



Clinical Performance of a Highly Porous Beta-TCP as the Grafting Material for Maxillary Sinus Augmentation

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The rehabilitation of the atrophic posterior maxilla by means of implant-supported fixed prosthesis is one of the most demanding challenges for the clinician.¹ Several treatment options have been developed over years such as increasing the local available bone by sinus grafting, adopting a lateral approach² or a transcresal approach,³ the use of tilted implants placed in the available cortical bone of anterior and posterior sinus walls,⁴⁻⁷ the use of implants placed at distance such as pterygoid or zygomatic implants,^{8,9} and the use of short implants.¹⁰⁻¹³

The maxillary sinus floor augmentation is a surgical technique developed in the 1970s that allows to apply implant treatment to patients with atrophic posterior maxilla.² Some alternative options like the pterygoid and the zygomatic implants are seldom used because they imply technical difficulties and high discomfort for the patient.^{8,9} When the thickness of the sinus floor is less than 5 mm, other alternative options such as short

Background: Beta-tricalcium phosphate (β -TCP) is a synthetic bone substitute having high porosity and fast resorption. This retrospective study aimed at evaluating the effectiveness of an highly macroporous β -TCP for maxillary sinus floor augmentation.

Methods: Twenty-seven consecutive patients (17 woman/10 men, mean age: 59.7 years) in 2 clinics underwent maxillary sinus augmentation by lateral approach using β -TCP as grafting material. Implant survival, prosthesis success, periimplant bone loss, oral hygiene level, soft tissue condition, complication occurrence, and patient satisfaction were assessed.

Results: Thirty-one sinuses were successfully augmented. Sixty implants were placed. No sinus membrane perforations occurred. The

mean follow-up after grafting was 39.3 ± 8.7 months (range, 22–52 months), and it was 30.5 ± 8.1 months (range, 15–43 months) after implant loading. No implants were lost. After 1 year of loading, marginal bone loss averaged -0.88 ± 0.46 mm ($n = 54$ implants). Mean full-mouth plaque and bleeding scores were $11.5\% \pm 4.8\%$ and $3.5\% \pm 2.8\%$, respectively. No biological or mechanical complications were recorded. Patient satisfaction was very high.

Conclusion: Despite limited sample size and follow-up duration, highly macroporous β -TCP proved a valuable bone substitute for sinus augmentation, even when used alone. (Implant Dent 2014;23:357–364)

Key Words: bone substitute, dental implants, maxillary sinus augmentation, tricalcium phosphate

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implants and sometimes the sinus floor elevation using the crestal approach become less feasible. In these cases, grafting of the posterior maxilla using a lateral approach to sinus floor elevation is recommended to achieve sufficient bone for implant placement. Currently, this technique is supported by a large amount of clinical evidence, and it is rather straightforward for the average oral surgeon.¹⁴⁻¹⁹ Some aspects such as the sinus anatomy and the residual alveolar bone height together with the type of graft represent critical variables affecting the success of

the procedure and the timing of the rehabilitation.^{14,16,18}

Autogenous bone has long been considered as the ideal grafting material because of its osteoinductive, osteogenic, and osteoconductive features. However, the volume of harvested bone is limited, and the need for an additional surgery is often associated with prolonged discomfort for the patient.²⁰ Over the years, various modifications to the original protocol have been introduced with the aim of improving the predictability of clinical outcomes and

reducing donor site morbidity as well. Many types of bone substitutes have been adopted to provide a scaffold for neo-osteogenesis and to avoid a second surgical site preserving the patients from demanding harvesting procedures.^{14–19} In particular, a variety of allografts, xenografts, and alloplastic materials have been used, alone or in combination with autogenous bone, to simplify the grafting phase and to minimize the patient's discomfort.^{14,16,18} Currently, there is no consensus in the literature on which is the best grafting material and whether a biomaterial should be used alone or in combination with autogenous bone.

Tricalcium phosphates (TCPs) are bone substitute materials characterized by a high biocompatibility, high porosity, fast resorption, and osteoconductivity.^{21–23} Pure-phase beta-tricalcium phosphate (β -TCP) is one such TCP. With respect to other bone substitutes, β -TCP is characterized by precise and regular physical and chemocrystalline properties, uniformity of purity, and chemical composition, which make its biological reactions predictable.

