UNIVERSIDADE DE LISBOA

INSTITUTO SUPERIOR TÉCNICO

Evaluation of the biomechanical repercussion of different surgical techniques and materials on the tendon-bone interface in a rotator cuff mechanical model

Carlos Eduardo Baião Nogueira Maia Dias

Supervisor: Doctor Jorge Manuel Alves Draper Mineiro

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Thesis approved in public session to obtain the PhD Degree in Bioengineering

Jury final classification: Pass with Distinction

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Jury

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2022

Para os meus filhos, Margarida e Vasco,

Para que entendam que antes do sucesso, vem o esforço e
que ninguém acreditará em vós, até estar feito.
Não prometam, façam!
Não tentem, sejam!

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ABSTRACT

Surgical repair of symptomatic rotator cuff tears is the gold-standard treatment, but retear and non-healing are still frequent complications which have been associated to some surgical technical options.

We proposed to evaluate the mechanical repercussion at the tendon-bone interface of different surgical variations of a transosseous equivalent repair.

Using two different types of force sensors, force, area and pressure contact, as well as maximum force and force applied in the medial region of the mock repair were measured in a simulated model of transosseous repair model with varying suture material, medial row mechanisms and number of suture passage holes in the tendon, while using controlled lateral row suture tension values.

Non-sliding medial row mechanisms applied most of their force at the tendon-bone interface when the first lateral row anchor was introduced and sutures tensioned, while sliding mechanisms depended mostly on the last anchor applied.

Non-sliding medial mechanisms generated higher values of all the studied parameters when compared to sliding mechanisms.

Isolated suture passage at the medial cuff generated higher contact area regardless of the other technical variations, while wire use, comparing to tapes, increased contact force, pressure, and maximum force at the tendon-bone interface.

Increasing lateral row tension increased the values of all parameters studied and it was the medial region of the repair that received the highest amount of force.

In summary, surgical technique variations influence the mechanical forces suffered by the tendon-bone interface but the ideal technique is yet to be established

The medial region of the repair is a critical area that receives high amounts of force and pressure, which can explain some retears that occur medial to it and considering the preponderant effect demonstrated by lateral row tension increase, a prototype was designed to allow intra operative lateral row tension measurement and control.

KEYWORDS: Rotator Cuff, Biomechanics, Materials, Surgical technique, Tendon-bone interface

Resumo

A reparação cirúrgica é o tratamento de eleição das ruturas da coifa dos rotadores sintomáticas, mas a reruptura e a não cicatrização ainda são complicações frequentes, e têm sido associadas a algumas opções cirúrgicas.

O objectivo deste trabalho foi avaliar a repercussão mecânica na interface tendão-osso da utilização de diferentes variantes técnicas de uma reparação transóssea equivalente.

Utilizando dois tipos diferentes de sensores de força e tensão controlada nas suturas da fileira lateral, foram medidas num modelo mecânico a força, área e pressão de contacto, bem como a força máxima e força aplicada na região medial da reparação, variando o tipo de sutura, o mecanismo da ancoragem medial e número de orifícios de passagem da sutura no tendão.

As montagens com mecanismos da fileira medial não deslizantes aplicaram a maior parte da sua força quando a primeira âncora lateral foi introduzida e as suturas tensionadas, enquanto a força aplicada no contexto deslizante dependeu principalmente da última âncora aplicada.

Os mecanismos mediais não deslizantes geraram valores mais elevados de todos os parâmetros estudados quando comparados com mecanismos deslizantes.

A passagem de sutura isolada na fileira medial gerou uma área de contacto mais elevada, independentemente das outras variações técnicas, enquanto a utilização de fios, comparados com fitas, aumentou a força de contacto e a pressão, bem como a força máxima na interface tendão-osso.

O aumento da tensão na fileira lateral elevou os valores de todos os parâmetros estudados e foi na região medial da reparação que foi exercida mais força.

Em suma, as variações da técnica cirúrgica influenciam as forças mecânicas sofridas pela interface tendão-osso, mas a técnica ideal ainda está por estabelecer.

A região medial da reparação é uma região crítica sujeita a uma força e pressão elevadas, o que pode explicar algumas reruptures mediais à reparação. Considerando o efeito preponderante demonstrado pelo aumento da tensão da fileira lateral, foi projetado um protótipo para permitir a medição e controlo intraoperatório da tensão na fileira lateral.

PALAVRAS CHAVE: Ruptura da coifa, Força, Pressão, Área, Interface tendão-osso

Abbreviations

AL – Antero lateral

AM – Antero medial

DR - Double Row

DP - Double passage

ECM – Extracellular Matrix

FSR - Force Sensing Resistor

GAGs - Glycosaminoglycans

KS – Knotless / Sliding

MBR – Medial Bearing Row

PA – Posteroior anterior

PGs - Proteoglycans

PL – Postero lateral

PM – Postero medial

RCT - rotator cuff tear

SB - Suture-bridge

SLDP - Sliding double passage

SP - Single passage

SR - Single Row

TBI – Tendon-bone interface

TDP – Tape Double Passage

TNS – Tied / Non sliding

TOE - Transosseous equivalent

TSP – Tape Single Passage

WDP – Wire Double Passage

WSP – Wire Single Passage

VS - Versus

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Introduction

Motivation

Rotator cuff tears (RCT) are common injuries [1], mostly secondary to rotator cuff disease[2], that create a severe burden for patients and healthcare systems [1,3,4].

Despite its relevance, the most adequate treatment has been a constant source of debate in the orthopedic community, considering its heterogeneous clinical pattern and severeness variability. Moreover, in the setting of tendon tear, achieving adequate long term clinical and imagiological outcomes is still a challenge[5].

For asymptomatic patients, it's generally well accepted that no other treatment is required besides regular surveillance of disease progression, and rotator cuff and scapula stabilizers muscular strengthening to maintain adequate scapular dynamics and a balanced shoulder [6,7], as even in the case of a tear, the majority will not progress in the short to medium term[8].

On the other hand, in symptomatic patients, treatment may vary according to the severeness of the disease. In the case of tendinopathy and Ellman[9] type 1 or even type 2 partial rotator cuff tears, conservative treatment[10,11] is usually the initial approach, comprising activity modification, Non Steroid Anti Inflammatory drugs (NSAIDs), pain medications and physiotherapy[12], which can be followed by more invasive but still nonsurgical options that can include steroid[13], hyaluronic acid[14], platelet rich plasma injections[13,15] or a conjugation of all of these[14].

In the setting of a high grade Ellman type 3[9] or complete rotator cuff tear, one should aim for surgical repair if feasible, especially in traumatic or acute[16] setting.

Despite surgeons´ best efforts to provide an adequate repair, which can promote tendon to bone healing and a future fully functional shoulder after proper rehabilitation, the complication rates of the injury and its treatment are not neglectable [17,18], including retears and nonhealing. There are multiple causes and risk factors for this undesired outcome and while most are patient related, some surgical choices can interfere with the result and that is why surgeons should bear in mind the pros and cons of several options at their disposal. These choices include:

- type of approach (open Versus (Vs) arthroscopic)
- type of implants (anchors or sutures)
- type of assembly (pure transosseous, single row, double row, transosseous equivalent, other types)
- type of medial row configuration (knotless Vs tied; double-hole passage Vs single-hole passages, number of sutures passed within the tendon)
- Type of sutures (tape Vs suture wires)
- Type of anchors (open Vs closed core; bioabsorbable Vs non absorbable; Rigid Vs suture; anchor dimension).

Some of the above options have been discussed in the literature[19–24], others have only scarcely been addressed[25–27], and some are yet to be evaluated, more specifically the progressive and final force pattern of different types of rotator cuff repairs and the effect at the tendon-bone interface (TBI) mechanics at time 0 of the use of different suture materials, different medial row anchor mechanisms and number of suture holes for suture passage in the medial cuff.

Considering the impact that rotator cuff tears have on patients and in the community, as well as the lack of robust evidence on the mechanical implications at the TBI of shoulder surgeons choices when repairing a cuff, corroborated by our recently reported 6,82% retear rate at an average of 7 months follow up[28], we were motivated to improve the knowledge on how surgical technical options can interfere with local biomechanical balance in the site of a rotator cuff tendon repair.

Aim of study and research questions

Transosseous equivalent (TOE)[29] arthroscopic repairs have gained popularity given their superior biomechanical properties and lower retear rates[30] when compared to other techniques. Despite that, when retears occurred they appeared to be more severe and difficult to treat[31,32]. Trantalis[32] was the first to describe a specific pattern of retear that occurred medial to the initial repair site, classified by Cho[31] as type 2 retears, which were much more frequent in TOE techniques, in opposition to type 1 retears, in which previously repaired cuff tissue at the insertion site of the rotator cuff was not at all observed to be remaining on the greater tuberosity. Type 2 retears were found to be much more challenging to revise given the fragility of the medially retracted tendon / myotendinous stump.

The exact causes and risk factors for type 2 retears is yet to be understood but some authors hypothesized that some surgical gestures could induce excessive mechanical stress at some areas of the tendon bone repair site[31–35]. This hypothesis is consistent with the our clinical impression that excessive stability of the tendon bone interface may create excessive stress on the medial row by preventing the normal tendon lengthening following repair [36]. The ideal TBI contact force, pressure and area, as well as the ideal medial bearing row (MBR) force is yet to be determined, but understanding how does surgical technique affect this mechanical variables places us one step closer to achieving that ideal balance between mechanics and biology [37,38].

This study essentially aimed to evaluate the biomechanical repercussion at different areas of the tendon bone-interface of the use of different materials, different medial row configurations and different lateral row anchor suture tension.

To achieve these objectives, we proposed several questions:

1. Does the type of medial row mechanism interfere with the progressive contact force load pattern at the TBI secondary during repair assembling? **(Chapter III)**

2. Does that medial row mechanism interfere with the individual stress induced in each lateral row anchor? **(Chapter III)**
3. Do tapes and suture wires generate the same contact force, area, and pressure in different locations of the TBI if the entire assembly is subjected to the same lateral row tension? **(Chapter IV)**
4. Are the number of suture passages points in the tendon relevant to increase contact force, area, or pressure in different locations of the TBI? **(Chapter IV and V)**
5. Does the type of medial row anchor mechanism interfere with those biomechanical parameters at the TBI? **(Chapter V)**
6. How does the contact force, area and pressure vary according to the lateral row tension induced? **(Chapter V)**
7. Do different medial row configurations respond differently to lateral row tension increase? **(Chapter V)**

Research strategy

This study was designed to occur in a highly controlled environment, in order to clearly demonstrate to surgeons what would be the results of their choices if most of the remaining variables were eliminated, meaning, what would be the sole effect of changing a specific surgical gesture at the tendon bone interface if all remaining procedures were the same.

To fulfill the objectives of this thesis and address the research questions, the following models and approaches were applied:

- A SAWBONES® SKU 1521-12-2 rotator cuff training model (SAWBONES®, Vashon, WA) was used to simulate the tendon bone interface in all tests. It consists of a rigid foam that mimics the biomechanical properties of the humeral head and includes a neoprene band that accounts for the tendon, that, nonetheless, does to replicate its biomechanical features.
- The implantable material used to mimic the several repair configurations were 5.5 mm Helicoil ® anchors (Smith & Nephew, London, UK) loaded with one Ultratape® and one Ultrabraid® sutures, in which one of them was removed when they were not needed, for the medial row, and 5.5mm Footprint Ultra PK® anchors (Smith & Nephew, London, UK) that received the suture limbs (ultratape or ultrabraid) both for the lateral row and medial row according to the technique to be studied.
- The distance between all anchors and suture passage points in the mock tendon was replicated in all tests with the use of a plastic template that allowed the marking of both suture passage sites and anchor placement location.
- Suture tapes and wires were passed on the mock tendon using the same single sized needle in all tests

- To assess the variation of contact force during TOE assembling, in chapter II a Force Sensing Resistor FSR® 402 (Interlink Electronics, Inc., Westlake Village, CA) (FSR) was used and connected to an Arduino Nano v3.0 board (Arduino LLC, Boston, MA). Following the manufacturer indications, a voltage divider circuit followed by a buffer amplification stage was introduced to measure the variation of the resistance in the FSR sensor. The circuit was designed, in such a way that the linear region of the sensor would fit the range between 0 N and 60 N (0.354 MPa), and the maximum force was around 150 N (0.886 MPa).
- The data provided by the FRS was posteriorly analyzed using MATLAB software (MathWorks, Inc., Natick, MA).
- TBI´s Contact force, area and pressure were evaluated using a Tekscan® 5051 pressure mapping sensor (Tekscan Inc.®, Boston, MA) at the *Centre for Mechanical Technology and Automation of the Mechanical Engineering Department of Universidade de Aveiro* for chapter IV and V analysis. The sensor was constituted by a flexible array of 46x46 force sensors, presenting a spatial resolution of 62 sensors per cm^2. This sensor had to be folded to fit the mock tendon bone interface in the experimental protocols in which it was used.
- The analysis of the contact force, pressure distribution and contact area collected by the Tekscan sensor was performed on I-Scan Lite® software and MATLAB. The single cell saturation was set for 0.69MPa, the maximum

pressure applied during the calibration procedure. Repair regions (repair box) were created to avoid collecting data from unloaded cells of the sensor outside the TBI which would inaccurately lower the mean values of contact force, area and pressure obtained as the sensor was quite larger than the simulated TBI. The repair box was defined on the acquisition software for each preparation for total contact force, pressure and area comparison and was similar for in each experimental protocol but differed between chapter IV and V studies.

- FSR Sensor calibration was performed in a universal testing/calibration machine – Instron 5544 (Instron, Norwood, MA) at *Instituto Superior Técnico*, while calibration of both the sensor and the suture tensioners for Chapter IV and V experiments was performed using a Shimadzu® calibrator (Shimadzu Corporation©, Kyoto, Japan) at *Universidade de Aveiro*.
- All statistical testing was performed in IBM SPSS Statistics v26 software (IBM, Armonk, NY). A level of significance of 5% was used for all the statistical analyses.
- Trials and tests described in chapter III were performed at *IDMEC – Instituto Superior Técnico, Universidade de Lisboa* while those in chapter IV and V were performed at *TEMA – Mechanical Engineering Department, Universidade de Aveiro*.

- The same shoulder surgeon with over 10 years of experience performed all essays.
- Suture material (tapes Vs wires) were tested regarding:
    a. contact force, area and pressure;
    b. local peak force;
    c. MBR applied force;
    d. suture path applied force;
    e. contact force pattern in the construct at time 0.
- Several different rotator cuff repair configurations were also tested and had their biomechanical influence at the TBI compared:
    a. Medial row mechanisms (sliding Vs. non-sliding) were compared in terms of:
        i. progressive force loading pattern during repair assembling;
        ii. lateral anchor stress;
        iii. contact force, area and pressure;
        iv. local peak force;
        v. MBR applied force.
    b. Number of tendon holes for suture limbs passage (single-hole Vs. double-hole) in medial row sliding and non-sliding mechanisms were compared regarding:

i. contact force, area, and pressure in different locations of the TBI;
ii. local peak force;
iii. MBRapplied force;
iv. Suture path applied force;
v. Contact force pattern in the construct at time 0.

- The effect of lateral row tension increase regarding the same mechanical variables of the TBI was evaluated and compared in sliding and non-sliding constructs and in single and double-hole medial passages.

Thesis outline

This thesis was designed to allow an independent reading of the different chapters. The reader must keep in mind that some redundancy can be found in the "Introduction" and "materials and methods" sections of chapters III, IV and V and that for a matter of organization, we chose to condense all the references in a single chapter at the end of the document.

In Chapter I, the main motivation, aim of the study, research questions and research strategies to answer those questions are presented.

Chapter II offers a literature review on rotator cuff basic science, as well as the background and state of art on rotator cuff tear treatment options, describing the most common repair techniques and their pros and cons based on biomechanical and clinical data. The risk of retear was also discussed, especially regarding the more severe type 2 retear.

Chapter III describes the study of the progressive load that the TBI receives when a rotator cuff repair is being executed well as the stress in the lateral row anchors. Two different types of medial row mechanisms were compared, in the case, knotless/sliding Vs tied/non-sliding, demonstrating that medial row mechanism interferes in the sequential load pattern at the TBI and in the load received by each of the two lateral row anchors. This is relevant clinically because in the setting of poor focal or diffuse bone stock in the proximal humerus, surgeons have now the tools that allow them to make a better judgment of the best medial row mechanism to avoid lateral row anchor loosening and global construct failure.

Chapter IV evaluates the biomechanical consequences at the TBI of different materials and types of medial row suture passage in a sliding medial row mechanism, by comparing suture wires and tapes and single-hole versus double-hole for the passage of medial row sutures, in terms of contact force, area and pressure, as well as peak force, MBR force and suture path force, showing that, contrary to previously published data, if similar lateral tension is applied, tapes generate less contact force and pressure when compared to suture wires, and increasing the number of suture passage points in the medial cuff increases tendon to bone contact area. It was also demonstrated that the most stressed region of the repair is the one closer to the medial row. This data offers some technical tips to slightly reduce the pressure in the tendon bone interface, either by increasing the contact area or by reducing contact force, which can be helpful in the clinical setting.

In chapter V we evaluate the biomechanical consequences at the tendon bone interface of using sliding and locked medial row mechanisms as well as single and double-hole suture passage in the tendon (this time in a medially locked mechanism), in terms of contact force, area and pressure, as well as peak force and MBR force. The effect of lateral row tension increase was also evaluated in all groups and compared. Results shown that the type of medial row mechanism, suture configuration and lateral row tension interfere with the mechanical forces sustained by TBI, and while medial sliding anchors and double-hole passage reduce contact force and pressure, especially in high lateral row tension settings when compared to their counterpart, increasing lateral row tension generates higher values of all studied parameters regardless of the repair technique.

Chapter VI demonstrates the development process of a prototype that allows intraoperative tendon and lateral row tension control in a reproducible and sustainable manner.

Chapter VII focused on the thesis discussion and future directions for which this document may be useful.

Chapter II

Background and state of the art

Rotator cuff

Anatomy and biomechanics

The shoulder is the most mobile joint in the human body[39] due to the intricate interaction of its 5 articulated spaces, which include the glenohumeral joint, the acromioclavicular joint, the sternoclavicular joint, the scapulothoracic and subacromiodeltoid spaces.

The connection of the upper limb to the axial skeleton is assured by the clavicle[40] through the sternoclavicular and acromioclavicular joints, which are stabilized by very robust ligaments, and by the scapulothoracic joint, a mobile space between the postero lateral thoracic wall and the scapula.

Under normal circumstances, scapular movement in the thoracic wall is a composite of three motions: upward/downward rotation around a horizontal axis perpendicular to the plane of the scapula, internal/external rotation around a vertical axis through the plane of the scapula and anterior/posterior tilt around a horizontal axis in the plane of the scapula[41].

Normal scapulohumeral rhythm, which is the coordinated movement of the scapula and humerus to achieve shoulder motion, is fundamental for an efficient shoulder function and while the majority of the mobility of the shoulder girdle occurs in the glenohumeral joint at a mean ratio of glenohumeral to scapulothoracic motion of

1.7:1[41], for adequate and functional movement of the shoulder to occur, the scapula must serve as a stable base for glenohumeral function while also moving through a substantial arc of motion. This stability and movement are provided by the dynamic muscle activation/relaxation of the rhomboids, anterior serratus, trapezius, and to a lesser extent by the activation/relaxation of the scapula elevator, subclavius and the pectoralis minor muscles [40,42]. These muscles are coordinated in task specific force patterns[40] to allow the stabilization of scapular position and control of dynamic coupled motion.

Glenohumeral joint adequate stability is also of paramount importance for adequate shoulder function and while the capsule and the superior, middle and inferior glenohumeral ligaments are responsible for the static stabilization of this joint, rotator cuff muscles are responsible for its dynamic stabilization[43] by providing a stable fulcrum during middle arc range of motion through the concavity-compression mechanism, which allows the deltoid to provide a powerful momentum to the arm[43,44] (Figure 2.1).

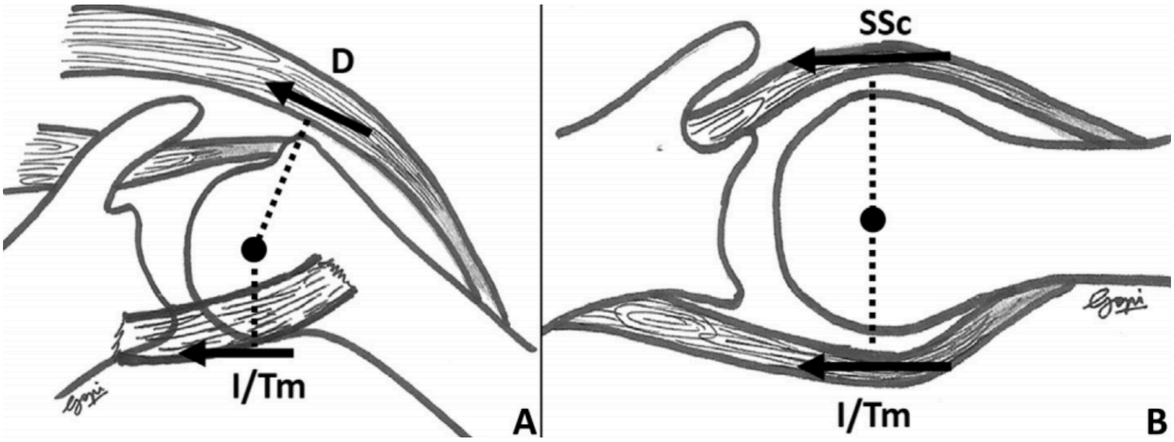


Figure 2.1 - The rotator cuff muscles force couple during motion providing a fulcrum for the deltoid to act (A – anterior view; B – superior view; D – Deltoid; I – Infraspinatus; SSc – Subscapularis; Tm – Teres Minor) (Reproduced from Pandey et al. (2014). Copyright from Asia-Pacific Journal of Sports Medicine, Arthroscopy, Rehabilitation and Technology).

The rotator cuff is an anatomical entity composed of four muscles: the subscapularis, supraspinatus, infraspinatus and teres minor, that not only serve as dynamic stabilizers of the glenohumeral joint but are also responsible for some of the strength required for range of motion: the subscapularis participates as an internal rotator and anterior stabilizer, the supraspinatus is partially responsible for forward flexion and abduction and acts as a vertical stabilizer, while the infraspinatus and teres minor are mainly responsible for external rotation and increase glenohumeral posterior stability [42].

These 4 muscles have an origin in the scapula and insert in the proximal humerus. The subscapularis is originated from the subscapularis fossa in the anterior aspect of the scapula and inserts through the subscapularis tendon in the lesser tubercule extending into the proximal humerus metaphysis, anteriorly to the intertubercular groove (Figure 2.2).

