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MAIN ARTICLE

First results of frontal sinus obliteration with a synthetic, resorbable and osteoconductive bone graft of ß-tricalcium phosphate

M ANDRATSCHKE[1,2], H HAGEDORN[1]

[1]*Department of Otorhinolaryngology, Head and Neck Surgery, HELIOS Amper-Klinikum Dachau, Teaching Hospital of the Ludwig Maximilian University of Munich, and* [2]*Department of Otorhinolaryngology, Head and Neck Surgery, University Medical Centre Schleswig-Holstein, Luebeck, Germany*

Abstract

Background: Despite advances in endoscopic sinus surgery, frontal sinus obliteration is still indicated in some cases. Current options for obliteration include autologous and synthetic materials. The use of ß-tricalcium phosphate as a resorbable bone graft substitute is a good alternative for frontal sinus obliteration. This study aimed to report our experience with this material.

Methods: A retrospective chart review of patients who underwent frontal sinus obliteration at our clinic between 2008 and 2013 was performed. Demographic data, indications, previous surgery, and immediate and late complications were examined. Information on persisting symptoms and patient outcomes was collected using a telephone questionnaire in February 2016.

Results: None of the patients underwent further surgery for frontal sinus disease. All of them reported a good cosmetic result and symptom improvement.

Conclusion: ß-tricalcium phosphate is a good, safe and cost-effective material for frontal sinus obliteration.

Key words: Calcium Phosphates; Frontal Sinus; Paranasal Sinus Diseases; Mucocele; Bone Remodeling

Introduction

Despite advances in pharmacology and physiology, chronic frontal rhinosinusitis, which is associated with significant morbidity, remains highly prevalent.[1]

For complicated frontal sinus disease, osteoplastic frontal sinus obliteration with abdominal fat has been used as a first-line therapy.[2,3] Unfortunately, there are a high number of associated complications, such as post-operative abdominal wound infection, unaesthetic cosmetic changes of the frontal bone, supraorbital neuralgia and frontal bossing.[4,5]

Advances in endoscopic techniques have made it possible to simulate external techniques like the Lothrop procedure. Draf developed the Draf type III frontal sinus drainage procedure, which is also known as the frontal sinus drill-out or endoscopic modified Lothrop procedure.[6] Furthermore, Weber *et al*. developed endoscopic techniques for widening the frontal sinus ostium.[7]

Currently, frontal sinus surgery involves a combination of minimally invasive endoscopic surgery and traditional open frontal sinus obliteration.[8]

The open approach is a reasonable option given its proven success.[5] Indications for open frontal sinus obliteration as a primary treatment are: the presence of intrafrontal cells; the presence of frontal disease in far lateral locations and a narrow frontal recess; frontal recess neo-osteogenesis; large osteomas; malignant tumours; osteomyelitis; complex frontal bone fractures; fractures of the posterior sinus wall with cerebrospinal fluid leakage; and failed endoscopic surgery due to chronic frontal sinusitis.[4,5,9,10]

For successful obliteration of the frontal sinus, the frontal sinus mucosa and the inner bony cortex of the sinus wall must be completely removed, and the nasofrontal duct must be occluded permanently.[11,12] The choice of material is also important for successful obliteration.[12] Techniques currently used include the implantation of autologous fat, bone and muscle, in combination with spontaneous osteogenesis.[11] While there are various alloplastic materials used in frontal sinus obliteration, autogenous fat remains the most popular.[13]

This paper aimed to demonstrate that frontal sinus obliteration with a synthetic, resorbable and osteoconductive bone graft of ß-tricalcium phosphate is a good alternative to the use of autologous fat, bone or

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muscle and to allogenic spongiosa. It is already used in trauma, orthopaedic and spinal surgical procedures, and in cranio-maxillofacial surgery.[14]

Materials and methods

Patients

We report on four patients who underwent osteoplastic frontal sinus obliteration. All were diagnosed with frontal mucocele. The patients' clinical charts were retrospectively reviewed, including demographics, diagnosis, imaging, prior sinus surgery history and post-operative complications. Information on persisting symptoms and patient outcomes was collected using a telephone questionnaire in February 2016.

