"Three-Dimensional Ring" of Zygomatic-Supported Prosthetics Rehabilitation in Bilateral Maxillary Defect

Zhen Wang, DDS, PhD[1]/Wenyan Wu, DDS, PhD[2]/Chenping Zhang, DDS, PhD[1]/
Jiannan Liu, Dr, DDS, PhD[1]/Xingzhou Qu, DDS, PhD[1]

Purpose: Patients with maxillary defects after a maxillectomy live with a range of functional and social problems. As techniques for functional reconstruction of the maxilla have been applied in a number of these patients, some of them regained confidence in their lives again. Nevertheless, there was still no clear consensus on the connecting and loading patterns of zygomatic implant–supported prosthetics in bilateral maxillary defects. This study aimed to investigate the function of a novel technique using "three-dimensional ring"–supported prosthetics based on zygomatic implants and compared its effects with two other conventional approaches through assessing the quality of the patient's life. ***Materials and Methods:*** Forty-five eligible patients who had different degrees of maxillectomy received treatment of conventional prostheses with a clasp (25 patients, group 1), a regular implant with obturator removal (10 patients, group 2), or a zygomatic implant combined with "three-dimensional ring"–supported prosthetics (10 patients, group 3). A questionnaire that included the indicators of the Obturator Functioning Scale (OFS) and EORTC Head and Neck 35 assessment was employed to evaluate the functional rehabilitation and quality of life (QOL) of patients in the study. The data were then summarized into a worksheet (Excel 2010), and the mean and standard deviation were calculated. The data were processed with SPSS 19.0 for Windows statistical software. ***Results:*** The questionnaire analysis showed a statistically significant difference in the OFS, EORTC H&N 35, and QOL scores between group 3 and group 1 or group 2. Importantly, in the assessment of EORTC H&N 35, the proportion of patients in group 3 who lost weight after the functional restoration of maxillary defection was lower than that of the other two groups. In this research, a new connection device mode, which provided a retentive force between the zygomatic implants and prosthetics through a 3D ring–shaped milling bar with golden galvanized frames, was conducted and proved to be a reliable and feasible functional reconstruction therapy through patients' questionnaire surveys. ***Conclusion:*** This research provided an effective reconstruction strategy for patients with maxillary resection that could remarkably improve the life quality of patients. *Int J Oral Maxillofac Implants 2021;36:1235–1246. doi: 10.11607/jomi.8799*

Keywords: EORTC Head and Neck 35, maxillary defects, OFS, three-dimensional ring, zygomatic implants

[1]Department of Oral and Maxillofacial-Head and Neck Oncology, Shanghai Ninth People's Hospital, Shanghai Jiao Tong University School of Medicine; College of Stomatology, Shanghai Jiao Tong University; National Clinical Research Center for Oral Diseases; Shanghai Key Laboratory of Stomatology & Shanghai Research Institute of Stomatology, 500 Quxi Road, Shanghai 200011, P. R. China.
[2]Department of Stomatology, Ruijin Hospital, Shanghai Jiao Tong University School of Medicine; College of Stomatology, Shanghai Jiao Tong University. 197 Ruijin Second Road, Shanghai 200025, P. R. China.

Zhen Wang and Wenyan Wu contributed equally to this work.

Correspondence to: Dr Xingzhou Qu and Dr Jiannan Liu, Department of Oral and Maxillofacial-Head and Neck Oncology, Shanghai Ninth People's Hospital, College of Stomatology, Shanghai Jiao Tong University School of Medicine; National Clinical Research Center for Oral Diseases; Shanghai Key Laboratory of Stomatology & Shanghai Research Institute of Stomatology, 500 Quxi Road, Shanghai 200011, P. R. China. Email: quxingzhou@126.com and laurence_ljn@yahoo.com

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Patients suffering from maxillary defects after a maxillectomy live with a series of functional and social problems. After the long-term application of functional maxillary reconstruction techniques in these patients, some of them have regained confidence in life.[1] However, because of the complicated 3D anatomy structure of the maxilla and midface, excellent facial contours, function, and acceptable esthetics are rarely achieved by single-stage surgery. Therefore, functional maxillary reconstruction may constitute major technologic hurdles, with unpredictable morbidity and mortality following surgery.[2,3] The indication of free vascularized flaps, such as the fibula, ilium, or scapula flap, was often absent or an ambiguous first operation in many maxillary disease patients, while the deformity resulting from scars or soft tissue defects especially amplified the complexity of secondary surgery.[4,5] Currently, only a few patients whose situation was under strict control had a strong intention to use maxillary reconstruction by the one-stage operation. Furthermore, complications such as titanium plate or mesh exposure,

looseness and displacement of graft bone, recurrence of the tumor, and even failure of the allograft reconstruction commonly occurred.[6,7] Therefore, the rehabilitation of these patients with maxillary defects by a maxillectomy continued to be a challenge for surgeons and prosthodontists.

