Motiva®
implant matrix

Motiva Implant Matrix® Silicone Breast Implants
Summary of Clinical Data
4-Year Follow Up

October 2010 - March 2015

Establishment LABS

OVERVIEW

A Prospective, 10-year follow-up clinical evaluation is being conducted to confirm Motiva Implant Matrix® Silicone Breast Implants safety and effectiveness in 220 augmentation and revision patients. Patient follow-up was established at 24 hours, 4 days, 2 weeks, 1 month, 3, 6 and 12 months, and will continue to evaluate the long- term (10 years) safety and effectiveness of Motiva products. The Clinical Evaluation Plan for the Evaluation of Motiva Implant Matrix® Silicone Breast Implants in Aesthetic Breast Augmentation was initially designed to include 40 patients, however addenda to the initial protocol were approved to include up to 220 patients in the study.

Safety was assessed by the presence of complications, such as implant rupture, capsular contracture, double capsules or late seromas that lead to reoperation. The efficacy of Motiva Implant Matrix® Silicone Breast Implants was measured by the surgeon and patient through an assessment of their level of satisfaction with the aesthetic results, as well as by the Quality of Life (QoL) Tool. Surgeon's level of satisfaction with the augmentation procedure was measured on a 5-point Likert scale, while the patient's satisfaction at the time of the follow-up visits assessment was based on 6-point Likert scale. The QoL measures were a combination of the Rosenberg Self Esteem Scale, the Body Esteem Scale, the Tennessee Self Concept Scale, and the SF-36, as explained in the Protocol. Data was collected before implantation and at all scheduled follow-up visits.

This evaluation was monocentric, conducted at a Plastic Surgery Center accredited by the American Association For Accreditation of Surgery Facilities, by a group of board certified Plastic and Reconstructive Surgeons.

Between September and October 2010, 36 augmentation patients (called group A) were operated on, using general anesthesia, for the following indications (as defined by the treating surgeons): Mammary hypotrophy and hypotrophy plus ptosis grade II or I. Regarding the reason for the surgery, 100% of the patients of group A were primary augmentation cases, with no cases of reconstructive surgery (according to the Protocol for this evaluation). Four revision surgeries were performed three, six, ten and 24 months after the initial augmentation procedure. Two of the four revision surgeries were performed on the same patient. The median age at surgery was 31 years. The average weight at surgery was 55.8 kg, and 4 out of 36 implanted patients were smokers.

Most of the patients requested a moderate augmentation, with an average cup size change of one cup. The estimated average implant size calculated by the surgeon prior the surgery was 318 cc, which was close to the actual average volume used across the 36 patients: 326.7 cc. The most frequently used projection family was the Full family (3.5-6.1 cm), in 75% of the cases. The average implant base (diameter) was 11.1 cm, which corresponds to a value very similar to the median in the Motiva Implant Matrix catalog.

The most common incision site was inframammary (97%) with only one case of transaxillary approach. The most frequent site of placement was submuscular (69%), followed by the subfascial placement (14%), the subglandular placement (14%) and the dual plane placement (3%).

Drains were not applied in any of the cases and no intraoperatory complications were reported. The perioperatory was characterized by the absence of infection, hematoma, and suture dehiscence; implant exposure, intra-operatory or immediate post-operatory complications.

According to the Protocol and subsequent addenda, the Motiva Implant Matrix® Silicone Breast Implants used are either SilkSurface™ (also commercially known as SmoothSilk®), or VelvetSurface™. These surfaces are manufactured by negative imprinting using 3D technology, in direct contrast with surfaces made with the projection of salt or sugar crystals. These are not conventional surfaces: SilkSurface™ has 8.000 contact points per cm^2 of an average size of 16 microns each and a profile roughness parameter (RA) of 2488. The VelvetSurface™ used in part for Group B, has 1800- 2200 contact points of 40-100 microns depth per cm^2 and a profile roughness parameter (RA) of 7001. The characterization of both implant surfaces was performed in collaboration with the Plastic and Reconstructive Surgery Research Center, at the University of Manchester, United Kingdom.

Figures 1 and 2 show Optical and Scanning Electron Microscopies characterizations of SilkSurface™ and VelvetSurface™.

Figure 1. Surface Optical Characterization (a) and Scanning Electron Microscopy (b) of Motiva Implant Matrix® Round SilkSurface™.

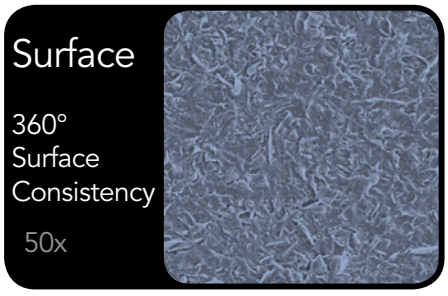
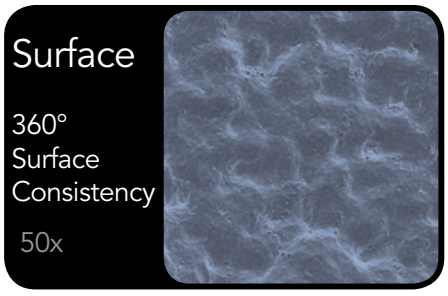


Figure 2. Surface Optical Characterization (a) and Scanning Electron Microscopy (b) of Motiva Implant Matrix® Round VelvetSurface™.



