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Thank you for reviewing manuscript ASJ-2021-0082 entitled "Short term results of Fixation of Unstable Thoracolumbar Fractures with and without intermediate screws: A Comparative Study" for the Asian Spine Journal.

On behalf of the Editors of the Asian Spine Journal, we appreciate the voluntary contribution that each reviewer gives to the Journal. We thank you for your participation in the online review process and hope that we may call upon you again to review future manuscripts.

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Dear Dr. Komang Irianto:

Manuscript ID ASJ-2021-0082 entitled "Short term results of Fixation of Unstable Thoracolumbar Fractures with and without intermediate screws: A Comparative Study" has been submitted to the Asian Spine Journal.

I invite you to review this manuscript. The abstract appears at the end of this letter. Please let me know as soon as possible if you will be able to accept my invitation to review. If you are unable to review at this time, I would appreciate you recommending another expert reviewer. You may e-mail me with your reply or click the appropriate link at the bottom of the page to automatically register your reply with our online manuscript submission and review system.

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Short term results of Fixation of Unstable Thoracolumbar Fractures with and without intermediate screws: A Comparative Study

Journal:	*Asian Spine Journal*
Manuscript ID	ASJ-2021-0082
Manuscript Type:	Original article
Keywords:	Thoracolumbar fractures, pedicle screw, intermediate screw

Short term results of Fixation of Unstable Thoracolumbar Fractures with and without intermediate screws: A Comparative Study

Abstract

Study design: Prospective cohort study

Purpose: Compare the efficacy of short segment pedicle screw fixation with and without Intermediate screw in correction of the vertebral body height, local kyphosis and maintenance of the correction in the treatment of unstable thoracolumbar spine fractures.

Overview of literatures: Posterior short-segment pedicle screw fixation is most widely used for unstable thoracolumbar fractures. Adding a pedicle screw at the fractured vertebrae could significantly improve the stability and decrease the stress on fixation construct.

Methods: Forty patients with unstable thoracolumbar fracture were divided randomly into 2 groups according to the surgical method used. In group B, 20 patients underwent fixation via short-segment pedicle screw instrumentation (1 level above and 1 level below the fractured level). In group A, 20 patients received additional screws at the fractured vertebrae. Radiological assessment was done immediate postoperative, at 6 months and at 12 months. Cobb angle and local kyphotic angle were measured and compared between both groups.

Results: Both groups had significant correction in Cobb angle, anterior body height and local kyphotic angle. However group A had significantly higher correction achieved in Cobb angle (10.35 ± 6.02), anterior body height (1.15 ± 0.50) and local kyphotic angle (13.30 ± 7.54) than group B (3.45 ± 3.94), (0.40 ± 0.41) and (5.05 ± 4.36) respectively. Nevertheless, the differences in VAS score (p=0.759) and ODI (p=0.934) were not significant. Moreover, group A had a significantly lower loss of correction in Cobb angle (p=0.025) after twelve months of follow up.

Conclusion: The construct with intermediate screw was associated with not only better correction but also less correction loss after 12 months. However, this was not reflected on clinical outcome.

Keywords: Thoracolumbar fractures, pedicle screw, intermediate screw.

Introduction:

Posterior short-segment pedicle screw fixation (one level above and one level below the fracture level) is most widely used for TL fractures around the world, which can provide immediate spinal stability, improved correction of kyphotic deformities, early painless mobilization, and indirect decompression of the spinal canal. However, some authors reported that short-segment pedicle screw was not adequate to achieve and maintain the reduction of TL fractures and associated with an unacceptable rate of failure [1, 2].

Since a study of pedicle screw fixation at fractured vertebrae was first reported in 1994, a series of biomechanical studies also showed that pedicle screw fixation combined with screws at the fractured vertebrae could significantly improve the spinal stability and decrease the stress of pedicle screws in the upper and lower normal vertebrae [3, 4].

The operative procedure had the same steps in conventional short fixation and intermediate method but in intermediate method the screws are also inserted into the pedicle of the fractured vertebrae. The rod is introduced to the screw heads from distal to proximal and the distal screw head is tightened first. The proximal and intermediate screw heads are kept loose. With the help of a rod holder and a distractor, the proximal screws are distracted along the rod. The locking heads of the proximal and intermediate screws are tightened to secure the distraction achieved. Reduction is checked under fluoroscopy.

