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Comparison between carbon-peek plate and conventional stainless steal plate in ankle fractures. A prospective study of two years follow up

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ABSTRACT

Introduction: The aim of our study is to compare the clinical and radiological outcomes of the treatment of distal fibular fracture with the traditional stainless steel or the new radiolucent CFR-PEEK plates. The hypothesis is that there are no differences in clinical and radiological outcomes at the final follow-up between the two fixation devices.
Methods: All consecutive patients aged from 18 or over, who had undergone operative treatment for malleolar fracture between 2013 and 2014, have been included in the study. 87 were available for the study. The patients were assigned to group A (47 patients, radiolucent plate group) and group B (41 patients, stainless steal plate group). At 6, 12 and 24 months all patients were prospectively reviewed with radiographic and clinical evaluations (OMAS scale, AOFAS, VAS, ROM).
Results: The groups were homogenous with regard to age, gender, BMI, dominance and disease duration. The mean follow-up was 23 +/− 2 months. The mean waiting time to operation was 2.94 days (SD 2.74) (range 0.2–6.8). Statistical analysis showed no difference ($p > 0.05$) about the VAS, OMAS, AOFAS and ROM evaluation at 6, 12 and 24 month follow-up between two groups. Radiographic evaluation showed no difference between two groups at all the follow-up with similar results obtained with the two fixation devices.
Discussion: Our results showed a substantial equivalence of the two fixation devices at 6, 12 and 24 month of clinical and radiographic follow-up. Fixation of the lateral malleolus fractures with a CFR-PEEK plate provides satisfying clinical and radiographic results after 2 years of follow-up. These results are comparable to those achieved with conventional plates.

Introduction

Ankle fractures represent 10% of all fractures with an incidence of around 137/100,000/year [1–4], making these the second most common lower limb fractures after hip fractures [5].

The already high incidence of ankle fractures is increasing sharply in line with the ageing demographic of populations, in particular in Western countries. Kannus et al. [6] reported an increase of 319% in the overall annual number of low-energy ankle fractures in elderly patients admitted to hospital over the three decades between 1970 and 2000.

The AO principles in the 1970s for early movement achieved by open reduction and rigid internal fixation led to rapid popularization of the use of a lag screw protected by a laterally placed neutralization Plate [7]. Early results achieved with this technique were good both clinically and radiographically [8,9] and it has remained the "gold standard" for 50 years.

Moreover, in the few last years some authors in a preliminary study described the use of radiolucent plates to observe the posterior malleolar fracture after a lateral malleolus fixation to treat complex ankle trimalleolar fractures [10].

These plates are made of 70% of longitudinal and diagonal continuous carbon fibre-reinforced with 30% of polyetheretherketone (CFR – PEEK) [11]. This material gives to the osteosynthesis device a radiolucent X-ray property, associated with no artefacts during CT and MRI scans, that enables good visibility through the plate during surgery and follow-up [12]. This Composite Material mimics the cortical bone's Modulus of Elasticity [13] with good mechanical properties. As well there are no cold welding events as titanium screws.

However, to our knowledge, there are no studies in the literature that compare in vivo the clinical and radiographic

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outcomes of carbon and traditional stainless steel plates for the treatment of ankle fractures.

The aim of our study is to compare the clinical and radiological outcomes of the treatment of distal fibular fracture with the traditional stainless steel or the new radiolucent plates.

The hypothesis is that there are no differences in clinical and radiological outcomes at the final follow-up between the two fixation devices.

Materials and methods

All consecutive patients aged 18 or over, who had undergone operative treatment for malleolar fracture between 2013 and 2014, have been included in the study.

Exclusion criteria were: previous fracture of the ankle, previous local and general infective disease, age < 18 years old and previous surgery on the index ankle. The study protocol was approved by the hospital's Ethical Review Board and it was conducted in accordance with the principles of the Declaration of Helsinki and its amendments. We fully informed all the Subjects about the characteristics of the study and they gave their consent.

From the original 103 patients, 16 patients were lost to the follow up or did not meet the inclusion criteria and 87 were available for the study. The 87 patients were assigned to group A [47 patients, radiolucent plate group, 14 men and 32 women; mean age (standard deviation, SD) = 56.8 (2.34);] and group B [41 patients, stainless steal plate group, 11 men and 30 women mean age (SD) = 58.3 (3.55)] according to the choice of the surgeon.

