Randomized controlled trial

Extraction of the deciduous canine as an interceptive treatment in children with palatal displaced canines—part I: shall we extract the deciduous canine or not?

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Summary

Objectives: To analyse whether extraction of the deciduous canines facilitates eruption of the palatal displaced canines (PDCs), and to analyse root resorption in adjacent teeth caused by the PDCs.

Materials and methods: Eligibility criteria for participants were as follows: children at age 10-13 years with either maxillary unilateral or bilateral PDC, persisting deciduous canine and no previous experience of orthodontic treatment. Sixty-seven patients (40 girls and 27 boys; age: mean ± standard deviation: 11.4±1.0) with unilateral (45) or bilateral (22) PDCs were consecutively recruited and randomly allocated using permuted block randomization method to extraction or non-extraction. No patients dropped out after the randomization or during the study. Patients underwent a clinical examination and cone beam computed tomography at baseline (T0), after 6 (T1) and 12 months (T2). The total observation time was 24 months. Outcome measures were eruption, positional changes, length of time until eruption, and root resorption of adjacent teeth. The baseline images were measured blinded while the 6- and 12-month control images were not, since it was not possible to blind the extracted canine.

Results: Significantly more spontaneous eruptions of the PDCs were seen in the extraction group (EG) than in the control group (CG), with rates of 69 and 39 per cent, respectively, with a mean eruption time of 15.6±5.6 months in the EG and 18.8±5.8 months in the CG. Significant differences in changes between the groups, in favour of the EG, were found for all variables except for the sagittal angle. In the EG, the changes in the distances of the canine cusp-tip were larger during the first 6 months, while the change of apex was larger between 6 and 12 months. There were no significant differences in resorption of adjacent teeth between the groups.

Limitations: Imputation values were used for the PDCs who had erupted at T2, since no x-rays were taken for ethical reasons, which might have given uncertainty in the positional changes between T1 and T2.

Conclusions: Extraction of the deciduous canine is an effective treatment in patients with PDCs. Significantly more positional changes and shorter mean eruption time were seen in the EG. Resorptions of lateral incisors were seen in both groups, but none exceeded grade 2 (resorption up to half of the dentine thickness to the pulp).

Registration: This trial was registered in “FoU i Sverige” (http://www.fou.nu/is/sverige), registration number: 40921.

Protocol: The protocol was not published before trial commencement.

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Introduction
Prevention of palatally displaced canines (PDCs) from becoming impacted is of significant importance because an impaction lengthens the orthodontic treatment, complicates orthodontic mechanics (1, 2), increases the treatment costs (3), and increases the risk of root resorption of adjacent teeth with a potential result of tooth loss (4–6). Early interceptive treatment is therefore desirable. The prevalence of PDC varies between 0.9 and 2.8 per cent and depends on the patient’s ethnic origin, gender, and the diagnostic methods used. Canine impaction occurs twice as frequently in females than in males and 85 per cent of the impacted canines are located palatally (7–9). The aetiology of PDC is still unknown, but two theories are widely mentioned in the literature, i.e. the guidance theory (10, 11) and the genetic theory 12–15.

One of the most common methods used to diagnose PDC is comprised of two periapical radiographs taken from different views, known as Clark’s rule (16–18). Cone beam computed tomography (CBCT) has recently been presented for imaging the craniofacial field, and several studies have reported the advantage of CBCT over conventional radiographs for localizing canines and identifying root resorptions on adjacent teeth (19–21).

Interceptive extraction of the deciduous canine was recommended in 1936 to facilitate the eruption of the impacted maxillary canines and prevent the risk of resorption (22). This treatment was later evaluated in a prospective uncontrolled study by Ericson and Kurol (23), who concluded that extraction in patients with PDCs is an effective intervention and the success rate depends on the mesio-distal location of the crown and the patient’s age at the diagnosis. The authors presented a treatment protocol that is widely used by many dentists all over the world.

However, in two newly published systematic reviews assessing whether interceptive treatment in the mixed dentition prevents impaction of PDC, it was concluded that the scientific evidence still is too weak to fully evaluate the effect that interceptive treatment might have on PDC (24, 25). Several randomized controlled trial (RCT) studies have been published after the two systematic reviews, comparing extraction of the deciduous canine to other treatment methods such as expansion (26), space maintainer (27), or double extraction, i.e. extraction of the deciduous canine concomitant to extraction of the first deciduous molar (28). All three treatment methods resulted in more successful canine eruption than extraction of the deciduous canine alone. A new prospective study comparing extraction of the deciduous canines with no extraction on patients with bilateral PDC was very recently published and concluded that extraction is an effective measure (29). According to the studies mentioned previously, the results show that extraction of the deciduous canine is effective in patients with PDC, but no previous study has assessed the three-dimensional (3D) ‘depth’ of the impaction and the outcome using the CBCT technique.

