Breast surgery: A problem of beauty or health?
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Chapter VII

Correlation between MRI results and intraoperative findings in silicone breast implants

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Introduction

The total number of patients with breast implants worldwide is estimated to be between 5 and 10 million by the U.S. Food and Drug Administration.\textsuperscript{1} Approximately 250,000 to 340,000 people in the United States receive breast implants each year.\textsuperscript{2} The most frequent long-term complications of implant placement include capsular contracture and implant rupture. Rupture is defined as a disruption of the implant shell, including focal rupture to large tears and may be the result of trauma, deterioration of implant shell with time, or manufacturing defects. Plastic surgeons are responsible for dealing with questions about potential negative health effects in case of undetected implant rupture. Therefore implant integrity and silent implant ruptures are important issues. In addition it has been questioned repetitively whether women with ruptured implants may be at risk for immunologic reactions due to the exposed free silicone entailing systemic diseases.\textsuperscript{3,4} Several imaging methods, including mammography, ultrasonography, computer tomography and magnetic resonance imaging (MRI) have been used to assess the integrity of breast implants. In previous studies MRI has proven to be superior in detection of breast implant rupture compared to other methods.\textsuperscript{5-8}

Because progress in detection of rupture has not been accompanied by knowledge of the frequency and severity of complications associated with rupture, there still is discussion about the appropriate way to deal with presumed implant ruptures detected on MRI exams in symptomatic and asymptomatic patients. In case of false positive MRI diagnosis, i.e. examen positive for implant rupture without correlation at time of explantation, the potential for unnecessary surgical interventions is a cause of concern. On the other hand, false negative MRI results, i.e. failure to detect an actually present implant rupture may expose the patient to potential negative sequelae of extracapsular implant rupture and silicone migration.

Therefore it was the aim of the presented study to investigate the congruence of MRI results and intraoperative findings in the diagnosis of breast implant rupture in both symptomatic and asymptomatic patients. Furthermore we aimed at simulating potential causes for the appearance of false implant rupture signs by experimental implant dissection.

Materials and Methods

Patients

50 consecutive patients with 85 silicone gel filled breast implants consulting the outpatient clinic from July 2001 until April 2003, were included into the study.
Of those 50 patients, 25 previously underwent implantation of silicone gel-filled breast prostheses for reconstructive and 25 for cosmetic reasons. All patients with cosmetic breast augmentation had bilateral breast implants, while patients after breast reconstruction had unilateral implants. The mean age of the patients was 51 years (range 21–72 years) with a mean duration of implant presence of 3.8 years (range 0.2-28 years). In all patients a clinical examination was performed followed by MRI of the breasts.

Clinical examination
All patients received a standardized clinical breast exam by a physician. As clinical symptoms of potential implant rupture the appearance of visible folds, shape change or volume reduction of the implant, capsular contracture and pain were defined as criteria (Fig. 1 A and B).

**Figure 1.** Patient presenting with clinical symptoms indicated by (A) visible rippling and form change of the implant and (B) capsular contracture Grade 4.

MRI
All MR-scans were performed on a 1.0T MR Scanner (Gyroscan, T10-NT, Philips Medical System, Eindhoven, The Netherlands) using a dedicated breast coil in prone position. The imaging protocol consisted of 5 sequences including a T2-weighted turbo-spin-echo sequence in axial and sagittal plane, a 3-dimensional T2-weighted fast-field-echo in sagittal plane, a T1-weighted turbo-spin-echo sequence in sagittal plane and an 3-dimensional T1-weighted fast-field-echo sequence. Both T1- and T2-weighted fast-field-echo sequences used water suppression for better visualization of silicone. MR images were read and interpreted before surgery by two independent experienced radiologists. Signs for intracapsular rupture of the implant were the keyhole and the linguine sign. The keyhole sign (also known as
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inverted teardrop sign) results from extraprothetic silicone gel trapped in an invagination of the implant shell after interruption of the envelope (Fig. 2A). It represents an uncollapsed rupture in which the silicone shell still covers the viscous core of the implant. On the other hand the linguine sign is represented by multiple curvilinear low signal intensity lines seen within the high signal intensity silicone gel (Fig. 2B). The curvilinear lines represent the collapsed implant shell floating within the silicone gel surrounded by the fibrous capsule. In contrast to this are radial folds of the implant usually seen during MRI, which are of no pathological value (Fig. 2C).

