

Development of Device for Patient-Specific Artificial Testicle Using 3D Printing

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Abstract

Men with the absence of testicles or suffering from acquired injury or disease receive artificial testicle surgery. The psychological wound that can arise in the absence of testicles in men are similar to the psychological shock in women after mastectomy or hysterectomy. Although the absence of testicles may not influence daily life significantly, it may result in psychic impotence caused by inferiority complex and failure in personal relationships, and artificial testicle surgery plays a significant role. Currently, there is no silicone implant production technology in Korea, so it is imported from AMS in the US, but they are manufactured in different sizes that are not customized for each patient, so patients can't control the size and the surgery is very costly. This study used 3D printer to design an implant that is very similar to the actual testicle, and developed artificial testicles using a harmless material for the localization of costly imported artificial testicles.

Keywords: Artificial Testicle, Medical Device, Localization

I. INTRODUCTION

The psychological wound that can arise in the absence of testicles in men are similar to the psychological shock in women after mastectomy or hysterectomy^[1-3]. Although the absence of testicles may not influence daily life significantly, artificial testicle surgery plays a significant role due to problems such as psychic impotence caused by inferiority complex and failure in personal relationships, and ^[4]. Generally, artificial testicle surgery is performed on men that were born without testicles or lost one or both due to acquired injury or disease. Acquired diseases include undescended testis, testectomy due to malignant tumor, infection and testicular torsion. Men lacking one or both testicles received artificial testicle surgery to boost confidence during intercourse or when using public bathhouses^[5]. Artificial testicle surgery does not recover the physiological functions like hormone and sperm production, but is performed to improve the exterior and stabilize psychological trauma. In the past, it was made using pure gold, which is harmless to the body, and now, imported silicone testicles are being used. Fig. 1. shows cohesive gel-type artificial testicles that are currently being used.



Fig. 1. Cohesive Gel Artificial Testicle Currently in Use

However, although individual's testicles vary in their size and shape, artificial testicles are sold in fixed sizes (large, medium, small) as opposed to custom orders, and their shapes are uniform as well, so patients complain about discomfort. Also, if the size is not compatible with the patient, it may escape from its position inside the body and cause complications. The artificial testicles currently in the market are in complete oval shape, and varies significantly from the actual testicle that consists of testis, epididymis, etc. Fig. 2. shows artificial testicle and actual testicle. With the absence of silicone implant production technology in Korea, the entire quantity is imported from AMS (USA) based on exclusive agreement, and its cost at approximately 800,000 KRW and uninsured surgery cost that is not covered by the health insurance are a significant financial burden to patients. There is a need for domestic distribution and overseas expansion to replace AMS. Also, it is urgently necessary to develop artificial testicle technology, which considers the individual's testicle size, using harmless and stable material for the body.

