A Qualitative Study on the Experiences of Women With Breast Implant Illness

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Disclosures: Dr Adams is an FDA IDE investigator for Motiva. The other authors declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

Funding: This study was supported by an Aesthetic Surgery Education and Research Foundation (ASERF) grant. Dr Newby is supported by an Australian Medical Research Future Fund Career Development Fellowship (APP1145382). Dr Faasse is supported by an Australian Research Council (ARC) Discovery Early Career Research Award (DE180100471). The ASERF, MRFF and ARC had no involvement in any aspect of the study, nor the preparation of this manuscript.

Abstract

Background: Breast Implant Illness (BII) is a term used to describe physical and psychological symptoms experienced by some women following breast implant surgery. Few studies have examined the experiences of women with BII – a poorly understood condition with no clear cause or treatment.

Objectives: To explore women's experiences of BII, including symptoms, healthcare encounters, social media and explant surgery.

Methods: Using an exploratory qualitative methodology, researchers undertook semi-structured interviews with twenty-nine women who self-identified as having BII**.** Interviews were audio-recorded and transcribed verbatim. Data were analyzed using inductive thematic analysis.

Results: Thematic analysis of the interviews identified six themes: 1. Symptoms without explanation; 2. Invalidation and invisibility; 3. Making the BII connection; 4. Implant toxicity; 5. Explant surgery: solution to suffering?; and 6. Concealed information. BII was described as distressing and debilitating across multiple domains including relationships, work, identity, physical and mental health, and symptoms were attributed to implant toxicity and immune system rejecting foreign objects. When their experience was not validated by health care professionals, many looked to social media for information, support and understanding, and explant as their only chance at recovery.

Conclusions: BII is disabling mentally and physically. Women with BII require support, understanding, and validation, and proactive treatment to prevent disability. With unclear pathophysiology, future research should examine how biopsychosocial approaches can be used to guide treatment, and how to best support women with BII, focusing on early detection and evidence-based education and intervention.

Breast implant surgery was first introduced in the early 1960s and quickly became one of the most common cosmetic surgeries in the world. In 2018 alone, over 1.8 million individuals underwent breast implant surgery worldwide.[1] Moreover, breast augmentation surgery was the most common aesethetic surgery performed in the United States in 2019.[2] Some women have reported experiencing a host of non-specific physical and psychological symptoms, including fatigue, pain, brain fog, depression and anxiety, following breast implant surgery. In recent years, the term 'Breast Implant Illness' (BII) has been used to describe this constellation of distressing and disabling symptoms.[3] The etiology and underlying pathophysiology of this condition have not yet been confirmed; however, we will use the term BII to describe groups of systemic symptoms reported by some women with breast implants, for the purposes of this paper.

Despite the growing attention to BII among consumer groups, advocates and the medical profession, and anecdotal reports of a growing demand for explant surgery,[4] there is a lack of peer-reviewed, scientific research on BII.[5] A few quantitative studies have investigated the symptoms and experiences of women with BII.[6-8] Two of these studies[6,8] examined the symptoms of women with BII prior to and after explant surgery to remove their implants, and found that explant surgery was associated with significant improvement or resolution of at least some BII symptoms. Another study compared the symptoms and experiences of women with and without self-reported BII using an online survey.[7] Compared to women without BII, women with BII reported more severe levels of somatic symptoms (e.g., pain, fatigue), cognitive problems, and depression and anxiety, with most women with BII reporting an onset of symptoms within two years of surgery. Somewhat surprisingly, women with BII who had undergone explant surgery continued to show more severe physical and psychological symptoms compared to women without BII, suggesting that explant surgery was not entirely effective in alleviating BII symptoms.

Women who report having BII commonly share experiences and seek information and support via social media groups.[7] These groups frequently involve discussion of symptoms, surgical management, and experiences and attitudes towards medical providers.[9] Many members of these online platforms report believing that the symptoms associated with BII are due to the leaching of toxic chemicals into the body, and the body's subsequent immune response.[10] Qualitative analyses of

posts on social media groups reveal that these groups are seen as supportive and validating by its group members;[9] however, several experts have theorized that the internet and social media may serve to exacerbate anxiety, through the spread of misinformation about the toxicity of breast implants[4,11-13] that has not been demonstrated in standard breast implant toxicology analyses.

Understanding patients' beliefs about BII will provide an important piece of the current clinical puzzle. Across a large variety of physical and psychological conditions, patients develop a set of beliefs to help them understand their illness, commonly referred to as *illness perceptions.*[14] These perceptions are not always aligned with medical understandings of the patient's illness[15], yet can have a more powerful impact on patient outcomes, including distress, disability, recovery and treatment-related behaviour, compared to physiological markers of disease,[16],[17] Of particular relevance to BII, beliefs about the cause of illness can influence decisions about treatment and other self-management behaviours. For example, breast cancer patients were more likely to opt for bilateral mastectomy if they believed their cancer was caused by genetic or hormonal factors, compared to those who attributed their illness to bad luck.[18] Women's perceptions of their BII may differ markedly from medical and scientific knowledge, and better understanding these beliefs will offer important insights into patient decision making.

