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Early clinical and radiographic outcomes of a mini-fragment, low profile plating system in tibial plafond fractures

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ABSTRACT

Objective: The Smith and Nephew mini-EVOS plating system is a mini-fragment, low profile, variable-angled plating system designed to obtain anatomic reduction while also minimizing soft tissue handling. However, literature has been limited in reporting the clinical and surgical outcomes of these specific plates. The goal of our study is to evaluate the safety and efficacy of the Smith and Nephew mini-EVOS plate in pilon fracture management, where significant high energy forces can result in severe fracture patterns and soft tissue injury.

Methods: Patients 18–65 years of age who underwent plate fixation of their tibial plafond fractures (OTA/AO) using the Smith and Nephew mini-EVOS plating system at our urban university-based level-1 trauma center were included in this retrospective investigation. A total of 37 patients (37 fractures) from January 2015 to March 2018 were included in this study. Primary outcome measure was mechanical hardware failure. Secondary outcome measures included nonunion, malunion, medical and surgical complications.

Results: The fractures were classified according to the OTA/AO classification as 43C1 (n = 15), 42C2 (n = 6), and 43C3 (n = 16). A mechanical failure was observed in three patients (8.1%). Six additional patients needed a re-operation of the surgical site including two nonunion repairs, one malunion repair, one symptomatic hardware removal, and two soft tissue debridements. The mean follow-up was 298.9 days (range: 96–936).

Conclusions: Early results of operative fixation of tibial plafond fractures using the Smith–Nephew mini-EVOS demonstrated low hardware failure and complication rates. This plating system is a safe and effective implant.

Level of evidence: Therapeutic Level IV.

Introduction

Tibial plafond or “pilon” fractures are commonly associated with significant high energy forces which can result in severe soft tissue injury and challenging fracture patterns. In such instances, it is important for soft tissue handling to be minimal in order to avoid infection, nonunion, or wound complications [1–3]. Extensive articular comminution or bony segmentation can also complicate fracture reduction after a traumatic injury.

Multiple surgical techniques have been developed to address the challenges associated with tibial plafond fractures. These treatment regimens include definitive external fixation, immediate open reduction and internal fixation (ORIF), staged reconstruction, and arthrodesis [4]. Each treatment modality has shown favorable outcomes in the literature but can be associated with complications such as non-union, hardware failure, soft tissue issues, and infection [2,4–6]. Risk factors associated with fixation failure and nonunion have been reported to include diabetes, smoking, increased body mass index, open fracture, screw density, construct rigidity, use of stainless steel hardware, and lower socioeconomic status [5,7–9]. Staged reconstruction has recently become the standard of care for most pilon fractures, while the implant used for fixation remains variable.

In order to obtain anatomic reduction while minimizing soft issue handling, a mini-fragment, low profile, variable-angled plating system has recently been introduced. These plates allow for versatile insertion of multiple fixation points and, importantly, maintain a low profile in areas of minimal soft-tissue. With its

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versatility, the plating system comes in a multitude of different lengths and geometry to address challenging fracture patterns. However, the literature has been limited in reporting the clinical and surgical outcomes of these specific plates.

The goal of our study is to further evaluate the safety and efficacy of the Smith and Nephew mini-EVOS plate in pilon fracture management. We hypothesize that the surgical and clinical outcomes associated with this plating system are favorable in these fractures.

Materials and methods

This was a retrospective study performed at an urban university-based level-1 trauma center. The study data was collected through a retrospective chart review and review of the existing radiographic studies. Patients were identified through the coding database of our institution. Approval of the study protocol was obtained from the Institutional Review Board (IRB) of our institution.

Patients 18 to 65 years of age who underwent plate fixation of their acute tibial plafond fracture using the Smith and Nephew mini-EVOS plating system between January 2015 and March 2018 were included in this investigation. Fractures were classified using the OTA/AO fracture classification [10]. Patients with pathologic fractures from neoplastic disease were excluded from this study.

All patients underwent staged reconstruction, which consisted of temporary external fixation followed by delayed ORIF after the soft tissue injury had resolved. The surgical technique was according to widely established recommendations as described in the literature [4,11–13]. Per the discretion of the treating surgeon, patients were instructed not to bear weight on their injured lower extremity for 12 weeks following their surgical fixation. Patients were considered as incomplete follow-up if clinical and radiographic outcome data was not available for a minimum of 12 weeks after surgery. A minimum follow-up of 12 weeks was chosen for inclusion in the analysis since previous reports emphasized high failure rates within this time period [14].

