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Navigation in bone-impacted premaxillary supernumerary tooth removal: a preliminary clinical trial

Abstract

Aim: The present clinical trial aimed to preliminarily assess whether navigation could help to position impacted supernumerary teeth (STs) and reduce surgical trauma.

Materials and methods: Subjects with an impacted supernumerary tooth (ST) in the premaxillary area were enrolled in the study and randomly distributed into a navigation group and a control group. In the navigation group, STs were positioned and extracted under real-time optic navigation. In the control group, STs were extracted depending on the surgeon's experience. Subjects were followed up for 12 to 24 weeks postsurgery. Operating time, futile bony trauma, and the positioning precision of the STs were the major outcomes assessed. Multivariate correlation analysis was performed.

Results: In 24 subjects, 32 STs were removed and no severe complications occurred in either group. The proportion of ST exposure at the planned access point was 100% in the navigation group and 68.75% in the control group ($\chi^2 = 5.926$, $P = 0.015$). Futile length, futile width, and the distance between the point where the ST was initially exposed and the bony point planned for accessing it were related to both navigation/control grouping and bone thickness in the access side. For challenging STs with bone thickness of > 0.5 mm in the access side (N = 22), the futile length in the navigation group (0.0 [0.0, 4.0] mm) was significantly smaller than that in the control group (3.0 [0.0, 8.0] mm, $P = 0.028$). Similarly, the futile width in the navigation group (0.0 [0.0, 2.0] mm) was significantly smaller than that in the control group (2.0 [0.0, 4.0] mm, $P = 0.018$).

Conclusions: Navigation helped to position impacted STs precisely and reduced surgical bony trauma to some extent, especially in challenging cases in which the bone in the access side was thicker than 0.5 mm.

Keywords: *supernumerary tooth, tooth extraction, image guide, surgical navigation, computer-assisted design, cone beam computed tomography*

Introduction

In the permanent dentition, the prevalence of a supernumerary tooth (ST) ranges from 0.4% to 6%, depending on ethnicity[1-3]. A higher prevalence of supernumerary teeth (STs) was reported in Mongoloid populations than in other ethnic groups[2]. STs in the region of the anterior maxilla are commonly observed in children and young adults. Various complications might occur as a result of a premaxillary ST, including delayed permanent tooth eruption, displacement, and malocclusion; a midline diastema; the impaction of the permanent incisors; abnormal root formation; cystic lesions; and root resorption of the adjacent permanent teeth[4,5]. If any of these complications occur or the patient requires orthodontic or implant treatment, the ST should be removed surgically.

Removal of a deeply impacted ST can be challenging for even the most experienced oral surgeon. Potential surgical complications include injury to the adjacent teeth; damage to adjacent structures such as the nasopalatal nerve, nasal floor, and maxillary sinus; displacement of teeth into tissue or sinus spaces; and fistula formation[6]. Precisely finding and removing STs without damaging other tooth germs and structures requires considerable clinician experience.

Adequate preoperative and intraoperative assessment of the 3D anatomy of an ST are important. The positions of STs are normally evaluated using radiography, including occlusal, periapical, or panoramic radiographs. CBCT provides valuable information such as an accurate location and shape of a mesiodens, including the condition of the permanent incisors, and is now considered the best tool for diagnosing and planning the path of approach for extraction[7]. CBCT should be used routinely for the treatment of STs[8].

As a real-time positioning apparatus, intraoperative image navigation has been a useful tool for oral and maxillofacial surgery. Computer-assisted navigation-guided systems can build a virtual reality bridge for surgical procedures such as osteotomy, orthognathic surgery, reconstructive surgery, dental implantology, temporomandibular joint arthroplasty, foreign body removal, and image-guided needle biopsy[9,10]. Importantly, the use of dynamic surgical guidance has been

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shown to be more accurate and precise than freehand surgery, both in implantation and in the reduction of fractured bone[11,12]. This enhanced accuracy and precision allows for less invasive implant placement approaches and better localization of adjacent structures.

Emery et al retrospectively reviewed 25 cases of an impacted third molar using dynamic optic navigation for surgical tooth removal[13]. According to these authors, the navigation system improved the visualization and localization of anatomical structures, enhanced surgical control, and decreased the morbidity of challenging cases.

Wang et al[14], Retana et al[15], and the present author team[16] all reported one case of using image navigation for impacted ST removal from 2017 to 2019. Retana et al were the only authors who used an in-office dynamic navigation system for ST removal[15]. Image navigation was considered helpful in challenging cases, especially for dental office use and with inexperienced oral surgeons. Lyu et al retrospectively reviewed 25 cases of impacted maxillary ST removal using image navigation and compared them with 25 cases of conventional extraction[17]. However, to date, no controlled prospective clinical trial has been reported in the literature. It remains unclear whether and how image-guided procedures benefit the extraction of impacted STs. The present clinical trial aimed to preliminarily assess whether navigation helps to position impacted STs and thus minimize surgical trauma.

Materials and methods

Subjects with STs in the premaxilla area who were referred to the Peking University Hospital of Stomatology, Beijing, were screened. Those who met the inclusion criteria were enrolled in the clinical trial. The enrollment criteria included: The necessity for ST extraction such as the ST blocking the permanent teeth or representing an obstacle to orthodontic treatment; a complete bone-impacted ST without bone bulge; the absence of craniofacial syndromes, cysts, cleft lip and/or palate; or any surgical contraindication[18]. The study project was approved by the Ethical Committee of Peking University Hospital of Stomatology (PKUSSIRB-201415058), and informed consent was obtained from all participating subjects or their parents.

Grouping

Subjects were randomly distributed into a navigation group and a control group using the sealed envelope method. As the interventions in this clinical trial involved apparently different surgical procedures, the subjects, surgeon, and researchers were not blinded and were all aware of the grouping results.

