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RESEARCH

Primary cancellous bone formation around micro-chambered beads[☆]



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KEYWORDS

Bone substitute;
Cancellous bone;
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Abstract

Objectives: The question has been raised whether benign bone defects in patients can be treated with bone forming osteoconductive ceramics achieving primarily a cancellous bone scaffold, which is under load from the beginning.

Materials and methods: Ten reconstructions were performed in 9 patients (6 women and 3 male), with a mean age of 49 (25–65) years, suffering a high variety of epi- and metaphyseal defects, four tibial fractures, two calcaneal fractures, one pathological phalangeal fracture, one chondroma of the distal femur and two open-wedge osteotomies were filled with micro-chambered ceramic beads of 4 and 6 mm in diameter. The mean follow-up was 22 (7–8) months. X-rays and CT-scans formed the basis for the evaluation of the reconstruction of the cancellous bone scaffolds.

Results: All cancellous structures were rebuilt, if completely filled with bone-forming elements. If the filling was incomplete, no physiological cancellous bone scaffold resulted. The β -TCP micro-chambered beads were completely reabsorbed or sandwich-like incorporated at the time of evaluation. The HA micro-chambered beads revealed a contrast enhancement and were integrated in the osseous construction of the bone scaffold.

Conclusion: Primary cancellous bone formation can be achieved with osteoconductive ceramic micro-chambered beads and can be combined with any osteosynthesis for stable fixation.

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PALABRAS CLAVE

Sustitutivo óseo;
Hueso esponjoso;
Defecto óseo;
Fractura;
Osteotomía de
apertura

Formación de hueso esponjoso con esferas microcompartimentales**Resumen**

Objetivo: Analizar el resultado del tratamiento y la evolución de los defectos en el hueso trabecular en pacientes tratados con cerámicas osteoconductoras.

Material y métodos: Se estudiaron 10 reconstrucciones efectuadas en 9 pacientes (6 mujeres y 3 hombres) con defectos epifisarios y metafisarios, con una edad media de 49 (rango: 25-65) años en diferentes etiologías, 4 fracturas de tibia, 2 fracturas del calcáneo, una fractura patológica de metatarsiano, un condroma de fémur distal y 2 osteotomías de apertura. Los defectos se rellenaron con esferas de cerámica de β -fosfato tricálcico (β -TCP) e hidroxiapatita, de 4 y 6 mm de diámetro. El tiempo medio de seguimiento fue de 22 (7-48) meses. La evaluación de la reparación se realizó con radiografías y TC.

Resultados: En todos los casos observamos la reconstrucción trabecular. Cuando el relleno era completo se observó la formación de hueso; por el contrario, si era incompleto no se apreció la formación de hueso trabecular. Las esferas fueron completamente reabsorbidas o integradas en el momento de la evaluación. Por su parte, las esferas de hidroxiapatita mostraron un mayor contraste en las imágenes, aunque se integraron en el esqueleto óseo.

Conclusión: La formación primaria de hueso esponjoso se puede lograr con cerámicas osteoconductoras que se pueden combinar con cualquier tipo de osteosíntesis.

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Introduction

Occasionally, in epiphyseal and metaphyseal fractures, particularly in osteoporotic bones, tumors, cysts, after an infection, in loosened implants and in open wedge osteotomies, large cancellous bone defects are created which are difficult to fill. There are very few studies on cancellous bone repair,^{1,2} and it has even been reported that trabecular bone defects cannot be repaired.² After studying biopsies taken from patients treated with compression arthrodesis, Charnley and Baker¹ indicated that cancellous bone healing offers low osteogenic activity. Based on this observation, Radin and Rose³ explained the pathogenesis of osteoarthritis noting that the calcified cartilage plate distributed the stresses of the underlying elastic cancellous bone, so that any defects in the trabecular bone altered the distribution of impacts on the joint surface. However, most studies have focused on proving joint incongruity, insufficient reduction, instability or metabolic changes in the joint cartilage caused by the inflammation itself or by cellular necrosis, following joint trauma.⁴

