FLEXIBLE SILICONE OCULAR PROSTHESIS

MARTIN SEIDL[1], JIRI HABR[2], JIRI SAFKA[1], JIRI BOBEK[1]

[1]Technical University of Liberec, Institute for Nanomaterials, Advanced Technologies and Innovation, Department of Industrial Technology, Liberec, Czech Republic

[2]Technical University of Liberec, Faculty of Mechanical Engineering, Department of Engineering Technology, Liberec, Czech Republic

DOI: 10.17973/MMSJ.2023_06_2023065

martin.seidl@tul.cz

These prostheses are generally produced using two materials, glass or acrylic, and the manufacturing process is currently based only on manual procedures. However, these materials have many disadvantages, such as high hardness and fragility of glass or gradual loss of glossing. All the main disadvantages have been eliminated in the newly developed ocular prosthesis made from silicone. The publication contains the production procedure of an innovative ocular prosthesis based on the use of additive technologies.

KEYWORDS

Ocular prosthesis, silicone material, additive technology, multi-layer system, cosmetic aid

1 INTRODUCTION

Ocular prostheses for covering visual defects of the eye after an injury or serious illness are cosmetic aids that are inserted either directly onto the user's damaged eye or into the eye socket (in the case of a missing eye) and imitate the appearance of a healthy eye. These prostheses are currently produced from either glass or acrylic. Glass ocular prostheses have been manufactured for more than 150 years, and during this time the manufacturing process has scarcely changed. [Martin 1979, Raizada 2007] The production is based purely on the extraordinary skill of the glassmaker, as it is an entirely manual process. Glass prostheses are characterised by a high gloss and depth of image (irises and lenses), witch truly imitate the appearance of a healthy eye. However, a large disadvantage is the hardness and fragility of the glass. The hardness of the prosthesis is the cause of significant discomfort when wearing it, while the fragility highly increases the risk of damage during careless handling. At the same time, fragility is also a risk when using the glass prosthesis during sports activities, when there is a risk of the prosthesis breaking accidently, potentially leading to further injury (cutting the covered defective eye). [Goiato 2014, Dyer 1980] Acrylic ocular prostheses have been manufactured for more than 50 years and are also handcrafted. Similar to glass prostheses, acrylic prostheses are hard and less comfortable to wear. The lower hardness of acrylic compared to glass and its time-varying mechanical properties, especially in the presence of a relatively aggressive environment such as tears during long-term exposure, cause a gradual loss of gloss, which is visually undesirable. This phenomenon is caused by an increase in the surface roughness of the acrylic prosthesis, which can subsequently irritate the mucous tissue in more sensitive individuals. [Patil 2008, [Ayanniyi 2013] From this point of view, it is necessary to mention another limitation aspect, which is the service life of glass and acrylic ocular prostheses. For the reasons mentioned above, it is recommended to replace the ocular prosthesis every few months (6 to 12 months). Each prosthesis, however, has a different shape and size due to the manufacturing process, and therefore individual designs differ not only in geometry but also in colour for one user. [Saxby 2019, Doshi 2005]

Information from the statistics of health insurance companies shows that there are over 5,000 users of ocular prostheses in the Czech Republic alone, and their number has not changed significantly over the past 30 years. [Darsova 2011] However, many more people have suffered an eye injury. Due to the discomfort or health risks associated with wearing a glass or acrylic prosthesis, they do not wear this compensatory supplement. Therefore, these people have to cope not only with the trauma of partial vision loss, but also with permanent consequences that have a significant impact on the aesthetics of their face. Individualised ocular prostheses made from a flexible material can help these people to increase their quality of life and restore their partially lost self-confidence. [Bartlett 1973, Jamayet 2013]

2 NEW CONCEPT AND PRODUCTION TECHNIQUES

After a thorough analysis of the issue, a flexible silicone prosthesis concept was designed, which minimises or completely eliminates the above-mentioned limits of existing solutions. This unique silicone ocular prosthesis solution demonstrates the benefits of combining advanced materials and the latest manufacturing processes based on additive technologies.

