Charles University in Prague

Faculty of Medicine in Hradec Králové

EVALUATION OF A COMPOSITE SYNTHETIC BONE SUBSTITUTE MATERIAL FORTOSS® VITAL IN THE TREATMENT OF PERIODONTAL INTRABONY DEFECTS

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Abstract of the dissertation

Doctoral study program in Dentistry

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Assoc. Prof. Antonín Šimůnek, M.D., Ph.D.
Chairperson of the Commission for Dissertation Defences
Doctoral study programme in Dentistry

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SOUHRN

Úvod. Aloplastické kostní štěpy se široce užívají v současnosti v kombinaci s membránami, což zajišťuje realizaci řízené tkáňové regenerace při léčbě nitrokostních parodontálních chobotů. Tato studie byla určena k hodnocení klinických výsledků kompozitního materiálu beta trikalcium fosfátu v kombinaci s kalcium sulfátem při léčení kostních parodontálních chobotů. Kombinace uvedených matriálů umožňuje realizaci řízené tkáňové regenerace.

Metoda. Celkem 47 kostních defektů u 26 pacientů bylo léčeno preparátem Fortoss® Vital (Biocomposites, Staffordshire, UK). Pacienti byli sledováni po 2 roky. Klinické parametry hodnocení zahrnovaly změny hloubky parodontálních chobotů, úroveň gingivodentálního spojení, gingivální recesy,přítomnost či absenci dentálního plaku, BOP na začátku (před operací) a za 2 roky po operaci.

Výsledky. Po chirurgickém ošetření se zmenšila hloubka parodontálních chobotů, zvýšila se úroveň gingivodentálního spojení. Redukce hloubky parodontálních chobotů poklesla po 1 a 2 letech od operace o 1,97 ± 1.15 mm ($p < 0,0001$) a 2,07 ± 1,14mm ($p < 0,0001$), úroveň gingivodentálního spojení stoupla o 1,68 ± 1.12 mm ($p < 0,0001$) a 1,93 ± 1,36mm ($p < 0,0001$), gingivální recesy se zvětšily o 0,30 ± 0.71 mm ($p = 0,009$) a 0,14 ± 0,73mm ($p = 0,571$). Procento plošek s plakem a s pozitivním BOP se redukovalo významně za 2 roky po operaci ve srovnáním s vyšetřením před operací.

Závěr. Léčba parodontálních kostních chobotů kombinací beta-trikalcium fosfátu a kalcium sulfátu vede k signifikantnímu zlepšení kostních parodontálních chobotů po dvou letech od operačním zákroku. Pro přesnější dokumentaci efektu tohoto způsobu léčby je potřeba dlouhodobější sledování a rozšíření počtu sledovaných defektů.

SUMMARY

Background Alloplastic bone graft materials are widely been used these days in combination with barrier membranes to achieve guided tissue regeneration in the treatment of periodontal intrabony defects. This study was designed evaluate the clinical outcome of a composite material, beta tricalcium phosphate in combination with calcium sulphate, in the treatment of periodontal intra-bony defects. The combination of these materials is believed to aid in guided tissue regeneration owing to their properties.

Methods Forty seven intrabony defects in 26 periodontitis patients were treated with Fortoss® Vital (Biocomposites, Staffordshire, UK). The patients were followed-up for 2 years. Clinical parameters were evaluated which included changes in probing depth (PD), clinical attachment level/loss (CAL) and gingival recession (GR), presence/absence of plaque and bleeding on probing (BOP) at baseline and at one and two years postoperatively.

Results A decrease in probing depths (PD) and a gain in clinical attachment level (CAL) were noticed in at one and two years postoperatively. The mean differences in measurements between the baseline and one year postoperatively are a reduction of 1.97 ± 1.15 mm ($p < 0.0001$) in case of PD, a gain of 1.68 ± 1.12 mm ($p < 0.0001$) in CAL and an increase of 0.30 ± 0.71 mm ($p = 0.009$) in GR. The mean differences in measurements between the baseline and two years postoperatively are a reduction of 2.07 ± 1.14 mm ($p < 0.0001$) in case of PD, a gain of 1.93 ± 1.36 mm ($p < 0.0001$) in CAL and an increase of 0.14 ± 0.73 mm ($p = 0.571$) in GR. The percentages of sites with presence of plaque and with BOP were reduced considerably at 2 years postoperatively compared to preoperative findings.

