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Silicone breast implant modification review: overcoming capsular contracture

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Abstract

Background: Silicone implants are biomaterials that are frequently used in the medical industry due to their physiological inertness and low toxicity. However, capsular contracture remains a concern in long-term transplantation. To date, several studies have been conducted to overcome this problem. This review summarizes and explores these trends.

Main body: First, we examined the overall foreign body response from initial inflammation to fibrosis capsule formation in detail and introduced various studies to overcome capsular contracture. Secondly, we introduced that the main research approaches are to inhibit fibrosis with anti-inflammatory drugs or antibiotics, to control the topography of the surface of silicone implants, and to administer plasma treatment. Each study examined aspects of the various mechanisms by which capsular contracture could occur, and addressed the effects of inhibiting fibrosis.

Conclusion: This review introduces various silicone surface modification methods to date and examines their limitations. This review will help identify new directions in inhibiting the fibrosis of silicone implants.

Keywords: Fibrosis, Inflammation, Silicone implant, Foreign body reaction, Capsular contracture, Modification

Introduction

Silicone is the most common material used in medical devices that are inserted into the human body due to its physiological inertness, low toxicity, and antiadhesive properties. In particular, silicone implants are used in plastic surgery for breast augmentation and breast reconstruction [1]. According to the Plastic Surgery Statistics Report of 2017, 300,378 breast augmentation operations were performed—a 3% increase from 2016. Silicone implant surgeries are the most common type of cosmetic surgery cases. However, this surgery is often accompanied by capsular contracture (CC) with an incidence of approximately 10.6% [2, 3]. CC results from the immune response to a foreign body, causing pain and discomfort and resulting in the distortion of both the implant and the patient's chest [4]. CC has long been studied; however, the precise mechanism by which it occurs has not yet been clarified. Bacterial contamination and the foreign body reaction (FBR) are known to be the main causes.

Implants are being improved to overcome these problems. The first improvement involves reducing bacterial contamination of the implant, and the second involves modifications to minimize the FBR. Whereas second-generation implants focused on functional and aesthetic improvements, in third- and fourth-generation implants, the shell was modified to reduce leakage of the gel filling agent and to increase the cohesion of the gel itself [5–10]. Through these improvements, an anatomical model was produced. When fifth-generation implants emerged, the CC incidence was reduced, and rupture of the silicone implants decreased. The safety of the implants also improved [8, 10]. The current sixth-generation implants focus on surface modifications that minimize the FBR. However, varying degrees of CC are still reported, depending on the topography of these surfaces [11, 12]. Previous studies have shown that more malignant CC occurs in smooth implants than in textured implants. A microtextured implant represents a compromise between smooth and textured implants.

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that induce collagen synthesis in the periphery of biomaterials are primarily expressed, rather than platelet-derived growth factor (PDGF), vascular endothelial growth factor (VEGF), or transforming growth factor beta (TGF- β) [34–36]. The MCP and MIP cytokine families are also expressed. During this period, macrophages play a major role. They are recruited by various factors and are expressed and activated during the fibrotic reaction. In chronic inflammation, granulation tissue forms around the biomaterials through the activity of the factors and cells described above [30, 37].

Foreign body reaction

The FBR step is the stage during which the FBGCs formed during chronic inflammation generate fibrosis. It is also the step during which cells that play a major role in the synthesis of collagen, such as fibroblasts, myofibroblasts, and FBGCs, are activated. FBGCs are formed by the fusion of macrophages that are activated via specific cytokines, and when the implant is present, this formation is maintained for a longer period. These FBGCs remove foreign substances in vivo through phagocytosis and cause cell activation. FBGCs express CD11, CD45, and CD31 proteins as well as other receptors capable of binding to IL-1, IL-2, IL-4, and IL-8 on their surface membranes [4, 38]. Notably, the expression patterns of macrophages in vivo are distinct (M1 and M2 macrophages), and the expression patterns of various cytokines vary according to the phenotype of each macrophage. IL-10, TGF-β, and MCP-1 are expressed in the early phase of the FBR, as are IL-1α, IL-6, IL8 and TNF-α, which are proinflammatory cytokines [39, 40]. The expression of these factors modulates the activity of macrophages and FBGCs, determines the presence or absence of fibrosis at the capsule formation stage, and regulates fibrosis severity by changing the activity of the factors according to the characteristics of the biomaterials [38].

Fibrous capsule formation

Finally, the fibrous capsule is formed through the several preceding steps, and fibrosis is terminated. In this step, collagen is synthesized in the peripheral region to isolate foreign materials in vivo, thereby stabilizing the biological reaction by reducing the stimulation of all biological reactions. At this stage, factors typically expressed by M2 macrophages play a major role in controlling collagen synthesis [39]. PDGF, VEGF, and TGF-β are typical factors that induce collagen synthesis and ECM remodeling by stimulating keratinocytes, fibroblasts, endothelial cells, thrombocytes, and adipocytes, which play a major role in collagen synthesis [31, 41]. Initially, collagen type III is synthesized to form a coarse matrix; over time, this matrix stabilizes and replaces collagen type I, resulting in complete isolation [42]. After this step, the in vivo reaction is stabilized, and the immune response by foreign materials in vivo is also stabilized. However, if isolation is not properly performed at this step, more severe fibrosis, such as scarring and CC, will occur.

Surface modification

Modification of surface topography

Smooth surface

The earliest form of silicone breast implant had a smooth surface and was made commercially available with little knowledge of the in vivo immune response. These smooth silicone implants continue to be used to the present day but are still reported to cause severe fibrosis. According to previous studies, smooth implants cause a reduced inflammatory reaction in in vivo implantation as well as reduced physical stimulation [43, 44]. Although smooth implants have been used consistently as implantable devices for breast reconstruction because of these advantages, their frequency of use is decreasing because the incidence of CC is greater with the use of smooth implants than other surface types. Furthermore, because of the inability to fix the smooth silicone breast implant by generating seroma in vivo [45], smooth silicone breast implants are no longer recommended [46, 47]. However, despite the drawbacks of smooth silicone breast implants, they are still being used due to their ability to create a perfect circular breast shape.

Textured surface

Implants with a textured surface represent an improvement over smooth-surfaced silicone breast implants: textured implants with a surface roughness of 100–300 μm avoid fibrosis. Textured implants have been developed through three generations of implant designs and continue to improve fibrosis inhibition as information about in vivo fibrosis is acquired [48]. In textured silicone breast implants, the capsule tissue of the collagen is constructed during in vivo implantation, which facilitates the fixing of the implant position in vivo. Because of this advantage, textured silicone breast implants are currently used in breast reconstruction surgery and are continuously being developed because they can be formed into various shapes by facile in vivo fixation. Droplet-shaped implants are available on the market today only with a textured surfaces. Textured silicone breast implants are known to cause less fibrosis in vivo, and the frequency of CC relative to smooth implants is 5–10% less [43]. Textured silicone breast implants are frequently used for various drug-loaded implants, which are being developed as the next generation of implants due to the ease of drug loading on the surface and sustained drug release from the surface in vivo. From this perspective, the development of functional silicone