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Anatomical Breast Implant Assessment Using Ultrasound: A Case Series from the International Breast Implant Check Clinic

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Background: Breast augmentation with anatomic implants can achieve a natural look, but over time, implant-related complications can occur. This includes a risk of potential rotation, which can cause a change in breast shape. Reported rates of rotation vary widely (0%–42%). Implant rotation is often detected by physical examination only or as a perioperative finding. Change in breast shape after augmentation requires clinical evaluation. In-office ultrasound allows for detailed assessment of implants for rotation and other complications.

Methods: Women with anatomical breast implants seeking follow-up at the International Breast Implant Check Clinic in Stockholm, Sweden, from April 2020 to July 2022 were included in the study. Using a standardized protocol, subjective symptoms were recorded, and a physical examination followed by an ultrasound assessment was performed by a single board-certified plastic surgeon (M.J.) trained in implant assessment via ultrasound. Rotation was defined as an implant rotated past 30 degrees off the breast midline at 6 o'clock.

Results: The study included 308 women (mean age 40.1, range 20-78) with bilateral anatomical implants. Overall, 40 women (13.0%) reported a change in breast shape; 35 had one or more implant-related complications, including five with rotation on ultrasound. Of the 308 women, 11 (3.6%) had rotations upon physical examination, and an additional 10 cases were identified using ultrasound.

Conclusions: Rotation is a potential complication of anatomical breast implants. However, in this study, change in breast shape was more commonly caused by other implant-related complications. Ultrasound is a valuable tool in evaluating causes of change in breast shape. *(Plast Reconstr Surg Glob Open 2023; 11:e5469; doi: 10.1097/GOX.0000000000005469; Published online 18 December 2023.)*

INTRODUCTION

There have been many advancements in breast implant technology since the first use of silicone implants in the 1960s. Both round and anatomically shaped implants are available today, each having different advantages and disadvantages.[1–3] Using anatomical breast implants for breast augmentation or reconstruction has been shown to provide women with a natural-looking breast shape and high patient satisfaction.[1,4–9]

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Implant rotation is a well-known potential complication with anatomical implants and has the potential to significantly alter breast shape, sometimes resulting in deformity.[7,10,11] Reported rates of anatomical implant rotation vary widely in the current literature. Published rates of rotation range from 0% to 42%, with most researchers reporting rotations in less than 10% of women.[4,6–8,10–14] Some of these studies evaluated a relatively small number of women or only assessed implant rotation visible on clinical examination within a short period of time after surgery.[3,5–8,11] Several large, long-term studies did not report the rate of rotation, only the rate of malposition of all types.[4,15–17] Other complications commonly seen with breast implants include seroma, capsular contracture, waterfall deformity, bottoming out,

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double bubble, animation deformity, rippling, and implant rupture.[4–6,10,17,18]

Anatomically shaped breast implants are mostly designed with a textured surface that provides implant stability, preventing rotation and other types of malpositioning.[19] Allergan Natrelle Style 410 breast implants and Eurosilicone Cristalline salt-loss texturing technology implants have a macrotextured surface that allows the capsule to grow into the surface pores, stabilizing the implant.[16,20,21] Mentor Contour Profile Gel (CPG) implants have a Siltex imprinted surface that increases surface area and friction between the implant and capsule, preventing movement of the implant.[20–22] POLYtxt, the Polytech standard shell texture, has a rough open cell structure, and Polytech Mesmo a microtextured surface to allow tissue adherence.[17] The only smooth anatomical implant on the market is Motiva Anatomical TrueFixation. This implant comes with fixation tabs to avoid rotation. Allergan 410 implants have two or three round raised silicone projections located on the anterior and three on the posterior surfaces, and Mentor CPG implants have an ovoid raised silicone ridge located on the anterior and posterior surfaces used for intraoperative orientation of the implant (Fig. 1). Markers on both of these styles of implant can be visualized using ultrasound to determine implant position, as shown by Sieber et al.[8] Eurosilicone, Polytech, and Motiva anatomical implants have radiopaque lines and dots that act as guides to achieve proper orientation during placement and allow for X-ray and ultrasound visibility during postoperative follow-ups.

