

Low Risk Primary Augmentation Mammoplasty and Capsular Contracture using Textured Round Cohesive Silicone Gel implants Revisited. A Long Term Follow Up in a Single Surgeon's Practice.

Mr. Umar Daraz Khan

Abstract:

Background: Capsular contracture following augmentation mammoplasty is the most common complication requiring revision surgery. However there is a lack of single surgeon's long term follow up regarding this most common complication.

Methods: Retrospective data was retrieved using XL Spread Sheet, primary augmentation mammoplasty performed between May 1999 and August 2015 was reviewed. All patients had their surgery performed and followed up by a single surgeon. All patients had textured round cohesive gel silicone implants using inframammary incision with a minimum follow up of 1.5 years, were selected. Asymptomatic capsular contractures (Baker Grade I and II) were compared with symptomatic contractures (Grade III and IV) on the basis of the age of the patient, size of the implants and duration of implantation. Asymptomatic and symptomatic capsular contracture rate was also compared based on the position of the implants, smoking status of the patients and presence and absence of the drains.

Results: There were 117 patients with a mean follow up of 6.6 years (range 1.5-12) in the series. Mean age of the patients was 32.2 years (range 18-53) with a mean implant size of 336.2 cc (range 230-540). Of 117 patients, 107 (91.5%) were asymptomatic with a mean age of 31.9 years, mean implant size of 336 cc with a mean implantation of 6.7 years as compared to symptomatic capsular contracture present in 10 patients (8.5%) with a mean age of 35.3 years, mean implant size of 339cc and with a mean duration of 6 years. Of the 49 patients who had mammoplasty in subglandular pocket, 3 (6.1%) presented with Grade III or IV capsular contracture. Submuscular augmentation was performed in 68 patients, of these 7 (10.3%) presented with symptomatic capsular contracture. Smoking status was known in 114 patients. Of these 114, 25 were smokers and Grade III and IV capsular contracture was present in 2 patients (8.0%) as compared to 89 non smokers of whom 8 (9.0%) presented with Grade III-IV capsular contracture. Drains were used in 15 patients, of these 2 patients (13.3%) developed capsular contracture. Of the 102 patients who had their surgery without drains, 8 patients (7.8%) developed Grade III-IV capsular contracture. Of the 117 patients, 11 patients who had implants failures, 3 (27.3 %) presented with Grade III-IV capsular contracture as compared 6 (11.8%) of the 51 patients who did not have implant damage.

Conclusion: Incidence of capsular contracture in current long term series was 8.5%. There was no single cause identified for capsular contracture, including pocket of the implant placement, use of drains, smoking or implant rupture.

Mr. Umar Daraz Khan, FRCS
2-4 High Street, West Malling, ME19 6QR, Kent
England
E-mail: mrmarkhan@aol.com
www.re-shape.co.uk
Home: 01634-686874 Mobile: 07966688893
Work 020-83114464 Fax: 01634-686219

Key words: Augmentation mammoplasty, Capsular contracture, Biofilm, Revision mammoplasty.

Introduction.

Breast augmentation is one of the most commonly performed aesthetic procedure performed today with a high satisfaction rate. However Capsular Contracture (CC) remains one of the leading cause for revision surgery.¹ Prevalence and causes of CC have been reported from time to time and vary from study to study. Incidence of Grade III/IV CC following primary augmentation mammoplasty using round Cohesive Gel implants may vary from 8.1% to 22%.²⁻³ When Form stable Style 410 shaped implants are used, the rate of CC may vary from 1.9% at 3 year to 9.2% at 10 years.^{4,5} Similarly Sientra round and shaped implants with High-Strength cohesive gel implants, 8 year follow up reported a CC rate of 11.2%.⁶ An overall 8.2% and 22% in a 15 year and 25 year follow up has been reported when different surgeons used various type of implants.^{3,7} Collective data where more than one surgeon performed the surgeries may give a combine results of individual surgeons and figures may not represent individual surgeons outcome. A zero percent CC has been reported in a 3 year study when a single Surgeon performed all the surgeries.⁸ However there is a paucity of long term rate of CC following augmentation mammoplasty by a single Surgeon using textured round cohesive gel silicone implants. Similarly there is a lack of information on the risk factors that may contribute towards the development of this most common complication and the leading reason for most revision surgeries following primary augmentation mammoplasty.

Patients and Method

Retrospective data using XL spread sheet was retrieved, primary augmentation mammoplasty performed between May 1999 and August 2015 was reviewed. All patients had their surgery performed and followed up by a single surgeon. All patients had textured round cohesive gel implants, using

inframammary incision with a minimum follow up of 1.5 years, were selected. Asymptomatic capsular contractures (Baker Grade I and II) were compared with symptomatic contractures (Grade III and IV) on the basis of the age of the patient, size of the implants and duration of implantation. Asymptomatic and symptomatic capsular contracture rate was also compared based on the position of the implants, smoking status of the patients and presence and absence of the drains.

Technique.

