

Update on the ELECTRA trial



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Disclosures

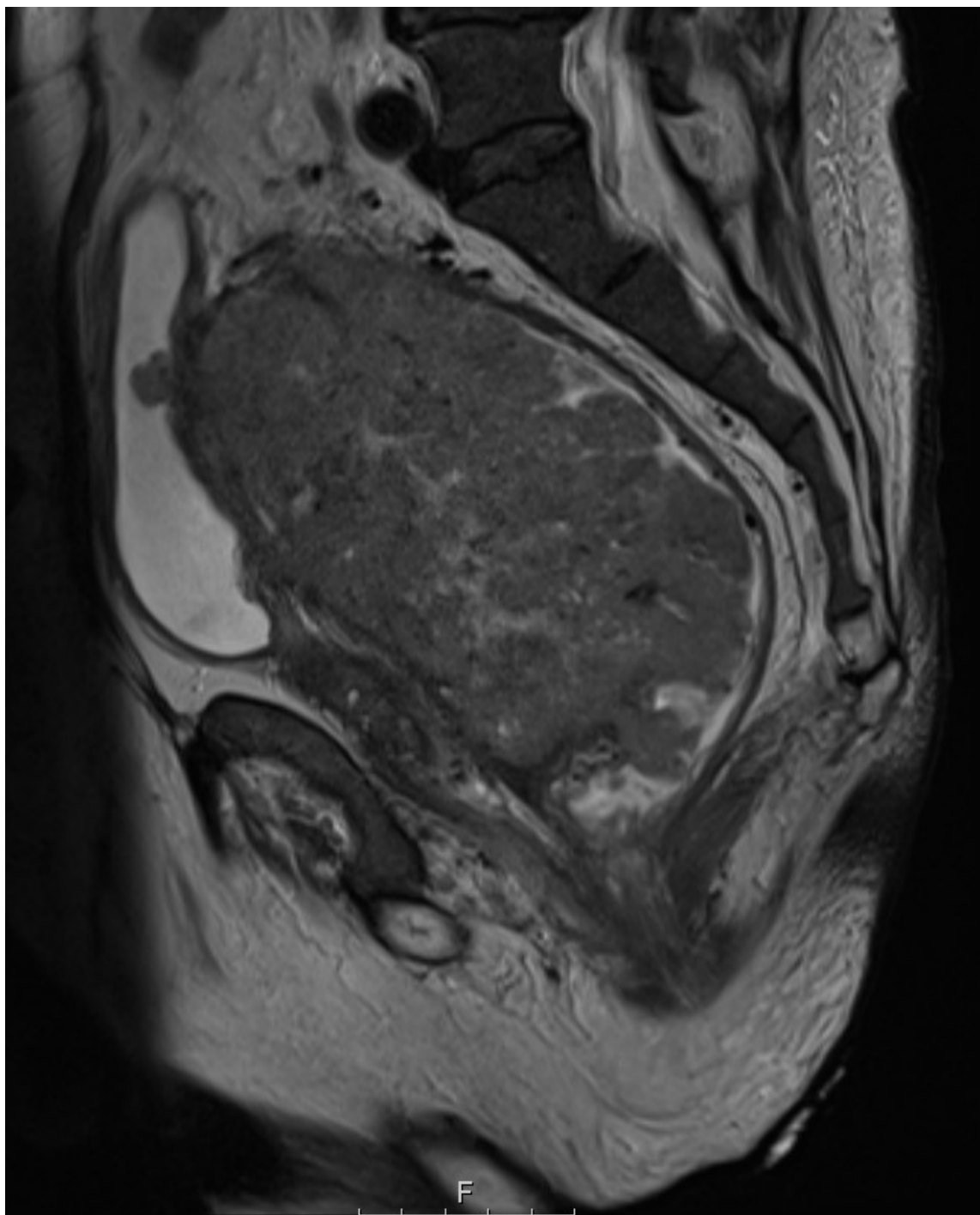
- Not a paid speaker for IntraOp (but have part funded the ELECTRA trial)
- Apologies....

Overview

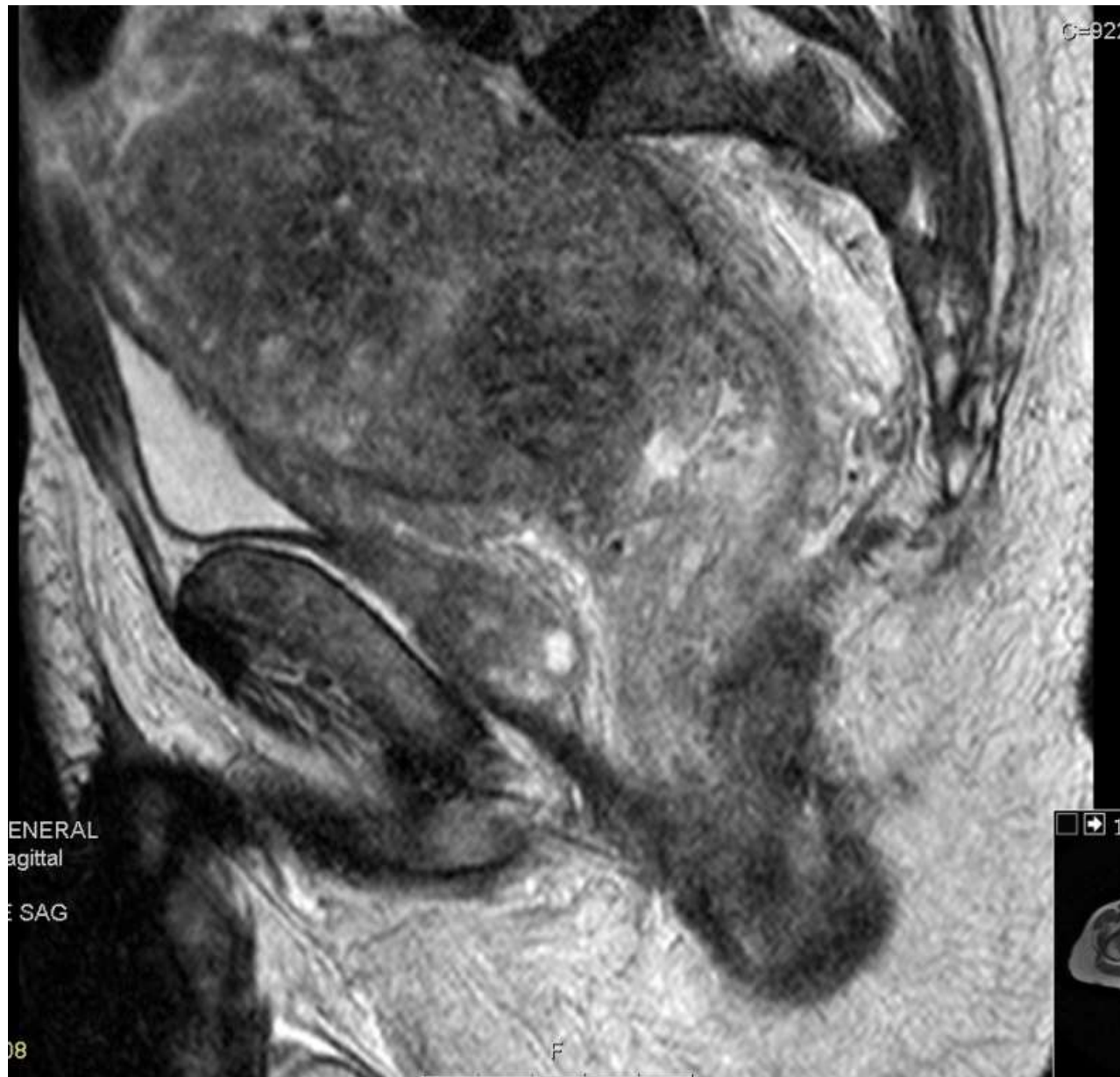
- Advanced and recurrent rectal cancers – the unmet need
- Better margin control as an Indication for IOERT in this setting
- The evidence base....(or lack of)
- Development of the ELECTRA trial – a randomised controlled blinded feasibility trial
- Trial details and example patients
- Current status....and my appeal to you....
- Highlighting the challenge facing the community for evidence and my appeal

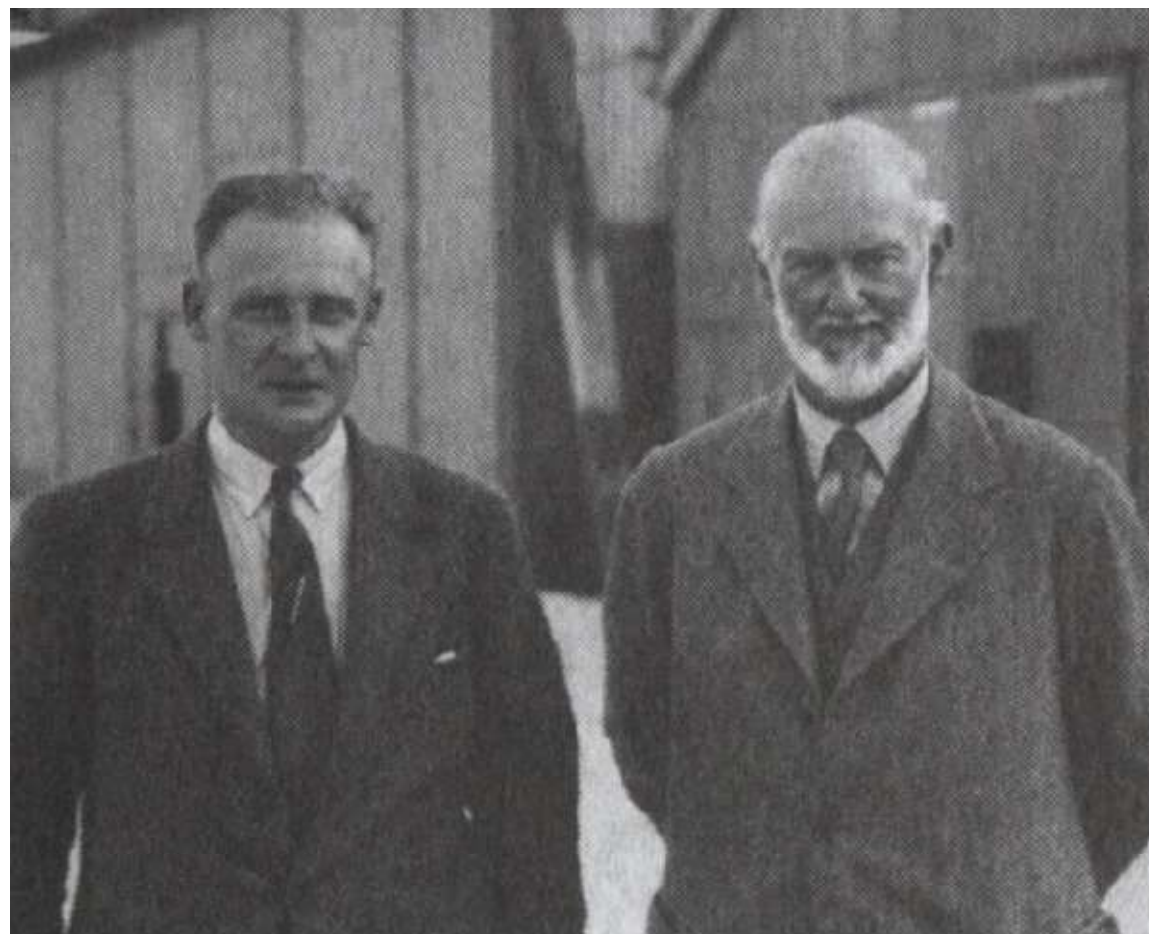
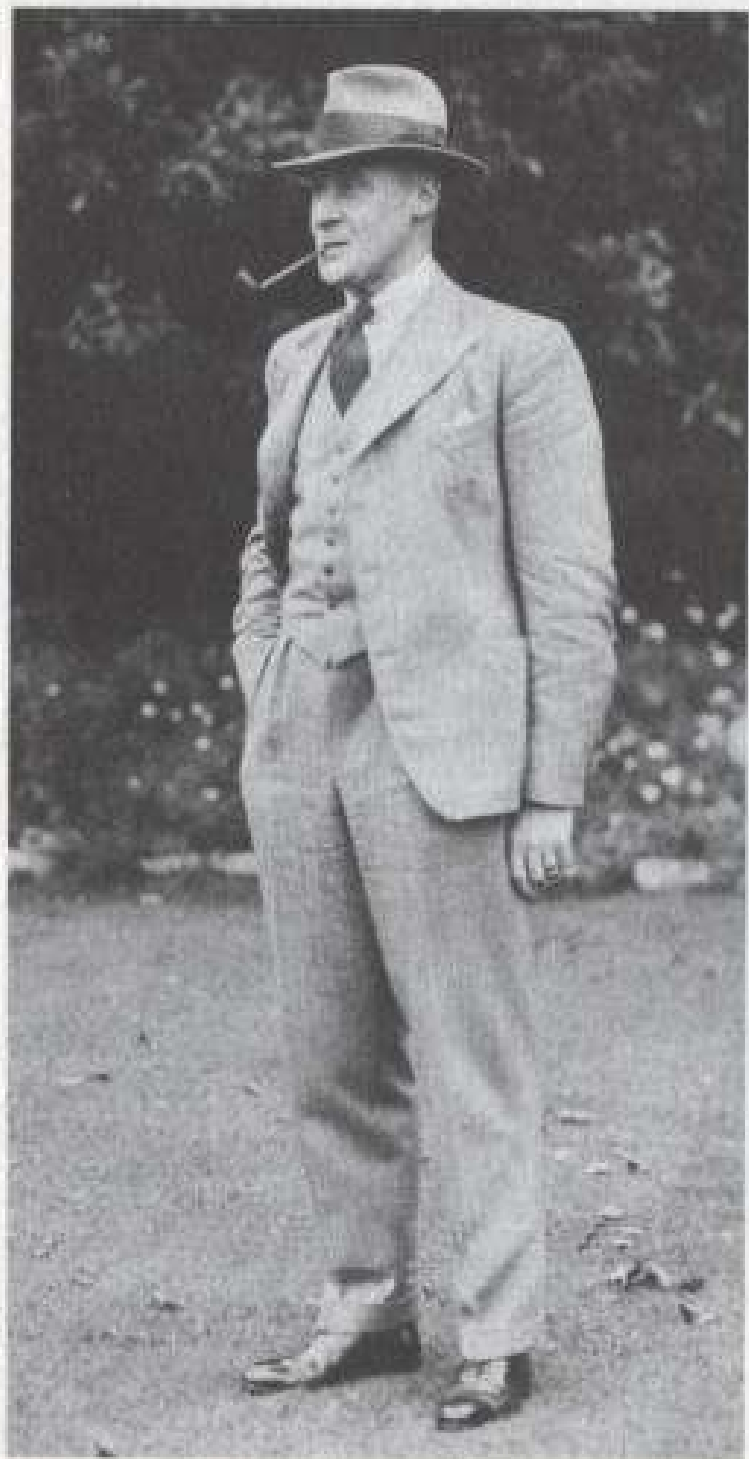
Advanced and recurrent abdomino-pelvic tumours

- Historically managed very poorly with dismal outcomes
- Often described as some of the worse ways to die
- Why?