Conclusions The treatment with a combination of beta tricalcium phosphate and calcium sulphate led to a significantly favourable clinical improvement in periodontal intrabony defects two years after the surgery. A longer-term evaluation and further studies are necessary to completely ascertain the effectiveness of this material, and a larger sample size is needed.

INTRODUCTION

Periodontitis is one of the two major dental diseases, the other being dental caries, that affect human populations worldwide at high prevalence rates and that results in loss of teeth. Hence the prevention and treatment of periodontitis is of utmost importance in the field of dentistry. Prevention of periodontitis is achieved through promoting healthy lifestyles including good oral hygiene and reducing or eliminating risk factors.

Contemporary periodontal therapy is directed towards controlling the infection and regenerating lost supporting structures. Infection control can be achieved by proper initial phase periodontal therapy including scaling and root planning (SRP), maintenance and antimicrobial therapy. Non-surgical therapy performed in the first phase may be sufficient to eliminate the signs and symptoms of mild periodontitis. However, many cases or sites with moderate to severe disease often continue to show signs of inflammation after a non-surgical approach. In such cases, surgical treatment is a necessity. The various surgical approaches implemented in the surgical phase are open flap debridement (OFD), resective flap surgery, mucogingival surgery and reconstructive/regenerative surgery. The ultimate goal in periodontal therapy is the regeneration of periodontal tissues affected by diseases to their original form, function and consistency. The current techniques in the treatment of periodontitis aimed at periodontal regeneration include open flap debridement- OFD,[5, 9, 20] the use of bone grafting materials,[21, 23] Guided tissue regeneration – GTR,[1, 2, 13] and also the use of certain biologic modifiers like Enamel matrix derivatives – EMD[24] or various other growth factors (i.e. Platelet Derived Growth Factor - PDGF, Insulin like Growth Factor – IGF, Transforming Growth Factor-β - TGF-β including Bone Morphogenetic Proteins – BMPs).[10, 14, 18]

The interest in bone replacement grafts has emerged from the desire to fill an intrabony or furcation defect rather than radically resect surrounding intact bone tissue. It is assumed that the application of bone grafts would potentially manipulate the biological response into a regenerative rather than a predominantly reparative pattern of periodontal healing. [6] A better clinical outcome is anticipated when bone grafts are used in combination with GTR (Guided tissue regeneration). GTR aims to isolate the periradicular bone wound from faster proliferating epithelial cells and other connective tissue cells thereby allowing the cells from the periodontal ligament to repopulate the blood coagulum that forms between the alveolar bone and root

surface. The isolation of the wound is achieved using a physical barrier like a membrane.[4, 15] There are different types of barrier membranes, both resorbable and non-resorbable.

Alloplasts are synthetic, inorganic, biocompatible bone substitutes that primarily functions as defect fillers in the treatment of periodontal intrabony defects. Alloplasts can aid in bone regeneration by a process called osteoconduction. Beta tricalcium phosphate is one of the earliest calcium compounds to be used as a bone graft substitute. Structurally porous beta tricalcium phosphate has a compressive strength and tensile strength similar to that of cancellous bone. It undergoes resorption over a 6-18 month period. Unfortunately, the replacement of beta tricalcium phosphate by the bone does not occur in an equitable way. That is, there is always less bone volume produced than the volume of the graft material resorbed. For this reason, the clinical use of beta tricalcium phosphate has been rather as an adjunctive with other less resorbable bone graft substitutes or as an expander for autogenous bone graft. Another calcium compound that is used as bone void filler is calcium sulphate. It has a compressive strength greater than that of cancellous bone. It can act as a barrier membrane as well, which makes it ideal as an adjunct with other graft materials.[12]

In the present study, we have evaluated the clinical outcome of a technique which is easier to perform, cost effective and imitates guided tissue regeneration principle using a composite material, beta tricalcium phosphate in combination with calcium sulphate (Fortoss® Vital, Biocomposites, Staffordshire, UK), in the treatment of human periodontal intrabony defects.

AIM OF THE STUDY

The study was aimed towards the long-term clinical evaluation of the effectiveness of a composite material, beta tricalcium phosphate in combination with calcium sulphate, in the treatment of periodontal osseous defects. Intra-bony defects remain a significant therapeutic problem in periodontal therapy. Regeneration of lost periodontal tissues is the ideal goal in the treatment of periodontal defects. Bone grafts are used mainly for the filling of the bony defects thereby aiding in regeneration. The indications of various bone grafts in periodontal therapy are similar, but the search for the ideal material is still on. This study was focused on one such synthetic graft material called Fortoss® Vital, which could be superior to other graft materials in terms of clinical outcome and usage owing to its properties.

