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(RESEARCH ARTICLE)

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A comparison of clinical outcomes between narrow and broad dynamic compression plate for femur fractures

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Abstract

Purpose: To review the short term performance 4.5/5.0mm Wise-Lock Narrow Dynamic Compression Plate with LC under cuts and 4.5/5.0mm Wise-Lock Broad Dynamic Compression Plate with LC under cuts for femur fractures in terms of postoperative complications and failure rates.

Methods: The total number of 46 patients, 24 to 55 years' age group, who underwent internal fixation with wise-lock narrow and broad dynamic compression plate for femur fractures were reviewed. These implants were manufactured at Auxein Medical Private Limited Sonipat (India). The wise-lock narrow dynamic compression plates were implanted to 24 patients (18 Male and 05 Female) and broad dynamic compression plates were implanted to 22 patients (15 Male and 08 Female). These plates were made up of SS 316L and Ti6Al4V alloy respectively. Clinical and radiological follow-ups were conducted at the end of 30 days, 90 days, 180 days, 270 days and 365 days after surgery to examine the bone union, non-union & other related complications. During the one year of follow-up by the surgeon the patient's health status was analysed by the American society of anesthesiologists grade and the visual analogue score (VAS) was also determined.

Results: Patients were followed up for one year. Out of 24 patients who were treated with wise-lock narrow dynamic compression plate, stainless steel, 04 patients (03 males & 01 female) were faced the complications of pain. However, out of 22 patients who were treated with broad dynamic compression plate, titanium, 02 patients (02 males) developed complications of pain. No biomechanical issue related to screw loosening, corrosion, bending, or other factors was not detected in 46 patients.

Conclusions: Femur plate fixation is feasible for the treatment of femur fracture. The clinical outcomes and prognosis of patients are dependent on the accuracy of intraoperative reduction and surgical expertise.

Keywords: Femur Fracture; Femur Bone; Wise-Lock Narrow and Broad Dynamic Compression Plate; Outcome; Complications

1. Introduction

The femur bone, which is located in the lower limb between the hip and knee joints, is the longest and strongest bone in the body. Because of the morphology of the femur, the bone can sustain the many muscle and ligamentous attachments in this area and yet extend the leg to its maximum length when walking. Fractures of the proximal femur are frequent injuries that mostly affect the elderly. While most fractures in the elderly age group are osteoporotic, the majority of injuries in young, healthy persons are caused by high energy trauma from inconsequential falls. Fractures of the intertrochanteric and subtrochanteric regions, or a combination of both, are included in proximal femur fractures

