



Liquid Three-Dimensional Printing for Constructing Premature Infants' Cannulaide Continuous Positive Airway Pressure Using Additive Manufacturing Technology

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Abstract

Objectives: Nurses and specialists face serious challenges, including nasal necrosis and infection at intensive care units for premature infants. Considering that therapeutic continuous positive airway pressure (CPAP) is necessary for premature infants needing respiratory support, nasal masks, and prongs transfer positive end-expiratory pressure. The infant's skin is highly delicate, and such products exert pressure on the nose and make nasal necrosis, in which case premature infants may suffer from infection and loss of nasal septum. Thus, prong support (Cannulaide CPAP) is employed to reduce the pressure. Each infant should use a specific prong since infants' noses vary in size and shape.

Materials and Methods: Computer-aided design (CAD) and additive manufacturing (AM) for medical 3D printing were implemented using soft materials (silicone). Accordingly, non-plastic and soft materials were implemented for infants at the neonatal intensive care unit because silicone is a fluid that hardens gradually.

Results: The setting ranges were transferred to the three-dimensional (3D) printer. Different prototypes were printed after applying these settings.

Conclusions: AM rises to meet this challenge by making ergonomic products. This study addresses the innovation and production of liquid silicone prong support through AM. This prototype was tested at Al-Zahra hospital in Tabriz, Iran, and the results turned out to be satisfactory.

Keywords: Additive manufacturing, 3D silicone printing, Infants premature, Continuous positive airway pressure

Introduction

Premature infants are physically vulnerable and need considerable help. Most importantly, they need respiratory support. Thus, many medical ventilators have been developed, along with different oxygen therapy models such as continuous positive airway pressure (CPAP) and synchronized inspiratory positive airway pressure to help premature infants (1,2).

These devices employ various oxygen therapy methods, among which nasal masks or prongs are more prevalent in Iran. However, these masks and prongs are not appropriate for every infant since they vary in size. According to Imbulana et al(3), despite companies' efforts to manufacture them in the most appropriate sizes, the vast number of sizes can confuse the nurses who need to spend a significant portion of their time taking care of other problems with infants at neonatal intensive care units (NICUs).

Additive manufacturing (AM) advances have

simultaneously helped medicine to facilitate tasks and improve health. In recent years, there has been a significant increase in the successful use of AM in medical engineering areas. These advances include the introduction of new substances and innovation in different printing methods. The printable materials in the field of medical devices have considerably changed, in as much as it is now possible to design a specific human body part by the computer and implant it in the body using particular materials (4-6).

Regarding premature infants, the most serious challenge is the inability to print liquid silicone substances using three-dimensional (3D) printers (7-9). Therefore, in this study, auxiliary devices were applied to print soft and liquid substances while putting aside conventional filaments. This study proposes the process of designing and producing silicone support introduced as a successful prototype for the AM of soft materials in medicine for premature infants.

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Key Messages

What is the current knowledge?

- ▶ Most of the research and applications of medical 3D printing are related to the physiotherapy area.
- ▶ Many types of research are about how to work with solid filaments in medical uses.
- ▶ Premature infants' Cannulaide CPAP is manufactured in limited sizes.
- ▶ There is an insufficient amount and size of Cannula CPAPs in the hospital.

What is the novelty of this study?

- ▶ Extracting the exact size of premature infants in Iran
- ▶ Occurrence of CAD and AM (manufacturing process) in a local hospital
- ▶ Use of a soft material (silicone) for medical 3D printing;
- ▶ An easy to use technique and working with ordinary 3D prints
- ▶ Precise investigation on the retraction of a soft medical grade material in our proposed AM technique

Nasal Necrosis in Premature Infants

A prong or mask is frequently used for oxygen therapy to help premature infants who need respiratory support. These prongs or masks cause nasal necrosis, leading to infection and the loss of nasal septum. Necrosis can destroy an infant's nasal septum, and thus these infants will need plastic surgery in the future (3,10).

According to Figure 1, prong support was employed to alleviate the problem. This product prevents a prong or a mask from exerting pressure on the nasal interior wall and the area around the nose (11,12).

