

Randomized Controlled Trial (RCT)

Conventional versus laser gingivectomy in the management of gingival enlargement during orthodontic treatment: a randomized controlled trial

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Summary

Objectives: To compare the use of diode laser with conventional surgery evaluating the effectiveness of gingivectomy as an adjunct to non-surgical periodontal treatment in the management of gingival enlargement (GE) during orthodontic treatment.

Trial design: Prospective three-arm parallel group randomized clinical trial with 1:1:1 allocation ratio.

Methods: Sixty subjects (33 males and 27 females), with a mean age of 14.4 ± 1.9 years, were selected according to inclusion criteria: overgrown gingivae on the labial side of the anterior teeth secondary to fixed appliance therapy, six maxillary anterior teeth present, and healthy non-smokers patients. Patients were enrolled in the study and randomly assigned to three groups by a computer-generated randomization list and by a block size of 4. The allocation information was concealed in opaque and sealed envelopes by the statistician. In the first group, all subjects underwent a conventional scalpel gingivectomy of the maxillary anterior sextant. In the second group, all subjects were treated using laser-assisted gingivectomy; while subjects assigned to the third group underwent only non-surgical periodontal treatment and served as control group (CG). The observer who performed all the measurements was blinded to the group assignment. Blinding was obtained by eliminating from the elaboration file every reference to patient group assignment. Intergroup comparisons of changes in the periodontal parameters were conducted at 1, 3, and 6 months using ANOVA with repeated measures and Tukey's *post hoc* tests. The significance level was set at $P < 0.05$.

Results: After 1 month, the TGs showed a significant improvement of all periodontal parameters when compared with the CG. No statistically significant differences were observed between the two TGs. At the 3-month observation, a relapse occurred in the TGs, while the CG showed the greater improvement of soft tissue health. In the 6-month versus 3-month evaluation, no significant differences between the three groups were found for any periodontal measurements. In the long-term evaluation (6 months versus baseline), a significant greater reduction of pockets were found in the TGs when compared with the CG.

Conclusions: The adjunct use of both scalpel gingivectomy and laser gingivectomy was more effective in controlling gingival inflammation than non-surgical periodontal treatment alone at 1, 3 and 6 months. In the control group, greater improvement in the periodontal parameters were

observed within 3 months, depending on a self-care approach for the management of GE.

Limitations: This study was a short-term study (6-month follow-up).

Trial registration: [ClinicalTrials.gov](https://clinicaltrials.gov) (registration number: NCT03514316).

Introduction

Orthodontic fixed appliances can be associated to chronic periodontal inflammation and gingival enlargement (GE) due to increased plaque stagnation and poor oral hygiene (1,2). The mechanism by which GE occurs in some patients during orthodontic treatment is not fully understood. The initiation and development of periodontal disease depend on a dynamic equilibrium between the microbial challenge and the host's immune-inflammatory responses (3). The presence of fixed appliances influences plaque accumulation around the retentive components attached to the teeth and the colonization of important periodontopathic bacteria (4). Kloehn and Pfeifer (5) have shown that mechanical irritation by bands, chemical irritation by cements, food impaction, and less efficient oral hygiene maintenance are etiologic factors for orthodontic treatment-induced gingival overgrowth. Chronic inflammation of the soft tissues is caused by a significant increase in oedema and inflammatory cells that can influence the subgingival ecosystem by creating an appropriate anaerobic environment, leading to a shift in the composition of the microflora (6). When gingival tissues are enlarged, varying from mild enlargement of isolated interdental papillae to segmental or uniform and marked enlargement affecting one or both jaws, the tooth surfaces become difficult to access, inhibiting good oral hygiene and resulting in more inflammation and bleeding because enlarged gingival tissues (7). In artificially deeper periodontal pockets, the root surfaces are contaminated with an accumulation of plaque and calculus, as well as infiltration of bacteria and bacterial endotoxins into cementum. Complete removal of these harmful substances is essential for the healing of periodontal tissue (8,9). However, non-surgical periodontal treatment (including oral hygiene instruction, scaling, and prophylaxis) is not always effective when GE is extensive and self-care is compromised.

When GE further impedes the maintenance of oral hygiene (resulting in further damage to periodontal tissues), causes aesthetic and functional problems, and compromises orthodontic tooth movement, it is necessary to provide additional treatment such as gingivectomy, in order to correct gingival border contours (10).

