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ORIGINAL RESEARCH

A Prospective Study to Compare the Outcomes of Autogenous Semitendinosus Tendon Graft with Modified Weaver Dunn Procedure for Chronic AC Joint Dislocation

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Abstract

Background: In this study, we wanted to compare clinical and functional outcomes of Rockwood's type III, IV, V, VI AC joint dislocation treated with open reduction and internal fixation via modified Weaver-Dunn procedure and autogenous tendon graft reconstruction approach.

Materials and methods: This was a hospital based prospective comparative study conducted among 30 patients who presented with painful, chronic complete AC joint dislocation, aged between 18 and 60 years irrespective of sex in the Department of Orthopaedics, M.K.C.G. Medical College and Hospital, Berhampur, over a period of 24 months from November 2019 to November 2021 after obtaining clearance from Institutional Ethics Committee and written informed consent from the study participants.

Results: The difference between semitendinosus graft procedure and modified Weaver-Dunn procedure was statistically significant with regard to the mean operative time of surgery, the mean pre-operative range of abduction, post-operative range of abduction, the mean pre-operative range of flexion, post-operative range of flexion, the mean pre-operative range of external rotation and post-operative range of external rotation, and the mean CC distance.

Conclusion: MWD is one of the most popular methods but anatomic reconstruction of CC ligament with autogenous STT graft is increasingly getting popular as it provides better stability, diminishes pain and better function as well as better strength is achieved with STT graft technique procedure. Statistically significant difference between the two groups was found in relation to operative time. The average operating time was more in STT group due to graft harvesting from the patient and strength of this graft obviates the need for augmentation with other non-biological devices. In the study we have seen that there is a statistically significant difference between the MWD and STT group in terms of final outcome as STT graft has better OSS, NCS and UCLA score.

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Keywords: Outcomes of Autogenous Semitendinosus Tendon Graft, Modified Weaver Dunn Procedure, Chronic AC Joint Dislocation

Introduction

Of all the joint dislocations, acromioclavicular joint dislocation corresponds to 8.6 % and it represents a major injury to the shoulder girdle. These kinds of dislocations most commonly occur in male patients < 30 years and are associated with contact sports or athletic activity where a direct blow to the lateral aspect of the shoulder occurs and these injuries most commonly occur in high risk group specially playing sports. In 1917, Cadenat described transfer of coracoacromial ligament, a procedure later popularized by Weaver and Dunn. The main objective of open reconstruction is to reduce the AC joint to an anatomic position. It is clear that a gold standard for surgical stabilization of acute, painful AC joint dislocations has yet to be established. Rockwood has classified AC joint dislocation in to 6 types. The treatment of type I and type II is conservative, whereas from type III onwards surgical treatments are now a days preferred.

Objectives

- To evaluate and compare clinical outcome in terms of mobilization between modified Weaver-Dunn procedure and autogenous tendon graft procedure.
- ➤ To evaluate and compare clinical outcome in terms of pain and level of activity in above mentioned patient group.
- To evaluate advantages and disadvantages involved with the use of each approach.
- To compare range of movement of affected shoulder girdle post-operatively in both groups.
- To compare radiological correlation following surgical treatment of AC joint dislocation via two groups.

Materials and methods

This was a hospital based prospective comparative study conducted among 30 patients who presented with painful, chronic complete AC joint dislocation, aged between 18 and 60 years irrespective of sex in the Department of Orthopaedics, M.K.C.G. Medical College and Hospital, Berhampur, over a period of 24 months from November 2019 to November 2021 after obtaining clearance from Institutional Ethics Committee and written informed consent from the study participants.

Inclusion Criteria

- Only those patients who give informed consent were included in the study.
- Rockwood's type II, IV, V, VI AC joint dislocations aged between 18 to 60 years
- Normal neurological and vascular status of the affected limb.
- Injuries more than 3 weeks old.

Exclusion Criteria

- Patients who did not give consent.
- Patients aged less than 18 and more than 60 years.
- Rockwood's type I and II AC joint dislocation.
- Fractures in the distal end clavicle on the same side.
- Inability to take part in post-operative rehabilitation.
- Medical contraindications to surgery.

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- Cervical spine diseases, rheumatoid arthritis, peripheral vascular disease of upper limb, brachial plexus injury.
- Fresh injuries less than three weeks.

