Long term results of arthroscopic rotator cuff repair: initial tear size matters.

A prospective study on clinical and radiological results at a minimum follow-up of ten years.

Abstract

Background: Arthroscopic techniques are now considered the gold standard for treatment of most rotator cuff (RC) tears; however, no consensus exists on the duration of results over time and long-term follow-up data have been reported for few cohorts of patients.

Purpose: The aim of this study is to present the long-term results associated to the arthroscopic treatments of RC tears and evaluate associations between preoperative factors and RC integrity at final follow-up.

Methods: After at least ten years from all-arthroscopic RC surgery, 169 patients were contacted and invited to a clinical evaluation. Information on preoperative conditions, tear size, subjective satisfaction and functional scores were collected, isometric strength and range of motion were also measured and each patient underwent an ultrasound examination to evaluate supraspinatus integrity and a shoulder radiograph to evaluate osteoarthritis.

Results: 102 patients were available for the final evaluation. Ultrasound revealed a prevalence of intact supraspinatus of 53.47%. Tear size was associated with supraspinatus integrity in univariate (HR = 3.04, 95% CI = 1.63–5.69, *P* = 0.001) and multivariable analysis (HR = 2.18, 95% CI = 1.03–4.62 *P* = 0.04). However, no significant differences were encountered in the subjective and functional scores collected, with the exception of the Constant-Murley score, which was significantly higher in patients with smaller tears at the index procedure. Strength testing revealed also a significantly superior abduction and flexion strength in this group and radiographs showed a significantly higher acromion-humeral distance and lower grades of osteoarthritis.

Patients with an intact supraspinatus at final follow-up showed superior results in all functional scores, greater satisfaction, superior abduction and flexion strength, higher acromion-humeral distance and lower grades of osteoarthritis.

Conclusions: Rotator cuff tear size at the time of surgery affects significantly supraspinatus integrity at a minimum follow-up of ten years. However, a larger tear is not associated with an inferior subjective result, although it negatively influences abduction and flexion strength, range of motion and osteoarthritis progression.

Intra-operative efforts to obtain a durable RC repair are encouraged, since supraspinatus integrity at final follow-up influences clinical and functional outcomes, patient satisfaction and osteoarthritis progression.

Level of Evidence: II, prospective cohort study

What is known about this subject:

Surgical management of rotator cuff tears is evolving rapidly and arthroscopic techniques are now considered the gold standard for treatment of most rotator cuff tears, providing similar functional results to open and mini-open surgery, with a decrease in post-operative complications. A wide variety of different treatment modalities can be performed arthroscopically, and most publications report satisfactory results at short-term follow-up evaluation. However, no consensus exists on the duration of results over time and long-term follow-up data have been reported for few cohorts of patients. Specifically, outcomes for patients treated with all-arthroscopic rotator cuff repair at a minimum follow-up of ten years have been reported only by the publication by Heuberer et al. on this Journal in 2017 for 30 patients.

What this study adds to existing knowledge:

This study presents the results of a large cohort of patients treated with all-arthroscopic rotator cuff repair at a minimum follow-up of ten years. Herewith, it provides clinicians and researchers with an updated standpoint about the results of arthroscopic rotator cuff management.

Furthermore, associations between preoperative factors and rotator cuff integrity at final follow-up were evaluated and confirmed the role of initial tear size in affecting long term cuff integrity. Surprisingly, here a stratified analysis of the study population permitted to find out that larger tears are not associated with inferior subjective results, although they negatively influence abduction and flexion strength, range of motion and osteoarthritis progression.

Finally, the role of cuff integrity, influencing clinical and functional outcomes, patient satisfaction and osteoarthritis progression, as previously documented at short- and midterm follow-up, was confirmed also at the long-term follow-up.

Introduction

Surgical management of rotator cuff (RC) tears is evolving rapidly and the number of publications regarding arthroscopic RC repair increases dramatically every year [33]. Arthroscopic techniques are now considered the gold standard for treatment of most RC tears, providing similar functional results to open and mini-open surgery, with a decrease in post-operative complications [48].

A wide variety of different treatment modalities can be performed arthroscopically, and most publications report satisfactory results at short-term follow-up evaluation. However, no consensus exists on the duration of results over time and long-term follow-up data have been reported only for few cohorts of patients. The goal of this study is to present the long-term results associated to the arthroscopic treatments of RC tears, in order to provide clinicians and researchers with an updated standpoint about the results of arthroscopic RC management.

Materials and methods

The primary aim of this prospective observational clinical trial on an historic cohort was to measure the proportion of patients which still presented an intact supraspinatus tendon (SSp) at least ten years after arthroscopic RC repair. Secondary goal was to evaluate associations between pre-operative conditions and integrity at a minimum follow-up of ten years. Finally, functional and radiological outcomes were compared between patients with and without intact SSp and between patient whose tear was classified as small (C1-C2 according to the Southern California Orthopaedic Institute – SCOI – classification system [47]) and large (C3-C4) during procedures for arthroscopic RC repair.

The study protocol was approved by the Regional Ethical Committee (authorization number [redacted]).

Surgery was performed under sedation and brachial plexus block with the patient in a lateral decubitus position, with the upper limb kept at about 30° of abduction and 30° of flexion. Diagnostic arthroscopy was performed from standard posterior, midglenoid and lateral portals; the size of the tear was classified according to the SCOI classification [47]. The tendon was repaired by use of double- or triple-loaded suture anchors. A standard single-row suture anchor repair was used in all patients. Acromioplasty was performed with Sampson's cutting block technique in patients with type 2 or 3 acromial morphology according to Bigliani's classification. All the patients were operated by a single surgeon ([redacted]).

After the operation all patients wore an arm-sling day and night for 4 weeks after surgery; during that period the sling was removed only to eat and perform personal hygiene and light exercises of mobilization of the elbow and scapulothoracic joint. From the 29th day, unless otherwise indicated, patients began passive physical therapy to recover the full range of motion of the shoulder joint. From the end of the second month, patients started active physical therapy, lasting 4 weeks, to regain muscle strength.

Patients who underwent arthroscopic treatment of RC tears January 2002 and July 2007 were prospectively evaluated from January 2014 to July 2017 ([redacted]).

After at least ten years from surgery, a telephonic interview was conducted to inquire if the patient had been re-operated on the index shoulder, to collect Simple Assessment Numeric Evaluation (SANE), Numeric Rating Scale (NRS), American Shoulder and Elbow Surgeons (ASES) and

Simple Shoulder Test (SST) scores, assess satisfaction and to invite each patient to a functional and radiological evaluation.

During the clinical evaluation, the Constant-Murley Score (CMS) was collected and isometric strength in shoulder forward flexion and abduction were measured. All measures were performed in triplicate with a dynamometer (Kern HCB, Kern & Sohn GmbH, Germany).

Each patient underwent also a shoulder radiograph and an ultrasound examination of the RC ([redacted]), performed using the high frequency linear transducer (12.5MHz) of a Samsung RS80A Prestige ultrasound. US was chosen because it is fast, thus increasing patients' compliance to follow-up, cost effective, and its reliability in evaluating RC integrity was already evaluated also at mid-term follow-up [18,19,25]. Furthermore the US agreement with MRI imaging was proven to be high in evaluating RCs at midterm follow-up [25,52].

The ultrasound was performed by a dedicated musculoskeletal radiologist and used to define tendon integrity as a dichotomic variable: an intact SSp was defined as such if the fibres were continuous for the full tendon thickness and throughout its course, up to the tendon footprint. A tendon presenting with a complete interruption of the fibres or with a hypoechoic area greater than 1 cm was defined as non-intact.

On standard anteroposterior shoulder views the acromio-humeral distance (AHD) was measured and the presence of shoulder osteoarthritis (OA) was classified according to both Hamada [20] and Samilson-Prieto [44] classifications.

<u>Statistical analysis</u>

A power analysis prior to study begin indicated that minimal sample size of 100 patients was sufficient to test the hypothesis that the proportion of patients who still presented and intact SSp at least ten years after arthroscopic RC repair is greater than or equal to 70% total operated patients, achieving a two-sided 95% confidence interval with an amplitude of 18% [0.61-0.79] (Gaussian approximation). The figure of 70% was chosen based on previous reports on mid-term follow-up results [18].

Statistical analysis ([redacted]) was performed using GraphPad Prism v 6.0 software (GraphPad Software Inc.) and SAS software, version 9.4 (SAS Institute, Inc., Cary, NC).

The differences between the groups of patients for continuous variables were evaluated with unpaired Student's t-test or Mann–Whitney test according to the characteristics of the data distribution. Categorical variables were evaluated with the Chi-square test or Fisher's exact test.

The proportional hazards regression model for interval-censored current time to event data was used to estimate univariate and multivariate harzard ratios for evaluating the association between covariates and SSp integrity [50]. We refer to current status data for patients of this study as only one clinical visit was performed for evaluating the integrity state of SSp after 10 years of follow-up. The exact time of any new lesions is not known. For all analyses, the significance level was set at p-value lower than 0.05.

Results.

One hundred sixty nine patients were eligible for clinical evaluation. A flow diagram illustrates the grouping and flow of patients in our clinical study (Figure 1).

