TRAPEZOIDAL FLAP *VS* ENVELOPE FLAP IN MANDIBULAR THIRD MOLAR EXTRACTION

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SUMMARY

Objective. The primary outcome of the study was to test the periodontal healing in the distal area of the mandibular second molar using two different surgical approaches, envelope flap and trapezoidal flap.

Methods. A total number of 52 consecutive cases of mandibular third molar surgical extractions was performed using randomly either a trapezoidal flap or an envelope flap. The following parameters were recorded on the second mandibular molar: probing pocket depth (PPD), distance between bottom of the pocket and occlusal plane (OP-BP), presence of plaque in both the distolingual and the distobuccal sites. Other paramenters recorded for the study were: bleeding on probing, full-mouth plaque score, full-mouth bleeding score, total time for the surgical intervention, age of the patient, type of inclusion, ostectomy. All the patients received a questionnarie to evaluate the post-intervention discomfort. Periodontal parameters were checked at 6-month follow-up.

Results. The study failed to demonstrate statistically significant differences in PPD and OP-BP reduction between the two surgical techniques tested at 6-month follow-up.

Nevertheless, a reduction in PPD values was found in both groups in distobuccal and distolingual sites. Significant lower reductions in PPD and OP-BP values were found in those sites where plaque or bleeding on probing were present at 6-month follow-up.

Envelope flap showed a better result in terms of patient's postsurgical pain and swelling.

Significant correlations were also found between the following paramenters: ostectomy- time for surgical intervention, patient's pain- ostectomy, patient's swelling- ostectomy, time for surgical intervention- patient's swelling, age- number of painkillers assumed.

Conclusions. This study failed to demonstrate the influence of the surgical technique on the periodontal healing of the mandibular second molar.

Nevertheless envelope flap showed better outcomes in postsurgical patient's discomfort.

Key words: mandibular third molar extraction, trapezoidal flap, envelope flap.

Introduction

Impacted mandibular third molar often require a surgical extraction: this represents a common procedure for dental clinicians, although accurate preoperative diagnosis, significant intraoperative skills and postoperative management are needed. Focusing on the surgical procedure, different flaps have been proposed in literature in order to gain access on the impacted tooth and allow for its extraction: trapezoidal flap and envelope flap are probably the two most relevant approaches that have been described by several Authors (1-3). Several clinical trials reported for clinical performances of these different surgical techniques, nevertheless there is no agreement to support one approach or the other. Envelope flap has several advantages: a good visualization of the surgical site, it is easy to be extended, it has a good blood supply: nevertheless many authors reported a higher risk of wound dehishence and a possible damage on the second molar's periontium (1).

On the other hand trapezoidal flap is considered more conservative, simple to be repositioned and closed but has a reduced blood supply and has a limited possibility to be extended (1).

One of the most relevant consequences of impacted third molar extraction is the loss of periodontal attachment in the second molars (4); the optimal surgical approach to prevent these defects is still under investigation. Some clinical trials concluded that flap design did not influence the health of the second molar periodontium, and therefore flap design becomes a matter of individual preference (7-9).
The main purpose of this study was to further evaluate the difference of periodontal parameters at baseline and 6-month follow up on the distal side of the mandibular second molar after impacted third molar extraction performed using an envelope flap or a trapezoidal flap.
A secondary aim of this trial was to compare the two surgical procedures, evaluating different clinical and patient's related outcomes.

Methods

The present article is reported in accordance with the CONSORT 2010 statement for improving the quality of reporting on randomized controlled trials.

Study design and ethics committee approval

The study was designed as a single-centre, randomized, clinical trial on the surgical extraction of impacted lower third molars. The study assessed two different treatment modalities: the envelope flap was compared to the trapezoidal flap in terms of clinical outcomes and patient-centred outcomes.
The study protocol was approved by the local ethical comittee of the "Azienda Ospedaliera-Universitaria Senese, Ospedale Le Scotte" Siena, Italy. Informed consent was obtained from all participants included in the study. The principles outlined in the Declaration of Helsinki were followed in obtaining the informed consent and in conducting the study.

