Long Head of Biceps Tenotomy Is Not Inferior to Suprapectoral Tenodesis in Arthroscopic Repair of Nontraumatic Rotator Cuff Tears: A Multicenter, Non-inferiority, Randomized, Controlled Clinical Trial

Derek F. P. van Deurzen, M.D., Kiem G. Auw Yang, M.D., Ph.D., Ron Onstenk, M.D., Eric E. J. Raven, M.D., Ph.D., Maaike P. J. van den Borne, M.D., Max A. Hoelen, M.D., Ronald N. Wessel, M.D., Nienke W. Willigenburg, Ph.D., Amanda D. Klaassen, and Michel P. J. van den Bekerom, M.D., Ph.D., the BITE Study Group

Purpose: To determine if long head of the biceps (LHB) tenotomy is not inferior to suprapectoral LHB tenodesis when performed in conjunction with arthroscopic repair of small- to medium-sized nontraumatic rotator cuff tears. **Methods:** This multicenter, randomized, non-inferiority trial recruited 100 participants older than 50 years who had a supraspinatus and/or infraspinatus tear sagittally smaller than 3 cm and arthroscopically confirmed LHB pathology. During arthroscopic rotator cuff repair, we randomized 48 patients to undergo suprapectoral LHB tenodesis and 52 patients to undergo LHB tenotomy. Data were collected preoperatively and at 6 weeks, 3 months, and 1 year postoperatively. The primary outcome was non-inferiority of the Constant-Murley score (CMS) at 1-year follow-up. Secondary outcomes included the Dutch Oxford Shoulder Score; Disabilities of the Arm, Shoulder and Hand questionnaire; Popeye deformity; elbow flexion strength index; arm cramping pain; and quality of life (EQ-5D score). The integrity of the rotator cuff repair was assessed with magnetic resonance imaging. Differences between intervention groups were analyzed by mixed modeling. **Results:** The mean CMS in the LHB tenotomy group improved from 44 (95% confidence interval [CI], 39-48) to 73 (95% CI, 68-79). In patients with LHB tenodesis, the mean CMS improved from 42 (95% CI, 37-48) to 78 (95% CI, 74-82). The difference between groups at

From the Department of Orthopedic Surgery, Shoulder and Elbow Unit, Joint Research, OLVG, Amsterdam, The Netherlands (D.F.P.v.D., N.W.W., A.D.K., M.P.J.v.d.B.); Department of Orthopedic Surgery, St. Antonius Ziekenhuis, Utrecht, The Netherlands (K.G.A.Y., R.N.W.); Department of Orthopedic Surgery, Groene Hart Ziekenhuis, Gouda, The Netherlands (R.O.); Department of Orthopedic Surgery, Gelre Ziekenhuis, Apeldoorn, The Netherlands (E.E.J.R.); Department of Orthopedic Surgery, Amphia Ziekenhuis, Breda, The Netherlands (M.P.J.v.d.B.); and Department of Orthopedic Surgery, Reinier de Graaf Gasthuis, Delft, The Netherlands (M.A.H.).

The authors report the following potential conflicts of interest or sources of funding: The BITE study was conducted with financial support of the Research Foundation OLVG, Dutch Arthroscopy Association, and Smith & Nephew; these parties were not involved with analysis of data and writing of the manuscript. D.F.P.v.D. receives research funding from Smith & Nephew, Dutch Arthroscopy Association, and Research Foundation OLVG. In addition, D.F.P.v.D. receives research funding from Wright Medical, outside the submitted work. K.G.A.Y. receives grant support from Arthrex for nonrelated studies and has educational consultancy agreements with Arthrex and Stryker, outside the submitted work. E.E.J.R. receives personal fees for consultancy from Zimmer Biomet and receives personal fees for lectures from Zimmer Biomet, Integra, and Arthrex, outside the submitted work. M.P.J.v.d.B. receives research funding from Smith & Nephew, Dutch Arthroscopy Association, and Research Foundation OLVG. R.N.W. is a paid instructor for Arthrex, outside the submitted work. N.W.W. receives research funding from Smith & Nephew, Dutch Arthroscopy Association, and Research Foundation OLVG. A.D.K. receives research funding from Smith & Nephew, Dutch Arthroscopy Association, and Research Foundation OLVG. Full ICMJE author disclosure forms are available for this article online, as supplementary material.

The BITE Study Group comprises Jacco A. C. Zijl, M.D., St. Antonius Ziekenhuis, Utrecht; Nienke Wolterbeek, Ph.D., St. Antonius Ziekenhuis, Utrecht; Koen L. M. Koenraadt, Ph.D., Amphia Ziekenhuis, Breda; Loes W.A.H. van Beers, OLVG, Amsterdam; W. Jaap Willems, M.D., Ph.D., Delairesseklinik, Amsterdam; Nina M. Mathijssen, Ph.D., Reinier de Graaf Gasthuis, Delft; Brechtje Hesseling, Reinier de Graaf Gasthuis, Delft; Eelke Lemmens, OLVG, Amsterdam; Roel Janssens, OLVG, Amsterdam; Frans L. Garssen, M.D., OLVG, Amsterdam; Navin Gurnani, M.D., OLVG, Amsterdam; Roos I. van Rhijn, OLVG, Amsterdam; Reinier Spek, OLVG, Amsterdam; Max Teuwen, OLVG, Amsterdam; Lukas P. E. Verweij, OLVG, Amsterdam; Mariella Volkers, OLVG, Amsterdam; and Vanessa A. B. Scholtes, Ph.D., OLVG, Amsterdam.

Received May 22, 2020; accepted January 12, 2021.

Address correspondence to Derek F. P. van Deurzen, Department of Orthopedic Surgery, Shoulder and Elbow Expertise Center, Joint Research, OLVG, Oosterpark 9, 1090 HM, Amsterdam, The Netherlands. E-mail: d.vandeurzen@olvg.nl

0749-8063/20750/$36.00

https://doi.org/10.1016/j.arthro.2021.01.036

1-year follow-up was 4.8 (97.5% CI, $-\infty$ to 11.4), with a P value for non-inferiority of .06. The secondary outcomes also improved over time, with no remarkable differences between groups. A Popeye deformity occurred in 33% of tenodesis patients and 47% of tenotomy patients ($P = .17$). Tenotomy was performed with a shorter operative time (73 minutes vs 82 minutes, $P = .03$). Magnetic resonance imaging showed a recurrent rotator cuff tear in 20% of all cases. **Conclusions:** Although statistically "inconclusive" regarding non-inferiority of the CMS at 1-year follow-up, any observed differences between patients with LHB tenotomy and those with LHB tenodesis in all outcome scores were small. **Level of Evidence:** Level I, randomized controlled trial and treatment study.

