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A case study to evaluate the efficacy and safety of Tendoshot Pro in tendon injury [Knee sprain, Ankle sprain (Achilles Heel), shoulder dislocation, post-operative recovery, plantar fasciitis] Patients of grade 2

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Abstract
Introduction: Tendon injuries can be categorized into acute or chronic and result in significant pain and loss of tendon function. The recovery of tendon damage is a complex and time-consuming recovery process. Tendon injuries produce considerable morbidity and cause disability for several months despite appropriate management. Nutritional interventions, e.g. intake of collagen, are a plausible, potential strategy to improve the prevention and healing of tendinopathy. Adequate intake of nutrients – macronutrients as well as micronutrients – is of great importance. Hence, the test product Tendoshot Pro tablet which is a synergistic blend of Protein hydrosylate, Marine collagen peptide, Chondroitin, Vitamin C, Vitamin D3, Vitamin B6, Vitamin B12, Magnesium, Zinc, Nano curcumin, Sodium hyaluronate, Manganese is evaluated in this study.
Aim: This study was designed as a single-arm, interventional case study aimed at evaluating the efficacy, safety and tolerability of Tendoshot Pro in Tendon Injury patients.
Materials and methods: Thirty adult patients with grade 2 tendon injuries of the knee, ankle, or shoulder were enrolled based on predefined inclusion and exclusion criteria. Participants received Tendoshot Pro (one tablet twice daily) alongside standard care for 12 weeks. Clinical assessments - including VAS pain scores, Activity Limitation Scale (MLQoL), ESR, hs-CRP, Global Rating of Change, SF-12 quality-of-life scores, and MRI imaging—were conducted at baseline and follow-up visits at weeks 4, 8, and 12. Safety was monitored through adverse event reporting and laboratory evaluations. Statistical analysis was performed using SPSS v21.0 with appropriate parametric and non-parametric tests. Participants were monitored throughout the study to evaluate primary and secondary outcome measures.
Results: VAS pain scores significantly decreased from 6.6 ± 1.8 at baseline to 3.06 ± 0.89 at week 12 ($p < 0.001$). ESR and hs-CRP levels showed marked reductions, indicating systemic anti-inflammatory effects. 73% of patients returned to pre-injury activity levels by week 12. SF-12 scores improved across physical and emotional domains, and MRI imaging confirmed tissue recovery. Mild gastrointestinal side effects were reported in 3 patients, with no serious adverse events.
Conclusion: Tendoshot Pro demonstrated statistically significant improvements in pain management, inflammation control, functional recovery and quality of life, with a favorable safety profile. These findings support its role as a valuable adjunct in tendon injury.

Keywords: Tendon injury, tendoshot pro, visual analog scale (vas), activity limitation scale

Introduction

Tendons are fibroblastic structures that link muscle and bone. Tendon injuries can be categorized into acute or chronic and result in significant pain and loss of tendon function. The recovery of tendon damage is a complex and time-consuming recovery process [1]. Tendon injuries produce considerable morbidity and cause disability for several months despite appropriate management. Injuries due to overuse of tendons account for 30% of all running-related injuries (athletes) [2]. Tendon injury may be secondary to acute trauma (e.g., rupture, laceration) or repetitive loading (e.g., overuse injury) [3]. Tendon-to-bone healing is a complex and slow process, including inflammation, proliferation, matrix synthesis, and matrix remodeling. Tendon vascularity (blood supply) is compromised at junctional zones and sites of torsion, friction, or compression. Moreover, tendon blood flow decreases with increasing age and mechanical loading [4]. Healing problems of the enthesis (part between the soft tendon and hard bone) may lead to undesired disabilities. Ischemia occurs when a tendon is under maximal tensile load. On relaxation, reperfusion occurs, generating reactive oxygen species (ROS); this may cause tendon damage, resulting in tendinopathy [5].

