Closed vs open surgical exposure of palatally displaced canines: Patients' perceptions of recovery, operating time, and complications—A 2-center randomized controlled trial

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Introduction: The objective of this trial was to compare, in a 3-week follow-up, patients' perceptions of recovery, surgery time, and complications related to surgical exposure of palatally displaced canines (PDCs) with either the closed or the open techniques. **Methods:** This study was a 2-center, 2-arm parallel randomized clinical trial with a 1:1 allocation ratio. A total of 100 participants with PDC from 2 university clinics, aged <16 years, with unilateral or bilateral PDCs with cusp tip position in sectors II-IV, were randomly allocated to either closed-exposure or open-exposure techniques. Outcomes related to surgery and surgery/dressing removal interventions were analyzed by blinded assessors. Patients' perceptions during both interventions and the week postinterventions were evaluated using take-home questionnaires, which included 3 question types: visual analog scale (VAS) questions about pain/discomfort, binary questions about analgesic intake, and open questions about complications. Surgical duration and professional-reported complications were assessed in patient journals. Mixed models with random intercepts were used to examine the effects of treatment on VAS scores (Gaussian model) and the use of analgesics (logistic model). Linear regression was used to examine the effect of the treatment on the operation. Statistical significance was set at <0.05. **Results:** A total of 92 participants were included with no baseline differences between the intervention groups. There were no significant differences in patient perceptions between the centers. The open approach showed higher VAS scores for pain (coefficient, 8.58 [95% confidence interval, 2.29-14.88]; P <0.01) and discomfort (coefficient, 9.15 [95% confidence interval, 2.33-15.98]; P <0.01) from the exposure operation onwards, with nonsignificantly higher scores for patients with bilateral than unilateral PDCs. No pain/discomfort score differences were observed between treatment groups or between patients with bilateral or unilateral PDCs at surgery/dressing removal intervention. There were no differences in analgesic intake after surgery, but there was significantly more consumption after suture/dressing removal with the closed technique. Overall, a shorter duration was observed for the open technique, particularly when no flap surgeries were performed. Few complications were detected and were more common in the open group. **Conclusions:** There was more pain and discomfort in the open group during surgery and the following week; however, no difference was observed during suture/dressing removal or the week after. There was increased

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The prevalence of maxillary canine impaction is approximately 1%-3% in the general young population[1,2] and as high as 23.5% in orthodontic practices.[3,4] According to Ericson and Kurol,[5] they are mostly located in a palatal position (43.0%-87.0%), and frequently presented unilaterally.[6] The incidence is reported to be twice as high in women as in men.[2]

Early diagnosis of a palatally displaced canine (PDC) allows clinicians to apply interceptive approaches, such as extraction of the deciduous canine and/or expansion techniques, to prevent the canine from becoming impacted[7-11] or to avoid complications, such as arch length loss, dental asymmetry[12] and risk of root resorption of the adjacent teeth.[9,13] If interceptive measures fail, or if the PDC is noticed late and a diagnosis of impaction is made, the recommended treatment approach is a surgical exposure of the canine's crown followed by orthodontic movement of the tooth into the correct position.[14,15]

Two major surgical techniques are used to expose PDC: closed and open. The closed technique is a standardized technique that involves full-flap replacement with a full recovery of the impacted canine after exposure and bonding of an attachment to the crown. The orthodontic force is applied to the canine shortly after surgery, and the canine is forced to move beneath the palatal mucosa. In the open technique, a similar amount of bone covering the canine crown is removed, but the crown is left exposed to the oral environment, with the opening maintained using a surgical dressing.[16] The treatment approach that follows depends on whether an attachment is bonded to the exposed tooth for immediate orthodontic traction or if the tooth is left to erupt spontaneously. In both circumstances, the tooth erupts above the palatal mucosa. The open technique may or may not involve flap surgery.[17,18] Different types of dressings are used in the open surgical exposure, including the Glass-Ionmer cement, the so-called Gopex technique.[18-20]

The amount of postoperative pain has been shown to last several days,[21] being identical for the 2 techniques during the first postsurgery day,[22,23] but recovery was faster in the closed technique.[21,22] In a randomized controlled trial (RCT)[20] in which a glass-ionomer was used, patients experienced more pain and impairment with open exposure on the day of surgery and 7 days postoperation. Surgery time has been claimed to be shorter with the open-exposure technique[22] or not significantly different compared with the closed technique.[20,23] Complications were less common with the closed technique in patients with bilateral impactions.[20]

Orthodontic treatment of PDC is invasive and often long-lasting.[24,25] Questions about the extent and duration of pain and discomfort that follow surgery, its duration, and possible complications are frequently asked by patients and their parents. Evidence-based answers to these treatment outcomes are still insufficient owing to the lack of RCTs.[16,26,27]

Specific objectives or hypotheses

This RCT aimed to compare the closed surgical exposure technique and the open surgical exposure technique over a 3-week follow-up in terms of patients' perception of recovery, surgery time, and complications related to surgery.

MATERIAL AND METHODS

Study design and setting

This was a 2-center randomized controlled trial with 2 parallel groups randomly allocated in a 1:1 ratio.

The trial was conducted at the University Orthodontic Department in Jönköping, Sweden (center A) and Oslo, Norway (center B).

The study protocol and informed consent were approved by the regional ethical committee of both Sweden (Dnr 2017/92-31) and Norway (2016/715/REK sør-øst). Trial registration: ClinicalTrials.gov ID: NCT05067712.

Participants and eligibility criteria

Patients from the 2 centers, diagnosed with PDC and with an indication for surgical exposure and orthodontic treatment, were consecutively invited between September 2017 and September 2023 to participate in the trial.

The inclusion criteria were (1) unilateral or bilateral PDCs, (2) patients aged ≤16 years, (3) no restriction for presenting malocclusion, and (4) canine cusp tip position in sector II-IV[9] documented by panoramic radiograph.

The exclusion criteria were (1) disease affecting somatic or craniofacial growth, (2) documented neuropsychiatric diagnosis, (3) agenesis of the adjacent lateral incisors, (4) communication-related difficulties when an interpreter was needed, (5) vertical position of the canine

above the roots of the adjacent incisors, and (6) past or ongoing orthodontic treatment.

In patients with bilateral PDCs, both PDCs were exposed in the same surgical intervention. The canine in the most difficult position according to the inclusion criteria was chosen as the study tooth.

Interventions

To investigate whether root resorption on adjacent incisors existed and to facilitate the localization of the canine before surgical intervention, cone-beam computed tomography (CBCT) analyses were performed in all participants in addition to panoramic radiography.

One specialist in oral surgery at each center was responsible for all surgical exposures. Both surgeons were experienced with the open and closed techniques. The open technique was performed slightly differently in the 2 centers. At center A, open surgical exposure was performed without flap surgery, whereas at center B, open surgical exposure was performed with flap surgery. Moreover, the procedures were equal.

Surgical exposure of palatally displaced canine with an open surgical technique. The deciduous canine was removed if present.

1. A circular section of the mucoperiosteal tissue was removed above the PDC (center A), or a flap of the mucoperiosteal tissue was elevated off the bone (center B).
2. The bone covering the canine was removed until the widest curvature of the crown. This was achieved using a bur and sodium chloride irrigation. Attention was paid not to reach the cementoenamel junction in instances of a more horizontal canine position.
3. The follicular tissue was partially removed.
4. In center B, the flap was fully repositioned and sutured back to its former location, and a window of mucoperiosteal tissue overlying the tooth was removed using a scalpel.
5. At both centers, a dressing was placed over the exposed canine area with sutures to prevent the dressing from falling off. The surgical dressing used was Coe-pak.
6. After 10-15 days, both sutures and dressing were removed.
7. The PDC was left to erupt spontaneously above the surface of the palatal mucosa without orthodontic assistance.

