Breast Surgery

Special Topic

Four-Dimensional Breast Imaging, Part I: Introduction of a Technology-Driven, Evidence-Based Approach to Breast Augmentation Planning

Craig N. Creasman, MD; David Mordaunt, PhD; Tom Liolios, MBA; Catherine Chiu; Allen Gabriel, MD; and G. Patrick Maxwell, MD

Abstract

Although there are many three-dimensional imaging systems currently available on the market, all of them require a high degree of interaction on the part of the user, making them clinically impractical. Moreover, though claims have been made regarding the validity of these systems for imaging the breast form, there have been no previous reports validating any commercially-available implant simulation models in the plastic surgery literature. In this article, the authors describe the development and evaluate the efficacy of a novel four-dimensional (automated three-dimensional) breast imaging system, validating it as an evidence-based simulation tool for patient consultation, surgical planning, and outcomes analysis in cosmetic breast augmentation. This report, based on a series of longitudinal correlation studies with several patient cohorts, found a highly statistically significant degree of correlation and reliability between the automated measurements obtained with the four-dimensional system and manual measurements.

Keywords

breast surgery, four-dimensional imaging, magnetic resonance imaging

Accepted for publication April 5, 2011.

Following the introduction of the silicone gel prosthesis in 1962, breast augmentation quickly became one of the most frequently performed procedures in cosmetic surgery.1,2 It is estimated that more than 3% of the adult female population in the United States (between two million and four million) has undergone breast augmentation.3 Recent data showed that breast augmentation remained the most popular aesthetic surgical procedure in 2010.4 Though there has been some debate about the validity of the reoperation rate as a metric of success or failure for this procedure,5-9 it is fair to assume that most plastic surgeons ascribe to the view that this is a salutary metric. Moreover, the US Food and Drug Administration premarket approval data have utilized various rates of and indications for reoperation as a measure of outcomes. Overall reoperation rates run as high as 25% at five years for saline implants and 23.5% for silicone gel implants at three years.10-13 It has been observed that reoperations for size change and other device issues, along with incision choice, asymmetry related issues, and correction of ptosis, form the majority of secondary procedures; all of these postoperative issues may be avoidable with better preoperative surgical planning.14

To reduce reoperation rates in breast surgery patients, much effort has been made to improve the safety and

Dr. Creasman is a plastic surgeon in private practice in San Jose, California. Dr. Mordaunt is founder and CEO and Mr. Liolios is president of Precision Light, Inc. Ms. Chiu is an undergraduate student at Brown University. Dr. Gabriel is a plastic surgeon in private practice in Vancouver, Washington. Dr. Maxwell is a plastic surgeon in private practice in Nashville, Tennessee, and a founder of Precision Light, Inc.

Corresponding Author:
Dr. Craig Creasman, 2400 Samaritan Drive, Suite 206, San Jose, CA 95124 USA.
E-mail: drc@creasman.com
consistency of cosmetic breast procedures. To this end, attempts at objectively measuring a patient’s anatomical dimensions have been made with various programs and algorithms, including the Biodimensional System, the TEPID System, the High-Five System, the Body Logic System, and the Akademikliniken System.15-22 Though no single scheme of measurement has predominated, the common paradigm remains true: Quantitative measurements are valuable in improving outcomes in breast augmentation.

A recent study examining the breast augmentation consultation process showed several areas ripe for improvement, including providing a means for patients to visualize potential outcomes, which enhances their trust in the surgeon.23 With any type of breast surgery—augmentation, reduction, reconstruction, or revision—the goal is to design a symmetrical and aesthetically-pleasing breast form. Clearly, achieving this goal entails developing a breast mound that is proportional to the body, with the nipple located at the most anteriorly-projecting portion of the breast form, which should have minimal ptosis and be tear-drop in shape.24-26

Existing methods of surgical planning involve different, somewhat primitive techniques to help the patient visualize how her breast form might appear under clothing and then help the surgeon subsequently quantify the necessary volume to achieve the desired goal. Brody had patients choose brassieres with well-formed cups and pad them appropriately until they arrived at a size that suited the image they were trying to obtain; volume was then assessed with water-filled bags.27 This did account for identifying some gross anatomical asymmetries, but subtle asymmetries were more difficult to appreciate with this model. Other plastic surgeons have suggested alternative approaches for determining the implant volume required to achieve aesthetic breasts.28-34 Most surgeons rely on their own techniques of assessment for identifying preoperative asymmetries, and it has become clear that selecting appropriate implants can be challenging.35,36 Preoperative planning worksheets with questions and measurements can become complicated; they also have their limitations.37,38

