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Evaluation of Gain in Clinical Attachment and Bone Levels after Treatment of Patients with Intra-bony Defects by Minimally Invasive Surgical Technique versus Open Flap Debridement: A Randomized Controlled Clinical Trial.

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Abstract

Background: Flaps used in surgical therapy of deep periodontal pockets include traditional access flap surgeries as open flap debridement (OFD). These flaps involve relatively large incisions and extension into non-periodontally involved areas which result in attachment loss and lead to morbidities like thermal sensitivity, food impaction and compromised esthetics due to gingival recession and can lead to scarring and edema during wound healing. Minimally invasive surgeries aim to have an advantage over conventional techniques by proving to be a less invasive technique with maximum benefits. Hence the goals of minimally invasive surgeries are less access trauma, maintain quality of surgical procedures, be less invasive: less pain and fast recovery with least physical discomfort during and post-surgery, no visible post-healing scarring. The purpose of this study was to evaluate the gain in clinical attachment and bone levels after treatment of the intra-bony defects by minimally invasive surgical technique when compared to open flap debridement.

Methodology: Seven healthy individuals (3 Males, 4 females) with twenty-two deep periodontal intra-bony defects were included in the study which satisfied for

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the eligibility criteria and completed follow up period. Each patient had preoperative and postoperative standardized periapical radiograph and measurement of periodontal parameters by a blinded examiner. After completion of phase 1 therapy, the patients were randomly assigned into 2 groups. In the test group, the patients were treated with minimally invasive periodontal surgeries while the control group patients were treated with the conventional open flap debridement.

Results: The results of the current study showed that from baseline - 3 and baseline - 6 months postoperatively, there was a statistically significant difference in CAL gain, PD reduction within both the groups and there was no significant difference between both groups at any time intervals. The postoperative bone gain was minimal but statistically significant between baseline and 6 months in both groups, with no statistically significant difference between the 2 groups.

Conclusions: Within the limitations of the present study, it can be concluded that Minimally invasive surgical techniques and open flap debridement were closely effective in improving the clinical parameters including clinical attachment gain, probing depth reduction and bone gain.

Introduction

Periodontitis is a chronic inflammatory disease destroying the tooth supporting attachment apparatus which may lead to tooth loss and considered a potential hazard for the development of systemic diseases (Pihlstrom et al. 2005; Könönen et al. 2019)the mildest form of periodontal disease, is caused by the bacterial biofilm (dental plaque. To repair the damage, traditional periodontal surgery, such as open flap debridement, has often been used over the last decades (Harrel et al. 1999; Trombelli and Farina 2008). The purpose of periodontal surgery is to reconstruct the attachment apparatus with the preservation of the pre-surgical soft tissue's contour and height (Trombelli & Farina, 2008). The conventional periodontal surgery is to raise large flaps to completely and exceedingly expose the area of interest and aims to reconstruct the attachment apparatus with the preservation of the pre-surgical soft tissue's contour and height. This gave results that seemed unsatisfactory due to large flap reflection possibly reduces regenerative potential and causes gingival recession over time (**Kao et al. 2015**).

Minimally invasive surgery (MIS), as a modern surgical procedure was introduced into the periodontal field with the intent to treat multiple and isolated periodontal intra-bony defects (Harrel and Rees 1995; Harrel et al. 2005; Cortellini and Tonetti 2007 and Cortellini et al. 2008). MIS was claimed to offer postsurgical comfort, less chair time, faster wound healing, and lower morbidity, less postoperative recession over time, compared with traditional periodontal surgeries (Harrel et al. 1999 and Tonetti et al. 2002)roots were conditioned for 2 min with a gel containing 24% EDTA. EMD was applied in the test subjects, and omitted in the controls. Postsurgically, a strict plaque control protocol was followed. At baseline and 1 year following the interventions, clinical attachment levels (CAL. There are not enough studies comparing the MIS to Open Flap Debridement (OFD).

