In previous reports, we introduced a system of three-dimensional (3D) breast imaging relying on structured light and automated measurement functions. This 3D rendering system, once automated, is referred to as four-dimensional (4D) imaging. In those previous reports, we described our validation studies to verify the accuracy of this system. While many other 3D imaging technologies exist and limited validation studies have been performed to confirm the accuracy of images, no extensive validation of clinically relevant, common parameters in various current surgical planning paradigms (including Biodimensional, BodyLogic, and Akademikliniken systems) had been published before our report. Moreover, the designs of existing, commercially-available 3D imaging systems require operator placement of cursors, which adds time and a degree of variability to the consultation process.
With automated landmark recognition, 4D imaging has the advantage of instantaneous display of a patient’s anatomical measurements, along with analysis of breast and chest wall asymmetries. This automated measurement system also affords the opportunity to serially study changing breast dimensions over time in a standardized way; with this comes the ability to develop simulation tools based on data rather than hypothetical illustrations.

To date, no study has examined the clinical effects of 3D imaging from the patient’s perspective. A recent study of the attitudes of European women seeking breast augmentation examined a number of perceived barriers that dissuaded patients from proceeding.11 One important finding was their need to visualize the outcome. Another important factor that discouraged patients was the inability to find a surgeon whom they could trust. To that end, we report the development and refinement of software to simulate breast augmentation and validate accuracy with objective measurements in a prospective group of 46 patients undergoing primary augmentation. Furthermore, we report on the subjective patient response to imaging technology as a means of communicating potential results during the consultation process.

In a separate analysis, the imaging system’s effect on practice productivity was evaluated in 100 consecutive breast augmentation consultations over seven months by the tracking the length of consultation times, conversion rates to surgery, the period of time from consultation to scheduling, and the volume of implants ordered year over year, as compared to historical data for the same time interval in the prior two years. Comparison of results in one private plastic surgery practice was corroborated to two other practices that subsequently began utilizing the system. In this way—through objective correlation data, subjective patient reports, and comparative practice statistics—we assessed the efficacy of this 4D imaging software in the clinical setting.

**METHODS**

**Precision Light Imaging Software**

The imaging system being investigated in this study is not currently available commercially but has been reported in this journal and presented elsewhere.1,2 Precision Light, Inc. (Los Gatos, California) is a proprietary 4D breast-imaging system that incorporates rapid image capture and processing with automated measurement functionality. Data from over 1000 breast augmentation consultations in which this system was incorporated have been accumulated and utilized to refine the image capture, automated measurement, and asymmetry analysis software. Additionally, preoperative and three- to six-month postoperative data have been gathered in a large database from the lead author’s (CNC) practice and three other practices.

These software algorithms are patented, but in general terms, the algorithm for simulating the postoperative breast appearance involves taking a captured 3D wire-frame and photographic skin color images, modifying the breast shape independent of the chest wall, and then reapplying it. With the ability to define the chest wall form through automated landmark recognition, the breast form is removed. After calculating the volume of the breast form’s soft tissue, the volume of the breast implant is added and, to a varying degree, a percentage of volume is subtracted, depending on the existing volume of breast and the size of implant chosen. The base width (BW) of the simulated breast is determined by the existing BW or the implant—whichever is greater—plus the upper breast soft tissue thickness entered for a given patient. The height of the resultant breast mound is applied depending on the type of implant specified, with resultant breast heights correlating highly to form-stable implants but to less than the BW of non-form-stable implants. Simulation projections are calculated from the volumes determined in earlier stages. The new breast form is added to the original chest wall but placed 1 cm below the original inframammary fold as a default. The peripheral boundaries of the breast are softened to mimic the contribution of the existing breast and subcutaneous tissue, calibrated from the original upper soft tissue thickness. The nipple-areola complex is separately expanded in diameter, and the subareolar region is copied and pasted from the original breast form back onto the rounded breast form, with positioning determined from accumulated data sets but generally rotating cephalically and laterally. Skin colors are copied from the original and registered to the chest wall and breast form, with data from three cameras registered and dithered along junctions of the three photographic images. Shadows are enhanced by artificially lighting the resultant 3D form to simulate standard medical photography conditions.

