



Delphi Consensus Recommendations: Intraoperative Technique and Postoperative Management of Patients with Natrelle 410 Implants

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Background: Anatomically shaped, form-stable Natrelle 410 breast implants were approved in Europe in 1993 and in the United States in 2013. Although general guidelines for breast augmentation are available, the distinctive characteristics of Natrelle 410 warrant specific guidelines for this device. The goal of this study was to generate consensus recommendations for intraoperative technique and postoperative management with Natrelle 410 in primary breast augmentation.

Methods: Surgeons were invited to participate in the study, which used a modified Delphi method. Participants completed 2 rounds of online surveys; the second survey (Recommendations Survey) was generated based on first survey results. Respondents also listed top priorities for use of Natrelle 410.

Results: Participants ($n = 22$) reached consensus on 15 of 18 perioperative and surgical techniques; dual-plane placement, tight pockets, and limiting the boundaries of dissection were among intraoperative techniques considered most important for Natrelle 410. Consensus was reached for 18 of 32 items regarding postoperative management and 6 of 9 open-ended postoperative activity restrictions. Consensus on activity restrictions with specified time limits were similar to consensus recommendations on general restrictions. Top participant-identified intraoperative and postoperative management practices for Natrelle 410 were dual-plane placement of the implant and wearing a bra postoperatively, respectively.

Conclusions: The Delphi method identified consensus recommendations on a broad range of intraoperative techniques and postoperative management practices for primary breast augmentation with Natrelle 410. These recommendations and priorities provide surgeons with a framework that, together with the surgeon's experience, will contribute to optimal clinical outcomes with Natrelle 410. (*Plast Reconstr Surg Glob Open* 2015;3:e557; doi: 10.1097/GOX.0000000000000388; Published online 16 November 2015.)

A successful outcome in breast augmentation surgery requires careful consideration of 4 elements: patient selection, preoperative plan-

ning, intraoperative technique, and postoperative management. There are numerous published approaches to breast augmentation, but each varies in

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areas of emphasis and level of detail, particularly regarding intraoperative technique¹⁻⁴ and postoperative management.^{3,5,6} In addition, surgeons have developed their own individual processes and procedures based on clinical training and day-to-day experience. Although a variety of approaches to breast augmentation surgery have been used successfully, some aspects of the surgeon's approach might best be customized to the specific type of implant used in each case.

The Natrelle 410 breast implant (Allergan, Inc., Irvine, Calif.) is an anatomically shaped, form-stable, textured silicone implant designed to resemble the natural slope of the breast.^{2,7} It was first approved for use in Europe in 1993,⁷ in South America in 1998, and in Canada in 2006 and became available in the United States in 2013. Consequently, although the long-term safety and effectiveness of Natrelle 410 have been demonstrated in a prospective, 10-year, multicenter study conducted in the United States,⁷⁻⁹ US surgeons are generally less experienced with Natrelle 410 implants compared with their colleagues in other parts of the world. Although more general surgical guidelines are available,^{1,10-12} recommendations focused specifically on the use of Natrelle 410 will be valuable to surgeons because of the implant's particular characteristics. These include the textured Biocell (Allergan, Inc., Irvine, Calif.) shell surface facilitating tissue integration¹³ and the specific anatomic shapes of the different Natrelle 410 implants with regard to point of maximum projection, angle of inclination, and slope of the upper pole. The objective of the current study was to arrive at consensus recommendations among experienced surgeons regarding the optimal use of Natrelle 410 implants for primary breast augmentation.

This study is the first to employ a modification of the Delphi method to generate recommendations for primary breast augmentation surgery. The Delphi method is a consensus-building process using a series of questionnaires to arrive at a convergence of opinion from selected individuals on a specific issue.^{14,15}

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No Delphi consensus articles on aesthetic surgery are found in the literature. However, the Delphi method has been used to arrive at consensus evaluations in an analysis of factors contributing to aesthetic outcomes in conservative treatment of breast cancer.¹⁶ In the current study, recommendations were generated for optimizing patient selection, preoperative planning, intraoperative techniques, and postoperative management in breast augmentation surgery using Natrelle 410 implants. Consensus recommendations for patient selection and preoperative planning are presented in a separate article.¹⁷ We report here on consensus recommendations and top priorities for intraoperative techniques and postoperative management of patients receiving Natrelle 410 implants.

