3D BREAST IMAGING FOR COSMETIC AND RECONSTRUCTIVE BREAST SURGERY: DOES 3D IMAGING IMPROVE PATIENT REPORTED OUTCOMES IN PRIMARY BREAST AUGMENTATION?

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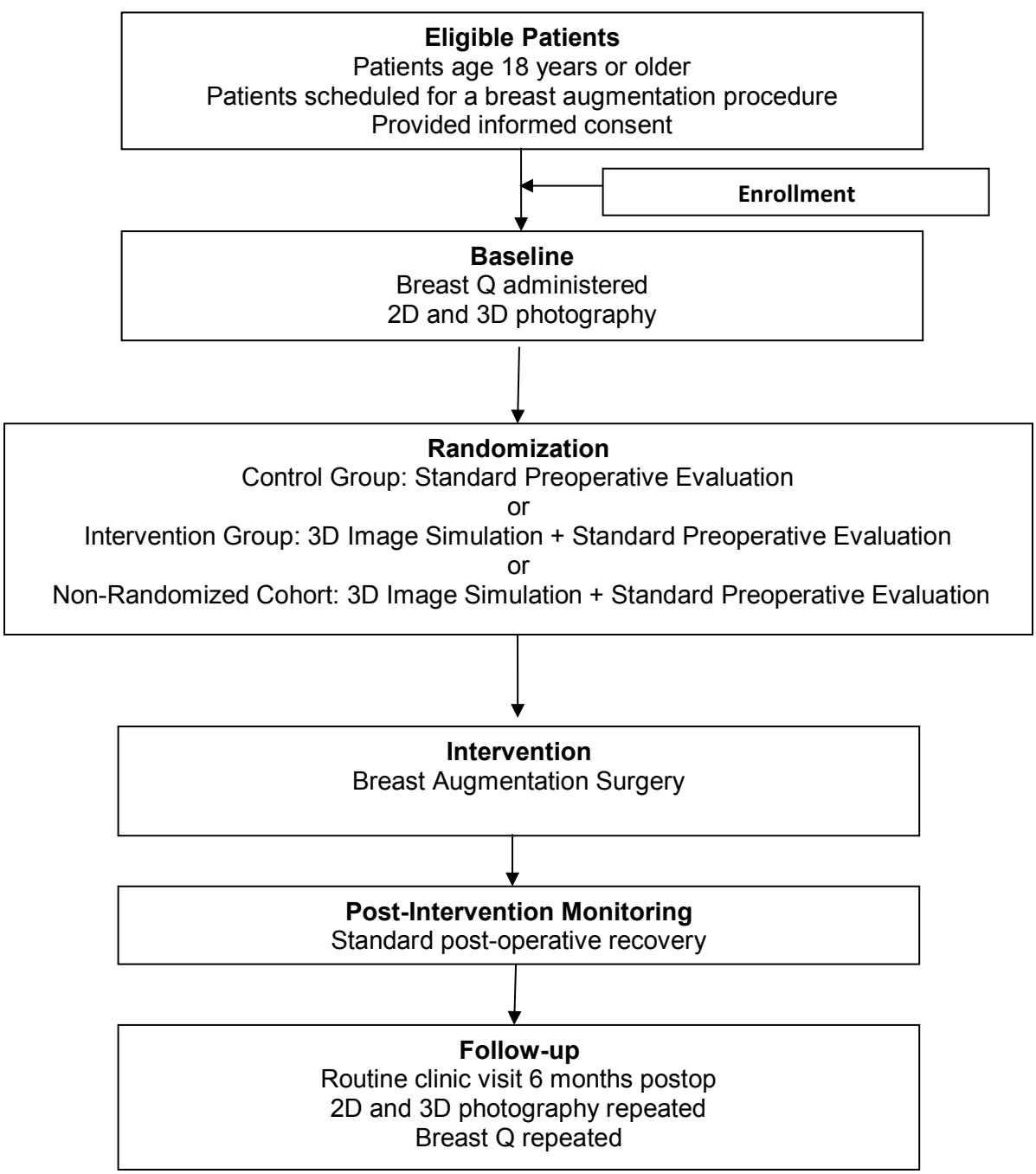
TREATMENT SCHEMA



