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Case Report

An Update of Eyeglasses-Supported Nasal–Facial Prosthetic Rehabilitation of Cancer Patients with Post-Surgical Complications: A Case Report

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Featured Application: This case report aims to describe an update of the digital protocol for the fabrication of a facial prosthesis for those patients who cannot be rehabilitated with plastic surgery because of post-surgical complications after maxillofacial surgery. In detail, it describes the application of the digital protocol to a mid-facial defect. The innovation proposed is oriented to simplify the procedures and reduce the time and cost of the process, aiming to recover the quality of life of inoperable patients.

Abstract: This case report aims to describe novel steps in the digital design/manufacturing of facial prostheses for cancer patients with wide inoperable residual defects, with a focus on a case of a mid-facial defect. A facial scanner was used to make an impression of the post-surgical residual defect and to digitalize it. The daughter's face scan was used for reconstructing the missing anatomy. Using 3D printing technologies, try-in prototypes were produced in silicone material. The substructure was laser melted. The final prosthesis was relined directly onto the patient's defect. The prosthesis resulted in a very low weight and a high elasticity of the external margins. The laser-melted substructure ensured the necessary rigidity with minimum thickness.

Keywords: computer-aided-design; virtual modeling; surgical complication; digital workflow; facial prosthesis

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1. Introduction

This case report aimed to describe novel steps in the digital workflow for designing and manufacturing nasal–facial prostheses for cancer patients with wide residual and inoperable facial open defects. The significant novelties deal with the design of the metal substructure to provide the maximal reduction in thickness and weight, while preserving the rigidity of the connection to eyeglasses and the adoption of a direct silicone relining process (as a variation of the standard molding technique) to obtain the final nasal–facial prosthesis.

Facial defects can cause functional impairment and decrease patient quality of life; facial prostheses may positively impact patients' daily social life and self-esteem. The prosthetic approach to facial defects represents a satisfying therapeutic solution for the patient in terms of psychological support and a good alternative when the surgical reconstruction after facial tissue resection [1] is impaired by the medical condition of the patient, the defect size, or by flap complications. The clinical choice of the type of prosthesis retention depends on several factors, such as the defect extent, undercut presence, patient's economic status, and aesthetic prominence of the site [2]. Implants, mechanical retentions, or skin glues are

the most common retention methods [3]. The benefits of eyeglasses-based retention are the ease of wearing, the possibility to support the prosthesis while maintaining it in the correct position, and the use of the skin glue to improve its stability, therefore favoring the longevity of the prosthesis. In addition, the eyeglasses-supported epithesis is an immediate prosthesis that may offer the patient a fast recovery from facial disfigurement [4]. Today, this prosthesis provides good clinical outcomes regarding functionality, aesthetics, and patient satisfaction. It is the most preferred option by clinicians and patients when surgical complications impair the implant or reconstructive surgery [5].

Indeed, in some cases, reconstructive surgery may fail because of multiple factors that affect osteointegration, such as the anatomic location, the quality/quantity of the available bone, the systemic health, and the field/dose of radiation therapy that can cause osteoradionecrosis [6–9].

Several authors described clinical cases of mechanical-retained facial prostheses to rehabilitate the significant volume loss of the patient's face [10], reported a case of a magnet-retained obturator and mid-facial prosthesis for a patient who had undergone total left maxillectomy and left orbital exenteration. The prosthesis was fabricated using traditional analog methods (without the aid of Computer Aided Design-Computer Aided Manufacturing technology) [10]. In 2019, Gupta et al. [11] reported a patient with a missing right eye rehabilitated with an eyeglasses-supported prosthesis using analog procedures; they reported optimum functional and cosmetic results and positive feedback from the patient in terms of self-compliance and comfort. In recent years, Neto et al. [12] described the design and rapid prototyping of a retention system, a plastic bar (substructure) interlocking with both the eyeglasses and the silicone nasal prosthesis at the level of the interocular part of the eyeglasses frame, which was hidden by the silicone prosthesis in the frontal side. This system showed appropriate retention strength, fit, easy placement, and cleaning by the patient.

One major challenge for clinicians is to design/create a connection between eyeglasses and the silicone prosthesis. Ciocca et al. [13] described the workflow for the construction of an immediate midfacial prosthesis using Computer Aided Design-Computer Aided Manufacturing (CAD-CAM) technologies. Laboratory components of oral implants were used to connect eyeglasses to the substructure [14].

