

Textured Implant Exposure in a Breast Reconstruction Cohort: Longitudinal Analysis of Outcomes, Management, & Disposition over 25 Years

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Background

- Breast cancer affects 1 in 8 women in Canada, and for patients who choose breast reconstruction, implants are a common post-mastectomy surgical option.^{1,2}
- Textured breast implants were widely used until evidence suggested they confer a risk for breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), ranging from 1/1306 to 1/19,551 women in Canada.^{3,4}
- In 2019, a global voluntary recall of Allergan BIOCELL® macrotextured implants and tissue expanders was issued due to association with BIA-ALCL, and their use has since been discontinued in Canada.⁴
- This prompted an urgent need to identify exposed patients, communicate risks, and provide education, counselling, and follow-up.
- As of 2024, Canada has ~76 confirmed BIA-ALCL cases, with 3 reported deaths.⁵
- Emergence of BIA-ALCL revealed key gaps in post-market surveillance and breast reconstruction care, with limited data on long-term patient outcomes following textured implant exposure and effectiveness of recall and follow-up strategies.

Challenges with textured breast implants

- BIA-ALCL:** An uncommon T-cell lymphoma linked to textured breast implants, arising in the peri-implant fluid or capsule.³
- Chronic inflammatory response:** Driven by high surface area and biofilm sequestration.⁵
- Mechanical friction:** Leading to possible late-onset seroma and double-capsule formation.⁷
- High rupture risk:** Increased surface friction may contribute to greater shell wear and rupture risk.⁸

Microtextured surface
100-200mm²

Adapted from [9]

Increasing surface area

Macrotextured surface
200-300mm²

Objectives

Evaluate the effectiveness of Textured Device Clinics in identifying exposed patients and providing counselling

Assess the long-term health outcomes in exposed patients and shared decision-making regarding management strategies

Characterize the prevalence of ongoing textured implant retention following the recall

Methods

 **PATIENT IDENTIFICATION**

- Review of operative logbooks (2000–2025)
- Patients exposed to textured implant: n = 288
- Patients with accessible medical chart data: N = 227

 **PATIENT CONTACT**

- Certified letters sent notifying patients of textured implant recall and associated BIA-ALCL risk

 **EDUCATION & CLINICAL ASSESSMENT**

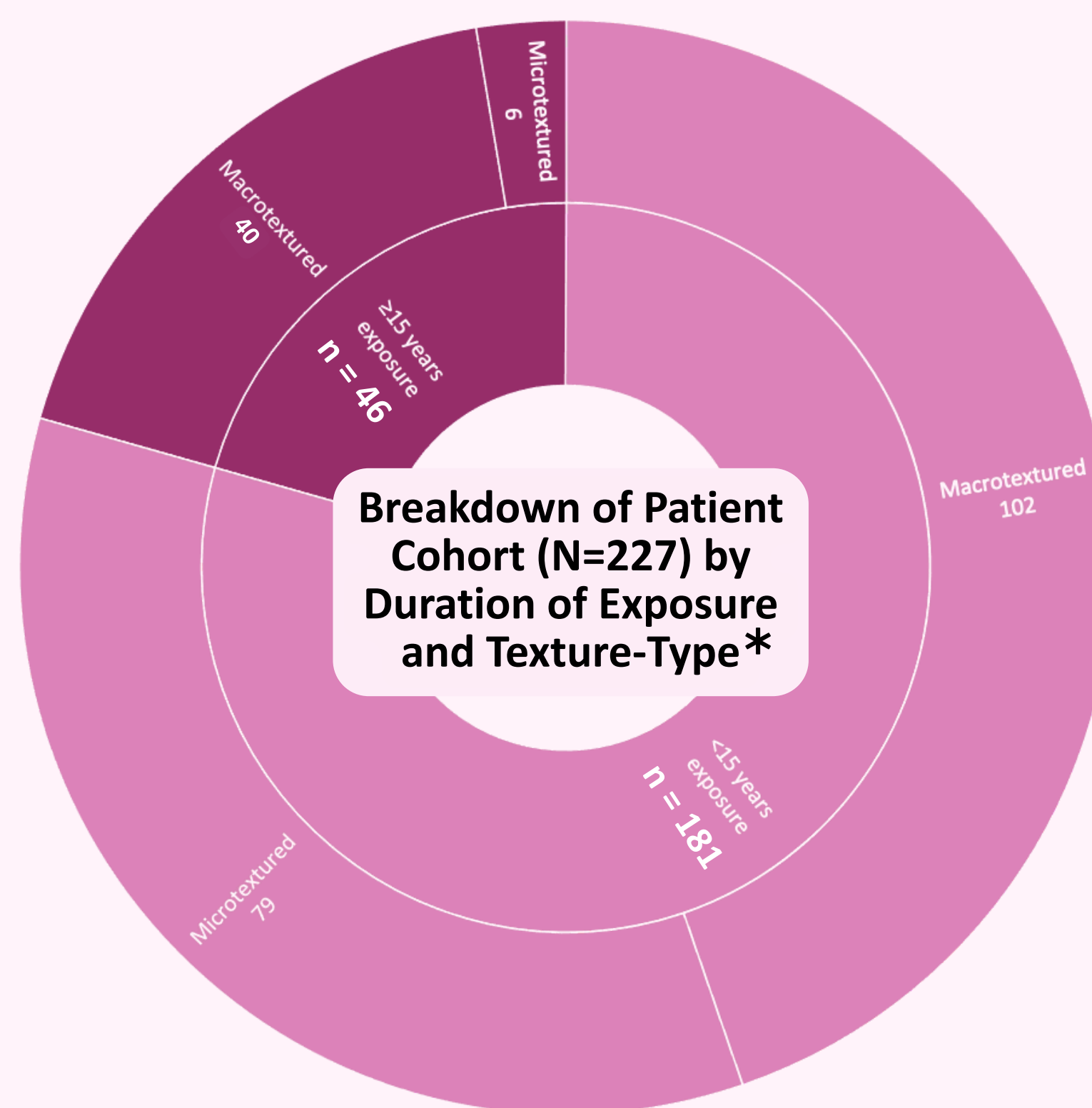
- Textured Device Clinics established:
 - Group teaching seminar
 - Individual consultation and clinical evaluation

