No difference in surgical outcomes between Open and Closed exposure of palatally displaced maxillary cuspids

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Abstract

Purpose: To investigate differences in the surgical outcomes between Open and Closed exposure for palatally displaced maxillary cuspids (PDC).

Methods: A multicenter, RCT involving two parallel groups. The settings were one dental teaching hospital in, and two hospital units near Sheffield, UK. Participants were aged <20 years with a unilateral PDC, who provided informed consent. They were randomly allocated to either receive the Open (O) or the Closed (C) surgical procedure. The outcomes were time spent in the operating room and 10-day post-operative patient questionnaire. Statistical differences between the two techniques were tested using independent *t* tests for continuous variables and chi-squared tests for frequencies.

Results: The final study sample was composed of 71 participants (64% females). There were no differences in the gender ratios (O: F=27, M=13; C: F=25, M=16) or mean ages of the two groups (O: 14.3 yrs SD 1.3; C: 14.1 yrs SD 1.6) at the start. The mean operating times for the Open and Closed techniques were 34.3 mins (SD 11.2) and 34.3 mins (SD 11.9) respectively (p=.986). There were no statistically significant differences between the two treatment groups for any of the patient-assessed outcomes (p>.05).

Conclusions: There were no differences in the surgical outcomes investigated in this study between Open and Closed exposure for PDC.

Introduction

The maxillary permanent cuspid usually erupts into the mouth between the ages of 11 and 12 years;[1] however in an estimated 1-3% of the population one or both teeth fail to appear.[2, 3] There are several reasons why the permanent cuspid might not erupt, but in approximately 50% of patients it is because the tooth is palatally displaced.[4]

The management of a palatally displaced cuspid (PDC) frequently involves a surgical procedure to enable the tooth to be orthodontically aligned. Two techniques of surgical exposure have been described:

- An 'Open' exposure, which involves raising a palatal flap, removal of bone and mucosa overlying the tooth and placement of a surgical pack.[5] The cuspid is subsequently orthodontically aligned above the mucosa.
- A 'Closed' exposure, which involves raising a palatal flap, limited removal of bone and instead of excision of the overlying palatal mucosa, an attachment is bonded to the crown of the exposed cuspid, allowing alignment of the tooth from below the mucosa.[6]

Proponents of each technique claim certain advantages; however a recent Cochrane collaboration systematic review was unable to find any evidence to support the use of one technique over the other.[7]

The purpose of this study was to determine if there are any differences in the outcomes between the Open and Closed surgical techniques for exposing a PDC. In this report the investigators tested the null hypothesis that there would be no difference in the surgical outcomes between the two techniques. The specific objectives were to examine any differences in surgical operating room time and post-operative patient-reported outcomes.

Methods and participants

The study design was a multicenter, randomized controlled clinical trial involving two parallel groups. It was approved by South Sheffield Ethics Committee (SS02/072) and for North and South Derbyshire Local Ethics committees (NDLREC REF: 857) and all participants signed an informed consent agreement. Recruitment to the trial commenced before the 2004 statement from the International Committee of Medical Journal Editors promoting compulsory registration of clinical trials prior to recruitment of participants.[8]

The settings were the Orthodontic Departments of one dental teaching hospital (Charles Clifford Dental Hospital, Sheffield) and two district general hospitals (Chesterfield and North Derbyshire NHS Foundation Trust and Royal Derby Hospitals NHS Foundation Trust) in the United Kingdom. Participants for the trial were identified from the treatment waiting lists and new patient clinics. The inclusion criteria were as follows:

- Patients with unilateral palatally ectopic maxillary cuspids who required surgical exposure and orthodontic alignment;
- Aged 20 years or below;
- Minimal orthodontic problems other than the ectopic cuspid;
- Good oral hygiene and motivated to wear fixed appliances for at least 2 years.