Quantitative research designs do not yield detailed insights into women's illness perceptions, the impact of symptoms on their daily functioning, or their experiences of the health care system, social media, and other sources of support. Qualitative research elicits more in-depth accounts of individual experiences and is ideally-suited to exploring conditions which are complex and poorly-understood.[19,20] Moreover, an understanding of patient experience can help inform intervention development, particularly when there is a combination of somatic and psychological symptoms. To date, only one qualitative study of BII has been conducted. This study examined the perceived challenges, barriers and worries examined by women with breast implants.[21] In contrast, the purpose of the current study was to explore the experiences of women who self-report experiencing BII through in-depth interviews, including their experience of symptoms, their beliefs about the causes of BII, the health care system, social media, and explant surgery.

METHODS

Participants and Recruitment

Participants were recruited via advertisements on Facebook and Instagram, posts on BII social media support groups, and via direct recruitment in USA-based plastic surgery clinics. Recruitment and interviews took place between August 2019-December 2019. Eligible participants were (i) women who have experienced negative physical or psychological effects following breast implant surgery, (ii) fluent in English, and (iii) willing to provide informed consent. All procedures were approved by the UNSW Human Research Ethics Committee (approval number: HC190578). All participants were reimbursed $20AUD for taking part in the study.

Procedure

Participants signed up to the study and provided online informed consent and basic demographic and surgical history information (see Tables 1 and 2) via the Qualtrics survey platform (Qualtrics, Seattle, WA, and Provo, UT, USA)[22]. Interviews were arranged via email and conducted via phone[23], or the video conferencing program, Zoom (Zoom Video Communications, Inc., San Jose, CA, USA)[24]. All interviews were audio-recorded, with participants' consent. Interviews were conducted by either JMN (a clinical psychologist) or ST (a psychologist) and transcribed verbatim. The interviewers were not previously known to participants. Interviews were semi-structured in format with interviewer prompts derived from previous research into BII experience (see Table 3 for interviewer prompts).

Data Analysis

As the purpose of this research was exploratory, we utilized inductive thematic analysis[25] underpinned by a critical realist approach,[26] to analyze the data. Thematic analysis is a robust and transparent qualitative approach with significant utility in the exploration of patient experience.[27] ST and JMN read the transcripts in detail, taking notes and independently coding transcript data. These codes were discussed, renamed and grouped together, with clusters of repeated, important or convergent ideas forming themes. Identification, naming and grouping of themes and subthemes were then further

refined in consultation with NA. Final themes were agreed upon by all authors. The thematic analysis process is further outlined in Table 4.

RESULTS

Participant Characteristics

A total of 32 interviews were conducted, with recruitment for the study ending at the point of meaning saturation.[28] The duration of interviews ranged from 20 minutes to 54 minutes. Data from three participants were excluded from the analysis due to technical problems in recording their interviews, resulting in a final sample of 29 women. The age of participants ranged from 29 to 73 years (M = 43.27). All participants were of female sex, and there were no transgender women. Tables 3 and 4 present the demographic and surgical characteristics of the sample. Five participants chose not to provide in-depth demographic information. For this reason – and to protect all participant anonymity – individual demographic data has not been reported with quotes.

Themes

Thematic analysis produced six themes, as outlined in Table 5. Key themes and subthemes, alongside illustrative quotes, are described below.

Theme 1: Symptoms Without Explanation

Symptom After Symptom

The first theme captures the progressive nature, course and severity of participants' symptoms. Symptoms were described as being unpredictable, with participants describing the emergence of new, unexplained symptoms over time. Participants reported a wide range of symptoms, including chronic fatigue and chronic pain. For some participants, new symptoms replaced old symptoms, whereas for other participants, new symptoms added to existing symptoms. For most participants, the severity and impact of reported symptoms worsened over time.

> *I just noticed that year I was just tired all the time and my energy was really, really low. And I had a hard time exercising, was going to bed earlier, I was waking up still feeling tired, like I haven't got enough sleep when I had. My lymph nodes were really swollen, I constantly had*

itchy skin, my hair was thinning, my eyes were dry. Just symptoms after symptoms after symptom would start and it wouldn't stop. – Participant 6

Left Without Answers

Participants described seeing multiple health professionals to determine the cause of their symptoms, getting inconclusive or 'normal' results from numerous tests and investigations. This left participants without answers.

It was like test after test comes back, quote normal, and desperately you're trying to tell them I'm not normal, something's going on, and I mean I've been to so many doctors I don't even remember all their names. – Participant 10

Loss of Identity

Many women felt like they had lost their old self due to their illness. They no longer felt able to connect with others, including friends and family, and were not the same happy, active person anymore. They missed their old life and described a sense of loss at how their illness and symptoms restricted their lives. Some women also reported no longer being able to work or study due to their illness.

