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*** Cover Letter**

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Dear Dr. Rohrich:

Attached is a copy of my and Bill Adams' manuscript entitled *Five Critical Decisions in Breast Augmentation Using 5 Measurements in 5 Minutes: The TEPID™ System Refined* for review and consideration for publication in the Journal.

We appreciate your considering this manuscript.

With best regards,

John B. Tebbetts, M.D.

*** Author Forms (Prior Publication Certification, Copyright Form,**

This piece of the submission is being sent via mail.

RE: PRS-D-04-00448, entitled "Five Critical Decisions in Breast Augmentation Using 5 Measurements in 5 Minutes: The TEPIDTM System Refined"

Reviewer Comments:

Reviewer #1: This paper, written by a recognized expert in the field of breast augmentation, contains Dr. Tebbetts' most recent analysis of what are purported to be the "quantifiable measurements" needed to match breast tissue characteristics and implant dimensions. It is a laudable goal that I believe falls short, but nevertheless is acceptable after revision for publication. I would list my concerns as follows:

(1) The author presents what he considers to be a simplified technique of assessment which is actually quite complex. The graph recordings and measurements are time consuming and of questionable value. It is universally agreed that nipple to notch, breast width, and nipple to IMF measurements are important preoperative parameters to consider. What proof does Dr. Tebbetts have that he can predict implant dimensions by pulling on a patient's nipple?

Five measurements and five decisions in 5 minutes do not seem overly complex to most patients and surgeons who have actually used the system. As stated on page 14 and 15 of the manuscript, the system is used routinely by our out-of-town patients who perform the measurements and decisions by e-mail before they have a consultation with us. Their use of the system is accurate in more than 90% of cases.

The author is unable to identify any “graph recordings” in the system. The entire measuring, measurement recording, and decision making process are routinely performed by surgeons who are using the system in 5 minutes or less. The transferability and utilization of these techniques is described in the paper.

It is not “universally agreed” that nipple to notch is an important preoperative parameter to consider. In fact, though many surgeons use it (and the author has used it in the past), this measurement, when carefully analyzed, is of little importance in the most critical preoperative decisions.

The system does not attempt to “predict implant dimensions by pulling on a patient’s nipple.” The paper suggests five critical decisions, and the system uses APSS as one of several measurements to predict volume, and then leaves selection of implant *dimensions* to the surgeon. On page 11, the manuscript states, “Having determined an optimal estimated volume for an individual patient’s envelope, the surgeon can then select implant type and dimensions to control the distribution of that volume within the breast.”

More importantly, is there any control group that he can use whose breast augmentation requirements were determined, as most plastic surgeons do, by the simple measurements noted above, combined with visual analysis. Since he does not compare his results with a series of patients who did not have the "Five Critical Decisions," how can we be certain that his system provides for greater accuracy and improved aesthetic results in breast augmentation?

It is likely impossible to establish comparative clinical cohorts in primary breast augmentation, because to do so requires establishing comparable groups taking into account all of the variables enumerated in the reference provided on page 1 of the manuscript under reference 1: see Table 1 of the authors previous publication in PRS: Tebbetts, J.B.: A system for breast implant selection based on patient tissue characteristics and implant-soft tissue dynamics. *Plast. Reconstr. Surg.*: 109 (4): 1396-1409, April, 2002. The reviewer and readers can judge whether accuracy and results may be improved by comparing the author’s published results in more than 1600 cases with up to 7 year followup (overall 3% reoperation rate, other statistics in papers) published in PRS (and listed and referenced in the manuscript) to any other published system, clinical series or combination of series currently published in the plastic surgery literature.

His system does not take into consideration the dynamic tissue forces that alter the actual final appearance of an implant inside the breast, especially if deforming muscular forces exerted by the pectoralis major muscle are involved during a subpectoral placement. What Dr. Tebbetts is measuring are static, not dynamic tissue forces.

The manuscript and five critical decisions do not purport to measure or quantitate dynamic tissue forces that occur postoperatively. This will be the topic of another submission to the Journal. The manuscript proposes five critical decisions in primary augmentation and provides a quantitative framework to help surgeons predict volume based on individual patient tissue characteristics.

(2) The manuscript is too long and much too repetitive. He mentions his five steps on pages 1, 2, 3, 4, and 5. Much of this repetition should be deleted.

*The author has addressed this concern in the revised manuscript. The author found mention of the five decisions on page 1 but no description of the five decisions. Descriptions of the decisions are located on page 2. The author was unable to find significant redundancy of the five decisions on page 3. Per the reviewer's suggestion, the author deleted repetitive text on page 4. The text on page 5, "performs 5 measurements, records the measurements, and makes 5 prioritized decisions within 5 minutes or less" is included to reemphasize the clinical practicality of the system.

(3) The re-operative rate is extraordinarily low at 0.2%, especially when compared with other studies. Dr. Tebbetts should tell us how he would respond to a request for a size change. Is Dr. Tebbetts saying that only 0.2% of over one thousand patients asked for a size change? This extremely low number stretches credibility.

The author did not include comments regarding indications for size change to limit the length of the paper, and because the answer to the reviewer's question is included in another publication by the author in the Journal.

All patients in the author's practice are informed and educated about the inherent risks, costs, and tissue consequences of size exchange when performed without medical indications. In the authors previous publication in PRS: Tebbetts, J.B.: Out points criteria for breast implant removal without replacement and criteria to minimize reoperations following breast augmentation. *Plast. Reconstr. Surg.:* 114 (5): 1258-62, October, 2004, the author describes management of the area of the reviewer's concerns. All of the author's patients sign informed consent documents that no size exchange will be performed without medical indications prior to their primary augmentation, and the author does not perform size exchange without medical indications. Truth does not stretch credibility when educated and informed patients are held responsible for the decisions they make and document preoperatively and when surgeons abide by their preoperative recommendations and commitments. In fact, surgeon credibility increases because unnecessary reoperation rates decrease.

(4) In point 6 on page 7, the author speaks of the need to "envision the envelope stretched over the estimates." This is, in my opinion, his weakest argument. After offering quantifiable variables, he switches to visions and estimates. He needs to address this apparent contradiction.

*The manuscript does not state, "envision the envelope stretched over the estimates." Surgeons can choose to use or not use PCSEF as an additional consideration. The author will so state in the revised manuscript.

In conclusion, I would recommend that after three initial measurements - breast width, sternal nipple to notch distance and nipple to IMF distance, that he proceed to step 3, implant type and dimension. Step 4 is even more complicated when dual plane tissue characteristics must be considered. Why not go to an implant sizer and assess on the O.R. table?

While sternal notch to nipple distance is a commonly performed measurement that the author included in his first publication of a dimensional system, SN:N really does not have much rational basis as a measurement to aid decisions in primary breast augmentation. The reason for not "going to an implant sizer and assess on the OR table is that implant sizers are unnecessary, based on the data in the more than 1600 cases the author has published in PRS in the past 4 years, using the measurement and decision system used in the current manuscript with refinements. Implant sizers for primary augmentation add unnecessary risks and costs as follows: sizers never match implant characteristics exactly; sizers prolong operations when all decisions can routinely be made preoperatively; sizer introduction, removal and possible reintroduction cause unnecessary tissue trauma and potential contamination of the pocket; sizers require that surgeons order more implants than necessary for each case, ultimately increasing costs to the patient unnecessarily; if sizers are reused, they substantially increase risks of contamination; many surgeons who have adopted measurement systems have proved that sizers are unnecessary in primary breast augmentation except in unusual or complicated asymmetry cases.

This is a complicated system that is being proposed. There is no control group of patients who were augmented following a simpler, different method of preoperative analysis combining three critical measurements, no charts, and the visual, non-quantitative assessments that all plastic surgeons perform. It is unfortunate that such a superb surgeon as Dr. Tebbetts did not compare his multi-measured group of patients with other carefully matched but not so extensively measured patients for breast augmentation.

