Prospective assessment of post-extraction gingival closure with bone substitute and calcium sulphate

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Abstract
Introduction: The closure of post extraction gingival defects has not been studied in depth, although their achievement is of great importance in certain situations, such as prior to radiotherapy treatment in patients with oral cancer. The aim of this study is to assess the influence of bone substitutes on the time of closure of post extraction gingival defects.

Materials and Methods: 22 patients underwent two symmetrical dental extractions. Using a split mouth model, with random assignment to one or other group, one was considered a control group (no filling with any type of material post extraction), whereas the other was considered the experimental group (filling with bone substitute and calcium sulphate post extraction). Gingival closure and healing were assessed in the first group at 2, 3, 4 and 6 weeks after extraction.

Results: No differences were seen between both groups in gingival health. Gingival closure was greater and faster in the experimental group than in the control group, and was statistically significant in the first and second week after extraction (1st week, control: 19.63mm² ± 2.52 - experimental: 11.76mm² ± 2.40 - p < 0.05) (2nd week, control: 15.09mm² ± 2.77 - experimental: 7.98mm² ± 1.99 - p < 0.05), although these differences evened out during subsequent periods. No medical accidents were seen and tolerance to treatment was good in both groups.

Discussion: According to our data, the use of filling material allows a faster initial gingival closure of the socket post extraction. However, we must assess the cost of intervention, with the aim of applying it in situations in which it may be of significant advantage (for example, patients that will undergo radiotherapy treatment), or in cases in which the use of these materials is justified due to other reasons in addition to the one mentioned (such as maintenance of bone crest architecture for implant restoration).

Key words: Tooth extraction, Gingival closure, bone substitutes, Split-mouth study model, clinical study.
Introduction
Post extraction socket treatment has been recognized as beneficial for the preservation of the alveolar crest (1,2). Many biocompatible materials have been used to try and correct the deformities of bone tissue caused by dental extraction, with the primary aim of creating an ideal situation for the placement of dental implants. Amongst these materials are autologous bone of intra- and extra-oral origin, demineralised allogeneic bone, and several alloplastic materials, xenotransplants, bone substitutes and barrier membranes, with, in general, good clinical results (3-7).

According to data from other authors, the non-use of graft material causes an average loss of bone matter of 4.4mm horizontally and of 1.2mm vertically after routine non-trauma dental extraction (8,9), although its use also has some drawbacks (it increases morbidity, cost and length of treatment) (1).

After dental extraction, several weeks of healing are necessary for the generation of granulation tissue and for gingival closure to take place, although there are few studies on gingival tissue behaviour in conjunction with the use of graft material post extraction. Furthermore, the incomplete adaptation of support structures after extraction may give rise to tissue invagination during healing.

The speed of gingival closure and therefore the time during which the underlying bone tissue is exposed may be a critical factor in the development of bone complications in specially vulnerable patients (osteoradionecrosis and chemonecrosis) (10,11).

The aim of this study is to assess the way in which gingival tissue closes the socket over graft material post extraction: Calcigen Oral® (Biomet 3I, Barcelona, Spain) (calcium phosphate), in combination with Biogran® (Biomet 3I, Barcelona, Spain) (synthetic bone substitute); in comparison with the non-use of any filling material.

Patients and Methods
This is a prospective clinical study that uses a split-mouth design, with randomization of experimental and control places.

This study was performed in the Faculty of Dentistry of the University of Seville on 22 patients, with a mean age of 26 years (range 16 to 64 years), that underwent surgery between September 2005 and March 2007. All the patients required the extraction of two teeth, from the maxilla or mandible, symmetrically located in relation to each other. The patients had to be in good medical condition and able to undergo surgery.

The aim of the study was to assess gingival closure post extraction after the use of bone filling material (experimental group) versus no use of any type of material (control group).

Exclusion criteria were: smoking, pregnancy, non-controlled diabetes mellitus, radiotherapy during the past 12 months, presentation with acute symptoms or any type of associated bone pathological condition.

The choice of the first place of extraction (the first place of extraction was that of the tooth with the smallest number) in one group or another was determined by tossing a coin, and the other place of extraction was assigned to the group not chosen for the first choice.

The independent variable was placement of bone filling material in the post extraction socket. Two groups were formed: control group, after extraction curettage of the socket was carried out and no filling was used with any material; and experimental group, after extraction curettage of the socket was carried out and the apical region was filled (up to 2mm below the level of the bone crest) with a mix of Calcigen Oral® (Biomet 3I, Barcelona, Spain) with Biogran® (Biomet 3I, Barcelona, Spain) (1:1). In its upper portion, and up to the gingival margin, the defect was filled with Calcigen Oral®. The whole process of mix and placement of the filling material was carried out in 3 minutes and the correct filling of the socket was confirmed by postoperative periapical X-rays.