Gingivectomy can be performed by conventional scalpels, electrosurgery, chemosurgery, and laser. The elimination of the pseudo pockets is the therapeutic endpoint of all these procedures (11,12). The conventional surgery performed by a small scalpel has been considered the most common method because of its ease of use, accuracy, and minimal damage to tissue (13). However, scalpels do not provide a good haemostasis, which is important on highly perfused tissues such as inflamed gingiva (14). The advent of diode lasers highly absorbable by melanin and haemoglobin allows soft tissue manipulations providing sound results in periodontal surgery, tissue alterations related to orthodontic treatment, and oral lesions (15). The diode laser separates and coagulates at the same time, facilitating immediate haemostasis and resulting in minimal bleeding. Healing is rapid and there is reduced potential for infection. The diode laser has an affinity for only soft tissue, thereby preventing damage to the surrounding bone and enamel (16). Therefore, using diode lasers might be advantageous because of better control, potentially lower pain and inflammation, and improved wound healing (17). Mavrogiannis *et al.* (18) compared conventional gingivectomy

with flap surgery and with laser excision in the management of drug-induced gingival overgrowth, reporting that laser excision results in a reduced rate of recurrence. To *et al.* (1) analyzed diode laser gingivectomy as an adjunct to non-surgical periodontal treatment reporting an earlier and greater improvement in gingival health by using lasers. Ize-Iyamu *et al.* (19) compared the diode laser with conventional surgery in orthodontic soft tissue procedures reporting that orthodontic patients treated with the diode laser required less infiltration anaesthesia, presented reduced bleeding during and after surgery, rapid postoperative haemostasis, elimination of the need for sutures, and an improved postoperative comfort and healing.

However, in literature, no studies directly compared conventional scalpel surgery versus diode laser-assisted surgery in orthodontic patients with GE, and the majority of studies (1,18,19) investigating laser-assisted surgery show some limits: they are not randomized, they are not prospective, and they have no control group in which no surgery is performed.

The null hypothesis underlying this investigation is that gingivectomy does not improve gingival health in patients undergoing fixed treatment beyond what can be obtained from non-surgical periodontal therapy.

Therefore, the aim of the present study was to evaluate the effectiveness of gingivectomy as an adjunct to non-surgical periodontal treatment in the management of GE during orthodontic treatment and to compare the use of the 810 nm diode laser with conventional surgery for gingivectomy procedure.

Materials and methods

Study design

The Consolidated Standards of Reporting Trials (CONSORT) checklist was used as a guideline for conducting and reporting this trial. The present RCT was designed as a prospective three-arm parallel group randomized clinical trial with 1:1:1 allocation ratio.

The study was approved by the Ethics Committee at the University of Rome 'Tor Vergata' (protocol number 206/17). After a full explanation of the nature, purpose, and material risks of the proposed procedures, informed consent was obtained from patients or from patients' parents for juvenile subjects. The trial was registered on [ClinicalTrials.gov](https://clinicaltrials.gov) (registration number: NCT03514316).

Population

Patients presenting with Class I malocclusion and crowding <6 mm undergoing orthodontic treatment at the Department of Orthodontic of the University of Rome 'Tor Vergata' were selected according to the following inclusion criteria: overgrown gingivae on the labial side of the anterior teeth secondary to fixed appliance therapy, six maxillary anterior teeth present, and healthy non-smokers patients. Patients with the following conditions were excluded from the study: patients with poor oral hygiene (FMPS > 25%); patients with mucogingival infection; patients taking medications that may cause drug-associated gingival enlargement (e.g. calcium channel blockers, anticonvulsants, or immunosuppressants); patients currently pregnant or lactating;

and patients with any medical condition affecting wound healing. Gingival overgrowth diagnosis was defined as presence of quadratic anterior teeth (crown width/length ratio ≤ 0.85) (20), gingival margin located incisal to the tooth cervical convexity (21), and presence of probing pocket depth (PPD) ≥ 4 mm coronal to the cement-enamel junction (CEJ). In order to exclude cases with altered passive eruption—subgroup B (22), in which bone crest was at the same level of the CEJ—a transgingival probing was performed after anaesthesia.

Treatment

All subjects who met inclusion criteria received instructions on oral hygiene. Patients who had not maintained adequate oral hygiene during treatment, although they received instructions, and who presented with hypertrophic gingival margins were enrolled in the investigation after orthodontic levelling and alignment in order to finish orthodontic treatment in terms of smile aesthetics. Subjects enrolled in the study were randomly assigned to the three groups: conventional scalpel gingivectomy (TG1: treatment group 1), laser-assisted gingivectomy (TG2: treatment group 2), and non-surgical treatment (CG: control group).

Scalpel gingivectomy (TG1).

Patients were anaesthetized with 2% lidocaine and 1:80 000 adrenalin. When sufficient anaesthesia was achieved, transgingival

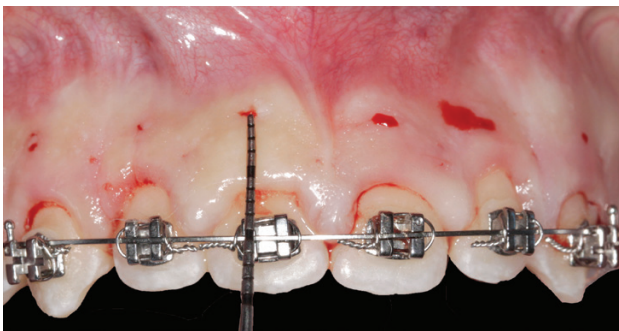


Figure 1. Evaluation of maximum amount of tissue removal. An explorer was used to mark reference spots of the biologic zone, serving as the visual finishing point.