5 measurements and 5 decisions in less than 5 minutes does not seem complicated to patients who use it (see page 14-15 of manuscript and previous comments), so it really shouldn't be overly complicated for most surgeons. The author is not aware of any published system with comparable clinical experience that offers a "*simpler, different method of preoperative analysis combining three critical measurements."* This paper does not purport to be a randomized comparison of equivalent cohort groups, and as noted previously, valid, comparative cohorts for such a study are virtually impossible due to the number of variables involved. "All plastic surgeons" do not necessarily rely on the "visual, non-quantitative assessment" mentioned by the reviewer. The purpose of this paper is to offer an alternative to visual, non-quantitative methods, based on the dramatic reduction in reoperation rates documented by the clinical experience reported in this and other papers in PRS.

The author thanks the reviewer for the reviewer's time and constructive criticisms of the paper, and the Journal for the opportunity to submit a revised manuscript.

John B. Tebbetts, M.D.

Five Critical Decisions in Breast Augmentation Using 5 Measurements in 5 Minutes: The High Five System

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Abstract

Background

Surgeons can select alternatives and control variables that impact long-term results and implant effects on tissues over time. Tissue assessment systems[1] that provide quantitative, objective data enable objective rather than subjective decisions. First generation dimensional systems for breast augmentation[2] defined a desired result dimensionally and recommend an implant to force tissues to the desired result. A second generation dimensional system, the TEPID™ system[1] defines measurements to fit the implant to the patient's tissue characteristics instead of forcing tissues to a desired result. This study defines a simpler, more focused third generation system that prioritizes five critical decisions, identifies five key measurements, and completes all preoperative assessment and operative planning decisions in breast augmentation in five minutes or less.

Methods

Key decision parameters and data from more than 2300 primary augmentations planned using the TEPID™ system[1] were analyzed to define the five most critical decisions that affect reoperation rates and risks of uncorrectable deformities, and define five critical measurements that affect those decisions.

Results

In 1664 cases with up to 7-year follow up, the overall reoperation rate was 3%, and the reoperation rate for implant size exchange was 0.2%[3-5]. The junior author's clinical experience includes over 300 augmentations with up to 6 year followup using this system with an overall reoperation rate of 2.5%.

Conclusions

The High Five system prioritizes five critical decisions in breast augmentation and defines five measurements that enable surgeons to address all preoperative assessment and operative planning decisions in breast augmentation in five minutes or less.

Five Critical Decisions in Breast Augmentation Using 5 Measurements in 5 Minutes: The High Five System

*To facilitate online review, table segments are inserted into the text where referenced.

Introduction

When planning and performing primary breast augmentation, surgeons consider important alternatives and variables that determine short-and long-term results, and the patient's risk of future tradeoffs, complications, and reoperations. Preoperative decision-making is equally important compared to any aspect of surgical technique, because preoperative decisions determine the adequacy of soft tissue coverage over the implant for the patient's lifetime, determine the weight and pressure that the implant device will exert on the tissues over time, and determine the position of the breast on the chest wall. Surgeon and patient preoperative decisions determine potential consequences to a patient's breast tissues over her lifetime with breast implants.

Identifying critical variables and decisions that affect outcomes and codifying those parameters into a simple, efficient, and reliable system provides surgeons a framework for preoperative assessment and operative planning. While more than 50 tissue and surgeon variables occur in every augmentation[1], any clinically practical and adoptable system must focus on the most important decisions and parameters that most affect outcomes.

A quantifiable approach to tissue assessment, measuring in lieu of subjective visual assessment, provides surgeons with quantifiable data on which to base decisions. How a surgeon uses this data—decision priority, sequence, and algorithm—determines outcomes, tradeoffs, reoperation risks, and tissue consequences. Previous dimensional systems for breast augmentation define a desired result and suggest methods to force tissues to that result[2]. The previously published TEPID™ system[1] introduced quantitative tissue assessment to select an implant to fit individual patient tissue characteristics, and instead of forcing tissues to a desired result, prioritized soft tissue coverage over the implant short-and long-term. The next logical step is to provide surgeons a simple and efficient decision-making process that addresses five of the most critical

decisions in breast augmentation, using only 5 measurements, with the entire assessment and planning process requiring 5 minutes or less—the High Five System.

By integrating quantitative preoperative tissue assessment with a systematic approach to five critical decisions in breast augmentation, surgeons have an opportunity to improve outcomes, reduce reoperation rates, and improve practice efficiency. This paper integrates a stepwise approach to five critical decisions in breast augmentation with a refined and simplified version of an established tissue assessment system for augmentation. The High Five system adds a decision and management component to an established system for quantitative tissue assessment.

Five critical decisions in breast augmentation planning

Surgeons must make decisions in 5 critical areas when planning a breast augmentation. Each of these decisions should be based on quantifiable measurements or data. In order of priority, these decisions define:

1) Optimal soft tissue *coverage/pocket location for the implant* - determines future risks of visible traction rippling, visible or palpable implant edges, and possible risks of excessive stretch or extrusion.
2) Implant *volume* (weight)- determines implant effects on tissues over time, risks of excessive stretch, excessive thinning, visible or palpable implant edges, visible traction rippling, ptosis, parenchymal atrophy.
3) *Implant type, size, dimensions*- determines control over distribution of fill within the breast, adequacy of envelope fill, and risks of excessive stretch, excessive thinning, visible or palpable implant edges, visible traction rippling, ptosis, parenchymal atrophy.
4) Optimal *location for the inframammary fold* based on the width of the implant selected for augmentation- determines the position of the breast on the chest wall, the critical aesthetic relationship between breast width and nipple-to-fold distance, and distribution of fill (especially upper pole fill).
5) *Incision* location- determines degree of trauma to adjacent soft tissues, exposure of implant to endogenous bacteria in the breast tissue, surgeon visibility and control, and potential injury to adjacent neurovasculature.

A comprehensive system for implant selection should address each of these critical decision areas and provide the surgeon with specific, quantifiable data to consider when making decisions.

Background of the TEPID™ system

The TEPID™ system (tissue characteristics of the breast (T), the envelope (E), parenchyma (P), implant (I), and the dimensions (D) and dynamics of the implant relative to the soft tissues) for breast implant selection based on patient's individual tissue characteristics and breast dimensions was published in this Journal in April, 2002[1]. The system has been refined and simplified to include only five measurements that address five prioritized decisions in implant selection and operative planning for breast augmentation that surgeons can complete in 5 minutes. This system is designed to address essential parameters that affect aesthetic results, compromises, complications, and reoperation risks in breast augmentation. Additional clinical experience with the TEPID™ system has redefined priorities in decision making and created a simpler and more efficient version for surgeons gaining familiarity with quantitative decision making in breast augmentation—the High Five System.

The TEPID™ system evolved from the senior author's experience with the first dimensional system (later licensed by Inamed Corporation as the BioDimensional System™) for breast augmentation[2], a system that defined a patient's desired result by dimensions, and then selected an implant to produce the desired result. The BioDimensional System™ system has been widely used by surgeons in the United States and internationally, but clinical experience with the system defined specific limitations that encouraged the development of the TEPID™ system.

The first generation BioDimensional System™ :

1) Defines implant dimensions and volume that *force patient tissues to an arbitrary result* defined by patient and surgeon desires instead of characterizing the patient's tissue dimensions and characteristics, and *selecting an implant to fit the requirements and limitations of the tissues.*
2) Incorporates no system to limit volume and weight according to patient tissue characteristics, allowing patients and surgeons to define a desired result dimensionally

and select implants that may be larger than ideal for the patient's tissues, risking potential long-term negative tissue consequences that can be irreversible and uncorrectable.

3) Does not specifically address the number one priority in breast augmentation: assuring optimal soft tissue coverage of the implant long-term.
4) Does not address a critical third dimension—tissue stretch—that is one of two critical measurements to estimate volume required for optimal envelope fill.