**Objective Correlation Through Automated Measurements**

To validate the simulation algorithms, the Precision Light breast imaging system was introduced in one clinical practice (CNC), and the simulation software tools were implemented during initial breast augmentation consultation beginning in March 2009. The software simulations enabled cooperative discussion between the patient and surgeon to determine implant size and type. Over six months, 46 consecutive primary breast augmentation patients were recruited to participate in a long-term study. Patients with ptosis were excluded, as were patients presenting with secondary issues. The 46 patients who were selected agreed to return for follow-up imaging and complete a questionnaire at six months postoperatively. The simulated measurements of sternal notch to nipple, nipple to inframammary fold, BW, and volume were stored as a reference, to be compared with follow-up measurements. The screen shots shown in Figures 1-11 demonstrate a typical sequence of images presented to patients during...
the consultation. Along with automated measurements, symmetry analysis was carried out to assess differences in nipple height, inframammary fold position, projection, and shift of the midline. The “worm’s eye” view (Figure 7) shows differences in breast projection compared to the chest wall contour. A simulation of postoperative appearance was shown to each patient, including a clothed version. Finally, an operative plan view was generated for projection in the operating room.

**Subjective Comparison Through Patient Feedback**

Questionnaires (see appendix, online at www.aesthetic-surgeryjournal.com), along with copies of the individual preoperative photos and simulation images, were mailed to all 46 patients six months postoperatively. Patients were asked to rate the role that 4D imaging played in their decision-making process, the accuracy of the imaging, and
other measures of patient satisfaction (including implant size choice). These early postoperative data were compared to longer-term follow-up in the form of phone calls placed by an independent nurse to all questionnaire respondents at an average of 18 months postoperatively. During that phone call, patients were queried about their overall satisfaction, implant size satisfaction, and the importance of imaging in their initial decision making.
Effect on Private Practice Productivity

For the seven-month period from March 2009 to September 2009, concurrent with the introduction of this technology into a single practice setting, selected data points (practice management metrics) were calculated and compared to the same seven-month period in the two prior years (2007 and 2008). These data were collected through chart review and practice scheduling software (NexTech, Tampa, Florida) and included consultation time, conversion (scheduling) rates, and the time interval between consultation and scheduling.

All consultations were performed entirely by the lead surgeon (CNC). After approximately eight months, 100 patients had been deemed appropriate candidates for primary breast augmentation; those patients were included in a cohort for this portion of the analysis. Results were calculated in terms of percentages and compared with the
The results from this practice were subsequently compared to two other clinical practices for corroboration.

**RESULTS**

**4D Measurements**

The demographic profile of the 46 patients enrolled in this prospective study is summarized in Table 1. Thirty-five patients (76%) returned for follow-up imaging at six months. Measurements derived from the simulations at the initial consultation were compared to 4D imaging measurements of actual six-month outcomes with the Pearson correlation coefficient. No manual measurements were compared, since the accuracy of the automated measurement function was already established in a prior study. Representative examples of objective comparison between simulated preoperative and actual postoperative outcomes at six-month follow-up are shown in Figures 12-14.

**Figure 7.** Asymmetry analysis: comparison of chest wall (blue) and breast (red), as seen from below.

**Figure 8.** Potential postoperative simulation: oblique view.
and 13. Statistical comparisons are shown in Figures 14-17 for each parameter measured. Comparison of simulated and actual outcome measurements showed an overall correlation of 68%.

**Patient Questionnaires**

Of the 45 patients surveyed, 37 responded to the six-month follow-up questionnaire sent by mail (80%). Questionnaire responses remained anonymous to the reviewers to maintain patient confidentiality and optimize the candor of the responses. (A copy of the questionnaire can be found at http://aes.sagepub.com/supplemental). Results of the questionnaire are summarized in Table 2. Most patients (a total of 83%) indicated that the imaging process was either the “main reason” they had chosen their surgeon or was “very important” in helping them choose their surgeon. Fifty-seven percent indicated that the consultation with the surgeon, which included 4D image simulations

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**Figure 9.** Preoperative simulation (left) and potential postoperative simulation (right): oblique view, clothed.

**Figure 10.** Preoperative simulation (left) and potential postoperative simulation (right): clothed, view from above.
and cooperative implant selection, had resulted in their having “complete trust” in their surgeon. Interestingly, 52% indicated that they were happy with the size of their implants at six months, but 48% indicated that, if they were to undergo the augmentation procedure again, they would select a larger implant. In terms of complications, one patient developed an early capsular contracture six weeks postoperatively, which was treated and remained soft 18 months after capsulectomy. There were no other complications in any of the respondents.

