J Clin Periodontol 2004; 31: 1092–1098 doi: 10.1111/j.1600-051X.2004.00615.x



Journal of Clinical Periodontology

# Healing, post-operative morbidity and patient perception of outcomes following regenerative therapy of deep intrabony defects

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*Tonetti MS, Fourmousis I, Suvan J, Cortellini P, Brägger U, Lang NP: Healing, post-operative mobidity and patient perception of outcomes following regenerative therapy of deep intrabony defects. J Clin Periodontol 2004; 31: 1092–1098. doi:10.1111/j.1600-051X.2004.00615.x.* © Blackwell Munksgaard, 2004.

***Abstract***

**Aim:** This prospective multicenter randomized controlled clinical trial was designed to compare the clinical outcomes of papilla preservation flap surgery with or without the application of enamel matrix derivatives (EMD). This article reports on early healing events, post-operative morbidity and patient perceptions of the surgical outcomes.

**Material and Methods:** One hundred and seventy-two patients with advanced chronic periodontitis and at least one intrabony defect of $\geqslant 3$ mm were recruited in 12 centres in seven countries (European Research Group on Periodontology (ERGOPERIO)). Papilla preservation flaps were used to obtain access and primary closure. After debridement, and root conditioning, EMD was applied in the test subjects, and omitted in the controls. Healing was monitored 1, 2, 3, 4, 6 and 12 weeks after surgery. During the first 12 weeks of healing, supracrestal soft-tissue density was evaluated with a computer-assisted densitometric image analysis system (CADIA) using underexposed radiographs taken on a subset of 34 patients. Patient perceptions were evaluated with a questionnaire immediately after the procedure, at suture removal 1 week later and at 1 year.

**Results:** Subjects reported little intraoperative or post-operative pain or discomfort for both test and controls. Twenty-four percent of controls and 30% of tests ($p = 0.64$) reported a degree of interference with daily activities for an average of 3 and 3.5 days, respectively. Post-surgical edema was noted in 25% of tests and 28% of controls. Wound dehiscence in the interdental portion of the flap was uncommon (14% of tests and 12% of controls at week 1) and of limited size. Root sensitivity was the most frequent post-operative adverse event: it affected 45% of test and 35% of controls ($p = 0.55$). Up to 6 weeks post-operatively, soft-tissue densities were significantly higher in subjects treated with EMD with respect to controls. One year after completion of the surgery, patients reported high levels of satisfaction with the outcomes. The most frequently reported benefits included the ability to preserve a tooth/dentition and to maintain/improve chewing ability. The cost and need for frequent follow-ups were cited as significant drawbacks.

**Conclusions:** This study portrayed the early healing events, pain, discomfort and adverse events of papilla preservation flap surgery and the 1-year patient perceptions of the benefits and disadvantages of periodontal surgery in intrabony defects. Earlier gains in soft-tissue density were observed following application of EMD. In terms of patient-centered outcomes, however, both procedures performed in a similar manner.

Key words: adverse events; intrabony defects; morbidity; patient-centered outcomes; periodontal surgery

Accepted for publication 15 March 2004

Recent systematic reviews have indicated that regenerative treatment of intrabony defects leads to significant improvements in clinical outcomes compared with access flap surgery alone (Needleman et al. 2002, Trombelli et al. 2002, Murphy & Gunsolley 2003). One established modality includes the application of enamel matrix derivative (EMD) to promote regeneration (Schonfeld & Slavkin 1977, Hammarström 1997, Heijl et al. 1997, Heden et al. 1999). Over the years, clinical scientists assessing the efficacy of different procedures have focused on estimating the outcomes of regenerative therapy in terms of clinical parameters such as clinical attachment level (CAL) gains and probing pocket depth (PPD) reductions. Patient-centered outcomes, on the other hand, have received relatively little attention and have been identified as a research priority area at the World Workshop on Emerging Science in Periodontology of 2003.

A recent survival analysis has indicated that, in patients who complied with the prescribed supportive periodontal care program, improvements in clinical attachments after periodontal regeneration could be maintained for more than 10 years, and that loss of teeth severely compromised by the presence of deep intrabony defects but treated in a regenerative way was infrequent and only observed in smokers (Cortellini & Tonetti 2004). While these data addressed the significance of CAL gains over a long period of time, little has been reported with regard to adverse events, post-operative morbidity and perceived advantages and disadvantages of regenerative therapy.

