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TECHNICAL PAPER

Design and Rapid Manufacturing of anatomical prosthesis for facial rehabilitation

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Abstract In this work a novel design and manufacturing procedure have been experimented in order to improve the production of implant-supported nasal prosthesis. The complete workflow was divided into three main steps: data capture, prosthesis design and prosthesis manufacturing. First, the data capturing of the patient's face was obtained by means of 3D laser scanning. Then, design and manufacturing phases were carried out through CAD–CAM procedures and Rapid Prototyping technologies to obtain the mold for the silicone processing and the substructure for the retention of the prosthesis. Moreover, to design the customized prosthesis based on real anatomic shapes, a novel "Ear&Nose Digital Library" was developed in the framework of a multidisciplinary project with the involvement of students from medicine and engineering faculties. Advantages in terms of improvement of retention and cost reduction are presented.

Keywords Reverse Engineering · Rapid Prototyping · Prosthesis design · Facial rehabilitation

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1 Introduction

This paper presents the design and manufacturing of a customized implant-supported nasal prosthesis. In general, prosthesis is an artificial device that replaces an absent part of the human body and craniofacial prostheses are specifically developed for replacing facial defects. Such defects can be caused by disease (such as tumor), trauma or congenital defects. Craniofacial prostheses can replace almost any part of the face, but most commonly ear (auricular prosthesis), nose (nasal prosthesis) or eye (ocular prosthesis).

This research provides a contribution since it proposes a design method and reports improvements in the usability, economic and aesthetic of the product. A further contribution is related to the specific case study here experimented. It requires the design of the prosthesis based on real anatomic reference models of an "Ear&Nose Digital Library" that was created by the authors for this purpose, since the defect is central and it cannot be reconstructed by mirroring the healthy contralateral side.

The usability and efficiency of the prosthesis depends on the capability of remaining stable and connected to the healthy surface of the face, appearing as much as possible continuous to the patient's skin. Facial prostheses are held in place either by osseointegrated implants, magnets [1] or mechanically supporting frameworks (a nasal prosthesis may be rigidly attached to the eyeglasses [2,3]), biocompatible adhesives and engagement of undercuts plus skin adhesives. Among the techniques used in maxillofacial rehabilitation for the retention of nasal prostheses, the use of osseointegrated implants have significantly increased in the last decade [4]. Compared to medical adhesives or mechanical based supporting frameworks, osseointegrated implants ensure a more stable connection and reduce the risk of irritations of the skin around the defect. To this purpose, it has been observed that

extraoral implants can be successfully applied in maxillofacial facial prosthesis retention when reconstructive interventions are not possible due to the extension of the facial defect [1]. Moreover, it has been demonstrated that implant based prostheses improve the quality of life [5]. When using implants to retain the prosthesis particular attention must be paid to the connection of the soft silicone prosthesis to the metal bar that usually hosts connection elements. Therefore, the design and manufacturing of the prosthesis involves both the anatomic part and the substructure that sustains the prosthesis and connects it to the implants.

The traditional process to manufacture a removable implant-supported silicone prosthesis usually involves the following main steps:

1. surgically placing craniofacial implants into the defective region of the patient if sufficient quantity of bone is available;
2. making impression of the defective region with the placed craniofacial implants;
3. manufacturing a retention framework for supporting the prosthesis on the cast obtained by the previous impression;
4. connecting the retention framework to the craniofacial implants of the patient;
5. manufacturing the substructure manually shaped on the retention framework;
6. manually wax sculpting the nasal epithesis;
7. manufacturing the relative mold using the sculptured nasal epithesis as master pattern;
8. conventional silicone processing procedures to obtain the final removable prosthesis with the embedded substructure.

With the aim of reducing some of the shortcomings of this traditional procedure a new procedure based on the use of Time Compression Technologies (TCT) is thus proposed.

Since the Rapid Prototyping (RP) techniques can be used both to direct manufacture some parts and to produce molds, authors decided to use the direct manufacturing approach to produce the substructure and the indirect method to create the mold of the nose. Even if today there are many materials available, the direct manufacturing of the prosthesis is not yet possible due to the difficulty in the layer by layer production of an artifact that is soft enough to replace end emulate external anatomies. Thus, an original design of the connection system is presented, based on the optimization of the substructure that is then directly manufactured in ABS plastic material and hosted in the mold while casting the prosthesis.

Such virtual and physical prototyping approach increases the possibility to produce customized and easily removable prostheses, while the substructure ensures a stable connection.

The digital models of prosthesis, mold and substructure are designed by reducing the manual contribution of an anaplastologist and eliminating several steps of the traditional reconstruction procedures based on impression making and plaster casting. Remarkable results in the appearance of the prosthesis are also reported.

In the next section a brief introduction to the techniques and to their application in medicine is presented. In Sect. 3 the case study is described, while Sect. 4 provides information about the "Ear&Nose Digital Library". Section 5 deals with the CAD–CAM procedure highlighting the subdivision in single steps. Finally, 6 and 7 are the results and conclusions sections.

2 Previous work

Researchers in medical and engineering interdisciplinary projects have proposed and experimented several applications dealing with the exploitation of the most recent design and manufacturing tools, usually involved for product and process improvements [6,7]. Time Compression Technologies, such as Reverse Engineering (RE), Free Form Modeling and Rapid Prototyping have shown their potential and are now boosting the change from mostly manual procedures to industrial-like methods for the production of prosthesis and surgery support tools. Thus, the use of such technologies in the production of anatomic shapes for medical prostheses is significantly increasing, particularly in interventions for maxillofacial rehabilitation [8,9]. This application field requires the manipulation of complex shapes with morphological variations from patient to patient and the development of customized prostheses reproducing missing parts that can fit and remain attached to specific anatomies. Therefore, in the last decade, RE–RP based procedures were proposed to construct facial prostheses (in particular nasal and auricular) for those patients who underwent ablative surgery of the external epithesis for cancer or suffer from congenital absence [10–13].