Patient enrollment and study inclusion criteria

Patients had been selected between the patient population group seeking mandibular third molar extraction at the University of Siena between January 2013 and September 2013. Patients were recruited according to the following inclusion criteria:

- Age > 18 years old
- Smoking status: maximum 10 cigarettes
- No systemic disease or pregnacy
- No history of irradiation therapy
- No medications
- Periodontal health, including the ability to achieve good oral hygiene and infection control with full-mouth plaque and bleeding score < 25%
- Presence of mild symptoms of pericoronitis affecting at least one mandibular third molar
- Presence of at least one totally or partially bone impacted mandibular third molar.

Outcome variables and their assessment

Clinical measurements were recorded at baseline and 6 months. A blinded examiner (F.F.) performed all clinical measurements. The following parameteres were recorded: Plaque Score (6 sites for tooth), BoP (6 sites for tooth), PPD (6 sites for tooth) and CAL (6 sites for tooth) were assessed for the mandibular second molar included in the surgery. Since in several istances the CEJ on the distal sites of this tooth was below the gingival margin, a reference point on the crown of the tooth was utilized; the attachment level was then defined as the distance between the occlusal surface of the tooth and the bottom of the pocket (OP-BP) at distolingual and distobuccal sites.
At the end of the surgical intervention a questionnaire was given to the patients, in order to assess from day 1 to day 7 after surgery: num-

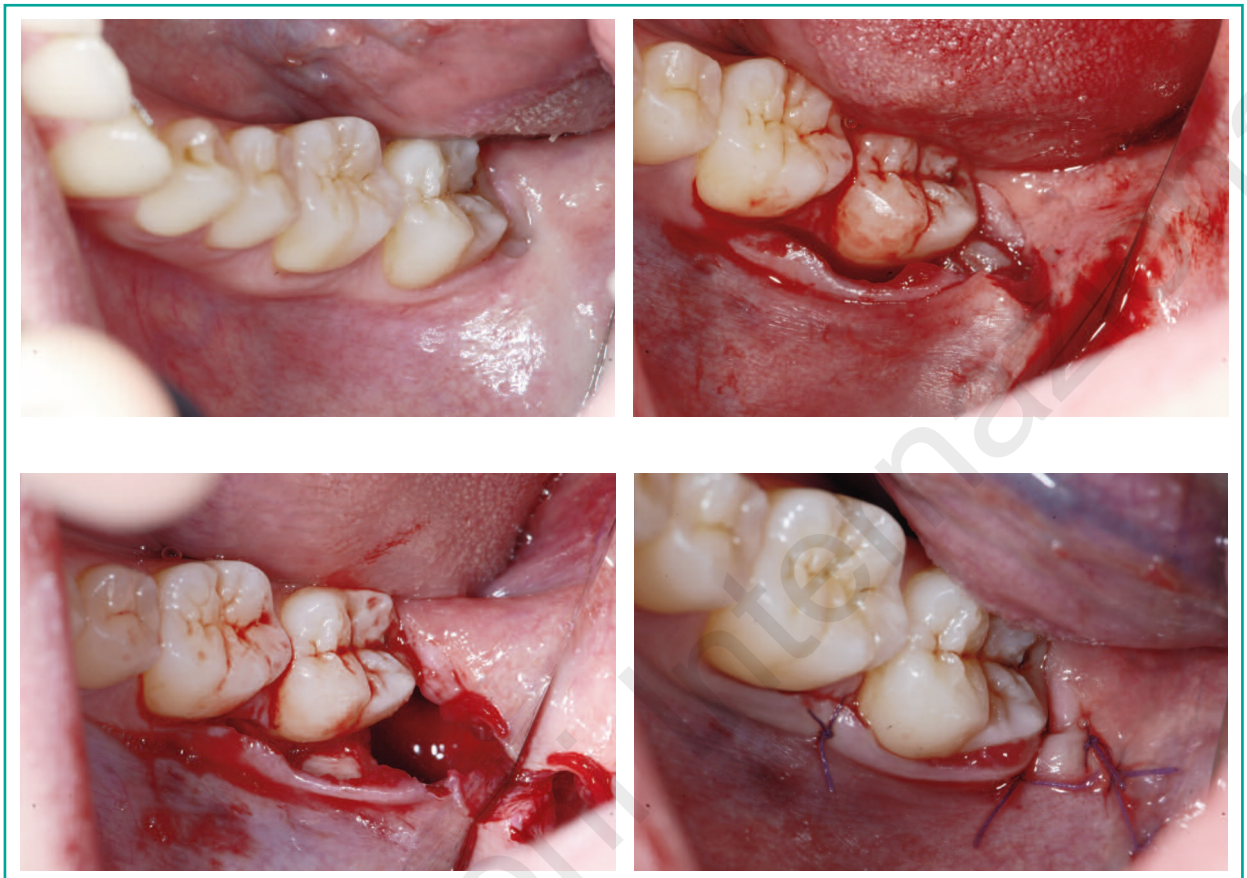
ber of painkillers needed, thrysma presence or not, pain and swelling adopting a VAS diagram. Primary outcome was the 6 month CAL on the distal and vestibular side of the mandibular second molar included in the surgery.
Secondary outcomes were the 6-month PPD, BoP and Plaque Index on the distal and vestibular side of the mandibular second molar included in the surgery and mean post-operative pain and swelling.
Moreover, in order to analyze possible influences on primary and secondary outcomes, the following parametres were assessed: FMPS and FMBS, Winter's classification of impaction (5) (vertical, horizontal, mesioangular, distoangular), Mc Gregor's method (6) of extraction, the need of ostectomy during surgery and the total time for the surgical procedure (from the first incision to the last suture).