Therefore, the aims of this study were to

1. Evaluate the effect of interceptive extraction of the deciduous canine in children with PDC compared with a control group (CG) using an RCT methodology with a CBCT technique.
2. Assess the radiographic changes in eruption between the extraction group (EG) and the CG in time, i.e. between 0 to 6 and 6 to 12 months after extraction.
3. Analyse root resorption on adjacent teeth caused by the PDCs.

It was hypothesized that there are no significant differences between the EG and the CG regarding 1) the success rate of spontaneous eruption of the PDC, 2) change in eruption pattern, or 3) for the number of root resorptions of adjacent teeth, after interceptive extraction of the deciduous canine.

Materials and methods

Trial design
This randomized controlled clinical trial with an equal patient allocation to the two groups:

- Extraction group (EG)
- Control group (CG)

which took place at the clinic of orthodontics, University Clinics of Odontology, Gothenburg, Sweden.

Patients with unilateral PDC were randomized either to have extraction of the deciduous canine or non-extraction and patients with bilateral PDC were randomized to have either the right or the left deciduous canine extracted (Figure 1).

Registration
This trial was registered in “FoU i Sverige” (http://www.fou.nu/is/sverige), registration number: 40921.

Ethical issue
The research ethics committee of the Sahlgrenska Academy, Gothenburg, Sweden, approved the protocol of the study (Dnr 578-08). Children and parents received verbal and written information, and informed consent was provided by the child and their parent or by an adult with parental responsibilities and rights in accordance with the Declaration of Helsinki.

Screening of PDC
The general practitioner identified participants for the trial, who were consecutively recruited from 15 public dental clinics in Gothenburg, Vastra Gotaland County Council, Sweden, between September 2008 and January 2011. During their visit to the public dental clinic, the consulting orthodontist then invited the potential patients to participate in the study.

Subjects, eligibility criteria and setting

Study setting and eligibility criteria
Patients interested in participating received an appointment letter in which a website (http://www.odontologi.gu.se/horntand.html) was enclosed that contained information about the study. Another website (http://www.odontologi.gu.se/horntand_rkd) was established for the general practitioners and for the orthodontists, where they could access information about the study.

The inclusion criteria were as follows:

- Caucasians at age 10–13 years with either maxillary unilateral or bilateral PDC
- Persisting deciduous canine
- No previous experience of orthodontic treatment

The canine was considered palatally displaced when clinical palpation of a labial canine bulge was absent and when the canine crown was diagnosed on intraoral radiographs as palatally positioned, using Clark’s rule (30).

Criteria for exclusion were as follows:

- Crowding in the maxilla exceeding 2 mm
- Ongoing orthodontic treatment
- Resorption of the adjacent teeth, grades 3 and 4 according to Ericson and Kurol (31), either at the start or during the trial caused by the displaced canine.
- Craniofacial syndromes
- Odontomas, cysts
- Cleft lip and/or palate
The Ericson and Kurol (31) classification of root resorption is 1) no resorption, intact root surfaces, and the cementum layer may be lost; 2) slight resorption, resorption up to half of the dentine thickness to the pulp; 3) moderate resorption, resorption midway to the pulp or more, the pulp lining being unbroken; and 4) severe resorption, the pulp is exposed by the resorption. Resorption grades 3 and 4 were excluded from the trial, while 1 and 2 were included.
A total of 70 patients were invited to take part in the study. Three patients, all girls with bilateral PDCs, declined to participate at the first visit when information was given about the study, i.e. before they were randomized. Two out of the three patients declined due to fear of extraction and one patient thought it was too far to travel to the clinic of orthodontics, University Clinics of Odontology, Gothenburg, Sweden. No patients dropped out after the randomization or during the study. Thus, in total 67 patients were randomly allocated to the extraction or the CG. Of these, 45 patients had unilateral PDC and 22 patients had bilateral PDCs (Figure 1).

