Disclaimer:

Providing ideas and not legal advice

All information presented as of October 21, 2020
Patient Decision Aid Series:

Cutting Edge Patient Education

&

Informed Consent for Primary Breast Augmentation

Made Possible by an Educational Grant from Allergan Aesthetics
Panelists

CHELSEA HAGOPIAN, DNP, APRN, AGACNP-BC

LAURIE A. CASAS MD, FACS

MELINDA HAWS, MD
why is shared decision-making important in plastic surgery?

“A [shared decision-making] process of communication, if properly performed and documented in the patient’s record, would constitute perfected informed consent.”

Download the PDA at: www.surgery.org/pda

Making quality decisions about primary breast augmentation surgery
A decision aid to support informed choices that reflect best evidence and what matters most to you

What is the purpose of this decision aid?
This decision aid is designed to prepare you for decision-making and to facilitate shared decision-making with your plastic surgeon, by helping to:
- introduce the decisions necessary to consider before primary breast augmentation surgery,
- educate you on the essential information you need to know to make each decision, and
- identify your goals, values, and preferences relevant to each decision and clearly communicate them to your plastic surgery care team.

Who should use this decision aid?
This decision aid is for you if:
- You are a woman age 18 or older, and
- You are considering primary breast augmentation (enlargement) surgery with saline or silicone implants, for cosmetic reasons.
- Primary breast augmentation means you have not previously had a breast augmentation surgery.

This decision aid is not for you if:
- You are under the age of 18, or
- You are considering breast implant surgery for:
  - reconstructive purposes after breast cancer surgery,
  - revision of a previous breast augmentation surgery, or
  - gender affirming male-to-female surgery.
- Breast implant surgery for reconstructive, revision, or gender affirming reasons have different or additional information essential for decision-making but not covered in this decision aid, including options, risks, benefits, expectations or limitations.

What content is and is not covered in this decision aid?
- This decision aid includes only the information considered essential for all patients to understand before surgery when considering primary breast augmentation surgery.
- This decision aid may not include information important to your individual decision-making process or relevant to your specific situation, such as information about certain treatment options, risks, or tradeoffs. This decision aid is not a replacement for consultation with a plastic surgeon.

How should I use this decision aid?
Use this decision aid before and throughout the consultation and informed consent process with your board-certified plastic surgeon. It is structured to help you answer the following questions:
- How should I prepare for decision-making?
- Is plastic surgery right for me?
- Should I have breast augmentation surgery?
- What questions should I ask my plastic surgeon?
- What are my next steps?
Agenda

01 overview of patient decision aids (PDAs) & shared decision-making

02 highlight key features of the PDA & relevant research
patient decision aids & shared decision-making
what is a patient decision aid?

Patient decision aids (PDAs) are evidence-based tools that help patients to meaningfully participate in decision-making about healthcare options.

Defining characteristics

01 PDAs make explicit the decisions that need to be made, the options, and their features.

02 PDAs help patients to clarify and communicate their values and preferences.

03 PDAs help patients and clinicians work together to make informed decisions based on the clinically appropriate options, the best available scientific evidence, and what matters most to the patient.
The informed consent process should work for you, not against you. Traditional informed consent documents are a source of waste in healthcare and are focused on clinician disclosure, not patient understanding. Informed consent is a process, not a form. Patient decision aids PDAs can help to make best practice, common practice.

<table>
<thead>
<tr>
<th>Traditional informed consent document (ICD)</th>
<th>Patient decision aid (PDA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signature on a form to conclude informed consent</td>
<td>Interactive tool to prepare patients for informed consent conversations &amp; facilitate shared decision-making</td>
</tr>
<tr>
<td>One-way communication (clinician disclosure)</td>
<td>Two-way communication (education and mutual understanding)</td>
</tr>
<tr>
<td>Variability (depth, breadth &amp; quality of content)</td>
<td>Reliability (evidence-based; leverages deference to expertise)</td>
</tr>
<tr>
<td>Content-oriented (type of information)</td>
<td>Context-oriented (essential information applied to the relevant decision)</td>
</tr>
<tr>
<td>Ineffective “ritualistic” formality</td>
<td>Evidence-based standards for ensuring quality</td>
</tr>
</tbody>
</table>

limitations of checklists & warnings

Checklist & box warnings do not:

✗ capture patient baseline understanding of concern(s) & available treatment options
✗ help to elicit patient goals, values & informed preferences
✗ assess comprehension
✗ reconcile misunderstanding of information
✗ confirm a mutually [patient/clinician] agreed upon treatment plan
✗ ensure compliance with national health literacy or numeracy guidelines, nor
✗ adhere to risk communication principles

Checklists
Consider as a call for process reliability and decreased variation in information disclosure

Box warnings
Recognizes a need for easily identifiable essential information
shared decision-making & PDAs...

**improve:**
- patient knowledge about risks & benefits\(^1,2\)
- decision concordance with patient values\(^2\)

**reduce:**
- decisional conflict\(^1,2\)

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Minimum standards for screening and certification are published by the National Quality Forum (NQF).
## Standards for Developing & Evaluating Patient Decision Aids

