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Sub-muscular plane for augmentation mammoplasty patients increases silicone gel implant rupture rate

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Abstract *Background:* Breast augmentation is one of the most common aesthetic procedures performed worldwide. One of the worst associated complications is implant rupture, a topic that will be addressed in the present study. The risk of developing silicone gel breast implant rupture following breast augmentation is associated with multiple factors, including: older generation implant, increased implant age, implant type, specific manufacturer, severe capsular contracture (Baker grade III or IV), and the presence of local symptoms. We hypothesize that the plane of the implant placement may also play a role in the development of implant rupture due to differences in opposing forces upon the implant between submuscular and subglandular planes.
Objectives: To assess the effect of potential risk factors on breast prosthesis rupture rate, focusing on implant pocket selection, capsular contracture and implant volume.
Methods: A retrospective cohort study was performed on patients with silicone breast implants in either subglandular or submuscular plane, who underwent an elective breast implant exchange, with or without mastopexy, between January 2012 and June 2017. Data collected included patient's age, implant age, implant pocket, implant volume, capsular contracture grade, and implant status (ruptured or intact).
Results: Data was collected on 362 women (700 breasts). A total of 284 women (542 breasts) met the inclusion criteria. The average age of the subjects was 43.4 ± 10.4 years. Average implant age during exchange was 10 ± 6.1. There was no difference between the characteristics of the submuscular group and the subglandular group, except from patient age. In a univariant analysis, patient's age (46.4 vs. 41.8, $p < 0.001$) and implant age (12.2 vs. 8.92 years,

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$p < 0.001$) were associated with significantly higher rupture rate. Among ruptured implants, the relative proportion of submuscular to subglandular implants was 64%, compared to 48% among non-ruptured implants ($p < 0.0001$). When controlling for potential confounders, submuscular pocket (OR = 0.1835, CI95% 1.25–2.69, $p = 0.002$) as well as implant size (OR = 1.004, CI95% 1.001–1.007, $p = 0.005$) were found to be a risk factor for implant rupture.

Conclusion: A sub-muscular implant pocket was identified as a significant risk factor for implant rupture. The prevailing theory that larger size implant carries an increased risk of complications, is also reinforced in this study. Large prospective studies are needed to further clarify risk factors for implant rupture.

Introduction

Silicone breast implants have been used for breast augmentation for over five decades.[2,16] Rupture and silicone leakage are the most devastating complications associated with breast implants.[3,15] One of the important goals in the design and manufacturing development process of silicone breast implants over the years has been to reduce rupture rate. However, reported rupture rates of modern implants are still relatively high, and have reached as much as 24.3% over a 10-year period.[6,712-14]

Risk factors for rupture have already been investigated and reported on in the literature.[5] Some of the more prevailing risk factors include: older generation implant, increased implant age, implant type, specific manufacturer, severe capsular contracture (Baker grade III or IV), and the presence of local symptoms.[4,5]

The effect of pocket selection on implant rupture rate was evaluated in several studies, However, the data have been ambiguous, and clear conclusions could not be drawn.[4,5,15-18] Moreover, these studies had various weaknesses with regard to the characteristics of the implants studied. A few studies evaluated 1st and 2nd generation implants which are not manufactured anymore.[4,5] Other studies were conducted on populations with Poly Implant Prosthèse (PIP) implants which contained non-medical grade silicone and thus, are also no longer manufactured.[16-18]

The aim of the current study was to assess if the plane of pocket selection affects the rupture rate of the implants.

Materials and methods

Data was collected from electronic and hard copy medical records of patients treated in the Department of Plastic Surgery, "Assaf Harofeh" Medical Center, Israel by six attending surgeons. Patients who underwent an elective breast implant exchange, with or without mastopexy, between January 2012 and June 2017 were included in the study. The study population was divided into two groups: breast implants in the submuscular pocket and those in a subglandular pocket.

