Three-Dimensional Simulated Images in Breast Augmentation Surgery: An Investigation of Patients' Satisfaction and the Correlation between Prediction and Actual Outcome

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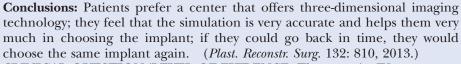
Stockholm, Sweden



Background: Breast augmentation is one of the most commonly performed operations. Three-dimensional outcome simulation can be used to predict and demonstrate for the patient what the planned operation aims to achieve in terms of size and shape. However, there are still few studies in the literature that look at how close the simulation is to the actual postoperative result and how patients perceive the accuracy and usefulness of the simulation.

Methods: A prospective series of 150 patients underwent breast augmentation following consultation with the aid of three-dimensional simulation images. These patients were evaluated with a questionnaire 6 months postoperatively. A retrospective chart review of 52 patients whose three-dimensional simulations were compared with the postoperative photographs were evaluated and graded by an independent panel of investigators.

Results: The independent panel graded the overall similarity of the three-dimensional simulations to the actual breasts with a total average score \pm SD of 7.5 \pm 0.80 (range, 4.5 to 8.9) using a visual analogue scale ranging from 1 to 10. The highest average score was given to projection, breast width, and height (7.8); the lowest average score was given to intermammary distance (7.0). Eighty-six percent of patients felt the simulated image was very accurate in predicting the actual result of their breasts.



CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, IV.



Preast augmentation is one of the most commonly performed operations in plastic surgery. One of the most important steps in performing a successful breast augmentation is the consultation and the planning of surgery. Choosing the right implant requires an accurate analysis of the patient's breast soft-tissue envelope characteristics, measurement of several breast parameters, and careful consideration of the patient's wishes and expectations. Several methods^{1–5} have been described to choose the implant based on the patient's conditions and desires. Even if the

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consultation process has been greatly enhanced by adopting methodical approaches, many patients have problems visualizing the expected outcome of the procedure and therefore remain hesitant.

Computerized imaging technologies have recently evolved as an important adjunct for the dimensional analysis of breasts. 4,6-22 Three-dimensional outcome simulation in the setting of breast augmentation can be used to predict and demonstrate for the patient what the planned operation aims to achieve in terms of size and shape. 15,23-27 It has been demonstrated that three-dimensional imaging is able to provide a more accurate and realistic visual prediction than conventionally used photographs of prior patients, drawings, or photographic data manipulation; a previous study²⁶ showed a difference of less than 1 mm for 89 percent of the breast surface when the preoperative simulation and postoperative results were compared. However, there are still few studies in the literature that look at how close the simulation is to the actual postoperative result and how patients perceive the accuracy and usefulness of the simulation.

PATIENTS AND METHODS

This study includes two case series with a total of 202 women older than 18 years who underwent primary breast augmentation surgery at Akademikliniken in Stockholm, Sweden:

Series A: One prospective series of 150 patients underwent breast augmentation following consultation with the aid of three-dimensional simulation images. These patients were evaluated with a questionnaire 6 months postoperatively.

Series B: A retrospective chart review of 52 patients whose three-dimensional simulations were compared with the postoperative photographs were evaluated and graded by an independent panel of investigators.

Based on the most recent literature on how to provide evidence-based medicine in plastic surgery, 28–32 the following description of the research methodology follows sequentially the acronym PICOST (population, intervention, control, outcome, setting, and time horizon) with the control group excluded. 29

Inclusion Criteria

A Canfield VECTRA 3d camera (Canfield Imaging Systems, Fairfield, N.J.) and Precision

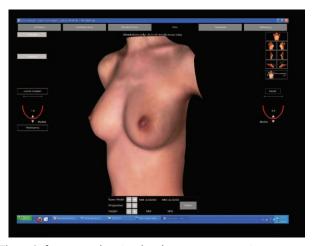


Fig. 1. Software used to simulate breast augmentation outcome. In this example, an anatomically shaped, cohesive gel, medium height, medium projection (MM-280) implant was used.

Light Software (Precision Light, Inc., Los Gatos, Calif.) (Fig. 1) were used for the study. Patients were told that the simulation is not able to precisely match the outcome but can provide a reasonably good idea of what their breasts will appear like. Image manipulation was also frequently used to show what the effect would be of implants that were much too large (e.g., symmastia), much too small, much too high, or too wide. To rule out selection bias, a series of consecutive patients who were operated on by five plastic surgeons were selected. Inclusion criteria were patients whose breasts had no ptosis or breasts that had such a moderate ptosis that it was correctable just by means of breast augmentation alone. Exclusion criteria were patients whose breasts had ptosis and pseudoptosis of such a degree that it would not have been correctable by means of breast augmentation alone, as described by Hedén.^{5,33}

As observational studies are particularly susceptible to bias, we included only patients who chose to undergo breast augmentation with anatomically shaped, cohesive gel, form-stable implants, and we ruled out round implants for two reasons. The first was to provide a more homogeneous "implant population" to reduce the variables involved when testing the imaging software and thus minimize confounding bias and measurement bias. The second was to have a more homogeneous population of "patients' implant preferences" to minimize the possible influence of personal likes on their perception of the results of surgery when filling out the evaluation questionnaire. We nevertheless included some (n = 4)cases of mild asymmetry that warranted the use of implants of different sizes (Table 1).

