Periodontal regeneration compared with access-flap surgery in human intra-bony defects, 20-year follow-up of a randomised clinical trial: tooth retention, periodontitis recurrence and costs

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AIMS

Persistent deep pockets associated with intra-bony defects represent an increased risk for tooth loss and the recurrence and progression of periodontitis. Over time, different treatment approaches have been proposed, including flap surgery and periodontal regeneration, and it has been observed that regenerative approaches can obtain greater gains in clinical attachment level (CAL) and reductions in probing pocket depth (PPD). However, the stability of the results obtained with regenerative and non-regenerative treatment modalities over a follow-up period longer than 15 years had not been compared.

• To compare the clinical stability of three treatment modalities (two different regenerative approaches and flap surgery alone) for intra-bony defects, over a follow-up period of 20 years of supportive periodontal therapy (SPT).
• To perform a recurrence analysis to evaluate the costs of the reinterventions required for each group.

METHODS

This article describes the 20-year follow-up of participants in a previous randomised clinical trial (RCT), first published by Cortellini et al. (1995). After basic periodontal therapy, 45 patients with 45 intra-bony defects (without furcation involvement) were randomly assigned to three treatment modalities: (1) titanium reinforced e-polytetrafluoroethylene (e-PTFE) membranes and modified papilla preservation technique (MPPT Tit group); (2) e-PTFE membrane with access flap (Flap e-PTFE group); and (3) access flap alone (Flap group).

SPT was performed every month during the first year and every three months during the rest of the 20-year follow-up in a private-practice setting. Disease recurrence at treated teeth was considered when an increase in PPD ≥2mm with persistent bleeding on probing was detected by the hygienists in the SPT visits, and when CAL loss ≥2mm was confirmed by a calibrated examiner. These sites received additional therapy, either non-surgical (scaling and root planning) or surgical (access flap or regenerative surgery).

Descriptive and analytic statistical analyses were performed, and the main outcome variables were mean changes in CAL, mean changes in PPD, and tooth loss. The number of recurrences in each group and the cost of the additional treatments were also assessed.

Baseline – one year:
- No statistically significant differences were detected at baseline.
- After one year, CAL gain was larger for the MPPT Tit group, followed by Flap e-PTFE and Flap alone. Residual PPD was higher in the Flap group compared to MPPT Tit and Flap e-PTFE (Cortellini et al., 1995).

20-year outcomes:
- Four patients were lost for follow-up (one in the MPPT Tit group, one in the Flap-alone group, and two in Flap e-PTFE). All remaining patients complied with the three-months SPT programme.
- Tooth loss: only two teeth were lost, both in the Flap-alone group.
- CAL changes: the Flap-alone group showed a statistically significant greater CAL loss compared to MPPT Tit (1.4±0.4mm; p=0.008) and Flap e-PTFE (1.1±0.4mm; p=0.029); no differences were observed between the two groups with regenerative approaches.
- Disease recurrence was detected in all groups, but it was more frequent in the Flap group (15 events in eight patients), than in MPPT Tit (five events in four patients) and Flap e-PTFE (six events in five patients). When recurrence was stratified according to the one-year residual PPD, a correlation between sites with PPD ≥5 mm and a higher frequency of recurrences that required reintervention (p=0.0024, R²=0.31) was observed.
- Need for reintervention: 26 recurrences required reintervention with SRP (21/26), flap surgery (2/26), regenerative surgery (1/26), or tooth extraction (2/26). The highest number of reinterventions was in the Flap group (15/26), followed by the Flap e-PTFE (6/26) and MPPT Tit (5/26) groups. The Odds Ratio (OR) that any visit requires a reintervention were compared and the Flap group showed an OR=3.4 (p=0.013) compared to the MPPT Tit group, and OR=2.6 (p=0.042) compared to the Flap e-PTFE group. No statistically significant differences were detected between the two regenerative groups.
- Average costs: both regenerative approaches had higher costs (€1,183) at the initial intervention compared to Flap alone (€549). However, the mean costs for the reintervention were higher for the Flap group (€501.27 ±€210.54), when compared to Flap e-PTFE (€159.00 ±€88.95) and MPPT Tit (€99.79 ±€54.14).

**LIMITATIONS**
- External validity, because the study represented a best-case scenario (highly motivated, mostly non-smoking subjects, treated in a private clinical setting with a high standard of periodontal care). As a result, larger groups and different clinical settings will be needed.
- The results are pilot in nature, so they will have to be confirmed in larger trials.

**CONCLUSIONS**
- Three surgical treatment modalities can be successful in the treatment of deep intra-bony defects and the results can be maintained for 20 years with regular SPT. However, sites treated with regeneration were clinically more stable, while those treated with flap surgery alone were associated with more episodes of recurrence.
- Regeneration provided better long-term benefits based upon greater short-term CAL gain, absence of tooth loss, less periodontitis progression, and less need for reintervention.
- The cost of the initial treatment was higher for regenerative approaches. Nevertheless, the cost of reintervention becomes progressively higher over a 20-year period for flap alone when compared to regenerative procedures.

**IMPACT**
- Clinicians should consider the long-term advantages of applying regenerative surgery when treating deep intra-bony defects.
- The cumulative cost analysis underlines that the initially higher costs of periodontal regeneration are partly offset by the lower need for and lower cost of retreatment.