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Project Title: Biceps Tenodesis versus Tenotomy in the Treatment of Lesions of the Long Head of Biceps Brachii : Randomized Clinical Trial - An Interim Analysis

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SUMMARY: (no more than 250 words single spaced)

Background: Both biceps tenotomy and tenodesis have been shown to produce comparable, effective results in treatment of lesions of the long head of biceps tendon (LHBT). The aim of this study was to provide an interim analysis of a level I prospective, randomized, clinical trial comparing subjective patient-reported outcomes and objective clinical results between biceps tenotomy and tenodesis.
Methods: Fifty-nine patients have consented to participate in the study, the current interim analysis was performed for twenty-six patients.The primary outcome measure was the American Shoulder and Elbow Surgeons (ASES) shoulder assessment form. Secondary outcome measures included the Western Ontario Rotator Cuff (WORC) index, strength, cosmetic appearance, pain and cramping pain and operative time. Outcome measures were completed pre-operatively and at 3 and 6 months after surgery.
Results: ASES scores improved in the tenotomy group post-op over time, scores in the tenodesis group improved at 3 months but not at 6 months. There were no differences found between the groups in ASES scores, WORC scores, elbow flexion or supination strength, pain, cramping pain, operative time and the incidence of a Popeye deformity at any time point. However at 6 months post-op a difference in elbow flexion strength was approached (p=.061) with the tenodesis group appearing stronger.
Conclusion: The results of this interim analysis suggest that there is no difference in clinical or functional outcomes between tenodesis or tenotomy for treatment of lesions to the LHBT. However, tenodesis may preserve some elbow flexion strength and appears to be technically more difficult. Further analysis of a larger sample size and longer follow-up time is required to

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Introduction and Background

Significance

Biceps tenotomy (Cutting tendon) and biceps tenodesis (Cutting tendon and reattaching) are both considered standard of care treatments for lesions of the long head of biceps tendon (LHBT), with both treatments yielding comparable results[1–3]. It has been suggested that tenotomy is technically easier than tenodesis, requiring less operative time, easier rehabilitation, and faster return to activity[2,4]. Alternatively, tenodesis allows for better preservation of elbow flexion and supination strength, avoidance of cosmetic deformity, and minimization of post-operative cramping pain compared to tenotomy[5,6]. Based on these findings, the general consensus is that tenotomy should be used for older patients, aged 55-60, with lower functional demand, while tenodesis is more suitable in younger patients that engage in activities of higher functional demand and may be concerned over cosmetic appearance of the arm[1,3,7,8].

To date, there are a limited number of studies that directly compare the clinical outcomes of these two procedures. Several authors suggest both procedures produce favourable clinical outcomes and that there is little clinical significant difference between biceps tenotomy and tenodesis[1,3,7,9]. However, the change in cosmesis with either procedure has been shown to be relevant with a Popeye deformity occurring more often in patients undergoing tenotomy, as highlighted by two recent systematic reviews[8,10] However, other studies have shown no difference between the two groups with respect to a Popeye deformity[3,9] Even though the systematic review and comparative studies have shown a statistically significant predisposition to the development of a Popeye deformity in patients undergoing biceps tenotomy, several authors have shown that this is well tolerated by patients[5,6,11]. Additionally, not all patients undergoing biceps tenotomy develop a cosmetic deformity which suggests that the tendon may rest in the bicipital groove after being cut rather than retracting down the arm[12,13].

The difference in strength changes following a tenotomy versus tenodesis procedures demonstrates varying results. A few studies have reported no differences in strength between the two procedures[1,3,4,14]. On the other hand, in a study comparing ruptured LHBT treated surgically and those treated non-surgically, the non-surgical group lost a mean of 21% of supination strength and 8% of elbow flexion strength. Additionally, Wittstein et al.[15] found through isokinetic testing that tenotomy decreased supination strength when compared with the non-operative side and the tenodesis group. Based on these findings, it still remains unclear whether there is a difference in post-operative strength between tenodesis and tenotomy groups.

It has been suggested that tenotomy is technically easier and requires less operative time than tenodesis[2,3,6]. Alternatively, Koh et al.[1] did not find a difference in operative times between groups, but did state that tenodesis is technically more difficult to perform.

To our knowledge there has only been one prospective randomized clinical trial conducted comparing tenotomy and tenodesis. Furthermore, the findings of that study were applicable to patients aged 55 and older, this age threshold is an important one. As a result, there is currently ongoing controversy over treatment protocols for lesions of the LHBT in patients of all ages.

Therefore the aim of this level I prospective, randomized, clinical trial is to address limitations in the literature by comparing subjective patient-reported outcomes, objective clinical results, strength and cosmetic changes between biceps tenotomy and biceps tenodesis. The results of this study will help to guide future treatment of LHBT lesions. Our hypothesis was that

there will be no difference in subjective patient-reported outcomes, objective clinical results, strength and cosmetic changes between tenotomy and tenodesis used to treat lesions of the LHBT.

Anatomy

The biceps brachii muscle is composed of two heads, a short head and a long head. The short head of biceps tendon originates from the coracoid process. The long head of biceps tendon (LHBT) originates from within the shoulder joint and is therefore associated with structures and pathology of the shoulder. The main actions of the biceps brachii muscle are forearm supination and elbow flexion.

The LHBT is approximately 9 cm long from its origin within the glenohumeral joint to the musculotendinous junction[7]. In a study of cadavers, Vangsness et al.[16] determined that the LHBT originated from the supraglenoid tubercle in 40-60% of study specimens, while the remainder originated from the superior glenoid labrum. The LHBT courses out of the glenohumeral joint through the rotator interval (RI), which is a triangular region bordered by the anterior fibres of the supraspinatus tendon and superior fibres of the subscapularis tendon. After the tendon passes through the RI, it enters the bicipital groove passing underneath the transverse humeral ligament, whose existence is debated[17,18], and is stabilized by the biceps pulley, formed by the coracohumeral ligament and superior glenohumeral ligament[19]. The LHBT is further stabilized as it courses into the bicipital groove by fibres of the subscapularis and supraspinatus tendons. Together, these structures play important roles in preventing anteromedial dislocation of the LHBT[19–21].

The blood supply to the long head of biceps tendon has been described as coming from three sources[22,23] which includes (1) the branches of the brachial artery (2)the deep brachial artery (distally) and (3) branches of the anterior humeral circumflex artery(proximally, supplying the intra-articular portion)[22]. The blood supply to the tendon is well adapted to the location and function of the tendon, as the fibrocartilaginous portion of the tendon that glides through the bicipital groove during movement of the arm is mostly avascular. This arrangement reduces the risk of occlusion or rupture of vessels by friction along the humeral head[22,23].