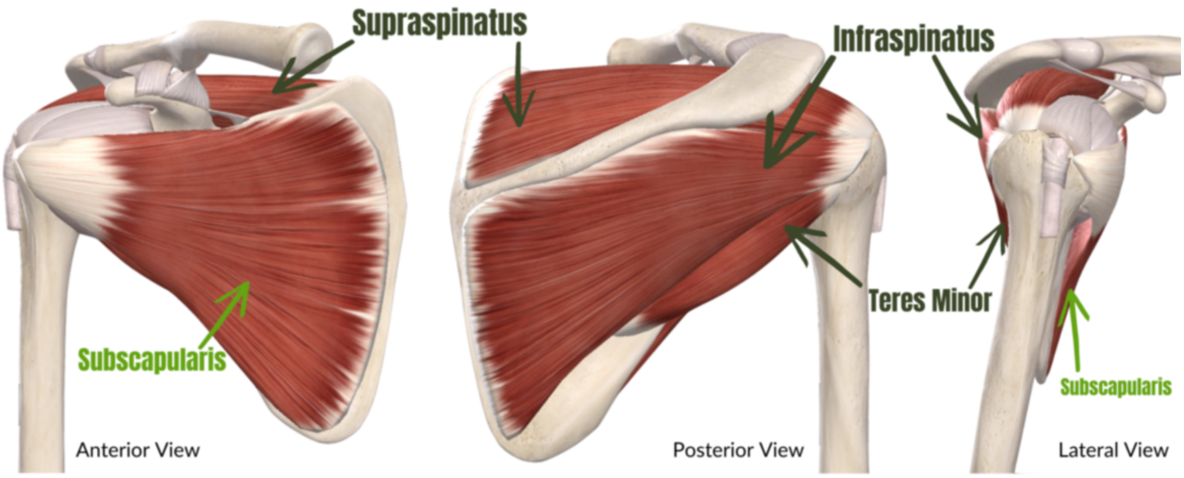


Figure 2.2 - The rotator cuff muscles in an anterior, posterior, and lateral view (Reproduced from movebetter.com. Copyright from Move Better Health and performance Inc.)

The supraspinatus has its origin in the supraspinous fossa, that is posteriorly bordered by the scapular spine which separates it from the infraspinatus, that has its origin in the posterosuperior area of the infraspinatus fossa of the scapular body, while its inferior area its occupied by the origin of the teres minor. Both the infra and the supraspinatus insert in the greater tubercule, the first in the most superior and anterior region, in a triangular or trapezoidal shape, while the latter has a more posterior insertion area in a rectangular or trapezoidal shape too[45,46]. Teres minor insertion is in the most posterior and inferior part of the lesser tubercule reaching down to the humeral neck[45].

Despite the separate origin of these muscles, their tendon insertions have interdigitations between them. The subscapularis and the supraspinatus connect over the intertubercular groove[47] surrounding the long head of the biceps[45], and the humeral insertion of the supraspinatus and infraspinatus seems to be unique in which the infraspinatus tendon overlaps anteriorly the supraspinatus[48] , the same happening between the infraspinatus and teres minor. There is also anatomical evidence of a clear relation between the capsule and the tendons [45,49], making the rotator cuff a capsular and tendinous continuum that serves as a glenohumeral stabilizer and force generator.

Histology

Tendons are the anatomical component that allows muscles to transmit tensile force to bone and are mostly composed of type I collagen molecules (65-80%) and elastin (1-2%), embedded in a proteoglycan (PGs)-water matrix[50,51].

They connect to muscle at the myotendinous junction and to the bone at the tendon bone interface or junction[50,52]. In healthy conditions they have a fibroelastic structure that provides them great resistance to mechanical loads and according to their anatomical location and function, they may vary considerably in shape and in bone attachment type, ranging from wide and flat tendons to cylindrical, fan-shaped, and ribbon-shaped tendons.

Collagen type I molecules have a natural tendency to aggregate [53] and they do so by organizing themselves into a polypeptide chain called tropocollagen, which is the structural basis of microfibrils that group themselves to create fibrils that derive into collagen fibers, which is the tendon basic unit. Collagen fibers organize themselves to form sub fascicles (primary fiber bundle), then form a fascicle (secondary fiber bundle) and finally a tendon fiber (tertiary fiber bundle). A tendon is then a composition of tertiary bundles (figure 2.3) [50].

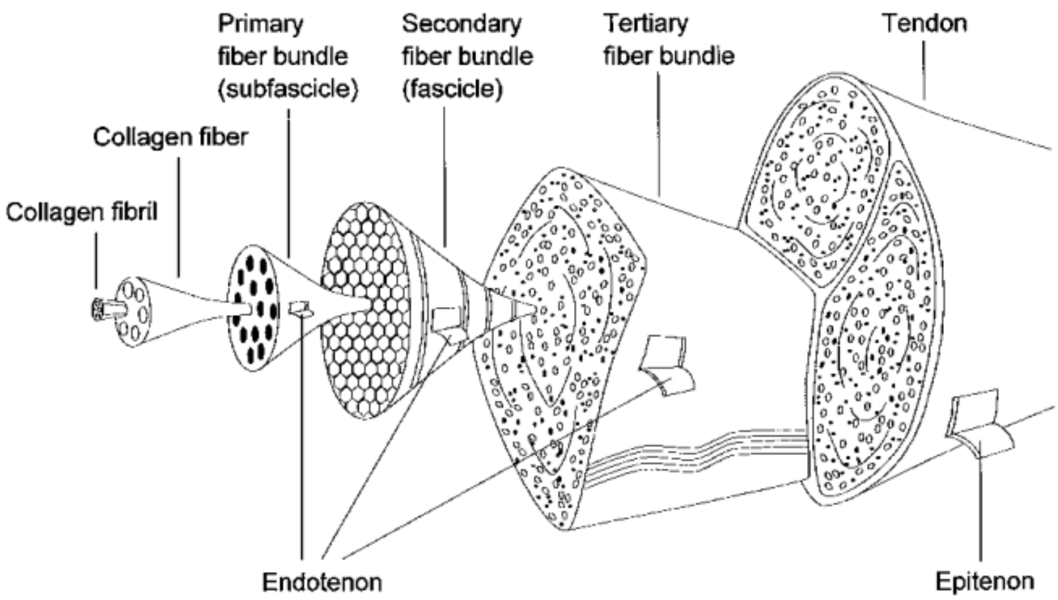


Figure 2.3 - The organization of tendon structure from collagen fibrils to the entire tendon (Reproduced from Kannus et al. (2000). Copyright from Scandinavian Journal of Medicine in Science and Sports)

These components are produced and remodeled by tenoblasts and tenocytes which are no more than elongated fibroblasts and fibrocytes between collagen fibers in the tendon extracellular matrix (ECM). This remodeling activity seems of particular importance for tissue homeostatis, especially in the supraspinatus where it represents a protective mechanism against tissue damage[54]

While collagen and its crosslinking provide tensile strength, the other components of the ECM allow for the structural support and regulate fibril assembly. It´s important to notice that changes in type of collagen and in its organization may alter its ability to withstand mechanical forces and are probably a pathological process that happens in tendinopathic tissues[51,53,55] and eventually contribute to tendon tear.

The ECM includes the ground substance, which is an hydrophilic gel that can vary in consistency depending on the relative proportions of hyaluronic acid and chondroitin sulphate, and consists of PGs, glycosaminoglycans (GAGs), structural glycoproteins, and a wide variety of other small molecules surrounding collagen fibers, non-collagenous proteins (elastin, tenascin, fibronectin), that may help in the elastic recoil during movement[50,53], and inorganic components that normally exist in a very small proportion that usually reaches no more than 0,2%, calcium being the most concentrated although others minerals are also present.

To prevent friction and allow motion, tendons are involved by different structures that also vary according to their location. In the rotator cuff, the subacromial bursae does that role, the same way the olecranon bursae protects the triceps or the infrapatellar bursae protects the patellar tendon. Some tendons are also surrounded by loose areolar connective tissue (paratenon) that functions as an elastic sleeve that also prevents friction, but probably not so effectively as tendon sheaths that are only present in long tendons in which change of direction and increase in friction requires very efficient lubrication[50]. Under the paratenon, the epitenon surrounds tendon fibers, connecting outwards with the paratenon and inwards with the endotenon, that involves the tertiary bundles.

More specifically in the rotator cuff, a microscopic five layer structure of both the supra and infraspinatus tendon insertion has been described in their confluence[56]. The first layer is the most superficial and contains fibers from the coracohumeral ligament. The second layer has parallel and densely packed collagen fibers that originate directly from the tendons, while the third layer corresponds to the overlap of the tendons, where the fibers are more loosely packed than in second layer. The fourth layer contains loose connective tissue and thick fibers from the deep extension of the coracohumeral ligament and the fifth and more profound is the true capsular layer with randomly oriented fibers (figure 2.4).

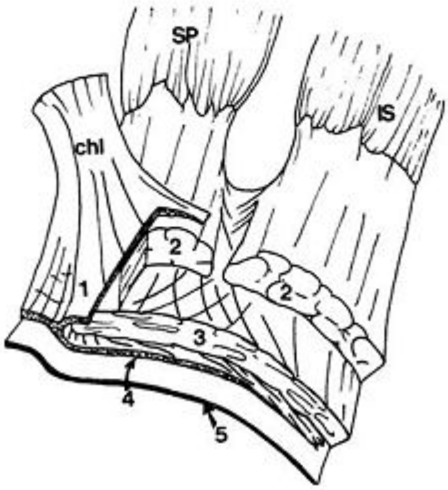


Figure 2.4 - The 5 layers organization of the supraspinatus and Infraspinatus common insertion site (adapted from https://www.shoulderdoc.co.uk/article/384)

The tendon bone junction on its hand comprises 4 layers, with a gradual and continuous change in composition between them, which include tendon midsubstance, fibrocartilage, calcified fibrocartilage, and bone[57,58]

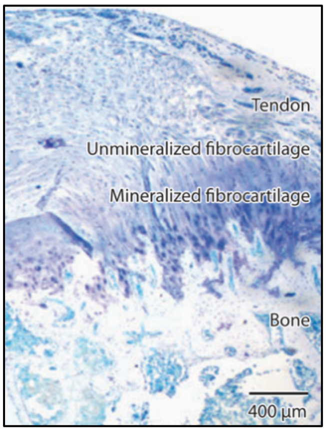


Figure 2.5 - The 4-layer organization of the tendon bone junction (Reproduced from Lu et al. (2013). Copyright Annual Reviews)

Rotator cuff tear

Epidemiology

Given the frequent asymptomatic status of patients with rotator cuff disease, its real incidence estimation is problematic. Moreover, due to the difficulty of establishing a correct diagnosis in the primary healthcare sector, especially in a relapsing and remitting disease such as this and considering the variability in healthcare informatic systems and registries, the endeavor of finding the real social burden of rotator cuff disease is quite challenging.

Despite the lack of robust literature, it´s estimated that rotator cuff disease reaches 87/100 000 persons and to be highest in the age range between 55 and 59 years old where it appears in 189/100 000 persons[59].

Reports on the incidence of rotator cuff tear repair are far more elucidating of the importance of this condition as it has been shown to reach over 80/100.000 persons in some countries [1,3,60,61], and if we consider rotator cuff disease as a continuum of disease[2,62] beginning as mild tendinopathy and ending as a tendon tear, and that the prevalence of asymptomatic rotator cuff tears can be as high as 54% in people older than 60 years old [63], with an overall prevalence ranging from 5 to 39% [64–66], one can truly appreciate the real importance of this illness.

Physiopathology and risk factors

Tendon disease has been characterized as a continuum[2,62] in which an initial injury generates a reactive tendinopathy, that then progresses to tendon disrepair. These are both reversible stages, but if left untreated or in the presence of a unequal load distribution or repeated strain [2,55,67], they will generate a degenerative tendinopathy that is identified in most tendon tears, which is the end stage of tendon disease[62], although it is postulated that any stage can occur in the same tendon at the same time.

This continuum has different histopathological features which help to prove this theory, but it is broadly characterized by changes in the proportion of collagen types, with a usual increase in type III collagen that contributes to tissue density reduction and loss of fiber orientation. Another important changes that occur include altered cellularity, cell rounding and apoptosis, decreased matrix and collagen organization, neovascularization and neoinnervation [2,53,55], that can explain why some patients have shoulder pain even in the absence of major imagiological alterations or evident rotator cuff tears.

Several factors have been shown to interfere with the risk of tendon disease and its subsequent tear. Increasing age is one of the most consistently reported[63,64,68,69], but male gender, trauma[69], heavy labor or physical exertion[64,70] and arm dominance have also been described as risk factors for rotator cuff tear (RCT)[64]. Recent genomic investigations have also found some genetic factors that can increase the risk of tendon tear[70–73]. Other comorbidities such as the metabolic syndrome[74], Diabetes Mellitus[47,51,75], hypertension[76,77], hyperlipidemia[78], thyroid disfunction[79] and smoking [80]have also been associated with a higher risk of tendon tear.

Local anatomic factors such as a critical shoulder angle[69] > 35º and some histopathologic characteristics, as the existence of tendinopathy in the adjacent tendons[70], also relate to rotator cuff tears.

This plethora is most likely to interact among itself to initiate tendon injury and disrepair, which then leads to a cascade of events which include changes in cellularity pattern, loss of fiber organization, calcium and lipidic deposition and chondroid, osseous or mucoid metaplasia[70,81]. These changes redound in the structural disorganization and loss of mechanical properties that are found in tendinopathy, which predisposes the tendon to tear[70].

Diagnosis

Patients with rotator cuff disease, including cuff tears, can be asymptomatic[63,82,83] . When symptomatic, they usually complain of night pain and a painful range of motion with variable strength deficit on the affected muscles.

There are specific subsets of clinical tests to evaluate each of the muscles of the rotator cuff that need to be performed in order to increase accuracy of the diagnosis and most of the times, several of them for each specific muscle needs to be performed to increase global specificity and sensitivity[16,84].

Final diagnosis is obtained with imaging techniques and while the X ray can only provide insights regarding associated pathology and tear chronicity, ultrasound permits the diagnosis of rotator cuff tears and other diseases.

Nonetheless, MRI and arthro-MRI provide the highest sensitivity and specificity for diagnosing rotator cuff tendinopathy and tear[16], while also providing adequate evaluation of other concomitant intra articular pathologies and allowing the establishment of prognosis criteria namely muscle atrophy[85–87], fatty infiltration[88,89] as well tendon quality[90], dimension[91] and retraction[92,93].

Retear risk factors and prevention

Several factors can interfere with tendon healing, and when deciding to perform a repair, the surgeon must anticipate the probability of complications to decide if the surgical benefit is worth the risk, following the principle of *"primum non nocere"*

Tendon retear is one of the most common[17] and is still an unsolved issue, with rates varying between 0%[94] and 94 % [95]. This high variability in different series is probably the indication that multiple factors interfere with the final anatomical result.

Increasing age [4,96–98], hyperlipidemia[99], high pre-operative levels of LDL[100], elevated total cholesterol levels[100], Diabetes Mellitus[78], smoking[101], high tendon fatty infiltration[96,100], progressive muscle atrophy[102], larger tear size[94,96], higher tendon retraction[103], tendon delamination[98,104], tendon length inferior to 15 mm[91], tendon quality in MRI[90] and acromio-humeral index[103] can all increase the risk of a poor anatomical result by facilitating retears.

Other factors such as osteoporosis, type of work and rehabilitation type are more controversial[105].

Besides these patient specific features that can inhibit tendon to bone healing or promote a retear, surgical technique has also been shown to influence, not only its rate but also the type of retear, which have been classified by Cho[31] in two types:

- Type 1 when the previously repaired cuff tissue at the insertion site of the rotator cuff is not observed to be remaining on the greater tuberosity;
- Type 2 retears, that occur medial to the previous repair site, while the repaired tendon is identified resting on its footprint.

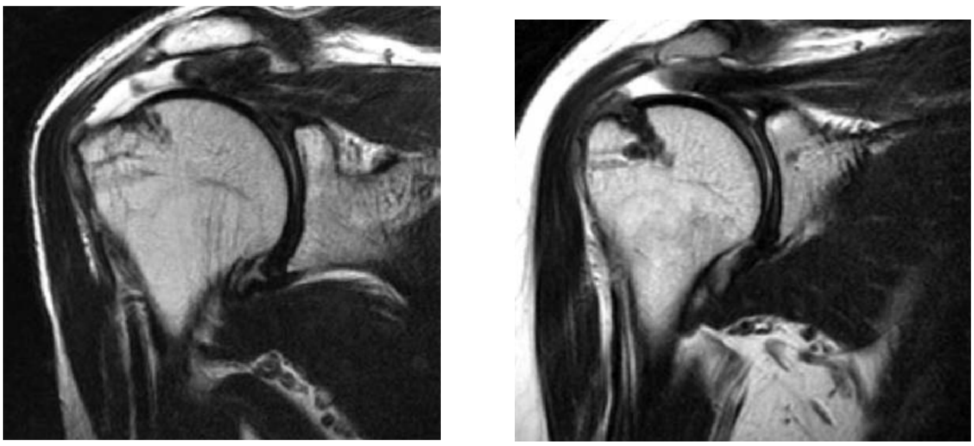


Figure 2.6 – Type 1 retear (left) and type 2 retear (right) (Reproduced from Cho et al. (2010). Copyright American Jounrla of Sports Medicine)

The latter was found to be much more challenging to revise, given the fragility and short dimension of the medially retracted tendon / myotendinous stump[34].

Using less biomechanically robust repairs has been associated with a higher risk of retear[94,96], but stiffer constructs have been consistently associated specifically with type 2 retears[32,34,106], which, as mentioned, are harder to revise, making the evaluation of the mechanical and biological implications of different technical options mandatory in order to understand which gestures should be adapted, as suggested by some authors[34]. Although RCT repair is required to be sufficient robust, it must not hamper the tendons´ biological healing ability by, for example, inducing broad ischemic areas that weaken the tendon-bone interface[24,107].

The positive effect of local biology in the repair has been supported by some evidence, namely by the demonstration that bone marrow stimulating techniques can enhance tendon to bone healing [108,109]. In fact, growing interest in this regard is demonstrated by several publications on biological enhancement strategies with the use of PRP, Hyaluronic acid (HA), stem cells[14,15,110] and more recently, bio inductive collagen scaffolds[111,112].

Rotator cuff tear repair – state of the art

Introduction

As described, not all rotator cuff tendon tears require repair as some occur in asymptomatic patients[12], while others due to their small dimension or degenerative etiology should benefit initially from conservative measures. There are also cases in which tendon and muscle quality as well as other patient specific conditions preclude surgical repair. In that setting of irreparability, partial repair[113], superior capsular reconstruction[114–116], tendon transfers[117,118], isolated biceps tenotomy[119–121], balloon interposition arthroplasty[122] or reverse shoulder replacement[123] are all viable options according to the age, clinical and remaining cuff status[113,124–127].

If the repair is considered, there is substantial evidence of a correlation between tendon healing, higher strength and better clinical outcomes[5,128–131], which has led surgeons to progressively improve their surgical and technical skills to achieve that objective.

Until the first reports of complete arthroscopic rotator cuff repair in 1993 by Snyder[20], rotator cuff full thickness tears were treated in an open or mini open fashion with the use of transosseus suture repairs[19] (figure 2.6 a) which stood as the gold standard until arthroscopy started to present other advantages such as identifying the different patterns of tears and associated glenohumeral pathology, while also allowing adequate tendon repair and promoting a smaller risk of infection, a less painful post-operative period and a shorter hospital stay[17,18].

Figure 2.7 - a) Transosseous configuration represented with green suture wires green. Note that there are no anchors b) example of tied Single row repair, with anchors inside the bone in blue and tied suture in green

Those apparent benefits were accompanied by some technical challenges that motivated a change in the type of materials used, as the creation of bone tunnels for suture wire passage used for open transosseous repair posed significant difficulties in the arthroscopic setting. This forced surgeons and manufacturers to develop simpler methods of tendon repair, mainly with the use of anchors (Figure 2.6b), initially applied in a single row (SR) fashion at the cartilage-bone interface of the supra and infraspinatus footprint. This initial setup motivated the development of new materials and types of suture passages techniques in order to obtain the best biomechanical performance[132,133].

Specific technical options and its consequences

Moezzi[134] recently highlighted the importance of tendon footprint restoration, and Apreleva *et al*[135] had already demonstrated that single row repairs only allowed for a footprint restoration of 67% of total area compared to 85% of the open gold standard transosseous repair. Considering this data, Lo and Burkhart[136] developed the a more robust and anatomic repair which they entitled "the double row (DR) repair" (Figure 2.7a), through the application of a medial row of suture loaded anchors at the articular margin and a lateral row of anchors in the greater tuberosity grabbing the most lateral part of the tendon stump. With these technical details they were able to increase tendon-bone contact area and promote a better healing environment[137], albeit stressing the importance of avoiding excessive tension in the repair. These surgical options remained popular for some time but nonuniform footprint contact and the complexity of the procedure arose some concerns[38], and new solutions started being developed.

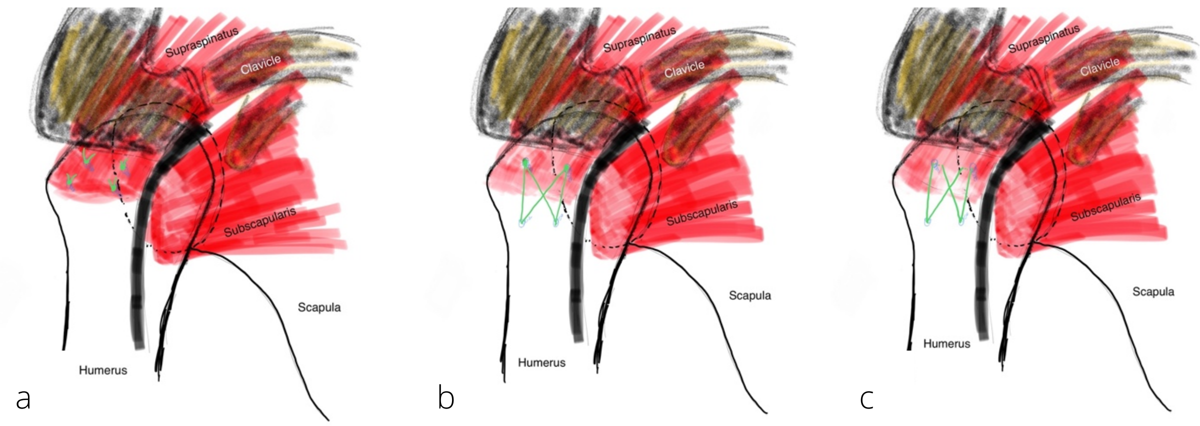


Figure 2.8 – a) Typical double row repair with four points of fixation in matress tied sutures to anchors; b) Tied suture-bridge repair, with two points of fixation in the medial row (tied matress) in which sutures cross over the tendon stump over to two knotless lateral row anchors.; c) knotless suture-bridge repair, with suture limbs from the same medial anchor passing in different locations in the tendon stump (double-hole passage) and then crossing over the tendon stump over to two knotless lateral row anchors.

While searching not only for higher contact area but also higher contact force, the transosseous equivalent (TOE) repair was introduced by Park[29,138] (posteriorly described as suture-bridge (SB) by Kim[139]) in which sutures from the medial row were spanned over the tendon to lateral anchors, bridging both rows and by that increasing compressive forces at the tendon bone footprint (Figure 2.7b). Both DR and TOE techniques demonstrated biomechanical superiority in terms of footprint coverage, tendon-bone contact pressure, gap formation and ultimate load to failure[23,138,140–142], and also lower retear rates and higher cost effectiveness[143] when compared with SR, even if, clinical benefit was only clear for tears larger than 3 cm[94,129,144–147]. TOE/SB repairs eventually superseded over regular DR, not only due to its stiffer and more robust mechanical features[138,148–151] but also because of its apparent superior clinical results[30,152,153] that provided an apparent correlation between higher initial fixation strength and better clinical outcomes.

The initially described TOE technique involved tying the medial row, which showed to contribute to an increase in the stability of the TBI at time 0[154], as using Mason-Allen stitches[155] and having multiple sutures passages in the tendon[156–162], but descriptions that associated type 2 retears to this more robust surgical technique technique[32,33,106] appeared, which motivated investigation on its causes and some technical shifts.