As reported by these previous papers, the manufacturing technology for a complete digital workflow can improve not only the quickness of significant midfacial rehabilitation through prosthetic solutions, but also can facilitate several steps (the impression, the design of complex anatomical parts, the construction of the substructure, the try-in, the creation of the mold). An update on the structure of the connection system was presented in 2015, when Ciocca et al. [15] described a method to precisely transfer the position of the prosthesis for the eyeglasses from the digital design to the patient's face. This protocol limits the patient's discomfort and the involvement of anaplastologists for the analogical modeling of the wax-up.

The presented updating of the digital workflow for the fabrication of a facial prosthesis supported by eyeglasses and without craniofacial implants showed actual results in reducing the procedure complexity and improving the patient's quality of life.

2. Case Presentation

2.1. Patient Case Report

An 87-year-old woman was scheduled for a facial prosthesis due to post-operative flap complications of the maxillofacial surgery, consisting of flap necrosis after a bilateral maxillary resection for cancer removal. The patient suffered from this complication that destroyed the nostrils, the upper lip, and the left zygomatic area of the face (Figure 1), with a residual frontal cavity that exposed the metal structure anchored to osseo-integrated implants that supported the oral prosthesis. The Computer Tomography (CT) scan showed an infectious area of peri-implantitis at the right zygomatic arch, with an active cutaneous purulent fistula in the inferior right periorbital area. The patient's general medical condition

was classified as ASA-3, and no further surgery was possible under total anesthesia due to the high-risk conditions of the cardiovascular system.

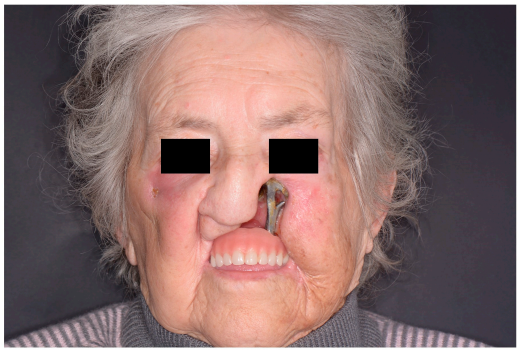

Figure 1. The residual defect after the surgical complication (flap necrosis).

Losing the upper lip made drinking, eating, and speaking extremely difficult for the patient and social relations impossible, even with relatives. Depression and intolerance were added to this medical condition. After consultation with the anesthesiologist, the maxillofacial surgeon, and the oncologist, the unique option was a removable facial prosthesis anchored to a mechanical support such as the eyeglasses, which could cover the defect, at least for aesthetic reasons.

2.2. Computer-Aided Design

The digital workflow (Figure 2) began with an extraoral impression: a 3dMD scanner (3dMD Inc., Atlanta, GA, USA) was used to make the facial impression and included the ears to allow for the correct virtual positioning of the digitalized eyeglasses. The eyeglasses were scanned separately with a lab scanner (E2, 3Shape, Erlangen, Germany) and then virtually positioned on the patient's face. Due to the loss of the original native anatomy of the nose and the upper lip, a digital extraoral impression was made to the front of the patient's daughter to restore a more harmonious face profile than that achievable using the Ear and Nose Digital Library. Other methods described in the literature to obtain a digital model of the missing part of the patient's face include the CAD design of the nose from scratch or the use of a digital copy of the patient's nose preserved before surgical resection; a suitable method is to create an own database (ear and nose library) by digitally scanning patients or patient's face casts [15,16].

The STL (Standard Tessellation Language) files resulting from the mother's and daughter's face scans were imported into 3-Matic (Materialise, Leuven, Belgium), a certified CAD software for medical use. The daughter's face scan was positioned on the mother's face scan to cover the entire defect, adjusting the size and the position using some anatomical landmarks, such as the eyes and the ears. Once the position was satisfactory, a local smoothing on the surface of the defect area and the Boolean union of the two facial scans were performed (Figure 3). The Boolean union result was used to design the final prosthesis. According to the defect area, the margins of the prosthesis were selected by including the nose and approximately 2 cm of the surrounding skin and the upper lip (Figure 4). Once the surface of the nasal prosthesis was designed, with Move Surface tool, the selected surface was extruded to obtain a thickness of 4 mm. For the external margins of the prosthesis (about 1 cm from the outer edge), a thickness between 1 and 2 mm was obtained using the Chamfer Edge tool, which creates a beveled surface on the selected edge.

