



Die Implantat- Sofortrekonstruktion:

Sind die Risiken am Ende zu hoch?

C. Schumacher

Brustzentrum

St. Elisabeth-Krankenhaus

Ma ... sie mit sofortiger implantatgestützter Brustrekonstruktion mit und ohne Netz

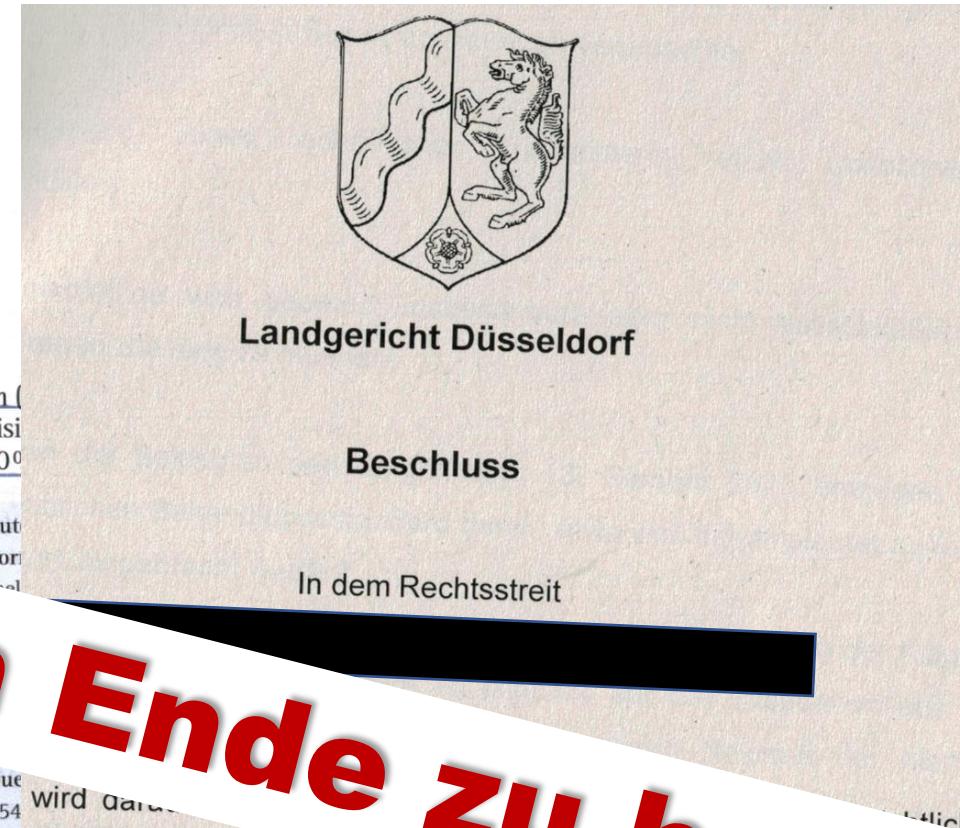
A Sind die Risiken zu empfehlen

B. ... implantatgestützte Brustrekonstruktion zum Zeitpunkt ... sie mit oder ohne biologischen oder synthetischen Netz mag theoretisch eine gute Idee sein, praktisch ist sie offenbar aber noch nicht ausgereift. Darauf deuten Ergebnisse einer multizentrischen, prospektiven Kohortenstudie hin. Demnach sind Komplikationen nach sofortiger implantatbasierter Brustrekonstruktion höher als nationale Standards empfehlen.

In diese Studie hatten Dr. Shelley Potter vom Bristol Centre for Surgical Research und ihre Kollegen 2108 Patientinnen mit 2655 Mastektomien teilgenommen.

Die Rekonstruktion an der Brustwand wurde aufgetrennt in eine mit einem Netz und eine ohne Netz. Die Rekonstruktion erfolgte bei 1376 Patientinnen, bei denen präoperativ eine Kombination von Implantaten. Daten zu den Ergebnissen nach 3 Monaten waren für 2081 (99%) Frauen verfügbare. Von diesen Patientinnen wurden 1376 (65%) mit biologischen (1133 [54%]) oder synthetischen (243 [12%]) Netzen, 181 (9%) mit nicht netzartigen submuskulären oder subfaszialen Implantaten, 440 (21%) mit dermalen Schlingenimplantaten, 42 (2%) mit präpektoralen Implantaten und 79 (4%) mit anderen Implantaten oder mit einer

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Landgericht Düsseldorf

Beschluss

In dem Rechtsstreit

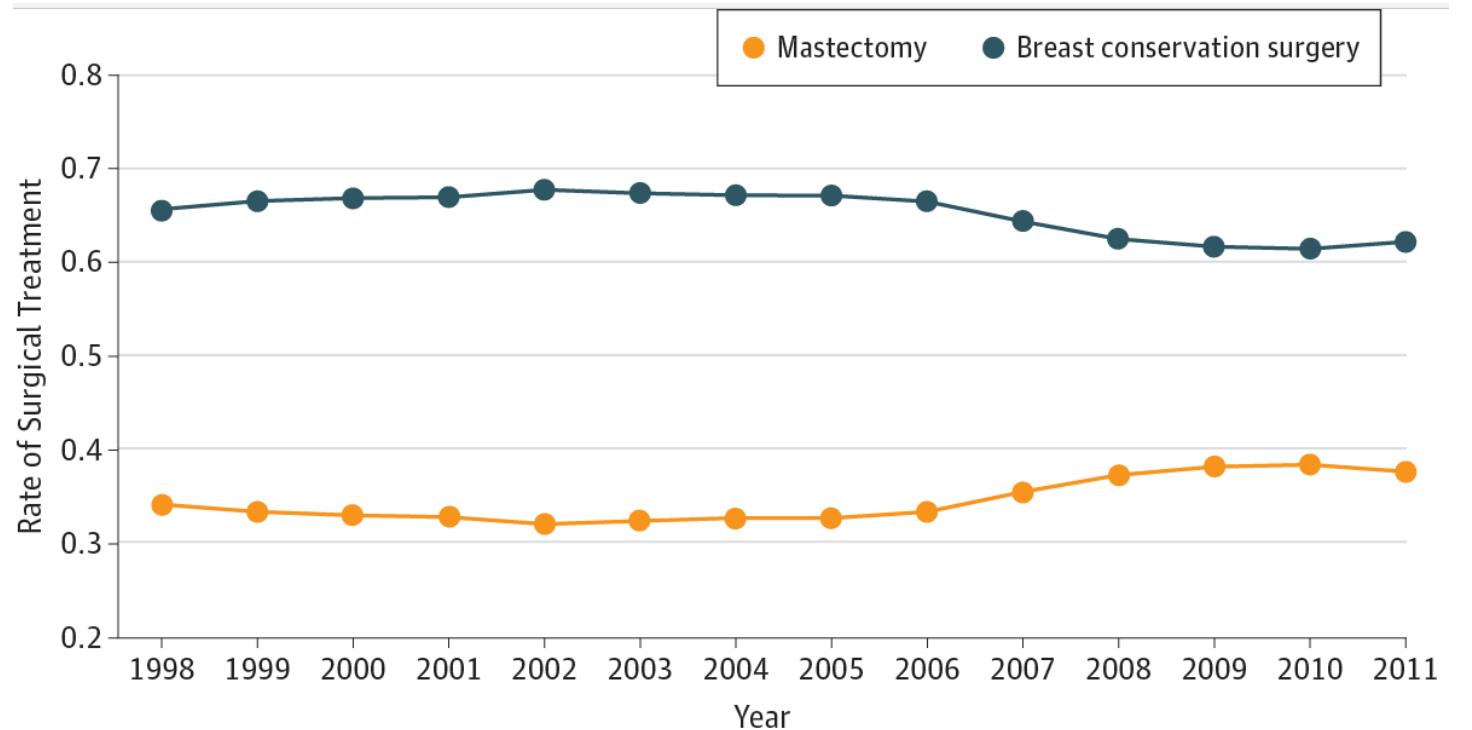
Mammarekonstruktion

**Aktuelle
operative Trends**



Trends in der Operativen Therapie des Mammakarzinoms

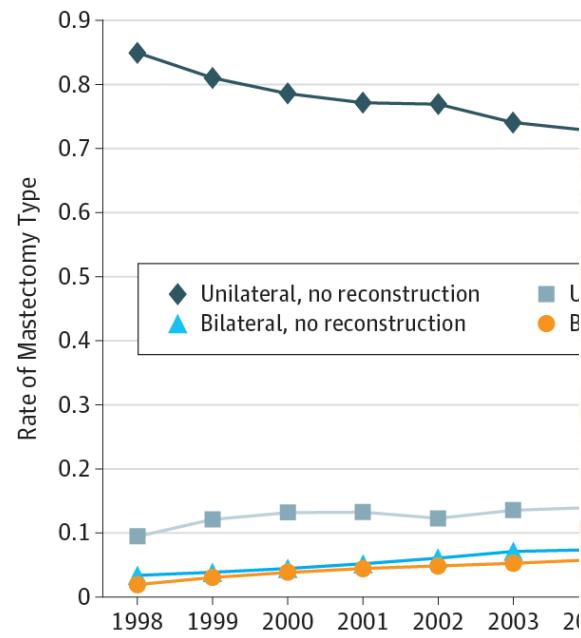
A retrospective cohort study of more than 1.2 million adult women treated at centers accredited by the American Cancer Society and the American College of Surgeons Commission on Cancer from January 1, 1998, to December 31, 2011, using the National Cancer Data Base.



Temporal Trends in Surgical Treatment of Early Breast Cancer

Proportion of women with early breast cancer who underwent mastectomy (orange line) and breast conservation surgery (blue line) by year of diagnosis in the National Cancer Data Base. All trends are significant ($P < .001$).

