ESPRAS Survey on Breast Reconstruction in Europe

ESPRAS Umfrage zur Brustrekonstruktion in Europa



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Schlüsselwörter

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ESPRAS, Breast Reconstruction, Free Flap, DIEP, Microsurgery, Breast Reconstruction Registry

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ZUSAMMENFASSUNG

Hintergrund Im Rahmen des ELF der ESPRAS wurde die Notwendigkeit standardisierter Richtlinien zur Brustrekonstruktion auf europäischer Ebene definiert. Ziel dieser Studie ist es, zunächst einen Überblick über den aktuellen Status, Entwicklungen und mögliche regionale Unterschiede der Brustrekonstruktion in Europa zu geben, wobei ein Schwerpunkt auf dem Angebot, der Verteilung und dem Zugang zur Brustrekonstruktion liegt.

Materialien und Methoden Es erfolgte eine internetbasierte Befragung von in der Brustrekonstruktion spezialisierten Plastischen Chirurgen, welche zusätzlich die nationalen Versorgungsstrukturen ihrer jeweiligen Länder überblicken. Geeignete Teilnehmer wurden über das ExCo der ESPRAS und nationale Delegierte von ESPRAS identifiziert. Die Ergebnisse wurden mit aktueller evidenzbasierter Literatur verglichen.

Ergebnisse 33 Teilnehmer aus 29 europäischen Ländern nahmen an der Studie teil. Im Vergleich zur Gesamtzahl durchgeführter Mastektomien war die Inzidenz der Brustrekon-

struktionen in Europa relativ gering, vergleichbar mit anderen großen geografischen Regionen, wie z. B. Nordamerika. Die Verfügbarkeit und der Zugang zur Brustrekonstruktion war innerhalb Europas gleichmäßig verteilt, allerdings kann die geografische Region das Verfahren der Brustrekonstruktion (Eigengewebe vs. Implantat) beeinflussen. Deutliche Differenzen zeigten sich bezüglich Brustrekonstruktionen bei bestrahlten Patientinnen.

Schlussfolgerung Die Studie identifizierte ein ausgeprägtes Maß an Inkohärenz in den internationalen Standards zwischen den europäischen Ländern. Es besteht großer Bedarf für kohärente europäische Leitlinien. Europäische, multizentrische klinische Studien sollten initiiert werden, um eine evidenzbasierte Grundlage zu schaffen.

ABSTRACT

Background The European Leadership Forum (ELF) of the European Society of Plastic, Reconstructive and Aesthetic Surgery (ESPRAS) previously identified the need for harmonisation of breast reconstruction standards in Europe, in order to strengthen the role of plastic surgeons. This study aims to survey the status, current trends and potential regional differences in the practice of breast reconstruction in Europe, with emphasis on equity and access.

Materials and Methods A largescale web-based questionnaire was sent to consultant plastic and reconstructive surgeons, who are experienced in breast reconstruction and with understanding of the national situation in their country. Suitable participants were identified via the Executive Committee (ExCo) of ESPRAS and national delegates of ESPRAS. The results were evaluated and related to evidence-based literature.

Results A total of 33 participants from 29 European countries participated in this study. Overall, the incidence of breast reconstruction was reported to be relatively low across Europe, comparable to other large geographic regions, such as North America. Equity of provision and access to breast reconstruction was distributed evenly within Europe, with geographic regions potentially affecting the type of reconstruction offered. Standard practices with regard to radiotherapy differed between countries and a clear demand for European guidelines on breast reconstruction was reported.

Conclusion This study identified distinct lack of consistency in international practice patterns across European countries and a strong demand for consistent European guidance. Large-scale and multi-centre European clinical trials are required to further elucidate the presented areas of interest and to define European standard operating procedures.

