

# Breast reconstruction de novo by water-jet assisted autologous fat grafting – a retrospective study

## Totale Brustrekonstruktion durch Wasserstrahl-assistierten autologen Eigenfettgewebettransfer – eine retrospektive Studie

### Abstract

**Background:** Autologous fat grafting has become a frequent, simple, reproducible and low-risk technique for revisional or partial breast reconstruction. The presented European multicenter study describes an optimized treatment and follow-up protocol for the de novo breast reconstruction after total mastectomy by lipotransfer alone.

**Methods:** A retrospective European multicenter trial included 135 procedures on 28 (35 breasts) postmastectomy patients (mean 52.4 years). All women were treated with the water-jet assisted fat grafting method (BEAULI™) combined with additional procedures (NAC reconstruction, contralateral mastopasty) and evaluated with at least 6 months follow-up (mean 2.6 years). Sonography or mammography, clinical examination, patient questionnaire (10-point Likert scale) and digital photographs were carried out.

**Results:** On average the patients received 4 to 6 procedures each with a single volume of 159 ml ( $\pm 61$  ml) over 21 months (range 9 months to 2.5 years). In total 1,020 ml ( $\pm 515$  ml) fat were grafted till a complete breast reconstruction was achieved. Irradiated patients needed a significantly higher volume than non-irradiated ( $p < 0.041$ ). Main treatment complications were liponecrosis (2.59%), infection (0.74%) and granuloma (0.74%). Patient satisfaction was overall high to very high (96%) and confirmed the good aesthetic results (68%) and the natural softness, contour and shape of the reconstructed breast.

**Conclusions:** A complete breast reconstruction with large volume fat grafting is alternatively possible to standard techniques in selected cases. It takes at least 4 to 6 lipotransfers in the course of 2 years. Patients with prior radiotherapy may require even up to 8 sessions over nearly 3 years of treatment.

**Keywords:** autologous fat grafting, lipotransfer, breast reconstruction, mastectomy

### Zusammenfassung

**Hintergrund:** Heutzutage wird der autologe Eigenfettgewebettransfer in der rekonstruktiven Brustchirurgie als eine risikoarme und einfach anwendbare Methode angesehen und derweilen routiniert für Zweiteingriffe oder Teilaufbauten verwendet. Bisher sind nur wenige Patientenfälle mit einem kompletten Brustaufbau nach totaler Mastektomie beschrieben worden.

**Material und Methoden:** Im Rahmen einer europaweiten Multicenterstudie erhielten insgesamt 28 Patientinnen einen kompletten Brustaufbau nach uni- oder bilateraler Ablatio mammae. Jener wurde ausschließlich mittels Wasserstrahl-assistierter BEAULI™-Methode vollzogen, wobei man diese individuell mit gängigen Verfahren wie einer MAK-Rekonstruktion oder einer kontralateralen Reduktionsplastik kombinierte. Zur Auswertung fand die klinische und radiologische Nachuntersuchung (Ultraschall oder Mammographie) nach abgeschlossener Behandlung

Delia Letizia Hoppe<sup>1</sup>

Klaus Ueberreiter<sup>2</sup>

Yves Surlemont<sup>3</sup>

Hilkka Peltoniemi<sup>4</sup>

Marco Stabile<sup>5</sup>

Susanna Kauhanen<sup>6</sup>

1 BG Unfallklinik Tübingen, Klinik für Hand-, Plastische, Rekonstruktive und Verbrennungschirurgie, Tübingen, Germany

2 Parkklinik Birkenwerder, Birkenwerder, Germany

3 Clinique Saint Antoine, Rouen University Hospital, Paediatric and Dermatologic Plastic Surgery, Bois Guillaume, France

4 Plastic Surgery Hospital KL, Helsinki, Finland

5 Azienda Sanitaria di Piacenza, Cremona, Italy

6 Helsinki University Hospital, Department of Plastic and Reconstructive Surgery, Helsinki, Finland

und mindestens 6 Monaten (durchschnittlich 2,6 Jahren) Verlaufszeit statt. Zusätzlich wurde anhand digitaler Fotoaufnahmen und Fragebögen (10-Punkte-Likert-Skala) das ästhetische Endergebnis bewertet und die Patientenzufriedenheit ermittelt.