Tension overload in the medial row (quantified by Park[163] in 2019), overtensioning of the repair, large holes for suture passage, increased abrasion by suture material and overmedialization of suture passage were all associated with the increasing number of these more severe retears[32,106,164]. Bedeir[34] suggested the optimization of suture-bridge surgical technique in order to decrease stress concentration in medial row anchors and reduce the risk of tendon hypoperfusion, previously demonstrated to be influenced by the chosen surgical technique both in animal[107] and clinical reports[24,165]. Some authors even questioned the need of footprint restoration[166] in the face of the use of more modern SR repairs that demonstrated to avoid type 2 retears when compared to tied SB[167,168].

The surge of knotless repairs, in some cases with the use of suture tapes, which had demonstrated higher resistance to load, and higher tensile stiffness but less abrasive properties when compared to suture wires [169–175], was motivated by these concerns and in the complexity of the tied procedure itself.

Several works compared the use of tied versus knotless suture-bridge repairs and although the latter showed inferior biomechanical results in terms of ultimate load, cyclic loading, stiffness, gap formation, and contact area [23,149,154,160], they also demonstrated a lower retear rate [176,177], and most importantly, a smaller risk of more severe and difficult to manage, type 2 retears[32,34,106,164,178]. Despite the above-mentioned hypothesis, clear reasons for the risk reduction of type 2 tears in knotless repairs was not established. In fact, and as a confounding factor, one must understand that suture tapes appeared almost at the same time as knotless repairs and evaluation of the mechanical effect of suture materials at the TBI and in the MBR is still missing, as only 2 papers have been published comparing tapes and wires[25,26] at the tendon bone interface, and even so using suboptimal measurement tools and non-controlled suture tension at the lateral row, which has been shown to be a major influence in contact force, area and pressure at the TBI[27].

In summary, numerous techniques for SR, DR and TOE have been described and this heterogeneity makes adequate biomechanical and clinical comparisons difficult if not impossible[168], which can preclude adequate surgeon decision making.

Although proposals to abandon the complete prioritization of strength and mechanical durability of the repair construct toward an emphasis on optimizing both repair biomechanics and biology of tendon healing have been made[38,166], the ideal repair is yet to be defined as apparently several factors (patient and technical related) can interfere with the risk of tendon repair failures and no evidence exists that the results of rotator cuff repairs are getting consistently better in terms of retear rate[179], while the tendon bone interface and the tendon medial to the repair [32,35,38,106,180] keep being the weakest link of the repair.

The scarce or inexistent studies evaluating the mechanical effect at the TBI of the use of different clinically available materials, medial row anchor mechanisms, medial row tendon passage patterns and lateral row tension are a pitfall in surgeons decision-making process and motivated the investigation that redounded in this thesis.

Chapter III

Influence of medial row configuration in the force applied at the tendon bone junction during transosseous repair assembling

Summary

The biomechanical stability of transosseous equivalent repairs in rotator cuff tears is critical to ensure proper tendon healing and decrease retear risk. Although several studies showed the effect of different types of TOE configurations in the contact pressure and area at the TBI, none explored the pattern of progressive compressive force during the surgical procedure nor its implications in lateral row anchor stress and location site.

Hence, this study aims to evaluate the compressive force pattern along a TOE repair simulation. The force at the tendon-bone interface was evaluated using a force sensor in a surgical model representative of the humeral head and rotator cuff. The effect of using sliding suture limb sutures in the medial row was compared with non-sliding approaches along the four most representative surgical gestures, namely lateral anchors placement and suture limb tensioning.

Results demonstrated differences on the evolutive contact force pattern for the two approaches. Non-sliding configurations led to a force increase of approximately 83% of the final force after the tensioning of the first lateral anchor, while the sliding technique showed a more distributed force pattern, with the second lateral anchor contributing with more force to the final assembly (68%). These are clinically relevant results as they can help surgeons to take decisions that reduce the risk of anchor

dislodgement and repair failure by adjusting anchor location or lateral row tension according to the patient's bone quality.

Keywords: Transosseous Equivalent Repairs, Rotator Cuff Tear, Shoulder, Compressive Force, Biomechanics

Introduction

Initial biomechanical stability has been substantially described as an important feature to promote tendon bone healing in rotator cuff tears[94,96]. TOE repairs, initially described by Park *et al.*[29], are nowadays a gold standard in clinical practice and several variations have been explored by surgeons[138,149,160]. In particular, the differences between using a tied and knotless technique in the placement of the medial row anchors have been analyzed, both from a clinical and biomechanical point of view, with some evidence that, at time zero, tying the medial row provides superior biomechanical characteristics[149,154,161]. However, when the clinical outcomes were evaluated, results differed. In general, more robust repairs tended to originate more severe type 2 retears[106,177,178,181], with some authors suggesting that technical adaptations should be performed to overcome this phenomenon[34,182], namely slightly decreasing the mechanical stability and the force applied on the tendon, since this could be hampering its biological ability to heal, a fact that has been described in previous animal[107] and clinical reports[165,183].

TOE repairs have their assembly finished when the last lateral row anchor is locked, after sutures from the medial row have been tensioned. Park *et al*[27] demonstrated the relation between lateral row suture tensioning and footprint contact force, area and pressure. This force translation depends on the ability of the medial row to counteract lateral row anchors tension and by that creating a compressive force vector. Although the final contact force at the tendon-bone interface (TBI) has been described in the literature[21,27,160,182,184,185], the pattern of progressive load force, while building the assembly during the surgical procedure, has not. This issue could be of particular relevance for surgeons, because it can provide insights about the causes for anchor dislodgement, which has been a described intra and post-operative complication[18] (Figure 3.1).

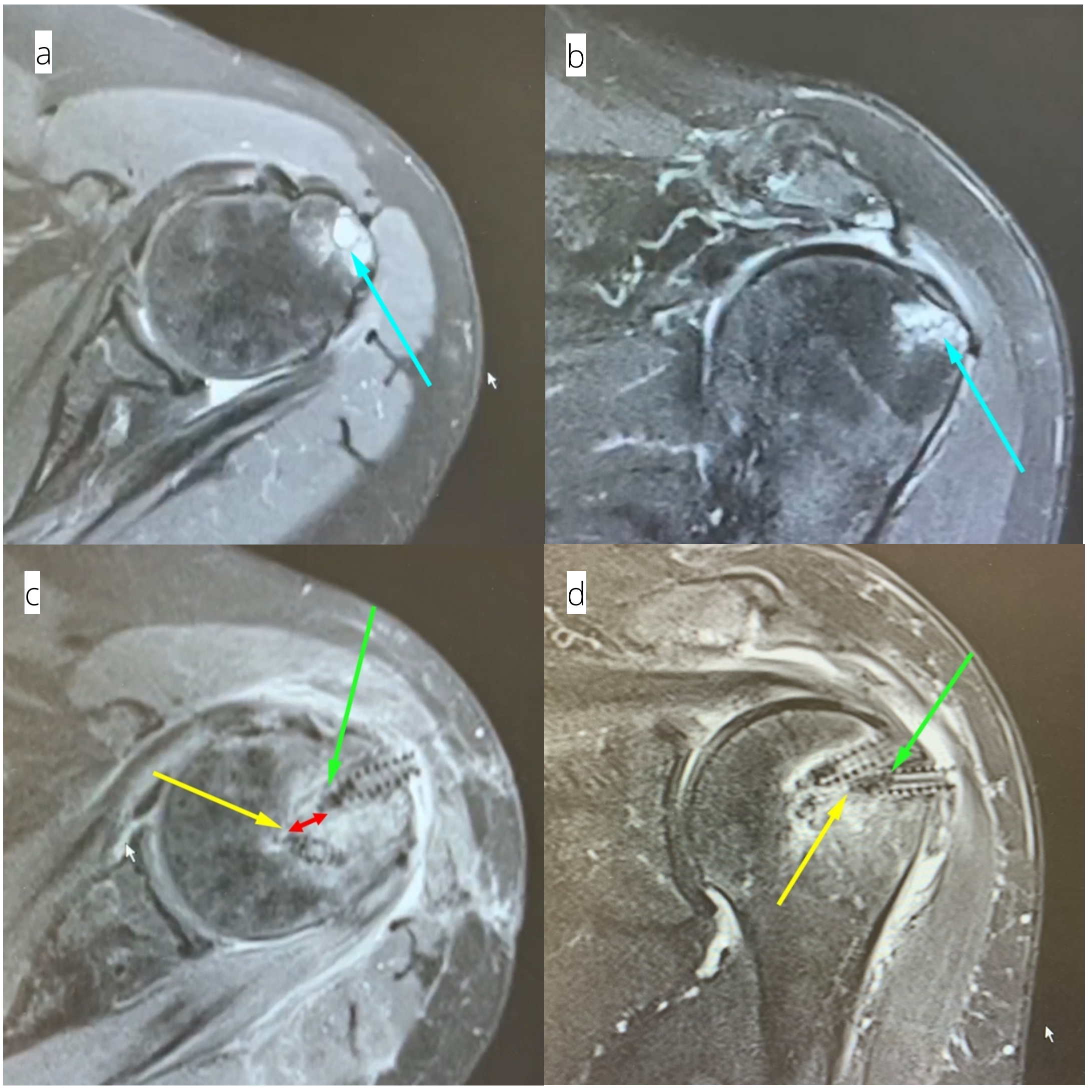


Figure 3.1 – Representation of a TOE repair with a postoperative anchor displacement: a) Bone Cyst in T2 axial in pre operative MRI; b) Bone Cyst in DP FS Coronal preoperative MRI; c) TOE repair with anchor dislodgement in axial T2 Coronal MRI; d) TOE repair with anchor dislodgement in coronal DP FS MRI; (Yellow and green arrows show respectively the postop anchor location and current position of the anchor, blue arrow the cyst location and red the displacement length).

In this Chapter, we aimed to evaluate the effect of sequential lateral row anchor placement and tensioning, according to the type of medial mechanism used in TOE repairs, namely tied/non-sliding mechanism (TNS) Vs. Knotless/sliding mechanism (KS).

Our hypothesis was that the different medial mechanisms cause different progressive contact force patterns at the TBI, and that individual lateral row anchors are submitted to a different stress during construct assembly.

Methods

Experimental setup

A) Measured parameters and used materials

The progressive force applied at the TBI in a mechanical model was measured while performing four key procedures of the TOE repair surgery, namely the placement of the two lateral row anchors and the tensioning of the lateral row sutures in those anchors.

Force evaluation was performed using a Force Sensing Resistor FSR® 402 (Interlink Electronics, Inc., Westlake Village, CA), connected to an Arduino Nano v3.0 board (Arduino LLC, Boston, MA). Following the manufacturer indications, a voltage divider circuit followed by a buffer amplification stage was used to measure the variation of the resistance in the FSR sensor. The circuit was designed in such a way that the linear region of the sensor would fit the range between 0 N and 60 N (0.354 MPa), and the maximum force was around 150 N (0.886 MPa). The sensor was calibrated using a universal testing machine – Instron 5544 (Instron, Norwood, MA) and the data posteriorly interpolated using MATLAB software (MathWorks, Inc., Natick, MA). A linear interpolation was used to describe the linear region and an 8^{th} degree polynomial curve was used to describe the exponential part.

To simulate the TBI, we used SAWBONES® SKU 1521-12-2 training model (SAWBONES®, Vashon, WA) that consists of a rigid foam mimicking the biomechanical properties of the humeral head. It also includes a neoprene band that simulates tendinous tissue, while not trying to replicate its mechanical characteristics.

B) Test groups

Two clinically common TOE repairs were performed: a KS and a TNS TOE repair that used two Helicoil® 5.5 mm anchors (Smith & Nephew, London, UK) loaded with one Ultratape® and one Ultrabraid® sutures for the medial row, and two 5.5mm Footprint Ultra PK® anchors (Smith & Nephew, London, UK) for the lateral row.

To study the biomechanical differences between the KS and TNS technique, a total of six different assemblies were performed: i) Sliding wires; ii) Sliding tapes; iii) Tied wires; Tied tapes, v) Tied wires with double thickness tendon; and vi) Tied tapes with double thickness tendon. The assemblies v) and vi) were considered in the present work to mimic a tendon with a different size (figure 3.2)

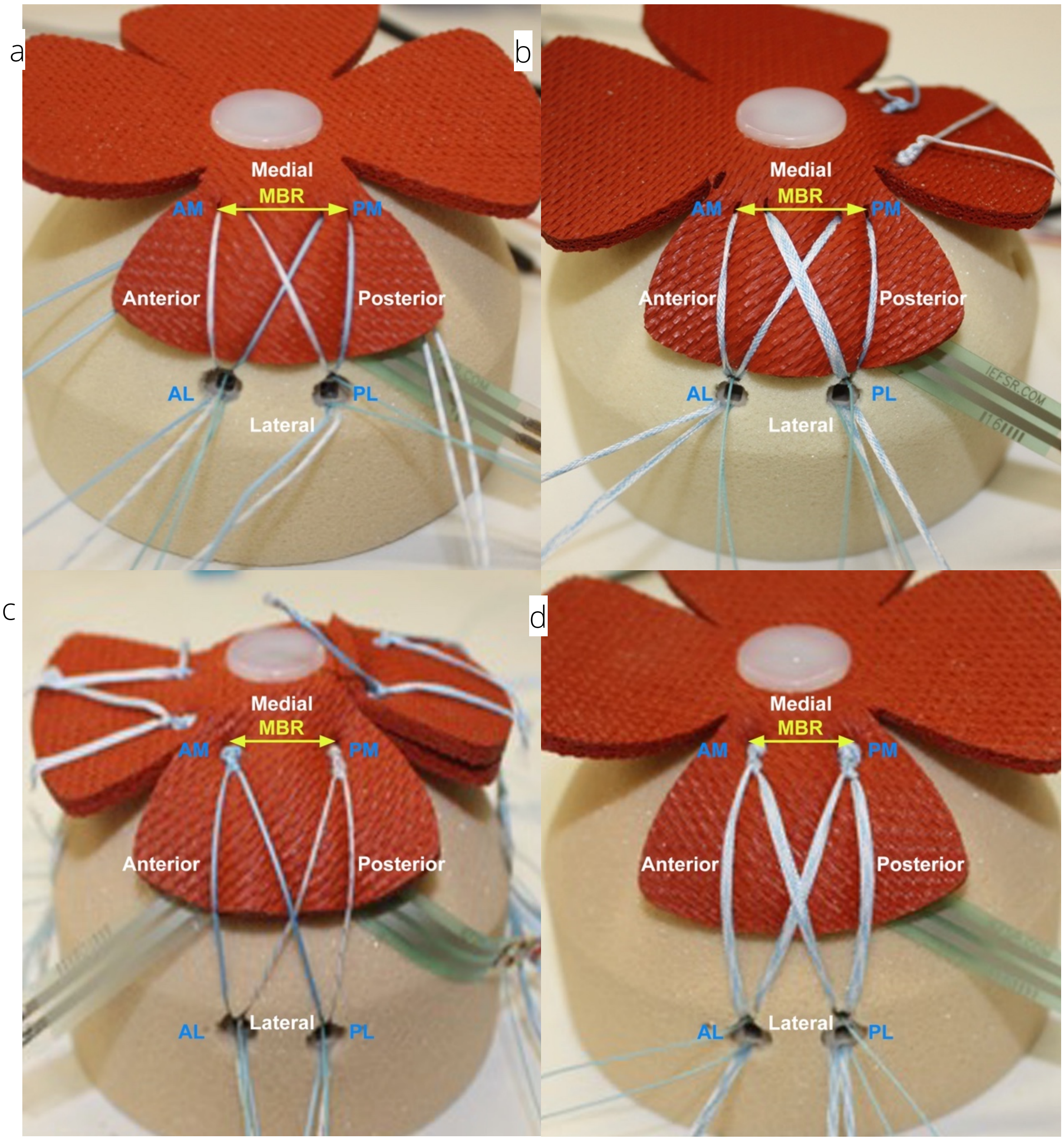


Figure 3.2 – Representation of the location of the anchors and wires/tapes for the 4 types of surgical techniques: a) Sliding wires; b) Sliding tapes; c) Tied Wires; d) Tied tapes (MBR: Medial Bearing Row – imaginary line connecting both medial anchors).

C) Mock surgical technique description

Each anchor was reproducibly placed in the same location in all trials, as well as all sutures, that were passed in the mock tendon using the same single-sized needle. The FSR was placed under the mock tendon and held at its base by the operator until the first lateral row anchor (anterolateral (AL)), which received the anterior suture limb of each medial anchor, was placed. Suture limbs were individually tensioned manually until maximum tension was perceived by the operator, which was a fellowship trained shoulder surgeon with over ten years of surgical experience, and the anchor was then locked. Sequentially, the posterolateral (PL) anchor was loaded with the posterior limbs of each medial row anchor, and then placed in the biomechanical model, followed by final suture tensioning and PL anchor locking.

D) Data Acquisition and Analysis

The operator was instructed to sequentially perform the four procedures, while the force evolution at TBI was being acquired. The timing at which each step was performed was registered to compare with force variation.

The acquisition and analysis of the force and pressure data was performed using the MATLAB software. The force differentials for each type of assembly were computed and compared between the different groups. Due to the lower number of trials, only descriptive statistics were used to evaluate the group differences.

Results

Despite the differences in the evolution of the force, the different techniques resulted in approximate values of force and pressure at TBI, achieving values that ranged from 51.0N (0.304MPa) to 62.2N (0.362MPa) (table 3.1)

Table 3.1 – Maximum force and pressure achieved at the tendon bone interface by each construct

Trial	Force (N)	Pressure (MPa)
Tied wires	51,4	0.304
Tied tapes	55,1	0.326
Sliding wires	55	0.326
Sliding tapes	56,7	0.335
Double tendon tied tapes	58,73	0.341
Double tendon tied wires	61,2	0.362

The analysis of the force variation along the four surgical steps enabled to distinguish two distinct patterns (Figures 3.3 a) and 3.3 b)).

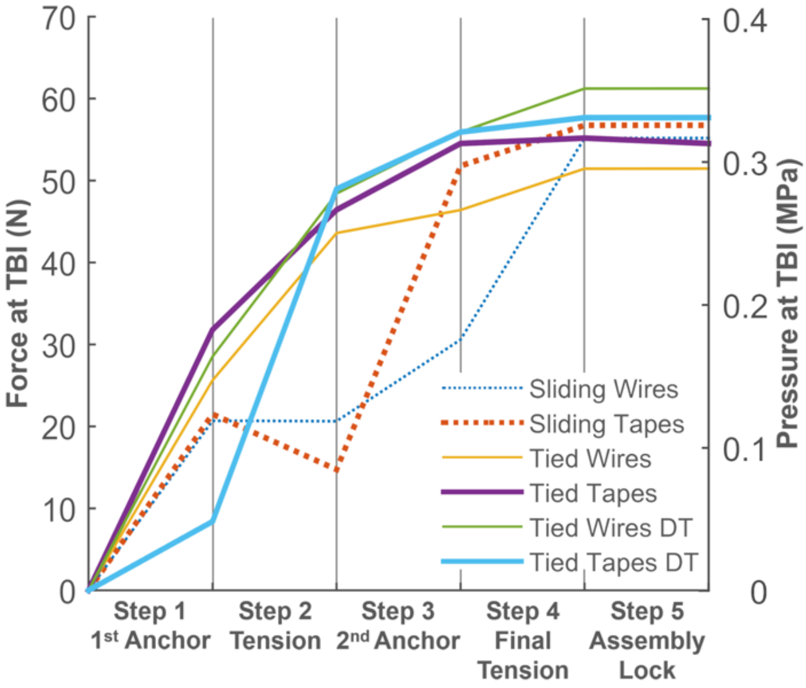


Figure 3.3a) – Force and pressure at TBI for each TOE repair procedure in each tested condition;

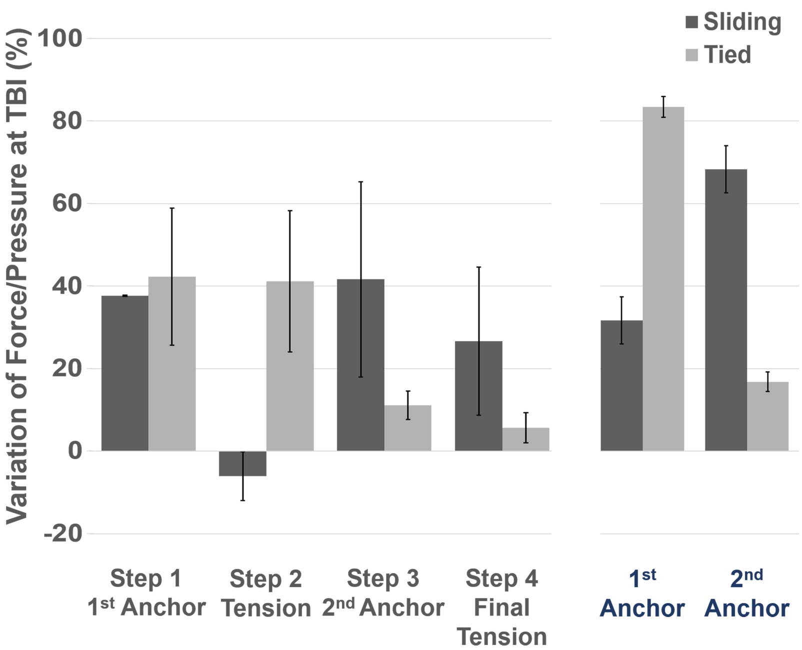


Figure 3.3b) - Force/pressure increment relative to the force/pressure measured in the final setting for both the sliding and tied group.

The first one, which is observed in the KS surgical technique, presents a more progressive behavior with the placement of the anchors and tensioning of the wires/tapes. In that group the force at the TBI increased when tension was applied to the suture limbs of the last placed lateral anchor in step 4, but that did not happen in step 2, where the translation of tension force to compressive force was prevented (Figures 3.3b) and 3.4).

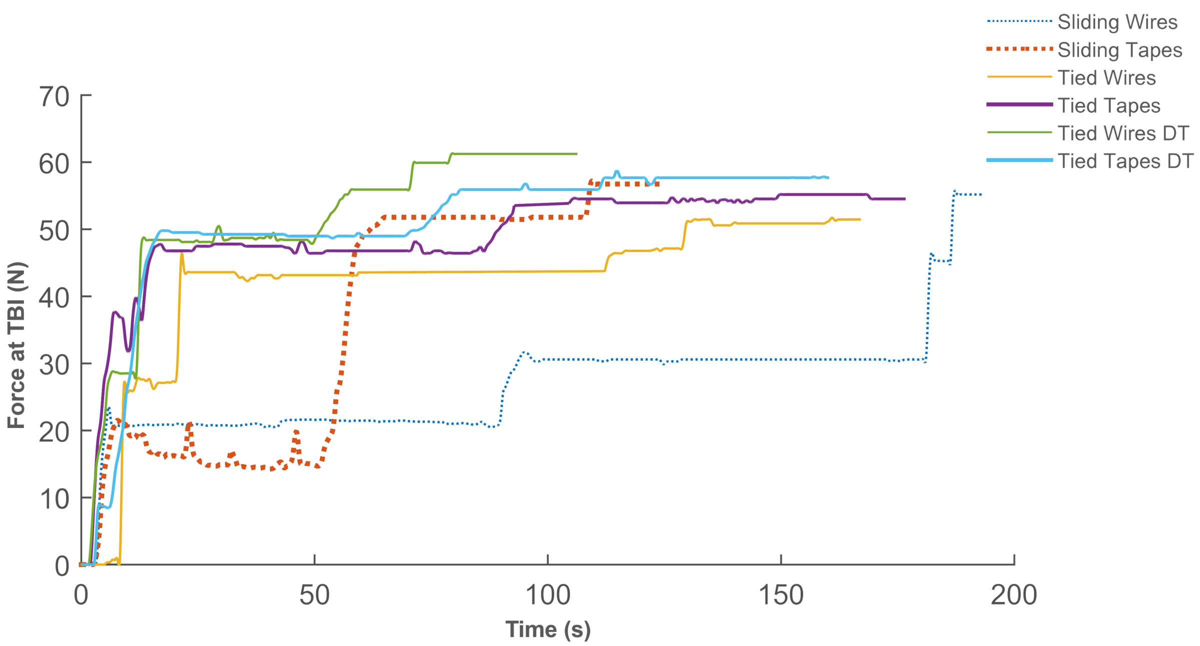


Figure 3.4 – Evolution of the Force at TBI along the TOE repair simulation

On its turn, the use of tied wires/tapes resulted in an increase of approximately 83% of the final force at the TBI when the first lateral anchor (AL) was placed. The placement of the second (PL) only lead to an increase of 11.1% of the final force. The final tensioning contributed barely with approximately 5.7% of the final force.

