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Acute open callus manipulation: Clinical experience with a new surgical technique for solving old problems in distraction osteogenesis

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A B S T R A C T

Background: Transport distraction osteogenesis is challenged as a potential alternative to free-flap reconstruction of segmental jaw defects due to its longer treatment time, vector control difficulties, need for additional bone-grafting, and problems creating a curvilinear shape. We propose a new technique of acute open callus manipulation and fixation (AOCMF), which addresses these challenges.
Methods: A retrospective analysis of all patients with jaw defects who underwent DO and AOCMF between 2006 and 2015 was performed. Clinical and demographic data were recorded and analysed. Representative treated cases were presented.
Results: Fourteen adult patients were treated, seven for maxillary and seven for mandibular defects of mixed etiology. The mean length of distraction was 4.9 cm (range 3–8 cm). AOCMF was performed between the first and third week of the consolidation phase. Average treatment time was 7.6 weeks (range 4–13 weeks). Mean follow-up was 38 months (range 25–76 months). Stable curvilinear bone shape and soft tissue coverage was achieved in all patients except one. Four complications were recorded.
Conclusions: AOCMF following DO is a safe and reliable technique for reconstruction of segmental defects. It represents a useful alternative to free-flap reconstruction in selected patients. When compared with traditional bone transport techniques, it allows a decrease in the number of surgical procedures and in average treatment time.

1. Introduction

The repair of large, three-dimensional, mandibular and maxillary bone defects caused by trauma, infection, cancer, or congenital malformation remains a reconstructive challenge. The restoration of maxillo–mandibular complex integrity improves facial aesthetics and is essential for such functions as speech, mastication, swallowing, and breathing.

Microvascular free flaps remain the gold standard for the reconstruction of large defects (Muñoz Guerra et al., 2003; Chang et al., 2016; Torroni et al., 2015; Gaggl et al., 2012). However, shorter, less invasive reconstructive techniques are an attractive option for high-risk surgical-anesthetic patients due to the morbidity associated with the prolonged operative time and hospitalization associated with free flaps (Torroni et al., 2015; González-Garcia et al., 2008). Donor zone pain and functional limitations remain a problem for young, active patients, particularly when limbs or iliac crest are selected. Intensive care unit facilities for postoperative free flap monitoring and experienced microvascular teams are not available in all centers.

Of particular concern are the problems related to free flap defect adaptation and reconstruction of the delicate intraoral lining. The insufficient vertical height of the fibula free flap, the bulkiness of transferred soft tissue for intraoral lining, and buccal sulcus obliteration are some examples of the problems associated with dental implant rehabilitation (Labbé et al., 2005).

Transport distraction osteogenesis has been proposed as an alternative treatment modality for mandibular and maxillary segmental defects (Cheung et al., 2003; Rachmiel et al., 2013). By means of bifocal or trifocal distraction osteogenesis, new bone is generated between the osteotomies, while the gradual expansion

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of the intraoral soft tissue simultaneously creates functional soft tissue coverage, achieving a true composite reconstruction.

Bone transport (BT) techniques still present some disadvantages, such as a relatively long treatment time, multi-stage treatment, vector control difficulties, and the need for bone-grafting for residual nonunion at the compression focus, and face challenges in creating and maintaining a curvilinear shape in the newly generated bone (Block et al., 1996; Sawaki et al., 1997; Shvyrkov et al., 1999). These disadvantages can all be obviated by performing acute open callus manipulation and fixation (AOCMF) of the transported segments, along with simultaneous device removal.

AOCMF takes place immediately after the activation phase, early in consolidation, thus decreasing treatment time. In contrast to traditional transport distraction, it does not involve placing a reconstruction plate across the defect during the first surgery. This allows unrestricted generation of bone during distraction osteogenesis, avoiding additional bone grafting during the second surgery. Manipulation and fixation of the segments using a premolded or patient-specific implant (PSI) reconstruction plate during second surgery allows the desired shape and symmetry of the reconstructed maxilla or mandible to be achieved and maintained.

We have previously published earlier, preliminary results using this technique (Pereira et al., 2016, 2017). This study reports our augmented clinical experience with 14 patients presenting complex 3D maxillary or mandibular defects, treated with distraction osteogenesis and AOCMF, with an average follow-up of over 3 years.

2. Materials and Methods

2.1. Study design and sample

The study retrospectively reviewed 67 consecutive patients treated by the first author with distraction osteogenesis of the maxillofacial skeleton between 2006 and 2015, following our institutional review board guidelines. Study inclusion criteria were: (1) maxillary or mandibular defects requiring the reconstruction of more than 3 cm of bone and soft tissue coverage; (2) curvilinear reconstruction required; (3) utilization of AOCMF; and (4) more than 2 years of follow-up.

