Original Article

Innovation of a New Silicone Prosthesis for Inguinal Hernioplasty: New Method for Silicone Prosthesis Production, A Preliminary Study

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Abstract

Purpose: The main strategy in inguinal hernia repair is mesh hernioplasty (specially prolene mesh). Pain in anterior femoral, inguinal and scrotal areas, mainly due to sensory nerve injury in the very regions and vas deferen injury are the main complications reported following repairing inguinal hernia. In this study we decided to use semiliquid silicone in order to form it in an in-*vivo* prosthesis production method to perform hernioplasty.

Methods: In this technique, silicone was produced through Room Temperature Vulcanization (RTV) technique, which is feasible in the room temperature. The produced semiliquid polymer was shaped in the inguinal canal in six cadavers.

Result: While the prostheses adequately covered all the anatomic area of the canal with an acceptable thickness in all of the cases, a satisfactory shape was developed in four cases. While 15 – 20 cc of silicone was needed to cover all anatomic areas properly, the hardness equal to 15 was achieved after curing process.

Conclusion: New silicone prosthesis forms satisfyingly in the inguinal canal and can protect it by encapsulation mechanism. It is soft with no risk of damage to the nerves or vas. It is inert and has no toxicity to the adjacent tissue. This technique of silicone remodeling can also be used in other fields of surgery such as plastic or vascular surgery.

Keywords: Hernia, inguinal, operative, postoperative complications, prosthesis design, silicones, surgical procedures

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Introduction

Inguinal hernia is one of the most common medical conditions which require surgical intervention.[1] The main surgical strategies adopted to treat the condition are classified under two main repairing techniques: tissue repair and repair using mesh prosthesis.[1] Nowadays, the latter technique, particularly those using prolene mesh are becoming more popular among the surgeons. They are considered to be not only tension-free but also associated with low recurrence rate and less post-operative pain. The mesh is also so inert and light which can easily be tolerated by patients.[1]

Pain in anterior femoral, inguinal and scrotal areas, mainly due to sensory nerve injury during the surgery is one of the main complications reported following repairing inguinal hernia.[1] Nerve entrapment in the slit formed in the prolene mesh is another reason contributing to the pain in these patients.[2] Frequent contact with the slit may also account for vas deferen obstruction, leading to azospermia and infertility in mainly young individuals undergoing bilateral hernioplasty.[2–5] While the complication is rare based on the few investigations done in this regard, it could be associated with major problems. This complication is particularly in young individuals and in case bilateral repair is needed or previous dysfunction of contralateral testis is reported.[4]

In view of the fact that the weakness of the floor of the inguinal canal and the myopectineal area is the main underlying condition contributing to hernia, various types of mesh are used to strengthen these areas; neither of which are totally safe or complication free.

Considering the above mentioned facts about prolene mesh, we decided to design a safer prosthesis for repairing hernia. Silicone, the main compound used in this innovative prosthesis, is an inert safe substance commonly used in breast implant construction since 1960. The safety of the compound was approved in 2000 by FDA.[6] Since it's innovation, many investigations have proved its safety in the body.[7–17] Considering the Cumberland criteria, silicone seems to be an ideal substance to be used for repairing hernia, as it is soft and does not damage the cord components.[18]The flexible and elastic structure of the silicone may also provide the surgeons with the capability to completely fill the weak area regardless of the structural differences frequently reported in different individuals.

After producing a medical grade silicone with the hardness suitable for covering the area, we decided to conduct the primary phase of the study on the cadaver to assess the feasibility of using silicone in its unformed status.

Materials and Methods

The medical grade raw materials for producing silicone

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(polydimethyl siloxan or PMDS) were imported from Walker Company in Germany (Elastosil RR plus4305: platinum-catalysed grade). Using chemical processes, five kilograms of liquid silicone with a hardness equal to 15 was produced in the laboratories affiliated to the Biomaterial Department of Iran Polymer and Petrochemical Institute.

In this technique, silicone was produced through Room Temperature Vulcanization (RTV) technique, which is feasible in the room temperature.[19] Curing or vulcanization accounts for a process through which monomers or oligomers of silicon are polymerized in order to produce a long silicon chain. There are two types of vulcanization: High Temperature Vulcanization (HTV), which performs at high temperatures, and Room Temperature Vulcanization (RTV), which begins in the room temperature.