**Ergebnis:** Im Durchschnitt wurden 4 bis 6 Einzelsitzungen mit jeweils 159 ml ( $\pm 61$  ml) über einen Zeitraum von 21 Monaten (9 Monate bis max. 2,5 Jahre) durchgeführt, um durch ein Endvolumen von 1.020 ml ( $\pm 515$  ml) einen kompletten Brustaufbau zu erreichen. Hierbei wiesen Patientinnen nach adjuvanter Radiatio eine signifikant höhere Eingriffsrate und Volumenbedarf auf ( $p < 0,041$ ). Als postoperative Komplikationen traten Infektionen (0,74%), Granulome (0,74%) oder Fettnekrose (2,59%) auf. Es konnte eine hohe Patientenzufriedenheit (95,42%) mit guten bis sehr gutem ästhetischem Ergebnis (67,68%) festgestellt werden.

**Schlussfolgerungen:** Der autologe Eigenfettgewebettransfer kann zu einem kompletten Brustaufbau nach Ablatio mammae in ausgewählten Fällen eingesetzt werden, wobei durchschnittlich 4 bis 6 Lipotransfers in einem Zeitraum von ca. 2 Jahren vorgesehen sind. Nach adjuvanter Radiotherapie können bis zu 8 Sitzungen im Verlauf von bis zu 3 Jahren notwendig sein. Die vorliegenden Ergebnisse führten in den entsprechenden Schwerpunktzentren zur Entwicklung optimierter Behandlungsstandards von Brustkrebspatientinnen.

**Schlüsselwörter:** autologer Eigenfettgewebettransfer, Lipofilling, rekonstruktive Brustchirurgie, Mastektomie

## Introduction

According to the American Cancer Society the incidence of breast cancer constantly increased during the last decades. In 2011 an estimated 230,480 new cases of invasive breast cancer are diagnosed in the U.S. [1]. Similar results were found 1995 to 2006 on European women in their 20s and 30s [39]. Hence younger patients contribute to an upward trend in breast reconstruction [5], [9], [11], [13], [30], [68].

The first report about lipotransfer in female breasts was already published by Holländer in 1910 [24]. Gradually autologous fat grafting has become a frequent, simply reproducible and low-risk technique in revisional or partial reconstruction of the breast [8], [12], [17], [27]. In order to meet the increasing demand and to ensure patient safety different societies of Plastic Surgery formed special Fat Graft Task Forces [6], [20], [51], [58]. The potential risk of free fat tissue transfer to the breast in oncologic patients remains to be discussed [29], [37], [45], [62], [70], [71], but one must clearly distinguish between the situation where there is breast parenchyma left and the situation, such as in our patients, where the whole gland has been removed. Although lipotransfer has become very popular, only a limited number of case series about autologous fat grafting for complete breast reconstruction has been reported up to date [3], [28], [46]. The presented European multicenter study describes an optimized treatment and follow-up protocol for the de novo breast reconstruction after total mastectomy by lipotransfer alone.

## Patients and methods

A retrospective study on complete breast reconstruction in post-mastectomy patients by autologous fat grafting was performed in four European centers in Germany, Finland and France between July 2008 and February 2012. Patient demographics, comorbidities, type of breast cancer with corresponding primary therapy, individual lipotransfer procedures and complications are listed in Table 1. We included 28 non-smoking women (mean age 52.4 years), after total mastectomy, failed implant reconstruction ( $n=1$ ) or single stage expander application ( $n=5$ ). Exclusion criteria were diabetes mellitus, obesity ( $\text{BMI } 30 \text{ kg/m}^2$ ), prior flap-based reconstruction and implants in situ. Also excluded were patients who received subcutaneous mastectomy or breast conserving therapy. Weight changes exceeding 5 kg during our treatment also led to exclusion of the study. Mean follow-up time was 2.6 years (range 6 months to 3.7 years). Cancer follow-up was carried out in an unchanged manner. Preoperative clinical and radiological (mammography or sonography) assessments were done to exclude recurrent disease. During follow-up adverse palpation findings or pain in the reconstructed breast were addressed by magnetic resonance imaging (MRI) and/or ultra sound (US) examinations and core needle biopsy (CNB) when needed. Aesthetic evaluation was performed using digital pre- and postoperative photographs. They were reviewed and scored on a 5-point scale by two independent, blinded board-eligible plastic surgeons. Patient satisfaction was detected by a questionnaire with a 10-point Likert scale [35]. Continuous

