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APPLICATION OF THREE-DIMENSIONAL PRINTERS FOR PRODUCTION OF PERSONAL ORBITAL IMPLANTS DURING PANDEMICS

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ABSTRACT

Objective: *The production of personalized prosthesis depends on human resources and involves a manufacturing process in which patients are involved individually in. As the world is experiencing the COVID-19 pandemic, less contact with the manufacturer is needed to stay safe. 3D printed prosthesis has reduced the need for human resource in the process, while allowing the patient to be completely removed from the design and manufacturing process. In this study an approach in which the patient is kept out of the manufacturing process was investigated.*

Material and Method: *The prosthesis model was created by using the image data obtained from the medical imaging devices. The outer part of the prosthesis was shaped with a developed image sampling system. The model was produced using three-dimensional printer. A cytotoxic analysis of the raw material used in the manufacturing process was performed.*

Results: *The total production cost of the orbital implants was approximately about 8$. The cytotoxic analysis showed that layered manufacturing strategies could be used to develop implants and prostheses applicable to patients.*

Conclusion: *COVID-19 underlined the importance of social distancing which is hard to apply during manufacturing of an eye prosthesis. The manual method results in an eye prosthesis which suits well after numerous trials. On the contrary, Digital Imaging and Communications in Medicine (DICOM) based eye prosthesis designation and manufacturing is not only rapid but also flawlessly fitting due to precise measurement during the manufacturing.*

Keywords: *Patient specific implant, pandemics, COVID-19, 3D printed implants, ophthalmic surgery, cytotoxicity.*

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PANDEMİ SIRASINDA KİŞİSEL SPESİFİK ORBİTAL İMPLANT ÜRETİMİ İÇİN ÜÇ BOYUTLU YAZICILARIN UYGULANMASI

ÖZET

Amaç: Kişiselleştirilmiş protez üretimi insan kaynaklarına bağlı olup hastaların bireysel olarak dahil olduğu bir üretim sürecini içermektedir. Dünya COVID-19 pandemisini yaşarken, güvende kalmak için üretici ile daha az temasa ihtiyaç duyulmaktadır. 3D baskılı protezler, süreçteki insan kaynağı ihtiyacını azaltırken, hastanın tasarım ve üretim sürecinden tamamen çıkarılmasını sağlamaktadır. Bu çalışmada hastanın protez üretim sürecinin dışında tutulduğu bir yaklaşım araştırılmıştır.

Materyal ve Metot: Bu çalışmada medikal görüntüleme cihazlarından elde edilen görüntü verileri kullanılarak protez modeli oluşturulmuştur. Protezin dış kısmı geliştirilmiş bir görüntü örnekleme sistemi ile şekillendirilmiştir. Model üç boyutlu yazıcı kullanılarak üretilmiştir. Üretim sürecinde kullanılan hammaddenin sitotoksik analizi yapılmıştır.

Bulgular: Orbital protezin toplam üretim maliyeti, protezin tasarımı, imalatı ve dekontaminasyonu dahil olmak üzere yaklaşık 8$ civarındaydı. Sitotoksik analiz, hastalara uygulanabilir implantlar ve protezler geliştirmek için katmanlı üretim stratejilerinin kullanılabileceğini göstermiştir.

Sonuç: KOVID-19, göz protezi imalatı sırasında uygulanması zor olan sosyal mesafenin önemli olduğunu göstermiştir. Manuel yöntem, sayısız denemelerden sonra uygun bir göz protezi ile sonuçlanır. Aksine, Digital Imaging and Communications in Medicine (DICOM) tabanlı göz protezi belirleme ve üretimi, sadece hızlı değil, aynı zamanda üretim sırasındaki hassas ölçüm sayesinde kusursuz bir uyum sağlamaktadır.

Anahtar kelimeler: Hastaya özgü implant, pandemiler, COVID-19, 3D baskılı implantlar, oftalmik cerrahi, sitotoksisite.

