## Safety & imaging of modern silicone breast implants

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# CHAPTER 4 ADDENDUM II

## Correspondence
## the Poly Implant Prothèse Debacle & Reply

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# ADDENDUM II, CHAPTER 4

**Sir:**

Having just published the results of our own 6- to 11-year Poly Implant Prothèse recall study[1], we read the article by Maijers and Niessen with great interest and congratulate them on their efforts.[2] In many respects, the two series are complementary and provide useful evidence-based medicine at a time where little is available for both surgeons and patients. There are, however, several observations we would like to make.

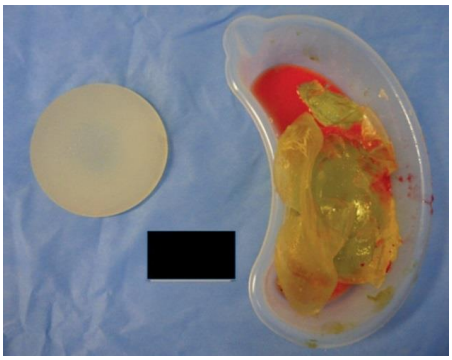

**Figure 1**. A pair of explanted Poly Implant Prothèse implants inserted in 2008 in the submuscular plane in which ultrasonography had diagnosed an otherwise asymptomatic rupture. As can be seen, surgical exploration revealed both complete elastomer disintegration and filler gel discoloration (on the right).

The authors' statement that "case reports have shown an unexpected high prevalence of rupture" is inaccurate on two counts. Although the first objection may be predominantly semantic—individual events cannot possibly produce any conclusions about prevalence—the latter should be corrected, as the original author expressed his concern not solely that an early rupture had occurred but importantly that the nature of elastomeric disruption was unusually extensive.[3] Many of us have now become familiar with such disintegration, as shown in Figure 1. The senior author of our own series had come to a similar conclusion independently and abandoned Poly Implant Prothèse implants for breast augmentation 2 years earlier. Recently, the British government's report of the Medicines and Healthcare products Regulatory Agency management of the Poly Implant Prothèse implant debacle was issued and it documents the "official" rupture rate— 0.28 percent overall— based on reported ruptures (Table 1).[4] However, it provides an underestimate and, in this case, one that Poly Implant Prothèse managed to exploit for years.

**Table 1. Annual Ruptures as Reported to the MHRA Compared with Sales***

| Year | Ruptures (%) | Sales |
|---|---|---|
| 2001 | 0 | 4575 |
| 2002 | 5 (0.11) | 4461 |
| 2003 | 2 (0.03) | 6168 |
| 2004 | 10 (0.06) | 16,639 |
| 2005 | 8 (0.06) | 12,844 |
| 2006 | 10 (0.11) | 9030 |
| 2007 | 46 (0.51) | 9042 |
| 2008 | 68 (0.05) | 12,875 |
| 2009 | 91 (1.05) | 8678 |
| Total | 240 (0.28) | 84,312 |

*MHRA, Medicines and Healthcare products Regulatory Agency.*Modified from Department of Health. Poly Implant Prothèse silicone breast implants: Review of the actions of the Medicines and Healthcare products Regulatory Agency (MHRA) and Department of Health. Available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_134043.pdf. Acce- ssed June 22, 2012.*

The reported study, which arrives at a conclusion similar to our own, differs in some important aspects. First, different planes were used and, although it is not explicitly stated, the reader is left unsure of whether a variety of techniques and

surgeons were used. Unfortunately, this introduces additional dimensions of bias. Presentation of the data is perhaps somewhat confusing, but if we have extrapolated correctly, of the 475 (or 474 according to the flowchart in Fig. 1) patients, only 364 (129 in 2000 and 235 in 2001) were confirmed to have Poly Implant Prothèse devices. If 112 presented for magnetic resonance imaging, only 30.7 percent of the study were investigated, and one is left to speculate about the remaining majority, which contributes further to selection bias.

**Table 2. Comparison of the Two Studies**

| | Berry and Stanek | Maijers and Niessen |
|---|---|---|
| **No.** | 453 | 364 |
| **Single surgeon** | Yes | NS |
| **Single technique** | Yes | NS |
| **Reviewed** | 213 (47%) | 112 (30.8%) |
| **Follow-up** | 6–11 | 10 |
| **Rupture by patient** | 15.9–33.8% | — |
| **Rupture by implant** | — | 7.4*–24% |
| **Surgical confirmation** | 115 (25.4%) | — |

*NS, not specified, *Extrapolated from data*

It is, of course, well known that breast augmentation patients are a difficult group to survey in the long term[5] and initially we too experienced a high (40 percent) level of noncontactability. One advantage of the media frenzy in January of 2012 has been an improvement in our follow-up to over 70 percent. In addition, in excess of 120 patients have reattended and upgraded their status. In recognition of this incomplete data capture, we presented our rupture prevalence as a range: the "best" assumes that all ruptures have been identified and the nonattenders have no ruptured implants. Conversely, the "worst" scenario assumes that attenders are representative of the population as a whole. The figure by Maijers and Niessen of 24.1 percent is therefore an example of the latter, but the true figure is likely to lie somewhere between the two extremes. As Table 2 shows, a comparison of the two studies, methodologic details aside, yields similar rupture prevalences.

