

A Randomized Clinical Study to Assess the Clinical Efficacy of Fat Injection Along with Conventional Approach in Patients with Flexor Tendon Injury

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Abstract:

Aim: The aim of the present study was to assess the clinical efficacy of fat injection along with conventional approach in patients with flexor tendon injury.

Methods: This randomized clinical trial study was performed on 100 patients suffering acute hand traumatic surgery with flexor tendon injury (zones II or III) that were scheduled for surgical repairing method in the Department of Plastic Surgery Nalanda Medical College and Hospital, Patna, Bihar, India. Patients were randomly classified into two groups, so that 50 cases were treated with the conventional method along with fat injection, and 50 cases were treated with the conventional method alone.

Results: There were 81% males in the study as compared to the females. Majority of the patients had education level upto academic degree. Mean body mass index in both the groups were 24.56 ± 1.44 and 14.16 ± 1.54 respectively. The two groups were similar in baseline characteristics including gender, average age, educational level, mean body mass index, underlying disorders, the time of trauma and History of Diseases including Diabetes, Hypertension, Ischemic Heart disease & Skin disorders and the involved zone and type of trauma (blunt or penetrating). Regarding treatment outcome with respect to post-procedural complications, in the second week after treatment, cellulitis, infection, and abdominal symptoms were observed in a few patients in both groups, and there was no difference between the two groups. In the fifth week after the treatment, the average adjusted Strickland score was 37.23 ± 12.84 and 38.82 ± 10.92 respectively, which showed no difference between the two groups. However, in the eighth week after treatment, the average Strickland score was 79.91 ± 18.22 and 66.94 ± 18.52 respectively, which was significantly higher in the first group.

Conclusion: Fat injection as a complementary treatment along with the usual method of reconstructive surgery is associated with accelerating the recovery and repair of the flexor tendon. In this regard, adding fat injection to the conventional method is a safe method and does not lead to an increase in postoperative complications.

Keywords: Fat injection; Flexor tendon; Repair.

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Introduction

Adherence of tendons is a common complication of tendon surgery, and becomes an important problem when skin and deep tissue, as well as bone are involved. Tenolysis is required to remove scar and free tendons to their original ROM, but this surgery is affected by a moderate/high level of incidence of relapse. [1] Among the methods the surgeon can apply to reduce further scarring, steroid injections and anti-adherence materials [2] have been attempted: steroids having proven poorly effective, whilst antiadherent materials, even if effective in the literature as well as in the corresponding

author's direct experience [3], remain too expensive. Another interesting approach is represented by bringing adipofascial gliding flaps, such as omentum [4] or perforator flaps. [5]

Hyaluronic acid (HA) is an important component of articular cartilage; it is present as a coat around chondrocytes, where it bounds to aggrecan monomers, which imbibe water and are responsible for the resilience of cartilage (i.e., resistance to compression). [6] Moreover, HA is a major component of the synovial fluid, and, along with lubricin, it is one of the fluid's main lubricating

components. The biological activities of HA are very complex: (a) it inhibits matrix metalloproteinases (MMPs) and the phagocytic activity of macrophages and leukocytes; (b) it promotes the release of prostaglandins and the production of tissue inhibitor of MMP-1 and favours the normalization of native hyaluronan synthesis; (c) it acts as free radicals scavenger and stimulates proteoglycans synthesis by chondrocytes; (d) finally, it is provided of protective effects on chondrocytes or cartilage explants from degradation by enzymes. [6]

The use of fat grafting as an adjunct to tendon repair appears to be very promising due to its high potential in enhancing tenocyte regeneration and its organization into structures that resemble a healthy functional tendon complex. [7] Despite the evolution and progress in tendon surgeries over the past decades, a significant proportion of patients have not experienced satisfactory results, primarily due to adhesions between the tendon and its surrounding tissues. [8] As a result, hand surgeons have begun to adopt protocols to minimize adhesions and thereby improve tendon slippage. According to some studies, patients who received fat injections had less adhesions compared to patients who were treated and managed without fat injections. [9]

Regarding the side effects after fat injection, contradictory results have been obtained. One study showed that those who received fat injections had a higher infection rate than those who did not, which may be attributed to the viability and survival of fat tissue as well as its tissue necrosis. [10] On the other hand, fat injection and graft seem to have a significant effect on tendon and joint range of motion, although this material does not seem to have an effect on tendon-related passive range of motion. In general, regarding the consequences of using fat injection, the results of studies have been very diverse.

The aim of the present study was to assess the clinical efficacy of fat injection along with conventional approach in patients with flexor tendon injury.