<table>
<thead>
<tr>
<th>Screening Criteria for PDA Eligibility</th>
<th>Certification Criteria</th>
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<tbody>
<tr>
<td>1. Describes the health condition or problem for which a decision is required.</td>
<td>1. Provides a balanced presentation of options.</td>
</tr>
<tr>
<td>2. Identifies the target user.</td>
<td>2. Contains content based on a rigorous and documented evidence synthesis method.</td>
</tr>
<tr>
<td>3. Explicitly states the decision under consideration.</td>
<td>3. Provides information about the evidence sources used.</td>
</tr>
<tr>
<td>4. Describes the options available for the decision, including non-treatment when appropriate.</td>
<td>4. Provides key outcome probabilities, adopting risk communication principles.</td>
</tr>
<tr>
<td>5. Describes the positive features of each option.</td>
<td>5. Provides a publication date.</td>
</tr>
<tr>
<td>6. Describes the negative features of each option.</td>
<td>6. Provides information about the update policy and next expected update.</td>
</tr>
</tbody>
</table>
| 7. Clarifies patient values for outcomes of options by:  
  b. asking patients to consider or rate which positive and negative features matter most to them; and/or  
  c. describing the features of options to help patients imagine the physical and/or social and/or psychological effects. | 7. Provides information about the funding sources used for development.  
  8. Provides information about competing interests and/or policy.  
  9. Provides information about the patient decision aid development process, including information about participation from target users and health professionals.  
  10. Provides information about user testing with target patients and health professionals.  
  11. Reports readability levels.  
  12. Follows plain language guidelines, to ensure understanding of people with low literacy and/or low health literacy skills. |

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Detailed criteria for evaluating the quality of PDAs is published by the International Patient Decision Aid Standards (IPDAS) Collaboration.

A to Z Inventory of Decision Aids

**Decision Aid Summary**

<table>
<thead>
<tr>
<th>Title</th>
<th>Making quality decisions about primary breast augmentation surgery.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Audience</td>
<td>Adult (age 18 or older) females actively considering primary breast augmentation (enlargement) surgery with saline or silicone implants for cosmetic reasons.</td>
</tr>
<tr>
<td>Options included</td>
<td>Is plastic surgery right for me? Should I have breast augmentation surgery?</td>
</tr>
</tbody>
</table>

Based on **IPDAS criteria (International Patient Decision Aid Standards)** this decision aid (and/or supporting materials) meets:

- 7 out of 7 criteria to be defined as a patient decision aid
- 8 out of 8 criteria to lower the risk of making a biased decision
- **Not applicable:** other criteria for decision aids about screening or testing

*PDA summary for Making quality decisions about primary breast augmentation surgery*
A to Z Inventory of Decision Aids

- **Online database** of patient decision aids
- Made publicly-available by the Ottawa Hospital Research Institute
- **PDA summary** for *Making quality decisions about primary breast augmentation surgery*

### Checklist

#### Criteria to be defined as a patient decision aid

<table>
<thead>
<tr>
<th>Criteria to be defined as a patient decision aid</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>The decision aid describes the condition (health or other) related to the decision.</td>
<td>Yes</td>
</tr>
<tr>
<td>The decision aid describes the decision that needs to be considered (the index decision).</td>
<td>Yes</td>
</tr>
<tr>
<td>The decision aid identifies the target audience.</td>
<td>Yes</td>
</tr>
<tr>
<td>The decision aid lists the options (health care or other).</td>
<td>Yes</td>
</tr>
<tr>
<td>The decision aid has information about the positive features of the options (e.g. benefits, advantages).</td>
<td>Yes</td>
</tr>
<tr>
<td>The decision aid has information about negative features of the options (e.g. harms, side effects, disadvantages).</td>
<td>Yes</td>
</tr>
<tr>
<td>The decision aid helps patients clarify their values for outcomes of options by: a) asking people to think about which positive and negative features of the options matter most to them AND/OR b) describing each option to help patients imagine the physical, social, and/or psychological effect.</td>
<td>Yes</td>
</tr>
</tbody>
</table>

#### Criteria to lower the risk of making a biased decision

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<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>The decision aid makes it possible to compare the positive and negative features of the available options.</td>
<td>Yes</td>
</tr>
<tr>
<td>The decision aid shows the negative and positive features of the options with equal detail.</td>
<td>Yes</td>
</tr>
<tr>
<td>The decision aid compares probabilities (e.g. chance of a disease, benefit, harm, or side effect) of options using the same denominator.</td>
<td>NA</td>
</tr>
<tr>
<td>The decision aid (or available technical documents) reports funding sources for development.</td>
<td>Yes</td>
</tr>
<tr>
<td>The decision aid reports whether authors of the decision aid or their affiliations stand to gain or lose by choices people make after using the decision aid.</td>
<td>Yes</td>
</tr>
<tr>
<td>The decision aid includes authors/developers' credentials or qualifications.</td>
<td>Yes</td>
</tr>
<tr>
<td>The decision aid reports the date when it was last updated.</td>
<td>Yes</td>
</tr>
<tr>
<td>The decision aid (or available technical document) reports readability levels.</td>
<td>Yes</td>
</tr>
<tr>
<td>The decision aid provides references to scientific evidence used.</td>
<td>Yes</td>
</tr>
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</table>
PDA overview

Making quality decisions about primary breast augmentation surgery
design overview

**Format**

PDF, can be viewed digitally or as a printed document.

Designed to replace traditional informed consent documents for primary breast augmentation surgery.

**PDA structure**

*context-oriented* to the relevant decision rather than *content-oriented* like traditional informed consent documents

- organized into useful chunks along the decisional timeline
- information is learned as it is needed and can be immediately applied to the patient’s actual decision-making

Each section [content block] is guided by an overarching question & includes:

- the relevant decision or decisions necessary to consider;
- the essential information needed to make a decision;
- details about why the information is important or how it should specifically inform the patients’ decision-making.
The Forgetting Curve

If new information isn’t applied, we’ll forget about 75% of it after just six days.