See commentary on page 1777

The surgical treatment of long head of the biceps (LHB) pathology when encountered during arthroscopic rotator cuff repair has been a topic of debate for years. Operative treatment of the LHB may be advocated in case of symptomatic partial rupturing, synovitis, or subluxation of the LHB tendon. Several studies have compared the results of LHB tenotomy versus LHB tenodesis, performed with and without arthroscopic rotator cuff repair.[1-7] Although both procedures have shown favorable clinical outcomes, the gold standard for the surgical treatment of LHB pathology has yet to be determined.

LHB tenotomy is a fast and safe procedure requiring limited surgical time and no implants.[8] Reported disadvantages include the possible occurrence of a Popeye deformity, fatigue, and cramping pain in the upper arm.[9-11] Because the LHB may play a role in both shoulder and elbow function and patients may fear a cosmetic deformity, LHB tenodesis has been suggested as the treatment of choice.[12,13] Performing LHB tenodesis, however, is more time-consuming and may be accompanied by a higher risk of complications. Moreover, it does not always prevent a Popeye deformity.[14] Several techniques to perform LHB tenodesis and LHB tenotomy have been reported in the literature, further complicating the choice between the 2 treatments.[1-3,7,15,16] A 3% to 16% increase in the performance of arthroscopic LHB tenodesis in conjunction with arthroscopic rotator cuff repair was reported from 2005 to 2011.[17] This increase was explained by the reported favorable results of biceps tenodesis in the literature.[18,19] However, Level I evidence in favor of LHB tenodesis over LHB tenotomy was not available at that time.

Since 2012, 3 randomized controlled trials (RCTs) have compared LHB tenodesis with LHB tenotomy when performed in conjunction with arthroscopic rotator cuff repair[1-3]; they found no significant differences regarding clinical outcome scores. However, interpretation of the results of these studies is hampered for several reasons including a small sample size, large size of rotator cuff tears, and unknown integrity of the rotator cuff repair at follow-up. Although the study by Lee et al.[1] included 128 patients, the study population predominantly comprised female patients (77%) and tenodesis was performed with a different technique than that used in the previous studies.[2,3] Owing to the ranging quality of evidence and risk of bias, the optimal treatment for LHB pathology remains unknown.[20]

The use of fixation devices as well as the additional operative time for tenodesis is associated with an increase in health care costs, which may be unnecessary.[1-3] As a significant increase in the number of rotator cuff repairs and concomitant LHB tenodeses is seen and as health systems in the Western world are challenged with a considerable financial burden, high-level evidence to justify these procedures is needed.

Therefore, we conducted an RCT to determine if LHB tenotomy is not inferior to suprapectoral LHB tenodesis when performed in conjunction with arthroscopic repair of small- to medium-sized rotator cuff tears. The primary endpoint was the Constant-Murley score (CMS) at 1 year after surgery. Secondary outcome parameters included patient-reported outcome measures of shoulder function and quality of life, cosmetic deformity, elbow flexion strength, and operative time. The purpose of this study was to determine if LHB tenotomy is not inferior to suprapectoral LHB tenodesis when performed in conjunction with arthroscopic repair of small- to medium-sized nontraumatic rotator cuff tears. The study hypothesis was that LHB tenotomy would not be inferior to LHB tenodesis when performed in this group of patients.

Methods

Trial Design and Participants

One hundred patients were enrolled in the Long Head Biceps Tenodesis or Tenotomy in Arthroscopic Rotator Cuff Repair (BITE) study, which was a multicenter, non-inferiority RCT. The study was conducted in 6 hospitals in the Netherlands. The methodologic details of the trial have been previously described in the published protocol[21] and are reflected in Appendix 1 (available at www.arthroscopyjournal.org).

Eligible participants were patients older than 50 years with a nontraumatic small- to medium-sized supraspinatus and/or infraspinatus lesion. The number of patients screened for eligibility was not documented.

All participants provided written informed consent on enrollment. In cases in which an inflamed or unstable LHB tendon or an LHB tear greater than 30% was

encountered during arthroscopic rotator cuff repair, patients were randomized to undergo either LHB tenodesis or LHB tenotomy. Patients were excluded in case of a traumatic or partial-thickness rotator cuff rupture, full-thickness tear larger than 3 cm measured using an arthroscopic ruler, accompanying (partial) subscapularis tendon tear, hourglass deformity or less than 30% tearing of the LHB tendon, SLAP lesion, arthropathy of the glenohumeral joint, acromion−to−humeral head distance measuring 6 mm or smaller, Hamada classification of grade 2 or higher, prior surgery on the involved shoulder, or inability to complete the questionnaires and assessments. Rotator cuff repair was performed using a variety of suture anchors manufactured by Arthrex (Naples, FL), Smith & Nephew (Andover, MA), and Johnson & Johnson (New Brunswick, NJ).

The study was conducted in accordance with the Declaration of Helsinki and was approved by the Medical Research Ethics Committees United (No. NL37898.100.11) and by the board of directors of each of the participating hospitals. This trial was registered with the Dutch Trial Register (No. NTR3255; January 12, 2012) and with ClinicalTrials.gov (No. NCT02655848; January 14, 2016).

Randomization Procedure

Random treatment allocation was obtained by a concealed, computer-generated, 1:1 randomization list, by use of random blocks with a maximum size of 6, with participants stratified according to center. Randomization was performed (DVD, KAY, ER, RO, MvdBo, RW, MH, MvdBe) during surgery via a secured website (TENALEA Clinical Trial Data Management System, Abcoude, The Netherlands) only accessible by the treating surgeon using a personal login code and password.

Surgical Technique

Patients who were randomized to the tenotomy group underwent arthroscopic release of the proximal LHB tendon. By use of arthroscopic scissors, the proximal biceps was cut at its junction with the superior labrum.[9] Patients who were randomized to the tenodesis group underwent a similar arthroscopic release of the LHB origin, followed by fixation proximally in the bicipital groove using the remaining sutures of the most anterior suture anchor that was used for arthroscopic rotator cuff repair. Arthroscopic rotator cuff repair was performed through standard portals, and acromioplasty and/or lateral clavicular resection was performed if needed. All procedures were performed by 8 shoulder surgeons (DVD, KAY, ER, RO, MvdBo, RW, MH, MvdBe) who either were fellowship trained or had more than 10 years' experience in shoulder surgery. A single- or double-row technique was performed according to surgeon preference. Rotator cuff repair was performed with the aim of a tensionless repair. In case this was not deemed feasible, patients were excluded.