**Table 1: Demographics, comorbidities, treatment and impact (BMI, Body Mass Index; SD, standard deviation)**

	No.	(%)	SD
<b>Demographics</b>			
Included patients	28	(100)	
Median age (years)	52.5		± 9.3
Median weight (kg)	69		± 10.2
Median BMI (cm <sup>2</sup> /kg)	24.1		± 4.4
Included breasts	33		
unilateral	23	(82.1)	
bilateral	5	(17.9)	
<b>Comorbidities</b>			
Irradiation	16	(57.1)	
Chemotherapy	20	(71.4)	
Prosthesis	5	(17.8)	
Expander	3	(10.7)	
Combined (expander plus prosthesis)	2	(7.1)	
<b>Treatment</b>			
Reconstructive sessions per patient	4.15		± 1.56
Additional touch-ups	12	(42.8)	
Total netto volume (ml) in clinical trial	21,449		
Average volume per patient (ml)	1,020.3		± 515.2
Average volume per procedure (ml)	158.9		± 60.6
<b>Impact of PMRT</b>			
Number of PMRT patients	16	(57.1)	
Number of non-irradiated patients	12	(42.8)	
<b>PMRT</b>			
– total volume grafted (ml)	13,430		
– number of procedures	80		
– average volume per procedure (ml)	167.875		± 51.09
– average procedures per patient	5		
– average volume per patient (ml)	833.8		
<b>Non-irradiated</b>			
– total volume grafted (ml)	8,019		
– number of procedures	55		
– average volume per procedure (ml)	145.8		± 48.98
– average procedures per patient	4.5		
– average volume per patient (ml)	668.3		
Compared PMRT volumes per procedure in irradiated to non-irradiated patients	p>0.0409; α=0.05		

data were described with average median, minimum and maximum, and categorical data with absolute and relative frequencies. Statistical analyses were performed by the software package Office (Microsoft Corporation, Redmond, WA, USA).

Autologous fat grafting was performed by one senior surgeon in each center according to the standardized protocol of the BEAULI™ method [65] (see also [21], [22], [64]). The abdomen, waist, back, thighs and upper arms served as donor sites. The BEAULI™ method is characterized by harvesting of small vital fat cell clusters by water-jet assisted liposuction (body-jet®). Constant irrigation in combination with a standard gentle suction pressure of 0.5 bar ensures a lipoaspirate of high quality without physical input from the surgeon's side. Continuous, simultaneous filtering and washing takes place in a sterile closed system (LipoCollector™). The fat is thereafter extracted into 50 cm<sup>3</sup> syringes, and *decanting* takes place for 5–10 min. For immediate reinjection, excess fluid is removed from the base of the 50 cm<sup>3</sup> syringe and the fat

transferred into smaller syringes (10 cm<sup>3</sup>). No centrifugation is done. The BEAULI™ injection cannula is inserted through 1–3 tiny stab incisions (≤2 mm) to the breast area. The total fat volume grafted per procedure differed individually between 50 ml and 360 ml. In 12 patients (43%) operative reconstruction of the nipple areola complex (NAC) or contralateral mastoplasty were combined with the large volume fat transfer in order to regain symmetry. Two patients suffered from excessive disturbing skin and subcutaneous fat in the axillary region. This excess fold was turned into a lateral fasciocutaneous flap and used to redefine the submammary fold in these two patients. The trial was designed and performed according to the Declaration of Helsinki. All patients treated were offered a full range of breast reconstruction methods but all chose explicitly the lipofilling method. Written informed consent about the risks (i.e. tumor induction), potential complications and the experimental character of the method were signed by all parties.

