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ORIGINAL ARTICLE

3D printed customized facemask for early treatment of Class III malocclusion: a two-center case series feasibility study

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ABSTRACT

BACKGROUND: This prospective two-center case series feasibility study aimed to investigate the potential of a novel maxillary protraction facemask customized to the patients' anatomy recorded with 3D face scanning and then produced by digital design and additive manufacturing.

METHODS: Ten subjects (5 females and 5 males, average age 7.7±1.0 years) with Class III malocclusion were treated with a rapid maxillary expander (RME) and a Petit-type facemask (FM), whose components were digitally designed on a 3D scan of the patient's face. Subjects' face scans were obtained either with a tablet or with face scanner. FM components were modelled with a 3D software. The pads were 3D printed in biocompatible resin, and the bar was printed in stainless steel. A questionnaire investigating the patients' experience was filled in after the first week of treatment and after 3, 6, and 9 months.

RESULTS: The customized FM showed an excellent adaptation to the anatomy of the face. No severe complications were reported during the 9 months of appliance wearing. Some reversible episodes of skin irritation were reported below the pads, mainly in the chin area. The reported time wearing ranged between 8.2±2.3 and 9.5±1.2 hours per day, mainly at night. Reported pain was overall low (maximum after 1 week with an average value of 1.9±1.7 on a visual analog scale [VAS] 0-10) and patients' satisfaction was adequate at the end of the facemask wear after 9 months (8.7±1.4 on a VAS 0-10).

CONCLUSIONS: The customized FM was overall well accepted by the patients and represents a valid alternative to conventional ones.

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KEY WORDS: Printing, three-dimensional; Malocclusion, angle class III; Laryngeal masks.

Facemask (FM) has been used since the 1970s to treat Class III skeletal disharmony.[1] Scientific evidence supports early treatment of this malocclusion and among the proposed treatment methods, FM usually combined with a rapid maxillary expander (RME) appears to be one of

the most effective.[2, 3] RME allows for the correction of the transverse discrepancy between the arches, a common sign associated with Class III malocclusion. It has been reported, in fact, that the maxillary skeletal width in Class III subjects is on average about 3.8 mm narrower when compared to Class I subjects.[4] The FM allows the sagittal correction in terms of maxillary protraction and control of mandibular growth using elastic bands stretched from the RME to the transverse bar of the FM.[3, 5-8]

The original design of the FM consists of two pads, one on the forehead and one on the chin, connected by two lateral vertical bars and a crossbar for the application of the elastic bands.[1] The Delaire-type design was later modified by Henri Petit, who proposed a single vertical central bar instead of two bars on the sides.[9] The two pads on the forehead and the chin are essential to transmit extraoral reaction forces and are present in both designs. Due to the applied forces, the skin areas below these pads, and especially the chin area, experience the most stress.[10]

Various degrees of discomforts and complaints such as skin irritations, hyperkeratosis, ulcers, and sores below the forehead and chin pads have been described.[11] A retrospective study on 177 subjects treated with FM reported that nearly half (43.5%) of them were affected by skin irritation.[12] The severity of the injuries is certainly related to several factors attributable to both the patient (chin anatomy, skin hypersensitivity, and perspiration) and the appliance (applied force, morphology, and adaptability of the pads). To counteract these problems, solutions for improving the fit of the chin and forehead pads to the patients face anatomy have been proposed.

Early proposals for customizing FMs were based on recording the anatomy of the patient's face by applying plaster or alginate directly to the patient's face.[13, 14] Such procedures were obviously unpleasant and challenging for both the patient and the clinician. Cacciatore *et al.*[15] proposed to use the putty-consistency polyvinyl to rebase directly the chin pad of the standard FM. More recently, Ierardo *et al.*[11] proposed to use a chin pad made of a 3-mm thick, soft-bite silicone disk thermoformed on the chin cast obtained from a silicone putty impression.

Modern digital technologies could allow for more precise and less invasive FM customization. As a matter of fact, nowadays, it is possible to obtain a three-dimensional (3D) scan of the patient's face on which digitally designed pads and bars can be additively manufactured with a 3D printer.[16]

This study aimed to investigate the hypothesis that an individualized Petit-design FM with the pads and the midline bar customized to the patients' facial anatomy could be comfortable and favorably accepted by the patients during early treatment of Class III malocclusion. In addition, the investigation meant to detect any complication possibly arising during therapy with the customized FM.

