Title: Evaluation of High-Purity Type I Collagen Biologic Wrap to Improve Function After Extensor Tendon Repair of the Hand

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INTRODUCTION

Extensor tendon injuries of the hand are common due to the superficial anatomical location of the tendons and the relatively thin soft-tissue envelope over the dorsum of the hand and wrist. Injuries involving zones VI to VIII, as defined by Verdan's classification, are particularly prone to postoperative complications, including peritendinous adhesions, extensor lag, stiffness, and delayed return to function. Despite advances in suture techniques and standardized rehabilitation protocols, adhesion-related functional impairment remains a persistent clinical challenge following extensor tendon repair [1,2].

Postoperative adhesions have been reported in up to 30–40% of extensor tendon injuries, even when repairs are performed under optimal conditions and followed by early controlled mobilization [3]. Adhesion formation results from an exaggerated fibroproliferative response within the peritendinous environment, leading to impaired tendon gliding, loss of excursion, and secondary joint stiffness. This pathological process is particularly problematic in zones VI–VIII, where tendons traverse beneath the extensor retinaculum and are closely related to subcutaneous tissues, increasing susceptibility to friction and scarring [4].

Several strategies have been explored to mitigate adhesion formation after tendon repair, including refinement of core suture techniques, epitendinous augmentation, early active motion protocols, and pharmacologic or mechanical anti-adhesion barriers [5,6]. While early mobilization has improved outcomes compared with prolonged immobilization, it has not eliminated adhesion-related morbidity, and aggressive motion may increase the risk of repair site failure in certain clinical scenarios [7].

Biologic barrier membranes have emerged as a promising adjunct to tendon repair, aiming to modulate the local healing environment rather than relying solely on mechanical or rehabilitative strategies. Experimental and clinical studies have demonstrated that biologic wraps, particularly amniotic membrane-based products, can reduce peritendinous fibrosis and improve functional outcomes after extensor tendon repair, especially in zone VI injuries [8–10]. However, limitations related to availability, processing variability, and regulatory considerations have restricted their widespread adoption. Unlike amniotic membrane, HPTC is a standardized, acellular scaffold with defined composition, consistent degradation kinetics, and a well-established safety record across multiple surgical disciplines.

High-purity type I collagen (HPTC) is a bioengineered, acellular collagen matrix composed of more than 97% pure type I collagen, manufactured to preserve the native triple-helical structure while eliminating immunogenic proteins, elastin, and lipids. Type I collagen is the

principal structural component of native tendon extracellular matrix and plays a central role in cellular adhesion, migration, angiogenesis, and tissue remodeling during healing [11,12]. When processed to high purity, collagen matrices demonstrate excellent biocompatibility, predictable biodegradation, and minimal inflammatory response.

HPTC is flexible, translucent, and easily tailored intraoperatively, allowing it to be fashioned as a loose circumferential wrap or sleeve around repaired tendons without increasing bulk or restricting tendon gliding. Preclinical studies have shown that collagen–glycosaminoglycan scaffolds can significantly reduce early postoperative tendon adhesions while preserving tensile strength and intrinsic healing [13,14]. These findings provide a strong biological rationale for the use of HPTC as a peritendinous barrier in tendon repair.

The safety and clinical efficacy of HPTC have been well established across a range of surgical applications. Multiple randomized controlled trials and prospective clinical studies by Narayan and colleagues have demonstrated that HPTC promotes faster healing, improved tissue quality, reduced pain, and favourable scarring outcomes in chronic wounds, pressure ulcers, diabetic foot ulcers, venous leg ulcers, and complex reconstructive settings [15–19]. Importantly, these studies consistently report excellent tolerability and an absence of foreign body reactions, supporting the use of HPTC in sensitive anatomical environments.

Despite this growing body of evidence, the application of HPTC as a biologic wrap around extensor tendon repair sites has not previously been evaluated in a randomized controlled clinical trial. Given the strong biological plausibility of type I collagen scaffolds, the demonstrated benefit of biologic wraps in reducing tendon adhesions, and the reproducible clinical performance of HPTC in other tissue systems, it is logical to investigate whether HPTC wrapping can improve functional outcomes following extensor tendon repair of the hand.

