

# First international consensus conference on standardization of oncoplastic breast conserving surgery

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## Abstract

**Purpose** To obtain consensus recommendations for the standardization of oncoplastic breast conserving surgery (OPS) from an international panel of experts in breast surgery including delegates from the German, Austrian and Swiss societies of senology.

**Methods** A total of 52 questions were addressed by electronic voting. The panel's recommendations were put into context with current evidence and the report was circled in an iterative open email process until consensus was obtained.

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Florian Fitzal, Vesna Bjelic-Radisic, Roland Reitsamer, Rupert Koller—Official delegates of the Austrian Society of Senology.

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**Results** The panelists considered OPS safe and effective for improving aesthetic outcomes and broadening the indication for breast conserving surgery (BCS) towards larger tumors. A slim majority believed that OPS reduces the rate of positive margins; however, there was consensus that OPS is associated with an increased risk of complications compared to conventional BCS. The panel strongly endorsed patient-reported outcomes measurement, and recommended selected scales of the Breast-Q™-Breast Conserving Therapy Module for that purpose. The Clough bi-level classification was recommended for standard use in clinical practice for indicating, planning and performing OPS, and the Hoffmann classification for surgical reports and billing purposes. Mastopexy and reduction mammoplasty were the only two recognized OPS procedure categories supported by a majority of the panel. Finally, the experts unanimously supported the statement that every OPS procedure should be tailored to each individual patient.

**Conclusions** When implemented into clinical practice, the panel recommendations may improve safety and effectiveness of OPS. The attendees agreed that there is a need for prospective multicenter studies to optimize patient

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selection and for standardized criteria to qualify and accredit OPS training centers.

**Keywords** Oncoplastic surgery · Breast conserving surgery · Breast surgery · Breast cancer

## Introduction

The number of breast conserving surgery (BCS) procedures increased during the last years. The emphasis on aesthetic outcomes and quality of life after breast cancer surgery has motivated surgeons to develop oncoplastic breast conserving surgery (OPS). The first OPS techniques were described more than two decades ago [1–3]. In the meantime, a wide range of techniques have become available and are selected based on the size and shape of the breast as well as the size and location of the tumor [4]. Even though various detailed classification systems and algorithms have been suggested for use in clinical practice, they achieved neither standardization, nor acceptance on an international level [5–13]. The lack of standardization of OPS nomenclature, indication, and outcome assessment challenges the interpretation and comparison of an increasing body of observational evidence. Therefore, standardization of OPS is necessary for structured education and training, and to plan well-designed, prospective multicenter studies. It is

mandatory to improve esthetic outcomes and patients' quality of life by reliable and well defined comprehensive procedures, which can be compared objectively. The aim of this international consensus conference was to address these urgent questions in order to identify and recommend OPS standards for use in clinical practice and research.

## Methods

The German, Austrian, and Swiss (D-A-CH) societies of senology nominated delegates that were invited to Basel (Switzerland) on February 23rd, 2017, together with selected international experts (see supplementary appendix 1). The group consisted of breast surgical oncologists, plastic surgeons, and gynecologists specialized in OPS.

Before the conference, all participants received a selection of key references and specific topics for presentation, as well as a draft of questions for the panel consensus conference by email. The panelists reviewed the set of questions, which was adjusted by the consensus chair according to the feedbacks by iterative consultation over the weeks preceding the conference.

Specific topics and a selection of classification systems were presented and discussed during the meeting (Fig. 1). Subsequently, 13 categories with a total of 52 questions were addressed by the expert group. The categories were introduced by a quick summary of the key references if required by members of the panel, and included questions on safety, goals, indications, specific needs for standardization, specific OPS standard procedures, several classifications systems, and algorithms as well as outcome assessment.

The panelists required no modifications for the majority of questions; however, several ad hoc amendments were made. Voting was predominantly in the format yes, no or abstain; only one category included mutually exclusive answers. Abstaining was recommended if a panel member had a conflict of interest (e.g., author of the addressed classification system).

After the conference, the results of the panel's voting were translated into panel recommendations by the panel chair. The wording was intended to convey the strength of panel support for each recommendation. Majority was defined by agreement among 50–75% of the panelists and consensus by agreement among >75% of the panelists. We did not follow strict guideline development standards and did not implement a formal Delphi process. However, the questions, answers and discussions were brought into context with the current clinical evidence in the form of this conference report, which was circled among conference participants in an iterative open email process until agreement was reached.