After their reduction, epiphyseal fractures leave large cancellous bone defects which are responsible for deformities and secondary displacement or epiphyseal subsidence.⁵ Therefore, the use of allografts,⁶ iliac crest autografts⁷ and bone substitutes⁸⁻¹¹ is recommended for the treatment of tibial plateau fractures. The question is whether these methods are able to reproduce the original structure. In some cases, such as metaphyseal fractures in elderly patients with defects or with brittle bones or in tumoral pathological fractures, they have been treated with internal fixation (osteosynthesis) and bone cement (polymethylmethacrylate [PMMA]).¹² PMMA has also been recommended for the treatment of collapses of proximal tibial metaphyseal fractures in elderly patients, in order to enable early load.¹³ Moreover, benign bone tumors, paratumoral lesions and those with a low grade of malignancy (giant cell tumors) are often treated by curettage and the defect

is filled with PMMA.¹⁴ On the other hand, bone cysts and open osteotomies have often been filled with granulated bone substitutes¹⁵ which do not reproduce the trabecular structure.¹⁶⁻¹⁸

The aim of our study was to determine if defects caused in benign skeletal lesions can be treated with osteoconductive ceramics, and whether these treatments regenerate cancellous bone so that it can withstand loads.

Materials and methods

Bone defects in the epiphysis and metaphysis of long bones were filled in 9 patients (Table 1). These defects were filled with micro-chambered beads made of β -tricalcium phosphate (β -TCP) or hydroxyapatite (HA) or a mixture of both. The beads had a diameter of 4 and 6 mm (Ceraball®, Karl Storz Endoskope LLC & Co. KG, Tuttlingen, Germany) (Fig. 1). The study was approved by the Ethics Committee of the University, and all patients signed informed consent documents. Osteosynthesis plates (Synthes Inc., Freiburg, Germany) were used in all cases of fracture.

We treated 3 fractures with collapsed lateral condyles of the proximal end of the tibia, 2 distal tibial fractures, 2 comminuted calcaneal fractures, 1 chondroma of the distal femur, 1 enchondroma with pathological fracture of the fifth metacarpal bone and 2 open wedge osteotomies (Table 1).

After fracture reduction or curettage of benign tumors, the spaces were filled with beads and fixed with the appropriate osteosynthesis to stabilize the bone, without destroying the ceramic material. The spheres were placed using a trocar, which was also used to lift the tibial plateau. In the remaining cases, placement was carried out directly into the fracture or within the wedge produced by the osteotomy itself.

Our study included 6 females and 3 males, with a mean age of 45 years (range: 25–65 years), with a mean follow-up period of 22 months (range: 7–48 months) and a minimum

Table 1 Demographic data of the studied population.

	Age (years)	Gender	Etiology	Technique	Bone substitute	Control	Observations
1	59	Male	Comminuted fracture of the external condyle of the right tibia	Osteosynthesis	Ceraball® 600 TCP	RX 3, 8 months	
2	87	Female	Fracture and collapse of the external condyle of the right tibia	Osteosynthesis	Ceraball® 600 TCP	RX 3 days, 2 weeks	Death
3	65	Female	Fracture and collapse of the external condyle of the left tibia	Osteosynthesis	Ceraball® 600, TCP/HA	RX 1 day, 1, 10 and 48 months	Osteoporosis
4	59	Female	Distal fracture of the left tibia	Osteosynthesis	Ceraball® 600, TCP/HA	RX 1 day, 1, 12 months; CT 1 month	
5	55	Male	Comminuted fracture of the left calcaneus	Plate	Ceraball® 600, TCP	RX 1 day, 9 months; CT 1 day, 10, 12, 18, 36 months	
6	35	Female	Comminuted fracture of the right calcaneus	Plate	Ceraball® 600, TCP	RX 12 months; CT 1, 3 day, 15, 24 months	Subtalar arthrodesis
7	42	Female	Chondroma of the right distal femur	Resection	Ceraball® 600, TCP	RX 1 day; CT 48 months; RM 36 months	
8	42	Female	Pathological fracture of the fifth metacarpal	Osteosynthesis	Ceraball® 600, HA	RX 87 day, 2 months; CT 13, 17 months	
9	25	Male	Right <i>genu varo</i>	Wedge osteotomy	Ceraball® 600, TCP	RX 2 day, 1, 3, 15 months	
10	25	Male	Left <i>genu varo</i>	Wedge osteotomy	Ceraball® 600, HA	RX 2 day, 1, 2, 3 months	

CT: computed tomography; HA: hydroxyapatite; RX: radiograph; TCP: β -tricalcium phosphate.

follow-up of 6 months. We excluded from the study 1 woman who died after 8 months and whose last radiograph took place at 2 weeks. Monitoring of the defects was performed through X-ray images in 2 perpendicular planes (antero-posterior and lateral), and through computed tomography (CT) in the case of tumors. The assessment was conducted by 3 independent orthopedic surgeons, who analyzed the cancellous bone structure. The trabecular structure was considered complete if there were no radiolucent cavities and no deformation of the joint surface. The KSS, AOFAS and Dash scales were applied to evaluate clinical outcome, according to the study area.