Innervation to the biceps tendon is through a network of sensory and sympathetic nervous system fibres and is most abundant in the proximal third of the LHBT[24]. Additionally, a recent cadaveric study showed that a small branch from the anterior branch of the axillary nerve was distributed in the connective tissue surrounding the LHBT[25]. This small branch pierced the cortical bone of the humerus at the superolateral aspect of the bicipital groove in three of the eight shoulders with this innervation pattern. Ultimately, these findings may offer some insight into the increased rate of persistent pain proximal to the groove following tenodesis[25].

Pathology

Lesions of the LHBT can be divided into instability of the tendon or tendinopathy; tendinopathy can be further divided into primary or secondary[26]. Primary tendinopathy occurs when lesions of the LHBT are not associated with other shoulder pathology. Secondary tendinopathy is more common and is typically associated with impingement syndrome or rotator cuff pathology[27]. In cases of secondary tendinopathy, the biceps tendon may become atrophic due to degenerative changes or hypertrophic from chronic inflammation[28] (Figure 1 and 2).

Instability occurs when the LHBT is either dislocated or subluxed medially. Instability of the biceps tendon is typically associated with loss or degeneration of tissues of the rotator interval which stabilize the biceps tendon[29,30]. Complete dislocation of the LHBT is most common in the presence of subscapularis tears[26].Based on anatomical location, structure and function, pathology of the LHBT is often associated with other shoulder injuries and therefore can be difficult and complex to manage.

Clinical Presentation

The symptoms of LHBT pathology are typically not specific to the LHBT and may present similar to rotator cuff lesions or impingement syndrome[31]. Lesions of the LHBT present with anterolateral shoulder pain and also may have associated loss of forward flexion at the shoulder[6]. However, changes in range of motion (ROM) vary significantly from normal to global losses in ROM[26]. Clinically, the most common finding on examination is pain with palpation over the bicipital groove attributed to the biceps tendon[4,26,32]. Often the pain radiates down the anterior arm into the biceps muscle[26]. Lateral migration of the pain with external rotation of the arm may allow the pain to be differentiated from rotator cuff pathology[4,26,32]. Patients with instability of the biceps tendon may experience a painful snapping sensation in their shoulder as the tendon moves about the bicipital groove, this pain may be more noticeable when the arm is internally or externally rotated overhead[32].

Since instability of the LHBT is commonly associated with subscapularis tears, it is also important to evaluate patients for pathology in the subscapularis tendon[32] and for any other evidence of shoulder pathology, especially rotator cuff tears or impingement syndrome.

LHBT as a Pain Generator

The long head of biceps tendon (LHBT) is known to be a pain generator and a cause of anterior shoulder pain[7,33]. Evidence exists suggesting that patients progressing from asymptomatic to symptomatic rotator cuff tears have some correlation with increased tear size, however it is possible that these tears may become painful regardless of tear size progression[34,35]. Patients experiencing anterolateral shoulder pain may be due to pathology of the LHBT. This has also been suggested by Moosmayer et al.[34] where 33% of patients becoming symptomatic also had imaging evidence of increased pathology in the LHBT; consistent with previous studies that have shown significant improvements in pain and function after isolated treatment of the LHBT with either tenotomy or tenodesis[7,33]. Therefore, it is reasonable to believe that treatment of the LHBT in the setting of both reparable and irreparable rotator cuff tears will provide patients with significant pain relief and improvement of function.

Methods

This study is an interim analysis of a prospective, randomized control trial. Patients eligible for this study are those referred for assessment of persistent shoulder pain and dysfunction that have failed conservative management strategies. These strategies include modification of activities, analgesic or anti-inflammatory medication and physical therapy aimed at regaining functional shoulder range of motion and strength. Inclusion criteria include patients who are 18 years of age or older, are undergoing arthroscopic shoulder surgery, and who have pathology in the LHBT confirmed intra-operatively. Lesions of the LHBT are: severe

inflammation or hypertrophy[28], subluxation or dislocation, tearing or fraying[26], or type II/IV superior labrum anterior to posterior (SLAP) tears[7].

Patients were excluded based on the presence of any significant comorbidities including previous surgery on the affected shoulder, active joint or systemic infection, significant muscle paralysis, Charcot's arthropathy, significant medical comorbidity that could alter the effectiveness of the surgical intervention (e.g., Cervical radiculopathy, polymyalgia rheumatica), major medical illness (life expectancy less than one year or unacceptably high operative risk), inability to speak or read English, psychiatric illness that precluded informed consent; or unwillingness to be followed for 2 years.

Patients were screened in clinic and, if deemed appropriate for the study, were approached by the research coordinator who explained the study and provided the opportunity for patients to consent to participate. Individuals who met the inclusion and exclusion criteria were randomly assigned to undergo either tenotomy or tenodesis based on a computer generated randomization enclosed in an envelope that was opened intra-operatively after a lesion of the LHBT was confirmed.

Surgical Technique

All of the arthroscopic procedures were performed by one of four fellowship trained orthopedic surgeons. Shoulder arthroscopy was conducted with participants in the lateral decubitus or beach chair position. Diagnostic arthroscopy was performed using a standard posterior portal and the biceps tendon was assessed with an arthroscopic probe using a standard anterior interval portal. Once study eligibility was confirmed via identification of tearing or degeneration of the long head of biceps, the patient was randomized to undergo either tenodesis or tenotomy.

For participants who underwent biceps tenotomy the long head of biceps tendon was detached from its proximal anchor to the superior labrum using an arthroscopic biter, an electrothermal device, or a scalpel based on individual surgeon preference.

For participants that underwent tenodesis, the technique was done either all arthroscopic or as a mini-open procedure using a bicipital groove or a subpectoral level of fixation depending on surgeon preference. The tendon was tagged with a monofilament suture prior to detaching it from its superior labral attachment. The long head of biceps was then mobilized arthroscopically, and retrieved through an incision either in the groove (which was opened arthroscopically in the subacromial space) or at the inferior border of the pectoralis major tendon. A No. 2 non-absorbable suture was whip-stitched at the appropriate length. The remainder of the biceps tendon was excised and the anterior cortex of the proximal humerus was prepared using a cannulated reamer inserted into the bicipital groove. One suture limb was then passed through an appropriate size interference screw and the tendon was placed within the reamed tunnel. The screw was then advanced until it is flush with bone.

