Universidade do Minho
Escola de Medicina

Clara Isabel de Campos Azevedo

Arthroscopic Superior Capsular Reconstruction with a Minimally Invasive Harvested Fascia Lata Autograft – Clinical Importance of Graft Survivorship

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Tese de Doutoramento
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Trabalho efetuado sob orientação do
Professor Doutor Nuno Eduardo Sevivas Sousa

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Statement of integrity

I hereby declare having conducted this academic work with integrity. I confirm that I have not used plagiarism or any form of undue use of information or falsification of results along the process leading to its elaboration.

I further declare that I have fully acknowledged the Code of Ethical Conduct of the University of Minho.

Reconstrução Capsular Superior Artroscópica com Autoenxerto de Fáscia Lata Colhido por Via Minimamente Invasiva – Importância Clínica da Sobrevivência do Enxerto

Resumo

A reconstrução capsular superior artroscópica (RCSA) é uma opção de tratamento cirúrgico recente para roturas irreparáveis da coifa dos rotadores (RICR). O primeiro estudo clínico sobre RCSA reportou melhorias significativas dos resultados clínicos e imagiológicos com autoenxerto de fáscia lata proximal (AFLP) colhido por via aberta. Preocupações com a morbilidade da zona dadora levaram a modificações da RCSA e ao uso do aloenxerto dérmico humano (ADH), mas foram reportados resultados clínicos inferiores e uma menor taxa de sobrevivência do ADH. Modificámos a RCSA e utilizámos autoenxerto de fáscia lata do terço médio da coxa (AFLM) colhido por via minimamente invasiva (MI). A importância da escolha do tipo de enxerto, visando maximizar os resultados clínicos, permaneceu por esclarecer. Esta tese teve como objetivo determinar os resultados da RCSA com autoenxerto de fáscia lata (AFL) ou ADH, comparar as propriedades biomecânicas do AFLP e AFLM, avaliar os resultados clínicos e de ressonância magnética aos 3 anos da RCSA com AFLM, e determinar a importância clínica da integridade do enxerto. As hipóteses eram que a RCSA com AFL teria resultados superiores à RCSA com ADH; as propriedades biomecânicas do AFLP e AFLM não seriam significativamente diferentes; os resultados clínicos melhorariam significativamente desde o pré-operatório até aos 3 anos e seriam significativamente piores em pacientes que tivessem uma rotura completa do enxerto aos 3 anos. Verificámos que a RCSA com AFL ou ADH resultou em melhorias clínicas significativas aos 12 meses; os valores médios da rigidez e do módulo de Young não diferiram significativamente entre o AFLP e o AFLM; o impacto da morbilidade da zona dadora da colheita MI do AFLM foi baixo, os resultados clínicos da RCSA usando o AFLM foram bons, e as roturas completas do enxerto correlacionaram-se com diminuição da força de rotação externa e maior grau de degenerescência gorda dos músculos infraespinhoso e pequeno redondo aos 3 anos. O presente trabalho mostra que a integridade do enxerto é importante para a manutenção de melhores resultados clínicos a médio prazo, e que o AFLM pode ser uma boa alternativa ao AFLP. As nossas observações biomecânicas podem contribuir para futuros trabalhos para determinar o papel do AFL, abrindo caminho para novas estratégias para melhorar a técnica, a cicatrização do enxerto e os resultados clínicos. Este trabalho contribuiu para aumentar o conhecimento sobre a RCSA e demonstrou ter um papel relevante na melhoria da qualidade de vida dos pacientes submetidos a RCSA por RICR.

Palavras-chave autoenxerto, fáscia lata, minimamente invasiva, reconstrução capsular superior, rotura da coifa dos rotadores

Arthroscopic Superior Capsular Reconstruction with a Minimally Invasively Harvested Fascia Lata Autograft – Clinical Importance of Graft Survivorship

Abstract

Arthroscopic superior capsular reconstruction (ASCR) is a recent surgical treatment option for irreparable rotator cuff tears (IRCTs). The first clinical study on ASCR reported significant improvements in clinical and imaging results using an open harvested proximal fascia lata autograft (FLA). Concerns about donor site morbidity led to modifications of ASCR and to the use of the human dermal allograft (HDA). However, inferior clinical outcomes and decreased allograft survival rates were reported. The importance of the choice of the type of graft for each patient, aiming to maximize clinical outcomes in ASCR, remained unclear. We modified ASCR and used a minimally invasively (MI) harvested mid-thigh FLA (MFLA) aiming to reproduce the good clinical results of ASCR using the open harvested proximal FLA (PFLA). This thesis aimed to determine the clinical outcomes of ASCR using either the FLA or HDA, compare the biomechanical properties of the PFLA and MFLA, assess the 3-year clinical and MRI outcomes of ASCR using the MFLA, and determine the clinical importance of graft integrity. The hypotheses were that the ASCR using FLA would produce superior clinical outcomes and a higher graft survival rate than ASCR using the HDA; the biomechanical properties of the PFLA and MFLA would not significantly differ; the clinical outcomes would improve significantly from preoperatively to 3 years and would be significantly worse in patients who had a complete graft tear 3 years after ASCR. We found that ASCR using either FLA or HDA resulted in significant clinical improvements at a minimum follow-up of 12 months; the average values of the stiffness and Young's modulus did not significantly differ between the PFLA and MFLA; the impact of the donor site morbidity of the MI harvesting of the MFLA was low and the clinical outcomes of ASCR using the MFLA were good at 3 years; and complete graft tears were correlated with significantly decreased external rotation strength and increased grades of infraspinatus and teres minor fatty degeneration. The present work shows that graft integrity is important for maintaining improved clinical shoulder outcomes at medium-term and that the MFLA may be a good alternative to the PFLA. Our biomechanical observations may assist in future research designed to determine the role of the FLA, paving the way to finding new strategies to improve the technique, graft healing, and clinical outcomes of ASCR. Finally, this work contributed to increase the knowledge about ASCR and proved to have a relevant role in contributing to the improvement of the quality of life of the patients who undergo ASCR for IRCTs.

Keywords autograft, fascia lata, minimally invasive, rotator cuff tear, superior capsular reconstruction

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List of abbreviations

ADL – Activities of daily living

AHI – Acromiohumeral interval

ASCR – Arthroscopic superior capsular reconstruction

CI – Confidence interval

CMS – Constant–Murley score

ERLS – External rotation lag sign

FLA – Fascia lata autograft

HDA – Human dermal allograft

IRCT – Irreparable rotator cuff tear

LHBT – Long head of the biceps tendon

LR – Likelihood ratio

MFLA – Mid-thigh fascia lata autograft

MI – Minimally invasively

MINORS – Methodological Index for Non-randomized Studies

MRI – Magnetic resonance imaging

PACS – Picture archiving and communication system

PFLA – Proximal thigh fascia lata autograft

PDX – Porcine dermal xenograft

PRISMA – Preferred Reporting Items for Systematic Reviews and Meta-analyses

PROMs – Patient-reported outcome measures

RCT – Rotator cuff tear

RTSA – Reverse total shoulder arthroplasty

SCR – Superior capsular reconstruction

SST – Simple shoulder test

SSV – Subjective shoulder value

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Thesis outline

The current thesis is organized in six chapters, followed by the bibliographic references at the end of the thesis, and one appendix.

Chapter 1 provides the introduction to the problem addressed by the thesis research and outlines the state of current knowledge in the field of irreparable rotator cuff tears (IRCTs) and arthroscopic superior capsular reconstruction (ASCR). The subject is first addressed by an extensive review with regard to the epidemiology, pathoanatomy, clinical history and physical exam, imaging, indications, contraindications, decision-making algorithm and the original and personal surgical techniques of ASCR for the treatment of IRCTs. This chapter ends by emphasizing the outstanding questions regarding ASCR and presenting the rationale for the thesis research.

Chapter 2 provides a detailed description of each of the objectives of the thesis work.

Chapter 3 presents a systematic review conducted to determine the clinical outcomes of ASCR using either the fascia lata autograft (FLA) or human dermal allograft (HDA) for IRCTs. The review showed that ASCR using either FLA or HDA results in significant clinical improvements at a minimum follow-up of 12 months. However, the data on MRI assessment of graft integrity presented in this systematic review strongly support the conclusion that FLA has a low tear rate, whereas no conclusion is supported regarding the graft tear rate of HDA because MRI was inconsistently (not systematically) ordered or was only ordered when there was a clinical concern about the reconstruction integrity in the allograft studies.

Chapter 4 presents the laboratorial part of the experimental work of the thesis and the study conducted to compare the biomechanical properties of proximal- and mid-thigh-harvested FLA constructs used for ASCR. This biomechanical study showed that the average values of the stiffness and Young's modulus did not significantly differ between the two types of FLA constructs. These biomechanical results support that the ASCR that uses the minimally invasively (MI) harvested mid-thigh FLA (MFLA) may be a good alternative to ASCR that uses the openly harvested proximal thigh FLA (PFLA).

Chapter 5 presents the clinical part of the experimental work of the thesis conducted to assess the 3-year clinical and magnetic resonance imaging (MRI) outcomes of ASCR using the MI harvested MFLA for

IRCTs and to determine the clinical importance of graft integrity and whether the results change from year 2 to 3. This clinical study showed that the overall 3-year clinical outcomes were good, despite an increased proportion of graft tears, and confirmed the medium-term low impact of the donor site morbidity of the MI harvesting of the MFLA. These clinical and imaging results show that the ASCR that uses the MI harvested MFLA may be a good alternative to ASCR that uses the openly harvested PFLA.

Chapter 6 presents an overall summary and discussion of the work, describes how the results contribute to solve key issues within the scope of the thesis, presents new perspectives for future research, and summarizes the conclusions of the present thesis.

CHAPTER 1

General introduction

1.1. Introduction

Rotator cuff tears (RCTs) are a frequent cause of disabling shoulder pain, with a prevalence of 20.7%, and an incidence of 36% in subjects presenting with shoulder symptoms.[124] Arthroscopic RCT repair is a successful treatment option and can lead to robust improvements in patient-reported outcome measures.[29] However, rotator cuff retear rates after arthroscopic repair are high, ranging from 11% to 94%;[39, 69, 74] and increase with higher degrees of tendon retraction and fatty infiltration, larger tear size, and shorter acromiohumeral interval (AHI).[39, 109] These characteristics, which are frequently found in patients who have retorn their rotator cuff tendons after arthroscopic RCT repair, have been identified as risk factors for IRCTs. Older age at surgery, longer duration of symptoms, longer duration of overhead sports activities, lower preoperative forward flexion of the shoulder, and shorter AHI have been shown to be independent risk factors for IRCTs.[108] Overall, RCTs are considered irreparable if a direct repair of the native supraspinatus tendon to the greater tuberosity is unattainable, or highly predisposed to healing failure. Patients who have IRCTs may become pseudoparalytic because the remaining shoulder muscles lack a stabilizing glenohumeral fulcrum to act upon. Pseudoparalytic patients are unable to elevate the shoulder above 90°, or to abduct the shoulder above 45°, depending on the definition of pseudoparalysis, which is controversial.[36] In fact, the shoulder function is very limited, and ultimately these patients become unable to perform trivial daily living activities that require shoulder elevation (comb their hair), external rotation (drink a glass of water) and internal rotation (reaching behind the back).

IRCTs have become a frequent problem among an aging population and range from 10% to 40% of all rotator cuff tears, and 80% of recurrent tears.[106] Nonoperative treatment, including nonsteroidal anti-inflammatory drugs, subacromial corticosteroid injections, and physical therapy can be successful in many cases, and should be offered initially.[65] For the subset of patients who fail to improve after conservative treatment and have IRCTs and a preserved glenohumeral articular cartilage, reverse total shoulder arthroplasty (RTSA), which is the standard surgical treatment option usually offered to elderly patients, raises concerns. In this setting, IRCTs are a challenge for orthopedic surgeons because, along with a long life expectancy, most patients wish to continue to lead active lives, and many desire a joint-preserving treatment option.[3] The former may be difficult after, and the latter is inherently incompatible with a RTSA. For the subset of elderly patients who have IRCTs and glenohumeral osteoarthritis, with severe degeneration of the glenohumeral articular cartilage, the surgical treatment option is more

straightforward and RTSA is usually considered an almost uncontested standard surgical treatment option.

Overall, different surgical solutions have been devised to address IRCTs, but none is exempt of limitations, risks or complications.[25, 40, 105, 122] A biomechanical cadaveric study conducted by Mihata et al., in 2012, showed that the superior capsule stabilizes the glenohumeral joint, preventing superior humeral head migration.[84] Moreover, a clinical study by Mihata et al. reported that ASCR effectively reversed pseudoparalytic shoulders in IRCTs.[80] It was hypothesized that the reconstruction of the superior capsule stabilized the glenohumeral joint through a tenodesis effect, allowing the force couples of the subscapularis, teres minor and deltoid muscles to restore shoulder elevation. Inspired by the promising clinical outcomes of ASCR, which is a joint-preserving treatment option, but discouraged by the risk of donor site morbidity after the open proximal thigh harvest of the fascia lata autograft (FLA), other authors proposed modifications to ASCR, and reported their results of ASCR using a human dermal allograft (HDA)[32, 97] or the autologous long head of the biceps tendon (LHBT) graft.[14, 23, 62] However, the preliminary clinical studies on ASCR using an HDA or LHBT[23, 32, 97] did not reproduce the groundbreaking clinical results reported in the studies by Mihata et al.[76, 80] No comparative studies between different types of grafts had been published, but the survivorship of the graft was one of the differences in the reported outcomes in each study. Clinical studies on ASCR using an HDA reported a higher proportion of graft tears, ranging from 20% to 75% in the short term (minimum of a 6-month to 2-year follow-up)[32, 97] whereas studies using an FLA reported proportions of graft tears ranging from 4.2% to 32% in the short to medium term (minimum of a 6-month to 5-year follow-up).[71, 76, 78, 80] It remains unclear and controversial whether the type of graft or graft construct used in ASCR is an important (or even the most important) factor in the clinical success of ASCR.[73] The correlations of graft integrity with clinical outcomes or graft tears as a cause of failure of ASCR have not yet been established.

In 2015, we modified ASCR and used the minimally invasively (MI) harvested mid-thigh FLA (MFLA).[31] The purpose was to reproduce the promising clinical results of the ASCR that used the open harvested proximal thigh FLA (PFLA) in IRCTs,[80] while reducing the risk of donor site morbidity.[5] We reported good 2-year clinical outcomes of ASCR using the MFLA,[31] comparable to those reported in the studies by Mihata et al.[80] that used the PFLA. However, only a short-term 6-month magnetic resonance imaging (MRI) analysis of graft survivorship was conducted, and the biomechanical properties of the MFLA construct remained unknown. The knowledge of the mid-term survivorship of this type of graft construct is important

to determine the clinical relevance of graft integrity in ASCR, and to support the use of the best type of graft that ensures the best outcome for the patient. A comparison between the biomechanical properties of the PFLA and the MFLA constructs is lacking, and this may assist orthopaedic surgeons in the choice of the location, harvesting technique, and type of graft construct for ASCR.

1.2. Pathoanatomy

In recent years, studies on the pathoanatomy of RCTs have begun to focus on the role of the superior capsule of the glenohumeral joint in RCTs.[61, 86, 90] Kim et al. showed that degenerative RCTs most commonly involve a region 13 to 17 mm posterior to the biceps tendon.[61] Nimura et al. showed that this region is near to the thinnest point of the articular capsule.[90] Both the thinnest point of the capsule attachment and supraspinatus insertion were hypothesized as mechanically being the most fragile areas, which might be related to the initiation of degenerative RCTs. According to these authors, the average width of the attachment of the superior capsule ranges from 3.5 ± 0.8 to 9.1 ± 1.7-mm.[90] They found that the wide attachment of the capsule on the humerus, at the border from the infraspinatus to the teres minor, compensated for the lack of tendinous insertion, and concluded that the superior capsule of the glenohumeral joint complements the insertion of the rotator cuff. Further evidence of the importance of the superior capsule was provided in the study by Momma et al.[86] These authors conducted an anatomic analysis of the whole capsule of the glenohumeral joint, with reference to the capsular attachment and thickness, and demonstrated that the articular capsule, compared to other areas, has a wider attachment on the humerus from the inferior edge of the subscapularis insertion to the inferior edge of the teres minor insertion, where no rotator cuff tendons insert. This evidence is contrary to the previously accepted belief that the superior capsule was a thin continuous sheet which was the deepest layer of rotator cuff tendons.[24]

1.3. Functional role of the superior capsule

The functional significance of the superior capsule was mostly overlooked until recently. In 1993, in a case report conducted by Hanada et al.,[50] the rationale of superior capsular reconstruction (SCR) was explained for the first time: the graft was meant to prevent superior migration of the humeral head and to stabilize the head in the anteroposterior plane in an IRCT.[50] A paraplegic patient who had a recurrent, massive and irreparable tear of the supraspinatus, infraspinatus and teres minor tendons, and who had severe pain and was unable to elevate the shoulder above 90 degrees, underwent open SCR. The superior capsule was reconstructed using a rectangular-shaped, four-layered FLA construct, which was implanted through an open approach to the glenohumeral joint and sutured medially to the superior glenoid labrum and bony rim, laterally to the stump of the torn LHBT, anteriorly to the subscapularis, and posteriorly to the stump of the infraspinatus. However, the functional results were unsatisfactory, and the severe pain

and inability to elevate the shoulder beyond the horizontal level persisted. In 2012, the studies conducted by Mihata et al.,[80, 84] were the first to report the biomechanical significance and good clinical results of ASCR for IRCTs.

The main rationale behind SCR is fundamentally that the tenodesis effect of the superior capsular graft restores the static vertical and horizontal glenohumeral stabilizing roles of the rotator cuff and superior capsule, which are lost in IRCTs. The optimal function of the intact glenohumeral joint depends on maintaining a stable center of rotation (COR) throughout the range of motion (ROM). The COR is maintained when the dynamic equilibrium between the vectorial forces in the vertical and horizontal planes provided by the two force couples shown in Fig. 1.1 is preserved.[13]

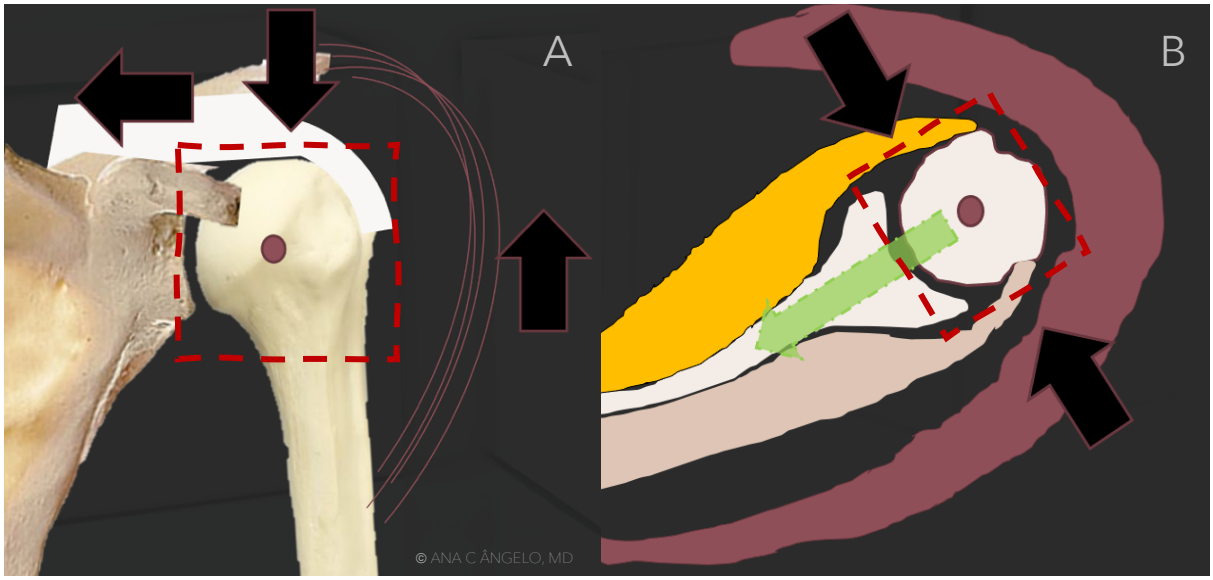

Fig. 1.1. Vertical and horizontal force couples stabilizing the intact glenohumeral joint. Fig. 1.1-A The deltoid (red curved lines) and posterosuperior rotator cuff tendons (white solid curve) pull the humeral head up, and the superior capsule and the tension created by the activation of the posterosuperior cuff push the humeral head down; the native center of rotation (red dot) of the glenohumeral joint is preserved and the humeral head is maintained inside the box (dashed red square) throughout the range of motion, and **(Fig. 1.1-B)** the anterior capsule and the contraction of the subscapularis muscle (yellow) push the humeral head posteriorly, and the posterior capsule and tension of the postero-inferior rotator cuff (light brown) push the humeral head anteriorly; these horizontal force couples compress the humeral head towards the glenoid concavity (green arrow) and maintain the native center of rotation (red dot) and the humeral head inside the box (dashed red square) throughout the range of motion of the glenohumeral joint. Reproduced and adapted from Dr. Ana Catarina Ângelo, with permission.[13]

The superior capsular graft in patients who undergo ASCR for the treatment of IRCTs acts as the fulcrum to the deltoid pulling vector and restores vertical stability of the glenohumeral joint, as shown in Fig. 1.2.[13] The suturing of the superior capsular graft to the remnants of the posteroinferior rotator cuff tendons posteriorly, and the integrity of the subscapularis tendon anteriorly, restore the horizontal stability of the glenohumeral joint. Theoretically, the restoration of the vertical and horizontal glenohumeral static role of

the superior capsule allows for the remaining shoulder muscles to act efficiently and recover painless forward flexion.

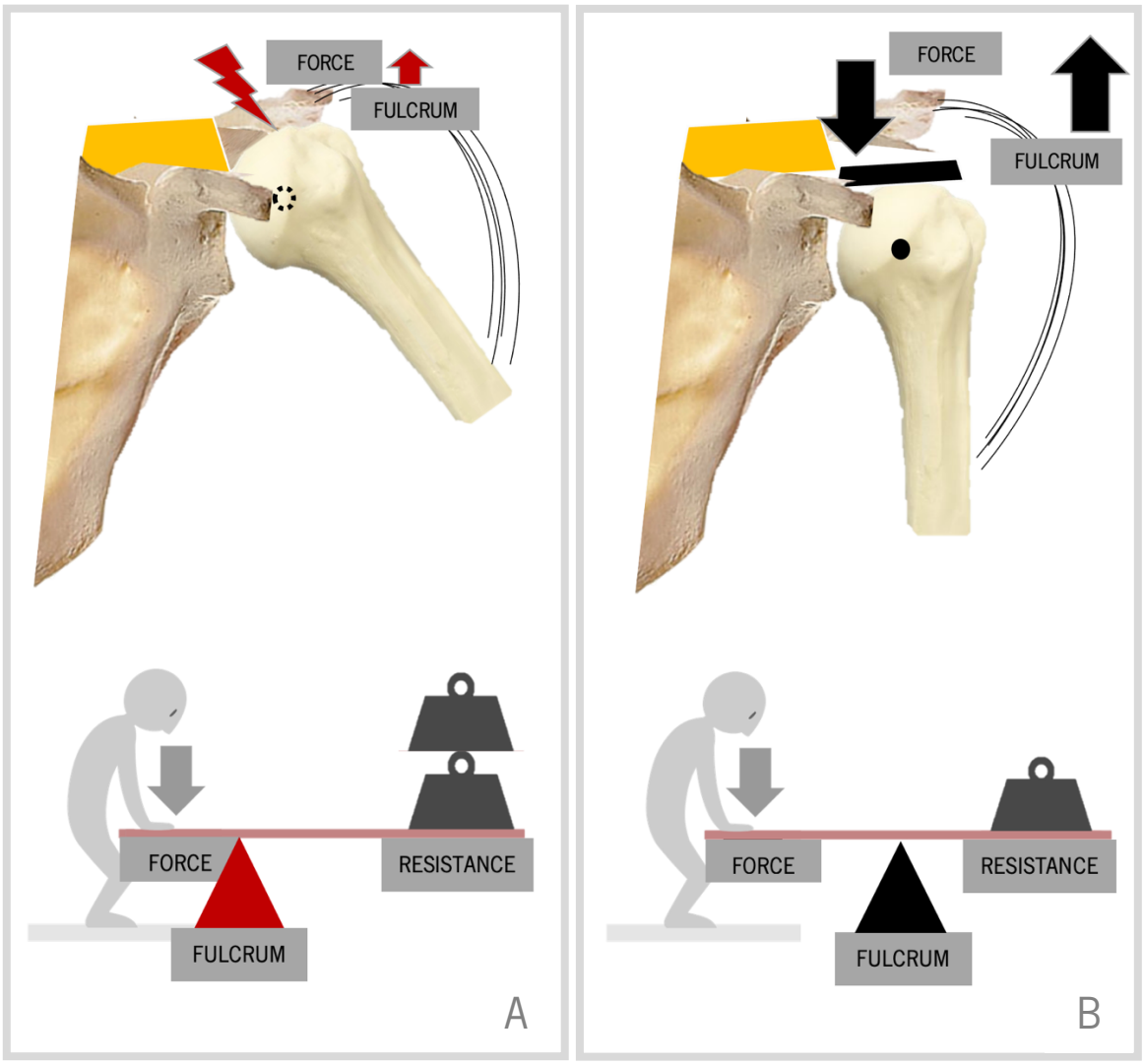

Fig. 1.2. Vertical instability of the glenohumeral joint in irreparable rotator cuff tears. Fig. 1.2-A Vertical stability is lost because the supraspinatus, which is retracted to the glenoid level (yellow trapezoid) is unable to transmit the stabilizing compressive and downward force to the humerus, and the vertical pulling vector of the deltoid muscle (curved black lines) is unresisted and disrupts the glenohumeral center of rotation (dashed dot) when the patient tries to elevate or abduct the shoulder, resulting in the typical "shoulder shrug" of pseudoparalytic patients, and **(Fig. 1.2-B)** vertical stability is restored after arthroscopic superior capsular reconstruction through the fulcrum effect of the superior capsular graft (black trapezoid) which transmits a compressive and downward force that maintains the native glenohumeral center of rotation (black dot) and resists the deltoid (curved black lines) pulling vertical vector when the patient initiates elevation or abduction, resulting in efficient elevation or abduction of the shoulder. Reproduced and adapted from Dr. Ana Catarina Ângelo, with permission.[13]

1.4. Patient history and physical examination

Patients who have a symptomatic IRCT typically present with chronic intractable shoulder pain, with or without a history of shoulder trauma. Active ROM is progressively reduced, while free passive forward flexion is usually preserved. Frequently patients are unable to maintain forward flexion of more than 90° and are severely limited in their ability to perform the activities of daily living (ADL). The combination of history and clinical tests optimal to establish the diagnosis of RCTs remains unknown,[118] and it is difficult to diagnose RCTs based purely on the history and physical exam. However, the various combinations of patient characteristics and shoulder-specific clinical tests are very useful to guide the decision of additional imaging, to confirm the diagnosis, establish a prognosis, and select the appropriate treatment option.[66]

1.4.1. History

Several shoulder-specific patient reported outcome measures (PROMs) have been described in the literature to standardize the clinical assessment of patients with different shoulder conditions.[6] Each PROM has advantages and disadvantages. Therefore, we routinely use a combination of the following PROMs to standardize the history questions in the clinical assessment of rotator cuff pathology, preoperatively and postoperatively at different follow-up periods: the simple shoulder test (SST),[72] the subjective shoulder value (SSV),[45] and the Constant-Murley score (CMS).[27]

The SST was originally described by Lippitt et al. in 1993,[72] and was designed to be used for patient self-assessment of general shoulder function. The test consists of 12 questions, and each positive answer scores 1 point (range, 1–12 points). For the scale range provided, higher values represent a better outcome. The test has been shown to be a highly reliable, valid, and responsive instrument, with an acceptable conceptual and measurement model, interpretability, and low administrative burden requirements, and has been recommended for use in longitudinal studies or clinical trials, where responsiveness to change and reproducibility are the maximum priority.[104] The SST was successfully validated for the Portuguese language in 2013.[89]

The SSV was first described in the study conducted by Gilbart and Gerber in 2007,[45] designed with the purpose of evaluating the SSV and comparing it with the CMS. The SSV is defined as a patient's subjective shoulder assessment expressed as a percentage of an entirely normal shoulder, which would score 100%.