Figure 2. External bevel incision performed by using a scalpel blade and gingival tissue excised.

probing was performed in order to mark a reference point serving as the visual finishing point indicating the CEJ (Figure 1). Once the amount of gingival tissue to be excised was demarcated, an external bevel incision was performed by using a scalpel blade (No. 15c) and the gingival tissue was excised with curettes. Left out tissue tags and any beads of granulations tissue were removed to attain a smooth surface (Figure 2).

Laser gingivectomy (TG2).

After the area was adequately anaesthetized with 2% lidocaine and 1:80 000 adrenalin, the clinician and the patient put on safety precautions such as safety glasses for the concerned wavelength and a laser-assisted gingivectomy was performed (810 nm FOX III diode laser; Sweden&Martina, Due Carrare, Padova, Italy). The laser unit, comprising of a 300 μ m disposable tip, was used in a contact mode with a setting of 1–1.5 W in continuous mode along the previously demarcated area with a paint brush-like strokes progressing slowly to remove the gingival tissue and expose adequate amount of tooth structure. During the entire procedure, the tip was constantly checked for any debris of the ablated tissues and was cleaned with sterile moist gauze. High-volume suction was used to evacuate the laser plume and charred odour (Figure 3).

Patients of both TG1 and TG2 were checked for haemostasis and then a surgical dressing (periodontal pack, COE-PAK® Automix; GC International Inc., Newport Pagnell, UK) was applied on the surgical sites to promote healing for the first week. Patients were given all the postoperative instructions and rinsing with 0.12% chlorhexidine gluconate twice daily for 2 weeks was advocated (1,13). Patients were prescribed acetaminophen tablets to control their postoperative pain if necessary (18).

Non-surgical periodontal treatment (CG).

Full-mouth periodontal debridement was performed with mechanical and ultrasounds instruments. Chlorhexidine (0.12% chlorhexidine gluconate) was also administered twice a day for 2 weeks after the periodontal treatment.

Both treatment groups were treated by one clinician, with 10 years of experience in periodontal surgery (MC), while control group was treated by a dental hygienist. Periodontal maintenance with full-mouth periodontal debridement and instructions on oral hygiene was performed every 3 months for both TGs and CG.



Figure 3. Laser-assisted gingivectomy.

Outcome measurements

All periodontal measurements were recorded using a North Carolina periodontal probe. At baseline (before treatment), all patients of the three groups underwent a full periodontal screening, in order to assess oral hygiene (Full Mouth Plaque Score) and gingival inflammation (Full Mouth Bleeding Score). After that, the following measurements were assessed at three buccal points around each tooth of the anterior area (mesial, mid-point, distal) (23). Plaque Index (PI) of Silness and Loe (24) and Gingival Index (GI) of Loe and Silness (25); PPD, as the distance between gingival margin and the tip of the periodontal probe inserted into the sulcus with a force of 0.25 N; and clinical crown length (CCL), as the distance between incisal edge and gingival margin along the tooth long axis.

For TGs, CCL was assessed also just after surgery. All measurements were repeated at 1, 3, and 6 months post-surgery.

Before the initiation of the study, a calibration session was conducted on five patients not included in the study. Measurements of PPD and CCL were recorded twice at a distance of 1 week, in order to assess the intra-examiner agreement by means of intraclass correlation coefficients (0.877 and 0.965, respectively).

Randomization, allocation concealment and blinding

Allocation of patients to the three groups was determined by a computer-generated randomization list using Rv.0.1 software (26) and by a block size of 4 (Figure 4). Then, the allocation information (randomization results) was concealed in opaque and sealed envelopes by the statistician. The observer (AN) who performed all the measurements was blinded to the group assignment. The study was blinded in regard to the statistical analysis: blinding was obtained by eliminating from the elaboration file every reference to patient group assignment.

Sample size

A sample size for this trial was calculated according to the method proposed by Whitehead *et al.* (27). For a standardized effect size of 1 (a clinically relevant change of 0.75 mm with a combined SD of 0.68 mm derived from Mavrogiannis *et al.* (18)) for the primary outcome variable PPD at 3 months, a sample size of 17 subjects per group was required for a type I error rate of 5% and a power of 80%. To account for potential dropouts, 20 subjects per group were recruited.

Statistical analysis

The primary outcome was considered the reduction of PPD while secondary outcome was considered increased CCL.

Exploratory statistics revealed that all periodontal variables were normally distributed (Kolmogorov–Smirnov test) with equality of variances (Levene's test).

Overall patient data were calculated as mean values by averaging measurements in all sites of six upper anterior teeth. Intergroup comparisons of changes in the periodontal parameters were conducted at 1, 3, and 6 months using ANOVA with repeated measures and Tukey's *post hoc* tests. The significance level was set at $P < 0.05$.

All statistical computations were performed with SPSS software (Statistical Package for the Social Sciences, SPSS, version 12, Chicago, Illinois, USA).