Nutritional interventions, e.g. intake of collagen, are a plausible, potential strategy to improve the prevention and healing of tendinopathy. Adequate intake of nutrients – macronutrients as well as micronutrients – is of great importance. Hence, the test product Tendoshot Pro tablet which is a synergistic blend of Protein hydrosylate (350mg), Marine collagen peptide (150mg), Chondroitin (200mg), Vitamin C (35mg), Vitamin D3 (10mcg), Vitamin B6 (1.5mg), Vitamin B12 (1mcg),
Magnesium (90mg), Zinc (5mg), Nano curcumin (250mg), Sodium hyaluronate (45mg), Manganese (2.5 mg) is evaluated in this study. Protein hydrolysates provide a rich source of protein - useful in conditions with excess protein needs e.g. for repair of tissue damage. They enhance repair

of tissue damage caused by surgery, ulcers, burns and muscle-damaging exercise [6]. Collagen also contributes ~ 65–80% dry weight of tendons, with collagen crosslinks aiding the tendon structure to endure resistance from high-impact stresses and shear forces. Thus, collagen plays a vital role in maintaining tendon health and mitigating potential injury-risk in sport [7, 8]. Dietary amino acid solutions, especially those rich in leucine and glycine is effective in enhancing collagen synthesis and heals tendon injury. Leucine directly influences signaling pathways to promote muscle protein synthesis. Small leucine-rich proteoglycans (SLRPs) link and interact with collagen fibrils to regulate tendon structure and biomechanics, which can provide a new and promising method in the field of tendon injury management [9]. Vitamin C and Taurine provides antioxidant action for faster tendon healing. Glycine shows direct effects on extracellular matrix tissue synthesis [10]. Taurine may reduce fibrosis and elevate repair integrity due to both antioxidant and anti-inflammatory effects, and inhibition of fibronectin expression and fibrin formation during healing. Application of nano-curcumin at the tendon repair site can significantly inhibit the early local inflammatory reactions, and prevent tendon adhesion [11].

The Tendoshot Pro is indicated for Achilles' heel tendinopathy, plantar fasciitis, tendon tear/rupture, sprain and after major orthopedic surgery. This study was designed as a single-arm, interventional case study aimed at evaluating the efficacy, safety and tolerability of Tendoshot Pro in Tendon Injury patients.

Materials and methods

This was a single arm, interventional case study done in Thirumalai Medical Centre, Puducherry for a period of 16 weeks. The study has been done after obtaining permission from Independent Ethics Committee - Ethique De La Nature (IEC approval number –EC/027/23-24) and registered with CTRI [Trial Number CTRI/2024/03/064567]. The development of study protocol, conduct of the study, data entry, followed by statistics and report were done in compliance with the ICH GCP, the Quality Policies and Standard Operating Procedures set forth by the organization.

Inclusion criteria

Participants who fulfilled the following criteria were enrolled in the study:

- Male or female patients aged more than 18 years with grade 2 tendon injury of knee, ankle or shoulder – with or without dislocation.
- Pain defined by a level of greater than or equal to 3 on a 10 Visual Analogue Scale (VAS)
- Patient who had not participated in any other clinical trial during the past 3 months.
- Patients, who were willing to give written, signed and dated informed consent to participate in the study.

Exclusion criteria:

Participants with the following criteria were excluded from the study:

- Prior knee/ankle /shoulder surgery;
- Torn or avulsed tendon;
- Periarticular or long bone fracture that is anticipated to preclude weight-bearing after surgery;
- Required use of an external fixator for greater than 10 days;
- Planned staged surgical treatment;
- Unable to bear weight on the contralateral uninjured leg;
- Traumatic brain injury (TBI) that limits their ability to participated in their post-operative care;
- Any condition that would preclude the ability to comply with post-operative guidelines
- Moderate to severe renal impairment
- Pregnant or lactating women
- History of hypersensitivity to any of the test products.
- Any condition decided as unfit for study by clinical investigator

Sample size: Sample size was calculated using Sample Size Calculator Pro. Version 1.0. considering the hypothetical proportion before treatment as 90% and proportion after treatment as 20%. With alpha error 0.05 and beta error 0.2. The required minimum sample size was calculated to be 30.