Surgical exposure of palatally displaced canine with a closed surgical technique. The deciduous canine was removed if present.

1. A mucoperiosteal flap was elevated off the bone.
2. The bone covering the canine was removed until the widest curvature of the crown. This was achieved

using a bur and sodium chloride irrigation. Attention was paid not to reach the cementoenamel junction in instances with a more horizontal canine position.
3. The follicular tissue was partially removed.
4. An attachment with a chain was bonded to the exposed crown.
5. The flap was fully repositioned and sutured back intact in its former location, with the chain exiting through the flap sutures on the distal aspect of the neighboring lateral incisors.
6. The end of the chain was bonded to the neighboring teeth with composite.
7. After 10-15 days, the sutures were removed.
8. Within 2-3 weeks after surgery, forced movement of the canine is initiated by orthodontic forces. The canines were then moved beneath the palatal mucosa.

None of the participants in any group received analgesics before surgery. After completion of the surgery, all participants in both groups were administered home analgesics by the surgical team and provided written information with the following recommendations: (1) analgesic intake every 6-8 hours on a needed basis for 2 days postsurgery, according to dosage recommendations and (2) chlorhexidine (0.12%) mouth rinse (Paroex) 2 times a day postsurgery for 7-10 days.

Primary outcomes

Patient-reported outcomes: pain/discomfort, analgesic intake, and complications perceived during interventions and within the week of postintervention. Two take-home questionnaires were given to the participants: 1 after surgical exposure and 1 after suture dressing removal interventions. Patients were instructed to deliver the completed first questionnaire (surgery) at the postsurgery follow-up for suture removal 10-15 days later. They were then given a second and similar questionnaire (suture/dressing removal) to be delivered at the next appointment, this time with the orthodontist 1-2 weeks later. The questionnaires were shown to be reliable and to have sufficient internal consistency.[28] Both questionnaires were completed the evening of the intervention day and every evening the following 7 days postintervention, both at surgical exposure and at suture/dressing removal interventions. Three types of questions were asked: (1) open questions about what was perceived as painful or uncomfortable during surgery and suture removal interventions, the evening of the interventions' day, and the following 7 days after each intervention (discomfort factor); (2) horizontal 100-mm visual analog scale (VAS) questions about pain and discomfort experienced during the

interventions (surgery and suture/dressing removal), the evening of the interventions' day, and the following 7 days; and (3) binary (yes/no) questions about analgesic consumption (interventions' day and the following 7 days).

Measurements of the VAS were made using a standard metric ruler to the nearest 0.5 mm.

Surgery time. Information about surgery time was gathered from the patients' journals. Surgery time was measured from the first incision to the last suture, not including the anesthesia.

Professional-reported complications. Information about objective complications from both surgeries and after 3 weeks was gathered from the patients' journals. Possible complications include bleeding, swelling, infection, loss of sutures, bonding failure of the attachment in the closed technique, and loss of dressing with the closure of the exposed area in the open technique.

Secondary outcomes

Secondary outcome measures were related to the position of the PDC, as assessed on panoramic radiographs: medial crown position (sector), angulation, and vertical distance.

The canines in this trial had their crown tips positioned parallel to the long axis, passing through the distal aspect of the lateral incisors and the long axis of the central incisor on the same side (sectors II, III, and IV).[9] Canine angulation was assessed by the angle between the long axis of the PDC and the maxillary midline, the midline being defined as the line from the frontal aspect of the intermaxillary suture through the alveolar process down to the anterior spina nasalis.[9] The vertical distance was measured from the cusp tip of the PDC to the occlusal plane.[9]

Sample size calculation

A pilot study with 10 randomized patients was conducted at the beginning of the trial. The mean VAS pain or discomfort score was 37 mm, and the standard deviation was 20 mm. Previous studies[29,30] have shown that a 15-mm VAS score represents a clinically relevant difference in pain/discomfort. The sample size calculation was based on a standard deviation of 20 units using a 2-tailed *t* test of the means with 90% power and a 5% level of significance. A sample of 74 subjects (37 in each arm) was considered sufficient to detect a clinically significant difference of 15 mm VAS in pain or discomfort experience between groups if such a difference really existed. Considering a dropout rate of 15%, the required sample size was 84 participants (42 per

group). The patients in the pilot study were not included in the trial. During the coronavirus disease 2019 pandemic, it was decided to include 16 more participants owing to an increase in dropouts; therefore, the total number of participants was 100. Because of the smaller average annual intake of new patients in center B, center A would have 58 patients, and center B would have 42 patients.

Interim analyses and stopping guidelines

Not applicable.

Randomization (random number generation, allocation concealment, and implementation)

The participants were recruited by an orthodontic specialist in charge of the orthodontic clinic at each center (A.M., L.F.F.). Both the parents and eligible study participants were provided with verbal and written information about the trial. Adult and child versions of the information brochure were provided. After obtaining informed consent, the study participants were allocated to 1 of the 2 surgical exposure techniques. The allocation was randomly generated using blocks of variable sizes (2, 8, and 10 blocks). Stratification was performed for each center. To prevent foreknowledge by the treating clinician, allocation concealment in each center was performed by an independent person not involved in the trial who communicated the participant's assigned trial group to the treating clinician (A.M., R.L., L.F.F.) on request.

Blinding

Care providers cannot be blinded for these reasons. The study participants were not informed of the treatment allocation. However, information was given to them in the recruitment phase and several participants understood which treatment they were receiving. Data analysis was performed by assessors who were blinded and unaware of participants' group allocation.

Statistical analysis (primary and secondary outcomes and subgroup analyses)

Descriptive statistics were calculated for each variable by treatment arm and time; spaghetti plots were drawn for the VAS pain and discomfort scores, and bar plots were drawn for the use of analgesics. Mixed models with random intercepts were fitted to examine the effect of treatment adjusted for time, unilateral/bilateral canine presence, and center on the VAS scores (Gaussian model) and the use of analgesics (logistic model). Treatment
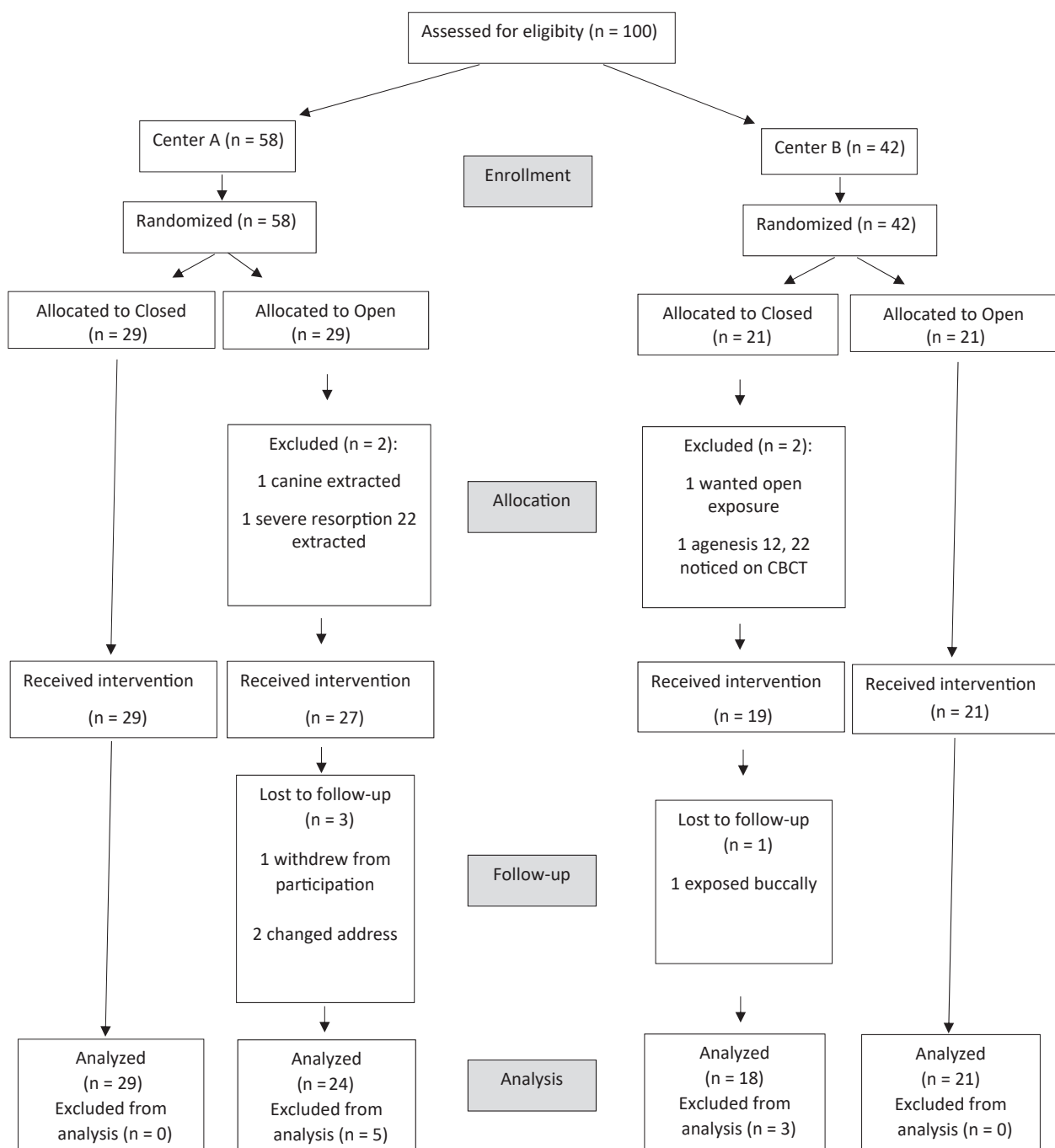
Fig 1. Consolidated Standards of Reporting Trials (CONSORT) flowchart.