INTRODUCTION

Ophthalmic surgery is used as a result of trauma, ocular tumor, impaired globe integrity and phthisis bulbi.[1,2] Surgical procedures in these cases are enucleation and evisceration operations.[3] Evisceration, the removal of the eye's contents, leaving the scleral shell and extraocular muscles intact, conventionally, can be performed by either removing the cornea or preserving it.[4] Enucleation, on the other hand, is the surgical procedure that involves removal of the entire globe and its intraocular contents while preserving all other periorbital and orbital structures.[1,5] Complications such as deep sulcus, pseudoptosis, facial asymmetry and deterioration of orbital bone development in pediatric cases may occur in these surgeries due to loss of orbital volume. In order to prevent these complications and to ensure patient's adaptation to daily life concurrently, an orbital implant should be replaced to make up for the lost volume. After surgical recovery is completed and dimensional stability is achieved, prosthesis production is started. The area should be carefully examined, and care should be taken to avoid any infections. Attention is paid to the mobility of the tissue bed and the width of the socket. In this kind of prosthesis, aesthetic concerns, and compatibility between the topography of the globe cavity and the implant are more important than its functionality. In this context, production is performed mainly using glass or plastic derivatives. Studies in the area in question include processes dependent on human resource and processes that require patients to be included. As the world is experiencing a pandemic, COVID-19, less contact with the manufacturer is needed to stay safe. It is obvious that digitalized and 3D printed items are more flexible, more individual (customizable), and therefore, fit flawlessly.[6] Researchers developed implants for the target site based on the DICOM data of the patients with cranial defects and used 3D printers to guide the application process.[7] Baumann *et al*. 2015, noted the efficiency of computer-aided approaches for planning and positioning in patient-specific implant development processes.[8] USOO6143026 serial-numbered ocular prosthesis manufacturing patent mentioned an algorithm comprising of a computer-aided design concept. The whole process was planned but due to the expired patent it was offered to the public. Looking at all this research, including examination of the person-specific orbital implants, and integrated ocular prosthesis manufacturing with computer-aided design, and computer-aided manufacturing processes, an approach in which the patient is kept out of the process at the highest level possible was investigated within the scope of the supported project. Within the scope of this study, the patient's anatomic and implant data was acquired with the help of medical imaging devices. Since the anatomical image can be created in a three-dimensional virtual environment, it was aimed primarily to completely remove the patient from the segmentation and manufacturing process, and to increase patient comfort by providing maximum adaptability by transferring the surface topography of the globe to the implant.

MATERIAL AND METHOD

Within the scope of the study, 3D SLICER open-source program version 4.11.0 was used for 3D modeling and segmentation of DICOM format data in a virtual environment. The version of Ultimaker Cura open-source program 4.0.2 (https://ultimaker.com/software/ultimaker-cura) was utilized to prepare the three-dimensional model for layered manufacturing. FDM type 3D printer (Robotürk, Turkey) with 300 mm*300 mm*300 mm printing area was used in the layered manufacturing process. The 3.2" TFT LCD screen was employed for sampling and monitorization of the sampling process, program parts required for the operation of the image sampling and processing systems were coded using Python programming language (https://www.python.org/) and Open CV library.

Three-Dimensional Modeling of DICOM Format Data

Since working with authentic patient data would require approval from the ethics committee, the study was commenced using sample data available in the DICOM library of the 3D SLICER program. The file containing the data in DICOM format was displayed on three different axes in the 3D SLICER interface and a three-dimensional image was derived from the obtained images. The three-dimensional image obtained with the Value Rendering tool, located among the program toolbars, was improved (Figure 1).

Topographic Characterization of the Globe Gap

Subsequent to modeling, globe space was characterized by using the Markup tool of the 3D SLICER program and the region to be studied was limited. The necessary contrast changes were made to mark the boundaries of the globe space on all three axes. With the Volume Rendering tool in the program, individual markings made on three axes were combined to form a monolithic three-dimensional model (Figure 2).

Segmentation of the Implant Model

In line with the determined globe model, three-dimensional segmentation of the region where the implant will be placed was done, and the markings necessary for the transfer of the cavity topography to the implant model were made in parallel in all three axes. Following the markings, the implant model was created by constructing the regions marked on the axes in three dimensions. The resulting implant model was saved with the stereolithography (.stl) extension to prepare it for the manufacturing step (Figure 3).

