



Application of 3D Printing Technology in Scleral Cover Shell Prosthesis

Miguel Angel Sanchez-Tena¹ · Cristina Alvarez-Peregrina¹  · Fabricio Santos-Arias² · Cesar Villa-Collar¹

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Abstract

3D printing has a great and surprising number of uses in the field of medicine. Some of these uses are nowadays on a trial phase but others are becoming more common as 3D printing of prosthesis and implants. This study uses the most advanced technology in topography to get a 3D image of the anterior surface of the eye and explores how to use this information to get a scleral cover shell prosthesis by 3D printing techniques. The reliable results of the study could lead the way to new ways of fitting scleral cover shell prosthesis. Advance topography and 3D printing simplify the process and benefit patients avoiding the step of getting an ocular mold and reducing the number of visits to the eye care professional.

Keywords 3D printing · Topography · Prosthesis · Eye · Sclera · Cornea

Introduction

3D printing is called to revolutionize the world. A lot of architecture firms and engineering companies are already benefiting to a substantial extent from this breakthrough. However, this technology has a great and surprising number of possible uses in the field of medicine.

Some of these uses are nowadays on a trial phase, such as the extrusion of living cells, which has led to bioprinting of tissues. Others are becoming more common. 3D printing of prosthesis and implants, such as hearing aids, dental prosthesis, bone implants, personalized cardiac prosthesis, tissue printing or even organ printing, are getting usual.

There are also important developments in the field of vision sciences, as impression of artificial corneas [1] or retinas [2] and some attempts to print contact lenses with educational purposes [3, 4] or to serve as trial lenses in complex fittings

or orbital implants [5]. In fact, there is already a patent explaining the method to print contact lenses by 3D printing since 2015 [CN201510255728]. The authors are going to study the use of 3D printing technology for the manufacture and fitting of scleral cover shell prosthesis (Fig. 1).

A scleral cover shell prosthesis has a maximum of 4 mm of thickness. It is designed to be worn over the imperfect eye, when after evisceration by a congenital or acquired disease, by an accident or by a congenital macrophthalmia, the eye is discolored or disfigured.

Clinical steps to fit the scleral cover shell are focused on the impression molding process with alginate to get the shape of the internal cavity, on the measurement of the iris and pupil diameter, on keratometry values and on taking photographs for chromatic evaluation of the iris, sclera, and vessels. The process ends testing the cover shell on the patient.

The authors' proposal would take together corneal and scleral parameters in a precise way, using a new topographer [6]. Then we would link these parameters to a 3D printer. This would simplify the process and benefit patients avoiding the step of getting the ocular mold and reducing visits, since the eye care professional would go directly to the step of painting the scleral cover shell and fitting it on the patient's eye.

The aim of the paper is to explain the pilot study carried out. The authors have reproduced the ocular shape measured by scleral topography through 3D printing techniques with a good result.

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✉ Cristina Alvarez-Peregrina
cristinaalvarezperegrina@gmail.com

¹ Faculty of Biomedical and Health Sciences, Universidad Europea de Madrid, Madrid, Spain

² School of Architecture, Engineering and Design, Universidad Europea de Madrid, Madrid, Spain

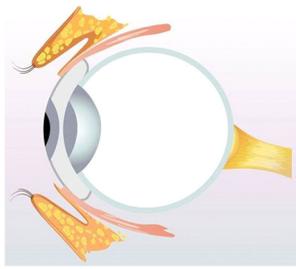


Fig. 1 Graphical representation of a scleral cover shell prosthesis in a smaller eyeball

Methods

Corneal and scleral topography was taken by the Eaglet-Eye (Eaglet Eye b.v, The Netherlands) ESP (eye surface profiler) topographer.

This new topographer is the first to offer to profile, not only of the cornea but also right across the limbus and over a large portion of the sclera. It gives a measurement of 20 mm of diameter and its accuracy allows generating 3D ‘height maps’ of the eye’s surface in detail [7].

The topography taken with the ESP topographer was recorded as a digitized file of the anterior surface of the patient’s eye, compatible with the 3D printer.

