Injury, Int. J. Care Injured 45S (2014) S36–S38

Contents lists available at ScienceDirect

Injury

journal homepage: www.elsevier.com/locate/injury

Preliminary experience with Piccolo Composite™, a radiolucent distal fibula plate, in ankle fractures

Marco Caforio [a,*], Dario Perugia [b], Massimiliano Colombo [c], Giorgio Maria Calori [c], Pietro Maniscalco [a]

[a] Department of Orthopaedics and Traumatology, AUSL Piacenza, Italy
[b] Department of Orthopaedics and Traumatology, S. Andrea Hospital, University of Rome, La Sapienza, Italy
[c] Reparative Orthopaedic Surgery Department, G. Pini Institute, University of Milan, Italy

ARTICLE INFO

Keywords:
Ankle fractures
PEEK
Radiolucent plate
Time of surgery

ABSTRACT

The radiolucent plate has many advantageous properties in the treatment of complex ankle fractures, particularly trimalleolar fractures. Surgeons may sometimes have difficulty observing the posterior malleolus after synthesis of lateral malleolus with a traditional plate because common materials of conventional plates are not radiolucent. In this study, the authors highlight the importance of the radiolucent property in the treatment of ankle fractures and describe their preliminary experience with a carbon fibre-reinforced polyetheretherketone distal fibula plate, with good results at 4 months' follow-up and no signs of tissue inflammatory reaction.

Introduction

Ankle fractures comprise a large part of traumatology [1] and are becoming increasingly common in both men and women as a result of road accidents and sporting injuries [2–4]. Although significant progress has been made in the care and treatment of these injuries, there are many issues associated with surgical approaches for treating ankle fractures [5,6]. These are articular fractures, which require scrupulous and precise reinstatement of the anatomical surface [7,8]. These kinds of fractures are usually multiplanar and X-ray devices, which provide a mono-planar view, do not enable the surgeon to fully understand how the fractures are expressed [9]. Many surgeons prefer to treat complex ankle trimalleolar fractures with radiolucent plates to enable them to observe the posterior malleolar fracture after a lateral malleolus fixation.

The Piccolo Composite™ Distal Fibula Plate (Unimedical Biomedical Technologies, Torino, Italy) is made of continuous, longitudinal, carbon fibre-reinforced polyetheretherketone (CF-PEEK) [10]. This material gives the osteosynthesis device a radiolucent X-ray property, is associated with no artefacts during CT and MRI scans, and enables good visibility through the plate during surgery and follow-up [11]. The elastic modulus is close to that of cortical bone [12], it has good mechanical properties and there are no cold welding events.

Aim of this study

The aim of this study was to outline the preliminary experience with the Piccolo Composite™ Distal Fibula Plate in 27 patients with a mean follow-up of 4 months at "Guglielmo da Saliceto" Traumatologic Department, Piacenza, and to illustrate the importance of the radiolucent property of this device in the treatment of ankle fractures and how this feature enables an easier surgical technique.

Materials and methods

A total of 44 patients were treated surgically for ankle fractures in our department from July 2012 to September 2013. All the patients required ORIF with plate and screws for lateral malleolus fracture. A radiolucent Piccolo Composite™ Distal Fibula Plate was implanted in 27 patients (14 male and 13 female). The mean age of these patients was 57.3 years (range 19–78 years). Eleven of the patients had trimalleolar fractures, 12 had bimalleolar fractures and four had monomalleolar fractures. Follow-up evaluations were at 30, 60, 90 and 120 days after surgery. During follow-up, a clinical and radiographic evaluation was conducted to investigate pain and range of motion (ROM) after ankle immobilisation, and period of fracture healing according to X-ray criteria.

Results

There was a complication in surgical treatment (instability) in only one patient, who had a trimalleolar ankle fracture (Fig. 1).