All patients were prospectively reviewed with radiographic and clinical evaluations.

Clinical evaluation

All patients were evaluated at 6, 12, 24 months follow-up with:

- OMAS (Olerud-Molander Ankle Score) [14]. It is a functional rating scale from 0 (totally impaired) to 100 (completely unimpaired) and is based on nine different items: pain, stiffness, swelling, stair climbing, running, jumping, squatting, supports and activities of daily living. OMAS has been frequently used to evaluate subjectively scored function after ankle fracture
- AOFAS Ankle-Hindfoot Scale. It is a clinician-based score that measures outcomes for the foot and ankle. The questionnaire consists of nine items that are distributed over three categories: Pain (40 points), function (50 points) and alignment (10 points). These are all scored together for a total of 100 points.
- VAS scale
- ROM (Range of Motion)
- Physical examination.

Radiographic evaluation

All patients were evaluated at 6, 12, 24 months follow-up with X-ray recording the talocrural angle, the lateral malleolus displacement and union, the medial malleolus displacement and union, the posterior malleolus displacement and union and the degree of ankle osteoarthritis (Fig. 1).

Surgical technique

The surgical technique was the same for all patients.

The patient is placed supine with a bolster under the ipsilateral hip to allow the foot to lie vertically. A tourniquet is applied and, after exsanguination, inflated to 250 mmHg. The lateral malleolus is addressed first through a longitudinal incision placed directly over the fibula and centered on the fracture. Blunt dissection is performed through subcutaneous fat to avoid damage to the superficial peroneal nerve. The fracture is identified and periosteum and ligamentous attachments are debrided back from the fracture edges by 1–2 mm: Just far enough to visualize the fracture clearly. The fracture itself is distracted gently to allow irrigation and curettage of clot and small bone fragments. Reduction is achieved with pointed reduction clamps. Plate is selected of sufficient length to allow the placement of three screws above and below the fracture.

Post operative protocol

The post operative protocol was the same for all patients.

For the first 4 weeks: immobilization with cast, ankle elevation above the heart, non-weight bearing, passive and active range of motion.

From 4 to 8 weeks: gradual progression to full weight bearing, restoration of normal gait mechanics, full active and passive range of motion, isometric and early isotonic ankle exercises and proprioception training.

From 8 to 12 weeks: restoration of full range of motion all planes, advance ankle and foot intrinsic strengthening, pool running progressing to dry land, linear progressing to lateral and rotational functional movements.

Statistical analysis

SPSS 22.0 (IBM, Armonk, NY, USA) was used for data analysis. Descriptive statistics were used to summarize characteristics of the study patients (i.e., score results) including means and ranges. The Wilcoxon test was used to detect significant differences in the evaluated scores at different follow-up examinations in the CFR-PEEK plate group. Results of the CFR-PEEK plate group and the

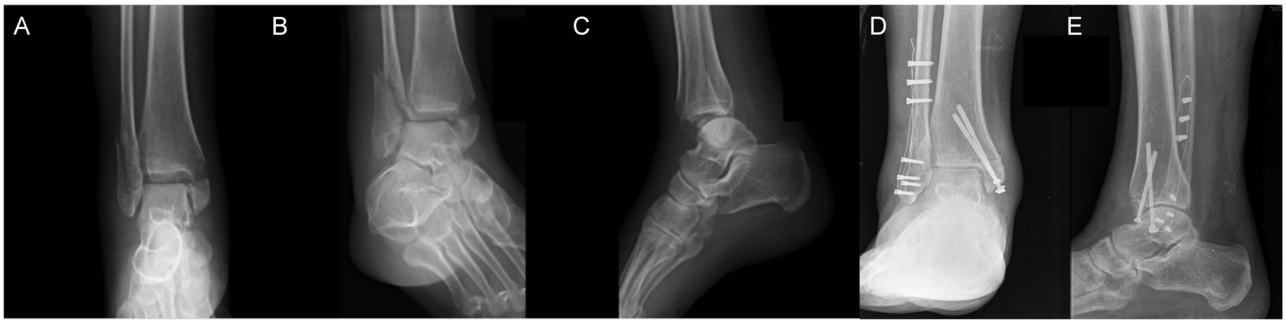

Fig. 1. A,B,C: Pre operative trauma series of a B2 malleolar fracture (Group A). **D,E:** Post operative X-ray of a B2 malleolar fracture treated with radiolucent plate at the final follow-up (Group A).