

Prospective Open-Label Trial to Compare the Effect of LISS vs POLYAX Plating on Distal Femur Fracture among Elderly

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Abstract

Introduction: The fractures which are usually located at the distal part of the femur can be supracondylar or intercondylar. Such fractures have been very hard to deal with since they have an unstable nature and possess a big challenge when it comes to defining their degree of comminution.

Nowadays with newer techniques and special materials, the results of surgical treatment are good, even in older patients who have poor bone quality. In our study, we compared the results of the less invasive surgical stabilization (LISS) plate and the multi-angled, POLYAX plate in old-age patients.

Methods: A prospective, comparative observational study carried out in a tertiary care trauma center among 40 subjects (20 in each group) above the age of 60 years.

Among both groups of patients, diabetes and hypertension were the most common co-morbidity. It was observed that 25 (62.5%) of the patients had 12 - 16 weeks of the time of fracture union while 12 (30%) had 17 - 20 weeks and 3 (7.5%) had non-union, diabetes was observed to be affecting fracture union among both groups.

The fractures were classified according to Gustilo Anderson's system of classification for compound fractures and the Muller AO system of classification. All patients were treated surgically either using a LISS plate or multi-angled, POLYAX plate, and functional outcome was compared at the end of one-year follow-up.

Results: Fracture union was found at the rate of 72.5% in LISS, and subsequently, it was 77.5% in POLYAX plate. As a result, only one patient from the POLYAX group and additionally, two from the LISS group needed another surgery, which is a revision surgery for the failure of the implant. The rate of complication was found to be more in the LISS plate.

Conclusion: Based on our findings, we conclude that elderly osteoporotic femur fractures will give a better union rate managed with Polyax plate than LISS.

Keywords: Femur; Distal end; LISS; POLYAX; OKS; KSS

Introduction

The distal femoral fractures are located within 15 cm of the femur distally and incorporate the metaphysis, epiphysis, and its articular surface [1-3]. These fractures are very challenging to treat because they have a highly unstable nature, and their degree of comminution is tedious. Further, their closeness to the knee joint makes its movements complicated [1-3].

Furthermore, a subgroup of patients which mostly includes elderly osteoporotic patients is enduring peri-prosthetic distal femoral fractures, which are very close location-wise to their total prosthetic knee replacements. These injuries can lead to serious functional damage and permanent disability. Additionally, it can also cause mal-union, limb shortening, and a decline in functional outcomes. Subsequently, non-union without or in conjunction with infection can thwart the treatment of distal femoral fractures.

The geriatric distal end femoral fractures may have poor functional outcomes because of their declining physiological condition, pre-existing diseases and comorbidities, deficiency of satisfactory organ reserves, and locally confined factors like inadequate bone stock and delicate soft tissues. All these conditions combined lead to a reduction in the patient's healing ability.

The present study was carried out to compare functional outcomes among elderly subjects who were managed using two different plating systems (LISS and POLYAX) in a tertiary care hospital in north India.

Methods

A prospective, observational comparative study was conducted from November 2018 to November 2020 at Amandeep Hospital, Amritsar, after obtaining ethical approval from the institutional review board. The study period included twelve months of follow-up. The study included patients over the age of sixty years who underwent surgical treatment for a distal end femoral fracture. After applying inclusion and exclusion criteria, a total of forty subjects were enrolled and divided into two groups, POLYAX and LISS, each containing twenty subjects. Patients with pathological fractures, peri-prosthetic fractures, those who were medically unsuitable for surgery, did not consent for surgery, or were lost to follow-up were excluded from the study.

Patients were allowed to choose the type of plating they preferred, and accordingly, they were assigned to either the POLYAX or LISS group. The study aimed to compare the outcomes of surgical treatment using these two methods.

All patients underwent surgery under regional spinal or general anesthesia, and a prophylactic antibiotic (intravenous Cefazolin 1 gm) was administered 30 minutes before the incision. Fracture fixation was done with polyaxial or LISS distal end femur locking plates as per the pre-decided protocol. The postoperative management included removal of the suction drain after 48 hours, wound inspection on the second postoperative day, and administration of intravenous antibiotics for 48 hours in closed fractures and 6 days in open fractures. Patients were instructed to perform actively assisted knee bending and quadriceps exercises to strengthen their legs from the first postoperative day. They were advised to mobilize the knee and ankle and perform weight-bearing ambulation on the normal side while using crutches or walkers on the affected side as early as possible. Sutures were removed on the 12th day of surgery, and an X-ray of the involved leg was taken postoperatively. Patients were allowed partial weight-bearing and subsequently total weight-bearing based on the fracture union and patient compliance.