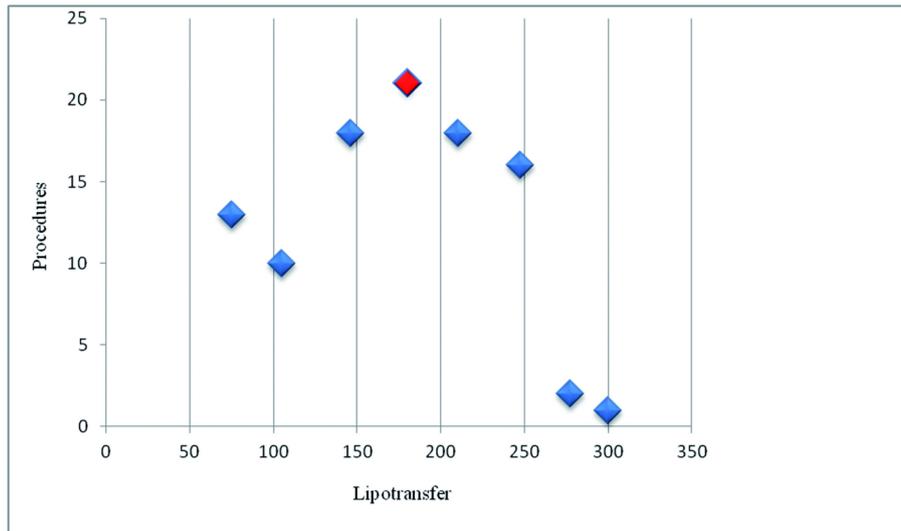


Figure 1: Numbers of procedures with median volumes (ml) grafted

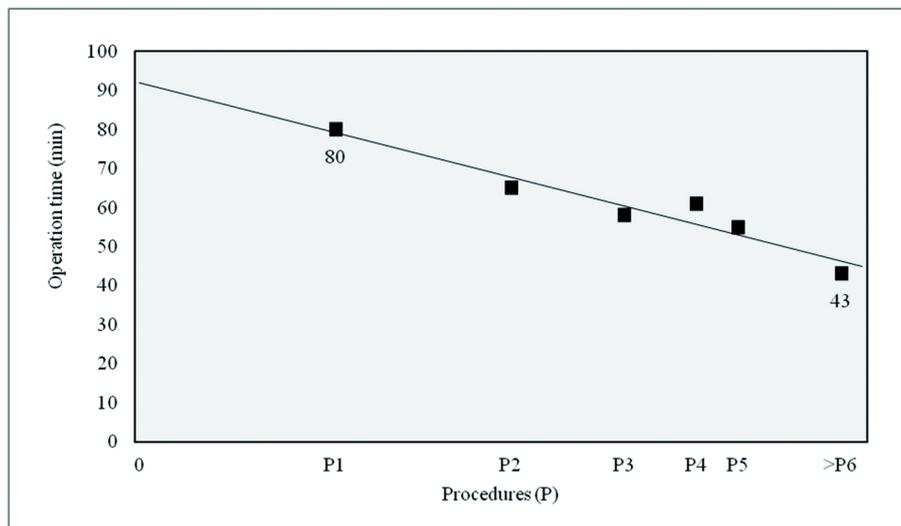


Figure 2: Median operation time (min) per procedure (P1–P10)

## Results

Inclusion criteria of this study were fulfilled in 28 registered postmastectomy cases (WHO database ID: DRKS00004234 <http://apps.who.int/trialsearch/Trial.aspx?TrialID=DRKS00004234>). Five cases were bilateral, amounting to 33 reconstructed breasts by altogether 135 large volume fat grafting procedures. Sixteen patients (58%) had previously received post-mastectomy radiotherapy (PMRT) and 20 patients (71%) chemotherapy. Twenty-three patients had turned down traditional breast reconstruction methods such as autologous flap reconstruction or implants or the patients were not suitable for them (poor tissue, cardiac issues). Five patients with complications after immediate breast reconstruction with implants (capsular contraction, hardness, infection, rupture) received a complete reconstruction by lipotransfer. In five patients with extremely tight skin, temporary expanders were inserted at P1 and gradually deflated in the following procedures. The reconstructive treatment

started after a mean time period of 5.6 years (range 2 months to 13.8 years) after the end of primary therapy. Most frequently about 150 ml to 200 ml fat were transferred per procedure (peak shows 180 ml at  $n=21$  in Figure 1). On average of 4.1 procedures (range 2 to 10) were performed to achieve a *complete breast reconstruction*. In our protocol the interval between the single procedures was at least 3 months, resulting in a mean total treatment period of 21 months (range 9 months to 2.5 years).

