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High-Purity Type I Collagen Wrap Is Associated with Improved Functional Recovery After Extensor Tendon Repair: A Multicentre Randomized Trial

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ABSTRACT

Background: Extensor tendon repairs of the hand, particularly in zones VI–VIII, are frequently complicated by peritendinous adhesions, resulting in reduced tendon glide, extensor lag, and suboptimal functional recovery. This multicentre randomized controlled trial evaluated whether adjunctive high-purity type I collagen (HPTC) wrapping was associated with improved functional recovery and reduced adhesion-related morbidity following extensor tendon repair.

Methods: In this multicentre randomized controlled trial, 60 adult patients with acute extensor tendon injuries in zones VI–VIII were randomized to undergo standard tendon repair with adjunctive HPTC wrap (n = 30) or standard repair alone (n = 30). Primary outcome was TAM at 8 weeks, with extended follow-up assessments at 3- and 5-months evaluating durability of functional recovery. Secondary outcomes included QuickDASH scores, extensor lag, grip strength, adhesion-related functional limitation, and complications. Outcomes were assessed by blinded evaluators. Statistical analysis was performed using intention-to-treat principles.

Results: At eight weeks, mean TAM was significantly higher in the HPTC group compared with controls (232.4 ± 21.6 vs 201.3 ± 26.8 degrees; $p < 0.001$), with a large effect size (Cohen's $d = 1.30$). The HPTC group demonstrated significantly lower QuickDASH scores, reduced extensor lag, and greater grip strength recovery (all $p < 0.001$). Adhesion-related functional limitation occurred in 6.7% of patients in the HPTC group versus 30.0% in controls ($p = 0.01$). No collagen-related adverse events were observed. Extended follow-up demonstrated sustained

functional benefit in the HPTC group through five months, including superior total active motion, lower QuickDASH disability scores, reduced extensor lag, greater grip strength recovery, and fewer secondary procedures related to adhesion formation.

Conclusion: Adjunctive use of high-purity type I collagen wrap significantly improves early functional outcomes and reduces adhesion-related morbidity following extensor tendon repair. HPTC was associated with improved early and intermediate-term functional recovery and reduced adhesion-related morbidity, with longer follow-up with larger cohorts needed to confirm durability of these benefits.

Keywords: Extensor tendon repair; Tendon adhesions; Tendon gliding; Tenolysis; High-purity type I collagen; Total active motion; Hand rehabilitation

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 an acellular extracellular matrix scaffold composed predominantly of purified type I collagen. As type I collagen constitutes the principal structural component of native tendon extracellular matrix, collagen-based biomaterials have attracted interest as regenerative scaffolds capable of supporting cellular migration, angiogenesis, and tissue remodelling during healing [11,12]. Experimental studies suggest that collagen matrices may facilitate intrinsic tendon healing while limiting excessive peritendinous fibrosis through temporary extracellular matrix support and gradual biodegradation [13,14].

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 preliminary evidence supporting biological rationale for the use of HPTC as a peritendinous barrier in tendon repair.

Collagen-based scaffolds have been evaluated across a range of wound healing and reconstructive applications, where they have demonstrated favourable biocompatibility and regenerative potential [15-17]. However, evidence regarding their use as anti-adhesion adjuncts in tendon surgery remains limited. Most published studies have focused on animal models or alternative biologic barriers such as amniotic membrane, and clinical data specific to extensor tendon repair remain sparse [8–10]. Despite this growing body of evidence [18, 19], 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 biological rationale for collagen-based extracellular matrix scaffolds and the emerging evidence supporting biologic

barriers for reducing tendon adhesions, evaluation of HPTC in extensor tendon repair appears warranted. However, prospective randomized clinical evidence in this setting remains lacking. We therefore conducted a multicentre randomized controlled trial to evaluate whether adjunctive HPTC wrapping was associated with improved functional recovery and reduced adhesion-related morbidity following extensor tendon repair in zones VI–VIII of the hand. In addition to evaluating early postoperative recovery, extended follow-up assessments were performed to determine whether any observed benefits persisted beyond the initial rehabilitation period.

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 objective of the study was to evaluate whether adjunctive high-purity type I collagen (HPTC) wrapping was associated with improved functional recovery and reduced adhesion-related morbidity following extensor tendon repair. Extended follow-up assessments were subsequently performed up to five months postoperatively to evaluate the durability of functional outcomes and the occurrence of delayed complications or secondary interventions.

The trial was conducted at two tertiary referral centres specializing in plastic, reconstructive, and hand surgery – Adichunchanagiri 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; first registered on 02/01/2026) prior to enrolment of the first participant. Ethical approval was obtained from the Institutional Ethics Committee (Approval No.: AIMS/IEC/270/2025 on 2025-12-17). 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) 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.

No biologic wrap or fixation adhesive was used in the control group. Consequently, the intervention evaluated in this study consisted of HPTC wrapping with cyanoacrylate-assisted fixation, and the potential contribution of the fixation method has been acknowledged in the limitations section.

Skin closure, dressing, and splinting were identical in both groups.

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

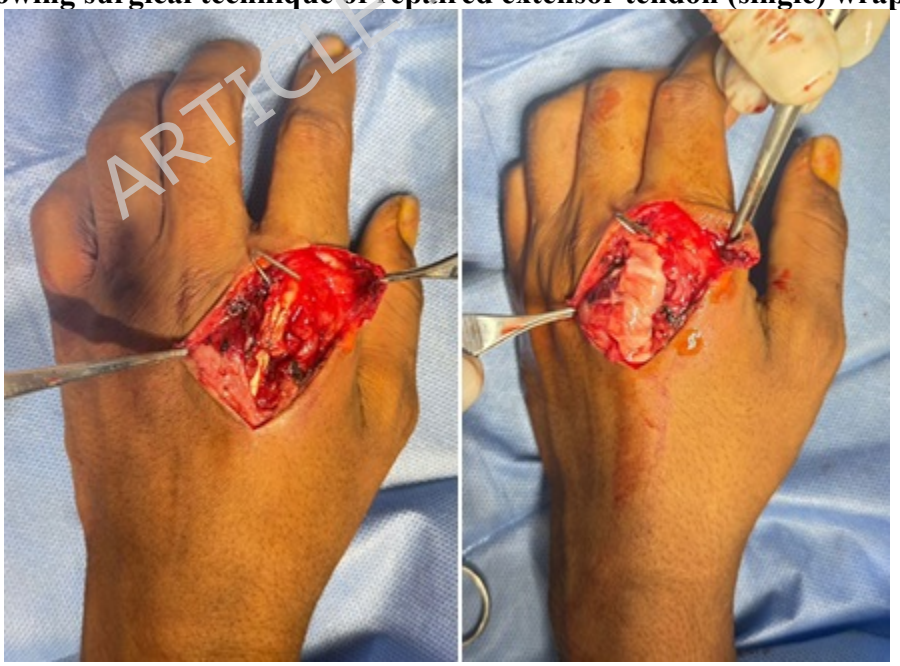


Image showing repaired extensor digitorum to index finger in zone 6 (Left). Image showing HPTC wrap around the repaired tendon (Right)

