Cohesive silicone gel implants with smooth, textured or polyurethane-coated surface to restore volume in eviscerated sockets

Article *in* Orbit (Amsterdam, Netherlands) · August 2017

DOI: 10.1080/01676830.2017.1353107

CITATIONS
0

READS
61

8 authors, including:

Seizo Yamashita
118 PUBLICATIONS **816** CITATIONS
SEE PROFILE

Alicia Galindo-Ferreiro
Hospital Universitario "Rio Hortega"
86 PUBLICATIONS **89** CITATIONS
SEE PROFILE

Marilia Modolo
São Paulo State University
12 PUBLICATIONS **74** CITATIONS
SEE PROFILE

Claudia Pellizzon
São Paulo State University
76 PUBLICATIONS **1,016** CITATIONS
SEE PROFILE

Orbit

The International Journal on Orbital Disorders, Oculoplastic and Lacrimal Surgery

ISSN: 0167-6830 (Print) 1744-5108 (Online) Journal homepage: http://www.tandfonline.com/loi/iorb20

Cohesive silicone gel implants with smooth, textured or polyurethane-coated surface to restore volume in eviscerated sockets

Cristiano Abreu, Seizo Yamashita, Alicia Galindo-Ferreiro, Marilia Modolo, Claudia H. Pellizzon, Carlos R. Padovani, Mariangela E. A. Marques & Silvana A. Schellini

To cite this article: Cristiano Abreu, Seizo Yamashita, Alicia Galindo-Ferreiro, Marilia Modolo, Claudia H. Pellizzon, Carlos R. Padovani, Mariangela E. A. Marques & Silvana A. Schellini (2017): Cohesive silicone gel implants with smooth, textured or polyurethane-coated surface to restore volume in eviscerated sockets, Orbit, DOI: 10.1080/01676830.2017.1353107

To link to this article: http://dx.doi.org/10.1080/01676830.2017.1353107

Published online: 18 Aug 2017.

ORBIT
https://doi.org/10.1080/01676830.2017.1353107

Taylor & Francis
Taylor & Francis Group

Cohesive silicone gel implants with smooth, textured or polyurethane-coated surface to restore volume in eviscerated sockets

Cristiano Abreu[a], Seizo Yamashita[a], Alicia Galindo-Ferreiro[b,c], Marilia Modolo[a], Claudia H. Pellizzon[d], Carlos R. Padovani[d], Mariangela E. A. Marques[a], and Silvana A. Schellini[a,c]

[a]Faculdade de Medicina de Botucatu, Universidade Estadual Paulista, Botucatu, Sao Paulo, Brazil; [b]Ophthalmology Department, Complejo Asistencial de Palencia, Palencia, Spain; [c]King Khaled Eye Specialist Hospital, Riyadh, Saudi Arabia; [d]Instituto de Biociências de Botucatu, Universidade Estadual Paulista, Botucatu, Sao Paulo, Brazil

ABSTRACT

The purpose of this article is to evaluate the three different surface coating on cohesive silicone gel implants in eviscerated rabbit eye sockets. Forty-five albino rabbits underwent right eye evisceration and received hemisphere-shaped cohesive silicone gel implants with smooth (Group 1), textured (Group 2), or polyurethane-coated surface (Group 3) in the socket. The animals were euthanized at 7, 30, and 90 days postoperatively. Computed tomography of the orbits was performed prior to euthanasia. Subsequently, the orbital contents were removed and underwent histologic and morphometric examination. Data were statistically analyzed. There were no adverse effects throughout the study. The majority of implants in the Group 1 exhibited 180° rotation. The Group 3 experienced an intense inflammatory reaction around the implant and implant deformation probably due to pseudocapsule contraction. Cohesive silicone gel implants had good integration into the scleral socket. Optimal results were obtained with cohesive silicone gel textured implants (Group 2). Smooth implants (Group 1) rotated significantly, whereas polyurethane (Group 3) coated implants precipitated an intense inflammatory reaction and were deformed postoperatively.