Once the long head of biceps tendon pathology had been addressed, the scope was switched to a standard lateral portal to assess subacromial pathology and the rotator cuff. Subacromial decompression or acromioplasty was performed if required, and the rotator cuff

was repaired if necessary using standard anterolateral and posterolateral accessory portals based on tear configuration.

Post-operative Care and Physiotherapy

Postoperative care and immobilization were identical for the two groups and consisted of the use of an immobilizer for 4-6 weeks. Patients were allowed to remove the immobilizer for activities of daily living in which the arm was not abducted or externally rotated beyond neutral. Active range of motion was started at 4-6 weeks and resistance exercises began when maximal range of motion had been achieved. No at-risk work, activities or sports were allowed for six months. Participants returned to the clinic at 2 weeks and 6 weeks post-op for wound check. Additional post-op visits are scheduled at 3, 6, 12, and 24 months post-op for follow-up. At each of these follow-up visits, the participants complete the appropriate study questionnaires in addition to having any adverse events/setbacks dealt with.

Outcome Measures

The primary outcome measure for this study was The American Shoulder and Elbow Surgeons (ASES) standardized form for the assessment of the shoulder[36,37]. This questionnaire assessed improvements in shoulder function and possesses a patient self-evaluation section and 100-point scale derived from the participant assessment of pain and function in activities of daily living. The ASES was administered pre-operatively and at all post-operative visits except for the 2 week and 6 week appointments. A difference of 6.4 points on the ASES was considered to be the minimal clinically important difference with a typical standard deviation of 53 points[37]. With alpha set at 0.05 and power 0.80, the sample size was determined to be 45 per group. With an expected dropout rate of 20%, 56 patients per group will be recruited for the study.

Participant outcome was also measured with the Western Ontario Rotator Cuff (WORC) Index, which was developed and has been validated as a patient-oriented and patient-derived measure of quality of life[38]. The questionnaire consists of 21 questions that delve into the domains of physical symptoms, social well-being, work, sports and recreation and emotional well-being.

Strength was monitored through the use of a handheld dynamometer (Manual Muscle Testing System 01163; Lafayette Instrument Company) to assess elbow flexion and supination strength. To test elbow flexion strength the participants were instructed to hold their elbow against their side with the elbow flexed at 90 degrees with their forearm in anatomically neutral position. The device was then placed on the anterior aspect of the distal forearm and patients were asked perform resisted elbow flexion. To test supination the same device was used by asking patients to place their elbow at their side with their forearm pronated. The participants were then asked to hold a wooden dowel and supinate their forearm against the resistance of the dynamometer placed at the opposite end of the dowel. Strength was assessed pre-operatively and at 3 and 6 months post-op.

Further secondary outcomes, which were monitored during the post-operative course include: operative times of the two procedures, complications, and the incidence of revision surgery in each procedure. Magnetic resonance imaging (MRI) will be obtained at one year

post-op to assess the integrity of the tenodesis or the amount of tendon retraction in the tenotomy. Participants and surgeons or clinical evaluators also completed questionnaires to assess the cosmetic appearance of the affected arm post-op. Participants were asked; (1) if they noticed a change in appearance of their arm and (2) if they noticed a bulge (Popeye deformity) above their elbow in the front of their arm. If participants indicated on these forms that they noticed a change in the appearance of their arm they were asked to evaluate the change in appearance on a 10 cm satisfaction visual acuity scale (VAS). The surgeons or clinical evaluators were asked three yes or no questions about the development of Popeye deformities in the participants; (1) Is a Popeye deformity present, (2) Has the participant mentioned their Popeye deformity (3) Has the participant complained or expressed concern about their Popeye deformity. Participants also completed a VAS to rate pain and cramping pain post-operatively. Scores of 10 on the VAS scales used in this study indicated “experienced no pain at all” or “satisfied” and a score of 0 indicated “extreme pain” or “unsatisfied”. For any VAS completed in this study, scores of 3.0 or less were considered poor/unsatisfied; scores of 3.1-6.9 were moderate scores and scores of 7.0 or higher were considered good/satisfied.

Data Analysis

The primary analysis was a two sample independent t-test to assess whether there was a significant difference between groups for the mean ASES scores at baseline and each follow-up appointment up to two years. The mean WORC index scores were evaluated in the same way as the mean ASES scores. (Repeated measures ANOVA will be used for future data analysis to determine the effect of surgery from baseline to two years post-op on ASES scores, WORC scores and strength findings for each group) The secondary analysis involved a comparison of the secondary outcome measures between the two surgical treatment groups. The elbow strength findings were analyzed for differences between the two groups at each time point up to 6 months. Nominal demographic data and cosmetic data were compared using the fisher exact test, while ordinal data was compared using a t-test. The 5% significance level was employed for all tests performed. For the current interim analysis only data from the 3 month and 6 month follow-up appointments was included.

Results

Fifty-nine patients have consented to participate in the study, current interim data analysis was performed for twenty-six patients. The age of this sample ranges from 41 to 69 (21males and 5 females). Sixteen patients were randomized to the tenotomy group and 10 patients to the tenodesis group, preoperatively there were no differences found between groups in sex (p=0.617), age (p=0.765), ASES scores (p=0.554) and WORC scores (p=0.341).Please refer to figure 2 for patient flow through this study and table 1 for demographical data of the groups.

ASES scores in the tenotomy group improved from pre-op to 3 months (p=0.010) and from pre-op to 6 months (p=0.020). ASES scores in the tenodesis group also improved from pre-op to 3 months (p=0.017) but did not show significant improvement from pre-op to 6 months (p=0.284). WORC scores in the tenotomy group demonstrated improvement after surgery from pre-op to 3 months (p=0.016) and from pre-op to 6 months (p= 0.001). WORC scores within the tenodesis group did not show significant improvement from pre-op to 3 months (p=0.099).

Currently, analysis of WORC scores within the tenodesis group for pre-op to 6 months was not possible due to an insufficient paired sample size between these time points.

Results of statistical analysis with equal variance t-tests for mean ASES index scores revealed no differences between groups at the 3 month (p=0.794) and 6 month (p=0.644) time points (Table 2 and Figure 3). With respect to mean WORC index scores, there was no differences between groups at 3 months post-op (p=0.714) and 6 months post-op (0.179) (Table 3 and Figure 4)

At 3 months and 6 months post-op, patients used a 10 cm VAS to evaluate both pain and cramping pain in their affected arm. There were no differences in mean VAS pain between the tenodesis and tenotomy groups scores at 3 months (p=0.593) or 6 months (p=0.426) (Table 4). Furthermore no differences were found in mean VAS cramping pain between groups at 3 months (p=0.679) or 6 months (0.147) (Table 4).