Statistical Methods

Data was entered in MS Excel and analysed using Statistical Package for Social Sciences (SPSS) software. Results were presented as tables.

Results

	Age in Years	No. of Patients	Percentage of Total		
Age distribution	20 - 29	7	23.33		
	30 - 39	16	53.33		
	40 - 49	5	16.67		
	50 - 59	2	6.67		
	Total	30	100		
	Age in Years	No. of Patients	Percentage of Total		
Age distribution in study group	20 - 29	3	20		
treated with modified Weaver Dunn	30 - 39	9	60		
procedure	40 - 49	2	13.33		
	50 - 59	1	6.67		
	Total	15	100		
	Age in Years	No. of Patients	Percentage of Total		
Age distribution in STT group	20 - 29	4	26.67		
	30 - 39	7	46.67		
	40 - 49	3	20		
	50 - 59	1	6.66		
	Total	15	100		
	Sex	No. of Patients	Percentage of Total		
Sex distribution in our study group	Male	26	86.7		
• • •	Female	4	13.3		
	Total	30	100		
		Male	Female		
Sex distribution in individual group	STT	14	1		
bea distribution in murvidual group	MWD	12	3		
	Total	26	4		
Demogra	aphic Distribu	tion			
Table 1					

The youngest patient was 22 years of age and oldest being a 54-year-old. The mean age was 35.1 years. The maximum number of cases observed were between the age group of 30 - 39 years (53.33 %). In MWD (Modified Weaver Dunn) procedure, the age ranged from 23 - 54 years, the mean age was 35.67 years with a standard deviation of 7.547. Maximum number of cases belonged to 30 - 39 years age group. The age range in group treated with autogenous semitendinosus tendon graft procedure was 22 to 53 years. The mean age was 34.53 years with a standard deviation of 9.249 with maximum number of patients in 30 - 39 years of age group. The age distribution in the STT group and the MWD group was analysed statistically

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and was not found to be varying significantly (p = 0.716). The male to female ratio was found to be 6.5 : 1 for the study population as a whole. In the modified Weaver Dunn (MWD) procedure, the male to female ratio was found to be 4 : 1 and in autogenous semitendinosus tendon (STT) graft procedure, it was found to be 14 : 1. In MWD group, there were 12 males and 3 females while in STT group, there were 14 males and 1 female. The sex distribution in the MWD procedure group and the STT graft procedure group was analysed statistically and was not found to be varying significantly (p = 0.283 Pearson Chi square).

Side	Frequency	Percentage		MWD		STT Group	
Left	13	43.3 %		7		6	
Right	17	56.7 %		8		9	
Total	30	100 %		15		15	
	Side Distribution						
Mode of Injury	No. of Patients	Total %	No. of Patients in STT Group	STT %	No. of Patients in MWD Group	MWD %	
Self-fall	16	53.3	6	40	10	66.7	
RTA	10	33.3	6	40	4	26.7	
Sports	4	13.3	3	20	1	6.7	
Total	30	100	15	100	15	100	
			Mode of Inju	ry			
Mode of Injury	No. of Patients	Total %	No. of Patients in STT Group	STT %	No. of Patients in MWD Group	MWD %	
Type V	27	90	13	86.67	14	93.33	
Type III	3	10	2	13.33	1	6.67	
Total	30	100	15	100	15	100	
Type of Injury							
Procedure Mean in Minutes			•	Standard deviation			
Semitendin	osus graft	72.00			1.7728		
Modified Wo	Modified Weaver Dunn 49.53		4.6424				
Table 2							

The side distribution in the MWD procedure and SST graft procedure was analysed statistically and was found to be insignificant (p = 0.713; Pearson Chi square. The commonest mode of injury in our patient was self-fall (53.34 %). On the other hand, road traffic accidents were the second most common mode of injury accounting for 33.33 % of total cases, whereas sports injury had only 13.33 %.Out of 15 patients operated for STT, 6 had a history of self-fall, 6 had history of road traffic accidents (RTA) and 3 patients had sports injury. Out of 15 patients who underwent MWD procedure, 10 patients had a history of self-fall, 4 had a history of RTA and 1 patient had sports injury. 27 patients had Rockwood type V AC joint dislocation while other 3 patients had type III AC joint dislocation. We did not encounter any case of Rockwood's type IV or type VI AC joint dislocations. 30 patients were operated under general anaesthesia.