The primary outcome measure was mechanical hardware failure defined as breakage of the plate. Secondary outcome measures included 1) need for re-operation, such as nonunion repair, malunion repair, staged treatment of traumatic segmental bone defect, and soft tissue debridement for infection; and 2) postoperative medical complications, such as thromboembolic events, pneumonia, urinary infection, and myocardial infarction. Nonunion was defined as lack of bridging callus of at least three out of four cortices at 3 months after surgery in the absence of visible progressive healing on consecutive radiographs.

Statistical analysis

All statistical analysis was performed using Stata 14 (StataCorp, College Station, TX). Given the relatively small number of events encountered for our main outcome measure (mechanical implant failure), no statistical comparisons between the mechanical failure group and the non-mechanical failure group were performed. All continuous variables were tested for normal distribution. Normally distributed data was reported as means with standard deviation (SD). Not normally distributed data was reported as median with range.

Results

Based on the Current Procedural Terminology (CPT) coding for surgical treatment of a tibial plafond fracture, a total of 75 patients were screened for participation in this study. 31 patients who were screened based on their CPT codes did not meet the inclusion criteria for the following reasons: less than 18 or greater than 65 years of age at time of injury (n = 5), prisoner (n = 1), significant psychiatric history (n = 1), fixation with a different implant (n = 5), fixation with supplemental hardware in addition to the implant of our study (n = 17), and duplicate subject (n = 1). 1 patient elected to transfer post-operative care to their city of residence and was subsequently excluded from the study. Thus, a total of 44 patients were enrolled in this study. 7 patients (15.9%) did not complete their minimum 89 day follow- up appointment. None of the 7 patients with incomplete 89 day follow up data was found to have any signs of mechanical hardware failure at their latest follow-up appointment. The outcome data reported herein are based on 37 patients with complete follow-up data. The demographic data of these patients are listed in Table 1.

Table 1
Patient demographics.

Age [years]	Mean 38.4 (Range 20–65)
Female	13 (35.1%)
Male	24 (64.9%)
Diabetes mellitus	4 (10.8%)
Body mass index [kg/m^2]	Mean 30.5 (Range 21.6–53.1)
Obese (BMI ≥ 30.0 kg/m^2)	17 (45.9%)
Tobacco use	18 (48.6%)
Illicit drug use	10 (27.0%)
EtOH use	20 (54.1%)

The initial surgeries were performed between January 2015 and March 2018. All patients were operated at a university-based urban level-1 trauma center and managed by the same orthopedic traumatologist. The number, size, type, and location of the plate were chosen based on the fracture pattern and surgeon's preference.

A total of 70 mini-EVOS plates were used as part of definitive management for pilon fractures in the 37 patients included in this study. Fractures were treated with 1 mini-EVOS plate (n = 10), 2 mini-EVOS plates (n = 22), 3 mini-EVOS plates (n = 4), or 4 mini-EVOS plates (n = 1). The average plate length used was an 11-hole plate (Range 6–20 hole). Average operative time was 98.4 min

Table 2
Patients' clinical data.

Mechanism of injury:	
Motor Vehicle Collision (MVC)	15 (40.5%)
Motorcycle Collision (MCC)	3 (8.1%)
Fall from height	16 (43.2%)
Motor Vehicle vs. Pedestrian (MVP)	2 (5.4%)
Fall from horse	1 (2.7%)
Open fracture	10 (27.0%)
Closed fracture	27 (73.0%)
Length of Hospital Stay [days]	Mean 7.4 (Range: 0–43)
Length of Follow up [days]	Mean 298.9 (Range: 96–936)
[a]Operative time from skin incision [min]	Mean 98.4 (Range: 52–192)
Estimated blood loss [mL]	Mean 57 (Range: 15–400)
Fracture management:	
1 EVOS plate	10 (27.0%)
2 EVOS plates	22 (59.5%)
3 EVOS plates	4 (10.8%)
4 EVOS plates	1 (2.7%)
AO/OTA classification:	
43C1.1	8 (21.6%)
43C1.2	5 (13.5%)
43C1.3	2 (5.4%)
43C2.1	2 (5.4%)
43C2.2	4 (10.8%)
43C3.1	2 (5.4%)
43C3.2	10 (27.0%)
43C3.3	4 (10.8%)

[a] Clinical data not available for all 37 patients.