MATERIALS AND METHODS

Type of study

The study was primarily retrospective in nature.

Subjects

In this study 26 patients who were treated using the composite material (Fortoss® Vital) were evaluated. These patients had advanced periodontitis, were in general good health presented with deep intrabony defects and were treated at the department of dentistry, faculty of medicine in Hradec Králové, Czech Republic. They were aged 21 to 58 years with a mean age of 42.27 ± 10.66 at the time of surgery. There were 9 males and 17 females, out of which 8 were smokers. All the smokers were medium smokers, smoking up to 5 cigarettes a day.

Subject inclusion was based on the presence of at least one tooth with a probing depth (PD) of ≥ 5 mm and radiographic evidence of intrabony defect after initial phase periodontal therapy. The exclusion criteria consisted of patients with systemic diseases or medically compromised conditions and taking any drug known to interfere with the wound healing during the previous 6 months, pregnant and/or lactating women and insufficient dental hygiene characterized by a papilla bleeding index (PBI) total score of >15. Teeth had to be vital or properly treated with root canal therapy. Signed consent form before surgery was obtained.

Study design and clinical procedures

All patients underwent initial therapy, consisting of oral hygiene instruction, full-mouth scaling and root planing, elimination of local plaque-retaining factors and restorations and occlusal adjustments when indicated. A total of 47 periodontal intrabony defects were identified in our study group of 26 patients after the initial phase therapy. These defects were either 2 or 3 walled defects with 33 of those located around the anterior teeth and 7 each around the premolars and molars. All the defects were treated by one clinician, using a standardized procedure. Clinical parameters like probing depth (PD), gingival recession (GR), clinical attachment level/loss (CAL), presence/absence of dental plaque and bleeding on probing (BOP) were recorded just before the surgery (baseline) and at 1 and 2 years postoperatively. The measurements were done using a calibrated periodontal probe (Williams color coded, Hu-Friedy, Chicago, IL, USA) at the vestibular/buccal, oral/lingual, mesial and distal surfaces on all teeth involved and the highest

value for each surface was quoted. The clinical parameters at the baseline and at 1 and 2 years postoperatively were compared and evaluated statistically to procure the study outcome. Radiographs were also made and compared to support the clinical outcome.

The surgical treatment phase was initiated only if the subject had a papilla bleeding index (PBI) total score of ≤ 15. After achieving sufficient local anaesthesia, a full-thickness mucoperiosteal flap was elevated using a crevicular incision on the facial and lingual surfaces of each tooth, segment or area involved. In the upper anterior regions papilla preservation incisions are made in the interdental area. Vertical release incisions were used as necessary. After the elevation of the flap, a thorough root surface debridement was done using Gracey or universal curettes (Hu-Friedy, Chicago, IL, USA). All granulomatous tissue were removed from the osseous defects and rinsed with saline. Root surface conditioning was done using 2.5% tetracycline hydrochloride for 2-3 minutes followed by flushing with saline. Fortoss® Vital powder is mixed with the fluid supplied along with it in to a gritty mouldable paste and applied it in layers using a sterile instrument. The graft material was firmly pressed into the site using finger pressure over sterile gauze. The defects were over-packed to allow for any settling of the mixture. Any excessive blood was removed from the site by using damp sterile gauze. Then the gauze was held on the graft for a few seconds. The mucoperiosteal flaps were approximated and sutured using resorbable sutures (Safil®, Braun, Tuttlingen, Germany).

The patients were given post-operative instructions including rinsing with Listerine® (Johnson & Johnson, Maidenhead, UK) mouth rinse for 2 weeks. Antibiotics (Amoxicillin 250 mg with clavulanic acid 125 mg or clarithromycin 250 mg) were prescribed to the patients for 7 - 14 days. The sutures were removed after 2 weeks and the surgical sites were cleansed gently with 3% hydrogen peroxide using a cotton swab. The patients were scheduled for recall visits at 3, 6 and 12 and 24 months postoperatively. Oral hygiene was evaluated and supragingival prophylaxis was carried out at each recall visit.