Introduction

In 2020, the European Commission published the breast cancer burden in EU-27 countries with an estimated incidence of 355,457 new cases and 91,826 deaths [1]. The lifetime risk of breast cancer increased to 1 in 7, thus being the most commonly diagnosed cancer in females [1]. While breast cancer is curable in 70–80% of

patients with early-stage, non-metastatic disease [2], locoregional and systemic therapy approaches, including surgery, radio- and chemotherapy often leave women physically and psychologically impaired. Thus, breast reconstruction plays a central role in holistic breast cancer therapy, increasing patients' self-esteem and quality of life by restoring the femininity that female breast cancer patients

often describe as lost during treatment [3–7]. Whilst reconstructive surgery has revolutionized the management of breast cancer and is now an invaluable part of recovery, the practice of breast reconstruction is challenged by several controversial topics which are subject to ongoing debate. Harmonization on an international level with the development of clear evidence-based guidelines is urgently required.

Due to differences in historical, cultural and health-economic backgrounds, healthcare in Europe is primarily organized on a national level and provided by a varying range of systems, from tax-financed national services to private social insurance funds [8]. Naturally, differences also exist in the organization, structure and size of national plastic surgery societies. The European Society of Plastic, Reconstructive and Aesthetic Surgery (ESPRAS) is the umbrella organization of all European national societies and, with its over 7000 members, exists to promote best practice of Plastic, Reconstructive and Aesthetic Surgery in Europe [9].

The Executive Committee (ExCo) ESPRAS organized the first ESPRAS European Leadership Forum (ELF) in October 2020 to discuss common challenges facing Plastic Surgery national societies [10]. This meeting highlighted a clear need for European standard operating procedures for breast reconstruction. Based on this and as a first step, the aim of the presented study was to survey the state and condition, current trends and potential regional differences in the organization and delivery of breast reconstruction in Europe, with a particular emphasis on equity of provision and access to breast reconstruction. It is an attempt to initiate policy development and to identify areas requiring further clinical research ultimately resulting in international, evidence-based guidelines leading to coherence and equity in the provision of breast reconstruction in Europe.

Materials and Methods

Design of Survey

A large-scale web-based questionnaire was designed to evaluate European trends in breast reconstruction, including the availability of different breast reconstructive methods and the equity of care within these countries. The following items were addressed: Structure of care, equity and access to breast reconstruction across European countries; Immediate and Delayed Breast Reconstruction; Risk reduction, symmetrizing procedures, and corrections; Radiation Therapy; Demand for European guidelines on breast reconstruction. The questionnaire was created and distributed using an online survey administration software (Google Forms, Google, California, U. S.) and sent electronically to identified experts in this field. The study was initiated on December 2020. Data entry was closed on 14.2.2021. A reminder for survey completion was sent to participants two weeks after study initiation.

Participants

Purposeful sampling was used to identify participants. Inclusion criteria were consultant plastic and reconstructive surgeons, experienced in breast reconstruction and with knowledge of current national trends. Suitable participants were identified via the ESPRAS Executive committee (ExCo) and national delegates. Members of the European Leadership Forum (ELF) including delegates to ES-

► **Table 1** Overview of participating national societies (number of participants).

European national society (No.)	Participants from ESPRAS mandated societies	Guest participants
1	Austria	Belgium
2	Azerbaijan	France (2)
3	Bosnia and Hercegovina	
4	Croatia	
5	Cyprus	
6	Denmark	
7	Estonia	
8	Finland	
9	Germany	
10	Greece	
11	Ireland	
12	Italy (2)	
13	Montenegro	
14	Netherlands (2)	
15	North Macedonia	
16	Norway	
17	Poland	
18	Portugal	
19	Romania	
20	Serbia	
21	Slovakia	
22	Slovenia	
23	Spain	
24	Sweden	
25	Switzerland	
26	Turkey (2)	
27	U.K.	

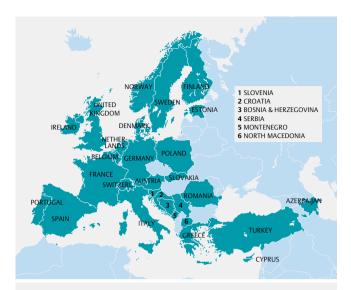
PRAS and members of the board (presidents, vice presidents, secretary generals) of each plastic surgery national society throughout Europe were included. At least one completed questionnaire for each national society was included and up to two different participants from each European country were included.