Fourteen patients were included, seven patients with mandibular and seven with maxillary defects. Clinical and management data such as age, sex, diagnosis, location of the defect, previous radiotherapy treatment, total activation length, number and location of devices, time of AOCMF second procedure, total length of hospital stay and treatment, number of operations, additional surgical procedures performed, perioperative complications, and follow-up were recorded and are listed in Table 1. No statistical analysis was performed due to the limited number of patients.

2.2. Surgical technique

All patients required two main surgical procedures under general anesthesia.

The first procedure involved osteotomy and distractor fixation via an intraoral approach for the maxilla and a submandibular approach for the mandible. Segmental osteotomies were performed at each margin of the defect — inverted L in the maxilla and mandibular angle, or vertical in other mandibular locations. Internal devices were placed without any reconstruction plate stabilization of the bone stumps, thus allowing unrestricted movement during distraction osteogenesis for full defect bridging with regenerated bone (Fig. 1, top).

In mandibular cases all the distraction vectors were parallel to the occlusal plane. In maxillary cases the vectors were planned in order to simultaneously obtain closure of the defect and the posterior–anterior advancement needed to achieve correction of the class III. The planning was performed using simple linear vector calculation, as previously published by the author (Pereira et al., 2016).

Table 1
Clinical data for the patients included in the study.

Patient	Age/gender	Etiology	Defect location	Defect size (cm)/Nº of devices	Radiotherapy	Time of AOCMF (weeks)	Total in-hospital stay (days)	Number of surgeries	Additional surgical procedures/dental implants placed in the regenerate (number)	Total treatment time (weeks)	Complications
P1	39/M	Trauma	Maxilla (anterior)	3.5/2	No	1	5	2	None	4	None
P2	16/M	Cleft palate (unilateral)	Maxilla (anterior)	3/2	No	2	4	2	Le Fort I DO	5	None
P3	26/F	Infection	Mandible (anterior)	8/4	No	2	8	3	None	12	None
P4	20/M	Tumor (secondary)	Mandible (angle)	6/1	Yes	1	10	2	Le Fort I DO; orbital PSI; rhinoplasty/dental implants (3)	13	None
P5	42/F	Cleft palate (bilateral)	Maxilla (anterior)	4/2	No	2	4	2	Dental implants (4)	7	Facial cellulitis
P6	26/M	Tumor (immediate)	Maxilla (anterior)	4.5/2	No	3	5	2	None	8	None
P7	52/M	Tumor (secondary)	Mandible (body)	7/2	No	1	5	2	None	8	None
P8	32/M	Tumor (immediate)	Mandible (body)	5/1	No	3	6	3	Costochondral graft	11	Device fracture
P9	41/M	Cleft palate (bilateral)	Maxilla (anterior)	4/2	No	2	4	2	Dental implants (3)	9	Facial cellulitis
P10	22/F	Tumor (immediate)	Mandible (body)	6/2	No	2	6	2	Dental implants (3)	7	Facial cellulitis
P11	62/M	Tumor (secondary)	Mandible (body)	4/2	Yes	2	5	2	None	6	None
P12	36/M	Tumor (secondary)	Mandible (anterior)	7/2	Yes	3	5	2	None	8	Reconstruction plate fracture
P13	18/F	Cleft palate (unilateral)	Maxilla (anterior)	3/2	No	1	3	2	None	4	None
P14	24/M	Developed anomaly	Maxilla (anterior)	3/2	No	1	4	2	None	5	None

