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Use of Cuban Granulated B-Tricalcium Phosphate "Biograft-G" as Maxilar Bone Graft

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Abstract

In maxillary bone, several pathologies or lesions may cause maxillary alveolar atrophic (MAA), that is, a bone reabsorption frequently provoked by tooth loses or extractions. Tooth loses or extractions are one of the most common clinical situations observed in patients. The MAA could become a significant functional and aesthetic risk for the use of tooth implants or any other prosthetic rehabilitation. Several biomaterials have been used as bone graft; they must fulfil requirements like biocompatibility and a suitable function. A synthetic dense ceramic granulate of β-TCP, BIOGRAFT-G® (BIOMAT), in form of irregular shape granules with a grain size between 0.1 mm and 0.4 mm, was used in this study as graft material. The clinical studies include 178 patients, treated in Pre-implantology and Trans-implantology bone remodelling, prevention of residual ridge reabsorption by socket grafting and Periapical Surgical. In the final evaluation of effectiveness after 6 month of surgery most of cases were qualified as *Success* (98.3%), observing in the treated site a remodeled bone similar to the one in the adjacent tissue and almost no trace of implanted biomaterial. However, 3 cases were qualified as *Failure*, all of them in patients that underwent the filling of dental sockets treatment, caused by the exfoliation of granules or a septic process. According to the obtained results, Biograft-G® proved to be a biodegradable, biocompatible, effectiveness and safety bone graft biomaterial in the studied treatments.

Keywords: β-tricalcium phosphate; Bone defects; Bone repairing; Oral surgery; Pre-implantology surgery; Bone filling

Introduction

The only adult human tissue with the capability of whole regeneration is bone tissue. However, in some cases depending on the defect type and the bone lesion cause, the bone regeneration could be a complex and delayed process [1].

In maxillary bone, several pathologies or lesions may cause Maxillary Alveolar Atrophic (MAA), that is, a bone reabsorption frequently provoked by tooth loses or extractions, which is a very common clinical situation observed in patients. The MAA could become a significant functional and aesthetic risk for the use of tooth implants or any other prosthetic rehabilitation [2,3]. According to several reports, mayor dimensional changes on the alveolar ridge take place during the three first months after tooth extraction, and can be treated with different surgical procedures and bone graft materials [4,5].

Currently, one the surgical procedures most requested by patients after a tooth extraction is the use of metallic implants. This surgical method allows the prevention of MAA when used immediately after tooth extraction and requires the use of a graft material in order to fix the metallic implant. In other cases the recommended treatment is to fill the cavity to achieve a bone remodelling after the placement of a metallic implant. The selection of the appropriate treatment in each case, as well as the suitable biomaterials to be used, must be done by a qualified physician [6-8].

Several biomaterials, that must fulfil requirements such as biocompatibility and a suitable function, have been used as graft material. During the 80´s and 90´s the Hydroxyapatite (HA) was the most common biomaterial used as graft. Once implanted, the HA provides support for new bone growth, allowing the filing of the defect, even in those cases where the bone cannot usually regenerate by itself. Though there is bone regeneration, the permanence of HA due to its stability increases the mechanical strength in the site causing some inconveniences for the placement of endosseous implants [3,9]. For this reason, new biodegradable materials started to be used. This is the case of β-Tricalcium phosphate (β TCP), a graft biomaterial which has been proved to allow new bone growth and site consolidation in bone defect while the material degrades [1,10].

Employing HA or β TCP graft in the form of granule material also requires the use of membranes in order to maintain the implanted material in the correct position [11]. Membranes help the bone regeneration process and avoid the interference of soft tissues on the bone cicatrisation, and could be made of polylactic/polyglicolic acid or collagen [12].

Biograft-G® is a synthetic ceramic granulate of β-TCP for bone regeneration, manufactured by the Centro de Biomateriales de la Universidad de la Habana (Biomaterials Centre at the Havana University, BIOMAT). This material has proved to be non cytotoxic, bioactive and biocompatible, according to preclinical and clinical

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essays [13-15]. This study presents the effectiveness of Biograft G® as bone graft in pre-implantology remodelling, trans-implantology remodelling, filling of dental sockets and periapical bone defects.

Materials and Methods

A synthetic dense ceramic granulate of β-TCP, BIOGRAFT-G® (BIOMAT), was used in this study in the form of irregular shape granules with a grain size between 0.1 mm and 0.4 mm.

The clinical studies included 178 patients treated with BIOGRAFT-G® to prevent MAA and periapical surgery. All patients gave their informed consent, according to Helsinki Statement. Treatments were carried out in several public dental services in Cuba (in La Habana, Pinar del Rio, Matanzas and Artemisa provinces) and in the city of Santo Domingo, Dominican Republic, between 2009 and 2013. Patients included in these studies were categorized according to the World Health Organization as 0 and 1 general state of health and in a range of age between 18 to 70 years old.

Treatments were classified as Pre-implantology and Trans-implantology bone remodelling, prevention of residual ridge reabsorption by socket grafting and Periapical Surgical.

In all cases, the surgical treatments and toilette of the bone defect were carried out using the conventional method before the refilling with Biograft-G®. The graft material was mixed with sterile water or the patient's blood before placing it and then covered with a collagen membrane to prevent particle migration [11]. After restoring the mucoperiosteum and the flap, the surgical incision was sutured with 3.0 silk suture and with tissue adhesive Tisuacryl® (BIOMAT) [16].