Ethics

This study was conducted in accordance with the Declaration of Helsinki. Personal data were treated in accordance with European General Data Protection Regulation. Participants provided written informed consent to participate in the study, prior to study initiation.

Results

The survey was completed by 33 participants from 29 European countries (▶ Table 1, ▶ Fig. 1).



▶ Fig. 1 Countries all over Europe participating in the questionnaire including: Austria, Azerbaijan, Belgium, Bosnia and Herzegovina, Croatia, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Ireland, Italy, Montenegro, Netherlands, Norway, North Macedonia, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, UK.

Structure of care, equity and access to breast reconstruction across European countries (> Fig. 2)

Breast reconstruction is covered by public health insurance across Europe, as reported by 91% of respondents. A majority of respondents (72%) reported that plastic surgeons belong to a multidisciplinary team treating breast cancer in their respective countries. Plastic surgeons are involved early on in the mastectomy process (partially or complete) only in a minority of countries (Are plastic surgeons involved in the mastectomy (partial or complete)? Yes: 32%, No: 36%, Other: 32%). 84% of participants stated that geographic location is not a limiting factor for access to breast reconstruction. However, over 25% of respondents found that geographic location has an impact on the type of reconstruction offered to women.

Immediate and Delayed Breast Reconstruction (> Fig. 3)

Breast reconstruction, both immediate and delayed, is not exclusively performed by plastic surgeons, but also by general/breast cancer surgeons as well as gynecologists (Who performs immediate/delayed breast reconstruction in your country? Mark all boxes which apply. Plastic Surgeons (IBR/DBR): 100/100%; general, breast cancer surgeons: 31/13 %; gynecologists: 16/13 %). Incidence of breast reconstruction after mastectomy is low across Europe. EUSOMA guidelines recommending a rate of 40% of immediate breast reconstruction (IBR) are applied in only 19% of respondents' countries. Over a third of respondents in this study noted that IBR was conducted only in 1-20% of cases on a national level, while another 18.8% reported IBR to be performed in $21\text{--}40\,\%$ of all cases. The responses for the rate of delayed breast reconstruction (DBR) were similar, with approximately twice as many respondents claiming 41-60% reconstruction rates (DBR: 16% vs. IBR: 9%).

Risk reduction, symmetrizing procedures, and corrections (► Fig. 4)

In most countries, prophylactic, risk-reducing mastectomy is offered to patients with mutations, or patients with high life-time risk of breast cancer (Which patients are offered prophylactic risk-reducing mastectomies? Mark all boxes which apply. Patients with mutations: 94%; patients with high life-time risk of breast cancer (no mutation): 69%; Patients who have had breast cancer and want contralateral risk-reducing mastectomy: 50 %; All patients that want one: 13 %; It is not offered: 0 %). Overall, rates of symmetrizing procedures are high across Europe. In over 81% of cases, all women are offered symmetrization, including breast reduction, mastopexy, implant-based augmentation, augmentation mastopexy, and lipofilling provided by the public health care system. The number of secondary corrective operations is not limited in most countries (78%). Lipofilling is an option for reconstruction after breast conserving therapy in most European countries, at least in a selected patient population.

Radiation Therapy (► Fig. 5)

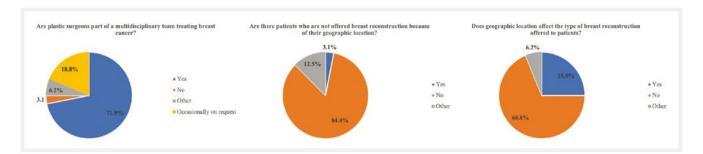
Responses varied greatly with regard to the optimal timing for breast reconstruction in irradiated patients (When is delayed breast reconstruction performed after adjuvant radiotherapy? 6 months: 22%; 12 months: 41%; 24 months: 3%; Other: 34%) The overwhelming majority of respondents (>90%) encountered failed implant-based reconstruction after radiation therapy, often or occasionally. Immediate implant-based breast reconstruction in patients who are expected to receive radiotherapy was generally rejected as an option by 44% of respondents. Delayed implant-based reconstruction was performed in over 50% of respondents in irradiated patients. Over 78% of participants responded that autologous IBR is performed in patients receiving radiotherapy in their respective countries.