β -TCP is thermodynamically stable in a biological environment and within a normal temperature range. Despite a similar degree of solubility, the biodegradation of β -TCP is faster than that of α -TCP, because the latter forms hydrolyses either partially or completely to hydroxyapatite $\text{Ca}_5[\text{OH}(\text{PO}_4)_3]$. The resulting crystals have a nonphysiological morphology and are not resorbed because of their very low level of solubility and may enter the lymphatic system by phagocytosis.^{24,25} Previous clinical studies with a multiphase, only partially resorbable TCP ceramic granulate (β - and β -TCP, hydroxyapatite) have demonstrated a correlation between bone-substitute resorption and bone regeneration that was dependent on the density and purity of the ceramic material, defect size, implant bed type, and individual osteogenetic potency of the bone.^{23,26,27}

The aim of this study was to assess the effectiveness of a β -TCP characterized by high macroporosity (approximately 90%) for maxillary sinus floor augmentation in patients with atrophic posterior maxilla in need for implant-supported rehabilitation.

MATERIALS AND METHODS

This report is based on a series of patients consecutively treated at 2 private practice offices in Paris. All patients were rehabilitated by means of implant-supported prostheses and were in need of maxillary sinus augmentation. Both clinicians (R.B. and B.G.) had more than 10 years of experience in implant dentistry and sinus augmentation procedure. The patients were treated after the principles embodied in the World Medical Association Helsinki Declaration of 1975 for biomedical research involving human subjects, as revised in 2000.

Patients' recruitment started on April 2009 until November 2010. Patients' inclusion criteria were those commonly adopted in the 2 clinics for the implant-supported rehabilitation of subjects edentulous in the posterior maxilla through maxillary sinus augmentation with the lateral approach: (a) at least 18 years of age; (b) absence of any local or systematic diseases that might contraindicate the sinus lift surgical treatment; (c) partially or totally edentulous or in need for extraction to be rehabilitated by means of implant-supported prostheses; (d) residual crestal bone height and width of 7 mm or less, evaluated by means of a cone-beam computed tomography (CBCT); (e) full-mouth bleeding score and full-mouth plaque score less than 25% at baseline; (f) absence of ongoing infection at the intended implant site or sinus pathologies; and (g) patients able to sign the informed consent form.

Patients were excluded if they presented one of the following exclusion criteria: (a) any systemic disease, condition, or medication that might compromise healing or implant osseointegration; (b) inability or unwillingness to return for standard follow-up visits; and (c) inability or unwillingness to maintain a good level of oral hygiene after the intervention.

Based on the selection criteria, 27 patients (17 women and 10 men) were treated from October 2009 to April 2012 in 2 private practice clinics. Patients' mean age \pm SD at surgery was 59.7 ± 10.8 years (range, 36–82 years). There were only 3 smokers. The mean residual ridge height and width at the implant site were 3.68 ± 1.55 mm (range, 1–7 mm)

and 4.23 ± 1.11 mm (range, 2–7 mm), respectively.

All patients underwent CBCT before surgery as a routine diagnostic approach to carefully evaluate the available bone at the intended surgical site and planning the grafting procedure. All patients received prophylactic antibiotic therapy consisting of 2 g of amoxicillin-clavulanic acid (or 600 mg of clindamycin if allergic to penicillin) 1 hour before the implant placement procedures. All patients rinsed for 1 minute with chlorhexidine digluconate mouthwash (0.2%) before the surgery. Local anesthesia was induced using 4% of articaine with adrenaline 1:100,000. A mucoperiosteal flap with releasing incision was elevated. The lateral antrostomy (approximately 10-mm wide and 8-mm high) was free of sharp edges that could cause perforation of the Schneiderian membrane. After careful detachment of the membrane, a graft composed of granular β -TCP (Kasios TCP Dental HP; Kasios, L'Union, France) was placed onto the sinus floor, below the sinus membrane. Before being placed into the cavity, such strip was shaped using a round diamond bur mounted on a handpiece, so as to fit exactly the sinus cavity. The full thickness flap was then closed to the primary incisions and sutured with 5.0 Vicryl.