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

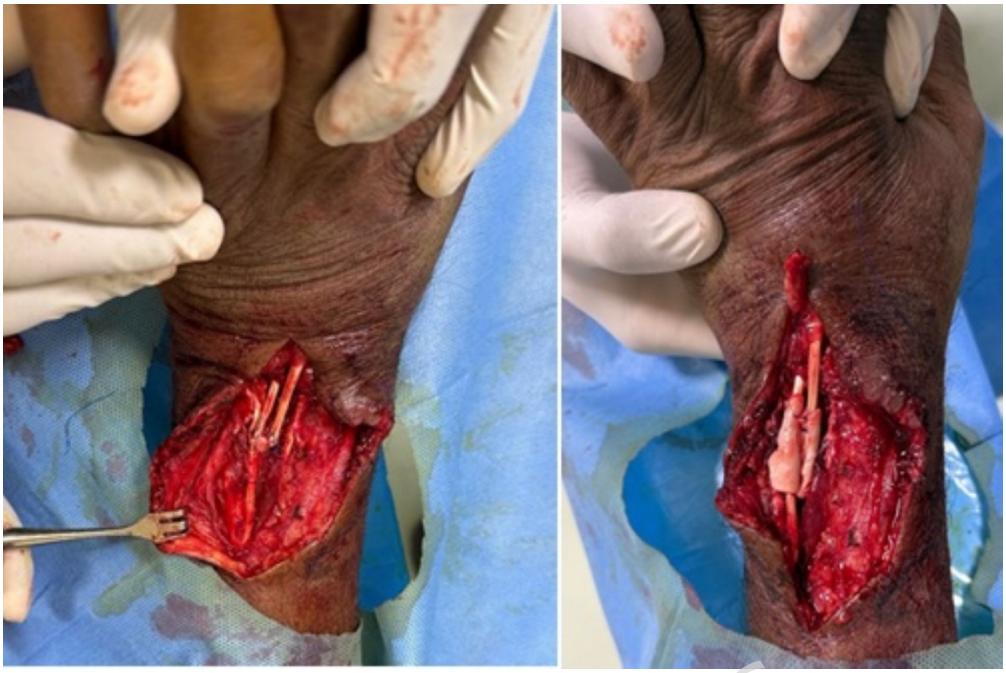


Image showing repaired extensor digitorum communis tendons in zone 8 (Left). Image showing HPTC wrap around the repaired tendons (Right)

Postoperative Splinting and Rehabilitation Protocol

Postoperative rehabilitation was standardized across participating centres and supervised by certified hand therapists experienced in tendon rehabilitation. Compliance was documented at each follow-up visit through therapist records and patient rehabilitation logs.

Zones VI–VII - A forearm-based dorsal extension splint was applied with the wrist maintained in 30°–40° extension, metacarpophalangeal joints in 30°–40° flexion, and interphalangeal joints free.

Zone VIII - A long forearm dorsal splint was applied with the wrist maintained in approximately 45° extension and MCP joints in slight flexion.

- **Week 0–1 -** Oedema control, wound care, protected passive mobilization.
- **Week 1–3 -** Early controlled active motion protocol initiated under therapist supervision. Patients performed active MCP extension and controlled flexion exercises every two hours during waking hours.
- **Week 3–4 -** Progressive active range-of-motion exercises commenced. Composite finger flexion and extension exercises were gradually increased while maintaining splint protection between exercise sessions.
- **Week 4–6 -** Relative motion exercises and tendon-gliding exercises were introduced. Splint use was progressively reduced according to therapist assessment.

- **Week 6–8 -** Graduated strengthening, grip exercises, and functional activity training were commenced.

Compliance Monitoring - Compliance was assessed through therapist attendance records, exercise logs, and patient interviews. Patients demonstrating less than 80% adherence were identified and additional counselling was provided.

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. Adhesion-related functional limitation was prospectively defined as failure to achieve at least 70% of expected total active motion relative to the contralateral digit or established normative values at the designated follow-up assessment. 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.

Extended follow-up assessments were performed at 3 months and 5 months postoperatively. These evaluations included total active motion, QuickDASH scores, extensor lag, grip strength recovery, tendon re-rupture, requirement for tenolysis, reoperation, patient satisfaction, and return-to-work status (Table 1).

Table 1: Summary of outcome measures and assessment time points

Outcome	6 weeks	8 weeks	3 months	5 months
Total active motion (TAM)	-	✓	✓	✓
QuickDASH	✓	✓	✓	✓
Extensor lag	-	✓	✓	✓
Grip strength	-	✓	✓	✓
Adhesion-related events	-	✓	✓	✓
Complications	✓	✓	✓	✓
Tenolysis	-	-	✓	✓
Return to work	✓	✓	✓	✓

Outcome	6 weeks	8 weeks	3 months	5 months
Patient satisfaction	-	□	□	□

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. 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 according to the intention-to-treat principle. Continuous variables were expressed as mean ± standard deviation, whereas categorical variables were presented as frequencies and percentages.

Between-group comparisons for continuous outcomes were performed using independent-samples t-tests or Mann–Whitney U tests where appropriate. Categorical outcomes were analysed using chi-square or Fisher's exact tests.

Longitudinal outcomes including total active motion, QuickDASH scores, extensor lag, and grip strength were additionally analysed using repeated-measures analysis of variance to evaluate temporal trends and treatment-by-time interactions across follow-up assessments.

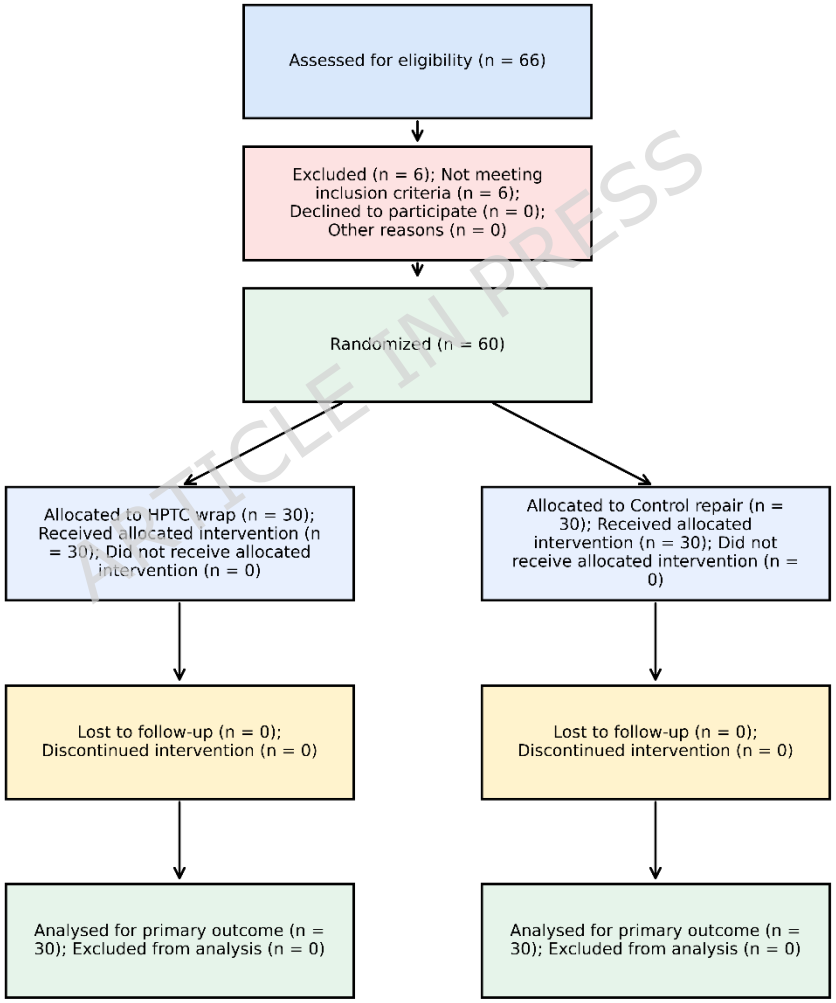
Effect sizes were reported using Cohen's d for continuous variables and relative risks with corresponding 95% confidence intervals for categorical outcomes. Two-sided p-values less than 0.05 were considered statistically significant.