METHODS

A modified Delphi method was used to reach consensus among international surgeons with expertise in breast augmentation surgery. Invited surgeons were known to Allergan and to the surgical community as having extensive experience with Natrelle 410 implants in clinical practice and/or clinical trials. Detailed methods are described by Hedén et al 2015¹⁷ and are summarized here briefly. The authors collaborated to develop 2 Web-based surveys focused on the topics of intraoperative technique and postoperative management with Natrelle 410 implants. Both surveys were administered via Survey Monkey. The survey participants' identities remained blinded to the authors and to each other, and their responses remained anonymous. Participants were informed that the study was sponsored by Allergan and that the consensus results would be reported by the authors.

Personal Practice Survey

The initial survey (Personal Practice Survey) queried participants on their specific practices for using Natrelle 410 implants in primary breast augmentation. The Personal Practice Survey included 113 items, 42 related to intraoperative technique and postoperative management. Participants were able to supplement their responses with write-in comments. The results of the Personal Practice Survey were shared with the participants and used as a guide for the authors to develop the subsequent Recommendations Survey.

Recommendations Survey

In the final phase of the modified Delphi process, the Personal Practice Survey was restructured and modified based on the participants' responses and write-in comments. The resulting Recommendations Survey consisted of several Topic Statements, worded

to elicit participants' recommendations for use of Natrelle 410 implants in intraoperative technique and postoperative management (eg, "I routinely recommend the following intraoperative techniques with Natrelle 410 implants"). Each Topic Statement was followed by a list of corresponding items that required a response from the participants. The Topic Statements and their corresponding items are listed in Tables 1 and 2. The "Intraoperative Technique" section comprised 1 Topic Statement, with 18 related items. Two additional items in this section asked participants to identify antimicrobials/antiseptics that they use to irrigate implants and implant pockets from a list of 5 options. The "Postoperative Management" section comprised 4 Topic Statements, with a total of 32 related items.

In most cases, there were 3 response options for each item: "Agree," "Neutral," and "Disagree."

Response to some items was not applicable to certain participants. For example, if a participant provided an earlier response indicating that they do not recommend a particular type of postoperative restriction, they would not be expected to provide a response concerning the duration of that restriction. For this reason, some items included a fourth response option (eg, "I do not use..." or "I do not restrict..."). Participants were also asked to identify their top 3 priorities for the Natrelle 410 implant from the list of items associated with each Topic Statement. For example, participants were asked to indicate the top 3 intraoperative techniques that are most important for Natrelle 410.

Statistical Analysis

The threshold criterion for responses to an item reaching consensus level in the Recommendations

Table 1. Intraoperative Technique with Natrelle 410 Implants for Primary Breast Augmentation

Item No.*	Item	Participants' Response (n = 22)				Percent Agreement with Recommendation
		Agree	Neutral	Disagree	Excluded from Response†	
Topic Statement 1. I routinely recommend the following intraoperative techniques with Natrelle 410 implants.						
1.	Patient's arms should be symmetrical and away from her side during surgery	18	0	4	NA	81.8
2.	Patient should be in the supine position with head of operating table slightly elevated during surgery	14	3	5	NA	63.6
3.	Inframammary incision length for Natrelle 410 should be approximately 5 cm but varies depending on implant volume	21	1	0	0	95.5
4.	Dual-plane (ie, partial subpectoral) placement of Natrelle 410	17	1	4	0	77.3
5.	Subglandular (ie, superficial to the pectoralis) placement of Natrelle 410	2	6	14	NA	9.1
6.	Subfascial (ie, under fascia of pectoral muscle) placement of Natrelle 410	4	7	11	NA	18.2
7.	Create more snug pocket space for Natrelle 410 implants compared with round implants	18	2	2	NA	81.8
8.	Ensure tight pockets by limiting the boundaries of dissection	21	0	1	NA	95.5
9.	Electrocautery for dissection	21	0	1	NA	95.5
10.	Confirm preoperative implant pocket size assessment during dissection	20	2	0	NA	90.9
11.	Irrigate implant pockets with antimicrobials	18	2	2	NA	81.8
13.	Irrigate implants with antimicrobials	17	3	2	NA	77.3
15.	Use sutures to help define the new IMF position	16	2	4	NA	72.7
16.	Use sizers to determine implant volume in more complex cases	16	2	4	NA	72.7
17.	Assess breast symmetry by using sizers if the surgeon is inexperienced with Natrelle 410	15	3	4	NA	68.2
18.	Assess symmetry with the operating table flexed at the level of the patient's hips and the head of the table elevated	19	1	2	NA	86.4
19.	Close skin incisions with absorbable sutures	20	0	2	NA	90.9
20.	Support skin incision closure with tissue glue or tape	19	2	1	NA	86.4