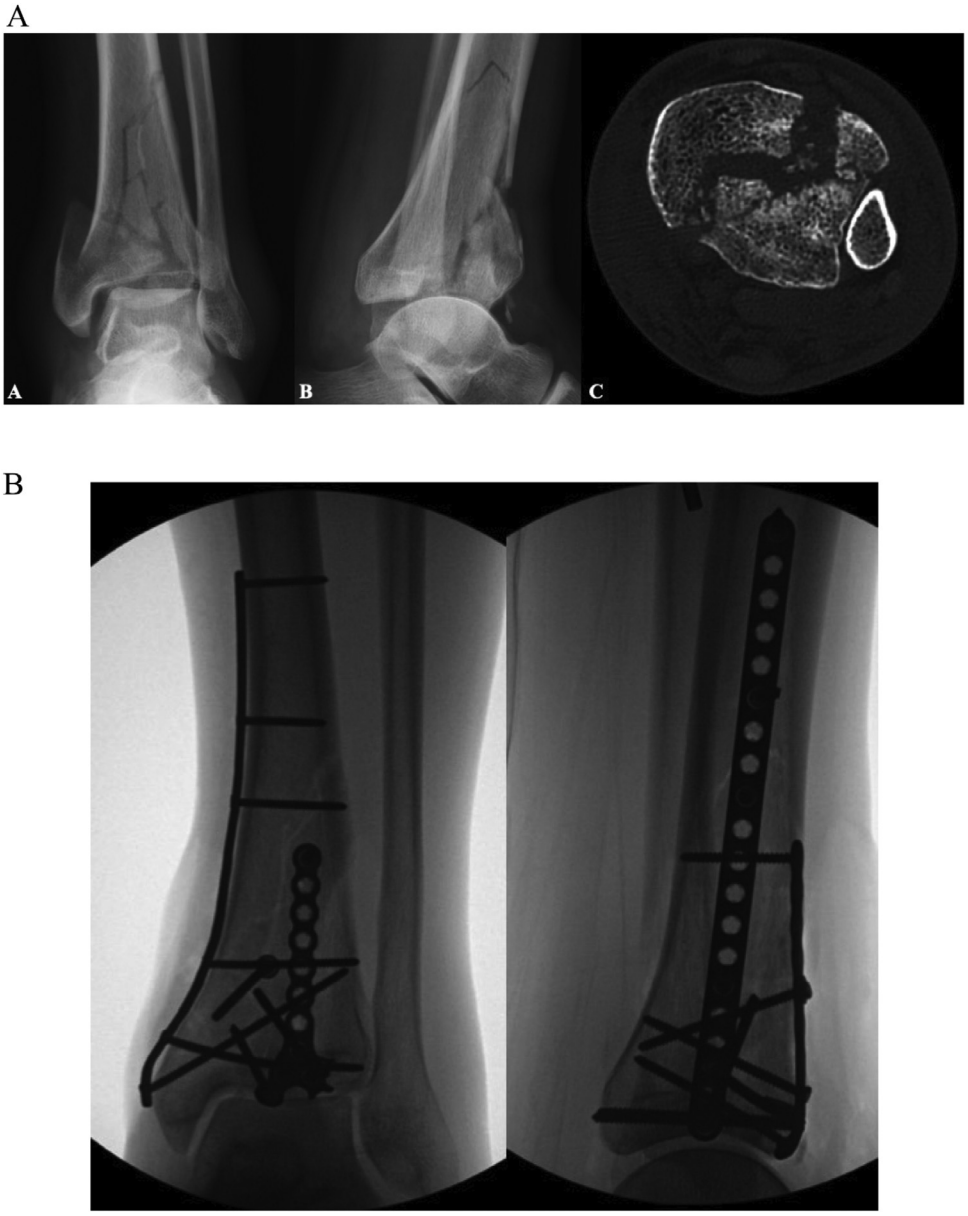

Fig. 1. (1) AP, lateral, and CT imaging demonstrating complex fracture pattern of the tibial plafond. (2) Postoperative imaging showing fixation with an anterior Y and medial straight mini-EVOS plates.