Subjects and methods

The present study is a randomized controlled trial (RCT), two arms parallel group with 1:1 allocation ratio and equivalence framework. Ethics approval by the Human Research Ethics committee at Faculty of Dentistry- Cairo University was taken. All subjects participated in this trial, signed a written consent and fully agreed to participate in this work. This trial included 26 intra-bony defects in 9 patients suffering from periodontitis. Two of the patients with 2 defects for each, did not attend their follow up appointments, so they were considered drop outs, so total of 22 defects had completed their follow ups and were included in this study. The inclusion criteria were at least one periodontal pocket (infrabony defect detected radiographically) with PD \geq 5 mm, after phase I therapy in addition to clinical attachment loss and Plaque index < 20 % (**O'Leary et al. 1972**). The exclusion criteria were hopeless tooth, Previous periodontal surgery within the last 2 years in the area of interest, Systemic conditions which are generally considered to be a contraindication to periodontal surgery which included but not limited to: osteoporosis, diabetes mellitus, Pregnant or lactating females, Current or former smokers, and Non-compliant patients.

Treatment Protocol:

I. Pre-surgical phase:

Initial examination, including full mouth probing and radiographic examination, was performed for the selected patients. Full mouth supra and subgingival debridement was performed using ultrasonic device (Woodpecker UDS-P with LED, China) with supra-gingival scaling inserts followed by Gracey curettes (HuFriedy universal and Gracey curette; HuFriedy, Chicago, USA) for proper subgingival debridement. Patient preparation was completed in 2-3 visits, over two weeks. Local anesthesia was used for patient comfort. 0.12 % chlorhexidine HCL mouth rinse (Hexitol) twice daily was prescribed for 2 weeks. After 6 weeks from the initial periodontal therapy, re-evaluation was performed to confirm the need for periodontal surgery. Blinded periodontist recorded the clinical measurements prior to surgery using a University of North Carolina periodontal probe, to the nearest 0.5 mm.

Periapical digital radiographs using Phosphor storage plate "size 2" using right angle long cone parallel technique to detect alveolar bone level, Minray machine, exposure parameters were 70 kVp, 7 mA, and 0.08 seconds exposure time. In order to standardize the images across the study, X-Ray XCP Holder kit (**KerrTotalCare**, Switzerland) was used and custom-made bite block using acrylic resin was fabricated for each case. Using Digora software (Digora for windows 2.5[™], SOREDEX Inc., Tuusula, Finland), linear measurements were made on digital periapical radiographs to assess the amount of alveolar bone defect.

Patients were randomly assigned to either test or control group using computer generated randomization (www.randomizer.org) to avoid detection bias. Clinical photographs were taken at baseline, during surgery, 3 months and after 6 months postoperatively.

II. Surgical phase:

After a period of 6 weeks from initial therapy, patients fulfilling the inclusion criteria were recalled and scheduled for surgery. Each defect was allocated into one of the two groups: Group A (Test): Patients receiving minimally invasive surgical technique. Group B (Control): Patients receiving Open Flap Debridement. For both groups, the operator anesthetized the surgical sites with 4% Articaine HCl with 1:100,000 epinephrine. For the minimally invasive surgical technique, it was carried out with 2.5X optical magnification dental loupes. After local anesthesia, an envelope flap without vertical releasing incisions was performed. Sulcular incisions were performed following the gingival margin of the teeth adjacent to the defect associated papilla. The defectassociated interdental papilla was accessed either with the simplified papilla preservation flap (SPPF) in narrow interdental spaces (\leq 2 mm) or the modified papilla preservation technique (MPPT) in large interdental spaces $(\geq 2 \text{ mm}).$

In the SPPF, a diagonal incision traced as close as possible to the buccal side of the papilla col was performed, whereas in the MPPT a horizontal incision traced on the buccal side of the papilla was done. Intrasulcular incisions were performed from the interdental side to the buccal and lingual sides of the teeth neighboring the defect; tiny buccal and lingual flaps were elevated to expose the bone crest. The soft tissue was sharply dissected from the osseous defect. All incisions were done using microsurgical ophthalmic blades. Buccal and lingual flaps were elevated using sharp dissection only. Defect debridement and root planing were performed with a combination of mini-curettes. Then sutures were placed using 6-0 vicryl modified vertical internal mattress suture. In the control group (OFD), buccal and lingual intra-sulcular incisions were done extending at least one tooth mesial and distal to the tooth associated with the intra-bony defect. Full thickness mucoperiosteal flaps were reflected to allow access for debridement of the defect. Surgical debridement was carried out to remove any subgingival plaque, calculus and granulation tissue using Gracey curettes. Surgical flaps were then sutured to the presurgical level with 5-0 black silk interrupted suture.

