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Original Research Article

Clinical performance of tibia bone plate system for fixation of tibia fracture

Sonika Bhatt[1]*, Mohit Kumar[1], Tarun Kumar[1], Bhawana Chawale[2], Gaurav Luthra[1]

[1]Department of Regulatory Affairs, [2]Department of Clinical Research, Auxein Medical Private Limited, Sonipat, Haryana, India

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***Correspondence:**
Dr. Sonika Bhatt,
E-mail: regulatory7@auxeinmedical.com

ABSTRACT

Background: In this study, we aimed to investigate the performance of the tibia plates system while treating the tibia fracture fixation. The objective of this study was to reduce the post-operative complications of proximal and distal tibia fracture by using indigenously manufactured implants (plates and screws).
Methods: In this retrospective study, we studied the results of the tibia plate system in treatment of tibia fracture. A total of 34 consecutive patients were included in this study (24 males, 10 females and average age 48.6 years). Fracture type was classified as per the Muller AO classification of fracture. According to the AO classification, proximal and distal tibia fractures 41-A, 41-B and 41-C was observed with one year follow up period followed by physical exercises after one month of the surgery. The fractures were treated with wise-lock proximal and distal tibia plates.
Results: The outcomes of clinical treatment were obtained in our study; no pain (88.2%), mild pain (11.7%) after 1 year follow up. The follow up of patients was taken on 1 month, 6 months and 1 year according to visual analog scale (VAS) score. No implant related problem have been found like loosening, bending and corrosion. X-ray was used to check the union, non-union. Functional outcomes were assessed with VAS.
Conclusions: Treatment of tibia fracture with wise-lock proximal and distal tibia plate shows good outcomes with less complications.

Keywords: Tibia fracture, AO classification, Visual analog scale, Open reduction and internal fixation

INTRODUCTION

The tibia, or shinbone/"shin splints" refers to pain along the shin-bone (tibia). It is the larger of the two bones in the lower leg. The fibula and the tibia constitute the major bones that are situated in the shin region of the leg. The tibia is larger and thicker than the fibula. The most common fractured long bone with a recorded incidence of 17-21 per 1,00,000 population, represents 2% of all fractures and 36.7% of all long bone fractures in adults.[1]

Proximal tibia fractures constitute a small fraction (1.2%) of adult fractures. Aetiologically, there are two main injury mechanisms: high energy trauma (e.g. traffic accidents), which appears mainly in younger patients, and low energy trauma, which frequently appears in older patients commonly regarding to reduced bone density. The standard procedure in the treatment of articular fractures of the proximal tibia remains to be the surgical treatment.

Specific symptom of proximal tibia fracture which includes as a pale look in the foot due to loss of blood supply. The open reduction and internal fixation (ORIF) with the use of an anatomical pre-shaped locking plate has been established as the standard procedure.[2] Tibial diaphyseal fractures (TDFs) are among the most common

long bone fracture encountered by the orthopaedic surgeon and arises from various forms of trauma and assume different patterns. They are responsible for high morbidity and mortality.[3]

They account for 1.9% of all fractures and for almost 35% of all cases of acute compartment syndrome (ACS). ACS is defined as a pressure increase within a confined space (an anatomical compartment) leading to compromised tissue per-fusion within that compartment. Missed or untreated ACS has the potential to lead to Ischemic contracture, muscle necrosis, renal failure, infection and even amputation. Specific symptoms includes as Palpation, Confusion, The mechanism of injury in TDFs can be direct or indirect. Direct mechanisms of injury are often high-energy fractures (road traffic accidents), penetrating injuries, and 3-point bending injuries. High-energy mechanisms produce transverse or comminuted displaced diaphyseal injuries. These have higher incidence of bone exposure and soft-tissue injury. Indirect mechanisms are mainly torsional, low-energy injuries.[3]

Distal tibia fractures, also known as pilon fractures. The surgical treatment of distal tibial fractures is still challenging as it happens during result from a high energy hit axially oriented, a fall from a height, or from the association between rotational forces and plantar flexion or dorsiflexion of the foot. Pilon fractures represent 3%–10% of all tibia fractures and in 70%−85% of cases, i.e. in more complex injuries, a concomitant fibular fracture could be present. Specific symptoms of distal tibia fracture include tingling in the foot, bruising and blueness.[4]