Preoperative preparation and CBCT

A panoramic radiograph and CBCT were taken for all subjects before or at initial observation (T0), after which the STs were surgically extracted within 2 months (T1).

In the navigation group, a patient-specific modified occlusal registration (MOR) device was placed in the subject’s mouth during the CBCT scan for later navigation registration. This apparatus was introduced in a previous study[16]. The scanning range was from the forehead to the bottom of the mandible, and the anterior edge included the tip of the nose. Vertical and horizontal calibration were checked before scanning. The CBCT scan parameters (NewTom, Verona, Italy) were: tube voltage: 90 KV; tube current: 6 mA; scanning time: 24 s; bulb frequency: 36 kHz; projection angle: 360 degrees for a single time. The pixel size was $0.3 \times 0.3 \times 0.3$ mm, and the matrix was 512×512 pixels, which was saved in DICOM format.

In the control group, the subjects did not wear an MOR device. Otherwise, the scanning protocol was the same as that for the navigation group.

Preoperative plan protocol

Navigation group: Data were input into iPlan CMF 2.1 (Brainlab, Munich, Germany). Figure 1 shows the preoperative plan procedure. Based on the threshold, the STs and adjacent teeth were segmented and reconstructed. 3D images clearly displayed the location and positional relationships of the STs with the adjacent teeth, the nasal floor, the maxillary sinus, and the nasopalatine nerve canal. The depth of impaction was defined according to the types described in Table 1[19]. The length and width of the STs were measured. Bone thicknesses in the palatal, labial, and nasal sides were measured (see Fig 1a). Initial bony access points were designed into the preoperative planning. If the STs needed to be divided into pieces, cutting lines were marked on the images. The best surgical plan was selected by the surgeon. The geometric centers of the five spheres on the MOR were identified automatically as registration points. Some landmark points on the MOR were added manually. Four to seven registry points were enough to provide good register precision (see Fig 1b). The 3D images were checked and exported from the software before surgery (see Fig 1c).

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Table 1 Depth of impacted supernumerary teeth (STs)

Type of impact depth	Description
Type I	Partially bone impacted
Type II	Fully bone impacted; lowest position of impacted ST is lower than the apex of the maxillary incisor
Type III	Fully bone impacted; lowest position of impacted ST is higher than the apex of maxillary incisor

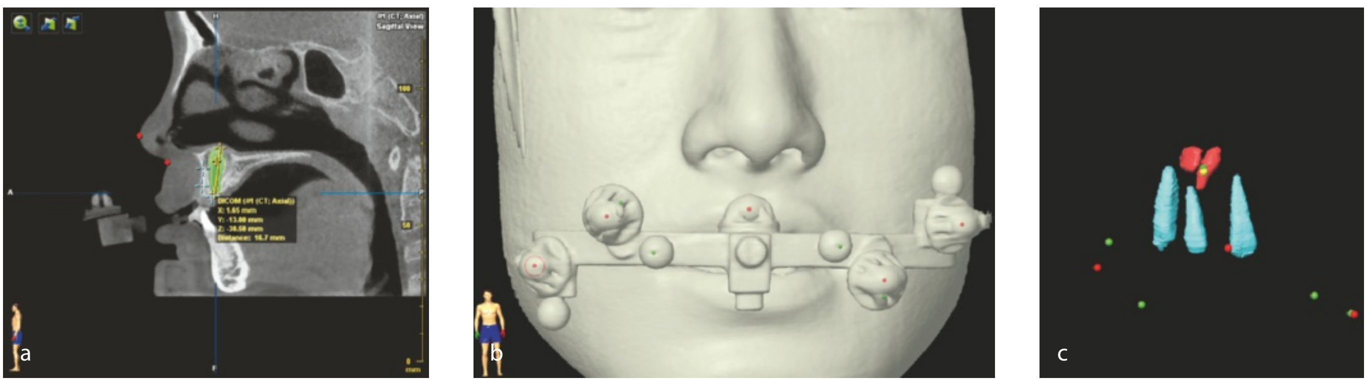

Fig 1 Navigation-guided ST removal: preoperative planning. (a) Preoperative measurements. The green tooth is the inverted ST. The length and width of the STs were measured. Bone thicknesses in the palatal, labial, and nasal sides were measured. (b) Reconstructive CBCT image showing the selection of registry points automatically and manually. The red registry points were automatically selected by iPlan CMF (BrainLab). The green registry points were selected manually. (c) 3D image in the preoperative planning. The red teeth are STs and the blue teeth are permanent teeth. The red points are automatically selected registry points, the green points are manually selected registry points, and the yellow point is the planned initial access point.

Control group: Data were input into iPlan CMF 2.1. No registration points were needed; otherwise, the planning procedure was the same as that for the navigation group. All preoperative planning was carried out by one experienced surgeon and reviewed by the surgeon who would perform the operation.

Surgical procedure

Navigation group: All subjects were operated on under intravenous sedation and local anesthesia. Figure 2 shows the surgical procedure under navigational ST extraction of a typical case.