The surgical procedure was carried out in the following manner. Both extractions were performed in the same surgical procedure. Regional anaesthesia was performed by means of trunk or periaxial infiltration techniques (intra-ligament anaesthesia was not used), with 2% Lidocaine with. Epinephrine Normon® (Laboratorios Normon, Madrid, Spain). An intrasulcus incision around the tooth to be extracted was used, so as to directly access the adjacent bone. Once extraction was performed with the appropriate elevators and forceps and after mixing and placing the filling material in the socket in the experimental group, the flap was sutured in its initial position using a mattress suture with 4/0 diameter silk. A postoperative periapical X-ray was used to check appropriate extraction and socket filling. The same incision and suture were used in the control group, but no material was placed in the socket.

After intervention patients were told to hold gauze down over the wound compressing it for 30 minutes, and not to rinse their mouths or spit for 24 hours. Pharmacological treatment indicated was Dexibuprofen 400mg (Atriscal®, Laboratorios Lácer, Barcelona, Spain) and Amoxicillin 875mg/Clavulanic Acid 125mg (Augmentine®, Laboratorios GSK, Madrid, Spain), one tablet of each every 8 hours during 5 days.

Before extraction, data were collected relative to patient’s sex and age, teeth to extract and reason for extraction. The principal variable assessed was the closure of the gingival socket post extraction.

Immediately after extraction the defects created were measured (control and experimental groups) using a periodontal probe calibrated in millimetres, measuring...
the mesio-distal side of the defect and its vestibulo-lingual (-palatine) depth on the mesial side of the defect, on the distal side of the defect and at the mid-point of the defect. Using these measurements, the volume of the gingival defect was calculated. These measurements were also performed during the follow-up visits, at first, second, third, fourth and sixth week after extraction. During these exams gingival gum health surrounding the sites of extraction in both the experimental and control group was visually determined, and the following score was used: 1) slight gingival inflammation (change of colour), 2) severe gingival inflammation (with marked reddening and gingival swelling), 3) severe gingival inflammation (with spontaneous bleeding, suppuration or ulceration). Tolerance to treatment was assessed by means of a 10cm visual analogue scale.

All the patients included in the study, or their legal representatives, gave their informed consent. The study was approved by the Ethics Committee of the University of Seville, keeping in mind the principles of the Declaration of Helsinki.

The statistical analysis of the collected data was performed with the SPSS v. 12 programme for MS-Windows, using the Student-t test to compare averages and the chi-square test to compare percentages. Normal data distribution was confirmed using the Kolmogorov-Smirnov test.

**Results**

Of the 22 patients studied, all completed the protocol, except for two who did not come in for the last medical exam.

The mean age of the patients was 26 years (range 16 to 64 years). Eleven were men (mean age, 28 years, range 16 to 64 years) and 11 were women (mean age, 24 years, range 16 to 52 years). Of the 44 teeth extracted, 8 were extracted due to cavities (18.2%), 32 for orthodontic reasons (72.7%) and 4 for periodontal reasons (9.1%). Of the teeth extracted 18 were molars (40.9%) and 26 premolars (59.1%), as well as 22 teeth from the maxilla (50%) and 22 from the mandible (50%).

The average size of defects immediately after extraction was 48.55mm² ± 3.53 in the control group and 48.98mm² ± 2.52 in the experimental group. The closure of the defects during the follow-up visits is seen in (Table 1).

Closure was greater in the experimental group than in the control group during the first and second week post extraction (p < 0.05).

Table 1. Size of the post extraction gingival defect during different exams.

<table>
<thead>
<tr>
<th></th>
<th>Control Group</th>
<th>Experimental Group</th>
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<tbody>
<tr>
<td>Immediately</td>
<td></td>
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<tr>
<td>after extraction</td>
<td>48.55 mm²</td>
<td>48.98 mm²</td>
</tr>
<tr>
<td>± 3.53</td>
<td>±2.52</td>
<td></td>
</tr>
<tr>
<td>1st week</td>
<td>19.63 mm²</td>
<td>11.76 mm²</td>
</tr>
<tr>
<td>after extraction</td>
<td>± 2.52</td>
<td>± 2.40</td>
</tr>
<tr>
<td>2nd week</td>
<td>15.09 mm²</td>
<td>7.98 mm²</td>
</tr>
<tr>
<td>after extraction</td>
<td>± 2.77</td>
<td>±1.99</td>
</tr>
<tr>
<td>3rd week</td>
<td>8.23 mm²</td>
<td>4.75 mm²</td>
</tr>
<tr>
<td>after extraction</td>
<td>± 2.34</td>
<td>±1.52</td>
</tr>
<tr>
<td>4th week</td>
<td>5.33 mm²</td>
<td>3.06 mm²</td>
</tr>
<tr>
<td>after extraction</td>
<td>± 1.78</td>
<td>±1.34</td>
</tr>
<tr>
<td>6th week</td>
<td>2.50 mm²</td>
<td>0.82 mm²</td>
</tr>
<tr>
<td>after extraction</td>
<td>± 0.94</td>
<td>±0.36</td>
</tr>
</tbody>
</table>

With reference to gingival health, this was appropriate during the whole healing process, and no statistical differences were seen between groups (Table 2).

