# An Expedited Sling Immobilization Protocol After Isolated Biceps Tenodesis Results in Clinical and Patient-Reported Postoperative Outcomes Equivalent to a Standard Rehabilitation Protocol



Mark A. Glover, B.S., Alexis Restrepo, B.S., Andrew J. Recker, M.D., Edward C. Beck, M.D., Garrett S. Bullock, D.P.T., D.Phil., Nicholas A. Trasolini, M.D., and Brian R. Waterman, M.D., F.A.A.O.S.

Purpose: To characterize clinical and patient-reported outcomes for patients after isolated biceps tenodesis (BT) who underwent either standard or expedited sling immobilization protocols following surgery. **Methods:** This retrospective cohort study compared patients who were assigned to use a sling for either 4 to 6 weeks (standard) or 0 to 2 weeks (expedited) following an isolated BT. Primary endpoint included rate of re-rupture, surgical revision, loss of fixation, and Popeye deformity. Secondary endpoints included shoulder range of motion (ROM) as well as pre- and postoperative patient-reported outcomes (PROs) of pain and function. Missing data were managed via multiple imputation with chained equations. Complication prevalence 95% confidence intervals were calculated using the Clopper Pearson method and a series of hierarchical mixed effects linear regressions were performed to assess differences between sling interventions in PROs and ROM. **Results:** The average age of the standard cohort (n = 66) was 49 years ( $\pm 14$  years), and the average age of the expedited cohort (n = 69) was 47 years ( $\pm 14$  years). The expedited and standardized cohorts demonstrated 0.4 and 0.3 complications per 10,000 exposure days, respectively, with no significant difference between groups (1.4 [95% confidence interval 0.2-10.0], P = .727). There was no demonstrated difference in forward flexion, abduction, or external ROM. The expedited group had less improvement in visual analog scale for pain scores that was not clinically significant and there were no differences in PROs of function. Conclusions: No statistically significant difference in the rate of re-rupture, surgical revision, loss of fixation, or Popeye deformity was noted between protocols after isolated BT. Furthermore, there were no clinically significant differences in ROM or PROs identified between protocols after isolated BT. This study suggests that patients who have undergone isolated BT may safely discontinue sling use within 2 weeks after surgery. Level of Evidence: Level III, retrospective comparative study.

**B** iceps tenodesis (BT) is a common orthopaedic procedure that is indicated for interstitial tears, instability, or tenosynovitis of the long head of the

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biceps tendon, as well as for primary or secondary treatment of superior labrum anterior and posterior lesions.<sup>1-5</sup> This procedure can be done with multiple techniques, including either a supra- or subpectoral approach, both of which show similar outcomes.<sup>6-8</sup> Postoperative rehabilitation protocols vary considerably in both sling immobilization duration and timing of initiation of physical therapy.<sup>9-12</sup>

Generally, the use of a sling is part of the rehabilitation protocol after BT, which is intended to protect the fixation of the long head of the biceps.<sup>13,14</sup> However, the use of a sling can increase patients' risk for falls, limit their ability to drive, and cause discomfort or inconvenience during activities of daily living (ADLs).<sup>15-17</sup> If the length of sling immobilization after surgery can be safely reduced, unnecessary limitations on patients' ADLs can be minimized. In contrast to the

From the Wake Forest University School of Medicine, Winston-Salem, North Carolina, U.S.A. (M.A.G., A.R.); and Department of Orthopaedic Surgery and Rehabilitation, Atrium Health Wake Forest Baptist Health, Winston-Salem, North Carolina, U.S.A. (A.J.R., E.C.B., G.S.B., N.A.T., B.R.W.).

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Address correspondence to Mark A. Glover, B.S., 1 Medical Center Blvd., Winston-Salem, North Carolina, 27157, U.S.A. E-mail: glovermarkalan@ gmail.com

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robust data surrounding immobilization periods following rotator cuff repair, there is paucity of literature evaluating expedited sling protocols after isolated BT.<sup>6,18-21</sup>

The purpose of this study was to characterize clinical and patient-reported outcomes (PROs) for patients after isolated BT who were treated with either standard or expedited sling immobilization protocols following surgery. It was hypothesized that expedited sling immobilization and standard sling immobilization durations following BT would show no clinically relevant differences in the collected outcomes.

