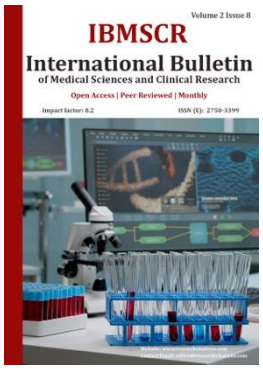

TAILORING TOTAL JOINT REPLACEMENT FOR PATIENT-SPECIFIC CONGENITAL MANDIBULAR HYPOPLASIA TO ADDRESS COMPLEX CRANIOFACIAL ANOMALIES

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Introduction

Mandibular hypoplasia, a significant anomaly of the mandible, encompasses congenital, developmental, or acquired deformities [1]. Developmental mandibular hypoplasia denotes mandibular underdevelopment of unknown etiology, often associated with Class II malocclusion [1]. Acquired mandibular hypoplasia arises from oncological defects, radiation injury, trauma, or hemifacial atrophy [2, 3]. Congenital mandibular hypoplasia (CMH) primarily stems from first and second branchial arch maldevelopment, occurring either unilaterally or bilaterally [1]. A classification framework proposed by Singh and Bartlett further delineates CMH into malformational and deformational groups, encompassing both syndromic and non-syndromic patients (Fig. 1) [1]. CMH presents as a heterogeneous spectrum of rare disorders with diverse clinical manifestations, leading to inconsistent nomenclature in medical literature. Most CMH cases are syndromic, with over 60 associated syndromes, including Goldenhar's syndrome, Treacher Collins syndrome, Nager's syndrome, and Pierre Robin sequence [3, 4, 5, 6]. Notably, around 6.8% of CMH cases occur without known syndromes [1]. Goldenhar's syndrome, a component of the oculo-auriculo-vertebral (OAV) spectrum, shares features with hemifacial microsomia, affecting the eyes, ears, and spine. While often unilateral, Goldenhar's syndrome can be bilateral in 10–30% of cases, though usually with a dominant side. Treacher Collins syndrome, part of the mandibulofacial dysostosis group, ranks among the most prevalent syndromes associated with mandibular hypoplasia [7].