A recent study reporting averse events and patient-centered outcomes indicated that significantly more edema was observed in defects treated with resorbable barrier membranes than with access flap alone (Cortellini et al. 2001). In general, however, the study did not discriminate between the adverse events, post-operative morbidity, benefits and disadvantages of regenerative therapy and access flap surgery.

The objective of the present clinical investigation was to assess, in a multicenter randomized-controlled clinical trial, the early healing events, the post-operative morbidity and patient-centered outcomes obtained following treatment of intrabony defects with papilla preservation flap surgery with or without application of EMD.

## Material and Methods

### Experimental design

The design of the study has been previously described in detail (Tonetti et al. 2002). In essence this was a parallel group, randomized, multicenter and controlled clinical trial testing the efficacy of two treatment modalities in intrabony defects. The test treatment consisted of access to the defect with a papilla preservation flap, surgical debridement, root conditioning and application of EMD to the debrided root surface. The same procedure was performed in the control group except for the omission of EMD application. A single defect was treated in each patient. Patient and clinical outcomes were evaluated during the healing period and at 1 year. This investigation was performed at two university and 10 periodontal practices constituting a practice-based research network (European Research Group on Periodontology (ERGOPERIO)). Centres were located in Belgium, Germany, Greece, Italy, the Netherlands, Switzerland and the USA. In each center, the examiner and the therapist were the same. To limit assessment bias, clinicians did not have previous measurements available to them and used a pressure-sensitive probe. Each clinical centre was connected with and supervised by a central monitoring facility at the University of Berne, Switzerland. Clinical outcomes and treatment effect at 1 year have already been presented in a companion paper (Tonetti et al. 2002). This paper focuses on healing outcomes, post-operative morbidity and patient perception of outcomes.

### Subject population

Inclusion and exclusion criteria were as previously reported (Tonetti et al. 2002). In brief, patients younger than 21 years, with uncontrolled or poorly controlled diabetes, unstable or life-threatening conditions, requiring antibiotic prophylaxis or heavy smokers (20 cigarettes/day or more) were excluded (Tonetti et al. 1995). Only patients with a diagnosis of severe periodontitis previously treated by at least a cycle of scaling and root planing and oral hygiene instructions were invited to participate. These subjects had to present with full-mouth plaque scores and full-mouth bleeding scores $<25\%$ at study baseline (following completion of the initial periodontal treatment phase consisting of scaling and root planing, patient motivation, and oral hygiene instructions with or without adjunctive antiseptics and/or antibiotics) (Tonetti et al. 1993, 1995, 1996, 1998).

Entry criteria (Tonetti et al. 2002) included the presence of a deep intrabony defect ($\geqslant 3$ mm), located in the interdental area, in anterior or premolar teeth. This was verified at surgery. One hundred and seventy-two subjects gave informed consent and were enrolled into the study.

### Randomization

All subjects were randomly assigned to one of the two treatment regimens. Assignment was performed by a central randomization facility using a custom-made program based on balanced random permuted blocks. Furthermore, to reduce the chance of unfavorable splits between test and control groups in terms of key prognostic factors, the randomization process balanced smoking status, average PPDs and number of deep pockets (PPD $>8$ mm) in the test and control groups.

### Surgical procedures

Details of the procedures have been reported before (Tonetti et al. 2002). In brief, test and control defects were accessed using either the simplified papilla preservation flap (Cortellini et al. 1999) or the modified papilla preservation technique (Cortellini et al. 1995) depending on the width of the interdental space. The exposed defects were carefully scaled and root planed to remove residual mineralized deposits, but not necessarily the root cementum. Root surfaces at both test and control sites were conditioned with a neutral pH ethylenediaminetetraacetic acid (EDTA) gel (PrepHgel®, Biora AB, Malmo, Sweden) for 2 min (Blomlöf & Lindskog 1995, Blomlöf et al. 1996). In the test sites, EMD (Emdogain®, Biora AB) gel was applied on the root surface and to overfill the defect. The flaps were then replaced and sutured using non-resorbable expanded polytetra fluoroethylene (e-PTFE) sutures (Gore-Tex™, W. L. Gore and Associates, Flagstaff, AZ, USA) as previously described (Cortellini & Tonetti 2000). The control procedure was identical to the test surgery, apart from the omission

of the EMD application. The duration of the surgical procedure was timed and the number of teeth involved in the surgical procedure was recorded. Hardship of the surgical procedure, presence (dichotomous) and intensity (visual-analogue scale (VAS), expressed in millimeters on a 100 mm scale) of pain and discomfort were evaluated upon completion of the surgery using a questionnaire (Revill et al. 1976). To reduce cultural bias, questionnaires were translated into the language of the participants (Dutch, French, German, Greek and Italian) and administered with the assistance of the investigators.