Obliteration material

For the obliteration of the frontal sinus after resection of the mucocele, we used a fully synthetic and resorbable bone graft substitute consisting of pure ß-tricalcium phosphate, with a compressive strength similar to that of cancellous bone (chronOS bone graft substitute; Synthes, West Chester, Pennsylvania, USA). This implant material is usually fully resorbed, and is completely remodelled into the host bone within 6–18 months.

We used granules of different sizes, which could be easily formed to completely obliterate the frontal sinus. In line with the principles of frontal sinus obliteration,[15] the sinus mucosa was first totally removed and the inner cortex of the sinus wall was drilled out. Subsequently, the granules of ß-tricalcium phosphate were filled into the sinus for obliteration. In two patients, we used freeze-dried human cancellous bone (DIZG, Berlin, Germany) for comparison.

A Medline search was then performed to compare our results with data reported in the literature.

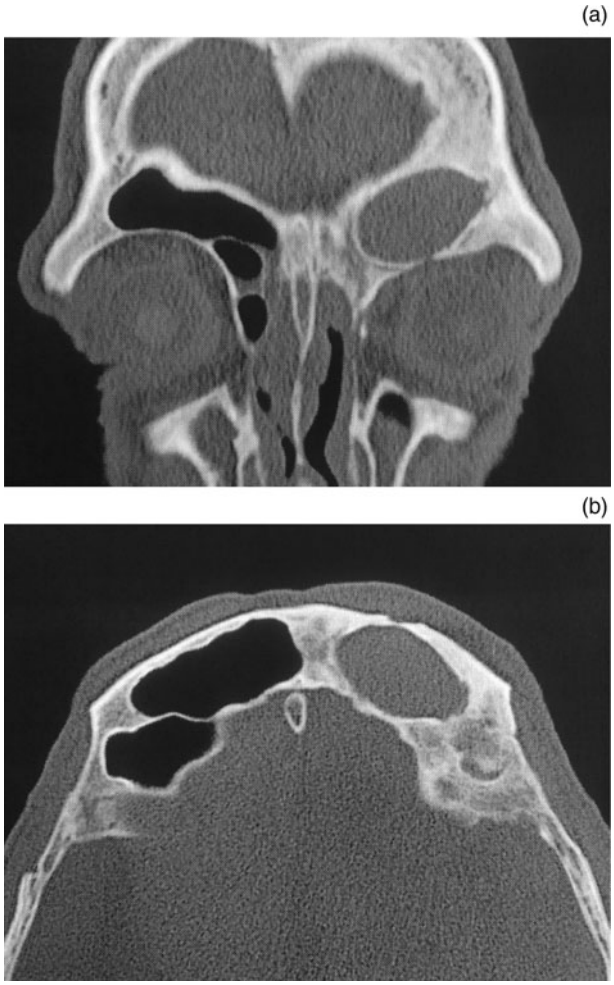

FIG. 1
(a) Coronal and (b) axial pre-operative computed tomography scans of a frontal mucocele in patient one.

Results

Our study included four patients: three males and one female (Table I).

Patient one, a 71-year-old male, was first diagnosed with a frontal sinus mucocele in 2008 (Figure 1). He had previously undergone external sinus surgery, in 1988, because of an anterior skull base fracture. Subsequently, osteoplastic frontal sinus surgery was performed as a first-line treatment because of ossified ethmoidal and frontal recesses. The complaints were: frontal stabbing pain, upper eyelid swelling, and eye bulb dislocation without double vision. The frontal sinus was obliterated with ß-tricalcium phosphate in 2008 (Figure 2).