Randomization and allocation concealment

Each experimental site was randomly assigned to one of the two treatment modalities. A randomization list was prepared to ensure a balanced allocation of treatments. Allocation concealment was performed by opaque sealed envelopes that were opened immediately prior to the surgical interventions.

Surgical procedure

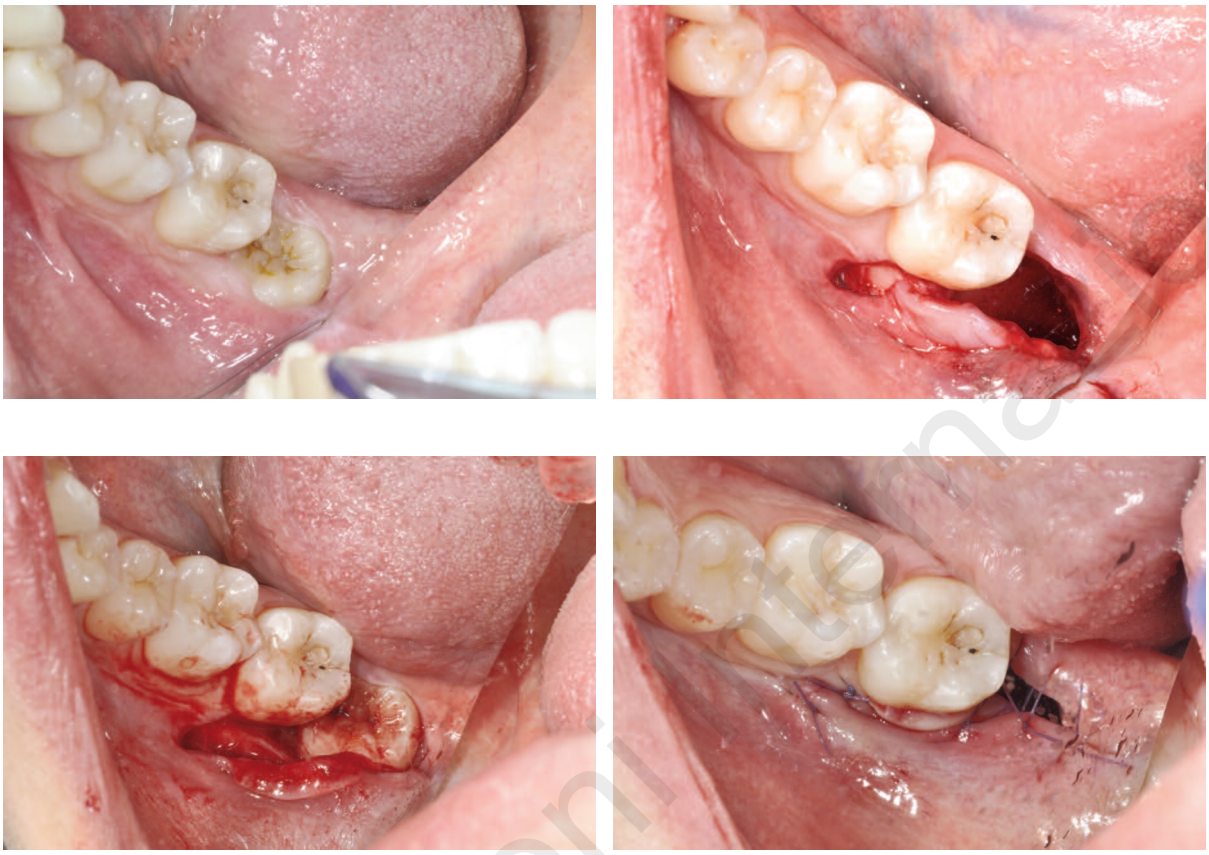
All surgical procedures were performed by the same expert operator (N.B.) at the "Azienda Ospedaliera-Universitaria Senese Ospedale Le Scotte", Siena, Italy.
In test group an envelope flap was performed. Briefly, following local anesthesia, an intrasulcular incision was performed starting from the bucco-distal area of the first mandibular molar, continuing along the base of the papilla between first and second molar and into the sulcus of the second mandibular molar (Figures 1, 2). In the area of the third molar two different approaches were allowed: if the tooth was partially erupted the incision was performed along the buccal side of the exposed surface of the tooth itself; if the tooth was completely impacted a straight incision was designed from the bucco-distal cuspid of the second molar to the base of coronoid process of mandibular ramus.
After the raising of the flap, the tooth was removed utilizing elevators (Figure 3). If necessary, ostectomy of the buccal bone plate and tooth separation were performed. Once the tooth had been removed, the cavity was cleaned, irrigated with saline; inflamatory tissue or any remaining dental follicle were eliminated. If exposed, the distal surface of the second molar was cleaned with curettes. Flap was then sutured using sling sutures (Vycril Ethicon 4/0, Johnson & Johnson, New Brunswick, NJ,USA) (Figure 4).
In control group a trapezoidal incision was performed: following local anesthesia, a vertical incision was placed, from the mesio-buccal cuspid of the second mandibular molar, apically into the buccal mucosa (Figures 5, 6). Then an intrasulcular incision war continued on the second molar and finally a straight incision was designed as described for test group. Extraction was then performed following the same steps previously described (Figures 7, 8).