Table 1. Series of 52 Patients Who Were All Operated on with Anatomical Cohesive Gel Implants*

				IMF Correction†	
Patient	Age (yr)	Asymmetry	Implant‡	Front View	Oblique View
1	22		MM-280	0	0
2	30		MM-280	0	0
3	30		MF-375	R, 1.5; L, 1.0	R, 1.5; L, 1.0
4	39		MF-225	0	0
5	35		MM-280	L, 0.5	L, 0.5
6	19	Yes	R, MF-255; L, MM-245	0	0
7	33		MF-255	R, 1.0; L, 1.0	R, 1.0; L, 1.0
8	33		L-270	R, 2.5; L, 2.0	R, 2.5; L, 2.0
9	33		MX-255	R, 0.5	R, 0.5
10	31		MF-225	R, 2.0; L, 1.0	R, 2.0; L, 1.0
11	18		MF-255	R, 2.0; L, 1.5	R, 2.0; L, 1.5
19	4.4		MV 900	D 10.1 10	R, -1.0; L,
12 13	44 36		MX-290 LX-330	R, -1.0; L, -1.0	-1.0 P 10.1 10
14	31		MM-245	R, 1.0; L, 1.0	R, 1.0; L, 1.0
15	32		MX-325	R, 1.0; L, 1.0	R, 1.0; L, 1.0
16	36		MX-329 MX-370	R, 1.5; L, 1.5	R, 1.5; L, 1.5
17	36		MF-375	R, 1.5, L, 1.5 R, 2.5; L, 1.5	R, 1.5, L, 1.5 R, 2.5; L, 1.5
18	45		MX-290	R, 0.5; L, 0.5	R, 0.5; L, 0.5
19	37		MX-290	L, 1.0	L, 1.0
20	43		LX-330	R, 1.0; L, 1.0	R, 1.0; L, 1.0
21	18		MX-290	L, 0.5	L, 0.5
22	25		MX-255	R, 1.5; L, 1.5	R, 1.5; L, 1.5
23	43		MM-320	R, 1.0; L, 5.0	R, 1.0; L, 5.0
24	45		MF-335	R, 2.0; L, 2.0	R, 2.0; L, 2.0
25	20		MX-290	R, 0.5; L, 0.5	R, 0.5; L, 0.5
26	21		MX-410	R, 1.0; L, 1.0	R, 1.0; L, 1.0
27	39		MF-225	0	0
28	21		MX-290	R, 1.0; L, 0.5	R, 1.0; L, 0.5
29	43		MF-335	R, 1.5; L, 1.5	R, 1.5; L, 1.5
30	36		LM-220	R, 1.5; L, 1.5	R, 1.5; L, 1.5
31	27		LX-365	R, 1.0; L, 3.0	R, 1.0; L, 3.0
32	34		MX-325	R, 0.5; L, 0.5	R, 1.0; L, 1.0
33	39		FX-410	R, 2.0; L, 2.0	R, 2.0; L, 2.0
34	47		FX-315	R, 1.0; L, 2.5	R, 1.0; L, 2.5
35	30		MX-325	R, 1.5; L, 2.5	R, 1.5; L, 3.5
36	25		MX-370	R, 3.0; L, 2.5	R, 3.0; L, 2.5
37	20		LX-255	R, 0.5; L, 0.5	R, 0.5; L, 0.5
38	33		MX-325	R, 3.5; L, 1.5	R, 3.5; L, 1.5
39	18	***	MM-245	L, 0.5	L, 0.5
40	25	Yes	R, ML-170; L, MM-215	R, 1.0	R, 1.0; L, -1.0
41	43		MF-335	R, 1.0; L, 1.0	R, 0.5; L, 0.5
42	42		LL-300 MM 990	R, 4.0; L, 4.0	R, 4.0; L, 4.0
43	40		MM-280	R, 0.5; L, 0.5	R, 2.5; L, 1.5
44	37 97		MX-290 MY 295	R, 0.5; L, 0.5	R, 1.0; L, 1.5
45 46	27 19		MX-325 MF-335	0 D 15:1-15	R, 1.0; L, 0.5
46	25	Yes	MF-333 R, MF-255; L, MM-245	R, 1.5; L, 1.5 0	R, 1.5; L, 1.5 L, -0.5
48	42	Yes	R, MF-295; L, MM-280	R, 1.0; L, 1.0	R, 1.0; L, 1.0
49	23	168	MX-410	R, 1.0; L, 1.0 R, 2.0; L 2.0	R, 1.0; L, 1.0 R, 2.0; L 2.0
50	40		LM-220	L, -0.5	L, -0.5
51	19		MX-325	ь, -0.9	L, -0.0
52	18		MX-410		
Average	31.67308		1,112 110		
	nmary fold; R, right;	T 1 C			

IMF, inframammary fold; R, right; L, left.

