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Anatomical pre-contoured plates in management of distal tibia fracture: a prospective study

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ABSTRACT

Background: Distal tibial fractures are complex injuries with high complication rate. Management of such fractures are often complicated by soft tissue injuries. Precarious vascularity around distal tibia also results in high non-union rates. This study aims to study and analyse the outcome of distal tibia fracture managed by anatomical contoured plate.
Methods: In this prospective observational study, we attempted to assess the functional and radiological outcome of distal tibia fracture managed by with distal tibia fracture with average follow up of 24 weeks. ORIF/MIPO with plating was done for fracture distal tibia with anatomical precontoured plates.
Results: Patients were evaluated using AOFAS and measure of ankle range of motion. Average functional score was 88 with complications in 3 patients.
Conclusions: We believe precontoured plates provide for better biological fixation than conventional plates.

Keywords: Distal tibia fracture, MIPPO, AOFAS, Precontoured plate, Anatomical plate

INTRODUCTION

Distal tibia fractures include extra-articular fractures of metaphysis and intra articular tibia fractures. These fractures remain a commonly encountered problem with high complication rate. They are often caused by high energy axial compression, direct bending or, low energy rotational forces.[1,2] These fractures constitute less than 7% of all tibia fracture and less than 10 % of all lower extremity fractures.[3-5]

Fractures of the distal tibia are unique in that the bone is subcutaneous with depleted muscle cover, the consequent decreased vascularity leads to complications like delayed bone union, wound complications such as dehiscence and infections.[1,3,4] These fractures can be managed with various techniques. Treatment selection is influenced by distance of the fracture from the articular surface, displacement or comminution at the fracture site and injury to the surrounding skin and subcutaneous tissues.

The aim of treating the fracture is to preserve normal mechanical axis, ensure joint stability and restore a near full range of motion.[1,3]

Conservative management can be an option in fractures that are stable and minimally displaced. High rate of complications like malunion limb length discrepancy, decreased range of motion and early osteoarthritis of the ankle have been reported following conservative treatment of these fractures.[5]

Surgical fixation is considered for most distal tibia fractures which require meticulous preoperative planning. While external fixators, nails and plates can be used in managing these fractures, choice of implants largely depends on pattern of fracture, quality of bone and

condition of soft tissues.[6] External fixation can be used in open fractures with soft tissue damage that precludes plate fixation and intramedullary nailing (IMN); however, malalignment (1-4%), mal union (5-25%), non-union (2-17.6%) and pin tract infection (10-100%) have been reported.[7-9]

The intramedullary nail spares the extra osseous blood supply, allows load sharing, and avoids extensive soft tissue dissection.[10,11] However, proximal and distal shaft fractures can be difficult to control with an intramedullary device, increasing the frequency of malalignment.[12]

Compression plate can devitalize the bone under the plate because of direct compression of periosteal as well as disturbance of blood flow between endosteal and periosteal systems causing devascularisation which increases the risk of infection.[13,14]

Contoured or anatomically designed plating has been available for management of distal tibia fractures for approximately 10 years. These plates are designed to be an accurate anatomic fit to the specific fracture site. This reduces or eliminates the need for bending intra operatively. More importantly the plate itself can be used as a template in areas where there has been impaction and or severe comminution. The early generation plates offered stabilization of ankle fractures from anteromedial and anterolateral distal tibia as well as the anatomic distal lateral and posterolateral fibular plates. Subsequent generations of these devices have added additional technology such as rolled/chamfered edges to assist in percutaneous application, angular stability for fixation locked screws prevent the plate from pressing the bone, preserving periosteal blood supply.[15-18] Newer designs employ multiple sizes of locking and non-locking screw options that give the surgeon great flexibility and dramatic enhancement of stability for the patient. This has allowed earlier weight bearing and enhanced recovery for patients.[19]

The objectives of our study was to assess the functional outcome in patients who were treated with anatomical pre contoured plate using AOFAS score and to analyse the extent of radiological union the distal tibia fractures during the study period.