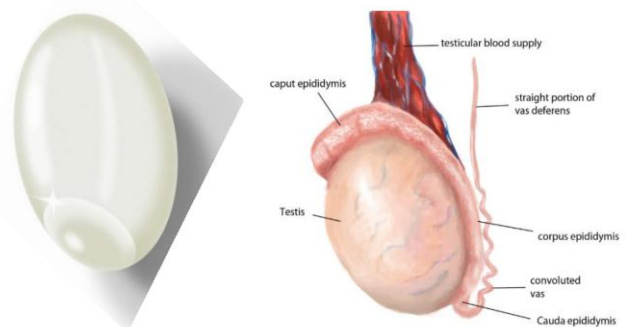


Fig. 2. Artificial Testicle and Actual Testicle

II. MATERIALS

Addition cure liquid silicone, used as the material for artificial testicle, is created by the cross-linkage in hydrosilylation reaction, and is divided into 1-component and multi-component types^[6]. 1-component type is extremely slowed down in terms of reaction speed near room temperature. Since its reaction speed can be controlled through heating and inhibitor, it is used in various industrial areas. Addition cure liquid silicone essentially doesn't have adhesive property, but tends to be improved into adhesive form due to the development of primer or adhesion enhancing agent. Hardening structure of addition cure liquid silicone cross-links siloxane chain through the addition reaction of polysiloxane containing vinyl group and polysiloxane containing Si-H linkage. At this time, platinum mixture is used as a catalyst, and no by-products are generated in hardening reaction. Addition cure liquid silicone doesn't require moisture. Rather, excessive moisture exerts a bad influence on foaming. Hardening speed gets faster with greater temperature dependence and higher temperature. It may also be controlled by changing the type or amount of platinum catalyst or adding a delay material. If there is a low-temperature hardening called LTV (Low-Temperature Vulcanizing) among addition cure liquid silicone, the temperature is between 100-200°C. Among the types of liquid silicones that can be used, there is hard-type silicone LSC-40. Fig. 3. shows hard-type silicone LSC-40 and its properties.



Fig. 3. Hard type silicone LSC-40 and Its Properties

Hard type silicone LSC-40 is used in art, sculpture and crafts as base resin and hardener (1:1 mixture). Hardening time is approximately 10 hours, and elongation percentage is 420%. Its tensile strength is 5.1Mpa, and it is flexible like rubber, so it is used helpfully in many works containing curves. When combining liquefied silicone, RTV-THINNER is used to remove bubbles. Fig. 4. shows RTV-THINNER.



Fig. 4. RTV-THINNER

Silicone thinner RTV-THINNER causes setting reaction in two liquids, and is properly combined under 10% of weight of silicone when used. It can control viscosity of silicone, and causes property change. Using 10% of RTV-THINNER reduces viscosity by half. However, when using more than 10%, hardening doesn't take place or cracks and bubbles are created, so the weight should be carefully verified before use. Fig. 5. shows the change rate based on amount of RTV-THINNER added.

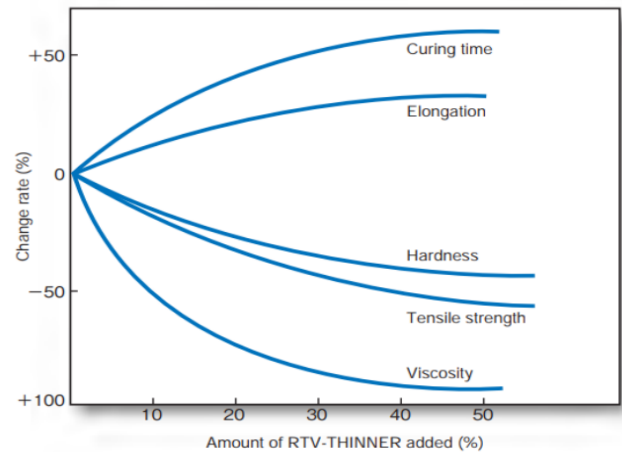


Fig. 5. Amount of RTV-THINNER added and Changes in physical properties

III. RESULTS AND DISCUSSION

Shape of artificial testicle was designed using a 3D designing program. Fig. 6. shows an artificial testicle that was designed by 3D program based on patient's data. The silicon molds needed to produce artificial testicle are designed in 3 sizes (small, medium, large) in consideration of the inlet and silicon area. In terms of the 3D program, Creo PTC – Parametric 3.0 was used. Artificial testicle designed for 3D printing are printed in sections to avoid effects on product quality during printing, and the position or speed of divided printing could be controlled.

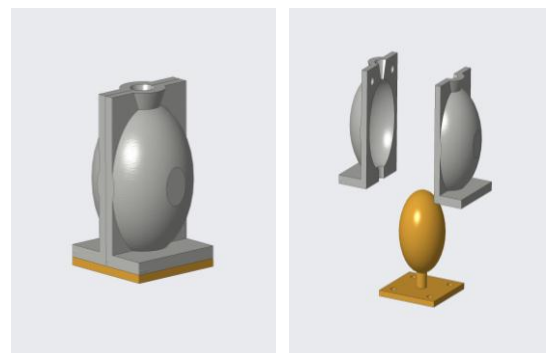


Fig. 6. Artificial testicle produced by 3D program

Printed products are recovered and dried after processing and applying adhesive. The adhesive used is 3M-super red putty.