We therefore conducted a multicentric RCT to evaluate the effect of HPTC wrap on total active motion, adhesion-related morbidity, and patient-reported outcomes at eight weeks following extensor tendon repair in zones VI–VIII.

MATERIALS AND METHODS

Study Design

This study was designed as a prospective, multicentric, randomized controlled trial evaluating the effect of high-purity type I collagen (HPTC) wrap applied around extensor tendon repair sites in zones VI–VIII of the hand. The trial employed a parallel-group design with 1:1 allocation to either standard extensor tendon repair with adjunctive HPTC wrap or standard extensor tendon repair alone. The primary purpose of the study was therapeutic, with the objective of improving functional outcomes by reducing adhesion-related morbidity following tendon repair.

The trial was conducted at two tertiary referral centres specializing in plastic, reconstructive, and hand surgery – Adichunchangiri Institute of Medical Sciences, B G Nagara and Mysore Medical College and Research Institute, Mysuru. The trial was prospectively registered with ClinicalTrials.gov (Identifier: NCT07335653; registered 2026-01-13) and approved by the Institutional Ethics Committee (Approval No.: AIMS/IEC/270/2025 on 2025-12-17). The study protocol was approved by the Institutional Ethics Committees of the participating centres, and the trial was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines. Written informed consent was obtained from all participants prior to enrolment.

This study was conducted and reported in accordance with the CONSORT (Consolidated Standards of Reporting Trials) 2010 guidelines for randomized controlled trials.

Study Population

Adult patients aged 18 to 65 years presenting with acute extensor tendon injuries of the hand involving zones VI, VII, and/or VIII were screened for eligibility. Only patients with complete extensor tendon lacerations involving at least 50% of the tendon cross-sectional area and requiring primary repair were considered for inclusion. Surgical repair was required to be performed within 72 hours of injury.

Patients with crush or avulsion injuries, segmental tendon loss requiring grafting or tendon transfer, associated open fractures requiring dorsal plating across the repair site, prior surgery or significant scarring in the region, major associated nerve injuries requiring grafting, uncontrolled systemic illness, active infection, known hypersensitivity to collagen, pregnancy, or inability to comply with postoperative rehabilitation were excluded.

Randomization, Allocation Concealment, and Blinding

Eligible patients were randomized in a 1:1 ratio to the experimental or control group using a computer-generated randomization sequence with variable block sizes of four and six. The randomization sequence was prepared by an independent statistician not involved in patient care.

Allocation concealment was ensured using sequentially numbered, opaque, sealed envelopes, which were opened in the operating room after confirmation of eligibility and completion of tendon exposure. Due to the nature of the intervention, blinding of the operating surgeon and patient was not feasible. However, outcome assessors, including hand therapists performing functional measurements and clinicians evaluating outcomes, were blinded to group allocation. The data analyst was also blinded to treatment assignment.

Surgical Technique

All procedures were performed under regional or general anaesthesia with tourniquet control. The affected upper limb was positioned on a hand table, and standard sterile preparation and draping were performed. A dorsal longitudinal or zig-zag incision was made over the injured extensor tendon, incorporating the traumatic wound where feasible.

The extensor tendon ends were identified, and devitalized tissue was carefully debrided while preserving maximal tendon length. The tendon was mobilized sufficiently to allow tension-free repair, taking care to minimize disruption of surrounding paratenon and soft tissues. Primary tendon repair was performed using a standardized core suture technique, typically a modified Kessler or four-strand repair, with nonabsorbable monofilament suture material (4-0). The core repair was reinforced with a circumferential running epitendinous suture using fine monofilament suture (6-0) to improve repair strength and smooth the tendon surface.

In the experimental group, following completion of the tendon repair and before skin closure, a sterile HPTC (Surgicoll-Mesh®) sheet was hydrated in normal saline according to manufacturer instructions. The membrane was cut into a rectangular strip measuring approximately 2 to 4 cm in length and 1 to 1.5 cm in width, tailored to the diameter of the repaired tendon. The HPTC strip was wrapped circumferentially around the repair site as a loose sleeve, ensuring overlap of approximately 2 to 3 mm at the edges. The wrap was secured using cyanoacrylate tissue adhesive, applied to the overlapping edges of the collagen membrane and sparingly to the epitenon (Figures 1 & 2). Care was taken to avoid constriction, folding, or bulk that could impede tendon gliding, particularly beneath the

extensor retinaculum in zone VII. Gentle passive flexion and extension were performed intraoperatively to confirm smooth tendon excursion and absence of mechanical block.
In the control group, no biologic wrap or anti-adhesive adjunct was applied after tendon repair. Skin closure, dressing, and splinting were identical in both groups.