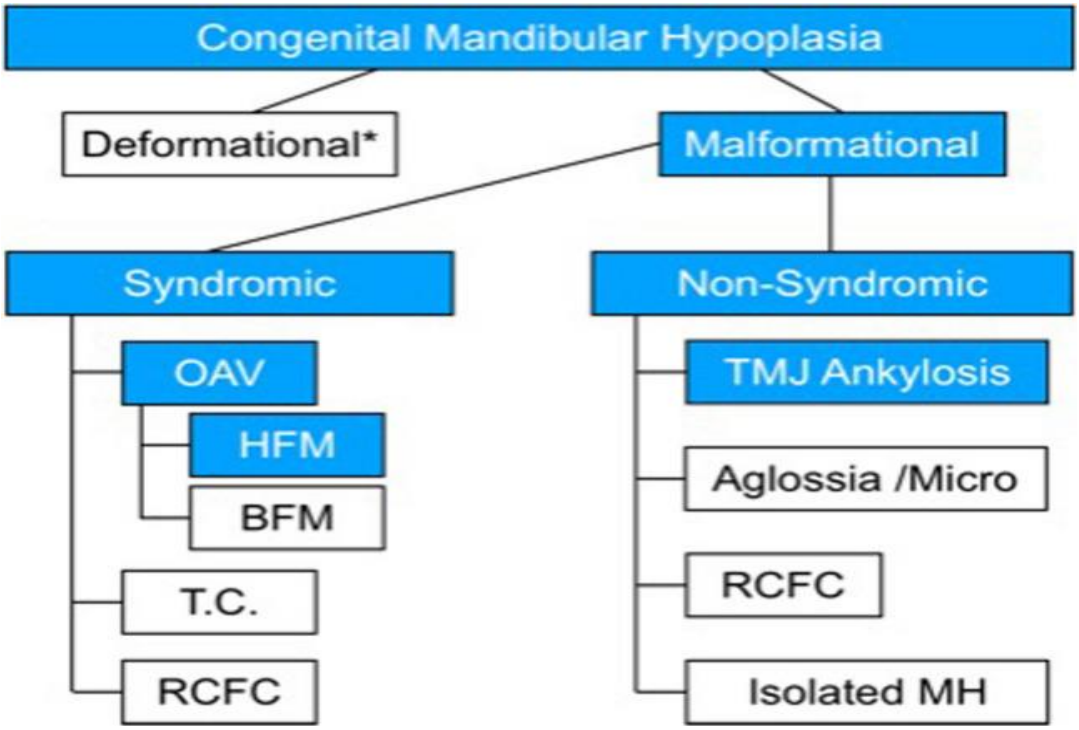

Fig. 1 Modified according to Davinder J. Singh, MD, Scott P. Bartlett, MD: Congenital Mandibular Hypoplasia: Analysis And Classification; THE JOURNAL OF CRANIOFACIAL SURGERY/VOLUME 16, NUMBER 2 March 2005; MH, mandibular hypoplasia; OAV, oculo-auriculo-vertebral; TMJ, temporomandibular joint; HFM, hemifacial macrosomia; BFM, bilateral facial macrosomia; T.C., Treacher Collins; RCFC, rare craniofacial clefts, *Deformational MH can also be subdivided into a syndromic and non-syndromic group, to which the Pierre Robin Sequence can be assigned to according to Singh and Bartlett et al.

Clinical Challenges Congenital mandibular hypoplasia (CMH) typically manifests bilaterally, although the underlying deformity may present unilaterally. Depending on the associated syndrome, the midface and cranium may be primarily affected or undergo secondary compensatory growth changes on the unaffected side. In cases of bilateral hypoplasia, particularly severe instances, there may be a symmetrical impact on the patient's airways necessitating interventions such as endotracheal intubation or tracheostomy [8]. Unilateral mandibular hypoplasia often coincides with midface and cranium involvement [3, 9, 10]. Distinguishing between symmetrical and asymmetrical deformities significantly influences treatment decisions [11]. Hemifacial CMH severity is graded with a focus on the ramus-condyle unit, employing three-dimensional (3D) analysis to characterize mandibular phenotypes [12–14].

The primary deformity or the secondary effects of isolated unilateral mandibular hypoplasia on adjacent anatomical structures contribute to complex asymmetric deformities, often leading to compensatory dental issues. In addition to the underdeveloped hard tissues, including the mandible, temporomandibular joint (TMJ), midface, and cranium, the soft tissue envelope is further compromised, characterized by scarring and poor vascularization. Addressing congenital soft tissue deficiency presents a significant clinical challenge crucial for achieving predictable long-term success.

Treatment Options The management of congenital mandibular hypoplasia (CMH) varies among institutions and healthcare systems, heavily contingent upon the severity of the deformity and associated clinical manifestations [15]. Treatment strategies universally strive

for achieving a symmetrical, aesthetically pleasing facial profile with stable occlusion and optimal temporomandibular joint (TMJ) function. Extensively researched approaches for patients with oculo-auriculo-vertebral (OAV) syndrome and Treacher Collins syndrome include craniofacial distraction, orthognathic surgery in conjunction with orthodontic intervention, as well as autologous (bone) grafts or microvascular transplants [16–20]. Recent findings suggest that distraction alone may not consistently resolve issues, often necessitating subsequent orthognathic surgery, genioplasty, or bone grafting procedures [16, 18, 19, 21]. Nonetheless, long-term satisfaction remains elusive due to relapse post-distraction and unpredictable resorption or growth of costochondral grafts [3, 18]. The application of mandibular distraction in children lacking respiratory or feeding challenges remains contentious regarding its impact on long-term mandibular growth and reduction of surgical interventions [20]. Microsurgical reconstructions are typically reserved for children with extensive, intricate mandibular defects when conventional options are exhausted [22]. Present treatment modalities primarily address skeletal abnormalities, neglecting soft tissue deficiencies [15].

