Journal of Plastic, Reconstructive & Aesthetic Surgery (2007) **60**, 482—489

JPRAS
An International Journal of Surgical Reconstruction
www.JPRASurg.com

Soft cohesive silicone gel breast prostheses: a comparative prospective study of aesthetic results versus lower cohesivity silicone gel prostheses☆

P. Panettiere [a,*], L. Marchetti [b], D. Accorsi [b]

[a] *Dipartimento ''A. Valsalva'', Discipline Chirurgiche, Rianimatorie e dei Trapianti, Università degli Studi di Bologna, Via Massarenti 9, 40128 Bologna (BO), Italy*
[b] *Poliambulatorio Privato Dr. Pietro Panettiere, Via Matteotti 23, 40129 Bologna (BO), Italy*

Received 7 January 2006; accepted 20 April 2006

KEYWORDS
Breast augmentation;
Silicone;
Prosthesis;
Cohesivity;
Wrinkling

Summary The flexibility of lower cohesivity silicone prostheses is the main reason for wrinkling, rippling and evidence of implant edges. The soft cohesive silicone implants promise to minimize such effects with minimal softness reduction.

Forty consecutive patients received soft cohesive prostheses (INAMED® Style 110 ST™) and were studied prospectively. A historical group, made up by the 40 consecutive patients who received lower cohesivity silicone implants (INAMED® Style 110™) in the immediately preceding months, was used as a control.

Wrinkling, prosthetic edge perceptibility and capsular contracture degree were assessed six months after surgery. The tissue coverage thickness was measured using ultrasonography. The patients were then asked to evaluate the breast softness by means of an anonymous questionnaire, where they also expressed their overall satisfaction by means of the five-steps linear analogical scales.

The wrinkling prevalence was 9.2% in the soft cohesive group vs. 55% in the lower cohesivity one ($p < 0.01$). The edge perceptibility was 14% in the soft cohesive group vs. 22% in the lower cohesivity one (no statistical significance). The coverage tissue thickness was not found to be significantly related to the wrinkling prevalence or to the edge perceptibility. The capsular contracture rate was almost identical in the two groups (Baker II: 2.6% vs. 2.7%, no Baker III or IV). A higher stiffness

☆ The present work was presented at the annual meeting of SICPRE — ''Società Italiana di Chirurgia Plastica, Ricostruttiva ed Estetica'' (Italian Society of Plastic, Reconstructive and Aesthetic Surgery), Genova, Italy, October 21—24, 2005.

* Corresponding author. Tel.: +39 051 377477; fax: +39 051 377794.
E-mail address: danilo.accorsi@fastwebnet.it (P. Panettiere).

1748-6815/$ - see front matter
doi:10.1016/j.bjps.2006.04.020

was noted in the soft cohesive group (average score: 4.2 vs. 4.4 in the control group, $p < 0.05$), but the overall satisfaction degree was higher for soft cohesive implants (average score: 4.5 vs. 3.8, $p < 0.01$).

The soft cohesive prostheses offered better overall results than the lower cohesivity silicone prostheses, even if a longer term follow-up should be advised. The soft cohesive prostheses showed a higher firmness, but this seemed not to have any influence on the overall satisfaction degree.

The softness of low cohesivity breast prostheses may lead to higher risks of silicone spreading in case of prosthetic leakage, and the occurrence of wrinkling, rippling and excessive edge perceptibility. High cohesivity silicone gels have been proposed, but their firmness is considered excessive by some patients. So some producers introduced the so-called 'soft' high cohesivity prostheses. Although studies have been conducted about the correlations between cohesivity and silicone spreading, no thorough work shows the role of cohesivity degrees in determining or preventing wrinkling, rippling or edge perceptibility. The present study aims at defining the effect of soft high cohesivity gels in reducing the prevalence of wrinkling, rippling and edge perceptibility and giving acceptable results in terms of softness.