Trends in der Operativen Therapie des Mammakarzinoms



Temporal Trends in Type of Mastectomy for Early Breast Cancer
 Proportion of mastectomies for early breast cancer that were unilateral without reconstruction (light blue line with squares), bilateral without reconstruction (orange line with circles) by year of diagnosis in the National Cancer Data Base for each breast cancer case (includes staged approaches). Reconstruction approaches. All trends are significant ($P < .001$).

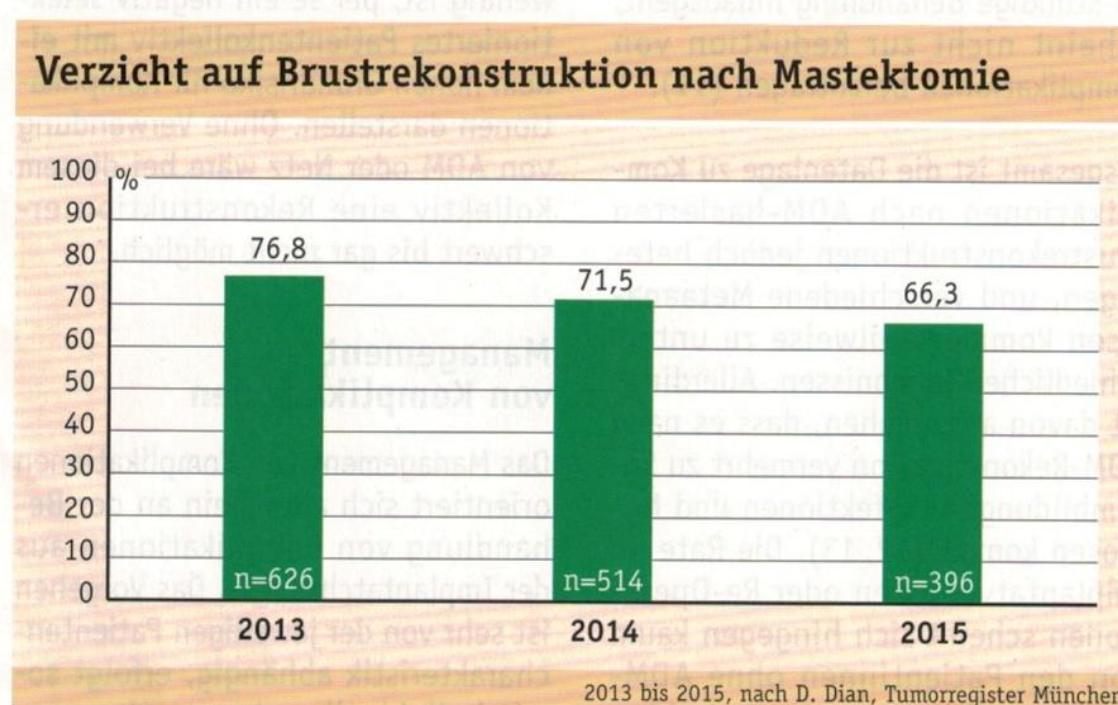


Abb. 3: Der Anteil der Patientinnen, die nach Mastektomie keine Rekonstruktion der Brust durchführen ließen, ist rückläufig.

Reconstructive Plastic Surgery Statistics

Trends

Top 5 procedures appear in bold.

PROCEDURES	2015	2014	2000	% CHANGE 2015 vs. 2014	% CHANGE 2015 vs. 2000
breast reconstruction	28,079	28,528	43,089	-2%	-35%
patients only)	30,383	29,221	40,076	4%	-24%
patients only)	17,892	17,496	16,287	2%	10%
patients only)	106,338	102,215	78,832	4%	35%
breast reconstruction	60,175	59,883	—	0%	—
breast reconstruction	15,606	15,457	—	1%	—
breast reconstruction	130,280	129,715	—	0%	—
breast reconstruction	27,987	27,281	—	3%	—
breast reconstruction	10,156	10,048	—	1%	—
microsurgical)	253,441	250,946	358,666	1%	-29%
microsurgical)	16,801	16,334	—	3%	—
microsurgical)	200,550	199,234	79,331	1%	153%
microsurgical)	1,348	1,351	—	0%	—
microsurgical)	179,066	177,345	221,858	1%	-19%
microsurgical)	4,472,153	4,440,186	—	1%	—
microsurgical)	264,743	264,584	376,270	0%	-30%
PROCEDURES	2015	2014	2000	% CHANGE 2015 vs. 2014	% CHANGE 2015 vs. 2000

Trends in der Operativen Therapie des Mammakarzinoms

Current Trends in Post-Mastectomy Breast Reconstruction

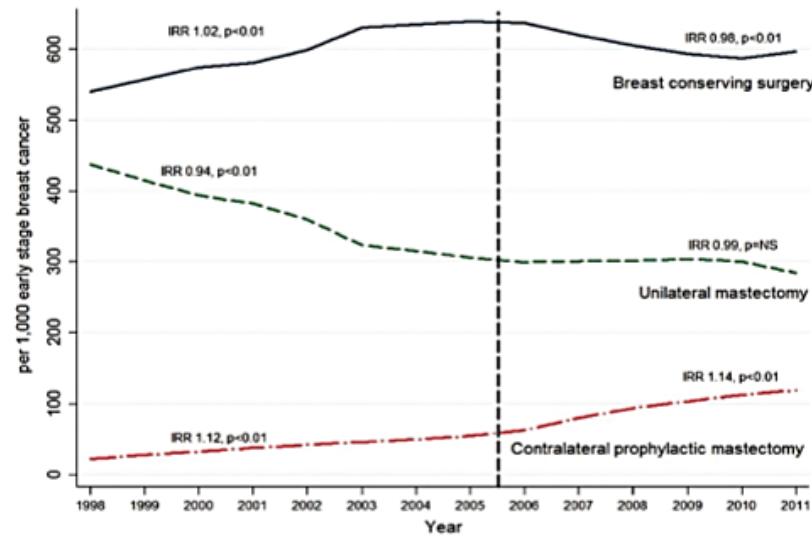


Figure 1.
Temporal Trends of Surgical Treatment in Patients with Early Stage Breast Cancer from 1998–2011 Using National Cancer Database. IRR: Incidence Rate Ratio; NS: Not significant; Adapted from Albornoz et al. 2015 Source: *Bilateral Mastectomy versus Breast Conserving Surgery for Early-Stage Breast Cancer: The Role of Breast Reconstruction*. Plastic and Reconstructive Surgery. 135(6): 1518–1526, June 2015.

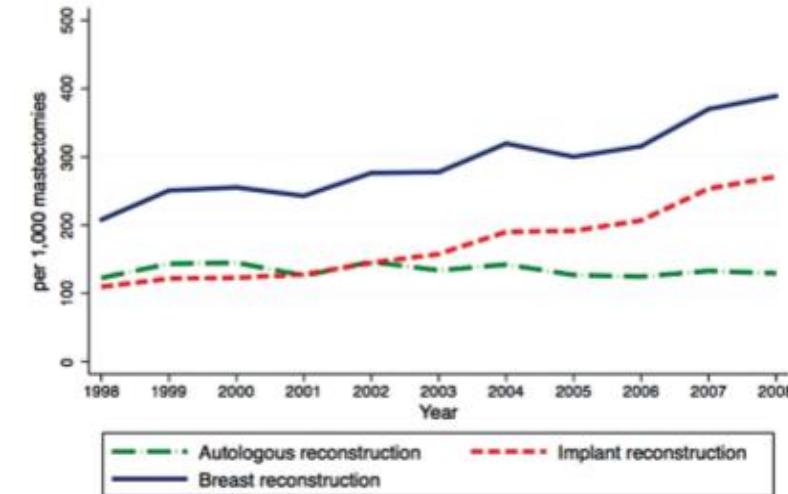


Figure 2.
Temporal Trends of Reconstructive Methods in Patients who underwent Mastectomy from 1998–2008, Using Nationwide Inpatient Sample Database IRR: Incidence Rate Ratio; NS: Not significant; Adapted from Albornoz et al. 2013 Source: *A Paradigm Shift in U.S. Breast Reconstruction: Increasing Implant Rates*. Plastic and Reconstructive Surgery. 131(1): 15–23, January 2013.

Over the past decade, prosthetic techniques have become the method of choice for postmastectomy reconstruction in over 70% of cases. Reasons for increased implant use are multifactorial, but include changes in oncologic practice, such as greater number of bilateral mastectomies and broader indications for PMRT

Trends in der Operativen Therapie des Mammakarzinoms

Breast reconstruction practices in a specialized tertiary referral centre in Ireland