METHODS

Study site

This prospective study was conducted in the Department of Joint Reconstruction and Orthopaedics of Tata Main Hospital, a 940 bedded multi-disciplinary hospital located in Jamshedpur of Jharkhand from July 2017 to June 2019. In this study 30 patients who gave informed consent were included in the study. They were admitted either through Outpatient Department or the Emergency Department of Tata Main Hospital. The fractures were classified according to AO classification.

Study population

It includes the patients attending the orthopaedic surgery OPD, emergency or admitted as indoor patients during two years' time interval (from July 2017 to June 2019).

Study design

It was a prospective, non-controlled, non-randomized, non-blinded observational study.

Selection criteria

Inclusion criteria

Patients who gave informed consent, patients who attained lower tibia skeletal maturity, with closed fractures, fresh fractures (<3 weeks), and both extra articular and intra articular were included.

Exclusion criteria

Patients who do not gave consent, not willing for surgery, not fit for surgery, with pathological fractures, definite major illnesses like malignancies, and chronic major systemic illness, old fractures (>3 weeks), and polytrauma patients and patients with head injury were excluded.

Study approval

Approval from the ethical committee of Tata Main Hospital, Jamshedpur was taken before embarking on the study.

Methodology

The study includes the patients with distal tibia fractures admitted and examined according to the protocol.

On admission of the patient a careful history of injury and the severity of trauma elicited from the patients and/or attendants. The patients were then assessed clinically to evaluate their general condition and the local injury.

The local examination of injured leg was done for swelling, deformity, loss of function and the altered attitude and any associated nerve injury was also looked for and noted.

Radiographs of both leg with ankle joint antero-posterior, lateral and mortise view were taken and fractures were classified according to the AO/OTA classification.

Next the limb was immobilized in above knee pop slab and elevated over Bohler-Braun splint.

The patient was taken for surgery after routine investigations and after obtaining fitness for the surgery by physician/anesthesiologist and any other related specialty.

The consent for surgery was taken from the patients and their attendants after explaining the procedure and the possible complications.

Preoperative prophylactic intravenous antibiotics were administered as per hospital protocol.

Patients underwent MIPPO/ORIF anatomical contoured distal tibia plate for the sustained fractures under spinal anesthesia. Post-operative physiotherapy was followed according to the protocol to evaluate the functional outcome.

Surgical technique

Patient positioning and draping

Patients were positioned supine on operating table with the leg raised over a pillow and a sandbag positioned beneath the ipsilateral hip for natural rotation of foot. Primary scrubbing of the part was done. Skin was prepared from knee up to foot and square off rest of the lower limb with drapes.

Reduction technique

The fracture was reduced under fluoroscopy by indirect means by using manipulation and traction and stabilized. Check for the reduction by anteroposterior and lateral roentgenograms or by image intensifier, paying special attention to cortical contact. Figure 1 shows preoperative AP view of fracture of distal tibia.

Figure 1: Preoperative fluoroscopic AP view of distal tibia fracture.

Approach

3-4 cm incision starting just distal to medial malleolus extending proximally overlying subcutaneous surface of tibia halfway between anterior and posterior border. Depending on position and size of implant used another incision given proximally over subcutaneous surface of tibia halfway between anterior and posterior border. Minimal open reduction was done in cases, where satisfactory reduction could not be achieved by indirect means. Percutaneous plate placement was performed after sufficient closed, indirect reduction or percutaneous direct reduction. The low contact plate (LCP) was placed sub muscularly and extraperiosteally and reduction was maintained by K-wires fixed on each of the major fracture fragments (Figure 2).

Figure 2: Implant inserted in subperiosteal plane and held with K wires.

