Research; development

Flexible (Polyactive®) versus rigid (hydroxyapatite) dental implants

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Abstract. In a beagle dog study, the peri-implant bone changes around flexible (Polyactive®) and rigid hydroxyapatite (HA) implants were investigated radiographically by quantitative digital subtraction analysis and by assessment of marginal bone height, with the aid of a computerized method. A loss of approximately 1 mm of marginal bone height was observed for both the dense Polyactive and the HA implants, after 6 months of loading. This value appeared to be stable from 12 weeks of loading onward. Along the total length of the implant during the first 6 weeks of loading, both the flexible (dense Polyactive) and the rigid (HA) implants showed a decrease in density. However, after this 6-week period, the bone density around the implants increased, and after 18 weeks the original bone density was reached. The flexible Polyactive implants provoked less decrease in density than the rigid HA implants, although not to a statistically significant level. This finding sustains the hypothesis that flexible implant materials may transfer stresses to the surrounding bone more favorably.

Key words: dental implants – flexible; hydroxyapatite.

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It has been demonstrated in various finite-element model studies that, when dental implants are loaded, the highest stress concentrations are located in the crestal, cortical part of the bone around the neck of the implant^{7, 11, 24–26, 34, 38, 41}. This phenomenon can be largely explained by the fact that most materials applied in dental implantology have a high Young's modulus (Table 1). Because of the absence of a periodontal ligament in dental implants, chewing forces are directly transmitted from the rigid implant material to the relatively flexible surrounding bone, causing relatively high cervical stress concentrations. Such peak stresses are considered detrimental and should be avoided or reduced^{7, 25, 34}.

Several attempts have been made to buffer the chewing stresses by sup-

raimplant devices^{8, 12, 17, 20, 22, 34, 36, 37, 39}. However, theoretic considerations, based on finite-element calculations, suggest that, if a stress-breaker is to be of use, it should be placed like the periodontal ligament; that is, around the implant, and not between the implant and the suprastructure²⁶. This would require flexible implant materials. The use of such materials, when compared to rigid implant materials, offers distinct biomechanical advantages. For example, in the case of vertical loading, both the compressive and tensile radial stresses at the bone-implant interface around the neck of the implant would be reduced considerably²⁶.

Recently, an elastomeric polyethylene-oxide (PEO) and polybutylene-terephthalate (PBT) segmented block

copolymer, called Polyactive®, has been introduced^{4–6, 15, 43–45}. The PEO/PBT ratios can be varied to give a range of Polyactive with different mechanical and biologic properties. Several studies have demonstrated the bone-bonding capacities of these copolymers, in both loaded and unloaded situations, and emphasized the importance of the PEO content for the occurrence of mineralization and thus bone-bonding^{4–6, 28, 32, 43–46}. The mobility of Polyactive dental permucosal implants resembles that of natural teeth, as tested by Periotest^{®27}.

It is postulated that implant bone-bonding materials with different Young's moduli generate distinguishable bone responses. This theory was tested in an animal experiment, in which flexible implants (Polyactive)

Table 1. Young's modulus of various materials

Materials	Young's modulus (MPa)
Cortical bone	13700
Trabecular bone	1370
Dentin (tooth)	12000
Periodontal ligament	0.2
Titanium	103400
Hydroxyapatite	100000
Polyactive® 55/45	100

were compared to rigid implants (HA).

Material and methods

Animal experiment

Twelve approximately 2-year-old beagle dogs, eight males and four females, whose initial weight range was 9–14 kg were used. The second, third, and fourth mandibular premolars were extracted bilaterally by the method described by VAN DER KUIJ²¹. After 3 months, an incision was made at the bone crest, and a full-thickness, mucoperiosteal flap was raised, both to the buccal and to the lingual side of the alveolar ridge. With a low-speed drill, a series of burrs, and continuous physiologic saline irrigation, two implant sites per mandibular half were prepared. The preparations, with a diameter of 4 mm and a depth of 10 mm, were at least 5 mm apart and were located at the former position of the third and fourth premolar. Subsequently, the implants were press-fit inserted into their designated positions, and, after 3 months, a re-entry operation was performed. The cover screws were removed, and the implants were loaded by standard titanium suprastructures (Fig. 1), which were cemented (Durelon®). Initially, after extraction of the teeth and after the implantation procedure, the dogs received soft food (Pal® dog food). Thereafter, they were fed standard dry dog food (Hopefarm Bostel, The Netherlands). Water was given *ad libitum*. The suprastructures were brushed twice weekly with 0.2% chlorhexidine gel (Hibitane®). Thirty weeks after the re-entry procedure, the animals were killed.

For objective testing of different implant materials, the implant configurations had to be anatomically identical. Furthermore, the implant had to be able to support a standard suprastructure (Fig. 1). To meet these requirements, standard hollow cylinders of the various implant materials were placed between two titanium caps connected by a central titanium bar, thus forming the core of the implant³¹ (Fig. 2).