TABLE I
PATIENTS' CHARACTERISTICS

Pt no.	Gender	Age (years)	Diagnosis	Cause	Prior surgery	Year of frontal sinus obliteration	Follow-up duration (months)
1	M	71	Mucocele	Anterior skull base fracture	External approach in 1988	2008	8
2	M	54	Mucocele	Chronic sinusitis	Endonasal surgery in 2011	2011	5
3	F	79	Mucocele	Frontal sinus pyocele	Combined endonasal & extranasal sinus surgery in 2007, 2012, 2013	2013	3
4	M	83	Mucocele	Anterior skull base fracture	External approach in 1971	2013	3

Pt no. = patient number; M = male; F = female

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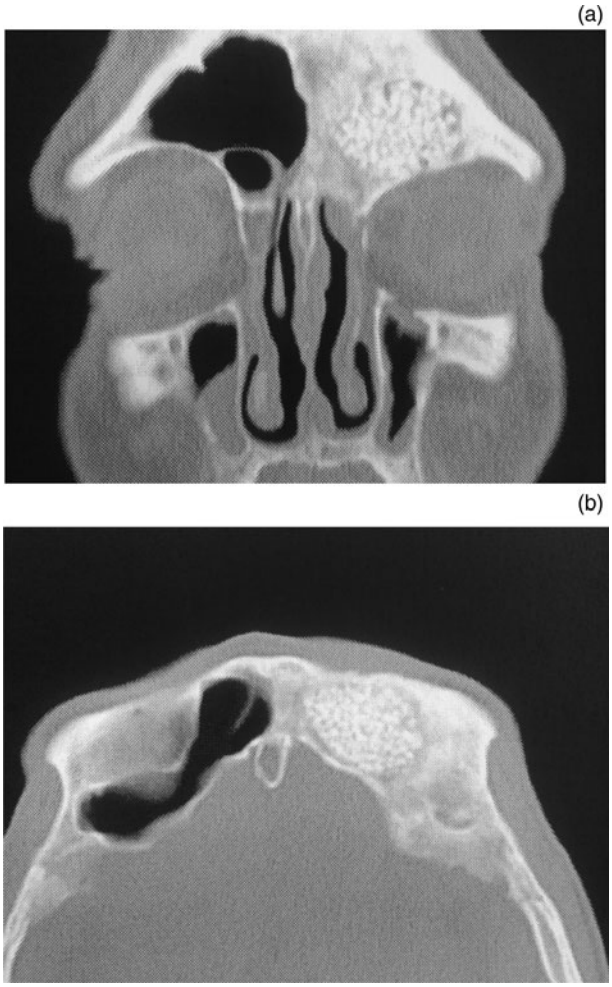

FIG. 2
(a) Coronal and (b) axial computed tomography scans of patient one at two months after frontal sinus obliteration with β-tricalcium phosphate.