Patients and methods

A clinical prospective study was performed on 40 consecutive patients (soft cohesive group, SC) undergoing either bilateral breast augmentation for aesthetic reasons (36 patients) or unilateral augmentation (symmetrization) in contralateral breast reconstruction (four patients). The average age was 31.3 years (range: 18—54 years). Seven surgeries were secondary ones, due to prosthetic rupture (one patient), preventive substitution (three patients) or malposition (three patients). All the secondary surgeries were bilateral ones. A total number of 76 INAMED® Style 110 ST™ prostheses with an average volume of 293 cc (range: 170—435 cc) were implanted using peri-areolar access. All the prostheses were implanted in a partially subpectoral location (some personal minor variations were adopted, as described elsewhere[1,2]). Six patients underwent associated bilateral mastopexy (four peri-areolar techniques and two inverted T ones). All the operations were performed by the senior surgeon between October 2004 and January 2005. A retrospective group formed by the 40 consecutive patients operated on in the immediately preceding months (April—September 2004) by the same surgeon was used as a control (lower cohesivity group, LC) for the present study. The average age in the LC group was 30.8 years (range: 18—45 years). Thirty-five patients in the control group underwent bilateral surgery for aesthetic breast augmentation, while the remaining five ones received a unilateral prosthesis for symmetrization in contralateral breast reconstruction. Five surgeries were secondary bilateral ones, due to prosthetic rupture (one patient), preventive substitution (two patients) or malposition (two patients). Two unilateral surgeries were secondary ones as well, both due to prosthetic rupture. Six patients received associated bilateral mastopexy (two peri-areolar techniques and four inverted T ones). A total number of 75 INAMED® Style 110™ prostheses with an average volume of 286 cc (range: 180—360 cc) were implanted in the same location and with the same technique as in the prospective group.

No specific selection criteria were adopted and all the patients operated on for breast augmentation during the considered periods were included in the present study.

Only intra-capsular ruptures occurred and no trace of silicone outside the capsule was found at MR in all the patients who underwent revision mastoplasties due to prosthetic ruptures, both in the study group and in the control group. Intraoperative findings confirmed the absence of extra-capsular silicone. A total capsulectomy was performed in all the cases with ruptured prostheses, taking particular care in preventing silicone spreading.

All the patients in both groups were followed up for at least six months after surgerys, with a standard of seven, 15, 30 and 180 days scheduled visit. At the follow-up visit at six months, a thorough examination for the detection of wrinkling or rippling was performed. Any minimal superficial waviness or indentation at tangential light observation was considered as a 'visible rippling or wrinkling' (Fig. 1 a, c) while any minimal but evident feeling of at least two wave crests or an indentation at touch was noted, respectively, as

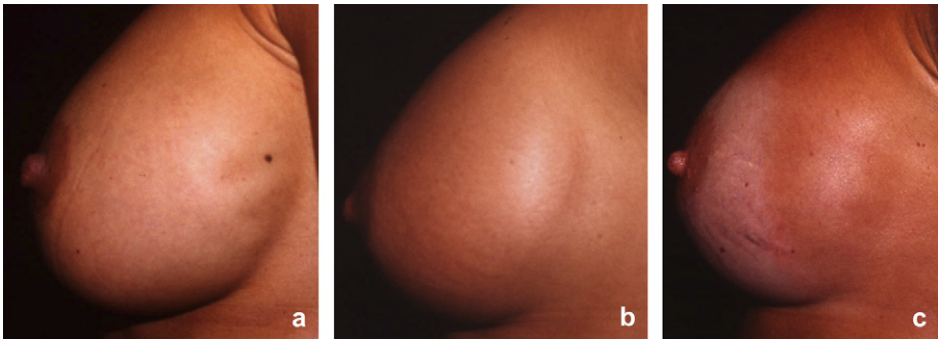

Figure 1 Visible defects of prostheses in the LC group. (a) Visible rippling; (b) visible border; and (c) visible rippling and visible border. No visible defect was found in the SC group.

a 'palpable rippling or wrinkling'. Border perceptibility was also examined, where a 'visible border' was defined as 'any case in which the margin of the breast faded to the thoracic wall with an even minimal discontinuity at tangential light observation' (Fig. 1 b, c); a 'palpable border' was defined as the 'perceptibility of a discontinuity in the transition between the breast border and the thoracic wall at touch'. The capsular contraction degree using the standard Baker's classification was also recorded. All the examinations were performed by a well-trained surgeon with the patient standing without her bra with lowered arms. Visual examinations were also performed both with the patient raising her arms and leaning forward. The examiner was not aware of the cohesivity degree of the prostheses being examined.