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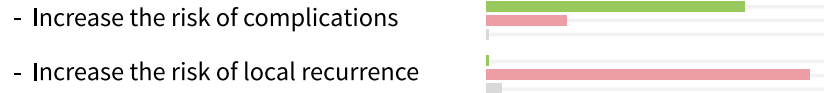
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**Fig. 1** Topics and questions presented to the panel with voting results

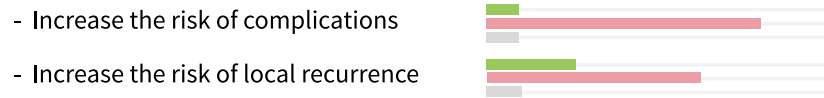
**1. Safety of OPS**

Yes No Abstain

Compared to conventional BCS, OPS does

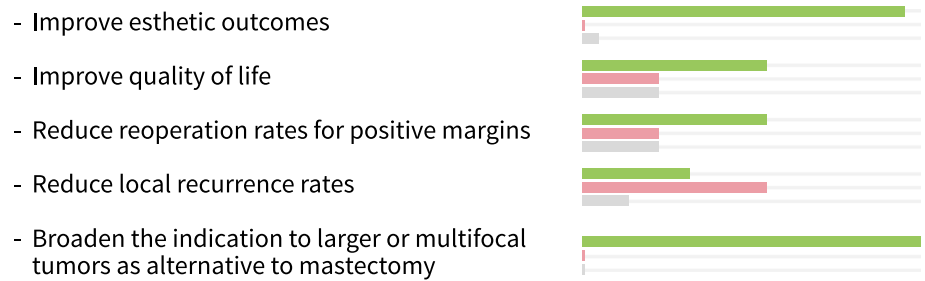


Compared to oncoplastic mastectomy, OPS does

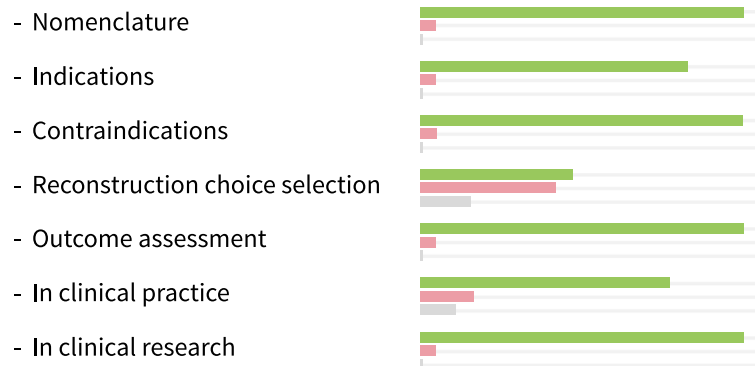


**2. Goals and Indications of OPS**

Compared to conventional breast conserving surgery, OPS can be used to



**3. There is a need for standardization of OPS**



**4. The following specific procedures are considered current standards in OPS**



Fig. 1 continued

**5. In general, every OPS procedure**

- Should be tailored to the individual patient 

**6. The Clough bi-level classification and quadrant per quadrant atlas are useful for standardization of OPS**

- In clinical practice for indicating, planning and performing the procedure 
- In clinical practice for classifying the procedure in the operative report 
- In clinical practice for billing purposes 
- In clinical research 

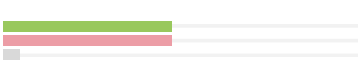
**7. The Tübingen complexity-based classification system for breast surgery is useful for standardization of OPS**

- In clinical practice for indicating, planning and performing the procedure 
- In clinical practice for classifying the procedure in the operative report 
- In clinical practice for billing purposes 
- In clinical research 

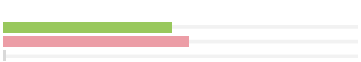
**8. Standardization of BCS and OPS nomenclature into the four categories conventional tumorectomy, oncoplastic mastopexy, oncoplastic tumorectomy and oncoplastic reduction mammoplasty is useful**

