

# BREAST SURGERY, CANCER & LITIGATION

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Barts and QMUL London

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# WELCOME !

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- ‘The two unforgivable sins of surgery. The first great error is to operate unnecessarily; the second, to undertake an operation for which the surgeon is not sufficiently skilled technically’ .
- Max Thorek 1880-1960

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- ‘It is usually the second mistake in response to the first mistake that does the patient in’ .
- Clifton K Meador

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## Main areas of litigation

- **Breast cancer**
- Delay in diagnosis - value in USA was 2nd only to neonatal neurological damage
- Poor cosmetic outcome
- Reconstruction failure
  
- **Breast cosmetic & aesthetic surgery**
- Implants
- Poor outcomes

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## What is the breast?

- Anatomical structure
- Cosmetic structure
- Physiological
- Social
- Relationships
- Personal identity
- Significance in art and culture

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## Breast cancer

- Major health problem
- UK mortality amongst world highest with 28 deaths per 100 000 women per annum
- 1 in 9 UK women, > 40 000 new cases and 14,500 deaths per year

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## In the last 10-15 years

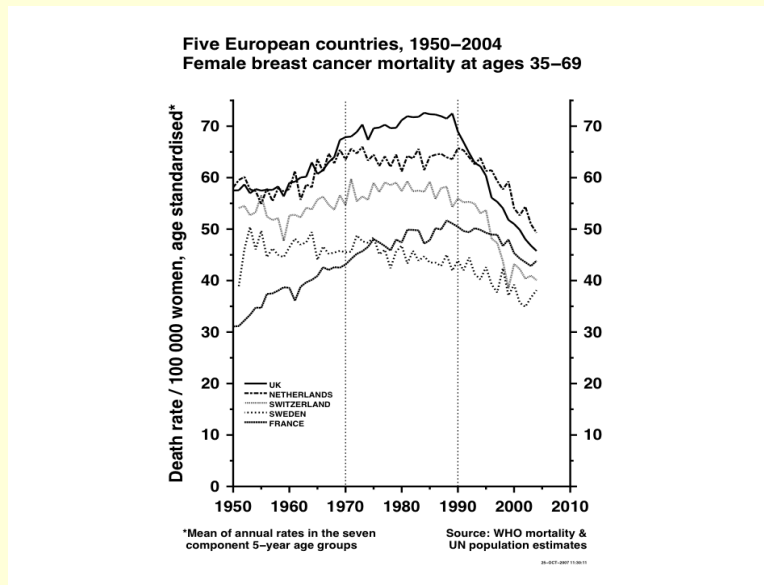
- Huge increase in understanding the biology
- Mechanisms of estrogen action
- Estrogen receptor blockers & now AIs
- Extensive operative surgery developments
- Multidisciplinary management
- More effective chemotherapy & radiotherapy
- Earlier diagnosis - NHS Breast Screening

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- Early detection
- Improvements in treatment
- Have led to a 30% reduction in UK breast cancer mortality over the last 20 years

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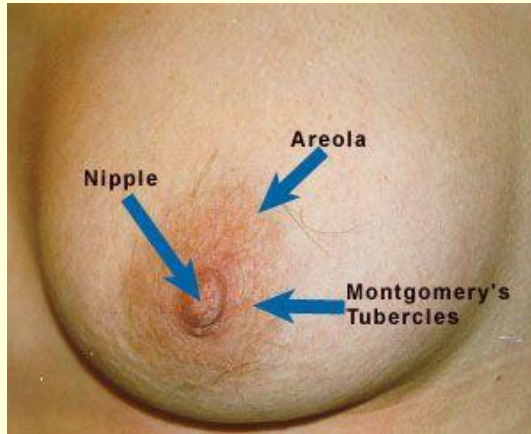
## Survival - Breast cancer mortality



