

Effect of Abduction Brace Wearing Compliance on the Results of Arthroscopic Rotator Cuff Repair

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Background: The benefit of protective bracing after rotator cuff reconstruction has been debated for many years, although immobilization compliance has never been assessed objectively to date. In a previous study, compliance with the wearing of an abduction brace was measured for the first time with use of temperature-sensitive sensors. The purpose of the present follow-up study was to assess the effect of immobilization compliance on tendon-healing after rotator cuff repair.

Methods: The clinical and radiographic outcomes for 46 consecutive patients with objectively assessed abduction brace wearing compliance after arthroscopic repair of a superior rotator cuff tear were prospectively analyzed. Rotator cuff integrity was examined with ultrasound. Clinical outcomes were assessed with the relative Constant-Murley score (RCS), the Subjective Shoulder Value (SSV), and pain and patient satisfaction ratings. Receiver operating characteristic (ROC) curves were used to determine the optimal cutoff value of abduction brace compliance for discriminating between shoulders that will and will not have a retear and the association of compliance with the failure of rotator cuff repair.

Results: After a mean duration of follow-up of 20 ± 9 months, the odds ratio for having a rotator cuff repair failure was 13-fold higher for patients with a compliance rate of $<60\%$ ($p = 0.037$). The retear rate was 3% (1 of 35 patients) in the high-compliance cohort ($\geq 60\%$ compliance) and 27% (3 of 11) in the low-compliance cohort ($<60\%$ compliance) ($p = 0.037$). No differences in RCS, SSV, pain, or postoperative patient satisfaction were observed between patients with $\geq 60\%$ compliance and those with $<60\%$ compliance.

Conclusions: Patients with a compliance rate of $<60\%$ had a 13-fold increase in the risk of rotator cuff retear. The 2 patients with the lowest compliance rates (11% and 22%) both had retears. Due to the small sample size, no final conclusions can be drawn regarding the influence of immobilization compliance on tendon-healing after rotator cuff repair. These findings justify a prospective trial with a larger cohort to confirm or disprove the value of compliance with abduction bracing.

Level of Evidence: Therapeutic Level II. See Instructions for Authors for a complete description of levels of evidence.

The rate of retear after rotator cuff reconstruction has been reported to range from 3%¹ to 94%². The retear risk depends on patient-specific, technical, and postoperative factors.

Patient-specific risk factors such as age^{3,4}, tear size¹, the extent of fatty infiltration and atrophy of the rotator cuff muscles^{5,6}, the length of the tendon stump⁷, the critical shoulder angle⁸, diabetes mellitus⁹, hyperlipidemia¹⁰, low bone mineral density¹¹, and smoking status¹² can be influenced only to a very limited extent.

Postoperative protection of the involved shoulder in an abduction splint should reduce tension on the tendon-to-bone repair site and allow safer healing of the repair, with ultimately better clinical outcomes. According to the existing literature, it remains unclear whether a sling alone or protection in an abduction brace improves clinical tendon repair integrity or even clinical outcomes. In multiple Level-I and II studies, no benefit was observed in patients who were managed with immobilization with a sling as compared with those who were not¹³⁻²⁰. However, the extent to which the patients actually

A **data-sharing statement** is provided with the online version of the article (<http://links.lww.com/JBJSOA/A389>).

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adhered to the immobilization regimen remains unanswered as immobilization compliance was not measured objectively in any of those studies. In studies of bracing therapy for scoliosis, temperature-sensitive sensors have been used to obtain objective data on wearing compliance^{21,22}. The same sensor technology has been used to record compliance with the wearing of a compression stocking after hindfoot surgery²⁹. In a prospective cohort study in which such sensors were used to objectively evaluate compliance with the wearing of an abduction brace after superior rotator cuff repair, the rate of patient adherence to the postoperative immobilization protocol was only 48%²³. The purposes of the present study were (1) to clarify whether compliance with abduction brace immobilization has an effect on tendon-healing and (2) to define the compliance rate associated with improved tendon-healing after rotator cuff repair.

Materials and Methods

Patients

The study was approved by the local institutional review board and was registered at clinicaltrials.gov (NCT03054753).

