Original Article

# Rapid Prototyping Technology for Silicone Auricular Prosthesis Fabrication: A Pilot Study

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## ABSTRACT

**Context:** Three-dimensional printing technologies have been used recently for patients with maxillofacial deformities who seek esthetic prosthesis. The aim of the present study was to assess the accuracy, surface texture, marginal adaptation, patient satisfaction, and ease of fabrication of silicone auricular prostheses fabricated by the rapid prototyping technology (RPT) when compared to the conventional method (CM). **Materials and Methods:** A pilot study was conducted on five patients who had partial auriculectomy defects. Ear prostheses fabricated by CM and RPT were compared. RPT include the fabrication of prostheses by the duplication of polymer model fabrication or by injecting silicone to mold obtained by Vacuum casting method (VCM). The prostheses were evaluated by 15 randomly allotted trained independent observers based on the Likert Scale. The patients performed a self-rating assessment followed by a report from the clinician and technician. **Statistical Analysis:** The scores for each of the dimension were analyzed using the ANOVA. The cost, time, and quantity of silicone material were expressed in means for three fabrication methods. **Results:** Prostheses fabricated by RPT yielded superior scores in terms of accuracy, texture, and marginal fit; the vacuum casted prostheses being more precise. The patient perspective was in favor of RPT though not significant statistically. Time for fabrication and number of patient visits were less for rapid prototyping methods than CM. **Conclusion:** The present study demonstrated the potential benefits of digital method in the fabrication of auricular prosthesis using RPT in the field of maxillofacial rehabilitation.

**Key words:** Auricular prosthesis, maxillofacial prosthetics, polymer model, rapid prototyping, silicone prosthesis, vacuum casting

## INTRODUCTION

The advent of rapid prototyping technology (RPT) has opened novel perspectives for the design and production in the field of maxillofacial prosthetics. Rapid prototyping (RP) refers to the automatic construction of mechanical models with three-dimensional (3D) printers or stereolithographic machines.[1] This technology was first evolved in the engineering field as a tool to make a solid model based on a computer file. Later, several applications were raised in the biomedical field for the fabrication of models to ease surgical planning mainly for bony reconstructions, simulations in neurosurgery, orthopedics, and head and neck surgeries.[2] RP technology can be used for the fabrication of silicone maxillofacial prosthesis.[3]

Auricular defects; either congenital or acquired, are the second prevalent craniofacial malformation.[4] Surgical reconstruction can be quite challenging; however, the fabrication of prosthetic ear is considered as the most conservative approach for correcting auricular defects. Rehabilitation with auricular prostheses matched to the contralateral ear provides enhanced morphological results than surgical reconstruction due to the convoluted nature of the ear.[5]

Traditional methods of auricular prosthesis fabrication are complicated and technique sensitive. The success of outcome depends on anaplastologist's artistry and skill. However, with the emergence of newer technologies such as 3D imaging and additive manufacturing/RP, the fabrication of auricular prostheses has become much simpler and less time-consuming.[6]

The RP systems have enabled creation of 3D anatomic models that can be customized and exhibit higher

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complexity compared to the traditional computer numeric controlled milling machines. The RPT involves the use of additive or subtractive process. Complex shapes with intricate internal details can be easily manufactured with RP methods.[7]

Auricular prosthesis provides esthetics and anatomically natural looking ear. It also helps to direct the sound waves into the auditory canal, and it can retain eyeglasses and hearing aid if required for the patient. Prosthetic ear mainly provides psychological support for the patient.[8] The patient comfort and satisfaction with the prosthesis are the best outcome of a successful treatment.

The present clinical investigation compares the accuracy, surface texture, marginal adaptation, patient satisfaction, ease of fabrication, potential advantages, and disadvantages of silicone auricular prosthesis fabricated by RPT (polymer model fabrication [PMF] and Vacuum casting method (VCM)) when compared to conventional methods (CM).

## MATERIALS AND METHODS

The study was conducted on five patients who had partial auriculectomy defects which include congenital defects and acquired defects due to burns. The Institutional Ethics Committee approval and informed consent from patients were obtained for the conduct of the study. For each patient, three silicone prostheses were fabricated: (1) by CM, (2) from polymer model fabricated in RP machine (PMF), and (3) packing silicone in separable mold formed by Vacuum casting method (VCM) from RP machine. Both the RP techniques were standardized before the commencement of the study.