Post-surgical follow-up was conducted at the end of the first month and subsequently at three, six, and twelve months. The patients' functional assessment was done using the Knee Society scoring system [5], subdivided into a Knee Score (AKSS) grounded on three chief clinical parameters (pain, joint stability, and range of movement) and a Functional Scores (AKFS) founded on the patient's insight of general knee function in specific activities (walking ability and ascending/descending stairs) [13]. The mentioned dual rating system eradicates the trouble of decreasing Knee Scores associated with rising age or other medical conditions. A score between 85 and 100 points is considered excellent; 70 - 84, good; 60 - 69, fair; and < 60, poor [14]. Also, radiographs of the knee joint and femur were obtained in the

anteroposterior and lateral planes at each follow-up to assess callus formation or healing, maintenance of fracture reduction, varus, and valgus collapse, articular congruity, and metaphyseal-diaphyseal alignment. Bony union was defined as the union of at least three cortices in AP and lateral views on follow-up radiographs [6], while non-union was defined as the absence of any signs of the union at regular follow-up until nine months after surgery [7].

The data were analyzed using SPSS software version 20, and descriptive statistics were used to present categorical and continuous variables as percentages and means ± standard deviation, respectively. Pearson's T-test or chi-square test was applied to identify differences in the functional outcome between the POLYAX and LISS groups. A p-value of less than 0.05 was considered statistically significant.

Results

There were a total of 40 subjects (20 in each group) with a mean age of 76.01 ± 16.8 yrs and an age range was 60 - 88yrs. There were 28 (70%) males and 12 (30%) females. The most common cause of fracture was fall and injury (32 - 80%) followed by RTA (8 - 20%). Fracture type (according to Gustillo Anderson Classification) most observed among study participants was closed fracture in 23 (57.5%), grade 1 compound in 4 (10%), and grade 2 compound in 7 (17.5%) and grade 3 compounds in 5 (12.5%). Among both groups, diabetes (35%) and hypertension (42.5%) were the most common co-morbidity. It was observed that 25 (62.5%) of the patients had 12 - 16 weeks of the time of fracture union while 12 (30%) had 17 - 20 weeks and 3 (7.5%) had non-union, Diabetes was affecting fracture union among both groups.

It was observed that the mean range of motion (ROM) of the knee at 1 month was 82.71 ± 15.45 for LISS and 85.00 ± 6.55 for POLYAX; at 6 months was 97.86 ± 15.36 for LISS and 101.53± 4.6 for POLYAX and at 1 year was 103.29 ± 16.04 for LISS and 107.00 ± 3.15 for POLYAX. It was observed that the functional knee society score (KSS) at 1 month was 66.06 ± 13.43 for LISS and 67.00 ± 6.55 for POLYAX while at 6 months it was 72.60 ± 7.34 for LISS and 73.29 ± 6.64 for POLYAX and at 1 year it was 76.43 ± 8.40 for LISS and 86.86 ± 8.14 for POLYAX. There was a significant difference in ROM and KSS at one-year follow-up among LISS and POLYAX study groups (p > 0.05). The union rate was more the POLYAX group than that the LISS group.

Variables	LISS (n = 20)	POLYAX (n = 20)	Total (n = 40)
Age in yrs (range; Mean ± SD)	66.06 ± 6.79	72.04 ± 9.42	76.01 ± 16.8
Male	12 (60%)	16 (80%)	28
Female	8 (40%)	4 (20%)	12
Mode of injury			
Fall and Injury	14(70%)	18 (90%)	32
RTA	6 (30%)	2 (10%)	8
Co-morbidity			
Hypertension	6 (30%)	11 (55%)	17
Diabetes	4 (20%)	10 (50%)	14
Other	3 (15%)	4 (40%)	7
Fracture site			
Right	12 (60%)	14 (70%)	26
Left	8 (40%)	6 (30%)	14
Operation time (Minutes)	107.7	95.6	
Fracture union time			
12 - 16 weeks	9 (45%)	16 (80%)	25
17 - 20 weeks	9 (45%)	3 (15%)	12
> 20weeks/nonunion	2 (10%)	1 (5%)	3

Table 1: Demographic profile of study participants.

	LISS (n = 20)	POLYAX (n = 20)	P value
ROM			
1month	82.71 ± 15.45	85.00 ± 6.55	0.545
6 months	97.86 ± 15.36	101.53± 4.6	0.315
12 months	103.29 ± 16.04	107.00 ± 3.15	0.318
KSS			
1 month	66.06 ± 13.43	67.00 ± 6.55	0.780
6 months	72.60 ± 7.34	73.29 ± 6.64	0.754
12 months	76.43 ± 8.40	86.86 ± 8.14	0.001

Table 2: Comparison of range of motion (ROM) and knee society score (KSS) among two groups.

	LISS (n = 20)	POLYAX (n = 20)
Implant failure	3 (15%)	0
Deep surgical site infection	1 (5%)	0
Secondary procedure for non-union	2 (10%)	1 (5%)
Lower respiratory tract infection	1 (5%)	1 (5%)
Common peroneal nerve palsy	0	1 (5%)

Table 3: A complication of LISS and POLYAX.