The mean operative time of surgery in semitendinosus graft procedure was 72.00 (ST 1.7728) minutes while in modified Weaver Dunn procedure, the mean was 49.53 (SD 4.6424) minutes. On statistical analysis of the mean operating time of the two groups, the p value was found to be 0.001 (unpaired t test), which is statistically significant.

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Post-operative Pos		Post-operative		Post-operative					
			Abduction	1	Flexion		Exte	rnal Rotation	
ST	Γ		149.80		177.80			64.73	
MW			143.93		172.60			55.60	
	Post-operative Range of Motion in Both the Groups								
Sl. No.			Abduction		Flexion			External	
	MW	D	STT	M	(WD	STT	MWD	STT	
1.	149		150		170	178	49	65	
2.	149		148		176	177	53	72	
3.	136		152		166	178	68	66	
4.	148		149		177	178	56	60	
5.	127		152		178	180	59	63	
6.	148		149	-	177	180	54	66	
7.	143		148		168	177	49	68	
8.	135		152		170	176	56	59	
9.	149		149		172	178	58	64	
10.	148		149		178	179	55	67	
11.	149		149	-	166	66 176		67	
12.	142		149	-	169	69 179		68	
13.	138		150		170	176	59	67	
14.	148		152		175	177	52	66	
15.	150		149		177	178	54	53	
Range of Motions									
CC Distanc	e in mm	MWD Group STT Group			roup				
Operative Non-		Non-(Operativ	-		Non Operative			
Without stress 12.20			11.66		12	2.55	11.38		
With st			15.67		17.14 13.06 15.41		15.41		
	CC Distance in MWD Group and STT Group								
Table 3									

Abduction: The mean pre-operative range of abduction in our study was 85.23 degrees. In STT group, pre-operative range was 85.20 (SD 2.7045) and in MWD group it was 85.26 (SD 3.3481). Post-operative range of abduction in STT group was 149.80 and in MWD group was 143.93. On statistical analysis, comparing the 2 groups, the p value was found to be 0.002 (unpaired t test), which is statistically significant.

Flexion: The mean pre-operative range of flexion in our study was 93.60 degrees. In STT group, pre-operative range was 92.73 (SD 2.763) and in MWD group it was 94.48 (SD 2.325).

Post-operative range of flexion in STT group was 177.80 and in MWD group it was 172.60. On statistical analysis, comparing the 2 groups, the p value was found to be 0.001 (unpaired t test), which is statistically significant.

External rotation: The mean pre-operative range of external rotation in our study was 27.90 degrees. STT group pre-operative range was 28.07 (SD 1.70992) and in MWD group it was 27.73 (SD 1.66762). Post-operative range of external rotation in STT group was 64.73 and in MWD group was 55.60. On statistical analysis, comparing the 2 groups, the p value was found to be 0.0001 (unpaired t test) which is statistically significant.

Radiological outcome: measured by coracoclavicular (cc) distance: Post operatively at 1-month, mean CC distance without stress for 30 patients was 12.38 mm with SD 0.948. With

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stress (10 kg), the mean CC distance was 14.36 mm with SD 1.604. In MWD group, mean CC distance without stress was > 12.21mm with SD 0.544, while in stress mean CC distance was 15.67 mm and SD 1.154. In STT group, mean CC distance without stress was > 12.55mm with SD 0.394 and in stress, the mean CC distance was 13.06 mm and SD 0.597. Post operatively at 1month, mean CC distance in the uninjured side was measured. In the STT group, the mean CC distance without stress was 11.38 mm with SD 0.714. While for the MWD group, the mean CC distance on the uninjured side without stress was 11.66 mm and SD 0.910. In stress with 10 kg weight in uninjured side in the STT group, mean was 15.41 mm with SD 1.600, while in MWD group, it was 17.14 mm with SD 2.70. So post operatively, when MWD group was compared with the uninjured side of the same group in stress, there was a statistically significant correlation (p = 0.008). Similarly, in post-operative period, STT group was compared with the non-injured side for CC distance under stress. There was also statistically significant correlation (p = 0.0001) so when post-operative CC distance between the MWD and ST groups were compared, a statistically significant difference existed during stress loading, when compared with uninjured side. Post operatively at six months, the mean CC distance was compared with the clinical scores of OSS, NCC and UCLA. No significant correlation was found between the mean CC distance without stress and the clinical sores viz NCC (p = 0.951, Pearson's correlation - 0.012), OSS (p 0.636, Pearson's correlation - .038) and UCLA (p = 0.114, Pearson's correlation - 0.294). But there was significant correlation noted between the mean CC distance and the NCC (p = .009, Pearson's correlation - 0.471), OSS (p = 0.001), Pearson's correlation - 0.777), and UCLA (p = 0.014, Pearson's correlation) under stress (10 kg). When post-operative CC distances between MWD and ST groups were compared, a statistically significant difference existed during stress loading, when compared with uninjured side (p = 0.001).