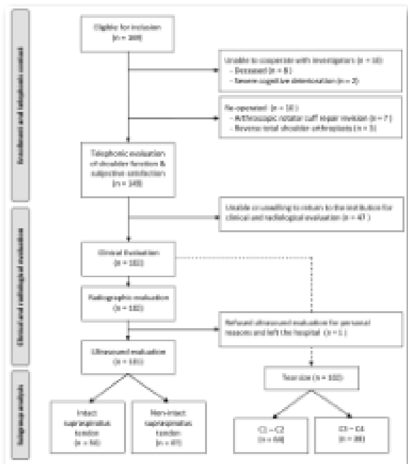


Figure 1

Eight patients had deceased during the follow-up period for reasons not related to the RC pathology, whereas two developed a severe cognitive deterioration and could not collaborate to the data collection; ten patients underwent a re-operation during the follow-up period (arthroscopic revision of the arthroscopic RC repair in seven cases and reverse total shoulder arthroplasty in three): all these patients were excluded from further analysis.

One hundred forty nine patients were available for a telephonic interview, and 102 patients also agreed to return to our institution for clinical and radiological evaluation. One patient finally refused the ultrasound evaluation. Demographic data of the group of patients who received a clinical assessment are reported in Table 1.

<u>Supraspinatus integrity.</u>

Ultrasound evaluation of 101 patients revealed a prevalence of intact SSp of 53.47%.

The association between possible risk factors and SSp integrity was evaluated with Cox regression models (Table 2) for current status data. Tear size was associated with SSp integry in univariate (HR=3.04, 95% CI=1.63–5.69, p=0.001) and multivariable analysis (HR=2.18, 95% CI=1.03–4.62, p=0.04). Concerning age, gender, operated side, BMI, smoking habits and diabetes, there was no evidence of association with RC integrity ten years after repair. The final Hamada grade was also significantly associated with SSp integry in univariate (HR=6.32, 95% CI=3.32–12.03, p<0.001) and multivariable analysis (HR=5.07, 95% CI=2.21–11.64, p<0.001), while Samilson grade and AHD were significant only in univariate model.

Subgroup analysis: tear size.

A stratified analysis of study populations was subsequently performed and the patients available to clinical follow-up were further divided in two groups, according the tear size as classified during surgery (small: C1-C2, large: C3-C4) and their demographic, clinical and radiological data were compared (Table 3, 4). Patients with smaller tears (C1-C2) were younger at the moment of intervention and showed a superior proportion of intact RC at final follow-up.

However, no significant differences were encountered in the clinical and functional scores collected, with the exception of the CMS and the SST (Figure 2; Figures e1-e10 – supplementary material).

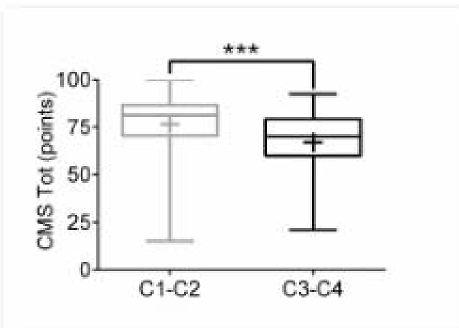


Figure 2

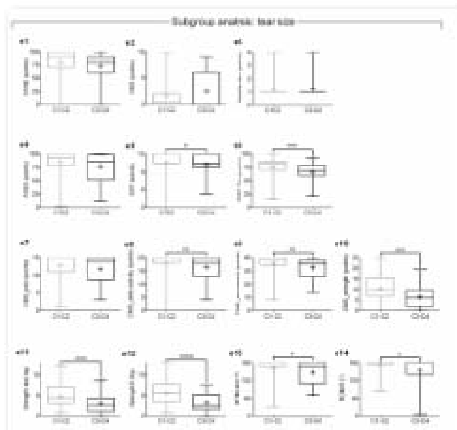


Figure e1-e14 – supplementary material

Strength testing revealed superior abduction and flexion strength in the C1-C2 group (Figures e11-e14 – supplementary material). A higher AHD and lower grades of OA according both to the Samilson-Prieto and to the Hamada classification were registered in the C1-C2 group (Figures 3-4).

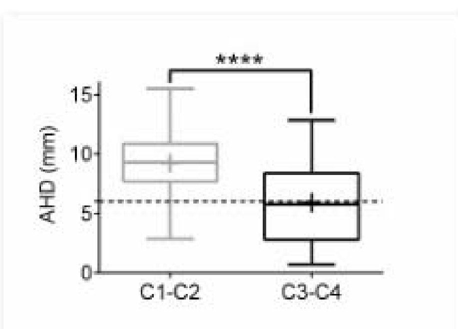


Figure 3

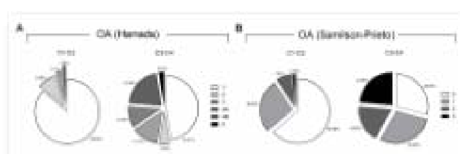
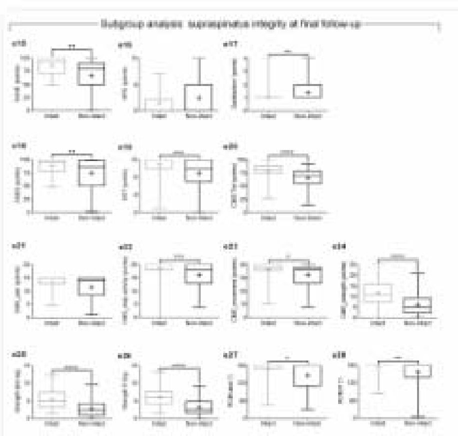


Figure 4

Subgroup analysis: supraspinatus integrity at final follow-up.

According to SSp integrity at final follow-up, patients were subsequently divided in two groups (intact, non-intact) and their demographic, clinical and radiological data were compared (Table e1, e2– supplementary material). Patients with intact SSp were younger at the moment of intervention and showed superior results in all scores, with the exception of the NRS. Strength testing revealed a superior abduction and flexion strength in the intact SSp group (Figures e15-e28 – supplementary material).



Figures e15-e28 – supplementary material

A higher AHD and lower grades of OA according both to the Hamada and Samilson-Prieto classification were registered in the intact SSp group (Figures 5-6).

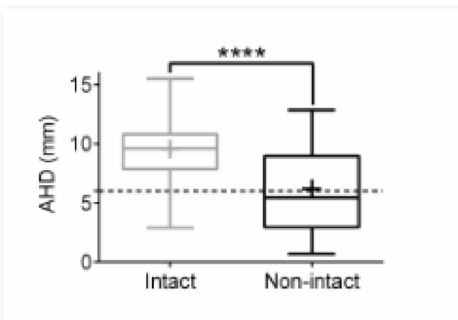


Figure 5

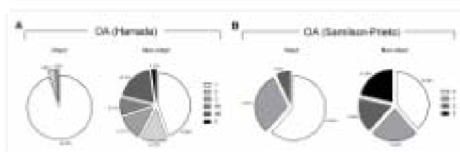


Figure 6

Discussion

This study has four main findings:

1) Tear size at surgery is associated with SSp integrity considering a minimum follow-up of ten years. Specifically, patients with larger (C3-C4) tears, have a 2.18 higher risk of presenting a non-intact RC during follow-up.
2) A difference in CMS, strength, ROM and OA progression, but not in subjective scores, can be identified when comparing patients with small (C1-C2) and large (C3-C4) RC tears.
3) The proportion of patients which still presents an intact SSp tendon (SSp) at least ten years after arthroscopic RC repair is 53.47% and is less than the expected.
4) SSp integrity at final follow-up influences clinical and functional outcomes, patient satisfaction and OA progression.

The cohort presented in this study is the first one where US evaluation is performed to assess RC integrity after arthroscopic repair at a minimum follow-up of ten years and the third one of which such long-term results are described. Heuberer et al. presented in 2017 the results of a case series of thirty patients, whose clinical outcomes were collected prospectively ten years after arthroscopic RC repair, together with MRI assessment of RC integrity [21]. More recently, several studies originating from the same cohort of patients enrolled under the direction of the Société Française de Chirurgie Orthopédique et Traumatologique (SOFCOT) in 2003 were published. These studies evaluated different aspects of RC repair and their results, including however a relevant fraction of patients who underwent open RC repair [2,9,15].

Predictive factors

A relevant finding of this study is that RC tear size at the index procedure is significantly associated with RC integrity at 10-years follow-up. Specifically, patients with C3 and C4 tears have a more than double risk of having a non-intact SSp tendon ten years after surgery (HR 3.04 in univariate and 2.18 in multivariate analysis). This information is precious for patient counselling and to help develop realistic expectations before surgery, since magnetic resonance imaging has been demonstrated to predict with high diagnostic accuracy and reproducibility the intra-operative findings as classified by the SCOI system [3]. Furthermore, this study extends the results of previous studies which already indicated that RC tear size (dimensions, area, and thickness) is strongly associated with re-tears at six [29,30] and nine months after surgery [22]. The role of tear pattern in predicting outcomes is still discussed [22,55].

Other predictive factors were previously identified: Tashjian et al. suggested that increased age and longer duration of follow-up can be associated with lower healing rates [51], Lee et al. showed that not only initial tear size, but also patient age and fatty degeneration of the SSp are independent risk factors for RC retear [30] and Jeong et al. also indicated SSp muscle atrophy and fatty infiltration of the infraspinatus as independent factors for RC retear [22]; a recent systematic review also suggested that additional biceps or acromio-clavicular procedures can have a negative influence on cuff integrity at follow-up [28].