The scale ranges from 0 to 100%; for this scale range, higher values represent a better outcome. The SSV is considered an easily administered, responsive, and valid measure of shoulder function, that offers an additional tool to measure shoulder function easily in addition to the more complicated outcome measures.[45]

The CMS, which was first described by Constant and Murley in 1987, is an instrument to evaluate overall shoulder function.[27] The score assesses four aspects related to shoulder pathology; two subjective: pain and ADL and two objective: ROM and abduction strength. The subjective components can receive up to 35 points and the objective 65. The pain and ADL questions are answered by the patient; the ROM and abduction strength questionnaire requires a physical evaluation and is answered by the examiner who measures the ROM and abduction strength using a goniometer and a digital dynamometer, respectively. The CMS scale ranges from 0 to 100 points, and higher values represent a better outcome. The CMS was recommended by the executive committee of the European Society for Surgery of the Shoulder and the Elbow and has been widely used as an assessment method ever since.[6] Systematic reviews have provided evidence to support the use of the CMS for specific clinical and research application, and it has been used in almost every language without official translations because surgeons perceived the score as a clinical measure.[103] Other authors have recommended the use of CMS for patients with subacromial pathology, and not for other shoulder conditions.[121] The CMS was successfully validated for the Portuguese language in 2016.[10]

1.4.2. Physical examination

The patients are systematically assessed using a goniometer to measure (in degrees) both the active painless shoulder ROM, and the passive ROM, in elevation (range, 0 – 180°), abduction (range, 0 – 180°), and external rotation with the arm at the side (range, 0 – 100°). Active internal rotation is defined as the highest vertebral body that the patient's thumb can reach without sustaining pain. Painless shoulder abduction strength in full pronation, with the elbow in full extension and the shoulder in 90° of abduction in the scapular plane, is systematically measured (in kilograms) using a digital dynamometer strapped to the forearm (range, 0 – 15 Kg). For each of the scale ranges provided, higher values represent a better outcome. An active shoulder elevation below 90° or an abduction below 45° in the plane of the scapula may be defined as a pseudoparalitic shoulder,[36] which is highly suggestive for the diagnosis of an IRCT. We follow the original recommendation made in the study by Constant and Murley,[27] and abduction

strength is scored as zero in patients who are unable to achieve 90° of abduction in the plane of the scapula.

Several authors have devised different shoulder-specific clinical tests that attempt to identify the affected tendons in RCTs. However, while more than 180 tests have been described in the literature, no clinical test is 100% of sensitive and 100% specific for the diagnosis of RCTs, and systematic reviews of the literature have shown that for each test there is a wide range of sensitivity and specificity across the studies.[56] Therefore, no single clinical test is sufficiently reliable to diagnose a RCT.[66] In clinical practice, shoulder surgeons should systematically perform a combination of clinical tests, oriented by the clinical history, which should be used to guide the decision regarding further imaging investigation, to establish the most accurate diagnosis, and tailor the treatment plan to suit the patient's functional and pain relief goals.[66] We systematically use a combination of two types of clinical shoulder tests in patients who present with the aforementioned clinical history suggestive of a RCT: integrity tests and lag signs. The integrity tests were designed to assess whether a movement can be performed actively, and we routinely use the Jobe,[57] Speed,[28, 46] Yocum,[126] bear-hug,[12] and lift-off tests.[41] The lag signs were designed to assess whether a passive position can be maintained, and we routinely use the external rotation lag sign (ERLS).[52] We use these tests sequentially. The order and rationale for the choice of each test is presented below.

First, the **Jobe test** is performed, which was first described by Jobe and Moynes in 1982,[57] and aims to isolate to some extent the activity of the supraspinatus tendon. The test is performed with the patient standing, with the shoulder placed in a position of 90° of abduction, 30° of elevation (in the scapular plane), and full internal rotation with the thumb pointing downwards (thus also being known as the "empty can test"). The patient is asked to maintain this position, and to resist against a downward force applied by the examiner. The test is considered positive when the patient demonstrates pain and weakness trying to resist the applied downward force. Despite a low specificity (range, 56.6% – 62%),[56, 118] several studies have reported that this test is one of the most sensitive tests for the diagnosis of a supraspinatus tendon tear (range, 68.4% – 88%).[56, 66, 118] Nevertheless, systematic reviews have reported a wide variation in sensitivity and specificity of Jobe's test to detect supraspinatus tears, ranging from 19% to 99% and 39% to 100%, respectively.[56]

Second, the **Speed test** is performed, which was first described in the literature in 1966.[28, 46] This test cannot isolate biceps tendon pathology, but it is highly sensitive for RCTs because the complex anatomic

relationship between the biceps tendon, rotator interval, subscapularis and supraspinatus tendons and association between anterior–superior RCTs and rotator interval injury, mean injury to any of these structures may provoke pain during this test.[19] The test is performed with the patient standing, with the shoulder placed in a position of 90° of elevation, and full external rotation (with the palm up). The patient is asked to maintain this position, and to resist against a downward force applied by the examiner. The test is considered positive when the patient demonstrates pain and weakness trying to resist the applied downward force. Despite a low specificity of 37%, this is one of the most sensitive tests for the diagnosis of a medium to large, or multitendon RCTs (sensitivity, 96%).[19] When discussing the treatment plan with the patients who have a positive Speed's test, we explain that we systematically perform a LHBT tenotomy or tenodesis concomitantly with the ASCR which theoretically contributes to the resolution of pain by eliminating one of the main pain generators involved in IRCTs.

Third, **Yocum's test** is performed, which was originally described by Yocum in 1983,[126] and was designed to identify subacromial space pathology. The test is performed with the patient standing, with the shoulder placed in a position of adduction, and the elbow flexed with the hand resting over the contralateral shoulder. The patient is asked to raise the elbow without moving the shoulder trying to resist against the downward pressure applied by the examiner on the elbow. The test is considered positive if the patient has pain while trying to raise the elbow. The diagnostic accuracy of the Yocum's test for detecting supraspinatus tendon tears is considered clinically useful because this test has a sensitivity of 78% and specificity of 96%, and a positive likelihood ratio (LR) of 19.5 (positive LR ≥ 2.0), and a negative LR of 0.23 (negative LR ≤ 0.5).[119] Indeed, patients who have a RCT only very rarely will not have at least one of the first three aforementioned tests positive. The choice to perform Yocum's test instead of the Hawkins-Kennedy's test,[51] which has comparable diagnostic accuracy for the detection of supraspinatus tears, is justified because Yocum's test is performed with the patient's shoulder in the same position required for the following test, and this assists the surgeon in conducting a fluid and systematic physical exam.

Fourth, the **bear-hug test** is performed, which was first described in 2006 in the study by Barth et al.[12] The test was designed to detect subscapularis tendon tears and was found to be one of the most sensitive clinical tests for subscapularis function because it recruited the fibers of the upper third of the subscapularis tendon. The patient maintains the aforementioned position, and the test is performed with the patient standing, the shoulder placed in a position of adduction, and the elbow flexed with the hand resting over the contralateral shoulder. The patient is asked to push the palm of the hand downwards on

the shoulder (while extending their fingers, to avoid the natural reflex of holding on to the shoulder) and is instructed to resist against the upward pressure applied by the examiner on the palm of the patient's hand. The test is considered positive when the patient cannot resist the examiner's upward force.

Fifth, the **ERLS** is performed, which was originally described by Hertel et al. in 1996.[52] The patient is seated with their back to the examiner. The elbow is passively flexed to 90°, and the shoulder is held at 20° of elevation (in the scapular plane) and near maximal external rotation by the examiner. The patient is then asked to actively maintain the position of external rotation in elevation as the examiner releases the wrist while maintaining support of the limb at the elbow. The sign is positive when a lag, or angular drop, occurs. The magnitude of the lag is recorded to the nearest 5°. The ERLS was originally designed to test the integrity of the supraspinatus and infraspinatus by reducing confounding factors, such as pain, and the magnitude of the lag was shown to correlate with the size of the rupture. Several authors found this sign to be more sensitive for the detection of RCTs involving the teres minor, and suggested that higher lag signs (> 40°) indicate the involvement of the teres minor.[21, 26] Indeed, the systematic review with meta-analysis of clinical studies reporting on the diagnostic accuracy of clinical tests to diagnose posterosuperior RCTs involving the infraspinatus, supraspinatus and/or teres minor conducted by Lädermann et al.[66] showed that combining the Jobe test and the ERLS could improve diagnostic accuracy to detect posterosuperior RCTs, and concluded that as no single clinical test is sufficiently reliable to diagnose posterosuperior RCTs, clinicians should consider various combinations of patient characteristics and clinical tests including the Jobe test and ERLS.

Sixth, the **lift-off test** is performed, which was first described by Gerber and Krushell in 1991,[41] and was originally designed to isolate a subscapularis tendon tear. The patient is seated with their back to the examiner, and the patient's shoulder is passively internally rotated, with their hand placed behind the back and off the patient's spine. The test is considered positive when, after the examiner releases the maximally internally rotated shoulder, the patient cannot actively maintain the internal rotation, and their hand drops straight back and cannot be lifted off the spine without the patient extending the elbow. The result is considered weak when the patient can maintain the position of maximal internal rotation but is unable to apply resistance to the examiner's hand. The lift-off test is considered one of the most specific tests for the detection of a subscapularis tendon tear, with reports of 100% of specificity,[12, 118] and of infinite positive LR,[118] meaning that if the lift-off test is positive, one can be sure that the subscapularis tendon is torn. However, the test has some limitations: it is impossible to perform in patients who are stiff and

cannot passively internally rotate the shoulder behind the back; it has a low sensitivity (sensitivity, 13.2%; negative LR, 0.87%),[118] meaning that a negative result of the lift-off test does not exclude the presence of a subscapularis tendon tear; it has been shown to be more sensitive to detect lesions affecting the lower subscapularis tendon,[116] and only after 75% or more of the subscapularis tendon is torn.[12]

We systematically use both the bear-hug and lift-off tests to help increase our sensitivity for the detection of subscapularis tendon tears, and to assist us in the preoperative prediction of the size of the subscapularis tendon tear. When the bear-hug test is positive and the lift-off test is negative, the preoperative suspicion is higher for a smaller-sized, upper-third, repairable subscapularis tendon tear, whereas when both tests are positive, the preoperative suspicion is higher for a larger-sized, with 75% or more of the subscapularis tendon torn, with involvement of the upper and lower subscapularis tendon fibers, which may be irreparable. This clinical information is important in the decision-making algorithm for the treatment of IRCTs. ASCR in a patient who has a reparable subscapularis tendon tear has a better prognosis than ASCR with an irreparable subscapularis tendon tear, and in this setting, ASCR combined with latissimus dorsi transfer for the subscapularis tendon tear should be considered.[77]

1.5. Imaging

The preoperative study of patients who have a presumptive diagnosis of an IRCT must include radiographic and magnetic resonance imaging (MRI). The purpose is to adequately identify any predictors of RCT irreparability.

1.5.1. Radiography (X-ray)

Radiographic changes are evaluated in terms of the AHI, which is the distance between the top of the humeral head and the undersurface of the acromion in the true glenohumeral joint anteroposterior view; this distance is frequently < 7 mm in patients with IRCTs.[42] RCT arthropathy is graded according to the revised radiographic classification of Hamada et al.:[48] grade 1 is defined as an AHI ≥6 mm, grade 2 as ≤5 mm, grade 3 as acetabulization (concave deformity of the acromion undersurface) plus an AHI ≤5 mm, grade 4 as narrowing of the glenohumeral joint plus conditions required for grade 3, and grade 5 as humeral head collapse.

1.5.2. Magnetic Resonance Imaging (MRI)

T2-weighted MRI scans are used to evaluate preoperative tear size of the supraspinatus tendon. Supraspinatus tendon retraction in the MRI coronal plane is classified according to Patte.[96] Patte stage 1 means that the supraspinatus tendon is close to the bony insertion on the greater tuberosity; stage 2 means that the tendon is at the level of the humeral head; and stage 3 means that the tendon is at the level of the glenoid. Patients with IRCTs usually present with severe medial retraction of the supraspinatus tendon to the glenoid level, classified as Patte stage 3.

Muscle atrophy of the supraspinatus is measured by use of the tangent sign on the T1-weighted sagittal oblique Y-scapular view. The tangent sign is regarded as positive, meaning that there is severe atrophy of the supraspinatus muscle, when the superior border of the supraspinatus muscle is inferior in relation to the line tangential to the coracoid and scapular spine;[127] this sign is usually positive in IRCTs.

Fatty infiltration of supraspinatus, infraspinatus, teres minor, and subscapularis muscles is evaluated in the T1-weighted sagittal oblique Y-scapular view by use of the 5-stage grading system that focuses on the

amount of fatty deposition within the muscle, as developed by Goutallier et al. for computed tomography (CT) scan,[47] and validated by Fuchs et al. for MRI.[38] Goutallier grade 0, means that there are no fatty streaks visible within the muscle; grade 1, means that some fatty streaks are visible within the muscle; grade 2, means that there is more muscle than fat; grade 3, means that there is as much muscle as fat; grade 4, means that there is less muscle than fat. Goutallier grades 1 and 2 each represent mild fatty infiltration of the muscle, which is usually present in reparable RCTs, whereas Goutallier grades 3 and 4 each represent severe fatty infiltration of the muscle, which is usually present in IRCTs.

1.6. Indications and contraindications for arthroscopic superior capsular reconstruction (ASCR)

1.6.1. Indications

Active patients with an intractable dysfunctional painful shoulder, complete passive ROM, and an irreparable posterosuperior RCT, i.e., with a supraspinatus and/or infraspinatus tendon tear, are candidates for ASCR.

1.6.2. Contraindications

Infection, lesion of the brachial plexus, or deltoid dysfunction of any cause are absolute contraindications for ASCR.

Patients with an irreparable supraspinatus and/or infraspinatus tendon tear, who present with an associated irreparable subscapularis tendon tear, with severe medial retraction of the subscapularis tendon, and fatty infiltration Goutallier grade 4[47] of the subscapularis muscle on preoperative MRI,[38] have a poorer prognosis after ASCR. Both a tear involving more than 50% of the subscapularis tendon, with fatty infiltration Goutallier grade 3, and a teres minor tear extension of the tear, compromise the balance of the horizontal force couple and are associated with true chronic pseudoparalysis, defined as the inability to actively abduct the shoulder above 45°;[36] the subscapularis tendon has been considered an important factor for achieving good clinical outcomes after ASCR in patients with pseudoparalysis;[114] thus, an irreparable subscapularis tendon tear is a relative contraindication for ASCR. In this setting, it has been suggested that ASCR should be combined with tendon transfer.[77]

Patients presenting with radiographic changes related to RCT arthropathy, Hamada grade 3 or 4,[48] may also have a poorer prognosis after ASCR;[32] therefore, radiographic changes Hamada grade 3 or 4 may be considered a relative contraindication for ASCR.

1.7. Decision-making algorithm

1.7.1. Preoperative decision-making

Patients who are diagnosed with a posterosuperior RCT, i.e., a supraspinatus and/or infraspinatus tendon tear presenting with clinical and imaging risk factors of RCT irreparability are candidates for ASCR. Older age at surgery, longer duration of symptoms, longer duration of overhead sports or work activities, lower preoperative forward flexion of the shoulder,[108] AHI of < 7 mm,[42] stage 3 or 4 fatty infiltration,[39, 42, 109] severe medial retraction of the supraspinatus tendon, and a positive tangent sign,[39, 109, 127] are considered clinical and imaging predictors of RCT irreparability, and should prompt surgeons to offer the option of ASCR. The preoperative decision-making algorithm of ASCR for IRCTs takes into consideration other factors (Fig. 1.3), such as the status of the articular cartilage of the glenohumeral joint, loss of passive ROM, and management of patient expectations with regard to joint preservation and ROM recovery.

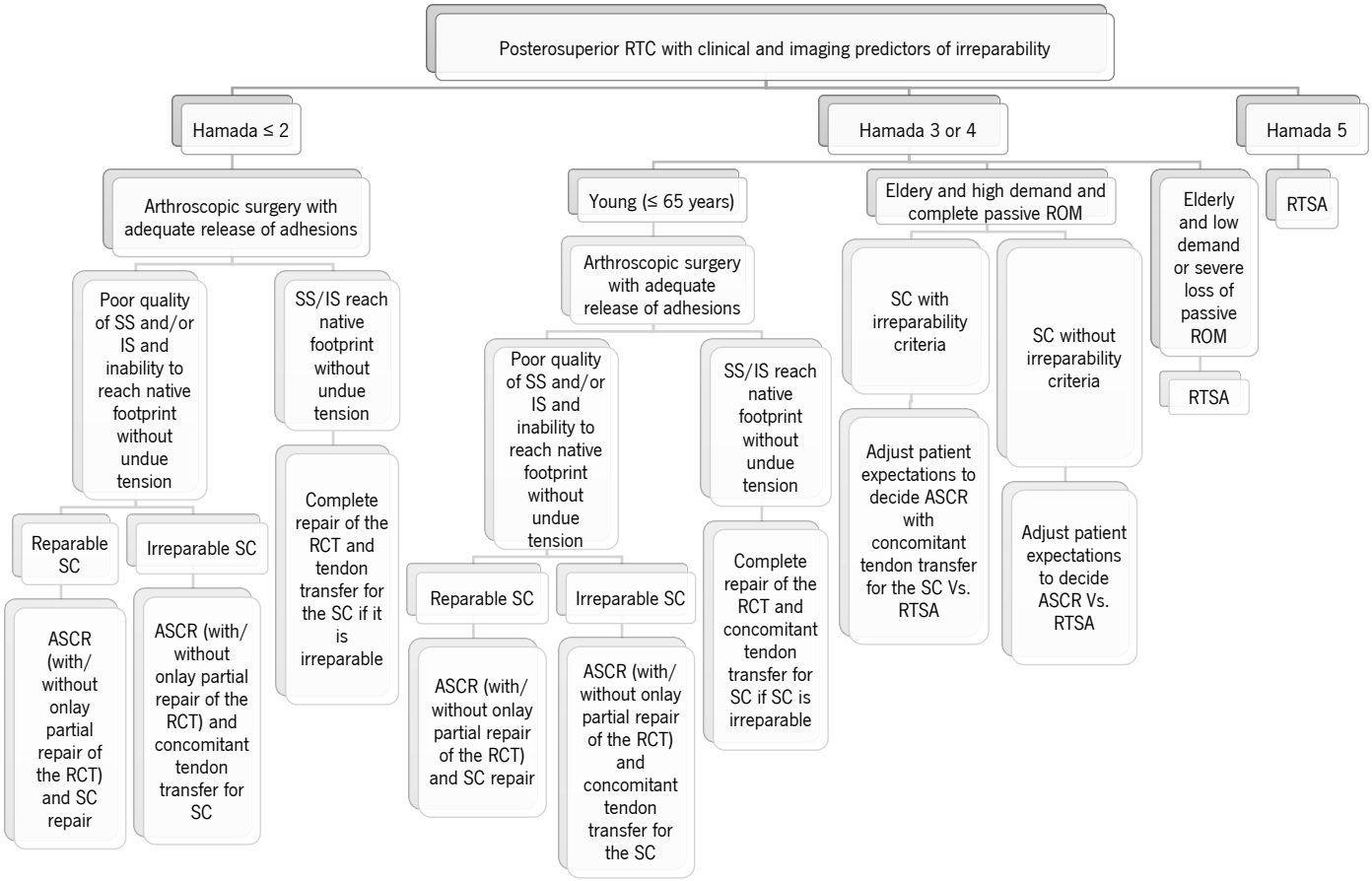

Figure 1.3 Decision-making algorithm for irreparable rotator cuff tears. ASCR, Arthroscopic superior capsule reconstruction; IS, Infraspinatus tendon; RCT, Rotator cuff tear; RTSA, Reverse total shoulder arthroplasty; SC, Subscapularis tendon; SS, supraspinatus tendon.

1.7.2. Intraoperative decision-making

The tendon's poor quality as evaluated intraoperatively is the ultimate criterion of irreparability. Every attempt is always made to successfully repair the posterosuperior RCT before deciding to proceed to ASCR; the grasper test is usually enough to determine poor tendon quality. However, any posterosuperior RCT repair ultimately may fail intraoperatively. Thus, patients who present with apparently reparable posterosuperior RCTs, with at least one clinical or imaging risk factor of irreparability, must provide their informed consent for ASCR. In addition, in patients who present with associated clinical or imaging risk factors of irreparability of the subscapularis tendon tear, ASCR combined with tendon transfer should be preoperatively discussed and consented for.

1.8. Surgical technique

The original technique of ASCR, which was first described in the study by Mihata et al.,[80] is performed with the patient in lateral decubitus, uses 3 arthroscopic portals, and an openly harvested PFLA, which is fixed to the superior glenoid rim and humeral head with the shoulder in 30 to 45 degrees of abduction. Other authors have described different ASCR techniques, with different patient positionings, using different arthroscopic portals (ranging from 3 to 5 portals), with other types of grafts (autografts, allografts, or xenografts), fixed with the shoulder in other angles of abduction, and using different fixation techniques.[1, 14, 15, 23, 31, 53, 88, 98] The ASCR technique used by the author of this thesis is described in detail below. In this technique, the MI harvested MFLA is used.[31]

Patients undergo surgery under general anesthesia and in the beach-chair position. The shoulder and ipsilateral thigh are surgically draped for shoulder arthroscopic surgery and for minimally invasive fascia lata harvesting. Shoulder passive ROM is confirmed. The forearm is placed in 3-kg forward traction at 70 degrees of forward flexion and 10 degrees of abduction and in neutral shoulder rotation. Alternatively, a mechanical arm positioner may be used to achieve equivalent shoulder position and traction during the procedure.

ASCR is performed through a 3-portal technique: a posterior (first) shoulder portal is established 2 cm medial to the posterolateral corner of the acromion, immediately under it, aiming the 4-mm and 30 degrees arthroscope at the coracoid process; an anterior (second) portal is established in the rotator interval under direct glenohumeral arthroscopic vision, and a working cannula (ideally a 5 X 85–mm cannula) with an outflow connection (attached to a closed-system arthroscopic pump) is placed through it; and a lateral (third) portal is established directly under the lateral acromion, and a needle is used to ensure the portal is placed with a good attack angle to the superior glenoid rim (usually this portal is 1 cm long and digitally tested to ensure an adequate dimension with no obstacles to graft shuttling).

A gauged probe and an arthroscopic grasper are used to confirm the poor quality of the supraspinatus and/or infraspinatus tendons and inability to reach the native footprint without undue tension. In recurrent RCTs, all previous sutures should be removed. The RCT is considered irreparable if the torn tendons are frail and do not pass the grasper or suture tests, therefore not reaching their native footprint without undue tension or further tearing. The RCT is considered reparable, and patients undergo RCT repair

instead of ASCR, if after adequate release of adhesions, the torn tendons pass the grasper or suture tests, therefore successfully reaching their native footprint without undue tension.

After the IRCT is arthroscopically confirmed, the graft is harvested. The FLA is harvested through 2 horizontal (transverse) 2 cm–long skin incisions on the ipsilateral thigh, both 4 cm anterior to the lateral intermuscular septum: one 15 cm distal to the anterior iliac spine and the other 10 cm proximal to the lateral femoral epicondyle (Fig. 1.4).

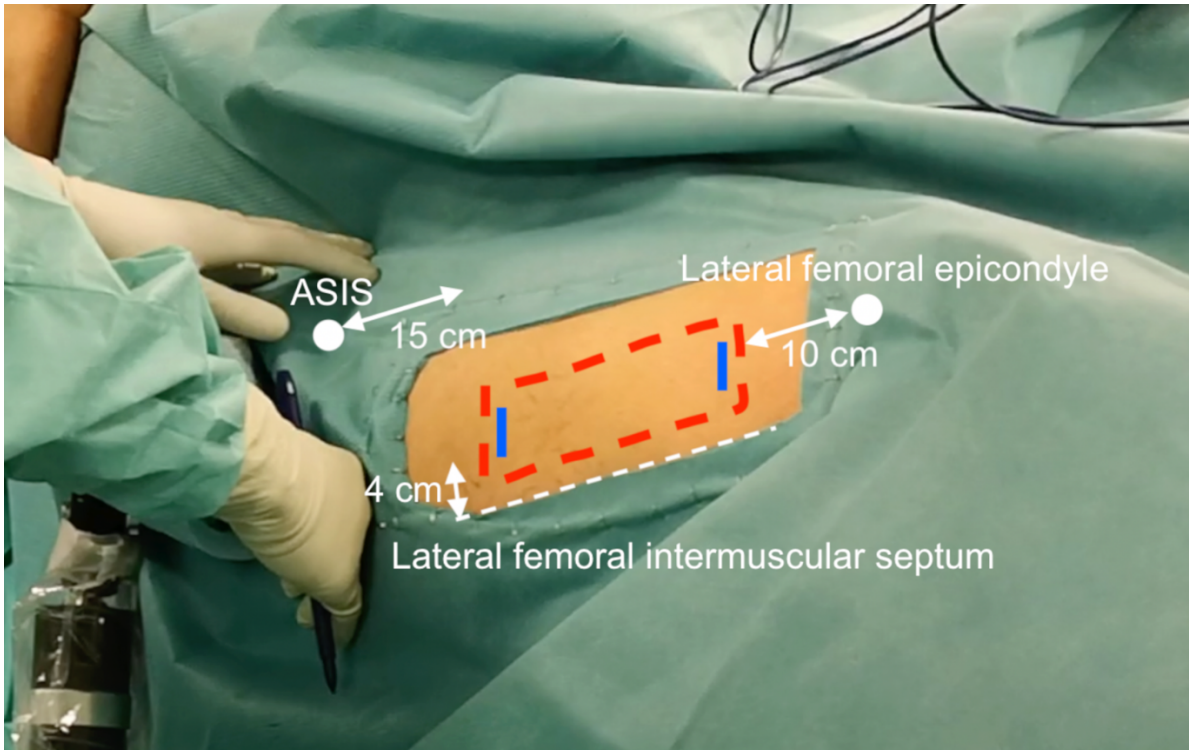

Fig. 1.4. Anatomical references for the minimally invasive harvest of the mid-thigh fascia lata autograft. The patient is in the beach-chair position and the right thigh is surgically draped for the harvest of the mid-thigh fascia lata autograft. Two horizontal (transverse) 2 cm–long skin incisions (blue lines), both 4 cm anterior to the lateral intermuscular septum: one 15 cm distal to the anterior iliac spine (**ASIS**, white dot) and the other 10 cm proximal to the **lateral femoral epicondyle** (white dot) are planned, aiming to harvest a 15 to 20 x 3–cm graft (red-dotted rectangle).

