A randomized controlled trial: evaluation of efficiency and safety of a novel surgical guide in the extraction of deeply impacted supernumerary teeth in the anterior maxilla

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Background: Preoperative X-ray and cone-beam computed tomography (CBCT) are helpful for locating supernumerary teeth, but the images cannot be transferred to the operation. To design a novel surgical guide plate for intraoperative navigation, we transfer the patient's oral CBCT and gypsum model scan data to a computer for analysis. In our study, we evaluate the efficiency and safety of a novel surgical guide plate for the extraction of deeply impacted supernumerary teeth (DIMSNT) in the anterior maxilla.

Methods: Forty patients treated at the Department of School & Hospital of Stomatology, Wenzhou Medical University from March 2019 to December 2020 with DIMSNT (type II/III according to Liu *et al.*) in the anterior maxilla were randomly divided into 2 groups (20 patients for each group) for the extraction. For group I, a novel surgical guide was selected using CBCT and gypsum model scan. In contrast, for group II who underwent freehand surgery, only the CBCT data was used. The evaluation of operation time, complications, satisfaction score, and the number of cases that underwent extraction immediately after removing the bone were performed to assess the efficiency and safety of this novel surgical plate.

Results: All patients completed the surgery successfully. The guides for group I had a good application effect. Group I's operation time $(23.35\pm5.39 \text{ min})$ was shorter than group II ($29.60\pm9.76 \text{ min}$) (P=0.0194). The average pain degree of group I (1.8 ± 1.08) was significantly less than group II (2.82 ± 1.68) (P<0.05). The average swelling score of group I (34) was significantly less than group II (44.7). Patient satisfaction was significantly higher in group I (8.95 ± 1.05) than in group II (7.90 ± 1.51) (P=0.0152).

Conclusions: The novel surgical guide assisted with DIMSNT extraction have been effective in improving the quality of the surgery, patient satisfaction, and reduce its difficulty and duration. We can construct a surgical guide plate to guide the incision and osteotomy in DIMSNT surgery through the data analysis of DIMSNT on computer, which has a broad application prospect for clinical use.

Trial registration: Chinese Clinical Trial Registry ChiCTR2100054523.

Keywords: Cone-beam computed tomography (CBCT); surgical guide; supernumerary teeth; minimally invasive

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Introduction

Supernumerary teeth are common clinical dental anomalies, which may lead to diastema, disturbances in tooth eruption, root resorption, dentigerous cysts, and other problems (1,2). At present, the treatment modalities are still inconsistent due to the difficulty and risk of locating the impacted supernumerary teeth during the operation (3). Nevertheless, the majority of studies suggest surgical extraction to be the primary treatment (4-6).

Preoperative X-ray and cone-beam computed tomography (CBCT) are helpful for locating superficial supernumerary teeth (7), but for deeply impacted supernumerary teeth (DIMSNT), these methods are imprecise (8,9). In the freehand operation of DIMSNT, a point was selected as a reference by the surgeon. To expose the operative area adequately, a wide incision was made and the mucoperiosteal flap was turned up. The surgeon removes the bone in the reference point to expose and extract the DIMSNT. The freehand operation of DIMSNT may cause damage to adjacent structures such as the potential nasopalatine nerve and the roots of the adjacent permanent teeth injury, which would affect the operation time, the incidence of trauma or complications, and the surgeon's confidence (10,11).

There has been increasing interest in osteotomy guide plates used to guide surgery in recent years (12). Recent evidence suggests that the osteotomy guide plate can reduce the risk and the difficulty during the operation of DIMSNT (13-18). Jo et al. reported that for 2 complicated DIMSNT, the osteotomy guide plate was used to avoid damage to adjacent teeth (19). The main disadvantage of the osteotomy guide is that it cannot guide the incision, and the angle and depth of bone removed during the operation may cause damage and may increase the risk of the procedure. Wang et al., through the operation navigation system, extracted DIMSNT successfully during the operation (20). However, navigation systems require a significant monetary investment. The cost of using this technology on an individual is not unacceptable. The much-debated question is how to design a surgical guide for incision consistent with osteotomy during the operation. There is little published data on this issue. In order to resolve the question, Liu et al. used the split guide plate for the osteotomy, but also the incision, successfully guiding labially approachable mesiodens (21). Nevertheless, the split guide plate is only suitable for impacted mesiodens on the labial side. A novel digital

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surgical guide has been designed with both incision and osteotomy navigation functions, which may achieve extract DIMSNT minimally invasive by navigating precisely. The surgical guide may be able to solve the problem of serious postoperative complications caused by the imprecise position surgery. This study attempted to design a novel digital surgical guide and explored its-efficiency and safety in DIMSNT extraction.