For the prostheses fabricated by CM, impression of defect side was made with minimum displacement of tissues using auto mix addition silicone impression material (Reprosil, Densply Sirona) for making master cast. The impression of the contralateral ear was obtained using irreversible hydrocolloid impression material (DPI Algitex) and poured to form the definitive cast to be used as a guide to sculpt the wax pattern. The wax pattern was tried on the patient and evaluated for the correct fit to the surrounding tissue, proper horizontal alignment in comparison with contralateral ear, projection of the ear in relation to the side of the head and marginal integrity during regular jaw movements.

The wax prosthesis was sealed to the cast base and the merging edges were thinned to allow the silicone edges to feather into the surrounding skin. The wax pattern was invested in white stone (Orthokal, Kalabhai, India) to prevent any color contamination. A three-part mold is mandatory for the ease of removal of cured prosthesis. Uncolored RTV Platinum silicone elastomer (A-2186, Factor II, Lakeside, AZ, USA) and liquid catalyst was weighed on the weighing machine. This desired amount was mixed properly to avoid air entrapment on a clean dry clear glass slab with intrinsic stains (Functional Intrinsic Skin Colors, Factor II, AZ, USA) for shade matching. Silicone mix was packed in the mold cavity and allowed to cure for 48 h. Final auricular prosthesis was delivered with extrinsic stains.

For prostheses fabricated with RPT, we have used two methods in this study to develop the prototype with stereolithographic files. One was polymer model fabricated (PMF) and the second method was fabrication of reusable molds by Vacuum casting method (VCM).

The 3D anatomic data were captured using 3D computed tomography (3D CT) as this method provided more accuracy with a slice thickness of 0.6 mm and overlap of 0.23 mm. MIMICS software (Materialize, Belgium) was utilized to provide interactive segmentation of the 3D anatomy which allowed the visual display of the soft tissue. The midline of the face was used as the axis of symmetry, and image of normal ear was extracted, mirrored, and superimposed on the side of the face with the deficiency [Figures 1 and 2]. In addition, the software allowed the mirror image to be moved anteroposterior or super inferiorly and projected from the skull with appropriate prominence. In bilateral auriculectomy case, where both ears of the patient are missing, the 3D CT of her mother was taken and superimposed on the patient's CT [Figure 3].

The image of the mirrored ear was smoothened, redundant margins were sculpted, and materials were added to cover the scars using Freeform software (SensAble Technologies, USA). Then, the data were exported to RP machine in stereolithography files, and the prototypes were obtained by additive process in two ways. In the first method, a polymer model of the ear was fabricated (PMF) using Spectrum Z 510 3D printing System [Figure 4]. Impression of ear model was made using addition silicone impression material (Aquasil, Densply Sirona), poured in hot wax to obtain a wax pattern of the defective side.

In the second method, separable mold was manufactured directly depicting the intricate details of the ear by vacuum casting method (VCM). In vacuum casting technology (RENISHAW apply innovation ™), typical polyurethane and nylon vacuum casting molds are formed in RTV (room temperature vulcanization) silicone rubber using a master model.

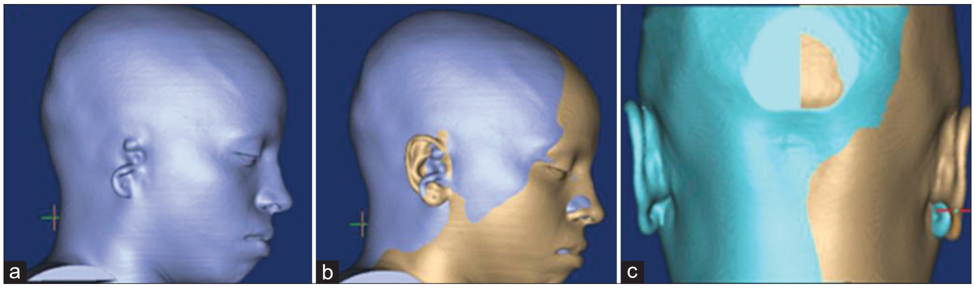


**Figure 1:** Generation of three-dimensional computer model using Stereolithographic files. (a) Image of the defect side. (b) Superimposing the contralateral ear on the defect. (c) Occipital view of the patient to assess the position and angulation of prosthesis