<table>
<thead>
<tr>
<th>Lapsed time since learning</th>
<th>None</th>
<th>20 min.</th>
<th>1 hour</th>
<th>9 hours</th>
<th>1 day</th>
<th>6 days</th>
<th>31 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>100% retention</td>
<td>58</td>
<td>44</td>
<td>36</td>
<td>34</td>
<td>25</td>
<td>21</td>
<td></td>
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Source: Hermann Ebbinghaus
From: “Where Companies Go Wrong with Learning and Development,” by Steve Glaveski, 2019
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Who should use this decision aid?
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- You are a woman age 16 or older, and
- You are considering primary breast augmentation (enlargement) surgery with saline or silicone implants, for cosmetic reasons.
- Primary breast augmentation means you have not previously had a breast augmentation surgery.

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Highest level of school completed: 92% report at least some college, with 53% having an undergraduate degree or higher; 0% report completing < grade 9.

Use plain language?
- Is written at a level that can be understood by the majority of patients in the target group (10.3)
- Is written at a grade 8 equivalent level or less according to readability score [SMOG or FRY]* (10.4)

Level of detail, preferred timing, format and presentation of information defined by the relevant patient experts
Minimum standards for screening and certification published by the National Quality Forum (NQF).

Detailed criteria for evaluating the quality of PDAs is published by the International Patient Decision Aid Standards (IPDAS) Collaboration.


Hagopian CO, Hagopian TM, Wolfsinkel EM, Ades TB, Stevens WG. Behaviors and perspectives of women considering primary breast augmentation surgery relevant to decision-making and informed consent [unpublished manuscript; not yet submitted for peer-review].
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Identifies the target user.

Procedure-specific core information set defined by relevant clinical experts

Helps patients recognise a decision needs to be made (12.1)

Use plain language?
- Is written at a level that can be understood by the majority of patients in the target group (10.3)
- Is written at a grade 8 equivalent level or less according to readability score [SMOG or FRY]*(10.4)

Highest level of school completed: 92% report at least some college, with 53% having an undergraduate degree or higher; 0% report completing < grade 9.

Level of detail, preferred timing, format and presentation of information defined by the relevant patient experts

Describes the health condition or problem for which a decision is required.
How should I prepare for decision-making?

- Know what is expected of me in decision-making
- Know what information to trust about plastic surgery
- Verify my surgeon is board-certified or eligible by the American Board of Plastic Surgery

Why is it important for me to actively participate in decision-making?

My plastic surgeon cannot read my mind to know what I do and do not want. Actively participating in decision-making means I need to know and clearly communicate with my plastic surgery care team:

- My specific concerns and goals for the result I want to achieve
- My values based on what risks and benefits matter most to me

Making sure my plastic surgeon and I have a clear understanding of my goals, values, and preferences can reduce my risk of being unhappy with my surgical results.

How do I know what information to trust when reading about plastic surgery?

5 key quality checks for appraising health information:

1. Author and qualifications. Who wrote the information? Are qualifications listed describing why they are credible to speak on the topic?

2. Up-to-date. Is a “date last reviewed” provided? Is the date within the past year?

3. Evidence-based. Is a reference list included to the sources of evidence used to support the information? Are the sources credible?

4. Unbiased. Are both pros and cons discussed equally? Does the author or publisher have a financial, or other, conflict of interest in how you use the information or your ultimate decisions? If so, is the conflict(s) disclosed?

5. Useful. Does the information answer your question? Does it make sense? Can you easily apply what you have learned to your decision-making?


- Use the American Board of Plastic Surgery (ABPS) website [surgeon search tool](https://www.abps.org) to verify board certification status
- Review FAQs about board certification

A board-eligible plastic surgeon has successfully completed the required training in plastic surgery (residency) and has an approved application by the ABPS to enter the board-certification process.

How should this inform your decision-making?

- Surgeon technique and judgement can increase or decrease your risk of complications.
- If your surgeon is not board-certified or board-eligible by the American Board of Plastic Surgery, he or she may not have completed the pre-requisites training needed to safely perform plastic surgery.

"Perhaps the biggest risk comes when the unsuspecting patient is operated by an unqualified surgeon" (free-text)
“...patients who have access to high-quality evidence and health information, and who also possess e-health literacy skills to make sense of it, can most meaningfully engage in shared decision making about their care.”

Free-text comments described risks as being either general or dependent based on the individual patient, surgeon, or specific decision.

Patients describe reasons for considering primary breast augmentation in terms of both goals they want to achieve and concerns they want to address.

Free-text comments repeatedly mentioned anesthesia and DVT/PE as two essential general risks of surgery.

Suggest ways for patients to share what matters most with others (4.3).
Clarifies patient values for outcomes of options by:
describing the features of options to help patients imagine the physical and/or social and/or psychological effects; and/or asking patients to consider or rate which positive and negative features matter most to them.

What are my preferences for how I want my breasts to look & feel after surgery?

How full do I want my breasts to look after breast augmentation?
- Minimal fullness
- Moderate fullness
- Maximum fullness

Check ☐ your preference:

How natural do I want my breasts to feel?

Check ☐ how much it matters to you that your implants feel natural:

Not important: 1, 2, 3, 4, 5, 6, 7

It may be helpful to review before-and-after photos to get a general idea of what you do and do not like. Look for a before-and-after gallery on your plastic surgeon’s website or ask their office. Choose photos of results with a similar body type to you.

I have a photo example of what I want my breasts to look like after surgery: ☐ Yes ☐ No

What do I need to know when deciding if breast augmentation surgery is right for me?
Check ☐ items that you feel are most important to your decision-making process.

General risks of breast augmentation surgery include:

- Bleeding, hematoma (a collection of blood), and infection
  - May require additional surgery (reoperation)
  - Reoperations have additional risks. There are certain situations that require implants to be removed but not replaced.
  - Complications following surgery may not be covered by your health insurance.

