Scientific Research Publishing

Open Journal of Orthopedics, 2024, 14, 441-452
https://www.scirp.org/journal/ojo
ISSN Online: 2164-3016
ISSN Print: 2164-3008

Optimizing Recovery Following Mihata Superior Capsular Reconstruction Surgery with Tensor Fascia Lata Auto Graft: A Comprehensive Rehabilitation Protocol

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How to cite this paper: Roache, P.B. and Naqvi, N. (2024) Optimizing Recovery Following Mihata Superior Capsular Reconstruction Surgery with Tensor Fascia Lata Auto Graft: A Comprehensive Rehabilitation Protocol. *Open Journal of Orthopedics*, **14**, 441-452.
https://doi.org/10.4236/ojo.2024.1410040

Received: September 30, 2024
Accepted: October 26, 2024
Published: October 29, 2024

Abstract

Objective: Superior Capsular Reconstruction (SCR) using a Tensor Fascia Lata (TFL) autograft is an evolving technique for treating irreparable rotator cuff tears. The Mihata technique, initially developed in Japan, has shown promising long-term results. However, a standardized post-operative rehabilitation protocol for this procedure in the USA is lacking. **Purpose:** This study aims to evaluate the outcomes of a comprehensive rehabilitation protocol following SCR with TFL autograft in a cohort of nine patients. **Participants and Methods:** A prospective observational study was conducted at Concentra Urgent Care, San Francisco. Nine patients, aged 55 - 65 years, underwent SCR with TFL autograft performed by a specialized orthopedic surgeon. Post-operative rehabilitation was managed using a structured protocol, divided into three phases focusing on passive exercises, progressive range of motion, and strengthening. Outcomes were measured using the Visual Analogue Scale (VAS) for pain, forward flexion range of motion (FF-ROM), and Single Assessment Numeric Evaluation (SANE) scores over a six-month period. **Results:** Significant improvements were observed in pain reduction (mean VAS decrease of −3.67 points, $p = 0.01$), ROM (mean FF increase of 41.11 degrees, $p = 0.014$), and SANE scores (mean improvement of 42.11%, $p = 0.009$), indicating the efficacy of the rehabilitation protocol. **Conclusion:** The comprehensive rehabilitation protocol following SCR with TFL autograft significantly improved pain, range of motion, and shoulder function in patients, suggesting its potential utility in clinical practice.

Keywords

Superior Capsular Reconstruction, Tensor Fascia Lata, Rotator Cuff Tears,

Rehabilitation Protocol

1. Introduction

Massive irreparable rotator cuff tears present a persistent challenge in the United States. Superior Capsular Reconstruction (SCR), particularly the Mihata technique utilizing a Tensor Fascia Lata (TFL) autograft, has emerged as a promising solution for addressing these complex injuries. While this technique is well-established in Japan and has excellent long-term outcomes, it is still evolving in the U.S.

This study evaluates the effectiveness of a comprehensive post-operative rehabilitation protocol for nine patients who underwent SCR surgery using the Mihata technique. The protocol, divided into multiple phases, aims to optimize functional recovery and provide a structured guideline for physical therapists to implement in clinical practice. To date, no standardized rehabilitation protocol for Mihata SCR exists in the U.S., making this contribution especially relevant for enhancing patient outcomes.

The SCR with TFL autograft Mihata technique is a novel approach developed to address the challenging clinical scenario of irreparable rotator cuff injuries. The TFL is a robust autograft used in this technique to reconstruct the superior capsule of the shoulder joint, aiming to restore stability and function. The superior capsule is crucial for maintaining the shoulder's integrity and biomechanics, and damage to it from rotator cuff tears often results in significant pain and functional limitations [1].

Historically, there were limited effective surgical options for treating irreparable rotator cuff tears, presenting a substantial therapeutic challenge. The need for a viable solution led to the development of SCR with TFL autograft in Japan.

Our ongoing research projects within the SCR^{FL} USA program seek to refine surgical techniques, define optimal rehabilitation regimens, and evaluate long-term outcomes. This protocol provides a foundation for discussing SCR with TFL autograft, highlighting its clinical significance, historical context, and potential impact on patient outcomes and shoulder function.