The LCP plate was fixed in relative or rigid mode depending on the nature of the fracture. The fibula was fixed in cases in which ankle anatomy and stability had to be restored. Initial fibula fixation provides lengthening and helps place the tibia in the correct position. Intraoperative C-arm fluoroscopy was used to evaluate the correct placement and fixation of the fractures (Figures 3 and 4).

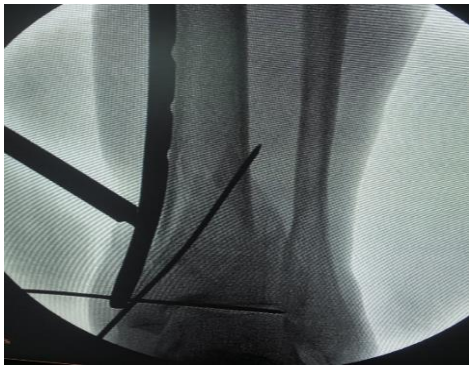

Figure 3: Showing application of distal tibia LCP application.

Deep tissues were brought together using braided suture materials while the skin was closed with monofilament sutures/skin staples (Figure 5).

Post-operative regimen

At 2nd post-operative day, post-operative check X ray was done, physical therapy with knee bending exercises and gentle active ankle exercises was started. Limb elevation, to achieve gravity-assisted venous drainage along with active toe and ankle movements were carried out for the initial two weeks. Wound was inspected on 3rd post-operative day or earlier if there is soakage. Supportive medical treatment was instituted as per requirements of the patient.

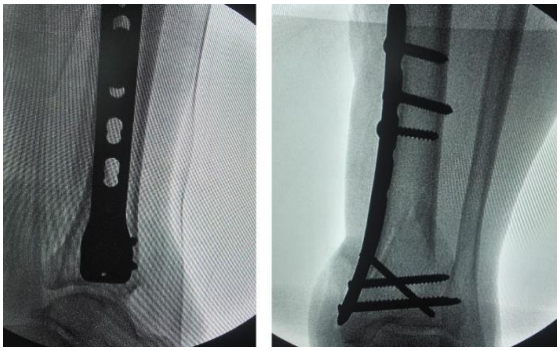

Figure 4: Showing fluoroscopic images after implant application in lateral and AP views.

Intravenous antibiotic regimen was continued for 3 days after the surgery. Another 5 days of oral antibiotics were advised. Suture removal was done at 12th-14th post-operative day.

Follow up

Non-weight-bearing ambulation was permitted at approximately two weeks, after proper wound healing and appearance of the wrinkle sign. Patients were followed up clinically and radiologically in the OPD at 4, 8, 16, 20, 24 weeks to assess progress of union and possible complications. AOFAS scoring (Table 1) of each patient was assessed at 24 weeks. This scoring system classified the evaluated items into three major categories: pain, function, and alignment. In this scale, 50 points have been assigned to function, 40 points to pain, and 10 points to alignment. Usually, a score between 90 and 100 was excellent, 75–89 good, 50–74 fair and <50 poor.

Figure 5: Sutured surgical wound.

Full weight-bearing was permitted only after clinical-radiological evidence of union. Union was defined as bridging of three of the four cortices and disappearance of the fracture line on the plain radiographs for a patient who was able to bear full weight. Fracture in the process of union but not united at six months was considered as delayed union. Malunion was defined as the incongruity of the articular surface of more than 2 mm or mal-alignment greater than 5° in any plane.

Non-union means that the fracture still exists and healing has stopped. The fracture will not unite without surgical intervention. Unless there is a bone loss; non-union was declared eight months after the fracture occurred.