 **RETROSPECTIVE CHART REVIEW**

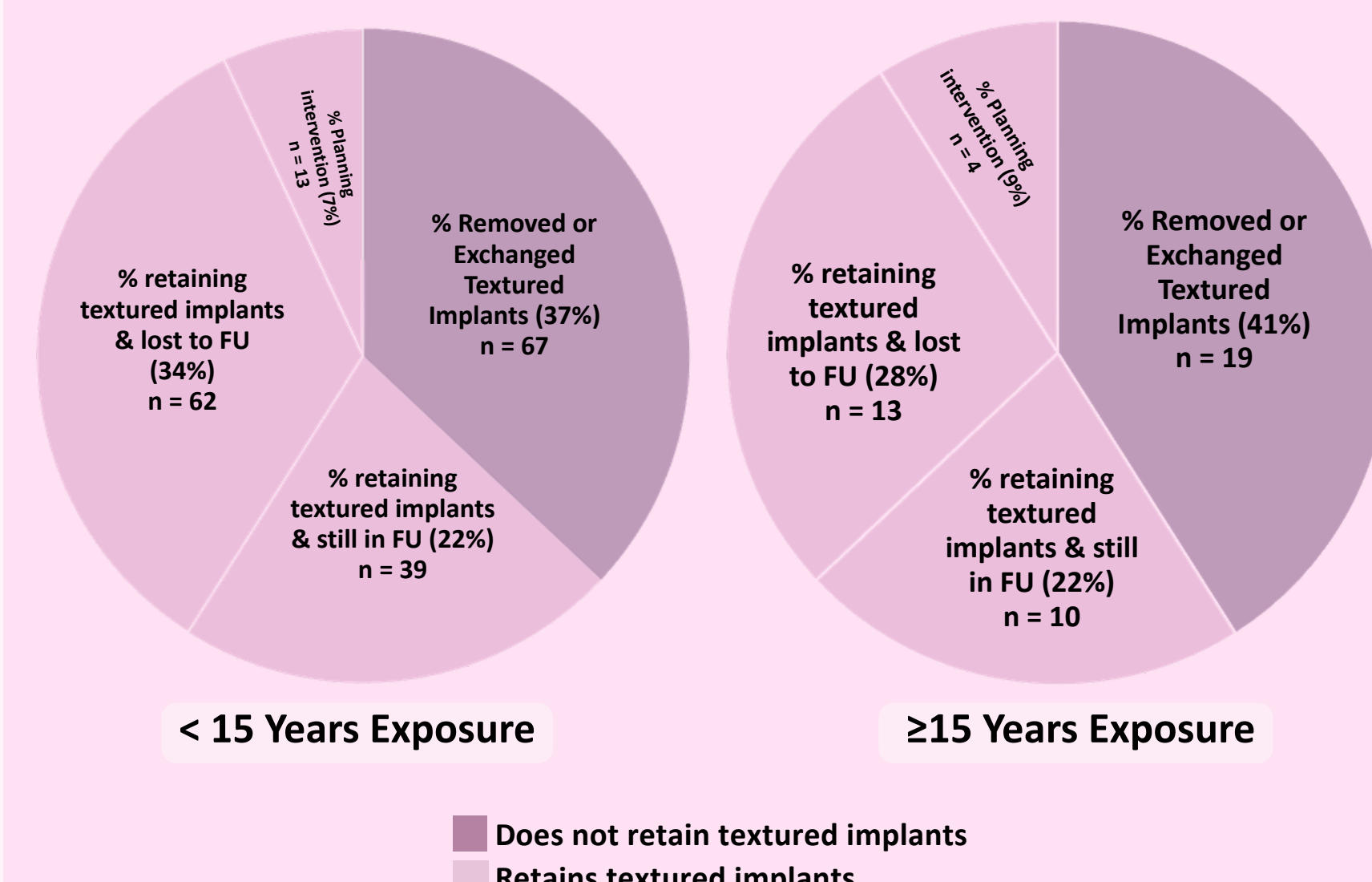
- On-going; assessing:
 - Follow-up
 - Recurrent breast cancer
 - BIA-ALCL diagnoses
 - Imaging, rupture, contracture
 - Surgical intervention and elective revision

