



**Qualitative Research
Reaction to New Breast Augmentation System**

Presented to

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I. Introduction

A. Background and Purpose

Dr. William Brennan has developed a new system for breast augmentation consisting of hundreds of miniature silicone implants instead of one larger silicone implant.

There was interest in obtaining reactions to the new implant system from women considering breast augmentation.

To that end, exploratory research was conducted to better understand:

- Level of awareness of currently available procedures
- Reactions to the new concept
- Concerns about the procedure

B. Methodology

Trotta Associates conducted one two-hour focus groups with eight women between 25 and 40 years of age. All were pre-screened to be seriously considering breast augmentation in the next 5 years. Those invited were also screened to have consulted a physician about the procedure, investigated methods for breast implant surgery on-line or in magazines, or discussed the procedure with others as part of their ongoing investigation.

The group was conducted on May 12, 2008 in Trotta Associates' Marina del Rey focus group facility and was moderated by Diane Trotta.

The topics discussed included the following:

- Awareness and attitudes toward currently available procedures
- Ratings on the importance of several attributes in decision making
- Reaction to a written concept describing the procedure
- Reactions to a more detailed and illustrated description of the procedure
- Ratings on the new procedure compared to other techniques

A copy of the discussion guide and presentation materials is included in the appendix to this report.

Caveat:

Qualitative research is based on small sample sizes. The findings of this study should not be considered to be representative of the total population of consumers. Observation and understanding of the reactions within this sample are useful in identifying the motivations of targeted individuals.

II. Summary of Findings

The women who participated in this research were very knowledgeable about the various procedures available for breast augmentation.

While cost is an important consideration, most would not choose a doctor or particular procedure based on cost.

Most of the women reacted very favorably to the concept of a micro-implant breast augmentation system. The size of the incision, natural look and feel, and low post-op pain were the perceived main benefits over standard silicone implants.

"I think that anyone would choose this new procedure over the old silicone procedure."

"I think the selling point of the new procedure is that it is less invasive and more natural."

The ease of increasing the size of the implant after initial surgery did not impress participants.

III. Detailed Findings

A. Background Information

Most participants have considered breast augmentation surgery for several years. Many claim they first considered it when they were in their twenties.

"I have been thinking about doing breast augmentation for at least the last 10 years."

"I was 28 when I started thinking about breast augmentation."

"I was in my early twenties when I thought about breast augmentation."

"I was such an athlete when I was in high school and through college that I didn't care at all and you couldn't have big boobs. For me, it has been more recently that I thought about breast augmentation. It's coincided with me being with my boyfriend."

Many understand that the procedure is expensive and being able to save the money to proceed with breast augmentation surgery is a concern. While cost is a factor, many claim they would not choose a doctor or procedure based on cost. They consider the surgery to be a one time expense and want it to be done right the first time.

"It costs a lot of money but even so, I am willing to pay what it takes to get the best doctor."

Others are concerned about the outcome. While many had consulted a physician, many were fearful and concerned they would not get the outcome they desired.

"About three years ago I really did research on different doctors and I actually went to the consultation. It was just one doctor that I was referred to by a girlfriend. During my research there was so much that had me leaning towards not getting it done because you just see the difference and what can maybe go wrong."

*"A lot of my friends have had theirs done and it's such a big difference in their sizes, the way they look and how much pain they have. The biggest fear for me is I don't know how I'm going to react to the surgery. I am also concerned about looking natural. Some of them have beautiful ones that look really natural and then others are on the other side of the spectrum."
"It all depends on the doctor. You really have to look and see the quality and the kind of artistry the doctor gives to the implant. I think that because I've seen the various before, after pictures online, and in doctors' offices. Some doctors do a good job and some do awful jobs."*

Some believe the doctor, not the procedure, makes the difference.

"The doctor makes a big difference in a breast augmentation experience."

"The shapes of the actual implant vary in different breast augmentation experiences."

"Where you have the incision varies in breast augmentation procedures."

Most had read about various methods and were interested in more information.

"I know of three ways the surgery is done. I know that you can get it done under your armpit, through your navel and through the nipple."

"The new way of surgery is through the areola or the belly button."

"Doctors don't really recommend the belly button procedure."

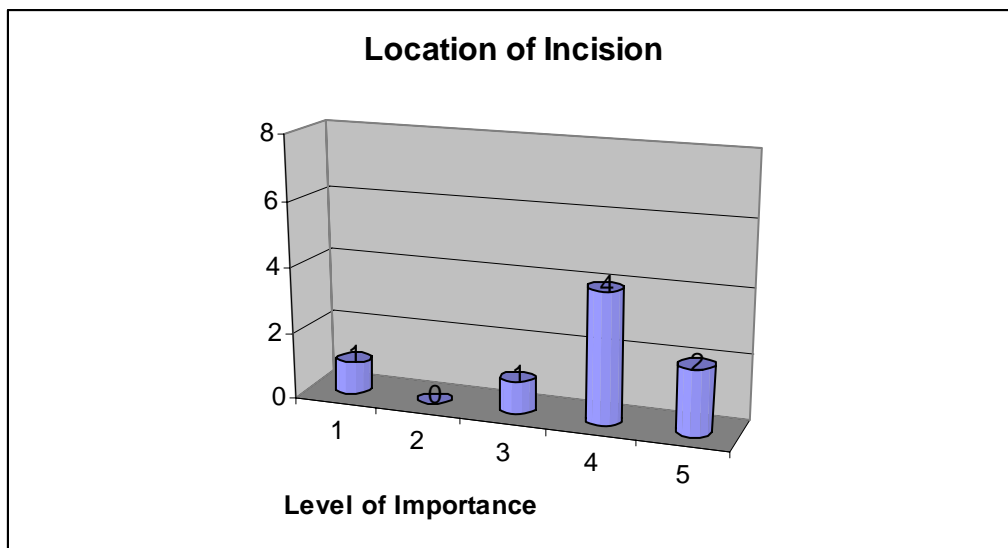
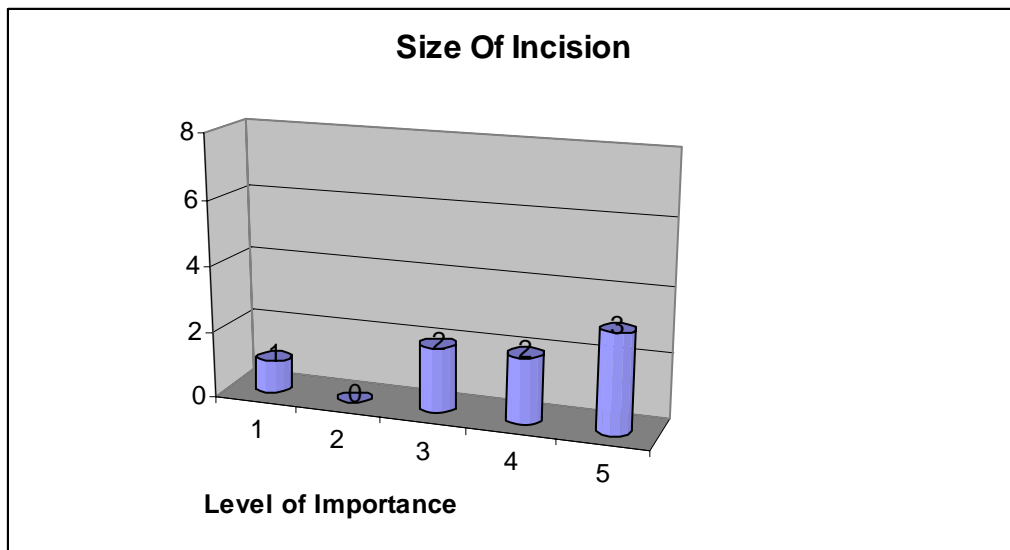
"For the best look it is through the nipple."