Table 1: American orthopaedic foot and ankle society ankle – hindfoot scale: (AOFAS ankle – hindfoot scale).[36]

Parameters	Points
Pain (40 points)	
None	40
Mild, occasional	30
Moderate, daily	20
Severe, almost always present	0
Function (50 points)	
Activity limitations, support requirement	
No limitations, no support	10
No limitations of daily activities, limitations of recreational activities, no support	7
Limited daily and recreational activities, cane	4
Severe limitations of daily and recreational activities, walker, crutches, wheelchair, brace	0
Maximum walking distance, blocks	
Greater than 6	5
4 – 6	4
1 – 3	2
Less than 1	0
Walking surface	
No difficulty on any surface	5
Some difficulty on uneven terrain, stairs inclines, ladders	3
Severe difficulty on uneven terrain, stairs, inclines, ladders	0
Gait abnormality	
None, slight	8

Continued.

Parameters	Points
Obvious	4
Marked	0
Sagittal motion (flexion plus extension)	
Normal or mild restriction (30˚or more)	8
Moderate restriction (15˚- 29˚)	4
Marked restriction (less than 15˚)	0
Hindfoot motion (inversion plus eversion)	
Normal or mild restriction (75% - 100% normal)	6
Moderate restriction (25% - 74% normal)	3
Marked restriction (less than 25% normal)	0
Ankle- hindfoot stability (anteroposterior, varus-valgus)	
Stable	8
Definitely unstable	0
Alignment (10 points)	
Good, plantigrade foot, midfoot well aligned	15
Fair, plantigrade foot, some degree of midfoot malalignment observed, no symptoms	8
Poor, nonplantigrade foot, severe malalignment, symptoms	0

Data entry

All the data collected was entered into a spread sheet on Microsoft office excel sheet and analyzed with statistical package for the social sciences (SPSS) IBM (version 24.0; SPSS Inc., Chicago, IL, USA) and GraphPad Prism version 5. Data validation checks were performed at a regular interval for data entered into the worksheet of MS excel.

Sample size with justification

Here, N is the total population which is 3000 per year (approximately), n is sample size for current study, Z is Z statistics for level of confidence (i.e. 1.96 for 95% confidence level), confidence level is 95%, P is expected prevalence or proportion (1%) which is 0.01, d is precision equal to 0.036.

$$n = \{z^2 p(1-p)\}/d^2$$

Therefore,

$$n = [(1.96)^2(0.01)(1-0.01)]/(0.036)^2 = 29.32 \approx 30 \text{ (for round off)}$$

Hence, 30 is the required sample size.

RESULTS

This study consisted of a total of 30 patients. In the present study maximum number of patients was found to be in the 5th and 6th decade of life with an average age of 52 years. There were 18 male and 12 female patients. Right side distal tibia fracture was more than the left side of the distal tibia fracture in the present study. In the present study mode of injury was RTA (63%) in most of the patients (Figure 6).

Associated injuries are given in Figure 7.

Table 2: Sex distribution among the patients.

Sex	No. of patients (n=30)	Percentage
Male	18	60
Female	12	40

Table 3: Age distribution among the patients.

Age (year)	No. of patients (n=30)	Percentage
≤20	1	3.33
21-30	2	6.67
31-40	4	13.33
41-50	6	20
51-60	8	26.67
61-70	8	26.67
>70	1	3.33
Mean±SD	51.2±14.13	

In the present study 14 cases of 43A2, 10 cases of 43A1 and 6 cases of 43A2 were there. Of all included patients 16 patients were operated by MIPO and 14 by ORIF and the fracture was fixed with the anatomically contoured distal tibia locking plates in all the cases. Mean duration of operation was 107 minutes and patients were operated on an average of 7th day after admission.

Fracture union was achieved in all the patient with mean duration of 21 weeks. All the cases were followed up as per the protocols and the finding were recorded. Functional outcome was analysed according to AOFAS score.

Excellent score was seen in 50 % of patient, good score in 40% of patient and fair in 10% of patient and poor result in zero case with mean score of 86 (Figure 8).

