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Comparison of the clinical and functional outcomes of two immobilisation protocols after arthroscopic peripheral triangular fibrocartilage complex (TFCC) repair in adults: a single-centre, double-blinded randomised controlled trial protocol

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ABSTRACT

Introduction Injury to triangular fibrocartilage complex (TFCC) is a common cause of ulnar-sided wrist pain, of which peripheral TFCC tears are amenable to repair. The surgical approaches to treat TFCC tears are well-established, with arthroscopic or arthroscopic-assisted repair as the preferred method. However, the postoperative rehabilitation protocols significantly vary across different studies, ranging from 2 to 9 weeks, often without sufficient justification.

Methods and analysis This research is designed to conduct a randomised controlled trial at a single centre with double-blinding to compare the clinical and functional results of two immobilisation protocols of 3 weeks and 6 weeks, following arthroscopic repair of peripheral TFCC tears (ie, Palmar 1B, 1C and 1D) in adults, considering the phase of ligament healing. The hypothesis that there will be no significant difference in outcomes between the two groups is considered. Adults aged 18–60 years of both genders who present with ulnar-sided wrist pain and satisfy the inclusion criteria are included in the study. Following the arthroscopic TFCC repair using the Polydioxanone Suture (PDS) inside-out suture technique, the patients will be immobilised in an above-elbow cast according to their assigned immobilisation groups, which will be determined by a computer-generated 1:1 block randomisation. In this study, each group will have at least 16 participants. The primary outcomes will be evaluated by the weight-bearing press test and the ballottement test. Secondary outcomes, including the Visual Analogue Scale (VAS) score, grip strength, pinch strength, foveal sign, Modified Mayo Wrist Score (MMWS), patient-rated wrist/hand evaluation (PRWHE) score and the range of movements in the wrist and forearm, will be assessed and compared across the groups at each point of assessment, with the results subsequently reported in a detailed manner. The study will be reported in accordance with Consolidated Standards of Reporting Trials (CONSORT) guidelines.

Ethics and dissemination The Ethics Committee of Kasturba Medical College, Manipal, approved the trial (approval No. IEC1 - 386). The data from this trial will be presented at academic conferences and published in peer-reviewed international journals.

Trial registration number This trial has been registered at the Clinical Trial Registry of India (registration number: CTRI/2023/03/050692).

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The study is designed as a single-centre, double-blinded, randomised controlled trial, which is considered the gold standard in clinical research.
⇒ By identifying the most effective immobilisation duration, the findings could lead to a standardised rehabilitation protocol, potentially reducing recovery times and improving functional outcomes for patients undergoing triangular fibrocartilage complex repair.
⇒ The study uses various outcome measures. However, relying on visual analogue scale, Modified Mayo Wrist Score and patient-rated wrist/hand evaluation scores involves subjective patient input, which can introduce variance due to individual pain tolerance, expectations and perceptions of function.

INTRODUCTION

The triangular fibrocartilage complex (TFCC) is formed by a conglomerate of various structures, that is, the dorsal and volar distal radioulnar ligaments, the fibrocartilaginous disc, the ulnar collateral ligament and the meniscus homologue.[1] It facilitates 40% load transmission of the wrist across the ulnar and prevents subluxation of the ulnar head in the sagittal plane during forearm rotations.

Injury to TFCC is a common cause of ulnar-sided wrist pain.[2] Acute TFCC tears occur primarily due to trauma when an axial load is applied on an extended and ulnar-deviated wrist or at the forced extreme movements of forearm rotation with axial loading of the wrist.[3] Adequate rest followed by rehabilitation can lead to the healing of acute tears, especially the peripheral tears. According to a study on the natural history of TFCC tears without distal radioulnar joint instability, it was found that the chance of complete recovery without surgery was 30% after 6 months and increased to 50% after 1 year of nonoperative treatment, and the trajectory of recovery observed demonstrates a marked acceleration within the initial 6 months postinjury, subsequently plateauing to a steady state until 1 year.[4] Hence, about 50% of TFCC tears require surgical intervention to heal.