Randomization method
For randomization, the permuted block randomization method was used and the allocations were concealed in sequentially numbered, sealed opaque envelopes opened by a dental nurse after the written consent was obtained.

Treatment protocol and process
All patients who decided to participate in the study, regardless of the group to which they were randomized, underwent a radiographic examination consisting of CBCT images at the Department of Oral and Maxillofacial Radiology, Institute of Odontology, Sahlgrenska Academy, Gothenburg, Sweden. The radiographic examination is explained in detail in a previously published study (32). Extraction of the deciduous canines was carried out by one orthodontist (JN) on the same day as the baseline radiographic examination (T0) in order to get a precise timing of the start of the intervention.

After 6 months (T1), patients in the EG and the CG were clinically examined by the same orthodontist who carried out the baseline examinations. If the permanent canine was not clinically visible, the patient underwent a new radiographic examination (CBCT images) the same day. This procedure was repeated at the 12 month control (T2). Figure 1 describes the protocol and the patients included in the study. All patients were given a diary to document the date of the eruption in those cases the canine started to erupt before the next check-up. In patients with clinically visible canines, i.e. that emerged through the gingiva, no further CBCTs were taken.

An individual treatment plan was drawn up for patients with unerupted PDCs after 12 months. The unerupted canines, in cases that the canine had improved its position on the radiographic examination, were followed until they emerged through the gingiva with continuing check-ups in the EG. In the CG, the deciduous canine was extracted if mobility of the tooth was not present. When the canine showed impairment or no change in its position at the 12 month control, a combined surgical exposure and orthodontic treatment was performed, regardless of the group to which the patient belonged.

Blinding
One oral radiologist unaware of the group to which the patients belonged carried out all the measurements on the CBCT images in axial, sagittal, and frontal views. The baseline images were, therefore, measured blinded, while the 6 and 12 month control images were not because it was not possible to blind the extracted canine.

The following outcome measures were assessed:

Primary outcome
- Eruption of the permanent canine, i.e. successful outcome (defined as canine emerged through the gingiva) during the total observation time, i.e. 24 months.
Secondary outcome

- Positional changes of the permanent canine over time (T1–T0 and T2–T1) measured from the radiographs: mesioangular angle, sagittal angle, vertical position, canine cusp tip-dental arch plane, canine root apex-dental arch plane, canine cusp tip-midline (Figure 2) and changes between T1–T0 and T2–T1 within and between the EG and the CG.

- Root resorption of adjacent teeth.

Positive values for the variables: canine cusp tip-dental arch plane and canine root apex-dental arch plane indicate a palatal position of the cusp-tip or apex and a negative value buccal position in relation to the dental arch plane.

The methodology of the radiographic measurements has been described in detail in a previously published study, in which the intra- and inter-examiner error of the 3D measurement and the validity of the measured angles were also evaluated (32). All randomized patients were included in the groups to which they were randomly assigned regardless of the treatment they actually received and regardless of a deviation from the protocol as randomized. Thus, in the analysis, the intention-to-treat (ITT) approach was applied.

Imputation of measurement values

Missing data can introduce bias and affect the results because most statistical packages ‘automatically’ discard cases with missing values. This can be avoided by applying imputation, a statistical process of replacing missing data with probability values based on other available information. In this case, angular and linear measurements of fully erupted maxillary canines were imputed.

As described previously, in patients in whom the permanent canine had started to erupt and was clinically visible, no further radiographic examinations were done. Instead, imputation values were used (applicable only at T2, 12 months), which were calculated by measuring the mean angular and linear measurements of 10 unilateral patients (8 girls, age: mean ± standard deviation [SD]: 11.2 ± 0.9; 2 boys, 11.7 and 10.6 years of age at baseline), whose contralateral non-PDC was fully or partially erupted.

Sample size calculation

The sample size was based on the alpha significance level of 0.05 and a beta of 0.10 to achieve a 90 per cent power to detect a difference of 5 degrees (SD 6.38) of the angle measured in the frontal and sagittal views, between the extraction and the CG. The calculation indicated that in total 60 patients with unilateral PDC were needed, i.e. 30 patients in each group. Inclusion of bilateral PDC reduced the number of patients needed. To compensate for possible dropouts during the study, in total 70 patients were identified, 67 were enrolled.

