Archives of Materials Science and Engineering

Volume 83
Issue 1
January 2017
Pages 30-35

International Scientific Journal published monthly by the World Academy of Materials and Manufacturing Engineering

CAD/CAM silicone auricular prosthesis with thermoformed stiffening insert

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ABSTRACT

Purpose: Epitheses (facial prostheses) for large facial tissue defects manufactured from silicones exhibit unsatisfactory rigidity and its stiffening is required, which creates technological problems. Moreover, facial epitheses have to be replaced in a relatively short period of use which creates a significant costs, often impossible to realize. The hypothesis of the study was that with use of additive manufacturing is possible to obtain the reusable form for thermoforming of the stiffening insert of auricular prosthesis and the mould which allows multiple casting of silicone prosthesis with the insert.

Design/methodology/approach: Manufacturing of the epithesis consisted of designing and manufacturing. In the first step, the auricular prosthesis and the stiffening insert were designed with use of engineering CAD software. In this first computer step, the split form for vacuum thermoforming of the stiffening insert and the split mould for casting of the silicone ear were designed. In the second step, additive printing was used for manufacturing the split and reusable model for vacuum thermoforming of the stiffening insert and the split form of ear. In the third step, stiffening insert was made of thermoformed polyurethane sheet of 0.1 mm thick (Biolon, Dreve), where dental thermoforming machine (Drufosmart, Dreve) was used. In the fourth step, the stiffening insert was located in the mould and the ear was casting of silicone.

Findings: CAD/CAM of epitheses with stiffening insert for large tissues defect/loss was proposed, where in case of re-producing, it required only thermoforming of insert and casting silicone with use of the reusable models. Dental technician, in case of damage or loss of a forms, is not much involved in their creation.

Research limitations/implications: Bond strength test between stiffening insert vs. soft silicone and manufacturing tolerance of epitheses have not been investigated.

Practical implications: Method of casting in a negative form, despite the more time-consuming when comparing with epithesis direct-printing, allows introducing a stiffening insert and performing a manual adjustment of margin shape and thickness. Method of negative form allows the use of a commercially available medical silicone without the need for medical tests of a new printed materials.

Keywords: Face and ear epithesis; Additive manufacturing; Stiffening polyurethane insert

Reference to this paper should be given in the following way:
J. Żmudzki, M. Burzyński, G. Chladek, C. Krawczyk, CAD/CAM silicone auricular prosthesis with thermoformed stiffening insert, Archives of Materials Science and Engineering 83/1 (2017) 30-35.

BIOMEDICAL AND DENTAL MATERIALS AND ENGINEERING

1. Introduction

Congenital abnormalities, trauma and surgery of tumors are reasons of maxillofacial defects. In Poland cases of skin cancer or melanoma occur about 5 thousand/year. For comparison, in the United States every year registered about 1 million/year. Skin cancer often occupies a large part of the head, for example, area of the nose, cheek, eye or ear. Surgery leads to loss of facial aesthetics or even disfigurement, resulting in a negative impact on well-being and various aspects of life, e.g. contacts and professional life. In cases of maxillofacial defects when aesthetic and functional demands cannot be surgically fulfilled in order to improve well-being and quality of life, patients can use facial prosthesis (epithesis) e.g. the ear, eye or nose [1-3].

Production of conventional epitheses is time-consuming, and the cost can reach several thousand dollars [4,5]. In addition to the costs associated with an aesthetic finish of prosthesis surface by technician, who must have great artistic talent, significant cost is generated by the manufacturing the prosthesis, where the shape of lost tissues is modeling in wax on the traditional model.

An important fact is that in a relatively short period of use is necessary to replace epitheses [3], which it constitutes a considerable financial load, often impossible to take. Currently, due to the availability of additive technologies, the cost of epithesis, especially in the case of re-producing based on an existing project has been greatly reduced and is competitive in comparison to repeatedly produce epitheses manual methods. The advantage of CAD compared to manual methods also involves the ability to use a symmetrical part of the face without having to manually design based on the view [6,7].