All patients had their surgery performed by a single surgeon (author). All patients had their surgery under general anesthesia, in supine position, with their arms abducted <90 degree. All patients had inframammary incisions used for pocket access. Full muscle relaxation was achieved for patients who had their implants placed in submuscular pockets. A single dose of intravenous cephalosporin was given to all patients at induction time followed by an oral course for 5 days. Double gloves were used by the surgeon and outer gloves changed before handling the implants. Nipple shields are used routinely to minimize operative field from bacterial contamination of ductal origin. Implants were placed in subglandular and partial submuscular pocket during the early part of the series and all implants are now placed in muscle splitting biplane pocket. Pocket dissection is performed using monopolar large diathermy forceps on cutting mode under direct vision using lighted retrator. Full prospective hemostasis is achieved using monopolar cautery and pocket irrigated with normal saline at least four times. Drains were used in the earlier part of the review period. Before insertion of the implants, skin is cleansed with Povidone Iodine solution and to minimize implant and skin contact, Povidone Iodine solution soaked large swab is placed to cover the lower incised skin of the inframammary incision. Implants are dipped in Povidone

Iodine undiluted solution just before insertion through the inframammary crease incision. Once implants are inserted, implant pocket cavity is checked again for any bleeders freshened up during insertion of textured implants. Incision is closed in layers and patients are discharged same day.

Statistical analysis.

The data were analysed using PASW version 18.0 software. The categorical variables are presented as frequencies and percentages, whereas the numeric variables are presented as mean \pm standard deviation. Statistical analysis was performed differences in age, implant volume, and duration of implantation using the Student's t-test. Chi-Square test was used for comparison between capsular contraction group and its association with implant position, implant damage, presence of drain, and smoking status.

A p -value less than 0.05 was considered statistically significant for all the statistical tests.

Results:

There were 117 patients with a mean follow up of 6.6 years (range 1.5-12) in the series. Mean age of the patients was 32.2 years (range 18-53) with a mean implant size of 336.2 cc (range 230-540). Of 117 patients, 107 (91.5%) were asymptomatic (Grade I & II) with a mean age of 31.9 years (sd 9.1) , mean implant size of 336 cc (sd 51.4) with a mean implantation of 6.7 years (sd 3.0) as compared to symptomatic capsular contracture (Grade III &IV) present in 10 patients (8.5%) with a mean age of 35.3 years (sd 7.9), mean implant size of 339cc (sd 64.0) and with a mean duration of 6 years (sd 3.2). There was no statistical difference in all three parameters compared (p-value 0.25, 0.84 and 0.47 respectively).

Of the 49 patients who had mammoplasty in subglandular pocket, 3 (6.1%) presented with Grade III or IV capsular contracture. Submuscular augmentation was performed in

68 patients, of these 7 (10.3%) presented with symptomatic capsular contracture with no statistical difference between two groups (p-value 0.43).

Smoking status was known in 114 patients. Of these 114, 25 were smokers and Grade III and IV capsular contracture was present in 2 patients (8.0%) as compared to 89 non smokers of whom 8 (9.0%) presented with Grade III-IV capsular contracture. There was no statistical difference between the two groups (p-value 0.88).

Drains were used in 15 patients, of these 2 patients (13.3%) developed capsular contracture. Of the 102 patients who had their surgery without drains, 8 patients (7.8%) developed Grade III-IV capsular contracture. There was no statistical difference between the two groups (p-value 0.48).

Of the 117 patients, 11 patients who had implants failures, 3 (27.3 %) presented with Grade III-IV capsular contracture as compared 6 (11.8%) of the 51 patients who did not have implant damage. There was no statistical difference between the two groups (p-value 0.19).

A Kaplan-Meir 10 year analysis showed that 8.5% of the patients experienced capsular contracture. (Fig 1)

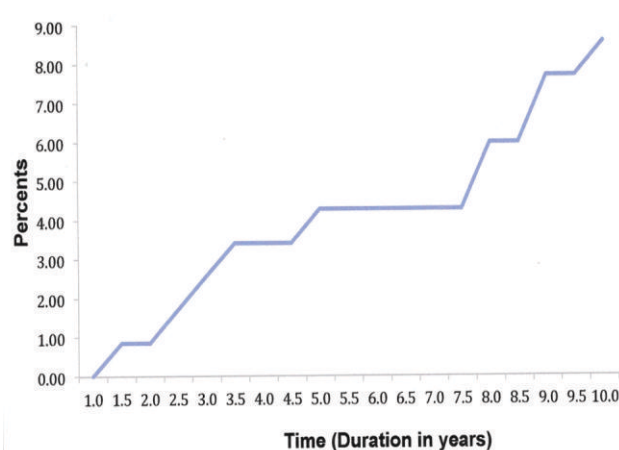


Fig 1. A 10- year Kaplan-Meir analysis of the risk of significant capsular contracture (Baker 3 or 4).