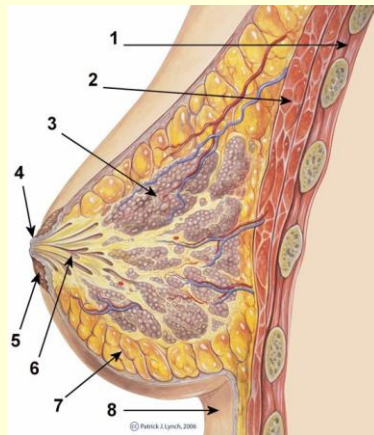
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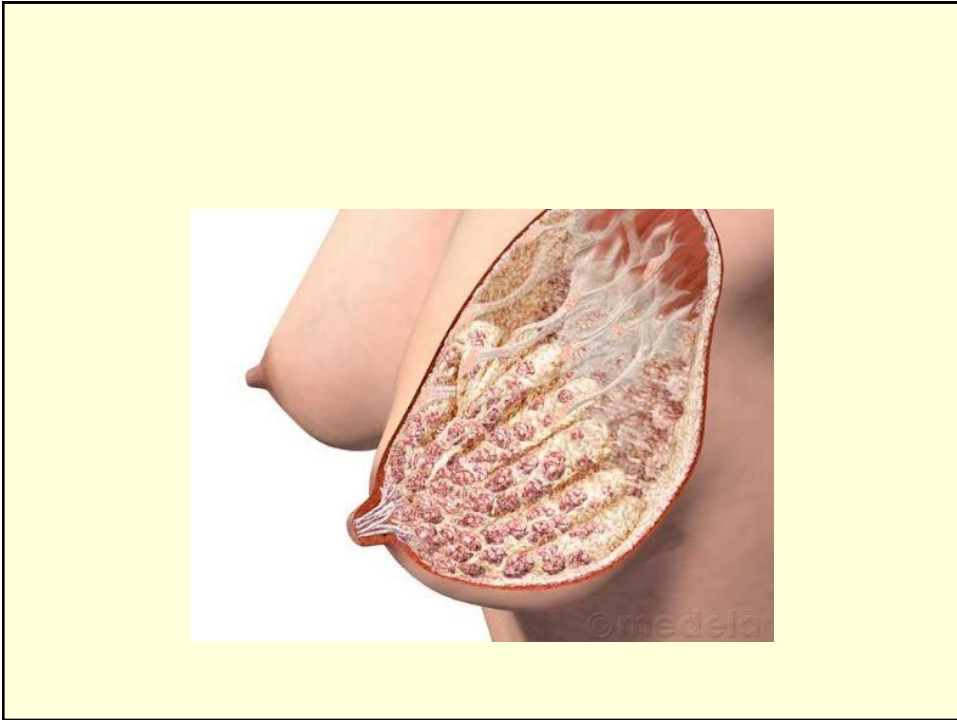
## The Breast



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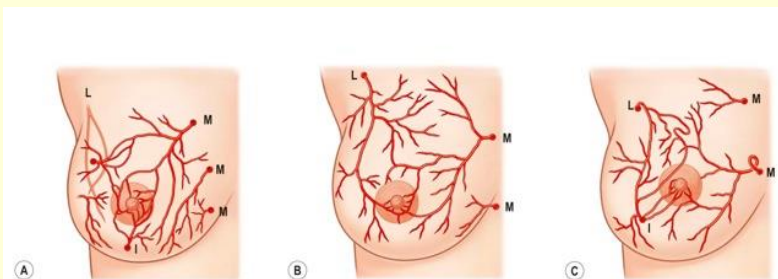


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## Breast & Nipple vascularity 1



▼ **Figure 1.10 (A-C)** Variations in blood supply to the breast. M, internal mammary perforator; L, lateral thoracic artery; I, intercostal perforator.

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## Why do patients sue?

- Something has gone wrong...?
- Anger
- Despair
- Desire to blame
- Want apology
- Want monetary compensation

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## Symptomatic presentations of breast malignancy

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## Mastectomy for breast cancer

- Political issue
- Misunderstood that the surgeon is the prime outcome person - not the oncologist

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### Adjuvant! Online

Decision making tools for health care professionals

#### Adjuvant! for Breast Cancer (Version 8.0)

**Patient Information**

Age:

Comorbidity:

ER Status:

Tumor Grade:

Tumor Size:

Positive Nodes:

Calculate For:

10 Year Risk:

**Adjuvant Therapy Effectiveness**

Horm:

Chemo:

**No additional therapy:**

69.1 alive in 10 years.  
29.8 die of cancer.  
1.1 die of other causes.