Postoperative Treatment

Postoperative rehabilitation was conducted by outpatient dedicated shoulder physiotherapists. Patients in both groups followed the same postoperative protocol. In the first 6 weeks, patients used an immobilizer and only passive range-of-motion exercises of the shoulder and elbow were allowed. After 6 weeks, active movements of both the shoulder and elbow were started and gradually increased. Full-weight loading of the rotator cuff and biceps was not allowed until at least 3 months after surgery.

Blinding

Patients were blinded to the treatment performed on the LHB tendon until final follow-up. Blinding of the outcome assessors was intended but proved infeasible in every institution that participated in the trial. For a substantial number of participants, assessment was performed by the treating surgeon in case a blinded assessor was not available during a follow-up visit. Data were processed and analyzed by a blinded investigator.

Data Collection

Clinical assessments and patient-reported outcomes were recorded preoperatively at enrollment and at 6 weeks, 3 months, and 1 year. The primary outcome was the CMS at 1 year after surgery.

The Disabilities of the Arm, Shoulder and Hand score[22] and Dutch Oxford Shoulder Score[23] provided additional insight into patient-reported shoulder function. The EQ-5D was used to assess patient-reported quality of life.[24,25] The incidence and level of pain in general, as well as pain in the bicipital groove, were evaluated on a numerical scale (0-10).

Clinician-reported cosmetic appearance was assessed by the presence of a Popeye deformity (yes or no). Patient satisfaction regarding the cosmetic appearance of the upper arm was assessed using a 5-point Smiley scale. Elbow flexion strength was assessed using a dynamometer (Innovative Design Distributors, Reading, England). The Elbow Strength Index was calculated by dividing the elbow flexion strength with the lower arm in full supination by the elbow flexion strength of the contralateral arm.[26] The CMS and elbow strength testing were not assessed at 6 weeks postoperatively so that the repair would not be jeopardized.

A preoperative magnetic resonance imaging (MRI) scan was used to select only small- and medium-sized rotator cuff tears, as well as to assess the quality of the rotator cuff according to the Goutallier criteria.[27] MRI at 1-year follow-up was used to assess the integrity of the rotator cuff repair. The repair was classified as intact, partially healed, or recurrent rupture.

Sample Size

The sample size of 98 participants was based on a 10-point non-inferiority margin in the CMS and a standard deviation (SD) of 16 points in both groups, with a 1-sided α level of .025, 80% power, and 20% loss to follow-up. The 10-point non-inferiority margin was based on a study by Kukkonen et al.[28] on the minimal important change in the CMS in patients undergoing rotator cuff surgery. Their study reported an SD of 15.2 at 1 year after rotator cuff repair. Given the multicenter design of our study, a conservative SD of 16 was chosen for sample size calculation, leading to a required number of patients of 98. To further minimize the risk of the study being underpowered, 100 patients were randomized. If a participant withdrew from the trial, the data collected prior to withdrawal were used in the analyses, with his or her approval.

Statistical Analysis

Statistical analysis was performed using SPSS software (version 22; IBM, Armonk, NY) and following the intention-to-treat principle. The primary hypothesis was tested using a 1-sided Z test of the difference between groups with respect to the non-inferiority margin of 10 points in the CMS. Non-inferiority was shown when the 97.5% confidence interval (CI) did not include the non-inferiority margin.[29] An exploratory "as-treated" analysis was performed to assess the influence of any protocol deviations on the differences between groups in the CMS and incidence of a Popeye deformity.

Mixed models were used for longitudinal data analyses.[30] Repeated measures were clustered within subjects as random effects, and subjects were clustered within centers when appropriate. Crude models included treatment group, time (categorical), and baseline score as fixed independent variables, as well as a time—by—treatment group interaction. Adjusted models additionally included age, sex, body mass index, and smoking as fixed independent variables. Missing data were handled using full maximum likelihood estimation within the mixed-model procedure. Secondary outcomes could not be statistically tested for non-inferiority because non-inferiority margins were not predefined in the trial protocol. Therefore, mean group effects with 95% CIs and without P values were reported. Dichotomous outcomes were compared between groups using the χ^2 test. Adverse events were reported descriptively.

Results

Population

Between July 2012 and August 2018, 100 patients with a mean age of 61 years were randomly assigned to either LHB tenotomy or LHB tenodesis in conjunction with arthroscopic rotator cuff repair (Fig 1). Baseline characteristics including sex, initial clinical scores, and rotator cuff quality on MRI are presented in Table 1. The mean follow-up period was 12.1 months for the tenotomy group and 12.5 months for the tenodesis group.

Arthroscopic repair of the rotator cuff tear was possible in all cases. In 4 cases, LHB tenodesis was not feasible because the suture pulled out of the degenerated proximal biceps stump. The total surgical time was significantly shorter for the tenotomy group (mean, 73 minutes vs 82 minutes; $P = .03$) (Table 2).

Primary Outcome: CMS

Fig 2 shows the improvement in the CMS over time. The mean CMS for patients in the LHB tenotomy group improved from 44 (95% CI, 39-48) to 73 (95% CI, 68-79), and that for patients in the LHB tenodesis group improved from 42 (95% CI, 37-48) to 78 (95% CI, 74-82). The difference between groups at 1-year follow-up was 4.8 (97.5% CI, $-\infty$ to 11.4) in favor of LHB tenodesis, with a P value for non-inferiority of .06. The difference between groups in the change in the CMS from baseline to 1 year was 7.9 (97.5% CI, $-\infty$ to 16.4), with a P value for non-inferiority of .31. Fig 3 shows the results of the non-inferiority analyses, both for the primary intention-to-treat analysis and for the exploratory as-treated analysis. In the as-treated analysis, the 4 patients in whom LHB tenodesis was not feasible were categorized in the tenotomy group. This slightly affected the results, but still, none of the between-group

