Updates on the Construction of an Eyeglass-Supported Nasal Prosthesis Using Computer-Aided Design and Rapid Prototyping Technology

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Abstract
This study was undertaken to design an updated connection system for an eyeglass-supported nasal prosthesis using rapid prototyping techniques. The substructure was developed with two main endpoints in mind: the connection to the silicone and the connection to the eyeglasses. The mold design was also updated; the mold was composed of various parts, each carefully designed to allow for easy release after silicone processing and to facilitate extraction of the prosthesis without any strain. The approach used in this study enabled perfect transfer of the reciprocal position of the prosthesis with respect to the eyeglasses, from the virtual to the clinical environment. Moreover, the reduction in thickness improved the flexibility of the prosthesis and promoted adaptation to the contours of the skin, even during functional movements. The method described here is a simplified and viable alternative to standard construction techniques for nasal prostheses and offers improved esthetic and functional results when no bone is available for implant-supported prostheses.

Nasal prostheses represent a viable option for patients after rhinectomy when surgical reconstruction cannot be performed due to the size of the residual defect. Two alternatives to support a nasal prosthesis exist: a craniofacial implant and eyeglasses. In the past, adhesive prostheses were widely used for small nasal defects; however, at this time, an adhesive prosthesis may not be considered a suitable solution for patients, given the risk of skin reactions and decay of the adhesion during use. Implant- and eyeglass-supported prostheses have specific indications related to the available quality and quantity of bone for inserting a craniofacial implant (i.e., tumor recurrence potential and esthetic demands). If bone is present in the glabella and the premaxilla, implants should be used to secure the nasal prosthesis to the face without any other mechanical support, giving the patient a good restorative result in terms of esthetic and social demands. However, if no anchoring implant can be inserted, an eyeglass-supported prosthesis is indicated to restore the contour of the face (Fig 1). Many approaches have been presented over the last two decades for creating a convenient and secure connection between eyeglasses and a nasal prosthesis.

Modern computer-aided design and computer-aided manufacturing (CAD/CAM) technology has facilitated customized clinical solutions, including a simplified connection between the substructure and eyeglasses. Recently, Ciocca and Scotti proposed that an oculo-facial prosthesis be secured to eyeglasses using CAD/CAM and rapid prototyped (RP) scaffold construction. The prosthesis was anchored to eyeglasses by means of strategic arms that enveloped the frame, thus connecting the volume of the ocular-facial prosthesis to the right lens frame and lateral shaft of the eyeglasses. The method also used the substructure to support the ocular bulb of the facial prosthesis.

The aim of this study was to use CAD/CAM technology to improve and simplify the protocol for constructing the connection system of an eyeglass-mounted nasal prosthesis. A sample case was used to document the procedure used for all patients.
scheduled for a nasal prosthesis when no surgical nasal reconstruction is possible and no craniofacial implant can be inserted.

**Updated construction technique**

The technique used to design and produce the prototype of the eyeglass-supported nasal prosthesis had steps similar to a previous study. Briefly, a digital impression of the entire face was made using a 3D laser scanner (3dMDface System; 3dMD Ltd., London, UK) to analyze the complete defect with all undercuts and the upper anterior part of the auricular region, where the eyeglasses rest on the ears. The use of this scanner was the first update: this scanner uses a noninvasive imaging technique and allows a 180° image to be captured (ear to ear) with a capture speed of about 1.5 ms at high resolution; thus, the patient has no difficulty maintaining a single facial expression during scanning. The scanning system generated a geometry of one continuous point cloud from the two stereo camera viewpoints, thereby eliminating the errors associated with merging/stitching datasets together (Fig 2). After the eyeglasses were scanned too, two standard triangulation language (STL) files (face and eyeglasses) were generated. To better reconstruct the nose of the patient, the digital ear and nose library may not be used if a preoperative face scan exists, or if a model (e.g., the patient’s son) is available. The nasal anatomy may be copied from one of these sources to duplicate the missing facial volume and integrate it onto the patient’s face. Once the STL files of the patient and model were integrated, and a good esthetic solution was achieved virtually, the digitized eyeglasses were superimposed using the ClayTools system (Freeform Modeling Plus software and Phantom Desktop Haptic device; Sensable, Wilmington, MA) (Fig 3). For optimal virtual eyeglass positioning, it was
necessary to print a resin model of the final nasal prosthesis for trying on the patient. The position was recorded using impression material (Occlufast CAD-CAM; Zhermack, Badia Polesine, Italy); after positioning the resin model in the facial defect, the eyeglasses were leaned in place on the resin try-in prosthesis. The reciprocal position of eyeglasses and prosthesis was registered in the glabella using the silicone impression material. The silicone position check was scanned to generate an STL file so that the informatics technician could superimpose the eyeglasses onto the nasal prosthesis in the correct clinical position.

Framework and substructure design

The main update regarded the procedure used to design the substructure. It was developed with two main endpoints in mind: (1) the connection to the silicone and (2) the connection to the eyeglasses. The first endpoint was obtained by means of a framework of polyamide resin that allowed for mechanical engagement of the silicone prosthesis to the inner holes of the framework. The design of the resin framework presented 1.2 to 2.0 mm diameter holes and a precise slot for the metal framework. The second endpoint was achieved using a laser-melted cobalt-chrome framework to engage both the eyeglasses and the polyamide substructure. This metal framework was designed to screw into the back of the interocular eyeglass frame so as to be invisible from the front. It was conceived for sustaining the main supportive forces and for this reason was prototyped in metal. Both components were produced using an RP machine (Eosint P100 Formiga; Electro Optical Systems GmbH, Munich, Germany).