Statistical analysis

Comparisons between baseline, 1 year and 2 year data were made using a paired t-test and Fisher's exact test. Mean differences in the PD, GR and CAL were calculated on individual surfaces separately as well as together. All the surfaces of an involved tooth were taken into account irrespective of the presence/absence of PD ≥ 5mm. This was done to assess the outcome

of surgery on the non-involved sites of the involved tooth as well. Data were expressed as means ± standard deviation. The level of significance was set at 0.05.

RESULTS

Clinically, the graft material used was easy to handle, strongly adherent, packed well into defects, appeared to harden as a solid in a few minutes and biocompatible. Wound healing was uneventful. No patients reported a significant postoperative pain during the first week. 8 patients did not turn up for all scheduled recall visits. All of them reported at 2 years postoperatively.
A decrease in probing depths (PD) was noticed in 24 patients out of the total 26 at one year postoperatively. At 2 years postoperatively, a decrease in PDs was found in all patients but one. The number of BOP positive sites in relation to the involved teeth was reduced from 67 (35.64 %) at baseline to 26 (13.83 %) at 1 year and 28 (14.89 %) at 2 years postoperatively. The number of sites with presence of plaque got decreased from 25 (26.60 %) to 15 (15.96 %) and then increased slightly to 18 (19.15 %) during the same interval. The difference between the percentage of plaque deposits at the baseline and 1 year and between baseline and 2 years were statistically significant as shown in table 1.

Table 1

Plaque and bleeding on probing (BOP) sites at the baseline and at 1 and 2 years postoperatively

Parameter	**Baseline**	**1 year**	**2 years**	***p***
Plaque	35. 64 %	13.83 %	14.89 %	0.0001
BOP	26.60 %	15.96 %	19.15 %	0.0001

The mean differences in measurements between the baseline and one year postoperatively are a reduction of 1.97 ± 1.15 mm ($p < 0.0001$) in case of PD, a gain of 1.68 ± 1.12 mm ($p < 0.0001$) in CAL and an increase of 0.30 ± 0.71 mm ($P = 0.009$) in GR. The mean differences in measurements between the baseline and two years postoperatively are a reduction of 2.07 ± 1.14 mm ($p < 0.0001$) in case of PD, a gain of 1.93 ± 1.36 mm ($p < 0.0001$) in CAL and an increase of 0.14 ± 0.73 mm ($p = 0.571$) in GR. These are illustrated in tables 2 - 7. No significance was found statistically between the results after 1 and 2 years postoperatively ($p > 0.05$ in case of difference in means: CAL, PD and GR) (Table 8).

Table 2

Mean difference in gingival recession (GR) measurements at baseline and 1 year postoperatively

GR (Increase= "+", decrease=" –")				
V	M	O	D	***Average***
+ 0.50 (-1 to 3) SD: ± 0.99	+ 0.18 (-3 to 3) SD: ± 1.18	+ 0.38 (-2 to 2) SD: ± 0.97	+ 0.26 (-3 to 3) SD: ± 1.51	***+ 0.30*** SD: ± 0.71

(Values in millimetres, maximum and minimum values in brackets, V- vestibular, M- mesial, O- oral, D-distal, SD- standard deviation)

Table 3

Mean difference in gingival recession (GR) measurements at baseline and 2 year postoperatively

GR (Increase= "+", decrease=" –")				
V	M	O	D	***Average***
+ 0.40 (-2 to 3) SD: ± 1.17	- 0.06 (-2 to 3) SD: ± 1.11	+ 0.27 (-2 to 3) SD: ± 0.94	- 0.04 (-3 to 2) SD: ± 1.33	***+ 0.14*** SD: ± 0.73

Table 4

Mean difference in clinical periodontal probing depth (PD) measurements at baseline and 1 year postoperatively

PD (Increase= “+”, decrease=“ –“)				
V	M	O	D	***Average***
- 0.89 (-7 to 3) SD: ± 1.91	- 3.10 (-9 to 5) SD: ± 2.75	- 1.51 (-6 to 2) SD: ± 1.99	- 2.38 (-9 to 1) SD: ± 2.26	***- 1.97*** SD: ± 1.15

Table 5

Mean difference in periodontal probing depth (PD) measurements at baseline and 2 year postoperatively