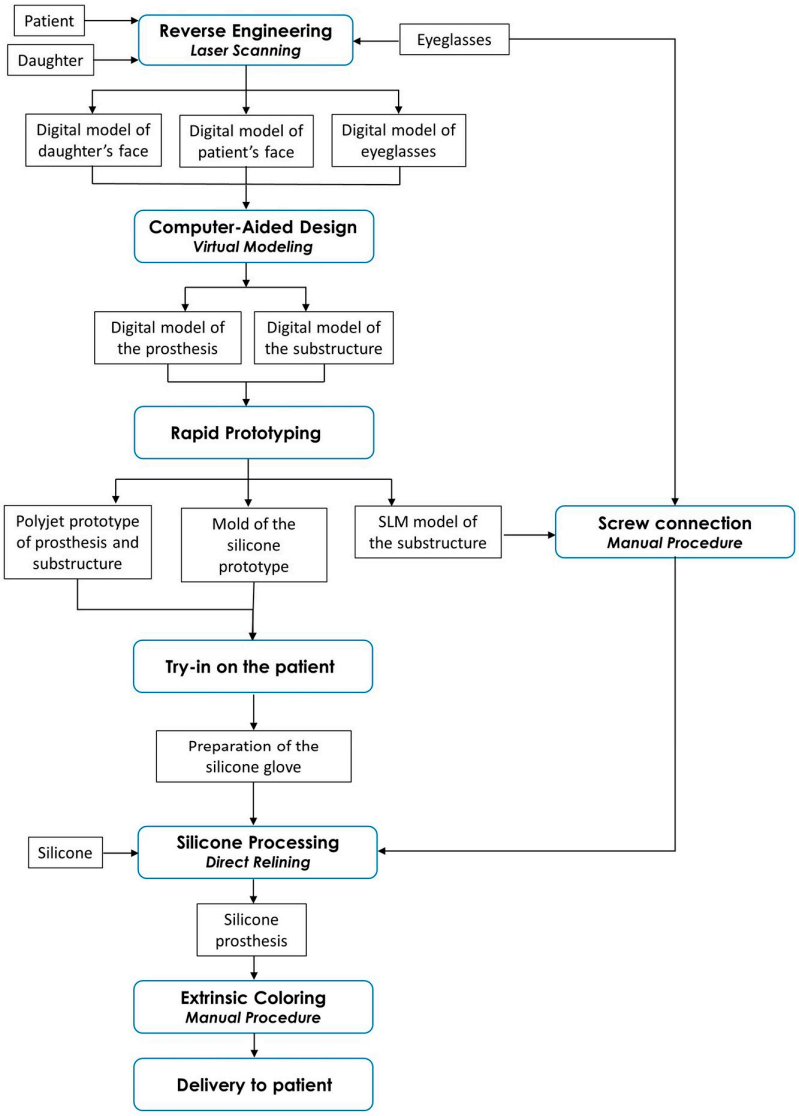

Figure 2. Graphic representation of the digital workflow used for the realization of the nasal–facial prosthesis.

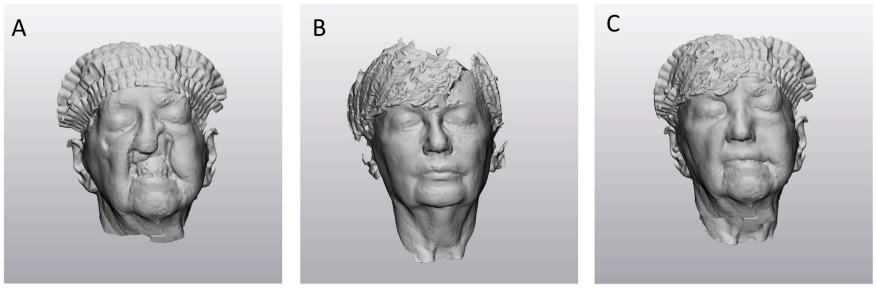

Figure 3. STL files of the facial scan of the patient (**A**), of the patient's daughter (**B**), and the result of the Boolean union of the two scans (**C**).

