

Development of Patient-specific Artificial Testicle Device

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ABSTRACT

In the case of not having a testicle inherently or missing one or both due to an acquired injury or disease, men are having the surgery of artificial testicle. The mental damage that men get from not having a testicle is similar to psychological shock that women get after mastectomy or womb extraction. Even if not having a testicle does not significantly affect daily life, the surgery of artificial testicle has a significant role because of the issues such as psychological impotence and failure in personal relationship according to the sense of inferiority. Currently, there is no manufacturing technique of silicon prosthesis in Korea, and cohesive gel type and ultra very sort type which are used in breast plastic surgery are now used as silicon prosthesis. It is exclusively imported from an American company, AMS. It is not adjusted to the patient's size, but it is produced by size, so many medical teams and patients are having difficulty because of the size control and high importing cost. Artificial testicle which is exclusively supplied is trying to be replaced by newly developed product in Korea and lowering the cost barrier, and professionalism of IT technology in the medical field is working to be improved.

Keywords: Artificial Testicle, Medical Device, Localization

I. INTRODUCTION

In the case of men not having testicle, a mental injury that men get is similar to psychological shock that women get after mastectomy or womb extraction[1-3]. Even if not having a testicle does not significantly affect daily life, the surgery of artificial testicle has a significant role because of the issues such as psychological impotence and failure in personal relationship according to the sense of inferiority[4]. In the case of not having a testicle inherently or missing one or both due to an acquired injury or disease, men are having the surgery of artificial testicle. Acquired diseases can be retained testis(cryptorchid), or for men who had testis extraction because of malignant tumor, they can be an infection and testicular torsion. Men who are missing one or both testicles need artificial testicle to fill up the confidence when having sex or using the public bath[5]. The surgery of artificial testicle does not recover the natural physiological function such as the creation of hormone and sperm, but it has the purpose of improving the physical appearance and mental injury. For the existing silicon material for artificial testicle, cohesive gel type is used. Its material needs to be improved to make it softer than cohesive gel type and for the feeling of irritation to be disappeared. Silicon which is currently under the procedure is not suitable to the patient's size, and it's produced by size, so the improvement of customized silicon material is needed. In addition, in the case of leaking or bursting in the body, many complications can be caused, so the improvement of harmless materials in the body is needed. Fig 1 represents the silicon cohesive gel type for artificial testicle. There is no manufacturing technology of silicon prosthesis in Korea, and it is used by importing from AMS company in the U.S.A. The price is about 800,000won, and if the surgery cost is added, the cost becomes more expensive, so there is a need of domestic circulation that can replace AMS company in the U.S.A. and the development of a foreign market.



Fig 1. Types of artificial testicle in cohesive gel type



Fig 2. Appearance of artificial testicle and actual testicle

Fig 2 represents the artificial testicle and the actual testicle. Silicon prosthesis currently used in the surgery of artificial testicle is cohesive gel type or ultra very sort type which is used in breast plastic surgery, and it is mostly used domestically, and one company(AMS company) in the U.S.A. is exclusively producing it. Therefore, the cost of size control and importing is high, so many medical teams and patients are having difficulty, and only one format is being produced which is not the product customized to a patient like in Fig 1. Fig 3 represents the appearance of a cohesive gel type.

