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Original Article

Open reduction internal fixation versus external fixation with limited internal fixation for displaced comminuted closed pilon fractures: A randomised prospective study

切開復位開內固定與外固定有限內固定用於移位的粉碎性閉合Pilon骨折：隨機前瞻性研究



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ABSTRACT

Background: Pilon fractures involve the dome of the distal tibial articular surface. The optimal treatment for high-energy pilon fractures remains controversial. Some authors advocate the use of open reduction and internal fixation (ORIF) to avoid articular incongruence. Others advocate the use of bridging external fixation with limited internal fixation (EFLIF) to reduce soft tissue complications. Literature reports of prospective studies comparing the radioclinical outcomes of ORIF and EFLIF in high-energy fractures are scarce. Retrospective studies have their limitations because of insufficient randomisation. The objective of this randomised prospective study is to compare the clinical, radiologic and functional outcomes of displaced and comminuted closed pilon fractures, Rüedi and Allgöwer type II and III, treated by either ORIF or EFLIF.

Materials and methods: Forty-two patients were selected for the study. Twenty-two patients were subjected to ORIF and 20 patients were subjected to EFLIF. We used the American Orthopaedic Foot and Ankle Society score as a standard method of reporting clinical status of the ankle. Patients were followed-up clinically and radiologically for over 2 years after the surgical treatment.

Results: The results of ORIF and EFLIF in treatment of high-energy pilon fractures are equally effective in terms of functional outcomes and complication rates on the short term.

Conclusion: Soft tissue integrity and fracture comminution seem to have a significant influence on outcomes of intervention. A prospective multicentre study with a larger sample size that controls for other associated variables and comorbidities is warranted.

Level of evidence: Level II.

中文摘要

背景： Pilon骨折涉及脛骨遠端關節面的圓頂。高能量Pilon骨折的最佳治療方法仍然存在爭議。一些作者主張使用開放復位和內固定(ORIF)來避免關節不一致。其他作者主張用橋接外固定和有限內固定(EFLIF)來減少軟組織並發症。比較ORIF和EFLIF在高能量骨折中的放射臨床結局的前瞻性研究的文獻報導很少。回顧性研究由於隨機化不足而有其局限性。這項隨機前瞻性研究的目的是比較以ORIF或EFLIF治療移位的粉碎性閉合Pilon骨折Rüedi和Allgöwer II型和III型的臨床、放射學和功能結果。

材料與方法： 選擇42例患者進行研究。二十二名患者接受了ORIF，二十名患者接受了EFLIF。我們使用美國骨科腳踝學會(AOFAS)評分作為報告踝關節臨床狀態的標準方法。患者的臨床和放射學隨訪超過手術治療後兩年。

結果： ORIF和EFLIF治療高能量Pilon骨折的療效在短期內功能結局和並發症發生率方面同樣有效。

結論： 軟組織完整性和骨折粉碎似乎對手術結果有顯著影響。具有較大樣本量的前瞻性多中心研究以控制其他相關變量和合併症是有必要的。

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Introduction

Pilon fractures involve the dome of the distal tibial articular surface and extend into the adjacent metaphysis. They are relatively rare fractures ranging from low- to high-energy injuries. The low-energy rotational injuries have been shown to have excellent functional results with open reduction and internal fixation (ORIF). The high-energy axial-loading injuries have had uniformly moderate results and higher complication rates.¹ These can be challenging to manage because of the usual high-energy involved and the limited soft tissue envelope that surrounds the distal tibia. The condition of the soft tissues is crucial with respect to timing of definitive surgery and method of surgical fixation. Poor timing is associated with poor outcomes. Soft tissues must be ready for the second insult dealt by surgery.^{2–4} Additional treatment outcomes vary depending on multiple factors such as degree of bony comminution, quality of reduction, the surgeon's experience and associated injuries. Therefore, the optimal treatment for high-energy pilon fractures remains controversial. Some authors advocate the use of ORIF to avoid articular incongruence and consequent posttraumatic arthritis and to maximise long-term results.^{1,5,6} Others advocate the use of bridging external fixation with limited internal fixation (EFLIF) in high-energy fractures to reduce soft tissue-related complications and blood loss.^{2,7} Proponents of the EFLIF may argue that the necessity for an anatomical restoration of the articular surface is controversial and does not always correlate with the clinical outcome.⁸ Literature reports of prospective studies comparing between the radioclinical outcomes of ORIF and EFLIF in high-energy fractures are scarce.⁹ This inspired us to set up a prospective study to compare the clinical, radiologic and functional outcomes of displaced and comminuted closed pilon fractures, Rüedi and Allgöwer type II and III,¹⁰ treated by either ORIF or EFLIF. The authors declare that no conflict of interest exists. No financing was received for this study. The local ethical committee authorised conducting this study.