Reverse Engineering techniques are used to reconstruct the digital model of the patient anatomy as it is. In medicine both reflective technologies are used, such as laser or structured light scanners, and X-ray based technologies, such as Computed Tomography (CT). Computed Tomography and other techniques based on the emissions of X-rays are capable of describing the internal volume of the human anatomy. Even if the external surface can be obtained by CT images, higher quality is obtained by the reflective systems. In some cases, internal and external data can be aligned in order to obtain a unique 3D model of the part with an improved external surface [14,15]. In this paper we use a 3D laser scanner since just the external surface of the defect must be acquired in order to design the prosthesis.

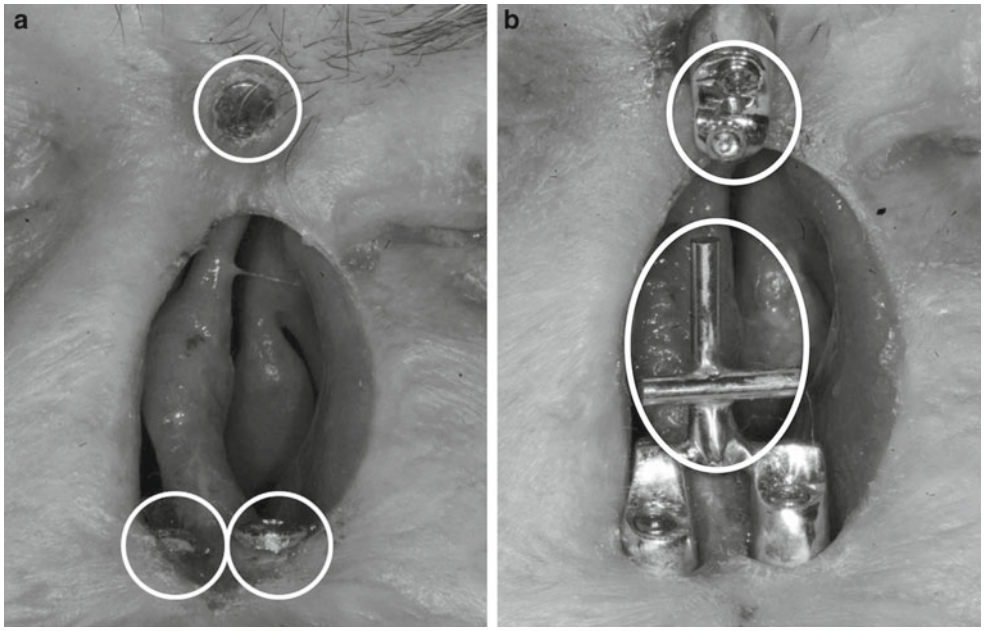

Fig. 1 **a** The three craniofacial implants placed in the nasal residual defect. **b** The cross-shaped metal bar and the custom-made ball attachment to retain the prosthesis

Rapid Prototyping and Rapid Manufacturing are successfully implemented in the production of models of human body parts since they meet the principal characteristics of biological models. These are mainly concerned with complex morphologies and high customization. In the field of prostheses manufacturing Rapid Prototyping refers to the use of additive manufacturing technologies that directly produce the artifact. Rapid Manufacturing concerns the layer-by-layer construction of tools, mainly molds, to be used in the production process. The different systems are characterized by the material and by the method applied to materialize and join the single layers. In medical applications selective laser sintering (SLS), selective laser melting (SLM), fused depositing modeling (FDM) are predominantly employed in the fabrication of implants, prostheses and scaffolds [16]. Nevertheless, other techniques are applied, such as the direct metal laser sintering (DMLS) and the electronic beam melting (EBM).

Besides the advantages measured in the precision of the missing anatomies manufactured by RP, improvements in medical procedures, such as time and cost reductions or process repeatability, are observed.

3 Case study

In this case study, a man with a total rhinectomy (surgical removal of the entire nose) was scheduled for prosthetic rehabilitation after a failed attempt to surgically reconstruct the epithesis.

First, three craniofacial implants were surgically placed in the nasal residual defect. In particular, two implants were positioned in the anterior nasal floor and one more craniofacial implant was added in the glabellar region (Fig. 1a). Then, after a healing period of six months, a traditional impression of the defective region with the implants was made to allow the manufacturing of a customized framework according to the previously placed craniofacial implants for the retention of the silicone prosthesis. The framework was manufactured in two parts in a conventional manner: a cross-shaped metal bar was connected to both the implant abutments in the anterior nasal floor and a custom-made ball attachment was created for stabilizing the nasal prosthesis also in the glabella abutment (Fig. 1b).

4 The “Ear&Nose Digital Library”

To facilitate the design of customized prostheses based on actual anatomic shapes, the development of a novel “Ear&Nose Digital Library” was conceived and supervised by the authors.

First, a physical library was created by anatomic stone models of ears or noses collected during the annual hands-on educational course of “Maxillofacial Prosthodontics” at the Dental School of the University of Bologna (Fig. 2). Students were requested to provide the physical models by applying the traditional procedures of impression making and plaster casting on themselves, reporting on the casts general information such as age, sex, height and weight.

Fig. 2 Some samples of anatomic stone models of ears and noses

Then, stone models were digitalized and collected to create the "Ear&Nose Digital Library" (Fig. 3) during the annual hands-on educational course of "Product Design" for the students of the Faculties of Mechanical and Biomedical Engineering of the University of Bologna. Data acquisition was carried out using Vivid-9i 3D laser scanner (Konica Minolta Sensing, Osaka, Japan) and post-processing was completed by Rapidform XOS2 (INUS Technology Inc., Seoul, Korea). Additional anthropometrical parameters directly measured on the 3d models, such as nasal height and nasal width, were also added to the previously recorded general information.

Since every year new students of medicine and engineering are involved in this project, the amount of both physical and virtual models is increasing year by year, even if they are limited to the age range of these young students.

The main advantage in using this library is that clinicians and CAD designers can choose in a collaborative way a reference model according to the anatomy of the patient in terms of both size and shape, for such cases where no symmetric volume may be mirrored to develop the prosthesis. Previous photos of the patient or relatives can be usefully used for selecting a first short list of available 3D nasal models. In fact, without the reference digital models of the "Ear&Nose Digital Library", it would not be possible to develop prostheses without involving a skilled anaplastologist who works the wax to model anatomic sculpts. However, this kind of manual work is expensive and time consuming so that it is not possible to provide a set of different solutions for choosing the final prosthesis. On the other hand, the "Ear&Nose Digital Library" allows a virtual approach in the esthetic evaluation of the prosthetic rehabilitation by superimposing different reference models onto the 3D face of the patient. This approach based on a virtual try-in allow clinicians and CAD designers operating in a collaborative environment to interactively define the final shape of the nose.