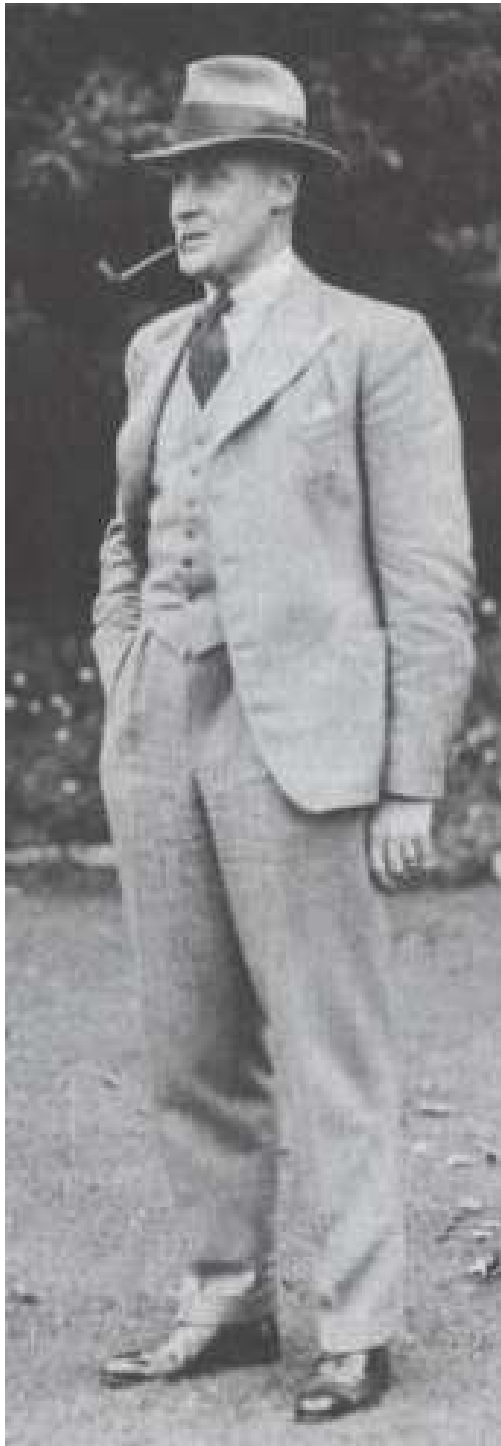








Reginald Mitchell with Sir Henry Royce

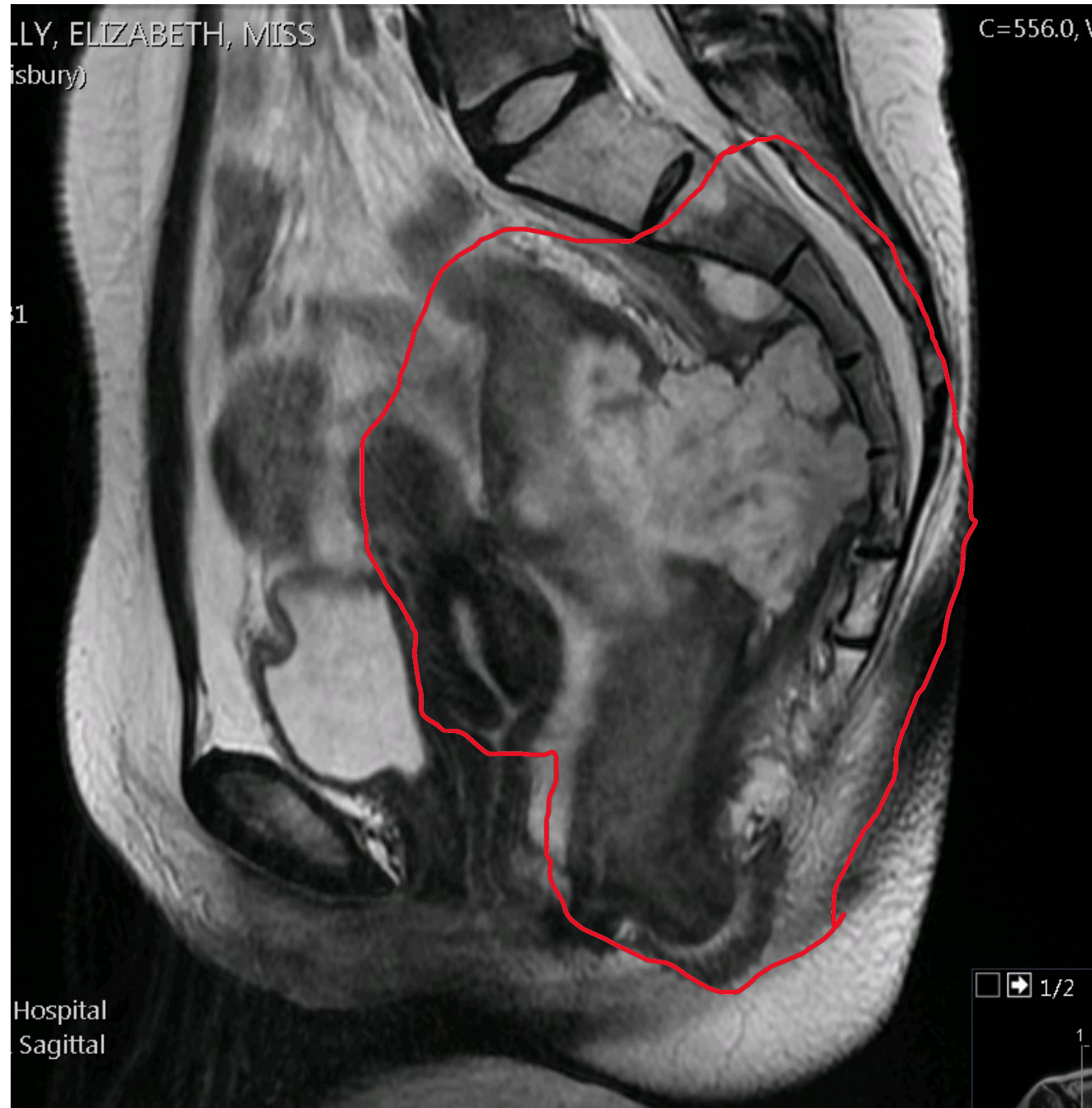


Advanced and recurrent abdomino-pelvic tumours

- One of the worst ways to die....
- As a result of this desperation, “pelvic exenteration” surgery was borne
- An extreme surgical solution for removal of internal pelvic organs
- Employs radical multi-visceral *en bloc* surgical resection of contiguously involved anatomical structures

LLY, ELIZABETH, MISS
(isbury)

C=556.0, W



Hospital
Sagittal

1/2

1

Approach

- Goal is to achieve an R0 resection – min of 1mm distance from cancer to the edge of resected margin
- Predicts for survival and QOL

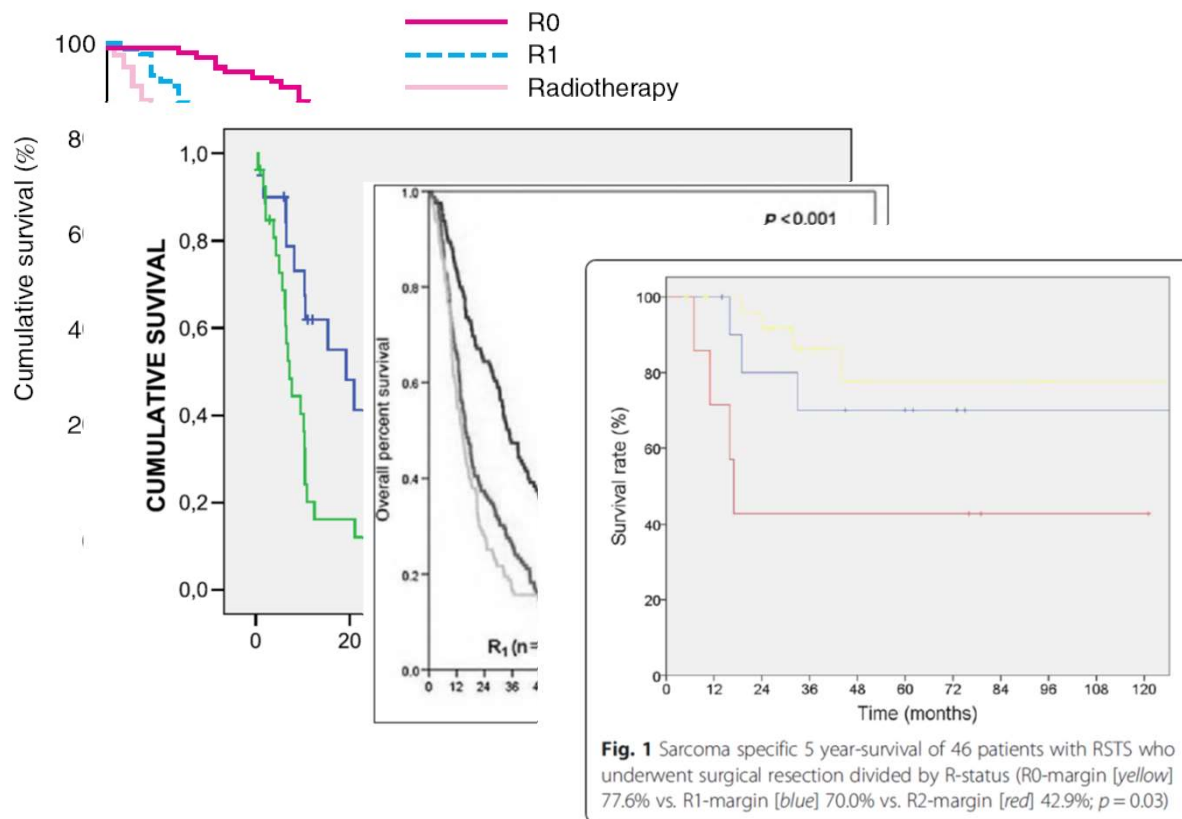
Nagtegaal et al 2002

Heriot et al 2007

Austin & Solomon 2009

Mirnezami et al 2010a

Mirnezami et al 2010b



Colorectal cancer

Hansen et al 2009

Gynaecological cancer

Chiantera et al 2013

Pancreatic cancer

Kostantinides et al 2013

Retroperitoneal Sarcomas

Hager et al 2017

Bladder and renal cancers

Hallemeir et al 2012 & 2013

Recurrent anal cancer

Hallemeier et al 2014

LARC and LRRC

- To enable an R0 resection within the confines of the pelvis for advanced or recurrent rectal cancers frequently necessitates multi-visceral pelvic exenteration operations
- Nevertheless, even with ultra radical surgery and in centres with significant experience positive margins may occur in 30-50% of patients

Heriot et al 2008

Harris et al 2016

PeLVEx collaborative 2019

Voogt et al 2021

LARC and LRRC

- Achieving an R0 also more difficult because:
- Radiology is imperfect
 - Poor resolution in some settings
 - Abutment vs direct invasion
 - Confusion from sepsis and neoadjuvant therapies
- Assessment at surgery is imperfect
 - Particularly if sepsis has occurred at some stage
 - Or post neoadjuvant therapies
- Because getting higher and wider resections in the pelvis is not always easy anatomically, surgically, or in terms of loss of function
- And not all close margins **can** be easily or **should** be modified with further surgical extensions
- Hence.....If margin control likely to be an issue (predicted close or involved) – IORT may have a role