An infant grows extremely fast, thus the nasal septum distance is continuously changing in infants (2,13,14). The



Figure 1. Using a Prong Support before Using a Prong or a Mask.

available products on the market cannot meet the real size required for the infant since prong support is expensive and this problem is not a priority for NICU nurses. The solution is to employ the AM technology to design and manufacture a growth-specific product that can be used simply by nurses at NICUs (15). For this purpose, an infant-specific questionnaire was designed to register nasal septum dimensions and distance (Figure 2). These dimensions can significantly help the design. In this questionnaire, the radius of each nostril and the distance between the two nostrils are measured for designing the cannula that reduces the pressure from the CPAP. It should be noted that premature infants are growing rapidly at this age, and the measured numbers can change within a few days. Therefore, there is a need to know the average condition for the growth of infants' nasal components at this age so that to make an optimal design.

Materials and Methods

Material Specifications and AM Device

Considering the high delicacy of an infant's skin in the NICU, bisphenol A-free materials are always a matter of interest (16,17). Given that prong support should eventually be placed on an infant's nose and be attached to the skin around the nose as far as its cheeks and lips, the selected material should offer a sufficient level of adhesion. Similar to medical stick dressings used in NICUs, it should be well-placed on an infant's face. Therefore, the CPAP silicone of the hardener-shore-25 medical grade was used in this study. The real challenge was the fact that room-temperature-vulcanizing silicone rubber (RTV-2) silicones gradually harden after being mixed at the ambient temperature. Moreover, a meticulous look at 3D printers indicates that the first layer should harden before preparing the second layering coming out of the nozzle. The properties of this material should be controlled by the 3D printer so that the final product meets the expectations.

An infant's dimensions and size affect the parameters which are involved in designing prong support. The dimensions and sizes were used in SolidWorks (2015) and then given to the 3D printer. In this project, the Ultimaker2+ (Ultimaker Company) was implemented as the 3D printer. Since this device was unable to print soft materials in 3D, it was necessary to add a fifth motor relying on its capability to be coupled with a new motor. The fifth motor of this printer required a secondary device

Mother First Name:		day after birth	Calorie intake	weight (gr)	measurement between two holes (mm)	radius of left hole (mm)	radius of right hole (mm)
Mother Last Name:		1					
Newborn First Name:		2					
Newborn Last Name:		3					
Date of Birth:		4					
Weight of Birth:		5					
Gestational Age:		6					
Province of Birth:		...					

Figure 2. Infant Nose Measurement Questionnaire.

named 'Discovery' to print soft materials such as chocolate, food, and designed silicone. The design was developed in Cura software (version 3.4.1) and then converted into a compatible G-code for 3D printing. Then, Discovery was used and controlled by Cura. Figure 3 shows the Ultimaker 2+ and Discovery used in this study.

Manufacturing Procedure

This section addresses the four-step procedure for manufacturing the silicone prong support for premature infants using a 3D printer. In the first step, the computer-aided design (CAD) model and the design pattern are explained, and then the configurations of the 3D printer are described in the second step. In the third step, it is necessary to elucidate mathematical calculations regarding the fluid flow through the pipe to obtain the configuration range of the device. Finally, the process of product manufacturing was discussed in the fourth step. This section represents the research innovation in the use of a 3D printer for designing and manufacturing a medical product with soft and liquid materials. This study can inspire researchers to come up with new ideas and innovations so that further studies can be conducted on soft, printable, liquid materials for medical applications using a printer and a simple secondary device, which, in turn, helps in creating more complicated designs.

Computer-Aided Design

First, standard prong support prototypes were used to design prong support in SolidWorks. It is noteworthy that a prong support prototype available in the market was applied at the Al-Zahra hospital of Tabriz.

The prong support was designed in SolidWorks so that it would be employed in Cura through the .stl output format. The received output was then converted into the G-code in the printer interface and provided to the printer. Finally, it was printed out after setting the configurations. Figure 4 displays the CAD model of the prong support.

Three-D Printing Configurations

After designing the product in 3D CAD software and receiving an appropriate file format, it was necessary to properly configure the parameters of the 3D printer software concerning the design type and materials injected out of the nozzle. In this project, it was crucial to configure and change several parameters such as the flow rate of the output liquid through the nozzle, the temperature of the device bed on which the liquid is located, motion adjustment along X and Y axes, the change rate along the Z-axis when injecting the second layer, and the size (7,9,18,19).

1. Output Liquid Flow Rate

Discovery was employed to print soft materials. It was essential to adjust the flow in proportion to the applied liquid type for printing. The liquid was transported

through a pipe from Discovery to nozzle head, and the liquid friction inside the pipe was considered for adjusting the speed of retraction. Figure 5 illustrates how the two devices were connected in this process.