The exclusion criteria were as follows:

- Patients with bilateral palatally ectopic maxillary cuspids or ectopic mandibular cuspids;
- Compromising medical conditions (patients requiring antibiotic prophylaxis to prevent infective endocarditis);
- Periodontal disease (Bleeding on probing, pocket probing depths greater than 3mm and reduced bone levels as diagnosed from the baseline panoramic imaging);
- Cases where the cuspid is to be brought into the position of the lateral incisor.

Potential participants and, if applicable, their parents were given a verbal explanation of the trial and written information to take away. They were allowed at least one week to decide whether or not to take part. If they agreed to participate then written consent was obtained.

Once consent had been obtained, each participant was randomly allocated to one of two interventions. The randomization was undertaken using computer generated random numbers in randomly allocated blocks of 2, 4, 6 and 8 to ensure that there were equal numbers allocated to each intervention. Allocation concealment was with consecutively-numbered, sealed, opaque envelopes held by one individual not involved with the trial at the coordinating center (CCDH), who was contacted by telephone by the consenting clinician. There was no stratification for age, gender or center.

All surgical procedures were carried out under general anesthesia by one of two specialist Oral Surgeons or Oral and Maxillofacial Surgeons at each unit, all of whom had had at least ten years

of experience of using both techniques. The surgical protocols were agreed before the start of the study amongst the research team and two surgeons from Center 3. The two interventions were:

Open surgical exposure

- Extraction of the primary cuspid (if present).
- Surgical bone removal exposing the greatest diameter of the ectopic cuspid crown.
- Surgical excision of the palatal mucosa - standardised using a preformed wire template.
- Surgical gauze soaked in Whitehead's varnish (iodoform 10g, benzoin 10g, prepared storax 7.5 g, tolu balsam 5 g, and solvent ether to 100 ml) or Coe-pack™ surgical dressing (GC America Inc, Alsip, IL US) was sutured in place.
- The patient was reviewed 10 days later and the surgical pack removed.

Closed surgical exposure

- Extraction of the primary cuspid (if present).
- Surgical bone removal exposing the greatest diameter of the ectopic cuspid crown.
- An eyelet attachment with a gold chain was bonded to the palatal or buccal surface of the ectopic cuspid crown (whichever was the most accessible). Surgical gauze and suction were used to maintain a dry field.
- The palatal mucosa was sutured back intact with the gold chain extending through an incision in the palatal flap.

Chlorhexidine digluconate 0.2% w/v mouthwash (Corsodyl®, GlaxoSmithKline, Brentford, UK) was prescribed after surgery (10 mls 3 times per day for 7 days, starting 4 hours after surgery).

Masking

It was not possible to mask those administering surgical treatment, therefore there was an unavoidable risk of treatment bias. For measurement purposes, the masked assessor would probably be able to guess which cuspid was previously impacted, owing to positional differences, but would not be able to tell which technique was employed.

Outcomes

The Finance Departments of each participating center were contacted and theater databases examined to obtain data from Korner datasets.[9] These are completed for each surgical procedure by a member of staff in the operating theater. Data for 'actual surgical time' in minutes from

incision to last suture (excluding anesthetic and recovery time) were used in the analysis. Any patient requiring an overnight stay was documented.

The patient reported outcome consisted of a post-operative questionnaire (see Appendix 1), which was given to participants at their 10 day surgical review appointment. This questionnaire was a modification of a previously validated questionnaire given to the team by a researcher working at Queen's University Belfast. The modification arose following piloting of the questionnaire amongst the research team. After the pilot, the team got together and made a few modifications leading to the development of the final questionnaire, which consisted of seven questions. The response formats for five of the seven questions was a ten-point Likert scale from 1 (no pain/difficulty) to 10 (severe pain/difficulty). The scores for each of these five questions were added together to obtain an overall response score. The distribution of the data was examined and found to be normal (Shapiro-Wilk; Closed: P=.347; Open: P=.173); therefore an independent t test was used to compare the means of the two groups. The responses to question 2 'How long did the pain or soreness last?' were collapsed into three categories ('None' to 'A few hours'; '1 day' to 'Several days'; '1 week' to 'Still present') and the frequencies compared using a chi-squared test for trend. The frequency of responses to question 5 'did you require any pain-killers?'('Yes'/'No') were tabulated and compared using a Fisher's exact test.