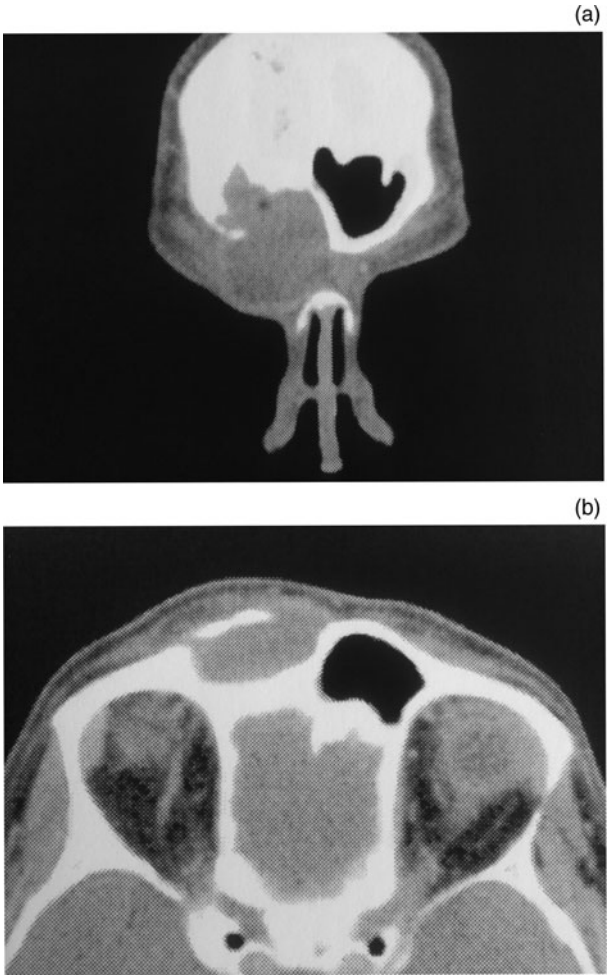

FIG. 3
(a) Coronal and (b) axial pre-operative computed tomography scans of a right frontal sinus mucocele in patient two.

Patient two, a 54-year-old male, was first diagnosed with a frontal sinus mucocele in 2011, a result of prior endoscopic sinus surgery for chronic sinusitis (Figure 3). Osteoplastic frontal sinus obliteration was performed in November 2011 as salvage surgery after previous endoscopic surgery (Figure 4). Pre-operatively, the patient complained of frontal stabbing pain and upper eyelid swelling. Subsequently, in addition to frontal sinus obliteration with ß-tricalcium phosphate, the frontal sinus roof was reconstructed with an absorbable polydioxanone (PDS™) plate (Johnson and Johnson Medical GmbH, Ethicon Germany, Norderstedt, Germany).

Patient three, a 79-year-old female, was first diagnosed with a frontal sinus mucocele in 2013, a result of prior endoscopic sinus surgery for a pyocele of the left frontal sinus. She had already undergone combined endonasal and extranasal sinus surgery four times, twice in 2007, and again in 2012 and 2013; these procedures were performed in other departments. She complained about an upper eyelid swelling and a stabbing pain in this area. She underwent frontal sinus obliteration as salvage surgery in March 2013, following multiple previous combined endonasal and extranasal sinus surgical procedures. The ethmoidal and frontal recesses were ossified as a result of the former surgical procedures. Pre-operatively, there was already a sinocutaneous fistula draining to the medial eyelid. The fistula was excised and the sinus was obliterated with freeze-dried human cancellous bone.

Patient four, an 83-year-old male, was first diagnosed with a frontal sinus mucocele on both sides in 2013. He had suffered a craniocerebral injury with an anterior skull base fracture in 1971. He complained about a stabbing pain in the frontal area and a proptosis on the left side. He underwent frontal sinus obliteration on both sides, with freeze-dried human cancellous bone, as a first-line treatment in April 2013. A posterior wall defect of the left frontal sinus was covered with TachoSil® (sealant matrix of human fibrinogen and human thrombin; Takeda, Konstanz, Germany) and the anterior wall defect was reconstructed with an absorbable polydioxanone (PDS) plate (Johnson and Johnson Medical GmbH, Ethicon Germany, Norderstedt).

All patients underwent computed tomography (CT) scanning prior to surgery and eyebrow incision.

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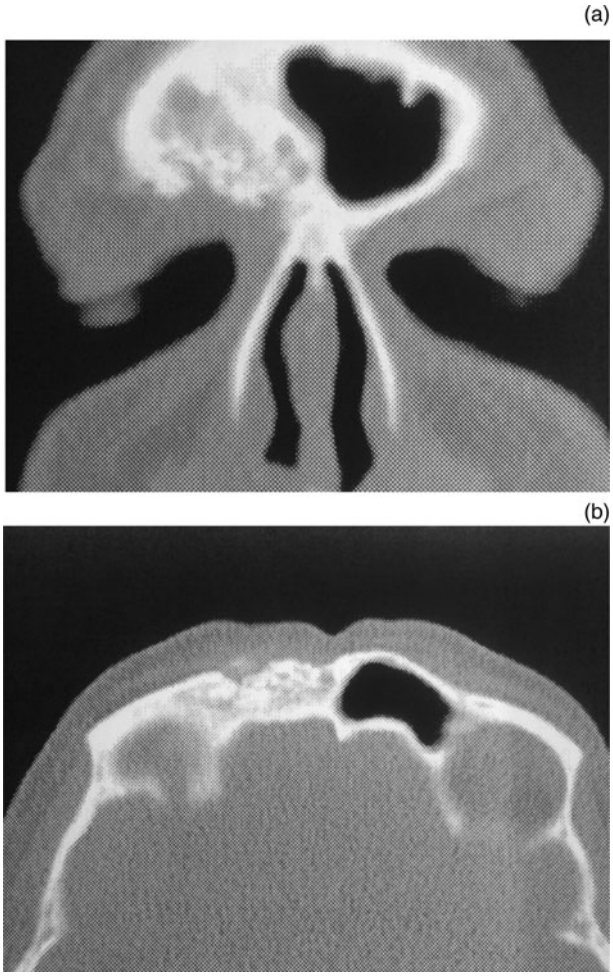