time interactions were also considered but were not included in the final models, as they were not significant. For the relatively small number of missing patients, their outcomes were considered missing at random, and the use of direct likelihood via random effects models on longitudinal data accounted for this missingness. Linear regression was used to examine the effect of treatment on the operation duration, adjusted for unilateral/bilateral canines and centers. A *P* value of <0.05 was considered statistically significant. Statistical calculations were performed using Stata software (version 18; StataCorp, College Station, Tex).

Table I. Sample characteristics

Characteristics	Closed exposure	Open exposure
Total	47 (51.9); 13.1 ± 1.4	45 (48.1); 12.9 ± 1.4
Boys	17 (53.1); 13.2 ± 1.5	15 (46.9); 13.3 ± 1.5
Girls	30 (50.0); 13.0 ± 1.4	30 (50.0); 12.8 ± 1.3
Tooth		
13	24 (51.1)	20 (44.4)
23	23 (48.9)	25 (55.6)
Unilateral/bilateral		
Unilateral	36 (76.6)	35 (77.8)
Bilateral[†]	11 (23.4)	10 (22.3)
Sector position[‡]		
II	5 (10.6)	3 (6.7)
III	25 (53.2)	29 (64.4)
IV	17 (36.2)	13 (28.9)
α-angle (°)	31.3 ± 10.2[§]	30.6 ± 7.0[‖]
Distance to OL (mm)	13.6 ± 2.8[§]	13.8 ± 2.3[‖]

Note. Values are presented as number (percentage) and/or mean ± standard deviation.
OL, occlusal line.
[†]The canine in the most difficult position according to sectors[9] is chosen as the study tooth; [‡]According to Ericson and Kurol[9]; [§]n = 47; [‖]n = 45.

RESULTS

Participant flow

Figure 1 shows the flow of participants through the trial. A total of 100 patients fulfilling the inclusion criteria were invited to participate in the trial. All patients agreed to participate and were randomized into one of the surgical exposure groups. A total of 8 participants were excluded from the trial: 4 after randomization (2 open and 2 closed) and 4 after allocation (3 open and 1 closed). One participant decided not to undergo treatment; the impacted canine was extracted, and the other wanted an open surgical exposure. One participant moved to another country to study, and the other 2 changed addresses. After a CBCT examination, 1 participant presented with severe root resorption of the adjacent lateral incisors that were extracted, and 1 was diagnosed with agenesis of the lateral incisors. The lateral incisors believed to be permanent on orthopantomography were deciduous on CBCT, and the permanent lateral incisors were missing. In the third patient, surgery was performed on the labial side. The tip of the impacted crown entered the interproximal area of the neighboring roots because of the transverse inclination of the canine with its apex toward the midpalatal suture, and there was room labially to perform the surgery. The final number of participants who completed this part of the trial was 92, with a mean age of 13.05 ± 1.40 years, of whom 59 were girls and 33 were boys. All participants were followed up for 3 weeks after the surgical exposure

intervention. There were 47 studied canines in the closed and 45 in the open group, with a total of 44 located on the right and 48 on the left sides. A total of 21 patients had bilateral PDC (Table I).

Baseline data (included in the baseline table). There were no significant differences between the 2 intervention groups in terms of age, sex, tooth position distribution, or any measurements of canine position severity (sector, angulation, and vertical height). The baseline demographic and clinical data are presented in Table I.

Numbers analyzed for each outcome, estimation and precision, and subgroup analyses

Patients' perceptions. The questionnaire administered after the surgical exposure intervention was returned by 87 participants, and the questionnaire administered after suture/dressing removal was returned by 75 participants, giving a response rate of 94.46% and 81.52%, respectively. Table II and Figures 2 and 3 show the patients' perceived pain and discomfort during the injection, interventions (surgical exposure and suture/dressing removal), and the week after each intervention.

The spaghetti plots for the evolution of pain and discomfort during and after surgery (Fig 2) showed great variability among patients, with an immediate increase during the first day and a sharp decline thereafter. The recovery appeared slower in the open-surgery group. The most common discomfort factor related to the surgical exposure intervention was injection in both groups, followed by drilling in the open group and sutures in both groups.

From the time of the operation and onwards, the regression models showed that the type of surgery was a significant predictor for both pain (coefficient, 8.58 [95% confidence interval (CI), 2.29-14.88]; P <0.01) and discomfort (coefficient, 9.15 [95% CI, 2.33-15.98]; P <0.01) with the higher VAS (on average 8.58 and 9.15 VAS score units for pain and discomfort, respectively) for the open approach (Table III). The treatment × time interaction was not significant; thus, the evolution of pain and discomfort was similar between treatments over time (Fig 4). Pain (P = 0.220) and discomfort (P = 0.062) scores were higher for the bilateral cases, but the differences were not statistically significant. No significant differences were observed between the centers for pain (P = 0.222) or discomfort (P = 0.723).