This study aimed to illustrate the viability of alloplastic reconstruction utilizing patient-specific total joint replacement (TJR) for TMJ in both adult and juvenile CMH patients. The primary objective was to assess the long-term stability of the reconstruction, aiming for zero implant failures. Secondary outcomes included evaluating TMJ function, pain management, and range of jaw movements achieved during the surgical procedure.

Keywords: Congenital mandibular hypoplasia, Mandibular reconstruction, Temporomandibular joint, TMJ, Total joint replacement, TJR

Materials and Methods

A review of the patient database at the Department of Oral and Maxillofacial Surgery, Hannover Medical School, Hannover, Germany, was conducted to identify individuals with congenital mandibular hypoplasia (CMH) who underwent total joint replacement (TJR) of the temporomandibular joint (TMJ). Patient records were examined for details regarding clinical presentation, surgical procedures, etiology, genetic diagnosis, and classification [23, 24]. Radiographic images and data from virtual surgical planning (VSP) were collected and analyzed.

Ethical approval for this study was obtained from the local ethics review committee at Hannover Medical School (study no.: 9275_BO_K_2020).

TMJ Prosthesis and Virtual Surgical Planning Patient-specific TMJ prostheses were sourced from Zimmer Biomet (Jacksonville, Florida, USA). As previously outlined, during virtual surgical planning (VSP), the prostheses were customized with functional design elements. These included incorporating an anterior suture hole in both the mandibular and fossa components to prevent condylar sagging, as well as posterior flanges on the mandibular component to ensure proper alignment [25]. In one case, an extended mandibular component was necessary due to bony reconstruction resorption, resulting in a hemi-mandibular segmental defect on the right side (Figures 2A, 3A). Another patient required an extended fossa component with a titanium base plate due to complete aplasia of the zygomatic arch and glenoid fossa (Figures 2B, 3B). The fossa component was constructed from ultra-high-molecular-weight polyethylene, while the mandibular components were fabricated from titanium instead of cobalt-chrome-molybdenum.

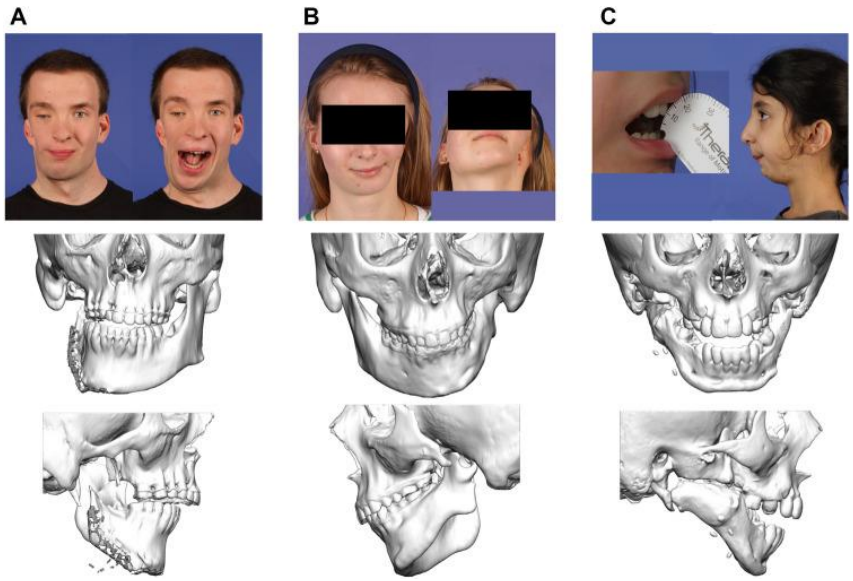

Fig. 2 Case 1–3 preoperatively, photography and 3D-rendering of the skull and mandible. Showing each's primary deformity A Case 1, a 20-year-old man with Goldenhar syndrome. Pruzansky III, O2 M3 E2 N1 S2, previous autologous reconstruction with fibular free flap. B Case 2, 22-year-old women with Goldenhar syndrome. Pruzansky IIb, O0 M2b E3 N0 S3, previous mandibular distraction. C Case 3, 9-year-old girl, with bilateral mandibular hypoplasia, MIO reduced to 10 mm, severe soft tissue deficiency, previous surgeries: costochondral graft, mandibular distraction, interpositional gap arthroplasty