Intra-articular LHBT tenotomy or tenodesis is always performed, except when the LHBT is intra-articularly absent. Subscapularis tendon tears should always be repaired to their native footprint. Mattress sutures using 2.8-mm all-suture double-loaded anchors are usually used. The supraspinatus and infraspinatus tendon footprints and the superior glenoid rim underneath the superior labrum are debrided using a 4 x 125–mm automated shaver and a 3.5 x 135–mm radiofrequency ablator probe. For initial graft preparation, the superior capsular defect is measured from anterior to posterior and from medial to lateral

using a gauged probe. The 15 to 20 x 3–cm harvested FLA is typically folded three times: first from anterior to posterior, next from distal do proximal, and last from proximal to distal; therefore, usually the final MFLA construct has six layers. This results in a 5 to 8 mm–thick final superior capsular graft, which is typically 3.5 cm long and 2.5 cm wide. This graft is peripherally sutured in a continuous fashion with 1 nonabsorbable suture (No. 2). Through the lateral portal, two 1.8-mm all-suture double-loaded anchors are implanted on the superior glenoid rim (approximately 1 cm apart) underneath the superior labrum. Additionally, two 2.8-mm all-suture double-loaded anchors are implanted on the supraspinatus footprint (approximately 1 cm apart). The distances between the anchors are measured using the gauged probe. Using a dermographic pen, the corresponding glenoid and humeral anchor placements are marked on the graft. After passing all suture limbs from the glenoid and humeral anchors through the graft and with the suture passer ex vivo (Fig. 1.5), the graft is shuttled through the lateral portal into the glenohumeral joint using the double-pulley technique. All the glenoid and humeral anchors' sutures are tied. Subsequently, two 4.5-mm knotless anchors are loaded with all the suture limbs from the humeral footprint anchors and are implanted lateral to the humeral footprint in a transosseous-equivalent configuration. When feasible, the limbs of the sutures from the humeral footprint anchors are passed through the supraspinatus and/or infraspinatus remnants with the suture passer before being loaded into the knotless lateral anchors and used in an onlay partial RCT repair to the superior capsular graft. Otherwise, 2 sutures (No. 2) are passed from the superior margin of the teres minor, or from the anterior margin of the remaining infraspinatus tendon, when available, to the posterior margin of the superior capsular graft. All knots are tied with the shoulder at 70 degrees of forward flexion and 10 degrees of abduction and in neutral rotation. A dynamic subacromial arthroscopic examination is performed to exclude any subacromial conflict with the graft and knots throughout shoulder ROM. Whenever the subacromial space conflicts with the graft or knots, anterior acromioplasty is performed using a 4 x 125–mm automated shaver blade.

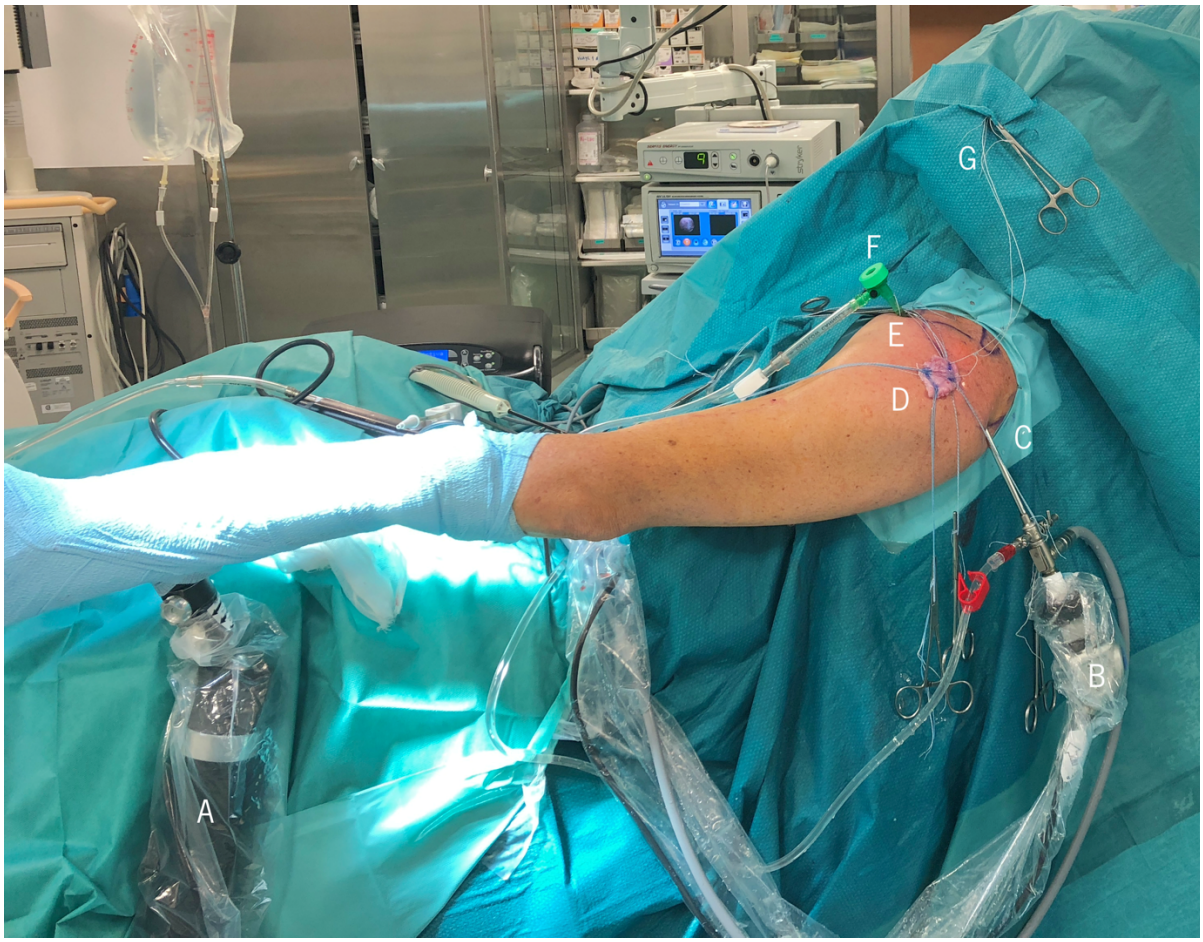

Fig. 1.5. Shoulder positioning and arthroscopic portals for arthroscopic superior capsular reconstruction. The left forearm is placed in a mechanical arm positioner **(A)** in forward traction at 70 degrees of forward flexion and 10 degrees of abduction and in neutral shoulder rotation. The arthroscope **(B)** is placed through the posterior portal **(C)**. The mid-thigh fascia lata autograft construct **(D**) with all suture limbs from the implanted anchors passed through is ready to be shuttled intra-articularly through the lateral portal. The anterior portal **(E)** is used for the outflow cannula **(F)**. The two suture limbs of the double-pulley knot are referenced and temporarily fixed to the surgical drapes using a hemostat clamp **(G)**, for suture management.

1.9. Rehabilitation protocol for ASCR

Several shoulder rehabilitation protocols for ASCR have been proposed, and succinctly described.[68] Each author recommends an unique rehabilitation algorithm, with different durations of use of a sling or brace, and different timings for the initiation of passive and active ROM, strengthening exercises, and return to full activity. The recommended immobilization period among ASCR studies ranges from 3 to 6 weeks, using either a sling, or an abduction brace with the shoulder placed either at 20 or 60° of abduction, with several authors allowing patients to start passive ROM of the shoulder immediately after surgery while still using the sling. Therefore, the date of initiation of passive and active ROM exercises ranges from immediately, as tolerated, to 5 to 8 weeks after surgery, with strengthening exercises starting from 8 to 24 weeks after surgery and beginning either with rotator cuff and scapula stabilizers strengthening, or with external rotation exercises exclusively. No consensus is found in the literature with regard to the timing of the return to full activity, that may range from 6 to 12 months after ASCR. Furthermore, ASCR is seldom performed as an isolated procedure, and concomitant procedures warrant for adjustments in the rehabilitation protocol. Patients who undergo LHBT tenotomy or tenodesis are instructed to delay active resisted flexion of the elbow for 6 weeks after ASCR to allow for LHBT healing in the bicipital groove, and avoid cosmetic deformities, such as the Popeye sign. The type of graft used also changes the rehabilitation protocol for ASCR, and using the LHBT autograft in situ warrants for shoulder and elbow immobilization in the sling for 4 to 6 weeks without passive ROM exercises while in the sling.[62]

CHAPTER 2

Objectives of the thesis

2.1. Objectives

Since the pivotal study by Mihata et al.,[80] published in 2013, most studies that had reported the clinical outcomes of ASCR for IRCTs were retrospectively designed (with different follow-up periods for each patient),[32, 70, 76, 97] and going forward, until 2019, very few other authors reported the clinical outcomes of ASCR using the FLA exclusively besides some more recent clinical studies conducted by Mihata et al.,[76, 78] Lim et al.,[71] and De Campos Azevedo et al..[31] Other studies reported the clinical results of ASCR using allografts,[123] or LHBT autografts,[23] or reported mixed outcomes using an allograft or a FLA,[70] mostly with inferior clinical outcomes and a higher proportion of graft tears compared with those reported in the studies conducted by Mihata et al.[76, 78, 80] It remained unclear and controversial whether the type of graft or of graft construct used in ASCR was an important factor in the clinical success of ASCR.[73] Therefore, we decided to work on understanding both the role and the impact of survivorship of the FLA in the clinical outcomes after ASCR for IRCTs. We aimed to understand the role and medium-term survivorship of the MFLA. We hypothesized that the mechanical properties of the MFLA construct would be at least similar to the PFLA construct, while allowing for a minimally invasive approach to the donor site instead of the open approach required for the harvest of the PFLA. We also hypothesized that the survival of the graft would be a critical condition to obtain good clinical results at medium term follow-up.

In summary, the main purposes of the current thesis are:

1) to determine the current knowledge on the clinical outcomes of ASCR for IRCTs.

2) to determine and compare the biomechanical properties of the PFLA and the MFLA constructs and verify the harvest-site specificity of the mechanical properties of these two types of FLA constructs.

3) to assess the 3-year clinical and radiological outcomes of the ASCR that uses the MI harvested MFLA, determine the survivorship of this FLA construct at 3 years using MRI, and determine the clinical importance of graft integrity in ASCR.

CHAPTER 3

Fascia lata autograft versus human dermal allograft in arthroscopic superior capsular reconstruction for irreparable rotator cuff tears: a systematic review of clinical outcomes

Fascia lata autograft versus human dermal allograft in arthroscopic superior capsular reconstruction for irreparable rotator cuff tears: a systematic review of clinical outcomes

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3.1. Abstract and Introduction

Systematic Review

Fascia Lata Autograft Versus Human Dermal Allograft in Arthroscopic Superior Capsular Reconstruction for Irreparable Rotator Cuff Tears: A Systematic Review of Clinical Outcomes

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Purpose: To determine the clinical outcomes of arthroscopic superior capsular reconstruction (ASCR) using either fascia lata autograft or human dermal allograft for irreparable rotator cuff tears (IRCTs). **Methods:** A systematic review was performed according to PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses) guidelines by searching the MEDLINE, Embase, and Cochrane Library databases through January 31, 2019. The inclusion criteria were as follows: 5 or more consecutive patients who underwent ASCR for IRCTs; clinical outcome measures reported at a minimum follow-up of 12 months; and magnetic resonance imaging assessment at a minimum follow-up of 6 months. The methodologic quality was evaluated using the Methodological Index for Non-randomized Studies (MINORS). A narrative synthesis of data was performed. Mean outcome improvements were compared with minimal clinically important differences. **Results:** We identified 7 eligible studies that included 344 shoulders in 338 patients who underwent ASCR for IRCTs (all Level IV studies). The mean MINORS score was 12.3 ± 1.60. Of the 7 studies, 5 had a high risk of bias (MINORS score ≤12): 2 studies using only fascia lata autograft and 3 studies using only human dermal allograft. The mean age of patients ranged from 59.4 to 66.9 years. The mean follow-up time ranged from 12 to 48 months. All studies reported statistically significant and clinically important mean improvements in active elevation (range of means, 28°-56°), the Constant score (range of means, 12-47.1 points), or the American Shoulder and Elbow Surgeons score (range of means, 29.3-56 points). In total, 218 shoulders underwent postoperative magnetic resonance imaging. The graft tear rate reported in studies using fascia lata autograft (181 shoulders) ranged from 5% to 32%, whereas the values reported in studies using human dermal allograft (37 shoulders) ranged from 20% to 75%. **Conclusions:** ASCR using either fascia lata autograft or human dermal allograft leads to significant and clinically important improvements in clinical outcomes in IRCT patients at 12 months or later. **Level of Evidence:** Level IV, systematic review of Level IV studies.

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3.2. Methods

An irreparable rotator cuff tear (IRCT) is a diagnostic and therapeutic challenge that has a controversial definition and a multitude of treatment options.[1-3] The available surgical techniques range from arthroscopic debridement, with or without biceps tenotomy or tenodesis,[4] to partial rotator cuff repair,[5] augmentation patches,[6] biodegradable spacer interposition,[7] tendon transfer,[8,9] arthroscopic superior capsular reconstruction (ASCR), or reverse total shoulder arthroplasty (RSA).[2] ASCR was originally proposed by Mihata et al.,[10,11] who used a fascia lata autograft to reconstruct the superior capsule, stabilize the glenohumeral joint, prevent superior humeral head migration, and reverse pseudoparalysis in shoulders with IRCTs. Other authors have proposed alternative types of grafts to reconstruct the superior capsule: hamstring[12] and long head of the biceps autografts[13] and human dermal allografts.[14] To date, fascia lata autograft and human dermal allograft have been the most widely used grafts in ASCR.[11,15-20] However, the importance of the type of graft has not been established, and which type of graft produces the best shoulder outcomes in ASCR remains unclear. In other fields of orthopaedics, such as anterior cruciate ligament reconstruction, allografts have shown unacceptably high failure rates[21,22] or inferior results regarding subjective evaluation.[23]

The purpose of this systematic review was to determine the clinical outcomes of ASCR using either fascia lata autograft or human dermal allograft for IRCTs. It was hypothesized that ASCR using fascia lata autograft would produce superior clinical outcomes and would have a higher graft survival rate than ASCR using human dermal allograft.

Methods

Literature Research

The systematic review was performed following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses) guidelines.[24] The review protocol was registered in January 2019 with the PROSPERO International Prospective Register of Systematic Reviews (registration No. CRD42019121196, publicly accessible at https://www.crd.york.ac.uk/prospero/).

Study Selection and Data Abstraction

A systematic search of the MEDLINE, Embase, and Cochrane Library databases was performed through January 31, 2019. No language or publication-date restrictions were applied. The following terms were used in the search strategy for the PubMed and Embase databases: ((“superior capsular reconstruction” OR “superior capsule reconstruction” OR ASCR)) AND (“rotator cuff” OR shoulder). The search term used for the Cochrane Library database was “superior capsular reconstruction.” The inclusion criteria were as follows: live adult human subjects; ASCR performed on a minimum of 5 consecutive patients; primary or recurrent rotator cuff tears (RCTs) classified as “irreparable” by the authors of the original study; a detailed description of the surgical technique provided in the original study; clinical outcome measures reported at a minimum follow-up of 12 months; and postoperative magnetic resonance imaging (MRI) for graft integrity assessment at a minimum follow-up of 6 months. The following types of studies were excluded: Level V studies, as designated according to the Oxford Centre for Evidence-Based Medicine (technical notes or surgical techniques, biomechanical studies, case reports, or editorials), and systematic reviews or meta-analyses. Study titles and abstracts were retrieved and screened independently by 2 review authors (C.I.d.C.A. and R.A.) to determine study eligibility. The full text of each of the eligible studies was reviewed by the same 2 review authors, and any eligibility disagreements were resolved through discussion with a third review author (N.S.). Data extraction was performed independently by 2 review authors (C.I.d.C.A. and R.A.) according to a standardized, pre-piloted Microsoft Excel form (Microsoft, Redmond, WA). Data on preoperative and postoperative outcome measures were extracted as the means and standard deviations (SDs). The corresponding authors of the eligible studies were contacted by email when data clarification was required. The references of the articles were also reviewed manually to identify any additional studies for inclusion. The decision tree for identifying patterns of duplicate publication of von Elm et al.[25] was used to identify and exclude duplicate studies. Any discrepancies were resolved through discussion with a third author (N.S.).

Risk-Of-Bias Assessment

The methodologic quality of each study was assessed independently by 2 review authors (C.I.d.C.A. and R.A.) according to the Methodological Index for Nonrandomized Studies (MINORS).[26] The items on the questionnaire were scored as 0 if not reported, 1 when reported but inadequate, and 2 when reported and adequate, with a maximum possible score of 16 for noncomparative studies and 24 for comparative studies. Studies with a MINORS score of 13 to 16 for noncomparative studies or 21 to 23 for comparative studies were considered at low risk of bias, whereas those with a MINORS score of 12 or less for noncomparative studies or 20 or less for comparative studies were deemed at high risk of bias (Appendix Table 1, available at www.arthroscopyjournal.org). Any discrepancies between scores were settled by consensus between the review authors.

3.3. Results

Data Analysis

Reliability statistics were calculated using the Cohen κ coefficient to quantify the degree of agreement between the raters for the MINORS scores.[27] A narrative synthesis of the findings of each of the included studies was structured according to patient demographic characteristics, details of surgical technique, type of graft, intraoperative findings, preoperative and postoperative clinical outcome measures, preoperative and postoperative radiologic and MRI findings, and complications. Outcome scores across the included studies were synthesized in a table format. Outcome measures reported in at least 3 studies were represented in forest plots, and I^2 values were calculated using Cochrane Review Manager, version 5.3 (The Cochrane Collaboration, Copenhagen, Denmark). The forest plots show the mean differences from preoperatively to last follow-up, as well as 95% confidence intervals. When the SD was not available, (1) the authors were contacted to provide the missing SD or (2) the SD was calculated using the instructions provided in the Cochrane handbook. The preoperative—to—last follow-up mean differences and MRI graft survival rates were calculated for each of the included studies using Microsoft Excel. The mean outcome improvement was compared with that of clinical importance considering the minimal clinically important difference (MCID), defined as the smallest change in an outcome measurement that signifies an important improvement in a symptom in a patient treated for rotator cuff disease[28-33]: 10° for active elevation,[31] 1.37 for the visual analog scale (VAS) score,[29] 11.1 for the American Shoulder and Elbow Surgeons (ASES) score,[30] 10.4 for the Constant score (CS),[33] and 2 for the Simple Shoulder Test (SST) score.[32] Because of the heterogeneity of the included studies, data pooling was not performed, and the range of the means from the different studies is reported. Subgroup analyses were performed by type of graft (fascia lata autograft or human dermal allograft).

Results

Study Selection

The combined MEDLINE/PubMed and Embase database search produced a total of 240 records. After duplicates were removed, 205 publications remained: 117 from PubMed, 87 from Embase, and 1 from Cochrane. After titles and abstracts were screened for study

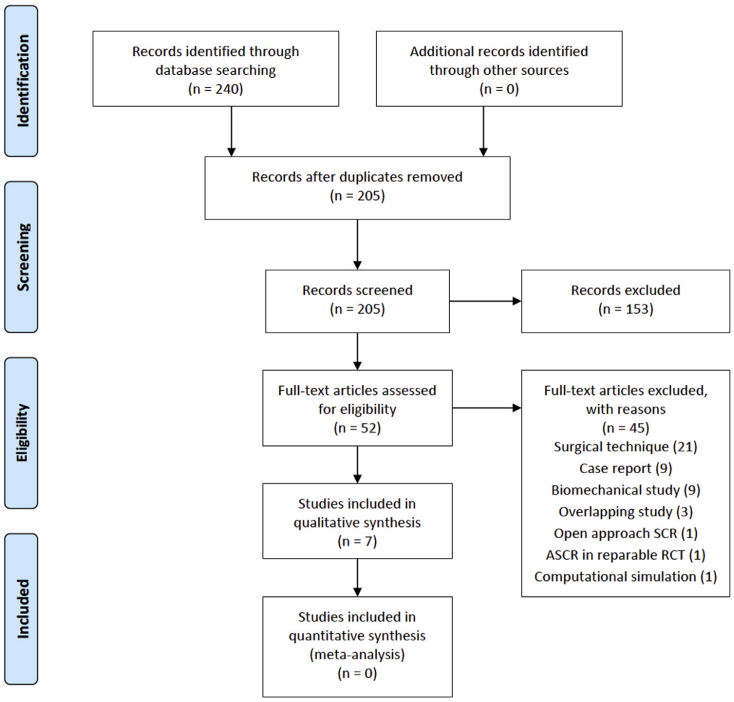

Fig 1. Flow of information through different phases of review. (ASCR, arthroscopic superior capsular reconstruction; RCT, rotator cuff tear; SCR, superior capsular reconstruction.)

relevance, 52 full-text articles were obtained. After the inclusion and exclusion criteria were applied, 10 articles were identified. Five articles had overlapping samples and reported the same outcome measures regarding some of the same subjects (type 3A and 3B patterns of duplicate publications according to von Elm et al.[25]). Of these 5 articles,[11,15,20,34,35] 3 with smaller samples were excluded.[11,34,35] Therefore, 7 articles were selected for inclusion in the systematic review (Fig 1). One study had a historical control group,[36] and 3 studies were subgroup analyses of subsets of patients within the studies[15,17,18]; 1 study was prospective,[16] whereas the remaining 6 studies were retrospective.[15,17-20,36] All studies were case series (Level IV) according to the Oxford Centre for Evidence-Based Medicine.[15-20,36] The mean MINORS score was 12.3 ± 1.6 (range, 11-15; Appendix Table 1, available at www.arthroscopyjournal.org). Of the 7 studies, 5 were assessed as having a high risk of bias (MINORS score ≤12)[15,17,19,20,36]: 2 using only fascia lata[15,17] and 3 using only human dermal allograft.[19,20,36] The Cohen κ coefficient, calculated to measure inter-rater reliability, was 0.89. The corresponding author of the study by Lee and Min[18] was contacted by email and provided the study's subgroup analysis of patients according to type of graft. De Campos Azevedo et al.[16] provided data clarification regarding rounded values, complications, and graft tear site for their study.

Characteristics of Included Studies

The 7 studies meeting the inclusion criteria included 344 shoulders in 338 patients.[15-20,36] Table 1 summarizes each of the included studies. In 2 studies, no patients were lost to follow-up.[17,19] The average loss to follow-up reported in the 5 remaining studies was as follows: 4.5%[16] and 4.8%[15] in studies using only fascia lata; 5.3% in the study using fascia lata or human dermal allograft[18]; and 11.1%[36] and 11.9%[20] in studies using only human dermal allograft. In the study by Denard et al.,[20] 11.9% of patients underwent conversion to RSA and were excluded from the final analysis of postoperative functional scores and range of motion, despite being included in the patient satisfaction assessment. Therefore, in this study, 22.4% of patients who underwent ASCR with dermal allograft were not included in the final analysis of postoperative functional scores and range of motion.[20]

Clinical Presentation

The duration of symptoms before surgery was reported in 2 studies, ranging from 24.7 to 27.0 months (mean values).[16,18] Four studies reported on patients with pseudoparalysis, defined as the inability to forward flex the shoulder over 90°.[15-17,19] In these 4 studies, 16.1% of patients,[17] 21% of patients,[15] 66.7% of patients,[16] and 78% of patients[19] had pseudoparalysis before surgery. Six studies reported the proportion of patients presenting with recurrent RCTs before undergoing ASCR.[16-20,36] Patients with recurrent RCTs underwent a range of 1 to 2[16] or 1 to 3 failed surgical procedures for RCT repair before undergoing ASCR.[20,36]

Preoperative Imaging

In the study by Denard et al.,[20] 96.6% of patients had preoperative radiographs and MRI scans available for analysis, whereas all patients in the remaining 6 studies had preoperative radiographs and MRI scans available.[15-19,36] Five studies reported the grade of arthritis of the RCTs according to the radiographic classification of Hamada et al.[37] Of these studies, 3 reported Hamada grade 1 or 2,[16,17,19] whereas the 2 remaining studies reported Hamada grade 1 to 4.[20,36] After outcome analysis, Denard et al. recommended avoiding Hamada grade 3 or 4 as an indication for ASCR. Five studies graded fatty infiltration[16,17,19,20,36] according to the Goutallier classification[38] and reported the actual Goutallier stage of the supraspinatus as follows: range of 1 to 4 (mean stages, 2.9 ± 0.94[16] and 2.8 ± 0.8[20]), range of 2 to 4 (mean stage, 3.3 ± 0.9[36]), range of 3 to 4,[19] and mean stage of 2.7 ± 0.6.[17] Two studies reported and graded supraspinatus retraction according to Patte,[39] with mean stages of 2.6 ± 0.7[16] and 3 ± 0.[18]

Surgical Technique

All studies reported their criteria for defining the rotator cuff as "irreparable" intraoperatively after a thorough diagnostic arthroscopy was performed. Irreparability was confirmed through the inability to repair the torn tendons to their original footprint without undue tension, and ASCR was not performed unless every attempt failed to completely repair the RCT. All superior capsular reconstruction procedures were performed arthroscopically. Table 2 depicts the surgical details across the included studies.[15-20,36] Some surgical details reported in this review were from the original reports of the surgical techniques,[14,40] as cited by the authors.[20,36]

Clinical Outcomes

Active elevation, active external rotation, the ASES score, the VAS score, and the CS were used as outcome measures in 3 or more of the included studies and are summarized in Table 3, Appendix Table 2 (available at www.arthroscopyjournal.org), and Figures 2 and 3. The mean ASES score improvements were statistically significant and clinically important (ASES score MCID >11.1)[30] in 6 studies.[15,17-20,36] The mean active elevation and VAS score improvements were statistically significant and clinically important in 5 studies[15-17,19,20] (active elevation MCID >10°)[31] and 4 studies[17,19,20,36] (VAS score MCID >1.37),[29] respectively. In the study

Table 1. Summary of Characteristics of Included Studies

Study (Level of Evidence)	Journal (Year)	Years of Study Enrollment	MINORS Score	No. of Patients (No. Of Shoulders)	Type of Graft (No. Of Shoulders)	Outcome Measures	Clinical Follow-Up, Mean ± SD (Range), mo	Age, Mean ± SD (Range), yr	No. of Shoulders in Female/Male Patients	% of Patients With Recurrent Tear
Studies using only fascia lata autograft										
Mihata et al.[15] (IV)	*Am J Sports Med* (2018)	2007-2014	12	100 (100)	Fascia lata autograft (153)	ASES, JOA, ROM	48 (24-88)	66.9 (43-82)	—	—
Lim et al.[17] (IV)	*Arch Orthop Trauma Surg* (2018)	2013-2016	11	31 (31)		ASES score, CS, VAS score, ROM, SS	15 (12-24)	65.3 (44-85)	22/9	80.6
de Campos Azevedo et al.[16] (IV)	*Orthop J Sports Med* (2018)	2015-2016	15	22 (22)*		CS, SSV, SST score, ROM, SS, PS	24 ± 0	64.8 ± 8.6 (47-77)	15/7	27.3
Studies using fascia lata or human dermal allograft										
Lee and Min[18] (IV)	*Knee Surg Sports Traumatol Arthrosc* (2018)	2015-2016	14	32 (36)	Fascia lata autograft (28) or acellular human dermal allograft (8)	ASES score, CS, VAS score, ROM	24.8 ± 6.9	60.9 ± 6.2	11/25	37.5
Studies using only human dermal allograft										
Hirahara et al.[36] (IV)	*Am J Orthop (Belle Mead NJ)* (2017)	2014-2017	11	8 (8)†	Acellular human dermal allograft (155)	ASES score, VAS score	32.38 (25-39)	61.3 (47-78)	2/6	87.5
Denard et al.[20] (IV)	*Arthroscopy* (2018)	2014-2016	11	59 (59)‡		ASES score, VAS score, SSV, ROM, PS	17.7 (12-29)	62.0 ± 8.7	20/39	42.4
Pennington et al.[19] (IV)	*Arthroscopy* (2018)	2015-2016	12	86 (88)		ASES score, VAS score, ROM, SS, PS	12 ± 0	59.4 (27-79)	27/59§	41

ASES, American Shoulder and Elbow Surgeons; CS, Constant score; JOA, Japanese Orthopedic Association; MINORS, Methodological Index for Non-randomized Studies; PS, patient satisfaction; ROM, range of motion; SD, standard deviation; SS, shoulder strength; SST, Simple Shoulder Test; SSV, Subjective Shoulder Value; VAS, visual analog scale.