In the suture/dressing removal intervention, the most frequently reported discomfort factors were suture removal (7 in the closed group and 10 in the open group), removal of the surgical dressing (5 in the open group), and touching the attachment chain (4 in the

Table II. Patient-reported outcomes during and after interventions

| Variables	Closed exposure (n = 47)			Open exposure (n = 45)		
	n	*Median (IQR)*	*Min-Max*	*n*	*Median (IQR)*	*Min-Max*
Surgical exposure						
Intervention day						
Pain injection	44	28.25 (47.25)	0.00-97.50	42	26.50 (39.00)	0.00-95.00
Discomfort injection	44	24.50 (47.25)	0.00-99.00	43	30.50 (53.50)	0.00-100.00
Pain during intervention	44	1.75 (5.25)	0.00-22.00	42	6.50 (16.50)	0.00-77.00
Discomfort during intervention	44	4.25 (17.50)	0.00-65.00	43	25.00 (43.00)	0.00-80.00
Pain postintervention	44	33.50 (37.00)	0.00-100.00	43	34.50 (36.00)	0.00-90.00
Discomfort postintervention	44	24.75 (38.00)	0.00-85.00	43	31.00 (33.00)	0.00-99.00
1 d postintervention						
Pain	44	11.25 (35.50)	0.00-100.00	43	25.00 (25.50)	0.00-100.00
Discomfort	44	18.50 (35.75)	0.00-76.50	43	34.00 (33.50)	0.50-99.00
2 d postintervention						
Pain	44	6.75 (21.25)	0.00-100.00	43	16.00 (32.50)	0.00-84.00
Discomfort	44	11.00 (31.00)	0.00-68.50	43	16.50 (35.50)	0.0-98.50
3 d postintervention						
Pain	44	2.50 (9.50)	0.00-70.00	43	10.00 (38.50)	0.00-81.50
Discomfort	44	8.25 (21.50)	0.00-78.00	43	11.00 (39.50)	0.00-98.50
5 d postintervention						
Pain	44	1.75 (5.00)	0.00-69.50	43	7.00 (38.50)	0.00-88.50
Discomfort	44	2.00 (10.25)	0.00-78.00	43	15.00 (37.50)	0.0-79.00
7 d postintervention						
Pain	44	0.00 (2.00)	0.00-49.00	43	1.50 (14.00)	0.00-74.00
Discomfort	44	1.25 (4.75)	0.00-55.00	43	4.00 (19.00)	0.00-76.00
Suture/dressing removal						
Intervention day						
Pain during intervention	30	3.00 (11.00)	0.00-100.00	35	19.00 (27.50)	0.00-92.00
Discomfort during intervention	30	4.75 (26.00)	0.00-100.00	35	13.00 (27.00)	0.00-95.00
Pain postintervention	30	1.25 (21.00)	0.00-100.00	35	2.00 (16.00)	0.00-62.50
Discomfort postintervention	30	2.25 (9.50)	0.00-100.00	34	3.00 (15.50)	0.00-99.50
1 d postintervention						
Pain	30	2.25 (6.00)	0.00-81.50	34	1.00 (8.00)	0.00-79.50
Discomfort	30	1.75 (8.00)	0.00-81.50	34	1.00 (9.00)	0.00-75.50
3 d postintervention						
Pain	30	1.00 (3.50)	0.00-53.00	34	0.00 (2.00)	0.00-61.00
Discomfort	30	1.00 (3.50)	0.00-61.00	34	0.00 (4.500)	0.00-52.00

Note. Pain and discomfort are measured in VAS scales.
IQR, interquartile range; *Min*, minimum; *Max*, maximum.

closed group). Great variability in perceptions among the participants was also observed after removing the sutures/dressing (Fig 3). Patients did not receive anesthesia during suture/dressing removal, and answers to the question targeting experiences during this intervention showed nonsignificant differences between the treatment groups for pain (coefficient, −0.59 [95% CI, −6.27 to 5.08]; P = 0.84) and discomfort (coefficient, 0.78 [95% CI, −5.88 to 7.44]; P = 0.82) (Table IV). Pain (P = 0.644) and discomfort (P = 0.631) scores did not differ between patients with unilateral and bilateral PDCs or between centers. The prediction plots showed that the pain and discomfort scores decreased in the evening and continued to decrease thereafter (Fig 5).

Analgesic consumption. The analgesic intake is shown in Table V and Figure 6 for each treatment arm and time point for surgery and suture/dressing removal. There was no difference between the treatment and use of analgesics after surgery (odds ratio [OR], 1.70 [95% CI, 0.39-7.30]; P = 0.48); however, the difference was significant for suture/dressing removal, with the closed group taking more analgesics (OR, 0.002 [95% CI, 0.00-0.44]; P = 0.03) (Fig 6; Table VI). The prediction plots for analgesic consumption in both arms are shown in Figure 7. Estimation of the center and unilateral/bilateral was not possible. The results should be interpreted with caution, particularly for suture/dressing removal, owing to sparse data, model convergence, and estimation issues.
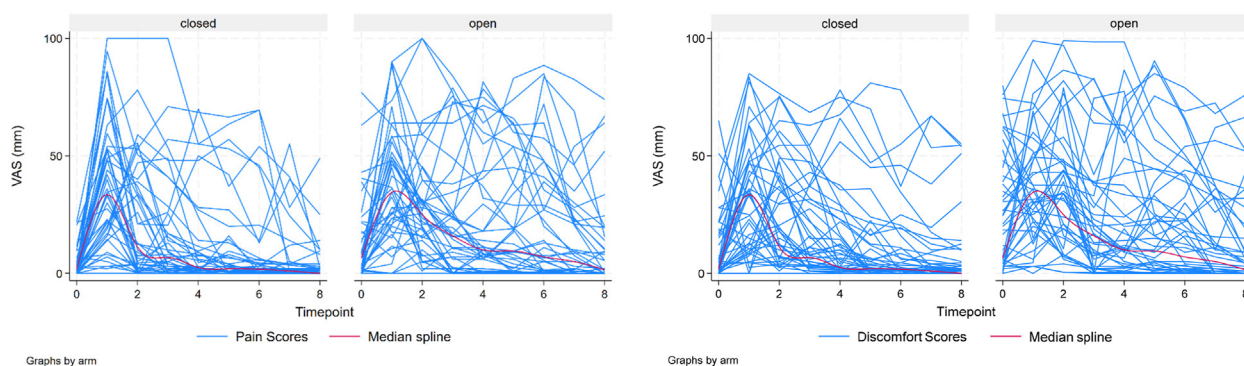
Fig 2. Spaghetti plots of reported pain (*left*) and discomfort (*right*) at surgery and the week after by treatment arm. *Red*, a fitted median spline.
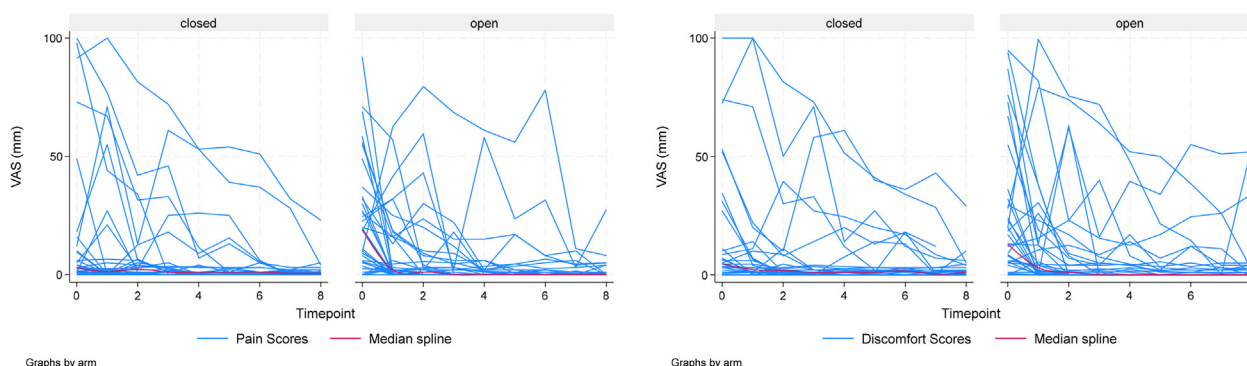

Fig 3. Spaghetti plots of reported pain (*left*) and discomfort (*right*) at suture/dressing removal and the week after by treatment arm. *Red*, a fitted median spline.

