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Christopher R. Davis
Matthew Fell
Umraz Khan

Department of Plastic and Reconstructive Surgery,
Frenchay Hospital, Bristol BS16 1LE, United Kingdom

E-mail address: chrisdavis959@hotmail.com

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PIP silicone breast implants



Dear Sir,

We read the Quabas' paper¹ reporting their experience of PIP breast implant management with great interest. The

authors had an enviable high follow up and should be congratulated on providing such robust data at a time of renewed uncertainty as to the long-term safety of PIP's mammary devices.^{2,3}

They kindly reference our preliminary study⁴ and draw attention to the low (9.3%) explantation figure, which initially provoked criticism of our reported rupture rate. The authors will not have been aware of our recently accepted update,⁵ but we are pleased that another large series has drawn similar conclusions about the PIP implant. Whilst a summary comparison (Table 1) evidences our improved recall and confirmation, we remain an order of magnitude in arrears. Their very high recall, perhaps reflecting the benefits of a large company, in this case Spire Healthcare, that both proactively sought patients and underwrote all costs.

There are several noteworthy observations: the first that there are now three sizeable studies, with slightly different methodologies, yielding similar rupture prevalences. The Quabas' explantation, our own intention-to-treat and Majiers et al.'s MRI study.⁶ The second being the quantum improvement in the accuracy of ultrasound scan (USS) lately. Whilst we have all experienced examples of catastrophic PIP elastomer disintegration, and concur that such ruptures are easy to spot sonographically,⁷ it is not our experience that this is universal so USS appears to a recommendable first line investigation. Thirdly, although the trial is in progress in Marseille at the time of writing, the alleged perpetrators have yet to assist with any detailed information so it is reassuring that our original finding of reducing implant durability with time has been corroborated. As with Quaba, prostheses implanted in the year 2000 fared no differently to their contemporaries, however, by 2005 median time-to-rupture had almost halved from 10.5 to 5.8 years. Finally, despite the huge amount of negative media coverage over the past 3 years, a

Table 1 Summary of three main PIP rupture studies.

	Quaba ¹ (%)	Stanek 1 ⁴ (%)	Majiers ⁶ (%)	Stanek 2 ⁵ (%)
Number	429	463	112	460
Study period	1999–2007	2000–2005	2000–2001	2000–2005
Study	Explantation	ITT	MRI	ITT
Explanted	283 (66)	42 (9.3)	0	163 (35.4)
Rupture (patient)	35.2%	15.9–33.8%	33%	See below
Uncontactable	55 (12.8)	180 (39.7)	ns	126 (27.4)
Treatment elsewhere	12 (2.8)	19 (4.2)	–	25 (5.4)
Awaiting	79 (18.4)	39 (8.6)	–	32 (7)
Explantation alone	5 (1.5)	–	n/a	5 (3.1)
USS – sensitivity	91%	–	n/a	97.3
USS – specificity	96%	–	n/a	93.1
Temporal decline	Yes	Yes	n/a	–
10-yr rupture	ns	–	24%	19–40%
Comments	• All funded • Higher rupture submuscular • Some technique heterogeneity	–	• No difference subglandular vs. submuscular	• Treatment at cost • Occult rupture in 31.6%

Key: ITT = intention to treat; MRI = magnetic resonance imaging; ns = not specified.