*A total of 22 patients underwent the preoperative and 6-month postoperative evaluations; 21 underwent the 24-month evaluation.

†A total of 9 patients underwent surgery; 8 were included in the outcome analysis, whereas 1 was excluded after reverse shoulder arthroplasty.

‡A total of 59 patients underwent satisfaction assessment; 52 underwent final analysis of postoperative functional scores and range of motion, whereas 7 were excluded after conversion to reverse shoulder arthroplasty.

§Number of patients.

Table 2. Surgical Details of Included Studies

	Studies Using Only Fascia Lata Autograft			Studies Using Fascia Lata or Human Dermal Allograft	Studies Using Only Human Dermal Allograft		
	Mihata et al.[15] (100 Shoulders)	Lim et al.[17] (31 Shoulders)	De Campos Azevedo et al.[16] (22 Shoulders)	Lee and Min[18] (36 Shoulders)	Hirahara et al.[36] (8 Shoulders)	Denard et al.[20] (59 Shoulders)	Pennington et al.[19] (88 Shoulders)
Type of graft (No. of shoulders)	Fascia lata autograft (153)			Fascia lata autograft (28) or acellular human dermal allograft (8)	Acellular human dermal allograft (155)		
Graft thickness, mean ± SD (range), mm	NR (6.0-8.0)	NR (6.0-NR)	NR (5.0-8.0)	—	3.3 ± 0.7 (1.5-3.5)	2.8 ± 0.6 (1.0-3.0)	3.0 (2.8-3.3)
Patient positioning	Lateral decubitus	Beach chair	Beach chair	Beach chair	Beach chair	Lateral decubitus	Lateral decubitus
Arm positioning	30°-45° abduction	—	10° of abduction, 70° of forward flexion, neutral rotation, with 3-kg forward traction	30° of abduction	Neutral rotation, neutral flexion, neutral abduction (with patient at rest, no traction)	20°-30° of abduction, 20° of forward flexion, neutral rotation with 5 to 10 lb of lateral weight suspended from standard arthroscopic boom	45° of abduction, 10° of forward flexion, neutral rotation
No. of arthroscopic portals (type)	3 (posterior, anterior, lateral)	3 (posterior, anterior, lateral)	3 (posterior, anterior, lateral)	—	5 (posterior, lateral, Neviaser, superolateral, anterosuperior)	4 (posterior, anterior, lateral, accessory lateral)	4 (posterior, anterior, midlateral, juxta-acromial)
Type of anchors on glenoid side	5.0-mm-diameter titanium suture anchors, double loaded	—	1.8-mm all-suture double-loaded anchors	3.0-mm-diameter suture anchors, 2.4-mm suture anchors	3.0-mm-diameter suture anchors	3.0-mm-diameter suture anchors	2.9-mm-diameter push-in anchors
Type of anchors on humeral side	Suture anchors or push-in anchors	—	2.8-mm all-suture double-loaded anchors, 4.5-mm knotless anchors	5.0-mm-diameter suture anchors	4.75-mm-diameter suture anchors	4.75-mm cannulated threaded anchors with braided suture tape	4.75-mm-diameter anchors
Configuration of graft fixation on humeral side	Double row or transosseous equivalent			Single row	Double row or transosseous equivalent		
Mean No. of anchors (range)	6	NR (6-7)	6	4	6.1 (4-8)	NR (4-9)	7
Mean No. of anchors on superior glenoid (range)	2	NR (2-3)	2	2	NR (2-3)	2.3 (2-4)	3
Mean No. of anchors on humeral head (range)	4	4	4	2	4	3.9 (2-5)	4

(continued)

Table 2. Continued

	Studies Using Only Fascia Lata Autograft			Studies Using Fascia Lata or Human Dermal Allograft	Studies Using Only Human Dermal Allograft		
	Mihata et al.[15] (100 Shoulders)	Lim et al.[17] (31 Shoulders)	De Campos Azevedo et al.[16] (22 Shoulders)	Lee and Min[18] (36 Shoulders)	Hirahara et al.[36] (8 Shoulders)	Denard et al.[20] (59 Shoulders)	Pennington et al.[19] (88 Shoulders)
Mean No. of anchors for subscapularis tendon repair	—	—	—	—	—	1.9	0
No. of tendons torn, mean ± SD (range)	ANS	ANS	2.1 ± 0.8 (1-3)	2.5 ± 0.6 (1-3)	ANS	2.5 ± 0.6 (1-3)	ANS
No. of shoulders with SC tear	25	7	8	2	ANS	33	0
No. of shoulders with SC repair	23	ANS	7	ANS	ANS	33	0
No. of shoulders with partial RCT repair	ANS	—	14	ANS	ANS	45	0
No. of shoulders with LHB tenotomy/ tenodesis	ANS	ANS/0	11/0	—	ANS/0	9/25	88/0
No. of shoulders with complete LHB tear	ANS	ANS	11	—	—	—	—
No. of shoulders with anterior acromioplasty	ANS	31	16	—	—	48	ANS
No. of shoulders with coracoplasty	—	—	0	—	—	16	0
No. of shoulders with anterior interval slide in continuity	—	—	0	ANS	—	27	0
No. of shoulders with distal clavicle excision	—	—	0	—	—	—	23
No. of shoulders with posterior interval slide	—	—	0	ANS	—	18	0

ANS, reported but specific amount was not specified; LHB, long head of biceps tendon; NR, not reported; RCT, rotator cuff tear; SC, subscapularis tendon; SD, standard deviation.

Table 3. Summary of Clinical Outcomes Used in 3 or More Studies

Study	Type of Graft (No. Of Shoulders)	AE, °		ASES Score		CS		VAS Score		ER, °	
		Preop	Postop	Preop	Postop	Preop	Postop	Preop	Postop	Preop	Postop
Studies using fascia lata autograft											
Mihata et al.[15] (100 shoulders)	Fascia lata (181)	91	147	36 ± 19	92 ± 12	—	—	—	—	26	41
Lim et al.[17] (31 shoulders)		133 ± 35	146 ± 18	54.4 ± 17.9	73.7 ± 10.8	51.7 ± 13.9	63.7 ± 8.1	6.0 ± 1.2	2.5 ± 1.2	28.0 ± 16.0	30 ± 15
de Campos Azevedo et al.[16] (22 shoulders*)		74.8 ± 55.5 (0-180)	143.8 ± 31.7 (80-180)	—	—	17.6 ± 13.4 (0-55)	64.9 ± 18 (29-100)	—	—	13.2 ± 18.4 (0-70)	35.6 ± 17.3 (0-60)
Lee and Min[18] (28 shoulders)		153.9 ± 27.2	—	51 ± 9.7	84.1 ± 5.1	56.7 ± 8.9	83.1 ± 5.9	1.1 ± 0.9	—	58.0 ± 13.8	—
Studies using fascia lata or human dermal allograft											
Lee and Min[18] (36 shoulders)	Fascia lata or human dermal allograft (36)	105.8 ± 41.2	158.0 ± 24.6† 106.7 ± 34.5‡	50.3 ± 9.1	84 ± 5	56.3 ± 9.0	82.8 ± 5.6	5.8 ± 1.2	0.8 ± 0.8† 2.3 ± 1.0‡	40.8 ± 16.9	58.2 ± 13.5† 45.8 ± 20.6‡
Studies using human dermal allograft											
Lee and Min[18] (8 shoulders)	Human dermal allograft (161)	133.8 ± 44.7	—	47.8 ± 6.4	83.4 ± 4.9	54.8 ± 9.8	81.9 ± 4.8	1.1 ± 1.3	—	49.4 ± 19.2	—
Hirahara et al.[36] (8 shoulders)		—	—	41.8 ± 12.7	86.5 ± 12.7	—	—	6.3 ± 1.6 (4-8.5)	0.4 ± 1.1 (0-3)	—	—
Denard et al.[20] (57 shoulders)		130 ± 48	158 ± 32	43.6 ± 18.6	77.5 ± 22	—	—	5.8 ± 2.2	1.7 ± 2.1	36.0 ± 18.0	45 ± 17
Pennington et al.[19] (88 shoulders)		121 (10-180)	160 (70-180)	52.2 ± 19.3	81.6 ± 10.2	—	—	4.0 ± 2.5	1.5 ± 1.2	—	—

NOTE. Data are presented as mean ± standard deviation (range).

AE, active elevation; ASES, American Shoulder and Elbow Surgeons; CS, Constant score; ER, active external rotation; Postop, postoperative; Preop, preoperative; VAS, visual analog scale.

*There were 22 shoulders preoperatively and 21 shoulders postoperatively, and the paired differences were taken into account in the original study (2 years postoperatively to preoperatively).

†Twenty-three shoulders in intact graft group.

‡Thirteen shoulders in retear group.

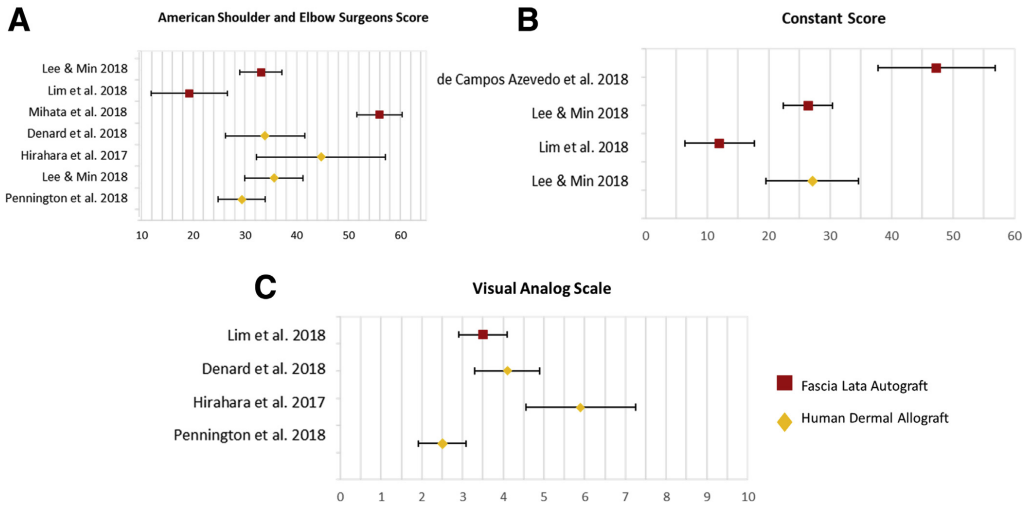

Fig 2. Forest plots of preoperative–to–last follow-up mean differences and 95% confidence intervals of outcome measures for each study. (A) American Shoulder and Elbow Surgeons score ($I^2 = 95\%$). (B) Constant score ($I^2 = 93\%$). (C) Visual analog scale score for pain ($I^2 = 70\%$).

by Lee and Min,[18] postoperative active elevation and the postoperative VAS score were reported regarding the subgroup analysis of the graft tear group versus the intact graft group. The CS was reported in 3 studies,[16-18] with statistically significant and clinically important improvements (CS MCID >10.4).[33] The Subjective Shoulder Value was reported in 2 studies,[16,20] with mean improvements of 35%[16] and 41.3%[20] ($P < .001$). In one study, a statistically significant and clinically important mean SST score improvement of 8.6 ± 3.5 points ($P < .001$, SST score MCID >2)[32] was reported.[16] Mean improvements in active external rotation were reported in 4 studies,[15-17,20] with statistically significant improvements in 3 studies.[15,16,20] Active internal rotation, with a range of mean improvements of 2 to 3 vertebral bodies, was reported in 3 studies ($P < .01$[15] and $P < .001$[16,20]). Mean abduction strength improvements of 2.3 kg ($P < .01$)[19] and 2.8 kg ($P < .001$)[16] were reported in 2 studies.

Patient satisfaction was reported in 3 studies.[16,19,20] In the study by de Campos Azevedo et al.,[16] the patients' individual perception of satisfaction was assessed at the 2-year follow-up, and 85.7% reportedly would agree to undergo the same surgical procedure again. In the study by Pennington et al.,[19] at 1-year follow-up, 90% of patients were satisfied. In the study by Denard et al.,[20] at a mean 17.7-month final follow-up, 72.9% of patients were satisfied and 69.5% had returned to normal activity.

Pseudoparalysis resolution rates of 66.7%,[15] 92.8%,[16] and 100%[17] were reported in 3 of the 7 studies. All of these studies used fascia lata autograft.[15-17]

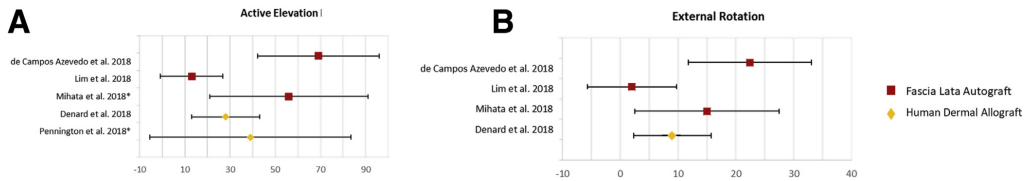

Fig 3. Forest plots of preoperative–to–last follow-up mean differences and 95% confidence intervals of range of movement (in degrees) for each study. (A) Active elevation ($I^2 = 75\%$). (B) External rotation ($I^2 = 70\%$). Asterisks indicate that standard deviations were computed from study data.

Table 4. Summary of MRI Outcomes

Study	Type of Graft	No. of Shoulders With Preop MRI	No. of Shoulders With Postop MRI	Minimum MRI Follow-Up, mo	Mean MRI Follow-Up, mo	No. of Shoulders With Graft Tears at Last Follow-Up MRI (%)	No. of Glenoid-Sided Graft Tears on MRI	No. of Midsubstance Graft Tears on MRI	No. of Humeral-Sided Graft Tears on MRI	Graft Survival Rate,* %
Studies Using Fascia Lata Autograft										
Mihata et al.[15]	Fascia lata	100	100	24	48	5 (5)	—	—	—	95
Lim et al.[17]	autograft	31	31	12	12.8	9 (29)	0	0	9	71
de Campos Azevedo et al.[16]		22	22	6	6	2 (9)	0	2	0	91
Lee and Min[18]		28	28	6	—	9 (32)	1	0	8	68
Studies using human dermal allograft										
Lee and Min[18]	Human dermal	8	8	6	—	4 (50)	1	0	3	50
Hirahara et al.[36]	allograft	8	5	24	—	1 (20)	0	1	0	80
Denard et al.[20]		57	20	12	—	11 (55)	1	3	7	45
Pennington et al.[19]		88	4	12	12	3 (75)	0	0	3	25

MRI, magnetic resonance imaging; Postop, postoperative; Preop, preoperative.
*Percentage of shoulders without graft tears at last follow-up MRI.

3.4. Discussion

Postoperative Imaging and Graft Survival Rate

Postoperative MRI results were reported in all 7 studies.[15-20,36] Of the 342 shoulders that had undergone preoperative MRI, 63.7% underwent postoperative MRI. Table 4 summarizes the MRI outcomes and graft survival rates.

In the studies that used human dermal allograft, 22.9% of shoulders underwent postoperative MRI and survival rates ranging from 25% to 80% were reported.[18-20,36] In the study by Hirahara et al.,[36] a postoperative MRI scan was ordered whenever there was any concern about the reconstruction (62.5% of shoulders). In the study by Denard et al.,[20] postoperative MRI was ordered in patients willing to undergo MRI (35.1% of shoulders). In the study by Pennington et al.,[19] postoperative MRI was prescribed in patients who expressed dissatisfaction or who had insufficient improvement in strength and range of motion (4.5% of shoulders). In their study, 2 of the reported graft failures were diagnosed in the subset of patients who had a minimum follow-up period of 2 years (2 of 38 shoulders). In the study by Lee and Min,[18] patients underwent MRI at 6 and 12 months postoperatively, and graft tears were diagnosed at an average of 8.7 ± 3.5 months postoperatively. In their study, the single-row repair technique was used for humeral-sided fixation of the graft, where most of the tears occurred (Table 3), and a higher fascia lata autograft survival rate (83.3%) was reported among patients who underwent side-to-side posterior remnant tissue repair.

Complication Rates

Postoperative infection rates of 1.7%,[20] 2%,[15] and 4.5%[16] were reported in 3 studies; infections required arthroscopic debridement and a course of intravenous antibiotic therapy,[15,16,20] and the superior capsular reconstruction site was kept intact after the infection resolved.[15,16] The rate of revision to RSA was reported in 5 studies[16,17,19,20,36] from countries where RSA had been available for at least 10 years before study enrollment (Portugal,[16] Republic of Korea,[17] and United States[19,20,36]). In 2 of these 5 studies,[16,17] which used fascia lata autograft, no patients required revision to RSA; in the remaining 3 studies,[19,20,36] which used human dermal allograft, the rates of revision to RSA were 1.1%,[19] 11.1%,[36] and 11.9%.[20]

Discussion

The most important finding of this systematic review is that ASCR using either fascia lata autograft or human dermal allograft results in significant clinical improvements at a minimum follow-up of 12 months. The data on MRI assessment of graft integrity presented in this systematic review strongly support the conclusion that fascia lata autograft has a low tear rate, whereas no conclusion is supported regarding the graft tear rate of human dermal allograft because MRI was inconsistently ordered or was only ordered when there was concern about the reconstruction in the allograft studies. The reported site of graft tear across studies showed a tendency toward higher failure of the graft on the humeral side. The lowest graft survival rate among fascia lata autograft studies was reported in the only study with a single-row configuration of graft fixation on the humeral side.[18] Therefore, surgeons should consider favoring the use of the originally described double-row or transosseous-equivalent graft fixation.[11]

The rate of pseudoparalysis reversal after ASCR using fascia lata autograft was high, whereas that after ASCR using human dermal allograft was not reported in the studies included in our systematic review. In the study by Burkhart and Hartzler,[35] which was excluded from this review because of overlapping samples, a rate of pseudoparalysis reversal of 90% and a graft tear rate of 30% were reported. However, this study was a subgroup analysis of a subset of 10 patients with pseudoparalysis and IRCTs who were previously included in the multicenter study by Denard et al.[20] Therefore, regarding the graft survival rate, extrapolation is erroneous because of sample selection bias. In a study by Mihata et al.,[34] also excluded from this review because of overlapping samples, a pseudoparalysis reversal rate of 95.3% after ASCR with fascia lata autograft was reported.

A conclusion to support the choice of fascia lata over human dermal allograft for the treatment of IRCTs cannot be made based on the data included in this systematic review because all 7 included studies had a low level of evidence. The studies showed considerable heterogeneity regarding either the mean improvement in outcome measures or the range of motion, with I^2 values ranging from 70% to 95%. The mean improvements varied substantially, even among studies using the same type of graft. This heterogeneity in mean improvements may be a result of other clinical or surgical differences among studies: number of tendons torn, grades of RCT arthropathy, fatty degeneration, or tendon retraction; differences in surgical techniques regarding patient positioning, arm positioning during graft fixation, configuration of graft fixation, type and number of anchors, or thickness of the graft construct; differences in additional intraoperative procedures (subscapularis tendon repair, partial rotator cuff repair, tenotomy or tenodesis of the long head of the biceps, anterior acromioplasty, or distal clavicle excision); and differences in the duration of follow-up or rate of loss to follow-up.

Two other systematic reviews, which synthesized the outcomes of ASCR for the treatment of IRCTs,[41,42] were recently published after data analysis of our review was finalized. The strength of the conclusions of both of

3.5. Conclusion and References

those reviews is limited by the inclusion of studies with lower levels of evidence (case reports, Level V studies). In one of these systematic reviews,[41] 10 studies were included, including a conference abstract with a 5-month follow-up period,[43] a case report with a mean follow-up period of 7 weeks,[44] and a conference abstract with a follow-up range of 6 to 92 months,[45] along with 3 studies with overlapping samples.[11,15,34] This same systematic review concluded that ASCR leads to short-term improvements in IRCT patients. In the other systematic review,[42] 6 studies were included, including a case report of 1 patient (Level V evidence)[46] and a subgroup analysis of patients (Level IV evidence).[15] Furthermore, only 1 study in each of the reviews used only fascia lata autograft; neither of these reviews reported or compared outcomes for each type of graft used in the study by Lee and Min[18] (in which fascia lata autograft and human dermal allograft were used).

In our review, only case studies with at least 5 patients and at least 12 months' clinical follow-up were included, all duplicate studies with overlapping samples were excluded from the synthesis despite being discussed, a precise analysis of MRI graft tear rates was performed, and outcomes of fascia lata autograft and human dermal allograft were compared (outcomes of only fascia lata from 4 studies[15-18] vs outcomes of only human dermal allograft from 4 studies[18-20,36] through the use of separate outcomes for fascia lata autograft and human dermal allograft provided by Lee and Min[18]).

Limitations

The limitations of this systematic review are a consequence of the low levels of evidence, heterogeneity bias, and the retrospective nature of most of the included studies. These limitations are not uncommon in systematic reviews of novel orthopaedic surgical procedures and are mostly unavoidable until higher-level studies of the current topic are conducted and published.

Conclusions

ASCR using either fascia lata autograft or human dermal allograft leads to significant and clinically important improvements in clinical outcomes in IRCT patients at 12 months or later.

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3.6. Appendix

Appendix Table 1. MINORS Scores of Included Studies

	Studies Using Only Fascia Lata Autograft			Studies Using Fascia Lata or Human Dermal Allograft	Studies Using Only Human Dermal Allograft		
	Mihata et al.[15]	Lim et al.[17]	de Campos Azevedo et al.[16]	Lee and Min[18]	Hirahara et al.[36]	Denard et al.[20]	Pennington et al.[19]
Clearly stated aim	2	2	2	2	2	2	2
Inclusion of consecutive patients	2	2	2	2	2	2	2
Prospective collection of data	2	2	2	2	2	2	2
Endpoints appropriate to aim of study	2	1[*]	2	2	2	2	2
Unbiased assessment of study endpoint	0[‡]	1[†]	1	1	0	1	1
Follow-up period appropriate to aim of study	2	1	2	2	2	1	1
Loss to follow-up $< 5\%$	2	2	2	1	1	1	2
Prospective calculation of study size	0	0	2	2	0	0	0
MINOR total score	12	11	15	14	11	11	12

NOTE. The items are scored as 0 (not reported), 1 (reported but inadequate), or 2 (reported and adequate), with the global ideal score being 16 for noncomparative studies and 24 for comparative studies.

MINORS, Methodological Index for Non-randomized Studies.

[*]The reviewers initially disagreed regarding the main endpoint: C.I.d.C.A. scored this item as 2 because the criteria used to evaluate the main outcome were considered adequate, but R.A. scored this item as 1. Finally, both agreed to a score of 1 because the timing of the main outcome assessment was ambiguous.

[†]The reviewers initially disagreed regarding endpoint bias assessment reporting: C.I.d.C.A. scored this item as 1 because an unbiased assessment was apparent although the reasons for not blinding were not stated, whereas R.A. scored this item as 0. Finally, both agreed to a score of 0 because no blinding was reported and there was no information regarding who performed the assessment of the study endpoints.

[‡]The reviewers initially disagreed regarding blinding: C.I.d.C.A. scored this item as 2 because an independent nurse practitioner performed the clinical evaluations, but R.A. scored this item as 1. Finally, both agreed to a score of 1 because blinding was only reported for magnetic resonance imaging assessment.

Appendix Table 2. Summary of Mean Improvements in Clinical Outcomes Used in 3 or More Studies

Study	Type of Graft (No. Of Shoulders)	Mean Improvement (*P* Value)				
		AE, °	ASES Score	CS	VAS Score	ER, °
Studies using fascia lata autograft						
Mihata et al.[15] (100 shoulders)	Fascia lata (181)	56 (<.001)	56 (<.001)	—	—	15 (<.01)
Lim et al.[17] (31 shoulders)		13 (.011)	19.3 (<.001)	12 (<.001)	3.5 (<.001)	2 (.4)
de Campos Azevedo et al.[16] (22 shoulders*)		69.3 (<.001)	—	47.1 (<.001)	—	22 (<.001)
Lee and Min[18] (28 shoulders)		—	33.1	26.4	—	—
Studies using fascia lata or human dermal allograft						
Lee and Min[18] (36 shoulders)	Fascia lata or human dermal allograft (36)	—	33.7 (<.01)	26.5 (.02)	—	—
					—	
Studies using human dermal allograft						
Lee and Min[18] (8 shoulders)	Human dermal allograft (161)	—	35.6	27.1	—	—
Hirahara et al.[36] (8 shoulders)		—	44.8 (<.001)	—	5.9 (<.00002)	—
Denard et al.[20] (57 shoulders)		28 (<.001)	33.9 (<.001)	—	4.1 (<.001)	9 (.008)
Pennington et al.[19] (88 shoulders)		39 (.0436)	29.3 (.005)	—	2.5 (.005)	—

AE, active elevation; ASES, American Shoulder and Elbow Surgeons; CS, Constant score; ER, active external rotation; VAS, visual analog scale.

*There were 22 shoulders preoperatively and 21 shoulders postoperatively, and the paired differences were taken into account in the original study (2 years postoperatively to preoperatively).

CHAPTER 4

Proximal and mid-thigh fascia lata graft constructs used for arthroscopic superior capsule reconstruction show equivalent biomechanical properties. An in vitro human cadaver study

Proximal and mid-thigh fascia lata graft constructs used for arthroscopic superior capsule reconstruction show equivalent biomechanical properties. An in vitro human cadaver study

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4.1. Abstract

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Proximal and mid-thigh fascia lata graft constructs used for arthroscopic superior capsule reconstruction show equivalent biomechanical properties: an in vitro human cadaver study

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Level of evidence: Basic Science Study; Biomechanics

Background: The proximal fascia lata (FL) graft construct used for arthroscopic superior capsule reconstruction (ASCR) is openly harvested, whereas the mid-thigh FL graft construct is minimally invasively harvested. The purpose of the current study was to compare the biomechanical properties of proximal thigh and mid-thigh-harvested FL graft constructs used for ASCR. The hypothesis was that, despite the different morphological characteristics of the proximal thigh and mid-thigh FL graft constructs used for ASCR, their biomechanical properties would not significantly differ. This information may assist orthopedic surgeons in the choice of the harvest location, technique, and type of graft construct for ASCR.

Methods: Forty FL specimens, 20 proximal thigh and 20 mid-thigh, were harvested from the lateral thighs of 10 fresh human cadavers (6 male, 4 female; average age, 58.60 ± 17.20 years). The thickness of each 2-layered proximal thigh and 6-layered mid-thigh FL graft construct was measured. Each construct was mechanically tested in the longitudinal direction, and the stiffness and Young's modulus were computed. Data were compared by Welch's independent t-test and analysis of variance, and statistical significance was set at $P < .05$.

Results: The average thickness of the proximal thigh FL graft construct (7.17 ± 1.97 mm) was significantly higher than that of the mid-thigh (5.54 ± 1.37 mm) [$F(1,32) = 7.333$, $P = .011$]. The average Young's modulus of the proximal thigh and mid-thigh graft constructs was 32.85 ± 19.54 MPa (range, 7.94 – 75.14 MPa; 95% confidence interval [CI], 23.71 – 42.99) and 44.02 ± 31.29 MPa (range, 12.53 –120.33 MPa; 95% CI, 29.38 – 58.66), respectively. The average stiffness of the proximal thigh and mid-thigh graft constructs was 488.96 ± 267.80 N/mm (range, 152.96 – 1086.49 N/mm; 95% CI, 363.63 – 614.30) and 562.39 ± 294.76 N/mm (range, 77.46 – 1229.68 N/mm; 95% CI, 424.44 – 700.34), respectively. There was no significant difference in the average Young's modulus or stiffness between the proximal thigh and mid-thigh graft constructs ($P = .185$ and $P = .415$, respectively).