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1.0 BACKGROUND AND RATIONALE

Advances in 3D breast imaging. Three-dimensional imaging, extensively utilized to provide objective outcome measures in craniofacial surgery, has been adapted for evaluation of the breast. Three-dimensional images of the breast can be used to facilitate patient education, surgical planning, as well as both a research and marketing tool by plastic surgeons. Over the past few years, investigators have identified breast measurements calculated from computerized renderings of three-dimensional photographs and documented changes in these measurements following surgical procedures such as breast reduction, breast reconstruction with implants, and breast augmentation. Changes in these parameters after operative intervention have enabled surgeon scientists to compile objective quantitative breast data, or "mammometrics" (1). Mammometric data can be statistically analyzed, longitudinally evaluated in the same patient over time, and correlated with other quantitative data including patient reported outcomes. Some of the useful mammometric measurements that can be used to quantify and compare pre- with postoperative breast surgery include total and split breast volumes, distances from the low breast crease to the nipple, and projection of the breast and nipple from the chest wall among others.

Outcomes research in plastic and reconstructive surgery is more likely to focus on patient reported outcomes than survival. While the plastic surgery literature is replete with surveys focused on judging patient satisfaction, they are infrequently validated or comprehensive. The Breast Q has been established as a validated instrument to provide a quantitative measure of the unique features of patient reported outcomes following breast surgery. This instrument represents the most comprehensive and specific quantitative method for patient self-assessment following breast surgery. Recently, McCarthy and colleagues published, for the first time, patient satisfaction in 41 patients who underwent breast augmentation and were evaluated with the Breast Q. This study found statistically significant improvements following breast augmentation in the "satisfaction with breasts" – 14 item scale, "psychological well-being" – 9 item scale, and "sexual well-being" – 5 item scale. This study does not, however, include information on either the benefits of 3D imaging or the mammometric parameters most closely associated with improved satisfaction. Interestingly, the core scale "satisfaction with care" was not evaluated in this study. While this particular core scale may not have been relevant to a study looking at the overall benefits of breast augmentation, we suspect that it may be highly relevant to the aesthetic surgery patient where the consultation experience is more likely to impact overall patient satisfaction.

This study will evaluate the impact of incorporating 3D imaging during preoperative consultation on patient reported outcomes in primary breast augmentation surgery. 3D imaging can be used to facilitate patient education and surgical planning in the context of breast augmentation. The purpose of this study is to utilize the most objective assessment available for assessing patient satisfaction with breast augmentation - the Breast Q - in a prospective randomized trial. We will evaluate whether 3D imaging used in consultation 1) can improve patient reported outcomes, and 2) whether there are measurable mammometric parameters that are associated with improved patient satisfaction and 3) if utilizing 3D imaging in the pre-operative consultation significantly influences final mammometric parameters compared to patients receiving a traditional consultation that does not involve 3D breast surgical simulation.

It is hoped that patients of surgeons that utilize this technology in the preoperative consultation will have significantly higher Breast Q breast augmentation module scores 6 months after surgery. "Satisfaction with care" - one of six core scales within the Breast Q - will be particularly impacted by using 3D image simulation in the consultation experience. Additionally, it is thought that superomedial pole fullness and central nipple position as quantified with mammometrics that

the 3D imaging can provide will be associated with higher Breast Q scores, especially the "satisfaction with breasts" items.

This study will represent one of the first randomized control trials performed to address patient satisfaction with breast augmentation.

2.0 OBJECTIVES

2.1 Primary Objective

To establish whether 3D imaging used in breast augmentation consultation can improve patient reported outcomes.

2.2 Secondary Objective

To determine if measureable mammometric parameters are associated with improved patient satisfaction.