The desktop 3D printer used was MakerBot™ model Replicator 2™ (MakerBot Industries, USA) with technology type FFF (Fused Filament Fabrication) with a resolution capability of 100 μm and a massive 410-cubic-inch build volume. It is one of the easiest, fastest and most affordable tool yet for making professional-quality models with printing reliability. This model extrudes a thermoplastic filament of PLA (polylactic acid), that is available in spools from 250 g to 4000 g with a diameter of 1.75 mm in different colors and consistencies. The extruder has a 0.4 mm nozzle, reaching a resolution of 100 μm. This printer allows a maximum construction volume of 28.5 × 15.3 × 15.5 cm.

The printer software was MakerWare™ (MakerBot Industries, USA). It supports extension files .stl, .obj, .thing, and is able to operate under Windows systems (XP / 7), Linux (Ubuntu 10.04+), Mac OS X (10.7 / 10.8). This software sections the model in as many parallel layers as needed depending on the resolution (0.05 mm of layer height in this pilot study) to proceed to its extrusion in the sections parallel to the bed of impression.

The material used was plastic filament PLA (polylactic acid). The color chosen was white to allow to better appreciate the geometry of any volume.

Results

Patient’s topography, taken at Novovision Clinic in December of 2018, is shown in Fig. 2.

Figure 3 shows the STL file, exported in the FABLAB at Universidad Europea de Madrid.

After programming, the 3D printer started producing the scleral cover shell prosthesis as Fig. 4 shows. Figure 5 exposes the result of the prosthesis.

Discussion

When vision has been lost, esthetic appearance is still very important for patients. There are different solutions depending on the eye condition. Cosmetic contact lenses would be the best option if the eyeball has not lost volume and is not retracted. Otherwise, fitting a scleral cover shell is a good option whether if the affected eye is fine or after a surgical procedure to recover the lost volume. Usually, a scleral cover shell prosthesis is made from a mold, obtained from the contralateral eye. This mold is reproduced in biocompatible material and painted with the same pupillary diameters and iris colors.

In this pilot study with one patient, we have explored how to obtain the mold not by injection of alginate but by a corneo-scleral topography with the ESP topographer. ESP topographer uses profilometry to generate very accurate height profiles on the anterior surface of the eye. It generates up to 500,000 information points per measurement with a vertical resolution of submicron level. For cornea, accuracy is 2 μm, while for sclera it is 10 μm. Although the instrument can assess up to 20 mm in diameter, eyelids limit the vertical measurement, that depends on the palpebral aperture. A blefarostate, like those used in eye surgery, could be used to get the largest palpebral aperture.

The profile from a volunteer patient has been printed by 3D techniques after the measurement with the ESP topographer. This process could be used as a model for the manufacture of scleral cover shell prosthesis.

We have chosen polylactic acid or PLA for the pilot study. PLA is biodegradable, it is manufactured from renewable raw materials, such as corn starch. It is one of the easiest materials to print. It is also important to highlight the slight shrinkage of this material after 3D printing. We should work with not very high temperatures, between 190 °C to 230 °C. The weakness of PLA is the handling difficulty due to its high cooling and solidification speed. It is important to mention that it can be damaged or stretch in contact with water. This material, generally translucent, is used by most cast deposition machines and is found in a wide variety of colors. Although a multitude of new materials are currently being developed [8], polymethylmethacrylate (PMMA) would be the ideal material for a scleral cover shell prosthesis. PMMA is the transparent thermoplastic material used in the first corneal contact lenses and a usual material in the scleral prosthesis. It is widely used in 3D printing techniques in dentistry. The main disadvantage