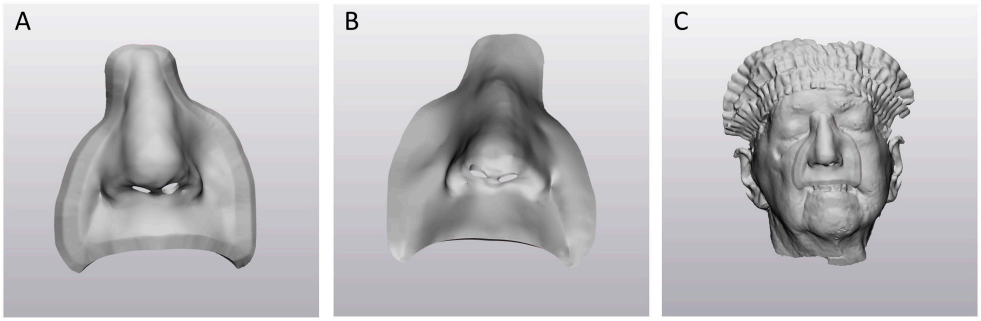

Figure 4. Final virtual design of the prosthesis. (**A**) Anterior view; (**B**) posterior view; (**C**) final prosthesis positioned on the patient's face scan.

Then, the resulting margins were moved by applying a negative 1 mm offset to obtain under-contoured margins to have a compressive effect on the patient's skin (Figure 4).

A solid geometry similar to the daughter's nostrils was created, and the nostrils on the prosthesis were obtained with the Boolean Subtraction tool. The final step consisted of the alignment of the digitalized eyeglasses on the patient's face scan to later design the connecting substructure: the digital model of the eyeglasses was positioned, taking care that the rims of the lenses were parallel to the pupils' axis; the temple arms were digitally placed over the ears and the bridge of the optical frame was put in contact with the upper part of the nasal prosthesis (Figure 5).

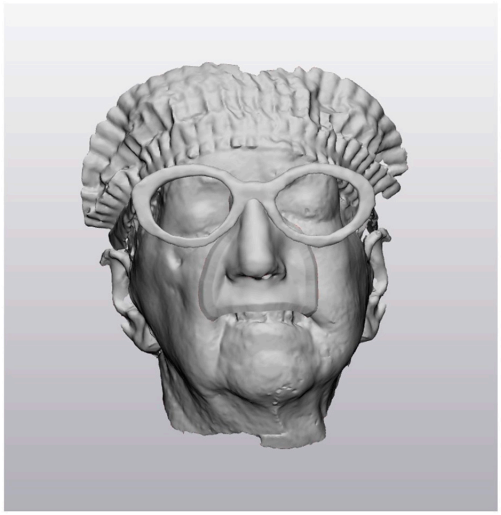

Figure 5. STL file of the laser-scanned eyeglasses after their positioning on the patient's face.

The connecting substructure was designed, considering the minimal volume constraints to guarantee the mechanical support, and the aesthetic requirements of thickness: the substructure was designed to remain entirely within the silicone facial prosthesis, except for the upper part, where it was connected to the eyeglasses behind the optical frame. This connecting part of the substructure was an innovative design: a wide metal platform entirely reproduced the rear surface of the interocular frame of the eyeglasses, and four holes were provided to allow for screwing of the fixing screws to the corresponding female parts that were resin-splinted (Splint Line, Lang Dental Mfg., Wheeling, IL, USA) in the resin framework of the eyeglasses (Figure 6A–C). The substructure was designed in a 3-Matic software environment to secure the maximum retention of the prosthesis.

