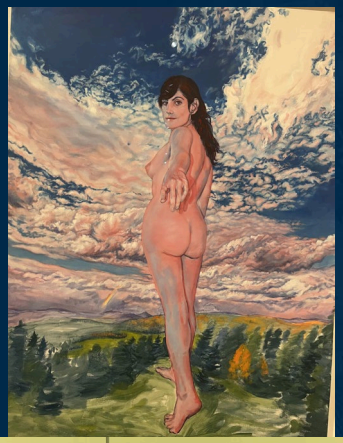
Klinikum rechts der Isar
Technische Universität München

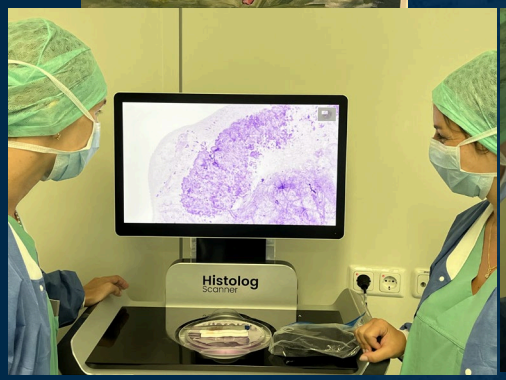
2023

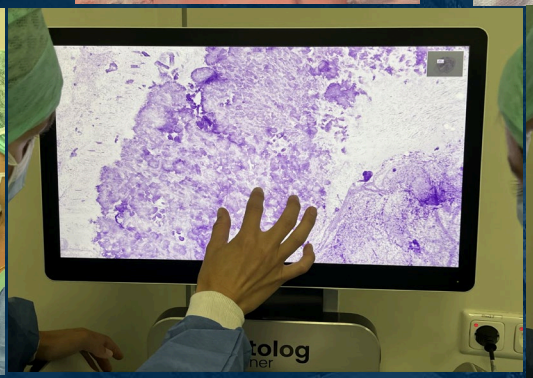
Navigating the Frontier: The Next Era of Intraoperative Assessment

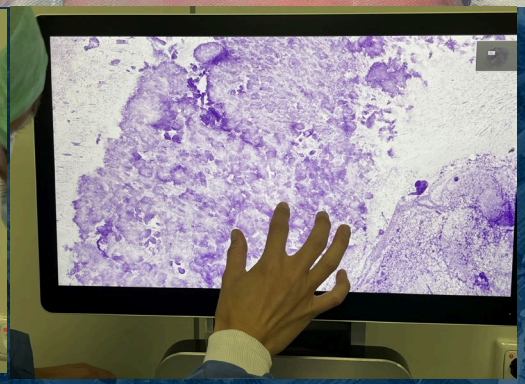
Stefan Paepke – Technical University Munich

Utrecht 2023









Next Era ?

- BCS
- NSM
- Lymph Nodes

The Margin Issue – Intraoperative Margin Assessment

Foreward-Back-Foreward....

Does margin involvement increase distant recurrence after BCS?

NICE and ABS (2009) recommended re-excision for patients with margins<1mm

One in Four patients who develop local recurrences die of their breast cancer

Houssami et al. (2010) in 28,162 patients found increased local recurrence(LR) with involved margins, but did not examine distant recurrence and included a smaller number of LR events

ASCO/ASTRO (2014) recommended no Tumour on Ink margins using a meta-regression analysis where both margin status and threshold margin distance were included as covariates in the model for the effect on local recurrence. **Effe of margin status (e.g. the OR for positive vs. negative margins) was assumed to be similar for any threshold margin distance.**

POSH UK 2017 study found 20% patients had tumour <1mm from the margin and margin involvement was associate with increased distant recurrence

ICE 2018 stated lack of evidence surrounding margin widths and local recurrence(based on 8 articles)!

Aim

o identify whether tumour distance from margin leads to distant and local recurren

