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A regimen of systematic periodontal care after removal of impacted mandibular third molars manages periodontal pockets associated with the mandibular second molars

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Abstract

Aim: This randomized, single-blinded control trial investigated the local effects of periodontal care on mandibular second molar delivered during and after impacted third molar surgical extraction.

Method: 30 subjects (50% male, 32.1 $\pm$ 7.8 years) out of 35 enrolled, with a mesio-angular impacted mandibular third molar, having probing pocket depth (PPD) $\geq$ 5mm at adjacent second molar distal, and crestal radio-lucency between the two teeth completed the study. Oral hygiene instruction, scaling and caries stabilization were performed before surgery. Controls (n = 16) had their third molar extracted followed by standard socket debridement. Test group subjects (n = 14) received the same treatment, except before wound closure the operator was informed of the group allocation and ultrasonic root debridement on the second molar was performed, followed by a 3-visit plaque control programme.

Results: 6-months post-extraction, statistically significantly ($P < 0.007$) better plaque control and shallower probing depths were observed at test second molars'

distal (%Plaque = 21; PPD = 3.2 ± 1.2 mm) than at control second molars (%Plaque = 88; PPD = 5.2 ± 0.7 mm).

Conclusions: The periodontal interventions investigated prevented residual pockets on periodontally involved second molars 6-months after ipsilateral impacted mandibular third molar removal.

Clinical Relevance: Periodontal pockets persisting on mandibular second molars after surgical removal of the ipsilateral impacted third molar are not uncommon. This randomized controlled trial showed that a regimen of systematic periodontal care including debridement, local antimicrobial use and plaque control for mandibular second molars with distal crestal bone loss after third molar removal could manage distal periodontal pockets. Dentists and oral surgeons should assess the periodontal conditions of adjacent mandibular second molars (pockets, radiographic bone loss) before third molar extraction and should scale/root plane affected second molars during the surgery and arrange follow-up oral hygiene care.

Third molars, the last teeth to erupt into the human dental arch, are ranked the most frequently impacted teeth of modern humans (Andreasen et al. 1997). Impacted third molars have been shown to have a higher prevalence in Chinese populations than has been reported for Caucasian populations (Chu et al. 2003, Quek et al. 2003). Impacted third molars may contribute to various problems such as: pericoronitis and/or oro-facial infection; caries, periodontitis and/or root resorption of the adjacent tooth; cystic or neoplastic changes; orthodontic problems; prosthetic problems; or even temporomandibular joint symptoms (National Institutes of Health 1980, Knutsson et al. 1996, Nemcovsky et al. 1996, Worrall et al. 1998). Problems like pericoronitis and consequent dento-alveolar infections can be managed by extraction of the culprit third molar (Worrall et al. 1998). However, sometimes surgical removal of the impacted tooth alone cannot rectify the pathology caused by its impaction (Kugelberg et al. 1985). Studies in Caucasians have shown that following surgical removal of impacted mandibular third molars residual periodontal and intrabony defects may persist at the distal aspect of mandibular second molars (Ash et al. 1962, Gröndahl & Lekholm 1973, Chin Quee et al. 1985, Marmary et al. 1985, Kugelberg et al. 1985, Kugelberg 1990). A study of Chinese in Taiwan showed periodontal breakdown detected on the distal surfaces of mandibular second molars following surgical removal of the adjacent mandibular third molars in adult

periodontitis patients, although attributed to the surgery rather than the impaction and the periodontitis (Peng et al. 2001). Furthermore, it was shown in an earlier study that up to 67% of Hong Kong Chinese who had undergone surgical removal of mesio-angularly impacted mandibular third molars exhibited probing pocket depth (PPD) $\geq$ 5 mm on the distal aspect of second molars, 6-36 months post extraction (Kan et al. 2002).

The present study was a randomized controlled clinical trial which aimed at studying the effects of intensive periodontal care on mandibular second molars that exhibited signs of possible periodontal involvement at the time of surgical removal of mandibular third molars with follow-up attention to oral hygiene of the site. The null hypothesis was that the 6-month clinically assessed periodontal status of the second mandibular molars of the test group subjects would be the same as those of the control subjects who had not received particular periodontal attention during or after similar third molar surgical removal.

