MEDICAL DEVICE FOR TREATMENT OF CLEFT LIP AND CLEFT PALATE AFTER SURGICAL PROCEDURE

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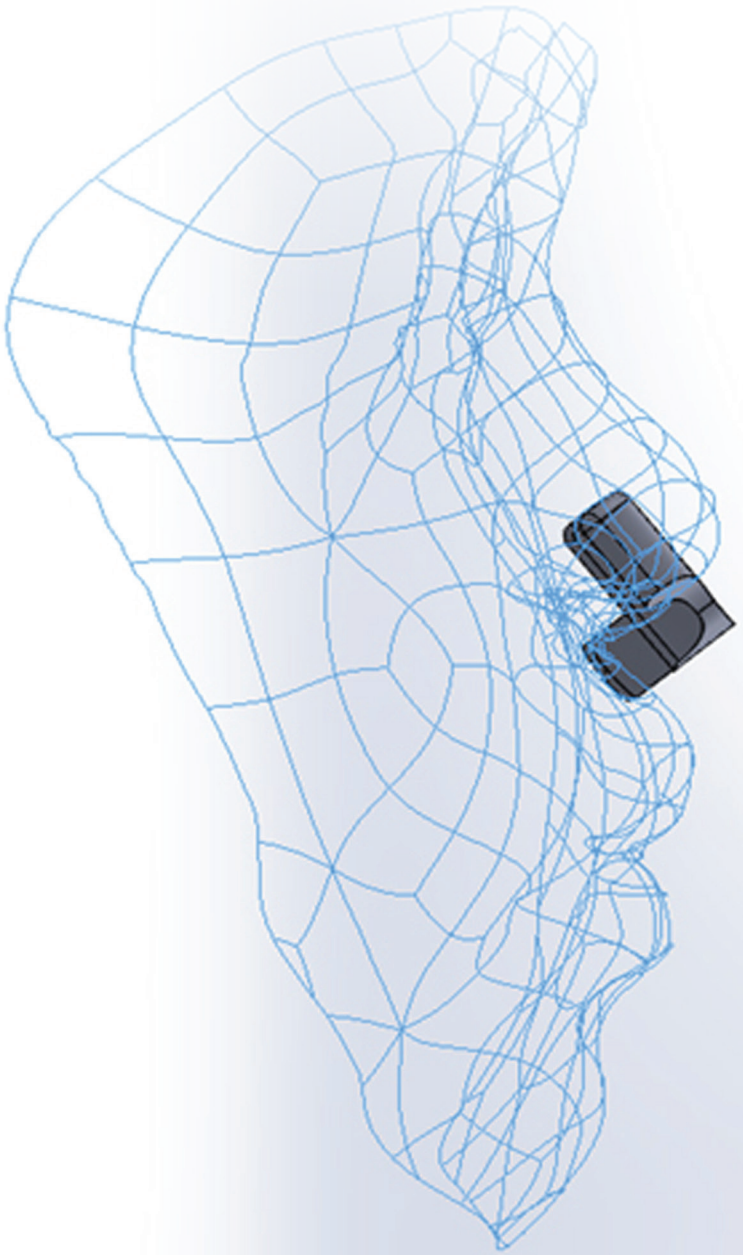

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ABSTRACT

The Cleft Lip and Cleft Palate condition has a low incidence in the population, between 0.014 and 0.2% of births worldwide. However, this illness requires that the patients undergo several surgeries throughout their life; therefore, it has a high impact at physiological and psychological level. The devices normally used are not effective because they offer little ergonomic support, which causes damage to tissues and allergies on infants who are attending on pre-surgical and post-surgical treatments, causing a less positive effect of the treatment. The project is intended to design a proposal post-surgical support device for treatment of cleft lip and cleft palate. The determination of design requirements was detected by interviewing doctors and parents. Subsequently, different 3D technologies were used to capture the face of an infant with the condition and final three proposal devices were modeled. The prototypes were constructed with three different printers and materials, the best result was found by using the PA 2200 material on the EOSINT P 730 printer. The results showed that two out of three devices were well-welcomed by the interviewers, noting that one could be used during the day and the other one at night.

