), substantial gaps have been seen during tenolyses (Seradge, 1983) and *in vivo* (Gelberman et al., 1999). Moreover, there are some contrary findings when compared to Study II. Haddad et al. (2010a) observed that four-strand Adelaide repairs using a simple running peripheral suture survived testing of 1 000 cycles between 3 N and 30 N with a mean of 1.9 mm gapping. Additionally, Kozono et al. (2016) showed that a six-strand Pennington-modified Kessler core suture with a circumferential interlocking cross-stitch peripheral suture lasted cyclical testing between 2 N and 85 N for over 8 000 cycles even after 6.2 mm of gapping. These opposite findings emphasise the significance of the suture configuration (both the core and peripheral sutures) and its individual elongation characteristics and strengths. Additionally, in Study II, the first substantially gapped and failed specimen was loaded up to 30.1 N, highlighting that the gap initiates to cumulate only with higher loads. Moreover, tendon selection (Havulinna et al., 2011) and suture materials (Lawrence and Davis, 2005) can have a notable effect on the result.

6.1.1 Limitations

The testing methodology in Studies I and II includes several limitations. First, the distraction rate was different between the static and cyclic tests even though the rate has an influence on the results (Parimi et al., 2012). However, higher velocity increases the peak force of the repair, and hence the effect is more reciprocal than the use of cyclic testing. There are two reasons for the difference in distraction rate. First, the cyclic testing method was built on the basis of the clinical situation: the excursion of the FDP tendon in its sheath is 11.8 mm (Sapienza et al., 2013) and typical finger flexion takes approximately two seconds. Secondly, it was impossible to use a distraction rate as high as 300 mm/min during static tests due to the inaccuracy of the load cell. Additionally, static tests are usually made with relatively low loads (Parimi et al., 2012).

The decision to use only 500 cycles can be challenged. However, these studies focused on the early phase of rehabilitation and, as stated, 500 cycles correspond to the first 5 to 10 days. Additionally, it has been observed that 90% of gap forms during the first 500 cycles (Haddad et al., 2010a). The absence of the preload was an error made during the study design. Due to the energy stored to muscles even during relaxation, it would be physiologically justifiable to have a minimum load of 2 N to 3 N during cyclic testing.

The statistical methods also have their own pitfalls. In Study I, the form of the estimate curve depends on the number of samples. If there is too small a number of samples, the steepest slope of the curve is almost vertical, and the safe load is positioned too near the critical load. Thus, there must be enough samples to have an overlap at the loads of the succeeded and the failed specimens. Moreover, power calculation is infeasible due to the nature of the mathematical model. In Study II, the deficiency is the arbitrary threshold of 0.3 degrees used in the slope analysis. With that threshold, the insignificant noise due to small slope changes within Sustained samples was avoided. Additionally, there was a statistically significant difference in the changes of angles of the slopes between the Sustained and the Fatigued specimens that supports the use of the threshold.

Finally, all studies were laboratory studies that cannot take into account the biological processes, such as postoperative biological changes in the tendon tissue (McDowell et al., 2002) and soft tissue oedema (Wu et al., 2012). Moreover, only one core and peripheral suture was used in Studies I and II, inducing care generalisation in clinical situations.

6.2 Enhancing performing repair

The ability of the surgeon, the core and peripheral sutures used, and the tendon itself are all factors that constitute the mechanical competence of flexor tendon repair. Naturally, these factors are also sources of variation between different repaired tendons. Decreased variation leads to better clinical outcomes since there are fewer mechanically suboptimal repairs that are prone to failure during postoperative rehabilitation. In other words, the more reproducible the repair, the smaller the probability is that a weak repair will fail (Figure 27). Usually, analysis of variance is used to compare means of outcomes of the repair method tests to each other (Altman, 1991). When, for example, load needed to rupture is refereed, half of the individual samples would fail with lower loads than the average. Hence, it would be more practical to converse on repair methods in terms of safety and reproducibility. Although numerous repair methods have been compared with each other, the factors that cause the variability to the repair have remained unknown.

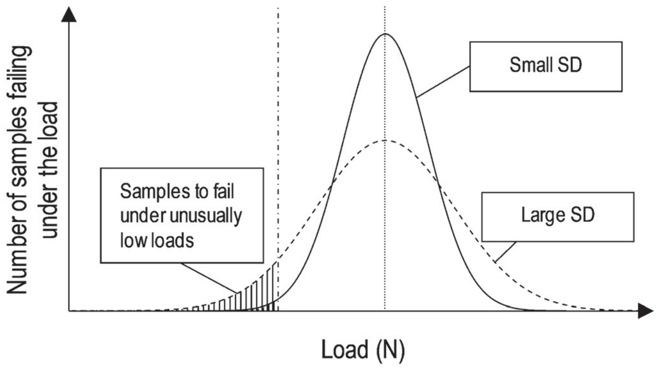

Figure 27. The significance of different standard deviations (i.e., reproducibilities) between two imaginary repair techniques. If the standard deviation is large (dashed line), several repairs will fail under unusually low loads during active rehabilitation (dot-dashed line). The repair technique with the lower standard deviation (solid line) remains intact more frequently during rehabilitation.

A spring analogy, developed by Lotz et al. (1998), is a biomechanical model that demonstrates that the durability of the repair is highly dependent on load sharing between the core and peripheral repairs. During loading, the force is subjected to two springs: one represents the core suture and the other the peripheral suture. These springs share the load with each other. When pulling force is subjected to the repair, the peripheral suture usually fails when the load increases and the strain transfers solely to the core suture. Irreversible deformations have occurred, and thus the yield load is the sum of the maximum loads carried by the two components of the repair. In Study III, the overall variation of the tendon repair in yield load was also the sum of the variations of its two components, the core and peripheral suture. The overall variation in ultimate load was similar, but the proportions were different.

Interestingly, the variations of the yield load outweighed the variations of the ultimate load. Two potential factors can explain this. First, the methodology of the analysis of the yield load is sensitive to inaccuracies, and small irregularities in the load-deflection curves can be interpreted as yield points. Second, asynchronous tightening of the two components of the repair cause uneven load bearing on the small segment of the repair and can lead to early rupture of the stressed segment of the repair, as described in the study of the spring analogy (Lotz et al., 1998). Thus, variation of the yield load can increase due to the asynchrony. Similarly, the factors causing the variation in the load sharing between the multiple suture strands (i.e., inter-surgeon performance and the combination of core and peripheral repairs) were highlighted in terms of the yield load.

Evidently, the simple loop has different properties in deforming tendon fibrils during pull-out compared with the more complex cross-lock loops of the Adelaide repair or over-and-over peripheral repair. Hence, every single repair technique was analysed independently. Interestingly, the variation in the pull-out loads of the simple loops was higher when compared with the peripheral or combined repairs. The variation in the cross linking of the tendon fibrils may provide an explanation. The variation diminishes when multiple loops are used as each loop constitutes only a fraction of the total pull-out resistance. Several loops compensate the heterogeneity of the resistance of the individual cross links. The constricting manner of the loops of the Adelaide repair could be assumed to diminish the variation. However, Dong et al. (2016) compared different repair methods but did not observe a lower variation of ultimate strength of suture loop that constricted around the tendon fibrils when compared with a non-constricting simple loop. Thus, there is no evidence to support the previous assumption.

A good tendon repair should 1) have enough biomechanical competence to sustain the rehabilitation and 2) remain small enough to glide properly in the sheath-pulley system. In Study IV, it was impossible to study the gliding properties of tendon repairs in symposium workshop conditions, but there were some properties of the repairs that were positively correlated to the outcomes of the static test. The more purchases that existed in the peripheral suture, the higher were all the biomechanical properties measured. This effect was independent of the cross-sectional area of the repaired tendon. The observation agrees with the previous study that emphasised the effect of suture pass number on the tensile strength and gap resistance (Kubota et al., 1996). Additionally, the Silfverskiöld technique proved to be superior to the conventional simple running peripheral suture technique in terms of yield load, ultimate load, and especially gapping loads. However, only two surgeons used the Silfverskiöld technique but, despite this, the finding is consistent with the previous evidence (Kim et al., 1996; Silfverskiöld and Andersson, 1993). Indeed, the results of Study IV emphasise the significance of the peripheral suture that is also highlighted in the spring analogy (Lotz et al., 1998). Finally, repairs in which the knot was placed outside the repair site sustained higher ultimate load than repairs with the knot between tendon ends. This is in line with the findings of a previous study (Aoki et al., 1995), but it should be noted that the advantage of knot placing diminishes after the initial phase of healing (Pruitt et al., 1996a).

Surprisingly, the resident hand surgeons tended to modify repairs as often as the specialists. It seems that the accumulated experience does not have an influence on this. Additionally, contrary to the assumption that modification could weaken the repair, the modified suture configuration techniques were fortunately as biomechanically competent as the original ones.

Typically, the Lim-Tsai repair (Lim and Tsai, 1996) was modified by using only one looped thread and completed either with one knot between the tendon ends (Figure 24 (D)) or with a separate knot outside the tendon surface (Figure 24 (C)). Theoretically, this kind of modification might result in increased strength during the initial rehabilitation (Aoki et al., 1995). Moreover, additional knots between the tendon ends probably make the repair weaker (Rees et al., 2009). Another unique modification pattern was to change the type of locking loops (Figure 24 (F)) or to modify locking loops to simple loops (Figure 24 (E)). Because the biomechanical properties of the unique modifications were similar to the standard repairs, changing the type of loop did not predispose the repair to premature failure. This is in accordance with previous reports (Wu and Tang, 2014a, 2011).

In Study III, the effect of tendon material properties on overall variation was inferior to the effects of the execution of the repair itself. However, addition of inter-surgeon related variation increased the variation of combined repair by only a tenth. It seems that coefficient of variation of inter-surgeon repairs remain consistent regardless of the repair method: in Study IV, CoVs in yield load were comparable with values in Study III (29% vs 32% in yield load and 23% vs 13% in ultimate load). Furthermore, modification of the repair did not alter CoVs substantially. The results from Study IV support our finding about the magnitude of the inter-surgeon variation even though multiple repair methods are used in Study IV.

The result of Study III can be summarised in a clinical example[1]: The mechanical properties and gliding properties (the latter was not investigated in this study) defines the quality of each surgeon's tendon repairs. Besides the average strength, the consistency of the repairs is significant. A surgeon is unable to influence the variation of the tendon properties (17.4%). However, the variation related to the execution (18.2%) is all about the surgeon's ability. If a surgeon can lower the variation of his execution from 18.2% to, for example, 12.6%, the failure rate of 4% could decrease by half (2%). This highlights the significance of the learning curve because when the surgeon repeats the same repair over and over again, variation within samples diminishes. Moreover, it should be recommended that surgeons use previously well-practiced repair methods instead of adopting every new technique they might read about.

6.2.1 Limitations

Both Studies III and IV have a limitation according to sample size. In Study III, the group size of ten samples was based on the number of hand surgeons at the clinic. In Study IV, the number of participants at the symposium limited the sample size and subsequently the statistical power. Symposium-conditions were also responsible for other limitations in Study IV. Larger FDP tendons of rays III and IV were used to allow repairing without magnification loupes even though the FDP-II resembles more human tendons (Havulinna et al., 2011). Moreover, the organizer of the symposium provided the suture materials, and therefore surgeons were unable to use the same materials they would normally use in daily clinical practice. Level of expertise was not gathered, and thus is not reported in results.

In Study III, only one core and peripheral suture configuration were evaluated. The Adelaide suture was selected because its locking loop provides mostly pull-out failures. If the repair was to fail by suture rupture, the biomechanical testing would

[1] The variations reposted in this example are variations of the combined repair in yield load with the following assumptions that may not be entirely true: 1) the variation of the porcine tendons is similar to the tendons of flexor tendon injury patients, 2) the execution of the tendon repair is similarly consistent in a laboratory and in an operating room, 3) the average yield load of the used flexor tendon repair is 62 N, 4) during the rehabilitation process, forces up to 35 N (Schuind et al., 1992) are applied, and 5) the failures take place during the rehabilitation and not if the tendon repair is subjected to accidentally higher loads.

examine the thread rather than the repair configuration. However, failure mode was not important in Studies I and II because the aim was not to study the repair itself but the testing methodology. Finally, both Studies III and IV were implemented with linear static loading despite cyclical loading being physiologically more relevant. However, there is still no established cyclic testing protocol and numerous sources of errors can be avoided by using static testing. Additionally, in Study III, the partial variations were compared and there was no intention to implement the exact values to a clinical setting. Thus, the cyclic testing would not provide any additional benefits from that point of view.

7 SUMMARY AND CONCLUSION

As previously stated, the determination of the early gapping is very interpreter-dependent. The methods developed in Studies I and II resemble the physiological situation and are based purely on the biomechanical test results and are therefore easily reproduced. Despite the comparison to the yield load of both the critical load and the fatigue point, these measures have distinct characteristics. The critical load – and specifically the safe load – are computational, hypothetical measures that apply to the comparison of repair methods due to the simple division to intact and failed. The fatigue load, however, is based on direct observation and thus describes the biomechanical competence of the repair. The following conclusions can be made based on Studies I and II:

1. The yield load is able to predict the ability of a tendon repair to withstand repetitive loading undamaged. More studies with other suture configurations are needed to ensure the congruence with the critical load.
2. The critical load is applicable to assess the biomechanical properties of tendon repairs, and it is recommended that cyclic testing be used instead of static testing.
3. The manifestation of a fatigue point and even minor gapping will lead to the failure of the repaired tendon if repetitive loading is continued. The harmfulness of even minor gapping was observed in relation to the safe load and to the fatigue point. Studies with other suture configurations are needed to verify the generalisability of this finding.

On the one hand, a surgeon can modify the original tendon repair without affecting the biomechanical competence of the repair. Moreover, using their ability, surgeons can also halve the failure rate of the repair. The following conclusions can be made based on Studies III and IV:

4. The overall variation of tendon repair comprises numerous small variations. None of the factor specific variations were markedly greater than the others. The effect of tendon material properties on overall variation was generally

inferior to the effects of the execution of the repair. However, the additional inter-surgeon variation derived from a group of several surgeons performing the tendon repair was surprisingly small. Further studies are needed to compare the variations of the different repair methods.

5. Modifying of the core suture configuration does not compromise the biomechanical competence of tendon repairs. However, the use of original repair techniques is recommended to maintain regular quality control.