#### Radiographic assessment of soft-tissue density

During the first 3 months of healing, supracrestal soft-tissue density was evaluated with a computer-assisted densitometric image analysis system (CADIA) using underexposed radiographs taken on a subset of 34 patients essentially as previously described (Fourmousis et al. 1994, 1998). Four study centres were trained and calibrated to obtain identical radiographs using a previously described technique (Bragger et al. 1988, 1998). Underexposed radiographs were taken at baseline, i.e. immediately after completion of the surgical procedure, and at 2, 4, 6 and 12 weeks after surgery using a custom-made bite block and aiming device. A region of interest involving the supracrestal soft tissues at the experimental site was defined on the baseline radiograph and used to quantitatively measure changes in soft-tissue density (Fourmousis et al. 1994, 1998).

#### Post-surgical instructions and infection control

Post-operative pain and edema were controlled with tablets of either 600 mg ibuprofen or 500 mg acetaminophen. Patients were given the first dose of analgesic before completion of the procedure and were instructed to take additional tablets as needed to control post-surgical pain. Patients were instructed to rinse twice daily with 0.12% chlorhexidine and to use modified oral hygiene procedures in the treated area for the first 4 post-operative weeks. They were instructed to start gentle wiping of the operated dentogingival area with a post-surgical toothbrush (Vitis Surgical, Dentaid SA, Barcelona, Spain) soaked in a 0.12% chlorhexidine solution from the third post-operative day. No interdental cleaning was allowed in the first 4 post-operative weeks. Smokers were asked to limit and possibly avoid smoking. Patient's experience of the surgical procedure and of the first post-operative week was evaluated with a questionnaire. The prevalence and extent of discomfort, pain, root sensitivity and interference with daily activities during the first post-operative week were evaluated using dichotomous questions and/or a VAS.

#### Post-surgical follow-up (week 1–6)

Sutures were removed after 1 week. Post-surgical controls and professional tooth cleaning consisting of supragingival prophylaxis with a rubber cup and 0.2% chlorhexidine gel (Plak-Out gel, Hawe-Neos, Switzerland) were performed at weeks 1, 2, 3, 4 and 6. At these time points, presence of edema, hematoma, suppuration, flap dehiscence and patient complaints were dichotomously recorded. Compliance with post-surgical follow-up appointments was greater than 95% at all time points.

#### Maintenance care (months 3, 6 and 9)

All patients were maintained in supportive-care programs and they received full-mouth professional prophylaxis and calculus removal at 3, 6 and 9 months as previously detailed (Tonetti et al. 1998).

#### Data management and statistical analysis

The trial was sized in order to detect a 0.5 mm difference in the primary outcome variable reported in the companion paper (Tonetti et al. 2002). Analyses reported in this paper are not based on formal sample size calculations. Data were entered in a microcomputer and proofed for entry errors. The resulting database was locked and loaded in SAS format (Statistical Application Software, SAS Institute, Cary, NC, USA). All calculations and analyses were performed using SAS Version 8. Data are expressed as mean $\pm$ SD.

## Results

#### Patient population and oral hygiene

A total of 172 subjects were entered and randomized. One hundred and sixty-six subjects, 83 tests and 83 controls completed the trial. This represented 96.5% of entered patients. Subject characteristics and oral hygiene have already been reported in detail in a companion paper (Tonetti et al. 2002).

#### Evaluation of surgical procedures and post-operative period

Table 1 describes the surgical procedures performed in the test and in the control groups. No significant differences in any of the measured parameters were detected between the test and control treatments.