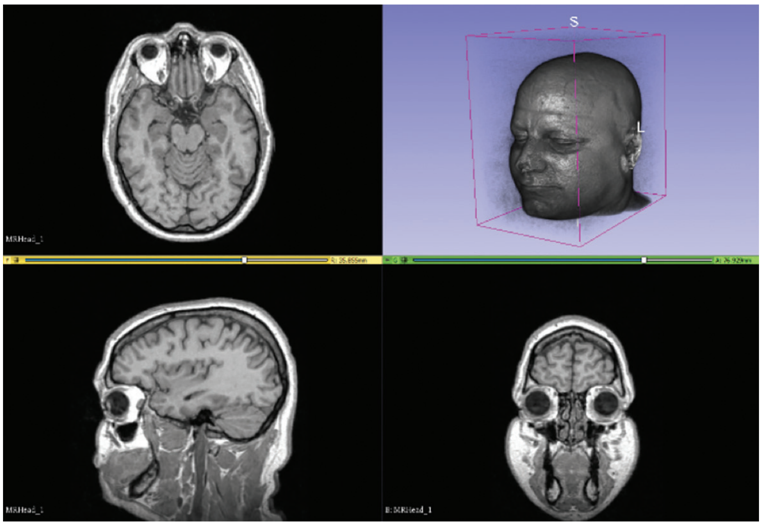

Figure 1. Digital Imaging and Communications in Medicine (DICOM) format displayed on three different axes in the 3D SLICER interface

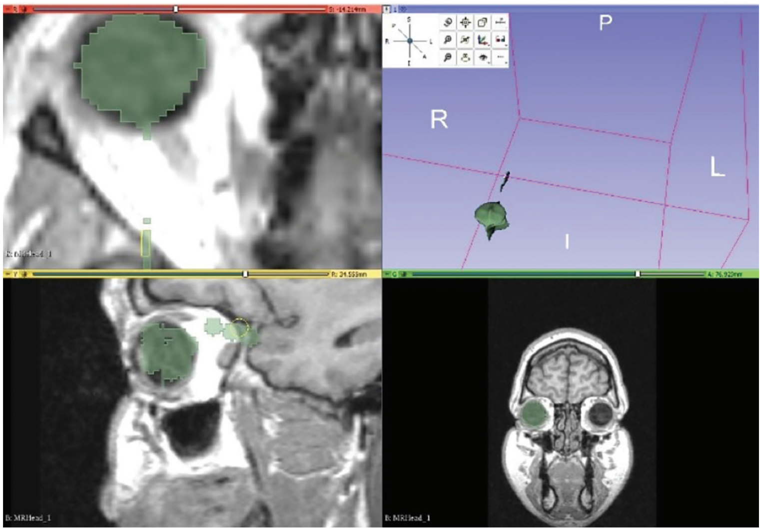

Figure 2. Marking the Globe Gap Boundaries with the Markup Tool of the 3D SLICER Program

