CENTRAL-EASTERN EUROPEAN BREAST CANCER SURGICAL CONSORTIUM

SZPITAL UNIWERSYTECKI
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The role of biological matrices and synthetic meshes in immediate postmastectomy breast reconstruction

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In modern implant-based immediate breast reconstruction it has become common to use matrices in combination with tissue expander or an implant!!!

2003 revisional aesthetic breast surgery
2005 breast reconstruction

Matrices/Meshes

- **Often stated advantages**

Better Control and definition of the implant pocket and inframammary fold

The possibility to use a dual plane technique and less muscle dissection

Less pronounced capsule formation

- Majority of surgeons in the USA are now using a biological ADM in implant based breast reconstruction!!!

BUT!!!

No patients has had ADM in situ for more than 16 years; few more than 5 years

SO!!!

We know little about the long-term effects of ADM

Author, Year, Country	Study Design	Study Duration (years)	Study Groups; Intervention versus Control
Antony 2010 USA [18]	Retrospective cohort BM	2004–2008	AlloDerm versus non-ADM
Baldelli 2016 Italy [19]	Retrospective cohort SM	2012–2013	Surgimesh-pet versus non ADM
Chun 2010 USA [10]	Retrospective cohort BM	2002–2008	AlloDerm versus non-ADM
Clarke-Pearson 2016 USA [20]	Retrospective cohort BM	2006–2011	AlloDerm versus non-ADM
Collis 2012 USA [21]	Retrospective cohort BM	2005–2009	AlloDerm versus non-ADM
Colwell 2011 USA [22]	Retrospective cohort BM	2006–2010	AlloDerm versus non-ADM
Davila 2013 USA [23]	Retrospective cohort BM	2006–2010	ADM versus non-ADM
Endress 2012 USA [24]	Retrospective cohort SM	2008–2010	Surgimend versus non-ADM
Forsberg 2014 USA [25]	Retrospective cohort BM	2005–2009	ADM versus non-ADM
Frey 2015 USA [26]	Retrospective cohort BM	2010–2014	ADM/fenestrated ADM versus non-ADM
Ganske 2013 USA [27]	Retrospective cohort BM	2008–2010	ADM versus non-ADM
Ibrhaim 2015 USA [28]	Retrospective cohort BM	2005-2011	ADM versus non-ADM
Israeli Ben-Noon 2013 Israel [29]	Prospective cohort BM	NR	ADM versus non-ADM
Kilchenman 2014 Switzerland [30]	Prospective cohort BM	2006–2011	ADM versus non-ADM
Liu 2011 USA [31]	Retrospective cohort BM	2004–2009	ADM versus non-ADM
Liu 2014 USA [32]	Retrospective cohort BM	2006-2011	Alloderm versus FlexHD versus dermal graft
Meyer Ganz 2015 Switzerland [33]	Retrospective cohort SM	2002–2010	Submuscular versus vicryl mesh
Nguyen 2012 USA [34]	Retrospective cohort BM	NR	ADM versus non-ADM
Nguyen 2010 USA [35]	Retrospective cohort BM	1998–2008	Alloderm versus non-ADM
Parks 2012 USA [36]	Retrospective cohort BM	2001–2011	Alloderm versus non-ADM
Peled 2012 USA [37]	Retrospective cohort BM	2006–2010	Alloderm (consecutive/selective) versus non-ADM
Potter 2015 UK [38]	Retrospective cohort BM	2011–2012	Technoss Protexa versus non-ADM
Preminger 2008 USA [39]	Retrospective cohort BM	2004–2005	Alloderm versus non-ADM
Sbitany 2009 USA [40]	Retrospective cohort BM	2004–2007	Alloderm versus non-ADM
Sbitany 2016 USA [41]	Retrospective cohort BM	2012–2013	Alloderm versus non-ADM
Seth 2012 USA [42]	Retrospective cohort BM	2006–2008	Alloderm /FlexHD versus non-ADM
Vardanian 2011 USA [6]	Retrospective cohort BM	2000–2008	Alloderm versus non-ADM
Winocour 2015 USA [43]	Retrospective cohort BM	2005–2011	ADM versus non-ADM
Barber 2015 UK [16]	Case series BM	2008–2012	I: Strattice/Permacol/Alloderm
Butterfield 2013 USA [44]	Case series SM	2005–2010	I: Surgimend/Alloderm
Dikmans 2016 Netherlands [45]	Case series BM	2010–2014	I = Strattice
Dieterich 2013 Germany [46]	Case series SM	2008–2011	I: TiLOOP
Eichler 2015 Germany [47]	Case series SM	2008–2013	I: Surgimend/Epiflex
Gunnarsson 2013 Norway [48]	Case series Unspec mesh	2011–2013	I: ADM unspec
Hanna 2016 USA [49]	Case series Unspec mesh	2008–2014	I: ADM unspec
Headon 2016 UK [50]	Case series SM	2012–2014	I: Surgimend
Hille-Betz 2015 Germany [51]	Case series BM	2009–2013	I: Strattice

Introduction

- ADM Acellular Dermal Matrix introduced in 1994 - initially a skin substitute in severely burned patients.
- ADM contains: collagen, elastin, hyaluronic acid, fibronectin, proteoglycans, and cell-free vascular canals.
- ADM - in the case of contact with living tissue, the structure is immediately repopulated by host cells (no rejection due to immunology, no chronic inflammatory response, no excessive fibrosis)

Introduction

Xenografts

- Obtained from different species:
  - Porcine (collagen closest to human collagen - 95%)
  - Bovine
  - Equine
- Use of various tissues:
  - Skin
  - Intestinal submucosa
  - Peritoneum
  - Pericardium

Allografts

- Most allografts available on the market are obtained from human corpses (not available on the European market)

Introduction

- Synthetic meshes available mainly in hernia repairs for many years, we still know little in breast reconstruction
- Currently, a wide range of products used - non-resorbable, fast resorbing, slow resorbing (new scheme - reduction in reactivity)
- Lack of possibility of replacing the structure by host tissues - the main difference when compared to ADM

ADM vs. synthetic mesh: a reaction from the body

- **ADM**

Scaffold for host cells
Neovascularization
Integration with host tissues

- Synthetic mesh

A massive inflammatory process
Degradation of the implanted material
Formation of a scar

The main difference is the presence of inflammation !!!

Biological Matrices and Synthetic Meshes Used in Implant-based Breast Reconstruction – a Review of Products Available in Germany

Biologische Matrizes und synthetische Netze im Rahmen der implantatgestützten Brustrekonstruktion – Eine Übersicht verfügbarer Materialien in Deutschland

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[3] Working Group of the German Society of Obstetrics and Gynecology for Plastic, Aesthetic and Reconstructive Surgery in Gynecology (AWOgyn)

Fig. 1 a to **j** Demonstration of synthetic meshes and biological matrices.

a TiLOOP®Bra,
b SERAGYN® BR,
c TIGR® Matrix,
d Strattice™,
e Permacol™,
f ALLOMAX™,
g Epiflex®,
h Surgimend® PRS,
i FLEXHD®,
j DermaMatrix®.

Table 3 Recommendations for the application of synthetic meshes or biological matrices in implant-based breast reconstruction.

Indication and benefits	Synthetic meshes	Biological matrix
Skin- and nipple-sparing mastectomy	XX	XX
Inherent breast deformities	X	X
Implant-associated breast deformities	X	XX
Implant exchange	XX	XX
Fixation of the pectoralis major muscle	XX	XX
Control of implant position	XX	XX
Implant support	X	XX
Implant coverage	–	XX
Additional soft tissue replacement	–	XX
Implant-based breast reconstruction after MRM	–	XX
Breast reconstruction after radiotherapy	–	X
Delayed immediate breast reconstruction (mastectomy with expander → radiation → final implant exchange)	–	XX
Decreased frequency of capsular contraction	unknown	unknown

X: recommended; XX: preferably recommended; –: not recommended, MRM: modified radical mastectomy

Most commonly used ADMs so far

ADM	Source	Aseptic/sterile
AlloDerm (LifeCell Corp, Branchburg, NJ)	Human	Aseptic
AlloDerm RTU (LifeCell Corp, Branchburg, NJ)	Human	Sterile (SAL 10^{-3})
AlloMax (Davol Inc, Murray Hill, NJ)	Human	Sterile (SAL 10^{-6})
FlexHD (Ethicon Inc, Somerville, NJ)	Human	Aseptic
DermaMatrix (MTF/Synthes CMF, West Chester, Pa)	Human	Sterile (SAL 10^{-6})
DermACELL (LifeNet Health, Virginia Beach, Va)	Human	Sterile (SAL 10^{-6})
NeoForm (Mentor, Santa Barbara, Calif)	Human	Sterile (SAL 10^{-6})
Strattice (LifeCell Corp, Branchburg, NJ)	Porcine	Sterile (SAL 10^{-3})
Permacol (Covidien, Boulder, Colo)	Porcine	Sterile (SAL 10^{-6})
SurgiMend PRS (TEI Biosciences Inc, Boston, Mass)	Bovine	Sterile (SAL 10^{-6})

*ADM indicates acellular dermal matrix; RTU, ready to use; and SAL, sterility assurance level.

Logan Ellis *et al. World Journal of Surgical Oncology* (2016) 14:121
DOI 10.1186/s12957-016-0874-9

World Journal of Surgical Oncology

REVIEW Open Access

Biological and synthetic mesh use in breast reconstructive surgery: a literature review

Hugh Logan Ellis[1*], Oluwatosin Asaolu[2], Vivien Nebo[2] and Abdul Kasem[1]

Complications - Infections

- **Mesh –** 1,3%- 4,7%; Dieterich et al. 6,1%

- **ADM –** 3,3% - 5,3%; Avashia et al. (post-operative antibiotic therapy – a significant reduction in infection rate in ADM)

Complications - Seroma

- **Mesh –** 0%- 5,7%

- **ADM –** Kim et al. (meta-analysis) 4,8% (1,5%-24,3%)

Complications – Capsular Contracture

- **Mesh – ??** Rietjens 68%; 13,7% Baker III/IV

- **ADM –** a significant reduction in the frequency of capsule formation in clinical and histological studies in relation to control groups

Table 5. *Studies comparing different ADM in postmastectomy breast reconstruction**

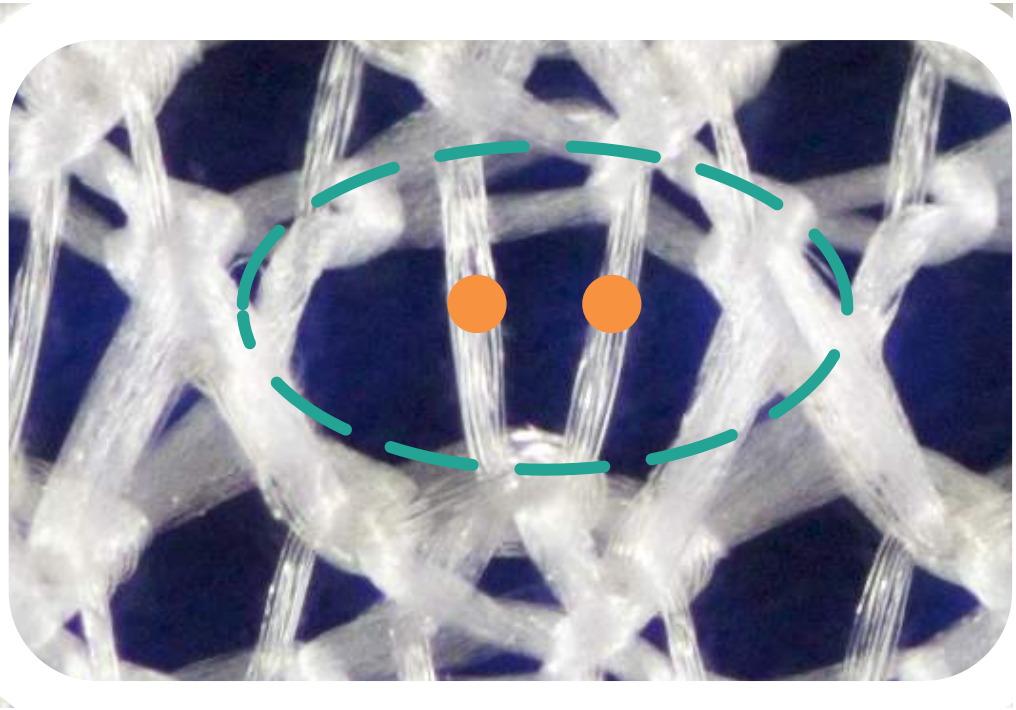
Pittman et al, 2016[46]	Retrospective	DermACELL	30	50	NR	0	10	8	0‡	Shorter time to drain removal with DermACELL (15.8 vs 20.6 days; $P = .017$)
	1 surgeon	AlloDerm RTU	28	50		6	24	4	26‡	
Hanna et al, 2013[53]	Retrospective	DermACELL	28	42	NR	7	2.4	NR	NR	Rates of infection and seroma lower with DermACELL (P .05)
	Single center	AlloDERM	37	51	NR	NR	NR	NR	NR	