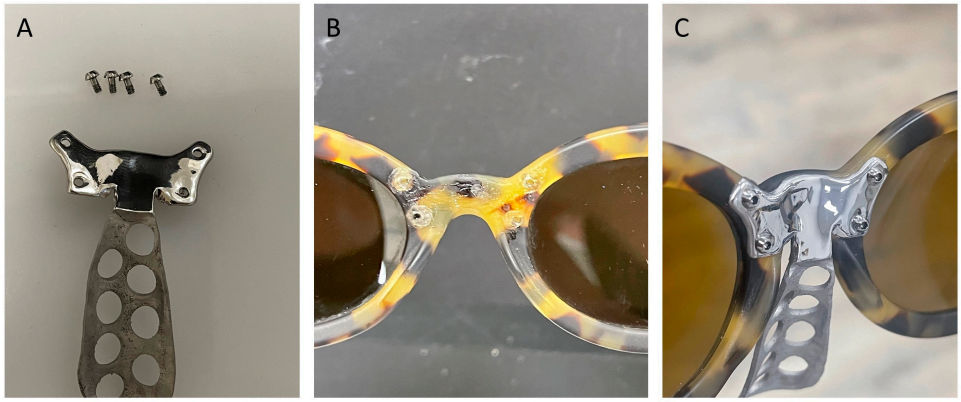

Figure 6. Final metal substructure, screws, and metal platform with four holes for connection to eyeglasses (**A**); female resin-splinted parts for screw fixation on the eyeglasses (**B**); substructure connected to the eyeglasses (**C**).

First, the substructure area was selected with a Mark tool applied to the prosthesis volume to achieve continuity between the substructure and the prosthesis. Once the correct substructure area with an eyelet shape was set, we extruded it through the Move Surface tool to obtain a 1 mm thickness. The substructure was then incorporated into the thickness of the prosthesis to leave 1 mm of silicone forward and 1 mm of silicone behind, for best hiding the metal color inside the prosthesis.

Finally, nine spherical holes were added to the main body of the substructure to facilitate the mechanical retention of the silicone prosthesis.

2.3. Computer-Aided Manufacturing

Once the digital design was completed, the resulting substructure was manufactured in Titanium using Selective Laser Melting (SLM) technology, at a minimum thickness (1 mm); then, it was connected to the eyeglasses with the novel connecting plate and micro screws. After completing the design, a prototype of the nasal prosthesis with the included substructure was manufactured for the clinical try-in session to best check the harmonization of the prosthetic volumes to the patient's facial profile. In detail, the prototype was produced using the Polyjet J720 Dental 3D printer (Stratasys Ltd., Eden Prairie, MN, USA), based on material jetting 3D printing technology that allows for manufacturing materials of different stiffnesses in a single process. The substructure was printed in a rigid photopolymer resin (VeroWhitePlus, Stratasys Ltd., Eden Prairie, MN, USA). In contrast, for the nasal prosthesis the rubber-like Agilus 30 White resin (Stratasys Ltd., Eden Prairie, MN, USA) was used (Figure 7). In parallel, a silicone prototype of the nasal prosthesis was produced starting from the CAD design, through a standard molding procedure. This silicone prototype was used during the try-in session on the patient in combination with the Polyjet prototype (Figure 7) to verify the fitting of the silicone prosthesis with the patient's face in relation to the substructure, which was replicated in the Polyjet prototype.

At this step, our updated digital workflow offers two options for manufacturing the final silicone facial prosthesis: total molding or direct relining after molding.

Total molding is a procedure widely described and briefly resumed as follows: when the definitive volume of the prosthesis is digitally determined, the volume of the facial prosthesis is represented as a negative volume at the inner of a parallelepiped, which is separated in two parts, the front and the rear part of the mold. In the rear part, a precise groove is prepared to reposition the metal substructure during molding, allowing for a secure fit during the silicone processing.

Figure 7. 3D-printed prototype of the nasal prosthesis manufactured using 3D printing Polyjet technology, including both the prosthesis volume in the rubber-like material and the connecting substructure in rigid polymer.

The second option is the procedure of direct relining after molding, which we used in this study for the fabrication of the nasal–facial prosthesis. A detailed description of this procedure is provided here below.

The direct relining after molding utilizes the 1 mm-thickness external volume of the designed prosthesis and connects the prosthesis to the substructure straight onto the patient's face, once the substructure is in position with the eyeglasses. The mold is used only to make the external 1 mm-thickness surface of the prosthesis (Figure 8A), similar to a silicone "glove" that is positioned onto the substructure after being relined with a room-temperature processing silicone, which is an unlabeled product certified for skin contact according to ISO 10,993 and possessing a shore-A 35 hardness (Acetoxy Glue, COP Inc., Saint-Nazaire en Royans, France) (Figure 8B).