Indications for surgery included: medical conditions such as pain or discomfort, capsular contracture documented by the surgeon, or implant rupture documented by mammography, ultrasound or magnetic resonance imaging (MRI). Some additional indications for surgery were: the desire of the patient to exchange the implants secondary to aesthetic deformities such as: ptosis, asymmetry, or implant displacement; and the desire for larger or smaller implants. Preventive indications for surgery included: implant age greater than 15 years and recall due to prior implantation of Poly Implant Prothèse (PIP) breast implants (according to the guidelines of the Israeli Ministry of Health).

Exclusion criteria included: patients with saline implants and patients who underwent urgent implant exchange secondary to infection, hematoma or implant extrusion. Patients who had a history of breast malignancy were also excluded, as well as patients who had a pre-operative clinical infection or had received a complete course of antibiotics in the 6 months preceding surgery.

The data collected included patient parameters: age, relevant medical history (e.g. diabetes or steroid use), smoking history; surgical parameters: operation time, type of operation (augmentation alone or with mastopexy), grade of capsular contracture (graded I to IV according to the Baker classification scale), capsular manipulation during operation (capsulotomy, capsulectomy or none); implant parameters: implant age (time from primary breast augmentation), both pre and postoperative implant positioning (retroglandular, retropectoral), both pre and postoperative implant size and difference (measured in cubic centimeters).

Surgical technique

The surgical procedure was performed under general anesthesia. The surgical approach employed an inframammary incision or periareolar incision for implant exchange only, and a periareolar incision with additional vertical incision for implant exchange with mastopexy. Intraoperatively, the surgeon either preserved the preoperative pocket or created a neosub-glandular or sub-muscular pocket as needed. In case the skin envelope was thin, a new retro-pectoral pocket was created in order to reduce the potential of future rippling. Capsular manipulation included capsulotomy, capsulectomy or no intervention. All new prostheses inserted were of the silicone gel-coated type, with a textured surface and a round shape. Silicone implant brands used were Mentor (Mentor Corporation, Santa Barbara, CA, USA), Silimed (Sientra, Santa Barbara, CA, USA) or Allergan (Allergan Inc, Irvine, California, USA).

Table 1 Patient's and implant characteristics of implant pocket.

	Sub-muscular (N = 289)	Sub-glandular (N = 253)	p value
Patient age (years, SD)	44.63 (10.22)	41.94 (10.36)	0.003
Implant age (years, SD)	10.50 (5.84)	9.51 (6.37)	0.060
Implant side -Lt	0.49 (0.50)	0.49 (0.50)	0.959
Implant size (cc. SD)	325.9 (65.9)	324.2 (82.3)	0.790
Capsular contracture	0.235 (0.433)	0.233 (0.424)	0.955

Table 2 Risk factors for implant rupture (univariant analysis).

	No Rupture (N = 357)	Rupture (N = 185)	p value
Patient age (years, SD)	41.8 (10.50)	46.4 (9.40)	< 0.001
Implant age (years, SD)	8.92 (6.10)	12.2 (5.52)	< 0.001
Implant side -Lt	0.50 (0.50)	0.47 (0.50)	0.532
Sub-muscular implant pocket	0.48 (0.50)	0.64 (0.48)	< 0.0001
Implant size (cc. SD)	322.9 (73.2)	329.3 (75.3)	0.342
Severe capsular contracture	0.22 (0.42)	0.25 (0.44)	0.440

Diagnosis of implant rupture required one of two inclusive criteria: implants with gel present diffusely on the surface of the implant shell or visualization of a tear in the implant shell.

Statistical analysis

Univariant and Multivariate analysis was performed with multiple logistic regression analyses for all relevant variables. All p values less than 0.05 were considered significant.

Statistical analysis was conducted using the Stata software v.15 (StataCop LLC, USA). Continuous variables were presented as averages and standard deviations and were compared using the independent Student's t-test. Differences in categorical variables were calculated using Pearson's $\chi 2$ test. Multivariate analysis was performed using a logistic regression model since the dependent variable was categorical and to assess independent predictors of outcome variables and control for potential confounders.