The Margin Issue

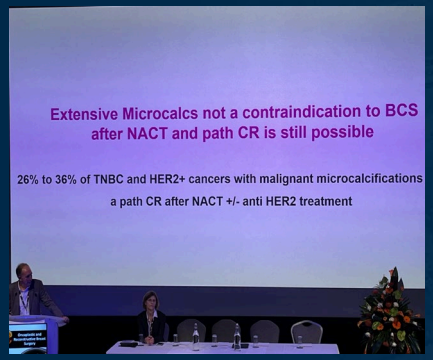
ore about reoperations from the NABCOP

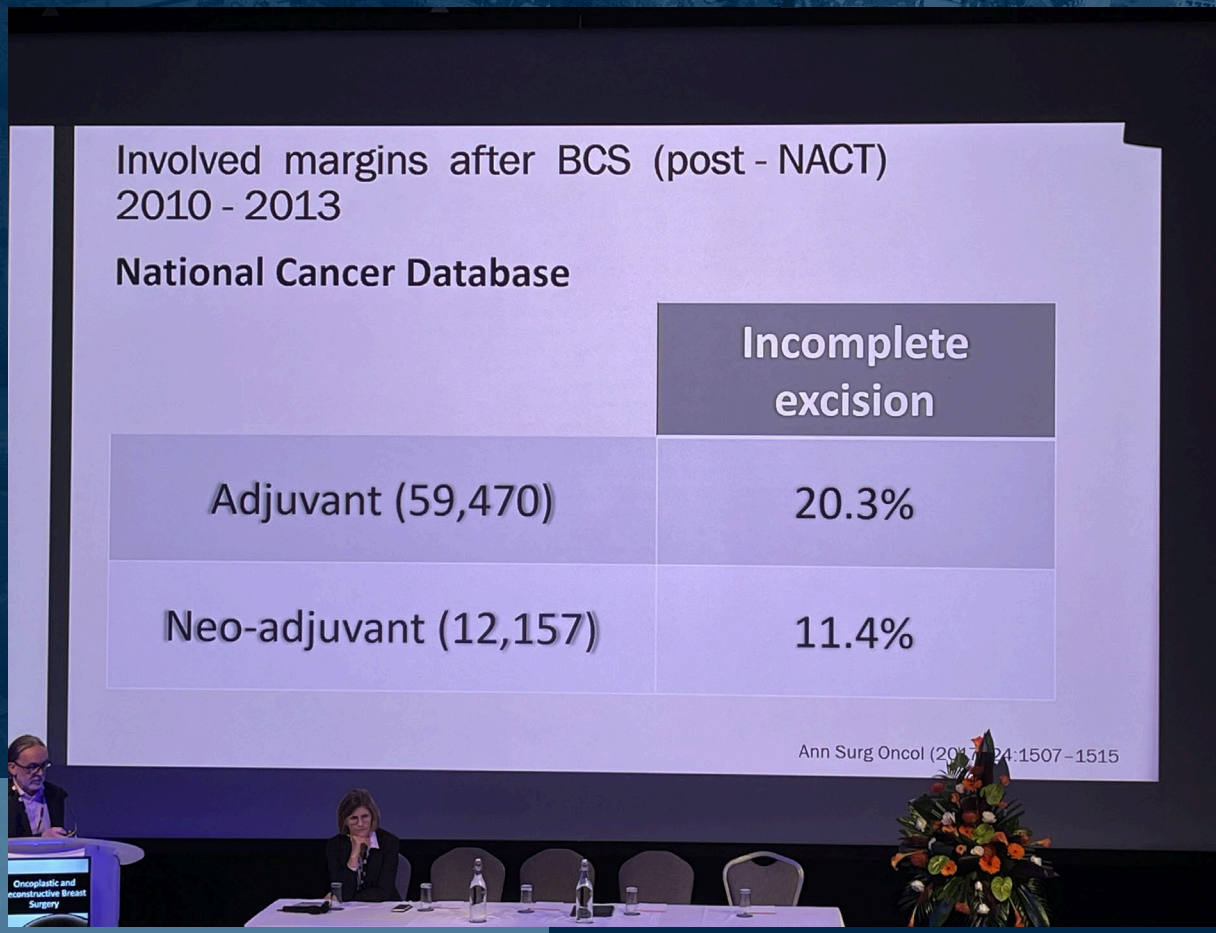
Reoperation rates increased with larger umour size and igher nodal volvement

	Total pts having initial BCS	% reoperation (95% CI)
Tumour size (cm) – EIBC only		
0.1-2	68524	10.9% (10.6-11.
2-5	28735	16.9% (16.5-17.
5+	1148	40.5% (37.6-43.
Number of nodes involved – EIBC only		
0	77188	12.0% (11.8-12.
1-3	16626	17.0% (16.4-17.
4+	2289	22.5% (20.8-24.
Risk group (based on TN stage)		
DCIS	17521	24.5% (23.9-25.
Low risk EIBC	86207	11.8% (11.6-12.
Intermediate risk EIBC	21040	16.5% (16.0-17.
High risk EIBC	3102	22.9% (21.5-24.