Our analysis could not confirm the role of age in predicting RC integrity at long-term follow-up and the study design did not include prospective collection of information on fatty degeneration of the RC, since at the moment of surgery the role of this parameter did not yet have the relevance which it has nowadays, both as predictor for RC outcome but also for reparability of the RC [24].

It is still unclear if a direct correlation between RC integrity and clinical outcome exist, with studies demonstrating that clinical improvements and pain relief after arthroscopic RC repair of large and massive tears can be durable at long-term follow-up, despite early structural failure of repair, especially in older patients [19,40]. Therefore, predictors of clinical outcomes were investigated in previous long-term follow-up studies of in open RC surgery: female gender, older age, associated biceps pathology, and larger tear size were related to poorer functional outcomes [43] whereas RC integrity at short- and long-term follow-up correlated positively with clinical and functional outcomes [25,54] – findings which have been confirmed also for arthroscopic surgery in the short- and long-term follow-up [39]. The design of this study does not allow to draw definitive conclusions on the predictive role of RC integrity on functional outcomes; however, when comparing patients with intact and non-intact RC at final follow-up, significant differences were encountered in favor of patients with intact RC in terms of strength, ROM and all functional scores evaluated.

SSp integrity at long-term follow-up

The SSp integrity ratio documented in the present (53.5%) study approximates closely the one reported by Heuberer et al. (50%) [21], but is markedly inferior to that reported in a previous similarly designed prospective study with a minimum follow-up of five years [18]. The conclusions derived these data support the hypothesis that a proportion of arthroscopic RC repairs can also fail several years after an initially successful repair. This is opposed as what previously documented for open and mini-open RC repairs, where survivorship analysis suggested that if a repaired RC repairs survives the early phase, then it’s highly likely it will survive also over the long term follow-up [17,25,34].

Both the results of this study and that by Heuberer et al. describe a slightly inferior proportion of RC integrity than previous studies in which an open technique was used in all enrolled patients [25] or in approximately half of them [2,9,15]. Possible explanation for these different findings can be the different initial patient selection, technical differences between surgeons and also the fact that arthroscopic repair was, at the time these surgeries were conducted, a relatively new procedure. In its initial phase, this innovation had to dismiss traditional, well-performing techniques (transosseous repair) because excessively technically demanding, and prefer minimally invasive but anatomically less-precise strategies (suture-anchors) [41]. The evolution of arthroscopic technique from single row to double row to transosseous equivalent and arthroscopic transosseous repair in order to imitate as closely as possible the anatomical results of open transosseous repairs has raised great expectations and long-term results of these technique are awaited. This considered, the results of this study on the gold standard but an “old” technique gives the reasonable hope that a surgeon performing RC repair with more developed techniques can expect a SSp integrity rate of at least 50% at a long-term follow-up. Of course this hypothesis should be confirmed by further study with a design similar to this one.

When analyzing the survivorship, Millet et al. created Kaplan survivorship curves for his series of open RC repairs and reported an extremely high survivorship of 94% at 5 years and 83% at 10 years [34], whereas Sperling et al. According to Kaplan-Meier analysis, the estimated rate of documented a survival free of additional surgery was 86% at 5 years, 86% at 10 years, and 79% at 15 years on patients operated at an age younger than 50 [49].

A relatively low CMS (mean 64.4) was documented at a further follow-up point of minimum 16 years [6], which was correlated with a high rate of full-thickness retear (94%) evaluated by MR arthrography [54].

In the SOFCOT cohort, RC repair was open in one half of the patients and arthroscopic in the other. Here the percentage of tendon healing was reported as ranging between 68% and 81%, depending on the initial type of tear [2] and a separate study by the same study group on massive tears indicated a retear rate of 34% [9]. Interestingly, no significant differences were noted in the re-tear rate between isolated SSp tears and tears with different extension, although the failure rate was higher in the group with posterior extension [2]. This is in contrast with the results of the present study, where a significant difference in the proportion of intact RC was documented in C1-C2 tears when compared with C3-C4 (68% vs 29%, p: *0.0002*). Our study strongly supports the hypothesis that initial tear dimension influences the chances of maintaining integrity at long-term follow-up. This hypothesis is also supported by studies reporting long-term results of open RC repair, which are more numerous than those investigating the recently introduced arthroscopic technique. For example Nich et al. reported the results of isolated SSp repair and observed a re-tear rate of 17.4% on MRI evaluation 8.6 years post-operatively [38], whereas Van Duerzen et al. repaired small- to medium-size full-thickness RC tears and reported loss of structural integrity in 24% of all cases at a mean follow-up of 11.3 years [11], both results which approximate well those of the SOFCOT cohort for the isolated SSp group (19% retear) [2].

On the contrary, when considering massive tears assessed by MRI at 9.9 years post-operatively, Zumstein et al. reported a much higher retear rate (57%), which comes closer to the figures reported in our studies for C3-C4 tears (SSp non-integrity 71%) [59].

Clinical outcomes

Good clinical outcomes of arthroscopic RC repair at long term follow-up have been shown both in the present study (Table 4) and in the previously cited work by Heuberer et al. (CMS 77.5 ± 15.6, UCLA 89.7% ± 15.9)[21]. Slight inferior clinical results were described by Agout et al. for the SOFCOT cohort (total weighted CMS 60.4 ± 19.3 – 70.6 ± 19.4 depending on tear type) [2].

Few other studies report results of arthroscopic RC repair with a medium-long follow-up: Marrero et al. evaluated 33 tears of different sizes at a minimum follow-up of 9 years, reporting a mean UCLA of 31.8, with 87.7% of excellent and good outcomes [31]. Similar results have been also reported by Miyazaki et al. on 35 arthroscopic repairs of massive RC tears, which maintained good functional results (UCLA 31.31) and satisfaction also after a minimum length of follow-up of 9 years [35]. Denard et al. reported 78% good to excellent outcome at a minimum 5-year follow-up after arthroscopic RC repair of massive RC tears (mean UCLA 30.7, mean ASES 85.7), further suggesting that double-row repair can provide a superior UCLA gain than single row technique [10]. In the series presented by Wolf et al., good to excellent outcomes were maintained in 94% of patients 4 to 10 years after surgery [56].

Other long-term results available refer to open or mini-open techniques: early studies on long-term outcomes of open RC repair suggested satisfactory results with decrease in pain after surgery and a return to preiniury activities [1,5], and more recent ones confirmed maintenance of good strength and high CMS score also 10 years after open repair [8,16]. Kluger et al. and Saraswat et al. described that those improvements obtained in the short-term are maintained up to 10 years after mini-open RC repair (ASES 95 [30-100][25]; ASES 90.4 ± 19.4, WORC 88.7 ± 17.8 [45]) and Bell et al. reported good or excellent outcomes in more than two-thirds of their patients treated with arthroscopic subacromial decompression with mini-open RC repair, without significant changes in the UCLA score between 2-, 7-, and 15-year follow-up [4]. In a mixed series of arthroscopic or mini-open repairs of small- to medium-size RC tears on 44 patients after a mean follow-up of 11.3 years, van Deurzen et al. could show satisfaction in 80% of the cases and 76% good to excellent functional outcome (median CMS 82, range 29–95, median DASH 5.0 range 1.0–54; median Oxford Shoulder Score 19, range 13–39) [11]. Finally, Collin et al. reported an average CMS of 78.5 in a mixed series of arthroscopic and open repairs of massive tears at ten years follow-up, documenting an association between the preoperative tendon retraction of the infraspinatus and the CMS [9].

Muscle strength

After arthroscopic RC repair, muscle strength demonstrates the slowest recovery as compared to pain and shoulder function. To reach the strength of the uninjured contralateral shoulder in all 3 planes of motion, recovery can take 6 months in patients with small tears and 18 months in patients with medium tears, whereas, in patients with large-to-massive tears strength can remain inferior to the contralateral shoulder also after 18 months follow-up. However, strength did not appear to significantly correlate with post-operative patient satisfaction [46]. A similar finding was reported by Dodson et al., who noted that at an average follow-up of 7.9 years, patients with recurrent RC defects showed progression of tear size and strength deficits, improvement in terms of pain, function, and satisfaction [12]. Our study was not designed to correlate strength deficits with clinical outcomes. However, we could observe that patients with smaller lesions presented at final follow-up a significantly superior strength in flexion and abduction, but this finding correlated only with a significantly superior CMS and neither to a superiority in other functional scores, nor to the level of satisfaction or in pain scale. These findings are in accordance with Dodson's and suggest that patients with recurrent defects can remain asymptomatic over the long term but will predictably lose strength in the involved extremity [12]. In any case, to ensure the maximal possible strength gain after surgery, it is recommended that patients with large tears should be encouraged to continue with rehabilitation beyond one year post-operatively [46].

Osteoarhtritis

The loss the RC's stabilizing function can lead to joint degeneration and RC tear arthropathy [7,13]. Specifically, arthritis progresses more in shoulders with degenerative RC tears as compared to controls [7] and size appears to be the strongest predictor for proximal humerus migration [23]. Therefore, especially in case of large, symptomatic tears, RC repair can slow down OA progression. This was recently confirmed in a retrospective analysis of mini-open RC repairs over a minimum of 10 years of follow-up, in which progression of OA was affected by cuff integrity and RC dysfunction due to poor cuff integrity was a risk factor for shoulder arthritis [32].

