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# Experimental

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## Effect of Povidone Iodine on Silicone Gel Breast Implants In Vitro: Implications for Clinical Practice

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Irrigation of breast implants and breast implant pockets with various solutions, including povidone iodine, has been a common practice among plastic surgeons for many years. Recent reports of potential weakening of silicone tubing have led the Food and Drug Administration to pronounce any contact of povidone iodine with breast implants a contraindication. An in vitro experimental study was undertaken to assess the effect of povidone iodine on the physical properties of silicone breast implant shells. Identical specimens were obtained from the shells of silicone breast implants according to published standards. The specimens were randomly assigned to eight groups of five and incubated in various solutions of decreasing concentration of povidone iodine (10% to 0.01%), and a control group (0.9% saline) was used. The containers were stored in a warming cabinet at 37°C for 4 weeks. Testing of the specimens for tensile strength following 4 weeks of incubation showed no significant difference among any of the groups, including the control group. In addition, no correlation was shown between the concentration of the solution used and the tensile strength of the specimens. (*Plast. Reconstr. Surg.* 114: 706, 2004.)

It is common practice among plastic surgeons to irrigate breast implants or the pocket itself before implantation with various solutions including antibiotics, normal saline, and povidone iodine in an attempt to minimize the risks of infection and capsular contraction.<sup>1-11</sup>

This practice has been mainly guided by anecdotal reports and personal experience. Several reports have addressed the effectiveness of various solutions with regard to prevention of gross and subclinical infection leading to capsular contraction,<sup>3,4,6,10,11</sup> but no reports have been published assessing the effects of these

solutions on the physical properties of the implants themselves.

The only exception is a recent study that looked at the effect of povidone iodine on the silicone tubing used to fill saline inflatable breast implants.<sup>12</sup> Apparently it had been common practice among U.S.-based surgeons to irrigate the inside of the implants with povidone iodine. According to this report, the effect of the povidone iodine solutions on the silicone tubing was detrimental.

After this study, as well as reports from implant manufacturers in the United States, the Food and Drug Administration issued a labeling requirement to manufacturers that any contact of breast implants with povidone iodine is contraindicated.<sup>2,11-13</sup>

The problem, however, is that the majority of breast implants used in the United States (as a result of the recent silicone controversy) are saline-filled instead of gel-filled (as opposed to the ones used in Europe). The above-mentioned study<sup>12</sup> only tested the effect of povidone iodine on the silicone tubing used in these saline-filled implants. There have been no studies investigating the effect of povidone iodine on the implant shells themselves, despite the fact that the two elastomers are manufactured in a different way. The tubing elastomer is peroxide-catalyzed (free radical cured), whereas the implant elastomer is platinum-catalyzed (addition cured), resulting in different physical properties.<sup>14</sup> An experimental in vitro study was therefore designed to

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assess the effect of povidone iodine on the physical properties of the implant shells.

#### MATERIALS AND METHODS

Twelve textured silicone breast implant shells were obtained from McGhan Ltd. (Santa Barbara, Calif.) for testing. The implants were cut into identical dumbbell-shaped specimens at room temperature according to published standards<sup>15,16</sup>. A stainless steel hollow punch was manufactured in accordance with the provisions of the European Norms EN-12180<sup>15</sup> and NF-T46-002,<sup>16</sup> which describe the standards for testing silicone breast implants. The appropriate specimen size was identified as test-piece H2, as described in NF-T46-002<sup>16</sup> (Fig. 1). The size of the specimens was 12.5 × 75 mm in a dumbbell shape. A total of 45 specimens were cut.

The shells obtained had no connections and were made from one continuous piece of silicone elastomer. As a result all test pieces were identical.

The specimens were randomly assigned to eight groups of five (groups A, B, C, D, E, F, G, and H) and incubated in various solutions of povidone iodine (10% [Betadine solution neat], 5%, 2.5%, 1%, 0.5%, 0.25%, 0.1%, and 0.01% povidone iodine). There was one control group (group I, five specimens), in which the specimens were incubated in 0.9% saline solution (normal saline).

The containers were stored in a warming cabinet at 37°C to simulate the effect of implant insertion in the human body. The duration of the incubation was arbitrarily set to 4 weeks, as we thought that after this time any solution would have been absorbed.

After the 4-week incubation period, the specimens were collected and placed in sterile bags

with random numbers identifying the various specimens to us and sent to the LNE Laboratory in Paris for testing. The LNE Laboratory is the notified body of the European Union for implant testing. It should be noted that the relation of the numbering of the bags to the study groups had not been made known to the staff at the laboratory, so that they were blinded. The specimens were sent using a courier service with next-day delivery.

