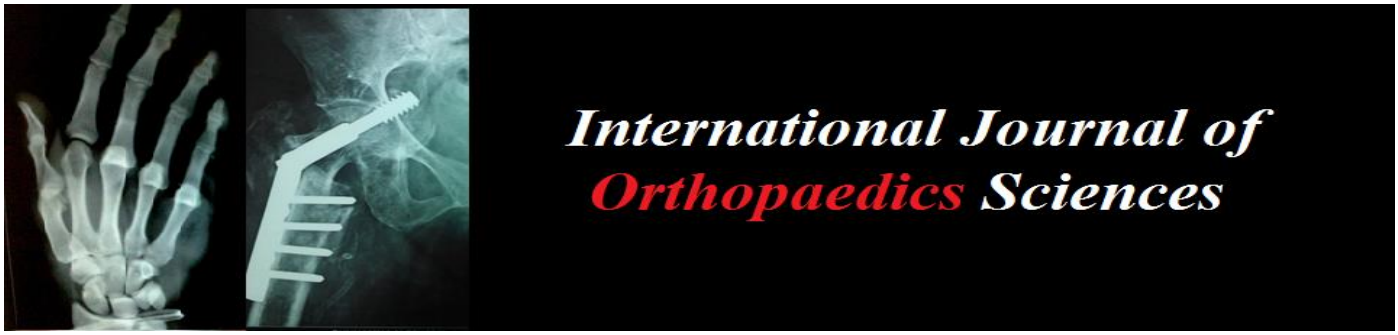

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Functional evaluation of distal third tibial fracture osteosynthesis with fix heal™ distal tibial locking plate: An observational study

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Abstract
Background: Fractures around the distal third tibia are one of the challenging problems faced by orthopaedic surgeons owing to associated conditions such as disruption of syndesmosis, fibula fractures, articular extensions, ankle joint dislocations, and compromised soft tissue envelope. The present study is a functional evaluation of the results of the fixHEAL™ locking compression plate for distal tibia fractures.
Materials and Methods: We conducted a single-centre study through our post-market surveillance project including data for 56 patients with distal third tibial fractures operated from August 2019-November 2021 was collected. The patient's pre-operative clinical and radiographic examination findings were noted. Orthopaedic procedures were performed by a single surgeon aptly skilled and experienced to handle complex orthopaedic trauma. The functional outcome was assessed by Olerud-Molander functional evaluation score (OMFES). Clinical assessment of bony union and complications in the perioperative and postoperative period was also considered.
Results: Radiographic union was observed in all cases by 6 months, except 2 cases where secondary surgery was done to achieve bony union.
Conclusion: Functional outcome is influenced by the fracture geometry, co-morbidities, associated soft tissue injury and perioperative complications. Excellent soft tissue handling during surgery and management of associated injuries is a prerequisite for satisfactory results.

Keywords: Osteosynthesis, tibia, plating, functional results

Introduction
The tibia is one of the most commonly fractured long bones seen in orthopaedic practice. Distal fractures of the tibia are severe injuries and are often described as tibial plafond/pilon fractures. The average age is approximately 37 years with a male preponderance [1].
These fractures are commonly associated with soft tissue injuries including skin loss, severe comminution and bone loss. Such fractures required satisfactory reduction as any malunion disturbs the normal biomechanics of the ankle and foot, thereby leading to arthritis of the ankle and foot joints.
In the past, closed fractures of the lower tibia have been treated by closed reduction and casting with a significant number of cases developing malunion. Operative modalities include plating (open reduction and minimally invasive percutaneous plate osteosynthesis, MIPPO), interlocking nails, external fixators including Ilizarov circular ring fixators, and limb reconstruction systems [2-5]. The present study was planned for assessing the functional outcome of distal third tibial fracture fixation with fixLock™ distal tibial locking plate by open reduction/MIPO technique.

Materials and Methods
The present study was conducted with the aim of functional evaluation of distal third tibial fracture fixation with the fixLock ™ distal tibial locking plate by GPC Medical Ltd. A total of 56 patients with distal third tibial fractures managed at the department of Orthopedics, KK Hospital Delhi, India between August 2016- November 2021 were included in the study.

