International Journal of Engineering Research and Technology. ISSN 0974-3154, Volume 12, Number 12 (2019), pp. 2859-2862

Development of Customized Penile Implant Technology Using 3D Printer

Hyun-Jun Park[1], Dong-Kyun Kim[2], Gyu-Cheol Kim[2], Jei-Pil Wang[3*]

[1]Department of Urology, Pusan National University School of Medicine, Busan, South Korea.

[2]University Research Park, Busan National University, Busan, Korea.

[3]Department of Metallurgical Engineering, Pukyong National University, Busan, Republic of Korea.

Abstract

Erectile dysfunction is defined as the inability to obtain or maintain an erection necessary for a satisfactory sex life and directly affects the male individual's life such as impaired physical function, social isolation and depression. Therefore, the development of therapeutic agents for erectile dysfunction is actively progressed, and the interest and treatment needs of the general public are increasing. Medications are effective in 70% of patients, but not in severely affected patients. Patients should proceed with penis implantation as the injection method also has no response, discomfort or side effects. However, it is difficult to insert and re-operation due to complications and side effects, and most of them are imported from foreign countries. In this study, we developed a penis implant made of harmless material after designing the patient's personalized penis using 3D printer and attempted to localization of foreign penis implant product.

Keywords: Erectile dysfunction, Artificial Testicle, Penis Implant, Medical Device

I. INTRODUCTION

Recently, number of men suffering from erectile dysfunction is increasing due to psychogenic causes due to stress from heavy workload, adult diseases such as diabetes, or factors such as aging, smoking, obesity and hypertension. Erectile dysfunctions refers to the inability to get or maintain erection enough for satisfactory sexual life, and its treatment options include drug treatment or implant. Drug treatment is effective in about 70% of patients, but not in severe cases, and procedures such as implant may cause side effects, or can't be reversed even after side effects in many cases. Also, penile implant surgery is performed on patients with severe discomfort, but the surgery is complicated and is frequently accompanied by complications that surgery needs to be performed again. In Korea, there is no case of customized artificial penile implant technology and most are imported, which causes additional inconveniences such as high cost and the size and shape that aren't compatible with patients in Korea. Therefore, by securing an optimum implant material to eliminate inflammation of tissue and rejection and secure safety before and after the surgery, and the development of customized penile implant production using 3D printer to treat erectile dysfunction for satisfaction in sexual life is in urgent need. Accordingly, this study used a 3D printer to design a patient-specific penile implant using the material that is harmless to the body to localize expensive imported penile implant.

II. MATERIAL AND PRODUCTION METHOD

II-1. EXPERIMENTAL MATERIAL

SUS304 wire (medical/stainless) was used for rotation axis at the center of penile implant, and silicone, latex rubber and material for 3D printer (Monocure Rapid Resin) were used to process the surface of implant, and Pro-e program (3D printer program) and Chitu-box (3D output conversion program) were used to produce penile implant.

Among the experimental materials, silicone refers to a polymer that is created by the combination of oxygen and silicon, which is an artificial high molecular substance that is slow in oxidizing and stable in high temperature, and it is used diversely in applied researches in medicine area. Silicone is produced through the process that is nontoxic to biological tissue due to additives such as catalyst and hardener, and this study used RTV (Room Temperature Vulcanization) by addition reaction.

This silicone is highly biocompatible as a medical material, and the compound catalyst of platinum and palladium is highly biocompatible and doesn't create additional by-products during reaction that it doesn't cause clinical problems on cells or skin.

KFDA regulates medical device or medical materials by grade according to medical stability and risks to the body, and the classification of medical silicone rubber as defined by "Regulations on Medica Device Item and Grade by Item" in KFDA Notice No. 2005-17 is as seen in Table 1.

Table. 1. Classification of medical silicone rubber by KFDA

Class	Item
1	Silicone material used for plastic surgery or treatment. Non-implanted materials in body shape such as ear, nose, breasts, etc. Dental compatibility test material.
2	None.
3	Silicone material used for plastic surgery or treatment. Firm implant-type material. Urethral insertion tube, eardrum tube, hard contact lens, bone cap, tendon prosthesis, middle ear mold
4	Silicone material used for plastic surgery or treatment, implant-type liquid material, artificial breast, artificial testicle

Class 1 includes medical device or material that is not in direct contact with the body or with almost no potential risk when in contact, and has minor effect on body in case of failure, and Class 2 includes medical devices or materials that has a risk on body due to failure or malfunction during use, but the risk of facing threat to life or severe dysfunction is low that its potential risk is low. Class 3 includes medical devices or materials that are inserted in the body for a certain period of time or has high potential risks, and Class 4 include medical devices that are permanently implanted in the body, medical devices that are in direct contact with heart, central nervous system or central vascular system, medical devices using animal tissue or extract, or raw materials that have insufficient information to prove the safety, or medical devices or materials used for a new purpose.