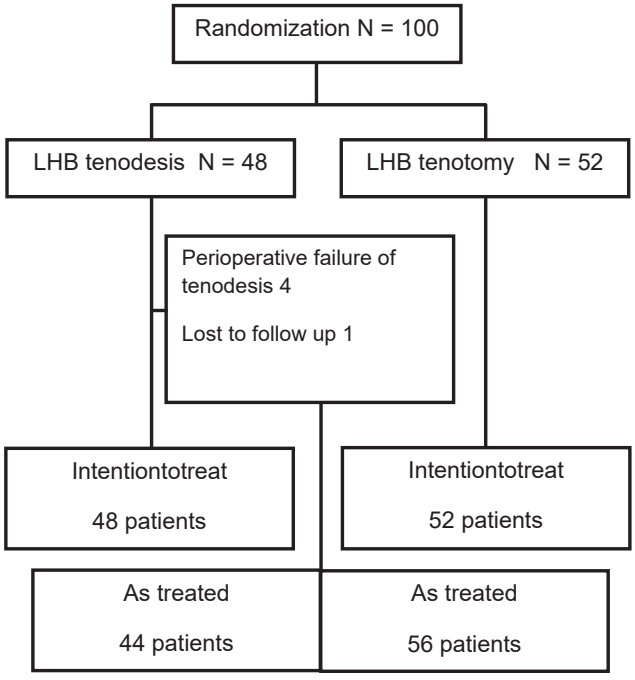


Fig 1. Patient flowchart showing randomization of patients to either long head of biceps (LHB) tenodesis or tenotomy.

Table 1. Baseline Characteristics

	LHB Tenodesis (n = 48)	LHB Tenotomy (n = 52)	Total (N = 100)
Age (range), yr	61 (51-76)	61 (51-79)	61
Male sex, %	58	64	61
Smoking, %	19	23	21
BMI (range)	27 (19-37)	27 (20-33)	27
Dominant side: right, n	29	31	60
Duration of complaints (SD), mo	16.2 (13.9)	25.8 (31.3)	21
Constant-Murley score	42	43	43
DASH score	68	58	64
DOSS	37	37	37
Cramping pain (VAS score)	5.7	5.2	5.4
EQ-5D score	0.77	0.77	0.77
ESI	0.84	0.86	0.85
Goutallier grade on MRI, % (n)			
0	16 (8)	29 (14)	22 (22)
1	63 (32)	53 (26)	58 (58)
2	22 (11)	12 (6)	17 (17)
3		4 (2)	2 (2)
Rotator cuff tear size (SD), mm	20.2 (6.4)	19.8 (6.3)	20.0

NOTE. Variables are presented as mean values unless specified differently.

BMI, body mass index; DASH, Disabilities of the Arm, Shoulder and Hand; DOSS, Dutch Oxford Shoulder Score; ESI, Elbow Strength Index; LCR, lateral clavicle resection; LHB, long head of biceps; MRI, magnetic resonance imaging; SD, standard deviation; VAS, visual analog scale.

differences exceeded the non-inferiority margin. Table 3 shows the unadjusted and adjusted between-group effects for each follow-up moment based on mixed modeling. Including the center of inclusion in the mixed model was not needed because outcomes were similar across hospitals (Appendix Fig 1, available at www.arthroscopyjournal.org).

Secondary Outcomes

Table 3 shows the group averages and between-group effects at 6 weeks, 3 months, and 1 year of follow-up. Except for external rotation in adduction, none of the time-by-group interactions was significant, indicating that both groups had similar improvement over time. For most outcomes, the between-group difference was largest at 6 weeks and reduced over time. At the 1-year follow-up, none of the between-group differences exceeded recently reported median estimates of minimal important differences.[31]

The incidence of reported Popeye deformities did not significantly differ between the LHB tenodesis group (33%) and the LHB tenotomy group (47%, $P = .17$). Tenotomy patients were not significantly less satisfied with the cosmetic appearance of their upper arm ($P = .8$). The exploratory as-treated analysis yielded similar results (31% vs 48%, $P = .12$). Fatigue associated with upper-arm use was present in 40% of all patients, with a borderline significant difference ($P = .05$) between groups (50% in tenotomy group vs 31% in tenodesis group).

Magnetic Resonance Imaging

The integrity of the rotator cuff repair was assessed at final follow-up using MRI in 89 patients. Most MRI scans (66%) showed healing of the rotator cuff repair. A recurrent full-thickness rotator cuff tear was observed in 20% of the MRI scans (8 cases in the tenotomy group and 10 cases in the tenodesis group), and partial healing of the repaired rotator cuff tear was observed in 13% (8 cases in the tenotomy group and 4 cases in the tenodesis group).

Serious Adverse Events

No serious adverse events (cardiovascular, neurologic, or internal medicine conditions or venous thromboembolism) occurred in any patients who were available for follow-up. One patient who underwent

Table 2. Operative Details

	LHB Tenodesis (n = 48)	LHB Tenotomy (n = 52)	Total	*P* Value
Mean rotator cuff tear size (SD), mm	20 (6.3)	20 (6.4)	20	.38
Repair type, %				
Single row	39	24	31	
Double row	61	76	69	.12
Acromioplasty, % (n)	51 (26)	55 (27)	53 (53)	
Distal clavicle resection, % (n)	6 (3)	2 (1)	4 (4)	.89
Combined Neer and LCR, % (n)	0 (0)	4 (2)	2 (2)	
Mean operative time, min	82	73	78	.03

LHB, long head of biceps; SD, standard deviation.

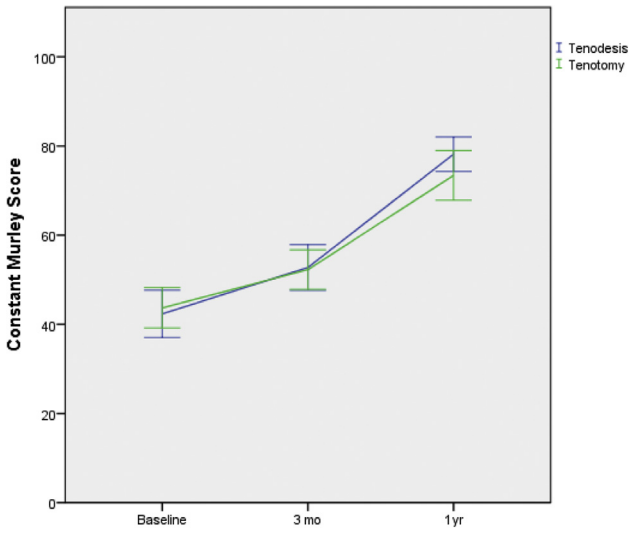


Fig 2. Increase in Constant-Murley score after both long head of biceps tenodesis and tenotomy.