Results

A total of 60 subjects (33 males and 27 females), with a mean age of 14.4 ± 1.9 years (range 11.7–19.8 years) were randomly assigned to the interventions. Two patients (one in TG2 and one in CG) were excluded since the bone crest was revealed at the same level of the CEJ during transgingival probing. During the follow-up, one dropout was observed in the TG1 and one drop-out was observed in the CG (Figure 4). The final sample that received the intended treatment

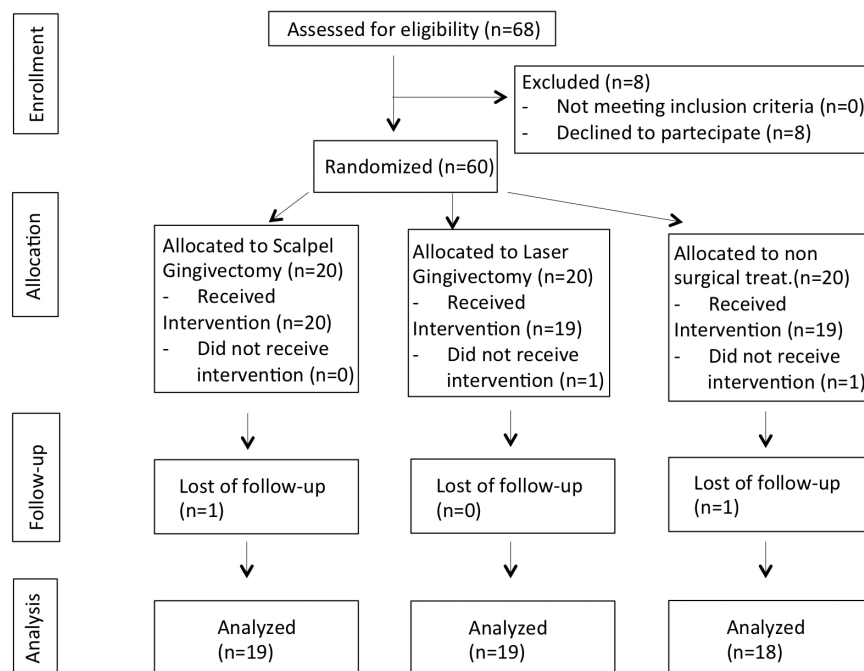


Figure 4. Study flow chart.

and analysis was composed of 56 patients (31 males and 25 females) with a mean age of 14.4 ± 1.9 years (range 11.7–19.8 years). The recruitment started in December 2016 and the observation period ended in May 2018. Descriptive statistics in periodontal parameters before treatment (baseline), immediately after surgery (for TGs), and at 1, 3, and 6 months postoperatively in the three groups are reported in Table 1. No significant differences between the TGs and the CG at baseline were found for any of the periodontal variables, and no significant changes were observed between groups at any follow-up periods for PI and GI.

A PPD reduction of 4.1 and 4 mm, with an increment of CCL of 2.9 and 2.4 mm, was immediately obtained by surgical procedure for laser and scalpel group, respectively (Table 1).

At 1-month versus baseline observation period, no statistically significant differences were observed for any of the analyzed variables between the two TGs. Both TGs presented with a significant

greater reduction of PPD (-2.6 mm TG1; -2.7 mm TG2) and significant greater increase of CCL ($+2.0$ mm TG1, 1.6 mm TG2) when compared with non-surgical group (CG). CG showed a light increased CCL ($+0.4$ mm) and a small reduction of PPD (-0.4 mm) with respect to baseline data (Table 2).

At the 3-month versus 1-month post-treatment observation, a relapse occurred in the TGs with a decrease of CCL (-1.1 mm TG1; -1.0 mm TG2) and an increment of PPD ($+0.7$ mm TG1; $+0.8$ mm TG2); while the CG showed a slight increase of CCL ($+0.3$ mm) and a reduction of PPD (-0.7 mm). As for the 1-month versus baseline changes, no statistically significant differences were pointed between the two TGs for all analyzed variables, while significant differences were observed comparing the TGs with the CG for all periodontal parameters (Table 3).

At 6-month versus 3-month observation, no significant differences were assessed between the three groups (Table 4).

Table 1. Descriptive statistics in periodontal parameters before surgery (baseline), post-surgery, and at 1, 3, and 6 months postoperatively in the three groups.