A difficult problem to solve is the excessive rigidity of epitheses [8] in relation to the surrounding tissues. In the case of hard tissues there is a problem to match the shape and compression. In the case of the soft tissues in addition to the mentioned problem occurs another difficulty, which is diametrically different biomechanical behavior under compression, and especially under strains accompanying facial expressions. Typical polymeric materials such as acrylics or thermoplastics are characterized by significant modules of elasticity, so it is necessary to supplement or replace them with soft materials, e.g. silicones. However, in the case of manufacturing such epitheses from silicone, for example, auricular prostheses poses undesirable and unnatural too low stiffness. In such epitheses is necessary to use a rigid core (frame), and supplement or cover it with soft material. In the case of implantologic retention the bar fastened to the implant can fulfill the role of stiffening. These solutions significantly increase the cost. Similarly, the framework made of the composites increases the costs of solutions both in regard of material and time consumption [9].

An efficient method of core manufacturing is thermoforming. Thermoforming is a technological process, in which rigid plate or film of polymeric material is heated to the softening temperature and then molded into the desired shape of the final product. In contrast to conventional technologies for producing prosthesis is needed only one positive model (stone cast) of the foundation without forming a wax model of the object and flasking procedures, which significantly reduces the amount of time. Infrared is the most commonly used method of heating, because they do not require contact with the material. Due to the molding method using a pressure difference, there are two main methods of thermoforming: the vacuum forming proceeds at a predetermined negative pressure produced by the vacuum pump; the pressure forming proceeds at a predetermined overpressure generated by the compressed air fed through the nozzles.

Molding can be made with or without pre-stretching: negative thermoforming – the punch pushes the plasticized polymer into the mold, then under pressure the material is fitted closely to the mold; positive thermoforming – the plasticized polymer plate is located in a mobile frame, the frame is lowered onto the mould, and then under pressure the material is fitted closely to the mould.

Thermoforming is widely used in dentistry to perform occlusal splints, braces, teeth "night guards", athletic mouthguards, dentures and transfers. During the thermoforming process the primary concern is thinning of the walls which it results in different wall thickness depending on mould shape.

In the case of undercuts the mould is usually destructed. Split of the mould with regard to undercuts allows for release without destruction and re-use of the mould. However, the complex shapes of the mould may cause undesired excessive irregularities of thickness or even discontinuity in the component.

The aim of the study was to achieve auricular epitheses using computer-aided design and additive manufacturing technology. The working hypothesis was that with use of additive manufacturing is possible to obtain the reusable form for thermoforming of the stiffening insert of auricular prosthesis and the mould which allows multiple casting of silicone prosthesis with the insert.

2. Methods

Manufacturing of the auricular prosthesis consisted from a few steps:

- auricular prosthesis was designed with use of engineering CAD software,
- split form was design for vacuum thermoforming of the stiffening insert,
- split mould for casting of the silicone ear was designed,
- additive printing was used for manufacturing the split reusable form for vacuum thermoforming of the stiffening insert,
- additive printing was used for manufacturing split mould of ear,
- stiffening insert was made with positive thermoforming with pressure,
- stiffening insert was located in the mould and the ear was cast using silicone.

CAD software Autodesk Inventor and Solidworks were used in construction of missing ear and the moulds – Fig. 1. The mould for silicone casting has been designed as a negative reflection of the designed missing ear. Next, a design of form for thermoforming was verifying in regard of available workspace of dental pressure thermoforming machine (Drufosmart, Dreve). Model for thermoforming of stiffening insert was divided into two parts in regard to undercuts to enable removal from the form – Fig. 2.

Additive printing was made using 3D printer RepRap NEO (thanks to Sabtom, Bytom, Poland). Polylactide (PLA) was used, because of low price and functionality of 3D printer. A heated table is not available in the printer, which can cause shrinkage due to rapidly polymerizing polymer, for example ABS, and emergency of detachment from the table.

