Biological & Engineering Materials II
MCG 2142A

Group Project
**New Biomaterials For Breast Implants**

Team # 10


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## Abstract

Breast cancer is the most common cancer among women, accounting for a quarter of all cancers worldwide. Although many treatments have come and developed, about 25% of women will still have a mastectomy, which removes the entire breast. Women who have had mastectomies become interested in breast reconstruction surgery. Hence, the market for breast implants is growing day by day. To avoid complications after surgery, optimal materials and techniques are required. Currently, the most popular breast implant is a silicone gel implant. There is also the saline implant, but it is not preferred over silicone gel implant due to its asymmetry, wrinkles and unnatural texture. Even silicone gel implants have problems that cause complications such as capsular contracture, necrosis, and rupture. To compensate for this, research on flaps, autologous tissue transplantation that uses a patient's own skin, subcutaneous tissue, and muscle to create a breast that is more suitable for the body than a silicone gel implant, is being actively conducted. However, flap surgery also creates two surgical sites, requires longer surgery and recovery time, and can lead to complications such as swelling, muscle damage or weakness. New arborescent block copolymer (TPE1) is a new biomaterial that complements the problems of flap procedure and silicone gel implant. TPE1 is a third-generation polymer of styrene-b-isobutylene-b-styrene (SIBS), which improves the problem of reducing the shape retention ability of SIBS and relieves fatigue. This material was prepared as a tree block copolymer (TPE1) via a living cationic polymerization system based on the inimer concept, a transformation of self-condensing vinyl polymerization technology. Prepectoral breast reconstruction is most suitable for inserting implants using supplemented biomaterials because they relieve pain related to muscle stretching. In order for new biomaterials like TPE1 to appear on the market, efficacy and safety must be proven through clinical trials by the US Federal Drug Administration (FDA) and Health Canada.

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# 1. Introduction

## 1.1 The Clinical Problem

Breast cancer is the second most common type of cancer among women after skin cancer, it accounts for roughly 33% of all cancers. In the United States, one out of every eight women will develop breast cancer within their lifetime (DeSantis et al., 2013). Currently, there are several treatments for breast cancer such as chemotherapy. Despite treatment efforts, approximately 25% of women who experience breast cancer will undergo a mastectomy, which is a surgical procedure where the entire breast is removed. After a mastectomy, a woman is left without one or both of her breasts which poses a major clinical problem. As many mastectomy patients elect to receive some kind of breast reconstruction, this creates a need for viable breast reconstruction options.

Currently, there are several options available to mastectomy patients seeking a reconstruction. Using artificial breast implants is a popular method for breast reconstruction. Ideally, a breast implant should imitate a natural breast as much as possible in terms of appearance and the way it feels. Also, it is preferred that an implant poses as little risk for medical complications as possible. However, many of the breast implants currently used do pose some risk for potential complications. One example of this are silicone breast implants, which can rupture when inside the body, causing foreign particles like silica to interact with internal organs (Agilinko et al., 2021). Since there is a constant need for breast reconstruction options for mastectomy patients, and existing breast implant options do pose potential risks, the field of breast implants is still advancing. Scientists are seeking new options for breast implants which limit the risk of any medical complications as well as acting as an alternative to natural breasts.

## 1.2 The Size and Description of the Market for Treatments

According to a report by Technavio reported in 2017, the global breast implants market was projected to grow at a CAGR of over 6% from 2016 to 2020. The reason is the increased breast reconstruction, beauty consciousness and breast surgery costs have been reduced. Therefore, many women who have lost or damaged their breasts due to surgery to remove breast cancer have also become interested in breast reconstruction. “Implant-based techniques are the leading method of breast reconstruction worldwide” (Rezai, Mahdi., et al.,2021). In addition, women’s interest in breast implants is increasing day by day as they perform surgeries such as breast augmentation for beauty purposes to increase their self-confidence. The cost of breast surgery is decreasing due to the increase in breast cancer and the widespread use of breast implants. At the same time, the number of skilled plastic surgeons has increased, and the cost of surgeries such as breast reconstruction and breast augmentation has decreased because plastic hospitals with low prices and good surgical skills can gain an edge in the plastic market. For this reason, the market for breast implants has grown as consumers have easier access to breast implants.

Currently, there are three types of implants commonly used : silicone gel, saline, and composite filler. Silicone gel implants use an elastomeric silicone shell filled with a viscous silicone gel. A sterile solution is used during surgery for saline implants. Composite implants are filled with a variety of fillers such as holy propylene strings, soy oil, etc. (Radiant Insights, Inc, 2019). Silicone gel implants are the most commonly used implants. Silicone gel implants are the most popular because they are soft and most closely resemble the shape of real breasts. Secondly, it is a saline implant. Saline implants are not preferred by consumers over silicone gel implants, as they are less natural than silicone, wrinkle when overfilled, and do not resemble the natural

look. Composite filler is not used because of high health risks that can lead to complications. Although both silicone gel and saline implants are Food and Drug Administration (FDA) certified as safe, they are not perfect. It is relatively uncommon, but possible that these artificial implants cause side effects and complications. Side effects include implant rupture, breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), and spheroid contracture. "*Risks linked to breast implants include infection, rupture, capsular contracture (when the body forms scar tissue around the implant), breast implant illness, and, in rare cases, breast implant-associated anaplastic large cell lymphoma, according to Chen*."(Ries, J, 2021). Complications that come as side effects include chest pain and fatigue due to inflammation.