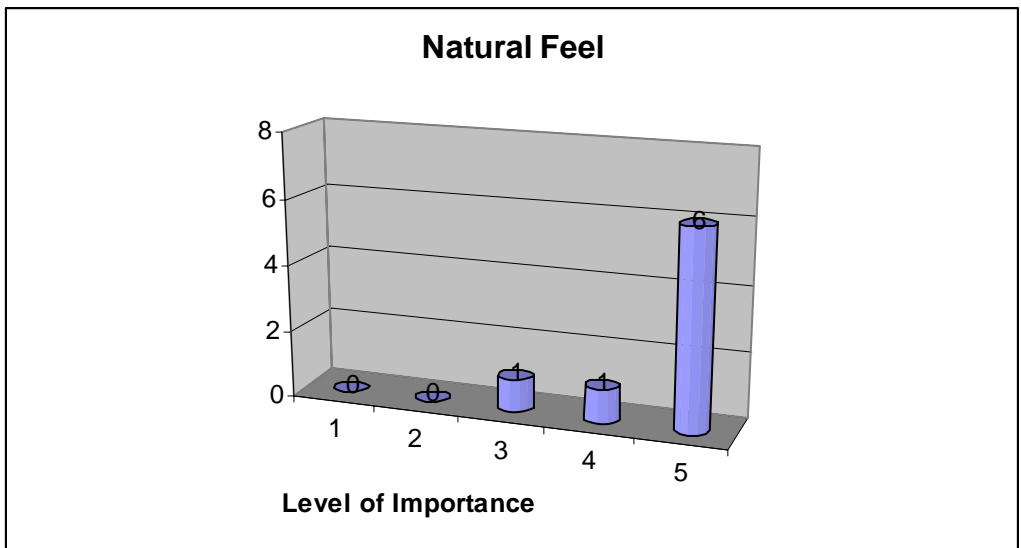
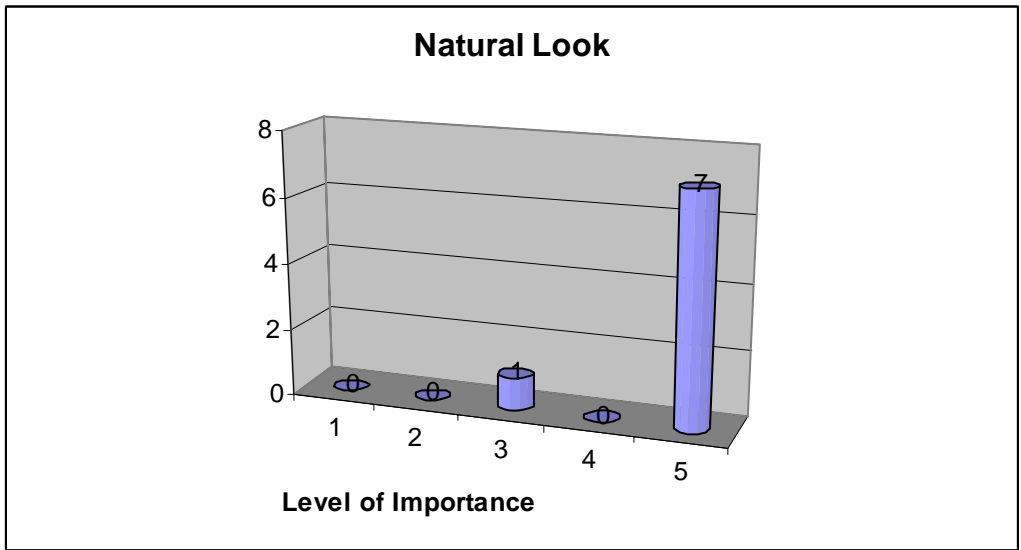
"You don't know if you can breastfeed if it's through the nipple, right?"

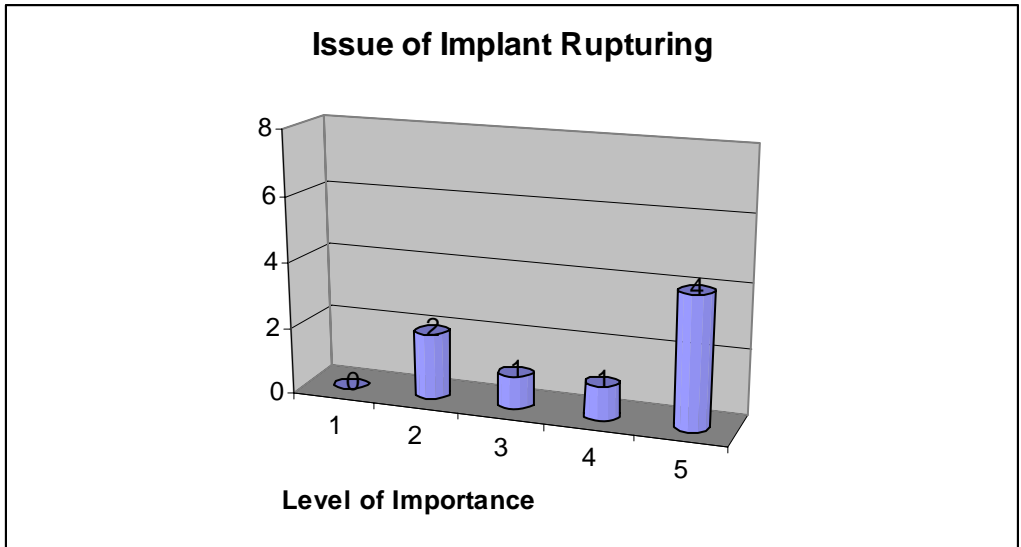
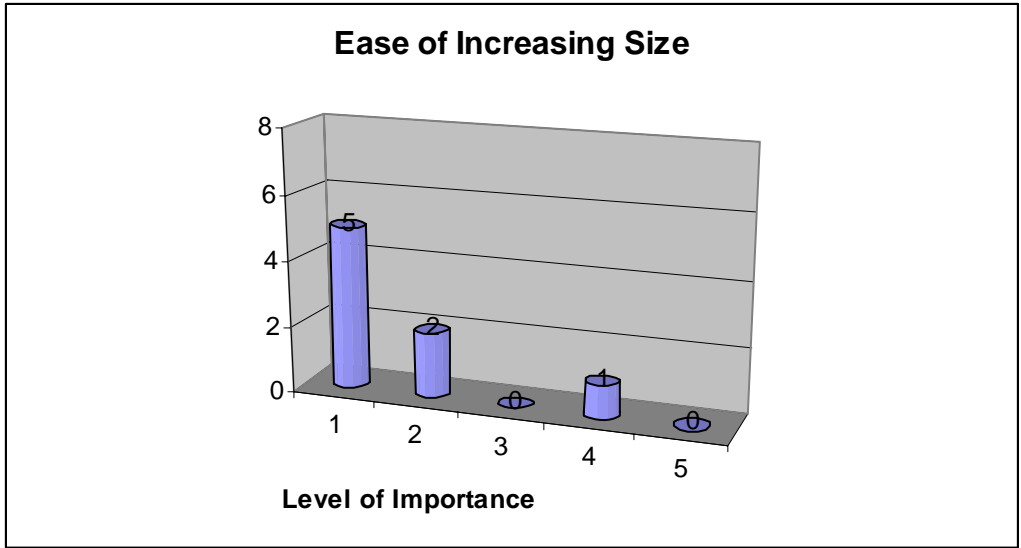
B. Importance of Issues