- In clinical practice for distinguishing BCS from OPS 
- In clinical practice for classifying the procedure in the operative report 
- In clinical research 

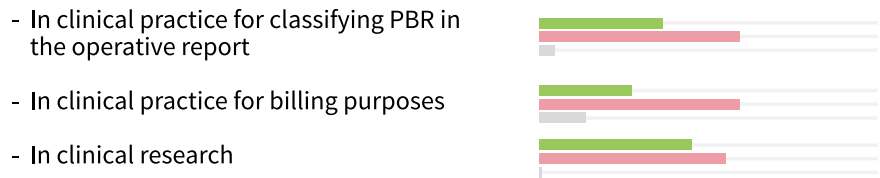
**9. The Basel indication algorithm is useful for standardization of the indication for OPS**

- In clinical practice for indicating, planning and performing the procedure 

**10. The Basel reconstruction algorithm is useful for standardization of partial breast reconstruction (PBR) during OPS**

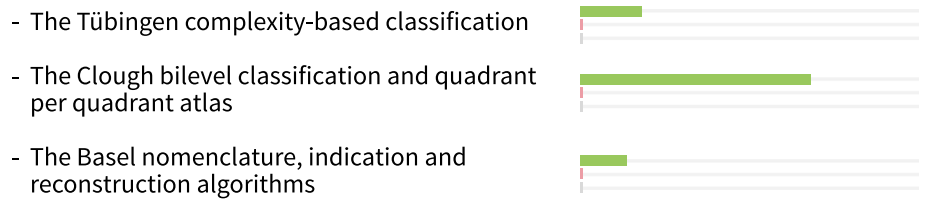
- In clinical practice for indicating, planning and performing PBR 

**Fig. 1** continued

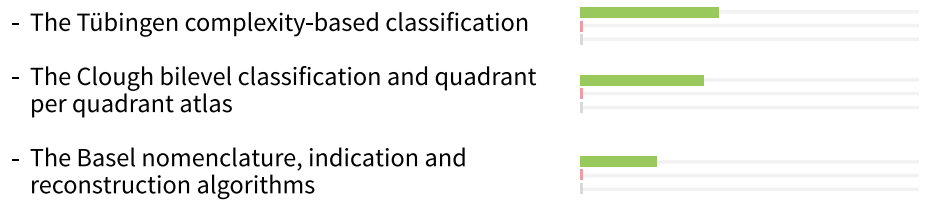


**11. Which one of the three proposed classification systems is most useful**

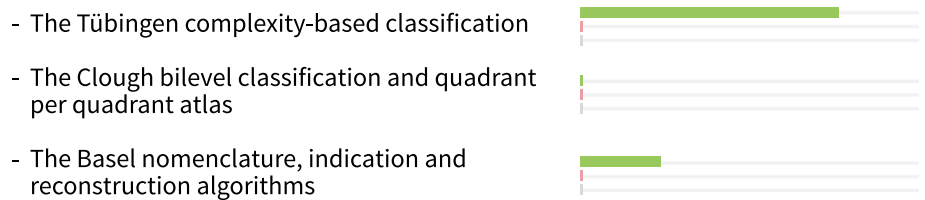
In clinical practice for indicating, planning and performing the procedure



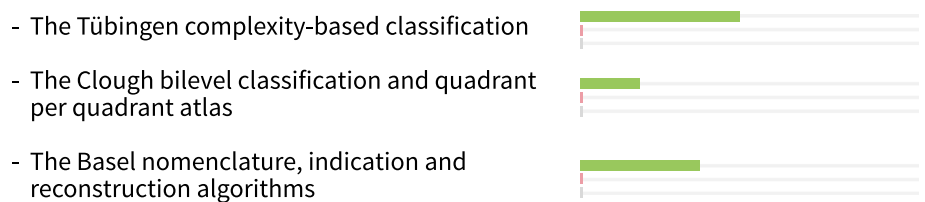
In clinical practice for classifying the procedure in the operative report