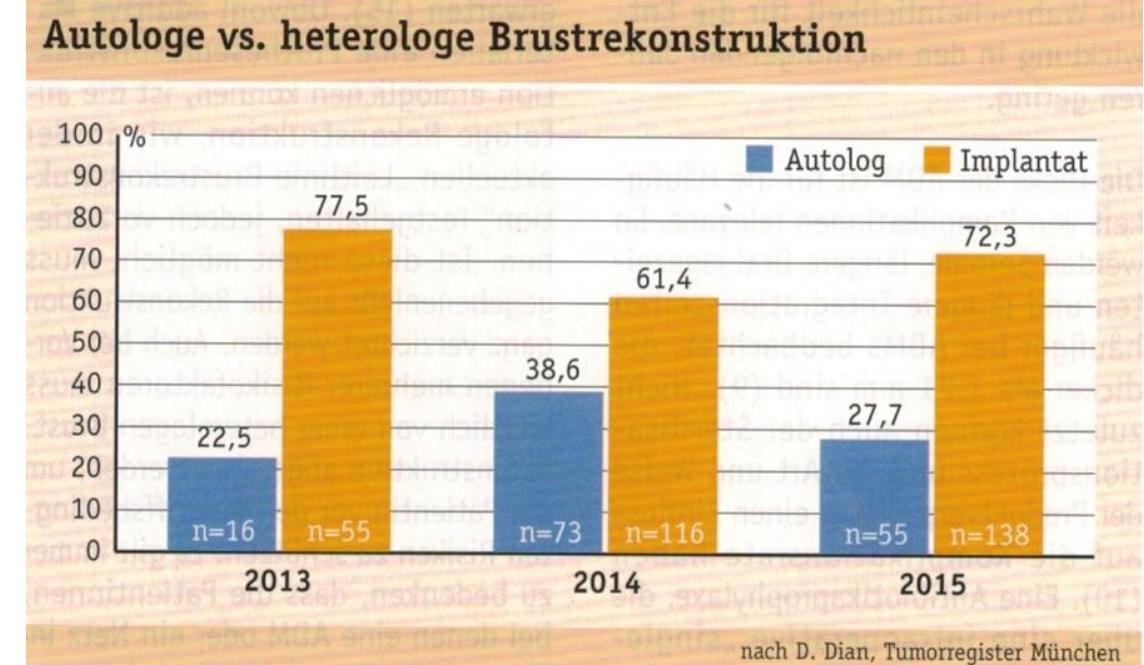
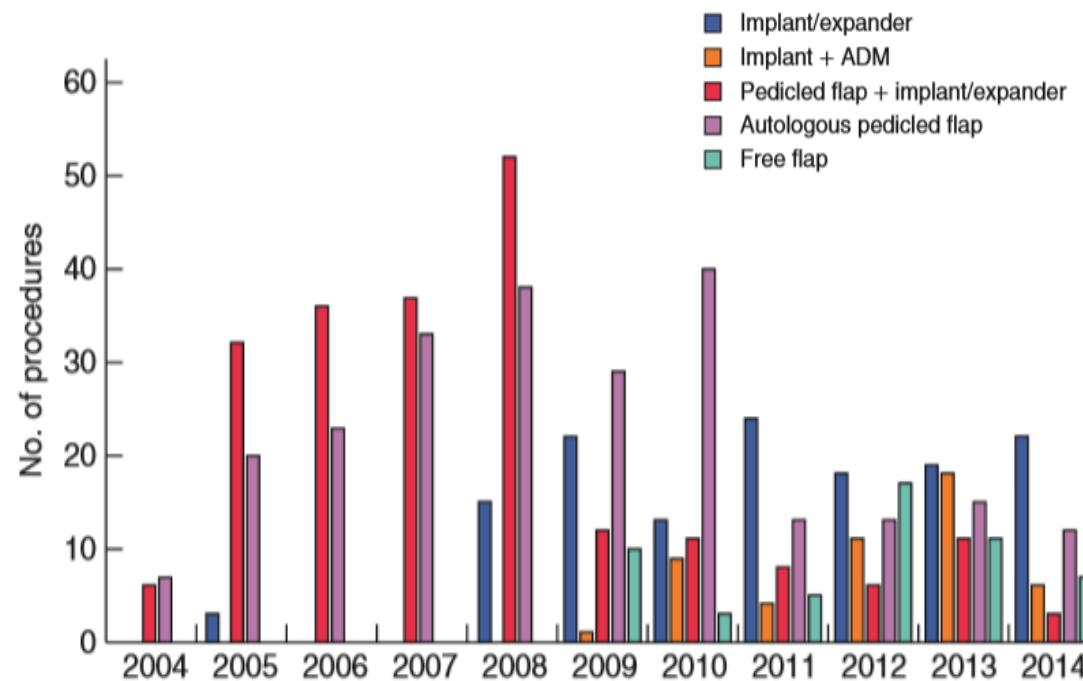


Abb. 2: Entwicklung der Brustrekonstruktionen von 2013 bis 2015

Complications in Postmastectomy Breast Reconstruction

One-year Outcomes of the Mastectomy Reconstruction Outcomes Consortium (MROC) Study

Eleven sites enrolled women undergoing first time, immediate, or delayed reconstruction following mastectomy for cancer treatment or prophylaxis. Procedures included expander/implant, latissimus dorsi (LD), pedicle transverse rectus abdominis musculocutaneous (PTRAM), free TRAM (FTRAM), and deep inferior epigastric perforator (DIEP) techniques.

Complication rates for 2234 patients were analyzed.

One-year Postoperative Complication Rate by Procedure Type

	Procedure Type					<i>P</i> *
	Implant (DTI and TE) N = 1615	PTRAM N = 84	Free TRAM N = 97	DIEP N = 365	Lat Dorsi N = 73	
Any complication	399 (24.7%)	32 (38.1%)	33 (34.0%)	171 (46.9%)	28 (38.4%)	<0.001
Major complication	291 (18.0%)	25 (29.8%)	23 (23.7%)	107 (29.3%)	13 (17.8%)	0.002
Reconstructive failure	95 (5.9%)	0 (0.0%)	2 (2.1%)	6 (1.6%)	2 (2.7%)	0.002

**P* value is computed from the mixed-effects logistic regression model adjusting for sites or Fisher exact test.

Mixed Effects Logistic Regression Model for 1-year Postoperative Any and Major Complication

Predictors	Model 1: Any Complication		Model 2: Major Complication		
	OR (95% CI)	P	OR, 95% CI	P	
Age group (ref. <35)					
35–45	1.52 (0.94–2.46)	0.091	2.07 (1.10–3.89)	0.024	
45–55	1.68 (1.04–2.70)	0.033	2.41 (1.30–4.49)	0.006	
55–65	1.96 (1.19–3.25)	0.009	3.01 (1.58–5.75)	0.001	
>65	2.30 (1.26–4.20)	0.007	2.84 (1.34–6.01)	0.007	
Obesity Class (ref. Normal)					
Underweight	0.73 (0.29–1.84)	0.508	0.79 (0.27–2.36)	0.677	
Overweight	1.13 (0.88–1.45)	0.324	1.26 (0.95–1.68)	0.108	
Obese I	1.54 (1.14–2.08)	0.005	1.73 (1.24–2.43)	0.001	
Obese II/III	2.29 (1.58–3.32)	<0.001	2.45 (1.64–3.65)	<0.001	
Procedure Type (ref. DTI and TE)					
PTRAM	1.89 (1.08–3.30)	0.025	1.86 (1.02–3.40)	0.044	
FTRAM	1.94 (1.17–3.23)	0.011	1.57 (0.89–2.76)	0.120	
DIEP	2.22 (1.57–3.13)	<0.001	1.75 (1.19–2.58)	0.004	
Lat Dorsi	1.95 (1.08–3.51)	0.026	0.98 (0.47–2.02)	0.953	
Timing (ref. Delayed)					
Immediate	1.82 (1.11–2.99)	0.017	1.17 (0.68–2.00)	0.566	
Laterality (ref. Unilateral)					
Bilateral	1.52 (1.22–1.89)	<0.001	1.60 (1.25–2.04)	<0.001	
Lymph node biopsy (ref. None)					
SLNB	1.08 (0.78–1.50)	0.647	1.23 (0.84–1.79)	0.284	
ALND	0.98 (0.67–1.43)	0.922	1.14 (0.75–1.75)	0.541	
Charlson Comorbidity Index (ref. ≤1)					
>1	1.43 (1.03–1.99)	0.032	1.77 (1.25–2.51)	0.001	
Smoking status (ref. Nonsmoker)					
Previous smoker	1.16 (0.93–1.44)	0.192	1.14 (0.89–1.45)	0.314	
Current smoker	1.62 (0.92–2.85)	0.093	1.95 (1.07–3.55)	0.028	
Radiation (ref. None)					
Before reconstruction	1.07 (0.76–1.51)	0.713	1.12 (0.76–1.65)	0.561	
During/after reconstruction	1.58 (1.18–2.11)	0.002	1.64 (1.19–2.27)	0.003	
Chemotherapy (ref. not during/after reconstruction)					
During/after reconstruction	1.00 (0.79–1.27)	0.994	1.13 (0.86–1.4)		



**Warum findet eine
einzelne prospektive
multizentrische Studie
solche Beachtung?**

- **Geringe Evidenz aufgrund
schlechter Datenlage**

Sofortrekonstruktion durch Implantate:

**Unzureichende
Standardisierung der
Vorgehensweise und der
Patientinnenselektion**

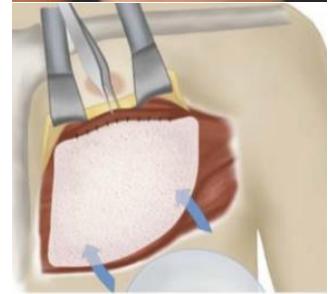
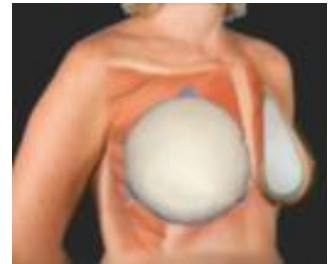


Aktuelle Vorgehensweisen

1. Implantat-Lager

TABLE 1. Classification of Implant Placement in Prosthetic Breast Reconstruction

	Dissection	Advantages	Disadvantages
P0	Complete prepectoral with 360-degree ADM wrap	Reduced postoperative pain No animation deformity More natural look	Requires fat grafting to mask upper implant interface Limited fat donor sites in thin patients Increased cost of using several large pieces of ADM Possible increased risk of implant rotation
P1	Muscle-sparing prepectoral with anterior ADM coverage	Reduced postoperative pain No animation deformity More natural look Superior coverage of the superior implant Long-term implant support	Increased operative time when compared with P0 reconstruction
P2	Superior pectoralis coverage with ADM sling	Improved shape of lower/lateral breast Superior upper-pole implant coverage	Moderate to severe animation deformity Increased postoperative pain Long-term discomfort
P3	Total pectoralis coverage with serratus sling	Superior soft-tissue device coverage	Unnatural shape of breast mound Lack of breast projection and ptosis Increased postoperative pain Extreme limitations in DTI reconstruction Severe animation deformity





Pro und Contra PO / P1-Methode:

Pro:

- Kleineres operatives Trauma
- Signifikante Reduktion von Schmerzen und Muskelpasmus
- Keine sichtbare Implantat-Verlagerung bei Bewegung
- Natürliche Brustform mit Ptosis
- Mehr Symmetrie zur nicht rekonstruierten Gegenseite



Contra:

- Dünnerer und damit schlechter vaskularisierter Weichteilmantel
- Höheres Risiko für das Sichtbarwerden des Implantates und für ein Rippling im oberen und medialen Brustanteil
- Häufig Lipofilling erforderlich

PO / P1- versus P2-Methode: Komplikationen

“Comparison of prepectoral and subpectoral breast reconstruction after mastectomies: A systematic review and meta analysis.”