I couldn't connect with people the way I was used to, and the sense of apathy was always with me which was also this difficult, conflicting emotion to have. I'm very compassionate and very loving towards everyone in my life, and to have that apathy there, it like tears your heart because that's not who you are, but you're experiencing it. – Participant 10

Theme 2: Invalidation and Invisibility

Medical Invalidation

Almost all participants stated that health professionals dismissed their symptoms as being caused by other conditions, including allergies, 'hysteria'or anxiety. Some women recalled being told that their symptoms were made up, 'all in their head' and that they were 'crazy' and were referred to psychologists or psychiatrists for treatment. Participants reported feeling disillusioned, defensive, angry, and alone as a result of these experiences.

The number one thing I get told is 'do you have anxiety? Oh, it's anxiety. Your heart rate's going like that because of anxiety. Anxiety. Anxiety'. That's the number one thing. It's like, no I have an actual illness that causes my heart to go like this. It has nothing to do with anxiety cause that's the number one thing I have to argue with them about. It's like the worst thing to get told, because they discredit you because of that, and that's the worst thing. – Participant 21

Participants also described being unable to get confirmation that breast implants may be causing their symptoms, or validation that their symptoms were real.

I feel like I'm trying to chase the pot of gold at the end of the rainbow that says yes you've got Breast Implant Illness. And like, you know, like the whole about the rainbow is every time you get close, you know, the pot of gold keeps moving away. – Participant 23

However, some participants reported having positive experiences with health care professionals. These positive experiences were generally the result of their doctors validating participants' experiences and the idea that breast implants could cause their symptoms. These, infrequently-encountered doctors, were described as 'believers'.

When I met her [explant surgeon], *I just knew that she was the right one, because she believed - and she wasn't pushy or trying to push me further – she had great information and she's been doing it for a very long time.* – Participant 27

Social Invisibility

Beyond feeling invalidated by health care professionals, some participants reported that their symptoms were 'invisible' to friends and family members because they had put on a 'façade' to be able to continue with their day-to-day lives.

And it's like an invisible disease. You know, it's not something that's on my skin, or you could look at me and tell. I look healthy, I'm in shape, you know, so it's not like you could look at somebody and see it, so it's kind of like, it's invisible and people don't really get you or understand you, and that's really frustrating. – Participant 28

Theme 3: Making the BII connection

Not Relating it to the Implants at First

Most of the participants described a transition in their beliefs about the cause of their symptoms. Initially, they did not relate their symptoms to their breast implants, instead attributing their symptoms to other causes, such as ageing, menopause, weight gain, and other medical conditions.

> *I was having health issues, but I didn't relate it to that. I never related it to the implants until this last May, I had a routine mammogram and that routine mammogram showed a rupture, and when I realized I had the rupture, that was when I started kind of researching it, and wondering can I leave it? Does it need to come out? And I started finding that other women were having the same issues that I was living with, and I had never made the connection. So, yeah. So I was unaware for 30 years of just what was going on with me. I didn't have any feeling towards the breast implants. I didn't think they were hurting me.* – Participant 24

After not initially relating their illness and symptoms to the implants, many subsequently realized there may be a connection between their implants and symptoms. This realization was often sudden, like an 'aha moment' and prompted by reading stories shared on social media and the internet, with participants strongly identifying with the experiences shared by other women on these platforms. Participants also made the connection between their implants and symptoms after having ruled out other possible explanations for their symptoms.

> *…And then I started doing research, and I had all the same symptoms as all these people, and they all had the exact same implants as me, and it was just too…then I started thinking back of all the infections I was getting, and all the fevers, and all the weird symptoms, and all the weird illnesses I'd been getting over the last couple years, and I was like 'oh my god' that's what's been causing it.* – Participant 21

Finding Support and Validation on Social Media

Social media appeared to serve as a strong source of support and validation for participants. Participants described feeling a sense of comfort and community in knowing that other women were going through the same experiences, and reassurance that they were not 'crazy'. Reading the stories of

other women on social media support groups provided participants with the knowledge that their experiences and symptoms were real.

> *Misery loves company I guess. Knowing that other women are going through the same exact thing that I have gone through validates my suspicion, you know? It validates my pain, it validates my everything that I've thought over my health.* – Participant 1

However, there were some exceptions to these mostly positive experiences. For instance, some participants described instances of bullying by members of these groups. Such bullying was often around issues such as a woman's choice of doctor and explant method. Some participants also recognized the potential for misinformation to be spread on social media platforms. Other participants reported that posts on social media groups exacerbated their anxiety about symptoms.

> *I think they're very good for information but I think that they are also scary…I think that our mind is a powerful thing and so I think reading these stories and things over and over and over can also create problems too, that might not be there… You can start reading the stuff and almost stress yourself out more and worry that you have things maybe that you don't have.* – Participant 27

Theme 4: Implant Toxicity

Toxic Chemicals and the Body's Immune Response

A common belief among participants was that their breast implants were leaching toxins and heavy metals into their bodies, and that their symptoms were linked to the body's immune response to having such toxins in their body. Participants believed that the body was constantly trying to fight these toxins, thus wearing the immune system down. Participants also reported believing their immune system was reacting to having foreign objects in the body.