In clinical practice for billing purposes



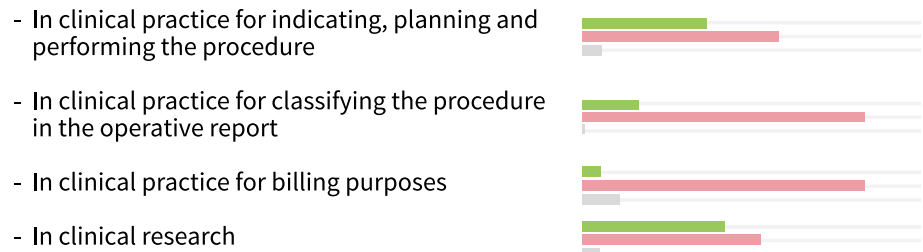
In clinical research



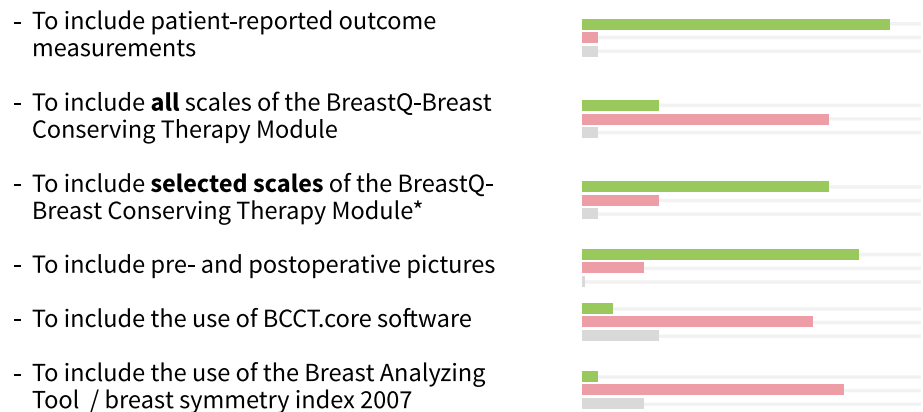
**12. Need for other classification systems**

We need another classification system other than these three

Fig. 1 continued



### 13. Outcome assessment of OPS should be standardized in clinical practice



\*e.g. satisfaction with breasts scale +/- psychosocial well-being

## Results

### Safety of oncoplastic breast conserving surgery

There was consensus among the panelists that OPS increases the risk of complications compared to conventional BCS (see supplementary appendix 2). This statement is supported by a recent review of 11 prospective studies including 998 patients with 7 studies reporting on complications [14]. Even though complication rates varied widely among studies, an early complication rate of 20% was commonly described, consisting mostly of delayed wound healing, partial skin necrosis, infection, hematoma, and seroma. Accordingly, a 3- to 8-fold increase in the risk of morbidity has been previously described [15].

Despite the potential impact of complications on the time to adjuvant therapy, virtually all panel members agreed that OPS does not increase the risk of local recurrence (LR) compared to BCS. In fact, even though there are no randomized controlled trials, there is an increasingly large body of observational evidence that consistently indicates that OPS is oncologically safe, even though the length of follow-up is still limited [16, 17]. A recent systematic review of oncological outcomes after OPS showed high rates of overall (95%) and disease-free survival

(90%), as well as low rates of LR (3.2%), positive margins (10.8%) and re-excisions (6%) at a mean follow-up of 4.2 years [17]. Concordantly, the largest single-center series published to date revealed no differences in overall and recurrence-free survival between the OPS and BCS groups at a median follow-up of 3.4 years [16].

### Safety of oncoplastic breast conserving surgery in comparison to nipple- or skin-sparing mastectomy with immediate reconstruction

The panel strongly felt that OPS does not increase the risk of complications, and a majority believed that OPS does not increase the risk of LR compared to nipple- or skin-sparing mastectomy with immediate reconstruction (NSM/SSM). Even though data on this comparison are scarce, the available evidence is in support of these panel statements [16]. Equivalent survival rates have long been recognized, and a large population-based observational study even showed a significant improvement of overall survival in patients with T1N0 breast cancer after BCS compared with mastectomy [18]. Therefore, BCS—which includes OPS—followed by radiation should be the standard care for patients with breast cancer whenever feasible. Neoadjuvant chemotherapy should be used to improve the rate of BCS

and OPS. Finally, strict adherence to guidelines on margins (“no ink on tumor”) also helps to improve the rate of BCS and OPS [19].