Traditional partial removable obturators have been utilized in all kinds of maxillectomy defects, with varying results according to the remaining tooth condition.[8] Even in edentulous cases, dental implants were also a valuable option when the basal alveolar bone crest was still present. Prominent surgeons with remarkable surgical technique could reconstruct the maxillary defect by fibula or other flaps; thus, oronasal communication would be tightly closed, and occlusion function would be restored with implants based on the reconstruction bone graft.[9] However, many complicated problems might exist that influence the smooth advance of maxillary reconstruction or cause severe complications during and after the operation.[10] Unlike lesions that only affected the unilateral maxilla, patients who suffered from subtotal bilateral maxillectomy mainly had malignant tumors with a high grade of malignancy and invasion.[11] Further treatment like affected side or bilateral neck lymph node dissection and radio-chemotherapy would be received subsequently.[12] In extreme cases, however, patients undergoing a subtotal bilateral maxillectomy lost not only all teeth but also both bone and oral mucosa. Unlike partial maxillectomy cases, conventional dental implants were not capable of obtaining a satisfactory mechanical retention of a dental prosthesis or obturator without bone flaps.[13,14] Not only the size of the maxillary bone defect, caused by the subtotal bilateral maxillectomy, but also the simultaneous soft tissue collapse was inestimable.[15] Combined severe soft tissue defects would result in catastrophic maxillofacial deformity, presenting midfacial collapse and cicatricial contracture of the upper lip from the front view, the loss of natural palatal construction, residual maxillary bone resorption, and regression.[16] The application of the fibular flap to reconstruct the maxillary defect was highly unlikely to be concretely implemented due to the limitation caused by a soft tissue defect. Skin paddle of the bone graft that was used to separate the environment between the oral and nasal cavity was merely structural separation and lacked normal nasal anatomy coated with mucosa. That was the major reason for long-term chronic nasal infection that originated from secretions of abnormal discharge after maxillary reconstruction surgery.[17] Therefore, patients who could be successfully treated by the surgery were very rare, let alone the implantation base on the bone graft. Furthermore, some problems still existed in the later implantation period, such as a graft skin paddle that was too thick, abnormalities of the dentofacial soft and hard tissue structures, a defect of the alveolar bone height, poor peri-implant soft tissue emergence profile, and obstinate peri-implantitis.[18]

Zygoma implants were invented by Brånemark and were originally designed to obtain stable retention in edentulous or oncologic patients with severe alveolar bone resorption who were not suitable for conventional dental implant placement.[19] Zygomatic implants integrated into the zygoma, so it was considered beneficial for maxillary defects after a subtotal bilateral maxillectomy.[20,21] The fact that utilization of zygomatic implants to support removable obturators could obtain reliable retention in the restoration of maxillary defects was proved by many case reports.[11,22–24] With the advance of CAD/CAM and navigation technology, the accuracy error of the zygomatic implant position or prosthetics was improved dramatically.[25] Nevertheless, there was still no clear consensus on the connecting and loading patterns for zygomatic implant–supported obturators.

The present study proposed a modified retention pattern of a "three-dimensional ring" and prosthetics with bar-gold deposition attachment to functionally repair patients' maxillary defects. Furthermore, the loading methods, spatial location, and oral perforation patterns of the zygomatic implants were analyzed and discussed in detail. Clinical outcomes were both evaluated by the Obturator Functional Scale (OFS) and Quality of Life (QOL) Questionnaire, and the comparison was made among several methods of maxillary defect rehabilitations. It was found that the use of zygomatic implant–supported prostheses to repair bilateral maxillary defects can greatly restore the oral and maxillary function of patients and improve the QOL and satisfaction.

MATERIALS AND METHODS

Forty-five patients who were diagnosed and finished their series of operations in the Department of Oral and Maxillofacial-Head and Neck Oncology, the Ninth People's Hospital, School of Medicine from March 2016 to October 2018 were enrolled in the present study. After informed consent was obtained from all study participants, all follow-up data were collected. Twenty-five patients who had a maxillectomy received treatment of conventional prostheses with a clasp (group 1; Fig 1). Regular implants were placed in either residual alveolar segments or reconstruction bone flaps (Nobel Biocare or Straumann) of 10 patients and restored with implant-supported removable obturators (group 2; Fig 2). Zygomatic implants combined with 3D ring–supported prosthetics were utilized for 10 patients to rehabilitate the loss of maxillary function (Zygomaticus fixtures, Brånemark System, Nobel Biocare Norden; group 3; Fig 3). According to the size of the maxillary defect, the 3D ring connector was designed