Intraoperative diagnosis
For intraoperative diagnosis we removed the implants within their fibrous capsule to prevent iatrogenic damage of the implant shell. The implant capsule was then opened carefully. Criteria to determine an implant rupture at time of explantation were a ruptured implant shell with silicone leakage and/or subsequent calcifications of the fibrous capsule. In case of a false positive MRI result we additionally performed ultrasound imaging of the harvested implant.

Experimental simulation of implant rupture signs
By outer compression of a new unused implant we produced complex radial folds in the MRI to analyse the source of a false positive keyhole sign. Additionally we separated the different shell layers of new silicone gel filled breast implants by microsurgical preparation to analyse the potential underlying cause of a false positive linguine sign. The implants then were examined by MRI to verify their imaging.
Results

Clinical examination
19 out of 50 (38%) patients displayed at least one of clinical symptom at time of examination. Out of these 19 patients 17 patients were operated with the suspicion of implant rupture.

MRI
The MRI results showed signs of rupture in 17 out of 50 patients (34%) and in 22 out of 85 implants (26%). 10 out of these 17 patients (59%) with presumed implant rupture did not exhibit any clinical symptoms, while 7 patients (41%) showed clinical signs of implant rupture. In 22 implants with signs of implant rupture, 12 implants (55%) were symptomatic, while 10 implants (45%) were asymptomatic (Fig. 3A). Of these 22 implants 19 implants were diagnosed with linguine signs and 3 with keyhole signs in the MRI as signs for implant rupture (Fig. 3B). 8 out of 19 (42%) implants with linguine signs and 2 out of 3 (67%) implants showing the keyhole sign had been asymptomatic.

Figure 3. Results of the MRI screening of 50 consecutive patients: (A) 22 out of 85 implants exhibited signs of rupture, while 63 did not. In patients with positive MRI 55% were symptomatic, while 11% in patients with negative MRI were. (B) In the MRI most implants were judged to exhibit the linguine sign, of those 61% were symptomatic.

Intraoperative diagnosis
Of the 17 patients with a positive MRI exam, 12 patients underwent surgical removal of the implants. The remaining 5 patients were all asymptomatic and refused to undergo surgery. Alltogether 17 implants were removed. Intraoperatively in 7 out of 17 (41%) explanted breast implants the suspected rupture was confirmed. Of these 7 patients 4 (57%) had been symptomatic. In 10 out of 17 patients (59%) no implant rupture was identified during the operation. Of these 10 patient 9 patients (90%)
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had been symptomatic before (Fig. 4). In the ultrasound imaging of the harvested implants we found signs of interrupted inner layers of the implant shell despite the integrity of the outer shell (Fig. 5 A-C).

Figure 5. Ultrasound imaging: (A) Three separate shell layers can be identified in an intact silicone gel breast implant. (B) Silicone gel found in between the dissolving shell layers of a harvested implant with positive linguine sign in the MRI. (C) Broken inner shell layer floating in the intraluminal silicone gel of an implant with linguine sign in the MRI.

Experimental simulation of implant rupture signs

Fig. 2C shows the MRI of an unused intact silicone gel-filled breast implant, which has been compressed during MRI exam. The simulated complex radial folds are difficult to differentiate from the keyhole sign. As seen in the ultrasound imaging of a new un-ruptured implant (Fig. 5A) the shell consists of 3 different layers. In implants with positive linguine sign in the MRI we found alterations in this shell structure with silicone gel in between these layers (Fig. 5B). In one case we were able to find the broken inner layer floating in the silicone gel (Fig. 5C).

In order to experimentally simulate the linguine sign an intact unused silicone-gel filled breast implant was dissected by a clean cut of the shell. Then the different layers of the implant were dissected and the shell then closed again with sutures.
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(Fig. 6 A and B). The MRI of the microsurgical prepared implant showed a low signal intensity line in the high signal intensity silicone gel mimicking the linguine sign (Fig. 6C).