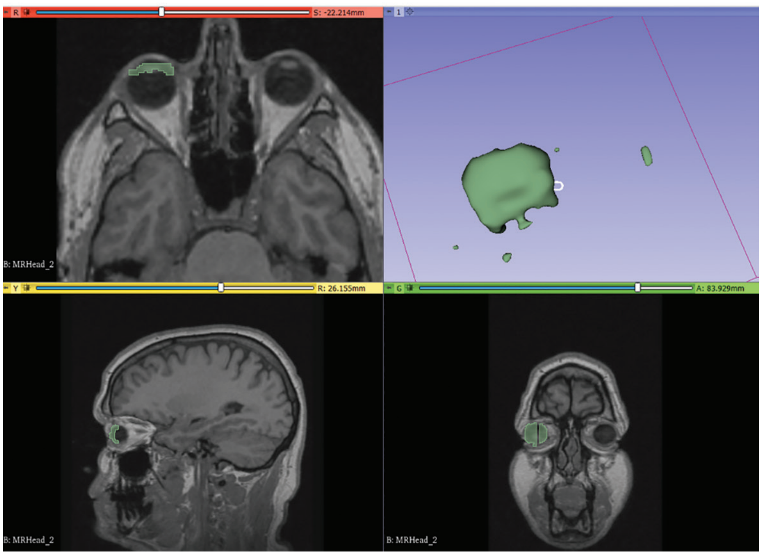

Figure 3. Marking the boundaries of the Implant Model Using the Markup Tool of the 3D SLICER Program

```python
#A simple version of camera capture using OpenCv and Tkinter:

import tkinter as tk
import cv2
from PIL import Image, ImageTk

width, height = 1080, 720
cap = cv2.VideoCapture(0)
cap.set(cv2.CAP_PROP_FRAME_WIDTH, width)
cap.set(cv2.CAP_PROP_FRAME_HEIGHT, height)

root = tk.Tk()
root.bind('<Escape>', lambda e: root.quit())
lmain = tk.Label(root)
lmain.pack()

def show_frame():
    _, frame = cap.read()
    frame = cv2.flip(frame, 1)
    cv2image = cv2.cvtColor(frame, cv2.COLOR_BGR2RGBA)
    img = Image.fromarray(cv2image)
    imgtk = ImageTk.PhotoImage(image=img)
    lmain.imgtk = imgtk
    lmain.configure(image=imgtk)
    lmain.after(10, show_frame)
def cek():
    ret,kamera=cap.read()
    cv2.imwrite('goruntu1.jpg',kamera)

def cıkıs():
    cap.release()
    cv2.destroyAllWindows()
    root.destroy()

def goz():
    i=0
    img= cv2.imread('goruntu1.jpg')

    eyes =cv2.CascadeClassifier('haarcascade_lefteye_2splits.xml')

    grayColors=cv2.cvtColor(img,cv2.COLOR_BGR2GRAY)

    eyes1=eyes.detectMultiScale(grayColors,1.1,9)
```

Figure 4. Part of the program developed for the image sampling

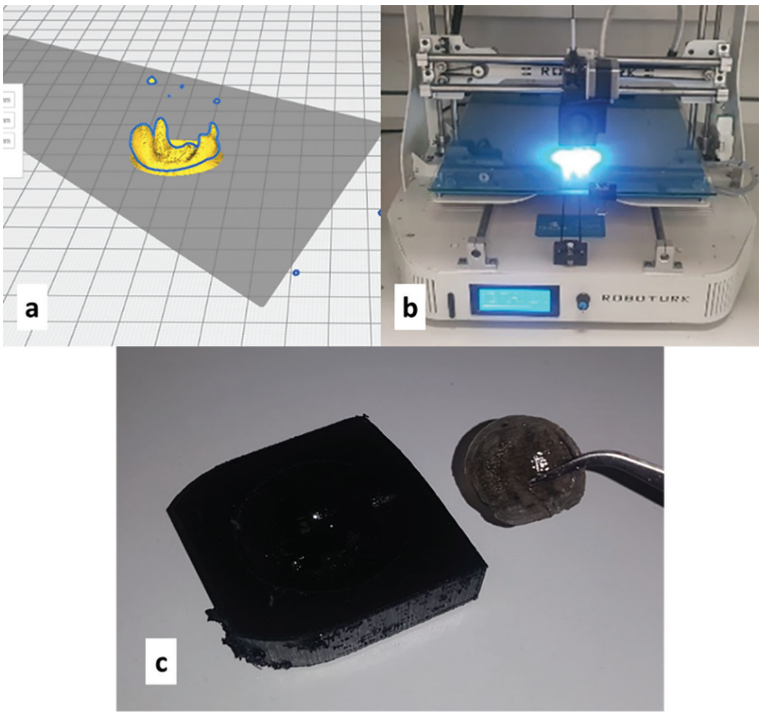

Figure 5. a) Ultimaker Cura Slicing Interface.
b) Production of implant model by layered manufacturing method.
c) Separation of cured resin-based lens from the mold

Image Sampling from the Equivalent Region

The sampling process was implemented by using a hardware combination of Raspberry Pi 3B+development board, 3.2" TFT LCD screen and PiCam 8 MP camera, and an image sampling and processing software coded in Phyton 3.7 programming language (Figure 4).