FIG. 4
(a) Coronal and (b) axial computed tomography scans of patient two at 27 months after frontal sinus obliteration with β-tricalcium phosphate.

There were no peri-operative complications. Only patient two had post-operative complications, which included a cutaneous fistula in the area of the incision two weeks after surgery. This fistula was excised six weeks post-operatively under local anaesthesia. None of the patients had any further symptoms after external frontal sinus obliteration and there were no aesthetic restrictions. None of the patients underwent any further sinus surgery following the frontal sinus obliteration. Both materials used (ß-tricalcium phosphate and freeze-dried human cancellous bone) were well tolerated.

The post-operative CT scans demonstrated that the frontal sinus was completely obliterated and that the ß-tricalcium phosphate, as expected, had almost completely remodelled into the host bone.

Discussion

There has been much discussion as to whether an endoscopic or an open approach is indicated for frontal sinus disease.

There are a number of radical procedures that use an external approach to treat frontal sinus mucoceles. Unfortunately, these surgical techniques are accompanied by high surgical morbidity, post-operative unaesthetic scar formation, and difficulty in radiological diagnosis of recurrence after obliteration.[16] Improvements in the endoscopic technique and the possibility of image-guided navigation have made it possible to use endoscopic procedures to treat these complicated cases.[17,18]

Open frontal sinus obliteration was once regarded as the 'gold standard' for frontal sinus disease treatment.[8,17] Techniques such as the Lynch procedure or the endonasal Lothrop procedure[19] showed high failure rates.[8] The modified subtotal Lothrop procedure was developed as an alternative.[20,21]

A review of the literature showed that the modified Lothrop procedure now functions as a rescue technique for a failed osteoplastic flap for frontal sinus obliteration. It also demonstrated that the endoscopic rescue procedure is technically challenging, requiring an experienced surgeon.[22] In a prospective study comprising 83 patients, Wormald showed that the endoscopic modified Lothrop procedure is a successful short-term option for different frontal diseases.[23]

A retrospective study of the endoscopic management of frontal sinus mucoceles with anterior table erosion, by Woodworth *et al*., showed that the endoscopic marsupialisation of frontal sinus mucoceles has a high success rate with a good cosmetic outcome, and often avoids routine reconstruction.[24] Marsupialisation using endoscopic sinus surgery is regarded as the treatment of choice for mucoceles, given the low recurrence rates and low morbidity.[25,26] Nomura *et al*. treated frontal mucoceles with conventional endoscopic sinus surgery, resulting in good outcomes.[27] Only one frontal sinus closed during follow up.

The success of endoscopic procedures for the treatment of frontal sinus mucoceles with lateral extension is undoubtedly linked to the localisation of the mucocele medial wall. The determination of mucocele extension beyond a virtual sagittal plane tangential to the medial side of the ocular globe is essential before deciding whether to use an external or an endonasal approach for lateral extended mucoceles.[28] Sama *et al*. proposed a new algorithm for the surgical treatment of frontal sinus mucoceles.[29] These authors emphasised variables such as mucocele position, drainage dimensions, the existence of fronto-ethmoidal cells and the degree of neo-osteogenesis. Decisions regarding the use of an endoscopic or external approach based on this classification resulted in a revision rate of 19 per cent.

