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Research Article

Impact of Sculpting Techniques on the Porosity of Porous Polyethylene Implants

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Abstract

Porous Polyethylene (PPE), an alloplastic implant material, is widely used in craniofacial reconstruction. PPE can be sculpted and customized for each patient. The implant's porous architecture is critical for vascular ingrowth. This paper evaluates the impact of various sculpting techniques on the surface porosity of PPE and introduces a more efficient method for shaping PPE. In this controlled experimental study, PPE sheets were sculpted using a scalpel, otologic drill (5mm cutter bur, 5mm coarse diamond bur, and 5mm fine diamond bur), electrocautery, and heat sculpting (soldering). The PPE blocks (including untreated control) were scanned using an electron microscope and the quantity and size of the surface pores were directly measured. When compared to untreated control, sculpting with a scalpel did not show a significant difference in pore size (p=0.22), however, the remainder of techniques did show a significant decrease. The sculpting techniques were then compared to scalpel, which revealed no significant difference for the cutter drill without irrigation (p=0.06). Other techniques, including soldering, electrocautery, and drilling with diamond burs, were found to significantly decrease the quantity and size of PPE pores. Irrigation during drilling did not have a significant impact on pore size. In this study, we identify a cutting otologic drill bur as an efficient alternative to shaping PPE with a scalpel while maintaining pore size within the reference range needed for tissue ingrowth. Further evaluation of porous structure on implantation success in vivo are warranted.

Introduction

Porous polyethylene (PPE), an alloplastic implant material, is used widely in facial implantation. Stock implants are available for augmentation of the malar eminences, mandible, orbital floor, frontal bone and temporal hollows among other areas [1-4]. Anatomic variation and patient preference frequently require intraoperative customization of PPE to achieve the desired result. The relatively recent addition of PPE as a reconstructive option in several facial applications, including microtia, has necessitated significant alteration of stock implants. Facial anatomy is regarded as one of the most challenging to reconstruct in the setting of congenital or acquired defects. One specific example of challenging anatomy in which PPE is used for reconstruction is the auricle. Aesthetically, a successful auricular reconstruction not only mimics the subtle curves and shapes that create distinct shadowing patterns, but it must also be a symmetric replica of the contralateral ear. Because auricular projection is a critical aspect of aesthetic success, a durable framework is required for reconstruction [5]. Traditionally, rib cartilage has been used for auricular reconstruction, however, PPE has gained popularity in head and neck reconstruction including the ear [1-4].

Historically, alloplastic implantation carries a risk of infection, extrusion, and chronic inflammation [6]. PPE has a porous structure that allows for vascular ingrowth and collagen deposition, reducing rates of infection and extrusion over non-porous implant materials [7]. Previous animal studies with polyethylene glycol implants show that larger pores (100-150 μm) permitted mature vascular ingrowth, while smaller pores (25-50 μm) limited cellular and vessel ingrowth to the external surface [8]. As a result, preservation of the porous structure during the implantation process is thought to play an important role in the long-term success of PPE implantation. PPE is manufactured from powdered polyethylene, which under high temperature and pressure, polymerizes to form a solid matrix of interconnected pores or channels [9] The pores range in size from 300-700 µm in diameter [10] After polymerization, PPE can be molded into the desired form or compressed into sheets for subsequent shaping. For facial reconstruction, PPE is sculpted using sterile technique in the operating room.

The extent of sculpting and alteration of the PPE implant is dependent upon the site of reconstruction. Chin augmentation involves less alteration of PPE, while auricular reconstruction demands extensive alteration. Pre-shaped ear implants are available; however, components must be fused using high temperature cautery and sculpted in order to customize the ear to fit the patient and to create symmetry with the contralateral ear.

In sculpting the implant, the surgeon must be cognizant of preserving the superficial porous structure, which allows for vascular ingrowth which ultimately leads to implant integration. PPE is traditionally contoured using a scalpel, however, this method is time-consuming, carries some risk to the surgeon and makes it more difficult to carve a smooth and rounded surface, which is especially important in sites where the implant will be covered with thin skin grafts such as microtia reconstruction. Alternatively, surgeons use a multitude of different sculpting methods in the operating room, however, the effects of alternative sculpting methods have not been reported. In this study, we introduce several alternative sculpting methods, and analyze their effects on the porous structure of the implant.

Materials & Methods

A controlled experimental study was conducted using 2cm x 1cm x 1cm blocks of PPE (Medpor; Stryker, Michigan, USA). In order to standardize treatment methods, one surgeon conducted all sculpting experiments. Nine blocks of PPE were sculpted, one for each method; a single unsculpted block served as a control. The sculpting methods included: scalpel carving, electrocautery, soldering, and drilling. The otologic drill burs used included: 5mm multiflute cutter, 5mm coarse diamond, and 5mm fine diamond (Stryker, Kalamazoo, MI) (Figure 1). Drilling was conducted at 50,000 revolutions per minute for all drill burs. Each drill bur was tested with and without irrigation during drilling. To minimize the impact of heat, the electrocautery and soldering samples were pre-soaked in normal saline.