Discussion

Ever since the introduction of silicone gel breast implants in the early 1960s plastic surgeons have been faced with the short and long-term consequences. Among the various sequelae of breast implant placement capsular contracture, asymmetry and implant malposition are the most frequent. However, the possibility of implant rupture and potential leakage of silicone into the body has been of continuous interest. In 2010, of the nearly 300,000 breast augmentations and 93,000 breast reconstructions performed in the United States, 51% and 59%, respectively, were performed with silicone implants. It can be assumed that these numbers are considerably higher in other western countries, in which no temporary ban on the use of silicone implants was in effect. Rupture of silicone implants was reported in 8% in asymptomatic women and in about 33% in symptomatic women. Typically symptoms are defined as the presence of new onset of pain, capsular contracture, form changes of the implant and breast asymmetry. Implant rupture in asymptomatic patients usually is suspected during routine screening imaging. The risk for implant rupture raises with the age of the implant. A rupture prevalence of 30% at implant age of 5 years, 50% at 10 years, and 70% at 17 years have been reported. The median age of implant at rupture has been estimated to be 10.8 years.

The clinical diagnosis of implant rupture in general is difficult considering the manifoldness of potential clinical rupture signs. The sensitivity of physical examination of
the breast only for implant rupture was shown to be as low as 30%\textsuperscript{17} Therefore MRI has evolved to become the number one imaging tool to discover both intra- and extracapsular implant rupture over the last 10 years. Mammography and computer tomography have been abandoned due to specific drawbacks, like risk of implant damage and radiation exposure.\textsuperscript{2} Ultrasound imaging may be the future. However, ultrasound imaging is very operator-dependent and the detection of intracapsular rupture largely relies on the experience of the examiner.\textsuperscript{18}

In light of this it was the aim of the presented study to investigate the ability of MRI screening in 50 consecutive patients to accurately detect implant rupture. However, due to the fact, that only 12 out of 17 symptomatic women underwent implant removal, and not all women examined by MRI, statistical variables like sensitivity and specificity were not defined. The explantation of all implants, e.g. also in asymptomatic women with a negative MRI screening would not have been clinically feasible. We found a strikingly low correlation between supposed implant rupture in the MRI exam and the intraoperative implant condition. A positive MRI finding was congruent with an implant rupture only in 41% of the cases, while the MRI result was false positive in 59% of implants. Moreover, of the above mentioned 59% intact implants, 90% had been symptomatic. This clearly demonstrates, that there was no coherence between clinical symptoms and actual presence of implant rupture in the study population.

However, MRI still is assumed to be the best imaging modality available to diagnose implant rupture, with a reported sensitivity and specificity of more than 90 percent.\textsuperscript{5,9,17,19} Implant rupture basically is divided into two categories: extracapsular rupture referring to free silicone outside the fibrous capsular formed by the body around the implant, and intracapsular rupture in which the silicon gel is still contained within the fibrous capsule.\textsuperscript{9} 80-90% percent ruptures are intracapsular ruptures.\textsuperscript{5,20} The most recent so-called third generation silicone gel implants, which were introduced in the late 1980s, consist of a cohesive viscous silicone gel encapsulated in a silicone shell. The older second generation silicone gel breast implants that were implanted before the late 1980s, consist of a shell filled with less viscous silicone gel.

Based on the fact that the composition of implant core is different, each implant generation exhibits specific MRI findings for detection of an implant rupture. The second generation of silicone gel implants tends to give the image of the classic collapsed implant shell floating in the more liquid silicone core creating the linguine sign. On the contrary the third generation of silicone gel implants consisting of a more cohesive silicone gel typically shows an uncollapsed rupture creating the keyhole sign. Therefore third generation implants will rarely depict the totally collapsed implant shell creating the linguine sign.\textsuperscript{9,21}
In the presented study patients in average had the implant in place for 3.8 years with a range from 0.2 to 28 years. This means that the large majority of patients had implants belonging to the third generation and were implanted in the 1990s, even though a small number of patients may have carried second generation implants. Overall in 18 implants the linguine sign was diagnosed in the MRI and in only 2 implants the keyhole sign. Based on the above mentioned assumptions it is highly likely that most changes of the breast implant inner structure that were interpreted as linguine sign indicating the silicone shell floating in the liquid gel, were actually artifacts caused by tears in the more cohesive gel of the third generation implants. The implant shell itself in these cases was intact. By ultrasound we were able to show tears in the viscous silicone gel. In an attempt to mimic possible artifacts during breast MRI, we compressed an intact silicone implant yielding deep folds in the MRI, which could be misjudged as keyhole signs. Secondly the microdissection of the implant shell from the cohesive silicon core in a third generation implant lead to the appearance of curvedlinear lines similar to the linguine sign in the MRI exam. Therefore many in MRI diagnosed linguine signs actually may merely be tears within the highly-cohesive gel of third generation implants without rupture of the implant shell. These findings should be taken into consideration by radiologists occupied with breast implant rupture diagnostic today. The linguine sign even today often is judged as a typical sign for intracapsular rupture ignoring the fact that most implants likely belong to the third generation, which will rarely exhibit this particular sign of rupture.