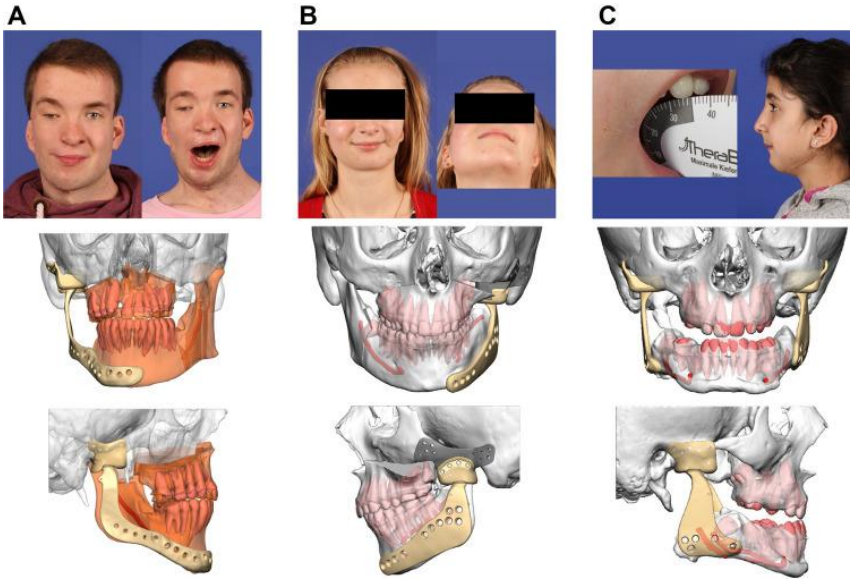

Fig. 3Case 1–3 postoperatively, photography and virtual surgical planning with TMJ implants. A Case 1, unilateral TJR on the right side with extended mandibular component due to mandibular defect, with additional LeFort I osteotomy and contralateral SSO (sagittal split osteotomy). Dentition and inferior alveolar nerve visualized. B Case 2, unilateral TJR on the left side with extended fossa component, due to complete aplasia of the zygomatic arch. Additional LeFort I osteotomy and contralateral SSO. Dentition and inferior alveolar nerve visualized. C Case 3, bilateral TJR with anterior movement of the mandible, class I dentition with head bite planned in anticipation of maxillary growth. Dentition and inferior alveolar nerve visualized

Intraoperative Real-Time Navigation and Intraoperative 3D Imaging

Our research team has previously showcased the advantages of utilizing intraoperative real-time navigation and 3D imaging for the intricate reconstruction of the temporomandibular joint (TMJ) [25, 26]. As outlined previously, initial planning computed tomography (CT) datasets served as the foundation for navigation, with patient registration facilitated through the intermaxillary navigational splint technique. Patient-specific prostheses' STL files were integrated into the 3D planning platform (Brainlab Elements®, Brainlab, Munich, Germany). Utilizing the Brainlab trajectorial planning feature, drilling vectors and lengths for fixing the fossa component were virtually determined. Navigation guided the dissection, resection of the medial skull base, drilling procedures, and verification of final implant positioning [25, 26]. Following the placement of individual components, intraoperative 3D cone-beam computed tomography (CBCT) was conducted. This acquired dataset was fused with preoperative virtual surgical planning (VPS) intraoperatively to assess the accuracy of the reconstruction.

3D-Image Analysis Consistent with prior methodology, preoperative, postoperative, and follow-up 3D images were merged using BrainLab Elements. The STL files of the prostheses, including the fossa and mandibular components, were provided by the manufacturer (Zimmer Biomet, Jacksonville, Florida, USA) and integrated into the initial planning CT dataset (Fig. 4). The positions of the components post-surgery were compared with intraoperative and follow-up 3D images. Additionally, measurements of mandibular and maxillary movements achieved during surgery were recorded in the postoperative and follow-up 3D images (Fig. 4B, C).