(Range 52–192 min) with a mean estimated blood loss (EBL) of 57.0 ml (Range 15–400 ml). Hospital length of stay averaged at 7.4 days (Range 0–43 days), and mean length of follow up was 298.9 days (Range 96–936 days). Clinical data is represented in Table 2.

With regards to our primary outcome, 92% of fractures were treated successfully without mechanical hardware failure. An example of our fixation is shown in Fig. 1(1, 2). A total of three mechanical implant failures were encountered among the 37 treated tibial plafond fractures (8.1%). The details of these three mechanical hardware failures are described below (Figs. 2 and 3).

The first patient (study ID 27) was initially treated for her open pilon fracture from a MVC with irrigation and debridement of open fracture and placement of an external fixation. At the time of her definitive fixation 7 days later, severe comminution and bone loss were noted. A 12-hole mini-EVOS Y plate with 8 screws was placed anteriorly as well as a straight 10-hole mini-EVOS plate with 5 screws medially. The patient was compliant with her post-operative protocol, but the patient had radiographic concerns of bony nonunion and screw loosening at 5 months. One month later, radiographs showed a broken anterior plate in the setting of malunion [Fig. 4]. Subsequently, the patient underwent removal of the broken hardware, iliac crest autografting, and revision fixation with a different plate construct. Ultimately, the patient experienced union and was able to ambulate with no restrictions.

The second patient (study ID 30) sustained a closed tibial plafond fracture after a fall from height and underwent staged fixation with external fixation placement. At the time of definitive fixation at 20 days later, significant bone loss and comminution were noted at the anteromedial aspect of the joint. A 12-hole mini-EVOS Y plate was placed anteriorly with 6 screws as well as a straight 15-hole mini-EVOS plate laterally with 5 screws. Local bone graft and calcium substitute were also used to address the patient's bone loss. The patient was non-compliant with his non-weight