The TEPID™ system was designed to specifically address the limitations of the first generation BioDimensional System™ by defining a paradigm shift in planning breast augmentation. Instead of forcing tissues to a desired result defined by the patient and surgeon, the TEPID™ system encourages patient and surgeon to prioritize the long-term welfare of the patient's tissues and assure optimal soft tissue coverage over the implant to minimize negative tissue consequences long-term and minimize reoperation rates. The TEPID™ system is designed to help patient and surgeons reconcile *wishes* with the *tissues* by quantifying important tissue characteristics and helping patients reconcile their preconceived desires for a specific result with the realities of their tissues. The High Five System presented in this paper further focuses and simplifies an established system of patient tissue assessment and decision priorities by prioritizing five critical decisions and quantitative parameters that most affect those decisions.

Clinical experience

The senior author's clinical experience with the TEPID™ system includes more than 2000 primary breast augmentation cases. In three series reported in this Journal, with up to 7-year follow up of 1664 reported cases, the overall reoperation rate was 3%, and the reoperation rate for implant size exchange was 0.2%[3-5]. The junior author's clinical experience includes over 300 augmentations with up to 6yr year followup using this system with an overall reoperation rate of 2.5% (Adams et al., PRS, accepted 10-2004). Although these rates are from a single surgeon experiences, these data provide an interesting comparison to the overall reoperation rates of 17% and rates for size exchange or adjustment rates of 8.7% from the averaged data of Mentor and McGhan submitted for their saline PMA studies in 2000[6,7].

Additional experience by the authors and input from other colleagues and residents have further codified and refined the TEPID™ system to specifically address five critical decision areas in

breast augmentation, enabling surgeons to perform five measurements, make implant selection and operative planning decisions in 5 prioritized areas, and perform all steps in measurement and operative planning in less than 5 minutes.

For efficiency, High Five System does not include any parameters that are not essential to one of these decisions and the system enables surgeons to perform all measurements and make all implant selection and operative planning decisions in 5 minutes or less.

Measurements, implant selection and operative planning

With the patient sitting and the High Five™ Clinical Evaluation and Operative Planning Form (Table 1) resting in the patient's lap, the surgeon performs 5 measurements, records the measurements, and makes 5 prioritized decisions within 5 minutes or less. During the process, the surgeon can discuss the measurements, decisions, implications, and tradeoffs with the patient.

A copy of the High Five™ Clinical Evaluation and Operative Planning Form is downloadable from the Journal's website at [insert URL], and a video file including measurement techniques and the entire decision process is available at [insert URL].

Details and illustrations of the required measurements and estimate are included in the original report of the system[1] and will be abbreviated in this report.

1. Soft tissue coverage and pocket selection

Table 1, A- Soft tissue coverage measurements and implant pocket selection

1. COVERAGE- Selecting Pocket Location to Optimize Soft Tissue Coverage Short- and Long-Term			
STPTUP		**If <2.0 cm., consider dual plane (DP) or partial retropectoral (PRP, pectoralis origins intact across IMF)**	**DP**
STPTIMF		**If STPTIMF <0.5 cm, consider subpectoral pocket and leave pectoralis origins intact along IMF**	**PRP**
POCKET LOCATION SELECTED BASED ON THICKNESS OF TISSUE COVERAGE			**RM**

The surgeon performs the first two measurements and records the measurements on the evaluation sheet.

1) STPTUP- soft tissue pinch thickness of the upper pole (skin and subcutaneous tissue superior to the breast parenchyma (Figure 1, A).
2) STPTIMF- soft tissue pinch thickness at the inframammary fold (Figure 1, B)

Implant pocket selection is based on quantified soft tissue coverage to assure optimal long-term coverage over the implant. If soft tissue pinch thickness of the upper pole (STPTUP) is less than 2.0 cm., the surgeon chooses a dual plane or partial retropectoral pocket location to assure optimal soft tissue coverage. Adding fascial coverage (retromammary, subfascial pocket) of less than 1 millimeter thickness is inconsequential long-term when pectoralis muscle coverage is available for medial and upper pole coverage long-term. When selecting a dual plane or partial retropectoral pocket location to optimize coverage, the surgeon *never divides* origins of the pectoralis major from the sternal notch to the sternal junction with the inframammary fold in order to assure optimal coverage in this critical area, regardless of a patient's desired intermammary distance. If STPTIMF is <0.5 cm., pectoralis muscle origins along the inframammary fold are preserved for additional coverage, creating a partial retropectoral pocket (compared to a dual plane pocket where the surgeon divides pectoralis origins along the fold).

Considering the quantified measurements of soft tissue thickness, the surgeon chooses either dual plane 1, 2 ,3 , partial retropectoral, or retromammary pocket location, and circles the choice on the form.

2. Implant volume

Table 1, B- Selecting an estimated implant volume for optimal envelope fill

2. IMPLANT VOLUME- Selecting an Estimated Implant Volume for Optimal Envelope Fill													
Estimating Desired Breast Implant Volume Based on Breast Measurements and Tissue Characteristics													
Base Width		**B.W. Parenchyma (cm)**	**10.5**	**11.0**	**11.5**	**12.0**	**12.5**	**13.0**	**13.5**	**14.0**	**14.5**	**15.0**	
		Initial Volume (cc)	**200**	**250**	**275**	**300**	**300**	**325**	**350**	**375**	**375**	**400**	**cc**
APSS$_{MaxStr}$		**[2]If APSS < 2.0, - 30cc; If APSS > 3.0, + 30cc; If APSS > 4.0, +60cc Place appropriate number in blank at right**											**cc**
N:IMF$_{MaxSt}$		**If N:IMF > 9.5, + 30cc Place appropriate number in blank at right**											**cc**
PCSEF %		**If PCSEF < 20%, + 30cc; If PCSEF > 80%, - 30cc Place appropriate number in blank at right**											**cc**
Pt. request													**cc**
[7]NET ESTIMATED VOLUME TO FILL ENVELOPE BASED ON PATIENT TISSUE CHARACTERISTICS													**cc**

Next, the surgeon measures and records the following parameters:

3) BW- base width of the existing breast parenchyma, a linear measurement (Figure 2).

4) APSS- anterior pull skin stretch, a measurement of maximal anterior skin stretch by manual traction comfortably tolerated by an awake patient (Figure 3 A, B).

5) $N:IMF_{max\ stretch}$- nipple-to-inframammary fold distance, measured under maximal stretch (Figure 4).

6) PCSEF - an estimate of the contribution of the patient's existing breast parenchyma to stretched envelope fill (PCSEF). To estimate PCSEF, the surgeon pulls the periareolar skin maximally anteriorly (APSS), then cups the hand or envisions the envelope stretched this same amount over the entire breast and estimates the amount of fill as a percentage that the patient's existing parenchyma will provide to the maximally stretched envelope.

The surgeon then locates the base width that corresponds with the patient's base width in the row to the right. In the cell immediately beneath, the surgeon circles the initial estimated desired implant volume for that base width breast, and transfers this number to the blank space at the far right of the row.

This volume represents an *estimated desired implant volume* based on the base width of the patient's existing breast parenchyma. These volumes were derived from data described in the initial TEPID™ report[1], and are adjustable by the surgeon depending on other parameters including patient wishes. Next, the surgeon adjusts the estimated starting volume depending on skin stretch.

If anterior pull skin stretch (APSS) is less than 2 cm. (very tight envelope), the surgeon subtracts 30cc (or another increment of the surgeon's preference) from the estimated starting volume. If APSS is > 3 cm., the surgeon adds 30cc, and if APSS is > 4 cm., the surgeon adds 60cc to the starting volume, recording the appropriate addition or subtraction in the cell at the far right of the "APSS" row.

If the nipple-to-inframammary fold distance ($N:IMF_{max\ stretch}$) is greater than 9.5cm. when measured under maximal stretch, the surgeon adds 30cc (or another increment of the surgeon's preference) to the starting volume to provide adequate additional fill volume for a larger lower

envelope. If applicable, the surgeon records this additional volume in the far right cell of the "N:$IMF_{max\ stretch}$" row.

The PCSEF estimate is necessary to adjust volume for patients whose skin envelopes are tighter (APSS < 2 cm.) and already filled with parenchyma (PCSEF >80%), or for patients with very lax skin envelopes (APSS > 3 cm.) who have very little breast parenchyma. If PCSEF is >80 % (tight, already full envelope), the surgeon subtracts 30cc from the initial estimated volume, and if PCSEF is < 20% (loose, empty envelope), the surgeon adds 30cc and records applicable additions or subtractions in the cell to the far right of the PCSEF row.