,N0; Intermediate risk = T3,N0 or T1-2,N1; High risk = T1-2,N2 or T3,N1-2

IMA – Utrecht 2023

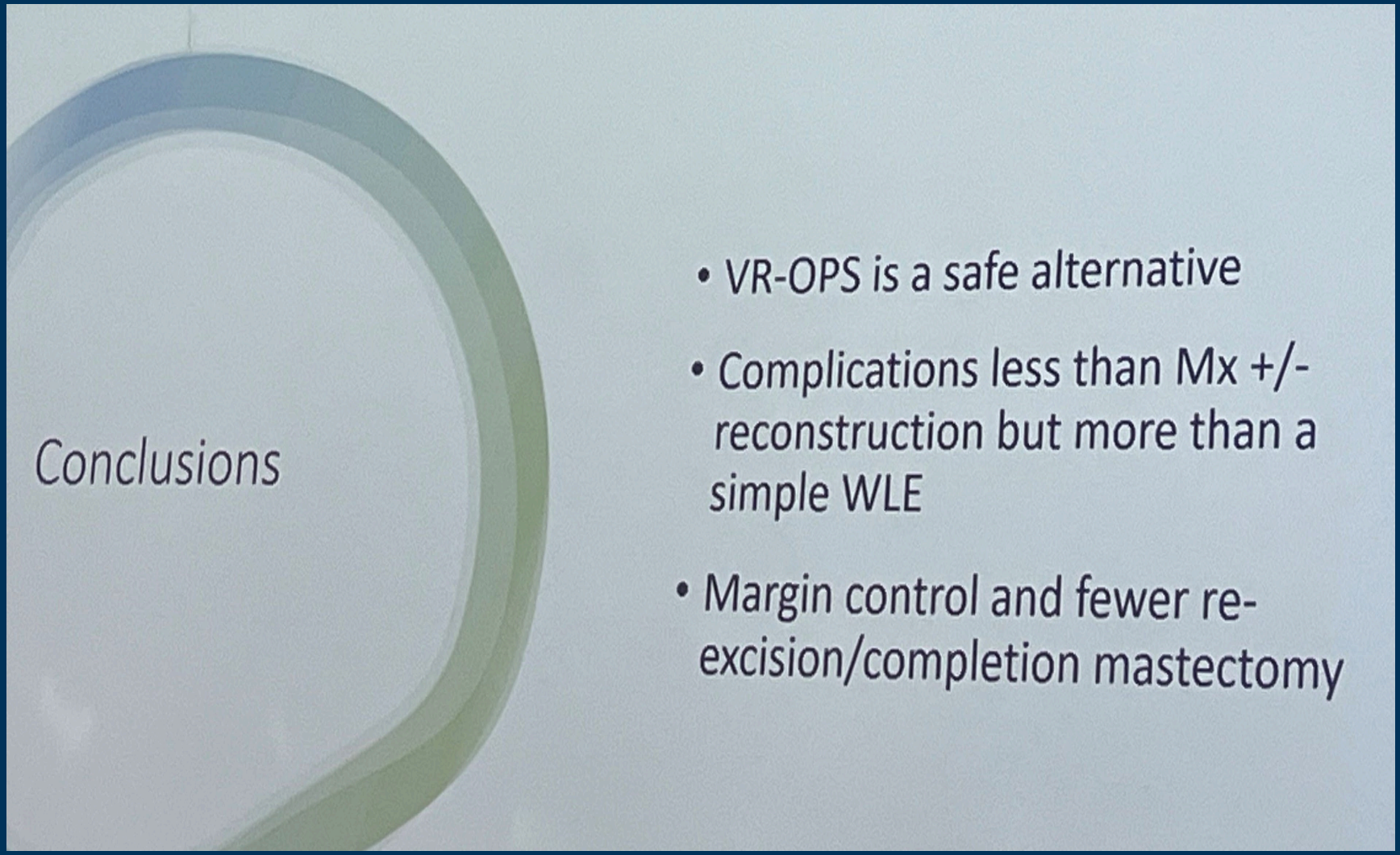




ISSUE

OPS
PST versus adj CTX R1 .

Oncoplastic Surgery



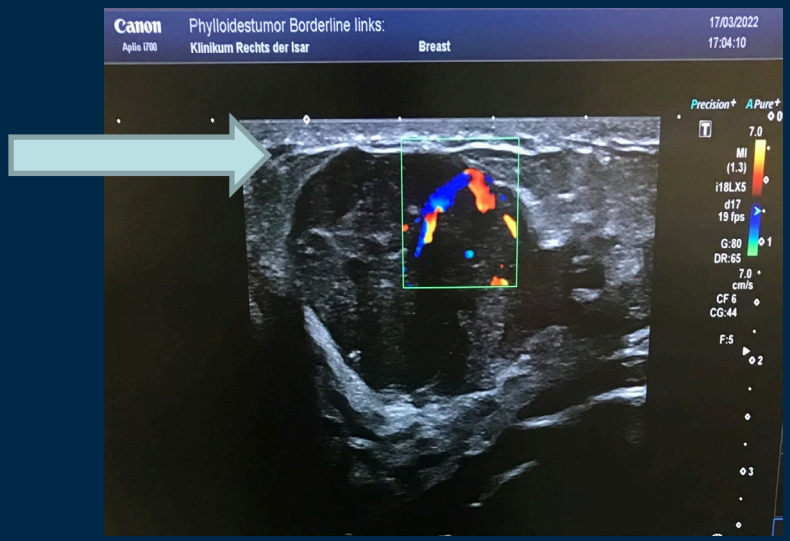
Involved Margins in Breast Conserving Surgery: 10-40%

invasives NST:	R1 ~ 5-10%
invasives NST + DCIS:	R1 ~ 12-25%
invasiv-lobuläres CA:	R1 ~ 15-35%
DCIS:	R1 ~ 15 -40%

Involved Margins in Nipple Sparing Mastectomies PRO-Bra trial (PRO-Bra-Trial (2013-2017) clinicaltrials.gov: NCT01885572, DRKS00005342; **subpectoral** implant placement; 2013 -2017

R1-rate in 362 breasts (269 patients): **12,4%** (n= 45).