Statistics

The data were statistically analysed using SAS, version 9.3 for Windows (SAS Institute Inc., Cary, North Carolina, USA). Arithmetic means and standard deviations were measured for numerical variables. Dependent and independent t-tests were used to compare the baseline variables and changes in time between and within the groups, respectively. The independent t-test was used to test whether there were any significant differences in the linear and angular variables between successful versus non-successful outcome. Fisher’s exact test was used to calculate differences in categorical data, such as the success in the eruption rate between the extraction versus the non-EG, gender, extraction site, and extraction versus non-extraction. To test whether the bilateral group would be considered independent observations or dependent paired observations, the main outcome, i.e. eruption or non-eruption, was tested with Fisher’s exact test and McNemar’s test. As no multiple comparisons have been tested, adjustment or correction with statistical analysis was not needed.

Harms

No harms were detected during the study.

Results

The extracted deciduous canines showed no root resorption or less than one-third of the root length resorbed, and none were mobile.

Participant flow

Fifteen out of the 67 patients (3 bilateral PDC and 12 unilateral PDC [3 from the CG and 9 from the EG]) did not have a radiographic examination at the 12 month control because the canines had emerged through the gingiva and were under eruption, i.e. clinically visible between T1 and T2. Imputation values were used in these cases (Figure 1).

Baseline findings

There were no significant differences at T0, either for the mean age between the unilateral and bilateral groups (Table 1) or between the angular and linear measurements in the EG and the CG (Table 2). Dividing the subject into age groups of 10–11- and 12–13-year-old individuals showed that there were a larger number of patients in the younger group. There were more females than males in total, but no significant differences were seen in gender distribution between the unilateral and bilateral groups or the extraction and non-EGs. In addition, no differences were seen between the left and right extraction sites (Table 1).

It was decided to analyse the whole material and not only the unilateral group as two independent observations because there was no difference in the correlation between extraction and successful outcome between independent observations and dependent paired observations in the bilateral group. Further, there were no significant differences in the patients’ characteristics when the unilateral and unilateral PDC patients were put together in the EG and CG.

Table 1. Patient characteristics in the unilateral and bilateral groups at baseline. PDC, palatal displaced canines; SD, standard deviation

<table>
<thead>
<tr>
<th></th>
<th>Unilateral PDC</th>
<th>Bilateral PDC</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients (n)</td>
<td>45</td>
<td>22</td>
<td>67</td>
</tr>
<tr>
<td>Age (mean ± SD)</td>
<td>11.2 ± 0.9</td>
<td>11.6 ± 1.0</td>
<td>11.4 ± 1.0</td>
</tr>
<tr>
<td>Age (yr), n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10–11</td>
<td>30 (67)</td>
<td>13 (59)</td>
<td>43 (64)</td>
</tr>
<tr>
<td>12–13</td>
<td>15 (33)</td>
<td>9 (41)</td>
<td>24 (36)</td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>29 (64)</td>
<td>11 (50)</td>
<td>40 (60)</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>16 (36)</td>
<td>11 (50)</td>
<td>27 (40)</td>
</tr>
<tr>
<td>Extraction, n (%)</td>
<td>23 (51)</td>
<td>22 (49)</td>
<td>45 (51)</td>
</tr>
<tr>
<td>Right side, n (%)</td>
<td>7 (30)</td>
<td>13 (59)</td>
<td>20 (45)</td>
</tr>
<tr>
<td>Left side, n (%)</td>
<td>16 (70)</td>
<td>9 (41)</td>
<td>25 (55)</td>
</tr>
<tr>
<td>Non-extraction, n (%)</td>
<td>22 (50)</td>
<td>22 (50)</td>
<td>44 (49)</td>
</tr>
</tbody>
</table>

n indicates number of patients and % indicates percentage of patients.
Table 2. Baseline variables (T0) for the unilateral and bilateral groups with mean, standard deviations (SD), and P-values. CG, control group; EG, extraction group; PDC, palatally displaced canines; SD, standard deviation.