Table 6. *Outcomes of studies comparing the use of aseptic ADM to sterile ADM**

Study	Design	ADM	No. patients	No. breasts	Complications, %					Notes
					Total	Infection	Seroma	Necrosis	RBS	
Klein et al, 2016[56]	Retrospective Single center	AlloDerm	63 total	53	NR	17	5.6	NR	NR	
		AlloDerm RTU		13		15.4	2.5			
		AlloMax (sterile)		15		0	0			
Frey et al, 2015[57]	Retrospective Single center	AlloDerm	620 total	91	NR	18.7	4.4	13.2†	NR	Significantly lower rate of infection and minor necrosis with AlloDerm C/F vs aseptic AlloDerm, and a higher rate of minor necrosis with AlloDerm C/F vs AlloDerm RTU
		AlloDerm RTU		164		7.3	1.2	8.5†		
		AlloDerm C/F		119		1.7	2.5	17.6†		
		No ADM		645		3.7	1.1	5.9†		
Lewis et al, 2015[58]	Retrospective Single center	AlloDerm	105 total	93	41.9‡	11.8	8.6	NR	7.5	
		AlloDerm RTU		74	27‡	10.8	2.7		2.7	
Yuen et al, 2014[59]	Retrospective 1 surgeon	AlloDerm	51	96	NR	NR	18.8	NR	NR	Higher rate of cellulitis with AlloDerm RTU (21% vs 12.5%; P = NS)
		AlloDerm RTU	52	100			22			
Buseman et al, 2013[60]	Retrospective Single center	AlloDerm	25	NR	NR	16	8‡	NR	NR	
		AlloDerm RTU	9			11.1	66.6†			
		No ADM	24			8.3	8.3‡			
Weichman et al, 2013[61]	Prospective Single center	AlloDerm	58	90	NR	20†	4.4	13.3	NR	Rate of explantation higher with aseptic vs AlloDerm RTU (6.6% vs 1.9%; P = .147)
		AlloDerm RTU	64	105		8.5†	1.0	10.4		
		No ADM	223	351						

TIGR® Matrix – synthetic but to what degree biological (syntetyczna, ale jak biologiczna)

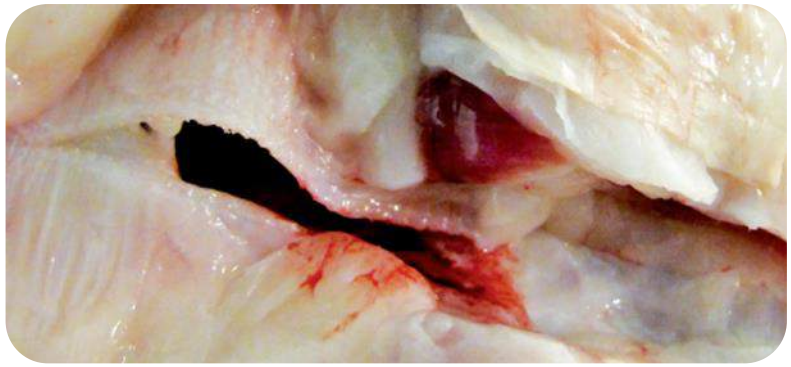
- Macro porous structure (> 1 mm) for improved integration
- Multi-filament for improved pliability
- Two fibers with different degradation times



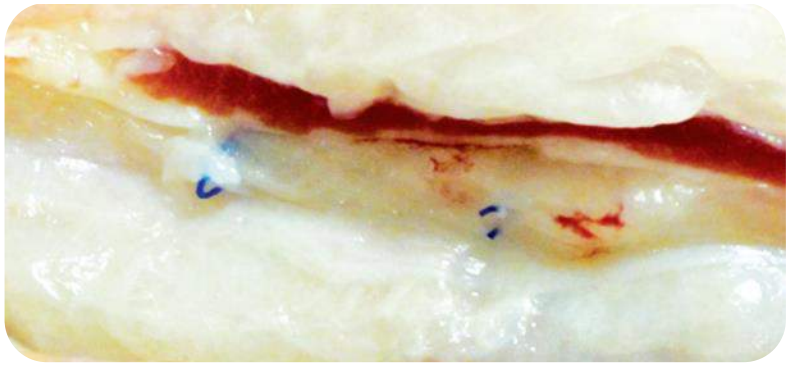
Fast resorbing fiber

Slow resorbing fiber

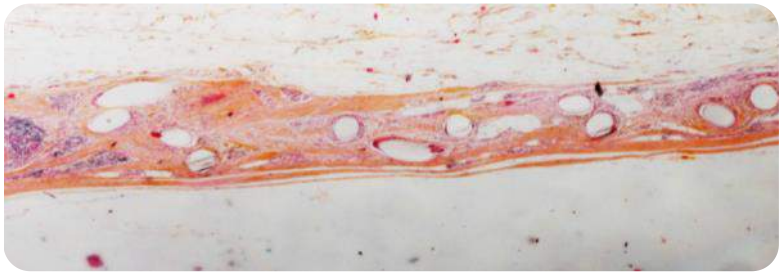
TIGR® Matrix – preclinical 3 year follow-up



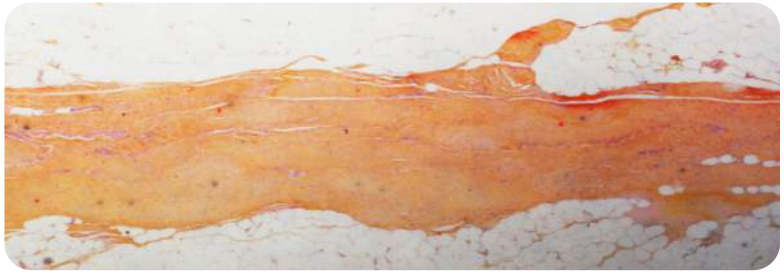
Polypropylene mesh encapsulated and delaminated form tissue after 3 years (clearly visible).



TIGR® Matrix macroscopically invisible 3 years post implant. Only permanent sutures remain and are visible.



At 36 months **Polypropylene** mesh still elicits an inflammatory response.



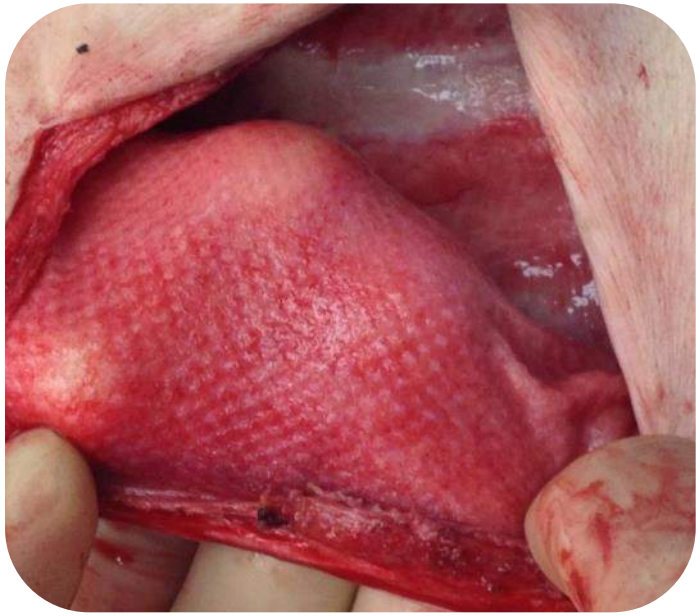
TIGR® Matrix has been completely replaced by thicker, healthy connective tissue (neo-fascia).

Hjort H,. Mathisen T., 2011

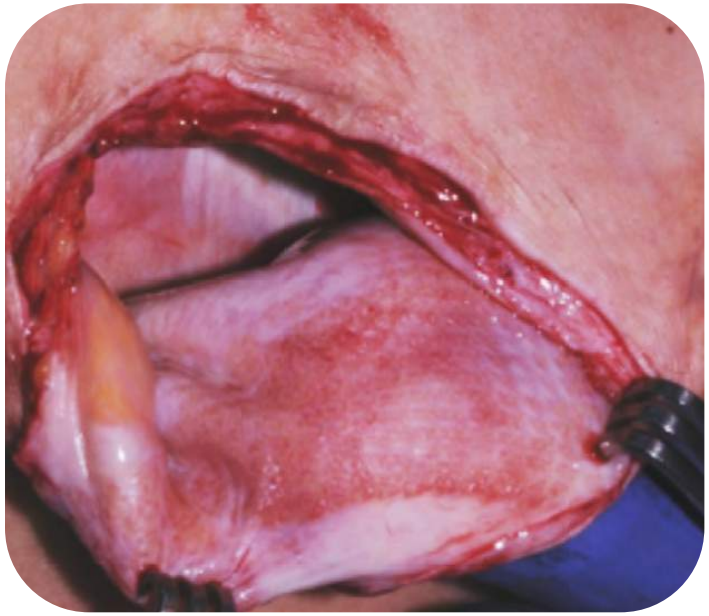
TIGR® Matrix – reconstruction and revision, integration

- TIGR® Matrix well integrated in healthy vascularized breast flap.

4 months

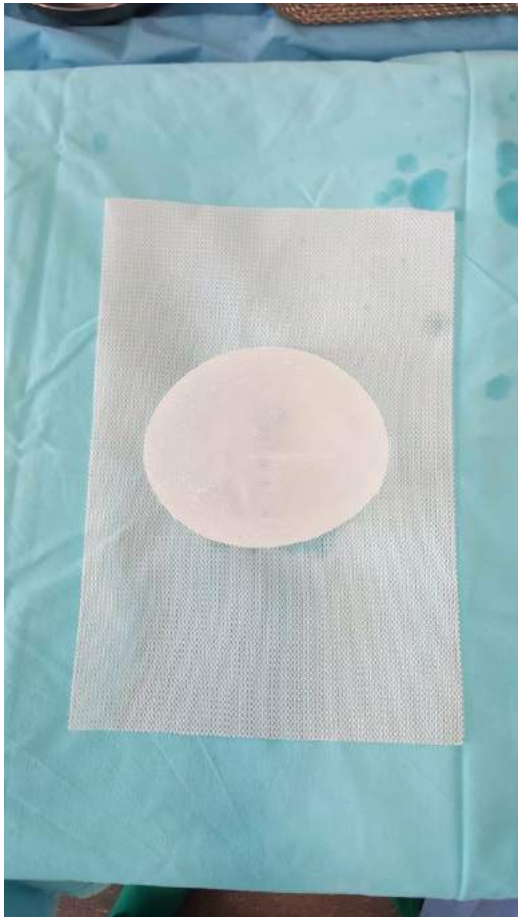


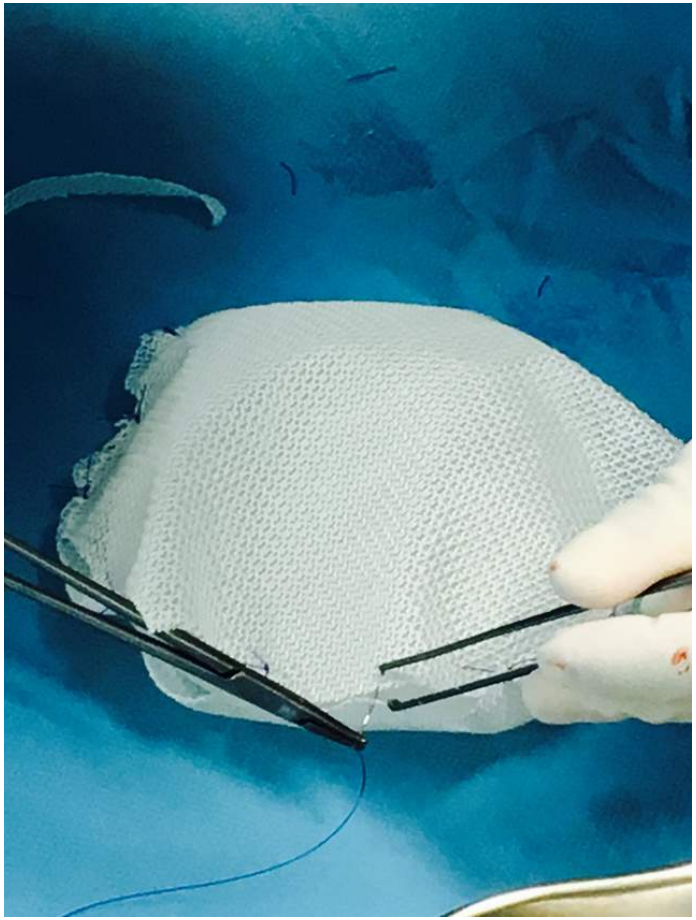
12 months



Becker H., Lind J. G., 2013

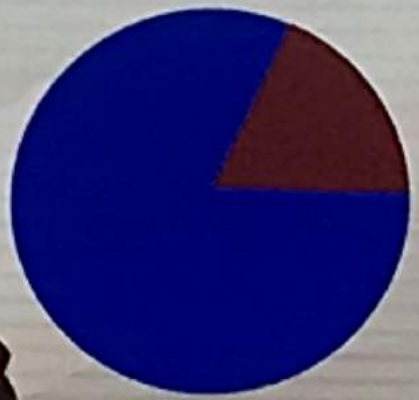
Prepectoral surgeries





The Prepectoral approach:
is it a feasible alternative?
Pro team VS Against Team

Referee: Rieka Taghizadeh
Stefano Pompei; Jaume Masià
Vs
Eyal Gur; Alexandre Mendonça Munhoz



OPEN

PRS GLOBAL OPEN

ORIGINAL ARTICLE

Breast

Subcutaneous Implant-based Breast Reconstruction with Acellular Dermal Matrix/Mesh: A Systematic Review

Table 2. Complications by Study

Authors	Major Infection†	Minor Infection‡	Seroma	Hematoma	Full NAC Necrosis	Partial NAC Necrosis	Major Flap Necrosis	Wound Healing	Explantation	CC: Grade III/IV
Berna et al[26]	1 (4.3)	0 (0)	4 (17.4)	0 (0)	0 (0)	0 (0)	0 (0)	2 (8.7)	3 (13.0)	0 (0)
Reitsamer et al[28]	0 (0)	0 (0)	0 (0)	1 (4.5)	0 (0)	2 (9.1)	0 (0)	0 (0)	0 (0)	0 (0)
Becker et al[34]*	1 (1.6)	0 (0)	1 (1.6)	1 (1.6)	0 (0)	0 (0)	2 (3.2)	1 (1.6)	2 (3.2)	2 (3.2)
Bernini et al[27]	0 (0)	0 (0)	0 (0)	1 (2.6)	1 (2.8)§	1 (2.8)	1 (2.6)§	1 (2.6)	2 (5.1)	0 (0)
Casella et al[25]	0 (0)	4 (16)	0 (0)	1 (4)	0 (0)	1 (8.3)	0 (0)	0 (0)	0 (0)	0 (0)

*Study does not specify number of NSM versus SSM.