Study Procedure

All the study participants who satisfied the study criteria were included in the study. The study protocol, CRFs, product related information and informed consent form (in English & Tamil) were submitted to the Human Ethics Committee for necessary approval. Ethics Committee approval was obtained before initiating the trial from the site. Only after obtaining proper informed consent from the study participants, the study commenced, complying with the study protocol. Thirty patients with tendon injury (knee sprain, ankle sprain, shoulder dislocation, post-operative recovery, plantar fasciitis) of grade 2, with equal distribution of cases were enrolled in the study. Demographic data (height, weight, BMI and age), personal history pertaining to cardiovascular disease, medical history, vitals and systemic examination were done at screening. Blood sample was taken for ESR and CRP levels. Baseline VAS score and Activity Limitation Scale score were also assessed. Every participant underwent a thorough general and systemic examination. The enrolled patients were requested to self-administer the test product - Tendoshot Pro, one tablet twice daily orally for 12 weeks along with the standard of care treatment. Patients were asked to visit clinical facility/institution for their follow up at the end of week 4, week 8 and week 12 and any other additional visits if needed. For 24 hours prior to subject admission to the study site and throughout the study period, patients were not allowed to consume alcohol or foods containing a caffeine-like substance (such as coffee, tea, soft drink and chocolate). If concomitant medication was required during the study period (systemic antibiotics and analgesics), all such concomitant drug administrations were documented in relevant forms. Participants were monitored throughout the study.

Any subject who developed any adverse reactions or clinically significant abnormal laboratory test values was evaluated by the Clinical Investigator and was treated and/or followed up until the symptoms or values returned to normal or acceptable levels, as judged by the Clinical Investigator. A physician at the study administered treatment for any serious adverse reactions. All serious adverse events were informed to the IEC within 1hr and to the sponsor within 24 hrs. The detailed report reached the sponsor within 7 calendar days. At the beginning of the second period, patients were questioned concerning unusual symptoms,

which may have occurred after the previous administration of the Test Product. In addition, patients will be regularly questioned about their well-being throughout the course of their stay.

Evaluation Criteria:

a. Primary Outcome Measures

- Changes from baseline to 16 weeks in pain intensity measured by Visual analogue scale (VAS Scale) (0-10) [12]
- Time to return to pre-injury level of activity
- Patient reported physical function on Activity Limitation Scale of the Multiple Ligament

Quality of Life (MLQoL) Questionnaire [13]. (The Activity Limitation Scale of the Multiple Ligament Quality of Life scale measures the degree of difficulty an individual with multiple tendon injury experiences with simple and complex activities as related to his/her knee. The Activity Limitation Scale score ranges from 0 to 100 with a score of 0 representing no activity limitations due to the multiple tendon injury).

- Changes from base line to 12 weeks in following laboratory parameter(s):
- hs- C Reactive Protein and ESR
- Global Rating of Change (GRC) [Time Frame: 3 months]

(The Global Rating of Change asked the individual to compare his/her current functional status to his/her functional status at the time of enrolment /post-injury. The responses for the Global Rating of Change range from +7 (greatly better) to -7 (greatly worse). Higher scores representing greater improvement in function since the time of enrolment /post-injury)

- Changes from baseline to 3 months in Quality of life-Questionnaires (Short Form Health-12)
- MRI Scan during pre and post study was done for few representative samples.

b. Secondary Outcome Measures

- The safety and tolerability of study product was assessed by monitoring clinical AEs, including laboratory abnormalities.

Statistical Analysis

Descriptive statistics were given for baseline characteristics like age, sex and any adverse events and tolerability profiles. All the other results will be compared and evaluated using Chi square/ Fisher's exact test or student t test between the baseline and post study data by SPSS software version 21.0.

Results

Thirty patients (N = 30) were screened and enrolled in a single group. All the patients completed the study. The distribution of participants according to their diagnosis were: Post surgical patients-9, Shoulder/ ankle sprain (Achilles Heel)-4, Plantar Fasciitis-8 and Shoulder dislocation-9 [Figure-1].