2. Device Bed Temperature

The mixed liquid (RTV2) hardens at the ambient temperature, thus it is vital to adjust the bed temperature. The liquid hardens and blocks the nozzle before it comes out if the bed temperature is extremely high while if the bed temperature is low, the liquid never becomes solid after it is poured on the bed and two problems arise accordingly. First, the liquid exceeds the design limits, thus the final shape will not be as expected, and as regards the second problem, the liquid is not ready to be the solid base unless the second layer is printed, as a result, two liquid layers are poured on each other and unable to form a particular shape.

3. Movement Speed Regulation along X and Y Axes

According to hardening limitations and the liquid pressure behind the main pipe, it is impossible to manufacture a decent product through the previously-mentioned parameters. However, if the speed of movement along



Figure 3. Ultimaker2+ and Discovery

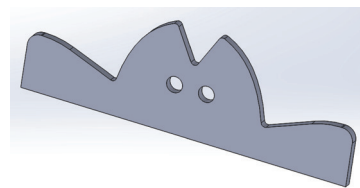


Figure 4. The Support Designed in SolidWorks.



Figure 5. The Pipe Connecting Discovery to Ultimaker2+ for Printing.

the X and Y axes is regulated, it is possible to properly direct the liquid flow out of the nozzle so that the second layer is placed on the first silicon layer, which is already hardening. Therefore, the speed of the pouring liquid should be calculated to adjust the device head speed along the X and Y axes. The calculation results are discussed in the following section.

4. Z-Axis Change Rate

Since a thick fluid such as silicone secrets out of the nozzle, it assumes a pellet shape while leaving the nozzle. Therefore, if the Z-axis change rate is not correctly adjusted and the printer does not work, the second layer dose not correctly cover the first layer and the final output is deformed accordingly (20).

5. Nozzle Output Size

The available nozzles offered by the Discovery device were selected, which were 0.84-millimeter nozzles in this project.

Determining the Ranges for the 3D Printer Configurations

Given that the liquid moves through a flexible pipe with an internal diameter of 10 mm connected to the printer nozzle, it is necessary to determine friction calculations for the viscous flow in the pipe since RTV2 is highly dense. Considering that discovery pushes the fluid through a pipe there is a friction between the liquid and the inner wall of the pipe, consequently, causing a portion of this pressure to be exerted inversely (21). The motor speed should be regulated when the fluid is pushed through the nozzle to prevent the injection of an excessively large or small amount of the liquid. It is highly essential to regulate the rotational speed because the 3D printer should be able to move along X and Y axes in proportion to the output liquid to correctly print out the final product.

The specific gravity of RTV2 was approximately 1.2 after mixing the two substances. Equation (1) was employed to determine the specific gravity ρ of the silicone, which shows specific weight denoted by γ

$$S.G_{RTV2} = \frac{\rho_{RTV2}}{\rho_{H_2O@4^{\circ}C}} \tag{1}$$

$$\gamma = \rho g$$

Accordingly, $\rho_{H_2O@4^{\circ}C} = 999.972kg / m^2$ and RTV2 silicone density is $\rho_{H_2O@4^{\circ}C} = 1199.9kg / m^2$ after preparing the mixture.

Determining the Input Silicone Flow Rate Through the Pipe for Printing

The speed of retraction is one of the settings on Discovery, thus, the study aims to determine the input fluid speed through the Pipe provided that the syringe plunger moves up at 10 mm/s. Therefore, the speed of retraction was calculated to determine the pressure drop in the Pipe

connecting Discovery to Ultimaker2+ in order to help the silicone reach the printer head (22). These figures help better identify the trial-and-error range, thus protecting devices from any physical harm.