Materials and Methods

This randomized clinical trial study was performed on 100 patients suffering acute hand traumatic surgery with flexor tendon injury (zones II or III) that were scheduled for surgical repairing method in the Department of Plastic Surgery, Nalanda Medical College and Hospital, Patna, Bihar, India for one year. The inclusion criteria were acute hand flexor tendon injury, patient availability and their consent to participate in the study. The simultaneous cut of both finger arteries, no return in the follow-up, previous surgeries on the hand, age over 50 years, lack of regular physical therapy,

and a history of previous complicating diseases joints like rheumatism and osteoarthritis and chronic systemic diseases like diabetes were considered as the exclusion criteria. Informed consent was obtained from all individual participants involved in the study. Patients were randomly classified into two groups, so that 50 cases were treated with the conventional method along with fat injection, and 50 cases were treated with the conventional method alone.

Study Intervention

Patients were randomly assigned to two groups. In one group, tendon repair was performed using the usual modified Kessler four-strand method, and in the other group, repair was done in the same way, but during tendon repair, fat was injected on the proximal and distal sides of the repair site. Patients with deep flexor tendon injuries in zones two and three were included in the study, and tendon injuries were studied in the same two groups. 10 cc of fat tissue was removed from the inguinal area by the Coleman method. Then it was centrifuged at 3000 rpm for 3 minutes. The patients underwent flexor tendon repair by a modified Kessler method by a single surgeon, and then the adipose tissue obtained from centrifugation was injected in the proximal and distal sides at a distance of two millimeters to one centimeter from the repair site in the amount of one cc. The assessment tool used in this study was a questionnaire developed by the researcher, which was designed according to the demographic information of the patients from the file and the goals investigated in the study. In the next visit to the clinic, the course of physical therapy and serial examinations of the patient was recorded. In the 5th and 8th week after the repair, the function status of the repaired tendon was evaluated with the strick lands grading test. The range of motion (by physical examination) and flexion and extension gaps (based on radiography) were also assessed.

Statistical Analysis

For statistical analysis, results were presented as mean \pm standard deviation (SD) for quantitative variables and were summarized by frequency (percentage) for categorical variables. Continuous variables were compared using t test or Mann-Whitney test whenever the data did not appear to have normal distribution or when the assumption of equal variances was violated across the study groups. The Chi-Square test or Fisher's exact test were used to compare the categorical variables. P values of ≤ 0.05 were considered statistically significant. For the statistical analysis, the statistical software SPSS version 23.0 for windows (IBM, Armonk, New York) was used.

Results

Table 1: Baseline characteristics of study population

Characteristics	Groups		P value
	Fat injection (+)	Fat injection (-)	
Male gender, %	40 (80)	41 (82)	1.000
Education level, %			0.314
Undergraduate	6 (12)	3 (6)	
Diploma	24 (48)	17 (34)	
Academic degree	20 (40)	30 (60)	
Mean age, year	35.05±6.94	34.64±7.05	0.350
Mean body mass index, (kg/m ²)	24.56±1.44	25.25±1.55	0.418
Mean time of accident, (hour)	15.40±1.76	14.16±1.54	0.428

There were 81% males in the study as compared to the females. Majority of the patients had education level upto academic degree. Mean body mass index in both the groups were 24.56±1.44 and 14.16±1.54 respectively.

Table 2: History of Diseases

History of Diseases, %	Groups		P value
	Fat injection (+)	Fat injection (-)	
Diabetes, %	3 (6)	6 (12)	0.664
Hypertension, %	6 (12)	8 (16)	0.723
Ischemic heart disease, %	3 (6)	2 (4)	0.565
Skin disorders, %	3 (6)	18 (9)	0.654
Allergy, %	3 (6)	2 (4)	0.560
Alcohol/substance use, %	3 (6)	2 (4)	0.670

Table 3: Zone & Type of Trauma

Groups	Involved zone		Types of trauma	
	II	III	Blunt	Penetrating
Fat injection (+)	17 (34)	33 (66)	26 (52)	24 (48)
Fat injection (-)	20 (40)	30 (60)	28 (56)	22 (44)
P value	0.823		0.812	

The two groups were similar in baseline characteristics including gender, average age, educational level, mean body mass index, underlying disorders, the time of trauma and History of Diseases including Diabetes, Hypertension, Ischemic Heart disease & Skin disorders and the involved zone and type of trauma (blunt or penetrating). Table 1-3)

Table 4: Regarding treatment outcome

Follow UP	Characteristics	Fat injection (+)	Fat injection (-)	P value
2-week	Cellulitis	3 (6)	2 (4)	0.540
	Infection	2 (4)	3 (6)	0.560
	Abdominal sign	2 (4)	0	0.314
5-week	Mean Strickland score	37.23 ± 12.84	38.82 ± 10.92	0.565
	Surgical complication, %	0 (0.0)	0 (0.0)	---
8-week	Mean Strickland score	79.91 ± 18.22	66.94 ± 18.52	0.007
	Surgical complication, %	0	0	---
	Range of motion	52.00±4.36	38.42±4.86	0.001
	Mean flexion gap	1.92±0.58	2.26±0.64	0.034
	Mean extension gap	1.28±0.42	1.66±0.84	0.048

Regarding treatment outcome with respect to post-procedural complications, in the second week after treatment, cellulitis, infection, and abdominal symptoms were observed in a few patients in both groups, and there was no difference between the two groups. In the fifth week after the treatment, the average adjusted Strickland score was 37.23 ±

12.84 and 38.82 ± 10.92 respectively, which showed no difference between the two groups. However, in the eighth week after treatment, the average Strickland score was 79.91 ± 18.22 and 66.94 ± 18.52 respectively, which was significantly higher in the first group.