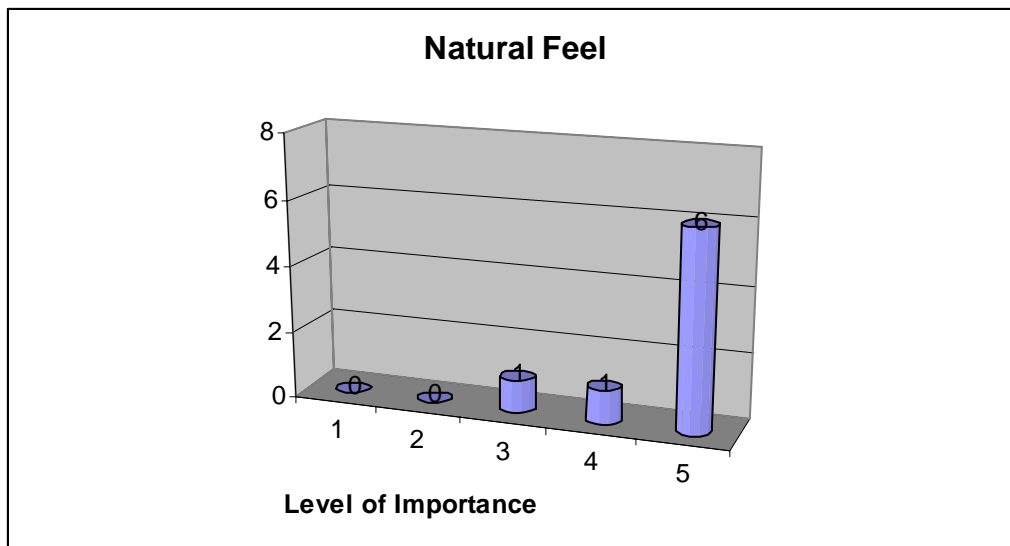
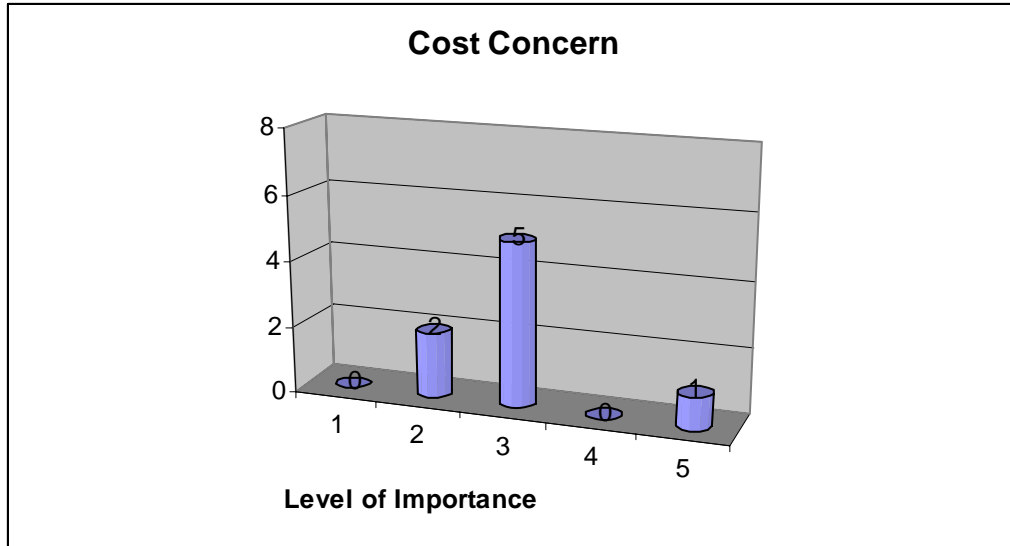
Participants were given a list of issues and asked to rate each on a 5 point scale indicating how important they were in decision making on having breast augmentation. A rating of 5 indicated it was very important and a 1 indicated not at all important.

The most important issues were natural look and feel.









C. Reaction to Written Description of the New Implant System

Participants were read a description of a new implant system and then asked to write down their immediate impressions of the system. The statement read to participants was as follows:

This new implant system consists of hundreds of miniature silicone implants, each the size of a raisin instead of one large implant the size of a grapefruit. In the traditional breast augmentation procedure, the surgeon makes an incision large enough for the implant to be inserted, then often does more surgical work inside the body, separating the muscle from the

chest to create a place to put the implant. Using these new implants, that work is not necessary. The tiny implants are placed inside the body using a micro incision. The implants are placed under the soft breast tissue above the muscle and conform to the shape of the breast.

Immediate impressions were positive and generated curiosity about the small silicone implants.

"The new implant procedure sounds modern like it's a microsurgery. So there are no scars, is less invasive and I like how it doesn't go under the muscle. It is much less of a full surgery."

"In this new procedure, do they do the little incision and stick all these in there how do they stay in the shape? If you're starting with a really small bust how do you shape all these little pieces into a natural looking boob?"

"For this new procedure, do the pieces move within your breast or do they stay in that spot? Where is the space coming from to fit in there?"

"Does the doctor who does this new procedure keep track of how many they put in you just in case you need to take them out for some reason?"

"Is the new procedure going to look bumpy?"

"To me, it sounds like if this new procedure is done right that it would be a more natural solution because instead of having one big thing they're kind of working with what you already have."

"I think the new procedure would look natural."

"I would want to know what the new procedure would feel like and what the cost would be compared to a traditional procedure."

"I would want to know if the new procedure would be less painful in the recovery period."

"The new procedure sounds like it would be less painful because it is much less invasive."

"I have heard my friends talk about under the muscle versus over the muscle and I think that if you do it over the muscle and you don't have a lot to start with it will not look as natural."

"I want to know where and how big the micro incision on this new procedure would be."

D. Reaction to Illustrated Description of the System

Participants were able to understand the differences between standard procedure for implants and the micro-implant procedure. The new micro-implant procedure was considered by most to be an improvement and was more modern and up to date.

"When I go to tell someone about this new procedure I would say, this procedure was innovative, interesting, and modern."

"I feel this new procedure is modern because everything is getting smaller, more precise, and less invasive and they're not going under the muscle. It seems like there is a lot less chance of hitting a major artery and you probably don't have to be as under as long. This new procedure seems safer."

"It just doesn't seem like there has been advancement on breast surgery in a long time. This seems like a step forward and advancement in breast augmentation procedure."

They were also impressed with the claim that it would have a natural look and feel, the small incision size, and reduced post operation pain.

"The micro implant looks more comfortable."

"This new procedure doesn't seem to be major surgery."

"I think the new implants would be a lot harder to rupture because they are little and there's no pressure."

"I think the new procedure is great."

"I think the new procedure is less invasive."

