

## EVALUATION OF THE INTRACAPSULAR RUPTURE OF SILICONE BREAST IMPLANTS BY MAGNETIC RESONANCE IMAGING IN ASYMPTOMATIC PATIENTS AND CORRELATION WITH SURGICAL FINDINGS

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### Abstract

The true incidence of implant rupture is very difficult to establish. Frequently implant rupture is asymptomatic because the free silicone remains within the fibrous capsule surrounding the implant. Therefore, the identification of rupture is based only on the use of imaging techniques. The aim of this study is to evaluate the effectiveness magnetic resonance imaging (MRI) in the detection of breast implant rupture and to correlate imaging findings with surgical ones. Patients were 73 women between 30 and 69 years. By MRI we found 20 intracapsular ruptures, no one extracapsular rupture, 53 normal implants. The most important findings at surgery were the 20 intracapsular ruptures that were previously diagnosed at MRI. In this study we found that magnetic resonance imaging diagnosed intracapsular rupture with a high sensitivity and an even higher specificity.

**Keywords:** breast, implant, rupture, MRI, practice guideline.

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**Received:** March 1<sup>st</sup>, 2010

**Revised:** April 09<sup>th</sup>, 2010

**Accepted:** May 15<sup>th</sup>, 2010

**Language of the Article:** English.

*No conflicts of interest were declared.*

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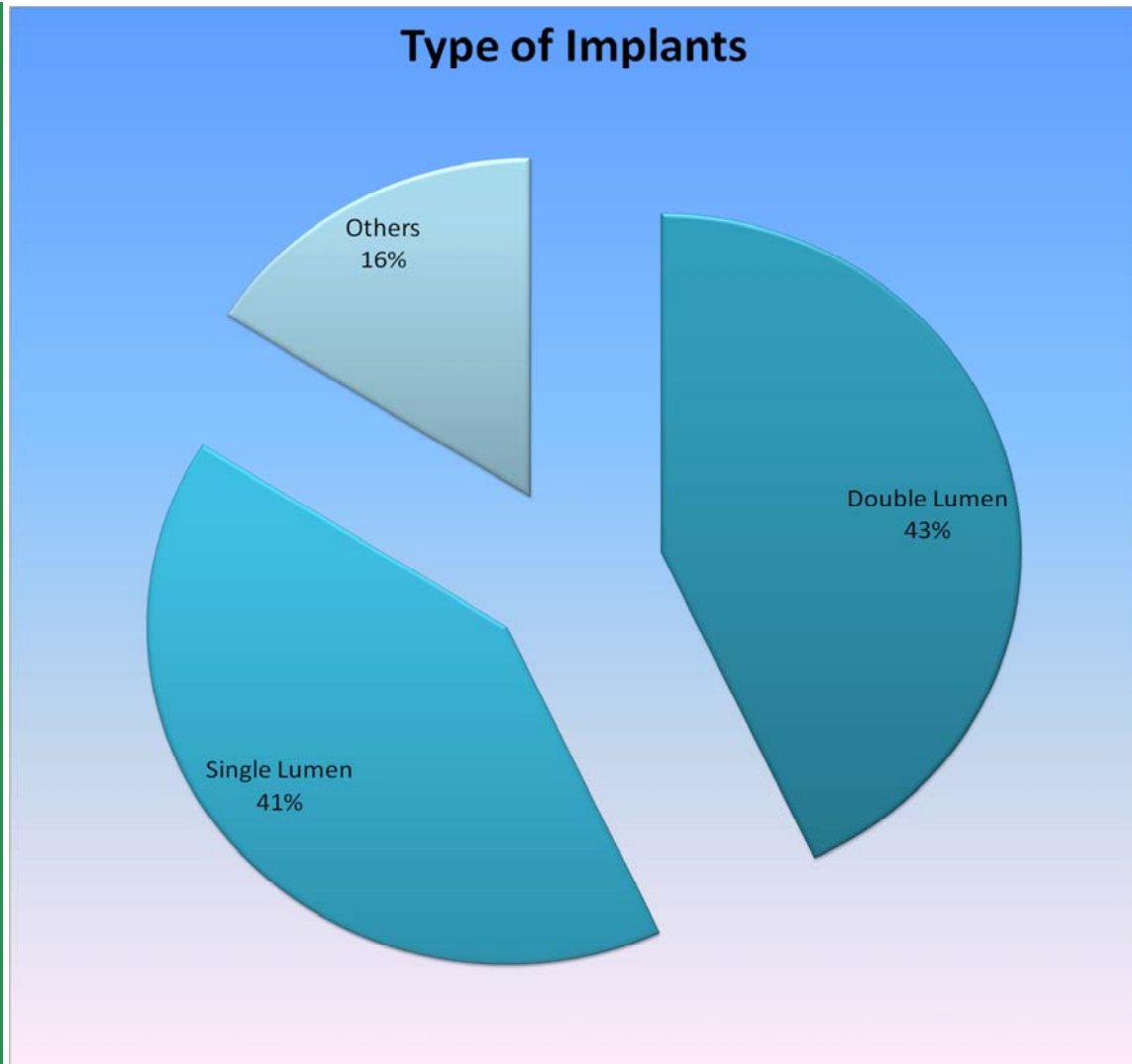
ISSN: 1970-5492