Materials and methods:

This is a prospective comparative study conducted on 40 patients presented by unstable fractures of the thoracolumbar spine. Patients with active systemic infection, sever osteoporosis and bilateral pedicle fractures were excluded. Patients' demographics represented in **Table 1**.

Patients were divided randomly into 2 groups according to the surgical method used. Group B; 20 patients underwent fixation via short-segment pedicle screw instrumentation. Group A; 20 patients received additional screws at the fractured vertebrae. A written consent was taken from all patients and the study was approved by the Ethical Committee Board of our institution.

As Regard the mode of trauma, motorcar accident was reported by 10 patients (50%) in group A and 6 patients (30%) in group B. Falling from height was in 5 patients (25%) in group A and 11 patients (55%) in group B. Falling on the ground and motorcycle accident were reported in one patient (5%) and 4 patients (20%) in group A respectively, while in group B were reported in 2 patients (10%) and one patient (5%) respectively.

The level of fracture was L1 in 10 patients from each group (50%). Fracture L2 was represented in 5 patients (25%) of group A and 2 patients (10%) in group B. Fracture T12 was in 2 patients (10%) in group A and 3 patients (15%) in group B. Fracture T11 was 2 patients (10%) in group A and 3 patients (15%) in group B. Fracture L4 was in one patient (5%) in group A and 2 patients (10%) in group B.

According to AO classification; type A2 was reported in 3 patients (15%) in group A and one patient (5%) in group B, A3 was in 14 patients (70%) in group A and 17 patients (85%) in group B, A4 was in 3 patients (15%) in group A and 2 patients (10%) in group B.

All patients in Group B were classified as E according to Frankel grading while in group A 19 (95%) patients were classified as E and only one patient (randomly be in group A) was classified as type C with conus injury.

All Patients underwent preoperative evaluation as regard history taking, clinical, neurological examination and radiographic imaging including preoperative Plain radiography, Computed Tomography for assessment of pedicle and Magnetic resonance imaging for evaluation of ligamentous injury and in neurocompromised patient. Postoperative evaluation was done radiographically using Plain radiography immediately post-operative, Computed Tomography at 3 or 6 months postoperative and Cobb's angle was evaluated. The neurological status was evaluated according to ASIA score and the Oswestry disability index was collected at 1, 3, 6 and12 months post-operative for conus injury patient.

Surgery was performed by a single senior spine surgeon, and the same instrumentation was used in all cases. Laminectomy was performed in only one patient with conus medullaris injury (Case no.1 in group A). Fusion was performed in all patients by using demineralized bone matrix (DBM) after fusion bed preparation using a high-speed burr. Early postoperative ambulation within 24 to 48 hours.

Results:

The study included 40 patients, 10 (25%) females and 30 (75%) males, age range (14 - 62 years). The mean age was 31.20 ± 14.85 for group A and 37.10 ± 9.72 for group B. (p=0.147). There was no significant statistical difference between the two groups according to mode of trauma (p=0.143). There were no significant statistical differences between the two groups according fracture level and AO classification. (p=0.415) and (p=0.569) respectively.

According to intraoperative parameters, there were significant statistical differences between the two groups regarding operative time (p=0.008) but not intraoperative blood loss (p=0.225). The mean intra operative time for group A (96.0 ± 8.68) was significantly higher than group B (88.55 ± 7.74). While the mean blood loss was 336.3 ± 39.63 and 325.3 ± 44.02 for group A and group B respectively which were almost the same.

We found significant statistical differences in the measurements of cobb angles immediately post-operative, after six months and after 12 months (3.0±2.87 and 5.22±3.06 and 7.39±3.97 for group A respectively) and (7.38±5.23 and 11.13±6.98 and 12.88±7.27 for group B respectively) (p<0.001), but not preoperatively as the preoperative mean cobb angle was 17.67±7.06 for group A and 15.56±7.04 for group B (p=0.284). **(Fig 1, 2)**

Significant differences were found immediately postoperative, 6 months postoperative and 12 months postoperative according to local kyphotic angle and anterior body height (p<0.001). For group A the mean kyphotic angle was 2.70 ±1.75, 3.85 ± 1.81 and 4.80 ± 2.38 immediately post-operative, 6 months post-operative and 12 months post-operative respectively while for group B the mean kyphotic angle was 6.05 ± 4.43, 8.45 ± 6.46 and 10.25 ± 6.89 respectively. **(Fig 1, 2)**

