Efficiency of Polylactide/Polyglycolide Copolymers Bone Replacements in Bone Defects Healing Measured by Densitometry

Davor Katanec¹, Božidar Pavelić² and Zoran Ivasović¹

¹ Department of Oral Surgery, School of Dental Medicine, University of Zagreb, Zagreb, Croatia
² Department of Dental Pathology, School of Dental Medicine, University of Zagreb, Zagreb, Croatia

ABSTRACT

Healing of bone defects is the most frequent cause of failure in surgical treatments of an odontogenic ostitic processes. The aim of this study was to determine successfulness in healing of bone defects after implantation of alloplastic co-polymer-polyglycol bone implant. A group of 45 cases with periradicular ostitic processes were examined. The densitometric measurements were taken from radiovisiographic dental x-ray images. Patients were observed throughout a period of one year. The results obtained were analyzed and presented graphically. Thirty-eight patients (84%) were treated successfully, and seven patients (16%) showed unsuccessful healing of the bone defects. The results obtained indicate that polyglycol copolymer bone implants can be successfully used in a treatment of odontogenically caused bone defects. Their fundamental advantage is a slow biodegradation, which ensures a more suitable area for the apposition of a new bone in the defect, simple application in clinical work and the possibility of a mutual combination of all three available forms.

Key words: bone defect, Fisiograft, densitometry

Introduction

Healing of odontogenically caused bone defects is the most frequent reason for failure in surgical treatment of an ostitic process. The therapy for smaller bone defects is primarily conservative (root treatment, according to the principles of contemporary endodontic). Larger bone defects (0 > 1 cm) and defects which do
not respond to conservative therapy, require surgical treatment\textsuperscript{1}. Apicoectomy is the method most often used for this purpose. Resection of one third of root apex and removal of the pathologically changed tissue from the bone defect enables healing by connective organization of a blood clot and the formation of bone. Incomplete or unsatisfactory healing frequently occurs after surgical treatment of larger bone defects. The need for reconstruction of such bone defects prompted the development of different kinds of bone replacements, which can be autologous, allogenic, xenogenic and alloplastic. The principal task of all these materials is osteoinduction or osteoconduction and mechanical prevention of ingrowing connective tissue in the lumen of bone defect rather than new bone formation\textsuperscript{2–4}.

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\textsuperscript{5}. On the other hand nonresorptive bone replacements have low osteoinduction ability, although they remain permanently in the lumen of the defect and create the basis for the formation of new bone\textsuperscript{6–8}. The problem is that the ingrowing connective tissue frequently occurs around the nonresorptive HA granules, instead of new bone formation. 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\textsuperscript{9,10}. Last year a new generation of resorptive alloplastic bone replacements appeared, based on synthetic copolymer 1-d polylactic and polyglycolic acid. The material used in this 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 has a 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 polylactic acid, while polyglycolic acid is biodegraded enzymatically into ethylene glycol\textsuperscript{11}.

Fisiograft is a mixture of polyethylene glycol 400 and poly(D,L-lactic-co-glycolic) acid in ratio of 75:25 with polymer degradation period of 6 months. It is manufactured in three different forms: powder, gel and sponge blocks (1×1 cm). It is sterilized 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.

The aim of this study was to valorize the successfulness in healing of bone defects that occurred as a result of periapical lesion, after the apicoectomy and implantation of copolymer-polyglycolic alloplastic bone replacements. Based on results achieved by densitometric measurements we shall determine its advantages and disadvantages in clinical application.

**Material and Methods**

Forty-five cases with periradicular osseous processes on the frontal teeth in the maxilla, with the size of 1.5 × 1.5 cm approximately, were examined. The cases were classified by random selection into three groups of 15 cases each. The causative teeth of the ostitic process were pre-
operatively endodontically treated on the same day.

Resection of the root apex of the causative teeth was then performed, and all of the pathologically changed tissue removed. The alloplastic bone implant was inserted (Figure 1).

We used a trapezoidal cut during the surgical procedure, which enables an optimal sight of the working field 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 first group – 15 cases, it was applied in the form of powder. In the second group of 15 cases Fisiograft was implanted in the form of a gel, and in the third group of 15 cases a combination of gel and powder was used, in the proportion 50:50. As a prophylaxis, patients received an antibiotic per os (Klimicin ad 3×150 mg) for ten days, i.e. two days preoperatively and eight days post-operatively, which is a standard procedure.
of penultimate generation. The film was always digitalized with the same spatial resolution of 14 pairs of lines per millimeter. 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 grayness and appropriate densities at any point on the film.

A computerized densitometry program is incorporated in the Trophy system of radiovisiography, which enables the determination of the density at certain points, within the plane and defined fields of the radiogram. We measured density at ten points along the edges of the bone defect (Figure 2). This area was chosen for measuring, since density measured in the middle of the bone defect after implantation of Fisiograph due to its translucency, would show increased density12.

