

Observations of a Potential Immune Response to Breast Implants After Immunization With COVID-19 Vaccines

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With great interest, we have read “A Case Report of Capsular Contracture Immediately Following COVID-19 Vaccination” by *Richard J. Restifo*.¹ A 34-year-old female patient had previously undergone bilateral breast augmentation and mastopexy with a 440-mL smooth-surface submuscular implant. After 5 months, she received the first dose of the BioNTech/Pfizer (BNT162b2) severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) messenger ribonucleic acid (mRNA) vaccine (New York, NY, USA) and the second dose 21 days later. Six days after her second immunization, the patient experienced sudden onset of left-sided axillary lymphadenopathy and consequent tenderness and pain of her left breast. Clinical evaluation resembled a Baker IV capsular contracture, and due to the severity of symptoms, the implant was exchanged and a capsulectomy was performed.

To our knowledge, this case report, published in May 2021, represents the very first reported case of a potential immune reaction to a breast implant after immunization with a SARS-CoV-2 mRNA vaccine. At the same time, we made similar observations in 4 of our patients who were breast implant carriers shortly after Coronavirus disease 2019 (COVID-19) vaccinations and published our findings 1 month later in June 2021.² In our article, we presented 4 potential immune reactions after receiving different vaccines from 3 companies: BioNTech/Pfizer, Johnson & Johnson (New Brunswick, NJ, USA), and AstraZeneca (Cambridge, UK). All patients developed pain and inflammatory symptoms within several days after their immunization. The initial time of surgery ranged from 2 to 64 months, and all of our patients developed symptoms after the first dose of the vaccine. While implant removal was necessary

in 1 patient, the other 3 patients showed a swift recovery and symptom relief under conservative therapy and oral nonsteroidal anti-inflammatory drug treatment.

Since the publication of our observations, we identified another case of a potential vaccine-related immune response. In this report, the patient was a 48-year-old woman who had received a bilateral cosmetic breast augmentation with 335 mL silicone implants 12 years prior. The texture of the implant was not rememberable by the patient and the implant pass was missing. The patient presented herself at our department with swelling, pain, and tenderness of the left breast. According to her, she had received the second dose of her BioNTech/Pfizer vaccine around 3 weeks before the onset of her symptoms. There were no symptoms or abnormalities described before. Clinical examination showed a Baker II capsular contracture and ultrasound revealed a periprosthetic seroma. The contralateral side was unaffected. Due to the age of the implants and the present symptoms, an implant exchange and breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) testing were scheduled.

Recently a third, similar observation was made and published by Kayser et al. from Belgium.³ In their case report,

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Table 1. Overview of Reported Patients, Medical History, and Symptoms

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7
Age (years)	34	55	76	52	52	48	48
Reason of operation	Cosmetic	Reconstructive	Cosmetic	Cosmetic	Cosmetic	Cosmetic	Cosmetic
Side	Unilateral	Unilateral	Bilateral	Bilateral	Unilateral	Unilateral	Bilateral
Time since operation	5 months	2 months	5 years	17 months	9 months	12 years	5 years
Onset of symptoms (after vaccination)	6 days	2 days	2 days	2 days	3 days	19 days	10 days
Vaccine	BioNTE/Pfizer 2. Dose	AstraZeneca 1. Dose	BioNTE/Pfizer 1. Dose	BioNTE/Pfizer 1. Dose	J & J (Single dose)	BioNTE/Pfizer 2. Dose	BioNTE/Pfizer 2. Dose
Symptoms	Swelling and lymphadenopathy	Pain, seroma, and inflammation	Pain and swelling	Pain and redness	Pain	Pain, swelling, and tenderness	Pain, swelling, and lymphadenopathy
Treatment	Surgery: capsulectomy and implant exchange	Surgery: implant removal and autologous breast reconstruction	Conservative: NSAIDs, cryotherapy	Conservative: oral antibiotic, cryotherapy, and NSAIDs	Conservative: oral opioid and metamizole	Surgery: scheduled implant removal	Conservative: NSAIDs

NSAIDs, nonsteroidal anti-inflammatory drugs.

they describe a patient with breast implant-related seroma and similar symptoms as reported in the cases observed by Richard J. Restifo and our group, 10 days after immunization with the BioNTech/Pfizer vaccine. The 48-year-old patient had a previously uneventful follow-up of the breast and developed pain and swelling of both breasts after experiencing common systemic side effects such as fever and body aches after either shot of the vaccine. The performed ultrasound showed a diffuse fluid collection around both implants with a dominance on the right side. Unilateral axillary lymphadenopathy was found on the left side and both implants were intact, without signs of rupture or silicone gel bleeding. Similar to our experience, a rapid improvement of symptoms was achieved by initiating conservative therapy using oral nonsteroidal anti-inflammatory drug treatment. Consequently, all symptoms as well as the bilateral seroma completely resolved within 10 days.

While all the described cases need to be seen in relation to the vast number of uneventful immunizations of patients with breast implants, we think this matter deserves the utmost attention of our surgical community (Table 1). Although some of these cases might be due to correlation by implied causation, it is our belief that there are many overlooked cases like these seen by colleagues all over the globe. Due to our observations and the recent reports, we adopted the standard of taking a detailed history of recent vaccinations in patients presenting with inflammatory symptoms or with a seroma after having breast implants.

It is important to note that similar immune reactions were reported in patients who had cosmetic treatments with hyaluronic acid dermal fillers as early as January this year.⁴ Although 2 of the described cases occurred after COVID-19 vaccinations, Moderna mRNA-1273 (Moderna, Cambridge, MA, USA) and BioNTech/Pfizer BNT162b2, the third described case occurred after native infection with the SARS-CoV-2 virus. These reports are essential information which we need to be aware of in order to offer the correct treatment and care for our patients.

The world is currently experiencing one of history's biggest vaccination campaigns, and its success is remarkable and an important testimony to the power of science. Now that there are enough vaccine doses available in some countries, the vaccination rate among the younger population is increasing likewise. In regard to the rising numbers of implant-related breast surgeries, more potential immune reactions resembling the described observations need to be expected in the future.

While the few cases listed here are the only published observed patient reports in the literature regarding this matter to our knowledge so far, a search of the internet using common search engines delivered more nonscientific results than peer-reviewed ones. Various news agencies and individual surgeons offer information on potential side effects of the COVID-19 vaccines to breast implants on their websites. The internet serves as one of the easiest accessible resources for many patients regarding medical issues today; however, the majority

of patients are not medical professionals, and it must be expected that patients will not be able to find valuable information in form of peer-reviewed articles when searching for information. Therefore, we want to urge colleagues to not only thoroughly examine potential cases and take a detailed history regarding recent vaccinations, but also collect and report their findings. The different COVID-19 vaccine trials showed an exceptional safety and efficacy of the immunizations. These numbers are supported by the millions of successfully vaccinated patients globally.⁵

None of our findings are any indication that the COVID-19 vaccines are unsafe or hazardous, and there is no current evidence to claim a contraindication for breast implant surgery. The observed symptoms are mostly mild and easy to treat conservatively with orally prescribed anti-inflammatory drugs and analgesics. Still, we can only treat what we see, and with the potential necessity of re-occurring booster shots of the vaccines in our ongoing battle against COVID-19 variants, we encourage physicians and surgeons to keep a potential correlation in mind and help the medical community by reporting their findings. More and larger studies are necessary, not only including clinical cases, but also examining the immunological and cytological aspects of these observations. This is especially important in the wake of other immune system triggered diseases related with implants such as BIA-ALCL.

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