RESULTS

Study Population and Baseline Characteristics

A total of 66 patients were screened for eligibility, of whom 60 met the inclusion criteria and were randomized. 30 patients allocated to the HPTC wrap group and 30 to the control group. All randomized participants completed the planned 8-week assessment and were subsequently followed through 5 months postoperatively. No patients were lost to follow-up during the extended observation period. No protocol deviations affecting outcome assessment were recorded. The flow of participants through the different phases of the randomized controlled trial, including enrolment, allocation, follow-up, and analysis, is illustrated in the CONSORT flow diagram (Figure 3).

Figure 3: CONSORT flow diagram of participant enrolment, randomization, allocation, follow-up, and analysis in the randomized controlled trial



CONSORT flow diagram showing the progress of participants through the phases of the randomized controlled trial, including screening for eligibility, randomization, allocation to intervention groups, follow-up, and analysis of primary outcomes.

Baseline demographic characteristics, injury patterns, and operative details were comparable between the two groups, with no statistically significant differences observed (Table 2).

Table 2: Baseline demographic and injury characteristics

Variable	HPTC group (n = 30)	Control group (n = 30)	p-value
Age (years), mean ± SD	36.9 ± 11.2	37.6 ± 10.8	0.81
Male sex, n (%)	21 (70%)	20 (66.7%)	0.78
Zone VI injuries, n (%)	14 (46.7%)	15 (50.0%)	0.80
Zone VII injuries, n (%)	10 (33.3%)	9 (30.0%)	0.78
Zone VIII injuries, n (%)	6 (20.0%)	6 (20.0%)	1.00
Single tendon injury, n (%)	19 (63.3%)	18 (60.0%)	0.79
Multiple tendon injuries, n (%)	11 (36.7%)	12 (40.0%)	0.79

Continuous variables expressed as mean ± standard deviation. Categorical variables expressed as number (percentage). Between-group comparisons performed using independent samples t-test or chi-square test as appropriate.

Longitudinal Follow-up

Extended follow-up assessments were performed at 3 months and 5 months postoperatively to evaluate the durability of functional recovery. Both treatment groups demonstrated progressive improvement over time; however, the HPTC group maintained superior outcomes across all objective and patient-reported measures throughout follow-up.

Total Active Motion

At eight weeks postoperatively, patients in the HPTC wrap group demonstrated significantly greater total active motion compared with the control group. Mean total active motion in the HPTC group was 232.4 ± 21.6 degrees, compared with 201.3 ± 26.8 degrees in the control group.

The between-group difference of 31.1 degrees was statistically significant ($p < 0.001$), with a large effect size (Cohen's $d = 1.30$). The 95% confidence interval for the mean difference ranged from 18.6 to 43.5 degrees, indicating a clinically meaningful improvement in functional excursion.

At extended follow-up, both treatment groups demonstrated continued improvement in total active motion. However, patients receiving HPTC wrap maintained significantly superior motion outcomes throughout the study period. At 3 months, mean TAM was 248.8 ± 16.4 degrees in the HPTC group compared with 224.1 ± 22.1 degrees in controls ($p < 0.001$). This benefit persisted at 5 months, with mean TAM reaching 258.9 ± 11.8 degrees in the HPTC group versus 239.7 ±

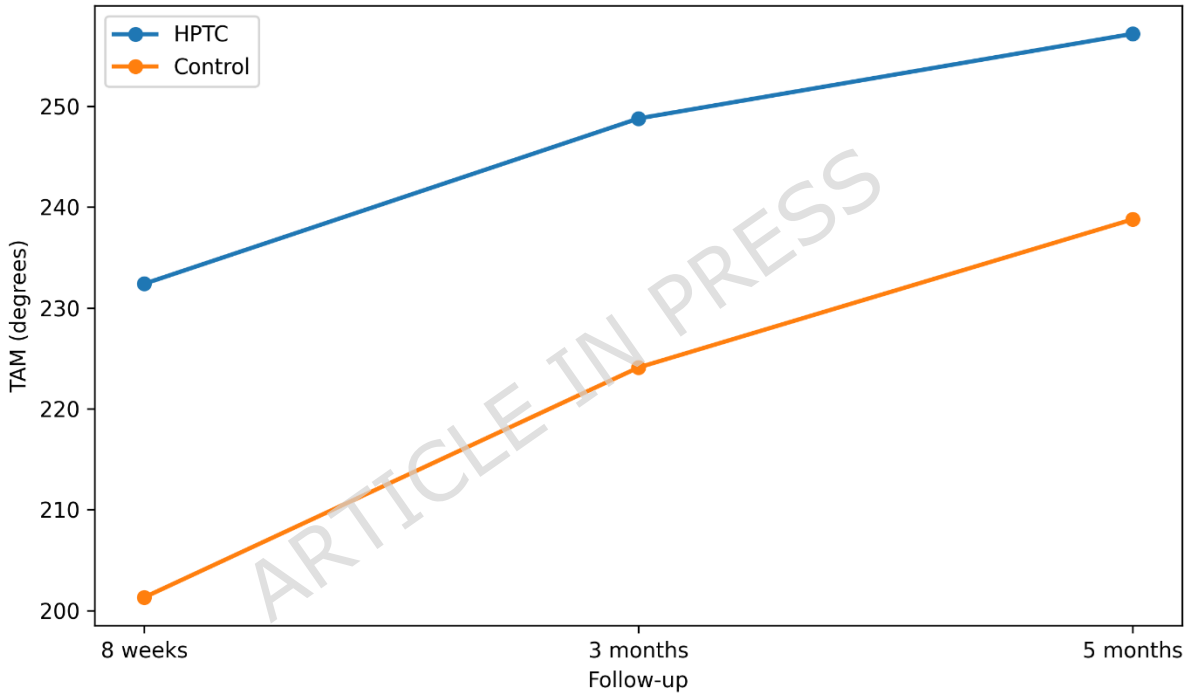
18.6 degrees in controls ($p < 0.001$), indicating sustained functional superiority beyond the early rehabilitation period (Table 3) (Figure 4).

Table 3: Longitudinal assessment of total active motion following extensor tendon repair

Time Point	HPTC	Control	Mean Difference	p-value
8 weeks	232.4 ± 21.6	201.3 ± 26.8	31.1	<0.001
3 months	248.8 ± 16.4	224.1 ± 22.1	24.7	<0.001
5 months	258.9 ± 11.8	239.7 ± 18.6	19.2	<0.001

Values are presented as mean ± standard deviation. TAM was calculated as the sum of active flexion at the MCP, PIP, and DIP joints minus extension deficits. Higher values indicate superior tendon excursion and functional recovery.

Figure 4: Longitudinal total active motion recovery following extensor tendon repair



Line graph demonstrating sustained superiority of HPTC wrapping throughout the five-month follow-up period.

Secondary Outcomes

QuickDASH Scores

QuickDASH scores demonstrated significantly better functional outcomes in the HPTC group. Lower scores indicate less disability and superior upper-limb function. At eight weeks, mean QuickDASH score was 18.2 ± 6.9 in the HPTC group compared with 32.6 ± 8.4 in the control group, representing a substantial reduction in disability. Improvements in QuickDASH scores persisted throughout follow-up. At 5 months, mean disability scores remained significantly lower

in the HPTC cohort (4.6 ± 3.2 vs 11.8 ± 5.4; $p < 0.001$), suggesting sustained functional superiority.