CLINICAL RESULTS

SAFETY OUTCOMES - GROUP A

Table 1 shows some of the main characteristics of the patients treated/procedures performed. The patient´s clinical evolution 4 years after the breast augmentation procedure was highly satisfactory, as shown in Table 2. This 4-year summary includes the results for 32 of the 36 patients originally implanted (Group A). Due to the fact that it is not possible to analyze the safety and efficacy of the original implants in the three reimplanted (3) patients, their results are detailed and reported separately.

Table 1: Breast Augmentation with Motiva Implant Matrix® Silicone Breast Implants (n=32), Group A.

Average age	31 (21 to 51 range)
Average weight	55.8 kg
Surface	SmoothSilk® / SilkSurface™ (100%)
Most frequent incision	Inframammary (97%)
Most frequent placement	Submuscular (69% traditional, 14% subfascial, 3% dual plane)
Average volume	326.7cc (235 cc to 400 cc range used)
Most frequent Projection	Full projection (medium height) in 75% of the implantations
Most frequent Base	11.1 cm (similar to Matrix median)

It is important to note that, for the entire Group A, no cases of pain, edema, erythema, inflammatory reaction, hematoma, seroma, infection, scaring, calcification, granuloma, stretch marks, pruritus, tightness, symmastia, extrusion, asymmetry, rippling, malposition of the implant or irregular appearance were observed during the 48- month follow-up visit.

Table 2: Relevant Clinical Data Recorded During the 4-Year Follow-Up Visit (n=32*), Group A.

Safety	
Changes in nipple sensitivity	15.6% of the patients (5 patients out of 32)[1]
Twinges	6.25% of the patients (2 out of 32)[2]
Ptosis	15.6% of the patients (5 out of 32 in both surgical sites)
Reported loss of volume[3]	6.25% of the patients (2 out of 32 in both surgical sites)

[1] One patient reported hypersensitivity in one surgical site, for a 1.6% of the surgical sites. Four patients reported loss of nipple sensitivity, one in both surgical sites, two in the left nipple and one in the right nipple, for a total of 7.8% of the surgical sites.

[2] Two patients reported twinges in a single breast, for a 3.1% of the surgical sites.

[3] Subjective perception not confirmed by imaging or 3D scans.

** n=32: The three revision surgeries are reported separately.*

Revision Surgery Cases

Of the 36 patients originally implanted, one patient requested a reoperation three months after the primary surgery to correct an aesthetic dissatisfaction due to a larger than desired breast size.

Safety data for this patient up to month 48, indicate that no other events were observed and her reported level of satisfaction at this visit is high (extremely satisfied).

A second patient was diagnosed with Grade II ptosis and her satisfaction level with her augmentation procedure had decreased significantly in comparison with the 3-month follow-up data (from extremely satisfied on month 3 to satisfied on month 6). The patient was reoperated on and a mastopexia with implants replacement was performed 6 months after the primary procedure. The patient reported to be satisfied with the outcome during the 1-year and 2-year follow-up visits.

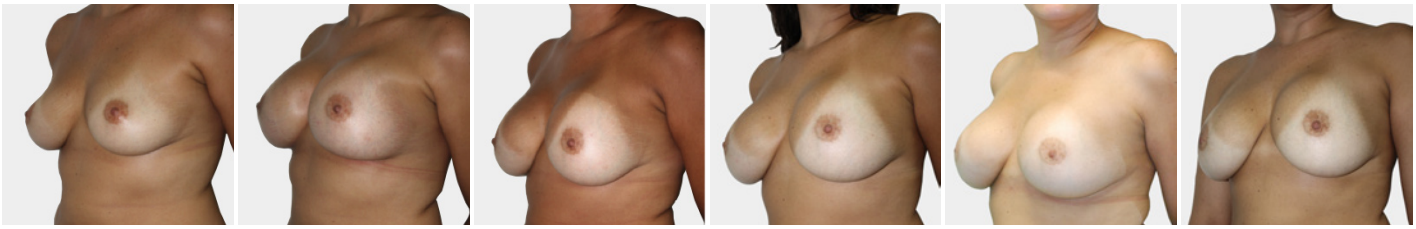
Safety data for this patient up to month 24 indicate that no adverse events were observed, however, the patient requested a new surgery to replace her implants for a larger size, a criteria not shared by the surgeons. The patient did not attend the 3-year and 4-year follow-up visits.

The third reoperation case, in which a periareolar "round block" mammoplasty was performed, was a patient with tubular breasts who, in spite of being satisfied with her aesthetic result after primary implantation, was considered by the treating surgeon to have a good improvement opportunity, as shown in Figure 3. The Motiva breast implants originally implanted were not removed or replaced during the round block procedure, performed 10 months after the primary augmentation surgery. In her 2-year follow-up visit, this patient reports a high level of satisfaction with her aesthetic result (extremely satisfied). However, and in spite of being extremely satisfied with the aesthetic result, the surgeon recommended a breast implant replacement, which was performed 26 months after the primary surgery, to improve the aesthetic result even further

Up to date, 24 months after her last surgery, no adverse events were reported for this patient. Both patients and surgeons reported a high level of satisfaction.

In the three cases, histological analysis of the removed implants pseudo-capsule did not show signs of contracture or any other anomaly (Figures 3, 4 and 5 depict the above-mentioned reoperation cases).