The mean anterior body height was 2.76 ± 0.30, 2.59 ± 0.36 and 2.53 ±0.36 immediately post-operative, 6 months post-operative and 12 months post- operative respectively while for group B the mean height was

2.08 ± 0.42, 1.84 ±0.45 and 1.76 ± 0.46 respectively. the significant statistical differences between the two groups according to correction achieved in Cobb angle **(Table 2, Fig 3)**, Local kyphotic angle and anterior body height .After a 12 months period, the mean Cobb angle was 10.35 ± 6.02 and 3.45 ± 3.94 for group A and group B respectively while the mean local kyphotic angle was 13.30 ± 7.54 and 5.05 ± 4.36 respectively (P<0.001) **(Table 3, Fig 4)**. The differences between the two group according corrections in anterior body height after 12 months were also significant as the mean height was 1.15 ± 0.50 and 0.40± 0.41 for group A and group B respectively and p value was <0.001 , correction achieved was significantly higher in group A than in group B. After 12 months the mean loss of correction was significantly lower in group A (3.70 ± 1.95) than in group B (5.55 ± 3.05) (p=0.025). There was only one case in our studied population (case number 33 Group B) was considered as a failure of fixation as 12 month- postoperative readings of cobb angle, anterior body height and local kyphotic angle deteriorated when compared to preoperative readings. As regards to clinical assessment, there were no significant statistical differences between the two studied groups neither for VAS score nor ODI score. These results were found not only preoperatively (p=0.417) and immediately postoperative (p=.766), but also 6(p=0.595) and 12 months (p=0.759) post- operative.

Discussion:

Ye et al[5] totally agreed with our results as they found that overall correction of Cobb angel was significantly higher in the patients received intermediate screws 1 week after the surgery. They found also that the better correction in favor of intermediate screws was maintained in the follow up visits 6 and 12 months after the surgery.

A meta-analysis conducted [6] in 2016 also matched our results regarding Cobb angle correction totally. The most recent meta-analysis of Tong et al conducted in 2018[7]also was consistent with our findings as they showed that the combined intermediate screws fixation technique was associated with significantly improved radiologic outcomes. Although was not a comparative study, Motizuki et al[8] also showed the intermediate screws technique achieved a significant correction in Cobb angle and also had the ability to maintain that correction significantly till 12 months follow up period.

Zhao et al[9] found the posterior fixation including the fractured vertebra is obviously superior to traditional short segment fixation; however, it still cannot completely avoid fractured vertebra's shell-like change, the secondary losses in fractured vertebra's height and correction degree, or the failure of internal fixation. Present results found a significant higher restoration of the anterior body height with the intermediate screw technique. In addition to its ability to maintain a better result of correction as regards to Cobb angel and local kyphotic angel, this method was also able to maintain a better anterior body height at least for one year after surgery.

This was in accordance to the recent study of Guzel et al[10] Their comparative study included 70 patients who underwent short-segment stabilization because of the diagnosis of thoracolumbar (T11-L2) burst fracture between 2008 and 2012. They concluded that short-segment instrumentation using additional screws at the fracture level in thoracolumbar burst fractures is a proper surgical approach for obtaining clinically and radiologically successful results in terms of the sagittal index, kyphosis angle, ratio of canal occupation, and correction of collapse in the anterior body. Two other studies[11, 12] have proved that.

Huang et al[13] disagreed with our results as they found no significant statistical differences between short pedicle fixation with and without intermediate screws as regards to anterior body height, however, they reported a significant differences between the two groups in Cobb angle. Regarding loss of correction, we found significant differences between the two techniques according to Cobb angle as the mean loss of correction was significantly lower in the intermediate screw group. Huang et al [13] showed the same as our observation in that the vertical stress screw fixation of fractured vertebrae is more effective at maintaining spinal postoperative physiological curvature of the spine and reducing the angle loss.

With contrast to our study [14], remarked there is no statistically significant difference between short segment fixation and short segment fixation plus intermediate screw regarding loss of correction. However, it was a retrospective radiographic review conducted to determine whether clinical factors or common classification systems can predict the radiologic outcome of short-segment thoracolumbar fracture fixation. Compared with conventional short pedicle technique, intermediate screw method can provide higher biomechanical stability. Firstly, a fractured screw-setting can exert a pressure stress toward the abdomen on the fractured vertebra, which can resist the suspension effect. Secondly, this procedure could improve the lateral stability of fixation. In addition, the additional fixation could reduce micro- movements on the bone-metal interface and provide higher screw pullout force[14].