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Validity of parameters in static linear testing of flexor tendon repair

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ABSTRACT

To study the biomechanical properties of flexor tendon repairs, static tensile testing is commonly used because of its simplicity. However, cyclic testing resembles the physiological loading more closely. The aim of the present study is to assess how the biomechanical competence of repaired flexor tendons under cyclic testing relates to specific parameters derived from static tensile testing. Twenty repaired porcine flexor tendons were subjected to static tensile testing. Additional 35 specimens were tested cyclically with randomly assigned peak load for each specimen. Calculated risks of repair failure during repetitive loading were determined for mean of each statically derived parameter serving as a peak load. Furthermore, we developed a novel objective method to determine the critical load, which is a parameter predicting the survival of the repair in cyclic testing. The mean of statically derived yield load equalled the mean of critical load, justifying its role as a valid surrogate for critical load. However, regarding mean of any determined parameter as a clinically safe threshold is arbitrary due to the natural variation among samples. Until the universal performance of yield load is verified, we recommend employing cyclically derived critical load as primary parameter when comparing different methods of flexor tendon repair.
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1. Introduction

Flexor tendon repair must be biomechanically adequate to withstand the method of rehabilitation used postoperatively (Tang, 2006). The postoperative rehabilitation regimens after flexor tendon repair range from passive movements (Duran and Houser, 1975) to early active flexion of the fingers (Elliot et al., 1994; Small et al., 1989). The trend has been towards early active protocols that increase excursion of the tendons but also the force applied to the repair. The tendon repair strength needed to withstand early active motion is not exactly known.

Traditionally, biomechanical properties of tendon repairs have been studied using static tensile testing until the failure of the repair (Pruitt et al., 1991). Static testing protocols follow general material science tensile testing principles allowing the determination of elongation, yield load, and ultimate load. However, a repaired tendon is not homogenous material. Because of the interaction between the tendon and the suture, the interpretation of elastic and plastic regions from the load-deformation curve is probably not as reliable as in homogenous materials. Ultimate force is often reached long after the repair has already gapped beyond clinically acceptable limits. Therefore, it has been suggested that instead of ultimate force, the yield force should be used for comparison of different repairs (Viinikainen et al., 2004). On the other hand, based on the gapping studies in animals, different gap forces have also been used to evaluate the strength of repairs (Momose et al., 2001). Currently, there is no consensus, which parameter derived from the static testing is clinically relevant.

In postoperative active rehabilitation programs, tendons are subjected to repetitive motion exercises. Therefore, it has been proposed, that cyclic testing enables the determination of the competence of the repaired tendon in a more physiologic way than static testing (Gibbons et al., 2009; Pruitt et al., 1991; Sanders et al., 1997). Cyclic loading has been shown to lead gapping between the tendon ends at lower loads than static loading (Pruitt et al., 1991; Viinikainen et al., 2009) and to decrease the ultimate strength of the repaired tendon (Gibbons et al., 2009). Cyclic testing would probably yield clinically more relevant mechanical property but currently there are no reliable standardized methods to determine biomechanical properties in cyclic testing. The aim of the present study was to assess the relationship between the parameters of repaired flexor tendons in static testing and the

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tendency to fail in cyclical loading. Based on the cyclic testing results, we also developed an objective method to determine an applicable parameter: the critical load, representing the load where irreversible deformations start predisposing the tendon repair to disruption.

2. Materials and methods

2.1. Samples

A total of 55 porcine flexor digitorum profundus II (FDP-II) tendons were used in this study. Fresh frozen pig hind-leg trotters were obtained from the abattoir. The ratio of males and females could not be retraced. Before surgery the trotters were thawed to room temperature, the tendons were dissected and the dimensions were measured using a caliber. Cross sectional areas of the tendons were calculated ($A = \pi^*ab$, in which a is the semi-minor and b the semi major axes). Each tendon was cut with a surgical scalpel and repaired. The repair was performed using two Pennington modified Kessler sutures (Pennington, 1979) with 4–0 braided polyester (Ethibond Excel, Ethicon, San Lorenzo, PR, US) as core suture and was completed with nine-purchase over-and-over peripheral repair with 6–0 polyamide (Ethilon, Ethicon, San Lorenzo, PR, US) (Fig. 1). The specimens were kept moist in saline-soaked gauzes, except when measured. Approval of ethical board was not needed for this study because no living animals were involved.

2.2. Biomechanical testing

Biomechanical testing of the specimens was performed using a materials testing machine (LR 5 K Lloyd Instruments Ltd, Hampshire, UK) connected to a computer with software (Nexygen, Lloyd Materials Testing, Ametek, Inc, Berwyn, PA, US). Of a total of 55 samples, randomly selected group of 20 repaired tendons were subjected to static tensile testing, and a group of 35 for cyclic testing.

2.3. Static tensile testing

Twenty repaired tendons were secured to the testing machine with clamps 30 mm apart from each other, and linear tensile loading was subjected to the specimen until the breakage of the repair. A preload of 0.5 N was used. Velocity of the loading was 20 mm/min. Ultimate load and the yield load were determined from the load-deformation curve. The yield load was determined with a 0.1 mm offset method (Lotz et al., 1998). The biomechanical testing was filmed using two diametrically placed cameras (Canon EOS 550D and Canon EOS M, Tokyo, JP) to enable the evaluation of gap formation (1 and 2 mm partial and total gapping loads) and failure mode. The gap was considered to be partial when the maximum opening of the repair site reached certain measurement (1 or 2 mm). On the other hand, the gap was considered to be total when the minimum opening of the repair site was more than the measurement (1 or 2 mm). The video recordings were independently interpreted by two authors to determine the gapping loads and the mean of their interpretations was considered legitimate. The interrater coefficient of variation was determined.

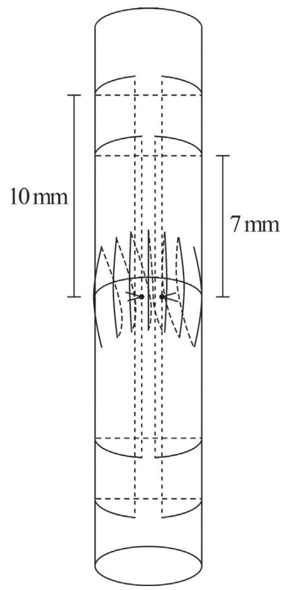

Fig. 1. A schematic illustration of the repair method.

2.4. Cyclic testing

Thirty-five repaired tendons were loaded in a cyclic manner using the same set-up, machine, and video recording as for static tensile testing. Maximum cycle count was 500. The velocity of loading was 300 mm/min. The base load was 0 N in all tests. The peak load was randomly adjusted for each specimen so that the group of 35 samples would cover the whole range of loads both under and over the yield load (from 17.0 N to 61.9 N) derived from static tensile testing pilot study. Each specimen was tested using constant peak load; the tendon either sustained all 500 cycles after which the testing ended or the repair disrupted during the testing.

Maximum likelihood estimation (MLE) is often used to estimate parameters of statistical model. Let θ be a vector that includes parameters of likelihood function and $x = x_1, x_2, \ldots, x_n$ be an observed sample. The likelihood of parameters θ with observations x equals the probability of observations x with parameter values θ: $\mathcal{L}(\theta|x) = P(x|\theta)$. For independent and identically distributed observations, the joint probability of observations x is product of the probabilities. Thus, for a continuous probability distribution $\mathcal{L}(\theta|x) = \prod_{i=1}^{n} f_\theta(x_i)$, in which f_θ is probability density function with parameters θ. The best likelihood is obtained by maximizing this result.

We used MLE to estimate the probability of failure for cyclically loaded specimens (Fig. 2A and D). Let $I_f(i)$ be an indicator function in which i is an index of an observation. The value of the indicator function is 1, if specimen failures, and value 0, if specimen sustains all 500 cycles. For convenience, let us call these two possible outcomes success (0) and failure (1).

Let $p_\theta(x)$ be the probability of failure, in which x is peak load used in cyclic tests and θ includes parameters of the probability distribution. If load x_i corresponds to observation i, probability of failure is $p_\theta(x_i)$ and probability of success is $1 - p_\theta(x_i)$. Utilizing the indicator function, the probability is $|p_\theta(x_i) + I_f(i) - 1|$ in both cases. So, the function to be maximized is $\prod_{i=1}^{n} |p_\theta(x_i) + I_f(i) - 1|$.

For simplicity, it is assumed that the cyclic peak load by which the repaired tendon barely sustains 500 cycles is normally distributed. Strictly, it is possible that the sample would present a double peak distribution, since sample most likely consists of tendons from both sexes. The probability of failure at given peak load equals the probability that the load which the tendon repair withstands is less than the load used. Thus, the probability of failure is obtained from cumulative distribution function of the normal distribution: $p_{\mu,\sigma}(x) = \frac{1}{2}\left[1 + \mathrm{erf}\left(\frac{x-\mu}{\sqrt{2\sigma^2}}\right)\right]$, in which parameters to estimate are expectation value μ and standard deviation σ.

The estimate parameters were assessed by computer software (MATLAB R2015b, MathWorks, Natick, MA, US). The steepest slope of the curve represents the average point where irreversible plastic changes begin to cumulate (coined to the critical load). However, it does not take into account the biological variation among samples and subsequent clinically safe threshold of loading. Due to the assumption of normal distribution, the risk of repair failure at theoretical critical load is 50%. Point $p_{\mu,\sigma}$ (-2σ) that is twice the standard deviation under mean of the critical load is coined to the safe load. It takes into account the effect of variation within the sample, and can be regarded as a more clinically relevant parameter than the critical load.

2.5. Analysis

The individual risk of repair failure for each statically derived parameter (ultimate load, yield load, and 1 mm and 2 mm partial and total gapping loads) to be used as a peak load of repetitive loading is judged from the estimate curve: $probabilityoffailure(\%) = y_1 * 100\%$, where y_1 represents the probability to failure (y-axis) at the point where load (x-axis) equals the mean of each statically derived parameter (Fig. 2B and C). The probabilities are related to the total variation within the present sample.

To rule out the possible confounding effect of caliber differences between specimens, Pearson's correlation coefficient was used for determination of the correlation between statically derived parameters and cross-sectional area, and unpaired T-test was used to compare cross sectional areas of the statically and cyclically tested tendons. Also, unpaired T-test was used to compare critical load of cyclically tested tendons to ultimate load, yield load and gapping loads of statically tested tendons. An alpha level of 0.05 was considered significant.

3. Results

The mean cross-sectional area of the repaired tendons was 5.8 (SD 1.2) mm^2. Ultimate loads of statically tested tendons were not related to cross-sectional areas of the tendons ($R = 0.130$,

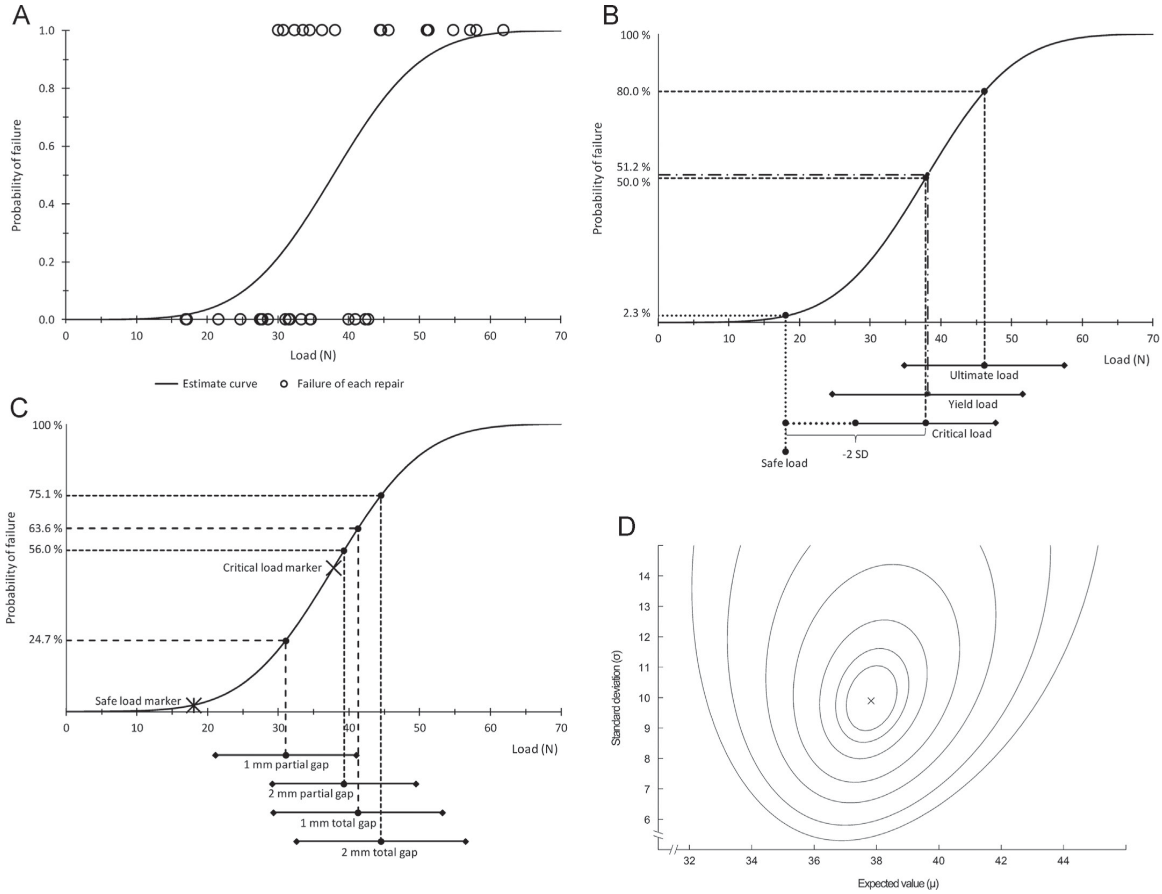

Fig. 2. Estimate curve based on cyclic testing of 35 repaired tendons, and determination of the probability of repair failure. (A) The relation between peak load during cyclic testing (*x*-axis) and the probability of failure (*y*-axis). Each circle represents a single tendon repair. (B), (C) Probabilities of repair failure during repetitive loading related to the use of the mean of each statically derived parameter or critical load as a peak load. Whiskers represent the standard deviation. The critical load (dashed line, cross, *X*) is determined as a point where the probability of failure (solid line) is 50%. The safe load (dot line, star, *) is assigned as twice the standard deviation under the critical load (see Material and Methods). (D) Graphical presentation of the MLE function. Beginning from the farthest, solid lines represent 95%, 90%, 80%, 60%, 40% and 20% relative likelihoods. Maximum likelihood (critical load) is marked as *X*.