> *My sense is that what's in these and the silicone that's surrounding the actual implant is putting things into my body that your body is not meant to have to deal with. They are foreign items, they are toxins and my body's immune system is constantly trying to fight back, fight them off but it doesn't know what is wrong, so, no matter what it does it can't get rid of the problem.* – Participant 31

Detoxification via Explant Surgery

Removing their 'toxic' implants via explant surgery was viewed as the only effective way to detox the body, and to start the 'healing process'. Some women reported a 'correct' way to explant, that is the en bloc capsulectomy, and fear that if the capsule surrounding the implant was not removed, then the toxic material, which may have 'migrated to other parts of the body' would remain and continue to cause their illness. The women who had undergone explant surgery and not experienced much symptom improvement after surgery often attributed the absence of symptom improvement to the body continuing to undergo a detoxification process.

> *… you look at other women's stories and progressions and what their stories are like, and it was pretty much saying, "Around week one or afterwards I became extremely nauseous, I was going through a major detox wave with all the heavy metals. You know, just like, stay positive, girls, like, it's just a detox wave."* Participant 32

Theme 5: Explant Surgery: Solution to Suffering?

Nothing Else Worked

Participants described spending a significant amount of time and money trying every possible treatment for their illness. The types of treatments received by participants varied widely, and included the use of numerous medications, surgeries (unrelated to breast implants), supplements, and diets. Participants also described having sought treatment from a variety of healthcare professionals, including general practitioners, chiropractors, psychologists, neurologists and physiotherapists, and implementing various lifestyle and dietary changes.

> *So you just go these doctors over and over and over again, and you wind up with no answers, or you're shoved a bunch of pills, and I've got a giant bag of different medications that they've tried to put me on to help me, but none of them have worked because they've never got to the root of the problem.* – Participant 10

Cautious Optimism

Participants described a cautious optimism and sense of hope around how explant surgery may help to alleviate their symptoms. This sense of hope was often derived from reading 'success stories' on social media, where women often described a significant improvement in their symptoms following explant surgery. However, before surgery, many participants were reluctant to fully believe that explant would be successful in alleviating their symptoms after having been ill for so long, and after having tried numerous treatments without success. Participants expressed a fear of disappointment should explant surgery serve to be yet another unsuccessful treatment, and shame and embarrassment at the possibility of mistakenly believing the implants caused their illness.

> *I was going into surgery thinking, you need a new set anyway, so just take them out and just see what happens, because after you try everything you know, and nothing helps you, if you go into explant surgery thinking this is it, I'm going to get better, and nothing happens, that's going to be devastating. And so I had to be very careful where I was with that mentally, and, you know, I'm glad I did, because it was just such a happy surprise that I'm getting better by the day, and it was just a huge blessing.* – Participant 10

Symptom Improvement

Most participants who underwent explant surgery reported a significant improvement in their symptoms shortly after surgery. For instance, participants reported that they had their energy back, and no longer experienced such symptoms as chronic pain, and muscle weakness.

> *The sleep problems are gone, the fatigue is gone, the achy joints are gone, the muscle weakness is gone, I want to say the depression is gone but it does come back almost like clockwork every 2 weeks for a couple of days and then it goes away. But ah, my eyes, I woke up and my eyes are not swollen anymore. I no longer have allergies. Everything pertaining to allergies is gone. I was on all kinds of medicine, I couldn't even breathe some days. Gone, completely gone. My heart palpitations are gone. Completely gone.* – Participant 9

An improvement in participants' symptoms often translated to improvements in their daily functioning, including returning to work, and regaining their sense of identity.

It saved my life. When I woke up from surgery, I'd say the first month, …I had my energy back, I [cries]…I'd say that one of the biggest things, I mean there were a lot of big things, was I was able to feel joy again. The kind of joy, like it starts in the centre of you and it spreads to your whole body. And I hadn't felt that for so many years, even though I'm a happy person. – Participant 10

Not all participants experienced an improvement in their symptoms following explant surgery, and those who did not experience symptom improvement often expressed feelings of disappointment and defeat.

So I got them out last week and it's been a bit of a rollercoaster cause none of my symptoms have dissipated…but it's only been, well it was only Thursday that I got them removed. But none of my symptoms have dissipated since then, and now I have no boobs, I still have all my symptoms. – Participant 22

Theme 6: Concealed Information

Uninformed of the Risks

Participants felt they had not been informed about the risks of breast implants. They wished they had been warned about the potential dangers of breast implants, noting that they would not have followed through with surgery had they been warned. Some women believed that their doctors had not been provided with information about the potential dangers of breast implants, and were therefore unable to relay accurate information to their patients.

