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ß-TCP bone substitutes in tibial plateau depression fractures

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ABSTRACT

Background: The use of beta-tricalciumphospate (ß-TCP, Cerasorb®) ceramics as an alternative for autologous bone-grafting has been outlined previously, however with no study focusing on both clinical and histological outcomes of ß-TCP application in patients with multi-fragment tibial plateau fractures. The aim of this study was to analyze the long-term results of ß-TCP in patients with tibial plateau fractures.
Methods: 52 patients were included in this study. All patients underwent open surgery with ß-TCP block or granulate application. After a mean follow-up of 36 months (14–64 months), the patients were reviewed. Radiography and computed-tomography were performed, while the Rasmussen score was obtained for clinical outcome. Furthermore, seven patients underwent biopsy during hardware removal, which was subsequently analyzed by histology and backscattered electron microscopy (BSEM).
Results: An excellent reduction with two millimeters or less of residual incongruity was achieved in 83% of the patients. At follow-up, no further changes occurred and no nonunions were observed. Functional outcome was good to excellent in 82%. Four patients underwent revision surgery due to reasons unrelated to the bone substitute material. Histologic analyses indicated that new bone was built around the ß-TCP-grafts, however a complete resorption of ß-TCP was not observed.
Discussion: ß-TCP combined with internal fixation represents an effective and safe treatment of tibial plateau depression fractures with good functional recovery. While its osteoconductivity seems to be successful, the biological degradation and replacement of ß-TCP is less pronounced in humans than previous animal studies have indicated.

1. Introduction

Tibial plateau fractures represent a common fracture site and account for 1–2% of all fractures [1]. Usually they occur due to excessive axial loading combined with valgus/varus forces leading to a possible depression of the articular surface. To avoid secondary osteoarthritis, anatomic reduction of depressed joint fragments is the main goal in fracture treatment [2,3]. Thereby, the metaphyseal void beneath the articular surface following fracture reduction compromises the stability.

Filling options include autologous (autogenous), allogeneic bone grafting, or synthetic bone materials. Autologous bone transplantation (from the same individual) is considered to be the gold standard, however it has a limited supply, and rather high

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donor site morbidity [4]. Allografting relies on a sophisticated bone banking system and may elicit antigenic responses that delay osseointegration and carry the risk of infection transfer [5]. Furthermore, it was reported to have low initial mechanical stability in metaphyseal defects, and an inadequate long-term incorporation to the host bone [6].

To meet the requirements of biocompatibility, availability and biomechanical stability, bone graft substitutes have been developed with a trend towards osteoconductive materials, particularly calcium phosphates (CP) [7,8]. CP grafts have been in focus of several animal studies, where its complete resorption and remodeling was observed within 12–26 weeks [9].

There are only few studies that have analyzed the incorporation of CP bone grafts in human. In different bony defects, a partial replacement of CP but visible residues were seen after six months [10]. In open wedge high tibial osteotomy for medial knee osteoarthritis, ß-TCP incorporation was successful, however with visible remnants in most cases [11]. In a different study, histological assessment showed CP cement residues and signs of bone formation around the CP surfaces [12]. Therefore, the main problem seems to be a non-predictability of this resorption process and associated problems in biomechanical stability and bony surrounding.

Due to inconsistent findings between animal and patient use and the limited knowledge on the osseointegration of ß-TCP especially in patients with tibial plateau depression fractures, we analyzed the long-term results of ß-TCP bone replacement material in 52 patients with tibial plateau fractures. In particular, we used the Rasmussen score for clinical outcome, as well as radiography and computed-tomography (CT). A number of biopsies was taken during the hardware removal and subsequently analyzed by undecalcified histology as well as backscattered electron microcopy.

2. Methods

2.1. Patients

Within four years 184 patients with tibial plateau fracture were treated operatively at the Department of Trauma Surgery, University Medical Center Hamburg-Eppendorf, Germany. 52 patients with complex tibia plateau depression fractures (31 females and 21 males; mean age: 57 ± 17 years) were included in this study. All of them underwent open surgery combined with ß-TCP application. Patients with extra-articular fractures, open fractures, known cruciate ligament injuries or primary knee joint diseases were excluded from this study. The tibial plateau fractures were diagnosed by plain radiography (anteroposterior and lateral views) as well as computed-tomography (CT). All cases exhibited a depression of the tibial plateau of >5 mm requiring surgery. According to the AO/OTA (Arbeitsgemeinschaft für Osteosynthesefragen/Orthopedic Trauma Association) classification, 40 type-B (77%) and 12 type-C fractures (23%) were diagnosed (Table 1). Informed consent was obtained from all patients and presented data in line with the rules of the local ethics committee of the University Medical Center Hamburg-Eppendorf, Germany.

2.2. Beta-Tricalciumphosphate

The beta-tricalciumphosphate bone substitution material (ß-TCP, Cerasorb®, Curasan inc, Kleinostheim, Germany) used in this study was of synthetic origin and pure phase. The bone defect was completely filled with ß-TCP granules and/or block forms. ß-TCP granules (Cerasorb® M Granulate) were compacted without destruction of the granule structure. These granules of 1–2 mm diameter feature an interconnecting, open multi-porosity with micro-, meso- and macropores (5–500 μm) and a total porosity of approximately 65%. They are polygonal (i.e., irregularly shaped) and facilitate canting and interlocking in the defect cavity. ß-TCP block forms have regularly aligned, parallel macropores with diameters of 1000 to 1400 μm.

2.3. Surgical procedure and perioperative management

The AO/ASIF techniques for fracture reduction and fixation were used in all cases. Buttress plate osteosynthesis using Locking Compression Plates (LCP) with locking and conventional (non-locking) screws was performed in 43 cases (83%) and internal fixation with AO cancellous screws in nine cases (17%) (Table 2). Major metaphyseal voids were filled with ß-TCP blocks (n = 11) or a combination of blocks and granules (n = 18), minor defects were charged with granules exclusively (n = 23) (Table 2). Prior to their application, the scaffolds were mixed with the patient's blood (Figure 1 A, B). Following surgery, the leg was placed in a foam splint, and no active or passive motion was allowed for the first 24 h. No weight-bearing was allowed until six weeks after the surgery. The patients were allowed to walk with two crutches without weight-bearing of the affected leg and they were encouraged to gradually increase the range of motion using active exercises and a continuous passive motion device with the aim of

Table 1
Number of patients and respective fracture types according to AO classification (total 52 patients).

AO classification	1	2	3
A - extra articular	0	0	0
B - partial articular	1	18	21
C - complete articular	2	4	6

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