Sample size calculation
Sample size was calculated using the G*Power software V3.1 (Dusseldorf, Germany). Implant age difference was used as the variable for sample size calculation. Based on a minimal clinical difference of 2 years, assuming standard deviation in both groups of 6.5 years, and a group ratio of 1:2, alpha was 0.05, and power of 90%. Sample size required was 176 for rupture group and 352 for the non-rupture group.

Results

Data was collected from 362 women (700 breasts). A total of 284 women (542 breasts) met the inclusion criteria. The average age of the subjects was 43.4 ± 10.4 years. Average implant age at the exchange procedure was 10 ± 6.1. There was no difference between the characteristics of the submuscular group and the subglandular group, except from patient age (Table 1).

In a univariant analysis, patient's age (46.4 vs. 41.8, $p < 0.001$) and implant age (12.2 vs. 8.92 years, $p < 0.001$) were associated with significantly higher rupture rate (see Table 2). Among ruptured implants, the relative proportion of submuscular to subglandular implants was 64%, compared to 48% among non-ruptured implants. This was statistically significant as well ($p < 0.0001$). When controlling for potential confounders, submuscular pocket (OR = 0.1835, CI95% 1.25–2.69, $p = 0.002$).as well as implant size (OR = 1.004, CI95% 1.001–1.007, $p = 0.005$) were found to be a risk factor for implant rupture (see Table 3).

Discussion

With the advent of the first modern breast augmentation procedure in 1962,[8] a new era began. Since then, breast augmentation has become one of the most popular procedures performed in the field of aesthetic plastic surgery.[9] The rise in popularity of augmentation mammoplasty has been paralleled by continuing efforts to improve the technology and standards of implant manufacturing, in order to create a safe and a long-lasting implant.[10,11] However, numerous implants have failed to completely embody the ideal specification and fulfill all requirements. Much effort has been dedicated over the years to reduce implant related complications, such as implant rupture and capsular contracture. Moreover, silicone lymphadenopathy is constantly being propagated by implant manufacturers. Currently, large scale cohort studies performed by breast implant manufacturers have demonstrated implant rupture rates at a range of 9–24.3%, 10 years following implantation.[12-14]

The decision of breast implant pocket (Subglandular vs. Submuscular) is crucial for the achievement of good aesthetic results during breast augmentation. Submuscular implant placement has the advantages of superior upper pole tissue coverage with the reduction of ripples,[20] better tissue visualization by mammography, and a slightly decreased incidence of capsular contracture.[19] Disadvantages of the procedure type include greater discomfort and potential breast distortion with pectoralis contraction. Advantages of subglandular pocket are ease of dissection and less pain. It is a reasonable choice for large pendulous breasts or very low breasts that have little breast-muscle overlap.

In the current study, the effect of pocket selection on implant rupture was evaluated. A submuscular implant pocket was identified as a risk factor for implant rupture. We

Table 3 Risk factors for implant rupture (multivariant analysis).

Rupture	Odds ratio	Std. Err.	Z	P > |z|	95% Conf. interval	
Age	1.021	0.011	1.94	0.052	0.999	1.043
Breast_side Lt	0.872	0.168	−0.71	0.479	0.597	1.273
Implant_years	1.093	0.021	4.53	0.001	1.052	1.136
Submuscular pocket	1.835	0.358	3.09	0.002	1.250	2.694
Implant_size	1.004	0.0014	2.83	0.005	1.001	1.007
Severe capsular contracture	1.050	0.236	0.22	0.828	0.675	1.631

Table 4 Summary of literature - implant pocket and rupture.