In 2006, the United States Food and Drug Administration (FDA) issued a recommendation for periodic screening of patients with silicone-filled implants to assess potential ruptures and recommends using magnetic resonance imaging (MRI) in asymptomatic patients to assess implants at 5–6 years post implantation and every 2–3 years thereafter.[23] However, MRI can be an inconvenience for patients, is not available for this indication in many countries, and is significantly more expensive than ultrasound. Research indicates that only 6% of patients follow these FDA recommendations.[24] Due to the need for repeated imaging studies throughout the life of the implant, MRI becomes impractical.

Takeaways

Question: Is ultrasound a valuable tool in evaluating breast implant related complications? Is implant rotation of anatomical implants a frequent cause of change of breast shape?

Findings: Ultrasound is a valuable tool in evaluating causes of change in breast shape. Change in breast shape was commonly caused by implant-related complications. The incidence of implant rotation was low.

Meaning: Ultrasound is an efficient and easy method for assessing change in breast shape caused by implant-related complications and is very useful when physical examination findings are inconclusive.

In-office ultrasound has the benefits of low cost, ease of use, convenience, and direct results for the patient and treating physician. In 2019, the FDA revised its recommendations to include ultrasound as an acceptable alternative to MRI for screening while still recommending MRI for symptomatic patients or suspected ruptures.[23]

Ultrasound, specifically high-resolution ultrasound (HRUS), has emerged as a powerful tool for in-office assessment of breasts and implants following surgery.[18,25–30] HRUS can have the same sensitivity and specificity as MRI for identifying implant-related complications, including seroma, capsular contraction, implant rupture, and rotation.[25,26] Research shows that HRUS performed in-office by a properly trained surgeon can have the same diagnostic accuracy as a radiologist-read ultrasound or surgical exploration.[25,26] Standard ultrasound has proven to be as useful as HRUS or MRI for postoperative assessment of breast implants.[12,29] The sensitivity and specificity of standard ultrasound for detecting intracapsular and extracapsular implant rupture is comparable or superior to MRI in recent studies.[31,32]

Study Aims

The primary aim of this study was to assess the rate of implant-related complications related to a change in breast shape detected clinically and/or with ultrasound.

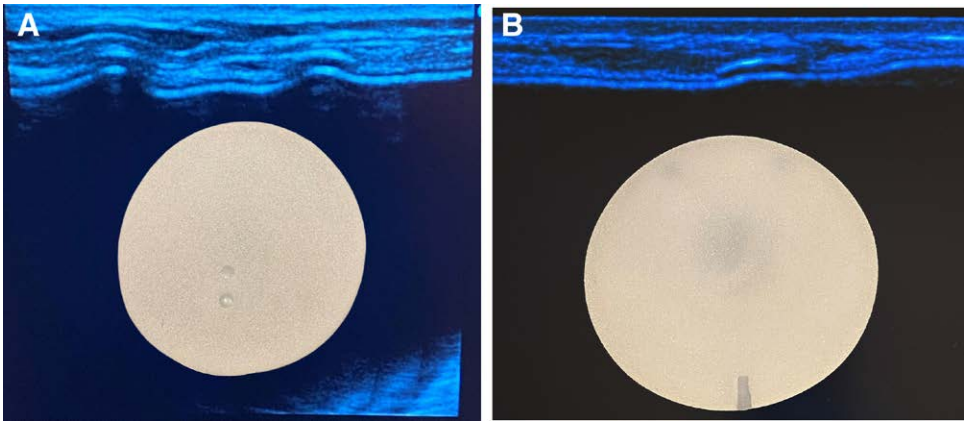

Fig. 1. A, Silicone projection on Allergan's 410 gel implant as seen on ultrasound. B, Silicone projection on Mentor CPG gel implant as seen on ultrasound.