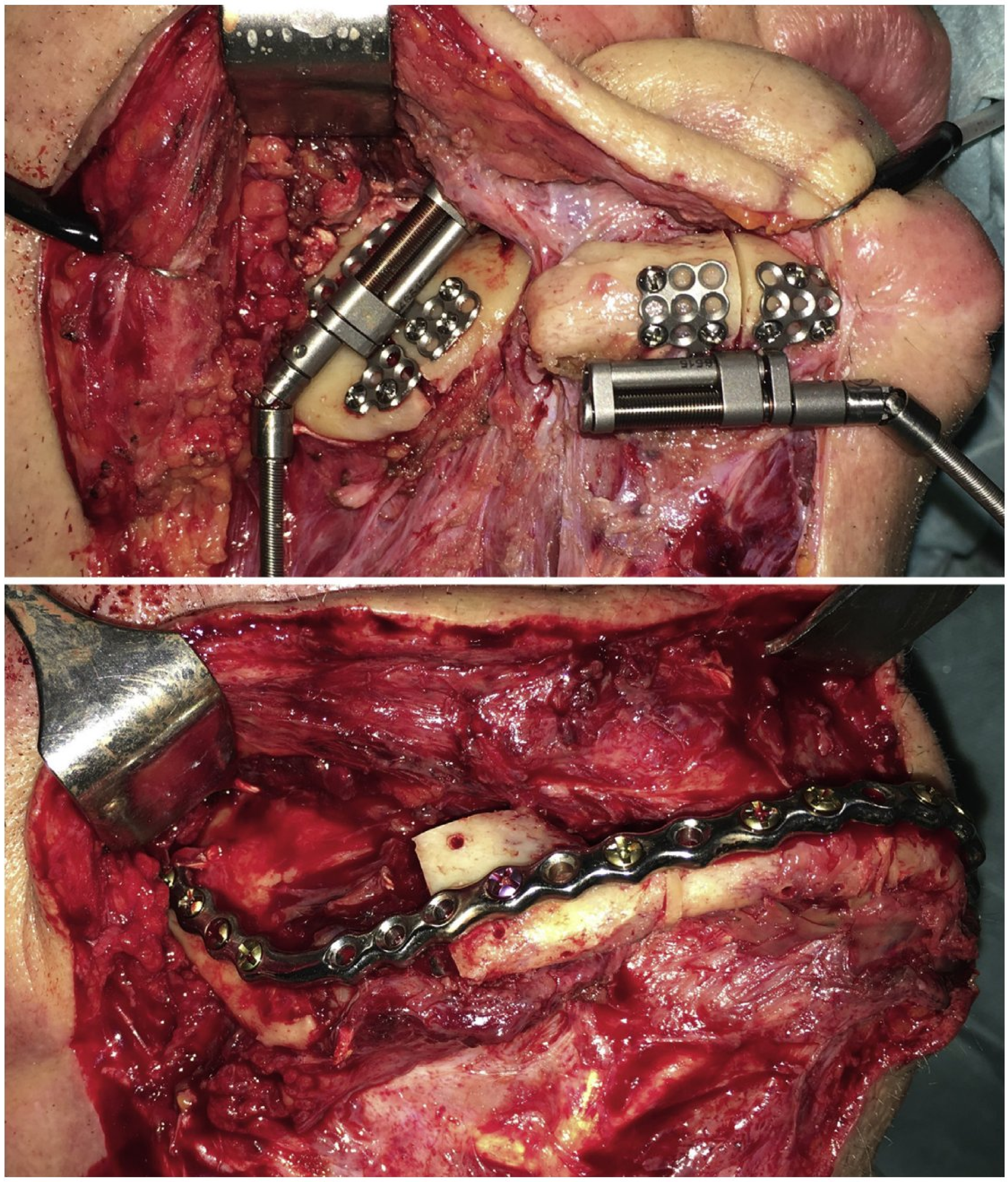

Fig. 1. Trifocal distraction followed by AOCMF of patient #11. (Top) A trifocal distraction system was constructed using two monofocal distractors fixed across the osteotomies without any reconstruction plate stabilization (30 mm mandibular telescoping, KLS-Martin, Tuttlingen, Germany). No attempt was made at this time to redirect the bone stumps. (Bottom) Second operative procedure after the removal of the distractor devices: bone stumps at the docking site have been freshened with the saw, to allow good contact of bleeding bone edges, which were fixed using a PSI reconstruction plate in the ideal shape of the mandibular arch.

All except three patients (P3, P4, and P8) received two devices to achieve trifocal distraction, allowing for a 50% reduction of the distraction phase time. P3 received four devices for a severe deformed micrognathia; P4 was treated with only one device for a mandibular angle and ascending ramus defect, and was the subject of a previous publication (Pereira et al., 2017); P8 received a costochondral graft during the first surgical procedure for reconstruction of the ascending ramus, fixed with one BT device for body and parasymphyseal reconstruction.

After a latency period of 5–7 days, distraction was initiated at a rate of 1 mm/day until the planned distraction length was achieved.

The second operative procedure was performed after the activation phase was completed, but before consolidation occurred. The devices were meticulously removed through the same incisions to avoid disruption of the regenerated tissue. Taking advantage of the soft callus formed during distraction, transported segments and/or bone stumps were manipulated with bone forceps and fixed with plates and screws in the ideal position in order to obtain and maintain adequate shape and symmetry (Fig. 1, bottom).