Conclusion: Despite the different morphological characteristics of the proximal thigh and mid-thigh FL graft constructs used for ASCR, their Young's modulus and stiffness did not significantly differ.

Ethical committee approval was provided by the local ethics committee of Instituto Nacional de Medicina Legal e Ciências Forenses (no. CE–23/2019).

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4.2. Introduction and Material and Methods

Arthroscopic superior capsule reconstruction (ASCR) was originally proposed by Mihata et al, who used the fascia lata (FL) to reconstruct the superior capsule, thereby stabilizing the glenohumeral joint to prevent superior humeral head migration[18] and reversing pseudoparalytic shoulders in irreparable rotator cuff tears (IRCTs).[15] Originally, the FL autograft was harvested through an open approach to the proximal lateral thigh. Later, a modification of the technique was proposed by de Campos Azevedo,[1,5] who harvested the FL autograft through a minimally invasive approach to the middle of the lateral thigh. The clinical studies on ASCR using either the proximal thigh– or mid-thigh–harvested FL autograft reported good shoulder outcomes in IRCTs.[2,5,13,15] However, the morphological characteristics and elastic properties of the FL have been shown to be site dependent.[21] The lateral FL has been shown to be significantly thicker than other sites (0.8 ± 0.2 mm versus 0.2 − 0.3 mm in other sites),[21] and the proximal region of the lateral FL is capable of undergoing elongation that is significantly greater than that of the middle and distal regions.[26] Therefore, the FL harvesting site may influence the biomechanical behavior of the resultant graft construct. Studies comparing the biomechanical properties between the proximal thigh– and mid-thigh–harvested FL graft constructs used for ASCR are lacking. Knowledge of how the mid-thigh FL graft, which is minimally invasively harvested, compares biomechanically with the proximal graft, which is openly harvested, may assist orthopedic surgeons in the choice of the location, harvesting technique, and type of graft construct for ASCR.

The purpose of this study was to compare the morphological and biomechanical properties of the proximal thigh– and mid-thigh–harvested FL graft constructs used for ASCR. The hypothesis was that, despite the different morphological characteristics of the proximal thigh and mid-thigh FL graft constructs used for ASCR, their biomechanical properties would not significantly differ.

Materials and methods

Study design

Historical data were not available for either the Young's modulus or the stiffness of the FL constructs, and pilot studies were not conducted. Therefore, the G*Power 3.1[7] was used for the *a priori* power analysis, the independent 2-tailed t-test was used for the sample size calculation, and the study was designed to achieve a power of 80% at a significance level of $P < .05$, with a beta = 0.2, alpha = 0.05, and Cohen's d effect size = 0.9. The number of subjects required to show a difference between groups was n = 20. The experimental design of the current study was approved by the local ethics committee of Instituto Nacional de Medicina Legal e Ciências Forenses (CE–23/2019) for an anticipated sample size of 40 FL specimens.

From April 12, 2019 through January 31, 2020, 40 specimens of FL were harvested from 10 unembalmed fresh (≤ 72 hours postmortem) adult human cadavers that had both thighs previously intact. A total of 20 thighs were harvested: 12 thighs from 6 males, and 8 thighs from 4 females; average age, 58.6 ± 17.20 years; range, 30 − 88 years. On the same day that each eligible fresh adult human cadaver was available, 4 specimens of FL were harvested, prepared, and put through morphological and mechanical tests for a total period of 6 hours. No specimens were excluded from the study.

Specimen preparation

The specimens of the FL were collected from 2 locations: the proximal part (20 specimens) and the middle part (20 specimens) of the lateral thigh.

The direction from the greater trochanter to the lateral femoral condyle was defined as the longitudinal direction and the direction orthogonal to it was defined as the transverse direction. The proximal thigh specimens were harvested according to the technique described in the studies by Mihata et al,[14,15] beginning 1 cm distal to the greater trochanter. Each proximal thigh specimen was 120 × 30 mm in the longitudinal (proximal–distal) x transverse (anterior–posterior) directions, and in the anterior–posterior direction, the harvesting was centered at the level of the lateral femoral intermuscular septum, which was included in the harvest. The mid-thigh specimens were harvested according to the technique described in the studies by Angelo and de Campos Azevedo[1] and by de Campos Azevedo et al,[5] except that the longitudinal open cutaneous approach was used instead of the minimally invasive cutaneous approach. Each mid-thigh graft was harvested 15 cm distal to the anterosuperior iliac spine, 10 cm proximal to the lateral femoral epicondyle, and 4 cm anterior to the lateral femoral intermuscular septum and was 200 × 30 mm in the longitudinal x transverse directions. The intermuscular septum was not included in the harvest. Figure 1 depicts the FL harvesting techniques used in the current study.

The proximal thigh and mid-thigh FL grafts and the final constructs were harvested and prepared by 2 shoulder surgeons equally experienced in each technique (C.I.d.C.A. and A.C.L.P.G.A.). Adipose and connective tissues were manually removed from the specimens using a rugine. After the FL specimens were harvested, the morphological tests were conducted, followed by mechanical tests. The specimens were kept moist throughout the morphological testing and until the mechanical tests were conducted (described below) by pipetting .9% sodium chloride solution onto them.

Morphological tests

The morphological tests were conducted by the 2 shoulder surgeons (C.I.d.C.A. and A.C.L.P.G.A.). The thickness of each specimen (single layer) of FL was measured using a digital caliper (MacFer® D304, Tavares & E. Faria Tavares, Portugal; precision, 0.02 mm) at 6 different points (anterior–proximal, anterior–middle and anterior–distal; posterior–proximal, posterior–middle and posterior–distal parts) that were randomly selected at each point, and the average value was calculated as the representative of the thickness of that sample.[21] To avoid the deformation of the tissue due to an applied pressure by the caliper, the flat part of the caliper was used, and close attention was paid to provide the lowest possible pressure to the sample.[21] Each step of the proximal FL graft construct preparation was performed according to the technique described in the studies by Mihata et al.[14,15] The proximal thigh FL specimens were folded 1 time, and the harvested lateral femoral intermuscular septum was included between the 2 layers of the FL.[14,15] To avoid graft delamination, the layers and the septum were then united peripherally and mattress suturing in the middle of the graft was performed. Braided absorbable sutures (No. 2 coated Vicryl®, Ethicon) were used. The final thickness of each graft construct sample was measured by C.I.d.C.A. and A.C.L.P.G.A. using the caliper at 6 randomly selected points, and the average value was calculated to represent the thickness of each graft construct sample. Each step of the mid-thigh graft construct preparation was performed according to the technique described in the studies by Angelo and de Campos Azevedo[1] and de Campos Azevedo et al.[5] Each mid-thigh FL specimen was folded 3 times (once in the anterior–posterior direction, and twice in the proximal–distal direction) producing a final 6-layered mid-thigh FL graft construct.[1,5]

4.3. Results and Discussion

The layers of the FL were then united peripherally with a continuous suture (No. 2 HiFi®, Conmed), and the final thickness of the graft construct was measured with the caliper (according to the same procedure described previously). Figure 2 shows the final appearance of the proximal thigh and mid-thigh graft construct samples after folding and suturing the FL layers.

Tensile tests

The tensile tests were conducted by the same technicians (C.Q., S.G., and J.F.), at the Department Mechanical Engineering of Instituto Superior Técnico de Lisboa, on the same day each graft construct was prepared, and in a random order. The proximal thigh and mid-thigh graft construct samples were tested in the longitudinal direction using a single Instron 5544 universal testing machine (Instron) integrated with the Standard Video Extensometer 1 (SVE 1, Instron, USA) and a 2 kN load cell (2530-418, Instron). The proximal and distal ends of each graft construct sample were positioned centrally between the 2 clamps of the pneumatic action grips (BioPuls Submersible Pneumatic Side Action Grips, Instron). To prevent slippage of the sample during loading, 2 pieces of sandpaper were fixed to each clamp using double-sided duct tape.[21] After applying a preload of 3-5 N,[10] the length, width, and thickness of each sample were measured using a digital caliper (Dexter®, France; precision, 0.01 mm). Without compressing the sample with the caliper, cross-sectional measurements were performed at 6 randomly selected sections where the optical strain measurements were to be performed.[21] The average values were calculated as the representative width and thickness of each graft construct sample and were used to compute the cross-sectional area, assuming a rectangular shape.[21,24] Strain-controlled tensile tests were conducted at a strain rate of 0.5%/s for cycling grip-to-grip strains of 12%, 24%, and 30%. Incremental cycling strains were considered to ensure the measurement of the specimens' linear behavior without slippage, which usually occurred for loads above 300 N. For each cycling strain test, 5 loading-unloading cycles were conducted. At the end of each cycling strain test, the samples rested for 180 seconds.[6] The SVE strain (mm/mm) and load (N) of the samples were recorded using the software Bluehill 3 (Instron). Figure 3 illustrates the experimental setup.

Experimental data analysis

Of the 5 loading-unloading cycles conducted for each cycling strain test, the first 2 cycles were considered preconditioning and the last 3 cycles were evaluated.[6] The cycling strain test analyzed for each sample was selected based on the average maximum load (N) reached during these last 3 cycles.

The stiffness and Young's modulus of each sample were computed using a custom Matlab script (Matlab, USA). To determine the stiffness (N/mm) in the toe and linear regions, a bilinear curve fit was applied to the displacement-load data for each loading-unloading cycle.[4; 24] The displacement (mm) was calculated through the multiplication of the SVE strain by the initial length measured by the SVE. The stiffness of each sample was determined in the linear region in each of the last 3 cycles, and the average value was calculated as the representative stiffness for that sample. The Young's modulus was computed as:

$$E(MPa) = \frac{k \times L_0}{A}$$

where k is stiffness, L_0 is the initial length according to the SVE, and A is the cross-sectional area.

Statistical analysis

The independent 2-sample 2-tailed Welch t-test and one-way and factorial analyses of variance (Excel for Mac software, version 16.35 [Microsoft, Redmond, WA], and SPSS software, version 26 [IBM, Armonk, NY]) were used for the statistical analyses. The thickness of each single FL layer, the thickness of the graft construct, the stiffness of the graft construct, and the Young's modulus of the graft construct were the dependent variables; the location of the harvest (proximal or mid-thigh), the side of harvesting (left or right thigh), and the sex of the subject (male or female) were the independent variables. The Bonferroni correction to adjust for multiple comparisons was not necessary because there were fewer than 3 groups. Data are presented as means ± standard deviations of the means, with ranges. Statistical significance was defined as $P < .05$.

Results

Morphological results

As shown in Table I and Table II, the average thickness of the proximal thigh—harvested single FL layer (graft prior to folding) and final FL graft construct was significantly higher than that of the mid-thigh. Table II shows the average thickness of a single layer of the FL and of the final graft construct according to sex, side, and location of the harvest. There was no statistically significant 3-way interaction between sex, side, and location of the harvest with regard to the thickness either of the single FL layer, $F(1,32) = 0.769$, $P = .387$, or of the final graft construct, $F(1,32) = 1.098$, $P = .303$, but there was a statistically significant difference between the proximal thigh and mid-thigh harvest locations with regard to the thickness both of the single FL layer, $F(1,32) = 23.753$, $P < .001$, and of the final graft construct, $F(1,32) = 7.333$, $P = .011$.

Mechanical results

The proximal thigh— and mid-thigh—harvested graft constructs had similar average Young's modulus and stiffness (Table III and Figure 4). There was no statistically significant 3-way interaction between sex, side, and location of the harvest with regard to either the graft construct's Young's modulus, $F(1,32) = 0.895$, $P = .351$, or its stiffness, $F(1,32) = 0.400$, $P = .532$.

The initial length according to the SVE (L_0) and the cross-sectional area (A) used to calculate the Young's modulus of each graft construct are summarized in Table IV.

Discussion

The main findings of this study were that the average values of the stiffness and Young's modulus did not significantly differ between the 2 types of FL graft construct, despite the greater average thickness of a single layer and of the final construct of the proximally harvested versus the mid-thigh—harvested FL. In the present study, while the mid-thigh FL single layers were found to have an average thickness comparable to that of the lateral FL found in the study by Otsuka et al[21] (0.87 ± 0.51 mm and 0.8 ± 0.2 mm, respectively), the average thickness of proximal FL single layers was found to be higher (2.37 ± 1.21 mm). This increased thickness of the proximal FL single layers may be explained by the contribution of lateral femoral intermuscular septum, which is included in the harvest of the proximal graft when performed according to the technique described in the studies by Mihata et al.[14,15] Furthermore, the increased thickness of both proximal thigh and mid-thigh final graft constructs results from the folding of the FL layers included in

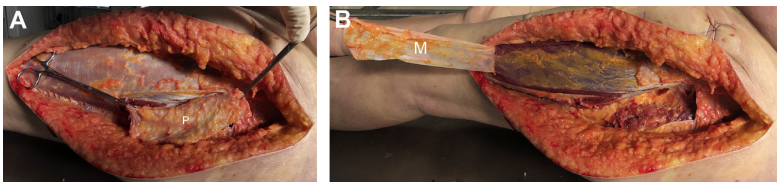

Figure 1 Picture of the (**A**) proximal thigh and (**B**) mid-thigh harvest of the fascia lata (FL) of the left thigh of subject 1. *P*, proximal thigh-harvested FL; *M*, mid-thigh-harvested FL.

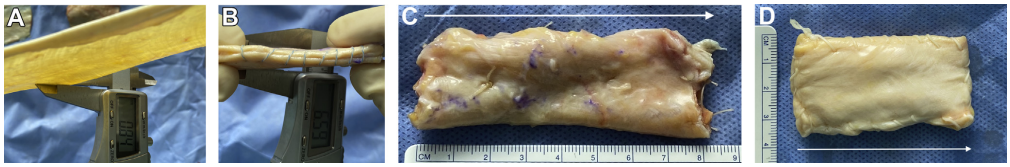

Figure 2 Fascia lata (FL) specimens. Measurement of the mid-thigh FL (**A**) single layer and (**B**) final 6-layered thrice-folded graft construct using the digital caliper, positioned at one of the 6 random points. (**C**) Final proximal thigh graft construct with the mattress suturing in the middle of the graft and peripheral sutures (white-colored sutures), and (**D**) final mid-thigh graft construct with peripheral suturing, showing that the FL layers are folded so that the FL fibers are longitudinally directed (the *white arrows* point from proximal to distal in each graft construct).

the constructs, and the increased thickness of the final proximal construct results mostly from the inclusion of the intermuscular septum. Theoretically, the tension may be unevenly distributed either across the folded layers of FL or the intermuscular septum, despite using a meticulous and reproducible suturing technique; therefore, some of the FL layers or the septum may not have contributed to the stiffness of the whole final graft construct. This might explain why the proximal graft construct, while thicker than the mid-thigh graft construct, does not show increased stiffness. In the biomechanical study conducted by Mihata et al,[16] the authors tested graft constructs that were 4- and 8-mm thick based on the information that the thickness of the superior shoulder capsule was 4.4- to 9.1-mm at the attachment of the greater tuberosity; it was hypothesized that increased graft thickness would lead to increased stiffness, which could explain the decreased superior humeral head translation shown when the thicker graft construct was used. In the study by Nimura et al,[20] it was stated that the superior capsule had an average width of attachment to the greater tuberosity of 4.4 to 9.1 mm, which is different from stating that the thickness of the superior capsule ranged from 4.4 to 9.1 mm throughout. Indeed, in the study conducted by Momma et al,[19] in a color representation through 3-dimensional micro-computed tomography images of the variations in capsular thickness distribution, it was shown that the superior parts of the capsule were consistently thinner, ranging from 0.1 to 0.5 mm, whereas at the glenoid and humeral attachment sites the superior, inferior and anterior parts of the capsule were thicker, ranging from 0.5 to 8.0 mm. The results of the present study suggest that the decreased superior translation of the humeral head shown in the biomechanical studies that used the SCR cadaveric models might have been explained by the influence of other external variables. Further studies should be conducted to compare graft constructs using the

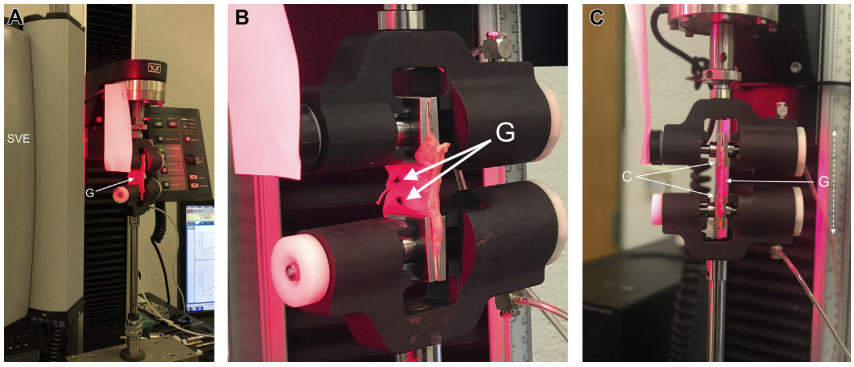

Figure 3 Experimental setup. (**A**) Universal testing machine with the Standard Video Extensometer: the graft construct sample is centrally placed between the pneumatic grips; (**B**) the *white arrows* point to the markings of the 2 control points on the graft construct used for the optical strain measurement. (**C**) The proximal and distal ends of the graft construct are clamped on the pneumatic action grips of the universal testing machine, and the *dashed arrow* represents the longitudinal direction of the fibers of the graft and of the test. *C*, clamps of the pneumatic action grips; *G*, graft construct; *SVE*, Standard Video Extensometer.

Table I
Characteristics of the cadavers and harvested fascia lata specimens

	Subject	Age, y	Sex	Harvest side	Harvest location	
					Proximal thigh (N = 20)	Mid-thigh (N = 20)
					Thickness of the fascia lata single-layer specimen, mm	
	1	54	Female	Left	0.74	0.32
	1	54	Female	Right	0.89	0.44
	2	66	Female	Left	1.51	0.79
	2	66	Female	Right	1.05	0.73
	3	55	Female	Left	1.64	0.65
	3	55	Female	Right	1.50	0.99
	4	30	Male	Left	2.88	1.80
	4	30	Male	Right	2.05	0.85
	5	58	Male	Left	2.92	2.33
	5	58	Male	Right	3.72	0.97
	6	55	Male	Left	2.52	0.44
	6	55	Male	Right	1.34	0.18
	7	46	Male	Left	3.08	0.82
	7	46	Male	Right	3.54	0.72
	8	88	Female	Left	4.46	1.39
	8	88	Female	Right	2.28	1.10
	9	87	Male	Left	4.77	1.03
	9	87	Male	Right	3.65	0.67
	10	47	Male	Left	1.08	0.63
	10	47	Male	Right	1.80	0.50
Mean		58.60			2.37	0.87
SD		17.20			1.21	0.51
Minimum		30			0.74	0.18
Maximum		88			4.77	2.33
P-value*					< 0.001	

SD, standard deviation.
* Welch's T-test.

Table II
Average thickness of a single layer of the fascia lata and of the final graft construct according to sex, side, and location of the harvest

Sex	Harvest side	Harvest location	Thickness, mean ± SD, mm		N
			FL single layer	FL graft construct	
Male	Right	Proximal	2.68 ± 1.07	7.72 ± 2.73	6
		Mid-thigh	0.65 ± 0.28	5.15 ± 1.31	6
	Left	Proximal	2.87 ± 1.18	6.66 ± 1.66	6
		Mid-thigh	1.17 ± 0.74	5.45 ± 1.38	6
	Total	Proximal	2.78 ± 1.08	7.19 ± 2.23	12
		Mid-thigh	0.91 ± .60	5.30 ± 1.29	12
Female	Right	Proximal	1.43 ± 0.62	6.67 ± 1.41	4
		Mid-thigh	0.81 ± 0.29	5.96 ± 0.50	4
	Left	Proximal	2.09 ± 1.63	7.63 ± 1.97	4
		Mid-thigh	0.79 ± 0.45	5.87 ± 2.22	4
	Total	Proximal	1.76 ± 1.20	7.15 ± 1.67	8
		Mid-thigh	0.80 ± 0.35	5.91 ± 1.50	8
Total	Right	Proximal	2.18 ± 1.09	7.30 ± 2.26	10
		Mid-thigh	0.71 ± 0.28	5.47 ± 1.10	10
	Left	Proximal	2.56 ± 1.35	7.05 ± 1.75	10
		Mid-thigh	1.02 ± 0.64	5.62 ± 1.66	10
	Total	Proximal	2.37 ± 1.21	7.17 ± 1.97	20
		Mid-thigh	0.87 ± 0.51	5.54 ± 1.37	20

FL, fascia lata; *SD*, standard deviation.

width of the attachment to the greater tuberosity as the independent variable (4- versus 9-mm-wide attachments).

ASCR using either the openly harvested proximal thigh FL autograft[13,15] or the minimally invasively harvested mid-thigh FL autograft[2,5] has been shown to produce good clinical outcomes, and the present study validates the biomechanical equivalence of the 2 types of FL graft constructs with regard to the stiffness and Young's modulus. Orthopedic surgeons and patients may find the mid-thigh harvesting of the graft advantageous versus the open harvesting technique because the mid-thigh FL autograft can be minimally invasively harvested using a reproducible technique,[3,25] with a low donor site morbidity.[1] This mid-thigh harvest location avoids the risk of damaging both the tensor FL muscle proximally and the iliotibial band distally and posteriorly, thereby preserving both the important postural function of the iliotibial tract and tensor FL, which help extend, abduct, and laterally rotate the hip, as well as preserving the role of the iliotibial band as an anterolateral knee stabilizer.[8] Furthermore, the minimally invasive approach to the mid-thigh is not more technically demanding than the open approach to the proximal thigh, requiring only simple and widely available orthopedic instruments.[1]

The present study has several strengths. First, the proximal thigh– and mid-thigh–harvested graft construct groups were equally sized with regard to the sex and the age of the subjects,

Table III
Young's modulus and stiffness of each graft construct

Subject	Harvest side	Young's modulus, MPa		Stiffness, N/mm	
		Proximal thigh	Mid-thigh	Proximal thigh	Mid-thigh
1	Left	56.01	56.23	836.48	660.95
1	Right	31.57	15.45	1086.49	418.98
2	Left	75.14	12.53	488.14	77.46
2	Right	23.71	25.53	208.12	256.74
3	Left	39.10	43.28	260.17	276.10
3	Right	69.62	25.96	573.83	334.51
4	Left	9.51	23.99	422.27	570.27
4	Right	7.94	13.20	152.96	207.81
5	Left	46.50	87.76	894.94	1229.68
5	Right	20.59	29.32	367.78	677.20
6	Left	26.53	15.11	425.69	665.01
6	Right	33.84	86.03	155.97	712.25
7	Left	12.00	28.49	350.88	1082.95
7	Right	8.77	120.33	313.72	688.43
8	Left	23.87	23.94	237.06	727.61
8	Right	37.64	26.01	484.48	251.33
9	Left	17.66	39.84	446.22	771.57
9	Right	27.88	95.36	437.97	782.58
10	Left	33.09	46.97	803.41	456.22
10	Right	55.98	65.05	832.67	400.16
Mean		32.85	44.02	488.96	562.39
SD		19.54	31.29	267.80	294.76
Minimum		7.94	12.53	152.96	77.46
Maximum		75.14	120.33	1086.49	1229.68
95% CI		23.71-42.99	29.38-58.66	363.63-614.30	424.44-700.34
P-value*		0.185		0.415	

CI, confidence interval; *SD*, standard deviation.
* Welch's T-test.

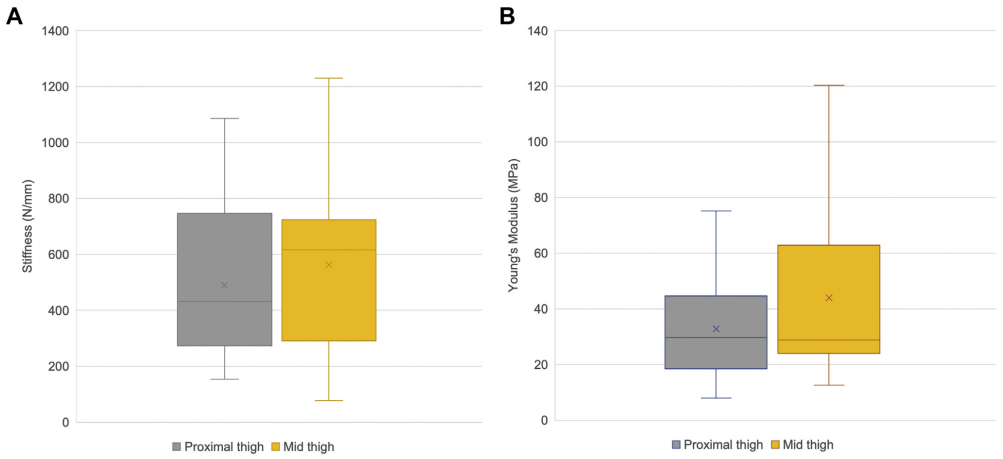

Figure 4 (**A**) Stiffness and (**B**) Young's modulus of the graft constructs according to the location of the harvest. The "X" inside the bars represent the mean values; the horizontal lines inside the bars represent the medians.

thereby avoiding the confounding influence of the sex- and age-dependent morphological and mechanical properties of the FL on the results.[21] Second, the specimens were harvested from fresh cadavers, while fresh-frozen cadaveric samples were used in all the biomechanical studies of SCR cadaveric models to date.[12,16-18,23] Fresh cadaveric specimens are the most suitable substitutes to living tissue when the Young's modulus and the stiffness are the main outcome measures because the average Young's modulus and stiffness of fresh tendons have been shown to be significantly lower than those of either fresh-frozen or embalmed cadaveric specimens,[11] and the mechanical properties of tendons and of the FL have been shown to be significantly influenced by the fixation methods used to preserve the specimens.[9,21] Third, the samples were fixed directly to the clamps, thereby avoiding the influence of

4.4. Conclusion

Table IV
Initial length and area of each graft construct*

Subject, side	Proximal thigh (N = 20)		Mid-thigh (N = 20)	
	L_0, mm	A, mm^2	L_0, mm	A, mm^2
1, R	9.51	327.35	7.89	213.85
2, R	13.56	119.02	11.04	111.04
3, R	24.77	204.16	18.46	237.94
4, R	14.19	273.44	15.16	238.68
5, R	13.45	240.12	13.38	308.95
6, R	16.27	75.00	14.87	123.08
7, R	15.53	555.24	13.53	77.43
8, R	18.08	232.74	18.86	182.21
9, R	16.46	258.59	17.22	141.29
10, R	17.33	257.71	19.80	121.79
1, L	10.54	157.45	10.33	121.40
2, L	16.14	104.84	10.28	63.52
3, L	18.32	121.89	14.22	90.71
4, L	9.97	442.84	10.73	255.04
5, L	14.09	271.27	17.22	241.28
6, L	16.15	259.05	11.14	490.20
7, L	11.31	330.50	10.98	417.24
8, L	20.23	200.93	16.80	510.56
9, L	13.47	340.28	16.32	315.98
10, L	15.31	371.67	18.21	176.93
Mean	15.23	257.20	14.32	221.96
SD	3.64	118.03	3.49	131.27

* *A*, cross-sectional area; L_0, Initial length between the control points according to the Standard Video Extensometer; *L*, Left; *R*, Right; *SD*, standard deviation.

the suture fixation method on the Young's modulus and stiffness of the graft constructs, which were the main outcome measures of the current study.[22]

Limitations

The current study has some limitations. First, a high variance of the morphological and biomechanical properties was found within both groups, which is a consequence of the high variability of the FL morphology according to the age and sex of the subjects. However, this reproduces what is found in the clinical setting of ASCR and increases the generalizability of the findings. Second, no comparison could be made with regard to the theoretical spacer effect that could result from the increased thickness of the proximal thigh graft construct versus the mid-thigh graft construct. A dynamic shoulder model would allow for this comparison and for the assessment of the effects of graft morphometry on the biomechanics of the shoulder, but it would introduce other, external variables and confounding factors, whereas the Young's modulus and stiffness of the graft constructs were the main outcome measures of the current study.