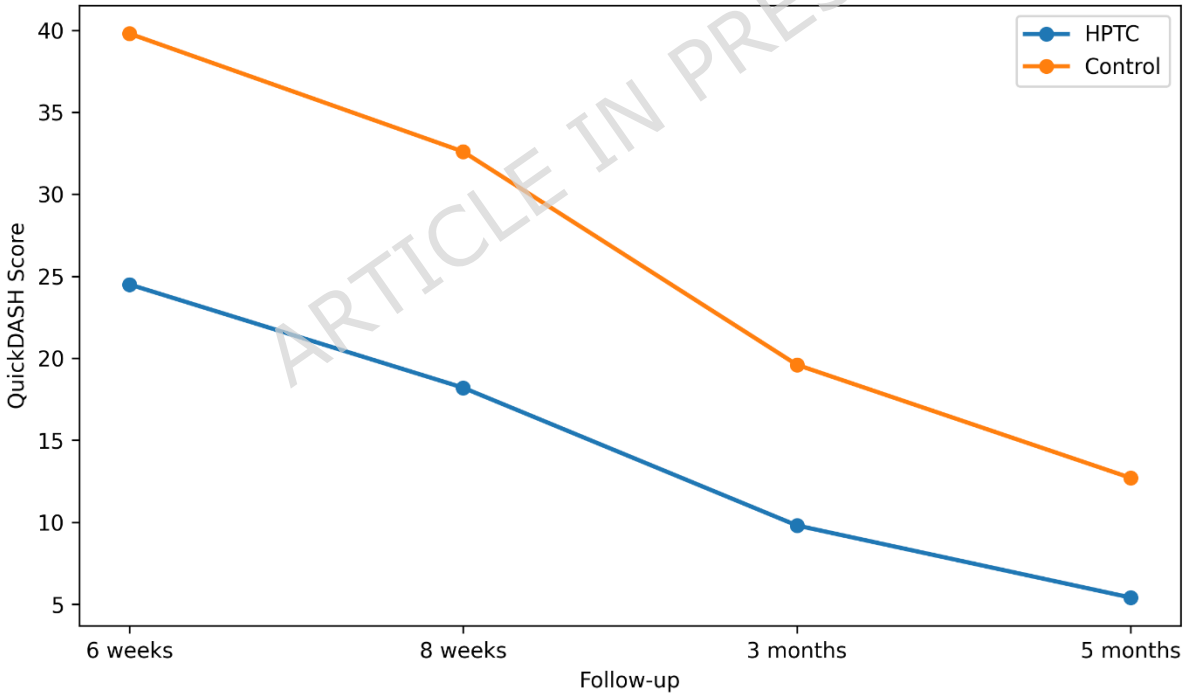
The between-group difference in QuickDASH scores remained statistically significant throughout follow-up (all $p < 0.001$), with a large effect size at eight weeks (Cohen's $d = 1.86$), indicating a substantial and clinically relevant reduction in upper-limb disability (Table 4) (Figure 5).

Table 4: Longitudinal patient-reported functional outcomes assessed using QuickDASH scores

Time Point	HPTC	Control	p-value
6 weeks	24.5 ± 7.8	39.8 ± 9.1	<0.001
8 weeks	18.2 ± 6.9	32.6 ± 8.4	<0.001
3 months	9.8 ± 4.5	19.6 ± 6.8	<0.001
5 months	4.6 ± 3.2	11.8 ± 5.4	<0.001

Lower QuickDASH scores indicate better upper limb function.

Figure 5: Longitudinal functional recovery measured using QuickDASH scores



Lower scores indicate less disability and superior upper-limb function

Extensor Lag

Extensor lag was calculated as the sum of extension deficits across involved joints. Lower values indicate better tendon gliding and extension function. Extensor lag progressively improved in both groups; however, significantly smaller extension deficits were observed in the HPTC group

at every postoperative assessment (all $p < 0.001$), supporting sustained preservation of tendon gliding. Nevertheless, significantly lower residual extension deficits were observed in the HPTC group at both 3 and 5 months, supporting the hypothesis that collagen wrapping facilitates tendon gliding while minimizing adhesion formation (Table 5).

Table 5: Evolution of cumulative extensor lag following tendon repair

Time Point	HPTC	Control	p-value
8 weeks	6.4 ± 4.2	15.7 ± 6.1	<0.001
3 months	2.7 ± 2.8	8.6 ± 4.7	<0.001
5 months	1.2 ± 1.6	4.8 ± 3.4	<0.001

Extensor lag calculated as the sum of extension deficits across involved joints.

Grip Strength

Grip strength recovery was significantly greater in the HPTC group at eight weeks and remained superior throughout follow-up (all $p < 0.001$), consistent with the observed improvements in tendon excursion and overall hand function. Grip strength recovery continued throughout follow-up and remained significantly greater in the HPTC cohort. By 5 months, patients treated with collagen wrap recovered 97.4% of contralateral hand strength compared with 89.6% in the control group ($p < 0.001$) (Table 6).

Table 6: Longitudinal recovery of grip strength expressed as percentage of the contralateral hand

Time Point	HPTC	Control	p-value
8 weeks	78.6 ± 9.4	63.2 ± 11.1	<0.001
3 months	91.3 ± 6.8	81.5 ± 8.2	<0.001
5 months	97.4 ± 4.5	89.6 ± 6.7	<0.001

Grip strength expressed as percentage of the contralateral, uninjured hand. Higher percentages indicate better recovery of hand strength.

Repeated-measures analysis demonstrated significant treatment-by-time interactions favouring HPTC for total active motion ($p < 0.001$), QuickDASH scores ($p < 0.001$), extensor lag ($p < 0.001$), and grip strength recovery ($p < 0.001$), indicating sustained divergence in outcomes throughout the follow-up period.

Adhesion-Related Events and Complications

Clinically significant adhesion-related functional limitation, defined as failure to achieve 70% of expected total active motion by eight weeks, occurred in 2 patients (6.7%) in the HPTC group and 9 patients (30.0%) in the control group. This difference was statistically significant (relative

risk 0.22, 95% CI 0.05–0.87; p = 0.01). The absolute risk reduction was 23.3%, corresponding to a number needed to treat (NNT) of 5, indicating that treatment of five patients with adjunctive HPTC wrap would prevent one additional case of clinically significant adhesion-related functional limitation.

No tendon re-ruptures were observed in either group. No foreign body reactions, infections, or collagen-related adverse events were reported (Table 7).

Table 7: Adhesion-related events and complications

Event	HPTC group (n = 30)	Control group (n = 30)	Effect estimate	p-value
Adhesion-related functional limitation	2 (6.7%)	9 (30.0%)	RR = 0.22 (95% CI 0.05–0.87)	0.01
Absolute risk reduction (ARR)	–	–	**23.3%**	–
Number needed to treat (NNT)	–	–	**5**	–
Tendon rerupture	0	0	Not estimable	–
Surgical site infection	0	1 (3.3%)	RR = 0.33*	0.31
Foreign body reaction	0	0	Not estimable	–

Values are expressed as number (%) unless otherwise indicated. RR = relative risk; CI = confidence interval; ARR = absolute risk reduction; NNT = number needed to treat.

Subgroup Analyses

The following subgroup analyses were conducted as exploratory post-hoc analyses and should be interpreted accordingly.