At the docking site, the opposing bone stumps of the transport segment and receiving bone were freshened with a saw to induce bleeding and achieve good surface contact. This procedure allowed consolidation across the compression focus without the need for bone grafting. Only manipulation and fixation were performed on those cases presenting in-continuity defects (P3, P4, and P14).

PSI or pre-contoured reconstruction plates (using stereolithographic models) were only utilized during the second surgical procedure. These functioned as guides to which the bone segments were adapted and fixed after a 3D manipulation through out-of-plane and/or in-plane regenerate bending.

Additional reconstructive procedures required to address other facial deformities were performed during the second surgery in P4. Four patients (P4, P5, P9, and P10) received dental implants in the regenerated segment 1 year after the second procedure. One cleft patient (P2) required a Le Fort I distraction osteogenesis 1 year later for correction of a class III malocclusion.

3. Results

The patients treated in this study comprised four females and ten males with a mean age of 32.6 years (range 14–62 years). The average length of distraction was 4.9 cm (range 3–8 cm).

Fig. 2. Preoperative (left) and 4-year follow-up (right) images of patient #3, a 26-year-old woman presenting with facial asymmetry, severe mandibular hypoplasia, and SAOS, resulting from osteomyelitis 17 years previously. A four-focus DO of 8 cm was performed followed by AOCMF. During the first operative procedure two 40 mm BC-CMF distractor devices were placed at the mandibular angles, and another two 25 mm BC-CMF distractor devices at the parasymphyseal regions (both Depuy-Synthes, Oberdorf, Switzerland). During the second procedure, AOCMF was performed using two pre-molded reconstruction plates for fixation of the anterior mandibular arch after counterclockwise rotation.

Fig. 3. Occlusal views of same patient in Fig. 2 (patient #3). (Left) Preoperatively the anterior mandibular dental arch presented with a completely horizontal deformation. (Right) After treatment a functional occlusion was obtained.

