Institute of Experimental Morphology and Anthropology

Acta morphologica et anthropologica, 9
Sofia • 2004

Histological Organization of the Capsulae Formed around Implanted Silicone Breast Prostheses

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Aim of this study is to examine and describe the organization of the fibrous capsule formed around silicone breast implant. Representative specimens of 18 explanted silicone breast implant capsules were cut and stained with hematoxilin-eosin and Masson's trichrome stain. Our results show that the capsule formed around implanted mammary prosthesis is highly differentiated and organized structure. The capsules consist of three layers: interface layer in three variations, intermediate fibrous layer of dense rough collagen fibers and light elongated cells with oval nucleus between them and adventitious layer. Between the fibers of the interface (mostly) and the middle strata we observed intra- and extracellular silicone droplets and bulks. This structure interacts active with the implant and represents the location where further pathological processes can take place.

Key words: silicone breast implant capsule, synovial metaplasia, silicone deposits, implant failure.

Introduction

The formation of capsule from recipient's tissues surrounding the mammary prosthesis and the following changes in it are a serious problem of the esthetic and restorative breast surgery. This capsule often compromises the operative result as the surrounding tissues become rigid. The subsequent capsular contracture and calcinosis emerging in some capsules shortens even more the survival of the silicone breast implant in situ and increases the risk of hidden prosthesis rupture followed by leakage of silicone gel into the surrounding tissues. This could lead to variety of local and general complications of incompletely clarified nature [1, 2, 3, 4, 5, 7, 8, 9, 10, 11].

The surrounding tissues appear to be an arena of dynamic interaction between the prosthesis and recipient's organism. The main factors of this interaction are the following: type and quality of prosthesis, its mechanical and physico-chemical properties, quality and type of the operative intervention, presence of silicone in the surrounding tissues caused by the so-called 'gel bleed' or through damage of implant external shell, reactivity of recipient's organism, presence of postoperative complications, etc. [3, 4, 5]. Immediately after the implantation, the recipient develops a local nonspecific acute

inflammatory reaction involving neutrophils, monocytes and macrophages. This reaction is initiated by the surgical intervention and complex formation between silicone and proteins of the complement. As the stimulus exerted by the implant is long lasting, the inflammatory reaction can become chronic [3, 4]. The chronic inflammatory reaction at the borderline with the silicone prosthesis includes fibrosis, focal neovascularization, granulome formation and other reactions with the participation of macrophages, lymphocyte infiltration and lymphocyte vasculitis, and calcinosis in the surrounding tissues as well [3, 4, 5, 6, 7, 8]. In the latter, commonly, droplets of silicone gel and pieces of shell elastomer could be established. The most often described histological findings present with formation of a fibrous capsule, foamy cells filled with silicone gel droplets (xanthoid reaction), mixed cellular reaction, granulomatous inflammation, leukocyte infiltration and vasculitis, calcinosis, etc. [3, 4, 6, 7, 8].

Prevention of these processes represents an issue of utmost importance as it could reduce the compromising effects of the implanted mammary prostheses. That is why a profound understanding of the mechanisms of development of these processes is required. **Aim** of this study is to examine and describe the organization of the fibrous capsule formed around silicone breast implant.

Materials and Methods

The study covered materials taken from connective tissue capsules formed around implanted silicone prostheses. The material was taken from 18 explanted mammary prostheses (from the Fund of the Quebec Biomaterials Institute, Quebec, Canada) after a differently long sojourn in the organism. The material was fixed in a 10 % formaline solution. The explanted capsules were examined using stereomicroscope. Representative parts sized 1 × 3 cm up to 2 × 4 cm were embedded in Histowax. Using paraffin microtome 5 μm-thick sections were prepared. Staining with haematoxylin-eosin and trichrome staining after Masson (blue) was used to evaluate the histological structure.

Results

We distinguish the following three layers in the connective tissue capsule:

– interface layer – a relatively thin part of the capsule adjacent to the prosthesis surface;

– intermediate layer – a thick fibrous layer forming the greater part of the capsule;

– external layer – a peripherically located part, which structure resembles the adventitia.