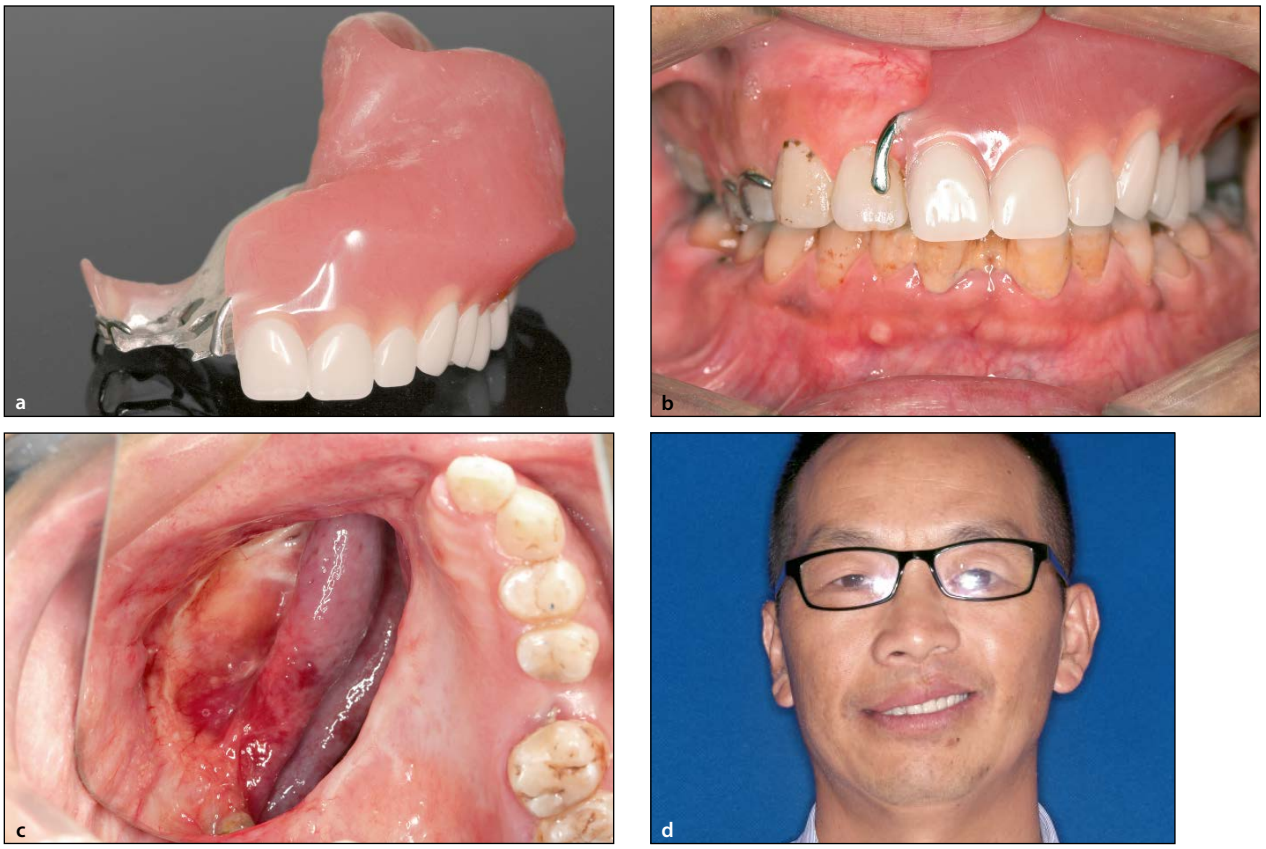

Fig 1 *(a)* Frontal view of obturator prosthesis. *(b)* A patient represented with a maxillary defect after treatment of maxillectomy. *(c)* Frontal view of implant-supported obturator delivery. *(d)* Frontal postoperative view.

along the contour of the palatal fornix to form a mechanical chimeric structure while avoiding the palatal protrusion of the prosthesis. The material was made of precious metal casting or pure titanium cutting, and the retention force and support force were obtained by inlaid in the upper obturator gold-plated ferrule. In addition, the CONSORT 2010 information checklist, including information when reporting randomized trials, is shown in Appendix 1 (see online version of this article at quintpub.com). All the studies have been approved by the Ethics Committee of the Ninth People's Hospital, the Medical College of Shanghai Jiao Tong University.

The inclusion criteria were as follows:

- Patients with bilateral maxillary defects: James Brown classification type II and III subtype C and stable condition after tumor resection.
- Patients after unilateral maxillectomy: Natural dentition on the contralateral side, local removable prosthesis restoration.
- Patients after unilateral maxillectomy: No natural dentition on the contralateral side, conventional implant + local attachment removable prosthesis restoration.
- After resection of the benign tumor, the radical cure is reliable, and the possibility of recurrence is extremely low.
- There was no recurrence more than 1 year after radical resection of the malignant tumor. One year after chemoradiotherapy, the patient's condition was stable and required improvement of the QOL.

The exclusion criteria were as follows:

- Patients with a unilateral maxillary defect who have poor condition of residual teeth or insufficient residual alveolar ridge bone and cannot accept an implant.
- Patients with bilateral maxillary defect with partial zygomatic bone resection, or congenital short zygomatic bone, who are unable to have zygomatic implants.
- Patients who cannot cooperate with the later implant and prosthesis maintenance due to advanced age, mental problems, and cognitive impairment.
- Patients with systemic diseases, bone marrow suppression after chemoradiotherapy, local osteoradionecrosis, etc, who have a clear risk of failure.