Discussion

Capsular contracture remains the most common overall indication for revision surgery following breast augmentation.⁷ Capsule formation itself is a normal tissue response consisting of inflammatory cell response and deposition of fibroblasts and collagen fibers around a prosthesis.⁹ This response is inevitable regardless the type of implant, pocket of the placement and the technique used. However the histology of the capsule may depend on the surface morphology of the implants. The smooth surface implants tends to have circumferential linear fibrosis associated with capsular contracture. Polyurethane and textured implants, as opposed to smooth surface implants, builds an irregularly arranged fibroblasts and collagen in the capsule. Textured surface in polyurethane foam or textured implants promote ingrowth of the tissue into the pores and the process disrupt the linear circumferential forces seen in smooth surface implant capsules.¹⁰ The Velcro effect provided by textured implants do prevent mobility of the implant in the pocket.¹⁰ Texturing of the implants may give some protection against the CC in some of the patients.^{6,11} Similarly protection against CC has been reported by the use of Polyurethane Foam-Covered implants when compared with smooth or textured implants.¹² However at the end of 10 years, significant capsular contracture based on surface morphology was seen in 25% of polyurethane foam covered implants as compared with 35% when smooth or textured implants used.⁷ Same study showed a small decrease in capsular contractures when textured implants were used as compared to smooth implants but the results were statistically insignificant.⁷ Use of intraluminal antibiotics or corticosteroid therapy through indwelling catheter also has shown a significant decrease in primary CC following primary augmentation mammoplasties and also has reduced the

recurrence of CC following the treatment of CC using capsulotomies.^{9,13}

As opposed to popular belief, submuscular implant positioning, whether silicone or saline does not offer any significant protection.³ This long term study based their results on the basis of location of implants regardless of the fill or texturing of implants. Earlier studies however have shown a significant reduction of grade III and Grade IV capsular contracture when implants were placed in submuscular pocket.¹⁴

Implant insertion with a funnel technique is gaining popularity and in a recently published article the procedure has shown to reduce the rate of capsular contracture from 1.49% to 0.68%. However the article has concentrated on rate of capsular contractures with and with out funnel technique and with out taking into account the other contributing cofactors or variables.^{15,16}

Contributing factors leading to CC are many and include haematoma, foreign body, periprosthetic infection, biofilm and subclinical infection in the breast implant capsules. Role of smoking, use of drains, size of the implants, time since implantation and age of the patients are not very clear and there is a paucity of available information. A significantly higher rate of capsular contracture has been reported in patients who developed haematoma when compared to patients who did not develop haematoma.^{3,7} However the study did not mention how the haematoma were treated. An untreated haematoma may raise the possibility of future development of capsular contracture as opposed to a treated haematoma using emergency exploration and evacuation of haematoma. In current series of 117 patients, there was no haematoma following augmentation mammoplasty. However, haematoma is always treated as an emergency by author and once treated in this way, the risk of developing capsular contracture was not observed more than the patients who did not

develop haematoma.

Periprosthetic infection following augmentation mammoplasty, whether treated surgically or conservatively, exponentially increases the risk of CC. The risk of Grade III and IV CC is higher with conservative nonsurgical treatment using antibiotic with a reported incidence of 76.9% as opposed to 28.6% CC when implants were explanted and replaced three months following wound healing.¹⁷ In authors current series two patients developed periprosthetic infection, both were treated conservatively and both developed CC requiring revision surgery. However implants were salvaged in patients when author treated periprosthetic infection with antibiotic and following three repeated negative bacterial swabs, implants were explanted under general anesthetics. The implant pockets were then debrided and irrigated with dilute aqueous povidone iodine, normal saline and diluted hydrogen peroxide and the new implants were replaced in the same setting. Patients were continued on oral antibiotics for a week following intraoperative intravenous antibiotics. Breast implant pockets were drained for two days. There was zero % CC in this group of patients.¹⁸

Relationship between Biofilms, bacterial subclinical infection and CC is well documented. Virden et al were the first to publish the work showing association between CC and biofilm. Explanted prosthesis and capsules showed presence of biofilms on approximately 56% of the specimen when examined under Scanning Electron Microscope.¹⁹ Normal swabs taken for bacterial culture from grade IV capsules and implants has a very low sensitivity for the growth of bacteria. However the process of sonication can greatly change the picture of these samples when prepared in this way. The process showed 89.5% positive bacterial cultures when grade III/IV capsules were prepared this way as opposed to 10.5% when

Grade I/II capsules were analysed using sonication. Similarly implants removed from patients with Grade III/IV CC showed positive bacterial culture in 38.5% of the samples as opposed to 12.5% of the samples of implants with Grade I/II CC when specimen were prepared using sonication method.²⁰ Texturing of implants and the presence of the biofilm is not fully established and varying studies have suggested conflicting reports on the presence of biofilms on textured and non-textured implants.¹ However strong the association between biofilm and CC may be, it is interesting that not all implants with Grade III/IV CC have biofilms on SEM and similarly implants with biofilms in Grade I/II capsular contracture remain asymptomatic. It also interesting that not all Grade III/IV capsular or implant specimen, prepared using sonication method, grow positive bacterial culture or samples from Grade I/II capsule or implants showing a positive bacterial culture do not proceed to Grade III/IV capsular contracture.