<table>
<thead>
<tr>
<th>Variable at T0</th>
<th>Unilateral PDC (patients, n = 45)</th>
<th>Bilateral PDC (patients, n = 22)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EG (n = 23)</td>
<td>CG (n = 22)</td>
</tr>
<tr>
<td></td>
<td>PDC</td>
<td>PDC</td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
</tr>
<tr>
<td>Mesioangular angle (°)</td>
<td>11.2 ± 0.9</td>
<td>11.4 ± 1.1</td>
</tr>
<tr>
<td>Sagittal angle (°)</td>
<td>105.2 ± 5.4</td>
<td>107.7 ± 9.6</td>
</tr>
<tr>
<td>Vertical position (mm)</td>
<td>98.0 ± 8.1</td>
<td>101.1 ± 9.5</td>
</tr>
<tr>
<td>Canine cusp tip-dental arch plane (mm)</td>
<td>15.9 ± 2.2</td>
<td>14.9 ± 2.4</td>
</tr>
<tr>
<td>Canine root apex-dental arch plane (mm)</td>
<td>2.2 ± 1.6</td>
<td>2.7 ± 1.7</td>
</tr>
<tr>
<td>Canine cusp tip-midline (mm)</td>
<td>9.7 ± 2.2</td>
<td>9.2 ± 2.7</td>
</tr>
</tbody>
</table>

P-value* for EG-CG

| NS, Not significant. |

* P-value < 0.05 is considered statistically significant.

Primary outcome

Significantly more PDCs erupted on the extraction site compared with the untreated control site, with a prevalence rate of 69 and 39 per cent, respectively, (P = 0.001). The mean eruption time in the EG was 15.6 months (SD 5.6) and in the CG was 18.3 months (SD 5.8), with no significant difference for the mean eruption time between the younger (age 10–11 years) and the older patients (12–13 years) (P = 0.238). At T2, 14 PDCs in the EG and 27 PDCs in the CG had impairment or no changes of the canine position. These teeth were surgically exposed and orthodontically treated. All remaining PDCs that were followed up after T2 erupted in both groups, with the latest at the 24 month control (Table 3). Of 10 PDCs in the CG that were followed up, five deciduous canines without mobility were extracted, while the mobile ones were left to spontaneously exfoliate.

Online supplementary figures 1 and 2 exemplify successful and impaired changes in position of the PDCs with two patients.

Secondary outcome

Positional changes of the canine over time observed by radiographic means

Between T0 and T1, five of six variables in the EG and three of six in the CG improved significantly. Between T1 and T2, five variables out of six in the EG and two in the CG improved significantly. Significant differences in changes between the groups, in favour of the EG, were found for three of six variables between T0 and T1 and for all variables except for the sagittal angle between T1 and T2 (Table 4).

Table 3. Number of palatally displaced canines (PDCs) in the extraction (EG) and the control group (CG) that had erupted, were impaired or had not changed at the 6 month control (T1), 12 month control (T2), or after T2 (>T2)

<table>
<thead>
<tr>
<th>EG (N = 45 PDCs)</th>
<th>CG (N = 44 PDCs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1</td>
<td>T2</td>
</tr>
<tr>
<td>Erupted PDCs</td>
<td>0</td>
</tr>
<tr>
<td>Impaired PDCs or no changes</td>
<td>—</td>
</tr>
</tbody>
</table>

* Note that five deciduous canines in the control group that were not mobile (n = 5) were extracted at T2.

The variables with significant changes between T0–T1 and T1–T2 in the EG and the CG, respectively, are presented in Figure 3. In the EG, significant larger changes between T0–T1 than T1–T2 were observed for the distance: canine cusp tip-dental arch plane (P = 0.0026) and canine cusp tip-midline (P = 0.0276), while the variable: canine root apex-dental arch plane (P = 0.0085) changed more between T1–T2 than between T0–T1 (Figure 3). When changes over time were compared between the groups, the variables for the distances: canine cusp tip-dental arch plane (P = 0.0013) and canine root apex-dental arch plane (P = 0.050) deviated more between the EG and CG between T1–T2 than between T0–T1.

Root resorption of permanent adjacent teeth

None of the patients were excluded in this trial due to resorption grades 3 and 4 of the adjacent teeth caused by the PDC either at the start of or during the study. Thirteen patients (14 PDC) showed root resorption grade 2 on adjacent teeth at the start of the trial, 16 patients (17 PDC) at the 6 month control and 20 patients (21 PDC) at the 12 month control (Table 5). Although more teeth where resorbed in the CG than the EG, significant differences were not found for either T1 (P = 0.4218) or T2 (P = 0.2123). The adjacent teeth that had root resorption caused by the PDC were all lateral incisors.