When elbow flexion and supination strength were compared there was no difference ($p < .05$) found at any time point. However, at 6 months post-op, the groups were approaching significance (p=0.061). (Table 5)

There was no difference found in the surgeon reported presence of a Popeye deformity between the groups at 3 months (p=0.174) or 6 months (p=1.000). Important to note is that at 3 months, none of the patients in either group, with a Popeye deformity present mentioned it to the surgeon during their clinical encounter nor did they express concern to the surgeon over the appearance of their arm. Only 2 (20%) participants in the tenotomy group mentioned the deformity in clinic at 6 months while none of the participants in the tenodesis group mentioned it, there was no difference between the groups (p=1.000). In regards to the Popeye deformity, no participants in either group expressed any concern to the surgeon or research assistant at 6 months.

Participants also reported on the cosmetic appearance of their affected arm at 3 and 6 months post-op. No significant difference was found between groups in participant-reported change of appearance at 3 months post-op (p=.691) and 6 months (p=.314). When asked if they noticed any bulge in their affected arm above the elbow, there was no difference in patient-reported appearance of a bulge between groups at 3 months (p=.630) or 6 months (p=1.000). Participant satisfaction for appearance in the tenodesis group was reported as 10.0, however this is based on only one participant as two patients who indicated they noticed an appearance change did not complete the satisfaction VAS. Refer to table 6 for data on participant and surgeon reported cosmetic data.

Operative times of both procedures were also tracked, there was no difference in mean surgical time between the tenotomy and tenodesis groups (p=0.932) (Table 7).

Discussion

The main finding of this interim analysis was that there was no difference in ASES index scores between the tenotomy and tenodesis groups at 3 months and 6 months post-op. Additionally, there were no differences between groups in WORC index scores, elbow flexion strength, supination strength, operative time and cosmetic appearance of the affected arm. Together these results suggest that at the time of this interim analysis, there is insufficient evidence to reject the hypothesis that treatment of the LHBT pathology with biceps tenodesis or tenotomy results in similar clinical outcomes. Due to the limited sample size and short follow-up time, no clinical recommendations can be made at this time based on these findings.

Pre-operatively there were no differences in age, sex and strength. The mean ages in each group and the ratio of male to females in the total sample size was similar to a previous rotator cuff repair study done at our centre; final follow-up time was two years with a mean age of 56.8 ± 8.8 years and 65% of patients were male.[39] Patient demographics of the current interim analysis are also similar to a retrospective study by Walch et al, 1998[31] in which 74% of patients were male and the average age at the time of surgery for rotator cuff repair was 57 years old. All patients included in that retrospective analysis had lesions of the LHBT. In addition, a recent therapeutic case-control study of open versus arthroscopic biceps tenodesis had groups with average ages of 51.5 and 53.5 years old.[40] The same study had groups that were 61.3% and 72% male. Therefore, the patients included in this interim analysis are representative in age and gender of patients who typically undergo surgery for treatment of rotator cuff tears and lesions of the LHBT.

The results of this interim analysis confirmed the results of several other authors that found no differences in patient-assessed functional outcomes between biceps tenotomy and tenodesis.[3,4,41] However, in the current study there may be evidence to suggest that treatment with biceps tenodesis may require more time post-op for recovery as has been suggested previously[2,11,41]. Patients in the tenodesis group showed no improvement in WORC scores from pre-op to 3 months and no improvement from pre-op to 6 months in ASES scores. The delay in return of shoulder function in patients who had biceps tenodesis may be related to the increased amount of time required for the tendon to heal to the bone at the tenodesis site. Confounding these results is that at the time of this interim analysis it was not possible to analyze WORC scores from pre-op to 6 months due to limited sample size; additionally, patients in the tenodesis group showed significant improvement in ASES scores from pre-op to 3 months. Therefore, it is currently unclear whether patients in the tenodesis group require more time to regain function post-op as a result of longer healing time or if these findings are a product of the limited sample size. Further follow-up and a larger sample size are required to determine if tenodesis requires more time to heal.

Strength changes between patients undergoing tenotomy or tenodesis have been well documented in the literature. Currently the results of our study are in line with others who suggest there is no difference in strength between groups[1,3]. However, it is worth mentioning that participants in the tenodesis group appeared to require more time to regain strength post-operatively as might be expected if longer healing time is required. Additionally, from the analysis of the absolute strength values there may be a trend suggesting that tenodesis preserves elbow flexion strength compared with tenotomy. However at this time no conclusions can be made from these results due to the limited sample size.

With respect to cosmetic appearance of the operated arm, previous studies have suggested a Popeye deformity occurs more in patients undergoing tenotomy (3-70%)[4,41]. More recently, a review by Hsu et al[8], suggested that in 376 tenotomy patients and 117 tenodesis patients, there was an incidence of a Popeye deformity in 41% and 25% of patients, respectively. Contrary to previous studies, the findings of this interim analysis showed no difference between the treatment groups. Furthermore, several authors have suggested that the deformity has no impact on clinical outcomes and patients are not bothered by the presence of a Popeye deformity[6,7,11]. The current findings of our study are in agreement that cosmesis of the affected arm post-op is not a major concern for patients as many patients either do not notice the deformity themselves or are generally satisfied with any change in appearance of their arm post-op. However, in the tenodesis group, patient rated satisfaction was slightly lower at 3 months but not at 6 months. At this time, due to the limited number of paricipants who completed the satisfaction VAS it was not possible to compare the two groups for a difference.

This interim analysis suggests that tenodesis may not offer as much avoidance of cosmetic deformity as previously thought in comparison to tenotomy[2,5,8].

Our study results are in agreement with those of Kelly et al[4], who found no difference in operative times between the two groups. However, there was evidence to suggest that tenodesis is technically more difficult to perform since three attempts of tenodesis had been abandoned intra-operatively to date based on technical difficulty and time constraints. These results are consistent with those of Gill et al[41] who found a higher complication rate of 33% in tenodesis patients compared with 12% in the tenotomy group. Several others also suggest that tenodesis is technically more demanding to perform[2,6]. Therefore it may be reasonable to choose tenotomy over tenodesis in patients who are at higher risk for intra-operative complications.

There are several strengths to our research. The study was prospective and randomized with surgical procedures performed by four fellowship trained orthopedic surgeons. Secondly, the primary outcome measure used was based on self-assessed shoulder function and comfort levels of the patient. Additionally, our study monitored both patient and surgeon detected incidence of a Popeye deformity, included patients of all ages over 18, and is being conducted in a North American population.