METHODS:

PubMed, EMBASE, the Cochrane Library, and Web of Science databases were searched to retrieve studies that compared PBR with SBR after mastectomies. The outcomes were complications, oncological safety, patient-reported outcomes and postoperative pain.

RESULTS:

- 16 comparative studies
- **No statistical differences** in overall complications, implant loss, seroma, nipple or skin flap necrosis, hematoma, reoperation, wound dehiscence, and wound-skin infection, rippling between PBR and SBR.

PO / P1- versus P2-Methode: Komplikationen

Implant-ADM based breast reconstruction: “A tale of two techniques” and PROMs

BACKGROUND:

- Immediate Implant and ADM based breast reconstruction accounts for 37% of work load, following mastectomy in the UK and is emerging as a viable alternative to tissue based breast reconstructions.
- We present our outcomes of our prospective study in a busy teaching Hospital of *subpectoral* and *prepectoral* IBR with ADM.

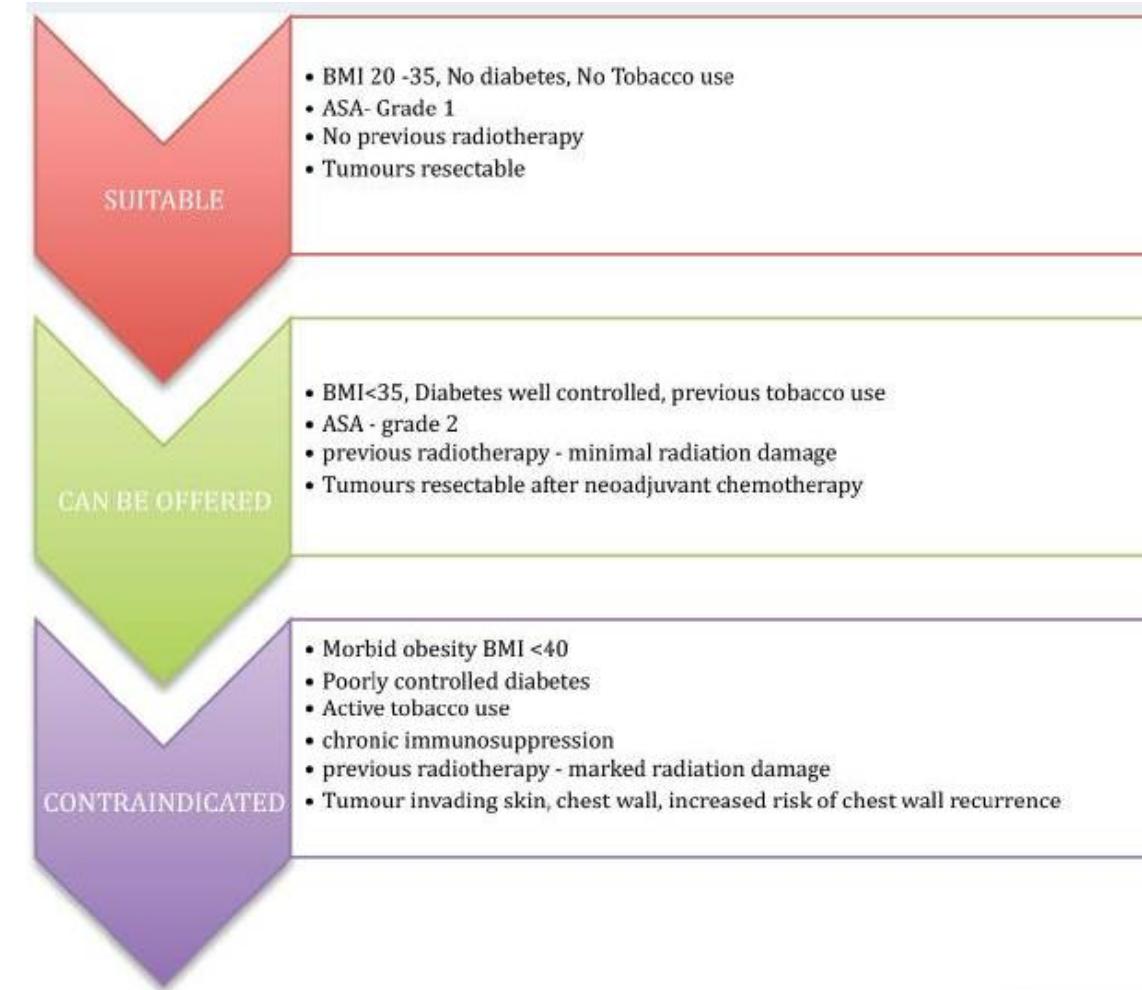
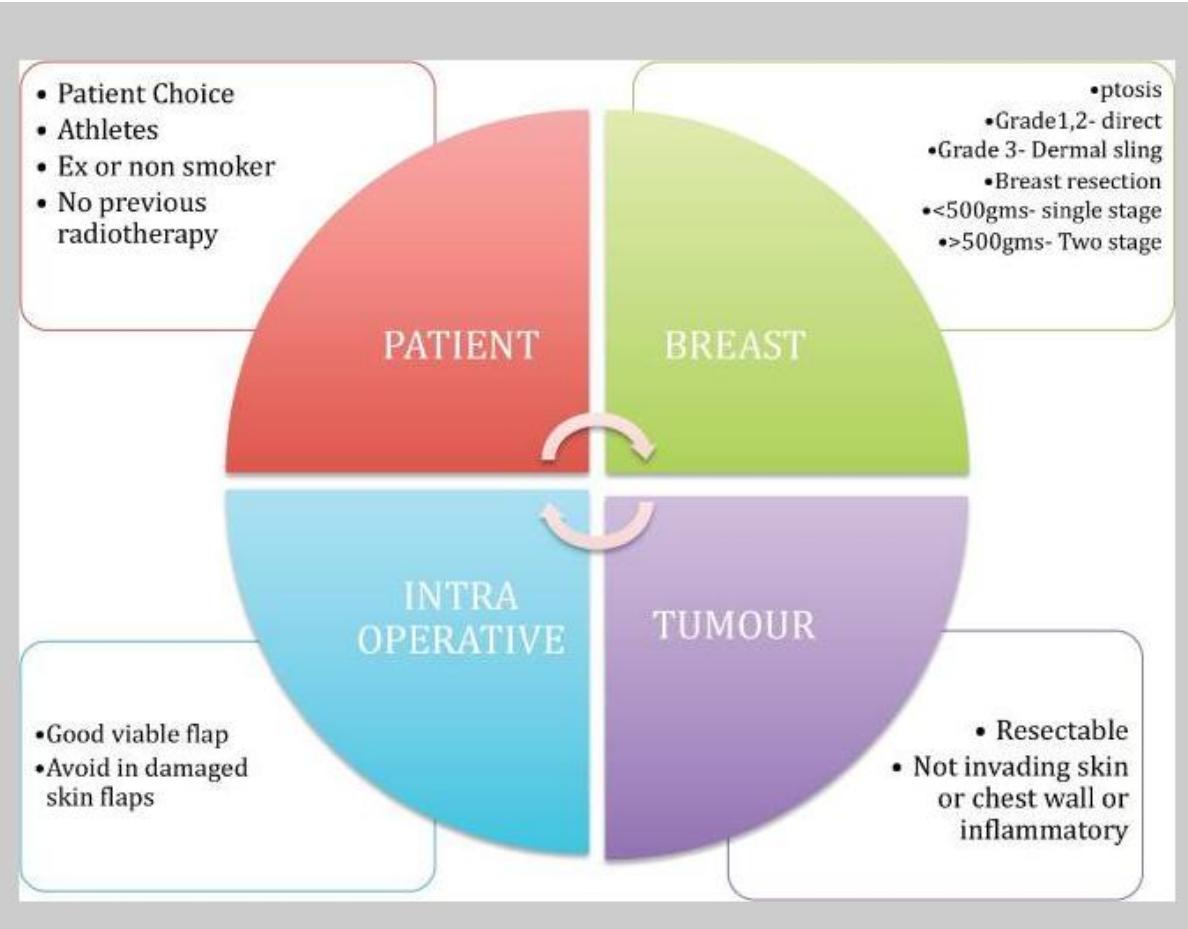
METHODS:

- Entire cohort of 255 patients
- 145 patients (57%) with Prepectoral breast reconstruction, 110 patients (43%) with Subpectoral breast reconstruction

RESULTS:

- The mean follow up period: 12 months
- The complications between the subgroups were similar and they were comparable to national standards.
- There were no delays to adjuvant treatment in any of our patients.