Especially in such cases where the defect is limited to a mid-face (e.g. the absence of one ear) a symmetry-based approach by mirroring the contralateral healthy side (with respect to the mid-sagittal plane) onto the defective region may be attempted to develop the prosthesis.

Moreover, when a surgical excision of an epithesis is planned on the basis of clinician considerations (e.g. due to the presence of a tumor), it is always recommended to carry out a laser scanning of the epithesis before the intervention for surgical removal. In such way the digital model of the pre-surgical anatomy may be used to design the replacing prosthesis. Although any possible morphological alterations to the external volume caused by the tumor will be reported in the digital model, all the necessary corrections may be carried out by virtual modeling to design the final proper prosthesis.

Finally, when large facial defects are present (e.g. involving nasal epithesis and one of the two oculofacial regions) a combined approach may be used. In such cases the prosthesis to replace the volume of the defect may be designed by mirroring the corresponding portion of the contralateral healthy side and adding a digitalized anatomic nose from the digital library.

5 CAD–CAM procedure

The workflow of the CAD–CAM procedure to develop the nasal prosthesis is shown in Fig. 4 and is based on three main steps: data capture, prosthesis design and prosthesis manufacturing. In the step of "Prosthesis Design" there is the external link to the "Ear&Nose Digital Library".

5.1 Data capture

First, the whole face of the patient was digitalized using a NextEngine Desktop 3D Scanner (NextEngine, Santa Monica, CA, USA) at the Maxillofacial Prosthesis Section of the Department of Oral Sciences—University of Bologna. During the 3D acquisition, the patient was asked to maintain the head firmly positioned in the headrest and not smile, keeping the maxillary arches closed in the maximal intercuspal position. The patient's eyes were also covered with a protective anti-UV device even if the class 1M laser beam allows eye-safe scanning. Anyway, it is very difficult to achieve a complete acquisition of the interior part of the defect to allow a correct 3D reconstruction of the retention framework.

Therefore, to overcome this problem, a conventional impression of defect and framework with bar/ball attachments was also taken. Then, the framework was disconnected from the implants and connected on the cast obtained the by this impression. The cast was digitalized using a Konica Minolta VI-9i laser scanner (Konica Minolta Sensing, Osaka, Japan) at the Virtual Reality and Simulation Laboratory of

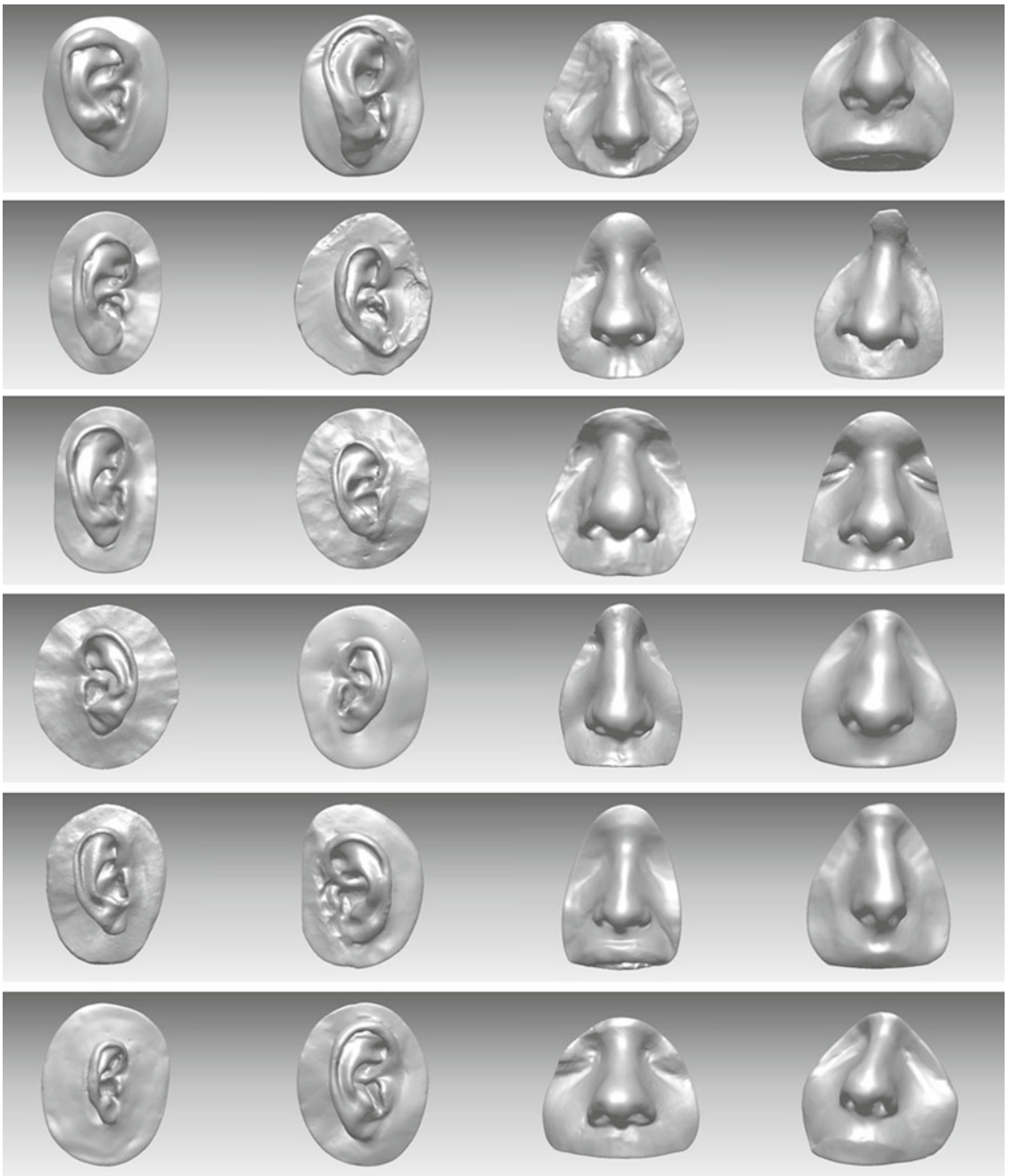

Fig. 3 Some samples of anatomic 3D models of ears and noses of the "Ear&Nose Digital Library"

the Second Faculty of Engineering—University of Bologna. The cross-shaped metal bar and the custom-made ball attachment connected to the implants were coated with talc powder to reduce problems during the scan process due to the highly reflective material of the framework.