Table 1
Biomechanical properties of statically tested tendon repairs. All parameters are expressed in Newtons.

Parameter	Mean (SD)
Ultimate load	46.2 (11.3)
Yield load	38.1 (13.5)
1 mm partial gapping load	31.1 (10.0)
2 mm partial gapping load	39.3 (10.2)
1 mm total gapping load	41.3 (12.0)
2 mm total gapping load	44.5 (11.9)

$p=0.585$), and there was no difference in cross-sectional area between the tendons subjected to static tensile testing or cyclic testing (5.6 (SD 1.5) mm^2 vs. 5.9 (SD 1.0) mm^2, $p=0.494$).

3.1. Static tensile testing

The biomechanical parameters of the 20 statically tested tendon repairs are summarized in Table 1 and Fig. 2B and C. The interrater coefficient of variation for determination of gapping loads were 7.7%, 4.2%, 3.2%, and 2.3% for 1 mm partial, 2 mm partial, 1 mm total, and 2 mm total gaps, respectively. Failure of the peripheral suture preceded the failure of the core suture in all static tests. The failure modes are summarized in Table 2.

Table 2
Failure modes of tendon repairs.

Suture	Failure mode	Static tests	Cyclic tests[a]
Peripheral	Suture rupture	5	10
	Suture pullout	15	6
Core	Suture rupture	20	16
	Suture pullout	0	0

[a] In cyclic testing, the failure modes were obtained from samples that failed during testing (16 out of 35).

3.2. Cyclic testing

Sixteen of 35 cyclically tested specimens failed before 500 cycles (Fig. 2A). The critical and safe loads were 37.8 (SD 9.9) N and

18.0 N, respectively. Both two repairs subjected to the cyclic loading below the safe load sustained the maximum cycles of 500.

The critical load differed significantly from the ultimate ($p=0.009$), 1 mm partial gap ($p=0.019$), and 2 mm total gap loads ($p=0.040$). There was no significant difference between the critical load and the yield, 2 mm partial gap or 1 mm total gap loads. Apart from one sample, the failure of the peripheral suture preceded the core suture failure. Failure modes are summarized in Table 2 and a typical failure mode is presented in Fig. 3.

3.3. Probability to fail

The probability of repair failure when adopting a mean of any statically derived parameter as a peak load (i.e. potentially adequate tendon repair strength for repetitive loads) was high (Table 3 and Fig. 2B and C). These risks are dependent on the variation within the present samples.

4. Discussion

In the quest of clinically relevant parameter to be used when investigating the biomechanical competence of flexor tendon repair, it is crucial to understand two properties of any measured parameter. First, the measurement has to be accurate so that it represents the clinically significant changes within the tendon repair. Specifically, knowing the dependency of the parameters of static and cyclic testing is important, as majority of biomechanical research relies on results from static tensile testing, but the clinical situation is closer to the cyclic testing. Secondly, a mean value represents the average of a group and the average does not reflect the fact that several repairs would have already failed in lower

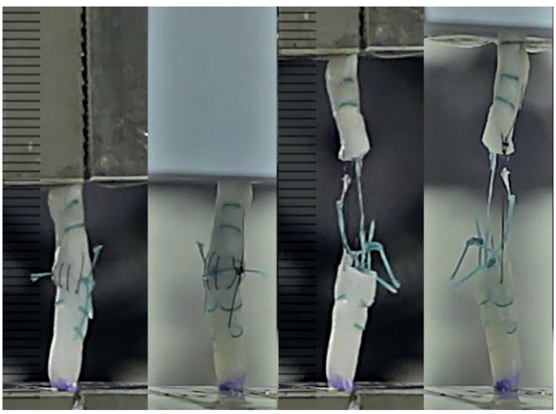

Fig. 3. Test setup (left) and a typical failure mode (right).

Table 3
Estimated probabilities of repair failure during cyclic loading for mean of each statically-derived parameter serving as peak load. See also Fig. 2.

Parameter	Probability of failure (%)	Probability at −2 SD (%)
Ultimate load	80.0	7.4
Yield load	51.2	0.4
Critical load	50.0	2.3
Safe load	2.3	
1 mm partial gapping	24.6	0.3
2 mm partial gapping	56.0	2.9
1 mm total gapping	63.6	1.9
2 mm total gapping	75.1	4.1

loads. Since the judgment about clinically safe repair configuration has to be based on the certainty that even the weakest of the repairs will sustain the subjected loading, the variation within the repairs has to be known. The present study was set to explore the validity of statically derived biomechanical parameters used in flexor tendon repair testing.

Utilizing cyclic testing, we developed an objective method for determining critical load to allow comparison of different repair methods. Critical load represents the point after which the otherwise harmless deformations begin to cumulate. If straining with loads greater than critical load continues repetitively, the repair will eventually fail. However, critical point is an average value of all samples, and its straightforward application to clinical situation is deceptive. According to the general statistical principles, in a normally distributed sample, the lowest 2.3% of samples reside under the limit of twice the standard deviation. Therefore, were coined the critical load subtracted by twice the standard deviation (Mean − 2SD) the safe load. On other words, the safe load is a conversion of critical load, where the variation within the samples is taken into account. We believe that safe load is the most relevant parameter to represent the overall competence of the repair from clinical point of view. However, it is applicable only if the present variation within the samples is assumed to be similar to the variation in clinical practice.

Cyclic testing is not a novel innovation, and several researchers have been using it for determination of biomechanical properties of repaired flexor tendons. Several different cyclic testing settings have been used – the most usual are the fixed peak load method (Aoki et al., 1994; Bhatia et al., 1992; Gibbons et al., 2009; Haddad et al., 2010b; Hausmann et al., 2009; Kuwata et al., 2007; Mishra et al., 2003; Pruitt et al., 1996; Tran et al., 2002), where all samples have the same predetermined peak load, and the incremental cyclical loading protocol (Barrie et al., 2000; Barrie et al., 2001; Sanders et al., 1997; Viinikainen et al., 2009; Williams and Amis, 1995; Wolfe et al., 2007), where the peak load incrementally increases during testing of each sample. A problem hampering both of these methods is that they are unable to yield a Newton-based outcome parameter. Instead, they enable only the determination of the number of cycles sustained. To overcome this problem, we developed a cyclic testing protocol with randomly assigned peak load for each specimen, thus enabling the determination of the critical load. The weaknesses of this method are that it requires *a priori* assumption about the vicinity of the biomechanical competence in order to adjust the suitable peak load distribution profile, and that the required sample size is greater than what is needed for more simple approaches.

Originally, the need for biomechanical testing arose, when it was noted that the clinical results were better when the tendons were mobilized early, and on the other hand early mobilization could lead to rupture of the repair. Thereafter, numerous biomechanical studies assessed the biomechanical properties of different repair techniques using static linear tensile testing. In the early studies, the ultimate force of the repair was considered the most relevant outcome. According to the present study, the mean of ultimate load was 46.2 N and the critical load was 37.8 N. This statistically significant difference is in accordance with the previous findings that tendons subjected to cyclic loading rupture at lower loads than implied by static testing results (Sanders et al., 1997). Later, it has been argued that the plain average cannot be regarded as a proper threshold, and percentile adjustments have been proposed. An 18% deduction was suggested due to the possible decrease in repair strength during the first three weeks after surgery if the finger was immobilized (Edsfeldt et al., 2015). Furthermore, same authors have deducted an additional 30% from the ultimate strength, rationalizing it with avoiding gapping greater than 2 mm, which occurs at approximately 70% of the ultimate repair strength (Edsfeldt et al., 2015). However, it has to be recognized that the validity of any deduction has not been clinically verified.

Overall variation observed in any parameter concerning the biomechanical competence of tendon repair reflects variations arising from tendon tissue, suture-tendon interaction, suture material, and measurement methodology. The proportion of variation caused by suture material and measurement methodology is most likely quite small. The variation caused by tendon properties is probably more pronounced, but surgeon's execution of the suture is probably the greatest cause for the variation between the specimens. The present study cannot differentiate the magnitudes of each variation. Nevertheless, due to the variation, it is debatable if mean of any parameter can be used to present the safe level of loading in a clinical context. A safety margin of 50% has been previously suggested (Strickland, 1999). Based on this deduction method, the safe level of loading would be 23.1 N (50% of ultimate load of 46.2 N), resulting in an estimated probability of repair failure of 6.8%. This deduction method yields a risk greater compared with the safe load (-2 SD of the critical load) in the present study. Furthermore, the magnitude of deduction was based on heuristics and not based on any valid outcome nor clinical correlation.

Researchers have proposed that statically derived yield load represents the threshold of the irreversible deterioration of the repair and should therefore be used to compare the repairs (Viinikainen et al., 2004). Yield load is determined as a decrease in slope of the load deformation curve in static testing. It can be determined objectively (Lotz et al., 1998), separating it from video derived parameters. In the present study, we showed that the mean of statically derived yield load is virtually identical to the critical load. Thus, we venture to suggest that both of these parameters are capable of predicting the load where irreversible deformations start and predispose the tendon repair to disruption during repetitive loading. However, the mean yield load as a clinical threshold entails the same pertinent risk of repair failure as a mean of any parameter. A risk of repair failure being as high as 51.2% in cyclical loading as we observed is intolerable. All in all, of the means of the statically derived parameters, only the partial 1 mm gapping value can be considered clinically eligible (probability of failure 24.7%). Theoretically, any substantial gapping would indicate that the safe load has been surpassed. Therefore, the start of gapping could also be used to represent the clinically relevant parameter. However, it has to be kept in mind that the results of a gapping analysis are interpreter-dependent and not objective. This is especially true as for 1 mm partial gapping load, where the interrater coefficient of variation was as high as 7.7%.

This study is burdened by some limitations. The velocity of static tensile loading was 20 mm/min, whereas it was 300 mm/min in cyclic test. It has been shown that the velocity of testing has an effect on the observed biomechanical properties (Parimi et al., 2012). The reason for our decision to use different loading velocities was based on two objectives: 1) to perform the cyclic loading as resembling to the clinical situation as possible, since during finger flexion the amplitude of FDP tendon is 11.8 mm (Sapienza et al., 2013), and empirically flexion of fingers in rehabilitation protocols takes two seconds; and 2) to be able to reliably determine the yield load in static tensile testing, requiring slower loading rate due to limited data sampling rate of the load cell. Also, it has to be kept in mind that relatively slow loading velocities are used in majority of the biomechanical studies concerning flexor tendon research (Parimi et al., 2012). Also, it can be questioned if 500 cycles are enough to resemble the clinical situation, although it has been previously shown that the deteriorating effect of cyclic loading takes place soon after loading is initiated (Haddad et al., 2010a). Furthermore, it can be argued that setting the base load for cyclic testing greater than 0 N would have closer resemblance to physiological situation, since even when the muscle is not active, it has stored some energy. In this study, only one core and one peripheral suture configuration was used, and thus, the generalization of the results has to be done with care. Similarly, it has to kept in mind that the absolute measures (e.g. the mean of safe load of 18.0 N) cannot be directly implemented to the clinical decision making, as this is a laboratory study having concomitant biases (e.g. the effects of postoperative tenomalacia (McDowell et al., 2002), soft tissue edema (Wu et al., 2012), and assumption about the equality of variations). Lastly, the shape of the estimate curve is somewhat dependent on the number of samples, because very low amount of samples would cause too steep slope of distribution curve. So, observations of failures and successes have to overlap at the critical point to minimize this bias. The present method does not enable the execution of a proper power analysis, and thus, the selection of the number of samples and the assigned peak loads can be criticized.

The aim of this study was to assess how the parameters determined using static tensile testing relate to the survival of tendon repair during cyclic loading. We found out that, besides being an objective parameter, yield load seems to be able to predict the ability of the tendon repair to withstand repetitive loading undamaged. To determine if yield load is a universally applicable parameter, its correlation to critical load in terms of other repair configurations has to be studied. Until that, to determine the properties of each tendon repair configuration or material, we recommend that the critical load utilizing cyclic testing is used.

Conflict of interest statement

Authors have no conflicts of interest to disclose.

Acknowledgments

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SCIENTIFIC ARTICLE

Gap Formation During Cyclic Testing of Flexor Tendon Repair

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Purpose Substantial gap formation of a repaired finger flexor tendon is assumed to be harmful for tendon healing. The purpose of this study was to investigate the relationship between gap formation and the failure of the repair during cyclic loading.

Methods Thirty-five porcine flexor tendons were repaired and tested cyclically using variable forces until failure or a maximum of 500 cycles. Depending on the biomechanical behavior during cyclic testing, specimens were divided into 3 groups: Sustained (no failure), Fatigued (failure after 50 cycles), and Disrupted (failure before 50 cycles). The relationships between the gap formations, time-extension curves, and group assignments of the samples were investigated.

Results The time-extension curves of the Fatigued specimens showed a sudden onset of repair elongation—a fatigue point—which preluded the subsequent failure of the repair. This point coincides with the start of plastic deformation and, thereafter, cumulative injury of the repair consistently led to failure of the repair during subsequent cycles. None of the sustained repairs showed a fatigue point or substantial gapping during loading.

Conclusions We conclude that the emergence of a fatigue point and subsequent gap formation during loading will lead to failure of the repair if loading is continued.

Clinical relevance The results of this experimental study imply that an inadequate flexor tendon repair that is susceptible to gap formation is under risk of failure. *(J Hand Surg Am. 2018;43(6):570.e1-e8. Copyright © 2018 by the American Society for Surgery of the Hand. All rights reserved.)*

Key words Hand surgery, finger, flexor digitorum profundus, biomechanical testing.

Online Exclusive

GAP FORMATION BETWEEN THE TENDON ends has been shown to result in harmful effects on recovery after flexor tendon repair surgery. Gapping leads to increased gliding resistance[1] and predisposes to adhesion formation, subsequent need for tenolysis,[2] and decreased mechanical strength.[3]

Gapping loads (eg, 1 or 2 mm) and ultimate load are among the most often reported parameters in static linear testing. These values are used to determine the biomechanical properties and strength of a tendon repair and to compare different techniques. In static linear testing, early gapping has been found to correlate with the onset of the disruption of the repair, and under the ultimate load, the tendon ends may be several millimeters apart from each other.[4] Therefore, early gapping loads have been proposed to provide a clinically more relevant estimation of repair competence compared with the ultimate load in static linear testing,[5] although its visual determination is imprecise.[6]

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Cyclic testing is more uncommon than static linear testing when investigating the biomechanical properties of flexor tendon repair. Cyclic testing is time-consuming, but the repetitive loading resembles the postoperative clinical loading of the tendon repair better than static linear testing.[5,7–10] The aim of this cyclic testing study was to compare the gapping behavior of repairs that withstood early loading but eventually failed with those that withstood the cyclic loading without failure. We hypothesize that the onset of plastic deformation and any gap formation during cyclic loading inevitably results in the failure of the tendon repair if the cyclic loading is continued.