Our study also has several limitations. The surgeons and clinical evaluators of the appearance of a Popeye deformity were not blinded to the procedure performed. Our interim analysis also did not monitor for any differences that existed within the tenodesis group based on which tenodesis technique was performed. This may be relevant as there is evidence suggesting that sub-pectoral tenodesis offers better fixation of the LHBT[40]. Finally, the groups were not sub-grouped for analysis based on rotator cuff tear size, biceps pathology or associated procedures performed.

Conclusion

It can be concluded from this interim analysis that there is no difference in clinical or functional outcomes six months post-op between tenodesis or tenotomy for treatment of lesions to the LHBT. Additionally, the cosmetic appearance of a Popeye deformity does not seem to be a major concern for patients. However, tenodesis may be technically more difficult and may be less appropriate in patients deemed to be prone to surgical complications. Due to the small sample size and limited follow-up data available at the time of this interim analysis, further analysis of the patient population and their outcome data is required to yield any definitive, evidence based conclusions for treating lesions of the LHBT. Final analysis for this purpose will be completed once data has been obtained for all 112 patients who have completed a two-year follow-up.

Literature Cited

1. Koh, K. H., Ahn, J. H., Kim, S. M. & Yoo, J. C. Treatment of Biceps Tendon Lesions in the Setting of Rotator Cuff Tears Prospective Cohort Study of Tenotomy Versus Tenodesis. *Am. J. Sports Med.* **38,** 1584–1590 (2010).
2. Frost, A., Zafar, M. S. & Maffulli, N. Tenotomy Versus Tenodesis in the Management of Pathologic Lesions of the Tendon of the Long Head of the Biceps Brachii. *Am. J. Sports Med.* **37,** 828–833 (2009).
3. 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. Off. J. ESSKA* (2013). doi:10.1007/s00167-013-2587-8

4. Kelly, A. M., Drakos, M. C., Fealy, S., Taylor, S. A. & O'Brien, S. J. Arthroscopic Release of the Long Head of the Biceps Tendon Functional Outcome and Clinical Results. *Am. J. Sports Med.* **33,** 208–213 (2005).
5. Boileau, P., Krishnan, S. G., Coste, J.-S. & Walch, G. Arthroscopic biceps tenodesis: a new technique using bioabsorbable interference screw fixation. *Arthrosc. J. Arthrosc. Relat. Surg. Off. Publ. Arthrosc. Assoc. N. Am. Int. Arthrosc. Assoc.* **18,** 1002–1012 (2002).
6. Walch, G. *et al.* 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 Elb. Surg. Am. Shoulder Elb. Surg. Al* **14,** 238–246 (2005).
7. Boileau, P. *et al.* Isolated arthroscopic biceps tenotomy or tenodesis improves symptoms in patients with massive irreparable rotator cuff tears. *J. Bone Joint Surg. Am.* **89,** 747–757 (2007).
8. Hsu, A. R., Ghodadra, N. S., Provencher, C. M. T., Lewis, P. B. & Bach, B. R. Biceps tenotomy versus tenodesis: a review of clinical outcomes and biomechanical results. *J. Shoulder Elbow Surg.* **20,** 326–332 (2011).
9. Osbahr, D. C., Diamond, A. B. & Speer, K. P. The cosmetic appearance of the biceps muscle after long-head tenotomy versus tenodesis. *Arthrosc. J. Arthrosc. Relat. Surg.* **18,** 483–487 (2002).
10. Slenker, N. R., Lawson, K., Ciccotti, M. G., Dodson, C. C. & Cohen, S. B. Biceps tenotomy versus tenodesis: clinical outcomes. *Arthrosc. J. Arthrosc. Relat. Surg. Off. Publ. Arthrosc. Assoc. N. Am. Int. Arthrosc. Assoc.* **28,** 576–582 (2012).
11. De Carli, A. *et al.* Reparable rotator cuff tears with concomitant long-head biceps lesions: tenotomy or tenotomy/tenodesis? *Knee Surg. Sports Traumatol. Arthrosc. Off. J. ESSKA* **20,** 2553–2558 (2012).
12. Wolf, R. S., Zheng, N. & Weichel, D. Long head biceps tenotomy versus tenodesis: A cadaveric biomechanical analysis. *Arthrosc. J. Arthrosc. Relat. Surg.* **21,** 182–185 (2005).
13. Karataglis, D. *et al.* Ultrasound evaluation of the distal migration of the long head of biceps tendon following tenotomy in patients undergoing arthroscopic repair of tears of the rotator cuff. *J. Bone Joint Surg. Br.* **94-B,** 1534–1539 (2012).
14. Shank, J. R. *et al.* A Comparison of Forearm Supination and Elbow Flexion Strength in Patients With Long Head of the Biceps Tenotomy or Tenodesis. *Arthrosc. J. Arthrosc. Relat. Surg.* **27,** 9–16 (2011).
15. Wittstein, J. R., Queen, R., Abbey, A., Toth, A. & Moorman, C. T. Isokinetic Strength, Endurance, and Subjective Outcomes After Biceps Tenotomy Versus Tenodesis A Postoperative Study. *Am. J. Sports Med.* **39,** 857–865 (2011).
16. Vangsness, C. T., Jorgenson, S. S., Watson, T. & Johnson, D. L. The origin of the long head of the biceps from the scapula and glenoid labrum. An anatomical study of 100 shoulders. *J. Bone Joint Surg. Br.* **76-B,** 951–954 (1994).
17. Gleason, P. D. *et al.* The transverse humeral ligament: a separate anatomical structure or a continuation of the osseous attachment of the rotator cuff? *Am. J. Sports Med.* **34,** 72–77 (2006).
18. MacDonald, K., Bridger, J., Cash, C. & Parkin, I. Transverse humeral ligament: does it exist? *Clin. Anat. N. Y. N* **20,** 663–667 (2007).
19. Walch, G., Nove-Josserand, L., Levigne, C. & Renaud, E. Tears of the supraspinatus tendon associated with 'hidden' lesions of the rotator interval. *J. Shoulder Elbow Surg.* **3,** 353–360 (1994).
20. Arai, R. *et al.* Functional anatomy of the superior glenohumeral and coracohumeral ligaments and the subscapularis tendon in view of stabilization of the long head of the biceps tendon. *J. Shoulder Elb. Surg. Am. Shoulder Elb. Surg. Al* **19,** 58–64 (2010).
21. Jost, B., Koch, P. P. & Gerber, C. Anatomy and functional aspects of the rotator interval. *J. Shoulder Elb. Surg. Am. Shoulder Elb. Surg. Al* **9,** 336–341 (2000).