Items not reaching the consensus recommendation threshold are in bold font. Consensus based on $P < 0.01$ level of significance for number responding "Agree" using a chi-square goodness-of-fit test.

*Items are numbered in the order presented in the survey.

†Participants who indicated that they did not use an element or restrict an item ("I do not use..." or "I do not restrict...") were not expected to provide a response concerning the use of an element or restriction of an activity and were thus not included in the statistical analysis of total number of responses to that item.

IMF, inframammary fold; NA, not applicable.

Table 2. Postoperative Planning with Natrelle 410 Implants for Primary Breast Augmentation

Item No.*	Item	Participants' Response (n = 22)			Excluded from Response†	Percent Agreement with Recommendation
		Agree	Neutral	Disagree		
Topic Statement 1. I routinely recommend the following essential elements to optimize postoperative healing with Natrelle 410.						
21.	Drains (inframammary and periareolar incision approach)	5	0	16	1	23.8‡
22.	Drains with a transaxillary incision approach	1	0	6	15	14.3‡
23.	Gauze dressing at the drain site	7	1	1	13	77.8
24.	Dressing other than gauze at the drain site (eg, Biopatch and Restore)	4	3	3	12	40.0
25.	Waterproof dressing over surgical site	11	4	7	NA	50.0
26.	Gauze used for drainage absorption/compression over surgical site	14	3	5	NA	63.6
Topic Statement 2. I routinely recommend the following pain management approaches when using Natrelle 410.						
27.	NSAIDs	20	1	1	NA	90.9
28.	NSAIDs used preferentially over opioids	14	2	6	NA	63.6
29.	Opioids for severe or breakthrough pain	16	3	3	NA	72.7
30.	Benzodiazepines, only as needed	5	6	11	NA	22.7
Topic Statement 3. I routinely recommend the following in the postoperative setting after breast augmentation with Natrelle 410 implants.						
31.	Binder	8	2	12	NA	36.4
32.	Bra	19	1	2	NA	86.4
33.	Avoidance of breast massage	22	0	0	NA	100
34.	Scar massage	10	6	6	NA	45.5
Topic Statement 4. I routinely recommend restrictions (and the durations specified) in the following physical activities postoperatively with Natrelle 410.						
35.	Restrict soaking the incision site	18	4	0	NA	81.8
36.	Restrict soaking of the incision site for 48 hours or longer	18	1	1	2	90.0
37.	Restrict driving a car	12	5	5	NA	54.5
38.	Restrict driving a car for 48 hours or longer or when the patient is off narcotics	16	2	2	2	80.0
39.	Restrict full arm motion	10	4	8	NA	45.5
40.	Restrict full arm motion over the first week and as tolerated	13	0	8	1	61.9
41.	Restrict lifting	16	5	1	NA	72.7
42.	Restrict heavy lifting for up to 2 weeks	19	0	2	1	90.5
43.	Restrict sexual activity	10	10	2	NA	45.5
44.	Restrict sexual activity for 1 week or longer	11	7	3	1	52.4
45.	Restrict push-ups	22	0	0	NA	100
46.	Restrict push-ups for 4 weeks or longer	21	0	1	0	95.5
47.	Restrict swimming	21	0	1	NA	95.5
48.	Restrict swimming for 4 weeks or longer	16	2	3	1	76.2
49.	Restrict displacement exercises (running, bouncing, etc.)	20	1	1	NA	90.9
50.	Restrict displacement exercises for 4 weeks or longer	18	2	2	0	81.8
51.	Restrict full activity	17	3	2	NA	77.3
52.	Restrict full activity for 4 weeks or longer	13	3	6	0	59.1

Items not reaching the consensus recommendation threshold are in bold font. Consensus based on $P < 0.01$ level of significance for number responding "Agree" using a chi-square goodness-of-fit test.