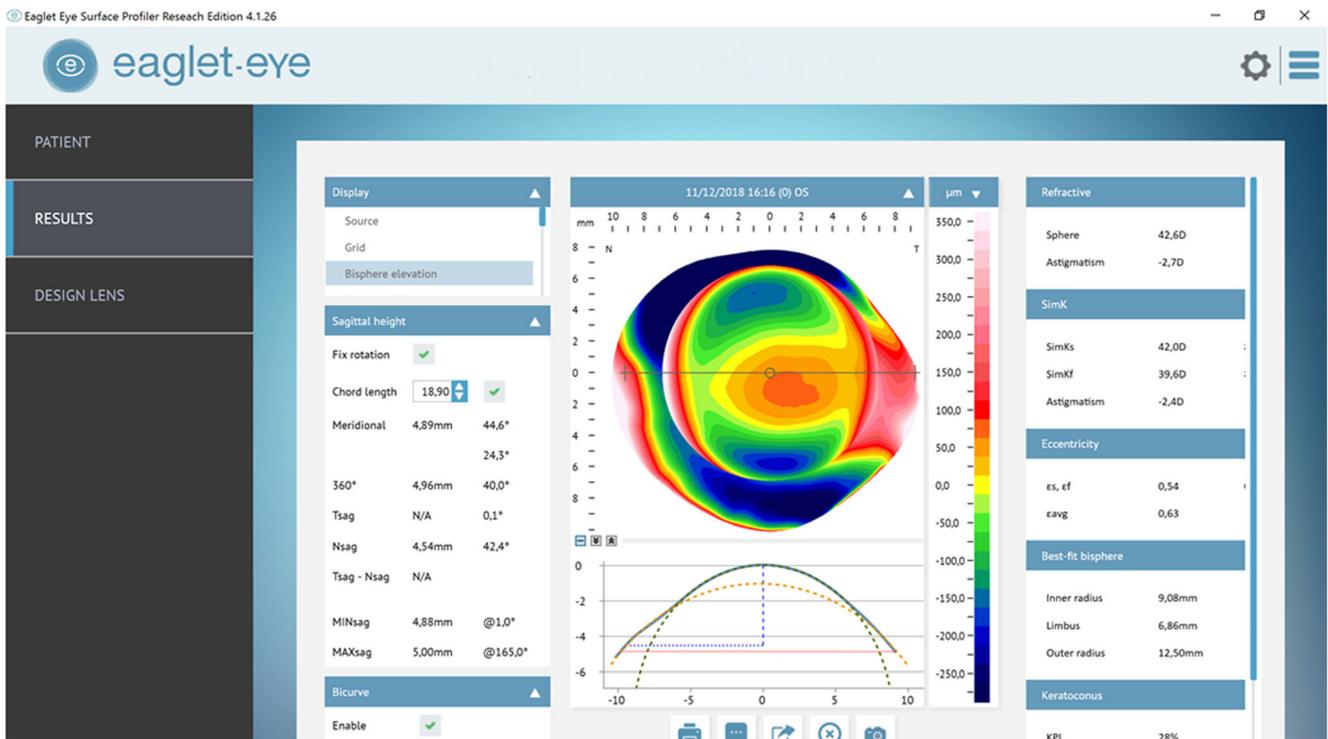


Fig. 2 Topography of sclera and cornea of our trial patient

of PMMA is that it is not permeable to gases, but this disadvantage is not a problem in blind eyes with eyeballs very retracted.

Another point to consider is the roughness of the prosthesis' surface. 3D printing technology is already being used in the manufacture of ophthalmic lenses where the roughness is a