**With hormonal therapy: Benefit = 8.4 alive.**

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Tumor Size: 1.1 - 2.0 cm  
Positive Nodes: 1 - 3  
Calculate For: Mortality  
10 Year Risk: 30 Prognostic

**Adjuvant Therapy Effectiveness**

Horm: Tamoxifen (Overview 2000)  
Chemo: 3rd Generation Regimens

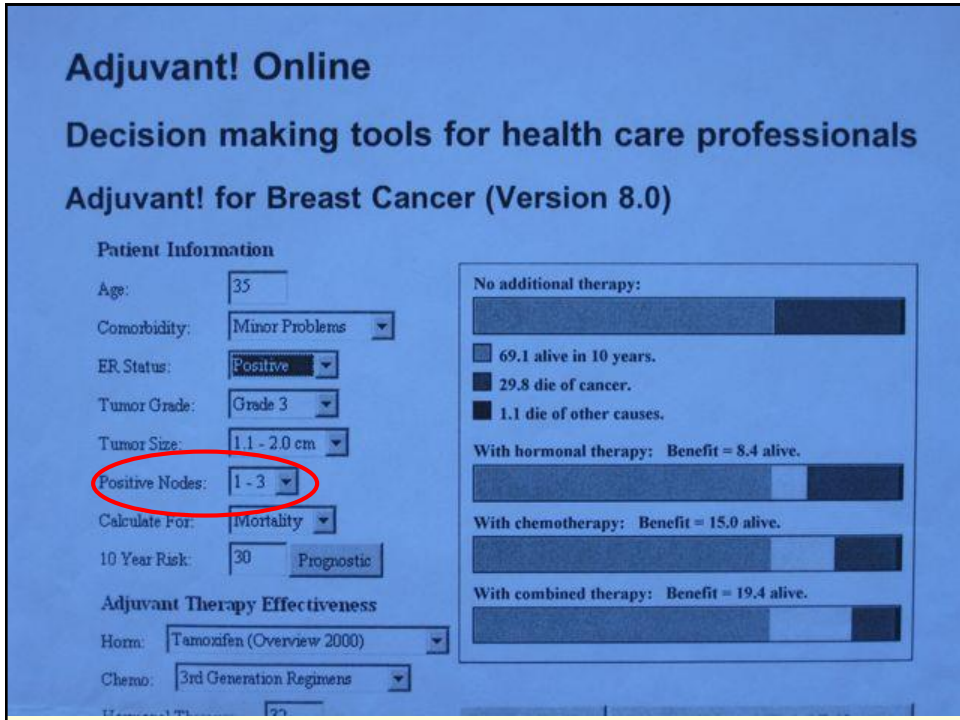
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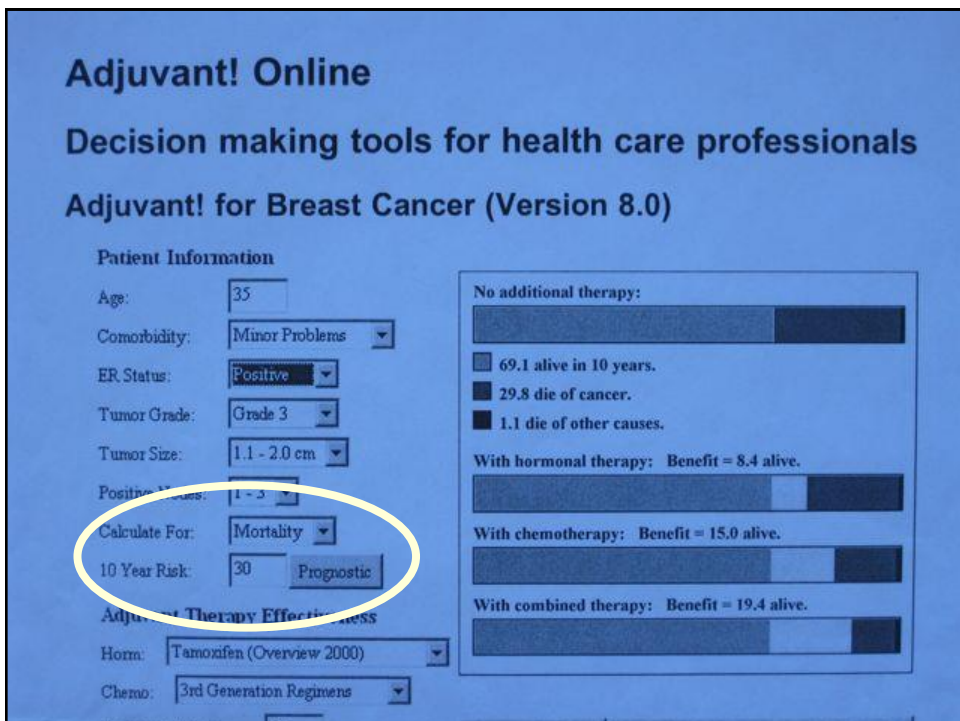
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**SURGERY ALONE**