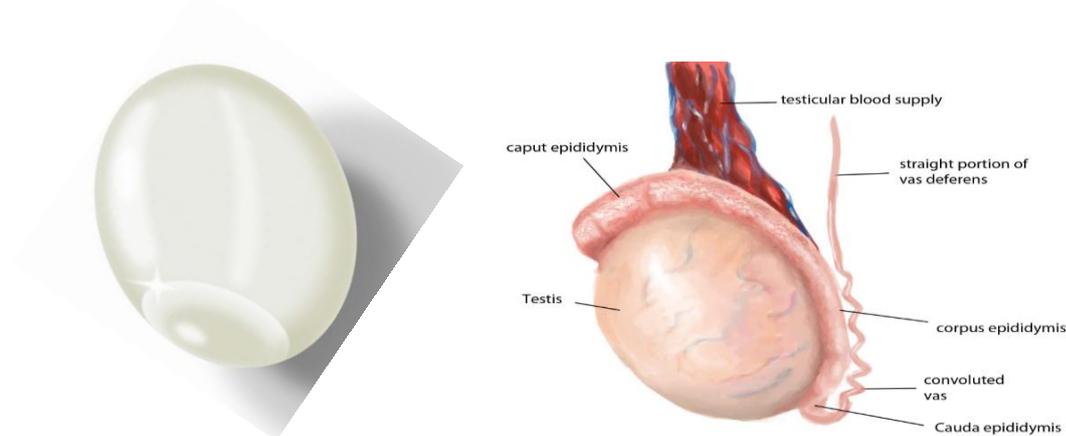


Fig 3. The appearance of cohesive gel type

Its material needs to be improved to be softer than cohesive gel type and ultra very sort type, and for a feeling of irritation to be disappeared. For silicon prosthesis which is currently used, in the case of leaking or bursting in the body, many complications can be caused, so there is a need to protect this by choosing the harmless materials to the body. Cohesive gel type and ultra very sort type are widely used in an artificial testicle, but the form is all the same, and the size is selectively produced. After understanding the size and shape of opposite testicle with imaging diagnosis devices and specifically being made by using a 3D printer, patient's satisfaction level can go up, and the cost of materials excluding the surgery fee of an artificial testicle due to importing of the high cost of foreign manufactures can be reduced.

II. MATERIALS

Supplementary liquefied silicon rubber used as a material for an artificial testicle is a product by cross-linking caused by hydro seal response, and it is classified into one-component and many-components[6]. Among these, one-component is the one that makes the response speed dramatically slow in the room temperature. It can control the response speed with heating and suppressant, so it is used in various fields. Supplementary liquefied silicon rubber does not essentially have adhesive property, but it has a significant tendency to improve to the adhesive form by the development of primer or adhesive improvement product. [6] When you look at the curing structure of supplementary liquefied silicon rubber, it is using the method of cross-linking the siloxane chain by additionally reacting polysiloxane that has vinyl group and polysiloxane that has the combination of Si-H. At this time, platinum compounds are used as a catalyst, and the occurrence of by-product does not happen during the curing reaction. Supplementary liquefied silicon rubber does not need the moisture, and excessive moisture instead causes a bad influence on the discharge. Curing speed has a significant dependence of temperature, and as the temperature goes up, it cures in a short time. Also, changing the type or the amount of platinum catalyst or using the delay



Fig 4. Hard liquefied silicon(Hard type silicon-LSC-40)

material can change the curing speed. Among supplementary liquefied silicon rubbers, there is low-temperature curing which is caused by slight heating, and it is called LTV(Low-Temperature Vulcanizing), and the curing temperature is 100-200°C [6]. Among supplementary liquefied silicon rubbers, LSC-40 and LSC-05 are used as an artificial testicle. Fig 5 represents the characteristic of a hard liquefied silicon(hard type silicon-LSC-40) and Fig 6 represents the characteristic of a soft liquefied silicon(soft type silicon-LSC-05). Hard type silicon LSC-40 is a material that uses the combination of base resin and curing agent(1:1 mixture), and it is utilized in art, sculpture, and crafts mold. Cure time is approximately 10 hours, and the elongation rate is 420%. The tensile strength is tough as 5.1Mpa, and it is usefully used in many products with curves because it is flexible like rubber. After making a silicon mold, spraying the release

agent, and drying it enough, we make liquefied silicon leak inside the mold and recover an artificial testicle.