In fact, so many approaches to measuring volume in the female breast have been described that a review of the literature might lead one to categorize it as a medical obsession for the last half century.35-48 Several authors have recently examined the validity of three-dimensional (3D) imaging in measuring breast volume compared to more classical methods as controls.49,50 While others have relied on internal controls,51 magnetic resonance imaging (MRI) has emerged as the accepted standard for noncontact volume measurement against which 3D imaging systems are judged. Over the past decade, technological advancements in digital 3D imaging have advanced from a research phase (in which they were bulky, slow tools), to a commercial, albeit rudimentary stage (in which they are widely available throughout the world for a variety of applications). The natural merger of surgical planning systems and digital imaging has stimulated interest from several centers, and verification of the accuracy of some imaging systems has been reported.52-54 However, all currently-available digital 3D imaging systems involve manually positioning anatomical markers before determining linear and/or volume measurements; thus, a gap exists between the technology and its ease of use.47,51-57

Breast measurements, whether taken clinically with a tape measure and caliper or recorded digitally by manual placement of landmarks, have suffered from being somewhat subjective. The process is also time-consuming as to be impractical for day-to-day clinical application. Moreover, the planning, or “morphing,” software systems designed to simulate surgical outcomes have been based not on accumulated patient data but on idealized outcomes.55-57 There is currently a dearth of published data to validate the commercial outcome simulations currently on the market. To make technological progress, improvements are needed in design, image capture and processing speed, and evidence-based simulation algorithms.

To that end, in this report, we introduce a completely automated four-dimensional (4D) image capture and software system with instantaneous anatomical landmark recognition, linear measurement, and volume calculation of the breast; we present results of a study to validate the accuracy of the automated linear measurements compared to manual measurements; we offer data comparing the accuracy of automated volume calculation against the current accepted standard (MRI); and we report our evidence-based approach to developing automated breast augmentation simulation algorithms.

**METHODS**

**Development of Technology**

**Hardware Image Capture**

A structured light-based image capture system was developed specifically for breast imaging. With this system, patients were positioned facing the device with arms akimbo. Structured light was generated from three digital projectors, aligned with mirrors to shorten the focal length to the patient. Both structured light and surface color images were captured by three high-speed CCD digital video cameras (Pike, Allied Vision Technologies GmbH, Taschenweg 2a, Stadtroda, Germany) and then processed with a Dell Precision T3400 desktop computer running Windows 7 Professional 32 Bit O/S, with an Intel Core 2 Duo 3 GHz processor and 4 GB of RAM (Dell Computer, Austin, Texas) using Precision Light Imaging (PLI) software (described in detail later; Precision Light, Inc., Los Gatos, California) (Figure 1). A sequence of 13 progressively-finer parallel line patterns was projected from each of three vectors to triangulate the patient (structured light method). In turn, each projected pattern was captured with the video cameras. By this method, each point in space was assigned a 39-character binary address from which a wire-frame 3D rendering of the form was generated. Finally, three individual color images of the subject were gathered from the same cameras, registered to the 3D form and to one another. Total projection and image capture time was 0.5 seconds. Total processing time to render a displayed image with measurements was 15 seconds.
Software Image Processing

Automated landmark recognition. Proprietary software was developed specifically for breast imaging (Precision Light, Inc.) to recognize key anatomical landmarks in a completely automated manner from 3D images. Hereafter, 4D imaging is used to refer to this mechanism of 3D imaging plus automation. This automation was accomplished by the following methodology: A point cloud arising out of the structured light images was converted to a 3D wire-frame reconstruction of the form of the patient. The method of processing the data points has been reported elsewhere but involves a technique of phase shifting to reduce errors. Onto this wire frame, the individual color images were registered to generate a life-like and recognizable rendering. A separate color contour map was generated from the relationships between adjacent minima and maxima of the wire-frame contour. Key anatomical landmarks—including the inframammary folds (IMF), the axillae, the umbilicus, the sternal notch, the heads of the sternocleidomastoid muscles, the trapezius muscles, the clavicles, the nipples, and the midlines of the IMF—were recognized by virtue of being minima and maxima within this color contour map. These landmark assignments reflected purely mathematical coordinates with a resolution of 0.1 mm (Figures 2 and 3).

Color value information from the photographic color overlay was the method by which the areolar diameters were recognized. Specifically, the software automatically found the location where the color value of the breast transitioned to the darker value of the areolar tissue (Figure 4).

Figure 1. Precision Light Imaging hardware, 78 × 76 × 22 in. (height × width × depth).

Figure 2. Three-dimensional wire-frame reconstruction
**Point-to-point measurements.** Armed with specific contour landmarks, software routines were developed to yield point-to-point measurements automatically. (Some of these were displayed [as in Figure 4] and some were not.)

