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Plane Change Vs Capsulotomy: A Comparison of Treatments for Capsular Contraction in Breast Augmentation Using the Subfascial Plane

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Abstract

Background The management of capsular contraction following breast augmentation has numerous, often conflicting potential treatment protocols, each designed to reduce the incidence of further recurrence. The use of the subfascial plane has not been investigated as an alternative to other treatment options.

Objectives To examine the outcomes from patients presenting with recurrent capsular contraction after being treated for the first capsule by placement of an implant into the subfascial (SF) plane.

Methods Retrospective analysis of 111 case notes of patients who presented with capsular contraction. 65 had undergone SF augmentation, 17 submuscular (SM) and 29 subglandular (SG) placement of implant at the primary procedure. At a secondary procedure, those with SF implants underwent open capsulotomy and those with SM and SG implants underwent a change in plane to SF.

Results There is a significant difference in the proportion of patients that developed a capsule following the second surgery between the groups that had undergone capsulotomy (SF = 16.9%) or plane change (SM = 47% and SG = 37.9%, X^2 (2,111) = 8.6, P = 0.02). When recurrence at the same site was examined, there was also a significant difference between the groups (X^2 (2111) = 10.7, $P < 0.01$). A ruptured implant significantly increased the incidence of further capsular contraction when in the SG plane (X^2 (2,29) = 12.1, $P < 0.01$).

Conclusions In the absence of implant rupture, changing the plane of an implant to a SF position at revision surgery does not reduce the incidence of subsequent capsular contracture compared with open capsulotomy. Open capsulotomy is a reasonable choice following recurrence of capsular contraction following initial SF placement.

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Introduction

Capsular contraction is one of the commonest reasons for revisional surgery following breast augmentation. There are multiple theories concerning its aetiology which have formed the rationale behind the treatment choices; namely capsulectomy, capsulotomy and changing plane of implantation, all with or without changing the implant [1]. Those who favour a biofilm or infective theory for development of capsules champion the use of capsulectomy with a site change, although there is little evidence for that approach [2–5].

There is little good evidence for one treatment protocol over another, given that there are multiple variables regarding the method of surgery and type of implant used.

This study examines the use of capsulotomy compared with a change to the SF plane in patients presenting with established capsular contraction in whom the implant was placed initially in one of three planes (subglandular, subfascial or submuscular) at the time of the primary procedure.

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Methods

Study Design

Patients who presented for treatment of capsular contraction following breast augmentation between January 2008 and 2018 were included in this study. Those patients who required additional treatment other that addressing the capsule (such as mastopexy) were excluded from the study.

Patients were divided into three groups (Fig. 1). A cohort had undergone previous subfascial (SF) breast augmentation by the author using a technique previously described [6].

Patients provided written consent to the study under the guiding principles outlines in the WMA Declaration of HELSINKI concerning ethical principles for medical research involving human subjects.

Surgery

Those that had either submuscular (SM) or subglandular (SG) implants underwent removal via an inframammary crease incision. The pocket was irrigated with dilute aqueous Betadine and wiped dry before closing with 3/0 Vicryl. A new SF pocket was created for the second implant. Patients who had undergone SF augmentation as the primary procedure underwent circumferential capsulotomy with radial incisions through the lower half of the capsule when necessary. All implants were replaced at the second surgical procedure.

In all cases implants were silicone, textured and from one manufacturer (Nagor Ltd, Cumbernauld, UK).

Patient was subsequently followed up prospectively, and the end point of the study taken when a third procedure was undertaken for recurrent capsular contraction if necessary.

Statistical Analysis

A Chi square test was employed to compare categorical data and a Kruskal-Wallis (one-way ANOVA) to examine differences in continuous data between groups. Statistical significance was taken as a P value of less than 0.05 in all cases.

Results

Population

A total of 111 patients were included in the study (mean age 32.2 years, range 18–58, SD = 9.6). The implants removed at the second operation (first revision) had a mean volume of 395 cc (range 200–705, SD = 92) and that used at the second operation 426 cc (range 240–655 cc, SD = 89.8).

There were 29 SG (26.1%), 65 SF (58.6%) and 17 SM (15.3%) placed implants in the study. The author had undertaken 71 (64%) of the primary procedures, which included all SF placements with 6 SG implants. The remaining 40 cases were performed by other surgeons and included all SM implants.

Recurrence Rates (Table 1)

Sixty-five patients underwent capsulotomy following initial SF placement and 11 (16.9%) subsequently reformed a capsule in either the same or different site. Nine (13.8%) were recurrent in the same site.