Discussion

According to our preliminary results, both techniques generate high values of compressive force at the TBI, in line with previous studies[182]. However, the force pattern along the execution of the surgical procedure is different between them as well as the amount of stress supported by each lateral anchor.

TNS repairs generate most of the force when the first lateral anchor is applied and tensioned, while the force in the KS setups is dependent on the last lateral row anchor placement and suture limbs tensioning. In the latter, by allowing medial sliding when the lateral tension is applied in the first anchor, only part of the tension was translated into a compressive force, which corresponds to the friction force limit between the suture and the medial anchor mechanism, which is higher if tapes are used. Moreover, after the anchors placement and tensioning of the limbs, the force at the TBI tends to decrease while the system is not locked. These two aspects can be seen in the force-time curves, in which after pulling the suture limbs, force only rises until a certain value, dropping afterwards when the friction force of the medial mechanism is overcome. This phenomenon of suture slacking is less evident in the locked group.

The high values of force obtained in this study may be beneficial from a biomechanics perspective, but some concerns exist regarding the increasing risk of more severe tears and anchors dislodgement[32,34,35,106]. Most importantly, our data corroborated

Park *et al*[27] findings that lateral tension increase results in higher contact forces, but in order to achieve this, a high stress is induced to the lateral anchors. According to our results, in KS repairs the region where the last anchor is placed sustains the most stress and induces the most compressive force at TBI. This aspect may have an important clinical repercussion regarding anchor location because if the last placed anchor displaces or is removed due to excessive pulling on the limbs, which has been described[17,18], the entire assembly can be compromised at that time due to slacking of all suture limbs. This will not occur in the TNS setups, as the medial suture limbs are independent from each other due to the locking mechanism.

Hence, in sliding TOE repairs, the second lateral anchor should be placed in an area of high bone density, preferably in the posterolateral region of the greater tuberosity [186,187] so that its immediate displacement is avoided and to counteract the higher pulling tension that needs to be applied to this anchor to promote an adequate tendon-bone contact. While this is also desirable in the case of locked medial anchors, that is not as critical, since the first lateral row anchor placed already contributed substantially to the compressive force. In this type of setups, careful attention should be given to the location of this anchor and not the last as in KS, also to avoid assembly failure during the procedure.

This report has some limitations, being the first the low number of trials. While not pretending to evaluate the numerical results of compression force, the progressive load pattern should be corroborated by a higher number of trials, which were not performed mainly due to the implants cost. Moreover, the lateral tension applied to the suture limbs was not controlled with a tensiometer, being its value dependent of the surgeon's experience. Nevertheless, the compressive force in the final setups was consistent between trials and with previous reported measures.

Our paper has also some strengths, namely it presents the first description of the progressive load pattern at the TBI with two different rotator cuff repair assemblies. In addition, by using a mechanical model with a reproducible setup, we were able to isolate the biological variables and provide a more robust understating of the results in similar settings. Finally. the same surgeon performed all the surgical procedures to increase the homogeneity between trials.

In conclusion, the present work offers a preliminary understanding on the effect of different TOE repair techniques in the evolution of the compressive forces on the TBI during the surgical procedure. It indicates that medial row tying imposes more stress on the bone region where the first anchor is placed. On its turn, medial sliding techniques lead to a more progressive compressive force pattern, being the variation more dependent on tension applied in the suture limbs in the last anchor, which can compromise the entire assembly in case of failure. These issues should be taken into consideration by the surgical team and considering these preliminary results they should anticipate fragile regions in the bone and avoid placing the most critical anchors that location or controlling the compressive force at the TBI and the stress produced suture tension in those anchors.

Chapter IV

Why are tapes better than wires in knotless rotator cuff repairs? An evaluation of force, pressure, and contact area in a tendon bone unit mechanical model

Summary

Purpose: Knotless repairs have demonstrated encouraging performance regarding retear rate reduction, but literature aiming at identifying the specific variables responsible for these results is scarce and conflictive.

The purpose of this paper was to evaluate the effect of the material (tape or wire suture) and medial tendon passage (single-hole or double-hole passage) on the contact force, pressure, and area at the tendon bone interface in order to identify the key factors responsible for this repair’s success.

Methods: A specific knotless transosseous equivalent cuff repair was simulated using 2 tape or suture wire loaded medial anchors and 2 lateral anchors, with controlled lateral suture limb tension. The repair was performed in a previously validated sawbones® mechanical model. Testing analyzed force, pressure, and area in a predetermined and constant size “repair box” using a Tekscan® sensor, as well as peak force and pressure, force applied by specific sutures and force variation along the repair box.

Results: Tapes generate lower contact force and pressure and double medial passage at the medial tendon is associated with higher contact area. Suture wires generate higher peak force and pressure on the repair and higher mean force in their tendon path and at the medial bearing row. Force values decrease from medial to lateral and from posterior to anterior independently of the material or medial passage.

Conclusion: Contrary to most biomechanical literature, suture tape use lowers the pressure and force applied at the tendon bone junction, while higher number of suture passage points medially increases the area of contact. These findings may explain the superior clinical results obtained with the use of suture tapes because its smaller compressive effect over the tendon may create a better perfusion environment healing while maintaining adequate biomechanical stability.

Keywords: Rotator, Cuff, Tape, Wire, Suture, Force, Pressure, Area.

Introduction

Rotator cuff tears are common and its surgical treatment is becoming increasingly frequent[1]. Repair integrity has been shown to correlate with clinical and strength improvement[25,31,96,128,131,188] but non-healing and retear rates still remain high[94,149].

Minimization of motion at the tendon footprint, its anatomical restoration, adequate initial fixation strength and low tension on the repaired tendon have demonstrated to be important factors for tendon healing[142,168]. Aiming to reach such benefits, new repair techniques such as trans-osseous equivalent (TOE) and suture-bridge (SB) repairs were developed[31,32,189] and tended to overcome double and single-row repairs in terms of footprint coverage, tendon-bone contact pressure, gap formation and ultimate load to failure[23,138,140–142].

Tying the medial row, using Mason-Allen stitches and having multiple sutures passages in the tendon were other technical approaches that showed to contribute to an increase in the stability of the TBI at time 0[137,158–160,162,190,191].

Stiffer and more stable constructs, such as the ones previously mentioned, helped to reduce retear rate[94,129,191–193], especially in large sized tears. However, a concerning shift towards type 2 retears[194] (medial to the repair site) occurred[31,32,34,164] as these are substantially more complex and difficult to treat.

In this context, the use of suture tapes instead of wires for knotless TOE repairs was proposed as they theoretically allowed a better distribution of compressive forces on the cuff, enhanced self-reinforcement[176,195] and showed a smaller abrasive effect than wires[169–171,174,196,197], but some authors found conflictive results[25,26]. Most probably, more stable constructs reduce retear rates, but those that occur are more serious and difficult to treat, therefore no clear gold standard technique has been established.

Evaluating TOE and SB repairs in detail and identifying particular factors that can contribute to maintain their mechanical benefits without inducing type 2 retears seems important. Such factors may include the type of material used for the repair, the number of sutures holes and sutures passed in the medial cuff and allowing suture sliding in that specific region.

Literature comparing tapes and suture wires used in the shoulder repair setting is scarce. Most of it is either focused on the mechanical properties of suture materials or explores its failure mechanism[169,170,174]. Very few studies evaluated the differences in terms of force, pressure, and contact area [25,26,180] and to our knowledge none compared truly homogenous groups.

The current study aims to compare tapes and suture wires in that setting, and to the best of our knowledge, for the first time, to evaluate the mechanical consequences (namely contact force, pressure, and area) at the TBI of passing one or two sutures from the medial anchors in a single hole at the medial cuff.

We hypothesized that under the same mechanical conditions, suture tapes increase force, pressure and contact area in the tendon bone junction and that suture limbs passed individually (double-hole passage group) in the medial cuff also increases contact area.

Methods

Experimental setup

a. Measured parameters and materials used

Total contact force, pressure, and area, as well as footprint loading pattern of 4-four different knotless TOE repairs were evaluated using a Tekscan® 5051 pressure mapping sensor (Tekscan Inc.®, Boston, MA). The sensor is constituted by a flexible array of 46x46 force sensors, presenting a spatial resolution of 62 sensors per cm^2. To avoid damaging its surface with punctures by sutures and needles, the sensor was folded to fit the area under the tendon model. The sensor was posteriorly calibrated using a Shimadzu® calibrator (Shimadzu Corporation©, Kyoto, Japan). In order to increase the resolution of the analysis, the maximum pressure was defined to 0.69 MPA, a value 39 times higher than the normal systolic blood pressure (<130/80 mmHg)[198]. Calibration settings were saved and reproduced in all the tests.

To ensure homogeneity between testing samples we chose to use SAWBONES® SKU 1521-12-2 training model (SAWBONES®, Vashon, WA) instead of cadaveric tissue to simulate tendon-bone interface. This type of model consists of a rigid foam that mimics the mechanical properties of the humeral head. This model also includes a neoprene foam that replaces the tendon, albeit not trying to replicate its mechanical characteristics. SAWBONES models have been previously used by the medical and biomechanics community to perform their training and research activities, being considered a valid tool for comparative analysis when the biological aspects are not relevant or when they induce experimental variability (e.g. analysis of orientation of the acetabular cup in osteotomy techniques, anchor fixation testing and rotator cuff repair evaluation) [189,199,200].

b. Test groups

Four different types of knotless TOE repairs were performed (4 test groups). The groups differed in the type of suture used (tape or suture wire) and in the type of medial passage (single-hole passage, in which both wire or tape limbs from the medial anchor were passed in a single hole (SP), or double-hole passage, in which each suture/tape limb from the medial anchors passed individually in the simulated tendon) (figure 4.1):

Group 1 - TSP (Tape/Single passage);

Group 2 - TDP (Tape/Double passage);

Group 3 - WSP (Wire/Single passage);

Group 4 - WDP (Wire/Double passage).

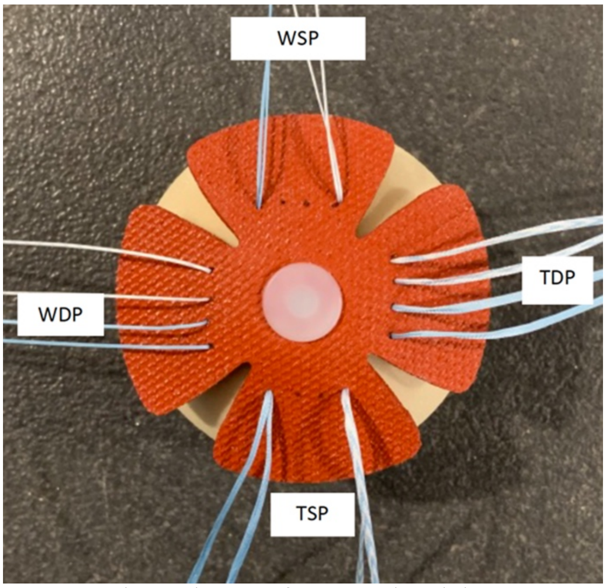


Figure 4.1 - Different types of repairs according to the type of suture and medial passage. TSP - Tape Single Passage; TDP -Tape Double Passage; WSP - Wire Single Passage; WDP - Wire Double Passage.

c. Mock surgical technique description

The mock repairs were performed using two Helicoil® 5.5 mm anchors (Smith & Nephew, London, UK) for the medial row, both either loaded with one Ultrabraid® suture (wire) or with one Ultratape® suture (tape). These anchors allow suture sliding in its eyelet. For the lateral row, two 5.5mm Footprint Ultra PK® anchors (Smith & Nephew, London, UK) were used. Five trials were repeated for each test group.

A flexible plastic template was used to ensure that all anchors and sutures were reproducibly placed (figure. 4.2a), b), c)). Tapes and wires were passed in the mock tendon, either in a single or double passage fashion, using for that purpose the same single-sized needle in all trials. The sensor was placed under the tendon model and held with finger pressure. One suture limb (tape or wire) of each medial anchor was pulled and placed in the anterolateral (AL) anchor. The AL was always placed before the posterolateral (PL) anchor, with the sutures slacked to avoid undetermined tensioning. Sutures limbs were then individually pulled and tensioned using 2 suture tensioners (EU000715 Suture Tensioner, Smith and Nephew, London, UK®) previously calibrated, which allow measurement of four different tension values: 25, 50, 75 and 100 N. The sutures were tensioned until sliding occurred. The anchor was then locked, and the tensioners released. To prevent backward sliding when pulling on the remaining sutures, a clamp was placed in the AL locked suture limbs.

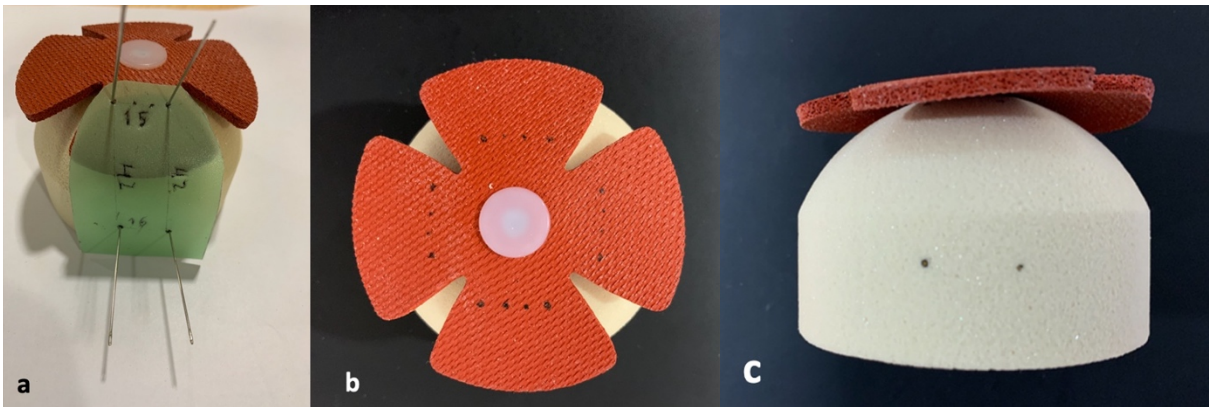


Figure 4.2 - a) Templating and medial and lateral anchor location marking with needles in the simulated bone; b) Suture passage location markings after templating; c) lateral anchor location marking after templating.

The PL anchor was then placed following the same sequential steps. In this case a tension of 75 N was applied in both suture limbs (figure 4.3).

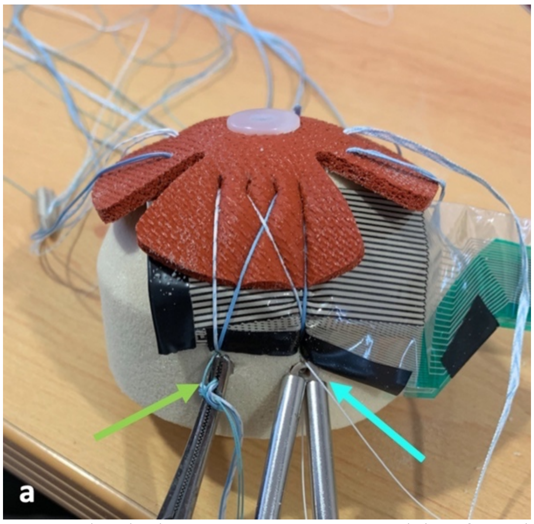


Figure 4.3 - Wire Double passage (WDP) trial with clamp protecting sutures sliding from the antero lateral anchor (see green arrow) and both suture tensioners pulling suture limbs placed in the postero lateral anchor (blue arrow) with the sensor beneath the tendon.

A specific 75 N of lateral row tension was used based in the previous reports of Park[27] showing that beyond 90N of lateral tension, tendon to bone contact area did not increase, so according to the type of tensioners used, 75N appeared the best option.

Sensor finger stabilization was released when sufficient contact to the mechanical model allowed sensor stable positioning. At that time a mapping of force, pressure, and area at the TBI was acquired using the I-Scan Lite software (Tekscan Inc.®, Boston, MA).

The assemblies were made by the same shoulder fellowship trained surgeon to increase trial homogeneity.

Data Analysis

The analysis of the contact force, pressure distribution and contact area were made on I-Scan Lite® software. The single cell saturation was set for 0.69MPa, the maximum pressure applied during the calibration procedure. A repair region of 729 mm^2 (27x27mm), i.e the "Repair Box" was defined on the acquisition software for each preparation for total force, pressure, and contact area comparison. An analysis of the maximum peak force and pressure for an area of sixteen (4x4) force cells (25.81mm^2) and its location was also performed.

Force distribution along the medio - lateral (ML) and posterior - anterior direction (PA) was measured to analyze its distribution pattern in the different repair types. The average force applied by the sutures in each sensor (force per sensor) was also evaluated in all trials (see figure 4.4). The four different sutures were defined according to their direction in the construct:

AM-AL – anteromedial (AM) to anterolateral suture;

AM-PL – anteromedial to posterolateral suture;

PM-AL – posteromedial (PM) to anterolateral suture;

PM-PL – posteromedial to posterolateral suture.

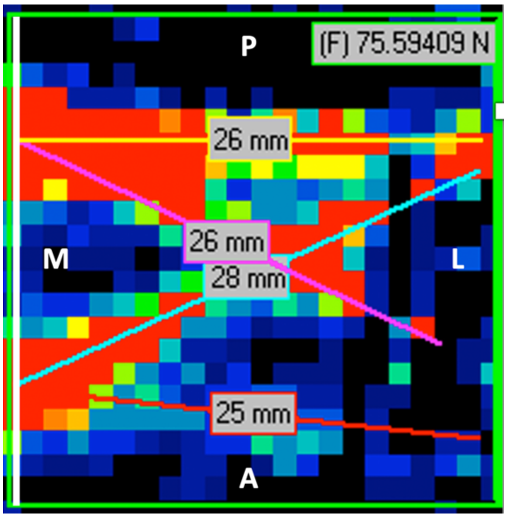


Figure 4.4 - Repair box (green square) example evaluated by I-scan lite software® (A – anterior; P- Posterior; M- medial; L - lateral). Red line represents the antero medial – antero lateral suture; Pink line represents the postero medial- antero lateral suture; Blue line represents the antero medial – postero lateral suture; Yellow line represents the postero medial – postero-lateral suture; White line (most medial line of the box) represents the antero medial- postero medial line.

An additional AM-PM (anteromedial to posteromedial) line was established to evaluate the contact force in the medial bearing row[32], which is the most medial area of apposition of the tendon to the bone. In this case, the value presented was not the average force / sensor, but the total force along that specific line as its size was constant for every essay.

The computation of the force values per sensor in the suture path and force variation in the "repair Box" region was performed using MATLAB software (The MathWorks, Inc., Natick, MA).

Statistical analysis

Descriptive statistics was applied for all variables and for variance group analysis. A Kruskal-Wallis test with a null hypothesis that group results were similar were used for comparison of the different types of repairs. A post-hoc analysis with Bonferroni correction for multiple tests was also applied to infer the existence of differences between the four individual groups. For analysis of differences between tapes and suture wires and between single and double medial passage, a Mann-Whitney test was applied. The statistical analysis was performed on IBM SPSS Statistics v26 software (IBM, Armonk, NY). A level of significance of 5% was used for all the statistical analyses.

Results

Total contact force, area, and pressure in the repair box

Table 4.1 summarizes results regarding total contact force, pressure, and contact area in the “Repair Box”. While WSP presents the highest total contact force and pressure, TSP and TDP showed the lowest total contact force and pressure respectively. WDP showed the highest total contact area of all groups, at values significantly different from the lowest value, obtained by the TSP group. Figures 4.5, 4.6 and 4.7 show the pairwise comparisons between all groups.