2.1 Material Base

The appropriate choice of material was a key factor for the development of a completely new generation of ocular prostheses. In the first step, the range of usable plastics was reduced to types that are suitable for applications in the healthcare sector and meet very specific requirements for flexibility and good processability without high demands on operating temperatures. These requirements are best met by two component silicones that are in a liquid state under standard operating conditions. Their hardening occurs only when the individual components are mixed, and the entire hardening process can be further accelerated by a slight increase in temperature or exposure to UV radiation. In addition to their natural flexibility, another advantage is their very good colourability in the entire volume and a high degree of mutual adhesion when they are gradually applied to already hardened layers. However, this material also has certain disadvantages, one of which is its very poor adhesion to any other material, which significantly limits the possibility of printing on the surface of silicone products. [Colas 2013, Colas 2014, Zare 2021]

Another level of the final manufacturing, for which the selection of suitable material was important, was the preparation of the casting moulds in which the final ocular prostheses were produced. The cavities of the casting moulds give the resulting shape of the ocular prosthesis and also determine its surface quality, especially the roughness and gloss. At the same time, the selected material and subsequently the entire construction of the mould must be sufficiently resistant to the pressure stress that is applied during the casting process. For reasons of high production flexibility and accuracy, the PolyJet Matrix technology was chosen, and from the material portfolio, the Digital ABS PolyJet Photopolymer material was selected for printing the moulds. [Volpato 2016, Sontakke 2020] Very good polishability and paintability of this material ensure the achievement of the desired mirror shine quality of the mould cavity surface.

2.2 Used Technologies

The ocular prosthesis is a very specific and individual cosmetic aid that places high demands on both the material and final design, as well as the production processes that can be used. As mentioned above, the basic element in the production of silicone ocular prostheses was the precise casting moulds, which were produced using the PolyJet technology. This additive technology was developed by Objet, nowadays incorporated in Stratasys, and is used for prototyping using photopolymer materials. The principle is based on the distribution of at least two photopolymer materials into the print head with micro-injectors. These materials can then be applied separately to the working area of the printer, thereby forming isolated elements from which the final product is subsequently composed, or they can be mixed with each other in defined proportions to create completely new, so-called digital materials. Each print head contains 196 nozzles for distributing the material on the build area to create a layer with a basic thickness of 16 µm. After the printing, the layer of photopolymer is immediately cured with a UV lamp. A subsequent layer is applied to the layer solidified in this way, and the whole process is repeated until the finalisation of the entire product. At the same time as the modelling material, the material for the construction of the support system is applied in the individual layers according to the demands of the product design. The casting moulds were produced on a Connex 500 device, which uses a soluble gel as the material for the support system. [Vdovin 2017, Gay 2015, Barclift 2012]

The limits of processed silicone, especially with regard to poor adhesion to other materials, have already been mentioned. However, these were eliminated in the production of the innovative ocular prosthesis by the use of special UV printers, which enabled a very stable and colour-fast printing of a silicone substrate, thereby creating an authentic imitation of the iris. For this particular case, a Roland VersaUV LEF-200 printer was used, which is characterised by an extended print area and, above all, a high-performance UV LED lamp providing very fast curing of the applied layers without excessive heat load on the substrate. The principle of UV printing used in VersaUV printers is based on a powerful movable arm on which both the printing head with injectors and the UV LED lamps surrounding the print head are located. The arm moves at high speed in the x-axis at a defined distance above the surface of the substrate, while the printing head applies individual pigments in the form of very fine drops according to the set pattern. UV LED lamps ensure immediate drying and curing of the applied ink drops, so there is no reaction or absorption between the medium and the ink. Roland is also a supplier of UV curable inks for VersaUV printers. These inks have a specific composition in order to cure very quickly under exposure to UV light and to achieve the required stiffness for immediate handling of the printed substrate. These inks are generally referred to as ECO-UV. For the requirements of the final product (high flexibility of silicone, print resistance, and high demands on print details), ECO-UVS inks were chosen from this product line, as they are characterised by extreme flexibility even when stretched up to 220% of the original size without any cracking or peeling marks. [Roland 2022, Kocacikli 2022]