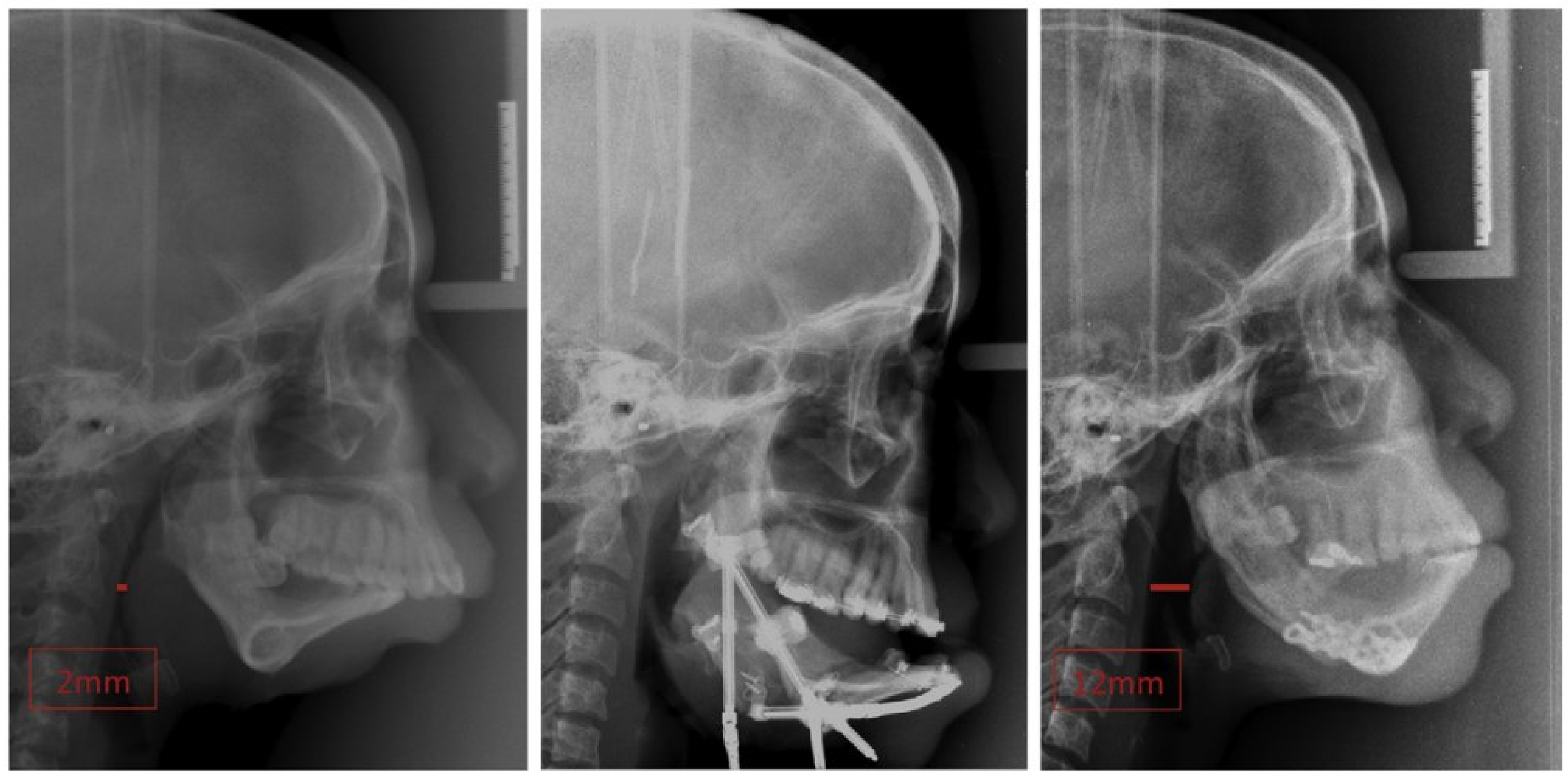

Fig. 4. Lateral cephalograms of the patient in Figs. 2 and 3 (patient #3). (Left) Before surgery the hypoplastic and deformed mandible was associated with a collapsed upper airway 2 mm in diameter. (Middle) After distraction osteogenesis of 8 cm the four devices were supporting the regenerate at the end of the activation phase. (Right) 3-year follow-up after AOCMF of the anterior arch, showing a stable mandibular form and an open upper airway, 12 mm in diameter.

Fig. 5. Preoperative (left) and 5-year follow-up (right) images of patient #5, a 42-year-old woman presenting with bilateral cleft palate, hypoplastic maxilla, and anterior segmental defect with oral-nasal fistula. Trifocal distraction osteogenesis and AOCMF allowed correction of the retrusion of the middle third of the face, along with projection of the upper lip, without any other soft-tissue or mandibular surgery.

Three patients underwent primary reconstruction by performing the first surgical procedure for BT during surgery for tumor excision: two with recurrent ameloblastomas of the mandibular angle (P8 and P10), and one with myxoma of the anterior maxilla (P6). The latter was previously the first-reported immediate reconstruction case involving BT in the maxilla (Pereira et al., 2016). The other eleven patients were all secondary reconstruction cases resulting from mixed etiology: four patients with cleft palate (two of them bilateral); one with a post-traumatic defect of the anterior maxilla; one presenting a severe development anomaly of the maxilla; one with mandibular deformity resulting from osteomyelitis during childhood; and four with defects resulting from tumor excision (three of which had postoperative radiotherapy).

The second surgery for AOCMF was performed between the first and the third week of the consolidation phase. All the regenerated segments were found to be moldable, allowing freehand manipulation of the segments and adaptation to the plates using bone forceps. After removal of the distraction devices, the callus of distraction was observed to be sufficiently stable to maintain the length of generated bone during the time necessary for manipulation and plate fixation, as confirmed by intraoperative measurements (Video 1 demonstrates the mobility of the transported anterior segment of the maxilla after removal of the distractor devices.).

Supplementary video related to this article can be found at https://doi.org/10.1016/j.jcms.2018.11.022

At 1-year follow-up, the main goals of treatment were achieved in all patients: (1) reconstruction of the segmental defect with good bone continuity; (2) stable soft tissue coverage; (3) stable curvilinear shape, allowing for facial symmetry. These outcomes were evaluated by clinical and radiological examination. Although no histological examination was performed, the form and quality of the new bone was evaluated by CT-scan and the continuity of the mineralization was confirmed in at least five 1-mm slices.

The follow-up period ranged from 25 months to 76 months (mean 38 months). The newly generated bone maintained good clinical and radiological stability during the follow-up period in all patients except one (P12). This patient was previously treated with anterior mandibulectomy and radiotherapy for squamous cell carcinoma. Some 25 months after the second operative procedure, the reconstruction plate was found on X-ray to be fractured during a follow-up appointment. Pseudoarthrosis and unstable soft tissue coverage were diagnosed and the patient was treated with an osteocutaneous radial forearm free-flap reconstruction.

Functional occlusion was obtained in all dentate patients after postoperative orthodontics. Dental implant rehabilitation was performed in four patients (P4, P5, P9, and P10). A total of 13 dental implants were placed in the newly generated bone and osseointegration was successfully achieved in all cases, including the patient who had previous radiotherapy (P4) (Pereira et al., 2017).