Complications arising from the use of such implants may hinder the expansion of the breast implant market. However, despite unsatisfactory results and unexpected complications, research is underway dedicated to achieving the ideal breast implant. (Park, J.-H., Park, J.-U., & Chang, H, 2021). With steady research, breast implants continue to develop, and as consumers' interest continues to increase, the breast implant market continues to grow. To prove the above statement, we can see the report of Uglamugle and Swain. They state that the breast implants market size exceeded USD 2 billion in 2020 and is projected to grow at a CAGR of over 8.3% between 2021 and 2027.

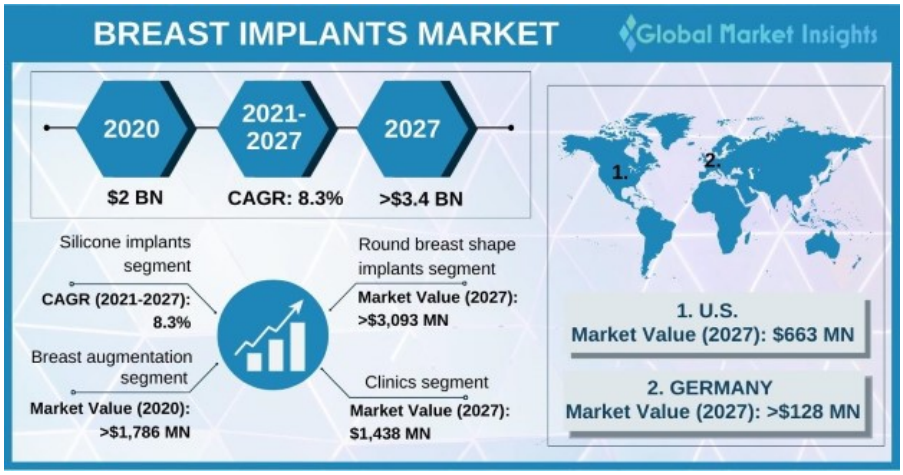


Figure 1. Breast Implants Market Forecast (Ugalmugle, S., & Swain, P, 2021)

## 1.3 The Current Clinical Solutions and Competing Technologies

Lightning-fast medical and technological advancement has greatly expanded the range of breast reconstruction options, yet choosing the suitable material and technique is critical to avoid postoperative complications. Among the types of implants that are approved by the FDA, silicone is the most commonly used. Silicone breast implants consist of a rubbery silicone shell that is filled with either silicone gel or saline solution (Lim et al., 2013).

The main difference between silicone gel and saline solution is their viscosity and consistency, which affect their surgical procedures. Saline solution, which usually has a concentration of 0.15M and a pH of 7.2-7.4, is filled to the desired volume after they are implanted; therefore, the size of the implants can be adjusted even months after the surgery (Jewell et al., 2018). However, the 10-year studies of 410 implant cases revealed that they are more prone to deflation, asymmetry, wrinkling and unnatural texture than silicone gel-filled ones (Spear and Jespersen, 2010).

Silicone gel implants offer many advantages over saline-filled ones, but they also come with their own set of challenges. Since the implants are pre-filled before surgery, an incision site (usually between 5 and 5.5 cm) tends to be bigger. In addition, since it is under higher gravity and inertia impact, malposition of implants has been a common problem. Due to its high form stability and gel cohesivity, the shape of the implants tends to appear unnatural.

The history and knowledge of silicone and gel based implants has been growing since 1962, when it was first discovered. Since these implants are viable to many different features and can be made compatible to different patients, they are the best current solution mastectomy procedures - overlooking the many flaws and complications that follow. Silicone and gel based implants have been FDA approved since 2006, (Puskas and Wyatt) and the growing concerns have led scientists to begin a search for new technology and materials to replace existing options. When the two the Allergan Natrelle and the Mentor MemoryGel implant types were approved in November 2006, they were marketed as "safe and effective when used as intended, but… carried certain risks (Wachter). Women who participated in the procedure were studied after 10 years from the time of approval, and complications and risks directly correlating with the two silicone based implants gave a better understanding regarding long term effects. The longer the amount of time that the implant is in a woman, the greater the risks of complications, needing a replacement for every 2 in 10 patients every 10 years. The most frequently observed complications and outcomes are capsular contracture, reoperation, and implant removal. Other common complications include implant rupture, wrinkling, asymmetry, scarring, pain, and infection. The most common failure is leakage, also called "gel bleed." of silicone filler due to mechanical failure or high permeability of the silicone shell, which can only withstand the maximum tensile strength of 1 to 3 MP (Lim et al., 2013). Even after the silicone rubber shell is reinforced with

silica nanoparticles, gel bleed is still a great concern, which requires reoperation or removal of implants.

## 1.4 The Current Efforts to Improve on the Current Treatments

There has been active research conducted on a tissue flap procedure: an autologous tissue transfer that uses the patient's own skin, subcutaneous tissue and muscle to create a breast mound (McNatt, 2013). The most common type is TRAM (Transverse Rectus Abdominis Muscle) flap procedure *(Fig. 1)*: in most surgical cases, the lower abdomen provides enough tissue for breast reconstruction (Bloom et al., 2019). One of the remarkable aspects of this procedure is that blood vessels remain intact on the abdominal flap, allowing the transferred tissue to continue to get its blood supply from where it originated (Bloom et al., 2019).