RESUMEN

El padecimiento de labio leporino y paladar hendido posee una baja incidencia en la población, entre 0.014% y 0.2% de los nacimientos a nivel mundial. Sin embargo, el paciente que posee la condición debe someterse a varias intervenciones quirúrgicas a lo largo de su vida. Actualmente, se emplean soportes poco ergonómicos que provocan daño en los tejidos y alergias en los infantes atendidos en los tratamientos pre y post quirúrgicos, causando un efecto no tan positivo en el tratamiento. El proyecto busca diseñar una propuesta para un dispositivo de soporte post quirúrgico para el tratamiento de labio leporino y paladar hendido. Las determinaciones de los requerimientos de diseño se detectaron por medio de encuestas a médicos y padres de familia; seguidamente, se emplearon diferentes tecnologías 3D para capturar el rostro de un infante con el padecimiento; después, se prosiguió a modelar las tres propuestas finales de dispositivo. Los prototipos se imprimieron con tres diferentes impresoras y materiales, el mejor acabado se obtuvo empleando como material el PA 2200 en la impresora EOSINT P 730. Los resultados mostraron que dos de los tres dispositivos fueron aceptados por los entrevistados, señalando que uno podría ser usado durante el día y el otro durante la noche.

Keywords:

Cleft Lip, Cleft Palate, 3D technologies, 3D images, medical device, prototyping.

Palabras clave:

labio leporino, labio paladar hendido, tecnologías en 3D, imágenes 3D, dispositivo médico, prototipado.

Introduction:

Cleft lip and cleft palate (CL&CP) are disruptions immediately present on the face structure. This disease has an incidence of infant mortality in children from third world countries [1]. The patient with cleft lip and cleft palate suffers problems in speaking, feeding, listening and social integration, among others. These facial and oral malformations can be corrected through several surgeries, dental treatment, speech therapy and psychological support [1].

The most common patterns of CL&CP involve a physical separation of the two sides of the upper lip, spreading inside the nostrils and/or palate (hard and soft tissues). Studies about the malformation have mentioned that the indents which imply backwards structures (clef lip and cleft palate), could be originated due to genetic and embryological matters involving only the secondary palate. Although there are a lot of disorders that affect all the craniofacial tissues, the overwhelming majority involves the upper lip and/or the palate [1].

Cleft lip and cleft palate requires surgical treatments with the objective to improve the aesthetics of patients, eliminate the difficulty to eat, speaking issues, occlusion, crossed bite and lost teeth [2]. These surgical procedures are performed between three and four months of patients' age to produce the join of their lips; afterwards, a surgery is done to close the mouth roof separation between 18 to 24 months of age. Depending on the severity of the malformation the patient could need more surgeries [3].

Some countries have in place a pre-surgery treatment that is a passive method called nosealveolar molding [4]. This method joins the lip and the alveolus applying force through the direction of growth. The main goal of this treatment is to reduce the severity of the initial deformity and improve long-term nasal symmetry before the corrective surgery.

Post-surgery deformities of one-sited and two-sided cleft lip and cleft palate are common on patients. In several cases, this situation occurs due to the tissues and skin softness, incorrect surgery planning or delayed surgeries [5]. Examples of deformities post-surgery are shown in Figure 1.

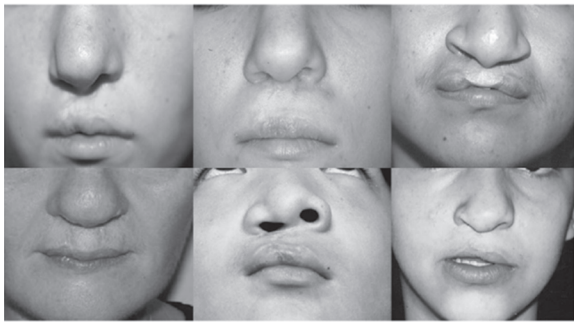

Figure 1. Deformities present on patients after surgeries of cleft lip and cleft palate [6].