LHB tenodesis was lost to follow-up owing to rerupture of the rotator cuff repair and the occurrence of a Popeye deformity, for which re-repair was performed at another facility. This patient declined follow-up assessment for the study, so these data were not available for analysis.

Discussion

The CMS in both the LHB tenotomy and suprapectoral LHB tenodesis groups at final follow-up showed substantial improvement. The mean difference between groups of 4.8 points on the CMS scale was less than half of the predefined non-inferiority threshold of 10 points. However, the upper bound of the CI was 11.4, resulting in a *P* value for non-inferiority of .06, which should be interpreted as inconclusive.[29]

Given that other outcome parameters revealed only small differences and LHB tenotomy is associated with a shorter operative time, these findings question the need for suprapectoral LHB tenodesis when performed in conjunction with arthroscopic rotator cuff repair. Previous meta-analyses were not able to draw firm conclusions regarding the optimal treatment of LHB pathology owing to the limited levels of evidence of the included studies and heterogeneity of included patients.[20] The results of our study are in line with those of 3 previously published RCTs that compared tenodesis versus tenotomy with concomitant rotator cuff repair.[1-3] However, the technique of both tenotomy and biceps tenodesis was different in each of these studies, including ours.

De Carli et al.[3] randomized 65 patients to undergo either LHB tenotomy or intra-cuff LHB tenodesis and found overall higher mean CMS values in both groups as compared with our study. However, they did not perform a power calculation, and they included patients with SLAP lesions and large-sized rotator cuff tears. Furthermore, they observed 100% rotator cuff coverage of the humeral head in both groups using ultrasound, possibly explaining the higher mean CMS values than in our study.

The RCT by Zhang et al.[2] included patients with large tear sizes as well. A T-shaped tenotomy was compared with fixation of the LHB tendon in the bicipital groove with a suture anchor. No significant differences in functional outcome parameters, Popeye deformities, and cramping pain were found, which is in line with our results. The authors found a shorter operative time and faster pain relief in the tenotomy group, suggesting that LHB tenotomy is to be favored for this group of patients.

Lee et al.[1] randomized 56 patients to undergo a T-shaped tenotomy and 72 patients to undergo tenodesis

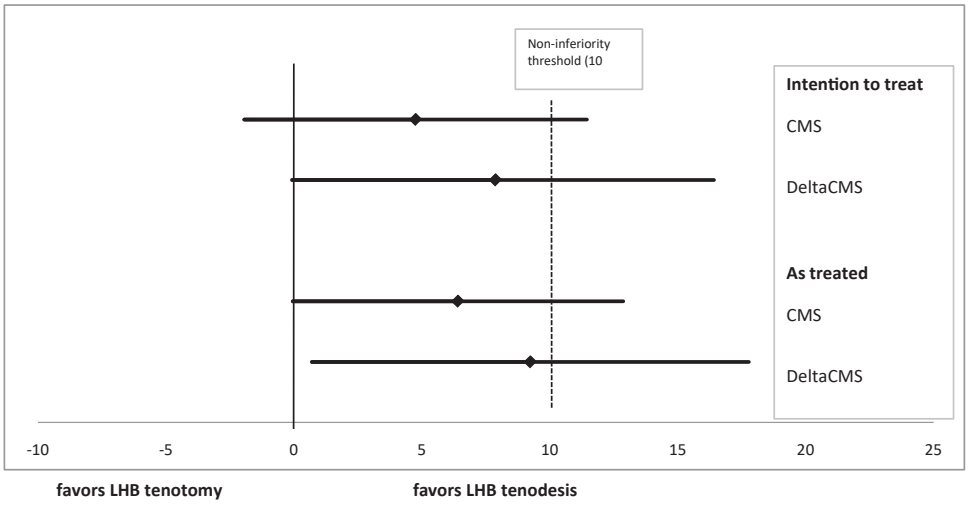


Fig 3. Constant-Murley score (CMS) at 1-year follow-up with minimal clinically important difference of 10 points. The vertical lines are the confidence intervals, and the triangles indicate the differences between the groups. The horizontal lines are the confident intervals. The box with: Non-inferiority threshold (10 points) should be connected to the vertical line. (LHB, long head of biceps.)

in the bicipital groove with an interference screw. Consistently with our study and the previous RCTs, no significant differences in functional outcome scores were found, except for supination strength being significantly higher in the tenodesis group. The authors stated that this difference in supination power was not reflected in the functional outcome scores because of the age distribution and female majority of the included patients. The occurrence of a Popeye deformity was 3 times higher in the tenotomy group than in the tenodesis group. MRI was used to assess postoperative rotator cuff integrity and revealed a retear rate of 16%, which is comparable to our findings.

Other than the occurrence of a Popeye deformity and rerupture of the rotator cuff, no complications were found in either group in our study. Similarly to previous studies regarding shoulder pain scores after surgical treatment of LHB pathology, patients in both groups did not become free of pain.[1,32,33]

Some authors have suggested that pain may still persist in the bicipital groove after proximal LHB tenodesis and therefore have recommended performing a subpectoral rather than suprapectoral LHB tenodesis.[33,34] However, only 1 RCT comparing subpectoral versus suprapectoral tenodesis with concomitant rotator cuff repair has been published, and it found no significant differences regarding both Popeye deformities and outcome scores.[35]

The occurrence of a Popeye deformity in our study was not significantly different between the groups but was relatively high in the tenodesis group (33%) compared with previous studies. A possible explanation for the high percentage of Popeye deformities may be that the tenodesis in our study was performed with the most anterior suture anchor that was used for the rotator cuff repair. The proximal stump of the tenotomized LHB tendon was subsequently transposed to the proximal end of the bicipital groove, which may have caused