Headbands (Brainlab) containing reflecting markers were tied on the forehead of each subject. Headbands and the MOR were used to register the preoperatively planned CBCT images from the patient by following the protocols of standard registration in the Brainlab ENT/CMF navigation system (see Fig 2a). Registration accuracy was verified to be < 0.5 mm; otherwise, the registration protocol was repeated. If necessary, the third-party instruments such as the surgical drilling system were registered with a registration accuracy of < 0.5 mm. After all the preparation was finished, the time was recorded as Operation Starting (OS). Mucosal reference points for accessing the ST were located using the navigation-guided system. According to the mucosal reference points, the mucoperiosteal flap was lifted. This time was recorded as O1. Flap elevation time was defined as O1–OS. The bony point for accessing the ST was located and marked under navigation. After confirming the access point, a small bony window was opened using a navigation-tracked electric handpiece (see Fig 2b and d). Positioning the ST is one of the most difficult tasks when extracting bone-impacted STs. Once the ST was exposed and confirmed, the time was recorded as O2. Positioning time was defined as O2–O1. The distance between the point where the ST was initially exposed and the bony point planned for accessing the ST was recorded as D. During the extraction procedure, navigation was used to detect and position the edge of the ST, the tooth split line, the adjacent teeth, and the nasal floor. Once

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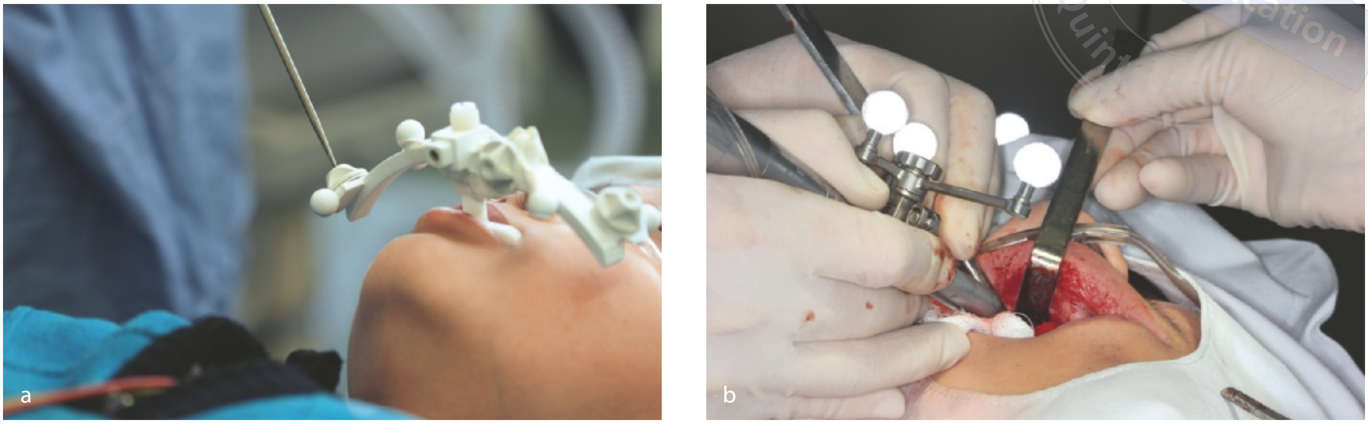

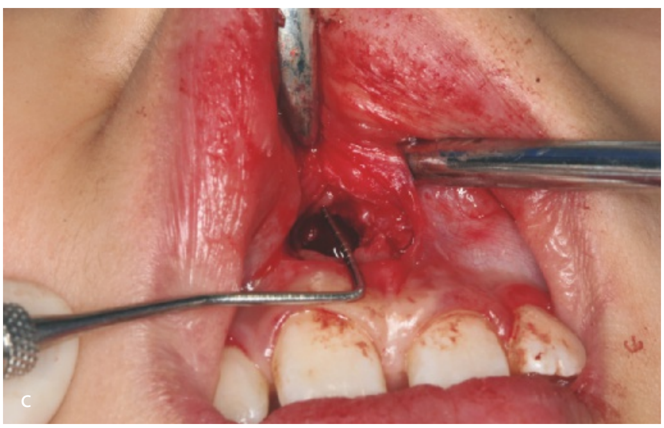

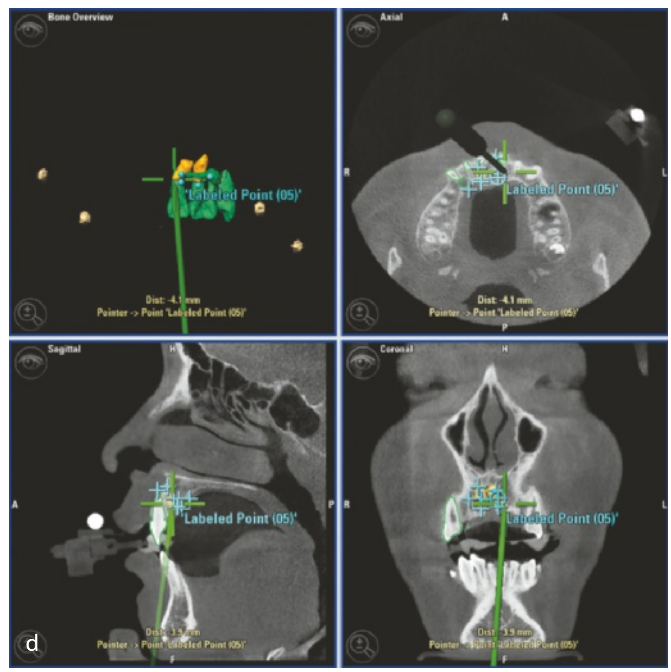

Fig 2 Navigation-guided ST removal: surgical procedure. (a) Patient registration using standard point registration. (b) Registered surgical bur for real-time navigation-guided surgery. (c) Bone trauma measurement using a periodontal probe. (d) Real-time navigation: the green probe was positioned at the access point.

the ST was extracted, the time was recorded as O3. Extraction time was defined as O3–O2. Total operation time was defined as flap elevation time + positioning time + extraction time. The accuracy of navigation should be verified every 15 min during the operation. The length, width, and depth of the extraction socket were measured (see Fig 2c). Extra removed bone was defined as the futile length and futile width, which were calculated as (length – tooth length – 1.0 mm), (width – tooth width – 1.0 mm), respectively. If the calculated futile length and futile width were negative, they were assigned as 0.0 mm. After the wounds were sutured, the patients were woken up and observed for 1 h before they left the clinic.