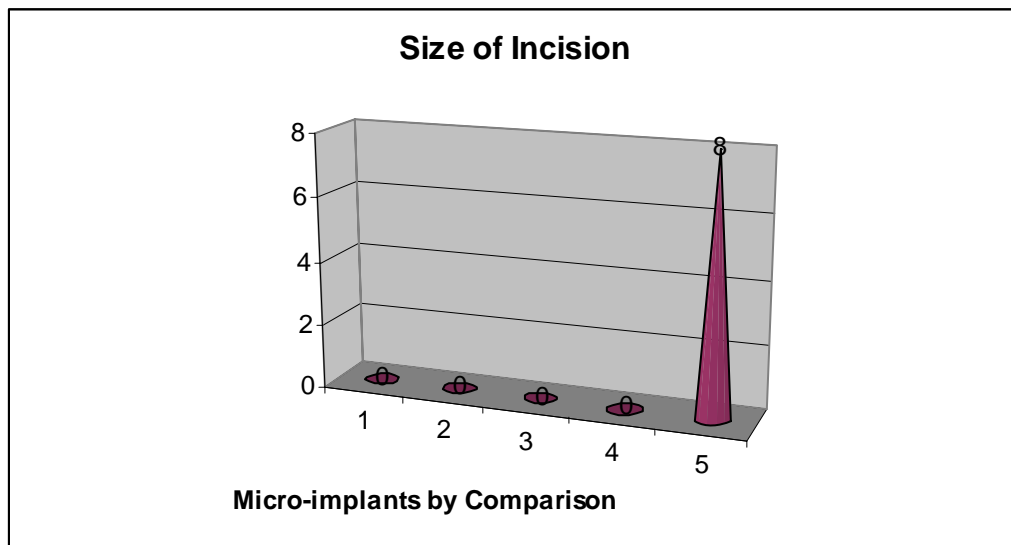
"I think the new procedure looks more natural."

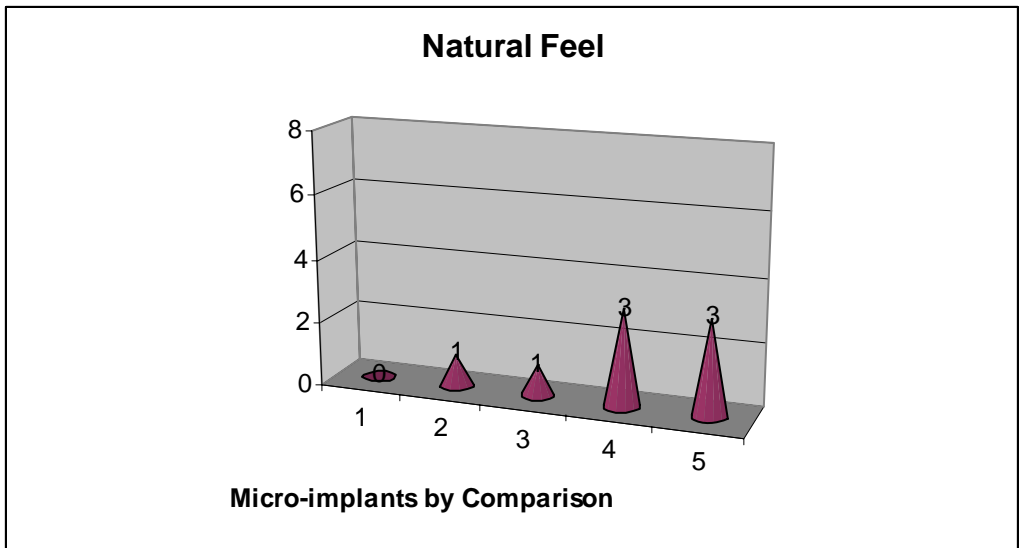
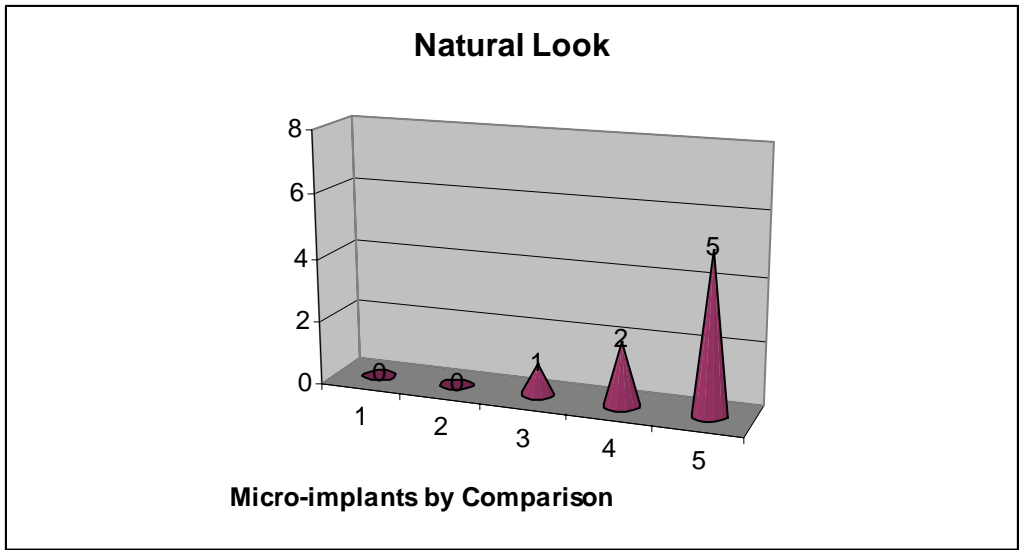
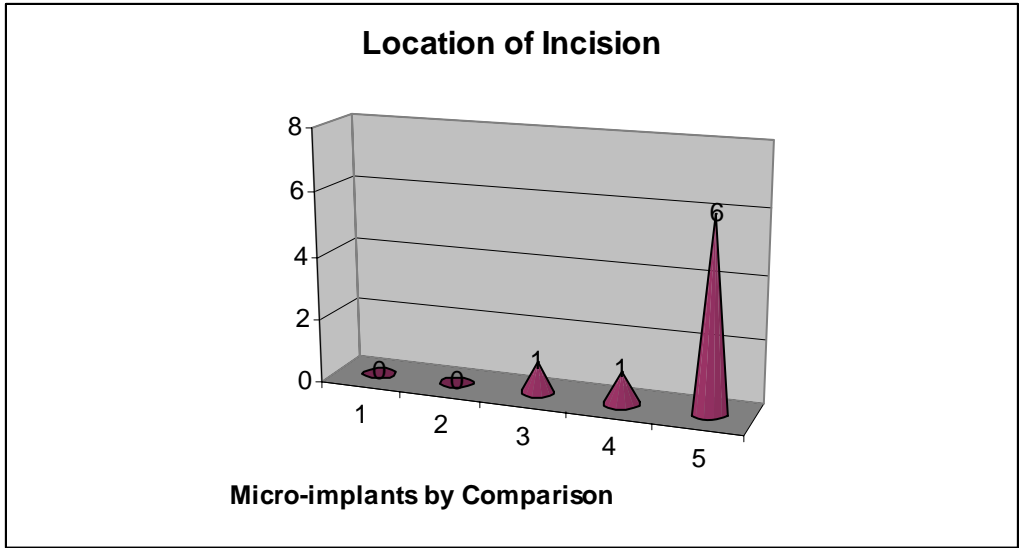
"I think the new procedure looks less painful."