Table III. Effect of treatment on the pain and discomfort during surgery and the week after adjusted by unilateral/bilateral canine location, center, and time

Covariate	Pain during and after surgery		Discomfort during and after surgery	
	Coefficient (95% CI)	*P value*	*Coefficient (95% CI)*	*P value*
Arm				
Closed	Reference		Reference	
Open	8.58 (2.29-14.88)	<0.010	9.15 (2.33-15.98)	<0.010
Canine				
Unilateral	−4.75 (−12.37 to 2.87)	0.220	−7.91 (−16.17 to 0.35)	0.062
Bilateral	Reference		Reference	
Center				
Center B	Reference		Reference	
Center A	4.05 (−2.35 to 10.45)	0.222	1.26 (−5.68 to 8.20)	0.723
Time				
During intervention	Reference		Reference	
1	29.03 (24.41-33.64)	<0.001	12.87 (8.32-17.43)	<0.001
2	16.82 (12.20-21.43)	<0.001	11.72 (7.16-16.28)	<0.001
3	11.55 (6.94-16.17)	<0.001	1.40 (−3.15 to 5.96)	0.554
4	8.73 (4.11-13.35)	<0.001	0.48 (−4.08 to 5.04)	0.843
5	7.73 (3.11-12.35)	<0.010	−2.53 (−7.09 to 2.02)	0.284
6	6.40 (1.78-11.01)	<0.010	−4.94 (−9.50 to −0.38)	0.034
7	1.40 (−3.22 to 6.01)	0.563	−8.34 (−12.90 to −3.79)	<0.001
8	−1.51 (−6.13 to 3.10)	0.524	−9.96 (−14.52 to −5.40)	<0.001
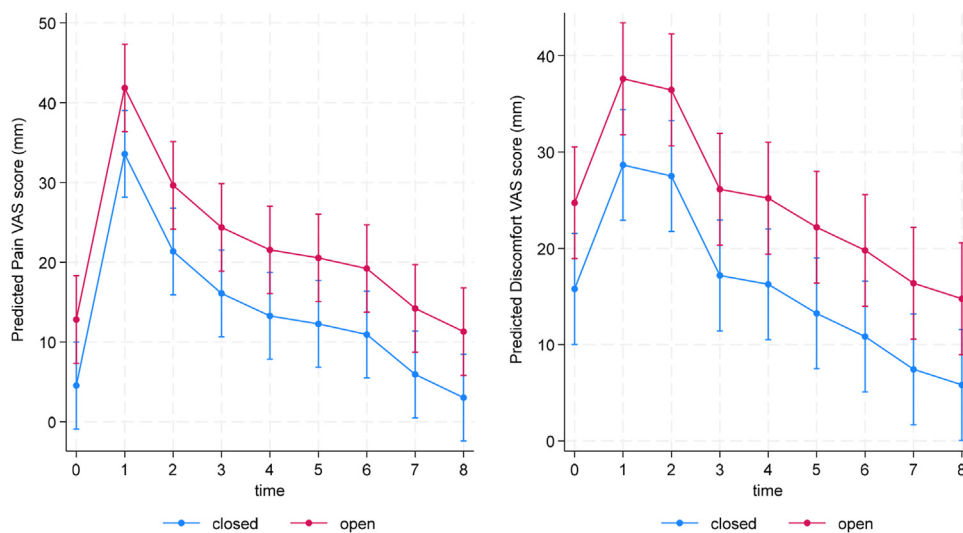
Fig 4. Predictive margin for pain (*left*) and discomfort (*right*) at surgery and the week after by treatment over time.

Table IV. Effect of treatment on the pain and discomfort during suture/dressing removal and the week after adjusted by unilateral/bilateral canine location, center, and time

Covariate	Pain during suture/dressing removal and the following week		Discomfort during suture/dressing removal and the following week	
	Coefficient (95% CI)	P value	Coefficient (95% CI)	P value
Arm				
Closed	Reference		Reference	
Open	−0.59 (−6.27 to 5.08)	0.838	0.78 (−5.88 to 7.44)	0.819
Canine				
Unilateral	−1.52 (−7.98 to 4.94)	0.644	−1.86 (−9.44 to 5.72)	0.631
Bilateral	Reference		Reference	
Center				
Center B	Reference		Reference	
Center A	−0.56 (−6.51 to 5.40)	0.855	−0.42 (−7.41 to 6.57)	0.906
Time				
During intervention	Reference		Reference	
1	−7.55 (−11.70 to −3.40)	<0.001	−7.887 (−12.12 to −3.63)	<0.001
2	−11.84 (−16.01 to −7.67)	<0.001	−11.59 (−15.84 to −7.34)	<0.001
3	−13.56 (−17.73 to −9.39)	<0.001	−13.21 (−17.46 to −8.96)	<0.001
4	−15.42 (−19.59 to −11.25)	<0.001	−15.12 (−19.37 to −10.87)	<0.001
5	−16.02 (−20.19 to −11.85)	<0.001	−16.69 (−20.94 to −12.44)	<0.001
6	−16.45 (−20.62 to −12.27)	<0.001	−16.40 (−20.65 to −12.15)	<0.001
7	−18.77 (−22.94 to −14.60)	<0.001	−17.84 (−22.09 to −13.59)	<0.001
8	−18.77 (−22.98 to −14.56)	<0.001	−17.79 (−22.08 to −13.50)	<0.001

Center A, Sweden; *Center B*, Norway.

Surgery time and anesthesia. Sedative premedication followed by local anesthesia was common to both interventions. Local anesthesia was used in only 34.8% of the participants in the closed group and 47.7% in the open group. In 3 participants with pronounced dental anxiety, general anesthesia was used (Table VII).

Registration of the surgery time was missing for 2 participants: 1 patient with a unilateral PDC in the closed group and 1 patient with a bilateral PDC in the open group. Therefore, the mean surgery time was calculated based on the 46 participants in the closed group and 44 participants in the open group.
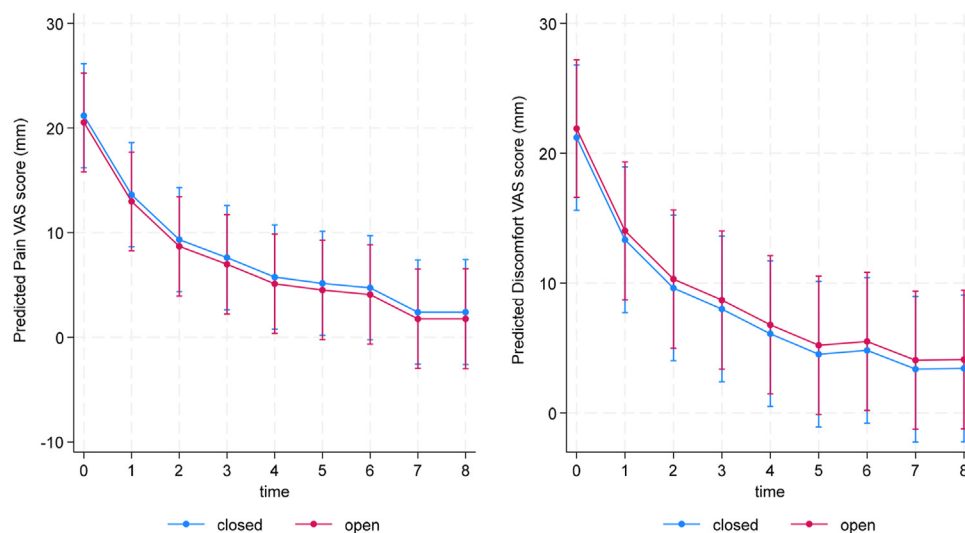
Fig 5. Predictive margin for pain (*left*) and discomfort (*right*) at suture/dressing removal and the week after by treatment over time.