Table 3. Group Averages and Between-Group Effects

	Tenodesis			Tenotomy			Crude Mixed Model		Adjusted Mixed Model	
Outcome	n	Mean	95% CI	n	Mean	95% CI	Group Effect	95% CI	Group Effect	95% CI
CMS										
3 mo	45	52.8	47.6-57.9	45	52.3	47.8-56.7	1.5	−4.7 to 7.7	1.1	−5.0 to 7.2
1 yr	45	78.2	74.3-82.1	45	73.4	67.9-79.0	6.7	0.4-12.9	7.3	1.1-13.4
ESI										
3 mo	43	0.91	0.80-1.02	43	0.86	0.75-0.96	0.02	−0.1 to 0.2	0.02	−0.1 to 0.2
1 yr	42	0.97	0.90-1.04	44	1.01	0.89-1.13	−0.05	−0.2 to 0.1	−0.04	−0.2 to 0.1
DASH score (0-100)										
6 wk	44	51.1	45.7-56.5	43	59.6	51.9-67.3	−9.5	−16.8 to −2.1	−8.8	−16.3 to −1.2
3 mo	47	33.8	28.5-39.2	46	40.8	34.9-46.6	−7.7	−14.9 to −0.53	−7.3	−14.7 to 0.01
1 yr	47	13.2	8.4-18.0	43	18.6	12.2-25.0	−6.7	−13.9 to 0.56	−6.7	−14.2 to 0.73
DOSS (12-60)										
6 wk	44	37.9	35.6-40.2	46	42.1	38.9-45.3	−5.2	−8.6 to −1.9	−4.5	-7.8 to −1.2
3 mo	47	28.4	26.4-30.5	47	32.2	29.7-34.8	−4.7	−7.9 to −1.4	−4.6	−7.8 to −1.3
1 yr	49	19.3	17.4-21.3	46	22.5	19.4-25.5	−3.4	−6.7 to −0.11	−3.6	−6.9 to −0.32
EQ-5D index										
6 wk	42	0.79	0.77-0.81	43	0.77	0.74-0.80	0.02	−0.02 to 0.05	0.02	−0.02 to 0.05
3 mo	47	0.83	0.80-0.86	46	0.82	0.79-0.84	0.01	−0.02 to 0.05	0.01	−0.02 to 0.05
1 yr	45	0.91	0.88-0.92	43	0.89	0.85-0.92	0.04	0.00 to 0.07	0.03	0.00 to 0.07
EQ-5D VAS score (0-100)										
6 wk	42	71.0	66.8-75.3	44	67.0	61.3-72.7	5.4	−1.1 to 12.0	5.0	−1.6 to 11.6
3 mo	47	74.2	70.5-77.8	46	70.9	65.8-76.0	4.2	−2.2 to 10.6	3.8	−2.6 to 10.2
1 yr	46	79.7	74.8-84.7	43	78.4	73.4-83.5	3.0	−3.5 to 9.5	1.7	−4.8 to 8.3
Pain: specific (0-10)										
6 wk	43	2.9	2.2-3.6	46	4.0	3.2-4.8	−1.3	−2.3 to −0.31	−1.4	−2.4 to −0.38
3 mo	43	2.4	1.8-3.0	47	3.0	2.3-3.7	−0.72	−1.74 to 0.30	−0.76	−1.78 to 0.26
1 yr	48	1.3	0.65-2.0	45	2.0	1.2-2.9	−0.82	−1.82 to 0.18	−0.87	−1.89 to 0.15
Pain: general (0-10)										
6 wk	44	2.8	2.1-3.5	46	3.7	2.9-4.6	−0.99	−1.99 to 0.01	−1.01	−2.03 to 0.01
3 mo	44	2.7	2.1-3.4	47	3.0	2.2-3.8	−0.26	−1.26 to 0.74	−0.25	−1.26 to 0.76
1 yr	47	1.5	0.8-2.2	46	1.6	0.9-2.4	−0.08	−1.07 to 0.91	−0.07	−1.08 to 0.94
Exorotation, °*										
6 wk	47	27.8	22.5-33.0	41	35.4	29.1-41.7	−8.4	−16.0 to −0.8	−8.9	−16.4 to −1.4
3 mo	47	46.9	41.5-52.3	46	45.0	39.7-50.3	2.1	−5.3 to 9.5	1.4	−5.9 to 8.7
1 yr	44	63.6	58.2-69.1	44	60.8	54.8-66.8	2.3	−5.3 to 9.9	2.3	−5.2 to 9.8

CI, confidence interval; CMS, Constant-Murley score; DASH, Disabilities of the Arm, Shoulder and Hand; DOSS, Dutch Oxford Shoulder Score; ESI, Elbow Strength Index; VAS, visual analog scale.

*Statistically significant time-by-group interaction ($P = .02$), indicating that the difference between groups became smaller over time.

distalization of the biceps muscle and the appearance of a Popeye deformity. Another explanation may be found in tearing of the LHB after suturing of its diseased proximal part. Although patients were assessed by dedicated shoulder physicians, the reporting of a Popeye deformity is susceptible to subjective interpretation and may therefore differ between assessors. Moreover, objective parameters to assess a Popeye deformity have not been clearly described in the literature. The subjective aspect in the assessment of a Popeye deformity may also explain the varying percentages of reported Popeye deformities in the literature.[7,15,36-38]

One of the strong points of our study concerns its multicenter design. Although a dropout rate of 20% was anticipated, only 1 patient in our study was truly lost to follow-up. Despite incidental missing values, all outcome measures had a minimum of 41 values in each group at all follow-up time points. Regarding future research, the following aspects may be considered: Given the lack of a clear benefit of tenodesis in all study outcomes besides CMS, it could be questioned whether exactly repeating this trial with an LHB-specific primary outcome score would be valuable. It may, however, be worthwhile to more thoroughly evaluate cost-effectiveness and compare different surgical techniques.

The non-inferiority margin in our study was based on the minimal clinically important difference, which is a patient-level metric. Although this is common practice in non-inferiority trials, we recommend further research to identify thresholds for the clinical relevance of between-group differences.

Recent studies have indicated that the transverse humeral ligament (THL) and bottleneck narrowing in the bicipital groove may play a role in persisting pain and the occurrence of Popeye deformities after both LHB tenotomy and LHB tenodesis.[39,40] Although not supported by Level I evidence, it may be hypothesized that a tenodesis site below the bicipital groove in combination with a THL release may lead to a more favorable outcome of LHB tenodesis.[40] The results of LHB tenotomy combined with a THL release in terms of pain may improve as well—although at the expense of a likely increase in the occurrence of Popeye deformities. Regarding the latter, however, our study indicates that patients in both groups do not seem to be bothered by this deformity.

Limitations

Although our randomized trial provides high-level evidence, the results must be viewed in light of the following limitations: The ability to assess the generalizability of the results was limited because a screening log of patients who were eligible but not randomized was not kept. Although blinded assessment of the participants in the study was intended, this was not feasible in every participating institution. Subsequent data handling and data analysis, however, were performed by a blinded investigator. In addition, a cost-effectiveness analysis—other than calculation of the difference in the duration of surgery, as well as assessment of quality of life using the EQ-5D—was not performed. Because LHB tenodesis was performed with the anchor that was used for rotator cuff repair and the rehabilitation protocol was the same for both groups, other costs were likely similar.

