Guided bone regeneration in dental implant treatment using a bioabsorbable membrane


The aim of this study was to evaluate an osteopromotive technique, using a bioabsorbable membrane, for its ability to restitute bone over buccal fenestration and dehiscence defects following fixture installation. 11 patients requiring dental implant treatment and exhibiting sufficient vertical height of the maxilla and compromised bucco-palatal dimensions, as determined clinically and radiographically, were included in the study. 17 Bränemark® titanium fixtures were placed with buccal defects which were augmented by a bioabsorbable membrane, Resolut®. No complications were observed post-operatively. At 6-8 months, abutment connection was performed, and clinical evaluation of the healed defect area was made. The number of exposed buccal threads at fixture installation (median 8; range 2-19), and abutment connection (median 0; range 0-5), respectively, was compared. Out of the 17 fixtures; 14 exhibited complete coverage with bone, whereas 3 showed some remaining threads. A small punch biopsy taken at abutment connection in an area where the membrane had been placed showed a combination of dense connective tissue and bone. Radiographic evaluation of the marginal periimplant bone level is in progress and results to date show a median bone loss of 1.2 mm after a loading period of 4-6 months. Results show that fixture dehiscence and fenestrations, augmented with this bioabsorbable membrane, demonstrate a highly significant amount of new bone formation.

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One of the requirements for the successful installation and osseointegration of an endosseous implant is adequate bone volume (Lekholm & Zarb 1985). Fixture stability and ideal positioning with regard to aesthetics and distribution of load may be compromised where localised osseous defects occur. Exposed threads of the implant fixture may lead to mucosal disorders, such as persistent inflammation, fistulae and/or hyperplasia formation, and mucosal retraction (Adell et al. 1981).

Guided bone regeneration is an osteopromotive technique where a cell occlusive membrane is placed, creating a secluded osteogenic environment by the exclusion of competing soft tissue cells. The putative mechanisms behind this technique have been discussed in a review by Linde et al. (1993a). Animal studies documenting membrane application and enhanced bone healing include those by Dahlin et al. (1988, 1990), Hämmerle et al. (1992), Linde et al. (1993b), Sandberg et al. (1993), Schenk et al. (1994), Zellin et al. (1995).

Dahlin et al. (1989) presented the first study demonstrating membrane application in conjunction with titanium implants in rabbits. This was followed by a controlled clinical study confirming bone regeneration at titanium dental implants following e-PTFE membrane application (Dahlin et al. 1991a). Further animal studies have supported these findings, both at dehiscence and fenestration sites (Becker et al. 1990; Gotfredsen et al. 1991; Zablotsky et al. 1991) and at immediate extraction implant installation sites (Warner et al. 1991; Gotfredsen et al. 1993; Lekholm et al. 1993). In addition, clinical case reports (Lazarra 1989; Becker & Becker 1990; Nyman et al. 1990; Dahlin et al. 1991b; Wachtel et al. 1991; Jovanovic et al. 1992; Andersson et al. 1993; Gelb 1993; Vlassis et al. 1993) and a controlled clinical study (Palmér et al. 1994) are available.
Thus, the use of membrane placement in conjunction with endosseous implant installation is an accepted method for bone augmentation. A non-resorbable expanded polytetrafluoroethylene membrane (e-PTFE), Gore-TEX® membrane was applied in the majority of these studies and is the most widely documented membrane.

Various biodegradable materials, including collagen and polydioxanone/polyglycolide copolymers, are available for use in periodontal regeneration and may offer the advantage in guided bone regeneration procedures of elimination of membrane removal. This would result in a less invasive procedure at abutment connection in the two-stage implant systems, and elimination of a second surgical procedure in the single-stage implant systems. Sandberg et al. (1993) and Zellin et al. (1995) demonstrated in experimental animal studies that biodegradable membranes may be as efficient as e-PTFE membranes for bone regeneration.

The aim of this investigation was to clinically evaluate an osteopromotive technique using a bioabsorbable membrane, a copolymer of polyglycolide and polylactide, (Resolut®) for its ability to restitute bone at endosseous implant dehiscence and fenestration defects. This has, to our knowledge, not been documented previously.

**Material and methods**

Eleven patients, 4 males and 7 females, aged 55–90 years (mean 68 years) requiring osseointegrated fixed reconstructions, participated in the study. All patients were in good health, and routine examination demonstrated no systemic or local contraindications to surgical treatment.

With the aid of computer-assisted tomography, patients exhibiting sufficient vertical maxillary bone height (210 mm) but insufficient bone width (<4 mm) in an area where the installation of an implant fixture was planned were selected. It was expected that the anatomic conditions would lead to exposure of several implant threads at fixture installation. None of the patients were in need of bone transplants. Informed consent was given by the patients.

