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AMERICAN SOCIETY OF PLASTIC SURGEONS: DERMAL FILLER SAFETY CONSIDERATIONS

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  - Development
  - Academic affairs Council

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- Consultant, Allergan Corp.
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- Consultant, Guidepoint Global
- Consultant, Gerson Lehrman Group
- Investor, Red Rock Holdings (Scar Guard)
- Investor, Stock Holder, Evolus Inc.

Patient education and informed consent procedures key for use of dermal fillers

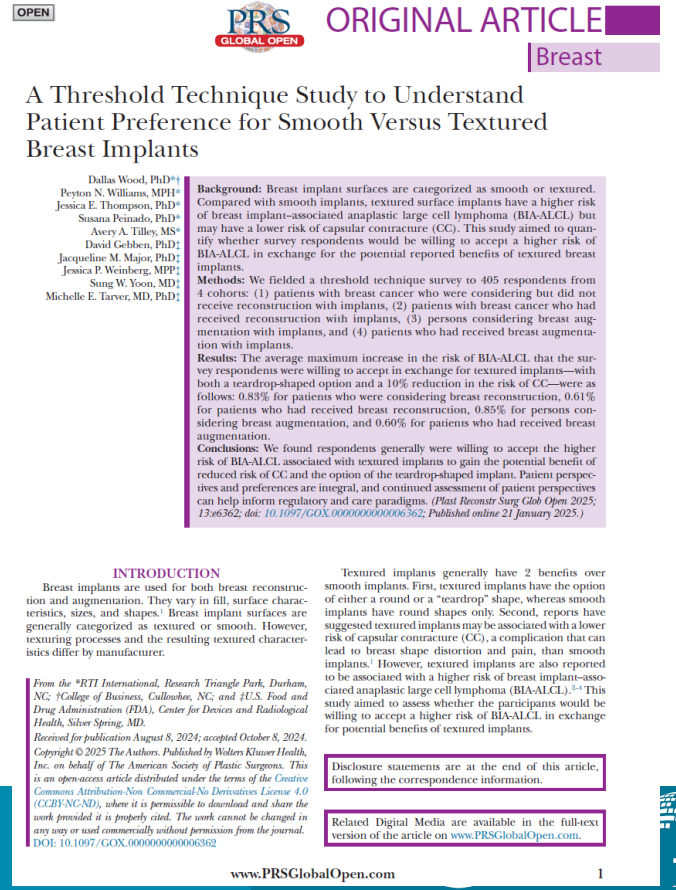
- ASPS advises members to obtain informed consent for all dermal filler procedures, which is an opportunity to discuss the risks and benefits of the procedure. This includes:
  - Type of product being considered.
  - Options for dissolution of filler if needed or desired (e.g., use of hyaluronidase or excision).
  - Location of injection and discussion of on/off-label use.
  - If injecting in the neck/chest/breast area – discussion of impact on cancer screenings (breast, head, neck, thyroid) and other radiological examinations.
  - Remind patients to inform relevant physicians about injections (placement and type of product)
  - Setting realistic expectations, including the range of outcomes that can be expected with the use of fillers or alternative or combination treatments.

New indications for dermal fillers/ alternative products to dermal fillers

- Off-label use (i.e., in the décolletage) should be clarified in the informed consent process.
- Anatomy and downstream impacts vary with each new indication of use, and new uses should be properly evaluated for risks and benefits.
- Migration is also a possibility and should be part of the discussion.
- Human or animal fat tissue-derived dermal and subcutaneous filler products offer an alternative to patients for some indications.
  - –Regenerative products tend not to interfere with imaging as they tend to become tissue
  - –Potential interference with imaging will be different based on each filler, and patients should be aware of the type of material being injected.

Incorporation of Patient Preference Research

- Patient preference studies collect data on which treatment aspects matter most to patients, including the tradeoffs they are willing to make.
- Patients may weigh risks differently than physicians and researchers: patient insights can help drive relevant study endpoints.



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ORIGINAL ARTICLE
Breast

A Threshold Technique Study to Understand Patient Preference for Smooth Versus Textured Breast Implants

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Background: Breast implant surfaces are categorized as smooth or textured. Compared with smooth implants, textured surface implants have a higher risk of breast implant–associated anaplastic large cell lymphoma (BIA-ALCL) but may have a lower risk of capsular contracture (CC). This study aimed to quantify whether survey respondents would be willing to accept a higher risk of BIA-ALCL in exchange for the potential reported benefits of textured breast implants.

Methods: We fielded a threshold technique survey to 405 respondents from 4 cohorts: (1) patients with breast cancer who were considering but did not receive reconstruction with implants, (2) patients with breast cancer who had received reconstruction with implants, (3) persons considering breast augmentation with implants, and (4) patients who had received breast augmentation with implants.

Results: The average maximum increase in the risk of BIA-ALCL that the survey respondents were willing to accept in exchange for textured implants—with both a teardrop-shaped option and a 10% reduction in the risk of CC—were as follows: 0.83% for patients who were considering breast reconstruction, 0.61% for patients who had received breast reconstruction, 0.85% for persons considering breast augmentation, and 0.60% for patients who had received breast augmentation.

Conclusions: We found respondents generally were willing to accept the higher risk of BIA-ALCL associated with textured implants to gain the potential benefit of reduced risk of CC and the option of the teardrop-shaped implant. Patient perspectives and preferences are integral, and continued assessment of patient perspectives can help inform regulatory and care paradigms. *(Plast Reconstr Surg Glob Open 2025; 13:e6362; doi: 10.1097/GOX.0000000000006362; Published online 21 January 2025.)*

INTRODUCTION

Breast implants are used for both breast reconstruction and augmentation. They vary in fill, surface characteristics, sizes, and shapes.[1] Breast implant surfaces are generally categorized as textured or smooth. However, texturing processes and the resulting textured characteristics differ by manufacturer.

Textured implants generally have 2 benefits over smooth implants. First, textured implants have the option of either a round or a "teardrop" shape, whereas smooth implants have round shapes only. Second, reports have suggested textured implants may be associated with a lower risk of capsular contracture (CC), a complication that can lead to breast shape distortion and pain, than smooth implants.[1] However, textured implants are also reported to be associated with a higher risk of breast implant–associated anaplastic large cell lymphoma (BIA-ALCL).[2–4] This study aimed to assess whether the participants would be willing to accept a higher risk of BIA-ALCL in exchange for potential benefits of textured implants.

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Incorporation of Patient Preference Research

- Example patient preference study for use of dermal fillers in decolletage:
  - Explore preferences of women with dense breast tissue or elevated risk of breast cancer.
  - Would patients accept a tradeoff of uncertainty related to breast screenings against the benefits of decolletage skin rejuvenation?

- ASPS hopes companies will voluntarily explore and consider patient preference research and consider patient preference as part of ongoing regulatory submissions to the FDA.

- ASPS urges the panel to consider appropriate times when patient preference research can best support indication expansion and updates to labeling.

Thank You

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