

Autologous Fascia Graft as a Biological Barrier to Silicone Application in Rabbits

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ABSTRACT

Objective: To determine the cellular effects of providing a fascial interface around subcutaneously-placed silicone implants, in terms of capsule thickness, myofibroblast/fibroblast cell count and inflammatory cell count.

Study Design: Interventional, comparative study.

Place and Duration of Study: Istanbul University Cerrahpasa Medical Faculty, Laboratory of Experimental Animals, Istanbul, Turkey, from May to September 2008.

Methodology: A total of 16 adult New Zealand male rabbits with mean weight of 2508 ± 360 g were used in the study. Animals were divided into two groups as experiment and control groups with equal number of rabbits in each. Fascia injection was applied on silicone implant in the experiment group and compared with the control group in terms of capsule thickness, myofibroblast/fibroblast cell count and inflammatory cell count. At the end of the experiment, tissue samples were examined macroscopically and microscopically for the above. Statistical analysis of data was performed using student's t-test.

Results: A statistically significant difference was found between experiment group and control group in terms of mean capsule thickness, mean myofibroblast and fibroblast cell counts and cell density ($p < 0.05$, each).

Conclusion: Fascia tissue barrier prevent silicone rod reaction and foreign body reaction developing against silicone prosthesis in the studied animal model.

Key words: Fascia. Silicone implant. Rabbit. Silicone rod reaction. Foreign body reaction.

INTRODUCTION

Silicone belongs to the polymers class and is used not only for cosmetic operations but in a wide range of tendon reconstruction, joint replacement and hypertrophic scar treatment as well. It is a non-toxic, non-irritating, non-allergic material and not prone to biodegradation.^{1,2} Capsule formed around the silicone implant has been found to thicken in time, contracted and thus cause distortion of the implant,³ and may be defined as the fibrous scar tissue formed around the foreign body.

Various studies have been conducted to prevent and decrease capsular contracture during and after capsule formation. In these studies, effects of surface properties of the implant, properties of the material filling the implant and localization of implant on capsule development were investigated.⁴ Pouch of implant washed with

povidone iodine solution and intraluminal antibiotics were tried.^{5,6} In peroperative and postoperative periods, steroids, vitamin A and E, and ibuprofen were used; effects of mitomycin-C, amniotic fluid injection were investigated.^{7,8}

Synovitis that develops against silicone implant applied for two-stage late phase tendon reconstructions is seen in 15 – 20% following the first session and is more frequent than the other complications like infection and mechanical insufficiency. The capsule thickens in the second session becomes less flexible. Expected success decreases at the end of the second session if this complication develops. Bacterial growth does not occur in cultures of the fluid obtained from this capsule. On the other hand, the cause of excessive inflammatory response is not clear.⁹

The objective of this study was to examine the cellular effects of providing a fascial interface around subcutaneously-placed silicone implants.

METHODOLOGY

Approval was obtained from Ethics Committee of Experimental Animals in Istanbul University Cerrahpasa Medical Faculty for this experimental study which was conducted from May to September 2008.

A total of 16 adult New Zealand male rabbits with mean weight of 2508 ± 360 g was used in the study. Animals were divided into two groups as experiment and control

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group with equal number of rabbits in each. In the first stage of the experiment, a Bruner incision was made on volar surfaces of the second digit of the right forelimb and flaps were removed, flexor tendons were exposed through dissections. Superficial and profound tendons were separated from junctions to the bone. In the second stage of the experiment, the late repair was waited for 3 weeks.

In the experiment group, Hunter prosthesis was inserted on the volar surface of the second digit of the forelimb. Fascia graft obtained from the right thoracodorsal region (measuring 1 x 1 cm) was cut with bistoury (No. 11) in Ringer lactate solution and injected over the implant through the closed incision.¹⁰

In the control group, Hunter prosthesis was inserted on the volar surface of the second digit of the right forelimb. Fascia graft was obtained from the right thoracodorsal region in order to provide standardization.

In the third stage of the experiment, waiting three months after second stage, subjects were sacrificed with high doses of anaesthetic agent injection and second digit of the right forelimb were amputated at the level of metacarpophalangeal joint. Obtained tissue samples were examined macroscopically and microscopically. Statistical analysis of data was performed using student's t-test.

In preparations obtained from control and experiment groups, the visible thickest part of capsule formation was measured using oculometry. All myofibroblasts and fibroblasts in the capsule were counted and cell number per unit was determined by rating with capsule thickness. In density screening of hystiocytes, lymphocytes and eosinophils (inflammatory cells), their number, clustering types and inter-relations of the cells were evaluated.

Data were expressed as means \pm standard deviation (SD). Student's t-test was used for statistical analysis of the data. Statistical analysis were carried out using Microsoft Excel software. Results were assessed at 95% confidence interval and at $p < 0.05$ level of significance.