The results of endoscopic and open approaches are comparable.[30] The use of an endoscopic approach or an open frontal sinus obliteration technique should be decided based on the surgeon's experience, the frontal recess anatomy and the nature of the disease.[5]

The long-term outcomes of the techniques are important. The failure rate of drill-outs performed as a result of mucoceles and tumours is significantly higher than that for other diagnoses. Most of the

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surgical failures occurred within 2 years, while late failures occurred after 12 years.[31]

The length of time between mucocele origins and presentation varies. In a study by Scangas *et al*., patients were diagnosed with a mucocele on average 17.7 years after paranasal trauma, 5.3 years after endoscopic surgery and 18.1 years after open sinus surgery.[32] Patients in that study presented with a mucocele as a result of open sinus surgery and trauma 20 years and 42 years later, respectively. Hence, long-term follow up is necessary to determine surgical outcomes.

Silverman *et al*. demonstrated that open frontal sinus obliteration is still indicated in selected cases as a first-line therapy.[5] The presence of intrafrontal cells, far lateral frontal sinus disease and a narrow frontal recess are named. The success rate in their study was 91 per cent.

Soyka *et al*. performed frontal sinus obliteration as a first-line treatment in 36 patients and as a second-line treatment in 41 patients.[9] They demonstrated good success, with 80 per cent of patients having no symptoms post-operatively. General complications were reported in 36.4 per cent of patients; of these, 90 per cent were only minor complications.

The material best suited for frontal sinus obliteration remains controversial. A number of various avascular materials have been used for frontal sinus obliteration, including fat, muscle, cancellous bone and hydroxyapatite. Biological properties such as fast revascularisation, no donor site morbidity and material availability are desired.

Kang *et al*. showed that the combined use of Tisseel® and autogenous calvarian bone for frontal sinus obliteration was suitable in their 17 patients.[33] This was associated both with a low complication rate and low donor site morbidity, and avoided the need for a separate donor surgical site. Vironneau *et al*. used an osteoplastic calvarian bone graft for frontal sinus obliteration in 11 patients.[34] All of these patients had improved symptoms and eight of them had no residual complaints following the procedure. Monnazzi *et al*. reported on eight sinus fracture patients who underwent frontal sinus obliteration with iliac crest bone grafts.[35] The complication rate was high in that study.

Obliteration with autologous bone works well in small sinuses with fewer complications. Cases of large and extensively pneumatised frontal sinuses present with many complications, requiring further surgery.

Rodriguez *et al*. used a mixture of calvarian bone dust and demineralised bone matrix (DBX; Musculoskeletal Transplant Foundation, Edison, New York, USA), a commercially available product, for frontal sinus obliteration in post-traumatic cases.[36] They demonstrated this technique to be safe and effective, with minimal morbidity, and with proven stability in the long term.

Moshaver *et al*. showed that an anteriorly based pericranial flap is a good option for frontal sinus obliteration.[37] None of their patients experienced recurrence.

Instead of bone or muscle, autologous fat is often used for frontal sinus obliteration. A retrospective study, by Kristin *et al*., of patients who received frontal sinus obliteration because of non-endoscopically accessible mucoceles, showed that obliteration with abdominal fat is a successful treatment option.[38] Nine of 10 patients were generally satisfied with the obliteration. Significant symptom improvements, significant reductions in the need for disease-specific drugs and fewer days of missed work were demonstrated.

Mendonca-Caridad *et al*. investigated a novel approach to frontal sinus obliteration and cranial tissue regeneration.[39] They used a totally autogenous material for frontal sinus obliteration. Platelet-rich and platelet-poor plasma was set to clot with cortical shavings from the skull face. This bioactive scaffold was placed and covered with a platelet-poor plasma membrane and a periosteal flap after the surgical work. No complications or recurrences were reported over the following 6–10 years, and bone formation recovery was demonstrated.

