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ORIGINAL ARTICLE

Beta-tricalcium phosphate for orthopedic reconstructions as an alternative to autogenous bone graft

Le phosphate bêta-tricalcique comme alternative aux greffes d'os autogène pour les reconstructions orthopédiques

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KEYWORDS
Beta-tricalcium phosphate;
Orthopedic surgery;
Bone defect;
Bone graft

Summary Autogenous bone graft (autograft) remains the gold standard in the treatment of many orthopedic problems. However, graft harvest can lead to perioperative morbidity and increased cost. We tested the hypothesis that an osteoconductive matrix, beta-tricalcium phosphate (β-TCP), would be a safe and effective alternative to autograft alone. Beta-tricalcium phosphate (β-TCP) is considered as one of the most promising biomaterials for bone reconstruction. This study analyzes the outcomes of patients who received β-TCP as bone substitutes in orthopedic surgery.

Methods. — A total of 50 patients were enrolled in a controlled, non-inferiority clinical trial to compare the safety and efficacy of β-TCP (25 patients) with those of autograft (25 patients) in indications requiring usually autograft. These 50 patients were categorized according to the etiology and morphology of the 54 bone defects resulting from elective surgical procedures, such as 34 open-wedge high tibial osteotomies, and 20 osteonecrosis treatments with core decompression. Radiographic (healing process with or without integration of β-TCP), clinical (no other surgical procedure), functional outcomes and safety (with or without complications) were assessed through fifty-two weeks postoperatively.

Results. — With regard to the primary endpoint (radiographic evolution), the fusion rate of the 34 open-wedge osteotomies was 100% (17 among 17) for patients in the group with β-TCP compared with 94% (16 among 17) for patients in the autograft group. For the 20 cavitary defects (osteonecrosis), the radiographic union rates, as determined by the presence of osseous bridging, were 100% for patients in the group with β-TCP and 100% for those in the autograft group. Clinically at one year, all quality-of-life and functional outcome data supported non-inferiority of β-TCP compared with autograft, and patients in the β-TCP group were found to have less pain and an improved safety profile.

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Conclusions. — Treatment with β-TCP resulted in comparable fusion rates, less pain and fewer side effects as compared with treatment with autograft. This study established clinical parameters where the β-TCP alone can successfully support the osteogenic process.

Résumé L'os autologue (autogreffe) reste la référence dans le traitement de nombreux problèmes orthopédiques. Toutefois, le prélèvement de greffons entraîne une morbidité périopératoire accrue et une augmentation du coût de l'intervention. Nous avons testé l'hypothèse selon laquelle une matrice ostéoconductrice, le phosphate bêta-tricalcique (β-TCP), pouvait être une alternative sûre et efficace à l'autogreffe seule. Le β-TCP est considéré comme l'un des biomatériaux les plus prometteurs pour la reconstruction osseuse. Cette étude analyse les résultats de patients qui ont reçu du β-TCP comme substitut osseux en chirurgie orthopédique. Un total de 50 patients a été inclus dans un essai clinique contrôlé de non-infériorité pour comparer l'innocuité et l'efficacité du β-TCP (25 patients) avec ceux d'une autogreffe (25 patients) dans des indications nécessitant habituellement une autogreffe. Les 50 patients ont été classés en fonction de l'étiologie et de la morphologie de 54 défauts osseux résultant de procédures chirurgicales spécifiques : 34 ostéotomies tibiales et 20 traitements à d'ostéonécrose avec forage-décompression. Les analyses radiographiques (guérison avec/sans intégration de β-TCP), cliniques (aucune intervention chirurgicale additionnelle), fonctionnelles et suites opératoires (avec/sans complications) ont été évaluées pendant 52 semaines après l'intervention chirurgicale. Le critère principal (évolution radiographique) a montré un taux de fusion de 100 % (17/17) des 34 ostéotomies pour les patients du groupe avec β-TCP par rapport à 94 % (16/17) pour les patients du groupe avec autogreffe. Pour les 20 défauts cavitaires (ostéonécrose), les taux d'union radiographique, déterminés par la présence d'un pont osseux, ont été de 100 % pour les patients du groupe β-TCP et 100 % pour ceux du groupe autogreffe. Cliniquement à un an, la qualité de vie et les résultats fonctionnels ont montré une non-infériorité du β-TCP par rapport à l'autogreffe et les patients du groupe β-TCP ont eu moins de douleurs et des suites opératoires meilleures. Le traitement par greffe de β-TCP a entraîné des taux de fusion comparables, moins de douleur et moins d'effets secondaires par rapport au traitement par autogreffe. Cette étude a établi des paramètres cliniques où le β-TCP seul a pu montrer ses capacités ostéogéniques.

Introduction

Surgeons use autograft to fill bone defects and promote fusion across osseous surfaces, particularly in higher-risk surgical sites, but its use comes with certain trade-offs. Important clinical complications [1] have been documented at the autograft donor site, including hematoma, pain, fracture, infection, heterotopic ossification, hernia and nerve injury. Furthermore, the quality and quantity of autograft are known to vary with patient age, body and overall health status. Equally important, harvesting autograft also requires additional operative time, hospitalization and cost.

Commercial bioactive ceramics [2—4] used for bone repair [5,6] include calcium carbonate ($CaCO_3$, in aragonite form), calcium sulfate ($CaSO_4 + H_2O$, plaster of Paris), calcium phosphates and bioactive glasses. Calcium phosphate ceramics include beta-tricalcium phosphate (β-TCP, $Ca_3(PO_4)_2$), hydroxyapatite [HA, $Ca_{10}(PO_4)_6(OH)_2$], and biphasic calcium phosphate (BCP) (consisting of an intimate mixture of HA and β-TCP of varying HA/β-TCP ratios).

These synthetic biomaterials have been proposed for many indications. However, there is no consensus in the literature if the biomaterial, when used alone, has the similar properties as autograft. In the present study, the bone loss was filled with pure beta-tricalcium phosphate in some patients and compared with autograft. We report here the investigation and data regarding the safety and efficacy of β-TCP compared with autograft in segmental and cavitary defects with a size lower than 9 cm^3.

Material and methods

The calcium phosphate granules

The β-TCP granules (Kasios; L'union; France) were produced by using the foam technology [7]. Briefly, 25 g of a β-TCP slurry were used to infiltrate, with manual pressure, 1 g of polyurethane foam. After drying and sintering at very high temperature (1200 degrees Celsius), β-TCP granules (size: 1 mm diameter) were obtained. The characteristics of these granules are the association of macroporosity surface and a microporosity structure. The macroporosity is controlled by the mesh of the polyurethane foam that is used to prepare the granules. The size of macroporosity is in the order of 400 μm at the surface of the material. This surface macro-roughness is also associated with a surface micro-roughness in relation with the fused grains of surface separated with the small holes that constituted the microporosity. The microporosity is in relation with holes

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