KEYWORDS

Anophthalmic socket; cohesive silicone gel implant; experimental study; orbital implants; superficial texture

Introduction

Studies on silicone implants to restore volume in an anophthalmic socket are rare.[1,2] However, cohesive silicone implants are widely used for cosmetic breast augmentation surgery.[3] Controversy remains on whether to use textured or polyurethane-coated silicone implants. Although polyurethane precipitates a more robust inflammatory reaction, it appears to results in less capsular contracture postoperatively.[4] However, textured silicone implants are widely used resulting in very similar outcomes to polyurethane-coated silicone implants.[3,5]

A rough external texture of implants placed in anophthalmic sockets can result in conjunctival erosion causing dehiscence with implant exposure and/or extrusion,[6] suggesting that implants with a textured surface should be used with discretion for this purpose.

There is only one experimental study about cohesive silicone implant in anophthalmic socket reporting good results and encouraging the use of this type of implants.[7] To our knowledge, there are no studies comparing different surface coatings on cohesive silicone gel implants placed in the orbital cavity.

The present study evaluates cohesive silicone gel implants covered with a smooth, textured, or polyurethane-coated silicone surface to determine the best alternative for use as an implant in eviscerated anophthalmic sockets.

Materials and methods

This single-blinded, randomized, experimental study evaluated 45 male albino Norfolk rabbits (*Oryctolagus cuniculus*) that underwent evisceration and cohesive silicone gel implants with one of three different surface coatings. This study was performed in accordance with the ethical principles for animal studies and approved by Institutional Research Ethics Committee. All the rabbits were between 3 and 6 months of age and weighed between 1,690 and 2,884 g. The rabbits were provided by the Central Animal House of the Universidade Estadual Paulista (UNESP), Campus of Botucatu, Sao Paulo State, Brazil.

All rabbits were anesthetized with an intravenous injection of tiletamine and zolazepam 15 mg/kg (Zoletil, Virbac, São Paulo, Brazil) and 2 drops of 0.4% oxibuprocaine (Oxinest, Latinofarma, São Paulo, Brazil) in the right eye.

CONTACT Silvana Artioli Schellini sartioli@fmb.unesp.br Faculdade de Medicina de Botucatu, UNESP, CEP: 18618-970, Botucatu, São Paulo State, Brazil.
Color versions of one or more of the figures in the article can be found online at www.tandfonline.com/iorb.

The right eye was eviscerated in all cases under aseptic and antiseptic conditions. Subsequently, hemisphere-shaped cohesive silicone gel implant with similar content to the breast implants were placed in the socket. The implants had either a smooth (Group 1) surface coating, a textured (Group 2) surface or a polyurethane-coated surface (Group 3) (Silimed Ltda, Rio de Janeiro, Brazil). The implants were placed within the scleral cavity with the convex side facing outward (Figure 1). The sclera was sutured with continuous stitches using a 6–0 nonabsorbable braided thread (Mersilene, Ethicon, Johnson & Johnson do Brasil Indústria e Comércio Ltda, São Paulo, Brazil) followed by a continuous running conjunctival suture using the same thread. There were 15 rabbits in each group, of which 5 rabbits per group were euthanized at 7, 30, or 90 days after implantation placement.

All of the animals were evaluated daily, for local or systemic changes. Immediately prior to euthanasia, computed tomography (CT) scans of the orbits (Shimadzu SCT 7800-TC, Japan) were performed with default positioning in the ventral decubitus. CT scans were composed of a total of 30 axial cuts of 1 mm thickness at 1 mm intervals (parameters 130 mA and 120 Kv) with three-dimensional reconstruction to evaluate implant position (rotation and/or migration) and possible changes surrounding the implant.

The animals were then euthanized by anesthetic overdose. The orbital contents were removed, fixed in 10% formaldehyde, embedded in paraffin and stained with hematoxylin-eosin. Morphometric examination was performed to evaluate pseudocapsule thickness in the anterior and posterior aspects of the implant using a Leica DMLS microscope (Germany) coupled to a video camera (Leica Qwin Software, Germany).