Material and methods

Sample size determination

The clinical trial targeted at subjects who had mesio-angularly impacted mandibular third molars and pre-extraction crestal radio-lucency at the distal aspect of the

adjacent second molar (Kan et al. 2002). Sample size for the study was computed using the following formula:

$$n = \frac{(\sigma_1^2 + \sigma_2^2)\,(Z\alpha_{/2} + Z\beta)^2}{(\mu_1 - \mu_2)^2}$$

where σ_1 is the standard deviation of PPD at distal aspect of the mandibular second molars in the control group after impacted mandibular third molar extraction

σ_2 is the standard deviation of PPD at distal aspect of the mandibular second molars in the test group after impacted mandibular third molar extraction

$Z\alpha_{/2} = 1.96$ if significant level is set a $\alpha = 0.05$

$Z\beta = 0.8416$ if the power of the test is set at 80%

μ_1 is the mean PPD at the distal aspect of the mandibular second molars in the control group after impacted mandibular third molar extraction

μ_2 is the mean PPD at the distal aspect of the mandibular second molars in the test group after impacted mandibular third molar extraction

According to our previous study, those subjects having crestal radio-lucency and mesio-angularly impacted mandibular third molars, a mean PPD of 7.1 ± 2.1 mm (mean ± SD), range 4-11 mm (Kan et al. 2002) was found at the associated second

molars 6-36 months post third molar extraction. Based on the null hypothesis, the treatment outcomes are assumed to be equal in every respect in both the test and control groups (i.e. $\sigma_1 = \sigma_2 = 2.1$ mm). Sample size required in the test and control groups of this study thus depends on the difference in mean PPD at distal aspect of the mandibular second molars between the test and control groups after the trial intervention. According to previous reports regarding non-surgical or surgical periodontal therapy, for pockets greater than 7 mm, a 2-3 mm mean PPD reduction was usually reported (e.g. Ramfjord et al. 1987, Kaldahl et al. 1988). This periodontal intervention study was planned to achieve 2 mm or more difference in mean PPD at distal aspect of the mandibular second molars between the test and control groups after impacted mandibular third molar extraction. According to the above mathematical formula, 17 subjects in each group were required.

Patient selection and screening

New patients attending the Reception Clinic of the Prince Philip Dental Hospital, The University of Hong Kong, and satisfying the inclusion criteria were recruited by one research group member (K.W.K.) to participate in the study. The target sample size was at least 34 subjects. For inclusion, patients had to be free of systemic disease, not undergoing orthodontic treatment, not having PPD > 5 mm (except at the mandibular

second molars so involved), and displaying the following oral features:

- Mandibular third molar - mesio-angular impaction, defined as a convergence angle, towards the coronal aspect, between the long axes of the third and second molars of ≥ 30° (Kan et al. 2002); no signs of cystic/neoplastic change.
- Adjacent second molar - present and responsive to electric pulp test; positive bleeding on probing (BOP) and PPD ≥ 5 mm at distal aspect; mobility ≤ degree 1 (Parfitt 1960); no furcation involvement.
- Radiographic feature on the panoramic oral radiograph: crestal radio-lucency (other than follicular space) between the second and third molars (Kan et al. 2002)

The target sample size was secured four months after the commencement of recruitment. All studied mandibular third molars were treatment planned for surgical extraction by dental surgeons in charge of the Reception Clinic who were unrelated to the study.

Patient management and surgery

The clinical study was carried out in the Periodontology Clinic, Faculty of Dentistry, the University of Hong Kong. Oral hygiene instruction, scaling and caries stabilization, if necessary, were completed before the surgical removal of the impacted

mandibular third molars. For each subject, only one impacted third molar, and its adjacent second molar, was included in this study. For subjects with two eligible mandibular third molars based on the criteria, a coin was tossed to select randomly either the left or the right side to be included. The third molar that was not selected for the study was surgically extracted at least 3 months before commencement of the study. All deep caries lesions were treated, except those on the distal surface of the study mandibular second molars, which were stabilized immediately after the surgical procedures. One member of the research team (W.K.L.) checked the eligibility of all subjects and that all necessary pre-operative preparations were carried out. Receptionists of the Periodontology Clinic were then instructed to arrange the surgical extraction appointment for all subjects within an 8-week period. At the appointment for surgery, the attending dental surgery assistant, in the absence of the surgeon, randomly allocated the subject into either the test (head) or the control (tail) group by tossing a coin before the patient. The grouping result was entered into a standard patient record form by the dental surgery assistant, which was then sealed inside an envelope and immediately passed to W.K.L., who maintained the concealment of the subjects' allocation until completion of the data collection. The surgeon was unaware of the subject group allocation until the third molar extraction was completed. Then the dental surgery assistant would inform him the patient's allocation. The subjects