The main objective of study was to optimize the surgical guide plate and compare the clinical effect and operative time between freehand and guided surgery in the extraction of DIMSNT. By performing comparative analysis of data, we evaluated the application value of the surgical guide in the area of DIMSNT surgery. We present the following article in accordance with the CONSORT reporting checklist (available at https://atm.amegroups.com/article/view/10.21037/atm-22-585/rc).

Methods

Study design

In our study, a new classification of DIMSNT was made based on the conceptual framework proposed by Liu *et al.* (9). In brief, type I: low position (the lowest point of supernumerary teeth is below the neck of adjacent permanent teeth); type II: middle position (the lowest point of supernumerary teeth is between the apex and neck of adjacent permanent teeth); type III: high position (the lowest point of supernumerary teeth is above the apex of adjacent permanent teeth) (*Figure 1*). Among these types, type II/III was defined as DIMSNT.

Patients with DIMSNT treated at the Department of School & Hospital of Stomatology, Wenzhou Medical University, were enrolled in the study from March 2019 to December 2020.

In this study, a randomized controlled trial was performed and 40 patients with DIMSNT in the anterior maxilla were randomly divided into two groups (allocation ratio is 1:1) were collected for the extraction. The randomization process was conducted by items 8–10 of the CONSORT statement 2001 checklist for randomized controlled clinical trials (22). Participants were allocated to one of the two groups by asking them to pick one of the sequentially numbered, opaque sealed envelopes containing any of the two interventions. Each participant had an equal chance of being assigned to one of the two groups. Participants are blinded to the allocation. During the single-



Figure 1 Classification of deeply impacted supernumerary teeth (DIMSNT). (A) Type I: below the neck of adjacent permanent teeth; (B) type II: between the apex and neck of adjacent permanent teeth; (C) type III: above the apex of adjacent permanent teeth.

blind study, randomization was conducted by the same hospital nurse who had research experience and was not involved in any trial section. All patients were treated with general anesthesia, and the same senior surgeon performed all the surgeries. Patients with any of the following were excluded from the study: acute infections; systemic diseases such as diabetes and blood dyscrasias; history of alcoholism, drug abuse, or heavy smoking; and severe psychiatric disease.

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by ethics board of School & Hospital of Stomatology, Wenzhou Medical University, Wenzhou, China (No. WYKQ2019008) and informed consent was taken from all the patients.

Design process of the surgical guide

The preoperative CBCT data of patients (120 kV, 6 mA, 6 cm \times 6 cm FOV, 0.3 mm voxel, 8.9-s scan time) were stored on a disk as Digital Imaging and Communications in Medicine (DICOM) files, using Mimics, version 18.0 (Materialise, Leuven, Belgium) software to perform the 3D reconstruction. An optical scanner was used to obtain the maxillary cast model information for each patient, which was then imported into the software. The model information reconstructed by CT in the 3D space was overlapped and matched to accurately restore the patient's crown and mucosal structures. The operation approach was determined by computer measurement and analysis (Figure 2).

The surgical guide plate was designed in 3 parts: the incision guide plate, osteotomy guide plate, and installation groove. The installation groove connects with the incision guide plate as a whole. The incision guide plate as an arch shape connects with the osteotomy guide plate by a T-slot. The fixing part of the installation groove matches with the teeth for stability (*Figure 3*).

The position of the incision guide plate was determined by the projection image of DIMSNT. The shape of the incision was designed as an arch to ensure blood supply and to apply the osteotomy guide plate to placement (*Figure 4A*,4B).