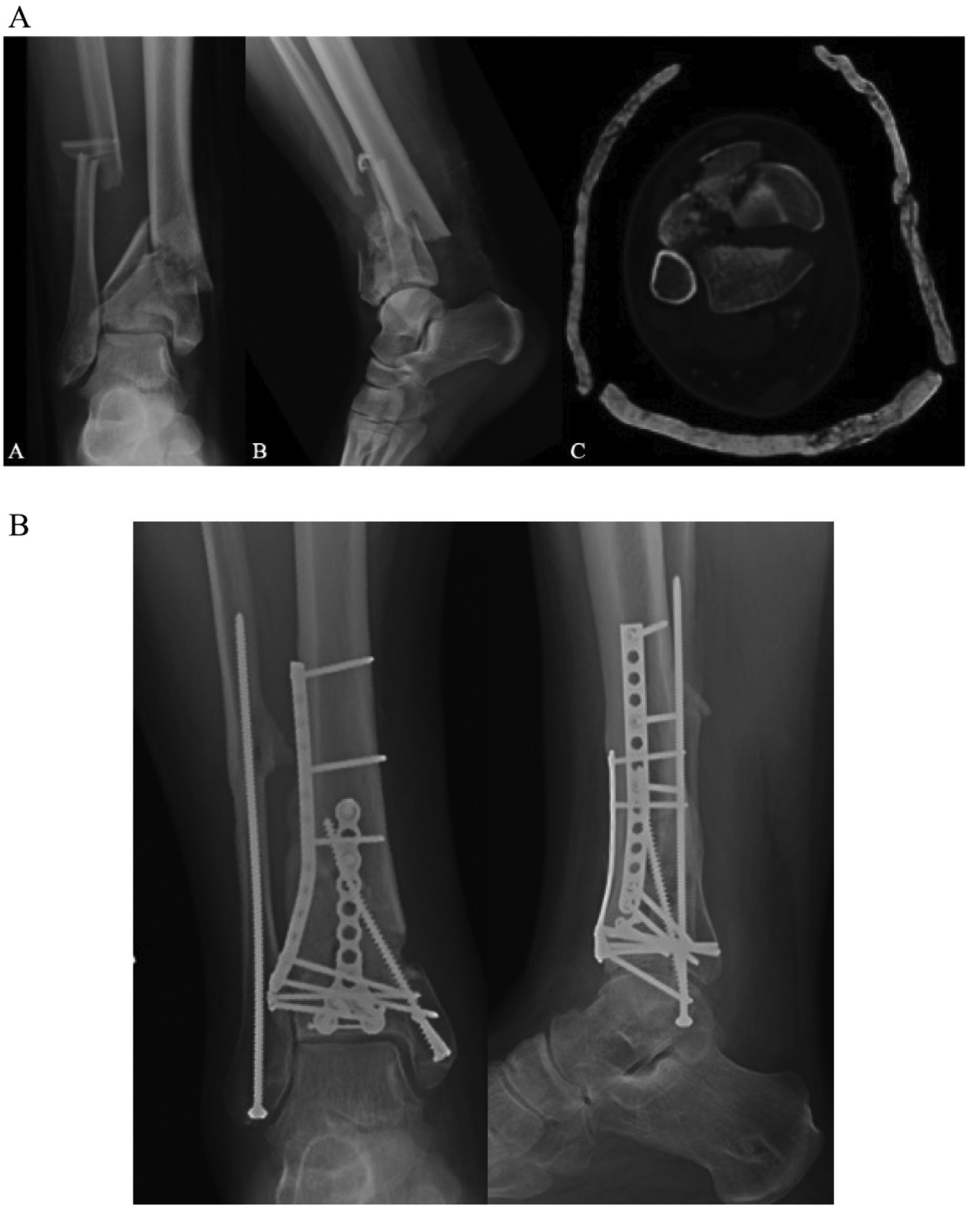

Fig. 2. (1) AP, lateral, and CT imaging demonstrating pilon fracture with associated fibula fracture. (2) Follow-up postoperative imaging showing fixation of the pilon fracture utilizing an anterior Y and lateral straight mini-EVOS plates.

bearing status and follow up appointments. He eventually appeared six months later at the emergency room after hearing a "pop" associated with significant pain and a deformity. Radiographs revealed nonunion, a broken medial plate with perihardware lucency, and 3 broken anterior screws [Fig. 5]. Subsequently, the patient underwent a hardware removal, a tibiotalar joint arthrodesis due to an arthosed, non-reconstructable joint with a nonunion repair with bone graft for treatment of his nonunion. The patient continued to have issues with non-compliance and was not interested in further surgical intervention. Ultimately, the patient experienced bony fusion and ambulated without restrictions.

The third patient (study ID 33) sustained a closed pilon fracture after a fall from height and was placed an external fixator for 11 days. At definitive fixation, a 10-hole mini-EVOS Y plate was placed anteriorly with 4 screws and a straight 16-hole mini-EVOS plate was placed medially with 5 screws. Calcium substitute was utilized in the setting of severe comminution. At approximately 7 months, he was compliant with his post-operative protocol, but radiographs revealed two loose screws in the anterior plate and one broken medial plate screw [Fig. 6]. He underwent removal for symptomatic screws, but he sustained a broken medial plate one month later. However, patient was asymptomatic, and his fracture had achieved radiographic union with adequate alignment. The patient declined further intervention.

A total of 6 patients (16.2%) needed a reoperation of the surgical site. Reasons for reoperation were hardware failure with nonunion (n = 2, 5.4%) malunion repair (n = 1, 2.7%) symptomatic hardware (n = 1, 2.7%) and infection (n = 2, 5.4%). Specifically, there was one case of deep wound infection which required hardware removal. There was 1 case of superficial wound infection, wherein the patient underwent irrigation and debridement and achieved resolution of their infection after antibiotics.

Medical complications (n = 2, 5.4%) included one acute renal failure in the setting of baseline end stage renal disease and one