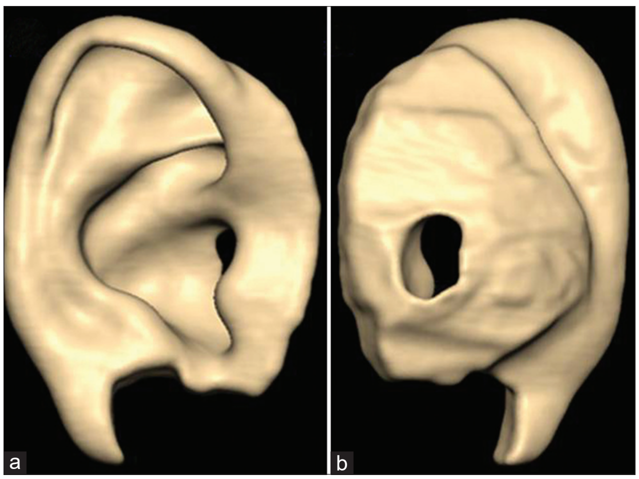


**Figure 2:** Computer-generated image of the prosthetic ear. (a) Medial view. (b) Lateral view

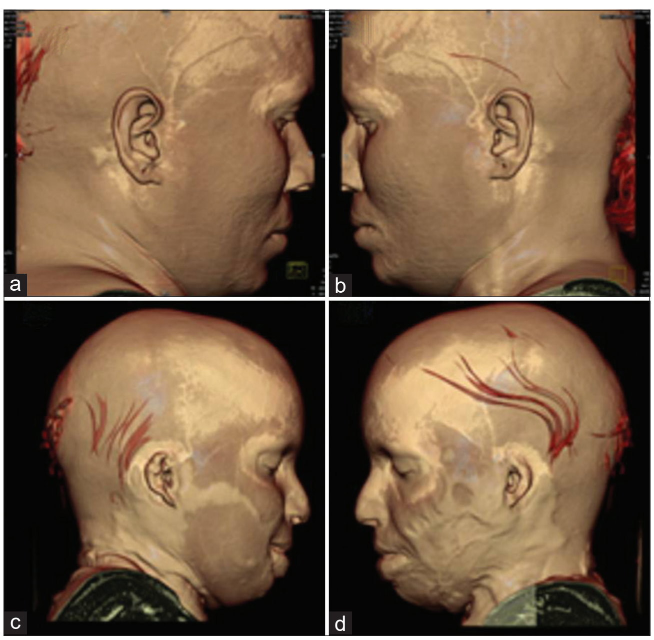


**Figure 3:** Three dimensional computed tomography images of bilateral auriculectomy case. (a and b) 3D CT of patient's mother to be superimposed on the defect. (c and d) 3D CT of right and left defective side of the patient

Silicone material was then packed into the mold which can be reused and avoids wax trial appointment on the patient. To achieve a thinner silicone thickness corresponding to the edge of the prosthesis, a light depression was made in the lower part of the mold. The final prosthesis was finished and delivered after extrinsic staining [Figure 5].

## Evaluation

Evaluation of each auricular prosthesis was done at three levels: First, by the independent observers (residents of the prosthodontics department), second, by a self-assessment from the patient, and third, by the clinician and technician assessment. These evaluations were based on the specific predefined dimensions.

### *Assessment by independent observers*

Fifteen trained independent observers were randomly selected to compare each prosthesis with the master cast and the contra lateral ear of the patient in terms of accuracy, surface texture, and marginal adaptation. The observers rated these dimensions of prosthesis on a Likert scale of 1-5, 1 being poor and 5 the excellent. All were blinded as to the nature of the production process involved in each case.

### *Self-assessment by patient*

Using the same scale, all the five patients performed a self-rating of the three different prosthesis based on the esthetics and fit of prosthesis. Esthetic assessment included evaluation of size, color, and anatomy in comparison with the natural ear, whereas the fit was assessed based on marginal adaptation and comfort of the prostheses.

### *Assessment by clinician and technician*

A single clinician and technician were involved in the whole study to avoid operator bias. Data were reported regarding the number of patient visits, cost of the method which include the material cost and labor charge, quantity of material required and time for fabrication of each prosthesis when using different methods.

## Statistical analysis

The data were analyzed for the statistical comparison. Both the independent observers and patient ratings were summed for each dimension of the three different methods used for

**Figure 4:** Polymer model fabricated for bilateral defect by rapid prototyping technology

the fabrication of ear prosthesis. The Likert ratings for each of the dimension were analyzed using the ANOVA. The cost, time, and quantity of silicone material were expressed in means for three fabrication methods.