TFCC tears on the periphery can be effectively repaired (ie, Palmer 1B, 1C and 1D). Research shows that both open and arthroscopic TFCC repairs are preferred treatments, and the outcomes from both methods are similar.[5 6] The surgical interventions for TFCC repair are characterised by their decisiveness, while the postoperative rehabilitation process is contingent on individual studies. A literature search revealed that there is no gold standard rehabilitation regimen to guide therapy following primary TFCC repair surgery.[7] The immobilisation period varies between 'no immobilisation'[8] postsurgery to '9 weeks of immobilisation', irrespective of the type of tear or repair.[9] Similarly, rehabilitation methods for wrist, forearm mobilisation and strengthening exercises differ across the various studies.[10–14]

Investigations at the cellular and molecular levels have conclusively demonstrated that tendons and ligaments originate from a common syndetome.[15] Consequently, they exhibit anatomical and physiological similarities. Following injury or repair, the healing process proceeds in three distinct yet overlapping stages: the stage of inflammation (0–3 days), the stage of proliferation (3 days– 4 weeks) and the stage of maturation or remodelling.[16 17] During the initial stages of inflammation, early mobilisation may result in excessive haematoma formation and discomfort. Mobilisation during the proliferation phase can aid in aligning immature collagen along stress lines, but it also carries the risk of rerupturing the repaired ligament. Although mobilisation during the maturation phase is generally considered safer according to most studies, evidence from animal models suggests that it can have a detrimental impact on collagen formation, leading to deficiencies at the repair site and also can lead to stiffness of the joint.[18]

In a pursuit to determine if the mobilisation in two different phases of ligament healing[16 17] influences the healing of repaired TFCC peripheral tear (Palmer 1B, 1C and 1D) at 6 months,[4] this single-centre, double-blinded, prospective randomised controlled trial is designed with an aim to compare the clinical and functional outcomes of two immobilisation protocols, namely those lasting 3 weeks and 6 weeks after arthroscopic peripheral TFCC repairs using PDS inside-out suture technique, in adults.

Based on a comprehensive review of the relevant literature, we hypothesise that there will be no significant difference in outcomes between the two groups.

METHODS AND ANALYSIS

Study design

This research is designed to conduct a randomised controlled trial at a single centre with double blinding to compare the clinical and functional results of two immobilisation protocols of 3-weeks and 6-weeks duration following arthroscopic peripheral TFCC repair using PDS suture technique in adults. The timeline and procedure of the trial are summarised in figure 1. From March 2023 to February 2026, patients presenting with ulnar-sided wrist pain satisfying the inclusion criteria will be explained about the surgery, the intervention they will be subjected to and the associated risks by the primary researcher. Patient data will be collected and documented after obtaining the written consent. The enrolment evaluation checklist is shown in online supplemental file 1, and written consent is obtained as depicted in online supplemental file 2. The protocol was prepared in compliance with the guidelines outlined in the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT).[19]

Study population

Adults between the ages of 18 and 60 years of both genders presenting with ulnar-sided wrist pain are clinically and radiologically assessed for the presence of peripheral TFCC tear. Of these patients, those satisfying the inclusion criteria are considered for the study. A comprehensive overview of the study, encompassing enrolment particulars, surgery details, duration of immobilisation associated risks and benefits, potential complications, specifics of the rehabilitation protocol, methods of assessment during the follow-up phase and the designated person of contact in the event of complications or emergencies, will be provided. Written consent is obtained from the patients who voluntarily participate in the study. The patient's privacy will be wholly ensured, and patients will be free to retract their consent or stop participating at any time during the study without facing any limitations.

Inclusion criteria

- Adult patients of all genders between 18and 60 years of age.
- All cases of posttraumatic symptomatic peripheral TFCC tear (PALMER type 1B, 1C, and 1D) undergoing arthroscopic TFCC repair between March 2023 and February 2026
- Patients with chronic ulnar-sided wrist pain of more than 6 weeks presenting after a period of nonoperative management.
- Patients willing to be a part of the study.