A median total volume of 1020 ml ( $\pm 515.2$  ml) per patient was grafted to achieve complete reconstruction. Variations depended on individual breast size and BMI. The mean operation time was 50 min ( $\pm 9$  min), but ranged to 60 min ( $\pm 29$  min) in procedures P1 and P2 when further reconstructive steps were carried out (Figure 2). Half of the patients (53%) underwent their intervention under *analgesic sedation* (remifentanyl hydrochloride plus propofol) with *spontaneous breathing*. All

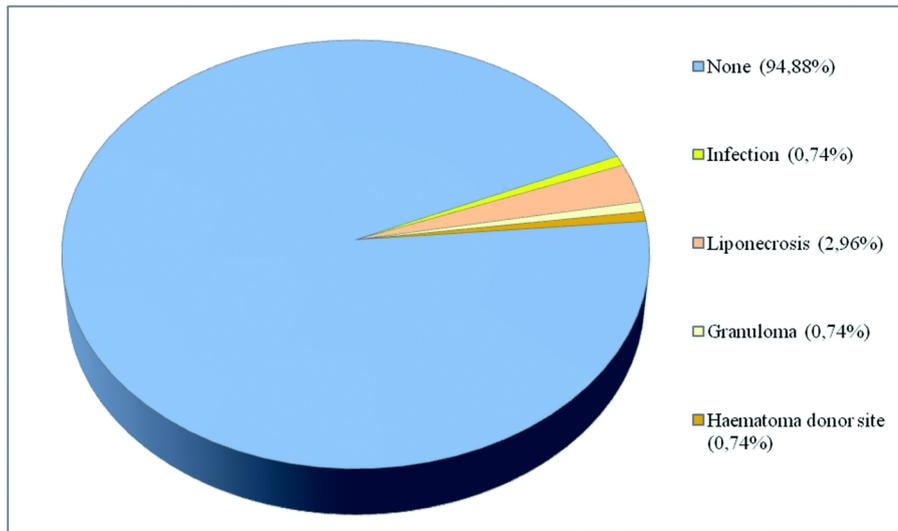


Figure 3: Recorded complications in all procedures

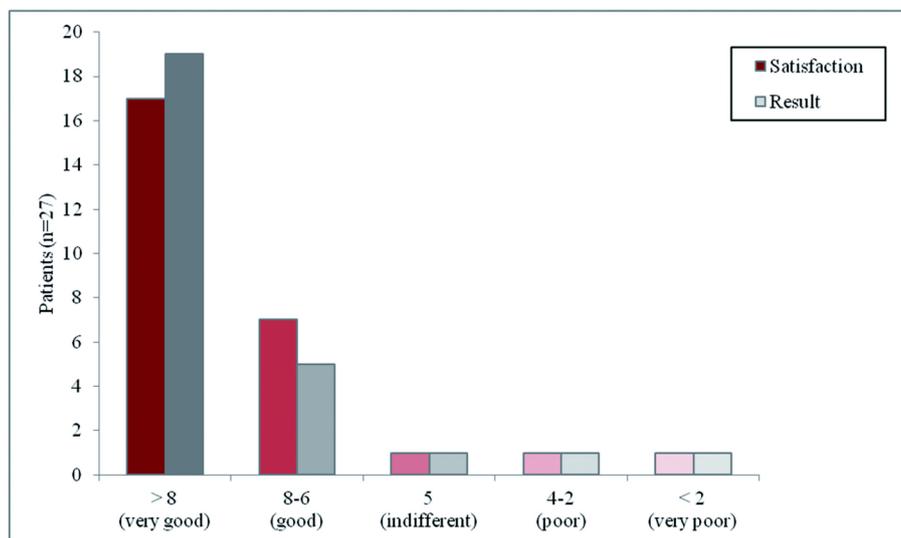


Figure 4: Evaluation of patient questionnaire (10-point Likert scale)

patients were either discharged from our institutions on the same day or stayed overnight for observation.