## RESULTS

The highest ratings were given to prostheses fabricated from vacuum casting method (VCM) and duplication of polymer models (PMF) for accuracy (contour, length, and width) when compared to CMs. The marginal adaptation to surrounding tissue and surface texture presented higher scores for prostheses fabricated by RPT. The VCM and PMF were clinically significant. Table 1 describes the total scores rated by 15 observers for three different methods of fabrication of the prosthesis.

The self-rated scores by the patient for the appearance (esthetics) and fit of prostheses showed that PMF and VCM methods of RPT were superior over the CMs. Table 2 presents the total scores rated by the patients for the prosthesis.

The assessment of data by the clinician and technician reported that the number of patient visits for PMF and VCM was nearly half of the CM. The time taken for the fabrication of prosthesis was the highest for CM (14 ± 1.6 h), whereas the fabrication of prosthesis from RP machine took less than half the time. The polymer model was fabricated in 6 h, whereas the time spent for vacuum casted mold was only 4 h. However, cost of fabrication was four times higher for VCM as compared to CM and PMF methods. CM method used slightly higher amount of silicone material for fabrication. Table 3 described the assessment of three methods by clinician and technician.

## DISCUSSION

Rehabilitation of patients with congenital or acquired defects pose a challenge as it ideally requires customized


**Figure 5:** Vacuum casting method. (a) Auricular defect. (b) Vacuum casted mold. (c) Final silicon auricular prosthesis

prosthesis to reproduce the morphology of natural ear as precise as possible. The conventional protocol followed is a complex, time-consuming process, and demands high level of artistic skill to achieve a good esthetic result.

Maxillofacial prosthetics is heading toward a digital era with revolutions in production technologies. RP either uses a subtractive method or additive process to develop the prototype.[9] In additive process, object is built in layers defined by a computer model that has been virtually sliced.[10] Additive technology scan yield arbitrarily complex shapes with cavities and undercuts; frequently the case in human anatomic structures.[11] Stereolithography is the standard interface for RP systems for auricular prosthesis as the ability to produce virtual models to develop more natural-looking prototypes and achieve the prototypes for further use.[12]

Obtained data in stereolithographic files were extracted to Free Form modelling software to achieve the virtual construction of the prosthesis. Two different RP systems were used to build the prosthesis prototypes for comparative evaluation. In PMF method, cast of the ear was obtained. Cast was then duplicated to get the wax pattern. The silicone mold of the ear prosthesis made by vacuum casting method has an advantage of reusability, which can permit multiple pouring without much distortion in dimensional accuracy of the prosthetic ear.[13] This is relevant since discoloration of the ear prosthesis demands replacement in about 2 years.[14] The RP machine that uses in most of the laboratories fabricate models with polymers but separate equipment is required for vacuum casting.

The accuracy of a maxillofacial prosthesis is essentially a subjective visual assessment.[15] RP generated auricular prosthesis was favored by majority of the observers providing a statistically significant difference in accuracy when compared to the conventional hand carving technique. The VCM reproduced more accurate anatomic dimensions; length, width, and contour close to the natural ear when compared to PMF, though not significant statistically. The investigation set out to compare conventional fabrication technique with RP technique for auricular prosthesis by Sykes *et al*. reported that the conventional process presented

**Table 1: Average scores rated for various dimensions by the independent observers**

| Dimension | Method | | | | | | | | | | | F* | *P* |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | VCM | | | PMF | | | | CM | | | | | |
| | Scores | | | | | | | | | | | | |
| | Excellent | Very good | Good | Excellent | Very good | Good | Fair | Excellent | Very good | Good | Fair | | |
| Accuracy (length and width) | 52 | 8 | 0 | 41 | 15 | 1 | 0 | 0 | 16 | 28 | 16 | 0.06 | 0.9 |
| Accuracy (contour) | 51 | 8 | 1 | 40 | 19 | 1 | 0 | 0 | 17 | 22 | 21 | 0.08 | 0.97 |
| Surface texture | 14 | 36 | 10 | 12 | 33 | 13 | 2 | 2 | 32 | 13 | 0 | 0.11 | 0.97 |
| Marginal adaptation | 16 | 39 | 5 | 11 | 36 | 30 | 0 | 12 | 33 | 15 | 0 | 0.08 | 0.93 |

