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The role of ultrasound imaging in the diagnosis of breast implant rupture: a prospective study

J. C. Liston, C. M. Malata, S. Varma, M. Scott and D. T. Sharpe

Departments of Radiology and Plastic Surgery, St Luke's Hospital, Bradford and Plastic Surgery & Burns Research Unit, University of Bradford, Bradford, UK

SUMMARY. **Breast ultrasound to assess possible implant rupture was performed on 24 consecutive patients (43 breasts) by the same radiologist immediately before revisional breast implant surgery. Comparison of the clinical, ultrasound and operative findings showed ultrasound to be three times as sensitive as clinical judgement in predicting implant rupture. The sensitivity of ultrasound in predicting impaired implant integrity was 70% (versus 23% for clinical examination) with a specificity of 96%. The ultrasound features indicating leakage are outlined later. The positive predictive value of an abnormal scan was 90% and that of a normal scan 87%. It is concluded that breast ultrasound is a simple, quick, non-invasive method which contributes significantly to the assessment of patients with suspected breast implant rupture.**

One of the major safety concerns about silicone breast implants is their long term durability and possible rupture *in situ*. Breast implant rupture is often asymptomatic and its incidence in the general breast implant recipient population is unknown. Although an accurate estimate can be obtained by surgical exploration of a large number of randomly selected breast implant recipients this is clearly not a feasible proposition. There is therefore a need for a safe, cheap, reliable and non-invasive method of detecting breast implant rupture. The availability of such a technique may also provide some of the long term safety data on silicone breast implants. The clinical and mammographic diagnosis of breast implant rupture remains difficult especially when the rupture is intra-capsular.[1–4] Magnetic resonance imaging,[5–7] and computerized tomography[8] are expensive and not widely available. There have been reports of the use of ultrasound to detect implant rupture[9–16] but, apart from De Bruhl's *et al.*[9], there has been no large prospective study correlating the results of ultrasound with the operative findings.

Patients and methods

Breast implant integrity was assessed preoperatively both clinically and ultrasonically. The results were then compared with the operative findings. During an 11-month period (January–November, 1992) 30 patients (age range: 25–60 years; mean: 39.7 years) who were undergoing revisional breast implant surgery—23 for unacceptable capsular contracture (Baker III and IV),[17] 5 for suspected implant rupture and 2 for unresolved implant-induced anxiety—were examined. The majority of the implants (27) had been inserted for aesthetic augmentation, 2 followed subcutaneous mastectomies and one was for the correction of congenital breast asymmetry. After an initial pilot study of 6 patients, the remaining 24 patients (43 breasts) were included in the study. Ultrasound was performed immediately preoperatively by the same radiologist using a 5 megaHz curvi-linear probe (*Aloka 650 SSD scanner*, Keymed Ltd, Southend-on-Sea, UK). The results were then correlated with the operative findings. All patients were operated on by one surgical team.

Results

All the breasts explored had smooth silicone gel-filled prostheses except one patient who had saline prostheses. The condition of the implants at operation and descriptions of the silicone gel leakage encountered are summarised in Table 1.

The ultrasound features studied were: (1) Implant outline i.e., regular or irregular (Figs 1 and 2); (2) The presence or absence of echogenic material within the prosthesis (Fig. 2)—later in the study, if only linear echoes (Fig. 3) were seen assessment was made as to whether they extended across the entire length of the prosthesis; (3) Presence or absence of hypoechoic masses adjacent to prosthesis.