Testing was performed according to EN-12180<sup>15</sup> and NF-T-46-002.<sup>16</sup> The testing consisted of fixing the specimens one by one on a specially designed stretching apparatus and stretching them at a speed of 500 mm/minute until the specimen ruptured. Because of the design of the test pieces, they predictably rupture at their center, where they are mechanically weaker. Two parameters were measured at the breaking point: elongation at break (measured as percentage of elongation compared with the original size) and stress at break (measured in megapascals).

#### RESULTS

The results were collected and tabulated (Table I) for elongation at break and stress at break. The results for each parameter were analyzed using one-way analysis of variance to see whether there were any significant differences among the various groups. The results of analysis of variance testing for the two parameters are presented in Table II. The *p* values for elongation at break and stress at break were 0.55 and 0.52, respectively. Neither *p* value was significant.

Further analysis was performed using regression to study a possible association between the concentration of povidone iodine in the solu-

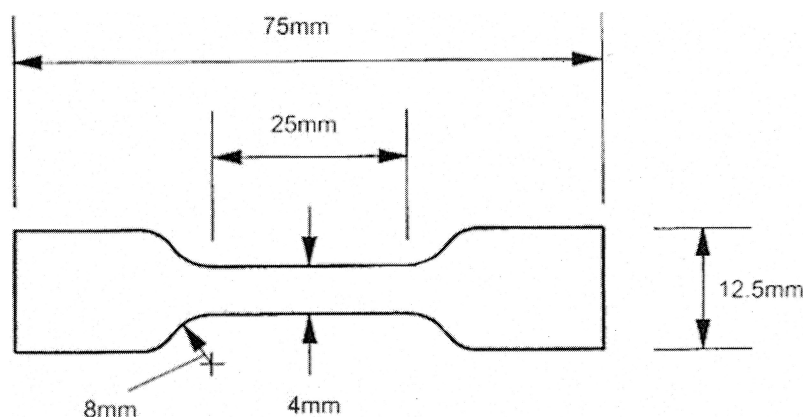


FIG. 1. H2 test piece.

TABLE I  
Results for Elongation at Break and Stress at Break

Group	Elongation at Break (%)	Stress at Break (MPa)
Group A	600	4.8
	600	5.4
	475	3.4
	625	5.4
	375	2.8
Group B	500	3.8
	500	3.5
	600	4.5
	485	2.7
	400	2.7
Group C	550	4.2
	650	4.6
	625	5.0
	525	3.8
	500	3.9
Group D	500	3.5
	525	4.1
	600	4.9
	200	2.3
	600	4.9
Group E	575	4.7
	550	4.2
	575	4.2
	675	5.0
	625	5.3
Group F	500	3.6
	550	4.5
	550	3.7
	525	3.9
	700	6.3
Group G	375	2.5
	500	3.4
	400	2.7
	600	5.2
	500	4.1
Group H	625	4.7
	425	2.9
	650	5.0
	500	3.7
	600	4.8
Group I	675	5.4
	650	4.9
	300	1.9
	425	2.7
	500	3.4

tion used and the parameters measured, namely, elongation at break and stress at break. The solution used for the control group (normal saline) was considered as having a concentration of 0. Because we chose the concentration levels, the x-regression model was used for the analysis, testing for zero slope and not rejecting this hypothesis. The results are presented in Figures 2 and 3. The regression equations for elongation at break and stress at break were as follows:

$$\text{Elongation} = 534.9 - 0.875 * \text{Concentration}$$

with a *p* value (for slope) of 0.86 and

$$\text{Stress} = 4.04 + 0.00868 * \text{Concentration}$$

with a *p* value (for slope) of 0.85.

Neither result was significant.

Statistical analysis consistently showed that there was no association between the solution used (normal saline or povidone iodine solution) and the tensile strength of the specimens. Power analysis showed that thousands of specimens would be needed in each group to give 80 percent power for detecting the observed regression slopes as significant at the 5 percent level. To give 80 percent power of detecting a difference of 25 in mean elongation in an analysis of variance (observed difference in means between groups A and I), 1100 specimens would be needed in each group, based on a SD of 150. In other words the number of specimens needed to demonstrate a possible difference would be at least 9900, meaning practically that there is no association present.