In both cases, to obtain a 3D model of the patient's face and of the impression of the defect with the framework, post-processing was completed using Rapidform XOS2 (INUS Technology Inc., Seoul, Korea) (Fig. 5a,b). The framework for the retention of the silicone prosthesis was also remodeled by primitive solid features using Rhino 4.0 (Robert McNeel & Associates, Seattle, WA, USA) since size and shape was exactly known.

5.2 Prosthesis design

First of all, a virtual comparison between a short list of selected reference noses of the "Ear&Nose Digital Library"

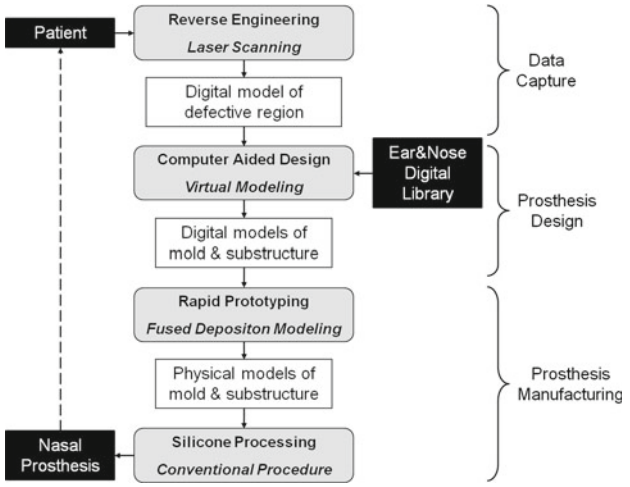

Fig. 4 Workflow of the CAD–CAM procedure

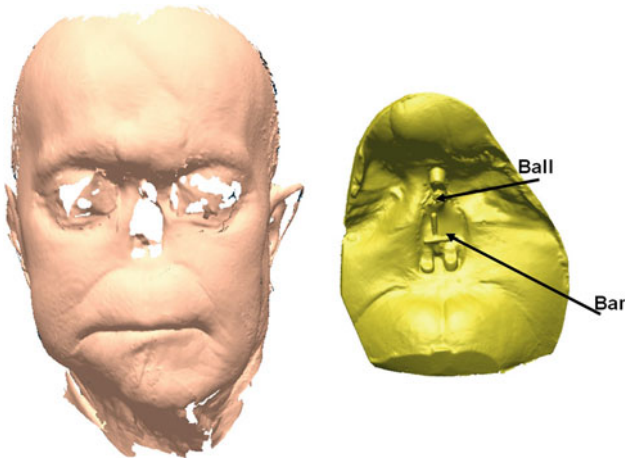

Fig. 5 Digital model of the patient's face and of the impression of the defect with bar/ball attachments

was made from an esthetic point of view before proceeding with the design of the definitive prosthesis. The simplest way to analyze and evaluate the different proposals for the members of the multidisciplinary team involved in the process is to interact with them. This was achieved by simply replacing onto the digital model of the face the pre-aligned 3D nasal shapes (Fig. 6). Also the patient can be involved in this process of decision making for what concern the choice of the digital model to be used for design the final customized prosthesis of the nose and develop the relative mold and substructure.

The 3D nose superimposed onto the digital face of the patient was then iteratively adapted to completely cover the defect. The prosthesis was designed with a thickness of 5 mm and the holes for the nostrils were added. The contact profile was also modeled to assure the proper adhesion of the prosthesis since the lateral margin was thinned and blended with the adjacent skin. These steps of the design process are carried out by the CAD designer and validated by the clinician who is the person in charge for delivering the prosthesis to the patient.

After the digital model of the prosthesis was completed, the relative substructure was designed taking into account the available volume and the position of the framework with the retention function (cross-shaped metal bar and custom-made ball attachment). The substructure should be entirely contained in the silicone prosthesis with at least a 2 mm thickness from the external surface, for not disturbing the final color of the silicone. Moreover, undercuts and holes were also added to the main body of the substructure to guarantee its mechanical fixing inside the silicone prosthesis. This original substructure was also designed to host, in the inner part, the bar-clip to be connected to the cross-shaped metal bar and the ball-cap to be coupled to the custom-made ball of the framework.

All the elements composing the removable prosthesis are shown in Fig. 7. The substructure containing the retaining elements (ball-cap and bar-clip) is embedded in the real silicone epithesis. This structure will easily allow removal operations of the prosthesis for cleaning and maintenance operations.

Both the retaining elements are commercially available while the substructure can be built by means of additive processes following a direct manufacturing approach. On the other hand, for what concern the silicone epithesis, two different approaches can be followed to produce the mold to be used during the conventional silicone processing procedures. In the indirect tooling method (pattern-based) the additive process builds the master pattern then used to produce the mold, while in the direct tooling method the additive process directly builds the mold. In the first method no further CAD operations are necessary since the designed nasal shape can be directly prototyped and then used as master pattern. Otherwise, choosing the second method the number of manual steps to obtain the silicone prosthesis are reduced since the prototyped mold can be directly used for silicone processing.

Therefore, the negative volume of the nasal prosthesis was provided in order to directly design the corresponding mold. The upper part was defined as the external custom-designed volume of the prosthesis. The lower part was represented as the defective region with the implants and the framework for the retention of the prosthesis. This element was also subdivided into two more parts (external and central) to facilitate the extraction of the prosthesis with the embedded substructure reducing the risk of silicone tear. Moreover, macro engagements in the mold, such as the designed shapes of the nostrils, were also added to guarantee a secure seal and positioning of the different parts of the mold during silicone processing procedures (Fig. 8).