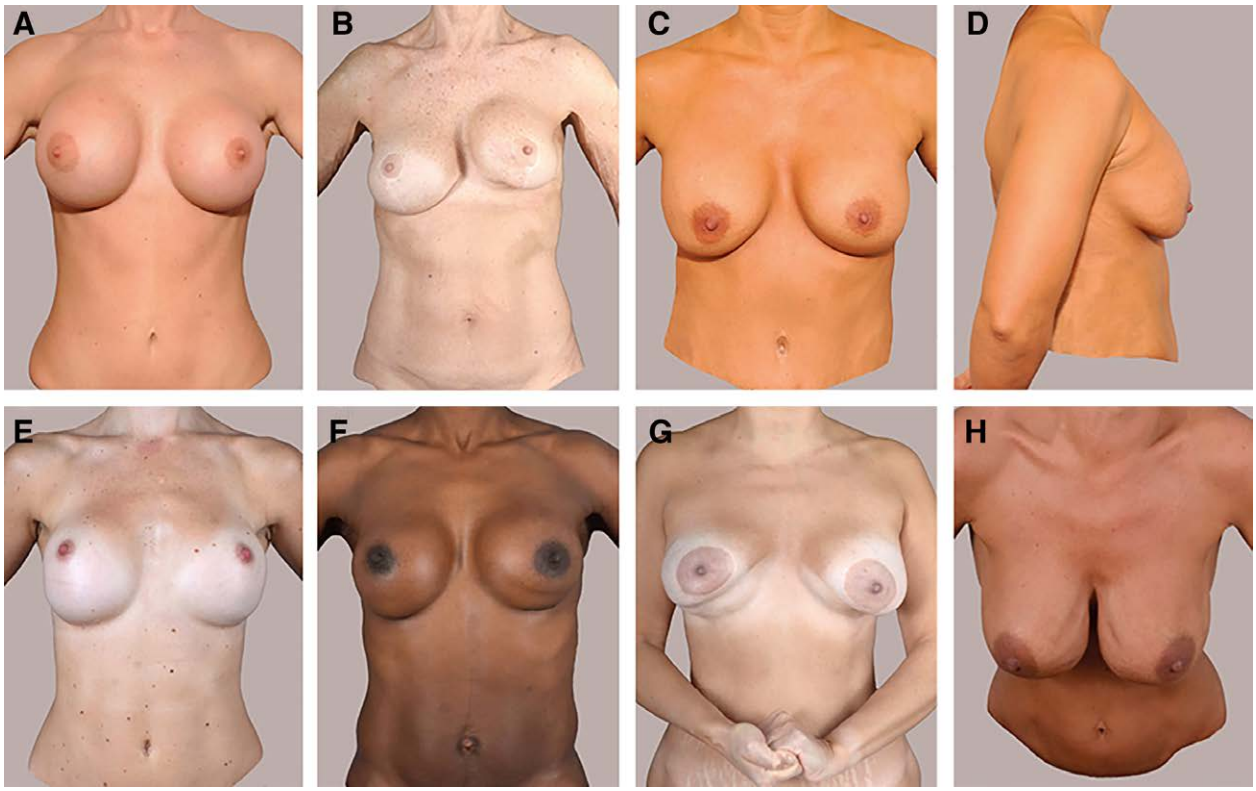

Fig. 2. Complications documented during physical examination: A, late onset seroma, right breast; B, capsular contracture, Baker grade IV, left breast; C, bilateral waterfall deformity; D, bilateral waterfall deformity; E, bilateral bottoming out; F, left sided double bubble deformity; G, bilateral animation deformity; H, bilateral rippling.

The secondary aim of this study was to assess the rate of rotation of anatomical implants and its relation to a clinically significant change of breast shape using physical examination and in-office ultrasound.

METHODS

This study was designed as a retrospective case series including women seen at the International Breast Implant Check Clinic (IBICC) of Victoriakliniken City in Stockholm, Sweden. Only women who had anatomic implants were included in the study. Patients, regardless of previous site of surgery, can access the clinic without the need for a referral. At the IBICC, their breasts are examined and assessed by a board-certified plastic surgeon with expertise in breast health. The clinical assessment includes a thorough breast and implant history, collection of any operative or implant data, and a physical examination of the breast/axilla, followed by an ultrasound examination. All subject's demographic information, patient-reported symptoms (lumps, change in breast shape, swelling), physical examination findings, implant details, and year of surgery were collected from the patient's records. Each subject underwent a physical examination by the same board-certified plastic surgeon (M.J.), who was trained in implant-related complications detectable via ultrasound before the start of the study. According to the IBICC protocol, the following implant-related complications causing change of breast shape were assessed during physical examination: seroma (sudden breast size change that leads to asymmetry); capsular contracture (defined as Baker grade III–IV); waterfall deformity (a sliding ptosis of parenchymal breast tissue over an implant); bottoming out (breast implant displacement where the implant either drops below the inframammary fold scar or stretches out the lower pole, leading to an obvious high riding nipple); double bubble (a crease that has developed across the lower part of the augmented breast creating two distinct breast mounds); animation deformity (change in shape of the augmented breast or distortion during contraction of the major pectoralis muscle); rippling (folds in breast implants that become visible on the breast skin); implant rupture (missing implant resistance or regaining of implant shape upon physical examination); and implant rotation (visible change of breast shape, most probably caused by implant rotation)[15,33–37] (Figs. 2 and 3). (**See appendix, Supplemental Digital Content 1,** which displays the IBICC protocol. **http://links.lww.com/PRSGO/C922**.)