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[1]. Because of osteoporosis, intertrochanteric fractures are prevalent in older women. A simple fall causes 90% of fractures, or 11.6% of all fractures. [1, 2]. Conservative approaches are now limited to older patients with high medical risk for anaesthesia and surgery, since they have been associated with increased fatality rates ranging from 4.5 to 22%. Therefore, internal fixation surgery is the best option. Benefits of the Plate and Screw Structure: basic mechanical process, less expensive implant, time-tested process simple learning curve. The femoral head may have an uncontrolled collapse and migration of the lag screw, Varus, and potential screw cut-out. Wagner M. conducted research on the development of LCP and general principles for its clinical applications as early as 2003. His findings demonstrated that the locking plate's locking screws reduce the compressive pressures the plate applies to the bone. Egol Ka, Kubaiken et al. came to the conclusion in 2004 that locking plates and normal plates rely on entirely distinct fracture fixation mechanical principles [3]. Anatomically precontoured locking plates transformed the treatment of many fractures, as demonstrated by Schmidt Andrew H. in 2008. A comparative investigation by Mc Gregory, Bj Lucas R in 2009 showed that the proximal femur locking plate was the stiffest build [4]. The plate's proximal section is precontoured to fit the proximal femur. In West Chester, USA, the AO group created Plate for the first time in 2007 [5]. It is possible to create an angularly stable construct using locking screws that is not dependent on the quality of the bone [6]. Usually in unstable proximal femur fractures, the lateral trochanteric wall is showing promise as a stabilising agent. In these situations, the proximal femur locking compression plate is the perfect implant as it may serve as a stress shield and a buttress for the lateral trochanteric wall. No lag screw should be used and cephalomedullary devices should not be used in fractures without a lateral trochanteric wall [7]. PFLCP is recommended in revision procedures following corrective osteotomies of malunions and non-unions of the proximal femur, as well as in sub trochanteric fractures where the use of an intramedullary implant is prohibited by distal implants [8]. For the treatment of proximal femur shaft fractures in 60 patients (6 to 12 age group), Shah FA, et al. [9] employed locking compression plates. There were 23 oblique fractures, 20 spiral fractures, 11 transverse fractures, and 6 comminuted children. There have been no reports of implant failure, non-union, delayed union, or malunion complications. B. Zhong et al. [10] conduct a study to compare the proximal femoral locking compression plates with dynamic hip screws in extracapsular femoral fractures. Results revealed that PFLCP fixation exhibit better functional outcomes and fewer complications for subtrochanteric femoral fractures but not for intertrochanteric femoral fractures. Several studies have reported success with PFLCP fixation for the treatment of complex femoral fractures and for revision operations after the failure of other implants [11–15]. Only one small study compared PFLCP and DHS fixation techniques and showed better bone union with the PFLCP fixation in patients with unstable intertrochanteric fracture [16]. The several researchers used different materials & different coating methods to combat corrosion and reported in the long term study that corrosion can be arises due to the application of wrong material, improper handling, cleaning etc. [17-21]. In the current study the device is made of biocompatible metal i.e. SS 316 L and Ti6Al4V alloy, which is light in weight, excellent biocompatible property and better corrosion resistance characteristics. Sanders, Roy et al. [22] conduct a study, uses 95-degree dynamic condylar screw was used on 32 patients with subtrochanteric femur fractures. A follow-up study with twenty-two patients was possible, with an average follow-up period of 23.8 months. A novel traumatic hip score rating method was used to assess the functional results. With 68% (15/22) of the functional outcomes assessed as excellent or good, the overall union rate was 77.3% (17/22). Extensive comminution of bone was linked to all five technical failures. In four of these cases, bone grafting was not done. There were no instances of the femoral head or neck being penetrated by screws. This gadget should not be used in situations where there is considerable comminution. Therefore, we performed a case control study to examine: the function, bone union rate and other complications

Abbreviation

- PFLCP – Proximal femur locking compression plate
- DHS – Dynamic Hip Screw

2. Method

With a one-year follow-up, this retrospective study was carried out at Mesoamerican University in Quetzaltenango, Guatemala, between April 2016 and December 2017. The patients were divided into the two groups, ‘group N’ and ‘group B’. The patients who were treated with wise-lock narrow dynamic compression are kept in ‘group N’ and the patients who were treated with broad dynamic compression plate for proximal femur fractures are kept in ‘group B’. The following information were collected from the patient: Age, device name, weight, type of fracture using the AO system classification. The total number of 46 patients, 24 to 55 years’ age group, who underwent internal fixation with wise-lock narrow dynamic compression plate and broad dynamic compression plate for diaphyseal femur fractures. The fracture occurs due to fall from height (5), accident (20), sports injury (10), slip (5), and trauma (6). The ASA (American Society of Anesthesiologists) score classification system is used globally for determining a patient's fitness prior to surgery. The VAS is the pain grading scale utilized for the first time in 1921 by Hayes and Patterson. The outcomes from the study were measured using VAS score (Fig. 1).