	No. of implants	Observation period (Years)	Rupture diagnosis	Pocket with higher rupture	Comment
Feng and Amini (1999)[5]	1619	11	Surgery	Subglandular	Aesthetic and reconstructive patients
Brown et al. (2000)[15]	687	10.8	MRI	Submuscular	
Collis and Sharpe[4]	231	1-28	Surgery	submuscular	Aesthetic and reconstructive patients
Maijers and Niessen (2012)[16]	224	10.2	MRI	Subglandular – Not statistically significant	PIP implants
Quaba and Quaba (2013)[17]	676	7.8	Surgery	Submuscular	PIP implants
Khan (2013)[18]	NA (65 patients)	7.2	Surgery	Submuscular	PIP implants
Present study (2017)	542	10	Surgery	Submuscular	

speculate that the increased strain over the upper pole of the implant compared to subglandular placement, and the shearing forces exerted by the muscle may contribute to a higher rupture rate. A review of the literature revealed six high quality studies that evaluated the effect of implant pocket selection on implant rupture (see Table 4).[4,5,15-18] In two of them, rupture was diagnosed by MRI[15,16] and in four, it was diagnosed surgically.[4,5,17,18] Similar to our results, a higher rupture rate was found in subpectoral placement of the implant as compared to subglandular placement in 4 out of 6 studies.[4,15,17,18] In one study, the rupture rate associated with subpectoral placement was almost twice that of those placed subglandularly.[17] In another study, which was conducted based on MRI findings, no significant correlation between rupture rate and implant location was found.[16] Interestingly, in one large study conducted by Feng et al. the subglandular approach was actually shown to increase implant rupture rate.[5] The difference in these results from those found in our study could be explained by a different study population. Our study population consisted only of aesthetic patients who underwent breast augmentation. In comparison, almost one third of Feng's study population had breast implants for reconstructive purposes.[5] Moreover, the vast majority of Feng's study population received 1st or 2nd generation implants which have very different characteristics to the ones we studied. These older generation implants are characterized by a thinner shell and a less viscous, more fluid like gel. The implants reviewed in our study were mostly 4th and 5th generation implants, which possess a thicker shell and a more cohesive gel filling. In our opinion, modern implants respond differently to pocket location and to the shearing forces exerted by the muscle. Only in our study, rupture rate was analyzed surgically among aesthetic patients with modern implants, which were not

PIP type. We, therefore, propose that this manuscript represents more reliable results for patients with modern implants.

After controlling the various confounders, we also found that implant size is correlated with rupture rate. To the best of our knowledge, this has not been documented before. We theorize that larger implants, especially when placed in breasts with smaller natural dimensions, cannot maintain their shape effectively for a long period of time and the shell wall collapses inward. These areas of folding in the envelope are prone to rupture due to shearing forces. The issue with this theory is the absence of pre-implant breast dimensions, which could have reinforced our assumptions in cases of greater implant diameter relative to breast width.

According to the literature, the correlation between capsular contracture and implant rupture is not clear. Several studies found no association between capsular contracture and implant rupture,[1,4,16] whereas others did find an association[5]. However, the cumulative data was collected on PIP implants and 1st and 2nd generation implants which are no longer manufactured today. One may speculate that implant rupture induces an inflammatory reaction leading to a dense capsular formation. However, the correlation may be bi-directional, as the stiff capsule may increase the strain over the implant with a consequent rupture. In the present study, no association between capsular contracture and implant rupture found.

Several limitations of the present study should be addressed. The retrospective nature of the study may be associated with selection bias of patients. Patient's age was not similar among the submuscular/subglandular groups. In our opinion, age has no direct impact on implant rupture. The older age of patients with ruptured implants probably

reflects the longer time elapsed from primary augmentation which affects rupture rates. Our theory that higher implant rupture rate is related to recurrent folding of the envelope should be reinforced by measuring pre-implant breast dimensions. This parameter was not collected in the present study.

Conclusion

Insertion of a breast implant under the pectoralis major muscle has become a preferred method for breast augmentation in the vast majority of cases. This pocket selection may be associated with increased implant rupture rate. Furthermore, the prevailing theory, among plastic surgeons that bigger implants are associated with more side effects, is also reinforced in this study. Large prospective studies are needed to further clarify risk factors for implant rupture.

The authors have nothing to disclose.

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