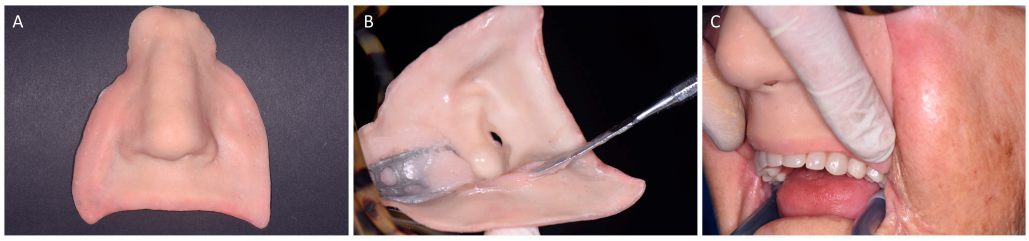

Figure 8. Silicone relining procedure on the patient's face: external appearance of the prosthesis before the extrinsic coloring (**A**); the relining technique (**B**); the application on the face during the silicone processing (**C**).

This was a relining process, similar to that for an intraoral prosthesis that is relined onto the mucosa. The intrinsic coloration had been programmed during the prototype try-in session, based on a specific chromatic guide for the corresponding silicone utilized for the prosthesis (Figure 9). After 15 min of setting time, depending on the manufacturer's instructions, under manual pressure on the substructure (Figure 8C), the facial prosthesis is ready for the extrinsic coloring. If necessary, the relining may be completed in the peripheral part of the margins, where the compressive effect may be perfectioned for the best sealing effect of the margins to the skin. The workflow ends with the extrinsic coloration that is carefully applied when the patient is wearing the prosthesis to achieve the best color matching to the skin (Figure 10). According to manufacturer's instructions, a setting time of 15 min is necessary for the complete adsorption of the acetonic residuals into the silicone that fixes and mattresses the color pigments to the prosthesis. After the extrinsic coloration, the nasal–facial prosthesis was delivered to the patient.

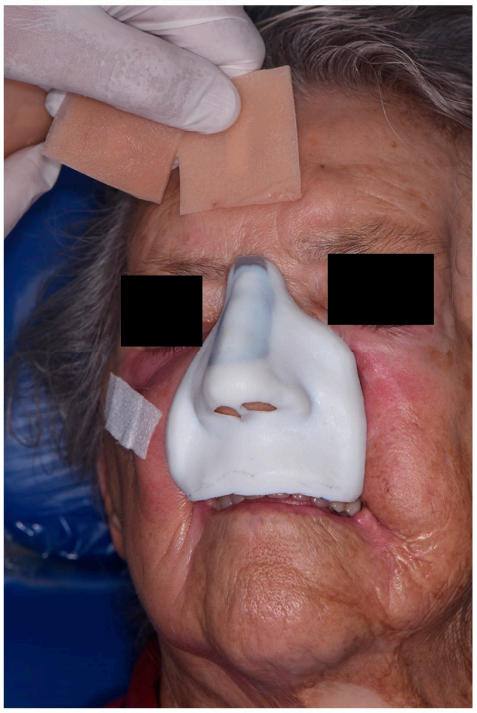

Figure 9. Color matching and try-in of the resin prototype.

Figure 10. Final result.

3. Discussion

The laser-melted metal substructure ensured the necessary rigidity of the connection to the eyeglasses and the minimum thickness to work in the reduced space between the external surface of the prosthesis and the underlining residual skin tissues of the nasal pyramid. The metal females of the connection screws, resin-splinted to the eyeglasses by polymethyl methacrylate (PMMA), allowed for tightening of the fixing screws with a 15 N torque without risk of dislodgment during the long-term follow-up. The option of direct relining to obtain the final silicone prosthesis allowed for the creation of a facial prosthesis

with an extremely thin silicone thickness at the borders, which resulted in very low weight and very high elasticity of the external margins (Figure 10).