Preparation of the Implant Model for Manufacturing

The implant model saved in stl. format was prepared for layered manufacturing using Ultimaker CURA program. The model was programmed to be produced at 200°C nozzle and 60°C bed temperature with a speed of 60 mm/sec and each layer to be 100 µm. In line with the specified parameters, the operating data were saved in G-code format and transferred to the portable memory.

RESULTS

Production of the Orbital Implant

The portable memory containing G-codes was placed in a printer capable of layered manufacturing using melt-wipe modeling (fused deposition modeling, FDM) with a printing area of 300 mm*300 mm*300 mm. Manufacturing was carried out by sequentially depositing layers in line with the data that included operating parameters such as temperature, layer thickness, and production speed (Figure 5a, 5b).

Production of the Iris Module

In accordance with the surface topography of the implant model, a mold was produced using the printer for the lens production. The lens structure was formed in the mold by using UV curable resin. The manufactured lens model was kept in 60°C acetone for 30 min, then in 60°C ethyl alcohol for 10 min to remove uncured resin residue and residue resulting from PLA used in the mold production. The residue-free squeegee (lens) was dried and prepared to be combined with iris stubs in the next step (Figure 5c).

Transferring Image Samples from Equivalent Region to the Module

The iris models obtained from the segmentation of the sample images by using a software prepared for image acquisition from the equivalent region were produced by using a printer with Inkjet manufacturing technology and were pieced together with the lens model which was obtained from the previous step. By bringing the components together, a model which had an iris based on the real visual and whose topographic features were prepared based on the topography of the globe cavity was produced (Figure 6). Each prosthesis cost approximately 8 USD (100 TL - 10.31.2021). The cost included the design, manufacturing, and decontamination of the prosthesis.

Cytotoxic Analysis

Acute toxicity tests are mandatory to identify the potential toxicity of a substance. The most commonly used acute toxicity test is the lethality test. The aim of this test is to determine the toxic symptoms and the degree of hazard that may result from exposure in organs such as the brain, kidney, and liver or to determine the lethal dose (lethality). The lethal dose value of a substance is also considered to be an indicator of how safely it can be used. The test is usually performed on test animals or cell cultures, such as mice or rats that are easy to supply and cost-effective. According to the results, the test can be repeated on a guinea pig or rabbit. The test animals to be used in the test should be very healthy; the mice and rats should be kept in the laboratory for one week; the dogs should be supervised for 3-4 weeks before the test procedures. The dose that kills 50% of the animals in the test group when given at a time is called the lethal dose (LD50) of that substance. The LD50 value is important to assess the acute toxic effects of short-term exposure of chemicals. When presenting the LD value, the test animal used, and the route of exposure should also be specified. Cytotoxic analysis for the UV curable resin used in the production of the model was performed in order to apply the model to the region of interest. After printing the 3D model, the resin was washed with isopropyl alcohol for 5 minutes. Following the washing process, the isopropyl alcohol was dried, and the model was put under a UV source to be cured for 15 minutes. SH-SY5Y neuroblastoma cells were seeded in 96-well plates at a density of 1×10^3 cells/ml culture medium. After 24 h pre-exposure incubation, the cells were treated with a range of concentrations of resin between 10 µg/ml and 200 µg/ml. Resin treated and control cells were incubated for 24 h at 37°C in humidified 5% CO_2 atmosphere. Following incubation, the medium was replaced by 0.5% crystal violet solution (w/v; in 50% Ethanol). Dye absorbed by live cells was extracted with sodium citrate (0.1 M in 50% ethanol). Absorbance was read at 630 nm. Cell viability was expressed as a percentage of the control, untreated cells. The cytotoxicity of resin in SH-SY5Y cells were investigated by crystal violet cell staining. As shown in Figure 7 resin treatment revealed a concentration-dependent cytotoxic effect on HepG2 cells. EC50 value for resin, was calculated 30.26 µg/ml in SH-SY5Y cells.