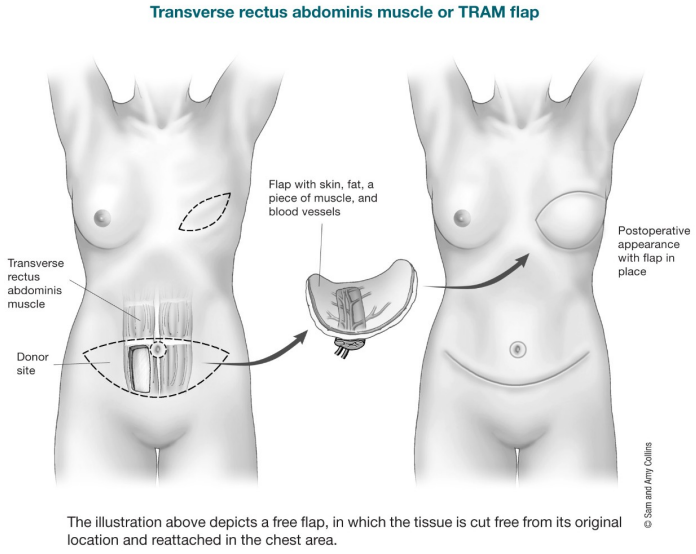


Figure 2. TRAM (Transverse Rectus Abdominis Muscle) Flap Procedure (Bloom et al., 2019)

The flap procedure poses many advantages over the conventional silicone implants. Its high biocompatibility ensures minimal infection, capsular contracture, calcification and rupture.

Furthermore, unlike breast implants with fixed volume and weight, tissue flaps will change in size as a person gains or loses weight (McNatt, 2013). However, this can actually cause serious deflation and malposition on the surgical sites. In addition, flaps require longer surgery and recovery time. It leaves two surgical sites that can have further complications such as bulging, muscle damage or weakness and dimpling of the skin (Bloom et al., 2019). Often, surgeons use flaps in conjunction with implants to add fullness and volume to the reconstruction (McNatt, 2013). As both the flaps and implants cannot be the absolute win, an invention of a novel biomaterial for breast implants can be a great treatment option. In the following section of the report, an innovative biomaterial that can overcome the limitations of both the flaps and implants will be introduced.

# 2. Proposal

## 2.1 The Profile of the Product

Currently, the most common and only FDA approved procedures for breast reconstruction of augmentation is using silicone gel-filled implants or saline-filled implants. There are many risks and complications that these implants are known for, affecting 34% of patients (Canadian Breast Cancer Society). Below, figure 3 is comparing the form stability of different textured implants. As can be seen, different shape and textured implants reveal slightly different measurements, opening the variety and versatility of the now-used technology for implants.

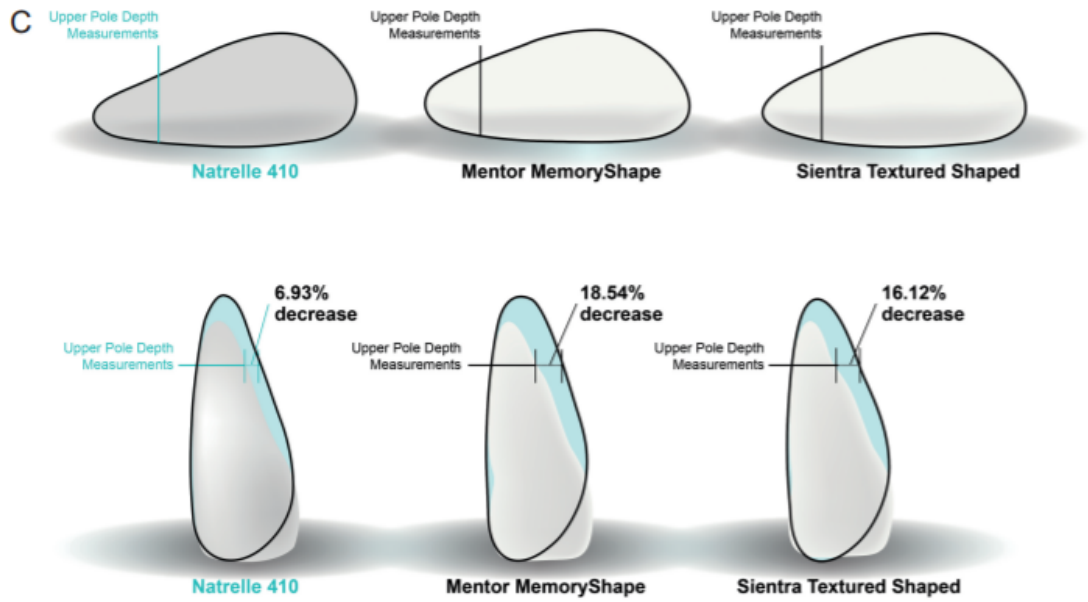


Figure 3. Form Stability of Textured Shaped Implants (Jewell, 2018)

Figures 3 and 4 give a better understanding of the physical features of the current implants. There are additional risks for those needing reconstructive surgery over augmentation surgeries due to the trauma, and loss of skin from the removal. Figure 4 is a bar graph representing the gel material properties, and shell thickness of textured shaped, textured round, and smooth round breast implants from 4 manufacturers: Allergan, Mentor, Sientra, and Establishment Labs, after bench testing. This further shows the wide-use characteristics the current day silicone implants can offer. The ultimate goal is to find a novel biomaterial that can be versatile and made personal to each patient requiring reconstructive breast tissue engineering.