* Corresponding author at: Ortopedia e Traumatologia Ospedale Guglielmo da Saliceto, Via Taverna 49, 29121 Piacenza, Italy. Tel.: +39 3494507950.
E-mail address: marco.caforio@tiscali.it (M. Caforio).

http://dx.doi.org/10.1016/j.injury.2014.10.020
0020–1383/

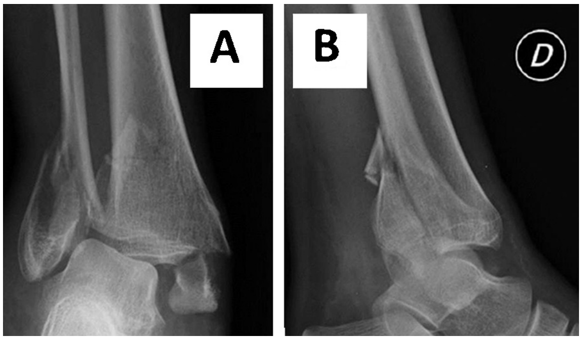

Fig. 1. Particular case of trimalleolar fracture: a female aged 67 years. Preoperative X-ray images.

Our philosophy for treatment of trimalleolar fractures is to first reduce the posterior malleolus with a dorsal approach in a prone position; the second surgical step comprises a lateral approach to reduce the fibular malleolus and then to reduce the tibial malleolus. In a specific case of a patient with trimalleolar fracture in which the posterior tibial synthesis was excised (Fig. 2), the radiolucent property of the Piccolo Composite™ plate enabled the surgeon to observe bone displacement while operating. The surgeon preferred to continue with other surgical steps and then decided to position an external fixator to put the posterior malleolar fracture in distraction, reduce it again and fix it with other cannulated screws.

In every case treated in this study, the articular surface was restored and fracture healing was evident at 1 month follow-up. All patients were then treated with a standard protocol. All patients apart from one, see below, showed full recovery of ankle ROM and had no pain at 2 months' follow-up after surgery.

The osteosynthesis Piccolo Composite™ device was removed from two patients during the study: a female aged 54 years and a male aged 27 years. These removals were conducted without complication and surgeons discovered during the removal procedure that a good fracture healing had already occurred. The female presented with a skin dyschromia near the fracture site. To avoid the risk of an allergic or inflammatory reaction, the plate was removed 9 months after surgery and the tissue near the lesion was sent to the Anatomo-Pathology Department for analysis. Anatomopathological images of tissue from this patient showed rich blood components and some fibroblast cells, which were poorly interpreted as an inflammatory reaction (Fig. 3).

There was no such skin reaction in the male, but the Piccolo Composite™ device was removed after fracture healing because this patient had limited ankle ROM in flexion and extension (15°, −15°) at the 1-year follow-up control. The patient was reassessed 1 month after surgical removal and he presented an optimal recovery of the ankle ROM (25° extension and 35° flexion). The authors do not think that this limitation of ankle ROM was due to the device, but rather to a lack of physiotherapy. After removing the device, the patient followed an intensive stretching programme and achieved an optimal recovery of function.

Discussion

Various radiolucent osteosynthesis devices have been used for years: cannulated screws for the neck of the femur to enable the view of a possible femoral head osteonecrosis; wrist volar plates for distal radius fractures; humeral plates for proximal epiphysis fractures, and radiolucent nails. The latter are now in common use for treatment of pathological fractures, because the radiolucent property enables the evolution of the tomographic lesion to be studied peri- and post-operatively, which circumvents imaging problems usually associated with implanted devices.

