Trial Protocol

In our research , 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.

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. During the single-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 preoperative CBCT data of patients (120 kV, 6 mA, 6 cm ×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).

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). 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, a gingival margin incision was used, and the trapezoidal flap was added. The other steps were the same as those except for the guide in group I. The sutures were removed 1 week after the operation.

The following data were evaluated intraoperatively

(I) Operation time: 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.

The following data were evaluated postoperatively

(I) Swelling and pain degree on the 1st, 3rd, and 7th days after the operation: the visual analogue scale (VAS) was used to evaluate the pain degree, 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. Scores of 9–10 were very satisfied, 6–8 were satisfied, and <6 were dissatisfied.

The Kruskal-Wallis rank-sum or nonparametric test was performed using SPSS 20.0 software (IBM SPSS, Inc., Chicago, IL, USA). Normally distributed data were presented in the form of mean ± standard deviation. Furthermore, a P value of less than .05 was accepted as statistically significant.

Article information: https://dx.doi.org/10.21037/atm-22-585