**Surgical technique: fixture installation**

The surgical recommendations according to the Brånemark system (Adell et al. 1985) were followed with some modifications. Surgery was performed under local anaesthesia using lidocain 20 mg adrenalin 12.5 µg (Xylocain® adrenalin; Astra, Södertälje, Sweden). The patients were preoperatively medicated with diazepam (Stesolid®; Dumex, Copenhagen, Denmark) 5 mg the night before surgery and 5 mg the morning of surgery. Vibramycin® (100 mg; Pfizer Inc., New York, USA) was prescribed 1 hour prior to surgery and for 10 days following surgery.

A midcrestal incision was made, and remote palatal and labial full thickness flaps elevated. Titanium Brånemark® fixtures (Nobelpharma; Gothenburg, Sweden) were installed using low speed (15–20 rpm) under cooling with saline. In areas where exposed buccal threads were evident, photographs were taken and the number of threads counted. All defects included were located within the confines of the alveolar process and could therefore be described as space-making.

A bioabsorbable membrane consisting of a copolymer of polyglycolide and polylactide (Resolut®; W. L. Gore & Assoc., Flagstaff, AZ, USA) was trimmed and shaped to cover the defect areas and 5 mm of surrounding bone. This membrane, designed for use in bone augmentation, consists of an occlusive film with a bonded, randomly-oriented, fibre matrix located on each surface (Zellin et al. 1995).

The membrane was adapted to the bone margins surrounding the defect and a blood clot between the defect and membrane established. The position of the membrane was recorded photographically and diagrammatically on a specific form. There was no fixation of the membrane or space making graft material applied. Prior to flap closure periosteal releasing incisions were made at the base of the buccal flap. The flaps were then repositioned and sutured using nonresorbable GORE-TEX® sutures (W. L. Gore). The suturing technique involved the use of modified vertical mattress sutures to secure the flap margins, followed by a continuous suture (one deep suture followed by one shallow suture), allowing close adaption of the wound margins to facilitate primary healing.

**Postoperative procedure**

Antibiotics were prescribed for 10 days following surgery. Patients were instructed to use saline mouth rinses and not to use their prosthesis for 2 weeks, at which time sutures were removed, and the prosthesis was reduced and relined with a resilient lining. The patients were followed on a regular basis until abutment connection to check for complications.

**Surgical procedure: abutment connection**

The abutment connection surgery was performed after a healing period of 6–8 months. A mid-crestal incision was made and a small flap raised buccally which enabled access to areas of initial defects. A clinical assessment of the coverage of initial defects was made after removal of the superficial layer of compressible fibrous tissue. The number of exposed
threads was counted, photographs taken, and the stability of fixtures recorded.

In addition, a small punch biopsy was taken at abutment connection, after the patient's consent, in an area where the membrane had been. The biopsy was taken in order to verify the nature of the regenerated tissue, as it has been argued that what appears clinically to be bone may be soft tissue (Palmer et al. 1994). Biopsies were fixed and embedded in paraffin, and sections were examined with routine methods.

The remaining part of the surgical procedure followed the standard procedure for abutment connection (Adell et al. 1985). The prosthesis was adjusted to accommodate the abutments and relined with resilient lining. Sutures were removed after 7 days and prosthetic procedures commenced 2 weeks later. At the time of bridge insertion, the stability of fixtures was checked. Patients were recalled on a routine basis, i.e. at 1 week, 1, 3 and 6 months, and 1 year.

Radiographic evaluation

Non-standardised periapical radiographs were taken using a parallel technique to verify correct abutment placement. One year after fixture installation, periapical and panoramic radiographs were taken to evaluate the marginal periimplant bone level after loading. Linear measurements were performed using a digital technique as described by Petersson et al. (1996), (personal communication).

Statistics

The mean number of exposed threads and standard deviation was calculated for dehiscence and fenestration defects at fixture installation and abutment connection. A Student t-test for paired observations was used to compare the number of exposed threads at fixture installation and at abutment connection for dehiscence and fenestration defects.

![Fig. 1. Effect of guided bone regeneration at titanium fixtures. *p < 0.05; ***P < 0.001.](image)
Results

Table 1 describes the defect characteristics at fixture installation and abutment connection. Of the 17 defects evaluated from the 11 patients, there were 12 buccal dehiscence defects and 5 buccal fenestration defects at fixture installation. The initial defect size ranged between 2 – 19 exposed threads (median 8, mean 7.8, SD = 4.4). The number of exposed threads at abutment connection ranged between 0 – 5 (median 0, mean 0.6, SD = 1.4). At abutment connection, 14 of the 17 defects had been completely covered, whereas 3 showed some remaining threads. This reduction in number of exposed threads was highly significant (p < 0.0005) (Fig. 1).