The Superior Capsule

The shoulder is essential for performing a variety of upper extremity movements and daily tasks. The glenohumeral joint is a ball-and-socket joint formed by the glenoid cavity of the scapula and the head of the humerus. The shallow depth of the glenoid cavity contributes to the joint's remarkable flexibility but at the expense of intrinsic stability.

A careful balance between rigidity and movement underlies the shoulder's mechanics. The four muscles (subscapularis, teres minor, supraspinatus, and infraspinatus) that make up the rotator cuff, along with their tendons, are critical for maintaining this balance. These muscles work together to anchor the humeral

head within the glenoid, preventing dislocation and allowing for a wide range of shoulder motion. Disruption of this delicate balance, as seen in irreparable rotator cuff injuries, can lead to pain, diminished quality of life, and functional disability [2].

The superior capsule, a key component of the shoulder's anatomy, greatly enhances joint stability and function. It spans the superior aspect of the glenohumeral joint, connecting the humerus and scapula. The integrity of the superior capsule is crucial for maintaining proper joint mechanics and preventing superior migration of the humeral head. When rotator cuff tears are irreparable, the importance of the superior capsule becomes particularly evident, as its deficiency can lead to altered biomechanics and significant functional limitations [3]. Reconstructing the superior capsule, restoring superior stability, and improving shoulder function are the objectives of SCR with TFL graft.

Dr. Mihata began performing SCR with TFL autograft in 2006. Originally developed to address irreparable rotator cuff tears and deltoid pseudo-paralysis, the procedure was introduced at a time when Reverse Total Shoulder Replacement (RTSR) was not yet available in Japan, and allografts were not permitted. The procedure aimed to restore superior stability, center the humeral head, and reestablish the horizontal and vertical force couples of the shoulder. In 2013, Dr. Mihata published his early results, which were highly positive [4].

The procedure was introduced to the USA in 2014 but was initially modified to avoid harvesting the fascia lata autograft from the upper thigh. Instead, a dermal allograft was used, with some initial success; however, this approach ultimately resulted in a high failure rate [5]. Subsequent attempts to use artificial ligaments and Achilles allograft also failed to replicate Dr. Mihata's results [6]-[9]. The high failure and retear rates with alternative grafts led some USA surgeons to conclude that SCR was ineffective. However, a review of the studies revealed that the Mihata SCR technique was not performed in these investigations.

Recently, the senior author (PBR) trained in Osaka, Japan, with Dr. Mihata, the pioneer of SCR using the fascia lata autograft. PBR established a program to bring Mihata's SCR technique to patients in the USA. This program, SCR^{FL} USA, commenced in 2023 and has since completed 33 cases. An early review of results shows 88% healing in patients (15/17) [10]. The graft design and surgical placement, as established by Mihata *et al.*, 2012, ensure that the graft prevents the superior migration of the humeral head during forward flexion. Furthermore, the graft acts as a mechanical spacer between the acromion's underside and the humeral head. This transition to the TFL graft represents a significant advancement in SCR surgery, addressing past issues and providing patients with more reliable and successful outcomes in superior capsule reconstruction [4] [5] [7].

2. Participants and Methods

This study employed a prospective observational design to evaluate the efficacy of a post-operative rehabilitation protocol following (SCR) surgery with a (TFL)

autograft. The study was conducted at Concentra Urgent Care, San Francisco, CA, from May 2023 to June 2024. The rehabilitation was managed by one of the authors, Noman Naqvi, PT, DPT, ensuring consistency in the rehabilitation approach. The SCR surgeries were performed by Dr. Paul Roache, MD, a specialist in orthopedic surgery.

2.1. Participants

Participants were selected based on specific inclusion criteria:

- Adults aged 55-65 years diagnosed with irreparable rotator cuff tears necessitating SCR surgery.
- No significant comorbidities affecting rehabilitation potential (e.g., severe cardiovascular or neurological conditions).
- Willingness to comply with the prescribed rehabilitation protocol and attend follow-up assessments.

Exclusion criteria included:

- Patients that sustained a fall during the first 90 days and graft disruption.
- Uncontrolled medical conditions include poorly managed hypertension (blood pressure consistently above 160/100 mmHg), uncontrolled diabetes (HbA1c > 9%), or severe psychiatric disorders affecting rehabilitation compliance.

A total of 9 patients met the criteria and consented to participate in the study.

2.2. Variables

The primary outcomes measured were:

1) **Change in Visual Analogue Scale (VAS) Scores:** Pain levels were assessed using the VAS, with scores ranging from 0 (no pain) to 10 (worst pain imaginable).