I honestly, I don't fault the doctors because they're going off of what medical science has published or what the FDA has said, and so their job is to look at everything from a scientific and medical standpoint, and if they're told the opposite of what's happening, then how do they even know to even treat us for BII, or that that could be the cause?' – Participant 10

Profits Over Safety

A smaller sub-group of women believed implant manufacturers, the Food and Drug Administration (FDA), and doctors had deliberately concealed information regarding the lack of safety of breast implants from them, or that insufficient and biased research had been conducted into the safety of breast implants. They concluded that this was due to a desire for profits over safety.

> *I think when it really comes down to it, it doesn't have anything to do with patient safety and patient care. It comes first to how much money am I going to make not just off of these procedures, but getting money from the manufacturers and the pharmaceuticals that help promote these?* - Participant 30

DISCUSSION

This is the first qualitative interview study to characterize the experiences of women with self-reported BII, a poorly understood syndrome with no definitive cause, or treatment. Qualitative research is suited to better understand poorly defined and complex conditions such as BII, including patient experiences, beliefs, behaviours, and treatment decision-making. Several key themes related to participants' experience of symptoms, the healthcare system, social media and explant surgery were identified. This study highlighted the considerable suffering experienced by women with BII; all women reported distressing, disabling unexplained symptoms that had a severe, negative impact on their quality of life, daily functioning, identity, and relationships.

This study also showed for the first time that BII appears to follow a chronic course, which worsens over time, with multiple new symptoms emerging after onset. Consistent with past research[6,7], fatigue and pain were most common, with other symptoms varying widely, ranging from infections, to dry skin, allergies, sensory sensitivities, 'brain fog', depression, panic attacks and anxiety, among others. Given the enormous toll BII takes on physical and mental health of these women, research efforts should focus on developing, evaluating and disseminating treatments to help cope with, manage, and alleviate these symptoms to improve their quality of life. In addition, our results show the dynamic, non-specific and variable nature of symptoms reported by women with BII, which may make it difficult for diagnostic tools to be developed that can accurately diagnose BII, and

discriminate it from other illnesses with similar symptoms. Therefore, longitudinal research that does not rely on potentially biased retrospective memories of symptoms is needed to identify the onset, course and progression of these disabling symptoms after implant surgery, and their prevalence.

Participants revealed negative experiences in their interactions with the health care system and health care professionals, which highlight opportunities for improving the treatment and support they receive. First, participants felt that they had not been adequately warned about the potential risks of developing BII before implant surgery, although it is unknown whether they were not told of the risks, or could not remember. Studies show that patients are more likely to recall surgical details than risks, partly because they do not perceive the risks as applicable to them,[29] and even when patients are fully informed of potential surgical risks and complications, 28% will not remember them.[29] Nonetheless, our results highlight the importance of providing a thorough and comprehensive patient education process regarding the possible risk of developing BII during the informed consent process, through both verbal and written means, as 40% of elective surgery patients do not read written consent forms.[29] Indeed, recent FDA guidelines have recommended that manufacturers include a boxed warning and patient decision checklist into their labelling, in addition to updates to silicone implant rupture screening recommendations, a description of materials used in the manufacture of implants, and provision of patient device cards.[30] Indeed, a thorough and comprehensive patient education process has been shown to optimise patient outcomes.[31] Educational aides such as Patient Decision Aides may also be helpful especially for practices that have not implemented systematic educational processes. Recent FDA guidelines have also highlighted the importance of doctors maintaining a transparent, trusting and respectful relationship with their patients, a part of which involves acknowledging what is not currently known about risks associated with breast implants. Recent FDA guidelines have also highlighted the importance of doctors maintaining a transparent, trusting and respectful relationship with their patients, a part of which involves acknowledging what is *not* currently known about risks associated with breast implants. Second, participants reported that many medical professionals dismissed their symptoms as either not real or being caused by hysteria, anxiety or hypochondria, which left them feeling like they were not believed or taken seriously. Consistent with past research,[7] many of the women interviewed reported severe depression, anxiety,

panic attacks, and in some cases, suicidal thinking. It is critical that these mental health conditions are detected and treated, via referral to mental health specialists (e.g. psychologists, psychiatrists). Initially to help aid the detection of mental health problems, brief self-report screening questionnaires such as the Beck Depression Inventory,[32] the Hamilton Depression Rating Scale,[33] or the Patient Health Questionnaire 9-item[34] for depression, and the Hamilton Anxiety Rating Scale[35] or the Generalised Anxiety Disorder 7-item[36] for anxiety could be used in surgery clinics to identify patients in need of further mental health assessment, and potentially treatment. However, it is important to reassure patients that these referrals are to help support them how to manage their mental health and cope with their illness, not to determine that it is 'all in their head', as it can further invalidate their concerns.