Conclusion

Despite the different morphological characteristics of the proximal thigh and mid-thigh FL graft constructs used for ASCR, their Young's modulus and stiffness did not significantly differ. Knowledge that both graft constructs show equivalent biomechanical properties may assist orthopedic surgeons and patients in the choice of the location, harvesting technique, and type of graft construct for ASCR, because the mid-thigh FL autograft can be minimally invasively harvested.

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CHAPTER 5

Clinical importance of graft integrity in arthroscopic superior capsular reconstruction using a minimally invasively harvested midthigh fascia lata autograft. 3-year clinical and magnetic resonance imaging outcomes

Clinical importance of graft integrity in arthroscopic superior capsular reconstruction using a minimally invasively harvested midthigh fascia lata autograft. 3-year clinical and magnetic resonance imaging outcomes

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5.1. Abstract

Clinical Importance of Graft Integrity in Arthroscopic Superior Capsular Reconstruction Using a Minimally Invasively Harvested Midthigh Fascia Lata Autograft

3-Year Clinical and Magnetic Resonance Imaging Outcomes

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Background: The clinical importance of graft type and integrity in arthroscopic superior capsular reconstruction (ASCR) remains controversial.

Purpose: To assess 3-year clinical and magnetic resonance imaging (MRI) outcomes of ASCR using a minimally invasively harvested fascia lata autograft (FLA) for irreparable rotator cuff tears (IRCTs) and to determine the clinical importance of graft integrity and whether the results change from year 2 to 3.

Study Design: Case series; Level of evidence, 4.

Methods: A total of 22 consecutive patients who underwent ASCR with a minimally invasively harvested FLA were enrolled in a prospective single-arm study. At 3 years, the patients answered a satisfaction questionnaire and underwent a clinical examination and MRI. The MRI scans were independently reviewed by 3 raters to determine the graft integrity, acromiohumeral interval, supraspinatus atrophy, and fatty degeneration of the rotator cuff muscles. Reliability statistics were calculated, and the outcomes were compared across subgroups of patients with and without complete graft tears.

Results: Overall, 21 patients (95.5%) answered the questionnaire, 20/21 (95.2%) were satisfied, 4/20 (20.0%) reported donor site pain, and 19 patients (86.4%) underwent examinations. From preoperatively to 3 years, the mean improvement was 73.68° in elevation (95% CI, 47.59°-99.77°), 89.21° in abduction (95% CI, 66.56°-111.86°), 24.74° in external rotation (95% CI, 4.72°-34.75°), 3.00 in internal rotation (95% CI, 2.36-3.64), 2.61 kg in abduction strength (95% CI, 1.76-3.45 kg), 50.79 on the Constant score (CS; 95% CI, 41.99-59.58), 7.47 on the Simple Shoulder Test (SST; 95% CI, 5.19-9.75), and 36.05% on the subjective shoulder value (SSV; 95% CI, 23.19%-48.92%), which were all significant ($P < .05$). From 2 to 3 years, the mean improvement in abduction was 20.26° (95% CI, 5.44°-35.09°), which was significant ($P = .010$). At 3 years, the raters perfectly agreed (kappa = 1; $P = .000013$) that 4 patients (21.1%) had complete graft tears; this subgroup of patients had decreased external rotation strength at 90° of abduction (1.77 ± 0.17 vs 4.45 ± 2.55 kg, respectively; $P = .027$) and increased grades of infraspinatus (3.50 ± 0.58 vs 2.20 ± 1.01, respectively; $P = .030$) and teres minor fatty degeneration (3.25 ± 0.96 vs 1.53 ± 0.64, respectively; $P = .005$) compared with those without a complete graft tear, but the mean CS, SST, and SSV scores did not differ from those of the overall group (69.50 ± 5.20 vs 69.63 ± 18.25; 9.00 ± 2.31 vs 9.74 ± 4.73; and 72.50 ± 15.00 vs 71.58 ± 26.70, respectively).

Conclusion: The 3-year clinical outcomes of ASCR using a minimally invasively harvested FLA for IRCTs were good, despite donor site morbidity. Active abduction improved significantly from 2 to 3 years. Complete graft tears were correlated with significantly decreased external rotation strength at 90° of shoulder abduction and increased grades of infraspinatus and teres minor fatty degeneration.

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5.2. Introduction and Methods

Keywords: superior capsular reconstruction; irreparable; rotator cuff tear; MRI; graft tear; fascia lata; minimally invasive; interrater reliability

Arthroscopic superior capsular reconstruction (ASCR) is one of the many treatment options for irreparable rotator cuff tears (IRCTs).[15,17,18,43,47] The biomechanical cadaveric study conducted by Mihata et al[38] in 2012 demonstrated that the superior capsule stabilizes the glenohumeral joint, preventing superior humeral head migration in IRCTs. In the pivotal clinical study conducted by Mihata et al[37] in 2013, ASCR using a proximally harvested fascia lata autograft (FLA) was shown to effectively reverse pseudoparalysis in shoulders with IRCTs. It was hypothesized that reconstruction of the superior capsule stabilized the glenohumeral joint through a tenodesis effect, allowing the force couples of the subscapularis, teres minor, and deltoid muscles to restore shoulder elevation. Modifications to ASCR, including the use of a human dermal allograft (HDA),[12,41] a long head of the biceps tendon (LHBT) autograft,[4,6,25] or other FLA constructs,[11,28,29] to reconstruct the superior capsule, were later proposed by other authors. The preliminary clinical studies on ASCR using an HDA or LHBT autograft[6,12,41] did not reproduce the outcomes reported in the studies by Mihata et al.[34,37] Survivorship of the graft was one of the differences in the reported outcomes. Clinical studies on ASCR using an HDA have reported a higher proportion of graft tears, ranging from 20% to 75% in the short term (minimum of 6-month to 2-year follow-up),[10,12,14,24,28,41,50] whereas studies using an FLA have reported proportions of graft tears ranging from 4.2% to 32% in the short to medium term (minimum of 6-month to 5-year follow-up).[10,11,28,29,34,36,37] It remains unclear and controversial whether the type of graft or type of graft construct used in ASCR is an important (or even the most important) factor in the clinical success of ASCR.[32] The correlations of graft integrity with clinical outcomes or graft tears as a cause of failure of ASCR have not been established.[29] Furthermore, in retrospectively designed studies on ASCR, to justify the pooling of results with different follow-up periods after ASCR, some authors have argued that clinical outcomes remain relatively constant beyond 2 years.[37]

The purposes of the present study were to assess the 3-year clinical and magnetic resonance imaging (MRI) outcomes of ASCR using a minimally invasively harvested midthigh FLA, to determine the clinical importance of graft integrity, and to test whether the results remain constant from 2 to 3 years. It was hypothesized that the clinical outcomes would improve significantly from preoperatively to 3 years, would not remain constant from 2 to 3 years, and would be significantly worse at 3 years after ASCR using a minimally invasively harvested midthigh FLA in patients who had a complete graft tear confirmed using MRI.

METHODS

Study Design

Between 2015 and 2016, a total of 22 consecutive patients were enrolled in a prospective single-arm study by de Campos Azevedo et al.[11] In this study, the patients were admitted with primary or recurrent RCTs, had nonoperative treatment that had failed, had no evidence of significant glenohumeral articular cartilage degeneration on true anteroposterior radiographs, and underwent arthroscopic surgery by a single orthopaedic shoulder surgeon (C.I.d.C.A.). If an IRCT was intraoperatively confirmed, the patients underwent ASCR with a minimally invasively harvested midthigh FLA as well as concomitant LHBT tenotomy (if the LHBT was present) and additional repair of the remaining rotator cuff over the superior capsular graft (onlay partial RCT repair). An RCT was considered irreparable if the torn tendons were frail and did not pass the grasper or suture tests, indicating that they did not reach their native footprint without undue tension or further tearing. This surgical technique has been previously described in detail,[1,11] and it is therefore summarized here. ASCR was always performed through a 3-portal technique. Subscapularis tendon tears were repaired to their native footprint with mattress sutures using 2.8-mm all-suture double-loaded anchors (Y-Knot RC; Conmed). The FLA was harvested through 2 horizontal (transverse) 2 cm–long skin incisions on the ipsilateral

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thigh, both 4 cm anterior to the lateral intermuscular septum: one 15 cm distal to the anterior superior iliac spine and the other 10 cm proximal to the lateral femoral epicondyle. For initial graft preparation, the superior capsular defect was measured from anterior to posterior and from medial to lateral using a gauged probe. The 15 to 20 × 3–cm harvested FLA was folded 4 to 5 times, depending on the intra-articular measurements, with at least 5 mm in excess medially and laterally. This resulted in a 5 to 8 mm–thick final superior capsular graft, which was typically 3.5 cm long and 2.5 cm wide. This graft was peripherally sutured in a continuous fashion using 1 nonabsorbable suture (No. 2 Hi-Fi; Conmed); no additional mattress sutures were used in the center of the graft. Further, two 1.8-mm all-suture double-loaded anchors (Y-Knot Flex; Conmed) were implanted on the superior glenoid rim (~1 cm apart) underneath the superior labrum. Additionally, two 2.8-mm all-suture double-loaded anchors (Y-Knot RC) were implanted on the supraspinatus footprint (~1 cm apart). The distances between the anchors were measured using the gauged probe. The corresponding glenoid and humeral anchor placements were marked on the graft with a dermographic pen. After all suture limbs were passed from the glenoid (n = 8) and humeral anchors (n = 8) through the graft and with the suture passer ex vivo, the graft was shuttled through the lateral portal into the glenohumeral joint using the double-pulley technique. All of the glenoid and humeral anchors' sutures were tied. Subsequently, two 4.5-mm knotless anchors (PopLok; Conmed) were loaded with all of the suture limbs (n = 4 each) from the humeral footprint anchors and were implanted lateral to the humeral footprint in a transosseous-equivalent configuration. There were 2 sutures (No. 2 Hi-Fi) passed from the anterior margin of the remaining infraspinatus tendon to the posterior margin of the superior capsular graft. All knots were tied with the shoulder at 70° of forward flexion and 10° of abduction and in neutral rotation. A dynamic subacromial arthroscopic examination was performed to exclude any subacromial conflict with the graft and knots throughout shoulder range of motion (ROM). Whenever the subacromial space was considered to be in conflict with the graft or knots, anterior acromioplasty was performed using a 4 × 125–mm automated shaver blade (Formula 6-Flute Barrel Bur; Stryker).

The patients were systematically assessed by the treating surgeon (C.I.d.C.A.) preoperatively and at 6 months and 2 years postoperatively, and graft integrity was confirmed using MRI at 6 months.

Between 2018 and 2019, before the 3-year postoperative time point was reached, each patient who had completed the preoperative and 6-month postoperative clinical, radiological, and MRI assessments was contacted by the treating surgeon and was invited to be enrolled in the present prospective single-arm study. The predefined primary outcome measures of the present study were active ROM, strength, and function of the shoulder at 3 years after ASCR using a minimally invasively harvested midthigh FLA. The predefined secondary outcome measures were integrity of the graft, as assessed using shoulder MRI, and the subjective effect of donor site morbidity at 3 years postoperatively.

At 3 years, an interview was conducted using the same subjective satisfaction closed-ended questionnaire that was used at 2 years in the study by de Campos Azevedo et al[11] with regard to overall satisfaction and donor site morbidity. Additionally, the patients were questioned about any secondary surgery that was performed on the shoulder between the 2- and 3-year follow-up visits. Secondary surgery for removal of the implanted FLA and surgery at the donor site were exclusion criteria for outcome analyses on the shoulder and on donor site morbidity, respectively.

At the 3-year follow-up visit, the Simple Shoulder Test (SST) score,[31] subjective shoulder value (SSV) score,[19] Constant score (CS),[8] active ROM, strength of shoulder abduction, and acromiohumeral interval (AHI) were recorded by the treating surgeon using the same methodology as that described in the study by de Campos Azevedo et al.[11] Additionally, the following outcomes were measured using a single digital dynamometer (Isometer Shoulder Muscle Strength Gauge; Innovative Design Orthopaedics): external rotation strength with the shoulder in neutral rotation and 0° of abduction, the arm at the side, and the forearm in neutral pronosupination with the thumb up; internal rotation strength with the shoulder in neutral rotation and 0° of abduction, the elbow in 90° of flexion, the arm at the side, and the forearm in neutral pronosupination with the thumb up; and external rotation strength with the shoulder in neutral flexion-extension and 90° of abduction, the elbow in 90° of flexion, and the forearm in neutral pronosupination with the thumb up.

At the 3-year time point, the patients underwent MRI of the shoulder under the supervision of 1 musculoskeletal radiologist (D.C.-C.). To prevent information bias from occurring, a single 1.5-T closed-type scanner (Magnetom; Siemens) with the following predefined protocol of image acquisition and shoulder positioning was used: the examined shoulder was positioned in external rotation; the forearm was positioned in full supination; 3 sandbags were placed over the palm of the patient's hand; 1 sandbag was placed over the patient's sternum; and images were acquired in the coronal (proton density fat-saturated and T2-weighted fat-saturated), sagittal (proton density fat-saturated and T1-weighted), and axial (T2*-weighted and proton density) planes.

The treating surgeon and 2 musculoskeletal radiologists (D.C.-C. and L.D.) independently reviewed the MRI scans. To avoid selection bias, the 3 reviewers were provided with all the acquired scans from each patient to determine the integrity of the graft, the AHI, the grades of fatty degeneration of all rotator cuff muscles, and supraspinatus muscle atrophy. To avoid outcome reporting bias, each reviewer was blinded to the results of the MRI assessments of the other reviewers until the final outcome analysis was conducted.

The AHI was defined as the distance between the top of the humeral head and the undersurface of the acromion and was measured in the coronal plane using a software measurement tool (Picture archiving and communication system [PACS]; Agfa HealthCare). The integrity of the graft was assessed in the coronal, sagittal, and axial planes. If complete discontinuity of the graft was

5.3. Results

identified, the case was defined as a complete tear of the graft and classified according to its location: proximal (at the level of the superior glenoid rim), intermediate (at the level of the top of the humeral head), or distal (at the level of the greater tuberosity). If partial discontinuity of the graft was identified, the case was defined as a partial tear and classified as proximal, intermediate, or distal.

Fatty degeneration of the supraspinatus, infraspinatus, teres minor, and subscapularis muscles was graded on the T1-weighted sagittal Y-scapular view using the classification system of Goutallier et al,[21] which has been validated for MRI by Fuchs et al.[16] Additionally, the Goutallier grades of the supraspinatus and infraspinatus were prognostically dichotomized into the following categories: none to mild fatty degeneration (grades 0-2) and moderate to severe fatty degeneration (grades 3-4).[30]

Muscle atrophy of the supraspinatus was measured using the tangent sign on the T1-weighted sagittal Y-scapular view.[51] The tangent sign was regarded as positive (severe atrophy) when the superior border of the supraspinatus muscle was inferior in relation to the line tangential to the coracoid and scapular spine.

This study was designed by the first author (C.I.d.C.A.), was approved by the local institutional review board and ethics committee of Centro Hospitalar de Lisboa Ocidental (approval No. 09/10/2018; "Comissão de Ética para a Saúde do CHLO"), was registered a priori and made publicly accessible on the website of the US National Library of Medicine (ClinicalTrials.gov: NCT03663036), and had no external sources of funding. The data were collected at Centro Hospitalar de Lisboa Ocidental. Each patient signed an informed consent form.

Statistical Analysis

A paired-samples *t* test (2-tailed) was used to compare the primary outcomes from preoperatively to 3 years postoperatively and from 2 to 3 years postoperatively. For the power analysis, an alpha level of .05 was used. The chosen variable was the SST score, and the paired-samples *t* test was used for the sample size calculation. According to data from the same participants included in the previous study by de Campos Azevedo et al,[11] the estimated SD ranged from 1.00 to 2.00, and the expected effect size ranged from 1.00 to 2.00. The sample size needed to obtain a power of 90% (beta = 0.100) for the functional outcome was 11; therefore, the sample included in the previous study was considered sufficient for this study.

To minimize the risk of chance and sampling errors,[13] the subgroup analysis was restricted to 2 subgroups, and the outcome measures used to compare the subgroups were limited to primary and secondary outcomes. The subgroups defined a priori included patients with or without a complete graft tear at 3 years. The Mann-Whitney *U* test was used to compare the primary and secondary outcomes. The Fisher exact test was used to compare the categorical variables. The Hedges *g* effect size of the mean changes in primary outcomes from preoperatively to 3 years postoperatively and from 2 to 3 years postoperatively in the study population and of the mean differences in the subgroup analysis were calculated using Excel (Microsoft Corp).[23]

Reliability statistics were calculated using the Cohen kappa coefficient to quantify the degree of agreement between the 3 raters in the MRI outcomes.[7] The interrater reliability was determined between each pair of raters. The guidelines provided in the study by Landis and Koch[27] were used to interpret the Cohen kappa values: 0.01-0.20 indicated slight agreement, 0.21-0.40 indicated fair agreement, 0.41-0.60 indicated moderate agreement, 0.61-0.80 indicated substantial agreement, 0.81-1.00 indicated almost perfect or perfect agreement, a negative value indicated that the 2 raters agreed less than would be expected just by chance, a value of 1 implied perfect agreement, and values <1 implied less than perfect agreement. No analyses accounting for missing data were performed; decreases in the number of participants throughout the study reflect those who were excluded because of missing data. SPSS Statistics 23 software (IBM Corp) was used for statistical analyses. The statistical significance level was set at a P value $<.05$.

RESULTS

Study Population

At 3 years postoperatively, 22 consecutive patients who underwent ASCR using a minimally invasively harvested midthigh FLA between 2015 and 2016 and who had been included in the study by de Campos Azevedo et al[11] were contacted. There were 21 patients (95.5%) who answered the questionnaire on subjective satisfaction, donor site morbidity, and complications. A total of 19 patients (86.4%) agreed to undergo clinical, radiological, and MRI examinations at 3 years. There were 3 patients (13.6%) who were lost to follow-up. One of these 3 patients (4.5%) could not be reached at 3 years postoperatively; therefore, this patient could not be invited to be enrolled in the present study. The 2 remaining patients declined to undergo clinical, radiological, and MRI examinations. A diagram of the flow of participants in the study, as presented by the modified Consolidated Standards of Reporting Trials (CONSORT) statement, is depicted in Figure 1.[3]

Overall, 2 of the 22 consecutive patients (9.1%) who had undergone MRI at 6 months in the previous study had a complete graft tear confirmed at 6 months (patients 3 and 9). Another 2 of the 19 patients (10.5%) who underwent MRI at 3 years in the present study had a complete graft tear confirmed at 3 years (patients 1 and 4; total: 4/19 [21.1%]). The baseline characteristics of the patients are summarized in Table 1 and Appendix Table A1 (available in the online version of this article).

Patient Satisfaction and Complications

At 3 years, 20 of the 21 patients (95.2%) were satisfied (would agree to undergo the same surgical procedure again); 12 of the 20 patients (60.0%) reported changes to the harvested thigh. The results of the questionnaire on

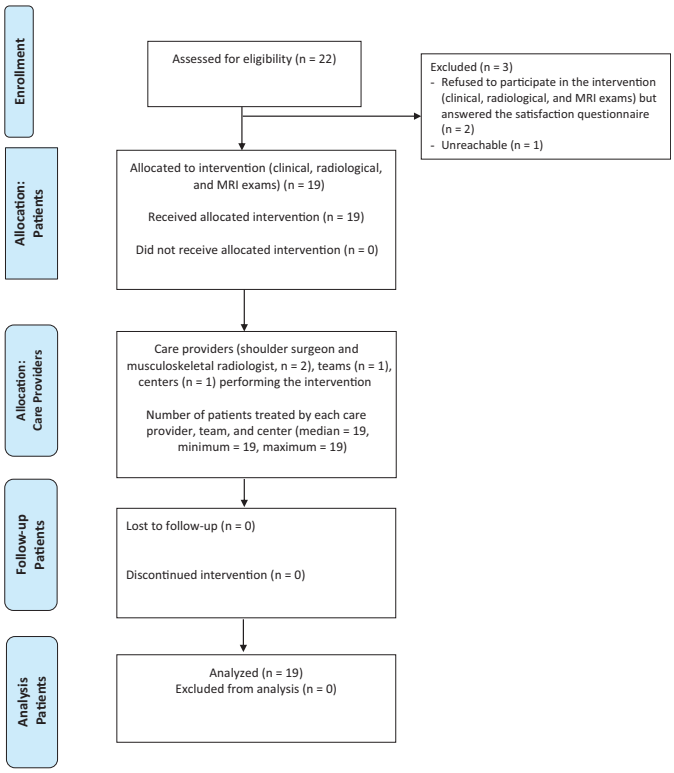

Figure 1. Diagram of the flow of participants in the study according to the CONSORT (Consolidated Standards of Reporting Trials) guidelines. MRI, magnetic resonance imaging.

subjective satisfaction and donor site morbidity are summarized in Table 2.

One of the 21 patients (4.8%) was excluded from the outcome analysis of the subjective questionnaire with regard to donor site morbidity at 3 years. This patient had a workers' compensation claim; underwent secondary surgery at the donor site between the 2- and 3-year follow-up visits but was satisfied with the outcome of ASCR (would agree to undergo the same surgical procedure again); stated that the shoulder surgery's end result compensated for the changes in the thigh; and agreed to participate in the 3-year clinical, radiological, and MRI assessments of the shoulder.

One of the 21 patients had undergone secondary surgery of the shoulder 4 weeks after the index procedure because of a superficial anterior portal infection, which had negative synovial liquid culture and biopsy findings, including those for *Cutibacterium acnes*. This patient was not excluded from the outcome analysis of subjective satisfaction of the shoulder after ASCR because the FLA and superior capsular reconstruction site were intact. The infection resolved after arthroscopic lavage was performed and a course of intravenous antibiotic therapy was administered. This patient had a workers' compensation claim; was not satisfied with the outcome of ASCR; stated that the shoulder surgery's end result did not compensate for the changes in the thigh; and declined to participate in the 3-year clinical, radiological, and MRI assessments. None of the 21 patients underwent revision to reverse total shoulder arthroplasty at 3 years.

Results of Examinations at 3 Years

Among the 19 patients who underwent the clinical examination, active ROM, strength of abduction, and functional scores of the shoulder improved significantly, with sufficiently large and consistent differences to be considered important from preoperatively to 3 years postoperatively. From preoperatively to 3 years postoperatively, the mean values of active ROM, abduction strength, the CS, the SST, and the SSV increased significantly. The mean changes in the clinical outcomes from preoperatively to 3 years postoperatively are summarized in Table 3.

TABLE 1
Baseline Demographic, Clinical, and Imaging Characteristics of the Study Population[a]

	Patients Who Completed Questionnaire at 3 y (n = 21)	Patients Who Underwent Clinical Examination and MRI at 3 y (n = 19)	Patients Without a Complete Graft Tear at 3 y (n = 15)	Patients With a Complete Graft Tear at 3 y (n = 4)
Age, y	64.81 ± 8.84	65.21 ± 9.21	64.87 ± 9.69	66.50 ± 8.23
Female sex	66.67	63.16	60.00	75.00
Duration of symptoms, mo	28.22 ± 51.49	31.03 ± 53.46	26.16 ± 44.33	49.32 ± 86.10
Manual-type job	90.48	89.47	86.67	100.00
Active job status	52.38	47.37	40.00	75.00
Right-sided lesion	71.43	68.42	66.67	75.00
Dominant-sided lesion	66.67	63.16	60.00	75.00
Workers' compensation claim	28.57	21.05	26.67	0.00
Recurrent tear	23.81	26.32	33.33	0.00
No. of torn tendons	2.10 ± 0.83	2.05 ± 0.85	1.80 ± 0.77	3.00 ± 0.00
Torn subscapularis	38.10	36.84	20.00	100.00
Hamada grade[b]	1.43 ± 0.51	1.47 ± 0.51	1.40 ± 0.51	1.75 ± 0.50
Radiographic AHI, mm	6.24 ± 3.33	5.74 ± 2.60	6.27 ± 2.34	3.75 ± 2.87
Patte stage[c]	2.52 ± 0.68	2.47 ± 0.70	2.47 ± 0.64	2.50 ± 1.00
Positive tangent sign	100.00	100.00	100.00	100.00
Goutallier grade[d]				
Supraspinatus	2.81 ± 0.93	2.74 ± 0.93	2.73 ± 0.96	2.75 ± 0.96
Infraspinatus	2.38 ± 1.20	2.32 ± 1.20	2.20 ± 1.26	2.75 ± 0.96
Teres minor	0.19 ± 0.40	0.21 ± 0.42	0.13 ± 0.35	0.50 ± 0.58
Subscapularis	1.81 ± 0.93	1.84 ± 0.83	1.73 ± 0.80	2.25 ± 0.96
Repaired subscapularis	33.33	31.58	13.33	100.00
Onlay partial RCT repair	61.90	57.89	60.00	50.00
LHBT tenotomy/absent LHBT	47.62/52.38	52.63/47.37	46.67/53.33	75.00/25.00
Anterior acromioplasty	71.43	78.95	86.67	50.00

[a]Data are presented as mean ± SD or percentage. AHI, acromiohumeral interval; LHBT, long head of the biceps tendon; MRI, magnetic resonance imaging; RCT, rotator cuff tear.

[b]Hamada classification[22]: grade 1, AHI ≥6 mm; grade 2, AHI ≤5 mm; grade 3, AHI ≤5 mm and acetabulization of the acromion; grade 4A, AHI ≤5 mm and glenohumeral narrowing without acetabulization of the acromion; grade 4B, AHI ≤5 mm and glenohumeral narrowing with acetabulization of the acromion; and grade 5, humeral head collapse.

[c]Patte classification[39]: stage 1, tendon close to the bony insertion; stage 2, tendon at the level of the humeral head; and stage 3, tendon at the level of the glenoid.

[d]Goutallier classification[21]: grade 0, no fatty streaks; grade 1, some fatty streaks; grade 2, more muscle than fat; grade 3, as much muscle as fat; and grade 4, less muscle than fat.

From 2 to 3 years, the mean shoulder active elevation, active external rotation, CS, and SST score improved, whereas the mean SSV score worsened; these changes did not show statistical significance and had small effect sizes. Active abduction improved significantly, with the largest effect size among the clinical outcomes measured. The mean changes in the clinical outcomes from 2 to 3 years are summarized in Table 4.

Interrater Reliability of MRI Outcomes at 3 Years

In the current study, a complete tear of the graft at 3 years after ASCR was the only MRI outcome measure with perfect agreement among the 3 independent raters (P = .000013). The detailed Cohen kappa values for each MRI outcome at 3 years after ASCR are summarized in Figure 2 and Appendix Table A2 (available online).

According to raw data from the individual ratings, in 2 of the 19 patients, there was perfect agreement among the 3 raters for the presence of a partial tear of the graft, whereas in 4 of the 19 patients, only the 2 musculoskeletal radiologists were in complete agreement regarding the presence of a partial tear of the graft. Furthermore, with regard to the location of the tears, in the 4 patients who had a complete tear of the graft, the 3 raters were in complete agreement regarding the location of the tear (intermediate), whereas in only 1 patient who had a partial tear of the graft, 2 of the raters (the orthopaedic shoulder surgeon and 1 of the musculoskeletal radiologists [L.D.]) were in agreement on the location of the tear (intermediate).