Results

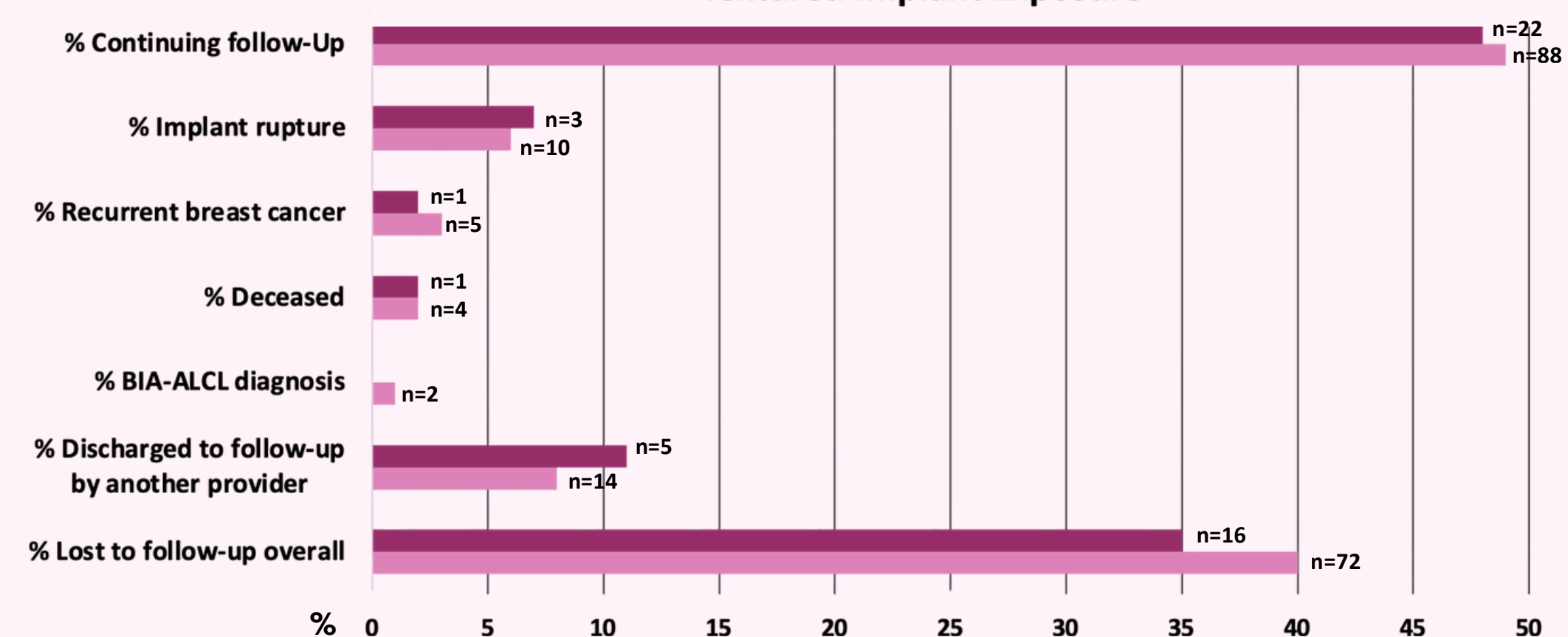
- ≥ 15 years exposure to textured devices
- < 15 years exposure to textured devices
- * p<0.05