OSS	STT	MWD				
Pre-operative mean	22.80	23.06				
Post-operative mean	51.33	43.13				
OSS	STT	MWD				
Pre-operative mean	48.866	50.733				
Post-operative mean	94.066	91.066				
Post-operative Nottingham Clavicle Score in Both Groups						
UCLA	STT	MWD				
At 6 weeks	15.87	16.73				
At 3 months	22.73	20.93				
After six months	29.87	24.87				
Post-operative UCLA Scores at Different Weeks in Both Groups						
UCLA	MWD	STT				
Poor	15 (100 %)	15 (100 %)				
Reasonable	0	0				
Good	0	0				
Excellent	0	0				
Grading of Post-operative UCLA Score at 6 Weeks						
Table 4						

The mean OSS score preoperatively was 22.80 in STT group with SD 1.373 and was 23.06 in MWD group with SD 1.496. In the postoperative period, the mean value in STT group was 51.33 with SD 1.489 and in MWD group, it was 43.13 with SD 0.915. And when this score

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was compared post-operatively in both the groups, it was found to be statistically significant (p value 0.000).

NCS Score: Preoperatively mean NCS was 48.87 for STT group with SD 3.481 and 50.73 for MWD group with SD 3.432. Postoperatively mean NCS was 94.067 for STT group with SD 3.473 and 91.067 for MWD group with SD 4.233. And when this score was compared postoperatively in both the groups, it was found to be statistically significant (p value 0.043).

The post-operative UCLA scores were compared between both the groups at six weeks. No significant difference was noted between the two groups.

UCLA	MWD	STT			
Poor	8 (53.33%)	1 (6.67%)			
Reasonable	7 (46.67%)	14 (93.33%)			
Good	0	0			
Excellent	0	0			
Grading of Post-operative UCLA Score at 3 Months					
UCLA (6 Months)	MWD	STT			
Poor	0	0			
Reasonable	13 (86.67 %)	3 (20 %)			
Good	2 (13.33 %)	11 (73.33 %)			
Excellent	0	1 (6.67 %)			
Grading of Post-operative UCLA Score at 6 Months					
Complications	STT Group	MWD Group			
Superficial infections	0 (0%)	1 (6.67%)			
Stiffness (up to 6 weeks)	2 (13.33%)	3 (20%)			
Hardware prominence	2 (13.33%)	0			
Post-operative Complications in Both Groups					
Table 5					

When the UCLA scores were compared at third month, significant difference was noted between the two groups (p = .032).

At the sixth month follow up in UCLA score, there was a statistically significant difference between MWD and STT groups (p=0.001). In MWD group, 13 patients showed reasonable UCLA scores and 2 patients showed good scores. While in STT group, only 3 patients showed reasonable scores, 11 patients showed good result and 1 patient showed excellent score.

In STT group, only 2 (13.33 %) patients had stiffness and 2 (13.33 %) patients had hardware prominence. One male patient was diabetic and had stiffness up to 6 weeks which gradually decreased following physiotherapy, another patient who developed stiffness was female. In MWD group, 1 (6.67 %) patient had superficial infection and 3 (20 %) patients had stiffness. Among 3 patients who developed stiffness, 2 were female diabetic and following physiotherapy which started at six weeks decreased the stiffness gradually. Other one patient in MWD group was male who developed stiffness.

Discussion

Inter trochanteric fractures in elderly is a frequent problem and is becoming more common as proportion of elderly person is increasing. The worldwide annual number of hip fractures in 1990 were 1.66 million, with an expected incidence of 6.26 million by the year 2050. Low energy trauma (fall < 1 metre) caused 53% of all fractures in the persons of 50 years and older. In those above 75 years, low energy trauma causes more than 80 % of all fractures. This is contributed of course due to osteoporosis. This is contributed of course due to osteoporosis.