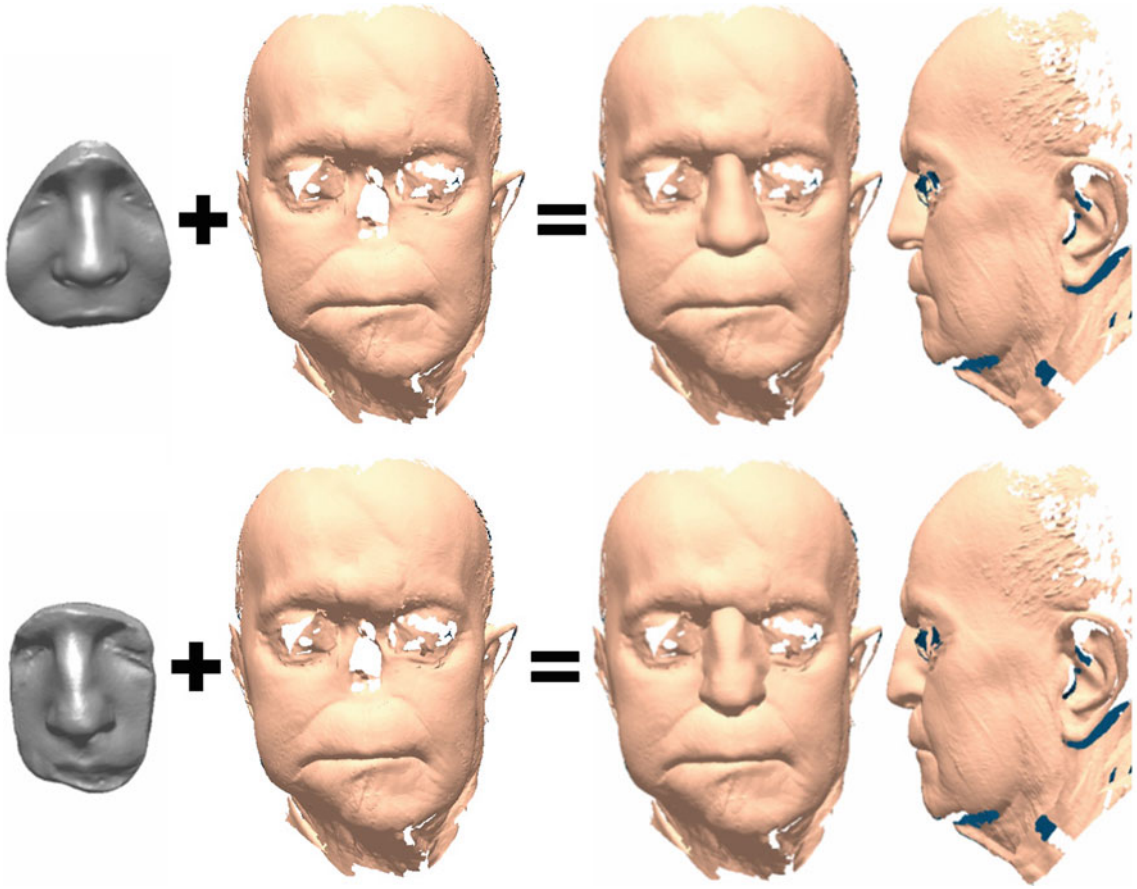

Fig. 6 3D reference models of the "Ear&Nose Digital Library" selected for the virtual try-in after adapting to the defect

5.3 Prosthesis manufacturing

The digital models of mold and substructure were exported in STL format (standard interface for RP systems) and directly manufactured in a single work session by means of dimension SST (Soluble Support Technology; Stratasys Inc., Eden Prairie, MN, USA).

The additive Rapid Prototyping process of Dimension SST is based on fused deposition modeling (FDM) by the deposition of both fused Acrylonitrile Butadiene Styrene (ABS) plastic material and soluble support material to sustain overhanging parts under construction. The prototype is built up layer by layer with a thickness of 0.254 mm each. The management software Catalyst (Stratasys, Eden Prairie, MN, USA) allows choosing between solid and sparse fill option. In the first case, each cross-section through the model is entirely filled with ABS material. In the second one, the inner part of the model is replaced with a kind of honeycomb structure. As result of these two different options, solid fills are stronger and heavier while sparse fills are weaker and lighter. Moreover, the honeycomb structure allows saving material and speeding up the build process. Finally, an automated support removal process for hands-free model completion is also provided by an agitation system with hot soapy water bath.

In this case study, the prototyping session was launched choosing sparse fill option for the mold and solid fill option for the relative substructure to obtain a stronger element. Finally, the process was completed by washing the models to remove the support material and obtain the final ABS parts (Fig. 9).

Then, conventional silicone processing procedures were carried out to obtain the final prosthesis. The ABS substructure was positioned in the lower part of the mold and connected to the prototyped framework before starting the silicone processing. The silicone was then squeezed out by a syringe tool to completely fill the mold and envelop the substructure avoiding the formation of any bubbles or voids. The mold was closed and placed under a press for four hours to make the silicone harden. Afterwards, the mold was opened and the prosthesis was carefully extracted with the embedded substructure trying to avoid damages and tears of the thin layer of silicone cartilage. The prosthesis was also refined by trimming all silicone excess at the margins (Fig. 10a). Once the silicone epithesis was ready, the ball-cap (Fig. 10b) and