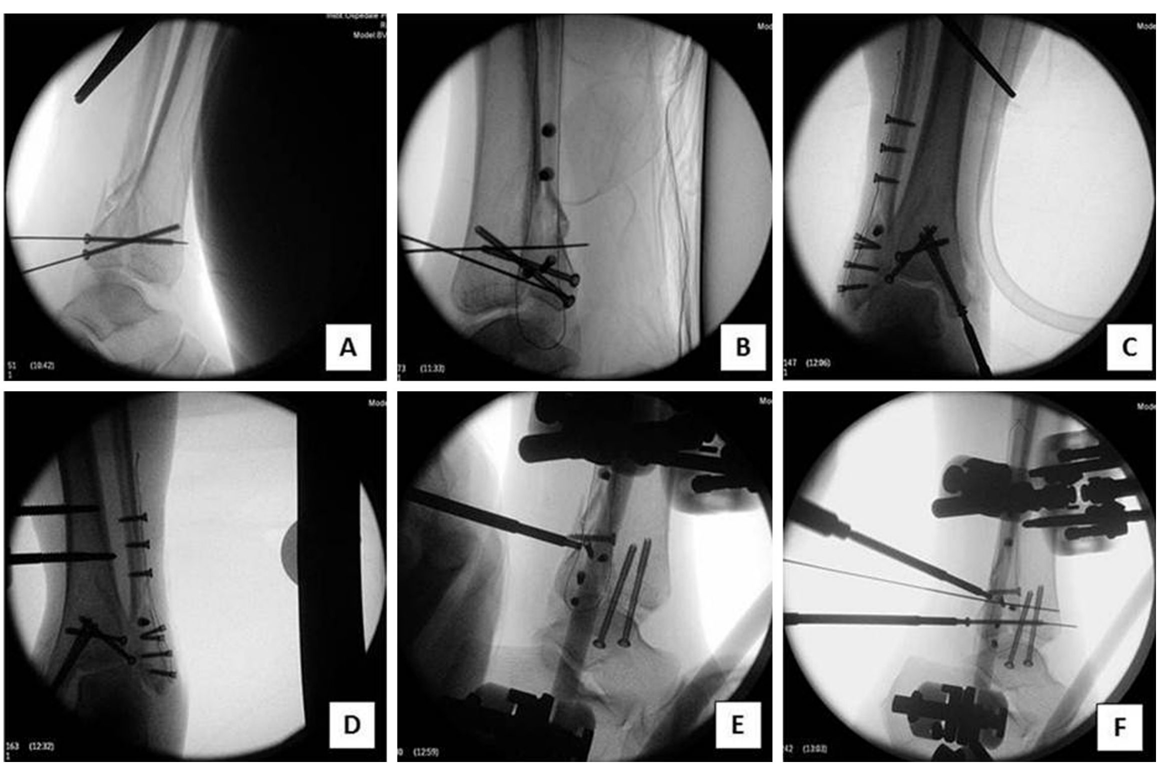

Fig. 2. Particular case of trimalleolar fracture showing surgical steps during treatment: posterior malleolar fracture reduction and fixation with two cannulated 3 mm screws in prone position and dorsal approach (A); when the surgeon positioned the Piccolo Composite™ plate he observed new posterior malleolar displacement (B); reduction and fixation of fibular and tibial malleolus fractures (C); external fixation (D) to put the ankle in distraction; screws removed and new posterior fracture reduction (E); and final synthesis (F).

Fig. 3. Dyschromic area where the Piccolo Composite™ plate was implanted (A), Piccolo Composite™ plate removal (B) and anatomopathological images of tissue near the plate (C and D).

The aim of the current study was to describe the advantageous properties of radiolucent plates in the treatment of complex ankle fractures and, in particular, the properties of CF-PEEK composites. The first 30 years of CF-PEEK use in fracture treatment [13] has highlighted a modulus that is similar to human bone and that has the ability to withstand prolonged fatigue strain [14]. The properties of the Piccolo Composite™ plate are therefore suitable for the treatment of complex ankle fractures. Many authors have already described the importance of CF-PEEK composites in the treatment of fractures [11,15].

Piccolo Composite™ Distal Fibula Plates have been used for bimalleolar and trimalleolar fractures in the Orthopaedic and Traumatology Departments of Piacenza and Milan since July 2012. The treatment of posterior malleolar fractures is very difficult [16] and the surgeon must use every device to ensure the articular surface is restored as well as possible.

In our experience, the Piccolo Composite™ plate helps surgeons in their work by enabling good observation of the fracture during reduction and healing and it is associated with rapid fracture healing [17]. This was emphasised by the current study in which all patients showed radiographic healing at 1 month follow-up. There were no signs of infection in the current study, although three cases of infection have been reported with a PEEK-derived implant in a study by Khonsari [18].

Two Piccolo Composite™ plates were removed without complication. One of the mechanical properties of CF-PEEK is that there are no cold welding events [12], which helps the surgeon to conduct the removal procedure safely and efficiently. One patient presented with a dyschromic area near the Piccolo Composite™ implant zone 9 months after surgery. The identification of non-inflammatory perilesional tissue in this patient is in keeping with the theory that Piccolo Composite™ plates do not cause inflammation. The dyschromia may have been because of some skin alterations before surgery; in fact the patient had a very swollen ankle and initial Piccolo Composite™ implantation surgery was delayed by 3 days.