**Midline of torso:** The midline of the upper torso was determined by referencing two areas: the midpoint of the area between the sternocleidomastoid muscles and the midpoint between the medial breast folds at the level of the nipples.

**Breast base width:** To reconcile the frequent issues between horizontal base width and lower pole length, the displayed breast base width corresponded to an average of the base width at the nipple level and twice the inferior breast radius (defined below).

**Nipple to midsternal line (not displayed):** The linear measurement of the nipple to midsternal line was calculated according to the shortest distance between the 3D coordinates for the nipples and the midsternal line.

**Nipple-to-nipple distance (not displayed):** The linear measurement between the two nipple positions was calculated as the shortest distance between the 3D coordinates of the left and right nipples.

**Intermammary distance:** The linear measurement of the intermammary distance was calculated as the shortest distance between the 3D coordinates of the medial boundaries of both breast base fold lines corresponding to the left and right breast.

**Inferior breast radius (not displayed):** The linear measurement from the IMF to the projected position of the nipple into the chest wall was calculated as the shortest distance between the most inferior point on the IMF to the projection of the nipple onto the virtual chest wall.

**Surface measurements.** The 3D system provided consistent and accurate surface measurements because once any two points of interest were identified, the line between those two points over the known surface contour was easily plotted and measured.

**Sternal notch-to-nipple distance:** The 3D surface measurement from the sternal notch to the nipple was calculated as the 3D line integral over the patient’s 3D contour surface along the vector defined between the 3D coordinates for the sternal notch and the nipple.

**Nipple-to-IMF distance:** The 3D surface measurement between the nipple and the IMF was calculated as the 3D line integral over the patient’s 3D contour surface along the vector defined as the 3D coordinates from the nipple to the IMF, with the vector being parallel to the midsagittal plane.

**Midclavicle-to-nipple distance (not displayed):** The 3D surface measurement from the midclavicle to the nipple was calculated as the 3D line integral over the patient’s 3D contour surface along the vector defined between the 3D coordinates for the center point of the clavicle and the nipple.
Volume measurement. To calculate the volume of the soft tissues of the chest, a construction of the underlying chest wall was rendered on the basis of several previously-described external landmarks, with a spline interpolation method. The boundaries of what constituted the breast were automatically determined by following some key anatomical landmarks and standard rules: The lateral boundary corresponded to a plumb line drawn from the anterior axillary fold and did not include tissue in the lateral tail of Spence. The lower boundary was defined as a line parallel to but 1 cm below the IMF. The medial boundary was defined as the midsternal line, and the upper boundary was an arc plotted from the anterior axillary fold to the upper sternal border, with a peak corresponding to 1/4 the distance from the clavicle to the nipple. (This configuration is based on multiple iterations of data and may appear high on the chest, but it allows capture of excessive superior fullness under various clinical conditions—for example, in the immediate period following implantation.) With the peripheral boundaries of the breast defined with this interpolated chest wall, the overlying soft tissues of breast and skin absent the pectoralis muscle were mapped, and the contained volume became calculable as the 3D integral between the 3D surface contour and the underlying chest wall (Figure 5).

Clinical Validation of Software: Manual vs Automatic Measurement Comparison

Linear measurement comparison. A linear measurement-comparison portion of the study was conducted with 25 randomly selected female volunteers presenting for breast augmentation consultation and 90 healthy volunteers who had undergone primary breast augmentation at least six months prior to data collection, for a total sample size of 115 patients. Manual measurements were made with the standard biodimensional approach (ie, with a measuring tape and calipers) to obtain clinically accessible measurements. Some automated measurements, such as inferior breast radius, not manually accessible. The specific manual measurements obtained were as follows: base width, nipple-to-IMF distance, sternal notch-to-nipple distance, internipple distance, and nipple-to-midline distance. At the same visit—but immediately after manual measurements, to avoid biasing the manual examiner—4D images were obtained with the PLI system. All manual measurements, 4D image capture measurements, and data processing were completed by one examiner (Ms. Chiu) for consistency. Table 1 summarizes the demographic and implant data for this large cohort. Comparison between manual and PLI measurements was analyzed statistically with the Pearson correlation coefficient for each measurement category.

Repeated automated measurement consistency. Consistency was established among repeated automated measurements by comparing measurement data from two images of the same patient. Twenty-five patients were randomly chosen, and two images were sampled per patient. Data were analyzed with the Pearson correlation method.