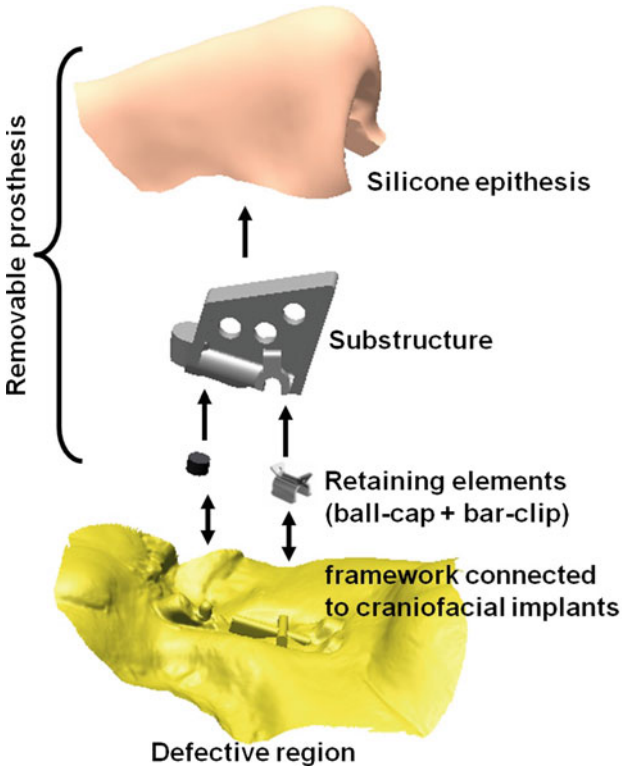

Fig. 7 View of the elements composing the removable prosthesis

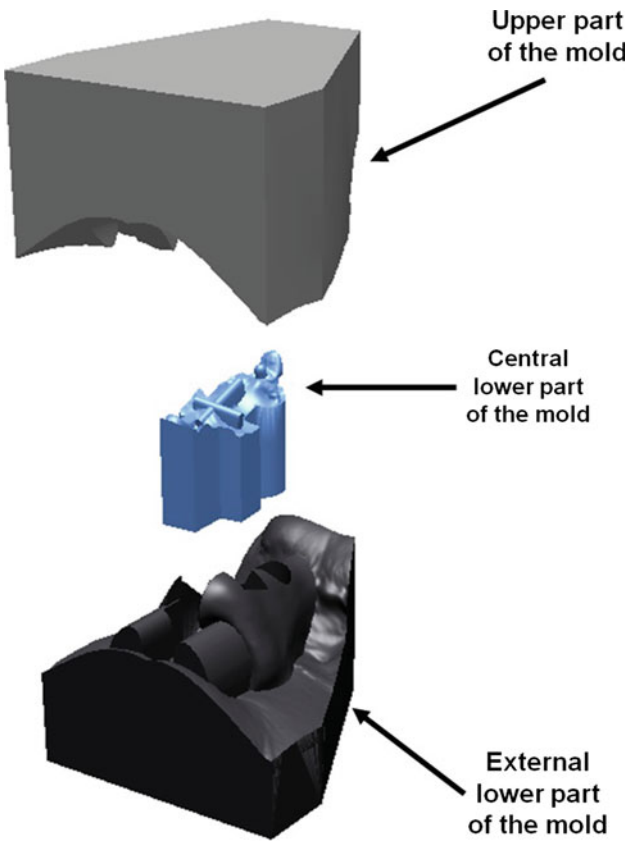

Fig. 8 Digital models of the three-part mold

the ball-cap (Fig. 10c) were glued in the inner part of the substructure to be firmly connected to the framework on the craniofacial implants of the patient.

Finally, after coloring to obtain a more realistic appearance, the prosthesis was ready for delivering.

6 Results

The design of the prosthesis based on real anatomic models of the "Ear&Nose Digital Library" offered the possibility to virtually evaluate the esthetic appearance of different prosthetic solutions. This resulted in a better choice of the reference model to be adapted to the defect that was actually appreciated by the patient (Fig. 11).

As for stability, the precise positioning of the substructure into the mold was obtained by the connection to the prototyped framework embedded in the mold basis. The mold resulted in a stable and secured position during silicone processing for the presence of engagements. The retention of the substructure into the silicone prosthesis was assured by the original design with the presence of features such as holes and undercuts. Therefore, according to the positive feedback obtained by the patient, we can affirm that this design