Since it is a retrospective study without patient identifiers, obtaining the informed consent of patients for the study may not be feasible. The sponsors of the study, while monitoring or auditing the trial will also have the access to data without violating the confidentiality of the patients, to the extent permitted by applicable laws and regulations. All data relating to the project will be in the custody of the designated investigators.

The study includes 47 males and 9 females. The mean age of the male and female patients was found to be 35.51 years and 53.66 years respectively. Fractures were classified according to AO classification.

Inclusion criteria

- Patients aged >18 years.
- Patients involving distal 5cm of the tibia and all closed and Gustillo Anderson grade I, II and up to IIIA open fractures

Exclusion criteria

- Patients aged <18 years.
- Gustillo Anderson grade IIIB and above open fractures, associated vascular injuries, Pathological fractures.
- Tibial fractures associated with ipsilateral ankle dislocation and talus fractures
- All patients had pre-operatively undergone pre-anaesthetic check-ups with necessary investigations, and a biplanar radiograph of the affected leg with ankle joint.

Pre-operative treatment included below knee slab for splintage, limb elevation over Böhler Braun splint, and Ice pack application. Active movements of the toes and static quadriceps exercises have been advised to patients for 10 minutes per hour when awake. For high-energy trauma patients, or patients with blisters were given calcaneal traction pin. All the fractures were fixed in a single stage after the swelling subsided and wrinkling of the skin occurred. Blisters were punctured and the overlying skin was left intact, topical application of Neomycin, Polymyxin, and Bacitracin, covered by a sterile dressing. Intravenous antibiotics are given to patients if blisters appear.

Management for Extraarticular Fractures is based on the concept of anatomical alignment and indirect reduction of fracture while Intraarticular Fractures need Anatomical reduction of the fracture and absolute stability with rigid fixation.

In cases of extraarticular fractures, the indirect reduction was achieved through manual reduction, percutaneous pointed reduction clamp, or joystick technique. If direct articular reduction was required in AO type C1, C2 and C3 transverse arthrotomy was done. For complex articular fractures, the anterolateral fragment was externally rotated followed by the reduction of a centrally impacted fragment to the posterolateral fragment. The K-wires were inserted in posterolateral fragments to act as a joystick for reduction. The K-wires were inserted from the anterior tibia to the posterolateral fragment. The medial fragment was reduced to the posterolateral fragment using

a reduction clamp followed by percutaneous K-wire fixation. At last anterolateral fragment was reduced in position and stabilized with K-wires. In cases of intraarticular fractures, small lag screws were placed between the major articular fragments before plate fixation depending on the fracture configuration [6].

Sutures were removed on the 14th day. Further follow-ups took place at 4, 6 weeks and then at monthly intervals for the first 3 months then quarterly till 1 year. Patients were assessed clinically, and radio graphically with anterior-posterior and lateral views, and functional assessment was done according to the Olerud-Molander functional evaluation score (OMFES).

Complications were defined as minor or major depending on the need for further operative intervention or residual morbidity. All the complications were documented and recorded separately.

Results

In the present study, a total of 56 patients were analyzed. The mean age of the male and female patients was found to be 35.51 years and 53.66 years respectively. The age of the patients ranged from 22-71years. The gender distribution of the study group is tabulated in Table 1.

Patients with Open injuries Type 1, Type 2, and Type 3a (Gustillo Anderson classification) were included in the study along with closed injuries. As shown in Table 2 Most of the patients suffered closed injuries. Open Injuries were sustained during a Road traffic accident (high-velocity trauma).

Co-author M.G assessed the patients radiographically, and was blinded to the clinical history and outcome of the study group patients.

The study was performed after approval by the Ethics committee of the hospital fully abiding by the Helsinki declaration. All the patients who agreed to participate in the study signed a written consent form.

Functional outcome was assessed under OMFES criteria and charted in Table 3, excellent results were observed in 23.2% of the cases while good results were present in 57.1% of the cases. Fair results were found to be present in 14% of the cases. Functional outcome was also analysed depending on the surgical technique performed was an open reduction or MIPPO technique and shown here in Table 4.

38 patients had associated fibular fractures, of which fibular fixation was done for 32 patients. 6 patients had minimally displaced suprasyndesmotic fibular fractures, they were not fixed. The mean distance between the posterolateral and anterolateral incision was 5.8 cm. The distance between the two incisions was less than 7 cm in 29 patients, whereas the ideal distance of more than 7 cm in only 3 cases.