Figure 1: Drill burs: **(A)** Multi-Flute Cutting Bur, **(B)** Coarse Diamond Bur, and **(C)** Fine Diamond Bur.

For each method, the PPE implant was sculpted using five long passes across the treatment portion of the implant. This method was utilized in an effort to mimic surgical technique in the operating room and was standardized across all sculpting techniques. In general, implants were sculpted to have a relatively flat surface to best evaluate surface porosity using two-dimensional electron microscopy, however, given the nature of each technique, the PPE implants did have some surface contouring, which was reflective of the real-world outcomes of sculpting.

The control and treated PPE blocks were then imaged using a scanning electron microscope (Quanta 250 FEG; FEI Company, Hillsboro, OR). Photomicrographs were acquired at 100x, 200x and 500x magnification and included measurement bars for reference. Three images from different locations on the PPE block were obtained from each sample at 100x magnitude; each image measured 8.2 mm^2 in total PPE surface area. The mean pore size was calculated from direct measurement of the pore diameters in three fields. The longest diameter was used to estimate pore size. Results were reported as a mean percent change in diameter compared to control. Continuous variables were reported as means, standard deviations, and ranges when normally distributed and medians when not normally distributed. Student *t* test was used to compare means with normally distributed data, while a Mann-Whitney test was applied to means with non-parametric values, with all tests two-sided and *P* values <0.05 considered statistically significant.

Results

Photomicrographs of PPE prior to sculpting demonstrate the porous network on the surface of the block with average pore diameter of 616 µm (range 216-856 µm) (Figure 2). Evidence of the polymerization network is observable on higher magnification. The photomicrographs of the PPE after sculpting demonstrate the variability in pore size and number with each technique (Figure 3). Qualitative analysis shows that the use of a scalpel maintains porous structure, compared to electrocautery and soldering, which melt the polyethylene and thus obstruct surface pores. The remainder of treated PPE was sculpted using three different types of otologic drill burs, with or without irrigation. Electron microscopy of these samples reveals greater pore preservation with a cutting drill bur, however, there is evidence of drill dust partially obstructing the preserved pores. The coarse and fine diamond drill burs largely obliterate the superficial porous network as evidenced in (Figure 3).

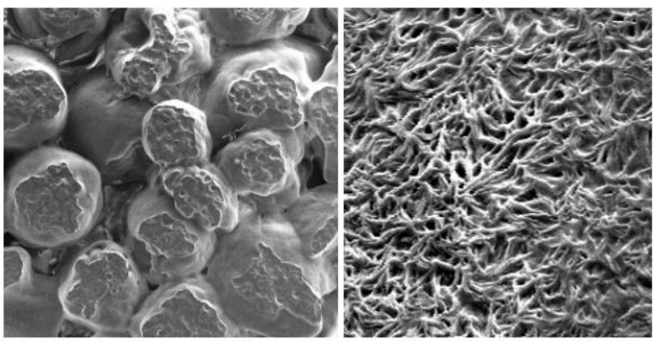
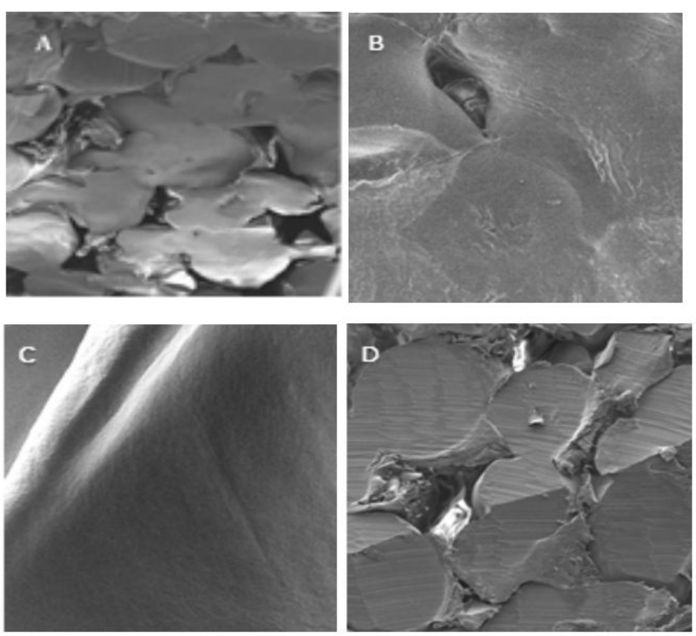


Figure 2: Electron microscopy of PPE implant material prior to sculpting. Microscopic view of PPE and pores (arrows) prior to carving at **(A)** 100x and **(B)** 10,000x magnification.