Dried artificial testicle is post-processed for smooth surface, and the final completed artificial testicle is recovered. Fig. 7. shows the appearance of processed artificial testicle after 3D printing.



Fig. 7. Appearance of 3D printed testicle

To produce the mold, the finished artificial testicle is placed in a paper cup and fixed. Silicone-40 is mixed at 20:1 ratio to remove bubbles in liquid silicone. Bubbles are created in liquid silicone due to its high density, when air gets in as it is combined with a hardener. In order to remove bubbles, proper mixture ratio, time and environment must be controlled first. After some time, pour it into the paper cup, where artificial testicle is fixed in, to harden. After drying the silicone mold for an hour, spray silicone stabilizer inside and dry for 20~30 minutes; repeat the process twice. When injecting silicone, one must be very cautious not to create bubbles, and remove bubbles for 30 minutes after injecting. Fig. 8. displays the mold produced by using 3D printed artificial testicle.



Fig. 8. Mold manufactured using 3D printed artificial testicle

After pouring hard-type silicon LSC-40 into the mold, combine liquid silicone using RTV-THINNER, and harden and dry for 10 hours. When hardening and drying are completed, collect completely dried artificial testicle from the mold, and cut out the residual silicone on the artificial testicle to create the shape of artificial testicle designed. Fig. 9. shows completely dried artificial testicle.

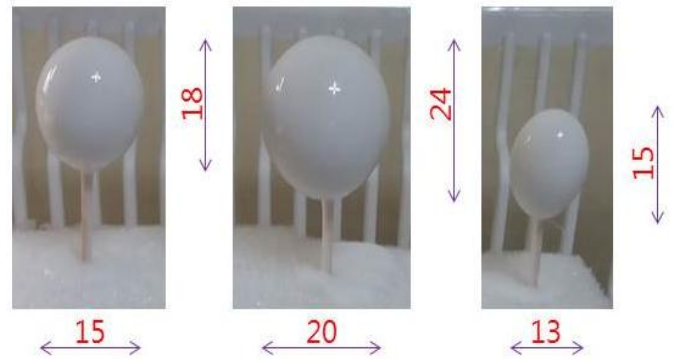


Fig. 9. Artificial testes by size, completely dried in mold

Because silicone contains oil called split oil, artificial testicle is cleaned thoroughly using a cleaning agent and dust is removed so it can be dried. Since the artificial testicle lacks utilization as a product with tiny bubbles and dust present on the surface, its surface is processed by applying silicone and drying. When the silicone viscosity is higher, it should be applied thinly once. Fig. 10. shows patient-specific artificial testicle that is completed with surface processing.