Statistical analysis of the quantitative variables was performed with two-way analysis of variance (Group X Stage) followed by Tukey's multiple comparisons test for continuous variables and a nonparametric method for discrete variables. For qualitative variables, the Goodman association test was performed for contrasts between and within binominal populations. A P value less than 0.05 was considered statistically significant.

Results

Clinical evaluation

All the animals exhibited good clinical course with no cases of extrusion or infection of the orbit or surrounding tissues.

CT scan evaluation

There was one case with peri-implant edema in Group 3 at 7 days postoperatively. A change of implant position occurred in 10 cases and was more frequent and intense in the Group 1, with 3 out of 5 animals exhibiting a 180° rotation by 90 days postoperatively. Groups 2 and 3 experienced rotation below 90° or no change in implant position (Figure 2). At 90 days postoperatively, there were discrete deformities in 3 implants in the Group 3 only.

Histological evaluation

On macroscopic evaluation, there were cases of the implant adherence to the sclera, especially in the Groups 2 and 3. There were no cases of inflammation within the implants and the scleral socket was preserved in all groups throughout the study. At 7 days postoperatively, tissue reaction was observed in the scleral-implant interface that was similar between groups, with characteristics of healing repair showing edema, numerous red blood cells (RBCs), fibrin network and a small number of inflammatory cells which were predominantly neutrophils. There were clinically significant differences in the pseudocapsule between groups. At 30 days postoperatively, groups 1 and 2 showed inflammatory processes around the implant. The pseudocapsule was composed of fibroblasts, a few histiocytes, new vessels containing RBCs, and hemosiderin deposits with no edema. At 90 days postoperatively, the pseudocapsules in Groups 1 and 2 were

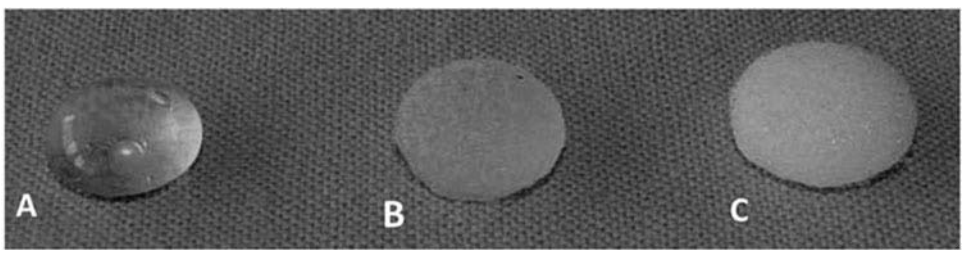

Figure 1. Implants used in this study in hemisphere-shaped, composed by cohesive silicone gel with a smooth (Group 1, A), textured (Group 2, B) or polyurethane-coated surface (Group 3, C).

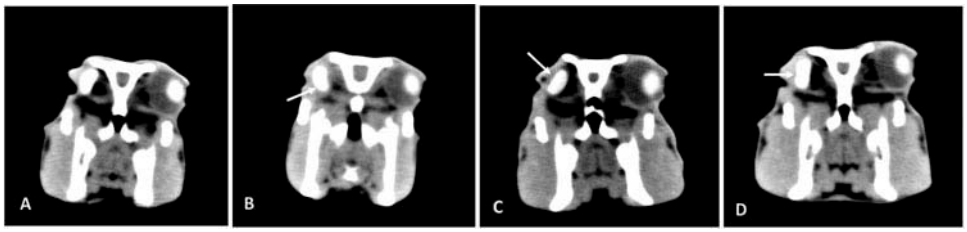

Figure 2. Tomographic images of rabbit skulls showing the right anophthalmic socket filled with a hemisphere-shaped silicone implant. **(A)** position of the implant in G2 animal with the external convexity, the same as when the hemisphere was inserted, *i.e.*, outward convexity. **(B)** implant in G1 animal with a partial rotation in the lower sector (arrow). **(C)** implant in G1 animal had rotated by 180° of the original the position and the convexity of the implant being turned towards the posterior part of the orbital cavity (arrow). **(D)** implant in G3 animal in position but distorted in the medial portion (arrow).