In the study of integrity of any implanted device, diagnostic test accuracy is paramount. Although magnetic resonance imaging has been long accepted as the best noninvasive modality,[6] its accuracy has recently been called into question,[7] and the criterion standard remains surgical exploration. Pure explantation studies will, by their very nature, overestimate rupture frequencies; thus, longitudinal studies remain highly desirable. Such challenges are highlighted in our initial analysis, which achieved surgical confirmation in 28 percent of our cohort. Our ongoing postpublicity analysis has, however, increased this figure toward 50 percent and will be published in due course.

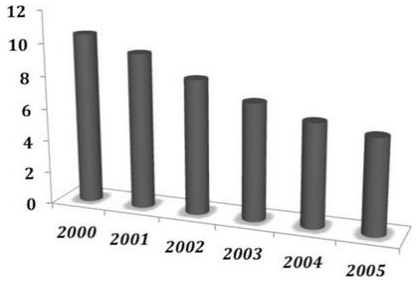


**Figure 2.** Median time to rupture according to year of implantation showing the progressive reduction in longevity with time.

The regulators' original advice to recall only those devices implanted after January of 2001 struck us as illogical and, as with Maijers and Niessen, no differences in rupture rates have been detectable between these two periods. In fact, the Medicines and

Healthcare products Regulatory Agency released further advice to this effect in March of 2012,[8] but the authors' omission is presumably a consequence of the publication process. Closer inspection into the effect of implantation year revealed a surprising temporal relation. With a median time to rupture of 10.5 years in 2000 and 5.8 years in 2005, we now have some evidence to support an impression that Poly Implant Prothèse's implants were becoming progressively less durable (Fig. 2).

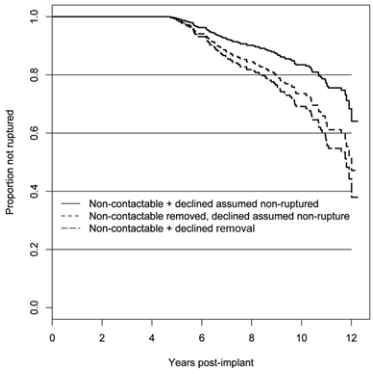


**Figure 3.** Interim Kaplan-Meier charts demonstrating the behavior of Poly Implant Prothèse implants with time.

Although incomplete, an interim Kaplan-Meier survival analysis (Fig. 3) provides further information about the longevity of Poly Implant Prothèse's silicone devices, although we echo the statement that both studies can only specify the point at which rupture has been detected rather than the time it actually occurred.

With 45,000 to 50,000 affected patients in the United Kingdom alone and an estimated 500,000 worldwide, both studies[1,2] report the merest tip of an iceberg that will undoubtedly yield many more studies and occupy the professional attention of aesthetic breast surgeons for some time to come.

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**Sir,**

We have read the letter by Berry and Stanek with great interest and are very pleased to learn that more study groups and private plastic surgeon clinics in Europe have taken up the responsibility of objectively providing data on prevalence and clinical consequences of the recalled silicone implants of the French manufacturer Poly Implant Prothèse. Berry and Stanek are to be congratulated, especially after the discussion in Britain which suggests that the majority of the British private sector was disappointingly failing to take responsibility in follow-up and costs in this Poly Implant Prothèse debacle.[1,2] Although on some points the two studies[3,4] could be called complementary as Berry and Stanek suggest, there are some significant differences we would like to point out and some questions asked we would like to answer.

Prevalence of rupture in silicone implants has been a difficult subject to investigate and to objectify and has been a subject of debate over the last decades.[5] As we admit that case reports alone do not show a higher prevalence of rupture as such they were in fact the first and only published concerns of colleagues that led to the surveillance and investigations of this specific brand and French manufacturer in 2009. Although from 2002 onward surgeons at our own clinic had already decided not to use Poly Implant Prothèse implants anymore for the same reasons the senior author of the series of Berry abandoned this brand 3 years later, no studies or publications have followed to address the quality concerns about PIP implants, until the recall in 2010. The disintegration however, shown in Figure 1 is not specific for a ruptured Poly Implant Prothèse implant but, in our experience, is also seen in silicone implants of other brands.



Our study does come to similar conclusions as the study of Berry, which makes the prevalence of rupture in Poly Implant Prothèse implants even more likely to be close to our findings. The study design, however, is significantly different. Berry and Stanek have focused on the whereabouts and secondary surgery outcomes of 453 patients who underwent implantation with Poly Implant Prothèse implants from 2000 to 2005. Their study is more a descriptive study of known medical history data on these women than a study cohort with the aim of studying the prevalence of rupture and clinical consequences, as our own study is. From their article, it remains unclear how many women exactly had symptoms, underwent physical examination and ultrasound screening to determine ruptured implants status, how many implants were ruptured and whether or not there was extracapsular leakage.