Discussion

The effectiveness of extracting the deciduous canine as an interceptive approach to achieve spontaneous eruption of PDC compared with non-extraction was investigated in this prospective, randomized, clinical longitudinal trial. The findings in the study show that extraction of the deciduous canine allows the PDCs to spontaneously erupt but the variables such as Mesioangular angle, Sagittal angle, Vertical position, Canine cusp tip-dental arch plane, Canine root apex-dental arch plane, Canine cusp tip-midline deviated more between the EG and CG between T1–T2 than between T0–T1.
Main outcome for the bilateral group was assessed as independent observations, the bilateral and unilateral PDCs were merged into one group. There was an uneven distribution of the number of patients in the age groups, with more 10–11-year-old (64 per cent) than 12–13-year-old patients (36 per cent) (Table 1). A possible explanation for the greater number of younger patients in this study is that, in Sweden, all children at the age of 10 are strictly monitored to capture PDCs at an early age. However, it is important to consider the overall stage of dental development of the child and not only the chronological age because there is a poor correlation between dental and chronological age (33). In accordance with other interceptive studies on canine displacement, there was a larger number of female than male patients (22, 23, 34).

### Table 4. Positional changes over time of the permanent canine: T1–T0 (6 months–baseline) and T2–T1 (12 months–6 months) with mean, standard deviation (SD), mean differences, and 95% confidence interval (CI), between the extraction (EG) and non-extraction (CG) site

<table>
<thead>
<tr>
<th>Variable</th>
<th>T1–T0 (patients, $n = 67$)</th>
<th>T2–T1 (patients, $n = 67$)</th>
<th>Differences EG-CG</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EG ($n = 45$ PDCs)</td>
<td>CG ($n = 44$ PDCs)</td>
<td>EG ($n = 45$ PDCs)</td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>Mean ± SD P-value*</td>
<td>Mean ± SD P-value*</td>
<td>Mean ± SD P-value*</td>
</tr>
<tr>
<td>Mesioangular angle (°)</td>
<td>−3.4 ± 5.8 0.000</td>
<td>−0.8 ± 5.8 0.369</td>
<td>−2.6 (−5.1, −0.0) 0.030</td>
</tr>
<tr>
<td>Sagittal angle (°)</td>
<td>1.9 ± 5.9 0.030</td>
<td>1.7 ± 1.6 0.000</td>
<td>0.7 (−2.1, 3.6) 0.604</td>
</tr>
<tr>
<td>Vertical position (mm)</td>
<td>2.7 ± 1.5 0.000</td>
<td>1.7 ± 1.6 0.000</td>
<td>0.9 (−3.1, 1.6) 0.003</td>
</tr>
<tr>
<td>Canine cusp tip-dental arch plane (mm)</td>
<td>−1.9 ± 1.5 0.000</td>
<td>−0.9 ± 1.7 0.002</td>
<td>−0.3 (−1.2, 0.6) 0.492</td>
</tr>
<tr>
<td>Canine cusp apex-dental arch plane (mm)</td>
<td>0.2 ± 1.9 0.419</td>
<td>0.1 ± 1.3 0.838</td>
<td>0.2 (−0.4, 0.8) 0.463</td>
</tr>
<tr>
<td>Canine cusp tip-midline</td>
<td>2.3 ± 1.5 0.000</td>
<td>0.6 ± 1.9 0.037</td>
<td>1.7 (0.9, 2.5) 0.000</td>
</tr>
</tbody>
</table>

Significant differences between and within the groups are given in $P$-values. $*P$-value < 0.05 is considered statistically significant.
In a Cochrane systematic review that assessed the effect of extracting the deciduous canine on the eruption of PDC, several observations for what should be included in future studies were discussed (25). The most important factors were concealed random allocation, blind assessment, sample size, and correct statistical analysis. We tried to fulfil these criteria in this study, but it was not possible to blind the patients to the allocated intervention except at baseline, where the radiographic measurements were blinded. It was not possible to block out the deciduous canine space on the radiographs on the 3D radiographs, as can easily be done on panoramic x-ray. An alternative would have been an assessor who had no knowledge of the study. This was not possible in this study, however, as a new 3D measurement method to evaluate the canine position had to be developed together with the oral radiologist (32).

In comparison with previously published studies where panoramic x-ray were used for diagnosis of PDC and assessment of the outcome, this trial is to our knowledge the first one to assess the effect of extracting the deciduous canine in patients with PDC using 3D images. A more accurate diagnosis of the canine position and 3D assessment of the canine movements are possible with 3D images. In addition, small resorptions of the adjacent teeth caused by the PDC can be detected.