As seen in Table 1, penile implant corresponds to Class 4, which is harmless to the body and suitable to use.

II-2. METHOD

Model was produced partially using a 3D printer and reproduced, and it was produced in two methods: first, by measuring the size and shape of patient's penis through imaging, printing out the connections and assembling them, and second, by producing a rotation axis of implant and reproducing by using printed mold, model and silicone.

First, the following matters were taken into consideration in penile implant production.
In terms of material, it has to be compatible with 3D printer (DLP) and harmless to the body, and doesn't easily break when operating inside the body and high abrasion resistance.
In terms of design, it has to enable smooth sexual life when implanted, has a firm straight shape during use, and can be bent when not using it to secure autonomy during daily activities. Lastly, it has to be produced in the form based on patient's size and shape.

First type of penile implant was produced by printing out each connection and connecting them. Patient's penis size was measured through imaging, and size of penile implant was decided through consultation.

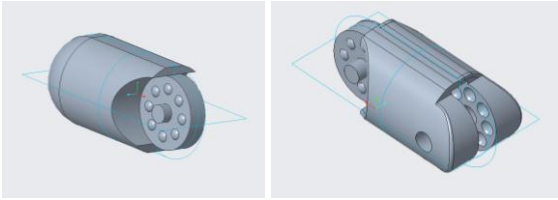

Fig 1. 3D Modeling Generation

3D program was used for modeling as seen in Fig. 1, using the data obtained. After modeling, the designed is produced in G-code and printed.

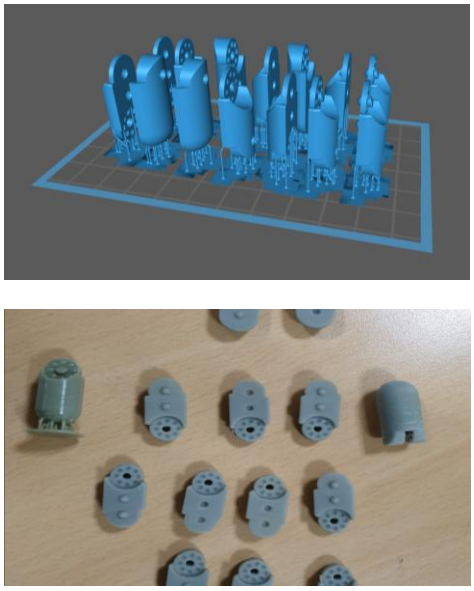

Fig 2. G-code Production and Output

Output was connected to create the frame of penile implant, and a silicone case was applied as seen in Fig. 3 to prevent any inflammation of skin caused by the gap that is created in the connecting area.

Fig 3. Assembled Product and Finished Product with Silicone Case

Second type was produced by creating an axis and reproducing using a mold.

The rotation axis (Fig. 4 Left) at the center of implant is made with SUS304 (medical/stainless) with 0.8mm wire inserted inside the spring, welded on both sides and covered rectangular stainless (Length 0.7mm, width 0.3mm) in a spring-like form. Stainless wire (0.4mm) was inserted inside the circular spring, and both ends were cut and connected using micro-welding (Fig. 4 Right)

Fig 4. SUS304 Wire (Left) and Wire in Spring Form (Right)

Using the 3D printer program Pro-e, patient's data is entered to create a penile implant model, and Chitu box was used to print out the model. (Fig 5. Fig 6. Left)

Printed model was post-processed for supporter removal and surface processing using sandpaper and hand grinder (Fig 6. Right)

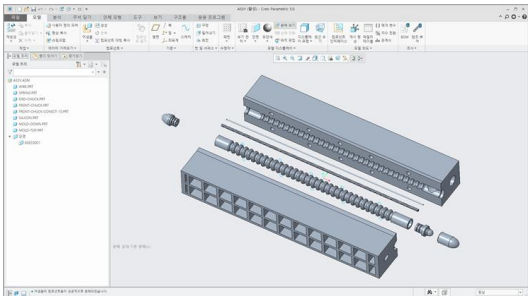

Fig 5. Pro-e Program Model Production

Fig 6. Printed Mold and Model (Left)
/ Post-Processed Model (Right)

The rotation axis is fixed at the center of post-processed mold, the model is inserted on both sides, and the model is reproduced using silicone. When the silicone is solidified, implant model was removed from the mold to evaluate.