The imaging results of 1 of the 4 patients who had a complete graft tear and 1 of the 4 patients who arguably had a partial graft tear are depicted in Figure 3. The MRI scans of patients who had the superior capsular graft successfully healed at 3 years are depicted in Figure 4.

5.4. Discussion

TABLE 2
Questionnaire on Subjective Satisfaction and Donor Site Morbidity

			Positive Responses at 3 y, %	
	Positive Responses at 2 y, %	Positive Responses at 3 y, %	Patients Without a Complete Graft Tear (n = 15)	Patients With a Complete Graft Tear (n = 4)
Would you undergo the same surgical procedure again?	85.7 (n = 21)	95.2 (n = 21)	100.0	100.0
Does your shoulder surgery's end result compensate for the changes in the thigh?	84.2 (n = 21)	90.5 (n = 21)	93.3	100.0
Does the harvested thigh bother you?	57.1 (n = 20)	45.0 (n = 20)	42.9	25.0
Do you have a thigh deformity?	9.5 (n = 20)	20.0 (n = 20)	28.6	0.0
Do you have thigh pain?	38.1 (n = 20)	20.0 (n = 20)	14.3	25.0
Do you have thigh numbness?	38.1 (n = 20)	35.0 (n = 20)	42.9	25.0
Do you have claudication?	4.8 (n = 20)	5.0 (n = 20)	7.1	0.0

TABLE 3
Mean Changes in the Clinical Outcomes From Preoperatively to 3 Years (n = 19)[a]

	Preoperative Mean	3-y Mean	Change From Preoperatively to 3 y, Mean ± SD	95% CI of Difference	*P* Value	Hedges *g* Effect Size
Active elevation, deg	77.63	151.32	73.68 ± 54.13	47.59-99.77	.000013	1.67
Active abduction, deg	54.47	143.68	89.21 ± 47.00	66.56-111.86	<.000001	2.24
Active external rotation, deg	13.95	38.68	24.74 ± 20.78	4.72-34.75	.000062	1.38
Active internal rotation[b]	1.37	4.37	3.00 ± 1.33	2.36-3.64	<.000001	2.39
Strength of abduction, kg	0.00	2.61	2.61 ± 1.76	1.76-3.45	.000005	2.06
CS	18.84	69.63	50.79 ± 18.25	41.99-59.58	<.000001	3.75
SST	2.26	9.74	7.47 ± 4.73	5.19-9.75	.000002	2.64
SSV, %	35.53	71.58	36.05 ± 26.70	23.19-48.92	.000014	1.76

[a]CS, Constant score; SST, Simple Shoulder Test; SSV, subjective shoulder value.
[b]Measured as the highest vertebral body that the patient's thumb could reach without pain: lateral thigh = 0, buttock = 1, sacrum = 2, lumbar = 3, T12 = 4, and T7 = 5.

The MRI outcomes measured by each independent rater were used independently in the outcome analysis and subgroup analysis of the patients with or without a complete graft tear. The clinical and imaging outcomes at 3 years in the subgroups of patients with or without a complete tear of the graft are summarized in Table 5.

Subgroup Analysis of Integrity of the Graft

In the subgroup analysis performed according to the integrity of the graft at 3 years, the following clinical and imaging characteristics were statistically significantly different between the subgroups with and without a complete tear of the graft: the baseline number of torn tendons ($P = .011$), presence of a subscapularis tendon tear ($P = .004$), repair of the subscapularis tendon ($P = .001$), 3-year external rotation strength at 90° of abduction, 3-year AHI measured on MRI, and 3-year infraspinatus and teres minor fatty degeneration.

DISCUSSION

In summary, the main findings of this study were that ASCR using a minimally invasively harvested midthigh FLA for IRCTs produced significant mean improvements in clinical outcomes from preoperatively to 3 years and a significant mean improvement in active abduction from 2 to 3 years postoperatively. At 3 years, there was high interrater reliability for complete graft tears confirmed using MRI, and the patients (21.1%) who had a complete tear of the graft confirmed using MRI had significantly less external rotation strength at 90° of abduction and higher grades of infraspinatus and teres minor fatty degeneration than patients who had a partial tear or no graft tear.

The clinical outcomes improved significantly from preoperatively to 3 years postoperatively, with sufficiently large and consistent differences that were also clinically important because they were higher than the minimal clinically important difference determined for patients who are

TABLE 4
Mean Changes in the Clinical Outcomes From 2 to 3 Years Postoperatively (n = 19)[a]

	Change From 2 to 3 y, Mean ± SD	95% CI of Difference	*P* Value	Hedges *g* Effect Size
Active elevation, deg	5.26 ± 26.79	–7.65 to 18.18	.403	0.18
Active abduction, deg	20.26 ± 30.75	5.44 to 35.09	.010	0.56
Active external rotation, deg	3.84 ± 11.61	–1.76 to 9.44	.167	0.27
Active internal rotation[b]	0.42 ± 0.90	–0.01 to 0.86	.057	0.45
Strength of abduction, kg	–0.37 ± 1.75	–1.22 to 0.47	.365	–0.17
CS	2.68 ± 13.20	–3.68 to 9.05	.387	0.17
SST	0.63 ± 2.19	–0.42 to 1.69	.225	0.22
SSV, %	–3.16 ± 20.01	–12.80 to 6.45	.500	–0.15

[a]CS, Constant score; SST, Simple Shoulder Test; SSV, subjective shoulder value.
[b]Measured as the highest vertebral body that the patient's thumb could reach without pain: lateral thigh = 0, buttock = 1, sacrum = 2, lumbar = 3, T12 = 4, and T7 = 5.

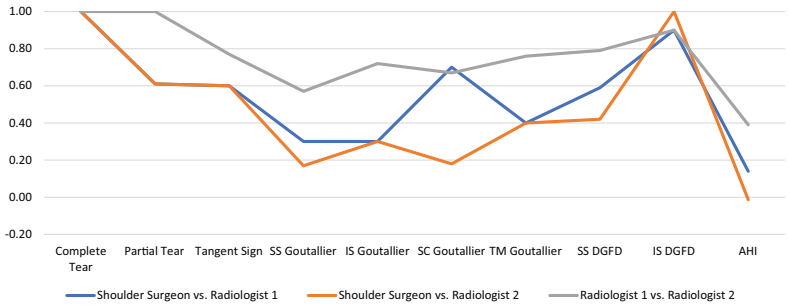

Figure 2. Interrater reliability of magnetic resonance imaging outcomes 3 years after arthroscopic superior capsular reconstruction using a fascia lata graft. The vertical axis shows Cohen kappa values. Shoulder surgeon: C.I.d.C.A. Radiologist 1: D.C.-C. Radiologist 2: L.D. AHI, acromiohumeral interval; DGFD, dichotomized grade of fatty degeneration (no to mild fatty degeneration [grades 0-2] and moderate to severe fatty degeneration [grades 3-4]); IS, infraspinatus; SC, subscapularis; SS, supraspinatus; TM, teres minor.

treated for rotator cuff disease. The minimal clinically important difference, defined as the smallest change in an outcome that signifies an important improvement in a symptom, is 10° for active elevation,[9] 10.4 points for the CS,[26] and 2 points for the SST[46] in patients treated for rotator cuff disease. Most clinical outcomes did not change significantly from 2 to 3 years; however, the mean improvement in active abduction was statistically significant, and this difference was the largest and most consistent among the clinical outcomes measured during this period of time. This result may theoretically be explained by the re-establishment of the 2:1 physiological scapulohumeral rhythm,[49] which may be a consequence of the glenohumeral center of rotation being maintained by the tenodesis effect of superior capsular reconstruction in the rotator cuff–deficient shoulder.[5] ASCR provides a fulcrum to the deltoid lever arm without compromising the native glenohumeral center of rotation, which allows the shoulder girdle to function in a physiological balance and prevents several unsolved mechanical problems of current reverse total shoulder arthroplasty implants that are used in the treatment of IRCTs.[2,20,40,48,52]

This is the first study to date to report the reliability statistics for the MRI outcomes of graft integrity, fatty infiltration, and atrophy of the rotator cuff muscles after ASCR.[11,12,28,29,36,37,41,50] The proportion of complete graft tears was 21.1% at 3 years, which was the most reliable MRI outcome of the present study, whereas the proportion of partial tears was less reliable and ranged from 10.5% to 21.1% across the 3 raters. The low agreement with regard to the location of partial tears of the graft further highlights the difficulty in the interpretation of MRI scans taken after ASCR. Postoperative MRI scans are challenging to interpret,[33] and there are no guidelines for the interpretation of MRI scans taken after ASCR. The normal postoperative appearance of an HDA on MRI is an area of low signal intensity and a taut graft with no fluid signal discontinuity and intact attachment to the superior glenoid and greater tuberosity.[42] This definition does not apply to ASCR using a minimally invasively harvested FLA or

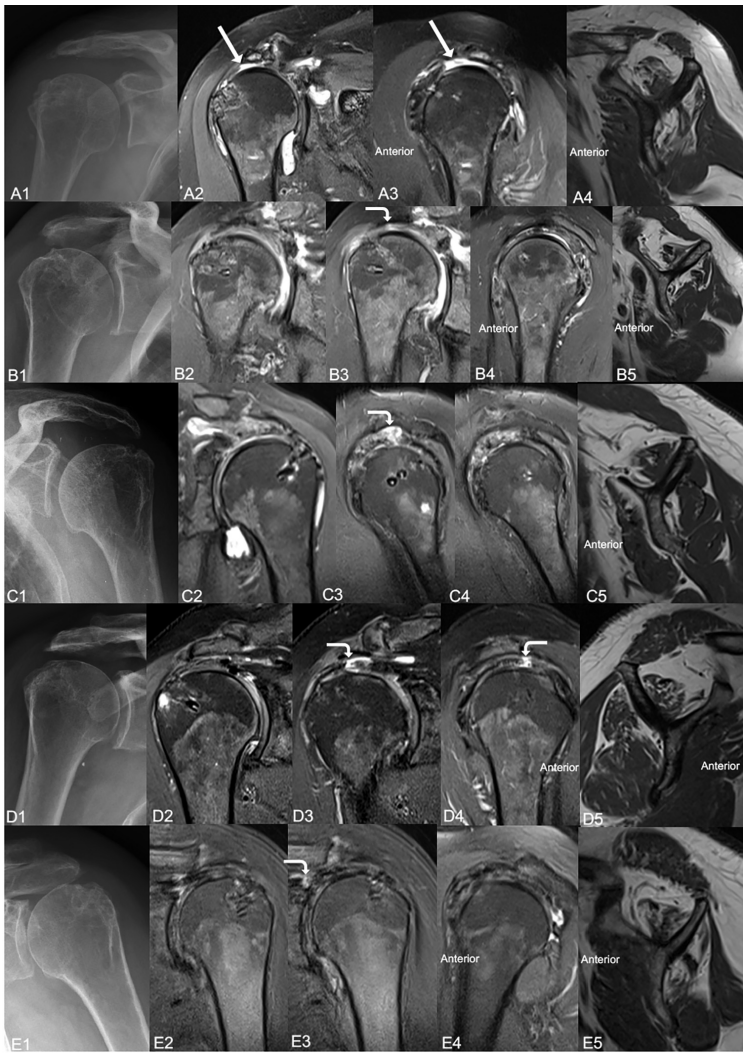

Figure 3. Imaging of patients who had a graft tear diagnosed at 3 years. (A1) True anteroposterior radiograph, complete graft tear (straight white arrow) on proton density fat-saturated (A2) coronal and (A3) sagittal magnetic resonance imaging (MRI) scans, and (A4) fatty degeneration of the rotator cuff muscles on T1-weighted sagittal MRI scan of the right shoulder of patient 1. (B1) Glenohumeral articular cartilage degeneration on true anteroposterior radiograph, no graft tears on proton density fat-saturated (B2) coronal and (B4) sagittal MRI scans, (B3) small tear or suture hole (curved white arrow) on 1 cut of proton density fat-saturated coronal MRI scan, and (B5) fatty degeneration of the rotator cuff muscles on T1-weighted sagittal MRI scan of the right shoulder of patient 12. (C1) True anteroposterior radiograph, no graft tears on proton density fat-saturated (C2) coronal and (C4) sagittal MRI scans, (C3) small tear or suture hole (curved white arrow) on 1 cut of proton density fat-saturated sagittal MRI scan, and (C5) fatty degeneration of the rotator cuff muscles on T1-weighted sagittal MRI scan of the left shoulder of patient 14. (D1) Glenohumeral articular cartilage degeneration on true anteroposterior radiograph, (D2) no graft tear on proton density fat-saturated coronal MRI scan, small tear or suture hole (curved white arrow) on proton density fat-saturated (D3) coronal and (D4) sagittal MRI scans, and (D5) fatty degeneration of the rotator cuff muscles on T1-weighted sagittal MRI scan of the right shoulder of patient 17. (E1) True anteroposterior radiograph, no graft tear on proton density fat-saturated (E2) coronal and (E4) sagittal MRI scans, (E3) small tear or suture hole (curved white arrow) on 1 cut of proton density fat-saturated coronal MRI scan, and (E5) fatty degeneration of the rotator cuff muscles on T1-weighted sagittal MRI scan of the left shoulder of patient 19.

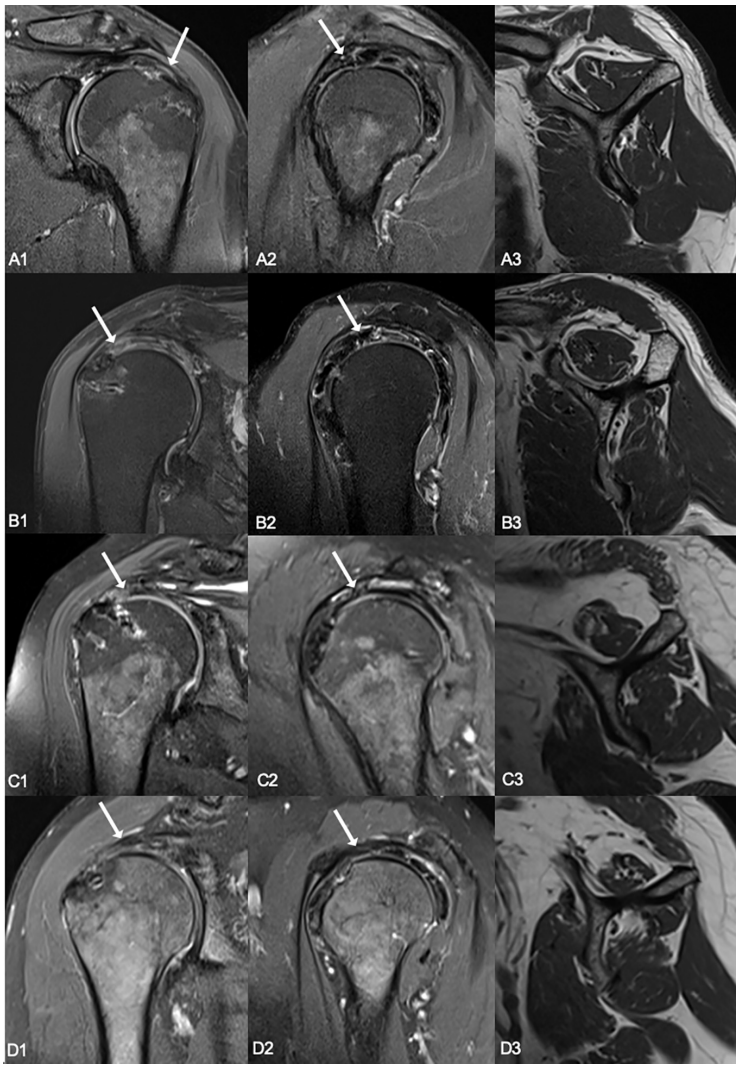

Figure 4. Imaging of patients who had an intact superior capsular graft at 3 years. Intact graft (straight white arrow) on proton density fat-saturated (A1) coronal and (A2) sagittal magnetic resonance imaging (MRI) scans and (A3) fatty degeneration of the rotator cuff muscles on T1-weighted sagittal MRI scan of the left shoulder of patient 2. Intact graft (straight white arrow) on proton density fat-saturated (B1) coronal and (B2) sagittal MRI scans and (B3) fatty degeneration of the rotator cuff muscles on T1-weighted sagittal MRI scan of the right shoulder of patient 8. Intact graft (straight white arrow) on proton density fat-saturated (C1) coronal and (C2) sagittal MRI scans and (C3) fatty degeneration of the rotator cuff muscles on T1-weighted sagittal MRI scan of the right shoulder of patient 16. Intact graft (straight white arrow) on proton density fat-saturated (D1) coronal and (D2) sagittal MRI scans and (D3) fatty degeneration of the rotator cuff muscles on T1-weighted sagittal MRI scan of the right shoulder of patient 22.

TABLE 5
Clinical and Imaging Outcomes of the Patients With and Without a Complete Graft Tear at 3 Years Postoperatively[a]

	Patients Without a Complete Graft Tear (n = 15)	Patients With a Complete Graft Tear (n = 4)	*P* Value	Hedges *g* Effect Size
Active elevation, deg	148.33 ± 26.84	162.50 ± 12.59	.337	0.57
Active abduction, deg	146.67 ± 33.01	132.50 ± 44.25	.615	0.42
Active external rotation, deg	42.00 ± 12.07	26.25 ± 25.62	.264	1.03
Active internal rotation	4.33 ± 0.82	4.50 ± 0.58	.822	0.22
Strength of abduction, kg	2.94 ± 1.85	1.34 ± 0.65	.071	0.94
Strength of external rotation at 0°, kg	4.91 ± 2.27	3.67 ± 1.61	.424	0.57
Strength of external rotation at 90°, kg	4.45 ± 2.55	1.77 ± 0.17	.027	1.16
Strength of internal rotation, kg	6.50 ± 3.43	6.72 ± 4.59	.841	0.06
CS	69.67 ± 14.74	69.50 ± 5.20	.802	0.01
SST	9.93 ± 2.74	9.00 ± 2.31	.254	0.35
SSV, %	71.33 ± 27.55	72.50 ± 15.00	.639	0.05
AHI on radiography, mm	9.16 ± 2.92	5.50 ± 4.36	.131	1.14
AHI on MRI, mm				
Rater C.I.d.C.A.	7.54 ± 2.08	5.26 ± 2.05	.045	1.10
Rater D.C.-C.	6.80 ± 2.08	4.25 ± 2.06	.047	1.23
Rater L.D.	6.80 ± 1.90	3.25 ± 1.50	.010	1.93
Goutallier grade of subscapularis				
Rater C.I.d.C.A.	1.53 ± 1.36	1.75 ± 1.71	.797	0.15
Rater D.C.-C.	1.67 ± 0.62	2.00 ± 1.15	.587	0.45
Rater L.D.	1.67 ± 0.72	2.00 ± 0.58	.589	0.47
Goutallier grade of supraspinatus				
Rater C.I.d.C.A.	2.80 ± 1.08	3.50 ± 0.58	.249	0.69
Rater D.C.-C.	2.27 ± 0.80	3.00 ± 0.00	.051	1.01
Rater L.D.	2.20 ± 0.68	2.50 ± 0.58	.435	0.45
Goutallier grade of infraspinatus				
Rater C.I.d.C.A.	2.40 ± 1.18	3.75 ± 0.50	.048	1.24
Rater D.C.-C.	2.20 ± 1.01	3.50 ± 0.58	.030	1.37
Rater L.D.	2.33 ± 0.96	3.50 ± 0.58	.038	1.30
Goutallier grade of teres minor				
Rater C.I.d.C.A.	0.00 ± 0.00	1.25 ± 1.89	.005	1.56
Rater D.C.-C.	1.53 ± 0.64	3.25 ± 0.96	.005	2.43
Rater L.D.	1.47 ± 0.64	3.00 ± 0.82	.005	2.27
Moderate to severe DGFD of supraspinatus,[b] %				
Rater C.I.d.C.A.	60.00	100.00	.137	
Rater D.C.-C.	33.33	100.00	.021	
Rater L.D.	33.33	50.00	.550	
Moderate to severe DGFD of infraspinatus,[b] %				
Rater C.I.d.C.A.	40.00	100.00	.038	
Rater D.C.-C.	33.33	100.00	.021	
Rater L.D.	40.00	100.00	.038	
Positive tangent sign, %				
Rater C.I.d.C.A.	46.67	100.00	.062	
Rater D.C.-C.	33.33	50.00	.550	
Rater L.D.	75.00	50.00	.550	

[a]Data are presented as mean ± SD unless otherwise specified. AHI, acromiohumeral interval; CS, Constant score; MRI, magnetic resonance imaging; SST, Simple Shoulder Test; SSV, subjective shoulder value.
[b]DGFD, dichotomized grade of fatty degeneration (Goutallier classification[21]): grades 0-2, no to mild fatty degeneration; and grades 3-4, moderate to severe fatty degeneration.

even to the FLA construct described in the study by Mihata et al.[37] In the former, to avoid delamination of the graft construct, 4 to 5 layers of the fascia lata were stitched together peripherally,[1] and at least 8 suture limbs from the glenoid anchors and 8 suture limbs from the humeral medial-row anchors were passed through the FLA construct.[11] In the latter, 2 layers of the fascia lata, including the intermuscular septum, were stitched together.[35] These stitches yield similar pitfalls in interpreting the appearance of the FLA and HDA constructs: there are small suture holes in the graft, which are evident >5 mm from the medial and lateral attachment margins in the

graft substance and should not be considered tears or perforations.[42] These difficulties in interpreting MRI scans are important to consider in the decision-making process after ASCR using an FLA and need to be critically weighed with the clinical outcomes before revision surgery is considered. In a study by Lim et al,[29] a 29% FLA tear rate at a mean follow-up of 12.8 months was reported. In contrast with the analysis in the current study, the subgroup analysis was performed with the inclusion of patients who had partial graft tears (analogous to Sugaya type-IV tears)[45] in the group of patients who had complete graft tears (analogous to Sugaya type-V tears)[45]; this graft tear group was compared with an intact graft group, and although the intact graft group showed better outcomes than the graft tear group, the results were not statistically significant. This grouping strategy may have undervalued the clinical effect of complete graft tears. Indeed, in the study by Sugaya et al,[45] the shoulders with type V retears demonstrated inferior outcomes, while those with type IV retears did not, suggesting that small defects remaining after surgery did not have an adverse effect on the clinical outcomes.

In the present study, the proportion of complete graft tears confirmed using MRI increased from 6 months to 3 years postoperatively. This proportion is among the lowest in the range of reported graft tears across different studies of ASCR and is lower than the reported proportion of graft tears among most of the studies of ASCR that used an HDA.[10,14] In the current study, the statistically significant interrater reliability for the Goutallier classification of the supraspinatus muscle was within the range of reliability statistics reported in other settings, such as those reported for preoperative MRI of supraspinatus tendon tears.[30,44] In the study by Lippe et al,[30] the interrater reliability for the Goutallier classification was fair to moderate (kappa = 0.41) and improved to moderate (kappa = 0.53) when using the dichotomized Goutallier classification of the supraspinatus. In the present study, the highest level of interrater reliability (kappa $\geq$ 0.90) corresponded to the dichotomized classification of the infraspinatus muscle, and moderate to severe fatty degeneration of the infraspinatus was correlated with the presence of a complete graft tear at 3 years after ASCR. The dichotomized Goutallier classification of fatty degeneration of the infraspinatus may be a useful tool because it has a potentially high prognostic value in the follow-up of patients who undergo ASCR and is very reliable. Indeed, in the current study, there was an almost perfect or perfect agreement for this MRI outcome among the 2 radiologists and the orthopaedic surgeon.

The clinical outcomes of the total study population at 3 years were good, and most patients had significantly improved, despite the presence of a complete graft tear. The patients who had a complete graft tear at 3 years had a higher probability of having 3 tendons torn (including the subscapularis) preoperatively, and complete graft tears were correlated with significantly less external rotation strength at 90° of abduction, higher fatty degeneration of the infraspinatus and teres minor muscles, and a lower AHI at 3 years. Because there were no significant differences between the groups of patients with and without complete graft tears in preoperative fatty degeneration either in the infraspinatus or teres minor muscle, these results suggest that a complete graft tear contributed to the increase in fatty degeneration of the infraspinatus and teres minor muscles. The higher grade of fatty degeneration of the teres minor muscle may have contributed to the relative loss of external rotation strength at 90° of abduction in these patients compared with the patients without a complete tear of the graft. This result supports the theory that the superior capsular graft has a tenodesis effect that rebalances the force couples in the axial, coronal, and sagittal planes, which enables the remaining muscles to improve function. This progressive fatty degeneration of the teres minor and infraspinatus muscles may lead to a decline of other clinical outcomes at future follow-ups in these patients who had complete graft tears, such as those reported among patients who had complete graft tears at 5 years in the study by Mihata et al.[36]

The patient satisfaction rate reported in this study was 100.0% in each subgroup of patients with or without a complete graft tear confirmed using MRI at 3 years. If patient satisfaction were used as the sole criterion of failure, complete graft tears would not be correlated with the failure of ASCR. Overall, from 2 to 3 years, patient satisfaction remained high and was within the highest range of satisfaction reported in other studies of ASCR; 90% and 72.9% of patients were satisfied in the studies by Pennington et al[41] and Denard et al,[12] respectively. However, in these studies, patient satisfaction was assessed at earlier postoperative time points: after 1 year[41] and after a mean final follow-up of 17.7 months.[12]

Patient satisfaction in the current study was high: 95.2% of patients would agree to undergo the same surgical procedure again, and 90.5% considered that the shoulder surgery's end result compensated for the changes in the thigh. However, a high proportion of donor site changes were reported. The high level of satisfaction in patients reporting changes in the harvested thigh may be explained by the limitations of the closed-ended type of questionnaire used in the current study. None of the patients had the opportunity to quantify the pain, deformity, paresthesia, or claudication either in frequency or intensity; therefore, the patients who experienced mild and infrequent donor site pain answered "yes," and this may have overstated the significance of the "yes" answer with regard to pain. In the cases (5.0%) reporting donor site dysfunction, there was a workers' compensation claim involved, and the patient, who was very satisfied, reported episodes of donor site–related claudication that was neither quantified nor present during the clinical examination. In a study on ASCR using a minimally invasively harvested midthigh FLA,[1] the same first 15 participants who were included in the current study were specifically observed for donor site morbidity, and each patient completed a nonarthritic hip score assessment. The authors reported that daily activity limitation, subjective loss of strength, and local complications decreased from 1 week to 6 months and from 6 to 18 months postoperatively, and it was concluded that the minimally invasive technique did not produce significant donor site morbidity or hip dysfunction at 18 months.