The position and shape of the osteotomy guide plate were determined by the projection image of the bone surface of DIMSNT. The depth of DIMSNT determined the osteotomy guide's height, guiding the depth of bone removal. The edge curvature of the osteotomy guide plate was designed with the contour of DIMSNT to guide the angle of bone removal (*Figure 4C-4F*). Then, the surgical guide was fabricated through manual procedures based on the measurements (*Figure 5*).

Surgical techniques

In group I, the surgeon embedded the fixing part of the installation groove in the occlusal surfaces of teeth for stability, and the incision was made according to the guide (*Figure 6A*). The mucoperiosteal flap was turned up and the osteotomy guide was fixed with the T-slot (*Figure 6B*).



Figure 2 Data transfer to computer reconstruction and measurement to determine the surgical approach. (A,B) Plaster model data and cone-beam computed tomography data fitting reconstruction; (C) the distance to the bone surface of deeply impacted supernumerary teeth (DIMSNT); (D) the distance to the labial and palate mucosa of DIMSNT.



Figure 3 Design diagram of the surgical guide plate. 1, installation groove; 2, incision guide plate; 3, osteotomy guide plate; 4, fixing part; 5, connecting part; 6, osteotomy guide plate ring; 7, T-slot; 8, joint of the incision guide plate.

The route and depth of bone removal were guided by the internal edge and the height of the osteotomy guide plate (*Figure 6C,6D*). During the procedure, the drill was moved against the osteotomy guide's inner edge and attention was paid to the depth of bone removal. Then, the bone was removed to expose DIMSNT and perform extraction.

Finally, the mucosal incision was sutured using a 4-0 braid suture after washing by 0.9% physiological saline (*Figure 6E,6F*). In group II, the surgeon used a gingival margin incision and made the trapezoidal flap. The other steps were the same as those except for the guide in group I. The sutures were removed 1 week after the operation.

Record indicators and evaluation criteria

In this study, intraoperative and postoperative assessments were used to measure the efficacy and safety of the novel surgical guide, and 2 surgeons performed evaluations independently to make a judgment.

The following data were evaluated intraoperatively to measure the efficacy of the novel surgical guide

- (I) Operation time (primary endpoint): the time from incision to the end of the suture.
- (II) The number of cases requiring additional osteotomy after lifting the bone followed by extraction of DIMSNT was recorded as an indicator of the accuracy of the osteotomy (primary endpoint).

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Figure 4 Design and manufacture of the guide plate. (A,B) Design of the incision guide plate with an arc of 114.5°; (C) the deeply impacted supernumerary teeth (DIMSNT) projection of the bone surface; (D) the depth of DIMSNT; (E) the height of the osteotomy guide plate; (F) the incision guide plate is connected with the osteotomy guide plate in a T-slot.



Figure 5 Surgical guide simulation before operation.

The following data were evaluated postoperatively to measure the safety of the novel surgical guide

(I) Swelling and pain degree on the 1st, 3rd, and 7th days after the operation (primary endpoint): the visual analogue scale (VAS) was used to evaluate the pain degree (23), and the total VAS score was 10. The higher the value, the higher the degree of pain. The surgeons' subjective evaluation index was used to evaluate the degree of swelling. Evaluation criteria for swelling: (i) no swelling; (ii) slight swelling; (iii)

moderate swelling; (iv) severe swelling.

(II) Patients were discharged from the hospital with a satisfaction survey score of 10 (secondary endpoint). Scores of 9–10 were very satisfied, 6–8 were satisfied, and <6 were dissatisfied.

Statistical analysis

The Kruskal-Wallis rank-sum or nonparametric test was performed using SPSS 20.0 software (IBM SPSS, Inc.,



Figure 6 Intraoperative imaging. (A) Placing the incision guide plate; (B) lifting the flap to expose the bone and place the osteotomy plate; (C) lifting the bone; (D) exposing the deeply impacted supernumerary teeth (DIMSNT); (E) extracting the tooth; (F) suture after washing.



Figure 7 CONSORT flow chart of the trial participants.

Chicago, IL, USA). Normally distributed data were presented in the form of mean \pm standard deviation. Furthermore, the P value for the two-sided test and a P value of less than 0.05 was accepted as statistically significant.