Our results showed significantly longer operative time with intermediate screw technique than the conventional method. The mean time was 96.0 ± 8.68 and 88.55± 7.74 for intermediate and conventional time respectively. Zaho et al [9] agreed to our results as they found that the mean time was 115 minutes for intermediate screws methods and 93 minutes for conventional method. Again, the most recent meta-analysis of Tong et al conducted in 2018[15] also matched our result as regard the operative time. However, some studies[14-16] mismatched our results and found no significant differences between the two techniques as regards to operation time.

It is logical to find that intermediate screws technique having a longer operation time as it contains additional fixation point. However, operation time does not depend entirely on the used technique but also on surgeon talent and experience and intraoperative events and complications as well as patient's status at the time of operation. These facts may explain the heterogeneity in the results of operation time. These facts may explain the heterogeneity in the results of operation time.

According to the current results the mean blood loss was 336.3 ± 39.63ml for the intermediate method and 325.3 ± 44.02 ml for the other method, so there were no significant differences in blood loss between the two methods. Ye et al.[5] found that the values of intraoperative blood loss were 507.5 ± 300.0 mL and 483.5 ± 186.6 mL for intermediate method and conventional method respectively, so they agreed with us in that there were no significant differences as regards to the amount of blood loss between the two groups.

Ye et al [5] found that the values of intraoperative blood loss were 507.5 ± 300.0 mL and 483.5 ± 186.6 mL for intermediate method and conventional method respectively, so they agreed with us in that there were no significant differences as regards to the amount of blood loss between the two groups.

From the 40 studied patients, only 7 patients had postoperative complications and these patients were distributed as follows: 1 patient had a seroma in group A, 2 patients had chest infection in group B and 2 patients had wound infection in each group. The distribution of these patients over the two groups shows that there were no significant statistical differences between the two groups as regards to post- operative complications. These results completely matched Dong et al [17] results as the found no significant differences between the two techniques as regards to rate of complications. They also reported the same types of complications. Many other studies[8, 9] agreed to our results in according to the rate of complications but not the type of complications. Some found the most common complication was implant failure including breakage and loosening of the pedicle screws or the rods [11, 12] and others found that deep vein thrombosis was the most common complication [8, 9].

The mean hospital stay for our study population was 5.55 ± 2.98 and 4.95 ± 1.79 for intermediate screws technique and conventional technique, respectively. These results showed no significant statistical differences between the two techniques. To the best of our knowledge, no study disagreed with us in our finding as all previously mentioned studies matched our results except studies which did not record the hospital stay days in their results [5, 18, 19].

Conclusion

The intermediate screw fixation technique was associated with better reduction of the fractured vertebrae, less correction loss in the follow-up and without additional complications. However, this was not reflected on clinical outcome as there was no significant statistical difference between the two groups. Given the lack of robust clinical evidence, these findings warrant verification in large prospective registries and randomized trials with long-term follow-up.

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Figure legends

Fig 1: Cobb angle and local kyphotic angle of group B; **A.** Immediate post X-ray, **B.** After 6 months, **C.** After 12 months.

Fig 2: **A.** Cobb angle and local kyphotic angle of group A; Immediate post X-ray, **B.** After 6 months, **C.** After 12 months.

Fig 3: Comparison between the two studied groups according to correction achieved (Cobb angle)

Fig 4: Comparison between the two studied groups according to local kyphotic angle.