Demand for European guidelines on breast reconstruction (► Fig. 6)

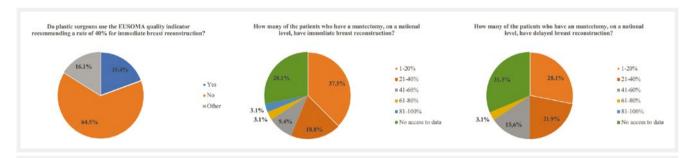
Only 45% of respondents reported the existence of national guidelines for breast reconstruction. National guidelines providing information regarding the choice of reconstructive technique were available in only 32%. 88% of respondents would value European guidelines, recommendations, and requirements for best practice in breast reconstruction. There was great interest in international European multi-center studies and the majority (>90%) of participants would like to be included along with their respective countries. Almost 100% of respondents wished to participate in a plastic surgical task force to strengthen plastic surgical breast reconstruction in Europe.

Discussion

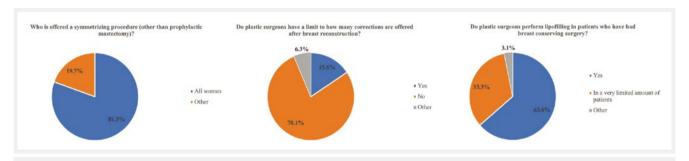
Joint European efforts moderated by the ExCo of ESPRAS have recently identified common challenges for the respective plastic surgery national societies under the umbrella of ESPRAS and shared solutions on a European level in different survey-based studies [10–12]. The aim of this study was to follow up one of the major challenges facing Plastic Surgery in Europe identified at the ELF in 2020 [10], namely the structure of care of breast reconstruction in European countries.



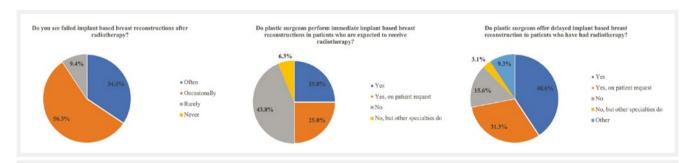
▶ Fig. 2 Pie charts depicting participants response to relevant items addressing structure of care, equity and access to breast reconstruction across European countries.



▶ Fig. 3 Pie charts depicting participants response to relevant items addressing immediate- and delayed breast reconstruction across European countries.



▶ Fig. 4 Pie charts depicting participants response to relevant items addressing symmetrizing procedures, and corrections after breast cancer surgery across European countries.



▶ Fig. 5 Pie charts depicting participants response to relevant items addressing radiotherapy and breast reconstruction across European countries.

Structure of care, equity and access to breast reconstruction across European countries

Although the life-expectancy is generally high in Europe, there remain considerable differences in health between different countries and within countries [13]. WHO Europe state that among the

most important drivers in creating health equity are policy coherence and accountability [14]. In terms of breast reconstruction, the European Society of Breast Cancer Specialists (EUSOMA) guidelines stipulate that plastic surgeons with expertise in breast reconstruction should be available for consultation in all cases [15, 16]. In ad-

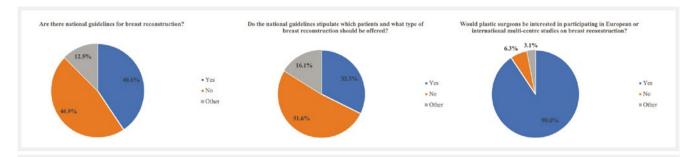


Fig. 6 Pie charts depicting participants response to relevant items addressing the demand for European guidelines on breast reconstruction.

dition, the European Parliament Resolution on breast cancer aims to protect the psychological well-being and physical integrity of women by ensuring that 'breast-conserving surgery is available to every woman in every instance where it is medically justified and that, wherever possible, breast reconstruction operations are performed using the patient's own tissue and within the shortest possible time' (§ 7c) [17]. It is possible to identify several factors contributing to inequity in breast reconstruction, including insurance cover, geographic location and access to care. For the majority of the European population, breast reconstruction is covered by public health insurance (reported by > 90% of respondents). While a large majority of participants in this study also stated that geographic location is not a limiting factor for patients to access breast reconstruction in general, regional differences with regard to the type of reconstruction offered were acknowledged in European countries.