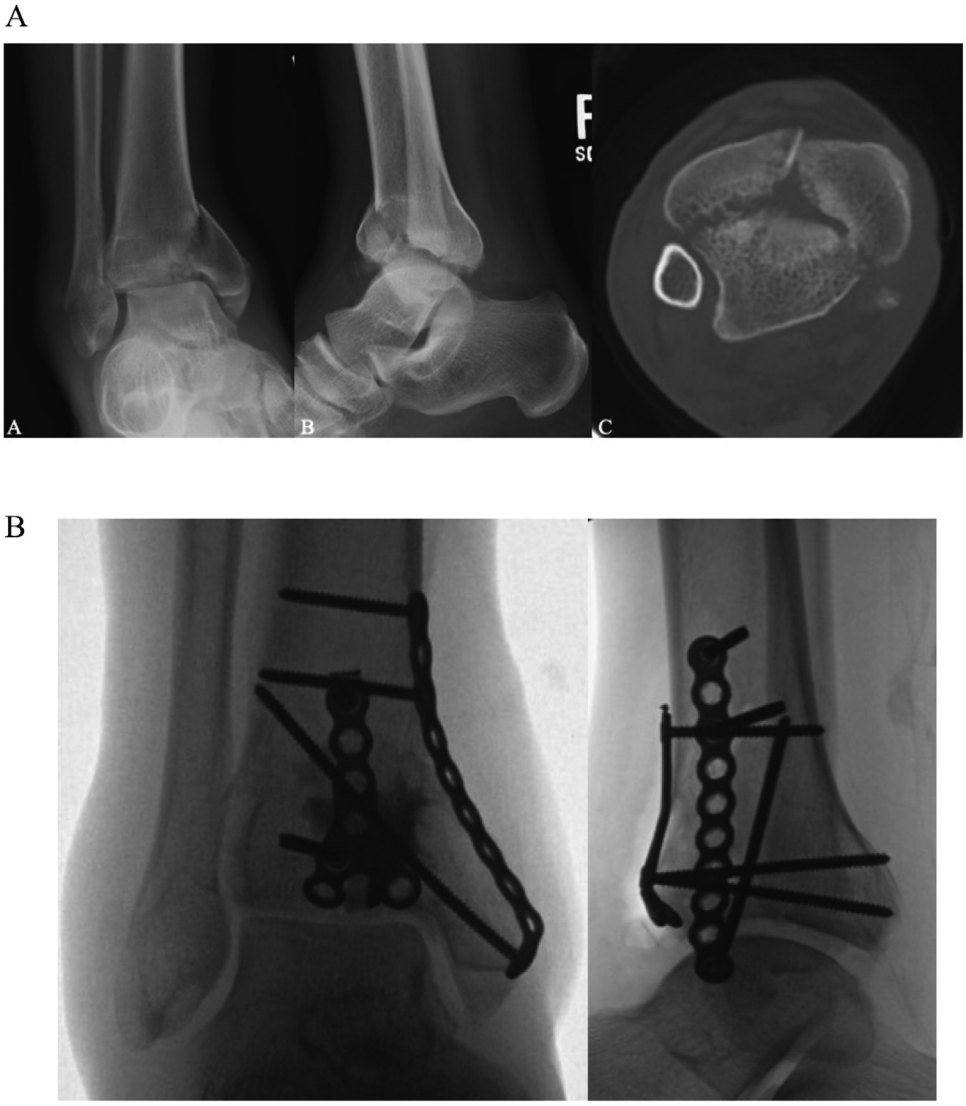

Fig. 3. (1) AP, lateral, and CT imaging demonstrating complex fracture pattern of the tibial plafond. (2) Intraoperative imaging showing fixation with an anterior Y and medial straight mini-EVOS plates.

thrombophlebitis at the intravenous site. Each complication was treated successfully by appropriate medical management.

Discussion

Treatment of tibial plafond fractures remains challenging, especially in the setting of traumatized soft tissue or extensive fracture comminution. Recent advances have resulted in the development of a low profile, variable angle mini plating system, which allows for screw insertion in multiple angles. Theoretical benefits of this plating system center on its application in areas of minimal soft-tissue and the multitude of different lengths and geometry available to address difficult fracture patterns. The results of our retrospective study confirmed our hypothesis that patients treated with this plating system experienced outcomes and mechanical failure rates that compare favorably with other plating systems.

The results of this study must be interpreted in the context of the patient demographics. The patients included in this study reflect the challenges that are encountered at urban trauma centers, namely relatively high rates of patients with obesity (45.9%) and tobacco use (48.6%). Moreover, all injuries were the result of high energy mechanisms, such as fall from height (43.2%) and motor vehicle collision (40.5%), and resulted in a high rate of open fractures (n = 10, 27.0%). Regarding our mechanical failures, they occurred at 6, 6, and 8 months, for the following patients respectively, in which one patient was non-compliant with his weight bearing status and follow up appointments. The second patient sustained an open comminuted tibial plafond fracture while the last patient's mechanical failure was asymptomatic in the setting of achieved bony union. We observed that the primary mode of failure was breakage at fracture site through adjacent screw holes and loosening of the screws. However, we did not observe this mode of failure until a minimum of six months after definitive fixation.