Generally, two types of devices are used to correct the nose misalignment: passive and active devices. Active devices are fixed in the intraoral way pulling the tissues through mechanical forces using elastic chains, screws and plates (Figure 2a). Passive devices maintain the distance between the maxillary segments, whereas the external force is applied to change the rear position. The device of nose alveolar molding (Figure 2b) is a well elaborated passive device which consists in an acrylic plate intraoral fixed with elastic extraorals and glue tape. Wire stabilizers are added to apply force prolonging the vestibule of the nostrils and elongation of the nose columella.

A)

B)

Figure 2. Examples of devices normally used on patients. A) External Maxillary Support. B) Molding Nosealveolar Device [3].

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The current study is intended to develop a prototype of an ergonomic medical device for the treatment of cleft lip and cleft palate on post-surgery patients by 3D technologies using different printers and materials.

Materials and methods

In general terms, the model used to develop this medical device follows the design control FDA proposal to assure that the specific design requirements were met as requested by the FDA el 21CFR 820.3 [6]. It is observed in Figure 3 that the design phases are an activate cycle in which there is a constant revision of the results, and those results will serve as input requirements for the next one. That verification and validation processes should be used to ensure compliance with design and use requirements respectively [7,8].

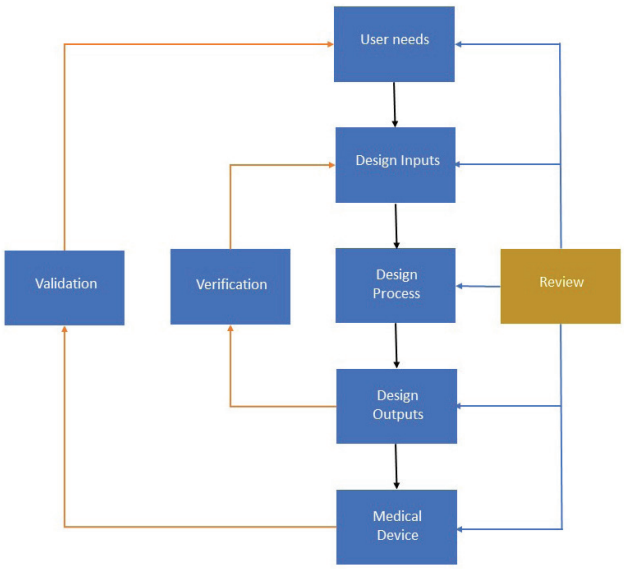

Figure 3. Phases of control design, diagram based on the FDA control design guide [7].

For the development of this process it was necessary to obtain the specifications of the product throughout surveys to internal medicine specialists and maxillofacial surgery, also to the parents and experts in the post-surgical treatment (The Association Pro Child with Cleft lip and Cleft Palate are experts in the post-operative treatment). It was identified that the designs must be ergonomic and functional by providing support to the nasal septum. Moreover, it should be aesthetically attractive to have the infant wearing it for as long as possible. Additionally, the device must be capable to adapt to the patient so that there are the least amount of usage restrictions and to have a user-friendly interface.

For obtaining a three-dimensional image of an infant with the condition, three tests were made with three different technologies to capture the image that can be used for the device design. The technologies used were the ItSeez3D app, 123D Catch app and the software Design X that uses the scanner REVScan of Creaform. Later, the prototype design was made using SolidWorks® software from Dassault Systems.

In order to have physical prototypes to show to the parents, doctors and experts, and to obtain their feedback, it was necessary to obtain 3D impressions of them. A print service search was performed, each service used a compatible material with the 3D printer model. PC-ABS plastic on a Stratasys Fortus 360mc printer, Ninja-Flex material with a Printrbot printer and PA 2200 polymer on EOSINT P730 printer were used.