Sagar 2014

Mirnezami et al DCR 2010

Mirnezami et al Surg Oncol 2013

Haddock 2016

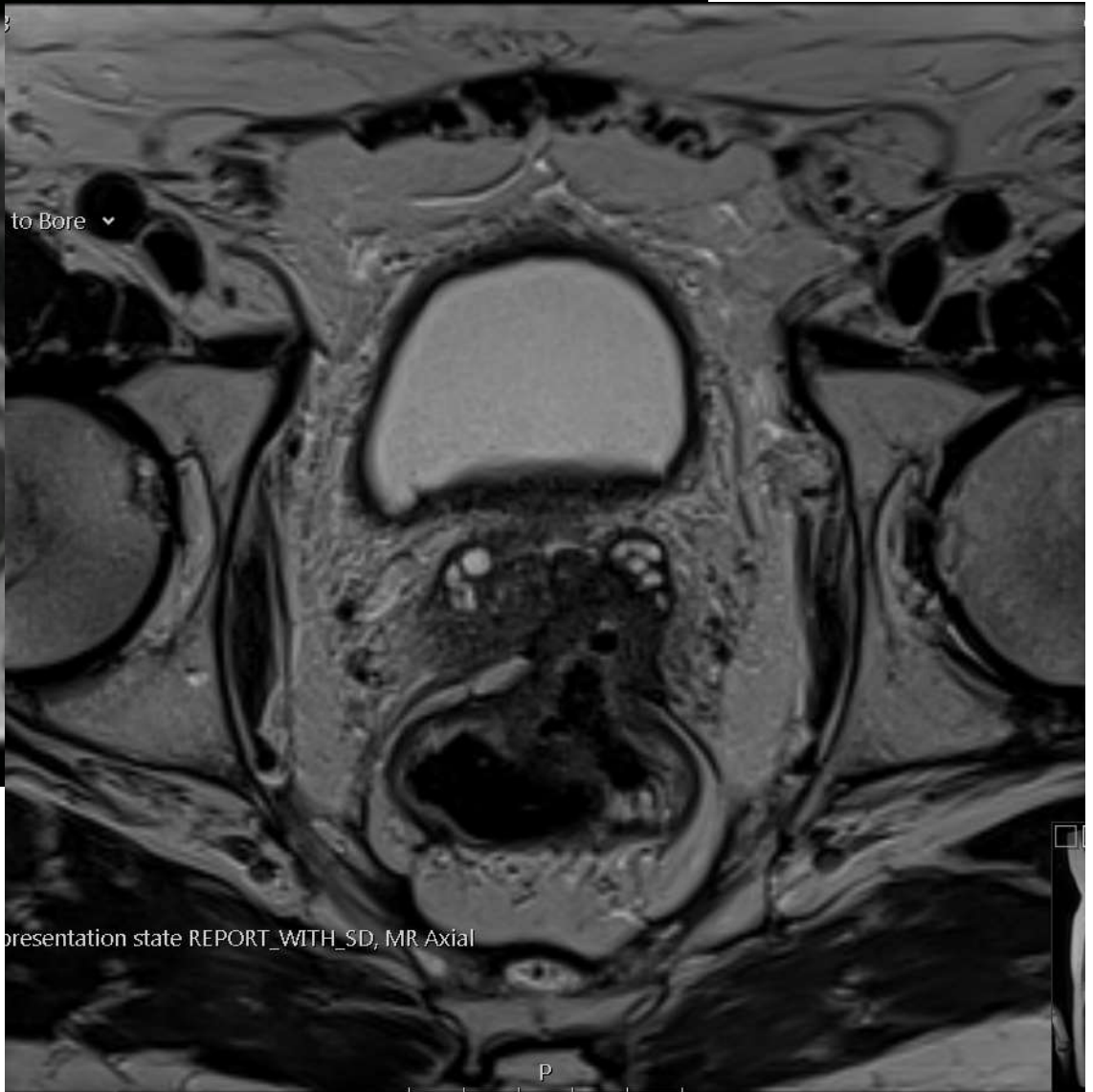
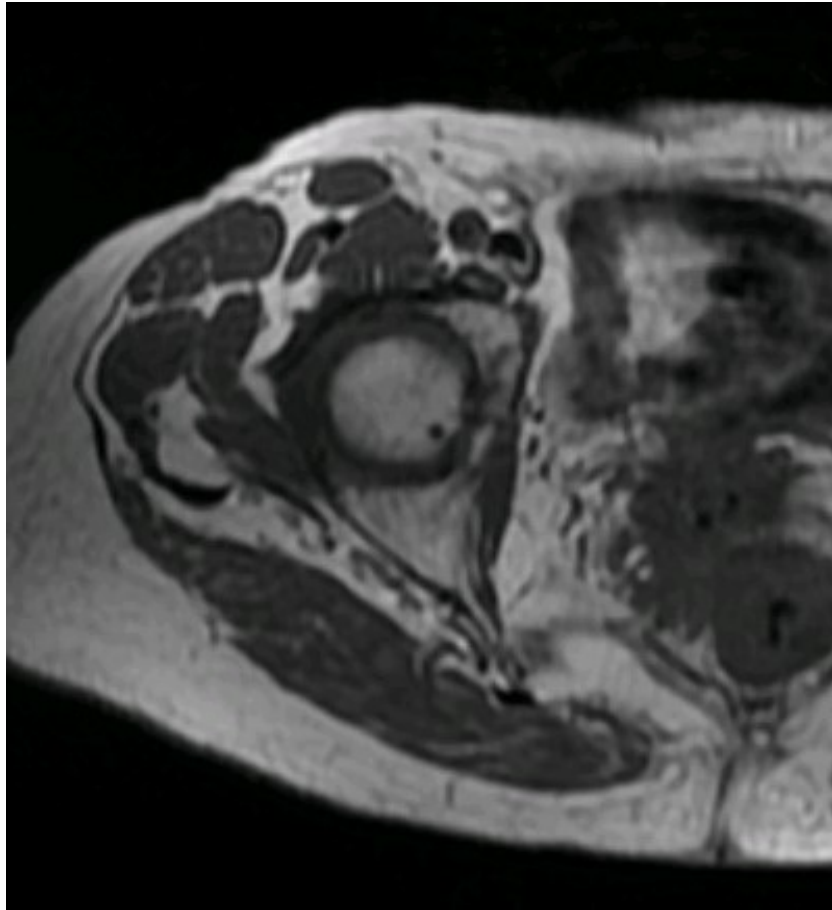
Chang 2018

LARC and LRRC

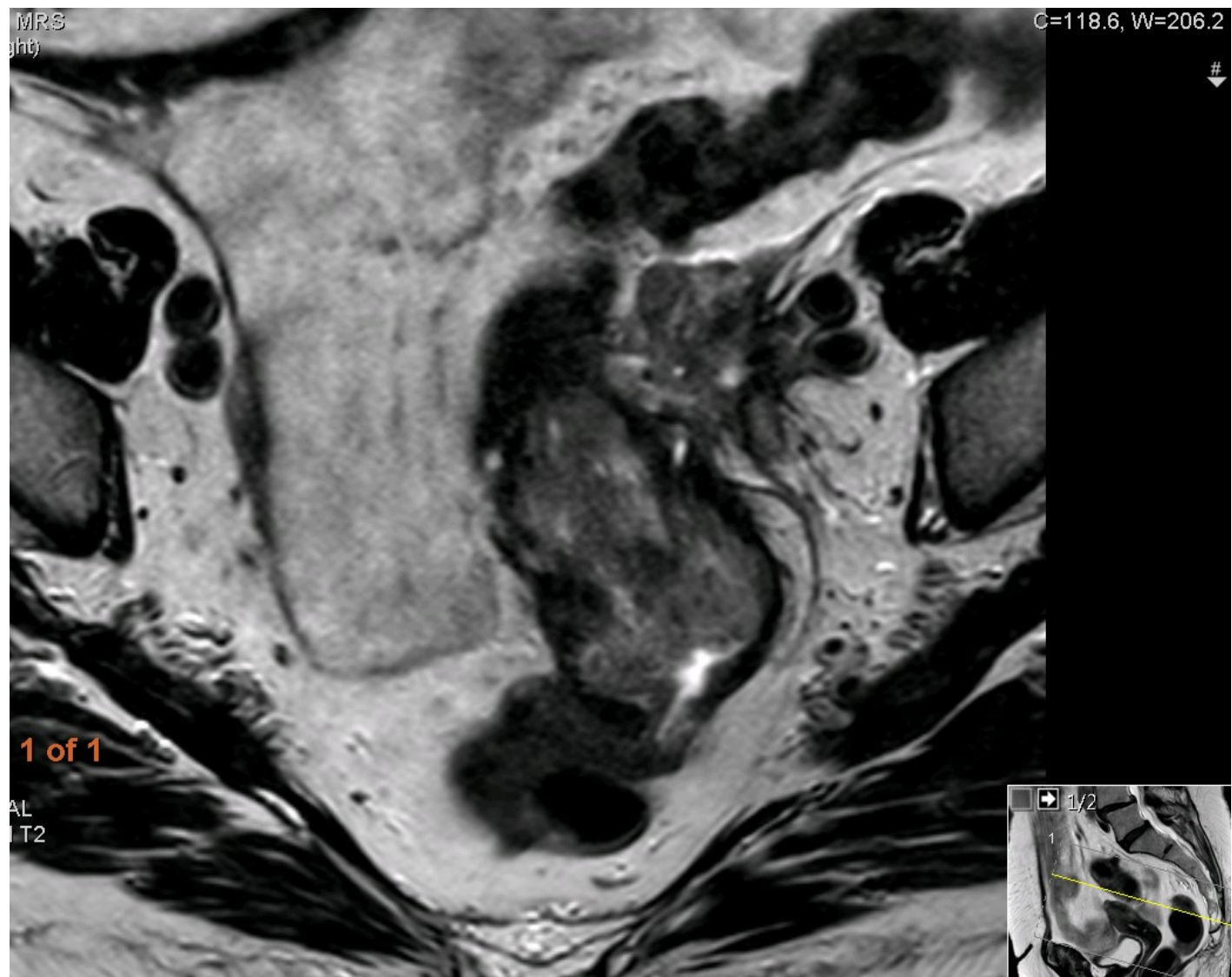
- In addition, certain anatomical zones carry a significantly greater risk of incurring a positive resection margin
- **lateral** (pelvic sidewall) and/or **posterior** anatomical zones pose the greatest risks of a positive margin
- Addition of IORT is one option...aims to convert an R1 resection to an R0 outcome
- Offers a therapeutic edge in challenging tumours and works synergistically with surgery
- While physically displacing and protecting radiation sensitive structures (eg small bowel, ureter)

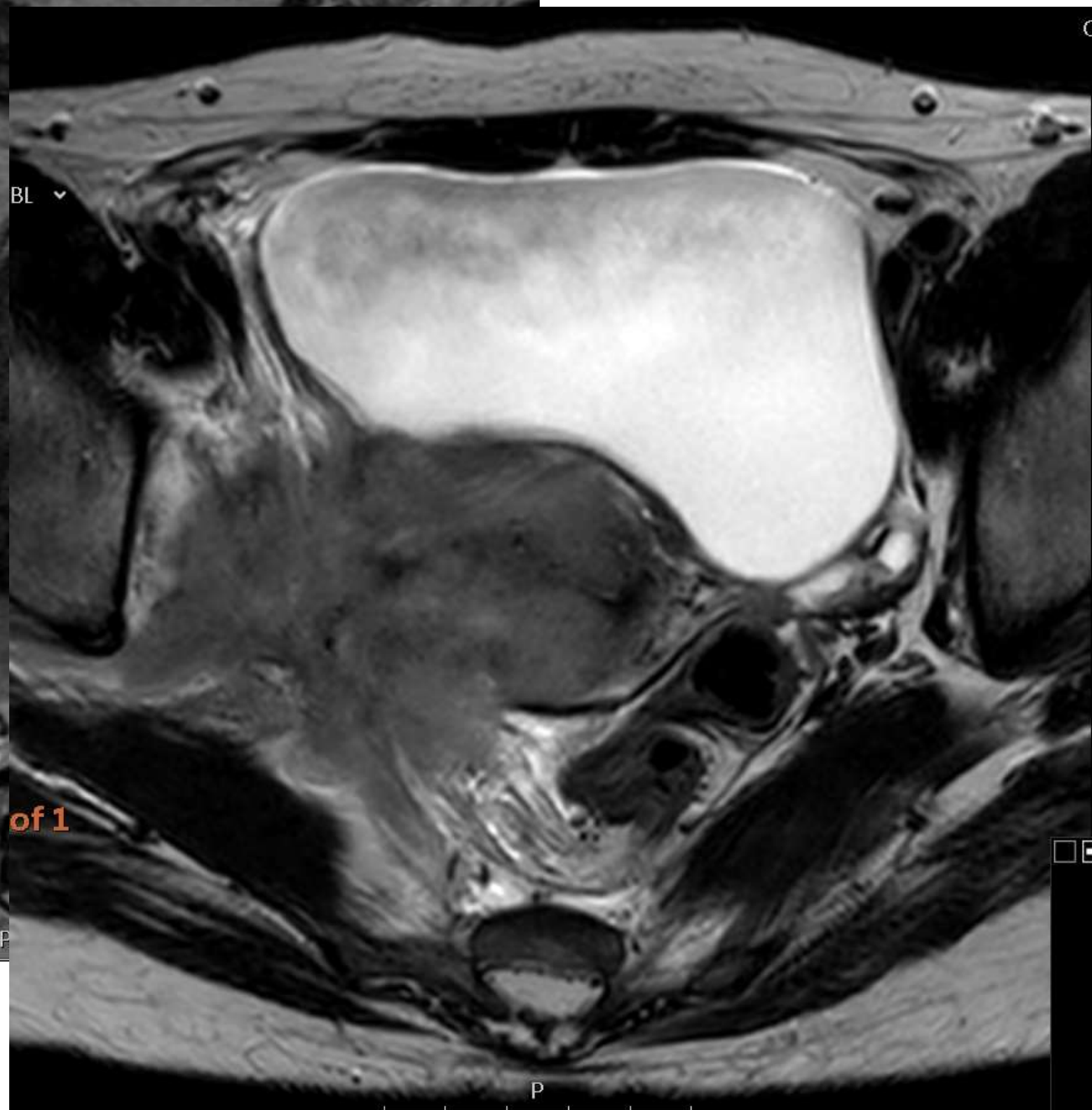
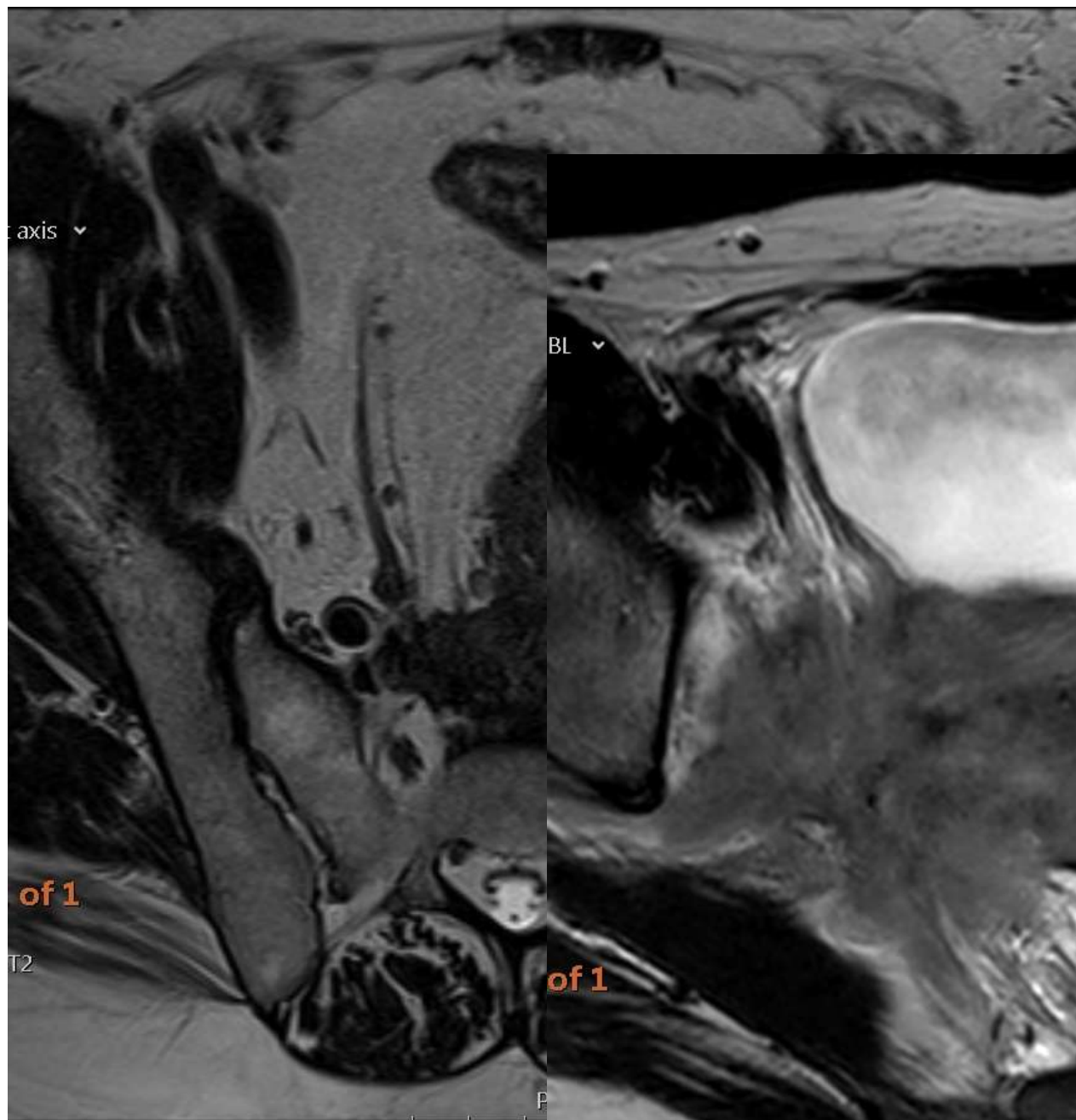
Mirnezami et al DCR 2010
Mirnezami et al Surg Oncol 2013
Haddock 2016
Chang 2018