PD (Increase= “+”, decrease=“ –“)				
V	M	O	D	***Average***
- 0.96 (-6 to 1) SD: ± 1.18	- 3.49 (-8 to 2) SD: ± 2.47	- 1.74 (-6 to 2) SD: ± 2.16	- 2.11 (-9 to 1) SD: ± 2.15	***- 2.07*** SD: ± 1.14

Table 6

Mean difference in clinical attachment level (CAL) measurements at baseline and 1 year postoperatively

CAL (Gain= "+", Loss= "-")				
V	M	O	D	***Average***
+ 0.36 (-2 to 7) SD: ± 1.88	+ 2.94 (-4 to 9) SD: ± 2.89	+ 1.13 (-2 to 5) SD: ± 2.10	+ 2.10 (-3 to 8) SD: ± 2.59	***+ 1.68*** SD: ± 1.12

Table 7

Mean difference in clinical attachment level (CAL) measurements at baseline and 2 years postoperatively

CAL (Gain= "+", Loss= "-")				
V	M	O	D	***Average***
+ 0.55 (-3 to 6) SD: ± 1.95	+ 3.55 (-2 to 9) SD: ± 2.60	+ 1.48 (-3 to 6) SD: ± 2.36	+ 2.13 (-3 to 8) SD: ± 2.54	***- 1.93*** SD: ± 1.36

Table 8

Mean differences and corresponding *p* values

Parameter (change)	Mean difference between baseline and 1 year	*p*	Mean difference between baseline and 2 years	*p*
CAL (gain)	1.68 ± 1.12 mm	0.0001	1.93 ± 1.36 mm	0.0001
PD (reduction)	1.97 ± 1.15 mm	0.0001	2.07 ± 1.14 mm	0.0001
GR (increase)	0.30 ± 0.71 mm	0.009	0.14 ± 0.73 mm	0.571

There were no significant differences between smokers and non-smokers ($p = 1.000$). But in one patient where an increase in PD and CAL were noticed 2 years after the surgery, a combination of different factors like smoking, bad oral hygiene and non-compliance with the follow-up schedule during the maintenance phase after surgery were present.

Intraoral periapical radiographs showed bone fill in the defects in patients where PD got reduced after the surgical treatment.

DISCUSSION

Bone grafting is now a well-recognized choice in the treatment of periodontal osseous defects, especially when used along with barrier membranes. Various types of bone grafts and also their combinations are used with varying degrees of success. Autografts are considered to be the gold standard among bone replacement grafts as they can induce osteogenensis.[7] However, there are some limitations for the autografts like a surgical donor site is needed and availability of graft bone is limited. The alloplastic grafts or synthetic bone graft substitutes as yet offer only a part solution to the management of localized bone loss. They possess some of the desired mechanical qualities of bone as well as osteoconductive properties but are largely reliant on viable periosteum/bone for their success. They primarily serve as defect filler. In the present study, we have evaluated the effectiveness of a novel composite alloplast in the treatment of periodontal intrabony defects.

The use of a composite graft containing beta tricalcium phosphate and calcium sulphate was described in only a few reports and studies.[17, 25, 26, 27] In those reports and studies it was found that the use of this particular graft provided good results. In a clinical study published in 2009 by Stein et al, it was found that the clinical benefits of a biphasic composite graft containing betatricalcium phosphate and calcium sulphate were equivalent to that of autogenous bone spongiosa and superior to that of OFD alone. At 12 months postoperatively, the patients treated with the composite graft exhibited a mean PD reduction of 3.6 ± 0.7 mm and a mean CAL gain of 3.0 ± 0.8 mm.[25] The study done on the iliac crest of dogs by Podaropoulos et al. in 2009 revealed that the mean percentage of new bone regeneration after 4 months by histological evaluation and morphometric analysis was 49.38 %.[17] Structurally porous beta tricalcium phosphate has a compressive strength and tensile strength similar to that of cancellous bone. It undergoes resorption over a 6-18 month period. Calcium sulphate has a compressive strength greater than that of cancellous bone. It can act as a barrier membrane as well, which makes it ideal for using as an adjunct with other graft materials. It requires only 5-7 weeks for complete resorption.

Fortoss® Vital which is a combination of betatricalcium phosphate and calcium sulphate is being used in the treatment of periodontal intrabony defects in our department since the year 2003. The main reasons for the choice of this bone graft material over the conventional membrane and graft technique to achieve periodontal regeneration are non-requirement of a membrane, reduced

surgical time, lesser cost and the ease and potential to treat periodontal intrabony defects spanning more than 2 teeth.

