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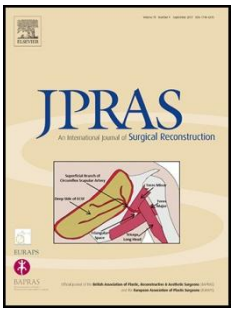

Title: Biodurability of poly implant prothèse (PIP) breast implants: a prospective analysis of 1028 prostheses in 514 patients.

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Biodurability of Poly Implant Prothèse (PIP) Breast Implants: A prospective analysis of 1028 Prostheses in 514 patients.

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Introduction

Poly Implant Prothèse (PIP) was a company that manufactured substandard breast implants using cheaper non-medical grade silicon. Around 40,000 women in the UK are thought to have PIP implants inserted(1). The advice for Women in Wales is: seek clinical advice prior to requesting routine removal. If there is clinical need, the National Health Service (NHS) in Wales funds removal and replacement of PIP breast implants inserted privately. This is in contrast to NHS in England where only PIP implants placed on the NHS are replaced.

The Department of Health estimates the rate of implant rupture or significant silicone bleed for PIP implants could rising to 15-30% after 10 years; whilst other brands demonstrate rupture rates of 10-14% after 10 years. Therefore, making this an important issue to address in terms of outcomes, implant longevity and health economics. We present the largest heterogenous (private and public health services) experience case series of PIP breast implants to date.

Patients & Methods

We performed a prospective cohort study of all Welsh patients requesting assessment of their PIP breast implants between April 2012 and July 2015.

All patients suspected of rupture were offered an ultra-sound scan. All patients with viable concerns of any nature were offered implant removal and replacement. Implant removal +/- replacement was conducted under general anaesthetic by a consultant plastic surgeon. Rupture was defined as a break in the continuity of the implant shell and the presence of implant rupture was documented by the operating surgeon. PIP implants were replaced with the same volume Mentor® MemoryGel® implant.

Binary Logistic Regression analysis was used to determine if symptoms/concerns or rupture was related to patient age, implant size and time to rupture.

Results

646 patients were referred, of which 514 patients attended clinic (80%). The mean implant size was 330cc (Mode 270cc).

Implant rupture was clinically suspected in 46 cases, no scan was requested and surgery was expedited. Of these patients 14 (30%) had a confirmed rupture at surgery. Where there was less clinical suspicion of a rupture, patients were scanned (n=141). 105 underwent Ultrasound (US) scan, 20 MRI, 16 US & MRI. After a scan 80 patients proceeded to have surgical intervention, 49 were discharged, 12 elsewhere.

368 (72%) patients had removal of implants, all but two patients having them exchanged (99.5%). 90 patients had ruptures confirmed (18%) with two bilateral. 33 of these were suspected clinically, 28 were picked up by US and 29 were incidental findings (See Image 1).

There was no statistical correlation (Odds Ratio (95% Confidence interval) between implant rupture and patient age (P=0.94), size of implant (1.0016 (0.976-1.027)), and time to implantation to rupture (1.0246 (0.926 – 1.133)).

Discussion

The rupture rate in this series of PIP implants is 18% (90/514) per patient or 9% (92/1028) per implant. Table 1 extrapolates the published data to give rupture rate per implant and per patient (assuming one rupture per patient). There is an overall rupture rate of 12.2% (661/ 5410) per implant and 20% (636/3165) per patient. These studies measure rupture rates over variable time frames and rely on differing methods to diagnose implant rupture (US, MRI & implant removal). An 11 year rupture rate of 8% using Inamed (Allergan Limited, Marlow, UK) breast implants in 199 implants (2) and 11.8% using Siltex gel implants (Mentor Medical Systems, Santa Barbara, California) by 13 years in 298 implants(3). Both studies diagnosed rupture using MRI. It is clear from these studies that the PIP implants have a similar implant rupture rate (12.2% in our combined series) in half the time.

Our results show a similar rupture rate compared to other studies in the literature, although a slightly lower rate of the combined series. Our rupture rate is based on inspection of the implant at explantation, whereas other studies rely on imaging to detect rupture rate. To some extent this may account for our slightly lower rupture rate. We found no correlation with patient age, implant size, length of implantation time and rupture. This supports the recent paper by Leckenby *et al.* which showed that implant size is not related to the prevalence of implant rupture (4).

Validated data on costs to the NHS for removal +/- replacement is scarce in the literature. A clinical assessment and ultrasound scan costing £300 and implant removal £1200 - £1250 . Additional costs arise from patient follow up and implant replacement.

Conclusion

The experience of PIP implants in a heterogeneous population in Wales, is similar to other studies with regards to overall rupture rate. Our data indicates that the rupture rate is independent of implant size, patient age and length of time from insertion. Our experience of PIP implants raise important questions on quality control of medical devises and strongly supports the recent introduction of a national breast implant registry in the U.K. (5).

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Image 1 – Illustration of clinical outcome

Table 1 – Summary of papers measuring at PIP implant ruptured