	Baseline mean \pm SD (95% CI)	Post-surgery mean \pm SD (95% CI)	1-month mean \pm SD (95% CI)	3-month mean \pm SD (95% CI)	6-month mean \pm SD (95% CI)
Laser group ($n = 19$; 9 males and 10 females)					
Clinical crown length (mm)	7.7 ± 0.8 (7.4–8.1)	10.6 ± 0.7 (10.2–10.9)	10.1 ± 0.8 (9.7–10.5)	9.0 ± 0.6 (8.7–9.3)	8.6 ± 0.6 (8.4–9.0)
Probing pocket depth (mm)	4.8 ± 1.0 (4.3–5.2)	0.7 ± 0.3 (0.6–0.9)	1.8 ± 0.4 (1.6–2.0)	2.5 ± 0.6 (2.2–2.7)	2.7 ± 0.5 (2.5–3.0)
Plaque Index* (0–3)	0.4 ± 0.2 (0.3–0.5)	—	0.6 ± 0.3 (0.3–0.9)	0.7 ± 0.4 (0.3–1.1)	0.6 ± 0.3 (0.3–0.9)
Gingival Index** (0–3)	0.3 ± 0.2 (0.2–0.4)	—	0.5 ± 0.2 (0.3–0.7)	0.6 ± 0.2 (0.4–0.8)	0.7 ± 0.3 (0.4–1.0)
Scalpel group ($n = 19$; 11 males and 8 females)					
Clinical crown length (mm)	7.9 ± 0.8 (7.6–8.3)	10.3 ± 0.8 (9.9–10.7)	9.9 ± 0.7 (9.5–10.2)	8.9 ± 0.6 (8.6–9.2)	8.6 ± 0.7 (8.3–8.9)
Probing pocket depth (mm)	4.9 ± 1.1 (4.4–5.4)	0.9 ± 0.3 (0.7–1.0)	1.8 ± 0.4 (1.7–2.0)	2.6 ± 0.6 (2.3–2.9)	2.9 ± 0.4 (2.7–3.1)
Plaque Index* (0–3)	0.4 ± 0.2 (0.3–0.5)	—	0.6 ± 0.3 (0.3–0.9)	0.5 ± 0.3 (0.2–0.8)	0.6 ± 0.3 (0.3–0.9)
Gingival Index** (0–3)	0.3 ± 0.2 (0.2–0.4)	—	0.5 ± 0.2 (0.3–0.7)	0.6 ± 0.3 (0.3–0.9)	0.7 ± 0.2 (0.5–0.9)
Control group ($n = 18$; 11 males and 7 females)					
Clinical crown length (mm)	7.6 ± 0.7 (7.2–7.9)	—	8.0 ± 0.7 (7.7–8.4)	8.3 ± 0.6 (8.0–8.6)	8.2 ± 0.7 (7.8,8.5)
Probing pocket depth (mm)	4.4 ± 0.5 (4.2–4.7)	—	4.0 ± 0.3 (3.9–4.1)	3.3 ± 0.4 (3.1–3.5)	3.8 ± 0.3 (3.7–4.0)
Plaque Index* (0–3)	0.6 ± 0.3 (0.4–0.7)	—	0.5 ± 0.2 (0.4–0.6)	0.4 ± 0.2 (0.3–0.5)	0.7 ± 0.3 (0.5–0.9)
Gingival Index** (0–3)	0.5 ± 0.2 (0.4–0.6)	—	0.4 ± 0.2 (0.3–0.5)	0.5 ± 0.2 (0.2–0.4)	0.6 ± 0.2 (0.5–0.7)

CI, confidence interval.

*Plaque Index: 0 no plaque; 1 mild accumulation of plaque on the free gingival margin; 2 moderate accumulation of plaque within the gingival pocket; 3 abundance of plaque within the gingival pocket.

**Gingival Index: 0 absence of inflammation; 1 mild inflammation; 2 moderate inflammation; 3 severe inflammation.

Table 2. Descriptive statistics and multiple comparisons (ANOVA with repeated measures and Tukey's *post hoc* tests) of the 1-month - baseline changes in all three groups.

	Laser group ($n = 19$; 9 males and 10 females)	Scalpel group ($n = 19$; 11 males and 8 females)	Control group ($n = 18$; 11 males and 7 females)	Laser group versus scalpel group	Laser group versus control group	Scalpel group versus control group	Laser group versus scalpel group	Laser group versus control group	Scalpel group versus control group
	Mean \pm SD			Diff.			P value (95% CI)		
Clinical crown length (mm)	2.4 ± 0.8	2.0 ± 0.8	0.4 ± 0.2	0.4	2.0	1.6	ns	0.000 (1.4–2.4)	0.000 (1.0–2.0)
Probing pocket depth (mm)	-3.0 ± 1.1	-3.1 ± 1.1	-0.4 ± 0.5	0.1	-2.6	-2.7	ns	0.000 (-3.3 to -1.8)	0.000 (-3.4 to -1.9)

CI, confidence interval; Diff, differences; ns, not significant, $P < 0.05$.

Table 3. Descriptive statistics and multiple comparisons (ANOVA with repeated measures and Tukey's *post hoc* tests) of the 3-month -1-month changes in all three groups.

	Laser group (<i>n</i> = 19; 9 males and 10 females)	Scalpel group (<i>n</i> = 19; 11 males and 8 females)	Control group (<i>n</i> = 18; 11 males and 7 females)	Laser group versus scalpel group	Laser group versus control group	Scalpel group versus control group	Laser group versus scalpel group	Laser group versus control group	Scalpel group versus control group
	Mean ± SD			Diff.			P value (95% CI)		
Clinical crown length (mm)	-1.1 ± 0.9	-1.0 ± 0.9	0.3 ± 0.3	-0.1	-1.4	-1.3	ns	0.000 (-1.9 to -0.8)	0.000 (-1.9 to -0.8)
Probing pocket depth (mm)	0.7 ± 0.7	0.8 ± 0.7	-0.7 ± 0.5	-0.1	1.4	1.5	ns	0.000 (0.9-1.8)	0.000 (0.9-1.9)

CI, confidence interval; Diff, differences; ns, not significant, *P* < 0.05.