Consistently with previous RCTs, the CMS was selected as the primary outcome parameter for our study.[1-3] Next to the disadvantage of being an investigator-dependent score, the CMS together with the Disabilities of the Arm, Shoulder and Hand score and Oxford Shoulder Score may be less appropriate to assess LHB treatment. The LHB score presented by Scheibel et al.[16] in 2011 is more focused on LHB pathology. Similarly to the CMS, however, the LHB score is assessed by a clinician or investigator.[16] Euler et al.[41] converted patient-reported symptoms regarding pain, strength, cosmesis, and cramping sensations into the Subjective Proximal Biceps Score. Although both scores seem promising to evaluate LHB pathology, neither was validated at the beginning of our study and, therefore, they were not used. The final follow-up of this study was scheduled at 1 year after surgery, so no conclusions can be drawn on the long-term outcomes. We believe that this period is sufficient to analyze the results of a soft-tissue procedure such as LHB surgery. Although changes in outcome may occur after this period, these could be related to other factors, for example, progression of rotator cuff degeneration. Furthermore, a longer follow-up period may be associated with the risk of loss to follow-up.

Conclusions

Although statistically "inconclusive" regarding non-inferiority of the CMS at 1-year follow-up, any observed differences between patients with LHB tenotomy and those with LHB tenodesis in all outcome scores were small.

Acknowledgment

The authors thank the BITE Study Group and the participating centers for cooperation in conducting this study.

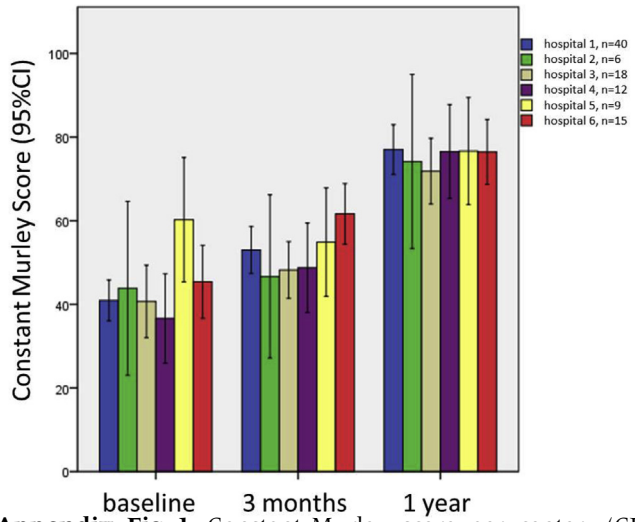
References

1. Lee HJ, Jeong JY, Kim CK, Kim YS. Surgical treatment of lesions of the long head of the biceps brachii tendon with rotator cuff tear: A prospective randomized clinical trial comparing the clinical results of tenotomy and tenodesis. *J Shoulder Elbow Surg* 2016;25:1107-1114.
2. Zhang Q, Zhou J, Ge H, Cheng B. Tenotomy or tenodesis for long head biceps lesions in shoulders with reparable