Table V. Analgesic consumption during the week after surgical exposure and suture/dressing removal interventions

Variables	Closed exposure (n = 47)	Open exposure (n = 45)
Surgery		
Evening intervention day	39/44 (88.64)	37/43 (86.05)
1 d postintervention	30/44 (68.18)	29/43 (67.44)
2 d postintervention	19/44 (43.18)	22/43 (51.16)
3 d postintervention	19/44 (43.18)	18/43 (41.86)
4 d postintervention	12/44 (27.27)	11/43 (25.58)
5 d postintervention	8/44 (18.18)	14/43 (32.56)
6 d postintervention	8/44 (18.18)	8/43 (18.60)
7 d postintervention	4/44 (9.09)	6/43 (13.95)
Suture/dressing removal		
Evening intervention day	12/30 (40.00)	4/35 (11.43)
1 d postintervention	8/30 (26.67)	0/34 (0.00)
2 d postintervention	4/30 (13.33)	0/34 (0.00)
3 d postintervention	2/30 (6.67)	0/34 (0.00)
4 d postintervention	1/30 (3.33)	0/34 (0.00)
5 d postintervention	1/30 (3.33)	0/34 (0.00)
6 d postintervention	0/30 (0.00)	0/34 (0.00)
7 d postintervention	0/28 (0.00)	0/34 (0.00)

Note. Values are presented as n/N (percentage).

Table VII presents the type of anesthesia used per treatment arm, distribution of bilateral and unilateral canine impactions by treatment arm and center, and corresponding surgery times.

The linear model for operation time using treatment, unilateral/bilateral impaction, center, and all interactions showed that all main effects were significant, as were treatment × center, treatment × unilateral/
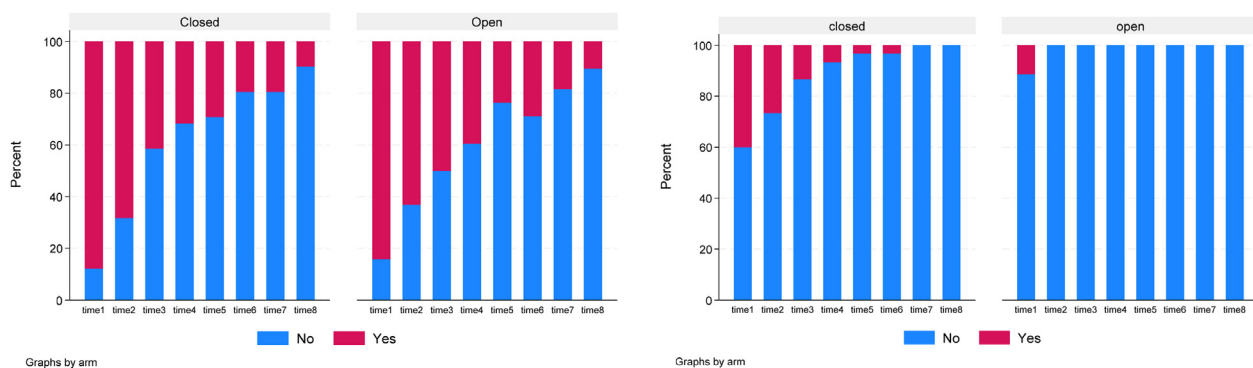
bilateral, and treatment × center × unilateral/bilateral effects (Table VIII). The results are shown in Figure 8. In both treatment arms, the operation time was consistently shorter in unilateral than in patients with bilateral PDCs. For both patients with unilateral and bilateral PDCs, surgery with the open technique without flap replacement (center A) was shorter than that with flap surgery (center B). In center A, the closed operation time was shorter in the bilateral group and longer in the unilateral group than in center B. In bilateral impactions, the operation time with the open technique was shorter than that with the closed technique, regardless of whether flap replacement was performed. In patients with unilateral PDCs, the operative time with the open technique without flap replacement was significantly shorter than that with the closed technique.

Harms. Complications were recorded during surgery and within 3 weeks after the surgical exposure intervention.

On the whole, few complications were detected.

There was evidence, although weak, of an association between the total number of complications and type of intervention (5/47 closed and 12/45 open) in favor of the closed technique (OR, 0.33 [95% CI, 0.04-1.14]; Fisher's exact test P value = 0.06). This difference was observed in both centers (Table IX).

Bleeding was the most reported complication in the open-exposure group, occurring in 8 participants. These included 4 patients with unilateral PDCs (17.8%) and 2 patients with bilateral PDCs (20.0%). Four patients in the open group had the surgical dressing fall off with consequent closure of the exposed area. All the patients had

Fig 6. Percentage of patients taking/not taking analgesics after surgery (*left*) and after suture/dressing removal (*right*) by treatment over time.

Table VI. Effect of treatment on analgesic intake adjusted for unilateral/bilateral canine location, center, and time

Covariate	Surgery		Sutures/dressing removal	
	OR (95% CI)	P value	OR (95% CI)	P value
Arm				
Closed	Reference		Reference	
Open	1.70 (0.39-7.30)	0.484	0.002 (0.00-0.44)	0.032
Canine				
Unilateral	0.26 (0.05-1.55)	0.141	Not estimable	
Bilateral	Reference			
Center				
Center B	Reference			
Center A	2.84 (0.63-12.76)	0.173	Not estimable	
Time				
0	Reference		Reference	
1	0.08 (0.02-0.28)	<0.001	0.06 (0.00-0.55)	0.013
2	0.01 (0.00-0.05)	<0.001	0.00 (0.00-0.14)	<0.010
3	0.00 (0.00-0.02)	<0.001	0.00 (0.00-0.15)	<0.010
4	0.00 (0.00-0.01)	<0.001	0.00 (0.00-0.23)	<0.010
5	0.00 (0.00-0.01)	<0.001	0.00 (0.00-0.26)	<0.010
6	0.00 (0.00-0.00)	<0.001	Not estimable	
7	0.00 (0.00-0.00)	<0.001	Not estimable	

Center A, Sweden; *Center B*, Norway.

unilateral impactions. In the closed group, the most common complication was hanging chain, which caused discomfort in 4 patients with unilateral and 2 patients with bilateral PDCs. One bonding failure of the attachment was reported during surgery in a patient with a bilateral PDC in the closed group, owing to difficulties in keeping the surgical field dry, and the attachment had to be rebonded. No infections were observed in any of the patients.

DISCUSSION

Main findings in the context of the existing evidence

The findings of this randomized clinical trial are objective measures of the impact of the 2 surgical techniques, usually empirically chosen, to expose the PDC on the following outcomes: patient perceptions, duration of surgery, and complications within 3 weeks postsurgery. Compared with previous research, this trial sheds light on 2 new outcomes: longitudinal assessment of patients' perceptions of surgery and longitudinal assessment of patients' perceptions of the intervention to remove sutures and surgical dressing, during the week after the interventions.

The baseline participant characteristics were quite homogeneous, and no differences between groups were observed with respect to age, sex, and canine location, as seen on panoramic radiographs. Eight canines located in sector II were included in this study. According
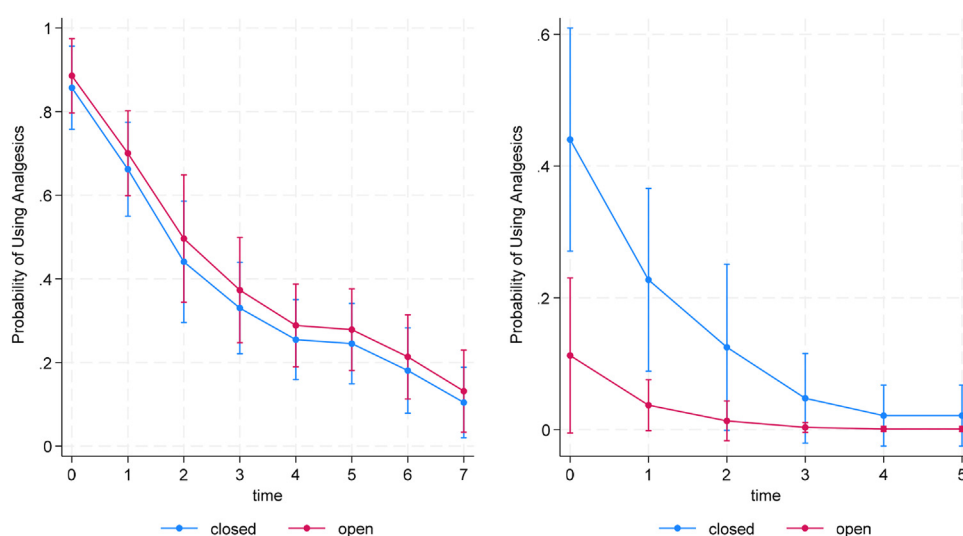
Fig 7. Probability plots for analgesics use after surgery (*left*) and after suture/dressing removal (*right*) by treatment over time.