CAD model (STL) of the first part of the form (Fig. 3), after making sure that it is "watertight" and does not contain errors, was imported to Repetier-Host software, which allows to handle the 3D printer RepRap NEO. Once set up, the subroutine Slic3r (conversion model in the G code), the model was divided into a single plane perpendicular to the vertical axis Z. Using the same setup and the same material the second part of the mould was printed (Fig. 4).

a)

b)

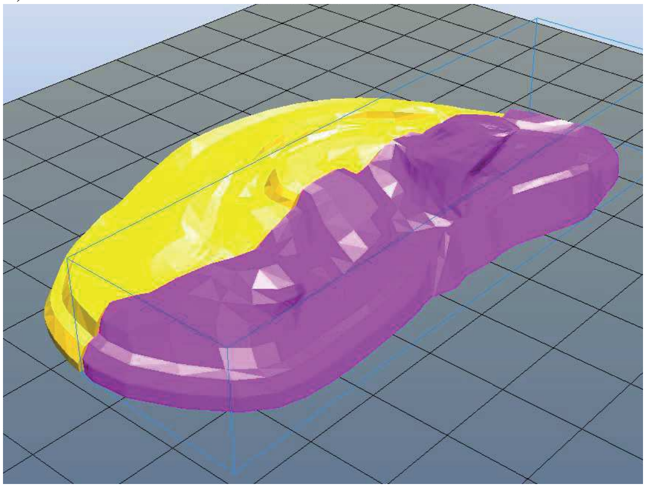

Fig. 1. Computer model of the misplaced ear (a) and computer model of the split form for thermoforming the stiffening insert (b) designed in standard engineering CAD software

Fig. 2. The reusable plastic model (form) manufactured with use of 3D printing for thermoforming the stiffening insert

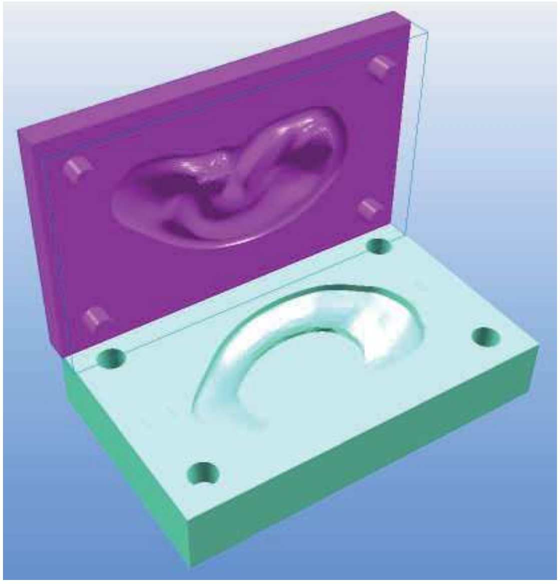

Fig. 3. Computer design of the split mould for casting of the silicone ear

Fig. 4. The reusable mould manufactured with use of 3D printing of plastics for casting of the silicone ear

Stiffening insert of epithesis was made by thermoforming of polyurethane sheet of 0.1 mm thick (Biolon 0.1, Dreve). After placing split form in the thermoforming machine (Drufosmart, Dreve) the polyurethane plate was heated by infrared in 1 minute and 10 seconds [11]. When softening, temperature was achieved, plasticized polymer sheet was stretched onto the split form by manually lowering the holding frame and underpressure was applied. After 1 minute cooling, the underpressure was released and reusable split form was removed from ready to trim stiffening inserts (Fig. 5). In the mould before silicone casting was made air vent hole, stiffening insert was attached to the one side of mould and the mould was sealed with wax to prevent leakage of the silicone.

Fig. 5. The stiffening insert ready to trim after thermoforming on the reusable split model

After casting and crosslinking of silicone the mould was opened and the prosthesis was removed. The prosthesis ready for a final color finishing shows Fig. 6.