DOI: 10.3269/1970-5492.2010.5.19

### Introduction

Silicone breast implants for augmentation and reconstruction mammoplasty were introduced for clinical use in the early 1960s. Device rupture has been identified as an issue for silicone gel-filled breast implants in the scientific literature, though rates of rupture (both suspected and confirmed) range widely depending on the selection criteria and implants studied. Implant rupture represents the main cause of implant removal (1).

The true incidence of implant rupture is very difficult to establish. Frequently implant rupture is asymptomatic because the free silicone remains within the fibrous capsule surrounding the implant. The standard test for implant rupture is explantation. However, studies on explantation patients do not give true rupture frequencies, as these studies suffer from the inclusion of women with symptoms or concerns about their implants. Several clinical studies have attempted to estimate the prevalence and incidence of rupture on the basis of findings at explantation. Because these studies primarily include symptomatic and self-selected groups of patients, selection bias is likely to be present and study populations are not representative of all women with breast implants. Estimating rupture rates of contemporary devices has also been difficult because implant designs have changed over time. Prospective investigations must determine whether silent ruptures of form-stable implants lead to an intracapsular and/or extracapsular silicone leak.



*Fig. 1:* Type of Breast Implants: 31 of them (43%) had double-lumen silicone implant, 30 (41%) had single-lumen silicone implant and 12 (16%) had breast expander implant.

Therefore, the identification of rupture is based only on the use of imaging techniques. Different imaging methods can identify the integrity of the breast implants and also the extent of possible silicone leakage going to the glands and adjacent tissues. Mammography, ultrasonography, computerized tomography and magnetic resonance imaging have been used to evaluate the integrity of breast implants in symptomatic patients, in relation to rupturing.

There are many studies that discuss different methods used to evaluate breast implant rupture, including in situ examination by radiologic examination alone, imaging studies in combination with direct visualization after explantation, or a precisely choreographed clinical examination

technique. Various levels of specificity and sensitivity have been reported for mammography, ultrasonography, breast magnetic resonance imaging (bMRI), and physician's examination (PE) with most concluding that PE is not sufficient, while the various imaging modalities offer a wide range of results with bMRI usually reported as being the most accurate. The U.S. Food and Drug Administration's recommendation appears to reflect a belief that mass magnetic resonance imaging screening of asymptomatic women may ultimately reduce patient morbidity caused by implant rupture (2,3).

Aim of this study was to evaluate the effectiveness magnetic resonance imaging (MRI) in the detection of intracapsular breast implant rupture and to correlate imaging

findings with surgical ones, in order to define a diagnostic algorithm for detecting breast implant rupture.

