Tissue Response to Expanded Polytetrafluoroethylene and Silicone Implants in a Rabbit Model

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Background: Expanded polytetrafluoroethylene (ePTFE) and silicone are safe and relatively biocompatible materials.

Objective: To compare, using multiple histologic parameters, the tissue response to a standard silicone soft tissue implant with the response to a modified ePTFE implant. The modified form of ePTFE is reinforced with fluorinated ethylene propylene (FEPRePTFE), which provides increased pliability and material integrity.

Methods: The implants were placed into a subperiosteal pocket over the skull of adult New Zealand white rabbits. At 7, 30, and 90 days after implantation, en bloc tissue specimens, including skin, implants, surrounding soft tissue, and underlying bone were harvested for gross and histologic evaluation.

Outcome Measures: The tissue response to the implants was assessed with respect to the number of foreign body giant cells present, the thickness of the fibrous capsule, and the general inflammatory response (n=6 for each implant at each evaluation period).

Results: There were no cases of rejection, extrusion, or infection. The silicone implants elicited a significantly thicker capsule and less neovascularization (P<.05).

Conclusion: The FEPRePTFE demonstrated a favorable tissue response when compared with silicone, particularly in regard to capsule thickness and vascular ingrowth.

Arch Facial Plast Surg. 2002;4:111-113

Various alloplastic materials are currently used for aesthetic and reconstructive soft tissue augmentation of the face. Among these alloplastic implants are silicone and expanded polytetrafluoroethylene (ePTFE). Initially used for vascular grafts and subsequently for hernia repair, ePTFE has now been used relatively safely for more than 20 years. More recently, use of ePTFE has been well documented for facial bony augmentation. Several clinical studies have demonstrated the potential advantages of ePTFE. The 2 most significant advantages are rapid stabilization and limited capsule formation. The purpose of our study was to examine the histologic response to a new formulation of ePTFE, one reinforced with fluorinated ethylene propylene (FEPRePTFE). This change in configuration has demonstrated improved carvability and firmness and could prove to be advantageous to clinical application. However, adverse effects of any new material must be assessed prior to widespread clinical use.

The biocompatibility of FEPRePTFE has not yet been well described. The histologic response of this new material was compared with that of silicone in this study.

RESULTS

None of the implants extruded. There was no case of postoperative wound infection, dehiscence, or hematoma. Also, no statistically significant difference was found between the 2 implants in regard to foreign body giant-cell response or number of macrophages at any evaluation period (P=.44, .17, and .58 for foreign body giant-cell response at 7, 30, and 90 days, respectively; P=.19, .15, and .22 for number of macrophages at 7, 30, and 90 days, respectively). Neither material resulted in any significant bone resorption during the study period. The number of peri-implant blood vessels that formed did not vary between the 2 implants at day 7 and day 30. However, by day 90, significantly more neovascularization had occurred in the FEPRePTFE group (P=.004). The cap-
MATERIALS AND METHODS

Thirty-six adult, female, New Zealand white rabbits, each weighing 2 to 4 kg, were used in the study. Twelve rabbits were assigned to each of the 3 in-life phases at 7, 30, and 90 days. Within each in-life phase, 6 rabbits were implanted with silicone and 6 rabbits, with FEPRePTFE. The rabbits were cared for and treated in a manner that complied with guidelines established by the Guide for the Care and Use of Laboratory Animals (National Institutes of Health, publication No. 86-23, revised 1985), the New York State Department of Health Administration, and the Animal Care Committee of Albany Medical College.

The implantation procedures were performed in a standard veterinary operating suite. The implantation site was shaved, and the area was prepared in the usual sterile fashion. A vertical incision was made over the caudal nasal dorsum through the peristeum. Minimal blunt dissection was used to create a subperiosteal pocket cephalad to the incision. Several 2.5 × 0.6 × 0.3-cm implants were carved from the 2 materials, a silicone chin implant (Extended Chin; Invokes International, Jacksonville, Fla) as well as an FEPRePTFE chin implant. The implants were then placed into a pocket just caudal to the external ocipital protuberance over the cranium to ensure that the implant would be placed in a position separated from the incision site. The peristeum and skin were closed in separate layers with 5-0 monofilament nylon suture. The skin sutures were removed 7 days after implantation.

The rabbits were killed 7, 30, and 90 days after implantation. The implants were removed en bloc with 1.5 cm of surrounding tissue and preserved in 10% neutral buffered formalin for histologic analysis. Five histologic characteristics were analyzed: (1) the deep bone-implant interface, (2) the superficial periosteal interface, (3) foreign body giant-cell response, (4) blood vessel formation, and (5) macrophage response. All of these parameters were compared between the 2 implants with a paired t test using Excel-Analyse-It software (version 1.62; Analyse-It Software Ltd, Leeds, England). As the results indicated, none of the implants were extruded or infected. We also found no evidence of bone resorption during the study period. The most notable and demonstrated the alloplastic materials to be unsuitable. While autologous materials are often preferred, they can be associated with problems such as absorption, donor site morbidity, warping, increased operative time, and insufficient donor material.

The past century has witnessed the advent of many synthetic polymers, few of which have stood the test of time. Silicone and ePTFE are among the most widely used polymers and are well described in the facial plastic surgery literature. These materials have many of the properties first described by Scales10 as being ideal for an implant. Among others, these properties include being chemically inert, noncarcinogenic, unmodified by soft tissue, pliable, and firmly resistant to strain. A relatively new form of ePTFE, FEPRePTFE was designed with the purpose of enhancing 2 of those ideal properties, namely, pliability and firmness. Our literature review failed to yield any studies on the histologic response to FEPRePTFE. Given these improved physical attributes, our goal was to determine if the tissue response histologically would reveal any adverse reactions. The initial evaluation was performed at 7 days to examine differences in the acute response. Since normal healing in rabbits is complete in 14 to 16 days,11 any inflammatory reaction at 30 and 90 days could be assumed to be due to the implant.

As the results indicated, none of the implants were extruded or infected. We also found no evidence of bone resorption during the study period. The most notable and
A consistent difference between the 2 implants concerned the thickness of the surrounding capsule. By day 90, nearly a 4-fold difference in the superficial interface thickness had developed, with the silicone implant eliciting a thicker capsule.

One other difference that was noted on histologic examination, but not quantified among our measured outcomes, was the more abundant collagen ingrowth in the FEPRePTFE implants than in the silicone implants (Figure 3 and Figure 4). This finding correlates with the higher vascular migration in the FEPRePTFE implants, which was statistically significant by day 90. These characteristics are thought to be the reason behind the more rapid stabilization of this material. Although stabilization is desirable, the ideal implant can also be easily removed if necessary. A limited capsule formation may facilitate this property. We noted a dramatic and statistically significantly thinner capsule around the FEPRePTFE implant.

In conclusion, the study demonstrates that FEPRePTFE, a new configuration of ePTFE, is characterized by a favorable vascular migration and limited capsule formation. These traits of the FEPRePTFE are advantageous in an implant candidate. The silicone elicited a more vigorous capsule formation and less neovascularization. No significant adverse reactions occurred in either implant. However, the relatively short 3-month examination period may not account for longer-term adverse effects such as implant migration, extrusion, or infection. Histologic analysis of ePTFE suggests that these complications are unlikely. Further clinical studies will more clearly delineate the benefits of FEPRePTFE in facial plastic surgery.

Accepted for publication October 31, 2001.

This study was presented at the Combined Otolaryngologic Spring Meeting, Orlando, Fla, May 13, 2000.

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REFERENCES