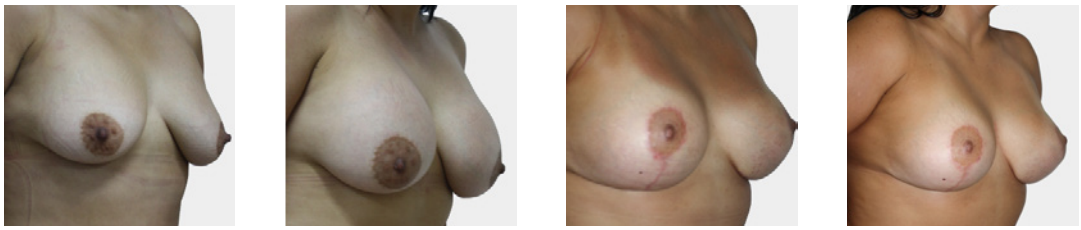
Figure 3: Preoperatory and Postoperatory with Motiva Implant Matrix® 375 cc, Full Projection, and After Reoperation and Replacement with Motiva Implant Matrix® 275 cc, Full Projection (3 months, 24 months, 36 months and 48 months).



Preoperatory | Primary Augmentation, 375cc Full | 275cc Full, 3 months | 275cc Full, 24 months | 275cc Full, 36 months | 275cc Full, 48 months

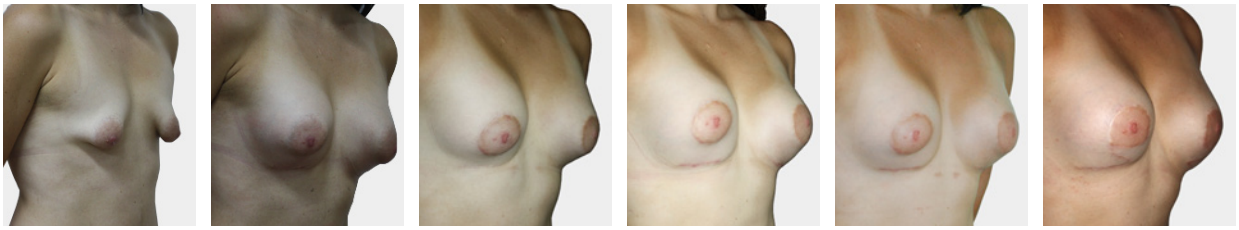
Figure 4: Preoperatory and Postoperatory with Motiva Implant Matrix® 375 cc Full Projection, and After Reoperation and New Implantation with Motiva Implant Matrix® 375 cc Full (3 months and 24 months).*

**This patient abandoned the casuistic two years after the primary implantation.*



Preoperatory | Primary Augmentation Before Mastopexia | Revision Surgery After Mastopexia | Revision 24 Months After Mastopexia

Figure 5: Breast Augmentation with Motiva Implant Matrix® 335 cc Full Projection, Subsequent Periareolar "Round Block" Mammoplasty and New Breast Augmentation with Motiva Implant Matrix® 350 cc Corsé Projection, Performed on a Patient with Tubular Breasts.



Preoperatory | After Primary Augmentation | After 24 months "round block" mammoplasty | New breast augmentation after 3 months | New breast augmentation after 12 months | New breast augmentation after 24 months

SAFETY OUTCOMES - GROUP B

Between November 2011 and March 2014, 73 additional patients (group B) have been implanted with Motiva Implant Matrix® Silicone Breast Implants in the same clinical center and following the same guidelines and procedures stated in the original Clinical Evaluation Plan for the Evaluation of Motiva Implant Matrix® Silicone Breast Implants in Aesthetic Breast Augmentation. 39 out of 73 patients have received SilkSurface™ and SilkSurface™ PLUS Motiva Implant Matrix® implants and 34 patients have been implanted with VelvetSurface™ and VelvetSurface™ PLUS Motiva Implant Matrix® Implants.

To the date of submission of this evaluation, of the total 73 additional patients implanted with Motiva Implant Matrix® Silicone Breast Implants 71, 67, 61, 53 and 18 patients have attended the first month, third month, sixth month, 1-year and 2-year follow-up visits, respectively. Table 3 shows some of the main characteristics of group B patients (n=73).

Table 3: Breast Augmentation with SilkSurface™ (n= 39) and VelvetSurface™ (n=34) Motiva Implant Matrix® Silicone Breast Implants, Group B.

Average age	34 (21 to 58 range)
Most frequent incision	Inframammary (78%)
Most frequent placement	Submuscular (60%)
Average volume	302.5 cc (135 cc to 500 cc range used)
Most frequent Projection	Full projection (medium height) in 51% of the implantations
Most frequent Base	10.5 cm

For this group of patients, the perioperatory was also characterized by the absence of infection, hematoma, suture dehiscence, implant exposure or intra-operatory or immediate post-operatory complications.

The results of the 1-year follow-up visit, available for 73% of the additional patients (n=53), are described below.

No cases of pain, edema, erythema, inflammatory reaction, hematoma, seroma, infection, calcification, granuloma, stretch marks, ptosis, extrusion, insufficient aesthetic result, asymmetry, rippling, malposition or irregular appearance were observed during the 1-year follow up visit. It is important to note that no cases of rupture, capsular contracture, double capsules, late seromas or ALCL were reported during the 1-year period evaluated.

Table 4: Relevant Clinical Data Recorded During the 1-Year Follow-Up Visit (n=53) of the Additional Cases Implanted with SilkSurface™ (n= 28) and VelvetSurface™ (n=25) Motiva Implant Matrix®.