The severity of the cuspid impaction was assessed by a single blind assessor, from the pre-treatment panoramic imaging film, using the criteria described by Ericsson and Kurol.[10]

Statistical analysis

The primary outcome of the overall clinical trial was the difference in periodontal outcomes between the Open and Closed surgical groups and will be reported elsewhere. An *a priori* sample size calculation suggested that a sample size of 60 was required to detect a significant difference in the mean loss of attachment between the two groups of 0.5mm (SD 0.61 mm;[11] 90% power; 5% significance level, two-tailed). The sample size was increased to 80 (Closed: 40; Open: 40) to allow for a 30% drop-out rate. The sample size was not related to the surgical outcomes; however it was decided that a *post hoc* power calculation could be used to determine the required sample size to detect a significant difference for non-statistically significant results.

The intention-to-treat principle was adhered to and the patients who received the non-allocated surgical procedure were kept in their original allocated groups.

Pretreatment equivalence between the two groups was examined using an independent *t* test for continuous variables (age, angulation, and vertical height) and Fischer's exact tests for categorical data (gender, side and sector collapsed into two categories). The distribution of the surgical times data was examined and found to be normal (Shapiro-Wilk; Open: P=.370; Closed: P=.120); therefore an independent *t* test was used to examined the differences between the Open and Closed groups.

Results

Recruitment commenced at the beginning of August 2002 and finished at the end of January 2007. Owing to difficulties in collecting data at three busy units, the total number of patients assessed for eligibility was not recorded. There were only two documented instances when patients declined to participate in the study, both of these were from Center 1. Eighty one participants were recruited, and Figure 1 describes the flow of participants through the trial.

One participant (2% of the total sample) randomized to a Closed exposure was inadvertently given an Open exposure. Four participants (10%) randomized to Open exposures were given Closed exposures. There was a deliberate deviation from the protocol for two of these four subjects. The reason for this deviation was because the surgeon believed that the canine was too high for an Open exposure and that there was a significant risk of palatal mucosal overgrowth. These five patients were analyzed in their original allocated groups.

Baseline Data

The baseline demographic and clinical data for the 81 participants recruited to the three centers are described in Table 1. The mean age of the sample was 14.2 years (SD 1.5; min 10.1, max 17.6). The majority of the sample was female (64%). There were no differences between the two groups at baseline for age (P=.730), gender (P=.352) or any of the measures for cuspid position severity (angulation P=.646; vertical height P=.611; sector P=.802). A higher proportion of the PDC were present on the right side (56%), and this was especially the case in the Open group (29 out of 40 cuspids, 73%), which was statistically significant (P=.002).

The data for severity of cuspid displacement are also shown in Table 1. In addition to the 10 participants who withdrew or dropped out, the start panoramic imaging film was not retrievable in seven participants (5 Open & 2 Closed). The mean angulation of the PDC was 33.1° for the Open group (SD 14.4; min 0, max 59) and 31.9° in the Closed group (SD 13.3; min 5, max 65). The mean Vertical Height of the tip of the cuspid to the occlusal plane was 13.6mm for the Open group (SD 3.1; min 8, max 21) and 13.2mm for the Closed group (SD 2.8; min 8, max 18). The mean

sector for cuspid displacement was 3.5 for the Open group (SD 1.0; min 1, max 5) and 3.6 for Closed group (SD 0.9; min 2, max 5).

Failure rates

Three participants out of 31 (9.6%) in the Open group required re-exposure owing to overgrowth of the palatal mucosa. In the Closed group, one subject out of 35 (2.9%) required re-exposure. The overall failure rate was therefore 6%.

Other complications

One participant suffered a post-operative infection, requiring antibiotic treatment. No re-exposure was required, but the gingival architecture around the PDC remained abnormal during its alignment. In one participant the chain was bonded too low and close to the cemento-enamel junction. The patient experienced pain during traction and the chain fenestrated the palatal mucosa. The chain was removed under local anesthesia and an eyelet bonded to the tip of the cuspid. One participant required re-exposure using an apically repositioned flap under local anesthetic two years after the initial exposure as it was felt that the cuspid was 'slow moving' and this would hasten its alignment.