IOUS

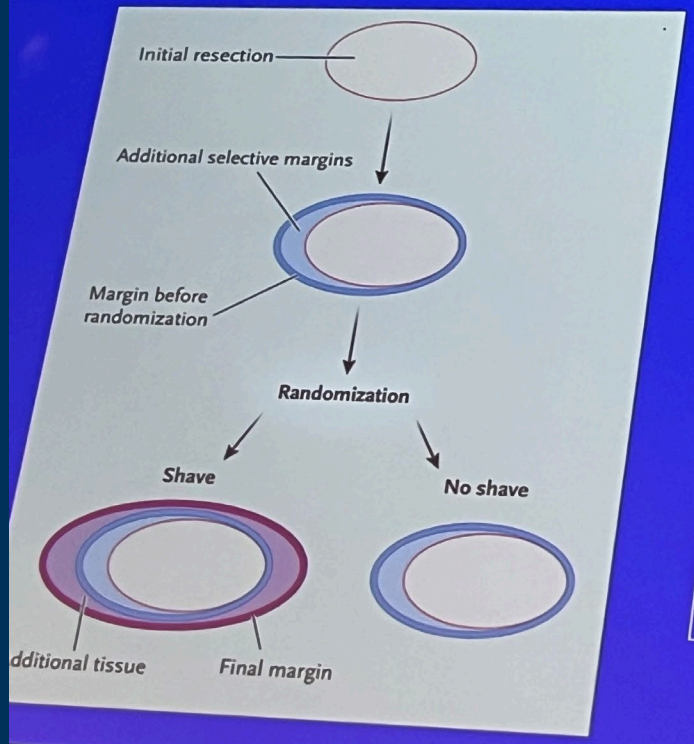

Canon
Aplio i700
Phylloidestumor Borderline links:
Klinikum Rechts der Isar
Breast
17/03/2022
17:04:10
Precision+
APure+
7.0
MI
(1.3)
i18LX5
d17
19 fps
G:80
DR:65
7.0
cm/s
CF 6
CG:44
F:5


Aplio i700
Canon
Phylloidestumor Borderline links:
Klinikum Rechts der Isar
Breast
17/03/2022
17:04:38
AP:100%
Canon

IOUS

Shaving- Technik

Margins
RCT of cavity shave vs usual care



	cavity shave n=119	usual n=116
margins+ pre-random.	36%	34%
rate margins+	19%	34% p=0.01
rate re-excision	10%	21% p=0.02

Chagpar A et.al. New Engl J Med 2015;373:503-

Histolog Scanner

a revolution for intraoperative diagnostics

Cédric Trabucatti, SamanTree Medical, VP Marketing and Sales

Mikulov 2023

SamanTree
Medical SA

Real-time Fresh Tissue Analysis

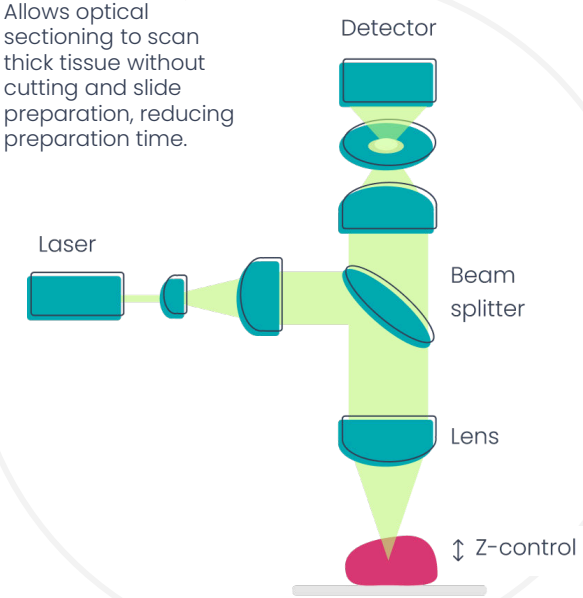
-> Guide **treatment plan & reduce delays**

Complete **digital solution** with **AI** algorithm & **software**

Already changing the game in **clinical workflow digitalization**

Novel ultra-fast confocal technology

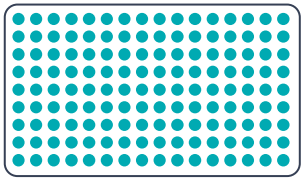
Confocal microscopy
Allows optical sectioning to scan thick tissue without cutting and slide preparation, reducing preparation time.



Micro-optics
Confocal microscopy was miniaturized using micro-optics (EPFL, 2010)

- miniaturized

30’000 micro-objectives
To enable real-time large specimen scanning with the Histolog Scanner

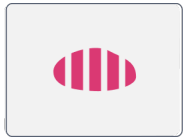


Alternative to FSA

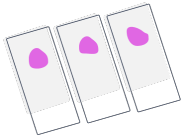
Standard steps to getting the gold standard*

☐ **Point of care assessment**

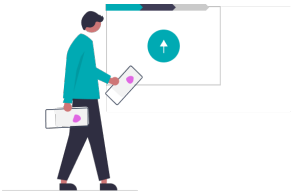
Send specimen to pathology lab or send pathologist
Inefficient