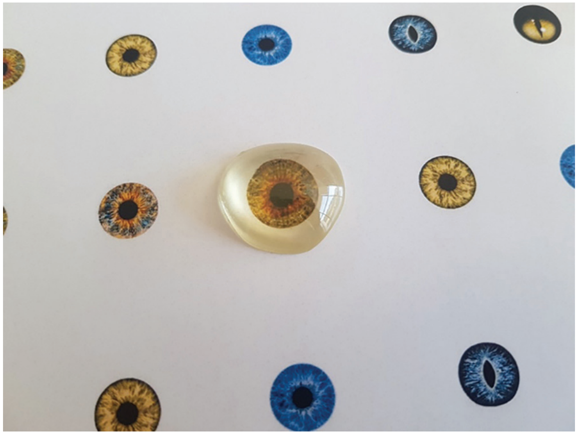

Figure 6. Combining the cleaned lens with the Iris Model

DISCUSSION

There are two types of ocular prosthesis available readymade or stock, which are readily available, inexpensive and can be fitted instantly; and custom-made prosthesis (CMP), which are tailored and customized to the individual user. CMP has several advantages over stock shells, such as better apposition with the anterior surface of the socket, better cosmesis and enhanced ocular movement.[9] The procedure of conventional CMP fabrication involves the following steps: examination by the ocularist, taking an impression, wax model for the socket, centration of the prosthesis, fabrication of iris and pupil to match the fellow eye, molding in acrylic, tinting to match the scleral shade, packing with the clear acrylic, polishing, instructions about hygiene and care of the prosthesis.[10] This procedure involves several manual processes, it is time-consuming, labor-intensive, and expensive.[9-11] In addition, as it is not possible to store data pertaining to a previously created ocular prosthesis, reproducing the original product in the case of damage or loss would require the same amount of time, effort, and cost. Commercially available orbital implants are very expensive, usually more than $1000, so it could be a burden to some people. In this study, we produced personal orbital implants using 3D printing. Here, the total production cost of our orbital implants was approximately about $8 including the design, manufacturing, and decontamination of the prosthesis. In addition, it is easy to re-produce without skilled ocularists because design data for each patient could be stored. In the present method, after CT measurement 3D printed patient-specific implants (PSI) was prepared in a short time. This method is a time saving and cost-effective method compared to impression-based method. Patients do not have to attend measurement and production phases. Complications of orbital implants are well known.[12-14] These complications may be related to implant, patient, and physician.[15] Sundelin

