Use of allogeneic cortical granulate for external surgical sinus floor elevation

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_Introduction

This study aimed to assess the effectiveness of external sinus floor elevation in 36 patients with severely atrophic posterior maxillae using allogeneic freeze-dried cortical granulate (Osteograft®, ARGON Medical). Implants were placed in a second session after a mean time of 7.6 months. As the study shows, the use of allogeneic cortical granulate in external sinus augmentation showed successful clinical results combined with great properties. It seems to be a reliable material for reconstruction of a severely atrophic posterior maxilla. It presents a good alternative to autogenous bone in sinus augmentation because of good ossification, less morbidity, unlimited availability, shorter duration of surgery as well as lower costs.

Implants preparation by sinus floor elevation

In order to sufficiently install dental implants in atrophic maxilla, preparative surgical procedures are often necessary. Successful osseointegration of implants depends on a suitable quantity and quality of surrounding bone. One of these procedures is the sinus floor elevation. First described by Tatum and Boyne[1, 2], it presents a very common preprosthetic surgery in dentistry. A grafting material is placed between the sinus floor and the lifted sinus membrane, resulting in an augmentation of vertical bone. Various articles have been published describing different grafting materials.[3-6] Implants are installed in a second operation if primary stability of the implants cannot be achieved. A minimum bone height of four to five millimetres is necessary to fulfil the criteria of primary stability.[7] Less bone height results in the necessity of a two-step approach.

Usage of allogeneic bone

Present gold standard is the use of autogenous bone, defined by donor and acceptor being the same individual.[8, 9] It presents osteoconductive, osteoinductive and osteogenetic properties.[8-10] However, at the same time it requires additional surgery, associated with corresponding risks, complications and additional morbidities. Also, duration and therefore cost of surgery rise. Harvesting bone from extraoral sites, e.g. the iliac crest, also demands general anaesthesia. In some cases, autogenous bone is limited.[11-14] Due to existence of various disadvantages, alternative graft-

Fig. 1_Sinus with elevated membrane.
Fig. 2_Allogeneic bone soaked in blood.

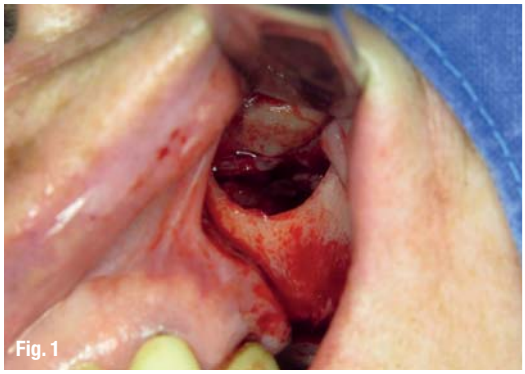
Fig. 1

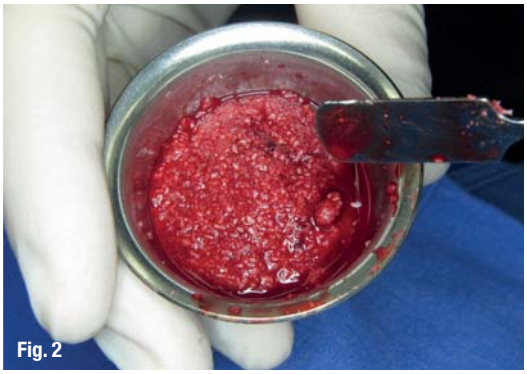
Fig. 2

ing materials with similar properties are sought after. One option to overcome these disadvantages of autogenous bone is the usage of allogeneic bone. The purpose of the following study is to evaluate the use of allogeneic particulate cortical bone for the surgical elevation of the sinus membrane in order to successfully install dental implants. The properties of allografts are described and a case report of failure surgery is analysed.