Of the 43 breasts in the main study (Fig. 4), 31 implants were reported to be intact, gel leak was identified in 10, and the scan findings were indeterminate in 2 breasts. A detailed analysis of the

Table 1 Condition of implants at operation

Condition of implant/Type of leakage	*Number of implants*
Localised deficiency of shell (small/confined/contained leak)	6
Complete disintegration of implant (gross leakage)	7
Intact	30

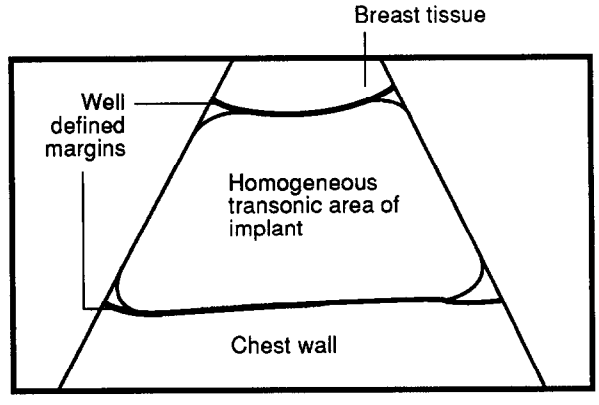

Fig. 1

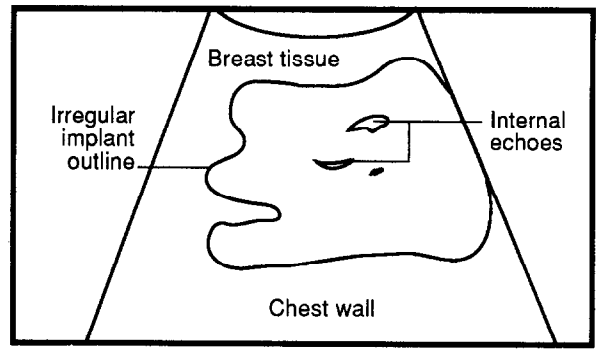

Fig. 2

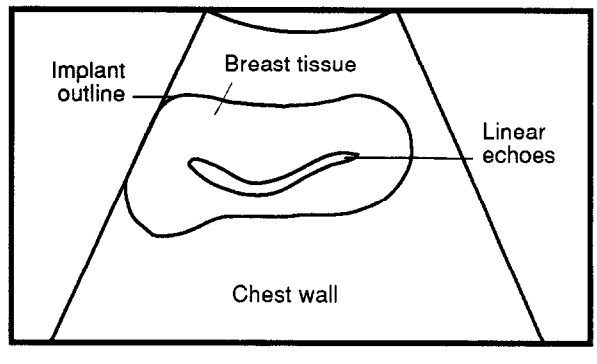

Fig. 3

Figure 1—U/S scan showing a well defined transonic intact implant. **Figure 2**—U/S scan showing a ruptured prosthesis with irregular outline and containing internal echoes. **Figure 3**—U/S scan showing an intact prosthesis containing linear echoes due to infolding.

ultrasound findings is shown in Table 2. In summary, the ultrasound findings were as follows: (a) 24 transonic well defined prostheses were found to be intact at surgery; (b) 2 transonic well defined prostheses were found to have localised leaks at surgery; (c) 2 transonic well defined prostheses were found to have disintegrated at surgery; (d) All 9 irregular prostheses containing echogenic material were found to have disintegrated or leaked at surgery; (e) All 4 prostheses with regular outlines but containing linear echoes only extending part of the way across the prosthesis were found to be intact at surgery. (One of these cases early in the study was incorrectly ultrasonically diagnosed as having leaked); (f) 2 prostheses with a regular outline but containing a focal collection of echogenic material were found to be intact at surgery. (One of these was a saline prosthesis).

Masses adjacent to the prosthesis were found in one breast only (case number 22, right breast). Two transonic masses were identified, one 1.8 cm in diameter and the other 1.3 cm. Biopsy showed one to contain silicone and the other to be a simple breast cyst.

Correlations of the operative findings to the clinical and ultrasonic diagnoses are shown in Tables 3 and 4. Of the 13 surgically confirmed leaks (Fig. 5), 9 were correctly identified on ultrasound giving a sensitivity of detecting prosthetic leakage of 70% (9/13). This is three times the clinical pickup rate of 23% (3/13). Furthermore the positive predictive value of an abnormal scan in the study was 90% (9/9+1) and that of a normal scan was 87% (27/27+4). Assessment of the 4 false negative ultrasound scan patients at surgery (Fig. 5) revealed that two implants had localised leaks while the other two had gross leaks with disintegration of the implants.