**ADJUVANT THERAPY TO ALL...**

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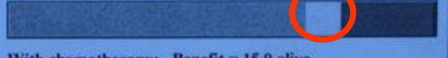
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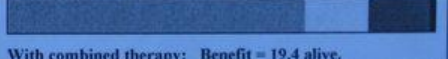


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BENEFITS...

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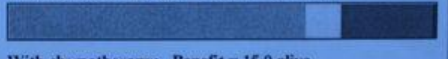
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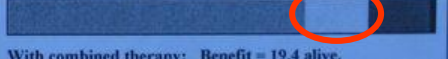


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## The main gene mutations and breast cancer

- BRCA-1 and BRCA-2
- TP53
- Li Fraumini
- Ataxia telangiectasia
- (BRCA '3 & 4')
- PALB1, CHEK2, CDH1
- 'SNIPS' single nucleotide polymorphisms

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## Inappropriate Risk Reducing Surgery



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## NHS - Breast Screening Program

- 2 view mammograms
- Age 47 - 70 y with extension on request
- 3 yearly
- Invitation from GP
- Rigorous QA for every aspect, eg surgery, radiology, pathology
- Preoperative diagnosis

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## NHS - BSP small cancer



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- But not all breast cancers are detected by mammograms
- Especially *Lobular* types – 10% of all breast cancers

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## Ultrasound scans

- Subjective reading
- Radiologist experience
- Do not use for screening
- Site specific

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## Triple Assessment

- Radiology
- Clinical assessment
- Needle Biopsy pathology – core needle bx

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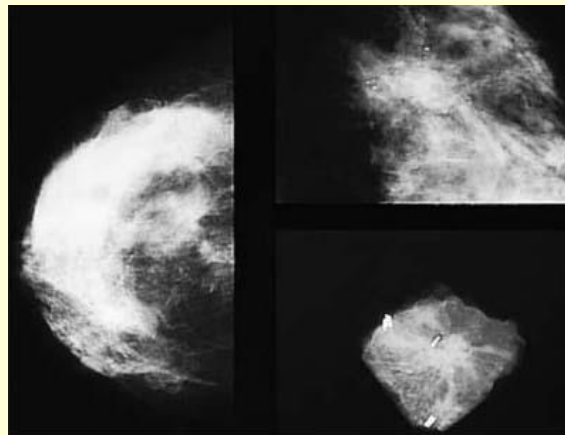


## MRI scans

- ‘Maps’
- Not binary diagnostic test
- Interpretation paramount
- Prolonged
- Agoraphobic situation
- Expensive
- Most accurate in younger women at high risk

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## Stellate lesion localised/excised