The tissue coverage thickness was measured at the six months follow-up visit by means of ultrasonography, by taking three different measures (from the skin surface to the capsule) near the inferior breast margin, which proved to be the area where such thickness was the lowest. The patients were in the standard position for breast ultrasonography (i.e. supine with the arm on the examined side lifted over their head). The probe (a 10.0-MHz high density linear array probe) was kept perpendicular to the skin without any pressure being applied to it. The average value between the three measures was assumed as the minimum tissue coverage thickness.

All the patients were (anonymously) asked to judge the softness of their breasts and express their overall satisfaction degree by means of two analogue five steps scales (from 'poor' to 'optimal'). The patients were asked to express their opinions always immediately before the six-month follow-up visit in order to avoid any influence of the examiner's findings over their statements.

The present study conforms to the World Medical Association Declaration of Helsinki (June 1964) and subsequent amendments. The research protocol of the present study needed no approval by the local Ethical Committee on the basis of the local ethical committee rules.

Statistical analyses were performed using Student's t, Chi square, Spearman's rank order correlation, and Fisher's exact tests.

Results

The two groups were substantially homogeneous regarding age, prosthetic volume, tissue coverage thickness, associated procedures and number of secondary surgeries.

Six months after surgery, capsular contracture degree was similar in the two groups: in the SC group, one patient presented a bilateral Baker II contracture (2.6%), while the remaining 39 patients were Baker I; in the LC group, one patient presented a bilateral Baker II contracture (2.7%), while the remaining 39 patients were Baker I. No Baker III or IV contractures were recorded at the six months follow-up visit.

Wrinkling or rippling were present (i.e. visible or palpable) in 41 out of the 75 breasts receiving lower cohesivity silicone gel prostheses (55%), significantly more than that in the SC group breasts (seven out of 76 breasts, 9.2%, $p = 0.0000000003564$ with a two tails Fisher's exact test). In particular, no visible wrinkling or rippling were observed in the SC patients, while wrinkling or rippling were visible in 17 breasts of the LC group. Wrinkling or rippling were palpable in seven breasts in the SC group vs. 24 breasts in the LC group ($p < 0.01$ with Chi square test).

Edge perceptibility was slightly higher in the LC group, but no statistical significance was found ($p = 0.14$ with Fisher's exact test). The edge was palpable in 11 breasts in the SC group and in 13 breasts in the LC group, and visible in no breasts in the SC group and in four breasts in the LC group (non-significant with Chi square test).

The average value of minimum tissue coverage thicknesses was 12.6 mm (range: 8—27 mm) in the SC group and 13.0 mm (range: 9—24 mm) in the LC one.

A weak correlation was found between the prevalence of wrinkling or rippling and the tissue coverage thickness in the LC group (Spearman's rank order correlation coefficient: −0.1), while no correlation could be found between the same parameters in the SC group (Spearman's rank order correlation coefficient: −0.024).

No significant correlation was found between the tissue coverage thickness and the edge perceptibility in the SC group (Spearman's rank order correlation coefficient: −0.03), while only a weak correlation between the same elements was found in the LC group (Spearman's rank order correlation coefficient: −0.28).

The patients generally evaluated the lower cohesivity silicone gel prostheses as softer than the SC ones. The average score using the five-steps linear scale (1 = poor, 2 = insufficient, 3 = sufficient, 4 = good, and 5 = optimal) was 4.2 in the SC group and 4.4 in the LC group. In particular, softness was judged as 'optimal' in 29 breasts of the SC group vs. 37 breasts of the LC group; a 'good' softness was stated in 34 breast in the SC group vs. 36 in the LC group; softness was evaluated as 'sufficient' in 12 breasts in the SC group vs. two breasts in the LC group; in one breast of the SC group the softness was judged as 'insufficient' by the patient ($p < 0.05$ with Chi square test).

Nonetheless, the overall satisfaction degree was found to be significantly higher ($p < 0.01$ at Chi square test) in the SC group patients than in the LC group. The average score using the five-steps linear scale (1 = poor, 2 = insufficient, 3 = sufficient, 4 = good, 5 = optimal) was 4.5 in the SC group and 3.8 in the LC group. In particular, the satisfaction degree was judged as 'very high' by 24 patients in the SC group vs. nine in the LC group as 'high' by 12 patients in the SC group vs. 16 in the LC group and a 'sufficient' satisfaction degree was indicated by four patients in the SC group vs. 14 in the LC group; no patient in the SC group judged her satisfaction degree as 'insufficient' vs. one in the LC group.