At the end of the surgical intervention an injection of methilprednisolone (Solumedrol® 40mg Novaplus USA) at the base of the flap was performed in each patient. Sterile gauze packs were placed on the surgical site to maintain pressure on the socket.
Amoxicillin/clavulanate 1gr (Augmentin® Glaxo-SmithKline UK) was administered twice a day for 5 days, Ibuprofen 600mgr (Brufen® Abbott USA) was prescribed as pain-killer, clorexidine rinses (Curasept® Curaden Healthcare Italy) were recommended for the first week after surgical intervention for plaque control.



Figures 1-4
Test group, envelope flap.

Statistical methods

The primary analyses of interest were to compare the various study variables between the control and test groups, in the presence of confounding variables. Within group changes over time in DV PPD, DL PPD, DV OP-BP, DL OP-BP were assessed with Wilcoxon Signed Rank Test. To detect differences in DVppd, DL ppd, DV OP-BP, DL OP-BP reduction between the two study groups (envelope flap, trapezoidal flap) t-test was applied. Where the t-test failed to meet the normality of distribution, Mann Whitney rank sum test was applied. Pearson test was applied to evaluate the correlation between full mouth plaque score and probing pocket depth, both at distovestibular site and distolingual site. The correlation between plaque index and probing pocket depth at DL and DV sites was assessed by using Spearman test. The same correlation test was applied to evaluate the correlation between bleeding on probing and PPD and OP-BP on each distal site of the mandibular second molar (disto-lingual and disto-vestibular). Mann Whitney rank sum test was applied to assess if the procedure of osteotomy produces differences in pain and swelling VAS scores; to evaluate if the osteotomy interferes with the lenght of surgery, where the t-test did not meet the normality of distribution, the significance of differences between the two groups was detect-