Radiological and clinical healing of fracture occurred at 3 months in 6 patients, 4 months in 39 patients, at 6 months in 9 patients, and 9 months in 2 patients (after the second procedure).

Every Complication in the study group patient was documented. 2 patients had Non-union which required an additional procedure of Autologous Iliac crest bone grafting, Malunion was seen in 5 patients. Although 30% of patients belonged to the Open fracture category, superficial infection was seen in 5 patients and deep infection in 2 patients. Marginal necrosis of fibular fixation wound was seen in a patient with superficial infection and wound lavage, and secondary healing with Vac dressing was done. Deep infections were seen in two patients, 3 months after the primary surgery. Both patients had pre-existing uncontrolled diabetes mellitus and implant removal was done at 9 months and 12 months respectively. Bony union was achieved in both cases. Additional below knee walking cast was given for 12 weeks and 6 weeks respectively after implant removal in these cases. Complications in patients under study are shown in Table 5. One patient reported syndesmotic screw breakage with no effect on his functional outcome.

There was a failure to achieve reduction (>5 degrees of varus/valgus; >10 degrees of procurvatum/recurvatum) in one case (patient 9). This patient had a comminuted osteoporotic fracture in both bone legs. The same distal tibial fracture had malunited in the varus position. The patient was offered the option of surgery but the functional outcome was good and the patient was satisfied with the primary surgery.

There was no incidence of intraoperative complications related to surgery or anaesthesia in the present study. No adverse event from anaesthesia in the postoperative period was reported. All patients received prophylaxis for Deep Vein Thrombosis (DVT) with oral Ecospirin 75 mg once a day for 3 weeks. Patients with a pre-existing cardiac disease on clopidogrel were restarted the same after surgery.

Discussion

Distal tibial fractures at metaphysis- diaphysis junction pose serious challenges to fixation owing to the intraarticular extension of fracture, soft tissue envelope damage, poor healing, thinner cortex, bone loss and planning of implant positioning. The ideal line of management of distal tibial spiral fractures includes a Computed Tomograph of the ankle joint to look for an intraarticular extension of the fracture and/ or fracture of the posterior malleolus. Studies have demonstrated the importance of CT scans in detecting previously unreported injuries as seen on plain radiographs.

Open reduction internal fixation and plating involve stripping of the periosteum affecting the blood supply of the distal tibia. Nonunion, delayed union and infection are reported in the range of 8.3 to 35% and 8.3 to 25% respectively with ORIF with plating [7, 8]. MIPO is by now an established technique of management of fractures of the distal third tibia.

The author has performed surgery by both these techniques and both groups of patients are included in this study. The current preference is towards the MIPPO technique but the role of open reduction cannot be surpassed by the MIPPO technique in certain fractures requiring open reduction.

Fixation must be undertaken following AO principles of fracture fixation. Anatomical fixation of the articular fragment is done with minimal soft tissue handling to preserve blood supply as demonstrated here in figure 1 and figure 2. Alignment of the fracture to prevent varus/ valgus malalignment must be ensured. The aim of the treatment of the distal tibial fractures is to achieve union of the fracture in normal alignment and regain the stable, mobile and painless ankle joint while avoiding infection and other complications [9]. Figure 3 shows the fixation of comminuted distal tibial fracture of an osteoporotic bone in an elderly female with fixHEAL™ distal tibial locking plate by GPC Medical Ltd. using the MIPPO technique. In Osteoporotic fractures, metaphyseal bone collapses and anatomical reduction in the metaphyseal area cannot be achieved. The author planned for open reduction and primary bone grafting in this case, however no consent for bone grafting was given by the patient and the surgical treatment plan was changed to the MIPPO technique. Gradual weight bearing was started in this patient after 12 weeks. The radiological union was achieved at 18 weeks postoperatively.

A study by Kapukaya *et al*. achieved excellent or good clinical results in 58%, fair in 21% and poor in 21% of patients [10].

Bourne *et al*. in a series of 42 patients with distal tibia fractures observed good or fair results in 86% of Reudi Allgower type 1 fracture patterns and 80% and 44% in type 2 and type 3 pilon fractures respectively treated with open reduction and internal fixation to achieve anatomical reduction [11].