Control group: All subjects were operated on under intravenous sedation and local anesthesia. After the preparation was completed, the time was recorded as OS. The mucoperiosteal flap was lifted according to the surgeon's experience. This time was recorded as O1. The bony point to access the ST was located and marked according to the surgeon's experience. After confirming the access point, the bony window was opened using an electric handpiece. Once the ST was exposed and confirmed, the time was recorded as O2. The distance between the point where the ST was initially exposed and the bony point planned for accessing the ST was defined as D. Once the ST was extracted, the time was recorded as O3. The flap elevation time, positioning time, extraction time, total operation

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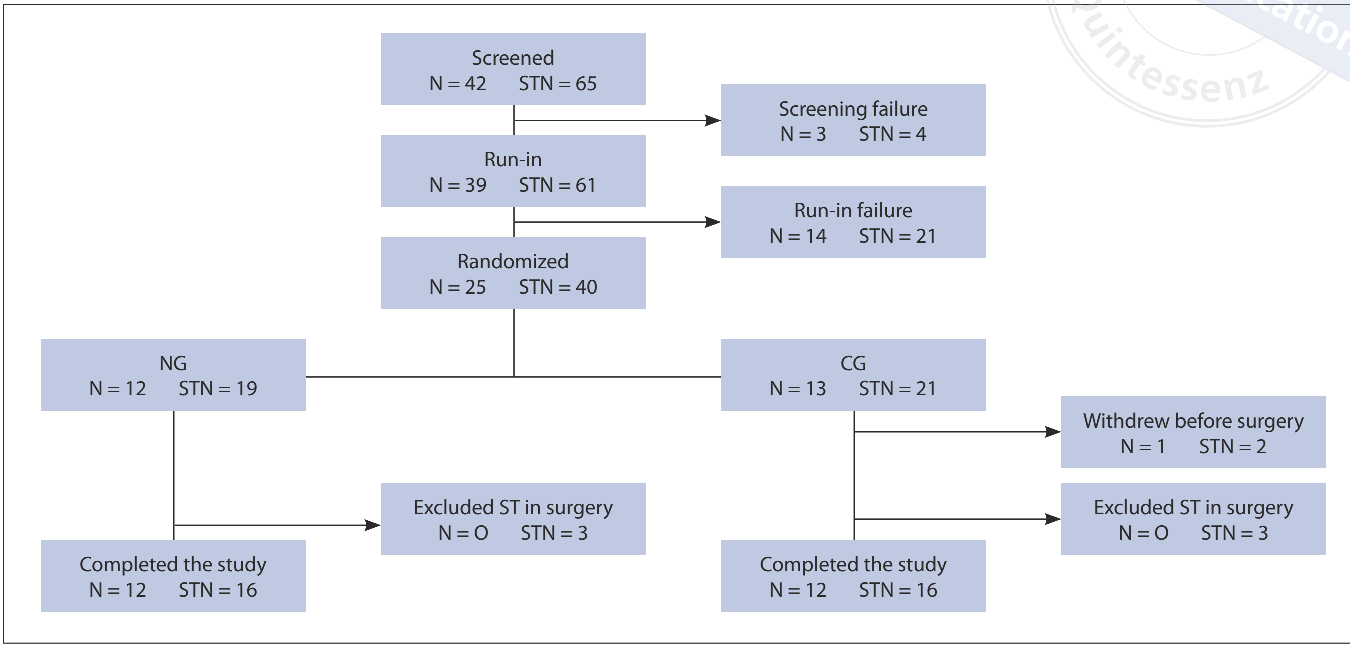

Fig 3 Study subject and ST disposition. N: number of subjects; STN: number of STs.

time, futile length, and futile width were defined as for the navigation group. After the wounds were sutured, the patients were woken up and observed for 1 h before they left the clinic.

All surgical procedures were carried out by one oral surgeon with 20 years of related experience.

Follow-up

Subjects were followed up on the second day (T2), the seventh day (T3), and at a median of 16 weeks (range = 12 to 24 weeks; T4) after surgery. Postoperative pain was recorded using a visual analog scale (VAS). Numbness in the operating area, hematoma, and infection were recorded at T2 and T3. A second panoramic radiograph was performed for all subjects at T4 and, where it existed, root heteroplasia was recorded.

Statistical analysis

Statistical analysis was performed on an intention-to-treat basis, based on the full analysis set. Individual STs were used as statistical units.

Futile length and futile width were the primary endpoints in the present study. Positioning time, total operation time, D, and whether the ST was exposed at the point of the initial bony access point planned (Ac) were the secondary endpoints. The patient's age, gender, ST length, ST crown width, access side, bone thickness of the access side, and clinical type were analyzed as independent variables. The normality of all these variables was tested using the Shapiro-Wilk test. All statistical analyses were calculated in SPSSAU (https://spssau.com/front/spssau/index.html).

For variables with a normal distribution, means were compared between the navigation group and control group using an independent sample *t* test. For variables without a normal distribution, distributions were compared between the navigation group and control group using the Mann-Whitney nonparametric test. Ac was analyzed using the chi-square test. Correlation analysis among primary and secondary endpoints and independent variables was performed using Spearman's correlation. If significant correlations were shown by $P \leq 0.05$, the variables were included in the multivariate statistical test.