However, even if RC tears are repaired, the progression of osteoarthritic changes cannot be halted, with some investigators reporting the rate of OA progression after primary RC repairs to be 18–20% at 9–10.5 years post-operatively [1,17] and other indicating a far higher rate of 61% in patients with massive RC tears [59].

The progression of cuff tear arthropathy, i.e. arthritis related to RC degeneration, can be represented by the Hamada classification: in our cohort, more than 70% of our patients maintained the lowest grade according to this classification, with this percentage being higher in patients with initially small lesions (86%) as compared to patients with larger lesions (47%). These figures are, as expected, higher than those reported by Paxton et al. in failed repairs of large or massive RC tears at ten-years follow-up [40] and than those reported by Ranebo et al. in patients with full thickness RC tear treated with acromioplasty without tendon repair at 22-years follow-up [42]; however, the last author reported a 93% Hamada grade 1 in patients with partial thickness RC tear, who also received the same minimal treatment: these findings support the hypothesis that RC tear is a potentially progressive disease in which cuff integrity is an important determinant for progression [23,42].

The SOFCOT study group also provided an analysis of OA progression after RC repair, including 401 patients treated by both open and arthroscopic techniques. Here the Samilson-Prieto classification was used, although it was originally described for use in patients with dislocation arthropathy and concentric glenohumeral OA. In this study, 45% of the patients had a Samilson-Prieto grade 0 and the CMS was significantly higher in this group than in patients with osteoarthritis. Furthermore, RC integrity was significantly associated with the absence of osteoarthritis, so that the authors conclude that an unhealed or re-torn cuff increases the risk of developing osteoarthritis [15]. Similar findings were encountered in our cohort, with a prevalence of 50% Samilson-Prieto grade 0 patients and a significant association between RC integrity and absence of OA (Figure 6, Table e2 – supplementary material).

When analysing only patients treated by arthroscopic repair by the SOFCOT study group, a rate of OA (defined as Samilson grade 2-3-4) of 14% was identified, slightly inferior to our figure of 21.8%. These difference can probably be explained by the fact that, in the SOFCOT cohort, patients with larger tears were more frequently allocated to open surgery treatment [15]. The fact that open repair could be associated to a higher OA progression is supported also by the results presented at ten-year minimum follow-up by Elia et al., who reported Samilson-Prieto grade 0 in only 21% of their cases [14].

<u>Non-operative treatment</u>

An important issue to consider when analyzing the result of the operative treatment of RC tears is the non-operative alternative. Unfortunately, the number of studies dealing with conservative treatment is way inferior to that dealing with surgical results. In the sole available long-term study on non-operative treatment, Moosmayer et al. analyzed the natural history of fourty-nine small to medium-sized full-thickness RC tears treated with physiotherapy and observed with sonography major changes of tear size (≥20 mm) in 16% of the cases at an average follow-up of 8.8 (8.2-11.0) years [36]. A similar rate of progression (16%) was identified in another study investigating high-grade partial-thickness RC tears at one-year follow-up [26]. The presence of medium- sized tears, full-thickness tears, and smoking were identified as factors influencing tear progression in patients treated conservatively [57].

The results of these studies suggest that the decisions to undertake surgical repair at time of presentation may be excessive, and an initial attempt of conservative treatment, combined with morphologic evaluation of tear progression, should always be warranted [26]. In contrast whit these results, however a case-control study revealed that tear size, together with sex and functional scores at presentation were not associated with treatment allocation. On the contrary, higher age, higher BMI, and duration of symptoms longer than 1 year were predictive of nonsurgical treatment [27]. Our patients with C1-C2 tears had a CMS at 10-years follow-up of 81.50 [70.47-86.54]. These results are similar to those reported by Moosmayer et al in the fraction in which the tear remained stable or progressed <20mm. The authors specify that this group maintained satisfactory CMS, ASES, VAS and strength, whereas these functional outcomes dropped significantly in patients who experienced a size change ≥20 mm [36]. When comparing the results of this latter group with our patients with C3-C4 tears, inferior pain score, superior CMS and ASES were obtained by operatively treated patients. The comparison of these data suggests to begin a conservative treatment in patients with small tears, monitoring tear progression; on the other hand, it appears that an operative treatment could lead to superior results than conservative treatment in case of tears already presenting as symptomatic large lesions, those progressing from small to large or those provoking recurrent symptoms.

Limitations of this study include the relatively high rate of patients unwilling or unable to return to the institution for the clinical evaluation: this is explained by the fact that arthroscopic RCR was not widely available across the country at the time surgery was conducted and, more than ten years later, many patients did not agree to travel again over a long distance for a follow-up evaluation. Furthermore, the study design (prospective observational clinical trial on an historic cohort) did neither allow to include a pre-operative evaluation, nor a short-term follow-up point. The latter could have been interesting to evaluate the rate of late RC failures, which isn’t clearly defined yet.

However, for the clinical evaluation, a single long-term follow-up point appears sufficient, since clinically significant improvement in patient-reported outcomes, range of motion, and strength occurs mostly up to one year after surgery, and rarely beyond this point [58].

Another limitation of this study is the lack of a control group treated by conservative treatment or simple arthroscopic debridement by the same surgeon. After an acromioplasty, most unrepaired full-thickness tears will, in long-term, increase in size and be accompanied by cuff tear arthropathy changes [42]. The possibility of evaluating the contralateral side as "healthy control" was discarded, since a high prevalence of asymptomatic lesions has been described in patients of this age [53].

Finally, the study was not designed to evaluate the effects of specific working or leisure activities on RCR survival and could not consider constitutional differences among the study population, all factors which can affect short- and long-term results [37].

Conclusions

RC tear size at the time of surgery affects significantly SSp integrity at a minimum follow-up of ten years after a full arthroscopic rotator cuff repair. However, a larger tear size is not associated with an inferior subjective result, although it negatively influences abduction and flexion strength, ROM and OA progression.

Considering that the results of this study are based on an arthroscopic traditional single row technique, a prevalence of intact SSp of at least 50% is reasonable to be expected ten years after surgery especially if conducted with more modern techniques, like arthroscopic transosseous. This information is precious for patient counselling and to help develop realistic expectations. Intra-operative efforts to obtain a durable RC repair are encouraged, since SSp integrity at final follow-up influences clinical and functional outcomes, patient satisfaction and OA progression.

Tables

Table 1. Patient's demographics

Age at surgery (years)	60.13 [54.76-65.54]
BMI (kg/m^2)	25.61 [23.62-28.41]
F/M ratio	0.54/0.46
Operated side L/R ratio	0.28/0.72
Dominant side L/R ratio	0.02/0.98
Tear size C1-C2/C3-C4 ratio	0.62/0.38
Smoking at surgery Y/N ratio	0.20/0.80
Smoking at follow-up Y/N ratio	0.15/0.85
DM at surgery Y/N ratio	0.06/0.94
DM at follow-up Y/N ratio	0.18/0.82
Trauma Y/N ratio	0.08/0.92

Data are reported as median [Q1-Q3] or frequency/ratio. BMI: Body Mass Index; C1-C2: small tear size; C3-C4: large tear size;DM: Diabetes Mellitus; F/M: Female/Male; Isp: Infraspinatus; L/R: Left/Right; N: No; Q1: first quartile; Q3: third quartile; Y: yes.

Table 2. Hazard ratios and 95% confidence intervals for non-integrity of the supraspinatus at final follow-up.

	HR (CI 95%)			
	Univariate	***p-value***	**Multivariate**	***p-value***
Age at surgery (years)				
≤60	Ref.			
>60	1.62 (0.88–2.98)	*0.12*		
Gender (%)				
Female	Ref.			
Male	1.19 (0.64–2.20)	*0.58*		
BMI (kg/m^2)				
Normal-weight	Ref.			
Overweight	1.12 (0.61–2.05)	*0.72*		
Smoking				
No	Ref.			
Yes	0.87 (0.39–1.91)	*0.72*		
Diabetes				
No	Ref.			
Yes	1.83 (0.61–5.51)	*0.28*		
Side of surgery				
Opposite	Ref.			
Dominant	1.02 (0.52–2.01)	*0.95*		
Tear size				
C1-C2	Ref.		Ref.	
C3-C4	3.04 (1.63–5.69)	***0.001***	2.18 (1.03–4.62)	***0.04***
ASES				
≤90	Ref.			
>90	0.62 (0.34 – 1.13)	*0.12*		
Hamada grade				
1	Ref.		Ref.	
>1	6.32 (3.32 – 12.03)	***<0.001***	5.07 (2.21 – 11.64)	***<0.001***
Samilson-Prieto grade				
0	Ref.		Ref.	
≥1	1.94 (1.06 – 3.55)	***0.03***	0.91 (0.43 – 1.97)	*0.82*
AHD				
>8.6	Ref.		Ref.	
≤8.6	3.63 (1.89 – 7.01)	***<0.001***	0.74 (0.31 – 1.73)	*0.48*

ASES: American Shoulder and Elbow Surgeons score; AHD: acromio-humeral distance; BMI: Body Mass Index; C1-C2: small tear size; C3-C4: large tear size; HR: Hazard Ratio.