Results

This study enrolled 52 patients and excluded 12 patients from March 2019 to December 2020. The remaining 40 patients were randomly divided between group I (20 cases) and group II (20 cases). One-week postoperative follow-up for every patient. None of the patients were lost to follow-up. Nine out of the 20 patients were females, 11 were males, and the mean of their ages was 9.4 ± 3.85 years (range, 5–22 years) in group I. Eight out of the 20 patients were females, 12 were males, and the mean of their ages was 9.52 ± 4.35 years (range, 6– 25 years) in group II (*Figure* 7).

All guide templates were positioned smoothly and conformed to the bone surface during the operation. However, one of the surgical guide plates was fractured during the operation. All the supernumerary teeth were extracted uneventfully. There were no significant differences in age, sex, impacted depth, direction, and location among the two groups. Thus, the two groups were comparable (*Table 1*).

The following outcomes of efficacy

The Kruskal-Wallis rank-sum test showed that the operation time of group I was significantly shorter than group II (P=0.0194; *Table 2*). Five cases needed additional osteotomy in group I, and 15 cases needed additional

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osteotomy in group II due to insufficient tooth exposure after lifting the bone. In one of the cases, the plate was fractured during the operation.

Table 1 Comparison of the baseline values among the grou	Table 1	Comparison	of the	baseline	values	among the	groups
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Variable	Template group	Freehand group	F value	P value
Gender			0.097	0.756
Male	11	12		
Female	9	8		
Age, years	9.4±3.85	9.52±4.35	0.001	0.97
Depth			0.095	0.759
II (middle)	11	10		
III (high)	9	10		
Location			0.150	0.701
Palatal side	18	18		
Labial side	1	2		
Arch	1	0		
Direction			1.114	0.297
Inversion	12	14		
Vertical	2	3		
Incline	5	3		
Horizontal	1	0		

F value, ratio of two mean squares.

	Table 2 Comparison	of the operative	time of the two	groups
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Group	Operative time, min	
Template group	23.35±5.39	
Freehand group	29.60±9.76	
P value	0.0194	
F value	5.963	

F value, ratio of two mean squares.

Table 3 Comparison of the postoperative pain of the two groups

The following outcomes of safety

The pain degree of group I on the 1st (P=0.0401), 3rd (P=0.0247), and 7th (P=0.0382) postoperative days was significantly less than group II (*Table 3*). The swelling degree of group I on the 1st, 3rd, and 7th postoperative days was significantly less than group II (*Table 4*). Patient satisfaction was significantly higher in group I than in group II (P=0.0152; *Table 5*).

Discussion

We designed a novel surgical guide plate including an incision and osteotomy guide to navigate the surgery for DIMSNT. This study demonstrates that the novel surgical guide plate can expose the DIMSNT to perform immediate extraction after the plate is removed. Prior studies have noted the importance of locating the DIMSNT during the operation (24). Studies have shown the advantages of the osteotomy guide plate for the extraction of DIMSNT (13-18), but it only indicates the area of DIMSNT without navigation. Retana et al., to overcome these defects, designed a dynamic surgical navigation system to expose the DIMSNT (25). Although navigation systems can be used for precise bone removal, they do not have broad application prospects for clinical use. Based on existing research, we improved the osteotomy guide plate to shape the supernumerary tooth. The bone is removed according to the height and edge slope of the osteotomy plate during the operation. Through precise positioning, the DIMSNT can be exposed and extracted immediately. For the design

 Table 4 Comparison of the postoperative swelling score of the two

 groups

8		
Days	Template group	Freehand group
1 day	38	39
3 days	40	58
7 days	24	37

Days Template group Freehand group F value P value 1 day 2.10±0.99 2.95±1.43 4.519 0.0401 3 days 2.60±1.20 3.80±1.88 5.472 0.0247	P======	PooroPooro Pooro Pooro Secoro			
1 day 2.10±0.99 2.95±1.43 4.519 0.0401 3 days 2.60±1.20 3.80±1.88 5.472 0.0247	Days	Template group	Freehand group	F value	P value
3 days 2 60+1 20 3 80+1 88 5 472 0 0247	1 day	2.10±0.99	2.95±1.43	4.519	0.0401
	3 days	2.60±1.20	3.80±1.88	5.472	0.0247
7 days 0.70±1.05 1.70±1.73 4.612 0.0382	7 days	0.70±1.05	1.70±1.73	4.612	0.0382

F value, ratio of two mean squares.