5.5. Conclusion and References

In the study by Mihata et al,[36] which had the longest follow-up period to date (5 years), 96.67% of the patients who underwent ASCR using an FLA needed no LHBT treatment, and inferior clinical and radiological results were reported in the 3 patients (10%) who had complete graft tears. In contrast, in the current study, 52.6% of the patients underwent concomitant LHBT tenotomy, and the remaining patients had an absent LHBT; 3 of the 4 patients who had a complete graft tear at 3 years after ASCR had undergone concomitant LHBT tenotomy. The theoretical pain relief provided by LHBT tenotomy, an advocated treatment option for massive RCTs,[47] cannot be excluded as one of the causes of the significant mean improvements and good clinical and functional outcomes in these patients. These good clinical outcomes, despite the presence of graft tears, support our decision to continue to perform LHBT tenotomy systematically as a concomitant pain-relieving procedure in ASCR. If ASCR is performed with concomitant LHBT tenotomy in the typical patient with an IRCT without significant glenohumeral articular cartilage degeneration, the results reported in the current study should be highly reproducible. This is generally the indication for ASCR across most studies that are conducted in similar settings and with identical definitions of IRCTs.[10]

Limitations

This study has some limitations. First, the sample size was relatively small for the subgroup analysis of graft integrity, even though the subgroup analysis was predefined and had only 2 subgroups, which reduces the risk of type I errors.[13] Nevertheless, the sample size was sufficiently large to achieve the statistical power needed to detect significant improvements in functional outcomes, and the emphasis of the discussion remained on the overall treatment effect among the total study population. Second, if this study is compared with studies of other treatment options for IRCTs,[17,18] the follow-up period may be considered relatively short. The length of the follow-up period was a consequence of a combination of factors, including the novelty of ASCR, the prospective design, and the MRI assessment. Indeed, the other studies that have reported graft integrity after ASCR using MRI are mostly retrospectively designed and have a minimum follow-up period of 6 to 12 months[11,12,28,29,41,50] or 2 to 5 years.[36,37] The 3-year time point for the assessment of graft integrity using MRI was considered important to fill the gap in knowledge on the outcomes of patients with a midthigh FLA beyond 6 months postoperatively. Third, the loss of 13.6% of the study population to follow-up for the MRI examinations introduced bias to the final analysis of the primary outcomes. This result is not uncommon in orthopaedic studies with enrollment by invitation, which require participants to undergo interventions at predefined time points and include patients from geographically distant referral centers. However, the loss to follow-up rate was lower for the subjective patient satisfaction and donor site morbidity assessments.

Last, LHBT tenotomy that was performed concomitantly with ASCR cannot be excluded as one of the causes of the improvement in the clinical outcomes in patients with a complete tear of the graft. This type of confounding factor is mostly unavoidable until prospective randomized studies comparing ASCR with or without LHBT tenotomy, regardless of LHBT-associated abnormalities, are ethically approved and designed.

CONCLUSION

The 3-year clinical outcomes of ASCR using a minimally invasively harvested midthigh FLA for IRCTs were good despite donor site morbidity. Active abduction improved significantly from 2 to 3 years. Complete graft tears were correlated with significantly decreased external rotation strength at 90° of shoulder abduction and increased grades of infraspinatus and teres minor fatty degeneration.

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CHAPTER 6

General discussion, future perspectives, and conclusions

6.1. General discussion

There are three main findings of the current thesis. First, ASCR using either FLA or HDA results in significant clinical improvements at a minimum follow-up of 12 months, but the FLA has a low tear rate, whereas no conclusion can be supported regarding the tear rate of HDA.

Second, the average values of the stiffness and Young's modulus do not significantly differ between the PFLA and MFLA, despite the significant difference in average thickness between proximal and mid-thigh harvested single layers of FLA.

Third, the impact of the donor site morbidity of the minimally invasive harvesting of the MFLA is low at medium-term, and the clinical outcomes of ASCR using the MFLA are good, despite the 21.1% of complete graft tears and the decreased external rotation strength in patients who have a graft tear at 3 years.

6.2. Current knowledge on ASCR

Since the original clinical study conducted and published by Mihata et al. in 2013,[80] several other authors have reported promising clinical outcomes of ASCR for the treatment of IRCTs.[16, 17, 23, 31, 32, 34, 54, 70, 71, 76, 79, 97] However, the studies on ASCR available to date have a low level of evidence, and most studies are either case series,[8, 16, 17, 23, 31, 32, 34, 54, 59, 70, 71, 76, 78, 79, 91, 97, 114, 123] case reports,[7, 87, 99, 107, 128] surgical techniques, [1, 4, 9, 14, 15, 18, 53, 62, 67, 85, 88, 93, 98, 113, 115] or biomechanical studies.[35, 75, 81-84, 111, 125] Among case series,[8, 16, 17, 23, 31, 32, 34, 54, 70, 71, 76, 78, 79, 91, 97, 114, 123] most of the studies that had a minimum follow-up of 12 months, magnetic resonance imaging assessment at a minimum follow-up of 6 months, and included 5 or more consecutive patients who underwent ASCR for IRCTs,[8, 17, 31, 32, 34, 54, 70, 71, 76, 78, 91, 97, 114] used either the FLA [8, 31, 70, 71, 76, 78, 91, 114] or HDA.[17, 32, 34, 54, 70, 97] Therefore, the systematic review of clinical outcomes of ASCR of the current thesis, which was conducted up to January 31, 2019, and reviewed the best available evidence in peer-reviewed literature on clinical and imaging outcomes of ASCR, was limited to the studies that used either the FLA or HDA. Going forward in time from 2019 to 2021, the number of clinical studies on ASCR using either the FLA or HDA, and reporting the longest-follow-up data, increased proportionately,[8, 17, 34, 44, 63, 64, 78, 91, 95, 102, 114, 123] whereas relatively less, or shorter-term follow-up data emerged regarding ASCR using other types of grafts: the LHBT autograft,[11] the porcine dermal xenograft (PDX),[37, 58, 100, 117] the FLA autograft augmented with synthetic mesh,[59, 101] or the stand-alone Teflon felt synthetic graft.[92] In the beginning, the type of graft choice was understated, because the

importance of graft type was unclear, and clinical studies and systematic reviews of clinical studies on ASCR either disregarded the type of graft,[70, 112] included case reports and very short-term studies in the outcome analysis,[22] or failed to determine the total number of shoulders that underwent an MRI postoperative control when calculating the proportion of graft tears.[60] In our systematic review, the importance of distinguishing between types of graft used in ASCR was made clearer, and the authors of the existing studies at the time we conducted the systematic review and whose results mixed different types of grafts in their outcome analysis were contacted and provided their study's subgroup analysis of patients according to type of graft.[70] Besides having obtained these data, we also calculated the proportion of graft tears in the autograft and allograft groups taking into consideration the total number of shoulders that underwent an MRI control to assess graft integrity, thereby avoiding the limitation reported by other systematic reviews that underestimated the rate of graft retears of the allograft group.[60] Going forward in time, other authors continued to disregard the type of graft; in the study conducted by Ohta et al.[91] that used the FLA, the authors used the iliotibial band in four patients and the tensor fascia lata in 31 patients, and prepared each final construct using the technique described by Mihata et al.[80]; these authors disregarded the meaningfulness of the choice of harvest location because they did not report the study's subgroup analysis according to harvest location.

The heterogeneity found among the existing studies published to date is not limited to the type of graft or harvest location choice; each study used different criteria for the definition of an irreparable tear, included different patient demographics regarding the number and type of tendons torn, and the grade of RCT arthropathy; the surgical technique of ASCR varied substantially across the studies, with relevant differences ranging from patient positioning (lateral decubitus or beach-chair), arm positioning (different angles of abduction, forward flexion, and axial rotation of the shoulder at the time of the attachment of the graft), type and number of arthroscopic portals (range, 3 – 5 portals), type, location and number of anchors (range, 6 – 9 anchors), type of concomitant surgical gestures (subscapularis tendon repair, rotator cuff partial repair, tenotomy or tenodesis of the LHBT, anterior acromioplasty, distal clavicle excision); the clinical outcome measures also varied, and used different methodologies, ranging from phone surveys,[17, 63] without range of motion measurements,[54, 63] to in-person visits that included objective measurements of both range of motion and strength; and the postoperative imaging assessment varied substantially across studies, with studies either with no postoperative imaging, or that used ultrasound instead of MRI for the postoperative graft integrity assessment,[11] or with a high proportion of patients who did not undergo the postoperative MRI examinations,[20, 97] or with patients who underwent the postoperative

MRI at distinct follow-up time-points from each other, and with very short-term minimum MRI follow-ups of 2 months.[20]

Regarding ASCR using either the FLA or the HDA, the mean improvements of outcome scores of ASCR in IRCTs were statistically significant and clinically important among each of the studies that have been published to date, which reported improvements in American Shoulder and Elbow Surgeons (ASES) score (range of means, 29.3 – 63 points),[17, 32, 34, 54, 70, 71, 76, 78, 97] active forward flexion (range of means, 28 – 74°),[8, 32, 34, 71, 76, 78, 97] external rotation (range of means, 9 – 25°),[8, 31, 32, 76], internal rotation (range of means, two to three vertebral bodies),[8, 31, 32, 76] visual analog scale (VAS, range of means, 2.5 – 5.9 points),[32, 54, 71, 97] CMS (range of means, 12 – 51 points),[8, 31, 34, 70, 71, 76] SSV (range of means, 35% – 41.3%),[31, 32], SST (6.1 – 8.6 points),[31, 34] and abduction strength (range of means, 2.3 – 4.5 kilograms).[31, 34, 97]

Furthermore, these studies reported rates of 66.7%,[31] 92.8%,[31] and 100%[34, 71] of pseudoparalysis resolution rates, which is an important outcome measure of the treatment of IRCTs. However, the definition and criteria for inclusion in the analysis of the pseudoparalysis differed across studies. In the study by Eigenschink et al.,[34] which used the HDA, patients with SCR failure (28.4%) were not included in outcome analysis at 12-month follow-up, and the majority of patients with SCR failure (67%) had presented with a preoperative pseudoparalysis. In the study by Burkhart et al.,[16] which used the HDA, a rate of pseudoparalysis reversal of 90% was reported, but this was a subgroup analysis of a subset of 10 pseudoparalytic patients with IRCTs who were previously included in the multicenter study by Denard et al.[32]. In a study by Mihata et al.,[79] a pseudoparalysis reversal rate of 95.3% following arthroscopic SCR with a fascia lata autograft was reported, but this study had overlapping samples with another study by Mihata et al.[76] Surgeons should be made aware of this heterogeneous range of criteria for either the definition of, or for the type of outcome analysis of pseudoparalysis, which may reduce the meaningfulness of the use of this outcome measure in the comparison of studies on the clinical outcomes of ASCR for the treatment of IRCTs. Moreover, the studies were heterogeneous regarding the type of tendons torn, specifically regarding associated subscapularis tendon tears, which has been shown to be one of the most important factors contributing to pseudoparalysis,[36] and to decreased clinical improvements after ASCR in IRCTs.[77]

High rates of patient satisfaction were reported in the studies on ASCR that used the FLA or the HDA. In the study by de Campos Azevedo et al.,[31] at the 2-year follow-up, 85.7% of patients would agree to undergo

the same surgery again. In the studies by Pennington et al.,[97] and by Denard et al.,[32], 90% and 72.9% of patients were satisfied at 1-year and at a mean 17.7-month mean follow-up, respectively. However, the heterogeneity of the definition of patient satisfaction across the existing studies may hinder the meaningfulness of the use of this outcome measure in the comparison between the studies.

Postoperative infection rates of 1.7%,[32] 2%[76], 4.5%[31] and 4.8%[34] were reported; infections required arthroscopic debridement and a course of intravenous antibiotic therapy,[31, 32, 76] and the superior capsular reconstruction site was kept intact after the infection resolved,[31, 76] or resulted in graft failure and led to RTSA.[34] The ASCR that uses the FLA typically requires longer operative times than the ASCR that uses HDA or PDX, because harvesting and preparing the autograft is time-consuming. Longer operative times theoretically increase the risk of infection, and reduced operative time is one of the arguments in favor of the use of the off-the-shelf HDA or PDX. However, ASCR using allografts or xenografts adds the risk of immunologic rejection to the risk of infection, whereas ASCR using autografts does not. In one study that used the PDX, a 15% rate of postoperative acute immunologic rejection of the xenograft was reported (in 3 patients); revision arthroscopy showed that the xenograft was completely degraded into small particles in each patient, and graft debris and all suture material were removed; one patient was dissatisfied with the outcome, and was revised to ASCR using the FLA, and improved significantly.[100]

The rate of revision to RTSA reported across the existing studies increased since the first clinical study conducted by Mihata was published in 2013,[80] and up to 2019, and continued to increase going forward from 2019 to 2021, which may have been related to the increased follow-up time, and to the increased approval rate of RTSA by local regulatory health agencies across the different countries where RTSA was previously unavailable. Overall, the rate of revision to RTSA was reported in studies from countries where RTSA had been available since at least a decade before study enrollment (Portugal,[8, 31] South Korea,[71], Japan,[91, 114], Austria,[34] and United States of America).[20, 32, 44, 54, 63, 95, 97] In three of these 13 studies, which used the FLA,[8, 31, 71] no patients had to be revised to RTSA; in two studies which used the FLA, 2.9%,[91] and 3.2% [95] of the patients had to be revised to RTSA; in the remaining 8 studies,[32, 34, 44, 54, 63, 95, 97] which used the HDA, 1.1%,[97] 5.6%,[44] 7.1%,[95] 9.4%,[63] 11.1%,[54], 11.9%[32], 16%,[20] and 19.0%[34] were revised to RTSA, respectively. However, a comparison of revision to RTSA rates between existing studies may be misleading because of the different follow-up periods and RTSA availability across studies, which are confounding variables.

Among patients who underwent postoperative MRI to determine the repair integrity, the reported graft tear proportion ranged from 4 to 41%,[30, 31, 59, 70, 71, 76, 91, 114] in studies that used the FLA, and ranged from 15 to 75% in studies that used HDA.[17, 20, 30, 32, 34, 54, 63, 70, 95, 97] The data on MRI assessment of graft integrity presented in the systematic review of the current thesis strongly supported the conclusion that FLA has a low tear rate, whereas no conclusion was supported regarding the graft tear rate of HDA because MRI was inconsistently ordered or was only ordered when there was concern about the reconstruction in the allograft studies. Going forward from 2019 to 2021, the same tendency of inconsistently ordering postoperative MRIs or only ordering MRIs when there was concern about the reconstruction, continued across studies that used either the HDA (none of,[44, 64] 53% of,[20] 60% of,[63] or 61 % of patients underwent a postoperative MRI),[17] or the PDX (none of,[58] 16% of,[100] or 25% of patients underwent a postoperative MRI),[37] whereas in the studies that used the FLA, each patient underwent a postoperative MRI.[91, 114] In the case-series study conducted by Barth et al. on ASCR using the LHBT, ultrasound instead of MRI exams were used to assess graft integrity postoperatively in each patient.[11] This inconsistency across most of the studies that used other types of graft other than the FLA is an obstacle to drawing meaningful conclusions from a comparison between outcomes of ASCR using the FLA and the LHBT, HDA or PDX.

In summary, the hypothesis that ASCR using the FLA would produce superior clinical outcomes and would have a higher graft survival rate than ASCR using the HDA could not be confirmed in the systematic review conducted by the author of the present thesis and has not been confirmed after a review of the literature going forward from 2019 to 2021. A wide range of clinical, imaging and surgical differences were found across the studies, besides differences in type of graft used, which may have influenced the reported outcomes of ASCR: number and type of tendons torn, grades of RCT arthropathy, fatty degeneration or tendon retraction; differences in patient positioning and arm positioning during graft fixation, configuration of graft fixation (the highest graft tear rate among studies that used the fascia lata autograft was reported in the only study with a single row configuration of the graft fixation on the humeral side),[70] type and number of anchors, or thickness of the graft construct; differences in additional intraoperative procedures (subscapularis tendon repair, partial rotator cuff repair, tenotomy or tenodesis of the LHBT, anterior acromioplasty, or distal clavicle excision); differences in the duration of follow-up and rate of loss to follow-up; differences in outcome measures and definitions, such as the definition of pseudoparalysis; differences in outcome reporting, because different methodologies were used, ranging from phone surveys to in-person visits, with either no shoulder strength measurement or different types of strength

measures, and finally with studies either reporting results from all patients in the final outcome analysis, or exclusively reporting outcomes from selected cohorts of patients with an intact graft.

ASCR for the treatment of IRCTs is a novel, and continuously evolving procedure, and the interpretation or comparison of the clinical results among existing studies is limited by their retrospective nature and heterogeneity bias. These limitations in the current knowledge on ASCR for IRCTs are mostly unavoidable until higher-level, comparative studies are conducted and published. Conducting higher-level studies is instrumental to research, and to understand the impact of the surgical decision-making and technique of ASCR, but higher-level studies are a challenge because they require long-term follow-up and meticulous clinical and imaging assessments, and there are several highly prevalent risk factors among orthopedic patients that have been shown to increase their resistance to the follow-up in-person visits for adequate physical examination, assessment of imaging, and evaluation of function.[2]

6.3. Biomechanical properties of the fascia lata graft constructs used in ASCR

The existing biomechanical studies conducted in cadaveric shoulders showed that ASCR using either the PFLA,[35, 75, 81-84, 110] or the HDA,[75] completely or partially restored the superior stability of the humeral head in shoulders with IRCTs, respectively. ASCR using a HDA was compared to the subacromial balloon spacer, and both techniques were shown to decrease superior humeral head migration, restore more normal glenohumeral joint position and forces during various abduction positions, and no substantial differences were identified between these techniques at time zero.[110] However, the existing biomechanical studies did not compare the material properties of the different types of FLA constructs. One single previous cadaveric study conducted by Otsuka et al. had determined the site specificity of the mechanical and structural properties of the single layers of fascia lata,[94] but the material properties of the different types of FLA constructs used in ASCR remained unknown. We hypothesized that the morphological properties of the final proximal- and mid-thigh-harvested FLA constructs would significantly differ because the morphological properties of the single layers of the FLA were site specific. The equivalent clinical outcomes of ASCR using either the PFLA or MFLA led us to hypothesize that the biomechanical properties of the PFLA and MFLA would not significantly differ. Determining the biomechanical equivalence between these two types of FLA graft constructs was important to support the choice of the MFLA versus the PFLA for ASCR, because the MFLA can be minimally invasively harvested. To test the hypothesis, the laboratory study was designed aiming to minimize the possible confounding variables of age, gender, preparation of

the specimens, and interfaces. First, knowing that the cadaveric study by Otsuka et al. had determined that the mechanical and structural properties of the single layers of fascia lata were gender specific,[94] we eliminated this confounding and also the confounding of age, and harvested the samples from the thighs of the same subjects: twenty proximally-harvested and twenty mid-thigh harvested samples from each side of the same 10 subjects were compared in the current thesis work. Second, with regard to the preparation of the cadaveric fascia lata, fresh cadaveric specimens were used, and this was the first study published to date that used fresh cadaveric fascia lata specimens, whereas the remaining cadaveric biomechanical studies used fresh-frozen specimens.[33, 35, 49, 75, 81-84, 110, 120] In a recent study, no significant differences in stiffness were found between fresh-frozen, fresh-frozen and gamma irradiated, freeze-dried, or freeze-dried and gamma irradiated fascia lata graft preparations.[120] However, the average Young's modulus and stiffness of fresh-frozen or embalmed cadaveric specimens have been shown to be significantly higher than those of fresh specimens,[55] and the mechanical properties of tendons and fascia lata have been shown to be significantly influenced by the fixation methods used to preserve the specimens,[43, 94] which means that existing biomechanical studies, which used fresh-frozen fascia lata graft preparations instead of fresh fascia lata grafts, have a confounding variable that compromises the meaningfulness of their conclusions. However, there is a generalized tendency among researchers to overlook this limitation because of the increased resources required to conduct a study using fresh specimens compared to fresh-frozen or embalmed specimens, because when using fresh specimens, the timing of each experimental procedure becomes dependent on the availability of eligible fresh cadaveric specimens, and legal and ethical regulations also restrict the harvest of fresh specimens to more than 24 hours post-mortem. This means that the mechanical properties of truly fresh fascia lata graft constructs are difficult to be accurately determined. Third, the current thesis was designed without the confounding produced by interposed sutures or anchors, allowing for the material properties of each fascia lata graft construct to be more accurately determined, while also avoiding the confounding variables involved in dynamic cadaveric shoulder models, which have several limitations when trying to reproduce the kinematics of living humans. Studies using dynamic cadaveric shoulder models have had the merit of determining that SCR with a FLA can normalize the superior stability of the shoulder joint when the graft is attached at 10° or 30° of glenohumeral abduction, that 8-mm-thick grafts have greater stability than 4-mm thick grafts,[81] and that side-to-side suturing to establish posterior continuity between the superior capsular FLA and the residual infraspinatus tendon completely restores the stability of the shoulder joint.[83] The knowledge produced through these studies has been clinical-practice-changing. However, we must interpret these results carefully because of the aforementioned arguments. These

concerns seem to be corroborated by the lack of consistent correlation between clinical outcomes and adherence to these technical aspects of ASCR.

In summary, in this work we aimed to determine and compare the material properties of the PFLA and MFLA. These two types of grafts were harvested from fresh human cadavers and were mechanically tested and, despite the significant difference in thickness between both single-layer and final construct of PFLA and MFLA, we found that the average values of the stiffness and Young's modulus did not significantly differ between the two types of FLA final constructs. Knowledge of the biomechanical equivalence of the MFLA and PFLA constructs may assist orthopedic surgeons in the choice of the location, harvesting technique, and type of graft construct for ASCR because the MFLA can be minimally invasively harvested using a reproducible technique, with a low donor site morbidity.

6.4. Mid-term clinical and imaging outcomes of ASCR and clinical importance of graft integrity

In the current study, we determined the clinical results and graft integrity at medium-term after ASCR using the MI harvested mid-thigh FLA in IRCTs. The hypothesis that the clinical outcomes would improve significantly from preoperatively to 3 years was confirmed, whereas the hypothesis that the outcomes would be significantly worse in patients who had a complete graft tear 3 years after ASCR was only partially confirmed. Indeed, despite the significantly decreased average external rotation strength at 90° of shoulder abduction in the group of patients who had a complete graft tear compared with the group without a complete graft tear, the remaining clinical outcomes at 3 years postoperatively did not significantly differ from the overall group. Evidence regarding the clinical relevance of graft integrity in the existing literature was lacking, and the results of this thesis work support the hypothesis that graft integrity correlates with better clinical outcomes at medium term after ASCR in IRCTs. Going forward in time, in the existing longer-term and/or better-designed studies that objectively measured shoulder ROM and strength and consistently ordered MRI examinations at final follow-up that used either FLA[71] or HDA[31] it has been shown that patients who have intact grafts fare significantly better than patients who have torn grafts,[34, 78] whereas in shorter-term and/or inferiorly designed studies without consistent MRI examinations at final follow-up that used HDA[63] or PDX[34] it has been argued that graft tears may have an insignificant impact on clinical outcomes after ASCR.[37, 63] Our thesis shows that graft integrity is important to preserve external rotation strength after ASCR at medium-term, and our results highlight the importance of

determining the predictive factors for graft tears because higher-demand patients target and value strength as an outcome of ASCR in IRCTs, whereas lower-demand patients may not; therefore, the latter may not report a significantly negative impact of graft tears on their outcome at medium-term. Caution is advised when interpreting the results of short-term studies on the clinical impact of graft tears because graft tears may cause further deterioration of the clinical outcomes with time. Nevertheless, the overall good clinical results despite the increase in the proportion of graft tears from 6 months to 3 years after ASCR in our series suggested that other factors contributed to the clinical improvement after ASCR, and we concluded that we should continue to perform the LHBT tenotomy systematically, or a tenodesis, concomitantly with ASCR, because the LHBT is a known pain generator in IRCTs.[122]

Furthermore, our thesis presents evidence of the low impact of donor site morbidity on the clinical outcomes of the ASCR that uses the MI harvested MFLA at medium-term, whereas evidence with regard to donor site morbidity of ASCR that uses the PFLA is lacking because the studies published to date on ASCR that uses the PFLA do not address donor site morbidity specifically.[59, 70, 71, 78, 91, 114]

In summary, several clinical studies have addressed the importance of graft integrity at short-term follow-up after ASCR. However, the correlations of graft integrity with clinical outcomes or graft tears as a cause of failure of ASCR at longer follow-up periods remained unclear. This thesis
assessed the 3-year clinical and MRI outcomes of ASCR using the MFLA and determined the clinical importance of graft integrity. Overall, we found that the 3-year clinical outcomes were good, despite donor site morbidity. Complete graft tears were correlated with significantly decreased external rotation strength and increased grades of infraspinatus and teres minor fatty degeneration. These results highlight the negative functional impact of the loss of graft integrity at a longer follow-up, and the importance of identifying the factors that contribute to increased graft longevity in maintaining improved clinical outcomes after ASCR.

6.5. Perspectives for future research

6.5.1. Predictive factors of graft tears

The predictive factors for graft tears after ASCR should be investigated to assist in the decision-making algorithm, and in the improvement of the surgical technique and clinical outcomes of ASCR for the treatment of IRCTs. As highlighted in the current thesis, the existing studies do not allow us to draw meaningful conclusions from the results because of the numerous confounding variables, ranging from different preoperative patient characteristics to several surgical technical variations. Eliminating all confounding variables is challenging in clinical studies and reduces the generalizability of the results. Computational studies that model human kinematics and biology using the material properties determined through experimental laboratory studies could overcome some of the challenges faced by clinical studies and could assist in determining the factors that correlate with a higher risk of the graft tearing. Computational models can be designed to analyze the kinematics of the shoulder after ASCR using the MFLA for the treatment of IRCTs using the material properties determined in the current thesis. Pursuing this line of research, we have collaborated in the first computational study of ASCR using the material properties of the MFLA determined in the current thesis. Full-thickness supraspinatus tendon tears were simulated to determine the shoulder position during ASCR that would result in increased shoulder stability and decreased risk of graft tear. Future research will allow us to determine the differences in shoulder stability and risk of graft tear after ASCR for the treatment of different combinations of type and number of torn tendons, and of different concomitant procedures, such as tenotomy or tenodesis of the LHBT. This methodology will allow us to analyze the kinematics of the shoulder after ASCR for the treatment of each specific type of IRCTs and to eliminate the confounding of the type and number of tendons torn, and of surgical technical variations such as the position of the shoulder, configuration of the reconstruction, number of anchors, acromioplasty, LHBT tenotomy or tenodesis.

6.5.2. Alternative types of graft construct

In the future, orthopaedic surgeons may offer patients the best-suited type of graft according to the specific characteristics of each patient, taking into consideration their risk factors for a graft tear, thereby offering tailored, made-to-measure, and best-fit suits instead of off-the-rack, prêt-à-porter clothes. Mixed types of graft constructs may be a solution to decrease the graft tear rate, improve the long-term clinical

outcomes of ASCR using the FLA, which ultimately may lead to a decrease in the dimension of harvested FLA required and to a decrease in the risk of donor site morbidity. Graft constructs of PFLA augmented with a type of synthetic mesh that has been widely and successfully used in other surgical fields have been shown to decrease PFLA tear rate.[59] This decrease in graft tear rate is not yet fully understood, and further research could help determine if it is a consequence of the increased structural properties provided by the mesh combined with the increased biological healing potential of the FLA. This alternative should also be investigated regarding MFLA augmented with mesh through further well-designed prospective comparative clinical and imaging studies, and biomechanical and computational studies.

6.5.3. Donor site morbidity across different types of harvesting

Donor site morbidity should be specifically addressed in future prospective comparative studies designed to determine the differences in donor site pain and disfunction between ASCR that uses the PFLA and the MFLA, fundamental in the decision-making of the surgical technique regarding the harvest location and autograft type. This could be achieved through a multicenter study, partnering with high volume referral shoulder surgery centers with surgeons who perform ASCR using the PFLA. Meanwhile, we have underway a retrospective study that includes an increased number of patients from our case series and uses a specifically designed methodology to determine the consequences of the choice of the harvest location in ASCR that uses the MFLA. This methodology could be used in future comparative studies.

6.6. Conclusions

The most current knowledge on ASCR, and the clinical, imaging, and biomechanical findings of the work of the current thesis show that the ASCR that uses the MI harvested MFLA is a good alternative to ASCR that uses either the HDA or the openly harvested PFLA. The findings of the current thesis confirm the importance of graft integrity for maintaining improved clinical shoulder outcomes and the low impact of the donor site morbidity of the ASCR that uses the MFLA at medium-term. The biomechanical observations of the PFLA and MFLA of the current thesis may assist in future research designed to determine the role of the FLA, paving the way to finding new strategies to improve the technique, graft healing, and clinical outcomes of ASCR. This work contributed to the improvement of the quality of life of the patients who undergo ASCR for IRCTs.

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