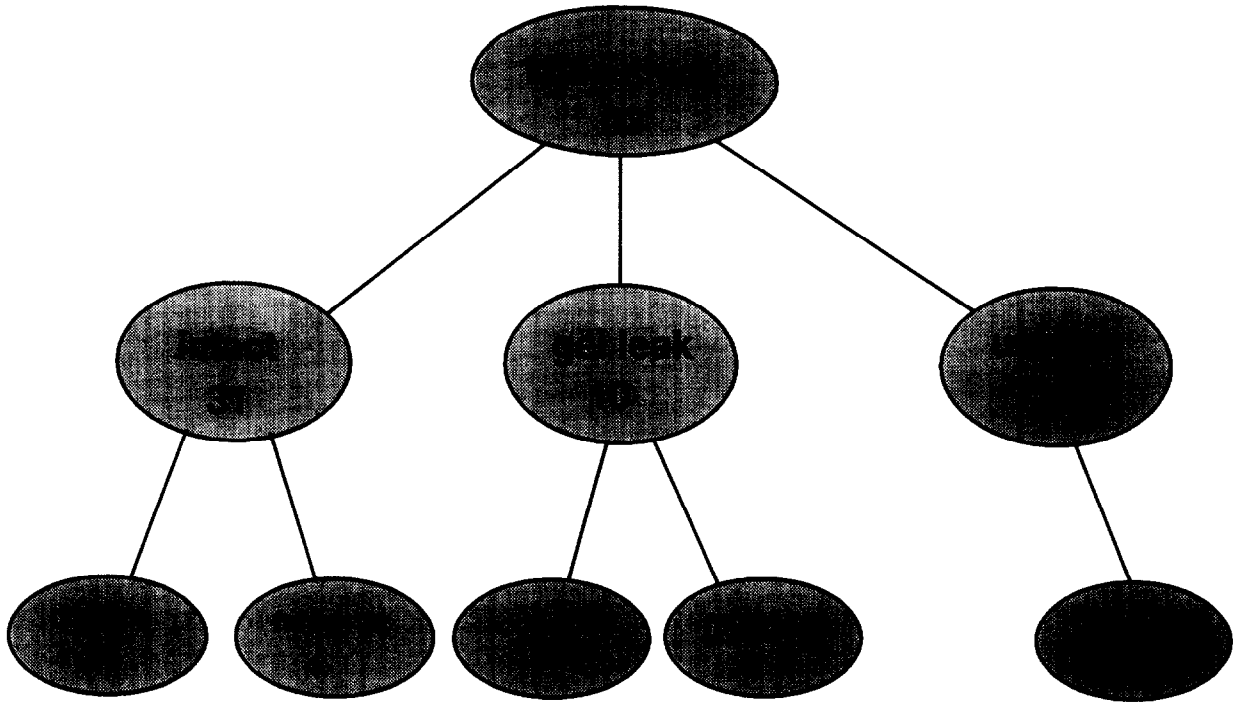

Fig. 4

Figure 4—Flow chart of the main ultrasonic findings.

Discussion

Although there are now a number of reports of the use of breast ultrasound to detect implant rupture, this study is one the first to evaluate prospectively the role of ultrasound in the assessment of breast implant integrity. The first report of the systematic use of breast ultrasound in the diagnosis of breast implant-related complications was by van Wingerden and van Staden in 1989.[16] Subsequently Levine and Collins successfully used it to detect 14 implant ruptures, 2 of which were asymptomatic.[12] Rosculet *et al.* retrospectively correlated sonographic and mammographic appearances with surgical findings in 16 patients with 19 ruptured silicone gel implants (from 2 hospitals) and radiologically confirmed the operative findings in 17 cases.[14] Following their retrospective review of 133 patients carried out to establish the normal radiographic appearances of various types of implants and the range of normal variations and to detect true implant complications, Gannot *et al.* recommended the complementary use of ultrasound and X-ray mammography for the evaluation of suspected silicone implant rupture.[18]