When the residual ridge condition allowed primary stability of the implants, they were inserted during the same surgical session as the sinus elevation (simultaneous procedure). Otherwise, the implants were placed in a subsequent surgical phase, after 5 to 6 months of graft healing (delayed procedure). The prosthetic phase occurred approximately 4 months after the implant placement. The following postoperative medications were prescribed: amoxicillin and clavulanic acid (1 g 3 times a day for 6 days), naproxen (500 mg twice daily, if needed), and chlorhexidine digluconate mouthwash (0.2% twice daily for 1 minute for 7 days). Macrolides were prescribed to patients who were allergic to penicillin. Partial fixed prostheses made of metal-reinforced acrylic were delivered. The patients were scheduled for control visits at 6 and 12 months after loading and yearly thereafter up to 5 years. A CBCT was taken at 3-year follow-up to assess the graft condition.

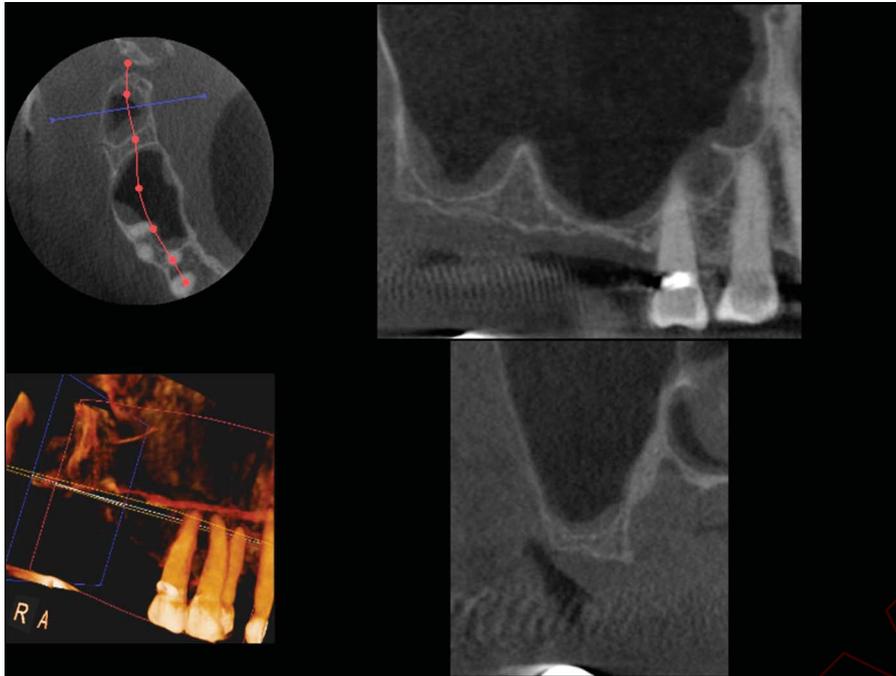


Fig. 1. Preoperative condition from a CBCT. It can be appreciated the highly thin residual ridge height and the presence of a bony septum protruding into the sinus.

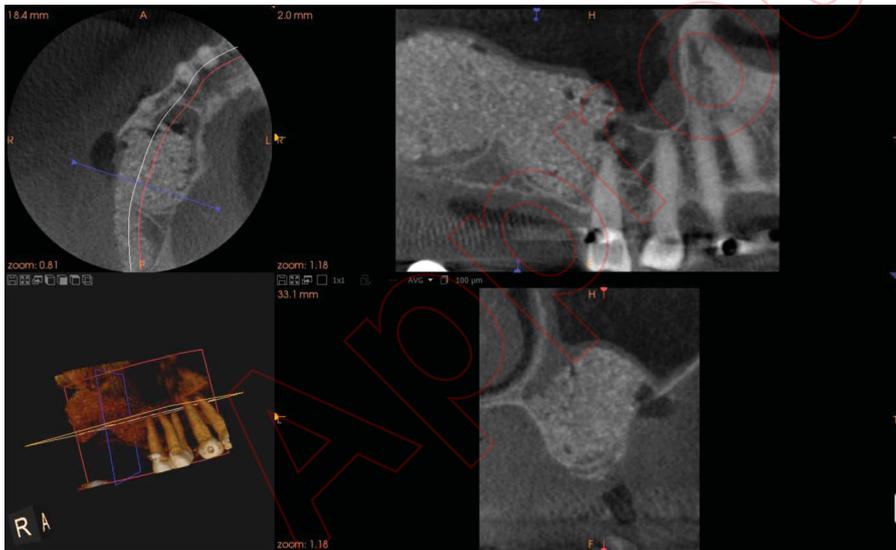


Fig. 2. Postoperative radiograph, showing the sinus augmented with β -TCP Kasios HP graft.

