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Unit 5 – Vigilance on Medical Devices

Italian National Breast Implant Registry

Report: years 2019-2023

March 25th, 2019 - August 31st, 2023

RNPM

REGISTRO NAZIONALE DEGLI IMPIANTI PROTESICI MAMMARI

Italian National Breast Implant Registry

Report 2019-2023

Ministero della Salute

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ITALIAN NATIONAL BREAST IMPLANT REGISTRY

REPORT 2019-2023

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PREFACE

The medical devices industry plays a crucial role in improving patients' quality of life by providing innovative healthcare solutions for diagnosis, prevention, monitoring, treatment, and user care. However, it's important to recognize that all medical devices carry both anticipated and unanticipated risks, so it's crucial to use a risk/benefit ratio to enable their market entry and ensure their continued presence. Implantable devices pose the highest risk under Regulation 745/2017, which has imposed stricter obligations on manufacturers and encouraged the establishment of registries by the European Commission and Member States. These registries are aimed at independently assessing the long-term safety, performance, and traceability of such devices. In this context, breast implants have been reclassified as Class III, the highest-risk class, by Legislative Decree No. 304 of December 2, 2004. The importance of registries is widely acknowledged by both the scientific community and regulatory authorities, who have observed the establishment of data collection systems by registries internationally over the past 12 years. Maintaining the long-term functionality of these registries and ensuring comprehensive coverage across the territory poses a significant challenge. It's essential to emphasize that only systematic and comprehensive data collection can guarantee genuine traceability of both breast implant patients and the devices themselves. This strengthens the reliability of epidemiological studies focused on the use of breast implants for reconstructive or aesthetic plastic surgery purposes.

Italy's national breast implant registry, established under the Ministry of Health, holds the distinction of being the first of its kind, setting a precedent internationally. Its primary aim is to provide the competent authority on medical devices with advanced tools for monitoring the safety of patients and breast implants over the short and long terms. Law 86/2012 established the national registry within the ex Directorate General of Medical Devices and Pharmaceutical Services of the Ministry of Health. It collects data from the regional and provincial registries provided by the Regions and Autonomous Provinces. It is the first registry where data entry and management procedures by public authorities are mandatory, ensuring transparency and objectivity in clinical or epidemiological monitoring activities.

Additionally, a technical-scientific committee has been established by ministerial decree to oversee the operationalization of the National Registry. Its aim is to promote educational activities and awareness, define the best procedures for monitoring the functionality of the IT platform and the efficiency of data reporting models, and propose research guidelines on breast implant-associated illness.

Today, the ex Directorate General of Medical Devices and Pharmaceutical Services is actively working to develop the capability to monitor the average timing of revision surgeries, identifying recurring reasons for reoperations for implant removal or replacement. These evaluations are crucial as they directly influence the management of patients with breast implants within the Italian National Health Service (SSN). According to the latest report "*I numeri del cancro 2022*"[1], breast carcinoma remains the most diagnosed neoplasm in women, with approximately 55,700 new cases in 2022 in Italy, and breast implants are utilized in over 80% of breast reconstructive procedures. Being aware of the time elapsed between breast implant placement and revision surgeries over a patient's lifetime is important to understand the impact on the costs of the national healthcare system.

It may be necessary to wait a few years before obtaining reliable data to estimate the average lifecycle of breast implants and identify differences in durability and performance among various types of devices. Furthermore, accurately defining the number of Italian individuals who have undergone breast implantation for either aesthetic or reconstructive purposes may take some time. These data are essential for estimating the incidence or prevalence of various pathologies, including those potentially associated to breast implants such as Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL), Squamous Cell Carcinoma (SCC), and Breast Implant Illness (BII). Estimating the recurrence of these clinical conditions is challenging due to their unknown etiology, which is why they are monitored by competent authorities at both European and international levels. Establishing and maintaining registries require significant efforts from the scientific community, regulatory authorities, and sometimes legislators. The development of registries is a complex process, one of the main hurdles to their widespread establishment.

[1] Report "*i numeri del cancro 2022*" available at this link:
https://www.aiom.it/wpcontent/uploads/2022/12/2022_AIOM_NDC-web.pdf

However, motivations such as clinical monitoring of breast implanted patients, complication prevention, healthcare evaluation, and policy intervention identification led the Ministry of Health to promote and establish the Italian National Breast Implant Registry.

Achille Iachino

SUMMARY

Breast implants are the most commonly used medical devices in breast surgery.

However, the absence of a breast implant registry in each country where such surgeries are performed makes it impossible to determine the exact number of individuals with breast implants. Without a registry that tracks each patient over time, it is impossible to determine whether a patient has one or two devices (one per breast) or whether, at a specific date, they still have the implant or if it has been removed. It is important to consider that breast implants have a limited lifespan, and a patient may undergo multiple implant replacement or removal in a lifetime.

From the literature, approximately 35 million individuals have breast implants, implanted for any purpose (aesthetic or reconstructive).

Surveillance activities conducted by the Ministry of Health on sales data provided by breast implant distributors in Italy estimate that approximately 63% of implant surgeries are performed for aesthetic purposes and 37% for reconstructive purposes. The establishment of a national registry for breast implants in our country, mandatory from August 1, 2023, will confirm or revise these percentages. Nevertheless, these percentages are consistent with those observed in other countries where registries have been active for several years, reporting a prevalence of surgeries performed for aesthetic purposes, with peaks of 71% and 75% in the Australian and Dutch registries, respectively. The data collected as of August 31, 2023, through voluntary registration in the registry, indicate an underrepresentation of recorded procedures compared to those actually performed in Italy, particularly for procedures conducted for aesthetic purposes. Specifically, 49.5% of the recorded procedures were performed in public facilities, where predominantly reconstructive procedures are carried out in accordance with the organization of the Italian National Health Service (SSN). Therefore, contrary to expectations based on surveillance data, the percentages of recorded procedures performed for reconstructive and aesthetic purposes are 53.4% and 46.6%, respectively.

The average age of registered patients undergoing breast implant or removal surgery is 48 years old. Among them, patients requiring primary breast implantation for reconstructive reasons have an average age of 51.1 years, while those seeking implants for aesthetic purposes have an average age of 36.7 years.
The analysis of clinical data of registered patients shows that 88.2% of patients undergoing breast implant or removal surgery for reconstructive purposes have significant medical history data for this type of surgery, compared to only 19.3% of those undergoing surgery for aesthetic reasons. Variables include smoking, hypertension, diabetes, coagulation disorders, allergies, autoimmune diseases, investigated genetic mutations, and previous oncological therapies.
In total, 59.7% of the recorded procedures were bilateral (involving both breasts). Unilateral procedures were performed in 55.7% of surgeries conducted for reconstructive purposes, while only in 4.5% of procedures performed for purely aesthetic reasons.

In **reconstructive surgery,** breast implant surgery followed a diagnosis of breast neoplasia in 77.9% of cases; it occurred after radical mastectomy with skin nipple sparing in 63.5% of cases. Immediate implantation was performed in 61.4% of cases, while it followed the removal of a tissue expander in 38.6% of cases. Additionally, for patients diagnosed with breast neoplasia, supplementary procedures included flap harvest in 14.6% of cases, fat grafting in 5.1% of cases, and both procedures in 0.9% of cases. In 14.1% of cases, implants were placed following prophylactic mastectomies, performed in 87.9% of cases with skin nipple sparing. In these mastectomies, supplementary procedures included flap harvest in 13.8% of cases, fat grafting in 2.3% of cases, and both procedures in 0.5% of cases were performed. Capsular contracture was the primary reason for revision surgery in patients initially undergoing breast implant surgery for reconstructive purposes, accounting for 31.7% of cases. In 15.1% of cases, revision was performed due to breast implant rupture, while it addressed asymmetries or volumetric variations without device-related issues in 20.4% of cases. Surgeons commonly implanted devices with an anatomic profile and microtextured surface (56.0%), followed by those with an anatomic profile and polyurethane surface (33.7%). The average volume of implanted prostheses was 368

cm^3, with a range from 50 to 775 cm^3. For patients who had implants for reconstructive reasons, the average time to revision was 4.9 years. Specifically, the average time for implant rupture and capsular contracture were 11.2 and 5.9 years, respectively. Patients who underwent preoperative chemotherapy and radiotherapy had the shortest average time for capsular contracture, with only 3.4 years.

In aesthetic surgery, breast implants were used to increase the volume of hypoplastic/hypotrophic breasts in 72.6% of cases. The implant was placed under the pectoral muscle using the surgical "dual plane" procedure in 47.5% of cases. In the subglandular approach, fat grafting was performed simultaneous by surgeons in a higher percentage compared to when the implant was positioned subfascially or submuscularly. The inframammary fold (IMF) was the preferred surgical access (53.3%). The tranxillary approach was mainly used for subglandular placement.
Data analysis reveals that the main reason for revision surgery in patients initially implanted for aesthetic purpose was not associated to device-related issues (37.1% of cases). Revision surgery was instead performed due to the occurrence of capsular contracture in 32% of cases or implant rupture in 24.2% of cases.
Most implants used were round-profile with a smooth surface (36.7% of cases), followed by round-profile with a microtextured surface (21.5% of cases) and anatomical-profile with a microtextured surface (14.9% of cases). The average volume of implants used in aesthetic procedures was 326 cm^3 (range: 55-925 cm^3). Revision surgery in patients who initially underwent aesthetic implantation showed an average time of 11.4 years, mainly due to implant rupture or capsular contracture (11.2 and 12.2 years, respectively).

Almost all implants, both for aesthetic and reconstructive purposes, were filled with silicone (99.5%); only a small percentage (0.5%) was filled with silicone and borosilicate microspheres.
In order to reduce the occurrence of postoperative complications international guidelines have been defined for patient care during pre-intra- and postoperative stages.

Antibiotic prophylaxis, timing of surgery, changing gloves before placing the implant, antiseptics or antibiotics' use for device management during the surgery, and drains' use are all variables that can influence the occurrence of incidents such as infection, hematoma, seroma and capsular contracture.
The analysis of the collected data shows that surgeons treated the implantation site in 87.2% of the procedures: with antiseptics in 53.0% of cases, with antibiotics in 14.1%, and with both in 20.1% of cases. In 93.8% of cases, surgeons treated the prosthesis before its placing: with antibiotics in 47.1% of procedures, with antiseptics in 24.1%, and with both in 22.7%. In 97% of cases, surgeons changed gloves before implanting the prosthesis. In 82.0% of procedures, drains were used in the immediate postoperative period, in 66.6% in those with aesthetic purposes, and in 95.5% in those with reconstructive purposes.

While the data analysis may not provide an exact scenario of reconstructive and aesthetic purpose in plastic surgery performed in our country, this report demonstrates how a well-structured informatics platform with clearly defined variables is capable of yielding high-quality and significant scientific potential data.

INTRODUCTION

In Italy, the establishment of the national registry and the regional and provincial registries of breast implants is governed by Law No. 86[2] of June 5, 2012. This law was enacted in response to the issues surrounding breast implants from the French company *Poly Implant Prosthesis* (P.I.P.). These implants were filled with silicone that did not comply with the requirements instituted by the then-applicable European Directive 93/42/EEC. This incident underscored the vulnerability of a system unable to promptly recall patients for examination or ensure traceability of implanted or non-implanted devices.

The Ministerial Decree of October 19, 2022, n. 207[3], fully the provisions of Law 86/2012, specifying the purposes of the registries. These purposes include clinical monitoring of patients to prevent complications and improve the management of any adverse effects and long-term outcomes associated with breast implants. In addition, the registries are used for epidemiological monitoring, scientific research, and study purposes in the clinical and biomedical fields, as well as for the planning, management, control, and evaluation of healthcare.

Furthermore, the aims of the registry include primary and secondary prevention, rapid alerting to exchange information on events that may require urgent measures to protect public health at national and international levels, alignment with the community surveillance network, strengthening surveillance capabilities at the national level, streamlining data exchange procedures, and health planning, evaluation, and monitoring of risk factors for monitored diseases. Within the scope of surveillance and monitoring activities on medical devices[4], a fundamental objective of registries is to develop medical-statistical knowledge on implanted devices and patients undergoing revision surgery.

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[2] Ministry of Health, Ministerial Decree, October 19, No. 207. available at this ink: https://www.gazzettaufficiale.it/eli/id/2023/01/18/23G00008/sg

[3] Ministry of Health, Ministerial Decree, October 19, No. 207. available at this ink: https://www.gazzettaufficiale.it/eli/id/2023/01/18/23G00008/sg

[4] Parliamentary Acts - Chamber of Deputies no. 3703 - 16th Legislature - Report http://documenti.camera.it/_dati/leg16/lavori/schedela/apriTelecomando_wai.asp?codice=16PDL0040840#RL

The Regulation defines the types of sensitive data and operations allowed, specifies the authorized subjects who can access the data from national and regional registries along with their different levels of aggregation. It also outlines the methods for transmitting data between regions when collected outside the subject's region of residence. Additionally, it establishes guarantees and security measures for handling personal data, ensuring the rights of subjects undergoing breast implant surgery. Furthermore, it defines the methods for assigning a unique identifying code to subjects, safeguarding their direct identification, except in cases where it becomes necessary to trace the identity due to incidents related to specific types or models of implanted prostheses.

Healthcare providers are required to input data into regional/provincial registers, as well as business operators, who feed the national register. Healthcare providers are required to submit, within three days of the surgery date, all data regarding patients undergoing breast implantation or removal, including the surgical procedures performed, plus the devices implanted or removed. Business operators transmit, on a monthly basis, data on each individual device intended to be implanted in the national territory, ensuring its traceability even when not yet implanted; specific penalties[5] are provided in case of non- compliance with these obligations.

All Regions and Autonomous Provinces have adhered to the use of the IT infrastructure provided by the Ministry of Health for the establishment of regional and provincial registries in accordance with the Regulation[6].

Since Aug. 1, 2022, as stipulated in Article 3 paragraph 2 Decree No. 207 of Oct. 19, 2022, regions and autonomous provinces are notifying the Ministry of Health on the organization of their registries. The Ministry of Health initiated the activation of regional registries through specialized training sessions primarily for healthcare professionals.

As of March 31, 2024, the following registries are active: Piemonte, Valle d'Aosta, Lombardia, Provincia Autonoma di Bolzano, Provincia Autonoma di Trento, Veneto,

[5] Article 4, paragraph 3 of Law No. 86 of June 5, 2012, for healthcare professionals; Article 27, paragraph 28 of Legislative Decree No. 137 of August 5, 2022, for economic operators
[6] Article 6, paragraph 3 of Decree No. 207 of October 19, 2022.

Friuli-Venezia Giulia, Liguria, Emilia-Romagna, Toscana, Umbria, Marche, Lazio, Abruzzo, Molise, Campania, Calabria, Puglia, Sicilia and Sardegna (Figure 1).

Figure 1. Regions and Autonomous Provinces that have established registries as of March 31, 2024.

This report presents the results of analyses conducted on data collected from March 25, 2019, to August 31, 2023, using the IT platform provided by the Italian National Institute of Health (Istituto Superiore di Sanità) during the "pilot phase", while awaiting the analysis of data collected in the National Breast Implant Registry, mandatory from August 1, 2023. The analysed data were voluntarily provided by Italian surgeons following the submission of informed consent by patients, in accordance with OPT-IN[7] method (1).

[7] Data collection via OPT-IN method: patients are registered only after giving their consent

The 2023 report updates the information contained in the pilot phase[8] Report published in September 2022, regarding reconstructive and cosmetic plastic surgery activities conducted nationwide.

Although the data are obtained through voluntary collection, the report provides valuable insights for a comprehensive understanding of nationwide breast implant usage and associated issues. Furthermore, it highlights clinical conditions associated with breast implant use, the etiology of which remains unknown. These conditions are monitored by the Ministry of Health, serving as the competent authority on medical devices in Italy.

[8] Report pilot stage from March 25th to August 31st, 2021availbe at this link: https://www.salute.gov.it/imgs/C_17_pubblicazioni_3255_allegato.pdf

1. EPIDEMIOLOGY OF BREAST IMPLANT USE

Breast implants, commonly implanted for aesthetic or reconstructive purposes, are medical devices regulated at the national level by Legislative Decree, n.137[9] and at the European level by EU Regulation 745/2017[10].

The first generation of breast implants appeared in the 1950s: these are silicone devices with rounded shape, smooth surface, and silicone content; since then, more than 200 different styles and more than 8,000 models have been manufactured worldwide. To date, a wide variety of breast implants are available on the European market, which can generally be grouped according to three characteristics: filling, shell surface, and shape. There are round or anatomical shaped breast implants; implants with a smooth, textured (rough) or polyurethane-coated surface (in accordance with the UNI EN ISO 14607:2018[11]); implants filled with silicone, saline solution or silicone and borosilicate microspheres; there are prostheses with two chambers filled separately with silicone and saline solution.

Throughout history, breast implants have been essential in plastic surgery, offering safe and effective solutions to improve volume in hypotrophic breasts or restoring shape and fullness to breasts affected by malformations or oncological defects.

Since their introduction to the global market, breast implant surgeries have steadily gained popularity among patients. Breast augmentation for aesthetic purposes has consistently been the most frequently performed procedure, while breast implant reconstruction stands out as the predominant technique following mastectomy.

To date, there remains a lack of comprehensive epidemiological data on breast implants' use, primarily sourced from surveys conducted by professional societies or national reports issued by countries with active breast implant registries. The establishment of these registries and subsequent data analysis will provide consolidated datasets useful to international comparisons.

[9] Legislative Decree 137/2022 available at the following link:
https://www.trovanorme.salute.gov.it/norme/dettaglioAtto?id=88953

[10] EU Regulation 745/2017 available at the following link:
https://www.trovanorme.salute.gov.it/norme/renderNormsanPdf?anno=2017&codLeg=69888&parte=1%20&serie=S2

[11] UNI EN ISO 14607:2018 "*Non-active surgical implants — Mammary implants — Particular requirements*"

Worldwide there are an estimated total of about 35 million breast implant patients (2). In the **aesthetic field**, according to the most recent data published by the International Society for Aesthetic and Plastic Surgery (ISAPS), breast augmentation continues to be the most requested surgical procedure since more than 5 years, accounting for 15% of all plastic surgery procedures performed worldwide. In 2022, 2,174,616 breast augmentations were performed with an increase of 29% compared to 2021 and 16.8% compared to 2018 (pre-pandemic period). Most of these procedures were performed in the United States (11.7%) followed by: Brazil (11.2%), Mexico (4.8%), Argentina (3.6%), Germany (3.5%), Colombia (2.9%), and Turkey (2.5%). Italy ranks eighth in the world with 42,058 breast augmentation (1.9%) performed in 2022, followed by Spain (1.8%) and India (1.4%). Demographically, analysis of all breast augmentation performed worldwide in 2022 shows that approximately 90% were on women aged between 18 and 50 (3).

In addition, the ISAPS 2022 report indicates that worldwide, 90% of breast augmentation procedures use silicone breast implants, with only 4% using saline implants. A similar trend is observed in Italy, where Italian surgeons prefer silicone implants in approximately 88% of cases and saline implants in about 1.5% of cases (3).

In the **reconstructive field,** according to the American Society of Plastic Surgeons, 151,641 procedures were performed in USA in 2022, marking a 12% increase compared to 2019. These procedures mainly involved patients aged 40 to 54 years (72,415 procedures, 48%) and 55 to 69 years (51,118 procedures, 44%) (4). It is also reported that in 78% of cases breast reconstruction was performed using breast implants, while in the remaining 22% of cases by autologous tissue (4-6). Thus, breast implants remain the most common choice for reconstructing breasts submitted to partial or radical breast surgery. The selection of the implant type is a crucial in reconstructive procedures. According to the American Society of Plastic Surgeons' 2020 report, among the 137,808 reconstructive procedures conducted in USA, silicone implants were utilized in approximately 70% of cases, whereas saline implants were employed in approximately 5% of cases. (7). Prasad et al. report that 70% of women with breast cancer had conservative breast surgery treatment, while 30% had mastectomy; among them, there is an increase in reconstructive surgeries with

implants plus other procedures (e.g., autologous fat grafting) (8). Breast reconstruction with implants continues to be the most common surgery after mastectomy, and the procedure may involve immediate prosthesis implantation (one-stage reconstruction) or immediate placement of a tissue expander and subsequent implant (two-stage reconstruction). Technological advances and improved surgical techniques have led to immediate breast implant at the time of mastectomy, being performed in 20% of all reconstructions (9).