However, *irradiated* patients needed a *higher amount* of fat for the accomplishment of complete breast reconstruction compared to non-irradiated ( $p>0.041$ ). We observed different stages of reconstruction from P1 to P4 in patients with *PMRT*. Appearance and the texture of the skin improved, while the subcutaneous layer increased to final reformation of the cleavage.

During the minimum 6 months follow-up period no serious or unexpected adverse event occurred (Figure 3). As in all invasive breast reconstructive procedures, we observed *liponecrotic pseudocysts* (2.96%), *infection* (0.74%) and *granuloma* (0.74%) after the fat grafting procedures. One hematoma after liposuction was treated with puncture and antibiotics. All formations were frequently controlled by breast imaging and 87% *spontaneously resolved* after 6–12 months. Persisting or suspicious specimen were further investigated by biopsy and MRI. However two irradiated patients showed reduced or

missing engraftment due to heavy scarring or radiodamage of the recipient area (poor skin envelope and tissue perfusion). One dropout showed progressive distant metastasis of an invasive carcinoma after P3 and one regional recurrence occurred after the trial.

The specific questionnaire showed a response rate of 96.4% (Figure 4). Some comments about the reconstructed breast like feeling soft to touch, superior symmetry or regain of natural contour were added voluntarily. Three patients complained about superficial skin irregularities on donor sites. Evaluation of the aesthetic outcome was based on digital photographs and done on a 5-point scale (Figure 5). Overall an excellent to good result was achieved in 68% of the patients (Figure 6, Figure 7).

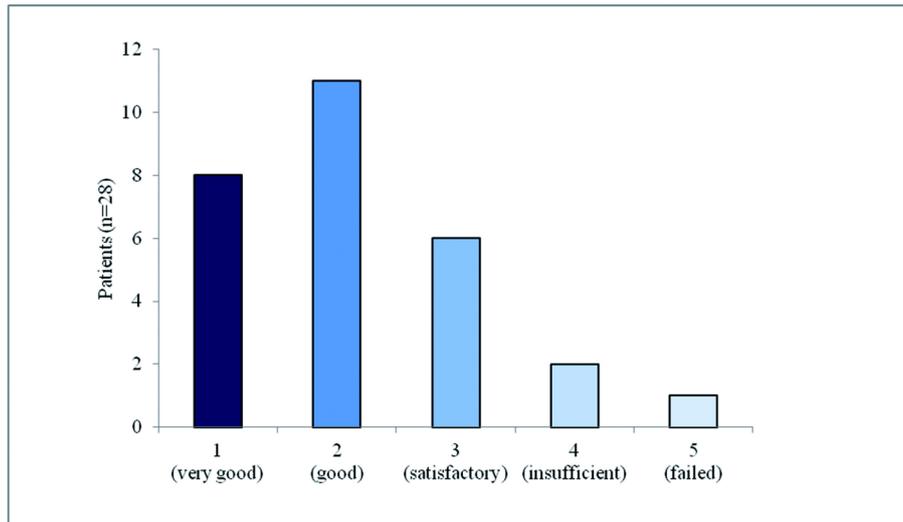


Figure 5: Results of the aesthetic outcome (5-point ranking scale)

