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The Double Capsule Phenomenon in a Case Series and its Relationship with the Macro-Textured Breast Implant

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Abstract

Background Silicone breast augmentation remains one of the most common aesthetic surgery procedures, and 2022 marks the 60th anniversary of the first case. Recent studies suggest a link between double capsule (DC) formation and macro-textured devices.

Methods Between 2010 and 2015, 268 aesthetic patients underwent bilateral mammary prosthesis exchange for indications including PIP exchange, adverse capsular contracture and ultrasonographic evidence of rupture. All surgery, in the form of implant exchange and capsulectomy, was undertaken by the senior author using standard techniques. A retrospective review was undertaken, and data analysed with descriptive statistics and Fisher's exact and Mann–Whitney U tests.

Results Of 268 patients identified, 40 (14.9%) showed some degree of capsular duplication and bilateral involvement was marginally more common (52.5%). Two macroscopic patterns of duplication were observed: *complete* and *subtotal*. Complete DCs correlated with a clinical triad of extreme firmness, mobility and minimal-to-no pain. Whilst a wide range of manufacturers was represented, macro-textured devices were associated with the highest DC prevalence (58.3% vs. 5.6%) (Fisher's exact test $p < 0.00001$). Patients with DC had been implanted for less than half the time, median 52 versus. 120 months ($p = 0.0003$) of those without.

Discussion An elevated prevalence of duplicate capsules in macro-textured prostheses is reconfirmed in addition to a novel symptom constellation that may assist with clinical diagnosis. Our study reinforces the aetiopathogenic influence of the elastomer in DC formation and reports DC for the first time in non-macrotextured implants.

- Single-surgeon cohort of 268 consecutive patients with 532 implants
- Statistically significant association of macro-textured devices with DC
- Statistically significant reduced duration of implantation of macro-textured devices
- First report of DC in non-macro-textured devices

Level of Evidence IV This journal requires that authors assign a level of evidence to each article. For a full description of these Evidence-Based Medicine ratings, please refer to the Table of Contents or the online Instructions to Authors www.springer.com/00266.

Keywords Breast implants · Pseudocapsule · Dual capsule · Duplicate capsule · Macrotexture

Introduction

Although stated to be 'recently described and rare' in a contemporary systematic review [1], double capsules (DC) were in fact first reported in the literature in 2002 [2]. Hall-Findlay published the first series a decade ago and noted a correlation with the Biocell macro-textured elastomer [3]. Van Slyke et al presented a larger study involving 539 implants over a 13-year period and reinforced the Biocell surface association. They also documented the shortest time to explantation and highest prevalence of failure in such devices [4].

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The double—aka duplicate or pseudo-—capsule has been linked with late seroma (defined as symptomatic swelling at least one year after implantation) [3, 5] and possibly with BI-ALCL (breast implant associated anaplastic large-cell lymphoma) [6]. Its management mandates surgical intervention, thereby adding a degree of potential risk, morbidity and additional cost to patients.

Having observed the novel appearance of DCs after switching to Allergan implants for breast implant exchange, we took advantage of the coronavirus-induced lockdown to undertake an in-depth practice review of breast implant exchanges over a consecutive 5-year period.

Patients and Methods

In total, 268 patients underwent bilateral breast implant exchange by the senior author between January 2010 and December 2015, and their clinical records were independently assessed for the presence of duplicate capsule and any aetiopathological factors. Of the 268, 4 underwent unilateral surgery only; thus, 532 implants were available for analysis.

Statistical analysis involved a combination of descriptive tests, the two-tailed Fisher's exact test for contingency analysis and the Mann–Whitney U test for independent group correlation. In all cases, a p value < 0.05 was considered significant.

Results

The median age of the cohort was 47 years (range 21–75) with comorbidity demographics summarised in Table 1. 187 patients had undergone a single previous operation, 53 two and 18 three or more breast implant-related procedures. The maximum was 7 previous operations. Active smoking was recorded in 45, and with Fisher's exact test yielding a p value of 0.0712, this cohort showed no correlation between smoking and DC formation. The device was unidentifiable in 37 patients leaving 231 for further analysis.