Results

CBCT was used to screen 42 subjects with impacted premaxillary STs, among whom 39 subjects fitted the enrollment criteria. Fourteen subjects did not accept the designated surgeon or the random operative protocol and withdrew from the trial. Twenty-five subjects with 40 STs were randomly distributed into the navigation group and control group. Twen-

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Table 2 Baseline data of STs in the navigation group and control group

Group	Navigation group	Control group
Tooth number	16	16
Age (years), median (min, max)	8 (7, 16)	9 (7, 28)
Gender (male/female)	15/1	14/2
Type (II/III)	9/7	10/6
Bone thickness (mm), median (min, max)	1.1 (0.1, 4.3)	1.5 (0.2, 3.9)
Tooth length (mm)	13.42 ± 0.43	13.68 ± 0.62
Tooth width (mm)	5.85 ± 0.34	5.63 ± 0.23
Access side (palatal/labial)	12/4	10/6

Only tooth length and tooth width fitted normal distribution. No significant differences for age and bone thickness in the Mann-Whitney test. No significant differences for tooth length or tooth width in the *t* test. No significant differences for gender, type, and access side in the chi-square test.

Table 3 Outcome data of STs in the navigation group and control group

Group	Navigation group	Control group	
Tooth number	16	16	
Positioning time (s)	130.0 (40.0, 663.0)	158.0 (10.0, 1136.0)	
Total time (s)	554.5 (210.0, 1109.0)	498.5 (110.0, 2079.0)	
D (mm)	0.0 (0.0, 4.0)	0.0 (0.0, 10.0)	
Ac (yes/no)	16/0	11/5	**
Futile length (mm)	0.0 (0.0, 4.0)	0.0 (0.0, 8.0)	*
Futile width (mm)	0.0 (0.0, 2.0)	0.5 (0.0, 4.0)	*
Pain (VAS)	1.37 ± 0.16	1.23 ± 0.17	
Complications	1 hematoma 1 permanent incisor root hypoplasia	1 palatal numbness 1 hematoma	

s: seconds. D: distance between point where ST was initially exposed and bony point planned for accessing ST; Ac: whether ST was exposed at the point of the initial bony access point planned. Pain was measured at T2 using a VAS. Significant difference for Ac between the navigation group and control group was determined using the chi-square test. There were no significant differences for positioning time, total time, D, futile length, and futile width using the Mann-Whitney test (alpha level: 0.05). *$P < 0.1$; ** $P < 0.05$

ty-four subjects completed surgery successfully (Fig 3). Six STs were excluded because they were exposed without bone on the surface after the mucoperiosteal flap was lifted during surgery. No subjects were excluded during surgery.

Baseline data are presented in Table 2. These subjects presented with 32 impacted STs inside the bone of the maxilla. The age range of the subjects was 7 to 28 years. All subjects completed follow up to T3. Three subjects did not complete follow up at T4, with no panoramic radiographs; however, it was established via phone calls that all three of them reported no discomfort at T4. There was one hematoma and one permanent incisor root hypoplasia in the navigation group, and one palatal numbness and one hematoma in the control group. There were no infections, no pulp necroses in adjacent permanent teeth, and no direct root injuries in either group.

Outcome data are presented in Table 3. In the navigation group, all the STs (100%, N = 16) were exposed at the planned access point; however, in the control group, 11 STs (68.75%, N = 16) were exposed at the planned access point, which was a statistically significant difference ($\chi^2 = 5.926$, $P = 0.015$). No significant differences were found in the positioning time, total operation time, D, futile length, and futile width in the Mann-Whitney test. Although there were no significant differences for futile length and futile width, they tended to be smaller in the navigation group (see Table 3).

Futile length was related to age and group in the Spearman's correlation analysis and was significantly related to age (B = 0.478, $P = 0.004$) in the regression analysis. However, group ($P = 0.075$) was not significantly correlated. The median futile length was 0.0 (0.0, 4.0) mm in the navigation group and 0.0 (0.0, 8.0) mm in the control group.

Futile width was related to age, group, and access bone thickness in the Spearman's correlation analysis. However, it was not statistically significant for all variables (age [B = 0.275, $P = 0.090$], group [B = -0.314, $P = 0.053$], and access bone

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Table 4 Spearman's correlation test among outcome data and independent variables

	Futile length		Futile width		D		Positioning time		Total time	
Age	0.690	***	0.429	**	0.212		0.450	***	0.577	***
Group	-0.376	**	-0.420	**	-0.374	**	-0.091		0.007	
Bone	0.196		0.420	**	0.360	**	0.640	***	0.618	***
Type	0.143		0.067		0.148		0.369	**	0.479	***
Tooth width	-0.049		0.134		0.086		0.330		0.241	
Tooth length	0.220		0.347		0.432	**	0.168		0.172	
Access	0.276		0.044		0.232		0.084		0.277	

D: distance between point where ST was initially exposed and bony point planned for accessing the ST. *** $P < 0.01$; ** $P < 0.05$

Table 5 Comparison of endpoints of STs with different bone thickness in access side

Endpoints	Median in bone thickness ≤ 0.5 mm	Median in bone thickness > 0.5 mm	Mann-Whitney	*P*
Futile length (mm)	0.0 (0.0, 2.0)	0.0 (0.0, 8.0)	1.342	0.180
Futile width (mm)	0.0 (0.0, 0.0)	0.0 (0.0, 4.0)	2.033	0.042**
Positioning time (s)	60.0 (10.0, 323.0)	175.0 (40.0, 1136.0)	2.805	0.005***
Total time (s)	340.0 (110.0, 567.0)	690.5 (210.0, 2079.0)	3.090	0.002***
D (mm)	0.0 (0.0, 0.0)	0.0 (0.0, 10.0)	1.423	0.155

s: seconds; D: distance between point where ST was initially exposed and bony point planned for accessing the ST. ** $P < 0.05$; *** $P < 0.01$

thickness [B = 0.310, $P = 0.053$]) in the regression analysis (F = 5.397, $P = 0.005$). The median futile width was 0.0 (0.0, 2.0) mm in the navigation group and 0.5 (0.0, 4.0) mm in the control group.