2) **Change in Forward Flexion Range of Motion (FF-ROM):** Measured in degrees from pre-operative to 6 months post-surgery.

3) **Single Assessment Numeric Evaluation (SANE) Scores:** Percentage improvement in self-reported shoulder function before and after discharge.

2.3. Data Sources and Measurement

Data were collected during scheduled clinical visits. VAS scores were recorded preoperatively, early post-operatively, and at the 6-month follow-up. FF-ROM was measured using a goniometer, and SANE scores were self-reported by patients during follow-up assessments. Additionally, demographic information and medical history were collected from patient records.

2.4. Surgical Procedure

SCR surgery with TFL graft was performed using a standardized technique. Under general anesthesia and in the lateral position, arthroscopic portals were created to visualize the subacromial space and glenohumeral joint. The superior capsule was

debrided, and the TFL graft was harvested from the ipsilateral thigh, prepared, and secured to the humeral head and glenoid rim arthroscopically.

2.5. Rehabilitation Protocol

The post-operative rehabilitation protocol was divided into three phases:

- Phase I (Weeks 4 - 13): Focused on passive exercises and precautions to protect the repair, the use of a sling was required, with duration based on surgical specifics.
- Phase II (Weeks 14 - 26): Gradual introduction of an active and assisted range of motion exercises, progressing to gentle strengthening.
- Phase III (Weeks 26+): Strengthening exercises and functional training were emphasized.

Criteria for progression through phases included proper healing, adherence to precautions, and controlled pain and inflammation. The details of the rehabilitation guidelines are shown below in Table 1.

Table 1. Post-operative physical therapy protocol.

Pre-PT	**(Sling 4 - 8 weeks (about 1 - 2 months)**
Interventions	*START THE FOLLOWING EXERCISES AFTER 2 WEEKS POST OP* • Pendulums o Do NOT actively use shoulder muscles • Table stretches (seated table bows) 3 sets of 5 with 5 second holds per repetition, PT to place hand on involved shoulder to ensure passive o Adequate rest breaks between each set (2 - 3 minutes if needed) • Pulleys facing forward only o Adequate rest breaks between each set (2 - 3 minutes if needed) • Ball squeezes o Hold for 5 seconds and perform about 30 times 2 - 3 times per day
Precautions	• Do not actively move surgical arm or active assisted exercises • No weight bearing through surgical arm • Wear sling until instructed by surgeon • No reaching overhead or behind back • No pushing and/or pulling • No lifting objects • DO NOT perform deep flexion of the hip joint (squatting past ~90 degrees) for 2 months postoperatively
Criteria to progress	• Appropriate healing of surgical repair • Good safety adherence to precautions and immobilization guidelines • Inflammation and pain controlled
Phase I	**(4 - 8 weeks (about 1 - 2 months) - 13 weeks (about 3 months) after surgery)**
Interventions	• Manual pain free passive range of motion up to 70 degrees of shoulder flexion, in supine or semi fowler's position only. o Less ROM if painful • Pendulums o Do NOT actively use shoulder muscles