At 18 months postoperatively, 28 of 35 previous questionnaire respondents were available for telephone interview. When asked about satisfaction with implant size and what they would select if they were to undergo the surgery again, 17 (61%) replied that they would select the same implant (mean implant size in these respondents, 325 cc); 10 (36%) replied that they would prefer a larger implant (mean implant size, 391 cc); and one patient (3.5%) indicated that she would prefer a smaller implant (she initially received a 400 cc low profile gel implant). These responses did not differ significantly from the six-month results, although the percentage of patients who were happy with their current implant size had increased. When asked to rate overall satisfaction with the surgical outcome on a five-point grading scale (1 = low, 5 = high), the patients who indicated size satisfaction reported an average rating of 4.9, while the other groups (combined) rated their satisfaction at 4.4. The overall satisfaction for the cohort was 4.7. No patient contacted in the 18-month survey had undergone reoperation for size change. All 28 patients expressed satisfaction with the value of imaging as a means of visualizing the outcome.

### Practice Productivity

Surgical scheduling rates and the time interval from consultation to scheduling were calculated and compared to the similar seven-month periods in the two years prior to implementing the imaging device. Scheduling rates for primary breast augmentation consultations increased from 40% to 73%. The percentage of patients scheduling surgery on the day of the consultation increased from 14% to 46%.

Orders for implants through the manufacturer during the study period were reviewed and compared with the same period in the prior year; the number of implants ordered increased by 29%. There was a coincidental rise in the number of silicone gel implants ordered (70%), which
contributed to the increase in the overall dollar amount spent on implants (43%). Since choice of implant type (saline vs silicone gel) is primarily based on patient preference, we do not believe that the increased placement of silicone devices is responsible for the increase in scheduling rates.

The duration of consultations initially increased from an average of 45 to 65 minutes in the first month after introduction of imaging. Toward the end of the first month, as familiarity improved with the process of integrating imaging into the consultation, the contact time during consultations quickly decreased from an average of 65 to 30 minutes and has remained stable for over one year. Manual measurements, bra stuffing, and other demonstration techniques to simulate postoperative implant size are no longer utilized in the lead physician’s practice. Physical examinations for masses, tissue integrity, and upper pole pinch thickness are still performed manually. Similar statistics were gathered from two other plastic surgery practices in other parts of the country (Nashville, Tennessee, and Louisville, Kentucky) utilizing the same imaging system. Comparable increases in productivity were realized (Table 3).
While a number of authors have published their work validating technology for imaging the breast, the implant outcome simulation models have, to date, been placed on the market without much in the way of data-driven support for the morphing component of the technology. In general, a leap of faith is required to correlate the published evidence supporting image accuracy with claims about the validity of simulations generated from those images. The predictive value of a surgical simulation does not necessarily follow the objective accuracy of a preoperative image. Implant simulations involve manipulation of an accurately portrayed and measured preoperative image to display a potential postoperative image under variable implantation circumstances, which is a complex process. We have set out to validate our simulation images with data-driven algorithms as a first step in what promises to be an ongoing process of refinement of the software.

The data showed an overall correlation of 68% when objective measurements were compared between the simulated images and the final result. Though this correlation may not seem as strong as one might expect, the most poorly correlated parameter was BW. The automated BW displayed by the software is a measure derived from the actual landmarks present horizontally but offset by the measurement of inferior breast radius as rendered by the software, so more variation is to be expected. Another reason for this finding may be that the images are captured with the patient’s arms akimbo, a posture that stretches the soft tissue overlying the implant, which accentuates the implant’s prominence in the actual postoperative images and, to some extent, minimizes the softening of the surrounding tissue.

**DISCUSSION**

Figure 14. Comparison of simulated postoperative results to actual six-month measurements of distance from sternal notch to nipple. Pearson correlation coefficient = 0.74, SD = 1.2 cm.

Figure 15. Comparison of simulated postoperative results to actual six-month measurements of distance from nipple to inframammary fold. Pearson correlation coefficient = 0.74, SD = 1.0 cm.

Figure 16. Comparison of simulated postoperative results to actual six-month measurements of base width. Pearson correlation coefficient = 0.50, SD = 1.1 cm.

Figure 17. Comparison of simulated postoperative results to actual six-month measurements of volume. Pearson correlation coefficient = 0.75, SD = 100 cc.
being satisfied that the original simulation accurately portrayed their outcome. This can only be interpreted as a subjective change of opinion, not a problem with soft tissue atrophy or failure of the imaging. Follow-up at 18 months showed persistence of this sentiment at almost the same rate, but no patient in the lead author’s practice has returned seeking size change during the two years since software implementation, and among the patients from this cohort who responded to the 18-month follow-up, none have undergone reoperation. No control group was followed during the study period or questioned at six months, because the questionnaire centered on the role of imaging in the process of undergoing breast augmentation, which would have been irrelevant in patients who were not imaged. Questions regarding size dissatisfaction could have been compared, but we chose to rely on previously published data on reoperation rates for comparison.16-18

Once again, our questionnaire data demonstrated that 48% of patients changed their minds about size. We make no claims that we can predict or control long-term satisfaction with breast size, even with preoperative imaging software. Rather, this software can effectively demonstrate for patients what can reasonably be achieved surgically. Because the latter is the aim of the Precision Light software, we designed our questionnaire to draw a distinction between satisfaction with imaging (and the accuracy of imaging in demonstrating the postoperative result) and satisfaction with postoperative breast size. In one sense, this should verify what most plastic surgeons already understand: that satisfaction with any aesthetic operation is a “moving target,” as the self-image of the patient evolves (or fails to evolve) postoperatively.