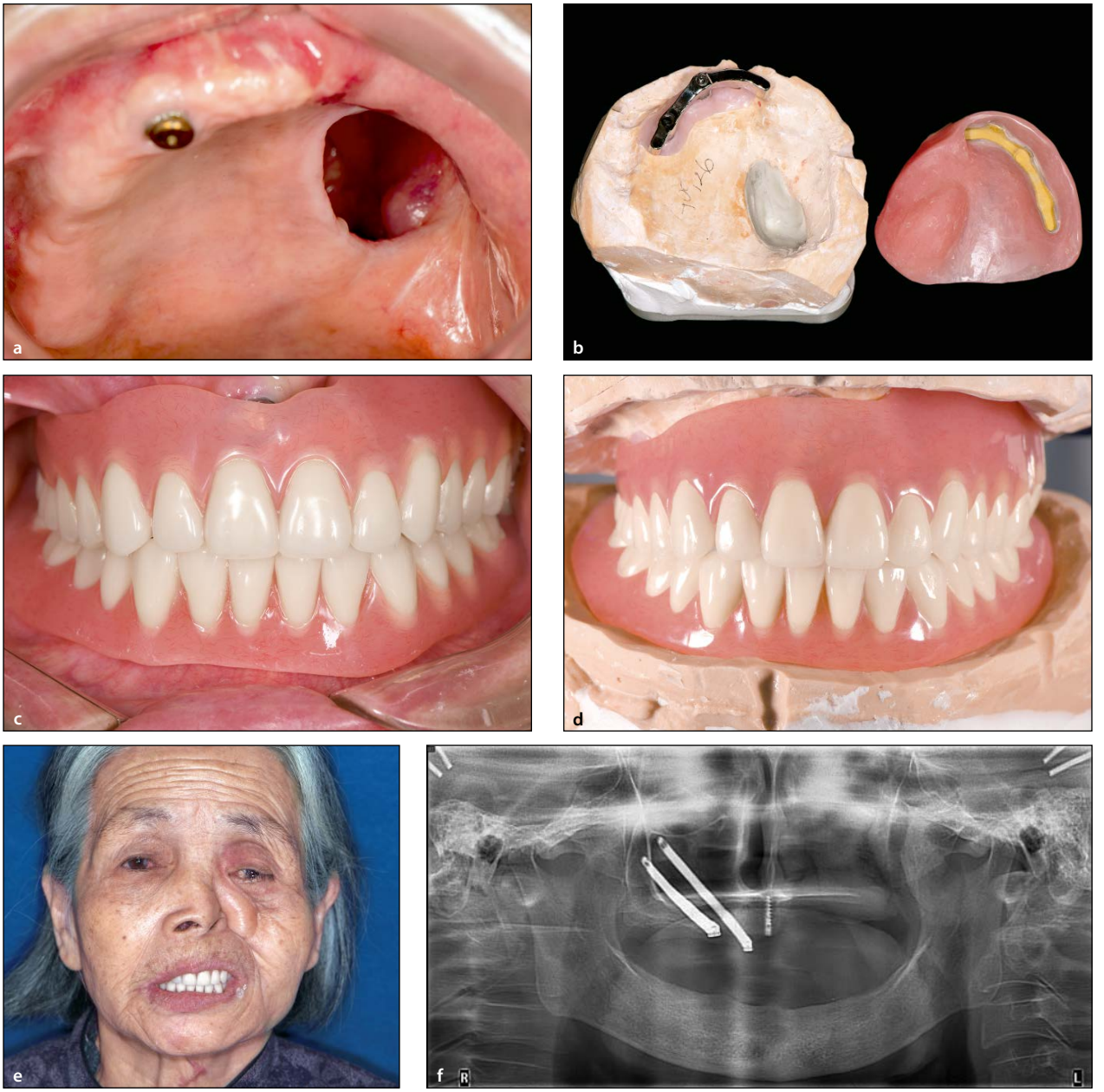

Fig 2 *(a)* A patient with unilateral maxillary defect after treatment of maxillectomy. *(b)* Repair of body grinding rod and overdenture. *(c)* Frontal postoperative view. *(d)* Frontal view of close frame denture bite. *(e)* Front view of the patient with prosthesis. *(f)* Panoramic radiography.

- Patients whose benign or malignant tumor has not been cured and had a potential for recurrence.
- Patients with other adverse factors that may affect the whole body and local repair site.

Eligible patients received a standardized questionnaire survey, and telephone interviews were conducted by a single trained interviewer. The following questionnaires were used to evaluate the functional rehabilitation and QOL of patients in the study.[26,27] The questionnaire was developed by the University of Washington, and its details were adjusted based on the OFS.[28,29] It consists of 15 questions to measure the patients' items such as pain, appearance, activity, recreation, swallowing, chewing, speech, shoulder problem, taste, saliva, mood, and anxiety. The Likert scale was applied to score each item in OFS, and descriptors were listed under each point.[30] The European Organisation for Research and Treatment of Cancer (EORTC) quality of life questionnaire (QLO)-head and neck (H&N) 35 is a specific self-report questionnaire for head and neck cancer patients.[31,32] The definitive version of EORTC QLO-H&N 35 includes seven scales, such as pain, swallowing, senses, speech, and sexuality, and 11 single items. The latter items are related to problems such as teeth, opening mouth, dry mouth, and sticky saliva. Most questions are scored on a 4-point response

Fig 3 *(a)* A patient represented with bilateral maxillary defect after treatment of maxillectomy. *(b)* Panoramic radiography. *(c)* Ring grinding bar. *(d)* Gold deposition retention prosthesis. *(e)* The gomphosis of stereoscopic ring grinding bar and prosthesis. *(f)* Palatal view of the definitive prosthesis. *(g)* Frontal view after implant-supported obturator delivery. *(h)* Frontal view with a smile. *(i)* Frontal postoperative view.

Table 1 Medical Characteristics of Patients

Patient characteristics	Group 1, n = 25	Group 2, n = 10	Group 3, n = 10
Sex (%)			
Male	15 (60)	9 (90)	9 (90)
Female	10 (40)	1 (10)	1 (10)
Mean age at operation (years)			
30–39	3	2	2
40–49	5	3	3
50–59	9	4	4
60–69	8	1	1
Tumor type (n)			
Palate pleomorphic adenomapleomorphic adenoma	3	2	0
Gingival squamous cell carcinoma	11	4	3
Ameloblastoma	6	3	3
Nasopharyngeal carcinoma	1	0	2
Maxilla sinus carcinoma	3	1	2
Hemangioma	1	0	0
Radiotherapy (%, n/n)	28%, 7/25	30%, 3/10	60%, 6/10
Maxillectomy classification (n)			
Class I	5	1	0
Class IIa	6	5	0
Class IIb	9	3	0
Class IIc	1	0	7
Class IIIb	4	1	0
Class IIIc	0	0	3

Class I defects involve maxillectomy without an oroantral fistula; Class II defects involve low maxillectomy (not including orbital floor or contents); Class III defects involve high maxillectomy (involving orbital contents); Class a defects involve unilateral alveolar maxillectomy; Class b defects involve bilateral alveolar maxillectomy; Class c defects involve total alveolar maxillary resection.

scale ranging from 1 (not at all) to 4 (very much). The last five questions are related to analgesia, supplemental feeding, and weight.[33]

The data were summarized in the worksheet (Excel 2010, Microsoft), and the means and standard deviations were computed. The data were processed with SPSS 19.0 for Windows statistical software (SPSS). Two-way analysis of variance (ANOVA) was used to analyze the statistical significance between the OFS, EORTC, and QOL item scores of patients in group 1, group 2, and group 3. For all statistical analyses, probability levels of $P < .05$ were considered statistically significant.

RESULTS

Clinical Features of Patients

Forty-five patients who received a maxillectomy were enrolled in this study, and their medical characteristics are shown in Table 1. There were 15 (60%) male and 10 (40%) female patients with an average age of 53 years (range: 30 to 68 years) in group 1, 9 (90%) male and 1 (10%) female patients with an average age of 48.0 years (range: 33 to 58 years) in group 2, and 9 (90%) male and 1 (10%) female patients with an average age of 47.4 years (range: 33 to 62 years) in group 3. The main histologic diagnoses were gingival squamous cell carcinoma and ameloblastoma in the three groups. Meanwhile, 28% (7/25), 30% (3/10), and 60% (6/10) of patients in group 1, group 2, and group 3 used to receive radiotherapy, respectively.

Among the 25 patients in group 1, the majority of them[16] were class 2 defect with low maxillectomy (excluding orbital floor or contents), followed by class 1 defect[5] with maxillectomy without an oroantral fistula, and class 3 defect[1] with high maxillectomy (involving orbital contents). The patients were treated with conventional prosthetics with a clasp. In group 2, eight patients suffered class 2 maxillary defects, and two other patients suffered class 1 and class 3b maxillary defects, respectively. They were all treated with implant-supported removable partial prostheses. Meanwhile, in group 3, seven patients suffered class 2c defects with low maxillectomy and total alveolar maxillary resection, and the other patients suffered class 3c defects with high maxillectomy and total alveolar maxillary resection. They were treated with zygomatic implants and "three-dimensional ring"–supported prosthetics for the functional restoration of maxillary defects.