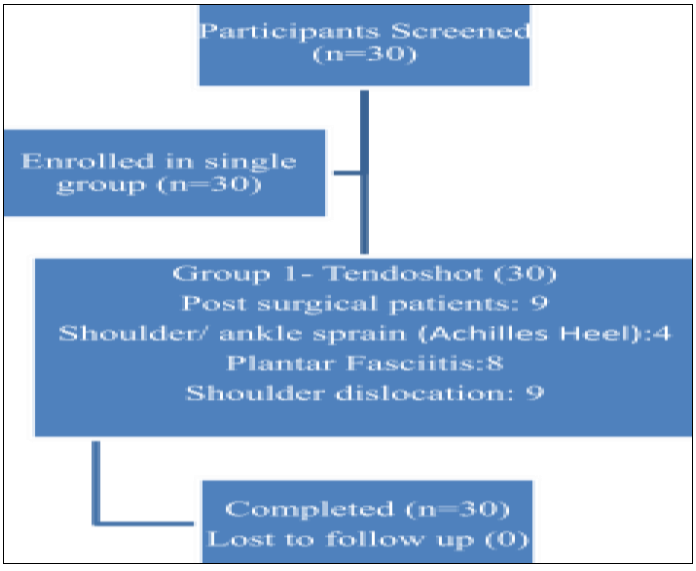

Fig 1: Participant Flow Diagram

Among them, males were 20 (67%) and females were 10 (33%). The mean age of the participants was 50.60 ±9.49 years. The mean BMI of the study participants were 25.06 ±1.88 (kg/m^2) [Table-1].

Table 1: Demographic details of the patients

Demographic data	Statistics	Value
Age (in years)	Mean ± SD	50.60 ±9.49
BMI (kg/m^2)	Mean ± SD	25.06 ±1.88
Gender N (%)	Male	20 (67%)
	Female	10 (33%)

There is a significance reduction in VAS pain score from 6.6 ± 1.8 (mean±SD) in baseline to 3.06 ± 0.89 (mean±SD) in week 12. There is a statistically significant improvement in the VAS pain score at week 4, week 8, and week 12 compared to baseline, post-treatment with Tendoshot Pro along with standard of care treatment [Table-2].

Table 2: Joint pain intensity measured by pain VAS Scale:

Sl. No.	Group		Pain VAS Scale (0-10) (Mean ± SD)			
			Day 0	Week 4	Week 8	Week 12
1	Tendoshot (n=30)	Pro	6.6 ± 1.8	4.5 ± 1.10 *	3.7 ± 1.32*	3.06 ± 0.89*
2	P value			*P < 0.0001	*P < 0.0001	*P < 0.0001

*P < 0.001 is considered statistically significant.

Twenty-two patients (73%) returned to pre-Injury Level of Activity with Tendoshot Pro treatment by 12 weeks, whereas 8 (27%) patients who recovered in 8 weeks, underwent surgical management along with Tendoshot Pro treatment. There is a significant improvement in the Activity Limitation Score from pre to post-treatment with Tendoshot Pro along with standard of care treatment [Table-3].

Table 3: Activity limitation score (Pre and Post Study): Score ranges from 0 to 100 with a score of 0 representing no activity limitations