Table 4.1 - Descriptive Statistics (Total contact force, area, and pressure)

		TSP	TDP	WSP	WDP
Force (N)	**Mean**	54.38	56.04	76.49	72.44
	St Dev	5.71	5.28	8.36	3.69
Area (mm^2)	**Mean**	466.80	511.40	495.40	527.40
	St Dev	14.31	21.65	31.01	23.77
Pressure (MPa)	**Mean**	.1165	.1094	.1542	.1375
	St Dev	.01152	.00711	.01105	.00762

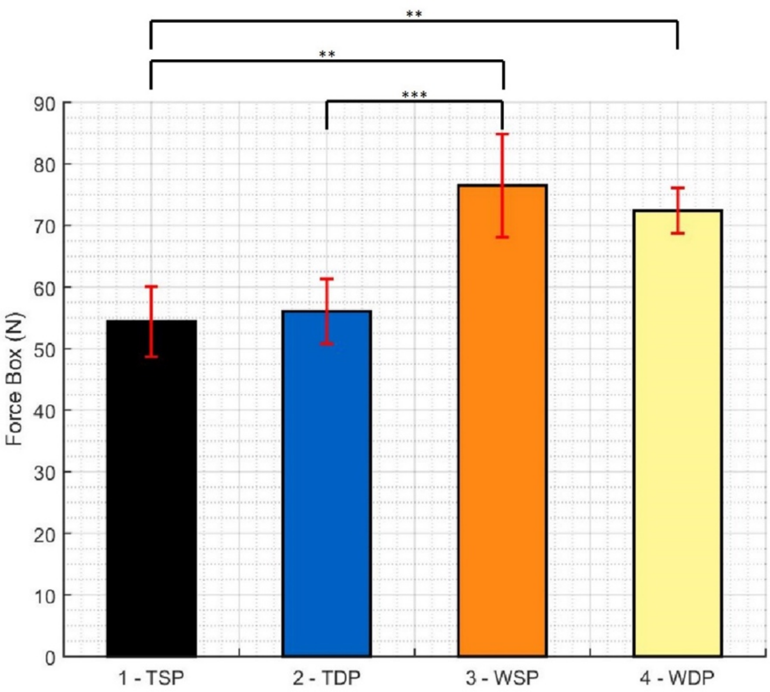


Figure 4.5 – Pairwise comparison of all groups regarding total contact force (* p<0.01, ** p<0.005, *** p<0.001)

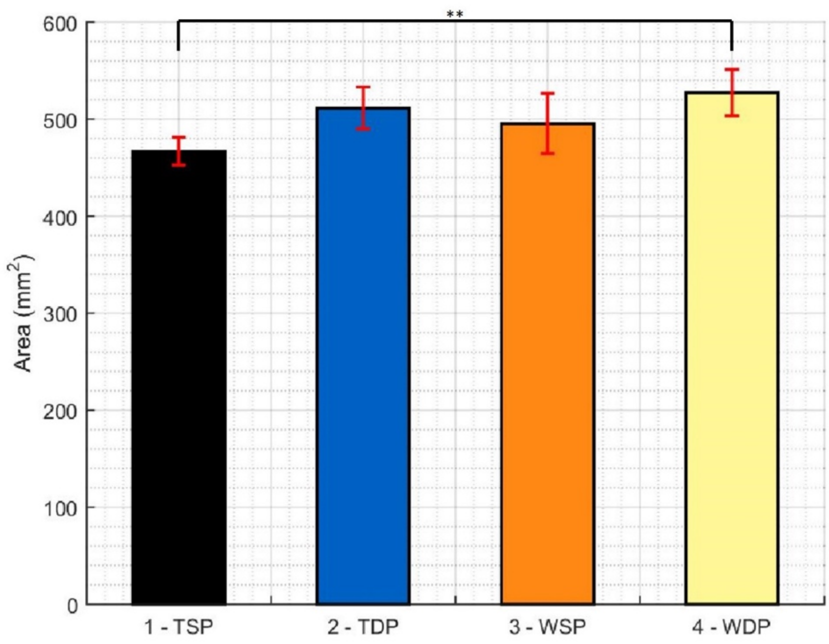


Figure 4.6 – Pairwise comparison of all groups regarding total contact area (* p<0.01, ** p<0.005, *** p<0.001)

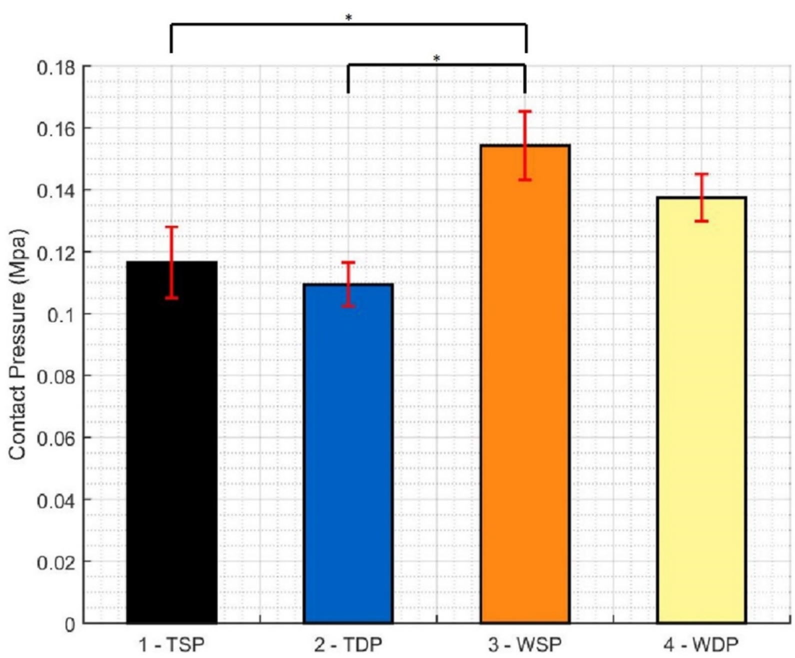


Figure 4.7 – Pairwise comparison of all groups regarding total contact pressure (* p<0.01, ** p<0.005, *** p<0.001)

When comparing single-hole and double-hole passage groups, independent of the material used, significant differences were only found in total contact area, with higher values for DP (p=0.011).

When comparing tape and wire repairs disregarding the type of medial passage, wire repairs showed significant higher total contact force and pressure (p<0.001 in both), but no significant differences between contact area values.

Peak force and pressure location and values.

Peak force was located at the posteromedial quadrant in 70% of cases regardless of the groups. The highest value was again found in the WSP and the lowest in the TDP group (figure 4.8).

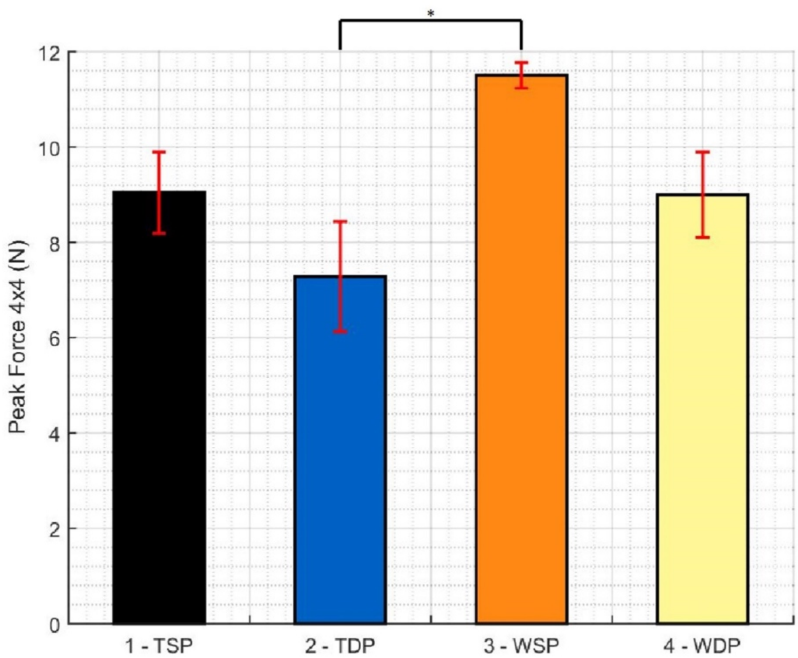


Figure 4.8 – Pairwise comparison of all groups regarding the maximum peak force in 4x4 cells area (25.81mm^2) (* p<0.01, ** p<0.005, *** p<0.001)

Comparing tapes and wires independently of the type of medial passage, significant higher values of peak force (p=0.007) and pressure (p=0.009) occurred in the wire group. Higher values of peak force (p=0.003) and peak pressure (p=0.004) were also found in the single passage independent of the type of suture used.

Force developed by sutures

Higher force was applied by the sutures locked in the PL anchor, independently of the type of material or medial passage (table 4.2).

Table 4.2 - Descriptive statistics - Mean Force per sensor applied by each suture in each different group

		TSP	TDP	WSP	WDP
Mean Force (N)	PM-PL Suture	.3731	.3529	.5710	.5558
	PM-AL Suture	.2826	.1931	.3815	.3496
	AM-PL Suture	. 2965	.4283	.4637	.4959
	AM AL Suture	.2111	.1930	.2605	.2378
	AM-PM line	5.530	5.191	6.871	7.773

When comparing single and double passage repairs no differences were found, but when comparing tapes and wires, the latter generated significant higher force per sensor in all, but in the AM-AL suture (p<0.001 in PM-PL and AM-PM; p=0.002 in PM-AL and p=0.019 AM-PL).

When comparing individual groups, significant statistical differences were only found for the PM-AL suture (table 4.3) and for the medial bearing row (table 4.4). Again, the highest force was applied by the WSP group, except in the medial region in which WDP surpassed. TDP generated the lowest forces (see table 4.2).

Table 4.3 - Pairwise comparisons of all groups for mean contact force per sensor applied in the PM-AL suture

	Test Statistic	Std. Error	Std. Test Statistic	Sig.	Adj. Sig.[a]
TDP-TSP	-6.200	3.742	-1.657	.098	.585
TDP-WDP	-10.000	3.742	-2.673	.008	.045
TDP-WSP	-12.200	3.742	-3.261	.001	.007
TSP-WDP	-3.800	3.742	-1.016	.310	1.000
TSP-WSP	-6.000	3.742	-1.604	.109	.653
WDP-WSP	-2.200	3.742	-.588	.557	1.000

Table 4.4 - Pairwise comparisons of all groups for mean contact force per sensor applied by AM-PM line (medial bearing row)

	Test Statistic	Std. Error	Std. Test Statistic	Sig.	Adj. Sig.[a]
TDP-TSP	-2.400	3.742	-.641	.521	1.000
TDP-WSP	-8.200	3.742	-2.192	.028	.170
TDP-WDP	-13.000	3.742	-3.474	.001	.003
TSP-WSP	-5.800	3.742	-1.550	.121	.727
TSP-WDP	-10.600	3.742	-2.833	.005	.028
WSP-WDP	4.800	3.742	1.283	.200	1.000

Variation of force in the repair box

Figure 4.9 demonstrates that the force applied in the tendon is maximum in the most medial area of the repair, with higher values for the wire groups, and that it progressively decreases in intensity along the suture path, from medial to lateral.

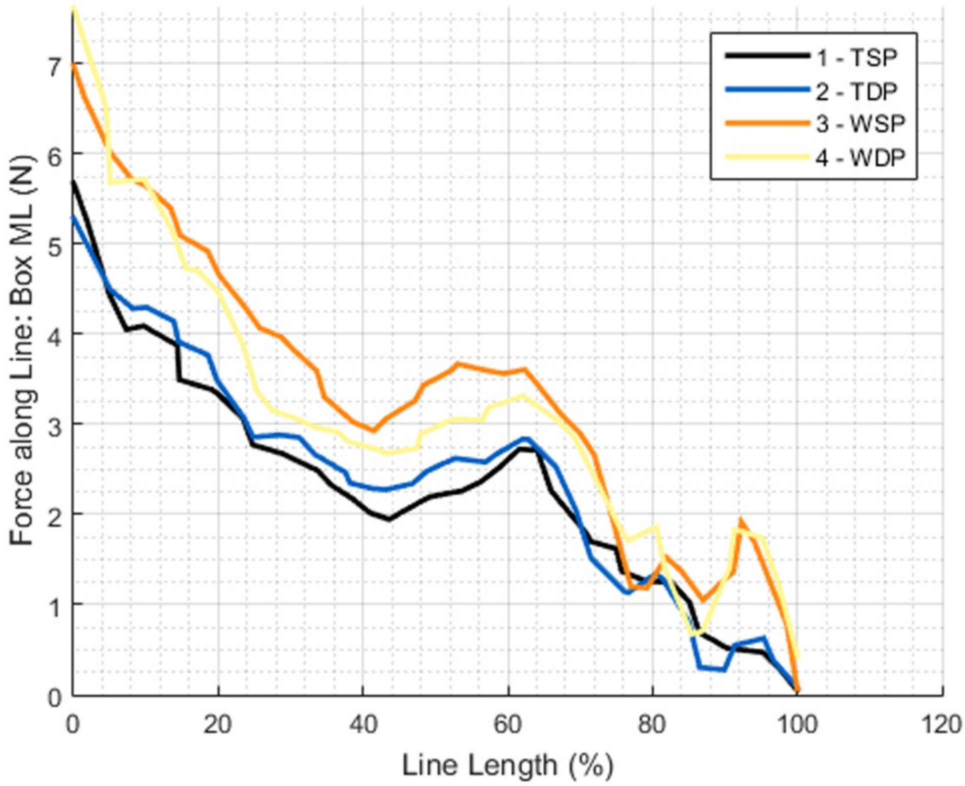


Figure 4.9 – Force variation in the repair box (medial to lateral)

Results also clearly indicate that the posterior half of the repair had the highest contact forces in every test, and again, results were higher for the wire groups (Figure 4.10).

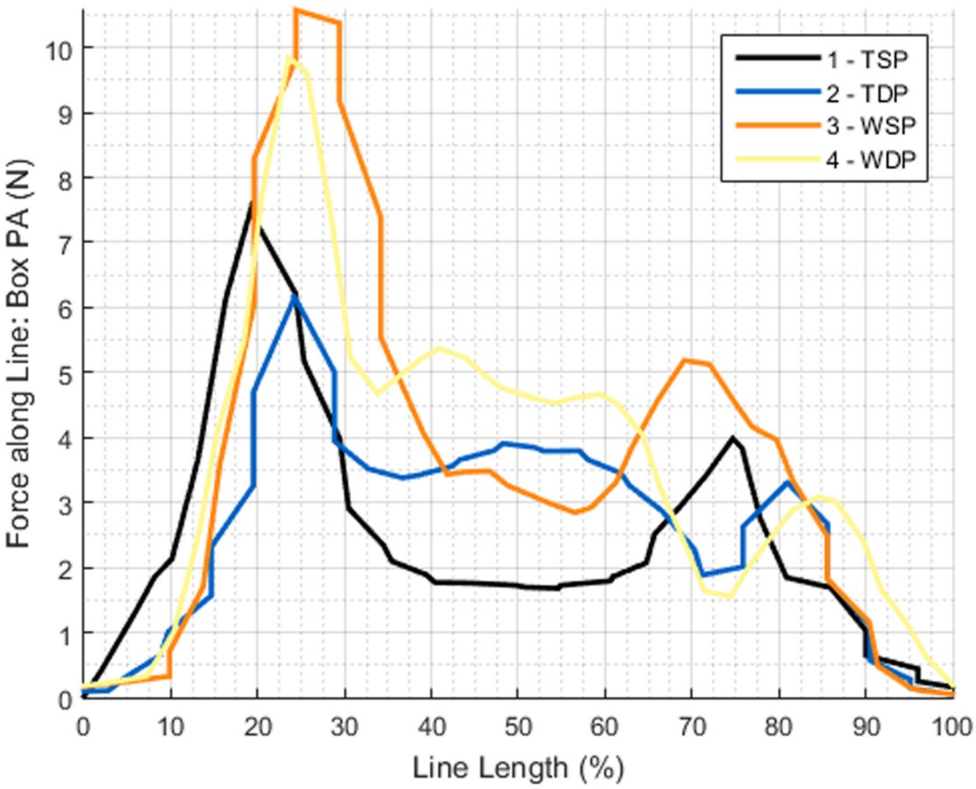


Figure 4.10 – Force variation in the repair box (Posterior to anterior)

Discussion

A compromise between adequate mechanical stabilization and good biological local environment of the tissues is essential for tendon healing[38] but literature is scarce and unclear regarding the influence of stiffer suture configurations and materials at the TBI. This paper aimed to evaluate the influence of some surgical options that interfere not only with the mechanical stability of the repair but also with the healing ability of the tissues, so that surgeons can better understand the consequences of their individual choices.

The initial hypothesis was partially refused because, indeed, total contact force and total contact pressure applied are higher when suture wires rather than suture tapes are used, meaning that the compressive effect at the TBI is smaller with tapes. This differs from the results obtained by Huntington[26] and Liu[25] and there may be several reasons for this:

a) We used electronic sensor mapping technology instead of pressure sensitive film[26] or pressure sensitive probes[25]. Other sensors have been previously used in similar settings[22,138,189,195,201] but the one we used has higher resolution and allows a more precise mapping, especially if compared to the methods used by Liu[25] and Huntington[26].
b) Huntington[26] performed SB repairs with medial anchors that did not allow suture slide. According to our data, non-sliding sutures (AM-PL and PM-PL sutures limbs, after AL anchor locking) generate higher contact forces than sutures tensioned at the AL anchor that slid along the AM and PM anchors, possibly explaining the higher values for pressure they obtained, which can be very concerning from a perfusion / tendon vascularization point of view[24,35].
c) Liu[25] and Huntington[26] used animal models but despite the large sample dimension, specimen variability induces mechanical biases that can obscure

final results. This is an important factor to have into account if only mechanical data is being evaluated.

d) Finally, some key experimental variables were not addressed in these reports. As demonstrated by other authors[27,151,185], the amount of force applied for lateral suture tensioning has implications in the force and footprint contact pressure, which means that in order to ensure trial homogeneity and study reproducibility, suture tension control in the lateral row is mandatory and to our best knowledge this was not performed.

Despite the differences shown above regarding total contact force and pressure, suture tapes and wires did not generate significant different total contact area, which is in accordance with Huntington´s paper[26]. In summary, rhis means that under the same bone and tendon conditions, when controlled lateral suture tension is used, tapes compared with suture wires, generate similar tendon-bone contact area and lower contact force and pressure. This theoretical mechanical disadvantage can reveal itself beneficial and explain the superior clinical results obtained by slightly less stable and stiff repairs[154,160,202177], when compared to those that the literature demonstrated to be the most biomechanically stable ones, namely those with smaller gap formation[149,154], higher contact pressure (especially in the medial bearing row)[195,202], contact area [195,202202], stiffness[154] and resistance to failure[149,160].

This work also confirmed that, not only does the total area of contact increase with the use of individually passed sutures limbs (double-hole passage) in the medial cuff, but also this technical variation tendentially decreases the total force and total pressure applied at the TBI. When compared to single-hole, double-hole passage led to a total contact force decrease of 3,1% if tapes were used and 5,6% if wires were chosen. Also, total contact pressure decreased from 6,5% in tapes group and 12,2% in case of the wires group. This data seems especially relevant because the distance between the most anterior and posterior passage sites was similar in single and double passage repairs, so even if the tendon repair box is similar, higher number of suture passages points medially, increases the total contact area between tendon and bone. This technical variation imposes a minor decrease in total contact force and pressure, eventually favoring tendon perfusion and tendon healing, while allowing better tension stress distribution over the tendon once healing has occurred.

It was also demonstrated that the use of double-hole passage lowered peak force and pressure at the most compressed areas, which can also lower the risk of biological failure in those specific locations[107].

To our best knowledge this is the first report demonstrating the influence of multiple passage points in total contact force, total contact pressure, total contact area and peak force and pressure at the TBI.

The type of knotless repair tested also provides insight on the mechanical consequences of medial anchors with locked sutures versus medial anchors with sliding sutures, especially regarding contact force pattern.

In this experimental setup, both medial anchors allowed suture sliding, so when the first lateral anchor was placed (AL) and one suture limb of each medial anchors pulled (AM-AL and PM-AL sutures), sliding occurred naturally in the medial anchor and at lower tension values for wires when compared to tapes (wires slid at an interval between 25 and 50N and tapes slid between 50-75N, but no exact value was obtained because this type of tensioner does not allow sequential numeric tension measurement), and this data was in line with Leishman´s[171] report.

After AL anchor locking, suture limb pulling on the PL anchor (AM-PL and PM-PL sutures) did not show suture sliding, so consistent and reproducible 75N lateral suture tensioning was possible, with a clearly higher compressive effect at the posterior portion of the repair box. This region of the repair box was stabilized by the non-sliding AM-PL and PM-PL sutures, while the anterior area of the mock tendon got stabilized by the AM-AL and PM-AL sutures (Figure 4.10).

This corroborates the findings of Park[27] that stated the importance of controlling lateral tension, not only in biomechanical studies but also in the clinical setting as higher lateral tension translates into greater force application at the tendon, moreover if tied TOE repairs or full medial locked knotless TOE repairs are chosen.

This increased continuous lateral tension in non-sliding sutures can promote growing and potentially supraphysiological compression force at the TBI with detrimental mechanical and tendon perfusion consequences[35], especially if wires and single medial suture passage are used.

In fact, most of this work´s findings help to support some of other author hypothesis for potential causes of type 2 retears[31,32], which include tension overload of the suture-tendon interface at the medial bearing row, overtensioning of the medial repair, overmedialization of suture passage, creation of large holes in the rotator cuff (by instruments or eventually by a larger number of sutures in the same hole)[133], increased abrasion induced by high resistance sutures[169] and suture induced tendon necrosis[35,107].

The evaluation of the mean force applied at the path of sutures and in the medial row also confirmed the previous global overview, in which wires create higher contact force especially in the posterior sutures and in the medial bearing row. Also, as expected, contact force in the repair box tends to be higher in the most medial region and lowers progressively as we approach the lateral side of the repair.

Both tape and wire results demonstrated higher medial bearing row contact force and pressure meaning that the medial row is the area subjected to the highest tensional stress.

Considering McCarron[36] demonstration that even if healed to the bone, all tendons tend to retract after surgical repair, taking into account the obtained data, Trantalis´s[32] hypothesis seems plausible because excessive force applied in the medial bearing row not only creates a local area of stress concentration as described by Park[195], but also stress shields the lateral tendon from self-reinforcement and normal post repair lengthening. Local tendon hypoperfusion due to the force exerted by sutures diminishes healing capacity[107] can aggravate this scenario and favor type 2 retears, while according to this investigation, wire use and excessive tension in the lateral sutures[185] may assist in this "perfect storm".

This work has some strong features that should be considered such as the use of a mechanical model that, despite precluding immediate clinical translation allows for a more reproducible evaluation of mechanical data, without the biological variability induced by biological specimens.

Also, the use of a template and a single sized needle for suture passage contributed to a reproducible application of anchors and sutures, and trial homogeneity.

The higher resolution of this specific sensor when compared to others previously reported [22,138,189,195,201] is also a strong feature that may have allowed a more reliable measurement of force and pressure mapping, without the need for sensor penetration/damage to prevent dislocation, following manufacturer instructions.

At last, and to our best knowledge, this is the first report that not only compares suture tapes and wires in a simulated rotator cuff repair using controlled lateral tension but also evaluates the influence of medial suture passage pattern in contact force, pressure, and area

There are also some methodological limitations that should be highlighted. First, due to its dimension, this specific sensor had to be folded to fit the mock repair, but the sensors´ integrity was respected, and this was confirmed upon calibration.

It is also impossible to assure that similar results could be achieved if the sensor had been perfectly adjusted to the mechanical model, but the calibration performed before the experimental trials and previous validation studies performed in similar sensors[201] validates the data obtained.

Also, the low number of essays per group can limit the robustness of our results. This was due to the costs involved, especially anchor wise. Despite this, several other reports have used an approximated number of trials while using animal or cadaver models, which have a higher variability in terms of bone and tendon mechanical properties[25,151,180,189,196,203].

Another specific limitation is related to suture passage path location in the sensor, which was inferred considering sensor and software obtained data and also the distance between suture holes and the force pattern in the repair box. Although subjected to variability, the same person performed all the observations and measurements.

At last, the specific tapes used in this paper do not have a core so these can behave like a wire in some assemblies (see figure 4.11), something that also happens in the clinical setting but in this case, it can create a confounding factor when evaluating tape results.

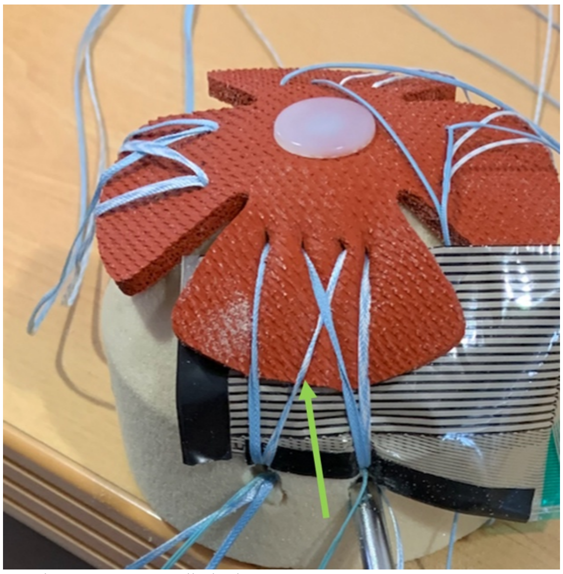


Figure 4.11 - Suture tape in a TDP trial macroscopically behaving as a wire (see PM-AL suture - green arrow)

In Summary, the use of tapes decreases total contact force, total contact pressure, peak force, and pressure at the tendon-bone interface, and double-hole passage also decreases those parameters, while increasing contact area. It was also demonstrated that the medial bearing row is the most stress area of the repair and that the last placed anchor in this specific type of repair supports most of the load as its responsible for most of the applied force at the TBI.