The clinical appearance of the regenerated tissue was similar for all patients. There was a layer of compressible, movable fibrous tissue covering the healed defect area, which when removed and probed revealed bone. No membrane remnants were observed at abutment connection. Figs. 2, 3 illustrate the clinical appearance of the original defects, placement of membrane, and regenerated tissue observed at abutment connection.

In all biopsies, a combination of dense connective tissue and bone was seen. Due to the fact that punch biopsies were taken tangentially to and not directly over the fixtures, to avoid re-exposure of the fixture threads, they were, however, considered to be of limited value.

No signs of membrane exposure or infection were observed during the healing period following fixture and membrane placement. All fixtures were found to be stable at abutment connection and at bridge insertion. No complications following bridge insertion have been observed to date.

After a loading period of 4–6 months, radiographs were available for 5 fixtures in 5 patients. Comparison of these radiographs, taken 1 year after fixture installation, with radiographs taken directly after abutment connection showed a median peri-implant marginal bone loss of 1.2 mm (range 0.8 – 2.4) (Table 2).

Fig. 2. (a). Clinical appearance of a dehiscence defect at fixture installation (fixture no. 6). (b). Clinical appearance of regenerated bone observed at the original defect site at abutment connection following membrane application at fixture installation.
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Fig. 3. (a) Clinical appearance of bone defects associated with fixtures 3, 4 and 5 at fixture installation. (b) Clinical appearance of bioabsorbable membrane covering defect sites and 5 mm of surrounding bone. (c) Clinical appearance of mucosa 4 weeks following fixture installation and membrane application. (d) Clinical appearance of regenerated tissue covering original bone defects at fixtures 3, 4 and 5 at abutment connection.

Discussion

Results of this investigation indicate that the osteopromotive technique described, using the bioabsorbable membrane Resolut®, in most cases enables complete bone coverage of exposed implant threads, whereas partial coverage only is obtained at a minority of sites. The defects studied were space-making and comprised buccal dehiscence and fenestration defects. The regenerated tissue consistently demonstrated a superficial layer of compressible fibrous tissue which, when removed and probed, revealed bone.

At the time of writing of this paper a limited number of fixtures were available for radiographic evaluation (4–6 months after loading), revealing a median marginal bone loss of 1.2 mm (range 0.8–2.4) when compared with radiographs at abutment connection (Table 2). This indirectly reflects the bone regenerated at the initial buccal defects. These preliminary results are in agreement with those of Adell et al. (1981), Dahlin et al. (1991a) and Becker et al. (1994b). Other studies have shown an increased bone loss following membrane treatment, and have recommended a longer healing period prior to loading following bone augmentation with barrier membranes (Jovanovic et al. 1992; Becker et al. 1994a). Continued radiographic evaluation is underway and will be subsequently reported.

For ethical reasons, no control fixtures without membrane were used, as it has been previously shown by Dahlin et al. (1991a) that the periosteum

Table 2. Radiographic evaluation; marginal periimplant bone loss following loading at fixture sites augmented with membrane at fixture installation.

<table>
<thead>
<tr>
<th>Fixture no.</th>
<th>Marginal periimplant bone loss (mm)</th>
<th>Loading period (months)</th>
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<tr>
<td></td>
<td>mesial</td>
<td>distal</td>
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<tr>
<td>1</td>
<td>0.2</td>
<td>1.4</td>
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<tr>
<td>2</td>
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<td>2.5</td>
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<tr>
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<td>1.3</td>
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<tr>
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alone is not capable of regenerating new bone at exposed titanium implants in adult humans.

The finding that bone was restituted at membrane-covered dehiscence and fenestration space-making defects is in agreement with results from previous studies using non-resorbable e-PTFE membranes. A clear advantage of the membrane used in this study is the elimination of removal of the membrane.

Recently, there has been an interest in the development of biodegradable membranes. Materials which have been investigated in animal studies and case reports include Polyglactin 910 (Balshi et al. 1991), collagen membranes (Sevor & Meffert 1992; Sevor et al. 1993), polyhydroxybutyrate (Kostopolous & Karring 1994), polyhydroxybutyrate hydroxyvalerate reinforced with polyglactin 910 (Gotfredsen et al. 1994), and polyglycolic acid and polylactic acid or copolymers of these materials (Sandberg et al. 1993; Lundgren et al. 1994; Zellin et al. 1995). There is, however, limited information available concerning the clinical bone regenerative capacity of biodegradable membranes and this is insufficient to evaluate their efficacy with regard to titanium implants (Mellonig & Nevins 1995).

A complication which may arise following the use of the e-PTFE membrane in conjunction with implant placement is membrane exposure with subsequent infection and interference with bone regeneration (Gotfredsen et al. 1993; Becker et al. 1994b; Simion et al. 1994). In our investigation, no signs of infection or membrane exposure were observed. This is in agreement with the results of the comparative investigation in rats made by Zellin et al. (1995), which showed a good osteopromotive effect of a polylactic/polyglycolic copolymer membrane, Resolut LT (a prototype material very similar to the final Resolut® product), with low inflammatory response in the surrounding tissue.