3.0 PATIENT SELECTION

3.1 Inclusion Criteria

- 18 years of age or older
- Scheduled for elective breast augmentation cosmetic procedure

3.2 Exclusion Criteria

- Cognitively unable to provide informed consent
- Breast reconstruction for malignancy

3.3 Inclusion of Women and Minorities

Due to the nature of the surgical procedure, men are excluded from participation in this study. Members of all races and ethnic groups are eligible for this trial.

3.4 Inclusion of Non-Randomized Cohort

Patients who refuse the option of randomization but otherwise meet the inclusion and exclusion criteria will be offered participation in this study as part of a non-randomized cohort. All aspects of the study as described in the protocol will be followed with exception of the randomization will be followed.

4.0 TREATMENT PLAN

4.1 Preoperative Evaluation

Standard preoperative evaluation will be conducted on all patients. It is routine practice in cosmetic surgery to take baseline pictures and measurements. Both 2D and 3D photography will be performed on all patients.

4.2 Randomization

100 patients will be recruited in the randomized cohort. Randomization will be performed by a Research Patient Coordinator and the patient assigned to the control group or the intervention group. Randomization will only occur after the patient has signed the informed consent and will be documented in the case report file as well as communicated to the treating surgeon.

Intervention group
In the intervention group, in addition to standard preoperative evaluation, 3D image simulation will be performed.

Control group
In the conventional group, only the standard preoperative evaluation will be performed.

Non-Randomized cohort
In the non-randomized cohort, the patient can choose to have the standard evaluation with the addition of the 3D image simulation or not based on discussion with their surgeon.

Minimizing measurement bias
Blinding of the patient or surgeon will not be possible due to the need for the 3D imaging simulation to be openly discussed and viewed prior to the operation for patients randomized to 3D intervention and for the nonrandomized cohort.

All subjects will be administered the Breast Q questionnaire prior to surgery regardless of assigned group. The questionnaire will take approximately 5-10 minutes of time to complete.

4.3 Operative Procedure

The elective surgical procedure will be conducted as planned.

4.4 Postoperative Care

The postoperative management is standard of care for all patients who undergo breast augmentation procedure and will not be altered by their participation in this study.

4.5 Duration of Follow-Up

Patients will be followed for 6 months following their surgical procedure. Postoperative complications and adverse events will be closely monitored. Patients will be followed until resolution or stabilization of the adverse event.

At the 6 month follow-up appointment, routine postoperative 2D and 3D images will be taken for comparison to baseline. As part of this research study, the Breast Q questionnaire will be re-administered to the subject.

4.6 Criteria for Removal from Study

If at any time the constraints of this protocol are considered to be detrimental to the patient's health and/or the patient no longer wishes to proceed with the protocol intervention, the patient should be removed from the study and the reason(s) for discontinuation documented in the case report forms.

Otherwise, the patient will receive the intervention and be followed as described.

5.0 ADVERSE EVENT REPORTING

5.1 Adverse Events

Definition: any unfavorable medical occurrence in a human subject including any abnormal sign, symptom, or disease.

Attribution (relatedness), Expectedness, and Seriousness: the definitions for the terms listed that should be used are those provided by the Department of Health and Human Services' Office for Human Research Protections (OHRP). A copy of this guidance can be found on OHRP's website: http://www.hhs.gov/ohrp/policy/advevntguid.html

5.2 Reporting to the Human Research Protection Office (HRPO) at Washington University:

All HRPO guidelines for reporting unanticipated problems will be followed.

6.0 DATA AND SAFETY MONITORING

The study principal investigator and Research Patient Coordinator will closely monitor for adverse events on an ongoing basis. Once the principal investigator or Research Patient Coordinator becomes aware of a research related adverse event, the AE will be reported to the HRPO according to institutional guidelines.

6.1 Potential risks

A possible breach of confidentiality of study data is an unlikely risk.