In this experiment, four types of hollow cylinders (A–D, height: 7 mm, diameter: 4 mm) were used. The implant types were allocated schematically according to the method of multiple Latin squares to ensure randomization of animal number, location, and

implant type. The first implant cylinder (type A) was made of smooth, injection-molded, dense Polyactive with a 55/45 PEO/PBT ratio. The second cylinder (type B) was made of dense, smooth hydroxyapatite with a thickness of 1.25 mm (Mega® implant). The third and fourth cylinders (types C and D) comprised a dense central layer coated with a porous outer layer, both made of Polyactive®. The concept of promoting mechanical locking through bone ingrowth into the pores of the Polyactive failed due to manufacturing problems^{27, 28}. Therefore, radiographic and statistical analyses were performed solely on the dense Polyactive and the HA implants (types A and B).

Radiographic procedure and analyses

From the moment of suprastructure placement, clinical assessments were performed every 6 weeks. At each of the control sessions, a radiograph was made of each side of the mandible of the dog, thus producing a total of 144 radiographs (12 dogs×2 sides×6 sessions). For standardization of image geometry, positioning devices were prepared.

For estimation of bony changes in volume of mass, a reference wedge^{35, 47, 48} was imaged during each radiographic procedure. If this aluminum wedge is exposed simultaneously with the object, a comparison can be made on the radiograph between the density as produced by the wedge and the regions of interest of the object⁴². The film (Kodak Ultra-Speed, DF 57) was exposed at 65 kV, 10 mA, 0.24 s by a Trophy Dental X-apparatus. At the end of the experiment, all films were developed in a standardized way¹⁸.

The radiographs were digitized with a video camera and an analog/digital converter into a 512×512 pixel image. By digitizing the wedge and the implant separately, a higher resolution with the camera could be obtained. The densities in a specific area, defined on the digitized image, were translated into the thickness of the wedge and integrated pixel per pixel over the area into an aluminum equivalent volume (AEV), by the method described by Vos et al.⁴⁷.

A total frame was constructed adjacent to the implant surface, equal in length to the bioactive implant material (7 mm) and 0.75 mm wide. The computer divided this frame

Fig 1. Standard suprastructures inserted on implants.

Fig 2. From left to right: titanium caps connected by central bar, implant material types A, C, and D, and, fixed between two caps, type B.

Fig 3. Schematic radiograph of implant in mandibular bone, showing four regions of interest (ROI I-IV) and bone level measured from top of bioactive material to bottom of bony pocket.

into four equal regions of interest (ROI I-IV) (Fig. 3 and 4). For each ROI, the differences in time in AEV values were calculated. A decrease in AEV values in time (less density) represented resorption, and an increase in AEV values (more density) represented apposition. Regions on the radiograph without density changes produced an AEV value difference of zero.

In addition to the assessment of changes in bone density, the height of the marginal bone level was determined with the aid of a simple computerized method at both proximal sides. The distance between the top of the bioactive material and the bottom of the bony pocket was measured (Fig. 3). The obtained value was corrected for distortion due to magnification, by multiplication by the magnification factor (measured length of the bioactive material divided by the actual length).

Statistics

By repeated measures of analysis of variance, potential differences in implant type ("Type") were determined, with the implant site (mesial, distal, "Site") and the observation period

(in weeks, "Time") as within-subject factors. Differences between "Type" were tested by paired *t*-tests.

Results

Animal experiment

One dense Polyactive implant was lost because it did not achieve osseointegration as a consequence of dehiscence of the wound during the healing phase. One HA implant was discarded from the experiment because of severe peri-implantitis during the whole of the experiment and final implant loss in the last week of the experiment. Therefore, analyses were performed on 11 dense Polyactive and 11 HA implants.

Marginal bone heights

In Fig. 5, the changes in proximal bone levels in time are described. In the first 3 months of loading, a decrease in marginal bone height of approximately 1 mm for both the Polyactive and the HA implants was observed. Thereafter, the bone level appeared stable.

Quantitative digital subtraction analysis

The differences in AEV values between the first control (start of loading of the implants) and the subsequent controls for both implant types and for each ROI are presented in Figs. 6 and 7. A positive value represents apposition of bone, whereas a negative value indicates resorption of bone. Immediately after loading, a decrease of bone density took place along the whole length of both implant types. This effect was seen for both the flexible Polyactive and for the rigid

Differences in Bone Levels Röntgen Analysis

→ Poly Mes → HA Mes * Poly Dist → HA Dist

Fig 5. Differences in bone levels for Polyactive and hydroxyapatite (HA) implants, measured at mesial and distal sides.

Digital subtraction Dense Polyactive

→ ROI I → ROI II * ROI III → ROI IV

Fig 6. Differences in bone density at each region of interest (ROI) for Polyactive implants.