^{*}This series was evaluated for resemblance of the three-dimensional simulated image to the actual photographs showing postoperative results. †IMF correction factor is a parameter in Precision Light Software that allows the user to change the vertical position of the implants on the chest wall; it allows the user to make the simulation appear as natural as possible and congruent with the planned operation. For instance, it can allow the vertical relationship of the implant height to the nipple position to be changed. In this study, all implants were placed exactly with their height 50 percent above and 50 percent below the nipple position (Hedén P, Jernbeck J, Hober M. Breast augmentation with anatomical cohesive gel implants: The world's largest current experience. *Clin Plast Surg.* 2001;28:531–552). We have reported the values when simulated correction was carried out for both front and oblique views. Values (e.g., 1, 1.5) are just arbitrary, they do not refer to centimeters. ‡All implants used were McGhan Style 410 Cohesive Gel.

Surgical Technique

The surgical technique for breast augmentation with anatomically shaped cohesive gel form-stable implants was very standardized, according to the technique developed at Akademikliniken over a period of 20 years and more than 17,000 implants.⁵ Rigorous technique standardization among all surgeons in a single center with a large experience in breast augmentation reduces possible confounding factors that can be introduced by a single surgeon's personal preferences and individual personalized technique, increasing congruency and homogeneity.

The surgical technique used has been in all cases a dual-plane type II to III³⁴ partial retropectoral breast augmentation, with the incision placed precisely in the anticipated new location of the inframammary fold as calculated on the chest wall by means of the Akademikliniken method described by Hedén.^{5,33} All of the implants were positioned with their height 50 percent above and 50 percent below the nipple, that is, with the nipple lying exactly midway between the implant upper pole line and the implant lower pole line.⁵

Dissection was performed with a Colorado tip connected to a Valleylab FX machine (Covidien, Boulder, Colo.); prospective hemostasis was achieved with monopolar cautery forceps. The pocket was irrigated with a solution of saline and clindamycin before implant insertion with a "notouch" technique. Meticulous fixation of the new inframammary fold with a continuous barbed thread Quill polydioxanone suture (Angiotech Pharmaceuticals, Inc., Vancouver, British Columbia, Canada) was performed, stitching the superficial fascial system of the breast and the chest wall Scarpa fascia to the chest wall deep investing fascia at the exact location of the implant lower pole border line.^{5,33} A single dose of cloxacillin prophylaxis was administered preoperatively, and no drains were used.

Outcomes Measures

There exist no validated instruments at present designed to evaluate the similarity of three-dimensional simulated images and the actual operated breasts that address specific mammometric parameters. Likewise, there exist no validated instruments designed to evaluate the degree of patient satisfaction related to the use of breast simulation images in breast augmentation. For series A, an eight-point questionnaire (Table 2 and Fig. 2) was designed and administered at the 6-month postoperative visit to the 150 patients.

For series B, direct comparison of the threedimensional simulated image and the true postoperative breast photographs was carried out on anterior and oblique views (Figs. 3 through 5), and judged by an independent panel made up of seven plastic surgeons (all of whom are aesthetic breast surgery fellowship trained) and four plastic surgery-trained nurses. [See Figure, Supplemental **Digital Content 1**, which is a PowerPoint (Microsoft Corp., Redmond, Wash.) presentation showing 20 examples of patients who underwent breast augmentation after three-dimensional simulation, http://links.lww.com/PRS/A840. The following are shown for each PowerPoint slide: (above, left) preoperative front view; (above, center) threedimensional simulation front view; (above, right) postoperative result front view at 6 months; (below, left) preoperative oblique view; (below, center) threedimensional simulation oblique view; (below, right) postoperative result oblique view at 6 months.]

Assessment of the simulated image comprised both quantitative and qualitative descriptions. (See Figure, Supplemental Digital Content 2, which is the slide used by the panelists to evaluate the similarity of the three-dimensional simulated images and the actual postoperative results, http://links.lww.com/PRS/A841. Both general and specific parameters were rated quantitatively. There was also space for additional comments and notes.) Postoperative photographs of results at 6 months were compared with the three-dimensional simulation images by each member of the panel and graded from 0 (no correlation) to 10 (identical) using a 10-point visual analogue scale. During the evaluation, both general parameters (i.e., overall, shape, and size) and specific mammometric parameters (i.e., intermammary distance, lateral protrusion of the lateral border of the augmented breast off the chest wall, breast width, breast height, projection, lower pole, and upper pole) were graded. Furthermore, each evaluator had additional space for a qualitative evaluation and comments on the predictive skills of the software/simulation.