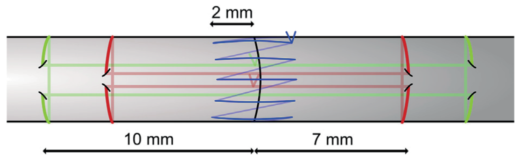

FIGURE 1: A schematic illustration of the repair method. Red and green lines: 4-strand Pennington modified Kessler core suture; blue lines: a 9-purchase over-and-over peripheral suture.

METHODS

Samples

Thirty-five frozen thawed porcine flexor digitorum profundus tendons of the second ray (FDP-II) were used in this study. The properties of porcine FDP-II tendons have been shown to be comparable with human flexor tendons.[11] The specimens were the same as those utilized in our previous study.[5] Because the study setting does not enable power calculation, the number of the specimens represented a convenience sample. In brief, the tendons were dissected from the middle segment of the tendon and the dimensions were measured using calipers. The cross-sectional areas of the tendons were calculated ($A = \pi * ab$, where a is the semiminor axis and b the semimajor axis). Each tendon was cut with a surgical scalpel and repaired by the same resident hand surgeon (L.L.). The repair was executed using 2 Pennington-modified Kessler sutures[12] with a 4-0 braided polyester thread (Ethibond Excel; Ethicon, San Lorenzo, Puerto Rico) as the core suture and a 9-purchase over-and-over suture configuration with a 6-0 polyamide monofilament (Ethicon) as the peripheral repair (Fig. 1). The repaired tendons were kept moist in saline-soaked gauzes except when measured. Approval of an ethical board was not needed for this study because no living animals were involved.

Biomechanical testing

Biomechanical testing of the specimens was performed using a material testing machine (LR 5 K; Lloyd Instruments Ltd, Hampshire, UK) connected to a computer with NEXYGEN software (Lloyd Materials Testing, AMETEK, Inc., Berwyn, PA). The repaired tendons were secured to the testing machine with clamps 30 mm apart from each other.

The repaired tendons were loaded in a cyclic manner, with the maximum cycle count being 500. Five hundred cycles correspond to 5 to 10 days of active rehabilitation, and according to an animal model, the biological strengthening only starts thereafter.[3] In addition, 500 cycles have been proven to be sufficient to indicate the possible failure of the repair in a similar testing setting.[10] Based on the excursion of the FDP-II tendon in its sheath during normal finger flexion (11.8 mm)[13] and finger flexion time during rehabilitation, the velocity of the loading was set to 300 mm/min. The lower limit for the load was 0 N in all tests. The upper limits ranged from 17.0 N to 61.9 N and covered the whole range of loads both under and over the anticipated static yield load. The constant upper limit for the load was randomly adjusted for each specimen. Each specimen was tested using only a constant upper limit for the load: the load changed repeatedly between 0 N and the chosen upper limit (eg, 31.1 N) during testing. The specimens either sustained the 500 cycles—after which the testing ended—or it failed during the testing. No further load-to-failure testing was used. The tendon repair was identified as failed when there was no resistance even though extension increased. Failure modes (suture break, suture pull-out, knot unravel) were assessed.

Time-extension graphs were formed for each specimen (Fig. 2). In specimens that sustained the first 50 cycles, the local lowest bound of the extension built up rapidly during the first cycles, but eventually leveled off, obeying the power law (Fig. 2).

Among the tests, there were specimens in which a sudden increase of the total extension was observed. After this point of change, the lowest bound of the extension increased linearly until the failure of the repair. In the present study, this point is referred as the fatigue point. The fatigue point can be determined mathematically by fitting a piecewise-defined function to the minimal extensions of the test. The more detailed statistical methodology is explained in Appendix A (available on the *Journal*'s Web site at www.jhandsurg.org).

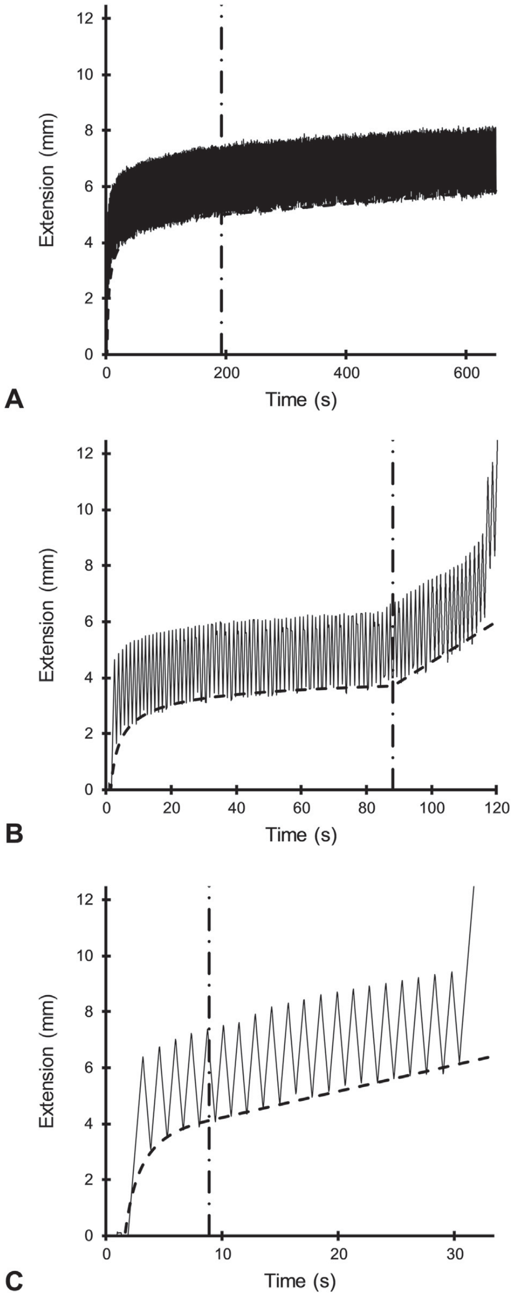

FIGURE 2: Examples of the time-extension graphs of the specimens in the **A** Sustained, **B** Fatigued, and **C** Disrupted groups. The fitting function (dashed line) is placed at the lowest bounds of extension. The fatigue point (semidotted line) is also presented in the figure. The shape of the power law is the most distinct in panel **B**. The value of the fitting function increases rapidly in the beginning of the graph. The larger the change in the slope, the steeper the line after the fatigue point.

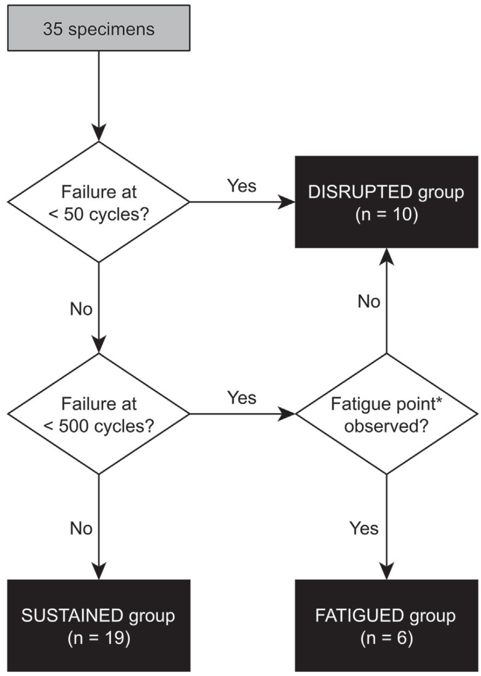

FIGURE 3: Group allocation. *The criterion for the fatigue point was a change in the slope greater than 0.3.

Accordingly, the specimens were subsequently classified into 3 groups based on their behavior during the cyclic testing: Sustained, Fatigued, and Disrupted (Fig. 3). The focus of this study was on (1) repairs that sustained all 500 cycles (Sustained) and (2) repairs that sustained the first 50 loading cycles, but eventually fatigued (expressed the criterion meeting the fatigue point) and then failed (Fatigued). Specimens that failed before 50 cycles or failed later without a fatigue point were allocated to the Disrupted group. The objective of the study was to discover signs that can be found only in the repairs that fatigue and fail. The differences in the loads that were used were of secondary importance and only a means to find the samples of interest.

GAP ANALYSIS

The biomechanical testing was recorded using 2 diametrically placed cameras (Canon EOS 550D and Canon EOS M; Tokyo, Japan). The gap between the tendon ends during the fatigue point and the last sustained cycle during the resting state was determined from still photographs using ImageJ 1.50i computer software (W. Rasband; http://imagej.nih.gov/ij/). The diameter scale was based on still pictures that were

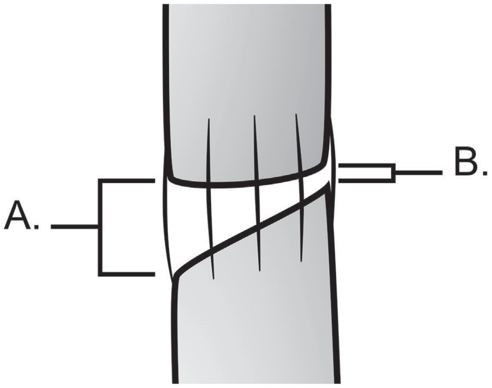

FIGURE 4: A gap measurement image. Gaps were determined by measuring the longest (**A** largest section of the gap) and the shortest (**B** smallest section of the gap) distance of the tendon ends.

taken before cyclic testing. The gap was determined by measuring pixels at the largest and smallest sections of the gap with a digital ruler, and the distance was determined in millimeters (Fig. 4). The largest section is the longest distance between tendon ends at the specific moment and the smallest section, conversely, is the shortest distance. If both sections were greater than 1 or 2 mm, the gap was determined to be 1 or 2 mm total gap, respectively. If only the largest section was greater than 1 or 2 mm, the gap was determined to be 1 or 2 mm partial gap, respectively. For those samples that sustained the maximum 500 cycles, the final gapping was similarly determined during the 500th cycle.

RESULTS

The mean cross-sectional area of the repaired tendons was 5.9 mm^2 (SD = 1.0 mm^2) (Table 1).

Biomechanical behavior

We observed 3 patterns of behavior: (1) in the Sustained group, the specimens did not manifest a fatigue point and sustained all 500 cycles (load range, 17.0−42.8 N) (Figs. 3, 5); (2) in the Fatigued group, the specimens sustained the initial 50 cycles, but later manifested a fatigue point, gapped, and failed (load range, 30.1−51.1 N); and (3) in the Disrupted group, the specimens either failed before the 50 cycles or their time-extension graphs expressed no fatigue point (load range, 30.8−61.9 N). One specimen broke during the first cycle and was, therefore, omitted from the gap analysis. Thus, 6 of 16 failed specimens were allocated to the Fatigued group, and

TABLE 1. Descriptive Data and Gap Measurements

Group	n	Cross-Sectional Area (mm^2)		Load (n)		Failure Mode of Suture		Failure Mode of Peripheral Suture		Section of Repair	Gap at Fatigue Point (mm)		Final Gap (mm)	
		Mean	95% CI	Mean	95% CI	Break	Pull-Out	Break	Pull-Out		Median	Minimum-Maximum	Median	Minimum-Maximum
Sustained	19	5.8	5.2−6.3	31.1	27.4−34.8	-	-	-	-	Smallest			0.0	0.0−0.3
										Largest			0.3	0.0−2.0
Fatigued	6	6.4	5.2−7.6	41.0	33.0−48.9	6	0	4	2	Smallest	0.0	0.0−0.8	1.6	0.9−3.7
										Largest	1.2	1.1−1.6	3.3	2.0−5.5
Disrupted*	10	5.7	5.1−6.3	45.9	37.2−54.6	10	0	6	4	Smallest			0.3	0.0−3.2
										Largest			1.2	0.0−6.5

95% CI, 95% confidence interval.
*One repair failed during the first cycle and was omitted from the gap analysis.

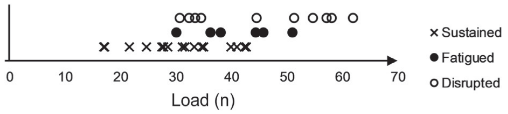

FIGURE 5: The loads used classified by groups. There was difference between the peak loads in the Sustained (cross), Fatigued (black circle), and Disrupted (white circle) groups (P = .006). Each symbol represents every single sample.

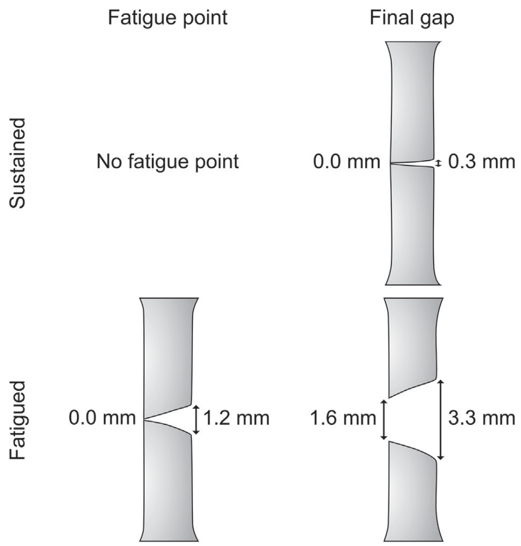

FIGURE 6: Gapping values. Each panel provides the medians of the smallest and the largest sections of the gap. For the ranges, see Table 1.

19 of the 35 specimens were allocated to the Sustained group. Failure modes of the samples are presented in Table 1.

The median changes in the slopes of the time-extension curves of the Sustained and Fatigued groups were 0.00° (range, −7.51° to 0.26°) and 3.00° degrees (range, 0.42° to 13.13°), respectively. The typical time-extension curves of specimens in the Sustained and Fatigued groups are presented in Figures 2A and 2B, respectively.

Gap

The measurements of the gap at the fatigue point and the final gap are presented in Table 1 and in Figure 6. Owing to the fatigue point criterion (Appendix A; available on the *Journal*'s Web site at www.jhandsurg.org), no fatigue points were found in the specimens in the groups other than the Fatigued group.