Fig 4. Radiograph of two Polyactive implants. Along implants, four regions of interest (ROI) are presented.

HA implants. After 6 weeks of loading, the AEV values in all ROIs had increased, and had more or less returned to their original bone density values and remained at the original density.

Statistics

Table 2 shows the results of the Manova procedure. There was a statistically significant difference in time for the marginal bone heights ("time", $P=0.00$) and the AEV values ("time", $P=0.03$).

Table 2. F values and P values of repeated measures analysis of variance for assessment of marginal bone height and digital subtraction method

Variables	Marginal bone height		Digital subtraction	
	F value	P value	F value	P value
Type	0.14	0.72	0.56	0.47
Site	2.08	0.19	0.04	0.85
Time	9.33	0.00*	3.12	0.03*
ROI			0.26	0.85
Type by site	0.02	0.88	0.86	0.38
Type by time	0.29	0.8	0.45	0.77
Type by ROI			2.12	0.12
Site by time	1.46	0.24	1.27	0.30
Site by ROI			0.05	0.98
Time by ROI			0.43	0.95
Type by site by time	0.20	0.94	1.45	0.24
Type by site by ROI			2.20	0.11
Type by time by ROI			3.55	0.00*
Site by time by ROI			1.39	0.18
Type by site by time by ROI			0.94	0.51

* $P < 0.05$.

No statistically significant differences between implant types could be observed, in marginal bone height and bone density, at any of the different observation times. For the AEV values, "type by time by ROI" was statistically significant ($P < 0.001$), indicating that differences between both implants in time were ROI dependent.

Discussion

In this study, the clinical performance of two bioactive implant materials, Polyactive and HA, was compared by monitoring the bone response adjacent

to the implant radiographically. Since both Polyactive and HA possess bone-bonding capacities but different mechanical properties, a different bone response was anticipated. Two radiographic techniques were used to monitor this bone response; namely, measurement of marginal bone levels and quantitative digital subtraction.

Measurement of the marginal alveolar bone levels on standardized and serial radiographs, and of their change over time, is considered to be an important parameter for the evaluation of implant success in long-term studies^{3, 40}. For assessment of marginal bone levels, the accuracy of a computerized method^{19, 29, 49} is higher than that of conventional methods such as the use of a magnification glass or sliding gauge²⁵.

In successful implants, mean crestal bone levels decrease 0.9–1.6 mm during the first year, followed by annual rates of bone loss less than 0.2 mm in the follow-up period^{1, 2, 13, 23, 49}. In the present study, approximately 1 mm of marginal bone height was lost, for both the dense Polyactive and the HA implants after 6 months of loading. This was within the limits of the above-mentioned critical values for success. The bone loss was already observed during the first 12 weeks of loading, suggesting that factors other than the Young's modulus of the implant materials were responsible for this finding, such as the surgical procedure to insert the implant abutment⁹ or the presence of plaque between abutment and implant¹⁴. No statistically significant differences in loss of marginal bone height between the Poly-

active and the HA implants could be observed.

Conventional analysis of serial radiographs can depict marginal bone levels to a fair degree of reliability. However, small amounts of loss or gain in bone density cannot be detected. Quantitative digital subtraction radiography was introduced in dentistry in the last decade to overcome this shortcoming^{10, 18, 35, 47}.

A statistically significant decrease in bone density along both the rigid and flexible (HA and Polyactive) implants during the first 6 weeks of loading could be observed, as compared to the initial bone density. Remarkably, this decrease took place along the whole length of the implant (ROIs I–IV), for both the Polyactive and HA implants. The reduced radiographic density of the bone along the implants during the first weeks after abutment placement can be explained by an increased remodeling phase induced by loading. A similar finding, based on histologic observations, was described by HOSHAU et al.¹⁶. They observed a decreased percentage of mineralized tissue along loaded implants, 12 weeks after application of a loading protocol.

After a 6-week period, the bone density around the implants in our study was restored, and an increase of the radiographic density was observed. The re-establishment of the original density of the bone surrounding both the flexible and rigid implants could take place, because the amount of stress in relation to the quality of bone at the bone-implant interface remained within physiologic levels.

In view of the finding that in dogs, during the first 18 weeks of loading, the density of the bone surrounding dental implants is reduced, it can be stated that the implants are especially vulnerable to chewing forces during this period. Extrapolation of these data to man would indicate a period of 27 weeks³³.

Although not to a statistically significant level, the flexible Polyactive implants provoked less decrease in density than the rigid HA implants. This might be explained by the fact that flexible implant materials are indeed more capable of transferring stresses to the surrounding bone. It is postulated that differences in Young's moduli between implant materials may be critical for long-term bone preservation around, and success of, loaded dental implants, es-

Fig 7. Differences in bone density at each region of interest (ROI) for hydroxyapatite implants.

pecially in regions of poor bone quality, such as the anterior and the posterior maxilla, where conventional dental implants show lower success rates³⁰.

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