Table 4. Descriptive statistics and multiple comparisons (ANOVA with repeated measures and Tukey's *post hoc* tests) of the 6 months-3 months changes in all three groups.

	Laser group (<i>n</i> = 19; 9 males and 10 females)	Scalpel group (<i>n</i> = 19; 11 males and 8 females)	Control group (<i>n</i> = 18; 11 males and 7 females)	Laser group versus scalpel group	Laser group versus control group	Scalpel group versus control group	Laser group versus scalpel group	Laser group versus control group	Scalpel group versus control group
	Mean ± SD			Diff.			P value (95% CI)		
Clinical crown length (mm)	-0.4 ± 0.3	-0.3 ± 0.3	-0.2 ± 0.2	-0.1	-0.2	-0.1	ns	ns	ns
Probing pocket depth (mm)	0.2 ± 0.1	0.3 ± 0.4	0.5 ± 0.5	-0.1	-0.3	-0.2	ns	ns	ns

CI, confidence interval; Diff, differences; ns, not significant, *P* < 0.05.

Table 5. Descriptive statistics and multiple comparisons (ANOVA with repeated measures and Tukey's *post hoc* tests) of the 6-month-baseline changes in all three groups.

	Laser group (<i>n</i> = 19; 9 males and 10 females)	Scalpel group (<i>n</i> = 19; 11 males and 8 females)	Control group (<i>n</i> = 18; 11 males and 7 females)	Laser group versus scalpel group	Laser group versus control group	Scalpel group versus control group	Laser group versus scalpel group	Laser group versus control group	Scalpel group versus control group
	Mean ± SD			Diff.			P value (95% CI)		
Clinical crown length (mm)	0.9 ± 1.1	0.7 ± 1.1	0.6 ± 0.3	0.2	0.3	0.1	ns	ns	ns
Probing pocket depth (mm)	-2.1 ± 1	-2.0 ± 1	-0.6 ± 0.5	-0.1	-1.5	-1.4	ns	0.000 (-2.1 to -0.9)	0.000 (-2.1 to -0.8)

CI, confidence interval; Diff, differences; ns, not significant, *P* < 0.05.

At 6 months versus baseline control, only a significant decrease of PPD in both TGs was observed when compared with CG (-1.5 mm TG1; -1.4 mm TG2) (Table 5; Figure 5).

Discussion

The primary objective of the present study was to test the efficacy of two different surgical techniques in the management of GE in patients undergoing fixed orthodontic appliance therapy. Orthodontic subjects are particularly suitable to conduct high-quality clinical trials because they are easily available for follow-up assessments. However, to our knowledge, no previous

studies in literature compared the use of the soft tissue diode laser with conventional surgery and with non-surgical periodontal treatment for GE treatment in orthodontic population. Moreover, the study design, i.e. a randomized controlled trial with sufficient power, ensured high scientific value. GE is one of the most common soft tissue problems associated with fixed appliance therapy, with a reported prevalence of almost 10% (1). Although the short-term effects of gingivectomy are well known (1-3, 8-10), in the present study, the long-term effects of the surgical procedures in patients with fixed appliances were observed, analysing the degree of relapse at 1, 3, and 6 months after the gingivectomy. In this way it was possible to evaluate as conventional surgery or laser-assisted surgery



Figure 5. (A) patient with gingival enlargement before laser-assisted gingivectomy; (B) the same patient at 6-month observation period.

influence gingival health respect to only non-surgical periodontal treatment, and if this procedure could be recommended for orthodontic population with GE.

Functional crown lengthening procedure involves either a gingivectomy or an open flap surgical technique with resective osseous surgery. Matter of choice between gingivectomy and open flap surgical technique depends upon several factors, as the width of attached gingiva and the position of the bone crest related to the CEJ (28). In our study, only patients with sufficient width of attached gingiva and bone crest >1 mm apical to the CEJ were collected (type 1A) (13). The conventional scalpel 45° gingivectomy was used as the standard approach. The alternative to scalpel excision was the laser gingivectomy, which offers several advantages as well as sterilization of the surgical field, reduced haemorrhage during excision, potential of prompt healing, and minimal postoperative discomfort (18).

Intragroup comparisons identified significant changes in periodontal parameters over time in both the TGs and the CG. After 1 month, the major changes in the TGs, with larger decrease of PPD mean value and the greater increment of the CCL mean value, were observed. After 3 and 6 months, a gradual relapse occurred in the same parameters, due to a decreased patient's compliance in maintaining good oral hygiene despite full-mouth periodontal debridement was performed every 3 months for both TGs and CG.

These results are in contrast with those of Mavrogiannis *et al.* (18) who found a lower rate of gingival changes between 1 month and 3 months, than that between 3 and 6 months suggesting that laser surgery appears to have a lower rate of recurrence of gingival overgrowth when compared with conventional gingivectomy. In the CG, significant variations in the periodontal parameters were observed within 3 months. Furthermore, the changes of the primary outcome (reduction of PPD) and secondary outcome (increase of CCL) were significantly smaller when compared with the TGs, depending on a self-care approach for the management of GE. After 6 months, a recurrence of gingival overgrowth also in the CG was observed. These results highlighted that non-surgical periodontal treatment can be effective in controlling gingival health problems only in the presence of a meticulous oral hygiene in the long period, while this therapy should not be recommended when GE is extensive and self-care is compromised.