No medical accidents occurred during the study, and tolerance values (EVA) were 2.14mm ± 0.27 for the control group and 2.52 ± 0.53 for the experimental group.

Table 2. Gingival health before extraction and during follow-up.

<table>
<thead>
<tr>
<th></th>
<th>Control Group</th>
<th>Experimental Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extraction</td>
<td>19 3 0</td>
<td>19 3 0</td>
</tr>
<tr>
<td>1st week</td>
<td>12 9 1</td>
<td>13 9 0</td>
</tr>
<tr>
<td>after extraction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2nd week</td>
<td>19 2 1</td>
<td>17 5 0</td>
</tr>
<tr>
<td>after extraction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3rd week</td>
<td>20 1 1</td>
<td>20 2 0</td>
</tr>
<tr>
<td>after extraction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4th week</td>
<td>21 1 0</td>
<td>22 0 0</td>
</tr>
<tr>
<td>after extraction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6th week</td>
<td>19 1 0</td>
<td>20 0 0</td>
</tr>
</tbody>
</table>
Discussion

There are many studies that have investigated the best way to preserve the alveolar crest, especially with the idea of future placement of dental implants (1-7).

This whole battery of studies has left out the study of post extraction gingival closure as a secondary variable in relation to bone regeneration, partly because this was always achieved in a greater or lesser time, reason due to which it is still little studied.

In spite of this, and even supposing that it is not as critical as bone healing (especially for future implant placement), we consider that it is not an unimportant issue. Therefore, for example, in situations as radiation of the maxilla or mandible, the importance of the closure of soft tissues is essential to prevent osteoradionecrosis according to some authors (10).

Rothwell (12) states that 10 to 14 days post extraction are sufficient to initiate radiotherapy, and only in cases of late healing or doses above 6500 Gy, it is necessary to wait one more week (13-15). In this sense, any intervention that will accelerate gingival closure and help to achieve tissue integrity as soon as possible, may be beneficial for the patient, not only at a local level, but in terms of survival, since radiotherapy can be soon started.

On the other hand, some authors recommend extraction procedures that include flap elevation and extensive alveolectomies to achieve primary wound closure (15). However, the use of implants in cancer patients is more and more frequent (16), therefore we consider that we must use criteria with relation to bone tissue in cancer patients that is similar to that used in other patients, except for the removal of bone tissue to eliminate neoplasia.

Studies such as this one, and other future studies, must help to abandon aggressive protocols, and have the aim of achieving short term post extraction gingival healing before radiation, while at the same time making easy restoration with implants possible once the cancer is overcome.

The study performed by Thoma (17) highlighted the importance of post extraction socket filling to achieve soft tissue closure, by applying said principal to oronasal and orosinus fistulae.

Our data led us to similar conclusions since gingival closure was almost 50% faster in the experimental group than in the control group, although this difference is only significant in the two first weeks of follow-up. These two weeks are the period during which material is still present in the socket before disappearing in all cases. Maybe methods to keep the material in place for a greater length of time such as those used by Thoma may achieve better results than those we say in our study (17).

With reference to gingival health, it did not suffer alterations in either group, and was classified as normal. Likewise, treatment was well tolerated by the patients, and no accidents were detected during the study.

Maybe one of the points that should be further discussed is the cost of intervention versus benefit obtained (with reference only to a faster gingival closure). In our opinion, the intervention carried out in this study should be incorporated to extraction protocols in cancer patients who are to undergo radiation, in which case there is an appropriate cost/benefit ratio.

In patients that are not under this pressure, the use of bone filling material to achieve faster post extraction gingival closure may be excessive, although it could be indicated based on other factors, as for example implant restoration and the achievement of appropriate bone regeneration, as has been pointed out in other studies (1,2).

On the other hand, there are other interventions, that must not be forgotten, not related to the use of bone filling material, that have shown improvement in gingival closure. For example, the use of plasma rich in growth factors (PGRF) makes it possible to achieve fast and predictable soft tissue regeneration (18).

In conclusion, treatment of extraction sockets with synthetic bone substitute and calcium sulphate makes it possible to achieve a faster gingival closure, which may have clinical application in patients undergoing radiation. New studies and data are necessary so we can improve our knowledge of post extraction gingival closure and how these new approaches can be included in clinical protocols.

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