The physical examination was followed by an ultrasound assessment using a Sonosite SII portable ultrasound machine (Fujifilm Sonosite Inc., Bothell, Wa.) with a 9-cm linear transducer probe. The following implant-related complications were recorded: seroma (visible fluid collection around the implant); capsular contracture (deformation of the implant, increased number of radial folds, and

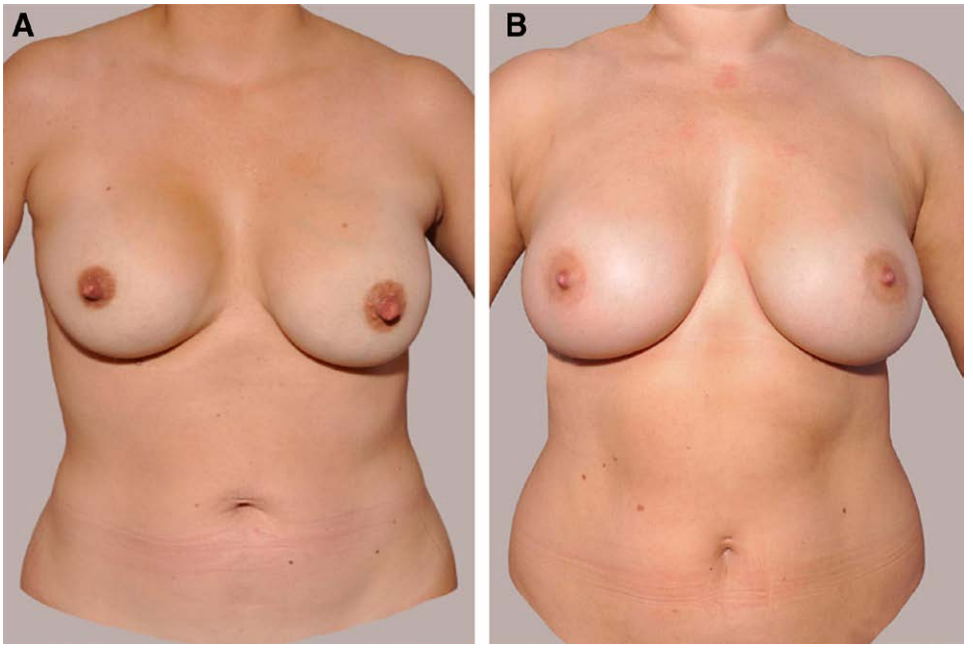

Fig. 3. A, Visible implant rotation, left breast. B, Invisible implant rotation, right breast.

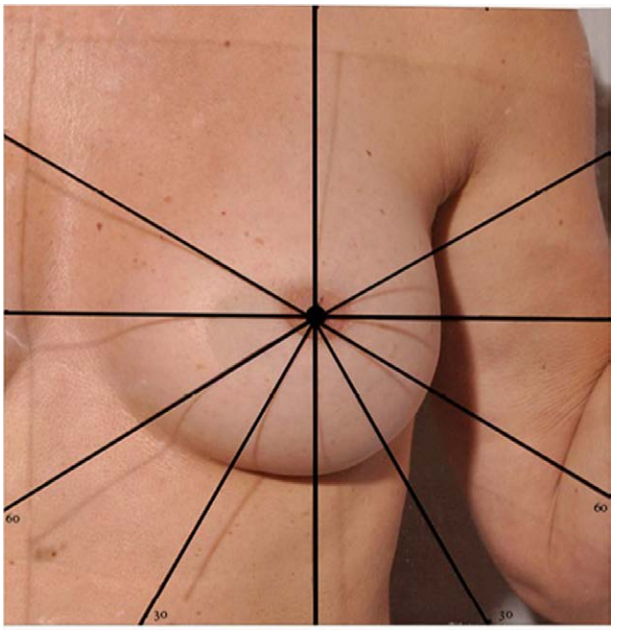

Fig. 4. Template used in conjunction with ultrasound to determine implant rotation.