similar and were easily identified from their intense pink color, composed of mature fibroblasts, and a hyalinized collagen on the entire implant. The Group 3 had a more robust inflammatory reaction throughout the study, forming a thicker pseudocapsule at 30 days postoperatively, that was composed by neutrophils and monocytes, irregular focal thickening with localized accumulation of inflammatory cells, active neovascularization and empty spaces in the pseudocapsule. At 90 days postoperatively, the pseudocapsules in the Group 3 were composed of mature fusiform fibroblasts, with a granulomatous reaction composed by multinucleated giant cells and a lymphoplasmocytic infiltrate. The spaces within the pseudocapsule increased in size. A pink, amorphous, birefringent phagocytized material was identified in the peri-implant reaction (Figure 3).

Quantitative evaluation of the pseudocapsule

The pseudocapsule was generally thicker after 7 days postoperatively and decreased by the last postoperative observation. At 30 days postoperatively, the anterior and posterior aspect of the pseudocapsule were thicker in the Group 3 compared to the other groups. At 90 days postoperatively, the thickness of the anterior aspect of the pseudocapsule did not differ between groups. The posterior aspect of the pseudocapsule was thinner in the Group 2 compared to the other groups at 90 days postoperatively. The area of inflammation was statistically significantly higher in the Group 3 compared to the other groups at 90 days postoperatively ($P < 0.05$; Table 1).

Discussion

The primary impetus for this study was to evaluate the use of cohesive silicone gel implants to replace volume in anophthalmic sockets because, theoretically, conventional implants have a rigid surface as well the external prosthesis, which can cause contact-induced damage during extraocular muscle movement. This damage can increase the risk of conjunctival or scleral dehiscence and extrusion. We believe that a soft implant in the socket can reduce traumatic contact with the external prosthesis, reducing complications. We elected to use hemispheric shaped implants due to the shallow format of the rabbits orbit.

This comparison of three different surface coatings on the cohesive silicone implants was performed in order to observe which one can have better results to be applied in an anophthalmic cavity. The lack of infection and/or implant extrusion indicated a clinically favorable result for the smooth, textured, or polyurethane-coated cohesive silicone implants in the current animal-model study.

Only the implants in Group 1 rotated by 180°. The remaining groups had only incomplete or no rotation of the implants. The smooth surface of the implants in Group 1 allow it to move freely, leading to changes in the position of the implant that may result in poor cosmesis. This finding confirmed the macroscopic findings of adherence between the implant and host tissues in Groups 2 and 3 but no adherence in Group 1.

The adherence to the scleral tissue at 30 days and, more so, at 90 days after implant insertion in Groups 2 and 3 was indicative of implant integration to the host tissue. The cohesive silicone gel implant is surrounded by impermeable membranes and integration only occurs with the coating, whereas the inner aspect remains inert, which was confirmed by the histological findings in the current study. Hence, as reaction with the host is limited to the coating, the texturized and polyurethane-coated silicone implants are considered semi-integrated or partially integrated implants.

In breast implants, the host tissue surrounds the implant composed of cohesive silicone gel with a pseudocapsule formed by fibroblasts, inflammatory cells, and collagen.[8] The role of the pseudocapsule in stiffening and contraction of breast implants has been extensively studied[3] and is