Specimen processing
Cutouts prone to sampling effect



Slide mounting and inking
Requires complex infrastructure and is a slow process

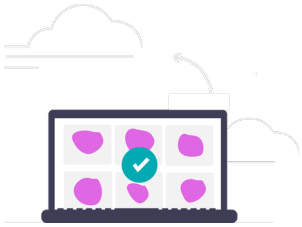


Manual digitization
Expensive

Histolog steps to getting the gold standard

☑ **Point of care assessment**

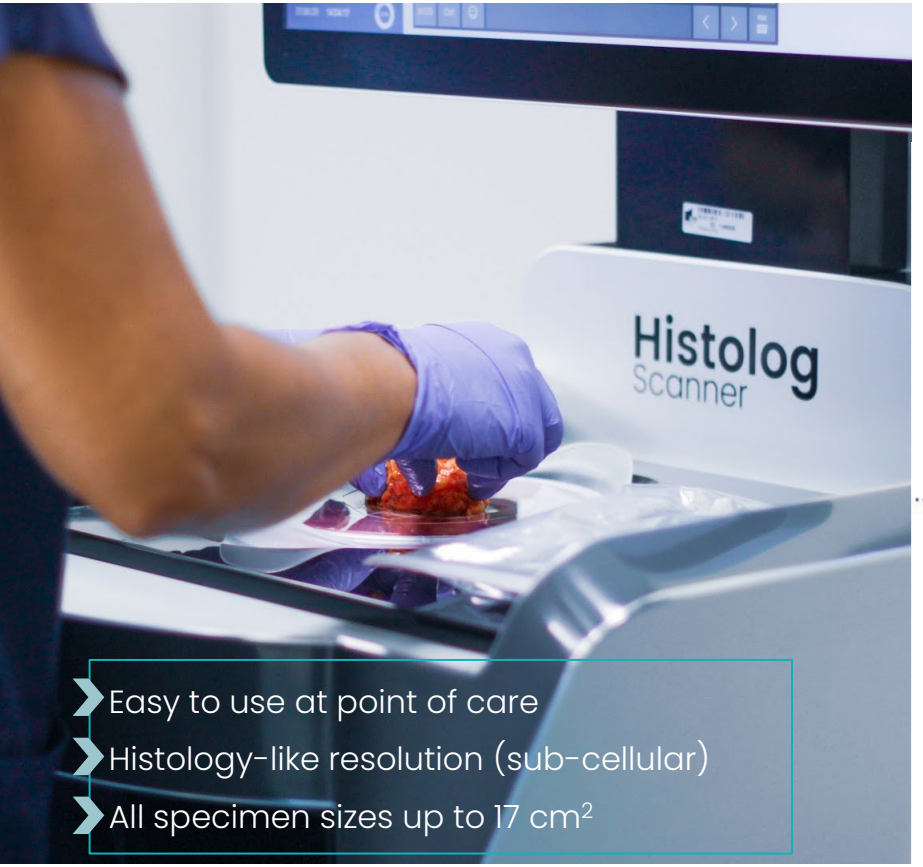
Fresh specimen scanning
In a minute during surgery



Digital images
DICOM and remote workflow easily available

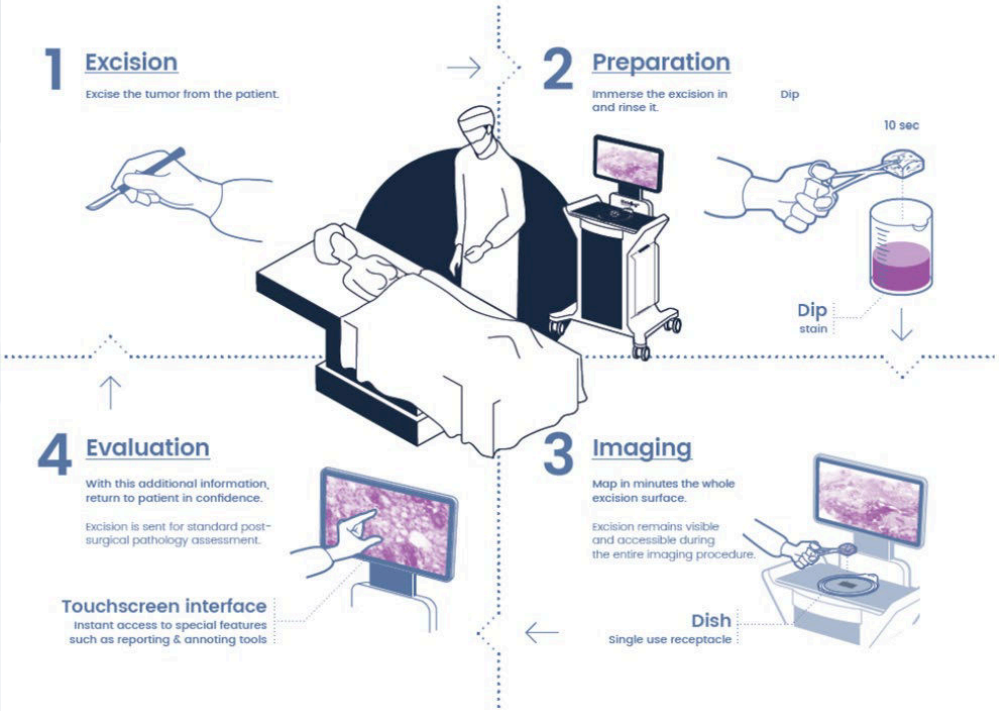
The Histolog® Scanner

Breakthrough margin assessment technology



- Easy to use at point of care
- Histology-like resolution (sub-cellular)
- All specimen sizes up to 17 cm^2