It could be speculated that regional inequity of the type of reconstruction offered could indicate any of the three following points:

- 1. No plastic surgical expertise available in certain regions,
- 2. Institutional reluctance to transfer patients to units with access to plastic surgical expertise [18, 19],
- 3. Lack of patient awareness and information regarding the different reconstructive options available [20].

Controversy exists regarding the most appropriate reconstructive techniques following tumor resection. Autologous breast reconstruction has been associated with long-term patient satisfaction and higher quality of life by yielding superior aesthetic, more natural and long-lasting results, as compared to implant reconstruction [21-26] but further high-quality data is required to verify this finding. Autologous reconstruction is not feasible for all women, and implant-based reconstruction should not be disregarded. It is therefore an imperative that breast cancer surgeons discuss selected cases with plastic surgeons prior to tumor resection and reconstruction in order to identify the most appropriate reconstructive technique for the individual patient. European clarification is required regarding the timing of plastic surgery involvement as part of multidisciplinary teams (MDT) treating breast cancer. Currently, 70% of respondents reported participation in an MDT but disappointingly only 30% stated that plastic surgeons are involved (partially or completely) in the mastectomy/primary resection, highlighting considerable potential for improvement on a European level. This is not to suggest that plastic surgeons be involved in all breast cancer cases, as skilled microsurgeons are scarce and resources can be limited. To summarize, all European patients should have equal access to healthcare and surgical teams competent to perform all types of breast reconstructions thus ensuring that breast cancer patients are afforded the most appropriate breast reconstruction. Strengthening the role of the plastic and reconstructive surgeon in breast reconstruction and policy development has potential to achieve more equitable distribution of limited resources.

Immediate and Delayed Breast Reconstruction

The number of women opting for breast reconstruction has increased over recent years [27]. According to data published by the Agency for Healthcare Research and Quality, breast reconstruction after mastectomy rose by 62% from 2009 to 2014 in the U. S. [28] but still remains underperformed overall, with a total rate of $\sim 40\%$ [27, 29].

The data presented here also demonstrates a relatively low number of immediate and delayed breast reconstructions in Europe in comparison to the total number of mastectomies. Given the benefits of breast reconstruction, there is considerable room for improvement. Importantly, almost 30% of respondents reported that data was not available to provide a clear answer to the rate of IBR and DBR performed in their countries. This further emphasizes the need for collaboration to increase transparency and visibility regarding breast reconstruction in Europe. EUSOMA guidelines recommending a rate of 40% of IBR are applied in merely 19% of respondents' countries. These guidelines, however, are not evidence-based and are subject of much debate. Whether these guidelines are appropriate is also a source of concern, especially in those cases where post-mastectomy radiation therapy is required [30].

Symmetrizing procedures, and corrections

Symmetrization procedures to create symmetrical breast mounds are common and are offered to a majority of women after breast cancer surgery in Europe. These include breast reduction, mastopexy or augmentation. Yet, results showed that one in five women is not offered symmetrization, further emphasizing need for European harmonization. Future studies will need to focus on the timing of symmetrization, as this may be performed either at the time of reconstruction or be delayed [31]. Overall, a majority of respondents claimed to consider lipofilling in selected patients after breast conserving therapy for volumization. While concerns have been raised as to whether lipofilling may cause dormant breast cancer cell growth, to date, most studies suggest the oncologic safety of lipofilling in breast reconstruction [32, 33].