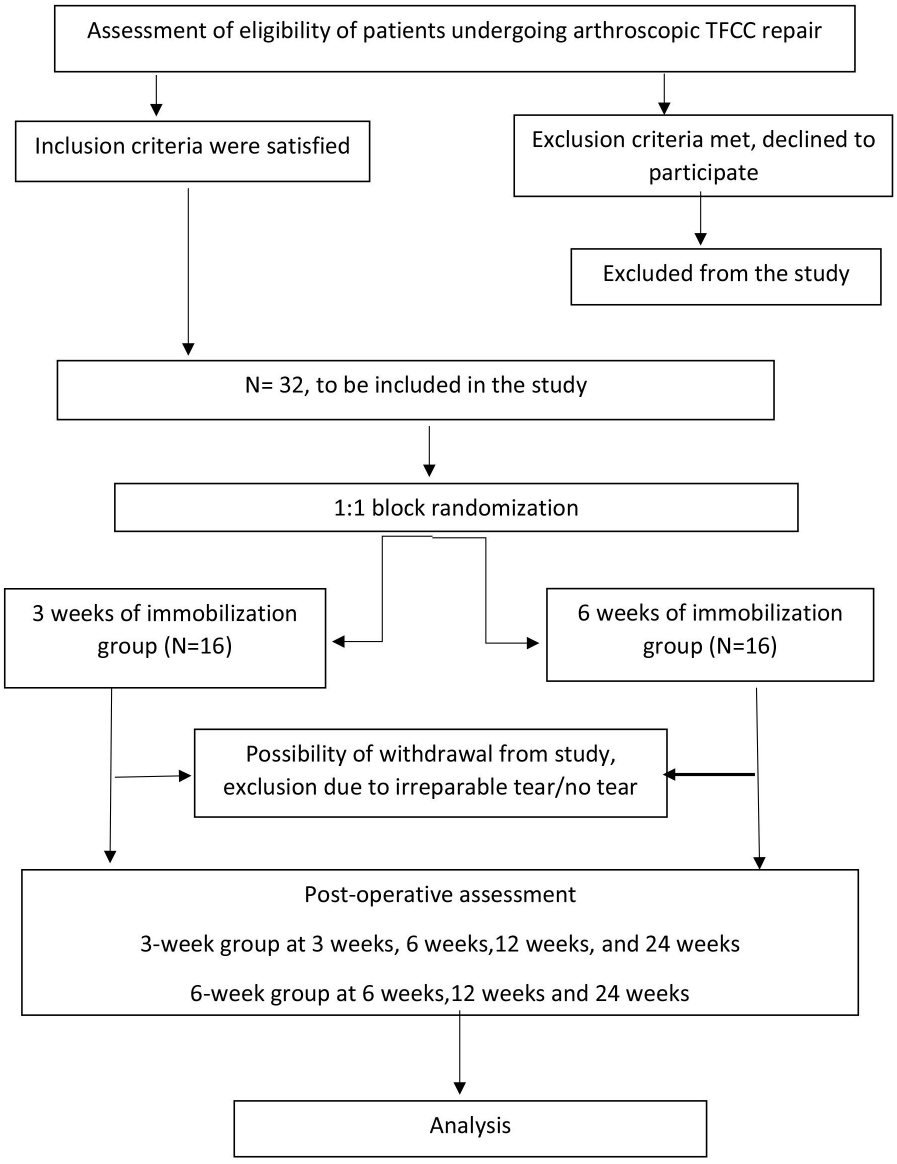

Figure 1 Flow chart of the trial. TFCC, triangular fibrocartilage complex.

Exclusion criteria

- Among the Palmer type 1B cases, irreparable foveal tears and foveal tears with distal radio-ulnar joint arthritis are excluded.
- Patients with concomitant conditions such as malunited distal radius and ulnar head fractures.
- TFCC peripheral tears associated with ulnar styloid base non-union, osteoarthritis of the wrist joint and distal radio-ulnar joints.
- Peripheral TFCC tears associated with carpal instability and avascular necrosis of carpal bones, which may affect the usual rehabilitation protocol.
- Generalised ligamentous laxity.