Time in operating room

Operating times were obtained for 57 of the 71 participants who underwent surgery (Open 31; Closed 26). Twelve operating times were missing from Center 1, two from Center 2 and none were missing from Center 3. The failure to obtain data from Center 1 in particular was due to inadequate completion of the data collection sheets, with either only start or only finish times being available and in three subjects there was no record of surgery. None of the participants had immediate complications or co-morbidities during their hospital stay and no patient required hospitalization overnight.

Descriptive data for operating times of the two surgical procedures are shown in Table 2. The means, standard deviations and ranges for the time in the operating room were virtually identical between the two groups (Open mean 34.3 mins, SD 11.2, range 19-62; Closed mean 34.3 mins, SD 11.9, range 19-59) and there was no significant difference (independent t test; P=.986). Just over half of the surgical procedures (35 out of 64; 55%) involved exposure of the cuspid only; 27 involved additional extraction of bicuspids and two participants (both in the Open group) had procedures that explained the longer surgical times (extraction of all first molars total surgical time 62mins; labial frenectomy surgical time 59mins). A second analysis without these outliers reduced

the mean theater time from 34.3 to 32.5 minutes, which again was not statistically significant (independent *t* tests; P=.540).

Patient reported outcomes

Sixty participants returned a satisfactorily completed patient reported outcome questionnaire. This represents a response rate of 85% of the 71 participants who underwent palatal surgery. The descriptive data for responses to questions 1, 3, 4, 6 and 7, which had similar response codes, are shown in Table 3. There were no significant differences between the Open and Closed groups for any of these questions.

The frequencies of responses to the question 'How long did the pain last?' are shown in Table 4. The majority of the responses (36 out of 60) claimed that the pain lasted for several days. Six out of the nine participants reporting that pain was still present after several days were in the Open group. Three out of the four participants reporting 'no pain' were in the Closed group; however the difference in pain duration between groups was not significant (chi-squared test for trend; P=.161).

The responses to Question 5; 'Following the operation did you require any pain-killers?' showed that 28 out of 31 participants (90%) in the Open group required pain relief, compared with 23 out of 29 participants (79%) in the Closed group, which was not statistically significant (Fisher's exact test; P=.140).

Discussion

This clinical trial involving young people with a unilateral PDC found no statistically significant differences in the length of time in the operating room or patient-reported outcomes following surgery, between those who were randomly allocated to receive either an Open or Closed surgical procedure. It appears therefore that either technique is acceptable to both the operator and the patient. Other outcomes such as length of orthodontic treatment, as well as periodontal and esthetic outcomes will be reported elsewhere.

The mean operating times for the two groups of patients were almost identical. Gharaibeh and Al-Nimri[12] undertook a clinical trial involving 32 patients randomly allocated to either an Open or a Closed surgical technique and found a mean operating time of 30.9 mins (SD 10.1) for the Open surgical exposure and 37.7 mins (SD 8.4) for the Closed surgical exposure, which was statistically significant (P=.006). If those participants in our study who had 'other' procedures performed at the same time as the surgical exposure were excluded from the analysis, then the mean operating times were similar to those of Gharaibeh and Al Nimri.

A prospective, cohort study involving 60 patients treated with either the Open or Closed surgical technique carried out by Chaushu and colleagues[13] reported longer mean operating times than the present study (Closed: 36.4 mins, SD 17.3; Open 44.6 mins, SD 15.2). However their participants had a range of ectopic teeth (including 14 impacted central incisors) and they provide no details about the experience of the operator. The increased operating time in the Open group was probably because they did not raise a flap over the unerupted tooth, but used an electrosurgical instrument to remove any overlying thick fibrous mucosa, then sutured a periodontal pack in place.