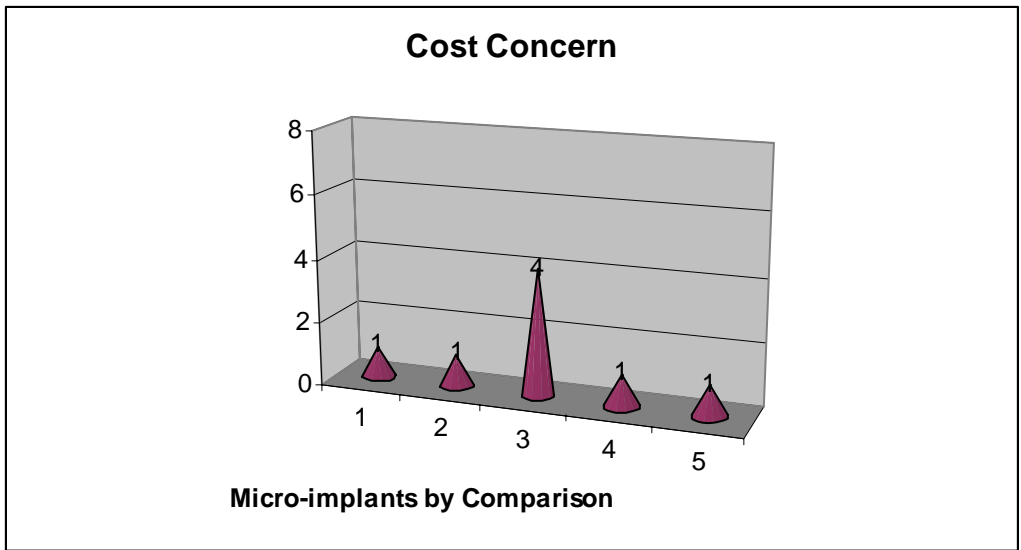
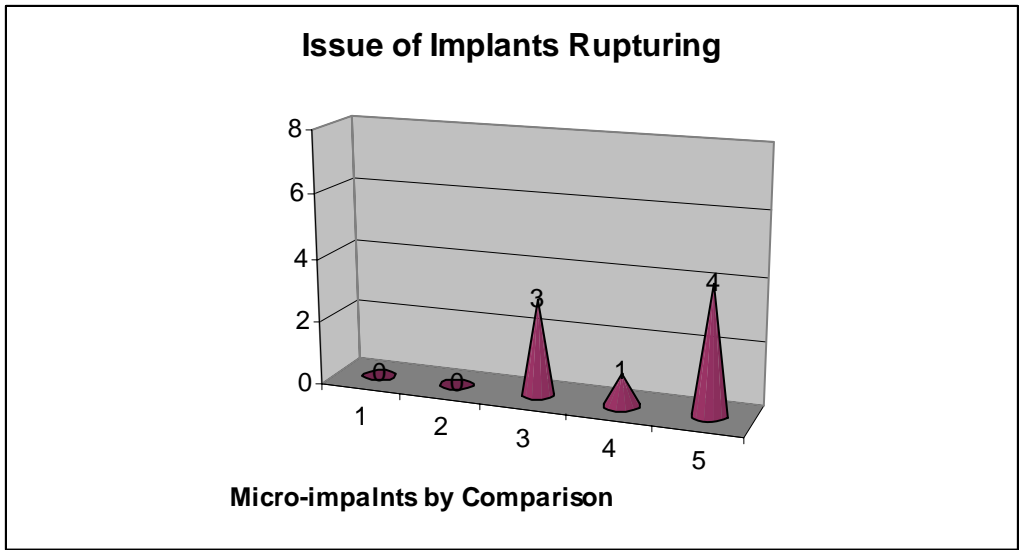
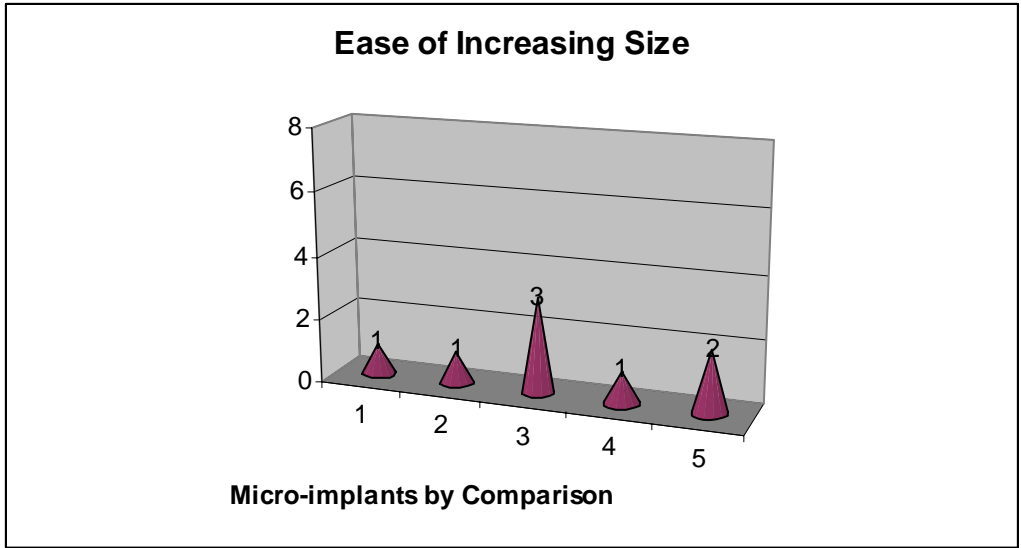
"If you were on the fence about getting breast augmentation and you heard about this new procedure I think you would lean more towards getting the procedure. If this new procedure were offered 10 years ago, I would have already had it done because it is less invasive, shows less scarring and there is a shorter healing process. I have to go to work and be able to function and pay my bills. If I'm down for a couple of weeks, that is important to me."

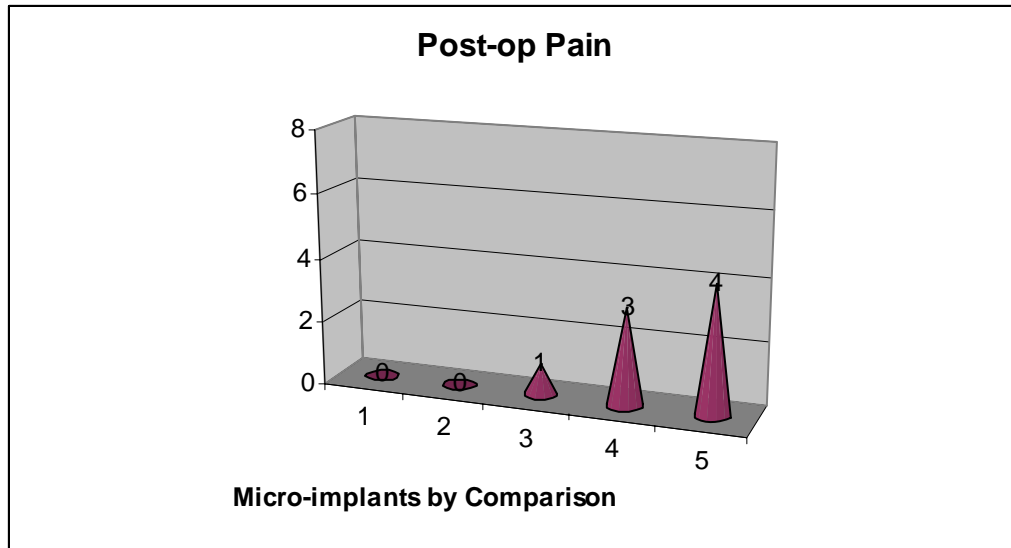
"This new procedure would be better than other procedures out there because post-operative pain, size of incision and the issue of implant rupturing would be less."