Tumours NOT for IOERT

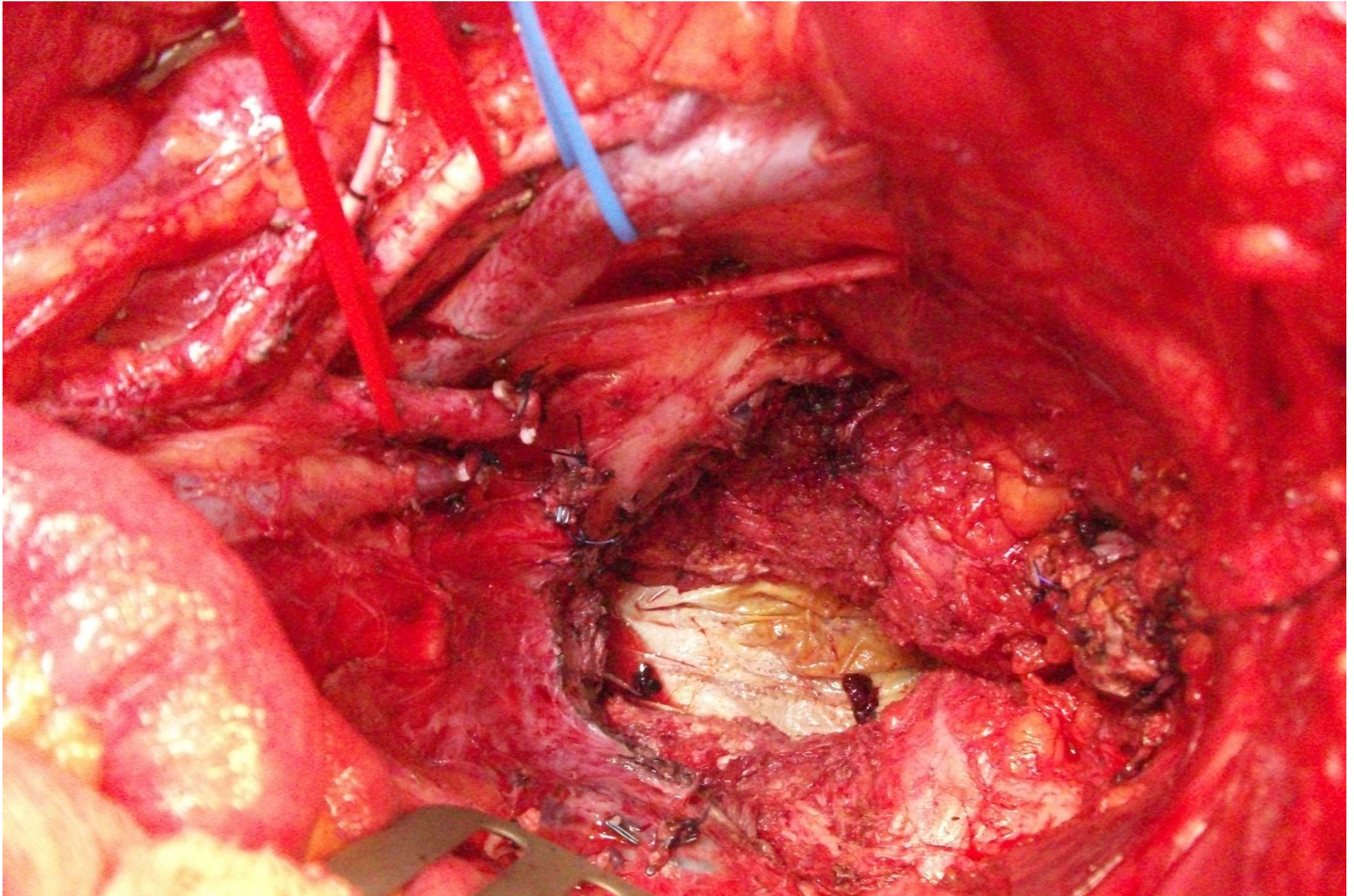


Examples of tumours
being discussed





44 yr old female with LRRC



R0 resection but margin 1.3mm



39 yr old male....R0 but 1.8mm margin

IORT may be a helpful option for these
challenging cases to optimise outcomes

Evidence base

- Collaborative study between Southampton, Imperial College and MDACC
- Aim – To review the data and summarise the field +/- meta-analysis for primary locally advanced and recurrent CRC

5 year local control

Study	IOERT (n/N)	No IOERT (n/N)	Odds Ratio (D-S, random [95%CI])	Weight (%)	Odds Ratio (D-S, random [95%CI])
Valentini et al ³⁵	2/11	20/26		18.1	0.07 (0.01-0.4)
Sadahiro et al ²⁶	2/99	11/68		19.6	0.18 (0.02-0.5)
Ferenschild et al ⁴⁰	5/11	8/8		11.4	0.05 (0.002-1.07)
Masaki et al ²⁹	3/19	2/22		17.4	1.88 (0.28-12.61)
Valentini et al ³¹	0/49	6/29		12	0.04 (0.002-0.68)
Dubois et al ³²	6/72	5/68			
Total	18/261	52/22			

Test for heterogeneity: $Q=15.83$; $I^2=68\%$

5 year disease free survival

Study	IOERT (n/N)	No IOERT (n/N)
Valentini et al ³⁵	9/11	22/26
Ratto et al ²⁸	10/19	15/24
Sadahiro et al ²⁶	21/99	31/68
Masaki et al ²⁹	8/19	7/22
Total	48/148	75/14

Test for heterogeneity: $Q=5.15$; $I^2=42\%$

5 year overall survival

Study	IOERT (n/N)	No IOERT (n/N)
Suzuki et al ⁵¹	34/42	60/6
Valentini et al ³⁵	6/11	22/2
Sadahiro et al ²⁶	21/99	29/6
Ferenschild et al ⁴⁰	7/11	8/8
Masaki et al ²⁹	7/19	12/2
Total	75/182	131/1

Test for heterogeneity: $Q=1.34$; $I^2=0$; $df=4$; $p=0.85$

- Quality of studies low.

- Improved OS, DFS, and Local control favouring IOERT.

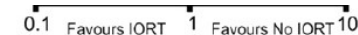
- Effect size can be as much as 4 times reduction in local relapse in margin close or positive cases



Wound complications

Study	IOERT (n/N)	No IOERT (n/N)	Odds Ratio (M-H, fixed [95%CI])	Weight (%)	Odds Ratio (M-H, fixed [95%CI])
Suzuki et al ⁵¹	3/42	1/64		7	4.85 (0.49-48.25)
Wiig et al ⁴⁴	8/59	7/48		31	0.92 (0.31-2.75)
Sadahiro et al ²⁶	23/99	8/68		48.7	2.27 (0.95-5.43)
Dubois et al ³²	5/72	2/68		13.3	2.46 (0.46-13.14)
Total					1.86 (1.03-3.38)

Test for heterogeneity: $Q=3.86$; $I^2=48\%$; $df=2$; $p=0.145$



Odds Ratio M-H, fixed [95%CI]
4.85 (0.49-48.25)
1.41 (0.57-3.49)
0.45 (0.07-2.75)
1.35 (0.84-2.82)

Odds Ratio M-H, fixed [95%CI]
0.25 (0.05-1.28)
1.4 (0.34-5.8)
1.97 (0.47-8.21)
0.94 (0.42-2.1)

Evidence base

- Since then:
- Further 2 systematic reviews and meta-analyses
 - IORT favours local control
 - No increase in complications
 - Overall survival unaltered
 - Both recommend the need for higher levels of evidence with better trial design and patient selection
- We have just updated our analysis now and again similar findings

Fahy et al 2021

Liu et al 2021

Author, year	Study design	Overall quality rating	Comments
Jeans, 2023	Retrospective cohort	Acceptable	Non-randomised comparative study from two separate institutions (one in Japan, one in USA), no propensity matching due to small sample size, some patients in CIRT group who had a re-recurrence underwent CIRT twice
Hall, 2023	Retrospective cohort	Acceptable	No information on resection margins for colorectal group, so corresponding survival data difficult to interpret, no information about neoadjuvant or adjuvant therapy
Ansell, 2022	Retrospective cohort	Acceptable	Multi-centre study, no methods for accounting for confounding factors
Voogt, 2021	Retrospective cohort	Acceptable	Multi-centre, non-randomised comparative study, a few baseline characteristics (including time from neoadjuvant radiation to surgery) between the two groups with LRCC, however these factors were added to a multi-variable analysis, no propensity matching, some missing data on complications
Masaki, 2020	Randomised controlled trial	Acceptable	Allocation concealment method not described, underpowered due to trial stopping early as patients in IOERT group had poorer distant metastasis-free survival
Gambacorta, 2018	Prospective cohort	Acceptable	Open-label trial testing addition of 5-fluorouracil and gefitinib to IOERT-containing multi-modality treatment, no adjustment for confounding
Coelho, 2018	Retrospective cohort	Acceptable	Small sample size of 12, no details of neoadjuvant therapy or resection margin for colorectal cohort
Brady, 2017	Retrospective cohort	Acceptable	Small sample size, no time span was stated for what constituted short and long-term complications, no details of neoadjuvant or adjuvant therapy stated
Holman, 2016	Retrospective cohort	Acceptable	Multi-centre study, multivariable analysis carried out to assess predictive and prognostic factors
Zhang, 2015	Retrospective cohort	Acceptable	Non-randomised comparative study, single-centre, majority R0 resections
Zhang, 2014	Retrospective cohort	Acceptable	Non-randomised comparative study, single-centre, only R0 resections
Sole, 2014	Retrospective cohort	Acceptable	Majority R0 resections, multivariable analysis carried out to assess predictive and prognostic factors
Klink, 2014	Retrospective cohort	Acceptable	Grouped primary and recurrent colorectal cancer cohort as one
Skrovina, 2014	Retrospective cohort	Unacceptable	No clear study objectives, outcomes not clearly defined, unclear whether IOERT in particular was used
Calvo, 2013	Retrospective cohort	Acceptable	Small sample size, prognostic factors study
Brisinda, 2013	Retrospective cohort	Acceptable	Standardised IOERT dose given to all patients, no time period for complications provided
Roeder, 2012	Retrospective cohort	Acceptable	Missing data on 16 patients, prognostic factors study

Our IOERT experience pre-ELECTRA trial

- Median age 63 (range 22-84); 54% male
- All except 3 had neoadjuvant treatment
- Median operative time 12.5 hours (range 6.5-28)
- Median IOERT dose delivered was 10Gy (10-15Gy)
- Median applicator diameter was 6.5cm (5-10cm)
- 13 had major vascular reconstructions of non-expendable vessels within the IOERT field
- Median length of stay 17 days (6-55)
- 30 day and 90 day mortality 0
- 65 % of patients had a minor complication; No Clavien-dindo IV or V complications
- 2 patients had a ureteric stricture needing stenting...not in but close to the IOERT field
- No other IOERT specific complications noted – eg bony necrosis, neuropathy; and no vascular complications (eg false aneurysm); and no correlation with empty pelvis syndrome