Table 2 OFS Scores of Patients

Item no.	Description	Group 1 Mean ± SD	Group 1 Median	Group 1 Q	Group 2 Mean ± SD	Group 2 Median	Group 2 Q	Group 3 Mean ± SD	Group 3 Median	Group 3 Q	*P* value Group 1 vs 2	*P* value Group 1 vs 3	*P* value Group 2 vs 3
Eating problem													
1	Difficulty in chewing foods	2.2 ± 1.2	3	1,3	2.0 ± 1.1	2	1,3	1.0 ± 0.0	1	1,1	ns	ns	ns
2	Difficulty in swallowing foods	2.4 ± 1.4	3	1,3	2.2 ± 1.4	2	1,3	1.8 ± 1.0	1	1,3	ns	ns	ns
Subtotal		2.3 ± 1.3	3	1,3	2.1 ± 1.2	2	1,3	1.4 ± 0.8	1	1,1	ns	ns	ns
Speech problem													
3	Voice	2.1 ± 1.2	3	1,3	1.8 ± 1.0	1	1,3	1.8 ± 1.0	1	1,3	ns	ns	ns
4	Talking	1.8 ± 1.0	1	1,3	1.8 ± 1.0	1	1,3	1.6 ± 1.0	1	1,2.5	ns	ns	ns
5	Pronunciation	2.2 ± 1.1	3	1,3	1.8 ± 1.0	1	1,3	1.8 ± 1.0	1	1,3	ns	ns	ns
6	Difficulty pronouncing words	2.3 ± 1.3	3	1,3	2.0 ± 1.1	2	1,3	2.0 ± 1.1	2	1,3	ns	ns	ns
7	Speech is nasal	2.6 ± 1.0	3	3,3	2.0 ± 1.4	1	1,3	2.2 ± 1.4	2	1,3	ns	ns	ns
Subtotal		2.2 ± 1.1	3	1,3	1.9 ± 1.1	1	1,3	1.9 ± 1.1	1	1,3	ns	ns	ns
Other items													
8	Snap ring insert or remove	1.6 ± 1.1	1	1,1	1.2 ± 0.6	1	1,3	1.4 ± 0.8	1	1,1	ns	ns	ns
9	Mouth feels dry	3.3 ± 1.9	5	1,5	2.6 ± 1.8	2	1,4.5	2.2 ± 1.4	2	1,3	ns	ns	ns
10	Facial deformity	2.0 ± 1.2	1	1,3	1.2 ± 0.6	1	1,1	1.2 ± 0.6	1	1,1	ns	ns	ns
11	Leakage of mouth and nose	2.2 ± 1.3	3	1,3	2.0 ± 1.4	1	1,3	2.0 ± 1.4	1	1,3	ns	ns	ns
12	Upper lip feels numb	1.6 ± 1.3	1	1,1	1.2 ± 0.6	1	1,1	1.2 ± 0.6	1	1,1	ns	ns	ns
13	Appearance	3.0 ± 1.7	3	1,5	2.4 ± 1.6	2	1,3	2.6 ± 1.6	3	1,3	ns	ns	ns
14	Snap ring effect	2.0 ± 1.2	1	1,3	2.0 ± 1.4	1	1,3	1.0 ± 0.0	1	1,1	ns	ns	ns
15	Social influence	1.7 ± 1.1	1	1,3	1.4 ± 0.8	1	1,1	1.4 ± 0.8	1	1,1	ns	ns	ns
Total		33.0 ± 10.7	31	23, 43	27.6 ± 7.4	27	25, 29	25.2 ± 5.8	24	23, 26.5	< .0001	< .0001	ns

Q = quartiles.

QOL of Patients

The OFS was applied to measure the patients' satisfaction with functional restoration of maxillary defects. The scores for items in the OFS are listed in Table 2. There were no significant differences between group 3 and group 1 or group 2 for each item. However, the total value of OFS score among group 1 patients (mean ± SD, 33.0 ± 10.7) was significantly higher than that in group 2 (mean ± SD, 27.6 ± 7.4; $P < .001$) and group 3 (mean ± SD, 25.2 ± 5.8; $P < .001$).

The EORTC H&N 35 has developed a cancer-specific multidimensional self-report questionnaire, which was used to assess the QOL of patients with head and neck cancer. The EORTC scores of patients are listed in Table 3. For the item-level analysis, each value of the first 30 items showed no notable difference among the three groups, but the total median of EORTC scores of patients in group 3 (mean ± SD, 48.9 ± 10.2) was markedly lower than that of group 1 (mean ± SD, 61.2 ± 16; $P < .001$) or group 2 patients (mean ± SD, 56.8 ± 12.8; $P < .001$). Meanwhile, the proportion of the patients in group 3 who lost weight after the functional restoration of maxillary defects was lower than that of the other two groups.

The comprehensive QOL score of patients is shown in Table 4, and it was found that the emotion scores showed a significant difference between group 3 (mean ± SD, 1.0 ± 0.0) and group 2 (mean ± SD, 3.5 ± 1.3; $P < .05$). In addition, the total QOL scores of the patients in group 3 (mean ± SD, 18.3 ± 1.6) were notably lower than those in group 1 (mean ± SD, 28.6 ± 6.4; $P < .001$) or group 2 (mean ± SD, 38.5 ± 16.1; $P < .001$).