Below are the ratings when participants were asked to compare this new method to the standard breast augmentation method. A rating of 5 meant the new micro-implant method was "Very good by comparison", a rating of 1 meant that the new micro-implant method was "Not as good as the standard method".









The size and location of the incision for the new procedure were rated higher than the standard procedure.

"The size of the incision is important to me because it would mean less pain, less scarring and a more natural appearance."

"With this new procedure it seems like there are less things being forced into your body or pulled open or shoved in."

"For me, being African American, our skin heals a little different and if I get scarred you see it more on my skin as opposed to everyone else. Therefore, I would want the smallest scar possible."

"To me, if there is a smaller incision I feel like there's going to be less pain."

"I like the location incision of the new procedure because it's underneath and you can't see it."

The concept of increasing the size of the implant did not resonate with the participants. They considered the research before surgery by the doctor and themselves would insure the size would be appropriate and achieve the desired result.

"It is not important to us that the size can be increased again after the initial breast augmentation procedure."

Some are still cautious. They want to know if the procedure is FDA approved and would like to talk to others who have had the procedure done.

"I think this new procedure is very interesting, but I would still want to see years down the line what happens with it."

Appendix A – Verbatim Responses after viewing Presentation Materials

Answers to Questions After Reading Concept

- First impression
- Most compelling idea
- Not compelling idea

Tisha

- 1) How many micro implants are needed and if they have to be removed do they know how many to take out?
- 2) Sounds fascinating can these micro implants move around or are they secure in one spot, does it create a lumpy feel?
- 3) I need to see before and afters and need for others to have done this before I proceed.

Carolyn

- 1) Sounds less painful, less invasive, and easier for the doctors, less recovery time, not as major of a procedure since no muscle is being cut, but I'm not sure about determining shape or where all the beads go. Can one get loose?
- 2) Compelling- micro- incision, things getting smaller, more precise, more sophisticated. Not compelling- how is size formed, how does it feel to the touch, what happens if they get loose, how are you approved for silicone.
- 3) How to make it more interesting- Feel, shape, photos, cost compared to traditional procedure, what can go wrong.

Cecilie

- 1) About muscle, are they individually inserted? How do they stay in place? In a sack of some sort? Will it look natural?
- 2) Compelling- conforming to own breast tissue. What is not good is will it seem bumpy? How would you get them out?
- 3) More interesting- Little to no pain, and recovery period.

Maria

- 1) Sounds like they would look and feel more natural, but wonder/ worry how they would stay in place.

- 2) Most compelling is that it seems like it would offer a more natural look and feel. Not compelling is so many pieces of silicone.
- 3) Knowing the facts behind the safety and hearing from women that have had the procedure.

Leslie

- 1) How do the results look? Does this change over time?
- 2) Small incision, and more things can rupture
- 3) Real life testimonials, more detailed info.

Timika

- 1) Sounds like less painful, less scary, natural look
- 2) More compelling- 100's of tiny implants with natural look, to fake shape of natural breast. Less compelling- what if the tiny implants travel?
- 3) How long studied? Worst case scenario? Do they need to be replaced?

Svetlana

- 1) Comfort to shape of breast, good but where will space come from, will it be big enough. I like that you don't have to remove muscle.
- 2) Compelling- Several instead of one, make it sound more realistic look/feel. Not compelling- Harder to remove if needed.
- 3) More interesting- organic assimilation to body, consistent.

Lashaun

- 1) Who thought and came up with this mini implant procedure, sounds a bit ridiculous and complicated.
- 2) Most interesting is there won't be a big incision.
- 3) What would make it more interesting is if they mention no side effect or no scarring.

Comments After Viewing Illustrations of Procedure

Tisha

- 1) I'm open to it as long as I've seen enough people get them done.
- 2) These are better because they conform to your natural shape.
- 3) They are worse because I am hesitant before the capsular contracture occurs, some of the "raisins" will move to undesirable areas. It's also still new and I don't want to be a guinea pig.

Carolyn

- 1) I feel very optimistic, seems more advanced, less invasive, more natural looking than regular implant.
- 2) Best feature is that it's multiple tiny implants rather than one so the shape can be more malleable.
- 3) Least attractive thing is that I've never seen one in real life. Also, the scar process seems to be trickier to get the implants to stay in place.

Cecilie

- 1) The look is more natural, and the incision is a lot smaller. I still wonder how they will be placed right and won't go anywhere in the body.
- 2) The best is less invasive and more natural
- 3) The worst is the shaping.

Maria

- 1) I think it's great it seems to mimic your natural fat and I would think you'd get a more natural appearance.
- 2) The best feature is that it seems more pliable because of it being a bunch of small pieces.
- 3) The worst is that it hasn't been done before.

Leslie

- 1) Looks interesting, less painful and more natural.
- 2) The best is that it's less invasive and no muscle separation.
- 3) The worst is what if the body doesn't take it or it deforms?

Timika

- 1) Interested in seeing how this procedure takes off, less pain, less time operating means a plus.
- 2) Smaller incision, less invasive as far as procedure would like to have done. Currently leaning towards implants.
- 3) What are the long term effects?

Lashaun

- 1) Procedure seems interesting but I would need to know a lot more about it.
- 2) The best part about this procedure, well what I can see from the illustration is breast looks a lot more natural and the incision is very small which is great.
- 3) That part that worries me is the amount of mini implants seems like it would take so many to form the size of breast.

Svetlana

- 1) Somewhat inclined to it because it seems less invasive and less painful. It would look real.
- 2) I like how you can insert under.
- 3) Will it hurt pressing against muscle, and also long term effects and research.

Other factors felt by the group to be important.

Accessibility to doctor

Doctor had malpractice

Type of Implant

New Studies

Long Term Effects

Appendix B – Discussion Guide

3616-1

Final Discussion Guide

Marina del Rey – Monday May 12, 2008

Surgical Arts of Beverly Hills

6:00 PM – Females interested in breast implants



I. INTRODUCTION

- introductions: name, do you work out of home, occupation, type of industry, family size
- purpose of research:
 - to introduce you to a newly developed breast implant system and determine your reaction

II. BACKGROUND INFORMATION

- You have expressed an interest in breast augmentation
 - How long have you been thinking about it
 - Have you done any research
 - What done:
 - magazine articles
 - talked to doctors
 - looked on internet, etc.
 - was the information helpful
 - which was most helpful
 - what do you still need to know
- Do you know others who have had it done
 - Have you talked to them about it
 - What do you think of their surgery
- What are the factors standing between you and having the procedure done
 - Finish this sentence – I would schedule surgery if
- How important do you feel some of these aspects HAND LIST of breast augmentation are in your decision making – **5 = very important and 1 = not at all important**

- Size, location of incision, natural look, natural feel, the ease of increasing the size if desired, issue of implant rupturing, cost
- What types of breast implants are there to choose from
 - What is the best - why
 - What is the worst – why
 - Do you have an idea on how the surgery is done
- What types of breast augmentation surgery are there to choose from
 - What is the best - why
 - What is the worst – why
- What if a company developed a new type of breast implant system
 - Would you be open to finding out more about it
 - Why/why not
 - What concerns would you have in looking at the new system