All 50 patients who had been included in a previous study assessing compliance with the wearing of an abduction splint after arthroscopic rotator cuff reconstruction²³ were enrolled in the present study. All patients with primary isolated full-thickness rotator cuff tears of the superior rotator cuff were included. Patients with retears, fatty infiltration of Goutallier ≥ 2 ³⁰, massive rotator cuff tears, tears with an anteroposterior diameter of >3 cm, anterosuperior rotator cuff tears, concomitant acromioclavicular joint resections, or labral repairs were excluded.

The 50 consecutive patients were prospectively recruited and were clinically and radiographically assessed for the original study. An arthroscopic single-row repair with 1 to 3 anchors was performed, combined with a biceps tenotomy and anterolateral acromioplasty. Postoperatively, all patients were managed with immobilization with an abduction brace for 6 weeks. On postoperative day 1, physical therapy consisting of passive joint mobilization above the level of the abduction splint was initiated. Active-assisted and active range of motion was allowed 6 weeks after surgery. Light weight-bearing was started 10 to 12 weeks after surgery, followed by full weight-bearing 16 weeks after surgery. The operations were performed between February 2017 and March 2019 by 4 different fellowship-trained shoulder surgeons. All patients with a minimum clinical and radiographic follow-up of 1 year were included in the present study.

Compliance Assessment

The assessment of abduction brace compliance was described in a previous study²³. Abduction brace wearing time was measured with a CE (Certification Europe)-approved temperature-sensitive sensor (Fig. 1) that was implanted in the abduction brace to measure body temperature and thus wearing time (hours per day). The patients were informed about the implanted sensor after 6 weeks of immobilization so that their natural wearing behavior was not influenced. The wearing compliance rate (expressed as a percentage) was defined as the

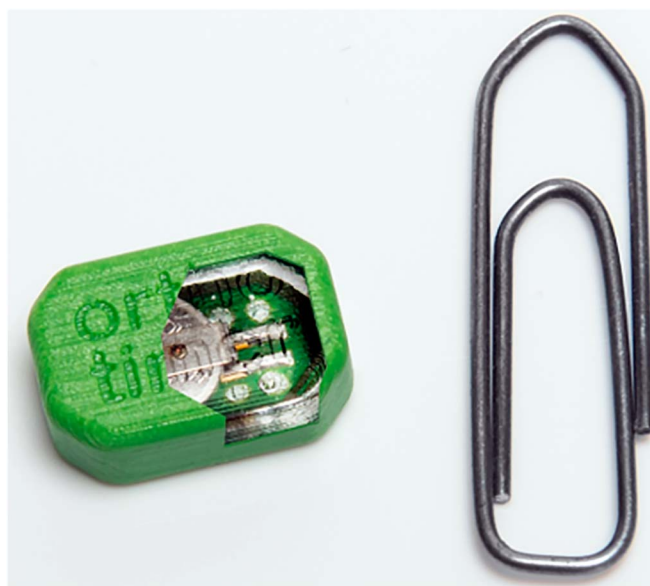


Fig. 1
Illustration of the size of the temperature-sensitive sensor.

absolute measured wearing time (hours per day for 6 weeks) divided by the recommended wearing time (23 hours per day for 6 weeks postoperatively).

Assessment of Rotator Cuff Integrity and Clinical Outcome

After a minimum of 12 months, 46 of the 50 patients were available for clinical and ultrasound examination of the involved shoulder; the other 4 patients were lost to follow-up. In cases in which a re-tear was suspected, magnetic resonance imaging (MRI) arthrography was additionally performed ($n = 11$). A re-tear was suspected in patients with continuous shoulder pain, a positive Jobe test, or an abnormal ultrasound examination at the time of the latest clinical follow-up examination. This means that an MRI examination was not performed for patients who presented with normal clinical and ultrasound findings. In case of a re-tear, the tear pattern was classified according to the system described by Sugaya et al.²⁴. The ultrasound and MRI examinations were performed by 2 fellowship-trained musculoskeletal radiologists who were blinded to the patient's compliance status. Clinical outcome was assessed preoperatively and at the time of the latest clinical follow-up (at least 1 year postoperatively) with the relative Constant-Murley score (RCS) and the Subjective Shoulder Value (SSV), pain (measured within the RCS score, with 15 representing no pain and 0 representing worst pain), and patient satisfaction (with 1 representing poor, 2 representing moderate, 3 representing good, and 4 representing excellent). Rotator cuff integrity was defined as the primary outcome parameter, and the RCS was defined as the secondary outcome parameter.