Fig 7. Rotation Axis Fixed in the Mold for Reproduction

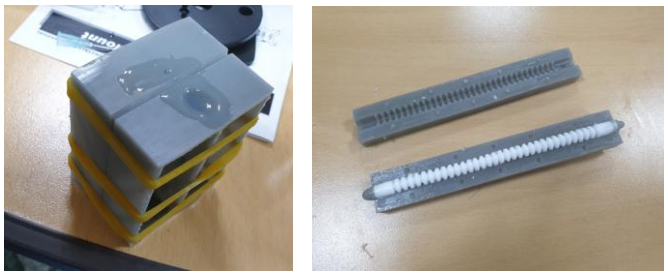

Fig 8. Reproduction Using Silicone (Left)
/ Prototype Produced in Mold (Right)

III. RESULTS AND CONSIDERATION

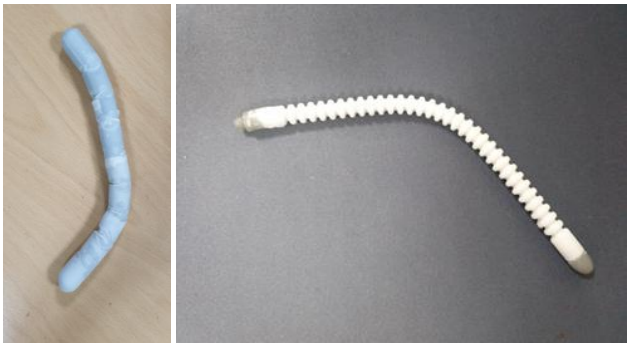

Fig 9. Completed Penile Implant Models

2 types of penile implants were produced through this study.

First method printed out each connection and connected them, and second method used a mold around the rotation axis and reproduced using silicone.

Since these devices are used in the body, they were produced in consideration of safety in the body as a priority, and the design aspect of product was considered to enable satisfactory sexual life.

① Securing optimal penile implant material

As the product needs to be implanted permanently in the body, this study had to select the material that is harmless to the body.

Accordingly, it used the silicone rubber that is applied and studied in various methods for medical device and implants, and is registered with KFDA.

In terms of the property, both silicone rubber and its catalyst do not react with the body, has properties such as high thermal resistance, non-toxic, water resistance, and insulation, and has outstanding physical properties in wide range of temperature; these properties are harmless inside the body and corresponds to the factor that it will be implanted permanently, so this is why silicone was selected as the optimal penile implant material.

② Production in terms of design aspect

When designing the penile implant, the operating range during sexual life and daily life was considered for maximum satisfaction, as well as patient's size and shape were taken into consideration.

In this study, patient's personal data was obtained through consultation and measurement for satisfactory customized production in terms of size and shape.

In terms of daily life, two methods each had pros and cons.

In daily life, both models can be bent down to eliminate discomfort due to penile implant.

However, they varied significantly in sexual life.

In the first method of attaching the connections, the degree of bending can be adjusted easily and firmly, but it couldn't be modified to the left and right.

Second method using a mold around rotation axis can easily modify the shape of penis in up, down, left and right direction, but could not be fixed as firmly as the first method.

IV. CONCLUSION

The two types of penile implants produced in this study could be customized for size and shape using 3D printing through patient consultation and measurement.

Also, by using silicone rubber as the material, production of a penile implant that is harmless to the body at the time of implant and during activities after the implant was possible.

However, this study mainly focused on the harmlessness and fixation power of penile implants, but did not cover property evaluation on product abrasion and possible damage during sexual life, so additional research would be needed.

V. ACKNOWLEDGEMENT

This research was supported by a grant from University Research Park Project of Busan National University funded by Busan Innovation Institute of Industry, Science & Technology Planning

VI. REFERENCES

[1] "Fabrication of implant for Medical using 3D Printing and vacuum forming processes" Major in Mechanical & Metallurgical Education Graduate School of Education, Chosun University Ym Hoon

[2] "Silicone Rubbers in Medical Engineering for Rehabilitation" 2009.Elastomers and Composites Vol. 44, No. 1 S. M. Lee, J. S. Song

[3] "Application of Medical Silicone Rubber" 2001.Rubber Technology Vol.2 No.2 [2001] Y. C. Kim

[4] "Prospect for 3D Printing Technology in Medical, Dental, and Pediatric Dental Field" 2016. 大韓小兒齒科學會(The Korean Academy of Pediatric Dentistry) Vol.43 No.1 [2016] Sang-Ho Lee

[5] "Study on 3D Printer Production of Auxiliary Device for Upper Limb forMedical Imaging Test" Journal of Radiological Science and Technology Vol. 38, No. 4, 2015. H. G. Kim, J. H. Yoon, S. D. Choi

[6] "3D-Printed Customized Titanium Implant Design and Manufacturing" 2018. Journal of the Korean Society for Precision Engineering. K. M. Lim, H. B. Jung, S .J. Park