# Methods

#### Study Design

After institutional review board approval (#00068529), a retrospective review of consecutively enrolled patients who underwent an isolated BT surgery from January 2018 to January 2022 at a single institution was conducted in line with Strengthening the Reporting of Observational Studies in Epidemiology guidelines (Fig 1).<sup>22</sup> Inclusion criteria required patients to have undergone an isolated BT surgery. Patients were excluded if they underwent concomitant reconstructive procedures, such as rotator cuff or labral repair, where the postoperative rehabilitation course was dictated by the concomitant procedures. Distal clavicle excision, superior labral or rotator cuff debridement, and/or subacromial decompression were permitted. They also were excluded if they were younger than 18 years of age or if they did not have a documented sling rehabilitation protocol, as characterization of their postoperative course would not be possible retrospectively. Race, sex, age, laterality, limb dominance, body mass index (BMI) at surgery, fixation site, fixation type, and surgical approach were documented for each group.

All operations were performed by 1 of 3 sports medicine fellowship-trained orthopaedic surgeons, including authors B.R.W. and N.A.T., via arthroscopic or combined arthroscopic and open approach for fixation of the long head of the biceps tendon. Patients who underwent surgery before December 2019 were treated with the standard protocol, whereas patients who underwent surgery after December 2019 were phased into treatment with the expedited protocol. The standard protocol called for 4 to 6 weeks of sling immobilization at all times besides hygiene and exercise, with PT initiation after 2 weeks. The expedited protocol called for 0 to 2 weeks of sling immobilization, with PT initiation within 2 weeks. Both protocols prohibited resisted elbow flexion/supination or lifting greater than 5 pounds for 6 weeks.

#### **Data Collection**

All data collection was performed via review of the electronic medical record, and all PRO data were collected via Surgical Outcomes System (SOS; Arthrex, Naples, FL). Primary outcomes were the rate of rerupture, surgical revision, loss-of-fixation, and Popeye deformity. Popeye deformity was evaluated via the documented physical examination in the electronic medical record visits by either the operative surgeon or an orthopaedic sports medicine-trained physician assistant. This is routinely collected as a part of the existing template for assessment at all pre- and postoperative time points. Secondary outcomes included range of motion (ROM) and PROs. Abduction, external rotation, and forward flexion range of motion were collected preoperatively, as well as 2, 6, 12, and 24 weeks' postoperatively. PROs data collected included visual analog scale for pain (VAS), American Shoulder and Elbow Surgeons (ASES), Single Assessment Numeric Evaluation (SANE), the shortened Disabilities of the Arm, Shoulder and Hand questionnaire (Quick-DASH), and the Patient-Reported Outcomes Measurement Information System (PROMIS-10) preoperatively as well as 6 months' and 1 and 2 years' postoperatively.23-33



**Fig 1.** Patient cohort selection for standard sling rehabilitation (n = 66) and expedited sling rehabilitation (n = 69) for patients enrolled in this study consistent with the STROBE guidelines.

# **Statistical Analyses**

Patient characteristics were analyzed using the  $\chi^2$  test. A priori statistical significance was defined as  $P \ge .05$ . Before analyses, missing data were assessed. Missing data prevalence was 73% and varied between variables (age: 0%, sex: 0%, BMI: 0%, days of follow up: 0%, preoperative external range of motion: 84%, 24-week external range of motion: 86%, preoperative VAS: 53%, 2-year VAS: 84%; Appendix Table 1, available at www.arthroscopyjournal.org). No patients were lost to follow-up; as a result, no right censor issues were present. No missing data differences in either sling intervention were observed, nor were differences in preoperative or end of follow-up PROs or ROM differences observed. The missing data mechanism was missing at random and to control for missing data, multiple imputation with chained equations were performed with 70 iterations. Variables for imputation included age, BMI, sling intervention, preoperative and follow-up times for range of motion (flexion, abduction, and external rotation), PROs (VAS, ASES, Quick DASH, and PROMIS), complications, and follow-up time. Rubin's rules of imputation iteration aggregation were performed for all analyses.