Retear Subgroup

A subgroup analysis was performed to assess wearing compliance, clinical outcome, preoperative tear pattern, fatty infiltration, critical shoulder angle, demographics, and the critical shoulder angle in patients with a rotator cuff re-tear.

Statistics

Normality of the distribution was assessed with use of the Shapiro-Wilk test. The risk of having a rotator cuff repair failure based on abduction brace compliance was assessed with use of odds ratios (ORs). Receiver operating characteristic (ROC) curves were used to determine the cutoff value of abduction brace compliance and its association with rotator cuff repair failure. The 2 groups (high versus low compliance) were compared with use of the unpaired t test (for a normal distribution) or the Mann-Whitney U test (for a non-normal distribution). Subgroup analysis (retear versus healed rotator cuff repair) was conducted with use of the Mann-Whitney U test. For categorical variables, the chi-square test and the Fisher exact test (if $n < 5$) were used. The level of significance was set as $p < 0.05$, and all p values were 2-tailed.

Source of Funding

The research project was funded by the clinical research fund of our orthopaedic department. The funding source did not play a role in the investigation.

Results

Patients

Forty-six of the 50 original prospectively and consecutively recruited patients were included in the present study; the mean age (and standard deviation) was 56 ± 10 years, and the mean duration of follow-up was 20 ± 9 months (minimum, 12 months). Four of the original 50 patients were not available for annual follow-up. All 4 patients were contacted by phone. No revision surgery was necessary in any of these 4 patients. During the phone conversation, the 4 patients reported SSVs of 90% (3 patients) and 100% (1 patient). Two of the 4 patients had not returned for follow-up because of a lack of time combined with a lack of symptoms. The other 2 patients had moved abroad and were therefore not available. ROC curve analysis determined a cutoff value of 60% compliance for discriminating between the intact and retear groups with a sensitivity of 81% and a specificity of 75% (Fig. 2). The area under the curve was 0.747. The OR for having a rotator cuff repair failure with a compliance of $< 60\%$ ($n = 11$) compared with $\geq 60\%$ was 13 ($p = 0.037$). Patients with a compliance rate of $< 60\%$ were assigned to the low-compliance group (LCG), and those with a compliance rate of $\geq 60\%$ were assigned to the high-compliance group (HCG). Compliance measurements, demographics, risk factors for retears, and preoperative scores for the HCG and LCG are shown in Table I. The baseline demographic characteristics of the 2 groups did not differ (Table I).

Rotator Cuff Integrity

Forty-two repairs healed and 4 failed, resulting in a retear rate of 8.7%. The retear rate was 2.9% (1 of 35) in the HCG and 27.3% (3 of 11) in the LCG ($p = 0.037$) (Table II). The OR for failure was 13-fold increased in the LCG compared with the HCG ($p = 0.037$). The 2 patients with the lowest compliance rates (11% and 22%) both had a retear of the tendon reconstruction (Fig. 3). Two patients had a type-IV retear, and 2 had a type-V retear.