Randomisation and blinding

Following the fulfilment of inclusion criteria and signing consent forms for the study, participants will be assigned to either a 3-week or 6-week immobilisation group. This allocation happens through block randomisation, with a block size of 4, executed by a computer-generated randomisation sequence. The patients will be assigned to their groups within 24 hours before their surgery, maintaining an even 1:1 fixed allocation between the two study arms. The patients will be identified by their registration number and will be blinded to the groups to which they belong at the time of intervention. The allocation sequence will be deposited in a sequentially numbered opaque sealed envelope. The operating surgeon is similarly blinded to the study groups to avoid bias intraoperatively. The lead researcher, responsible for data collection, outcome evaluation, data maintenance and patient follow-up, is not blinded.

Intervention

Following the arthroscopic repair, patients will be placed in an above-elbow cast with the elbow at a 90° flexion, the forearm at 45° supination and the wrist in a neutral position up to the distal palmar crease with fingers free. This

position of the forearm is maintained to relax the dorsal and volar radioulnar ligaments and to prevent pronation of the forearm.[20] This immobilisation will last for a period of 3–6 weeks, as determined by their randomisation group.

Procedure

When a patient presents with ulnar-sided wrist pain, a thorough clinical examination is done to identify signs of TFCC tear, such as foveal tenderness, press test, stress test, compression test, ballottement test and resisted supination test in a standardised manner. Additionally, tests for differential diagnosis, including Extensor Carpi Ulnaris (ECU) tendinitis, lunotriquetral instability and ulnar impaction syndrome, are performed to rule out other potential conditions. Plain wrist radiographs are taken to rule out associated arthritis, nonunion or malunion of the distal end radius and ulna. The duration from the injury to diagnosis is recorded. If the duration is less than 6 weeks, or if the patient presents after 6 weeks without having undergone any form of treatment, then the patient undergoes a trial of non-operative management, which includes splinting and rehabilitation of wrist and forearm muscles, for at least a further 6 weeks. In cases where patients show no signs of improvement, further investigations will be necessary. This will involve performing an MRI of the wrist to confirm the presence of a peripheral tear. If the tear is determined to be reparable and the patients meet the specified criteria, formal written consent will be obtained before the procedure. The range of wrist and forearm movements, grip strength, pinch strength, objective press test, physician and patient-reported outcome measures are documented as per the proforma (online supplemental file 1). Subsequently, patients will undergo the necessary arthroscopic repair of the TFCC tear, and the stability of the distal radio-ulnar joint (DRUJ) will be confirmed postoperatively by the ballottement test. The operated limb is then placed in an above elbow cast as described for 3 or 6 weeks, based on their assigned study group, to which the patients are blinded till cast removal. After the immobilisation period, patients will be instructed to use a Muenster splint for the next 3 weeks intermittently and begin a carefully structured wrist rehabilitation programme, which is the same for both groups (refer to table 1). They will also undergo periodic assessments at predetermined intervals.

Follow-up

Both groups will be followed up for a period of 6 months (24 weeks). Evaluations will be conducted at intervals of 3, 6, 12, and 24 weeks for the group subjected to 3 week immobilisation. For the group subjected to 6 week immobilisation, assessments will be conducted at 6, 12, and 24 weeks. The range of movements of the wrist and forearm, grip strength, pinch strength, visual analogue scale (VAS), and objective press test are assessed at each follow-up. Foveal sign, ballottement test, physician-reported (Modified Mayo Wrist Score; MMWS) and patient-reported outcome measures (patient-rated wrist/hand evaluation; PRWHE) are noted at the final follow-up, along with the above parameters. Once included, participants will be barred from participating in additional clinical studies until the final follow-up is finished.

Outcomes

The outcomes will be compared between the two groups at the 6-month mark. Additionally, comparisons will be made between the preoperative and postoperative outcomes within the same groups. The weight-bearing press test was selected as the primary outcome measure due to its specificity in assessing TFCC pathology. Additionally, this test demonstrates a strong correlation with grip strength, further reinforcing its relevance in evaluating wrist function.[21]

Primary outcome

- Objectively – weight-bearing press test.
- Clinically, Ballottement test is done by assessing the translation of the ulna on the radius in supination, mid-prone and pronation forearm positions.