Safety	
Changes in nipple sensitivity	18.9% (10 out of 53)[1]
Pruritus	1.88% (1 out of 53 in both surgical sites)
Tightness	5.7% (3 out of 53 in both surgical sites)
Twinges	17% (9 out of 53)[2]
Bilateral loss of volume	1.88% (1 out of 53)
Bilateral symmastia	1.88% (1 out of 53)
Bilateral scarring	1.88% (1 out of 53)

[1] One patient reported hypersensitivity in one breast, for a total of 1% of the surgical sites. One patient reported loss of nipple sensitivity in a single surgical site and eight patients in both breasts, for a total of 16% of the surgical sites.

[2] One patient reported twinges in a single breast and eight patients in both breasts, for a 17% of the surgical sites.

SAFETY OUTCOMES GROUPS A AND B

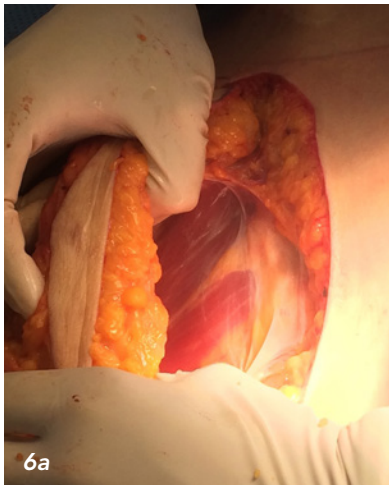
As shown in Table 5, there are no cases of rupture, capsular contracture, double capsules, late seromas reported during the 4-year period evaluated for patients in group A at Year 1, 2, 3 and 4 or group B at Year 1. Given the special nature of these surfaces, the clinical results observed and the survival rate of the complications are very promising. These surfaces were engineered to have very low roughness parameters, theoretically with the aim of reducing inflammation in the post-operative period and preventing chronic inflammation after the recovery period. A first level of evidence is shown in Figure 6, in two cases of patients requesting breast implant replacement for aesthetic reasons and who originally had SilkSurface™ implants for (a) 6 months and (b) 26 months. In both cases a very thin pseudocapsule is the result of a breast implant surface characterized by a multitude of contact points with a low roughness parameter. It is significant that the group of surgeons participating in the clinical evaluation follows a best-practice protocol[1] for breast augmentation that in combination with these surfaces, has so far resulted in no capsular contracture or rupture cases.

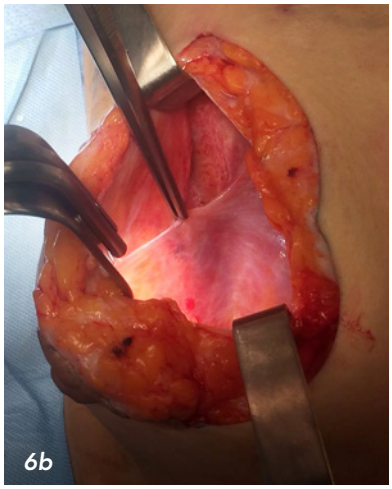
[1] *Tebbets, J.B. Achieving a zero percent reoperation rate at 3 years in 50 consecutive case augmentation mammaplasty PMA study. Plast. Reconstr. Surg. 108(6): 1453-1457, 2006.*

Table 5: Percentage and Total Number of Adverse Events Reported in Groups A and B.

	Year 1 After Surgery	Year 2 After Surgery	Year 3 After Surgery	Year 4 After Surgery
Capsular Contracture	0% (0/172)	0% (0/104)	0% (0/66)	0% (0/64)
Rupture	0% (0/172)	0% (0/104)	0% (0/66)	0% (0/64)
Double Capsules	0% (0/172)	0% (0/104)	0% (0/66)	0% (0/64)
Late Seromas	0% (0/172)	0% (0/104)	0% (0/66)	0% (0/64)

Figures 6A and 6B Show the Resulting Pseudocapsules After Primary Breast Augmentation with Silksurface™ in Two Different Patients Requesting a Reoperation for Aesthetic Reasons, At 6 Months and 26 Months Respectively. A Very Thin Capsule Demonstrates the Positive Clinical Outcome of these Surfaces.





EFFECTIVENESS OUTCOMES - GROUP A

Patient and Surgeon´s Level of Satisfaction

In general, the level of satisfaction for both patients and surgeons was high at all endpoints during all the follow-up visits, up to month 48. The results show that a 100% of the patients were satisfied to extremely satisfied with the aesthetic results, as depicted in Charts #1 and #2. Additionally, the surgeons were very satisfied to extremely satisfied with the aesthetic results in 94% of the cases, as shown in Charts #3 and #4.

Chart #1: Patient´s Level of Satisfaction with the Breast Augmentation Procedure Aesthetic Results, 48 Months After The Implantation (n=32), Group A.

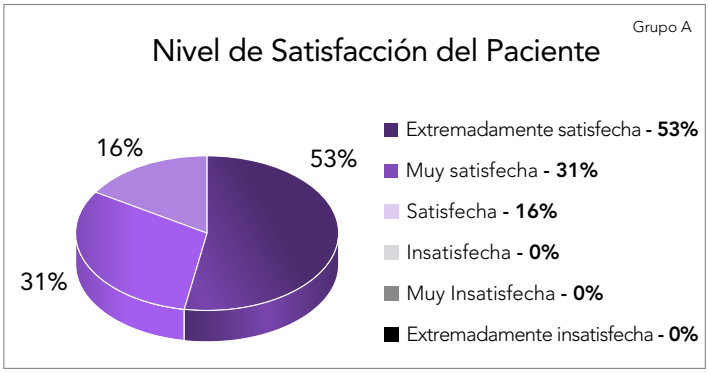


Chart #2: Patient's Level of Satisfaction 48 Months After the Implantation, Using Gaussian Distribution of the Data (n=32), Group A.