Ex vivo imaging for improved decision-making



Clinical data highlight

The Histolog Scanner has been utilized on 2200 patients, where it has proven to be instrumental in enhancing cancer treatment outcomes

Breast	**800+** patients **22** centers	• Sensitivity >75% and specific >85% • Up to 75% reduction re-operation rate • Adaptable to any clinical workflow
Prostate	**250+** patients **3** centers	• Sensitivity >90% and specific >90% • Results in ~8' versus >45' with NeuroSAFE • Usable in autonomy or via remote workflow
Skin	**500+** patients **5** centers	• **Same performance as FSA:** 80% sensitivity on BCC and 100% specificity • **Drastic time saving:** Results in ~5 minutes versus >30 minutes • **Easy preparation:** No glass slides, 15 seconds preparation
Pathology	**200+** patients **4** centers	• **Triage:** Whole scanning of blocks in minutes • **Easy preparation:** No glass slides, 15 seconds preparation
Brain	**50+** patients **1** center	• **Alternative to FSA:** Comparable performances (S&S >90%) • **Drastic time saving:** Results in minutes, enable multiple assessments • **Easy preparation:** No glass slides, 15 seconds preparation
Others	**150+** patients **6** centers	• **Alternative to FSA:** Comparable performances • **Drastic time saving:** Whole specimen scanning in minutes • **Easy preparation:** No glass slides, 15 seconds preparation

Key partners

GUSTAVE ROUSSY CANCER CAMPUS GRAND PARIS

Technische Universität München

HEIDELBERG UNIVERSITY HOSPITAL

NHS University College London Hospitals NHS Foundation Trust

CWZ

CHUV

Universitätsklinikum Tübingen

NHS Guy's and St Thomas' NHS Foundation Trust

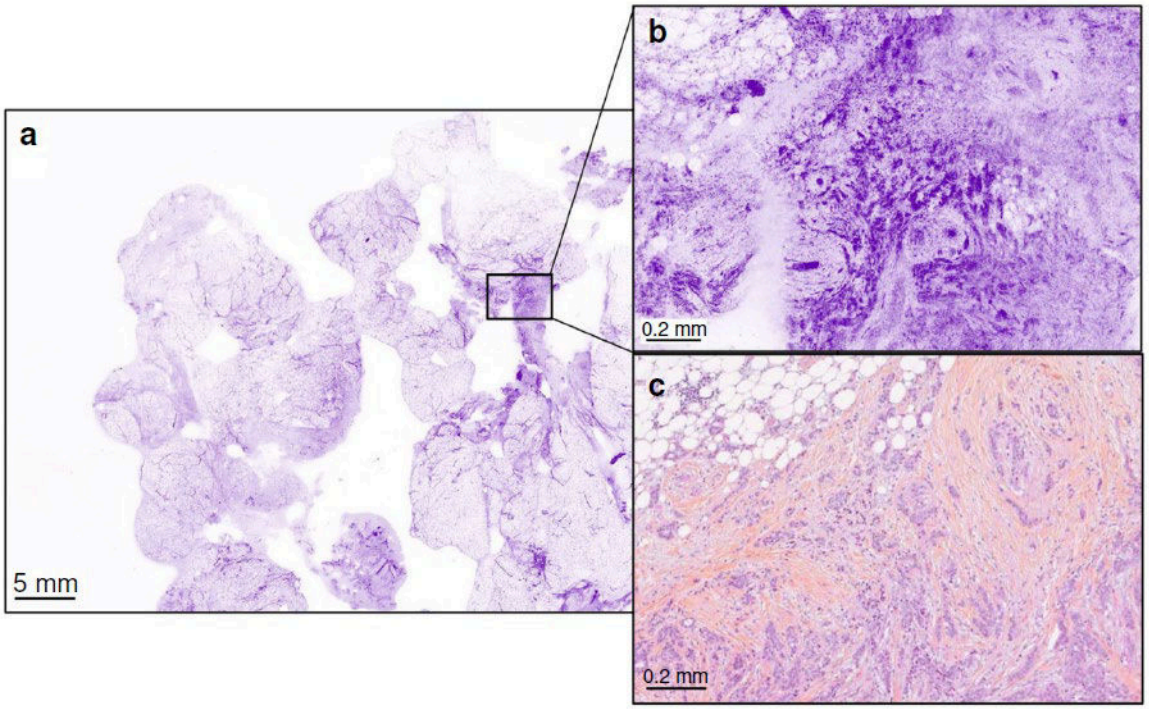
SERVIZIO SANITARIO REGIONALE EMILIA-ROMAGNA Aziends Unità Sanitaria Locale di Reggio Emilia