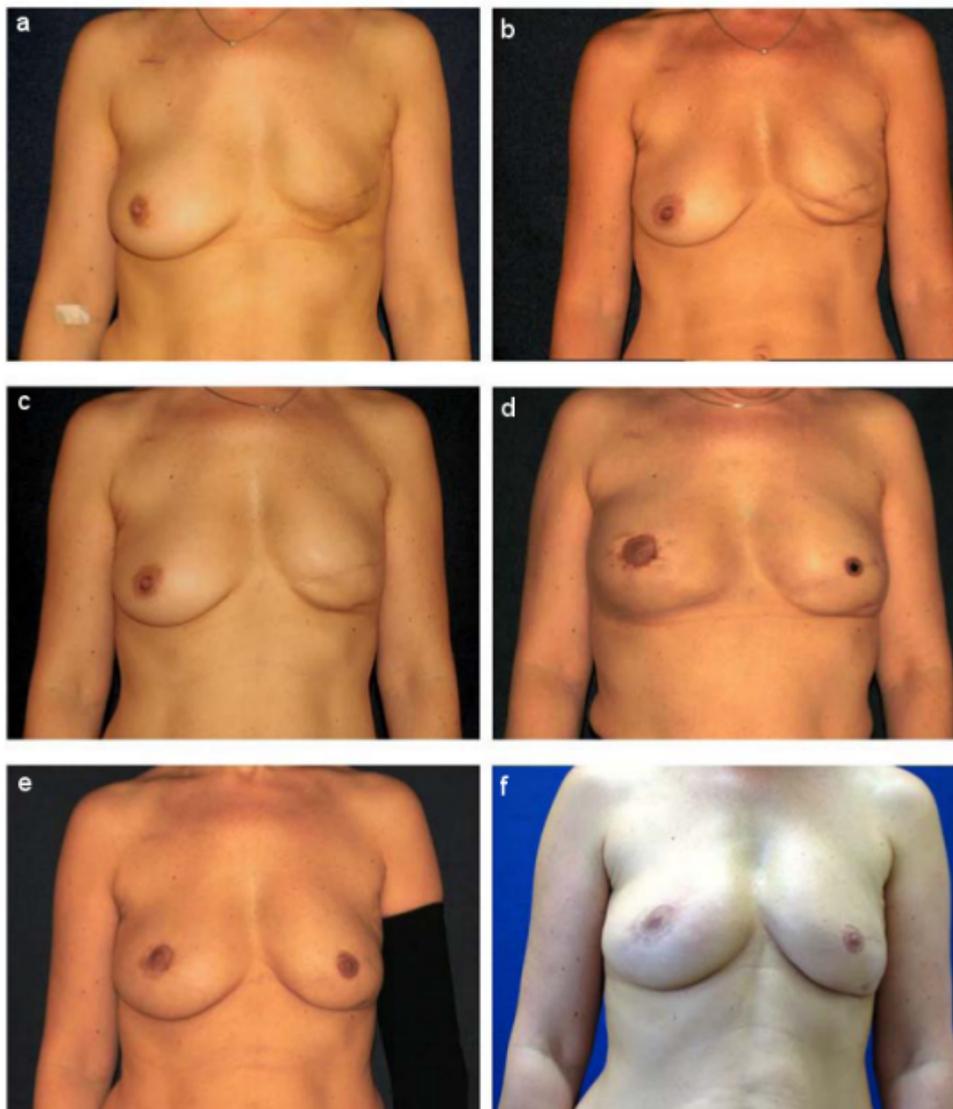


Figure 6: 56-year-old patient after total mastectomy left side in 2006. Outcome after 3 months (a) 300 ml grafted in P1, (b) 250 ml in P2. Below result (c) after P3 with 230ml transferred and (d) P4 with 210 ml combined with NAC reconstruction. Follow-up results after 12 months (e) and 18 months (f).



Figure 7: 66-year-old patient after total mastectomy left side in 2002 with PMRT. Outcome in March 2009 after P1 (250 ml) and P2 (250 ml). Below results after three more sessions (P3 with 200 ml, P4 with 150 ml, P5 with 300 ml plus NAC reconstruction) and 3 months follow-up in June 2010. Final outcome after P6 with 100 ml, P7 with 250 ml and 6 months follow-up in December 2011.

## Discussion

Fat tissue transplant has been approved as a safe and reliable method for breast reconstructive issues in oncologic patients [14], [50], [52]. Correction of soft tissue defects and deformities after breast cancer or insufficient reconstruction can be achieved [10], [19], [36], [54]. After five years of experience with over 276 primarily reconstructive procedures to the female breast, the authors support the BEAULI™ method. In selected cases it can supply an efficient and safe alternative to flap or implant based reconstruction. The treatment started on average 5.6 years (2 months to 13.1 years) after the end of primary therapy. We suggest waiting for at least 6 months after PMRT, because acute radiation injury can compromise the survival of the fat graft [4], [40], [69]. Autologous fat grafting offers a *stepwise breast reconstruction*. It generally consists in 4 to 6 procedures with a mean of 50 minutes operation time. They all can be applied over