Table 1: Comorbidity within the cohort

Comorbidity	Number
Nil	222
HRT/OCP	12
Depression	11
Hypertension	5
Hypothyroidism	4
Immunosuppression	2
Asthma	2
Psoriasis/eczema	2
Raynaud's	1
	261

HRT hormone replacement therapy

OCP oral contraceptive pill

Duplicate capsule formation was identified in 40 patients, being bilateral in 21. Patient prevalence is therefore 14.9% ($^{40}/_{268}$) with a device prevalence of 7.5% ($^{40}/_{532}$). Complete encasement of the prosthesis (Fig. 1) was observed in 19 and partial in 21 (Fig. 2). Figure 3 shows examples of both types of capsule *in situ* after implant extraction.

A wide range of implant manufacturers was represented (Table 2), the highest rates being observed in macro-textured devices. Statistical analysis strongly correlated macro-textured surfaces with duplicate encapsulation (Fisher's exact test $p < 0.00001$).

Devices with duplicate capsules were also found to have been implanted for a significantly shorter time—median 52 versus. 120 months—than non-DC implants (Mann–Whitney U test Z score of 3.62, $p = 0.0003$).

Discussion

Whilst axiomatic that any foreign body too large for the immune system to either remove or destroy is walled off with a protective fibrous tissue barrier, adverse capsular contraction (ACC) continues to impact mammary prosthesis implantation. The host-to-device interface is important, and evidence exists for a beneficial reduction with textured silicone elastomers, although most obviously in the subglandular plane [7]. The rough topography of

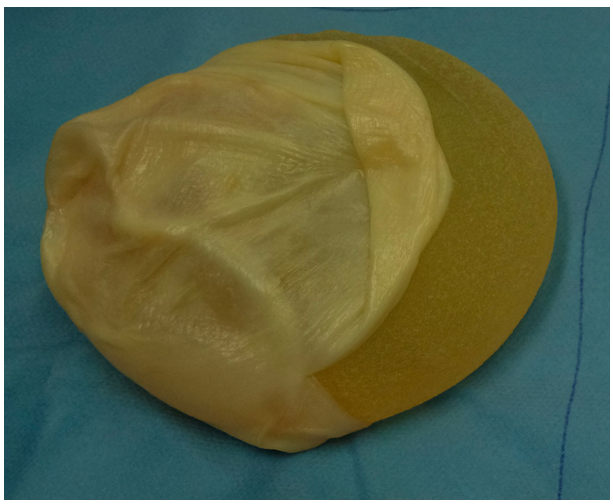


Fig. 1 Typical example of a *complete* duplicated capsule in a 40-year-old woman 57 months after primary breast augmentation.

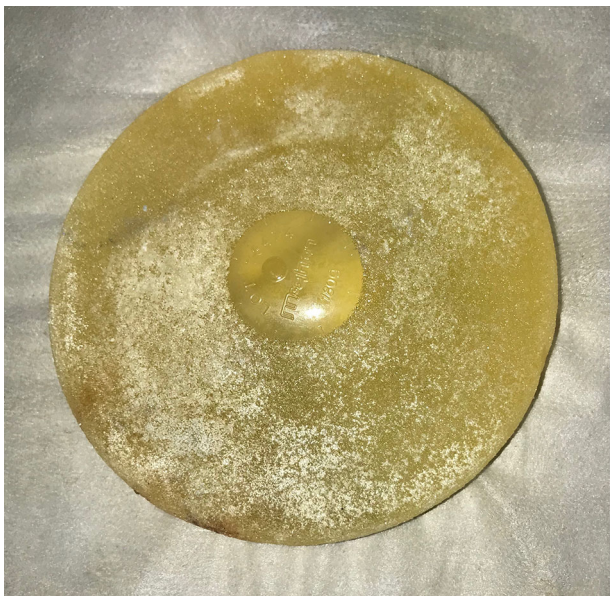


Fig. 2 The *subtotal* capsule of a 54-year-old, 15 months after Natrelle implants had been used to replace Siltex devices, without DC, inserted 16 years earlier. Note also the lack of capsule formation over the filling disc