Complication prevalence 95% confidence intervals (95% CIs) were calculated using the Clopper Pearson method. Complication rates were calculated per 10,000 exposure days. Rate ratios were performed to compare complication rates and sling intervention. To assess potential differences between sling interventions and ROM and PROs, a series of hierarchical mixed effects linear regressions were performed. Hierarchical random effects were at the individual patient and surgeon level. Fixed effects controlled for an interaction of sling intervention and time of follow-up. All analyses were performed in R 4.1.2 (Core Team [2021]. R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria; https:// www.R-project.org/). The naniar package was used for missing data analyses, the mice package for multiple imputation, the GenBinomApps package for Clopper Pearson prevalence measures, the *fmsb* package for rate

ratio analyses, the *lme4* package for mixed effects analyses, the *broom.mixed* package for Rubin's rule aggregation with multiple imputation, and the *ggeffects* package for mixed effects model visualization.

# Results

The average age of the standard cohort (n = 66) was 49 years ( $\pm$ 14 years), and the average age of the expedited cohort (n = 69) was 47 years ( $\pm$ 14 years) (Table 1). Average follow-up time for the standard group was 3.09 ( $\pm$ 1.04) years, which was on average longer than that for the expedited group at 2.09 years ( $\pm$  0.77 years) (*P* < .001). There were no significant differences in the ratios of gender and race as well as the BMI for this cohort (Table 1).

#### Complications

A total of 52,649 exposure days were collected for the expedited sling cohort and 74,478 exposure days for the standard sling cohort. Complications for the purpose of this study include re-rupture, surgical revision, loss-of-fixation, and Popeye deformity. Overall complication prevalence for the expedited sling cohort was 3% (95% CI 0-10) and the standard sling cohort was 3% (95% CI 0-11) (Table 2). Complication rates for the expedited cohort were 0.4 complications per 10,000 exposure days and for the standard cohort were 0.3 complications per 10,000 exposure days, with no differences in rates of complications between cohorts (1.4 [95% CI 0.2-10.0], P = 0.727).

#### **Patient-Reported Outcomes**

The standard sling cohort reported -0.8 (95% CI -1.2 to -0.30) lower pain, measured by VAS, over the follow-up period compared with the expedited sling cohort (Figure 2). There were no differences in in PROs between the 2 treatment groups over the follow-up period for the ASES Functional Score (0.14 [95% CI -3.54 to 3.52]), ASES Index Score (5.3 [95% CI -26.3 to 36.9]), SANE (5.7 [95% CI -31.9 to 43.3]), Quick DASH (-0.2 [95% CI -28.6 to 28.2]), PROMIS Physical Component Score (-0.2 [95% CI -28.6 to 28.2]), nor

Table 1. Demographics for Patients in the Standard and Expedited Sling Rehabilitation Cohorts

Variable	Standard (n = $66$ )	Expedited $(n = 69)$	P Value
Age	$49 \pm 14$	$47 \pm 14$	.341
Sex (male/female)	34/32	33/36	.671
BMI	$30 \pm 6$	$31 \pm 7$	.636
Follow-up, y	$3.09 \pm 1.04$	$2.09\pm0.77$	.001*
Race (White/Black/other)	55/9/2	57/11/1	.777
Laterality of surgery (dominant/nondominant/unknown dominance arm)	24/28/14	26/21/22	.2478
Surgical approach (arthroscopic)	28/38	47/22	.0033*
Fixation site (suprapectoral/subpectoral)	28/38	47/22	.0033*
Fixation type (suture anchor/interference screw/button)	28/36/1	41/28/0	.0699

NOTE. Values are shown as mean  $\pm$  standard deviation.

\*Statistically significant.