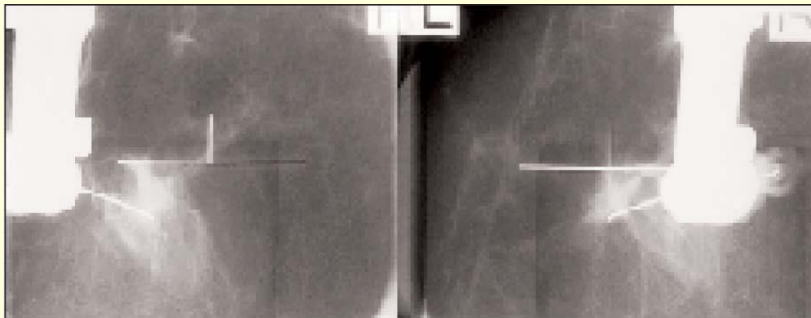
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## Imaging Research

- Tomograms
- Contrast enhanced mammography
- AI interrogated imaging
- Screening – risk stratified breast screening

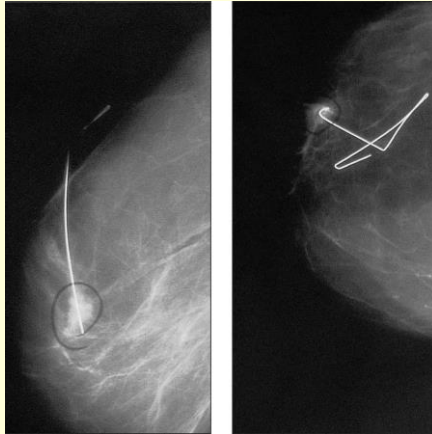
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## Stereotactic core biopsy preoperative diagnosis



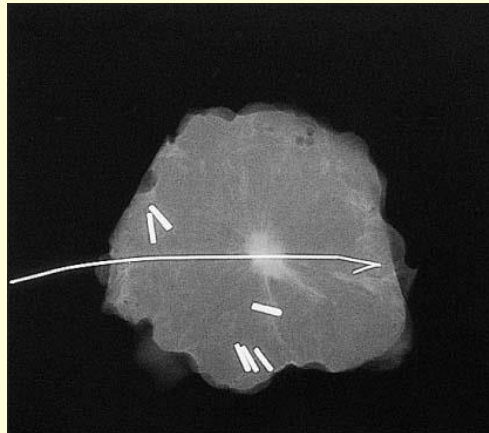
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## Needle localised surgery



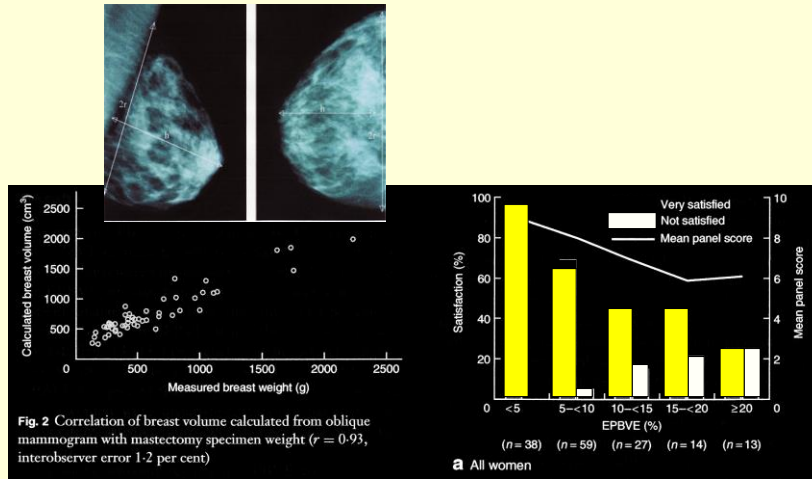
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## Specimen radiograph



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## Satisfaction and volume resected



Cochrane et al BJS 2003

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## Unusual for a patient to sue for WLE defects

- If a defect is successfully corrected
- They have a good relationship with the primary surgeon

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## **Total mastectomy**

- Patient thinks that they should have had breast conservation, not mastectomy
  - sues
- Patient had breast conservation, now has local recurrence
  - sues

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## **Simple/total mastectomy**

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## 'Type V'



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## LD flap based immediate reconstruction