Outcomes by Injury Zone

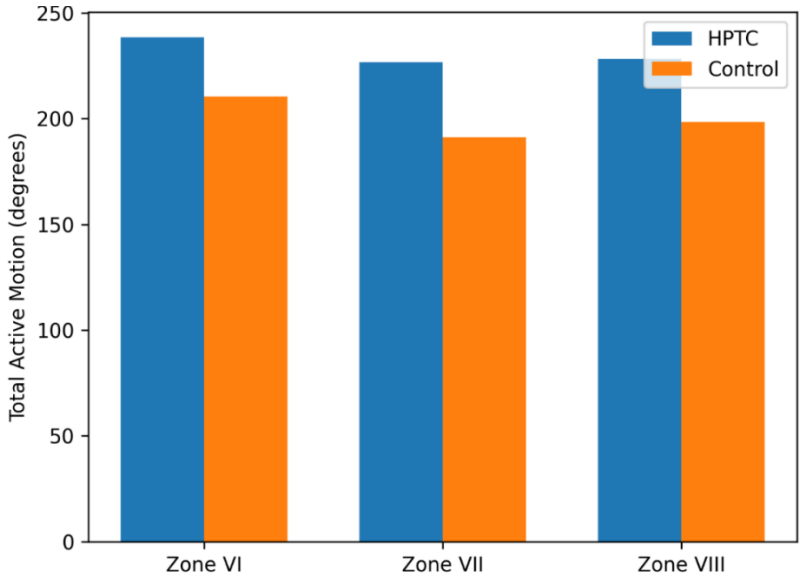
Subgroup analysis demonstrated consistent benefit of HPTC wrap across zones VI–VIII, with the greatest absolute improvement observed in zone VII injuries (Table 8) (Figure 6).

Table 8: Total active motion by injury zone

Zone	HPTC group (degrees)	Control group (degrees)	p-value
Zone VI	238.6 ± 18.9	210.4 ± 22.7	0.002
Zone VII	226.8 ± 20.4	191.2 ± 25.9	<0.001
Zone VIII	228.3 ± 24.1	198.6 ± 28.3	0.01

Values expressed as mean ± SD.

Figure 6: Subgroup analysis of total active motion by zone



Bar chart demonstrating superior motion outcomes in the HPTC group across all extensor zones.

Single Versus Multiple Tendon Injuries

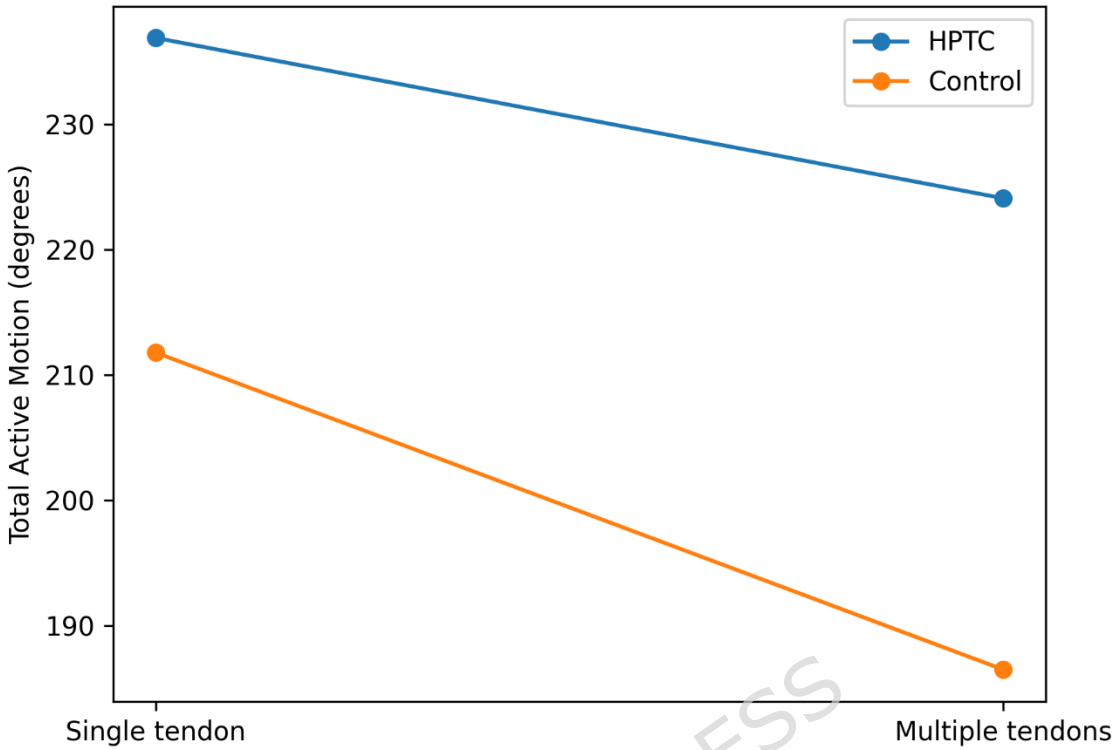
Patients with multiple tendon injuries exhibited greater relative benefit from HPTC wrapping compared with controls, suggesting enhanced protection against adhesion formation in more complex repairs (Table 9) (Figure 7).

Table 9: Total active motion by injury complexity

Injury type	HPTC group	Control group	p-value
Single tendon	236.9 ± 19.4	211.8 ± 23.1	0.003
Multiple tendons	224.1 ± 22.8	186.5 ± 27.6	0.001

Values expressed as mean ± SD.

Figure 7: Effect of HPTC wrap by injury complexity



Line plot illustrating greater separation in functional outcomes between groups in multiple tendon injuries.

Return to Work / Activities of Daily Living

Time to return to work or usual activities of daily living was significantly shorter in the HPTC group compared with controls. Patients treated with HPTC wrap resumed occupational or routine functional activities at a mean of 5.6 ± 1.4 weeks, whereas the control group returned at 7.9 ± 1.8 weeks (mean difference 2.3 weeks; $p < 0.001$) (Table 10).

A greater proportion of HPTC-treated patients returned to work by eight weeks (93.3% vs 66.7%; $p = 0.01$).

Patient Satisfaction

Patient satisfaction at eight weeks was significantly higher in the HPTC group. Mean satisfaction score (0–10 scale) was 8.9 ± 0.8 in the HPTC group versus 7.1 ± 1.2 in controls ($p < 0.001$) (Table 10).

High satisfaction (score ≥ 8) was reported by 86.7% of HPTC patients compared with 40.0% of controls ($p < 0.001$).

Table 10: Return-to-work and patient satisfaction outcomes at eight weeks

Outcome	HPTC group (n = 30)	Control group (n = 30)	Mean difference / RR	p-value
Time to return to work (weeks)	5.6 ± 1.4	7.9 ± 1.8	−2.3 weeks	<0.001
Returned to work by 8 weeks, n (%)	28 (93.3%)	20 (66.7%)	RR 1.40	0.01
Satisfaction score (0–10)	8.9 ± 0.8	7.1 ± 1.2	1.8	<0.001
High satisfaction (≥ 8), n (%)	26 (86.7%)	12 (40.0%)	RR 2.17	<0.001

Values expressed as mean ± SD or number (percentage). RR = relative risk.