Point 8 on the evaluation form ("Which one looks aesthetically better according to you") was designed to investigate the likelihood of patients being disappointed by an actual result perceived as being "inferior" aesthetically to the simulation. (See Supplemental Digital Content 2, which is the slide used by the panelists to evaluate the similarity of the three-dimensional simulated images and the actual postoperative results, http://links.lww.com/PRS/A841.) An image generated by software could potentially be unrealistically pleasant to the

Table 2. Evaluation Questionnaire Administered to the Series of Patients Who Underwent Breast Augmentation with Anatomical Shaped Cohesive Gel Implants at the 6-Month Postoperative Visit

Question	Results (%)*
1. What were you most concerned with, regarding the final outcome of the operation?	
a. That the breast would be too small	23
b. That the breast would be too big	10
c. That the breast would not have looked natural	61
d. That it would have been difficult for me to explain to the surgeon my wishes	6
2. How much has the 3D simulation helped you in deciding the implant (size, height, width, projection, overall shape)?	
a. Very much	81
b. Yes but not decisively	16
c. Not so important	3
d. Not at all	0
3. How accurate do you feel the simulation you were shown during consultation was if you compare it with the actual result in yourself?	
a. Very accuraté	86
b. Rather accurate	11
c. Little	3
d. No similarity at all	0
4. In terms of the size of the implant, would you choose the same or a different one if you could do it all over again?	
a. Choose a smaller implant	1
b. Choose a bigger implant	18
c. Choose the same implant	81
d. I would not undergo surgery	0
5. How satisfied are you with how well the simulated image predicted the shape of your actual breast?	
a. Very happy	82
b. Happy	10
c. Not so happy	5
d. Completely unhappy	3
6. Overall, what role do you think that the 3D simulation has had in your breast augmentation experience at Akademikliniken?	
a. Very important	55
b. Important	34
c. Not so important	11
d. A waste of time	0
7. Overall, do you feel that being able to see a simulation of how you would look like afterward has affected your decision to undergo surgery?	
a. Very much so	83
b. Reasonably but not decisively, I wanted surgery anyway	12
c. Little	4
d. No, I trusted my doctor's words	1
e. Undecided	0
8. After having had surgery at a clinic where they offer 3D simulations, would you advise a friend to have surgery at a clinic where they do <i>not</i> offer a simulation?	
a. Yes, simulation is not necessary	4
b. No, why go there if I can be given the chance to see what I will look like	74
c. Why not, if the surgeons are competent and have a good reputation	19
d. Maybe	1
e. Undecided	2

3D, three-dimensional.

eye by creating an artificial "attractiveness" of the simulation.

The 150 patients who filled out the questionnaire were selected consecutively, to rule out selection bias in a prospective fashion (Table 2 and Fig. 2). The 52 patients whose images were evaluated by the panel were also chosen consecutively, but in a retrospective fashion with chart review. All follow-up photographs were taken at 6 months postoperatively, and all questionnaires were administered at the 6-month postoperative visit. Retrospective data were reviewed to determine whether conducting consultations with the aid of a three-dimensional imaging system has increased the number of patients who decided to undergo surgery during the time frame of our study. Instead of gathering data from all of the surgeons working at our center, we chose to review data from a single investigator: this was done for the purpose of avoiding the confounding bias caused by different experience levels between surgeons and different consultation approaches.

^{*}Postoperative visit results are presented as percentage of responders who chose a specific answer.