During the procedure, 35% of test subjects reported feeling moderate pain ($20.5 \pm 15.7$ VAS units, with 0 = no pain and 100 = unbearable pain); this compared with 27% of control subjects who reported similar pain intensity ($18.4 \pm 15.6$ VAS, $p = 0.65$). Subjects in the test group estimated the hardship of the procedure at $28 \pm 25$ VAS units, while control patients gave values of $23 \pm 24$ VAS units (with easy to cope with = 0 and difficult to cope with = 100). The difference was not statistically significant ($p = 0.22$).

The prevalence and extent of post-operative pain is described in Table 2. No significant differences were observed in terms of the prevalence of test

*Table 1.* Surgical parameters ($N = 166$)

| Variables | Test | Control | Significance ($p$-value) |
|---|---|---|---|
| periosteal incision | 22% | 18% | 0.56* |
| vertical releasing incision | 13% | 19% | 0.20* |
| interdental primary closure | 95% | 95% | 1.0* |
| number of teeth involved | $4.6 \pm 1.2$ | $4.7 \pm 1.2$ | 0.53† |
| surgical time (minutes) | $80 \pm 34$ | $76 \pm 36$ | 0.57† |
| surgical time/tooth (minutes) | $18 \pm 7$ | $17 \pm 7$ | 0.24† |

*$\chi^2$.
†$t$-test.

*Table 2.* Subject's experience in terms of post-operative pain

| | Test | Control | Significance ($p$-value) |
|---|---|---|---|
| frequency of subjects reporting pain | 50% | 58.8% | 0.27 |
| intensity of pain (if reported, VAS) | 28 ± 20 | 31 ± 23 | 0.49 |
| duration of pain (if reported, hours) | 31 ± 58 | 27 ± 31 | 0.65 |
| number of analgesic tablets | 4.3 ± 4.5 | 5.3 ± 5.2 | 0.19 |

VAS, visual analogue scale.

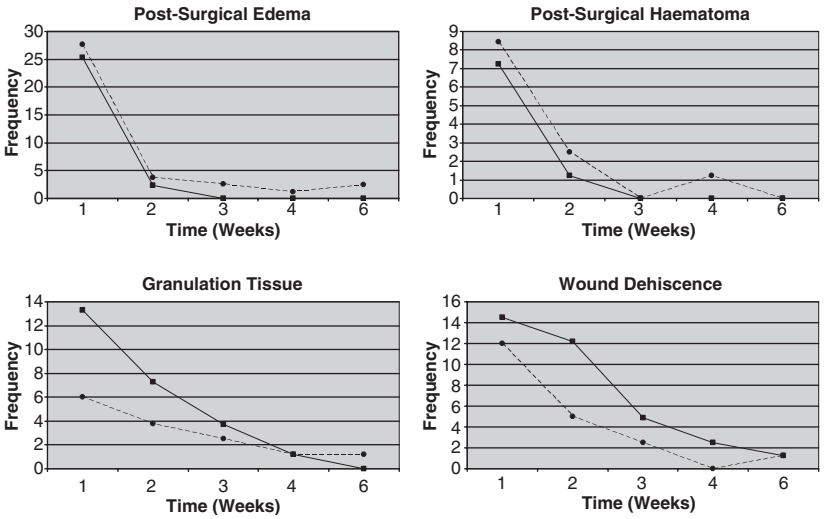


*Fig. 1.* Frequency of detection of post-operative complications in test (filled squares, continuous line) and in control (filled circles, dashed line) subjects at 1, 2, 3, 4 and 6 weeks after surgery. No significant differences between test and control were observed at any time point.

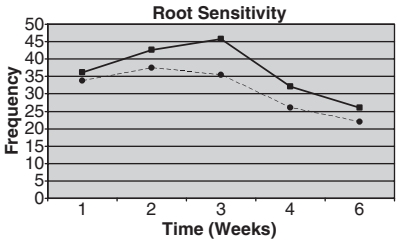


*Fig. 2.* Frequency of detection of root sensitivity in the operated area in test (filled squares, continuous line) and in control (filled circles, dashed line) subjects at 1, 2, 3, 4 and 6 weeks after surgery. No significant differences between test and control were observed at any time point.

and control subjects reporting post-operative pain ($p = 0.27$). Forty percent to 50% of the subjects in both groups did not experience post-operative pain. Among the subjects reporting pain, pain intensity was described at values of 28 ± 20 VAS (test group) and 31 ± 23 VAS (with 0 = no pain, and 100 = unbearable pain, $p = 0.49$). In the patients who experienced it, pain lasted an average of 31 ± 58 h in the test group and 27 ± 31 h in the controls ($p = 0.65$). 47.5% of test subjects and 41.5% of control subjects reported post-operative discomfort other than pain ($p = 0.44$).