Complications during treatment were recorded in four cases. Three involved facial cellulitis treated with oral antibiotics in an outpatient setting (P5, P9, and P10). Only one patient required reoperation, due to a fracture of the activation arm of the distraction device 6 days after the beginning of the distraction phase (P8).

Fig. 6. Preoperative 3D CT-scan of the patient in Fig. 5 (patient #5), showing the wide anterior segmental maxillary defect and hypoplastic maxilla.

Fig. 7. Intraoperative images of the patient in Figs. 5 and 6 (patient #5). (Top) During the first operative procedure, two segmental inverted-L osteotomies were performed bilaterally in the margin of the defect and two modified 25 mm maxillary internal distractor devices (both Depuy-Synthes, Oberdorf, Switzerland) were fixed. (Bottom) At the end of the distraction phase, but prior to AOCMF, showing the medial collapse of the transported segments, with scar tissue present in the palate. This was subsequently corrected with AOCMF, using a 2.0 mini-plate for fixation of both transported segments in the midline, after repositioning and debridement of the interposed soft tissues.

The BT device was maintained for internal fixation and another unidirectional distraction device was fixed, allowing the treatment to resume as planned.

In-hospital stay was, on average, 5.3 days (range 3–10 days) and the average total treatment time from distraction osteogenesis surgery to AOCMF surgery was 7.6 weeks (range 4–13 weeks).

Patient 3 is shown in Figs. 2–4 and Video 2 as an example of a mandibular incontinuity defect type treated with in-plane AOCMF. Two segmental maxillary defect patients treated with out-of-plane AOCMF are demonstrated in Figs. 5–9 (P5) and PowerPoint 1 (P9).

Supplementary video related to this article can be found at https://doi.org/10.1016/j.jcms.2018.11.022

4. Discussion

The treatment of large maxillary-mandibular defects is a long-standing challenge. Traditional reconstructive methods with autografts have been successful in achieving reconstruction of segmental defects but are dependent on adequate mucosal and cutaneous coverage, absolute stability, and sufficient vascularization (Bergland et al., 1986). Microvascular transfer of autografts has increased the success rate of the treatment of large defects, but suffers from the need for team expertise, prolonged operative time and hospitalization, and non-anatomical tissue for repairing the unique anatomy of the oral cavity.

Recent advances in tissue engineering techniques, using expanded *in vitro* stem cells or growth factors such as bone morphogenetic protein, combined with recent advances in computer-assisted manufacturing of 3D-printed scaffolds, promises less invasive treatment of facial bone defects (Zamiri et al., 2013; Wang et al., 2016; Vella et al., 2018). Among the limitations of these future approaches is the requirement for adequate soft tissue coverage, the expense, and the lack of consistency in clinical results (Chanchareonsook et al., 2014). In the meantime, distraction osteogenesis remains an alternative approach to bioengineering bone *in vivo*. It offers an *in situ* regenerative technique with consistent clinical results, and is capable of simultaneous bone and soft tissue reconstruction. Through using distraction, new bone is formed in the bone gap, as previously observed by Constantino et al., with the diameter of the newly formed bone similar to that of the transport disc (Costantino et al., 1990). Moreover, distraction osteogenesis allows the simultaneous reconstruction of surrounding soft tissues and good-quality attached gingiva. These factors may facilitate the subsequent placement of osseointegrated dental implants and dental rehabilitation (Labbé et al., 2005; Cheung et al., 2003; Molina and Monasterio, 1995; Pingarrón-Martín et al., 2015).

Previous problems associated with BT treatment of maxillary-mandibular defects were the resistance created by interposed soft tissues, vector planning and control, the need for docking site bone-grafting to achieve good consolidation, and relatively long treatment times, primarily due to multi-staged procedures and the prolonged consolidation phases (Pereira et al., 2017). Additional problems have arisen when curvilinear segments need to be reconstructed, since even curvilinear devices or plate-guided distraction devices create straight reconstructed segments between the start and end points after retraction and consolidation of the regenerate (González-Garcia et al., 2008; Whitesides et al., 2005; Herford, 2004).

Other authors have proposed closed callus molding to avoid vector-related problems, utilizing multi-vector external devices or orthodontic elastics (Hoffmeister and Wolff, 1998; McCarthy et al., 2003; Kunz et al., 2000). Hoffmeister was the first to propose this closed method of manipulation to avoid open bite in patients on whom mandibular distraction has been performed, introducing the floating bone concept (Hoffmeister and Wolff, 1998). The experimental studies by Kunz showed that closed callus molding can be safely performed between the first and third weeks of the consolidation phase (Kunz et al., 2005a, 2005b). Finally, Wei et al. have shown that molding can be successfully performed 8 weeks into the consolidation phase (Wei et al., 2007).