Table 3. Subgroup analysis: tear size: patients' demographics

Group	C1-C2	C3-C4	*p-value*
Age at surgery (years)	58.12 [53.03-62.70]	64.56 [57.75-69.10]	*0.0004*
BMI (kg/m^2)	24.62 [23.61-27.44]	25.66 [23.26-29.50]	*0.4308 (n.s.)*
F/M ratio	0.59/0.41	0.47/0.53	*0.3042 (n.s.)*
Operated side L/R ratio	0.27/0.73	0.29/0.71	*0.8214 (n.s.)*
Dominant side L/R ratio	0.03/0.97	0/1	*0.5279 (n.s.)*

Data are reported as median [Q1-Q3] or frequency/ratio. BMI: Body Mass Index; C1-C2: small tear size; C3-C4: large tear size; F/M: Female/Male; L/R: Left/Right; n.s.: not significant; Q1: first quartile; Q3: third quartile.

Table 4. Subgroup analysis: tear size: summary of main clinical and radiological results

Table 4. Subgroup analysis: tear size: summary of main clinical and radiological results

Group	Overall	C1-C2	C3-C4	*p-value*
SSp integrity/non-integrity ratio	0.53/0.47	0.68/0.32	0.29/0.71	*0.0002*
SANE: 0-100 (points)	80 [70-100]	90 [70-100]	80 [60-90]	*0.0856 (n.s.)*
NRS: 0-10 (points)	0.00 [0.00-3.25]	0.50 [0.00-2.00]	0.00 [0.00-6.00]	*0.4803 (n.s.)*
ASES: 0-100 (points)	90.00 [73.33-100.00]	92.50 [78.33-100.00]	86.67 [51.67-98.33]	*0.1048 (n.s.)*
SST: 0-12 (points)	11.00 [9.00-12.00]	12.00 [10.00-12.00]	10.00 [9.00-12.00]	*0.1015 (n.s.)*
Satisfaction: 1-4 (points)	1 [1-1]	1 [1-1]	1 [1-1]	*0.4674 (n.s.)*
CMS Tot: 0-100 (points)	78.05 [65.63-85.20]	81.50 [70.47-86.54]	69.96 [60.17-79.39]	*0.0007*
CMS_pain: 0-15 (points)	14.75 [10.00-15.00]	15.00 [11.00-15.00]	14.00 [8.75-15.00]	*0.1458 (n.s.)*
CMS_daily activities: 0-20 (points)	20.00 [16.00-20.00]	20.00 [18.00-20.00]	18.00 [13.00-20.00]	*0.0073*
CMS_movement 0-40 (points)	38.00 [32.00-40.00]	38.00 [34.00-40.00]	35.00 [26.00-38.00]	*0.0084*
CMS_strengh: 0-25 (points)	7.92 [4.35-13.39]	10.56 (± 5.93)	5.94 [2.05-9.76]	*0.0007*
Strength ab (Kg)	3.60 [1.98-6.09]	4.475 [3.11-7.05]	2.70 [1.06-4.44]	*0.0006*
Strength fl (Kg)	4.43 [2.34-6.80]	5.59 (± 2.76)	2.55 [1.60-5.29]	*<0.0001*
ROM ab (°)	180.0 [143.8-180.0]	180.0 [170.0-180.0]	170.0 [110.0-180.0]	*0.0174*
ROM fl (°)	180.0 [170.0-180.0]	180.0 [176.3-180.0]	180.0 [140.0-180.0]	*0.0164*
AHD (mm)	8.63 [5.41-10.50]	9.23 (± 2.63)	5.91 (± 3.35)	*<0.0001*
Hamada OA_grade 1/> 1 ratio	0.72/0.28	0.86/0.14	0.47/0.53	*<0.0001*
Samilson and Prieto OA_grade 0/> 0 ratio	0.51/0.49	0.64/0.36	0.29/0.71	*0.0009*

Data are expressed as mean (± SD), median [Q1-Q3] or frequency/ratio. ab: abduction; AHD: AcromioHumeral Distance; ASES: American Shoulder and Elbow Surgeons score; C1-C2: small tear size; C3-C4: large tear size; CMS: Constant-Murley Score; fl: flexion; NRS: Numeric Rating Scale; n.s.: not significant; OA: osteoarthritis; Q1: first quartile; Q3: third quartile; ROM: Range Of Motion; SANE: Simple Assessment Numeric Evaluation; SD: Standard Deviation; SSp: supraspinatus tendon; SST: Simple Shoulder Test.

Figure legends

Figure 1. Flow diagram of the study. C1-C2: small tear size; C3-C4: large tear size.

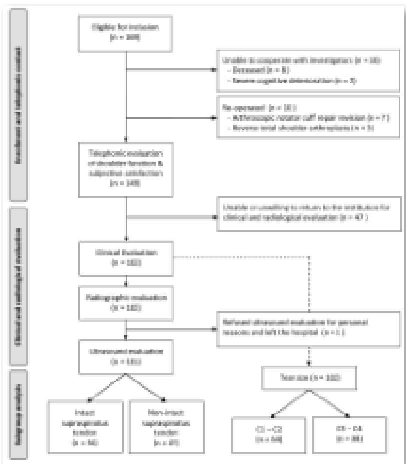


Figure 1

Figure 2. Box and whisker plots of Constant-Murley Score (CMS) in patients with small (C1-C2) and large (C3-C4) rotator cuff tears. Each box represents the interquartile range (from the 25th to the 75th percentile) within which 50% of the values are represented. The plus sign and the line crossing horizontally each box represent the median and the mean of the data, respectively. The error bars show the minimum and maximum values. Unpaired t test was used to test for differences between C1-C2 and C3-C4 groups. Only p-values <0.05 are indicated: ***, p<0.001.

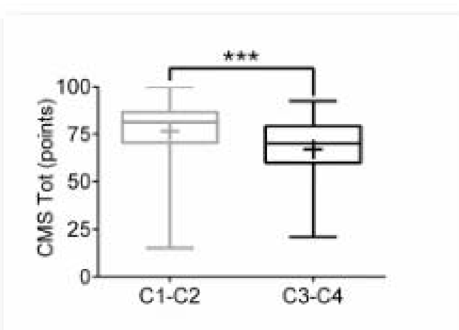


Figure 2

Figure 3. Box and whisker plots of acromio-humeral distance (AHD) in patients with small (C1-C2) and large (C3-C4) rotator cuff tears. Each box represents the interquartile range (from the 25th to the 75th percentile) within which 50% of the values are represented. The plus sign and the line crossing horizontally each box represent the median and the mean of the data, respectively. The error bars show the minimum and maximum values. The dashed line indicates the cut-off value of 6mm. Unpaired t test was used to test for differences between C1-C2 and C3-C4 groups. Only p-values <0.05 are indicated: ****, p<0.0001.

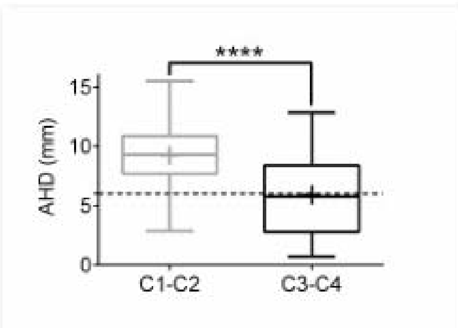


Figure 3

Figure 4. Pie chart illustrating the distribution of patients with different grades of shoulder osteoarthritis, classified according to the Hamada (A) and the Samilson-Prieto (B) classification in patients with small (C1-C2) and large (C3-C4) rotator cuff tears.

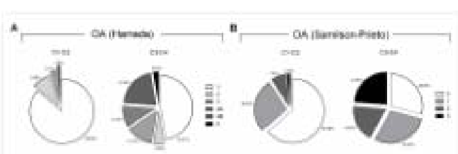


Figure 4

Figure 5. Box and whisker plots of acromio-humeral distance (AHD) in patients with and without intact supraspinatus tendon (SSp) at final follow-up. Each box represents the interquartile range (from the 25th to the 75th percentile) within which 50% of the values are represented. The plus sign and the line crossing horizontally each box represent the median and the mean of the data, respectively. The error bars show the minimum and maximum values. The dashed line indicates the cut-off value of 6mm. Unpaired t test was used to test for differences between intact and non-intact groups. Only p-values <0.05 are indicated: ****, p<0.0001.

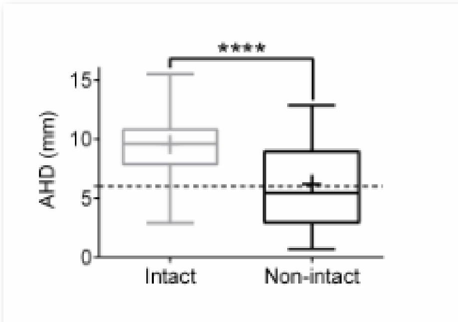


Figure 5

Figure 6. Pie chart illustrating the distribution of patients with different grades of shoulder osteoarthritis, classified according to the Hamada (A) and the Samilson-Prieto (B) classification in patients with and without intact supraspinatus tendon at final follow-up.