6.2 Minimization of risks

PHI will be collected and include the patient's name, date of birth, date of surgery and date of follow-up. The patient's name and other identifiers will be kept in a password-protected database in which access will be granted to only the research team.

Participants will be assigned a study number and after the data is collected, all identifiers with the exception of date of birth will be removed.

All study papers with and without identifiable study information will be kept in a locked file cabinet in a locked room in a locked office for the duration of the study data collection period. All information will be entered into a database. The database is secure, saved on a firewall protected network, and password protected. All hard copies of identifiable information will be disposed of by shredding after the information is reviewed and locked into the database, the analysis has been made, and the report has been written, and one year has passed from the date of publication.

6.3 Potential benefits

Direct benefit to the patient is unknown. The patients randomized to receive the 3D simulation of what their implants are anticipated to look like may feel greater satisfaction with the aesthetic results after their surgery.

7.0 STATISTICAL CONSIDERATIONS

7.1 Study Endpoints

Primary endpoint
BREAST Q Augmentation Module. This includes 6 core items, each with several sub-items. Of the 6 core items, 3 are recently shown to statistically significantly improve in patients undergoing breast augmentation: 1) satisfaction with breasts 2) psychological well-being 3) sexual well being. A fourth, 4) satisfaction with care, however, may be particularly relevant to the discerning aesthetic surgery patient using 3D imaging in consultation. The other core items in this instrument are 5) physical well-being and 6) satisfaction with overall outcome which will also be recorded.

Secondary endpoints
All patients will undergo standard 2D as well as 3D imaging before and after surgery. During consultation, and in the postoperative period, reviewing 3D imaging and morphing software will be unique to the experimental group. 3D imaging from all patients will be used to obtain mammometric data. Pre- , and post- op mammometric data (volumes, vectors, surface distances, anatomic landmarks), as well as the measurable change in these parameters before and after surgery will be correlated with changes in Breast Q patient reported outcomes scores. This will enable us to identify particular mammometric parameters that are a) associated with improved patient reported outcomes and b) determine whether certain mammometric parameters are significantly different in patients who had 3D image simulation as part of their preoperative consultation relative to those that did not.

7.2 Study Design

To achieve comparable groups for known and unknown risk factors randomization will be performed as unistratified block randomization with random block sizes in a 1:1 allocation ratio. Allocation to treatment will be carried out by means of a computer-generated random study numbers with group assignment.

Non-randomized cohort

Patients who choose not to be randomized but otherwise meet the inclusion and exclusion criteria will be offered participation in this study as part of a non-randomized cohort. Their data will still be analyzed for the purpose of addressing the secondary objective.

7.3 Sample Size

Appropriate sample size is calculated based on assumption of difference of 20 percent in patient satisfaction as compared with the control group. This difference is considered clinically relevant baed on previous similar studies. A sample size of 100 patients (50 in each group) is considered sufficient to prove this difference, if present (alpha error set at 0.05, power>99 percent).

Approximately 75 patients per year undergo a breast augmentation procedure at Washington University Medical Center. The estimated time frame to randomize 100 patients is approximately 24 months.

Non-randomized cohort

Up to 50 patients will be included in the non-randomized cohort.

7.4 Data Analysis

Data analysis for this study will be descriptive in nature. Demographic and clinical characteristics of the sample, as well as post-surgery complications will be summarized using descriptive statistics and the confidence intervals will also be provided.

Patients assigned to the intervention group (3D simulation) will be compared with those who had conventional techniques using x^2 tests for categorical variables and Student's t-tests for continuous variables. For the t-tests equal variances were not be assumed, unless significant by Levene's test. Mann-Whitney *U* tests will be utilized for non-normally distributed variables. Two-tailed P values 0.05 will be considered statistically significant.

Multivariate analyses for Breast Q scores, mammometric parameters, and patient satisfaction will be performed using binary logistic regression and linear regression models to examine the relationship between intervention groups and examined outcomes and to identify potential confounders. The results of multivariate analyses will be expressed as odds ratios with corresponding 95% confidence intervals. All analyses will be performed using SPSS 20.0 statistical software (SPSS Inc. Chicago, IL).

