

Evaluation of the Successfulness of Applying Polyglycol Copolymer Bone Replacements in the Treatment of Bone Defects of Odontogenetic Aetiology

Davor Katanec¹
Irina Filipović-Zore¹
Mato Sušić¹
Zoran Ivasović
Marija Ivić- Kardum²
Greta Škaljac-Staudt³

¹Department of Oral Surgery
School of Dental Medicine
University of Zagreb
²Department of Periodontology
School of Dental Medicine
University of Zagreb
³Department of Dental
Pathology
School of Dental Medicine
University of Zagreb

Summary

The problem of healing bone defects of odontogenetic aetiology is the most frequent cause of failure in surgical treatment of an ostitic process. The aim of this study was to valorise the successfulness of healing of bone defects after implantation of a new alloplastic copolymer - polyglycol bone implant (Fisiograft).

A group of 45 subjects was examined with an ostitic process on teeth of the intracanine region. The results were valorised on the basis of densitometric measurement over a period of 12 months after implantation. The results obtained indicate that polyglycol copolymer bone implants can be successfully used in the treatment of bone defects of odontogenetic aetiology. Their fundamental advantage is slower biodegradation, which ensures a more suitable area for the apposition of new bone in the lumen of the bone defect, simple application in clinical work and the possibility of a mutual combination of all three available forms.

Key words: *bone implants, Fisiograft*

Acta Stomat Croat
2001; 65-68

ORIGINAL SCIENTIFIC
PAPER
Received: January 18, 2001

Address for correspondence:

Davor Katanec, D.D.S. Ph.D
Department of Oral Surgery
School of Dental Medicine
Gundulićeva 5, 10000 Zagreb
Croatia

Introduction

The problem of healing bone defects of odontogenetic aetiology is most frequently the reason for failure of surgical treatment of an ostitic process. The therapy for smaller bone defects is primarily conservative (treatment of the causative tooth root, according to the principles of modern endodon-

tology). Larger bone defects (>of 1 cm) and defects which do not respond to conservative therapy, require surgical treatment (1). Apicotomy is the method most often used for this purpose. Resection of the tooth apex and removal of the pathologically changed tissue from the bone defect enables healing by connective organisation of a blood clot and the formation of bone. Incomplete or unsatisfactory

healing or recurrence frequently occurs after surgical treatment. The need for reconstruction of such bone defects prompted the development of different kinds of bone replacements, which can be autologous, allogeneic, xenogeneic and alloplastic. The principal task of all these materials is osteoinduction and mechanical prevention of ingrowing connective tissue in the lumen of the bone defect (2,3).

Because they are simple to apply alloplastic bone implants have become widely used in the treatment of such bone defects. Currently the most frequently used alloplastic implants are resorptive tricalcium phosphate (TCA) and nonresorptive hydroxylapatite (HA). Each of these materials has advantages and disadvantages. Resorptive materials usually have high osteoinductive ability, although the period of their biodegradation is much faster than the possibility of bone apposition in the lumen of the defect (4). On the other hand nonresorptive bone replacements have very low osteoinductive ability, although they remain permanently in the lumen of the defect and create the basis for the formation of new bone (5,6). The problem is that ingrowing connective tissue frequently occurs around the nonresorptive HA granules, instead of the formation of new bone. Thus the majority of studies in this field are connected with the discovery of a material which will have better osteoinductive potential and a slower period of resorption (7,8). Last year a new generation of resorptive alloplastic bone replacements appeared, based on synthetic copolymer 1-d poly-lactic and polyglycolic acid. The material used in the present study belongs to this group of materials, and its trade name on the market is Fisiograft (manufacturer Ghimas s.p.a., importer SD Informatika). It is of low molecular weight, which enables biodegradation over a period of 3-8 months, depending on the amount of material needed and reactivity of the organism. The process of absorption and biodegradation evolves via Krebs cycle, which represents a chain of biochemical reactions, resulting in the formation of water and carbon dioxide as the final product of the metabolism of poly-lactic acid, while polyglycolic acid is biodegraded enzymatically into ethylene glycol (9).

Fisiograft is manufactured in three different forms: powder, gel and sponge blocks (1x1cm), and the basic components of all three forms are lactic and glycolic acids, polyethyleneglycol (PEG) and

dextran. It is sterilised by gamma radiation. Depending on the size and shape of the bone defect, all three forms can be mutually combined during application in the bone defect (15).

Aim of the investigation

The aim of the study was to valorise the successful healing of bone defects of odontogenic aetiology after the implantation of copolymer - polyglycolic alloplastic bone replacements. To determine the advantages and disadvantages in clinical application, based on the results obtained by densitometric measurement, and to compare the results with those obtained in similar studies carried out with alloplastic bone replacements on the basis of hydroxylapatite, which is routinely used for this purpose in the Department of Oral Surgery.

Material and method of work

Forty-five subjects were examined with periradicular osteitic processes on teeth of the intracanine region of the maxilla, for which absolute indication for apicotomy existed. The subjects were classified by random selection into three groups of 15 subjects each. The causative teeth of the osteitic process were pre-operatively endodontically treated according to the principles of modern endodontology. After which resection of the root apex of the causative teeth was performed, all pathologically changed tissue removed and the alloplastic bone implant inserted (Fig. 1).