3 TECHNICAL REALISATION

The production of the resulting sets of prototypes of silicone ocular prostheses was a multi-level process. The first level involved the preparation of an electronic model of the ocular prosthesis and its splitting into two layers with a design intermediate layer formed by the colour print, see Figures 1 and 2. On the second level, the cavities of the casting moulds were designed, and the construction must enable two-step production. After optimising the geometry of the cavities, the moulds were produced and the cavities were polished to the required quality, see Figure 3. The third level focused on the production of the silicone ocular prosthesis, see Figure 4. In the first step of production, a fully-coloured silicon base layer was cast, which was subsequently printed with the desired pattern of the iris and its surroundings. In the second step, the entire profile was subsequently laminated with a transparent layer of silicone, creating the final prototype. In the next steps, the overflows were cut off with the use of a trimming and fixing tool, and the ocular prosthesis took the final shape. Considering the fact that the silicone ocular prosthesis is a highly individualised cosmetic aid, each newly manufactured silicone ocular prosthesis must go through all of these levels, especially with regard to the unique colour composition of the iris and the size of the prosthesis in relation to the extent of the eye defect. If the casting moulds are completed and the colour composition of the iris and the entire eye is processed, then the production of a particular ocular prosthesis is almost unlimited.

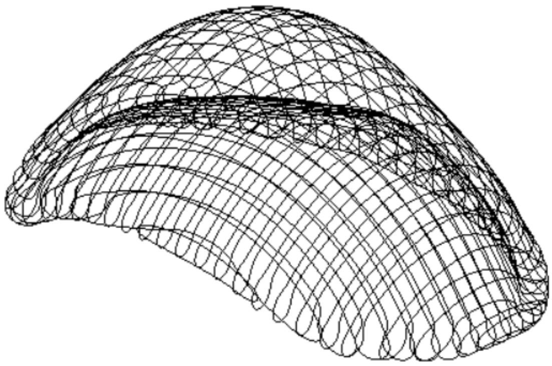

Figure 1. Parametric model of the ocular prosthesis

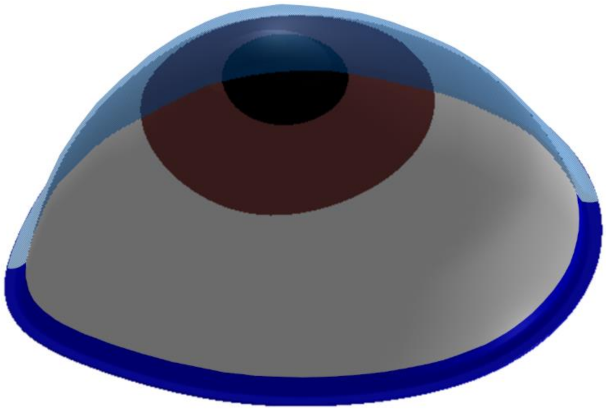

Figure 2. Model of the ocular prosthesis in a partial cross-section

Figure 3. Shape cavities of prototype casting moulds

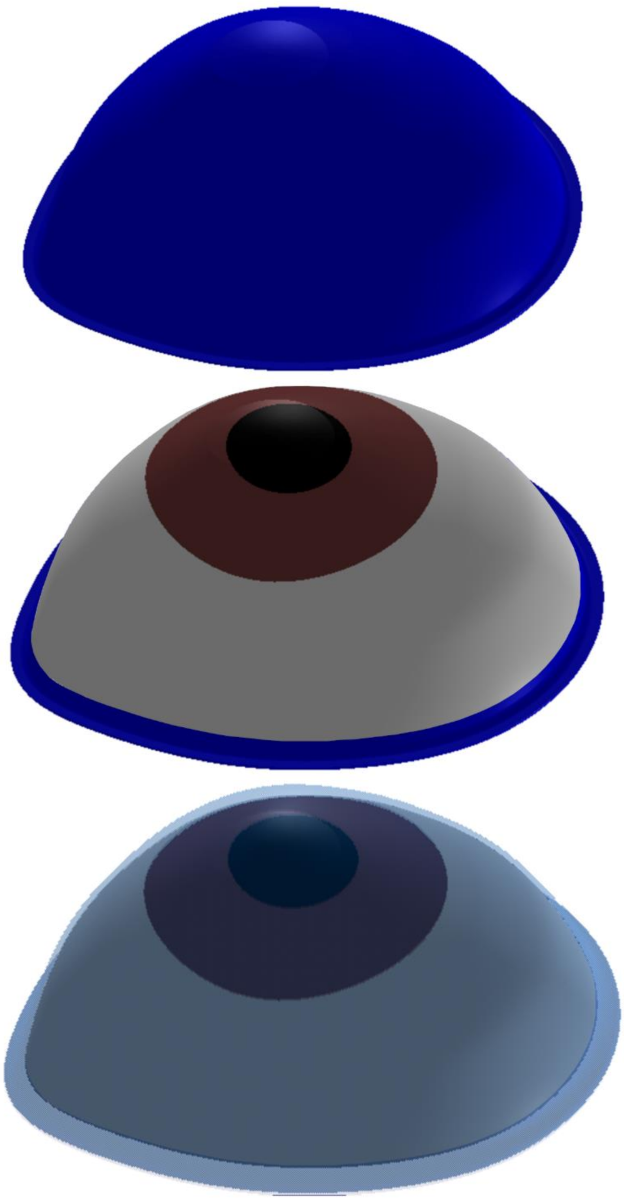

Figure 4. The production process of casting a silicone ocular prosthesis (coloured base layer at the top, intermediate design layer in the middle, transparent cover layer at the bottom)

4 CONCLUSION

A completely new generation of ocular prostheses, see Figure 5, is intended primarily for people who have a permanent aesthetic eye defect due to a serious injury or illness. The developed silicone ocular prosthesis represents a globally unique concept and provides a significantly higher level of quality compared to existing prostheses. High comfort of use and significantly longer service life are other important benefits of this solution. In order to manufacture the silicone ocular prosthesis, it was necessary to introduce a completely new complex production procedure, which combines additive technology and modern materials.