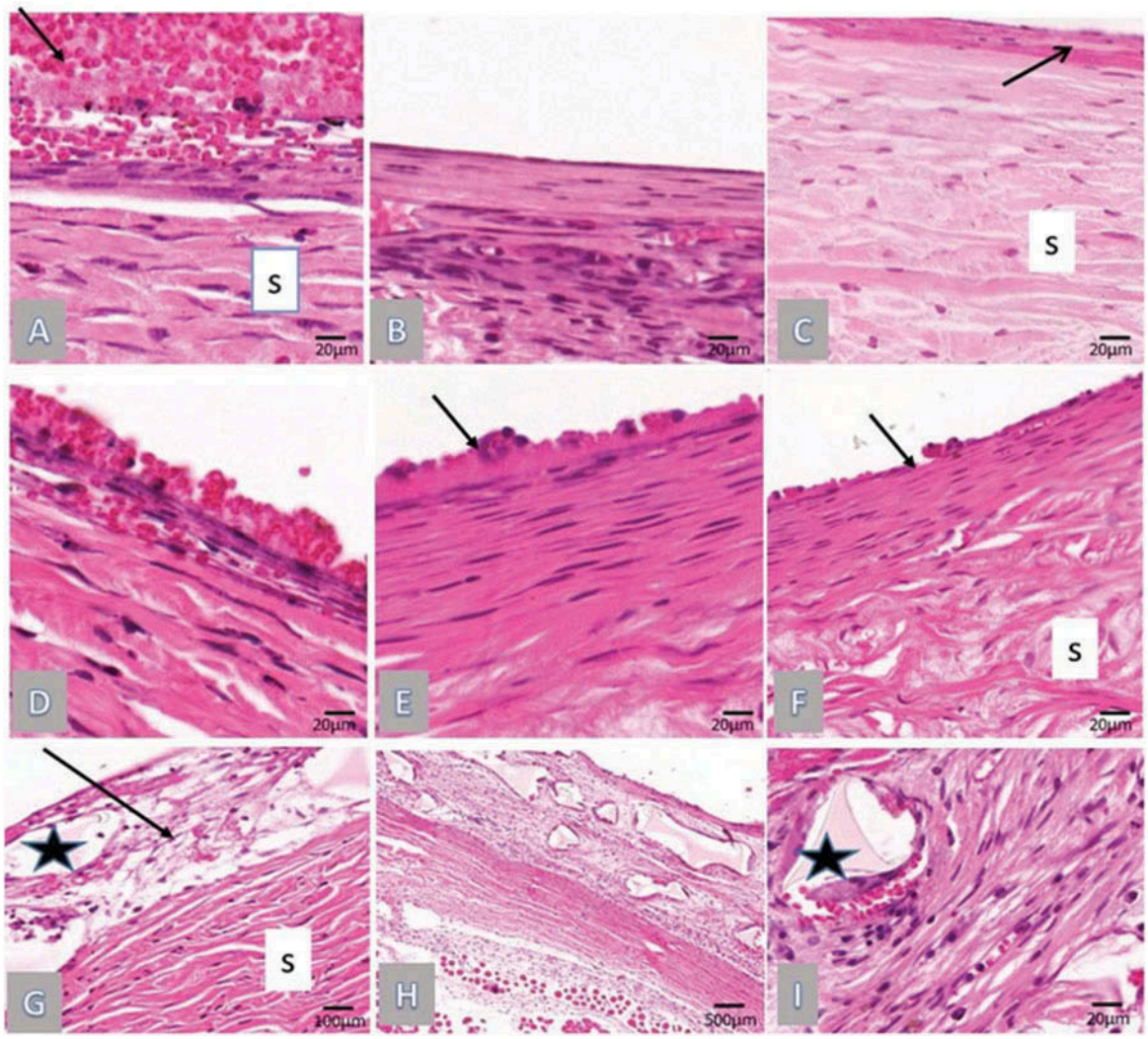

Figure 3. G1 - (A) Tissue reaction at 7 days after surgery showing a large number of red blood cells, edema and inflammatory reaction around the implant and over the sclera, composing the pseudocapsule (arrow); sclera (s); (B) after 30 days there are less cellular reaction and the fibrin is well organized; (C) 90 days after surgery the pseudocapsule (arrow) is well defined as composed of mature fibroblasts and a hyalinized collagen membrane; sclera (s). G2 – (D) Similar tissue reaction than observed in GI 7 days after surgery; (E) after 30 days, pseudocapsule (arrow) composed of fibroblasts and a small number of inflammatory cells was observed, similar than in GI; (F) pseudocapsule (arrow) composed by fibroblasts and a small amount of inflammatory cells; sclera (s). G3 – (G) The polyurethane-coated surface is well defined after 7 days of the surgery, with edema, inflammatory reaction and pieces of a pink and amorphous material (star) surrounded by tissue reaction, forming a pseudocapsule (arrow) around the implant; sclera (s); (H) 30 days after surgery the inflammatory reaction persists; (I) also 90 days after surgery is possible to observe neovessels and inflammatory reaction around the pink pieces (star) of the polyurethane-coating.