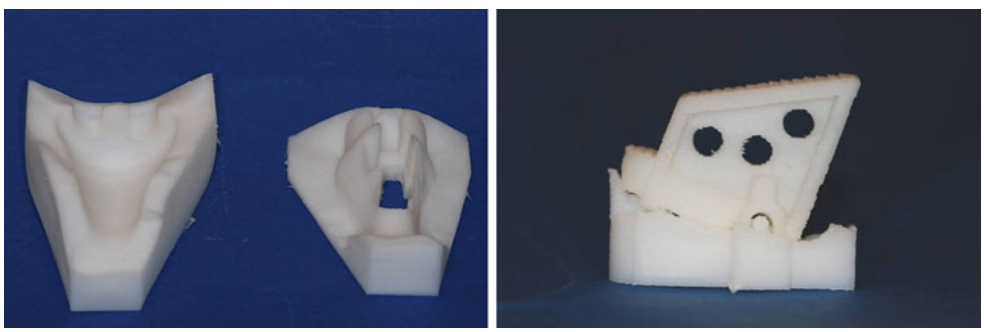

Fig. 9 Physical models of three-part mold and substructure

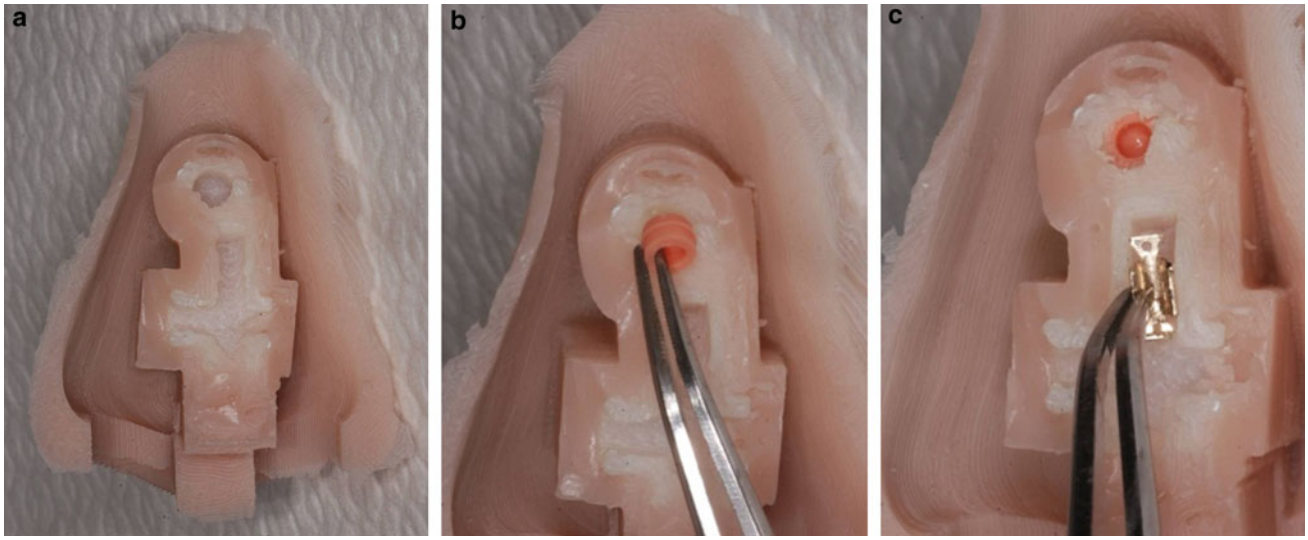

Fig. 10 **a** Final prosthesis with the embedded substructure before gluing the bar-clip and the ball-cap. **b** Gluing the ball-cap. **c** Gluing the bar-clip

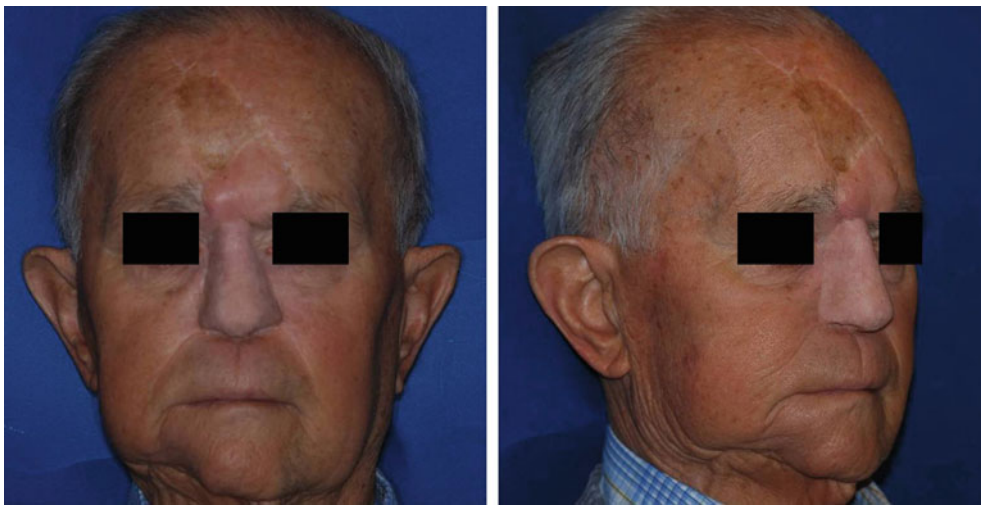

Fig. 11 Application and try-in of the nasal prosthesis before the extrinsic coloring to obtain the final realistic appearance

and manufacturing method ensures a correct retention of the prostheses. Also the removal operations of the prosthesis for cleaning and maintenance are easily conducted by the patient without any risk of damages.

7 Discussion

The main advantages of this CAD–CAM procedure for the construction of nasal prosthesis are listed below.

Concerning the data capture, eye-safe laser scanning is very comfortable for the patient since a virtual impression is obtained without any contact. On the other hand, traditional impression making procedures can cause patient discomfort and stress due to the intensive contact of impression material on the face. Moreover, the pressure, that must be applied to assure the required quality of the cast, inherently deforms the soft tissues precluding an accurate replica of the anatomy of the face. Recently, laser scanners were simplified and cost reduced, allowing the clinicians easily using these systems for making a virtual impression of the patient's face in the same medical department of the hospital, where the surgery is carried out. Therefore, the use of CT for the 3D reconstruction of the digital model of the face is not needed at all. It is also important to remember that CT scanning is more invasive than 3D laser scanning due to X-ray exposure for the patient.

Concerning the design of the prosthesis, the main contribution of this work is the use of the "Ear&Nose Digital Library" created for this purpose. Clinicians and CAD designers can choose different digital models according to the correct anatomy of the patient in terms of both size and

Table 1 Cost comparison

	Cost of CAD–CAM procedure (€)	Notes	Cost of manual procedure (€)	Notes
CAD designer	250.00		–	
Substructure	12.00	Manufactured by Rapid Prototyping	120.00	Manufactured by a technician
Mold	60.00	Manufactured by Rapid Prototyping	600.00	Manufactured by an anaplastologist
Silicone	4.00		4.00	
Bar clips–ball cap	32.00		32.00	
Total	358.00		756.00	

Direct cost of implants and connected framework are not listed since they are the same for both procedures

Table 2 Time requirements

Steps	Sub-steps	With patient	Without patient	Total
Reverse Engineering	3D laser scanning of the face	40 min		40 min
Computer Aided Design			6 h	6 h
Rapid Prototyping	Building time		7 h[a]	7 h[a]
	Washing time		6 h[a]	6 h[a]
Silicone processing	Silicone injection		20 min	20 min
	Silicone harden		4 h[a]	4 h[a]
Clips connection			20 min	20 min
Extrinsic coloring		3 h		3 h
	Total	3 h 40 min	23 h 40 min	27 h 20 min

[a] These operations do not need the presence of the operator

shape. A virtual try-in can be also carried out to evaluate, from a qualitative point of view, the better reference model to design the final prosthesis. In this case study, since the entire nose was missing, a symmetry-based approach by mirroring the contralateral healthy side onto the defective region was not possible. Therefore, without the reference model of the "Ear&Nose Digital Library" it would not have been possible to carry out the design of the nasal prosthesis based on real anatomic shapes rather than standardized and simplified models.

