



This document is work in progress

Consensus Conference on Knowledge Gaps in Oncoplastic Surgery

Thursday, 12 Sept 2019, 2.00 p.m. - 7.00 p.m., followed by faculty dinner, University Hospital Basel

Scientific secretaries

- Walter Weber (Switzerland)
- Joerg Heil (Germany)
- Jana de Boniface (Sweden)
- Monica Morrow (USA)
- Marie-Jeanne Vrancken-Peeters (The Netherlands)
- Shelley Potter (United Kingdom)
- Andrea Pusic (USA: confirmed as scientific secretary; attendance at meeting to be confirmed)

Background

The Oncoplastic Breast Consortium (OPBC) is committed to bringing safe and effective oncoplastic breast surgery to routine patient care, namely oncoplastic breast-conserving surgery, as well as nipple- and skin-sparing mastectomy (NSM/SSM) with immediate reconstruction. The OPBC pursues this mission by performing relevant clinical research projects, by offering oncoplastic training courses and by bringing international experts together to address controversial topics. The OPBC consensus panel currently consists of 20 coordinators and 40 panelists from 22 countries across all continents and includes oncologic, oncoplastic and reconstructive breast surgeons from private and public settings and four patient advocates.

Several knowledge gaps have recently been identified in two consensus conferences in the fields of oncoplastic breast conserving surgery¹ and nipple-sparing mastectomy with immediate reconstruction², calling for high-level scientific evidence to guide treatment. Moreover, the Association of Breast Surgery Gap Analysis Working Group recently identified current key breast surgical research gaps.³

Aim

The OPBC plans to prioritize knowledge gaps in the field of oncoplastic surgery and to propose concrete, consensual strategies to address the most important gaps.

Methods

Modified Delphi process performed by the OPBC panel, which consists of OPBC coordinators, panelists, patient advocates, special guests and surgical trainees. The Delphi process will consist of three rounds. While the first two rounds will be based on emails, with two reminders per round to optimize response rates, the third will be based on an in-person consensus conference. **Participation in the first two rounds is allowed even without attendance at the consensus conference.** Survey Monkey will be used for data collection. Responses will be summarized using purely descriptive statistics.

In preparation for the Delphi rounds

The section leaders of the scientific secretariat will be tasked with identifying key knowledge gaps in oncoplastic surgery practice and research based on voting results of prior consensus conferences and a combination of personal opinion and unsystematic searches of their own files.^{1,2} All knowledge gaps that were identified by significant disagreement ($\geq 25\%$) among experts when addressing the respective questions during the first international consensus conference on OPS¹ and the first OPBC consensus conference on NSM² will be included in this list.

1st Delphi round: Priorities:

The scientific secretaries will forward the list of identified knowledge gaps to the entire OPBC consensus panel for email-based ranking on a 10-point Likert scale from 1 (not important) to 10 (most important) based on the following two criteria:

1. Relevance: Estimated impact that additional research on this topic may have on oncoplastic surgery practice or research.
2. Feasibility: Likelihood that additional research can successfully address the gap

2nd Delphi round: Strategies

The section leaders of the scientific secretariat will compile the list of knowledge gaps according to the ranking and propose a range of strategies on how the most important gaps could be specifically addressed. The OPBC panel will vote on those proposals during the 2nd round. Controversial or unclear findings will be brought to the 3rd round (in-person consensus conference)

3rd round: In-person consensus meeting

OPBC panelists, coordinators, patient advocates, special guests, surgical trainees and scientific secretaries will be invited to meet in Basel on 12 September 2019. Special guests will include experts in radiation oncology, medical oncology, clinical trial epidemiology and biostatistics, as well as stakeholders from ethics committees, the pharmaceutical industry and funding agencies and, finally, moderators specialized in modified Delphi methodology. In the first half of the meeting, panelists and special guests will present specific topics that were selected by the scientific secretaries, followed by an interactive discussion. In the second half, controversial or unclear findings from the second Delphi round will be discussed, followed by electronic re-voting if indicated, with the objective of achieving consensus on specific strategies to address the most important knowledge gaps in oncoplastic surgery practice and research.

Program of in-person meeting on 12 September 2019

Time	Speaker	Topic
2.00-2.10	Joerg Heil	Welcome and introduction
2.10-2.30	Walter Weber	Update OPBC
2.30-2.45 (+5min discussion)	Monica Morrow (TBC)	Challenges in breast surgical research

2.50-3.05 (+5min discussion)	Shelley Potter (TBC)	Opportunities and priorities in breast surgical research ³
3.10-3.25 (+5min discussion)	TBD	The pragmatic trial design ⁴
3.30-4.00	Coffee break	
4.00-7.00	Consensus conference	

Appendix 1. Identification of knowledge gaps

Section 1. Knowledge gaps in oncoplastic surgery practice

Section 1A. Nipple sparing mastectomy and immediate reconstruction (NSM)