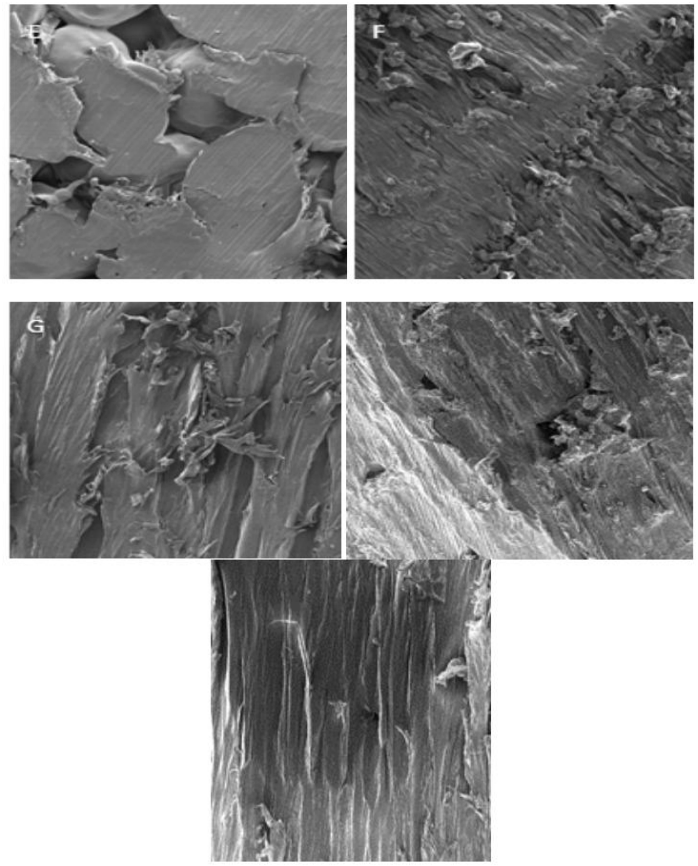


Figure 3. Electron Microscopy of Control and Treated PPE Samples. PPE Carved with **(A)** Scalpel (Control) Shows Maintenance of Pores (Arrow). Experimental Samples Carved Using: **(B)** Electrocautery, **(C)** Soldering, **(D)** Otologic Cutter Drill with Evidence of Drill Dust (Arrowhead), **(E)** Cutter Drill with Irrigation, **(F)** Coarse Diamond Drill, **(G)** Coarse Diamond Drill with Irrigation, **(H)** Fine Diamond Drill, **(I)** Find Diamond Drill with Irrigation.

The measured pore sizes for each sculpting method are summarized in the (Table 1). Comparison of the 10 samples revealed a significant difference in pore size ($p<0.0001$, ANOVA). When compared to the untreated control, PPE sculpted with a scalpel or drilled with a cutting bur (with and without irrigation) did not show a statistically significant decrease in pore size ($p=0.219$, $p=0.061$, and $p=0.083$, respectively), while the remainder of sculpting techniques did show a significant decrease in pore size. There was no significant difference in mean pore size between samples when sculpted with or without irrigation for the cutter, coarse, and fine diamond drills ($p=0.806$, $p=0.667$, and $p=0.800$, respectively). The mean number of pores per magnified field was decreased compared to the untreated control (16.7 pores per field) in all cases. PPE sculpted with a scalpel preserved the most pores (15.3 pores per field), followed by the cutter drill with and without irrigation (12.3 and 13.7 pores per field, respectively). The remainder of techniques retained two or fewer pores per field.

Sculpting method	Mean pore diameter in µm (SD)	% decrease compared to unsclupted	P value (vs unsclupted)	Mean number of pores per field
Unsculpted PPE	616 (123)	-	-	16.7
Scalpel	566 (136)	8.1	0.219	15.3
Electrocautery	119.5 (78)	80.6	**< 0.0001**	2
Soldering	0 (0)	100	**< 0.0001**	0
Drill: Cutter, irrigation	497 (197)	19.3	0.061	12.3
Drill: Cutter	484.27 (213)	21.4	0.083	13.7
Drill: Rough diamond, irrigation	46.5 (25)	92.5	**0.005**	0.7
Drill: Rough diamond	30.5 (5)	95	**0.005**	0.7
Drill: Fine diamond, irrigation	85 (38)	86.2	**0.005**	0.7
Drill: Fine diamond	55 (47)	91	**0.002**	1

Table 1: Changes in Pore Size and Quantity by Sculpting Technique. (Bold Numbers Indicate Statistical Significance).