TABLE 2. Number of Repairs in Each Group Classified According to the Magnitude of Final Gap Formation

Parameter	Sustained	Fatigued	Disrupted*
< 1 mm partial gapping	15	0	3
1 mm partial gapping	3	0	2
2 mm partial gapping	1	1	1
1 mm total gapping	0	3	1
2 mm total gapping	0	2	2

*One repair failed during the first cycle and was excluded from this table.

In the Sustained group, none of the repaired tendons showed a gap larger than a 2-mm partial gap (Table 2). A total gap of over 1 mm was seen only if the repair broke during the very next cycle.

Because the focus of the study was to investigate the biomechanical and gapping behavior of those repairs that sustained the repetitive loading and those that fatigued, the difference between the gaps of the Fatigued group at the fatigue point and the gaps of the Sustained group at the last cycle were investigated. The median of the largest sections of the gaps was larger at the fatigue point in the Fatigue group than the final gap in the Sustained group (1.2 mm vs 0.3 mm, respectively). The smallest sections of the gaps were similar (0.0 mm).

DISCUSSION

This study emphasizes the possible harm of even the smallest gap formation between the repaired flexor tendon ends. We have described 3 patterns of behavior for the specimens. Repairs that sustained 500 cycles did not manifest a fatigue point or substantial gapping, whereas the failed tendon repairs either fatigued, gapped, and eventually failed before the end of the test or disrupted very early without a fatigue point. We believe the fatigue point denotes a transition from the elastic phase to the plastic phase, like the yield point observed in static testing. The occurrence of the fatigue point inevitably leads to the failure if cyclic loading is continued using the same load. None of the sustained specimens expressed a fatigue point and all of them sustained the full 500 cycles with less than 1 mm total gapping. On the contrary, all repairs that represented any substantial gapping failed either instantly or through a process where fatiguing was involved.

It has been shown that gap formation has several harmful effects on recovery after tendon repair surgery. Elongation of the repaired tendon has been shown to be susceptible to adhesion formation and a subsequent need for tenolysis.[2] Furthermore, gap formation is correlated with increased gliding resistance.[1] Moreover, using a canine model, Gelberman et al[3] have established that 3 mm of gapping is harmful to the strength accrual of the repair. According to our results, if over 1-mm gap is present in the repair, the fatigue point must have occurred and the repair is already on the verge of a failure. However, the clinical evidence shows that even though substantial gaps have been seen during tenolyses[2] and *in vivo*,[3] healing is possible owing to the ability of the living tendon to regenerate over the gap.[14] Nevertheless, it is probable that an inadequate flexor tendon repair that is susceptible to gap formation is under a considerable risk of failure.

The method of rehabilitation determines the amount of loading the repairs are subjected to. The mechanical requirements are greater with early active mobilization than with controlled passive mobilization. Furthermore, the type of tendon repair technique has an influence on the strength of the repair. Clinically, fatigue of the repair might result in the failure of the repair during the early phase of rehabilitation. Although the biological strengthening starts after 5 to 10 days of surgery with postoperative mobilization, in an animal model,[3] in humans, the timeline may be different. During later healing, the tendon's strength increases and the repair can probably handle a greater load compared with the first weeks.

In a previous study, 4-strand Adelaide repairs with a simple running peripheral suture survived cyclic testing between 3 and 30 N with a mean of 1.9-mm gapping at the end of 1,000 cycles,[10] and a 6-strand Pennington-modified, Kessler core suture with a circumferential interlocking cross-stitch peripheral suture broke up during cyclic testing at between 2 and 85 N at the end of 8,000 cycles even after 6.2 mm of gapping.[15] This differs from our results and shows that different repair configurations (both core and peripheral sutures) have their own elongation characteristics and strengths. Furthermore, tendon selection,[11] suture materials, and the test settings may have an influence on the results.

There are some limitations to this study. The specimens were not allocated to the groups randomly but based on their biomechanical behavior. Therefore, the statistical comparisons between groups would be biased owing to the differences in the loads used. Furthermore, only 1 core and 1 peripheral suture configuration were used, and thus, the results should be generalized with care. In addition, there was no preload prior to cyclic testing, and the load at the resting state was 0 N, although using a small load during the resting state would represent a more physiologically accurate model. Moreover, we did not determine the fatigue point in the specimens that failed before the 50th cycle. Those specimens expressed only the linear part in their time-extension curves and an instant substantial gap formation, whereas we were interested in those repairs that can sustain the repetitive loading but fatigued and eventually failed. For the same reason, we were obliged to use an arbitrary threshold value for the fatigue point (a change in the slope > 0.3) to ensure that insignificant noise within the extension curves was not interpreted as a false fatigue point.

The aim of this study was to assess the significance of gapping and plastic deformation during cyclic loading of repaired flexor tendons. Our study showed that manifestation of a fatigue point and even minor gapping will lead to the failure of the repaired tendon if loading is continued. However, the generalizability of the finding needs to be verified with other suture configurations. Similarly, the clinical applicability of the finding is limited because surpassing of the fatigue point or minute gapping of the tendon repair cannot presently be detected in patients going through rehabilitation after surgery.

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APPENDIX A. Mathematical determination of the fatigue point

The fatigue point can be determined mathematically by fitting a piecewise-defined function to the minimal extensions $x(t)$ of the test. Let the first part of the function follow the power law and the latter part be linear:

$$x(t) = \begin{cases} k_1 t^b + c, & t < t_0 \\ k_2(t - t_0) + k_1 t_0^b + c, & t \geq t_0 \end{cases}$$

in which t and t_0 are time and fatigue point, respectively. In addition, k_1, k_2, b, and c are parameters of the curve fitting. To determine the difference of the change, the slope of the linear part of the function was subtracted from the slope of the tangent of the power function at the fatigue point, and the fatigue point was considered legitimate only if the change in the slope was greater than 0.3.

EDITOR'S CHOICE

Factors Accounting for Variation in the Biomechanical Properties of Flexor Tendon Repairs

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Teemu Karjalainen, MD, PhD,‡ Olli V. Leppänen, MD, PhD*

Purpose To investigate factors that cause variation in the mechanical properties of flexor tendon repairs.

Methods One surgeon repaired 50 homogeneous absorbent sticks and 40 porcine flexor tendons with a simple loop, an Adelaide repair, a peripheral over-and-over repair, or a combination of the latter 2 repairs. Ten hand surgeons repaired 1 porcine flexor tendon with the combined Adelaide core and over-and-over peripheral repair. We loaded the samples statically until failure and calculated the variations caused by the testing process, tendon substance, and surgical performance in terms of yield and ultimate load.

Results Tendon material and surgical performance both caused about half of the variation in the yield load of the combined repair. Surgical performance caused all variations observed in the ultimate load of the combined, peripheral-only, and core repairs. The effect of the tendon material was negligible in ultimate load. The intersurgeon variation was present only in yield load, and it represented one-tenth of the total variation.

Conclusions The effect of tendon substance on variation of the ultimate load is minimal. In yield load, both tendon and surgical performance are responsible for the variation.

Clinical relevance In clinical realm, variation caused by testing is not present, but intersurgeon variation may cause additional variation in yield load. A hand surgeon cannot change the variation due to tendon properties, but with a more meticulous surgical technique, the variation related to the surgical performance can probably be diminished. *(J Hand Surg Am. 2018;43(12):1073−1080. Copyright © 2018 by the American Society for Surgery of the Hand. All rights reserved.)*

Key words Reproducibility, finger, flexor digitorum profundus, biomechanical testing.

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An ideal flexor tendon repair is one that enhances and facilitates the healing process and has sufficient tensile strength to resist loads during early rehabilitation.[1] In addition, surgeons should be able to perform the repair consistently and with low variability in strength. Two repair techniques having an identical mean strength in a laboratory setting are clinically different if one repair technique is highly variable and the other repair technique is highly reproducible. A repair technique with small variation is desirable because it lessens the

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probability of weak repairs that are prone to failure (Fig. 1). In other words, when there is variation in technique, there will be a greater risk that the repair will not perform, as it has been shown to in a laboratory setting. When there is a little variation, the repair should perform like it appears to in those same controlled settings.

The potential factors causing variation in the biomechanical performance of a repair are: (1) the structure of the tendon substance, (2) surgical performance (intrasurgeon and intersurgeon reproducibility), and (3) the testing procedure. The proportion of variation attributable to each of these factors is unknown. Understanding the sources and their relative contribution to variability could help optimize repair techniques.

The primary purpose of this study was to quantify the relative variation caused by tendon substance, surgical performance, and testing methodology. We designed a study, which can isolate these factors and identify the sources of variation in a flexor tendon repair model.

MATERIALS AND METHODS

Background

We tested 10 groups of 10 repairs to isolate the factors causing the variation in the tensile strength of the repairs. Each group had different factors producing variation and we used the differences to quantify the sources of variation (Figs. 2, 3). One author (LL) cut samples with a scalpel and performed all the repairs except the 10 repairs that tested the intersurgeon variability. We randomized the order of performing the repairs within the groups to minimize bias arising from a learning curve.

Samples

Absorbent sticks: Absorbent sticks (BD Visisorb, Beaver-Visitec International, Inc., Waltham, MA) are homogeneous, soft, nonwoven cylinders with a diameter of 5 mm (Fig. 4). The sticks mimic tendons in shape without variation in the quality of tissue. Dental rolls that have a similar structure as absorbent sticks have been used in previous studies for both surgical training[2] and in biomechanical flexor tendon studies.[3–5] We assumed that the source of variation in the stick model is negligible and all variation is caused by variation in the testing procedure or by surgical performance.

We used 10 samples to define the methodological variation related to the testing procedure (baseline

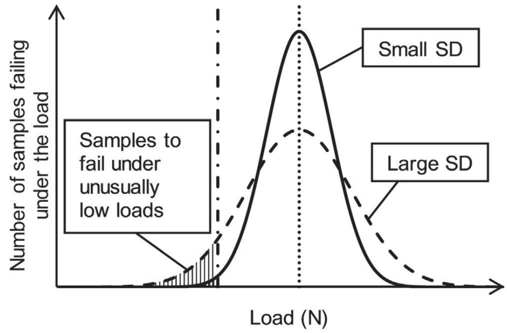

FIGURE 1: The significance of different standard deviations (ie, reproducibilities) between 2 imaginary repair techniques. If the standard deviation is large (dashed line), several repairs will fail under unusually low loads (dot-dashed line) during active rehabilitation. Despite the same mean strength (dot line), the repair technique with the lower standard deviation (solid line) remains intact more frequently during rehabilitation.

variation). The investigator placed a 3-0 braided polyester (Ethibond Excel; Ethicon, San Lorenzo, Puerto Rico) simple loop (Fig. 5A) into sticks using a custom-made jig (Fig. 6), which standardized the repair. The rationale for this was to minimize variation caused by both substance and surgical performance. We considered this to represent the variation in the testing procedure. We subtracted this variation from the total variation of the repairs to quantify the technical and tendon-related variation (Table 1).

Next, the investigator placed 10 simple loops free-handed, without the jig, into 10 sticks to quantify the variation caused by surgical performance. We assumed that these samples had no variation due to tendon substance, and therefore, all variation was caused by variation in the surgical technique. We calculated the baseline variation by subtracting the variation of jig-made simple loops from the variation of free-handed simple loops (Appendix A, available on the *Journal's* Web site at www.jhandsurg.org). This was followed by 10 core-only Adelaide repairs[6] (Fig. 5B), 10 peripheral-only repairs (Fig. 5C), and 10 combined repairs on sticks (Adelaide + peripheral repair) to measure the variation caused by surgical performance in these techniques using similar calculations (Table 1). We used a 5-0 polyamide monofilament (Ethilon; Ethicon) in all peripheral repairs.

Porcine tendons: We used porcine tendons to assess the effect of the tendon substance on the variation of the biomechanical properties. We dissected out 50 frozen

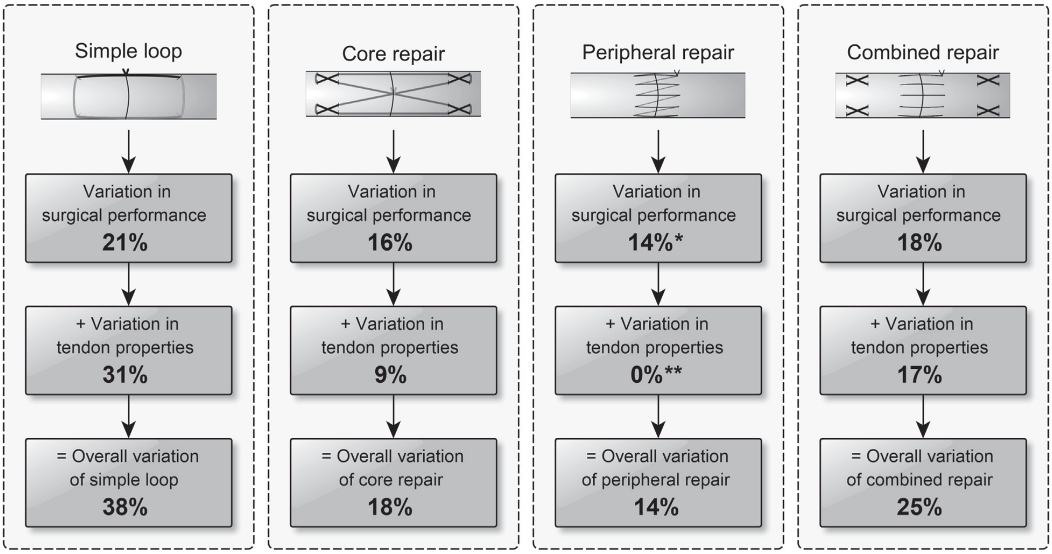

FIGURE 2: Flow chart of the variations for specific factors of the yield load. See also Table 1 for the context of formulas. *The variation for a specific factor outweighed the overall variation and was thus assumed to be equal to it. **The variation for a specific factor was overpowered by the variation of the preceding group.