The structure of the interface layer varies not only along one and the same capsule but also in single capsules under examination. These variants could be classified in the following three main types:

a) hypercellular interface zone (Fig. 1)– formed by a network of collagen fibers between which numerous dispersed cells are located, such as macrophages, lymphocytes, and fibroblasts. In some regions this type is covered by one row flat epithelium-like cells with dark elongated nucleus (Fig. 2);

b) hypo/acellular interface zone (Fig. 3)– formed by a thin sublayer of gross collagen fibers between which few very few flattened cells with dark nuclei and hardly distinguishable cytoplasm (fibroblasts) are located;

c) synovial metaplasia zone (Fig. 4) – formed by several sublayers of cells arranged as in the epithelium with dark nuclei and of irregular shape; below them, large

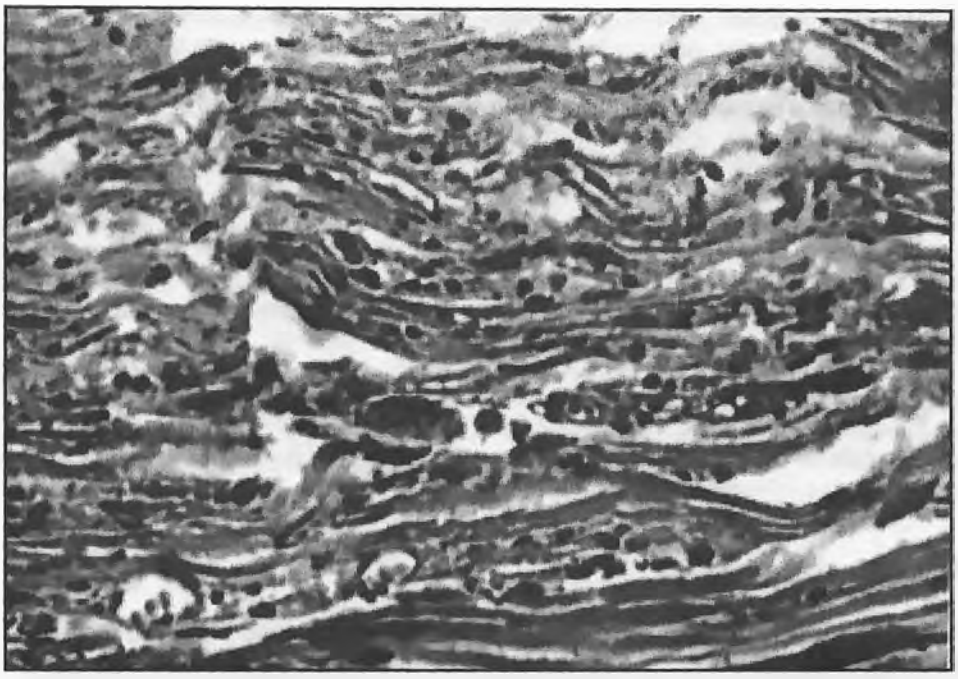

Fig. 1

Fig. 2

polyedric cells with large, light nuclei and light cytoplasm are located. Some of the latter display mitotic signs.

In the interface layer of some capsules hypercellular regions alternate with hypo/acellular ones and/or with parts of synovial metaplasia.

The cells of the hypercellular zone and of the zone of synovial metaplasia lay on a thin, richly blood-supplied sublayer of tender collagen fibers. These two variants often occur in one and the same capsule.

In the regions of intact interface layer, with the hypercellular variant and synovial metaplasia as well, certain cells of foamy cytoplasm and large light nuclei can be observed that resemble the xanthomic cells containing micronized silicone.

In the hypo/acellular zone the transition between the interface and intermediate layer is difficult to distinguish because the fibers that form the first one do not differ significantly from these forming the other one. In all the three types of the interface layer among collagen fibers one can observe droplets of alien transparent material, most probably, of silicone.