Orthopantomograms and periapical radiographs were taken at implant insertion, at prosthesis delivery, and at each scheduled follow-up visit. Periapical radiographs were taken using a long-cone paralleling technique and an individual x-ray holder (bite block) to ensure reproducibility. A clinical case is radiographically documented in Figures 1–4.

The following outcome variables were evaluated:

1. Prosthesis success: The prosthesis is in function, even in face of 1 or more implant failure. No mobility or pain is present. At each follow-up visit, prosthesis stability was tested by means of 2 opposing instruments' pressure.
2. Implant survival: The implant is in function and stable. No evidence of periimplant radiolucency, suppuration or pain at the implant site or ongoing pathologic processes is present.
3. Implant success: The success criteria proposed by Buser et al²⁸ and Cochran et al²⁹ were adopted for each implant at each follow-up visit. These criteria were: (a) no clinically detectable mobility when tested with opposing instrument pressure, (b) no evidence of periimplant radiolucency, (c) no recurrent or persistent periimplant infection, (d) no complaint of pain, and (e) no complaint of neuropathies or paresthesia.
4. Occurrence of complications: They include both biological complications (such as periimplant mucositis, periimplantitis, fistula, or abscess) and mechanical or prosthetic complications (such as fracture of the implant or of any prosthetic component and screw loosening).
5. Marginal bone level change: Intraoral radiographs were scanned at 600 dpi with a scanner (Epson Perfection Pro; Epson Italia, Rome, Italy), and the periimplant bone level was assessed with an image analysis software (UTHSCSA Image Tool version 3.00 for Windows; University of Texas Health Science Center,

Table 1. Study Data From the 2 Centers

	Center 1 (B.G.)	Center 2 (R.B.)	Total
No. of patients	15	12	27
Men/Women	6/9	4/8	10/17
Smokers	1	2	3
No. of sinuses	16	15	31
No. of implants	21	39	60
Simultaneous/delayed cases	0/16	6/9	6/25
Simultaneous/delayed implants	0/21	18/21	18/42

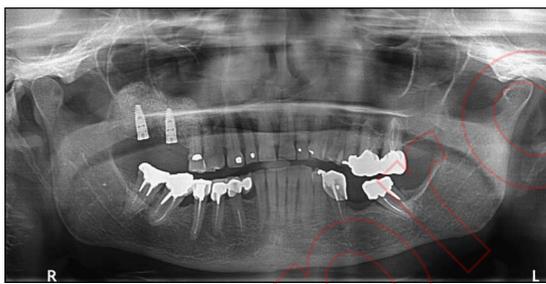
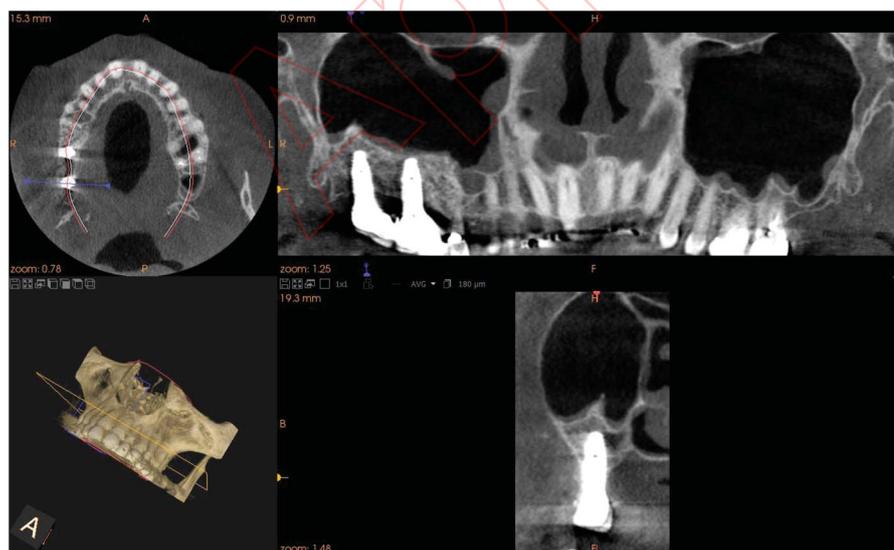
Table 2. Distribution of Implants' Diameter and Length