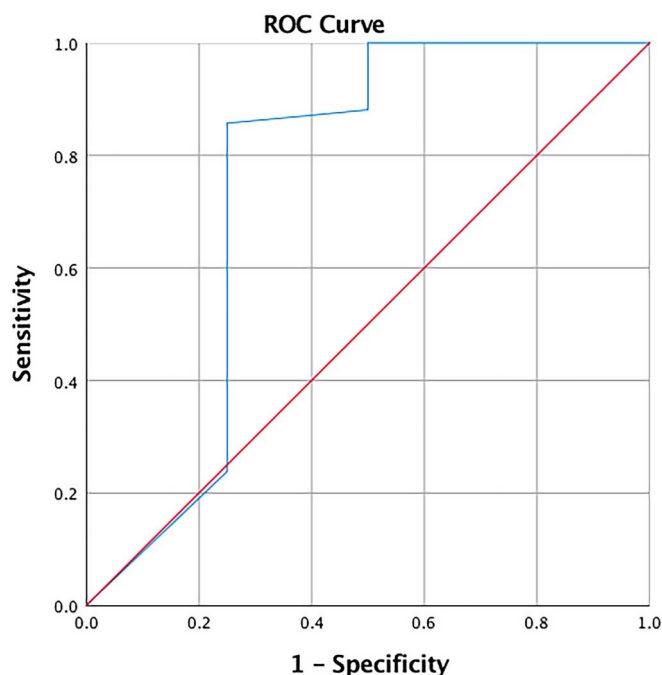


Fig. 2

ROC curve (blue line) to determine the optimum cutoff value of abduction brace compliance for discriminating between intact and failed rotator cuff repair. The reference line indicating no discrimination is indicated in red. The area under the curve was 0.747.

Clinical Outcome

No significant differences were observed between the HCG and LCG in terms of the RCS ($86\% \pm 16\%$ versus $85\% \pm 17\%$; $p = 0.849$), SSV ($85\% \pm 22\%$ versus $85\% \pm 24\%$; $p = 0.995$), pain scores (13.4 ± 3 versus 13.6 ± 4 points; $p = 0.811$), or postoperative patient satisfaction (3.6 ± 0.7 versus 3.4 ± 0.9 points; $p = 0.474$) (Table II).

Subgroup Analysis: Retear Versus No Retear

Patients with a retear had a significantly lower mean absolute wearing time in comparison with those without a retear (456 ± 385 versus 750 ± 190 hours; $p = 0.011$). The compliance with immobilization was significantly lower in the retear group as compared with the no-retear group ($47\% \pm 40\%$ versus $79\% \pm 18\%$; $p = 0.010$). The clinical outcome was significantly worse in the retear group as compared with the no-retear group in terms of the RCS ($69\% \pm 30\%$ versus $88\% \pm 13\%$; $p = 0.021$) and patient satisfaction (2.50 ± 1.7 versus 3.63 ± 0.6 ; $p = 0.007$). The SSV was decreased ($66\% \pm 36\%$) in the retear group as compared with the no-retear group ($88\% \pm 20\%$), but the difference was not significant ($p = 0.058$). Three of the 4 patients with a retear were smokers, compared with 11 of the 42 patients with no retear ($p = 0.078$). No significant differences were seen in terms of preoperative fatty infiltration, tendon retraction, tear size, critical shoulder angle, or body mass index (BMI) (Table III).

Discussion

The present study assessed the effect of compliance with abduction brace protection (which, for the first time, was

TABLE I Data on the Patients with High and Low Compliance

	High-Compliance Group (N = 35)	Low-Compliance Group (N = 11)	P Value
Compliance*			
Objectively assessed wearing time (hr)	822 ± 135	413 ± 145	<0.001
Relative wearing time (%)	86 ± 12	43 ± 15	<0.001
Subjectively declared wearing time (%)	98 ± 6	86 ± 20	0.080
Prescribed wearing time (hr)	966 ± 23	970 ± 9	0.462
Demographics, risk factors, preoperative scores			
Female sex	37%	27%	0.549
Age* (yr)	56 ± 10	56 ± 11	0.970
Body mass index* (kg/m ²)	29 ± 5	27 ± 3	0.147
Dominant shoulder	71%	73%	0.933
Right shoulder	66%	55%	0.503
Employed	94%	91%	0.569
Fatty infiltration (Goutallier stage 0 to 4)*	0.66 ± 0.7	0.45 ± 0.7	0.418
Smoker (no. of patients)	10 (29%)	4 (36%)	0.713
Tendon retraction (Patte stage 1 to 3)*	1.8 ± 0.6	1.6 ± 0.7	0.235
Anteroposterior tear size* (mm)	22 ± 5	24 ± 9	0.340
Critical shoulder angle* (deg)	32 ± 4	34 ± 4	0.163
Relative Constant-Murley score* (%)	65 ± 17	59 ± 20	0.389
Subjective Shoulder Value* (%)	44 ± 22	34 ± 16	0.194
Pain score*† (points)	8.4 ± 3	8.8 ± 2	0.683