Sl. No	Questionnaire	Activity score Pre (Mean)	limitation study	Activity limitation score Post study (Mean)
1	Straightening your knee/ankle/shoulder is difficult or impossible.	100		10
2	Sitting is difficult due to your knee/ankle/shoulder	70		5
3	It is difficult to rise from bed due to your knee/ankle/shoulder	100		5
4	Walking on flat surfaces is difficult due to your knee/ankle/shoulder.	70		0
5	Lying in bed is difficult due to your knee/ankle/shoulder (including turning over and maintaining knee position).	70		10
6	Going shopping is difficult due to your knee/ankle/shoulder	90		10
7	Putting/removing on socks and/or stockings is difficult due to your knee/ankle/shoulder	80		0
8	Getting on and/or off the toilet is difficult due to your knee/ankle/shoulder	70		5
9	You need support during walking due to your knee/ankle/shoulder problem (i.e., a cane, crutches, walker, or other person).	70		10
10	You require a wheelchair due to your knee/ankle/shoulder problem	30		0
11	Your knee/ankle/shoulder condition makes you limit light duties	70		0
12	Your knee/ankle/shoulder limits your daily activity level	70		0
Sl. No	Questionnaire	Activity score Pre (Mean)	limitation study	Activity limitation score Post study (Mean)
13	Your knee/ankle/shoulder condition makes you limit moderate work	70		10
14	Bending your knee/ankle/shoulder is difficult	100		10
15	Your knee/ankle/shoulder makes it difficult to participate in your favourite sport or recreational activity.	100		20
	P value			<0.0001

*P < 0.001 is considered statistically significant.

There is a statistically significant improvement in the primary inflammatory markers like ESR and hs- CRP from baseline to week 12 after treatment with Tendoshot Pro along with standard of care treatment. ESR has reduced from 25.5 ± 5.3 mm/hr in baseline to 13.06 ± 5.19 mm/hr in week 12, similarly hs-CRP has reduced from 6.12 ± 1.8 mg/L in baseline to 4.1 ± 1.1 mg/L in week 12. There is also a statistically significant improvement in the Participant's Global Rating of Change at week 8 and week 12 compared to baseline post-treatment with Tendoshot Pro along with standard of care treatment [Table-4].

Table 4: Changes from baseline to 12 weeks in Inflammatory markers and Global Rating of Change

Sl. No.	Group	Esr (mean ± Sd)		Hs-crp (mean ± sd)		Global rating of change (mean ± sd)			
		Day 0	Week 12	Day 0	Week 12	Day 0	Week 4	Week 8	Week 12
1	Tendoshot Pro (n=30)	25.5 ± 5.3	13.06 ± 5.19*	6.12 ± 1.8	4.1 ± 1.1*	-5.9 ±2.9	-5.1 ± 2.7*	2.15 ± 0.90*	3.4 ± 1.09*
2	P value	*P < 0.0001		*P < 0.0001			P = 0.27	*P = 0.0019	*P < 0.0001

*P < 0.001 is considered statistically significant.

Treatment with Tendoshot pro demonstrated statistically significant improvement in physical functioning**,** general health perception**,** pain management, and some aspects of emotional well-being over the study period. These findings suggest a positive impact of the treatment on health-related quality of life. There is a significant improvement in the mean percentage scores of most the SF-12 domains after treatment for week 12 with Tendoshot Pro [Table-5].

Table 5: Changes from baseline in Quality of life- Questionnaires (Short Form Health-12)

Sl. No.	Questionnaire	Tendoshot Pro (%) (N=30)	
		Day 0	Week 12
1	In general, would you say your health is: *		
	Excellent	0	0
	Very good	0	57
	Good	24	43
	Fair	70	0
	Poor	6	0
2	Moderate activities such as moving a table, pushing a vacuum cleaner, or playing. *		
	YES, limited a lot	76	0
	YES, limited a little	24	43
	No, not limited at all	0	57
3	Climbing several flights of stairs. *		
	YES, limited a lot	76	0
	YES, limited a little	24	43
	No, not limited at all	0	57
4	Accomplished less than you would like (due to problems in physical health) *		
	Yes	94	16
	No	6	84
5	Were limited in the kind of work or other activities (due to problems in physical health) *		
	Yes	94	16
	No	6	84
6	Accomplished less than you would like (due to any emotional problems) *		
	Yes	94	16
	No	6	84
7	Did work activities less carefully than usual. (due to any emotional problems) *		
	Yes	94	16
	No	6	84
8	During the past 4 weeks, how much did pain interfere with your normal work (Including work outside the home and housework)? *		
	Not at all	0	20
	A little bit	6	80
	Moderately	24	0
	Quite a bit	50	0
	Extremely	20	0
9	Have you felt calm & peaceful? *		
	All of the time	0	20
	Most of the time	6	80