A particularly helpful feature of the 4D imaging simulation is that it enables the patient to collaborate on the decision to undergo breast augmentation, 21% of respondents indicated that they would not have elected to have the procedure without the imaging tool allowing them to visualize the outcome, and 83% indicated that the simulation was very helpful or primary in their decision to choose their surgeon. Seventy-four percent of patients thought the imaging was useful in choosing implant size. At eighteen months, all 28 phone questionnaire respondents felt that imaging had been an important factor in their decision to undergo the procedure and in their choice of an implant size. Interestingly, according to the six-month questionnaire, 48% of patients indicated that if they were to undergo the surgery again, they would choose a larger implant, despite being satisfied that the original simulation accurately portrayed their outcome. This can only be interpreted as a subjective change of opinion, not a problem with soft tissue atrophy or failure of the imaging. Follow-up at 18 months showed persistence of this sentiment at almost the same rate, but no patient in the lead author’s practice has returned seeking size change during the two years since software implementation, and among the patients from this cohort who responded to the 18-month follow-up, none have undergone reoperation. No control group was followed during the study period or questioned at six months, because the questionnaire centered on the role of imaging in the process of undergoing breast augmentation, which would have been irrelevant in patients who were not imaged. Questions regarding size dissatisfaction could have been compared, but we chose to rely on previously published data on reoperation rates for comparison.16-18

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drawn on implant volumes,19,20 and while others have augmentation philosophies, including absolute limits consuming, approach of educating patients on their authoritarian, not to mention complex and time-consuming, patient management. While some have taken a some-tended but positive consequences of this technology on underpinning it, and presenting data regarding the unin-

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Nearly 80% of women who sought consultation did not proceed further, representing at best a significant waste of consultation time and cost and at worst a failure to address the needs of women. The central conclusion of this important study was that more effective communication tools are needed to identify and agree on the anticipated outcome of breast augmentation.

How consultations are conducted is a personal decision and speaks to the style of each surgeon; this report is not intended to persuade others to adopt a specific bedside approach or an algorithmic, “one style fits all” formula. Instead, we are reporting on the clinical application of a novel device, demonstrating the validity of the technology underpinning it, and presenting data regarding the un-intended but positive consequences of this technology on our practice productivity and our collaborative approach to patient management. While some have taken a somewhat authoritarian, not to mention complex and time-consuming, approach of educating patients on their augmentation philosophies, including absolute limits drawn on implant volumes,19,20 and while others have applied time-honored “bra stuffing” techniques for estimating size,21,22 implant sales data available from manufacturers, such as Allergan Medical and Mentor Corporation, in personal communication reveal that the sizes of implants sold in the United States are far greater than what either of these planning methods would predict (Figure 18). This begs the question of whether these extensively published breast augmentation planning methods are actually being adopted or if they actually conflict with the day-to-day experience of plastic surgeons trying to counsel patients. This discrepancy does not necessarily indicate a lack of merit for traditional methods but may indicate a need for more appropriate visualization tools to simplify decision making.

As this study shows, available technology can be refined to assist not just the patient in visualizing her result but also the surgeon in diagnosing asymmetry, educating the patient, and fostering a bond of trust prior to the surgical event. Implementing 4D imaging in breast surgery consultations eliminates the subjective factor of evaluating chest wall asymmetry and identifying the existing volume of each breast.4 By explaining that breast asymmetries are the rule rather than the exception and that subtle preoperative differences may be more obvious after breast augmentation, patients will have a more realistic expectation for their final results, which will minimize postoperative complaints. We have found that patients are very open to learning about their anatomical measurements, limitations, and the impact of placing anatomically inappropriate prostheses when they understand how appropriate preoperative decision making will improve their eventual results. It may be that body analysis is perceived more positively by patients because the process is more objective; the receptiveness may also be due to something as simple as the patients being more at ease, since they can be clothed rather than exposed in front of a mirror. More extensive questioning in future studies could identify the reasons for patients’ openness to this type of consultation, but regardless of the cause, the response of patients is overwhelmingly positive.