We used a trapezoidal cut during operations, which enables optimal sight of the working area and healing of the wound per primam, with complete coverage of the alveolar bone. After surgical treatment Fisiograft was implanted into the bone defect in the form of powder in 15 subjects. In the second group of 15 subjects Fisiograft was implanted in the form of gel, and in the third group of 15 subjects a combination of gel and powder was used, in the proportion 50 : 50 (Fig. 2). As prevention all subjects received an antibiotic per os (Klimicin ad 3x150 mg) for ten days, i.e. two days pre-operatively and eight days post-operatively, which is standard procedure for implantation of alloplastic bone implants of this type (9).

The subjects were followed-up for a period of one year, i.e. a pre-operative X-ray was performed, and one, six and 12 months after the operation. The X-rays were performed radiovisuographically, on a high-frequency X-ray apparatus "Elitys" (manufacturer Trophy, importer SD informatika), exposure time up to 0.014 s, so that the dose of radiation was reduced by 90% compared to classical X-ray apparatus. After which digitalisation was performed. Digitalisation of the X-ray films was performed with a RVG HDS kit for radiovisuography, which has a CCD sensor with optic fibres of penultimate generation (Fig. 3). The film was always digitalised with the same spatial resolution of 14 pairs of lines per millimetre. In this way a dynamic range of 256 levels of grey shades was achieved. This resolution is quite adequate for accurate interpretation of the levels of greyness and appropriate densities at any point on the film (Fig. 4).

A computerised densitometric programme is incorporated in the Trophy system of radiovisuography, which enables determination of the density at individual points, in the plane and defined areas of the X-ray, and a sequence of morphometric and densitometric measurements of objects on the film. We measured density at ten points along the edges of the bone defect (Fig. 5). This area was chosen for measuring because density measured in the middle of the bone defect after implantation of Fisiograph, because of its translucency, would show unrealistic increased density of the measured area.

Results

In 35 subjects *ostitis periapicalis chronica granulomatosa* on one of three teeth of the intracanine region was diagnosed by a clinical and X-ray examination. In the remaining 10 subjects *radicular cyst* was diagnosed on one or two teeth from the intracanine region (Table 1).

The results of densitometric measurement during the follow-up period of one year are shown graphically for each individual subject (Table 2).

After one year the results obtained were analysed and presented graphically. Thirty-eight successfully treated cases were determined by densitometric measurement, i.e. 84% of the total number of

subjects. A decrease in density or unsuccessful healing of the bone defect was determined by densitometric measurement in 7 subjects, i.e. 16% of the total number of analysed cases (Table 3). Diagnosis, sex and age did not have an effect on the final results.

Discussion and conclusion

At the beginning of clinical application of alloplastic bone implants, it was considered that they have exceptionally high osteoinductive and osteogenetic ability (10). This was substantiated by the results of basal investigations which almost all emphasised the high osteoinductive ability of these materials (11,12). More recent clinical studies on a large human sample carried out by Denissen and Walker, demonstrated that these materials, when implanted into a bone defect, behave similarly to devitalised autologous or homologous bone transplants, with the difference being that during the process of new bone formation they do not have a phase of osteoclastic resorption of dead bone but that integration into new bone tissue occurs immediately (13,14). This hypothesis was accelerated by Klein's study, in which it was reported that all synthetic hydroxylapatites are bioinert and that in 55% of cases in clinical application fibrous incapsulation occurs around the HA granules instead of the formation of new bone (15,16).

We obtained similar results in our studies with these materials, particularly with the introduction of sophisticated and objective methods for following such cases, such as CADIA, which unexpectedly showed a significantly higher percentage of unsatisfactory healing of bone defects after implantation of HA (1,17).

Because of the need for expensive hardware and software support, computerised densitometric analysis was only applied in some highly specialised institutions. With the development of informatics in dental medicine, primarily digital technology of RVG HDS kits for radiovisuography, and their wide application in dental practice, the possibilities for computerised densitometry have greatly increased, and it has become an integral part of the RVG package software. Such programmes for densitometric measurement of objects shown on digitalised

X-ray films enable objective and accurate measurement of density, on the basis of which an objective evaluation of post-operative healing of a bone defect can be made.

We used this method in our study to enable objective evaluation of the effectiveness of Fisiograft, as a new alloplastic material for the treatment of bone defects of odontogenetic aetiology.

The results obtained, compared with the results of similar studies carried out with resorptive ceramic hydroxylapatite, indicate the advantages of Fisiograft, for which the decrease in density on the last follow-up X-ray examination, in which complete resorption of the material and replacement of new tissue had occurred, was significantly less than in the case of ceramic HA (18,19). Another advantage

of this material is the possibility of combining its different forms, such as mixing gel and powder, which provides a very adaptable consistency for application in a bone defect (9). No recurrences occurred in the group of subjects in whom we applied a combination of gel and powder, while in the subjects in whom we applied a pure form of Fisiograft (only powder or gel) seven recurrences occurred.

On the basis of the clinical results obtained it can be concluded that polyglycol copolymer bone replacements can be successfully used in the treatment of bone defects of odontogenetic aetiology. The most suitable form of material for application in bone defects is a combination of gel and powder, in a proportion 50% : 50%.