The role of antibiotics when a revision surgery is performed in secondary surgery especially when complete capsulectomy is not performed is not fully understood. With 89.5% of bacterial presence in Grade III/IV and 10.5% in Grade I/II capsules, a higher incidence of clinical periprosthetic infection should be the norm, especially when 56% of the patient showed biofilm when capsules from Grade III/IV capsular contracture samples were analysed under SEM. Surprisingly a decreased rate of periprosthetic infection has been reported in revision augmentation mammoplasty surgery regardless of the degree of capsulation or the way these capsules were treated.²¹ Are these bacteria virulent anymore or they have started living in symbiosis are the questions remains to be explored and investigated.

With so much uncertainties regarding established factors leading to the pathogenesis and development of Grade

III/IV CC requiring surgeries, it is almost imperative to look into other cofactors or causes that may possibly lead or contribute to the most common reason for revision surgery following augmentation mammoplasty. It is surprising to see that most of the leading articles on the subject lack information on the use of drains, age and smoking status of the patients, size of the implants, association of implant damage and duration since implant surgery.

The age of the patients who developed Grade III/IV CC was looked into and compared with the group which was associated nonclinical Grade I/II CC. Of the 117 patients 10 (8.5%) patients with a mean age 35.3 years developed Grade III/IV CC as compared to asymptomatic CC in 107 (91.4%) patients with a mean age of 31.9 years. Significant CC was seen in little older population but there was no statistical difference between the two groups (p=0.25). Table 1

Larger implants are expected to result in more stretch to the breast skin envelope, changing the Implant skin dynamics and interaction. The process may or may not contribute to the development of clinically significant CC and hence was analysed in the study. Of the 117 patients analysed, 10 (8.5) patients with a mean implant size of 339.5 cc developed Grade III/IV CC as compared to 107 (91.4%) patients with an implant size 335.9 cc who had grade I/II CC. There was no statistical significance between implant sizes of the two groups analysed (p=0.84) concluding no role of implant sizes on development of capsular contracture (table 1).

It also is a common belief that the longer the duration of implantation is, higher the chance of developing clinically significant CC. Again there is limited information available on this aspect. The duration of implantation in group with grade III/IV CC was analysed to see any different pattern of local response to duration of the implants. Of the 117 patients, 10 (8.5%) developed Grade III/IV CC. The mean

duration of implantation was 6.0 years in this group of patients as opposed to 6.7 years in 107 (91.4%) patients who did not have clinically significant CC. Surprisingly Grade III/IV capsular was seen little earlier than the patient who were asymptomatic, however, when the results were analysed statistically there was no significant difference between the two groups (p=0.47). The results strongly put into question the common belief that capsular contracture is a time dependent process and longer the duration of implantation, more likely they are to develop capsular contracture (Table 1)

	Capsular Contracture groups	N	Mean	sd	P-value
Age in years	Baker Grade I-II	107	31.9	9.1	0.25
	Baker Grade III-IV	10	35.3	7.9	
Implant size	Baker Grade I-II	107	335.9	51.4	0.84
	Baker Grade III-IV	10	339.5	64.0	
Duration since implantation (years)	Baker Grade I-II	107	6.7	3.0	0.47
	Baker Grade III-IV	10	6.0	3.2	

Table. 1: Association of age, implant sizes and duration of implantation to development of Capsular Contracture.

In current series of the 117 patients, 8.5% developed grade III/IV CC. The submuscular subgroup (10.3%) had a higher incidence of clinical CC than subglandular group (6.1%) but without a statistical significance (p=0.43) (Table2)

Implant Position	Capsular Contracture Grade I/II	Capsular Contracture Grade II/IV	Total	P-value
Submuscular	61 (89.7%)	7 (10.3%)	68 (100%)	0.43
Subglandular	46 (93.9%)	3 (6.1%)	49 (100%)	
Total	107 (91.5%)	10 (8.5 %)	117 (100%)	

Table. 2. Association of Implant position to the development of Capsular Contracture.

Sub muscular pocket used were muscle splitting biplane and partial submuscular plane. The incidence of Grade III/IV CC was seen 4.2 % in muscle splitting biplane group as opposed 25% in partial submuscular subgroup. The statistical analysis between two submuscular pocket was not performed due to the smaller number of implants placed in partial submuscular pocket. Clearly Grade III & IV CC was markedly lower in muscle splitting biplane pocket.

A silicone cohesive gel implant rupture is usually asymptomatic and usually referred as silent rupture. However these implant failures, may initiate an inflammatory process that may potentially contribute towards symptomatic grade III/IV CC. Presence of implant damage and its association with the development of grade III/IV CC was analysed. Information on implant damage was available in 62 patients. Of the 62 patients, 11 had implant ruptured at the time of explantation. Of these 11 ruptures, 3 (27%) were associated with Grade III/IV CC. Of the 51 patients with no implant rupture, Grade III/IV CC was present in 6 (11%). The risk of significant CC is more than double when an implant is ruptured, however there was no statistical significance between the two groups when analysed (p=0.19) (Table 3).

Implant Damage	Capsular contracture I-II	Capsular contracture III-IV	Total	p-value
No	45 (88.2%)	6 (11.8%)	51 (100%)	0.19
Yes	8 (72.7%)	3 (27.3%)	11 (100%)	
Total	53 (85.5%)	9 (14.5%)	62 (100%)	

Table.3: Association of implant damage to the development of Capsular Contracture.