Common symptoms of tibia fracture include numbness, swelling, deformity in the knee, pain, inability to bear the weight, limited bending motion, difficulty in walking, running, or kicking and bone protruding. Tibia plateau fractures are common injuries that often require surgical treatment.[5]

Various strategies are used to treat distal tibia fractures such as ORIF, external fixation, and minimally invasive plate osteosynthesis (MIPO). Among all these strategies ORIF occur in favorable outcomes when the soft tissue envelop is intact. The main aim of the retrospective study in this article was to examine the safety and effectiveness of tibia plates which were used for fracture treatment of tibia bone.

Materials

All patients were treated with the following tibia plates which includes the proximal tibia plates and distal tibia plates which are (manufactured by Auxein Medical Pvt. Ltd.) as shown in (Table 1). All the Implants were made up of SS and Ti material (Stainless Steel Alloy as per ISO 5832-1 and Titanium Alloy Ti-6AL-4V as per ISO 5832-3). Implants and instruments used during the surgery were biocompatible.

METHODS

A retrospective study was organized at Changuinola Hospital (PANAMA), M. O. H. Jeetoo Hospital Surg. Stores (MAURITIUS), City Clinic Ltd (MAURITIUS), M. O. H. J. Nehru Hospital Surg.Store (MAURITIUS) and Serviclinicos Dromedica S.A (BUCARAMANGA) from February 2020 to July 2021. Clinical data were collected for patients who received tibia plates system.

Inclusion criteria

Male or female, skeletally mature patients above 22 years and patients with tibia bone fractures were included in the study.

Exclusion criteria

The participant may not enter the study if any of the following apply: subject having any neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care; subjects with substance abuse/alcohol issues; subjects who are incarcerated or have pending incarceration; subject having infection local to the operative site; any uncontrolled systemic disease that, in the opinion of the investigator, would preclude participation in the study (e.g. unstable medical status including uncontrolled elevated blood pressure, cardiovascular disease, and glycemic control) or put the subject at risk due to study treatment or procedures; subject with rapid joint disease, bone absorption, osteopenia, and/or osteoporosis and; subject having suspected or documented metal allergy or intolerance.

A total of 34 patients were recruited for the surgery. All of them were operated on between 70 to 80 minutes of the injury. Out of 34 patients 10 were women (29.4%) and the rest 24 were men (70.5%). As shown in (Table 2), the average age of patients was 48.6 years, ranging from 19 to 77 years.

According to the AO classification, proximal and distal tibia fractures 41-A, 41-B and 41-C were observed in 24 (70.5%) Male Patients and 10 (29.4%) female patients respectively. The fracture classification shows the Fracture types with the percentage of the fracture type as per the patients involved, which includes the following results 41-A {23 (67.6%)}, 41-B {7 (20.5%)}, 41-C{4 (11.7%)} as shown in below (Table 2).

Before surgery American Society of Anesthesiologists Physical Status classification System (ASA grade) is used for assessing the Fitness of patients. As per ASA grade, 24 Patient were having Grade 1 (Healthy individual) and 10 patients felt under Grade II (A patient with mild systematic disease) with no report of previous surgery on the affected fracture.

Implants used in the surgery were used with the same material instruments which have Biocompatibility in Tibia Plates and Distal Tibia Plates.

Fixation with metal wire is recommended when rigid stabilization which is not achieved with screws. Functional outcomes were assessed with VAS. This consists of a straight line with the endpoints defining extreme limits such as 'No Pain at All' and 'Pain as Bad as it could be'. The patient is asked to mark his pain level on the line between the two endpoints. The distance between 'no pain at all' and the mark then defines the Subject's Pain.

We use Microsoft excel for the percentage calculation. The surgery was performed with the patients under general anesthesia. All surgery was performed by the same surgeon. Pre-operative conditions were assessed in term of pain with VAS score (range 0-10 cm) as shown in (Figure 1).