Pearson *et al*[14] reported a retrospective audit of 104 consecutive patients treated either with the Open or Closed surgical techniques at two centers in the UK. They found a considerably shorter mean operating time for the exposure of one tooth in one center where the Open technique was used (mean 12 mins, range 9-22) compared with a different center where the Closed technique was used (mean 36 mins, range 27-43). The shorter operating time was almost certainly due to their use of an acrylic cover plate, manufactured before the operation, to dress the surgical wound for 10 days following Open exposure, rather than a sutured surgical dressing sutured. No details are provided in the report about the number and experience of the operators involved.

The overall failure rate of 6% in this study compares favorably with previous reports. Pearson *et al* [14] had a very high failure rate of 15% with the Open procedure (mainly due to re-growth of the palatal tissue covering the crown of the PDC) and 31% with the Closed procedure (mainly due to debonding of the orthodontic attachment). However another retrospective audit of patients treated over 3 years (2005-8) using a gingival-sparing open technique and dressed with Coe-pak™ found that only 9 teeth out of a sample of 247 teeth (3.5%) required a second surgical procedure.[15] Other studies have reported very low rate bond failure rates with the Closed technique.[16-18] In our trial, the fact that only one of the chains debonded post-surgery suggests that bonding intra-operatively, by experienced oral surgeons, was uncomplicated and an adequate bond strength was consistently achieved. At the start of the trial, equipoise for both surgical techniques was established, all surgeons being familiar with both exposures. We felt that previous experience is especially important with the closed exposure, owing to the delicate nature of bonding a gold chain. At the start of the trial it was decided that the method of bonding the gold chain to the unerupted cuspid using the Closed technique would be left to the discretion of each surgeon. Following further discussion it was discovered that all participating surgeons, except one were using self-etching primer (Transbond™ Plus, 3M Unitek) rather than the more traditional acid-etch procedure. Those using this technique felt that it made bonding in a wet field much quicker and easier.

Patient-based outcomes

Little research has been undertaken to determine which technique has the least impact on a patient's daily life. There has been no qualitative research to-date and in terms of quantitative research, only three studies could be found in the literature investigating the patient perceptions of recovery after surgical exposure of PDC. One study was a randomized controlled trial,[12] and two studies were prospective cohort studies following patients undergoing a Closed[19] or an Open[20] surgical technique for exposing unerupted teeth.

Gharaibeh and Al-Nimri[12] assessed the worst pain in their sample of 32 patients for seven days following surgery, using a numerical pain scale of 1 to 10. They found no differences in the perceptions of pain between individuals treated with either an Open or Closed technique, which concurs with the results of our study. As expected, pain is evident in the immediate post-operative period and 52 out of 60 (87%) participants in the current study required analgesics, which is a slightly higher proportion than Chaushu and colleagues, who found that 80% of patients undergoing the Open procedure required analgesia in the first 24 hours, compared with 76% of patients undergoing the Closed procedure.[19, 20] However it is standard practice in all the centers involved in the study to provide analgesics for the patients to take home. This might therefore explain the increased proportion of patients reporting the use of analgesia, as their expectation of pain and the need to take analgesia would be increased and the tablets would be readily available.

In terms of duration of pain, 60% of the sample stated that the pain lasted for 'several days' and this was the case in both groups. Three patients in the Closed group and six patients in the Open group reported that the pain lasted for more than several days, but this was not statistically significant. This result does not agree with the findings of Chaushu et al[13], who found that there was a reduced need for analgesics in the Closed group after day two. However it does support the findings of Gharaibeh and Al-Nimri[12] who also found no significant difference in the two groups with regard to magnitude and duration of pain.