Results

First, the ItSeez3D app was used which required a mobile device (tablet or cell phone) to capture the 3D image of the object (Figure 4a); however due to its low resolution and that the infant could not keep still for the required time, a digital file could not be used for modelling. With the 123D Catch app, a better resolution was obtained (Figure 4b), in which a series of digital photographs captured from different angles to generate the 3D image are superimposed. Despite of having a better resolution while the infant remained asleep, the result was still far from the requirements to be employed in the design software. Finally, the software Design X that uses the scanner REVScan of Creaform generated an image with the resolution of surface that was

adequate to be used in the design of the devices (Figure 4c).

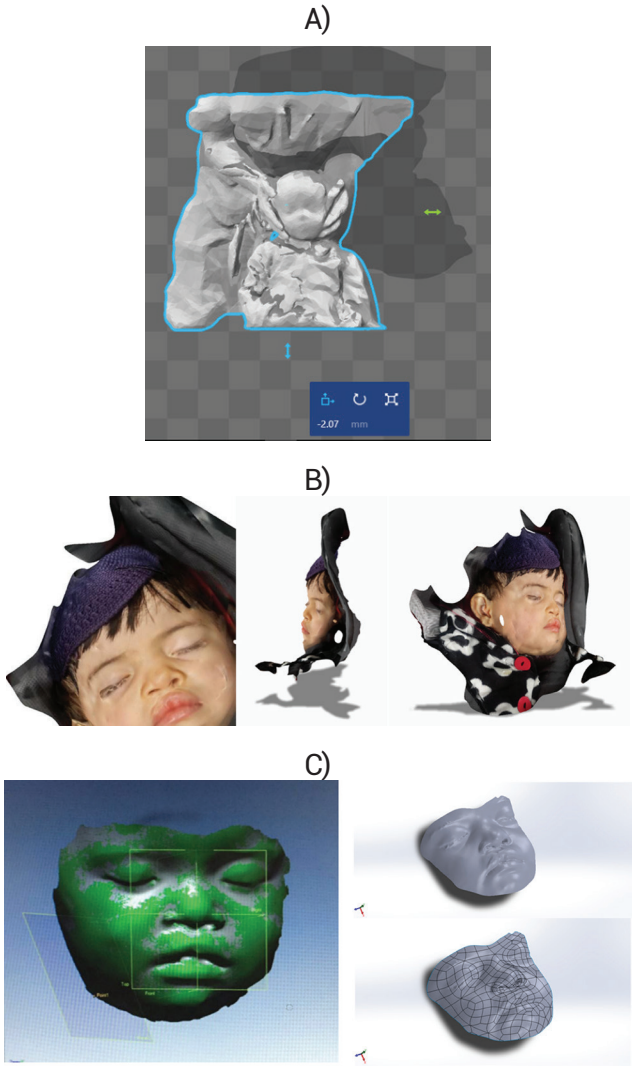

Figure 4. Scanning image of a child with CL&CP from a) ItSeez3D app, b) 123D Catch app and c) Design X software.

Prototype design was used to identify the patient's nostrils and the dimensions of the device based on the size, then added the point of force for the base of the nose. This process was used for the development of the three device proposals: basal support, front support and column support, names chosen by the point where the force of subjection to the nasal septum is generated, as illustrated and identified in Figure 5A, B and C, respectively.