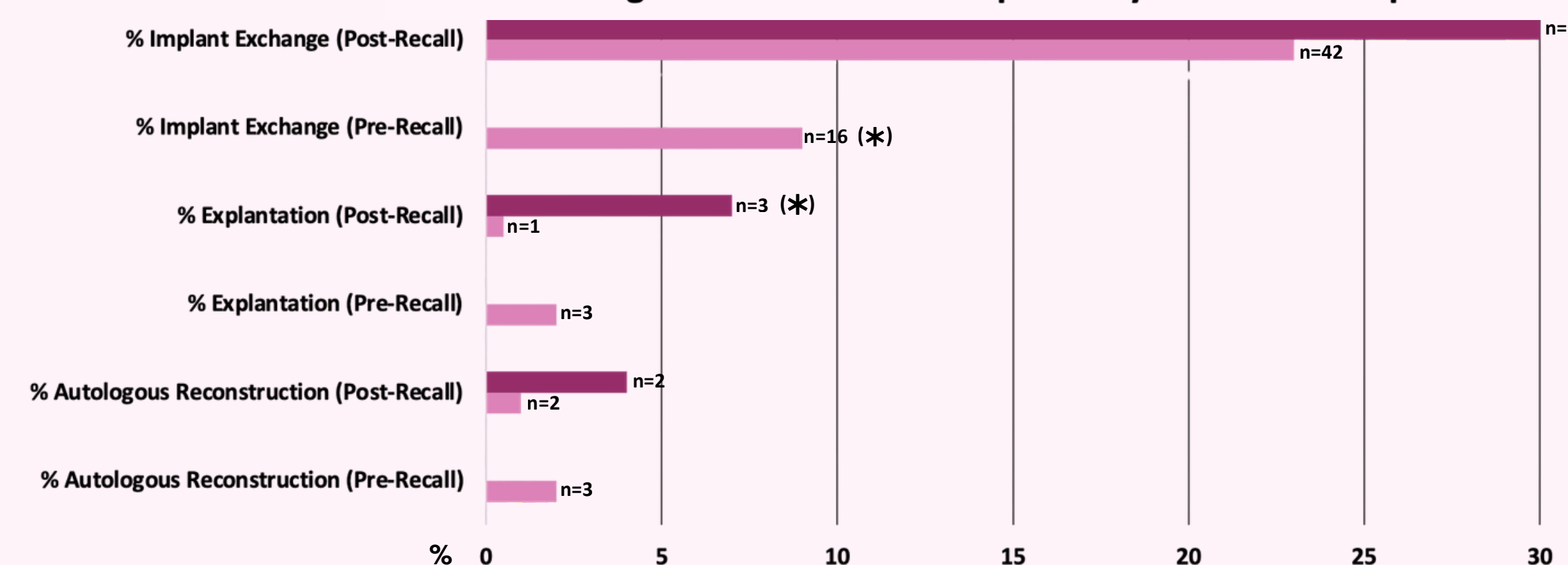
Disposition of Patients according to Duration of Exposure to Textured Implants