thickening of the fibrous capsule); rupture ("snowstorm" appearance of an extracapsular rupture or "stepladder" sign of an intracapsular rupture); and rotation (any implant rotated more than 30 degrees from midline—outside the 5–7 o'clock position), as previously described by Sieber et al (Fig. 4). [**See figure, Supplemental Digital Content 2,** which displays (A) ultrasound image of a seroma demonstrating anechoic periprosthetic fluid, (B) ultrasound image of capsular contracture demonstrating multiple folds in the implant shell, and (C) ultrasound image of an intracapsular implant rupture. **http://links.lww.com/PRSGO/C923**].[8,38,39]

Data Analysis

Descriptive statistics were calculated. Statistical analysis was performed using Python 2.7.14 software (Anaconda, Inc., Austin, Tex.) and StatView (SAS Institute Inc., Cary, N.C.). Descriptive statistics were calculated, including the mean, median, minimum, and maximum patient age, implant age, and age at implant surgery. An unpaired *t* test was used to analyze the effect of implant volume, implant projection, and implant placement on rotation for Allergan and Mentor brand implants; *P* values are reported.

RESULTS

In total, 308 women with bilateral anatomical breast implants (616 implants) who were assessed at the Victoriakliniken City IBICC in Stockholm, Sweden, between April 2020 and July 2022 were included in the study. All women had undergone aesthetic mammoplasty (cosmetic breast augmentation) using bilateral textured cohesive gel anatomical breast implants. All subjects provided informed consent to participate in the study. Mean age at implantation was 29.9 (range 16–71). Mean implant age at IBICC examination was 10.1 years (range 1–22). Out of 308 women, 156 (50.6%) had implants for more than 10 years (Table 1).

Upon presentation to the IBICC clinic, 40 of the 308 women (13.0%) reported a change in breast shape. Of these 40 women, 35 women were recorded to have one or more implant-related complications. Four women (10%) had a seroma (Fig. 2A),16 (40%) had a Baker grade III or IV capsular contraction (Fig. 2B), one (2.5%) had a waterfall deformity (Fig. 2C, D), two (5%) had a bottoming out

Table 1. Patient Characteristics and Findings

All Patients	Mean	Median	Range			
Patient age (y)	40.1	39	20–78			
Implant age (y)	10.1	10.5	1–22			
Age at implant surgery	30.6	29.5	17–72			
Clinical Findings	**Right Implant**		**Left Implant**		**Combined**	
None	203	65.9%	197	64.0%	400	64.9%
Swelling	4	1.3%	4	1.3%	8	1.3%
Capsular contracture	52	16.9%	61	19.8%	113	18.3%
Lump			5	1.6%	5	0.8%
Rotation	10	3.2%	4	1.3%	14	2.3%
Bottoming out	5	1.6%	6	1.9%	11	1.8%
Waterfall deformity	6	1.9%	6	1.9%	12	1.9%
Double bubble deformity	9	2.9%	7	2.3%	16	2.6%
Animation deformity	15	4.9%	12	3.9%	27	4.4%
Other	21	6.8%	23	7.5%	44	7.1%
Ultrasound Findings	**Right Implant**		**Left Implant**		**Combined**	
Normal	233	75.6%	223	72.4%	456	74.0%
Seroma	5	1.6%	5	1.6%	10	1.6%
Rupture	19	6.2%	27	8.8%	46	7.5%
Rotation	15	4.9%	10	3.2%	25	4.1%
Folding (due to CC)	35	11.4%	53	17.2%	88	14.3%
Patients with Rotations						
Patient age (y)	38.4	37.5	26–60			
Implant age (y)	8.6	8.5	1–20			
Age at implant surgery	38.9	37.6	26–60.9			
Clinical Findings	**Right Implant**		**Left Implant**		**Combined**	
None	9	42.9%	12	57.1%	21	50.0%
Swelling	1	4.8%			1	2.4%
Capsular contracture	2	9.5%	2	9.5%	4	9.5%
Lump			1	4.8%	1	2.4%
Rotation	9	42.9%	4	19.0%	13	31.0%
Bottoming out			1	4.8%	1	2.4%
Waterfall deformity	1	4.8%	1	4.8%	2	4.8%
Double bubble deformity	2	9.5%	1	4.8%	3	7.1%
Animation deformity			1	4.8%	1	2.4%
Other	3	14.3%	3	14.3%	6	14.3%
Ultrasound Findings	**Right Implant**		**Left Implant**		**Combined**	
Normal	6	28.6%	10	47.6%	16	38.1%
Rotation	15	71.4%	10	47.6%	25	59.5%
Folding (due to cc)			1	4.8%	1	2.4%