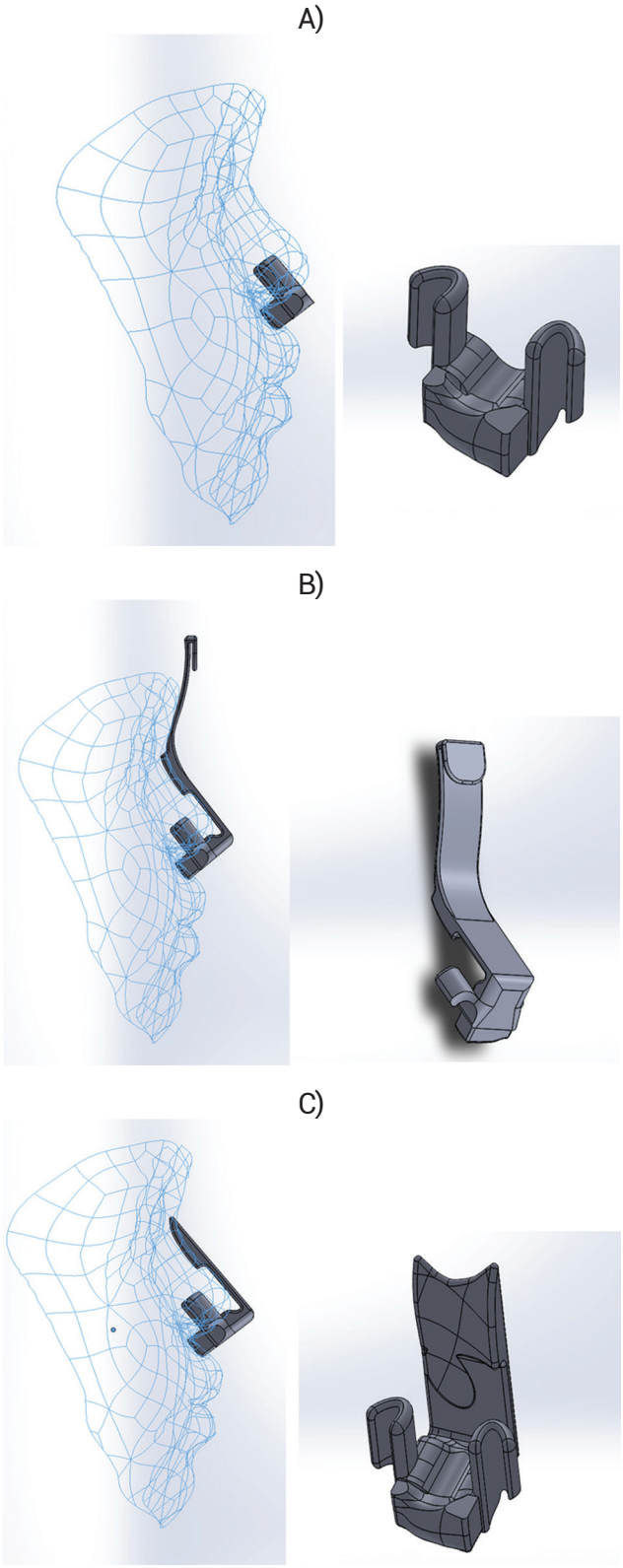

Figure 5. Three proposal prototype created in SolidWorks® software. A) Basal support. B) Front support. C) Support Column.

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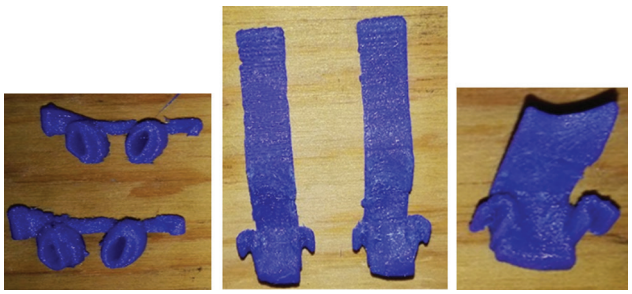
Figure 5 shows the different results for the prototype of Basal Support, to the nose, rigid but at the same time flexible enough to provide an ergonomic interface with the user. Figure 6a shows the impression obtained with a PC-ABS plastic on a Stratasys Fortus 360mc printer, the material is rigid and produced that the device break easily during handling. In contrast, using the Ninja-Flex material with a Printrbot printer (Figure 5b), the device was too flexible and with a very porous surface finish, that it could not confer support to the nasal septum. Finally, using a PA 2200 polymer on EOSINT P730 printer, the desired finishing in prototype was obtained with rigidity and balanced flexibility to be used in testing and data collection of the focus group (Figure 5c).