Many participants turned to social media to seek support, validation and information, often *after* attempting to seek answers and support from qualified health professionals, and trying various treatments without success. It was common for participants to make the connection between their illness and implants after reading information online, and identifying with other womens' stories on social media. These results have important implications. If these women felt validated, supported, and empowered to manage their symptoms earlier in their illness trajectory, they may not seek out the connection with other patients describing BII on social media, or make the implant-symptom attribution. In addition, given social media groups provided a key source of support and information, which is consistent with the trends toward health information seeking on social media in the general community,[37] it could be used to provide an avenue for education about BII, and increase collaboration and communication between patients and health professionals (e.g, the *Breast Implant Illness Patient-Clinician Discussion on Facebook*). However, patients with BII should also be informed of the risks of using unregulated social media groups to source health information given alarming, inaccurate and misleading information is often found online,[38,39] which can exacerbate anxiety.[7] One example of inaccuracies that are falsely propagated on social media is the level and number of heavy metals in implants, which are likely to contribute to the common belief among participants that their implants were leaching toxic chemicals and heavy metals into the body. These misnomers are inconsistent with the fact that no heavy metals are used in the ingredients to make any

breast implant. The metals found and known from testing are are all well below acceptable levels as defined by regulatory bodies,[40] and platinum, the only heavy metal used as a catalyst in the manufacturing process, is present at a zero valence state and at a level that has no known toxicity.[41]

What a person believes about their illness influences their emotions, thoughts, behaviours, coping, and treatment decisions. Beliefs about the cause of symptoms are linked to symptom severity in conditions such as Irritable Bowel Syndrome (IBS),[42] chronic fatigue syndrome,[43] and medically unexplained symptoms,[44] and the acceptance of medical versus psychological interventions. For instance, in IBS, attributing symptoms to underlying physical causes, rather than psychological causes such as stress, is linked with worse symptom severity and poorer quality of life.[42] Our results showed that participants strongly believed that their implants were toxic, and that their bodies and immune systems were negatively reacting to, and rejecting a 'foreign object'. Although explant surgery was seen as a last resort after trying other treatments, it was believed to improve symptoms through the process of 'detoxing'. Providing accurate information about the safety of implants (e.g., heavy metals) and the efficacy and risks of explant surgery might be helpful to correct inaccurate beliefs or misinformation, and guide treatment decisions, especially for patients who are still uncertain about whether implants are causing their symptoms. However, participants also reported significant mistrust of health professionals, implant manufacturers and regulatory bodies. In these cases, education-based interventions will be unlikely to change beliefs, attitudes or behaviours. Rather, doctors are encouraged to establish trust with their patient through empathy and honesty, and by listening to and understanding their needs and concers.[45] Indeed, a recent qualitative study found that patients with breast implants wanted plastic surgeons to sincerely listen to their concerns, and to acknowledge that patients' concerns may be real and have a significant impact on their lives.[21] As part of maintaining a trusting relationship with patients, it is also recommended that surgeons respect the autonomy and preferences of patients.[45] For instance, it is recommended that surgeons respect the patient's choice to remove their implants.[9] However, it is also worth noting that most surgeons are implementing recommended practices, and that inaccurate information obtained online can make it difficult for a trusting relationship to be formed between patients and surgeons.

Most of the participants described some symptom improvement after explant surgery, although those who did not felt defeated, and disappointed. The symptom improvement reported by women was consistent with the findings of two longitudinal studies showing *some* symptoms of BII improved following explant surgery.[6,8] However, past research[7] has also found that women with self-reported BII who had undergone explant surgery had poorer mental and physical health than a control group of women with implants but no BII, suggesting explant surgery may not cure all symptoms. Notably, patient reports of an immediate improvement in symptoms following explant surgery are inconsistent with the belief that implants are causing BII through the release of toxic chemicals or by activating an immune response. It is possible that there are other factors contributing to changes in BII symptoms following explant surgery, such as the alleviation of chronic bacterial infection,[4] relief from the anxiety about having a 'toxic' object in the body, or placebo effects. Further research is required to identify the mechanisms underlying symptom improvement following explant surgery, and factors that may moderate the effectiveness of explant surgery in alleviating BII symptoms. Future research should also explore whether explant surgery is perceived as the only way of treating symptoms once a woman believes their implants are toxic.

How should we approach treatment and management of patients who believe they have BII? First, because many of the symptoms described by participants could be attributed to other underlying medical issues, thorough medical evaluation is recommended for all patients who believe they have BII. Second, BII is complex: it has unclear pathophysiology, a diverse array of disabling symptoms, there is a mismatch between patient and practitioner beliefs about the underlying cause of symptoms, and there is a lack of data on whether removal of implants effectively alleviates all symptoms of BII. Therefore, a multimodal, biopsychosocial approach to conceptualisation and treatment, similar to the approach used to support people with medically unexplained symptoms[46] or somatic symptom disorder [47] is a possible treatment approach.