Secondary outcome

- Pain using the VAS score.
- Grip and pinch strength by using a Jamar dynamometer and pinch gauge.
- Range of movement of the wrist and forearm using a goniometer.

Table 1 Rehabilitation programme for 3-week and 6-week immobilisation group

3-week /6-week group	3-week /6-week group	3-week /6-week group
3–5 weeks/ 6–8 weeks	6–11 weeks/9–14 weeks	12-week/15-week
Pain and oedema control ► Active, active assisted range of movement exercises of wrist and forearm ► Open and closed kinetic chain exercises ► Mirror therapy ► Isometric exercises for the Pronator Quadratus, Extensor Carpi Ulnaris, Biceps, Brachialis, Triceps, Abductor Pollicis Longus, Extensor Pollicis Brevis	Total Range of movement gain ► Advanced closed kinetic chain, semi-closed kinetic chain, and open kinetic chain perturbation exercises ► Isotonic exercises for the Pronator Quadratus, Extensor Carpi Ulnaris, Biceps, Brachialis, Triceps, Abductor pollicis longus, Extensor Pollicis Brevis	Specific exercises for apprehension ► Palmar support and ► Plyometric exercises.

- MMWS and PRWHE questionnaire to assess functional outcome.

Safety monitoring and adverse events reporting

The principal investigator will conduct specific inquiries regarding any adverse events after surgery, cast immobilisation and during each follow-up. Adverse events will be diligently monitored and recorded in the electronic medical record system, and any occurrences will be promptly reported to the ethics committee within 24 hours to assess the severity of the adverse event. It is anticipated that the likelihood of serious adverse events, such as rerupture of the TFCC ligament caused by mobilisation, will be minimal due to an extensive literature review, which indicates that the risk of rerupture following repair is potentially as low as 1%.[7] In the event that complications arise, any subsequent treatment expenses will be covered by the respective Department of Hand Surgery and MAHE University.

Sample size calculation

In the literature reviewed, it has been noted that the grip strength of patients in the 3-week immobilisation group varied between 82%[22] and 99% of the contralateral side[23] and the 6-week immobilisation group varied between 64%[24] and 88% of the contralateral side.[25] Thus, assuming to detect a difference of 31% in the outcome measures, that is, clinical outcome between the 3-week and 6-week groups, assuming 95% CI and 80% power, the sample size estimated for the study is 16 in each group inclusive of 10% loss to follow-up. Hence, a total of 32 patients who meet the inclusion and exclusion criteria will be recruited for the study.

Formula:

$$N = \frac{[Z1-\alpha/2 * \sqrt{2p*1-p} + Z1-\beta \sqrt{p_1\ (1-p_1)+p_2\ (1-p_2)}]2}{L^2}$$

where

Z– $\alpha/2$: standard normal variant corresponding to 95% CI

$Z_1-\beta$: power of the study

P_1-P_2: proportions

L: difference in the proportions

Statistical analysis

In the proposed study, data representation and statistical analysis methodologies shall be meticulously employed to ensure a robust examination of the research hypotheses. Specifically, categorical data will be succinctly articulated through percentage metrics. In contrast, continuous variables will be delineated either by means and SD or medians and interquartile ranges, contingent on the data distribution.

To scrutinise the significance of differences in outcome measures across distinct groups, the independent t-test or Mann-Whitney U test will be judiciously applied, depending on the data's adherence to parametric assumptions. Furthermore, intragroup comparisons, particularly the evaluation of outcome measures before and after the intervention, will necessitate using the paired t-test or a suitable nonparametric counterpart chosen in line with the normality of the data distribution.

Statistical significance throughout this study will be defined under the conventional threshold of $p<0.05$, underpinning the rigour and reliability of the inferential statistical procedures employed.