Chart #2 shows that the median for patient´s level of satisfaction is 1.625, which means that the vast majority of the implanted patients are extremely to very satisfied with the aesthetic results provided by their breast augmentation surgical procedure. This is statistically significant, with a 95% level of confidence (SD: 0.7513).

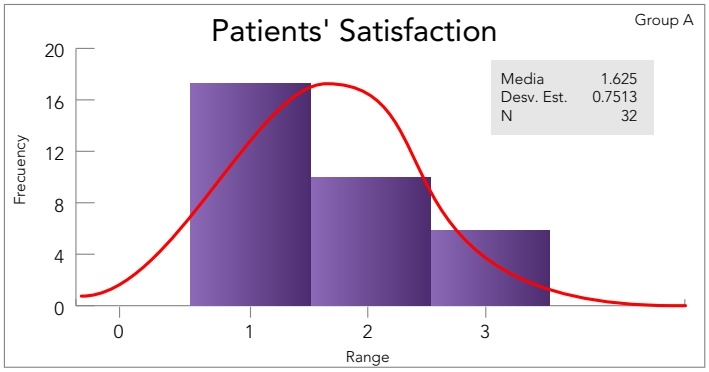


Chart #3: Surgeon´s Level of Satisfaction with the Breast Augmentation Aesthetic Results, 48 Months After the Implantation (n=32), Group A.

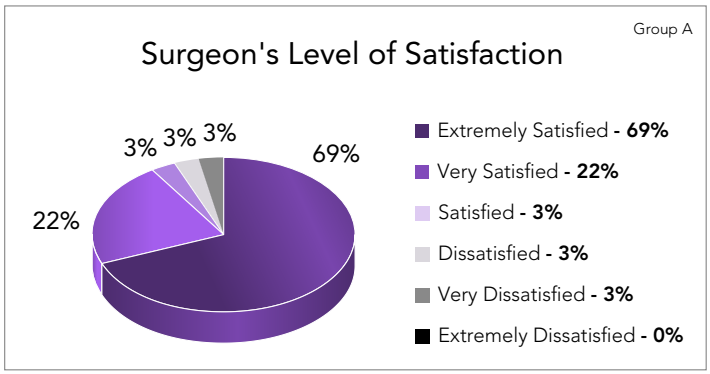
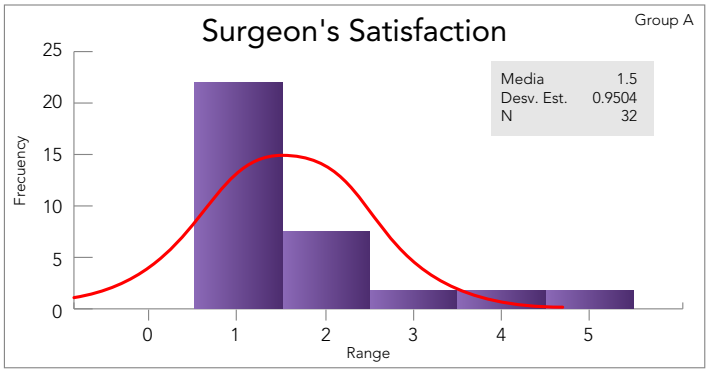


Chart #4: Surgeon´s Level of Satisfaction 48 Months After the Implantation Using Gaussian Distribution of the Data (n=32), Group A.

Chart #4 shows that the median for surgeon´s level of satisfaction is 1.5, which means that the treating surgeons are extremely to very satisfied with the use of Motiva Implant Matrix® in the implanted population. This is statistically significant, with a 95% level of confidence (SD: 0.9504). It should be noted that the surgeons report dissatisfaction with the aesthetic results on the fourth year visit in 6% of the cases (2 out of 32 patients) due to the patient´s significant weight gain.



Reoperation Cases Satisfaction Level

Up to date, satisfaction data is only available for two of the three reoperation cases. For these two cases, both patient and surgeon report to be at least "very satisfied" with the aesthetic result.

Quality of Life and Self-Esteem

As stated in previous reports, an improvement in the self-esteem and quality of life scores has been observed in comparison to the preoperative values. Preoperatively, the patient´s average score on the 9 self-esteem and quality of life variables evaluated was 8.86 (1 being the lowest value and 10 the highest). The average scores on all 9 variables recorded preoperatively and during the 2-week, 1-month, 2-month, 3-month, 6-month, 12-month, 24-month, 36-month and 48-month follow-up visits were 8.86, 8.88, 9.07, 9.19, 9.22, 9.25, 9.34, 9.27, 9.17 and 8.98, respectively. A 1.2% increase in overall self-esteem / quality of life scores was observed 48 months after the implantation, compared to the baseline level. Although a reduction in overall self-esteem / quality of life scores was observed 48 months after the implantation, compared to the previous post-operatory follow-ups, this is believed to be due to individual variables such as weight gain, pregnancies and other personal situations at the moment of evaluation. In fact, 5 out of the 32 evaluated patients reported an important weight gain and significant reductions in their self-esteem / quality of life scores, causing the average scores to be lower.

The following chart shows the change of quality of life / self-esteem average scores from the preoperative visit up to the 48-month follow-up visit.