#### DISCUSSION

The practice of breast pocket or even breast implant irrigation before breast implant insertion has been a common occurrence among plastic surgeons for years, driven mainly by personal experience and anecdotal reports.

Courtiss et al.<sup>1</sup> were the first to link an infectious process to the development of capsular contracture, and soon afterward Burkhardt et al.<sup>3,4</sup> hypothesized the subclinical infection theory as a cause for capsular contracture. Burkhardt et al.<sup>3-5</sup> were the first to show that irrigation with antibacterial solutions reduced the incidence of capsular contracture by as much as 85 percent.<sup>4</sup>

In the years that followed, povidone iodine became one of the main solutions used for this purpose,<sup>6,10,11</sup> until the spring of 2000, when the Food and Drug Administration, following reports from implant manufacturers and an independent study by Becker,<sup>12</sup> issued a labeling requirement to the manufacturers, stating that any contact of breast implants with povidone iodine was a contraindication.<sup>2,11,13</sup>

The problem with this restriction on the use of povidone iodine was that it was based on studies performed on saline-inflatable breast implants and concerned mainly with the effect of povidone iodine on the silicone tubing used to fill these implants. In Europe, the bulk of breast implants used are filled with silicone gel, and because the tubing is not made of the

TABLE II  
One-Way Analysis of Variance for Elongation at Break and Stress at Break

	SS	df	MS	F	p	F crit
Elongation at break						
Between groups	75540	8	9442.5	0.864566	0.554559	2.208516037
Within groups	393180	36	10921.67	—	—	—
Stress at break						
Between groups	7.282831	8	0.910354	0.909149	0.519869	2.208516
Within groups	36.04771	36	1.001325	—	—	—

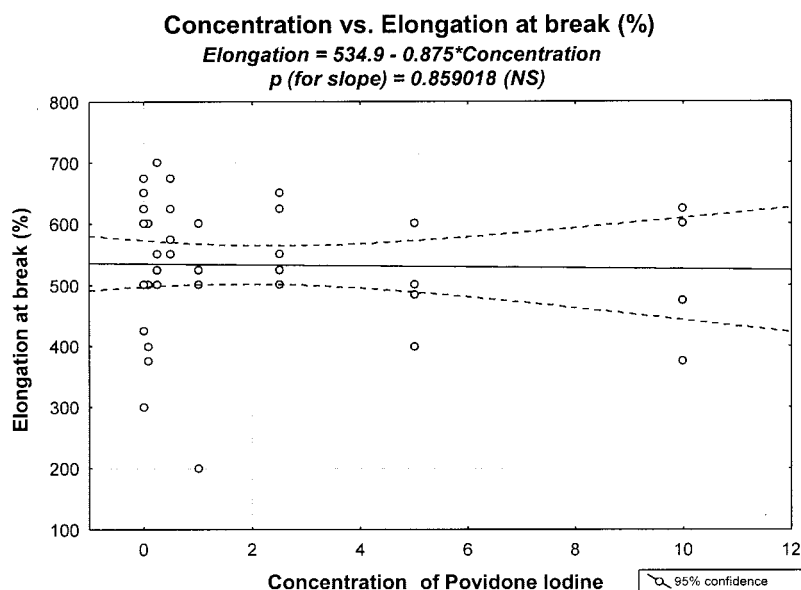


FIG. 2. Regression analysis for elongation at break.

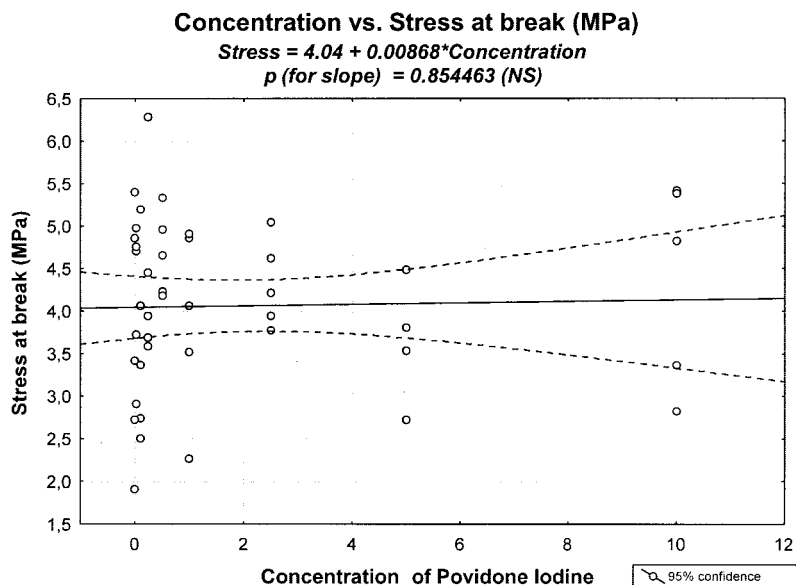


FIG. 3. Regression analysis for stress at break.

same silicone elastomer as the shells,<sup>14</sup> the findings of the aforementioned studies do not necessarily apply.