Overall, our clinical and radiographic outcomes compared favorably with other plating systems reported in the literature [3,15,16]. Looking at minimally invasive plate fixation of distal tibial plafond fractures, Lau et al. [3] reported an infection rate of 15% with hardware removal in 52% of their patients. Their rates infection and revision surgeries of the surgical sites were higher than our rate of infection (5.4%) and need for repeat surgery (16.2%). They also reported skin impingement as the most common indication for hardware removal while we only observed one instance (2.7%) of

Fig. 4. (A) Sixty-five-year-old female presented after motor-vehicle collision with a right open pilon fracture. (B) Definitive open reduction and internal plate fixation at 7 days after immediate irrigation and debridement, external fixation. (C) At 6 months after the definitive procedure, she presented with plate breakage at fracture site and loss of reduction. (D) She underwent hardware removal and revision with another plate construct.

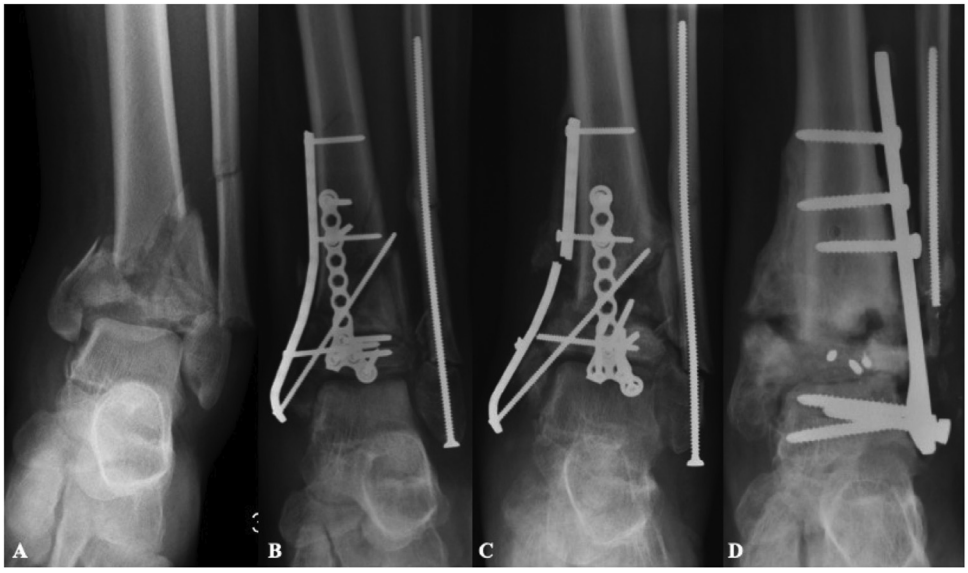

Fig. 5. (A) Thirty-five year old male presented with a left closed pilon fracture after a fall from height. (B) Definitive open reduction and internal plate fixation at 20 days after external fixation placement. (C) At 6 months after definitive fixation, he presented with a broken medial plate with loose anterior screws after a period of noncompliance. (D) He underwent hardware removal and tibiotalar arthrodesis. The patient continued to have issues with non-compliance and was not interested in further surgical intervention.

symptomatic hardware. In their series of pilon fractures treated with a low-profile plate, Borens et al. [15] found no mechanical failure but reported a rate of hardware removal of 23.5% in their 17 patients. Unlike the mini-EVOS plate measuring 1.2 mm thickness, they used a plate of 3.5 mm thickness. The thicker plate would have likely resulted in a higher instance of symptomatic hardware in anatomic regions with less soft tissue coverage, but may offer a construct of greater strength. Lastly, Bone et al. [16] reported a delayed union rate of 15% and nonunion of 5%, compared to our rate of nonunion (5.4%) and malunion (2.7%).