Data management

Each patient will receive a unique identification number, which will be used to record all clinical data. The primary researcher will be responsible for evaluating and examining patients before their surgical procedures. A single hand surgeon with level 4 expertise will conduct surgeries for all cases. The primary researcher and a hand therapist from the Department of Occupational Therapy will assess patients after their surgeries. The primary researcher will monitor the patients for 6 months postsurgery at regular intervals. Once data are collected, a database will be created and electronically backed up. All original data will be stored in a medical recording room for at least 5 years after the study concludes. All the principal investigators will have access to the data, which is password-protected. The data will be presented as per CONSORT guidelines.[26]

Data monitoring and auditing

The inspector overseeing the research process will verify that all study participants have signed informed consent prior to their involvement in the study. The inspector will ensure that the research adheres to the study protocol and all relevant principles and that the research data and observations are fully reliable and complete. A data monitoring committee will conduct regular interviews or phone calls to audit the research and retain the right to audit patients at any point. The audit procedure will be conducted independently of the investigators.

ETHICS AND DISSEMINATION

The Ethics Committee of Kasturba Medical College, Manipal, approved the trial (approval No. IEC1 - 386). The study protocol and informed consent forms addressed the minimal potential risks of this Randomized Controlled Trial (RCT). Each participant who meets the inclusion criteria will provide written informed consent before enrolment. This trial has been registered at the Clinical Trial Registry of India (registration number: CTRI/2023/03/050692). The data from this trial will be presented at academic conferences and published in peer-reviewed international journals. Any protocol modifications (eg, changes in population, sample sizes, study procedures, inclusion criteria, interventions, outcomes or analyses) will be communicated to relevant parties, including trial registries and scientific ethical committees. Approval will be obtained from the Ethics Committee of Registering Clinical Trials before implementation.

Patients and public involvement

The design, conduct, reporting, or dissemination plans of this research did not involve patients and/or the public.

DISCUSSION

To our knowledge, this is the first of its kind, single-centre, double-blinded, randomised controlled study. Our study aims to determine the minimum immobilisation period necessary to achieve favourable clinical and functional outcomes after arthroscopic repair of primary TFCC tears. Additionally, we will assess the percentage of grip strength restored through surgery and structured rehabilitation.

The intrinsic characteristics of tendons and ligaments, notably their hypocellularity and hypovascularity, play a significant role in the protracted nature of their healing processes, an observation that persists even in instances of surgical intervention. This inherent quality of these connective tissues significantly contributes to the challenges faced in facilitating rapid and effective recovery postdamage or surgical manipulation.[27] Research indicates that even a year postinjury, the morphological and functional properties of the regenerated tissue remain suboptimal compared with their intact counterparts in scenarios where adequate rehabilitation has not been implemented.

The musculature surrounding the wrist and forearm, including the Pronator Quadratus, Extensor Carpi Ulnaris, Biceps Brachii, Brachialis, Triceps Brachii, Abductor Pollicis Longus and Extensor Pollicis Brevis, plays a critical role in exerting force on the DRUJ. The aforementioned muscles function as secondary stabilisers of the DRUJ, thereby enhancing its stability and functionality.[28] Hence, rehabilitation of these muscles has been found useful.

Research on animals has indicated that mechanical stress plays a crucial role in the healing process of soft tissues.[29] The phenomenon of stress shielding, as can happen in prolonged immobilisation, resulted in a significant reduction in the tangent modulus, tensile strength and strain at the failure of collagen fascicles,[30] hence impairing the healing process. However, early mobilisation, which results in forces exceeding the physiological limit, can lead to rupture at the repair site. Hence, an optimal balance is required, which will be observed in this study.

The limitations of this research are primarily associated with it being conducted within a singular institutional framework. Nevertheless, it will ensure uniformity in the management of the patients.

To summarise, the purpose of this research is to ascertain the minimal duration of immobilisation required to ensure sufficient healing of a peripheral tear of the TFCC subsequent to arthroscopic repair under the condition that a standardised rehabilitation protocol is implemented.

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Contributors AKB and DP conceptualised the study and participated in the design. AKB and AA revised the manuscript. AKB is the primary operating surgeon. DP coordinated the study, documentation, and data collection for the study. MAK participated in the randomisation and statistical analysis. Guarantor- AKB. AI from Grammarly was used to check the vocabulary and paraphrasing the sentences.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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