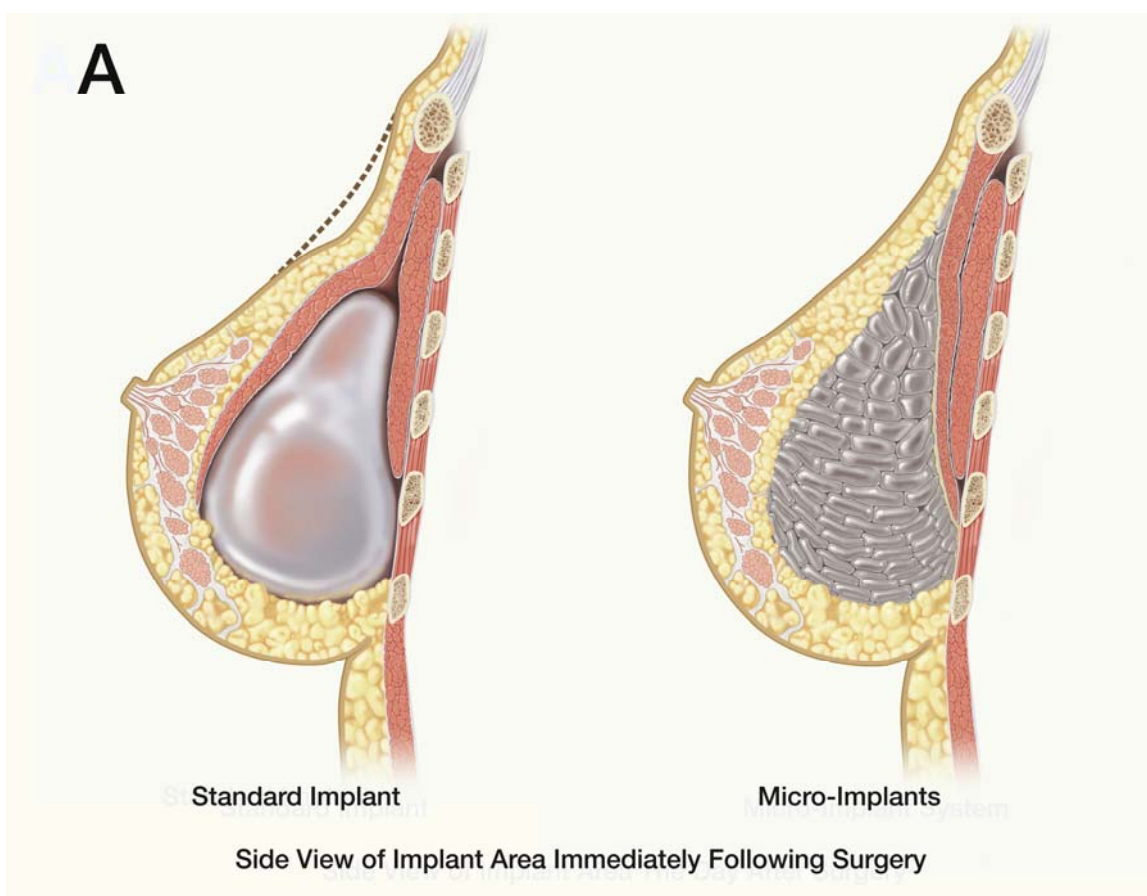
III. NEW CONCEPT

- Let's talk about a new method of breast augmentation using a new implant system. I am going to read a written statement about this concept.

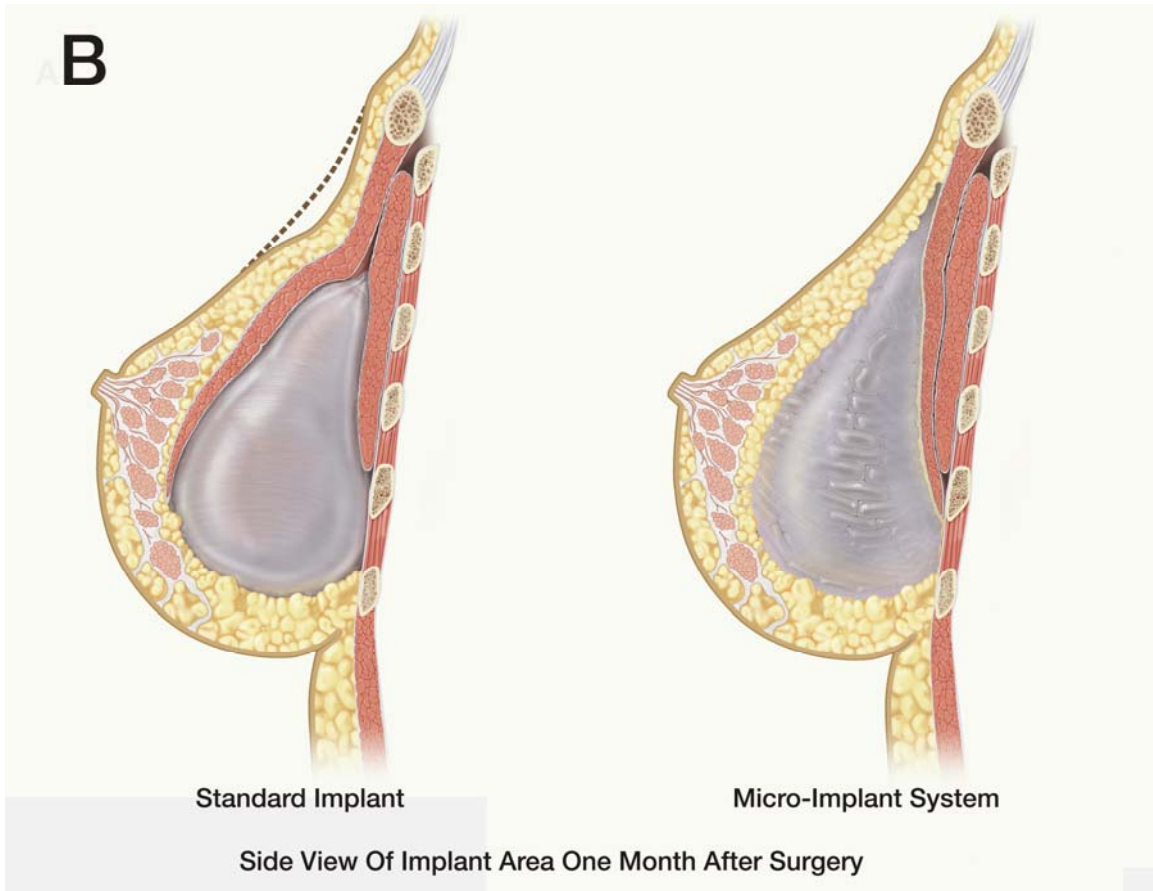
Please let's read it together and then – without talking about it as a group – I would like you to give me your reaction by jotting down your **FIRST IMPRESSION** at the bottom of the page. **JOT DOWN**

This new implant system consists of hundreds of miniature silicone implants, each the size of a raisin instead of one large implant the size of a grapefruit. In the traditional breast augmentation procedure, the surgeon makes an incision large enough for the implant to be inserted, then often does more surgical work inside the body, separating the muscle from the chest to create a place to put the implant. Using these new implants, that work is not necessary. The tiny implants are placed inside the body using a micro incision. The implants are placed under the soft breast tissue above the muscle and conform to the shape of the breast.