- How to reduce your risk
  - Follow your plastic surgeon’s pre- and postoperative instructions and activity restrictions.
  - Identify and address with your plastic surgery care team any risk factors specific to your medical history and lifestyle.

- Change in nipple sensation including increased, decreased, or complete loss of sensation
  - Nipple sensation changes may be temporary or permanent.
When asked how respondents expect implants will change their breasts:
- larger (81%)
- lifted (80%)
- different shape (72%)
- unsure (1%)

68% prefer the format for presenting information about what to expect over the long-term after surgery.

56% prefer the format for presenting information about what results to expect.

There are known and unknown risks of breast implants.

- A known, or true, risk is defined and supported by scientific evidence of causation. A key example is breast-implant associated anaplastic large cell lymphoma (BIA-ALCL) with textured implants.
- An unknown, or poorly understood, risk is not supported by scientific evidence of causation, but may still be a consideration for some patients. These risks may or may not be defined. For example, a wide spectrum of systemic symptoms have been reported by some women with both saline and silicone, smooth and textured surfaced breast implants. The true relationship between breast implants and these systemic symptoms has yet to be scientifically defined.

Current research shows that silicone gel breast implants do not increase your risk of autoimmune illnesses or connective tissue diseases. However, breast implant manufacturers are required to list them as possible risks in the directions for use of breast implants.

Breast implants are not lifetime devices.
It is likely you will need additional surgery related to your implants at some point in your lifetime.

- Expect future out-of-pocket expenses:
  - Health insurance plans likely will not cover any expenses related to your breast implants, including for any complications.
  - Available financial assistance programs include implant manufacturer warranties and surgeon-specific cosmetic complication insurance.

- Long-term considerations:
  - Breast implants may impact breast cancer surveillance.
  - Continue routine screening as recommended by your doctor.

Reoperations for implant maintenance is expected and is not a complication.

What implants can and cannot do.
Implants increase breast size and expand the breast envelope. Minimal breast ptosis (drooping or sagging) can often be corrected with implants, but implants will not correct significant skin laxity or severe ptosis. There may be alternative or combination procedures for you to consider.

- A breast lift (mastopexy) may be appropriate to consider to reshape or lift the breasts.
- While not interchangeable with breast implants because the results are less predictable, fat grafting may be a reasonable alternative or addition to implants to add breast volume.
- Not having surgery is an option. Paired bra and inserts can be used to give the appearance of larger breasts without surgery.

Alternative or combination procedures have different or additional risks to consider beyond what is presented in this decision aid.

Your cosmetic result is directly related to your anatomy.
Understanding the limitations of your specific breast and chest wall characteristics is a key component of good preoperative planning and can help you to set realistic expectations.

- Asymmetry:
  - 100% of women have differences between their breasts (such as in size, nipple position, inframammary fold position, or chest wall anatomy).
  - These differences will not be corrected, and breasts will never match.

- Cosmetic dissatisfaction:
  - You can expect your results will change over time as your body changes, for example with pregnancy, weight change, and normal aging.
  - Satisfaction with your implants may change over time and is not a complication.

Need to inform there are known and unknown risks of implants (free-text).

BII did not meet consensus threshold but several free-text entries mentioned the need for its inclusion.

Need to clearly differentiate between complications and expectations (free-text).
Describe uncertainty around probabilities (3.4)

>50% prefer the format for presenting information about:
• general description of how breast augmentation surgery is performed (video)
• available implant options (physical models in the office)

Explicitly states the decision under consideration.

Describes the options available for the decision, including nontreatment when appropriate.

Provides a balanced presentation of options.
**Level of detail**

>80% believe it is necessary to know before making a decision: a list of the risks, potential consequences, the likely signs & symptoms, any risk reduction strategies, and what to do if the complication occurs.

### Decision #3: Implant shell

<table>
<thead>
<tr>
<th>Options:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key risk of breast implant associated anaplastic large cell lymphoma (BIA-ALCL)</td>
</tr>
<tr>
<td>Why is this important?</td>
</tr>
<tr>
<td>Key benefit</td>
</tr>
<tr>
<td>Textured</td>
</tr>
<tr>
<td>- All textured implants have an association with ALCCL.</td>
</tr>
<tr>
<td>- There is an increased risk with high degree of texturing and lower risk with lower degree of texturing.</td>
</tr>
<tr>
<td>- Macrotexured devices carried the highest risk and are now no longer available.</td>
</tr>
<tr>
<td>Smooth</td>
</tr>
<tr>
<td>- No known risk of BIA-ALCL with smooth implants</td>
</tr>
</tbody>
</table>

#### Why is this important?

| 80% of BIA-ALCL cases present with an enlargement of one or both breasts, called a seroma. Other (less common) symptoms are breast lumps, hardness of the breast, pain, and skin rash on the breast. |
| All patients diagnosed promptly have been cured; however, more advanced cases and patient deaths have occurred. |
| Treatment typically involves removing the implant and surrounding scar capsule, but may include other therapies such as chemotherapy or radiation. |
| Continue to follow-up with your plastic surgeon for the lifetime of the implant. |
| Review the [FDA: Questions and Answers about Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)](https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/Implants/implants-breastimplants) for more information. |

This decision is related to Decision #2: Implant shape. Discuss with your plastic surgeon your desired preference for how full you want your breasts to look and whether textured or smooth implants are right for you.