The low weight determined minimal loading of the substructure at the screw connection; the high elasticity allowed for the optimal elastic adaptation of the prosthetic margins to the facial skin during its function. For this study, having only the patient imaging at the beginning of the rehabilitation treatment (i.e., after resection, with the nose and upper lip already missing), we based the facial reconstruction on the intact face of the patient's daughter as a reference. In detail, we combined the patient's surface scan after resection with the surface scan of the daughter, and the resulting combination (scan REF) was taken as the reference anatomy to aim for nasal–facial rehabilitation. At the end of the rehabilitation, we compared the achieved results, i.e., the final facial scan of the patient wearing the prosthesis (scan_POST) with scan_REF, via a deviation analysis (distance mapping) performed using CloudCompare software (Figure 11). As a result, the maximum deviations (about 4 mm) occurred in correspondence with the nasal profile, while at the edges of the prosthesis, at the interface with the patient's facial surface, there were minimal deviations demonstrating the good adhesion of the prosthesis to the face.

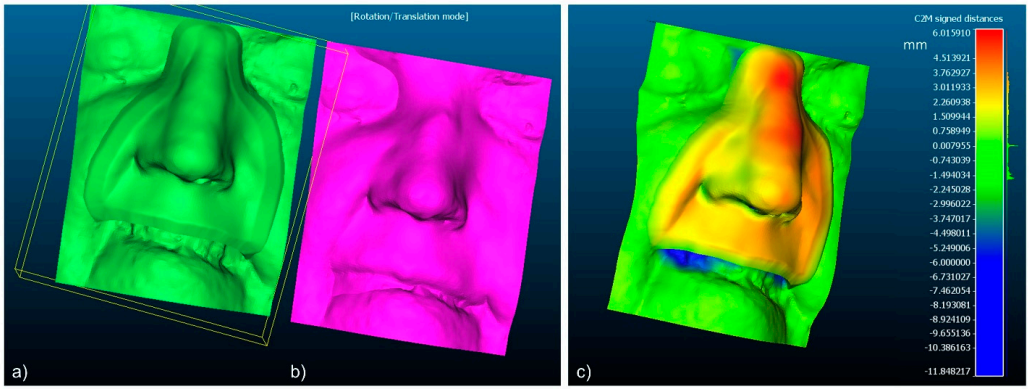

Figure 11. (**a**) STL after rehabilitation using the designed ephitesis (scan_POST); (**b**) STL of the combination of the patient and the daughter's face scans (scan_REF); (**c**) the obtained distance mapping between scan POST and scan_REF.

Because of the optimal sealing effect of the facial cavity achieved with the prosthesis, the cohabitant relatives registered a better understanding of several phonemes. At last, the improvement of the aesthetic profile increased the self-esteem of the patient and the acceptance of the facial appearance by the relatives. Consequently, the patient gained a better quality of life, confirmed by her improved social relationships and her happiness to be finally understood when speaking.

Today, the fabrication of prostheses for facial defect rehabilitation usually uses of CAD-CAM technologies, taking advantage of digital image processing, 3D virtual modeling, and additive manufacturing procedures. This approach provides faster, cheaper, and more customized solutions and is widely documented in the literature [17–19]. The first step of the procedure is data acquisition: surface laser scanning, 3D photogrammetry, CT, and an MRI scan, which are standard methods mentioned in the scientific literature [6,20–23]. For example, to manufacture an auricular prosthesis supported by craniofacial implants, the overlapping of CT and surface laser scan data ensures the best accuracy thanks to the combination of the skin surface and the bony skull data in a single STL file, which is useful to determine the position of the craniofacial implants in relation to the prosthesis [11]. Moreover, for a nasal prosthesis, laser scanning provides optimal results in terms of aesthetics. At the same time, in the case of wide facial defects, digital stereophotogrammetry represents the gold standard method for data acquisition [24]. After the patient data acquisition, it is possible to design the virtual prosthesis with the aid of the acquisition of the digital data from the patient's daughter or sister/brother, similar to that in the presented case report, using specific design software, such as Geomagic studio (Geomagic Inc., Cary, NC, USA),

3-Matic (Materialise, Leuven, Belgium), Freeform Model Plus (SensAble Technologies, Boston, MA, USA), or to make use of a digital library. Implementing a digital design and using digital libraries may provide faster, repeatable, and shareable CAD models of the prosthesis. The connecting substructure of the prosthesis can also be designed with CAD technologies [20,22]. Once the virtual design of the prosthesis is completed, the process involves manufacturing the final prosthesis with silicone.