#### Materials and methods

From the 2006 to 2008, 73 patients with silicone implants had scheduled magnetic resonance imaging, scanning to screen for silent rupture, and underwent surgical explantation.

Patients were women between 30 and 69 years. 31 of them (43%) had double-lumen silicone implant, 30 (41%) had single-lumen silicone implant and 12 (16%) had breast expander implant (fig. 1).

Each MRI was performed using the same scanner with a dedicated breast coil at 1.0 Tesla. The images were evaluated as either evidence of extracapsular rupture, evidence of intracapsular rupture, no evidence of rupture or indeterminate.

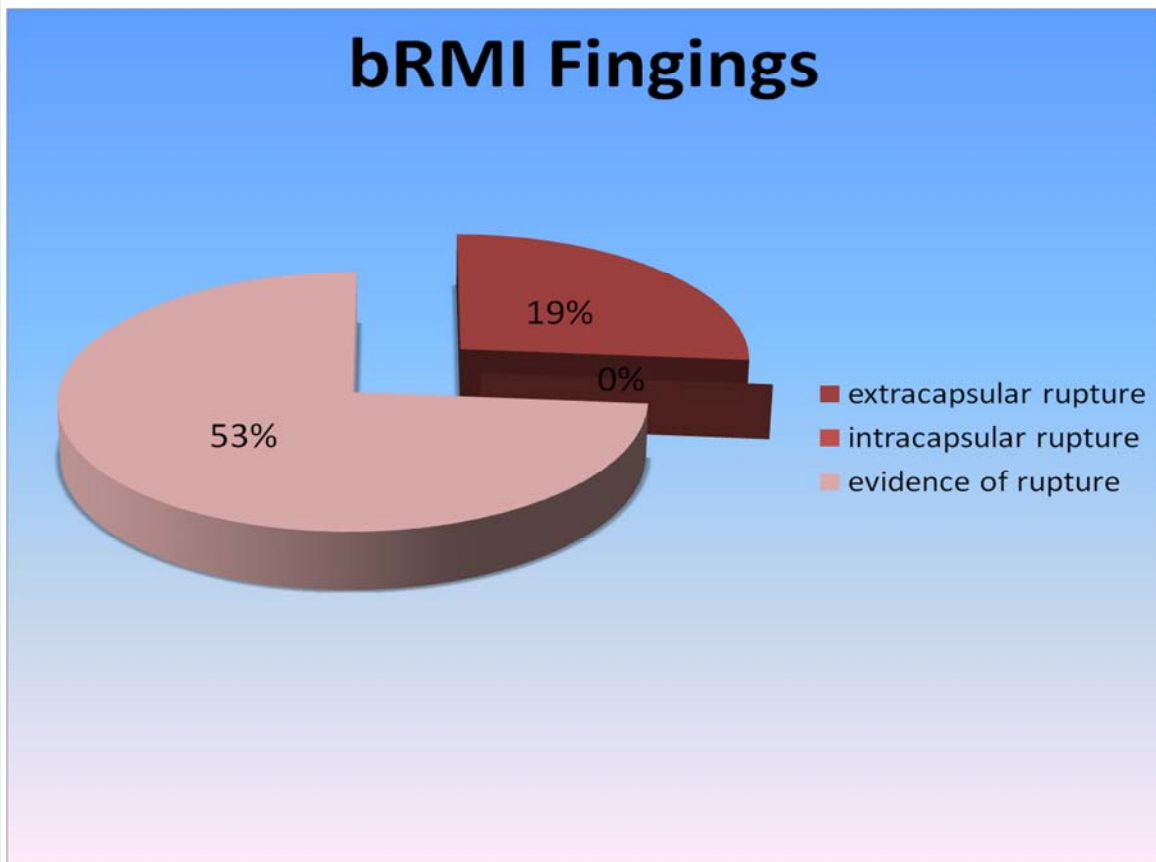
The findings at surgery were classified in normal implant when the elastomeric envelope was complete without perforations, including also a silicone gel layer

because of the bleeding and in ruptured implant when the elastomer shell presented a lack of continuity. This category was divided into an intracapsular type, when the silicone remained defined by the fibrous capsule, and an extracapsular type, when the silicone was present outside the fibrous capsule into the surrounding breast tissue.