In Italy, based on market surveillance and vigilance activities conducted by the ex Directorate General of Medical Devices and Pharmaceutical Service (DGDMF), an average of approximately 57,000 breast prostheses are implanted annually between 2011 and 2022. Of these, 63% are for cosmetic purposes and 37% for reconstructive purposes, with an estimated 41,000 patients receiving an implant each year (10,11).

When examining global trends **in breast implants**, geographical variations are highlighted. Historically, surgeons in the United States have shown a preference for smooth breast implants, whereas in Europe and Australia have reported a higher use of textured ones, both in cosmetic and reconstructive procedures (12-16). As reported by Zingaretti et al. in 2019, textured breast implants accounted for only 13% of all breast implants in the United States, compared with 90% in Europe (17).

In Italy, until the end of 2018, the majority of implants used were textured (about 93%): macrotextured in 53.5% and microtextured in 39.5% of cases; approximately 5.5% were in polyurethane, and only 1.5% were smooth. However, since 2019, there has been a shift in the type of prostheses sold with an increase of microtextured and smooth surface prostheses. This change was attributed partly to the removal from the market of macrotextured device by the Allergan Limited, which held a significant share of the Italian and European markets, and partly due to the potential association of macrotextured devices with the BIA-ALCL (Breast Implant-Associated Anaplastic Large Cell Lymphoma) pathogenesis. In 2022, based on data provided by Italian distributors of breast prostheses to the Ministry of Health, it emerges that 52.9% of the devices sold are microtextured and 22.8% are smooth, indicating that despite the

decrease in sales of macro-textured prostheses, microtextured prostheses continue to be sold mainly compared to smooth ones. Additionally, 13.2% of the prostheses sold have a polyurethane shell surface.

It's important to clarify that breast implants are not lifetime devices, and patients might have multiple implant replacement surgeries throughout their lives; the timing depends on unpredictable and unforeseeable factors. Therefore, patients with breast implants require long-term follow-up to monitor the status of these devices constantly (18).

In this context, the establishment of the national breast implant registry aims to provide the Ministry of Health with a valuable tool for conducting epidemiological monitoring, scientific research, and healthcare management.

TYPES OF COLLECTED DATA

The IT platform established in March 2019 and used for the national breast implant registry's "pilot phase" collected data about breast implantation or removal surgeries performed in Italy up to August 31, 2023.

The surgical procedures performed were recorded by the surgeons using OPT-IN method, after the informed consent[12] signed by the patient.

For each procedure, the following information were collected: healthcare facility where the procedure was performed, surgeon's identification data, surgeon's postgraduate title and patient's data (personal and clinical history), details on surgical procedure performed and implanted or removed devices' references.

Table 1 details the data collected for each surgery.

Table 1. Data collected for each surgery

Healthcare facility
Surgeon
Patient
Age
Registry sex

[12] *Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC; Legislative Decree 30 June 2003, no.196, containing the 'Code regarding the protection of personal data.*

Biological sex
Smoking
Hypertension
Diabetes
Coagulation disorders
Food and drug allergies
Autoimmune disorders
Familiality in breast cancer
BRCA1/BRCA2 mutation
Chemotherapy
Radiation therapy
Surgical procedure
Date
Side (right, left, bilateral)
Initial indication for implantation (aesthetic or reconstructive)
Type of surgery (primary or revision)
Diagnosis
Details of surgical procedure
Access incision
Access from previous surgery
Previous expander
Axillary dissection
Capsulectomy
Flap harvesting
Fat grafting
Other medical devices implantation
Good practice
Pocket irrigation
Glove change
Prosthesis treatment before the implantation
Drainage

It is important to emphasize that the data collected, as defined during the pilot phase and outlined in the technical annex of Regulation No. 207 dated October 19, 2022, aligns with the information gathered by other international breast prosthetic implant registries and adheres to the minimum dataset established by the International Collaboration of Breast Registry Activities (ICOBRA). Regarding the implanted prosthetic device, the system recorded the following details: manufacturer, serial number, batch number, manufacturer-assigned code, trade name, shell surface

texture (macro-textured, micro-textured, smooth, polyurethane-coated in accordance with ISO14607), shape (round, anatomical), content (saline, silicone, mixed), and volume. For removed devices, the system captured the serial number, batch number, manufacturer's code and name.

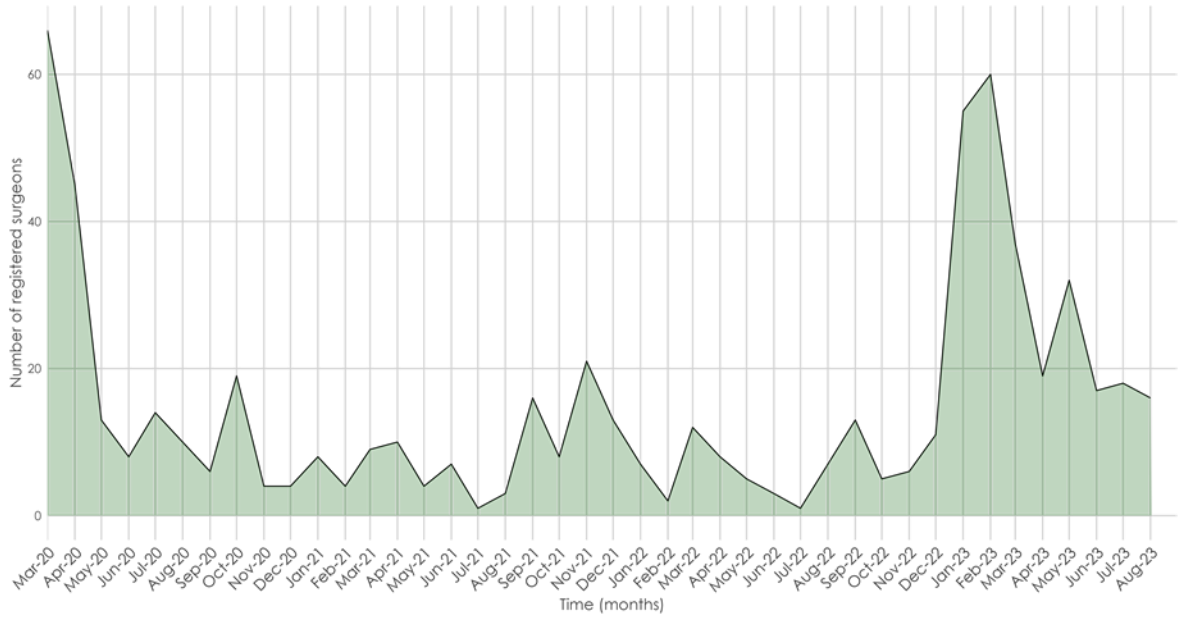
All information was required by the system as mandatory; patient registration and the procedures performed could only be finalized once each field had been completed.

2. DATA ANALISYS

Until August 31, 2023, surgeons registered the procedures performed on voluntary basis; awareness campaigns promoted by scientific societies have enabled an increasing number of surgeons and access to the registry.

Figure 2 illustrates the trend of surgeons' registrations on the IT platform. As of August 31, 2023, a total of 618 surgeons have signed up. Spikes in registrations were observed following press releases or information letters issued by the Italian Ministry of Health and scientific societies. Additionally, it is noteworthy that the publication of Regulation 207 on January 18, 2023 led to a further increase in registrations.

Figure 2 Trend of registrations on IT platform from March 25, 2019 to August 31, 2023.



Source: RNPM – Ministry of Health – Figures as of August 31, 2023

During the period from March 25, 2019 to August 31, 2023, compared to the 618 surgeons registered in the platform, only 250 surgeons effectively registered their work performed in 213 healthcare facilities (public and private). There were 13,269 registered procedures performed on 13,054 patients. The total number of procedures performed was 21,188, in which 20,720 were for breast implantations and 5,424 were breast implants removal. The total number of devices uploaded to the platform by distributors was 145,665 (Table 2).

Table 2. Data collected in the registry as of August 31, 2023

Healthcare facilities with at least one upload	**213**
Surgeons with at least one upload	**250**
Surgeries	**13.269**
Patients	**13.054**
Procedures	**21.188**
Device implanted	**20.720**
Device removed	**5.424**
Registered devices	**145.665**

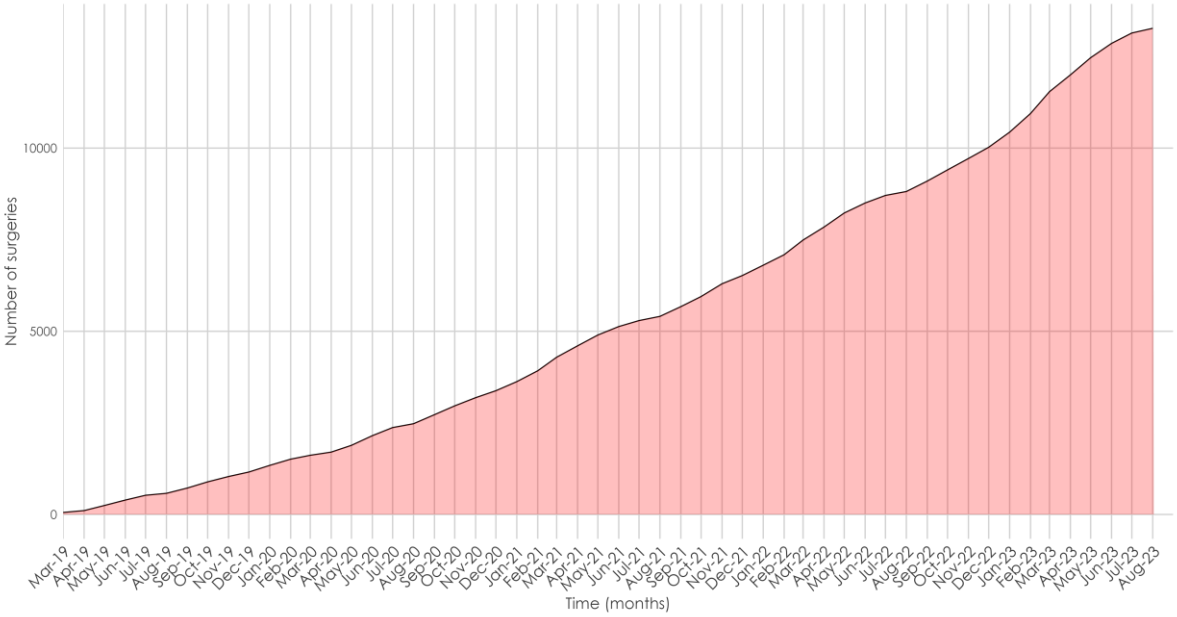
Source: RNPM – Ministry of Health – Figures as of August 31, 2023

Given that some patients underwent multiple surgeries within the observed period, the total number of surgeries performed exceeds the number of individuals. Furthermore, patients may have undergone either single or bilateral surgeries, accounting for the numerical disparity between recorded surgeries and actual procedures performed.

Figure 3 illustrates the cumulative trend of surgeries performed from March 25, 2019, to August 31, 2023, demonstrating a consistent growth pattern.

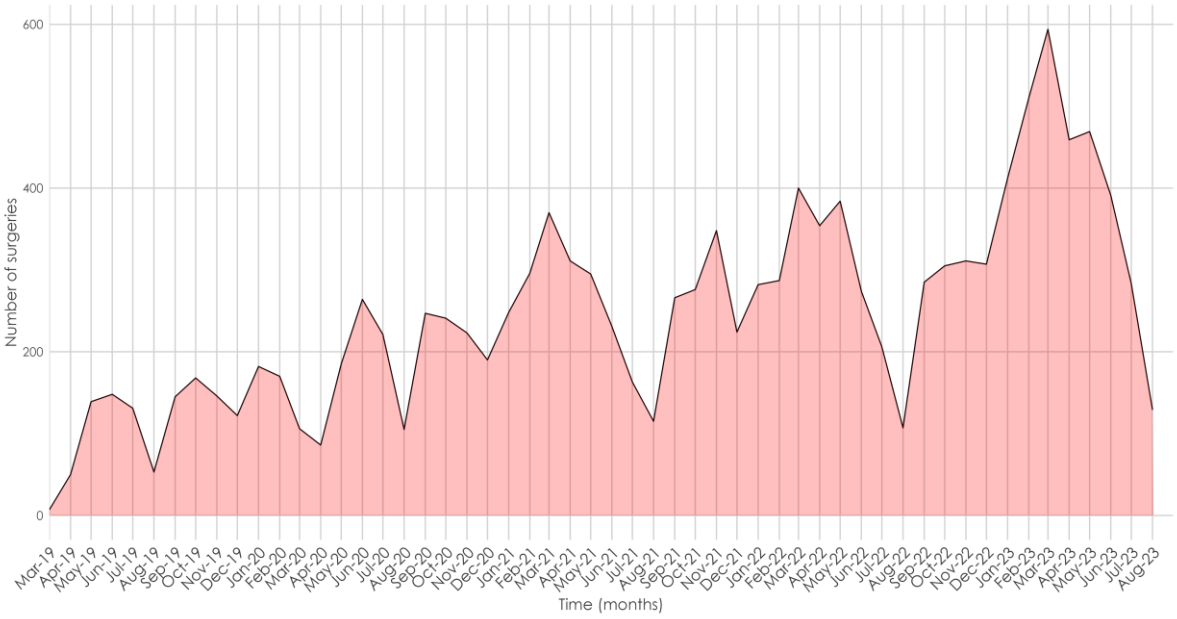
Figure 4 highlights the seasonal trend of these surgeries, indicating a decline during the summer months. The SARS-COV-2 pandemic led to a reduction in surgeries performed during the lockdown months.

Figure 3. Cumulative trend of recorded surgeries between March 25, 2019 and August 31, 2023



Source: RNPM – Ministry of Health – Figures as of August 31, 2023

Figure 4. Monthly trend of recorded surgeries between March 25, 2019 and August 31, 2023



Source: RNPM – Ministry of Health – Figures as of August 31, 2023

Table 3 shows the number of healthcare facilities in each Region and Autonomous Province where at least one surgical procedure for breast implantation or removal was recorded, along with the count of surgeons who performed these procedures.

Table 3. Number of surgeons and healthcare facilities by Region and Autonomous Province

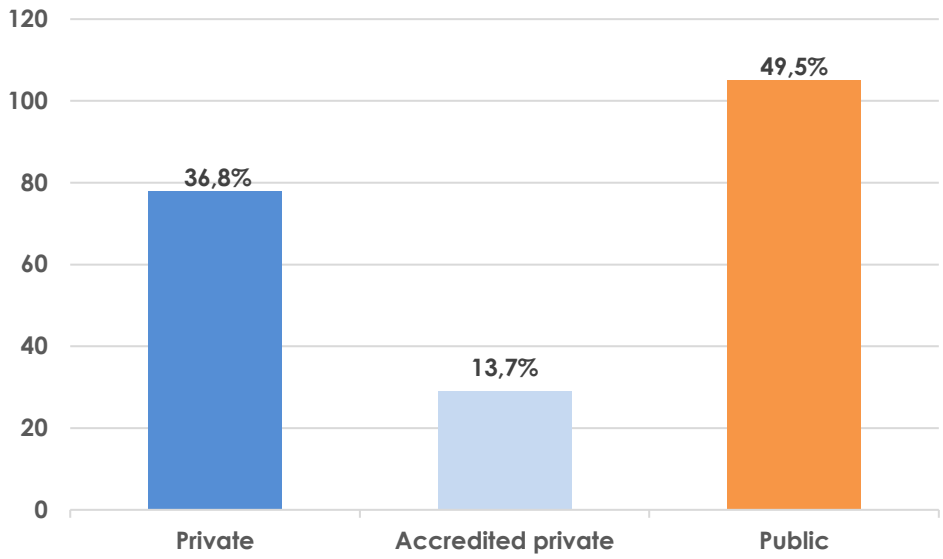
Region	Number of healthcare facilities	Number of surgeons
Piemonte	13	9
Valle D'Aosta	1	1
Lombardia	26	45
Provincia Autonoma di Bolzano	7	7
Provincia Autonoma di Trento	1	4
Veneto	15	15
Friuli-Venezia Giulia	7	12
Liguria	9	8
Emilia-Romagna	14	18
Toscana	27	40
Umbria	-	-
Marche	4	5
Lazio	36	43
Abruzzo	1	1
Molise	-	-
Campania	11	14
Puglia	9	11
Basilicata	-	-
Calabria	2	2
Sicilia	24	32
Sardegna	6	6
TOTAL	**213**	**273***

Source: RNPM – Ministry of Health – Figures as of August 31, 2023

* The total in the table is higher than the total number of surgeons who made at least one upload (No. 250) because a surgeon can operate in multiple regions and multiple healthcare facilities even within the same region.

Figure 5 shows the type of healthcare facility (public, accredited private, or private) where breast implantation surgeries or removals were performed.

Figure 5. Type of healthcare facilities where implantation or removal was performed

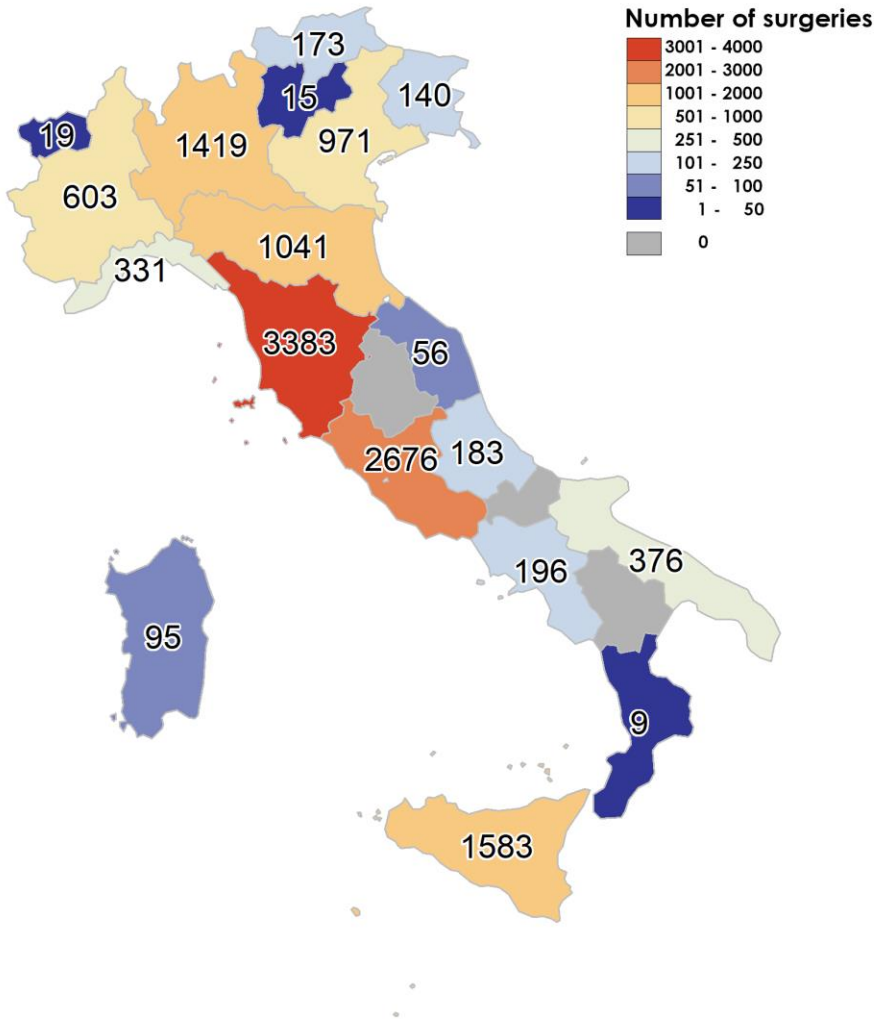


Source: RNPM – Ministry of Health – Figures as of August 31, 2023

About surgeons' postgraduate title, it is observed that out of the 250 surgeons, 80.0% (n = 200) are qualified in Plastic, Reconstructive, and Aesthetic Surgery, 18.0% (n = 45) in General Surgery, and 2 surgeons are qualified in Thoracic Surgery.

Figure 6: the map illustrates the distribution of surgeries registered in each Region and Autonomous Province. Toscana region stands out with the highest number of surgeries, likely due to local initiatives aimed at raising awareness and promoting the inclusion of breast prosthetic implant procedures in all Breast Units of regional healthcare facilities. After Toscana, there are regions of Lazio, Sicilia, and Lombardia. Conversely, Basilicata, Molise, and Umbria have reported no surgical procedures.