Results

During the intervention, we noted that the beads had a hemostatic effect and were not destroyed by the osteosynthesis screws. Also, Ceraball® beads remained in place when the blood became coagulated after vacuuming.

Two of the fractures in the proximal end of the tibia were reduced with good results. One case was excluded from the radiographic evaluation. In another case, 8 months after the operation the β -TCP had been almost fully absorbed, although the contour of the beads could be discerned and

there were some TCP residues which were replaced by cancellous bone (Fig. 2). The KSS score of the patient was 85. Another reconstruction of the tibial plateau did not produce the expected result (KSS score of 55), as it revealed a deformity on the plateau requiring further surgery. However, the cancellous bone structure had been completely reconstructed and the contrast of the HA beads was pronounced, while the β -TCP beads had been reabsorbed.

One year after the operation, the distal tibial fracture presented complete healing with an anatomical reduction. The HA beads and the contours of the β -TCP beads were visible between the screws, revealing an adequate cancellous bone structure. Some of the Ceraball® beads presented contrast, while others had been replaced by newly formed bone.

In comminuted calcaneal fractures the anatomy was reconstructed, with a satisfactory result being obtained in 1 of the 2 cases, which formed new cancellous bone, although leaving a persistent defect with a sclerotic edge which was visible in both planes (Fig. 3). The β -TCP beads had been reabsorbed and were barely recognizable 22 months after surgery. Moreover, the score reached 89 points on the AOFAS scale. The other case of highly comminuted calcaneal fracture (Sanders type IV) was not anatomically reduced. The healing process left a severe deformity and a poor clinical outcome (AOFAS score of 49). Nevertheless, it presented a

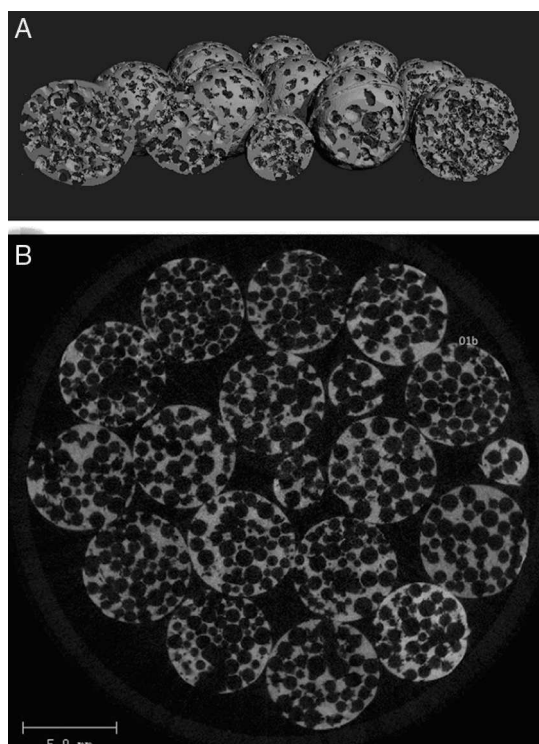


Figure 1 (A) Micro-chambered beads (Ceraball®) of 6 and 4 mm diameter with interconnected pores. MicroCT of sections and 3D reconstruction (μ -CT Scanco 40). (B) MicroCT section of a Ceraball® β -TCP bead showing its network of interconnected pores.

normal cancellous bone structure, with visible HA beads. The patient had to undergo subtalar arthrodesis.

The case of distal femoral chondroma presented a cavity which was filled with 20 cm³ of beads and showed a complete restoration of the cancellous bone structure on the CT scan. Meanwhile, the pathological fracture of the fifth metacarpal by an enchondroma treated with curettage and filling of the cavity with HA beads and osteosynthesis, presented a stable condition after 1.5 years, with a good integration of the HA beads (Fig. 4).