### Goals and indications of oncoplastic breast conserving surgery

The panel unanimously considered OPS useful for improving aesthetic outcomes, while only a bare majority believed that this improves quality of life (QoL). Indeed, the association between aesthetic outcomes and the benefit from the patient’s perspective is complex. A recent observational study from Brazil compared the aesthetic results between 57 patients after OPS and 65 patients after BCS [20]. When rating was done by a semiautomatic software, there were significantly more excellent results after OPS (22.8 vs. 6.2%,  $p = 0.004$ ). When rating was performed by surgeons, there were many more excellent results after OPS (50.9 vs. 18.5%,  $p < 0.001$ ). However, patients rated their own results with no significant difference between the two groups (61.4 vs. 69.2%,  $p = 0.320$ ). This highlights the need for questionnaires to assess patient-reported outcomes that are sensitive enough to detect differences in QoL and patient satisfaction of clinical relevance. A recent review of observational studies including 8659 patients suggested slightly higher patient satisfaction after OPS compared to BCS (89.5 vs. 82.9%,  $p < 0.001$ ) [21].

A slim majority of the panel believes that OPS can be used to reduce the rate of positive margins. This advantage of OPS is consistently supported by several observational studies. Carter et al. found lower rates of positive or close margins (5.8 vs. 8.3%, respectively;  $p = 0.04$ ) and Down et al. found a lower need for re-excision (5.4 vs. 28.9%,  $p = 0.002$ ) favoring OPS over BCS [16, 22]. The meta-analysis by Losken et al. showed that the rate of positive margins is overall approximately halved by the use of OPS (12 vs. 21%,  $p < 0.0001$ ) [21]. However, even though large-volume resections as obtained by OPS seem to lower re-excision rates, a simple majority of the panel believed that OPS does not decrease the rate of LR compared to BCS.

Finally, the panel voted unanimously that an important goal of OPS is to broaden the indication for BCS towards larger or multifocal tumors as alternative to mastectomy. Two observational series evaluated this indication and found low rates of re-operation for margins of 11.9 and 18.9% after OPS in patients with large primary tumors [23, 24].

### Specific areas in need for standardization

The panel reached consensus when identifying the following OPS domains in need for standardization:

nomenclature, indications, contraindications, outcome assessment, and clinical research. A large majority of the panel thought that there would also be a need for standardization of OPS in clinical practice. However, the panel was almost equally divided by the question if the selection of the partial breast reconstruction method should be standardized.

### Specific OPS standard procedures

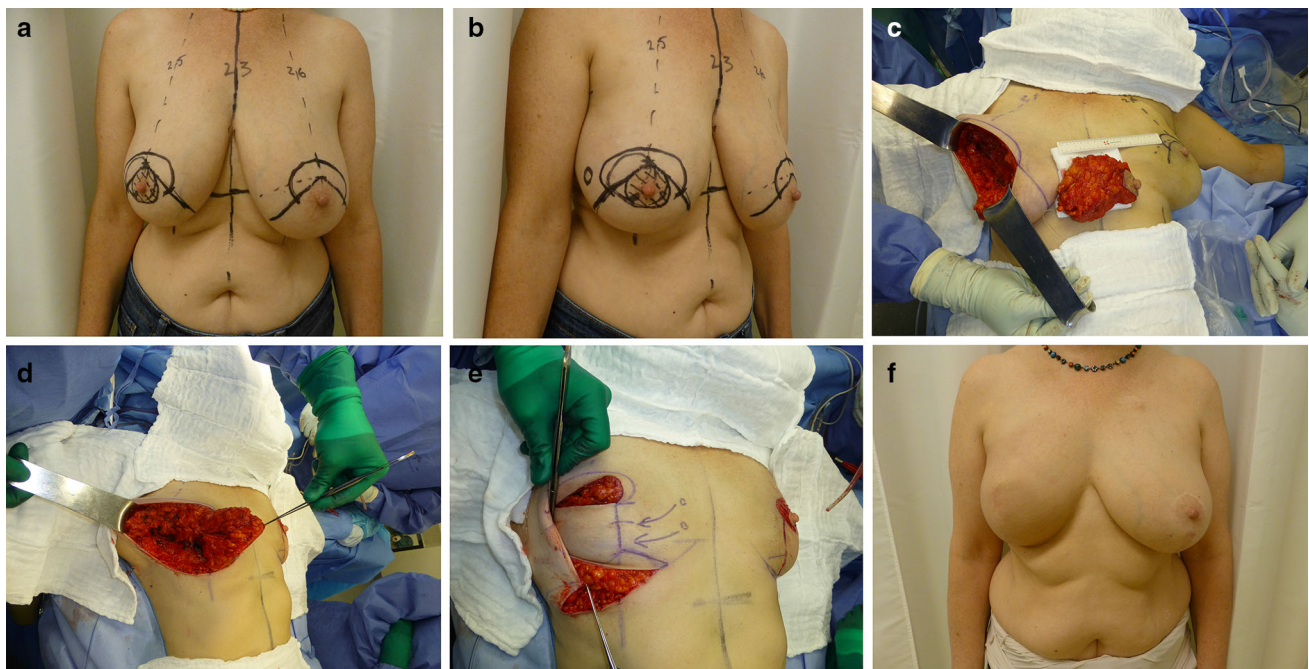
When asking for a selection of specific procedures that a specialized OPS unit should be able to offer, the panel refused to use specific terms, such as Benelli or Grisotti mammoplasty [1, 3]. Instead, the panel strongly endorsed that in general, every OPS procedure should be tailored to the individual patient. Therefore, the panel changed the questions ad hoc, to unanimously propose only two categories of OPS procedures that every OPS unit should be able to adjust to any given situation: Tumor adaptive reduction mammoplasty and mastopexy (see Figs. 2, 3).