Figure 6. Map of surgeries' distribution per Region registered on the IT platform



Source: RNPM – Ministry of Health – Figures as of August 31, 2023

Table 4 illustrates the interregional mobility of patients who underwent surgery for breast implantation or removal. It shows the number of patients residing in each region who had surgery within their residence region or elsewhere. For instance, only 3.6% of patients from Sicilia and 5.0% from Lazio underwent surgery in different regions, while 55.8% of patients from Campania had surgery outside. However, it is important to note that these results are heavily influenced by the sample of recorded surgeons. Therefore, if there were no surgeons actively registering in a region, no surgeries would have been recorded in that region. This could be the reason why Molise, Umbria, and

Basilicata have 100% passive mobility rate (the percentage of patients undergoing surgery in regions other than their region of residence).

Table 4 also presents data on the patient mobility of each region (active mobility): 66.1% of patients treated in Marche healthcare facilities are coming from other regions anyway it's only a small number of patients (37 out of 56). On the other hand, in Lombardia a higher volume of surgeries was recorded and 28.2% of patients came from outside. Furthermore, the table enables visualization of the regions where the 424 foreign patients (3.2%) underwent surgery in Italy.

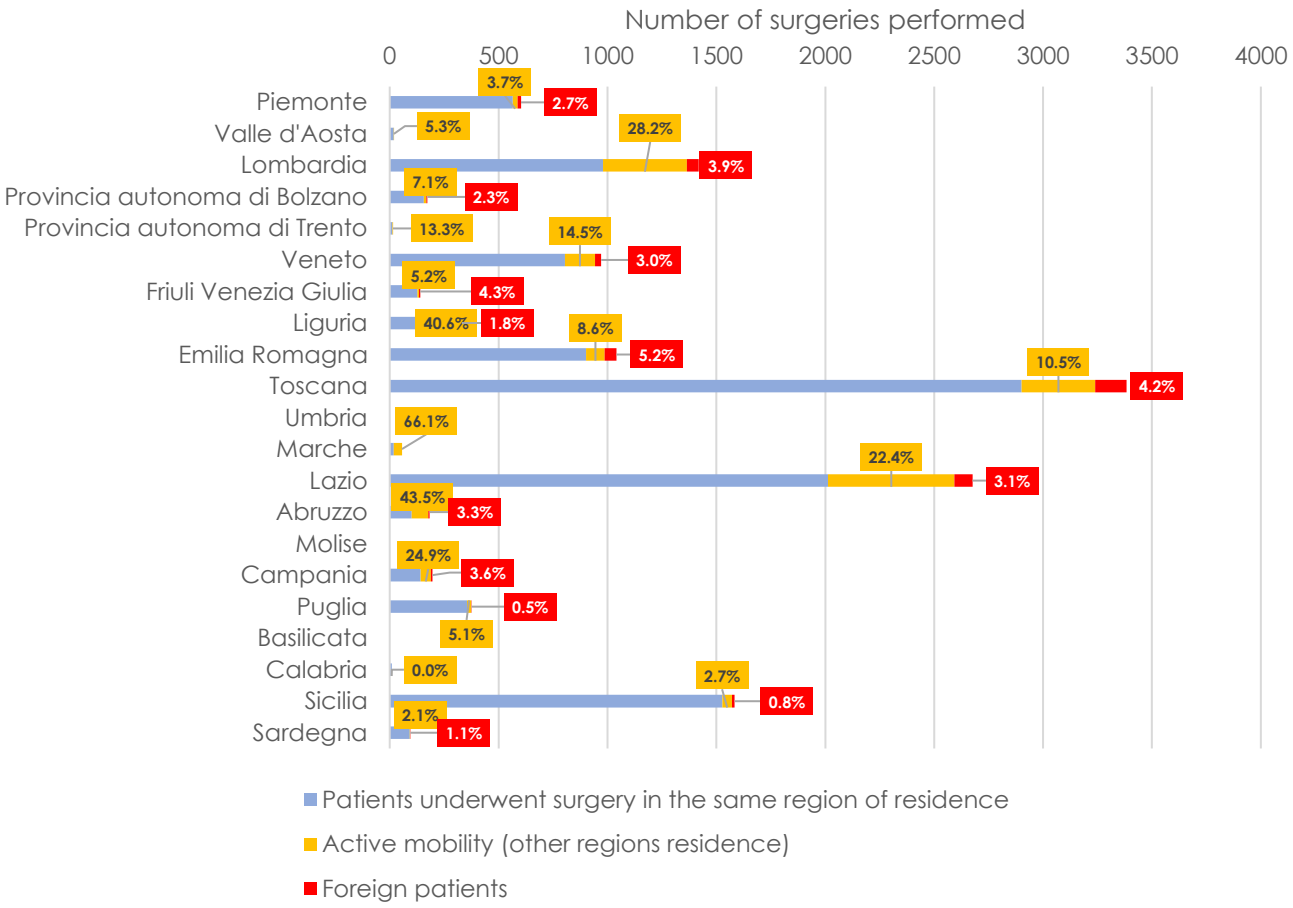
Table 4. Interregional Mobility – Surgeries Performed

	Residence by region																					Active mobility			
Region/ hospital	Piemonte	Valle D'Aosta	Lombardia	PA Bolzano	PA Trento	Veneto	Friuli Venezia Giulia	Liguria	Emilia Romagna	Toscana	Umbria	Marche	Lazio	Abruzzo	Molise	Campania	Puglia	Basilicata	Calabria	Sicilia	Sardegna	Total surgeries performed	Surgeries performed	%	Foreign residents
Piemonte	**565**		3			2		10								1			3	2	1	**587**	22	3,75	16
Valle D'Aosta	1	**18**																				**19**	1	5,26	0
Lombardia	102	6	**979**	6	15	74	10	30	58	15		8	6	3		14	14	2	6	9	7	**1.364**	385	28,23	55
PA Bolzano				**157**	11	1																**169**	12	7,10	4
PA Trento			1		**13**															1		**15**	2	13,33	0
Veneto	3		43	3	14	**805**	15	1	24	7	2	8			1		9		2	3	2	**942**	137	14,54	29
Friuli Venezia Giulia						6	**127**									1						**134**	7	5,22	6
Liguria	20		14					**193**	2	92			1	1			2					**325**	132	40,62	6
Emilia Romagna			14			4		1	**902**	3	1	29	2			14	9		4	2	2	**987**	85	8,61	54
Toscana	22	1	27	3	12	8	1	75	35	**2901**	46	1	30	1	6	16	19	2	19	10	5	**3.240**	339	10,46	143
Umbria																									
Marche									1			**19**		33	2		1					**56**	37	66,07	0
Lazio	11	1	23	1	2	9	4	1	7	29	23	22	**2013**	58	13	123	85	13	103	28	24	**2.593**	580	22,37	83
Abruzzo			2						1		2	5	48	**100**		6	10	1	1	1		**177**	77	43,50	6
Molise																									
Campania	2		7					1	2			1	18	2	2	**142**	6	1	5			**189**	47	24,87	7
Puglia									1			1		2	3	1	**355**	5	5	1		**374**	19	5,08	2
Basilicata																									
Calabria																			**9**			**9**	0	0,00	0
Sicilia	1		5			1			1	1					1	3	4	1	25	**1528**		**1.571**	43	2,74	12
Sardegna	1			1																	**92**	**94**	2	2,13	1
Total residents	**728**	**26**	**1.118**	**171**	**67**	**910**	**157**	**312**	**1.034**	**3.048**	**74**	**94**	**2.118**	**200**	**28**	**321**	**514**	**25**	**182**	**1.585**	**133**				**424**
Passive mobility	163	8	139	14	54	105	30	119	132	147	74	75	105	100	28	179	159	25	173	57	41				
%	22,4	30,8	12,4	8,2	80,6	11,5	19,1	38,1	12,8	4,8	100,0	79,8	5,0	50,0	100,0	55,8	30,9	100,0	95,1	3,6	30,8				

Source: RNPM – Ministry of Health – Figures as of August 31, 2023

Figure 7 indicates how each region attracts patients residing in other regions or abroad.

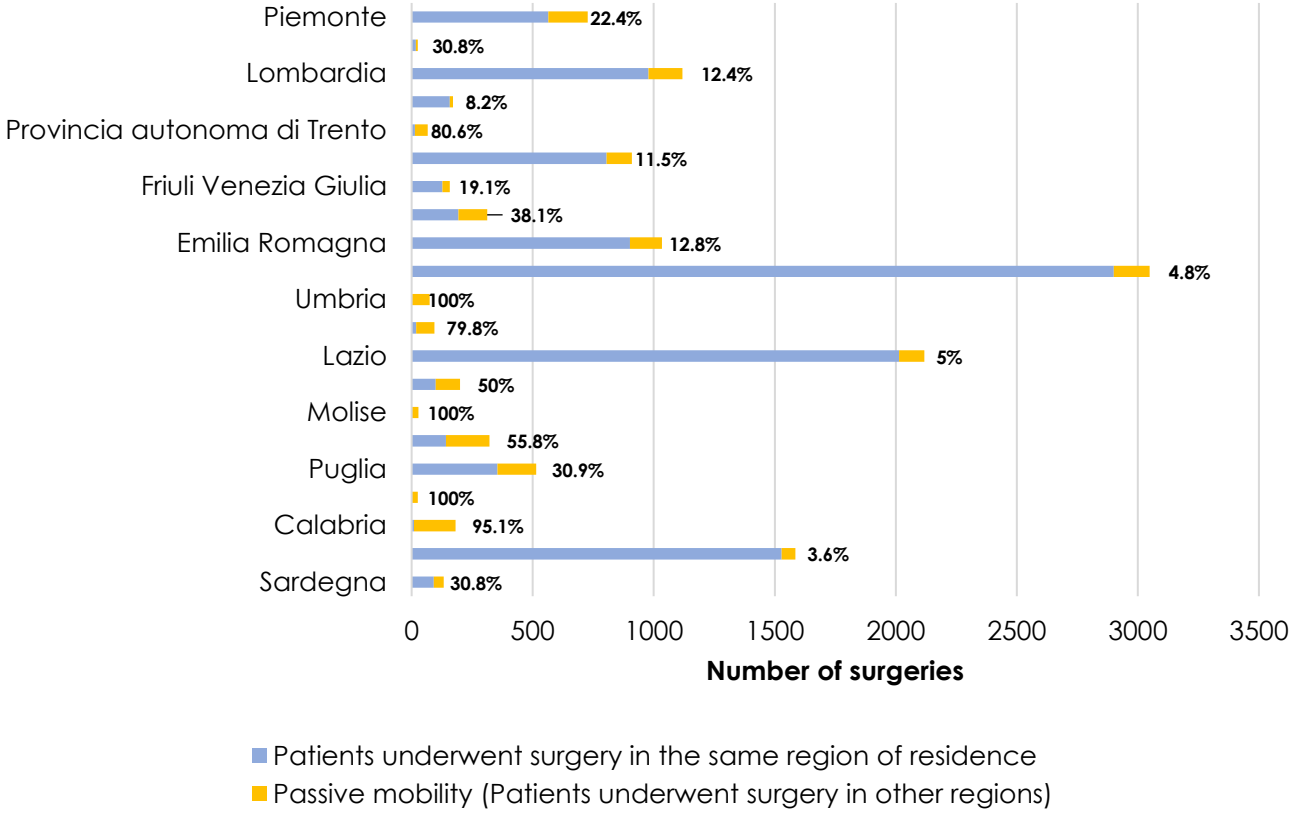
Figure 7. Attractiveness of healthcare facilities registering interventions in the IT platform by region



Source: RNPM – Ministry of Health – Figures as of August 31, 2023

Figure 8 points out the percentage of patients who underwent surgery in a region different from the one they reside.

Figure 8. Passive mobility- Distribution of surgeries by patient's region of residence and location (same/different region)



*The percentage value displayed refers to passive mobility

Source: RNPM – Ministry of Health – Figures as of August 31, 2023

To properly read the data described in this Report, it's essential to acknowledge that they may not yet reflect the entirety of surgical activities performed in Italy between March 2019 and August 2023. Indeed, these data represent the surgical activities of only approximately 11% of Italian surgeons.

Table 5 presents biographical and clinical history of registered patients. On 13,025 patients: 99.8% were female and 0.2% were male. The patients' mean age was 48 years. Furthermore, 64.9% of patients had no relevant clinical history for this type of surgery, while 9.7% were smokers, 5.4% were hypertensive, 0.9% had diabetes, 1.0% had coagulation disorders, 5.6% had food or drug allergies, and 2.1% had autoimmune diseases. Additionally, 8.1% had a positive family history of breast cancer, and 5.8% had mutations in the BRCA1 and BRCA2 genes.

Table 5. Biographical data and clinical history of registered patients

Anamnesis data	N=13.054
Biological sex, N (%):	
Female	13.025 (99,8%)
Male	29 (0,2%)
Age, Mean (SD)	48.0 (12,6)
Nothing in particular, N (%):	
No	8.474 (64,9%)
Yes	4.580 (35,1%)
Smoking, N (%):	
No	1.1781 (90,2%)
Yes	1.273 (9,8%)
Hypertension, N (%):	
No	1.2348 (94,6%)
Yes	706 (5,4%)
Diabetes, N (%):	
No	12.928 (99,0%)
Yes	126 (1,0%)
Coagulation disorders, N (%):	
No	12.917 (99,0%)
Yes	137 (1.0%)
Food and drug allergies, N (%):	
No	12.318 (94,4%)
Yes	736 (5,6%)
Autoimmune diseases, N (%):	
No	12.784 (97,9%)
Yes	270 (2,1%)
Familiality in breast cancer, N (%):	
No	11994 (91,9%)
Yes	1060 (8,1%)
Presence of BRCA1 BRCA2 mutation, N (%):	
No	12.295 (94,2%)
Yes	759 (5,8%)

Source: RNPM – Ministry of Health – Figures as of August 31, 2023

The procedures were primary surgeries in 74.4% of cases (patients have implanted a breast implant for the first time) and were revisions in 25.6% of the cases, (patients were submitted to implant replacement or removal) (Figure 9). The procedures were for reconstructive purposes in 53.4% of cases and for cosmetic purposes in 46.6% (Figure 10).

Figure 9. Type of surgical procedures

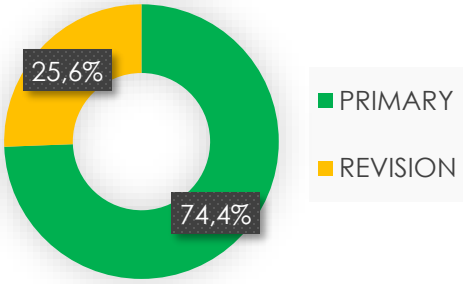
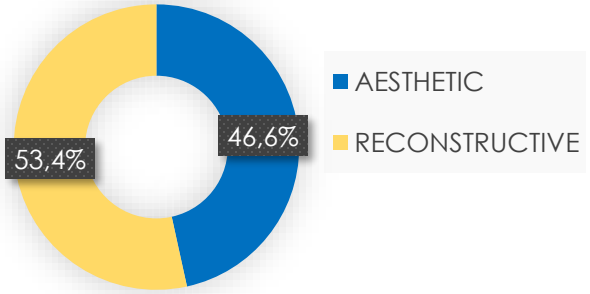


Figure 10. Surgical procedures according to the purposes



Source: RNPM – Ministry of Health – Figures as of August 31, 2023

Breast implantations in primary procedures for reconstructive purposes were overriding those performed for cosmetic purposes (Figure 11); Breast implantations in revision surgeries were more performed in patients who had initially implanted the prosthesis for aesthetic purposes (Figure 12).

Figure 11. Primary surgeries according to the purposes

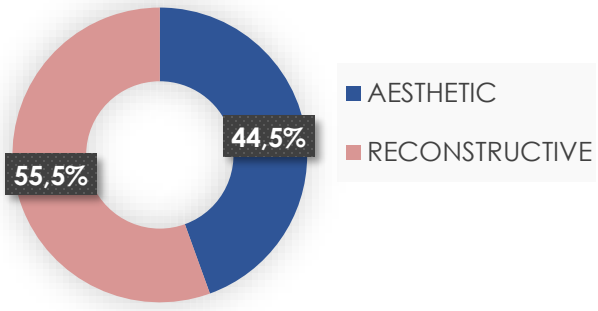
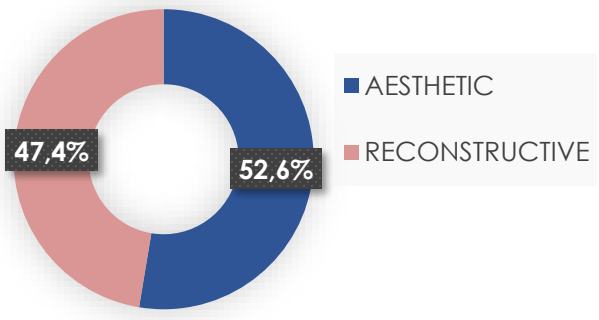


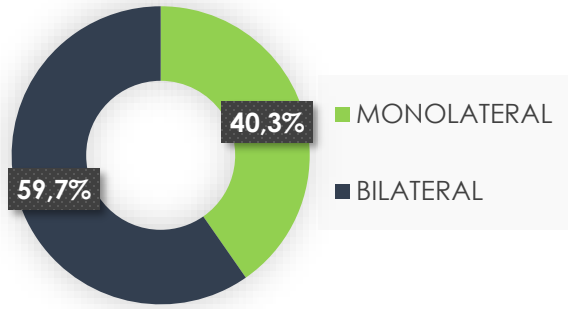
Figure 12. Revision surgeries according to the purposes



Source: RNPM – Ministry of Health – Figures as of August 31, 2023

The procedures were performed bilaterally in 59.7% of cases (Figure 13)

Figure 13. Side of the surgical procedure



Source: RNPM – Ministry of Health – Figures as of August 31, 2023

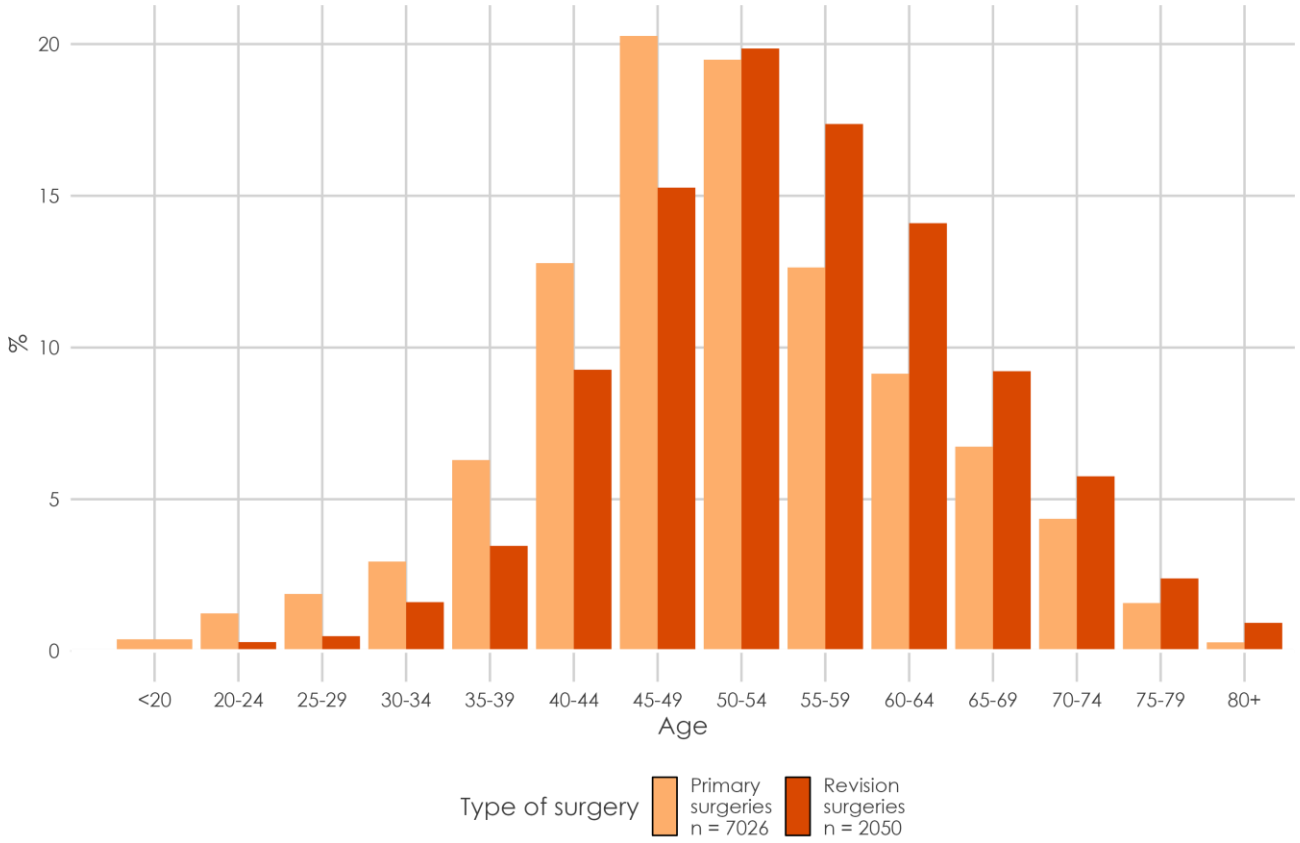
2.1 RECONSTRUCTIVE BREAST SURGERY

The number of breast surgeries - implant or removal - performed for reconstructive purposes was 11,322; surgeries were performed on 8,645 patients.