*The values are given as the mean and the standard deviation. †Pain was rated on a scale of 15 points (no pain) to 0 points (worst pain).

objectively measured with a temperature-sensitive sensor) on tendon-healing and clinical outcomes after arthroscopic supraspinatus tendon repair. We found that patients who wore the abduction brace <60% of the recommended wearing time had a 13-fold increased risk of a rotator cuff retear. The LCG had a significantly higher retear rate as compared with the HCG (27% compared with 3%; $p = 0.037$). The overall retear rate was low (8.7%). However, the clinical outcome for patients with a retear was significantly worse than that for patients

without a retear, and 3 of the 4 patients with a retear had a compliance rate of <60%.

Interestingly, the 2 least-compliant patients were among the 4 patients with a retear. The patient with the worst compliance wore the splint for only 110 hours instead of the recommended 966 hours (compliance rate, 11%), and the patient with the second-worst compliance wore the brace for only 212 hours (compliance rate, 22%). The preoperative tear size, tendon retraction, fatty infiltration, critical shoulder angle, and BMI in the retear subgroup

TABLE II Radiographic and Clinical Outcomes in the High and Low-Compliance Groups*

	High-Compliance Group (N = 35)	Low Compliance Group (N = 11)	P Value
Radiographic outcome			
Retear (no. of patients)	1 (3%)	3 (27%)	0.037
Clinical outcome†			
Relative Constant-Murley score (%)	86 ± 16	85 ± 17	0.849
Change from preop. to postop. (%)	22 ± 15	26 ± 12	0.426
Subjective Shoulder Value (%)	85 ± 22	85 ± 24	0.995
Change from preop. to postop. (%)	44 ± 23	51 ± 11	0.358
Pain‡	13.4 ± 3	13.6 ± 4	0.811
Patient satisfaction§	3.6 ± 0.7	3.4 ± 0.9	0.474

*All patients were followed radiographically and clinically for a mean of 20 months (minimum, 12 months). †The values are given as the mean and the standard deviation. ‡Pain was rated on a scale of 15 points (no pain) to 0 points (worst pain). §4 = excellent, 3 = good, 2 = moderate, 1 = poor.