Continued

Interventions	• Table stretches (seated table bows) 3 sets of 5 with 5 second holds per repetition, PT to place hand on involved shoulder to ensure passive o Adequate rest breaks between each set (2 - 3 minutes if needed) • Putty gripping/ball squeezes o 5 second holds 30 times • Table slides with foam roller or pillowcase on table to reduce friction with table inclined at 30-degree angle, have patients utilize their body while passively allowing their shoulders to move into forward flexion. Perform 3 sets of 15 slowly. • Elbow flexion/extension AROM, can perform gently throughout the day • Begin active scapular exercise (protraction, retraction, shrugs) for 3 sets of 12 repetitions o Avoid if subscapularis requires repair • Supine fist to head with contralateral upper extremity assist (interlock fingers), this should be 90 degrees of forward flexion and external rotation to 45 degrees. 3 sets of 15 repetitions, can use bar/wand/dowel o Progress to shoulder flexion and external rotation with wand in supine position after 8 week mark and progress to active assisted shoulder flexion after 12 weeks in supine or semi fowler's position. 3 sets of 10 each. o Only perform this in pain free ROM, many patient do not gain adequate ROM until ~4 - 5 months post op • Pulleys facing forward only o Adequate rest breaks between each set (2 - 3 minutes if needed)
Precautions	• Do not actively load surgical arm • No weight bearing through surgical arm • Wear sling if in public places to avoid accidents • No reaching overhead or behind back • No pushing and/or pulling
Goals	• MRI cleared (if performed, usually at 3-month mark) • 90 degrees passive pain free range of motion
Criteria to progress	• Appropriate healing of surgical repair • Good safety adherence to precautions and immobilization guidelines • Inflammation and pain controlled
Phase II	**(14 weeks (about 3 months) – 26 weeks (about 6 months) after surgery)**
Interventions	*DO NOT STRENGTHEN UNTIL CLEARED BY SURGEON BASED ON GRAFT HEALING, IF GOOD HEALING THEN START STRENGTHENING* • Manual passive range of motion up to 180 degrees of shoulder flexion and 60 degrees of external rotation IF PAIN FREE, in supine or semi fowler's position o Less ROM if painful. • Wall slides with towel on wall and contralateral upper extremity assist with ascending AND descending • Supine wand flexion with 1lb AAROM, 3 sets of 15 repetitions • Shoulder isometrics o FF, ABD, ER, EXT 10 second holds, 10 times each direction at ~10% strength starting • Active ROM in Forward flexion for 3 sets of 10 repetitions • Prone shoulder rows and extensions 3 sets of 8 repetitions with emphasis on proper scapular retraction o Progress to using exercise bands • Prone A's and Y's 2 sets of 10 repetitions with emphasis on scapular retraction

Continued

Precautions	• No excessive loading • Avoid aggressive and painful range of motion • Avoid any upper extremity weight bearing of the surgical arm
Goals	• Initiate AAROM exercises • Improve pain free PROM and AAROM • Full forward flexion ROM of shoulder
Criteria to progress	• Appropriate healing of surgical repair • Good safety adherence to precautions and immobilization guidelines • Inflammation and pain controlled • MRI at 6-month mark cleared
Phase III	**(26 weeks (about 6 months) after surgery)**
Interventions	Continue Phase II exercises • Shoulder rows and shoulder extensions with TheraBand 3 sets of 10 - 12 repetitions • Shoulder ER/IR walk-outs 3 sets of 10 repetitions with TheraBand • Shoulder flexion active range of motion standing 3 sets of 10 with 1 - 2 lb dumbbells • Shoulder scaption active range of motion standing 3 sets of 10 • Side lying shoulder external rotation with towel under armpit 3 sets of 10 • Horizontal abduction with TheraBand 3 sets of 10 repetitions • Wall push ups 3 × 12 o Progress to table push ups at incline 3 × 12 • Box lift and carry progression
Precautions	• Ensure no pain during any exercises and progress SLOWLY • Expect only 50% of strength into flexion and 25% of strength in abduction compared to contralateral shoulder
Goals	• Improve shoulder functional mobility, return to ADL's and strength
Criteria to progress	• Appropriate healing of surgical repair

ROM = Range of motion, PROM = Passive range of motion, AAROM = active assisted range of motion, SCR = superior capsular reconstruction, PT = Physical therapist/therapy.

2.6. Statistical Methods

Descriptive statistics were utilized to summarize the demographic and clinical characteristics of the participants. For the primary outcomes—VAS scores, FF-ROM, and SANE scores—paired t-tests were conducted to compare pre- and post-intervention measures. For VAS, FF-ROM, and SANE scores, paired t-tests were used. Chi-square tests were applied for categorical variables. Statistical analyses were performed using SPSS. The results were presented as means with standard deviations and 95% confidence intervals. A p-value of less than 0.05 was considered statistically significant. Statistical analysis was performed using SPSS ensuring standardization and accuracy. This tool was used to ensure the accuracy of the statistical procedures and to provide clarity in the presentation of results.

3. Results

3.1. Visual Analog Scale (VAS) Pain Scores

Following the intervention, there was a decrease in pain, as evidenced by the mean

change of −3.67 points in the VAS pain scores for the nine patients. 3.32 points represented the standard deviation of the VAS pain score change. It was determined that the mean change in VAS scores had a 95% confidence interval of ±2.17 points.

The p-value, calculated using the t-distribution table for 8 degrees of freedom (n − 1), is approximately 0.01. This p-value indicates that the pain reduction is statistically significant because it is less than 0.05.