*Items are numbered in the order presented in the survey.

†Participants who indicated that they did not use an element or restrict an item ("I do not use..." or "I do not restrict...") were not expected to provide a response concerning the use of an element or restriction of an activity and were thus not included in the statistical analysis of total number of responses to that item.

‡Item reached significance ($P < 0.01$) in a chi-square goodness-of-fit test for number responding "Disagree."

NA, not applicable; NSAID, nonsteroidal anti-inflammatory drug.

Survey was set at the $P < 0.01$ level of significance when measuring agreement of answers using a chi-square goodness-of-fit test. Participants were excluded from the statistical analysis of any item for which they chose the "I do not use..." or "I do not restrict..." response. The $P < 0.01$ threshold correlated with 63.65% "Agree" responses for all items with 3 possible responses (ie, "Agree," "Neutral," or "Disagree"); threshold

percentages for items that included responses of "I do not use..." or "I do not restrict..." varied according to the number of participants included in the chi-square test. Items for which a statistically significant percentage of participants responded "Disagree" were also noted.

The 2 questions on specific antimicrobials/antiseptics (items 12 and 14) were not statistically analyzed; rather, they were evaluated for trends in usage.

RESULTS

A total of 30 surgeons practicing worldwide were invited to participate: 7 declined and 23 completed the Personal Practice Survey. In all, 22 of 23 surgeons (96%)¹⁷ completed the Recommendations Survey.

Intraoperative Technique

Analysis of the responses to items regarding intraoperative technique for breast augmentation with Natrelle 410 revealed consensus on a broad range of perioperative and surgical techniques, including 15 of the 18 items (Table 1). Consensus was reached on recommendations to irrigate implants and implant pockets with antimicrobials or antiseptics. Antimicrobials effective against Gram-positive bacteria and against Gram-negative bacteria were endorsed by the greatest number of participants (Gram-positive bacteria: 15 and 17 participants for implant and implant pocket irrigation, respectively; Gram-negative bacteria: 13 and 15, respectively). Antiseptics such as Betadine (Purdue Products L.P., Stamford, Conn.) were endorsed by 13 participants (implants and pockets), whereas antimicrobials effective against atypical and anaerobic bacteria were each endorsed by fewer than half of the participants. Intraoperative technique items that did not reach consensus are shaded in Table 1.

Postoperative Management

Consensus was reached for 18 of 32 items regarding the postoperative management of patients receiving Natrelle 410 implants (Table 2). Consensus recommendations were similar for postoperative restrictions on activities when the restrictions were described with specific durations and when they were open-ended (6 of 9 items each; Table 2, Statement 4). Exceptions included “Restrict driving a car,” which met consensus only when the time period and narcotic-free timing were specified, and “Restrict full activity,” which met consensus open-ended, but not for a duration of 4 weeks or longer.

Among the items not reaching the consensus threshold for recommendation (shaded items in Table 2), there were 2 items wherein the number of “Disagree” responses reached statistical significance ($P < 0.01$): 16 of 21 participants (76.2%) disagreed with recommending drains with an inframammary and periareolar incision approach, and 6 of 7 participants (85.7%) disagreed with recommending drains with a transaxillary incision approach (15 of 22 participants were excluded from the analysis of the transaxillary incision item because they responded “I do not use transaxillary incision approach”).

Top Recommendations for the Natrelle 410 Implant

The items selected by the most participants as being among the most important intraoperative techniques specifically for Natrelle 410 were dual-plane placement (selected by 11 of 22 respondents), ensuring tight pockets by limiting the boundaries of dissection (9 of 22) and creating more snug pocket space compared with round implants (8 of 22).