In current series all patient had textured implants so a comparison between smooth and textured implant was not possible to carry out.

Smoking has deleterious effects on wound healing and its association with infection is well known. There is a paucity of the effects of smoking, on the development of Grade III/IV CC. Smoking status of 114 patients was recorded in the sample analysed. Of the 114 patients, 25 patients were smokers and of these 2 (8%) developed CC. Of the 89 non-smokers, 8 (8.9%) patients developed Grade III/IV CC. There was no statistical difference between the two groups concluding no association between smoking and clinically symptomatic CC (Table 4)

Smoking status	Capsular Contracture I-II	Capsular contracture III-IV	Total	P-value
No	81 (91%)	8 (9%)	89 (100%)	0.88
Yes	23 (92%)	2 (8%)	25 (100%)	
Total	104 (91.2%)	10 (8.8%)	114(100%)	

Table.4: Association of smoking and development of Capsular Contracture.

In Augmentation mammoplasty, drains are not a substitute for meticulous haemostasis still drains are commonly used to minimise risk of haematoma and to prevent any residual blood collection following augmentation mammoplasty. A haematoma following augmentation mammoplasty has been shown to significantly increase the risk of CC and its association has been reported in long term studies.^{3,7} However the use of drains in patient developing haematoma or whether haematoma was treated conservatively or surgically was not documented in the articles.^{3,7} There was no haematoma in 117 patients analysed in the current series therefore association of haematoma with capsular contracture, whether treated or not, cannot be assessed. However drains were

used in 15 (13.3%) out of 117 patients. Of these 15 patients, 2 (13.3%) developed Grade III/IV CC. On the contrary 102 (87.17%) surgeries were performed without using drains. Of these 102 patients only 8 (7.8%) developed grade III/IV CC. Interestingly the use of drain to keep inside free of blood or to prevent collection of blood did not offer any reduced incidence of Grade III/IV CC. On the contrary the incidence of symptomatic clinical CC was seen in almost twice as many patients when drains were used. However the difference between the two groups was not significant when statistically analysed ($p=0.48$) (Table 5).

Drain	Capsular contracture I-II	Capsular Contracture III-V	Total	P-value
No	94 (92.2%)	8 (7.8%)	102 (100%)	0.48
yes	13 (86.7%)	2 (13.3%)	15 (100%)	
	107 (91.5%)	10 (8.5%)	117 (100%)	

Table. 5: Association of use of drain to development of Capsular Contracture.

Capsular tissue is a useful material and can be used in secondary or revisionary surgeries. An excellent overview of the use of the capsules is reported by Persichettie et al.²² But the use of capsular flaps or capsular tissue is mostly limited to Grade I/II capsules. Advanced capsular thickening in Grade III/IV generally requires capsulectomy disallowing the use of this tissue in most of the cases. In current series, patients presenting with CC were treated with capsulotomies, partial or complete unilateral or bilateral capsulectomies, depending on the presentation (Fig 2-5).

Fig.2 (a-c.) Preoperative views of a 36 year old patient with a history of 465cc high profile cohesive gel round subglandular implants who presented with bilateral capsular contracture III. Her preoperative cup size was 34G. She was interested in CC treatment, downsizing her implants and breast cup size.

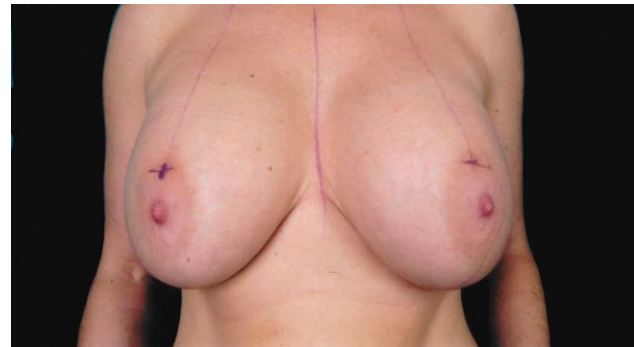


Fig. 2a



Fig. 2b



Fig. 2c

fig.2 (d-e.) Explanted implants along with the capsule. Change in the shape and size of the implants due to tight encapsulation can be noticed.

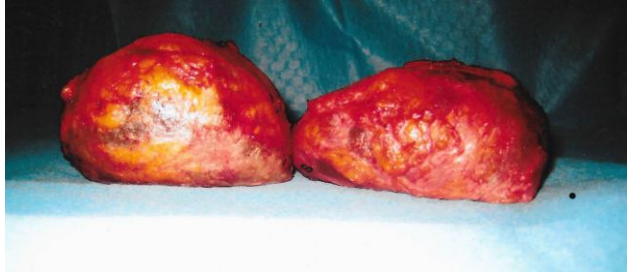


Fig. 2d



Fig. 2e

Fig. 2. f-h Postoperative views following mastopexy with 330cc moderate profile cohesive gel silicone round textured implants placed in muscle splitting biplane pocket. Excised skin and tissue weighed 80 and 82 from her right and left breast respectively. Her postoperative cup size was 34D.