### How do I choose the right size?

<table>
<thead>
<tr>
<th>Sizing methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>During your consultation, the plastic surgeon will take measurements of your breasts and chest. Using a variety of methods, the plastic surgeon can help guide you to select the right size implant for you.</td>
</tr>
</tbody>
</table>

#### Key risk of reoperation for cosmetic reasons

<p>| |</p>
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>- Reoperations for cosmetic reasons include implant style or size change.</td>
</tr>
<tr>
<td>- Reoperations carry additional risks.</td>
</tr>
<tr>
<td>- Reduce this risk by carefully selecting with your plastic surgeon an implant size, projection, and style that fits with your body and your goals.</td>
</tr>
</tbody>
</table>

#### Advisory of increased risks with oversized implants

Risk of cervical spine changes, back/neck pain.

---

**Learn more about the risks and complications of breast implants.** This resource from the FDA includes a glossary of risks and photo examples of capsular contracture and saline implant deflation as well as links to additional information and resources about breast implants.

**Notes and additional quality information resources:**
Only the IMF and PA incision options met criteria for consensus

Describes the negative features of each option.

>60% prefer the format for presenting information about:
- options for implant placement and incision location (photos)
- risks of breast augmentation surgery (text description)
Informed by questions respondents most commonly answered incorrectly

Questions are written to help patients appreciate and draw correct inferences about important risks and expectations

Applies the core information set as a reference standard for assessing a patient’s background knowledge

Helps to focus consultations on what patients need to know rather than on what they already know

What else do I need to prepare for decision-making?

Find out how well this decision aid helped you learn the key facts. Check ☑ the best answer.

1. The risk of breast implant associated anaplastic large cell lymphoma (BIA-ALCL) is associated with:
   - Textured implants □ Smooth implants □ I am not sure

2. Unless I experience a complication, it is unlikely that I will need to have another surgery related to my breast implants during my lifetime:
   - True ☑ False □ I am not sure

3. My plastic surgeon and I may not be able to tell if __ implants rupture just by looking at or feeling my breasts.
   - Saline □ Silicone □ Both saline and silicone □ I am not sure

4. After undergoing primary breast augmentation surgery, additional out-of-pocket costs may include:
   (Check ☑ all that apply)
   - Image screening tests for implant monitoring, such as MRI or ultrasound ☑
   - Reoperation(s), one or more repeat surgery related to my breast implants ☑
   - There are no further expenses beyond my initial breast augmentation surgery, everything else is covered by insurance and the breast implant warranty ☑
   - I am not sure

5. The true relationship between breast implants and a wide spectrum of systemic symptoms reported by some women with breast implants has yet to be scientifically defined.
   - True ☑ False □ I am not sure

6. My board-certified plastic surgeon can correct any asymmetry I have with implants so that my breasts are symmetric after surgery:
   - True ☑ False □ I am not sure

7. Capsular contracture is a risk of breast augmentation that can lead to what?
   - I am not sure

8. If __ implants rupture, my plastic surgeon and I will be able to tell by looking at or feeling my breasts.
   - Saline □ Silicone □ Both saline and silicone □ I am not sure

9. How will implants change your breasts? (Check ☑ all that apply.)
   - Make them larger ☑ Lift them ☑ Make them a different shape □ I am not sure

Check your answers for the key facts:

7. Hardening of the affected breast, pain, and an unnatural appearance; commonly requires surgery,
Include tools [worksheet, question list] to discuss options with others (6.3)

Suggest ways to talk about the decision with a health professional (6.2)

 Provides ways to help patients understand information other than reading [audio, video, in-person discussion] (10.5)

88% want a list of risks; risks are applied to the relevant decision

**IPDAS quality items related to presenting outcome probabilities (3.1-3.13)**

---

**What questions should I ask my plastic surgeon?**

<table>
<thead>
<tr>
<th>Key risks and considerations</th>
<th>Notes</th>
</tr>
</thead>
</table>
| **Am I a good candidate for plastic surgery?**
- General risks of surgery:
  - Anesthesia risks
  - DVT/PE |
  - Do I have any specific risk factors in my medical or social history? |
| **Is breast augmentation the right decision to address my cosmetic concerns?**
- General risks of breast augmentation surgery:
  - Bleeding
  - Hematoma
  - Infection
  - Reoperation for complication
  - Reoperation requiring removal without replacement
  - Nipple sensation changes |
| **Which implants will best help me to achieve my goals?**
- How will my specific breast and chest wall anatomy and tissue characteristics impact my cosmetic result?
- Patient-dependent risks and tradeoffs:
  - Asymmetry (preexisting [persistent] or new)
  - Ability to see or feel the implant in a way that is not cosmesisally desirable
  - Implant wrinkling or rippling |
| **What size is right for me?**
- Decision-dependent risks and tradeoffs:
  - Reoperation for cosmetic size exchange |
| **Are my goals realistic?**
- What results can I reasonably expect?
- Decision-dependent risks and tradeoffs:
  - Cosmetic dissatisfaction
  - Reoperation for cosmetic style exchange |
| **How likely are complications?**
- Complications are surgeon-specific. This [icon array tool] can help you and your plastic surgeon talk about risks that matter most to you. |

---

**Current print info, write a question list, and/or take notes during consult (free-text)**

**Certification criteria**

**Crowdsourcing quality criteria**

**Quality criteria**

---

**The Aesthetic Society**
Sample description:

[Risk] within [timeframe]

Description: [e.g., consequences, signs/symptoms, what to do if experience this complication, how to reduce risk]

What does the data show?
Blocks of 100 persons show a ‘best estimate’ of what happens to 100 people following primary breast augmentation with implants over [time frame].

Each person (♀) stands for one person. The shaded areas show the number of people affected.