Post-operative morbidity was limited to a minority of patients. 29.5% of test patients and 23.8% of controls reported that the procedure somehow interfered with daily activity for an average of 3.6 ± 2.5 days in the tests and 3.2 ± 2.1 days in the controls ($p = 0.64$).

The most frequent post-operative complications are displayed in Fig. 1. No significant differences between test and control treatments were observed at any time point ($p > 0.1$, $\chi^2$). For all complications, prevalence was highest at week 1 and rapidly decreased over the following weeks. In all cases, edema and hematoma could only be detected by intraoral examination. Wound dehiscence was always limited to the interdental incision line of the papilla preservation flap used. Suppuration was never observed.

A composite index of healing complications was constructed: subjects in whom primary closure could not be achieved, subjects presenting wound dehiscence, presence of granulation tissue at the wound margin or suppuration at any time point were considered to have complicated healing. Complicated healing was observed in 21.7% of test and 19.2% of control subjects. The difference was not statistically significant ($p = 0.7$, $\chi^2$).

A multivariate model was constructed in order to assess the significance of complicated healing in the determination of the 1-year CAL in this material ($p < 0.0001$, $R^2 = 0.38$). CAL gains at 1 year were significantly influenced by the treatment effect ($p = 0.04$), the centre effect ($p < 0.001$), the baseline pocket depth at the defect ($p < 0.0001$), the corticalization of the defect ($p = 0.0015$), but not by a complicated healing (defined as the presence of any of the following: lack of achievement of primary closure, presence of suppuration, granulation tissue or flap dehiscence, $p = 0.1192$).

The incidence of root sensitivity is displayed in Fig. 2. Root sensitivity was a frequent occurrence with both treatment modalities (no significant differences were observed comparing test and control), peaked at 3 weeks and decreased below baseline frequency by week 6.

#### Soft-tissue healing

Healing of the supracrestal soft tissues was assessed using underexposed radiographs in a subpopulation consisting of 34 patients. This subgroup did not significantly differ from the overall population in terms of potential confounders such as demographics, plaque control and disease severity. An equal number of subjects had received the test or the control treatments. Table 3 shows that 2 weeks following access flap surgery alone, tissue density (expressed as changes in CADIA units) decreased below the pre-surgical level. Tissue density remained below baseline values for the first 6 weeks of healing. Following application of EMD, on the other hand, already at week 2, tissue density appeared to be higher than before surgery. During the initial 6 weeks of healing, soft-tissue CADIA values of EMD-treated sites were significantly higher than those of the control treatment ($p < 0.03$, $t$-test). Differences in CADIA values between test and control were no longer detectable at week 12.

#### Patient-centered outcomes at 1 year

The clinical outcomes for both test and control at 1 year have been reported in a companion paper (Tonetti et al. 2002). Table 4 describes patient perceptions of the outcomes of treatment at 1 year. Significant improvements compared with baseline (numbers above 50 in the VAS) were observed in terms of chewing comfort, esthetic appearance and health of the gingivae, while no significant improvements were reported in terms of speaking ability. Of interest was also the report that patients reported very high levels of satisfaction with treatment. No significant differences were observed comparing test and controls.

The major perceived benefits from the surgical therapy are displayed in Table 5. The most frequently reported was the ability to preserve the tooth/dentition involved in the procedure followed by maintenance/improvement of chewing ability. Interestingly, only 5.1% of tests and 1.4% of controls did not perceive any major benefit from the surgery.

In terms of disadvantages, 39.7% of test and 45.2% of controls did not perceive the presence of disadvantages from the surgery (Table 6). The most frequently cited disadvantages from the procedure were the cost and the need for frequent follow-up appointments (both for test and control, no significant difference). Pain and fear/anxiety were cited as major disadvantages by a significant minority of subjects (11–18%).

