Patient Decision Aid Series:

How to Implement in Clinical Practice

Made Possible by an Educational Grant from Allergan Aesthetics
Disclaimer:

Providing ideas and not legal advice

All information presented as of November 16, 2020
Panelists

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Speaker
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Moderator
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Agenda

01 overview of key concepts and how to implement shared decision-making and patient decision aids in practice
02 early experiences & insights using the PDA
03 roundtable discussion and Q&A with the attendees
patient decision aids & shared decision-making

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

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.
Why shared decision making & PDAs in plastic surgery?

Decisions…

- are largely **preference-sensitive**
  - values affect decisions
  - success is decision quality rather than patient uptake of a specific clinical course of action

Decision-making…

- approach may differ from patient-to-patient based on their unique values, preferences, and circumstances
- requires clarifying patient values and preferences & assessing for decisional conflict
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.\(^1\)\(^-\)\(^3\) Informed consent is a process, not a form.\(^4\) 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>Passive</td>
<td>Active</td>
</tr>
<tr>
<td>Signature on a form to <strong>conclude</strong> informed consent</td>
<td>Interactive tool to <strong>prepare</strong> patients for informed consent conversations &amp; <strong>facilitate</strong> 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>
</tbody>
</table>

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shared decision-making & PDAs...

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

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

Making quality decisions about primary breast augmentation surgery
usefulness of the PDA supports a quality decision-making process focusing on 4 commonly overlooked elements of SDM…

1. Explicit statement of the decision or decisions
2. Assess the patient’s decisional needs
3. Tailor decision support to the patients’ needs
   - unique to the individual patient, and
   - according to stage of decision-making
4. Facilitate progress in decision-making
   - maintain awareness of changes in patients’ decisional needs
   - monitor for decision conflict
using the PDA in practice

1. before consult
prepare for decision-making

2. during consult
facilitate shared decision-making

3. after consult
assess decisional needs, identify & address decisional conflict, confirm decision
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? (pages 2 & 9)
- Is plastic surgery right for me? (page 3)
- Should I have breast augmentation surgery? (pages 3-8)
- What questions should I ask my plastic surgeon? (page 10)
- What are my next steps? (pages 11-12)

 tailor decision support to patient needs
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

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 my 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 my 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:


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?

Consider using the HONcode eGuide for Health Consumers [website evaluation tool](#).
“...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.”

clarify patient values & preferences

Should I have breast augmentation surgery?
- Clarify my cosmetic concerns, goals, and preferences
- Set realistic expectations for breast augmentation surgery and implants
- Identify the decisions, options, and what matters most to me when weighing the pros & cons

Why am I considering breast augmentation surgery?
Work through the following questions to clarify your cosmetic breast concerns, goals, and preferences.

What are my cosmetic breast concerns? Check all that apply to you.
- Too small
- Not proportionate with my body
- Deflated after pregnancy or breastfeeding
- Uneven
- Not as firm as when I was younger
- Not as full as when I was younger
- Other cosmetic breast concern or concerns (please specify):

What goals do I hope to achieve with primary breast augmentation? Check all that apply to you.
- Have a more balanced figure
- Increase the size of my breasts
- Make my breasts more symmetrical
- Restore volume:
  - Lost with aging
  - After weight loss
  - After pregnancy or breastfeeding
- Feel more:
  - Attractive
  - Confident naked
  - Feminine
  - Confident in how clothes fit
  - Other (please specify):

What are my preferences for how I want my breasts to look & feel after surgery?
Check □ your preference:
- Minimal fullness
- Moderate fullness
- Maximum fullness

How full do I want my breasts to look after breast augmentation?
Check □ your preference:
- Minimal fullness
- Moderate fullness
- Maximum fullness

How natural do I want my breasts to feel?
Check □ how much it matters to you that your implants feel natural:
- Not important
- Very important

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 surgeon 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.
### Implant style decisions

For each option, check ☑ if you have a preference.