The mean age of patients who underwent primary implant[13] was 51.1 years, while the mean age of patients who underwent revision was 55.2 years. Figure 14 shows the age distribution, according to primary or revision surgery for reconstructive purposes.

[13] Primary implant: breast implant is placed for the first time. The implantation is considered primary whether the implant is placed immediately (after oncologic surgery) or following tissue expander removal.

Figure 14. Age distribution of patients who had surgery under reconstructive indication, divided by primary and revision surgeries



Source: RNPM – Ministry of Health – Figures as of August 31, 2023

Table 6 shows biographical data and clinical history of patients submitted to surgery for reconstructive purposes.

Patients submitted to primary surgery reported relevant clinical history for this type of surgery in 87.5% of cases; this percentage is even higher in patients who underwent revision procedures (91.7%).

Table 6. Biographical data and clinical history of patients – reconstructive purposes

	PRIMARY N=6.968	REVISION N=1.934	*TOTAL N=8.645*
Biological sex, N (%):			
Female	6961 (99,9%)	1.931 (99,8%)	*8.635 (99,9%)*
Male	7 (0,1%)	3 (0.2%)	*10 (0,1%)*
Age, Mean (SD)	51,1 (11,3)	55,2 (10,4)	*52.0 (11,2)*
Nothing particular, N (%):			
No	6.094 (87,5%)	1.774 (91,7%)	*7.624 (88,2%)*
Yes	874 (12,5%)	160 (8,3%)	*1021 (11,8%)*
Smoking, N (%):			
No	6.384 (91,6%)	1.724 (89,1%)	*7.885 (91.2%)*
Yes	584 (8,4%)	210 (10,9%)	*760 (8,8%)*
Hypertension, N (%):			
No	6.483 (93,0%)	1.745 (90,2%)	*7.989 (92,4%)*
Yes	485 (7,0%)	189 (9,8%)	*656 (7,6%)*
Diabetes, N (%):			
No	6.873 (98,6%)	1.906 (98.6%)	*8.527 (98,6%)*
Yes	95 (1.,4%)	28 (1,5%)	*118 (1,4%)*
Coagulation disorders, N (%):			
No	6.895 (99,0%)	1.912 (98,9%)	*8.554 (98,9%)*
Yes	73 (1,0%)	22 (1,1%)	*91 (1.,1%)*
Food and drug allergies, N (%):			
No	6.513 (93,5%)	1.785 (92,3%)	*8.056 (93,2%)*
Yes	455 (6,5%)	149 (7,7%)	*589 (6,8%)*
Autoimmune diseases, N (%):			
No	6.815 (97,8%)	1874 (96.9%)	*8437 (97.6%)*
Yes	153 (2.2%)	60 (3.1%)	*208 (2.4%)*
Familiality in breast cancer, N (%):			
No	6.125 (87,9%)	1750 (90,5%)	*7642 (88,4%)*
Yes	843 (12,1%)	184 (9,5%)	*1003 (11,6%)*
Presence of BRCA1 BRCA2 mutation, N (%):			
No	6.318 (90,7%)	1808 (93,5%)	*7888 (91,2%)*
Yes	650 (9.3%)	126 (6,5%)	*757 (8,8%)*

The total does not equal the sum of the two types of surgery (primary or revision) because a patient can undergo both primary as well as revision procedures at the same time

Source: RNPM – Ministry of Health – Figures as of August 31, 2023

Among all procedures performed for reconstructive purposes: 6,302 were unilateral and 5,020 bilateral (

Table 7).

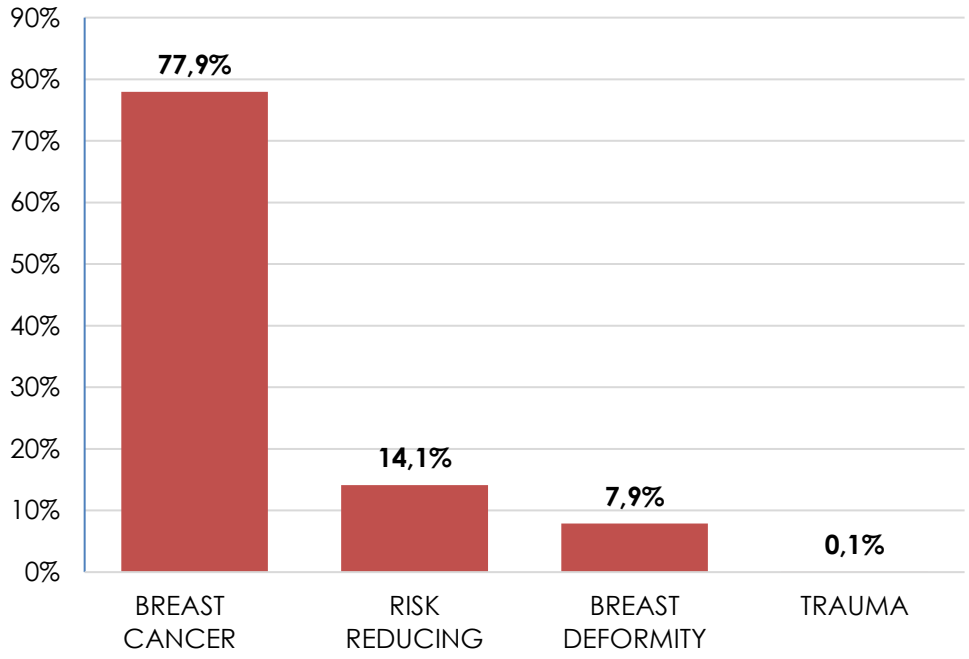
Table 7. Percentage for reconstructive purpose - unilateral or bilateral.

RECONSTRUCTIVE SURGERY	N	%
UNILATERAL	6.302	55,7%
BILATERAL	5.020	44,3%
TOTAL	**11.322**	

Source: RNPM – Ministry of Health – Figures as of August 31, 2023

Figure 15 shows the clinical conditions for which the primary surgery was performed.

Figure 15. Percentage of primary surgeries with reconstructive indication, by diagnosis.



Source: RNPM – Ministry of Health – Figures as of August 31, 2023

Table 8 displays all clinical conditions for breast reconstruction with immediate primary implantation (one stage procedure) or after an expander removal (two stage procedure). A notable preference for immediate implantation was observed in 5,868 cases, while 2,884 implants have been performed after an expander removal. The trend aligns with actual practices that emphasize the breast cancer early diagnosis or prophylactic mastectomies minimizing an extensive skin removal.

Table 8. Number of procedures with primary reconstructive purpose by expander use and diagnosis

	TISSUE EXPANDER				
	NO	%	YES	%	TOTAL
BREAST CANCER	4.190	61,4%	2.631	38,6%	6.821
HIGH RISK OF MALIGNANCY	993	80,3%	244	19,7%	1.237
BREAST DEFORMITY	681	98,8%	8	1,2%	689
TRAUMA	4	80,0%	1	20,0%	5
TOTAL	**5.868**		**2.884**		**8752**

Source: RNPM – Ministry of Health – Figures as of August 31, 2023

Table 9 shows some details on surgeries performed according to the diagnosis.

Table 9. Primary procedures with reconstructive purpose by diagnosis

Diagnosis	Surgery performed	n	%
Breast Cancer			
	DEALYED IMPLANT	791	11,6%
	IMMEDIATE IMPLANT AFTER PARTIAL MASTECTOMY	15	0,2%
	IMMEDIATE IMPLANT NIPPLE SPARING TOTAL MASTECTOMY	4.331	63,5%
	IMMEDIATE IMPLANT SKIN SPARING TOTAL MASTECTOMY	1.436	21,1%
	IMMEDIATE IMPLANT WITHOUT SKIN SPARING TOTAL MASTECTOMY	248	3,6%
		6.821	
High risk of malignancy	IMMEDIATE IMPLANT NIPPLE SPARING TOTAL MASTECTOMY	1.087	87,9%
	IMMEDIATE IMPLANT SKIN SPARING TOTAL MASTECTOMY	119	9,6%
	IMMEDIATE IMPLANT WITHOUT SKIN SPARING TOTAL MASTECTOMY	31	2,5%
		1.237	
Breast malformations	DUAL PLANE IMPLANT	324	47,0%
	SUBFASCIAL IMPLANT	49	7,1%
	SUBGLANDULAR IMPLANT	213	30,9%
	SUBMUSCULAR IMPLANT	103	14,9%
		689	
Trauma	DUAL PLANE IMPLANT	2	0,3%
	SUBFASCIAL IMPLANT	1	0,1%
	SUBGLANDULAR IMPLANT	1	0,1%
	SUBMUSCULAR IMPLANT	1	0,1%
		5	

Source: RNPM – Ministry of Health – Figures as of August 31, 2023

It is highlighted that the early diagnosis of breast cancer has enabled skin nipple sparing mastectomies, giving patients the opportunity to obtain breast reconstructions in a single stage.

In presence of a diagnosis of breast cancer, the implantation was performed in addition to these procedures: flap harvesting in 14.6% of cases, fat grafting in 5.1% and both procedures in 0.9% of cases. In prophylactic mastectomies the implantation was performed in addition to these procedures: flap harvesting in 13.8% of cases, fat grafting in 2.3% and both procedures in 0.5% of cases. Due to breast deformity, the implantation was performed in addition to these procedures: flap harvesting in 6.0% of cases, fat grafting in 3.0%, and both procedures in 0.9% of cases (Table 10).

Table 10. Number of procedures with primary reconstructive purpose by type of ancillary surgery performed by diagnoses

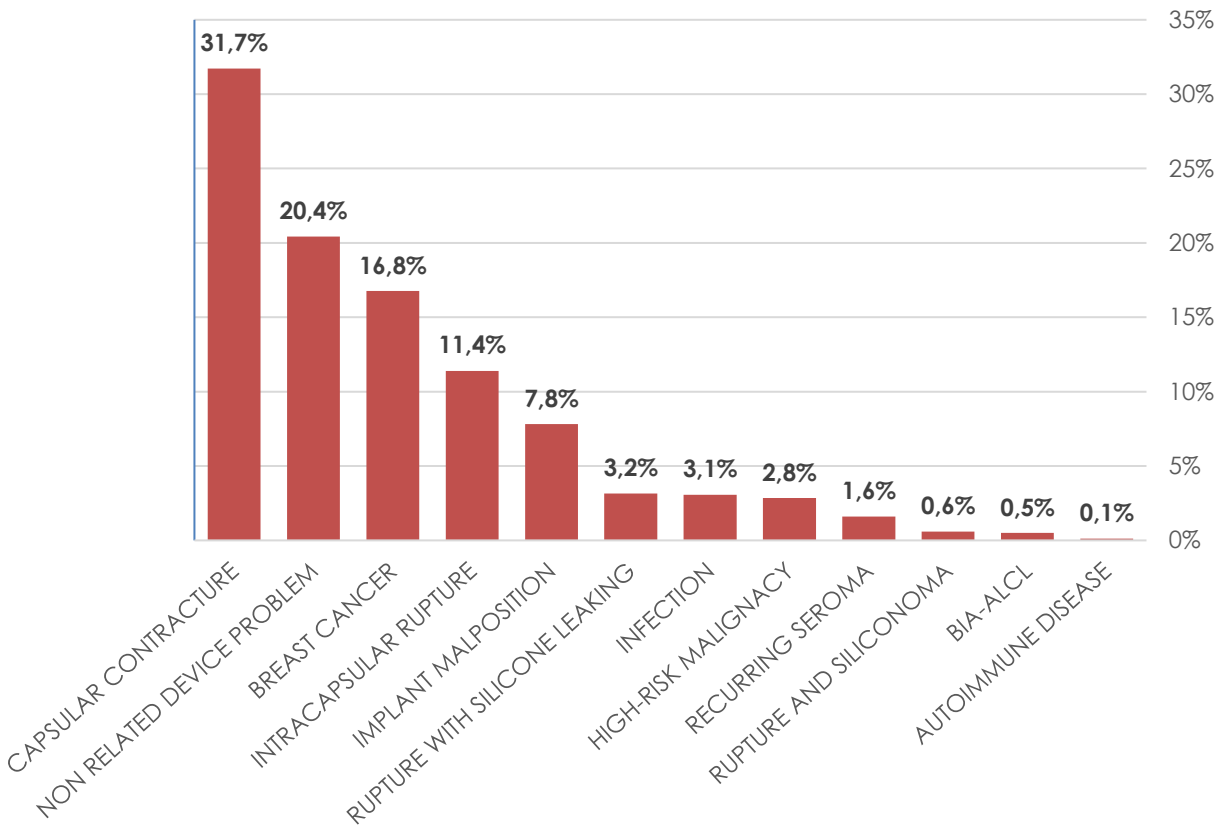
	NONE		ONLY FLAP		ONLY LIPOFILLING		BOTH PROCEDURES		
	n	%	n	%	n	%	n	%	TOTAL
BREAST CANCER	5.414	79,4%	998	14,6%	348	5,1%	61	0,9%	6.821
HIGH RISK OF MALIGNANCY	1.031	83,3%	171	13,8%	29	2,3%	6	0,5%	1.237
BREAST DEFORMITY	621	90,1%	41	6,0%	21	3,0%	6	0,9%	689
TRAUMA	5	100,0%	-	-	-	-	-	-	5
TOTAL	**7.071**	**80,8%**	**1.210**	**13,8%**	**398**	**4,5%**	**73**	**0,8%**	**8.752**

Source: RNPM – Ministry of Health – Figures as of August 31, 2023

Breast implants were placed in association with other medical devices (mesh/ADM) in 1681 procedures (19.2%). shows the clinical conditions of patients who initially received breast implants for reconstructive purposes and then underwent revision surgery. The main cause of revision was capsular contracture (31.7 %), the procedure occurred without having a device-related problem in in 20.4% of cases (i.e. to treat any asymmetry or volumetric changes); the procedure was performed due to implant rupture inn 15.2% of the cases.

Figure 16 shows the clinical conditions of patients who initially received breast implants for reconstructive purposes and then underwent revision surgery. The main cause of revision was capsular contracture (31.7 %), the procedure occurred without having a device-related problem in in 20.4% of cases (i.e. to treat any asymmetry or volumetric changes); the procedure was performed due to implant rupture inn 15.2% of the cases.

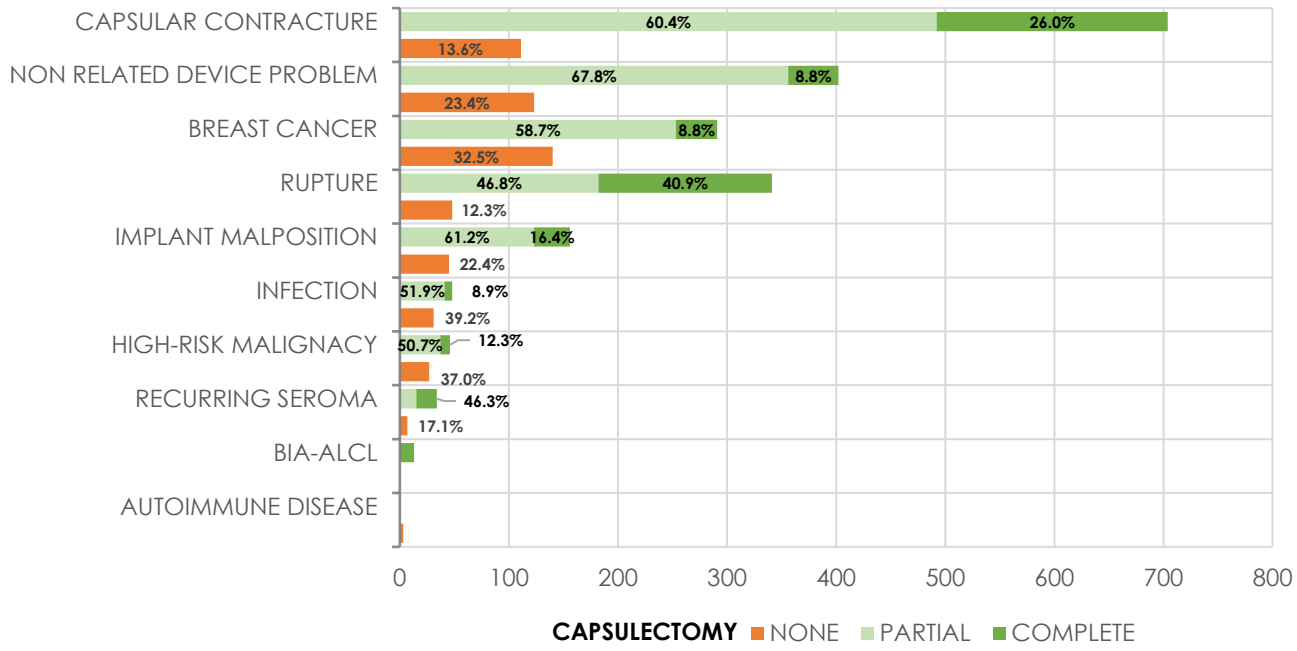
Figure 16. Causes for revision surgery



Source: RNPM – Ministry of Health – Figures as of August 31, 2023

Figure 17 illustrates the type of capsulectomy (partial or radical) when performed according to the diagnoses. Radical capsulectomy was performed in 20.9% of all revision surgeries.

Figure 17. Capsulectomies - reconstructive indication in revision surgery



The percentages represent the proportion of different types of capsulectomies for each distinct cause. Only the percentage of the main reasons for revision are shown.

Source: RNPM – Ministry of Health – Figures as of August 31, 2023

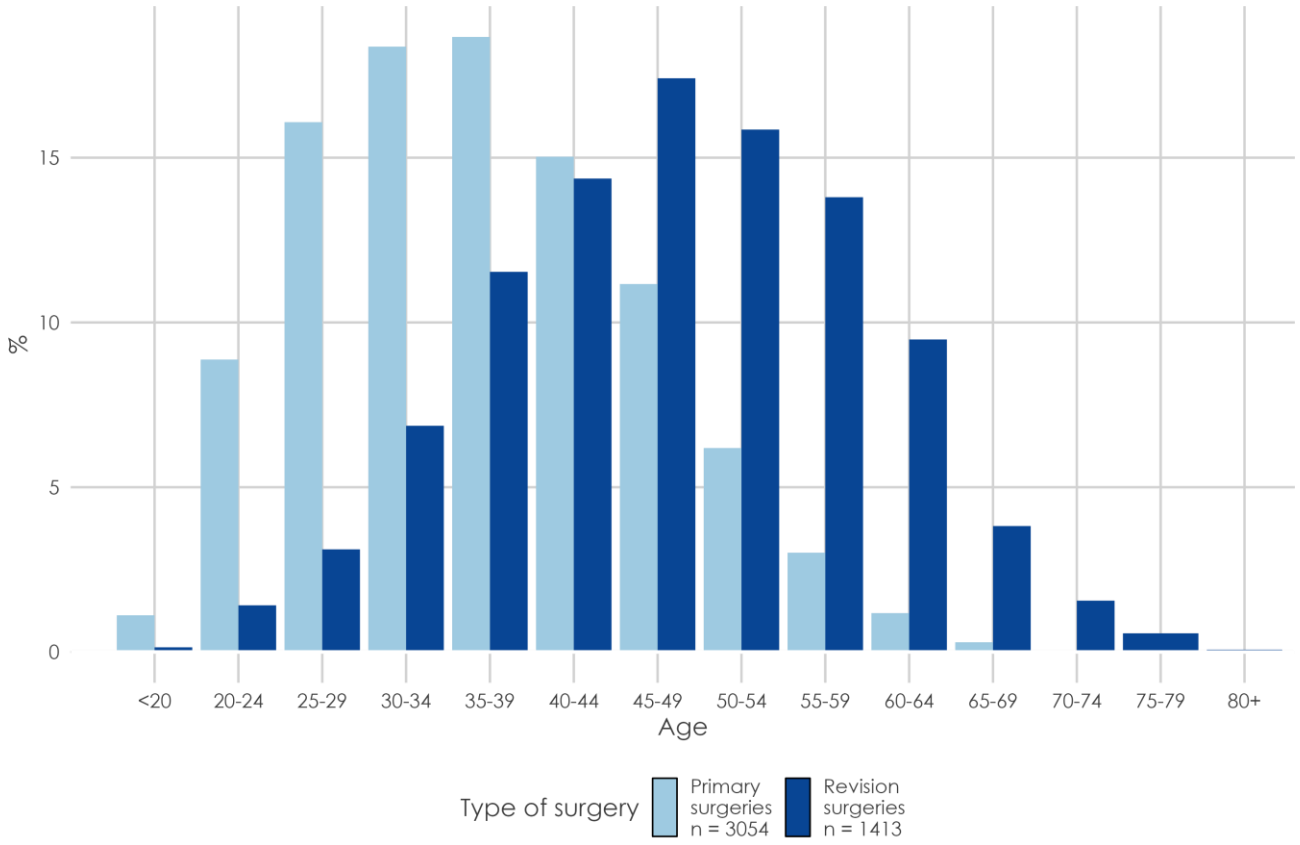
In 90.5% of cases, revision surgery was performed accessing previous surgical scar.