Sl. No.	Questionnaire	Tendoshot Pro (%) (N=30)	
		Day 0	Week 12
	A good bit of the time	24	0
	Some of the time	50	0
	A little of the time	20	0
	None of the time	0	0
	Did you have a lot of energy? *		
	All of the time	0	20
	Most of the time	6	80
	A good bit of the time	24	0

10	Some of the time	50	0
	A little of the time	20	0
	None of the time	0	0
11	Have you felt downhearted and blue?		
	All of the time	20	0
	Most of the time	50	0
	A good bit of the time	24	0
	Some of the time	0	0
	A little of the time	0	80
	None of the time	0	20
12	During the last 4 weeks, how much of the time have y our physical health or emotional problems Interfered with your social activities (like visiting friends, relatives, etc.)? *		
	All of the time	20	0
	Most of the time	50	0
	Some of the time	24	0
	A little of the time	0	80
	None of the time	0	20

The side effects observed were mostly gastrointestinal (nausea in 2 patients and gastritis in 1 patient), and no serious adverse events were recorded during the study period. MRI observations of the representative patients before and after treatment has been attached below [Figure 2&3].

Figure 2: Plantar Fasciitis

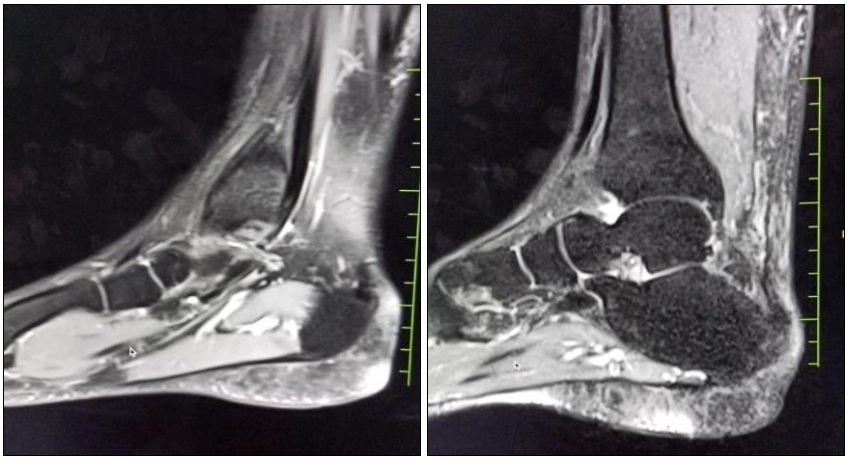

Fig 1a: **Fig 2b:**

Fig 2a: Plantar Fasciitis: Subchondral edema noted at the attachment site of plantar fascia. Soft tissue edema noted around the plantar fascia, Findings are suggestive of Plantar fasciitis. (Subject- S- 1)

Fig 2b: Post treatment image. Patient symptomatically improved. On MRI, there is resolution of edema in the soft tissues around plantar fascia. There is resolution of subchondral edema as well.

Figure 3: Complete tear of the Supraspinatus tendon

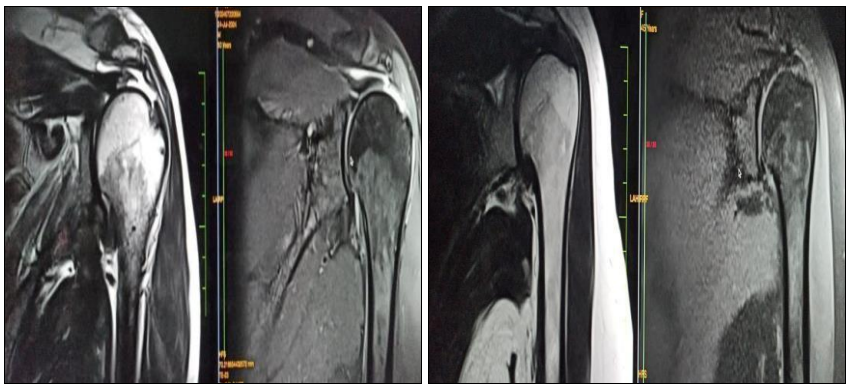

Fig 3a: **Fig 3b:**

Fig 3a: Complete tear of the Supraspinatus tendon from its insertion site at the Greater tubercle. Mild effusion in the Subacromialsubdeltoid bursa (s- 7)

