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Symptoms and Diagnoses of 449 Women Before and After Explant Surgery: Implications for “Breast Implant Illness,” Registries, and Informed Consent

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Background

- ◆ Manufacturers excluded women with history of autoimmune disease from studies submitted to FDA.
- ◆ FDA's 2005 Summary for Inamed/Allergan's data, "the increases in the following CTD categories occurred despite age": general issues, muscle weakness, joint pain, and skin symptoms.
- ◆ FDA's Summary for Mentor: significant increases in fatigue, exhaustion, joint swelling, frequent muscle cramps, joint pain, and fibromyalgia among augmentation patients "not due to age."

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Background

- ◆ Manufacturers' Breast Implant Booklets state:
Caution: “Notify your doctor if you have any of the following conditions, as the risks of breast implant surgery may be higher: Autoimmune Diseases (for example, lupus and scleroderma).”
- ◆ **The FDA website does not include that warning.**
- ◆ The FDA, manufacturers, and plastic surgeons have stated there is “no evidence” of systemic disease from breast implants despite research on **symptoms**.
- ◆ A 2018 Israeli study of 11,500 women with implants found **significant increases in Sjögren's syndrome, MS, and other disorders.**

Methods of Our Study

- ◆ Contacted **792 women** who had previously asked NCHR for help getting insurance coverage for implant removal. We were familiar with their medical issues prior to explant. All had implants removed in 2016, 2017 or 2018.
- ◆ Emailed them a link to an online survey **November 2018-January 2019**
- ◆ **57% (449 women)** filled out questionnaire

Why Women Wanted Their Implants Removed (all that apply)

- ◆ 54% because of **breast pain**
- ◆ 34% because of **breast hardness** (capsular contracture)
- ◆ 27% because of **rupture**
- ◆ **85%** because of **other health issues**

Table 1 – Patients' Characteristics

Sociodemographic Characteristics	Number of Patients (N= 451)	
Age, years	440	$\bar{x} = 49$
Race		
White	407	93%
Black or African American	5	1%
Other	23	6%
Ethnicity	439	
Hispanic	33	8%
Type of Implants	448	
Saline filled	216	48%
Silicone gel filled	175	39%
Both (more than one set of implants)	55	12%
Don't know/Unsure	2	0.4%
Number of breast implants total	449	
1 implant	64	14%
2 implants	291	65%
3-4 implants	65	14%
5 or more implants	7	7%
Diagnosis of implant rupture	448	
Yes	126	28%
No	300	67%
Don't know/Unsure	22	5%

Demographic Traits and Implant History

- Ages ranged from **24-82** ($\bar{x}=49$). One-third were between the ages of 40-49.
- **93%** identified as White
- Three out of 4 (**77%**) had implants for **at least 10 years**. Almost two-thirds (65%) had a lifetime total of 2 implants. 21% had more than 2 implants.
- **48%** had **saline** implants, **39%** had **silicone gel**, and 12% had both.

Medical History

- **59%** reported that their symptoms lasted at least 5 years before explant; **25%** of women reported more than 10 years.
- **28%** reported that their doctor told them after removal that their implants were ruptured.
- **56%** reported having an **en bloc** surgery to remove their implants and **26%** reported having a **total capsulectomy**.

Autoimmune Diseases

69% had a **family history** of autoimmune disease

3% had a **personal history** of autoimmune disease before getting breast implants