_Material and methods

Patients

In the period between July 2008 and October 2010, 36 patients (19 females and 17 males) with an average age of 54 years underwent surgery at the Dorow Clinic in Waldshut, Germany. All patients suffered from a severe maxillary atrophy (bone height less than four millimetres), making augmentation necessary for successful installation of dental implants. External sinus membrane elevation was carried out as exclusive surgical technique. Allogeneic particulate cortical bone was used as grafting material in all patients. In each case, implants were installed in a second intervention. A cone beam computer tomography (CBCT) was created preoperatively to display the bony structures and precisely evaluate augmentative surgery indications. In this study, success was defined as the ability to install dental implants in the augmented sites. Certainly, the desired criterion of success ought to be the success of the subsequent prosthetic treatment after years of follow-up. Due to our being only one part of the medical referral chain, we have not been able to keep track of all patients involved in this study. Also, not all patients have yet been restored prosthetically. Additionally, we have been using allogeneic bone grafts in our clinic for only a few years now. As a consequence, the focus of this study lies exclusively on augmentation itself.

Grafting material

In all cases allogeneic bone transplants were used. All grafts were obtained from ARGON Medical, the German distributor for allogeneic dental transplants processed by the German Insitute for Cell and Tissue Replacement (Deutsches Institut für Zell- und Gewebeersatz, DIZG). The DIZG uses a peracetic acid-ethanol sterilisation (PES) procedure on its transplants. This validated procedure proves to be a reliable method for the sterilisation of human bone transplants.[11, 15-17] After thorough cleaning of blood and fat tissue by using sterile water under high pressure, the bone is scoured by chloroform and ethanol. Then the actual sterilisation is performed under low pressure

Fig. 3_Placing allogeneic bone in sinus.
Fig. 4_DVT after augmentative surgery.

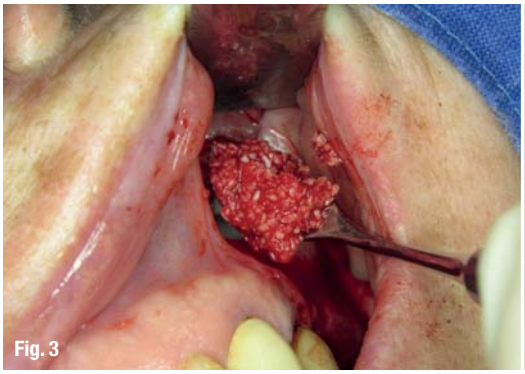
Fig. 3

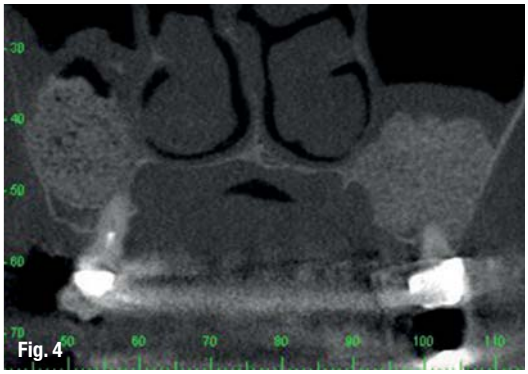
Fig. 4

(200 mbar). Therefore, the bone is covered with peracetic acid. Ethanol is used to reduce the surface tension. After four hours of vacuum-incubation, a buffer agent is applied. Eventually, the grafts are freeze-dried and packaged aseptically. Processing demonstrably inactivates HI-Virus 2, Hepatitis A-Virus, Polio-Virus, Pseudorabies-Virus as a model for Human Herpes-Virus, Porcine Parvo-Virus as a model for Human Parvo-Virus B19 and Bovine Diarrhoe-Virus as a model for Hepatitis C-Virus. Also a reduction in the titer of viable micro-organisms (*Staphylococcus aureus, Enterococcus faecium, Pseudomonas aeruginosa, Bacillus subtilis, Clostridium sporogenes, Mycobacterium terrae, Candida albicans* as well as spores of *Bacillus subtilis* and *Aspergillus niger*) below the detection level is achieved.[10-13]