and the surgeon were therefore aware of the patient allocation but both parties were reminded not to disclose such information to any person.

- Control Group:

  The impacted mandibular third molar was extracted according to a conventional surgical protocol (Howe 1985), i.e. standard three-sided buccal flap; buccal bone gutter creation; tooth sectioning, if necessary; third molar elevation; surgical wound debridement and closure with sutures. The sutures were removed one week after the surgery. Patients were reminded to resume their regular oral hygiene care except at the surgical wound region one day after the surgery. No antibiotics were prescribed.

- Test Group:

  Impacted mandibular third molar was extracted as described above. However, before suturing, the operator (K.W.K.) was informed of the patient's allocation to the test group. According to the study protocol, the distal root surface of the periodontally involved mandibular second molar adjacent to the extracted third molar was subjected to ultrasonic root surface debridement (regular ultrasonic tip in a standard handpiece fitted onto a Piezon Master 400, Electro-Medical Systems, Switzerland). Post-extraction, the test group subjects were instructed

to perform mouthrinsing with 10 ml 0.2% w/v chlorhexidine gluconate (Adams Healthcare Ltd., Leeds, UK) twice daily, starting one day after the surgery, for 2 weeks. No antibiotics were prescribed. Sutures were removed one week after the surgery and at that appointment the subjects were instructed to use 1% chlorhexidine gel (Corsodyl Gel, Smithkline Beecham, UK) on a single-tufted brush to clean the distal surface of the study mandibular second molar twice daily, until the first recall at six weeks post-operation. The test group subjects were recalled every 6 weeks (total 3 times) for focused oral hygiene instructions targeting the distal aspect of the study mandibular second molar. They also received debridement at that site, if clinical examination revealed plaque deposits. At the first recall, the test subject also received tooth polishing to remove the chlorhexidine staining, if any, on their teeth.

Caries, if any, on the distal surface of the study mandibular second molar was removed during the surgery, and after tooth extraction, an amalgam or glass ionomer restoration was inserted as appropriate. All clinical treatments were performed by a single investigator (K.W.K.) who was not involved in the clinical data collection. Any residual periodontal problems at the second molars detectable at the conclusion of the study at six months, namely those in the control subjects and for second molars

adjacent to eligible third molars which had been extracted ahead of the study in patients with bi-lateral clinically similar situations, were followed-up and appropriate periodontal treatment was arranged and delivered without delay.

Recall examination

All patients were examined 6 months after the surgery by one independent examiner (J.K.S.L.) who was blinded to the group assignment of the patients. The examiner was well trained and had previously been involved for the same role in a related study (Kan et al. 2002). A simple questionnaire was administered before the 6-month examination to record any spontaneous, thermal or food related pain or discomfort (secondary outcome) within the two-month period before the 6-month recall. A manual constant pressure periodontal probe, the True Pressure Sensitive (TPS) probe (Vivacare Schaan, Liechtenstein), made of a flexible plastic material, was used for assessing the periodontal parameters. The following local periodontal parameters of the test and control mandibular second molars were recorded at mesio-buccal, mid-buccal, disto-buccal, mid-distal, disto-lingual, mid-lingual and mesio-lingual surfaces: probing pocket depth (PPD, primary outcome); recession (Rec, primary outcome); clinical attachment level (CAL, primary outcome); bleeding on probing (BOP, secondary outcome); suppuration on probing (SOP, secondary outcome); and

tooth mobility (secondary outcome). Local plaque control (primary outcome) of the study tooth was recorded at mesio-buccal, buccal, distal and lingual surfaces in a dichotomous fashion: i) plaque detectable by visual inspection and/or by collection on the probe; and ii) no plaque detected visually or on the probe tip. One out of six patients was randomly selected for a re-examination 30 minutes after the clinical examination. Reproducibility of clinical assessments was assessed by calculating the percentage agreement, or percentage agreement $\pm$ 1 mm for PPD, Rec and CAL, between the two sets of data.