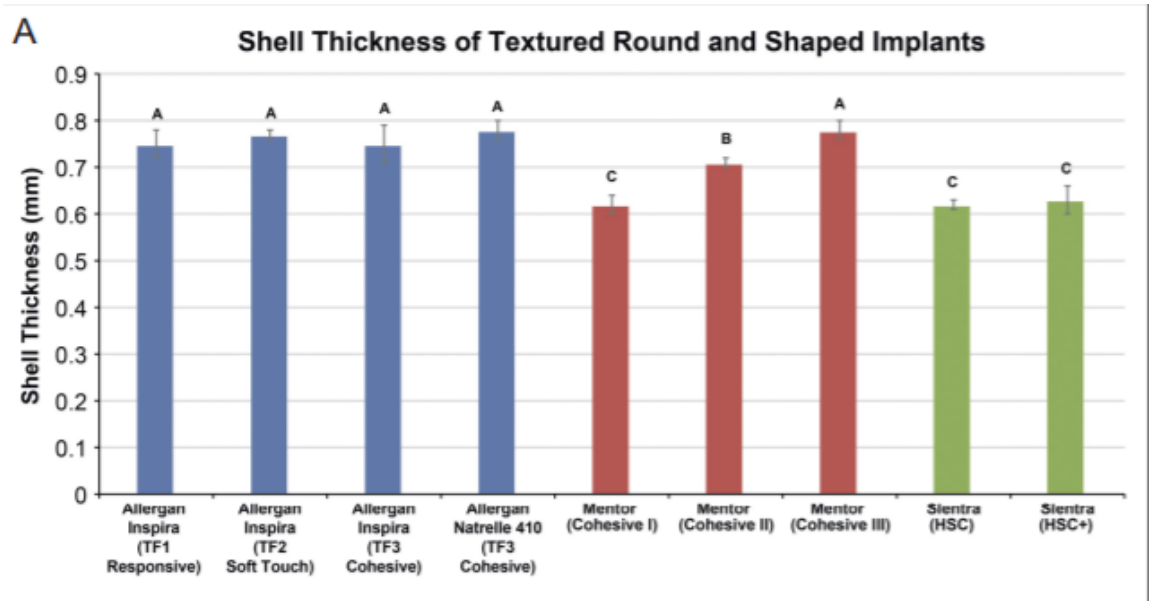


Figure 4. Shell Thickness of Textured Shaped Implants (Jewell, 2018)

The new biomaterial that will replace the current breast implants is called the GKLL polymer, which is the improvement of the TPE1 polymers. The goal is to create a design that ensures high gel cohesivity, resistance to gel deformation and lower energy absorption. The two types of polymers that will be heavily investigated for use as a new biomaterial implant are SIBS-type block copolymers and TPE1 polymers. The two polymers are essentially the same component wise, just under different conditions. In its original form, it can be considered as the SIBS polymer, but when applied in a living organism, it is considered as the TPE1 polymer. When comparing these two polymers, SIBS are self-assembling nanostructured thermoplastic rubbers that do not need chemical crosslinking.

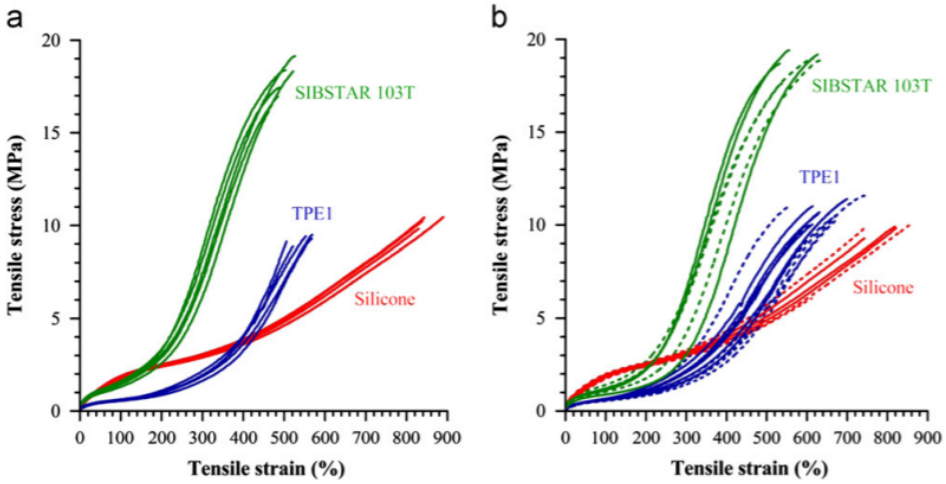


Figure 5. Tensile stress-strain plots of (a) pristine materials, and (b) explanted materials. All samples tested at 500 mm/min (Lim et al., 2013)

The new biomaterial, the GKLL polymer, has the same ultimate tensile strength (9.2 MPa) as the TPE1 polymers (Table 1). TPE1 has lower tensile strength and elongation than the medical grade silicone rubber investigated, while it is much softer with significantly lower moduli values at low strain (Lim et al., 2013). TPE1 is based on PIB, which has the lowest permeability of all known rubbers (Fig. 5).