We therefore decided to conduct an in vitro experimental study to test the effects of povidone iodine on the outer shell of silicone gel

implants. Shells only (and not whole implants) were used because we wanted to study the effect of povidone iodine on the outer shell of the implants, which comes in contact with the solution in clinical practice, and also because removing the gel from the inside of the shells for testing would require the use of chemicals<sup>16</sup> that might alter the physical properties of the specimens.

Our results showed conclusively that there was no significant difference in the tensile strength of the specimens among any of the groups, including the control group. In addition, there was no correlation between the concentration of the solution used and the tensile strength of the specimens.

In conclusion, we submit that the use of povidone iodine for breast pocket irrigation or external irrigation of the silicone gel-filled implants themselves has no effect on the tensile strength of the implant shells.

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#### REFERENCES

1. Courtiss, E. H., Goldwyn, R. M., and Anastasi, G. W. The fate of breast implants with infections around them. *Plast. Reconstr. Surg.* 63: 812, 1979.
2. Brandon, H. J., Young, V. L., Jerina K. L., et al. Mechanical analysis of explanted saline-filled breast implants exposed to Betadine pocket irrigation. *Aesthetic Surg. J.* 22: 438, 2002.
3. Burkhardt, B. R., Fried, M., Schnur, P. L., and Tofield, J. J. Capsules, infection and intraluminal antibiotics. *Plast. Reconstr. Surg.* 68: 43, 1981.
4. Burkhardt, B. R., Bempsey, P. D., Schnur, P. L., and Tofield, J. J. Capsular contracture: A prospective study of the effect of local antibacterial agents. *Plast. Reconstr. Surg.* 77: 919, 1986.
5. Virden, C. P., Dobke, M. K., Stein, P., Parsons, C. L., and Frank, D. H. Subclinical infection of the silicone breast implant surface as a possible cause of capsular contracture. *Aesthetic Plast. Surg.* 16: 173, 1992.
6. Burkhardt, B. R., and Eades, E. The effect of Biocell texturing and povidone-iodine irrigation on capsular contracture around saline-inflatable breast implants. *Plast. Reconstr. Surg.* 96: 1317, 1995.
7. Dobke, M. K., Svahn, J. K., Vastine, V. L., et al. Characterization of microbial presence at the surface of silicone mammary implants. *Ann. Plast. Surg.* 34: 563, 1995.
8. Becker, H., and Springer, R. Prevention of capsular contracture. *Plast. Reconstr. Surg.* 103: 1766, 1999.
9. Burkhardt, B. R. Prevention of capsular contracture (Discussion). *Plast. Reconstr. Surg.* 103: 1769, 1999.
10. Adams, W. P., Jr., Conner, W. C., Barton, F. E., Jr., and Rohrich, R. J. Optimizing breast pocket irrigation: An in vitro experimental study and clinical implications. *Plast. Reconstr. Surg.* 105: 334, 2000.
11. Adams, W. P., Jr., Conner, W. C., Barton, F. E., Jr., and Rohrich, R. J. Optimizing breast-pocket irrigation: The post-Betadine era. *Plast. Reconstr. Surg.* 107: 1596, 2001.
12. Becker, H. The effect of Betadine on silicone implants. *Plast. Reconstr. Surg.* 105: 1570, 2000.
13. Food and Drug Administration. Personal communication, October 2001.
14. Inamed Aesthetics (McGhan) Research and Development. Personal communication, May 2003.
15. European Committee for Standardization. European Standard EN-12180: Non-active surgical implants—Body contouring implants—Specific requirements for mammary implants. October 1999. Available from the European Committee for Standardization (CEN) at <http://www.cenorm.be/cenorm/index.htm>.
16. AFNOR. French Norm NF-T-46-002: Vulcanized or thermoplastic rubber: Tensile strength test. September 1988. Available from the European Committee for Standardization (CEN) at <http://www.cenorm.be/cenorm/index.htm>.