If the patient or surgeon desires a greater or lesser volume than the system recommends, the surgeon can add or subtract an additional volume increment and record it in the space provided in the far right cell of the "Patient request" row. The High Five™ system does not replace patient or surgeon preferences or choices. The system provides guidelines based on quantified tissue characteristics of each individual patient. By adding or subtracting increments described above from the initial estimated volume, the surgeon derives a *net estimated volume* that is appropriate for the patients quantified tissue characteristics and records the appropriate number in the cell at the far right of the "Net Estimated Volume" row.

3. Implant type and dimensions

Table 1, C- Selecting specific implant characteristics

3. IMPLANT DIMENSIONS, TYPE, MANUFACTURER- Selecting specific implant characteristics					
[13]*Implant* Manufacturer	Implant Style/Shape/Shell/Filler Material	Implant Vol (cc)	*Implant Base Width	Breast Base Width[1]	Implant Projection
		cc	cm.	cm.	cm.
*For optimal long-term coverage, implant base width should not exceed base width of patient's existing parenchyma, even if wider IMD results.					

The High Five™ system is applicable to a wide range of implant types, sizes, and dimensions. Having derived a net estimated implant volume based on quantified tissue parameters, the surgeon can then consult size and dimension charts for any type of implant, and select implant dimensions (width, height, projection) that the surgeon feels are most appropriate.

The surgeon records the implant volume, the base width of the implant selected, the base width of the patient's existing parenchyma (B.W. measured previously), and implant projection. *For*

optimal long-term coverage, the base width of the implant selected should not exceed the base width of the patient's existing parenchyma, except in cases of tubular breasts, constricted lower pole breasts, or breasts with a base width less than 10.5 cm. Implant projection is an important dimension that may affect distribution of fill and tissue consequences postoperatively, and is included only for postoperative reference.

4. Inframammary fold location

Table 1, D- Estimating desired postoperative inframammary fold position

4. INFRAMAMMARY FOLD LOCATION- Estimating desired postoperative inframammary fold position										
(Circle Volume closest *to net estimated implant volume* calculated above, and *circle suggested N:IMF* in the cell beneath that volume)										
		Volume closest to calculated "net estimated implant volume" from 2 above	**200**	**250**	**275**	**300**	**325**	**350**	**375**	**400**
		Recommended new N:IMF distance (cm.) under maximal stretch►	**7.0**	**7.0**	**7.5**	**8**	**8**	**8.5**	**9.0**	**9.5**
Planning Level of New Inframammary Fold*		**Transfer the patient's N:IMF$_{MaxSt}$ measurement from above to corresponding cell at right. Then transfer the TEPID™ recommended new N:IMF to the corresponding cell at right. If the patient's preop N:IMF is shorter than the TEPID™ recommended new N:IMF, consider lowering the fold. If the patient's preop N:IMF is equal to or greater than the TEPID™ recommended new N:IMF, no change in IMF position is indicated.**			**Patient's Preoperative N:IMF$_{MaxSt}$**		**TEPID™ Recommended N:IMF$_{MaxSt}$**		**Change In Fold Position**	**Lower the Fold**
						cm.		**cm.**	**Yes/No**	**cm.**
***Other factors may affect optimal IMF level and require surgeons to modifiy the TEPID™ System recommendations for N:IMF**										

The ideal nipple-to-inframammary fold distance to mark preoperatively and set intraoperatively depends on the projected width of the postoperative breast. To estimate the optimal level of the inframammary fold, the surgeon first locates the volume closest to the previously calculated "net estimated implant volume". In the cell immediately beneath, the system lists a "High Five™ recommended new N:IMF distance measured under maximal stretch". The surgeon circles the recommended number, and then transfers that number to the cell in the row below labeled "High Five™ recommended N:IMF$_{max\ stretch}$." Next, the surgeon transfers the preoperative N:IMF IMF$_{max\ stretch}$ measurement to the cell labeled "Patient's Preoperative N:IMF IMF$_{max\ stretch}$ " in the same row.

If the recommended N:IMF $_{intraop}$ for the planned volume implant is greater than the patient's preoperative N:IMF$_{max\ stretch}$, the surgeon can consider lowering the fold to the recommended

level. If the recommended N:IMF $_{stretch}$ is the same or longer than than the patient's preoperative N:IMF$_{max\ stretch}$, no lowering of the fold is indicated. After comparing the preoperative N:IMF with the recommended N:IMF, the surgeon decides whether to lower the fold, and circles either "Yes" or "No". If the choice is to lower the fold, the surgeon then records the appropriate number of centimeters to lower the fold in the cell below "Lower the Fold."

5. Incision location

Table 1, E- Selecting desired incision location

5. INCISION LOCATION- Selecting desired incision location			
Inframammary	**Axillary**	**Periareolar**	**Umbilical**

Incision location is based on patient preference, patient considerations of degree of surgical control, tissue trauma, and tradeoffs, and surgeon preferences and skill set. The surgeon records the planned incision location in the appropriate space in Table 1.

Discussion

An accurate, efficient, decision support system defines priorities and identifies a minimal number of essential decisions and provides quantifiable parameters on which to base those decisions. When prioritizing soft tissue *coverage* in breast augmentation, two pinch thickness measurements are a minimum to make decisions regarding muscle coverage, and location of muscle coverage. To estimate an appropriate *volume* for an envelope, minimum parameters include base width, skin stretch, nipple-to-inframammary fold measurements, and the existing parenchyma's contribution to fill of the stretched envelope (resulting fill= implant + parenchyma).

Optimal volume for a breast soft tissue envelope is the *least* volume that is required to either 1) achieve the desired result in a previously unstretched breast), or 2) adequately fill a previously stretched envelope, while assuring optimal soft tissue coverage and minimizing negative tissue effects by the implants. When forcing tissues to a desired result, surgeons and patients must carefully consider potential tissue consequences and possible uncorrectable deformities that may occur long-term. Instead of forcing tissues to a desired result, the High Five^{TM} system estimates

a volume the tissues are likely to tolerate without selecting an implant that is wider than the patient's existing parenchyma (sacrificing coverage medially and laterally), and without adding excessive weight that can produce irreversible tissue changes by stretching and thinning soft tissues covering the implant and causing parenchymal atrophy.

Having determined an optimal estimated volume for an individual patient's envelope, the surgeon can then select implant type and dimensions to control the distribution of that volume within the breast. For any specific volume, implant width, projection, and height can vary. Width is the most important parameter affecting volume because of its range of variability and the effect of a change in width on a change in volume. Height of an implant in vivo depends on many factors, including overlying tissue characteristics, implant fill volume relative to mandrel volume, implant filler characteristics, and implant shell-filler interactions. Since implant height is so variable and difficult to measure accurately in vivo, implant width and projection are the most clinically significant parameters.

Refinements to the system directly address suggestions from surgeons and residents who routinely use the TEPID™ system to assist with augmentation decisions. For resident education, the system provides a codified, logical template with priorities and specific measurement techniques that allow residents to make decisions based on quantifiable parameters instead of stuffing test implants into bras or using other arbitrary and subjective methods.

The High Five™ system is a dimensional system based on the base width of the breast that specifies an initial estimated volume for each base width. The volume this system recommends is *an averaged volume for a range of implant devices that provides maximum volume without exceeding the base width of the patient's existing parenchyma.* These volumes were derived from implant width-volume relationships from implant manufacturer's size chart publications for all implant types (saline and silicone) in the United States. Averaging the dimension-volume relationships provided a range of volumes for implant widths at half-centimeter increments. To make the system easier to use and memorize, the volume increments were rounded to the nearest 25cc increment.