rotator cuff tears: A prospective randomised trial. *Knee Surg Sports Traumatol Arthrosc* 2015;23:464-469.
3. De Carli A, Vadala A, Zanzotto E, et al. Reparable rotator cuff tears with concomitant long-head biceps lesions: Tenotomy or tenotomy/tenodesis? *Knee Surg Sports Traumatol Arthrosc* 2012;20:2553-2558.
4. Castricini R, Familiari F, De Gori M, et al. Tenodesis is not superior to tenotomy in the treatment of the long head of biceps tendon lesions. *Knee Surg Sports Traumatol Arthrosc* 2018;26:169-175.
5. Oh JH, Lee YH, Kim SH, et al. Comparison of treatments for superior labrum-biceps complex lesions with concomitant rotator cuff repair: A prospective, randomized, comparative analysis of debridement, biceps tenotomy, and biceps tenodesis. *Arthroscopy* 2016;32:958-967.
6. Belay ES, Wittstein JR, Garrigues GE, et al. Biceps tenotomy has earlier pain relief compared to biceps tenodesis: A randomized prospective study. *Knee Surg Sports Traumatol Arthrosc* 2019;27:4032-4037.
7. Cho NS, Cha SW, Rhee YG. Funnel tenotomy versus intracuff tenodesis for lesions of the long head of the biceps tendon associated with rotator cuff tears. *Am J Sports Med* 2014;42:1161-1168.
8. Slenker NR, Lawson K, Ciccotti MG, Dodson CC, Cohen SB. Biceps tenotomy versus tenodesis: Clinical outcomes. *Arthroscopy* 2012;28:576-582.
9. Kelly AM, Drakos MC, Fealy S, Taylor SA, O'Brien SJ. Arthroscopic release of the long head of the biceps tendon: Functional outcome and clinical results. *Am J Sports Med* 2005;33:208-213.
10. Hsu AR, Ghodadra NS, Provencher MT, Lewis PB, Bach BR. Biceps tenotomy versus tenodesis: A review of clinical outcomes and biomechanical results. *J Shoulder Elbow Surg* 2011;20:326-332.
11. Walch G, Edwards TB, Boulahia A, Nove-Josserand L, Neyton L, Szabo I. Arthroscopic tenotomy of the long head of the biceps in the treatment of rotator cuff tears: Clinical and radiographic results of 307 cases. *J Shoulder Elbow Surg* 2005;14:238-246.
12. Godenèche A, Kempf J-F, Nové-Josserand L, et al. Tenodesis renders better results than tenotomy in repairs of isolated supraspinatus tears with pathologic biceps. *J Shoulder Elbow Surg* 2018;27:1939-1945.
13. Elser F, Braun S, Dewing CB, Giphart JE, Millett PJ. Anatomy, function, injuries, and treatment of the long head of the biceps brachii tendon. *Arthroscopy* 2011;27:581-592.
14. McCrum CL, Alluri RK, Batech M, Mirzayan R. Complications of biceps tenodesis based on location, fixation, and indication: A review of 1526 shoulders. *J Shoulder Elbow Surg* 2019;28:461-469.
15. Boileau P, Baque F, Valerio L, Ahrens P, Chuinard C, Trojani C. Isolated arthroscopic biceps tenotomy or tenodesis improves symptoms in patients with massive irreparable rotator cuff tears. *J Bone Joint Surg Am* 2007;89:747-757.
16. Scheibel M, Schroder RJ, Chen J, Bartsch M. Arthroscopic soft tissue tenodesis versus bony fixation anchor tenodesis of the long head of the biceps tendon. *Am J Sports Med* 2011;39:1046-1052.
17. Jensen AR, Cha PS, Devana SK, et al. Evaluation of the trends, concomitant procedures, and complications with open and arthroscopic rotator cuff repairs in the Medicare population. *Orthop J Sports Med* 2017;5:2325967117731310.
18. Yi Y, Lee JM, Kwon SH, Kim JW. Arthroscopic proximal versus open subpectoral biceps tenodesis with arthroscopic repair of small- or medium-sized rotator cuff tears. *Knee Surg Sports Traumatol Arthrosc* 2016;24:3772-3778.
19. Meeks BD, Meeks NM, Froehle AW, Wareing E, Bonner KF. Patient satisfaction after biceps tenotomy. *Orthop J Sports Med* 2017;5:2325967117707737.
20. Na Y, Zhu Y, Shi Y, et al. A meta-analysis comparing tenotomy or tenodesis for lesions of the long head of the biceps tendon with concomitant reparable rotator cuff tears. *J Orthop Surg Res* 2019;14:370.
21. van Deurzen DF, Scholtes VA, Willigenburg NW, et al. Long head biceps tenodesis or tenotomy in arthroscopic rotator cuff repair: BITE study protocol. *BMC Musculoskelet Disord* 2016;17:375.
22. Veehof MM, Sleegers EJA, van Veldhoven NHMJ, Schuurman AH, van Meeteren NLU. Psychometric qualities of the Dutch language version of the Disabilities of the Arm, Shoulder, and Hand questionnaire (DASH-DLV). *J Hand Ther* 2002;15:347-354.
23. Berendes T, Pilot P, Willems J, Verburg H, te Slaa R. Validation of the Dutch version of the Oxford Shoulder Score. *J Shoulder Elbow Surg* 2010;19:829-836.
24. Lamers LM, Stalmeier PFM, McDonnell J, Krabbe PFM, van Busschbach JJ. Kwaliteit van leven meten in economische evaluaties: Het Nederlands EQ-5D-tarief. *Ned Tijdschr Geneeskd* 2005;149:1574-1578 [in Dutch].
25. Rabin R, de Charro F. EQ-5D: A measure of health status from the EuroQol Group. *Ann Med* 2001;33:337-343.
26. Shank JR, Singleton SB, Braun S, et al. A comparison of forearm supination and elbow flexion strength in patients with long head of the biceps tenotomy or tenodesis. *Arthroscopy* 2011;27:9-16.
27. Goutallier D, Postel J, Bernageau J, Lavau L, Voisin M. Fatty muscle degeneration in cuff ruptures. *Clin Orthop Relat Res* 1996;304:78-83.
28. Kukkonen J, Kauko T, Vahlberg T, Joukainen A, Aarimaa V. Investigating minimal clinically important difference for Constant score in patients undergoing rotator cuff surgery. *J Shoulder Elbow Surg* 2013;22:1650-1655.
29. Piaggio G, Elbourne DR, Altman DG, Pocock SJ, Evans SJW, CONSORT Group. Reporting of noninferiority and equivalence randomized trials: An extension of the CONSORT statement. *JAMA* 2006;295:1152-1160.
30. Twisk JW, de Vente W. The analysis of randomised controlled trial data with more than one follow-up measurement. A comparison between different approaches. *Eur J Epidemiol* 2008;23:655-660.
31. Hao Q, Devji T, Zeraatkar D, et al. Minimal important differences for improvement in shoulder condition patient-reported outcomes: A systematic review to inform a BMJ Rapid Recommendation. *BMJ Open* 2019;9:e028777.
32. Gurnani N, van Deurzen DF, Janmaat VT, van den Bekerom MP. Tenotomy or tenodesis for pathology of the

long head of the biceps brachii: A systematic review and meta-analysis. *Knee Surg Sports Traumatol Arthrosc* 2016;24:3765-3771.
33. Nho SJ, Frank RM, Reiff SN, Verma NN, Romeo AA. Arthroscopic repair of anterosuperior rotator cuff tears combined with open biceps tenodesis. *Arthroscopy* 2010;26:1667-1674.
34. Levy AS, Kelly BT, Lintner SA, Osbahr DC, Speer KP. Function of the long head of the biceps at the shoulder: Electromyographic analysis. *J Shoulder Elbow Surg* 2001;10:250-255.
35. Mardani-Kivi M, Keyhani S, Ebrahim-Zadeh MH, Hashemi-Motlagh K, Saheb-Ekhtiari K. Rotator cuff tear with concomitant long head of biceps tendon (LHBT) degeneration: What is the preferred choice? Open subpectoral versus arthroscopic intraarticular tenodesis. *J Orthop Traumatol* 2019;20:26.
36. Kerschbaum M, Maziak N, Scheuermann M, Scheibel M. Arthroskopische Tenodese oder Tenotomie der langen Bizepssehne bei vorselektionierten Patienten: Macht es einen Unterschied? [Arthroscopic tenodesis or tenotomy of the long head of the biceps tendon in preselected patients: Does it make a difference?]. *Orthopade* 2017;46:215-221 [in German].
37. Koh KH, Ahn JH, Kim SM, Yoo JC. Treatment of biceps tendon lesions in the setting of rotator cuff tears: Prospective cohort study of tenotomy versus tenodesis. *Am J Sports Med* 2010;38:1584-1590.
38. Osbahr DC, Diamond AB, Speer KP. The cosmetic appearance of the biceps muscle after long-head tenotomy versus tenodesis. *Arthroscopy* 2002;18:483-487.
39. Snow BJ, Narvy SJ, Omid R, Atkinson RD, Vangsness CT Jr. Anatomy and histology of the transverse humeral ligament. *Orthopedics* 2013;36:e1295-e1298.
40. Taylor SA, Ramkumar PN, Fabricant PD, et al. The clinical impact of bicipital tunnel decompression during long head of the biceps tendon surgery: A systematic review and meta-analysis. *Arthroscopy* 2016;32:1155-1164.
41. Euler SA, Horan MP, Ellman MB, Greenspoon JA, Millett PJ. Chronic rupture of the long head of the biceps tendon: Comparison of 2-year results following primary versus revision open subpectoral biceps tenodesis. *Arch Orthop Trauma Surg* 2016;136:657-663.

Appendix



Appendix Fig 1. Constant-Murley score per center. (CI, confidence interval.)