Concerning the manufacturing of the prosthesis, this procedure involves Rapid Prototyping technologies to directly fabricate the mold for silicone processing and the substructure to retain the prosthesis. The FDM 3D printer, employed in this project, produces models in ABS plastic material without requiring additional fabrication processes. Models are very stable and resistant for this kind of applications due to mechanical and thermal properties. Therefore, the overall process efficiency and repeatability is increased by directly obtaining both reusable mold and any needed substructures to be used every time the prosthesis has to be reconstructed. The disadvantage of this material deposition technique is the lack of a correct surface roughness because of the staircase effect owing to the thickness of the layers. To reduce the impact of the staircase effect, the CAD technician should orient the STL model properly during the building process to limit this problem and to improve the surface resolution of the mold. Therefore, this growing direction should be parallel to the long axis of the nose.

Advantages in terms of cost reduction between CAD–CAM and manual procedures are shown in Table 1. In this application we observe that the RP manufactured prosthesis costs 50 % less then the traditionally produced one.

Finally, in Table 2 the time requirements for delivering a customized prosthesis after the surgery and the following healing period are listed. Compared to the conventional manual procedure also the try-in time on the patient's face is reduced, because the clinician need only three appointments to deliver the prosthesis (1st: conventional impressions of the defective region with the placed implants; 2nd: connection of the framework to the implants, conventional impressions of the defective region with the framework and laser scanning of the face; 3rd: extrinsic coloring of the silicone and delivering of the prosthesis).

Tools and methods are applied in order to favor the collaboration among the different persons involved in the process described in Fig. 4. With the aim to highlight the level of interactivity we should identify the decision points, the people who act in such steps and which is the competence or the feed back provided by each person. The total impact of the interactivity can be measured as the amount of collaborative activities performed versus the total amount of work needed

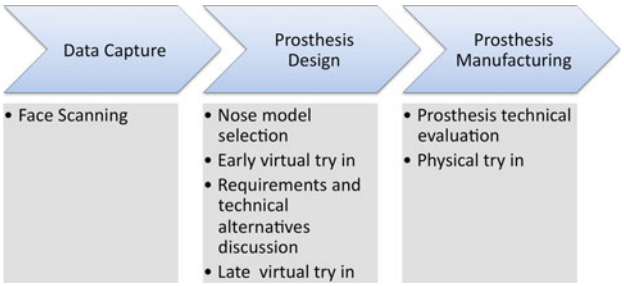

Fig. 12 Map of the main interactive tasks in the design and manufacturing procedure

to complete the prosthesis design and manufacturing. The patient and the engineer take part to the data capture phase. This is just a technical collaboration and the out coming (the virtual model of the defective region) depends on the ability of the person who operates the laser scanner. Laser scanner and RE software are used. On the other hand, the first part of the prosthesis design phase is strongly collaborative since it requires the completion of three tasks: choice of the virtual nose from the library, physical constrains evaluation and aesthetic try in on the virtual representation. The selection of the replacing anatomy is supported by a 3D navigation tool, while the virtual try in is enhanced by the possibility of observing the face-nose assembly in the CAID interface. An early virtual try in can be performed in this point, in order to check the general fit of the nose to the defect. In the second phase of the prosthesis design engineers and clinicians can discuss on the technical solutions applied in the design of the substructure, that should meet some set requirements and be engineered in order to optimize different aspects, such as interfacing with the retention framework and visibility under the silicone layer. Once the virtual model of the prosthesis is ready a late try in can be performed. In this point also the patient could provide a feed back on the aesthetic effect of the planned result. At the end of the manufacturing phase the patient and the operators evaluate the delivered prosthesis. First the clinicians verify that the final product meets the technical requirements. Afterwards, the physical try in of the prosthesis is proposed to the patient, that is asked to provide a feedback on the aesthetic appearance, on the retention feeling and on the quality of the wear and remove operations. The interactive tasks in the whole process are mapped in Fig. 12.

To complete the whole process two further steps can be added to enhance the collaborative approach between engineers and clinicians, one at the beginning and the other at the end of the workflow described in this paper.

At the beginning of the process, as usual in dentistry, the planning of the implant position (two implants positioned in the anterior nasal floor and one more craniofacial implant added in the glabellar region) can be obtained using software for virtual implant surgery by the clinician. Then, the virtual planning can be transferred in a free-form CAD modeling software by the engineer for the design of the surgical guide for bone drilling. This surgical device can be manufactured by Rapid Prototyping systems and can be provided to the surgeon in order to replicate in the operative room the virtual planning. An accuracy evaluation between the planned and the placed final position of each implant can finally carried out by measuring the inclination of the axis of the implant (angular deviation) and the position of the apex of the implant (deviation at apex), as described by the authors in [17].

At the end of the process, after the firmly connection of the prosthesis to the framework on the craniofacial implants, a further step of data acquisition of the whole face of the patient can be carried out by means of 3D laser scanning. Post-processing will allow to obtain a 3D model of the patient's face plus customized prosthesis. Therefore, to evaluate the accuracy of the whole process a comparison between planned shape and position and final shape and position of the customized prosthesis can be carried out. A quantitative evaluation can be obtained by a surface deviation analysis after the registration process between the 3D models.

8 Conclusions

Several studies in the past decade focused on customized facial prostheses construction using various approaches. However, the problem of design well-fitting prostheses reducing patient discomfort and stress are challenging. This paper described a protocol that can be used to produce customized implant-supported nasal prostheses for maxillofacial rehabilitation.

The virtual and physical prototyping approach based on the novel "Ear&Nose Digital Library" of real anatomic models represents the end of the old way to construct facial prostheses using anaplastologists, wax and stone, as described by founders of Maxillofacial Prosthodontics. A new era of cooperative and collaborative work among engineers, clinicians, surgeons, and prosthetic designers paved the way for efficient exploitation of available tools and technologies, such as Reverse Engineering, Computer Aided Design and Rapid Prototyping.

A main common aspect between industrial products and facial prostheses development processes are the use of the same modeling and manufacturing tools in a creative and knowledge based process. Therefore, facial prostheses need to be engineered in order to gather valuable results in the field of maxillofacial rehabilitation.

The multidisciplinary nature of this project, involving both engineers and clinicians, has offered the opportunity to share innovative technologies opening the way towards new solutions in the field of the prosthetic maxillofacial rehabilitation.

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