Results

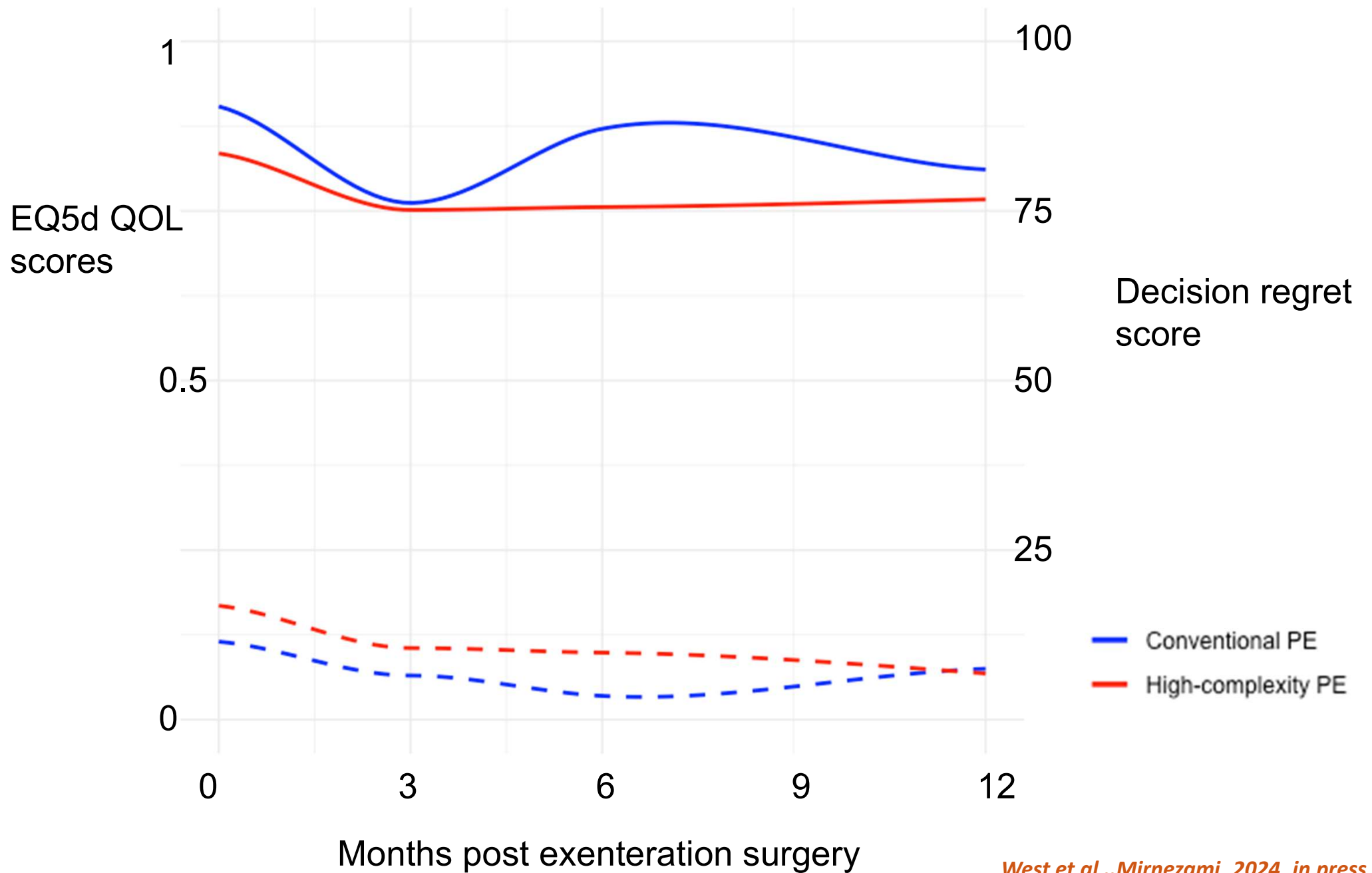
- 15 patients had an R1 resection
- 42 patients had R0 but close margins (<3mm)
- **IOERT field recurrences** **1**
- Loco-regional non-IOERT field recurrences 3 (1 contralat sidewall; 2 crural)
- Systemic recurrences 24%

Rangarajan et al 2018

ACPGBI meeting 2019

NCRI cancer conference 2018, Wessex Cancer Conference 2021

Trajectory of EQ5D and decision regret in pelvic exenteration patients



Evidence base

- Conclusions (of UK NHS and NICE (National Institute for health and Clinical Excellence)):
- More high-quality data needed.

1 Recommendations

- 1.1 Evidence on the safety of intraoperative electron beam radiotherapy for locally advanced and locally recurrent colorectal cancer is adequate. Evidence on efficacy is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research. Find out [what only in research means on the NICE interventional procedures guidance page](#).
- 1.2 Further research should preferably be in the form of suitably powered randomised controlled trials and should report details of patient selection (including tumour type and staging), the technique of radiotherapy and the extent of surgery undertaken, and key outcomes (as detailed in [sections 3.2 and 3.3](#)).
- 1.3 Patient selection and the procedure should only be done in specialist centres by a multidisciplinary team experienced in managing colorectal cancer. The multidisciplinary team should include a colorectal surgeon, a clinical oncologist, a medical physicist, a radiographer and an anaesthetist with specialist training in the procedure.

Trial development and design –
commenced in 2018/19

Trial development, approach and design

- Multiple meetings and workshops....experts, methodologists, radiation oncologists, surgeons, statisticians
- Using ESCP and ACPGBI as well as ASCRS meetings to set up sub-meetings
- Presented and discussed at previous IntraOp Users group meeting and preceding ISIORTs
- Discussed with patient groups and referring hospitals and clinicians in our network and nationally
- Discussed with research funding bodies and charities

The challenges & pitfalls ?

- Identifying the correct question (s)
 - LARC, LRRC, or both?
 - As additive to existing standard of care?
 - As replacement/reduction of EBRT?
 - To modify the margins of planned surgery – potential for de-escalation?
- Using unified definitions and standardised approaches for radiology, surgery, clinical oncology, and pathology
- Good trial design and a pre-study feasibility stage
- Phase 2 or phase 3 subsequently
- Blinding ?
- Case selection critical – Previous attempts at RCT heavily criticised for suboptimal selection of cases for IOERT – and to aim to stratify for R1 and for dose of previous RT
- Most importantly – maintaining equipoise
- The right outcome measure – *IOERT field local recurrence*

Trial development, approach and design

- Results:
 - Likely that best initial question to evaluate is the role of IOERT as an additive to existing care
 - Needs randomisation for impact and practice change
 - Needs blinding for credibility and to avoid confounding
 - Phase 2 or 3 after feasibility can be practice changing
- Key challenges repeatedly highlighted were:
 - **Ability to recruit** in a subset (lateral and posterior zones) of a rare field
 - **Lack of standardisation** in radiology, surgery, and pathology
 - **Measurement of the key endpoint**/outcome

Why a feasibility stage ?

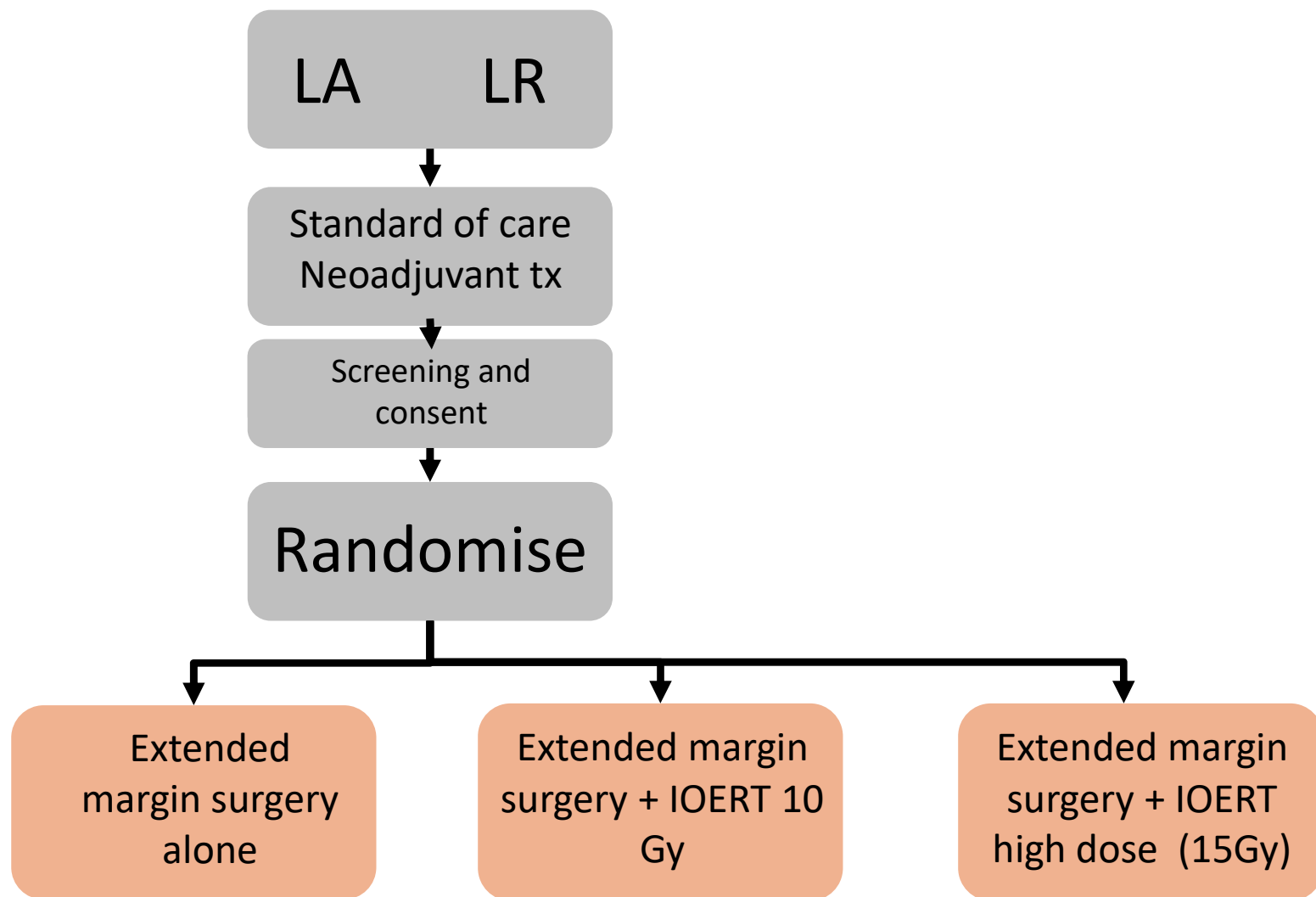
- Feasibility stage felt to be key as would aim to:
 - Determine acceptability to patients for recruitment and randomisation to IOERT containing and especially omitting arms
 - Obtain pilot oncological, QOL, Health economics to allow estimation of the key parameters needed to design and inform the subsequent late phase study
 - Feasibility of obtaining international and national support for running a subsequent phase2/3

Trial development, approach and design

ELECTRA

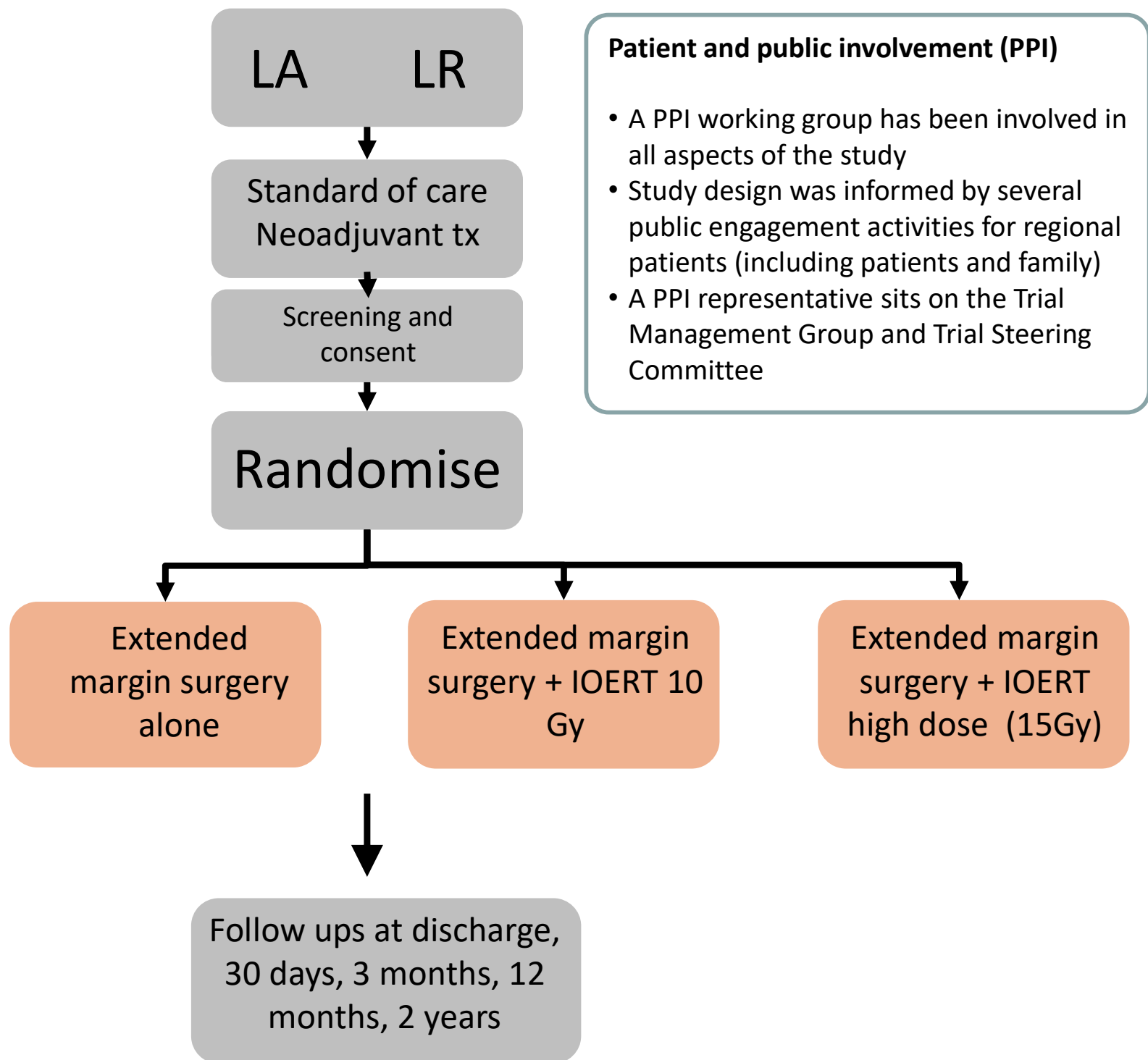
- Intraoperative **E** **e**LECTron radio**T**herapy in **R**ectal **c**Ancer
- A randomised, controlled, three armed, double blinded, feasibility first, trial with planned run in to multicentre international late phase study
- Funded by charity support, IntraOp, and CRUK
- Run by the University of Southampton CTU
- <https://www.isrctn.com/ISRCTN48105173>
- <https://www.southampton.ac.uk/ctu/trialportfolio/listoftrials/electra.page>