Reynolds transform theorem refers to a moving volume control. As part of the fluid leaks out of the syringe (leakage), Figure 6 depicts the obtained equation:

$$\frac{\partial}{\partial t} \int_{CV} \rho dv + \dot{m}_2 + \rho Q_{Leak} = 0 \tag{2}$$

Where dv and \dot{m}_2 denote a differential volume and the needle output mass rate, respectively, when Q_{Leak} indicates the leakage flow rate leaving the syringe. Usually, 10% of the silicone fluid leaks through the printing process. In these equations, a steady-state flow was assumed for the leakage and output fluid, therefore,

$$\int_{CV} \rho dv = \rho(LA_1 + v_{needle}) \tag{3}$$

where L and v_{needle} indicate the length of the syringe container and the needle volume, respectively. Substituting Eq. (2) in Eq. (3) results in Eq. (4):

$$\frac{\partial}{\partial t} \int_{CV} \rho dv = \rho A_1 \frac{dL}{dt} = -\rho A V_1 \tag{4}$$

Where V_1 is the plunger speed depending on the speed of retraction in Cura software, which is a critical printing setting. Now, Eq. (2) can be rewritten as follows:

$$\begin{aligned} -\rho A V_1 + \rho Q_2 + \rho(0.1)Q_2 &= 0 \\ \Rightarrow A V_1 &= 1.1 * A_2 V_2 \end{aligned} \tag{5}$$

The syringe output is now the parameter of importance. If the plunger speed is regulated (V_2), it can be approximately obtained through trial and error in Cura, by using which the pressure drop in the pipe connecting Discovery to Ultimater2+ head can be approximately determined to ensure that the device is protected from any

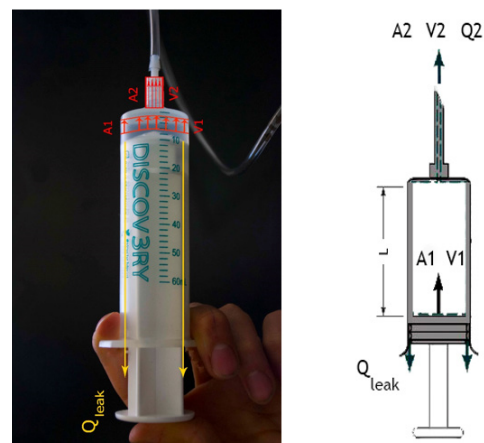


Figure 6. Flow-through Discovery Syringe.

physical harm when the fluid flows along the pipe. If the radius of the syringe container and the syringe head was 30 mm and 10 mm, respectively, an output speed of $V_2 = 16.37 \text{ mm/s}$ would be obtained since $V_1 = 2 \text{ mm/s}$. The pressure drop inside pipe V_2 is calculated in the following section.

Determining Pressure Drop Through the Pipe Connecting the Syringe to the Printer Head

The conservation of the mass equation can be used as Eq. (6):

$$\sum F_x = \dot{m}(V_{out} - V_{in}) \quad (6)$$

Assuming constant input and output rates for the Pipe and incompressible fluid flow, we may write $v_1 = v_2$. The pressure difference (Δp) can be calculated by applying the momentum equation along the pipe axis:

$$\sum F_x = \dot{m}(V_{out} - V_{in}) \quad (7)$$

Given that the velocities are equal in Eq. (1), Eq. (2) equals zero:

$$\Delta p(A) + \rho g \frac{\pi D^2}{4} \Delta z - \tau_w \pi D \Delta L = 0 \quad (8)$$

By simplifying Eq. (8):

$$\frac{\Delta p}{\rho g} + \Delta z - \frac{4\tau_w \Delta L}{\rho g D} = 0 \quad (9)$$

Using the conservation of energy equation or Bernoulli's equation:

$$\frac{p_1}{\rho g} + \frac{v_1^2}{2g} + z_1 = \frac{p_2}{\rho g} + \frac{v_2^2}{2g} + z_2 + h_f \quad (10)$$

Given Eqs. (9) and (10), Eq. (11) is as follows:

$$h_f = \frac{4\tau_w \Delta L}{\rho g D} \quad (11)$$

The Darcy-Weisbach equation can then be used to write Eq. (12):

$$h_f = f \frac{LV^2}{D2g} \quad (12)$$

Considering that the silicone flow is laminar and fully-developed in the pipe, coefficient f results from Eq. (13):

$$f = \frac{64}{Re} \quad (13)$$

where Re represents the Reynolds number. Finally, the pressure drop formula is obtained by using Eqs. (10), (12), and (13) for the 3D printer pipe connecting Discovery to

head off the Ultimaker2+ device:

$$\Delta p = \frac{32\mu LV}{D^2} + \rho g \frac{\pi D^2}{4} \Delta z \quad (14)$$

A significant pressure drop $\Delta p = 91.66 \text{ kPa}$ is obtained for the flow in the Pipe by assuming $V = 16.37 \text{ mm/s}$, $L = 0.5 \text{ m}$, $\mu = 35 \text{ pas}$, $D = 10 \text{ mm}$, $\Delta z = -18 \text{ cm}$ (according to Figure 7, there was an 18-cm height difference between the nozzle and the syringe when the two devices were connected), and $\rho_{RTV2} = 1199 \text{ kg/m}^2$. Nevertheless, the maximum pressure exerted by the Discovery motor on the syringe was 640 kPa. Therefore, the device can manufacture a decent quality product by setting the speed to 10-30 mm/s.

