Design and Development of Low Cost Silicone Implant Used in Augmentation Rhinoplasty Suitable for the Indian Sub-continental Population

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***Abstract*—The objective of this research was to design and manufacture an implant for Augmentation Rhinoplasty, an additive plastic surgery of nose, to suit the face morphology of patients of the Indian subcontinent and to reduce the cost substantially by incorporating innovative design and manufacturing practices, thus overcoming the twin problems of deficiencies in design of existing implants and the high cost of around $150-$200 which puts them out of the reach of the needy. This research involves the customized design of nasal implant, design and manufacturing of die and setting up a manufacturing process for the implant. Design of implant involved customization of geometrical parameters to suit Indian sub-continental face morphology, solid modeling in Computer Aided Drawing (CAD) software and selection of a suitable implant grade material that fulfills the norms of biocompatibility for long term implantation. The design of die included solid modeling and selection of appropriate material. The solid modelling of the implant and the die was done using Solid Edge software. An appropriate grade of biocompatible Liquid Silicone Rubber (LSR) was selected to achieve required mechanical properties. Die casting process was selected for manufacturing the implant. Die was manufactured by Computer Numerically Controlled (CNC) machining followed by finishing operations to ensure mirror finish. Process parameters for the implant manufacturing were established after several experimental trials and the process was standardized. As a result, implant having desired design features and mechanical properties with no manufacturing defects was obtained. Manufacturing cost of the implant was reduced substantially to $20 apiece. The established standards of manufacturing process and materials in this research can be extended for making implants for other body parts like chin, calf and ear which will benefit trauma victims and those with congenital defects.**

***Index Terms*—Augmentation Rhinoplasty, Indian subcontinent, Liquid Silicone Rubber (LSR), nasal implant, solid modelling, die casting, vacuum degassing**

I. Introduction

Augmentation Rhinoplasty is the plastic surgery of the nose which is performed for both aesthetic and functional reasons. Saddle nose [1] is one of the most common deformity of the nose which entails a short nasal dorsal height resulting in a compromised support structure of the nose and obstruction of the nasal airway apart from aesthetic considerations. Causes include congenital defect, secondary effects of diseases like leprosy and syphilis, autoimmune disorders that attack the cartilage and trauma. Augmentation Rhinoplasty involves augmenting the nose using implants made of natural or synthetic materials. In case of synthetic silicone implants, currently surgeons either use manufactured silicone implants or carve them from a silicone block. The problem with the former is that they come in specific dimensions which quite often are unsuited for the Indian sub-continental nose structure. Thickness of the body portion of those implants is 2 mm which is less than required. Hence to fill a greater void of cartilage they have to be stacked and implanted, thus increasing the risk of the implant getting dislodged requiring revision surgery. Another downside is the cost, with each implant costing around $150-$200 USD putting it out of the reach of the needy. The implants carved from silicone block require a lot of skill on part of the surgeon which is also a time consuming process. Also the implant lacks the finish and the texture of a manufactured implant. To overcome the shortcomings of design and high cost, this research was conceptualized to design the implant and set up a manufacturing process to fulfill the requirements of the medical fraternity.

II. Materials

A. Implant Material

The implants used for augmenting the nose are categorized as alloplasts (synthetic implants), allogenous (obtained from cadavers) and autologous implants (harvested from the patient's own body) [2]. All of them have their advantages and disadvantages. Allogenous and alloplastic materials include cartilage and bone grafts obtained from ribs, ears, skull and various other parts of

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the body. They suffer from disadvantages like resorption, warping and donor site morbidity. Among alloplasts, silicone, Polytetrafluoroethylene (commonly known as Gore-Tex), and porous Polyethylene are used commonly. Silicone implants are widely used and have proven biocompatibility with low rates of extrusion and infection [3]. Alloplasts are easy to fashion into the desired shape, they resist warping and resorption, and they have no donor-site morbidity. Biocompatible [4] LSR (Liquid Silicone Rubber) [5] was chosen as raw material because of the above advantages, ready availability and its ability to be molded into desired shape. To get the desired mechanical properties [6] of implant, LSR-25A grade Liquid Silicone Rubber (having the shore hardness 25A) was selected [7].

B. Die Material

Bio-compatible metals were considered for manufacturing of die to reduce risk of contamination of medical implant during die casting. Stainless Steel (SS 316), Cobalt-Chromium alloys (ASTM 2007a), Cobalt Nickel Chromium Molybdenum (ASTM 2007b) and Titanium alloys are commonly used biocompatible metals [8]. Medical grade Stainless steel (SS 316) was selected due to ease of machining and economic viability.

III. Design

A. Design of Implant

The implant was designed in Solid Edge software after extensive consultations with the surgeons. The implant was divided in 3 parts namely the head, body and the tail as shown in Fig. 1.