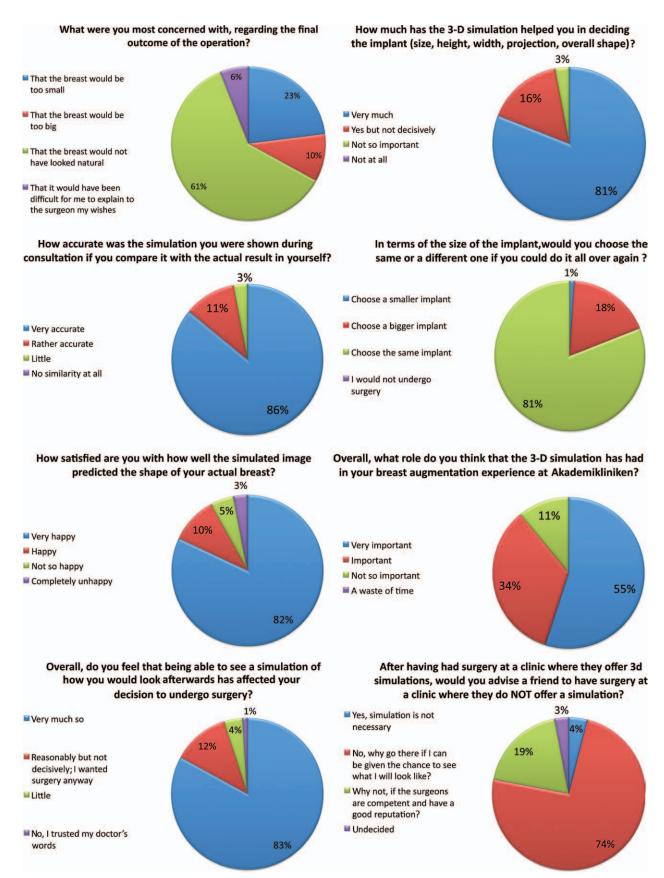


Fig. 2. An evaluation questionnaire was administered to the series of 150 patients who underwent breast augmentation with anatomically shaped cohesive gel implants at the 6-month postoperative visit. Results are presented in pie charts as percentage of responders who chose a specific answer. *3-D*, three-dimensional.

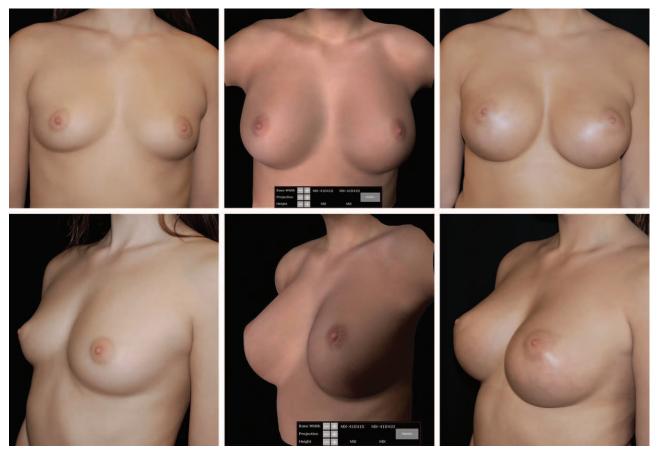


Fig. 3. Example of evaluation slide that was rated by our panel. Anterior and oblique views are shown. (*Above, left*) Preoperative front view; (*above, center*) three-dimensional simulation front view; (*above, right*) postoperative result front view at 6 months; (*below, left*) preoperative oblique view; (*below, center*) three-dimensional simulation oblique view; (*below, right*) postoperative result oblique view at 6 months. The implant used was the anatomically shaped, medium height, extra-projection MX-410. Note how the lateral protrusion of the breasts off the chest wall is overestimated. Also, the medial implant borders are less defined than in the real postoperative result.

RESULTS

In conformity with recent published studies on how to properly perform a case series in plastic surgery, ^{28–30} results are reported descriptively. Figure 2 shows results of the patient questionnaire, with the results shown as percentage of responders who chose a specific answer.

Sixty-one percent of patients were afraid that the breast might appear unnatural after undergoing augmentation, 10 percent were afraid that it might appear too large; and 23 percent were afraid that it might appear too small. Eighty-one percent of patients felt that three-dimensional image simulation helped them very much in choosing the implant, and 16 percent felt that it helped them but not decisively.

Eighty-six percent of patients felt the simulated image was very accurate in predicting the actual result of their breast; 11 percent felt that

it was rather accurate. Eighty-one percent of patients would choose the same implant again; 18 percent would choose a larger implant; and 1 percent would choose a smaller implant if they could go back in time and undergo surgery again.

Eighty-two percent of patients were very happy with the result of the simulation; 10 percent were happy; 5 percent were not so happy; and 3 percent were completely unhappy about the simulation. Fifty-five percent of patients felt three-dimensional simulation had a very important role throughout their experience of breast augmentation; 34 percent felt it had an important role; and 11 percent felt it was not so important. Eighty-three percent of patients felt that that seeing a simulation has affected very much their decision to undergo surgery, and 74 percent of patients stated that they would not advise a friend to have surgery in a clinic where they do not offer three-dimensional simulation.



Fig. 4. Example of evaluation slide that was rated by our panel. Anterior and oblique views are shown. (*Above, left*) Preoperative front view; (*above, center*) three-dimensional simulation front view; (*above, right*) postoperative result front view at 6 months; (*below, left*) preoperative oblique view; (*below, center*) three-dimensional simulation oblique view; (*below, right*) postoperative result oblique view at 6 months. The implant used was the anatomically shaped, medium height, extra-projection MX-290. The puffy nipple was intentionally left uncorrected, as the patient was not willing to accept a periareolar scar. Short lower pole expansion by extra-projecting implants was slightly underestimated by the simulation on the oblique view.

Three-Dimensional Simulated Image Evaluation

Tables 3 through 6 summarize the results of the image evaluation by the independent panel.

There have been no major complications in these series at the 6-month follow-up, but there have been two cases of double-bubble deformity type A. Regarding quantitative assessment, the total average score \pm SD was 7.5 \pm 0.80 on the visual analogue scale (range, 4.5 to 8.9). The highest average scores were given to projection, breast width, and height (7.8); the lowest average score was given to intermammary distance (7.0).