Table 1. Media and standard deviation of pseudocapsule according to the type if implant and postoperative day of euthanasia.

		Postoperative day of euthanasia		
Pseudocapsule	Group	7 days	30 days	90 days
	G1	533,39 (63,10) aA	368,86 (82,89) abA	501,17 (144,91) aAB
Thickness	G2	532,02 (112,93) aB	345,72 (95,65) aA	462,31 (161,5) aAB
Anterior	G3	509,83 (90,28) aA	524,89 (136,3) bA	458,39 (112,69) aA
	G1	475,87 (89,40) aB	300,64 (79,05) aA	395,53 (151,86) bAB
Thickness	G2	444,47 (63,78) aB	267,36 (52,17) aA	197,24 (33,77) aA
Posterior	G3	412,11 (92,93) aAB	467,15 (94,55) bB	337,35 (64,56) bA
	G1	0,51 (0,03) aB	0,50 (0,02) aB	0,44 (0,05) aA
Area	G2	0,55 0,05) aB	0,50 (0,03) aA	0,49 (0,04) bA
	G3	0,54 (0,02) aA	0,54 (0,03) aA	0,56 (0,03) cA

Lower case letters: comparison of groups (G1, G2, G3) fixed sacrifice moments.
Capital letters: comparison of moments (7,30,90 days) fixed groups.
Same letters mean no significant difference between data.

considered a major complication of cosmetic breast reconstruction.[9] There were 3 cases of implant deformity in Group 3 at 90 days postsurgery. This finding might be suggestive of pseudocapsule contracture.

The thickness of the anterior and posterior aspects of the implants did not significantly differ between groups and tended to be higher in the initial postoperative period in all groups when edema is higher and collagen is not organized. However, by 30 and 90 days the pseudocapsule around the implants is easily recognized. Pseudocapsule thickness and fibrosis can cause hardening and deformation of the implant.[3,10] The histological peri-implant reaction, observed mainly in Group 3 at 90 days postoperatively was characterized by an extended inflammatory reaction, including active neovascularization and edema resulting from the nonselective permeability of the numerous newly formed vessels. These signs may indicate an unstable scarring process in Group 3, even at 90 days postoperatively, suggesting that the tissue repair process was still active.[11]

Texturizing the surface of breast implants is considered an advancement because the pseudocapsular thickness and indices of capsular contracture are lower than in smooth implants over the long term.[3,5] However, the implant surface alone does not appear to influence the pseudocapsular thickness or contracture. Peri-implant fluid collects for a variety of reasons, including the degree of surgical trauma and increased bleeding due to systemic complications may also lead to a higher tendency for capsular contraction, favoring a prolonged inflammatory process.[3,5]

In the current study, histologic evaluation indicated a more intense inflammatory reaction in Group 3. However, there were very few statistically significant differences in the quantitative evaluation of the peri-implant reaction. Notably, the cell number measurements were highly variable necessitating nonparametric analysis.

The histologic evaluation indicated that the pseudocapsule in Group 3 was very different from the other groups mainly in the robust granulomatous reaction and the fragments of polyurethane foam that had been phagocytized by multinucleated giant cells. This aggressive reaction could have been a result of the polyurethane itself or due to any of the other substance adsorbed onto its surface, such as talc, inciting inflammatory cell phagocytosis, and a tendency for a chronic inflammatory reaction,[8,12,13] maintained for a longer time in Group 3.

Polyurethane-coated implants promote a disorganized collagen fiber architecture with a mutually neutralizing three-dimensional distribution of the contractile forces, thus hampering the formation of deforming contractures.[13] However, in the present study, some of the polyurethane-coated implants exhibited possible contracture on CT examination, a finding that warrants further investigation.

The scleral socket was preserved in all cases in all groups, highlighting the positive role of the cohesive silicone gel implants in volume replacement after evisceration.