These results offer a better understanding of the mechanical interactions at the tendon-bone interface when using different suture materials and repair configurations and open the door for some technical adaptations that can improve surgical outcomes.

Chapter V

Biomechanical consequences of different medial row configurations, anchor mechanisms and lateral row tension at the tendon bone junction of the rotator cuff

Summary

Little is known about the direct influence of different technical options at the rotator cuff tendon-bone interface and at the medial row, regarding contact force, area, and pressure, hence, we evaluated the biomechanical repercussions of different medial row mechanisms and configurations in that setting.

Three different types of knotless suture-bridge repairs were tested in a mechanical model, with 2 different values used for lateral row tension. We compared locked versus nonlocked medial anchors and again single versus double-hole suture passage in the medial cuff but in the context of locked/non-sliding medial anchor mechanism. Contact force, area, pressure, peak force, and medial row applied force were evaluated at the simulated TBI.

When compared to locked anchors, medial row sliding configurations generate lower values for all the above-mentioned parameters, being also more susceptible to variations in lateral row tension.

The use of double-hole suture passage in the medial cuff generates consistently higher contact area and lower values of the remaining parameters if higher lateral row tension is used, although force distribution at the TBI is less homogeneous, when compared to single-hole suture passage.

Increasing lateral row tension generated higher values of all the studied parameters regardless of the repair technique tested.

Medial row mechanism, suture configuration and lateral row tension interfere with the mechanical forces sustained by TBI.

These results can help surgeons choose the right technique considering its biomechanical effect at the TBI.

Keywords: Rotator cuff; medial row; contact force; pressure; area

Introduction

Rotator cuff tears are common injuries[1] and several factors have been shown to interfere with tendon-bone healing in this scenario. While those related with the injury or the patient[76,96] are difficult to manage by the surgeon, those related to the surgical technique are its direct responsibility, so learning the mechanical implications of their choices at the TBI is of key importance when aiming for better clinical outcomes and reduction of the retear risk[31,32].

Some clinical and biomechanical superiority has been shown for stiffer and more robust repairs such as the suture-bridge and double row constructs[23,94,129,138,142,191,193]. On the other hand, stress overload in the medial row, overtensioning of the repair, large holes for suture passage, increased abrasion by suture material and overmedialization of suture passage have been associated with an increased proportion of type 2 retears, which are substantially more difficult to revise[31,32,34,164] as they occur immediately medial to the previous repair site. In a recent review[34], the optimization of suture-bridge surgical technique was recommended to decrease stress concentration in medial row anchors and to reduce the risk of tendon hypoperfusion. Overmedialization[204], abrasion of the suture material[169,170,205,206] and repair overtensioning[163,207] have all been investigated.

To our knowledge, only one author[182] has evaluated the mechanical effect of different medial suture passage configurations at the medial bearing row. Moreover, no study to date has compared the biomechanical implications of the use of medially locked anchors versus sliding anchors in knotless suture-bridge repairs at the TBI and at the MBR.

Hence, this study aims the evaluation of different mechanical parameters, namely contact force, pressure and area, peak force and MBR force in different suture configurations using for that purpose a rotator cuff mechanical model.

We hypothesized that under identical mechanical conditions, locked medial anchors increase the contact force, area, and pressure at the TBI and the force applied in the MBR, when compared to sliding medial anchors and that passing suture limbs individually in the medial cuff (double-hole suture passage) would increase TBI contact area without increasing contact force or pressure, while decreasing the MBR contact force, when compared to conjoined passing in the same pilot hole (single-hole suture passage). We also hypothesized that increasing tension in the sutures applied in the lateral row would increase all the above-mentioned parameters.

Methods

Experimental setup

a. Measured parameters and used materials

This was an experimental biomechanical study in which total contact force, pressure and area, peak pressure and total force at the MBR were measured using a Tekscan® 5051 pressure mapping sensor (Tekscan Inc.®, Boston, MA) for three different knotless transosseous equivalent repairs (TOE)[29]. The sensor has a flexible array of 46x46 force sensors, presenting a spatial resolution of 62 sensors per cm^2. To avoid damaging its surface with punctures by sutures and needles, while following the manufacturers recommendation, the sensor was folded to fit the area under the tendon model. The sensor maximum pressure was defined to 0.69 MPA, a value 39 times higher than the normal systolic blood pressure[198] and its calibration was performed using a Shimadzu® calibrator (Shimadzu Corporation©, Kyoto, Japan).

To simulate the TBI, we used SAWBONES® SKU 1521-12-2 training model (SAWBONES®, Vashon, WA) that consists of a rigid foam that mimics the mechanical properties of the humeral head. It also includes a neoprene band than simulates tendinous tissue, while not trying to replicate its mechanical characteristics.

b. Test groups

Three different types of knotless TOE repairs were explored in this work. The techniques were divided according to the type of anchor mechanism adopted for the medial row and the medial passage configuration.

In the first division, the effect of tape sliding in the medial anchors (sliding anchors) was compared with the case in which the tape sliding is blocked (locked anchors). In the second one, the differences between using a single-hole passage and a double-hole passage configuration were analyzed, i.e., the effect of passing both tape limbs in a single hole was compared with passing each tape limb individually in the tendon model (figure 5.1). Hence, three groups were considered: Group 1 – Double passage and locked anchor (DP); Group 2 – Double passage and sliding anchor (SLDP) and Group 3 – Single passage and locked anchor (SP). All the above-described groups were submitted to 2 different values of suture tension in lateral row as described below.

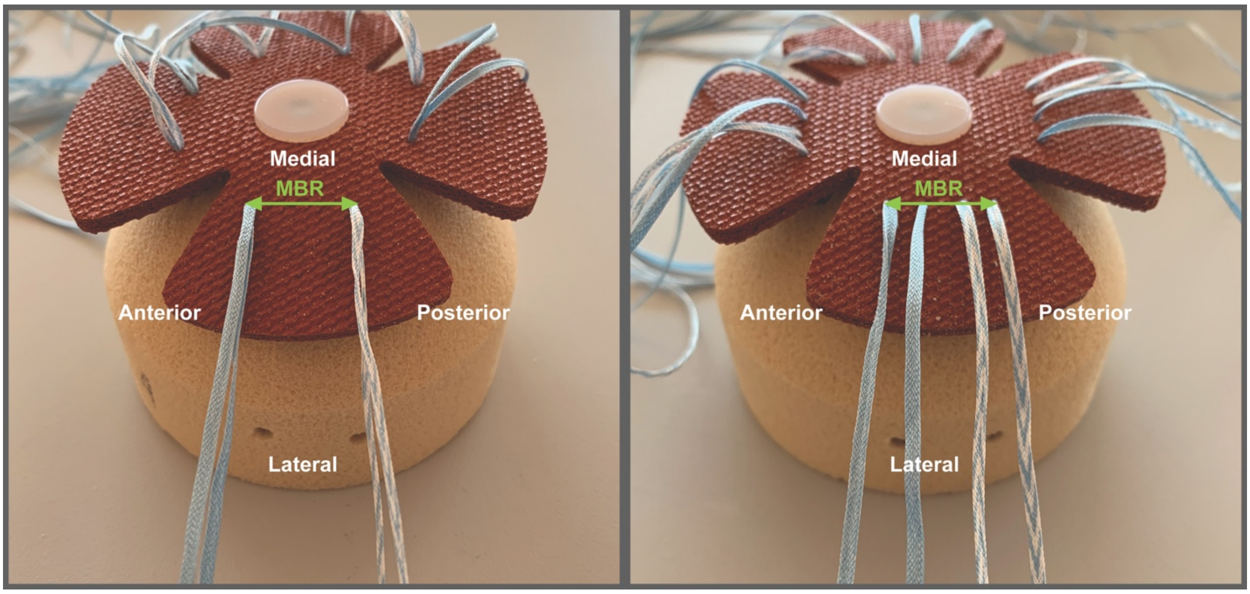


Figure 5.1 – Representation of the medial row configuration and MBR (green): a) Single hole suture passage (SP Group); b) Double hole suture passage (DP and SLDP Groups).

We did not compare all groups among themselves because our aim was not to rank the repairs, but to compare the effect at the tendon bone interface of specific surgical options between each other. We also did not add a fourth group (SP with sliding anchors) as that type of construct is rarely used in the clinical setting and by that reason the increased cost associated with it seemed to provide no benefit for the purpose of this work.

c. Mock surgical technique description

For the medial row we used two locked 5.5 mm Footprint Ultra Pk anchors® (Smith & Nephew, London, UK), single-loaded with Ultratape® in groups 1 and 3. In its turn, in group 2 (SLDP), two Helicoil® 5.5 mm anchors (Smith & Nephew, London, UK) also single-loaded with Ultratape® were chosen for that purpose. For the lateral row, two 5.5mm Footprint Ultra PK® anchors (Smith & Nephew, London, UK) were used in all groups.

Five trials, considering new anchors and suture limbs, were performed for each test group (n=5).

A flexible plastic template was used to ensure that each anchor was reproducibly placed and that all sutures had the same distance among them in each trial. We used the same single-sized needle for tape passage in each trial, regardless of the medial row configuration. The sensor was placed under the mock tendon and held with finger pressure. Both most anterior tape limbs of each medial anchor were pulled and placed in the AL anchor with the sutures slacked to avoid undetermined tensioning. Sutures limbs were then individually tensioned using two suture tensioners (EU000715 Suture Tensioner, Smith and Nephew, London, UK®) previously calibrated using a Shimadzu® calibrator (Shimadzu Corporation©, Kyoto, Japan), which allow for the measurement of four different tension values: 25, 50, 75 and 100 N.

In each of the 3 groups, the sutures in the AL anchor were tensioned until the 25N mark was reached. The anchor was then locked, and the tensioners released. The posterolateral (PL) anchor was then placed following the same sequential steps but using the most posterior suture limbs of each medial row anchor. Sensor finger stabilization was released when sufficient contact to the mechanical model allowed stable sensor position. After reaching the 25N tension mark in the PL anchor suture limbs, the force map was acquired using the I-Scan Lite software (Tekscan Inc.®, Boston, MA)

The lateral anchors were then unlocked, and all four suture limbs were slacked for reuse using the exact same mentioned methods, but this time, performing the lateral anchor locking at 50N of lateral tension (Figure 5.2).

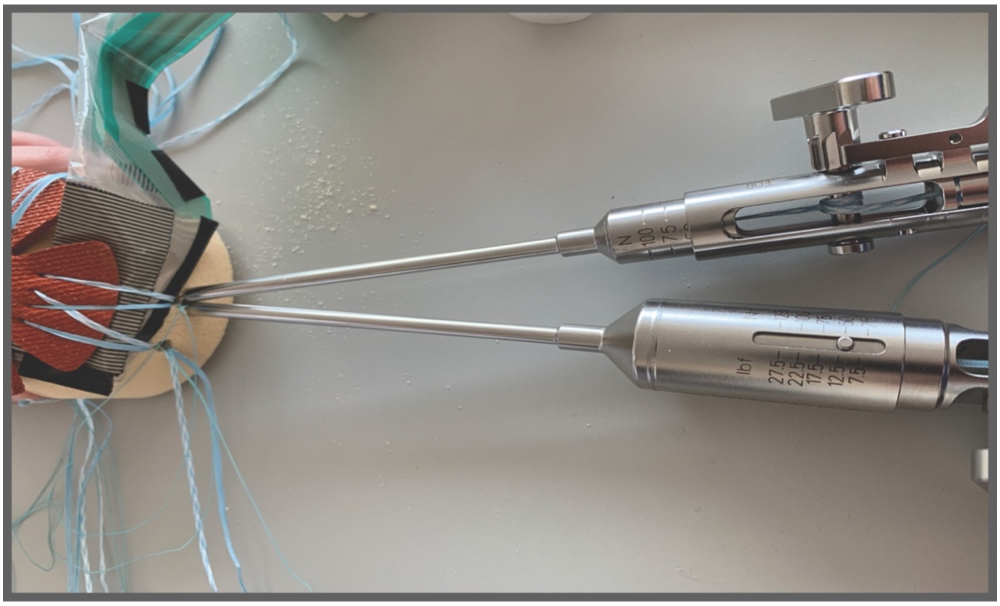


Figure 5.2 – Representation of the experimental setup used for measuring the contact force, area and pressure in the model, and the tension in the tapes for the SLDP configuration (please note the 50N mark in the calibrated tensioners).

We chose to evaluate the results at 25 and 50N taking into consideration Park´s 90N threshold[27] and our previous work[182], in which the use of 75N of lateral tension generated TBI pressure values that largely exceeded the arterial and capillary pressure. In addition, we also experienced some anchor pullout at 75N during preliminary trials, so 25 and 50N of lateral tension seemed adequate values for this study.

To increase trial homogeneity, all assemblies and tests were performed by the same shoulder fellowship trained surgeon with over 10 years of shoulder surgical experience.

Data Analysis

The analysis of the contact force, area and pressure distribution were performed using I-Scan Lite® software. The single cell saturation was set for 0.69MPa, the maximum pressure applied during the calibration procedure. A repair box of 586 mm^2 (27x21,85mm), i.e., the region of analysis that simulate the TBI, was equally defined for each trial. An analysis of the maximum peak force for an area of sixteen (4x4) force cells (25.81mm^2) and force in the MBR line was also performed.

The repair box was also divided into 2 hemiboxes (anterior and posterior) and the same parameters were evaluated to assess the distribution of the mechanical load in the anterior and posterior part of the construct (Figure 5.3).

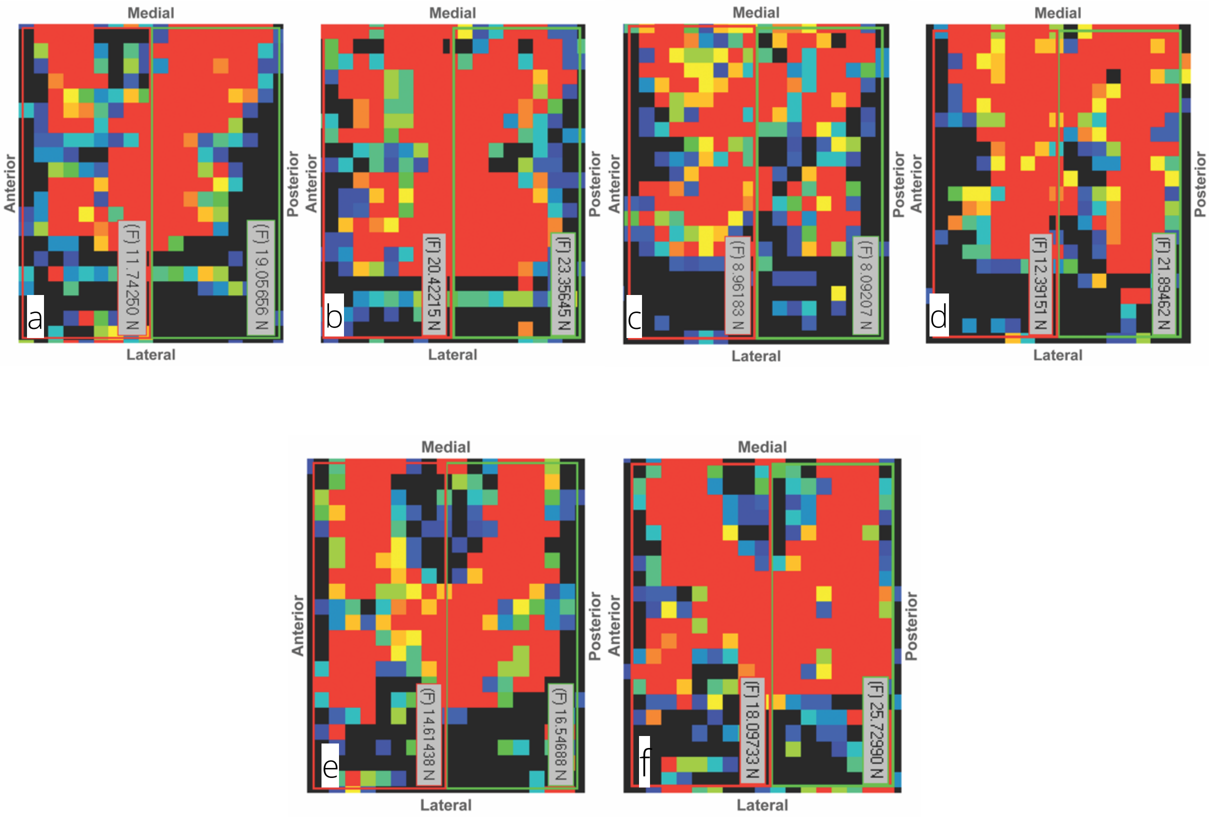


Figure 5.3 – Force mapping for the total repair box and anterior (red) and posterior (green) hemiboxes: a) DP with a lateral tension of 25 N; b) DP with a lateral tension of 50 N; c) SLDP with a lateral tension of 25 N; d) SLDP with a lateral tension of 50 N; e) SP with a lateral tension of 25 N; f) SP with a lateral tension of 50 N.

Statistical analysis

The type of medial mechanism, medial suture configuration and lateral tension were considered independent variables in this work. Contact force, area, and pressure as well as peak force and MBR force were the dependent ones.

A *post hoc* power analysis using G*Power software v 3.1.9.7® was performed.

A Mann-Whitney test with a null hypothesis that group results were similar was used for comparison of the biomechanical parameters among them (DP Vs. SLDP and DP Vs. SP).

The variation of the mechanical parameters between the anterior and posterior hemiboxes, as well as the influence of the lateral tension within each group was analyzed using the Wilcoxon signed rank test. The statistical analysis was performed on IBM SPSS Statistics v26 software (IBM, Armonk, NY). Statistical significance was set at $p<0.05$, but tendencies were highlighted for three intervals: $p\leq0.01$ (*), $0.01<p\leq0.05$ (**) and $0.05<p\leq0.1$ (***).

Results

1. Locking (DP) Vs. non locking medial row anchors (SLDP)

Figure 5.4 summarizes results for all groups regarding the total contact force, pressure, and contact area, as well as peak force and MBR force in the repair box according to the lateral row tension imposed in the repair.

The use of locked anchors (DP) generated a higher mean contact force, area, and pressure, irrespective of the applied lateral tension. However, significant differences were only obtained for the box force ($p=0.032$) and pressure ($p=0.008$) when a lateral tension of 25N was used.

Local peak pressure and MBR force were also higher for the locked anchors for both tested tensions, being the differences between groups more notorious at lower lateral tension values ($p<0.10$).

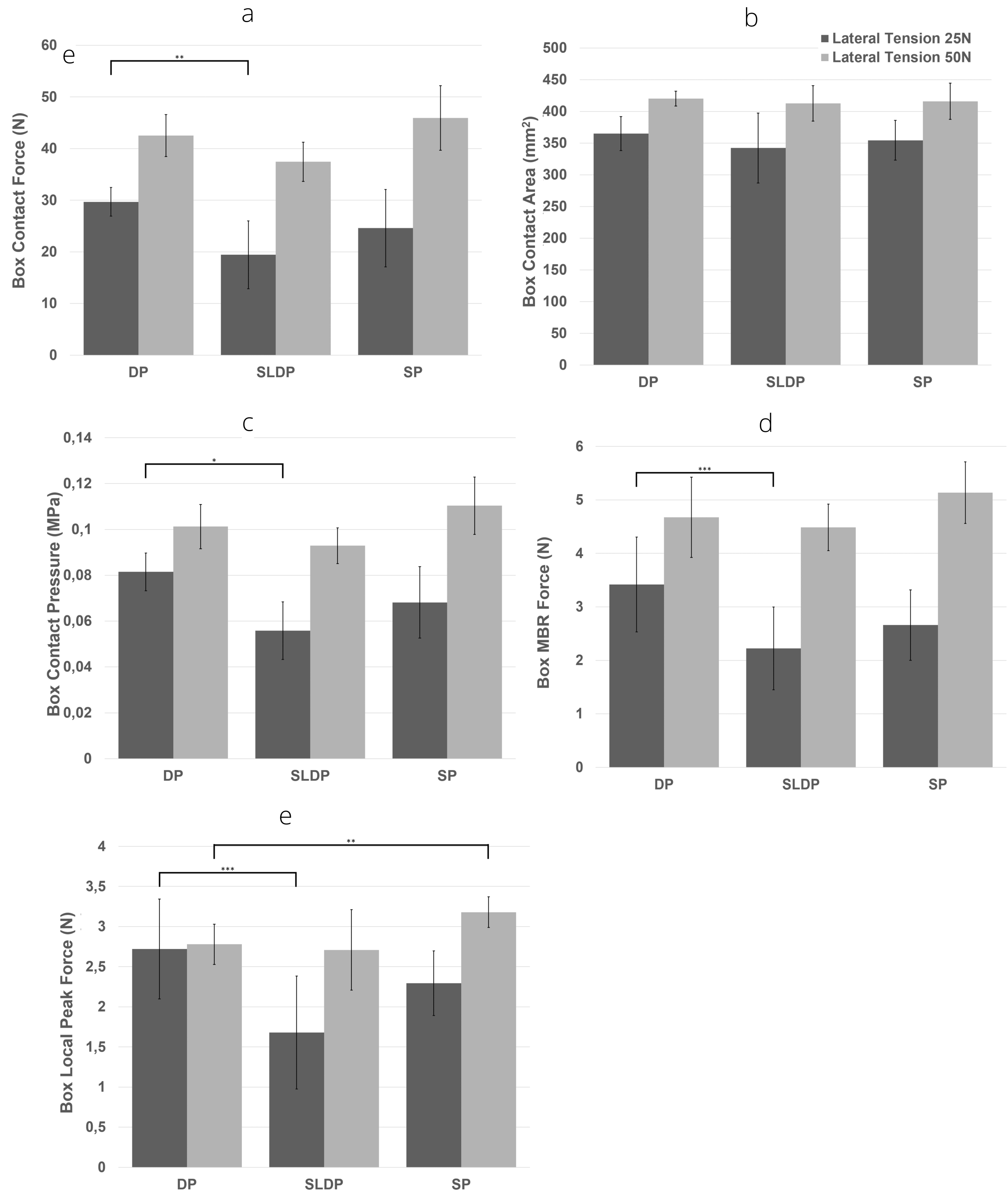
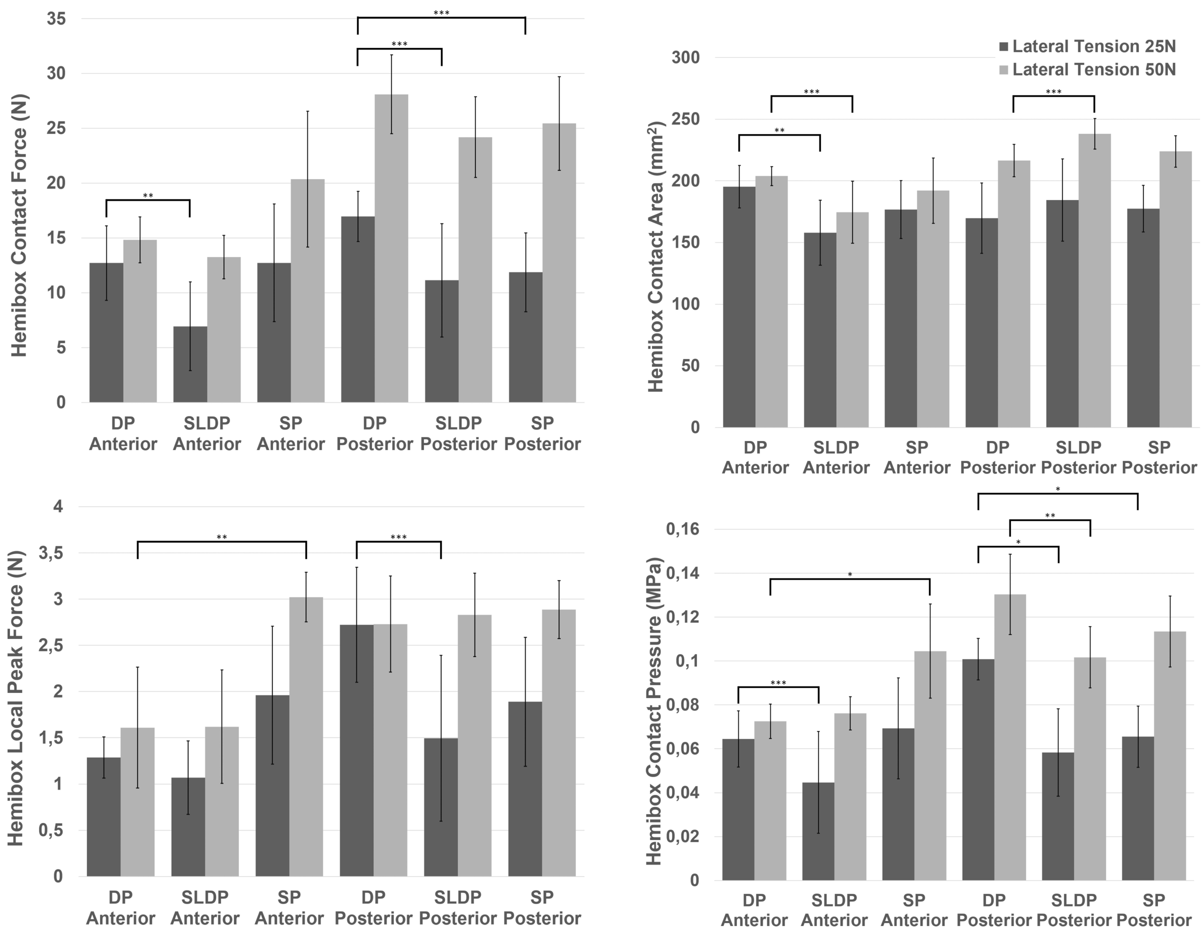


Figure 5.4– Comparison of the biomechanical outcomes for the repair box between the DP and SLDP groups and between the DP and SP groups for a value of lateral tension in the tapes of 25 N (dark gray) and 50 N (light gray): a) Total contact force; b) Contact area; c) Contact Pressure; d) Local Peak Force; e) Total force in the MBR (p≤0.01 (*), 0.01<p≤0.05 (**), 0.05<p≤0.1 (***)).