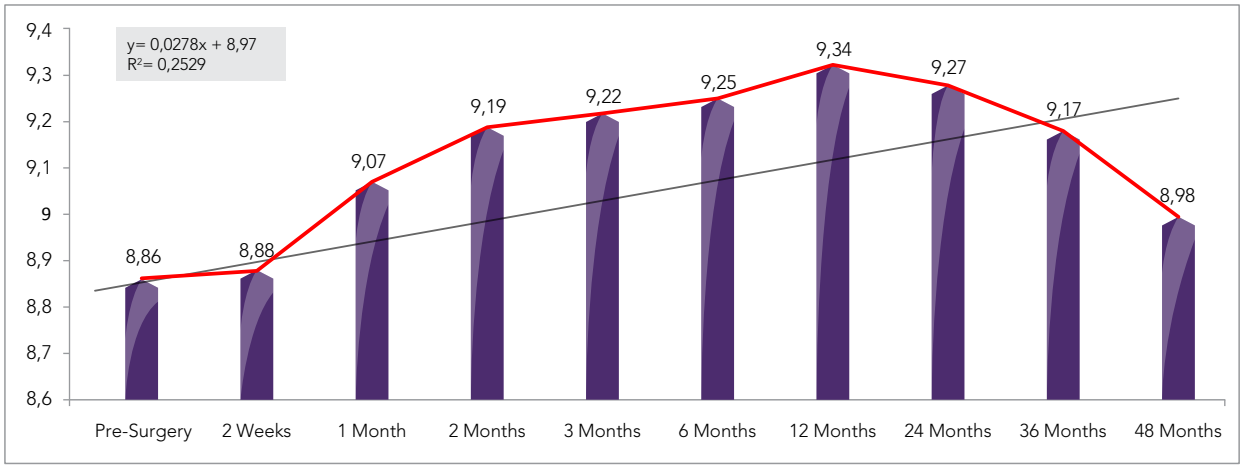
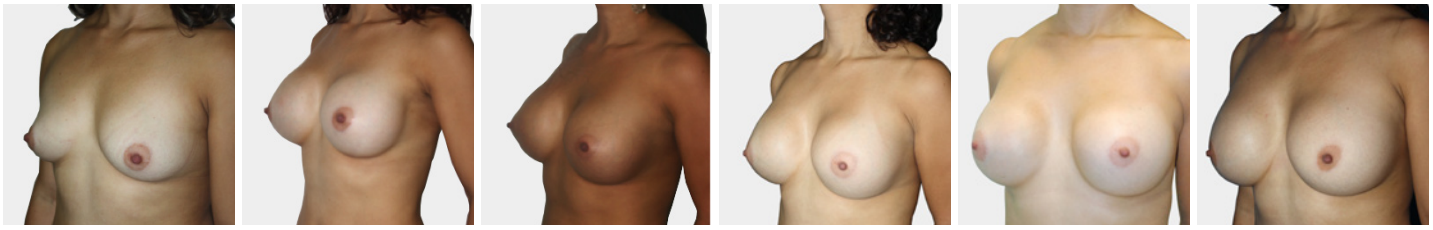


Chart 5: Average Scores on the Self-esteem and Quality of Life Scales (from a 1 to 10 scale) Before the Augmentation Surgery and 2 Weeks, 1 Month, 2 Months, 3 Months, 6 Months, 12 Months, 24 Months, 36 Months and 48 Months After the Breast Augmentation Procedure (n=32).

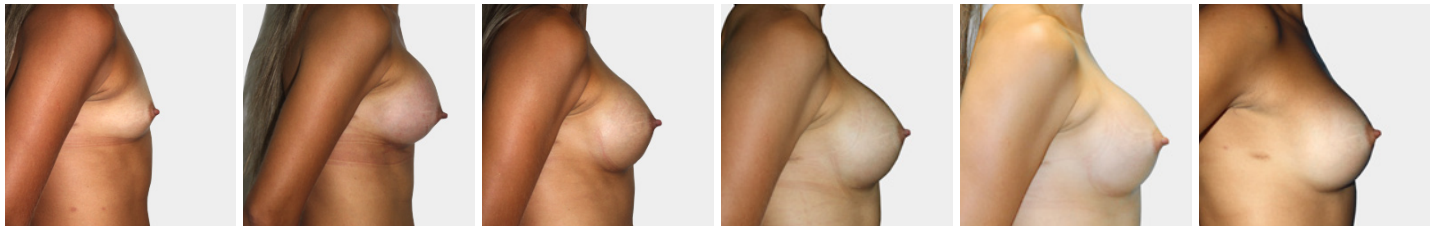
Figures 7 and 8 depict some of the patients that underwent breast augmentation with Motiva Implant Matrix® Silicone Breast Implants within this prospective clinical evaluation.

Figure 7: Breast Augmentation Results with Motiva Implant Matrix® Silicone Breast Implants 355 Full Projection.



Preoperatory | 6 Months | 1 Year | 2 Years | 3 Years | 4 Years

Figure 8: Breast Augmentation Results with Motiva Implant Matrix® Silicone Breast Implants 325 Corsé Projection.



Preoperatory | 6 Months | 1 Year | 2 Years | 3 Years | 4 Years

ADDITIONAL EFFICACY EVIDENCE

EFFECTIVENESS OUTCOMES - GROUP B

Patient and Surgeon´s Level of Satisfaction

In general, the level of satisfaction of both patients and surgeons was high at all endpoints during all the follow-up visits, up to year 1 (Group B). The results show that a 98% of the patients were satisfied to extremely satisfied with the aesthetic results, as depicted in Charts #6 and #7. Additionally, the surgeons were very satisfied to extremely satisfied with the aesthetic results in 100% of the cases, as shown in Charts #8 and #9.