Several RCT studies discuss the topic of interceptive treatment of PDCs, both with and without a combination of different appliances such as cervical headgear (HG) (34), rapid maxillary expansion (RME) (35), RME followed by HG (36), extraction of both the deciduous canine and the first deciduous molar (28), RME followed by transpalatal arch (TPA) (27), extraction of the deciduous canine followed by TPA (26), or extraction of the deciduous canine on one side in patients with bilateral PDCs (29). These studies all point toward the benefit of the interceptive treatment. However, some weaknesses are noted, for example questionable power analysis (26–28), questionable randomization, and the unequal descriptive statistics at baseline between the different groups (26) and missing allocation concealment concerning unilateral and bilateral PDCs (26, 27), and uncertain diagnosing of PDC from only panoramic radiography (28). The results of this study showed that significantly (P = 0.001) more canines erupted on the extraction site (69 per cent) compared with the control site (39 per cent). These findings are comparable and confirm the results of previous studies that presented successful results between 62 and 67 per cent on the extraction site and 28 and 42 per cent on the non-extraction site (26, 29, 33, 34). Some studies present higher success rates of around 80 per cent (23, 28) or a lower success rate of 42 per cent (37). The high success rate in the prospective uncontrolled study of Ericson and Kurol (23) can be explained by that the authors having counted both canine eruption and improvement of the canine eruption path as a successful outcome. In the study by Bonetti et al. (28), patients with centrally placed canines together with PDC were included and the CG was not randomized, which could have influenced the results. The lower success rate found in the study of Smallieën et al. (37) might be explained by the older age of the patients that were included, as a higher age increases the probability of impactions. Some previous studies (27, 28, 38) defined successful outcome as fully erupted canines, thus permitting bracket positioning for final arch alignment when needed or as defined by Bazargani et al. (29) ‘in an esthetical acceptable location in the dental arch’. This variation in definitions of successful outcome could be another reason for the different success rates reported. In this clinical trial, canines that emerged through the gingiva were considered successful. In addition, in this study, only an ITT approach was used when the outcome was assessed, which may be another explanation for the differences in the success rate.

Significantly more changes for both angular and distance variables were found between both T0–T1 and T1–T2 in the EG, which was not surprising because the successful outcome was higher in the EG than in the CG.

In the EG, the movement of the cusp-tip in relation to the dental arch and in relation to the midline was larger during the first 6 months after extraction, while the movement of the apex was larger between 6 and 12 months (Figure 3). These results support Ericson and Kurol (23) finding that improvement of the position of the PDCs can already be seen after 6 months.

The prognosis for successful orthodontic end results when adults are treated for PDCs is poorer than in younger patients and the prognosis worsens with age (1). Furthermore, the duration of orthodontic treatment to address impacted canines correlated with age in that the treatment duration increases with increased age (1). Permanent canines that have been impacted for many years undergo pathological changes that prevent their eruption even when all other factors are favourable (40). The risk for developing ankylosis either a priori or during treatment is higher the older the patient is (40). We, therefore, considered it unethical to follow-up patients longer than 1 year without making any individual treatment plan, especially as data from this study shows a tendency toward more resorbed adjacent teeth in the CG at T2 than at T0 and as more canines had erupted in the EG during the first 12 months. This was also the reason for extracting the remaining deciduous canines in the CG that were not mobile at T2.

The frequency of root resorption caused by PDCs has been reported in the literature to be around 50 per cent of which the majority are lateral incisors (41–44). In this study, however, 23.5 per cent showed resorptions, and only on lateral incisors. The low figures may be explained by that this study comprise of prospective randomized design with the exclusion criteria: root resorption of grades 3 and 4, while the above-mentioned studies either had a

<table>
<thead>
<tr>
<th>Grade 1 (no resorption)</th>
<th>Grade 2</th>
<th>Grade 3</th>
<th>Grade 4</th>
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<tr>
<td>N (%)</td>
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<tr>
<td>T0</td>
<td>38</td>
<td>84.5</td>
<td>7</td>
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<tr>
<td>T1</td>
<td>38</td>
<td>84.5</td>
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<tr>
<td>T2</td>
<td>37</td>
<td>82.2</td>
<td>8</td>
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Table 5. Root resorption of adjacent permanent teeth during T0–T2 expressed in amount of teeth (N) and % of teeth. CG, control group; EG, extraction group
retrospective material or included only patients that were selected for a CT imaging. Furthermore, the patients in this study were younger. Ericson and Kurol (41) found that the peak frequency of root resorption is between 11 and 12 years of age. However, as the authors also mention in their article, the selection and complexity of the material including more severe cases might have affected the results.