Radiation Therapy

The ideal timing of breast reconstruction in irradiated patients remains a cause of controversy and much debate in literature [34– 36]. Unfortunately, to date no clear recommendations have been defined regarding the timing of any reconstruction. Nava et al. conducted an extensive literature review on radiotherapy and breast reconstruction and published an international multidisciplinary expert panel consensus concluding that there is a lack of evidence-based guidelines, with a clear need for high-quality data from randomized clinical trials or large registries to deduce the optimal type and timing of breast reconstruction in the irradiated patient [37]. This is also reflected in the respondents' answer to this question in the presented study, varying greatly with delayed reconstruction being performed from 3 to 12 months post-radiation. Over 75% of participants responded that autologous IBR is performed in patients receiving radiotherapy in their respective countries, corresponding to recent literature showing that neoadjuvant radiotherapy can facilitate IBR post-mastectomy [38]. A majority of respondents reported encountering failed implant-based reconstruction after radiation therapy. Concurrently, ethical reasons have been advanced to decline implant-based IBR when post-mastectomy radiation therapy is anticipated [30]. Several studies implicate impaired outcome of implant-based reconstruction and radiation therapy with frequent complications and decreased aesthetic results, whereas autologous reconstruction can yield superior patient-reported outcomes with lower complication rates in irradiated patients [22, 39-43]. A further source of controversy is that only ~40% of respondents generally rejected immediate implant-based breast reconstruction in patients who are expected to receive radiotherapy, and approximately 50% of respondents provide delayed implant-based reconstruction in irradiated patients. This study clearly identifies the need for evidence-based guidelines and the development of a European strategy to approach these cases. There is a clear lack of evidence regarding this topic and future research should prioritize the field of breast reconstruction in irradiated patients, both in regard to technique and timing of any reconstruction.

Demand for European guidelines on breast reconstruction

40% of respondents reported that while national guidelines for breast reconstruction exist, only a minority of these stipulate which patients should be offered what type of breast reconstruction. Thus, there is great potential for a streamlined European consensus. The desire for European guidelines is reflected by over 85% of respondents who would value recommendations and requirements to achieve best practice. An equal number of respondents would participate in international European multi-center studies and ~ 100% of respondents would participate in a plastic surgical task force to strengthen plastic surgical breast reconstruction in Europea. European harmonization and perspectives can also support smaller European societies, with less manpower and organizational resources.

Limitations

This study is not without limitation, and the results presented must be considered and interpreted with caution. First, the design of the study, being an electronically disseminated survey, merely provides descriptive data of limited quality. Responses were obtained from a very selected study population, which can be considered both a strength and a limitation of the study. Participants were exclusively selected by the ExCo and national delegates of ESPRAS. All were consultant plastic and reconstructive surgeons, experienced experts in the field of breast reconstruction and with knowledge of the national situation in their country. Thus, although sample size was limited, the data obtained can be regarded as reliable. While the data give a broad overview of breast reconstruction in Europe, the production of clear recommendations or guidelines is not possible. On the contrary, the authors highlight that the aim of this study was to outline the current status of care, initiate further European collaboration, and to identify areas for further research. As a next step, and utilizing the relationship built between the ExCo and delegates from national societies under the umbrella of ESPRAS, the proposed survey will be modified and distributed to members of the respective national societies to reach a larger group of respondents. In addition, large-scale and multi-center European clinical trials must be conducted to further elucidate the presented areas of interest. The implementation of European registries for breast reconstruction, as has been successfully executed on a national level yielding high-quality data in regard to several outcome parameters [18, 44-50], could provide the basis for further data acquisition. Finally, using evidence-based data acquired through European collaboration and efforts will fuel the establishment of European guidelines on breast reconstruction and enable uniform best practice.

Conclusions

Health care in Europe differs within countries based on the individual historical, cultural and health-economic backgrounds. Similarly, national societies of plastic surgery differ with regard to size, structure and organization. The umbrella of ESPRAS, with its 7000 members and 40 European member countries, provides large potential to establish coherence and equity in breast reconstruction in Europe in a united approach. This study has identified a distinct lack of coherence in international practice patterns across European countries plus a strong demand for coherent European guidance. Large-scale and multi-center European clinical trials must follow to further elucidate the presented areas of interest and to define European standard operating procedures. ESPRAS is appropriately positioned to facilitate this process through its contact with national societies.

Conflict of interest

The authors declare that there is no conflict of interest.

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