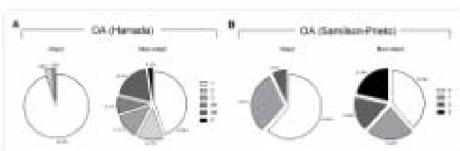


Figure 6

Supplementary material

Tables

Table e1. Subgroup analysis: supraspinatus integrity: patients' demographics

Group	SSp: intact	SSp: non-intact	*p-value*
Age at surgery (years)	58.38 [52.30-64.73]	61.26 (± 8.07)	*0.0438*
BMI (kg/m^2)	25.79 (± 3.60)	25.71 [23.44-29.04]	*0.4586 (n.s.)*
F/M ratio	0.57/0.43	0.51/0.49	*0.5533 (n.s.)*
Operated side L/R ratio	0.30/0.70	0.26/0.74	*0.6637 (n.s.)*
Dominant side L/R ratio	0.02/0.98	0.02/0.98	*1.0000 (n.s.)*
Tear size C1-C2/C3-C4 ratio	0.80/0.20	0.43/0.57	*0.0002*
Smoking at follow-up Y/N ratio	0.19/0.81	0.11/0.89	*0.4010 (n.s.)*
Smoking at surgery Y/N ratio	0.22/0.78	0.17/0.83	*0.6194 (n.s.)*
DM at follow-up Y/N ratio	0.11/0.89	0.26/0.74	*0.0715 (n.s.)*
DM at surgery Y/N ratio	0.04/0.96	0.09/0.91	*0.4129 (n.s.)*
Trauma Y/N ratio	0/1	0.17/0.83	*0.0016*

Data are reported as mean (± SD), median [Q1-Q3] or frequency/ratio. BMI: Body Mass Index; C1-C2: small tear size; C3-C4: large tear size; DM: Diabetes Mellitus; F/M: Female/Male; L/R: Left/Right; N: No; n.s.: not significant; Q1: first quartile; Q3: third quartile; SD: Standard Deviation; SSp: supraspinatus tendon; Y: yes.

Table e2. Subgroup analysis: supraspinatus integrity: summary of main clinical and radiological results.

Group	**SSp: intact**	**SSp: non-intact**	***p-value***
SANE: 0-100 (points)	92.50 [70-100]	80 [50-90]	*0.0012*
NRS: 0-10 (points)	0.00 [0.00-2.25]	0.00 [0.00-5.00]	*0.4681 (n.s.)*
ASES: 0-100 (points)	95.83 [78.33-100.00]	86.67 [50.00-98.33]	*0.0062*
SST: 0-12 (points)	12.00 [10.00-12.00]	10.00 [7.00-12.00]	*0.0025*
Satisfaction: 1-4 (points)	1 [1-1]	1 [1-2]	*0.0041*
CMS Tot: 0-100 (points)	82.49 [75.16-88.68]	70.07 [54.42-78.79]	*<0.0001*
CMS_pain: 0-15 (points)	15.00 [13.00-15.00]	14.00 [8.50-15.00]	*0.0688 (n.s.)*
CMS_daily activities: 0-20 (points)	20.00 [18.00-20.00]	18.00 [13.00-20.00]	*0.0003*
CMS_movement 0-40 (points)	38.00 [35.50-40.00]	36.00 [26.00-38.00]	*0.0135*
CMS_strengh: 0-25 (points)	11.76 (± 5.59)	4.95 [1.98-9.24]	*<0.0001*
Strength ab (Kg)	4.98 [3.25-7.34]	2.25 [0.90-4.20]	*<0.0001*
Strength fl (Kg)	6.05 (± 2.50)	2.40 [1.60-4.85]	*<0.0001*
ROM ab (°)	180 [170-180]	180 [110-180]	*0.0111*
ROM fl (°)	180 [180-180]	180.0 [140-180]	*0.0082*
AHD (mm)	9.56 (± 2.26)	6.18 (± 3.47)	*<0.0001*
Hamada OA_grade 1/> 1 ratio	0.94/0.06	0.45/0.55	*<0.0001*
Samilson and Prieto OA_grade 0/> 0 ratio	0.61/0.39	0.38/0.62	*0.0286*

Data are expressed as mean (± SD), median [Q1-Q3] or frequency/ratio. ab: abduction; AHD: AcromioHumeral Distance; ASES: American Shoulder and Elbow Surgeons score; CMS: Constant-Murley Scoree; fl: flexion; NRS: Numeric Rating Scale; n.s.: not significant; OA: osteoarthritis; Q1: first quartile; Q3: third quartile; ROM: Range Of Motion; SANE: Simple Assessment Numeric Evaluation; SD: Standard Deviation; SSp: supraspinatus tendon; SST: Simple Shoulder Test.

Supplementary material

Figure legends

Figures e1-e14. Box and whisker plots of the clinical results in patients with small (C1-C2) and large (C3-C4) rotator cuff tears. Each box represents the interquartile range (from the 25th to the 75th percentile) within which 50% of the values are represented. The plus sign and the line crossing horizontally each box represent the median and the mean of the data, respectively. The error bars show the minimum and maximum values. Unpaired t test was used to test for differences between C1-C2 and C3-C4 groups. Only p values < 0.05 are indicated: * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$, and **** $p < 0.0001$.

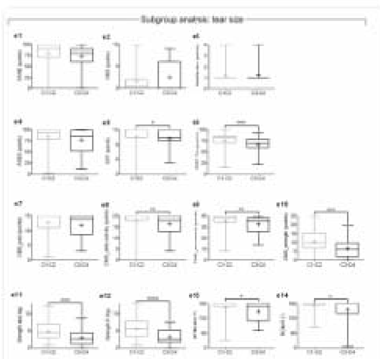
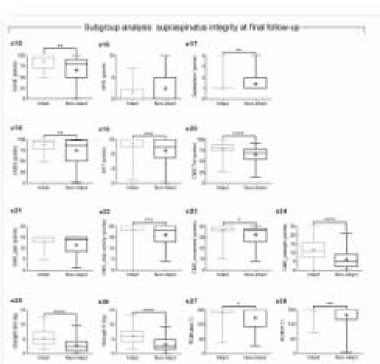


Figure e1-e14 – supplementary material

Figures e15-e28. Box and whisker plots of the clinical results in patients with and without intact supraspinatus tendon (SSp) at final follow-up. Each box represents the interquartile range (from the 25th to the 75th percentile) within which 50% of the values are represented. The plus sign and the line crossing horizontally each box represent the median and the mean of the data, respectively. The error bars show the minimum and maximum values. Unpaired t test was used to test for differences between intact and non-intact groups. Only p values < 0.05 are indicated: * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$, and **** $p < 0.0001$.



Figures e15-e28 – supplementary material

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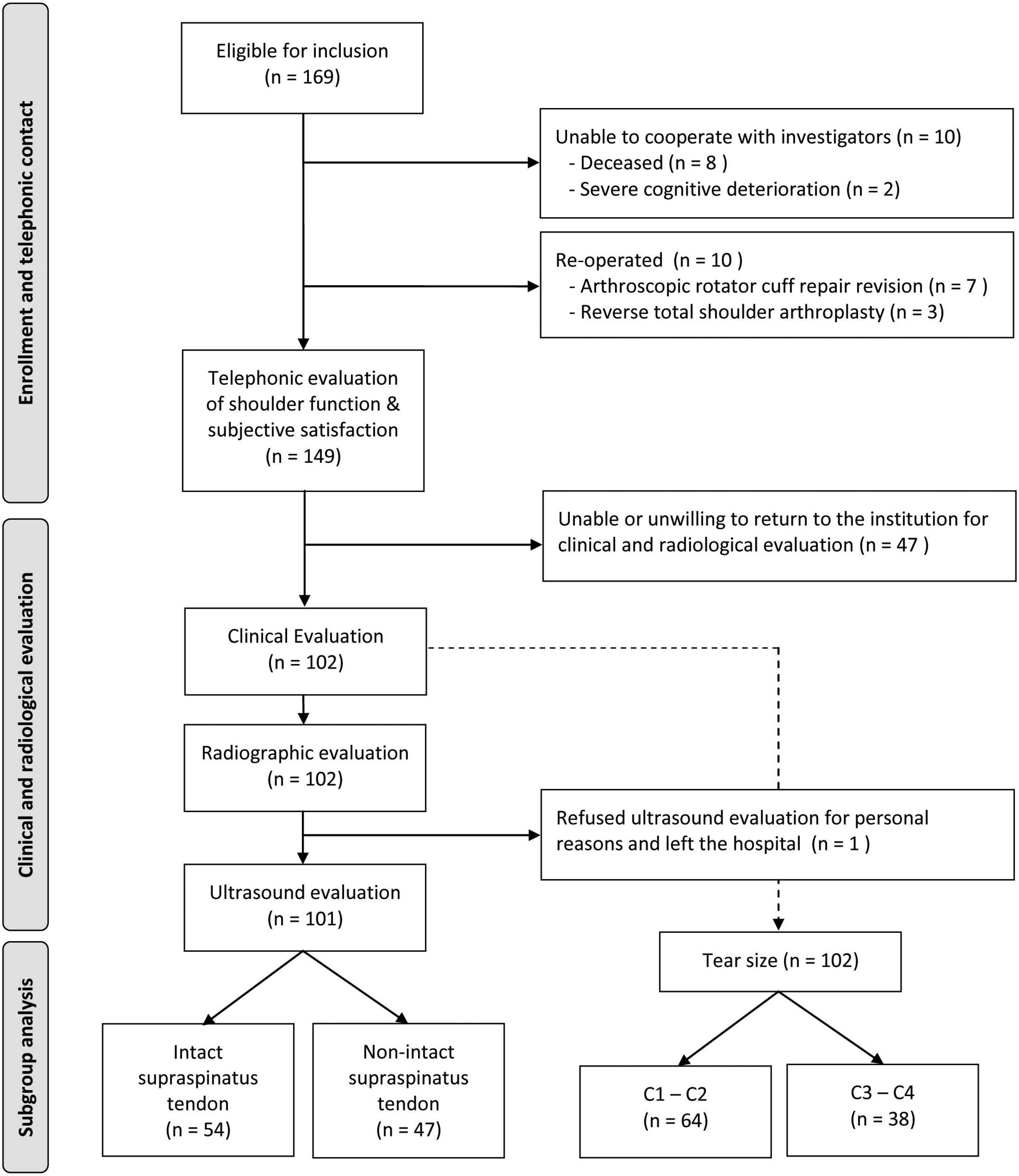
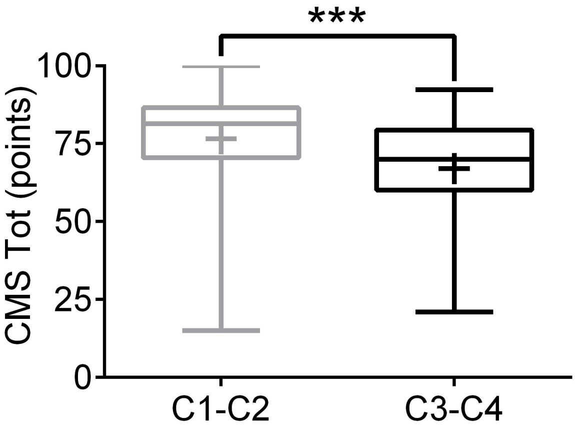
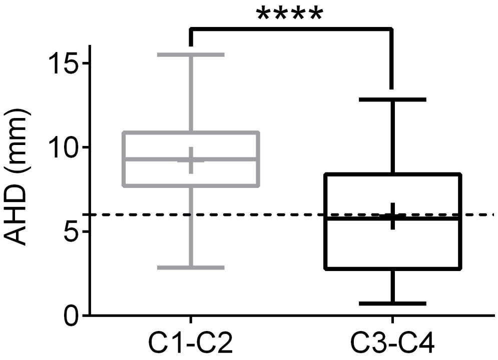