Conclusion

Cohesive silicone gel implants resulted in a good tissue response, inducing a weak inflammatory reaction with no significant complications out to 90 days postoperatively. The outcome of this study indicates that textured implants (Group 2) resulted in the best outcomes including maintaining position and lower inflammation of the pseudocapsule. Further studies should investigate texture cohesive silicone gel implants to replace volume in the human anophthalmic cavity. Greater understanding of the interaction between the textured cohesive silicone gel implant and the external prosthesis is required.

Acknowledgments

This paper was presented as a poster at 2015 American Academy, Las Vegas, USA. This study was conducted at Faculdade de Medicina de Botucatu/King Khaled Eye Specialist Hospital.

Disclosure statement

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the article.

References

1. Rycroft PV. The use of silicone rubber as an implant following enucleation. *Proc R Soc Med.* 1965;13:736–738.
2. Son JH, Kim C-S, Yang JW. Comparison of experimental porous silicone implants and porous polyethylene implants. *Graef Arch Clin Exp Ophthalmol.* 2012;250:879–885. 10.1007/s00417-011-1902-7.
3. Collis N, Coleman D, Foo ITH, Sharpe DT. Ten-year review of a prospective randomized controlled trial of textured versus smooth subglandular silicone gel breast implants. *Plast Reconstr Surg.* 2000;106:786–791. doi:10.1097/00006534-200009020-00005.
4. Pompei S, Arelli F, Labardi L, et al. Breast reconstruction with polyurethane implants: preliminary report. *Eur J Plast Surg.* 2012;35:441–447. doi:10.1007/s00238-011-0612-z.
5. Wong CH, Samuel M, Tan BK, Song C. Capsular contracture in subglandular breast augmentation with textured versus smooth breast implants: a systematic review. *Plast Reconstr Surg.* 2006;118:1224–1236. doi:10.1097/01.prs.0000237013.50283.d2.
6. Schellini SA, Hoyama E, Padovani CR, Ferreira VLR, Roca R. Complicações com uso de esferas não integráveis e integráveis na reconstrução da cavidade

anoftálmica. *Arq Bras Oftalmol*. 2000;63:175–178. doi:10.1590/S0004-27492000000300002.
7. Kanamura MS, Padovani CR, Pereira EJ, Mamprim MJ, Schellini AS. Comparative study between soft and rigid silicon spheres in eviscerated cavity of rabbit. *Arq Bras Oftalmol*. 2012;75:197–201. doi:10.1590/S0004-27492012000300010.
8. Luke JL, Kalasinsky VF, Turnicky RP, Centeno JA, Johnson FB, Mullick FG. Pathological and biophysical findings associated with silicone breast implants: a study of capsular tissues from 86 cases. *Plast Recontr Surg*. 1997;100:1558–1565. doi:10.1097/00006534-199711000-00029.
9. Raposo-do-Amaral CM, Tiziani V, Trevisan MA, Pires CH, Palhares FB. Capsular contracture and silicone gel: experimental study. *Aesth Plast Surg*. 1992;16:261–264. doi:10.1007/BF00190074.
10. La Trenta GS. *Breast Augmentation. Aesthetic Plastic Surgery*. 2nd. Philadelphia, PA: WB Saunders; 1994.
11. Kumar V, Abbas AK, Fausto N, Aster JC. Tissue renew, regeneration and repair. In: Robbins SL, Cotran RS, Kumar V, et al., eds. *Robbins & Cotran. Pathologic Basis of Disease. 8th Ed*. Rio de Janeiro, Brazil: Elsevier; 2010.
12. Mendes PRS, Bins-Ely J, Lima EAS, Vasconcellos ZAA, Acampora AJ, Neves RE. Histological study on acute inflammatory reaction to polyurethane-coated silicone implants in rats. *Acta Cir Bras*. 2008;23:93–101. doi:10.1590/S0102-86502008000100015.
13. Berrino P, Galli A, Rainero ML, Santi PL. Long-lasting complications with the use of polyurethane covered breast implants. *Br J Plast Surg*. 1986;39:549–553. doi:10.1016/0007-1226(86)90133-5.