Fig. 2f



Fig. 2g



Fig. 2h

Fig. 3. a-c. Preoperative views of a 30 year old patient who had augmentation mammoplasty 11 years ago and presented with bilateral CC. She had 310cc high profile silicone cohesive gel implants in subglandular pocket with a breast cup size of 32D. She requested for smaller breast and nipple areolar complex size (NAC).



Fig. 3a

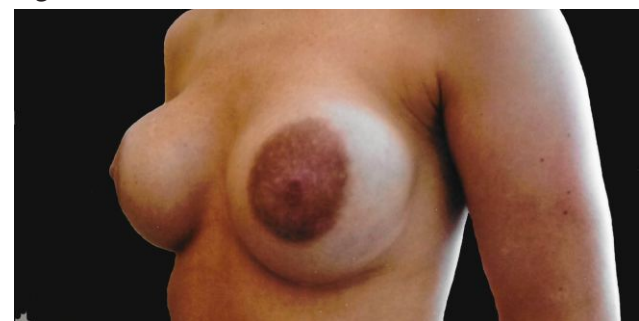


Fig. 3b



Fig. 3c

Fig. 3. d. Both explanted prosthesis with near total capsulectomy

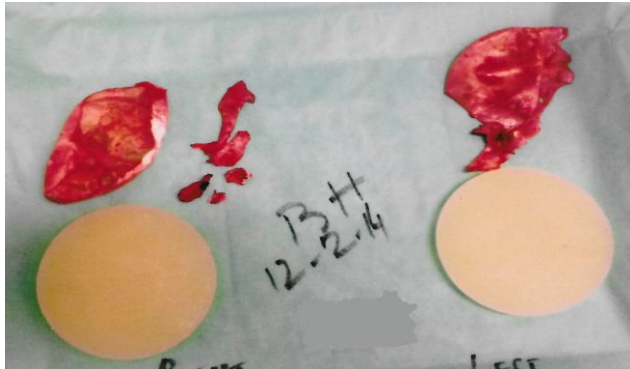


Fig. 3d

Fig. 3. e-g. Three months postoperative views following 260cc round moderate profile cohesive gel silicone round textured implants. Implant pocket was changed from subglandular to muscle splitting biplane, NAC size was reduced to 4.2cm using circumareolar excision and her post breast cup size was changed to 32C.

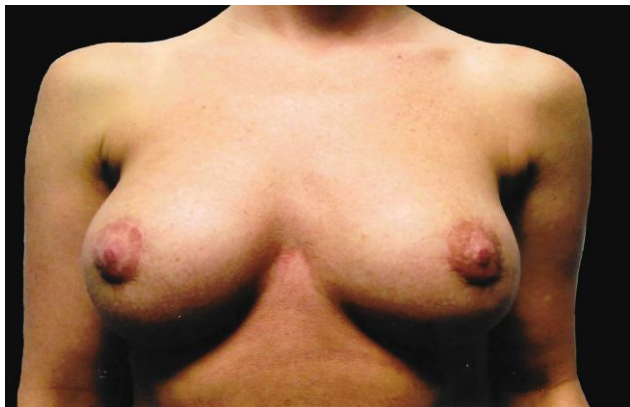


Fig. 3e



Fig. 3f



Fig. 3g

Fig. 4. a-c. Preoperative pictures of a 42 year old female presenting with grade IV CC. She had her augmentation mammoplasty 8 years ago with 290 cc high profile silicone cohesive gel silicone round texture implants, placed in subglandular pocket.

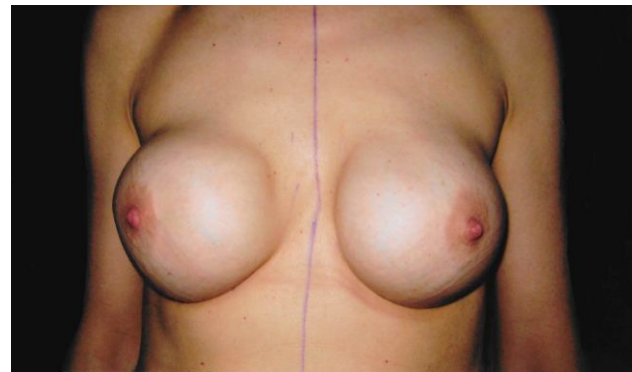


Fig. 4a



Fig. 4b



Fig. 4c



Fig. 4f

Fig. 4. d. Undamaged explanted prosthesis with complete capsulectomies.

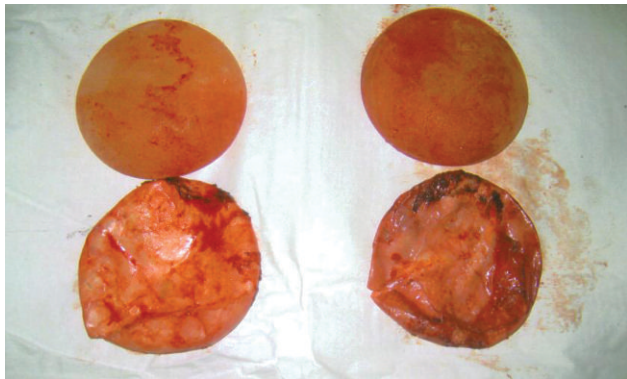


Fig. 4d

Fig. 4. e-g. Postoperative pictures taken 4 months following surgery. She had 380 cc silicone cohesive gel round textured implants. Her implant pocket was changed from subglandular to muscle splitting biplane



Fig. 4e



Fig. 4g

Fig. 5. a-c. A 40 year old patient who presented with Grade III/IV CC. She had augmentation mammoplasty 8 years ago. She had 300cc cohesive gel silicone round textured implants in muscle splitting biplane.