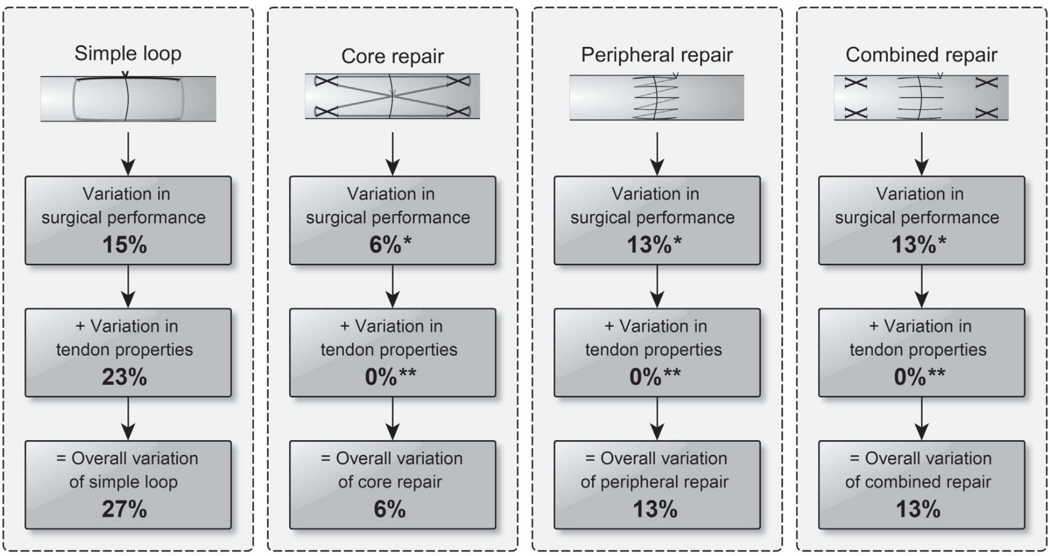

FIGURE 3: Flow chart of the variations for specific factors of the ultimate load. See also Table 1 for the context of formulas. *The variation for a specific factor outweighed the overall variation and was thus assumed to be equal to it. **The variation for a specific factor was overpowered by the variation of the preceding group.

thawed porcine flexor digitorum profundus tendons of the second ray of the trotter (FDP-II) and used them in 5 groups, 10 samples in each group. We measured the diameter with calipers. Then we calculated the cross-sectional areas of the tendons ($A = \pi \times ab$, where a is the semi-minor axis and b the semi-major axis). After repair, the repaired tendons were kept moist in saline-soaked gauzes

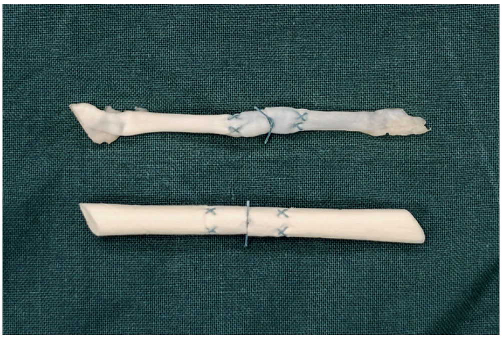

FIGURE 4: Examples of Adelaide repairs to a tendon (upper) and an absorbent stick (lower).

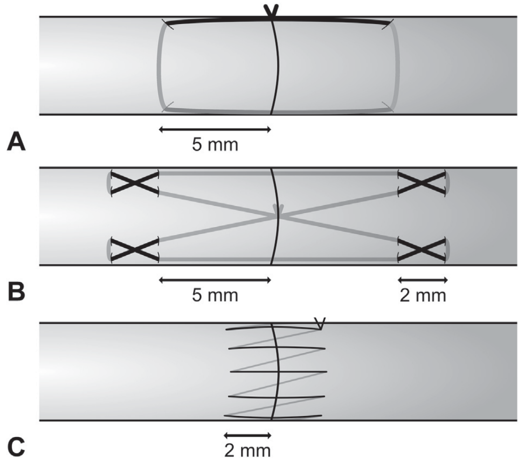

FIGURE 5: Repair techniques. A simple loop (**A**), an Adelaide repair as the core repair (**B**), and an over-and-over repair as a peripheral repair (**C**) were used. The combined repair included both **B** and **C**.

except when they were being measured. The investigator repaired the porcine tendons using identical repair methods (free-handed simple loop, core-only Adelaide repair, peripheral-only repair, and Adelaide + peripheral repair) to those used for the absorbent sticks.

Finally, 10 hand surgeons performed the combined Adelaide and peripheral repair to measure the inter-surgeon performance-related variability. We gave schematic illustrations of the repair techniques (Fig. 5B, C) to the surgeons. Although they were all experienced in tendon surgery, none of them used the Adelaide repair in their clinical work. We chose this technique to minimize the effect of level of experience in the repair.

Biomechanical testing

We performed biomechanical testing of the specimens using a material testing machine (LR 5 K; Lloyd Instruments Ltd, Hampshire, United Kingdom) connected to a computer with NEXYGEN software (Lloyd Materials Testing; AMETEK, Inc., Berwyn, PA). The author who performed the tests secured the samples to the testing machine with clamps 30 mm apart from each other, preloaded to 0.5 N, and then distracted at a constant rate of 20 mm/min velocity until they failed.

We measured yield load using a previously described technique (Lotz et al,[7] Appendix A, available on the *Journal's* Web site at www.jhandsurg.org). We recorded the testing with 2 diametrically placed cameras (Canon EOS 550D and Canon EOS M, Tokyo, Japan) and used slow-motion videos to detect the mode of failure (suture pullout, suture rupture, or knot unraveling).

Analysis of data

The coefficient of variation—also known as relative standard deviation (SD)—was our primary variable representing the variation caused by each factor. The coefficient of variation allows a comparison of variations of datasets having considerably different magnitude (eg, simple loop vs combined Adelaide + peripheral repair). SD is dependent on the magnitude of the measurement: the higher the mean, the higher the SD, and therefore we did not use it in the primary analysis.

We calculated the coefficient of variation using the formula $\frac{\text{SD}}{\text{mean}} \times 100\%$. Thus, throughout the results, the presented variations are percentages of the corresponding mean load (and not of total variation).

To isolate the variation caused by tendon substance, we subtracted the variation observed in sticks from the total variation observed in the corresponding tendons, that is, we assumed that the variation caused by surgical performance and measurement procedure was similar between the corresponding groups, and thus the difference was due to the variations in the tendon substance (Table 1).

To isolate the variation caused by surgical performance, we subtracted the variation caused by testing from the variation observed in sticks. That is, we assumed that the variation caused by stick substance was zero and all observed variance was due to the variation in the placement of the suture (Table 1).

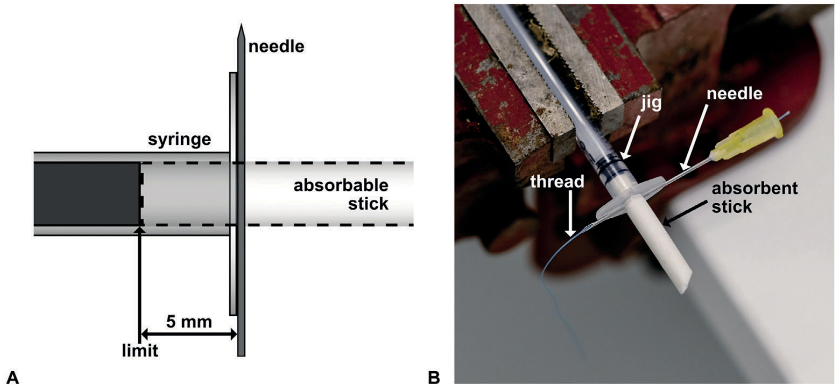

FIGURE 6: A custom-made jig was used to maximize the reproducibility of the simple loop in the absorbable sticks. A trail was sewn onto the top plate of a 1-mL syringe. The piston from the syringe was cut to a specific length to limit the stitch to 5 mm from the cut end of the absorbable stick. The piston was used as the limit in the syringe. The absorbable stick (dashed line) was pushed into the syringe against the limit. A 20G needle was pushed through the absorbable stick. A 3-0 braided polyester thread was driven by the needle through the absorbable stick along the trail. This procedure was repeated in both halves of the repair.

TABLE 1. Calculated Factor-Specific Variations

Factor	Formula	Coefficient of Variation (%) Yield Load	Ultimate Load
Testing procedure	Simple loop on stick with jig (baseline)	14	11
Surgical performance			
Simple loop	Simple loop on stick — baseline	21	15
Core repair	Core on stick — baseline	16	15
Peripheral repair	Peripheral on stick — baseline	30	23
Combined repair	Combined on stick — baseline	18	14
Intersurgeon	10 surgeons — 1 surgeon	14	N/A
Tendon			
Simple loop	Simple loop on tendon — simple loop on stick	31	23
Core repair	Core on tendon — core on stick	9	N/A
Peripheral repair	Peripheral on tendon — peripheral on stick	N/A	N/A
Combined repair	Combined on tendon — combined on stick	17	N/A
Surgical performance and tendon combined			
Simple loop	Simple loop on tendon — baseline	38	27
Core repair	Core on tendon — baseline	18	6
Peripheral repair	Peripheral on tendon — baseline	14	13
Combined repair	Combined on tendon — baseline	25	13

N/A, not available.

To isolate the intersurgeon variation, we subtracted the variation observed in tendons repaired by a single surgeon from the variation observed in samples repaired by several surgeons (Table 1). Please see Appendix A (available on the *Journal's* Web site at www.jhandsurg.org) for full details of the calculations.

One-way variance analysis was used to assess the differences in the cross-sectional areas of the tendons between the groups.

TABLE 2. Measured Loads, Standard Deviations, and Coefficients of Variation (CoV)

		Yield Load (N)			Ultimate Load (N)		
Material	Repair	Mean	SD	CoV (%)	Mean	SD	CoV (%)
Absorbable stick	Simple loop (jig)	21.2	2.9	14	23.8	2.6	11
Absorbable stick	Simple loop (free)	24.2	6.0	25	27.8	5.2	19
Absorbable stick	Adelaide repair	28.1	5.8	21	32.6	6.1	19
Absorbable stick	Peripheral repair	26.6	8.8	33	36.1	9.0	25
Absorbable stick	Combined repair	43.2	9.9	23	51.1	9.1	18
Tendon	Simple loop (free)	8.9	3.6	40	14.2	4.2	29
Tendon	Adelaide repair	30.0	6.8	23	45.1	5.6	12
Tendon	Peripheral repair	23.5	4.6	20	32.7	5.7	17
Tendon	Combined repair	53.5	15.4	29	74.6	12.7	17
Tendon	Several surgeons	45.2	14.4	32	60.4	8.0	13

Every group consisted of 10 samples.

RESULTS

The mean of the tendon cross-sectional areas was similar between the groups (6.09 mm^2, SD 0.76 mm^2, $P = .70$).

Failure mechanism

In the stick repairs, sutures pulled out in all but one repair, which failed by core suture rupture after the pullout of the peripheral repair. In the tendon repairs, 3 peripheral repairs and 3 core repairs failed by suture rupture (in samples repaired by 10 different surgeons), whereas the others failed by pullout.

Variations

The means, SDs, and coefficients of variation of each group are presented in Tables 1 and 2.

Yield load: Total variation in the yield loads was the sum of the components of variation: variation caused by the surgical performance and variation caused by the tendon. In the combined repairs, both constituted about half of the total variation. In the core-only repairs, the technical performance constituted two-thirds, and the tendon one-third, of the total variation. In the peripheral-only repair, the technical performance caused all the variation. The total variation of the combined repair was the sum of the variations of its components (variation observed in the core and peripheral repairs). The variation caused by tendon was most pronounced in the simple loops.

Surgical performance caused a higher portion of the total variation in the peripheral-only repairs compared with the core-only or combined repairs, which showed comparable variations (Table 1). Of the total variation observed in the repairs performed by the 10 surgeons, only one-tenth was related to the intersurgeon performance (Appendix A, available on the *Journal's* Web site at www.jhandsurg.org).

Ultimate load: The coefficients of variation in ultimate load were consistently lower compared with the corresponding variation in yield loads. Surgical performance showed similar variations to those observed in yield load. The variation caused by surgical performance constituted all the observed total variation in the peripheral-only, core-only, and combined repairs. Therefore, the variation caused by the tendon was negligible in all but the simple loop. The intersurgeon variation in ultimate load was also negligible. Thus, the surgical-performance-dependent variation explained mostly all variations in the ultimate load (Table 1).

The variation in combined repairs was the sum of its components as in the yield load: the variation of the core repair constituted one-third of the total variation and the peripheral repair two-thirds.

DISCUSSION

We found that both the tendon material and the surgical performance constituted about half of the observed variation in the yield load. Only about one-tenth of the total variation was related to the intersurgeon variation in yield load, but in ultimate load, the intersurgeon variation was negligible. Whether we calculated the values from the components of the combined repair (core and peripheral repairs) or from factors causing the variation (surgical performance and tendon), the results were similar and concurred with the observed total variation.

Lotz et al[7] suggested that combined repairs behave like 2 springs under load. The 2 components of the combined repair, the core and peripheral repairs, divide the load, as long as they stay intact, until the yield point. Our results suggest that the observed variation is the sum of the variations of its components, similar to load distribution. When the repair reaches its ultimate load, the peripheral repair is no longer intact but part of that can share loads up to the ultimate load. Therefore, the variation of the combined repair in ultimate load is higher than the variation of the core repair alone.

The yield load is the strength of the intact tendon repair.[8] Thus, it is the initiation of the repair failure. Forces exceeding yield load cause gapping of the repair, which often results in complete failure if the cyclic loading is continued.[9] Therefore, yield load may be a more important variable to be assessed than ultimate load. Our data show that irregularities in the placement of the suture cause half of the variation, and this may be decreased by standardizing the placement of suture. If the surgeons can lower the variation caused by their performance from 18% to, for example, 13%, the failure rate of 4% could decrease to half (2%) (see Appendix A, available on the *Journal's* Web site at www.jhandsurg.org, for the details of this calculation). Moreover, we discovered that the variation increases if several surgeons, who are unfamiliar with the specific core suture, perform the repairs instead of a single surgeon who is experienced in performing the suture. That emphasizes the significance of the learning curve and suggests that surgeons consider using their previously well-practiced repair methods rather than necessarily adopting a new technique about which they might read.

In ultimate load, the variation caused by the tendon was negligible. Our model may overestimate the effect of the surgical performance as the stick model, which was used to assess the effect of surgical performance, may demonstrate magnified technical variation compared with porcine tendon because of different amounts of friction between suture and tendon/stick substance. However, the effect of the tendon must be relatively small because it was not measurable. Thus, we suggest that the variation observed in ultimate load is mostly variation caused by technical performance and the tendon-related variation plays little, if any, role.

The technical performance was also the greatest source of variation in the peripheral-only repairs. Peripheral repair has multiple loops, and it is plausible that it shows greater variance related to the placement of suture. Multiple loops also decrease the tendon-related variation as each loop constitutes only a fraction of the total pull-out resistance, and several loops offset the heterogeneity of the resistance of individual cross-links. Thus, tendon-related variance decreases in more complex repairs. This is supported by the observation that tendon substance was the greatest source of variation in the simple loop repair, where irregularities in tendon substance are more important because the simple loop depends on the individual cross-links between tendon fibrils.