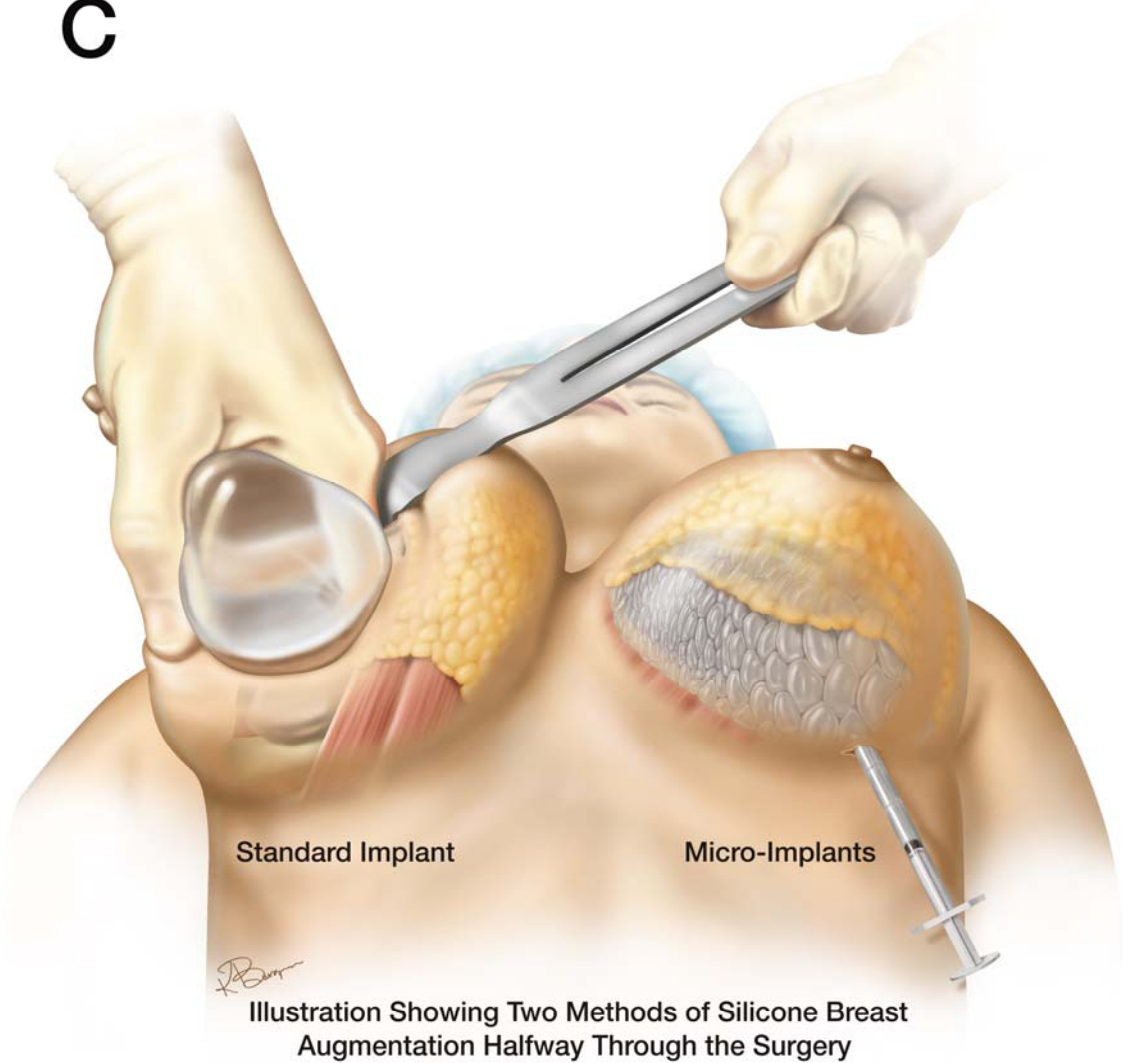
- What is your first impression
 - What is compelling about it
 - What is not compelling
 - What could make it more interesting to you
 - What more do you want to know about it
- And now, I would like to show you some illustrations of the system. Again, please hold your comments until the end and then JOT DOWN your comments on this piece of paper. I am going to read a description of each picture and we will go through them one by one. When we are finished, please jot down your impression.



A. The first page labeled "A" is a side view of a patient the day after having breast augmentation using a standard silicone implant on the left and the micro-implant system on the right. As you can see the standard implant is seen placed under the chest (red layer) muscle where as the micro-implant system is placed above the muscle. The dotted line on the left is showing where the breast profile differs from the profile on the right.



B. The second page labeled "B" is a side view of the patient one month after surgery showing that the healing capsule around both types of implants. The body creates its own form of natural scar tissue around the implants to keep them from moving around within the body.

C

C. The third page labeled "C" shows a surgical illustration of halfway through both surgeries. On the left, we can see the insertion of a standard silicone implant under the muscle. On the right, we can see the insertion of the micro-implants above the muscle through a syringe at a location selected by the patient.

D**Micro-Implant**

- D. In our final illustration labeled “D” we see an image of the micro-implant by itself demonstrating the similarity to a smaller version of a silicone implant but having a less filled appearance.
- Now please jot down your thoughts regarding...
 - How you feel about this procedure
 - What is the best feature of this implant system versus the standard method
 - What you see as the least attractive aspect of this micro-implant procedure versus the standard method
 - What additional information would you like to know

 - **DISCUSS ISSUES ABOVE**

 - Would you be interested in this method if it were available
 - Why/ why not
 - What would need to change to make you interested

- If this procedure was available and FDA approved, would you tell friends about it to make them aware
 - What would you tell them
- If this method were available along with the others you are familiar with, which would you consider
 - Which do you find most interesting
 - Would you investigate this procedure more

IV. RE- RANK

- Here is another form similar to the last. This time, rank this procedure compared to others - on the same issues - on a scale of 5 down to 1. Remember 5 means this procedure is Very Good by comparison to other procedures and 1 means it is Not as Good as others
 - What do you see as the biggest barriers, if any, to the acceptance of this new micro-implant method

V. BOARD OF DIRECTORS

- You are now on the board of directors of the company that making this new product
 - Who do you see as the ideal patient
 - Would you as a board member feel good about placing the company money behind this product because you think many people – like you - would be interested in it

NAME: _____ **Group:** _____

While all are important, please tell me how important each of the following aspects of breast augmentation are to you in your decision making.

Please rate the importance of each of the following on a 5 point scale **with 5 meaning Very Important and 1 meaning Not that Important.**

	RATING
Size of incision	_____
Location of the incision	_____
Natural look	_____
Natural feel	_____
Ease of increasing the size if desired	_____
The issue of the implant rupturing	_____
Cost	_____

OTHER VERY IMPORTANT FACTORS:

NAME: _____ GROUP: _____

NEW PROCEDURE

Based on what you know from this presentation, how would you rate this procedure on this list of attributes?

Please tell me, based on what you know, how you feel this procedure would be by comparison to other procedures for breast augmentation.

Please rate **this** method we have just described on each of the following using a 5 point scale.

Please remember **5 means it is Very Good by comparison to other procedures and 1 meaning Not as Good as other procedures.**

	RATING
Size of incision	_____
Location of the incision	_____
Natural look	_____
Natural feel	_____
Ease of increasing the size if desired	_____
The issue of the implant rupturing	_____
Perceived Cost	_____