Fig. 5a

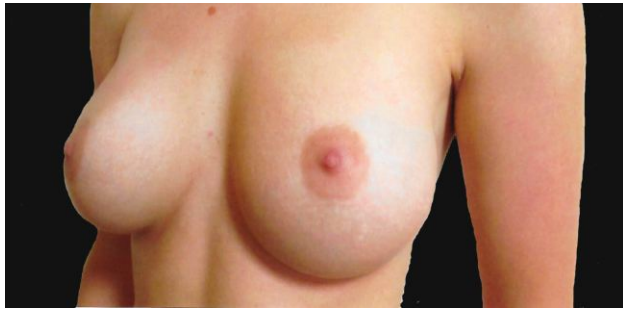


Fig. 5b



Fig. 5c

Fig. 5. d-f. Postoperative pictures taken four months following capsulotomies. She had 375cc round cohesive gel silicone texture implants placed without pocket change.



Fig. 5d



Fig. 5d



Fig. 5e

Grade III/IV CC recurrence is reported higher in revision surgeries treated for clinically advanced CC.¹⁷ Use of Dual plane has been described for the correction of CC following mammoplasty in sub glandular pocket to reduce CC recurrence.²³ In the current series implant pockets were routinely changed to muscle splitting biplane pocket when CC developed following sub glandular or partial submuscular mammoplasty.^{21,24-25} The purpose is twofold, firstly, the audit of the current series has shown that occurrence of grade III/IV CC was least common in muscle splitting biplane and secondly by changing the pocket for the replacement of new implants, the risk of recurrence can be reduced. Intraluminal antibiotics also has been used to reduce the recurrence capsular contracture following the treatment of capsular contracture using capsulotomies.¹³ Use of corticosteroids through indwelling suction catheter has been reported to decrease the recurrence of Grade III/IV capsular contracture following capsulectomies and replacement of implants.⁹ The overall CC, in the current series of primary augmentation mammoplasties, with a mean follow up period of 6.6 years (Range 1.5-12) is 8.5 %. In the series, all surgeries were performed and followed up by the same surgeon. In another published study, zero% CC was reported when single surgeon did all

the surgeries and followed up all the patients for three years.⁸ The Danish national prospective study showed a Grade III/IV CC rate of 1.3% with a maximum follow up for four years.²⁶ The 8.5% Grade III/IV CC rate in a single surgeon series is lot lower than the 22% found in 25 year study.⁷

With an expected 10-15% chance of 5th generation implant rupture at 10 years and an expected 8.5% rate of CC with a mean duration of 6.5 years, it is expected that about 15 to 20% of the patients will require an unplanned surgery within 10 years following their primary augmentation mammoplasty.

Limitations of the study.

Long term studies and data collection is not without its limitations. Author has performed over 2,400 primary augmentation mammoplasties and only 117 patients had a record of 1.5 years or more on the status of the degree of Capsular Contracture. Vast majority of the patients were not followed up longer than 1.5 years. However all the patients were followed up and examined by the author and thus have uniformity in the assessment of the degree of Capsular Contracture.

Conclusion

The development of Capsular contracture remains a challenging subject as ever. The current single surgeon study does show an acceptable and comparable rate of capsular contracture when followed up to 12 years. There was no specific factor identified in this study for the development of capsular contracture.

For This type of retrospective study formal consent is not required.

ACKNOWLEDGMENT

The authors declare that they have no conflicts of interest to disclose.

References

1. Adjic D, Zoghbi Y, Gerth D, Panthaki ZJ, Thaller S. The Relationship of

Bacterial Biofilms and Capsular Contracture in Breast Implants. *Aesthetic Plast Surg*,2016;36:297-309