3.2. Range of Motion (ROM) Forward Flexion Degrees

After the intervention, there was an improvement seen in the nine patients' ROM forward flexion degrees, with a mean change of 41.11 degrees. 39.51 degrees was the standard deviation of the ROM change. It was determined that the mean change in ROM had a 95% confidence interval of ±25.81 degrees.

The p-value is approximately 0.014 using the t-distribution table for 8 degrees of freedom (n − 1). This p-value indicates that the improvement in ROM is statistically significant because it is less than 0.05.

3.3. Single Assessment Numeric Evaluation (SANE) Percent Change

The SANE percent change scores for the 9 patients who had their SANE scores recorded showed a mean percent change of 42.11%, indicating an overall improvement (Table 2). The standard deviation of the SANE percent change was 36.23%. The 95% confidence interval for the mean SANE percent change was calculated to be ±24.89%. Using the t-distribution table for 8 degrees of freedom (n − 1), the p-value is approximately 0.009. Since this p-value is less than 0.05, the improvement in SANE scores is statistically significant.

Table 2. Patient demographics.

Patient #	Date of Surgery	Sex	Age	Pre-OP VAS	Post-op VAS	Pre-OP SANE%	Post-OP SANE%
1	4/8/2023	M	55	8/10	2/10	25%	35%
2	5/8/2023	M	62	10/10	2/10	10%	99%
3	6/8/2023	M	53	5/10	4/10	20%	60%
4	6/8/2023	M	59	8/10	3/10	50%	80%
5	7/10/2023	M	64	2/10	3/10	60%	40%
6	8/10/2023	F	58	4/10	3/10	80%	100%
7	10/12/2023	M	54	2/10	1/10	10%	60%
8	11/9/2023	F	64	8/10	0/10	30%	100%
9	10/12/2023	M	63	5/10	1/10	30%	80%

3.4. MRI and Clinical Images

To provide further context for understanding the improvements in shoulder function that result from SCR using TFL autograft, we have included two figures with

clinical and MRI imaging of two patients (Patient 2 and Patient 6). Preoperative MRI, 3-month postoperative MRI, 6-month postoperative MRI, and a picture of the patient performing shoulder flexion actively to demonstrate the improvement in range of motion (ROM) make up each figure.

- **Preoperative MRI:** This initial scan highlights the degree of the rotator cuff tear and superior capsule deficiency, illustrating the state of the shoulder joint prior to the SCR operation. Patient 2 had a prior failed rotator cuff repair in the past.
- **3-Month Postoperative MRI:** The second pictures demonstrate the superior capsule's early healing phases as well as the graft's integration.
- **Six-Month Postoperative MRI:** The third picture shows the thickness of the TFL graft as it mends into the superior capsule and is further stabilized in both patients.
- **Shoulder Flexion Image:** Patient 2 and 7 are shown in the fourth image performing shoulder flexion, demonstrating a notable improvement in active forward flexion range of motion following surgery at the conclusion of their recovery [10] (**Figure 1**, **Figure 2**).

Figure 1. MRI and Clinical Images of Patient 2. SCR = Superior capsular reconstruction, ARCR = arthroscopic rotator cuff repair, ROM = range of motion.

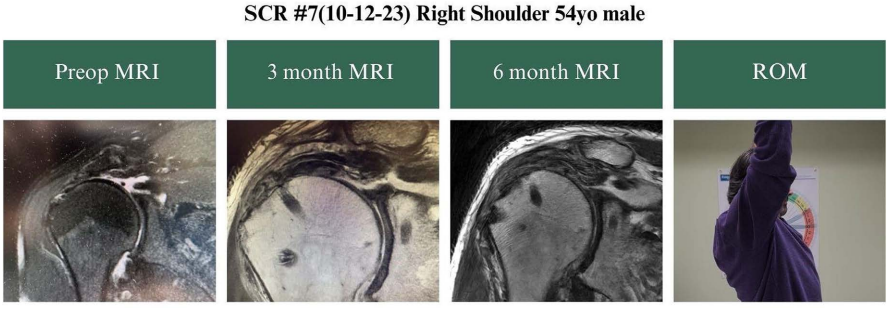

Figure 2. MRI and Clinical Images of Patient 7. SCR = Superior capsular reconstruction, ARCR = arthroscopic rotator cuff repair, ROM = range of motion.