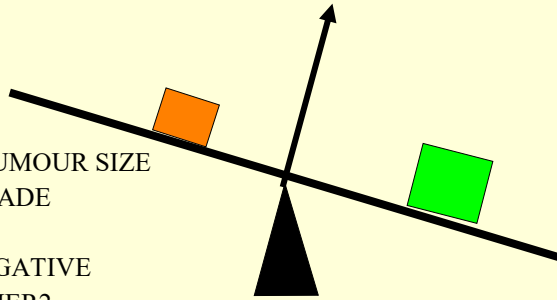
- Autologous LD flaps
- Implant assisted LD flaps

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## The Mastectomy/Conservation Decision Balance

**PATHOLOGY** | **COSMESIS**

- SMALL TUMOUR SIZE
- GOOD GRADE
- NO LVI
- NODE NEGATIVE
- ER+ PR+ HER2 -
- 'LARGE BREAST'

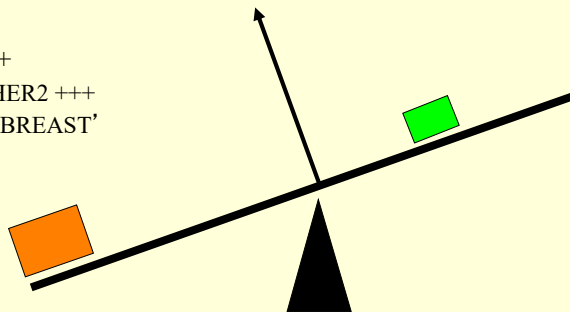


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## The Mastectomy/Conservation Decision Balance

**PATHOLOGY** | **COSMESIS**

- HIGH GRADE
- LARGE TUMOUR SIZE
- LVI +
- NODES +
- ER- PR- HER2 +++
- 'SMALL BREAST'



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Development of a new specialty

## Oncoplastic Breast Surgery

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**Oncoplastic techniques to  
extend the range of Breast  
Conserving Surgery**

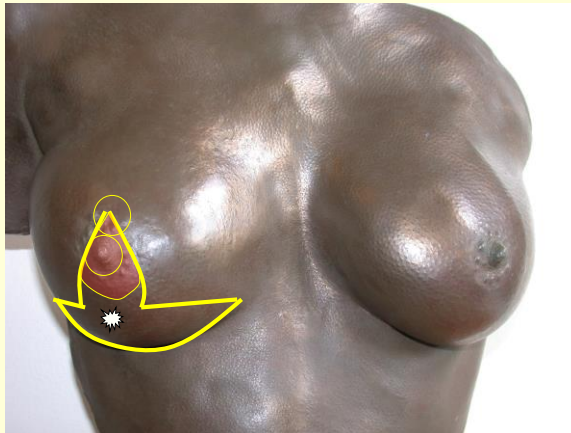
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## Complex therapeutic mammoplasty procedures

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### Standard reduction with superior NAC pedicle



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## Extended superior NAC pedicle



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## Litigation

- **Breach of Duty - Liability**
  - As a result patient suffered an injury
- **Causation**
- **Determined *on the balance of probabilities***

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## Litigation UK

- **Breach of Duty - Liability**
  - As a result patient suffered an injury
- **Causation**
  - The injury caused a significant detriment, eg years of life lost, functional loss, aesthetic loss, pain, greater treatment
- **Determined *on the balance of probabilities* ie 51% v 49%, not 'beyond all reasonable doubt'**
  - Civil law v criminal law

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## Breach of Duty

- Duty of care
- Bolam and Bolitho modification
- Guidelines
- Practice within guidelines easier to defend
- Practice outside of guidelines not always indicative of negligence

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## Litigation – Consent

- **Montgomery v Lanarkshire HA 2015**
  - Supreme Court changed the understood legal definition of informed consent
- No longer what information a reasonable doctor would have given, but whether a reasonable patient has been given all information pertinent to treatment including those treatments not offered by that doctor
- **Poorly communicating risks is a Breach of Duty**

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## Litigation – Consent

- **Montgomery v Lanarkshire HA 2015**
- **Poorly communicating risks of an operation is a Breach of Duty**
- **What about communicating risks of *not having* an operation?**
- True informed consent – ‘without this spinal operation there is a risk of 90% you’ll be paralysed in 6 months, with this operation there’s a reduction to 10%...but a 5% risk of paralysis the same day of operation’

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## Causation

- Prove that a negligent act caused a foreseeable injury
- Difficulty in proving both liability and causation

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## Delay in the diagnosis of breast cancer

- Did the delay necessitate more extensive treatment?
- Did the delay reduce the chance of cure?