RESULTS

While fascia-like capsule formation was observed clearly around implants in control group, neovascularization-related hyperaemia was noted. Implant and surrounding capsule formation were found adherent to the neighbouring tissues and was difficult to be isolated from these tissues.

In the experimental group, surrounding tissues were separated more easily when implants were removed. A significant capsule formation could not be discriminated around implants.

Although capsule thickness varied between 30 μ m and 100 μ m in tissue samples of control group, it was found

to be $76.25 \pm 21.34 \mu$ m. The interfibrillary space in capsule structure was seen to be narrow. Fibrosis and new capillary proliferations were noted. Capsule structure was seen to be darker. This dark coloration was considered to be related with increased fibroblast/myofibroblast cell amount. Mean myofibroblast/fibroblast cell count was found as 120.37 ± 56.46 (Figures 1A and 1B).

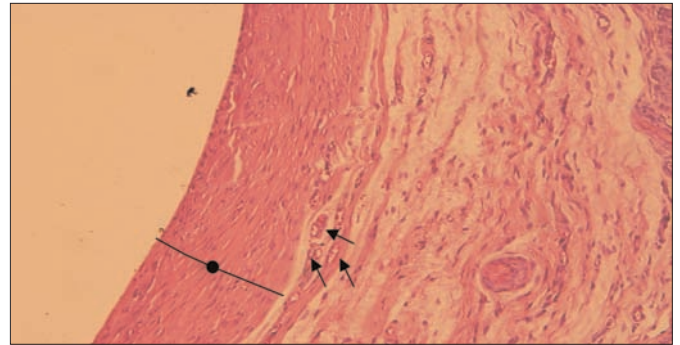


Figure 1A: Appearance of capsule formation around implants in control group, with greater capsule thickness and capillary vessel proliferation (HE x 40).

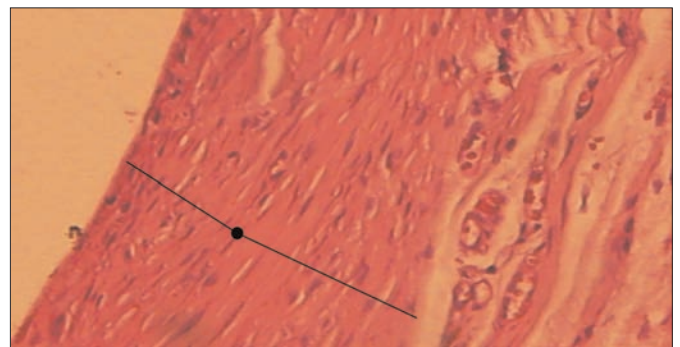


Figure 1B: Collagen fibers showing tight arrangement in capsule structure formed around implants in control group and preponderant, dark coloured fibroblasts (HE x 100).

As the result of examining capsule formation of implants in experiment group under light microscopy; capsule thickness was found to be $20 \pm 8.50 \mu$ m (ranging from 14 to 40 μ m). Myofibroblast/fibroblast cell count in capsule formation was less compared to control group and they were seen to color lighter. Mean myofibroblast/fibroblast cell count was found as 38 ± 16.15 field. Interfibrillary space was seen to increase. Capsule formation could not be separated from neighbouring subcutaneous tissue with sharp borders. Neovascularization was much less compared to control group (Figures 2A and 2B).

A statistically significant difference was found between experiment group and control group in terms of mean capsule thickness, myofibroblast and fibroblast cell counts, cell density (Table I).

DISCUSSION

At present, there is much interest exhibited towards prevention of complications that can be caused by

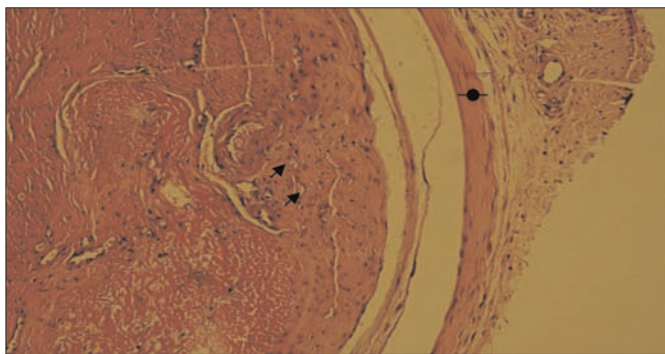


Figure 2A: Capsule structure in experimental group. Neovascularization is minimal (HE X 40).

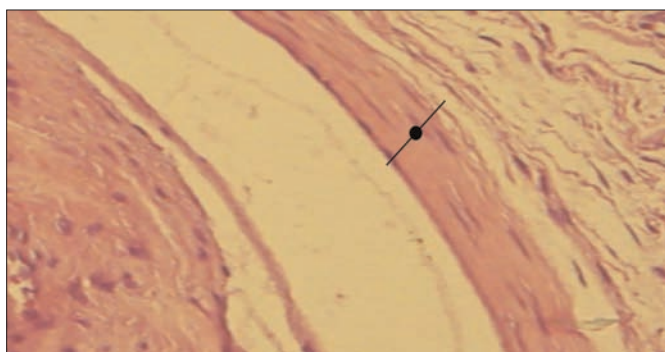


Figure 2B: Experimental group, scarce fibroblasts in capsule and increased space between collagen fibers (HE X 100).