D was related to group, access bone thickness, and tooth length in the Spearman's correlation analysis. It was significantly related to bone thickness (B = 0.335, $P = 0.019$) and tooth length (B = 0.506, $P = 0.001$) but not significantly related to group (R = -0.260, $P = 0.062$) in the multivariate linear regression analysis. The median D was 0.0 (0.0, 4.0) mm in the navigation group and 0.0 (0.0, 10.0) mm in the control group.

Positioning time was related to age, type, and bone thickness in the Spearman's correlation analysis (Table 4) and was significantly related to access bone thickness (B = 0.565, $P < 0.000$) in the regression analysis. However, age and type were not significantly correlated ($P = 0.062$).

Total operation time was related to age, type, and bone thickness in the Spearman's correlation analysis (see Table 4) and was significantly related to age (B = 0.369, $P = 0.013$) and access bone thickness (B = 0.468, $P = 0.002$) in the regression analysis. However, type was not significantly correlated ($P = 0.238$).

All the residuals in the above regression analysis fitted a normal distribution.

STs with a thin bone covering and thick bone covering were defined by an access bone thickness of ≤ 0.5 mm and > 0.5 mm. Positioning time, total operation time, and futile width were statistically different between STs with a thin bone and those with a thick bone in the Mann-Whitney test. For STs with a thicker bone in the access side, the positioning time and total operating time were longer, and the futile width was larger (Table 5).

For challenging cases in which the access bone thickness was > 0.5 mm (N = 22), the futile length in the navigation group (0.0 [0.0, 4.0] mm) was significantly smaller than that in the control group (3.0 [0.0, 8.0] mm) in the Man-Whitney

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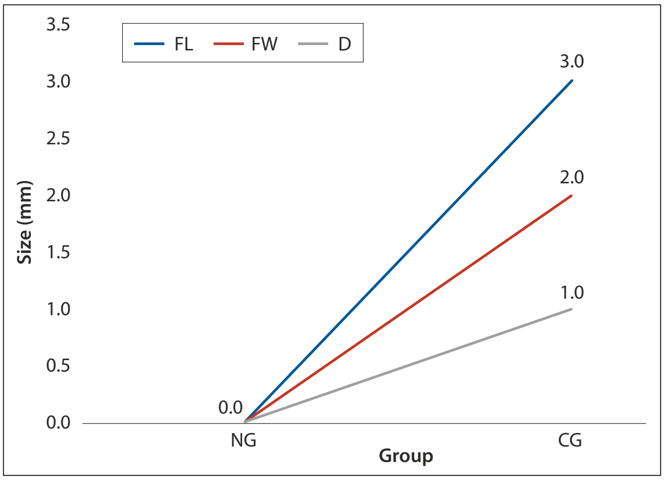

Fig 4 Median comparison of futile length, futile width, and D in the navigation group and control group in challenging cases (access bone thickness > 0.5 mm). Futile length, futile width: $P < 0.05$; D: $P < 0.1$; NG: navigation group; CG: control group.

test ($P = 0.028$). The futile width in the navigation group (0.0 [0.0, 2.0] mm) was significantly smaller than that in the control group (2.0 [0.0, 4.0] mm) in the Mann-Whitney test ($P = 0.018$). No significant differences were found for D, but medians of D in the navigation group (0.0 [0.0, 4.0] mm) tended to be smaller than those in the control group (1.0 [0.0, 10.0] mm, $P = 0.071$; Fig 4). No significant differences were found for positioning time and total operation time. Ac showed a significant difference between the navigation group and control group using the chi-square test ($\chi^2 = 6.471$, $P = 0.011$; Table 6).

Discussion

For oral surgeons, bony impacted STs are challenging because of their variety, difficulty of exposure, and high risks of injury to other tooth germs or adjacent anatomical structures. There are insufficient studies to grade and predict the surgical difficulties of these STs.

Some studies have indicated that age, height of the ST in the sagittal direction, and bone thickness of the ST are the major factors that contribute to the surgical difficulty of impacted ST removal[7,8]. In the present study, these parameters were used as an independent factor. The results indicated that bone thickness in the access side was one of the key parameters affecting the surgical difficulty and risks. Positioning time, total time, futile width, and distance from the access point to the ST, all of which represented surgical difficulty and trauma, were related to the bone thickness in the access side. With a thicker bone in the access side, operating time was longer and bone trauma was more pronounced, especially when the bone thickness exceeded 0.5 mm. The present study suggests that an experienced surgeon is recommended for the removal of STs with a bone thickness of > 0.5 mm.

Other variables such as age and tooth length also contributed to the surgical difficulty. However, sagittal height (clinical type) did not seem to be significantly related in this group of subjects. In this study, the STs were in the premaxilla and most of them were mesiodentes. For some highly impacted STs, surgeons have the option of accessing the ST from the labial side, which reduces the surgical difficulty and risks. If other STs in the premolar or molar area had been included, this could have been different.