Surgical technique

Preoperatively, an antibiotic was given intravenously (2.000 mg Amoxicillin with 200 mg clavulanic acid). All patients received a prescription for an antimicrobial prophylaxis (875 mg Amoxicillin with 125 mg clavulanic acid; twice a day for five days) and analgesic (600 mg Ibuprofen; as needed). Local anaesthesia was performed by using a minimum of 4 ml of high-dose articaine (1:100.000). A crestal incision was made on the alveolar ridge with vertical releases into the vestibule if needed. A full-thickness mucoperiosteal flap was created to gain access to the anterior wall of the maxillary sinus. A rectangular-shaped osteotomy is cut into the lateral antral wall by means of rotating instruments, revealing the sinus membrane. The inferior horizontal segment was kept 3-4 mm above the floor of the sinus in order to help keeping the grafting material in place in the floor of the sinus. The exposed membrane with the covering adherent bone was carefully elevated with special instruments following the usual procedure (Fig. 1). The bone flap was displaced inward with the carefully lifted Schneiderian membrane, forming the new floor of the maxillary sinus. Space was created in the primary floor of the sinus for the grafting material. If tearing of the Schneiderian membrane occurred, repair was carried out with a layer of resorbable collagen (Osteogide®, ARGON Medical, Germany). The grafting material (Osteograft®, ARGON Medical, Germany) was soaked in venous blood taken from the antecubital fossa for five minutes and placed underneath the sinus membrane and lightly condensed towards the sinus floor (Figs. 2 and 3). An absorbable collagen membrane was also placed onto the bony window. A complete and strainless wound closure was performed by means of sutures. Clinical and radiographic examinations were done during the postoperative phase, mostly by means of CBCT or orthopantogram. Sutures were removed after 14 days.

_Results

All data is presented in Table 1. 36 patients underwent external sinus floor augmentation surgery using allogeneic bone as grafting material. In 35 cases implants were able to be installed in a second intervention (97.2 % success). After a mean time of 7.6 months, implants were installed. In only one case the grafting material was lost and had to be removed in additional surgery (2.8 % failure). Not all implants were installed in our clinic. Many patients are referred to our clinic only for augmentation, implants are then installed elsewhere. However, it is known to us that implants definitely were installed in these patients, just not the exact date. Therefore these dates are not included in our study. Mean time of follow-up after augmentation is 18.2 months. Mean time of follow-up after implantation is 11.1 months.

_Discussion

This study confirms previous results showing that allogeneic bone grafts work excellent as bone substitute and manage to build up healthy and well-dimensioned bone suitable for uncompromising installation of dental implants.[10,18-22] Main point of criticism regarding allogeneic bone grafts are the often-quoted fears of possible transmission of disease and antigenicity. These potential disadvantages were studied to a large extent.[11,15-17] Using the modern PES-sterilization procedure, they are practically non-existent. An inactivation of potential viruses, bacteria, fungi and spores takes place by means of interna-