Variable (%)	Standard	Expedited	P Value
Popeye deformity	2% (n = 1)	3% (n = 2)	.5857
Loss of fixation	0% (n = 0)	0% (n = 0)	.999
Revision rate	2% (n = 1)	0% (n = 0)	.3048
Re-rupture rate	1% (n = 1)	1% (n = 1)	.9747

**Table 2.** Prevalence of Primary Outcomes of Loss of Fixation,

 Re-Rupture, Revision Rate, and Popeye Deformity for Patients

 in the Standard and Expedited Group

the PROMIS Mental Component Score (-0.2 [95% CI -28.6 to 28.2]).

# **Range of Motion**

There was no difference in range of motion between both sling interventions in forward flexion (-5.7 [95% CI -69.0 to 55.6]), abduction (-4.3 [95% CI] -93.3 to 88.7]), or external rotation (-6.8 [95% CI -38.6 to 25.0]) during the duration of follow-up (24 weeks) (Figs 3-5).

#### Discussion

The most important finding of this study was that, for patients who underwent an isolated BT, there was no clinically significant difference in overall complication rates, ROM, or PROs between the standard and expedited sling cohorts, which supported our hypothesis. The only observed difference was a greater improvement in pain by 0.8 points on the VAS scale among the standard protocol group. However, this difference in pain did not meet the threshold of minimum clinically important difference for the VAS pain scale and is likely not clinically significant.<sup>34</sup> Otherwise, there was no difference observed in risk of Popeye deformity, loss of fixation, or re-rupture, and there was no difference in PROs as quantified by SANE, VAS, ASES, QuickDASH, PROMIS-10 Physical, and PROMIS-10 Mental subscores. In patients undergoing isolated BT,

expedited sling protocol may be a safe option without notable increased risk of adverse events.

These results suggest that patients who have undergone BT may safely discontinue sling use within 2 weeks after surgery. Early sling discontinuation allows patients to perform ADLs sooner, which may offer improved balance and earlier initiation of physical therapy.<sup>15-17</sup> Conservative rehabilitation measures have been driven by concern that tendon healing requires prolonged immobilization; however, our study suggests that expedited mobility does not impact risk of surgical failure, ROM, or functional PROs.<sup>35,36</sup> Other clinical studies investigating rehabilitation after BT have shown that early mobilization is as safe as the standard 4 to 6 weeks of immobilization, although no others examined isolated BT with both subpectoral and suprapectoral approaches.<sup>6</sup> In 2018, Liechti et al.<sup>37</sup> showed that patients who underwent mini-open subpectoral BT and were given no postoperative restrictions had failures requiring revision at rates comparable with rates published by others, at 2.2%, but had no comparison group.<sup>38</sup> Similarly, our study found no differences between expedited and standard sling cohorts. Further, a cohort study done by Keeling et al.<sup>38</sup> in 2021 compared 21 patients with sling use for comfort only with 44 patients with 4 weeks of sling use, and found no differences in ASES, SANE, or ROM at 6 months, consistent with the findings of our study. However, their study included both isolated BT and BT with concomitant rotator cuff repair, and patients with concomitant rotator cuff repair were given different restrictions.

This study included heterogenous surgical approaches, fixation sites, and types of fixation. However, based on recent comparative studies, type and site of fixation are equivocal in terms of clinical outcomes. A metanalysis in 2020 by Dekker et al.<sup>39</sup> indicated that there was no difference in load to failure or cyclic displacement in a cadaveric model between either suprapectoral or subpectoral tenodesis location or



**Fig 2.** Visual analog scale for pain (VAS) for patients in the sling (green) and expedited (red) cohorts preoperatively, 2 and 6 weeks, as well as 3, 6, 12, and 24 months' postoperatively.



**Fig 3.** Abduction range of motion for the standard (green) and expedited (red) cohorts preoperatively, as well as 2, 6, 12, and 24 months' postoperatively.

between the following types of fixation: cortical button, interference screw, and suture anchor. Furthermore, Diaz et al.<sup>40</sup> in 2020 found that in a comparison of 6 methods of fixation (interference screw, cortical button, double-loaded anchor, single-loaded anchor, and softtissue tenodesis), that the tendon-suture interface was the main site of failure, rather than the fixation site. They also found that there was no significant difference in fixation type, concluding that the most important factor dictating that tendon quality and suture parameters were the most important factors in determining failure load rather than fixation type.<sup>40</sup> In human research, Forsythe et al.<sup>6</sup> found no difference in PROs or complication rates between open subjectoral and arthroscopic suprapectoral BT. As such, the heterogeneity of this sample likely does not impact the results of this study.