The variation in yield load was greater compared with the variation in ultimate load. There are 2 plausible reasons for this. First, the analysis of the yield load is sensitive to inaccuracies related to the methodology, because small irregularities in the load-deflection curves can be interpreted as yield points. However, that is also a strength of the yield load measurement, because it is more sensitive to revealing early rupture of the repair. Secondly, based on the spring analogy,[7] the asynchrony in the load sharing of the core and peripheral repairs has a greater effect on yield load compared with ultimate load.

There are several limitations in this study. The format of this study does not allow a power calculation, because greater sample size does not affect the size of SD or the coefficient of variation. The group size of 10 samples was chosen based on the number of surgeons working at the clinic. Also, the assumption that the coefficient of variation in the baseline group consisted solely of the methodological variation related to the testing procedure is not entirely justified as, for example, the cutting of the stick and the placement of suture through the jig are also potential sources of variation. Thus, variations derived from surgical performance may appear lower than they actually are because the variation of the baseline group is subtracted from the variations of surgical performance groups (Table 1). In addition, handling of nonwoven material and tendon tissue may cause variation, which was not included in our model. Furthermore, only one core suture configuration was used in this study. The Adelaide core repair was used because of its biomechanical properties and tendency to fail by suture pullout instead of suture rupture. If suture rupture was more frequent, the variation would most likely decrease, as the testing would increasingly resemble testing of the suture material, which would obscure the contribution of technical variation. Finally, clinically tendons are loaded cyclically, and the results are applicable only to static testing. However, there is no clearly established method of carrying out cyclic testing, and cyclic testing provides a cycle count instead of a load with mean and SD.

To conclude, our study shows that the total variation in the yield load of the combined 4-strand Adelaide repair consists of similar variations caused by the tendon and the surgical performance. In ultimate load, the variation caused by the tendon is negligible and the variation is mostly due to the surgical performance. Because small variation is desirable, and the tendon properties cannot be affected, a focus on finding ways to reduce the variation in the surgical performance is important.

ACKNOWLEDGMENT

Matthew James, MSc, is acknowledged for the linguistic revision.

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Appendix A

Determination of yield load and ultimate load

Yield load is the strength of the intact tendon repair and, thus, the beginning of irreversible deformation of the repair.[E1] The difference of the yield load and the ultimate load is that a repair can usually sustain higher loads (ultimate load) even though the integrity of the repair has been lost at the yield point resulting in a slight gapping between the tendon ends and inevitable failure of the repair if the loading is continued.[E2] We determined yield load using the method introduced by Lotz et al.[E3] with a 0.1 mm offset. We used custom computer software to determine yield load. We draw the offset line 0.1 mm under the steepest slope of the load-deflection curve. Yield load was at the intersection of the offset line and the load-deflection curve. If the load-deflection curve did not express an identifiable yield load, we used ultimate load instead. The computer software recorded ultimate load as the highest load monitored by the load cell.

Determination of coefficient of variation and isolation of partial variations

We calculated means and standard deviations for each group. On the basis of these, we calculated coefficients of variations (CoV) by $\mathrm{CoV} = \frac{\mathrm{SD}}{\mathrm{mean}}$. To isolate the variations of specific factors, we used the following equation: $\mathrm{CoV}_A = \sqrt{\mathrm{CoV}_{(A+B)}{}^2 - \mathrm{CoV}_B{}^2}$ (Fig. E1). In the equation, $\mathrm{CoV}_{(A+B)}$ equals the overall variation within the group with multiple variation-inducing factors. These include CoV_A that is to be calculated, and CoV_B that equals the overall variation within another group in which the same variation-inducing factors are present, except for the variation CoV_A. For example, we isolated the variation due to heterogeneity in the pull-out resisting properties of porcine tendons by comparing simple loop repairs between tendons and sticks (Table 2). Because the aim of the study was to investigate clinically significant variation within the biological tissue (the tendon), the sum of the variations of specific factors cannot exceed the variation of the tendon repairs. Subsequently, if the value in the equation to be squared was negative (ie, the subtrahend is larger than the minuend), the calculation could not be fulfilled, and we assumed the variation of the specific factor to be equal to the overall variation. In addition, we also calculated the variation of the combined repair as the sum of the variation of the core repair and the variation of the peripheral repair. The equation is applicable if normal distributions of 2 or more independent, additional factors are assumed.

Determination of proportions of CoVs

Some CoVs are expressed as proportions in the text. For example, intersurgeon variation proportion of the total variation was calculated by dividing the CoV of the several surgeons (32%) by the subtraction of the latter and the CoV of the combined repairs (29%) resulting in 1/10. Calculation is based on the yield load of the combined repair.

Assumptions and calculations of clinical example

The variations reposted in the clinical example are variations of the combined repair in yield load with following assumptions that may not be entirely true: the variation of the porcine tendons is similar to the tendons of flexor tendon injury patients (1), the surgical performance of the tendon repair is similarly consistent in a laboratory and in an operating room (2), and the failures take place during the rehabilitation and not if the tendon repair is subjected to accidentally higher loads (3).

As was stated in the main text, the variation due to tendon properties was 17% and the variation due to the surgical performance was 18%, thus, yielding the total variation of 25%. The dataset was considered as a normally distributed sample with the mean of 62 N—the assumption of the average yield load of the used flexor tendon repair (4). The distribution describes the dispersion of yield loads with the number of samples bearing single yield load. Because forces up to 35 N were assumed to exist during the rehabilitation process[E4] (5), a cutoff point could be set at 35 N. If the failure rate was 4%, 4% of samples would leave under the cutoff point. If surgical performance hypothetically improved, the variation would decrease from 18% to 13% and the total variation would be 21%. With the same cutoff point of 35 N, only 2% of samples would leave under the cutoff point. Thus, failure rate would decrease from 4% to 2%.

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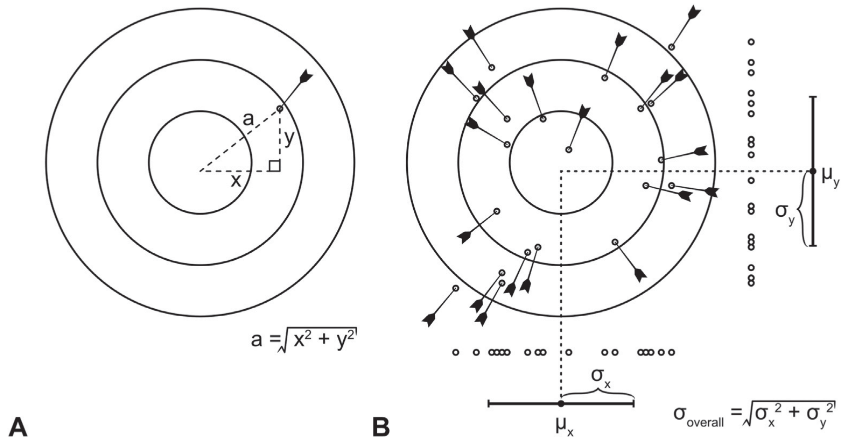

FIGURE E1: The mathematical model used in the study can be simplified in the following way: hit of the arrow to the target depends on the accuracy of the archer (vertical variation) and environmental conditions (eg, wind, horizontal variation). If the archer shoots a single arrow, the total distance from the assumed aiming point can be calculated using the Pythagoras theorem (**A**). When the archer has shoot several arrows, the total variation can be calculated based on the standard deviations (σ) of the horizontal and the vertical variations (**B**). μ = mean.

Full Length Article

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Suture configurations and biomechanical properties of flexor tendon repairs by 16 hand surgeons in Finland

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Abstract

The aim of this study was to find out how common it is to modify standard core suture configurations in flexor tendon repair and whether the use of standard core suture configurations gives a stronger repair. A total of 16 hand surgeons or residents participated in a workshop, in which they were asked to draw the suture configurations they used and to repair a porcine tendon. The properties of the repaired tendons were measured. Seven participants used a standard core suture configuration, and nine used a modified core suture. The biomechanical properties of the repairs were not affected by modifications to the core suture. However, they were affected by the number and lengths of peripheral suture bites, type of peripheral suture and the location of the core suture knot.

Keywords

Hand surgery, finger, flexor digitorum profundus, biomechanical testing, work-shop, modification

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Introduction

There are many different flexor tendon repair suture configurations (SCs) and suture materials (Neumeister et al., 2014; Savage, 2014; Wu and Tang, 2014). Given the abundance of different techniques, a surgeon may have difficulties in the selection of a SC and modification of existing techniques is probably not unusual. In fact, even the most popular configurations have been repeatedly modified, re-modified and misnamed (Sebastin et al., 2013). Although information is given about the repair techniques and suture materials that are used by the clinics that publish their results, there are few surveys that investigate everyday practice (Healy et al., 2007; Sarig et al., 2013; Tolerton et al., 2014). The aim of this study was to investigate current practice in flexor tendon repair among Finnish hand surgeons, and particularly to find out how common it is to modify existing standard core SCs. The other aim was to find out whether modifications affect the biomechanical properties of the repaired tendons.

Methods

Participants

Representatives of the six largest hand surgery units in Finland were contacted and invited to attend a national symposium on flexor tendon repair held in Tampere, Finland, on 24 April 2015. A total of 16 hand surgeons (eight specialists and eight residents) took part.

Tendon repair

All participants were asked to name and draw to scale the peripheral and core SCs they used in their everyday practice. They also reported the suture materials that they normally used in flexor tendon repair. Thereafter, they were asked to carry out the same tendon repair on a thawed fresh frozen porcine tendon (hind limb flexor digitorum profundus (FDP) from ray III or IV), which was dissected out from the trotter and transected using a surgical scalpel. The pulleys were vented if necessary but the tendon was repaired in situ. All participants were told to use a

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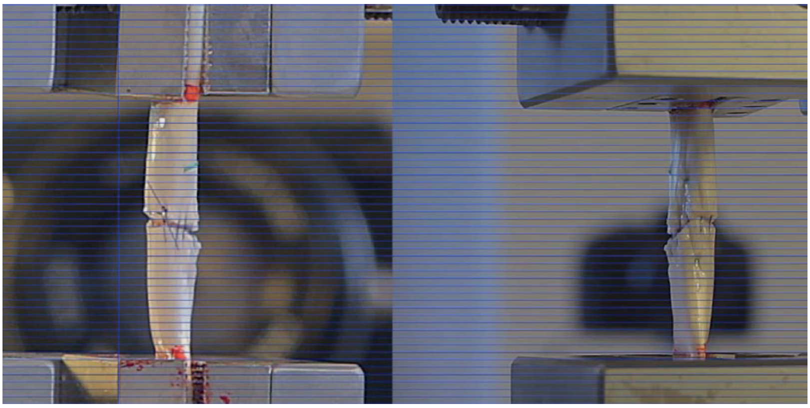

Figure 1. Biomechanical testing viewed from two diametrically placed cameras.

looped 3–0 braided polyester core suture (Tendo Loop®, B. Braun Surgical GmbH, Melsungen, Germany). They had the option to cut the loop to use it as a single suture. They were provided with a 5-0 polyamide monofilament (Dafilon®, B. Braun Surgical GmbH, Melsungen, Germany) for the circumferential repair.

The study did not require an ethical board approval, as no living animals or patients were involved.

Analysis of repaired tendons

The repaired tendons were kept moist in saline-soaked gauze, except when being measured. The width and height of the repaired tendons were measured using a calliper and the cross-sectional area was calculated ($A = \pi \times ab$, where a and b are the semi-major and semi-minor axes). The number of purchases of the peripheral suture was counted. The repaired tendons were photographed with a Fujifilm X-T1 camera (Fujifilm Holdings Corporation, Tokyo, Japan) for a comparison of the drawing with the actual repair. The lengths of the core and peripheral suture purchases were measured from the calibrated photographs.

The biomechanical properties of tendon repairs were tested using a materials testing machine (LR 5 K Lloyd Instruments Ltd, Hampshire, UK) (Figure 1). The tendons were secured to the testing machine with clamps 30 mm apart from each other. A linear tensile loading (20 mm/min) was applied to the specimen until the repair failed. A preload of 0.5 N was used. The ultimate load, the load at yield point and the stiffness were determined. The yield point was determined using a 0.1 mm offset method (Lotz et al., 1998). The stiffness was determined from a linear regression in moving cell fashion for all data points, starting from the beginning until the peak load (25 data points/second) and searching for the linear regression line that best represented the slope of the load–deformation curve in its most linear region (Lotz et al., 1998).

The biomechanical testing was filmed using two diametrically placed cameras (Canon EOS 550D and Canon EOS M, Canon Inc., Tokyo, Japan) to determine the pattern of the repair failure (e.g. rupture of the suture material, opening of the knot, suture pull-out). In addition, the gap formation was measured for 1 and 2 mm partial opening of the repair site and 1 and 2 mm total opening of the repair site. The gap measurements were determined by two authors and the mean of their interpretations was considered legitimate. The interobserver coefficient of variation was determined.

Statistical analysis

The primary outcome was the ratio between standard core SCs and their unique modifications. The criterion for regarding a SC as a unique modification was that it had not been described in an academic publication (either journal or book). For example, the Pennington modified Kessler (Pennington, 1979) or Gan modified Lim-Tsai (Gan et al., 2012) repairs were regarded as standard repairs. The secondary outcome was the difference in the biomechanical competence of the standard and modified repairs. A two-way analysis of variance was used to detect differences between groups. An a priori power calculation for the ultimate load was based on the following assumptions on a two-sided level: difference between the groups 25%, standard deviation 15%, power $(1 - \beta)$ set at 0.80 and $\alpha = 0.05$. This yielded a minimum of six

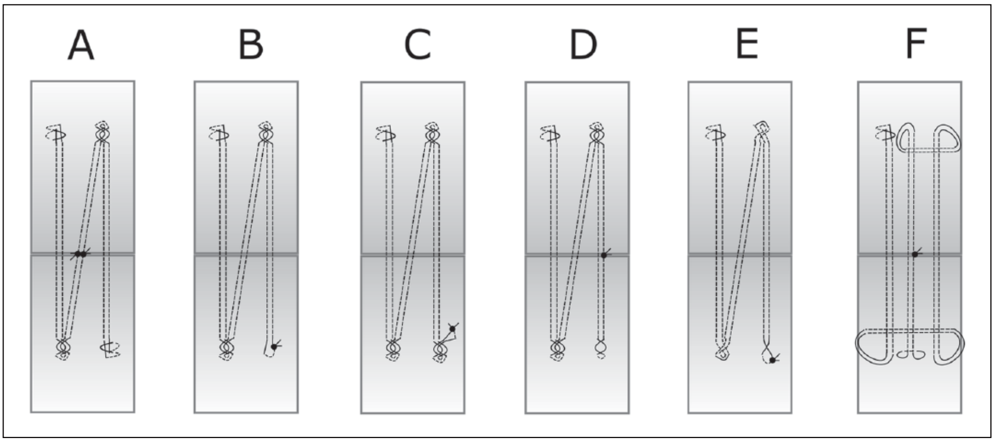

Figure 2. Schematic drawings of typical core SCs in this study. (A) Lim-Tsai (standard SC). (B) Gan modified Lim-Tsai (standard SC). (C) Modified Lim-Tsai with one looped thread, with knot outside the tendon surface. (D) Modified Lim-Tsai with one looped suture, with knot between the tendon ends. (E) Modified Lim-Tsai with one looped thread, with Tsuge locks changed to simple loops. (F) Modified Lim-Tsai with on looped thread, with Tsuge loops changed to Pennington locks. Note that different modifications had some minor within-group differences.