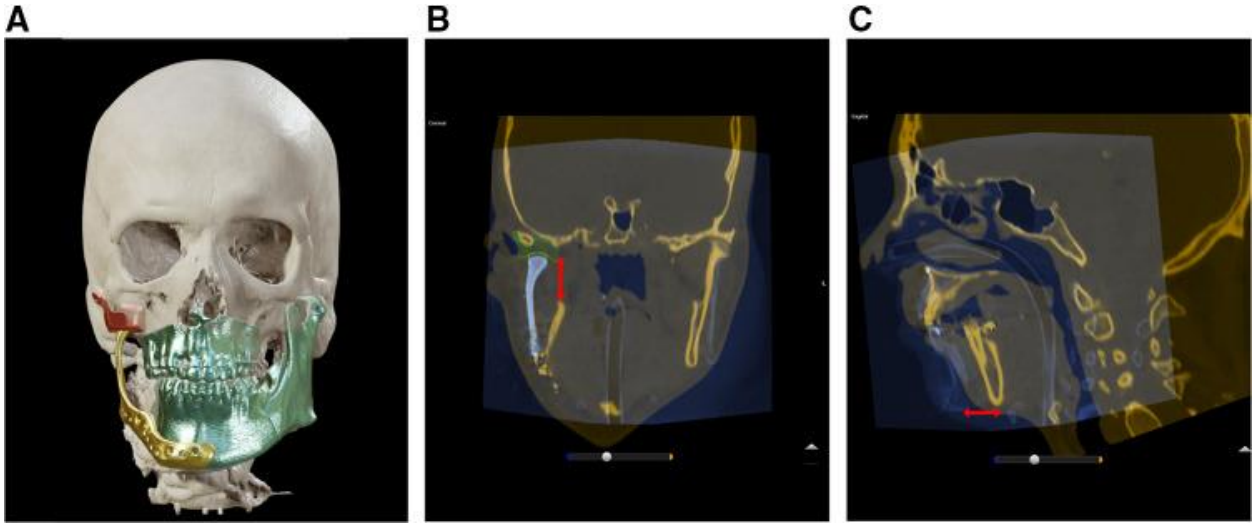

Fig. 4

Case 1 A 3D-rendering (Brainlab® Elements, Brainlab, Munich, Germany) of preoperative CT-scan with TJR fossa (red) and mandible (gold) component. Simulated movements of the maxilla and mandible body are shown in green, with contralateral sagittal split osteotomy. B Fusion of preoperative (amber) and postoperative (blue) CT or CBCT scan, coronal orientation. Planned positions of TJR fossa (green) and mandible (yellow) component are shown and match perfectly to achieved (blue) position. Red arrow indicates gained height of mandibular ramus (20.2 mm). C Fusion of preoperative (amber) and postoperative (blue) CT or CBCT scan, sagittal orientation. Red arrow indicates sagittal anterior movement of the mandible/pogonion (16.4 mm)

Retrospective Assessment of Postoperative Follow-Up Appointments

Following our department's established protocol, patients undergoing total joint replacement (TJR) typically received follow-up assessments at 1, 3, 6, and 12 months post-surgery. After the initial year, subsequent follow-ups were scheduled annually. These standard visits consisted of both radiological and clinical evaluations. Radiological assessments encompassed panoramic radiography or cone-beam computed tomography (CBCT) imaging. Clinical examinations adhered to standard-of-care procedures, focusing on monitoring mandibular movement range, facial nerve functionality, pain levels, and occlusal status.