Of the ultrasonographic findings said to be useful in diagnosing breast implant rupture,[9–16,18] irregularity of implant outline and the presence of echogenic material within the prosthesis were found to be reliable indicators of prosthetic leakage in the present study. The pathogenesis of internal echoes is unclear—they may be due to alteration in the nature or composition of the gel, i.e. gel differentiation, or may represent the envelope crumpled up within extruded gel. Difficulties in interpretation may arise in prostheses with regular outlines but with focal echogenic material or linear echoes. If the latter extend only a short distance from the implant margin they are thought to represent infolding of the prosthesis and are not usually indicative of rupture, although differentiation may be difficult.

Unlike van Wingerden and van Staden[16] we did not find the reduction in the antero-posterior diameter of the implant to be useful in the diagnosis of breast implant rupture, except in the one patient with a spontaneously deflated saline prosthesis which was clinically apparent anyway. Rosculet *et al.* also concluded that the antero-posterior diameter was of little value in assessing implant integrity.[14]

Extrinsic collections of silicone appear as hypoechoic masses adjacent to the characteristic transonic area of the prosthesis and in our experience cannot be differentiated from breast cysts. Such hypoechoeic masses may also represent a bulge or herniation of the implant rather than a separate silicone collection.[11]

Even on retrospective analysis of the scans none of the cases in this study demonstrated the sonographic sign of echogenic confusion or "snow storm" as described by Harris *et al.*[10,11] and Rosculet *et al.*[14] and alluded to by Levine and Collins.[12] This may be because even in the cases in this study where the prosthesis had completely disintegrated none had diffuse extra-capsular spread of silicone into the tissues. (The snow storm appearance occurs only if silicone leaks into the tissues and the "inflammatory" response to the silicone breaks it up into microscopic droplets leading to multiple accoustic interfaces between the globules of silicone and the surrounding tissues which strongly reflect ultrasound waves).[10]

DeBruhl *et al.*,[9] in a series of 28 patients who had surgical exploration of their scanned prostheses, reported a 70% sensitivity for detecting implant rupture with ultrasound which is identical to our findings.

Table 2 Details of the ultrasonic features found (n = 43 breasts)

Patient no.♣		*Well defined prosthesis*	*Irregular prosthetic outline*	*Transonic prosthesis*	*Prosthesis with internal echoes*	*Ultrasound diagnosis*	*Operative findings*
7	Rt	+		+		N	I
	Lt	+			+*	evidence of leakage	I
8	Rt	+		+		N	I
	Lt	+		+		N	I
9	Rt	+		+		N	I
	Lt	+		+		N	I
10	Rt		+		+	evidence of leakage	prosthetic disintegration
	Lt	+		+		N	I
11	Rt	+		+		N	I
	Lt	+		+		N	I
12	Rt	+		+		N	I
	Lt	+		+		N	intracapsular leak
13	Rt	+		+		N	I
	Lt	+		+		N	I
14	Rt		+		+	evidence of leakage	prosthetic disintegration
	Lt		+		+	evidence of leakage	prosthetic disintegration
15	Rt	+		+		N	I
	Lt	+		+		N	I
16	Lt	+		+		N	prosthetic disintegration
17	Rt	+		+		N	I
	Lt		+		+	evidence of leakage	prosthetic disintegration
18	Rt	+		+		N	prosthetic disintegration
	Lt	+		+		N	I
19	Rt	+		+		N	I
20	Rt	+		+		N	I
	Lt	+		+		N	I
21	Rt	+		+		N	I
	Lt	+		+		N	I
22	Rt		+		+	evidence of leakage	prosthetic disintegration
	Lt		+		+	evidence of leakage	prosthetic leakage
23	Rt	+			+	?leak	I
	Lt		+		+	evidence of leakage	prosthetic leakage
24	Lt	+		+		N	I
25	Rt	+			+*	N	I
	Lt	+			+*	N	I
26	Rt	+		+		N	I
	Lt	+			+	?leak	I
27	Rt	+		+		N	I
	Lt	+		+		N	I
28	Lt	+		+		N	I
29	Rt		+		+	evidence of leakage	prosthetic disintegration
30	Rt		+		+	evidence of leakage	prosthetic disintegration
	Lt	+	+*			N	I