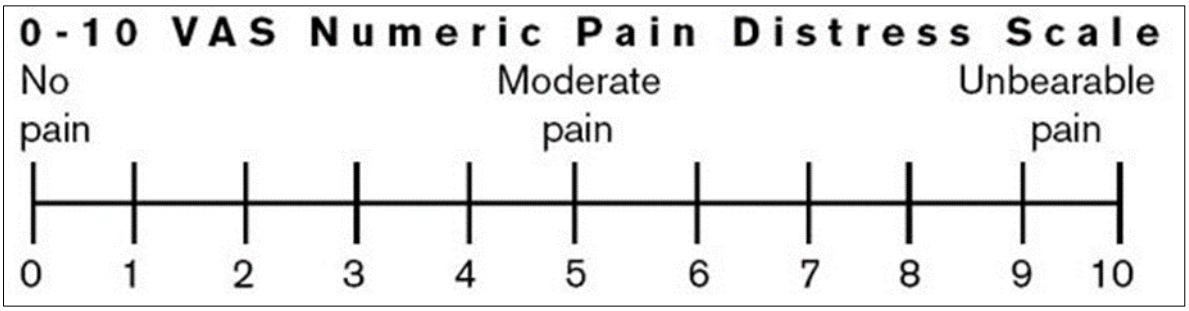

Figure 1 Example of a VAS

2.1. Inclusion criteria

Patients with diaphyseal femur bone fractures and skeletally mature (age between 24years to 55 years) were included in the research study. Patients who met the criteria for a proper body mass index (BMI), were free of any diseases, and were physically fit with the exception of the wounded location were included.

2.2. Exclusion criteria

Should any of the following hold true, the participant will be excluded from the study: subjects with substance abuse or alcoholism; subjects connected to cardiovascular disease; subjects with high blood pressure; patients with fast joint disease; subjects with bone absorption; subjects with suspected or confirmed metal allergy or intolerance. Subjects with any neuromuscular disorder that would present complications; subjects with an unacceptable risk of fixation failure in postop care.

2.3. Material Used

Both plates were manufactured in Titanium alloy Ti-6AL-4V and Stainless steel alloy (SS 316L). The Femur plate system direct contact with the femur bone and surrounding tissues.

The below table show, the type of materials used for the plates.

Product Description	**Materials**	
	Titanium (N in %)	**Stainless Steel (N in %)**
4.5/5.0mm Wise-Lock Narrow Dynamic Compression Plate with LC under cuts with LC under cuts	06	13
4.5/5.0mm Wise-Lock Broad Dynamic Compression Plate	09	18
Total	15	31

2.4. Indications of Use

Both the plates i.e. 4.5/5.0mm Wise-Lock Narrow Dynamic Compression Plate with LC under cuts and 4.5/5.0mm Wise-Lock Broad Dynamic Compression Plate with LC under cuts are used to treat the long bone fractures such as the femur and for use in fixation of peri-prosthetic fractures, osteopenic bone and fixation of non-unions or malunions in adult patients. The actual image of 4.5/5.0mm Wise-Lock Narrow Dynamic Compression Plate with LC under cuts and 4.5/5.0mm Wise-Lock Broad Dynamic Compression Plate with LC under cuts of Ti alloy is shown in Fig. 2 & Fig. 3 respectively.

Figure 2 5.0 mm Wise-Lock Narrow Dynamic Compression Plate 08 Holes with LC under cuts

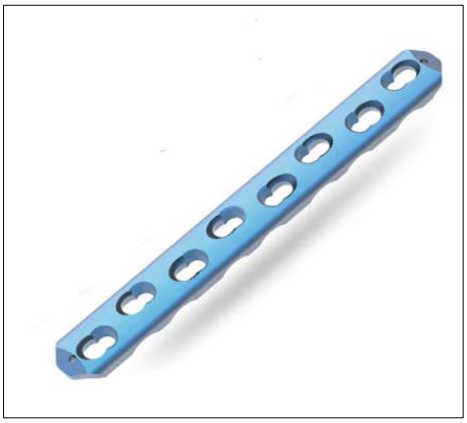

Figure 3 5.0 mm Wise-Lock Broad Dynamic Compression Plate 08 Holes with LC under cuts

3. Results

Clinical and radiological follow-ups were conducted at the end of 30 days, 90 days, 180 days, 270 days and 365 days after surgery to examine the bone union, non-union & other related complications. Every patient had satisfactory radiographic and clinical characteristics. Range of motion (ROM), and total functional outcomes score were all in the plate's favour. The radiography parameters showed improvement. Out of 24 patients (18 Male and 05 Female) were treated with 4.5/5.0mm Wise-Lock Narrow Dynamic Compression Plate with LC under cuts and 22 patients (15 Male and 08 Female) were treated with 4.5/5.0mm Wise-Lock Broad Dynamic Compression Plate with LC under cuts. The average mean age of patients was 33.5 years (Table 1).