Table 1
Patients

	Case		
	1	**2**	**3**
Gender	Male	Female	Female
Age at surgery	20	22	9
Congenital mandibular hypoplasia (CMH)	Syndromic	Syndromic	Non-syndromic
Dominant side	R	L	Bilateral
Type of syndrome	Goldenhar	Goldenhar	–
Pruzansky classification	III	IIb	–
OMENS + Classification	O_2 M_3 E_2 N_1 S_2	O_0 M_{2b} E_3 N_0 S_3	Severe soft tissue deficiency
Additional surgery	LeFort 1 & SSO	LeFort 1 & SSO	–
Preop. orthodontic treatment	+	+	
Postop. orthodontic treatment	+	+	+
Previous surgeries	Fibula free flap	Unilateral mandibular distraction	CCG, bilateral mandibular distraction, IGA

OMENS+: O, orbital distortion; M, mandibular hypoplasia; E, ear anomaly; N, nerve involvement; S, soft tissue deficiency; SSO, sagittal split osteotomy; CCG, costochondral graft; IGA, interpositional gap arthroplasty (fat)

Measurement of Postoperative Movements

The Brainlab Elements 3D planning platform (Brainlab, Munich, Germany) was utilized to assess surgically achieved movements of the maxilla and mandible (Fig. 3, Table 2). The most notable movements, ranging from 16.4 to 20.1 mm, were observed in the sagittal projection of the mandible. TJR resulted in vertical ramus height increases ranging from 13.4 to 24.4 mm. In the instances of Goldenhar's syndrome, occlusal cant was effectively reduced and aligned

with the horizontal plane (Table 2). Notably, condylar sagging of the mandibular component was observed, with measurements ranging from 0.1 to 10.4 mm.

Table 2

Surgical movements

	Case		
	1	**2**	**3**
Occlusal cant preop [°]	18.2	7.1	3
Occlusal cant postop [°]	9.3	3.7	3
Upper jaw sagittal 11 [mm]	4.9	3.1	0
Pogonion sagittal [mm]	16.4	18.8	20.1
Pogonion lateral [mm]	9.2	24	2.6
Vertical ramus height [mm]	20.2	13.4	20.7
Vertical ramus height 2nd side [mm]			24.4
Condylar sagging [mm]	4.8	10.4	0.1/5.4

Follow-up

Over the follow-up period, which ranged from 24 to 42 months for the three patients, all prostheses remained functional during the latest assessment. There were no instances requiring revision surgeries, and no material failures were detected in any components of the prosthesis. Importantly, the planned positions of the maxilla and mandible, as determined virtually, showed no signs of instability or relapse throughout the observation period. This stability extended to occlusion as well (see Fig. 3). Notably, there were no long-term complications such as permanent facial nerve palsy, chronic infections, or persistent pain or discomfort, as outlined in Table 3. Additionally, the maximal interincisal opening remained consistent, ranging from 21 to 40 mm across all follow-up visits. All patients were able to maintain a full diet throughout the duration of the follow-up.

Table 3

Adverse events

	Case		
	1	**2**	**3**
Complications			
Facial nerve palsy			
Transient (< 6 month)			
Frontal branch	+	+	+
Buccal branch		+	
Marginal branch		+	
Permanent (> 6 month)	–	–	–
Others (SSI*, PJI**, material failure, scars, allergies, discomfort, salivary	–	–	Keloid

	Case		
	1	**2**	**3**
fistula)			
TMJ function & pain			
TMJ Pain [VAS]	0	0	1
MIO [mm]	21	34	40
Mediotrusion (TJR side) [mm]	1	2	0
Protrusion [mm]	3	2	2

MIO maximal interincisal opening, *TMJ* temporomandibular joint, *TJR* total joint replacement
*Surgical site infection
**Prosthetic joint infection

Discussion

In this study, we utilized alloplastic temporomandibular joint replacement (TJR) to reconstruct congenital mandibular deformities in growing patients with craniofacial microsomia (CMH). Our results demonstrated mandibular movement ranging from 16.4 to 20.1 mm in the sagittal direction. Throughout the follow-up period of 24 to 42 months, no long-term complications were observed. At the last follow-up, the maximal interincisal opening reached 31.67 ± 7.93 mm, with all implants functioning effectively.