Enrollment and telephonic contact
Eligible for inclusion (n = 169)
Unable to cooperate with investigators (n = 10)
- Deceased (n = 8)
- Severe cognitive deterioration (n = 2)
Re-operated (n = 10)
- Arthroscopic rotator cuff repair revision (n = 7)
- Reverse total shoulder arthroplasty (n = 3)
Telephonic evaluation of shoulder function & subjective satisfaction (n = 149)
Clinical and radiological evaluation
Unable or unwilling to return to the institution for clinical and radiological evaluation (n = 47)
Clinical Evaluation (n = 102)
Radiographic evaluation (n = 102)
Refused ultrasound evaluation for personal reasons and left the hospital (n = 1)
Ultrasound evaluation (n = 101)
Tear size (n = 102)
Subgroup analysis
Intact supraspinatus tendon (n = 54)
Non-intact supraspinatus tendon (n = 47)
C1 – C2 (n = 64)
C3 – C4 (n = 38)


***
100
75
50
25
0
CMS Tot (points)
C1-C2
C3-C4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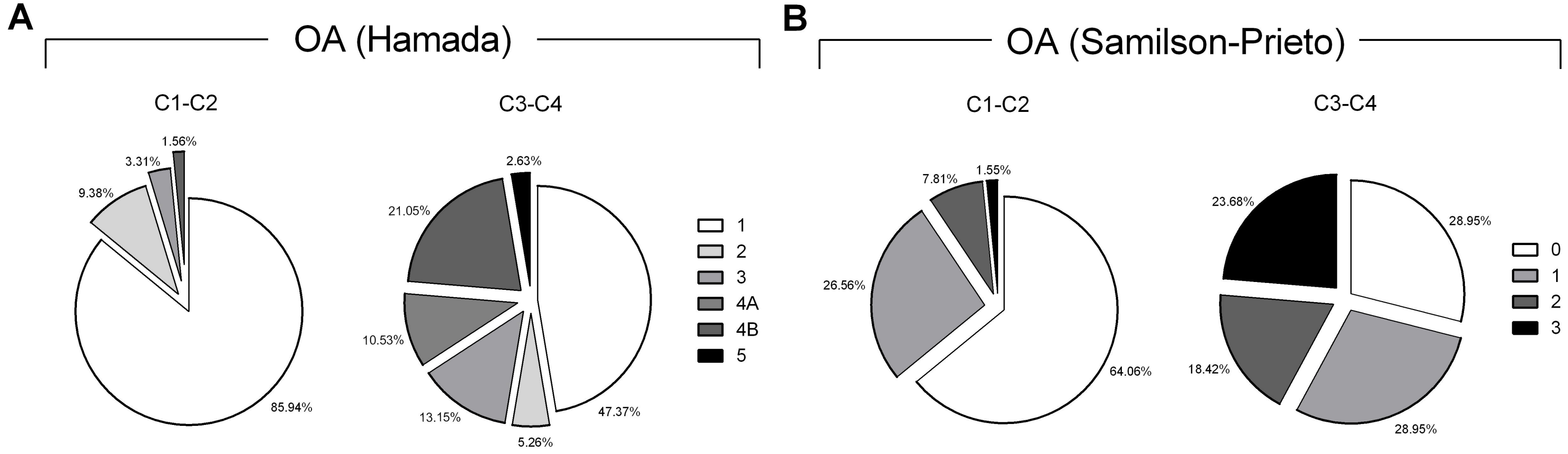
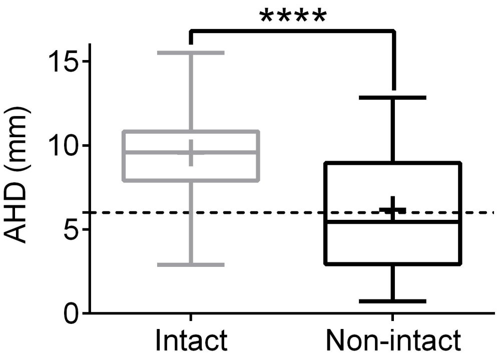
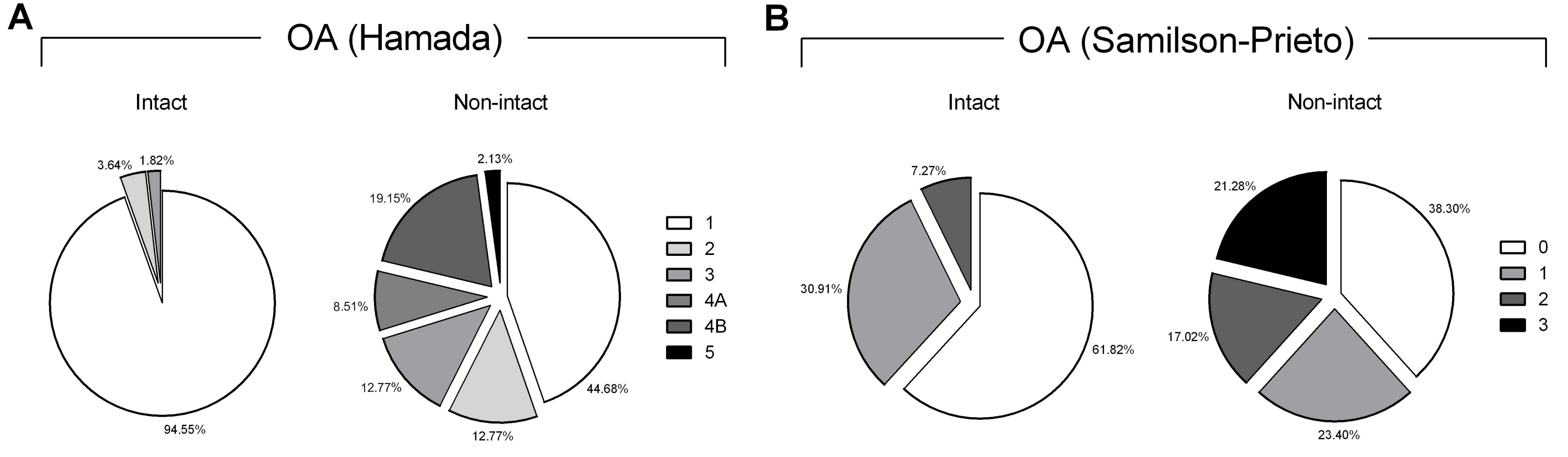
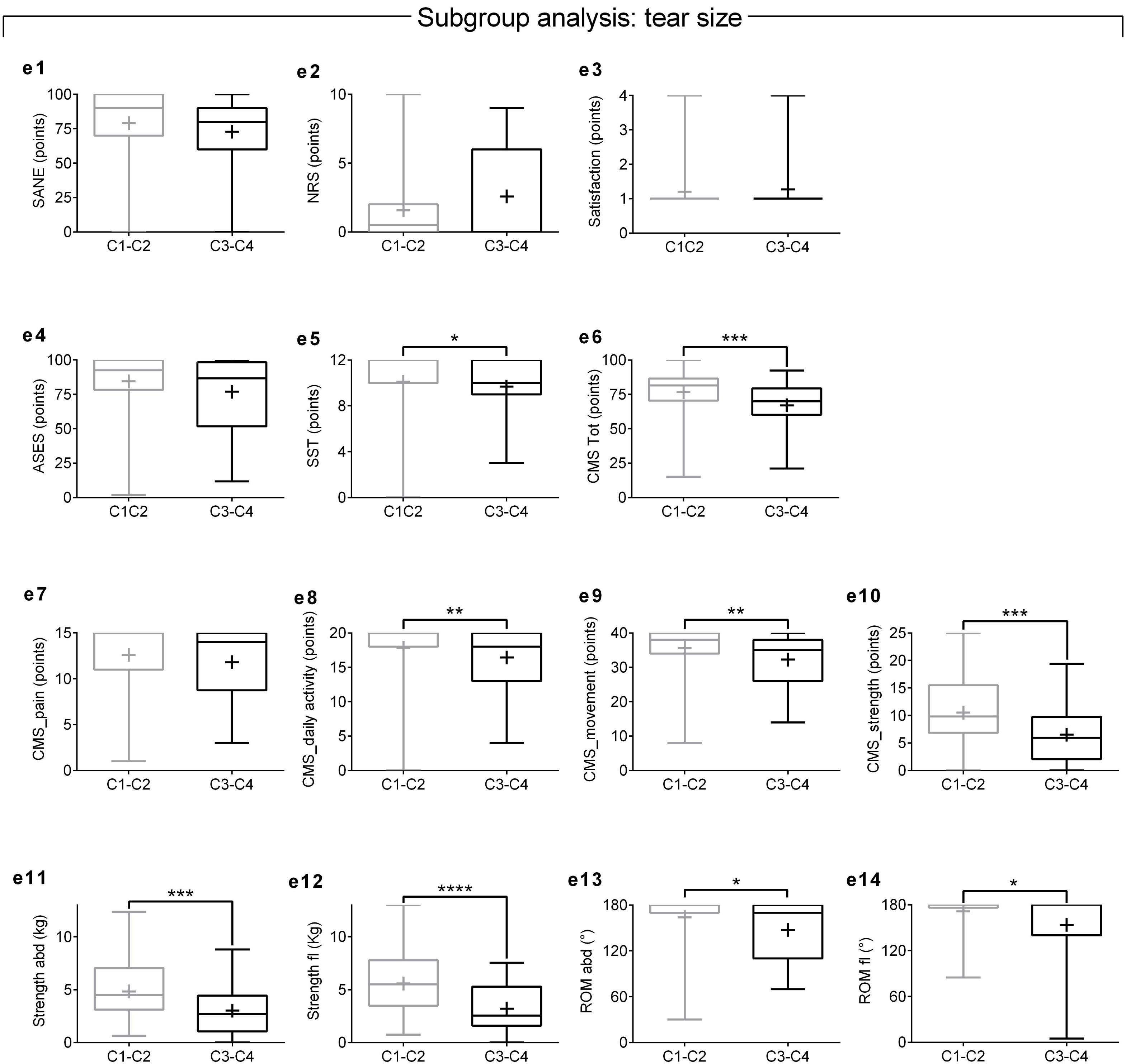
AHD (mm)
15
10
5
0
C1-C2
C3-C4