Particularly when coupled with persistent symptoms, a Popeye deformity is a major difference in outcome

between BT and biceps tenotomy.<sup>41</sup> In the current practice, the latter is reserved for pathology of the long head of the biceps in elderly, low-demand patients, and/or patients with morbid obesity. This study evaluated for Popeye deformity via retrospective review of documented patient reports and formal physical examination. However, no formal radiographic correlation, with ultrasound or advanced imaging was performed. As such, this can lead to an underestimation of a Popeye deformity.<sup>41,42</sup> A recent meta-analysis of Level I randomized controlled trials comparing BT with tenotomy demonstrated Popeye deformity occurred in 6.8% of tenodesis patients and 23.3% of the tenotomy group.<sup>5</sup> Although it is possible the prevalence of a Popeye deformity was underestimated in this study, the prevalence identified is consistent with reported values in literature.<sup>43,44</sup> Patients with more subtle findings may have been detected with ultrasound or magnetic resonance imaging. However, due to the primarily



**Fig 4.** Forward flexion range of motion for the standard (green) and expedited (red) cohorts preoperatively, as well as 2, 6, 12, and 24 -months' postoperatively.



**Fig 5.** External range of motion for the standard (green) and expedited (red) cohorts preoperatively, as well as 2, 6, 12, and 24 months' postoperatively.

cosmetic nature of Popeye deformity, the increased patient burden of additional imaging to detect subtle deformity was not justified for this study.

BT is a safe procedure that provides significant clinical benefit and high patient satisfaction.<sup>45-47</sup> As BT remains a common operation, standard postoperative rehabilitation is essential in formulating safe, evidence-based guidelines for that minimize unnecessary restrictions and secondary loss of motion to patients.<sup>48</sup> Given the results of this study, physicians may safely elect to pursue early discontinuation of sling use with expedited mobilization, though further multi-centered randomized trials are necessary to solidify these findings.

# Limitations

This study is not without limitations. First, all patients were treated by 1 of 3 surgeons at a tertiary referral center, which may limit the generalizability of this study. Second, characteristics that influenced surgeon choice in rehabilitation protocol, such as handedness or occupation, were not analyzed and may impact patients' comfort and ability to undergo an expedited sling protocol. Future studies can prospectively collect this information to better qualify their results. Third, given the modest sample size of this cohort and the retrospective nature of data collection, the results and demographics in this study would, again, benefit from a prospective randomized control or cohort design. Lastly, the standard cohort had a significantly longer follow-up time than the expedited group, which was due to fact that most patients who had surgery before December 2019 also underwent the standard sling protocol. Shortened characterization of surgical outcomes for the expedited group is possible as a result of this incongruency.

# Conclusions

No statistically significant difference in the rate of rerupture, surgical revision, loss-of-fixation, or Popeye deformity was noted between protocols after isolated BT. Furthermore, there were no clinically significant differences in ROM or PROs identified between protocols after isolated BT. This study suggests that patients who have undergone isolated BT may safely discontinue sling use within 2 weeks after surgery.

#### Disclosure

The authors declare the following financial interests/ personal relationships which may be considered as potential competing interests: B.R.W. reports publishing royalties from Arthroscopy and Elsevier; consulting fees from DePuy and FH Ortho; paid presenter for Arthrex and Vericel; board member for American Academy of Orthopaedic Surgeons, American Orthopaedic Society for Sports Medicine, American Shoulder and Elbow Surgeons, Arthroscopy, and AANA and editorial or governing board for Video Journal of Sports Medicine; stock options from Kaliber AI, Sparta, and Vivorté; and other financial or material support from the Musculoskeletal Transplant Foundation and Smith & Nephew. All other authors (M.A.G., A.R., A.J.R., E.C.B., G.S.B., N.A.T.) declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper Full ICMJE author disclosure forms are available for this article online, as supplementary material.

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