Looking at the qualitative section, it appears that the imaging system has specific strengths and weaknesses. Good prediction of overall shape and size, height and width, and nipple ascent are among the strengths. Among weaknesses are widened intermammary distance, poorly defined implant borders, apparent convexity of central chest wall, and excessive lateral implant protrusion. Table 6 shows that 52.6 percent of evaluated images (n = 301) of postoperative results appeared aesthetically better than the simulations, 28.6 percent (n = 164) appeared worse, and 18.7 percent (n = 107) appeared equivalent.

Conversion Rate

The impact of including the simulation image technology is exemplified by evaluation of the conversion rate (ratio of patients undergoing surgery/patients seeking consultation) of one of the authors (P.M.). With inclusion of the three-dimensional simulation in his consultations, there has been an increase in conversion from 67 percent to 86 percent. This result was seen in a series of 301 consecutive patients, of whom 151 were consulted conventionally and 150 were consulted with the aid of three-dimensional simulated images.

DISCUSSION

Patient Experience

Analysis of the descriptive data shows that three-dimensional imaging has a positive impact on the whole process of breast augmentation surgery, from the initial consultation to postoperative patient satisfaction. Some patients' fears are alleviated by means of a more effective "image-based" conveyance of the expected result. Implant choice is no longer the surgeon's guess of what the patient tries to communicate with words but is chosen together, seeing what the breasts will

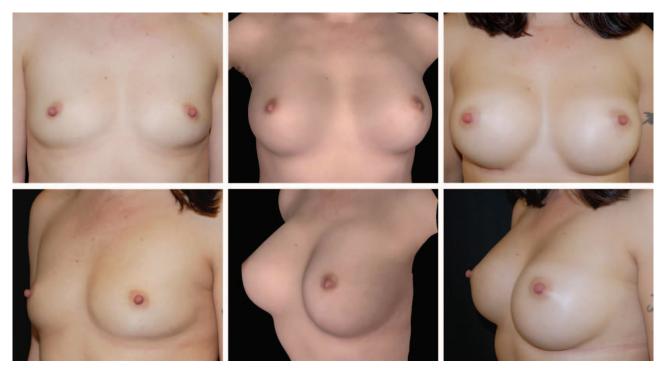


Fig. 5. Example of evaluation slide that was rated by our panel. Anterior and oblique views are shown. (*Above, left*) Preoperative front view; (*above, center*) three-dimensional simulation front view; (*above, right*) postoperative result front view at 6 months; (*below, left*) preoperative oblique view; (*below, center*) three-dimensional simulation oblique view; (*below, right*) postoperative result oblique view at 6 months. The implant used was the anatomically shaped, medium height, extra-projection MX-370. The three-dimensional simulated image overestimated the intermammary distance and blurred the medial implant borders. Also, it underestimated the nipple-to-inframammary fold distance on the oblique view on the left breast.

appear like with several types of implants after undergoing surgery.

Patients prefer a center that offers threedimensional imaging technology. Patients' fears that the breast might not appear natural are alleviated by seeing the simulated image; they feel that the simulation is very accurate and helps them very much in choosing the implant; if they could go back in time they would choose the same implant again.

Three-Dimensional Simulated Images and Software Evaluation

A total average value of 7.5 can be considered good, as 10 (identical) would by definition be impossible to achieve for a simulation. The horizontal relationship in the anteroposterior axis of the soft-tissue expansion caused by the implant relative to the chest wall was predicted very well, as pointed out by the fact that projection was one of the most accurately predicted values $(7.8 \pm 0.7; \text{ range}, 5.8 \text{ to } 8.8)$. Intermammary

Table 3. Quantitative Results of Image Evaluation*

•	•			
Parameter	Final	Minimum	Maximum	SD
Overall	7.6	3.8	9.1	0.94
Shape	7.3	2.8	9	1.07
Size	7.7	5.2	8.8	0.74
Intermammary distance	7	3	9	1.32
Lateral protrusion	7.5	4.8	9	0.83
Breast width	7.8	5.6	9.1	0.7
Breast height	7.8	6.2	8.8	0.62
Projection	7.8	5.8	8.8	0.7
Lower pole	7.3	4	9.2	0.99
Upper pole	7.2	4.2	8.7	0.93
Total	7.5	4.54	8.95	0.884
Total approximated	7.5	4.5	8.9	0.8

^{*}Each parameter is the average value of all of the scores given by the 11 evaluators to all of the 52 patients' images in the series.