Materials and methods

This case series was written according to the PROCESS Guideline.[17]

This prospective two-center case series feasibility study was conducted in accordance with the Declaration of Helsinki and approved by the Regional Pediatric Ethics Committee at University of Florence (Florence, Italy; protocol number 236/2020; chairperson of the Ethic Committee: Prof. Alessandro Mugelli; date of approval: 04/09/2020). Informed consent was obtained from the subjects' parents or guardians. The study sample included 10 consecutive patients aged between 5 and 9 years old who presented with indications for early treatment of Class III malocclusion. Five patients (3 males and 2 females) were treated at the Orthodontic Clinic of the University Hospital of Careggi, Florence, Italy and 5 patients (3 females and 2 males) were treated at the Orthodontic Clinic of the University of Belgrade, Serbia. Patients presenting with dental abnormalities in number (excess or deficiency) in the upper arch, cleft lip and/or palate, or any congenital craniofacial syndrome were excluded.

All the patients were initially treated with Hyrax-type RME that was activated only in the presence of transverse discrepancy between the arches. RME was activated at the rate of a one-quarter turn per day, corresponding to 0.2 mm of expansion, until a slight overcorrection was

achieved (palatal cusps of the upper posterior teeth approximating the buccal cusps of the lower posterior teeth).

When active expansion was stopped, patients' face scans were acquired either with iPad Pro 2018 tablet (Apple Inc., Cupertino, CA, USA) and Bellus3D DentalPro application (Bellus3D, Campbell, CA, USA) or with Face Scanner Maxi 6 (Polishape 3D, Bari, Italy) and Agisoft Photoscan Professional Edition software (Agisoft LLC, St. Petersburg, Russia). Scanning was performed in a bright room and a disposable cap was used to retain hair by preventing it or its shadow from obscuring part of the skin of the face. The patients were invited to sit in a resting posture, and to keep the teeth in occlusion and the lips relaxed. For Bellus3D DentalPro application the scan lasted a few seconds during which the patients gently tilted and rotated their heads guided by a robotic voice. The acquired 3D image was then exported in .stl format. For Face Scanner Maxi 6 six Canon reflex cameras 1200D 18Mpx (Canon, Tokyo, Japan) connected with 2 external flashes (Metz BL-400; SB 50-70) simultaneously took a photograph from different angulations. The 6 photographs were then digitally processed, and the resulting file was exported in .obj format.

The digital design and manufacturing of the FMs were performed at the Santa Chiara Fab Lab digital manufacturing laboratory of the University of Siena, Siena, Italy, in accordance with the patented protocol (European Patent N. EP 3752091, USA Patent N. US20200397536). The frontal and chin pads and the central bar of the FM were modelled on the 3D image of the patients' face, using a 3D modelling software.[18] Then, the pads were printed with BioMed Clear biocompatible resin (Formlabs, Somerville, MA, USA) using the Form 3 3D printer (Formlabs, Somerville, MA, USA), while the 3D model of the bar was printed in stainless steel by a 3D printing service.[19] Finally, each piece was polished and assembled together. To improve further patient comfort, the frontal and chin pads were coated with protective pads in polymeric gel (Silipos, Niagara Falls, NY, USA).

Each customized FM was then delivered to the patients by the orthodontist (Figure 1), who secured the sliding crossbar to the central bar with a setscrew so that the rubber bands reached a 30° downward inclination relative to the occlusal plane. The orthodontist also selected and delivered extraoral elastics that produced a tensile force of about 500 grams per side. Patients and their parents or guardians were adequately instructed by the orthodontist on how and for how long (about 14 hours per day) to wear the FM.