Ethics

The research protocol was approved by the Ethics Committee, Faculty of Dentistry, The University of Hong Kong. Written informed consent was obtained from all participants before the commencement of the study.

Data analysis

Data analysis was carried out using the statistics software: SPSS (SPSS V.11.0, Chicago, IL, USA). Standard descriptive statistics were used to summarize the variables studied. Variations in demographic data, and smoking habit, between control and test groups were assessed by unpaired t-tests with *P* value set at 0.05.

Differences in Plaque%, BOP%, SOP% between the control and test groups, at the mandibular second molar, were assessed by Fisher Exact tests. For PPD, Rec and CAL, the differences between the control and test groups were assessed by 2-sample t-tests. To account for the possible error due to the use of multiple bi-variate statistical tests on the same data set, the level of statistical significance was adjusted to 0.007.

Results

35 subjects were enrolled and 30 of them completed the study (Fig. 1). Two and three subjects in control and test group respectively were lost to follow up. One subject from test group emigrated to a foreign country. Two each from both groups could no longer attend the scheduled recalls due to contemporaneous conflict with their job time-tables (Fig. 1). All participants completing the study were Chinese, aged 18-52 years. Half of them were men and 30% were smokers. Their demographic background and clinical parameters on recruitment are shown in Table 1. There were 16 subjects in the control group and 14 subjects in the test group. One control and two test subjects had two impacted third molars and hence one of the teeth was randomly selected to be extracted before the commencement of the study. Except that test group subjects were older than the controls (P = 0.014), other demographic

background, smoking habits and clinical parameters were similar among the two groups. All studied mandibular second molars had PPD ≥ 5 mm with positive BOP pre-operation at the disto-buccal and/or disto-lingual site(s). Because the impacted mandibular third molar crown may have hindered the accurate measurement of the PPD and CAL prior to extraction, the pre-extraction data **were** not compared to the data collected at the 6-month post-extraction recall.

The periodontal conditions of the study mandibular second molars at the 6-month recall are shown in Table 2. Mean PPD at the mid-distal aspect of the test second molars was significantly less than that of the control second molars. Multiple linear regression analysis was performed with mean PPD at mid-distal of the studied second molar at six months as the dependent variable and all other variables recorded as independent variables, including group assignment, smoking and distal caries lesion of the second molar. The only variable which was retained in the final regression model was subject group assignment, indicating that the other features did not have any statistically significant influence on the mid-distal PPD of second molars after six months. Four (29%) of the test second molars and five (31%) of the control second molars exhibited Grade 1 mobility and none exhibited mobility greater than Grade 1. The percentage agreement of the duplicate examinations on mobility and BOP% of the study teeth was 80%, and 66%, respectively. The percentage agreement ± 1mm

for PPD, Rec and CAL measurements of the second molars were 100%.

Overall, a statistically significantly (P = 0.045, Fisher exact test) higher percentage of control group subjects (n = 8, 50%) than test group subjects (n = 2, 14%), reported having pain or discomfort of any kind within the two months preceding the 6-month recall.

Discussion

The present study investigated the effect of intensive periodontal care on periodontally involved mandibular second molars, the periodontal involvement being indicated by the distal crestal radio-lucency on the panoramic oral radiograph, during and after surgical extraction of ipsilateral mesio-angularly impacted third molars. A previous cross-sectional study in the same population had shown that periodontal pockets persisting on mandibular second moloars after surgical extraction of the adjacent third molars was not uncommon (Kan *et al.* 2002). Early studies of mostly non-periodontally involved second molars concluded that the periodontal status of the second molar was unaffected by the scaling and 'root planing' of the second molar at the time of third molar removal (Ash et al. 1962, Osborne et al. 1982). Nonetheless, publications on the periodontal implications of third molars have advocated that scaling/root planing of the second molar should be part of the management (Corn &