In next phase of trial - For units
who feel do have equipoise in
randomising to a non-IORT arm

For international units who feel
don't have equipoise in
randomising to a non-IORT arm



Trial design

Inclusion criteria:

- Non-metastatic/oligo-metastatic LARC or LRRC involving the **posterior or lateral compartments of the pelvis** and predicted to be resectable but with close or involved margins from MRI as determined by a specialist MDT (sMDT)
- Colorectal sMDT review with experience in pelvic exenteration, which has proposed IORT

Exclusion criteria:

- Unresectable disease/likelihood of R2 resection
- sMDT determined excess prior radiotherapy within IORT target zone

Trial design

- **Primary Outcome at feasibility:**
 - Acceptability and feasibility of recruiting, randomising; remaining randomised; and delivering IOERT in a RCT setting; and collecting the relevant data points
 - Acceptability of randomising to a non-IOERT arm for patients
- **Secondary outcomes during feasibility:**
 - Assessing efficacy and cost-effectiveness endpoints
 - Obtaining oncological, QoL, and HE data on patients treated with or without IOERT as a modality to inform future late phase RCT studies
- **Primary outcome at future late phase stage:**
 - **IOERT field local control**

Developing appropriate
quality assurance measures

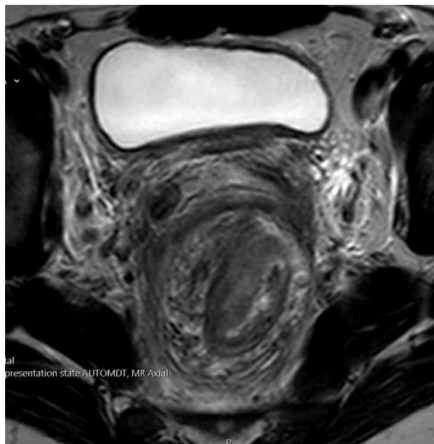
Standardised approach to Radiology

Overview

Patient selection for extended margin surgery in the pelvis and the application of IOERT is determined by MRI staging, which therefore feeds into the ELECTRA trial.

However, the exact methods and protocols vary internationally, and such variation greatly affects the ability to interpret the results of such an intervention.

Examples of optimal and suboptimal MRI staging are shown in the figure below. In the left panel, although the rectum is clearly visible, however the planning of margins and the extent of the disease is not clear. In the right panel, the imaging shows a much sharper image, allowing for better planning showing that the case shown is a T1b, and the disease extension does not involve the pelvic sidewall.



Complex – rectum in situ: Supervised LARC or LRRC

• Sagittal SFOV high resolution T2	30/20/3, 230/121.9%
• Axial T1 whole pelvis	40/20/5, 380
• Axial True LFOV high resolution T2	30/20/4, 380
• Coronal Oblique SFOV high resolution T2	20/10/3, 200
• Axial Oblique SFOV high resolution T2	20/10/3, 200
• DWI axial whole pelvis	40/20/5, 380

Review and perform if needed:

• Sagittal T1	30/20/3, 250
• Post contrast Axial T1	30/20/3, 250
(45 MINS)	

Complex – rectum removed: Supervised LRRC

• Sagittal high resolution T2 – sidewall to sidewall	45/10/4, 230/121.9%
• Axial T1 whole pelvis	40/20/5, 380
• Axial True high resolution T2 – sigmoid to perineum	30/20/4, 380
• Coronal True high resolution T2	50/10/3, 200
• DWI axial whole pelvis	40/20/5, 380

Review and perform if needed:

• Sagittal T1	45/10/4, 250
• Post contrast Axial T1	45/10/4, 250
(45 MINS)	

Standardised approach to Pathology

Standards for specimen handling and reporting of pelvic exenteration specimens for colorectal cancer in the ELECTRA trial

Overview

The most important indicator of the effectiveness of IOERT is field local relapse in patients with a close or microscopic margin. Consequently, an important objective of the ELECTRA feasibility study is to establish standardised criteria for the preparation and evaluation of pelvic exenteration specimens. In addition, in any subsequent late-stage trial, standardisation and quality control in the preparation of the tumour specimen will be critical, and the nominated institution will be asked to attend physical or remote educational training data.

Background

The cancer datasets published by The Royal College of Pathologists in combination of textual guidance, educational information, and digital datasets enable pathologists to grade and stage cancers in compliance with international standards and provide a high standard of care management for specific clinical circumstances.

Pelvic exenteration may be defined as a radical and extensive en bloc removal of internal abdomino-pelvic organs and tissues in advanced or locally recurrent cancers. Pelvic exenteration specimens sent to histopathology often include different neurovascular structures, and often bony elements and in part of a multi-modality approach to cancer therapy.

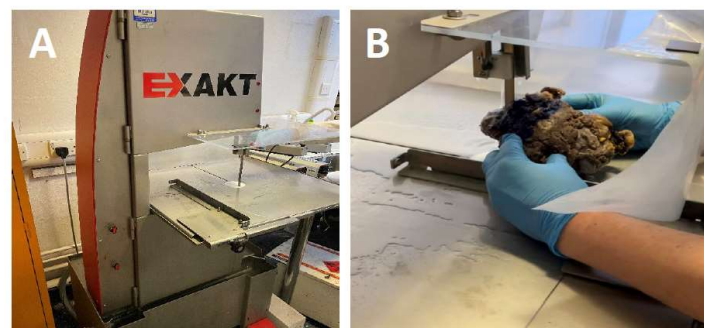
Outcome in these cases is strongly dependant on the completeness of the most optimal outcomes achieved in patients with advanced disease, those with clear but very narrow margins, or microscopic macroscopic residual disease (R2) have significantly poorer outcomes.

Consequently, the pathology reporting of such specimens is critical and may form part of the process for determining at specimen meetings what subsequent management patients should have.



Figure 4: Illustrative images of a patient who has had IOERT to the pelvic sidewall following an exenterative operation for LARC. The example shown represents an infralevator total pelvic exenteration with en bloc S3 level sacrectomy and en bloc pelvic sidewall resection. The left panel shows the post-fixation specimen with the sacrum attached prior to inking (grey with red edge). The middle panel shows that this is then inked jointly by surgeon and pathologist and bony segments excised to enable sectioning (red arrow). In the middle panel the extent of cancer creeping cephalad up the sacrum can be seen. In the right panel, the specimen is bread-loafed prior to finer sectioning.

Secondly, and if possible, the surgeon and pathologist may elect to use a pathology department diamond band saw (e.g the EXAKT system; figures 4) to cut the whole specimen.



Standardised approach to Surgery and descriptions

Pelvic Exenteration Surgical Lexicon

Posterior

P1 Presacral
P2 Low sacrectomy ($\leq S3$)
P3 High sacrectomy ($\geq S2$)
P4 Sacrectomy requiring stabilisation

Anterior

A1 Partial cystectomy
A2 Total cystectomy or radical cystoprostatectomy
A3 Cystectomy with pubic bone resection
A4 Cystectomy with complete penectomy

Central

C1 Rectum or TAH/BSO
C2 Rectum + TAH/BSO/partial vaginectomy (female) or seminal vesicle/prostatic shave (n
C3 Rectum + TAH/oophorectomy + total vaginectomy

Pelvic sidewall

Vessels

SV1 Lymphadenectomy
SV2 Ureteric resection with reimplantation
SV3 Distal branches of internal iliac artery
SV4 Proximal internal iliac artery and vein
SV5 External iliac artery or vein +/- internal iliac artery or vein

Nerves

SN1 Obturator nerve
SN2 Single nerve root
SN3a Multiple nerve roots at the level of S2 or below or partial sciatic nerve resection pre
L5/S1
SN3b Multiple nerve roots including S1 and below or partial sciatic nerve resection prese
nerve root
SN4 Complete sciatic nerve including lumbosacral trunk resection (includes L5 nerve root
extensive notch clearance

SV4 Proximal internal iliac artery and vein

SV5 External iliac artery or vein +/- internal iliac artery or vein

Nerves

SN1 Obturator nerve
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L5/S1
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nerve root
SN4 Complete sciatic nerve including lumbosacral trunk resection (includes L5 nerve root
extensive notch clearance

Pelvic floor/muscles

PM1 Levator Ani
PM2 Levator Ani, sacral ligaments and muscles +Ischial spine
PM3 Iliacus/ iliopsoas resection

Additional

E1a Common iliac lymphadenectomy
E1b Para-aortic lymphadenectomy
E2 Femoral nerve resection
E3 Common iliac artery or vein resection
E4 Other not included above, please state

Expanded lexicon with notes

Posterior

P1 Presacral

Dissection in subperiosteal plane

P2 Low sacrectomy ($\leq S3$)

Coccygectomy alone excluded

P3 High sacrectomy ($\geq S2$)

This may include anterior cortex only

P4 Sacrectomy requiring stabilisation

High Subcortical Sacrectomy (HISS) will be considering according to the level of sacrectomy
i.e. a HISS at S1 will be P3

Anterior

A1 Partial cystectomy

A2 Total cystectomy or radical cystoprostatectomy

A3 Cystectomy with pubic bone resection

A4 Cystectomy with complete penectomy

A cystoprostatectomy with base of penis will be considered as A2

Central

C1 Rectum or TAH/BSO

Total or partial mesorectal resection with or without total abdominal hysterectomy
and/or bilateral salpingo-oophorectomy

C2 Rectum + TAH/oophorectomy/partial vaginectomy (female) or seminal vesicle/prostatic shave (male)

Enbloc resection of seminal vesicles with bladder would be considered as A2

C3 Rectum + TAH/oophorectomy + total vaginectomy

Pelvic sidewall

Vessels

SV1 Lymphadenectomy

Defined as an obturator, external and internal iliac node clearance NB this excludes
sampling

SV2 Ureteric resection with reimplantation

SV3 Distal branches of internal iliac artery and/or bilateral salpingo-oophorectomy

C2 Rectum + TAH/oophorectomy/partial vaginectomy (female) or seminal vesicle/prostatic shave (male)

Enbloc resection of seminal vesicles with bladder would be considered as A2

C3 Rectum + TAH/oophorectomy + total vaginectomy

Pelvic sidewall

Vessels

SV1 Lymphadenectomy

Defined as an obturator, external and internal iliac node clearance NB this excludes
sampling

SV2 Ureteric resection with reimplantation

SV3 Distal branches of internal iliac

Defined as ligation of the internal iliac artery distal to the superior gluteal artery

SV4 Proximal internal iliac artery and vein

Defined as ligation of the internal iliac artery proximal to the superior gluteal artery
close to the origin