Section leader: **Joerg Heil** and **Andrea Pusic**

1. Optimizing type and timing of reconstruction in the setting of adjuvant radiotherapy
2. Assessment of the oncological safety of NSM when used for locally advanced breast cancer without neoadjuvant chemotherapy?
3. Understanding the impact of surgical technology on risk of skin flap necrosis (scalpel/scissors vs electrocautery vs Plasma Blade)
4. Developing strategies to reduce the risk of skin flap necrosis by intraoperative skin flap viability assessment
5. Identifying the best technique for intraoperative skin flap viability assessment (e.g., indocyanine green fluorescence, thermography)
6. Assessment of tissue conditioning with nitroglycerin as method of reducing the risk of skin flap necrosis
7. Assessment of immediate use of compression bra or compression dressing to reduce the risk of skin flap necrosis
8. Identifying the optimal site of incision for specific patients (e.g., tumors with a distance <1cm to the nipple on imaging, tumors in the upper inner quadrants in large breasts)
9. Defining and standardizing contraindications for skin preservation, such as
 - a. Locally advanced breast cancer without neoadjuvant chemotherapy
 - b. cT4b and cT4c breast cancer limited to a 1x1cm area of skin ulceration
 - c. Absence of any distance between tumor and skin on preoperative imaging, but without clinical signs of skin infiltration
 - d. Histological margin of less than 1mm on frozen section or definitive histology
10. Defining and standardizing contraindications for nipple preservation, such as:
 - e. Atypia in the margin to the nipple on frozen section, not 100% consistent with the diagnosis of DCIS or invasive cancer
 - f. Bloody nipple discharge
 - g. Status post whole breast radiotherapy
11. Optimizing treatment of a positive retroareolar margin
12. Defining the optimal axillary staging in risk-reducing NSM
13. Defining role and indications for retroareolar frozen section
14. Defining the role of synthetic and biological meshes in implant-based breast reconstruction (IBBR)

15. Defining current standards in IBBR, such as one- vs two-staged IBBR and pre- vs sub-pectoral IBBR
16. Optimizing timing and contents of follow-up for patients after NSM
17. Defining indications for risk-reducing surgery
18. Defining indications for contralateral prophylactic mastectomy

Section 1B. Oncoplastic breast conserving surgery (OPS)

Section leader: **Jana de Boniface** and **Marie-Jeanne Vrancken-Peeters**

19. Understanding the effect of OPS on quality of life
20. Understanding the effect of OPS on local recurrence risk
21. Optimizing current OPS classification systems for use in clinical practice for indicating, planning and performing the OPS procedures
22. Optimizing current OPS classifications system for use in clinical research
23. Understanding the optimal timing for contralateral symmetrizing procedures

Section 2. Knowledge gaps in oncoplastic surgery research

Section leader: **Shelley Potter**, **Jörg Heil** and **Monica Morrow**

24. Understanding the role of register / prospective / retrospective cohort studies
25. Finding the best designs for randomized controlled trials (RCTs) to evaluate clinical efficacy including cost-effectiveness and safety of different surgical techniques and devices (e.g., pragmatic vs explanatory⁴)
26. Defining thresholds for non-inferiority or superiority for specific relevant endpoints
27. Standardizing robust evaluation of novel procedures and techniques using appropriate methodology (e.g., IDEAL framework⁵)
28. Identifying the most relevant outcomes after oncoplastic surgery that should be used as primaries: patient-reported outcomes, objective aesthetic outcomes, complications, oncologic outcomes, etc.
29. Finding ways to implement standardized outcomes sets to allow comparisons across studies⁶
30. Finding ways to incorporate oncoplastic surgery research questions in other trials (e.g., funded by pharma, run by medical oncologists, etc.)
31. Obtaining more standardized information on the exact surgical procedure with codes including information on surgeons, techniques, excision volume, etc.
32. Combining pre-existing national efforts regarding audits on implants (e.g., the Dutch breast implant registry [DBIR])
33. Developing proper registries for oncoplastic surgery and ensuring adequate participation

Next steps

- Send this proposal to all scientific secretaries and Martin Paul Putora (Delphi navigator) and ask for comments/adjustments by the end of the year
- Send next OPBC newsletter in early January 2019
 - o Announce change of time for conference from 2.00 p.m. to 7.00 p.m., which was necessary to allow arrivals from Europe on the same day

- Ask for participation of surgical trainees (residents or fellows) in the Delphi process including the consensus conference in Basel. The first 3 applicants will be selected.
- Attach this proposal as work in progress
- Ask one more patient advocate to participate
- Confirm speakers and topics for presentation during the first part of the conference

References

1. Weber WP, Soysal SD, El-Tamer M, et al. First international consensus conference on standardization of oncoplastic breast conserving surgery. *Breast Cancer Res Treat* 2017; **165**(1): 139-49.
2. Weber WP, Haug M, Kurzeder C, et al. Oncoplastic Breast Consortium consensus conference on nipple-sparing mastectomy. *Breast Cancer Res Treat* 2018; **172**(3): 523-37.
3. Cutress RI, McIntosh SA, Potter S, et al. Opportunities and priorities for breast surgical research. *Lancet Oncol* 2018; **19**(10): e521-e33.
4. Ford I, Norrie J. Pragmatic Trials. *N Engl J Med* 2016; **375**(5): 454-63.
5. McCulloch P, Feinberg J, Philippou Y, et al. Progress in clinical research in surgery and IDEAL. *Lancet* 2018; **392**(10141): 88-94.
6. Potter S, Holcombe C, Ward JA, Blazeby JM, Group BS. Development of a core outcome set for research and audit studies in reconstructive breast surgery. *Br J Surg* 2015; **102**(11): 1360-71.