A)

B)



C)

Figure 6. Results of different 3D printing technologies in the Front Support. A) PC-ABS plastic on a Stratasys Fortus 360mc printer. B) Ninja-Flex with a Printrbot printer. C) PA 2200 polymer on an EOSINT P730 printer.

The prototype impressions were shown to the focus group and experts to evaluate the product specifications, previously identified for the three proposals against the current device position (Figure 2a). The experts who participated in the evaluation process of the medical devices proposal were parents of infants with the condition, an Internist and a Maxillofacial Surgeon, and the members of the Pro Niño Clef lip and Cleft Palate Association. Each person gave a score of 1 to 5, providing the maximum rating of 5 if the prototype reached 100% the desired requirement, this was done for each of the specifications and for each prototype and for the current device. Figure 7 shows how the Basal Support prototype got the highest score in all product specifications, followed by Frontal Support, thirdly the prototype of Column Support and finally, the current device.

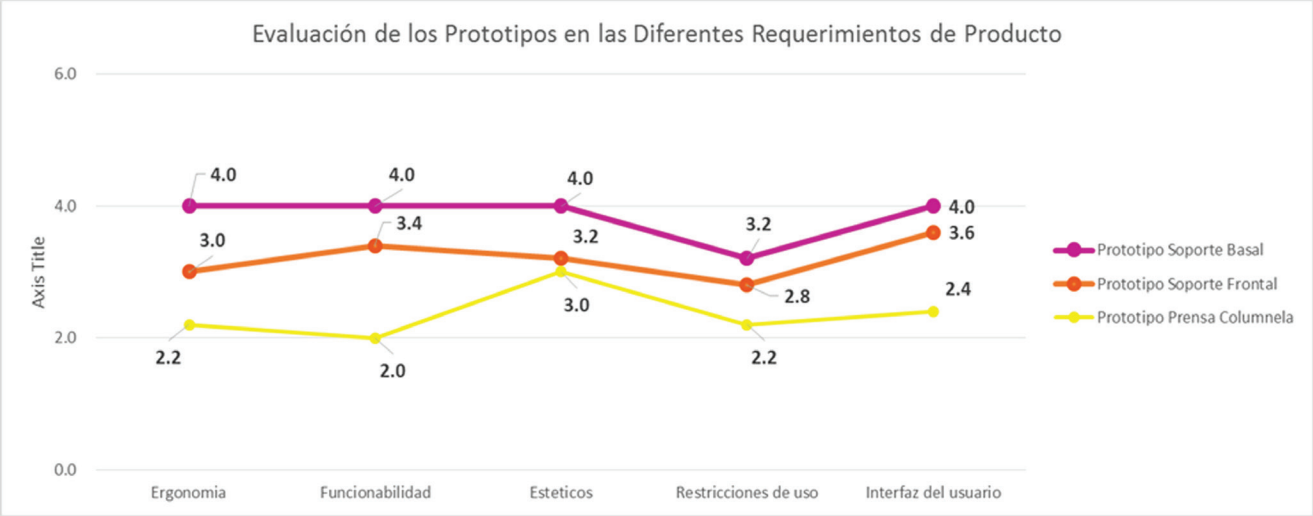


Figure 7. Evaluation of product requirements by prototype.

Discussion of results

The current nasal support used in these patients is uncomfortable and unsafe for the infant. This creates the necessity to develop a new ergonomic and safe device to allow patients to use it for different periods of time. Thus, providing the corrective reinforcement required to align the patient's facial features.

The 123D Catch and ItSeez3D scanning programs did not provide the level of detail required for an ergonomic development of nasal support. However, Creaform's REVscan System, using the VXElements program, provided the level of resolution and precision required to be used as the basis for nasal support design. However, it is a challenge to keep the patient immobile for the five minutes required to perform the scan.

There were several factors that could influence the scan result; for example, the individual to be scanned was asleep and immobile during scanning with the REVscan and 123D catch, while in scanning with ItSeez3D, the individual was awake and in constant motion, so the program cannot generate the required definition. The technologies 123D catch and ItSeez3D are limited by being a technology of superposition of photographs in different perspectives of an object, whereas the REVscan generates a cloud of points that allows it to generate greater precision and resolution of the object scanned.