Figure 5.5 compares the anterior and posterior hemiboxes for all groups. DP showed lower posterior hemibox area at 25 and 50N, lower anterior hemibox pressure at 50N, lower hemianterior and posterior peak force at 50N and lower hemianterior MBR force at 25N, while higher values of the remaining parameters. Results were significantly higher for mean anterior hemibox force (p=0.016) and area (p=0.032) and mean posterior hemibox pressure at both 25 (p=0.008) and 50 N (p=0.032).



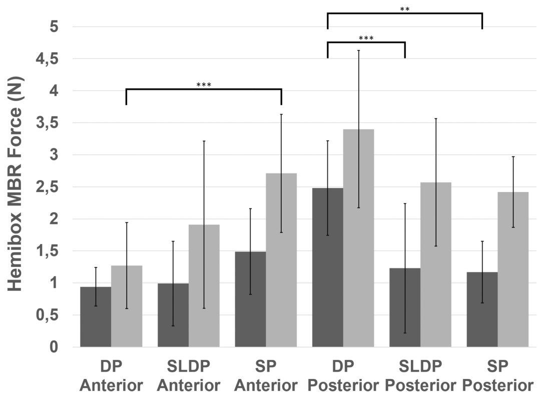


Figure 5.5 – Comparison of the biomechanical outcomes for the anterior and posterior hemiboxes between the DP and SLDP groups and between the DP and SP groups for a value of lateral tension in the tapes of 25 N (dark gray) and 50 N (light gray): a) Total contact force; b) Contact area; c) Contact Pressure; d) Local Peak Force; e) Total force in the MBR (p≤0.01 (*), 0.01<p≤0.05 (**), 0.05<p≤0.1 (***)).

2. Single-hole passage (SP) Vs. double-hole passage (DP)

Regardless of the lateral tension applied, DP originated non-significant higher values of contact area.

At 25N, DP achieved non-significant higher values for all studied parameters. However, when a lateral tension of 50 N was used, the SP group achieved higher values of contact force, pressure and MBR force, reaching statistical significance (p=0.032) in local peak force, but lower values of contact area (see figures 5.4).

Anterior hemibox evaluation at 25 N showed only minor differences across groups, but in the posterior hemibox, DP constructs exerted higher mean contact force and local peak force, and significantly higher contact pressure (p=0,008) and MBR applied force (p=0,016).

At 50N, the opposite pattern occurred, meaning that the SP group had significantly higher contact pressure and peak pressure in the anterior hemibox (see figures 5.4).

3. Variation between anterior and posterior hemiboxes

At 25 N of lateral tension values, the DP group showed the greatest variation between hemiboxes in most of the studied parameters, except for contact area, reaching statistically significance in contact pressure, peak pressure and MBR force. In the SLDP group, only contact area showed a significant variation (figure 5.6).

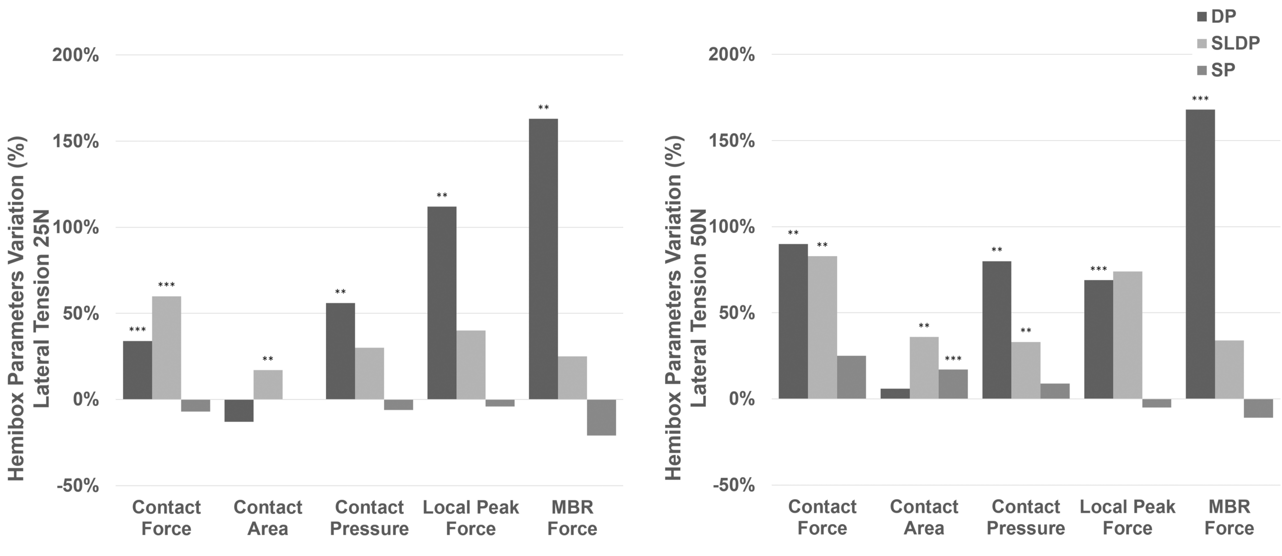


Figure 5.6 – Variation of the biomechanical outcomes between the anterior and posterior hemiboxes (positive value reveals higher values for posterior): a) lateral tension of 25 N; b) lateral tension of 50 N (p≤0.01 (*), 0.01<p≤0.05 (**), 0.05<p≤0.1 (***)).

In the SP group, both at 25 and at 50N, no relevant variation was identified between the posterior and the anterior hemiboxes, while at higher lateral tension values, both SLDP and DP showed again differences, the former in contact force (p=0.043), area (p=0.043) and contact pressure (p=0.043), and the latter in contact force (p=0.043) and pressure (p=0.043). At 50 N, all groups demonstrated higher contact force, area, and pressure in the posterior hemibox.

4. Consequences of the increase in lateral row tension

An increase in 100% of the lateral row tension resulted in significant variations in the contact force for all groups (figure 5.7), as well as contact area in the medial locked anchor groups (SP and DP) and pressure in the double-hole passage groups (DP and SLDP).

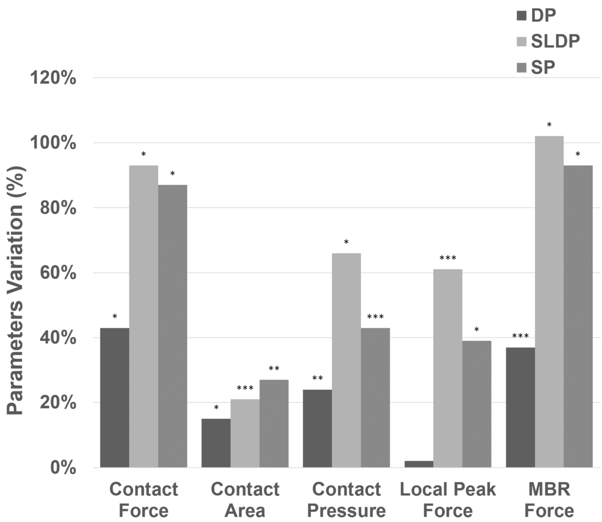


Figure 5.7 – Variation of the biomechanical outcomes within each group for an increase of 100% (25 to 50 N) in lateral row tension (p≤0.01 (*), 0.01<p≤0.05 (**), 0.05<p≤0.1 (***)).

Nevertheless, for the values in which the difference did not reach statistical significance, a tendency to increase was demonstrated.

MBR force also increased in all groups, but only significantly in SP and SLDP (p=0.008).

Results also demonstrated that an increase in the in lateral row tension has a more pronounced effect in contact force and MBR force than in all other parameters, regardless of the group.

Figure 5.3 presents a representative pattern of the contact map selected for each group, from which all parameters were obtained. The obtained values for the biomechanical outcomes and statistical tests can be consulted in appendix (Supplementary Table S-1 to S-11).

Discussion

The main findings of our work were that the type of medial anchor mechanism and type of medial passage have a direct influence over the contact force, area, and pressure as well as on peak force and MBR force at the TBI in knotless rotator cuff repairs. Moreover, careful attention should be provided to the amount of lateral row tension applied during surgery as this proved to have major impact in the mechanical parameters evaluated, regardless of the type of construct. The above-mentioned variables are the product of surgeon's technical choices and technique and, in theory, can affect the rate and type of retear that can occur[31,32,35].

Most biomechanical studies to date aimed to evaluate the mechanical characteristics of the materials and rotator cuff assemblies, and their capacity to withstand deformation and failure in time 0[149,156,158,201,208–210]. However, only a small number of reports have analyzed the consequences in contact force, area and pressure at the tendon bone interface using pressure mapping sensors[22,141,184,195,201] while even less used controlled lateral tension for that purpose despite its enormous relevance for the compressive effect of sutures in TOE repairs at the TBI[27,185]. To the best of our knowledge, none compared medial sliding anchors to medial locked anchors, which justifies the relevance of this specific investigation.

When comparing the medial anchor mechanism (sliding Vs. locked), the outcomes demonstrated that medial anchors with locked tapes generates tendentially higher mean contact force, area, and pressure, as well as peak force and MBR force irrespective of the lateral tension applied.

These results are explained by the interaction between different forces in knotless rotator cuff tear repairs. According to Newton´s second law, a resultant force is the single force acting on the object when all the other individual forces have been combined. Literature has detailed how friction force generates an efficiency loss in a pulley, in such a way that in order to move an object on one side of the pulley, the tension force on the other side needs to be higher than the force acting on the object itself[211]. This explains why, in the SLDP group, the lateral row pull in the posterolateral anchor does not generate the same tension in the anterior hemibox as in the posterior, as the medial sliding row behaves like a (rigid) pulley and induces a loss of efficiency in the translation of lateral row pull force into compressive force at the TBI, at least in the anterior region of the box. It is important to notice that the force transmitted in the SLDP pulley mechanism $(\boldsymbol{T_1})$ depends on the coefficient of friction $(\boldsymbol{\mu})$ and on the angle of contact in radians $(\boldsymbol{\beta})$ between the tape and the medial mechanism , and it can be calculated using the Capstan equation (also referred as Euler-Eytelwein equation)[212] :

$$T_2 = T_1 e^{\mu\beta}$$

in which T_2 is the tension applied by pulling the tapes[211,213]. The purpose of this study was not to measure this specific medial mechanism friction force, nor could we do it with the available data, but our outcomes demonstrate its effect, and the previous explanation suffices.

With medial locked anchors, no pulley system exists so the pulley friction force is removed from the net force equation meaning all tension force and its vector of pull are counteracted only by the locked medial anchor mechanism, which generates a compressive force vector at the TBI, helping to explain the higher contact force present both at lower and higher lateral tension values in the DP group when compared to SLDP and its more homogenous distribution of force, area and pressure.

It´s also clear the importance of the last placed lateral anchor in the SLDP group as it locks the construct, making the entire assembly stability dependent on in it.

This relates to another relevant aspect of the present work, which is the influence of the type of medial row configuration in the homogeneity of the force and pressure distribution. The obtained results show that the distribution of force, area and pressure for the SP group was almost equally distributed in the two halves of the construct, regardless of the applied lateral tension. On its turn, higher values of contact force and pressure were observed in the posterior region of the repair for the double-hole passage configurations (DP and SLDP). The reasons for this phenomenon, in particular the differences observed between SP and DP groups, are not so clear and contradict our initial supposition, as we were expecting a more heterogeneous load distribution in the SLDP group, which were observed in the results, but a more homogenous pattern in both locked configurations (SP and DP). However, significant differences between the posterior and anterior region were observed in the locked double passage group (DP).

This heterogeneity can be explained by the addiction of several non-accountable friction locations generated by the multiple suture inflections and points of contact secondary to the position of the medial anchor. This phenomenon can eventually result in a variable reduction of the tape´s ability to deliver its compressive force to the tendon explaining the differences observed between the two regions. On its turn, in single passage configurations, in which the tape exit point was straight vertical and right on top of the medial anchor, the number of friction points was smaller. This can also explain the higher values of contact force, pressure and MBR force seen in this group at higher lateral tensions. Nonetheless, this idea requires further studies for proper validation.

Data regarding MBR force is also quite relevant. Bedeir *et al*[34] stated that stress reduction in this area could help explain why double row and knotless suture bridge repairs show lower rates of type 2 retears. SLDP group generated a non-significant lower force in that region when compared to DP, which is probably explained by the dissipation of some of the tension force during tape friction of the medial sliding mechanism, that has previously discussed and can be clinically relevant as the MBR is the most stressed area of the repair[182].

Regarding suture passage, if larger lateral row tension values are used, a tendency for DP to confirm our initial hypothesis occurs, in which double-hole passage configurations increase the contact area without increasing the maximum force applied in the TBI. This issue is also of particular relevance because it contributes to lower contact pressure, which can have advantageous implications on the biological process of healing. These results are aligned with our previous report[182], which demonstrated that passing sutures individually (DP) significantly increased the contact area when compared to combined passage of suture limbs in a single pilot hole (SP).

Curiously, when compared to DP, the SP group generated higher MBR force at higher lateral tension values, and lower at lower lateral tension values, in line with the values of contact force and pressure, meaning that if higher lateral row tension is used, more force is applied in smaller sections of the MBR. This implies that pressure in those locations is clearly higher than if multiple passage points are used, which prevents stress distribution and probably jeopardizes this important tendon area[34]. To add up, and as previously reported [182], results also demonstrated that at higher lateral tension values, single-hole passage in the medial cuff significantly increases peak force, which may provide higher focal stability but also hamper biological healing in that specific location[107], usually quite close or at the MBR[182]. Of specific interest, looking at McCarron *et al*[36] description of failure in continuity, in which regardless of tendon healing, some tissue retraction always occurs, excessive stress at the MBR prevents this phenomenon and can, hypothetically, increase the risk of type 2 retears.

Like Park *et al*[27], Kummer[185] and Andre *et al*[207], we also demonstrated that lateral row tension is one of the most important variables to be considered when performing any type of biomechanical evaluation at the TBI because it clearly impacts contact force, area and pressure, as well as MBR force, in all studied groups. Despite having significant differences between 25 and 50N lateral tension, DP group was the most compliant one meaning that the increase in lateral tension translated into an increase in all studied variables but in a less pronounced manner than both SP and SLDP. In fact, the latter demonstrated the highest susceptibility to lateral row tension increase in all parameters except for area, in which SP superseded.

Data scarcity[27,182] regarding the biomechanical consequences of the increase of suture tape tension in the lateral anchors of knotless rotator cuff repairs should be a concern, as well as the near absence of lateral row tension control in most biomechanical studies available, which should motivate further investigations on this matter.

Our study has some strengths that should be highlighted. First, by avoiding the use of biological specimens, results reflect a more reproducible evaluation of the mechanical data, and reduced experimental variability, like reported by other authors[182,199,200,214]. Second, the use of a template and a single sized needle for suture passage increased the homogeneity of anchor placement, suture passage location, and mock tendon damage. Third, by using a high resolution sensor, contact force, area and pressure evaluation was performed using a more accurate method if compared to other published reports[22,138,195,201,214]. Fourth, to the best of our knowledge, this is the first report that evaluates the mechanical consequences at the

TBI of using locked or sliding mechanisms in the medial row anchors, which is clinically relevant because it can interfere with the surgeons *in locum* choices, and lastly, lateral row tensioning was performed individually, which is the only way to accurately control lateral tension. By using only one tensiometer to control tension in multiple sutures, if sutures have different initial tension, which they usually do, the measured lateral tension corresponds only to the tauter suture limb, not both.

The current study also presents some limitations. First, despite the statistical power analysis demonstrated that the sample was adequate for the evaluation of the effect of lateral row tension and for part of the dependent variable evaluation in the medial mechanism comparison (tables S-12 and S-13 in appendix), a small sample size is a drawback of most biomechanical reports[25,180,196,203,214] and this rule applies to our study. The cost per trial, mainly driven by implant cost, was the major limiting factor for the sample number in this study and makes statistical power unobtainable for some comparisons that require over 400 trials.

Second, even though a single surgeon placed all the anchors and utilized a template so that their location would be reproducibly replicated, the angle and depth of placement of the medial anchors was not controlled. Considering that a constant lateral tension was applied, by changing both the angle at which the anchor enters the bone and its depth, the compressive force at the TBI, especially in the MBR, can change because the resultant compressive force depends on the angle between the pull force and the vertical axis of the anchor.

As mentioned, friction force also interferes with the final compressive force and if the anchor is placed deeper, the tape can have a higher contact area with the bone, which increases friction and lowers the resultant force. Also, if the tape loses its flat form and turns into a wire, which has been reported[182], its contact area and friction with other materials are reduced.

Nonetheless, our work can help surgeons decide which is the most adequate technique, when facing different patients or types of tears, although it is, unfortunately, insufficient to provide a critical analysis of the clinical consequences of these choices and to define the ideal compressive force at the medial bearing row to prevent retears and avoid nonhealing.

In summary, knotless rotator cuff repairs generate a TBI contact force, area and pressure that is highly dependent on the lateral tension applied in the lateral anchors, especially in constructs that use medial sliding mechanism anchors. When compared to locked configurations, these tend to generate lower values of contact force, area, and pressure. The adoption of single or double-hole suture passages in the medial row also has mechanical consequences at the TBI as double-hole passage configurations generates a slightly larger area of contact if higher lateral row tension is used and a more heterogenous distribution of force, pressure, and area, which is more evident if a medial sliding mechanism is used. Moreover, the forces applied in the MBR also presented lower values in this type of configurations. On its turn, configurations based on single pilot holes generated the most homogenous distribution of force, area, and pressure at the TBI, but higher forces were seen in the region of the medial row.

Chapter VI

Development of a prototype for intraoperative measurement of lateral row tensioning

Background

As described, tension in the lateral row sutures in SB repairs has been demonstrated to be a major influence for TBI´s contact force, area and pressure[27,182] and even MBR force has shown to be influenced by it, although, as previously revealed, other surgical technical features may also interfere. Park´s[27] work demonstrated that beyond 90N of lateral row tension contact force and pressure kept increasing but contact area did not, and the authors assumed that increasing lateral row tension above that value would have no benefits, and it would probably be detrimental for rotator cuff healing.

Associating that data with the fact that more robust repairs seem to have a higher risk of type 2 retears[33,34], it seemed plausible to think that lateral row tension should be limited up to the point where mechanical stability was sufficient enough to allow tendon bone healing but not compromising it´s biological capacity to do so, and the 90N threshold seemed a good ending point.

Nonetheless, in 2020, the same group[215], demonstrated that increasing lateral row tensioning to the maximum possible value, generated lower retear rates. This was the first clinical paper that tried to establish a relation between lateral row tension and repair integrity, and although well designed, this study evaluated only lateral row tension in a tied/non-sliding TOE with multiple suture passages, which in light of the facts exposed in this thesis, can´t be completely extrapolated to all TOE assemblies.

Moreover, the paper has some other major limitations that were not discussed. First, apparently both suture limbs of each lateral row anchor were tensioned at the same time, and most likely they had different initial tension as it´s usually seen intra-operatively, so it may very well be that the registered tension was the one measured in the most tensioned suture limb, while the other limb had inferior tension values, meaning that the results presented may be misleading. Second, despite having comparable types of tear, tension required to bring the tendon to the footprint, was not measured, and this was also demonstrated as a very relevant factor for tendon-bone healing to prevent retears[163].

Having that in mind and considering Oh´s statement in the discussion in which *"...proper bridging suture tension during TOE repair may be important; however, there has been no basic or clinical research regarding this issue..."* we decided to further investigate this subject.

Rationale and design

Besides having evaluated only a specific TOE technique that used medially locked mechanism with tied suture wires, Oh´s work[215] also used a specific lateral row anchor and instrument that allows non-accountable but controlled lateral tension, which led him to develop custom-made tensiometer that is difficult to reproduce, as recognized in the limitations section, which was justified by the fact that " *... there is no device to measure bridging suture tension in a real clinical situation... surgeons cannot* *determine the exact bridging suture tension intraoperatively…"* and the authors challenged the scientific and entrepreneur community to develop a *"lateral suture anchor with a tensiometer…".*

Given the above-mentioned limitations, lack of robust clinical literature on the subject, supported by inadequate and irreproducible measurement methods, we decided to develop a sterilizable, reusable and sustainable surgical instrument that not only allows integration with commercially available tensiometers, but can also adjust to multiple lateral row anchors and permits tendon excursion tension measurement.

A Portuguese company specialized in the development of precision instruments was approached to develop a small and light instrument with the above desired requirements. The final product was a 250 g, stainless steel prototype, designed to allow its insertion and locking in the lateral row anchor deploy instrument, while also permitting the use of calibrated and commercially available suture tensioners for lateral row suture tensioning and tendon excursion tension quantification (Figures 6.1 and 6.2.