†Major infection: infection requiring return to operating room.

‡Minor infection: infection requiring oral or intravenous antibiotics.

§Same patient.

CC, Capsular contracture.

Table 5. Complications in ADM- Versus Mesh-assisted Reconstruction

Complication	ADM (n = 45)‡	Mesh (n = 64)‡
Major infection*	1 (2.2)	0 (0)
Minor infection†	0 (0)	4 (6.3)
Seroma	4 (8.9)	0 (0)
Hematoma	1 (2.2)	2 (3.1)
Full NAC necrosis	1 (2.5)	0 (0)
Partial NAC necrosis	2 (5.0)	2 (4.2)
Major flap necrosis	0 (0)	1 (1.6)
Wound healing	2 (4.4)	1 (1.6)
Explantation	3 (6.7)	2 (3.1)
CC: grade III/IV	0 (0)	0 (0)

*Major infection defined as infection requiring return to operating room.
†Minor infection defined as infection requiring oral or intravenous antibiotics.
‡n=40 (NAC necrosis, ADM), n=48 (NAC necrosis, mesh).

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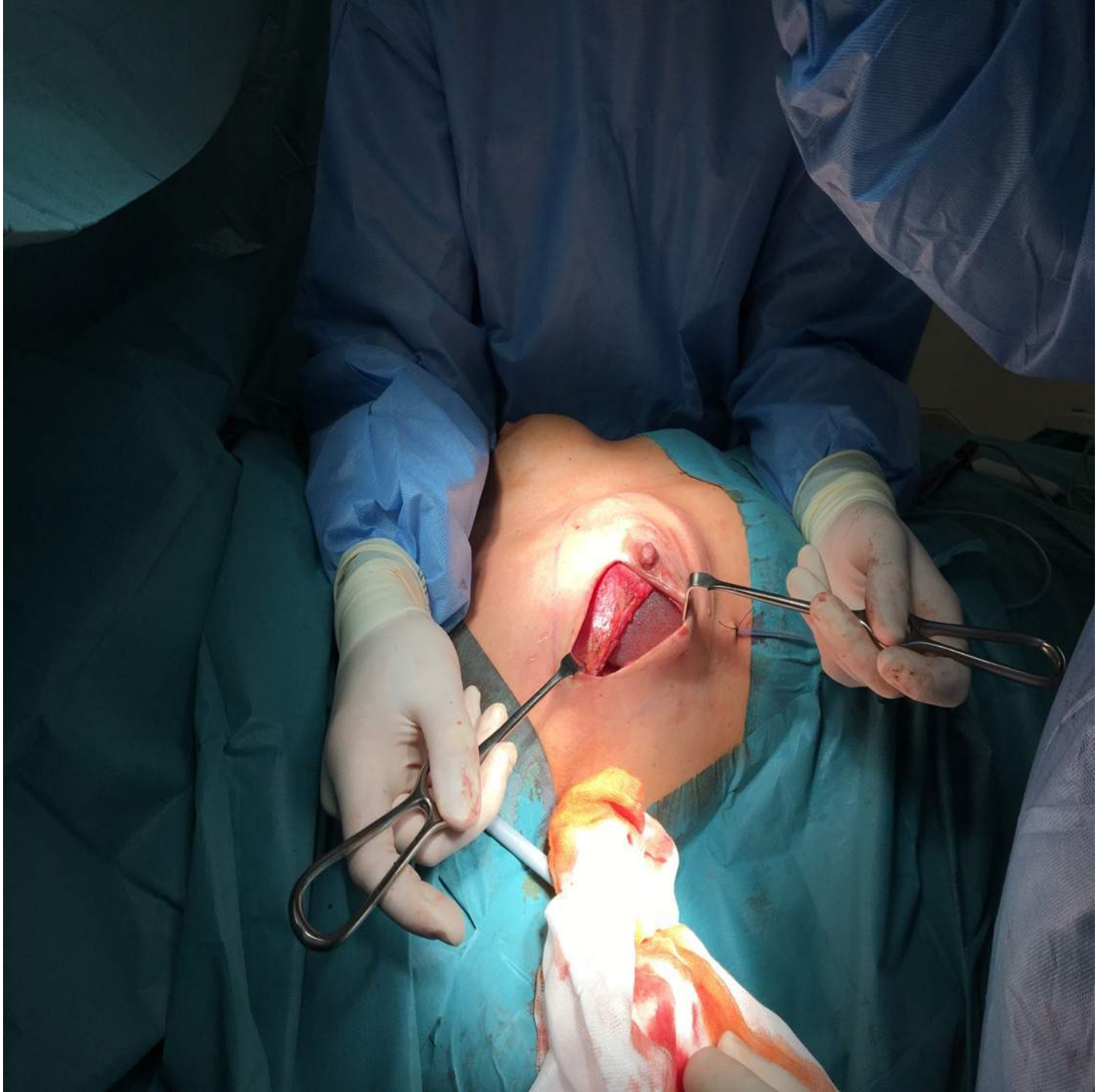
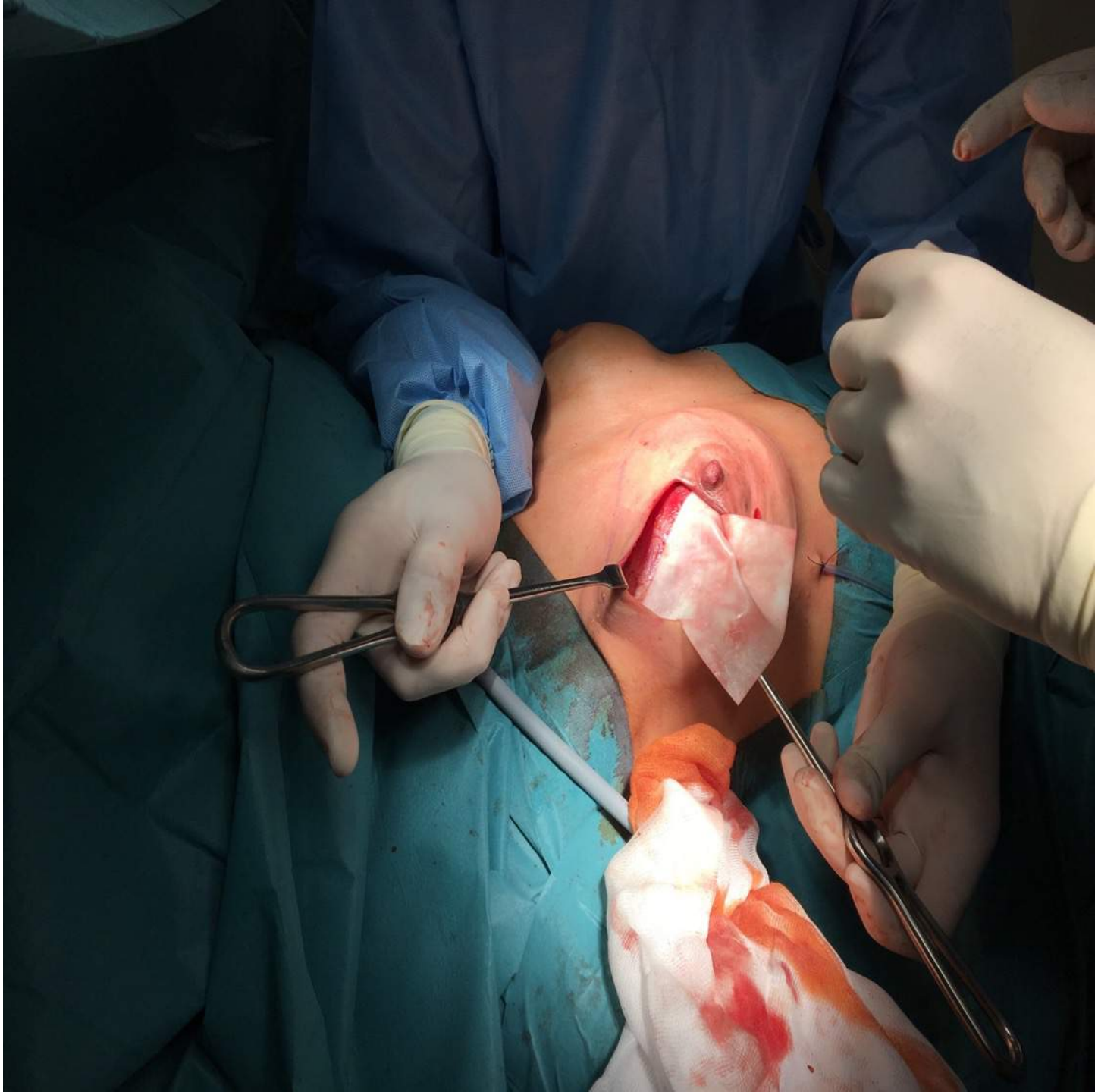
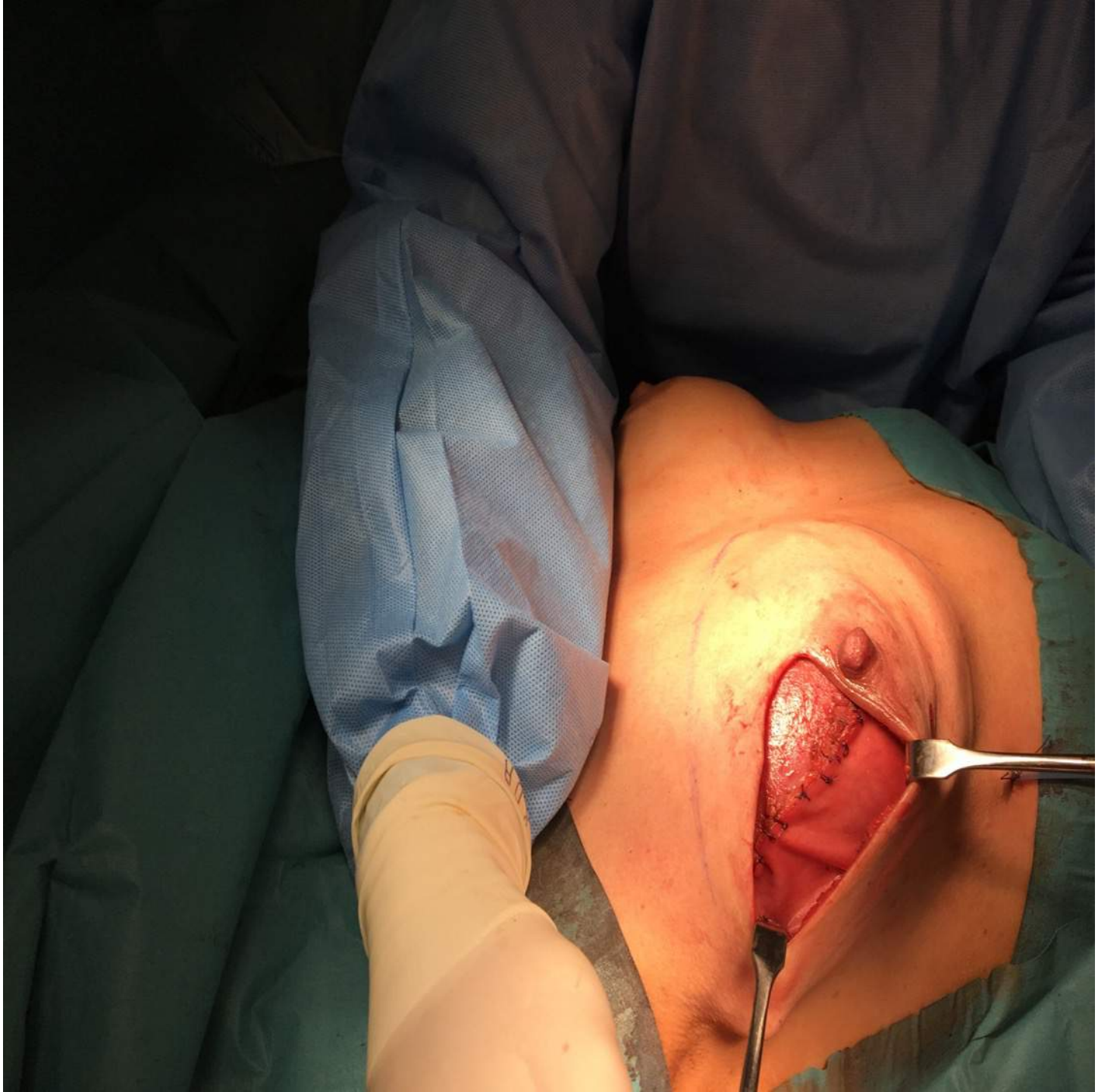
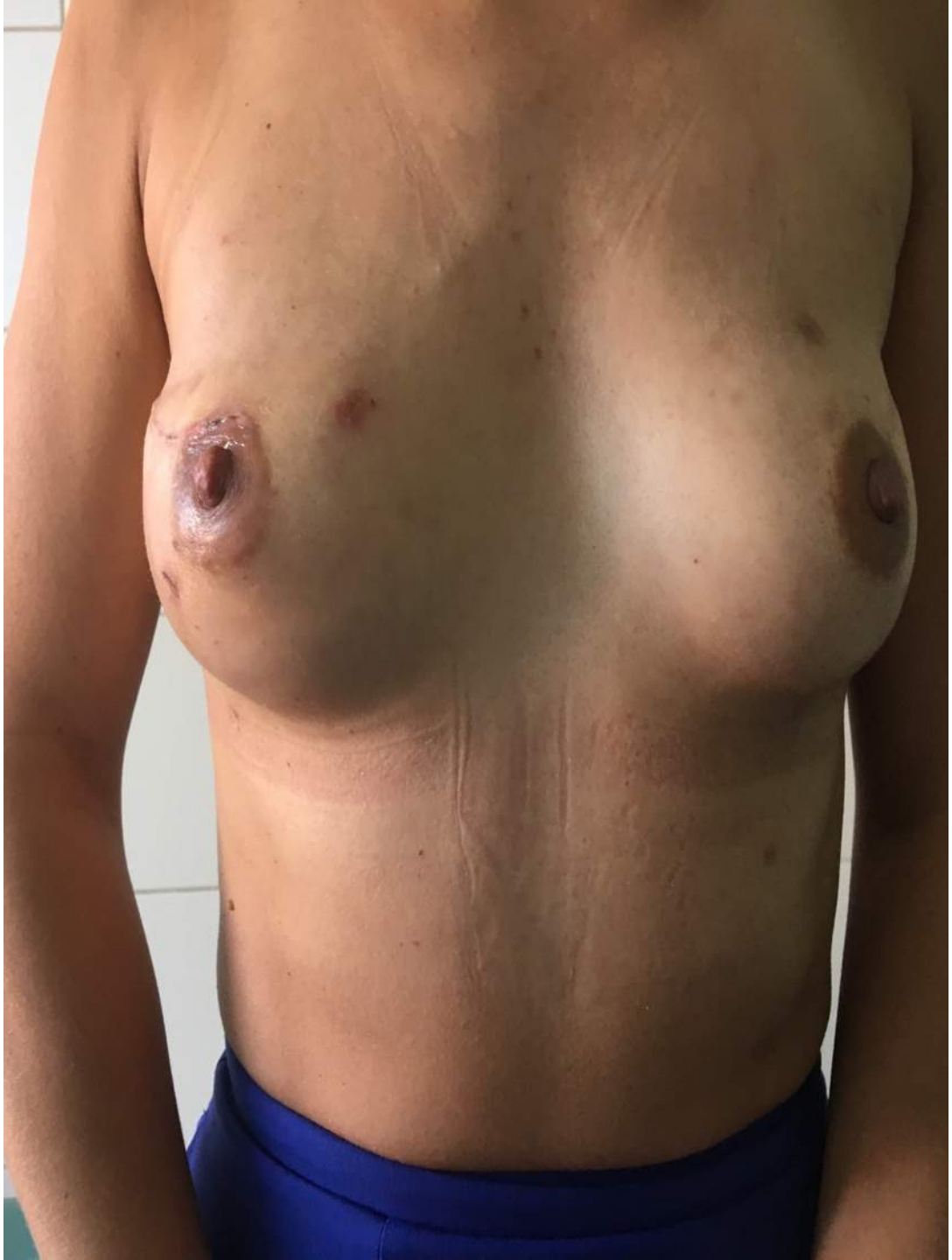
Benefits and risks with acellular dermal matrix (ADM) and mesh support in immediate breast reconstruction: a systematic review and meta-analysis