*Table 3*. Changes in supracrestal soft-tissue densities between baseline and 2, 4, 6 and 12 weeks after surgery determined as CADIA* values using underexposed identical radiographs of the treated area

| Outcome | Test Emdogain® | Control Open flap debridement | Significance ($p$-value) |
|---|---|---|---|
| subject number | 16 | 18 | |
| 2 weeks post-surgically | $0.87 \pm 3.1$ | $-1.99 \pm 3.3$ | $<0.01$ |
| 4 weeks post-surgically | $2.46 \pm 7.4$ | $-1.96 \pm 5.6$ | $<0.01$ |
| 6 weeks post-surgically | $3.42 \pm 6.2$ | $-0.97 \pm 7.1$ | $<0.03$ |
| 12 weeks post-surgically | $3.82 \pm 5.2$ | $3.08 \pm 10.1$ | n.s. |

n.s., not significant.
*CADIA, computer-assisted densitometric image analysis. Positive units indicate an increase in tissue density, while negative ones indicate loss of soft-tissue density.

*Table 4*. Patient perception of the outcomes at 1 year

| Outcome | Test (EMD) | Control (access flap) | Significance ($p$-value) |
|---|---|---|---|
| change in chewing comfort | $69 \pm 20$ | $67 \pm 20$ | 0.49 |
| change in esthetics appearance | $63 \pm 23$ | $62 \pm 19$ | 0.84 |
| change in the health of the gums | $87 \pm 14$ | $87 \pm 13$ | 0.96 |
| change in speaking ability | $54 \pm 13$ | $54 \pm 12$ | 0.89 |
| change in oral hygiene ability | $75 \pm 19$ | $76 \pm 17$ | 0.72 |
| overall satisfaction with treatment | $87 \pm 17$ | $85 \pm 16$ | 0.51 |

Changes in visual analogue scale, with 50 = no change and numbers greater than 50 indicating an improvement.
EMD, enamel matrix derivative.

*Table 5*. Major perceived benefits 1 year after the surgery

| Benefit | Test (EMD) | Control (access flap) | Significance ($p$-value) |
|---|---|---|---|
| preservation of tooth/dentition | 87.2% | 82.2% | 0.39 |
| avoid bridge/denture | 42.3% | 37.0% | 0.50 |
| maintain/improve chewing ability | 55.1% | 43.8% | 0.16 |
| maintain/improve esthetics | 25.6% | 17.8% | 0.24 |
| other | 6.4% | 4.1% | 0.53 |
| no perceived benefit | 5.1% | 1.4% | 0.20 |

EMD, enamel matrix derivative.

*Table 6*. Major perceived disadvantages 1 year after the surgery

| Benefit | Test (EMD) | Control (access flap) | Significance ($p$-value) |
|---|---|---|---|
| cost | 26.9% | 21.9% | 0.47 |
| pain | 12.8% | 11.0% | 0.72 |
| fear/anxiety | 18.0% | 11.1% | 0.24 |
| frequent follow-up | 25.6% | 30.1% | 0.54 |
| unsatisfactory result | 2.6% | 1.4% | 0.60 |
| other | 2.6% | 2.7% | 0.95 |
| no perceived disadvantage | 39.7% | 45.2% | 0.50 |

EMD, enamel matrix derivative.

## Discussion

This study describes for the first time the patients' experience of periodontal surgery, their perceptions of the post-operative period, of the achieved benefits and of the disadvantages encountered along with an account of the post-operative complications and soft-tissue healing observed by the periodontist.

Results indicate that subjects were unable to discriminate between the test and control procedures but more interestingly describe patient perceptions in a multicenter design involving a wide variety of clinical practice settings in seven western countries. Furthermore, reading these data in the context of the additional benefits in clinical outcomes demonstrated in the first part of this study (Tonetti et al. 2002) indicates that, with the exception of the costs of the material, no additional complications or suffering are expected following EMD application in order to promote regeneration of intrabony defects.

The data portray that papilla preservation flaps used alone or in combination with EMD application to treat intrabony defects seem to be associated with little intraoperative and post-operative pain or discomfort. Post-operative morbidity (interference with daily activities) was detected in a minority of

patients. When present it lasted for an average of 3–3.5 days. These data were consistent with the professional assessment of the healing outcomes: no suppuration was detected, edema and hematoma were a rare occurrence and only detectable by intraoral inspection; wound dehiscence at the incision of the papilla preservation flap was limited in size and detected in a minority of treated cases. Using a composite index based on stringent parameters, complicated healing was detected in one out of five patients. A multivariate model, however, indicated that the presence of these ''small'' healing complications did not have a significant impact on the observed gains in CAL at 1 year.