Chart #6: Patient's Level of Satisfaction with the Breast Augmentation Procedure Aesthetic Results, 1 Year After the Implantation (n=53), Group B.

**The only case of dissatisfaction corresponds to a patient who suffered a case of symmastia, which is unrelated to efficacy or safety of the implants.*

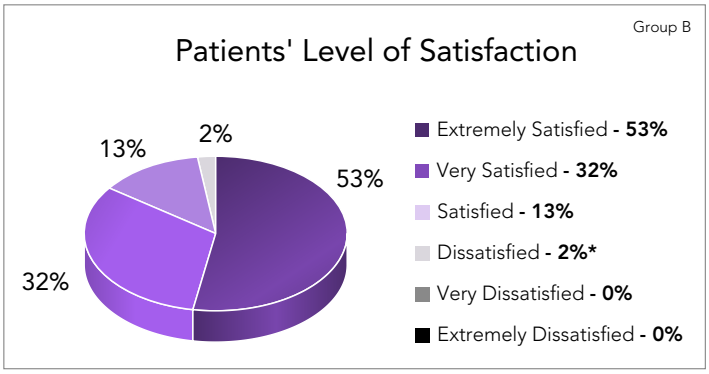


Chart #7: Patient's Level of Satisfaction 1 Year After the Implantation, using Gaussian Distribution of the Data (n=53), Group B.

Chart #7 shows that the median for patient´s level of satisfaction is 1.660, which means that the vast majority of the implanted patients are very to extremely satisfied with the aesthetic results provided by their breast augmentation surgical procedure. This is statistically significant, with a 95% level of confidence (SD: 0.8536).

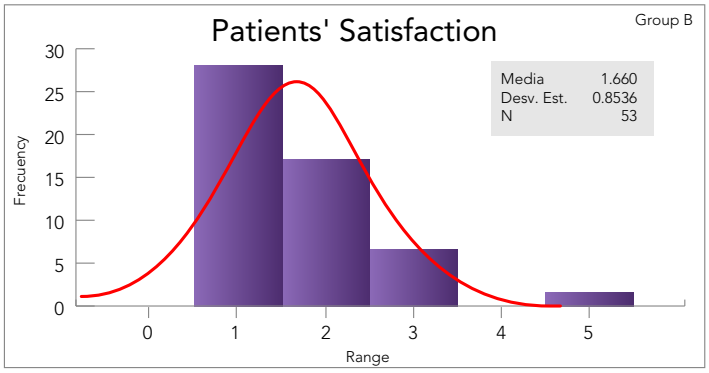


Chart #8: Surgeon´s Level of Satisfaction with the Breast Augmentation Aesthetic Results, 1 Year After the Implantation (n=53), Group B.

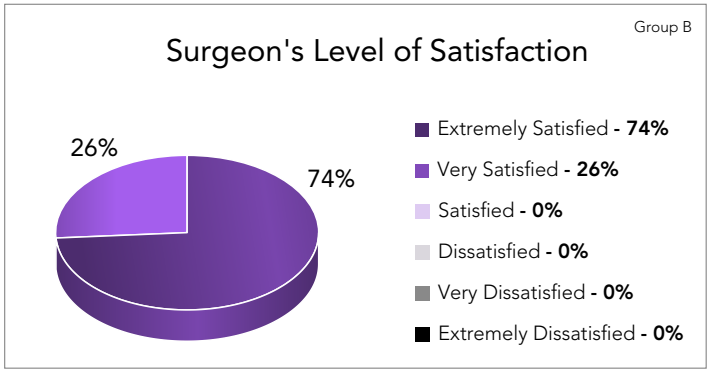
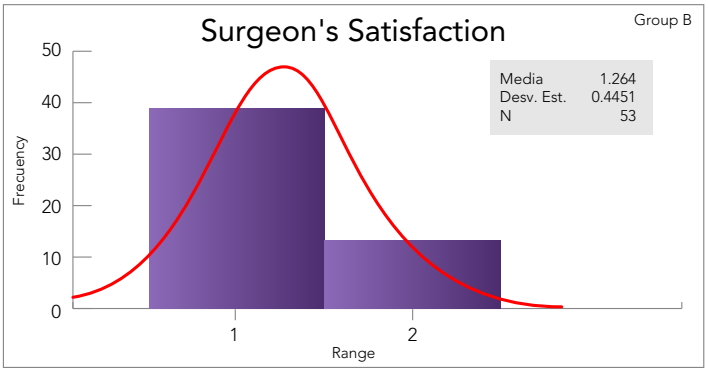


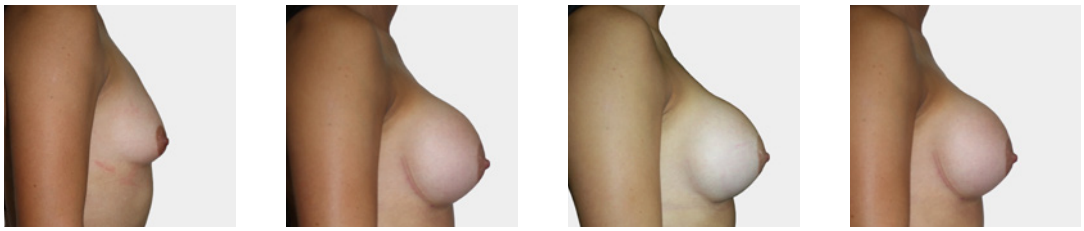
Chart #9: Surgeon´s Level of Satisfaction 1 Year After the Implantation, using Gaussian Distribution of the Data (n=53), Group B.