Implant Type	Diameter, mm	Length, mm	Quantity
Aesthetica+	3.6 × 4.2	12	2
	3.6 × 4.8	12	1
	4.1 × 4.2	8	2
	4.1 × 4.2	10	3
	4.1 × 4.8	10	2
	4.1 × 4.8	12	1
	4.8 × 4.8	8	2
	4.8 × 4.8	10	3
	4.8 × 6.5	10	4
	4.8 × 6.5	12	1
ID ^{ALL}	4.2	10	8
	4.2	12	23
	5.2	10	1
	5.2	12	3
ID ^{CAM}	5.2	10	4

The double diameter indicated for Aesthetica implants refers to body and platform, respectively.

San Antonio, TX). An experienced blinded evaluator performed twice all the measurements. Cohen kappa test was applied to assess

the reliability of the measurements. The known distance between the screw threads or the implant length was used to cali-

**Fig. 3.** Panoramic radiograph at implant placement.**Fig. 4.** Radiographic control 1 year after loading. Minimal bone resorption can be appreciated as compared with the prosthesis delivery phase.

brate each image. The implant platform was used as the reference for each measurement. Radiographs taken at the prosthesis delivery served as the baseline for evaluation of the marginal bone level change over the study period. The linear axial distance between the implant platform and the most coronal bone-to-implant contact was measured. To have a single value for each implant, mesial and distal values were averaged.

6. Oral hygiene level: The presence of plaque and bleeding on probing was evaluated at 4 surfaces per each tooth or implant and expressed as percentage of positive sites over total sites assessed (full-mouth score).
7. Patient satisfaction: Aesthetics, mastication function, and phonetics were assessed after 1 year of loading using a questionnaire. Each item was rated according to a 5-point Likert-type scale, choosing among the following possible answers: excellent, very good, good, sufficient, or poor.

Statistical Analysis

Descriptive statistics were adopted to summarize the results of this study.

RESULTS

Among the 27 patients treated, there were 3 bilateral cases, all treated in the same center (R.B.). A total of 31 maxillary sinuses were treated. No sinus membrane perforations occurred. In all the cases, a graft composed of 100% β -TCP was used. The contribution of the 2 clinics is resumed in Table 1. A total of 60 implants have been inserted (20 Aesthetica+ [Euroteknika Group, Sallanches, France]; 36 IDI^{ALL} and 4 IDI^{CAM} [Implants Diffusion International, Montreuil, France]). The distribution of implant size and diameter is shown in Table 2. The implant location distribution is shown in Figure 5. In 6 cases (18 implants), the implants

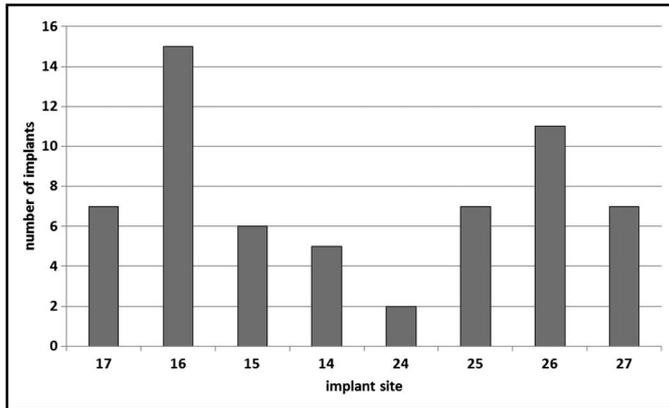


Fig. 5. Implant site distribution.

were inserted simultaneously to the grafting procedure. In the remaining 25 cases, implant surgery was delayed by 4 to 15 months (mean, 8.5 ± 2.6 months) after sinus elevation surgery. The prosthesis was delivered 4 to 5 months after the implant placement. The mean follow-up from graft surgery was 39.3 ± 8.7 months (range, 22–52 months), and the mean follow-up from implant loading was 30.5 ± 8.1 months (range, 15–43 months).

During this period, all grafts were successful, and no graft-related complications occurred. No biological or mechanical complications were reported throughout the observation period. No implant failures were recorded, leading to an overall implant survival and success rate of 100%. Prosthesis success rate was 100%.