The patients' experience with the customized FM was recorded through a questionnaire filled in by the patients, with the help of their parents or guardians, after 1 week, and after 3, 6, and 9 months from appliance delivery. The question-

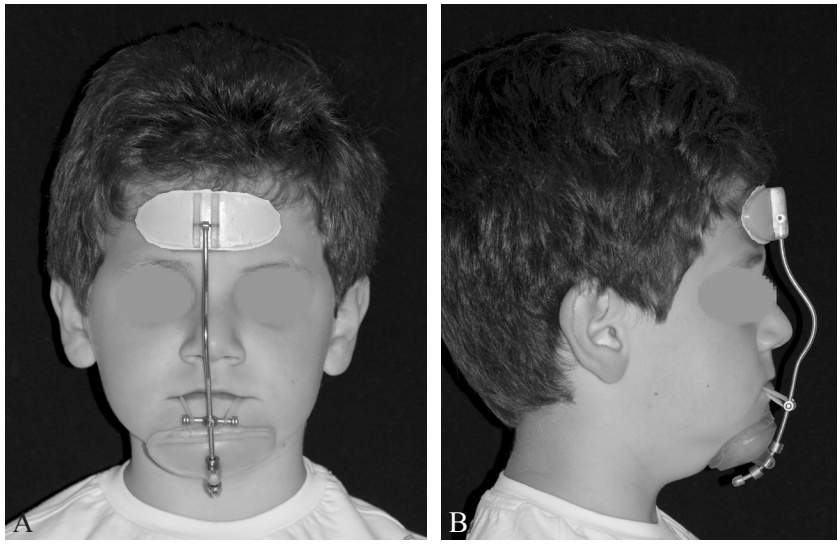

Figure 1.—A, B) Patient wearing the customized facemask.

naire included 2 visual analog scales (VAS): 1 for assessing pain, ranging from 0 (no pain) to 10 (worst imaginable pain), and 1 for assessing patient's satisfaction with the therapy, ranging from 0 "no satisfaction" to 10 "maximum satisfaction." The questionnaire was also meant to assess patient's compliance with FM therapy, as well as the occurrence of any complications, particularly skin irritations.

Statistical analysis

Data extrapolated from the questionnaires were analyzed using a statistical software (JMP version 13.0.0, SAS Institute Inc, Cary, NC, USA) and descriptive statistics were provided.

Results

Ten patients with an average age of 7.7±1.0 years (min 5.7 and max 8.7 years) were treated with a customized FM. Nine patients successfully completed the treatment. One male subject who was treated at the University of Belgrade interrupted the therapy before the last survey at 9 months due to personal reasons.

The reported FM wear time per day was 8.9±2.3 hours (min 3; max 12 hours) during the first week. After 1 week the pain measured by VAS was 1.9±1.7 (min 0; max 5). Seven out of 10 patients reported pain: 4 at the teeth, 1 at the teeth and palate, 1 at the gingiva, and 1 at the mandible (Table I). Compliance after 1 week was satisfactory: 7 patients wore the FM without parental intervention and only in 4 cases a small reward was needed to motivate the patient who did not want to wear the device. Three patients presented skin irritations below the pads and at the mouth corners, however, no irritation on the lower lip reported. One patient was affected by night awakenings caused by the device (Table II).

Data analysis after the first 3 months of therapy showed a reported wear time of 9.5±1.2 hours (min 8; max 11.5 hours) per day. Patient satisfaction presented a score of 8.4±2.0 (min 5; max 10) while the scale measuring pain showed a score of 1.1±1.4 (min 0; max 4). Five out of 10 patients reported the presence of pain: 3 at the teeth, 1 at the gingiva, 1 at the chin (Table I). Compliance remained satisfactory. In 7 cases, parents did not have to remind children to wear the device, and no rewards were necessary to motivate them. In 8 cases, however, parents had to explain to their

TABLE I.—*Descriptive statistic of wearing time, reported pain and patient satisfaction after 1 week, 3, 6, and 9 months (mean±standard deviation).*

Parameter	1 week N.=10	3 months N.=10	6 months N.=10	9 months N.=9
Reported wearing time (hours)	8.9±2.3	9.5±1.2	8.2±2.3	8.9±0.8
Frequency of patients who reported pain	7	5	5	
Reported pain (VAS 0-10)	1.9±1.7	1.1±1.4	1.7±2.4	
Patient satisfaction (VAS 0-10)		8.4±2.0	7.8±2.6	8.7±1.4

VAS: visual analog scale.