Figure 1: Showing surgical technique of repaired extensor tendon (single) wrap with HPTC

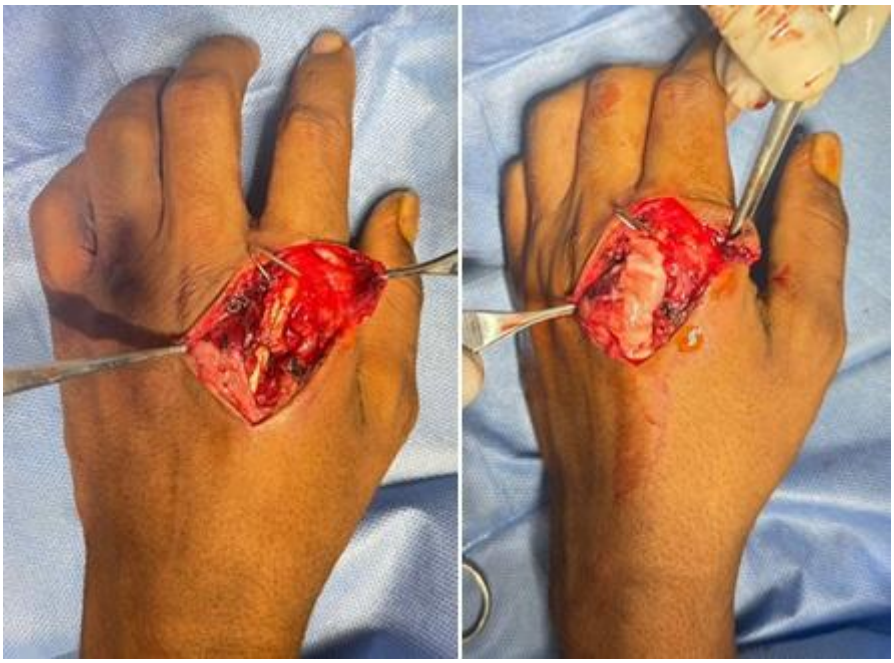

Image showing repaired extensor digitorum to index finger in zone 6 (Left). Image showing HPTC wrap around the repaired tendon (Right)

Figure 2: Showing surgical technique of multiple repaired extensor tendon wrapped with HPTC