Open osteotomy, in a 25-year-old patient, was bilateral and treated on the right side with β -TCP beads and a Tomofix® plate (Mathys Medizinaltechnik AG, Bettlach, Switzerland), with incomplete filling of the bone defect. The patient began partial load at 2 weeks and complete load at 8 weeks. At 15 months, radiographs revealed an irregular cancellous bone structure on the right side, indicating persistent defects in the anterior and lateral portions, visible at 21 months (Fig. 5). Meanwhile, the defect on the left side was completely filled (Fig. 5). The radiograph at 14 weeks revealed new bone formation in the medial third of the defect, with almost complete resorption of the β -TCP beads. At 7 months, the contour of the beads was no longer visible (Fig. 5).

Discussion

The limitations of our study are clear, as it was based on a small number of patients suffering various pathologies and undergoing different situations and surgical techniques.

Since we were unable to compare the evolution of defects with other treatments, we decided to observe the behavior in the integration with HA and β -TCP beads in cancellous bone defects.

Cancellous bone does not regenerate by itself and requires support for its repair.¹⁶ Despite being very common lesions which in many cases affect the cartilage and lead to the development of osteoarthritis, there are very few works on epiphyseal and metaphyseal bone repair.^{1,2,17} Therefore, we believe that all large, trabecular bone defects should be filled with grafts or substitutes,¹⁸ and their use is particularly interesting in open osteotomies and epiphyseal reconstructions reporting pain, functional disability and those presenting a risk of pathological fracture.^{19,20} Clear examples are the distortions and inconsistencies in tibial plateau fractures.^{21,22} Autologous bone grafts are limited and entail pain in the donor area,²³ while allografts may be reabsorbed very rapidly, in addition to the usual complications.⁶ Treatment with HA bone substitutes has, from our perspective, 3 main drawbacks: they are difficult to manage in order to fill a defect, the fixation screws can cause fractures²⁴ and integration requires an excessively long remodeling process.¹⁸ Meanwhile, calcium phosphate cements withstand stresses better than autologous grafts.⁷ Another aspect to consider is that the trabecular structure does not regenerate with inorganic bone cements.¹¹ The micro-chambered beads used in our study have shown rapid bone growth, revealing a mineralized laminar bone contrast and formation of a normal trabecular structure.^{17,18}

In metaphyseal defects there is no doubt that, for elderly patients suffering comminuted intertrochanteric or tibial plateau fractures with a brittle bone or in patients with tumoral cavities, cement increases the stability of the osteosynthesis and can represent the best option.^{12–14,25,26} PMMA has sometimes been recommended in bone cysts and benign or low-grade malignant tumors in order to make the most of the heat generated by polymerization and destroy any cells remaining after tumor resection or curettage.

However, it also entails problems, as it is difficult to remove^{14,27} and is often associated with a radiolucent area, an image of osteolysis, as is the case with HA beads which are not reabsorbed.¹⁷ The use of β -TCP or HA blocks to fill large cavities offers incomplete results, while granular material is combined with autologous bone and does not allow an adequate reconstruction of the trabecular morphology.^{17,28} The use of micro-chambered beads of 4 or 6 mm diameter enables a complete filling of the large cavities and has a hemostatic effect, since the beads arrest the hemorrhage of the cavities themselves and do not interfere with the positioning of the screws of a stable implant.

Spontaneous filling of the space created by wedge osteotomies is difficult and radiographs show a slow and incomplete formation of new bone, leaving persistent defects.² The two cases presented in our work showed that HA beads were pushed against the plate by the bleeding itself, leaving persistent defects in the central and lateral parts of the osteotomy, despite allowing full load 2 weeks earlier than recommended according to the literature.¹⁷ However, the osteoconduction process on the side filled with β -TCP beads was fast, a normal trabecular architecture was



Figure 2 (A–F) Comminuted, lateral, tibial plateau fracture in a 59-year-old male patient. The collapse was elevated and the defect was filled with beads (Ceraball®). The plate was removed at 8 months. The shadows of the beads were recognizable (arrows).

obtained and full load with no pain was achieved 4 weeks sooner than on the right side, which had an incomplete filling.