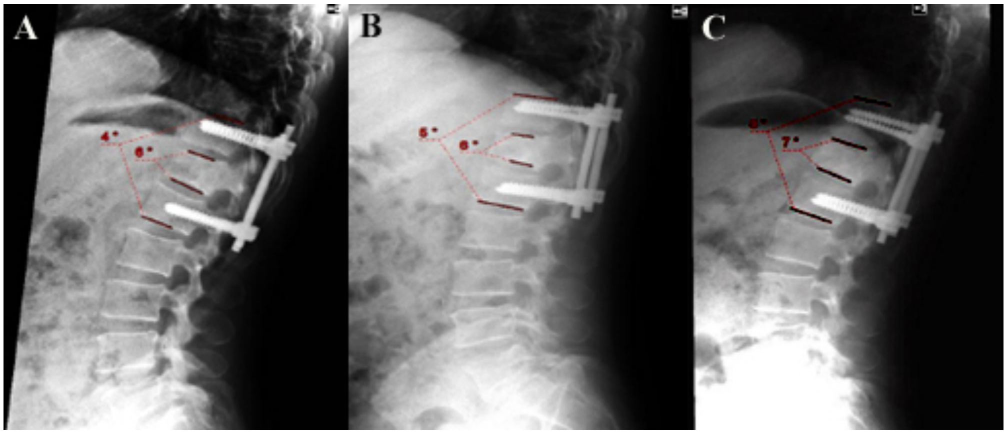

Fig 1: Cobb angle and local kyphotic angle of group B; A. Immediate post X-ray, B. After 6 months, C. After 12 months.

180x77mm (72 x 72 DPI)

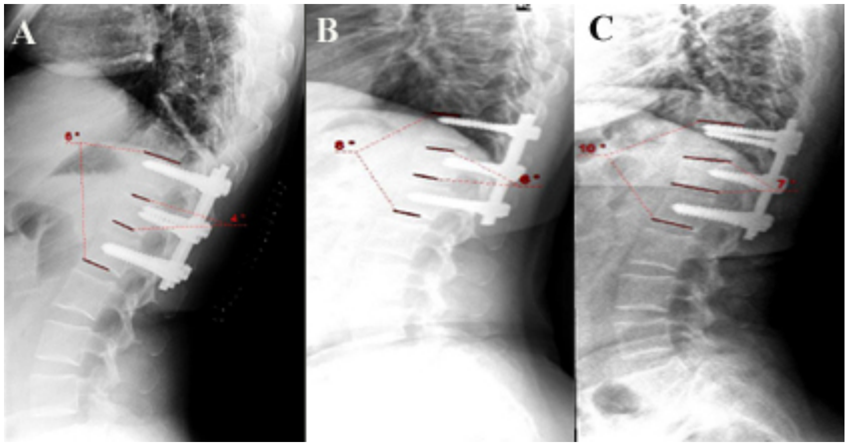

Fig 2: A. Cobb angle and local kyphotic angle of group A; Immediate post X-ray, B. After 6 months, C. After 12 months.

148x77mm (72 x 72 DPI)

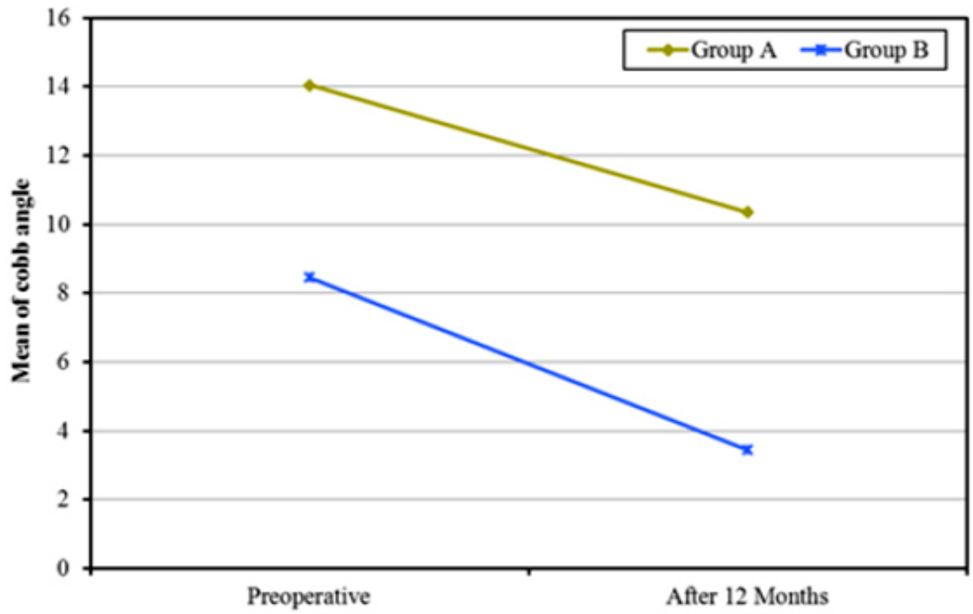

Fig 3: Comparison between the two studied groups according to correction achieved (Cobb angle).