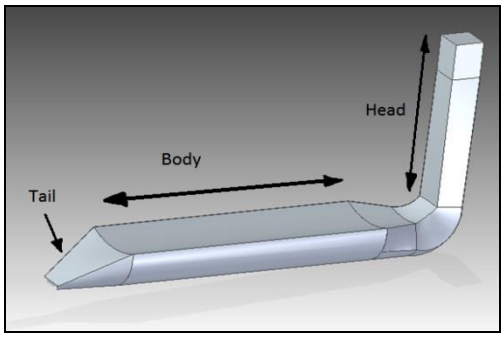

Figure 1. Three parts of implant.

Various cross sections according to the contour of the nose were defined and the implant was modeled as indicated in Fig. 2.

To enable better visualization for the surgeons, a Rapid Prototyping (RP) model was constructed [9] and various features like modifying the curvature of the head, increasing the length and the thickness of the body (to 55 mm and 5 mm respectively) and increasing the length of the head to improve handling of implant during surgery were incorporated. Table I indicates dimensions of various attributes of the implant which are defined in the Fig. 3.

B. Design of Die

Initially, conventional die design consisting of two parts split along the plane of symmetry was considered. Owing to difficulties in machining the curvature of the cavity, an innovative design was made in which the cavity of the head was completely in one part of the die and the cavity of the body was in the other part. Fig. 4 indicates the wireframe models and assembly of the two halves of die. This design minimized the casting defects by ensuring that the length of parting line on the implant surface was minimum. Also the base of the implant was inclined to the base of the die at an angle of 45^0 which eased the machining considerably as well as reduced the loss of implant material in the runners and sprue.

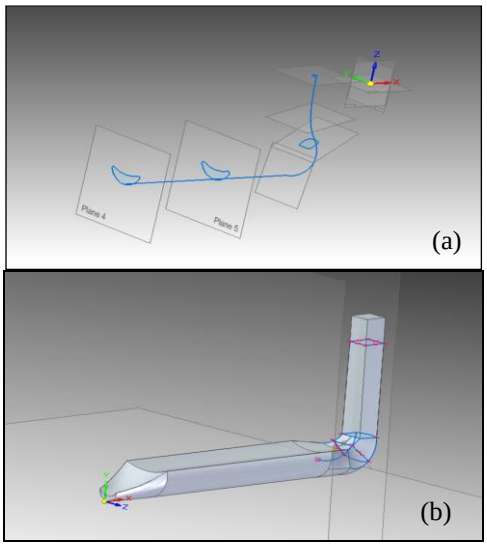

Figure 2. Solid modelling of implant: (a) Defining cross section on the contour and (b) Final model of implant.

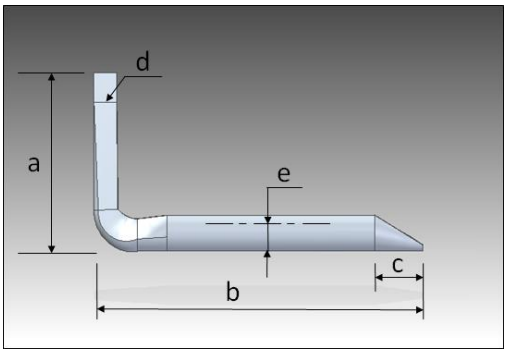

Figure 3. Different attributes of implant.

TABLE I. Dimensions of Various Attributes of Implant

Label	Attribute	Dimension
a	Height of head	30 mm
b	Length of Implant	55 mm
c	Length of tail	8 mm
d	Cross section of head	3.8 X 3.8 mm^2
e	Thickness of body	5 mm

IV. Fabrication

A. Fabrication of Die

The die was machined on a 3-axis CNC machine. The edges and corners of the die were sharpened with Electro-Discharge Machining (EDM) [10]. To ensure excellent finish of the implant, the cavity was mirror finished via diamond polishing. Locating pins were used for alignment of the two halves of die. Fig. 5 shows the fabricated die and positioning of locating pins along with the openings for sprue and riser.

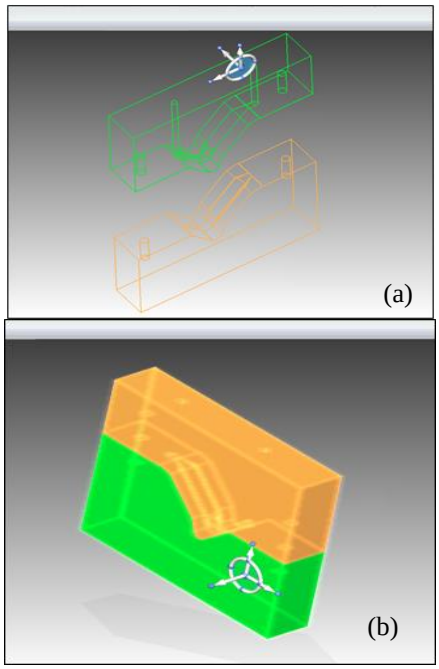

Figure 4. Solid modelling of die: (a) Wireframe model of two halves of die and (b) Assembly of die.