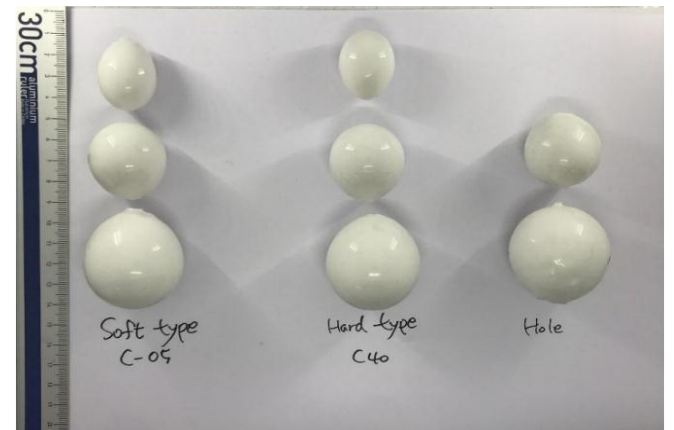


Fig. 10. The appearance of manufactured patient-specific testicles

By replacing the artificial testicles that are exclusively supplied from AMS and used with new domestic product, a customized artificial testicle similar to the original size and shape of testicle was developed. The adhesive gel type and microscopic type are used in most artificial testicles, but are identical in shapes. The newly developed artificial testicle's size can be produced selectively. After determining the size and shape of patient's testicle using imaging diagnosis device, a testicle can be produced in an identical size. When the silicone implant in the market escapes into the body or bursts, it causes complications and corrective surgeries, and damaging it may cause many problems. Newly developed artificial testicle has improved the material to improve durability and similarity, and an optimal medical device was developed. Fig. 11. displays the production process of patient-specific artificial testicle.

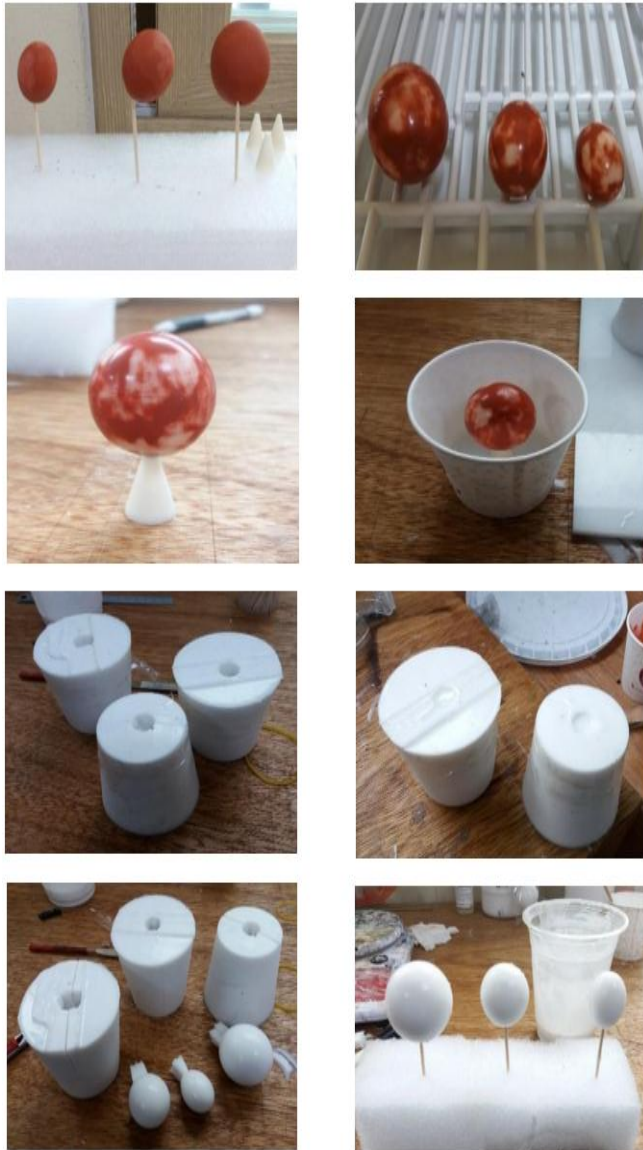


Fig. 11. Production process of an artificial testicle

IV. CONCLUSION

The patient-specific artificial testicle device developed in this study is to improve the exterior of testicle and stabilize psychological injury, and aims to be distributed in hospitals through localization. Since silicone implant production

technology is absent in Korea, a patent for silicone implant production technology of testicle needs to be established. By lowering the cost of newly developed artificial testicle and customize according to patient's size, the inferiority complex and inconvenience in daily life are compensated through artificial testicle. Product's physical excellence will be evaluated through satisfaction survey on patients that received the surgery. In order to proceed with commercialization, registration of medical device will be performed to be utilized in the medical environment. As it will be supplied at a lower cost than foreign manufacturers, number of patients that can undergo the surgery at a lower cost is expected to increase.

ACKNOWLEDGEMENTS

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

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