Fig 3b: Post intervention (surgical)-Tendinopathy changes noted in the Supraspinatus tendo

Discussion

Tendon injuries, including tendinopathies and partial tears, often leads to chronic pain and impaired mobility. The healing process is complex due to the tendon's limited vascularity and high mechanical demands, making effective therapeutic strategies essential. Recent advances in regenerative medicine emphasize the role of collagen supplementation, anti-inflammatory agents, and micronutrients in accelerating tendon repair. Tendoshot Pro, a multi-component supplement containing nano-curcumin, collagen peptide type I, chondroitin sulfate, and sodium hyaluronate, has shown promising results in enhancing tendon healing by modulating inflammation, promoting collagen synthesis, and improving joint lubrication. Curcumin, in particular, has demonstrated potent anti-inflammatory effects by downregulating NF-κB and COX-2 pathways, contributing to reduced pain and improved tissue regeneration in tendon injuries [15]. Collagen peptides have also been shown to stimulate tenocyte activity and extracellular matrix production, which are critical for tendon remodeling [16].

This study evaluated the efficacy and safety of Tendoshot Pro in conjunction with standard care for tendon injuries. The results demonstrate statistically significant improvement across multiple clinical parameters, including pain reduction, inflammatory markers, functional recovery and quality of life. The significant reduction in VAS pain scores from 6.6 ± 1.8 to 3.06 ± 0.89 over 12 weeks reflects robust analgesic and anti-inflammatory effects. These findings are consistent with prior evidence showing that curcumin and chondroitin sulfate—key components of Tendoshot Pro—exert potent anti-inflammatory actions by modulating NF-κB and COX-2 pathways, thereby reducing pain and improving mobility [17].

The return to pre-injury activity levels in 73% of patients by week 12, and the improvement in Activity Limitation Scores, suggest accelerated functional recovery. This aligns with the systematic review by Giraldo-Vallejo *et al*., which emphasized the role of targeted nutritional strategies—including collagen peptides and hyaluronic acid—in enhancing tissue repair and restoring physical performance in athletes. Collagen peptide type I, present in Tendoshot Pro, has been shown to stimulate tenocyte proliferation and extracellular matrix synthesis, both critical for tendon and ligament healing [18].

Biochemical improvements in inflammatory markers—ESR and hs-CRP—further support the anti-inflammatory efficacy of the formulation. These reductions resemble findings from studies where curcumin supplementation led to significant decreases in systemic inflammation in patients with joint and soft tissue disorders [19]. The observed improvements in the Participant's Global Rating of Change and SF-12 domains, including physical functioning and emotional well-being, underscore the broader impact of Tendoshot Pro on health-related quality of life. This is in line with emerging evidence that integrative nutritional therapies can positively influence both physical and psychosocial recovery metrics. The safety profile of Tendoshot Pro was favorable, with only mild gastrointestinal side effects and no serious adverse events. MRI observations further corroborated clinical improvements, showing reduced edema and improved tissue integrity post-treatment.

Conclusion

The test product Tendoshot Pro when given as a supplement to the current standard of care management, has proved to be very safe and effective in the management of tendon injury (knee sprain, ankle sprain, shoulder dislocation, post-operative recovery, plantar fasciitis) patients, by reducing inflammation, providing adequate pain relief, improving the tendon healing both posts operatively and in conservative management. It improves the patient's functional capacity and collagen synthesis, promoting better healing and reconstruction of the joint tissues, without causing any major side effects or drug interactions.

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