Decisions of breast implant size and implant pocket location can be based on subjective and arbitrary patient and surgeon preferences, or can use quantifiable data to characterize individual

patient tissue characteristics. Scientific analysis and evidence based outcomes analysis require quantified data. Reoperation rates of 15-20% in multiple PMA studies over the past two decades with silicone and saline implants[8-10] suggest an opportunity for better decision-making processes by surgeons and patients. Reoperations for size exchange, visible rippling or wrinkling, implant malposition, implant exposure or extrusion, ptosis, and other deformities can relate directly to the consequences of decisions that the patient and the surgeon make preoperatively.

Establishing quantitative criteria for optimal soft tissue coverage, implant pocket location, and implant size can significantly impact overall reoperation rates[3-5]. Comprehensive, staged patient education is essential to help patients understand and accept responsibility for the potential long-term implications of their wishes and their decisions[11]. A system that prioritizes decisions, provides quantified data to assist with decisions, and defines specific criteria for soft tissue coverage and implant volume based on individual patient tissue characteristics is an additional tool for surgeons and patients.

Any system that suggests a volume range relative to the width of breast parenchyma (prioritizing soft tissue coverage) mandates a balance between implant width, height, and projection. Volume is weight, and weight applied to breast envelope tissues over time has consequences that are obvious to anyone who has observed a D cup breast at age 18 and the same breast at age 30 or later, and obvious to anyone who has seen the stretch effects of pregnancy on the breast. For any base width implant, increasing implant projection requires an increase in the volume (weight) of the implant. Increased projection also can place additional pressure on overlying tissues—breast parenchyma, subcutaneous tissue, and skin. Increasing projection, therefore, has two potentially negative tissue consequences: increasing weight effects and increased pressure effects. Weight and pressure over time can cause stretch and thinning of the envelope, and focal pressure or excess pressure of high profile implants over time can cause atrophy of parenchyma and subcutaneous tissue. Envelope thinning and parenchymal atrophy are irreversible, and may permanently preclude a patient having optimal soft tissue coverage, increasing risks and compromising results of any future reoperations.

Implant manufacturers currently provide surgeons and patients the widest array of implant device dimensions in history, enabling patients and surgeons to choose a device with dimensions (size and volume) to force tissues into virtually any configuration a patient may desire. Forcing

tissues to go where they have never been (and some might argue, were never intended to go) has potential short- and long-term tissue consequences, some of which are irreversible. Whether a system of implant selection is purely dimension based, volume based, or a combination of dimension and volume (as the High Five™ system), negative tissue consequences are usually the result of excessive weight (volume), pressure (projection), or both. What is "excess" weight or projection depends on individual patient tissue characteristics, and surgeons must individualize clinical judgments in each case.

One important question is whether patients and surgeons have an inherent right to place any volume they desire in a breast. The answer is yes, provided both are aware of and willing to accept responsibility for potential tissue consequences. A second important question is whether the TEPID™ system recommends volumes that satisfy patients while protecting tissues. While this is a difficult question to answer scientifically, in published reports of 1664 cases with up to 7-year follow up[3-5], when integrated with staged, repetitive patient education, the volumes recommended by the system produced results that resulted in 3% overall reoperation rates and a reoperation rate of 0.2% for size exchange. In an independent review the junior author has clinical experience with over 300 augmentations over a 6 year period using this system producing an overall reoperation rate is 2.5% and a 0.5 % for size exchange (Adams et al., PRS, accepted 10-2004). The High Five™ system does not replace or define patient or surgeon preferences or choices. Instead, the system prioritizes decisions and provides guidelines based on quantified tissue characteristics of each individual patient, and provides an opportunity for surgeons to consider patient requests during the process and make choices outside the recommendations of the system.

To assure optimal, long-term coverage, the base width of a breast implant should not exceed the base width of the patient's parenchyma. In practice, this means that surgeons must be willing to explain to patients that narrowing the intermammary distance (cleavage gap) surgically requires placing an implant edge medial to existing parenchymal coverage, risking edge visibility, palpability, and traction rippling long-term. Each of these problems is largely uncorrectable, especially if surgeons divide medial origins of the pectoralis in order to narrow the intermammary distance. These problems are almost totally preventable by advising patients that narrowing of the cleavage gap is more safely accomplished by pushing the breasts with a bra compared to surgically placing an implant under thin, inadequate soft tissue coverage.

In patients with extremely narrow base width breasts (BW < 10 cm) or tubular or severely constricted lower pole breasts, achieving a satisfactory aesthetic result may require an implant with a base width that exceeds the base width of the existing parenchyma. In these cases, patients and their surgeons should thoroughly discuss the potential long-term tradeoffs and tissue consequences (thinner areas of tissue, palpable or visible implant edges or shell, and visible traction rippling), and arrive at a mutually acceptable risk-benefit decision, documenting surgeon and patient acceptance of responsibility for potential long-term tradeoffs in informed consent documents.

In aesthetically appealing breasts, the wider the breast, the longer the nipple-to-inframammary fold distance. Determining optimal inframammary fold position at the time of breast augmentation is a major factor that affects the aesthetic result.

An excessively short N:IMF relative to breast width produces a wide, boxy appearing breast with inadequate lower pole dimensions and fill. An excessively long N:IMF relative to breast width produces a "bottomed out" appearance with excessive lower pole dimensions and fill, often accompanied by upward tilted nipple-areola malposition. The premise that surgeons should never lower the inframammary fold ignores the critical aesthetic relationship between breast width (determined largely by implant base width) and N:IMF that defines optimal postoperative aesthetics. When indicated, lowering of the inframammary fold is a critically important maneuver in breast augmentation, and is accurate and predictable when surgeons use optimal measurements and techniques. .

Many factors, including stretch factors that surgeons cannot control, can affect inframammary fold position long-term, but surgeons need basic guidelines during operative planning to decide whether repositioning of the inframammary fold may be necessary for optimal aesthetics. The High Five™ system guidelines for inframammary fold position are derived from pre- and postoperative measurement data on large numbers of patients[1], and can be modified by surgeons according to specific clinical situations and considerations.

The High Five™ system is currently being used not only by surgeons, but also by clinical assistants, patient educators, and patients who wish to perform self-assessment as part of their

educational process. In the senior author's practice, many out-of-town patients who express an interest receive a special, condensed version of the High Five™ Clinical Evaluation Form with numbered instructions by e-mail. Interestingly, their self-assessments have been accurate in more than 90% of cases, and the majority of these patients fully understand the concepts of the system.

Conclusions

The refined and simplified TEPID™ system, renamed the High Five System™ defines five critical decisions in primary breast augmentation, allows surgeons and patients to quantify individual patient's tissue characteristics, and base decisions about soft tissue coverage (implant pocket location) and implant volume (size, weight, dimensions) on objective parameters instead of subjective, arbitrary parameters. The High Five System™ is a comprehensive, yet simple and efficient, decision and management model for primary breast augmentation.

The system addresses five critical priorities and decisions in breast augmentation: optimal soft tissue coverage, implant size (volume/weight), implant dimensions, location of the inframammary fold, and incision location. While providing volume recommendations relative to the base width, stretch characteristics, and nipple-to-inframammary fold distance, the system also allows surgeons to add or subtract volume based on specific patient requests, considering possible long-term tissue tradeoffs and consequences.

In conjunction with staged, repetitive patient education and decision-making algorithms, the TEPID™ system has helped minimize reoperations for size exchange (0.2% versus 8.7% in PMA studies) and reduce overall reoperation rates (3% versus 17% in PMA studies) [3-7].

For any system to be effective, surgeons must use it. The demands of clinical practice mandate a system that is efficient while comprehensively addressing essential clinical priorities. A comprehensive system must address a wide range of implant types while prioritizing patient's tissues long-term. This refined and simplified version of the TEPID™ system focuses on those requirements. The High Five System™ system prioritizes 5 decision categories, involves only 5 measurements and 5 decisions, and requires less than 5 minutes to perform all measurements and make all operative planning decisions.