Prepectoral implant-based breast reconstruction: a joint consensus guide from UK, European and USA breast and plastic reconstructive surgeons



Aktuelle Vorgehensweisen

2. Zeitlicher Ablauf

➤ Sofortrekonstruktion, 1-Stage:

Sofortrekonstruktion mit einem endgültigen Implantat

➤ Verzögerte Sofortrekonstruktion, 2-Stage:

Sofortrekonstruktion mit einem Expander,
Wechsel auf ein endgültiges Implantat nach abgeschlossener
Wundheilung bzw. nach einer evtl. indizierten Radiatio



Pro und Contra:

Sofortrekonstruktion, 1-Stage

Pro:

- Nur ein Eingriff erforderlich
- Vermeidung der ambulanten Vorstellungen zur Expansion
- Vermeidung von Expander-Komplikationen bei langer Liegezeit im Falle erforderlicher adjuvanter Therapien

Contra:

- Erhöhte postoperative Komplikationsrate bei falscher Selektion der Patientinnen
- Lt. Studien fragl. erhöhte Kapselfibrose-Rate im Falle einer erforderlichen adjuvanten Radiotherapy

A Systematic Review and Head-to-Head Meta-Analysis of Outcomes following Direct-to-Implant versus Conventional Two-Stage Implant Reconstruction.

A literature search identified all articles published after 1999 involving prosthetic-based breast reconstruction as a two-stage tissue expander/implant or direct-to-implant technique. The primary outcomes of interest, including implant loss, capsular contracture, reoperation, and infection, were analyzed by means of head-to-head meta-analysis. Thirteen studies involving 5216 breast reconstructions were included.

RESULTS:

- Wound infection, seroma, and capsular contracture risk were similar between groups.
- Direct-to-implant reconstruction was associated with a higher risk for skin flap necrosis (OR, 1.43; $p = 0.01$; $I^2 = 51$ percent) and reoperation (OR, 1.25; $p = 0.04$; $I^2 = 43$ percent).
- The risk for implant loss was nearly two-fold higher with direct-to-implant reconstruction compared with tissue expander/implant reconstruction (OR, 1.87; $p = 0.04$; $I^2 = 33$ percent).

Direct-to-Implant versus Two-Stage Tissue Expander/Implant Reconstruction: 2-Year Risks and Patient-Reported Outcomes from a Prospective, Multicenter Study

Of 1427 patients, 99 underwent direct-to-implant reconstruction and 1328 underwent tissue expander/implant reconstruction

Complication Rates Overall and by Procedure Type at 2 Years Postoperatively

	Overall (%)	DTI (%)	TE (%)	p *
No.	1427	99	1328	
Complication				
Any complication	380 (26.6)	32 (32.3)	348 (26.2)	0.407
Major complication	279 (19.6)	25 (25.3)	254 (19.1)	0.365
Any infection	155 (10.9)	16 (16.2)	139 (10.5)	0.189
Major infection	85 (6)	10 (10.1)	75 (5.7)	0.138
Reconstructive failure	106 (7.4)	8 (8.1)	98 (7.4)	0.879

DTI, direct-to-implant; TE, tissue expander/implant.

* For the comparison of complication rate between procedure types, adjusting for sites (hospitals).

Sofortrekonstruktion durch Implantate:

**Unzureichende
Standardisierung der
verwendeten Materialien**



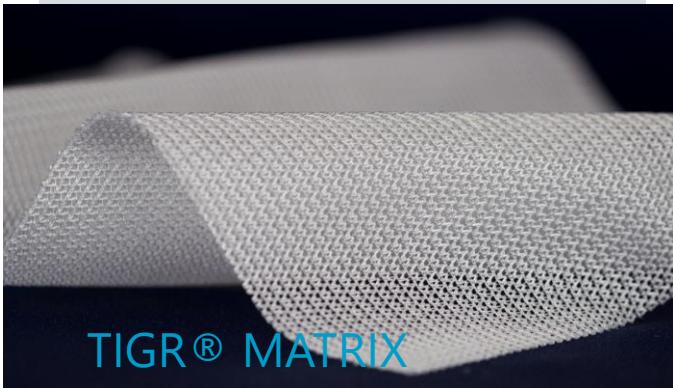
Materialien



μCT Epiflex



TiLOOP® Bra



TIGR® MATRIX



AlloDerm®



SERAGYN® BR



SurgiMend®

Certified Non Irritant
Rich in Type III Collagen
Foetal Bovine ADM



Meso BioMatrix®
Acellular Peritoneum Matrix

by DSM



TUTOMESH

Benefits and risks with acellular dermal matrix (ADM) and mesh support in immediate breast reconstruction: a systematic review and metaanalysis

Fifty-one studies were eligible and included in the review. The certainty of evidence for overall complication rate and implant loss is low. The certainty of evidence for delay of adjuvant treatment, implant loss, infection, capsular contraction and aesthetic outcome is very low. No study reported data on recurrence of cancer or health related quality of life. In conclusion, there is a lack of high quality studies that compare the use of matrix with no matrix in immediate breast reconstruction. Specifically, there are no data on risk of recurrence of cancer, delay of adjuvant treatment and Health related quality of life (HRQoL). In addition, there is a risk of bias in many studies. It is often unclear what complications have been included and how they have been diagnosed, and how and when capsular contracture and aesthetic outcome have been evaluated. Controlled trials that further analyse the impact of radiotherapy, type of matrix and type of procedure (one or two stages) are necessary.

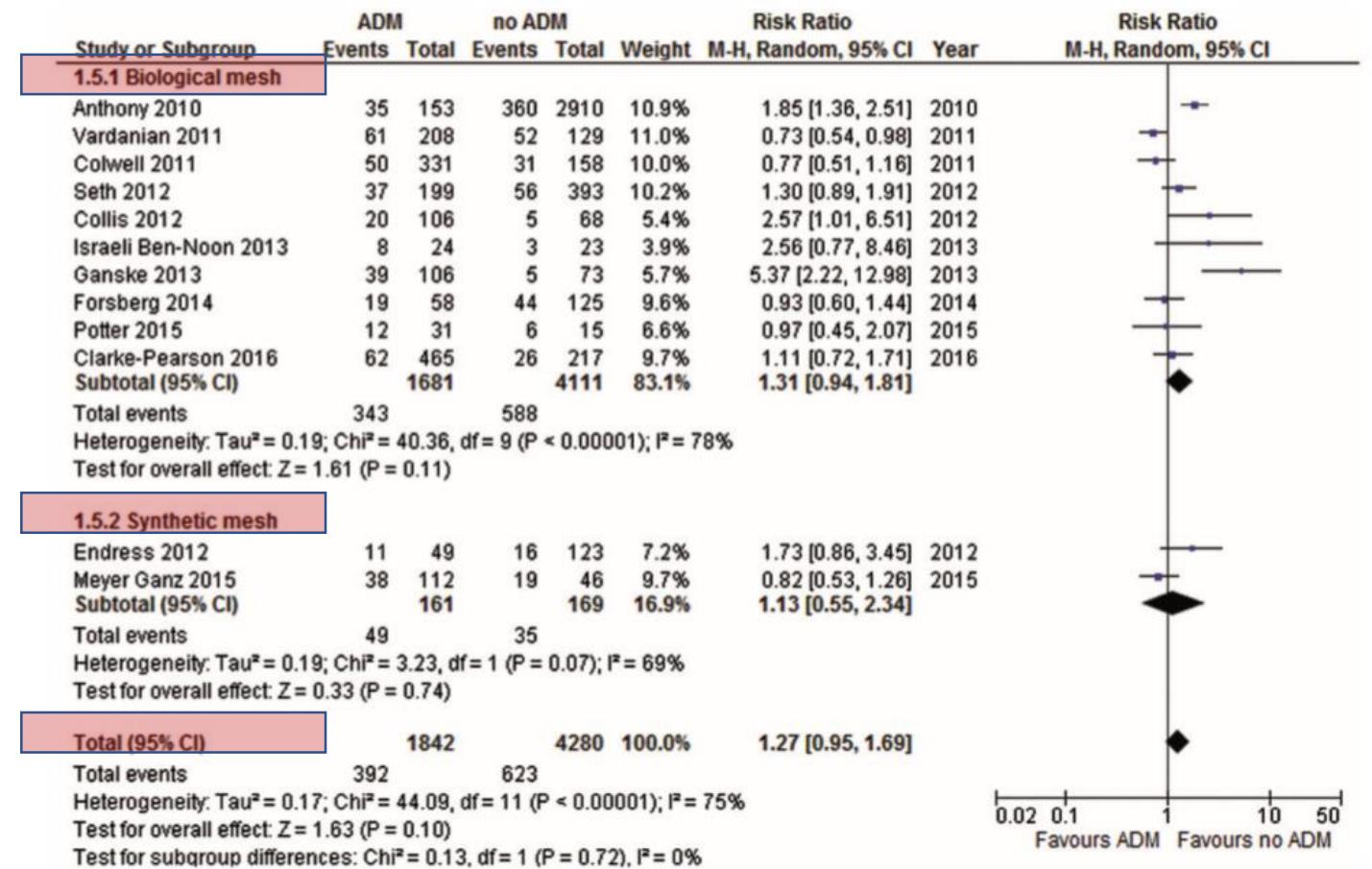
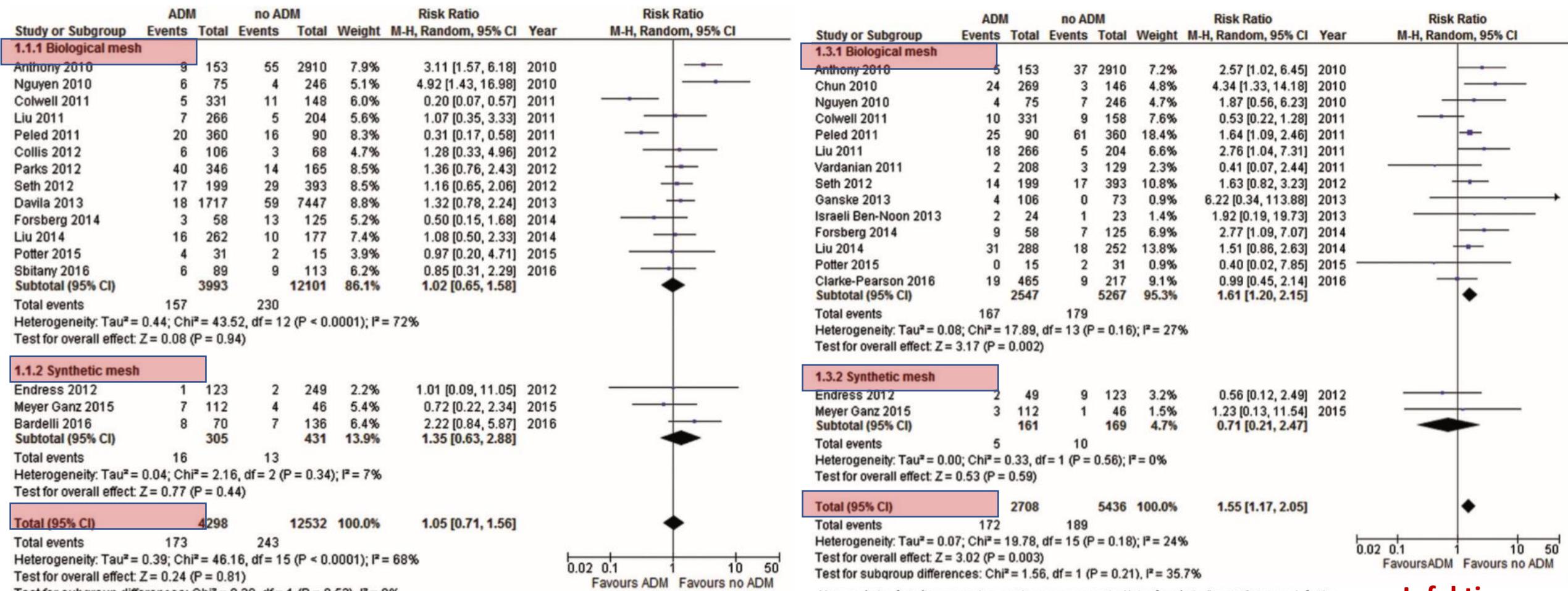