Figures 5-8
Control group, trapezoidal flap.

ed by using Mann Whitney rank sum test.
Kruskal Wallis one way analysis of variance was applied to assess if the tooth position influenced the surgical time.
Conversely Mann Whitney rank sum test analysis assessed if the surgical time influenced the number of painkillers needed by patients and it was secondly utilized to find out statistically significant differences between the two surgical procedures respect to the extraction time.
T-test was applied to evaluate whether the surgical procedure influenced the number of painkillers taken by patients. The same test was utilized to evaluate such as pain and aedema (recorded in VAS scale). Where normality tests failed, Mann Whitney Rank sum test was applied. Sperman Rank Order Correlation test was applied to evaluate the relationships between pain (recorded in vas scale) and age of patients.

Results

A sample of 52 patients (20 male, 32 female), mean age 37,2 years (range 18-46 years) was enrolled for this study: a total number of 52 mandibular third molar extractions was performed.

Periodontal healing on mandibular second molar

The study failed to demonstrate statistically significant differences in PPD and OP-BP reduction between the two surgical techniques tested at 6-month follow-up. None of the variable concering the probing pocket depth and the clinical attachment level (OP-BP), measured both at the lingual (p= 0.910) and at the buccal site (p = 0.381) were found to be influenced by the flap design (Table 1).

Nevertheless, a statistically significant reduction in PPD values was found in both test and control groups in distobuccal and distolingual sites (Table 2). Significant lower reductions in PPD and OP-BP values were found in those sites where plaque or BoP were present at 6-month follow-up (Table 3). Plaque index, recorded on the distal aspect of the second molar adjacent to the impacted tooth, was the most important factor affecting the change over time of probing pocket depth, rather than flap design. The Wilcoxon test showed that there was a statistically significant difference between baseline and 6-month-postoperative measurements of PPD ($p < 0.001$) and OP-BP ($p = 0.002$).

Table 1 - Peridontal healing on the distal side of mandibular second molar (Δ = 6-month values – baseline values in mm) in the two treatment groups, envelope flap (test) and trapezoidal flap (control) in mm.

	Test group (n = 27)	Control group (n = 25)
Δ PPD dv	1.22 ± 1.31	1.08 ± 1.26
Δ PPD dl	1.26 ± 1.23	1.46 ± 1.28
Δ POBP dv	0.48 ± 1.34	0.68 ± 1.18
Δ POBP dl	0.78 ± 1.15	0.72 ± 1.57

Table 2 - Periodontal measurements, probing pocket depth PPD, distance between occlusal plane and bottom of the pocket OP-BP, on the distal side of mandibular second molar at baseline and 6-month follow-up in mm.

Test group (n=27)	Baseline	6-months
PPD DV	5.99±1.96*	4.37±1.44*
PPD DL	6.07±2.01*	4.81±1.9*
PO-BP DV	9.03±1.93	8.55±2.25
PO-BP DL	9.51±2.13	8.74±2.17
Control group (n=25)		
PPD DV	4.84±1.49*	3.76±1.09*
PPD DL	5.76±1.83*	4.44±1.12*
PO-BP DV	8.28±1.51	7.6±1.58
PO-BP DL	8.8±1.82	8.08±1.99

Surgical time

The extraction time was defined as the interval between the first incision and the last suture. Statistical analysis suggested that the mean time for the surgical procedure was 15.11±6.91 minutes; there was no association between the length of surgery and the flap technique (14 .07±7.46 minutes for envelope flap Test group, 16,5±6.17 minutes for trapezoidal flap Control group): the results of Mann Whitney Rank Sum test showed that difference in the median values between the two groups was not great enough to exclude the possibility that the difference was due to random sampling variability (p= 0.127).