1	1 1		0 1		
Group	Cases	Very satisfied	Basically satisfied	Dissatisfied	Score
Template group	20	15	5	0	8.95±1.05
Freehand group	20	9	9	2	7.90±1.51
P value	-	-	-	-	0.0152
F value	-	-	-	-	6.470

Table 5 Comparison of the postoperative satisfaction score of the two groups

F value, ratio of two mean squares.

of the surgical guide plate compared with the navigation system, we chose the method of point to point to guide the surgery, which may be more imprecise than the navigation system. Nevertheless, we simplified the structure of the guide and overcame several of the limitations of navigationassisted extraction.

Additionally, we compared the effect of the novel surgical guide with the traditional group. This study found that the surgical guide plates can significantly reduce the operation time and postoperative complications. A possible explanation for this might be the precise exposure of the DIMSNT (2,26-28). At the same time, the results indicate that surgical guide plates can enhance patients' satisfaction scores, which may be explained by a reduction in operative time and postoperative complications.

For the incision design of DIMSNT surgery, the traditional methods use gingival or posterior gingival incision to expose the surface of the bone. Inappropriate incision may lead to increased damage, inadequate bone exposure, and nerve injury. In order to solve the above problems, some studies on incision guide plates have focused on approaching from the labial side of the maxilla. Zheng et al. had the outer edge of the guide positioning component designed as a soft tissue incision line and the inner edge as an osteotomy area to guide labially approachable mesiodens in patients (28). However, the research ignored the approach from the plate side of the maxilla. Based on this, our study innovated the incision guide plate applicable to the labial and palate side. The incision guide plate was designed as an arch shape to guarantee the flap's blood supply and ensure space for osteotomy guide plate placement. Simultaneously, it connected with the osteotomy guide plate in the form of a T-slot, which effectively realized the transfer of 2 surfaces stably and precisely.

The application of the surgical guide plate in oral surgery still has its limitations. Firstly, in this study, 3 patients had errors in image acquisition during presurgical procedures which led to inadequate exposure of DIMSNT during surgery (19). It is necessary to try the surgical guide plate on patients before surgery. due to differences that may be found between the preoperative analysis data and the actual surgery. Secondly, our study showed that the swelling score of group I was higher than group II in some cases. It seems possible that these results are due to the expanded incision size to accommodate the osteotomy guide plate. Limited space available for oral surgery and placing the guide plate in the deep anatomical area will affect the vision of surgeons and the operation space, and can increase the operation time (21). At the same time, 2 cases needed additional osteotomy in group I, it might the drill placement imprecisely due to the limited space available for oral surgery. Finally, in one of the cases, the plate was fractured during the operation. This finding was unexpected and suggested that the material of the surgical guide was not adequate to withstand the pressure during surgery.

This study only included general anesthesia cases because of the complexity of the oral environment and the differing degrees of patient cooperation. However, it may have a broad application prospect under local anesthesia. When patients are diagnosed, they can communicate, undergo CBCT scanning, provide the oral impression when necessary, wait for the guide to be manufactured, and then revisit the clinic for surgery. Through the use of the surgical guide, the operation time can be shortened, surgical trauma can be reduced, patient fears about the tooth extraction process can be reduced (29), and the doctor-patient relationship can be improved (30).

Conclusions

In conclusion, the novel surgical guide plate can enhance patient satisfaction, shorten the operation time, and improve the operation quality by facilitating precise osteotomies and incisions. Although the novel surgical guide still has some flaws, we believe it has a broad application prospect for clinical use.

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Footnote

Reporting Checklist: The authors have completed the CONSORT reporting checklist. Available at https://atm. amegroups.com/article/view/10.21037/atm-22-585/rc

Trial Protocol: Available at https://atm.amegroups.com/ article/view/10.21037/atm-22-585/tp

Data Sharing Statement: Available at https://atm.amegroups. com/article/view/10.21037/atm-22-585/dss

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://atm. amegroups.com/article/view/10.21037/atm-22-585/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by ethics board of School & Hospital of Stomatology, Wenzhou Medical University, Wenzhou, China (No. WYKQ2019008) and informed consent was taken from all the patients.

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