Repeated manual measurement consistency. Consistency was established among repeated manual measurements (ie, interrater reliability) by comparing measurement data for the same patient but from two examiners. The same 25 randomly-selected patients who were included in the cohort to ensure automatic measurement consistency were manually measured by two independent examiners and the following distances were compared: sternal notch-to-nipple distance, internipple distance, nipple-to-IMF distance, and base width. The Pearson correlation was used to compare the independent manual measurements between the two examiners. Statistical analysis was carried out with the Pearson method.

Volume measurement comparison. Eleven healthy volunteers were selected semirandomly and included in a separate
cohort to assess the validity of volume measurement. Semirandomly is meant to indicate that within a group of randomly selected patients, participants were stratified by bra cup size to assess volume measurement across the spectrum of patients presenting clinically for breast augmentation. Three of the 11 patients had previously undergone breast augmentation. MRI scans were obtained with a Siemens Magnetome Symphony 1.5 Tesla MRI scanner (Siemens, Berlin, Germany). All patients were placed in the prone position. Bilateral, noncontrast, T1-weighted, fat-suppressed, and non-fat-suppressed axial and coronal images at 2-mm slice thickness were obtained with a dedicated breast array. These images were processed for 3D volume calculation with the following protocol: On the axial images, control points were placed manually around the entire breast in a manner consistent with the algorithm for the PLI software described previously, avoiding the tail of Spence but delineating the right from left breast by the sternal notch. A line connecting all control points was automatically drawn on all slices, and the volume was calculated with the “fuzzy means” technique, incorporating all tissue types contained within the skin envelope but excluding the chest wall structures, to define a region of interest consistent with the automated software algorithm of PLI. A fuzzy C-means segmentation technique was used to label all magnetic resonance voxels (volumetric pixels) within the tissue contained by the breast skin envelope.62

A graphical user interface was developed to interactively delineate the regions of interest in the non-fat-suppressed slices of interest. Regions of interest were accomplished with a combination of Bezier splines and a Laplacian of Gaussian filter.53-66 The researcher placed control points of Bezier splines close to the edges of the regions of interest (here, the breast contour). The final contour was displayed after automatic attachment of the Bezier spline control points to the closest edges. Points that did not reach the desired final position were manually adjusted by the researcher to yield a final regions of interest, as shown in Figure 6. On the same day, patients were photographed with the PLI system at a separate location, and volume calculations were carried out automatically. Data were compared with the Pearson correlation coefficient.

## Development of Breast Augmentation Simulation Algorithms

Forty-seven patients were studied longitudinally prior to and following primary breast augmentation, to gather measurement data to assist software designers in the development of simulation tools. Patients were imaged preoperatively and at one, six, 13, and 26 weeks postoperatively. Based on these measurements, trends of linear and volumetric change were compiled. No unoperated control group was studied. Though it is possible that some measurable changes in breast dimensions (particularly volume) might be found over time in a normal population of women on the basis of weight fluctuations or menstrual cycles, our system is not sensitive enough to detect such minor normal anatomical fluctuations. Proprietary simulation software was initially based on these data, and data were retrospectively obtained in one practice (CNC) and in a prior study by our group.67 Subsequently, additional measurement data sets have been obtained from five other clinical sites across all implant types and from the two major US implant manufacturers.

## RESULTS

The PLI automated measurement results correlated, with a high degree of statistical significance, to manual measurements in the sternal notch-to-nipple distance (Figure 7), base
width (Figure 8), nipple-to-IMF distance (Figure 9), and internipple distance (Figure 10) categories. Volume comparisons to 3D MRI measurements showed a high degree of precision but had less significant accuracy than the linear measurements (Figure 11). Thus, the overall correlation of manual to automated measurements in this series was 91%. The repeatability of the automated measurements ($R = 0.996$) compared favorably to interexaminer variability with manual measurements ($R = 0.993$).

The longitudinal analysis yielded massive quantities of data too extensive and complex to be of practical publication value. General trends in the parameters measured varied by implant type more than by volume but were otherwise consistent with clinical experience. There were quantitative increases primarily in breast projection (average, 63%) and lower pole lengthening (average, 43%), with very little change after the three-month postoperative period (Figure 12). Volume trends showed an initial expected increase, followed by progressive decline averaging 13% over the first three months, after which they remained stable (Figure 13), consistent with the clinical observation of “implant settling.” The observed trends were included in designing the initial simulation computer algorithms that were subsequently refined by over 1000 additional consultation data sets in a reiterative process. In a companion publication, a description of the method and validation of simulation software is reported.
The promise of a practical 3D imaging tool for everyday application in clinical practice has not been fully realized, because of the need for manual intervention on the part of the clinician. This is time-consuming; it requires a degree of comfort with technology along with some training; and it insinuates the computer between the doctor and the patient. Advancement of the field demands automation. With automation, one realizes much greater ease of use, speed, and consistency of measurement. Absent the distractions of patient-positioning problems, calibration sensitivity, and manual cursor placement, the consultation “flow” is unimpeded and allowed to progress quickly to analysis of anatomical features, asymmetries, and, ultimately, simulation of implantation under various scenarios.