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Table 1- TEPID™ Clinical evaluation and operative planning form

TEPID™ Tissue Analysis and Operative Planning

Patient Name:		Date:	
1. COVERAGE- Selecting Pocket Location to Optimize Soft Tissue Coverage Short- and Long-Term			
STPTUP		If <2.0 cm., consider dual plane (DP) or partial retropectoral (PRP, pectoralis origins intact across IMF)	DP
STPTIMF		If STPTIMF <0.5 cm, consider subpectoral pocket and leave pectoralis origins intact along IMF	PRP
POCKET LOCATION SELECTED BASED ON THICKNESS OF TISSUE COVERAGE			RM

2. IMPLANT VOLUME- Selecting an Estimated Implant Volume for Optimal Envelope Fill													
Estimating Desired Breast Implant Volume Based on Breast Measurements and Tissue Characteristics													
Base Width		B.W. Parenchyma (cm)	10.5	11.0	11.5	12.0	12.5	13.0	13.5	14.0	14.5	15.0	
		Initial Volume (cc)	200	250	275	300	300	325	350	375	375	400	cc
$APSS_{MaxStr}$		[2]If APSS < 2.0, - 30cc; If APSS > 3.0, + 30cc; If APSS > 4.0, +60cc Place appropriate number in blank at right											cc
$N:IMF_{MaxSt}$		If N:IMF > 9.5, + 30cc Place appropriate number in blank at right											cc
PCSEF %		If PCSEF < 20%, + 30cc; If PCSEF > 80%, - 30cc Place appropriate number in blank at right											cc
Pt. request													cc
[7]**NET ESTIMATED VOLUME** TO FILL ENVELOPE BASED ON PATIENT TISSUE CHARACTERISTICS													cc

3. IMPLANT DIMENSIONS, TYPE, MANUFACTURER- Selecting specific implant characteristics					
Implant Manufacturer	Implant Style/Shape/Shell/Filler Material	Implant Vol (cc)	*Implant Base Width	Breast Base Width[1]	Implant Projection
		cc	cm.	cm.	cm.
*For optimal long-term coverage, implant base width should not exceed base width of patient's existing parenchyma, even if wider IMD results.					

4. INFRAMAMMARY FOLD LOCATION- Estimating desired postoperative inframammary fold position											
(Circle Volume closest *to net estimated implant volume* calculated above, and *circle suggested N:IMF* in the cell beneath that volume)											
		Volume closest to calculated "total estimated implant volume" above	200	250	275	300	325	350	375	400
		Recommended new N:IMF distance (cm.) under maximal stretch►	7.0	7.0	7.5	8	8	8.5	9.0	9.5
*Planning Level of New Inframammary Fold**	Transfer the patient's $N:IMF_{MaxSt}$ measurement from above to corresponding cell at right. Then transfer the TEPID™ recommended new N:IMF to the corresponding cell at right. If the patient's preop N:IMF is shorter than the TEPID™ recommended new N:IMF, consider lowering the fold. If the patient's preop N:IMF is equal to or greater than the TEPID™ recommended new N:IMF, no change in IMF position is indicated.				Patient's Preoperative $N:IMF_{MaxSt}$		TEPID™ Recommended $N:IMF_{MaxSt}$		Change In Fold Position	Lower Fold
					cm.		cm.		Yes/ No	cm.
*Other factors may affect optimal IMF level and require surgeons to modifiy the TEPID™ System recommendations for N:IMF										

5. INCISION LOCATION- Selecting desired incision location			
Inframammary	Axillary	Periareolar	Umbilical

Figure Legends

Figure 1, A- Measure soft tissue pinch thickness of the upper pole (STPTUP) by isolating skin and subcutaneous tissue superior to the breast parenchyma, pinching firmly, and measure the thickness with a caliper.

Figure 1, B- Measure soft tissue pinch thickness at the inframammary fold (STPTIMF) by isolating skin and subcutaneous tissue at the inframammary fold, pinching firmly, and measure the thickness with a caliper.

Figure 2- Measure the base width of the breast mound (BW) as a linear measurement from the visible medial border of the breast mound to the visible lateral border of the breast mound in front view.

Figure 3, A- Measure anterior pull skin stretch (APSS) by grasping the skin of the areola and pulling it maximally anteriorly (while holding a caliper in the same hand), then mark that point with a fingernail on the opposite hand.

Figure 3, B- To complete the measurement of anterior pull skin stretch (APSS), release the skin, and caliper measure from the point marked by the fingernail back to the resting plane of the areola.

Figure 4- To measure nipple-to-inframammary fold distance under maximal stretch ($N:IMF_{maxstretch}$), first place dots at the exact inframammary fold crease near the 6 o'clock position, and just medial to the midpoint of the nipple. Place the tip of a flexible tape measure exactly at the dot beside the nipple, lift maximally to place the lower pole skin under maximal stretch, and measure to the dot at the inframammary fold.

Figure 5, A, B- To estimate parenchymal contribution to stretched envelope fill (PCSEF), first measure APSS by the techniques described previously.

Figure 5, C- Place a pen or envision a line from the point of maximal stretch tapering into the upper pole.

Figure 5, D- Cup the hand or envision a curved line that parallels the lower pole profile of the breast at a distance equal to APSS.

Figure 5, E- The white dotted line simulates the maximally stretched envelope for this patient based on the patient's APSS. Envision this line, and estimate the percent of this stretched envelope that is filled by the patient's existing parenchyma. This concept is easy to demonstrate to the patient using the pen and cupped hand.

Figure 1A

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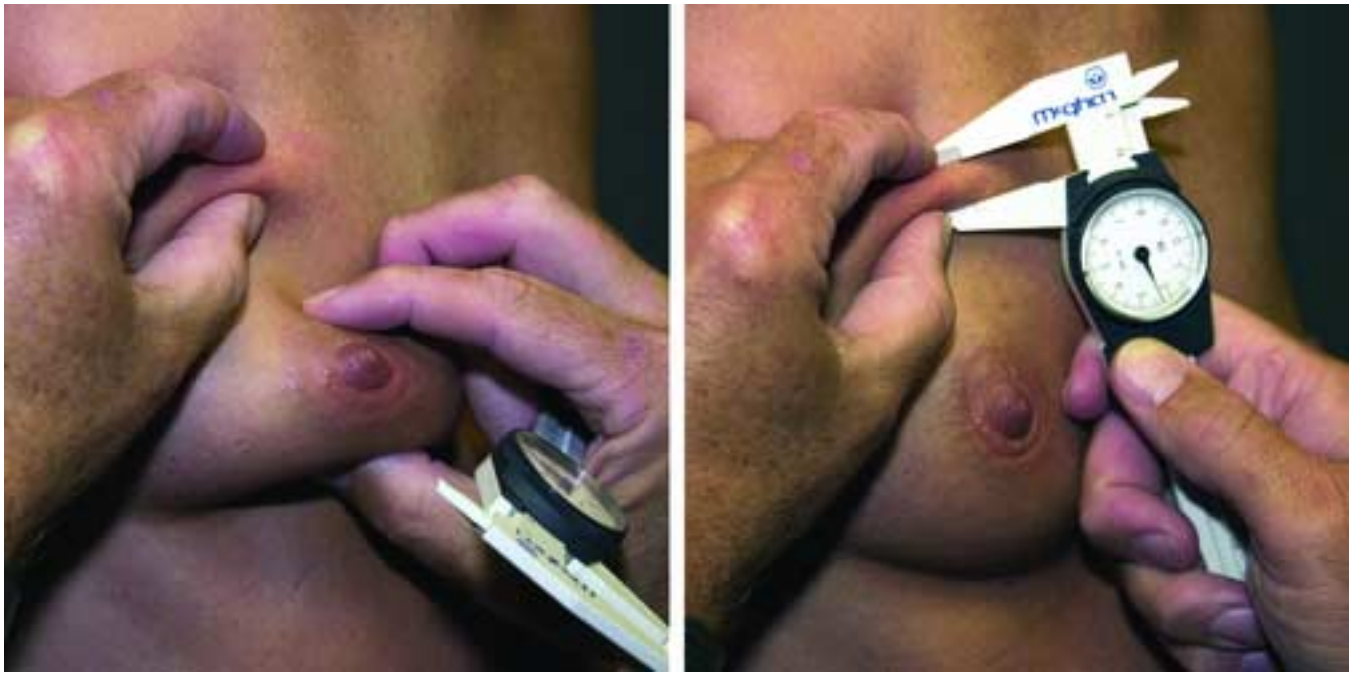