The panel then spontaneously addressed a current controversy and formulated a question on the routine use of fat grafting in immediate breast reconstruction during OPS. The subsequent discussion on its oncological safety and effectiveness is mirrored by several recent publications [25, 26]. Even though observational evidence emerged that delayed fat grafting does not jeopardize oncological safety after reconstruction following both mastectomy and BCS, the panel considered the current evidence on immediate fat grafting insufficient and strongly voted against its standard use during initial OPS at present [27, 28]. Finally, the panel was in agreement with the recommendation for the use of pedicled flaps and against the use of free flaps as standards for reconstruction during initial OPS.

### Classifications systems

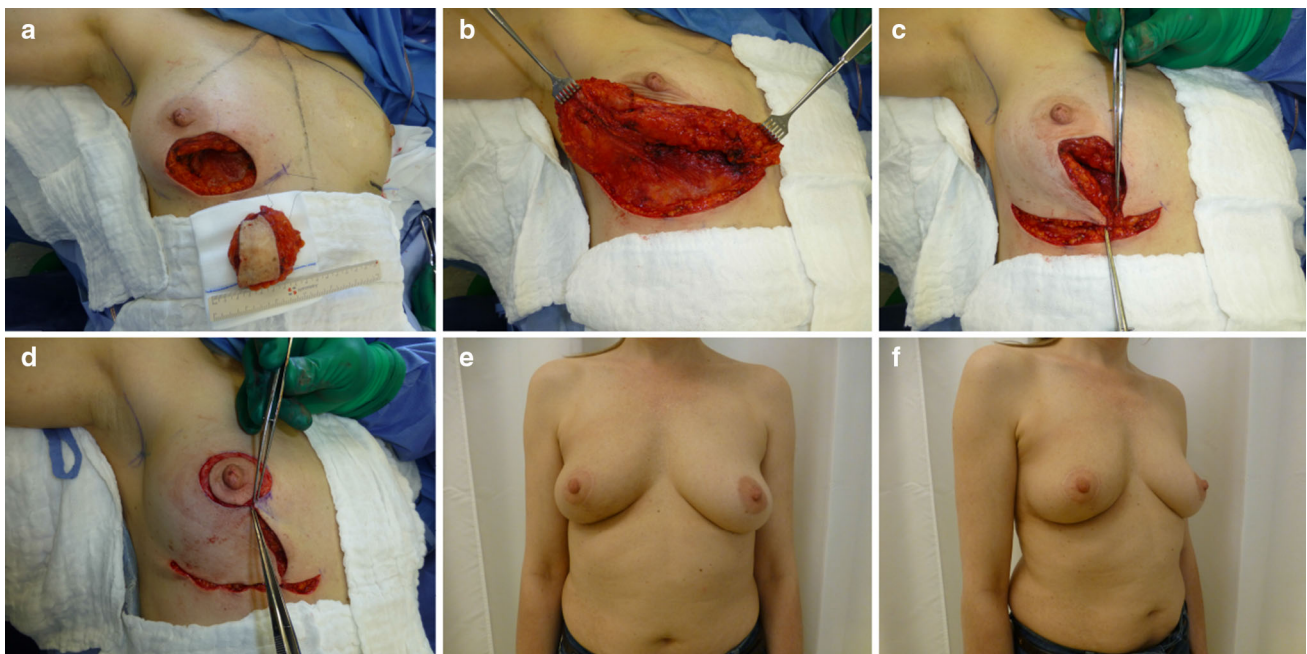
During the weeks prior to the conference, three classification systems were selected for presentation, discussion, and voting based on the preferences of the panelists. The panel first addressed questions on the Clough bi-level classification system after a quick presentation of its original publication by the chairman. [6] The Clough system classifies OPS procedures as level I when <20% of the volume is excised and as level II when 20–50% of the volume is excised. It further includes a quadrant per quadrant atlas to propose one or more specific techniques according to the exact location of the tumor within the breast, which were outlined in detail. A large majority of the panel considered this classification useful as a standard in clinical practice for indicating, planning, and performing the procedure. However, the panel reached consensus not to recommend it in clinical practice for billing purposes,