While there are a variety of technical means for acquiring an image and rendering the human form in three dimensions, the method of structured light and the utilization of software that automatically recognizes standard anatomical landmarks described here provide a high degree of precision and reproducibility. In other areas, structured light 3D imaging has been used for scanning machine parts with specifications and tolerances far more precise than what is needed in physiological systems. First reported by Boot et al, the Bodymap software was a structured light-based system for studying breast asymmetry. The last decade has ushered in other pioneering investigations with laser scanning, other forms of structured light, digital photography, and digital photogrammetry. While a few manufacturers have entered the commercial marketplace, their systems are too slow and unwieldy for most practitioners, and the machines interfere in, rather than enhance, the consultation process. By dint of first-generation design flaws, they often encumber the physician, who cannot delegate this task to an ancillary provider because of the need to apply clinical judgment at multiple decision points in the manual interfaces of these systems. These first-generation products also require large capital expenditures, and, consequently, such systems have found applicability primarily in a research sphere or in large multiphysician groups or have ultimately fallen into disuse. As a result, there has not been wide adoption of 3D imaging by practicing plastic surgeons as part of their consultation process.

Moreover, though a significant body of literature exists demonstrating the technical aspects of image capture and validation of linear measurements (and in a few instances, volume measurements), no systems to date have been placed on the market with any significant aspects pertaining to

**DISCUSSION**

**Figure 11.** Volume correlation, $R = 0.91$ (SD = 60 cc).

**Figure 12.** Linear trends in soft tissue stretch, six months after breast augmentation (mean values). Lower pole elongates 43%; projection increases 63%.

**Figure 13.** Postoperative volume loss curve. Average loss of volume was 13% over first three months, then remained stable in subsequent months.
validation of the implant simulation features of the technology. Our data, drawn from several studies presented here, demonstrate the PLI system’s ability to rapidly capture and process an image into a clinically useful format in approximately 15 seconds. The validity of the measurements is shown with an overall correlation to manual measurements of 91%. Reproducibility of measurement was also shown, with a reliability of 99.6%.

One important issue for practicing plastic surgeons is the practical consideration of how such systems might be employed clinically. For clinicians to embrace the often-stunning imaging technology now available as a practical clinical tool, the system must not only be user-friendly but also offer some reliability in terms of the image outcomes being presented to each patient and their correlation with actual postoperative results. Only through rigorous validation testing can confidence in such technology develop. In a companion article, we present more information about the development and testing of our simulation algorithms for breast implant placement, along with personal experience with this imaging system in a clinical practice.

CONCLUSION

Precision Light, a novel 3D digital imaging system, offers software capable of automatically recognizing anatomical landmarks and measuring linear, surface contour, point-to-point, and volume parameters for prospective breast implant patients. Validation testing shows this to be a reliable tool when compared to the controls of manual linear measurement and MRI volume measurement. Repeatability analysis showed a nearly-perfect result when compared to repeatability of manual measurements. Longitudinal studies show a variety of trends over time in the postoperative course of the augmented breast; the large amounts of data acquired were of significant help in the design of computer simulation algorithms. Because of the automated features of this system, the full process (image acquisition, processing, and display of the patient’s form with applied measurements) is completed with such rapidity as to make the imaging process practical in a practice setting. While more work is necessary to refine and validate the simulation features of the software, at the present time this system is functional in several private practice settings, and expansion to a larger group of practices is planned.

Acknowledgment

We thank Catherine Klifa, PhD, UCSF Department of Radiology for her assistance with the magnetic resonance imaging volume study.

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. Mordant was a founder, CEO, shareholder, and board member at Precision Light. Mr. Liolos was president, shareholder, and board member at Precision Light. Dr. Gabriel was a shareholder at Precision Light. Dr. Maxwell was also a Founder, shareholder, and Board member at Precision Light. Ms. Chiu has nothing to disclose. Drs. Creasman, Mordaunt, Gabriel, and Maxwell as well as Mr. Liolos, 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 summer work-study student.

Funding

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

REFERENCES

14. McCafferty LR, Casas LA, Stinnett SS, Lin S, Rho J, Skiles M. Multisite analysis of 177 consecutive primary breast...


56. 3dMD. Technical specifications. Available at: http://www.3dmd.com/3dmd-leadership-technology.html.


