



Toxicological Aspects of Medical Device Implants

Edited by
Prakash Srinivasan Timiri Shanmugam
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Introduction to medical implants

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Abstract

This chapter mainly focuses on the history and evolution of the medical implants, materials used in biomedical implantable devices, and consideration for medical implant materials that discuss the ease of fabrication, biocompatibility, and flexibility. It also discusses their characteristics such as electrical, chemical, thermal, and mechanical behaviors with a combination of different materials/alloys/prosthetics as composites. Implantable devices reside in the human body/biological medium either temporarily or permanently, for the purpose of diagnostics, monitoring, or therapeutic purposes. With the unique responsiveness and design in terms of clinical needs, responsive polymers have been used to facilitate the deployment or removal of the devices with minimum damage to the host tissue, support function of current devices to treat ailments, deliver drugs, control infection, or monitor physiological factors or biomolecules. This chapter also reviews the use of responsive polymers as various implants and devices, starting with addressing the biocompatibility issue of responsive polymers. Application of responsive polymers is based on the areas on which it is applied, including ophthalmic devices, surgical devices, cardiovascular devices, orthopedic dental, breast, respiratory devices, urogenital devices, and implantable biosensors. The biocompatible implants used for medical implants still have some chronic effects on the human body.

Keywords: Medical implants; generation/evolution of medical implants; silicone gel; inflammation; capsular contracture; rupture and deflation; implant materials; biological medium; tissues; alloys; polymers; temporary and permanent implants; biocompatibility; biosensors; chronic effects; implantable devices; standards



1.1 Introduction to medical implants

1.1.1 What is a medical implant?

Medical implants are planted into a human body by surgery or naturally formed cavity and are planned to retain over a short or long period

depending upon the type of surgery. FDA came up with the standards to classify the devices that are placed in the human body regardless of the location and period also called as medical implants.

Implantable devices are partly human-made implants or natural implants that are fully introduced into the subject and planned to retain after the surgery for a period of time depending on the need.

It has been observed that around 10% of the people in the United States and around 6% of the people in industrial revolutionized countries have gone through the surgically medical implants for reconstructing the human body functions and attaining a better standard of life or increasing life span.

1.1.2 History of medical implants

In the olden days (in the late 1880s), body anatomy was improved by changing the size and shape of the breast. The materials used to fill in the breast were different forms made of synthetic materials, oil, rubber, ivory, and glass. Then, silicone and even injections were used to augment the breast.

Injecting liquid substances are the most used technique to augment the breast shape and size by using substances such as paraffin wax or oil and petroleum jelly. Later, silicone fluid was injected into the breast by some illegal practitioners. These methods caused severe damage to the human body including pain, skin color changing, infection to other parts of the body, breast disfigurement and breast loss, respiratory issues and pulmonary issues, liver damage, and even unconsciousness or death.

When the first silicone gel breast implant was introduced, it became popular even though there were many disadvantages; the silica gel is a gum with amorphous silica, which has a high modulus. These olden day implants are made of gel and thick outer shell, whereas the modern-day silicone rubber shell has a smooth surface and inside fluid with a sturdy silicone gel. The burst rates were low compared to other breast implants because of the strong shell. However, when the capsule shrinks, tightens, and compresses the breast implant, seepage complications occur.

To avoid the seepage and leaks, the implant is manufactured with inside partitions; this keeps the implant to hold the gel from sagging, and the holes/slits and layers are sealed with patches, holes, or slits to avoid leaks during manufacturing.

With the advancement of technology, thin implant shells with no gaps between one part and another are manufactured. When the first saline-filled implants emerged, they were heavy and easy to break, with

splashing noise that was audible, and the deflation rate was very high; the manufacturing process involves vulcanization to strengthen the product.

Around the 1980s, the thick shell implants were replaced with thin shells, but this caused high burst rates and seepages that led to deflation. The next-generation implants were made with soft shells and different gel fluids that caused the burst rates and seepages to be high. Later, polyurethane foam, which was introduced in the market, reduced the burst rates and was increasingly popular among most women who underwent implant with this polyurethane foam shell. This foam shell implant was discontinued around the 1990s owing to inflammation, fluid buildup, swelling, pain, and infection side effects.

Breast implant types during these years evolved with different substances and shells; some of them were temporary or permanent. The burst rates or seepage frequencies for the implants vary in percentage based on the manufacturers with different generations.

The new-generation implants have improved silicone-gel implants and saline implants with less deflate rates with the help of stronger shells, partition layers, and textures. This type of implants comes with deflation and rupture rates and less gel diffusion or seepage. As there were no proper standards for breast implant manufacturing in America, more than 200 types of breast implant models were manufactured by different manufacturers with a difference in materials, shapes, sizes, and gels. It is also estimated that over 8000 types of breast implants are manufactured by different manufacturers with different materials over the years.

The major implant manufacturers today use single-lumen implants that are filled with silicone gel. The cover or shell is made of silicon rubber, which is a kind of elastic material called elastomer, and the inside partition is coated with fluorosilicone to prevent silicone gel seepage or bleeding from inside. The outer shell has a textured surface that allows the tissue to grow on its surface, causing an inflammatory reaction. The growth of fibrous scar tissue which is made of collagen that forms around the medical implant, tightens the capsule and squeezes the implant material leading to capsular contraction.

The modern-generation implants are not sure to be continued to use; the analysis and study results from the FDA will lead to a new generation of implants. The history of use and information is very less about the saline implants which was quickly evolved to silicone-gel implants. The saline implants history and usage information is very less which was quickly evolved to silicone-gel based implants.

1.1.3 Medical implant types and materials for implants

Natural as well as artificial medical implants are placed inside the body. Some of the artificial implants are made from prosthetics metal, ceramic, and plastic, which are placed inside the body for soft and hard missing body parts. The natural implants that are made from tissues, bone, and skin are used to support the human body to live a normal life. The implants are mostly used for medication, monitoring, and providing support to organs.

Implants can be temporary or permanent based on their use; some can be removed when the purpose is solved, or it can be placed permanently to provide life support to the human patient. For example, some of the tissues, skin, hip implants, and knee implants are intended to be permanent to support the human patient. In contrast, screws that are used to repair broken bones or metal plates are temporary, and they can be removed when no longer needed by the human patient.

Most surgical procedures have very less recovery time and very less risks, and the risks involved in medical implants are mostly related to the placement, infection, and implant failure; if the implant is not working as intended, then there is a high risk of operating again. Some implants are allergic and infectious to certain human patients and cause infections. The materials used to manufacture the implants can cause bruises, swelling, pain, and redness at the surgical site or even after recovering from surgery. Some of the implants are expected to have some common effects on the human patient like infections and bruises that will be reduced once the human patient's body adapts the implant, but some are very high risks that damage other parts of the body.

The implant life span is considered that, over time, they could break or are not working as expected. This could result in additional surgeries to repair or replace the implant in the human patient body.

1.1.4 Implant materials and purpose

Materials used for implants

- Alloys
- Biosensor
- Titanium
- Prosthetics
- Polymer
- Biocompatibility
- Biomaterials