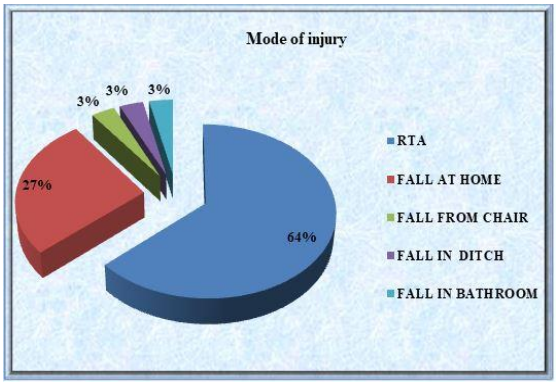

Figure 6: Mode of injury.

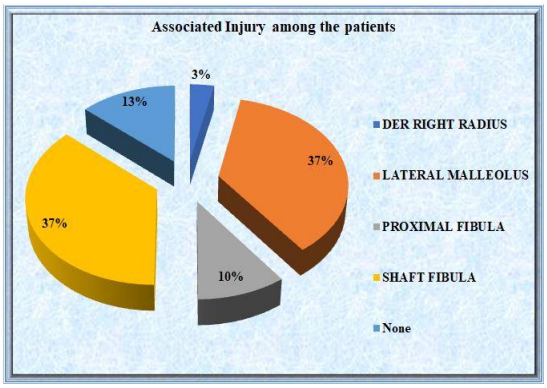

Figure 7: Associated injury.

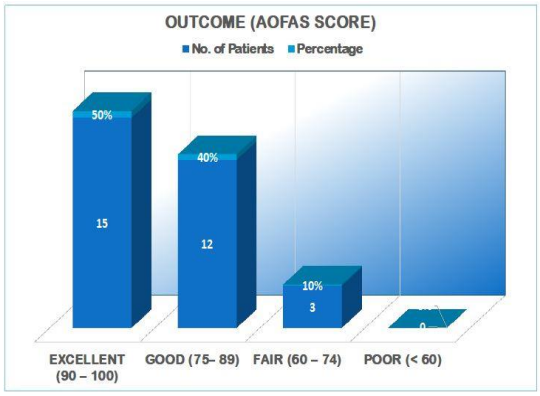

Figure 8: AOFAS functional outcome.

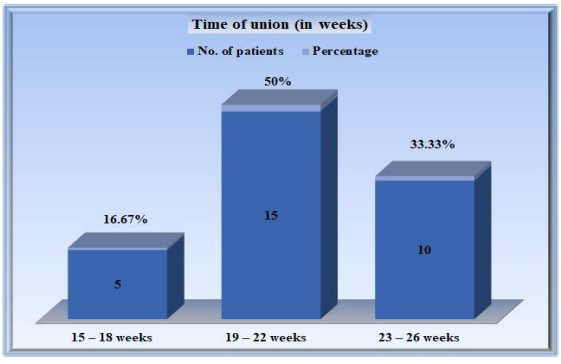

Figure 9: Time of union (in weeks).

Time of radiological union varied from 15 weeks to 26 weeks (Figure 9). Ankle range of motion at 24 weeks is depicted in Figure 10.

Few complications like superficial, delayed union was reported among patients, despite these complications the overall functional result was good.

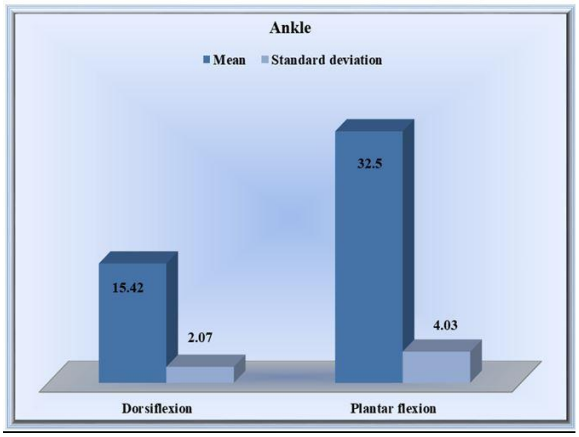

Figure 10: Ankle range of motion at 24 weeks.