B. Manufacturing Process of Implant

The two parts of Liquid Silicone Rubber (LSR-25A), base and cross-linker were weighed correctly and mixed in a ratio of 9.53:1. The ratio was decided after numerous experiments in order to make an implant that resembled the natural cartilage and provided support to the nose structure. It was observed that air was entrapped inside the mixture during stirring owing to high viscosity of Liquid Silicone Rubber. This mixture was then vacuum degassed in order to remove the entrapped air by applying a vacuum equivalent to 740 mm of mercury [11]. At such low pressure, the bubbles of entrapped air were observed to increase in size, rise to the surface, rupture and leave the mixture. This air free mixture was injected inside the die through sprue hole. To avoid entrapment of air while pouring, the die was evacuated using a vacuum pump. Utmost care was taken so that no additional air gets entrapped inside the mixture. Die was then placed inside oven for heat curing. Temperature of 200 ^{0}C was maintained and die was kept inside for 40 minutes [12]. After complete curing, die was allowed to cool to room temperature. Two part die was then separated and the implant was taken out from the die. Fig. 6 indicates this stage of process. The splashes observed on the implant were removed using a surgical knife. To stabilize the mechanical properties of implant, it was post cured at 150^{0}C for 60 minutes. Certain precautions were strictly followed while handling and storing the raw material (below 43^{0}C) and also while fabricating the implant.

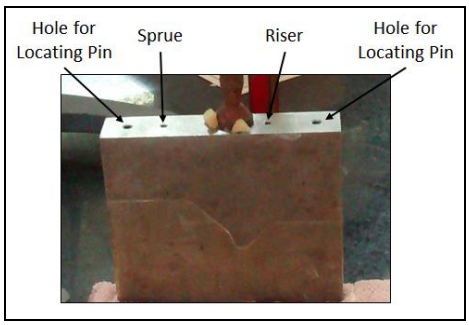

Figure 5. Solid modelling of die: (a) Wireframe model of two halves of die and (b) Assembly of die.

Figure 6. Manufacturing process of implant.

V. Results and Discussion

The design of the implant conformed to the requirements of the medical community and helped fill an important void by overcoming the shortcomings of existing implants resulting in better patient care. The manufactured implant was found to be free from defects of any kind. Fig. 7 shows the manufactured implant. The surface finish obtained by diamond polishing the stainless steel die resulted in a very smooth texture of the implant. The body of manufactured implant had a uniform thickness of 5mm which overcame the complications caused by stacking of implants during surgery. The head of implant was purposefully increased to ease its handling during surgery. Also the designed curved portion of the tail of implant resulted in easy resting over the shape of the nose bridge. Implants were also tested for elemental content in BIS and FSSAI certified laboratory. Fabrication process of the implant could be finished within 2 hours and it does not involve very high initial investment. The cost of manufacturing works out to be around $20 USD. Mass production of this nasal implant would bring down its cost further. Hence the twin objectives of designing an implant that suits the needs of a large number of patients and cost reduction were successfully achieved by employing innovative design

and manufacturing techniques. Ethical approval for the human trials is also being sought and hence clinical trial hasn't been carried out yet. Further this process can be easily generalized and extended to design and manufacture various other implants that are used for reconstructive surgery of the chin, ear, calf and other soft tissues.

VI. Conclusion

This research proposed a design and manufacturing process of a nasal implant for Augmentation Rhinoplasty. The proposed design of implant is more suitable for the facial structure of Indian sub-continental population. The manufacturing process was established on the basis of experimental results. Also the cost per implant was substantially reduced so as to benefit the masses. Hence the twin objectives of implant customization and cost reduction were achieved.

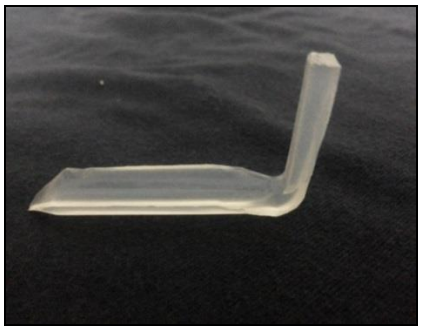

Figure 1. Manufactured implant.

The process parameters established through this research can be extended to manufacture various implants for other parts of the body involving soft tissues.

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