**Fig. 2** One example of a tailored tumor adaptive reduction mamoplasty **a, b** patient with multicentric cancer in central portion of right breast with second focus between outer quadrants; **c** centrolateral

tumorectomy; **d, e** mobilization and rotation of dermoglandular flap (before de-epithelialization); **f** Patient two years after surgery



**Fig. 3** One example of a tailored oncoplastic mastopexy **a** tumororectomy en bloc with skin resection in inferior quadrants; **b**: mobilization of two dermoglandular flaps; **c** rotation of flaps into defect; **d** crescent mastopexy; **e, f** patient one year after surgery

and a simple majority voted against its use in clinical practice for classifying the procedure in the operative report. The panel was almost equally divided when asked if the classification is useful for standardization of OPS in clinical research.

Second, the Hoffmann classification was addressed by the panel [7]. It is based on the complexity of the procedure and has been designed for use in all types of oncologic, oncoplastic, and reconstructive breast surgery. However, the panel considered it detailed enough for use in OPS. It



was unanimously recommended for billing purposes, and consensus was reached to its recommendation as standard for operating report classification, as well as for use in clinical research. However, when asked about recommending it in clinical practice for indicating, planning and performing the procedure, the panel was equally divided.

The third system, which we called the Basel classification, proposed a novel nomenclature to divide BCS and OPS into four categories based on specific aspects of the procedures, such as the use of non-oncological skin or tissue resection or glandular flaps and pedicles [13]. A clear majority of the panel considered this nomenclature useful in clinical practice for distinguishing BCS from OPS and for classifying the procedure in the operative report, while a slim majority voted against its use in clinical research. The classification further included an indication algorithm that recommended one of the four categories based on the size and shape of the breast, as well as the size and location of the tumor. The panel was equally divided to recommend for or against the standard use of this algorithm in clinical practice for indicating, planning, and performing the procedure. Finally, the classification involved a reconstruction algorithm that was designed to suggest the use of specific glandular flaps and pedicles based on the location of the tumor. A simple majority of the panel voted against its use as a standard in all domains of clinical practice and research.

The next set of questions were designed to identify the classification system that was considered the most useful by the panel. A clear majority voted for the Clough system as a standard in clinical practice for indicating, planning, and performing the procedure. The panel reached consensus in recommending the Hoffmann system as standard for billing purposes. However, the panel strongly disagreed on what procedure should be recommended as best standard in clinical practice for classifying the procedure in the operative report and for use in clinical research.

Finally, the next group of questions were developed ad hoc by a panelist, asking if the panel members recommended another classification system that was either not presented during the meeting, or still needs to be developed. There was panel consensus that this is not necessary for the operative report and for billing purposes. In addition, a bare majority voted against another system in clinical practice for indicating, planning, and performing the procedure and for clinical research.