8.0 REFERENCES

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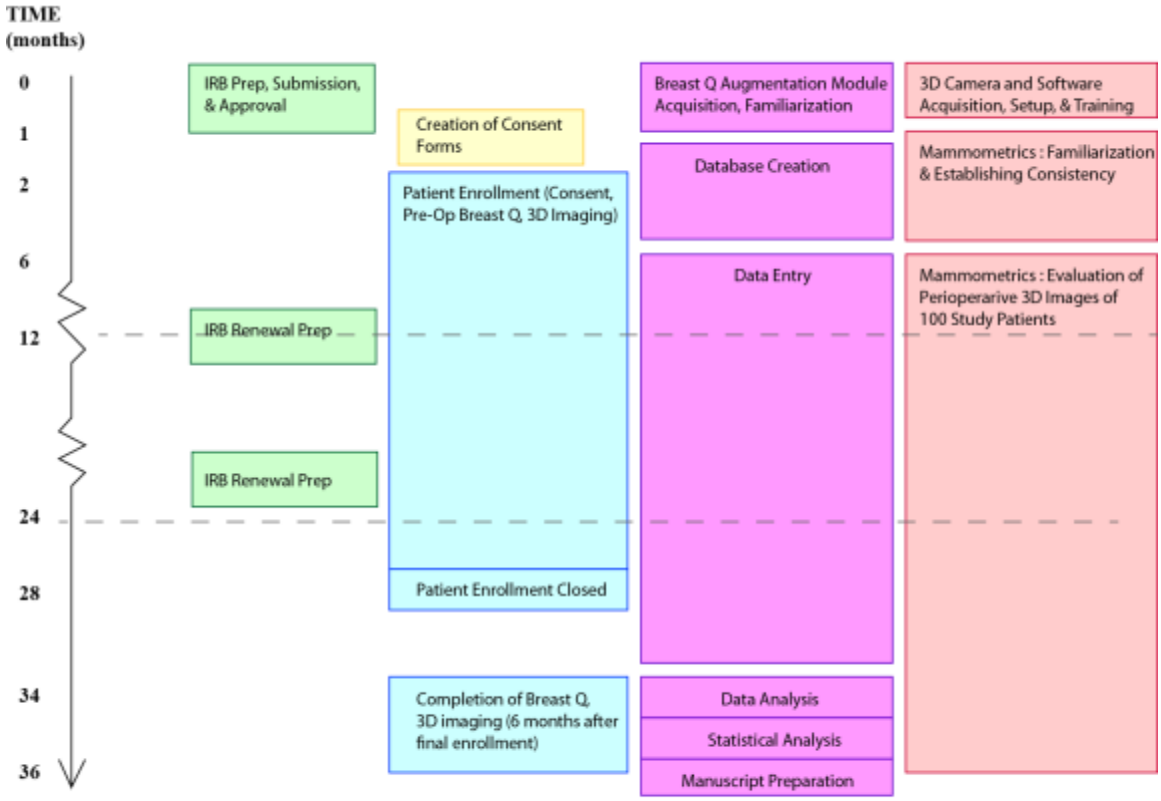
APPENDIX A: STUDY TIMELINE



APPENDIX B: STUDY VISIT SCHEDULE

	Screening[2]	Intervention	6 Months Post-Op[4]
Standard Pre-operative Evaluation[1]	X		
Informed consent	X		
Breast Q Questionnaire	X		X
Randomization		X	
2D and 3D Photography	X		X
3D Simulation		X[3]	
Peri and postoperative complications			X

[1] Study-relevant past medical and surgical history to be documented from consult and pre-surgical evaluation
[2]Screening procedures to be completed within 90 days of surgery
[3]Only for subjects randomized to intervention group
[4]To be performed 6 months from day of surgery ± 60 days.