While a single compound hardens directly under the action of atmospheric humidity in RTV-1, RTV-2 is a process in which two-component products are mixed at room-temperature to form a solid elastomer, gel, or flexible foam. In the latter form, which we used in this study, substances such as platinum, palladium or radium are added to the mixture to accelerate the process (addition curing).

Using this technique, the curing rate is independent of the environmental temperature. The resultant paste turns out to become elastic, starting from the surface and moving down to the depth.

In order to produce a polymer with suitable hardness for our purpose, various proportions of the two compounds (Silicone & Hardener) were combined. In other words, the process was repeated with different proportions of the two substances until the polymer achieved the required hardness within an acceptable time for the future operation (Figure 1).

In the second part of the study, the feasibility of using the product as prosthesis was assessed on fresh cadavers, whose time of death was not more than 24 hours ago and did not have any history of trauma to the inguinal area. The cadavers were not exposed to any chemicals in the medical forensic department and hence were identical to a live human being. The cause of death in these cadavers was reported to be reasons other than trauma and contagious diseases.

After issuance of related justification by the Legal Medicine Organization six inguinal dissections were performed in this study; except for the cord dissection and the closure of the sac, all the dissection steps were similar to that in a real such surgery. The dissections were performed after cadaver temperature reached to the room temperature. Skin was opened via a para-inguinal incision, the classic incision used in hernioplasty surgeries. Subcutaneous fat was dissected until the aponeurosis of the external oblique muscle was exposed. The aponeurosis was then opened through the direction of its bands until the cord was exposed. The cord was separated from the bed of the canal from the pubic tubercle to the internal ring. Dissection was continued to the iliopubic tract in the lateral, and until 4 cm over the conjoint tendon in the medial side. Doing all this, the internal ring was completely freed (Figure 2).

Thereafter PDMS mixed with the appropriate amount of catalyst was injected into the canal before the final hardness was achieved. The product was then distributed in the dissected area; therefore it would cover the entire region from the inguinal ligament in the lateral, 3 cm over the int. oblique muscle in the medial, and the pubic tubercle inferiorly. In the superior, the internal ring was also fully covered with the substance in a way that the size of the ring would be similar to the diameter of the cord. The cord was held outside the product, using a retractor, until the product reached its final hardness and shape (Figure 3). At the end, the superfluous particles of the product were separated from the adjacent tissue and fat. The external fascia was then closed using continuous sutures; the skin was also closed using separate sutures with non-absorbable sutures.

Finally the prosthesis was extracted in four of the cases in order to evaluate the shape, hardness and the thickness of the product.

Results

The prosthesis was studied on six cadavers. In each case some 15 to 20 cc of silicone was poured into the inguinal canal. While the prostheses adequately covered all the anatomic area of the canal with an acceptable diameter in all of the cases, a satisfactory shape was developed in four cases.

The study showed that the Hardener: PDMS ratio of 1: 3 by the hardening time of 10 – 15 minutes is acceptable for such surgical purposes. Using less hardener would elongate the remodeling time and subsequently the anesthesia time. On the other hand, large amounts of the hardener would make the process too fast for the surgeon to be able to remodel the polymer properly.

The thickness of the formed prostheses ranged from 1.5 to 2.4 cm, depending on the anatomical shape of the area. The hardness of the formed prosthesis was about 15 in all the cases and covered the entire anatomical areas including pubic tubercle, internal oblique muscle, deep ring and iliopubic tubercle sufficiently. After the termination of the procedure, there was no excessive silicone in the adjacent area or subcutaneous tissue. Unacceptable bulging in the surgical area after skin closure was, similarly, not

Figure 1. Preparation of silicone prosthesis during surgery by "addition curing"(in-vivo curing)