The intermediate fibrous layer in all the capsules under examination is of similar structure. Usually, two not always clearly distinguishable sublayers can be observed composed by dense, gross bundles of collagen fibers. Some fibers are strongly thickened and irregularly stained. In the internal sublayer (closer to prosthesis surface) the course of the fibers is in parallel with the capsular surface while in the external sublayer this course is in perpendicular direction. In some preparations of thick capsule, in this layer bundles of collagen fibers of irregular course can be established that form nodules at places. Among the bundles, predominantly fibroblasts as well as macrophages and lymphocytes can be seen. The differences between single capsules concerning this particular layer consist in the thickness of the layer and the amount of the cells in it. In the capsules with a hypercellular interface layer, the intermediate layer is infiltrated mostly by great amount of mononuclear or/and gigantic cells, which in some capsules form real granulomes. On the contrary, in the capsules with a hypo/acellular interface layer, the cells in the intermediate layer the cells are fewest and among them the fibroblast-like cells predominate. Among the fibers, mainly in the basis of the layer, few vessels can be observed.

Among the collagen fibers of this and of the interface layer optically empty spaces can be found out. In some of them, predominantly at the borderline between the interface and fibrous layer but, sometimes, even deeper, droplets of alien transparent material (silicone) can be seen. In five capsules, granulomes around the silicone droplets are established. In three of them alien material of filamentous structure could be seen representing, probably, remnants from silk stitches. Collagen fibers and/or silicone enter among the filaments of this material. Along with the extracellular silicone, an intracellular silicone was established, most commonly, in the form of small droplets in the giant and foamy cells. In the capsules with granulomatous inflammation the layer structure of the intermediate layer is destroyed as both sublayers pass one into another without any marked border.

The external layer of all the capsules is formed by a loose connective tissue. There are numerous blood vessels in it in some of which microemboli of silicone were detected.

Discussion

The great variability in the structure of the capsule formed around the silicone mammary prosthesis as well as the various pathological processes having developed in it are