Data source: [numerator/denominator]

http://clinician.iconarray.com
A main reason patients seek consultation is to learn their next steps (free-text)

Before scheduling surgery
1. Am I clear about what to expect before, the day of, and immediately after surgery?
   - Postoperative expectations (e.g., pain) and restrictions (e.g., exercise)
   - After surgery, you will be given a Device Identification Card that contains your implants unique identifier number. It is important to keep this card for your records because if you experience any issues with your implants this information should be shared with your health care provider and the implant manufacturer.
   - I have received pre- and postoperative instructions from my plastic surgeon

2. What are my financial responsibilities, both now and in the future?

<table>
<thead>
<tr>
<th>What am I responsible for now?</th>
<th>Quote for cost of surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>What will I, or could I, be responsible for in the future?</td>
<td></td>
</tr>
<tr>
<td>Expected out-of-pocket costs associated with implant surveillance (silicone) and maintenance (all implants)</td>
<td></td>
</tr>
<tr>
<td>Possible out-of-pocket costs if I experience a complication following surgery</td>
<td></td>
</tr>
</tbody>
</table>

   | What financial assistance is available? |
   | Implant manufacturer warranty |
   | Cosmetic complication insurance |

3. Find out how comfortable you feel about deciding.

   1. Do you know the benefits and risks of each option? Yes No
   2. Are you clear about which benefits and risks matter most to you? Yes No
   3. Do you have enough support and advice to make a choice? Yes No
   4. Do you feel sure about the best choice for you? Yes No

   If you answered ‘No’ to any of these, you are not ready to make a decision. Consider the following suggested activities to try: based on your specific decision-making needs and discuss with your plastic surgery care team.

   - Need more information? Review the additional quality information resources linked throughout this decision aid, and ask your plastic surgery care team for additional resources specific to your informational needs.

   - Unsure what matters most to you? Work through this decision aid again with your plastic surgery care team, a trusted friend, family member, or significant other.

   - Need more support? List your support concerns and discuss with your plastic surgery care team:

   - If you answered ‘Yes’ to all of these, you are ready to make a decision.

>60% prefer the format for presenting information about financial responsibilities and what to expect immediately after surgery (recovery) (text description)
# Confirm your decision

- I have decided to **proceed** with primary breast augmentation surgery with the following specifications:

<table>
<thead>
<tr>
<th>Fill:</th>
<th>Shape:</th>
<th>Shell:</th>
<th>Manufacturer:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silicone</td>
<td>Round</td>
<td>Smooth</td>
<td>Sientra</td>
</tr>
<tr>
<td>Traditional saline</td>
<td>Anatomic</td>
<td>Textured</td>
<td>Ideal Implant</td>
</tr>
<tr>
<td>Structured saline</td>
<td></td>
<td></td>
<td>Allergan</td>
</tr>
</tbody>
</table>

- I have decided to **decline** primary breast augmentation surgery.

### Considering your decisions selected above, please answer the following questions:

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither Agree nor Disagree</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I feel I have made an informed choice.</td>
<td>❑</td>
<td>❑</td>
<td>❑</td>
<td>❑</td>
<td>❑</td>
</tr>
<tr>
<td>2. My decision shows what is important to me.</td>
<td>❑</td>
<td>❑</td>
<td>❑</td>
<td>❑</td>
<td>❑</td>
</tr>
<tr>
<td>3. I expect to stick with my decision.</td>
<td>❑</td>
<td>❑</td>
<td>❑</td>
<td>❑</td>
<td>❑</td>
</tr>
<tr>
<td>4. I am satisfied with my decision.</td>
<td>❑</td>
<td>❑</td>
<td>❑</td>
<td>❑</td>
<td>❑</td>
</tr>
</tbody>
</table>

**Patient Acknowledgement of Informed Consent**

- I confirm my decision and voluntarily give my consent to undergo primary breast augmentation surgery with the specifications detailed on this form.
- I authorize ___ and assistants to perform the procedure.
- I understand and accept the possibility of unforeseen circumstances that require other procedures not described on this form. I voluntarily give my consent and authorize my surgeon and assistants to perform such procedures as deemed necessary based on the professional medical judgement of my surgeon to save my life or to prevent serious harm to my health.
- I confirm my acceptance and voluntarily consent to be photographed or recorded before, during, and after surgery for the purposes of medical documentation.
- I authorize the release of my protected health information for the purposes of medical device registration and registry reporting.
- I actively participated in a shared decision-making informed consent process with my plastic surgeon and plastic surgery care team as demonstrated in this decision aid and informed consent workbook.

---

**Surgeon Acknowledgement of Informed Consent**

I confirm my agreement with the decision detailed above and agree to perform the procedure as authorized.

---

**The Aesthetic Society**
Provides a publication date.

Includes developers’ credentials / qualifications (1.1)

Provides information about the update policy and next expected update.

Provides information about competing interests and/or policy.

Provides information about the funding sources used for development.

**Development and design**

Hagopian CO, Hagopian TM, Wolfsink EM, Ades TB, Stevens WG. Development and preliminary evaluation of a patient decision aid to replace traditional informed consent documents for primary breast augmentation surgery [unpublished manuscript; not yet submitted for peer-review].

Hagopian CO, Hagopian TM, Wolfsink EM, Ades TB, Stevens WG. An expert consensus study for informed consent in primary breast augmentation surgery [accepted 2020-08-13 for publication in *Aesthet Surg J*].

Hagopian CO, Hagopian TM, Wolfsink EM, Ades TB, Stevens WG. Behaviors and perspectives of women considering primary breast augmentation surgery relevant to decision-making and informed consent [unpublished manuscript; not yet submitted for peer-review].