Figure 2. Meta-analysis of studies comparing matrix versus no matrix. Unit of analysis: Breast. Outcome: Complications.

Komplikationen

Benefits and risks with acellular dermal matrix (ADM) and mesh support in immediate breast reconstruction: a systematic review and metaanalysis



Meta-analysis of studies comparing matrix versus no matrix. Unit of analysis: Breast. Outcome: Infection.

Implantatverlust

Mesh versus acellular dermal matrix in immediate implant-based breast reconstruction – A prospective randomized trial

This prospective, randomized, controlled, multicenter pilot study was performed at four Austrian breast cancer centers. Fifty patients with oncologic or prophylactic indication for mastectomy and IBBR were randomized to immediate IBBR with either an ADM (Protexa[®]) or a titanized mesh (TiLOOP[®] Bra).

- Overall complication rate: 31.25% with similar rates in both groups (Protexa[®] group: 9 versus TiLOOP[®] Bra group: 6; $p = 0.188$).
- Higher incidence of severe complications leading to failed reconstructions with implant loss in the Protexa[®] group than in the TiLOOP[®] Bra group (7 versus 2; $p < 0.0001$).
- An inverted T-incision technique led to significantly more complications and reconstructive failure with Protexa[®] ($p = 0.037$, $p = 0.012$, respectively).



**Warum gibt es so viele
gerichtliche
Auseinandersetzungen
wegen fehlgeschlagener
Implantat-
Sofortrekonstruktionen?**

- ***Hohe Komplikationsrate***
- ***Nicht ausreichende
Aufklärung über die Risiken***

**Sofortrekonstruktion
durch Implantat:**

Frühe Komplikationsrate



iBRA - Studie

Potter et al. Pilot and Feasibility Studies (2016) 2:41
DOI 10.1186/s40814-016-0085-8

Pilot and Feasibility Studies

STUDY PROTOCOL

Open Access



The iBRA (implant breast reconstruction evaluation) study: protocol for a prospective multi-centre cohort study to inform the feasibility, design and conduct of a pragmatic randomised clinical trial comparing new techniques of implant-based breast reconstruction

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Abstract

Background: Implant-based breast reconstruction (IBBR) is the most commonly performed reconstructive procedure in the UK. The introduction of techniques to augment the subpectoral pocket has revolutionised the procedure, but there is a lack of high-quality outcome data to describe the safety or effectiveness of these techniques. Randomised controlled trials (RCTs) are the best way of comparing treatments, but surgical RCTs are challenging. The iBRA (implant breast reconstruction evaluation) study aims to determine the feasibility, design and conduct of a pragmatic RCT to examine the effectiveness of approaches to IBBR.

Methods/design: The iBRA study is a trainee-led research collaborative project with four phases:

- Phase 1 – a national practice questionnaire (NPQ) to survey current practice
- Phase 2 – a multi-centre prospective cohort study of patients undergoing IBBR to evaluate the clinical and patient-reported outcomes
- Phase 3 – an IBBR-RCT acceptability survey and qualitative work to explore patients' and surgeons' views of proposed trial designs and candidate outcomes.
- Phase 4 – phases 1 to 3 will inform the design and conduct of the future RCT

(Continued on next page)

iBRA - Studie

Ergebnisse Phase 1

Highlights

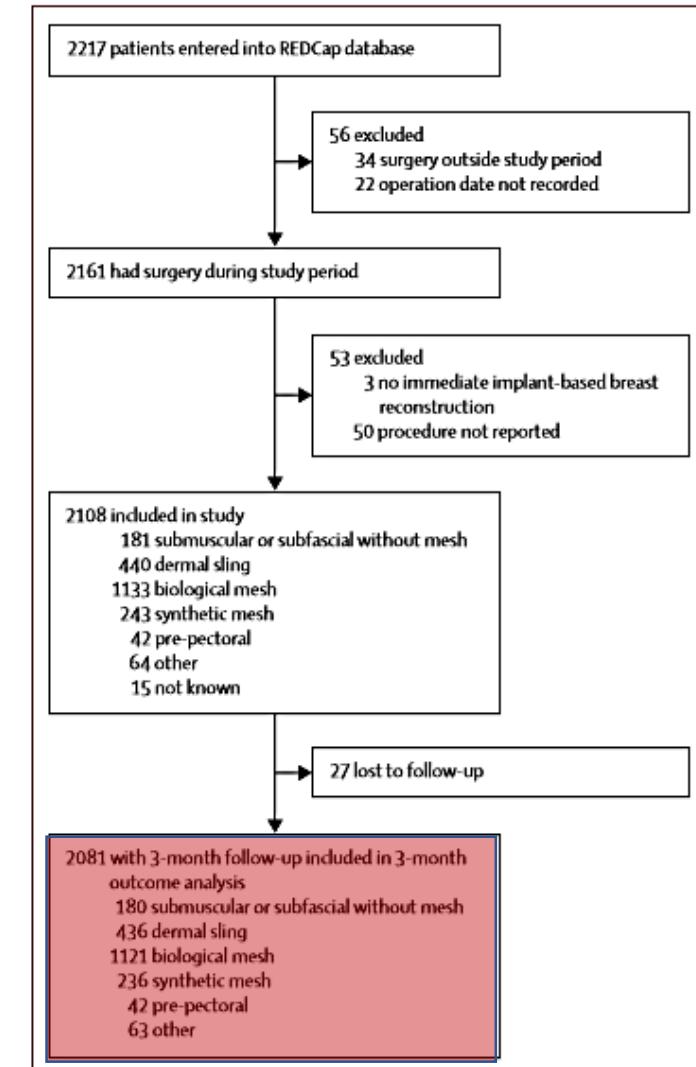
- Implant breast reconstruction (IBBR) and the range of techniques is poorly evidence based.
- We aimed to explore the current practice of IBBR in the UK to inform the design of a future definitive study.
- Significant variation was demonstrated in the availability of techniques and patient selection for IBBR.
- There is a need for well-designed studies to establish best practice and improve outcomes for patients considering IBBR.

Short-term safety outcomes of mastectomy and immediate implant-based breast reconstruction with and without mesh (iBRA, phase 2): a multicentre, prospective cohort study

In this **prospective, multicentre cohort study**, women aged 16 years or older who had any type of immediate implant-based breast reconstruction for malignancy or risk reduction, with any technique, at **81 participating breast and plastic surgical units in the UK** were consecutively recruited

Outcomes of interest up to 3 months after reconstruction:

- implant loss (defined as unplanned removal of the expander or implant)
- infection requiring treatment with antibiotics or surgery
- unplanned return to theatre
- unplanned re-admission to hospital for complications of reconstructive surgery



Short-term safety outcomes of mastectomy and immediate implant-based breast reconstruction with and without mesh (iBRA): a multicentre, prospective cohort study

	All patients in iBRA with 3-month follow-up (n=2081)	Submuscular or fascial (n=180)	Dermal sling (n=436)	Biological mesh (n=1121)	Synthetic mesh (n=236)	Pre-pectoral (n=42)	Other (n=63)	Not known (n=11)	NMBRA outcomes at 3 months	National Quality Criteria for Breast Reconstruction*
Reoperation	370; 18% (16–20)	30; 17% (12–23)	79; 18% (15–22)	193; 17% (15–20)	48; 20% (15–26)	9; 21% (10–37)	9; 14% (7–25)	2	5%	<5%
Re-admission	372; 18% (16–20)	31; 17% (12–24)	85; 19% (16–24)	185; 17% (14–19)	49; 21% (16–27)	10; 24% (12–40)	10; 16% (8–27)	2	16%	<5%
Infection	522; 25%, (23–27)	39; 22% (16–28)	138; 32% (27–36)	251; 22% (20–25)	61; 26% (20–32)	11; 26% (14–42)	19; 30% (19–43)	3	25%	<10%†
Implant loss	182; 9% (8–10)	17; 9% (6–15)	47; 11% (8–14)	90; 8% (7–10)	24; 10% (7–15)	3; 7% (2–20)	2; 3% (0–11)	1	9%	<5%

Data are n; % (95% CI), n, or %. NMBRA=National Mastectomy and Breast Reconstruction Audit. *Oncoplastic Breast Reconstruction—Guidelines for Best Practice. †Acellular dermal matrix-assisted breast reconstruction procedures: joint guidelines from the Association of Breast Surgery and the British Association of Plastic, Reconstructive and Aesthetic Surgeons. There were 2108 patients with implant-based reconstruction, of whom 2081 (99%) were included in the outcome analysis: complete outcome data (event data for all four key outcomes) are available for 2078 patients , who have been included in the analysis 27 (1%) patients have no outcome data and were excluded from the analysis. Partial outcome data (event data for three of four outcomes) are available for three patients, who were included in the analysis and who were assumed to not have had the event for the fourth missing outcome.