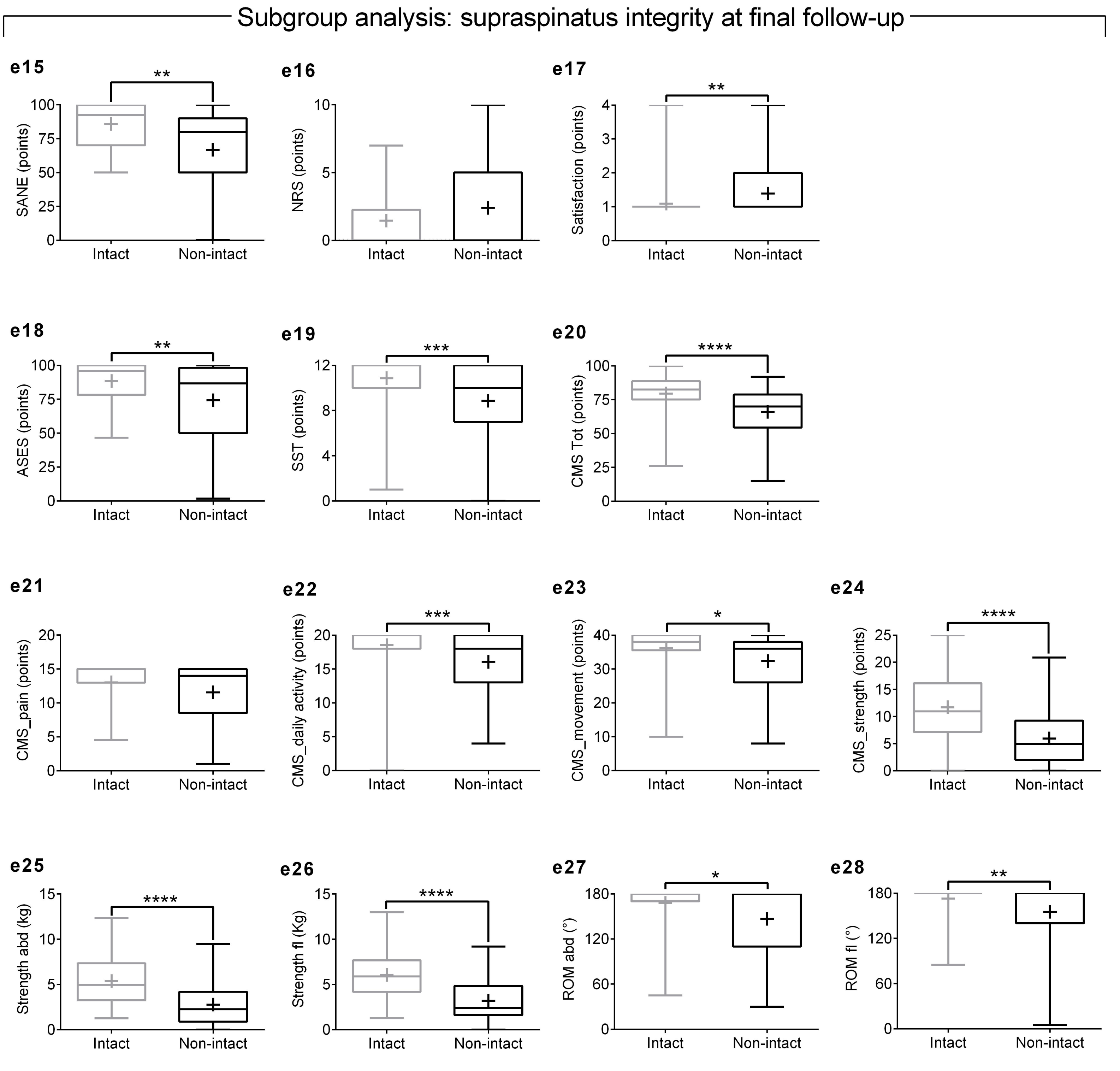

A
OA (Hamada)
C1-C2
1.56%
3.31%
9.38%
85.94%
C3-C4
2.63%
21.05%
10.53%
13.15%
5.26%
47.37%
1
2
3
4A
4B
5
B
OA (Samilson-Prieto)
C1-C2
7.81%
1.55%
26.56%
64.06%
C3-C4
23.68%
28.95%
18.42%
28.95%
0
1
2
3


****
15
10
5
0
AHD (mm)
Intact
Non-intact


A
OA (Hamada)
Intact
Non-intact
3.64%
1.82%
94.55%
2.13%
19.15%
8.51%
12.77%
12.77%
44.68%
1
2
3
4A
4B
5
B
OA (Samilson-Prieto)
Intact
Non-intact
7.27%
30.91%
61.82%
21.28%
38.30%
17.02%
23.40%
0
1
2
3



Subgroup analysis: tear size
e1
SANE (points)
C1-C2
C3-C4
e2
NRS (points)
C1-C2
C3-C4
e3
Satisfaction (points)
C1C2
C3-C4
e4
ASES (points)
C1C2
C3-C4
e5
SST (points)
*
C1C2
C3-C4
e6
CMS Tot (points)
***
C1-C2
C3-C4
e7
CMS_pain (points)
C1-C2
C3-C4
e8
CMS_daily activity (points)
**
C1-C2
C3-C4
e9
CMS_movement (points)
**
C1-C2
C3-C4
e10
CMS_strength (points)
***
C1-C2
C3-C4
e11
Strength abd (kg)
***
C1-C2
C3-C4
e12
Strength fl (Kg)
****
C1-C2
C3-C4
e13
ROM abd (°)
*
C1-C2
C3-C4
e14
ROM fl (°)
*
C1-C2
C3-C4


Subgroup analysis: supraspinatus integrity at final follow-up
e15
SANE (points)
**
Intact
Non-intact
e16
NRS (points)
Intact
Non-intact
e17
Satisfaction (points)
**
Intact
Non-intact
e18
ASES (points)
**
Intact
Non-intact
e19
SST (points)
***
Intact
Non-intact
e20
CMS Tot (points)
****
Intact
Non-intact
e21
CMS_pain (points)
Intact
Non-intact
e22
CMS_daily activity (points)
***
Intact
Non-intact
e23
CMS_movement (points)
*
Intact
Non-intact
e24
CMS_strength (points)
****
Intact
Non-intact
e25
Strength abd (kg)
****
Intact
Non-intact
e26
Strength fl (Kg)
****
Intact
Non-intact
e27
ROM abd (°)
*
Intact
Non-intact
e28
ROM fl (°)
**
Intact
Non-intact