In 3 cases, accounting for 6 implants, the marginal bone loss could not

be evaluated at the 1-year follow-up because of poor quality of the radiographs; therefore, the analysis was based on 54 implants. The mean marginal bone level change after 1 year of loading was -0.88 ± 0.46 mm. There were no values of bone loss exceeding 1.5 mm. Cohen kappa value was 0.92, showing excellent reproducibility of the evaluator.

Mean full-mouth plaque scores and full-mouth bleeding scores after 1 year were $11.5\% \pm 4.8\%$ and $3.5\% \pm 2.8\%$, respectively, showing a good oral hygiene control and a low level of soft tissue inflammation.

One patient did not fill the 1-year questionnaire. A score of “excellent” or “very good” was reported in 24 of 26 cases for aesthetics, 23 of 26 cases for mastication, and 25 of 26 cases for phonetics. No patients reported “sufficient” or “poor” scores for any of the items investigated.

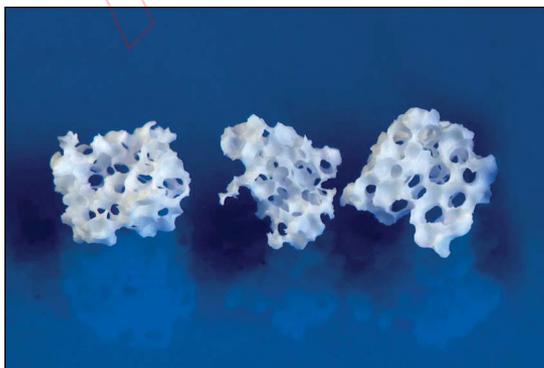


Fig. 6. Granules of Kasios β -TCP Dental HP showing high macroporosity (approximately 90%).

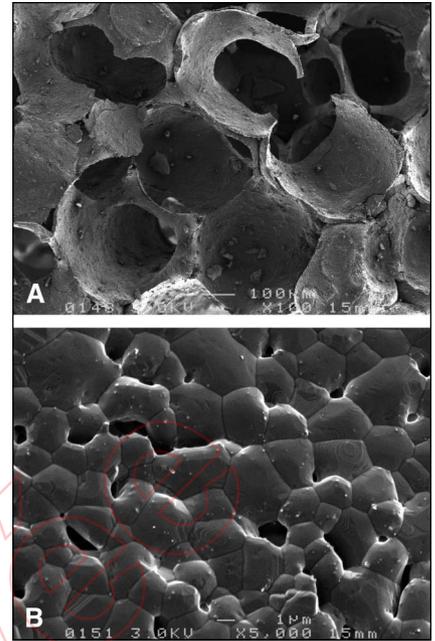


Fig. 7. SEM image of a Kasios β -TCP Dental HP granule. **A**, Macroporosity with pore size between 200 and 500 μm (magnification, $\times 100$; bar length, 100 μm). **B**, Microporosity with pore size between 1 and 5 μm (magnification, $\times 5000$; bar length, 1 μm). Provided by Prof Daniel Chappard, University of Angers, France.

DISCUSSION

The results of this study are promising, although the limited sample size and follow-up duration suggest caution in generalizing the results that need to be confirmed by further studies, possibly comparative with larger sample size and longer follow-up duration. Moreover, the histological and histomorphometric analysis are needed to evaluate the amount of newly formed bone when using such scaffold.

Equivalent results were achieved by 2 different expert clinicians, in the 2 centers that used 2 different implant systems, showing no influence of implant type on the study results. The fact that no graft or implant failures were reported and no complications occurred to patients suggests that macroporous β -TCP may be considered a valuable bone substitute for maxillary sinus augmentation procedure.

Synthetic calcium/phosphate biomaterials are currently used for the repair of bone defects. They offer considerable safety compared with

bone allografts or xenogenic bone. An ideal biomaterial must be able to stimulate a localized neo-osteogenesis, which represents the first step of the ossification process. It should be followed by a phase of resorption of the material. The β -TCP has long been recognized as a suitable ceramic material with bioactive features.^{30–32}

Kasios TCP Dental HP is a synthetic bone substitute with exceptionally high porosity (90%). Figure 6 shows the high macroporosity of a granule of β -TCP, prepared by the polyurethane foam technology.³³ Both macroporosity and microporosity are present. The macroporous component is made up of large-sized pores (200–500 μm), all interconnected (Fig. 7, A). Such interconnected macroporosity allows bone tissue to penetrate into the core of the biomaterial, allowing osseointegration by osseointegration. The microporous component, shown in Figure 7, B, is made up of small-sized pores (1–5 μm), which are found between TCP grains that merged when the material is highly hydrophilic, so that it can easily impregnate with blood because it is placed in the grafting site. Because of this porosity and its chemical composition, when implanted in bone, β -TCP provides an ideal environment for neo-angiogenesis, cell proliferation, and tissue growth and is replaced in 6 to 7 months by newly formed bone tissue.