Chaushu et al[21] investigated patients' perceptions of recovery in a cohort of young people following bicuspid extraction using the same health related questionnaire. They found that 70% of participants in the Extraction group required analgesics, which was a lower proportion than both the Open and Closed exposure groups and that recovery from premolar extractions was approximately one day sooner than from surgical exposure (2 instead of 3 days). The most frequently reported impact in the Extraction group was when eating, with 80% of the sample reporting difficulty in eating and enjoying food and the most distressing symptom was reported to be 'bad taste', with 30% of the sample experiencing this impairment. These results were similar to

those previously reported by participants in the Open group[20], which might be due to both the extraction socket and open exposure healing by secondary intention. The participants in the Closed exposure group[19] reported fewer impacts with eating and bad taste. In comparison we found no differences between the Open and Closed groups in terms of impacts on eating, brushing, bad taste and speaking, even though participants in the Open group had a pack *in situ* for 10 days following surgery.

Chaushu et al[21] also found that participants who were older than 15 years of age reported more impacts following a dental extraction than those in the younger age groups. Few participants in our study were older than 15 years and even though the criteria allowed patients up to 20 years of age to be included in the trial the oldest participant was 16.8 years. A comparison of the total combined scores for questions 1, 3, 4, 6, 7 showed no difference in the overall responses for participants below the age of 15 years of age and those 15 years and above (<15 years mean 22.2 SD 8.2; ≥15 years mean 20.5 SD 8.9).

One limitation of our study was that we only collected the impact data at one point in time (10 days post-operatively). The study team believe that this was sufficiently close enough to the operation to capture the patients overall experience of the two procedures without encountering the perils of collecting and analyzing reliable serial data designed to record the patient's daily lows and highs.[22] The questionnaire used was extensively piloted before starting the trial and included additional impacts on the patient other than pain and discomfort, such as interference with everyday activities, such as eating, speaking and cleaning teeth. It is important to further develop and evaluate such patient-based measures to use as outcome measures in future clinical trials. Although this was not the primary outcome of the study and it could be argued that the sample size might not have been sufficient to detect a statistically significant difference in patient reported outcomes between the two surgical groups; examination of the descriptive data (Mean Total Impact Scores Open 21.7 SD 9.5; Closed 21.6 SD 7.3) would suggest that a sample size into the thousands would be required to detect a significant difference between the two surgical procedures, if indeed there is a difference to be found.

There was a slightly higher prevalence of PDC on the right side in the sample of patients in this study, with a statistically higher proportion in the Open group, which has not been a consistent finding in other studies. We do not believe this will have an effect on the outcome, as all the participating clinicians were experienced surgeons, who were skilled at operating on either side. The lack of a number of the operating times from Center 1 was disappointing; however examination of the data suggest that there were no differences in any of the baseline

characteristics between those that were included in the analysis and those that were excluded for this reason.

Conclusions

- There was no difference in the operating time between the Open and Closed surgical techniques for PDC;
- There were no differences in any of the patient reported outcomes between the two surgical procedures;
- Although most participants reported pain, discomfort, impairment to every-day activities and need for regular analgesia following surgical exposure, in the majority of patients this was of short duration and subsided after a few days.