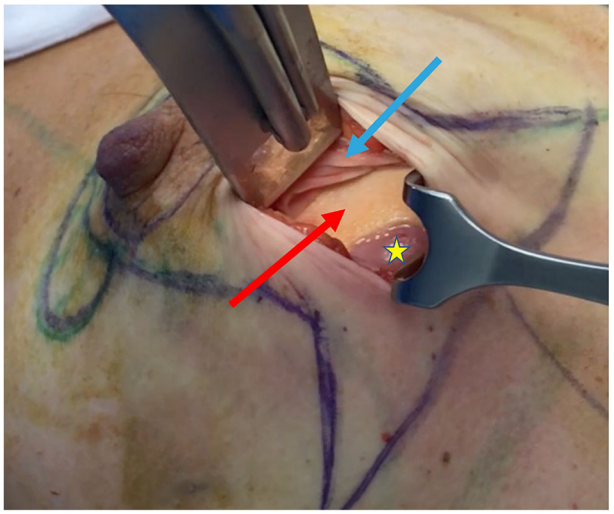


Fig. 3 Intraoperative example of standard (→) and duplicated (→) capsule. Absence of capsule formation over the filling disc (★)

polyurethane devices precipitated the development of aggressively textured silicone elastomers, but we are now aware that devices at the more aggressive end of the spectrum may both reduce ACC less than anticipated [3, 8] and contribute to additional problems.

Studies suggest an overall duplicate capsule prevalence of 2.2–8.3% [3, 4]; however, both studies saw DC only in Biocell macro-textured devices where the prevalence was 13.3% in Hall-Findlay's series. Van Slyke et al. did not

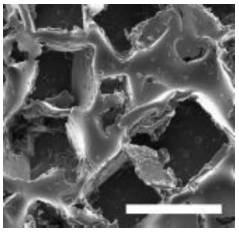
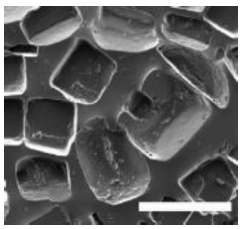
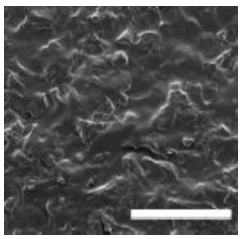
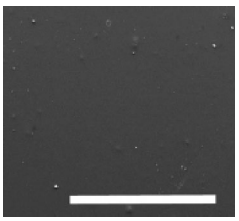
Table 2 Number of implants and DC by manufacturer

Implant	Total	Unilateral DC	Bilateral DC	%
PIP	149	4	1	3.4
Natrelle	21	4	9	61.9
CUI	19	3	–	15.8
McGhan	13	3	4	53.8
Siltex/Mentor	10	1	1	20
Hydrogel	8	–	–	–
Nagor	3	–	1	33
Saline (McGhan)	2	1	–	50
Eurosilicone	2	–	–	–
Smooth	2	–	–	–
Trilucent	2	–	–	–
	231	16	16	13.9
Unknown	37	3	5	21.6

detail the breakdown of their 45 DCs in 123 Biocell patients so their rate sits somewhere between 18.3% ($^{45}/_{246}$) and 36.6% ($^{45}/_{123}$), extrapolating unilateral and bilateral, respectively. Although not yet peer review published, Sforza et al. presented a 6.7% ($^{53}/_{794}$) prevalence of DC in a 3-year series of patients with Biocell devices in primary breast augmentation [9]. Our rates of patient and device prevalence of 14.9% and 7.5% are broadly similar and provide important supporting evidence for the high rates in macro-textured devices. Thus far, there have been no reports of DC with non-macro-textured mammary implants; however, as Table 2 shows, other topographies are not immune.