Conflict of interest statement

The authors state that there is no conflict of interest.

References

[1] Court-Brown CM, Caesar B. Epidemiology of adult fractures: a review. Injury 2006;37(8):691–7.
[2] Hong CC, Roy SP, Nashi N, Tan KJ. Functional outcome and limitation of sporting activities after bimalleolar and trimalleolar ankle fractures. Foot Ankle Int 2013;34(6):805–10.
[3] Hay-David AG, Clint SA, Brown RR. The impact of the major trauma network: will trauma units continue to treat complex foot and ankle injuries? Injury)2014;(July). http://dx.doi.org/10.1016/j.injury.2014.07.005. pii: S0020-1383(14)00324-6 [Epub ahead of print].
[4] Morris N, Lovell ME. Demographics of 3929 ankle injuries, seasonal variation in diagnosis and more fractures are diagnosed in winter. Injury 2013;44(July (7)):998–1001. http://dx.doi.org/10.1016/j.injury.2013.01.030.
[5] Rammelt S, Zwipp H, Mittlmeier T. Operative treatment of pronation fracture – dislocations of the ankle. Oper Orthop Traumatol 2013;25(3):273–91. quiz 291–293.
[6] Zaghloul A, Haddad B, Barksfield R, Davis B. Early complications of surgery in operative treatment of ankle fractures in those over 60: a review of 186 cases. Injury 2014;45(April (4)):780–3. http://dx.doi.org/10.1016/j.injury.2013.11.008.
[7] Valderrabano V, Horisberger M, Russell I, Dougall H, Hintermann B. Etiology of ankle osteoarthritis. Clin Orthop Relat Res 2009;467(7):1800–6.
[8] Stufkens SA, Knupp M, Horisberger M, Lampert C, Hintermann B. Cartilage lesions and the development of osteoarthritis after internal fixation of ankle fractures: a prospective study. J Bone Joint Surg Am 2010;92(2):279–86.
[9] Black EM, Antoci V, Lee JT, Weaver MJ, Johnson AH, Susarla SM, et al. Role of preoperative computed tomography scans in operative planning for malleolar ankle fractures. Foot Ankle Int 2013;34(5):697–704.
[10] Carbon Fiber Reinforced Plastics – Properties. Comprehensive Composite Materials. Volume 2: Polymer Matrix Composites; 2000;p. 107–50.
[11] Kurtz S, Devine J. PEEK biomaterials in trauma, orthopedic, and spinal implants. Biomaterials 2007;28:4845–69.
[12] Fujihara K, Huang ZM, Ramakrishna S, Satknanantham K, Hamada H. Performance study of braided carbon/PEEK composite compression bone plates. Biomaterials 2003;24:2661–7.
[13] Tayton K, Johnson-Nurse C, McKibbin B, Bradley J, Hastings G. The use of semi-rigid carbon-fibre-reinforced plastic plates for fixation of human fractures. Results of preliminary trials. J Bone Joint Surg Br 1982;64(1):105–11.
[14] Steinberg EL, Rath E, Shlaifer A, Chechik O, Maman E, Salai M. Carbon fiber reinforced PEEK optima – a composite material biomechanical properties and wear/debris characteristics of CF-PEEK composites for orthopedic trauma implants. J Mech Behav Biomed Mater 2013;17:221–8.
[15] Williams D. Polyetheretherketone for long-term implantable devices. Med Device Technol 2008;19(1):8–11.
[16] Haraguchi N, Haruyama H, Toga H, Kato F. Pathoanatomy of posterior malleolar fractures of the ankle. J Bone Joint Surg Am 2006;88:1085–92.
[17] Zhao Y, Wong HM, Wang W, Li P, Xu Z, Chong EY, et al. Cytocompatibility, osseointegration, and bioactivity of three-dimensional porous and nanostructured network on polyetheretherketone. Biomaterials 2013;34:9264–77.
[18] Khonsari R, Berthier P, Rouillon T, Perrin JP, Corre P. Severe infectious complications after PEEK-derived implant placement: report of three cases. Journal of Oral and Maxillofacial Surgery Medicine and Pathology 2013 [in press].