NHS The Leeds Teaching Hospitals NHS Trust

Erasmus MC University Medical Center Rotterdam

Breast atlas

Cancer tissue



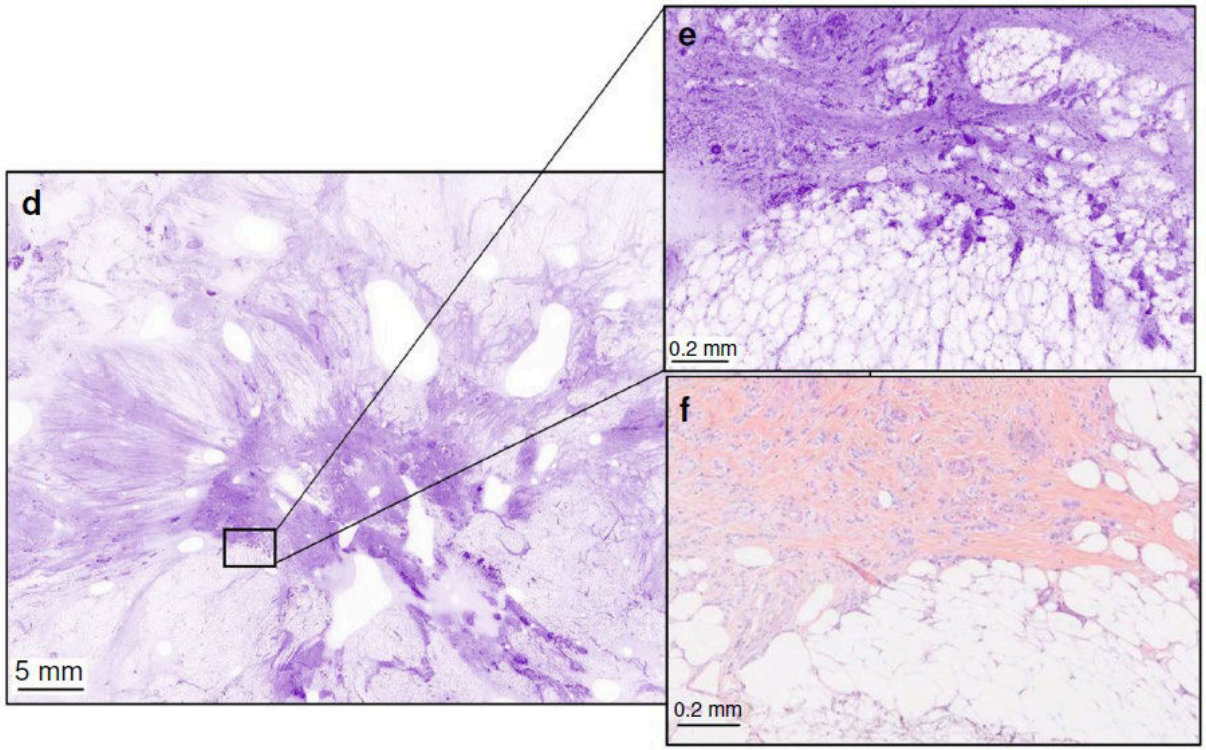
Same morphological criteria defined in histopathology such as tissue architecture and cell features can be applied to describe Histolog images

Invasive ductal carcinoma

Strongly disorganized area with a high density of Tumor Nests mixed with Indian Files and bright single-cell nuclei

Breast atlas

Cancer tissue



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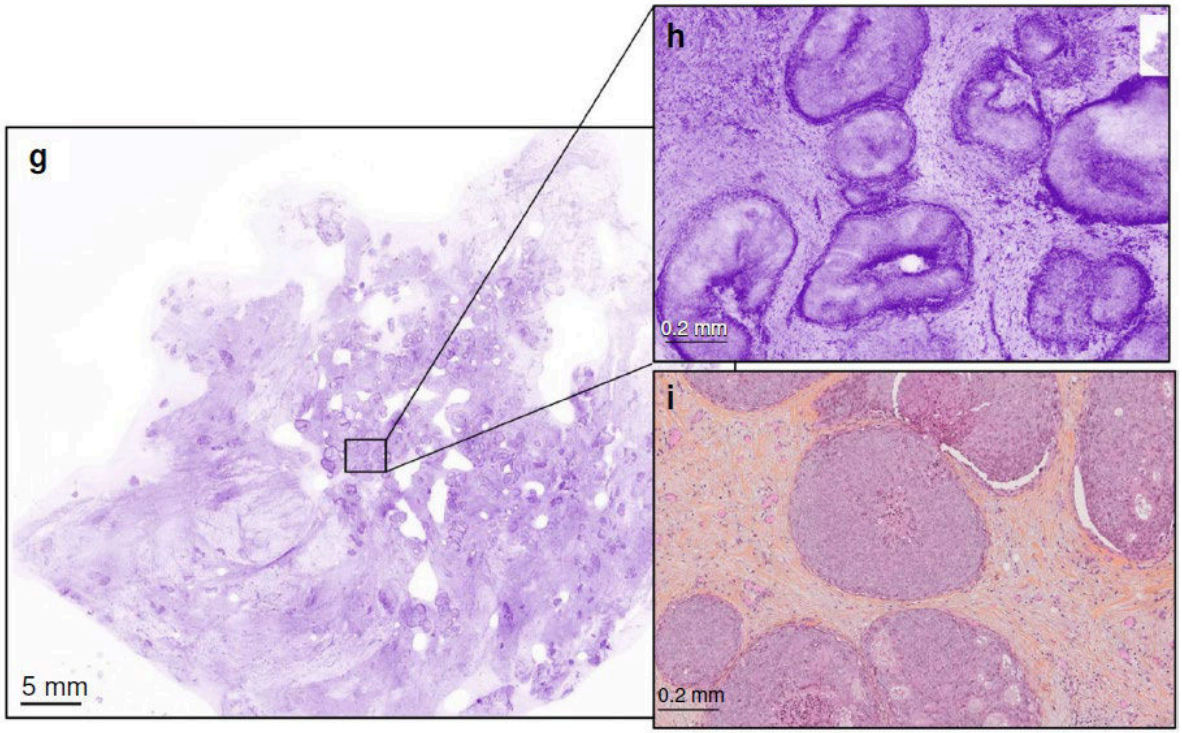
Invasive lobular carcinoma