SV5 External iliac artery or vein +/- internal iliac artery or vein

Nerves

SN1 Obturator nerve

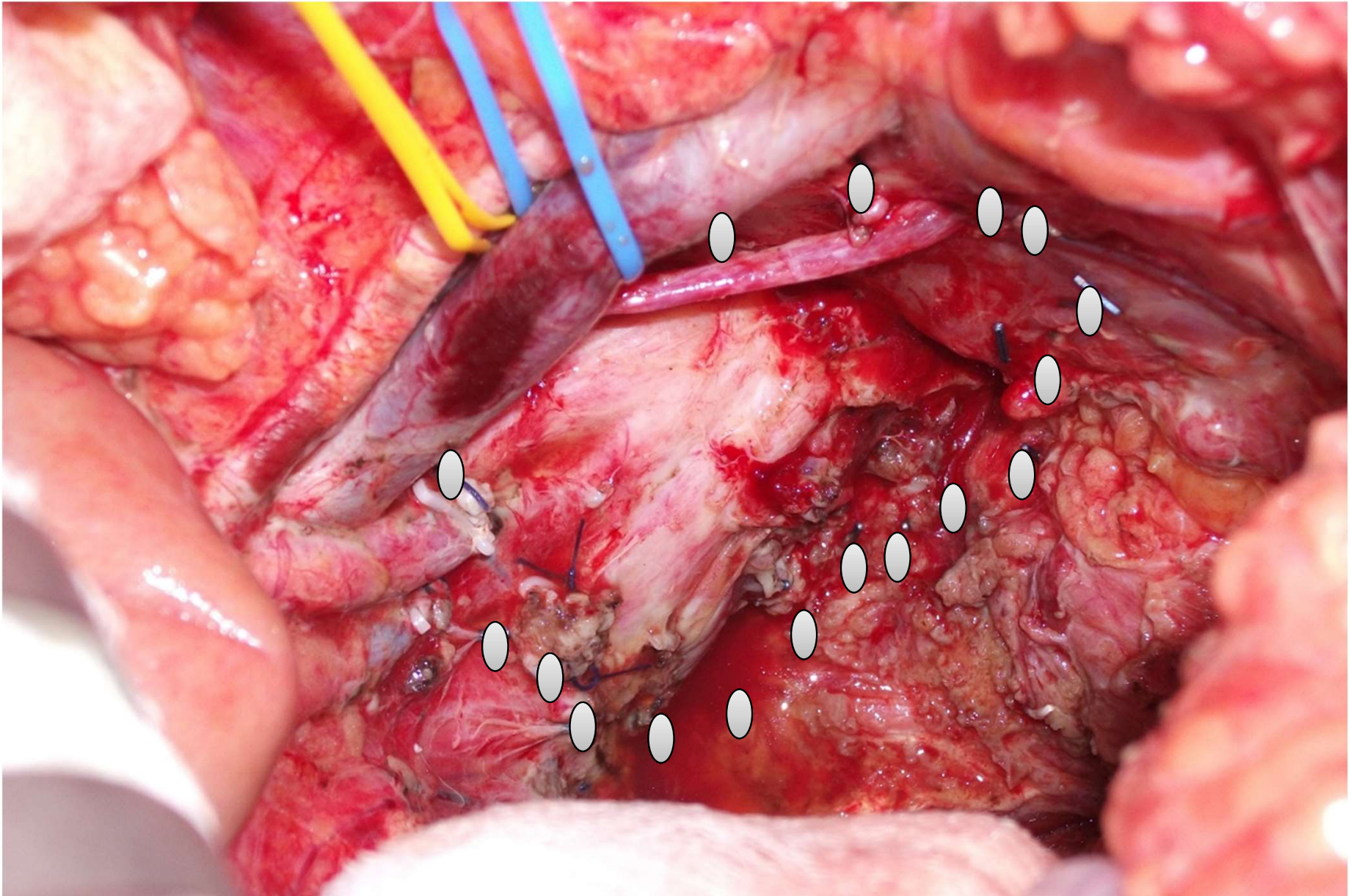
SN2 Single nerve root

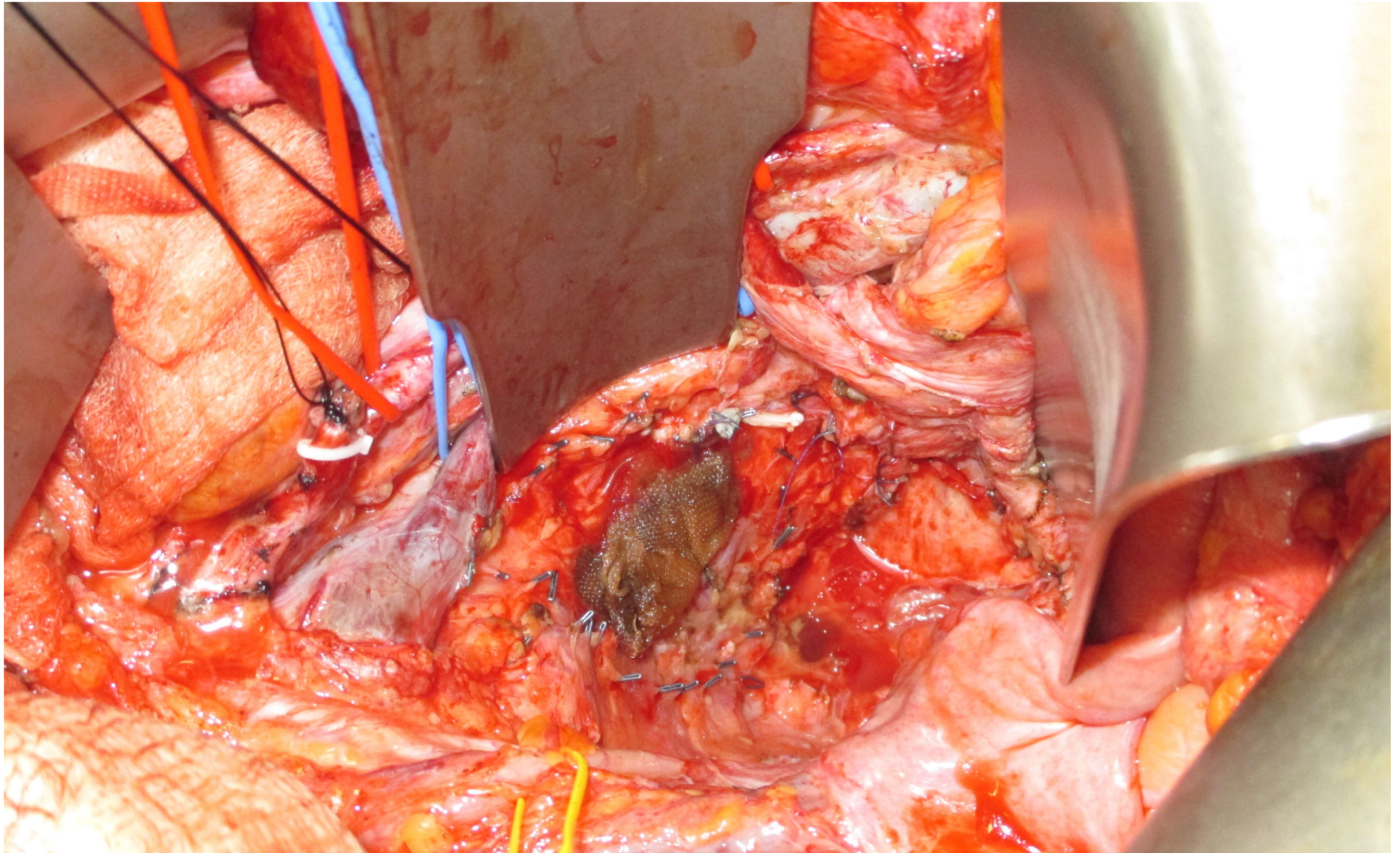
- Three workshops held in UK to date

What about volume of cases ?

- Centralisation of complex cancer surgery units – our catchment currently 5m
- Formation of national and International organisations
- Development of guidelines
- Have allowed the landscape of low volume highly complex surgical interventions to change nationally
- We now do 1-2 cases per week

Primary outcome measurement: Application of clips to localise exact IOERT field





Standardised approach to follow up



at examination: 49 years

2_tse_tra_p2_320 ▾



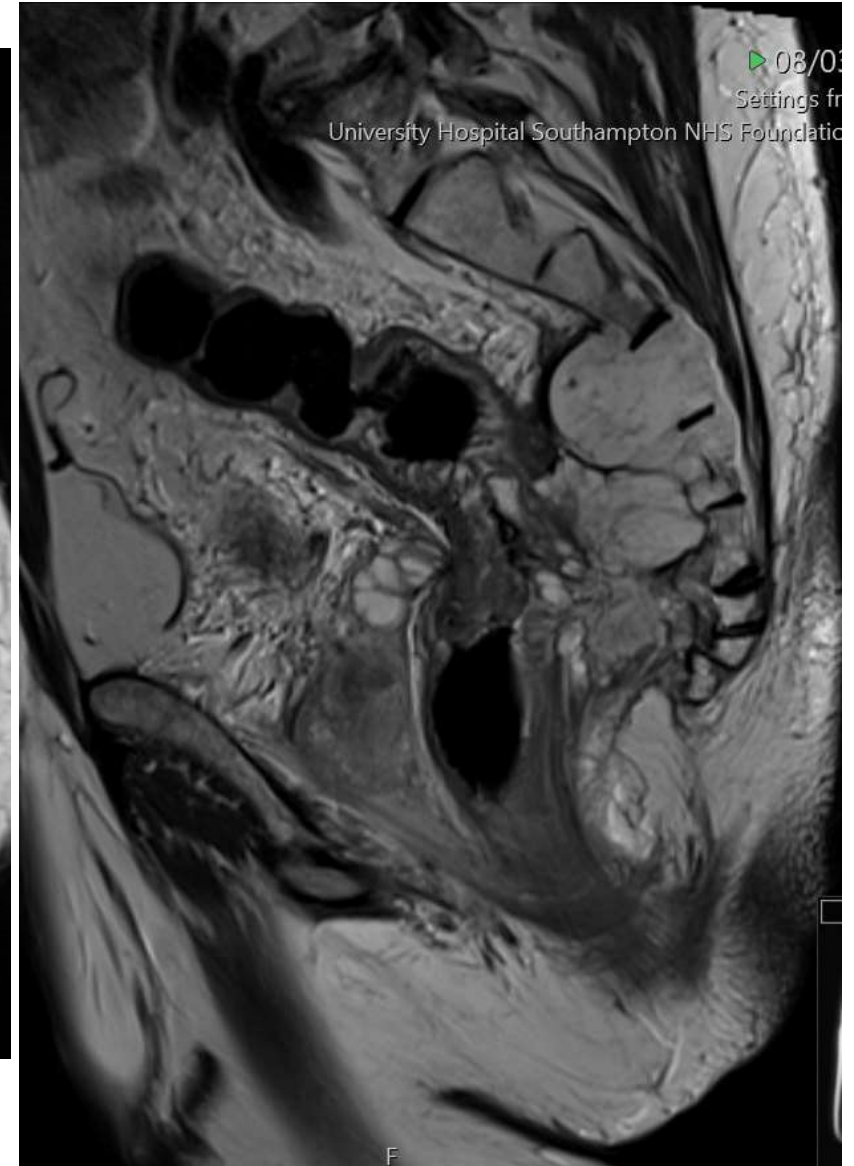
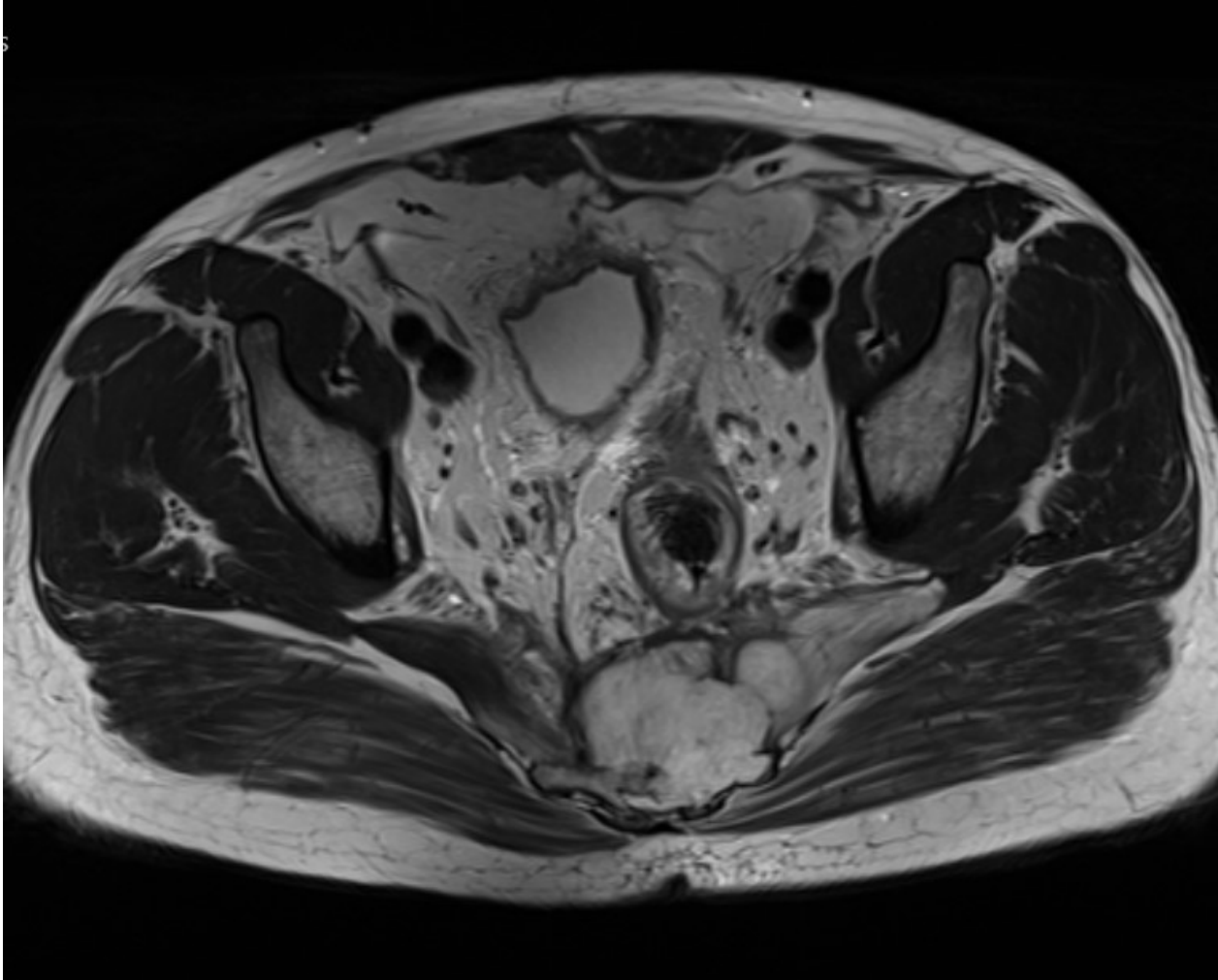
The ELECTRA trial

- Opened in May 2022
- First two months – unable to recruit patients as operating on patients previously lined up and “promised to have IOERT”
- Subsequently all patients told they could only access this as part of trial
- Over recruited patients in subsequent 6 months
- Then machine needed upgrading which took 5 months rather than 1 (a mistake with hindsight)
- Post upgrading some teething issues
- Then trial had to be stopped as funding was withdrawn by IntraOp