#### Results

By MRI we found (fig. 2): 20 (19%) intracapsular rupture, 0 (0%) extracapsular rupture (because the clinical evidence was enough to make diagnosis of rupture, patients directly underwent surgical operation without MRI and they were not included in the study), 53 (50%) normal implant.

Of all 73 patients, only 28 underwent surgical explantation of breast implants: all 20 patients with suspected intracapsular rupture diagnosed by MRI and 8 for other reasons (breast augmentation, complications like implant exposure, etc). All 20 intracapsular ruptures were confirmed by



*Fig.2:* MRI findings: 20 (19%) intracapsular rupture, 0 (0%) extracapsular rupture (because the clinical evidence was enough to make diagnosis of rupture, so patients directly underwent surgical operation without MRI and they were not included in the study), 53 (50%) normal implant.

surgical findings (100%) while the other 8 implant were normal (according to MRI results) (fig. 3).

### Discussion

In this study we found that magnetic resonance imaging diagnosed intracapsular rupture with a high sensitivity and an even higher specificity. The positive predictive value was very high, with more than 99% of MRI-diagnosed ruptures in fact being ruptured at surgery.

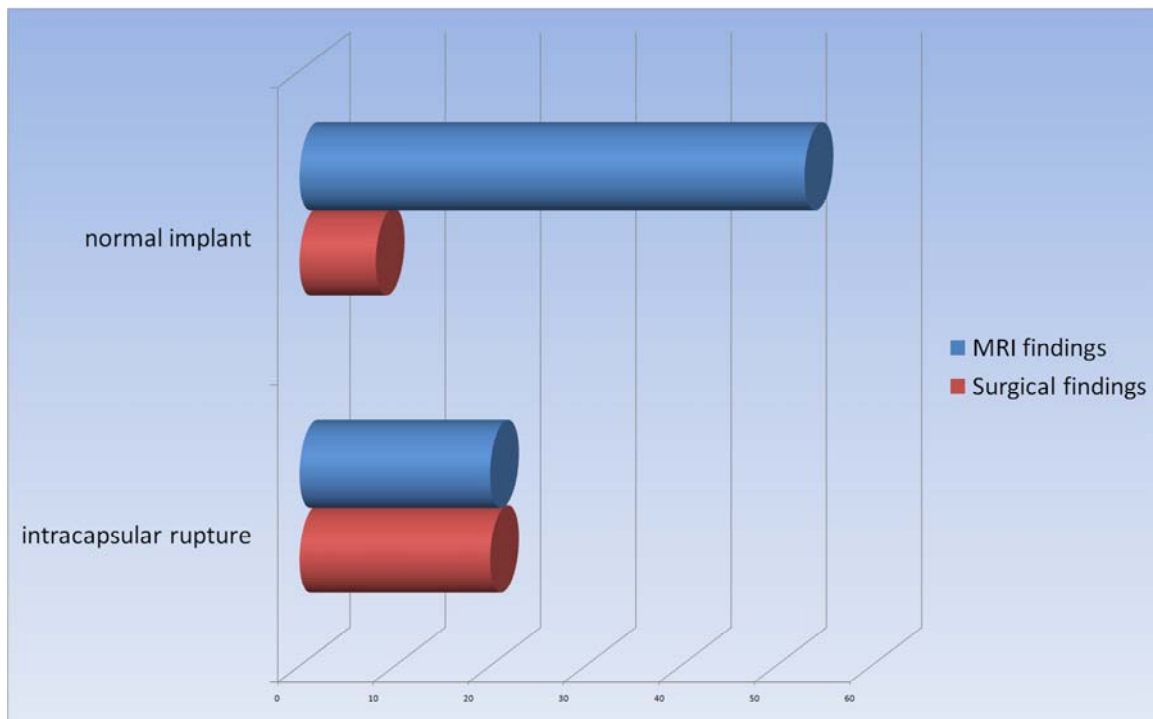
In fact intracapsular rupture, that is frequent but often clinically silent, cannot be easily detected, for example, by mammography because of the radiopacity of the implant, and by ultrasonography because of the presence of nonspecific echographic signs such as the discontinuous echogenic lines. The utility of MRI seems to reside in better detection of intracapsular rupture because it can reveal shell fragments floating inside the implant (linguine sign). Further studies with a prospective design, evaluating a possible diagnostic algorithm based whether the patient has had breast augmentation or breast reconstruction and