It may be that there is less incidence of membrane exposure and subsequent infection following the use of this bioabsorbable membrane. The remote flap design and use of periosteal releasing incisions at the base of the buccal flap, in order to obtain adequate coverage of the membrane and reduce pressure, may also have contributed to the avoidance of membrane exposure and infection. However, in the event of an infection following treatment with a resorbable membrane, it may be impossible to completely remove the membrane once disintegration has begun.

In addition to compatibility, one of the main requirements for the regeneration of bone using the membrane technique is the space maintaining properties of the membrane (Scantlebury 1993). It is important that the membrane retains its mechanical strength for a sufficient time in order to resist collapse due to pressure from overlying tissue. The membrane used in our investigation is claimed to remain intact for a 6–8 week period. The length of time required for bone regeneration may depend on the size and nature of the defect. For this reason, it remains to be studied if bioabsorbable membranes such as Resolut® are suitable for large bone defects.

An intriguing observation in our study was that, while treatment of 14 of the 17 defects resulted in complete bone coverage of the fixtures, the remaining 3 fixtures displayed 2–5 exposed threads. This means that, while the osteopromotive technique was capable of totally restituting defects as large as 19 exposed threads, a small number of defects, nevertheless, only partially healed with new bone. Whether this result was due to membrane micro-movements, lack of space maintenance, or some other factor, remains to be elucidated.

The question still remains as to whether there is a negative influence of exposed threads at fixture sites. There are no studies which show a correlation between exposed threads and implant failure. However, if our aim is to achieve maximal coverage of the fixture with bone, whilst obtaining an aesthetic and functional result, then this technique is applicable.

In conclusion, the results of this clinical study indicate that the membrane tested was efficient in the regeneration of bone at implant dehiscence and fenestration sites, where there were space giving defects.

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Résumé

Le but de cette étude a été d’évaluer une technique favorisant l’os en utilisant une membrane bioabsorbable, pour sa capacité à restituer l’os sur des fênetrations vestibulaires et des lésions de déhiscence suivant l’installation d’implants. Onze patients recevant le traitement par implants dentaires et montrant une hauteur verticale suffisante du maxillaire et des dimensions vestibulo-linguales risquées comme cela avait été déterminé cliniquement et radiographiquement, ont été inclus dans cette étude. Dix-sept implants ad modum Brånemark® ont été placés avec des lésions vestibulaires qui ont été protégées par une membrane bioabsorbable Résolut®. Aucune complication post-opératoire n’a été décelée. Après six à huit mois la jonction avec le pilier a été effectuée et l’évaluation clinique de la lésion guérie a été faite. Le nombre de filetages vestibulaires exposés lors de l’installation de l’implant(médiane 8; de 2 à 19) et lors du placement du pilier (médiane 0, de 0 à 5) a été comparé. Des 17 implants, 14 montraient un recouvrement osseux complet tandis que trois laissaient encore apparaître quelques filetages. Une petite biopsie locale, prise à la jonction du pilier dans une zone où la membrane avait été placée, montrait
Resumen
La intención de este estudio fue evaluar una técnica osteopromotora, usando una membrana bioreabsorbible, por su habilidad en restituir hueso sobre fenestraciones bucales y defectos de dehiscencias trascendiendo la instalación de fijaciones. Se incluyeron en este estudio once pacientes que requerían tratamiento de implantes dentales mostrando suficiente hueso vertical maxilar y una dimensión buccopalatinal comprometida, determinada clínica y radiográficamente. Se colocaron diecisiete fijaciones de titanio Bränemark® con defectos bucales que fueron cubiertos con una membrana bioreabsorbible Resolut®. No se observaron complicaciones postoperatorias. A los 6–8 meses se conectó el pilar y se realizó una evaluación clínica de la cicatrización del defecto. Se comparó el número de roscas expuestas en el momento de la instalación de la fijación (media 8; rango 2–19), y al colocar el pilar (media 0; rango 0–5), respectivamente. De las 17 fijaciones; 14 mostraron una completa cobertura con hueso, mientras que tres mostraron algunas roscas expuestas. Una pequeña biopsia tornada al conectar el pilar en el área donde había estado la membrana, mostró una combinación de tejido conectivo denso y hueso. La evaluación radiográfica del nivel marginal de hueso perimplantario en progresión y los resultados a la fecha muestran una pérdida media de hueso de 1,2 mm, tras un periodo de carga de 4–6 meses. Los resultados muestran que las dehiscencias y fenestrações de fijación, se cubrieron con esta membrana bioreabsorbible, demostrando un aumento significativo de hueso de nueva formación.

Referencias
Guided bone regeneration with a bioabsorbable membrane