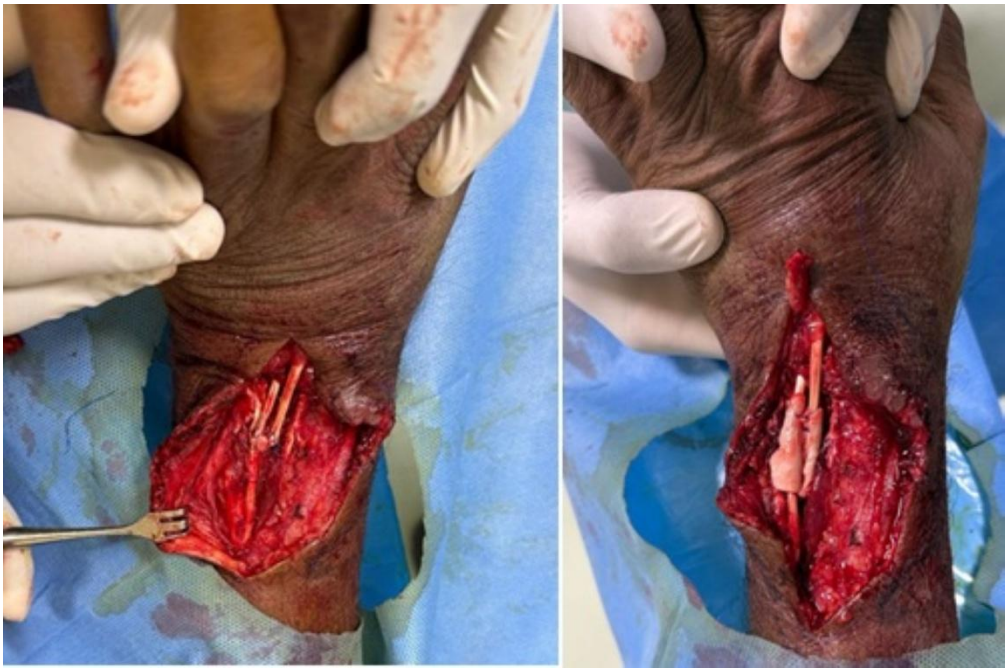

Image showing repaired extensor digitorum communis tendons in zone 8 (Left). Image showing HPTC wrap around the repaired tendons (Right)

Postoperative Splinting and Rehabilitation Protocol

All patients were placed in a standardized dorsal protective splint with the wrist in extension and the metacarpophalangeal joints positioned according to the involved zone and institutional extensor tendon protocol. Postoperative rehabilitation was standardized across both groups and supervised by certified hand therapists.

Initial immobilization was maintained for five to seven days. Controlled early active or early controlled motion protocols were then initiated based on institutional standards for zones VI–VIII, progressing to increased range of motion exercises by three to four weeks and gradual strengthening by six weeks. No additional anti-adhesion agents or topical products targeting tendon healing were permitted during the study period.

Outcome Measures

The primary outcome measure was total active motion of the involved digit or digits at eight weeks postoperatively. Total active motion was calculated as the sum of active flexion at the metacarpophalangeal, proximal interphalangeal, and distal interphalangeal joints minus extension deficits. Results were expressed in degrees and as a percentage of the contralateral uninvolved digit or standardized normative values.

Secondary outcomes included QuickDASH scores at six and eight weeks, extensor lag at individual joints measured in degrees at eight weeks, grip strength measured using a calibrated Jamar dynamometer at eight weeks, incidence of adhesion-related events including failure to achieve functional motion thresholds or need for tenolysis, complication rates, time to return to work or activities of daily living, and patient satisfaction scores (Table 1).

Table 1: Summary of outcome measures and assessment time points

Outcome	Assessment time point
Total active motion	8 weeks
QuickDASH	6 and 8 weeks
Extensor lag	8 weeks
Grip strength	8 weeks
Adhesion-related events	Up to 8 weeks
Complications	Intraoperative to 8 weeks
Return to work	Up to 8 weeks
Patient satisfaction	8 weeks

Data Collection and Management

Clinical and functional data were collected prospectively using standardized case report forms at each follow-up visit. Data were anonymized using unique study identifiers and entered into a secure, password-protected electronic database with restricted access. Data validation checks were performed to minimize entry errors, and all study records were maintained in accordance with institutional and regulatory requirements.

Sample Size Calculation

The sample size was calculated to detect a clinically meaningful difference in total active motion between the two groups at eight weeks. Assuming a moderate-to-large effect size of 0.75, a two-sided alpha level of 0.05, and a power of 80%, a minimum of 28 patients per group was required. To account for potential attrition and incomplete follow-up, the sample size was increased to 30 patients per group, resulting in a total sample size of 60 participants.

Statistical Analysis Plan

All analyses were performed using an intention-to-treat approach, including all randomized participants in their allocated groups. A per-protocol analysis will be conducted as a secondary exploratory analysis.

Continuous variables were expressed as mean ± standard deviation or median with interquartile range, depending on distribution. Categorical variables will be expressed as frequencies and percentages. Between-group comparisons of the primary outcome were performed using an independent samples t-test for normally distributed data or the Mann–Whitney U test for non-normally distributed data. Proportions of patients achieving good or excellent functional outcomes based on established extensor tendon scoring systems were compared using chi-square or Fisher's exact tests.

Secondary outcomes were analysed using appropriate parametric or non-parametric tests. Repeated-measures analysis of variance or mixed-effects models was used to evaluate changes in functional scores over time. Effect sizes were reported using Cohen's d for continuous outcomes and relative risk or odds ratios for categorical outcomes, with corresponding 95% confidence intervals. Two-sided p-values less than 0.05 was considered statistically significant.