Patient	Sex	Date of birth	Age	Compli-cation	Augmentation date	Implants installed	Implantation date	Healing time	Follow-up A	Follow-up B
1	f	29.07.1957	53	no	23.02.2010	yes	23.08.2010	6	12	6
2	m	08.09.1955	55	no	19.02.2009	yes	09.11.2009	8	24	15
3	f	30.12.1956	54	no	12.02.2010	yes	08.10.2010	7	12	4
4	m	23.10.1937	73	Graft lost	30.05.2009	no	***	***	***	***
5	f	02.12.1976	34	no	01.07.2010	yes	28.01.2011	6	7	1
6	f	19.08.1987	23	no	20.07.2009	yes	18.01.2010	5	19	13
7	m	08.07.1953	57	no	15.09.2009	yes	23.02.2010	5	17	12
8	f	05.09.1959	51	no	07.01.2010	yes	20.11.2010	10	13	3
9	m	15.06.1951	59	no	23.11.2009	yes	05.08.2010	8	15	6
10	f	11.12.1955	55	no	07.11.2008	yes	17.12.2009	13	27	14
11	f	15.08.1950	60	no	06.05.2009	yes	15.12.2009	7	21	14
12	m	11.01.1958	53	no	20.01.2009	yes	01.09.2009	7	25	17
13	m	26.12.1957	53	no	10.12.2008	yes	17.06.2009	6	26	20
14	f	16.04.1951	59	no	07.07.2008	yes	03.02.2009	6	31	24
15	f	05.03.1945	65	no	13.07.2009	yes	06.07.2010	11	19	7
16	m	10.02.1969	42	no	17.03.2009	yes	21.09.2009	6	23	17
17	f	28.04.1943	67	no	29.09.2008	yes	23.02.2009	4	28	24
18	f	17.02.1956	55	no	01.09.2009	yes, alio loco	***	***	17	***
19	f	12.05.1947	63	no	21.12.2009	yes, alio loco	***	***	14	***
20	m	24.02.1967	44	no	26.10.2010	yes, alio loco	***	***	4	***
21	m	18.09.1932	78	no	14.05.2009	yes	18.11.2009	6	21	15
22	m	28.09.1969	41	no	12.03.2009	yes	03.08.2009	4	23	18
23	f	22.11.1952	58	no	22.07.2010	yes	24.01.2011	6	7	1
24	f	26.10.1952	58	no	14.03.2009	yes	08.08.2009	4	23	18
25	m	06.07.1949	61	no	18.05.2009	yes	21.10.2010	17	21	4
26	f	17.02.1943	68	no	08.07.2008	yes	02.02.2009	6	31	24
27	m	19.04.1954	56	no	12.11.2009	yes	01.09.2010	9	15	5
28	m	10.10.1961	49	no	08.05.2009	yes, alio loco	***	***	21	***
29	f	25.10.1950	60	no	15.09.2009	yes, alio loco	***	***	17	***
30	f	03.02.1978	33	no	01.12.2009	yes, alio loco	***	***	14	***
31	m	01.05.1968	42	no	09.09.2009	yes	22.02.2010	5	17	12
32	m	27.01.1964	47	no	24.02.2009	yes	22.06.2010	15	24	8
33	f	24.02.1963	43	no	30.11.2009	yes	30.11.2010	12	14	2
34	m	24.12.1952	58	no	09.12.2009	yes, alio loco	***	***	14	***
35	f	04.11.1957	53	no	25.02.2010	yes	08.10.2010	7	12	4
36	m	26.06.1947	63	no	21.04.2010	yes	08.12.2010	7	10	2

Table 1_Patients, follow-up and complications.
m = male
f = female
Healing time = time between augmentation and implantation in months
Follow-Up A = Follow-up in months after augmentation
Follow-Up I = Follow-up in months after implantation

tional standardised and validated processing.[11] Since 1985, over 250.000 PES-sterilized allogeneic bone grafts of the DIZG have been transplanted. Since today, there has been no report about transmission of disease or immunologic response.

PES sterilisation for bone regeneration

Regarding biologic properties, the grafts show osteoconductive as well as osteoinductive characteristics. Various studies report unanimously that PES sterilization shows no significant effects on reduction of osteoinductive properties on allogeneic bone grafts.[23-26] After PES-sterilisation, following growth factors are detectable amongst others: BMP-2, BMP-4, IGF-1, TGF-ß1, VEGF and PDGF.[26] It is well known that these growth factors have the ability to promote bone regeneration.[27] Additionally, there is no limitation regarding procurement. Any quantity and quality can effortlessly be acquired. Figure 4 shows an example of the amount that is possible in augmentation. It is doubtable that such results can be economically managed with autogenous bone or other bone substitutes. The costs are relatively low and therefore such grafting results are reasonable, establishing a situation for an uncompromising, prosthetic-based implant placement. Also, grafts have a shelf-life of five years.