Marks 1969, Groves & Moore 1970). One short-term (2 months) study showed that mechanical periodontal treatment of mandibluar second molars, not all of which were periodontally involved, at the time of forceps extraction of adjacent third molars, resulted in better periodontal conditions on the scaled/root planed second molars compared to control second molars (Ferreira et al. 1997). The present study focused on studying the effects of periodontal interventions on periodontally involved mandibular second molars after third molar surgical extraction. These second molars run a high risk of having persistent residual periodontal defects at mid-distal site, as shown in the current study's control group at six months post-extraction and from a survey conducted earlier by the current research group (Kan et al. 2002). The subjects recruited for this study were not significantly affected by periodontitis, except for the mandibular second molar of concern. The reason for this decision on the study design was so that it can be recognized that localized periodontal defects can be associated with mesio-angularly impacted mandibular third molars in mouths otherwise generally free of periodontitis.

The present clinical trial planned to recruit at least 17 subjects from each group. Due to drop-out, only 16 and 14 subjects were available from the control and test groups respectively for recall at 6 months. Nevertheless, the test second molars' mid-distal PPD measurements observed among the two groups at six months were

found to be significantly different, indicating more favourable periodontal healing responses in the test group. The periodontal therapy at and after impacted third molar surgical removal in the test group resulted in statistically significantly shallower PPDs at the mid-distal of second molars in the test group than in the control group. Test group second molars also exhibited greater Rec and had better CAL than controls, both favouring test second molars and both contributing to the statistical significance of the PPD difference at the mid-distal. Perhaps a larger sample size would have allowed these differences in Rec and CAL to reach statistical significance. Nevertheless, the periodontal care provided in the test group was successful in improving the oral hygiene around the second molar of interest and hence significantly prevented the establishment of residual periodontal pockets at the distal aspect of the second molar tooth.

Prior to the present study there had not been published a randomized controlled study on the impact of periodontal interventions on second molars having pre-extraction characteristics shown to be associated with persistence of periodontal pockets after third molar removal, and indicative of periodontal involvement of the second molar, e.g. crestal radio-lucency at the distal aspect of the second molar (Kugelberg et al. 1991, Kan et al. 2002). While extraction of the third molar adjacent to the periodontally involved second molar, the periodontal involvement being

indicated by the distal crestal radio-lucency, would be expected by itself to favorably impact on the periodontal condition of the second molar (Grassi et al. 1987), the present study has clearly demonstrated the additional benefits to periodontally involved second molars through the completion of root surface debridement at the time of surgical extraction of mesio-angularly impacted third molars, followed by specific attention to the oral hygiene of the site. Such a simple approach to the management of defects at the distal aspect of mandibular second molars may obviate the need for complex regenerative therapies, shown to have some effectiveness in this situation (Pecora et al. 1993, Oxford et al. 1997, Karapataki et al. 2000).

While an intra-individual study design would have excluded the influence of patient specific characteristics, a previous study (Kan et al. 2002) suggested that the recruitment into a study of patients with bi-lateral similarly impacted third molars associated with bi-lateral second molars displaying a distal crestal radio-lucency, without significant periodontitis on other teeth, would be a long drawn-out process given the population at hand, despite the high prevalence of impacted teeth (Chu et al. 2003). This study adopted a parallel group study design and allocated subjects randomly into the test and control groups. The only statistically significant difference in demographic background between the two groups is that the test group subjects were older. This characteristic of the test subjects fortuitously accords with a patient

characteristic shown to be associated with residual distal periodontal defects after third molar extraction (Kugelberg 1991), which the procedures applied to test subjects specifically sought to address. The operator did not know of the subject allocation to the test group until the third molar had been successfully removed, so the surgical protocol, apart from the root surface debridement at its conclusion, was unaffected by the assignment. Various studies have investigated the effect of flap design and manipulation in the management of aspects of periodontal complications of mandibular third molar extraction (Groves & Moore 1970, Woolf at al. 1978, Stephens et al. 1983, Schofield et al. 1988, Motamedi 1999 & 2000, Rosa et al. 2002, Suarez-Cunqueiro et al. 2003). Most of these studies were on second molars without obvious periodontal involvement at the outset, so perhaps unsurprisingly no approach has been shown to be superior, and hence a standard buccal flap was raised in this study. Bone guttering around the impacted third molar was performed, taking care not to remove bone from around the second molar. A recent study, which did not employ any periodontal interventions, has shown that disto-lingual bone removal from impacted mandibular third molars being surgically extracted resulted in better periodontal healing on mandibular second molars following third molar extraction compared to disto-buccal bone removal and tooth division, a similar approach to that employed in the present study (Chang et al. 2004). Antibiotics were not prescribed,

as only mechanical interference, versus non-interference, with plaque bacteria was being tested; but post-operative prophylactic antibiotics in third molar surgery have been shown not to prevent the inflammatory complications following surgery for which such antibiotics are usually prophylactically prescribed (Poeschl et al. 2004).