Figure 1B

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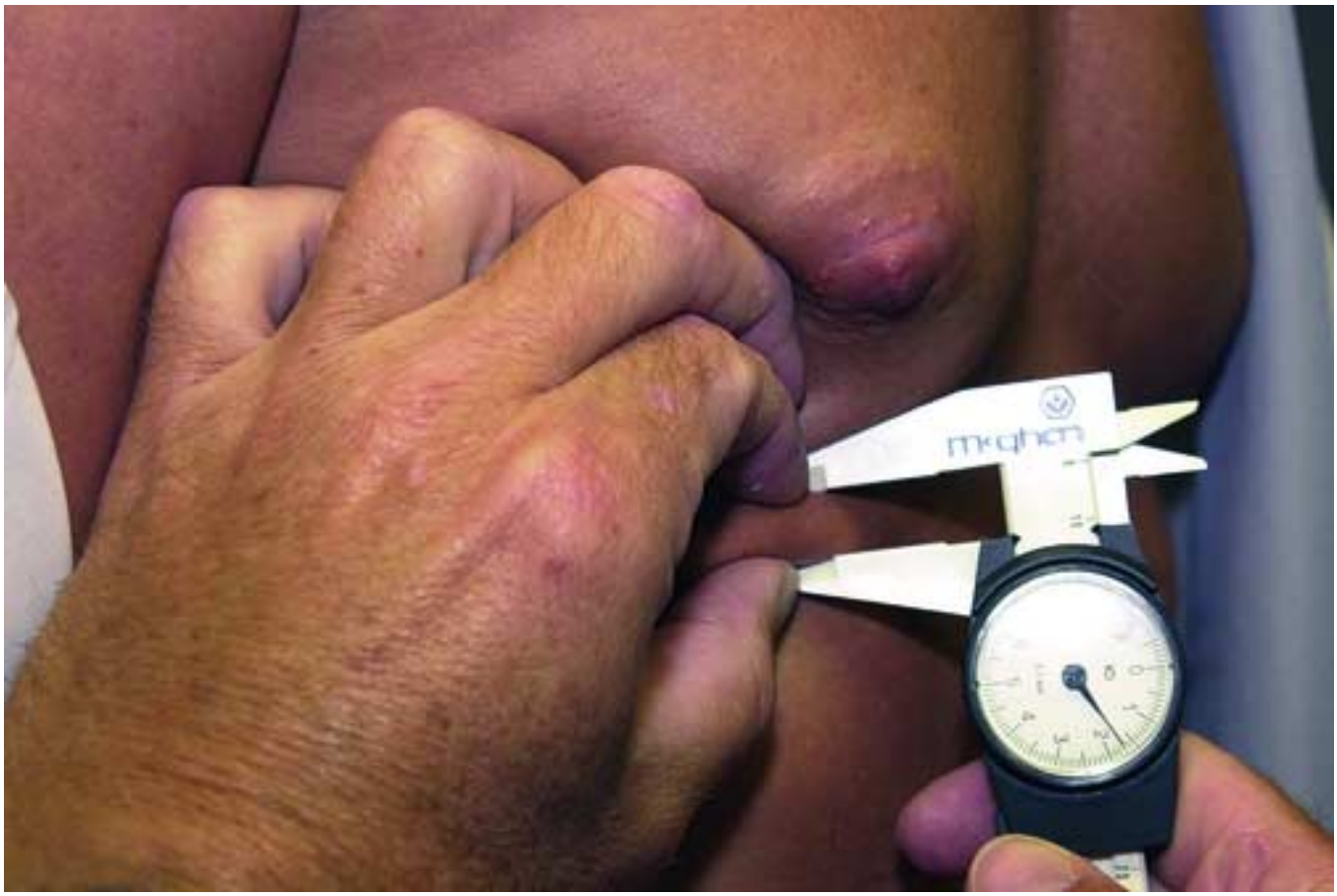

Figure 2

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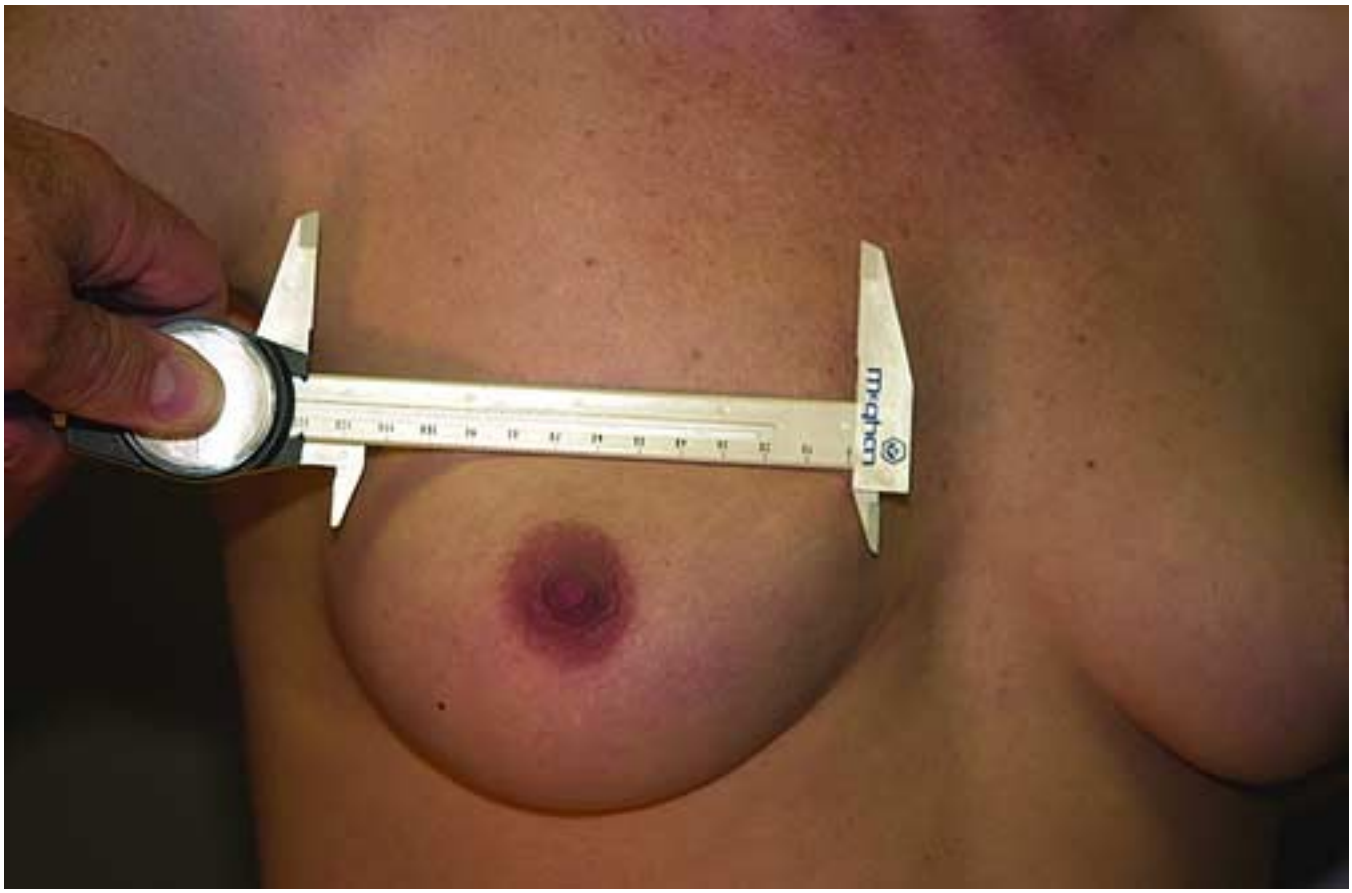