2.2 AESTHETIC BREAST SURGERY

The number of surgical procedures for breast implantation or removal with aesthetic purposes was 8,756. These were performed on 4,409 patients for aesthetic surgery on both sides and on 1,102 patients for aesthetic surgery one side only (reconstructive surgery on other side). The mean age of patients submitted to surgery purely cosmetic (aesthetic indication on both sides) was 36.7 years for primary surgery and 48.2 years for revision surgery.

Figure 18 shows patients age distribution according to the type of surgery (primary or revision).

Figure 18. Age distribution of patients - aesthetic indication, by primary or revision surgeries



Source: RNPM – Ministry of Health – Figures as of August 31, 2023

Table 11 shows differences in biographical data and clinical history among patients who underwent to cosmetic procedures, particularly between those submitted to primary and revision surgery. Notably, as this type of surgery is elective, patients who underwent aesthetic surgeries reported a significantly higher percentage of negative clinical history compared to those submitted to reconstructive surgery (80.7% vs. 11.8%, respectively). Furthermore, differences are observed in terms of hypertension, coagulation disorders and autoimmune disorders, which are slightly more prevalent in patients submitted to revision surgery.

Table 11. Biographical data and clinical history of patients – aesthetic purpose

	PRIMARY N=3.046	REVISION N=1.373	TOTAL N=4.409
Biological sex, N (%):			
Female	3.037 (99,7%)	1.363 (99,3%)	4.390 (99,6%)
Male	9 (0.3%)	10 (0,7%)	19 (0,4%)
Age, Mean (SD)	36,7 (9,7)	48,2 (11,0)	40,3 (11,4)
Nothing particular, N (%):			
No	545 (17,9%)	306 (22,3%)	850 (19,3%)
Yes	2.501 (82,1%)	1.067 (77,7%)	3.559 (80,7%)
Smoking, N (%):			
No	2.685 (88,1%)	1.221 (88,9%)	3.896 (88,4%)
Yes	361 (11,9%)	152 (11,1%)	513 (11,6%)
Hypertension, N (%):			
No	3.032 (99,5%)	1.337 (97,4%)	4.359 (98,9%)
Yes	14 (0,5%)	36 (2,6%)	50 (1,1%)
Diabetes, N (%):			
No	3.040 (99,8%)	1.371 (99,9%)	4.401 (99,8%)
Yes	6 (0,2%)	2 (0,1%)	8 (0,2%)
Coagulation disorders, N (%):			
No	3.016 (99,0%)	1.357 (98,8%)	4.363 (99,0%)
Yes	30 (1,0%)	16 (1,2%)	46 (1,0%)
Food and drug allergies, N (%):			
No	2.947 (96,7%)	1.325 (96,5%)	4.262 (96,7%)
Yes	99 (3,3%)	48 (3,5%)	147 (3,3%)
Autoimmune diseases, N (%):			
No	3.016 (99,0%)	1.341 (97,7%)	4.347 (98,6%)
Yes	30 (1,0%)	32 (2,3%)	62 (1,4%)
Familiality with breast cancer, N (%):			
No	3.011 (98,9%)	1.351 (98,4%)	4.352 (98,7%)
Yes	35 (1,1%)	22 (1,6%)	57 (1,3%)
Presence of BRCA1 BRCA2 mutation, N (%):			
No	3.046 (100%)	1.371 (99,9%)	4.407 (99.95%)
Yes	0 (0.00%)	2 (0,1%)	2 (0,05%)

The total does not correspond to the sum of the two types of procedures (primary or revision) because a patient may undergo both primary and revision procedures simultaneously

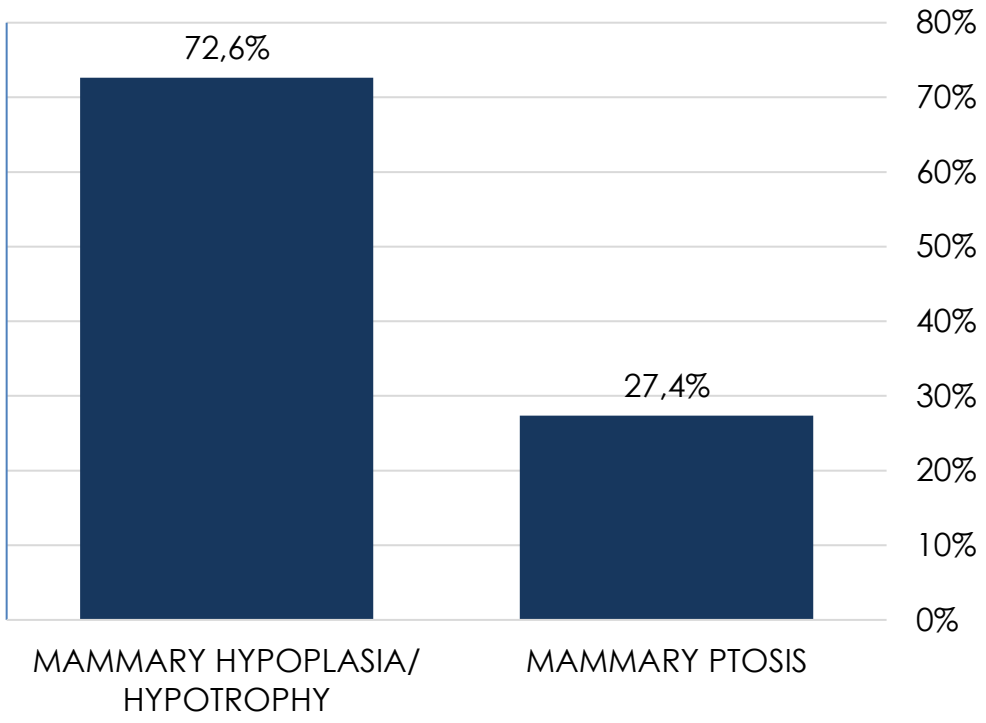
Source: RNPM – Ministry of Health – Figures as of August 31, 2023

Out of the 4,457 surgeries performed: 4,299 were bilateral (96.5%) and 158 were unilateral (4.5%). Among the unilateral surgeries 49 were primary procedures aimed at treat breast asymmetries (unilateral hypotrophic/ptotic breast).

The indications for breast implantation for cosmetic purposes are illustrated in Figure 19.

The 72.6% of primary surgeries occurred for hypoplastic/hypotrophic breasts, while 27.4 were performed for breast ptosis.

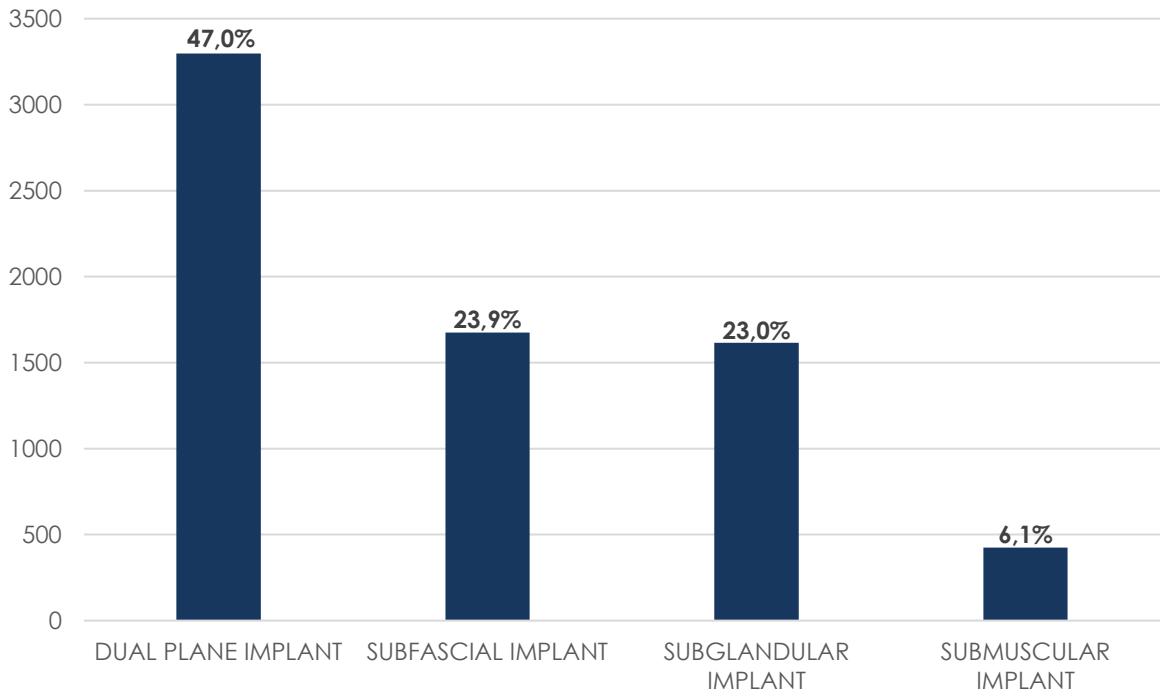
Figure 19. Percentage of primary surgeries with aesthetic indication, by diagnosis



Source: RNPM – Ministry of Health – Figures as of August 31, 2023

Figure 20 shows where the implant was placed. The number of procedures performed using 'dual plane' was higher (47%).

Figure 20. Anatomical pocket - aesthetic indication



Source: RNPM – Ministry of Health – Figures as of August 31, 2023

Table 12 reports where the implant was placed according to the diagnosis.

Table 12. Primary procedures - aesthetic indication by diagnosis

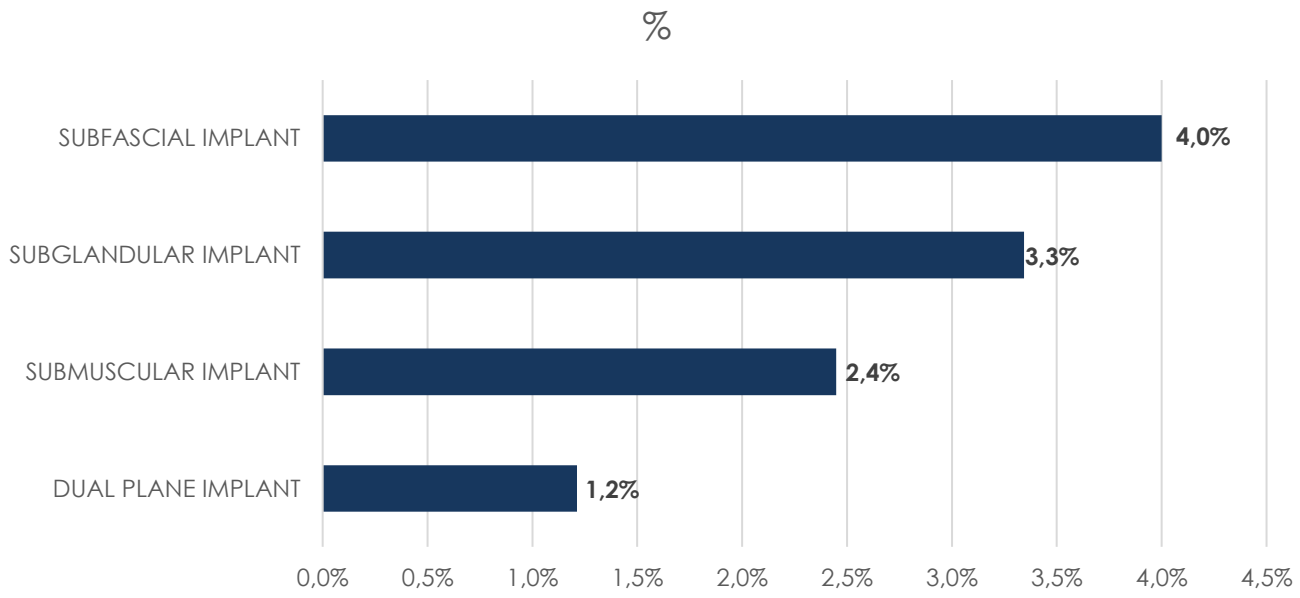
Diagnosis	Procedure	n	%
MAMMARY HYPOPLASIA/HYPOTROPHY			
	DUAL PLANE IMPLANT	2.587	50,8%
	SUBMUSCULAR IMPLANT	1.174	23,0%
	SUBGLANDULAR IMPLANT	1.020	20,0%
	SUBFASCIAL IMPLANT	313	6,1%
	TOTAL	**5.094**	
MAMMARY PTOSIS			
	DUAL PLANE IMPLANT	710	37,0%
	SUBMUSCULAR IMPLANT	595	31,0%
	SUBGLANDULAR IMPLANT	501	26,1%
	SUBFASCIAL IMPLANT	112	5,8%
	TOTAL	**1.918**	

Source: RNPM – Ministry of Health – Figures as of August 31, 2023

In both hypoplasia/hypotrophy and breast ptosis, the prosthesis was predominantly inserted by "dual plane" procedure.

Data shows that fat grafting, performed in 2.2% of the cases in addition to the implantation, was most frequent in subfascial and subcutaneous breast augmentations (Figure 21). This observation aligns with surgeons' preference to ensure better prosthesis coverage reducing device visibility when placed more superficially.

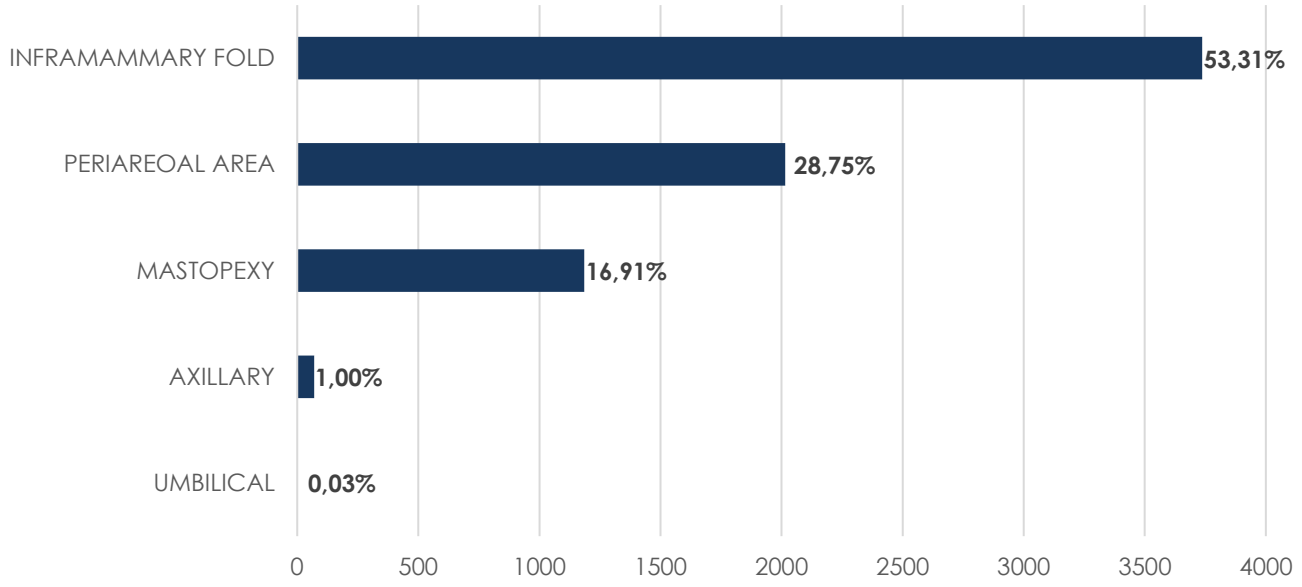
Figure 21. Percentage of fat grafting in primary procedures - aesthetic indication



Source: RNPM – Ministry of Health – Figures as of August 31, 2023

Data analysis reveals that the inframammary fold was the most common surgical access (53.3%), followed by the periareolar access (28.7%), and the mastopexy approach (16.9%) (Figure 22).

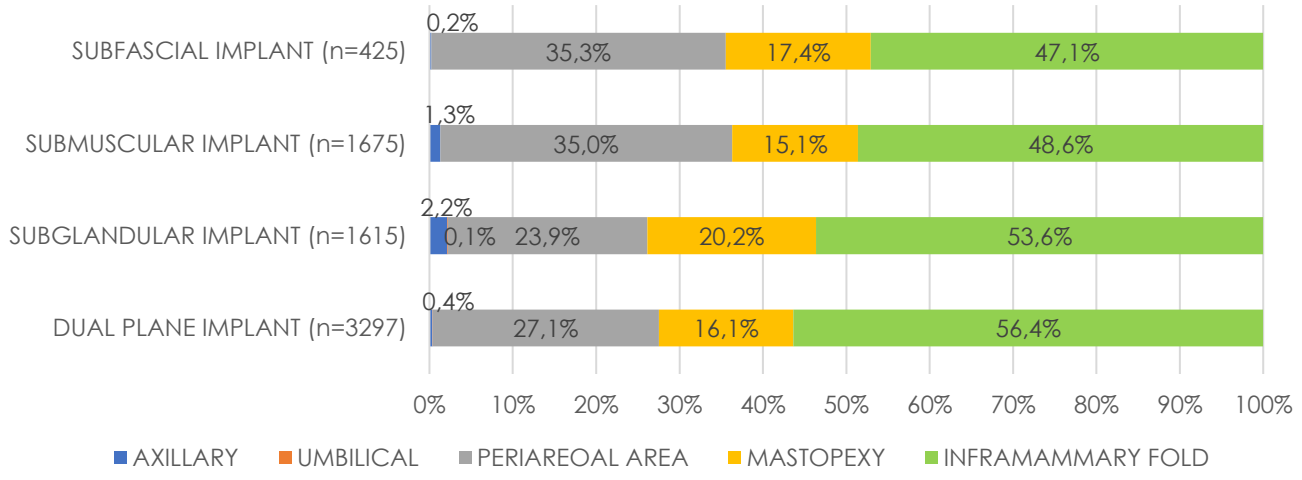
Figure 22. Surgical access in aesthetic surgery.



Source: RNPM – Ministry of Health – Figures as of August 31, 2023

Figure 23 shows the different accesses according to the anatomical site of the implantation: the axillary one, although less frequent, was mainly used when the prosthesis had to be implanted in the subglandular area.