Duplicate capsule formation is an incompletely understood entity first documented with two cases in association with the now defunct Trilucent device [2]. Being known to stimulate a significant inflammatory reaction, causation was duly implicated possibly in combination with trans-elastomer filler bleed [10]. A third case prompted the *mechanical* aetiology hypothesis: that is, shear force disruption of an original capsule particularly strongly adherent to an aggressively textured elastomer [8]. Haemorrhage and subsequent organisation lead to the formation of the second capsule and low friction between the two capsular surfaces further facilitates malrotation of the original capsule-implant construct within the neo-capsule. A small study of Biocell-associated DCs has recently shown the inner lamina to range between a thin layer of nascent capsule and an identifiable organised one. Histological analysis revealed hypocellular fibrosis with synovial metaplasia and provided a clinicopathological correlation between DCs and failed tissue adherence [11].

Table 3 Characteristics of mammary prosthesis surface textures. After Barr et al. [17] and Maxwell GP et al. [19]

Surface	Sa	Pore diameter	Devices	
Macro-	Sa > 75 μm	600 – 800 μm	Biocell (Allergan); Sebbin	
Micro-	10 μm < Sa < 75 μm	70 – 150 μm	Siltex (Mentor); Eurosilicone; PIP; Sientra	
Meso-	Sa < 15 μm		Silk surface™	
Nano-	Sa < 5 μm		SM smooth (Mentor)	

Sa = roughness

With macro-textured devices acknowledged by their proponents to harbour more bacteria [12], an infective element may also be part of the multifactorial pathogenesis of DC. Implants inserted into a porcine model were co-inoculated with *S epidermidis,* and after 20 weeks, two of the six were found to have duplicate capsules and biofilm [13]. Moreover, scanning electron microscopy has shown significantly greater bacterial loads and biofilm deposition at the implant-capsule interface, as compared to the inter-capsular surface, suggesting that a degree of impaired capsule formation might facilitate delamination [14, 15]. Lately, strong biofilm formation has been demonstrated with a range of Gram-positive micro-organisms with thicker growths on textured (micro- and standard) rather than smooth implant surfaces. [16]

DC has been reported after both primary [3] and secondary breast augmentation [5], although the latter far less frequently. One patient with 3 prior sets of implants presented with seroma 4 years after the exchange and capsulectomy of a ruptured aggressively textured (Biocell Style 110) implant [5]. Our cohort comprised predominantly primary augmentations, but 28.4% had undergone at least one previous implant exchange (range 1–7 procedures). A Fisher's exact test of 0.1861 ($p < 0.05$) suggests implant texture itself to be far more important a determinant of DC formation than 'surgical load'.

Whilst no precise definition of implant texture has hitherto been available due to proprietary considerations, a recent classification (Table 3) has been proposed based on characteristics including implant hydrophobicity, macrophage-based biocompatibility assay and surface roughness

characteristic (Sa) [17]. The coarsest surface, with pore sizes in excess of 300 µm diameter, is known as *macro*-textured. The underlying premise is one of causality of ACC, or not, through texture-mediated inflammation at the prosthesis interface. Allergan's devices employ a 'salt-elution' technique, and their intention was to maximise host tissue ingrowth in order to resist rotation. The main alternative texturisation process is the 'imprint' technique as favoured by manufacturers such as Mentor [6]. Interestingly, although the macro-texture was invented to mimic the contracture-minimising topography of polyurethane, reduced contracture has perhaps counter-intuitively been associated with less aggressively textured surfaces [8].

We observed two broad macroscopic patterns of DC: *subtotal* and *complete* encasement. The latter is self-explanatory and represented well by the case in Fig. 1. 'Subtotal' is incomplete so tends to deform implants to a lesser extent (Fig. 2). Of course, such division may well be arbitrary and simply reflect a temporal continuum. We have been unable to correlate time with degree of encapsulation not least because the date of surgery rarely coincides with actual DC appearance, merely recording its previous occurrence.

We also investigated the duration of implantation. Those without DC had been *in situ* for a median of 120 months (range 7–408) as compared to 52 months (6–252). Mann–Whitney U test Z score of 3.62 yielded a highly significant p value of 0.0003. Many of the macro-textured prostheses had been used in exchange of PIP devices so the resulting DCs had occurred within 5 years; thus, speed of onset may equally have prompted exchange. This latter point certainly generated a considerable degree of patient complaint.