Postoperative medication and instructions

Administration of E-mox (500 mg tabs) T.I. D for 7 days) (**Steffer 2013**), and Chlorhexidine rinse 0.12% Hexitol (B.I.D for 14 days).Patients were asked to abstain from mechanical plaque control procedures in the surgical area for 2 weeks. Sutures were removed 2 weeks postsurgically. Three weeks post-surgically, the patients were instructed to gently brush the operated area with a soft toothbrush with roll technique.

Statistical analysis:

Numerical data were presented as mean, standard deviation (SD) and confidence interval values. Data were explored for normality by checking the data distribution, calculating the mean and median values and using Kolmogorov-Smirnov and Shapiro-Wilk tests. Parametric data were analyzed using independent t-test for intergroup comparisons and one-way repeated measures ANOVA followed by Bonferroni post hoc test for intra group comparisons. On-parametric data were analyzed using Mann Whitney U test for intergroup comparisons and Friedman's test of repeated measures followed by multiple pairwise comparisons utilizing Wilcoxon signed-rank test with Bonferroni correction for intragroup comparisons. The significance level was set at P ≤ 0.05 within all tests. Statistical analysis was performed with IBM SPSS Statistics

Version 25 for Windows.

Results

intra-bony defects Twenty-two were enrolled for this study and were randomly allocated to both groups i.e. (11 defects) per group. (72.7%) (8 defects) of the (MIST) group were in males, while (27.3%) (3 defects) were in females. For (OFD) group, (45.5%) (5defects) were in males, while (54.5%) (6) were in females and there was no significant difference in gender distribution in both groups (p=0.193). The mean age value in the (MIST) group was (33.64 ± 3.26) , while for (OFD) group it was (32.27 ± 2.05) and there was no significant difference in ages of participants in both groups (p=0.255).

Regarding the CAL, the MIST group showed a statistically significant difference between baseline with a mean value (6.54 ± 0.93) and 3 months (3.82 ± 1.08), and between baseline (6.54 ± 0.93) and 6 months (4.00 ± 1.18) (p<0.001) with no statistically significant difference between 3 (3.82 ± 1.08) and 6 months (4.00 ± 1.18). while for the OFD group there was a statistically significant difference between baseline with a mean value (8.00 ± 2.14) and 3 months (4.64 ± 1.43), and between baseline (8.00 ± 2.14) and 6 months (4.72 ± 1.19) (p<0.001) with no statistically significant difference between 3 (4.64 ± 1.43) and 6 months (4.72 ± 1.19).

When comparing both groups, at baseline the OFD group (8.00 ± 2.14) had a higher mean value than MIST group (6.54 ± 0.93) (p= 0.059). At 3 months: OFD group (4.64 ± 1.43) had a higher mean value than MIST group (3.82 ± 1.08) (p= 0.146). at 6 months: OFD group (4.72 ± 1.19) had a higher mean value than MIST group (4.00 ± 1.18) and there was no statistically significant difference at all time intervals between both groups (p= 0.166). The was no significant difference between both groups for the CAL gain between baseline- 3 months, baseline- 6 months and 3- 6 months.