Key. ♣ = patient serial number; Rt = right breast, Lt = left breast; * = linear echoes; N = normal; I = intact prosthesis.

Table 3 Comparison of clinical and operative findings

	Clinical evidence of rupture	*Clinically intact*	*Total breasts*
Surgically confirmed rupture	3	10	13
Surgically intact	0	30	30
Totals	3	40	43

Their positive and negative predictive values for rupture of 82% and 85% respectively are comparable but lower than those obtained in the present study.

Our four false negatives (Fig. 5) were equally distributed between localised (contained) leaks and gross leaks (resulting from disintegration of breast implant shells). [This is similar to the findings of Peters and Pugash[13] if the latter's findings of "profound

Table 4 Comparison of ultrasound and operative findings

	U/S evidence of leak	*Normal U/S*	*Indeterminate U/S*	*Total breasts*
Surgically confirmed rupture	9	4	0	13*
Surgically intact	1	27	2	30
Totals	10	31	2	43

* Complete disintegration of prosthesis (7 breasts); small confined leak (6 breasts).

silicone gel bleed" represented localised leaks due to occult ruptures]. These 4 breasts were all scanned in the early part of the series highlighting the importance of a learning curve.[10,11,18] It should also be noted that the use of a pilot study to establish the ultrasound criteria of implant rupture prior to the main study is not unique to the present series.[9]

X-ray mammography has also been used to evaluate breast implant integrity[1–4,8,18–21] but it was found to be unreliable when the silicone was contained within the capsule.[1–4] An overall sensitivity of 67% using X-ray mammography was reported by Andersen *et al.*[19] which compares well with our result of 70% as all the silicone leaks in our study were contained within the capsule. Magnetic resonance imaging[5–7] has been reported to have a sensitivity for detecting implant rupture of 76%[6] but it is expensive and not widely available. Ultrasound, like MRI, is especially well suited for evaluating implant rupture in the younger breast augmentation patients, for whom it has been argued that repeated breast irradiation by X-ray mammography should be avoided because of the theoretical risk of carcinoma.[22]

Ultrasound diagnosis of an intact prosthesis is unlikely to alter the management of the augmented breast with capsular contracture but could conceivably be used to avoid operative intervention in patients with only mild symptoms and to reassure a patient with implant-induced anxiety. An abnormal scan, on the other hand, may be used to prioritise symptomatic patients for revisional breast implant surgery. Prior confirmation by ultrasonography that a breast about to be explored contains a ruptured implant can aid surgical planning by identifying patients in whom extracapsular excision of a ruptured implant would be appropriate, thus avoiding or minimising soiling of the tissues and the operative field with silicone gel.

Conclusion

It is concluded from this prospective study that, after the initial learning curve, ultrasound is a quick and reliable technique for the assessment of possible implant rupture and should be an integral part of the clinical assessment of augmented breasts. A normal ultrasonic scan may be used to reassure an anxious patient that their implant is intact with a confidence level of 87%.