A study investigating the effect of twice daily 0.12% chlorhexidine gluconate mouthrinse on periodontal healing at sites next to simple extraction sockets demonstrated that the chemical therapy provided benefit one-month post extraction (Brägger et al. 1994, Lang et al. 1994). The one-month mouthrinse therapy, in addition to the regular concurrent non-surgical periodontal therapy, appeared to assist healing in the alveolar bone at six month post-extraction. Except suppression of BOP in test sites, no significant benefit on periodontal healing was observed 6 months post operation with or without 0.12% chlorhexidine mouthrinse. The current test subjects practiced 2 weeks of 0.2% chlorhexidine gluconate twice daily mouthrinses followed by 4 weeks 1% chlorhexidine gel usage daily at the test second molar. In strict sense, the current study could not be compared to that of Brägger and co-workers (Brägger et al. 1994, Lang et al. 1994) for their study categorically excluded surgical extractions, especially of mandibular third molars. Nevertheless, from both studies, BOP of the test sites was similarly suppressed, indicating that the influence of the 1-1.5 month application of topical chlorhexidine could be noted until 6 months

post-extraction, supporting our current rationale of using the agent in augmenting the effects of the periodontal debridement and mechanical plaque control.

The crown of the mesio-angularly impacted third molar often interferes with registering pre-extraction pocket depth. Hence no comparisons were made between pre-extraction and post-extraction measurements. The outcome measure was the periodontal status of the second molar six months after extraction and these measurements were taken by a recorder unaware of the patient assignment. Six months was the ethical limit of this study, as treatment of residual periodontal defects on control second molars and second molars adjacent to third molars extracted ahead of the study, due to bi-lateral similarly impacted third molars and affected second molars, required immediate periodontal intervention.

Only a small proportion of Norwegian adults (0.3%) who had surgical removal of impacted third molars 4-6 years beforehand, reported chronic pain associated with periodontal problem at the related second molar (Berge 2002), indicating that residual periodontal problems at mandibular second molars after removal of associated impacted third molars can remain relatively silent. Despite pain or discomfort being felt by 8 control and 2 test subjects within two months preceding the 6-month recall in the present study, the pain/discomfort appeared not severe enough to trigger the subjects to contact the research group for early review, or to seek dental care from

others. Ash et al. (1962) reported 26% of American subjects experienced pain and discomfort on ipsilateral mandibular second molars one year after the third molar removal. A similar 36% incidence of discomfort was reported in a group of Hong Kong adults who had undergone third molar extraction within the previous 6-36 months (Kan et al. 2002), which compares with an incidence of discomfort of 50% within 4-6 months post-extraction in the control subjects of the present study.

In conclusion, within the limitations of the current study, careful root surface debridement, at the time of surgical extraction of mesio-angularly impacted third molars, of the adjacent second molar which exhibited distal crestal radio-lucency suggestive of periodontal involvement, and a focused follow-up plaque control programme was found to reduce significantly the probing depth at the distal aspect of the second molar.

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Legend

Fig. 1. CONSORT diagram showing the flow of participants through each stage of the randomized trial.

Table 1. Subjects' demographic background, smoking habit and clinical parameters at recruitment.