22. Kolts, I., Tillmann, B. & Lüllmann-Rauch, R. The structure and vascularization of the biceps brachii long head tendon. *Ann. Anat. Anat. Anz. Off. Organ Anat. Ges.* **176,** 75–80 (1994).
23. Cheng, N. M., Pan, W.-R., Vally, F., Le Roux, C. M. & Richardson, M. D. The arterial supply of the long head of biceps tendon: Anatomical study with implications for tendon rupture. *Clin. Anat. N. Y. N* **23,** 683–692 (2010).
24. Alpantaki, K., McLaughlin, D., Karagogeos, D., Hadjipavlou, A. & Kontakis, G. Sympathetic and sensory neural elements in the tendon of the long head of the biceps. *J. Bone Joint Surg. Am.* **87,** 1580–1583 (2005).
25. Nasu, H., Nimura, A., Yamaguchi, K. & Akita, K. Distribution of the axillary nerve to the subacromial bursa and the area around the long head of the biceps tendon. *Knee Surg. Sports Traumatol. Arthrosc. Off. J. ESSKA* (2014). doi:10.1007/s00167-014-3112-4
26. Sethi, N., Wright, R. & Yamaguchi, K. Disorders of the long head of the biceps tendon. *J. Shoulder Elbow Surg.* **8,** 644–654 (1999).
27. Ii, C. S. N. Anterior Acromioplasty for the Chronic Impingement Syndrome in the Shoulder. *J. Bone Jt. Surg.* **54,** 41–50 (1972).
28. Boileau, P., Ahrens, P. M. & Hatzidakis, A. M. Entrapment of the long head of the biceps tendon: the hourglass biceps—a cause of pain and locking of the shoulder. *J. Shoulder Elbow Surg.* **13,** 249–257 (2004).
29. Bennett, W. F. Arthroscopic repair of anterosuperior (supraspinatus/subscapularis) rotator cuff tears. *Arthrosc. J. Arthrosc. Relat. Surg.* **19,** 21–33 (2003).
30. Slätis, P. & Aalto, K. Medial dislocation of the tendon of the long head of the biceps brachii. *Acta Orthop. Scand.* **50,** 73–77 (1979).
31. Walch, G., Nové-Josserand, L., Boileau, P. & Levigne, C. Subluxations and dislocations of the tendon of the long head of the biceps. *J. Shoulder Elbow Surg.* **7,** 100–108 (1998).
32. Ahmad, C. S. & ElAttrache, N. S. Arthroscopic biceps tenodesis. *Orthop. Clin. North Am.* **34,** 499–506 (2003).
33. Szabo, I., Boileau, P. & Walch, G. The Proximal Biceps as a Pain Generator and Results of Tenotomy. *Sports Med. Arthrosc. Rev. Sept. 2008* **16,** 180–186 (2008).
34. Moosmayer, S., Tariq, R., Stiris, M. & Smith, H.-J. The natural history of asymptomatic rotator cuff tears: a three-year follow-up of fifty cases. *J. Bone Joint Surg. Am.* **95,** 1249–1255 (2013).
35. Dunn, W. R. *et al.* Symptoms of pain do not correlate with rotator cuff tear severity: a cross-sectional study of 393 patients with a symptomatic atraumatic full-thickness rotator cuff tear. *J. Bone Joint Surg. Am.* **96,** 793–800 (2014).
36. Richards, R. R. *et al.* A standardized method for the assessment of shoulder function. *J. Shoulder Elbow Surg.* **3,** 347–352 (1994).
37. Michener, L. A., McClure, P. W. & Sennett, B. J. American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form, patient self-report section: Reliability, validity, and responsiveness. *J. Shoulder Elbow Surg.* **11,** 587–594 (2002).
38. Kirkley, A., Alvarez, C. & Griffin, S. C. The Development and Evaluation of a Disease-specific Quality-of-Life Questionnaire for Disorders of the Rotator Cuff: The Western Ontario Rotator Cuff Index. *J. Sport Med. March 2003* **13,** 84–92 (2003).
39. MacDonald, P., McRae, S., Leiter, J., Mascarenhas, R. & Lapner, P. Arthroscopic Rotator Cuff Repair with and without Acromioplasty in the Treatment of Full-Thickness Rotator Cuff Tears. *J. Bone Jt. Surg.* **93,** 1953–1960 (2011).
40. Werner, B. C. *et al.* Increased Incidence of Postoperative Stiffness After Arthroscopic Compared With Open Biceps Tenodesis. *Arthrosc. J. Arthrosc. Relat. Surg.* doi:10.1016/j.arthro.2014.03.024
41. Gill, T. J., McIrvin, E., Mair, S. D. & Hawkins, R. J. Results of biceps tenotomy for treatment of pathology of the long head of the biceps brachii. *J. Shoulder Elb. Surg. Am. Shoulder Elb. Surg. Al* **10,** 247–249 (2001).

Figure 1 – (1-A) Arthoscopic view of a normal LHBT; (1-B) Arthoscopic view of the LHBT which is fissuring and partially torn.