In addition, Video 1 (see QR code on page 1246) was the speech video recorded before and Video 2 (see QR code on page 1246) was the speech video recorded after the patient used zygomatic implants and "three-dimensional ring"–supported prosthetics for the functional restoration of maxillary defects. It was found that the speaking

Table 3 EORTC Head and Neck 35 Scores of Patients

Item no.	Description	Group 1			Group 2			Group 3			*P* value		
		Mean ± SD	Median	Q	Mean ± SD	Median	Q	Mean ± SD	Median	Q	Group 1 vs 2	Group 1 vs 3	Group 2 vs 3
1	Pain in mouth	1.7 ± 0.7	2	1,2	1.5 ± 0.7	1	1,2	1.4 ± 0.5	1	1,2	ns	ns	ns
2	Pain in jaw	1.4 ± 0.6	1	1,2	1.3 ± 0.5	1	1,1.8	1.1 ± 0.3	1	1,1	ns	ns	ns
3	Soreness in mouth	1.7 ± 0.7	2	1,2	1.5 ± 0.7	1	1,2	1.1 ± 0.3	1	1,1	ns	ns	ns
4	Pain in throat	1.2 ± 0.6	1	1,3	1.2 ± 0.6	1	1,1	1.0 ± 0.0	1	1,1	ns	ns	ns
5	Problems in swallowing liquids	2.1 ± 1.1	2	1,3	1.9 ± 1.1	1.5	1,2.8	1.9 ± 1.0	1.5	1,3	ns	ns	ns
6	Problems in swallowing pureed foods	2.4 ± 0.9	3	2,3	2.0 ± 1.1	2	1,3	2.0 ± 1.1	2	1,3	ns	ns	ns
7	Problems in swallowing solid food	2.2 ± 0.9	2	1,3	1.9 ± 1.0	1.5	1,3	1.8 ± 0.9	1.5	1,2.8	ns	ns	ns
8	Choking while swallowing	1.8 ± 0.9	2	1,3	1.6 ± 0.8	1	1,2	1.5 ± 0.5	1.5	1,2	ns	ns	ns
9	Problems with teeth	2.1 ± 1.1	3	1,3	2.0 ± 1.1	2	1,3	1.0 ± 0.0	1	1,1	ns	ns	ns
10	Problems in opening mouth wide	1.5 ± 0.7	1	1,2	1.6 ± 0.8	1	1,2	1.1 ± 0.3	1	1,1	ns	ns	ns
11	Dry mouth	2.6 ± 1.4	3	1,4	2.1 ± 1.2	2	1,3	2.0 ± 1.1	2	1,3	ns	ns	ns
12	Sticky saliva	2.1 ± 1.0	2	1,3	2.0 ± 0.8	2	1.25,2.75	1.5 ± 0.7	1	1,2	ns	ns	ns
13	Problems with sense of smell	1.2 ± 0.5	1	1,1	1.2 ± 0.6	1	1,1	1.1 ± 0.3	1	1,1	ns	ns	ns
14	Problems with sense of taste	1.9 ± 0.8	2	1,2	1.7 ± 0.8	1.5	1,2	1.2 ± 0.6	1	1,1	ns	ns	ns
15	Coughing	1.3 ± 0.6	1	1,2	1.0 ± 0.0	1	1,1	1.0 ± 0.0	1	1,1	ns	ns	ns
16	Hoarseness	1.0 ± 0.2	1	1,1	1.0 ± 0.0	1	1,1	1.0 ± 0.0	1	1,1	ns	ns	ns
17	Feeling of illness	2.3 ± 0.8	2	2,3	2.3 ± 0.7	2	2,3	1.6 ± 0.7	1.5	1,2	ns	ns	ns
18	Bothersome appearance	2.5 ± 1.1	3	1,3	2.3 ± 1.2	3	1,3	2.3 ± 0.9	3	1.25,2	ns	ns	ns
19	Trouble with eating	2.5 ± 0.8	3	2,3	2.3 ± 1.1	2.5	1.25,3	1.6 ± 0.7	1.5	1,2	ns	ns	ns
20	Trouble with eating in front of family	2.0 ± 0.6	2	2,2	2.1 ± 0.9	2	1.25,3	1.7 ± 0.8	1.5	1,2	ns	ns	ns
21	Trouble with eating in front of others	2.6 ± 0.9	3	2,3	2.4 ± 1.1	3	1.25,3	1.8 ± 0.9	1.5	1,2.75	ns	ns	ns
22	Trouble in enjoying meals	2.5 ± 0.8	3	2,3	2.3 ± 0.7	2	2,3	1.6 ± 0.7	1.5	1,2	ns	ns	ns
23	Trouble in talking to other people	2.1 ± 1.0	2	1,3	2.4 ± 0.8	3	2,3	2.4 ± 0.8	3	2,3	ns	ns	ns
24	Trouble in talking on the telephone	2.1 ± 1.0	2	1,3	2.6 ± 0.8	3	3,3	2.5 ± 0.7	3	2,3	ns	ns	ns
25	Trouble in having social contacts with family	1.6 ± 0.7	1	1,2	2.2 ± 0.8	2	2,3	1.8 ± 0.6	2	1.25,2	ns	ns	ns
26	Trouble in having social contacts with friends	2.2 ± 0.9	3	1,3	2.1 ± 1.0	2.5	1,3	1.9 ± 0.9	2	1,2.75	ns	ns	ns
27	Trouble going out in public	2.1 ± 0.8	2	1,3	1.8 ± 0.9	1.5	1,2.75	1.5 ± 0.8	1	1,1.75	ns	ns	ns
28	Trouble having physical contacts with family or friends	1.7 ± 0.6	2	1,2	1.6 ± 0.5	2	1,2	1.4 ± 0.8	1	1,1	ns	ns	ns
29	Less interested in sex	3.4 ± 0.9	4	3,4	3.0 ± 1.1	3	2.25,4	2.6 ± 1.3	3	1.25,3.75	ns	ns	ns
30	Less joy in sex	3.2 ± 1.1	4	3,4	1.9 ± 0.6	2	2,2	2.5 ± 0.8	2.5	2,3	ns	ns	ns
Total		61.2 ± 16.0	64	51,73	56.8 ± 12.8	60	48.25,64.75	48.9 ± 10.2	48.5	41.25,58.5	< .0001	< .0001	< .0001

Q = quartiles.

