

VU Research Portal

Safety & imaging of modern silicone breast implants

Maijers, M.C.

2014

document version

Publisher's PDF, also known as Version of record

[Link to publication in VU Research Portal](#)

citation for published version (APA)

Maijers, M. C. (2014). *Safety & imaging of modern silicone breast implants: The PIP recall placed in perspective*. [PhD-Thesis - Research and graduation internal, Vrije Universiteit Amsterdam].

General rights

Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

- Users may download and print one copy of any publication from the public portal for the purpose of private study or research.
- You may not further distribute the material or use it for any profit-making activity or commercial gain
- You may freely distribute the URL identifying the publication in the public portal

Take down policy

If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

E-mail address:

vuresearchportal.ub@vu.nl

CHAPTER 7

A new, Simple Method to Describe Magnetic Resonance Imaging of Silicone Breast Implants:
Silicone Implants Reporting and Data System



M.C. Maijers
F.B. Niessen
J.F. Veldhuizen
M.J.P.F. Ritt
R.A. Manoliu

ABSTRACT

MRI silicone breast implant screening studies have been criticized for not using a uniform terminology on implant condition or status. For more simple, uncomplicated and uniform reporting of the condition of in situ silicone breast implants the authors developed a new reporting protocol with two categories. These categories are (A) implant status and (B) signs of extracapsular silicone leakage. The multiple choice answers to these two categories were inspired by the BI-RADS methodology in breast oncology. We found an improved sensitivity and specificity of MRI screening in asymptomatic women with PIP breast implants when using this new reporting system of MRI findings, called SI-RADS, compared to previous MRI reporting.

CHAPTER 7

Sir,

We would like to share with colleagues a newly designed method to record radiologist’s magnetic resonance imaging findings on silicone breast implant condition in two categories, to avoid subjective interpretation of inconclusive text, called Silicone Implants Reporting and Data System (SI-RADS). We designed this tool to re-evaluate magnetic resonance images in our ongoing studies of women previously implanted with Poly Implant Prothèse implants. Magnetic resonance imaging silicone breast implant screening studies have been criticized for not using a uniform terminology on implant condition or status. We also found a somewhat disappointing accuracy of magnetic resonance imaging screening in asymptomatic women with Poly Implant Prothèse breast implants¹ when compared with a recent magnetic resonance imaging validation study.² Validation studies, however, use multiple radiologists, who are assigned to the sole task of evaluating the images for research purposes, which improves sensitivity and specificity but is not often applicable to common daily practice. In our daily clinical practice, we noticed a broad spectrum of terminology used by individual radiologists to describe implant condition. Terms such as “leaking”, and “fluid seen” or “released” provided by radiologists are left to plastic surgeons to interpret as implants being ruptured or not. The decision to advise explantation is often based on these, at times not conclusive, Magnetic resonance imaging reports.

Unlike the diagnosis of a bone fracture, the radiologic diagnosis of a ruptured implant is subject to different degrees of confidence of the reporting radiologist. In breast cancer, one has an identical problem regarding the confidence in the interpretation of the radiologic findings in individual patients. The Breast Imaging Reporting and Data System (BI-RADS) was developed and introduced by the American College of Radiology to solve this problem and to provide a clear and simple radiologic describing system; it improved communication between physicians and can be used in the daily practice of decision making by the oncologic surgeon.^{3,4} This Breast Imaging Reporting and Data System methodology has been used successfully in the Dutch national breast cancer screening program for many years.⁵ Why not use an analogous system to screen silicone breast implant condition?

The simple and structured Silicone Implants Reporting and Data System tool was developed with two categories: (A) implant status and (B) signs of extracapsular silicone leakage. The multiple-choice answers as a

Table 1. Silicone Implant Reporting and Data System (SI-RADS)

A. Integrity of the implant

Category	Description	Clinical*
0	Incomplete**	Ad imaging**
1	Intact	None
2	Probably intact	None
3	Probably ruptured	Referral
4	Ruptured	Referral

B. Extracapsular leakage of silicone

Category	Description	Clinical*
0	Incomplete**	Ad imaging**
1	No EL***	None
2	Probably no EL***	None
3	Probably EL***	Referral
4	Extracapsular leakage	Referral

*Clinical Management; **the MRI is inconclusive, either additional imaging or second opinion from colleague radiologist should be sought; *** extracapsular leakage

measure of confidence, inspired by the Breast Imaging Reporting and Data System methodology, left no room for inconclusive or descriptive text (Table 1). This Silicone Implants Reporting and Data System methodology was then applied to re-evaluate the 2 year old magnetic resonance images of 214 implants completed by two of the three original radiologists. The radiologists found the silicone implants tool easy to use and time sparing. An example of a clearly ruptured and partially collapsed silicone implant in the left breast is shown in Figures 1 and 2.