Of the 17 patients who initially underwent SM placement and were changed to SF plane, 8 (47.0%)

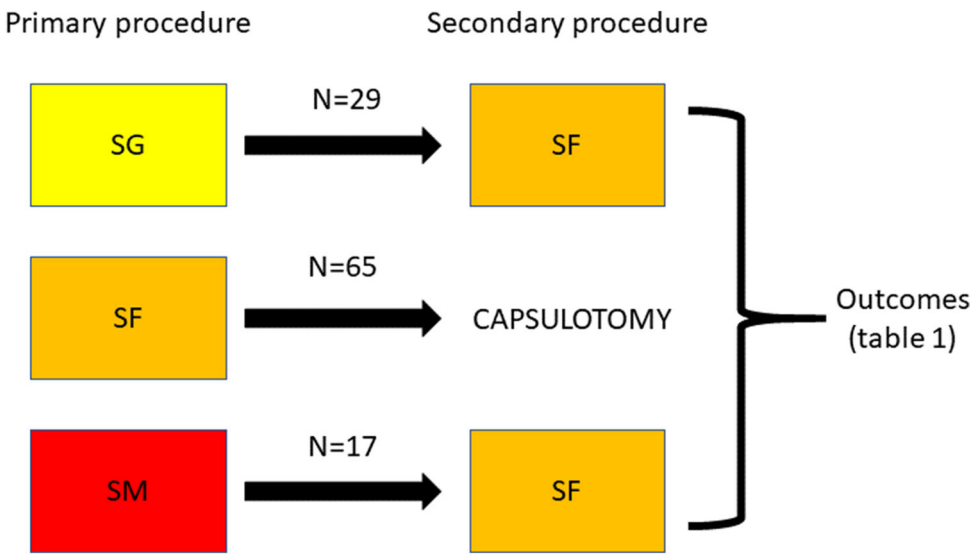

Fig. 1 Study design

Table 1 Population of patients included in study

		Age (years)	Volume 1st implant (cc)	Time to first capsule (months)	Volume 2nd implant (cc)	Time to second capsule (months)
SG (n=29)	Minimum	20.0	200	14.0	240	2.0
	Maximum	50.0	470	542.0	620	124.0
	Mean	28.8	325	177.2	439	43.7
	Standard deviation	6.9	85	141.0	90	36.4
SF (n=65)	Minimum	18.0	275	3.0	235	1.0
	Maximum	58.0	705	138.0	655	72.0
	Mean	33.6	419	48.0	409	23.0
	Standard deviation	10.6	86	39.0	95	21.7
SM (n=17)	Minimum	20.0	270	25.0	240	2.0
	Maximum	55.0	425	362.0	620	103.0
	Mean	32.8	331	143.9	441	37.7
	Standard deviation	8.8	52	94.0	120	32.1
	p	0.14	$< .01$	$< .01$	0.26	0.55

P values from Kruskal-Wallis (one-way ANOVA) test. Significance taken AS $P < .01$

subsequently developed a recurrent capsular contraction, of which 5 (29.4%) were recurrent in the same site.

Of the 29 patients who initially underwent SG placement and were changed to SF plane, 11 patients (37.9%) subsequently develop a recurrent capsular contraction of which 6 (21.0%) were recurrent in the same site (Table 2).

There is a significant difference in the proportion of patients that developed a recurrent capsule following the second surgery between the groups that had undergone capsulotomy (SF) or plane change (SG and SM) (X^2 (2111)=8.6, $P = 0.02$). When recurrence at the same site was examined, there was also a significant difference between the groups (X^2 (2,111) = 10.7, $P < 0.01$).

Time to Recurrence

There is a significant difference in the time for a capsule to recur following a capsulotomy:

A second capsule recurs more rapidly following capsulotomy (48 months, range 3–138 months, SD = 38.9) as a treatment following SF placement when compared to changing plane (SM mean = 137 months, range 25–362, SD=86.3. SG mean = 163 months, range 14–409 months, SD = 123.9. H(2) = 32.5, $P < 0.01$)

Effect of Rupture

Six patients in the SM group presented at the second procedure with a rupture in association with a capsule. Rupture had no effect on subsequent development of a second capsule (X^2 (2,17) = 1.4, $P = 0.34$), and there was no difference in the time for a subsequent capsule to occur following change to a SF plane (mean = 146 months, SD = 97.5. H(2) = 1.5, $P = 0.23$).

Nine patients in the SG group presented at the second procedure with a rupture in association with a capsule. Development of a recurrent capsule was significantly affected by the presence of rupture (X^2 (2,29) = 12.1, $P < 0.01$). However, recurrence occurred significantly less quickly in the presence of a rupture following change to a SF plane (H(2) = 6.1, $P = 0.013$, mean with rupture=277 months, SD = 143, mean without rupture = 132 months, SD = 113).