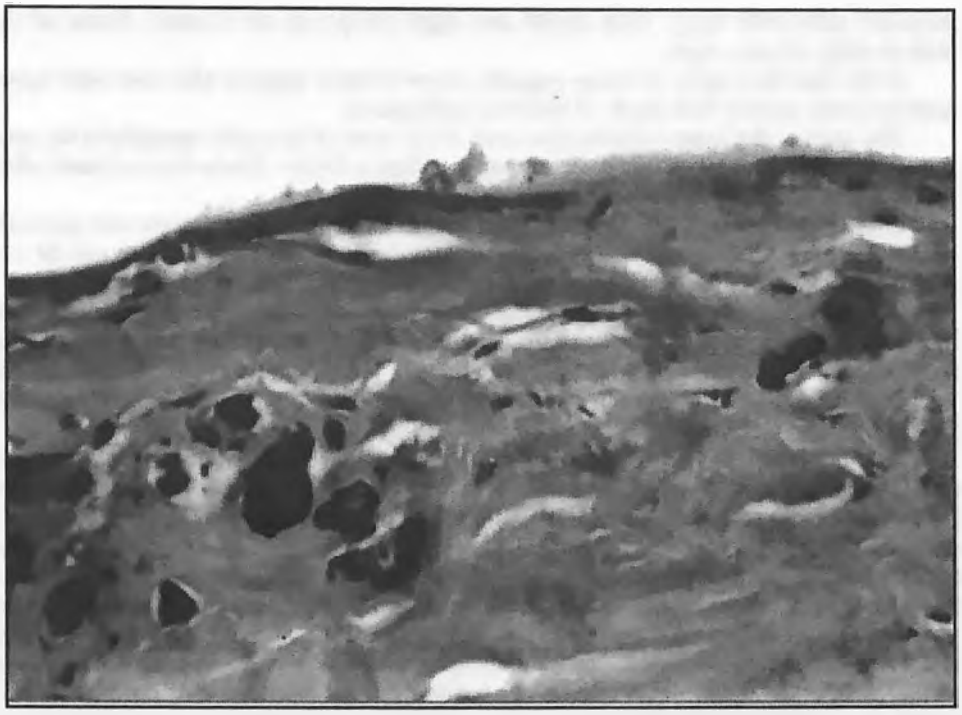

Fig. 3

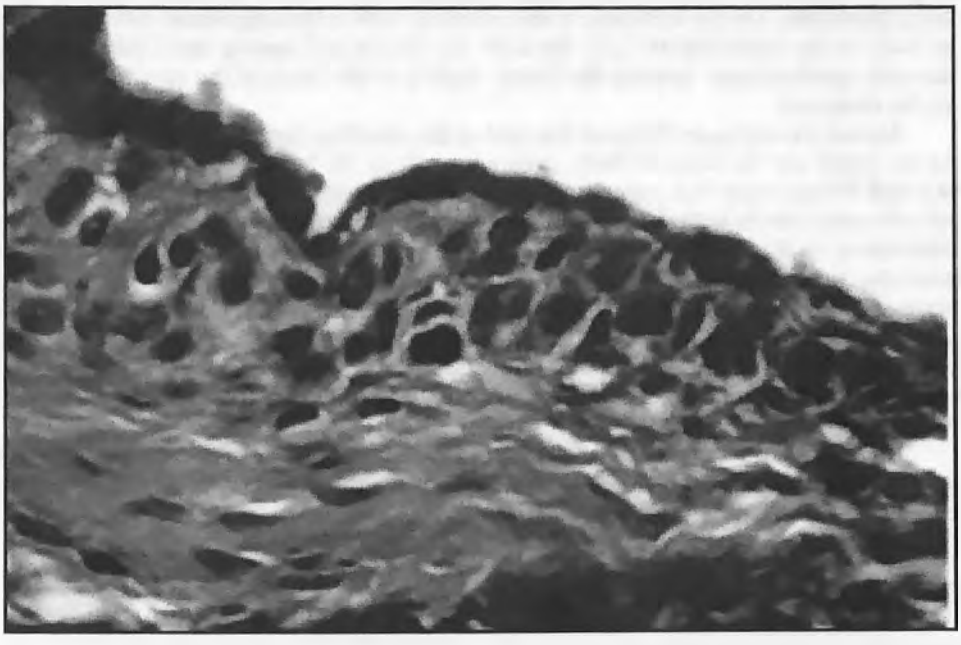

Fig. 4

the reason for the presence of numerous, differing not only in essence but also in terminology, descriptions of this capsule. This circumstance hampers the comparison of data reported by single authors on this topic and often leads to misunderstanding. That is why the task of the present work was to describe in detail the structure of the capsule with a view to more precise characteristics of the advancing important pathological processes: silicone infiltration (penetration), calcium deposition, and degeneration.

In principle, independently of the differences in single capsules, in all of them a similar three-layer structure was identified: interface layer with three main variations (hypercellular, hypo/acellular, and synovial metaplasia); intermediate fibrous layer consisting of two sublayers of collagen fibers and fibroblasts and macrophages dispersed among them, and external layer of loose connective tissue possessing an adventitia-like structure. In most capsules we observed a typical blood supply: an abundance of vessels in the external layer, scanty blood vessels in the intermediate layer, and dense capillary network in the basis of the interface layer. We failed to detect such a capillary network in the capsules with a hypo/acellular interface layer and in those with advanced destruction only. These peculiarities are found out even in the capsules presenting with considerable pathological alterations such as laceration and new formation of collagen fibers, granulomatous inflammation around silicone droplets with abundance of macrophages, mononuclear cells, and giant cells, 'alien body' type granulomes, xanthoid reaction (xanthoma-cell-like macrophages with foamy, poorly stainable cytoplasm because of high micronized silicone content) [3, 7, 8], and calcinosis.

In the literature available there are certain attempts for histological classification of the capsules formed around silicone prostheses [5]. The authors, however, describe and interpret the connective tissue capsule around the implanted silicone breast prosthesis as a pathological fibrosis of the tissues surrounding the implant that has advanced to a different degree [3, 5, 7, 8]. Taking into consideration the present complex structure and typical blood supply of these capsules we draw the conclusion that the capsule formed around the silicone prosthesis represents a newly-formed structure which basic function consists in isolation of the implant from the recipient organism as well as in interaction between both of them.