Figure 5. Silicone ocular prosthesis at the end of the production process within the casting mould

ACKNOWLEDGMENTS

This publication was written at the Technical University of Liberec as a part of the project TP01010031 PROSYKO - Pro-Active System of Commercialization at TU Liberec 2 supported by The Technology Agency of the Czech Republic. Publishing of the results was financially supported by the Ministry of Education, Youth and Sports of the Czech Republic and the European Union (European Structural and Investment Funds - Operational Programme Research, Development and Education) in the framework of the project “International Research Laboratories”, Reg. No. CZ.02.2.69/0.0/0.0/18_054/0014685.

REFERENCES

[Artopoulou 2006] Artopoulou, L., et al. Digital imaging in the fabrication of ocular prostheses. The Journal of Prosthetic Dentistry. 95(4), 327-330. 2006. ISSN 00223913. Available from doi:10.1016/j.prosdent.2006.01.018

[Ayanniyi 2013] Ayanniyi, A. Emotional, Psychosocial And Economic Aspects Of Anophthalmos And Artificial Eye Use. The Internet Journal of Ophthalmology and Visual Science [online]. 7(1) [cit. 2022-10-20]. 2013. ISSN 1528-8269. Available from: https://ispub.com/IJOVS/7/1/8540

[Barclift 2012] Barclift, M. W. and Williams, C. B. Examining Variability in the Mechanical Properties of Parts Manufactured via PolyJet Direct 3D Printing. In: International Solid Freeform Fabrication Symposium [online]. 2012, pp. 876-890 [cit. 2022-10-21]. Available from doi:10.26153/tsw/15397

[Bartlett 1973] Bartlett, S. O. and Moore, D. J. Ocular prosthesis: A physiologic system. The Journal of Prosthetic Dentistry. 29(4), 450-459. 1973. ISSN 00223913. Available from doi:10.1016/S0022-3913(73)80024-1

[Colas 2013] Colas, A. and Curtis, J. Medical Applications of Silicones. In: RATNER, B. D., ed. Biomaterials Science: An Introduction to Materials in Medicine. Third Edition. United States: Elsevier Science Publishing, pp. 1106-1116. 2013. ISBN 978-0-12-374626-9.

[Colas 2014] Colas, A. and Curtis, J. Silicones. In: Modjarrad, K. and Ebnesajjad, S., ed. Handbook of Polymer Applications in Medicine and Medical Devices. Plastics Design Library, pp. 131-143. 2014. ISBN 978-0-323-22805-3.