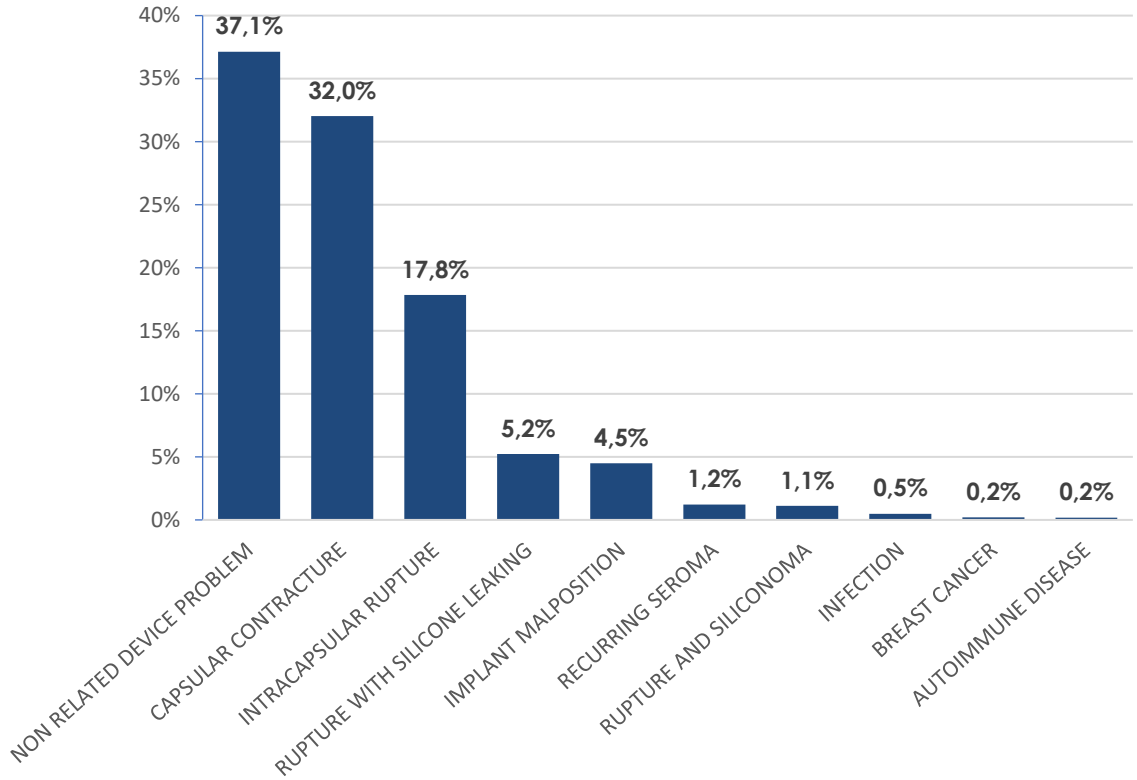
Figure 23. Anatomical pocket and surgical accesses for implant.



Source: RNPM – Ministry of Health – Figures as of August 31, 2023

The leading cause of revision surgery in patients who were implanted for aesthetic purposes was not linked to device-related issues (37.1%), following capsular contracture (32.0%) and all types of ruptures (24.2%) (Figure 24).

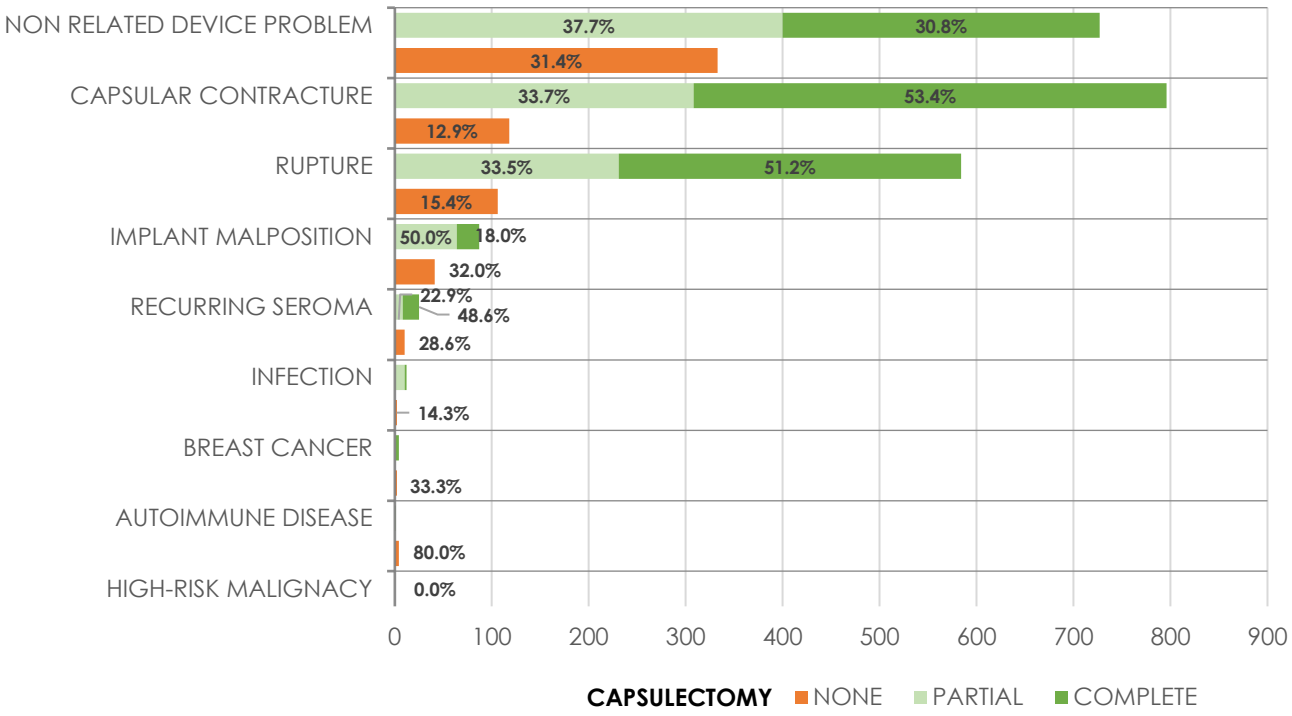
Figure 24. Causes of revision surgery - aesthetic



Source: RNPM – Ministry of Health – Figures as of August 31, 2023

Figure 25 shows the type of capsulectomy performed according to the diagnoses in revision surgery. From data analysis it emerges that radical capsulectomy was performed in 42.5% of all revision surgeries.

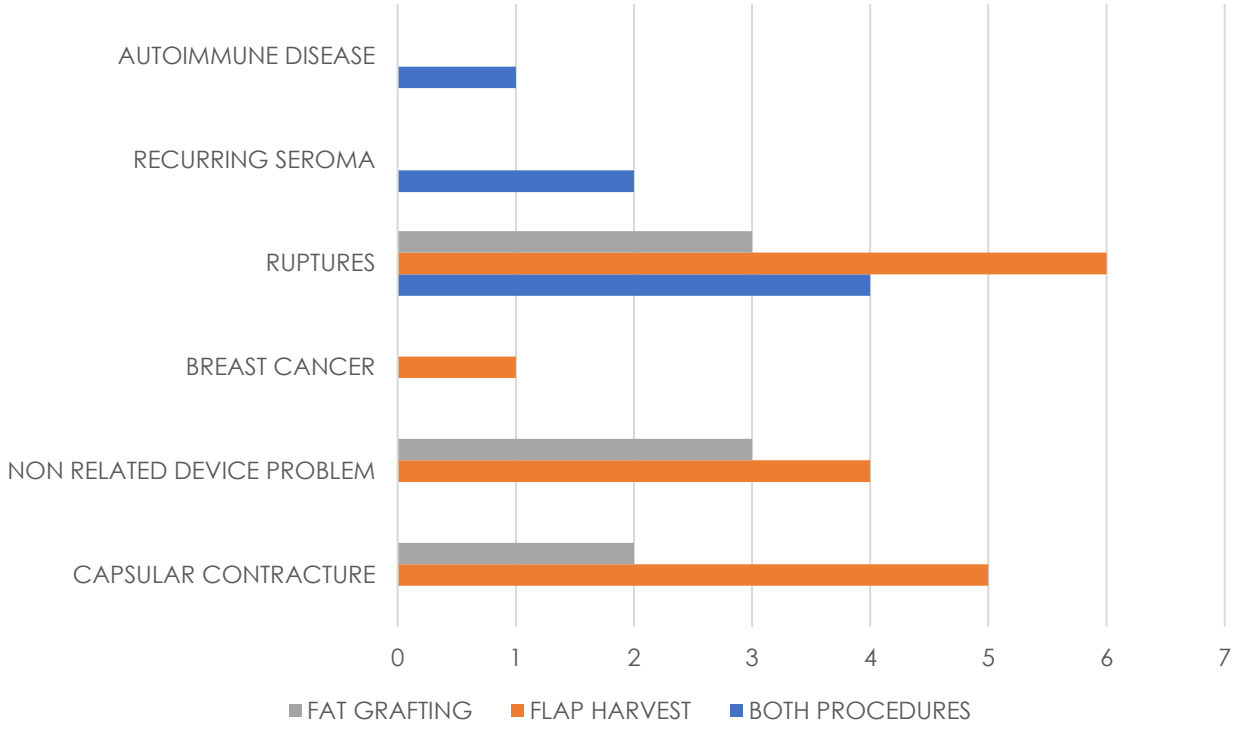
Figure 25. Capsulectomy in revision surgery - primary aesthetic surgery



Source: RNPM – Ministry of Health – Figures as of August 31, 2023

Out of the 2,854 revision surgeries, the device removal only was performed in 4.8% of cases. Among these, in 22.6% of cases device removal was performed with an additional procedure: fat grafting in 5.8% of cases, flap harvesting in 11.7% of cases, and both procedures (flap harvesting and lipofilling) in 5.1% of cases (Figure 26).

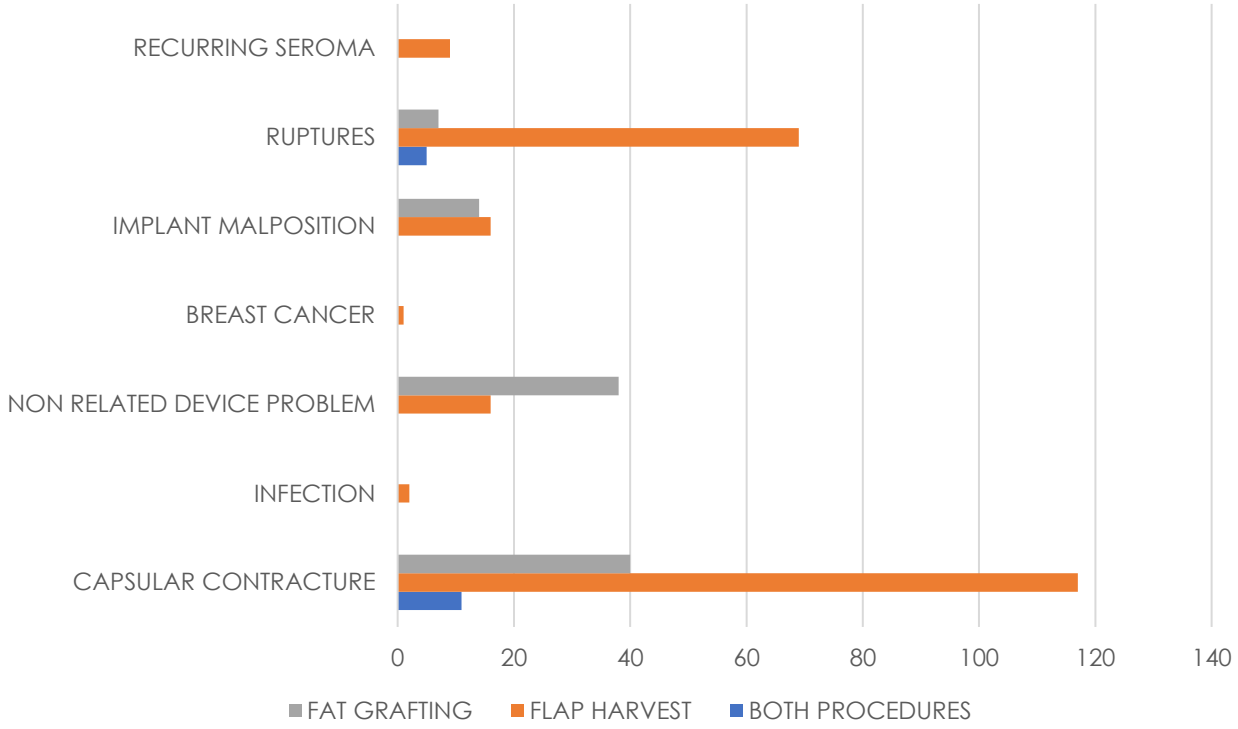
Figure 26. Ancillary procedures in revision surgery after implant removal



Source: RNPM – Ministry of Health – Figures as of August 31, 2023

Figure 27 shows the type of additional procedures performed at the same time of replacement, according to the diagnosis.

Figure 27. Additional surgical procedure performed at the same time of replacement



Source: RNPM – Ministry of Health – Figures as of August 31, 2023

Out of a total of 4,125 surgeries performed on patients that received the implant bilaterally, a different weight of devices was used in 9.2% of cases. Considering also the procedures performed unilaterally, the total percentage of the surgeries performed for breast asymmetry rises to 12.3%.

2.3 TYPE OF BREAST IMPLANTS

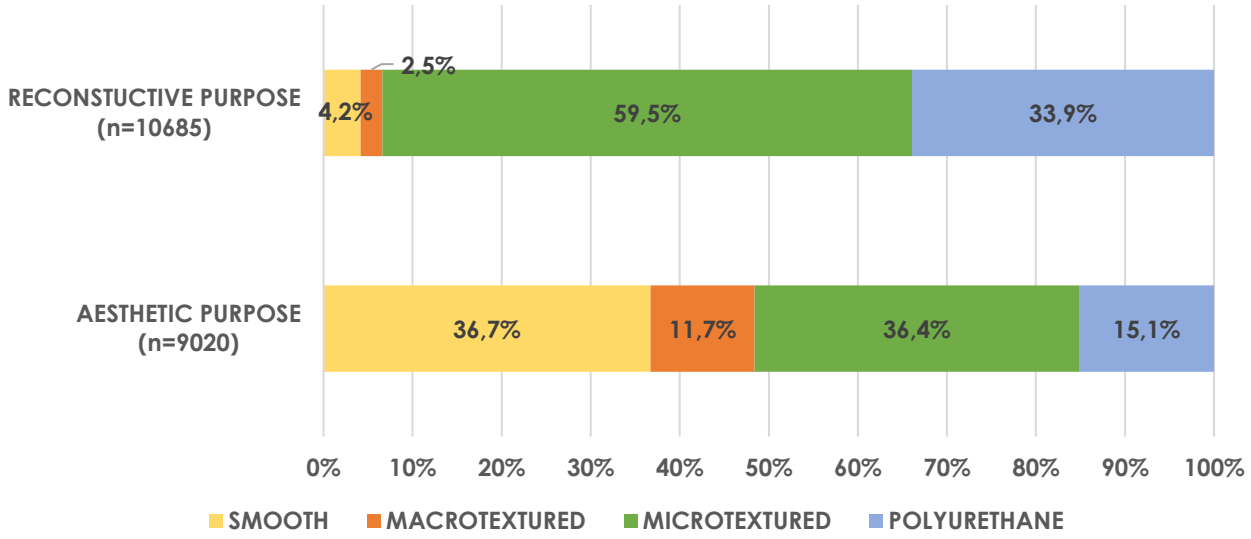
SURFACE

The characteristics of breast prostheses implanted can be summarized as follows: 55.6% of the devices have a textured shell surface (48.9% microtextured and 6.7% macrotextured), 25.3% were in polyurethane, and 19.1% were smooth (ISO UE 14607[14]).

In surgeries performed for reconstructive purposes, device with microtextured surfaces are the most commonly used (59.5% of cases), followed by polyurethane-coated prostheses (33.9% of cases). In procedures with aesthetic purposes, the number of smooth-surface device rises to 36.7% (Figure 28).

This finding is consistent with the prevalent use of anatomical prostheses in reconstructive surgery (Figure 29). These prostheses are designed with a textured surface, specifically intended to reduce the risk of rotation.

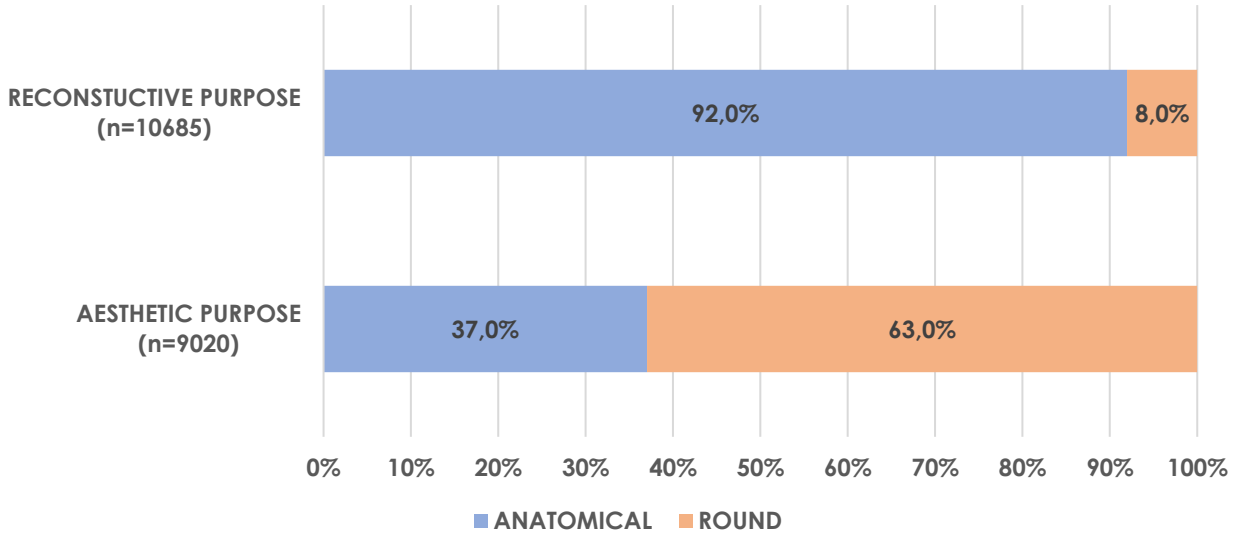
Figure 28. Surface of the prosthesis implanted based on the surgical indication



Source: RNPM – Ministry of Health – Figures as of August 31, 2023

[14] International Organization for Standardization. ISO 14607:2018 Non-active surgical implants—Mammary implants—Particular requirements, available at the following link: https://www.iso.org/standard/63973.html .

Figure 29. Device shape by surgical indication



Source: RNPM – Ministry of Health – Figures as of August 31, 2023

Although data collected on the types of device implanted cannot yet be considered representative nationwide, they are consistent with sales trends in breast implants in Italy. Indeed, market surveillance analyses, based on data provided annually by distributors, indicate an increase of microtextured and smooth surface devices' sales.

This could be due, on one hand, to the removal from the market in 2019 of macrotextured surface breast implants produced by Allergan Limited which held a significant share of the Italian and European markets; on the other hand, to the recent hypotheses regarding the involvement of macrotextured surface implants in the etiopathogenesis of BIA-ALCL.

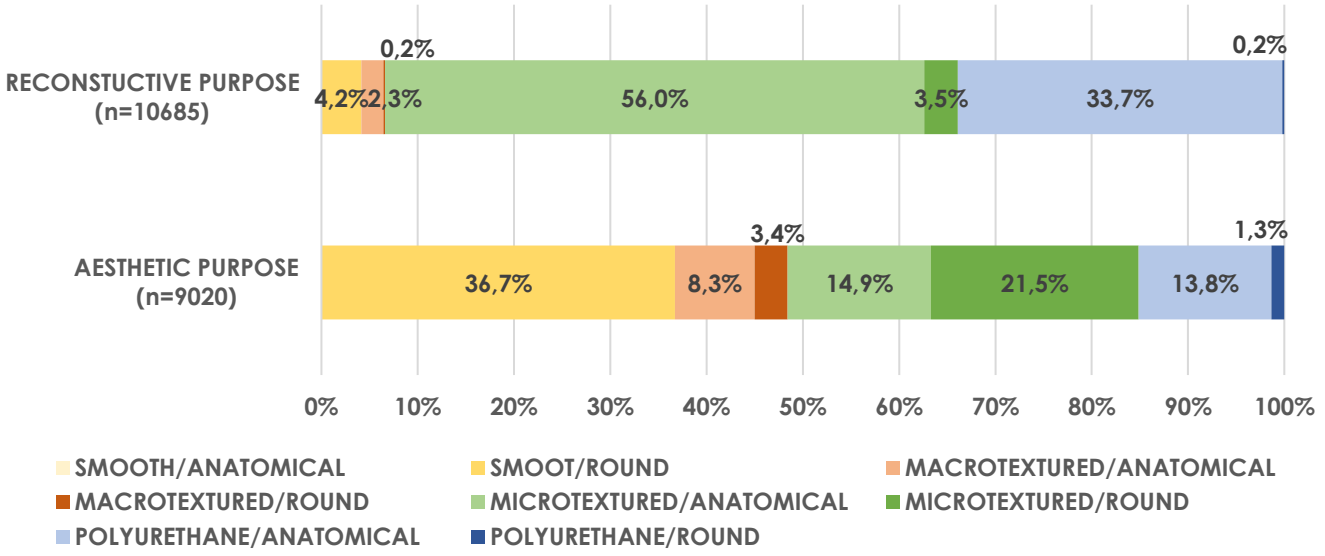
However, compared to the market trends in the United States, which are mostly characterized by the sales of smooth implants (87.5% smooth vs 12.5% textured), in Europe, textured surface devices continue to be predominant (94.8% textured vs 5.2% smooth) (19).