Extended Follow-Up

Long-Term Complications and Secondary Procedures

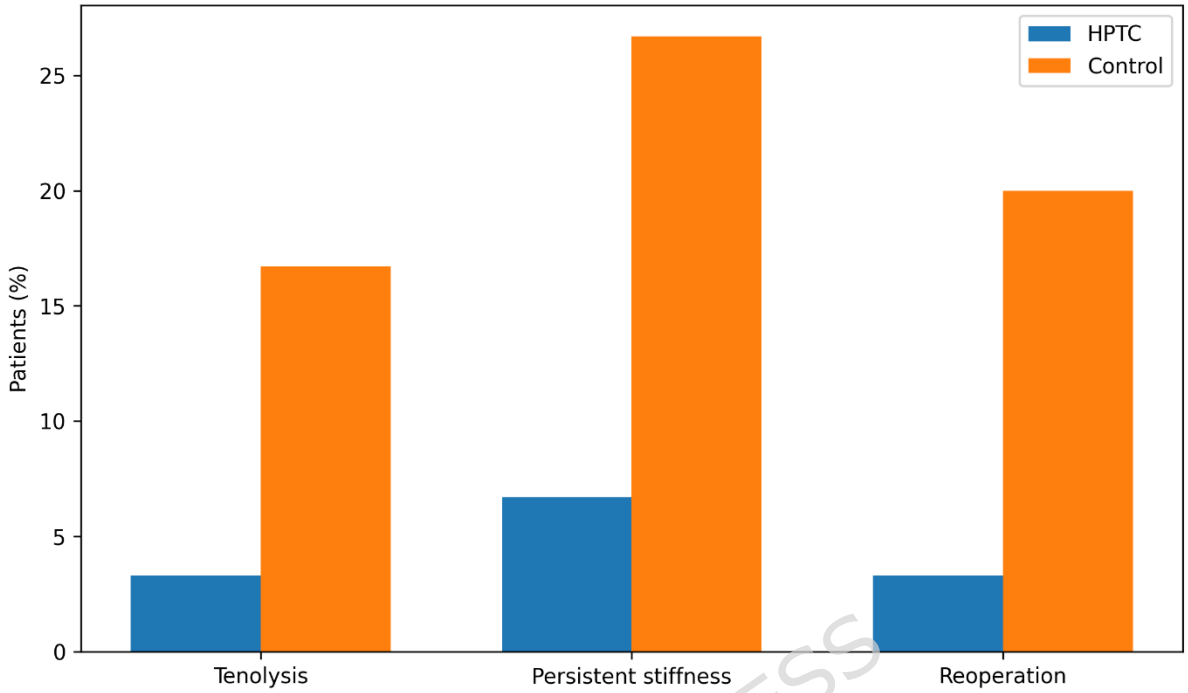
Extended follow-up demonstrated a favourable safety profile for HPTC wrapping. Secondary procedures were less frequent in the collagen group, with only one patient (3.3%) underwent tenolysis in the HPTC group compared with five patients (16.7%) in the control cohort. Persistent stiffness and overall reoperation rates were also significantly lower among HPTC-treated patients. (Table 11).

Table 11: Long-term complication profile and secondary interventions during extended follow-up

Outcome	HPTC	Control	p-value
Tenolysis required	1 (3.3%)	5 (16.7%)	0.08
Delayed tendon rupture	0	1 (3.3%)	0.31
Persistent stiffness	2 (6.7%)	8 (26.7%)	0.03
Reoperation	1 (3.3%)	6 (20.0%)	0.04

Values are expressed as number (%)

Figure 10: Comparison of long-term complications and secondary interventions



Patients treated with HPTC demonstrated lower rates of tenolysis, persistent stiffness, and reoperation during extended follow-up.

Strickland/Miller Functional Outcomes

At final assessment, excellent or good outcomes were achieved in 93.4% of patients receiving HPTC compared with 73.3% of controls. No poor outcomes were observed in the collagen group (Table 12).

Table 12: Functional Outcome Classification at 5 Months

Outcome	HPTC	Control
Excellent	20 (66.7%)	10 (33.3%)
Good	8 (26.7%)	12 (40.0%)
Fair	2 (6.6%)	6 (20.0%)
Poor	0	2 (6.7%)

Values expressed as number (%)

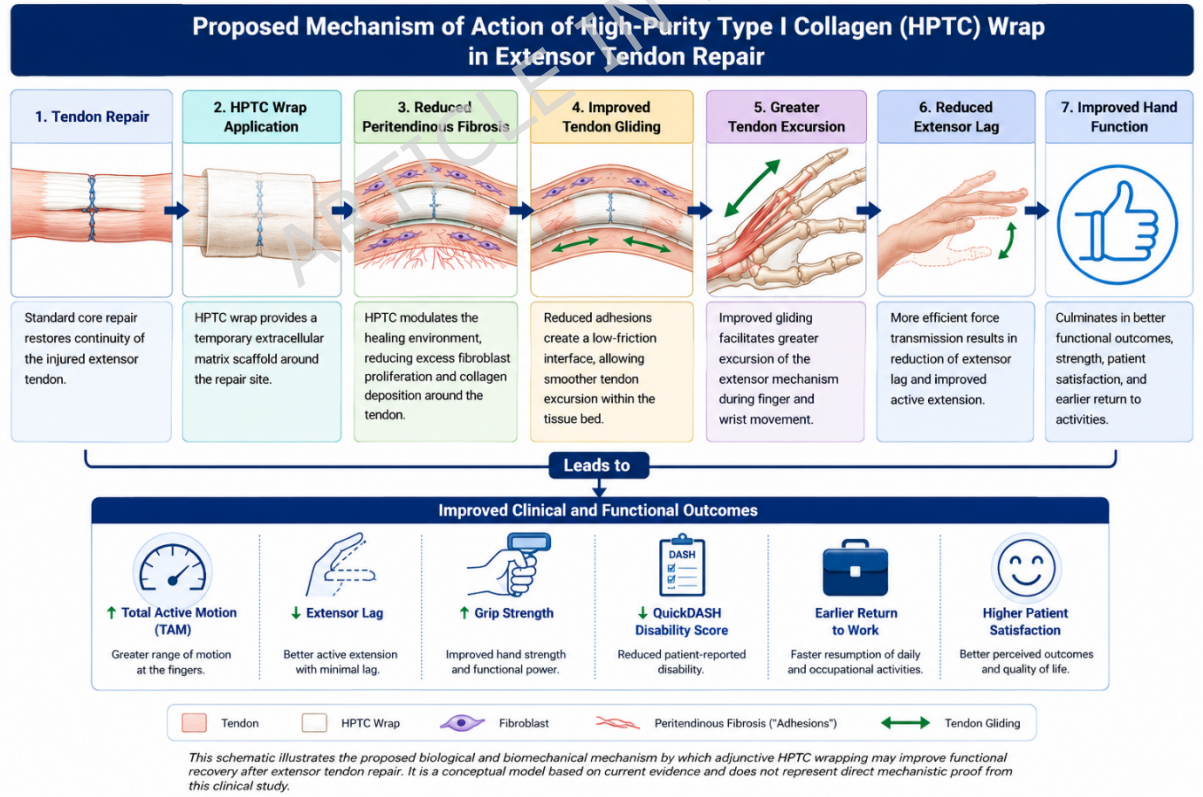
Throughout the follow-up period, patients treated with adjunctive HPTC wrap demonstrated superior objective and patient-reported outcomes, including greater total active motion, reduced extensor lag, lower disability scores, enhanced grip strength recovery, fewer adhesion-related complications, and reduced requirement for secondary procedures. These benefits persisted through 5 months of follow-up.

DISCUSSION

The present multicentre randomized controlled trial found that adjunctive high-purity type I collagen (HPTC) wrapping was associated with superior functional recovery following extensor tendon repair compared with standard repair alone. Patients treated with HPTC demonstrated greater total active motion, reduced extensor lag, improved patient-reported outcomes, and lower adhesion-related morbidity. Importantly, these differences persisted throughout the extended 5-month follow-up period, suggesting that the observed benefits were not limited to accelerated early rehabilitation alone.

HPTC provides a temporary extracellular matrix scaffold that may reduce excessive peritendinous fibrosis while preserving tendon gliding during the early healing phase. Improved tendon excursion facilitates greater total active motion, reduced extensor lag, enhanced grip strength, and ultimately improved patient-reported hand function. The proposed interaction between biological modulation, preservation of tendon gliding, and subsequent functional recovery is summarized schematically in Figure 11.