In addition, 3D printing using the EOSINT P 730 material, proved to be the ideal technology for the manufacturing of nasal supports because of its precision, multi-material printing capability, moldability and low cost. When analyzing the three impressions obtained, the use of rigid materials such as PC-ABS for the printing of the nasal support, including the printing of the prototypes, was ruled out because of the lack of physical properties, such as the flexibility and superficial softness that favor the ergonomics of the device and patient safety. The Ninja Flex polymer is very soft, does not provide the necessary reinforcement to correct the post-surgery condition. This balance between flexibility and rigidity, which allows to have the corrective reinforcement but also the ergonomics for the treatment, was obtained with the material PLA 2200, achieving greater ergonomics and comfort in the patient for prolonged use.

The most accepted prototype for the corrective treatment of CL&CP is the basal support device, because this device has the smaller volume and fewer areas of contact with the patient, which makes it the most comfortable support and at the same

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time, has fewer fixing points. It makes the support less stable and easier to remove. Among the results of the interviews, it was suggested the use of this device in adolescents, young adults and adults and population with awareness of the necessity of using this device.

The specialist in maxillofacial surgery suggested different technologies, such as dental tomography to get the inside of the nostrils and for a fast digitization and good resolution "3DM phase" technology. Besides that, the surgeon proposed the use of a 3D projection of the patient, to generate several devices that sequentially correct the condition after the first surgical procedure.

The prototype of the frontal support was the second most accepted device. The internist doctors found that it was the best design to treat the target population of the study and gave the recommendation that the band that will attach the prototype to the head should take advantage of the irregularities of the head and even the ears to provide greater support in correcting the nasal septum. Since this device has two protrusions (which have sharp shapes) that allow it to attach to the upper part of the nose. Because it is close to the eyes, this makes the device the least safe for patients.

The last prototype evaluated was the prototype column support, this device was the least accepted, because its design has several sharp ends, despite that it is not ruled out its use in ages older than 5 years, since having two points of support and two of fixation, allows for better fixation in the nasal support, which is ideal to avoid being removed consciously or unconsciously by the patient. At the same time, this is the support with the greatest volume and visual impact on the patient face.

The results show that the three proposed prototypes are likely to be used in the post-surgical treatment of patients with CL&CP, but their use will depend on slight modifications in designs, the choice of hypoallergenic materials and the patient's maturity, therefore, all three devices could be used in different statistical populations of patients with CL&CP.

As recommendations, to use high-resolution scanning and printing technologies, the scanning method must have the ability to obtain the internal dimensions of the nostrils to improve the adaptability and effectiveness of the treatment.

For future work, it is important to develop devices that allow a gradual adjustment of nasal alignment; making the use of simulation software for progressive correction, as well as the 3D printing of a set of exchange devices over time until reaching the expected final form.

Finally, it is important to work together with the National Council for Biomedical Research (CONIS) with the objective of planning, approving and executing clinical studies with patients with cleft lip and cleft palate.

Conclusions

- ✓ Devices that were investigated to assist in the corrective treatment of cleft lip and cleft palate in nasal correction do not have design criteria; also, do not have fully documented acceptance criteria to know the patient's needs, representing a health risk and low corrective effectiveness.
- ✓ The Geomagic Design X software through the REVSCAN capture device presented the best resolution and surface modeled required in 3D of the patient, but it has the disadvantage that it is necessary for the patient to remain still and with eyes closed during the scan time.
- ✓ The combination of PA 2200 with the 3D printer EOSINT P 730 presented the best result in the manufacturing of the three prototypes in terms of surface finish, appearance and precision, however it is not the optimum material for the final version of the device.
- ✓ Of the three prototypes designed (Basal Support, Nasal Support, Columnar Support), the Basal Support device joins the most needs of the patient.

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