In Italy, based on data provided by distributors to the Ministry of Health, textured surface implants still account for the majority of sales (64.1% textured vs 22.8% smooth); the remaining 13.2% is represented by implants with a polyurethane surface (data as of 2022).

SHAPE

The percentage of anatomical breast implants has been significantly higher overall compared to round ones: 67.5% versus 32.5%. However, there is an important difference in usage between anatomical and round implants in both reconstructive and aesthetic contexts (Figure 29).
In reconstructive surgery, anatomical microtextured breast implants have been predominantly used (56.0%) followed by anatomical ones with polyurethane shell surface (33.7%). In aesthetic surgery round implants with smooth surface were mainly used (36.7%) followed by the anatomical microtextured (21.5%) and round microtextured (14.9%) (Figure 30).

Figure 30. Surface and shape of breast implants by purpose



Source: RNPM – Ministry of Health – Figures as of August 31, 2023

FILLING

Almost all of the implants were silicone filled (99.5%). Only 0.5% contained both silicone and borosilicate microspheres.

SIZE

Data analysis shows that 61.9% of the implants were of medium size (300-550 cm^3), 33.3% were small (< 300 cm^3), and only 4.8% were large (555-800 cm^3).

The average volume of the device implanted was 349 cm^3 (range: 50-925 cm^3).
The average volume of the implants used with reconstructive purposes wad 368 cm^3 (range: 50-800 cm^3).
The average volume of the implants for aesthetic purposes was 326 cm^3 (range: 55-925 cm^3).
Some studies on sales data from a single manufacturer of breast implants report that implants of medium size (300-550 cm^3) represent the majority of sales both in USA and in Europe: respectively 69.3% in USA and 67.7% in Europe. Large-sized implants (555-800 cm^3) are more sold in USA rather than in Europe: 17.8% in USA, and only 3.3% in Europe. In the United States, small implants (100-295 cm^3) represent the smallest percentage of sales at 12.8%, compared to the more substantial 29.1% of European sales (19).

2.4 "GOOD PRACTICES"

Reducing the incidence of short and long-term postoperative complications was the aim that brought internationally to the establishment of guidelines for patient management in pre, intra and post-operative time (20-23).

Antibiotic prophylaxis, operative times, changing gloves before implant placement, the use of antiseptics or antibiotics for device management during surgery and the use of drains can all influence the occurrence of infections, hematomas, seromas, capsular contracture, etc.

Data highlighted that in 87.2% of procedures, surgeons treated the anatomical pocket before implanting the device: with antiseptics in 53.0% of cases, with antibiotics and antiseptics in 20.0%, and with antibiotics alone in 14.1%. There are some differences in behaviour among surgeons who performed surgery for aesthetic (Figure 31) and reconstructive purpose (Figure 32) especially in the use of antiseptic alone or in combination with antibiotic.

Figure 31. Anatomical pocket irrigation - aesthetic

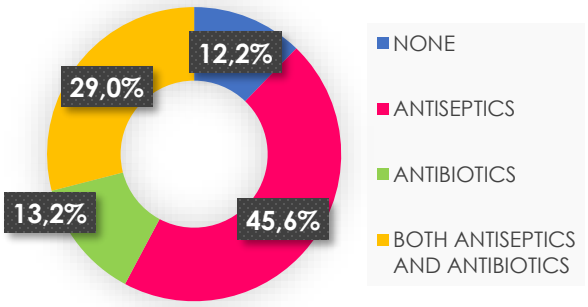
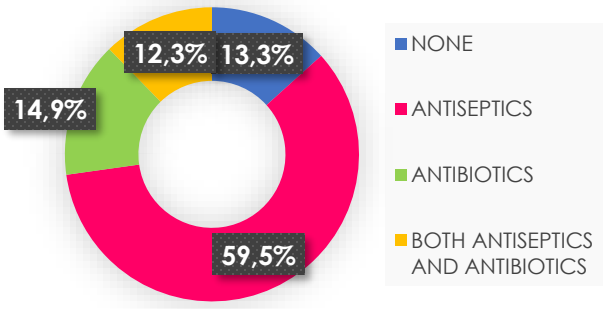


Figure 32. Anatomical pocket irrigation - reconstructive



Source: RNPM – Ministry of Health – Figures as of August 31, 2023

In 93.8% of the procedures (independently by the purposes), surgeons treated the device before the implantation: with antibiotics in 47.1% of procedures, with antiseptics in 24.1%, and

with both in 22.7%. Again, there is a different surgeon behaviour whether the implantation is for aesthetic (Figure 33) or reconstructive (Figure 34) purposes.

Figure 33. Implant irrigation - aesthetic

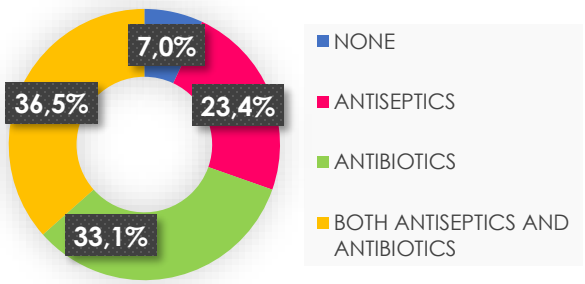
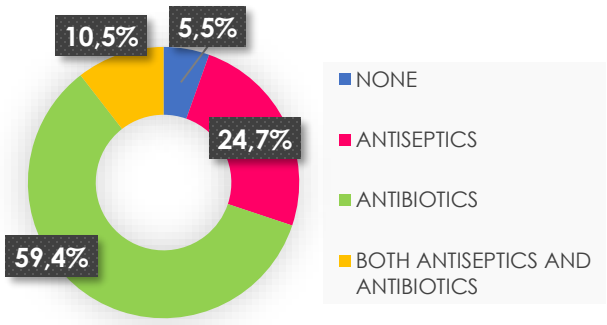


Figure 34. Implant irrigation - reconstructive



Source: RNPM – Ministry of Health – Figures as of August 31, 2023

Gloves were changed before the implantation in 97,0% of cases: 99.1% in surgeries for aesthetic purposes (Figure 35) and 95,0% in surgeries for reconstructive reasons (Figure 36).

Figure 35. Change of gloves - aesthetic

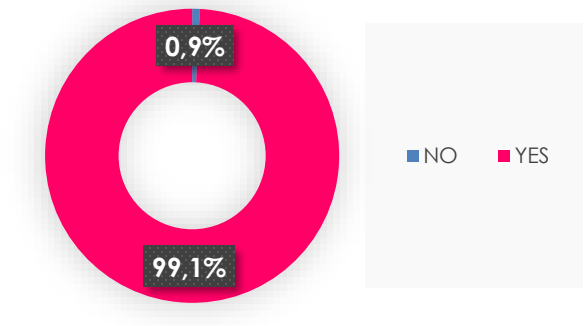
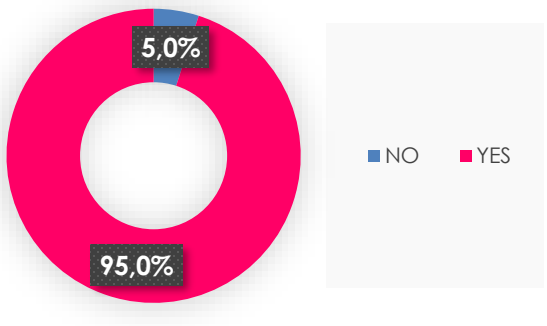


Figure 36. Change of gloves - reconstructive



Source: RNPM – Ministry of Health – Figures as of August 31, 2023

In 82.0% of the procedures, drains were used in the immediate postoperative period: in 66.6% of those performed for aesthetic purposes (Figure 37) and in 95.5% in reconstruction (Figure 38). A higher percentage of drain use was observed in procedures performed for reconstructive purposes and in revisions surgeries for aesthetic purposes (Figure 39). This data is in line with the principle that more complex surgical procedures may involve greater bleeding.

Figure 37. Drain use - aesthetic

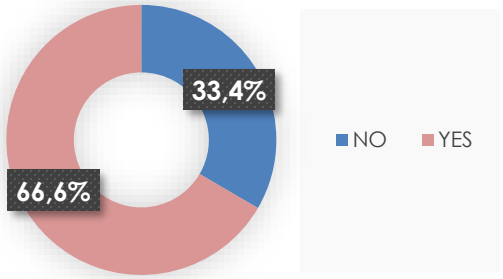
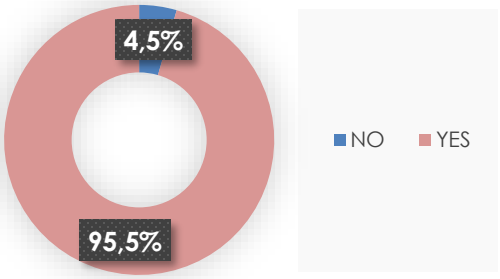
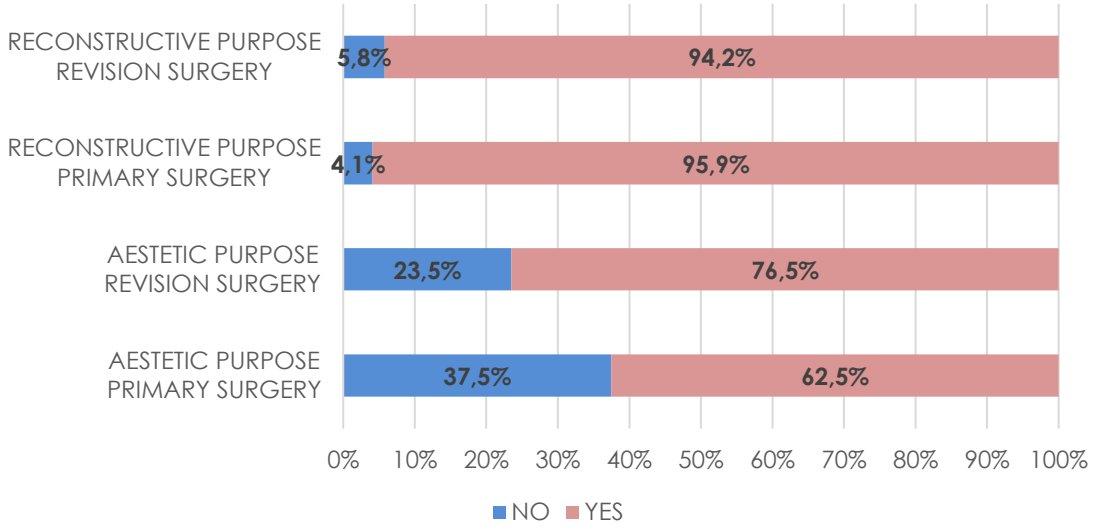


Figure 38. Drain use- reconstructive



Source: RNPM – Ministry of Health – Figures as of August 31, 2023

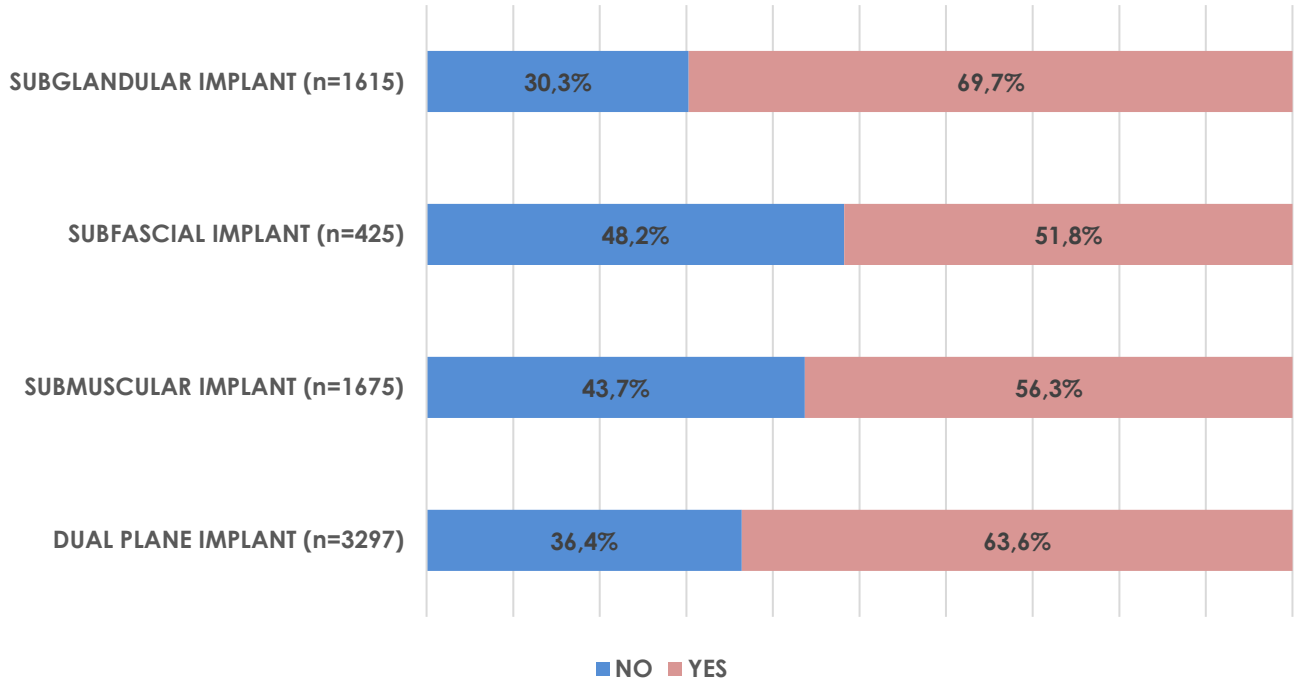
Figure 39. Drain use by indication and type of surgery



Source: RNPM – Ministry of Health – Figures as of August 31, 2023

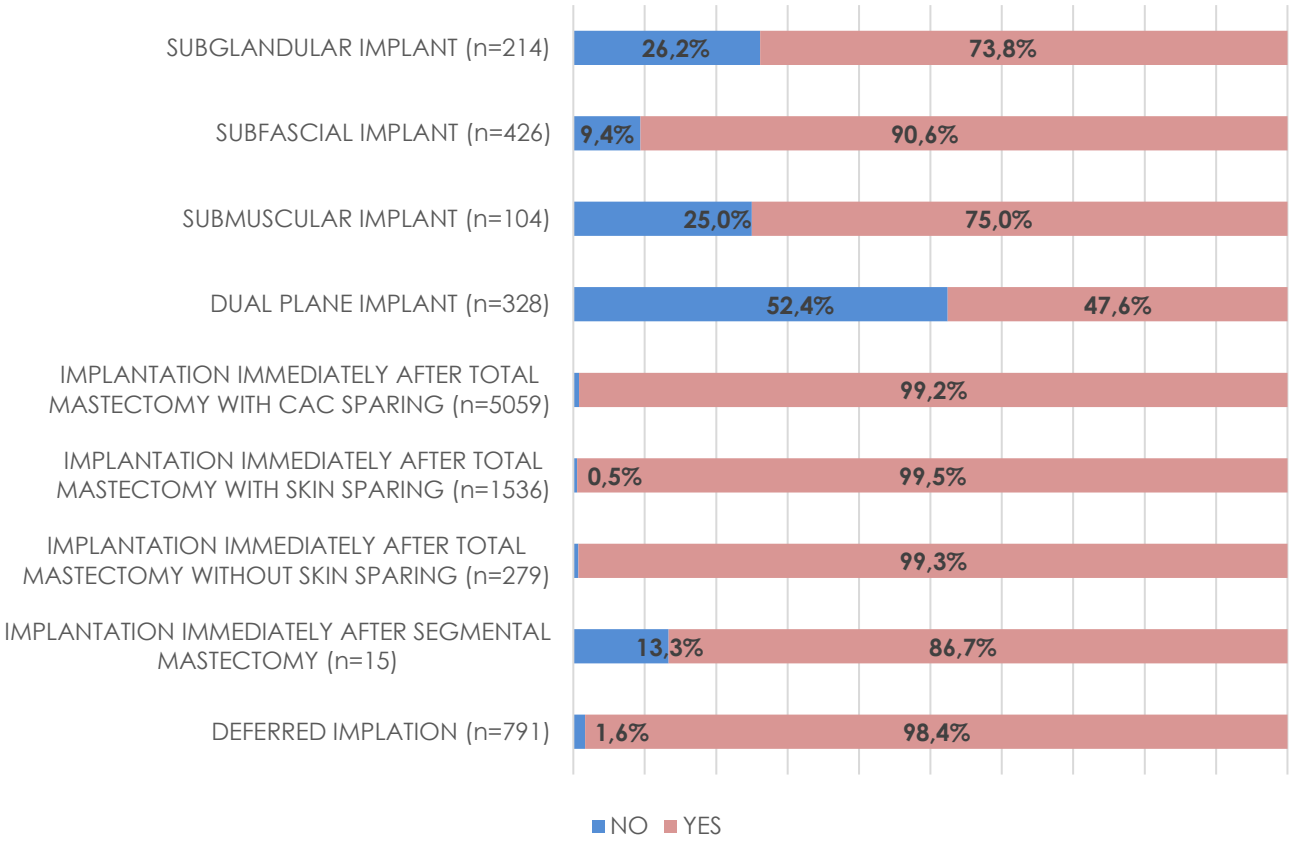
The following graphs show drain use during primary surgery for aesthetic purpose (Figure 40) and primary surgery for reconstruction (Figure 41).

Figure 40. Drain use during primary surgery for aesthetic purpose



Source: RNPM – Ministry of Health – Figures as of August 31, 2023

Figure 41. Drain use during primary surgery for reconstructive purpose



Source: RNPM – Ministry of Health – Figures as of August 31, 2023

3. MARKET SURVEILLANCE

One of the main aims of the ex DGDMF, where the Registry has been established, is to monitor the timing of revision surgery, to understand the factors that can influence revisions, and to identify the most common reasons for implant removal or replacement. The importance of these assessments lies in the impact that those revisions surgery have on the Italian National Health Service (SSN).

As the competent authority on medical devices, the Ministry of Health detects, monitors, and manages all clinical conditions potentially connected to the devices themselves.

3.1 BREAST IMPLANT REVISION SURGERY

One of the main aims is to define the mean lifetime of the implant. Predicting the number of future surgeries for a patient is crucial for assessing their health risk and for an efficient economic planning. Efficacy in expense prediction is fundamental for the SSN, which covers all expenses for breast implantations or removals with reconstructive purposes.

Indeed, the ex DGDMF is monitoring the revision times of surgical procedures performed for aesthetic and reconstructive purposes, even though the number of procedures recorded in the platform as of August 31, 2023, is not yet representative of this type of surgery in Italy.

All data indicate a median revision time for breast implants of approximately 8.1 years, with significant differences between the revision for aesthetic purposes and those for reconstructive purposes: 11.4 years vs. 4.9 years, respectively.

Analyzing the primary causes of secondary surgery for both aesthetic and reconstructive purposes, it appears that the median time to re-intervention for capsular contracture is 12.2 years in aesthetic cases and 5.9 years in reconstructive. For rupture, the median time is 13.5 years in aesthetic cases and 11.2 years in reconstructive.

Capsular contracture's occurrence is more influenced by patient's clinical conditions and therapies compared to implant rupture. Data analysis has been focused on patients' clinical histories. Specifically, it was found that the median revision time for patients treated with chemotherapy and radiotherapy is only 3.4 years; 4.4 years for patients treated with

chemotherapy alone; 3.8 years for patients treated with radiotherapy alone and 5.6 years for patients no treated.

While these data may not yet be fully statistically significant, they can address surveillance and research on the short and long-term chemotherapy and radiotherapy impact in reconstructive patients.

3.2 CLINICAL CONDITIONS POTENTIALLY ASSOCIATED TO BREAST IMPLANTS

Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL), Squamous Cell Carcinoma (SCC), and Breast Implant Illness (BII) are among the emerging clinical conditions under European Competent Authorities' surveillance activities due to the possible pathogenesis associated to breast implants.

In order to raise awareness among healthcare professionals about the early detection of suspicious symptoms, correct diagnosis, and treatment of these clinical conditions based on current scientific knowledge, the Italian Ministry of Health has defined and disseminated specific recommendations[15]. Confirmed cases' reporting has also been made mandatory in order to monitor their occurrence.