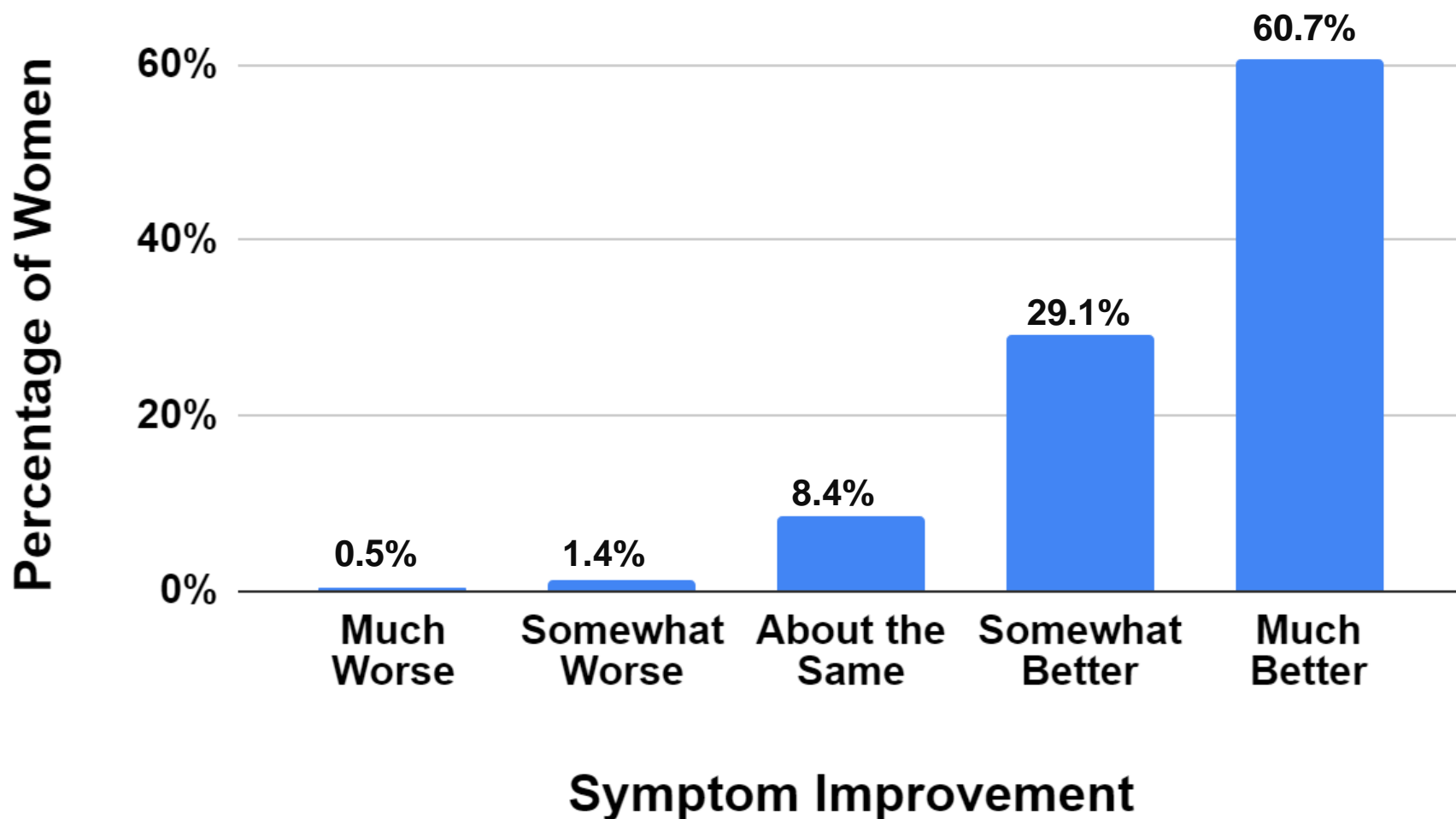
51% reported that they were diagnosed with an autoimmune disease after getting their breast implants.

Most common symptoms prior to surgery

1. **Joint, Muscle, or Back pain, weakness, stiffness**
2. **Fatigue**
3. **Brain Fog, Memory & concentration issues**
4. **Anxiety and Depression**
5. **Hair loss**
6. **Breast pain**
7. **Skin Irritation (rashes, itchiness, dry skin)**
8. **General Pain (body aches, pain, nonspecific pain)**
9. **Gastrointestinal problems**

Other symptoms included dry eye or vision problems, other allergies and autoimmune symptoms)

“Are the symptoms you listed above better, worse, or about the same, since having your implants removed?”



Individual Variables that Predict Improvement After Explant

	N	Odds Ratio (95% CI)	p-value
# of Years you had Implants <u>10+ years</u>	429	0.23 (0.07, 0.76)	0.016
Had <u>Autoimmune Symptoms</u> <u>Before Implants</u>	429	0.41 (0.19, 0.90)	0.026
<u>Rupture</u> or Leakage as Reason for having implant removed	429	0.51 (0.27, 0.99)	0.045
Other health related issues (BII) as Reason for having implant removed	429	2.32 (1.13, 4.81)	0.022
Cosmetic as Reason for having implant removed	429	0.35 (0.12, 1.00)	0.050
En Bloc or Total Capsulectomy for removal	357	2.97 (1.34, 6.56)	0.007

Logistic Regression: Variables that Independently Predict Improvement After Explant (Adjusted for confounders)

	N	Odds Ratio (95% CI)	p-value
Family History of Autoimmune Disease	357	0.33 (0.14, 0.77)	0.010
En Bloc or Total Capsulectomy Removal	357	2.54 (1.09, 5.91)	0.031

Conclusions

- Many women have systemic symptoms and diseases for years before explant surgery.
- The symptoms and diseases women report (BII) are the same ones that were reported to the FDA prior to approving breast implants.
- Family history and # years with implants has significant impact on patients' health after explant.
- How implants are explanted has significant impact on patients' health.

Implications

- **Informed Consent:**
 - Women need to be warned about possible role of **family history**.
 - Women need to be informed that **systemic symptoms (BII) may be caused by implants**.
 - Women need to be informed that appropriate **explant can significantly improve health**
- **Registries will not be good source of data unless they include systemic illness, because many women can't afford explant**



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