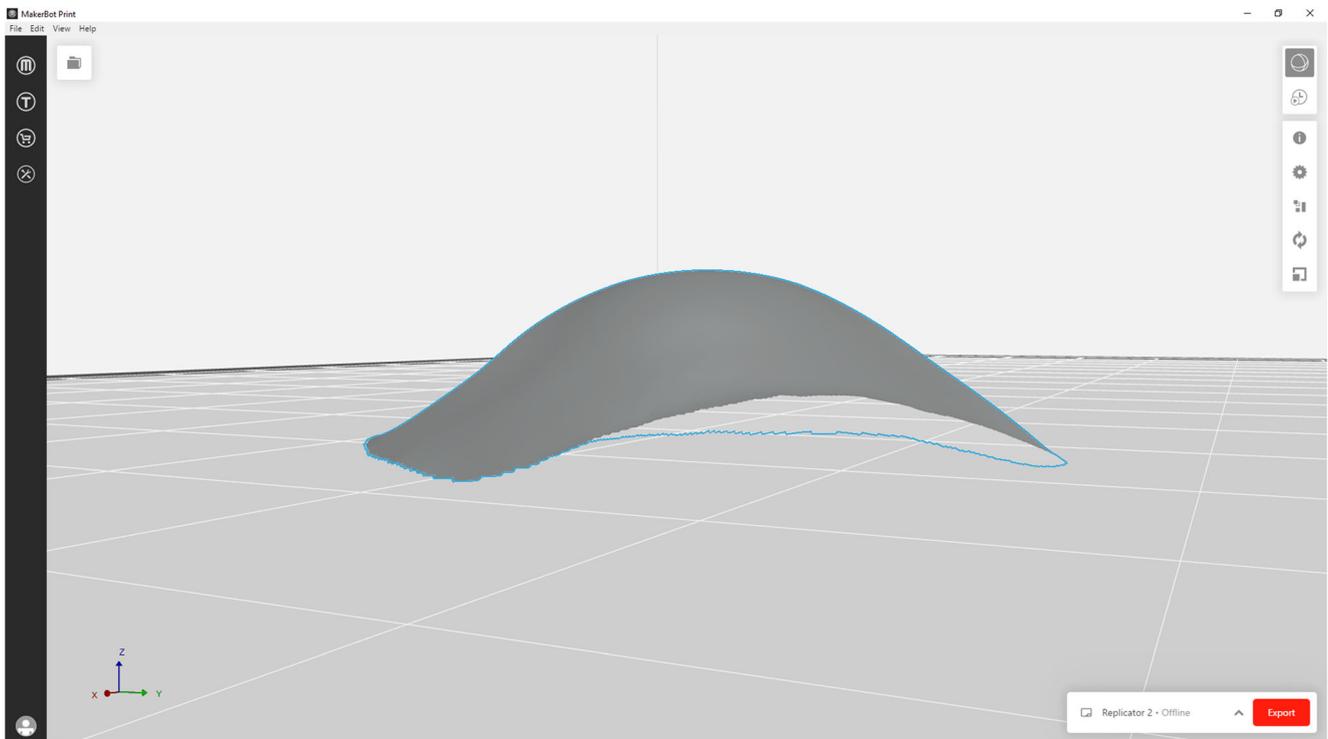


Fig. 3 Image of STL file from software MakerBot MakerWare™

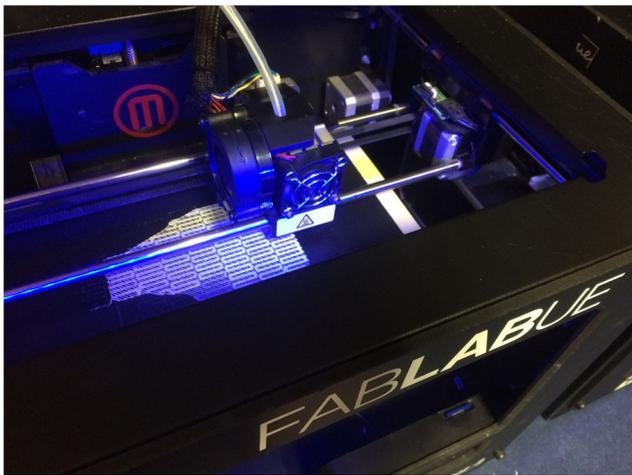


Fig. 4 Desktop 3D printer MakerBot™ Replicator 2™ type FFF (Fused Filament Fabrication)

critical issue because it could produce aberrations. Gawedzinski et al. have compared roughness of ophthalmic lenses manufactured by 3D printing techniques with those manufactured in a traditional way, concluding that there are no differences [9]. In our study, aberrations are not important because we are working on blind eyes, but roughness could produce discomfort by eyelid friction. Therefore, it is important to get as less roughness as possible in the final prosthesis.

The future of 3D printing in the field of vision is promising. Just for giving some examples, it could be used in the



Fig. 5 Scleral cover shell prosthesis printed in PLA

development of customized contact lenses or even ophthalmic lenses. After this pilot study, we think that the next step should be focus on using the best biocompatible materials in the current 3D printers.

Following with future applications and in relation to customized contact lenses, rigid gas permeable contact lenses (RGPCl) are the ideal choice to improve the vision of patients with keratoconus or corneal transplantation. In these cases, as well as in the case of scleral cover shell prosthesis, professionals need to try many different lenses to get better contact lens fitting. Simulating RGPCl fitting in 3D printing models could improve fittings and minimize the number of visits that patients need to do. Preliminary experimental results from Zhao et al. [3, 4] confirm this hypothesis.

In conclusion, we have been able to get a corneo-scleral profile of enough diameter to be printed by 3D printing technology. This will lead the way to new ways of fitting scleral cover shell prosthesis.

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