With respect to the three-layer structure of the capsule observed by us and to our consideration that it should be interpreted as a highly differentiated and complex structure, we classified these capsules into the following three groups:

– capsule with a hypo/acellular interface layer – Poorly supplied with blood vessels. Very few fibroblast-like cells can be found among the gross collagen fibers;

– capsule with a hypercellular interface layer – Loose capsule, very well blood supplied. This type of capsule presents with various forms of abundant cell infiltration, including granulomatous inflammation.

– capsule with synovial metaplasia of the interface layer – The blood supply and the cell infiltration in the intermediate layer is abundant, too, as the mononuclears prevail.

The adventitia does not display any significant differences between these three types of capsules. In three preparations, the interface layer was entirely absent and that is why they could not be assigned to any type at all. Five capsules, on the other hand, bear the signs of more than one capsular type (Fig. 5).

The detailed description of the capsular structure presented above enabled us to relate the kind, localization, and type of deposition of silicone having infiltrated the capsule to definite details of its structure. It has been established that extracellular silicone droplets are found out among the collagen fibers of the interface and intermediate layers as going deeper their density and amount diminishes. In some vessels we observed silicone microembols inside the blood vessels of the intermediate and the adventitious layer. Intracellular silicone occurs in two forms: micronized silicone in the

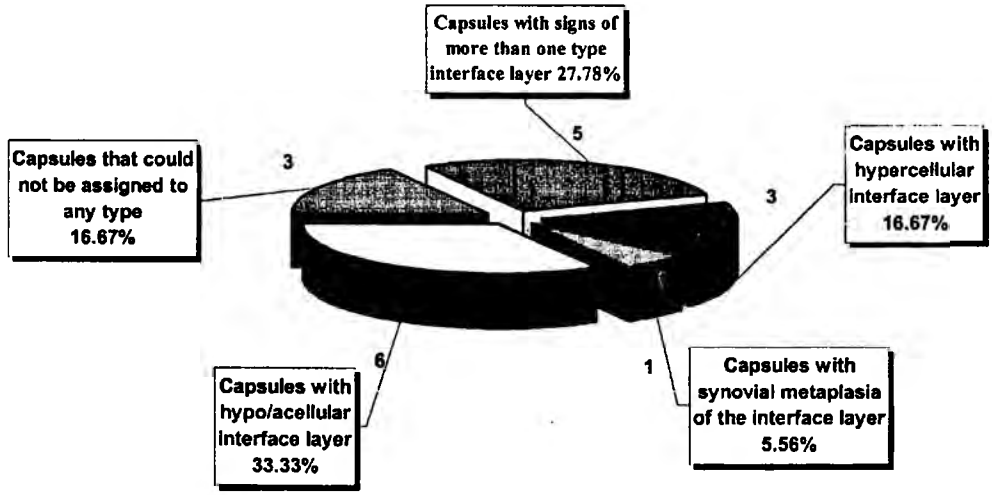

Fig. 5. Distribution of the examined silicone breast implant capsules by the type of the interface layer

cytoplasm of foamy cells (xanthoid reaction) and small droplets in the cytoplasm of macrophages and giant cells. The first form occurs in the interface layer and in the parts of the intermediate layers close to it of the capsules with hypercellular interface layer and synovial metaplasia. Cells with phagocytized silicone droplets were observed in any layers, including in the adventitia, too, as well as in any capsule types.

The role of silicone for the formation and evolution of the fibrous capsule is contradictory. It is assumed that either the implant as a whole, or the silicone gel entered the surrounding tissue through the so-called 'gel bleed' represent a stimulus for the organism to isolate the prosthesis through a fibrous capsule [7] that can, consequently, undergo a degeneration. In our opinion, these two processes are mutually linked.

Conclusion

The capsule formed around the implanted silicone mammary prosthesis represents a well-defined structure emerging as a result from contact interaction between the recipient and implant. It is a structure isolating the organism from the prosthesis and, simultaneously, is that structure of the organism directly contacting and interacting with the implant. Therefore, this is a mutual interaction – prosthesis-capsule and capsule-prosthesis.

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