deformity (Fig. 2E), five (12.5%) had a double bubble deformity (Fig. 2F), eight (20%) had an animation deformity (Fig. 2G), three (7.5%) had rippling (Fig. 2H), and seven (17.5%) had implant rupture. The remaining five (12.5%) had no clinical or ultrasound findings; these women were found to have normal breast shape changes due to aging, pregnancy, or weight change but did not fulfill the criteria of an implant-related deformity upon physical examination or ultrasound.

Of the 308 women examined, 11 (3.6%) were classified as having implant rotation by clinical examination (Fig. 3A), whereas 21 women (6.8%) in total were found to have a rotation on ultrasound, of whom four women (1.3%) had bilateral implant rotation. Of the 21 women with rotated implants detected on ultrasound, only five (23.8%) of them had a self-reported change in breast shape. Consequently, 10 women (47.6%) had a silent rotation that was only visible on ultrasound and not detected by either the patient or the plastic surgeon (Fig. 3B).

In total, 616 breast implants were assessed (308 women). Of these, 490 were recorded as Allergan devices; 114, Mentor CPG; two, Motiva Anatomical True Fixation; six, Polytech Mesmo; and four, Eurosilicone (Fig. 5). Seven Allergan implants had rotations, all unilateral. Seventeen Mentor implants had rotations, four of which were bilateral. One Eurosilicone implant was rotated (Table 2).

Rotation was not correlated with implant volume for either Allergan ($P = 0.08$) or Mentor ($P = 0.37$) implants. Implant projection also showed no correlation with rotation for either Allergan ($P = 0.086$) or Mentor ($P = 0.99$) implants. Insufficient data were available to assess the effect of submuscular versus subglandular surgical placement on implant rotation. Only 14 Allergan implants (2.9%) and 14 Mentor implants (10.5%) were placed subglandularly. Of these, three Mentor implants showed rotation (21.4%). The other brand's devices were too few to perform a statistical analysis.