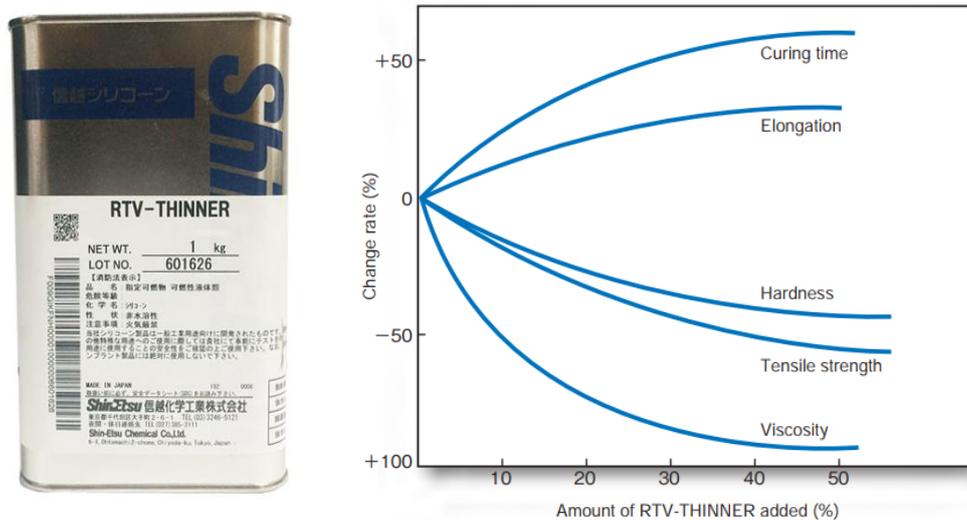


Fig 5. Soft liquefied silicon(Soft type silicon-LSC-05)



Fig 6. Amount of RTV-THINNER added and changes in physical properties

To remove the bubble when combining the liquefied silicon, RTV-THINNER is used as diluent silicon. Diluent silicon of RTV rubber is a condensation response type of two liquid, and when using it, it is adequately combined under 10% of silicon weight. Viscosity control of silicon is possible and general property changes. According to the working condition, the property after curing does not significantly drop down, and it is diluent silicon to use when you only want the viscosity of RTV rubber to decrease [7]. If you add 10%, the viscosity can be dropped down to about half [7]. However, if you use more than 10%, the curing of a product does not occur or cracking and the faulty of

bubble generation can happen, so it has to be used after confirming the weight. Fig 6 represents the changing rate according to the additive contents of RTV-THINNER.

III. RESULTS AND DISCUSION

The shape of an artificial testicle is designed by using the 3D program. Fig 7 is the appearance of an artificial testicle produced by the 3D program. The size of an artificial testicle is designed with a total of 3 shapes – small, medium, and large – by calculating the inlet and the area silicon when producing the silicon mold during the design (Design program: Creo PTC – Parametric 3.0). Artificial testicle which was designed is converted and printed for 3D printing to be possible (When printing, do the divided printing for the quality of product not to get influenced). Printed product is processed afterward and is dried by covering with perty (Perty: 3M-super red perty). The dried product is processed again afterward, and it is completed by processing the surface smoothly. Fig 8 represents the processed appearance of artificial testicle after 3D printing. For mold production, processed product afterward is inserted in the appropriate size of the paper cup and fixed. After taking suitable amount of silicon(silicon-40) (ratio 20:1) and mixing it well, we removed the bubble (Due to the high density of silicon, the bubble is made because the air goes in when combining with curing agent. To solve this, we work after adjusting the mixing ratio, time, and environment). After a certain time passes, we pour the silicon into the mold and cure it (curing time: approximately 8 hours). After drying the made silicon mold for 1 hour, spray the silicon release agent inside and dry it for 20~30 minutes (repeat it twice). Do the duplication after pouring the hard silicon(c-40) and soft silicon(c-05) in order (You have to be very careful not to make bubbles when pouring the silicon and extract the bubbles for 30 minutes after pouring).