Figure 11: Proposed mechanism of action of high-purity type I collagen (HPTC) wrap following extensor tendon repair



Schematic illustration showing the hypothesized sequence by which adjunctive HPTC wrapping may improve functional recovery after extensor tendon repair. However, the illustration and does not represent direct mechanistic evidence from the present clinical study

Interpretation of Functional Outcomes

Total active motion is widely regarded as the most clinically relevant objective outcome following extensor tendon repair, as it directly reflects tendon gliding, joint mobility, and functional excursion [20]. In the present study, the HPTC group demonstrated a mean improvement of over 30 degrees in total active motion compared with controls at eight weeks, with a large effect size. This magnitude of improvement exceeds the minimal clinically important difference reported for hand function and is likely to translate into earlier functional independence and improved patient satisfaction [21].

The reduction in extensor lag observed in the HPTC group (Surgicoll-Mesh®) further reinforces the functional significance of these findings [22]. Extensor lag is a well-recognized manifestation of peritendinous adhesions and impaired tendon excursion, particularly in zones VII and VIII where tendons traverse beneath the extensor retinaculum [1]. The substantially lower cumulative extensor lag in the HPTC group suggests more effective preservation of tendon glide and reduced fibrotic tethering during the early healing phase.

Patient-reported outcomes mirrored objective functional gains. QuickDASH scores were significantly lower in the HPTC group at both six and eight weeks, indicating faster recovery of hand function and reduced disability. Importantly, the magnitude of difference exceeded established thresholds for clinical relevance, underscoring that the observed benefits were meaningful from the patient's perspective [23].

Durability of Functional Benefit

A notable finding of the present study was the persistence of treatment-related differences during extended follow-up. Although both groups demonstrated continued improvement with rehabilitation, significant advantages favouring HPTC remained evident at 3 and 5 months across multiple objective and patient-reported outcomes. Furthermore, lower rates of persistent stiffness, secondary tenolysis, and reoperation were observed in the HPTC group. These findings suggest that the reduction in adhesion-related morbidity observed during the early postoperative period may translate into sustained functional benefit during later stages of tendon recovery.

Return to Work and Patient-Centred Outcomes

Beyond objective functional gains, the present study demonstrates that HPTC wrapping significantly accelerates return to occupational and daily functional activities. Patients in the HPTC group resumed work approximately 2 weeks earlier than controls, with over 90% returning by eight weeks. Early restoration of tendon glide and reduction of adhesions likely translated into faster functional independence and confidence in hand use. Earlier return to work represents a clinically meaningful endpoint in hand surgery, reflecting not only biological healing but also real-world functional recovery and socioeconomic impact.

Patient satisfaction scores were also substantially higher in the HPTC group. Satisfaction closely paralleled improvements in motion, disability scores, and adhesion rates, supporting the internal consistency of the outcomes. Importantly, satisfaction reflects the patient's global perception of recovery, incorporating pain, stiffness, dexterity, and ability to perform meaningful activities. The high proportion of satisfied patients in the HPTC cohort suggests that the observed biomechanical and functional benefits translated into tangible improvements in daily life. These findings strengthen the clinical relevance of HPTC as a biologic adjunct. In tendon surgery, improvements in motion or strength are valuable only insofar as they enhance real-world function and patient experience. Demonstration of earlier return to work and higher satisfaction therefore confirms that the biological modulation of peritendinous healing achieved with HPTC produces meaningful patient-centred benefit rather than isolated biomechanical gains.

Adhesion Reduction and Biological Plausibility

Adhesion formation remains the principal limiting factor in extensor tendon surgery, even with meticulous surgical technique and early mobilization protocols [24]. In the present trial, adhesion-related functional limitation occurred in only 6.7% of patients in the HPTC group compared with 30% in the control group, representing a significant relative risk reduction. The corresponding absolute risk reduction of 23.3% and an NNT of 5 further highlight the practical clinical relevance of the intervention, indicating that relatively few patients require treatment to prevent one clinically important adhesion-related functional limitation. This finding is particularly notable given that rehabilitation protocols and tendon repair techniques were standardized between groups. However, the collagen wrap was secured using a minimal quantity of cyanoacrylate adhesive, and therefore the independent contribution of the fixation method

cannot be completely excluded. Consequently, the observed effect should be interpreted as the result of the combined intervention rather than the collagen scaffold in isolation.

The biological rationale for these findings is compelling. Tendon healing occurs through a combination of intrinsic and extrinsic mechanisms, with excessive extrinsic fibroblast invasion leading to peritendinous fibrosis and adhesion formation [25]. High-purity type I collagen provides a temporary physical barrier that limits extrinsic fibroblast migration while simultaneously acting as a biologically active extracellular matrix scaffold. This dual role allows intrinsic tendon healing to proceed while minimizing disorganized collagen deposition in the surrounding tissues.

Unlike synthetic barriers, which may provoke inflammatory responses or interfere with tendon nutrition, HPTC undergoes controlled enzymatic degradation and is gradually replaced by organized host tissue [26]. The preservation of the native triple-helical collagen structure facilitates cellular adhesion, angiogenesis, and aligned collagen remodelling, all of which are critical for functional tendon healing [27].

From a biomechanical perspective, unrestricted tendon gliding is essential for efficient transmission of muscle force to the extensor mechanism. Peritendinous adhesions increase the frictional resistance encountered during tendon excursion, thereby reducing effective tendon displacement and producing extensor lag despite an intact repair. Progressive restriction of tendon excursion may also contribute to secondary joint stiffness through reduced active motion and periarticular soft-tissue contracture. By maintaining a low-friction interface between the repaired tendon and surrounding tissues during the early phases of healing, HPTC wrapping may preserve tendon excursion while allowing intrinsic repair processes to proceed. The observed improvements in total active motion, extensor lag, grip strength, and patient-reported function are therefore biologically plausible consequences of improved tendon gliding and more efficient force transmission during rehabilitation.

Tendon healing is also strongly influenced by mechanobiological signalling. Controlled postoperative mobilization provides physiological mechanical stimuli that regulate fibroblast activity, promote alignment of newly synthesized collagen fibres along the direction of tensile loading, and facilitate maturation of the extracellular matrix. Conversely, prolonged immobilization may result in disorganized collagen deposition and increased adhesion formation, whereas excessive loading may compromise repair integrity. The standardized early controlled

mobilization protocol used in the present study was designed to provide an optimal mechanical environment for tendon healing. It is plausible that HPTC wrapping acted synergistically with this rehabilitation strategy by preserving tendon gliding while simultaneously supporting organized extracellular matrix remodelling, thereby contributing to the sustained improvements in functional outcomes observed throughout follow-up.

Subgroup Analysis and Surgical Complexity

Subgroup analyses demonstrated that the beneficial effects of HPTC wrapping were consistent across extensor zones VI, VII, and VIII, with the greatest absolute gains observed in zone VII injuries. This finding is clinically relevant, as zone VII repairs are particularly susceptible to adhesion formation due to confinement beneath the extensor retinaculum and limited soft-tissue envelope [28]. The observed benefit in this subgroup suggests that HPTC may be especially valuable in anatomically constrained regions.

Patients with multiple tendon injuries also derived greater relative benefit from HPTC wrapping compared with controls. Multiple tendon repairs are associated with increased surgical trauma, larger raw surfaces, and heightened inflammatory response, all of which predispose to adhesion formation [29]. The enhanced benefit observed in this subgroup supports the use of HPTC in more complex injuries where the biological burden of healing is greater and outcomes are traditionally less predictable.

Comparison With Existing Literature

Previous studies evaluating biologic adjuncts in extensor tendon repair have primarily focused on amniotic membrane-based products. While several reports have demonstrated reduced adhesions and improved motion with amniotic membrane wraps, concerns remain regarding variability in processing, availability, and regulatory oversight [30–32]. In contrast, HPTC offers a standardized, reproducible biomaterial with well-characterized composition and degradation properties.