There are currently three shapes of implants available in the market: textured shaped, textured round and smooth round. The height, lower pole depth, and upper pole depth of these three different types were measured when moved from a horizontal orientation to a vertical supported orientation (Figure 3). The result revealed that the textured shaped implants retained significantly more of its original dimensions than the other two shaped implants (Jewell, 2018). The GKLL polymer is a textured-shaped implant that ensures the greatest form stability in height and projection, and this is crucial to prevent deformation, malposition and deflation of the breast

implants. The textured shaped implants have a mean shell thickness of 0.70 mm (Figure 4), which gives the natural texture and shape while withstanding the maximum tensile strength.

Table 1. Specifications of the GKLL (TPE1) Polymer

| Specifications | Value |
|---|---|
| **Material** | SIBS polymer |
| **Molecular Weight** | 114,100 g/mol |
| **Polystyrene content** | 23.1% |
| **Shape** | Textured shaped |
| **Mean Shell Thickness** | 0.70 mm |
| **Ultimate Tensile Strength** | 9.2 MPa |
| **Ultimate Tensile Strain** | 544 % |

Table 1 are the specifications of GKLL (TEP1). In comparison to the original silicone gel material, the characteristics of this polymer allows for improved biocompatibility without eosinophils present in the capsules after 6 months of implantation.

## 2.2 Innovative Features and Advantages

The introduction of the TPE1 polymer is a promising alternative to the currently approved silicone implants. Over the use of silicone gel–filled and saline-filled implants, both types have exhibited different flaws and the hopes of an alternative method have been introduced. Related concerns of the silicone gel-filled implants include capsular contracture, gel bleed, implant rupture and infection. While the saline-filled implants are not as prone to these complications, they are often overlooked due to them having less of a “natural” look. Overtime,

the implants have shown to break down from the original form and often bleed gel into other areas surrounding the implant.

The SIBS form of the polymer demonstrated its high biostability in the pre-clinical trials from the composure and properties. In the TPE1 form showed a consistent level of biostability while in vivo. Even with just a thin sample of the biomaterial, leakage of silicone gel that is known to cause inflammatory responses in patients can be avoided and the static and dynamic mechanical properties of the polymer can dramatically be improved by the nanofillers.

## 2.3 The Manufacturing Procedure

GKLL polymer (TPE1) is a randomly arborescent polymer (arbIBS) that is a new generation of SIBS polymer. First-generation non-oxidizing polyisobutylene (PIB)- based linear poly (SIBS) is biocompatible, safe, and has excellent mechanical properties. However, there is a problem in that the shape maintaining ability is reduced. (Lim et al., 2013). The synthesis process of SIBS is as follows.

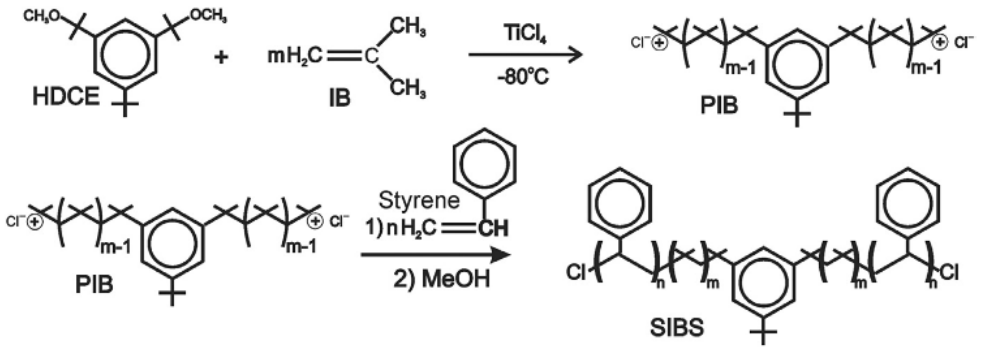


Figure 6. Synthesis of SIBS from an HDCE Initiator (Lubnin & Erdodi, 2021,p.212)

The combination of HDCE and isobutylene (IB) produces PIB, and the result of combining PIB and styrene is SIBS. SIBS also joins rubber PIB segments by carbocation polymerization of meltable glassy crosslinks at both ends of a polystyrene PIB central block for processing into moldable or extrudable medical devices (Lubnin & Erdodi, 2021,p.212).

Poly, a thermoplastic elastomer (TPE) of IB, was developed to improve the problems of the SIBS. However, this elastomer can only be polymerized through the carbocation method. (Lubnin & Erdodi, 2021,p.237). Puskas lab has developed a living cationic polymerization system based on the inimer concept, a transformation of self-condensing vinyl polymerization technology, which resulted in the production of arborescent block copolymer (TPE1). Hence, this polymer exhibits improved fatigue and shape retention properties (Lim et al., 2013).