β -TCP beads allowed any kind of defect to be filled and could be implanted with a syringe containing Ringer's solution and a damp towel to prevent them from being displaced by the bleeding itself. The blood mixed with them and, once it coagulated, stabilized their position.¹⁶

The spherical shape of the substitute employed also helped bone formation,¹⁷ while commercial preparations in granules were not suitable for the formation of a trabecular structure. Furthermore, HA beads must be combined with ground autologous bone²⁸ or with β -TCP.¹⁷ Micro-chambered beads are a three-dimensional replica of the characteristic trabeculae of cancellous bone; they resemble a negative mold of the intertrabecular spaces that is easily colonized

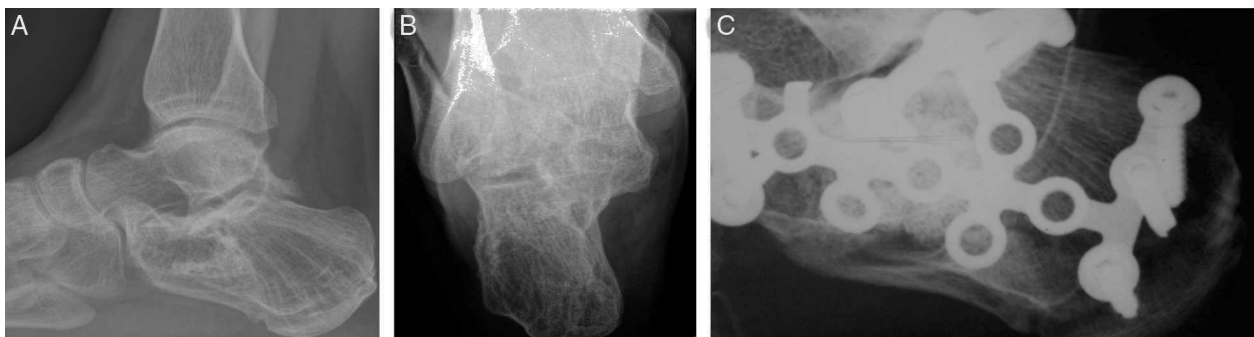


Figure 3 (A–C) Comminuted fracture of the calcaneus in a 35-year-old female patient treated with osteosynthesis and β -TCP beads (Ceraball®). The implant was removed at 22 months after surgery: resorption of the bone replacement and trabecular reconstruction.

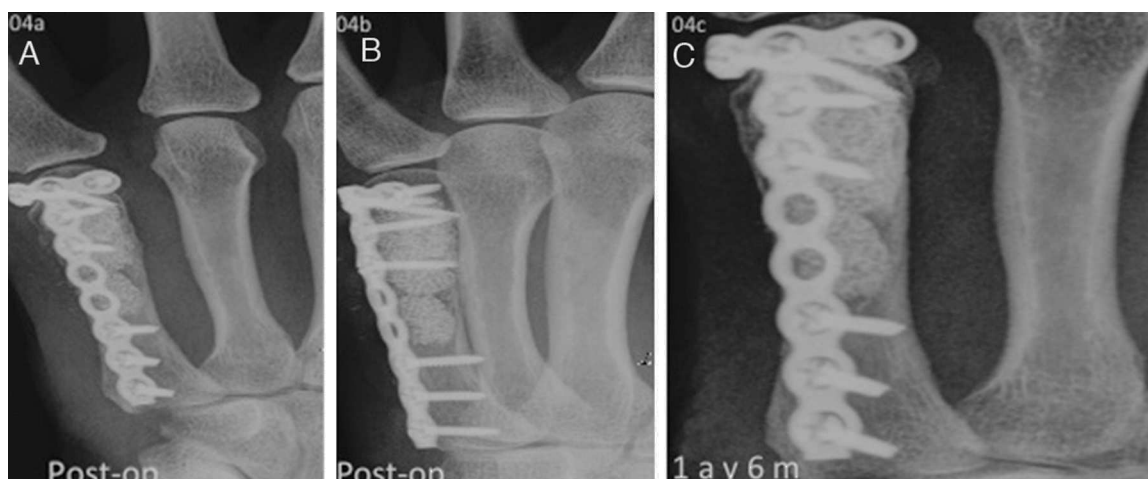


Figure 4 (A–C) Pathological fracture of the fifth metacarpal due to enchondroma in a 42-year-old male patient. After the tumor was treated by curettage, the defect was filled with HA beads (Ceraball® HA) and osteosynthesis. At 18 months after surgery, the fracture had healed: the HA replacement remained present.

by new bone which can undergo load from the start, without requiring remodeling. This is the fastest method for the reconstruction of a cancellous defect. Another advantage is that it can be combined with some drugs, such

as BMP.¹⁶ In addition, their spherical morphology allows them to be easily displaced when the screws of the osteosynthesis are applied, moving them without destroying them.