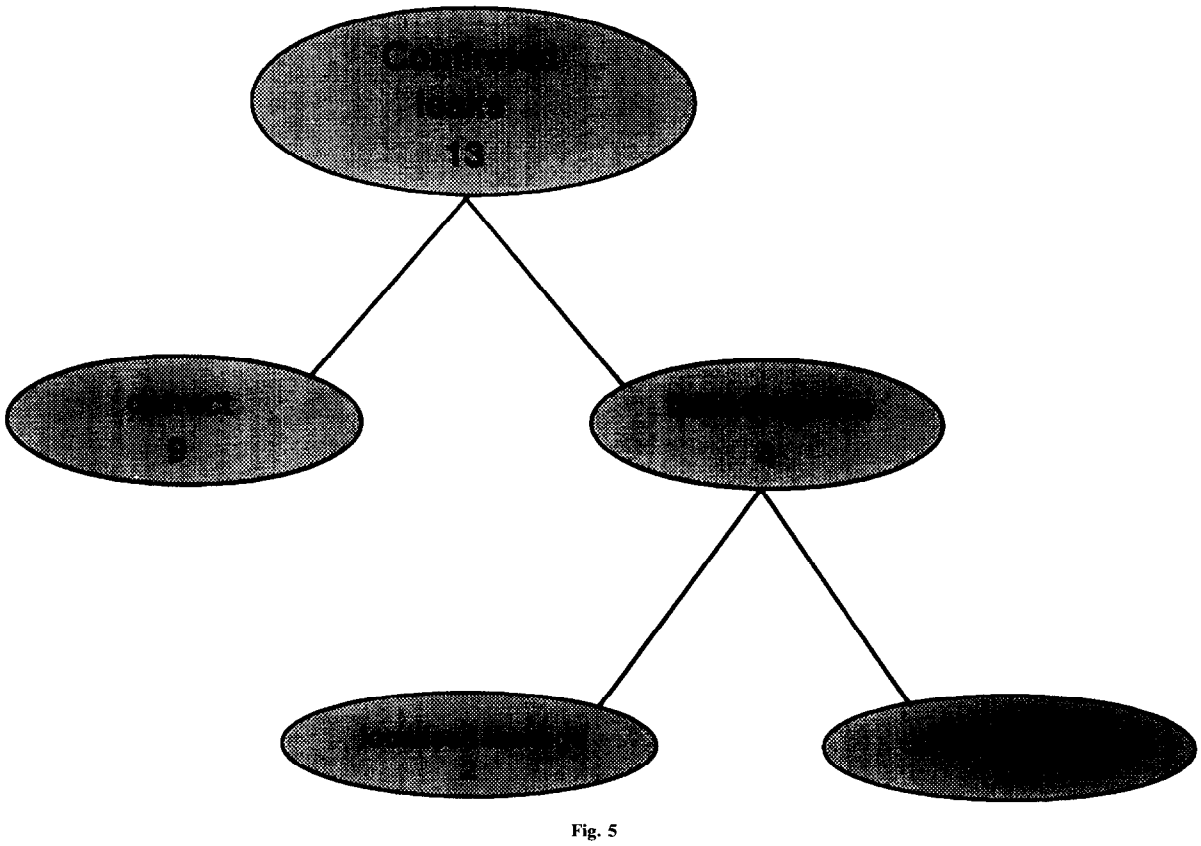

Fig. 5

Figure 5—Flow chart depiction of the operative and U/S findings in the surgically confirmed ruptured implants.

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The Authors

J. C. Liston, MBBS, DMRD, FRCR, Consultant Radiologist
C. M. Malata Bsc, MBChB, LRCP, MRCS, FRCS(Glasg), Research Registrar, Plastic Surgery and Burns Research Unit, University of Bradford
S. Varma, MBBS, MS, FRCS(Plast), Senior Registrar in Plastic Surgery
M. Scott, MBBS, FRCS, Registrar in Plastic Surgery
D. T. Sharpe, OBE, MA, FRCS, Consultant Plastic Surgeon,
St Luke's Hospital, Bradford.

Address for reprints to Dr J. C. Liston, Consultant Radiologist, St Luke's Hospital, Bradford, West Yorkshire, BD5 0NA, UK.

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