A microscopic silicone leakage through an intact implant shell is referred to as gel bleed.\textsuperscript{5,22} The majority of gel bleeds cannot be detected by magnetic resonance imaging. If a larger amount of gel bleed collects in a radial fold of the implant, the keyhole sign can develop. In a study performed by Chung et al. in asymptomatic women and a low prevalence of rupture (8%), the predictive value of a positive test was low for both ultrasound (19%) and magnetic resonance imaging (20 %). On the other hand, in symptomatic women, with a prevalence of 33 percent, the predictive value of a positive test was higher for both ultrasound (68%) and magnetic resonance imaging (81 %).\textsuperscript{2} This means that these modalities are better in detecting implant ruptures in a study population exhibiting a high incidence and do not perform well as pure screening modalities. Therefore, in the general population of women having silicone breast implants and in which the prevalence of implant rupture is significantly lower, the positive predictive value of magnetic resonance imaging is too low to make it suitable as a screening method.\textsuperscript{23} This again is supported by the results of our study. In symptomatic implants the MRI was able to accurately identify implant rupture in 55% of the cases, while it was able to do this in the asymptomatic group in only 11% of the cases.
Any unnecessary explantation of a breast implant can result in considerable aesthetic impairment and potential perioperative and anesthesia-related complications. Moreover, it is to be avoided from an economic point of view. The national average for surgeon/physician fees in 2010 for breast augmentation was $3351 and for removal it was $2288 in 2010. After the US Food an Drug Administration (FDA) repermitted the use of silicone gel filled breast implants in 2006, they recommended yearly MRI screening in all women carrying silicone breast implants to rule out asymptomatic ruptures. However, the consequences of silent silicone implant rupture have been shown to be minimal in a prospective study in 271 women with cosmetic breast implants. In this study the majority of the women with implant rupture had no visible magnetic resonance imaging changes of their ruptured implants over a time period of 2 years. In 11% of implants the authors observed progression of silicone migration, either as a conversion from intracapsular into extracapsular rupture, as progression of extracapsular silicone or as increasing herniation of the silicone within the fibrous capsule. However, in most cases, these changes were minor. In the same study no increase in levels of autoantibodies during the study period in either study group was seen. From their results the authors concluded that rupture is a “relatively harmless condition, which only rarely progresses and gives rise to notable symptoms”. Song et al. studied the diagnostic accuracy of MRI examinations regarding breast implant rupture. They found that most studies using MRI and ultrasound examined symptomatic subjects and therefore had 14-fold higher diagnostic accuracy to studies using an asymptomatic sample. This underlines the lack of proof that routine screening of patients with breast implants will results in proper detection of implant ruptures.

Likewise McCarthy et al. stress this aspect in their evaluation of the suitability of MRI screening to provide health benefits to women with breast implants.

The consequences of the two types of implant rupture have to be considered when making decisions. In asymptomatic patients with an implant rupture, the integrity of the implant shell becomes impaired yet there are no symptoms experienced by the patient and no obvious shape changes of the breast or the implant. In contrast to this, in patients with a symptomatic rupture silicone gel leaks from the implant shell into the intracapsular and/or extracapsular space, which results in a change in breast appearance and/or the development of silicone granulomas or axillary lymphadenopathy.

Conclusively, sole reliance on MRI findings in asymptomatic patients most likely will result in a larger number of unnecessarily explanted implants. On the other hand pure clinical examination will be limited in accurately and definitely confirming or ruling out a potential implant rupture. Therefore the decision to re-operate a patient has to be made carefully and in agreement with the patient after all advan-
tages and disavantages as well as risks of such a procedure have been weighted up. The tolerance level of each individual patient for insecurity regarding a potentially silently ruptured silicone implant within the body also should be taken into account. If the patient decides against the explantation close clinical and radiological examinations of the breast should be performed to detect possible progression of a silicone leak.
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References