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Various treatment options have been mentioned in the literature ^[5-9] but no definite solution has been found till date especially when the fracture is of unstable variety. Internal fixation methods by using sliding hip screws and nails were described by various authors but these methods have lots of complications and high failure rate in treating unstable fracture patterns. ^[10-13] Primary hemi-replacement arthroplasty has been described in the literature for treating such fractures as immediate post-operative weight bearing can be allowed to the patients preventing lots of post-operative complications and decreasing future morbidity specially in the geriatrics age groups. ^[14]

In our study, we choose 35 patients of more than 65 years old having unstable inter trochanteric fracture pattern and treated them with primary hemi replacement arthroplasty and reconstruction of the calcar done by various^[15-17] methods. Outcome of this treatment modality has been evaluated on the basis of Harris Hip score and various future complications.

In our study, among the 35 patients, 3 patients died due to medical conditions and 2 patients lost in follow up. Total 30 patients were up for at least 1-year post operatively.

The mean age of patients in our study was 75.20 with standard deviation of 6.05. Age of the youngest patient was 66 years and eldest was 86 years. 22 (70 %) patients were between (66 - 80) years and 8 patients (30 %) were more than 80 years. 12(40 %) patients were female and 18 (60 %) were male. Among the 12 female patients, 6 (50 %) had age more than 80 years and among the 18 male patients, 2 (11.1%) had age more than 80 years. Total 11 (36.7 %) patients had left side fracture and 19 (63.3 %) patients had right side fracture.

Total 12 (40 %) patients had some of the co morbidities like hypertension, diabetes, COPD etc. This is statistically significant. Among the 8 patients of more than 80 years, 6 (62.5 %) had some form of co-morbidities. Higher age group patients had increased number of comorbidities which significantly influence the future functional outcome. Total 18 (60 %) had Evans type II fracture and 12 (40 %) had type III fracture. 4 female patients had type II fracture and 8 had type III fracture. Most of the female patients (66.6 %) had type III fracture which is statistically significant (p = .024). Among the 22 patients between age (66 -80) years, 6 (27.2 %) had type II fracture and among 8 patients more than 80 years 6 (75 %) had type III fracture which is significant (p = .070). Mean age in type II fracture was 72.50 with standard deviation of 4.82 and mean age of type III fracture was 79.25 with standard deviation of 5.55. This signifies that higher age group is associated with more comminuted fractures. In our study, 12 right side fractures had type II variety and 7 had type III variety. Among the 18 patients of type II fracture, 4 (22.2 %) had some form of co-morbidity but among the 12 patients of type III variety, 8 (66.7 %) had some form of co-morbidity which is statistically significant (p = .024). For calcar reconstruction, s-s wire was used in 12 (66.7 %) male patients, TBW for 5 (27.8 %) male patients and ethibond was used for 5 (27.8 %) male patients. Among total 18 patients with type II fracture, s-s wire was used for 11 (61.1%), TBW for 6 (33.3%) and ethibond for 1 (5.6%). In all 12 patients with type III fracture, calcar was reconstructed using both s-s wire and ethibond. Higher fracture type needs dual modality of calcar reconstruction. 17 (94.4 %) patients among the 18 patients with type II fracture were allowed to bear weight within 5 days after operation, which is statistically significant (p < 0.001). On the other hand, only 2 (16.7 %) patients with type III fracture were allowed to bear weight within 5 days after operation and 8 (66.7 %) patients with type III fracture were allowed to bear weight after 20 days of operation. (56.5 %) patients in whom s-s wire was used for calcar reconstruction were allowed to bear weight within 5 days of operation (83.3 %) patients in whom TBW was used were allowed to bear weight within 5 days post operatively. Mean operating time in type II fracture was 52.22 minutes with standard deviation of 6.56 which is significant (p < .001). Mean intra operative blood loss for type II fracture was 349.72 ml. with standard deviation of 14.90 and mean intra operative blood loss

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for type III fracture was 380.83 ml with standard deviation of 9.25 which is significant (p < .001). Higher fracture pattern is associated with more operating time and more intra operative blood loss.