Table 3 EORTC Head and Neck 35 Scores of Patients *(continued)*

		Percentage of "Yes"		
		Group 1	Group 2	Group 3
31	Painkiller use	40%	30%	30%
32	Taking any nutritional supplements	76%	60%	100%
33	Used a feeding tube	76%	60%	100%
34	Lost weight	72%	70%	20%
35	Gained weight	28%	30%	80%

Q = quartiles.

Table 4 QOL Scores of Patients

		Group 1			Group 2			Group 3			*P* value		
Item no.	Description	Mean ± SD	Median	Q	Mean ± SD	Median	Q	Mean ± SD	Median	Q	Group 1 vs 2	Group 1 vs 3	Group 2 vs 3
1	Pain	1.1 ± 0.3	1	1,1	1.2 ± 0.6	1	1,1	1.0 ± 0.0	1	1,1	ns	ns	ns
2	Appearance	2.0 ± 1.1	3	1,3	2.4 ± 1.0	3	1.5,3	1.6 ± 0.8	1	1,2	ns	ns	ns
3	Activity	1.4 ± 0.8	1	1,3	1.6 ± 1.0	1	1,3	1.0 ± 0.0	1	1,1	ns	ns	ns
4	Recreation	2.0 ± 1.1	3	1,3	2.2 ± 1.4	2	1,3	1.0 ± 0.0	1	1,1	ns	ns	ns
5	Swallowing	2.5 ± 1.0	3	1,3	1.8 ± 1.0	1	1,3	1.3 ± 0.5	1	1,1.75	ns	ns	ns
6	Chewing	2.2 ± 1.4	3	1,3	2.2 ± 1.0	3	1,3	1.2 ± 0.4	1	1,1	ns	ns	ns
7	Speaking	2.3 ± 0.9	3	1,3	2.6 ± 0.8	3	3,3	1.4 ± 0.5	1	1,2	ns	ns	ns
8	Shoulder	1.0 ± 0.0	1	1,1	1.2 ±0.6	1	1,1	1.0 ± 0.0	1	1,1	ns	ns	ns
9	Gustation	1.2 ± 0.6	1	1,3	1.8 ± 1.0	1	1,3	1.2 ± 0.4	1	1,1	ns	ns	ns
10	Saliva	1.8 ± 1.0	3	1,3	2.6 ± 1.5	3	1,4	1.0 ± 0.0	1	1,1	ns	ns	ns
11	Emotion	1.6 ± 0.7	2	1,4	3.5 ± 1.3	4	3,4.5	1.0 ± 0.0	1	1,1	ns	ns	.0493
12	Anxiety	1.6 ± 0.7	2	1,3	2.5 ± 0.8	2.5	2,3	1.0 ± 0.0	1	1,1	ns	ns	ns
13	Before treatment of tumor	2.4 ± 1.4	3	3,4	3.5 ± 0.7	3	3,4	1.2 ± 0.4	1	1.25,1	ns	ns	ns
14	After treatment of tumor	2.7 ± 0.8	3	3,4	3.2 ± 0.6	3	3,4	1.7 ± 0.5	2	1.25,2	ns	ns	ns
Total		28.6 ± 6.4	35	30,39	38.5 ± 16.1	34	31.25,39.75	18.3 ± 1.6	18	17.25,19.5	< .0001	< .0001	< .0001

Q = quartiles.

ability of the patients was significantly improved after the use of zygomatic implants and "three-dimensional ring"–supported prosthetics for the functional restoration of maxillary defects. The patient also recorded a video of eating food (Video 3; see QR code on page 1246), showing that the difficulty of chewing and swallowing food was improved after using zygomatic implants and "three-dimensional ring"–supported prosthetics for the functional restoration of maxillary defects.

DISCUSSION

Treating bilateral maxillary defects was a complicated issue that struck both surgeons and patients for a long time. Considering the high risk of maxillary reconstruction surgery, the one-stage operation was not accepted by most of the patients. The stage-two maxillary reconstruction still had extraordinary difficulty and great uncertainty after the maxillary tumor was in complete control. Moreover, the retentive force of traditional prosthetics would not be sufficient due to the utilization of undercut of soft tissue, thus having poor stability of the prosthetics, almost no pronouncing and chewing function, and strong foreign body sensation. Partial patients even abandoned the prosthetics because they were too hard to tolerate.[34,35]

Multiple reports showed that using zygomatic implant–supported prosthetics to reconstruct bilateral maxillary defects could provide a positive outcome with less trauma.[36] Biconical bone integration of zygomatic implants offered strong retention and supportive

force, which guaranteed good efficiency of the prosthetics.[37,38] Benefits of zygomatic implant integration were distant from the tumor lesion. Tumor recurrence and radiotherapy had little chance to affect the implant, and zygomatic peri-implantitis was rarely seen.[39] Current studies of zygomatic-supported prosthetics were mainly case reports, and the patterns of prosthetics varied.[40,41] Most of the retentive patterns were multipoints or segmental bar connections, and hence, the prosthetic effects on the restoration were not the same. Zygomatic implants supporting a decentralized multipoint retentive connection were able to provide an appropriate retentive force, which referred to the resistance of the denture to forces tending to displace it in any direction other than along its path of insertion. However, it might also lead to difficulty in fitting or removing the prosthesis. The present study proposed a new pattern of connection set, which provided a retentive force between the zygomatic implants and prosthetics by a 3D ring–shaped milling bar with golden galvanized frames. Using a 3D ring–shaped milling bar to solidly connect all zygomatic implants together as a unit rendered not only reasonable occlusal stress distribution but also high stability, benefiting from its upper mechanical interlocking between the 3D milling bar and golden galvanized frames, which comprised a combining body that can prevent the rotation and misalignment of the prosthesis. By comparing the retention and stability effect of a magnetic attachment and golden galvanized frames supported by a 3D milling bar in subtotal bilateral maxillectomy cases, the present study found that golden galvanized frames were more effective in resisting the tangential direction separating force. Another advantage of the golden galvanized frame attachment was the convenience for subsequent maintenance. The retention force attenuation caused by daily wear and tear could be conveniently regained by inner-layer gold re-deposition or welding spot addition of golden galvanized frames. Therefore, the application of a 3D milling bar and golden galvanized frames was predominant to restore the bilateral maxillary defects after zygomatic implantation.