### Standardization of outcome assessment

The panel strongly felt that outcome assessment of OPS should be standardized in clinical practice to include patient-reported outcomes measurements. In the long run, documenting the benefit from the patients' perspective is

mandatory to successfully implement OPS into routine patient care. The chairman then provided an overview of the Breast-Q™ patient-reported outcomes instruments [29]. These comprehensive questionnaires include several scales to cover various domains of patient satisfaction and quality of life before and after different types of breast surgery. The Breast Conserving Therapy Module is designed for use after breast conserving surgery and radiation. A large majority of the panel voted against the use of all scales in clinical practice for feasibility reasons due to the size of the questionnaire. However, the scales are independent of each other, which allows the selection of the most appropriate scales. Indeed, a strong majority voted for the standard use of selected scales of the Breast-Q™-Breast Conserving Therapy Module (e.g., Satisfaction with breasts scale ± psychosocial well-being) in routine clinical OPS practice. The panel decided to coordinate the translation of this Breast-Q™-module into the German language including official linguistic validation. Moreover, the panel reached consensus to recommend photographic documentation of all patients before and after surgery as standard for clinical routine. However, while recognizing the important value of semiautomatic software for objective aesthetic evaluation as a key element of continuous improvement of OPS, the panel did not recommend its standard use in daily clinical practice for feasibility reasons and due to the limited correlation between objective and patient-reported outcomes [30, 31].

### Future directions

To implement safe and effective OPS into routine patient care, several domains are in need of standardization. First, indications and contraindications need to be clearly defined to avoid misuse and abuse with unnecessary complications. For this purpose, prospective multicenter studies comparing different OPS techniques to conventional BCS are needed. These studies should follow pre-defined algorithms and use both objective aesthetic and patient-reported outcome measurement tools like the Breast-Q, the breast analyzing tool or the bcct.core [30–33]. In addition, prospectively maintained registers for OPS should be introduced using preferably the same or at least well aligned databases for optimum international comparability. Prospective data collection concerning surgical procedure and outcome within clinical trials, especially those involving neoadjuvant treatment, can easily be achieved if surgical oncologists are present during protocol writing and review.

Second, education and training need to be standardized to allow young surgeons to enter the field and learn from experienced oncoplastic surgeons. To achieve this goal,

criteria need to be defined to qualify and accredit OPS training centers. While many countries have some centers of excellence for OPS, national and international standards are scarce. However, Great Britain for example has nationally initiated a similar process 10 years ago by publishing guidelines to assist with the setting up and delivery of an oncoplastic breast service [34]. Similarly, OPS is a mandatory element of the gynecological oncology board certification in Germany and there are some certified (AWOGyn, society of gynecologic reconstructive and esthetic surgery) centers and specialists for aesthetic and reconstructive breast surgery. The goal should be to broadly install standardized training opportunities within structured fellowships.

Finally, adequate reimbursement is a key condition for the successful introduction of OPS into routine patient care. Clearly, a fee-for-service reimbursement would best reflect the difference in surgical complexity between OPS and BCS. However, in the era of increasing bundled payment or diagnosis-related reimbursement, attention must be paid not to disadvantage OPS. Otherwise, the hospitals may discourage the use of OPS in the long run despite its substantial potential to improve outcomes in patients with breast cancer.

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#### Compliance with ethical standards

**Conflict of interest** Author Florian Fitzal invented the Breast Analyzing Tool (BAT) for symmetry measurements in breast surgery. Walter P. Weber, Savas D. Soysal, Mahmoud El-Tamer, Virgilio Sacchini, Michael Knauer, Christoph Tausch, Nik Hauser, Andreas Günthert, Yves Harder, Elisabeth A Kappos, Fabienne Schwab, Peter Dubsy, Vesna Bjelic-Radistic, Roland Reitsamer, Rupert Koller, Jörg Heil, Markus Hahn, Jens-Uwe Blohmer, Jürgen Hoffmann, Christine Solbach, Christoph Heitmann, Bernd Gerber, Martin Haug, Christian Kurzeder declare that they have no conflict of interest in the context of this publication.

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