Despite a few exceptions in literature, magnetic resonance imaging is well accepted to be the criterion standard for detecting silicone implant rupture or silicone bleed, especially when looking for “silent” ruptures[6-8]. Our study showed that most Poly Implant Prothèse implant ruptures were in fact asymptomatic intracapsular ruptures. However, some have questioned lately the specificity, and we also found a lower specificity of magnetic resonance screening as discussed in our latest publication. The rationale for using ultrasound screening instead of magnetic resonance imaging screening is an understandable and economical decision, but it now remains difficult to compare Berry and Stanek’s results to magnetic resonance screening rupture prevalence studies.

The calculation of prevalence in Berry and Stanek’s cohort remains a wide assumption and is therefore presented by Berry as a range between 15.9% (when all unknown status patients would have no ruptured implants) and 33.8% (when the known status patients in the cohort are representable for the whole population). We would like to correct Berry and Stanek in the assumption that the worst scenario would be if the group is representable of the population as a whole. The worst would of course be when al

nonattenders and decliners would also have had ruptured implants, either silently or already explanted in other clinics. Thus, if Berry and Stanek would follow their own logic, they would have to present an even greater range. As we decided to offer all our women physical examination and magnetic resonance screening and had no decliners, we were able to have strong data on rupture status of both implants of all included women. We believe the group presented therefore is a good representation of the total group of contacted women and the prevalence of 24% of rupture in Poly Implant Prothèse implants 10 years after implantation time a good estimate of the real prevalence Tabel 1).

Like Berry and Stanek, we had the problem of contacting all women with Poly Implant Prothèse implants, as our follow-up was at least 10 years in contrast to the 6- to 11-year follow-up of Berry and Stanek. Of course, the same phenomenon occurred in our ongoing study as in their practice, and since our publication more women have come forward for follow-up and data are still being collected. Therfore, this media frenzy mentioned by Berry and Stanek did lead to a more recent higher follow-up percentage but also introduced a new sort of bias, in which patients present with other symptoms than before. We will document this phenomenon and the clinical and diagnostic consequences of PIP implants in our next publication.

**Table 1. comparison between 2 studies on PIP implants**

| | Berry & Stanek | Maijers & Niessen |
|---|---|---|
| **Number** | 453 | 364 |
| **Single surgeon** | yes | no |
| **Single technique** | yes | yes |
| **Rupture identified by** | USS | MRI |
| **Reviewed** | 213 (47%) | 112 (30.8%) |
| **Definition of review** | *All had USS? Not possible to extrapolate the 213 "reviewed" from data available in original article* | *All had MRI, physical examination and were interviewed for complaints* |
| **Follow-up (years)** | 6-11 | 10 |
| **Rupture by patient (%)** | 33.8 | 33.0 |
| **Rupture by implant (%)** | - | 24.0 |
| **Surgical confirmation** | 115 (25.4%) | 70 (19.2%) |

The fact that silicone breast implants become progressively less durable, is news as old as silicone rupture studies are and is not typical for Poly Implant Prothèse implants as such. Figure 3 in our opinion therefore sheds no new light to the discussion. In figure 2, Berry and Stanek conclude that the median time to rupture would decline according to implantation year. We would like to remind the authors of the fact that their follow-up time of the implants from 2005 is significantly shorter than that for the implants implanted in 2000. As in our study, the exact timing of rupture is impossible to identify in a retrospective study- the implants from 2000 could have just easily ruptured in 2005, as most ruptures have proven to be silent ones. Therefore, the conclusion that batches from different years would be of different quality is unjust and also not in line with the National Health Service report, which concluded that there is no significant variation between batches[9].

All implantations in 2000 and 2001 were performed in the Jan van Goyen clinic by five different surgeons, all using the same technique through an inframammary incision, a technique still routinely used in Dutch clinics. The position was subglandular in 93 percent, and no differences in rupture prevalence were found between subglandular and submuscular position. Our study is representative for a common Dutch private clinic and will be more comparable to other private practices and to previously published literature on prevalence, as Berry and Stanek noticed too. We believe that in fact a one surgeon series has a greater chance of being biased toward a certain technique and professional expertise, which could result in either a more positive or a more negative view of the real prevalence of rupture.

The regulators' original advice struck us as illogical too, that was exactly the reason why we decided to also recall the implants from 2000, and we are glad that eventually Jean-Claude Mas admitted to the use of the unauthorized gel also before 2001. This was as Berry and Stanek presume after our publication was accepted on February 6, 10 days before their own publication. The aim of our study was to give timely, clear, uncomplicated data from the daily practice of a typical Dutch private clinic which unfortunately happens to have used the feared Poly Implant Prothèse implants for 2 years in 2000 and 2001. We did not aim to be the first independent product recall study in aesthetic breast surgery or even the first independent product study of a medical device, but learned from Berry and Stanek that in fact we are.

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