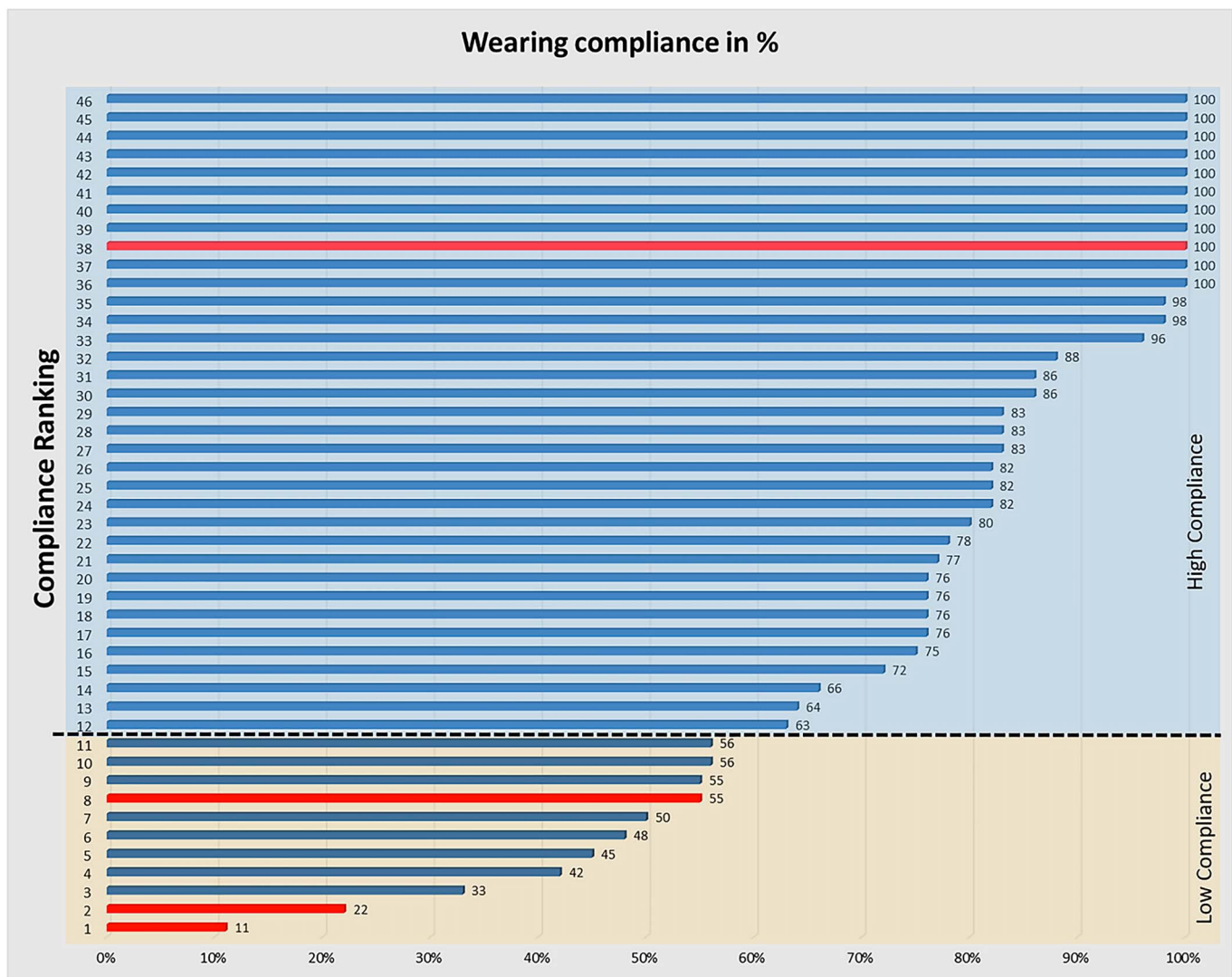


Fig. 3

Compliance rate ranking of all 46 patients. The red bars represent patients with retears. Patients 1 to 11 constituted the low-compliance group, and patients 12 to 46 constituted the high-compliance group.

were comparable with those in the no-retear subgroup. However, 3 (75%) of the 4 patients with a re-tear were smokers, compared with only 14 (30%) of the 46 patients in the total population.

The present study, along with previous studies investigating the influence of immobilization on clinical outcomes and re-tear rates, was limited by the facts that (1) the overall re-tear rate was low in both groups and (2) the cohort (and specifically the re-tear subgroup) was too small to perform a robust subgroup analysis^{14,15,19}.

Sheps et al., in a Level-I study of 206 patients, reported that 22 patients (30%) in the non-sling-immobilization group and 23 patients (33%) in the sling-immobilization group had a rotator cuff re-tear; thus, both rates were higher than those in the present study¹³. Unfortunately, no subgroup analysis was performed in that study¹³. Tirefort et al., in another Level-I study, reported that no clinically relevant differences in clinical

outcome or cuff integrity were observed after 1 year between 40 patients who were managed with sling immobilization and 40 patients who were not managed with sling immobilization after the repair of a small to medium-sized rotator cuff repair¹⁵. Nevertheless, their finding that the 2 retears in the study occurred in the non-sling group is of interest. Keener et al., in a Level-I study, also found no differences in clinical and structural outcomes between sling-immobilized and non-sling-immobilized groups after rotator cuff repair¹⁴. Lee et al., in a Level-II study, reported that the re-tear rate after the repair of mid- and large-sized rotator cuff tears was 9% in the abduction brace immobilization group and 23% in the non-immobilization group²⁵. The study by Lee et al. and the present study showed re-tear rates of <10% after brace immobilization, which were lower than the 33% re-tear rate in the Level-I study by Sheps et al., in which immobilization was carried out only in a sling^{13,25}. At the same time, the re-tear rates in