TABLE II.—*Questionnaire results after 1 week, 3, 6, 9 months.*

Question	1 week N.=10	3 months N.=10	6 months N.=10	9 months N.=9
Do you wear the FM every day without being reminded by your parents?*	7	7	6	8
Do you often ask to be allowed to remove the FM?*	3	3	1	2
When you do not want to wear the FM, do your parents explain you that it is important for your teeth?*	6	8	7	6
When you do not want to wear the FM, do your parents offer you a small reward?*	4	0	1	1
Skin irritation (reddened skin) on the forehead*	3	6	4	3
Skin irritation (reddened skin) on the chin*	3	9	6	7
Irritation at the corners of the mouth*	3	2	0	1
Irritation on the lower lip*	0	0	0	0
Did you sleep badly with the FM on?*	1	1	2	2
Have you had any other discomfort due to FM? *	5	1	1	1

*Frequency of affirmative responses.

children how important the device was for the health of their mouths. Some skin irritation remained, especially below the chin pad where 9 patients reported some discomfort (Table II).

After 6 months of therapy, the reported average hours per day of device use was 8.2±2.3 hours (min 2; max 10 hours). Satisfaction score was 7.8±2.6 (min 3; max 10) while pain score was 1.7±2.4 (min 0; max 7). Five out of 10 patients reported pain: 4 at the teeth, 1 at the teeth and the chin (Table I). To keep compliance high, parents had to motivate their children by explaining the importance of the treatment in 7 cases but again no rewards were needed. Chin irritations remained the main annoyance (reported by 6 patients) (Table II).

At the end of the therapy, after 9 months, the average hours per day of reported FM use was 8.9±0.8 hours (min 8; max 10.5 hours). The degree of satisfaction with treatment at the end of therapy had a mean value of 8.7±1.4 (min 6; max 10) (Table I). Compliance remained high: 8 out of 9 patients did not need their parents to remind them to wear the mask. Reported chin irritation remained constant (reported by 7 out of 9 patients) (Table II).

During the 9 months of individualized FM treatment, 4 complications occurred: in 2 cases the chin support broke, in 1 case the gel pad detached from the chin support, and in 1 case the hole for the metal rod on the chin support broke.

Discussion

The customized FM allowed to obtain forehead and chin pads with an optimal adaptation to the anatomy of the face. Additionally, the shape of the central vertical bar reproduced the patient's profile without the need to be bent as for the standard FM.

The clinical use of commercially available standard FM has revealed several limitations due to their inability to perfectly fit the individual patient's face, especially if we consider very young children or children with craniofacial deformities who may present Class III malocclusion.

It is well established that the FM is the least accepted orthodontic device by patients.[20] This may be due to the main complaints reported by patients to the orthodontist, such as bulkiness, instability on the face, and, overall, uncomfortable use of the device. The discomfort felt by the patient may lead to loss of compliance and, consequently, may contribute to the failure of orthodontic therapy.

Early attempts of customization proposed somewhat invasive materials and techniques.[11, 13-15] Nowadays, thanks to new 3D technologies, a customized device can be obtained with noninvasive procedures. Indeed, the facial scan can be acquired in few seconds by means of an application for tablet, which is a portable and relatively inexpensive device. Several studies have also shown that applications for tablets, while less expensive, can provide face scans comparable to more expensive devices.[21-23]

The primary endpoint of this two-center feasibility study was to evaluate the occurrence of complications (such as mask breakage, pressure ulcers, gingival recession of the lower incisors) during the period of treatment with the customized FM. There were only 4 complications that occurred during the 9 months of treatment in a sample of 10 patients. All complications were located at the chin support of the FM. However, the damaged FMs were all easily repaired either by re-printing the chin support or by substituting the gel pad. The occurrence of chin support complications is not an unexpected event. Indeed, a finite element analysis by Gazzani *et al.*[10] demonstrated that for both FM designs (Delaire's design and Petit's design) the greatest stress was at the level of the chin support, with greater intensity observed for Petit's design.

No other complications such as pressure ulcers on the patient's face or gingival recession of the lower incisors were observed and, therefore, the individualized device met the "safety" criteria in all patients in the study.