We wonder whether *complete* DCs may be an entity. The key symptom triad includes a very firm and mobile construct. It almost appears separate and, unlike other high-grade capsular contractures, is pain-free. This hard 'ball in a pocket' effect is presumably explained by the contractile forces of the neo-capsule being applied to the insensate prosthesis rather than the patient's parenchyma as with standard capsular contracture of the new, external capsule. With many of the DCs occurring within 5 years, the speed of onset would be considered rapid as alluded to previously [13]. Whilst some authors have noted an association between DC formation and delayed seroma collection [3, 14], this was not observed in our cohort.

There were 6 patients with at least one ruptured device in association with DC. Whilst such small numbers preclude worthwhile statistical analysis, it is worth noting that whilst 4 were bilateral and the degree of encapsulation varied, 5 (83.3%) were macro-textured. Moreover, they had been *in situ* for less than 5 years, much shorter than the single ruptured PIP device. Time will tell whether the severe contracture of the peri-prosthetic capsule is so much more forceful than a standard contracture that it actually precipitates elastomer rupture. An alternative explanation might be that patchy or subtotal DCs produce a localised concentration of force at the point of adherence. This then exaggerates fold-flaw defects predisposing to consequent elastomeric fragility.

Another interesting phenomenon has been the frequent observation of a 'mesentery' on the posterior surface. Additionally, and as observed by other authors [3, 18], the filling disc is devoid of any encapsulation (Fig. 3). With this element being smooth, one might conclude that some form of texturisation is fundamental to DC formation.

There are inherent limitations with any non-prospective study, for example, incomplete information about prior device history; however, we feel this to be considerably ameliorated by the bias minimisation associated with a single, highly experienced surgeon and good subject retention. It is, however, frequently the situation in which surgeons find themselves when undertaking breast prosthesis exchange so has clinical relevance.

It is worth noting that a defence of the aggressively, or macro-textured, implant surface was posited by a group of KOLs who reiterated that large pore diameters and depths promoted implant immobilisation through enhanced adhesion [19]. Whilst acknowledging a 'slightly higher risk of double capsule and later seroma', their defence regarding adverse capsular contracture (ACC) included only those studies that compared the Biocell (aggressive) with smooth devices. Direct comparisons of the 4 main grades of textured surface prostheses have yet to be made and will undoubtedly make interesting reading when they eventually appear.

There are no official figures for the prevalence of DC, other than Allergan's own rate of 0.02%, although this figure has yet to be subjected to peer review [19]. The consensus group also observed that DC is 'not necessarily associated with complications' and, given that a proportion are discovered incidentally, this may be true in some cases. However, when they do present, our experience is of rather dissatisfied patients who not only have to undergo further intervention, but significant cost, not long after their last surgical episode. Surgery is also not entirely risk-free, and no doubt contributes to the risk of infection, with device loss, future capsular contracture, and so on.

Finally, there was no mention in the consensus paper [19] as to whether any differences exist between primary and secondary cases vis-a-vis recurrence and our series materially contributes. Previous implantation has clearly changed the local milieu both irrevocably and in an incompletely understood fashion. The relative contributions to the genesis of a second capsule are at present unknown and unknowable; however, similar series of PIP

implants have reported far less ACC over a much longer period [20].

Conclusion

Our series reports an entity more prevalent than most are aware of. Our figures support the previous studies showing both a higher prevalence of DC in macro-textured devices along with their earlier failure rate. Our higher rate may well reflect a greater proportion of secondary cases, and we report for the first time the phenomenon of breast implant capsule duplication in non-macrotextured devices.

We also characterise 3 key clinical features of the complete duplicate capsule—a particularly firm and mobile, yet pain-free, construct that appears to move independently of the breast parenchyma on palpation.

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Declaration

Human or Animal Rights This article does not contain any studies with human participants or animals performed by any of the authors.

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