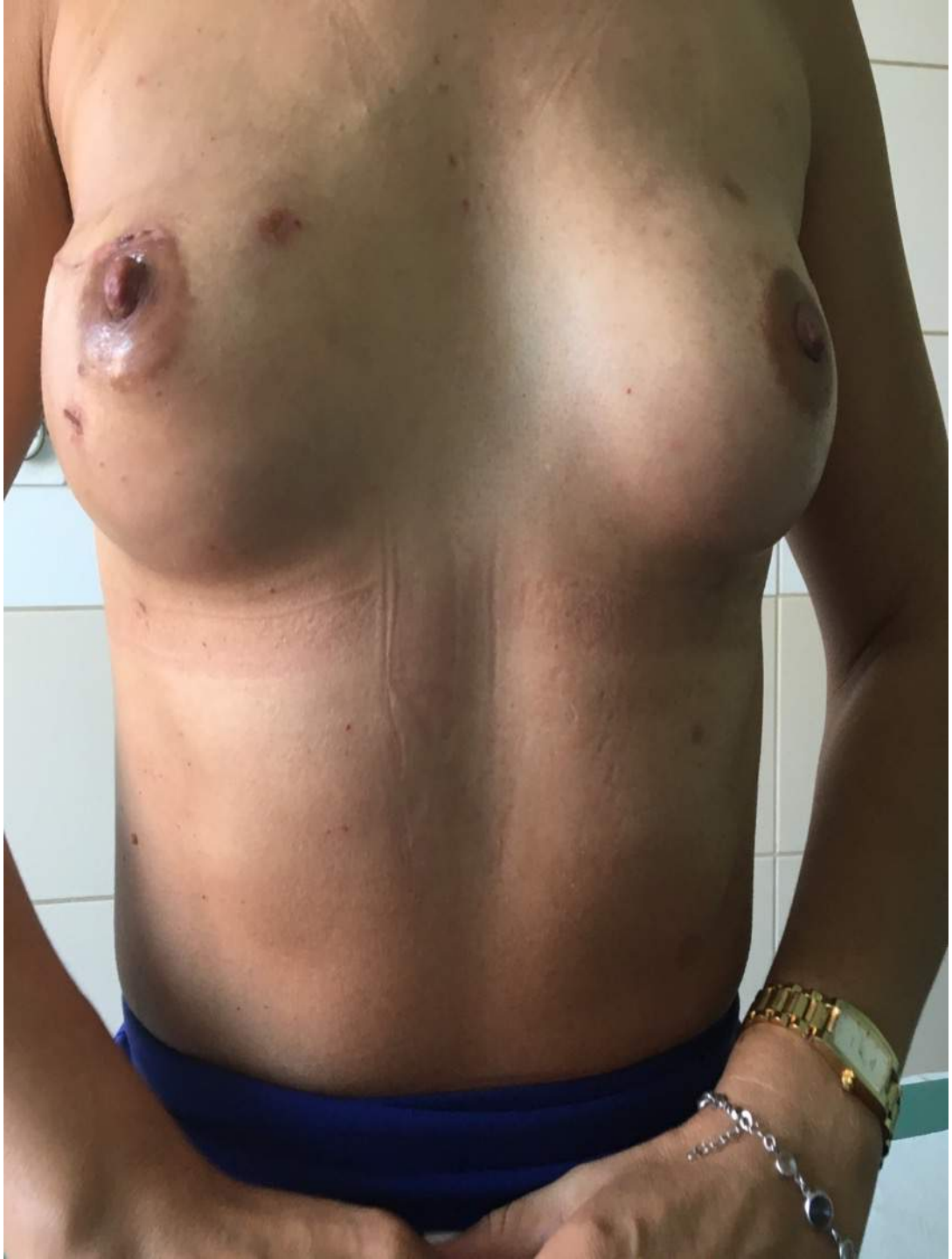
recurrence of cancer, delay of adjuvant treatment and Health related quality of life (HRQoL). In addition, there is a risk of bias in many studies. It is often unclear what complications have been included and how they have been diagnosed, and how and when capsular contracture and aesthetic outcome have been evaluated. Controlled trials that further analyse the impact of radiotherapy, type of matrix and type of procedure (one or two stages) are necessary.