Case of failure surgery

One graft was lost and removed in second surgery. It is unlikely that immunologic response or transmission of disease was reason for loss of graft. In this case a bilateral sinus floor augmentation was performed and only one side caused problems. Figure 4 shows

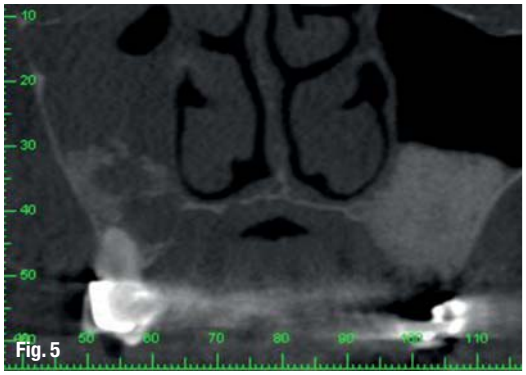
Fig. 5

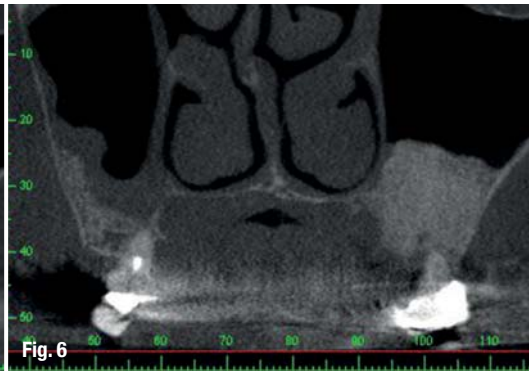
Fig. 6

Fig. 5_Right sinus totally shadowed with infected graft.
Fig. 6_Remains of graft and slightly thickened membrane.

the result of augmentation two days after surgery. A swelling of the sinus membrane exists on both sides; additionally a haematoma is visible on the right side. Two weeks after surgery, a light swelling of the right posterior maxillary area appeared and the patient felt a discomfort at the surgical area. Radiologic examination revealed infection of the right sinus (Fig. 5), indicating an immediate removal of the graft. The other side healed normally and showed clinically and radiologically no signs of infection or rejection.

Removal of graft in additional surgery

Sinus floor augmentation is in fact a very predictable procedure and complications are rare.[7, 28, 29] Failures can be caused by perforation of the sinus membrane, excessive bleeding, infection of the grafted tissues e.g. with saliva, wound dehiscence, and lack of aseptic conditions.[30-33] Infected sinuses should be treated immediately. Different studies show success in treatment with antibiotics and local debridement or on the other hand complete surgical removal of the graft combined with high dosage administration of antibiotics.[30, 34, 45] We decided to completely remove the graft in an additional surgery. Saline irrigation had been performed for over one week due to chronic sinusitis and antibiotics were prescripted (875 mg Amoxicillin with 125 mg clavulanic acid; twice a day for five days). The infected sinus was successfully treated leaving sparse remains of grafting material (Fig. 6). We see the reason for failure in a known massive perforation of the sinus membrane. The inserted membrane possibly did not cover the entire perforation. Repeating surgery was planned but the patient decided not to undergo this procedure. This case presents another advantage of allogeneic bone. If failure occurs, repeating surgery is not as extensive as using autogenous bone and can be more excusable from a patient's point of view.

Postoperative follow-up

The postoperative follow-up ranges to 18.2 months from first augmentative surgery and 11.1 months from installation of dental implants. Only patients with successfully installed implants were considered in this issue. A longer range has not been analysed yet, due to the relatively recent implementation of the grafting materials. The short period of follow-up might stand out as a possible point of criticism of this study. But considering the relatively quick remodelling time (compared with some xenogenic bone substitutes), a longer period may not actually be necessary for the discussion of this fact. Histologic studies show already after six to nine months of healing time vital, newly formed bone with sparse remaining allograft particles without evidence of acute inflammatory infiltrate.[36-39] Allogeneic bone grafts show analogous histologic characteristics as autogenous bone chips.[19] Allogeneic bone is completely transformed into patient's own bone tissue.[40] However, further studies must discuss the relevance on long term success of dental implants in allogeneic grafts.

_Conclusion

Our experience and the results of various studies show that the use of allogeneic bone grafts for bone augmentation of the atrophic alveolar ridge works successfully. After a period of healing, the resulting bone is equal to autogenous bone. And additionally, we see more advantages in the use of allogeneic bone than in autogenous bone._

Editorial note: A list of references is available from the publisher.

_contact implants

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