High density of single cancer cells either haphazardly distributed, or organized under Indian file patterns

Breast atlas

Cancer tissue



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Ductal Carcinoma in situ

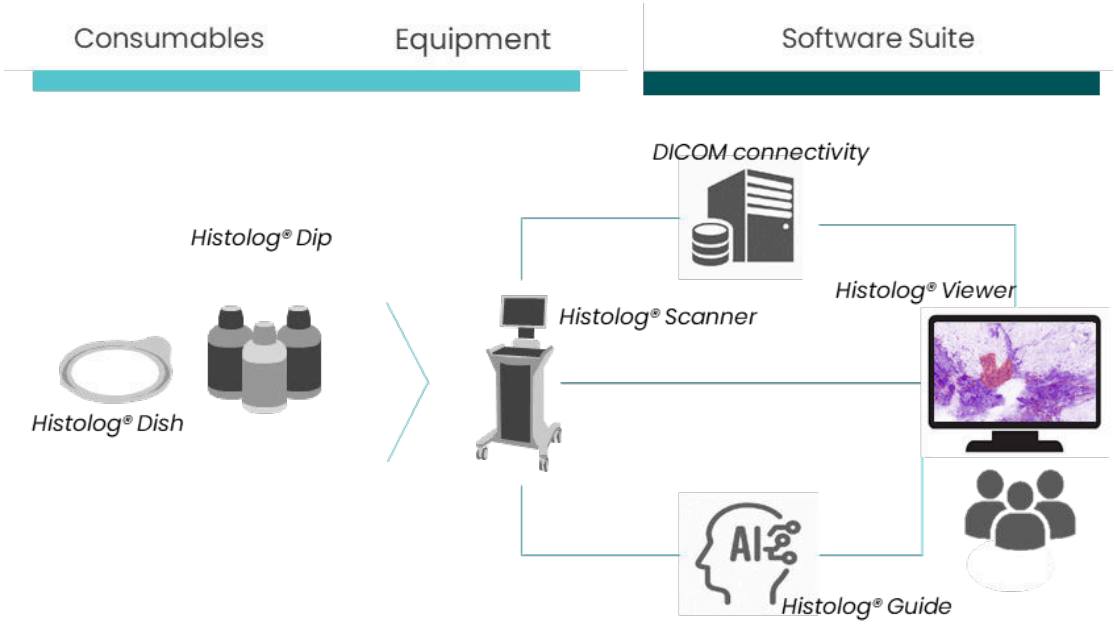
roundish patterns delimited by well-defined borders usually with a strong purple coloration. These patterns are ducts filled with cancerous cells that may be larger than normal cells

Histolog® Digital Solution

reddot winner 2020

CE mark

20 issued patents



Complete proprietary ecosystem & Digitalization of the workflow

- Connected surgery and digital pathology
- Compatible with current clinical workflows

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Involved Margins in Nipple Sparing Mastectomies

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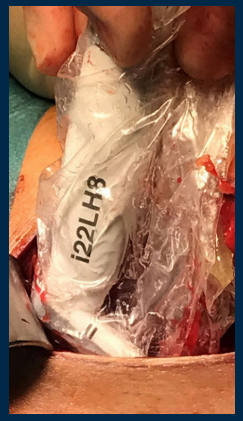
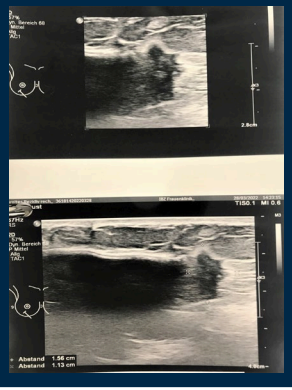
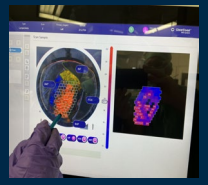


How **To make it better:**

Precise (guided) Radical
Dissection
Intraoperative Direct
Margin Assessment





TiLOOP®Bra supported Pre-Pec Breast Reconstruction

minimized harm

aesthetic

functionality in daily doings & profession