ANAPLASTIC LARGE CELL LYMPHOMA ASSOCIATED WITH BREAST IMPLANTS

Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) is a rare form of Non-Hodgkin Lymphoma (NHL) that grows in the T lymphocytes of the immune system around the peri-prosthetic tissues in patients with breast implants placed for aesthetic or reconstructive purposes. It is a rare condition with an unclear aetiopathogenesis to date. It is hypothesized that a chronic inflammatory process triggered by some types of implants (such as macrotextured breast devices) or by a bacterial surfaced biofilm could be involved in the onset of this lymphoma. The role of any genetic predisposition of the patient remains to be understood. In this regard, the ex DGDMF has financed specific research aimed to clarify why only a very few patients develop this clinical condition despite implanted with the same type of device. The analysis of data collected by researchers is still ongoing.

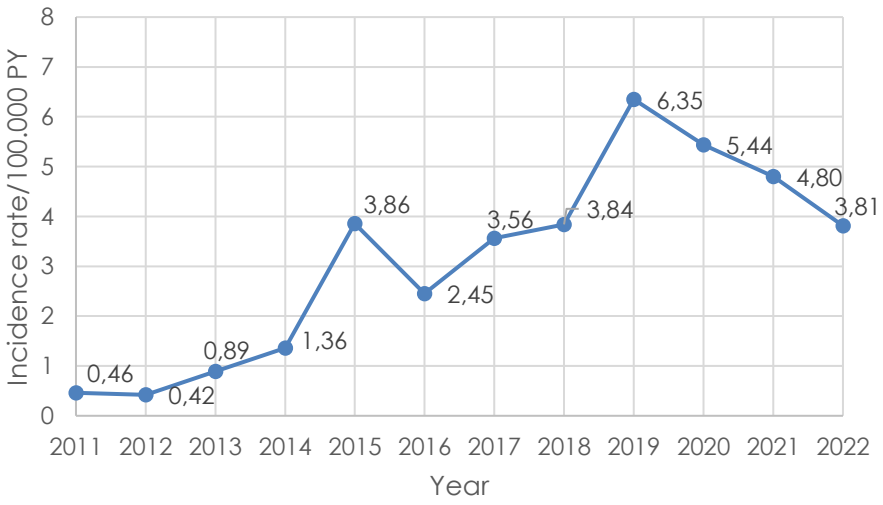
[15] circular of November 29, 2022, link:
https://www.trovanorme.salute.gov.it/norme/renderNormsanPdf?anno=2022&codLeg=90834&parte=1%20&serie=null
circular of Squamous Cell Carcinoma of November 2, 2022, link:
https://www.trovanorme.salute.gov.it/norme/renderNormsanPdf?anno=2022&codLeg=90235&parte=1%20&serie=null

To date, BIA-ALCL has been considered among the risks associated with breast implantation and, as stated by the Italian Health Council (Consiglio Superiore di Sanità), it is included in the informed consent among the potential risks of this type of surgery.

The Italian National Breast Implant Registry, active since March 2019, has collected data on 13 cases of BIA-ALCL. However, the ex DGDMF has established a specific registry that collects all BIA-ALCL cases diagnosed in Italy. This registry includes much more specific clinical data than those provided in the national breast implant registry. The existence of two registries is motivated by their different purposes: clinical research for patients with BIA-ALCL and epidemiological monitoring for the short and long-term clinical evaluation of device efficacy and safety for the national breast implant registry.

The cases of BIA-ALCL reported to the Ministry of Health in the last 10 years are 111 (as of April 2024). Figure 42 shows the fluctuations of incidence over time in Italy, with a peak of 6.35 cases per 100,000 patients in 2019.

Figure 42. BIA-ALCL trend in Italy – Years 2011-2022. Values per 100,000 patients



Source: Ministry of Health – Data 2011-2023

To date, worldwide BIA-ALCL occurrence exhibits considerable variability, ranging from 1 case per 3,817 to 1 per 30,000 (10,24-31). This variability is attributable to different measures used and to various factors influencing the numerator and denominator in each country. The Ministry of Health's initiatives to raise awareness of this issue, coupled with the mandatory reporting of new

cases to Unit 5 of ex DGDMF, ensure consistency in the Italian analysis of this disease occurrence. Among the variables that influence the denominator there are the estimation of the number of implants per year for aesthetic or reconstructive reasons, the number of implants per patient for aesthetic or reconstructive purposes, and the median revision time of the implant. The Ministry of Health has considered all these variables to define a method capable of estimating the denominator value as reliably as possible.

The analysis of data from the registry of patients affected by BIA-ALCL reveals that the average time to symptom onset is 7.7 years. In 92% of cases, this clinical condition emerges with a peri-prosthetic seroma, which is easily diagnosable via ultrasound (32,33).

Despite being classified among non-Hodgkin lymphomas, BIA-ALCL exhibits behaviour similar to solid tumours, where the role of surgery is critical in defining prognosis.

The Italian experience shows that over 95% of patients have been healed through a radical surgical treatment involving the removal of the implant, the periprosthetic capsule, and all the tissue potentially involved in the neoplasm. Even in advanced stages, patients have shown a good response to systemic pharmacological treatments (33).

Currently, with over 35 million patients worldwide who have received breast implants, the number of cases of BIA-ALCL remains extremely low. This limited number of cases does not provide statistically significant data to establish a causal association between implantation and the onset of this condition. The lack of significance in the small number of cases reported in scientific literature does not exempt the Ministry of Health, in terms of public health protection, from continuing to study this pathology, especially regarding aspects that remain unclear to date. The Ministry of Health continues to carefully monitor and manage the issue, also through the establishment of a permanent working group composed of national and international clinical experts in oncology, haematology, genetics, pathology, and plastic surgery; the ex DGDMF is part of an international task force that, along with other European Competent Authorities on medical devices, monitors and collects data uniformly on all new cases registered in Europe.

For further information, please visit the dedicated page on the Ministry of Health's official website at the following link:

https://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=4419&area=dispositivi-medici&menu=vigilanza

4. BREAST IMPLANTS REGISTRIES WORLDWIDE

Since their introduction into the market in the 1960s, breast implants (34) have been involved in various issues, leading the Competent Authorities and Institutions to recognize the importance to establish registries in order to enhance vigilance and surveillance activities on such devices.

In 1990s the down corning crisis already led to the establishment of the first national breast implant registries. Among these, one of the earliest was the Australian registry (BIR), developed in 1997 and based on voluntary data submission (OPT-IN method). Due to the issue of Poly Implant Prothèse (PIP) implants in 2010, it became clear that although the BIR had collected over 30,000 registrations, it had significant issues, including the inability to retrieve complete information regarding PIP implants; at the time, only 3.4% of the 13,000 PIP implants had been effectively registered in the BIR database (35).

Not only was it necessary to establish registries of breast implant devices, but it was equally crucial that these registries were populated with representative, complete, and high-quality data, and that they had enough coverage to ensure, if necessary, the ability to initiate health surveillance activities for patients' safety.

Experience has underscored that is necessary to establish next-generation registries able to gather clinically high-quality data (Clinical Quality Registry - CRQ) and representative of a specific national territory (Real World Data). These registries should be able to collect data that are useful for identifying or recalling devices and patients when necessary, serving as an effective tool for epidemiological studies and clinical research. Today, the importance of implant registries, particularly for breast implants, is widely acknowledged internationally, as evidenced by numerous published scientific papers about their advantages and challenges (36-39).

Due to their importance over the past 10 years several international breast implant registries have been established. Although their ultimate goal is the same, each registry has its own structure, organization and governance. Some registries are well-established and have been active for many years, while others are still in a pilot stage. There are registries with excellent coverage levels and others that, despite being active for years, do not achieve efficiency in

coverage. Additionally, in most cases, registries are established with the support of relevant scientific societies, are not mandatory and feeded by the opt-out[16] method.

In the United Kingdom, registration is mandatory in England but not in Scotland and Northern Ireland. Besides Italy, only Germany is moving towards mandatory data feeding, aiming for coverage levels close to 100%. Another important point is how to finance registries. For example, Becherer et al. report that few registries have a sustainable long-term funding structure (40).

It's understood the necessity to have registries able to communicate with each other even if developed in different countries and to achieve this goal, it is necessary to harmonize and standardize the data collected method by registries at an international level. To this end, registries established internationally have come together in the International Collaboration of Breast Registry Activities (ICOBRA), which includes representatives from the following countries: Australia, Austria, Canada, France, Germany, Ireland, Italy, the Netherlands, New Zealand, the United Kingdom, the United States, and South Africa (1, 41). ICOBRA has developed an harmonized data set (minimum data set) that all breast implant registries should refer to (1, 42).

A recent scientific study (43) analysed and compared data from four different breast implant registries (Australia ADBR, the Netherlands DBIR, Sweden BRIMP, and the United States NBIR) with the aim of assessing potential benefits of sharing data from breast implant registries. In particular, the study compared the national coverage level, the total number of registered implants, patients' data, implants' characteristics, the use of infection control measures (ICM), and the cumulative incidence of revisions.

The study showed that by the end of 2018, the four registries had collectively recorded over 200,000 implanted breast implants. A partial view of the results presented in the article is shown in

[16] OPT-OUT method: the patient is registered unless they explicitly refuse to participate.

Table 13.

Table 13. International breast implant registries' main features

COUNTRY	AUSTRALIA	SWEDEN	THE NETHERLANDS	USA
REGISTRY ACRONYM	**ABDR**	**BRIMP**	**DBIR**	**NBIR**
NATIONAL COVERAGE*	85%	NA	98%	2.5%
BREAST IMPLANTS	88.759	34.501	82.236	1.639
PATIENTS	36.284	14.406	33.698	866
MEAN AGE - RECONSTRUCTIVE	42,0 ± 14,1	41,3 ± 14,4	48,8 ± 12,6	NA
MEAN AGE - AESTETHIC	32,3 ± 9,2	32,8 ± 9,3	31,6 ± 9,4	35,9 ± 9,8
BREAST IMPLANT FEATURES RECONSTRUCTIVE (anatomical, textured surface, silicone filling)	57,1%; 73,8%; 99,5%	63,8%; 89,4%; 93,9%	93,0%; 86,1%; 76,2%	NA
BREAST IMPLANT FEATURES AESTETHIC round, textured surface, silicone filling)	64,2%; 65,9%; 98,9%	60,0%; 87,4%; 98,4%	66,0%; 89,2%; 97,2%	98%; 99%; 80%
2-YEAR REVISION OCCURENCE RECONSTRUCTIVE	11,4%	6,5%	15,8%	NA
2-YEAR REVISION OCCURRENCE AESTETHIC	2,8%	3,5%	1,6%	NA

* National coverage is defined as the number of participating institutions in the registry compared to the potential number of institutions performing breast surgery

Table from *Comparing 200,000 Breast Implants and 85,000 Patients over Four National Breast Implant Registries. Babette E Becherer et al. 2023*

Please find below an overview on the main breast implant registries currently active worldwide. The information provided are coming from evolving scenario; for specific and updated insights on individual registries in different countries it's necessary to consult their annual reports and official web pages.

The **Australian Breast Device Registry - ABDR** (Link: https://www.abdr.org.au/), is considered an evolution of the BIR; it was established in 2014, and the first patient was entered into the registry in June 2015. The registry is managed by the Monash University's Alfred Campus in Melbourne and is endorsed by major Australian surgical societies such as the Australian Society of Plastic Surgeons (ASPS), the Australasian College of Cosmetic Surgery and Medicine (ACCSM), and the Breast Surgeons of Australian & New Zealand Inc (BreastSurgANZ). Participation in the ABDR is voluntary, and data entry occurs on an opt-out method. As indicated in ADBR Report 2022[17], the access rate continues to ensure high levels of coverage; from 2012 to 2022, the majority of aesthetic procedures (99.5%) and reconstructive procedures (77.1%) recorded in the ABDR were performed in private healthcare facilities. In 2022, the registry was feeded by 445 surgeons, and the opt-out rate (i.e., patients who chose not to include their data in the registry) remains very low (less than 1%). Since its inception, 87,339 patients have been registered undergoing a total of 100,114 procedures with 171,092 devices implanted. In 20.5% of cases, it was a reconstructive procedure, in 71.4% an aesthetic procedure, and in 8.1% no indication was specified. In 2022, a total of 11,347 patients were registered, along with 13,287 procedures (of which 8,831 were for cosmetic purposes and 3,103 were for reconstructive purposes) and 22,022 devices. Additionally, in 2022, there was an increase in explant-only procedures, with 5 new cases of BIA-ALCL reported, bringing the total reported cases to 64.

The **Dutch Breast Implant Registry** (DBIR) (Link: https://dica.nl/dbir/home) supported by the Dutch scientific society of plastic surgery (NVPC), was established in June 2014 and became fully operational in April 2015 after a pilot phase. The DBIR is a national, prospective registry with a data collection system based on an opt-out method, requiring mandatory registration for all plastic surgeons in The Netherlands who are members of the Dutch Society of Plastic Surgery (NVPC). The maintenance of the registry is ensured by a contribution from the National Health

[17] Link report ADBR del 2022: https://abdr.org.au/wp-content/uploads/2023/12/ABDR_2022_Annual-Report_Spreads_Screen.pdf

Insurance (ZN) of 25 euros per implant. As shown in the 2021[18] Report (published in November 2022) the coverage achieved by this registry within its national territory is 100% of public healthcare facilities and 93% of private clinics. The wholeness of the data collected in the registry was also over 95% in the year 2021. In 2021, 13,941 patients, 14,639 procedures, and 28,629 implants were registered. Among them, 75% were for aesthetic surgery, while 25% were for reconstructive surgery. About revision rate, it emerges that in 2021, 1,171 patients (who had reconstructive surgery) underwent revision surgery due to: capsular contracture (28%), pain (23%), asymmetry (18%), rupture (15%), displacement (9%); 4,451 patients underwent a re-intervention after aesthetic surgery, due the following main reasons: capsular contracture (26%), rupture (20%), patient dissatisfaction with volume (18%), breast illness (12%), silicone leakage (11%). The DBIR has recorded information (since the beginning of the registry in April 2015 until the end of 2021) on 69,622 patients, 73,822 procedures, and 148,950 breast implants has been recorded in the DBIR.

The **national breast implant registry of Sweden** (BRIMP *Brostimplantat registet*) (link: https://brimp.registercentrum.se/; www.brimp.se) is active since 2014. It was initiated by the Swedish Plastic Surgery Association and the Swedish Association for Aesthetic Plastic Surgery. It is funded by the State and the Regions, the Swedish Association of Plastic Surgery, and the Swedish Association for Aesthetic Plastic Surgery. The data collection is based on an opt-out method. The latest report for the year 2022 indicates that 65% of implants sold in Sweden have been entered into the registry. In 2022, 6,700 procedures were registered, of which 4,020 were primary procedures and 2,680 were revision procedures (16% more than the previous year). Additionally, in 2022, the BRIMP recorded 8 cases of BIA-ALCL.

The **Breast and Cosmetic Implant Registry** (BCIR) (link:https://digital.nhs.uk/data-and-information/clinical-audits-and-registries/breast-and-cosmetic-implant-registry) was established in October 2016 and collects data from England (where it is mandatory), Scotland, and Northern Ireland (where it is voluntary). The data collection is based on an opt-out method. The 2022[19] Report indicates 392 registered healthcare facilities, 16,850 patients who underwent

[18] DBIR Annual Report link: https://dica.nl/media/2891/DBIR%20Annual%20Report%202020.pdf
[19] BCIR data available at : https://app.powerbi.com/view?r=eyJrIjoiNjBmMDBjYWEtZTQzOS00MDMxLTgyMWUtMGZmYmU5NDk3NmIyIiwidCI6IjM3YzM1NGIyLTg1YjAtNDdmNS1iMjIyLTA3YjQ4ZDc3NGVlMyJ9

at least one surgery, 17,300 surgeries, 29,420 devices, and 31,370 procedures. The majority were performed for aesthetic purposes. In 2022, approximately 8,000 revision surgeries were performed, with the majority requested due to patient preferences rather than complications device related. Since the establishment of the registry until 2022, a total of 90,650 patients, 175,335 procedures, and 168,415 devices have been recorded.

The **Implant Register Deutschland** (IRG) (link: https://mtrconsult.com/news/establishment-implants-registry-germany) is regulated by a national law that came into effect in January 2020[20]. The governance of this registry is supported by the German Institute for Medical Documentation and Information (DIMDI), which will oversee centralized data collection. Initial funding will be provided by the federal government, followed by specific fees. In order to ensure the completeness of the registry, data entry will be mandatory for healthcare institutions, public and private health insurance companies, and all patients. All manufacturers will also be required to register their products in the registry database. For the purpose of maximum transparency and information dissemination, the publication of annual reports will be ensured. The register is currently in the test phase; full operation is expected in 2024. In order to implement the law, the German Ministry of Health has enlisted the help of the German Society of Plastic and Reconstructive Surgery (DGPRAC), and it has been recently published an article describing the German model. (44).

The **National Breast Implant Registry** (NBIR) (link: https://www.thepsf.org/research/registries/nbir) promoted by the scientific societies American Society of Plastic Surgeons (ASPS) and Plastic Surgery Foundation (PSF) and supported by the Food and Drug Administration (FDA), has been active in the United States since 2018, but became fully operational in 2019. Data collection occurs through an opt-out method. Although there has been a significant increase in the number of registrations in recent years, obtaining a good level of national coverage is still a goal to be achieved. From October 2018 to September 2021, more than 36,000 procedures were registered; according to the ASPS report in 2020, more than 300,000 procedures are performed annually in the United States. Of all the procedures entered in the registry for the year 2021, 81% were for aesthetic purpose

[20] Gesetz zur Errichtung des Deutschen Implantatregisters. https://www.bgbl.de/xaver/bgbl/start. xav?startbk=Bundesanzeiger_BGBl&jumpTo=bgbl119s2494.pdf#__bgbl__%2F%2F*%5B%40attr_id%3D%27bgbl119s2494.pdf%27%5D__1611951620736).

while 17% for reconstructive; furthermore, 73% were primary procedures and 27% were revision procedures. The 2021 annual report shows that the breast implant devices mainly used in the United States are smooth implants (99%) and round (99.7%), while silicone filling is used in 88% of cases. The revision surgery rate is 27% of all registered procedures; reasons are multiple, but in 49% of cases, they are coming from patient requests (like modification of size or type of implant) and not related to device issues (23%) or complications (27%).

Table 14 collects data from the latest annual reports published by some international registries.

Table 14. International breast implants registries data published in annual reports

COUNTRY	THE NETHERLANDS	AUSTRALIA	SWEDEN	UK	USA
ACRONYM	**DBIR**	**ABDR**	**BRIMP**	**BCIR**	**NBIR**
FULL NAME	Deutch Brest Implant Registry	Australian Breast Device Registry	Brostimplant Register	Breast and Cosmetic Implant Registry	US National Breast Implant Registry
LINK	https://dica.nl/dbir/home	https://www.abdr.org.au/	www.brimp.se	https://digital.nhs.uk/data-and-information/clinical-audits-and-registries/breast-and-cosmetic-implant-registry	https://www.thepsf.org/
ESTABLISHMENT	2015	Established in 2014, active in 2015	2014	2016 in England, 2019 in Scotland, 2021 in North Ireland	2018
GOVERNANCE	Deutch Plastic Surgery Association NVPC, DICA	Monash University, ACSQHC, Australian Governament	Swedish Plastic Surgery Association and Swedish Society of Aesthetic Plastic Surgery	NHS DIGITAL (Health and social care Information Center)	American Society of Plastic Surgeons (ASPS) and Plastic Surgery Foundation (PSF) and FDA
FUNDS	Device fee (25 Euro)	Australian Government	By State, Region, Scientific Foundations	UK Government	-
DATA COLLECTING METHOD	OPT-OUT	OPT-OUT	OPT-OUT	OPT-OUT	OPT-OUT
STATUS	ACTIVE	ACTIVE	ACTIVE	ACTIVE	ACTIVE
PROCEDURES/SURGERIES SINCE ACTIVATION	73.822* surgeries	100.114 procedures	about 58.000 surgeries	175.335 procedures and 96.220 surgeries	Approximately 36,000 procedures
TOTAL PATIENTS SINCE ACTIVATION	69.622*	87.339	19.685	90.650	NA
TOTAL DEVICES SINCE ACTIVATION	148.950*	171.092	37.906	168.415	NA
PROCEDURES IN 2022	14.639* surgeries	13.287 procedures	6.700 surgeries	31.370 procedures and 17.300 surgeries	15.632 procedures
PATIENTS IN 2022	13.941*	11.347	2.121	16.850	NA
BREAST IMPLANTS IN 2022	28.629*	22.022	4.020	29.420	NA
TOTAL REVISION SURGERIES (2022)	5.622*	6.364 procedures	2.680	Approximately 8.000	Approximately 27% of procedures

* Data form the latest report available 2021.

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