	Control Group (n =16)	Test Group (n =14)
Age[a] (year, mean ± SD)	28.9 ± 7.3	35.7 ± 6.8
% male	63	36
% smoker	38	22
Clinical data		
No. of teeth[b]	28.8 ± 1.5	28.1 ± 1.7
% BOP	50.2 ± 24.0	35.6 ± 23.2
% Pocket 4-5mm[c]	1.5 ± 2.3	1.2 ± 2.3
Study mandibular second molars		
% left side	38	57
% with distal caries lesion	56	21
Mean PPD (mm)		
DB	6.5 ± 1.5	6.1 ± 1.4
DL	5.6 ± 1.8	5.6 ± 2.2

[a]Statistically significant difference between the Test and Control Groups, $P = 0.014$, unpaired t-test

[b]except impacted mandibular third molar(s)

[c]except impacted mandibular third molar and associated second molar

Table 2. Periodontal conditions of the mandibular second molars at the 6-month recall.

	PPD[a] (mm)		Rec[a] (mm)		CAL[a] (mm)		% of subjects with BOP		% of subjects with SOP		% of subjects with Plaque	
Surface	Control	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control	Test
Mid-buccal	2.1 ± 1.1	1.7 ± 0.6	1.2 ± 0.4	1.7 ± 0.9	3.3 ± 1.4	3.4 ± 1.2	44	14	0	0	50	29
Mid-lingual	1.9 ± 0.7	1.6 ± 0.5	1.1 ± 1.0	1.8 ± 1.0	3.0 ± 1.1	3.4 ± 1.2	44	14	0	0	94	29[c]
Mid-distal	5.2 ± 0.7	3.2 ± 1.2[b]	1.5 ± 1.0	2.7 ± 1.3	6.7 ± 1.0	5.9 ± 1.5	81	43	19	0	88	21[c]
Mesiobuccal	2.8 ± 1.1	1.9 ± 0.7	0.3 ± 0.5	0.6 ± 0.5	3.1 ± 1.0	2.4 ± 1.0	38	29	0	0	56	21
Distobuccal	2.7 ± 1.0	2.1 ± 1.1	1.5 ± 0.5	2.1 ± 1.0	4.2 ± 1.1	4.3 ± 1.1	63	21	0	0	ND[d]	ND
Mesiolingual	2.8 ± 0.7	2.3 ± 0.6	0.5 ± 0.7	1.1 ± 0.8	3.3 ± 1.0	3.4 ± 0.8	69	50	0	0	ND	ND
Distolingual	3.6 ± 2.1	2.0 ± 1.2	1.4 ± 1.0	2.4 ± 1.0	5.0 ± 1.9	4.4 ± 1.4	56	29	6	0	ND	ND

[a] mean ± SD

[b]Statistically significant different between the control and test groups, $P < 0.007$, 2-sample t-test.

[c]Statistically significant different between the control and test groups, $P < 0.006$, Fisher exact test.