TABLE III Subgroup Analysis of Retear and No-Retear Groups*

	Retear Group (N = 4)	No-Retear Group (N = 42)	P Value
Compliance			
Mean objectively assessed wearing time (hr)	456 ± 385	750 ± 190	0.011
Mean relative wearing time (%)	47 ± 40	79 ± 18	0.010
Clinical outcome			
Relative Constant-Murley score (%)	69 ± 30	88 ± 13	0.021
Subjective Shoulder Value (%)	66 ± 36	88 ± 20	0.058
Patient satisfaction†	2.5 ± 1.7	3.6 ± 0.6	0.007
Risk factors			
Fatty infiltration (Goutallier stage 0 to 4)	0.75 ± 0.9	0.6 ± 0.7	0.684
Smoker (no. of patients)	3 (75%)	11 (26%)	0.078
Tendon retraction (Patte stage 1 to 3)	1.75 ± 0.5	1.76 ± 0.617	0.967
Anteroposterior tear size (mm)	23.8 ± 14	23 ± 7	0.971
Critical shoulder angle (deg)	34 ± 4	32 ± 4	0.537
Body mass index (kg/m ²)	27 ± 3	29 ± 5	0.469

*All values, with the exception of those related to smoking status, are given as the mean and the standard deviation. †4 = excellent, 3 = good, 2 = moderate, 1 = poor.

the Level-I studies by Tirefort et al.¹⁵ and Keener et al.¹⁴ were also <10%. On the basis of these data, it is not possible to clarify which immobilization (brace or sling) is preferable.

In the Level-I studies by Tirefort et al.¹⁵ and Keener et al.¹⁴, immobilization was performed in a sling only. It remains our hypothesis that “immobilization” is only useful if it reduces the tension on the tendon-to-bone repair. For the supraspinatus, which was torn in every patient in our study, this reduction in tension can be achieved with an abduction pillow or abduction splint. In contrast, in cases of subscapularis tear, tension can be reduced by means of internal rotation with the arm at the side (i.e., in a sling)²⁶.

To our knowledge, no previous study has objectively assessed bracing compliance. We know from a previous study that self-reported wearing compliance differs from objective wearing time. The conclusions drawn from previous Level-I and II studies must be questioned as the true brace-wearing time was not known in any of those studies¹³⁻²⁰. To date, we are aware of only 1 Level-II study in which abduction brace-wearing adherence after rotator cuff reconstruction was assessed with use of a questionnaire²⁷. In that study, Silverio and Cheung observed no difference in outcomes between patients with high versus low immobilization compliance. Along with our previous study documenting that self-reported compliance differs from objectively assessed compliance²³, the study by Silverio and Cheung should be interpreted as an investigation of the results of prescribing—not of wearing—an abduction brace.

As the re-tear subgroup in the present study consisted of only 4 patients, this subgroup analysis was underpowered. Accordingly, the differences described must be considered in that context. As the patients with structural retears also presented with an inferior outcome, it remains imperative to prevent retearing. With the results of this study, it appears

justified to ask for a prospective large evaluation of compliance monitored abduction bracing for supraspinatus tears.

The major limitations of the present study were the small group size and the lack of a control group. The study revealed that 35 patients had a compliance rate of ≥60% and 11 patients had a compliance rate of <60%. Moreover, the baseline values of the 2 groups showed no significant differences and were therefore comparable. Another limitation is the short duration of follow-up (minimum, 1 year), although it is known that clinical treatment outcomes after rotator cuff repair do not change substantially after the 1-year follow-up²⁸. The core strength of the study is the use of a temperature-sensitive sensor for the objective assessment of immobilization compliance, which has never been performed before, to our knowledge. The assessment of compliance with use of temperature-sensitive sensors has been established in the treatment of scoliosis^{21,29} and also has been used in other orthopaedic fields^{23,29}.

Conclusions

This was the first study to objectively assess immobilization compliance and its influence on tendon-healing after rotator cuff repair. A compliance rate of <60% was associated with a 13-fold increased risk of re-tear. However, the small number of patients in the re-tear group does not allow for definitive conclusions. The findings of the present study justify a prospective trial with a larger cohort to confirm or disprove the value of postoperative immobilization. ■

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