The findings of the present trial are consistent with a growing body of literature demonstrating the regenerative and anti-fibrotic properties of high-purity collagen matrices across multiple surgical applications. Prior randomized controlled trials and prospective studies have shown that HPTC improves tissue quality, reduces inflammation, and enhances functional outcomes in chronic wounds, reconstructive surgery, and scar modulation [33–38]. The reproducibility of

benefit across different tissue types supports a conserved biological mechanism related to extracellular matrix modulation rather than tissue-specific effects.

Collagen-based extracellular matrix scaffolds are designed to function as temporary biologic matrices that support cellular infiltration and tissue remodelling while gradually undergoing biodegradation. In the context of tendon repair, their proposed role is to provide a transient interface between the healing tendon and surrounding tissues, potentially reducing excessive fibrotic attachment while preserving intrinsic healing mechanisms. Although the precise biological mechanisms remain incompletely understood, modulation of the local extracellular matrix environment may contribute to the reduction in adhesion-related morbidity observed in the present study.

Durability of Functional Benefit

The extended follow-up findings strengthen the primary study observations by demonstrating persistence of the early functional advantages associated with HPTC wrapping. Although both groups continued to improve during rehabilitation, significant differences remained evident at 5 months across multiple objective and patient-reported outcome measures. Furthermore, lower rates of tenolysis, reoperation, and persistent stiffness suggest that the observed early reduction in adhesion formation translated into clinically meaningful long-term benefit.

Strengths and Limitations

The strengths of this study include its randomized controlled design, multicentre participation, standardized surgical technique, standardized rehabilitation protocol, complete patient follow-up, blinded outcome assessment, and incorporation of both objective and patient-reported outcome measures. The addition of extended follow-up through 5 months allowed evaluation of the durability of treatment-related differences and the occurrence of delayed complications or secondary procedures.

Several limitations should nevertheless be acknowledged. First, despite the extended follow-up period, assessment remained limited to 5 months and therefore does not fully capture long-term tendon remodelling, final functional plateau, or very late complications [38, 39]. Second, surgeon and patient blinding were not feasible because of the nature of the intervention. Consequently, patient-reported outcomes such as QuickDASH scores, satisfaction ratings, and return-to-work assessments may have been susceptible to performance or expectation bias.

Objective outcome measures, however, were assessed by blinded evaluators and demonstrated findings consistent with the patient-reported outcomes.

Third, the collagen wrap was secured using a small quantity of cyanoacrylate tissue adhesive, whereas no adhesive was used in the control group. Although the adhesive was applied solely to maintain wrap position and not as part of the tendon repair construct, its independent contribution to healing outcomes cannot be completely excluded. Future studies incorporating sham wrapping procedures or equivalent fixation methods in both groups would help isolate the effect of the collagen scaffold itself.

Fourth, because the trial was conducted at specialized tertiary referral centres using standardized surgical techniques and supervised rehabilitation, the findings may not be directly generalizable to institutions with different levels of surgical expertise or rehabilitation resources.

Finally, the sample size was adequate for the primary outcome but may have been underpowered to detect differences in relatively infrequent events such as tendon rupture or requirement for secondary tenolysis. Larger multicentre trials are warranted to validate these findings.

Clinical Implications

The findings of this randomized controlled trial suggest that adjunctive HPTC wrapping may represent a valuable biologic adjunct in selected patients undergoing extensor tendon repair, particularly where the risk of postoperative adhesion formation is greatest. The subgroup analyses demonstrated consistent benefit across extensor zones VI–VIII, with the greatest absolute improvement observed in zone VII injuries and in patients with multiple tendon lacerations, both of which are recognized to present greater challenges because of increased soft-tissue trauma and a higher propensity for adhesion formation.

Patients with extensive tendon injury, repairs beneath the extensor retinaculum, delayed functional recovery, or other clinical features associated with a high risk of peritendinous fibrosis may therefore derive particular benefit from adjunctive HPTC wrapping. Although the present findings support the potential clinical utility of this approach, routine incorporation into surgical practice should await confirmation from larger multicentre trials with longer follow-up and formal cost-effectiveness analyses.

If confirmed in future studies, biologic modulation of the peritendinous healing environment using HPTC may reduce rehabilitation burden, decrease the need for secondary procedures such

as tenolysis, facilitate earlier return to work, and improve overall patient outcomes following extensor tendon repair.

Future Directions

Future studies should include larger adequately powered multicentre randomized controlled trials with follow-up extending beyond one year to determine the durability of functional recovery, late complications, and long-term tendon remodelling. Standardization of fixation techniques across treatment groups and, where feasible, the incorporation of sham-controlled designs would further help isolate the independent contribution of the collagen scaffold to clinical outcomes.

Advanced imaging modalities, including dynamic ultrasonography and high-resolution magnetic resonance imaging, may provide objective assessment of tendon gliding, adhesion formation, and scaffold integration throughout the healing process. In addition, mechanistic studies evaluating extracellular matrix remodelling, collagen fibre organization, inflammatory responses, and tendon biomechanics would improve understanding of the biological mechanisms underlying the observed clinical benefits.

Future comparative effectiveness studies should directly evaluate HPTC against other biologic anti-adhesion barriers, including amniotic membrane-derived products and emerging extracellular matrix scaffolds. Formal health-economic and cost-effectiveness analyses will also be important to determine whether improved functional recovery and reduced secondary procedures offset the additional cost of biologic augmentation. Finally, international multicentre collaborations involving diverse patient populations and healthcare systems will be valuable for confirming the generalizability and external validity of these findings.

CONCLUSION

This multicentre randomized controlled trial demonstrates that adjunctive HPTC wrapping is associated with superior early and intermediate-term outcomes following extensor tendon repair. Improvements in total active motion, grip strength, extensor lag, and patient-reported function were sustained through 5 months of follow-up, accompanied by lower rates of adhesion-related morbidity and secondary procedures. These findings suggest that HPTC may represent a promising biologic adjunct for enhancing tendon healing and functional recovery following extensor tendon repair, supporting the concept that biologic modulation of the peritendinous healing environment, rather than reliance on surgical technique and rehabilitation alone, plays a critical role in optimizing tendon healing. Further adequately powered multicentre studies with

longer follow-up are required to confirm these findings and better define the role of HPTC in extensor tendon surgery.

Ethics approval and consent to participate

The study was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines. Ethical approval was obtained from the Institutional Ethics Committee of Adichunchanagiri Institute of Medical Sciences (Approval No.: AIMS/IEC/270/2025), Mysore Medical College (Approval No.: MMC EC 07 26) and from the Institutional Ethics Committees of the participating centres. The trial was prospectively registered at ClinicalTrials.gov (Identifier: NCT07335653; first registered on 02/01/2026). Written informed consent was obtained from all participants prior to enrolment.

Consent for publication

Written informed consent for publication of anonymized clinical data and intraoperative images was obtained from all participants. No identifiable personal information is included in this manuscript.

Availability of data and materials

The datasets generated and analysed during the current study are available from the corresponding author on reasonable request. Data are stored in a secure institutional research database with coded participant identifiers to ensure confidentiality.

Competing interests

The authors declare that they have no competing financial or non-financial interests related to this study. The investigators had full control of study design, data collection, analysis, interpretation, and manuscript preparation. The manufacturer of the collagen matrix had no role in the conduct or reporting of the study.

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Authors' contributions

NN - conceived the study, performed surgeries, supervised data collection, and drafted the manuscript.

VK and SNG contributed to surgical procedures, patient recruitment, and clinical assessments.

SS and BSK participated in data acquisition, follow-up evaluations, and database management. All authors contributed to study design, critically revised the manuscript for intellectual content, and approved the final version.

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