including whether implants are mono or bilumen and whether or not there is capsular contracture, may be the areas of fruitful future research.

### Conclusions

From the results obtained from the evaluation of the efficacy of magnetic resonance imaging in the detection of breast implant rupture among an asymptomatic population, it can be concluded that MRI with a dedicated breast coil had the highest sensitivity, while the specificity was similar to other methods like ultrasonography or mammography.

The examination must include pictures in two planes and silicone specific sequences to look for extracapsular silicone. Evaluation should be based on presence of well-defined rupture criteria of which linguine sign and subcapsular lines are certain signs of rupture. Teardrop and keyhole/ noose sign are indicative of rupture, but we suggest that these signs should be seen in more than one picture and preferably in two planes to be diagnostic, and if discrete can be seen in intact implants only suffering from gel-bleed. Specific caution



**Fig. 3:** Comparison between MRI findings with surgical ones: only 28 underwent surgical explanation of breast implants: all 20 patients with suspected intracapsular rupture diagnosed by MRI and 8 for other reasons (breast augmentation, complications like implant exposure, etc). All 20 intracapsular ruptures were confirmed by surgical findings (100%) while the other 8 implants were normal (according to MRI results).

should be exerted when examining and evaluating double lumen implants.

According to Samuels et al. (4) in the breast implant evaluation clinical examination, MG and ultrasound can be used as the first examination in the follow-up of symptomatic and asymptomatic patients. MRI is the most sensitive technique and its utility seems to reside in better detection of intracapsular rupture and investigation of auspicious imaging findings at mammography and ultrasonography.

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### VALUTAZIONE DELLA ROTTURA INTRACAPSULARE DELLE PROTESI MAMMARIE IN SILICONE TRAMITE RISONANZA MAGNETICA IN PAZIENTI ASINTOMATICI E CORRELAZIONI CON I RISCONTRI CHIRURGICI

La vera incidenza di rottura di protesi è spesso difficile da stabilire. Spesso tale rottura è asintomatica perché il silicone rimane all'interno della capsula fibrosa che circonda l'impianto. Per questo la diagnosi di rottura si basa solamente sull'utilizzo di tecniche di diagnostica per immagini. Lo scopo di questo studio è valutare l'efficacia della risonanza magnetica (MRI) nel riscontrare le rotture protesiche e di correlare tali risultati con quelli chirurgici. Le pazienti erano 73 donne tra i 30 e i 69 anni. Alla MRI abbiamo riscontrato 20 rotture intracapsulari, nessuna rottura extracapsulare e 53 protesi integre. Il riscontro chirurgico più importante è stato la presenza di 20 rotture intracapsulari preventivamente diagnosticate mediante MRI. In questo studio abbiamo riscontrato che la risonanza magnetica ha diagnosticato le rotture intracapsulari con un'alta sensibilità e anche con una migliore specificità rispetto ad altre metodiche.

**Parole chiave:** mammella, protesi mammaria, rottura, RMN, linee guide pratiche.

CAPSULA EBURNEA, 5(19):111-115, 2010

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