Our Study reported 80% excellent to good results according to OMFES criteria for fixation using fixHEAL™ distal tibial locking plate by GPC Medical Ltd. There was no statistically significant difference in functional outcome results by open reduction or MIPPO technique in our study group. However, the author reported favourable outcomes in the MIPPO group of patients in terms of pain, wound-related complications, short hospitalization and early functional recovery.

Understanding the mechanical background for choosing the proper implant length and the type and number of screws is essential to obtain a sound fixation with a high plate span ratio and a low plate screw density. A high plate span ratio decreases the load onto the plate. A high working length of the plate reduces the screw loading, thus fewer screws need to be inserted and the plate screw density can be kept low. Selection of mono or bi-cortical screws is done according to the quality of the bone structure and it is important to avoid problems at the screw thread bone interface with the potential pullout of screws and secondary displacement. We recommend bicortical locking screws for the tibia since the working length of the monocortical screw depends only on the thickness of the bone cortex [12, 13].

Table 1: Gender distribution of patients in the study group.

Age (in years)	Male N (%)	Female N (%)
15-25	2 (3.57)	0
26-35	27 (48.21)	0
36-45	9 (16.07)	1 (1.78)
46-55	1 (1.78)	5 (8.92)
56-65	7 (12.5)	2 (3.57)
66-75	1 (1.78)	1 (1.78)
Total	47 (83.92)	9 (16.07)

Table 2: Type of fracture presentation by Gustillo Anderson classification

Fracture type	Patients (%)
Open fractures	18
Type 1	12 (21.42)
Type 2	2 (3.57)
Type 3A	4 (7.14)
Closed (others)	38 (67.85)
Total	56 (100.0)

Table 3: Functional outcome according to OMFES

Functional outcome	Number of patients	Percentage
Excellent	13	23.21
Good	32	57.14
Fair	8	14.28
Poor	3	5.3

Table 4: Functional outcome according to OMFES with the surgical technique.

Operative technique N (%)	Excellent N (%)	Good N (%)	Fair N (%)	Poor N (%)	Total N (%)
Open reduction	2 (9.5)	13 (61.9)	4 (19.04)	2 (9.52)	21 (100)
MIPO	11 (31.42)	19 (54.28)	4 (11.42)	1 (2.8)	35 (100)
Total	13	32	8	3	56

Table 5: Complications encountered during the study

Complications	Number of patients
Superficial infection	5
Deep infection	2
Non-union	2
Malunion	5
Primary shortening of the bone	1
Flap cover surgery	1

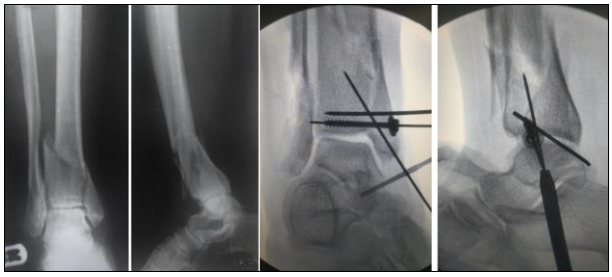

Fig 1: Preoperative and Intraoperative images demonstrating an intraarticular extension of distal tibial fracture and anatomical reduction of articular fragment and fixation with 4.0mm low profile cancellous screws (GPC Medical Ltd.)

Fig 2: Post-operative images of final fixation of the distal tibia using fixHEAL™ distal tibial locking plate by GPC Medical Ltd and distal fibula using 3.5mm dynamic self-compression plate by GPC Medical Ltd including syndesmotic fixation.

Fig 3: Comminuted distal tibia fracture of an osteoporotic bone in an elderly female with fixHEAL™ distal tibial locking plate by GPC Medical Ltd. using MIPPo technique.

Conclusion

The MIPO technique is a reliable fixation approach to fractures of the distal third tibia, preserving most of the osseous vascularity and fracture haematoma and thus providing for a more biological repair. fixHEAL™ distal tibial locking plate by GPC Medical Ltd. can be effectively used by both open and MIPPO approaches for stable fixation of complex distal tibial fractures.

Careful evaluation of pre-operative x-rays, anatomical reduction and meticulous following of operative technique steps effectively reduce the incidence of complications.

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