Patients and methods

We carried out a two matched group, assessor-blinded prospective randomised clinical study comparing the results of ORIF to that of EFLIF for closed displaced pilon fractures, Rüedi and Allgöwer type II and III. The study was conducted during the period from February 2010 to December 2012. Patients were followed-up for over 2 years after the surgical treatment.

Patient selection and randomisation

A total of 45 patients were randomised to the study. One patient refused treatment. Two patients—one to each group—were randomised, and they received planned treatment but dropped out. They had insufficient follow-up and incomplete data to be included and analysed for the results. Therefore, 42 patients were selected for the study. Twenty-two patients were subjected to ORIF (Group I), 14 males and eight females in that group. Twenty patients were subjected to EFLIF (Group II), 13 males and seven females, and the study was conducted at the authors' institution. Patients were explained about the study, and written consent was obtained. Patients were eligible if they were aged 18 years or more, with a recent (less than 3 weeks) closed intraarticular displaced distal tibial fractures of Rüedi and Allgöwer type II and III. Exclusion criteria were other serious leg injuries sufficient to affect outcome at 2 years such as peripheral angiopathy, neuropathy in the injured limb, multiple fractures, morbid obesity and compartment syndrome. We included patients with bilateral fractures provided that both of the fractures met the inclusion criteria. Patients who consented to participate were randomised by flipping a coin 1:1 to

receive either ORIF or EFLIF. We used adaptive minimisation to avoid development of significant differences between the two groups in some prognostic factors such as smoking status, Rüedi and Allgöwer type fractures, and soft tissue injury severity. Bilateral fractures were allocated the same treatment on both sides.

Surgical interventions

The preliminary management for all participants was bed rest, analgesia, elevation of the foot and application of ice and a posterior slab. Patients were subjected to plain radiographs, including anteroposterior, mortise and lateral views centred over the ankle and full-length radiographs of the leg including the knee and ankle. Targeted X-ray examinations were conducted on other areas depending on clinical findings. Additionally, patients were routinely subjected to computed tomography of the distal tibia and ankle joint. Soft tissue injury severity was assessed according to Oestern and Tscherne classification.¹¹ The classification has demonstrated an adequate level of intraobserver and interobserver agreement in tibial plateau and tibial pilon fractures.¹² Surgical interventions were performed by a single surgeon, the first author. ORIF was performed through a medial approach, with interfragmentary screws and application of a distal tibial anatomical neutralisation plates. The anterolateral fragment was fixed percutaneously with a lag screw under image intensifier control. A K-wire was inserted into the fragment to assist in manipulation and reduction of fracture fragment. EFLIF was achieved by stabilisation of the fibula first to restore length and alignment and to provide stability to tibial fracture, through a lateral approach by means of plate or K-wire. Closed technique for fracture reduction was carried out for all cases except four cases, where restoration of the ankle joint could not be achieved except with minimal open reduction. The closed technique of fracture reduction was initiated by ankle distraction by the traction construct, utilising constrained circular external fixator. The fixator consisted of two rings; the proximal was the tibial block, and a floating ring at the level of the ankle joint. The nuts securing the distal tibial ring to the threaded rods were loosened so the ring can be manipulated up or down, and a foot plate transfixing the ankle joint was mounted over the calcaneus. The frame is then checked in the frontal and sagittal planes after distraction and reduction of fracture by ligamentotaxis. Some important technical aspects of both treatment groups are demonstrated in (Figures 1 and 2).

Patients were instructed 6 weeks of nonweight bearing. After removal of the foot plate, partial weight bearing was started with early active mobilisation of the ankle and subtalar joints. A standardised physiotherapy rehabilitation regimen was then implemented.

Outcome measures

We used the American Orthopaedic Foot and Ankle Society score as a standard method of reporting clinical status of the ankle and hindfoot.¹³ The system incorporates both subjective and objective factors into numerical scales to describe pain, function and alignment. It has been widely used in studies of foot and ankle surgery, including a large multicentre clinical trial.¹⁴ Ankle range of motion was measured with a goniometer with the knee fully extended. Patient-reported outcomes were gathered at 12 and 18 months. We measured the primary outcome at 2 years postoperative when most patients would be expected to have reached maximal recovery. Objective and subjective clinical parameters were recorded by a single orthopaedic surgeon, who was unaware of treatment allocation. Patients were evaluated radiologically immediately postoperative, at 12 and 18 months and 2 years by serial anteroposterior and lateral X-rays of foot and ankle (Figure 3A–C).

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