Table 6 Comparison of endpoints between navigation group and control group in challenging cases (bone thickness > 0.5 mm)

Endpoints		Navigation group (N = 11)	Control group (N = 11)	Mann-Whitney/χ^2	*P*
Futile length (mm)		0.0 (0.0, 4.0)	3.0 (0.0, 8.0)	2.200	0.028**
Futile width (mm)		0.0 (0.0, 2.0)	2.0 (0.0, 4.0)	2.364	0.018**
Positioning time (s)		130.0 (40.0, 663.0)	190.0 (90.0, 1136.0)	1.280	0.200
Total time (s)		642.0 (210.0, 1109.0)	772.0 (363.0, 2079.0)	0.775	0.450
D (mm)		0.0 (0.0, 4.0)	1.0 (0.0, 10.0)	1.806	0.071
Ac	Yes	11 (100%)	6 (54.55%)	6.471§	0.011**
	No	0 (0%)	5 (45.45%)		

S: seconds; D: distance between point where ST was initially exposed and bony point planned for accessing the ST. ** $P < 0.05$; § χ^2 value

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The timing of ST removal is a critical decision. Surgical extraction of unerupted anterior STs during primary dentition can displace or damage the permanent incisors[20]. The American Academy of Pediatric Dentistry recommends that the extraction of a mesiodens can wait until the adjacent incisors have developed two-thirds of the root, but not a completed apex, to avoid irreversible surgical trauma to the root apex of the developing adjacent incisors and to allow a normal eruptive force[21]. However, if the mesiodentes are impacted in an inverted direction, delayed extraction will not only increase adverse events such as malocclusion or cyst formation but also result in a more complicated surgical extraction[7,22]. For inverted STs in the maxillary bone, the depth of the mesiodens tended to be larger with increasing age and incisor development. Therefore, early extraction of a mesiodens before the age of 6 to 7 years and at Class 6 in Nolla's classification is recommended to avoid the risk of surgical extraction and occlusal complications[7].

During impacted ST removal, surgeons found that in challenging cases, locating and identifying the ST is a key step. Adjacent teeth, including roots, tooth germs, and papillae, are vulnerable. It is often time consuming to accurately position STs and distinguish them from adjacent impacted permanent teeth and tooth germs, especially when exposure is quite challenging or the field of view is limited, which happens frequently in palatal access. Excessive bony trauma was observed frequently during the procedure when looking for bone-impacted STs, which may lead to hematoma, swelling, pain, delayed healing, postoperative infection, and periodontal defects.

The results of the present trial showed that subjects in the navigation group had a smaller distance between the ST exposure point and the initial planned bony window center compared with that of the control group. The distance between the ST exposure point and the planned bony window center revealed the positioning accuracy of the ST. The bony window centers in the preoperative planning were usually set to the point where the bone on the surface of the ST was the thinnest, or at the widest area in the crown of the ST. Before surgery, surgeons review the preoperative plan and try to access the ST from the planned point. With navigation, the surgeon uses a pointer to confirm the access point in the navigation system. In the control group, this confirmation was performed by the surgeons according to their personal experience and the anatomical reference. In the navigation group, the smaller D value revealed a potentially better accuracy in the positioning of the ST compared with that in the control group.

The futile width and futile length measurements revealed the bony trauma after ST removal. Futile width, futile length, and futile depth were generated at the positioning stage and the extraction stage. If the position of the ST means it is difficult to extract (eg, the ST is not found in the area of the planned access point), it becomes necessary to explore around, which often causes extra bone trauma distal from the ST. This is difficult to control, especially for challenging, deeply impacted cases. In addition, if extraction is not easy, removal of the surrounding bone might be necessary in order to extract the ST, which would also cause extra bone trauma. If the position of the ST means it is easy to extract, experienced surgeons usually control bone trauma by extracting the tooth within 1 mm around it. However, in challenging cases, bone trauma may increase markedly.

In the present study, for challenging cases whose access bone thickness was > 0.5 mm, the futile length and futile width values were both significantly lower in the navigation group compared with those in the control group, which indicated that navigation might help in the positioning process by reducing the need for exploration to locate hidden STs, resulting in reduced bone trauma. This result revealed that navigation might be more valuable in challenging cases with larger bone thickness in the access side.

Navigation-guided systems can probably provide the following help during the removal of impacted teeth: To locate deeply impacted teeth for accurate selection of an access point and to minimize bone loss and trauma; to distinguish STs from permanent tooth germs; to precisely divide an ST at a specific level to ensure the least risk and maximum convenience; to mark safe margins for the incision canal, apical papilla, or any other important structures to avoid complications; and to enhance the confidence of the surgeon to distinguish STs from permanent tooth germs and other important structures. Given the absence of a bony bulge or bony landmark, positioning STs can be challenging. Intraoperative real-time navigation provides dynamic control of apparatus such as the detector, handpiece, osteotomy drill, and patient's anatomy from the CBCT image, which is not clearly shown in the direct view. Navigation is valuable when opening the bony window to find STs and when confirming that a particular tooth is the ST when it is exposed. With navigation, surgeons gain more confidence. Therefore, the results of the present study suggest that an intraoperative guide or an image-guided system might be used to reduce risk and minimize trauma, especially for challenging cases with thick bone on the surface of the impacted ST.

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Lyu et al retrospectively reviewed 25 cases of removal of impacted maxillary STs using image navigation compared with 25 cases of conventional extraction[17]. They found that the operating time was shorter with navigation; however, the preoperative planning time was longer. In the present study, the operating time, which was divided into flap time, positioning time, and extraction time, did not show a significant difference between the navigation group and the control group. One of the major reasons could be that the impacted STs were heterogeneous. Positioning time ranged from 5 to 1136 s, while the total time ranged from 110 to 2079 s. A study with a larger sample size is needed to explore whether navigation reduces the operating time for impacted STs.

Despite the potential benefits of the navigation-guided procedure, it should be noted that it needed additional time for preoperative planning and registration before surgery. Additionally, the use of navigation devices will increase medical costs. Proper indications should be further studied to maximize the benefits of navigational technology. Preoperative CBCT could be used to pre-assess bone thickness surrounding the ST to screen for challenging cases that might benefit the most from new navigation-guided surgery, as was shown by the results of the present study.