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## Delay in Primary Care

- General Practice
- Benign lumps common
- GP sees 1-3 breast cancer patient per year
- Increasing reluctance to refer patients in for investigations
- Budgetary issues
- Patients seldom sue GPs

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## Delay after Specialist Referral

- Clinical examination non-suspicious
- Failure to arrange clinic follow up
- Negative mammogram
- Misreading of mammogram/ultraosund
- Over-reliance on normal radiology
- Failure to perform a biopsy
- MDT dynamics – failure to act on clinical suspicions

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## Diagnosis of breast cancer

- Triple Assessment
- Clinical examination
- Mammography and Ultrasound scan
- Cytology and core needle biopsy
- None is 100% sensitive nor 100% specific...

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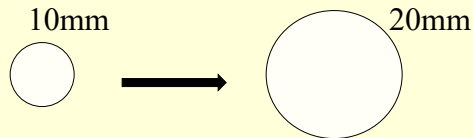
## Tumour Doubling Time

- Age related - Pearlman
- <50 years mean 80 days (44-147)
- >50 years mean 157 days (121-204)
- Lymph node metastases
- Blood borne - haematogenous - spread

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## Tumour doubling time

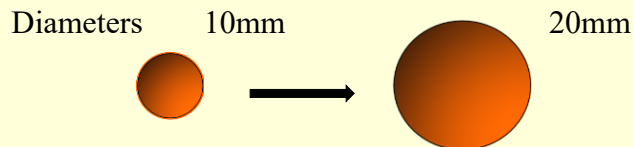
- It's not the measured maximum tumour *diameter* that matters



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## Tumour doubling time

- It's the tumour *Volume* that matters



- $Volume = \frac{4}{3}Pi \times R \times R \times R$  (R is the radius)
- 10mm vol is 0.52cc
- 20mm vol is 4.52cc

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## Types of breast cancer

- At least 27 types
- All different
- Multimodal therapy - surgery, radiotherapy, chemotherapy, hormone therapy, monoclonal antibody (Herceptin)
- Behave differently...

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## Types of breast cancer

- Ductal carcinoma in situ (DCIS)
- Invasive Ductal, WHO grades 1-3
- Invasive Lobular
- Mucoïd, tubular
- Special types
- Receptors ER, PR, Her2
- Oncotype DX and Endopredict
- Ki67 proliferation index

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## Delay in diagnosis: causation

- Public expectation is that earlier diagnosis=better outcome
- So any delay=worse outcome
  
- More extensive treatment
- Psychological issues
- Dilemma in calculating loss of life years

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## Cosmetic/aesthetic outcomes

- Breast cancer surgery
- Wide excision defects
- Reconstruction defects
  
- Aesthetic surgery
- Augmentation - implants
- Breast uplifts - mastopexies
- Breast reductions

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## Recent UK examples

- Nipple loss after reduction mammoplasty
- Nipple loss after augmentation mastopexy
- Loss of ADM and implant
- Consent for ADM which failed
- Local recurrence after SSMx/LD flap
- Lymphatic fistula after mastectomy & ANC

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## Recent UK examples 2

- Breast lump clinically 'P5' by surgeon, benign triple assessment, pt discharged
- Patient delayed >1 year with lump, sued when diagnosed with Metastases 9/12 after initial surgery, claiming alleged '3 month delay in Radiotherapy'

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## Disasters can be...

- Psychological
- Surgical
- Aesthetic
- Oncological
- ...and sometimes all four...