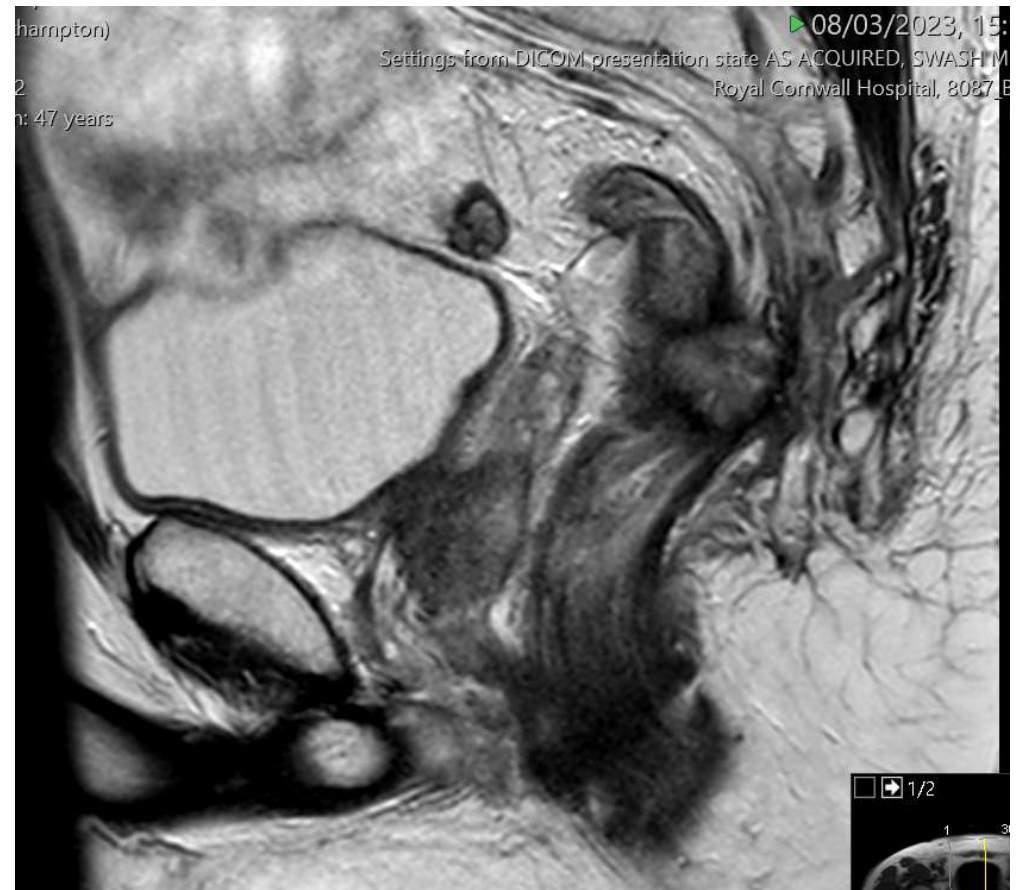
The ELECTRA trial

- Closed to further recruitment after 31 patients (had planned for 42 in total)
- Now evaluating the data on the 31
- Comments from the recruited patients:
 - *31/31 (100 %) Would prefer to not be randomised to non IOERT arm*
 - *In the setting of imperfect preop information, abnormal and hard to judge anatomical planes at surgery, and a well-tolerated intervention that doesn't add hugely to an already long operation, is there much to lose?*

Example Electra patients imaging



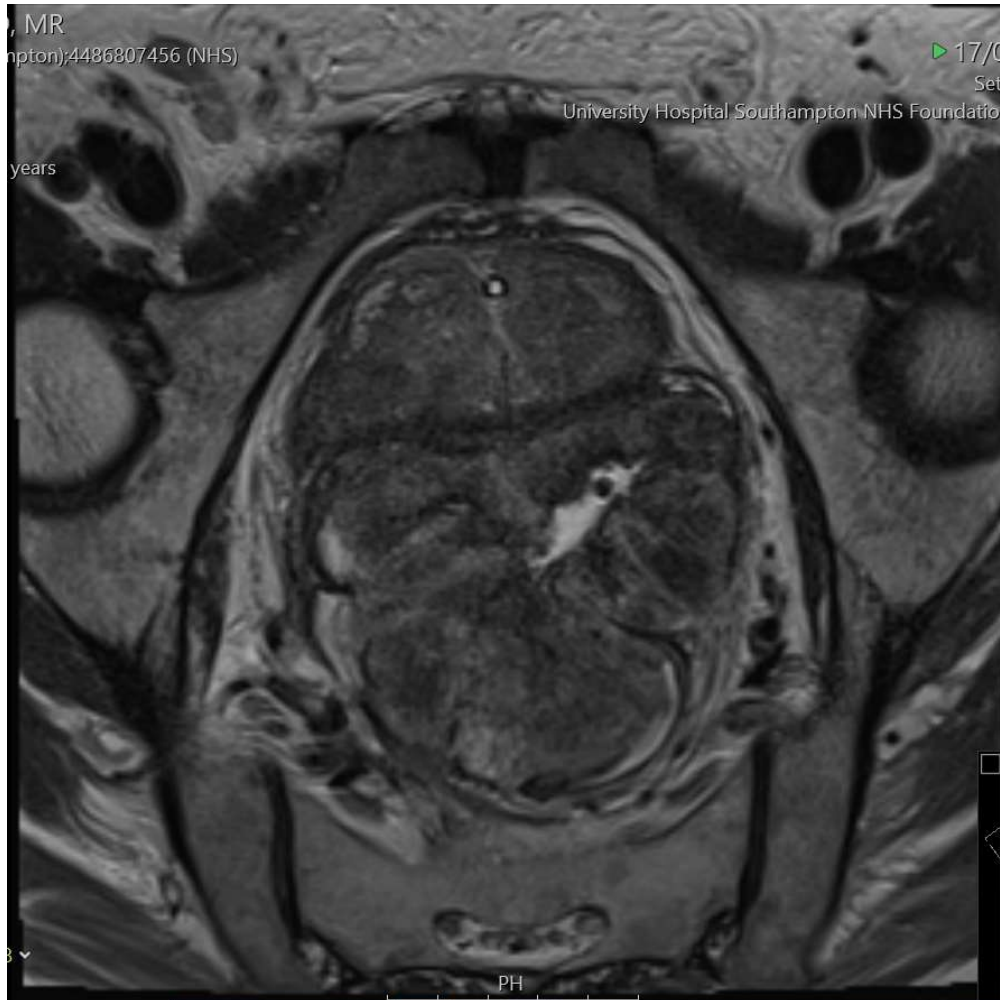
Example Electra patients imaging



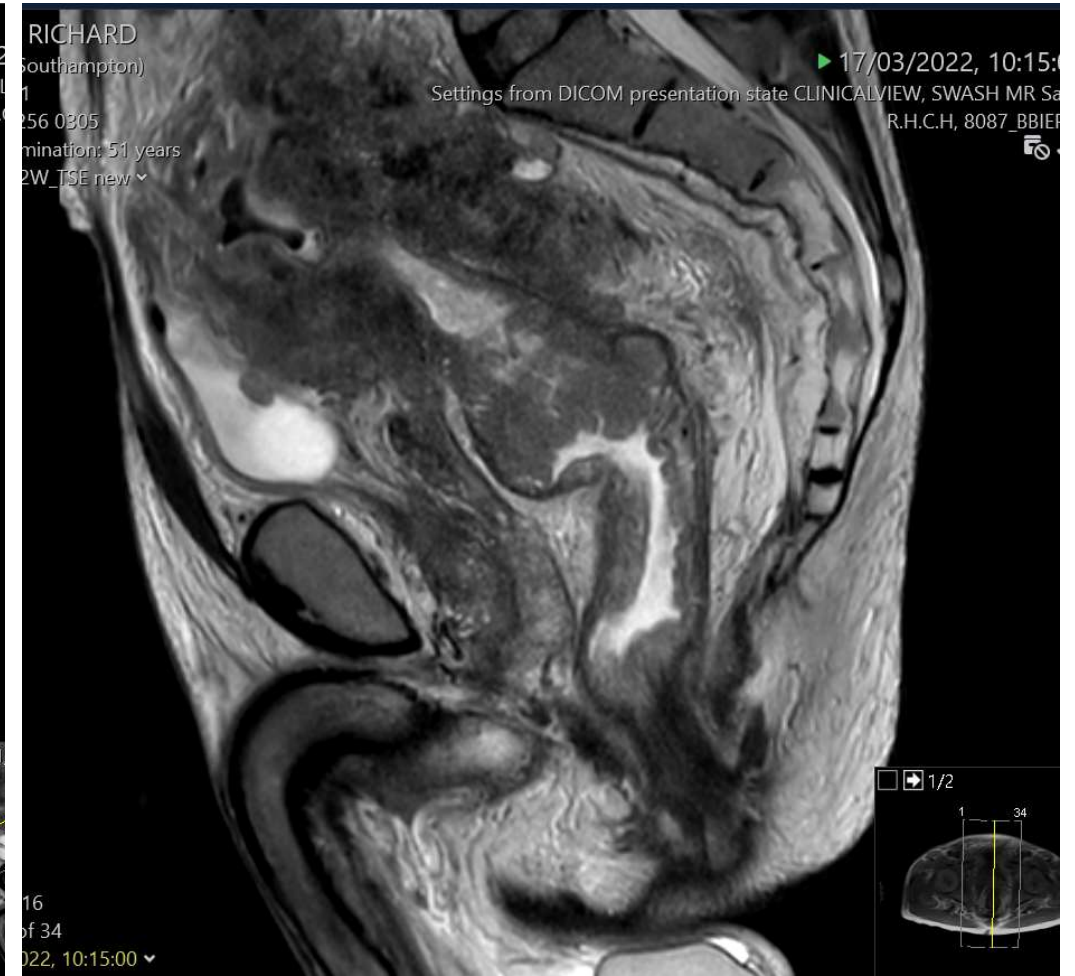
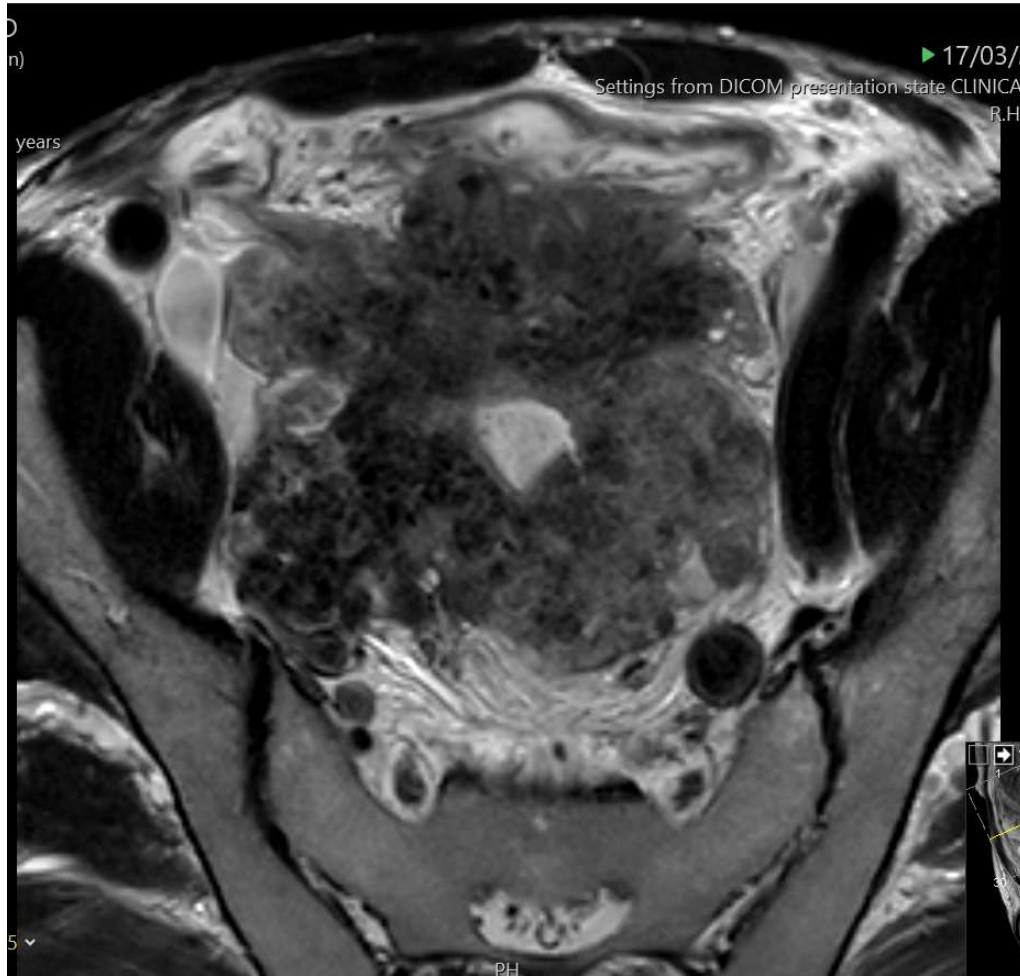
Example Electra patients imaging



Example Electra patients imaging



Example Electra patients imaging



The ELECTRA trial

- *Need your help....*
- Seek to involve international units interested in participating in the next post-feasibility phase – to evolve the process and optimise design
- To discuss surgical; and radiological and pathological QC across units
- To start the process with funding

Summary

- IORT in LARC and LRRC is a complementary treatment to surgery and multimodality treatment....in carefully selected cases of LARC and LRRC
- But....it has a poor evidence base... and it is up to us in this community to challenge and change that.....and attempt to develop some level 1 evidence
- Theory of marginal gains And opening up the theatre to oncology..... a further frontier in the evolution of multi-modality care, for treatment of the most challenging cancers
- An international, multicentre collaborative research effort in carefully designed trials is the only way to influence this field

Acknowledgements

UHS Teams

- Theatre staff and management
- Anaesthetic teams
- Oncology teams
- Radiographers
- Physicists
- Surgery teams (colorectal, HPB, Urology, Vascular, Ortho, Spinal)

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