Besides the presence of superficial unevenness, the overall aesthetic results were fully satisfactory in both the SC group (Fig. 2) and the LC one (Fig. 3).

The subset of the patients undergoing primary breast augmentation without any mastopexy with either low cohesivity (LC subset: 27 patients, 51 implants) or soft-cohesive prostheses (SC subset: 29 patients, 54 implants) was also considered, in order to exclude any interference of the procedure on the results. Age, implant volume, tissue coverage thickness and contracture degree were similar in the two subsets.

Wrinkling or rippling were present in 30 out of the 51 breasts in the LC subset (59%), significantly more than in the SC subset breasts (seven out of 54 breasts, 13%, $p = 0.000001388$ with a two tails Fisher's exact test). No visible wrinkling or rippling were observed in the SC subset, while they were visible in 12 patients of the LC subset. Wrinkling or rippling were palpable in seven breasts in the SC subset vs. 18 breasts in the LC subset ($p < 0.01$ with Chi square test).

There was no significant difference between the two subsets regarding edge perceptibility ($p = 0.08$ with Fisher's exact test, non-significant with Chi square test).

The patients' evaluation of prosthetic softness in the primary surgery subsets was similar to the full group one: the average score was 4.2 in the SC subset and 4.5 in the LC subset. Softness was stated as 'optimal' in 21 breasts of the SC subset vs. 28 breasts of the LC subset, as 'good' in 24 vs. 22 breasts and as 'sufficient' in eight vs. one breasts; softness was judged as 'insufficient' in one breast of the SC subset. Nonetheless, no significant difference was found in the two subsets with the Chi square test.

Overall satisfaction degree in the two subsets was similar to that found in the total groups and it was significantly higher ($p < 0.01$ at Chi square test) in the SC subset than in the LC subset. The average score was 4.5 in the SC subset and 3.9 in the LC subset. The satisfaction degree was judged as 'very high' by 18 patients in the SC subset vs. five in the LC subset, as 'high' by eight vs. 14 patients and as 'sufficient' by three vs. seven patients; no patient in the SC group judged her satisfaction degree as 'insufficient' whereas one did in the LC group.

Discussion

The natural softness of third generation silicone gel prostheses, though being lower than the one of the non-cohesive gel in second generation prostheses, is the main reason for their wide use outside the US. Their feel on touch is similar to the soft tissues of the human breast and, when no capsular contracture occurs, it can be quite difficult to recognize their presence. Nonetheless, besides a higher risk of silicone diffusion in the case of shell rupture, the drawbacks for such softness are a higher perceptibility of their edge (mostly the lateral and the inferior portions in sub-glandular or double plane

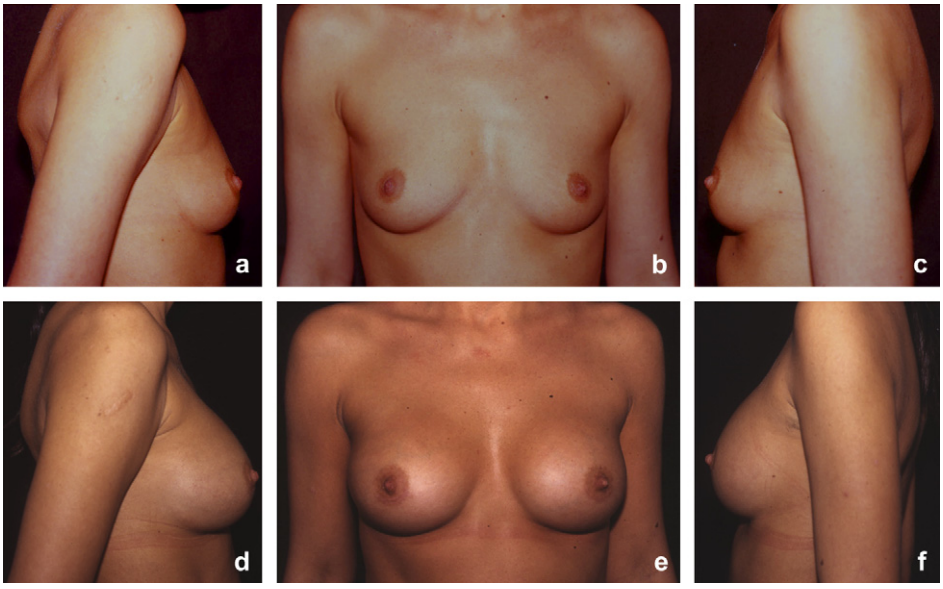

Figure 2 SC group result. (a—c) Before surgery; (d—f) after surgery.