There are also other intraoperative guiding methods for bony impacted ST removal. Jo et al used CAD/CAM surgical guidance to remove impacted STs[23]. Nam et al reported the resolution of an ST case using an individual surgical stent with a guided hole to precisely position the pilot drill to avoid damage to the surrounding structures[24]. Using a surgical guide for the initial positioning and osteotomy is quite convenient and precise for locating an ST. However, after this step, more complicated osteotomy procedures, even the splitting of the ST, are often needed to facilitate its complete removal. In the present study, the surgical guide needed to be detached, and a conventional surgical method was used by the surgeon, which might also have increased the risks of damage to adjacent tooth roots. Compared with the inflexibility of a surgical guide, navigation might have an advantage during the entire surgical procedure. Using a registered surgical bur or drill, the tip of the apparatus can be shown in real time on the CBCT images from multiple planes and with a 3D view, thus avoiding extra damage as far as possible.

The most critical step during navigation-guided surgery is accurate registration and location, which should be carefully controlled during the entire procedure to ensure reliability of the navigation-guided system. Positional accuracy of navigation is typically < 1.5 mm, if carefully controlled[25]. The crucial factors that affect the precision of navigation-guided systems include clinical registration methods, distance from the center of gravity of the reference markers used for patient registration[26], 3D distance between registration points[27], and the mobility of the noninvasive headband. The MOR designed by the present authors used five registration points, evenly distributed in the dentate and maxillary area, to ensure precision of the registration. In principle, this device performs a similar function to dental splint registration, which is noninvasive and has been proven to be applicable, with good registration accuracy[28]. The MOR uses occlusal records and bite forks, without the need for impressions and plaster casts, and is thus more convenient than a dental splint. With a spiral CT image, registration could be performed precisely using a face scan in the orbital area, yet using a CBCT with a 15×10 cm visual field, the orbital area was often omitted, which decreased the registration success rate and precision of the face scan method. In the present authors' clinical experience, registration failure with face scan occurs more in children than in adults. Although MOR therefore offers another choice for navigation registration, its accuracy and rate of registration success need to be further studied.

The present study had some limitations. The subjects in the two groups were divided randomly, but the surgeon, patients, and researchers were not blinded to the groupings, which might have introduced bias. The study used multivariate regression analysis to analyze several factors in detail, including the operating surgeon. The sample number was small considering the multiple interfering factors. Thus, a larger randomized clinical trial is required to assess the value of navigation in impacted ST removal in high-risk cases.

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Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the Institutional Research Committee of Peking University School of Stomatology and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. This clinical trial was registered in Chinese Clinical Trial Registry (http://www.chictr.org.cn/index.aspx), registration number: ChiCTR1900024845.

Disclaimer

The authors declare no conflicts of interest in relation to this study.

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Navigierte Entfernung retinierter überzähliger Zähne im Bereich des Zwischenkieferknochens: eine präliminäre klinische Studie

Zusammenfassung

Ziel: In dieser klinischen Studie sollte untersucht werden, ob ein navigiertes Vorgehen bei der exakten Lokalisierung retinierter überzähliger Zähne hilft und das operative Trauma reduzieren kann.
Material und Methode: In diese Studie wurden Patienten mit einem retinierten überzähligen Zahn im Bereich des Zwischenkieferknochens aufgenommen und randomisiert auf eine Navigations- und eine Kontrollgruppe verteilt. In der navigierten Gruppe, wurden die überzähligen Zähne unter optischer Echtzeitnavigation lokalisiert und entfernt. In der Kontrollgruppe führte der Chirurg die Extraktion gestützt auf seine Erfahrung durch. Die Probanden wurden 12 bis 24 Wochen postoperativ nachbeobachtet. Eingriffsdauer, überflüssige Knochenentfernung und Genauigkeit der Lokalisierung des Zahns waren die wichtigsten Ergebnisvariablen. Zur Auswertung wurde eine multivariate Korrelationsanalyse durchgeführt.
Ergebnisse: Bei 24 Patienten wurden 32 überzählige Zähne entfernt. In keiner Gruppe traten ernste Komplikationen auf. Die Anteil der am geplanten Zugangspunkt tatsächlich exponierten Zähne betrug in der navigierten Gruppe 100 % in der Kontrollgruppe 68,75 % (χ^2 = 5,926, p = 0,015). Die Länge und Breite der überflüssigen Knochenentfernung und der Abstand zwischen dem Punkt der ersten Freilegung des überzähligen Zahns und dem als Zugang geplanten Knochenpunkt zeigten eine Korrelation mit der Gruppenzugehörigkeit (Navigation/Kontrolle) und der Knochendicke an der Zugangsstelle. Bei anspruchsvollen Zähnen mit einer Knochendicke von > 0,5 mm an der Zugangsstelle (n = 22) war die Länge der überflüssigen Knochenentfernung in der Navigationsgruppe (0,0 [0,0–4,0] mm) signifikant kleiner als in der Kontrollgruppe (3,0 [0,0–8,0] mm, p = 0,028). Auch die überflüssige Breite lag in der Navigationsgruppe (0,0 [0,0–2,0] mm) signifikant unter derjenigen der Kontrollgruppe (2,0 [0,0–4,0] mm, p = 0,018).
Schlussfolgerung: Das navigierte Vorgehen ermöglichte eine präzise Lokalisierung retinierter überzähliger Zähne und konnte insbesondere in anspruchsvollen Fällen mit mehr als 0,5 mm Knochendicke an der Zugangsstelle das operative Knochentrauma deutlich reduzieren.

Indizes: *überzähliger Zahn, Extraktion, bildgeführte Chirurgie, chirurgische Navigation, CAD, digitale Volumentomografie*

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