The mean eruption time in the EG was shorter than in the CG (15.6 versus 18.3 months). In total, 30 PDCs erupted after 12 months: therefore, canines with an improved position after 1 year follow-up should, therefore, be clinically and, if necessary, radiographically followed up as spontaneous eruption after 12 months is still possible. Ten of 30 PDCs that erupted after 12 months were in the CG, while five deciduous canines were extracted at T2, as these canines were not mobile. If these five extracted deciduous canines are excluded, the mean eruption time in the CG increased to 19.3 ± 4.7 months.

According to this study, early diagnosis of PDCs and extraction of the deciduous canine as an interceptive approach is recommended. The protocol with systematic use of CBCT in this trial was designed so as to make it possible to draw out the results. However, for everyday diagnostics and follow-up of uneventful cases of lost canines, we suggest the use of 2D imaging. Furthermore, as some permanent canines erupt without extracting the deciduous canine first and some permanent canines do not erupt in spite of extraction (see online supplementary figure 2), the question arises as to whether it is possible to distinguish these cases. Thus, unnecessary interceptive extractions may be avoided or perhaps a decision in favour of surgical exposure of the impacted canine immediately without preceding interceptive extraction of the deciduous canine can be made.

Because extraction of the deciduous canine or surgical exposure might be the child’s first experience of invasive dental treatment, it is important that the child does not develop dental fear as a consequence of the intervention. Although Naoumova et al. (45) showed that the experience of pain and discomfort during and after extraction of the deciduous canine in patients with PDC was low, 42 per cent of the children in their study nevertheless used analgesics, indicating post-extraction pain. Therefore, some surgical interventions may be avoided by predicting and calculating cut-off points for a successful outcome. A more detailed determination of predictors and cut-off points for successful outcome will be analysed in part II of this study.

Limitations

As no CBCT’s were taken, for ethical reasons, of the PDCs that were erupted at T2, imputation values were used as an alternative of excluding these cases. Using the imputation values instead of considering these patients as dropouts is, in our opinion, an advantage, as those teeth that had erupted spontaneously probably are those in “best” position and excluding them would have biased the results. However, as imputation values of normally erupting canines at T2, from the unilateral patient group were used in 15 patients, this might have affected the results of the angular and positional changes between T1 and T2. To find out how the results might change using imputation values of normally positioned canines, a comparison was made between the imputed values and values from the bilateral patient group that had one PDC under eruption while the other was still palatally displaced i.e. x-rays were taken at T2. Seven spontaneously erupting PDCs were identified and compared. No significant differences were found either for the angular or for the positional changes between the erupted PDCs and those with normal position. However, an imputation can always give uncertainty in the results, therefore the changes between T1 and T2 should be interpreted with some caution.

Generalization

The results of the main sample obtained from the present sample can be generalized only in a Caucasian population aged 10-13 years and in the case that the exclusion criteria are met. The use of imputation values as mentioned above, may curtail the generalization of the results regarding the positional changes of the canine between T1 and T2. In addition, due to the selective exclusion of PDCs resorbing adjacent teeth with grades 3 and 4 at the start and during the trial, may limit its representativeness, and thus limit the generalization of the frequency of root resorption caused by PDCs in a general population.

Conclusions

• Extraction of the deciduous canine in patients with PDC is an effective interceptive approach: 69 per cent of the permanent canines erupted when the deciduous canine was extracted, while 39 per cent erupted in the non-EG. The mean eruption time was 15.6 months in the EG and 18.3 months in the CG.

• Significantly more angular and distance changes occurred in the EG compared with the CG.

• In the EG, the movement of the cusp-tip in relation to the dental arch and in relation to the midline was larger during the first 6 months after extraction, while the movement of apex was larger between 6 and 12 months.

• Canines with an improved position at the 12 month control should be followed up with a clinical and if necessary a radiographic examination, as spontaneous eruption after 12 months still is possible.

• No significant differences in root resorption of adjacent teeth was found at T2 between the CG and the EG.

Supplementary material

Supplementary material is available at European Journal of Orthodontics online.

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