Several animal and clinical studies have been performed to evaluate the performance of β -TCP as a scaffold in bone regeneration procedures. The β -TCP is known to be a promotor of osteoblastic formation and is readily resorbed by macrophages and osteoclasts. Direct bone matrix anchorage has been shown with collagen fibers deposited in the micropores.³⁴ Resorption of β -TCP by giant cells has been recently reported in a rabbit model with cells having or not a ruffled border (a characteristic of osteoclasts).³⁴

A study by Chappard et al³⁵ investigated the histological features of bone biopsies in patients submitted to maxillary sinus augmentation procedures and grafted with a mixture of β -TCP and morselized autograft bone harvested by the chin. Biopsies were harvested

immediately before placing the implants, 6 to 12 months after grafting. They concluded that the granules of β -TCP seem to be a very promising biomaterial for sinus lift augmentation because this material does not induce inflammation, favors osteoconduction, and is highly degraded by macrophages and osteoclasts. The morphology of the granules, in which a macroporosity in the order of 400 μm is present, ensures a suitable space for neoangiogenesis and for osteoprogenitor cells invasion. The 3-dimensional arrangement of granules is also a factor that could favor osteoconduction³⁶ and deserves further investigation.

Many clinical studies adopted β -TCP as a bone substitute for maxillary sinus augmentation, either alone or mostly combined with autogenous bone or other materials, with follow-up variable between 6 months and 5 years.^{37–51}

Only a few of them^{37–40,42,48} used β -TCP alone as the grafting material, similar to this study. Among these, 1 randomized clinical study compared 100% β -TCP versus autogenous bone in 20 patients undergoing bilateral maxillary sinus augmentation.⁴² Such study concluded that β -TCP is a satisfactory graft material, even without autogenous bone, confirming the results of a preliminary study on a smaller cohort of patients.³⁷

Another randomized study on 35 patients undergoing unilateral maxillary sinus augmentation compared 100% β -TCP and β -TCP with the adjunct of platelet-rich plasma (PRP).³⁸ The authors found that when PRP was added to β -TCP, bone regeneration was supported to a small extent. The resorption of β -TCP was not accelerated, and foreign-body giant cells and soft tissue surrounding the β -TCP granules were present.³⁸

In adjunct to the above-mentioned 2 studies, only other 3 comparative studies^{39,40,48} adopted 100% β -TCP as a bone substitute material for maxillary sinus augmentation. All these studies reported satisfying clinical results concluding that β -TCP is a safe and effective material, well comparable with autogenous bone,^{40,48} and more resorbable than anorganic bovine bone.³⁹

A recent randomized clinical study evaluated the safety and efficacy of recombinant human growth and

differentiation factor-5 (rhGDF-5) coated onto β -TCP for sinus lift augmentation, using a mixture of β -TCP and autogenous bone harvested from intraoral regions as the control material.^{49,50}

This study found that the osseous regeneration after 4 months of healing was similar in each treatment group. The rhGDF-5 is a potent osteoinductive material, member of the transforming growth factor- β superfamily and was added to a highly resorbable scaffold-like β -TCP with the intent to replace the need for autogenous bone and achieve shorter healing times. However, one has to consider that such addition also contributes to markedly increase the overall cost of the procedures, in face of a relatively small gain in terms of bone regeneration.

In summary, the satisfying results of this study are in agreement with those reported in previous studies that used β -TCP alone as the grafting material.^{37–40,48} Given the low cost and high safety and efficiency of β -TCP, it may be considered a valuable option among the numerous types of bone substitutes currently on the market.

CONCLUSION

The β -TCP characterized by very high macroporosity is a valuable bone substitute for maxillary sinus augmentation procedure, achieving satisfying outcomes even when used alone in a short-term observational study.

DISCLOSURE

The authors claim to have no financial interest, either directly or indirectly, in the products or information listed in the article.

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