Fig. 6. The silicone auricular prosthesis with polyurethane stiffening insert ready for artistic finishing

3. Description of achieved results

Improvement in the durability of materials for epitheses going hard which encourages the development of technologies that reduce the cost of re-production. The main cost of epithesis is artistic finishing, but the substructure manufacturing is 1/3 of whole price [3]. Color 3D printing technology is not enough perfect in regard of reproduction of skin shades, so direct printing requires manual coloring as in the case of the casting into the mould. Due to the need for frequent re-production of prostheses, if taking into account their average cost approx. 1000 $, seeking to reduce the production cost of a substructures is very reasonable.

The most common cause of epitheses re-production are color change (71%) [3] and thin margins destruction or its permanent deformation (curling) and silicone delamination [10-13]. The choice of manufacturing technology of stiffening insert in presented work was dictated by the results of research in the work [11] that reveal that polyurethane insert improves the tensile strength from 7.80 (±0.19) MPa to 15.55 (±0.31) MPa and tear strength from 1.21 (±0.09) MPa to 1.92 (±0.11) MPa, as also provides better marginal integrity and durability of prostheses.

The increasing availability of an additive technology seems to encourage direct 3D printing of a prostheses instead of mould casting. However, negative mould technology, despite to a more time-consumption, characterized by the major advantage compared to a direct 3D printing. Accuracy of thin margins can be improved by fine manual adjustments of split form, and also the fragility of the wax model edge is avoided [14]. Fit to tissues is particularly important in the case of prostheses without implantologic retention, which can not always be used.

Availability of implantologic retention reduces the its significant costs [15], as well as radiotherapy, which considerably increases the loss of implants from 4-6% to 18-39% [16-18].

Time efficiency and the amount and cost of material used in show a considerable workload of CAD designer and a longer production time of forms with the 3D printer. However, compared with the traditional manual method of manufacturing, advantage is the lack of human involvement in the production of the mould. Material cost of disposable plaster cast is more than four times lower in comparison with the cost of the polymeric material for the printer. However, the polymeric form is reusable, which compensates the costs and, above all, the human involvement during preparation of the next forms in traditional way.

Reusable forms allow to re-production of epitheses, without the need for a new process design, modeling and manufacturing of forms, which significantly reduces labor costs. If epitheses is damaged or its aesthetics is lost, the re-production consists only of the thermoforming process and silicone casting in the form. Even if there is damage or loss of form, then its re-manufacturing does not require the time consumption of the dental technician, and only a printer. Also, there is no need making impression, because the project of epithesis is stored with digital data of tissue surface, when making an impression of large facial tissue defects is troublesome for both the doctor and the patient.

It is worth noting [5] on the significantly better biological response of skin under epitheses in the case of laminating the epitheses interface with polyurethane. Pain, discomfort, and burning sensation after six months from the insertion of the laminated auricular prostheses had been retained at mild level and at moderate or severe level at wearers of non-laminated epithesis.

The combination of lamination with proposed stiffening insert creates additional opportunities to tailoring a stiffness while increasing resistance to delamination.

4. Conclusions

Despite the more time-consumption of negative method of silicone casting in the mould compared to the direct-printing in the proposed method a thin stiffening insert was achieve and manual adjustment of the shape and thickness of margins can be introduced in the mould.

Negative method allows the use of commercially available medical silicones without the need for validation of new printed materials.

The proposed method allows the mimicking of biomechanical behavior of a real ear through the selection of an appropriate stiffness of insert and soft material.

In the future studies can be determined the mechanical properties of material of stiffening insert and silicone, as well as durability of the connection between them which will ensure the most advantageous effect.

Acknowledgements

Special thanks for 3D printing to Sabtom from Bytom (www.era3d.pl).