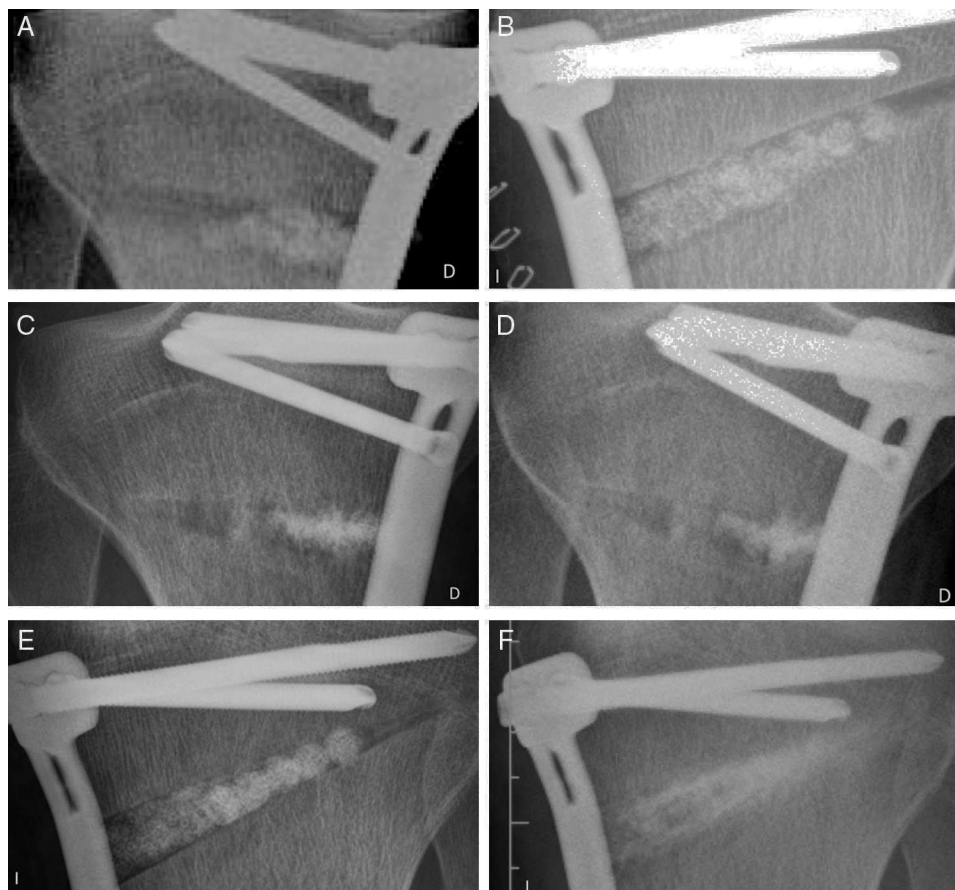


Figure 5 (A–C) Open wedge osteotomy in a 25-year-old male patient treated with osteosynthesis (Tomofix® plate) and incomplete filling of the defect with Ceraball® β -TCP beads. Monitoring for 21 months with partial filling and permanence of lateral and anterior defects. (D–F) Osteotomy in the contralateral tibia using the same treatment with a follow-up period of 7 months: the beads are visible but replaced by bone. At 7 months they were completely resorbed.

Level of evidence

Level of evidence IV.

Ethical responsibilities

Protection of people and animals. The authors declare that this investigation adhered to the ethical guidelines of the Committee on Responsible Human Experimentation, as well as the World Medical Association and the Declaration of Helsinki.

Confidentiality of data. The authors declare that they have followed the protocols of their workplace on the publication of patient data and that all patients included in the study received sufficient information and gave their written informed consent to participate in the study.

Right to privacy and informed consent. The authors declare having obtained written informed consent from patients and/or subjects referred to in the work. This document is held by the corresponding author.

Conflict of interests

The authors have no conflict of interests to declare and have not received financial support to elaborate the present work. ZOW, an orthopedic science research center, which is a private research center, was financially supported through grants from the government and a family foundation.

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