Sample Size

The internal diameter of the nose was measured, and five neonates were require based on the first outcome indicating a reduction in nasal necrosis with the prevalence of necrosis about 30%, an accuracy of 0.9, and the power of 80%.

Results

Manufacturing Process

The questionnaire dataset was designed to register the infant's nose size and nasal septum distance. After designing the product in SolidWorks, the appropriate output was prepared for the 3D printing interface. The configurations were then set according to the manufacturing process using silicone. Next, two-component RTV2 silicones were mixed, and then the content was put into the Discovery container for printing. Eventually, the product was ready for use after controlling the quality. Figure 8 shows the AM process of the silicone fluid for the production of a premature infant's prong support or mask. According to the proposed method, the setting ranges were transferred to the 3D printer. Different prototypes were printed after

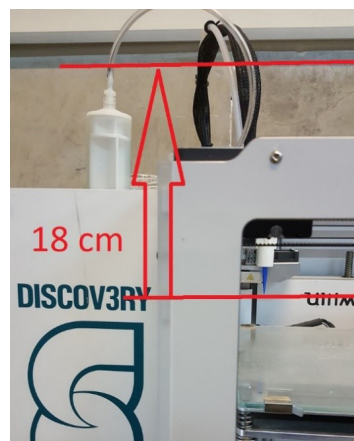


Figure 7. The Height Difference Between the Syringe Connected to the Discovery Device and the Nozzle in the Ultimaker2+ Device.

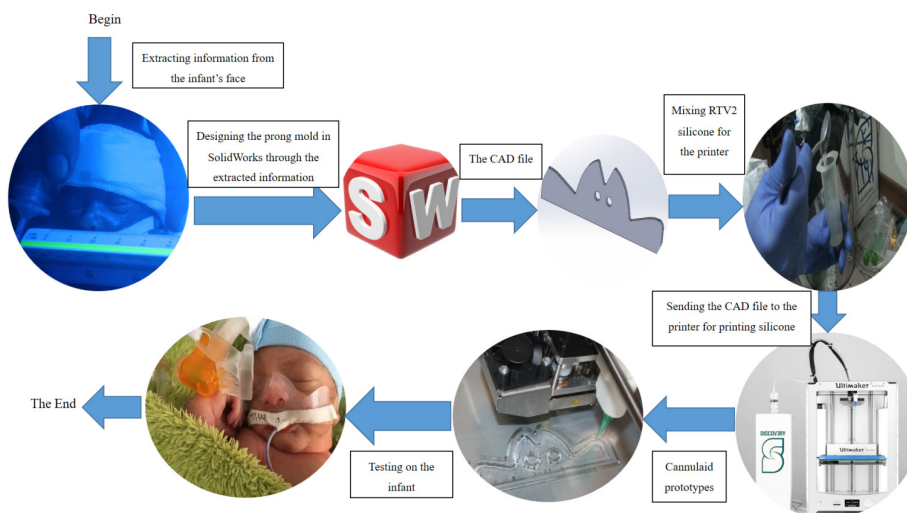


Figure 8. The Process of Silicone Fluid Printing for Manufacturing Prong.

applying these settings. Figure 9 displays two-prong support prototypes in production with different settings.

Ultimately, test prototypes 2, 3, and 6 were considered appropriate for use. Silicone was baked at the printer bed temperature and the final product was sterilized, thus, there was no concern about using it on a human subject. Therefore, the prong support test prototype 3 was evaluated as appropriate by testing it on an infant at Al-Zahra hospital in Tabriz, Iran. Table 1 provides device settings for the approved sample. Figure 10 demonstrates this sample. No necrosis was found on the nasal septum after two weeks of examination on the neonates.