Another factor that could be associated with increasing extraction time was tooth position according to Winter's classification: the mean values for the four groups were 13.7 ± 6.2 minutes for vertical, 18.3±8.97 minutes for distoangular,

Table 3 - Influence of plaque index (0-1) in periodontal healing on the distal side of mandibular second molar (Δ = 6-month values – baseline values in mm).

	Plaque 0	Plaque 1
Δ PPD dv	1.55±1.67 (n=20)*	0.9±0.92 (n=32)*
Δ PPD dl	2 ±1.07 (n=20)*	0.84 ±1.27 (n=32)*
Δ OP-BP dv	1.05±1.39 (n=20)*	0.28±1.08 (n=32)*
Δ OP-BP dl	1.45±0.99 (n=20)*	0.31±1.37 (n=32)*

15.2±6.84 minutes for mesioangular, 18.5±6.13 minutes for horizontal. On examing these data we found that the correlation between extraction time and tooth position, analized with the Kruskal- Wallis one way analysis, showed not statistically differences in the median values among the treatment groups (p= 0.209).
Finally the influence of osteoctomy on the lenght of the surgical procedure was evaluated: 10,17±2.6 minutes the mean value in the cases without ostectomy; 19.03 ± 6.76 minutes the mean value with ostectomy. In this case the results of Mann Whitney Rank Sum test showed that the difference in the median values between the two groups was statistically significant (p< 0.001).
Ostectomy was necessary in 12 cases in Test group and 17 patients in Control group (Table 4). Two-way Anova analysis confirmed the significant effect of ostectomy on surgical time (p<0.001), while neither flap (p=0.818) nor interaction ostectomy-flap (p=0.236) resulted statistically significant.

Patient's feedback

Envelope flap showed a better result in terms of patient's postsurgical pain and swelling: the scores obtained from the VAS diagram showed a significant difference in favor of the envelope flap in terms of postsurgical pain (p= 0.001) and swelling (p= 0.005) severity (Table 5a).
A longer extraction time was associated with a trend of worse scores of postsurgical pain and swelling; nevertheless the association between these two variables is not statistically significant either for pain (R= 0.06) and swelling (R = 0.21).
A significantly higher incidence of post surgical pain (p=0.007) and swelling (p<0.001) was found when ostectomy was necessary (Table 5b); nevertheless ostectomy did not influence the number of painkillers, such as evidenced by the Mann Whitney Rank Sum test (p= 0.38).
The overall amount of painkillers during the monitored postsurgical phase, such as declared by patients, showed no statistically significant differences between test and control group (p= 0.097).
Sperman Rank Order Correlation test showed no significant relationships between patient's age and pain measured in VAS (p> 0.05); conversely respective to the correlation between age and both swelling (p= 0.001) and number of painkillers (p= 0.017), Sperman Rank Order Correlation test confirmed a statistically significant association.

Table 4 - Influence of ostectomy on total time of surgical interventions in the two groups.

Descriptive Statistics

Dependent Variable: time (s)

ostectomy	flap	Mean	Std. Deviation	N
no	Envelope (Test)	9,40	1,352	15
	Trapezoidal (Control)	11,63	3,777	8
	Total	10,17	2,622	23
yes	Envelope (Test)	19,92	7,891	12
	Trapezoidal (Control)	18,41	6,021	17
	Total	19,03	6,764	29
Total	Envelope (Test)	14,07	7,462	27
	Trapezoidal (Control)	16,24	6,227	25

Table 5a - Patient's feedback in Test and Control groups. Pain and Swelling Vas scores were recorded every day during the first week: the mean values of the addiction of the 7 measurements for each group are reported. The mean values of the total number of painkillers assumed during the first week after surgery are reported.

	N	Pain VAS score	Swelling VAS score	N painkillers
Test group	27	11.8 ± 7.1*	14.6 ± 10.9*	4.3±2.6
Control group	25	13.7 ± 6.2*	25.4 ± 12.6*	5.5 ± 2.6

Table 5b - Patient's feedback in ostectomy and no ostectomy groups.