Intergroup comparisons identified significant differences in the magnitude of changes in some of the clinical parameters between the TGs and the CG. The reduction of PPD and the increase of CCL were significantly greater in the TGs compared to the CG after 1 month and 3 months, indicating that both the scalpel gingivectomy and the laser gingivectomy can quickly resolve GE. In addition, the adjunct use of gingivectomy was more effective in controlling gingival inflammation than non-surgical periodontal treatment alone at 1, 3, and 6 months, in according with To *et al.* (1).

Finally, after 6 months, the primary outcome PPD resulted improved in both TGs with a net gain of 2 mm and with recovered biologic width. The novelty of the present study was not comparing two different surgical procedures, but to investigate the need of surgical intervention as an adjunct procedure to non-surgical periodontal treatment in orthodontic population. All subjects were followed and the periodontal parameters were recorded after 1, 3, and 6 months to assess the recovery of soft tissue and the stability of gingival health.

Dental plaque is considered the main causative factor in periodontal disease and orthodontic treatment with fixed appliances is a risk factor for plaque accumulation. Therefore, educational efforts should be made to accomplish orthodontic therapy with gingival health to avoid GE. When oral hygiene practices remain poor, surgical approaches are necessary to quickly recover soft tissue inflammations that compromise efficient orthodontic finishing.

However, clinical relevance should be interpreted with care because surgical gingivectomy is not effective in the long observation if self-care is compromised.

No differences were observed in the magnitude of changes of periodontal variables at 1, 3, and 6 months between the two TGs, showing the same effectiveness and the same degree of recurrence in the long period. The only differences between the two procedures are intra-operative. The surgical technique was faster than laser and helped reducing the duration of the procedure, whereas the laser has the advantage of better haemostasis (7). Patients in the laser group had minimal bleeding which permitted better visualization of the operative area and better assessment of the necessary tooth structure to be exposed, while the scalpel wound resulted in unpleasant bleeding with poor visualization of the operative area (13,19).

It has been shown that a collagen secretion is initiated as early as 6 hours after laser surgery allowing a better healing of the gum (7). However, Ize-Iyamu *et al.* (19) indicated that scalpel repair was equivalent or even better than laser repair as a result of thermal damage to the tissues advocating the clinical use of the low-level diode laser as an alternative to scalpel incision.

Limitations

The present trial had a relatively short-term follow-up (i.e. 6 months) investigating gingival overgrowth in patients treated with fixed appliance only to recover crowding. Comprehensive fixed treatment to correct severe crowding or severe malocclusions can be iatrogenic to periodontal health particularly if treatment periods are lengthy. Therefore, a study with a longer follow-up and larger samples is required to support our claim that gingivectomy as an adjunct to non-surgical periodontal treatment improves gingival health.

Generalizability

The results of the present study can be generalized for patient groups with similar mean age, inclusion/exclusion criteria, and treatment protocol.

Conclusions

- The adjunct use of both scalpel gingivectomy and laser gingivectomy was more effective in controlling gingival inflammation than non-surgical periodontal treatment alone at 1, 3, and 6 months.
- After 6 months, the primary outcome PPD resulted improved in both TGs with a net gain in reducing PPD of 2 mm and with recovered biologic width.
- In the CG, greater improvement in the periodontal parameters were observed within 3 months. The reduction of PPD and the increasing of CCL were significantly smaller when compared with the TGs, depending on a self-care approach for the management of GE.

Conflicts of interest

No funding was used for the present study.