Participant-identified priorities for postoperative management with Natrelle 410 included select wound healing measures, pain management approaches, and activity restrictions (Table 3). Several items were among the top 3 identified by participants as being most important for Natrelle 410, yet did not reach the threshold for consensus recommendation. For example, 8 participants included the use of drains for inframammary and periareolar approach in their top 3 items, but the majority of participants would not recommend the use of drains for any approach. It is possible that participants were providing their top 3 recommendations with only inexperienced surgeons in mind, thus accounting for the apparent discrepancies. Top postoperative management priorities for Natrelle 410 identified by the greatest number of participants included the use of a bra (selected by 19 of 22 respondents), avoidance

Table 3. Survey Participant Priorities for Postoperative Management Priorities with Natrelle 410 Implants

Postoperative Management Priorities	No.
Three most essential elements for healing (6 items total)	
Waterproof dressing over surgical site*	10
Gauze used for drainage absorption/compression over surgical site*	9
Drains (inframammary and periareolar approach)*†	8
Three most important pain management approaches (4 items total)	
Opioids for severe or breakthrough pain	18
NSAIDs	14
NSAIDs used preferentially over opioids	14
Three most important postoperative recommendations (4 items total)	
Bra	19
Avoidance of breast massage	18
Scar massage*	8
Three most important restrictions on activity (9 items total)	
Restrict displacement exercises	13
Restrict lifting	9
Restrict soaking the incision	8
Three postoperative restrictions for which duration of restriction is most important (9 items total)	
Restrict displacement exercises for 4 weeks or longer	13
Restrict push-ups for 4 weeks or longer	10
Restrict lifting for up to 2 weeks	9

*Item did not reach consensus for recommendation.

†Thirteen participants indicated that they do not use drains. NSAID, nonsteroidal anti-inflammatory drug.

of breast massage (18 of 22), and opioids for severe or breakthrough pain (18 of 22).

DISCUSSION

Using a modification of the Delphi method, a panel of surgeons with extensive experience in breast augmentation surgery using anatomically shaped implants arrived at consensus recommendations for intraoperative technique and postoperative management when using Natrelle 410 breast implants. This report represents the first use of the Delphi method in developing consensus recommendations for breast augmentation surgery in a study designed to collect feedback on surgeons' experience specifically with the Natrelle 410 implant. Users of other devices may not find these recommendations useful or suitable to their practice, as they reflect the respondents' experience with this device and its distinctive characteristics, including the textured Biocell shell surface.¹³ Experienced surgeons have developed preferred approaches to primary breast augmentation that can be tailored to the specific features of each individual case. The recommended approaches presented here are intended to guide clinical decision making for the use of the Natrelle 410 implant.

Intraoperative Technique

There was broad agreement among participants regarding general intraoperative techniques for breast augmentation, such as arm position during surgery, the use of sizers by inexperienced surgeons in complex cases (such as asymmetry cases), electrocautery for dissection, antimicrobial usage, and incision closure techniques. Many of the items that reached consensus for recommendation are long-standing, basic techniques for breast augmentation, in general.^{18–22}

Intraoperative techniques for which consensus was reached that were considered to be of particular importance for Natrelle 410 implants included techniques that contribute to ensuring a hand-in-glove fit for Natrelle 410 in the implant pocket to help maintain stability and minimize the risk of rotation.^{2,8} These included limiting the boundaries of dissection,⁴ creating more snug/tight pocket space relative to round implants,²² and the use of electrocautery, which gives better control of the pocket size than blunt dissection.¹⁹ Indeed, ensuring tight pockets by limiting the boundaries of dissection and creating more snug pocket space compared with round implants were noted as top intraoperative priorities for Natrelle 410, along with dual-plane placement of the implant. Consensus was reached for the recommendation of an inframammary incision length of approximately 5 cm for Natrelle 410, somewhat

longer than generally used for low-cohesive implants. In the authors' opinion, the length of the incision should be increased for larger implants (up to 6–6.5 cm) and reduced for small implants (down to 4 cm), but an average incision length of 5–5.5 cm allows for proper placement of the highly cohesive implant and reduces the likelihood of gel fracture or deformation during placement.^{20,23,24}

Dual-plane placement of the Natrelle 410 implant reached consensus for recommendation by the participants, whereas no consensus was reached on subfascial or subglandular placement. General advantages of dual-plane implant placement include a lower likelihood of implant visibility,² better tissue visualization by mammography,²¹ and a reduced risk for capsular contraction.^{6,21} The authors have found that for the Natrelle 410 implant, the dual-plane approach provides good upper pole cover, allows for lower pole subglandular positioning, and still allows for control of rotation when compared with a subglandular pocket on its own.¹⁹ In the authors' opinion, although the risk of rotation is low for the Natrelle 410 implant,^{7–9} it is increased with nonsubpectoral placement. In patients lacking soft-tissue coverage, the lower likelihood of upper-pole implant visibility with dual-plane placement may be an important consideration.^{20,21} In addition to these observations, the absence of controlled, long-term, prospective clinical studies evaluating the efficacy of the subfascial placement, introduced in the 2000s, may have contributed to the lack of consensus for the subfascial position.²⁵