a period of 21 months. Most of patients have been discharged on the same day. A surgical learning curve, reducing the risk of complications and the operation time has been demonstrated [15]. As a major advantage, additional reconstructions of the breast can be performed in conjunction with the fat grafting procedure (e.g. NAC, contralateral mastoplasty). Occasionally expanders were inserted as temporary space holders to maintain or increase the skin envelope [48]. Successive expander's deflation of 50 ml to 80 ml was combined with lipofilling. In five cases autologous fat grafting was used as a salvage method after failure of implant reconstruction. In contrast to other large volume fat grafting techniques, our complication rates per procedure for liponecrotic pseudocysts formation (2.96%), infection (0.74%) or granuloma (0.74%) are very low [7], [26], [32], [34], [66]. Fat necrosis within the breast mainly occurs as common phenomenon after trauma, biopsy, implant removal, flap reconstruction, lipotransfer or radiation [16], [18], [41],

[44], [60], [63]. Thus oncologic patients must be advised about side effects before the discovery of suspicious specimen postoperatively [47]. Serial fat injection to post-irradiated mastectomy scars improved fibrosis and skin elasticity [2], [55], [59], [61]. Our findings on the higher fat volume grafted after PMRT confirm recent studies [53], [57]. Future evaluations should include a scoring system like LENT-SOMA [23], [43]. Limited or total missing size increase in two cases was definitively contributed to severe post-irradiation skin atrophy and local tissue radio-damage [31], [38], [53]. Possible scar excision, facioto-mies or temporary space holders should be considered as a pretreatment of PMRT patients [33], [49]. Patient satisfaction was overall high to very high (96%) and confirmed the good aesthetic results (68%) and the natural softness, contour and shape of the reconstructed breast. No significant unfavorable results were detected in the determined follow-up, however our findings don't allow any conclusions about the long-term risk of breast cancer recurrence after lipotransfer [25], [42], [56], [67], [72]. The investigators emphasize the importance of regular clinical and radiological follow-up in post-mastectomy patients irrespective of the reconstruction procedure applied.

## Conclusions

Our study demonstrates that autologous fat grafting is a suitable way not only to restore local defects after conservative breast reconstructive surgery or radiodamages, but also to achieve complete breast reconstruction. Based on the presented results and recent literature a new *treatment protocol* has been developed in our institutions. Now patients with PMRT receive a pretreatment with 4 *ambulant small volume graftings* of 50–80 ml fat to *resolve scar fibrosis* after a safety period of at least 6 months to the last irradiation session. In this way, chronic tissue injury decreases gradually and an adequate recipient area can be obtained. The grafting technique is easy combinable with other oncoplastic methods like NAC reconstruction or contra lateral mastoplasty. Our follow-up and patient satisfaction reveal encouraging results, but further investigations on lipotransfer in breast cancer patients are mandatory.

## Notes

### Authorship

Delia Letizia Hoppe and Klaus Ueberreiter have equally participated.

### Competing interests

Klaus Ueberreiter has filed after the publication in Germany a U.S. patent application in 2009 for the water-jet assisted fat grafting technique called BEAULI™. As one

of the inventors of the LipoCollector™ System, he receives some royalties from Human Med Inc. (producer of the Body-jet® and the LipoCollector™ System). He has not received any financial support for the presented trial. Neither he has commercial interests based on the subject of the study nor on its publication.

The other authors declare that they have no competing interests.

## Ethics

An institutional review board (IRB) review was not required as all reported devices were cleared for marketing by the FDA.

The study was carried out under European law and the Declaration of Helsinki.

## Meeting presentations

Content of the original article has been presented on the IMCAS in July 2012 (Shanghai – China), the 44<sup>th</sup> DGPRÄC conference in September 2012 (Bremen – Germany) and the 8<sup>th</sup> BEAULI™-Workshop in June 2013 (Berlin – Germany)

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**Corresponding author:**

Delia Letizia Hoppe, M.D.  
 BG Unfallklinik Tübingen, Klinik für Hand-, Plastische, Rekonstruktive und Verbrennungschirurgie,  
 Schnarrenbergstrasse 95, 72076 Tübingen, Germany,  
 Phone: +49 711-64897212  
 dhoppe@bgu-tuebingen.de

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