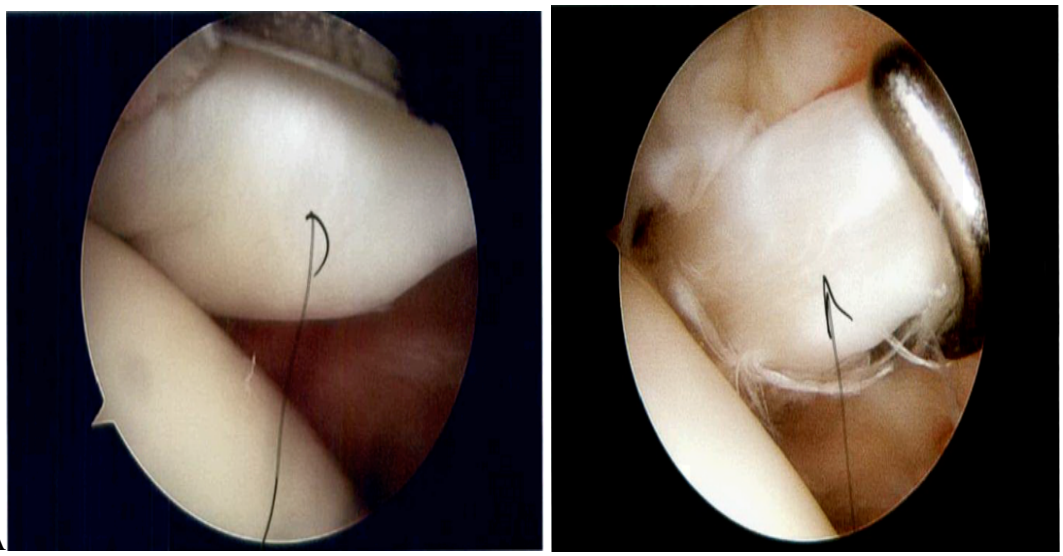
1-A  1-B

Figure 2 – Flow diagram of subject progress through the study

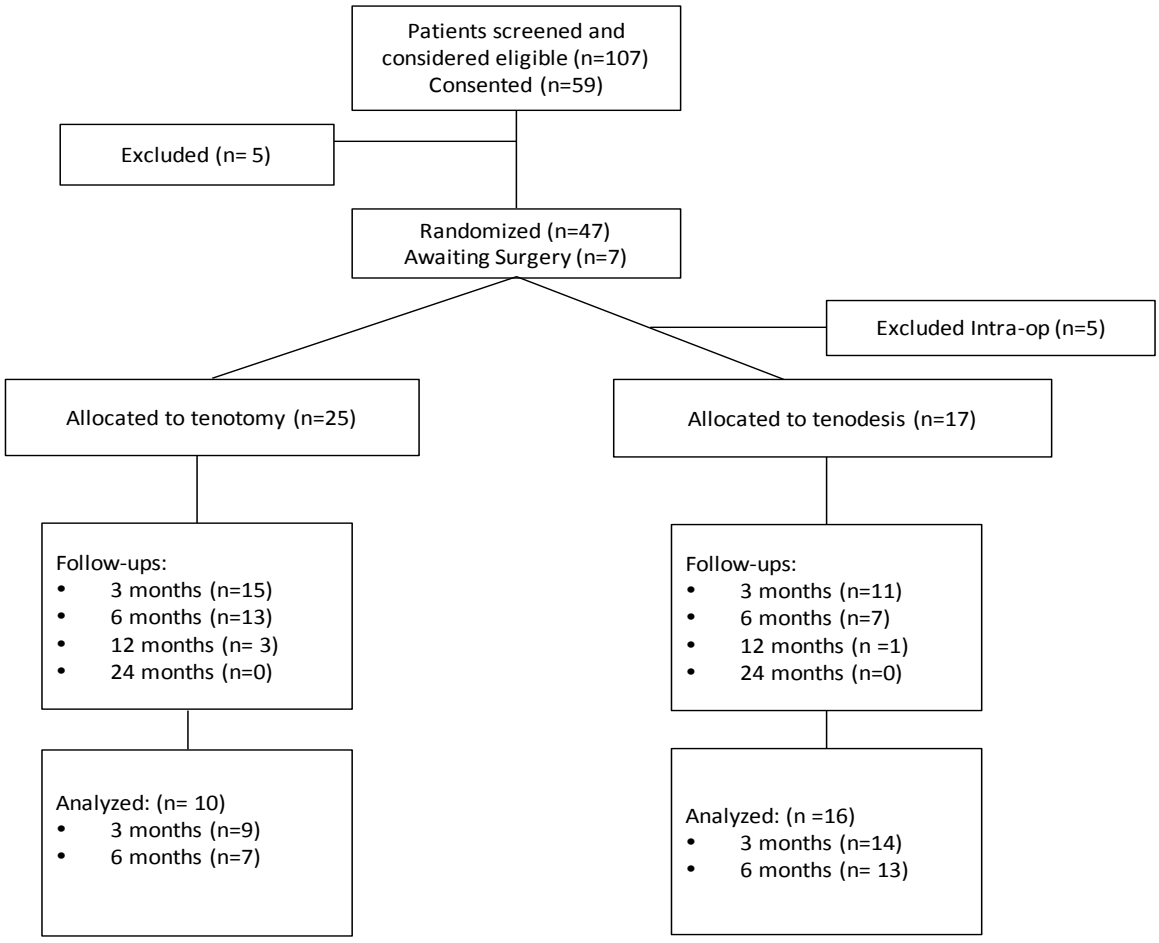


Table 1 – Demographics by group

	Tenotomy	**Tenodesis**	**p-value**
Variable			
Sex (# [%])			
Male	12 (75)	9 (90)	0.617
Female	4 (25)	1 (10)	
Age	58.25 (8.14)	57.20 (9.32)	0.765
Pre-Op ASES	58.26 (16.19)	54.13 (16.52)	0.555
Pre-Op WORC	44.95	37.66	0.341
Pre-Op Strength	16.3 (5.53)	19.4 (4.69)	0.233

Table 2 – Mean ASES index scores by group

	Tenotomy		**Tenodesis**		
	# of Patients	Mean (Std. Dev.)	# of Patients	Mean (Std Dev)	p-value
ASES Score					
Pre-Op	15	58.3 (16.19)	9	54.1 (16.52)	0.554
3 mo	13	72.7 (20.27)	9	70.7 (10.96)	0.794
6 mo	12	76.5 (26.18)	5	82.4 (14.67)	0.644

Figure 3 - The mean ASES scores (in percentages) and error bars (±1standard deviation) across time points by study group, according to ASES