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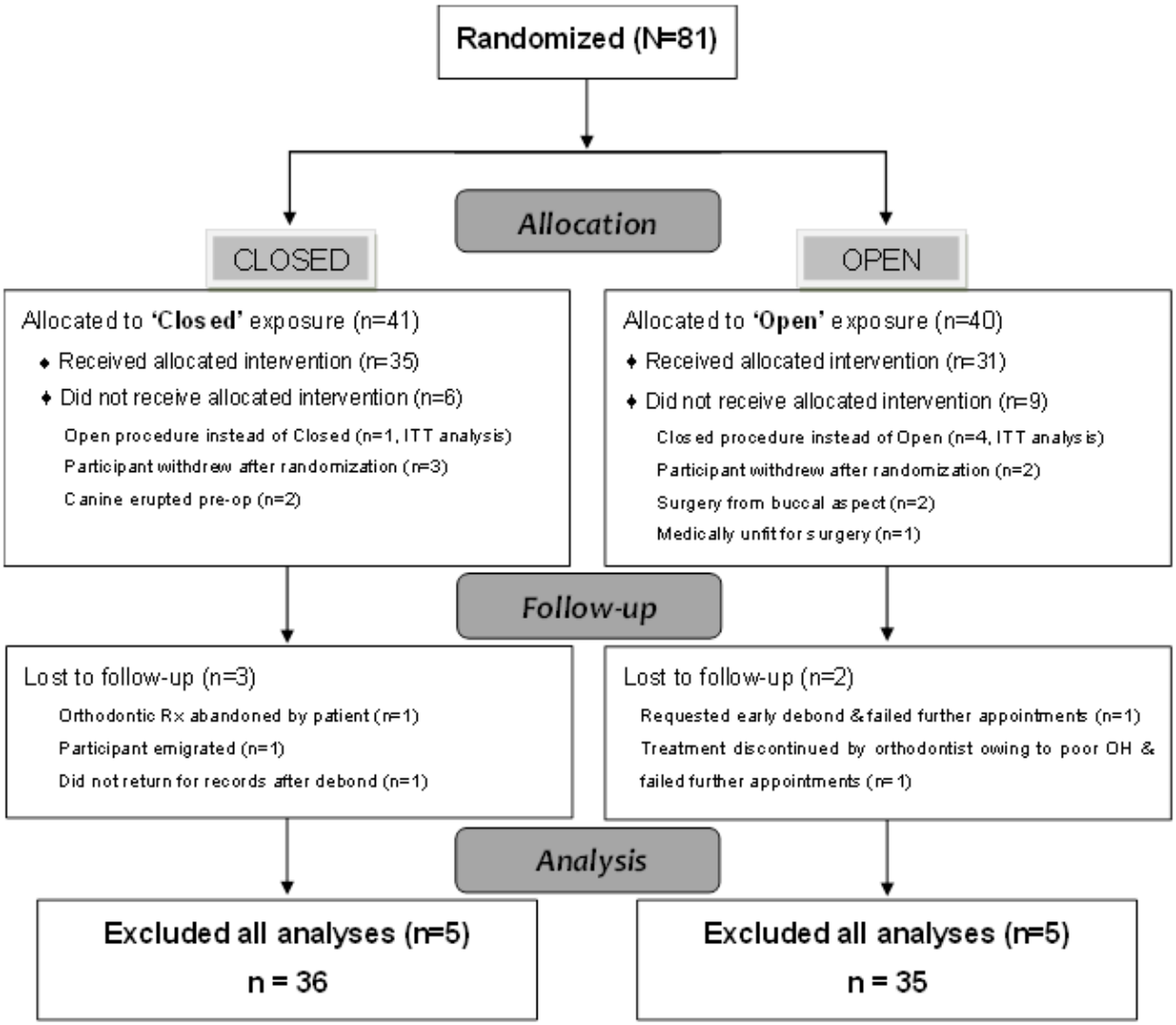
Figures

Figure 1 – Flowchart showing progress of participants through the trial.



Tables

Table1: Baseline data for all consented participants n= 81

	Center 1 (N=33)		Center 2 (N=24)		Center 3 (N=24)		All centers (N=81)	
	Open (N=14)	**Closed (N=19)**	**Open (N=13)**	**Closed = (N=11)**	**Open (N=13)**	**Closed (N=11)**	**Open (N=40)**	**Closed (N=41)**
Mean age in years (SD)	14.7(1.1)	14.3 (1.5)	14.3 (1.3)	14.6 (1.9)	13.8 (1.4)	13.8 (0.9)	14.3 (1.3)	14.1 (1.6)
Gender	F=10, M=4	F=14, M=5	F=7, M=6	F=5, M=6	F=10, M=3	F=6, M =5	F=27, M=13	F=25, M=16
Side of impaction	L=4, R =10	L=11, R =8	L=3, R=10	L=7, R=4	L= 4, R= 9	L=7, R=4	L=11, R=29[a]	L=25, R=16
Severity of Impaction according to Ericsson and Kurol [10]								
	Center 1 (N=31)		**Center 2 (N=13)**		**Center 3 (N=20)**		**All centers (N=64)[b]**	
	Open (N=13)	**Closed (N=18)**	**Open (N=7)**	**Closed (N=6)**	**Open (N=10)**	**Closed (N=10)**	**Open (N=30)**	**Closed (N=34)**
Mean α Angle (SD)	32.5 (13.1)	32.9 (13.0)	32.4 (18.6)	22.6 (16.2)	35.5 (14.3)	35.6 (10.4)	33.1 (14.4)	31.9 (13.3)
Mean Vertical height in mm (SD)	13.8 (2.3)	13.5 (2.8)	12.6 (3.6)	11.8 (2.8)	14.2 (3.8)	13.3 (2.6)	13.6 (3.1)	13.2 (2.8)
Mean Sector	3.5 (0.8)	3.4 (0.7)	3.1 (1.1)	3.2 (1.7)	3.6 (1.2)	4.0 (0.9)	3.5 (1.0)	3.6 (0.9)