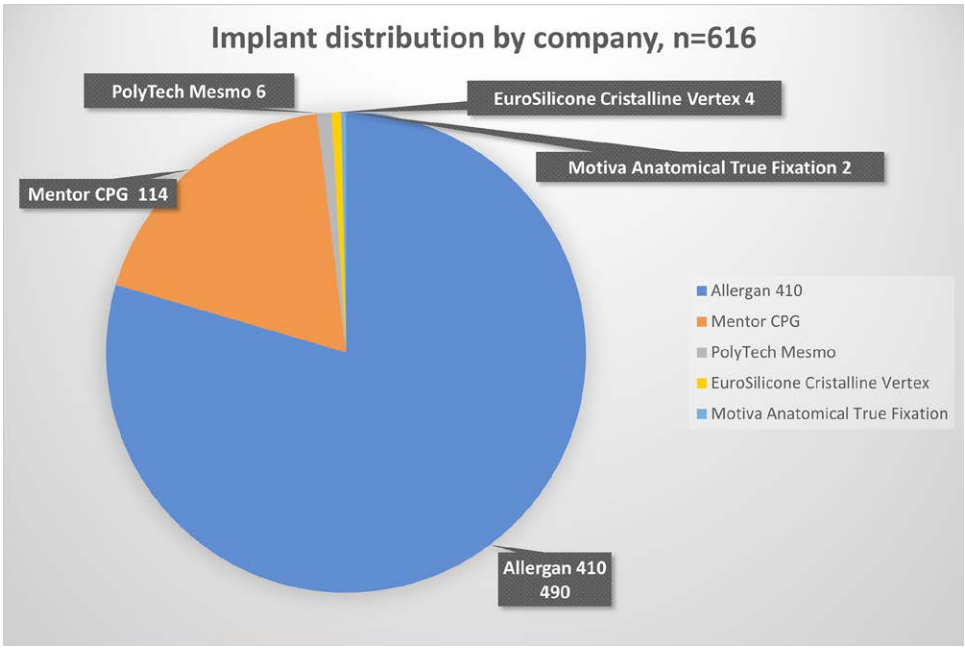

Fig. 5. Implant distribution by company.

Table 2. Implant Details of All Rotated Implants

Patient	Patient Age	Implant Years	Incision Site	Placement	Manufacturer	Design	Model		Volume (cc)		Projection (cm)		Rotation on Ultrasound	
							Right	Left	Right	Left	Right	Left	Right	Left
1	40	6	IMF	sm	Mentor	CPG	UNK	UNK	UNK	UNK	UNK	UNK	Yes	Yes
2	29	11	IMF	sm	Mentor	CPG	322	322	375	375	5.3	5.3	Yes	Yes
3	29	9	IMF	sm	Mentor	CPG	321	321	280	280	4.2	4.2	Yes	Yes
4	30	12	IMF	sm	Mentor	CPG	321	321	280	280	4.2	4.2	Yes	Yes
5	52	15	IMF	sm	Allergan	Natrelle 410	FF	FM	290	270	4.6	4.2	Yes	No
6	37	5	IMF	sm	Mentor	CPG	322	321	420	355	5.5	4.6	No	Yes
7	46	1	IMF	sm	Mentor	CPG	321	321	245	245	4.0	4.0	No	Yes
8	44	7	IMF	sm	Mentor	CPG	321	321	355	355	4.6	4.6	No	Yes
9	45	4	IMF	sm	Allergan	Natrelle 410	ML	ML	220	220	3.4	3.4	Yes	No
10	39	2	IMF	sm	Allergan	Natrelle 410	ML	ML	170	170	3.1	3.1	Yes	No
11	31	5	IMF	sg	Mentor	CPG	332	332	395	395	5.3	5.3	No	Yes
12	47	8	IMF	sm	Mentor	CPG	321	321	315	280	4.4	4.2	Yes	No
13	60	20	IMF	sm	Allergan	Natrelle 410	MM	MM	320	320	4.6	4.6	Yes	No
14	32	13	IMF	sm	Mentor	CPG	321	321	245	245	4.0	4.0	Yes	No
15	32	9	IMF	sm	Allergan	Natrelle 410	FM	FF	350	375	4.6	5.1	Yes	No
16	34	14	IMF	sm	Allergan	Natrelle 410	MM	MM	215	215	4.0	4.0	No	Yes
17	43	10	IMF	sg	Mentor	CPG	UNK	UNK	UNK	UNK	UNK	UNK	No	Yes
18	38	11	IMF	sm	Allergan	Natrelle 410	FM	FM	270	270	4.2	4.2	Yes	No
19	53	20	IMF	sm	Eurosilicone	Cristalline Vertex	E. S.	E. S.	250	250	4.2	4.2	Yes	No
20	32	2	IMF	sg	Mentor	CPG	321	321	315	315	4.4	4.4	Yes	No
21	26	3	IMF	sm	Mentor	CPG	323	323	390	390	6.0	6.0	Yes	No

DISCUSSION

Many types of deformities and implant-related complications can occur after breast augmentation, especially over time; as with other medical devices, silicone gel breast implants may have a definite life span.[4,40] In this study of 308 patients with anatomical implants, most women did not report any implant-related symptoms, even though a long time had passed since the breast augmentation surgery. However, 40 women (13.0%) reported a change in breast shape. In the majority of these 40 patients, the change in breast shape was caused by one or more implant-related complications, including seroma (10%), capsular contraction (40%), waterfall deformity (2.5%), bottoming out (5%), double

bubble deformity (12.5%), animation deformity (20%), rippling (7.5%), implant rupture (17.5%), or implant rotation (12.5%), confirmed upon clinical examination together with ultrasound. The present study indicates that long-term follow-up and implant assessment are essential for providing safety and security for women with breast implants and should be part of any best breast practice.