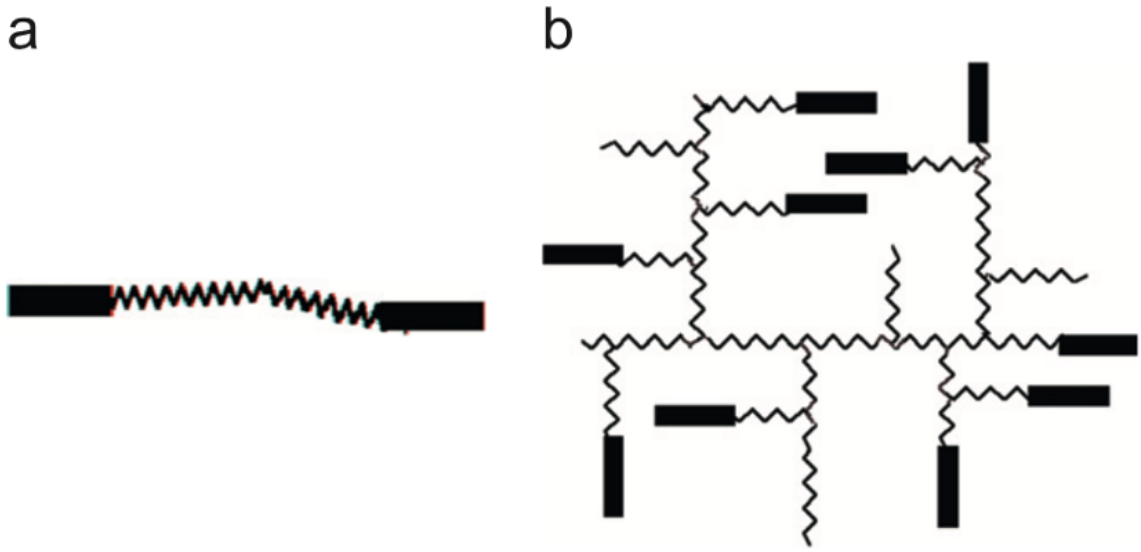


Figure 7. Architecture of (a) SIBSTAR 103T and (b) TPE1 (Lim et al., 2013).

SIBS consists of polyisobutylene rubber segments and TPE1 consists of polystyrene plastic segments. It can be seen that compared to the linear shape of SIBS, TPE1 has a branched shape and is more rigid.

The manufacturing process of GKLL (TPE1) is made on PIB-based basis with ZAF encapsulated in fibers allowing for higher doses and longer release times. In addition, a modular surface functionalization method of TPE was developed with functionalization, and the functionalized PIB layer is attached to the TPE surface through chain entanglement.

## 2.4 Details and Feasibility to Deliver

For the last twenty years, the most frequently performed breast reconstruction procedure was the implant insertion under the pectoralis major muscle (Kim, 2019). The major drawback of this procedure is that patients could feel persistent discomfort and tightness on the surgical site due to incisions in the muscle (Lerman, 2017). On top of that, this method creates an unnatural appearance as the muscle movements are visible on top of the implant (Lerman, 2017).

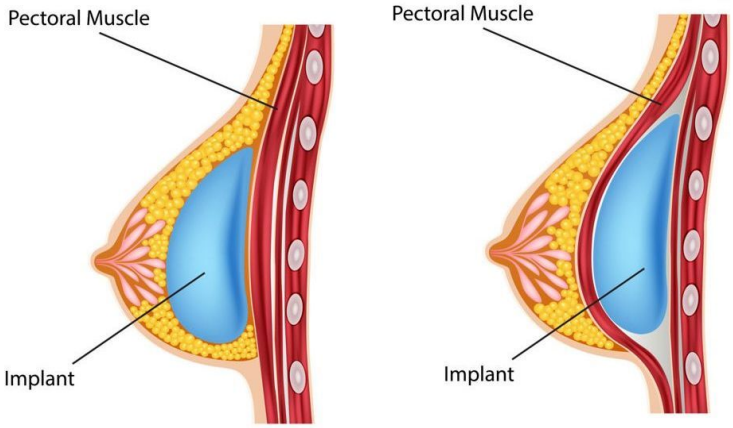

Figure 8. Prepectoral (left) vs. Pectoral (right) Breast Implant Reconstruction (Lerman, 2017)

In recent years, prepectoral breast reconstruction (Fig.5 (left)) has emerged to overcome the limitations of the traditional approach. It alleviates the pain associated with muscle stretching.

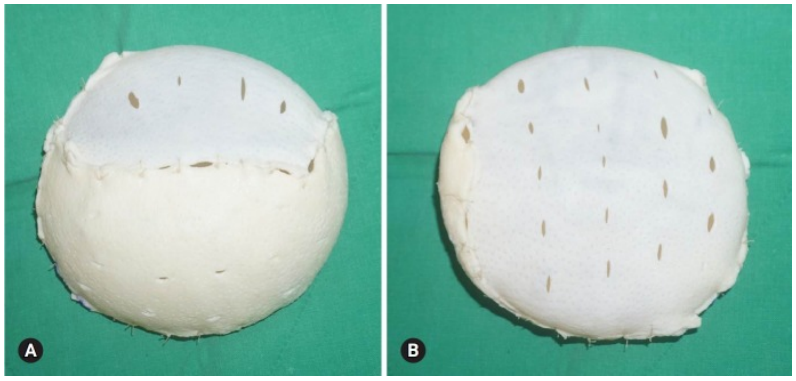

Figure 9. Implant covered with two sheets of ADM (Kim, 2019)

A breast implant in prepectoral surgeries is typically reinforced with an acellular dermal matrix (ADM) or "biologic mesh" for protection and tissue support (Lerman, 2017). ADM is also proven to lower the capsular contracture rate as well as infection, malposition or deflation in patients (Kim, 2019). The prepectoral method is especially recommended for athletes, who use extensive pectoral muscle, or for those whose shoulder function should be preserved (Kim, 2019). Overall, prepectoral implant procedures offer more advantages such as more protection, functionality, and aesthetic outcomes than the traditional pectoral implant reconstruction.