2. Cunningham B. The Mentor Core Study on Silicone Memory Gel Breast Implants. *Plast. Reconstr. Surg.* 2007;120(7 Suppl 1):19S-P129S
3. Codner MA, Mejia JD, Locke MB, Mahoney A, Thiels C, Nahai FR, Hester TR, Nahai F. A 15-Year Experience with Primary Breast Augmentation. *Plast. Reconstr. Surg* 2011;127:1300-1314
4. Bengston BP, Van Natta BW, Murphy DK, Slicton A, Maxwell GP; for the Style 410 U.S Core Clinical Study Group. Style 410 Highly Cohesive Silicone Breast Implant Core Study Results at 3 Years. *Plast. Reconstr. Surg.* 2007;120(7 Abstract Suppl !):40S-48S
5. Maxwell GP, Van Natta BW, Bengston BP, Murphy DK. Ten-Year Results From Natrelle 410 Anatomical Form-Stable Silicone Breast Implant Core Study. *Aesthetic Plast Surg.*2013;35:145-155
6. Stevens WG, Harrington J, Alizadeh K, Broadway D, Zeidler K, Godinez TB. Eight-Year Follow-Up Data from the U.S. Clinical Trial for Sientra's FDA-Approved Round and Shaped Implants with High-Strength Cohesive Silicone Gel. *Aesthetic Plast Surg.*2015;35(S1);S3-S10
7. Handel N, Cordray T, Gutierrez J, Jensen JA. A Long-Term Study of Outcomes, Complications, and Patient Satisfaction with Breast Implants. *Plast. Reconstr. Surg.*2006;117:757-767
8. Tebbet JB. Achieving a Zero Percent Reoperation Rate at 3 Years in a 50-Consecutive-Case Augmentation Mammoplasty Premarket Approval Study. *Plast. Reconstr. Surg.*2005;118:1453-7
9. Costagliola M, Atiyeh BS, Rampillon F. An Innovative Procedure for the

- treatment of Primary and Recurrent Capsular Contracture (CC) Following Breast Augmentation. *Aesthetic Plast Surg.* 2013;33:1008-1017
10. Barone FE, Perry L, Keller T, Maxwell GP. The Biomechanical and Histopathologic Effects of Surface Texturing with Silicone and Polyurethane in Tissue Implantation and Expansion. *Plast. Reconstr. Surg.* 1992;90:77-86
 11. Maxwell GP, Schefflan M, Spear S, Nave BM, Haden P. Benefit and Limitation of Macrot textured Breast Implants and Consensus Recommendations for Optimising Their Effectiveness. *Aesthetic Plast Surg.* 2014;34:876-881
 12. Neal Handel. Long-Term Safety and Efficacy of Polyurethane Foam-covered Breast Implants. *Aesthetic Plast Surg.* 2006;26:265-274
 13. Burkhardt BR, Fried M, Schnur PL, Tofield JJ. Capsules, Infection, and Intraluminal Antibiotics. *Plast. Reconstr. Surg.* 1981. 81;68:43-49
 14. Biggs TM, Yarish RS. Augmentation Mammoplasty: A comparative Analysis. *Plast. Reconstr. Surg.* 1989;85:368-372
 15. Flugstad NA, Pozner jn, Baxter RA, Creasman C, Egrari S, Martin S, Messa III CA, Oliva A, Schlesinger L, Kortesis BG. Does Implant Insertion with a Funnel Decrease Capsular Contracture? A preliminary Report. *Aesthetic Surg J* 2014;36:550-556
 16. Deva AK, Commentaryon: Does Implant Insertion with a Funnel Decrease Capsular Contracture? A preliminary Report. *Aesthetic Surg J* 2014;36:557-558
 17. Courtiss EH, Golgwyn RM, Anastasi GW. The Fate of Breast Implants with Infections Around them. *Plast Reconstr Surg.* 1979;63:812-16
 18. Khan UD. Breast Augmentation, Antibiotic Prophylaxis and Infection: Comparative Analysis of 1628 Primary Augmentation Mammoplasties to Assess the Role and Efficacy of Length of Antibiotic Prophylaxis. *Aesth Plast Surg.* 2010; 34:42-47.
 19. Virden CP, Dobke MK, Stein P, Parsons CL, Frank DH. Subclinical infection of the silicone breast implant surface as a possible cause of capsular contracture. *Aesthete Plast Surg.* 1992;16:173-179
 20. Pajkos A, DevaAK, Vickery K, Cope C, Chang L, Cossart YE. Detection of subclinical infection in significant breast implant capsules. *Plast Reconstr Surg.* 2003;111:1605-1611
 21. Khan UD. Secondary Augmentation Mammoplasties and Periprosthetic Infection. A Three Year Retrospective Review of 92 Secondary Mammoplasties Performed by a Single Surgeon. *Aesthetic Surg J.* 2012; 32:465-473
 22. Persichetti P, Segreto F, PendolinoAL, Buono RD, Marangi GF. Breast Capsule Flaps and Grafts: A Review of the Literature. 2014;38:540-548
 23. Spear SL, Carter ME, Ganz JC. The Correction of Capsular Contracture by Conversion to "Dual-Plane" Positioning: Technique and Outcomes. *Plast. Reconstr Surg.* 2002;12:456-467
 24. Khan UD. High Transverse Capsuloplasty for the Correction of Malpositioned Implants Following Augmentation Mammoplasty in Partial Submuscular Plane. *Aesth Plast Surg.* 2012; 36:590-599
 25. Khan UD. Subglandular to Muscle Splitting Biplane Conversion for Revision Augmentation Mammoplasty. In: Mugea TT, Schiffmann MA, editors. *Aesthetic Surgery of the Breast.* 1st ed. Berlin: Springer; 2015. p. 535-41.
 26. Henriksen TF, FryzekJP, HolmichLR, McLoughlin JK, Kjo;erK, Hoyer AP, Olsen JH, Friis S. Surgical Intervention and Capsular Contracture After Breast Augmentation. A prospective Study and of Risk Factors. *Annals od Plastic Surger.* 2005;54:343-351