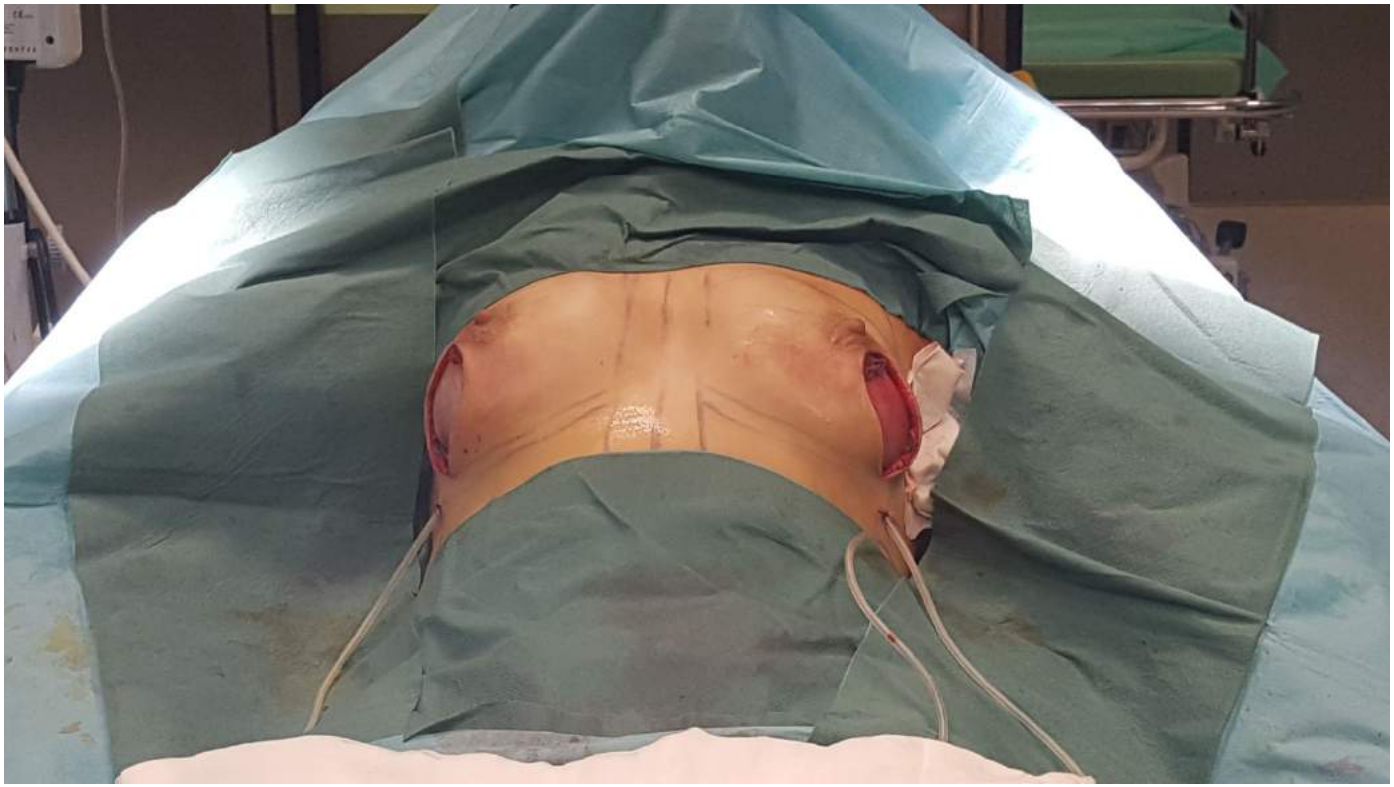


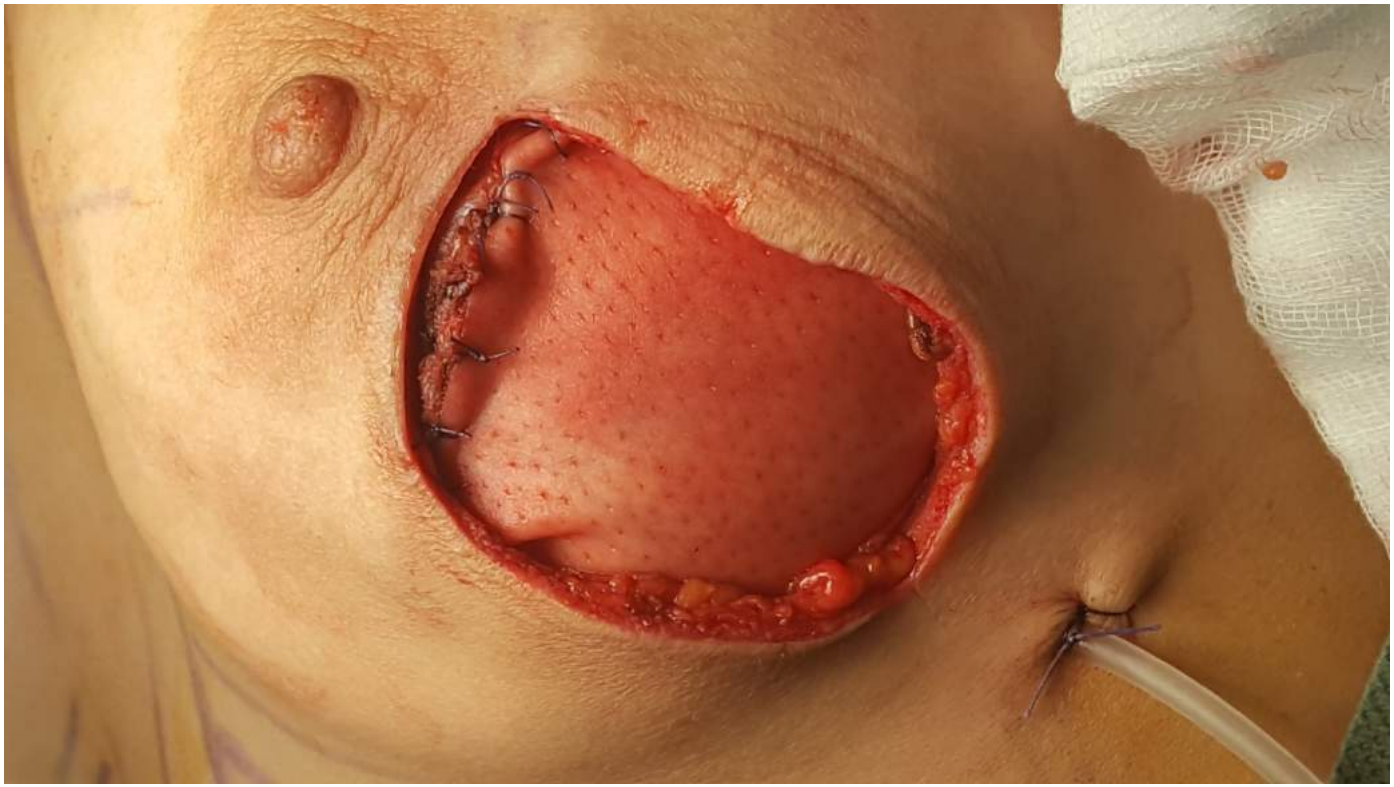


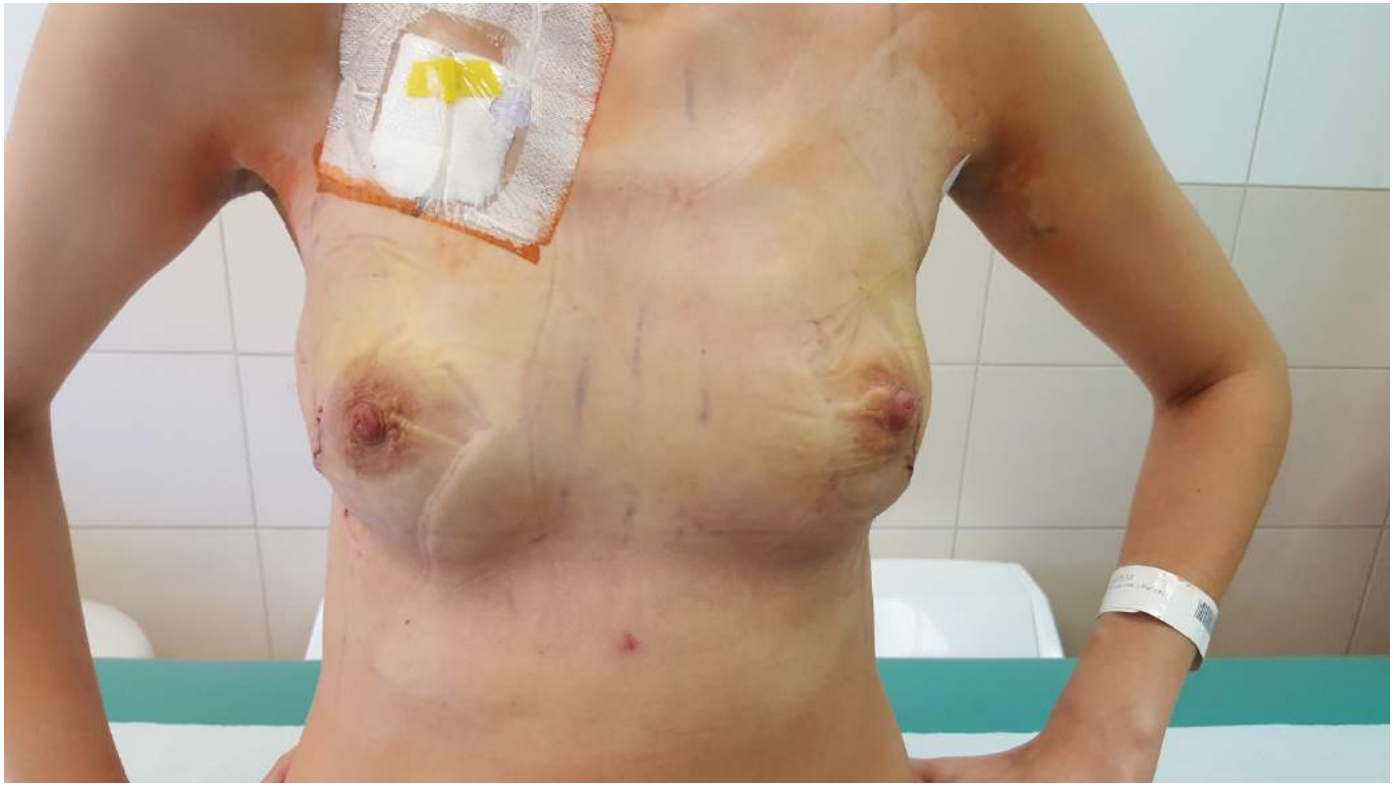


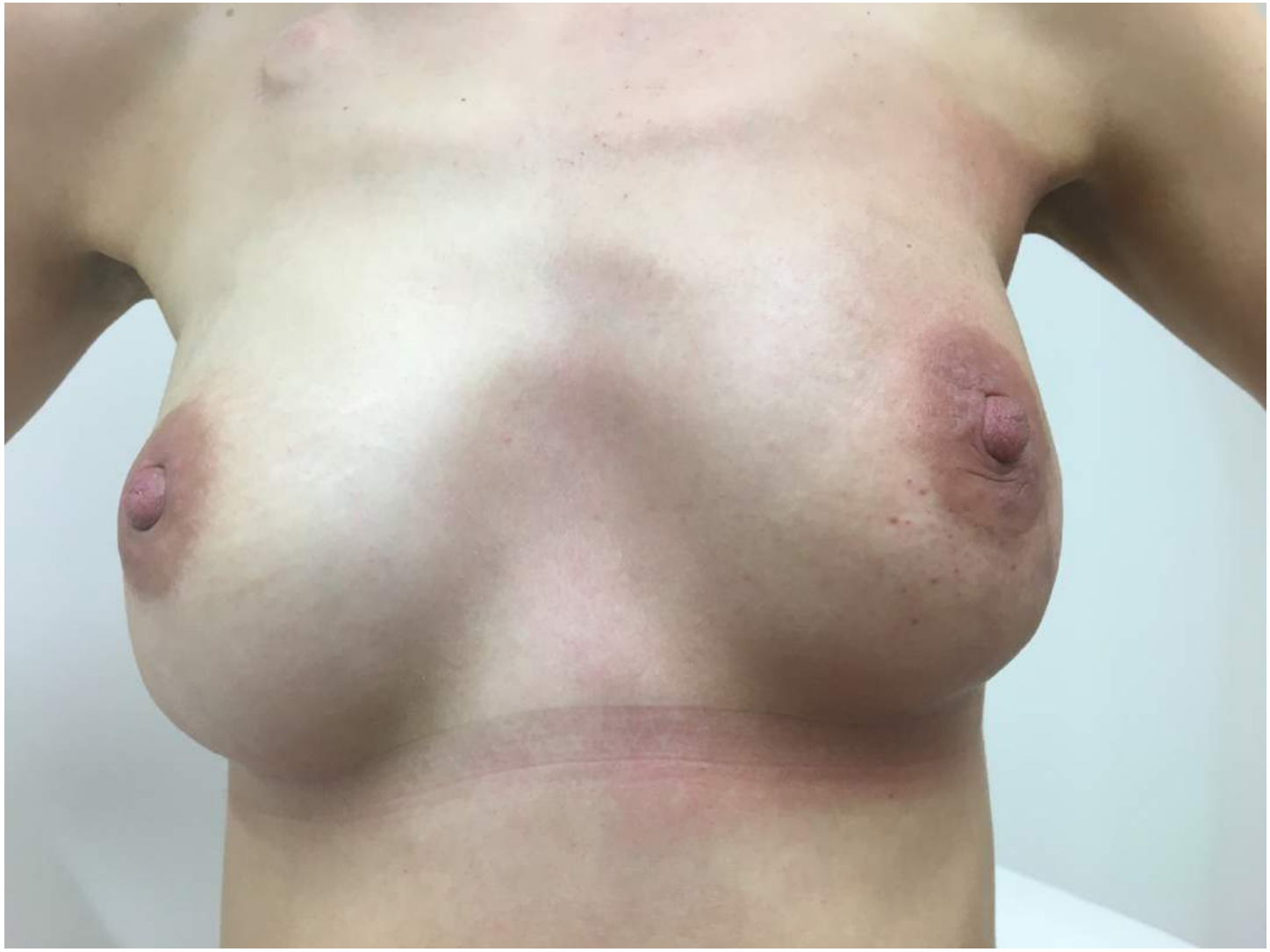


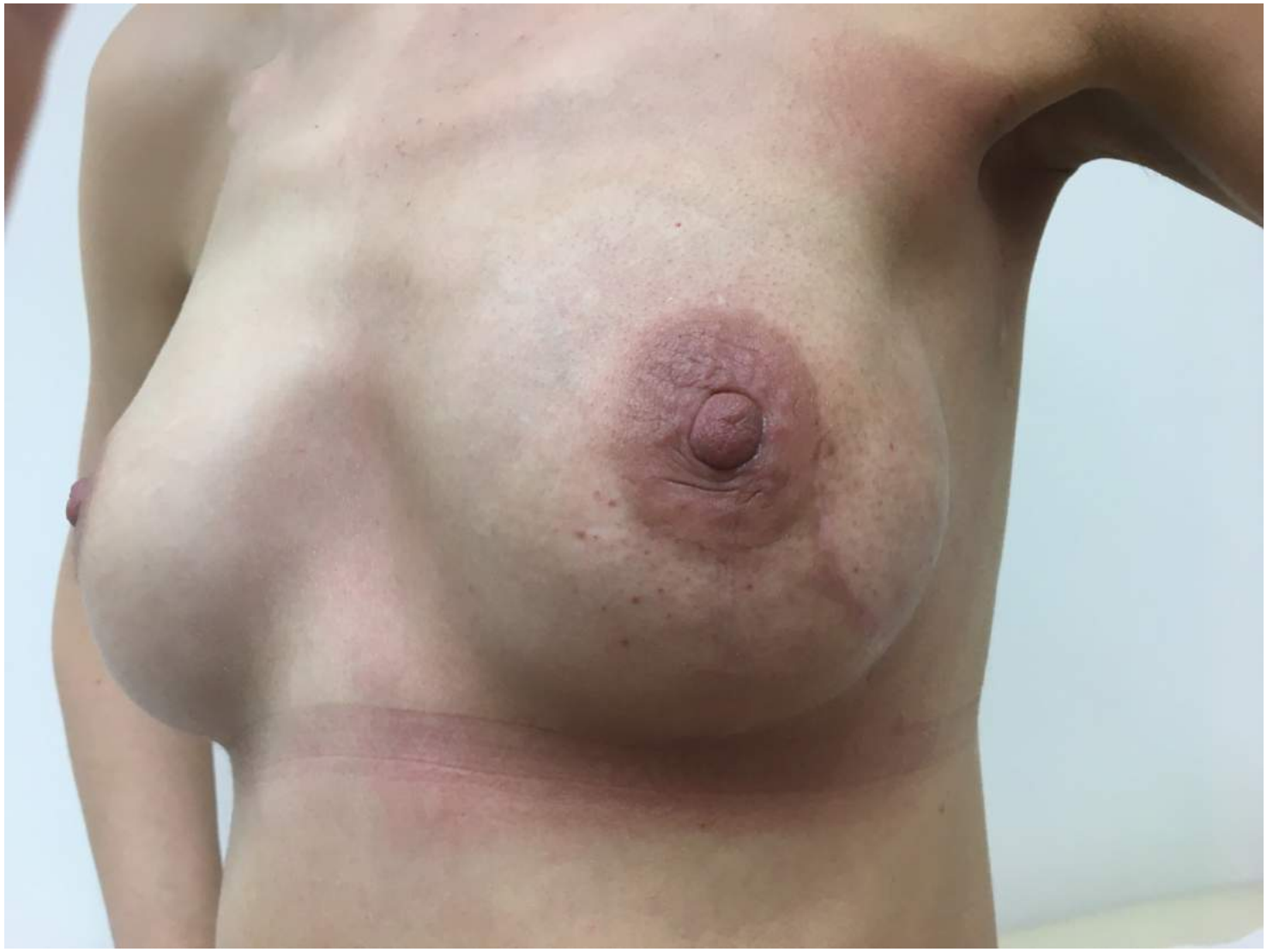


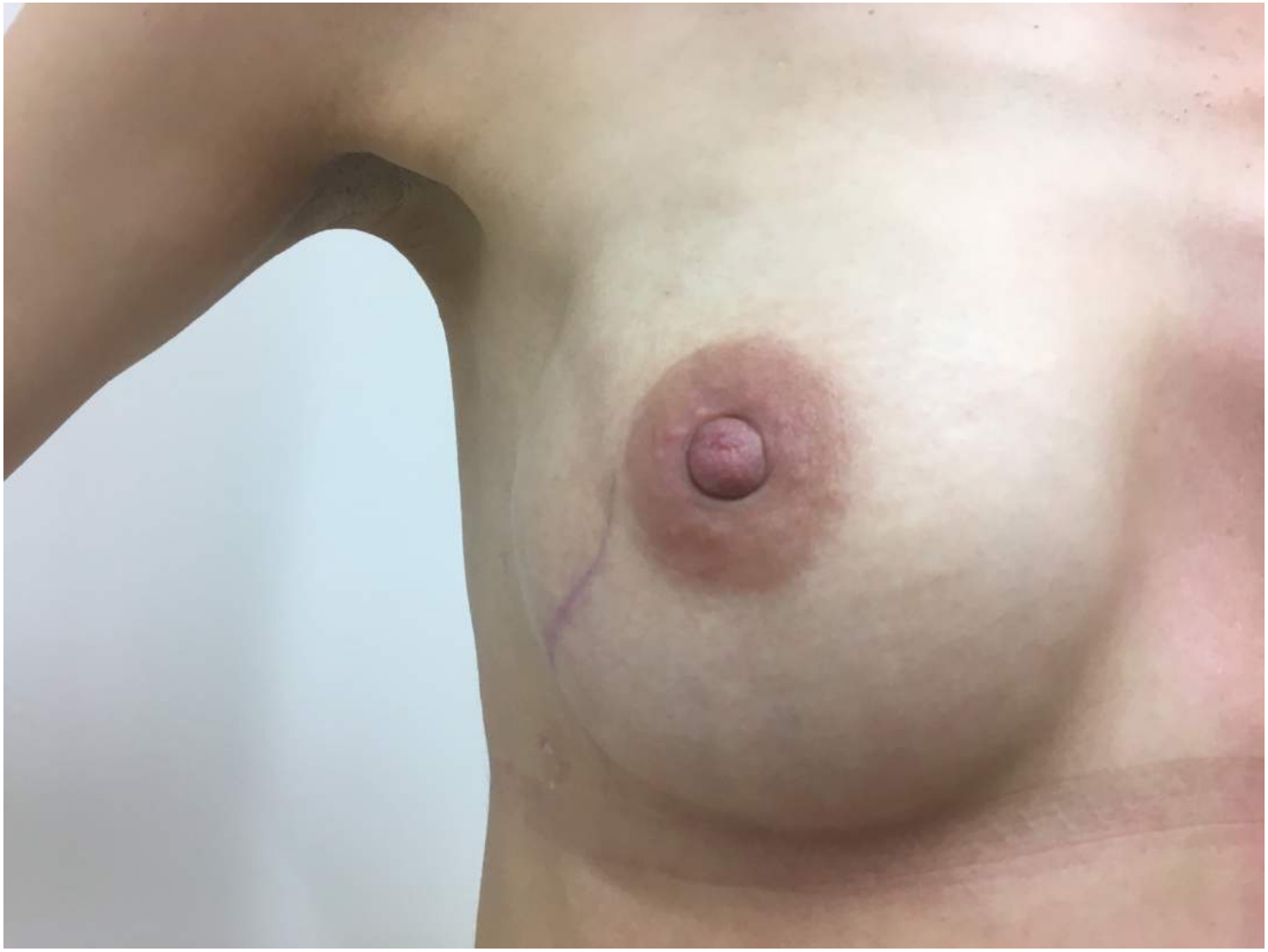


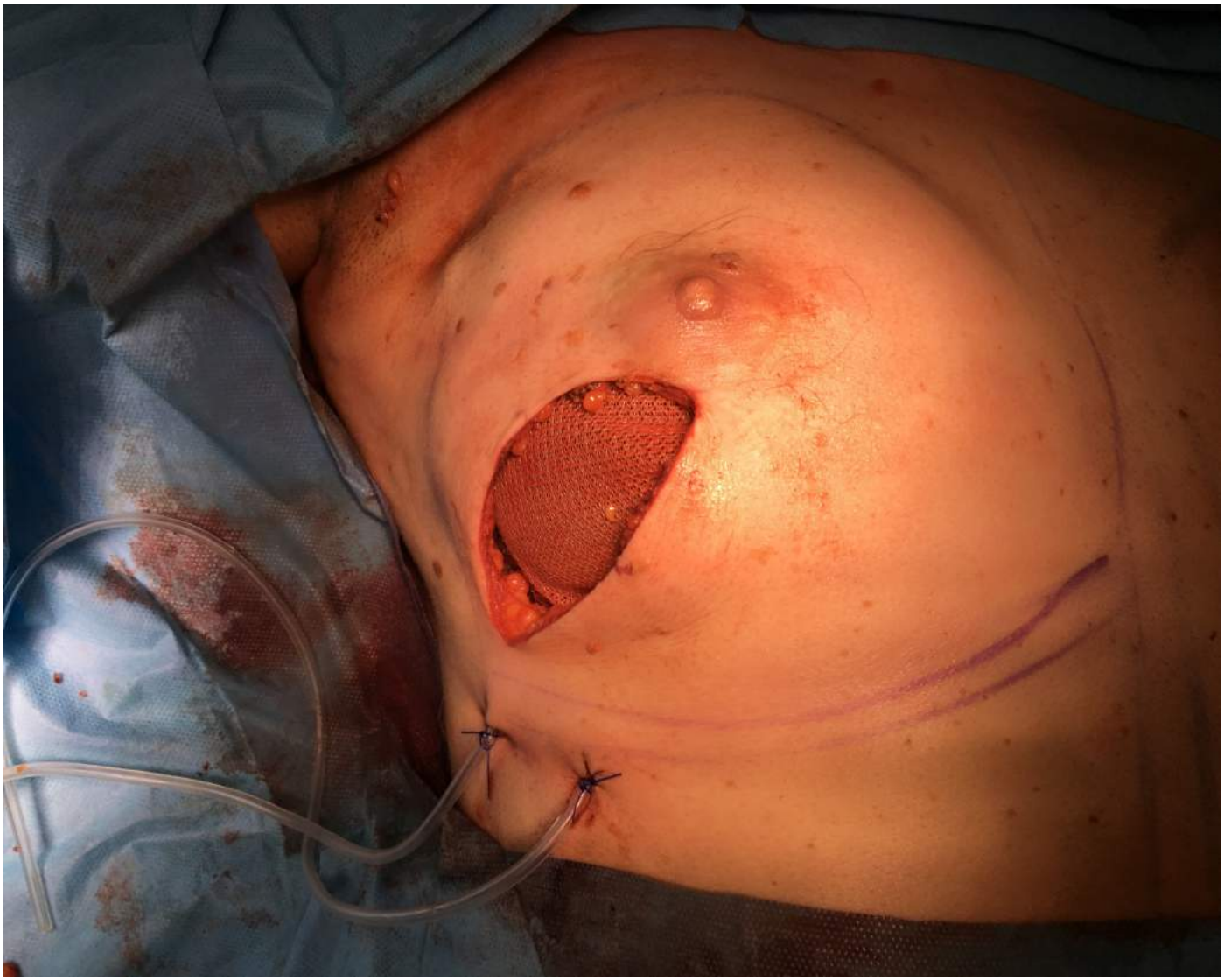


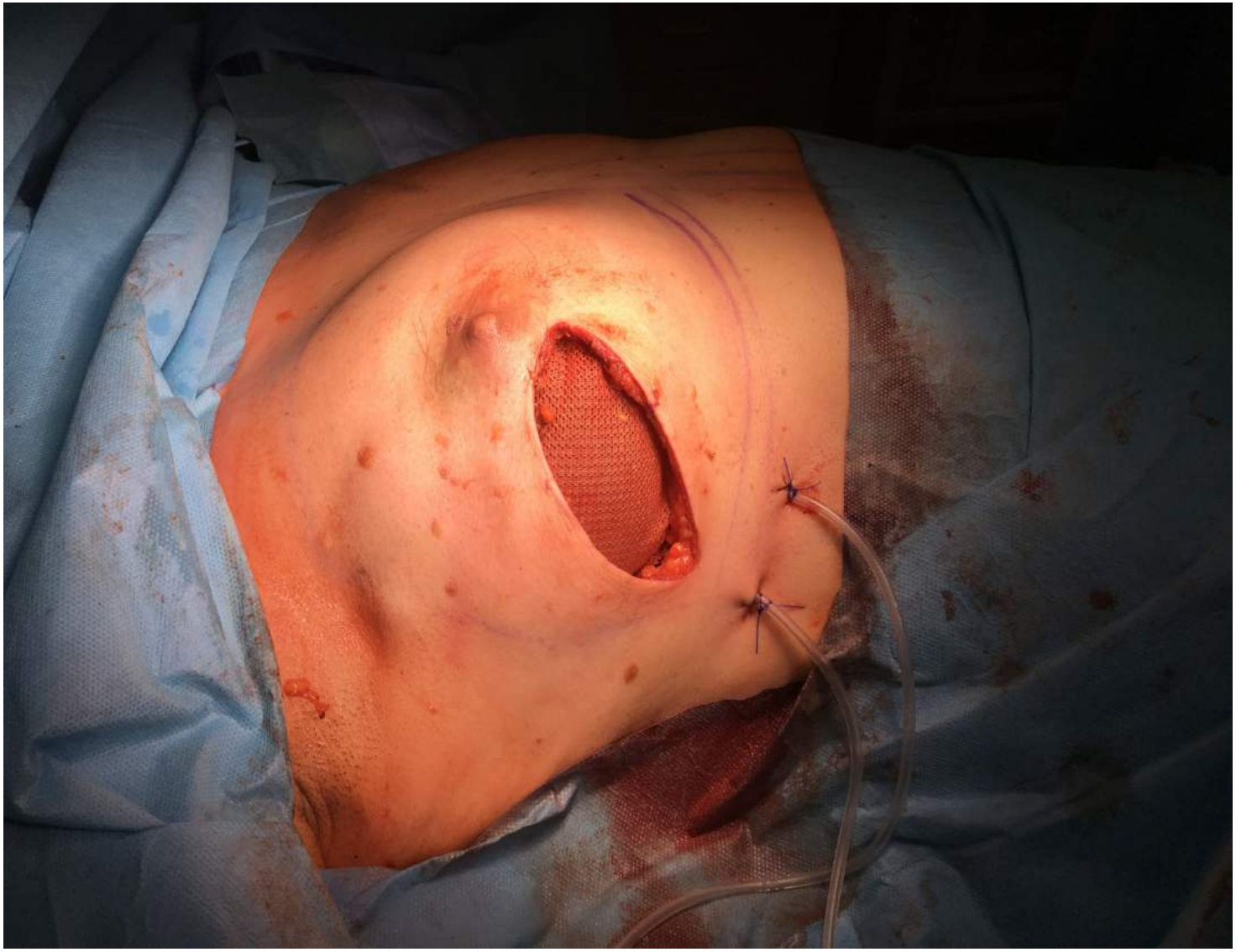


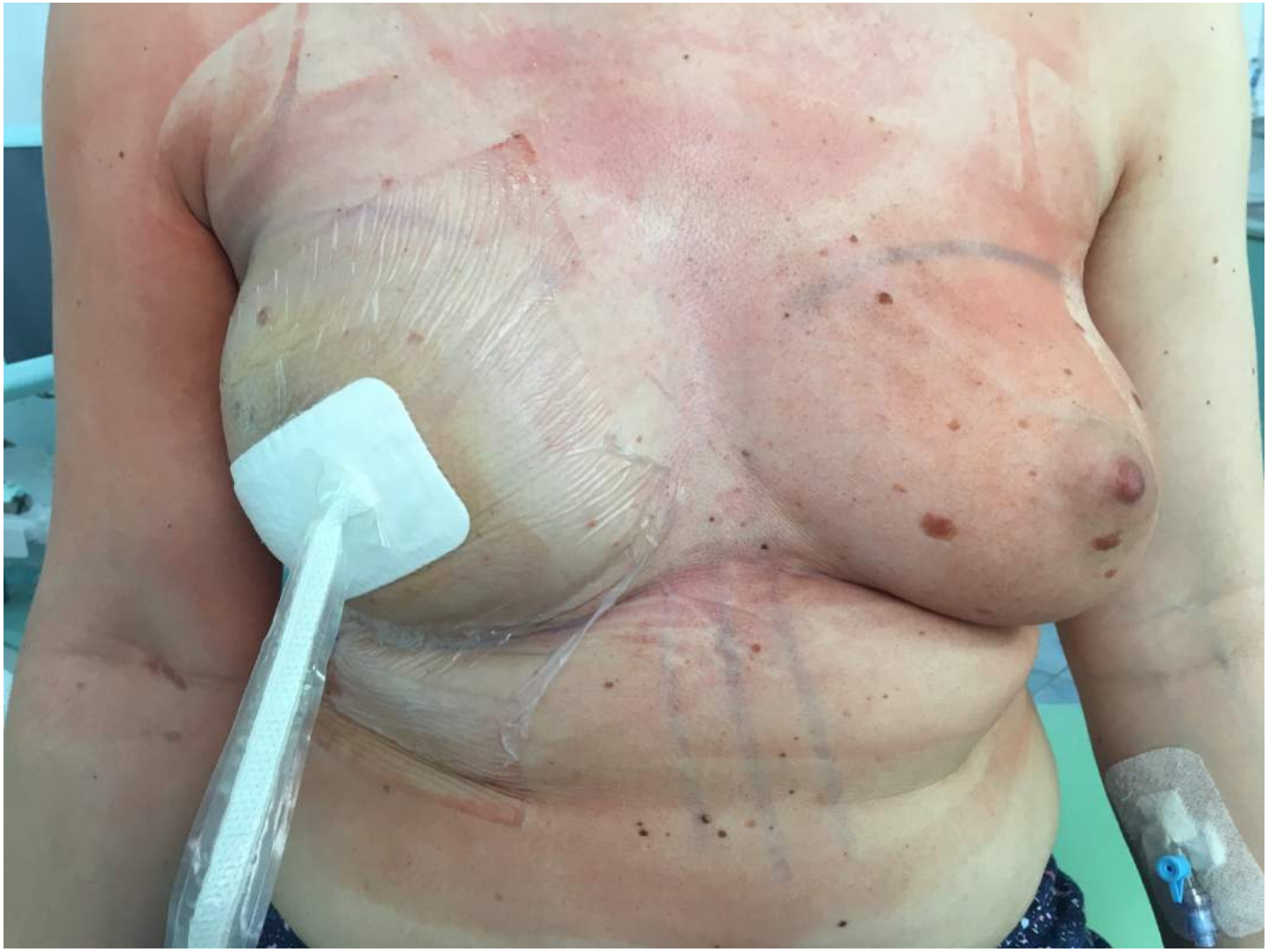


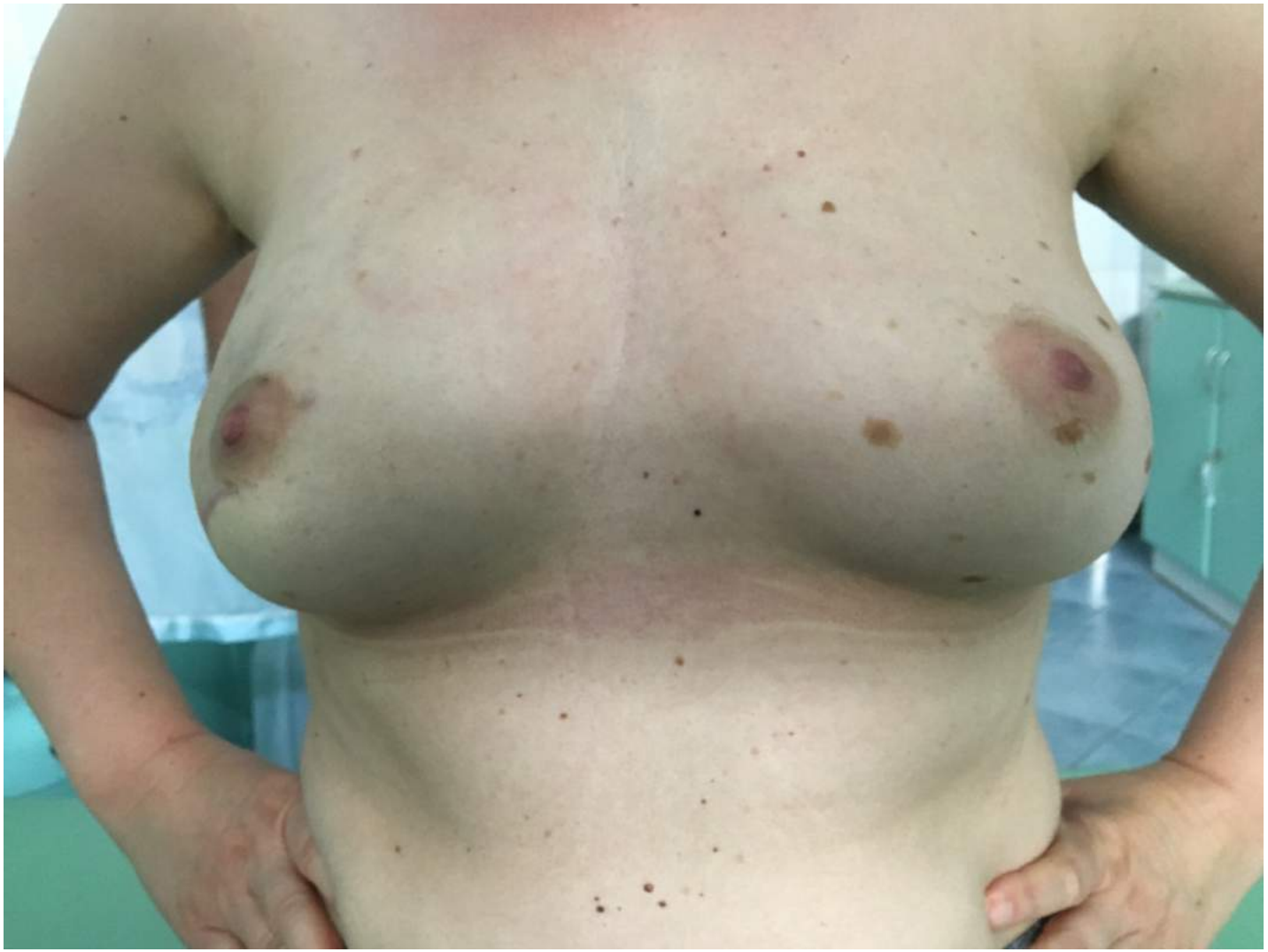