Two patients in the SF group presented at the second procedure with a rupture in association with a capsule. Rupture had no effect on subsequent development of a recurrent capsule (X^2 (2,65) = 5.4, $P = 0.06$), and there was no difference in the time for a subsequent capsule to occur following change to a SF plane (mean = 146 months, SD = 97.5. H(2) = 1.5, $P = 0.23$).

Discussion

Whilst it is agreed that chronic inflammation can lead to thick scar formation surrounding a breast implant, the aetiology for the inflammatory process remains controversial. Low grade bacterial infection leading to a biofilm,

Table 2 Study outcomes

a. subglandular implants at first procedure		
n = 29	2nd operation	3rd operation
Bilateral capsule	16	4
Bilateral capsule and rupture	4	
Bilateral recurrent capsules		4
Unilateral capsule	4	1
Unilateral capsule and rupture	5	
Unilateral recurrent capsule		2
Total	29	11
b. subfascial implants at first procedure		
n = 65	2nd operation	3rd operation
Bilateral capsule	16	1
Bilateral capsule and rupture	0	
Bilateral recurrent capsules		2
Unilateral capsule	47	1
Unilateral capsule and rupture	2	
Unilateral recurrent capsule		7
Total	65	11
c. submuscular implants at first procedure		
n = 17	2nd operation	3rd operation
Bilateral capsule	3	2
Bilateral capsule and rupture	3	
Bilateral recurrent capsules		2
Unilateral capsule	8	1
Unilateral capsule and rupture	3	
Unilateral recurrent capsule		3
Total	17	8

Significant difference between the groups that had undergone capsulotomy (SF) or plane change (SG and SM) X^2 (2,111) = 8.6, P = .02

minor trauma, free silicone gel and blood from a haematoma have all been suggested as responsible for activating the process [1–4]. The incidence of capsular contracture remains one of the unique selling points for both implant manufacturers and surgeons alike, with estimates following initial surgery ranging from 2 to 15% following primary surgery to 5–22% after revision surgery [1].

Closed capsulotomies are no longer performed, but open capsulotomy and capsulectomy both remain popular choices for treatment with or without implant exchange [7–9]. The rationale behind capsulectomy relates to the belief that a capsule is colonised by biofilm-producing bacteria, which if not eradicated, will produce a recurrent capsular contracture. The evidence for capsulectomy is poor and produces similar recurrence rates (0–54%) to open capsulotomy (0–46%) [1] and as such many patients may be undergoing unnecessarily prolonged and destructive surgery for no tangible benefit [9].

Change in Plane and Capsulotomy

In the absence of implant rupture, this study demonstrates a difference between capsulotomy for SF placed implants compared to changing the plane in which an implant was initially placed to SF. A recent meta-analysis [1] suggests a lower incidence of capsular contraction when an implant is placed in a different site from the original implant as a treatment for capsular contraction. However 6 out of 7 studies cited [10–15] refer to the creation of a "neopocket" rather than a new plane *per se*, and the single study [16] which does examine conversion of SG to a dual plane, with 0% recurrence, had a short follow up (12 months). Of note within that analysis are two studies that examined the role of changing the plane from SM to a SG position. One study [17] had a 0% recurrence rate reported at 21 months following surgery compared to 47% in this study.

A second study [14] reported a series of 25 cases with a transfer from a SM to SG pocket and a recurrence rate of 12% at 12 months post revision. The contrast with the recurrence reported in this study (47%) is accounted for by the difference in length of follow up. The follow up in the present study was considerably longer than previously reported, with the mean time to development of a capsule being 137 months, and none developing before 24 months (range 25–362, SD = 86.3), so it is probable that the previous studies have not appreciated the true incidence of recurrent capsular contraction following a change from SM to SG or SF plane.

The incidence of recurrence following capsulotomy in patients that had an initial SF placement (16.9%) is similar to that reported in SM placed implants (22.7%) [9], but with recurrence occurring later (mean = 48 months, range 3–138 months, SD–38.9, *cf* 8.4 months). Open capsulotomy in SG patients is less well reported, with all studies published between 1972 and 1987. Recurrence rates of 0–54% have been reported, [18–23] but with widely differing types of implants and follow up. On this basis, changing a SG implant to a SF or SM plane would seem a reasonable choice compared to capsulotomy given the recurrence rate of 37.9% in this study, particularly if an improvement in shape is required.