Chart #9 shows that the median for surgeon´s level of satisfaction is 1.264, which means that the treating surgeons are very to extremely satisfied with the use of Motiva Implant Matrix® in the implanted population. This is statistically significant, with a 95% level of confidence (SD: 0.4451).



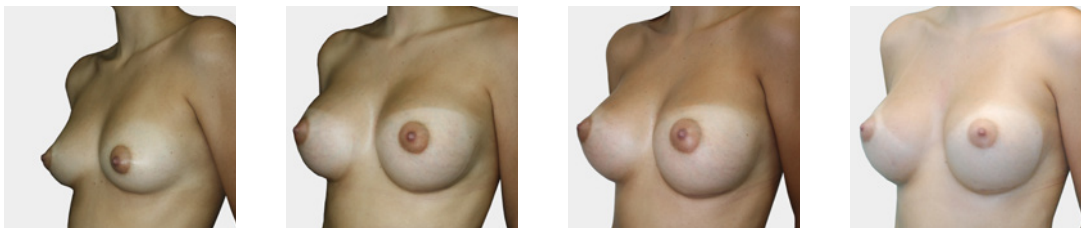
Figures 9, 10 and 11 depict some of the patients (group B) that underwent breast augmentation with Motiva Implant Matrix® Silicone Breast Implants within this prospective clinical evaluation.

Figure 9. Breast Augmentation Results with Motiva Implant Matrix® Silicone Breast Implants VelvetSurface™, 325 cc, Corsé.



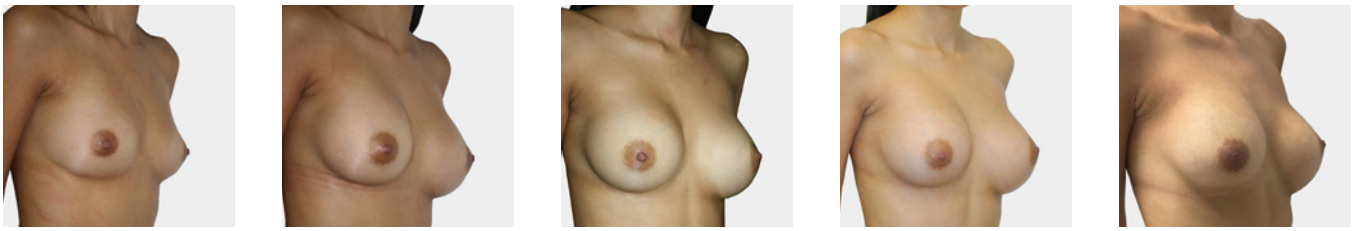
Preoperatory 3 Months 6 Months 12 Months

Figure 10. Breast Augmentation Results with Motiva Implant Matrix® Silicone Breast Implants SilkSurface™, 355 cc, Full.



Preoperatory 3 Months 6 Months 12 Months

Figure 11. Breast Augmentation Results with Motiva Implant Matrix® Silicone Breast Implants VelvetSurface™, 230 cc, Demi.



Preoperatory 3 Months 6 Months 12 Months 24 Months

CONCLUSION

After 4 years of being implanted, the 64 Motiva implants in group A evaluated to date, have shown to be safe and effective in the aesthetic breast augmentation procedures performed in this prospective evaluation. The rate of implant replacement in this group at four years is 8.33% (3 out of the originally 36 recruited patients) and the main reason for requesting a new surgical procedure was the patient´s or surgeon´s criteria of a possible improvement over the aesthetic results obtained with the primary surgery. None of the above cases were associated to the implants themselves. The rate of implant replacement for safety reasons in this group remains unchanged after four years.

For the 64 implants evaluated at 4 years, patients and surgeons reported a high rate of satisfaction with the aesthetic results (100% of the patients were satisfied, very satisfied or extremely satisfied with the results and the surgeons were very satisfied or extremely satisfied with the augmentation procedure aesthetic result in 94% of the cases). The adverse events frequency has behaved as expected, with no serious illness or poor aesthetical results attributable to the implants. No incidents or deaths have occurred since the beginning of the clinical evaluation.

The evaluation at 1 year of 106 out of 146 additional implants in group B, included after the recruitment and treatment dates stated in the Clinical Evaluation Plan for the Evaluation of Motiva Implant Matrix® Silicone Breast Implants in Aesthetic Breast Augmentation, provide further evidence that Motiva Implant Matrix® Silicone Breast Implants are safe and effective in breast augmentation surgical procedures. For the 106 implants in Group B evaluated at 1 year, patients and surgeons reported a high rate of satisfaction with the aesthetic results (98% of the patients were satisfied, very satisfied or extremely satisfied with the results and the surgeons were very satisfied or extremely satisfied with the augmentation procedure aesthetic result in 100% of the cases). The adverse events frequency has behaved as expected, with no serious illness or poor aesthetical results attributable to the implants.

No incidents or deaths have occurred in any group.

It is relevant to mention that in both groups, A and B, no cases of rupture, capsular contracture, double capsules, late seromas or ALCL were reported during the periods evaluated. Both SilkSurface™ and VelvetSurface™ have shown an optimal safety record. This is an ongoing study and further evaluations will follow, but the clinical results so far are very promising for these innovative implant surfaces.

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