The reported frequencies of adverse healing events are broadly in agreement with those reported in two previous trials from this research group that used similar methodology and criteria (Cortellini et al. 2001, Sanz et al. 2004). These studies, however, assessed the adverse healing events associated with the use of resorbable barrier membranes against papilla preservation flap alone or in combination with EMD application. In those studies, the groups treated with barrier membranes presented with significantly higher frequencies of wound dehiscence and thus membrane exposure. In the current study, the presence of an adverse healing outcome was detected in a minority of cases and did not significantly affect the 1-year outcome. These observations can be interpreted as an indication that papilla preservation flaps used alone or in combination with the application of biological modulators heal with remarkably few complications and that the outcomes are not significantly affected by the small post-operative complications encountered in this study. Complications associated with the application of membranes under the papilla preservation flaps, on the other hand, had a significant negative impact on clinical outcomes (Sanz et al. 2004). This seems to be in agreement with the notion that the application of biological agents to promote healing of periodontal defects may be more forgiving than the use of barrier membranes: membrane exposure has been associated with impaired outcomes (Falk et al. 1997).

The most frequently detected adverse healing event was the presence of root sensitivity, with up to 45% of test patients reporting it. Its frequency peaked at week 3 and slowly decreased thereafter. In this study, no objective measure of root sensitivity was included and the questionnaire does not allow discrimination of the type of stimulus eliciting it or its intensity. Further investigations are needed to better explore this important aspect. It should also be noted that root conditioning with EDTA gel performed both in the test and control subjects may have influenced the reported levels of root sensitivity.

Of interest was the analysis of tissue density in the supracrestal region above the defect during the first 12 weeks following surgery. In this analysis, performed with computer-assisted densitometry of underexposed radiographs (Fourmousis et al. 1994), control sites displayed a significant decrease of tissue density over the first 6 post-operative weeks, with soft-tissue density reaching above the baseline values by week 12. EMD-treated sites, however, displayed a significantly different response: already at week 2 the average soft-tissue density was above baseline and by week 6 had reached the values observed in both test and controls by week 12. Differences between test and control tissue densities were significant over the initial 6 weeks. These data support the clinical observation that EMD-treated sites display a more rapid healing with little clinically evident inflammation. These data are also in agreement with recent reports from this research group, which have indicated that periodontal ligament fibroblasts exposed to EMD express less inflammation associated genes and more growth factors (Brett et al. 2002, Parkar & Tonetti 2004).

At 1 year, the level of overall patient satisfaction with both test and control surgical procedures was high. The most significant perceived improvements were in the ''health of the gums'' and the ''ability to clean the operated area''. The major perceived benefits were the preservation of the tooth/dentition and maintenance/improvement of chewing ability. Only very few patients did not perceive a benefit from the procedures (1–5%). With regard to disadvantages, 40–45% of subjects perceived that there were no major disadvantages from the surgery. The most frequently reported disadvantages from the procedures were the cost and the need for frequent follow-ups. These data portray a highly positive perception of periodontal surgery. Some caution in interpretation, however, seems appropriate. It should be noted that the questionnaire was not empirically developed based on patient response and observations but rather it was developed based on possible benefits and disadvantages identified by the authors and used as the basis for questionnaire development. Such an approach may have biased the outcome. The data, however, clearly indicate what the areas of concern to patients are and thus can be an important step in developing better tools to assess patient perceptions of surgical/regenerative outcomes.

## Acknowledgments

This study was partly supported by ERGOPERIO, Switzerland, the Clinical Research Foundation (CRF) for the Promotion of Oral Health, University of Berne, the Accademia Toscana di Ricerca Odontostomatologica (ATRO), Firenze, Italy, the Periodontal Research Fund of the Department of Periodontology of the Eastman Dental Institute, University of London, UK and a research grant from Biora AB, Malmö, Sweden. The authors wish to express their gratitude to Dentaid SA, Spain, for kindly providing the oral hygiene aids used in the post-operative phase.

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