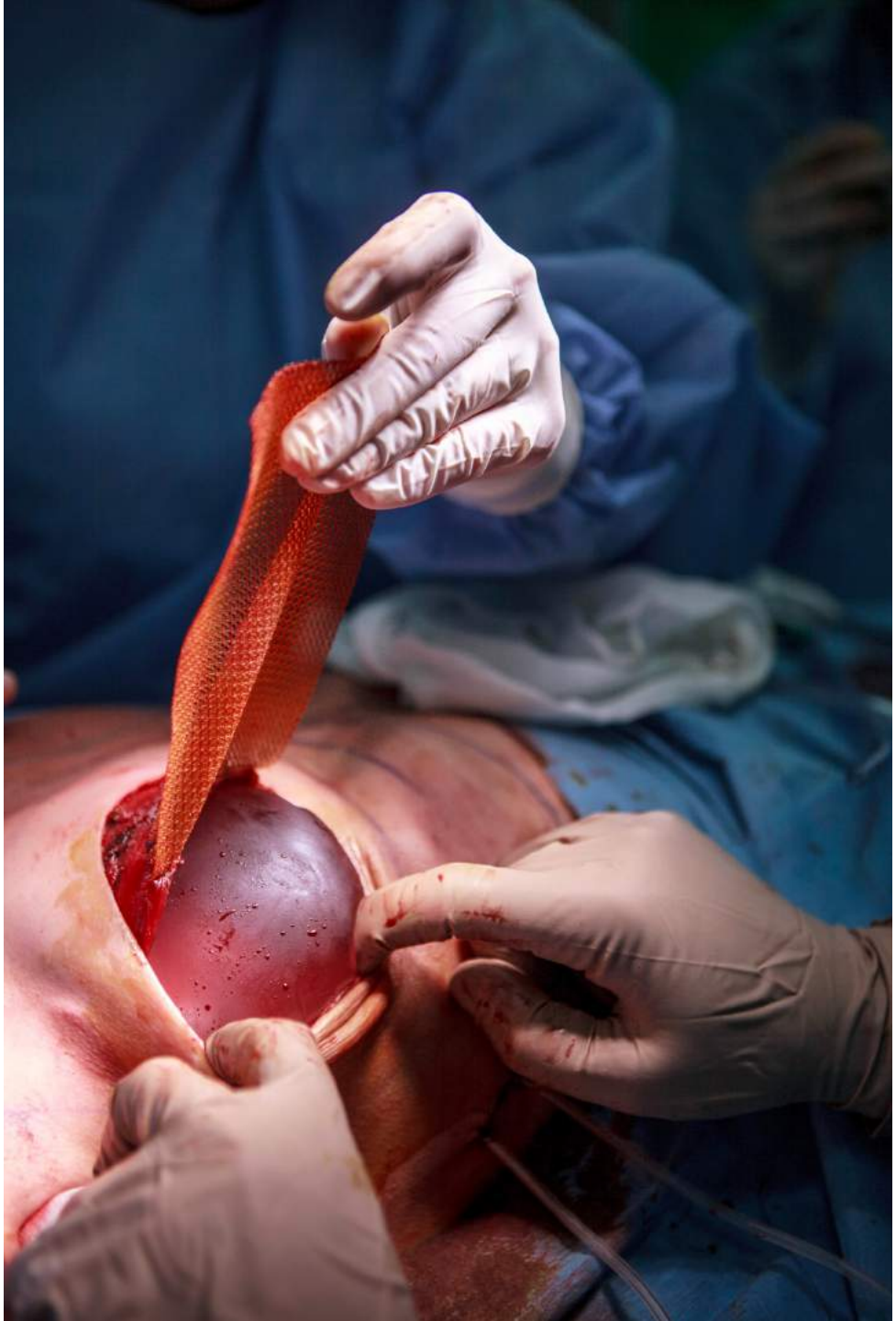


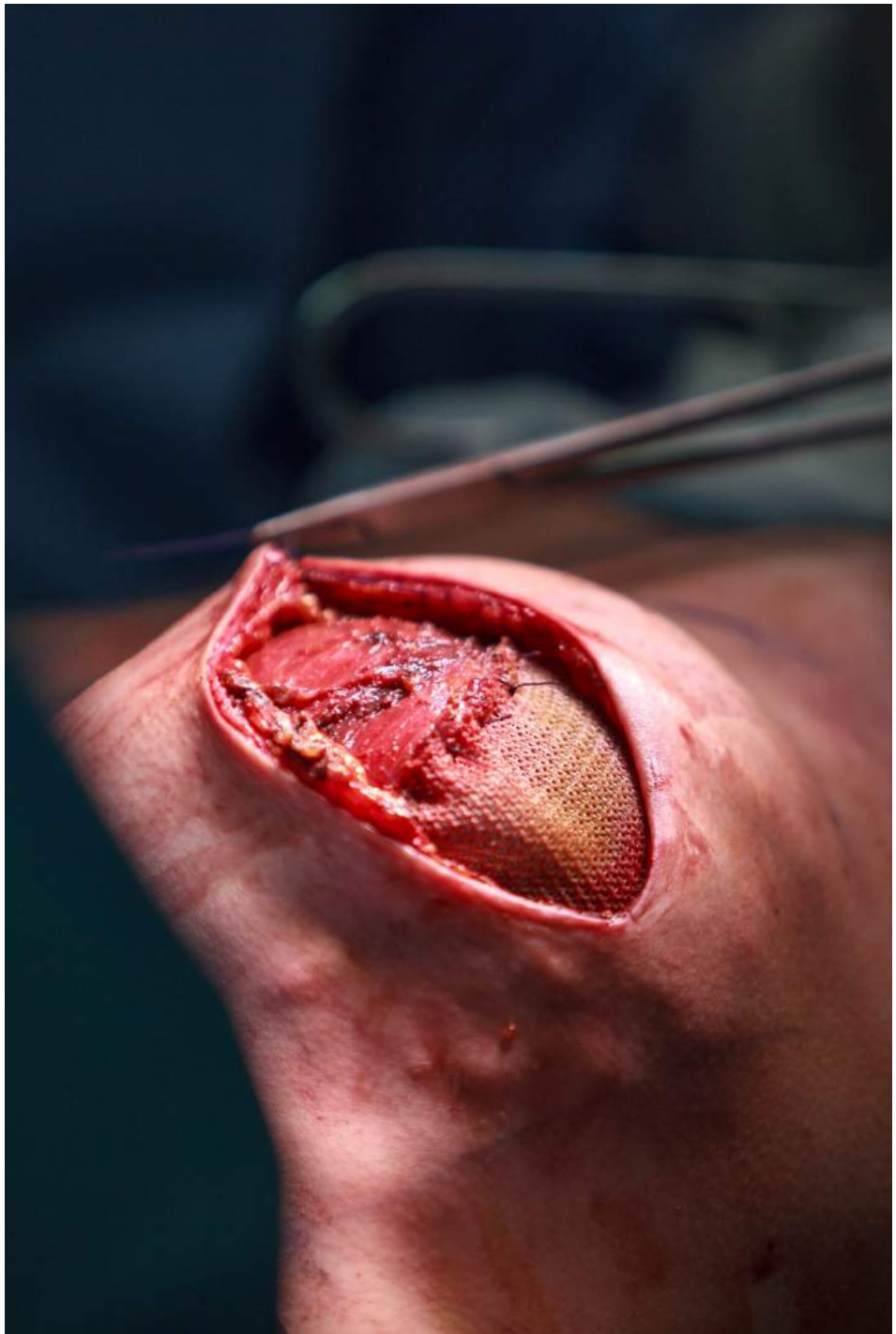


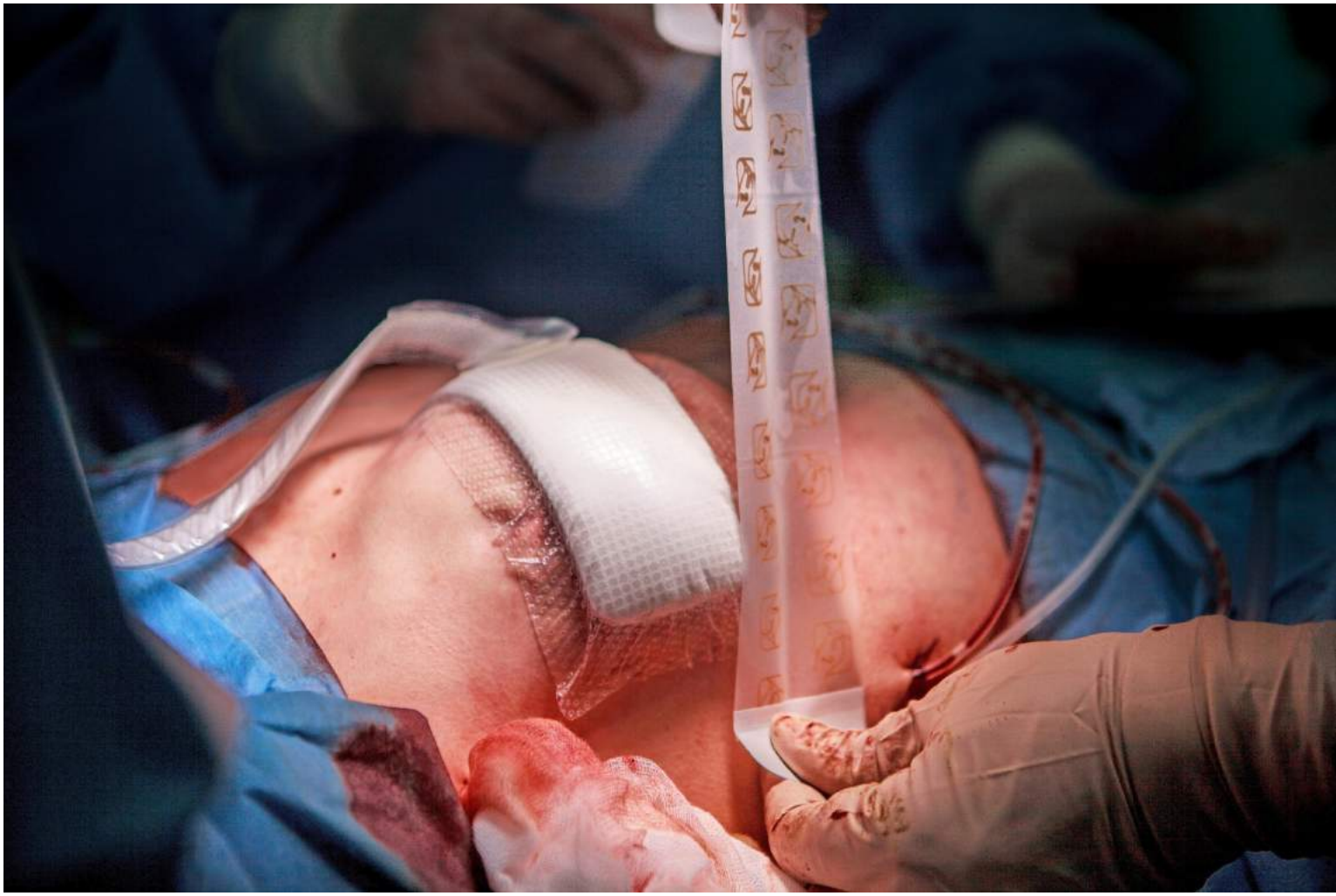


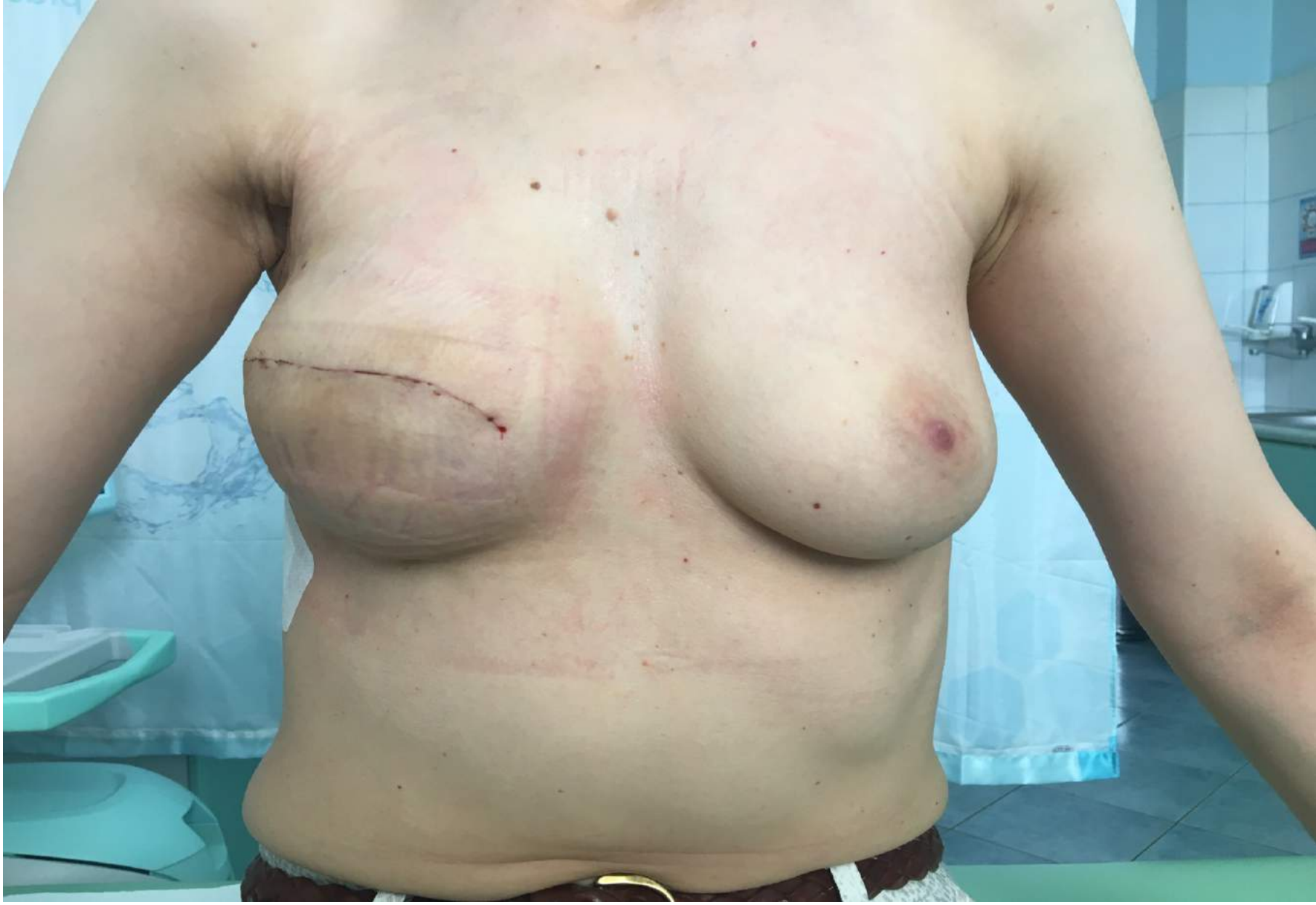










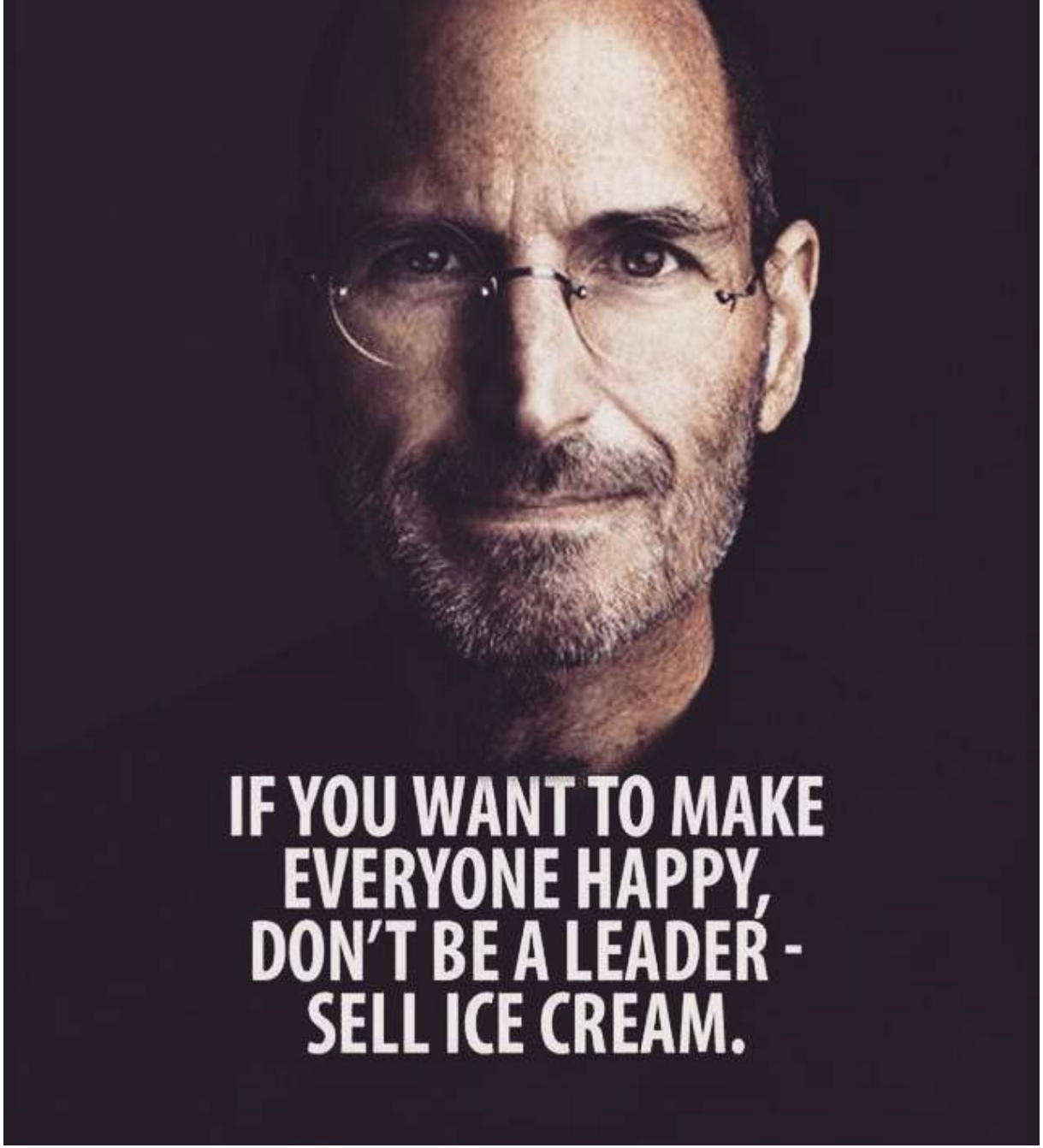


Is the choice obvious?

YES – we need reconstruction materials

NO – biological vs synthetic; still many questions !!!

- new products
- possible complications involve dependences: mesh/type of implant (texture, smoothness, nano-coating)
- individual assessment of each patient (breast size, thickness of adipose tissue, oncological treatment - radiotherapy?


IF YOU WANT TO MAKE
EVERYONE HAPPY,
DON'T BE A LEADER -
SELL ICE CREAM.

OPEN

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VIEWPOINT

A Novel Technique of Breast Reconstruction: Inflation of Breast Tissue Expander with Air

Matthew Green, MbChB; Habib Tafazal, FRCS; Raghavan Vidya, FRCS

Maybe the new way??????????????

One of the biggest problem for reconstruction

Chung et al. Systematic Reviews (2019) 8:58
https://doi.org/10.1186/s13643-019-0958-z

Systematic Reviews

PROTOCOL Open Access

The effect of post mastectomy radiation therapy on breast reconstruction with and without acellular dermal matrix: a systematic review and meta-analysis protocol

Amy M. Chung[1*], Michael J. Stein[2], Ammara Ghumman[2] and Jing Zhang[1,2,3]

Thank you for your attention