Discussion

Distal femoral fractures pose a serious threat to the aging population due to their tendency to lead to various complications, like chronic infections, non-union, or implant failures. These conditions are further complicated due to declining physiological reserves and pre-existing osteoporosis in these patients. Such cases may require subsequent surgeries for correction and management.

Additional concerns with patients with distal femoral fractures are a lengthy hospitalization and compromised movements since these factors significantly affect the expected quality of life in such patients.

To address the problem of non-fixation in osteoporotic bone attributable to bolt cut- outs, locked osteosynthesis tightening practices were established to surpass the usage of non-sealed osteosynthesis implants. In such practices, the steadiness of the structure and the transference of weight from bone to the implant is reliant on the frictional push produced by the interaction of the osteosynthesis plate against the bone lying underneath.

The procedure for the above-mentioned practice is that with the help of locked osteosynthesis instruments, a pointed angular, fixed-angle structure is made by the individual tightening of screws on the osteosynthesis plate. The Polyax™ plate exemplifies a whole new world of locking osteosynthesis plates, which very conveniently permits freedom of 30 degrees, and can rotate 15 degrees in any direction regarding the incorporation of the tightening screws of the distal end. Conversely, the LISS implant which is considered the first-generation tightening osteosynthesis instrument has just a single angle of screw incorporation at 90 degrees on the surface of the implant.

The hypothetical benefits of the polyaxial, Polyax™ plate method stand undisputed. Due to its enhanced surgical ease, which permits the surgeon to circumvent the sections of prosthesis or comminution and focus regions with sufficient bone stock distally, enhancing the repair construct by a diverse placement of distal bolts. Additionally, clinical, and biomechanical studies have also substantiated the usage of poly-angled securing plates for the fixation of distal femoral fractures [8,9].

However, Otto., et al. [8] has raised questions about the credibility of distal femoral fixations with locked polyaxial tools over one-angled implants. In his study, the axial load to failure of the LISS implant is 24% more than the load to the error of the crossed Polyax fixation, and 33% more than parallel Polyax fixation. As has been mentioned before in this research paper, the 30 degrees of freedom of distal screw insertion in the polyaxial plate rises from the bushings enclosed in the screw pits, where the implanted screws lock.

Even though the bushing technology mentioned above seems to be technically beneficial, it is also found to pose a weakness with stress concentrations at this point, which fails the implant. Perverse to this, the mono-angled, LISS implant does not have this bushing locking mechanism, since in its case, the screws lock directly onto the plate. So, the locking system, organized with the elevated young's modulus of stainless steel over titanium, can certainly be the cause for the above-mentioned biomechanical interpretations.

The medical fraternity across various specializations strongly believes in the challenging shift from laboratory developments to clinical patient advantage. Surgical Implants may show outstanding outcomes during mechanical testing but fail in their real test of clinical use. There is not enough clinical research like high- quality journal publications to compare poly-angled fixations with mono-angled ones used for distal femoral fractures.

The rate of complications following the distal femoral fractures is believed to show significant differences according to the type of patient population researched. For example, as explained before the distal femoral fractures commonly have a bimodal occurrence, primarily in the aged female populace, because of the low energy falls due to pre-existing osteoporosis and in youngsters because of high energy trauma.

The injury patterns, physiology, and co-morbidities in these two groupings are altogether different and so, we can undoubtedly expect a varied clinical outcome.

The results of a potential clinical trial namely Mono- versus polyaxial locking plates in distal femoral fractures [10], published by Hanschen., et al. informed about 0% rate of surgical complications and 100% rate of fracture union in their 27 studied respondents. Additionally, Kregor., et al. [11], subsequently researched and published about the treatment of distal femoral fractures using L.I.S.S implants.

Their study [11] of the total of ninety-nine patients comprised the full demographic range of distal femoral fractures, most of them, 70%, being below the age of 65 years. They informed of an infection rate of 3%, a fixation failure rate of 5%, a non- union rate of 7%, and a death rate of 5% where one of the deaths was reported to be due to pulmonary embolism.

Additionally, another research study where a systematic review of 415 patients with peri-prosthetic distal femoral fractures was conducted by Herrera., et al. [12] revealed an infection rate of 3%, a fixation failure rate of 4%, and a non-union rate of 9%.

Our research team found this research to be more appropriate for comparison since the patient population researched by them is somewhat similar to our study cohort. Also, the analysis of our findings shows a striking resemblance to the result and analysis of existing literature on the same subject [10,12].

Limitations of the Study

The conducted research study had many deficiencies. The surgical fixations were done by various surgeons who specialized in trauma, according to their past experiences. Their expertise in the mentioned implants was not determined preceding inclusion in the surgical procedure.

One more limitation of this study was found to be the incapacity to manage the case factors and then effectively being able to balance them in every treatment group.

Conclusion

Despite the above-mentioned limitation our study findings conclude that POLYAX plating will help for early union, less failure rate, and good outcomes among elderly osteoporotic fractures. POLYAX can be chosen over LISS among elderly distal end femur fractures as a treatment of choice.

Acknowledgment

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Conflict of Interest

None.

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