203x128mm (72 x 72 DPI)

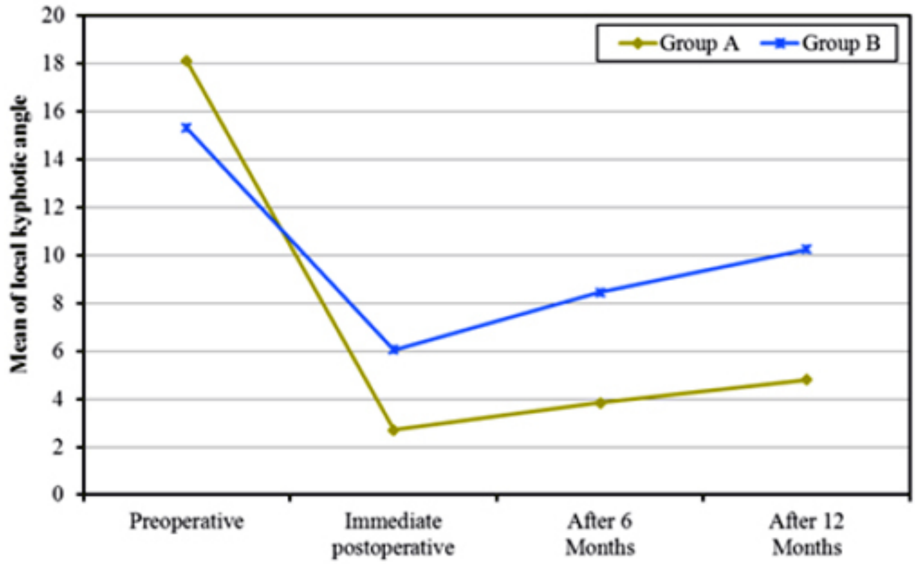

Fig 4: Comparison between the two studied groups according to local kyphotic angle.

195x112mm (72 x 72 DPI)

	Group A (n=20)		Group B (n=20)	
	No.	%	No.	%
Sex				
Male	15	75	15	75
Female	5	25	5	5
Age (Mean)	31.20 ± 14.85 ys		37.10 ± 9.72 ys	
Mode of trauma				
Motorcar accident	10	50	6	30
Falling from height	5	25	11	55
Falling on ground	1	5	2	10
Motorcycle accident	4	20	1	5
Level of fracture				
T11	2	10	3	15
T12	2	10	3	15
L1	10	50	10	50
L2	5	25	2	10
L4	1	5	2	10
AO classification				
A2	3	15	1	5
A3	14	70	17	85
A4	3	15	2	10
Frankle grading				
E	19	95	20	100
C	1	5	0	0

Table 1: Patients' demographics

Correction achieved (Cobb Angle)	Group A (n=20)	Group A (n=20)	U	p
Preoperative				
Min – Max	5.0 -31.0	2.0 - 17.0	93.00*	0.004*
Mean ± SD	14.05 ± 6.52	8.45 ± 3.95		
Median	13.50	8.0		
After 12 months				
Min – Max	1.0 -27.0	-6.0 - 15.0	60.50*	<0.001*
Mean ± SD	10.35 ± 6.02	3.45 ± 3.94		
Median	10.0	3.50		

U, p: U and p value for **Mann Whitney** test for comparing between both groups
*: Statisticaly significant at $p \leq 0.05$

Table 2: Comparison between the two studied groups according to correction achieved (cobb angle)

Local kyphotic angle	Group A (n=20)	Group A (n=20)	U	p
Preoperative				
Min – Max	6.0 -33.0	7.0 - 28.0	157.00	0.243
Mean ± SD	18.10 ± 7.74	15.30 ± 6.26		
Median	13.50	8.0		
Immediate postoperative				
Min – Max	1.0 -8.0	2.0 - 18.0	80.00*	<0.001*
Mean ± SD	2.70 ± 1.75	6.05 ± 4.43		
Median	2.0	5.00		
After 6 months				
Min – Max	2.0 -9.0	3.0 - 30.0	71.50*	<0.001*
Mean ± SD	3.85 ± 1.81	8.45 ± 6.46		
Median	3.0	6.50		
After 12 months				
Min – Max	2.0 -13.0	3.0 - 33.0	69.00*	<0.001*
Mean ± SD	4.80 ± 2.38	10.25 ± 6.89		
Median	4.0	8.50		

U, p: U and p value for **Mann Whitney** test for comparing between both groups

*: Statisticaly significant at $p \leq 0.05$

Table 3: Comparison between the two studied groups according to local kyphotic angle