In this study of 14 consecutive patients, we demonstrate a more effective approach to callus molding, known as acute open callus manipulation and fixation, that avoids most of the problems previously attributed to BT. In the AOCMF technique, distraction osteogenesis without a plate or external fixation of the defect allows unrestricted generation of sufficient bone to fill the three-dimensional space. Post-activation open callus molding and fixation, along with device removal early in the consolidation phase, improves the control of shape and decreases the total treatment time.

The need for bone-grafting at the docking site is avoided, because the length of distraction regenerate can be planned to fit the entire curvilinear defect or even to achieve some overlapping of transported discs. The molding during the second procedure allows for accurate positioning and fixation of the generated bone, so the procedure is not completely dependent on the planned vector during distraction. The preformed plate fixation of the manipulated segments also keeps the desired shape of the newly formed bone, even in curvilinear segments, supports surrounding soft tissues,

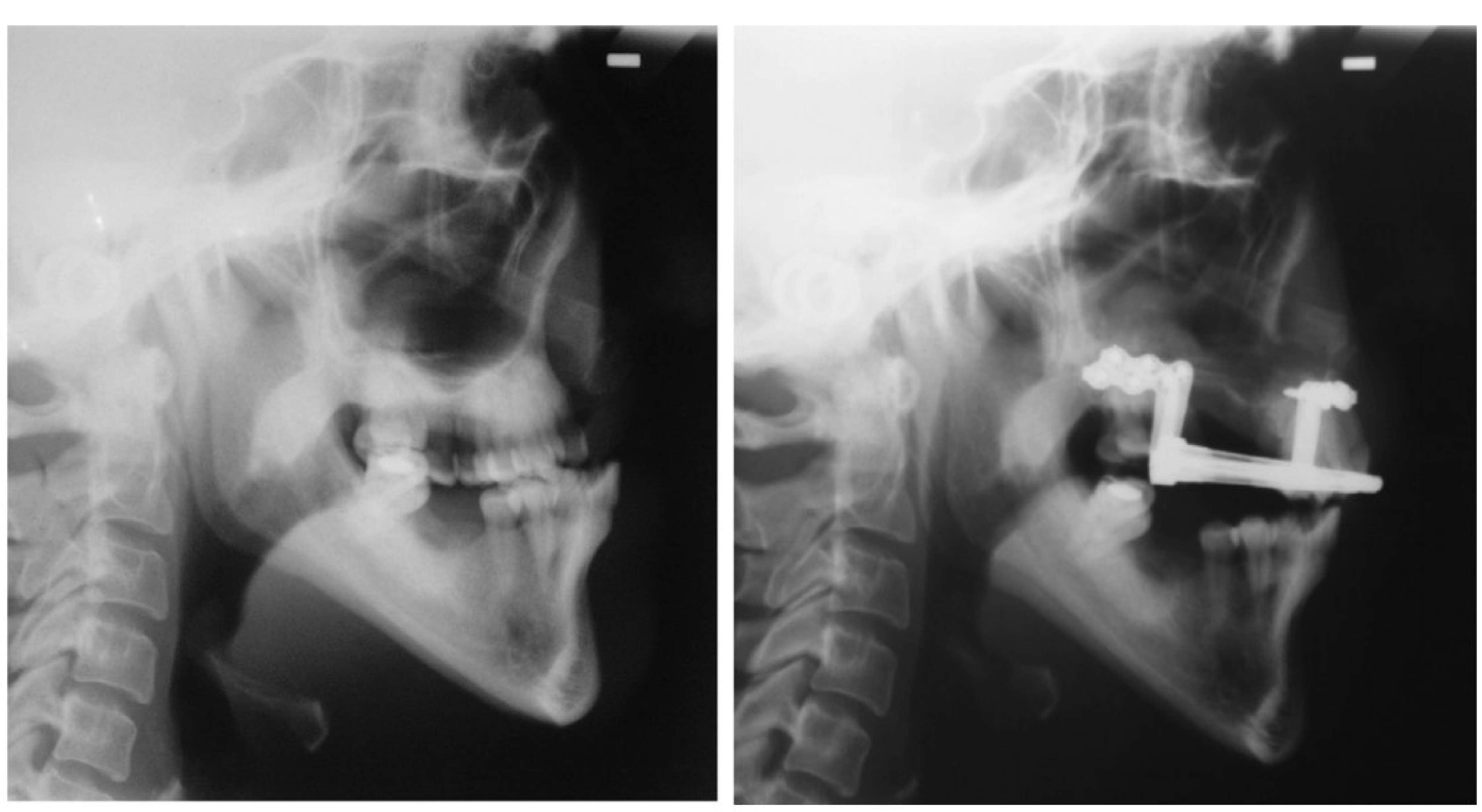

Fig. 8. Lateral cephalograms of the patient in Figs. 5–7 (patient #5): (left) preoperative and (right) post-distraction phase, showing both distractors fully open, maintaining a parallel position, with transported segments in a more anterior and inferior position.

Fig. 9. Intraoral views of the patient in Figs. 5–8 (patient #5). (Top) Initially there was a segmental anterior defect, with wide oral-nasal fistula. (Middle) 2 years after the two-stage surgery the segmental defect and fistula remained closed. (Bottom) Functional occlusion was obtained after orthodontics and the placement of four dental implants in the posterior newly regenerated bone.

and avoids compression and loss of reconstructive length during the consolidation phase. The total length of treatment is shortened because the consolidation phase with distraction devices in place is eliminated, and the total number of surgical procedures is reduced to only two.

All patients in this series were treated with internal devices, which offer several advantages in comparison with external devices: (1) better stability; (2) a lower incidence of infection and dehiscence; (3) a lower incidence of unaesthetic scarring; and (4) greater comfort and subsequent tolerance by the patients (Whitesides et al., 2005; Takenobu et al., 2007; Rubio-Bueno et al., 2005). These advantages are particularly important for adult patients, contributing to a reduction in duration of social stigmas and time away from work. For pediatric patients, AOCMF can also be an option if considering fixation with resorbable plates or with titanium plates for later removal, in order to avoid interference with potential bone growth.

In recent years, the availability of PSI reconstruction plates has simplified the planning of the second procedure, allowing better simulation of the missing bone, predicting the movements needed for the manipulation of the segments, and reducing surgical time. Most of the cases in this series were planned with stereolithographic models for plate pre-molding, which is a good alternative to the more expensive PSI plates.