Breast Device Collaborative Community (BDCC). Jamee Cook, Raylene Hollrah, Mindy Haws MD, Lisa Schlagter, Pat McGuire MD, Andrea Pusic MD, Madris Tomes, Debra Johnson MD, William P. Adams Jr. MD, Rosalyn I'honeti, Kourtho Cavallo, Raina Daurie, Robert Hamas MD. Implant Checklist Submitted FDA 10-2019, 2-1-2020. This checklist was used to cross-check the FDA for content comprehensiveness. BDCC functions to bring together stakeholders with diverse perspectives to address challenges and concerns surrounding breast implants and related topics for the FDA.

**Additional content contributors**

The following contributors are board-certified plastic surgeons who participated in a follow-up survey of active members of the American Society for Aesthetic Plastic Surgery (ASAPS) exploring current practices for confirming patient comprehension before primary implant-based breast augmentation surgery conducted to further inform the content of this decision aid. Additional survey participants chose to remain anonymous.

Benjamin Van Raalte, MD; David J. Levens, MD; Robert Grant, MD; Brian J Lee, MD; Elsa Raske, MD; Scott Greenberg, MD; William Bull, MD; Juhett Sanches, MD; Melinda Haws, MD; Diane Colgan, MD; Winston Santos, MD; Robert Zubowsk, MD; Paul Weiss, MD; Kent V Hasen, MD; Hisham Seify, MD; Tiffany Mccormack, MD; Thomas George Fiala, MD; Mike Burgdorf, MD; Michael Bogdan, MD; Mark Jeffell, MD; Susan MacLen, MD; Tracy Pfeffer, MD; Emily Hartmann, MD; Roberta L Gartsde, MD.
Download the PDA at: www.surgery.org/pda

Making quality decisions about primary breast augmentation surgery
A decision aid to support informed choices that reflect best evidence and what matters most to you

What is the purpose of this decision aid?
This decision aid is designed to prepare you for decision-making and to facilitate shared decision-making with your plastic surgeon, by helping to:
- introduce the decisions necessary to consider before primary breast augmentation surgery,
- educate you on the essential information you need to know to make each decision, and
- identify your goals, values, and preferences relevant to each decision and clearly communicate them to your plastic surgery care team.

Who should use this decision aid?
This decision aid is for you if:
- You are a woman age 18 or older, and
- You are considering primary breast augmentation (enlargement) surgery with saline or silicone implants, for cosmetic reasons.
- Primary breast augmentation means you have not previously had a breast augmentation surgery.

This decision aid is not for you if:
- You are under the age of 18, or
- You are considering breast implant surgery for:
  - reconstructive purposes after breast cancer surgery,
  - revision of a previous breast augmentation surgery, or
  - gender affirming male-to-female surgery.
  - Breast implant surgery for reconstructive, revision, or gender affirming reasons have different or additional information essential for decision-making but not covered in this decision aid, including options, risks, benefits, expectations or limitations.

What content is and is not covered in this decision aid?
- This decision aid includes only the information considered essential for all patients to understand before surgery when considering primary breast augmentation surgery.
- This decision aid may not include information important to your individual decision-making process or relevant to your specific situation, such as information about certain treatment options, risks, or tradeoffs. This decision aid is not a replacement for consultation with a plastic surgeon.

How should I use this decision aid?
Use this decision aid before and throughout the consultation and informed consent process with your board-certified plastic surgeon. It is structured to help you answer the following questions:

- How should I prepare for decision-making?
- Is plastic surgery right for me?
- Should I have breast augmentation surgery?
- What questions should I ask my plastic surgeon?
- What are my next steps?
thank you

contact information
For more info, please contact me directly at:

chelsea.hagopian@alumni.emory.edu
404-307-5004

www.chelseahagopian.com
early experiences using the PDA in practice
Thank you for your time.

Made Possible by an Educational Grant from Allergan Aesthetics
looking ahead

long term goals
scale-up & spread

research
effectiveness evaluation
long-term goals

scale-up

Interactive, defined as allows for user input (both patient and practice), web-based platform with:
- Foundational content to provide the general structure of the PDA (e.g., How to prepare..., Is plastic surgery right for me, etc.), and
- Procedure-specific content blocks.

Modifiable, to populate relevant procedure-specific content when the procedure block is selected.

spread

If prototype is acceptable to end-users (plastic surgeons and patients), the ultimate goal is to have a database of procedure-specific content blocks.

Apply the strategy of mass customization with buildable educational informed consent modules tailored to the specific needs of the individual patient.

PDAs use a variety of mediums to meet the needs and preferences of the target audience

Examples:
- For any decision
- Knee Osteoarthritis: Is it time to think about surgery?
- Advanced care planning
- Hidradenitis Suppurativa Patient Decision Aid

Internet-based PDAs must meet additional quality criteria
scale-up to web-based platform

- Decision summary
- Summary of patient pre-consultation learning & choice predisposition

Example of a PDA decision summary document:
- Knee Osteoarthritis: Is it time to think about surgery?
- Summary of Clinical Priority and Patient’s Preference for Total Joint Replacement
spread to other procedures

Format

Consider changing color coding to make all foundational content a single anchor color and procedure-specific content different colors, e.g., primary breast augmentation [purple], liposuction [blue].

Making quality decisions about aesthetic plastic surgery

Title applicable to all aesthetic plastic surgery procedures

Anchor color (content common to all procedures) Procedure-specific colors

Making decisions about aesthetic plastic surgery

A decision aid to support informed choices that reflect best evidence and what matters most to you.

Purpose of this decision aid

This decision aid is designed to prepare you for each decision concerning surgery and to help you:

- understand the decision to be made before undergoing primary breast augmentation and liposuction surgery;
- use essential information you need to make each decision;
- identify your goals, values, and preferences and clearly communicate them to your plastic surgeon;
- facilitate shared decision-making with your board-certified plastic surgeon.