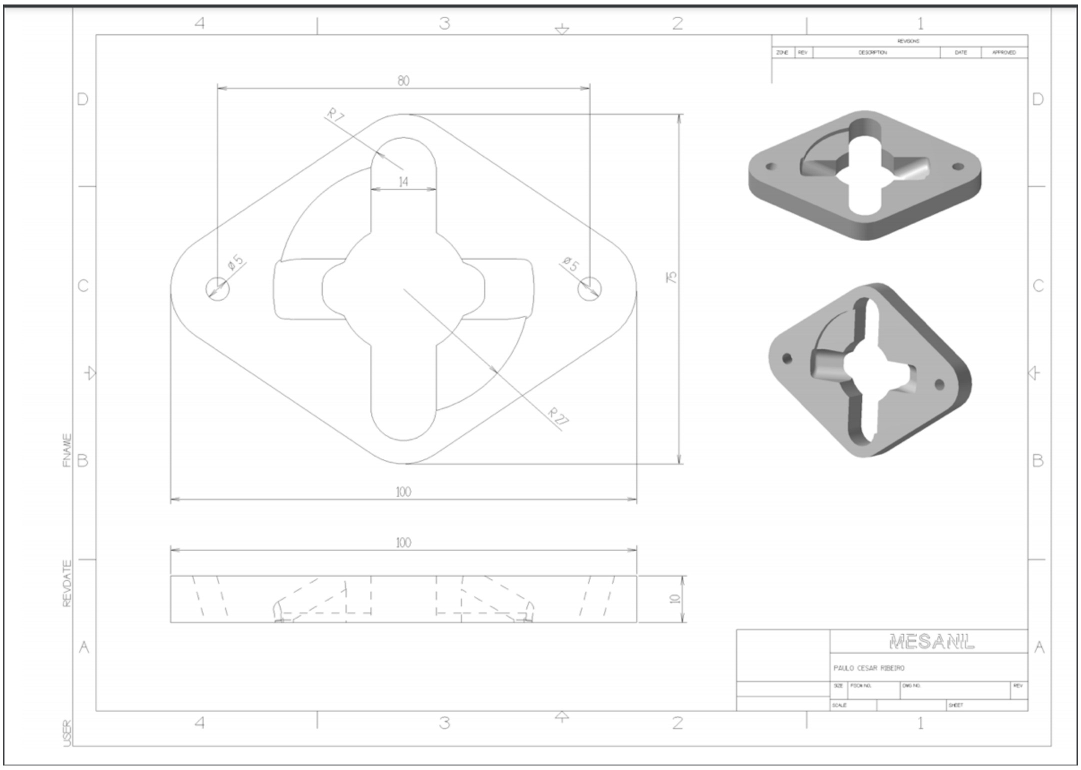


Figure 6.1– Prototype Autocad® planning.

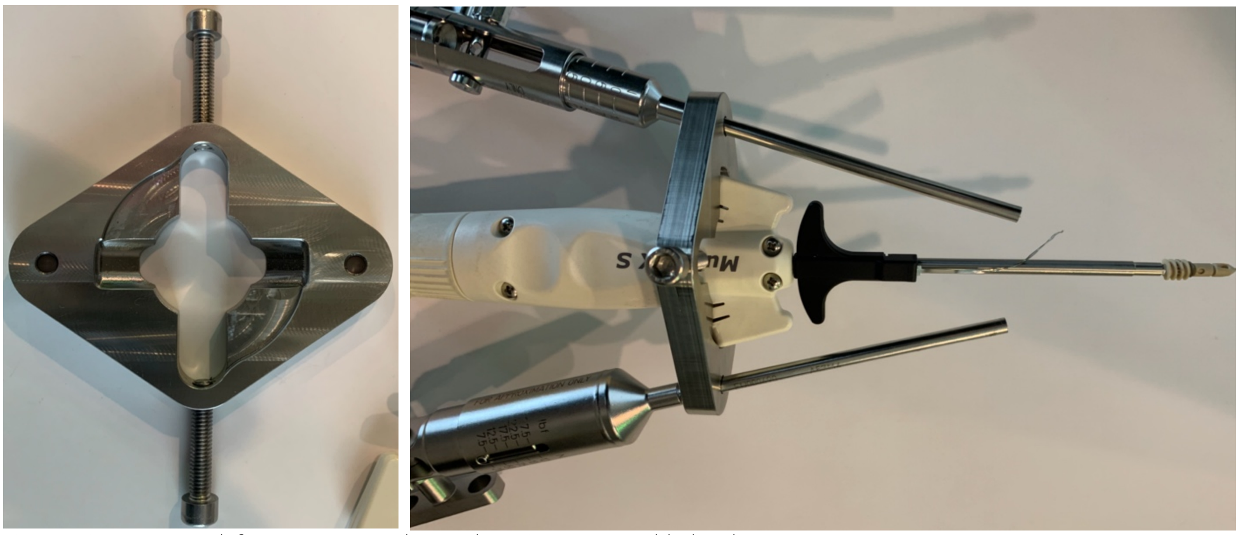


Figure 6.2 –Prototype (left); prototype, anchor and tensioners assembled (right).

Chapter VII

Conclusion and future directions

The present work offers several insights on the influence of chosen materials and surgical technique at the tendon bone interface mechanical forces.

It demonstrated that suture tapes exert significant less force and pressure at the TBI when compared to suture wires, which contrasted with the current biomechanical data [25,26175]. Several reasons for this divergence were pointed out, but considering the subsequent developments in this investigation, it seems clear that those papers lacked a methodological step that showed to be fundamental, which was to use controlled lateral row tension, that, as demonstrated in chapter V, proved to have a significant influence on the compressive force at the tendon bone interface irrespective of the material used.

To our best knowledge, this was also the first work to compare the biomechanical effect of suture wires and tapes in a simulated tendon bone interface using controlled lateral row tension, which should eventually merit adequate consideration by surgeons when selecting their implants.

The effect of the type of medial row mechanisms were also evaluated. Data obtained suggest that medially locked anchors generate higher values of contact force and pressure, peak force and MBR force, irrespective of the applied lateral tension. These results are especially relevant because they were obtained when two knotless techniques were compared in chapter V, meaning that the higher risk of type 2 retears[31], thoroughly described in the clinical setting [31,33,34] in tied suture bridge repairs effect may not derive only from the biological compromise induced by knot-tying and the already described stress increase in the tendinous knot region[216] (and consequently in the medial bearing row [32,216]) but also from mentioned increased stress induced by the non-sliding mechanism, which to date had not been described.

Medial row mechanism also interferes with the progressive compressive force pattern seen during TOE assembling. In sliding repairs, compressive force grows gradually as lateral anchors are placed and sutures tensioned, and the construct stability is dependent on the lastly placed anchor, which should be in the best bone density area as this anchor is the one receiving the higher load / stress. The fact that peak force was observed in the postero lateral quadrant of sliding repairs (chapter IV) corroborates this proposal.

In the locked mechanism, most of the total force is applied when the first anchor is placed and then tensioned, so the first applied lateral anchor should be placed in a good bone stock region, although if the anchor fails, it´s possible that the repair may succeed because the last lateral anchor placed receives sutures that are independent of those of the first anchor.

Still regarding force patterns, this work also demonstrated that contact force and pressure his higher in the medial regions of the repair, which confirms the medial row as the tension supporting area of the repair [32] and a weak spot for medial failure.

Literature has supported the used of more sutures to improve the mechanical properties of the repair but having more sutures passing in the tendon or more holes for the sutures to pass is different. Previous authors had already demonstrated that increasing the number of sutures passed in the tendon tended to generate more robust constructs [156,158,167,217] but to our best knowledge, no study had been published on the biomechanical consequences of having one or more than one sutures passing in the same hole. In this investigation the number of sutures that passed in the medial tendon remained constant, but the number of holes in which they passe varied and results demonstrated that individual passage of sutures (meaning more passage points in the tendon) increased TBI contact area, which can contribute to tendon bone healing by allowing larger area of contact between the tendon and the bone bed, while at the same time favoring pressure reduction, favoring better blood perfusion in that area.

One of the most important findings in this work relates to the effect of the controlled increase of lateral row tension, which generated higher values of all studied mechanical parameters, in all groups, although it was also demonstrated that for most of them, the TBI of knotless medial sliding repairs was the most susceptible to lateral row tension increase. This data is relevant because one of the hypothesized risk factors for type 2 retears was overtensioning of the repair, which seems to depend not only on lower tendon elasticity and excursion[163] but also on exaggerated lateral row suture tension.

In summary, the optimum biomechanical strength of rotator cuff repairs is yet to be described, but ideally, a construct would provide adequate strength for healing while limiting the risk of failure, especially type 2 retears[31]. As described in the literature, most likely higher failure loads beyond a certain level may not correlate with incremental clinical advantages [32–35,106], suggesting that there is likely a clinically optimal biomechanical strength, that is yet to be determined. Our investigation demonstrated that in order to lower the contact force and pressure in the TBI, one can use suture tapes, sliding medial row mechanisms and refrain lateral row suture tensioning, while adding more suture passage points in the cuff increases contact area.

This investigation can support a prospective controlled clinical trial with the use of the developed prototype, to identify the ideal relation between tendon tension and lateral row tension to avoid retears. It is also plausible that those clinical results can be correlated with pre-operative MRI imaging and other clinical measurable factors eventually with the support of mathematical algorithms, so that the repair or other alternative solutions can be found and discussed preoperatively with the patient to adequately manage their expectations and avoid the growing burden of patient-doctor litigancy.

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APPENDIX

List of publications

Oral Communications

- 9º Congresso Nacional de Biomecânica;Porto; 19th and 20th February 2021; **Carlos Maia Dias**, Sérgio B. Gonçalves, António Completo, Martina Tognini, Manuel Ribeiro da Silva, Jorge Mineiro, Frederico Ferreira, João Folgado; *"Serão as fitas melhores que os fios para reparar a coifa dos rotadores? Estudo em modelo mecânico da força de contacto, área e pressão na interface tendão-osso"*
- SCERG Seminar – 12th March 2021; Lisboa; **Carlos Maia Dias**, Sérgio B. Gonçalves, António Completo, Martina Tognini, Manuel Ribeiro da Silva, Jorge Mineiro, Frederico Ferreira, João Folgado; *"Implications and complications of different types of materials and its application in knotless rotator cuff repairs - An evaluation of force, pressure and contact area in a tendon bone unit mechanical model and evaluation of clinical outcomes"*

Publications

- *"Why are tapes better than wires in knotless rotator cuff repairs? An evaluation of force, pressure and contact area in a tendon bone unit mechanical model"*; **Carlos Maia Dias**, Sérgio B. Gonçalves, António Completo, Martina Tognini, Manuel Ribeiro da Silva, Jorge Mineiro, Francisco Curate, Frederico Ferreira, João Folgado; Journal of Experimental Orthopaedics; DOI: 10.1186/s40634-020-00321-y

Publications under review

- *"Biomechanical consequences of different medial row configurations and anchor mechanisms at the tendon bone junction of the rotator cuff"*; Carlos Maia Dias, António Completo, Sérgio B. Gonçalves, Manuel Ribeiro da Silva, Clara de Campos Azevedo, Jorge Mineiro, Frederico Ferreira, João Folgado; Submitted to Journal of Orthopaedic Research on January 5th 2022, Manuscript number JOR-22-011
- *"Influence of Medial Row Configuration in the Force Applied at the Tendon-Bone Interface during Transosseous Repair Assembling*"; Carlos Maia Dias, António Completo, Sérgio B. Gonçalves, Ana Catarina Ângelo, Clara de Campos Azevedo, Jorge Mineiro, Frederico Ferreira, João Folgado; Submitted to Clinical Biomechanics on January 29th. Manuscript number CLBI-D-22-00073

Tables

Supplementary Table S1 – Variation between posterior and anterior hemiboxes at 25 N (positive value reveals higher values for posterior and negative reveals higher values in the anterior hemibox) - * reached statistical significance

Lateral Tension 25N	DP	Wilcoxson ($p<0.05$)	SLDP	Wilcoxson ($p<0.05$)	SP	Wilcoxson ($p<0.05$)
Hemibox force (N)	34%	0.078	60%	0.08	-7%	0.5
Hemibox area (mm^2)	-13%	0.221	<u>17%</u>	<u>0.043*</u>	0%	0.786
Hemibox pressure (Mpa)	<u>56%</u>	<u>0.042*</u>	30%	0.225	-6%	0.5
Hemibox peak force (N)	<u>112%</u>	<u>0.042*</u>	40%	0.225	-4%	0.893
Hemibox MBR force (N)	<u>163%</u>	<u>0.042*</u>	25%	0.893	-21%	0.5

Supplementary Table S2 – Variation between posterior and anterior hemiboxes at 50 N (positive value reveals higher values for posterior and negative reveals higher values in the anterior hemibox) - * reached statistical significance

Lateral Tension 50N	DP	Wilcoxson ($p<0.05$)	SLDP	Wilcoxson ($p<0.05$)	SP	Wilcoxson ($p<0.05$)
Hemibox force (N)	<u>90%</u>	<u>0.043*</u>	<u>83%</u>	<u>0.043*</u>	25%	0.345
Hemibox area (mm^2)	6%	0.225	<u>36%</u>	<u>0.043*</u>	17%	0.08
Hemibox pressure (Mpa)	<u>80%</u>	<u>0.043*</u>	<u>33%</u>	<u>0.043*</u>	9%	0.5
Hemibox peak force (N)	69%	0.08	74%	0.144	-5%	0.5
Hemibox MBR force (N)	168%	0.08	34%	0.5	-11%	0.686

Supplementary Table S3 – Mean Comparison between locked medial anchor (DP) and sliding medial anchors (SLDP) regarding contact force. area and pressure, peak force and MBR force in the repair box (25N lateral tension) - * reached statistical significance

Lateral Tension 25N	DP	Range (+/-)	SLDP	Range (+/-)	Mann Whithney ($p<0.05$)
Box Force (N)	<u>29.68</u>	2.77	<u>19.44</u>	6.57	<u>0.032*</u>
Box Area (mm^2)	365.00	26.72	342.40	55.15	0.548
Box pressure (Mpa)	<u>0.0815</u>	0.01	<u>0.0558</u>	0.01	<u>0.008*</u>
Box peak force (N)	2.7214	0.62	1.6801	0.70	0.056
Box MBR force (N)	3.417	0.89	2.22	0.77	0.095

Supplementary Table S4 – Mean comparison between locked medial anchor (DP) and sliding medial anchors (SLDP) regarding contact force, area and pressure, peak force and MBR force in the repair box (50N lateral tension) - * reached statistical significance

Lateral Tension 50N	DP	Range (+/-)	SLDP	Range (+/-)	Mann Whithney ($p<0.05$)
Box Force (N)	42.52	4.05	37.44	3.80	0.151
Box Area (mm^2)	420.20	11.82	412.80	27.97	0.69
Box pressure (Mpa)	0.1012	0.01	0.0929	0.01	0.151
Box peak Force (N)	2.7788	0.25	2.7088	0.50	1
Box MBR force (N)	4.67	0.75	4.46	0.43	0.421

Supplementary Table S5 – Mean comparison between locked medial anchor (DP) and sliding medial anchors (SLDP) in both hemiboxes (25N lateral tension) - * reached statistical significance

Lateral Tension 25N	DP	Range (+/-)	SLDP	Range (+/-)	Mann Whithney ($p<0.05$)
ANT hemibox Force (N)	<u>12.71</u>	3.41	<u>6.94</u>	4.04	<u>0.016*</u>
ANT hemibox Area (mm^2)	<u>195.20</u>	17.28	<u>158.00</u>	26.35	<u>0.032*</u>
ANT hemibox pressure (Mpa)	0.0645	0.01	0.0447	0.02	0.095
ANT Hemibox Peak Force (N)	1.2863	0.22	1.0675	0.40	0.31
ANT Hemibox MBR force (N)	0.94	0.66	0.99	0.66	1
POST hemibox Force (N)	16.97	2.29	11.14	5.17	0.056
POST hemibox area (mm^2)	169.80	28.52	184.40	33.42	0.548
POST hemibox pressure (Mpa)	<u>0.1008</u>	0.01	<u>0.0583</u>	0.02	<u>0.008*</u>
POST Hemibox Peak Force (N)	2.7214	0.62	1.4944	0.90	0.056
POST Hemibox MBR force (N)	2.48	0.74	1.23	1.01	0.056

Supplementary Table S6 – Mean comparison between locked medial anchor (DP) and sliding medial anchors (SLDP) in both hemiboxes (50N lateral tension) - * reached statistical significance

Lateral Tension 50N	DP	Range (+/-)	SLDP	Range (+/-)	Mann Whithney (p<0.05)
ANT hemibox Force (N)	14.82	2.10	13.25	1.99	0.421
ANT hemibox Area (mm^2)	203.80	7.69	174.60	25.21	0.056
ANT hemibox pressure (Mpa)	0.0725	0.01	0.0761	0.01	0.548
ANT Hemibox Peak Force (N)	1.61	0.65	1.62	0.61	0.841
ANT Hemibox MBR force (N)	1.27	0.67	1.91	1.30	0.69
POST hemibox Force (N)	28.10	3.60	24.19	3.68	0.151
POST hemibox area (mm^2)	216.40	13.18	238.00	12.39	0.056
POST hemibox pressure (Mpa)	<u>0.1303</u>	0.02	<u>0.1017</u>	0.01	<u>0.032</u>
POST Hemibox Peak Force (N)	2.73	0.52	2.83	0.45	0.73
POST Hemibox MBR force (N)	3.40	1.23	2.57	1.00	0.421

Supplementary Table S7 – Mean comparison between tape double-hole passage (DP) and single-hole passage (SP) regarding contact force, area and pressure, peak force and MBR force in the repair box (25N lateral tension) - * reached statistical significance

Lateral Tension 25N	DP	Range (+/-)	SP	Range (+/-)	Mann Whithney ($p<0.05$)
Box Force (N)	29.68	2.77	24.60	7.49	0.222
Box Area (mm^2)	365.00	26.72	354.5	31.34	0.421
Box pressure (Mpa)	0.0815	0.01	0.0698	0.02	0.31
Box peak Force (N)	2.7214	0.62	2.2951	0.40	0.31
Box MBR force (N)	3.42	0.89	2.66	0.66	0.222

Supplementary Table S8 – Mean comparison between tape double–hole passage (DP) and single-hole passage (SP) regarding contact force, area and pressure, peak force and MBR force in the repair box (50N lateral tension) - * reached statistical significance

Lateral Tension 50N	DP	Range (+/-)	SP	Range (+/-)	Mann Whithney ($p<0.05$)
Box Force (N)	42.52	4.05	45.90	6.25	0.31
Box Area (mm^2)	420.20	11.82	416.00	28.53	0.69
Box pressure (Mpa)	0.1012	0.01	0.1103	0.01	0.222
Box peak Force (N)	<u>2.7788</u>	0.25	<u>3.1791</u>	0.19	<u>0.032*</u>
Box MBR force (N)	4.67	0.75	5.14	0.58	0.421

Supplementary Table S9 – Mean comparison between tape double-hole passage (DP) and single-hole passage (SP) in both hemiboxes (25N lateral tension) - * reached statistical significance

Lateral Tension 25N	DP	Range (+/-)	SP	Range (+/-)	Mann Whithney ($p<0.05$)
ANT hemibox Force (N)	12.71	3.41	12.73	5.36	0.421
ANT hemibox Area (mm^2)	195.20	17.28	176.75	23.48	0.151
ANT hemibox pressure (Mpa)	0.06447	0.01	0.06928	0.02	0.421
ANT Hemibox Peak Force (N)	1.29	0.22	1.96	0.75	0.151
ANT Hemibox MBR force (N)	0.94	0.66	1.49	0.67	0.222
POST hemibox Force (N)	16.97	2.29	11.87	3.59	0.056
POST hemibox area (mm^2)	169.80	28.52	177.50	18.93	0.421
POST hemibox pressure (Mpa)	<u>0.1008</u>	0.01	<u>0.0655</u>	0.01	<u>0.008</u>
POST Hemibox Peak Force (N)	2.72	0.62	1.89	0.70	0.151
POST Hemibox MBR force (N)	<u>2.48</u>	0.74	<u>1.17</u>	0.48	<u>0.016</u>

Supplementary Table S10 – Mean comparison between tape double-hole passage (DP) and single-hole passage (SP) in both hemiboxes (50N lateral tension) - * reached statistical significance

Lateral Tension 50N	DP	Range (+/-)	SP	Range (+/-)	Mann Whithney ($p<0.05$)
ANT hemibox Force (N)	14.82	2.10	20.37	6.20	0.222
ANT hemibox Area (mm^2)	203.80	7.69	192.00	26.48	0.548
ANT hemibox pressure (Mpa)	0.0725	0.01	0.1045	0.02	0.008
ANT Hemibox Peak Force (N)	1.6132	0.65	3.0217	0.27	0.016
ANT Hemibox MBR force (N)	1.27	0.67	2.71	0.92	0.056
POST hemibox Force (N)	28.10	3.60	25.44	4.27	1
POST hemibox area (mm^2)	216.40	13.18	223.80	12.79	0.69
POST hemibox pressure (Mpa)	0.1303	0.02	0.1134	0.02	0.222
POST Hemibox Peak Force (N)	2.7274	0.52	2.8849	0.31	0.69
POST Hemibox MBR force (N)	3.40	1.23	2.42	0.55	0.151

Supplementary Table S11 – Variation within each group if lateral row tension increases 100% - * reached statistical significance

Variation %	DP	Wilcoxson (p<0.05)	SLDP	Wilcoxson (p<0.05)	SP	Wilcoxson (p<0.05)
Force (N)	43%	0.008*	93%	0.008*	87%	0.008*
Area (mm^2)	15%	0.008*	21%	0.056	27%	0.016*
Pressure (Mpa)	24%	0.032*	66%	0.008*	43%	0.095
Peak force (N)	2%	0.841	61%	0.056	39%	0.008*
MBR force (N)	37%	0.056	102%	0.008*	93%	0.008*

Supplementary Table S12 - Statistical power analysis performed using G power software for comparisons of the dependent variables between groups. Considered acceptable statistical power if power > 0,75; Alpha error probability = 0,05

		Force			Area			Pressure			PFORCE			MBR		
		Power	Effect size	Ideal N	Power	Effect size	Ideal N	Power	Effect size	Ideal N	Power	Effect size	Ideal N	Power	Effect size	Ideal N
SLDP - DP	25N	0,78	2,02	NA	0,11	0,52	59	0,9	2,42	NA	0,56	1,56	13	0,49	1,43	15
DP - SP		0,22	0,89	35	0,08	0,36	211	0,3	1,07	25	0,75	1,98	43	0,25	0,96	31
SLDP - DP	50N	0,25	1,29	31	0,07	0,34	231	0,25	0,95	32	0,05	0,17	872	0,07	0,31	289
DP - SP		0,14	0,64	67	0,05	0,19	231	0,19	0,81	46	0,67	1,89	10	0,15	0,68	118

Supplementary table S13 – Statistical power analysis performed using G power software for comparisons of tension variation within groups.

Considered acceptable statistical power if power > 0,75; Alpha error probability = 0,05

	Force			Area			Pressure			PFORCE			MBR		
	Power	Effect size	Ideal N	Power	Effect size	Ideal N	Power	Effect size	Ideal N	Power	Effect size	Ideal N	Power	Effect size	Ideal N
DP	0,23	0,91	34	0,95	2,6	6	0,83	2,19	7	0,05	0,12	1861	0,54	1,53	13
SLDP	0,99	3,35	NA	0,58	1,61	12	0,99	3,55	4	0,62	1,68	11	0,98	3,6	5
SP	0,98	3,38	NA	0,79	2,05	8	0,97	2,98	NA	0,96	2,81	NA	0,99	3,99	NA