Clinical and radiographic evaluation of the treatment effectiveness was carried out. Clinical evaluation includes: presence of edema, granule exfoliation and presence of infection. The presence of edema was qualified, according to the increase of mucous volume noticed, as *Absence* for no increase, *Slight* for a small or medium increase and *Severe* for a large increase of mucous volume. Granule exfoliation was evaluated as *Absence* or *Occurrence*. The presence of infection was evaluated as *Absence* or *Occurrence* in accordance with the appearance or not of suppuration. Radiographic evaluation was made in seven days and after six months of implantation and qualified as *Satisfactory* (more than 80% of filled cavity with radiopacity) or *Not Satisfactory* (less than 80% of filled cavity with radiopacity).

Treatment effectiveness was qualified as *Success* or *Failure*.

Success: when there was *Absence* of edema, infection and granule exfoliation and radiographic evaluation was *Satisfactory*.

Failure: when at least one of the evaluation parameters don't fulfil the previously mentioned requirements.

Results and Discussion

Patient distribution by sex, age and surgical treatment are shown in table 1. The most common treatment was the filling of dental sockets, in almost 61% of the cases treated. No significant differences on results according to sex and age groups were observed.

At short time evaluation, after seven days of the treatment was carried out, 94.4% of *Success*ful cases were observed. There was no infection or presence of dental plaque in any of the cases. However, in patients that underwent the treatment of dental socket filling, the presence of edema was reported in 10 cases and granules exfoliation in 2 of them, while the other treatments did not report any adverse effect.

The presence of edema in a short time may occur as a natural consequence of the surgical intervention, but granules exfoliation should be caused by an incorrect handling of the graft material or the incorrect placement of collagen membrane during the surgical treatment. Similar observations have been reported by other authors, e.g. Kalish et al. [17], that attribute the granules exfoliation to the

Control variables	Quantity	Percentage
Sex		
Female	92	52,8
Male	86	47,2
Age Groups		
18-44	86	48,3
45-70	94	51,7
Surgical interventions		
Pre-implantology remodelation	34	19,1
Trans-implantology remodelation	19	10,7
Filling of dental sockets	108	60,7
Periapical Surgical	17	9,6
Total	178	100

Table 1: Patient distribution by sex, age and surgical treatment.

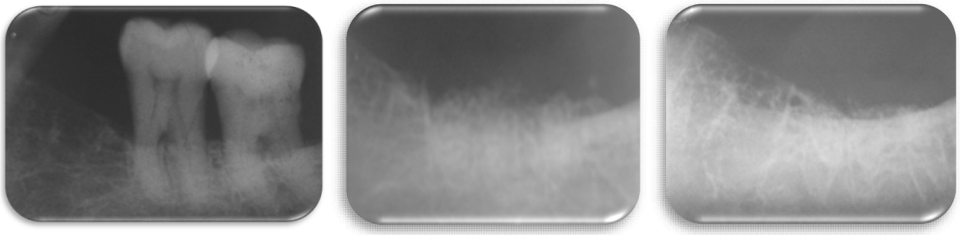

Figure 1: Radiography evaluation: initial, after 7 days and after six months of treatment.

handling difficulties, mainly due to the lack of cohesion typical on this kind of materials supplied in granule form.

It should be noticed that in cases of implantology remodelling and periapical surgery, the bone cavities has less tendency to present exfoliation of granules due to a more closed shape, in accordance with the results observed in this and other studies [18-21].

In the final evaluation of effectiveness, after 6 months of surgery, most of the cases were qualified as *Success* (98.3%), observing in the treated site a remodeled bone similar to the one in the adjacent tissue and almost no trace of implanted biomaterial. All Implantology remodelling and periapical surgery treatments were qualified as *Success*. Only 3 cases were qualified as *Failure*, all of them in patients that underwent the treatment of dental sockets filling. *Failure*s reported were caused by the exfoliation of granules in 2 of the cases and the other one due to a septic process adjacent to the alveolus that caused the treatment *Failure* after 3 months. These results are similar to the ones reported by other authors [22] that consider the placement of β-TCP P as graft for bone remodelling in dental implants, combined with a reabsorbable membrane, an implantology *Success* treatment.

Figure 1 show radiography of post extraction alveolus after 7 days and 6 months of surgery; at a short time the biomaterial placed could be observed, while after 6 months a newly form bone that allows keeping the desired bone height is observed.

At the end of the study (six months), only a few traces of the material could be seen in the X-ray films images, observing the almost *Absence* of Biograft G® in the implanted site. Several authors agree that filling dental sockets with bone graft biomaterials at the moment of the tooth extraction to preserve alveolar morphology is an effective treatment to prevent the bone reabsorption and MAA [23-27].

Conclusions

Bone treatments with Biograft-G® demonstrate to be effective in Pre-implantology and Trans-implantology bone remodelling, prevention of residual ridge reabsorption by socket grafting and Periapical Surgical, observing in the treated site a remodeled bone similar to the one in the adjacent tissue and almost no trace of implanted biomaterial after six months. According to the obtained results, Biograft G® proved to be a biodegradable, biocompatible, effectiveness and safety bone graft biomaterial in the studied treatments.

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