Discussion

Many researchers have attempted to use new sciences and technologies in the field of construction to help specialist doctors. Among the manufacturing methods, AM is the most modern one. This method helps in simulating a design idea on a computer. Then, any design can be printed using a 3D printer if there are no restrictions on working with this type of device. This method is also called 'rapid prototyping'.

The 3D printing of soft objects used in hospitals is a field of medical engineering that has received less attention. Usually, products made with AM techniques in the medical field are mostly related to physiotherapy or tissue printing although less attention is paid to soft silicone products, which are widely used in medicine.

Table 1. Printer Settings for the Best Product

Parameter	Value
Speed of retraction	5 mm/s
Bed temperature	50°C
Print speed	12 mm/s
Nozzle size	0.84 mm
Layer height	1.2 mm

This study focused on the procedure for manufacturing a product through rapid prototyping and using RTV2 liquid silicone in 3D printers for premature infants. The applied device was a typical 3D printer made by Ultimaker Company. First, the model was designed by the computer and then convert to G-code for transferring to the printer for printing. The discovery device, which is an additional engine for this 3D printing enabled us to replace hard materials with liquid or soft materials needed for our works.

The use of nasal masks or prongs not compatible with the facial ergonomics of infants can cause nasal necrosis, leading to infection in premature infants that is highly dangerous in very low birth weight infants. The prong support prevents the mask or prong from exerting excessive pressure on the infant's nose. The AM

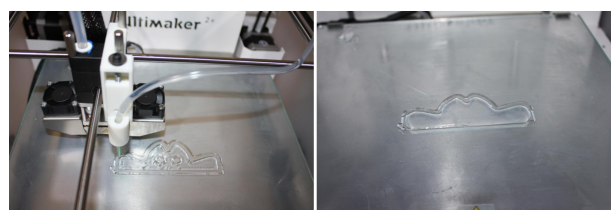


Figure 9. Two Prong Support Prototypes Under the Printing Process.



Figure 10. The Final Prong Support Tested on a Human Subject.

technology enabled us to manufacture prong support in a way that is matching an infant's face, nasal septum size, and nasal septum distance.

After carefully examining the size of the baby's nose, a neonatologist can communicate his design to the engineering designer. He will also simulate it using a computer. After approval by a specialist doctor, the computer-designed product was prepared for printing.

All the above-mentioned steps can be done at the same hospital location using a usual 3D printer that has a plug-in for sending liquids to the 3D printer. We described the novelty of working with soft materials, how to work, and the calculations of working with soft materials. The final product is printed and used on a neonate's face with hygienic and ethical protocols.

According to research findings, the authors suggest that conventional 3D printers can be modified to expand the range of printable materials. For example, this study attempted to use RTV2 silicone as its printing material by extracting its features. Moreover, the pattern of manufacturing can be used for other soft products that are applied in different areas. One of the benefits of production by this method and expanding it is that it can be used to make disposable teaching aids for beginners. For instance, artificially produced soft vessels or tissues in limited designs can be developed and printed in a variety of designs and materials with different material properties. The researchers of this study suggest scholars pay attention to the construction of teaching aids in the field of medicine in the form of interdisciplinary teams, and design and produce various soft materials using the proposed method in this article.

Limitations

The limitation of this plan, given its newness in the world, is an understanding of specialized content between an engineer and a physician. That is why we need an interdisciplinary specialist. Additionally, restrictions in the NICU made it difficult for an engineer to gather the required information by nurses, which was extremely difficult to perform accurately. Another limitation of this design was the use of an additional motor connected to the 3D printer. Considering that a limited body of knowledge is available in this regard due to the newness of this device in the world, we had to set the settings for our first experiment, which increased the project execution time. In general, the most serious limitation of this plan is the lack of similar research and collaboration at this level between physicians and engineers in the NICU sector in the field of AM technology.

Conclusions

AM technology helps us to produce prongs compatible with babies' faces. This technology decreases not only

nasal necrosis but also is cost-benefit for the hospital.

The proposed method can inspire future studies of different medical areas to print fluids for use in various fields. Finally, it is possible to develop a unit at the hospital to design and apply products satisfying the needs of hospitalized patients.

Conflict of Interests

Authors have no conflict of interests.

Ethical Issues

The obtained ethical code for this research is I.R.TBZMED.A.C. 1396.426. The project is under ethical principles and national norms and standards for conducting medical research in Iran and the contract number is 96-202.

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