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## ONCOLOGY SURGERY mantra

- Get clear margins
- Avoid transgressing malignant tissue
- Meticulous technical attention to detail
- Don't leave malignant tissue behind
- Minimise complications of surgery

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## National Mastectomy & Breast Reconstruction Audit

- Rate of ‘immediate breast reconstruction’ assumes an issue of high/low quality care
- Anticipation of CRx and Radiotherapy ?
- Radiotherapy can be a disaster for reconstructions
- Increasing use of ‘spacer’ immediate

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## National Mastectomy & Breast Reconstruction Audit (UK)

- Rate of ‘immediate breast reconstruction’ assumes an issue of high/low quality care
- Anticipation of CRx and XRT ?
- XRT can be a disaster for reconstructions
- Any delay in Chemotherapy translates into diminished reduction in chances of survival

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## POSTOPERATIVE COMPLICATIONS

- Much more likely to involve the donor site than the breast
- Loss of an immediate abdominal flap is not just a reconstructive disaster, even more crucially it is a cancer surgery catastrophe
- Wound breakdown and infection lead to deterioration in cancer outcome, with increased rates of recurrence

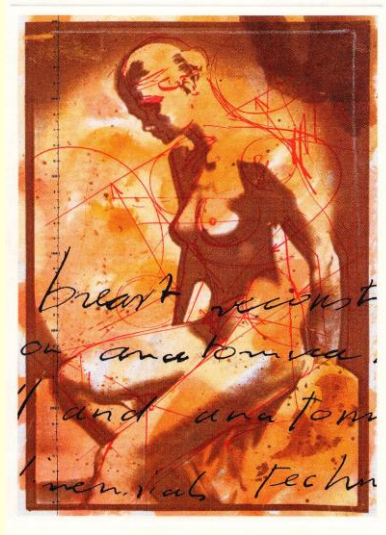
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## How do you avoid litigation?

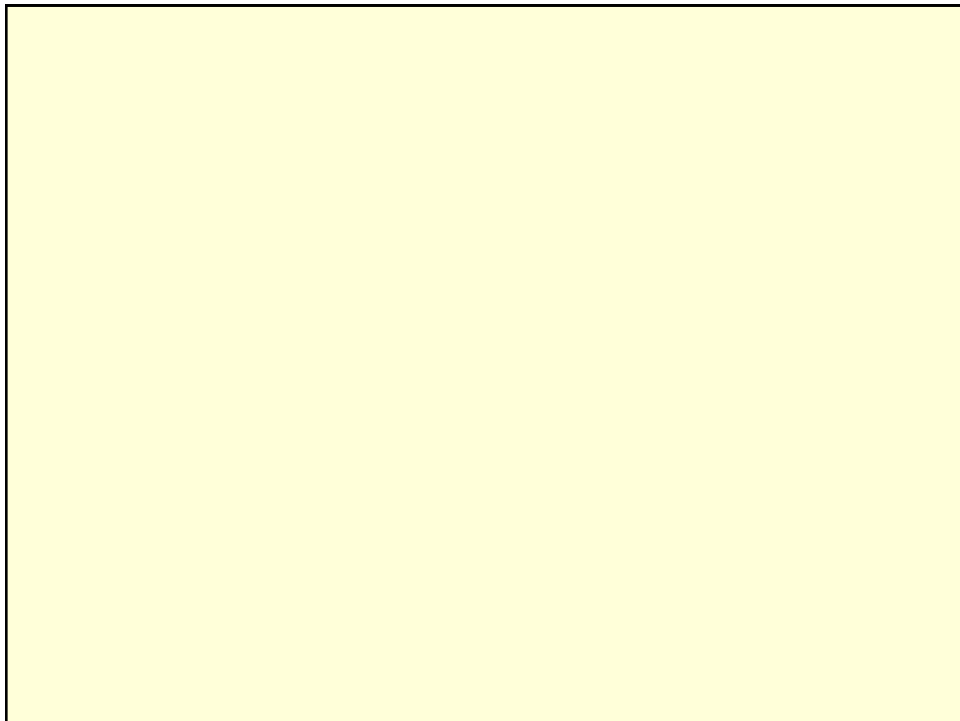
- Conscientiousness
  - Attention to detail
  - Technical surgery
- Compassion
- Communication
  - With patients and relatives
  - Medical records and other doctors - MDT
- Courage
  - Do not take too high risks
  - Be thorough
  - Make good decisions

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Thank you for your attention



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