There are no previous studies examining the effect of changing an implant to a subfascial plane, but these data would suggest that there is little benefit in changing plane from the point of reducing recurrence of capsular contraction in the absence of implant rupture. However, when an implant is already in a SF plane, capsulotomy produces

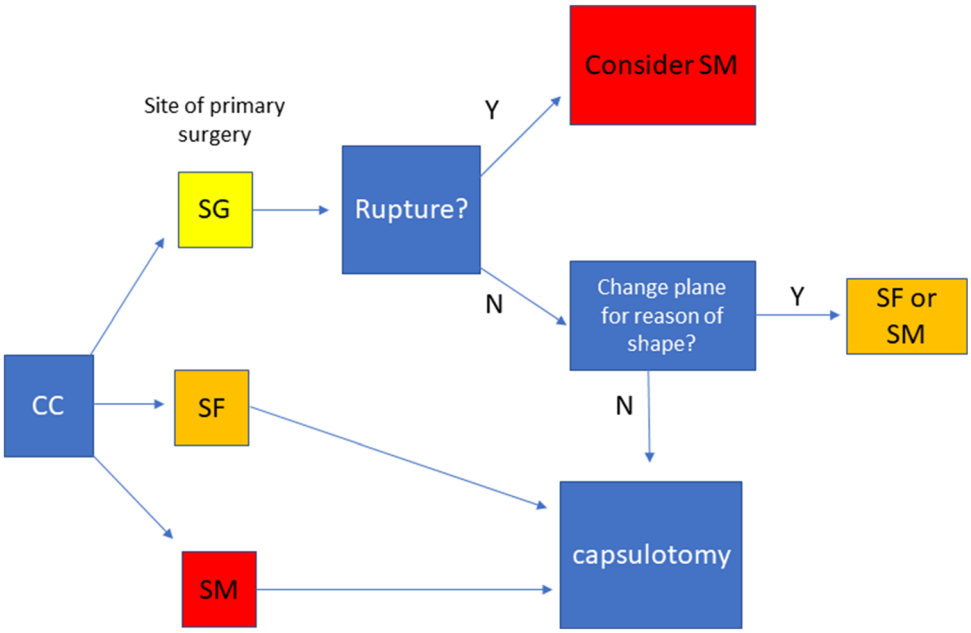

Fig. 2 Treatment algorithm for management of capsular contraction

comparable results to that undertaken when an implant is in the SM plane.

There is a marked difference between in incidence of recurrence of capsule in the *same* site (both bilateral and unilateral) and formation of a capsule at *any* site following change of plane (29.4% vs. 47% for SM, 21% vs. 37.9% for SG). This difference is not seen when a capsulotomy alone is undertaken (13.8% vs. 16.9% in the SF group). Changing a plane appears to create additional stimulus to the formation of capsular contraction in addition to that which caused the initial event.

Implant Rupture

Rupture of an implant did not significantly affect the recurrence of a capsule in a SF plane when the disruption has occurred in a SM or SF position. However, if the rupture has occurred in a SG position, replacement in a SF position is associated with significantly increased risk of recurrence. Possibly the tissue barrier produced by the pectoral muscle is sufficient that free silicone does not create a new focus of chronic inflammation compared to the less separated SG placement. The SF plane behaves differently from the SG plane with respect to rupture, indicative of the barrier that the additional tissue plane provides. These results differ from that of Swanson [9] who found that capsulotomy in SM placed implants was less successful at preventing recurrence in the presence of a rupture, which is not the finding when the SF plane is utilised. Given the numbers of ruptures associated with SF placement in the present study are small (2 patients), the level of confidence in the *P* value (0.06) is not high.

Strengths and Weaknesses of the Study

The study is the first of its kind to examine the SF plane and its role in revision surgery for capsular contraction. This study has great homogeneity in that it represents the work of a single surgeon using a single implant type in the same operating facility. Follow up of patients was similarly conducted by the same operator, producing consistency in the diagnosis of capsular contraction, which is subjectively reported. An attempt to objectively quantify capsular contraction has been made and used successfully to map the development of post implant fibrosis, which if more widely adopted might reduce such problems [24, 25].

Whilst all the primary SF procedures were undertaken by the same surgeon, none of the SM and 6 of the SG placements were by the author. Consequently, a degree of homogeneity is produced by the range of techniques, and implants presenting with capsular contraction for revision. Whilst potentially a source of error within the study, the results are similar to those previously reported for SM placed implants [10].

Conclusions

It is not possible to produce a panacea for the surgical management of capsular contraction to prevent further recurrence, and the literature is far from complete. This study demonstrates that in the absence of implant rupture, open capsulotomy is a preferred treatment choice in SF as there is no benefit in changing the plane of implantation. However, taken in the context of previous work

summarized by Wan and Rohrich [1], some recommendations are proposed (Fig. 2).

Compliance with Ethical Standards

Conflict of interest The author has no conflicts of interest to disclose.

Human and animal participants Patients provided written consent to the study under the guiding principles outlined in the WMA Declaration of HELSINKI concerning ethical principles for medical research involving human subjects.

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