Systematic reviews have shown that multidisciplinary cognitive behavioral therapy (CBT) improves physical functioning, and reduces psychological distress and disability in patients with somatic symptom disorders and medically unexplained physical symptoms,[48] although a substantial proportion of patients with unexplained symptoms may not accept these treatments.[49] Treatment based

on biopsychosocial models of health and illness involve a multidisciplinary team of health professionals (e.g., physician, dietician, psychologist and others) to integrate physical and mental health care. The biopsychosocial model recognizes the complex relationships between biological, physical and psychological aspects of health (e.g., thoughts, emotions), behaviours, social influences and the environment, and how they interact and serve to maintain impairment and disability. This approach seeks to modify and address cognitions, information processing biases, behaviours and emotions, and facilitate adaptive coping strategies, positive lifestyle changes (e.g., exericise, diet, smoking cessation) and social functioning through a combination of medical and psychological interventions. A core part of this approach is the need for a collaborative, open and supportive relationship between health professionals and patients,[9,12] as without it, patients are at risk of poorer outcomes and treatment adherence.[50-52] It is particularly important in light of the current findings which highlight the fraught relationships between women with BII and health practitioners, and their lack of trust in the broader regulatory bodies which oversee the approval of the use of breast implants. Future research needs to evaluate the efficacy of multidisciplinary treatment approaches for women with BII, including patients who choose not to remove their implants, as well as those who have symptoms still remaining after explant surgery.

There were a number of strengths and limitations of the current study. A strength of the current study was that we interviewed a large sample of women, from five countries who provided detailed responses producing a rich source of data about their experience of a poorly-understood condition. However, the majority of women were from the United States, thereby limiting the generalisability of the findings to other countries. Furthermore, the sample was self-selected, and most women had undergone explant surgery, although we still obtained detailed interviews from women who had their implants in place. The self-selected nature of participants means that their experiences may not be reflective of the experiences of the millions of other women worldwide with breast implants. Indeed, only a small subset of patients who have undergone breast implant surgery report experiencing symptoms of BII. Moreover, there is research showing that the prevalence of BII symptoms is similar between women with self-reported BII and women without breast implants.[53] However, it is worth highlighting that sampling bias is less relevant in qualitative designs, as

participants are typically selected specifically because they can provide insight into the phenomenon being studied[54]. Nonetheless, there remains a need for further research to determine the etiology underlying BII, and to identify individual difference factors that may increase a person's vulnerability to developing BII.

CONCLUSIONS

This was the first study to explore the experiences of women with BII using qualitative methods. BII symptoms had a significant impact on participants' identity and functioning. Invalidation by others, including health professionals, contrasted with validation and support found on social media. Doubts were raised about the safety of breast implants, leading many participants to engage in explant surgery as a means of treating their symptoms. Future research should determine how health professionals can provide effective support and minimize distress for women with BII, and how BII can be understood from a biopsychosocial perspective.

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Table 1. Demographic Characteristics

	Mean (SD)	Range
Age (years)	43.27 (11.4)	29-73
	N	**%**
Children		
Yes	19	65.5
No	5	17.2
Not stated	5	17.2
Marital status		
Never married	4	13.8
Married/de-facto	16	55.2
Divorced/separated/widowed	4	13.8
Not stated	5	17.2
Education		
High school	6	20.7
Undergraduate degree	8	27.6
Postgraduate degree	3	10.3
Other	7	24.1
Not stated	5	17.2
Employment status		
Full-time paid work	9	31.0
Part-time paid work	2	6.9
At home parent	3	10.3
Student	1	3.4
Retired	2	6.9
Not working – sick/disabled	6	20.7
Not working – other	1	3.4
Not stated	5	17.2
Country		
United States	21	72.4
Canada	3	10.3
Australia	3	10.3
New Zealand	1	3.4
Argentina	1	3.4

SD, standard deviation.

Table 2. Participants' Surgical History

	Mean	SD
Years since implant	12.2	7.4
	n	**%**
Surgery		
Both breasts	21	72.4
Left breast	2	6.9
Right breast	1	3.4
Not stated	5	17.2
Reason for surgery		
Augmentation	10	34.5
Reconstruction	14	48.3
Not stated	5	17.2
Type of implant		
Saline	10	34.5
Silicone	14	48.3
Unknown/not stated	5	17.2
Implant surface		
Textured	9	31.0
Smooth	12	41.4
Unknown/not stated	8	27.6
Implant placement		
Above muscle	4	13.8
Below muscle	19	65.6
Unknown/Not stated	6	20.7
Incision placement		
Underneath breast	14	48.3
Around areola	8	27.6
Other	2	6.9
Unknown/not stated	5	17.2
Manufacturer name		
Allergan plc (Dublin, IE)	6	20.7
Mentor (Santa Barbara, CA)	10	34.5
Other	3	10.3
Unknown/not stated	10	34.5
Explant		
Yes	19	65.5
No	10	34.5

SD, standard deviation.

Table 3. Interviewer Prompts

	Questions
Surgical history	When was your surgery? What made you decide to have surgery? How have you found the experience overall?
Symptoms	When did you first start noticing symptoms that troubled you? Have your symptoms changed over time? How have these symptoms impacted your life?
Supports	What have you been told by others about these symptoms? What supports have you accessed (prompt: social media, health professionals)?
Explant	Have you decided to remove your implants? How has explant surgery impacted your symptoms?
Outlook	How do you feel about the future?