[a] All tests of pretreatment equivalence were non-significant (P>0.05), except the side of impaction where there was a difference between the two groups (Fisher's exact test, P=.002).

[b] Ten participants excluded as they did not receive surgery & seven baseline radiographs were missing.

Table 2 compares the mean operating times for the Open versus Closed groups

Group	Mean surgical time	Sd	95% Confidence Interval		Min	Max	P-value
			Lower	Upper			
Open (n=31)	34.3	11.2	30.2	38.4	19	62	0.986
Closed (n=26)	34.3	11.9	29.4	39.1	19	59	

Table 3 shows the descriptive data for five questions from the Patient Reported Outcome Measure

Question	Group	Mean Scores	Sd	95% Confidence Interval		Min	Max	P-value
				Lower	Upper			
1. After the operation on your palate did you experience any pain or soreness?	Open	4.6	2.1	3.8	5.4	1	9	0.913
	Closed	4.6	2.2	3.7	5.4	1	8	
3. Following the operation on your palate did you have any difficulty eating?	Open	5.2	2.5	4.3	6.2	1	9	0.474
	Closed	4.8	2.0	4.0	5.6	1	8	
4. Following the operation on your palate did you find it difficult/uncomfortable to brush the inside of your upper teeth?	Open	5.1	2.8	4.1	6.2	1	10	0.126
	Closed	5.9	2.4	5.0	6.8	1	9	
6. Following the operation on your palate did you notice a bad taste in your mouth?	Open	3.7	2.7	2.8	4.7	1	10	0.462
	Closed	3.8	2.6	2.9	4.8	1	10	
7. Following the operation on your palate did you experience any difficulty in speaking?	Open	2.9	2.6	2.0	3.9	1	9	0.354
	Closed	2.5	1.7	1.8	3.1	1	6	

Table 4

Frequency of responses to question ‘How long did the pain or soreness last?’ collapsed into 3 groups (chi-squared test for trend; P=.161).

Response codes	Open		Closed	
	N	%	N	%
‘None’ to ‘A few hours’	3	10	6	21
‘1 day’ to ‘Several days’	22	71	20	69
‘1 week’ to ‘Still present’	6	19	3	10

Appendices

Appendix 1: Patient Reported Outcomes following surgery

Randomisation number:

Center:

1. After the operation on your palate did you experience any pain or soreness? Please circle

1 2 3 4 5 6 7 8 9 10

No pain Unbearable pain

2. How long did the pain or soreness last? Please circle

None A few hours 1 day Several days 1 week Still present

3. Following the operation on your palate did you have any difficulty eating?

1 2 3 4 5 6 7 8 9 10

No difficulty Could not eat

4. Following the operation on your palate did you find it difficult/uncomfortable to brush the inside of your upper teeth?

1 2 3 4 5 6 7 8 9 10

No difficulty Could not brush

5. Following the operation did you require any pain-killers? Yes/No

Please detail.....

6. Following the operation on your palate did you notice a bad taste in your mouth?

1 2 3 4 5 6 7 8 9 10

No bad taste Very bad taste

7. Following the operation on your palate did you experience any difficulty in speaking?

1 2 3 4 5 6 7 8 9 10

No difficulty Unable to speak