Table 4. Summary of the Strengths and Those Parameters That the Simulation Has Predicted with Greatest Accuracy as Expressed by Comments from the Evaluators

Parameter/Comment	Frequency*
Overall shape	155
Total general appearance	172
Size	122
Breast width	81
Breast height	99
Nipple ascent caused by implant	21
Nipple ascent in ptotic breast	19
Upper pole slope	19
Upper pole fill	9
Lower pole fill	76
Anatomical shape of breast caused by tear-	
drop implant with thin envelope	31
Anatomical shape of breast caused by tear-	
drop implant with medium envelope	46
Anatomical shape of breast caused by tear-	
drop implant with thick envelope	12
Vertical position of the implant on the	
chest wall	17
Lateralization of NAC caused by soft-tissue	
expansion relative to breast footprint	27
Vertical position of implant relative to native	
breast/NAC position	89
Shape prediction with tight soft-tissue	
envelope	9
Relationship of nipple to inframammary fold	15
Lower pole expansion by extra-projecting	
implants	3
Relationship of implant position relative to	
soft-tissue envelope	7
Tilt of nipple	2
Position of nipple relative to implant	29
Position of nipple relative to breast footprint	17

NAC, nipple-areola complex.

distance was instead the most poorly predicted value $(7.0 \pm 1.32; \text{ range}, 3 \text{ to 9})$ and, of note, this was associated with the highest standard deviation value, which is likely attributable to less accuracy in predicting the horizontal position of the implant in the coronal axis.

The vertical relationship of the nipple to the inframammary fold, and nipple ascent attributable to implant soft-tissue envelope expansion, were among the strengths. Thus, it can be stated that the system is more accurate in predicting the vertical relationship of the implant to the chest wall and to the soft-tissue envelope than it is in the coronal horizontal relationship to the chest wall.

The Precision Light Software that was used in this study allows changing the vertical position of the implant on the chest wall during the simulation, which allows for better case-by-case customization (see inframammary fold correction in Table 1). When the chosen implant is anatomical, changing the vertical position alters also the distance from the nipple to the inframammary fold. This allows the user a certain freedom of customizing the operation. For example, some surgeons prefer placing round implants 55 percent below and 45 percent above the nipple level. Further software development could allow horizontal movement of the implant also during the simulation, which would improve the horizontal relationship of the implant to the chest wall and soft-tissue cover. For example, the frequently overestimated intermammary distance and lateral protrusion off the chest wall are related to the horizontal position of the implant.

The ascent and lateralization of the nipple caused by soft-tissue expansion and the horizontal position of the nipple relative to the breast footprint were among the strengths; thus, the system appears to create an illusory lateralization of the "implant-breast complex" relative to the chest wall, which is in agreement with the illusory chest wall convexity that appears in some examples. In some cases, though, the simulated intermammary distance was rated 10 (identical) and in some cases it was decreased. Of note, when the horizontal position of the implants appears widened, the implant borders are often more blurred, and when the implants are closer together, their borders appear better defined.

Evaluators' comments point out the fact that three-dimensional imaging simulation is more accurate for small- to moderate-size breasts with tight to normal soft-tissue envelopes, no ptosis, and no asymmetries. When a breast augmentation is not straightforward and there are features such as moderate ptosis, lax skin envelope, slightly constricted base and lower poles, asymmetries, tuberous-like shape, hypoplastic inferomedial quadrants, pseudoptosis, and high inframammary fold, the simulation system is less accurate, it can fail to predict adverse outcomes such as double-bubble deformity, and the simulated image can appear deceitfully good.

Patients are usually not promised an unrealistically beautiful breast but are delivered a result that is either better (52.6 percent) or equivalent (18.7 percent) compared with the simulation (Table 6). However, even though 86 percent of patients think the simulation is very accurate, 28.6 percent of the actual results have been judged as appearing aesthetically worse than the simulation.

Justifying to a patient the fact that the result she carries on her body is perceived as being disappointing compared with the simulation she was shown is a challenge that the surgeon can be

^{*}Number of times that the parameter or comment was cited by the panel.

Table 5. Weaknesses, Shortcomings, and Those That Have Been Felt to Be More Poorly Predicted Parameters