Data from the administered questionnaires showed that the patient-reported wear time of the FM throughout the treatment period was always between 8 and 10 hours daily, except for two cases (Table I). Although subjective measurements tend to overestimate compliance,[24, 25] the reported time is still less than the 14-hour daily prescription required by the orthodontist at the time of delivery. However, the results of the present study are in line with what has been shown by Tsomos *et al.*,[26] who, through objective mea-

surements using sensors mounted on removable appliances, concluded that a realistic device use time is 8 hours even when there is a higher demand from the orthodontist. Future studies may compare the reported wear time of a customized FM with objective data obtained by sensor included in the forehead pad of the device.

Data collected on the pain experienced by the patients showed minimal values throughout the duration of the treatment. Indeed, the average pain experienced by the patients never exceeded 1.9 on a VAS ranging from 0 to 10. It should be emphasized that this maximum value was collected after the first week of therapy, which, presumably, is the period of initial adaptation to the new therapy. Perceived pain tended to decrease from the first week to subsequent follow-ups (Table I). The teeth were the main site for pain, followed by the chin where the reaction forces derived from FM therapy were mainly transmitted.[10]

Patient's satisfaction throughout treatment averaged consistently above 7.8 on a VAS ranging from 0 to 10, with a maximum value of 8.7 recorded at the end of therapy (Table I). This finding indicates how, even though the FM is the device with the lowest acceptance among all orthodontic devices,[20] an individualized device could facilitate patient acceptance of therapy.

During the first week of treatment, irritation occurred at the chin level, at the forehead level and at the level of the mouth corners. In subsequent follow-ups, skin irritations were still seen in most patients at the chin level, while the development of sores at the mouth corners became less frequent over time (Table II). Chin irritations were successfully addressed with an emollient non-cortisonic cream, usually prescribed to protect, and moisturize the skin in adults and children with sensitive and dehydrated skin (Decortil Lipocrema, IDI Farmaceutici s.r.l., Pomezia, Rome, Italy). A previous study[11] reported a prevalence of skin irritations in the chin area of about 45% after 6 months of treatment with the standard FM, a value that is comparable to that observed in the present study. During the 9 months of therapy, no irritation or injury were observed at the level of the lips.

During the first week, 3 patients reported disturbances during sleep. However, night-time issues tended to decrease with time as the patient adjusted to treatment (Table II).

Regarding patient compliance, the present study showed that already in the first week of therapy, 70% of the patients wore the FM independently without parental intervention. This percentage increased to 89% at the end of the therapy. Parental intervention was maintained consistently in 10-20% of cases as the patient was reluctant to wear the mask. Most of the interventions were based on motivational reinforcement through explanation of the importance of the treatment for the child's health, while reinforcements administered as small rewards were more frequent in the first week of treatment and then tended to disappear during subsequent follow-ups (Table II).

The cost of the custom-made FM is approximately the double of that of the standard FM available in the market. Nevertheless, a cost-benefit analysis is challenging to conduct without a control group of patients who are wearing the standard FM.

Limitations of the study

This feasibility study successfully demonstrated the possible clinical application of the customized 3D printed FM. However, one limitation of this study was that the patients were treated exclusively with that FM type. To verify whether this custom-made appliance can improve patient's acceptability and cooperation, future randomized investigations should assess the patients' experience wearing alternatively the standard and the customized 3D printed FM. An additional development of the project should take into consideration the use of sensors to evaluate objectively the compliance of the patients.

Conclusions

The customized FM tested in this clinical study proved to be a safe, effective, and well-accepted device. Three-dimensional registration of facial anatomy and 3D printing made it possible to obtain a device that was perfectly adapted to the patient's face, achieving adequate patient cooperation and satisfaction, with minimal occurrence of skin irritations and other complications.

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Conflicts of interest

The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

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Authors' contributions

Francesco Caroccia has given substantial contributions to manuscript writing, Jovana Juloski and Jelena Juloski to data investigation, Patrizia Marti, Alessandro Vichi, Cecilia Goracci and Lorenzo Franchi to study conception and manuscript editing, Flavio Lampus to data provision, Veronica Giuntini and Valentina Rutili to data analysis and investigation, Michele Nieri to manuscript editing and data analysis. All authors read and approved the final version of the manuscript.

History

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