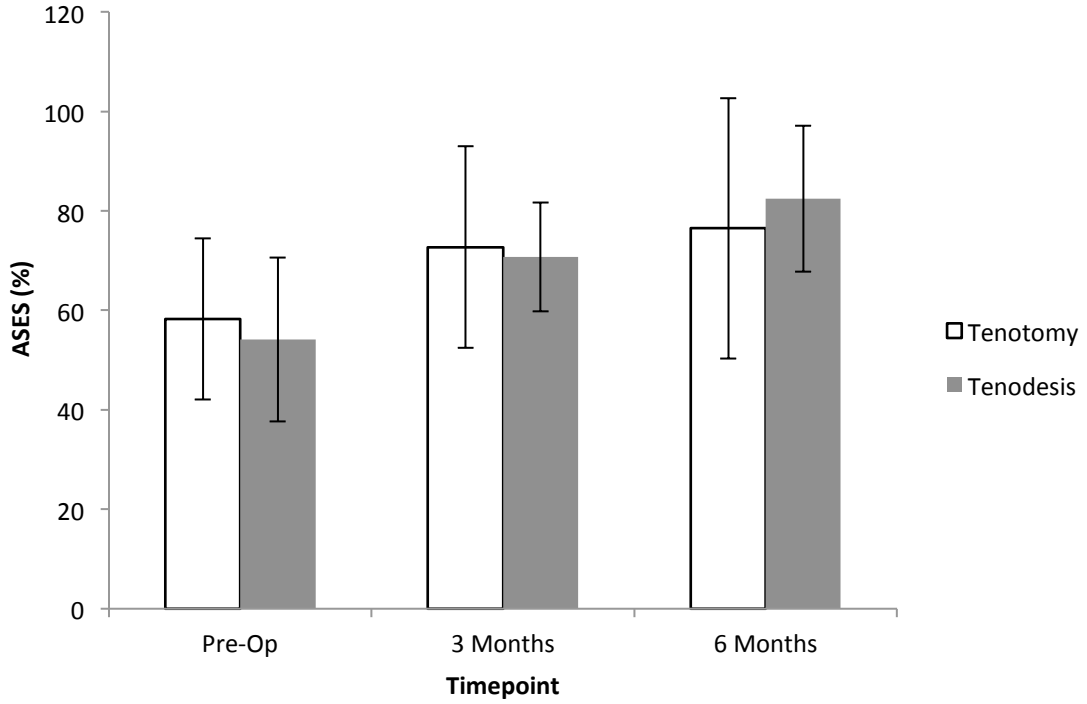


Table 3 – Mean WORC index scores by group

	Tenotomy		Tenodesis		
	# of Patients	Mean (Std. Dev.)	# of Patients	Mean (Std. Dev.)	p-value
WORC Score					
Pre-Op	11	44.9 (12.6)	5	37.7 (16.14)	0.342
3 mo	14	61.0 (18.3)	9	58.3 (15.10)	0.714
6 mo	11	66.7 (23.7)	5	84.7 (10.02)	0.129

Figure 4 - The mean scores (in percentages) and error bars (±1standard deviation) across time points by study group, according to the WORC scoring system

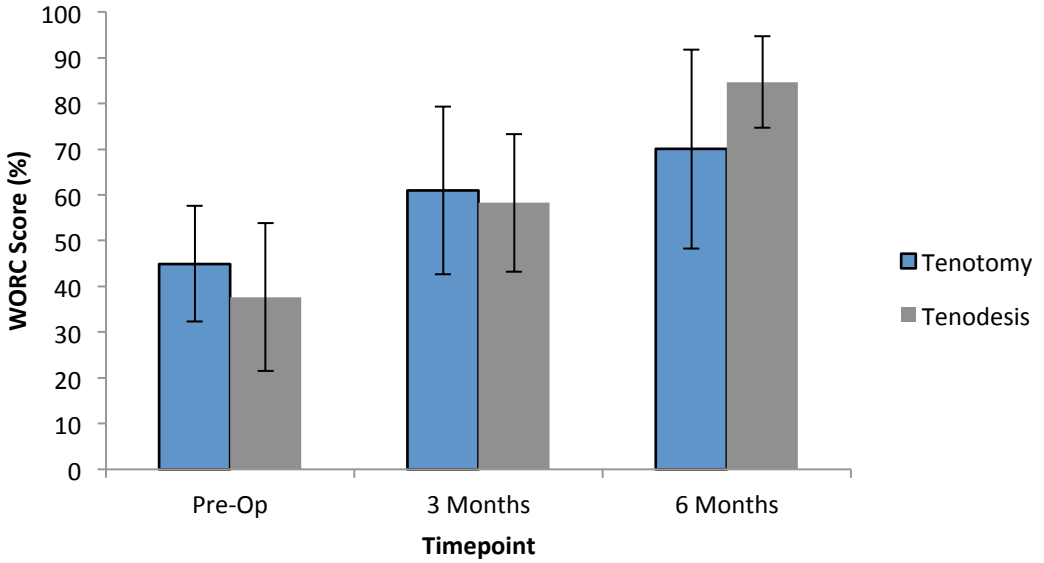


Table 4 – Patient evaluated Pain and Cramping Pain on VAS scale (0-10) where 10 is extreme pain or cramping and 0 is no pain or cramping

	Tenotomy		Tenodesis		
	# of Patients	Mean (Std. Dev.)	# of Patients	Mean (Std Dev)	p-value
Pain VAS					
3 mo	14	7.0 (2.61)	9	6.3 (3.73)	0.593
6 mo	13	7.5 (2.94)	5	8.7 (2.64)	0.426
Cramping Pain					
3 mo	14	8.1 (3.00)	9	8.6 (2.43)	0.679
6 mo	13	7.4 (3.15)	5	9.6 (0.49)	0.147

Table 5 – Mean absolute strength values (kg) of unaffected and affected arms with standard deviations and p-values for comparison of the affected arm between groups.

	Tenotomy			Tenodesis			
	# of Patients	Unaffected Arm	Affected arm	# of Patients	Unaffected Arm	Affected Arm	p-value
Elbow Flexion							
Pre	10	19.9 (6.67)	16.3 (5.53)	8	20.8 (5.90)	19.4 (4.69)	0.233
3 mo	12	16.1 (5.56)	18.2 (6.02)	7	13.3 (5.07)	13.1 (5.78)	0.090
6 mo	10	14.9 (8.50)	12.2 (5.48)	4	20.2 (12.72)	20.6 (9.78)	0.061
Supination							
Pre	NA	NA	NA	NA	NA	NA	NA
3 mo	8	2.8 (1.97)	3.2 (1.93)	5	2.7 (0.71)	2.4 (0.67)	0.395
6 mo	9	3.0 (1.25)	2.6 (1.43)	3	3.3 (2.34)	3.4 (1.93)	0.493
NA = Indicates insufficient date due to late introduction of supination protocol.							

Table 6 –Surgeon and Patient reported cosmesis for affected arm post-op.

	Surgeon Reported Cosmesis			Patient reported cosmesis	
3 month					
	Popeye Present?	**Popeye mentioned**	**Concerned**	**Popeye present?**	**Satisfaction VAS**
Tenotomy	6 (46%)	None	None	3 (21%)	8.1 (2.37)
Tenodesis	1 (13%)	None	None	1 (11%)	4.2 (3.75)
P-value	.174	-	-	.630	N/A
6 month					
	Popeye Present?	**Popeye mentioned**	**Concerned**	**Popeye present?**	**Satisfaction VAS**
Tenotomy	6 (60%)	2 (20%)	None	3 (23%)	7.6 (3.26)
Tenodesis	2 (50%)	None	None	1 (20%)	10.0*
P-Value	1.000	.560	-	1.00	N/A
***Only 1 patient completed the VAS, NA = insufficient data to compare groups**					

Table 7 – Mean surgical times (min) with standard deviations by group

	# of Patients	Mean Surgical Time (min)	p-value
Tenotomy	16	86.2 ± 36.15	0.932
Tenodesis	9	87.7 ± 48.58	