Table 1 Demography data (n=46)

Demography Data:		
Average Age (Range)		**33.5 years**
Gender	**Male**	**Female**
Number with %age/Device	24 patients: 18 Male (75%) (Wise lock narrow dynamic compression plates)	06 Female (25%) (Wise lock narrow dynamic compression plates)
	22 Patients: 15 Male (68.18%) (Wise lock broad dynamic compression plates)	07 Female (31.81%) (Wise lock broad dynamic compression plates)
Total	33 (71.73%)	13 (28.26%)

According to the AO classification system, the type 32D/4.1 fractures were present in 18 (39%) patients and type 32D/4.2 in 28 (61%) patients (**Table2**).

Table 2 Fracture characteristics (n=46)

Fracture Type							
type 32D/4.1				**type 32D/4.2**			
Male		**Female**		**Male**		**Female**	
12		**6**		**21**		**7**	
Left	Right	Left	Right	Left	Right	Left	Right
4	8	3	3	8	13	3	4

Cause of injuries with corresponding number of patients is shown in Table 3. Apart from this the clinical evaluation for pain, aesthetic appearance and satisfaction with treatment was rated by patients on a VAS score (maximum score, 10 points) at the final follow-up as shown in (Table 4). The mean VAS score (maximum score, 10 points) at the final follow-up is shown in Table 5. The follow-up of patients at the end of 30 days, 90 days, 180 days, 270 days and 365 days to examine the bone union, non-union & other related complications.

Table 3 Cause of fracture with corresponding number of patients (n=46)

Cause of Injury	**N %age**
Sports	10
Road accident	20
Slip & Fall	15
Trauma	06

Table 4 Patient satisfaction data

Evaluation Parameters	**Number of Patients**			
	Wise lock narrow dynamic compression plates		**Wise lock broad dynamic compression plates**	
	Satisfied N (%)	**Not Satisfied N (%)**	**Satisfied N (%)**	**Not Satisfied N (%)**
Pain (n=46)	91	8	96	4
Aesthetic appearance (n=46)	82	18	80	20

Table 5 VAS score (1 year clinical follow up)

VAS score (in month)	**Wise lock narrow dynamic compression plates' patients**	**Wise lock broad dynamic compression plates' patients**
01 Month	08	08
03 Month	06	07
06 Month	03	03
09 Month	02	01
01 Years	01	01

ASA Score; All the patients score ASA1.

4. Discussion

Fracture of femur plate system is common type of fracture. It is mainly occur due to the high energy collision like road accident, falls from height, slip, etc. In this study also, all the patients have high energy collision and it can also be show in the above table 3.

As mention in the method section above, the two plate having same indication and different design was used to fix the femur fracture (type 32D/4.1 and 32D/4.2). After the treatment both the groups of patients were followed up to one years. During the follow up, the VAS score, X-ray, weight, general body check-up was done. The VAS score of the both groups of patients is similar and both the groups shows the 100% result. None of groups' patients shows no biomechanical issue related to screw loosening, corrosion, bending and neither other factors was detected. Similar, no any complication like non-union, mal-union and infection were occurred.

At the time of 2nd follow up, about of 46 patients 6 patients have face pain (4 patients form 'group N' and two patients were from 'group B'. However, at the 3rd follow up, all the patients have good health condition. Similarly, some of the patients were unsatisfied with aesthetic appearance of surgery line as shown in the above table 4.

Similar type of retrospective study was also conducted by Cheng, J. C. Y. where 32 patients were taken in the study (26 male and 6 female) with an average of 36 years old. All the patients' femoral shaft fracture were treated with AO dynamic compression plate, however, in the study, only the 90.6% patients shows the excellent result [23].

5. Conclusion

Clinical outcomes show that, despite of design changes of the both with respect to each other, they show the same clinical result. No major complication has been found till the date of writing this paper.

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