## 2.5 Strategy to Bring the Product to the Market

With any new medical product, a functional strategy needs to be devised to bring the product to market. Before the GKLL breast implant can be brought to the market and used as an option for breast implant surgeries, it will need to be approved by medical organizations across

the world such as the Federal Drug Administration (FDA) in the United States and Health Canada in Canada. Furthermore, it is important to discuss why this product is one that should be brought to the market, and how it will be beneficial to both the manufacturing company and the medical world.

The GKLL will need to be approved for medical use before it can be brought to the market. Oftentimes, this process can be lengthy, therefore it is important to strategize as to how the product can be approved as quickly as possible. The average FDA approval time for a new device from pre-clinical testing to approval is seven years (Van Norman, 2016). In order for the implant to be approved, it will have to undergo clinical trials, where the implant is used in human patients to test its efficacy as well as its safety. Funding will be required for the trials of this product; also, one way to speed up the approval time will be by increasing funding. By allocating more funds to the product, it could be included in more clinical trials, which would demonstrate the product's safety and effectiveness in a shorter period of time. Moreover, the approval of a breast implant should not take as long as other new devices since it is not a brand new technology. The GKLL breast implant is made from SIBS polymer. While this is a new biomaterial being introduced for breast implants, it does share some physical and mechanical properties with silicone, which is a common material found in breast implants. This is another factor that would speed up the approval process, because biomaterials similar to SIBS have already been used for breast implants, which should decrease the skepticism around using SIBS for breast implants.