Alternative synthetic materials are also available. Taghizadeh *et al*. compared the use of fat with hydroxyapatite cement for frontal sinus obliteration after mucocele resection.[40] Treatment failed for 2 of the 16 patients in the fat obliteration group; there were no cases of failure in the hydroxyapatite group. The authors concluded that, given the minimal morbidity and lack of contour deficit, hydroxyapatite is an effective and well-tolerated material for frontal sinus obliteration.

Eloy *et al*. demonstrated that calcium phosphate bone cement was an alternative material for sinus obliteration in a rabbit model.[41] Further investigations are needed for long-term evaluation and proof of benefit in chronically infected sinuses.

In our patients, we used a fully synthetic, osteoconductive and resorbable bone graft substitute consisting of pure ß-tricalcium phosphate, with a compressive strength similar to that of cancellous bone. Over the past 25 years, this material has been used in trauma, orthopaedic and spinal surgical procedures.[42,43] Autologous bone grafting is associated with various deficiencies and several complications. Donor site pain can continue for many years after surgery. Inadequate quality or volume can limit bone harvesting. Allogenic bone grafts may be infected as a result of the donor.

The advantage of using a synthetic material like ß-tricalcium phosphate is the uniform quality, the unlimited availability, and the avoidance of a donor site with all its possible associated complications such as wound infection, pain, paraesthesia and scar formation. The osteoconductive property of ß-tricalcium phosphate, associated with overall porosity and macropores, helps to induce the bone remodelling process by encouraging the ingrowing of bone cells and blood vessels. ß-tricalcium phosphate mimics cancellous

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bone. It is resorbed and completely remodelled into the host bone within 6–18 months after implantation. It is easy to use as an 'off-the-shelf' product, and is available as granules of different sizes to fit precisely into the bone defects. Thus, operating time is significantly reduced. ß-tricalcium phosphate is rapidly resorbed because it is chemically and structurally similar to bone. Osteoclasts resorb the ß-tricalcium phosphate. Fortunately, resorption and bone remodelling takes place at the same time. While osteoclasts resorb, the tricalcium-phosphate osteoblasts fill the lacunes created by osteoclasts by producing an extracellular matrix, which is subsequently calcified. In contrast, hydroxyapatite resorbs very slowly.[44] The bone remodelling is evident on post-operative CT scans.

- **Osteoplastic frontal sinus obliteration is a key first-line and salvage surgical treatment for chronic frontal sinus disease**
- **The best material for frontal sinus obliteration remains controversial**
- **This paper reports our experience with resorbable β-tricalcium phosphate for frontal sinus obliteration in frontal sinus mucocele patients**
- **β-tricalcium phosphate is a good, safe and cost-effective alternative to autologous and allogenic materials**
- **Its use avoids donor site morbidity and complications, and shortens surgery time**
- **Furthermore, it has unlimited availability and uniform quality, with no chance of infection**

In our study, both ß-tricalcium phosphate and freeze-dried human cancellous bone were well tolerated. Both are easily used as 'off-the-shelf' products. Nevertheless, the cost of ß-tricalcium phosphate is a third lower than that of allogenic spongiosa, and there is no possible chance of donor infection.

Hence, ß-tricalcium phosphate is a good, safe and cost-effective alternative to autologous bone and fat, because it avoids donor site morbidity and complications, shortens the duration of overall surgery, and has unlimited availability and uniform quality. It is a good alternative to commercially available allogenic bone grafts regarding possible donor infection and costs. No patient in the ß-tricalcium phosphate group showed further symptoms or had additional surgery during the five- and eight-year follow-up periods. Further studies comprising more patients are needed to confirm these findings.

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Address for correspondence:
Dr Michaela Andratschke,
Department of Otorhinolaryngology, Head and Neck Surgery,
HELIOS Amper-Klinikum Dachau,
Krankenhausstrasse 15,
D-85221 Dachau, Germany

Fax: +49 8131 764909
E-mail: michaela.andratschke@helios-kliniken.de

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