*ANOVA. VCM: Vacuum casting method, PMF: Polymer model fabrication, CM: Conventional method

**Table 2: Average scores rated based on self-assessment by the patient**

| Dimension | Method | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | VCM | | | PMF | | | | CM | | | |
| | Scores | | | | | | | | | | |
| | Excellent | Very good | Good | Excellent | Very good | Good | Fair | Excellent | Very good | Good | Fair |
| Appearance/aesthetics | 0 | 60 | 0 | 45 | 2 | 0 | 0 | 0 | 15 | 30 | 15 |
| Fit | 0 | 60 | 0 | 30 | 30 | 0 | 0 | 0 | 30 | 30 | 0 |

CM: Conventional method, PMF: Polymer mold fabrication, VCM: Vacuum casting method

**Table 3: Assessment of three methods by clinician and technician**

| | Methods | | |
|---|---|---|---|
| | CM | PMF | VCM |
| Number of patient visit | 6 | 3 | 2 |
| Time of fabrication (h) | 14±1.6 | 6.2±1.2 | 4.25±0.43 |
| Cost (Indian Rupee) | 5000±504 | 6000 | 20333.5±1257 |
| Amount of silicone material used (g) | 25±5.04 | 19.05±4.59 | 21.25±4.18 |

CM: Conventional method, PMF: Polymer mold fabrication, VCM: Vacuum casting method

0.21 mm greater error than RP method.[3] This limitation was overcome by the RP technology by opting 3D CT images with minimal slice thickness in this study.

The surface texture was also evaluated to be on the highest preference for RP auricular prosthesis when compared to conventional technique. Precise features like stippling which simulate the original appearance could be designed in Freeform software followed by addition of flocking agents while mixing silicone. In CM also, stippling was done with a denture brush in the wax pattern and flocking agents were used but the quality of desired skin texture was compromised.

The present study points to comparable marginal adaptation of prosthesis fabricated using both techniques. In CM, we try to thin the margins of wax pattern as much as possible, whereas a slight depression provided in the lower part of the mold reduce the silicone thickness in the prosthetic margin.

Patient satisfaction may not be sufficiently objective to evaluate the results but is still substantially important to assess the outcomes. The patient perspective featured in this study reflects the dominance of RP for auricular prosthesis in terms of esthetics and fit. The harmonizing properties, such as surface texture and coloring were recorded to be highly satisfactory for prosthesis fabricated using vacuum cast mold when compared to the other RP technique.

The traditional prostheses fabrication depends on the skill, expertise, and experience of the prosthodontist and technician, and results were often less than satisfactory.[3] The time of production in hours was three times more for manual technique than RP technique when assessed qualitatively by questioning the clinician and technicians involved. Fabrication of polymer model was slightly more time-consuming when compared to vacuum casted technique.

The main limitation of RP includes the expense of the equipment, need of sophisticated machinery, and dependence on trained expert to run the software and digital scanner.[16] Although the polymer-based model had comparable expense to conventional technique, cost of vacuum casting prosthesis was in the higher scale. The expense could be justified by establishing a centralized service or multi-disciplinary integration in light of applications to oral and craniofacial surgeries.[13-15,17] The number of patient visit was reduced to half for RP prosthesis and the reusable molds eliminated the need for wax trial which could be a drawback in patients with high esthetic demands. The patient's physical presence is not needed for fabricating prosthesis by this method.

The results of this pilot study undoubtedly ascertain the capabilities of the RP method in producing highly realistic facial prostheses with accurate adaptation and external contours. The future avenue in the research accounts to trial with increased sample size.

## CONCLUSION

Now we have only scratched the surface of RP technologies full potential. Initial feedback from both clinician and patients has been positive. Hence, this study demonstrated the definite advantage of fabrication of auricular prosthesis using RPT. The sequential development of virtual images of the contralateral ear and prosthesis prototype eliminates the potential errors of sculpting a precise anatomic model. If the institution could run the utility of machine for multiple medical applications, it would be cost-effective and improve the quality of life of the needful patients.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

### Disclosure

This material has never been published and is not currently under evaluation in any other peer reviewed publication.

### Ethical approval

The permission was taken from the Institutional Ethics Committee before starting the project. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

### Informed consent

Informed consent was obtained from all individual participants included in the study.

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