Parameter/Comment	Frequency*
Apparent increased convexity of central part of anterior thorax	27
Overestimated intermammary distance	24
Underestimated intermammary distance	2
Overestimated breast (NAC) projection	12
Underestimated breast (NAC) projection	19
Poor definition of implant borders	59
Poor definition of medial implant borders	26
Poor definition of inferomedial implant borders	13
Poor location of implant on chest wall: implant too cranial	1
Poorer predictive capacity with moderate breast ptosis	77
Poorer predictive capacity with lax soft-tissue envelope	46
Poorer predictive capacity with preexisting high IMF	8
Missed double-bubble deformity	1
Poorer predictive capacity when features of constricted lower pole are present	9
Poorer predictive capacity when slight inferomedial quadrant hypoplasia	17
Overestimated lateral protrusion	24
Overestimated teardrop shape/poor upper pole slope	2
Overestimated projection of upper pole	$1\overline{1}$
Underestimated upper pole fullness	
Slightly upturned NAC/upper pole slope too horizontal	2 2 2
Upper pole slope too vertical/underestimated upper pole fullness	$\frac{1}{2}$
Overestimated upper pole fullness	ī
Overestimated distance between implants/lateral protrusion/IM distance	8
Position of implants on chest wall	O
Too wide apart (lateralized)	18
Too close (medialized)	2
Too cranial	ī
Too caudal relative to clavicles	2
Too low when long rib cage is present	$\bar{1}$
Underestimated tissue tension	2
Underestimated glandular pseudoptosis visible in postoperative result	5
Underestimated nipple ascent caused by augmentation	2
Exaggerated concavity of upper pole	3
Apparent poor position of implants on chest wall: apparent lateralization of implants with increased	3
intermammary distance and increased protrusion off lateral chest wall	1
Poor prediction of unsightly result when pseudoptosis (parenchymal ptosis) is present preoperatively	9
Illusory excessive convexity of central part of sternum and rib cage	18
Medial implant borders are blurred if implants are lateralized, medial implant borders are more defined if	10
implants are medialized	7

^{*}Number of times that the parameter or comment was cited by the panel.

presented with; thus, careful communication with patients remains as important as it was before the advent of three-dimensional imaging technologies. This caveat is all the more true for those anatomical situations described in Table 5, in which cases the imaging system was felt to perform more poorly. These findings emphasize the importance of the fact that software cannot substitute

or override the surgeon's judgment. Overall, our data show that including three-dimensional imaging simulation into a plastic surgery practice makes patients who consider breast augmentation and seek consultation more likely to undergo surgery if they are shown a simulated image of the final result and if the implant is chosen together with the surgeon.

Table 6. Comparison of Simulation versus Actual Result in Terms of Aesthetic Appearance*

Which One Looks Aesthetically Better According to You?	Value	Answers	Percentage of Overall Answers	Algebraic Sum*
Postoperative photograph	Value = 1	301	52.6	301
Equal	Value = 0	107	18.7	0
Simulated three-dimensional image	Value = -1	164	28.6	-164
Total				137
Overall no. of responses for point 8†				572

^{*}An algebraic sum of the arbitrary values that were assigned (postoperative better = 1; simulation better = -1; equal = 0) was carried out. †Overall number of responses for point 8 of the evaluation form, that is, number of patients × number of evaluators' answers ($52 \times 11 = 572$).

NAC, nipple-areola complex; IMF, inframammary fold; IM, intermammary.

We designed this study to provide descriptive data from a single-center experience by means of case series. As the use of three-dimensional imaging in breast augmentation surgery will increase in popularity throughout the plastic surgery community worldwide, further research from multicenter randomized controlled trials, systematic reviews, and meta-analyses will be able to provide higher levels of evidence.

CONCLUSIONS

We have been incorporating three-dimensional simulation technology in the setting of breast augmentation consultations since 2008 at our center and have found that it is a useful tool that enhances communication with patients and helps in the process of implant choice. Patients seem to perceive it as very useful instrument too. It may not be unrealistic to speculate that this technology will revolutionize the consultation process and that, in the future, every plastic surgeon will make use of three-dimensional simulated images, probably for several operations, including reconstructions.

We have observed that adopting threedimensional imaging simulation has led to an increase in the conversion ratio of patients (i.e., more patients who seek a consultation decide to undergo surgery if they are shown a simulation). A software program cannot substitute for or override the plastic surgeon's judgment; thus, careful analysis of the breasts' anatomy, thoughtful implant choice, and skillful communication with patients remain cornerstones of the consultation.

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Instructions for Authors—Update

Registering Clinical Trials

Beginning in July of 2007, *PRS* has required all articles reporting results of clinical trials to be registered in a public trials registry that is in conformity with the International Committee of Medical Journal Editors (ICMJE). All clinical trials, regardless of when they were completed, and secondary analyses of original clinical trials must be registered before submission of a manuscript based on the trial. Phase I trials designed to study pharmacokinetics or major toxicity are exempt.

Manuscripts reporting on clinical trials (as defined above) should indicate that the trial is registered and include the registry information on a separate page, immediately following the authors' financial disclosure information. Required registry information includes trial registry name, registration identification number, and the URL for the registry.

Trials should be registered in one of the following trial registries:

- http://www.clinicaltrials.gov/ (Clinical Trials)
- http://www.anzctr.org.au/Default.aspx (Australian New Zealand Clinical Trials Registry)
- http://isrctn.org (ISRCTN Register)
- http://www.trialregister.nl/trialreg/index.asp (Netherlands Trial Register)
- http://www.umin.ac.jp/ctr (UMIN Clinical Trials Registry)

More information on registering clinical trials can be found in the following article: Rohrich RJ, Longaker MT. Registering clinical trials in *Plastic and Reconstructive Surgery*. *Plast Reconstr Surg*. 2007;119:1097–1099.