Table I: Comparison of capsule thickness, myofibroblast (mf) and fibroblast (fb) cell counts and inflammatory cell density data as mean \pm standard deviation (SD).

Total (n = 16)	Capsule thickness (μm) mean \pm standard deviation	mf-fb cell count mean \pm standard deviation	inflammatory cells mean \pm standard deviation
Control group (n = 8)	76.25 \pm 21.34	120.37 \pm 56.46	5.87 \pm 2.41
Experiment group (n = 8)	20 \pm 8.50	38 \pm 16.15	2 \pm 0.75
p-value	< 0.0001	0.004	0.0007

implant materials due to their extended use and applications. Although they do not cause a biologic reaction, varying degrees of scar tissue that has the property of contraction may develop around silicone implants.³

Capsular contracture is considered to develop as the result of activation of fibroblasts and myofibroblasts in the capsule structure.¹¹ Implant is forced to cover the possible minimal surface area i.e. to become spherical as a result of altered surface area / volume ratio due to capsule contraction. Consequently asymmetry and deformation may develop.

Studies towards prevention of capsule formation have utilized many options. Intraluminal methylprednisolone was used to minimize capsule formation. Capsule was observed to be thinner in treatment group compared to control group.⁴ In the mechanism of action of methyl

prednisolone was considered to reduce noncollagenous proteins in proteopolysaccharide structure.¹² However, this method could not be used routinely due to leakage from the capsule into the surrounding soft tissue and leading to thinning of the tissues. Vitamin A and E were used to prevent capsule formation, however, its use was limited as they needed to be used in higher doses and for long durations and their effect was not proven.¹³ Topical administration of mitomycin-C, an antineoplastic agent into the pouch created in test animals was shown to reduce capsule thickness and fibroblast-myofibroblast count and thereby decrease the probability of contraction. However, possible side effects of this procedure was not mentioned.¹⁴ Topically administered ibuprofen was also shown to provide a softer capsule formation.⁷ Amniotic fluid injection was tried around silicone implant in test animals due to high hyaluronic acid content in amniotic fluid of the human and was shown to reduce capsule thickness and cellular content.^{8,15} In another experimental study, capsule thickness and cellular content were shown to reduce by administering transforming growth factor-beta-1 inhibitor peptide in an experimental model created by storing silicone implants in tetraglycerol dipalmitate solution.¹⁶

The pouch that the implant would be placed in, was washed with bacitracin and povidone-iodine against *Staphylococcus epidermidis*. The latter is accepted as a aetiologic agent based upon infectious capsule formation hypothesis; intraluminal cephalosporin antibiotics were also tried, however, these methods could not yield the desirable results.^{5,6}

Expansion and massage application were described in order to minimize contraction following capsule formation. Capsular contraction incidence was reported to reduce with these applications, however, satisfactory information was not given about the effects of this compression on the implant and breast tissue.¹⁷ In recent years, studies have been conducted to reduce capsular contracture incidence by covering the implant with another tissue or implant material. Vacanti reported that capsule thickness could be reduced by covering implants with PHEMA (poly-2-hydroxyethyl metacrylate) instead of silicone.¹⁸

In general, fascial tissue content of a thin, well vascularized and tight extracellular matrix enabled to utilize it as a flap or graft.^{19,20} The aim of using fascia around implants may be considered that it may mask implant contours and viability of fascia grafts may be sustained depending on thickness and surrounding tissue vascularity.²¹ In literature, capsular thickening was determined in contracted capsules and fibroblast /myofibroblast counts were shown to increase.^{11,23}

In this study, fascia injection was applied on silicone implants in an experimental group of animals and compared with control group in terms of capsule

thickness, myofibroblast/fibroblast cell count and inflammatory cell count. A thinner and softer capsule formation was detected in the experimental group. Thus, it was suggested to be able to reduce capsular contracture and silicone rod reaction incidence.²² In the experiment group, arrangement of fibroblast / myofibroblast cells and collagen were found irregular and scarce supporting capsule formation. When fibroblast/myofibroblast count in capsule formation in experimental group was compared with control group, it was found to be significantly less.

When the experimental group was compared with the control group in terms of the third parameter, inflammatory cell count, a statistically significant difference was found between groups and it was concluded that fascia graft injection was a quite suitable tissue as a biologic barrier.

Reactions that may develop against silicone rod in late phase tendon reconstruction especially in hand surgery increase the number of sessions and adhesion formation. Based upon this study, fascia injection was considered to affect the wound healing processes positively.

CONCLUSION

The present findings showed that fascia tissue barrier effectively prevented silicone rod reaction and foreign body reaction developing against silicone prosthesis in the studied animal model.

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