Postoperative Management

Fewer items reached consensus on postoperative management compared with intraoperative technique, possibly reflecting the diverse training, practices, and experiences of the participants. Specific areas of agreement included the use of a gauze dressing at the drain site, nonsteroidal anti-inflammatory drugs and opioids for pain management, avoidance of breast massage, wearing a bra, and restrictions on selected physical activities such as lifting, displacement exercises, and swimming. These recommendations generally apply to primary breast augmentation with any implant; however, massage is often encouraged for round implants. In the authors' opinion, massage is contraindicated with the Natrelle 410 implant as it may reduce tissue adhesion to the textured Biocell surface and thereby increase the risk of displacement, rotation of the implant, and capsule complications.²⁵ Imobility of the anatomically shaped Natrelle 410 implant is a necessary outcome that is achieved

with placement of the implant in a snug pocket and, perhaps, with tissue adhesion. Immobility combined with low capsule complications leads to immobility with softness or what is described as the “one breast feel.” Similarly, restriction of postoperative physical activity may be particularly important with textured implants; the duration of activity restrictions is generally longer for textured implants compared with round implants. Restriction of displacement exercises for 4 weeks or longer and avoidance of massage were both listed by participants as top postoperative management priorities for Natrelle 410. Subjects’ use of a bra was also a top postoperative priority for Natrelle 410. Areas of disagreement were associated with various surgical dressings and drains, benzodiazepine use, binder use, scar massage, restrictions on driving a car, full arm motion, and sexual activity. It is important to note that although there was agreement on the use of gauze dressings around drains, the use of drains themselves was not recommended. Indeed, 7 participants agreed with recommending gauze dressing at the drain site, but 13 stated they did not use drains. The authors agree that certain techniques work well for some surgeons, but specific postoperative techniques are generally less important than intraoperative technique for final outcome.

Strengths and Limitations

The current study had several important strengths and limitations. The recommendations reported here represent a unique view of real-world clinical practice approaches to breast augmentation with Natrelle 410 implants based on the experiences of an international group of surgeons. In this study, the participants were asked to consider not only the technical aspects of breast augmentation but also management approaches beyond the surgical procedure. Limitations of the study methods are described in Hedén et al 2015.¹⁷ Briefly, they include the lack of universally accepted consensus thresholds for the Delphi method^{14,27} and the possible influence of the iterative process inherent in the Delphi method on the responses provided in the Recommendations Survey.¹⁴ In addition, regional practice differences among the survey participants may not have been captured: strong support for 2 differing approaches, for example, could result in a lack of consensus for an item. Recommendations offered by this group of surgeons might differ from those of clinicians with a different breadth of experience or those with patient populations that differ in demographic characteristics and geographic distribution.

CONCLUSIONS AND IMPLICATIONS FOR CLINICAL PRACTICE

The Delphi method identified consensus recommendations on a broad range of intraoperative and postoperative management techniques for primary breast augmentation with Natrelle 410 implants. These recommendations can serve as a guide for assessment and refinement of a surgeon’s current procedures with the Natrelle 410 implant. Future areas of consensus-building for intraoperative technique and postoperative management for the Natrelle 410 implant include surgical techniques for positioning the inframammary fold scar and for optimizing the pocket size, postoperative restrictions, and best practices for minimizing the risk of complications.

The Natrelle 410 implant has been shown to be a predictable implant with advantages over smooth, round, and non-form-stable devices that deliver good aesthetic results and a low incidence of complications.^{7–9,28} As with any medical device, success can best be achieved through a well-defined process of patient selection, preoperative education, precise surgical technique, and a clear postoperative protocol. Given the wide range of specific features in any clinical case, the surgeon must always choose the course best suited to the individual patient. However, the consensus recommendations generated in this modified Delphi method provide surgeons with a framework for intraoperative technique and postoperative care that will contribute to good clinical outcomes with Natrelle 410 for their primary breast augmentation patients.

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