locations) and the occurrence of rippling and wrinkling. The higher edge perceptibility derives from the fact that the prosthetic shell can easily flatten in the most peripheral areas, because usually the gel does not completely fill up the shell. In the upright position, the longitudinal and the transverse tensions on the anterior portion of the prosthetic shell are not equal. So, longitudinal wrinkles and ripples can appear.[3] When a textured surface is adopted, the peri-prosthetic capsule adheres to the prosthetic shell and all the surface alterations are transposed, even if usually in a softer fashion, to the covering tissues up to the skin. So, wrinkling and rippling become visible (traction wrinkling and rippling).[4,5] Mostly when a thin tissue coverage is present, such adverse effects can turn an optimal aesthetic result into a failure. On the other hand, wrinkling and rippling can reduce the implant shell lifespan, because a mechanical stress is added[6] and rupture usually occurs along such flexures, usually when a capsular contracture is associated. So, wrinkling and rippling should be considered not only when they become aesthetically relevant.

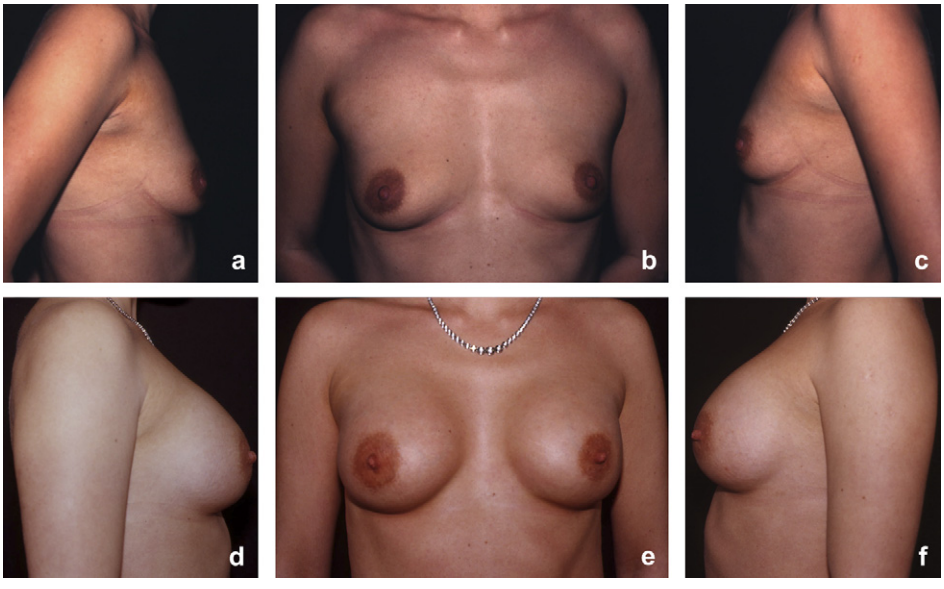

Figure 3 LC group result. (a—c) Before surgery; (d—f) after surgery.

Rippling and wrinkling, and also border perceptibility can be camouflaged by the use of various flaps,[7–10] but such solutions can only improve the aesthetic appearance while the mechanical adjunctive stress applied to the prosthetic shell still remains and can reduce the prosthetic shell duration.

The cohesivity is the tendency of a gel to stick or hold together. In silicone polymers, it is strictly dependent on the amount of cross-links in the polymer mass. Silicone gel prostheses can be produced by each manufacturer with various degrees of cohesivity, by changing the amount of 'crosslinker' in the making of the implant.