Discussion

Tendon injuries are currently treated with conservative treatments or surgery. However, scientific evidence has shown that, in general, non-surgical treatment is less successful, with only 60% of repaired tendons being functional. In addition, up to 29% of patients needed surgical treatment after failure of conservative treatments. [11] Therefore, surgery will be the main option followed by allogeneic transplantation. Besides considering some complementary and conservative methods along with surgical repair had led to improved outcomes after treatment. [12,13] Current conservative and favorable strategies for treating tendon disorders include a combination of shock wave therapy, exercise therapy, ultrasound therapy, low-intensity laser therapy, and fat grafting. [14] For the first time, the method of using stem cell grafts derived from fat or adipose tissue was presented by a team of plastic surgeons and researchers in Pittsburgh. These adipose-derived stem cells (ASCs) have the potential to differentiate into other cell types such as tenocytes and myocytes [15] and have paracrine functions through the release of growth factors and cytokines. [16]

Recently, fat injection and grafting have been used as an effective method to improve more and faster flexor tendon damage. In fact, due to the high potential of SVFs in regenerative repair along with the secretion of growth factors and cytokines, it seems that the injection or graft of adipose tissue to the damaged tendon area will accelerate its healing process. However, few clinical trial studies have been conducted regarding the effectiveness of this treatment method. What we discussed in the present study was to investigate the effectiveness and at the same time the safety of adipose tissue injection as a complementary treatment in the recovery and repair of the damaged flexor tendon. In this regard, a randomized clinical trial study was designed in such a way that one group of patients experienced only the conventional method of repairing the injured flexor tendon and the other group experienced the conventional method along with fat injection. The evaluation of tendon movement status and complications after treatment were examined and compared during eight weeks of treatment. There were 81% males in the study as compared to the females. Majority of the patients had education level upto academic degree. Mean body mass index in both the groups were 24.56 ± 1.44 and 14.16 ± 1.54 respectively. The two groups were similar in baseline characteristics including gender, average age, educational level, mean body mass index, underlying disorders, the time of trauma and History of Diseases including Diabetes, Hypertension, Ischemic Heart disease & Skin disorders and the involved zone and type of

trauma (blunt or penetrating). Most of the studies conducted regarding the effectiveness of fat injection or grafting in healing damaged tissues indicated the effectiveness of this method in tissue healing and repair. In the study of Taha et al [17], patients were randomly divided into two groups in such a way that the first group underwent tendon repair using conventional surgical technique alone, and the second group underwent fat injection after conventional surgical technique. In this study, the total range of motion or TAM after the procedure was significantly higher in the second method. Fat injection also led to a reduction in adhesions around the tendon after surgery.

Regarding treatment outcome with respect to post-procedural complications, in the second week after treatment, cellulitis, infection, and abdominal symptoms were observed in a few patients in both groups, and there was no difference between the two groups. In the fifth week after the treatment, the average adjusted Strickland score was 37.23 ± 12.84 and 38.82 ± 10.92 respectively, which showed no difference between the two groups. However, in the eighth week after treatment, the average Strickland score was 79.91 ± 18.22 and 66.94 ± 18.52 respectively, which was significantly higher in the first group. In Behfar et al.'s study [18], the effect of SVF taken from adipose tissue on the repair of rabbit flexor tendons was studied and it was shown that the amount of repair and stiffness in the eighth week was much higher in the group under fat graft. In Lu et al.'s study [19], local injection of SVF with adipose tissue origin caused a slight increase in collagen in the damaged rotator cuff tendon and therefore accelerated tendon repair. Also, in the study of Polly et al [20], the effect of adipose tissue-derived SVF on tendon repair was investigated, which indicated a significant increase in type I and III collagen. In the study of Rayes et al [21] also in the report of an acute rupture of the posterior tibial tendon in a basketball player, which was done using hamstring tendon transfer and its reinforcement with autologous fat method, favorable results were also reported in tendon healing. Therefore, it can be said for sure that fat injection or grafting in the flexor tendon of the hand accelerates the repair of the damaged tendon by stimulating the production of collagen due to the regenerative potential of SVF.

Conclusion

Fat injection as a complementary treatment along with the usual method of reconstructive surgery is associated with accelerating the recovery and repair of the flexor tendon. In this regard, adding fat injection to the conventional method is a safe method and does not lead to an increase in postoperative complications.

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