Figure 3AB

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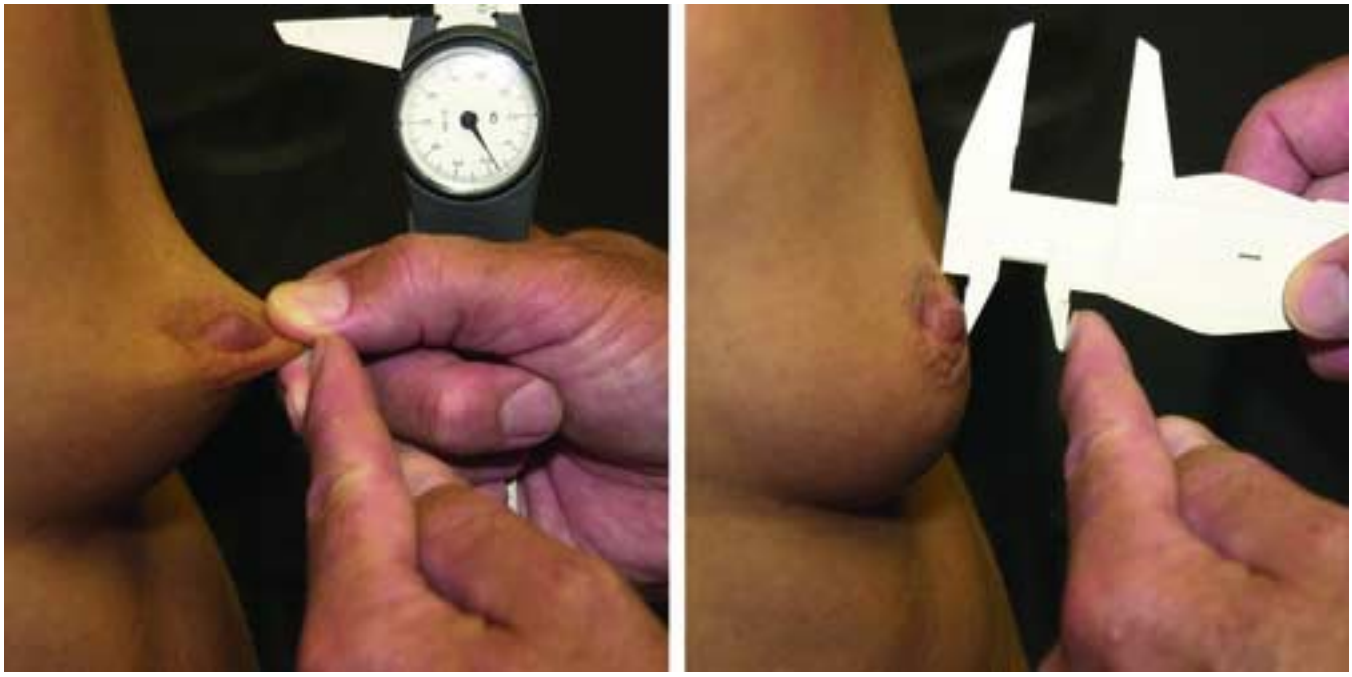

Figure 4AB

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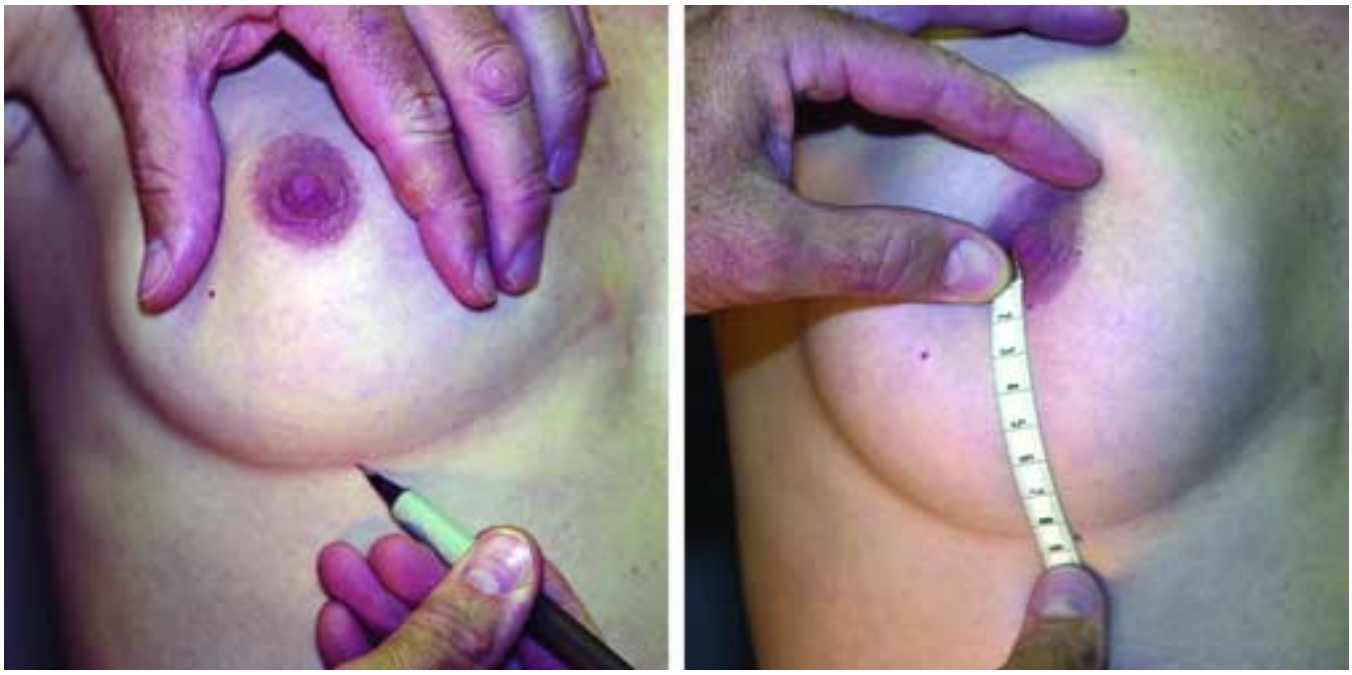

Figure 5ABC

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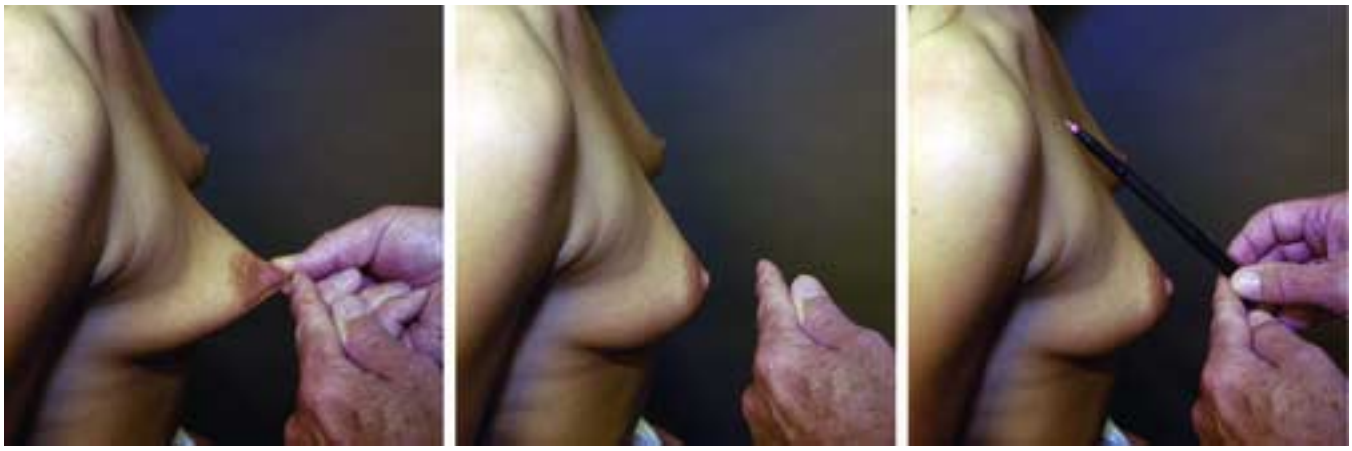

Figure 5DE

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