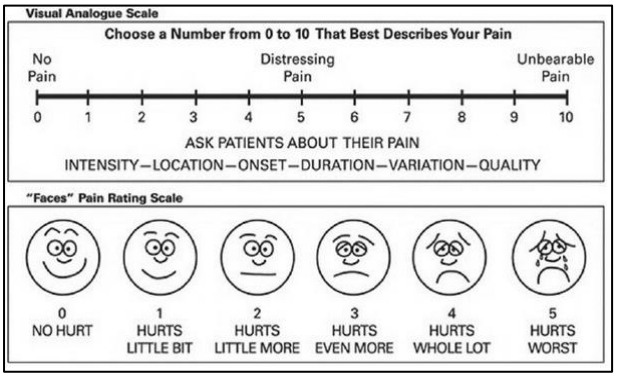


Figure 1: Visual analogue scale.

Treatment

A total of 34 consecutive patients meeting the inclusion exclusion criteria were included in this study. All patients with proximal and distal tibia plate fracture (41A, 41B and 41C) according to AO classification of fracture) were included in the study. The mean age of patients was 48.6 years (range above from 22-77 years).

Patients with the previous proximal and distal tibia surgeries were excluded from the study. All patients involved in the study have high energy open fracture. The Fracture Type in Tibia Plates is Classified according to the AO/OTA Classification which is shown in below (Table 3).

After osteosynthesis, radiography (X-ray) was used to examine bone union, implant failure and deformities. X-rays were examined on 1 month, 6 months, 12 months and 24 months.

All radio-graphic measurements were performed by the same surgeon. All patients were involved in the Radiography performed by the same surgeon. No complaints were found.

RESULTS

The most common etiology of injury as shown in (Table 2) with 8 patients having fall from height, 13 having road accidents, 9 having sports injury and the remaining 4 having slip and fall.

Table 1: Classified wise-lock tibia plates types according to the proximal and distal tibia plates.

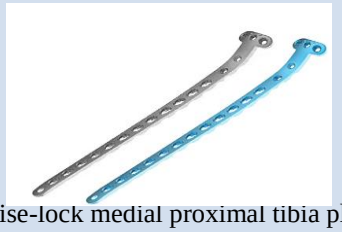
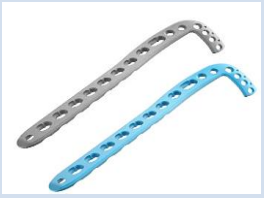
Proximal tibia plates	
 4.5/5.0 mm wise lock medial proximal tibia plate (4.0 mm)	 4.5-5.0 mm wise lock proximal tibia plate (3.9 mm)
 3.5 mm wise-lock proximal tibia plate (3.5 mm)	 4.5/5.0 mm wise-lock proximal lateral tibia plate (5.0 mm)
 3.5 mm wise-lock medial proximal tibia plate (4.0 mm)	
Distal tibia plates	
 3.5 mm wise-lock medial distal tibia plate, without tab (4.0 mm)	 3.5 mm wise-lock anterolateral distal tibia plate (4.0 mm)
 3.5 mm wise-lock anterolateral distal tibia plate (4.0 mm)	

Table 2: Demographic data.

Demographics	Percentage (%)
Sample size	34
Mean age/average age (years) (range)	49.9
Sex	
Male	24 (70.5)
Female	10 (29.4)
Fracture classification	
41-A	23 (67.6)
41-B	7 (20.5)
41-C	4 (11.7)
Injury	
Fall from height	8 (23.5)
Road accidents	13 (38.2)
Sports injury	9 (26.4)
Slip and fall	4 (117)

Table 3: Tibia plates fracture type classification according to AO/OTA.

Plate/implant name	Fracture type
4.5/5.0 mm wise lock medial proximal tibia plate (4.0 mm)	41A1.2
4.5-5.0 mm wise lock proximal tibia plate (3.9 mm)	41C1.1
3.5 mm wise-lock proximal tibia plate (3.5 mm)	41B2.2
4.5/5.0 mm wise-lock proximal lateral tibia plate (5.0 mm)	41B1.3
3.5 mm wise-lock medial proximal tibia plate (4.0 mm)	41C2.3
3.5 mm wise-lock medial distal tibia plate, without tab (4.0 mm)	43A2.2
3.5 mm wise-lock anterolateral distal tibia plate (4.0 mm)	43A2.1
3.5 mm wise-lock anterolateral distal tibia plate (4.0 mm)	43A2.1

All the patients were assessed according to ASA Grade before the surgical process.