Implant rotation is a feared drawback of anatomical devices and can occur at any point during the life of an implant, with previous studies finding rotation at 3 months to 5.7 years postoperatively.[11,14] compared with other studies of anatomical implant rotation that mainly present short-term results, this study of 308 patients with anatomical implants also included women seen for long-term follow-up 10 years or more after implant surgery.[5,7] The results of this study, which used ultrasound to evaluate implant rotation as a cause of change in breast shape, found a low incidence of implant rotation (6.8%), with only half of those patients (3.6%) showing clinical signs suggesting rotation. The low rate of apparent rotation on physical examination is consistent with some previously published studies.[4,6,11,14] Additionally, the number of rotations found using ultrasound was higher than the number of suspected rotations, based on nonimaging clinical findings of change in breast shape upon physical examination. This is also consistent with the results found by Sieber et al in a previously published study of 69 patients evaluating implant rotation with ultrasound.[8] This highlights that the incidence of implant rotation cannot be evaluated or excluded by physical examination alone. In this study, we found no statistically significant correlation between risk of rotation and implant size or projection. Other researchers have also not found any factor that was correlated with malrotation.[7,8,14] The only exception is Montemurro et al, who found a statistically significant increase in rotation rates related to a relative increase in cup size but not implant volume.[11] Further research is still needed to identify measurable risk factors of implant rotation.

Ultrasound for breast implant surveillance is also important for identifying late seromas or masses around breast implants, which can be indicators of potentially deadly complications such as BIA-ALCL and squamous cell malignancies.[41] Based on our long-term findings, our belief is, therefore, that facilities that offer breast implant surgery should incorporate and become more familiar with ultrasound, how it is used to screen for breast implant issues, and the benefits it brings to patient safety.

The ultrasound examination also adds valuable information to the surgeon's analysis and preoperative planning in patients presenting with breast symptoms. The information that the ultrasound provides is probably even more important in breast reconstruction patients, where the secondary surgical procedure is associated with higher risk of implant-related complication.[42] In our experience, ultrasound screening for breast implant complications does not require a radiologist´s interpretation; it just requires basic familiarity with ultrasound concepts, sufficient hands-on training on the part of the surgeon or the staff, and repetitive clinical use.

Limitations

This study has several limitations. First, there is an obvious selection bias because many patients seeking a breast implant checkup have symptoms or are worried about potential problems. The incidence of implant-related complications is likely overrepresented in this study population. Furthermore, the study collected data only from IBICC visits with the latest implant. Women with previous implant changes or corrections due to rotation were not considered because the correction of implant rotation often includes a device change to round-shaped implants.

Additionally, all women in this study had aesthetic breast augmentation; breast reconstruction patients are not represented in this study. An implant rotation after breast reconstruction is probably more visible because all breast tissue that covers the implant has been removed during mastectomy, resulting in a more significant clinical problem for the woman when it occurs. Finally, in the seven women in this study who had ruptured implants, implant rotation may have been underdiagnosed ultrasonically due to the potential for poor visibility of orientation markings due to the rupture.

CONCLUSIONS

Ultrasound is an efficient and easy method for assessing change in breast shape caused by implant-related complications and is very useful when physical examination findings are inconclusive. Ultrasound is also a very valuable tool for preoperative decision making and planning before secondary breast implant procedures. In this study, the majority of women who presented with a change in their breast shape had one or more implant-related complications. This makes in-office ultrasound an indispensable tool for providing the best possible long-term care for breast implant patients, ultimately leading to better safety for women with breast implants.

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DISCLOSURES

Dr. Jaeger is a subclinical investigator for the US Motiva Breast Implant Clinical Trial (Establishment Labs, Alajuela, Costa Rica) and a medical consultant for Establishment Labs. Dr. Randquist is a medical consultant for Establishment Labs and Mentor Worldwide LLC (Irvine, Calif.), a shareholder in Establishment Labs Holdings Inc. (NASDAQ: ESTA), and a primary clinical investigator for the US Motiva Breast Implant Clinical Trial (Establishment Labs, Alajuela, Costa Rica). Dr. Gahm is a Mentor and EMEA Reconstruction Advisory Board expert.

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