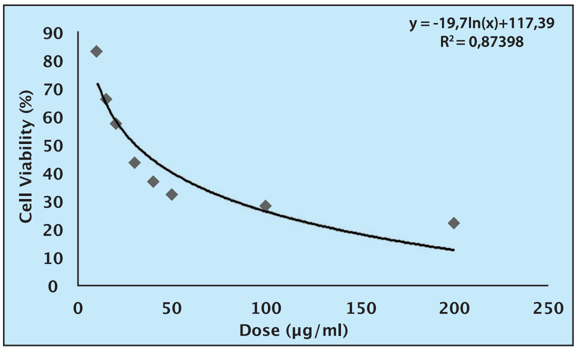

Figure 7. Cytotoxic effect of resin on HepG2 cells

et al. found that implant-related complications to be such as migration of the implant (13%), insufficient orbital volume (10%), exposure/extrusion/infection (8%), mechanical obstruction (1%), and socket edema (1%).[16] Until now studies have focused on PSI to prevent implant complications especially on secondary to implants and patients.[17,18] Several recent studies that utilize 3D printing technology to manufacture CMP have been reported. For example, Ruiters *et al*. produced a 3D printed mold, instead of impression molds, by CT imaging in anophthalmic patients.[19] Their technique avoids the process of fabricating the impression mold, which patients may find uncomfortable. However, it has several drawbacks. First, it entails replacing the impression mold with a 3D-printed device, and the ocular prosthesis itself is manufactured by hand, as in the conventional method. Ruiters *et al*. reported that the patient did not have any cosmetic or wearing problem for 6 months follow-up period. Alam *et al*. recently proposed a method of fabricating ocular prostheses with polyjet 3D printing using Polymethyl Methacrylate (PMMA).[9] They reported that the proposed method reduces the fabrication time while maintaining a satisfactory cosmetic outcome. However, as with the conventional method of ocular prosthesis fabrication, it produces a wax model from an impression and records a CT scan of the model to obtain a 3D model for 3D printing. Considering that an acrylic mold can be manufactured directly from the wax model in the conventional ocular prosthesis fabrication method, substituting it with CT scanning followed by 3D printing does not appear to be highly advantageous. In a study done by Dave *et al*. the inferotemporally migrated spherical orbital implants have been corrected by using a 3D printed patient-specific orbital implant.[20] They concluded that PMMA implants produced by 3D printers were more cost-effective than porous orbital implants. SEDLAK *et al*. designed a prototype of aesthetic eye prosthesis based on a 3D model obtained by scanning acrylic prosthesis and manufactured it using additive PolyJet technology. The printed core of the prototype achieved considerable aesthetic qualities especially in the iris region. The overall appearance after the application of veined cotton and acrylic coating is comparable to handmade prostheses.[21] Beiruti *et al*. proposed using 3D printing and 3D scanning to create personalized eye shape interior, dip coated with state-of-the-art external surface material. Preliminary results demonstrated the feasibility of the combination of new scanning, printing and coating method. A simulated run of four CMPs produced showed that the integrated process allows throughput of more than four CMPs per day for a two-person team, with accumulated errors within defined 0.5mm targets and total material costs less than \$9.[22] Ko *et al*. proposed a novel semi-automated method for fabricating customized ocular prostheses using three-dimensional (3D) printing and sublimation transfer printing. In the proposed method, an impression mold of the patient's anophthalmic socket is first optically scanned using a 3D scanner to produce a 3D model. The ocular prosthesis is then produced via a digital light processing 3D printer using biocompatible photopolymer resin. Subsequently, an image of the iris and blood vessels of the eye is prepared by modifying a photographed image of the contralateral normal eye, and printed onto the 3D-printed ocular prosthesis using a dye sublimation transfer technique. Cytotoxicity assessments of the base material and fabricated ocular prosthesis indicate that there is no adverse effect on cellular viability and proliferation. The proposed method reduced th time and skill required to fabricate a customized ocular prosthesis.[23] 3D printing with computer-based techniques has advantages when compared to impression-based techniques. For example, distortion of the impression material is possible, if the material is soft. 3D printed implants provide the best accordance with the patients' orbital anatomy. In impression-based techniques, patients are required to attend all stages of the measurement procedure. This can be a source of psychological stress for the patients. Studies have reduced the need for human resource in the process, while allowing the patient to be completely removed from the design and manufacturing process. In line with all these processes, it has been concluded that studies on multi-layered manufacturing devices capable of high-resolution manufacturing and decision support systems for globe segmentation are important and that the technologies to be developed in this field will save both human resource and time while providing added value for patient comfort. Since the implant model in this study, obtains its topographic features from the globe space, it was determined that it can provide an increase in patient comfort. As the visual characteristics are sampled from the symmetrical region, it has the potential to provide maximum adaptation to daily life. Cytotoxic analysis of the raw material used in the manufacturing process showed that layered manufacturing strategies could be used to develop implants and prostheses applicable to patients. While no other studies have been found on this subject in the Republic of Turkey. The present work is a preliminary study. Future research is planned to be conducted with real patients who need ocular implants. Patients would be exposed to X-ray related to CT, however, X-ray dose may be reduced with cone beam CT.

CONCLUSION

The world is changing. The pandemic of COVID-19 underlined the importance of social distancing which is hard to apply during manufacturing of an eye prosthesis. The manual method results in an eye prosthesis which suits well after numerous trials. On the contrary, DICOM based eye prosthesis designation and manufacturing is not only rapid but also flawlessly fitting due to precise measurement during the manufacturing. Additionally, digitalized technique costs 8 USD whereas the cost for manual method is around 1000 USD which is significantly high. Within the scope of this study, globe topography was obtained in a virtual environment by using DICOM data and the image obtained from the symmetrical region was transferred to the model with the developed sampling system. The implant model was produced using three-dimensional printer and a cytotoxic analysis of the raw material used in the manufacturing process was performed.

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*The authors declare that there are no conflicts of interest.

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