Discussion

The primary objective of this paper is to characterize and measure the changes in PPE surface porosity when sculpted using various techniques commonly found in the operating room. This study shows that several techniques used to sculpt PPE significantly reduce the size and quantity of pores. Soldering, electrocautery and diamond drill burs reduce the mean pore size to below the 100 µm diameter threshold which has been associated with decreased vascular ingrowth [8]. The use of a scalpel or a cutting drill bur with or without irrigation best preserves the pore size and number, and the average pore diameter for these techniques remains within the range needed for tissue ingrowth. Although animal studies have shown improved vascular ingrowth with larger pores, studies have not directly evaluated extrusion or infection rates in implants with smaller or fewer pores. Additionally, this study evaluated the impact of various sculpting methods on a single surface of an implant, however, *in vivo*, the three-dimensional shape of the implant and porous structures must be considered in the evaluation of vascular ingrowth. In general, implant exposure (0-6.4%) and infection (0-5.8%) rates are low [11-13], however, an assessment of a potential association between the integrity of implant porous structure and complications is warranted.

Along with the changes in porous microstructure, drill dust may impact vascular ingrowth and implant integration. Photomicrographs of PPE samples sculpted with the cutter drill show evidence of drill dust within the surface pores (Figure 3). The presence of drill dust within the porous network may effectively decrease pore size, although the effects of drill dust on vascular ingrowth have not been previously studied. One possible way to address drill dust within surface pores may be suctioning, although this remains to be tested. Further studies are required to understand the relationship between drill dust and vascular ingrowth, and the potential impact on long-term implantation success. Interestingly, this study did not show a significant difference between irrigated and non-irrigated samples, which suggests that irrigation does not impact pore size with various drilling burs. This finding was unexpected, as drilling at high speeds typically creates heat, which was expected to negatively impact the surface porosity of the implant. One explanation may be that there was insufficient drill-implant contact time to cause thermal damage to the surface pores. Although there are no prior studies evaluating the impact of high-speed drilling and thermal damage on PPE, prior studies evaluating the impact of high-speed drilling on bone demonstrate that temperatures change as a function of drilling time [14,15] Consequently, in the setting of drilling PPE with a short duration of contact, heat created by high-speed drilling may not be a significant factor.

An important finding of this study was to demonstrate the modest impact on surface porosity of both the standard technique for PPE modification (scalpel) and a proposed new technique (cutter drill). The otologic cutter drill is readily available in the operating room and affords many advantages over the scalpel-speed, precision and smoother contours. These findings are not exclusive to microtia reconstruction with PPE but any of clinical applications for PPE. For example, customization of a PPE chin or mandibular angle implant or modification of a PPE wedge implant for orbital floor augmentation may be done using a cutter drill. While the primary objective of this study was to evaluate the changes in PPE pore structure in the setting of various sculpting techniques, the *in vivo* implications of these changes were not formally tested. Given that the porosity of PPE has been associated with tissue ingrowth and biocompatibility [8], the authors extrapolate that minimal changes in porosity that remain within the product's reference range of 300-700 µm [10] would have minimal clinical impact on tissue ingrowth, while dramatic changes in porosity would have negative effects on tissue ingrowth and biocompatibility.

The proposed alternative sculpting method, the cutter drill, has an average pore diameter of 454 µm, which is within the reference range. In this study, we used the long axis of multiple PPE samples to measure average pore size for a given sample; although there exist different measurement techniques that could lead to a discrepancy in pore sizes amongst different studies, pore sizes in this study are comparable to those found in other examples within the literature. [8,10]. In this study, the PPE samples were sculpted with tools commonly used in the operating room, however, the samples did not precisely replicate the auricular shape that would be implanted in auricular reconstruction cases. Intraoperatively, PPE may be shaped using more than one sculpting technique, thus future in vivo studies may consider closely replicating these intraoperative techniques. Along the same lines, this study utilized 5mm drill burs to reflect current operative technique, however, it is possible to use larger or smaller burs. Ultimately, *in vivo* evaluation of vascular ingrowth and complication rates for the different sculpting techniques is required to determine the impact of more time-effective sculpting on implantation success. Alternatively, custom-made implants may serve as an option that decreases the mount of sculpting needed, however, this option may be cost-prohibitive for many practices.

In this study, we propose the use of an otologic cutting drill bur as an efficient alternative to sculpting PPE with a scalpel. Although all sculpting techniques were found to decrease the average pore diameter, the cutter drill maintained an average pore size within the reference range for tissue ingrowth. Other techniques, such as soldering, electrocautery, and diamond drill burs, were found to significantly decrease the quantity and size of PPE pores and potentially impede vascular ingrowth which may impact integration and potentially implant exposure. Further studies evaluating the *in vivo* implications of altered porous structure on implantation outcomes are warranted.

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