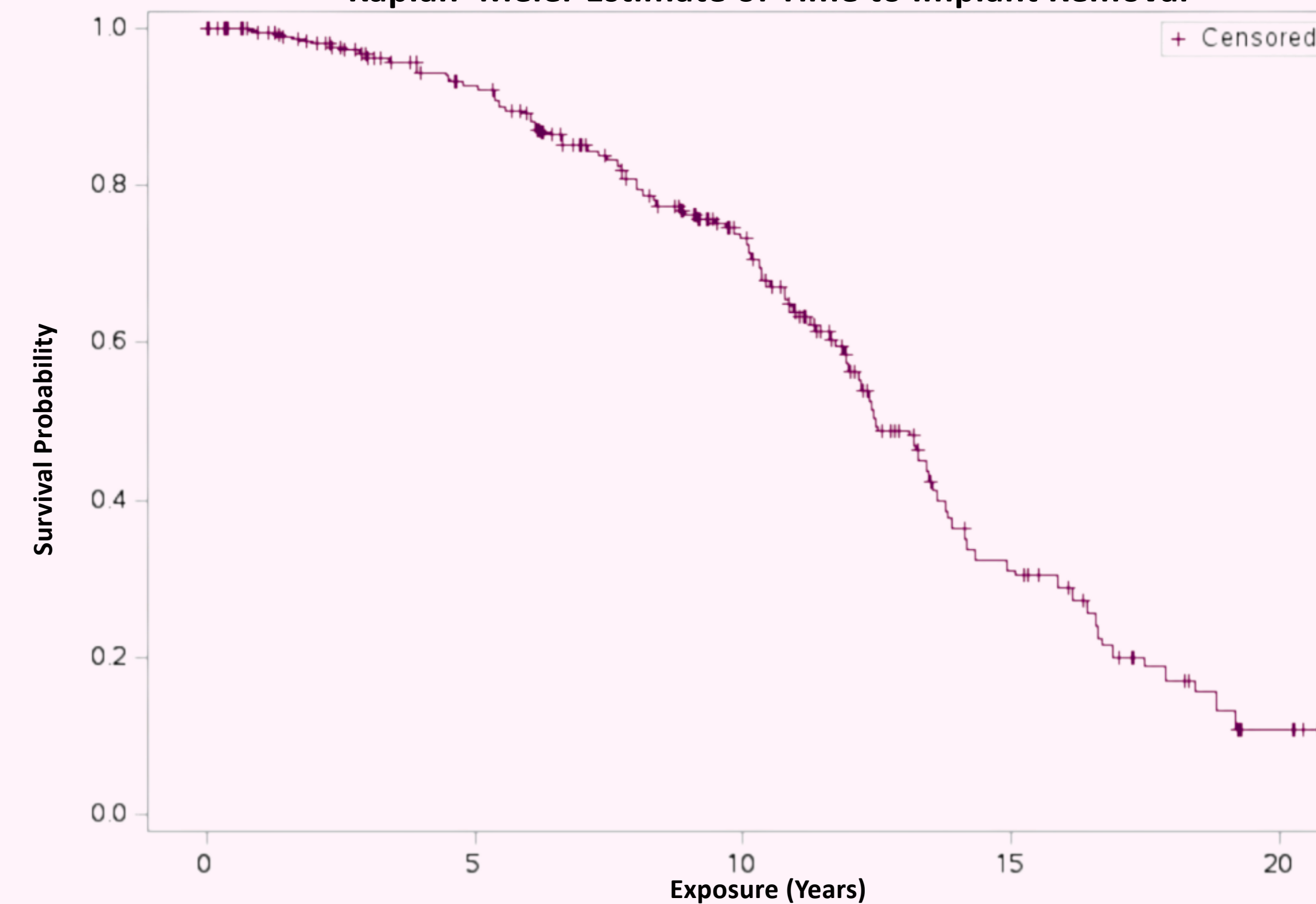
Clinical Outcomes & Disposition by Duration of Textured Implant Exposure



Management of Textured Implants by Duration of Exposure



Kaplan–Meier Estimate of Time to Implant Removal



Discussion

Key Findings

- The probability of a textured breast implant remaining in-situ is estimated to be ~ **75% at 10-years and 10% at 20-years**.
- Management patterns differed significantly by exposure duration with **pre-recall implant exchange seen only in the <15-year group** (8.8% vs. 0.0%; p=0.047) and **post-recall explantation more common in the ≥15-year group** (6.5% vs. 0.6%; p=0.027).
- Implant exchange post-recall was overall the most frequent intervention in both groups**, with a relatively higher proportion of explant and exchange post-recall in patients with ≥15 years of textured implant exposure.
- Overall, the majority retained textured implants**, with a higher proportion in the ≥15 years exposure group.
- BIA-ALCL incidence was 2 in 227 women** (0.90%), both with <15 years exposure to macrotextured implants.
- Intervention decisions were driven by:** cancer recurrence, rupture, anxiety, pain, capsular contracture, cosmesis, patient preference, etc., not solely BIA-ALCL concerns.

Impact

- Assesses long-term outcomes, including BIA-ALCL, in patients exposed to textured implants, adding to the limited evidence on the incidence of BIA-ALCL.
- Models longitudinal retention of textured breast implants and time-to-removal.
- Demonstrates approach for identifying at-risk patients, delivering education, and managing textured implant complications.
- Highlights need to advocate for resources and funding to support breast cancer survivorship and on-going follow-up programs.

Next Steps

- Assess device-, treatment-, clinical-, and patient-level predictors of time-to-textured implant removal using an exploratory multivariable analysis.
- Assess the impact of the BIOCELL® recall on patient decision-making and implant disposition by comparing indications for intervention pre- and post-recall.
- Further characterize longitudinal patterns of implant management to inform follow-up care and counseling.