DISCUSSION

Managing distal tibia fractures is considered a challenging task because degree of comminution, status of soft tissue along with compromise in vascularity sustained at the time of injury, affects the clinical outcome. The aim of treatment is to obtain anatomical alignment of joint surface by providing stability to allow early weight bearing. Distal tibia has near total circular cross-sectional area with thinner cortex compared to triangular diaphysis with thicker cortex. Intramedullary nails which are designed for tight interference fit at diaphysis can't provide same stability at distal fracture.[19,20] ORIF with conventional plate requires stripping of periosteum and is not an ideal treatment option as tibia is subcutaneous bone and periosteum provides 2/3rd of blood supply. Non-union, delayed union and infection are reported in fractures managed with conventional plates.[21-24] External fixators as a definitive method of treatment for distal tibia fracture are also reported but associated with higher rate of infection, implant failure, malunion or non- union and so it is usually kept as temporary method of stabilization in open fracture with severe soft tissue injury.[25,26]

LCP which preserves extraosseous blood supply, respect osteogenic fracture haematoma, biologically friendly and stable fixation method is available for distal metaphyseal tibia fracture. Indirect reduction method and sub-cutaneous tunnelling of the plate and application of locking screws with small skin incisions in MIPO technique prevents iatrogenic injury to vascular supply of the bone.[27] Unlike conventional plates, LCP is a friction independent self-stable construct which provides both angular and axial stability and minimizes risk of secondary loss of reduction through a threaded interface between the

screw heads and the plate body.[28] The goal of the study was to assess the functional and radiological outcome of distal tibia fractures managed by anatomical contoured plates. Our study consisted of 30 patients with distal tibia fractures managed by pre anatomical contoured distal tibia locking plate either by ORIF or MIPPO. The following variables of each patient record were analyzed: age, sex, fracture type and pattern, mode of injury, limb involvement, associated injuries, sizes of implant used, timing and duration of operation, duration of hospital stay in days, follow up in months, complications, and final outcomes. Table 2 shows comparison of current study with some of the previous studies.

Reduction of fracture by direct or indirect maneuvers before applying plate is a very important step. Mal reduction and sub optimal pre contouring of plates results in delayed union, non-union, prominent hardware, malleolar skin irritation and pain. Shrestha et al reported pain and malleolar skin irritation and pain in 6 patients leading to implant removal.[31] Also, in skinny and thin patients prominent hardware becomes a cosmetic concern and causes difficulty in wearing shoes.

Patients were between 18-74 years of age, with a mean age of 51.2 years. The age group of 51-60, 61-70 years comprised the highest number of patients (52%). This is slightly higher to findings of Gupta et al where the median age was 36 years (range: 17–58 years).[32]

In our study, there were 18 male and 12 female patients (M: F = 2.0: 1). Similar male preponderance was seen by other authors; Gupta et al reported 63 male to 16 female (M: F=3.93:1), and Gao et al reported it as 2.55:1.[32,35] Associated injuries were seen in 26 of 30 patients (86%). This is far more than reports by Shrestha et al where associated injuries were seen in 5 of 20 patients (25%).[31] Associated fibula fracture also played a key role in success of reduction if both the fractures are at same level, some authors recommend fixing fibula first to achieve better tibial alignment and for preventing valgus malalignment. All associated injuries were appropriately managed with a favorable outcome