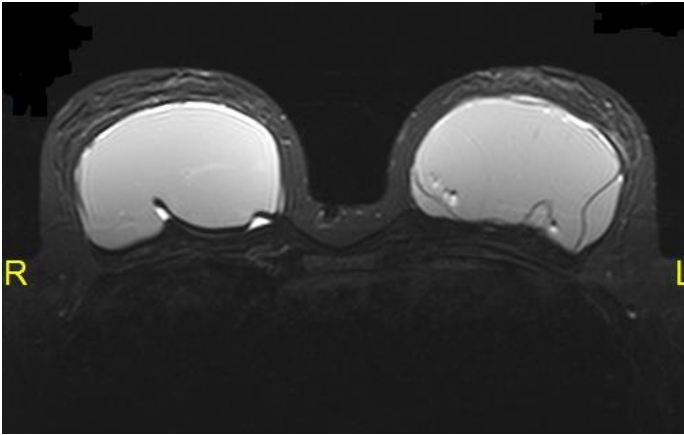


Figure 1. Water-suppressed STIR-T2-weighted axial image of both breasts shows infolding of an intact implant in the right breast. Shell rupture and partial collapse of the implant in the left

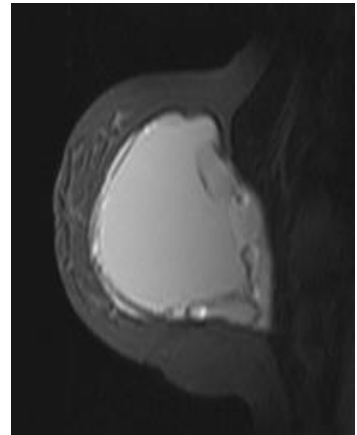


Figure 2. View of the ruptured implant in the left breast on a sagittal water-suppressed STIR-T2-weighted image

We compared the magnetic resonance imaging reports with the explantation results and found an improved sensitivity and specificity from 80 and 91 percent to 93 percent and 93 percent, respectively, of magnetic resonance imaging screening in asymptomatic women with Poly Implant Prothèse breast implants when using the silicone implants tool, compared with the previous magnetic resonance imaging reporting. We would advise colleagues to implement this new Silicone Implants Reporting and Data System (SI-RADS) methodology of simple, uncomplicated, and uniform reporting of silicone implant in their daily practices, as we believe this would improve communication between radiologists and plastic surgeons.

REFERENCES

1. Majiers MC, Niessen FB. The clinical and diagnostic consequences of poly implant prothese silicone breast implants, recalled from the European market in 2010. *Plastic and reconstructive surgery*. Mar 2013;131(3):394e-402e.
2. Holmich LR, Vejborg I, Conrad C, Sletting S, McLaughlin JK. The diagnosis of breast implant rupture: MRI findings compared with findings at explantation. *European journal of radiology*. Feb 2005;53(2):213-225.
3. Kallergi M, Gavrielides MA, He L, Berman CG, Kim JJ, Clark RA. Simulation model of mammographic calcifications based on the American College of Radiology Breast Imaging Reporting and Data System, or BIRADS. *Academic radiology*. Oct 1998;5(10):670-679.
4. Taplin SH, Ichikawa LE, Kerlikowske K, et al. Concordance of breast imaging reporting and data system assessments and management recommendations in screening mammography. *Radiology*. Feb 2002;222(2):529-535.
5. Timmers JM, van Doorne-Nagtegaal HJ, Zonderland HM, et al. The Breast Imaging Reporting and Data System (BI-RADS) in the Dutch breast cancer screening programme: its role as an assessment and stratification tool. *European radiology*. Aug 2012;22(8):1717-1723.