Fig 7. Artificial testicle produced by 3D program



Fig 8. Production process of an artificial testicle

Remove the wholly dried duplicate from the rack and cut the silicon which was left at the inlet and make the format of an artificial testicle. Neatly clean the duplicate using the cleaning agent and dry it (Because silicon has the oil(distillate), remove the dust by using the cleaning agent). There is no utilization as a product because of small bubbles and dust on the surface of a duplicate, so for surface treatment, put the duplicate on the silicon again as if it's thinly coated and dry it as it is (When the viscosity of silicon during coating is high, you have to put it on once thinly). By replacing the artificial testicles exclusively supplied and used from AMS company in the U.S.A. with a new product developed in Korea, personally customized artificial testicle was developed which is similar to the original size and shape of testicles. Cohesive gel types and ultra very sort type are mostly used for artificial testicles, but the shape is all the same. The

size of artificial testicles which are newly developed is possible to be produced selectively. After understanding the size and shape of patient's testicles with imaging diagnose devices, it is possible to produce the same size of a patient's. When silicon prosthesis which is used on the market is leaking into the body or bursting, many complications and revision surgery can be caused, and in the case of damaging it, many problems can occur. Newly developed artificial testicle expands the improvement of durability and similarity by improving the materials, and the optimal medical device was developed. Fig 9 represents the appearance of the newly developed artificial testicle.

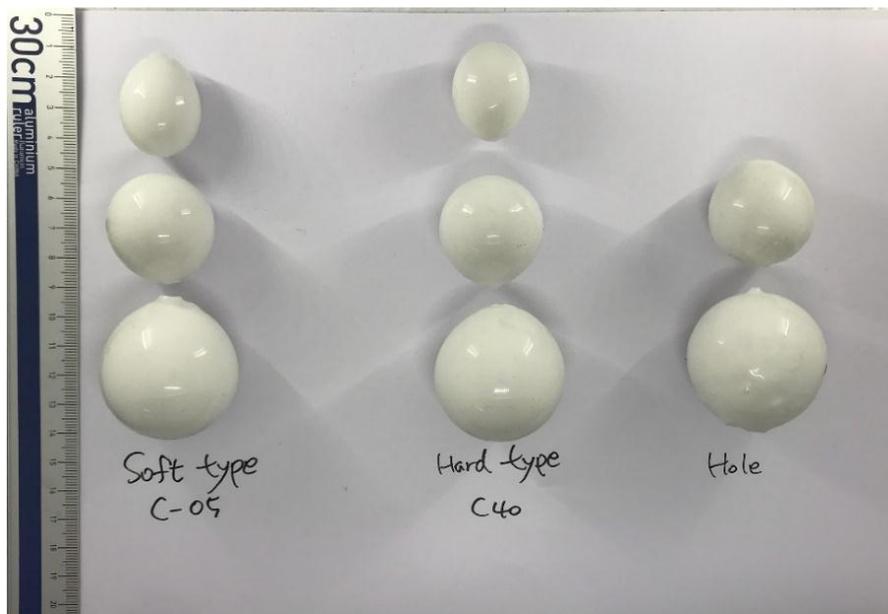


Fig 9. Newly developed artificial testicles

IV. CONCLUSION

The customized device of artificial testicle which will be newly developed is the technology that improves the appearance of men's testicles and stabilizes the mental injury, and it has a goal to supply to hospitals through localization. Because there's no production technology of silicon prosthesis in Korea, the patent establishment of silicon prosthesis production technology for testicles is needed. By lowering the cost barrier of newly developed artificial testicles and customizing it to patient's size, it has a role to fill up the sense of inferiority and the inconvenience in daily life through customized artificial testicle. Through the satisfaction survey of the patients who got the surgery, The evaluation of material excellence will be performed. To process the commercialization, registration of medical devices will be done to utilize it in a medical setting at last. It will be supplied at a reasonable price compared to the one from a foreign manufacturer, so more patients will have opportunities to get surgery at a lower price.

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