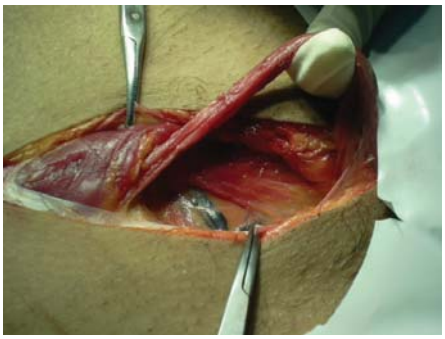

Figure 2. Disection of inguinal canal before prosthesis insertion

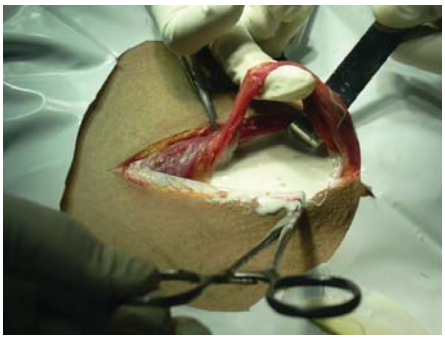

Figure 3. Spreading liquid silicone through the inguinal canal floor

reported in any of the cases.

Discussion

An abdominal hernia is a protrusion that occurs when parts of the small bowel or other abdominal organs protrude through a weakness in the abdominal wall. When occurred in the groin, it is described as an "inguinal" hernia, which accounts for 75 percent of all hernias.[1] A hernia is not dangerous in itself, but may lead to life-threatening conditions such as gangrene and peritonitis, when it gets strangulated. If left untreated, it may get more uncomfortable, larger and consequently contributing to the bowel obstruction.[1]

The main treatment for inguinal hernia is hernioplasty, a surgery to repair the opening in the muscle wall. Inguinal hernia repair has been evolving for the past 130 years, since the pioneering days of Marcy, Annandale and Bassini. The pace of evolution accelerated in the last decade with the introduction of the tension-free and the laparoscopic repair techniques.

Sometimes the weak area is reinforced with mesh; the operation is known as hernioplasty and is the procedure of choice for adult hernias. The characteristic of the mesh, particularly its material and pore size, plays an important role in the outcome of the procedure.[20] After implanting a mesh in the canal, a subacute inflammation starts in the area, leading to the formation of granuloma and fibrosis, a process which per se contributes to the integration of mesh into the adjacent tissue, forming a protective layer against myopectineal orifice. This technique reduces the recurrence rate by 60%.[20]

The present study was conducted to evaluate the efficacy of silicone in treating hernia and reducing its related complications. The benefits of this compound include its flexibility and elasticity, the fact that it can be reformed and develop the shape of the area through which it is spread, its softness and subsequently the reduced risk of damaging the near nerves and cord, and its protective properties against trauma.

Silicone theoretically does not integrate with the adjacent tissue because of its very small pore size, but it forms a pseudo-capsule, which prevents any kind of movements of the prosthesis and consequently the recurrence of hernia.[20] The elastic property of the prosthesis also acts as a protector against external forces and therefore prevents hernia recurrence. The short time needed for the curing process has made silicone an acceptable compound for being used in the operation room. This study was performed in the room temperature, but according to the chemical reaction rules, in the body temperature prostheses formation will be a bit faster. The softness of the edges of the silicone products is believed to overcome the possible vas and nerve injury reported following the use of other prostheses. The flexible and elastic structure of the substance provides surgeons with the capability to simply fill the area, regardless of the differences frequently reported in the anatomy of the inguinal canal in different individuals. No bulging is reported at the injection site following the use of these prostheses.

Considering the fact that medical grade catalyst (containing platinum which is safe and inert for the tissue) is used in this procedure its use is not associated with any toxic effects. Further studies, will need to be undertaken on living animals to assess not only the short term and long-term influence of this chemical interaction in the body but also the complication and recurrence rate following such operations.

After testing the product in the cadavers, it was concluded that silicone can be used as prosthesis for treating hernia in the near future. In other words, while the existing prostheses are offered in certain size and shape, the innovation of "In vivo curing" technique provides silicone with the capability to remodel and fit into the area based on the anatomic characteristics of the patient. This distinctive feature can soon make silicone the option of choice in various surgeries, particularly vascular surgeries in which the rough areas can be covered with prosthesis in order to prevent any damage the adjacent vessels and nerves. Plastic surgeons can also benefit from PMDS injections in performing more accurate augmentative mammoplasties. The substance can also be helpful in other cosmetic operations such as chin and cheek augmentation, as using this technique the surgeons can achieve the suitable shape more precisely, all of them will be feasible after complementary studies.

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