3.5. Statistical Methods

To evaluate the significance of changes in VAS pain scores, ROM forward flexion degrees, and SANE percent change, the mean, standard deviation, 95% confidence intervals, and p-values were computed. Statistical significance was determined

using confidence intervals that did not include 0 and p-values less than 0.05. Paired t-tests were used to compare pre- and post-intervention measurements for continuous variables such as VAS, FF-ROM, and SANE scores. For categorical variables, chi-square tests were applied. All statistical analyses were performed using SPSS (version 28.0), and a p-value < 0.05 was considered statistically significant [11] [12].

4. Discussion

The management of irreparable rotator cuff tears remains a complex challenge in orthopedic surgery, and the introduction of SCR with a TFL autograft represents a significant advancement in this field. This study aimed to evaluate the efficacy of a comprehensive post-operative rehabilitation protocol for patients undergoing SCR with a TFL graft, focusing on functional outcomes such as range of motion, pain reduction, and overall shoulder function.

4.1. Improvements in Functional Outcomes

The comprehensive physical therapy approach resulted in significant increases in important functional outcomes, as demonstrated by our study's results. The protocol's efficiency is demonstrated by the mean increase in active flexion range of motion (ROM) of 41.11 degrees (±25.81 degrees) between pre-operative and six months post-operative. This notable gain in range of motion emphasizes the possibility of restoring substantial shoulder mobility with this surgical technique in conjunction with this rehabilitation program.

The success of the rehabilitation treatment is further supported by the reduction in VAS pain levels, with a mean change of −3.67 points (±3.32 points). The hypothesis that enhanced mechanical stability and decreased discomfort can be attained with SCR and a well-crafted rehabilitation program is supported by the statistically significant decrease in pain ($p = 0.01$). This pain relief is essential as it makes it possible for the patient to participate in everyday activities while assisting in their functional recovery.

Significant improvements in self-reported shoulder function and satisfaction are also reflected in the improvement in SANE scores, with a mean percent change of 42.11% (±24.89%). However, the significant variation in SANE scores points to a variety of individual responses, which may be impacted by things like shoulder function at baseline, individual healing responses, and protocol adherence [11] [12].

4.2. Internal Rotation ROM

Notable gains were observed in internal rotation ROM, although it was evaluated by visualization of the hand placement of patients as they reached behind their back rather than quantitatively. Future research should consider this element of shoulder function, which is important for numerous daily activities and overall shoulder functionality. The significant increase in internal rotation quality underscores the

value of comprehensive rehabilitation techniques that address shoulder function holistically.

4.3. Limitations and Implications

The small sample size of 9 participants limits generalizability and reduces statistical power. Future studies with larger cohorts are needed. The lack of a control group limits the ability to conclusively determine the protocol's efficacy compared to standard care. Furthermore, the subjective nature of the SANE ratings and VAS scores emphasizes the necessity for future study to use more standardized and objective measuring instruments.

The findings of this research have significant ramifications for orthopedic surgeons and physical therapists. Optimizing results following SCR with a TFL graft requires a systematic and comprehensive rehabilitation strategy, as evidenced by the notable improvements in ROM, pain reduction, and self-reported function that have been seen. Larger cohorts and control groups should be a goal of future research in order to confirm these results and improve rehabilitation techniques.

5. Conclusions

According to the study's findings, shoulder range of motion, pain relief, and self-reported function can all be significantly improved by utilizing this physical therapy protocol. The efficacy of the rehabilitation protocol is demonstrated by the mean increase in active flexion range of motion of 41.11 degrees from pre-operative to six months post-operative, as well as a significant decrease in VAS pain scores (mean change of −3.67 points, $p = 0.01$) and improvement in SANE scores (mean percent change of 42.11%, $p = 0.009$). These results underline the need for this structured post-operative rehabilitation program to attain optimal functional outcomes and support the use of SCR with a TFL graft as a feasible alternative for addressing irreversible rotator cuff injuries.

These results should be expanded upon in future studies by examining larger sample sizes and adding more objective metrics for internal rotation ROM and other functional measurements. The encouraging outcomes from this study indicate an optimistic prognosis for patients undergoing the Mihata technique for SCR with TFL autograft and provide insightful information for improving rehabilitation procedures for severe shoulder injuries [11] [12].

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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