In benign tumor cases where the reconstruction can be planned in advance, the first step of this technique (osteotomy and placement of devices) can be performed simultaneously with tumor excision. This was safely done both in the mandible (P8 and P10) and in the maxilla (P6), avoiding one additional surgery.

In malignant tumor cases, radiotherapy introduces an element of unpredictability regarding the outcome of the distraction reconstruction, as with other reconstructive techniques (Kashiwa et al., 2008). Its impact on bone and soft tissues should be individually evaluated, and a delay of at least 2 years is recommended before performing distraction osteogenesis. Three of the treated patients in this series (P4, P11, and P12) had previous radiotherapy 18, 3, and 5 years before distraction osteogenesis, respectively. Only one (P12) failed, 25 months after the second operative procedure as described above, while the other two patients remained stable after more than 1 and 4 years of follow-up, respectively.

All patients in this series achieved stable curvilinear reconstructed segments, independently of the reconstructed region (seven in the anterior maxilla, one in the mandibular angle and six in the anterior mandibular arch/parasymphyseal regions).

Manipulation of the bone segments was performed through adaptation to the plates, achieving real 3D movements, which would not have been possible with distraction osteogenesis alone. The regenerate was molded in-plane (P3, P4, and P14) and out-of-plane (all the others) without compromising the final result.

5. Conclusion

This series of patients illustrates the author's clinical experience with a new technique, which effectively reconstructed curvilinear segmental defects with only two surgical procedures by eliminating the consolidation phase and utilizing the second surgical procedure for distraction device removal, open manipulation, and fixation of segments in the ideal position.

AOCMF is a complementary technique for complex 3D monofocal distraction osteogenesis or BT reconstructive cases. Further clinical experience at other centers would be able to demonstrate its efficacy, and experimental animal studies would be beneficial in better defining the possible degree of molding and the impact of timing on bone healing.

Based on the authors' favorable experience, distraction osteogenesis followed by early AOCMF has replaced bone grafts and bone free-flaps as the first-choice surgery to be considered in patients presenting critical segmental defects in the maxilla and mandible.

Authorship contributions

Dr Alberto Pereira reviewed and summarized the data, and wrote the manuscript. Dr André Pereira collected the data, collected and edited images and supplemental digital content, and reviewed the manuscript.

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Conflicts of interest

The authors have nothing to disclose.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jcms.2018.11.022.

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