According to VAS system the total patients sample size is 34 where 88.2% patient had showed no pain, and 11.7% patients had showed mild pain as shown in (Table 4).

No implant related complications have been found like implant loosening, bending, corrosion, and related size issue.

The complete follow-up has evaluation after every 6 months till 1 year with respective observations of callus formation, union and full weight bearing as shown in the (Table 5). The meantime showing good callus growth which is radio logically evident is 9.7 weeks with a range of 8-12 weeks. The meantime for full weight bearing was 13 weeks with a range of 8-20 weeks and for Union it was 26.6 weeks with a range of 24-29 weeks. All the observations showed good results.

For the postoperative care the initial 6 months, patients were suggested rehabilitation exercises followed by Physiotherapy. At every interval the progress was examined which showed good post-operative results. Till the 1st year of the follow up period. With no complications of indications of re-operation good surgical outcome was reported. It included no cases of failure of fixture, non-union and infections.

DISCUSSION

A broken tibia is a fracture in the lower leg and connects the knee and ankle. They are separate bones that happen when a fall or blow places more pressure on the bones than they can withstand. This is a serious injury that requires prompt immediate medical attention. With timely and proper treatment, a broken Tibia can heal completely.

Treatment used in Tibia fractures like the proximal and distal tibia fractures and various methods used as bone plate (plates and screws) fixation whose main principle of operation is fracture reduction and anatomical relationship gaining.

The present study represents the treatment of Tibia fractures surgically by using the tibia plate fixation system which was designed and manufactured by Auxein Medical Pvt. Ltd, India. Major complications like Superficial wound infections and stiffness have been reported by many studies but none was reflected in the outcome of our evaluation.

Table 4: Result of VAS score.

Follow-up time	No. of patients					
	No pain	Mild pain	Nagging	Distress	Intense	Worst possible
1 month	0	22	12	0	0	0
6 month	0	0	16	18	0	0
1 year	30	4	0	0	0	0

Table 5: Patients clinical evaluation data.

S. no	Evaluation categories	Recovery time (range in weeks)
1	Callus time	8-12
2	Union	24-29
3	Full weight bearing	8-20

A study conducted by Beck et al, in which 24 patients with complicated proximal segmental tibia fractures were treated with stabilization locking plate system. The study showed that 2 patients having deep-seated infections, 5 patients underwent postoperative misalignments and 11 patients (47.8%) suffered from a complicated healing process.

But in our study pain was observed in the patients during the Follow-up period but no complication such as infections, postoperative misalignments and do not suffered from the complicated healing process.[6]

A study conducted by Singh et al, in which 30 patients with the distal tibia fractures underwent surgery. This study showed excellent outcomes of a fracture healed with a short period of immobilization with continuous follow up of twenty-eight weeks. But in our study patients showed delay bone union and no infections reported.

As for the present study the trial was conducted after one month, six-months, one year. The outcome was presented by calculating the VAS score. This has shown good acceptance outcomes.[7]

The limitations of the study are the sample size and the retrospective study design, which encounter the risk significance of the present study are that: the sample size was small, No proper statistical data was there and should be increased in the sample size, the average follow-up was less, which is a relatively short evaluation period. A larger sample size and longer follow-up would be helpful in a future study.

Naturally, these limitations could be avoided when applying a different study design. Considering the limited case load of these injuries, a register or a multi-center setup would be preferable.[8]

CONCLUSION

From this study, we concluded that the internal fixation of tibia plate system is the best treatment for tibia fracture but it could be possible after counting the VAS score, AO classification, and sample size. It has also been considered a better surgical option as it offers significant in terms of motion, blood loss, mean operating time, hospital stay, full weight bearing time, and union time. The fixation of tibia plate provides the superior stability properties in the clinical setting.

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Ethical approval: The study was approved by the institutional ethics committee

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