The need for prostheses with an anatomical shape, along with the concern about silicone spreading, induced the production of highly cohesive silicone gel prostheses. Such implants have no risk of rippling or wrinkling if no severe contracture occurs, but their firmness can be easily recognized and is not always accepted by the patients, especially when thin tissue coverage is present. Soft cohesive silicone gel prostheses have been marketed by Mentor® (Mentor Corporation, Santa Barbara, CA), Polytech® (Polytech Silimed Europe GmbH, Dieburg, Germany) and by INAMED® (INAMED Aesthetics, Santa Barbara, CA) with the aim of preventing silicone spreading and reducing wrinkling and rippling formation and border perceptibility, without excessively affecting softness. No precise information was given by the producers about the exact degree of cohesivity. Soft cohesive prostheses can be considered as an intermediate cohesivity grade between the lower cohesivity gels of third generation prostheses and the higher cohesivity gels of the anatomical prostheses available until now.

Soft cohesive gel prostheses were expected to be less prone than lower cohesivity ones to collapsing and to wrinkling and rippling,[5] due to their higher tendency to keep their shape and their lower susceptibility to deforming forces. We also expected that such behaviour could reduce edge perceptibility, because the shell should collapse less evidently at the edges and a less sharp border should appear.

The present study was designed to test the impact of silicone cohesivity on the aesthetic aspects of breast augmentation by comparing the behaviour of two different cohesivity degrees in the same prosthesis model. In particular, the INAMED® Style 110 ST™ and the INAMED® Style 110™ prostheses were chosen because of the experience accumulated by our group using them in the past years. Style 110™ is a round moderate projection textured model which is available either filled with a lower cohesivity silicone gel (merely named Style 110™) or with a soft cohesive silicone gel (the so-called Soft Touch™ model). Gel filling levels and prosthetic measures are the same in both the models. Thus, no bias effect can be attributed in the present study to the adequacy of shell filling.[6]

No specific inclusion criteria were adopted and all the patients asking for breast augmentation surgery were considered for the present study. The control group was formed by all the 40 consecutive patients operated on in the immediately preceding period, when Style 110™ prostheses were adopted by us as a standard model for breast augmentation. The two groups were homogeneous and similar, as no significant difference was found in terms of age, tissue coverage, prosthesis volumes and prevalence of secondary or associated procedures. Another extra value is added to the present study by the fact that all the patients (in both groups) were operated on by the same surgeon, thus reducing the effects of different techniques or surgical skills.

The subpectoral location is commonly adopted to reduce the prevalence and the evidence of wrinkling and rippling.[3] Nonetheless, wrinkling and rippling cannot be completely ruled out, especially in the lower poles, which are not covered by the pectoral muscle, and when textured implants are adopted.[4,5]

The different cohesivity was found not to be responsible for a different prevalence in capsular contracture.

Wrinkling and rippling rates were significantly higher in the patients where lower cohesivity silicone gel prostheses were implanted. So, the soft cohesive gel prostheses proved to be able to reduce the prevalence of such adverse effects, confirming the first part of our hypothesis. The true limit of the present study is related to the relatively short follow-up period. In our experience the large majority of wrinkling and rippling phenomena (on the contrary of other defects) occur within the first six months since surgery.

In order to maximize the detection of adverse effects, stringent method of wrinkling and rippling identification was adopted. Even if such a policy could lead to overestimate the prevalence of superficial unevenness, the main goal of the present study was to compare the behaviours of two different cohesivity gels and not to perform an epidemiological study. Secondarily, we believe that the presence of minimal but evident shell distortions should be emphasized, because of their possible role in prosthetic rupture, even if they

don't necessarily create an aesthetic defect. In any case, the same detection rules were applied to both groups, so any overestimate should have been evenly applied to both study branches. The main reason why the level of patients' satisfaction was also taken into account was to counterbalance such a possible overvalue. In fact, overall satisfaction degree was good in both groups, regardless of the prevalence of unevenness. However, longer follow-up observations are needed to verify the stability of the results and different prosthetic locations should be examined too.

The edge perceptibility was only slightly lower in the patients receiving soft cohesive prostheses and no statistically significant result could be demonstrated. An important role in the edge perceptibility is undoubtedly played by the thickness of the covering tissue, mostly in the lower quadrants when using the partial submuscular location. But the present study failed in finding such correlation, because in the SC group, edge perceptibility was found to be independent from tissue coverage. Therefore, no conclusion can be assumed about the role played by gel cohesivity in edge visibility or palpability.