Table 4: 3-month outcomes after implant-based breast reconstruction, by procedure type, compared with outcomes in NMBRA and UK National Quality Criteria for Breast Reconstruction

BACKGROUND

Immediate implant reconstruction after a skin sparing or a nipple sparing mastectomy is an attractive option made easier by the use of mesh to cover the lower implant pole. A titanium-coated polypropylene mesh (TCPM) is an alternative to acellular dermal matrices but only few clinical data have been published.

Demographic and clinical characteristics of patients

Age [years, med (range)]	52.4 (25,1-84)
BMI [kg/m ² , med (range)]	23,2 (16,5 – 56,4)
- BMI ≤ 25 [n,(%)]	178 (69,3%)
- BMI > 25 [n,(%)]	79 (30,7%)
Smokers [n,(%)]	64 (24,8%)
Previous radiotherapy [n,(%)]	69 (21,6%)
Neoadjuvant treatment [n,(%)]	
- chemootherapy	12 (3,7%)
- chemotherapy + radiotherapy	2 (0,6%)

Baseline characteristics of the surgeries

Prophylactic mastectomy [n,(%)]	112 (34,9%)
Curative mastectomy [n,(%)]	
- first treatment	161 (50,2%)
- local relapse with previous radiotherapy	44 (13,7%)
- local relapse without previous radiotherapy.	4 (1,2%)
Skin Incision [n,(%)]	
- small elliptical (patey incision)	204 (63,6%)
- external radial incision	70 (21,8%)
- periareolar	7 (2,2%)
- skin reducing mastectomy (+ LCDI*)	28 (8,7%)
- infra mammary fold	12 (3,7%)
Nipple sparing mastectomy [n,(%)]	89 (27,7%)
Cutaneous abdominal flap [n,(%)]	56 (17,4%)
Drainage duration [day, med (range)]	10 (2-27)

OBJECTIVE

In this retrospective single-institution series we report short term outcomes and surgical complications in patients with skin sparing or nipple sparing mastectomy and immediate implant reconstruction using TCPM (TiLoop® Bra).

The overall complication rate was 33,6%

Only 8 patients had a delay to their adjuvant treatment.

Surgical complications

Delayed wound healing [n,(%)]	62 (19,3%)
Skin ischemia / necrosis [n,(%)]	11 (3,4%)
Nipple areola complex necrosis [n,(%)]	11 (3,4%)
Infection [n,(%)]	31 (9,7%)
- conservative treatment (antibiotherapy only)	13 (4%)
- implant removal	14 (4.4%)
- implant replacement by expander	4 (1.2%)
Infection + delayed wound healing [n,(%)]	16 (5%)
- implant removal	8 (2.5%)
- implant replacement by expander	3 (0.9%)
Hematoma [n,(%)]	15 (4,7%)
Seroma [n,(%)]	19 (5,9%)
Major complication [n,(%)]	27 (8,5%)
- implant removal	22 (6,8%)
- Implant replacement by expander	5 (1,6%)

- 50% of infection were associated with delayed wound healing
- 61% of implant removal or replacement for infection had also delayed wound healing

Prepectoral direct to implant reconstruction following nipple sparing mastectomy using the TiLOOP® Bra Pocket

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Material and methods

Between October 2017 and February 2019, 57 patients underwent nipple sparing mastectomy in the certified breast cancer centre, at the AGAPLESION Markus Hospital, Frankfurt, Germany. Data was collected in a prospective registry. All of the patients underwent a prepectoral direct to implant reconstruction using the new TiLOOP® Bra Pocket, that exists in three different sizes. We present the first analysis of this prospective unicentric registry. To measure and to analyse the cosmetic outcome and patients' satisfaction, the BREAST-Q questionnaire was used, an established modular questionnaire to assess patient reported outcome (PRO).

Results

All of the 72 patients were available for postoperative analysis. In 41/72 (56%) of the cases a seroma occurred and was worth to be punctured. The median number of punctures was 4 (average volume: 70 ml). Drain was removed after 10 days. 7/72 had a postoperative hematoma and had to undergo another surgical procedure. 3/72 developed a skin necrosis or severe wound healing problem due to bad quality of the soft tissue and skin mantle and had to undergo implant explantation. 1/72 suffered from implant infection but could be treated conservatively. The analysis of patients' reported outcome via the BREAST-Q resulted in a high satisfaction rate regarding the cosmetic outcome.

10%

4%

14%

Ergebnisse Sofortrekonstruktion

Hohenlind 1-2018 / 10-2019

Retrospektive Analyse von 88 Patientinnen bzw. 100 Sofortrekonstruktionen

Primäre Operationen

61 (61%)

Sekundäre Operationen

39 (39%)

Epipectoral

72 (72%)

Retropectoral

18 (18%)

ADM

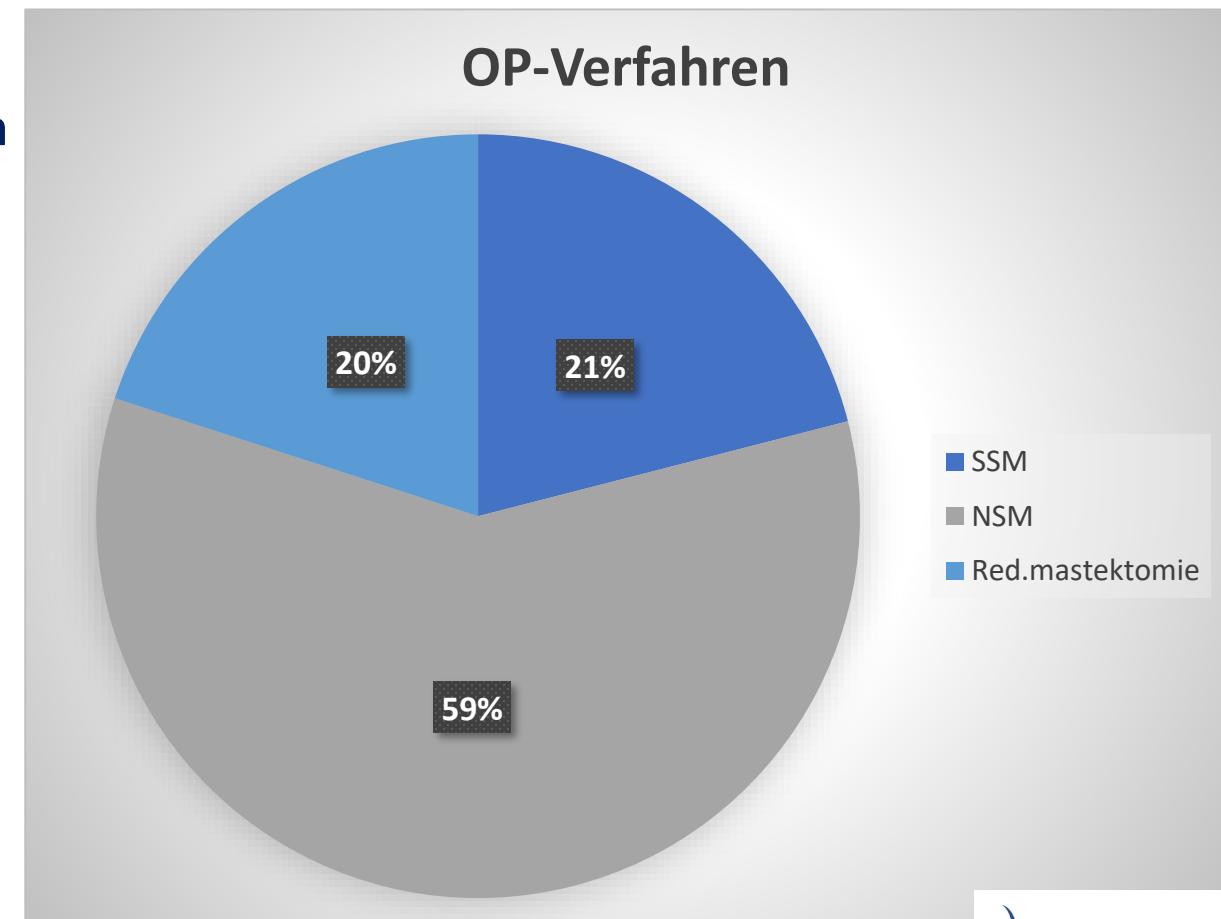
55 (55%)

Titannetz

17 (17%)

Kein Mesh

28 (28%)



Ergebnisse Sofortrekonstruktion

Hohenlind 1-2018 / 10-2019

Komplikationsrate 28%

Implantatverlust	7 (7%) in 6 Fällen durch eine allschichtige Nekrose mit Sekundärinfekt
Nekrose	9 (9%)
Infektion	12 (12%)
Serom	12 (12%)

Sofortrekonstruktion durch Implantat:

Risikofaktoren



Short-term safety outcomes of mastectomy and immediate implant-based breast reconstruction with and without mesh (iBRA): a multicentre, prospective cohort study