Table 1. Core SCs used by the individual participants ($n = 16$).

Suture configuration as named by participant	Suture configuration used	Details
Adelaide (4-strand)	Adelaide (4-strand)	Correctly named and done
Lim-Tsai (6-strand)	Lim-Tsai (6-strand)	Correctly named and done, Figure 2(A)
Lim-Tsai (6-strand)	Lim-Tsai (6-strand)	Correctly named and done, Figure 2(A)
Lim-Tsai (6-strand)	Lim-Tsai (6-strand)	Correctly named and done, Figure 2(A)
Lim-Tsai (6-strand)	Unique Modification (6-strand)	Misnamed, Figure 2(E)
Modified Kessler (4-strand)	Pennington modified Kessler (4-strand)	Misnamed, correctly done
Modified Kessler (6-strand)	Unique Modification (6-strand)	Figure 2(F)
Modified Lim [sic] (6-strand)	Modified Lim-Tsai (Gan modification) (6-strand)	Misnamed, correctly done, Figure 2(B)
Modified Lim-Tsai (6-strand)	Modified Lim-Tsai (Gan modification) (6-strand)	Correctly named and done
Modified Lim-Tsai (6-strand)	Unique modification (6-strand)	Figure 2(C)
Modified Lim-Tsai (6-strand)	Unique modification (6-strand)	Figure 2(C)
Modified Lim-Tsai (6-strand)	Unique modification (6-strand)	Figure 2(C)
Modified Lim-Tsai (6-strand)	Unique modification (6-strand)	Figure 2(D)
Modified Lim-Tsai (6-strand)	Unique modification (6-strand)	Figure 2(F)
Modified Tsuge (6-strand)	Unique modification (6-strand)	Figure 2(D)
Modified Tsuge (6-strand)	Unique modification (6-strand)	Figure 2(F)

samples per group. Pearson's correlation coefficient was used to rule out the possible confounding effect of differences in cross-sectional area between the repaired tendons.

Results

Suture configuration

Seven of the 16 participants used a standard core SC. Two of them misnamed their core SC. The most frequently used standard core SC was the Lim-Tsai (Lim and Tsai, 1996) (Figure 2(A)) (Table 1). Other core SCs used were the Pennington modified Kessler (Pennington, 1979), Adelaide (Sandow and McMahon, 2011) and Gan modified Lim-Tsai (Gan et al., 2012) (Figure 2(B)). Nine surgeons used a unique modification that had not been previously described. One of them misnamed the repair as a standard one. The Lim-Tsai suture and its modifications are shown in Figure 2. The tendency to modify the core SC did not differ between senior hand surgeons and residents (four of eight specialists and five of eight in the residents; $p = 1.000$, Fisher's exact test).

All except two participants used an over-and-over (i.e. simple running) peripheral SC. The remaining two used the Silfverskiöld technique (Silfverskiöld and Andersson, 1993) either all the way round the repair or to the anterior part of the repair (completing it with a simple over-and-over repair).

The suture materials used by the surgeons in everyday practice are summarized in Tables 2 and 3. There were no differences between the drawings and actual tendon repairs in terms of the SCs, number of knots or length of suture purchases.

Table 2. The core suture materials that the surgeons stated they used in everyday practice.

Core suture material	Number of surgeons using the core suture material
FiberLoop® 4–0[a]	6
FiberLoop® 3–0[b]	1
Braided polyester loop 3–0	7
Simple braided polyester 3–0	2

[a]Arthrex, Inc.Naples, FL, USA.
[b]FiberLoop® 3-0 is not commercially available.

Table 3. Peripheral suture materials used in everyday practice.

Peripheral suture material	Number of surgeons using the peripheral suture material
Polyamide monofilament 5–0	1
Polypropylene monofilament 6–0	7
Polypropylene monofilament 5–0	8

Biomechanical properties

The results are summarized in Table 4. The type of disruption of the core suture was breakage of the suture in all samples.

The cross-sectional area of the repaired tendon did not correlate with the biomechanical properties of the repaired tendons. The biomechanical properties of tendons repaired with modified core SCs did not differ from those of standard repairs (Table 4, Figure 3). Misnaming the repair had no effect on the biomechanical properties of the repair. Tendons repaired by the senior hand surgeons or residents did not differ in biomechanical competence.

The ultimate load, the load at yield point and stiffness were correlated with the number of peripheral suture purchases ($R = 0.709$, $p = 0.002$; $R = 0.834$, $p < 0.001$; and $R = 0.554$, $p = 0.024$, respectively). The repairs with the knot of the core suture left outside the repair site were stronger, the ultimate load being 102 N (SD 22), compared with 80 N (SD 16) for repairs in which the knot was placed between the tendon ends ($p = 0.043$). The Silfverskiöld suture, as a peripheral repair, yielded higher ultimate and yield load compared with the over-and-over SC (125 N (SD 22) vs 82 N (SD 14), $p = 0.002$; and 115 N (SD 7) vs 64 N (SD 14), $p < 0.001$, respectively).

The interrater coefficient of variation for the determination of the gapping values were 11.4%, 6.8%, 4.6% and 2.0% for loads needed to create 1 mm partial, 2 mm partial, 1 mm total or 2 mm total gap between the tendon ends, respectively. All gapping values correlated with the number of peripheral suture purchases ($R = 0.804$–0.852; $p < 0.001$). The Silfverskiöld

Table 4. Biomechanical data and measurements of the repaired tendons and drawings. All parameters are expressed as mean (SD).

Parameter	All		Standard core SCs		Modified core SCs	
Ultimate load (N)	88	(20)	84	(15)	90	(24)
Load at yield point (N)	68	(22)	64	(17)	70	(22)
Load at 1 mm partial gap (N)	55	(22)	59	(22)	52	(23)
Load at 2 mm partial gap (N)	67	(23)	69	(19)	64	(27)
Load at 1 mm total gap (N)	73	(22)	75	(18)	71	(26)
Load at 2 mm total gap (N)	76	(23)	78	(18)	75	(27)
Stiffness (N/mm)	12	(2)	12	(2)	13	(2)
Cross-sectional area (mm^2)	40	(9)	40	(9)	41	(10)
The number of peripheral suture purchases	13	(3)	14	(5)	13	(3)
The length of core suture purchases in drawing (mm)	9.0	(2.0)	9.6	(1.2)	8.4	(2.3)
The length of core suture purchases in tendon (mm)	8.1	(2.0)	8.3	(2.2)	8.0	(2.0)
The length of peripheral suture purchases in drawing (mm)	1.6	(1.9)	1.9	(2.3)	1.4	(1.6)
The length of peripheral suture purchases in tendon (mm)	1.7	(0.7)	1.8	(1.1)	1.6	(0.2)

p = NS for all between-group differences.
N: newtons; SC: suture configuration.

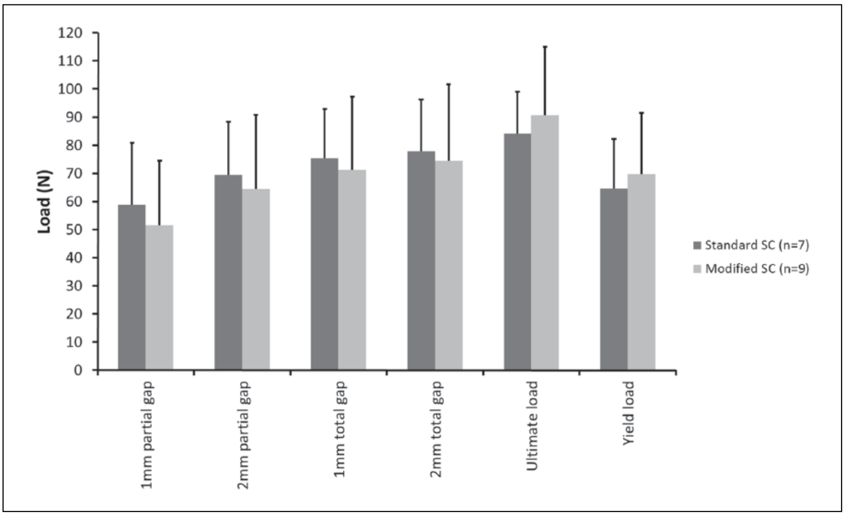

Figure 3. Early gapping values, ultimate load and yield load categorized according to the core SCs used. No statistically significant differences were found. The error bars represent standard deviations.
SC: suture configurations.

peripheral suture yielded higher gapping loads than the over-and-over suture. The Silfverskiöld repair had a 1 mm partial gapping load that was 124% greater than that found with the over-and-over SC. The differences were 102%, 82% and 79% for 2 mm partial, 1 mm total and 2 mm total gapping loads, respectively ($p < 0.001$ for all gapping loads). The load needed to create a 1 mm partial gap between the tendon ends correlated with the length of the peripheral suture purchases ($R = 0.569$; $p = 0.021$). Otherwise, the length of the purchases of either the core or peripheral sutures had no effect on the biomechanical properties of the repairs.

Discussion

The management of flexor tendon injuries is one of the most studied topics in hand surgery. In particular there has been a great deal of experimental research on flexor tendon repair configurations, probably because it is straightforward to do, but also because of innovations in suture materials. However, little is known about the prevalence of the various peripheral and core SCs in the everyday practice of hand surgeons. In our sample of 16 hand surgeons and residents, modification of the core SC was frequent. Nine of the 16 used a core suture that was a unique modification of a standard configuration.

Finland is a sparsely populated country with 5,500,000 inhabitants, fewer than 60 hand surgeons and with educational hand units in five university hospitals. The hand surgeons are frequently in contact with each other. It can be assumed that they use similar managements for common problems, such as tendon repair. The popularity of the Lim-Tsai configuration (Lim and Tsai, 1996) and its modifications is probably a local phenomenon. Different configurations are popular in other countries, for example the Kessler-type configuration in Ireland and Israel (Healy et al., 2007; Sarig et al., 2013) and the Adelaide suture in Australia (Tolerton et al., 2014).

It might be thought that modification is most frequent in hand surgeons who have knowledge of many techniques of tendon repair and their long experience has convinced them that their modification is an improvement. However, we found the tendency to modify the core SC was similar in specialists and residents.

We thought that the repairs using an established core SC would be biomechanically stronger than repairs with modified SCs. However, we found that modifying the core SC did not affect the overall biomechanical performance of the repair in this study.

Typically, the Lim-Tsai repair (Lim and Tsai, 1996) was modified by using only one looped thread and completed either with one knot between the tendon ends (Figure 2(D)) or with a separate knot outside the tendon surface (Figure 2(C)). Theoretically, this kind of modification might result in improved biomechanical properties since additional knots between the tendon ends probably make the repair weaker (Rees et al., 2009). Another unique modification pattern was to change the type of locking loops (Figure 2(F)) or to modify locking loops to simple loops (Figure 2(E)). It cannot be inferred that changing the type of loop would entail a risk of premature failure of the repair, as the biomechanical properties of the unique modifications were similar to the standard repairs. This is in accordance with previous reports (Wu and Tang, 2011, 2014).

Although the porcine tendon is commonly used as a surrogate for human flexor tendons in research (Havulinna et al., 2011), the selection of FDP III or IV tendons from the hind limb can be criticized because their cross-sectional areas are larger and the loop-holding capacity may be greater than in the human FDP tendon. The practical reason for choosing these tendons was that the III and IV FDP tendons could be easily dissected and the larger size enabled easier handling without the use of surgical loupes in the workshop facilities.

Although there were insufficient numbers to statistically test differences between specific SCs, there were other factors apart from knot placement that statistically significantly influenced the biomechanical competence of the tendon repairs. The number of peripheral suture purchases was positively correlated with all biomechanical properties measured in this study, irrespective of the cross-sectional area of the repaired tendon. This is in agreement with previous reports (Kubota et al., 1996). Similarly, the present study showed that in terms of ultimate load, yield load and especially gapping loads, the Silfverskiöld technique was better than a simple over-and-over suture, although there were only two surgeons who used it. Despite the limited numbers, this finding is probably reliable, since it has been already been decisively established (Silfverskiöld and Andersson, 1993). Certainly, these findings highlight the importance of the peripheral suture for the biomechanical competence of the repair (Lotz et al., 1998), although it must be acknowledged that the execution of a complex peripheral suture in everyday practice may be more difficult than in the laboratory.

Biomechanical competence is only one property of an adequate tendon repair. The repaired tendon has to allow free gliding within the pulley system. The tendon repair was done in the workshop facilities and the pulleys were vented without hesitation. Therefore the gliding properties of the repaired tendons within the tendon sheath could not be tested.

There are some limitations to this study. The number of participants to the symposium was small, reducing the statistical power of the study. The participants were all hand surgeons or residents that were especially interested in management of flexor tendon injuries, and they may not be representative of all hand surgeons in Finland, giving a potential selection bias. The surgeons had to use the suture materials that were provided by the organizers rather than those they would have chosen to use clinically. The biomechanical testing was linear, although some authorities think that cyclic testing would provide more reliable information about the behaviour of the tendon repair under stress (Gibbons et al., 2009; Sanders et al., 1997).

According to this study, modifying the core SCs in flexor tendon repairs is common among Finnish hand surgeons, although this does not seem to compromise the biomechanical competence of the repairs. Nevertheless, we recommend that hand units be aware of the tendency to modify SCs and maintain regular quality control.

Declaration of Conflicting Interests

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