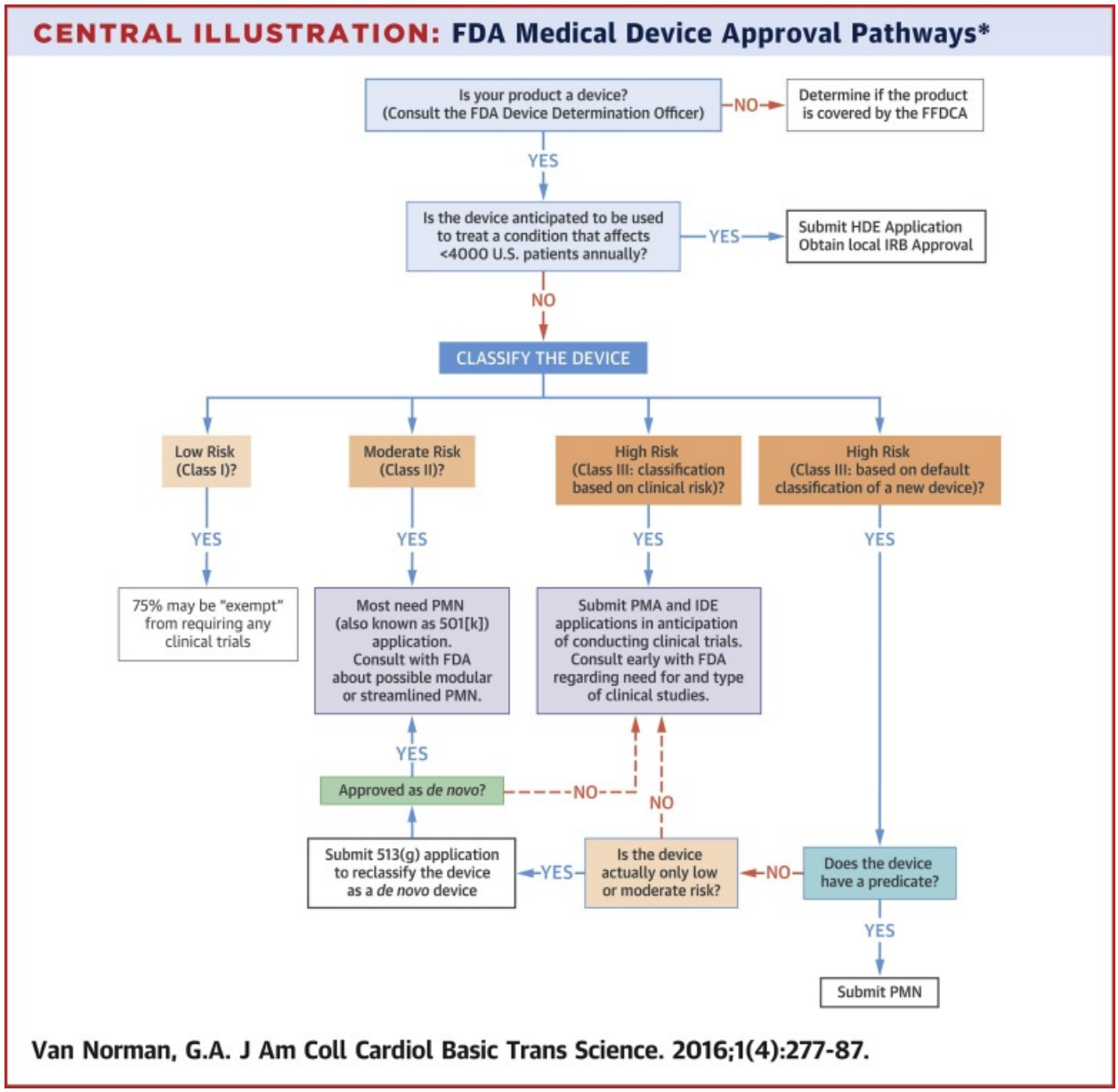


Figure 10. FDA Medical Device Approval Pathways (Van Norman, 2016)

Figure 10 displays the potential processes necessary for a device to undergo FDA approval. As mentioned in section **2.3**, SIBS polymer is a safe biomaterial with strong mechanical properties. Therefore, the GKLL breast implant would not be classified as a high risk device. It is reasonable to assume that the GKLL polymer would have a relatively shorter

approval time compared to other medical products due to the several factors mentioned in this section.

The market for breast implants is a massive one and it is only set to get even bigger. Breast implant surgeries are at an all time high. Whether for cosmetic augmentation, or reconstructions for breast cancer patients, more women are getting breast implants than ever before (Furnham & Levitas, 2012). This is why manufacturing breast implants can be extremely profitable for any company. The new GKLL breast implant will provide a new alternative to conventional silicone and saline breast implants. The SIBS polymer is a new biomaterial that provides new features that existing breast implants do not. Although breast implants are very popular, it is well documented that they are the source of many medical complications. Existing breast implants have the potential to cause short-term and long-term health problems for women that have received them. A new implant made out of SIBS polymer will reduce the potential health risks associated with breast implants. It will also act as a strong implant that does well in mimicking the shape and feeling of a natural breast. Due to the high demand for breast implants, it is reasonable to assume that the product will do very well on the market, as it is a new, innovative alternative to existing breast implants. Therefore, this product should be invested in by the manufacturing company because it is a safer, better alternative to existing options, and it has potential to generate significant revenue.

# 3. Conclusion

Breast reconstruction and breast augmentation procedures are common medical practices in the world today. Whether for breast cancer patients who underwent a mastectomy or women seeking cosmetic breast augmentation, there is a large need for breast implants. Currently there are several breast implant options such as silicone or saline implants. Although these implants

are quite popular, they still pose some potential risks for complications. Some of these implants can possibly expose the human body to harmful chemicals due to degradation or rupture while inside the patient. In addition, many of these implants do not accurately mimic a natural breast in terms of texture and shape. For these reasons, advancements are being made in the area of breast implants.

One example of advancement would be the tissue flap procedure, where adipose tissue from the abdomen of a patient is removed and transferred to the pectoral region to form a new breast. Such a procedure has some advantages over conventional breast implants. For example, using fat tissue reduces risk of infection since it is not a foreign substance being introduced to the body. However, there are also some disadvantages such as having two surgical sites which could increase surgical complications. Overall, this procedure has its benefits, but it does not eliminate the need for synthetic breast implants.

Since there is a need for innovation in the field of breast implants, we are proposing the new GKLL breast implant. The GKLL implant biomaterial is made from SIBS polymer and TPE1 polymer which are self-assembling nanostructured thermoplastic rubbers. This new alternative provides an implant with a high gel cohesivity and a high resistance to gel deformation when comparing it to existing implants such as silicone implants. This would reduce the likeliness of rupture, which decreases the chance of foreign substances interacting with the internal environment of the body. Also, the material used is biocompatible, which ensures that it will easily integrate with the necessary body parts. With the help of advanced manufacturing technology, the GKLL implant will be made to have the texture and shape of a natural breast, all while exhibiting excellent mechanical properties which is why the new GKLL breast implant is a safer, and better alternative to existing breast implant options.

In order for the GKLL breast implant to be brought to market, it will first have to be approved by government medical organizations such as the FDA. By investing in this project, it should be approved with relative ease. Research on this subject has indicated that the polymers being used for the novel biomaterial are safe for use in humans. When clinical trials take place, the safety and benefits of the GKLL implant will be demonstrated, pushing for it to be brought to the open market. We are confident that this product has great potential to make a legitimate change in way breast augmentations and reconstructions are done due to it being a significantly better alternative to existing options.

Finally, it should be known that there is a massive market for breast implants. Mastectomy patients are in need of implants as are women seeking cosmetic augmentations, creating a high demand in breast implant surgeries. The need for such medical procedures are only set to grow in the future. Therefore, the production of an innovative breast implant would be the source of major revenue for the manufacturing company. This is why the GKLL breast implant is the best product that can be brought to the market at this time.

## Statement of contribution

Yunsu Lee : Section 1.3, 1.4, 2.4, Create and Edit Document, Editing of Report

Samantha Lowe : Section 2.1, 2.2, Editing of Report

Minjung Gong : Abstract, Section 1.2, 2.3, Editing of Report

Usman Khan : Section 1.1, 2.5, Conclusion, Editing of Report

*Each member contributed at least 5 sources to the research of the report.*

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