For the probing depth, the MIST group showed a statistically significant difference

between baseline with a mean value (6.27 ± 0.65) and 3 months (3.27 ± 0.65) , and between baseline (6.27 ± 0.65) and 6 months (3.45 ± 0.69) (p<0.001). While there was no statistically significant difference between 3 (3.27 ± 0.65) and 6 months (3.45 ± 0.69) . Although for the OFD group that showed a statistically significant difference between baseline with a mean value (7.09 ± 1.51) and 3 months (3.64 ± 0.92) , and between baseline (7.09 ± 1.51) and 6 months (3.45 ± 0.69) (p < 0.001). While there was no statistically significant difference between 3 (3.64 ± 0.92) and 6 months (3.45 ± 0.69) . At baseline: OFD group (0.45 ± 0.52) had a higher mean value than MIST group (0.36 ± 0.50) . At 3 months: OFD group (0.91 ± 0.70) had a higher mean value than MIST group (0.82 ± 0.75) . While at 6 months, both groups had the same mean value (3.45±0.69) with no significant difference between both groups (p=1.000) at all time intervals. The was no significant difference between both groups for the PD reduction between baseline- 3 months, baseline- 6 months and 3-6 months.

For the Radiographic outcome (Bone level), MIST group recorded significantly higher Mean value at baseline (4.24 ± 1.33) than that after 6 months (4.10 ± 1.30) (p<0.001). although for OFD group, the mean value recorded at baseline (3.98 ± 1.42) was significantly higher than value recorded after 6 months (3.88 ± 1.43) (p<0.001). MIST group (0.14 ± 0.10) had a higher mean value for the bone gain after 6 months than OFD group (0.10 ± 0.07) but the difference was not statistically significant (p= 0.428) as shown in the following table.

Discussion

Classic techniques such as OFD with the large flap reflection for access compromises blood supply to the area, which possibly reduces regenerative potential and causes gingival recession over time. Thus, new techniques have been sought to achieve periodontal regeneration without the drawbacks associated with conventional flap surgery (**Kao et al.** 2015) both reviewers read the full-text version of potentially eligible studies, made a final article selection, and extracted the data of the selected studies considering specific clinical scenarios. The clinical scenarios contemplated in this review included the following: 1. An alternative approach to access the intrabony defects is through minimally invasive techniques. All the patients were selected to be free from any systemic condition such as diabetes mellitus which lowers resistance to infection with propensity for delayed wound healing that may affect the clinical outcomes (Steffer et al. 2013). Smokers were excluded from this study as recommended by **Ryder** 2007 who reported that smoking might have detrimental effect on the treatment outcomes in a variety of periodontal procedures.

Regarding the CAL in the MIST treated sites, The CAL gain for the MIST group between baseline-6 months has a mean value was (2.54 mm ±1.13). These results are in accordance to those obtained by the study done by **Losada et al. 2017** who reported, using MIST with EMD, a mean CAL gain after 6 months of 3 mm. In addition, **Cortellini and Tonetti 2007 and Corbella et al., 2019** obtained a statistically significant CAL gain using MIST with a mean value of 4.8 mm and 4.3 mm respectively. The higher value in CAL gain obtained in the study of **Cortellini and Tonetti 2007** might be attributed to the longer follow up period 1 year.

As for the OFD treated sites, These results were in accordance with **Patel et al. 2017** who reported a statistically significant difference in the CAL between baseline with a mean value of (6.8 mm) and at 6 months (5.9 mm) with a minimal mean CAL gain of 0.9 mm which increased later to 1.5 mm and 2.1 mm at 9 and 12 months.

Regarding the probing depth of the MIST group, **Fickl et al. 2009** reported similar results after using MIST in management of deep periodontal pockets. They found a statistically significant difference between pocket depths mean values between baseline and 6 months with a mean pocket depth reduction value 2.1 mm.

While for the OFD group in the current study, the results were in accordance with the results of **Steffer et al. 2013** who reported a statistically significant difference between the PD mean value at baseline (5.5 mm \pm 1.3) and at 6 months (3.3 mm \pm 0.7) with a PD reduction of 2.2 mm.

Conclusions

Within the limitations of the present study, it can be concluded that minimally invasive surgical techniques and open flap debridement were closely effective in improving the clinical and radiographic parameters including clinical attachment gain, probing depth reduction and bone gain.

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