First in Human Study Using the 'GLOW' Near Infrared Camera System in Breast Cancer

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Introduction:

The clinical challenge :
1 in 4 women undergoing breast conserving surgery will have **positive tumour margins** on resection, thus necessitating further surgery.

Our solution :
Fluorescence from molecules in the tumour can guide tumour resection in real time. This is known as **Fluorescence Guided Surgery (FGS).**

Our objectives are to develop the imaging system and test its performance in clinical trials.
Our research question is: Can the system accurately detect the cancer and reliably guide surgeons?

Impact of this work:
Preventing positive margins and thus subsequent operations will benefit the patient (cancer treatment & cosmesis), and could save the health service millions of pounds annually.

'GLOW' Camera Development:

Figure 1: The dual camera head system

1: The lens system simultaneously collects visible light and fluorescence.
2: A beam splitter separates the light in two beams.
3: Fluorescence is transmitted through a band-pass filter to the monochrome camera.
4: Colour images are captured in the second camera.

Methodology:

- single centre prospective clinical study
- UK Research Ethics Committee Approval (18/LO/2018)
- 10 patients due to undergo BCS recruited
- Injected 12.5mg ICG intraoperatively
- Colour & NIRF images taken of:
  - tumour in situ
  - tumour ex vivo
  - cavity shaves
  - lymph nodes
- Fourier transform and image primitive analysis applied in post-processing

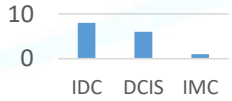
Results:

Patient Demographics:

- Mean Age 56 (45-70)
- BMI 24.2 (19.2-30.2)
- No adverse events recorded
- TBR 1, but 2 cases of aberrant vasculature noted

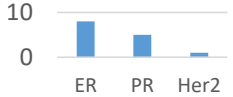
Tumour Characteristics:

Histology



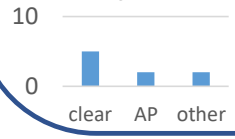
Histology of tumours (IDC= Invasive Ductal Carcinoma, DCIS= Ductal Carcinoma in Situ, IMC= Invasive Mucinous Carcinoma).

Receptor Status



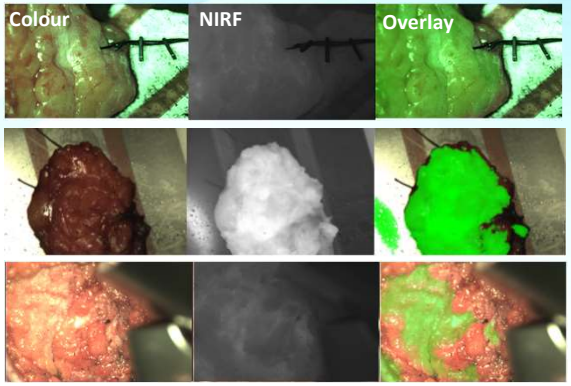
Receptor Status of Tumours where ER= estrogen, PR= progesterone, Her2= Herceptin.

Margin Status



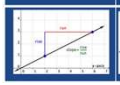
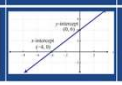
Marginr Status of Tumours where AP= anterior or posterior positive margins.

Figure 2: Ex-vivo specimen images taken using GLOW camera system



Images taken of tumour specimen using colour camera, near infrared camera (NIRF), and display of overlay of both images.

Figure 3: Image Analysis

Slope p=0.001	Intercept p=0.002	Euler Number p<0.001	Hausdorff box-counting fractal dimension p=0.38	Lacunarity p=0.16
		image connectivity between image features and corresponding holes	change of image pattern detail with scaling	image inhomogeneity

Results of post-processing image analysis.

Conclusions:

- First in woman study using the GLOW camera for fluorescence-guided BCS
- Fourier transform and image primitive analysis of the GLOW images are worth investigating to reveal differences between tumour and normal tissue
- Future studies will focus on further image analysis with ICG and the use of targeting fluorophores such as ALA (REC 19/LO/0927) to further analyse the potential of fluorescence guided breast cancer surgery

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