Results from present investigation showed that the graft material used was effective in significantly improving the clinical parameters at 2 years after surgery. The overall reduction in PD and gain of attachment were found to be highly statistically significant and the mean difference in GR between the baseline and at 2 years postoperatively was negligible and not significant statistically. Ideally, a comparative study with open flap debridement and/or using a different bone graft material in treating comparable defect pairs would have been more significant to highlight the outcome of treatment using Fortoss® Vital. The amount of PD reduction was found to be greater in the deeper defects. In some cases, this reduction was up to 9 mm. PD reduction was achieved in 25 of the total 26 patients; there was an increase of PD in one patient 2 years postoperatively. The local factors and the non-compliance of the patient probably would have resulted in the undesired result. After 2 years, the number of sites with bleeding on probing was reduced to almost half. The number of proximal sites (mesial and distal) with plaque deposits also got reduced.

Several studies were done to evaluate the effectiveness of calcium sulphate and of beta tricalcium phosphate in combination with other materials resulting in good clinical outcomes. A study by Harris in 2004 evaluating a composite bone graft (demineralized freeze-dried bone allograft, calcium sulphate, tetracycline and porous hydroxyapatite) and calcium sulphate barrier showed a mean decrease of 4.7 mm of PD, 3.7 mm of CAL and a mean increase of 1.0 mm of GR at 4-6 months postoperatively.[8] In another study by Paolantonio et al. using calcium sulphate barrier implant and barrier revealed a mean decrease of 4.4 mm of PD, 2.7 mm of CAL and a mean increase of 1.6 mm of GR at 12 months postoperatively.[16] In a study published in 2008 by Döri, at 1 year after therapy, the sites treated with platelet rich plasma + β-TCP + GTR showed a reduction in mean PD from 9.1 ± 0.6 mm to 3.3 ± 0.5 mm ($p < 0.001$) and a change in mean CAL from 10.1 ± 1.3 mm to 5.7 ± 1.1 mm.[3] Most of these studies used clinical measurements along with standardized radiographs for comparison. Unlike the present study, all these studies were short-term studies and have considered only the affected area around the tooth, where the pocket depths were deeper, which may influence the results.

Measurement methods for the assessment of clinical outcome variables, such as probing depths, attachment level and gingival recession, have varied between studies, particularly with regard to

the use of automatic or pressure sensitive or conventional probes and the use of a stent as a reference point.[19] The key element is the consistency of the assessment throughout the study. In the present study, an occlusal stent was not fabricated; the cement enamel junction and the free gingival margin served as the reference point. Manual probes were used to measure the variables. The ability of a probe to penetrate into a periodontal pocket is related to several factors like the probing force, diameter of the probe and the gingival tissue tone.[11, 22] In our study, Williams color-coded probe (Hu-Friedy, Chicago, IL, USA) was used throughout in order to ensure the consistency in probe diameter. The clinical measurements were performed by 2 examiners randomly. Both the examiners recorded similar measurements during a 2 year trial period of cross-checking which ensured the similarity in probing force and method.

Unlike usual studies, we have considered the unaffected sides of the tooth as well. We have done this as the surgical wound included all the sides of the tooth. But this has affected the outcome, with a lesser than expected gain of attachment even though the reduction in deep pocket depths are much more significant. The shortcomings of the study could be a small patient group, no standardised radiographic analysis or surgical re-entry to establish the bone fill / regeneration, the non-usage of stents during clinical measurements and the non-involvement of a control group in which another surgical technique or material was used.

CONCLUSIONS

Within the limitations of this retrospective study, the following conclusions were drawn:

- The treatment with a synthetic bone graft containing a combination of beta tricalcium phosphate and calcium sulphate led to a significantly favourable clinical improvement in periodontal intrabony defects two years after the surgery.
- The graft material was easy to handle, strongly adherent, packed well into defects, appeared to harden as a solid in a few minutes and biocompatible.
- There was a statistically significant difference in terms of clinical attachment level (CAL) and periodontal probing depth (PD) between the baseline and one year postoperatively and between baseline and two years postoperatively. Even though there was a slight positive difference between one and two year results clinically, the difference was not statistically significant.
- A much longer term evaluation and further studies are necessary to completely ascertain the effectiveness of this material, and a larger sample size is also recommended. Also, standardized radiographic or a surgical re-entry is recommended for confirmation of the clinical results.

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