Primary Radiotherapy And DIEP flap reconstruction. The PRADA study

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Introduction
• We hypothesize that delivering RT prior to autologous reconstruction:
  • Lessen the cosmetic impact of radiotherapy on reconstruction following neoadjuvant chemotherapy
  • Is oncologically safe: there is increasing evidence to support pre-surgery RT for other tumour sites (rectal, head and neck)
  • Will reduce wound healing delay in completion of oncological treatment
  • Increase immediate reconstruction rates

Aim
• To determine the surgical outcomes of radiotherapy prior to surgery.

Inclusion Criteria
• Women >18 years with histopathologically-confirmed breast cancer, who:
  - require mastectomy for any reason (e.g. extensive disease, failed conservative management etc.)
  - and require adjuvant radiotherapy and who are suitable for DIEP flap reconstruction at the time of mastectomy

Exclusion Criteria
• Inability to give informed consent
• MDM unable to make recommendation for radiotherapy based on pre-operative histopathological and imaging findings ie mastectomy pathology required for MDM to decide on need/ target volume for post-mastectomy RT
• Severe chemotherapy toxicity affecting treatment planning schedule

Primary Endpoints
• Presence of open breast wound at 4 weeks after mastectomy & DIEP flap reconstruction
  (Open wound defined as wound requiring a dressing ≥1cm)

Secondary Endpoints
• Presence of an open breast wound at 8 and 12 weeks after mastectomy & DIEP flap reconstruction; DIEP loss rate
• Difference in volume and symmetry between the reconstructed and non-reconstructed breast using 3D-surface imaging at 3 months and 12 months after surgery.
• Patient satisfaction (as measured using the BREAST-Q reconstruction module – before, three months after, and 12 months after surgery.)

Study Design
• A two-centre non-randomised intervention trial investigating whether reversing the order of mastectomy (axillary nodal clearance/SNB) with immediate DIEP flap and adjuvant radiotherapy is safe.

- Number of patients= 20
- Trial recruitment started Jan 2016 and aim for completion July 2017

- SSMx and DIEP reconstruction after RT is surgically feasible with low complication rates, after a pilot study of nearly 20 patients. DIEP failure rate 0% and no open wounds
- Translational sub-protocols are being run in parallel as part of the TRANS-PRADA study
- A larger multi-centre RCT is being planned