	Implant loss (n=1722)	Infection (n=1722)	Re-admission (n=1722)	Reoperation (n=1722)
Age, years*	1.00 (0.98-1.02); p=0.87	1.01 (1.00-1.02); p=0.27	1.00 (0.99-1.01); p=0.77	0.99 (0.98-1.01); p=0.35
Body-mass index (kg/m ²)†	1.07 (1.03-1.11); p=0.0002	1.07 (1.04-1.10); p<0.0001	1.05 (1.03-1.08); p=0.0001	1.04 (1.01-1.07); p=0.0032
Operative time, min	1.00 (1.00-1.01); p=0.049	1.00 (1.00-1.00); p=0.073	1.00 (1.00-1.00); p=0.049	1.00 (1.00-1.01); p=0.013
Smoking				
No	1 (ref)	1 (ref)	1 (ref)	1 (ref)
Yes	1.92 (1.19-3.09); p=0.0074	1.53 (1.09-2.17); p=0.015	1.92 (1.33-2.77); p=0.0005	1.87 (1.30-2.70); p=0.0008
Previous radiotherapy to ipsilateral breast				
No	1 (ref)	1 (ref)	1 (ref)	1 (ref)
Yes	1.35 (0.70-2.60); p=0.37	1.72 (1.12-2.62); p=0.013	1.15 (0.69-1.91); p=0.59	1.24 (0.75-2.03); p=0.41
Neoadjuvant chemotherapy				
No	1 (ref)	1 (ref)	1 (ref)	1 (ref)
Yes	0.64 (0.33-1.21); p=0.17	0.72 (0.48-1.08); p=0.11	0.82 (0.53-1.28); p=0.38	0.73 (0.47-1.15); p=0.18
Bilateral surgery				
No	1 (ref)	1 (ref)	1 (ref)	1 (ref)
Yes	1.72 (0.85-3.47); p=0.13	1.27 (0.81-1.97); p=0.30	1.24 (0.76-2.03); p=0.39	1.15 (0.70-1.90); p=0.58
Nipple-sparing mastectomy				
No	1 (ref)	1 (ref)	1 (ref)	1 (ref)
Yes	1.24 (0.80-1.92); p=0.33	1.09 (0.82-1.46); p=0.55	1.04 (0.75-1.44); p=0.81	1.20 (0.88-1.64); p=0.25
Risk-reducing surgery				
No	1 (ref)	1 (ref)	1 (ref)	1 (ref)
Yes	0.87 (0.37-2.06); p=0.75	0.87 (0.48-1.56); p=0.64	1.13 (0.59-2.14); p=0.71	1.28 (0.68-2.41); p=0.45

Table 5: Logistic regression of risk factors for key outcomes

Short-term safety outcomes of mastectomy and immediate implant-based breast reconstruction with and without mesh (iBRA): a multicentre, prospective cohort study

	Implant loss (n=1722)	Infection (n=1722)	Re-admission (n=1722)	Reoperation (n=1722)
Therapeutic mastectomy				
No	1 (ref)	1 (ref)	1 (ref)	1 (ref)
Yes	1.36 (0.69-2.69); p=0.38	0.80 (0.49-1.29); p=0.36	0.92 (0.55-1.54); p=0.74	1.11 (0.67-1.84); p=0.68
Fixed-volume implant				
No	1 (ref)	1 (ref)	1 (ref)	1 (ref)
Yes	0.87 (0.60-1.26); p=0.46	0.92 (0.72-1.16); p=0.46	0.86 (0.66-1.13); p=0.27	0.90 (0.69-1.18); p=0.45
Type of IBBR				
Biological mesh	1 (ref)	1 (ref)	1 (ref)	1 (ref)
Dermal sling	0.85 (0.52-1.38); p=0.50	1.21 (0.89-1.64); p=0.22	0.91 (0.64-1.30); p=0.60	0.85 (0.59-1.22); p=0.38
Other	0.17 (0.02-1.25); p=0.082	1.34 (0.73-2.46); p=0.34	0.82 (0.39-1.74); p=0.60	0.80 (0.38-1.70); p=0.56
Pre-pectoral	0.91 (0.20-4.04); p=0.90	1.02 (0.39-2.66); p=0.96	1.92 (0.76-4.82); p=0.17	1.37 (0.52-3.60); p=0.52
Submuscular or fascial	1.06 (0.55-2.08); p=0.86	0.89 (0.56-1.41); p=0.63	1.03 (0.63-1.70); p=0.90	1.00 (0.61-1.63); p=0.98
Synthetic mesh	1.12 (0.66-1.90); p=0.68	1.13 (0.79-1.61); p=0.50	1.20 (0.81-1.78); p=0.37	1.09 (0.74-1.62); p=0.66
Data are odds ratio (95% CI); p value. IBBR=immediate implant-based breast reconstruction. *Increase in odds for each additional year. †Increase in odds for each additional body-mass index unit.				
Table 5: Logistic regression of risk factors for key outcomes				

RESULTS

The overall complication rate was 33,6%

Only 8 patients had a delay to their adjuvant treatment.

Univariate analysis :

- **Risk factor for major complication** : smoking, high breast weight and implant infection occurrences.
- **Risk factor for any surgical complication** : smoking, high breast and implant weight.
- **Risk factor for implant infection** : smoking, high breast and implant weight and drainage duration.
- **Risk factor for delayed wound healing** : skin reducing mastectomy and periareolar incision, smoking, high breast and implant weight.
Realization of a CAF* was a protective factor.

Multivariable analysis

- **Risk factor for surgical complication** : smoking, high breast weight and skin reducing mastectomy.
- **Risk factor for major complication** : smoking, implant infection, high breast weight and previous radiotherapy but skin reducing mastectomy and external radial incision were protective factors.

Ergebnisse Sofortrekonstruktion

Hohenlind 1-2018 / 10-2019

N=100	Keine Komplikation n=72 (72%)	Komplikation n=28 (28%)	Implantatverlust n=7 (7%)	Nekrose n=9 (9%)	Infektion n=12 (12%)	Serom 12 (12%)
Mittleres Alter	40,5 Jahre	44,6 Jahre	56 Jahre	48 Jahre	52 Jahre	43 Jahre
Primäreingriff Sekundäreingriff	48 (79%) 24 (61%)	13 (21%) 15 (39%)	4 (7%) 3 (8%)	2 (3%) 7 (18%)	7 (12%) 5 (13%)	9 (15%) 3 (7%)
Implantatlager: epipectoral retropectoral	47 (65%) 15 (83%)	25 (35%) 3 (17%)	5 (7%) 2 (11%)	7 (10%) 2 (11%)	10 (14%) 2 (11%)	11 (15%) 1 (6%)
OP-Verfahren: Red.mastektomie NSM SSM	11 (55%) 43 (73%) 18 (86%)	9 (45%) 16 (27%) 3 (14%)	3 (15%) 3 (5%) 1 (5%)	6 (30%) 3 (5%) 0 (0%)	4 (20%) 6 (10%) 2 (10%)	3 (15%) 8 (14%) 1 (5%)
Netz: ADM Titannetz kein Netz	38 (70%) 13 (76%) 21 (75%)	17 (30%) 4 (24%) 7 (25%)	3 (5%) 1 (6%) 3 (11%)	4 (7%) 2 (12%) 3 (11%)	8 (14%) 3 (18%) 1 (4%)	7 (13%) 2 (6%) 3 (11%)
Aktives Rauchen	6 (55%)	5 (45%)	3 (27%)	4 (36%)	1 (9%)	0 (0%)
Adipositas	11 (42%)	15 (58%)	3 (11,5%)	3 (11,5%)	6 (23%)	9 (35%)
Z. n. Radiatio	3 (43%)	4 (57%)	3 (43%)	2 (29%)	1 (14%)	0 (0%)
Z. n. neoadjuvanter Chemo	12 (75%)	4 (25%)	0 (0%)	2 (12%)	2 (12%)	5 (29%)
Drüsenkörpergewicht	226 g	493 g	511 g	473 g	441 g	461 g

Ergebnisse Sofortrekonstruktion

Hohenlind 1-2018 / 10-2019

	N	Sek. Eingriff	Rauchen	Red.mast.	Z. n. Radiatio	Z.n. NACT	Kein RF
Kompl. insges.	28	15 (54%)	5 (18%)	9 (32%)	4 (14%)	4 (14%)	4 (14%)
Implantat-verlust	7	3 (43%)	3 (43%)	3 (43%)	3 (43%)	0 (0%)	0 (0%)
Nekrose	9	7 (78%)	4 (44%)	6 (67%)	2 (22%)	2 (22%)	0 (0%)
Infektion	12	5 (42%)	1 (8%)	4 (33%)	1 (8%)	2 (16%)	1 (8%)
Serom	12	3 (25%)	0 (0%)	3 (25%)	0 (0%)	5 (41%)	3 (25%)

Bei Ausschluss der Raucherinnen, der Patientinnen mit Z.n. Radiatio und Vermeidung der Red.mast.:

Komplikationsrate insges.	6/46 (13%)
Implantatverlust	0/46 (0%)
Nekroserate	0/46 (0%)
Infektrate	2/46 (4,3%)

Bei Ausschluss der Raucherinnen und der Patientinnen mit Z. n. Radiatio:

Komplikationsrate insges.	19/73 (26,0%)
Implantatverlust	2/73 (2,8%)
Nekroserate	4/73 (5,6%)
Infektrate	78/73 (11,0%)

Zusammenfassung



Zusammenfassung

- Die hautsparende Mastektomie beinhaltet ein hohes Komplikationsrisiko.
- Eine Verringerung der Komplikationsrate scheint nur durch eine strenge Selektion der Patientinnen möglich.
- Insbesondere bei Vorliegen von Risikofaktoren ist die detaillierte Aufklärung (informed consent) der Patientinnen über das individuelle Risiko unerlässlich.
- Es werden dringend prospektive randomisierte Studien benötigt zur Standardisierung des operativen Vorgehens.

13. Brustkrebs Kongress 2020

Köln und Niederrhein

18. Januar 2020



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