[d]ND = not determined

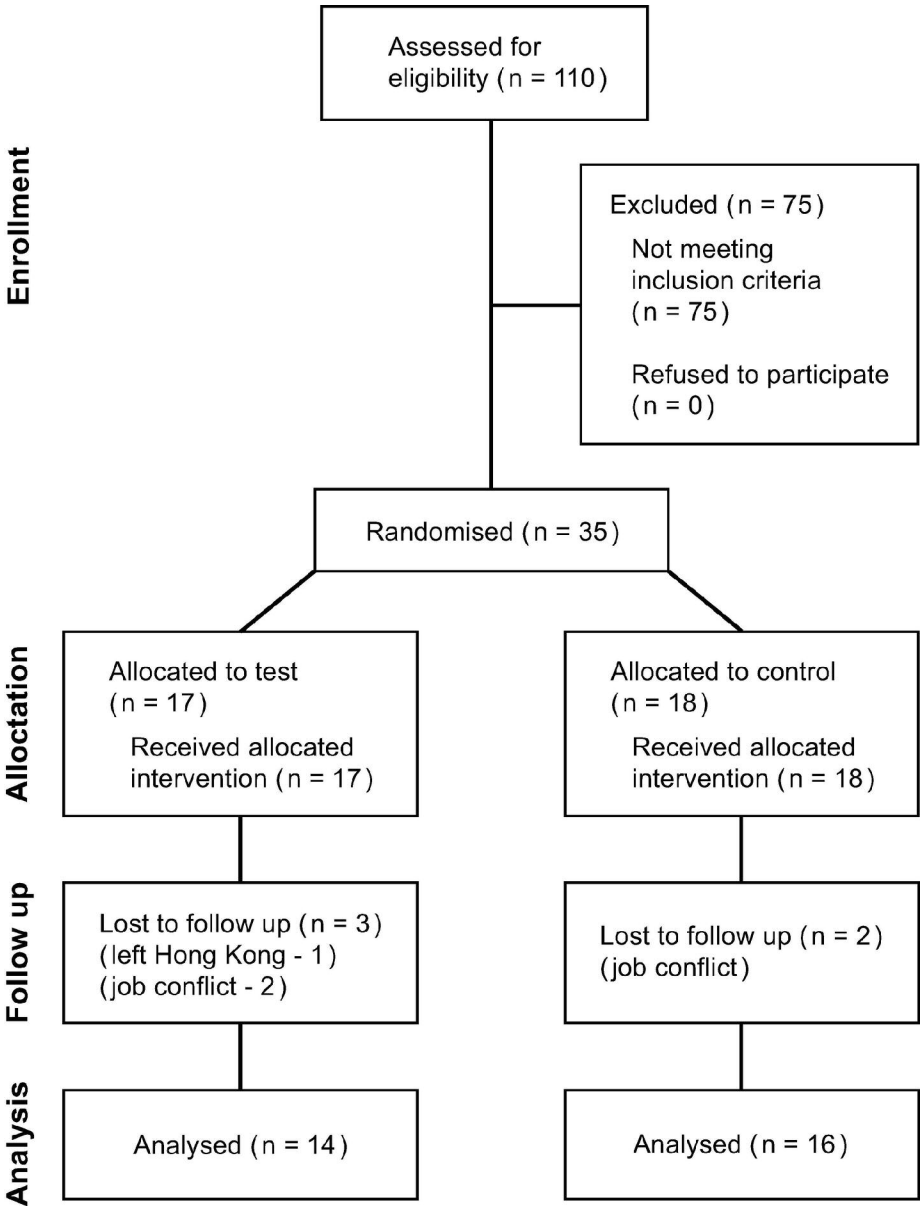

Fig. 1. CONSORT diagram showing the flow of participants through each stage of the randomized trial.
129x170mm (300 x 300 DPI)

CONSORT Checklist

Paper section and topic	Item	Description	Reported on page#
Title and abstract	1	▪ Randomized single-blinded controlled trial	3
Introduction			
Background	2	▪ scientific background and explanation of rationale	5-6
Methods			
Participants	3	▪ Eligibility criteria for participants	8-9
		▪ Settings and location where the data were collected	9, 13
Interventions	4	▪ precise details of the interventions intended for each group and how and when they were actually administered	10-14
Objectives	5	▪ specific objectives and hypothesis	6
Outcomes	6	▪ define primary and secondary outcome measures	13
		▪ methods used to enhance the quality of measurements	13-14
Sample size	7	▪ How sample size was determined	6-8
Randomization -*sequence generation*	8	▪ method used to generate the random allocation sequence	10
-*allocation concealment*	9	▪ method used to implement the random allocation sequence	10-11
-*implementation*	10	▪ who generated the allocation sequence	10
		▪ who enrolled participants	8
		▪ who assigned participants to their groups	10
Blinding (masking)	11	▪ participants were not blinded	10
		▪ administer of the interventions blinded until last moment	11
		▪ assessor of outcome blinded	13
Statistical methods	12	▪ statistical methods used to compare groups for primary outcome(s)	14-15
Results			
Participant flow	13	▪ Figure 1	Figure 1
Recruitment	14	▪ dates defining the periods of recruitment and follow-up	8-13
Baseline data	15	▪ baseline demographic and clinical characteristics of each group	Table 1
Numbers analyzed	16	▪ number of participants (donominator) in each group included in each analysis	Figure 1
Outcomes and estimation	17	▪ A summary of results for each group	Table 2, 15-17
Ancillary analysis	18	▪ Address multiplicity by reporting any other analyses performed	N.A.
Adverse events	19	▪ All important adverse events or side effects in each intervention group	Nil
Discussion			
Interpretation	20	▪ Interpretation of the results	17-19, 22
Generalizability	21	▪ Generalizability of the trial findings	20, 23-24
Overall evidence	22	▪ General interpretation of the results in the context of current evidence	20-21

N.A. = Not applicable