Therefore, this workflow is essential to minimize visits, for example by fabricating templates of the prosthesis volume and the substructure for a single clinical check on the patient's face. In the case presented here, it was possible to manufacture a realistic prosthesis template for a clinical try-in on the patient's face (Figure 9), using a cutting-edge 3D printing technology, previously described by our research group to build facial portions of a multi-material patient-specific simulator [25]. The great potential of such 3D printing technology is the capability of printing both rigid and rubber-like materials in a single part, so that it is possible to manufacture both the rigid substructure and the soft nasal prosthesis during the same printing process.

Several studies documented using digital design and CNC milling technologies to fabricate retentive component systems for facial prosthesis devices [26–28]. Yoshioka et al. [29] described a workflow for creating a four-dimensional (4D) facial expression model to fabricate nasal prostheses over several time points, from neutral to smiling expressions. They emphasized the importance of the prosthesis fit during patient's facial movements. The silicone processing and the intrinsic and extrinsic coloring are still made with traditional procedures; the use of colorimetry and spectrophotometry systems may provide easily acquired and repeatable skin-color matching [30].

Furthermore, previous digital protocols [15,31–33] improved other aspects of this kind of removable facial prosthesis, especially those related to stability and function.

In this study, the design of the substructure provided a four-hole retention in the rear part of the glabellar surface of the eyeglasses that ensured a stable connection by distributing the functional loads all over the connecting area. A fundamental feature of this new connection is the usage of custom-made micro screw-females inserted and relined with PMMA resin (Split-Line) in the framework of eyeglasses (Figure 6B). This new system guaranteed a more balanced load distribution without overloading a single screw.

Moreover, the laser melting 3D printing technology allowed for the manufacturing of a metal substructure with a minimal thickness (1 mm). This feature is conducive to reducing the prosthesis's weight and minimize the space necessary to overcover the underlying irregular scar skin tissue when it cannot be surgically remodeled with further plastic surgery, as in this case. At the same time, the minimal thickness of the metal substructure allowed for hiding of the metal color inside a 2 mm thickness of the final relined silicone, thus generating an over-contouring of at least 3 mm for the residual skin surface. The reduction of the silicone thickness was also essential to guarantee enough elasticity of the prosthesis that, at the peripheral margins of the defect, can quickly adapt to the muscular movements of the skin. The marginal area of the prosthesis was designed to be compressive onto the skin. This compression was created by simply designing an under-contoured margin in the digital model all around the defect that will result in a slight compressive margin of the silicone, having a significantly reduced thickness that guarantees high elasticity.

The direct relining of the silicone prosthesis straight onto the patient's face to embed the connecting substructure in the silicone is a variation of the standard molding technique and aimed to simplify the workflow. This direct relining is realized by molding only the 1 mm-thickness external volume of the designed prosthesis to obtain a silicone "glove" that is adapted to the substructure straightly positioned on the patient's face (Figure 8B). During the relining, it is necessary to maintain the prosthesis in position until the silicone processing is completed (Figure 8C), without introducing any distortion of the anatomy of the prosthesis.

In terms of costs and time reduction, this option eliminates the time for repositioning the substructure in the mold (both digitally and analogically) and the cost of manufacturing

more complex molds, except the one that is relatively simple and necessary to produce the silicone glove.

4. Conclusions

The presented case report demonstrated the feasibility of adopting an updated digital protocol for the fabrication of a facial prosthesis for those patients who cannot be rehabilitated with plastic surgery because of post-surgical complications, especially using the facial scan of the patient's daughter to reconstruct the missing nasal anatomy of the patient. The use of a metal substructure allowed us to provide a maximal reduction in thickness and weight, while preserving the rigidity of the connection to eyeglasses, and the adoption of direct silicone relining process allowed us to obtain a facial prosthesis with extremely thin silicone thickness at the borders, thus achieving optimal elastic adaptation to the facial skin during its function.

These improved features are correlated with the quality of life of the patient who may experience a new and improved social relationship, especially with cohabitant relatives. The disadvantages of the presented procedure are related to the prosthesis's intrinsic features of being removable and only wearable with eyeglasses. However, in extremely severe medical conditions, it remains a viable option to recover a respectable quality of life for cancer patients.

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Institutional Review Board Statement: The study did not require ethical approval because the treatment is part of routine care practice.

Informed Consent Statement: Informed consent was obtained from the subject involved in the study.

Data Availability Statement: The datasets generated during and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Conflicts of Interest: The authors declare no conflict of interest.

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