[Doshi 2005] Doshi, P.J. and Aruna, B. Prosthetic management of patient with ocular defect. The Journal of Indian Prosthodontic

[Darsova 2011] Darsova, D. Oční protézy u dětí a žáků se zdravotním postižením. In: Asociace zrakových terapeutů o.s. [online]. 2011. Praha [cit. 2022-10-18]. Available from: http://www.iazt.cz/publikace_download/Kurz%20Ocni%20Protezy%20-%202011.pdf

[Dyer 1980] Dyer, N.A. THE ARTIFICIAL EYE, 1980. Australian and New Zealand Journal of Ophthalmology. 8(4), 325-327. ISSN 0814-9763. Available from doi:10.1111/j.1442-9071.1980.tb00293.x

[Gay 2015] Gay, P., et al. Analysis of Factors Influencing the Mechanical Properties of Flat PolyJet Manufactured Parts. Procedia Engineering. Elsevier, 132, pp. 70-77. 2015. ISSN 18777058. Available from doi:10.1016/j.proeng.2015.12.481

[Goiato 2014] Goiato, M., et al. Fabrication Techniques for Ocular Prostheses – An Overview. Orbit. 33(3), 229-233. 2014.ISSN 0167-6830. Available from doi:10.3109/01676830.2014.881395

[Jamayet 2013] Jamayet, N. B. A Complete Procedure of Ocular Prosthesis: A Case Report. International Medical Journal. 20(6), 729-730. 2013. ISSN 13412051.

[Kocacikli 2022] Kocacikli, M. An alternative technique by using digital photography and UV printing for fabricating a custom made ocular prosthesis. The International Journal of Artificial Organs. 2022. ISSN 1724-6040. Available from doi:10.1177/03913988231151

[Martin 1979] Martin, O. and Clodius, L. The History of the Artificial Eye. Annals of Plastic Surgery. 3(2), 168-171. 1979. ISSN 0148-7043. Available from doi:10.1097/00000637-197908000-00014

[Patil 2008] Patil, S. B., et al. Ocular prosthesis: a brief review and fabrication of an ocular prosthesis for a geriatric patient. Gerodontology. 25(1), 57-62. 2008. ISSN 0734-0664. Available from doi:10.1111/j.1741-2358.2007.00171.x

[Raizada 2007] Raizada, K. and Rani, D. Ocular prosthesis. Contact Lens and Anterior Eye [online]. 30(3), 152-162 [cit. 2022-10-22]. 2007. ISSN 13670484. Available from doi:10.1016/j.clae.2007.01.002.

[Roland 2022] VersaUV LEF2-200 UV flatbed printer, 2022. Roland DG [online]. [cit. 2022-10-19]. Available from: https://www.rolanddga.com/products/printers/versauv-lef2-200-flatbed-printer

[Saxby 2019] Saxby, E., et al. Living with an artificial eye—the emotional and psychosocial impact. Eye [online]. 33(8), 1349-1351 [cit. 2022-10-24]. 2019. ISSN 0950-222X. Available from doi:10.1038/s41433-019-0398-y

[Sontakke 2020] Sontakke, B. N. and Ahuja, B. B. Mechanical Characterization and Process Optimization of PolyJet 3D Printing Using Digital ABS with Different Part Geometries. Advances in Additive Manufacturing and Joining. Singapore: Springer Singapore, 2020-10-17, pp. 31-45. Lecture Notes on Multidisciplinary Industrial Engineering. 2020. ISBN 978-981-32-9432-5. ISSN 978-981-32-9433-2. Available from doi:10.1007/978-981-32-9433-2_3

[Vdovin 2017] Vdovin, R., et al. Implementation of the Additive PolyJet Technology to the Development and Fabricating the Samples of the Acoustic Metamaterials. Procedia Engineering, Vol 176, pp. 595-599, ISSN 595-599

[Volpato 2016] Volpato, N., et al. An analysis of Digital ABS as a rapid tooling material for polymer injection moulding. International Journal of Materials and Product Technology. 52(1/2). 2016. ISSN 0268-1900. Available from doi:10.1504/IJMPT.2016.073616

[Zare 2021] Zare, M., et al. Silicone-based biomaterials for biomedical applications: Antimicrobial strategies and 3D printing technologies. Journal of Applied Polymer Science [online]. 2021, 138(38) [cit. 2022-10-23]. 2021. ISSN 0021-8995. Available from doi:10.1002/app.50969

CONTACTS:

Ing. Martin Seidl, Ph.D.

Technical University of Liberec, Institute for Nanomaterials, Advanced Technologies and Innovation, Department of Advanced Technology

Bendlova 1409/7 - building L, 460 01 Liberec 1, Czech Republic

Telephone: 00420 485 353 801, martin.seidl@tul.cz, https://cxi.tul.cz/en/