4 patients had immediate post operative complication in the form of bed sore, all of them had type III fracture and age more than 80 years which is significant (p = .018). Among the 12 patients with type III fracture, 10 (83.3 %) had abductor lurch which is significant (p = < .001). 1 patient with infection also had both hypertension and diabetes. All 4 patients with bed sore post operatively were allowed to bear weight after 20 days of operation which is significant (p = .009). Delayed weight bearing is associated with more post-operative complications. 1 patient who had infection treated through wound debridement and a period of i.v. antibiotics for four weeks according to the culture sensitivity report. As the infection was superficial and implant was stable, implant removal was not done. The patient who had dislocation was treated by open reduction and abduction cast was done for four weeks post operatively. Then the cast was removed and position of the implant was confirmed by x-ray and was then instructed to bear weight.

Mean preoperative Harris Hip score was 13.87 with standard deviation of 2.32. Mean one year post operation Harris Hip score was 77.06 with standard deviation of 10.78. 27 (90 %) patients of our study had pre-operative Harris Hip score between (11- 20) and 24 (80 %) patients of our study had one year post-operative Harris Hip score between (71-80). Mean pre-operative Harris Hip score with type II fracture was 15.36 with standard deviation of 1.49 and mean one year post-operative Harris Hip score with type II fracture was 79.96 with standard deviation of 1.71. Mean pre-operative Harris Hip score with type III fracture was 11.65 with standard deviation of 1.33 and mean one year post-operative Harris Hip score with type III fracture was 72.72 with standard deviation of 16.35. This is significant (p = .071+). Higher fracture pattern is associated with less improvement in Harris Hip score with time. In patients with age < 75 years, the mean preoperative Harris Hip score was 15.25 with standard deviation of 1.64 and mean 1 year post-operative Harris Hip score was 79.97 with standard deviation of 1.61. In patients with age > 75 years, the mean preoperative Harris Hip score was 12.09 with standard deviation of 1.84 and mean one-year pot operative Harris Hip score was 73.25 with standard deviation of 15.8. This is statistically significant (p = .091+). Patients who were allowed to bear weight within five days after operation had mean six weeks post-operative Harris Hip score of 65.70 with standard deviation of 1.03 and mean one year post-operative Harris Hip score of 79.97 with standard deviation of 1.6. Patients who were allowed to bear weight after 20 days of operation had mean six weeks post-operative Harris Hip score of 62.88 with standard deviation of 1.11 and mean one year post-operative Harris Hip score of 69.93 with standard deviation of 19.79 which is significant (p = .170). Patients with younger age group and early post-operative weight bearing had better improvement of Harris Hip score post operatively with time.

Our study had several limitations. The sample size was small (N=35) and the follow up period was only one year. The post-operative rehabilitation was done under supervision only for first 5 - 10 days before the patients were discharged and it was not possible to determine whether the patients were following the rehabilitation protocol with equal motivation. Also, we were able to eliminate the other various patient's variables like socio-economic status, physio social encouragement in our study. Our aim was to find the result of primary hemi arthroplasty in case of unstable trochanteric fracture in elderly and we found this modality of treatment as a good option in this type of fracture with good functional outcome.

Conclusion

AC joint dislocation is one of the most common shoulder injury. Dislocations most commonly occur in the young adult age group and with preponderance in the males. Self-fall,

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road traffic accident and sports injury are common cause of injury. For chronic AC joint dislocations (Rockwoods type III, IV, V, VI), operative procedure is recommended. For AC joint reconstruction, the optimal operative method remains controversial. MWD is one of the most popular methods but anatomic reconstruction of CC ligament with autogenous STT graft is increasingly getting popular as it provides better stability, diminishes pain and better function as well as better strength is achieved with STT graft technique procedure. The goal of surgical therapy in chronic dislocation is to provide AC joint stability, eliminating sequel, relieving pain, to improve function as well as to restore original strength. Statistically significant difference between the two groups was found in relation to operative time. The average operating time was more in STT group due to graft harvesting from the patient and strength of this graft obviates the need for augmentation with other non-biological devices. In this study, we have seen that there is a statistically significant difference between the MWD and STT group in terms of final outcome as STT graft has better OSS, NCS and UCLA score. With longer immobilization period (up to 4 weeks) and then starting adequate physiotherapy is the key to offer pre-injury status to all the patients. But there is clear indication for a detailed prospective randomized controlled study, involving a significant larger number of subjects for a longer duration, to prove the further clinical utility of these approaches.

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