Unilateral implant–supported prosthetics including obturators had no essential difference in bearing force mode compared with conventional-clasp removable prosthetics. This kind of prosthetic was a unilateral retentive prosthesis: Regardless of any retentive means that were applied, it was still unilateral retention, and no supportive force could be provided for the obturator.[42,43] Notably, the downward movement of the obturator side was inevitable when chewing functional movement and force were loading. It was consistent with the result of a prior study reporting that the restorative effects of unilateral implant-supported prosthetics had no significant difference in comparison with conventional clasp–retained prosthetics if the remaining teeth with proper anatomical undercut were sufficient and healthy.[44] Although the restorative difficulty level of patients with bilateral maxillary defects was much higher, zygomatic implant–supported 3D ring bar prosthetics were able to not only provide outstanding support for chewing functional movement, but also bite firmly to withstand the lateral force. The 3D ring bar prosthetics in the present study were still one kind of overdenture, but its restorative effects were much better than conventional prosthetics. The 3D ring bar securely connected all zygomatic implants by screws and fixed multiunit abutments into a solid unit. This connection and supportive pattern might structurally avoid the cantilevered beam design that had great chances of lateral side implant overload. This connection and supportive pattern could also help to reduce the risk of abutment abrasion and even break. In addition, Buurman et al found that compared with traditional obturators, implant-supported prosthetic obturators after a maxillectomy significantly improved oral function, chewing, and eating comfort.[45] Recently, a review showed the special use of zygomatic implants in supporting and retaining the definitive prosthesis, and proved that zygomatic implants could be used in head and neck tumor patients to repair the maxillofacial and midface defects.[46] Compared with the segmented structure and horseshoe-shaped stem clamp structure, the stress distribution of zygomatic implant–supported 3D ring bar prosthetics was more uniform, and there was a mechanical chimeric effect between the 3D ring structure and the prosthesis, which might be more stable when performing functions. The 3D ring bar prosthetics exhibited notable advantages in maxillary reconstruction after a bilateral maxillectomy, but its wide application needs further research and improvement. The present authors plan to conduct further research associated with the stress analysis of their 3D ring bar–supported prosthetics. A finite element analysis was used to calculate and evaluate the stress of the zygomatic implants. A zygomatic implant–supported prosthetics model was constructed in vitro to simulate chewing function. Then, real-time multispot pressure tensioning was tested using radiographs. All data collected were summarized and analyzed, and then, the partial stress concentration of zygomatic implants and abutments or the reasonable number and distribution of zygomatic implants were determined.

There are still some limitations in this study, such as the small number of sample cases and the small number of patients conforming to the zygomatic implant–supported prosthetic restoration. The follow-up study will expand the sample size and subdivide the groups according to the maxillary defect shape, sex, age, and repair methods, in order to obtain a more comprehensive evaluation of different repair methods.

CONCLUSIONS

Through the full analysis and investigation of the maxillary defect patients' questionnaire surveys and other functional testing results, zygomatic implant–supported 3D ring prosthetics were a reliable and feasible functional reconstruction therapy. In particular, it was of great significance to those patients who did not have conditions to undergo stage-two maxillary reconstruction. The application of zygomatic implants could achieve the definite effect and the utilization of minimal invasive surgery and could minimize trauma to the surrounding tissues and organs, which not only extended operation indications, but also reduced the complications and cost for the patients. Finally, this new approach allowed the patients to return to a normal life.

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Video 1 Speech video recorded before patient used zygomatic implants and "three-dimensional ring"–supported prosthetics.

Video 2 Speech video recorded after patient used zygomatic implants and "three-dimensional ring"–supported prosthetics.

Video 3 Video of patient eating food, showing that the difficulty of chewing and swallowing food was improved after using zygomatic implants and "three-dimensional ring"–supported prosthetics.

APPENDIX

Appendix 1: CONSORT 2010 Checklist of Information to Include When Reporting a Randomized Trial

Section/Topic	Item no	Checklist item	Reported on page no.
Title and abstract	1a	Identification as a randomized trial in the title	N/A
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1235
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	1235–1236
	2b	Specific objectives or hypotheses	1235–1236
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	1236–1240
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	N/A
	4b	Settings and locations where the data were collected	1236–1240
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	1236–1240
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	1236–1240
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	1236–1240
	7b	When applicable, explanation of any interim analyses and stopping guidelines	1236–1240
Randomization:			
Sequence generation	8a	Method used to generate the random allocation sequence	N/A
	8b	Type of randomization; details of any restriction (such as blocking and block size)	N/A
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	N/A
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	N/A
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	1236–1240
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	N/A
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome	N/A
	13b	For each group, losses and exclusions after randomization, together with reasons	N/A
Recruitment	14a	Dates defining the periods of recruitment and follow-up	N/A
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	1240–1243

The authors strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, the authors also recommend reading CONSORT extensions for cluster randomized trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up-to-date references relevant to this checklist, see www.consort-statement.org.

Appendix 1: CONSORT 2010 Checklist of Information to Include When Reporting a Randomized Trial

Section/Topic	Item no	Checklist item	Reported on page no.
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	1240–1243
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	1240–1243
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	1243–1244
Generalizability	21	Generalizability (external validity, applicability) of the trial findings	1243–1244
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	1243–1244
Other information			
Registration	23	Registration number and name of trial registry	N/A
Protocol	24	Where the full trial protocol can be accessed, if available	N/A
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	1243–1244

The authors strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, the authors also recommend reading CONSORT extensions for cluster randomized trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up-to-date references relevant to this checklist, see www.consort-statement.org.