Road traffic accidents (RTA) accounted for majority of fractures (63.33%), falls accounted for 37%. Similar findings seen by Shrestha et al in which RTA accounted for 50%, falls for 40%, and assault and sports in combination accounted for 8% of these fractures.[31] Gupta et al reports the figure as 86% for RTA and 14% for falls.[32] Joveniaux et al reported 41.5% RTA cases, 31.6% cases due to fall from height and 26.7% cases due to twisting injuries.[20] In our study, 43A1 type accounted for 33%, 43 A2 for 47%, and 43A3 for 20%. In a study done by Li et al (15) 43A1 cases accounted for 34.7%, 43A2 for 47.8%, and 43A3 for 17.39% which were similar to our study. Shrestha et al found 60% cases for 43A1, 20% for 43A2, 10% for 43A3 and 10% for 43B1.[31] Due to subcutaneous location, distal tibia fractures are prone to gross swelling, blisters, if leg remains unsplinted and injury hospital arrive interval is prolonged. The average time interval between injury and surgery in our study was 7 days (range 4-14 days), which is more as compared to Gupta et al who reported 5 days, and Shrestha D et al who reported as 4.45 days.[31,32] This average time of 7 days between injury and surgical procedure was mainly due to delay in reporting to the hospital or time taken to reduce the gross swelling.

The average time for fracture union in various studies conducted using various methods was 16–24 weeks. Our study had an average fracture union of 20.5 weeks which were comparable with studies conducted using the locking compression plates. Collinge et al had an average fracture union of 21 weeks, Mushtaq et al had an average union of 22 weeks, Shrestha et al had average union of 20 weeks, Li et al had 18.5 weeks, Gupta had 19 weeks, Lau et al had 18.7 weeks (12), Bahari et al had 22.4 weeks, Hasenboehler et al had 27.7 weeks, and Ronga et al had 22.3 weeks. [24,26,27,29,31-34]

In our study complications were encountered in the form of superficial surgical site infection in 3 cases (10%), delayed union in 1 case (3.33%). No implant failure was seen. These results are similar to study done by Shrestha et al on 20 cases, reported superficial infection in 3 cases (15%), deep infection in one case (5%), delayed union in one case (5%), and valgus angulation in 2 cases (10%).[31] Li et al in a study on 23 patients, reported superficial infection in 3 cases (13%), malalignment (>5 degree) in 1 case (4.34%), varus/valgus angulation in 1 case (4.34%), with no cases complicated by delayed union and non–union.[33] The higher percentage of complication in studies by Joveniaux et al who reported as 20–50%, and Gupta et al who reported 55% complication in LC–LCP group, 23% in metaphyseal LCP group and 15% in distal medial tibia LCP, were due to inclusion of both intra–articular and extra–articular fractures.[20,32] No incidence of injury to saphenous nerve or great saphenous vein was found in current study.

Based on the assessment parameters of AOFAS score used in this study, 15 patients (50%) had excellent, 12 patients (40%) had good outcome, 3 patients (10%) had fair outcome and none of the patient (0%) had poor outcome, and average functional score was 86.33 points in the result. Joveniaux et al in a study on 101 distal tibia fractures (22 cases of 43A, 51 cases of 43B, and 28 cases of 43C) reported excellent outcome in 31 patients (30.69%), good outcome in 25 patients (24.75%), fair outcome in 37 patients (36.63%) and poor in 8 patients (7.9%), and average functional score was 76 points.[20] Gao et al in a study on distal tibia fractures treated with polyaxial locking plates, reported average functional score of 87.3 points (range,72–98 points).[35]

CONCLUSION

With this study we conclude that anatomical pre contoured distal tibia plate provides good fixation for distal tibia fracture whether extra or intra-articular if proper

preoperative planning, good reduction and surgical technique are followed, leading to high rate of bone union and minimal soft tissue damage. As our study was time bound, the patients were followed up for only 6 months. Therefore, the long-term effects of this intervention remain unknown in our cohort. A longer follow up would have made a complete assessment of this surgical intervention. Our sample size reflects the routine patient inflow in our hospital. A study with a larger sample size, would have made a better assessment of this surgical intervention. The plates are designed according to the anthropometric measurements of western population, so it necessitates optimal contouring for Indian population

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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