As stated, practice productivity was dramatically improved with this imaging system after a brief learning curve. This finding may help mitigate physician concerns about the initial costs incurred in setting up such a system, although that factor is beyond the scope of this report. One intangible, unanticipated consequence of this technology has been a much more sophisticated quality to the consultation process. In our practices, the technology has helped change our approach from authoritative to collaborative. Bringing a patient-empowered, self-educated, collaborative spirit into the consultation process acknowledges the modern state of affairs. Web-based access to information has dramatically increased the level of patient access to information, and information about breast augmentation is no exception. In fact, the Internet is now the primary way in which women in the breast augmentation demographic acquire information about this procedure.23,24 While plastic surgeons may remain the “authority” in terms of required technical skills, general patient management skills, and breadth of experience, they cannot maintain their status as the sole arbiters of procedural knowledge, as in the past. It has been shown that patients are increasingly demanding...

Figure 18. U.S. silicone gel breast implant sales by size. Combined data from Allergan Medical and Mentor

![Figure 18](https://example.com/figure18.png)
collaboration with their physicians, and technology is at the heart of this transformation.  

For plastic surgeons to embrace imaging technology, they must feel confident not only that the system is user-friendly but also that the result displayed by the software is one they can deliver in the operating room. We recognize that only through rigorous testing and refinement can this confidence be solidified, but Parts I and II of this study are aimed at satisfying an evidence-based standard for claiming accuracy in the prediction models. This potential commercial value of a technology must remain the purview of the developers, but scientific studies conducted by clinicians must be published for any technology to provide validation of the manufacturers’ product or process claims, which was our intent with this report. It would be a conceit to claim that perfect predictive ability—or “the end of the road” in terms of perfecting this technology—is even in sight. As has been discussed elsewhere, both intense misgivings and supreme overconfidence characterize the attitude of surgeons toward computer imaging. Both opinions are at once justified and highly irrational. . . . On the other hand, apprehensive surgeons should know that with a few precautions, careful and conservative computer imaging greatly enhances surgical practice.” We appreciate that our data do not highlight a perfected system, but this system does offer an advantage in that it moves beyond the subjective realm of current illustration software into one based on evidence.

As such, 4D technology will continue to evolve as more accumulated data sets yield more refined simulation algorithms and more accurate images. The process of developing simulation algorithms is reiterative. It involves dependable image capture and reliable, standardized measurements. It then requires large amounts of data collected under many anatomical and clinical situations. As this process moves forward, the predictive value and legitimacy of the simulations will improve. As surgeons, though, we must keep in mind that the anatomy of the female breast is infinitely variable; surrounding soft tissue thickness, varying degrees of ptosis, and areolar pigmentation all conspire to challenge clinicians as well as software engineers. Just as there will likely never be a perfect breast implant, it would be unrealistic to assume that there will ever be a perfect imaging system. However, automation promises to standardize the necessary measurements and transform 3D imaging into a practical and effective clinical tool.

CONCLUSIONS

Though still nascent, 4D imaging technology holds promise as a practical tool for patient education and preoperative planning in breast augmentation. As patients’ access to web-based procedural information increases and the availability of new implants with different soft tissue effects adds to the already vast options for implant choice, the demands on surgeons’ time in the preoperative phase of breast augmentation will likely increase. Our experience shows that this clinically-validated simulation tool for consultation appears to improve communication between patient and surgeon, increase surgeon productivity, and may even assist in lowering reoperation rates. In short, 4D breast imaging appears to be an accurate system for analysis, planning, simulation, and patient education for women considering primary breast augmentation, and application of this technology during the consultation process correlates with a high degree of patient satisfaction.

Disclosures

At the time of acceptance of this research, Dr. Creasman was a principal investigator and a shareholder with stock options at Precision Light, Inc., the manufacturer of the products discussed in this article. Dr. Mordaunt was a founder, CEO, shareholder, and board member at Precision Light. Mr. Liolios was president, shareholder, and board member at Precision Light. Dr. Gabriel was shareholder at Precision Light. Dr. Maxwell was also Founder, shareholder, and Board member at Precision Light. Drs. Creasman, Mordaunt, Gabriel, and Maxwell as well as Mr. Liolios, as stockholders in Precision Light, Inc., received financial returns when Precision Light, Inc. was purchased by Allergan Medical after acceptance of this article. Ms. Chiu was paid by Precision Light, Inc. as a work-study student.

Funding

The authors received no financial support for the research, authorship, and publication of this article.

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