Mold design

The mold design represents an updated version of a protocol described previously. This update consists of the diverse parts that composed the mold, each of which was carefully designed to allow for easy release after silicone processing and to facilitate extraction of the prosthesis without any strain. The main body (Fig 4A) of the mold was designed in two parts: the front and the back. The front was composed of two pieces (Fig 4E), the minor one for the nostrils in order to create open breathing channels (Fig 4F). The component visible in Figure 4E had to be removed first, so that the rear part of the nostrils could be disengaged during removal of the prosthesis. The back of the mold was composed of three parts (Fig 4B) in such a way that the lateral parts could be extracted first, allowing for removal of the residual central component with little force. Thus, the central part was easily removed.

Also, the retaining system was an update of previous techniques. It was designed to stabilize the substructure and metal framework at the inner mold during silicone processing. It was necessary to secure the metal framework in exactly the virtually planned position with respect to the substructure and the prosthesis. Thus, two sliding slot slices (Figs 4C and D) were created to secure the framework and substructure during molding. This is a fundamental innovative point because during silicone processing, high hydrostatic pressure is developed when the mold is pressed in the vise, and the substructure and metal framework can be consequently dislodged in the wrong position. This would, in turn, result in incongruent eyeglass-prosthesis malposition.

Discussion

The main outcome of this updated procedure for connecting a nasal prosthesis to eyeglasses was the perfect transfer of the position in the virtual environment to the actual prosthesis after molding. This connection system will simplify previous technological solutions, making it possible to position two securing screws straight in the eyeglass interocular frame without the use of other components.

A secondary result was the reduction in prosthesis weight, which was obtained by reducing the thickness by 1.7 mm in the facial part of the prosthesis. This made the facial portion of the prosthesis surface extremely flexible and similar to the consistency of natural skin when touched. This flexible portion will make it possible for the prosthesis to follow facial movements during mastication, speaking, and smiling.

New CAD/CAM technologies have led to improved approaches for the construction of nasal prostheses. In the last decade, scientists have reported the automation of impression making for nasal prostheses and diagnostic wax-up, substructure design by CAD and printing by means of RP machines, try-in automation and the elimination of stone molds, and optimized surface roughness due to changes in the surface of the prototyped mold. When a nasal prosthesis has to be stabilized in place through mechanical support (e.g., eyeglasses) rather than implants, long-term follow-up of the connection system is very important. The main features of this connection should be esthetic invisibility and sufficient mechanical support for the prosthesis during function. In this protocol, a novel substructure design for a metal framework and the connection for a nasal prosthesis were created for patients in whom no craniofacial implant could be used.

To obtain good esthetic results, two challenges had to be overcome: the design of the connection system itself and its positioning in the mold prototype. The connection was designed in two parts, one for engaging the silicone (polyamide
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Figure 4 RP of the mold. (A) the assembled mold; (B) the three parts of the back portion; (C) the resin and the metal framework in position; (D) the two-piece securing system; (E) anterior mold component for nostrils; and (F) the two components for the nostril holes.

resin framework) and one for securing the prosthesis to the eyeglasses and the resin framework (laser-melted metal structure). The polyamide resin structure was designed as a 1.5- to 2.0-mm network for mechanical retention of the silicone and engagement to the metal framework to ensure optimal distribution of the loading force between the prosthesis and eyeglasses.

To ensure sufficient mechanical support, the metal framework possesses two screw holes for retention on the eyeglass frame. In the mold, it is positioned by means of a female slot to guarantee the correct location; in the eyeglasses, it is positioned using the precise engagement with the frame. The effect of the screws on stabilization is augmented by their duplicity (two screws), making rotation impossible.

A novel system for molding is hereby proposed. As shown in Figures 4C and D, a special system for recombining the sliding parts of the mold was constructed not only to ensure the correct position but also to secure the resin/metal connection during silicone processing. Indeed, without constructing a two-piece securing system (Fig 4D), the resin/metal connection system may shift during compression when the silicone is poured into
the mold. These two sliding pistons guarantee secure engagement of the connection system in the required position due to their precise dimensions with respect to the external margin of the mold. In this way, when the mold is compressed between the two parallel planes of the vise (top and bottom), the sliding components cannot shift and remain in position.

A minor feature of this updated method is the reduction in thickness of the prosthesis. This influences the weight and peripheral margin flexibility of the silicone, allowing for optimal adaptation to the skin during physiologic functions (e.g., swallowing, speaking, and smiling). This adaptive effect is a side product of the mold design. As described by Ciocca et al.,\textsuperscript{12} the 1.5-cm marginal area of the prosthesis is CAD-modeled with a light depression (5–8 mm) toward the virtual face volume along the contact prosthesis profile with the skin. The thinness of the silicone at the periphery and the artificial depression allow for the adaptive effect during physiological function, due to the creation of flexible and compressive margins. Moreover, the reduced thickness of the entire prosthesis (apart from the nasal pyramid) confers a natural consistency to the prosthesis that mimics natural skin, and which patients usually enjoy (Fig 5). The cost of this procedure was €1200 and the working hours for the CAD technician were 34.

Limitations of this technique may be the final esthetic result, due to the use of eyeglasses and to the difficulty obtaining a correct profile when a large part of the pre-maxilla was ablated during cancer surgery. The upper lip, as presented here, may be withdrawn, resulting in a nose in disharmony with the lower portion of the face; however, even if only a partial restoration of the esthetics may be obtained, the patient is no longer obliged to wear a bandage to cover the defect and can wear his therapeutic eyeglasses.

Conclusions

The updated CAD/CAM technique used in this study to construct a novel engagement system for eyeglass-mounted nasal prostheses allows for simplification of the design and aesthetic improvement with respect to previous techniques, and it may represent a viable protocol for patients in whom no bone is available for craniofacial implants to support a nasal prosthesis.

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References