References

- To, T.N., Rabie, A.B., Wong, R.W. and McGrath, C.P. (2013) The adjunct effectiveness of diode laser gingivectomy in maintaining periodontal health during orthodontic treatment. *The Angle Orthodontist*, 83, 43–47.
- Fornaini, C., Rocca, J.P., Bertrand, M.F., Merigo, E., Nammour, S. and Vescovi, P. (2007) Nd:YAG and diode laser in the surgical management of soft tissues related to orthodontic treatment. *Photomedicine and Laser Surgery*, 25, 381–392.
- Gong, Y., Lu, J. and Ding, X. (2011) Clinical, microbiologic, and immunologic factors of orthodontic treatment-induced gingival enlargement. *American Journal of Orthodontics and Dentofacial Orthopedics*, 140, 58–64.
- Al-Anezi, S.A. and Harradine, N.W. (2012) Quantifying plaque during orthodontic treatment. *The Angle Orthodontist*, 82, 748–753.
- Kloehn, J.S. and Pfeifer, J.S. (1974) The effect of orthodontic treatment on the periodontium. *The Angle Orthodontist*, 44, 127–134.
- de Oliveira Guaré, R., Costa, S.C., Baeder, F., de Souza Merli, L.A. and Dos Santos, M.T. (2010) Drug-induced gingival enlargement: biofilm control and surgical therapy with gallium-aluminum-arsenide (GaAlAs) diode laser-A 2-year follow-up. *Special Care in Dentistry*, 30, 46–52.
- Aboujaoude, S., Cassia, A. and Moukartzel, C. (2016) Diode laser versus scalpel in the treatment of hereditary gingival fibromatosis in a 6-year old boy. *Clinics and Practice*, 6, 895.
- Aoki, A., Sasaki, K.M., Watanabe, H. and Ishikawa, I. (2004) Lasers in nonsurgical periodontal therapy. *Periodontology 2000*, 36, 59–97.
- Ristic, M., Vlahovic Svabic, M., Sasic, M. and Zelic, O. (2007) Clinical and microbiological effects of fixed orthodontic appliances on periodontal tissues in adolescents. *Orthodontics & Craniofacial Research*, 10, 187–195.
- Zanatta, F.B., Ardenghi, T.M., Antoniazzi, R.P., Pinto, T.M. and Rösing, C.K. (2014) Association between gingivitis and anterior gingival enlargement in subjects undergoing fixed orthodontic treatment. *Dental Press Journal of Orthodontics*, 19, 59–66.
- Allen, E.P. (1993) Surgical crown lengthening for function and esthetics. *Dental Clinics of North America*, 37, 163–179.
- McGuire, M.K. and Scheyer, E.T. (2011) Laser-assisted flapless crown lengthening: a case series. *The International Journal of Periodontics & Restorative Dentistry*, 31, 357–364.
- Farista, S., Kalakonda, B., Koppolu, P., Baroudi, K., Elkhatat, E. and Dhaifullah, E. (2016) Comparing laser and scalpel for soft tissue crown lengthening: a clinical study. *Global Journal of Health Science*, 8, 55795.
- D'Arcangelo, C., Di Nardo Di Maio, F., Proserpi, G.D., Conte, E., Baldi, M. and Caputi, S. (2007) A preliminary study of healing of diode laser versus scalpel incisions in rat oral tissue: a comparison of clinical, histological, and immunohistochemical results. *Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontics*, 103, 764–773.
- Amaral, M.B., de Ávila, J.M., Abreu, M.H. and Mesquita, R.A. (2015) Diode laser surgery versus scalpel surgery in the treatment of fibrous hyperplasia: a randomized clinical trial. *International Journal of Oral and Maxillofacial Surgery*, 44, 1383–1389.
- Marver, D.M. and Yanosky, M. (2005) Principles of cosmetic dentistry in orthodontics: part 2. Soft tissue laser technology and cosmetic gingival contouring. *American Journal of Orthodontics and Dentofacial Orthopedics*, 127, 85–90.
- Sobouti, F., Rakhshan, V., Chiniforush, N. and Khatami, M. (2014) Effects of laser-assisted cosmetic smile lift gingivectomy on postoperative bleeding and pain in fixed orthodontic patients: a controlled clinical trial. *Progress in Orthodontics*, 15, 66.
- Mavrogiannis, M., Ellis, J.S., Seymour, R.A. and Thomason, J.M. (2006) The efficacy of three different surgical techniques in the management of drug-induced gingival overgrowth. *Journal of Clinical Periodontology*, 33, 677–682.
- Ize-Iyamu, I.N., Saheeb, B.D. and Edetanlen, B.E. (2013) Comparing the 810 nm diode laser with conventional surgery in orthodontic soft tissue procedures. *Ghana Medical Journal*, 47, 107–111.
- Sterrett, J.D., Oliver, T., Robinson, F., Fortson, W., Knaak, B. and Russell, C.M. (1999) Width/length ratios of normal clinical crowns of the maxillary anterior dentition in man. *Journal of Clinical Periodontology*, 26, 153–157.
- Silva, C.O., Soumaille, J.M., Marson, F.C., Progiante, P.S. and Tatakis, D.N. (2015) Aesthetic crown lengthening: periodontal and patient-centred outcomes. *Journal of Clinical Periodontology*, 42, 1126–1134.
- Coslet, J.G., Vanarsdall, R. and Weisgold, A. (1977) Diagnosis and classification of delayed passive eruption of the dentogingival junction in the adult. *The Alpha Omegan*, 70, 24–28.
- Lindhe, J. and Nyman, S. (1985) Scaling and granulation tissue removal in periodontal therapy. *Journal of Clinical Periodontology*, 12, 374–388.
- Silness, J. and Loe, H. (1964) Periodontal disease in pregnancy. II. Correlation between oral hygiene and periodontal condition. *Acta Odontologica Scandinavica*, 22, 121–135.
- Loe, H. and Silness, J. (1963) Periodontal disease in pregnancy. I. Prevalence and severity. *Acta Odontologica Scandinavica*, 21, 533–551.
- R Core Team. *R: a language and environment for statistical computing*. R Foundation for Statistical Computing. <http://www.Rproject.org/>. (December 2016, date last accessed).
- Whitehead, A.L., Julious, S.A., Cooper, C.L. and Campbell, M.J. (2016) Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable. *Statistical Methods in Medical Research*, 25, 1057–1073.
- Hempton, T.J. and Dominici, J.T. (2010) Contemporary crown-lengthening therapy: a review. *Journal of the American Dental Association* (1939), 141, 647–655.