	N	Pain VAS score	Swelling VAS score	N painkillers
Ostectomy	29	18.4 ± 7.3*	18.4 ± 7.3*	5.2 ± 2.7
No ostectomy	23	12.7± 8.4*	12.4 ± 9.6*	4.4± 2.6

Discussion

Whithin the limits of this study, flap design seems not to influence the periodontal health of the lower second molar: no statistically significant differences merged at 6-month follow up between the two groups regarding periodontal parameters and this result confirms data reported by several clinical trials (1, 7-9).

A significant reduction of the PPD values in distal area of the second molar was found irrespective to flap technique, a similar reduction on OP-BP values was not found in this trial: a possible explanation is due to the removal of the cause of inflamation; it may be argued that a predictable soft tissue contraction seems not to be necessarily followed by a clinical attachment level gain distal to the second mandibular molar.

This study confirms that other factors like plaque index or bleeding on probing appear to be more strongly related to periodontal healing than flap design.

Nevertheless, from patient's standpoint, a significant better result was found with envelope flap (Test group) in terms of post surgical pain and swelling.

Pain, swelling, trismus are common sequelae of third molar surgery.

In this study severe trismus was reported in none of the patients treated: a possible reason to explain this result has to be found in the special care of not exceed the lenght of the distal incision. In fact, a negative role of the distal incision for trismus occurrence had been postulated by several Authors (1, 3), nevertheless there is no evidence supporting this assessment.

In this trial patients were requested to fill in a form everyday, during the first week after surgical intervention, was VAS diagrams for pain and swelling were present and the number of painkillers assumed was recorded for each day. On the basis of patient's feedback the tested surgical procedure appears to be less affected by post surgical sequelae. It has to be underlined that no significant differences were found in the number of painkillers between the two groups.

Some Authors suggest that flap design may influence primary wound healing, determining a difference in post-operative outcomes for the patients. In particular trapezoidal flap seems to facilitate primary closure and to be less affected by adverse effects determining a better outcome in terms of primary wound healing, reduction of discomfort and pain, reduction of incidence of alveolar osteitis (2).

The negative role of secondary healing is a con-

troversial issue: Dubois (10) and Pasqualini (11) found better outcomes for pain and swelling in cases of secondary healing and other Authors reported positive results for secondary healing and the drainage placement (12-15). Kirk et al. (1) found no differences in post-operative pain between envelope and modified traingular flaps although an increased swelling was found for triangular flaps. Jakse (2) found that flap design significantly affected primary closure of the flap and reported better results with modified triangular flap. Authors postulated an adverse role of flap dehiscence for patient's pain and discomfort and the possibility of an increased incidence of alveolar osteitis. A recent systematic review (14) concluded that, on the basis of the small number and eterogeneity of trials, there are insufficient data to chose between primary and secondary closure of the flap.

In this trial drainages were not utilized in any of the patients treated; flaps were repositioned trying to obtain a primary closure wherever it was possible. No periosteal releasing incisions were performed to obtain primary closure in those cases where it was not possible.

According to several studies, age is a significant factor in the evaluation of difficulty in lower third molar removal (16-19), in older patients extractions may be more complex and this fact may be determined by an increased bone density and the presence of areas of ankylosis. In this trial a positive correlation between age and the number of pain killers has been found, but no significant correlations were found between age and the patient's discomfort and age and surgical time; it may be argued that older patients get used to painkillers also if they were not strictly necessary.

All these patient related variables, in both test and control group, were found significantly affected by ostectomy: when ostectomy was necessary the surgical intervention requested more time and post-operative healing resulted more complicated.

Conclusions

This study failed to demonstrate the influence of the surgical technique on the periodontal healing of the mandibular second molar.

A significant reduction in PPD values at 6-month follow-up was found irrespective to the surgical technique.

Nevertheless, within the limits of this trial, envelope flap showed better outcomes in postsurgical patient's discomfort.

A longer surgical time was significantly affected by ostectomy: in those patients post-operative healing resulted more complicated.

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