Our results with the staged reconstruction with this low-profile plating system also compared favorably to other surgical techniques reported in the literature. Several studies have found favorable results with both staged fixation and primary ORIF [6,17]. In his meta-analysis, Wang et al. [18] found no significant difference in bone healing complications, nonunion, malunion/delayed union, infections, arthritis symptoms and deep osteomyelitis between staged plating and immediate ORIF. In this meta-analysis, the mean rate of nonunion was 4.5% vs 4.0%, and mean rate of malunion was 7.6% vs 5.8% in the staged plating group vs.

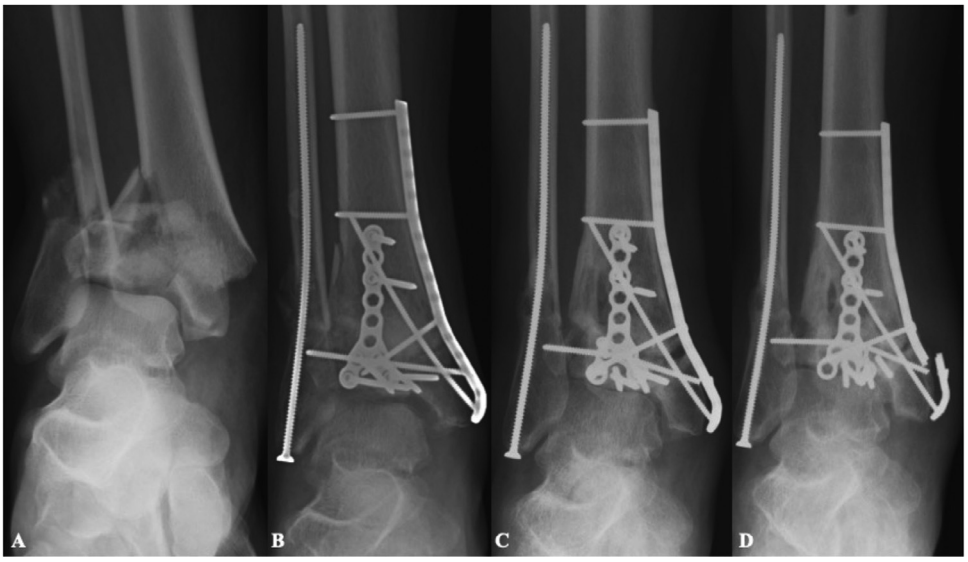

Fig. 6. (A) Thirty-eight year old male with a closed pilon fracture. (B) Definitive open reduction and internal plate fixation at 11 days after external fixation. (C) Seven months follow-up radiographs show broken screws with the fracture appropriately consolidated in acceptable alignment. (D) One month later after screw removal, the medial plate broke. Patient declined further intervention.

primary ORIF, respectively, compared to the rate of nonunion of 5.4% and malunion of 2.7% in our study. While both definitive external fixation and arthrodesis are less commonly performed, they have shown positive outcomes in severely comminuted articular fractures or patients with multiple medical comorbidities [19,20]. Papadokostakis et al. [21] reported a mean time to union of 4.3 months in his patients treated with solely external fixation, and Zelle et al. [22] reported a mean time to union of 132 days/4.3 months for tibial plafond treated with arthrodesis.

Limitations of our study include the retrospective design. In addition, we did not have a comparison group treated with a different plating system and we can only compare our results with historical data from the literature. We encountered a loss of follow-up of 15.9% and we acknowledge that this may have potentially biased the study results. Moreover, we would like to emphasize that our minimum follow-up only allows for conclusions on early mechanical failure rates associated with this implant. Our study does not allow for conclusions on long-term outcomes and had a relatively small sample size of 37 patients. However, previous studies found statistically significant results with a similar study population [14,17,20]. Also, the configuration of plate fixation was not standardized and chosen under the discretion of the senior author. A standardized protocol would be difficult given the significant variability of the fracture pattern.

Published investigations looking at the biomechanical and clinical outcomes associated with the use of this mini-fragment plating system in pilon fractures have been scarce. In conclusion, the Smith and Nephew mini- EVOS Plate demonstrated a relatively low early mechanical failure rate of 8.1% which compares favourably to the results recorded for other surgical options. This implant can be suggested as a safe and effective fixation device. Our study did not show any catastrophic early failure rate.'

Role of the funding

The study was partially funded by a research grant from Smith and Nephew, London, UK.

Conflict of interest

KHD, SSO, RAH, JCD, RP, and RAK report no other conflicts of interest with other people or organizations that could inappropriately influence their work.

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