This decision aid is not for you if:

- You are a woman age 18 or older, and
- You are considering breast augmentation (implants) surgery with saline or silicone implants, for cosmetic reasons.

This decision aid is not for you if:

- You are under the age of 18, or
- You are considering breast implant surgery for reconstructive purposes after breast cancer surgery;
- You are considering a previous breast augmentation surgery, or
- You are considering male-to-female transgender top surgery.

Breast implant surgery for these indications carry different or additional information, including options, risks, benefits, expectations, limitations, and decisions making that are not specifically covered in this decision aid.

Additional or different specifications for consideration with liposuction:

- Additional or different specifications for consideration with liposuction.
# Research

## Preliminary Evaluation

<table>
<thead>
<tr>
<th>Evaluation type</th>
<th>Description</th>
</tr>
</thead>
</table>
| **Preliminary evaluation** (alpha testing) | Acceptability* to relevant medical experts:  
- PDA development process [Acceptability questions in Delphi surveys]  
- PDA [The Aesthetic Society Informed Consent Task Force]  

Quality of PDA [PDA reviewed against IPDAS quality criteria checklist]  

Fidelity of the development process [Adherence to development process model] |
| **Beta (field) testing** | Acceptability of PDA to primary end-users [acceptability questionnaire & ‘Preparation for Decision Making’ scale]:  
- clinicians involved in counseling patients on the index decision patients actively considering the index decision  

Effectiveness [Hagopian et al., 2019, Figure 3, & IPDAS quality criteria checklist]  
- decision quality  
- informed consent process |
| **Comparative effectiveness evaluation** | PDA compared to usual care (traditional informed consent documents) |

*Consideration for further alpha testing with relevant patient experts (previously faced index decision)
## research

**effectiveness evaluation**

<table>
<thead>
<tr>
<th>Evaluation type</th>
<th>Description</th>
</tr>
</thead>
</table>
| **Preliminary evaluation**          | **Acceptability** to relevant medical experts:  
  - PDA development process [Acceptability questions in Delphi surveys]  
  - PDA [The Aesthetic Society Informed Consent Task Force]  
  **Quality of PDA** [PDA reviewed against IPDAS quality criteria checklist]  
  **Fidelity of the development process** [Adherence to development process model] |
| **Beta (field) testing**            | **Acceptability** of PDA to primary end-users [acceptability questionnaire & ‘Preparation for Decision Making’ scale]:  
  - clinicians involved in counseling patients on the index decision patients actively considering the index decision  
  **Effectiveness** [Hagopian et al., 2019, Figure 3. & IPDAS quality criteria checklist]  
  - decision quality  
  - informed consent process |
| **Comparative effectiveness evaluation** | **PDA compared to usual care** (traditional informed consent documents)                                                                 |

*Consideration for further alpha testing with relevant patient experts (previously faced index decision)*
effective informed consent

realistically achieving both the ethical standards and legal requirements for informed consent reliably in practice without imposing additional burdens of time or expense to the clinician or patient

need for measurable outcomes
standard value equation employed in quality improvement of value = quality / cost

decision quality
- informed
- meaningfully involved in decision-making
- decision concordant with patient values

cost
- time
- liability
- revision procedures
- materials & training

PDA research review

1. define best practice for informed consent
2. gap analysis to identify leverage point for improvement
   - traditional informed consent documents → replace with patient decision aids
3. design of a multiphase evidence-based development process model for creating IPDAS/NQF compliant PDAs to replace traditional informed consent documents for elective aesthetic procedures
4. pilot study focused on primary breast augmentation surgery with saline or silicone implants in collaboration with The Aesthetic Society

Figure. Development process model.


Additional references and hyperlinked content, by section

How should I prepare for decision-making?


Links
HONcodeHealth website evaluation tool (https://www.hon.ch/HONcode/Patients/HealthEvaluationTool.html)
American Board of Plastic Surgery (ABPS) FAQs about board certification (https://www.abplasticsurgery.org/public/faqs/)

Is plastic surgery right for me?


Links
Centers for Disease Control and Prevention (CDC) What is Venous Thromboembolism? (https://www.cdc.gov/nccdphp/dvtfacts.html)

Should I have breast augmentation surgery?

Links

What should I know when deciding if breast augmentation surgery is right for me?

Provides information about user testing with target patients and health professionals.

Follows plain language guidelines*,

*Readability scores
SMOG 11-12th-grade
FRY 8th grade

Reports readability levels.*

*Manuscript reporting on the PDA development and preliminary evaluation not yet submitted for peer-review.
SMOG score

SMOG Grading

1. Count 10 consecutive sentences near the beginning of the text to be assessed, 10 in the middle and 10 near the end. Count as a sentence any string of words ending with a period, question mark or exclamation point.

2. In the 30 selected sentences count every word of three or more syllables. Any string of letters or numerals beginning and ending with a space or punctuation mark should be counted if you can distinguish at least three syllables when you read it aloud in context. If a polysyllabic word is repeated, count each repetition.

3. Estimate the square root of the number of polysyllabic words counted. This is done by taking the square root of the nearest perfect square. For example, if the count is 95, the nearest perfect square is 100, which yields a square root of 10. If the count lies roughly between two perfect squares, choose the lower number. For instance, if the count is 110, take the square root of 100 rather than that of 121.

4. Add 3 to the approximate square root. This gives the SMOG Grade, which is the reading grade that a person must have reached if he is to understand fully the text assessed.

**FRY score**

- **8th grade**