The actual effect on patient satisfaction of a higher prosthetic stiffness was assessed. Other studies show good patient satisfaction when using soft cohesive gel prostheses,[11] but such studies were not based on a comparison between two different gel cohesivity degrees. The present study was designed to obtain patient's opinion by means of an anonymous questionnaire. The patients received instructions to only take into account the situation at six months and not to be influenced by whatever events could have occurred in the first few months, in order to make them evaluate what were believed to be stable results. When stating their overall satisfaction degree, they were asked not to take into account any possible concern about risks of silicone spreading and only to focus on their opinion about the aesthetic aspects of their breast augmentation.

The patients with soft cohesive prostheses reported their implants as stiffer than those who received lower cohesivity prostheses, and the results about the softness of the prostheses in the SC group (82% of prostheses judged as soft) were consistent with those already published in the past by other authors.[11] Nonetheless, the overall satisfaction degree was significantly higher in the SC group. The patients were not asked to justify their satisfaction degree (it could have compromised the anonymity of the questionnaire) and no direct correlation could be made between non-optimal results and wrinkling, rippling, border perceptibility, contracture or prosthesis stiffness, due to anonymity. But in our opinion, such results can be interpreted to mean that the patients have a higher interest in the absence of superficial defects, even if a higher stiffness is to be accepted, as demonstrated by other studies in the past.[5]

A subset of the two studied groups was also analysed, considering only primary augmentations and excluding any added procedure (periareolar or inverted T mastopexy), in order to prevent any possible procedure-linked bias. The results were almost identical to the total groups, besides the lack of statistical significance in differences between stiffness perception degrees.

To our knowledge, the present study is the first one designed to directly compare different silicone cohesivity degrees regarding border perceptibility and stiffness; it should be completed by a comparison between soft cohesive silicone gel prostheses and highly cohesive prostheses, in order to assess the actual acceptance degree of prosthetic stiffness.

Soft cohesive silicone gel prostheses proved to be able to reduce the incidence of visible or palpable wrinkling and rippling.

Their higher stiffness is well recognized by the patients, but proved not to influence significantly the satisfaction degree. On the contrary, the occurrence of wrinkling and rippling seemed to significantly weigh negatively in evaluating overall satisfaction degree.

A higher cohesivity seems to play no significant role in edge perceptibility.

Further studies should be made with longer follow-up periods and to test the weight of stiffness in overall satisfaction degree when comparing soft cohesive prostheses against highly cohesive ones.

Acknowledgements

No funding or other support was obtained for the present study. The authors declare that they have no commercial interest in products used in the present study.

References

1. Panettiere P, Marchetti L, Accorsi D, et al. Augmentation mammaplasty of teardrop-shaped breasts using round prostheses. *Aesthetic Plast Surg* 2003;**27**:20—6.
2. Pelle-Ceravolo M, Del Vescovo A, Bertozzi A, et al. A technique to decrease breast shape deformity during muscle contraction in submuscular augmentation mammaplasty. *Aesthetic Plast Surg* 2004;**28**:288—94.

3. Nicolle FV. Capsular contracture and ripple deformity of breast implants. *Aesthetic Plast Surg* 1996;**20**:311—4.
4. Handel N, Jensen JA, Black Q, et al. The fate of breast implants: a critical analysis of complications and outcomes. *Plast Reconstr Surg* 1995;**96**:1521—33.
5. Dionyssopoulos A. Imperfections de résultats des implants mammaires. *Ann Chir Plast Esthet* 2005;**50**:534—43.
6. Tebbetts JB. Patient acceptance of adequately filled breast implants using the tilt test. *Plast Reconstr Surg* 2000;**106**: 139—47.
7. Baxter RA. Intracapsular allogenic dermal grafts for breast implant-related problems. *Plast Reconstr Surg* 2003;**112**:1692—6.
8. Gargano F, Moloney DM, Arnstein PM. Use of a capsular flap to prevent palpable wrinkling of implants. *Br J Plast Surg* 2002;**55**:269.
9. Massiha H. Scar tissue flaps for the correction of postimplant breast rippling. *Ann Plast Surg* 2002;**48**:505—7.
10. McGregor JC, Bahia H. A possible new way of managing breast implant rippling using an autogenous fascia lata patch. *Br J Plast Surg* 2004;**57**:372—4.
11. Fruhstorfer BH, Hodgson EL, Malata CM. Early experience with an anatomical soft cohesive silicone gel prosthesis in cosmetic and reconstructive breast implant surgery. *Ann Plast Surg* 2004;**53**:536—42.