Results

In 35 cases ostitis periapicalis chronica granulomatosis was diagnosed by means of clinical and X-ray examination on one of teeth within the intracanine region. In the remaining 10 cases, a radicular cyst was diagnosed on one or on two teeth within intra-canine region (Table 1).

The results of densitometric measurements during the period of one year are shown graphically for each case (Figure 3).

Table 1: Presentation of the Total Number of Examined Subjects

<table>
<thead>
<tr>
<th>Type of lesion</th>
<th>Female</th>
<th>Male</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>OPC</td>
<td>21</td>
<td>14</td>
<td>35</td>
<td>78</td>
</tr>
<tr>
<td>CR</td>
<td>7</td>
<td>3</td>
<td>10</td>
<td>22</td>
</tr>
<tr>
<td>Total</td>
<td>28</td>
<td>17</td>
<td>45</td>
<td>100</td>
</tr>
</tbody>
</table>

OPC – Ostitis periapicalis chronica, CR – Cysta radicularis

Thirty-eight (84%) successfully treated cases were determined by densitometric measurements. A decrease in density i.e. unsuccessful healing of the bone defect was determined in seven (16%) cases (Table 2).

Discussion

At the beginning of clinical application of alloplastic bone implants, it was considered that they have an exceptionally high osteoinductive and osteogenetic ability13. This was substantiated by the results of basic investigations in vitro, which emphasized the high osteoinductive ability of these materials14,15. More recent clinical studies, demonstrated that these materials, when implanted into a bone defect, behave similarly to devitalize autologous or homologous bone transplants. The only difference being that during the
process of new bone formation they do not have an osteoclastic resorptive phase. 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 a fibrous encapsulation occurs around the HA granules instead of new bone formation. 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 significant high percentage of unsatisfactory healing of bone defects after implantation of HA.

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 odontogenically caused bone defects. The obtained results, compared with the results of similar studies carried out with resorptive ceramic hydroxylapatite, highlight the advantages of Fisiograft. Although this material showed a decrease in density, in which complete resorption of the material and replacement of new tissue had occurred, yet it was significantly less than in the cases where ceramic HA were implanted. 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.

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

<table>
<thead>
<tr>
<th>Successful</th>
<th>Unsuccessful</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>%</td>
<td>N</td>
</tr>
<tr>
<td>Female</td>
<td>24</td>
<td>85</td>
</tr>
<tr>
<td>Male</td>
<td>14</td>
<td>83</td>
</tr>
<tr>
<td>Total</td>
<td>38</td>
<td>84</td>
</tr>
</tbody>
</table>

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 odontogenically caused bone defects. The obtained results, compared with the results of similar studies carried out with resorptive ceramic hydroxylapatite, highlight the advantages of Fisiograft. Although this material showed a decrease in density, in which complete resorption of the material and replacement of new tissue had occurred, yet it was significantly less than in the cases where ceramic HA were implanted. 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.

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

REFERENCES


D. Katanec

Department of Oral Surgery, School of Dental Medicine, University of Zagreb, Gundulićeva 5, 10000 Zagreb, Croatia

EFIKASNOST POLIGLIKOLNOG KOPOLIMERNOG KOŠTANOG NADO MJESTA U CIJELJENJU KOŠTANIH DEFEKATA MJERENA DEN ZITOMETRIJOM

SAŽETAK

Cijeljenje koštanih defekata je najčešći uzrok neuspjeha kirurškog tretmana odontogenih koštanih procesa. Srhva ove studije je procjena uspješnosti cijeljenja koštanog defekta poslije implantacije aloplastičnog kopolimernog koštanog implantata. Grupi od 45 ispitanika s ostitijkim periradikularnim procesom, nakon operativnog zahvata, ugrađen je kopolimeri koštani nadomjestak (Fisiograft, Ghimas s.p.a.). Ispitanici su praćeni na osnovu kliničkog i rtg nalaza u periodu od dvanaest mjeseci. Rezultati su valorizirani na osnovi denzitometrijskog mjerenja na digitaliziranim rtg slikama učinjenim pomoću radioviziografije. Dobiveni rezultati su analizirani i prezentirani grafički. Trideset osam pacijenata (84%) uspješno je liječeno, a kod sedam pacijenata (16%) došlo je do neuspješnog cijeljenja koštanog defekta. Dobiveni rezultati pokazuju da se poliglikolni kopolimerni koštani implantati mogu uspješno koristiti u tretiranju odontogenih koštanih defekata. Njihova osnovna prednost je spora biorazgradnja, koja osigurava povoljan prostor za apoziciju nove kosti unutar defekta, jednostavna primjena u kliničkom radu i mogućnost međusobnog kombiniranja sva tri proizvodna oblika.