The utilization of alloplastic TJR for congenital mandibular deformities is uncommon, with only a handful of case reports focusing primarily on non-growing patients. Treatment approaches with alloplastic TJR vary significantly across countries and healthcare systems, particularly between adults and juvenile patients. However, its adoption has increased globally with the introduction of virtual surgical planning (VSP) and computer-aided design/computer-aided manufacturing (CAD/CAM) techniques, facilitating the customization of prostheses to individual patients. Patient-specific prostheses offer not only precise anatomical fit but also the integration of virtually planned mandibular movements, often in conjunction with conventional or bimaxillary orthognathic surgery. In cases of congenital temporomandibular joint (TMJ) deformities where a reliable TMJ is lacking, TJR serves as an extension of orthognathic surgery to address severe TMJ deformities.

Our study highlights the feasibility of combining patient-matched TJR with orthognathic surgery for the treatment of CMH, even in multiply pretreated growing patients. Medium-term follow-up revealed satisfactory TMJ function, achieving corrected and symmetrized stable skeletal and occlusal outcomes that were unattainable with previous autologous reconstruction or distraction osteogenesis. Additionally, TJR facilitates substantial sagittal mandibular movements without skeletal relapse and can be utilized to augment vertical ramus height and mask lost facial prominences, such as the mandibular angle.

Reevaluation of Distraction Osteogenesis and Costochondral Grafting

A common misconception surrounds the use of distraction osteogenesis and costochondral grafting in cases of craniofacial microsomia (CMH), presuming that deficient bone should be replenished solely with distraction or bone grafts to correct deformities. However, both distraction and bone grafting, including costochondral grafts, focus solely on rectifying bony

deficiencies and fail to establish a stable soft tissue envelope capable of hyperplasia, which is crucial for significant improvement. Despite temporary stretching of the soft tissue envelope following grafting or distraction, long-term deficiency and scarring typically lead to its retraction, resulting in relapse of distraction and resorption of grafts. As a result, the current options are limited to either employing rigid, non-resorbable materials capable of withstanding soft tissue retraction to maintain surgical outcomes long-term or enhancing the soft tissue envelope before or concurrently with grafting or distraction procedures.

Surgical Risks

The array of potential complications associated with costochondral grafts is extensive. Apart from the risk of inducing pneumothorax, the placement of the graft necessitates positioning it in a nonexistent or rudimentary glenoid fossae and attaching it to a rudimentary or severely malformed ramus, often in areas characterized by scarring, poor vascularization, and deficient soft tissue envelopes, particularly in severe cases of hemifacial macrosomia. Some authors have highlighted the challenge of orienting the rib graft during surgery, leading to potential lateral or superior displacement postoperatively. Moreover, costochondral grafts have demonstrated unpredictable growth patterns and susceptibility to fracture at the costochondral joint. Additionally, the risk of graft infection, resorption, pain, relapse, and facial nerve damage cannot be ignored. Furthermore, the likelihood of temporary or permanent facial nerve palsy remains significant in cases involving complex congenital deformities, extensive ankylosis, and multiple operated joints, irrespective of the implanted materials.

Alloplastic Total Joint Replacement

While alloplastic temporomandibular joint replacement (TJR) does not enhance the quantity or quality of deficient soft tissues, the prosthesis offers sufficient rigidity to maintain the stability of a stretched soft tissue envelope. Several case reports documenting TJR in congenital deformities have shown promising outcomes. The surgical risks associated with TJR are comparable to those of autologous procedures or distraction, as similar surgical approaches are employed. Unlike rib grafts, TJR carries no risk of donor-site morbidity, and there are no concerns regarding graft loss or resorption. Nonetheless, alloplastic materials can still be prone to infection, and treating periprosthetic joint infections (PJIs) presents challenges. Allergic reactions to implant materials, such as cobalt, chromium, molybdenum, nickel, and polyethylene, are also possible. Additionally, a manufacturing period of 8–12 weeks is required for the production of the prosthesis.