References

[1] P. Scolozzi, B. Jaques, Treatment of midfacial defects using prostheses supported by ITI dental implants,

Plastic and Reconstructive Surgery 114 (2004) 1395-1404.
[2] J.C. Lemon, S. Kiat-amnuay, L. Gettleman, J.W. Martin, M.S. Chambers, Facial prosthetic rehabilitation: preprosthetic surgical techniques and biomaterials, Current Opinion in Otolaryngology & Head and Neck Surgery 13 (2005) 255-262.
[3] M.M. Hatamleh, C. Haylock, J, Watson, D.C. Watts, Maxillofacial prosthetic rehabilitation in the UK: a survey of maxillofacial prosthetists' and technologists' attitudes and opinions, International Journal of Oral & Maxillofacial Surgery 39 (2010) 1186-1192.
[4] S.M. Hooper, T. Westcott, P.L. Evans, A.P. Bocca, D.C. Jagger, Implant-supported facial prostheses provided by a maxillofacial unit in a U.K. regional hospital: longevity and patient opinions, Journal of Prosthodontics 14 (2005) 32-38.
[5] L. Ciocca, R. Mingucci, G. Gassino, R. Scotti, CAD/CAM ear model and virtual construction of the mold, , Journal of Prosthodontics 98 (2007) 339-343.
[6] L. Ciocca L, R. Scotti, CAD-CAM generated ear cast by means of a laser scanner and rapid prototyping machine, Journal of Prosthodontics 92 (2004) 591-595.
[7] M. Al Mardini, C. Ercoli, G.N. Grasser, A technique to produce a mirror-image wax pattern of an ear using rapid prototyping technology, Journal of Prosthodontics 94 (2005) 195-198.
[8] K.F. Thomas, The art of clinical anaplastology. Techniques and materials guide for successful facial and somato prosthetic rehabilitation, 2nd ed. London, 2006.
[9] H. Kurunmäki, R. Kantola, M.M. Hatamleh, D.C. Watts, P.K. Vallittu, A fiber-reinforced composite prosthesis restoring a lateral midfacial defect: A clinical report, Journal of Prosthodontics 100 (2008) 348-352.
[10] D.H. Lewis, D.J. Castlebery, An assessment of recent advances in external maxillofacial materials, Journal of Prosthodontics 43 (1980) 426-432.
[11] M.Y. Abd El-Fattah, R.N.A. Kashef, M.A. El Ebiary, Evaluation of two different reinforcing materials used with silicone auricular prostheses, Tanta Dental Journal 10/2 (2013) 31-38.
[12] D.M. Hecker, J.P. Wiens, T.R. Cowper, S.E. Eckert, C.A. Gitto, R.F. Jacob, G.K. Mahanna, G.E. Turner, A. Potts, H. Logan, R.L. Wiens, Can we assess quality of life in patients with head and neck cancer? A preliminary report from the American Academy of Maxillofacial Prosthetics, Journal of Prosthodontics 88 (2002) 344-351.
[13] R.M. Watson, T.J. Coward, G.H. Forman, Results of treatment of 20 patients with implant-retained auricular prostheses, International Journal of Oral & Maxillofacial Surgery 10 (1995) 445-449.
[14] Y. Bi, S.Wu, Y. Zhao, S. Bai, A new method for fabricating orbital prosthesis with a CAD/CAM negative mold, Journal of Prosthodontics 110/5 (2013) 424-8.
[15] G. Pekkan, S.H. Tuna, F. Oghan, Extraoral prostheses using extraoral implants International Journal of Oral & Maxillofacial Surgery 40 (2011) 378-383.
[16] S.M. Parel, A. Tjellstrom, The United States and Swedish experience with osseointegration and facial prostheses, The International Journal of Oral & Maxillofacial Implants 6 (1991) 75-79.
[17] J.F. Wolfaardt, G.H. Wilkes, S.M. Parel, A. Tjellstrom, Craniofacial osseointegration: the Canadian experience, The International Journal of Oral & Maxillofacial Implants 6 (1993) 197-204.
[18] A. Charpiot, O. Chambres, J.F. Herve, P. Million, A.M. Riedinger, P. Hemar, Osteointegrated cranio-facial implants: 49 patients report, Rev Laryngol Otol Rhinol (Bord) 127 (2006) 217-222.