Table 4. Thematic Analysis [Adapted from Braun and Clark][24]

Stage of analysis	Process
Data familiarization	Interviewing, transcribing, reading through transcriptions, making notes about initial impressions e.g. interview setting, interviewee behaviour, intonation, non-verbal content, uncertain vs. emphatic responses
Coding	Descriptive, inductive category notation, assigning initial codes to data to describe manifest content (subjects, ideas) and latent content (emotional expression, linguistics)
Generating themes	Organizing idea clusters, grouping common codes, finding patterns of common themes across different interviews. Grouping over-arching key themes and any associated subthemes.
Refining themes	Reviewing theme names and descriptions, importance and frequency and discussing divergence and convergence.
Finalizing themes	Ensuring themes describe key central concepts – succinctly capturing what is most important, emphasized, repeated or key within participant data
Reporting analysis	Thematic table and description of finalized themes and subthemes, presented with generous illustrative extracts

Table 5. Key Themes, Subthemes, and Illustrative Quotes

Theme	Subthemes	Illustrative quotes
1. Symptoms without explanation	Symptom after symptom	*I was getting bladder infections constantly. I had fungal infections. I had sinus issues, migraines, dry skin, dry mouth, altered taste, altered smell. I kind of remember all of them there were just so many. Light sensitivity, the cough, the unexplained fractures, hypothyroid, low vitamin B…I had abnormal test results in terms of blood results but no nobody could ever say for sure. Mental issue.* – Participant 2
	Left without answers	*For five and a half years I saw probably over 50 medical doctors trying to figure out what was wrong with me, and none of them could figure it out* – Participant 16
	Loss of identity	*So it's now come to the point where I don't volunteer for life, I volunteer for rest… There were many days in the last couple of years where I said I wanted to die. I felt so ill, and so unable to move, or do anything.* – Participant 31
2. Invalidation and invisibility	Medical invalidation	*I've had so many doctors say well 'it's just a social media trend, you just think this because you've seen the Facebook group. This is just hysteria from people that have all gone together online…'* – Participant 6
	Social invisibility	*Lots of people were supportive in the beginning, but once it's been going on for so long, they just kind of disappear, and don't really say much anymore. They're just like 'oh, you're still sick'.* – Participant 21
3. Making the BII connection	Not relating it to the implants at first	*I wasn't relating it to the implants right away, because the illnesses were all over the place, like they were in different parts of my body, different parts of…like different organs, and eventually, like, I was like, okay, that have to be related, like there's no way I'm just getting sick all the time, and they aren't related, you know?* – Participant 21
	Finding support, and validation on social media	*I guess I don't feel totally crazy, that other women who have had breast implants are suffering with a lot of the same symptoms, majority of the same symptoms that I am, so that's been some comfort.* – Participant 22
4. Implant toxicity	Toxic chemicals and the body's immune response	*I think that you know it was an immune, immunological response to having like a device in my body that it basically rejected and then over the years, I believe because I had very thin capsules when I explanted. I noticed that if I would exercise and I got very hot, my symptoms would get worse. And I feel like, from what I've read, I feel like the shell which was made from like 40 different chemicals, was probably absorbing into my body, and my body was unable to handle these chemicals and these toxins.* – Participant 9

	Detoxification via explant surgery	*They* [symptoms following explant surgery] *went in waves. So right away I felt better,, and then I would go through this detox period where I didn't feel so good. And then it would get better and then a little worse, and then it would get better.* – Participant 26
5. Explant surgery: solution to suffering?	Nothing else worked	*I was going to doctors and they would tell me try this and try that, so there were supplements, there was medications. I went to this – he called himself a functional neurologist and he had different equipment, I went to the chiropractor, I went to acupuncture, I went to physical therapy, I did biofeedback. I was basically at doctors' appointments or therapy, three times per week trying to feel better.* – Participant 16
	Cautious optimism	*A part of me thinks nothing else is working, so despite the risks of surgery, if nothing else is going to help, then you have to do it - you have to try that one thing that might help. I'm feeling sort of vaguely hopeful really but also there's a big question mark.* – Participant 31
	Symptom improvement	*I would say I am about 85% better. I don't get migraines anymore. I don't get chronic – I don't get sinus infections anymore. I am not having any breathing difficulty. My hair is the thickest and longest it's been in over 25 years. Let's see, what else? I don't have sensitivity to light or sound anymore.* – Participant 16
6. Concealed information	Uninformed of the risks	*I wasn't told anything. I was not told that they had a 10 year shelf life. I wasn't told there was any danger because these were saline and not silicone. I wasn't told that I may end up with a loss of sensation. I was given no information.* – Participant 31
	Profits over safety	*Like the breast implant companies know about this. They know what's happening. And they just – it's all just a money thing. We're all just a number, we're all just – it's a money system.'* – Participant 32