Table VII. Anesthesia characteristics and surgery time

Characteristics	Closed (n = 46)	Open (n = 44)
Anesthesia		
LA	16 (34.8)	21 (47.7)
LA combined with midazolam	25 (54.4)	23 (52.3)
LA combined with nitrous oxide	2 (4.3)	0 (0.0)
General anesthesia	3 (6.5)	0 (0.0)
Surgery time (min)		
Total		
Unilateral	35 (50.0); 28.42 ± 7.83	36 (50.0); 24.83 ± 8.95
Bilateral	11 (55.0); 50.00 ± 8.84	9 (45.0); 39.33 ± 8.44
Center A		Without flap
Unilateral	20 (48.8); 31.05 ± 6.60	21 (51.2); 22.14 ± 6.92
Bilateral	8 (72.7); 46.12 ± 4.94	3 (27.3); 35.33 ± 12.86
Center B		With flap
Unilateral	15 (51.5); 24.93 ± 8.18	15 (48.3); 28.86 ± 10.35
Bilateral	3 (33.3); 60.33 ± 9.24	6 (66.7); 41.33 ± 5.79

Note. Values are presented as number (percentage) and/or mean ± standard deviation.
*LA*, local anesthesia; *Center A*, Sweden; *Center B*, Norway.

to previous research, canines located in sector II have a high potential for self-correction after extraction of the deciduous canine.[9] However, these canines were diagnosed impacted up to 12 months after radiographic follow-up because of no improvement or worsening of their ectopic eruption path.

The findings showed that patients in the open-surgery group reported significantly more pain and discomfort than those in the closed-surgery group. At suture/dressing removal, no significant differences in pain perception and discomfort were found; however, after this intervention, patients in the closed-technique

Table VIII. Contrasts after fitting the linear regression model for the adjusted effect of treatment on operation time

Variables	F	P value
Arm (closed/open)	16.77	<0.001
Canine location (unilateral/bilateral)	80.40	<0.001
Center (B/A)	6.00	0.023
Arm × canine location	8.54	<0.010
Arm × center	0.30	0.594
Canine location × center	5.33	0.023
Arm × canine location × center	6.14	0.022

Center A, Sweden; *Center B*, Norway.
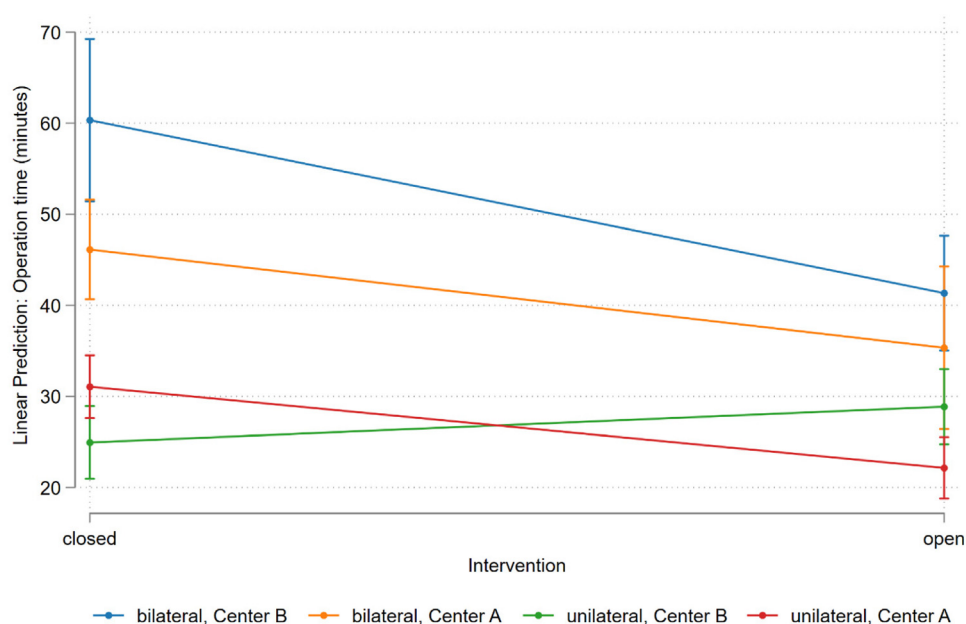
Fig 8. Predictive margins for operation time over unilateral/bilateral impaction and center by treatment group. *Center A*, Sweden; *Center B*, Norway.

Table IX. Complications within 3 weeks of postsurgical exposure intervention

	Total				Center A		Center B	
	Closed (n = 47)		Open (n = 45)		Closed (n = 29)	Open (n = 24)	Closed (n = 18)	Open (n = 21)
Complications	n (%)	Bilateral	n (%)	Bilateral	n (%)	n (%)	n (%)	n (%)
Bleeding			8 (17.8)	2		7 (29.2)		1 (4.8)
Loss of chain	1 (2.1)	1	NA				1 (5.6)	NA
Loss of dressing/gingival overgrowth	NA		4 (8.9)		NA		NA	4 (19.0)
Discomfort hanging chain†	4 (8.5)	2	NA		4 (13.8)	NA		NA
No complications	42 (89.4)	8	33 (73.3)	8	25 (86.2)	17 (70.8)	17 (94.4)	16 (76.2)

Center A, Sweden; *Center B*, Norway; *NA*, not applicable.
†Closed exposure: attachment chain bonded to the adjacent tooth.

group had significantly greater consumption of analgesics. Operative time was significantly shorter in the open group with no flap replacement. There was evidence of more complications in the open-surgery group.

The pain and discomfort experienced with the injection of local anesthetics during the surgical exposure intervention were similar between the groups. Although this is not surprising, results from a previous trial showed higher levels of pain with injections in the closed-exposure group.[20]

The open group perceived more pain and discomfort during surgery than the closed group. This is consistent with the findings of Björksved et al[20] and Chaushu et al[21]

at 1 day postsurgery. In contrast, 2 other studies reported no significant differences in pain perception between the open- and closed-eruption techniques.[22,23] These studies used a 10-point Likert scale to compare ratings of patients' perceptions of pain, whereas in this trial, as well as by Björksved et al[20] and Chaushu et al,[21] a VAS scale was used. It has been described that the use of the VAS scale enables the rater, including small children, to make more fine-grained responses with minimum constraints produced by categories, compared with Likert-type scales.[31,32] Furthermore, in the study by Parkin et al,[23] all surgical procedures were performed under general anesthesia, and patients'

perceptions of pain were assessed retrospectively 10 days after surgery. It can be assumed that this could have affected patient responses and probably minimized the patients' experience of reported pain.