#### Decision #1: Implant fill

<table>
<thead>
<tr>
<th>Options:</th>
<th>Silicone</th>
<th>Saline</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA-approved for:</td>
<td>Women ages 22 and older</td>
<td>Women ages 18 and older</td>
</tr>
<tr>
<td>Key risk of implant rupture or deflation</td>
<td>Risk of “silent” rupture, meaning you and your surgeon will likely not be able to tell if the implant is ruptured just by looking at or feeling the implant.</td>
<td>Saline implants will deflate partially or completely if ruptured, so you will know by looking at or feeling implants.</td>
</tr>
<tr>
<td>Why is this important?</td>
<td>Additional monitoring is needed with imaging tests, such as MRI or ultrasound, periodically over the lifetime of the implant.</td>
<td>No additional monitoring is needed beyond following up with your board-certified plastic surgeon.</td>
</tr>
<tr>
<td>There is more than one type of silicone and saline implants.</td>
<td>Silicone options: There are a range of silicone gel types and styles that range in cohesivity, or consistency, of the implant that vary by manufacturer.</td>
<td>Saline options: Traditional implant is placed deflated and then filled with sterile saline solution, allowing for a smaller incision and minor volume adjustment.</td>
</tr>
<tr>
<td>Implant style options vary by manufacturer.</td>
<td></td>
<td>Structured An inner and outer shell structures how the sterile saline solution fills the implant for a different feel compared to traditional saline</td>
</tr>
<tr>
<td>Why is this important?</td>
<td>Different implants have different risks. Implant manufacturers use different terms to describe their portfolio of implant styles and different methods for collection and reporting of risk data. Specific risk probabilities are not listed in this decision aid because available data does not allow for direct comparison of different implants and their risks across manufacturers.</td>
<td>Review current FDA: Labeling for Approved Breast Implants to learn more.</td>
</tr>
<tr>
<td>Key benefit</td>
<td>Discuss with your plastic surgeon which implant fill option will best meet your desired preference for how you want your breasts to feel.</td>
<td></td>
</tr>
</tbody>
</table>

#### Decision #2: Implant shape

<table>
<thead>
<tr>
<th>Options:</th>
<th>Anatomic</th>
<th>Round</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key risk of implant rotation or displacement</td>
<td>Risk of implant rotation or displacement. Anatomic implants are textured to reduce this risk.</td>
<td>No concern of implant rotation, you will not be able to tell any difference.</td>
</tr>
<tr>
<td>Why is this important?</td>
<td>If a breast implant rotates or becomes displaced your breasts will change shape or become noticeably asymmetric and may require surgical correction.</td>
<td>There is a possibility for round implants to become displaced or flipped in relation to the pocket.</td>
</tr>
<tr>
<td>Key benefit</td>
<td>Discuss with your plastic surgeon which implant shape option will best meet your desired preference for how full you want your breasts to look.</td>
<td></td>
</tr>
</tbody>
</table>
**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 |
| | • Should I consider any alternative or combination procedures to best address my cosmetic breast concerns?  
• If so, what different or additional risks do I need to know? |
| 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 cosmetically desirable  
- Implant wrinkling or rippling |
| | Implant styles vary by manufacturer, and different implants have different risks & benefits |
| | Implant-dependent risks and tradeoffs: |
| | - Implant rupture or deflation  
- BIA-ALCL  
- Capsular contracture  
- Implant rotation or displacement  
- Is my activity level a concern? (such as body-building) |
| 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](https://example.com) can help you and your plastic surgeon talk about risks that matter most to you. |
enhancing support with additional resources
What are my next steps?

- Am I clear about what is expected of me and about what matters most to me?

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>Expected out-of-pocket costs associated with implant surveillance (silicone) and maintenance (all implants)</td>
</tr>
<tr>
<td>What financial assistance is available?</td>
<td>Implant manufacturer warranty</td>
</tr>
<tr>
<td></td>
<td>Cosmetic complication insurance</td>
</tr>
</tbody>
</table>

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.

Assess & address decisional conflict

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></td>
<td></td>
<td></td>
<td></td>
</tr>
<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></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Placement</th>
<th>Incision location</th>
<th>Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subpectoral</td>
<td>IMF</td>
<td>Left</td>
</tr>
<tr>
<td>Subglandular</td>
<td>Periareolar</td>
<td>Right</td>
</tr>
</tbody>
</table>

- I have decided to decline primary breast augmentation surgery.

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

1. I feel I have made an informed choice. Strongly Agree Agree Neither Agree nor Disagree Disagree Strongly Disagree
2. My decision shows what is important to me. Strongly Agree Agree Neither Agree nor Disagree Disagree Strongly Disagree
3. I expect to stick with my decision. Strongly Agree Agree Neither Agree nor Disagree Disagree Strongly Disagree
4. I am satisfied with my decision. Strongly Agree Agree Neither Agree nor Disagree Disagree Strongly Disagree

*Effective Decision Scale Score of the Decisional Conflict Scale © AM O'Connor, 1993; revised 2005*
early experiences using the PDA in practice
thank you

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Thank you for your time.

Made Possible by an Educational Grant from Allergan Aesthetics