Impact on Skeletal Growth and Facial Asymmetry

Alloplastic materials lack inherent growth potential; however, they offer predictable short- and long-term clinical outcomes. In contrast, costochondral grafts possess inherent growth potential but exhibit unpredictability. Studies on long-term mandibular growth in children who underwent reconstruction with costochondral grafts revealed excessive growth on the treated side in 54% of cases. Research investigating mandibular growth post-costochondral grafting corroborates previous findings, indicating the graft's inability to adapt to the growth velocity of its new environment. Moreover, negligible mandibular growth can be anticipated on the affected side in patients with craniofacial microsomia (CMH), particularly those classified as Pruzansky III, where the temporomandibular joint (TMJ) is absent.

In our study, we observed that maxillary growth in a 9-year-old female, who experienced ankylosis due to failed costochondral grafts and subsequent relapse following distraction and

conventional interpositional gap arthroplasty (case No. 2), remained unaffected by bilateral temporomandibular joint replacement (TJR) (see Fig. 5). LG Mercuri suggests that these patients may benefit more from undergoing alloplastic TMJ TJR, acknowledging that revision and/or replacement surgery may be necessary in the future depending on growth, rather than persisting with autogenous tissues prone to continued failures, which would likely necessitate further surgical interventions down the line.

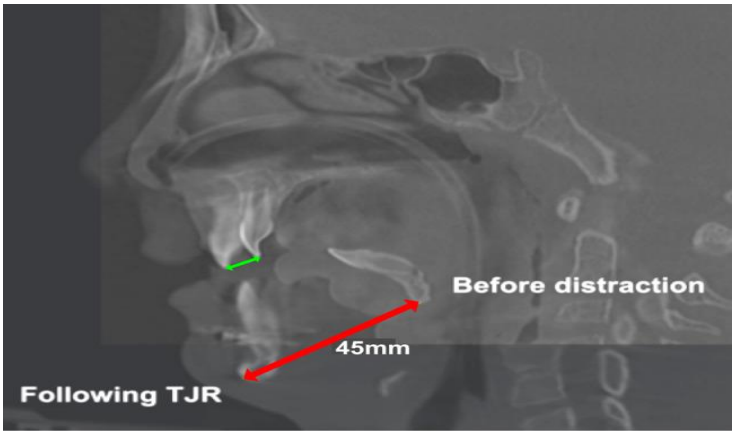

Figure 5 illustrates Case 3, showcasing the fusion of the initial/pre-distraction CBCT-scan (prior to temporomandibular joint replacement - TJR) with the postoperative/post-TJR CBCT-scan. The patient presented with severe bilateral mandibular hypoplasia, necessitating a permanent tracheotomy and resulting in an inability to eat. The red arrow highlights a substantial mandibular movement of 45 mm between the initial situation and the situation after TJR. Additionally, there was a movement of 20.1 mm between the post-distraction and post-TJR situations (refer to Table 2). The green arrow denotes observed maxillary growth between the two CBCT scans.

The long-term outcomes of temporomandibular joint replacement (TJR) in patients with craniofacial microsomia (CMH) hold promise. Existing literature demonstrates a success rate exceeding 90% after 20 years of TJR in general. Additionally, the need for prosthesis exchange due to material wear is minimal, as the replaced TMJ is considered a non-load-bearing joint, reducing the likelihood of friction wear during functional use. Nevertheless, these assertions necessitate validation through long-term follow-up studies involving both patients and materials specific to CMH cases.

Given the rarity of CMH, our study is constrained by its small sample size. Future studies must expand both the number of CMH patients treated using our described technique and the duration of follow-up periods to provide more comprehensive insights.

Conclusion

For specific cases of craniofacial microsomia (CMH), including those with a history of multiple prior treatments, the combination of temporomandibular joint replacement (TJR) and orthognathic surgery offers a reliable and medium-term stable treatment alternative, even in patients who are still growing. Moving forward, it is imperative to thoroughly assess distraction osteogenesis and autologous grafting procedures on a case-by-case basis, especially for individuals exhibiting severe soft tissue deficiency (OMENS 2-3).

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