In this trial, 3 participants in the closed group underwent general anesthesia because of pronounced dental anxiety that would otherwise have made exposure surgery impossible to perform. It can be argued that this type of anesthesia influences pain perception and recovery outcomes. Anticipation of dental pain is likely to influence patients' perceptions, and it has been shown that patients with high levels of presurgical dental anxiety report more pain and discomfort for periodontal and implant surgery.[33] On the basis of these findings, we may assume that, in this trial, higher levels of pain and discomfort could have been reported by these 3 patients if they had not received general anesthesia. Anxiety-related pain and discomfort may not be associated with surgery alone.

Gharaibeh et al[22] prescribed antibiotics and ibuprofen 5 days after surgery. The use of antibiotics could have indirectly affected the pain experience among patients by reducing infection, inflammation, and evened out pain perception in both groups. In this study, no antibiotics were prescribed, and free analgesics were administered on an as-needed basis. There was no significant difference in the use of analgesics between the 2 groups 1 week after surgery. This finding confirms reports from previous studies, irrespective of pain perception.[20,22,23]

So far, no studies have evaluated patients' perceptions related to the postsurgery control intervention when sutures are removed in both exposure techniques and surgical dressing in the open technique. Usually, no anesthesia is administered during the intervention. However with mild intensity, patients experience sufficient pain and discomfort to consume analgesics. Although comparable pain and discomfort were experienced by both groups while removing sutures and dressing, 4 of the 35 participants in the open group received analgesics in the evening after the operation only, whereas, in the closed group, analgesics were administered in the evening of the intervention day and the following 3 days. The chain of attachment lying under the repositioned flap in the closed technique may delay the healing process of the tissue beneath the mucosa in the sutured area, owing to movements of the chain in all directions during eating and tooth brushing. Removing sutures in a more wound-like area in the closed group compared with the open group, combined with eventual touching of the chain, may lead to a longer analgesic intake compared with the open group. However, these

findings should be interpreted with caution because of the small number of respondents. Further investigation is necessary to explore the eventual need, for the comfort of the patient, of waiting longer to remove the sutures after surgical exposure with the closed technique than with the open technique.

Surgery times were compared between the treatment groups for the total sample and the subgroups. Although the sample size calculation was based on clinically relevant differences in the pain/discomfort VAS score, significant differences in surgery time between the subgroups were observed. Overall, a significantly shorter duration was observed for the open technique, particularly when no flap replacement was performed. In a similar trial, in which a glass ionomer was cemented on the exposed canine crown after flap replacement, a shorter but nonsignificant duration of surgery with the open technique was observed.[20] In agreement with this trial. Parkin et al[23] showed a comparable surgical exposure duration for the 2 exposure techniques among patients with unilateral PDCs, all of them performed with flap surgery. Gharaibeh et al[22] reported a significantly shorter surgical time for open exposure. However, the small sample size and allocation method used in the latter study might have led to a selection bias.

In this trial, open exposure with flap surgery took longer than open exposure without flap surgery. A previous, nonrandomized study reported that, in patients with unilateral PDCs, the closed-exposure surgery took, on average, 3 times longer time than the open exposure without flap replacement.[34] The use of a premanufactured acrylic cover plate as a dressing may explain such shorter surgery duration of 12 minutes with the open technique compared with this trial. Conversely, another study reported a longer surgery time in open exposures without flap surgery than in the closed technique.[21] However, their sample also comprised impacted incisors as well as buccally impacted canines, and an electrosurgical instrument was used to remove the overlying thick fibrous mucosa in the open technique.

Complications were uncommon in this study. More complications were reported in the open group at both centers, confirming previous findings.[20] Bleeding was the most reported complication in the present trial and was related to the open-exposure technique. No bleeding occurred in the closed group. Interestingly, most patients with bleeding reported in the open-exposure group did not undergo flap surgery. The mucoperiosteum over the palate is highly vascularized and supplied by the palatine artery, and it can be argued that without raising a flap, the surgical removal of a circular area of thick mucosa, bone, and follicular tissue may create deep and raw access to the

impacted canine that is prone to both intraoperative and postoperative bleeding complications. In addition, raising the flap improves the view of the surgical area, which may shorten the search for impacted teeth and provide better hemostasis control. However, these bleeding events are easily controlled by the surgeon using compression, suturing, or electrocoagulation, which, together with the reduced visibility of the operation area after bleeding, may lead to increased operation time and discomfort for the patient. Only 1 patient with bleeding was reported in the open-exposure group with flap surgery in this trial, confirming previous results.[20]

Loss of surgical dressing in the open technique occurred in 8.9% of the total open exposures and comprised 10% of the patients of flap surgery. It is reasonable to assume that suturing the dressing to a loose margin of a newly excised circular portion of the mucosa may increase the risk of loss of sutures and dressings. In a similar study, no dressing was sutured in the open technique for spontaneous eruption when a glass ionomer was used as a dressing.[20] However, the glass ionomer became loose, and subsequent gingival overgrowth occurred.

The most common complication in the closed group was the discomfort caused by the hanging attachment chain (8.5%). This agrees with the complications reported previously,[20] although with a higher frequency of hanging chains compared with this trial. No hanging chain-related complications were reported in the trial conducted by Parkin et al,[23] probably because of the different types of questionnaires used and the retrospective nature of the patient outcome assessment.

Comparing the type and frequency of complications between studies is difficult because of the different types of questionnaires and different timeframes. In this trial, the home questionnaire included open-ended questions about pain and discomfort instead of fixed questions related to specific issues. Complications were recorded during surgery and the 3 weeks after surgery. However, the frequency of complications may increase with treatment that follows surgical exposure, as shown in previous trials.[23,35]

Interpretation

The invasive nature of surgery to expose palatally impacted canines is a concern not only among patients and their parents but also among care providers who believe they need to fully inform their patients about the procedure. This trial shows that although surgical exposure with the open-exposure technique might be shorter, the associated amount and duration of postsurgery pain and discomfort for the patient seem to favor the closed technique. At suture and dressing removal

intervention, patients experienced milder impairment than that at surgical exposure; however, this was sufficient to make them consume analgesics, especially in the closed-exposure group. Surgery-related complications are rare and favor a closed technique. Open exposure without flap surgery is shorter than that for surgery with a flap; however, the risk of bleeding complications is higher. Performing a flap in the open technique, however, increases the risk of premature dressing loss and, consequently, the risk of gingival overgrowth during the healing period. Flap surgery does not appear to be associated with increased pain or discomfort in open surgical exposures. These findings provide evidence-based answers to questions related to the informed consent procedure and help care providers choose the most appropriate exposure technique for an individual patient.

Limitations

This trial included 2 centers from 2 different countries with similar cultural backgrounds and accepted norms. Routine clinical practice in the university setting is also identical; therefore, differences in operators' and patients' expectations between centers were probably insignificant. The operators could not be blinded for obvious reasons; however, the outcome assessments and data analyses were blinded, and the risk of detection bias was considered low.

The power calculation for the total sample size was based on the clinically relevant difference in pain/discomfort experience. Analysis of subgroups that are, by definition, smaller than the entire trial must, therefore, be interpreted with caution, as results may be misled by chance because of a lack of power, and it is uncertain if a larger sample size would have affected the significance of the findings.

Generalizability

This trial used an open-exposure technique with spontaneous eruption. Other open-exposure approaches, including the bonding of an attachment with a chain for orthodontic traction of the impacted canine, have not been evaluated.

The results of this RCT can be generalized to a similar population not older than 16 years, given that the exclusion criteria were met.

CONCLUSIONS

1. Patient perceptions showed great variability, with some patients experiencing a great deal of pain and discomfort that lasted beyond a week after surgical exposure.

2. Patients in the open group experienced significantly more pain and discomfort during the surgical intervention and the following week than those in the closed group.
3. After the removal of the surgical dressing and/or sutures, patients in the closed group consumed significantly more analgesics than those in the open group.
4. Surgical exposure using the open technique required a shorter time, especially when no flap surgery was performed.
5. Complications were sparse and more common after surgical exposure with the open technique.

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