INTRAFRACTION MOTION WITH OPEN VS. CLOSED H&N FACE MASKS: WHAT CONTINUOUS SGRT MONITORING ADDS IN A RANDOMIZED PHASE III TRIAL

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ST LUKE'S RADIATION ONCOLOGY NETWORK, DUBLIN, IRELAND

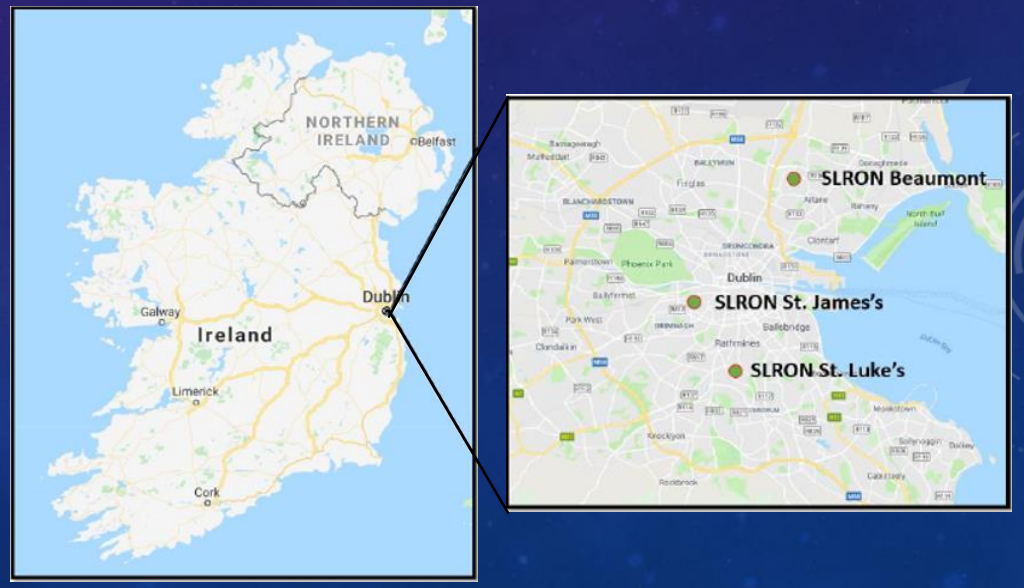
DISCLOSURES

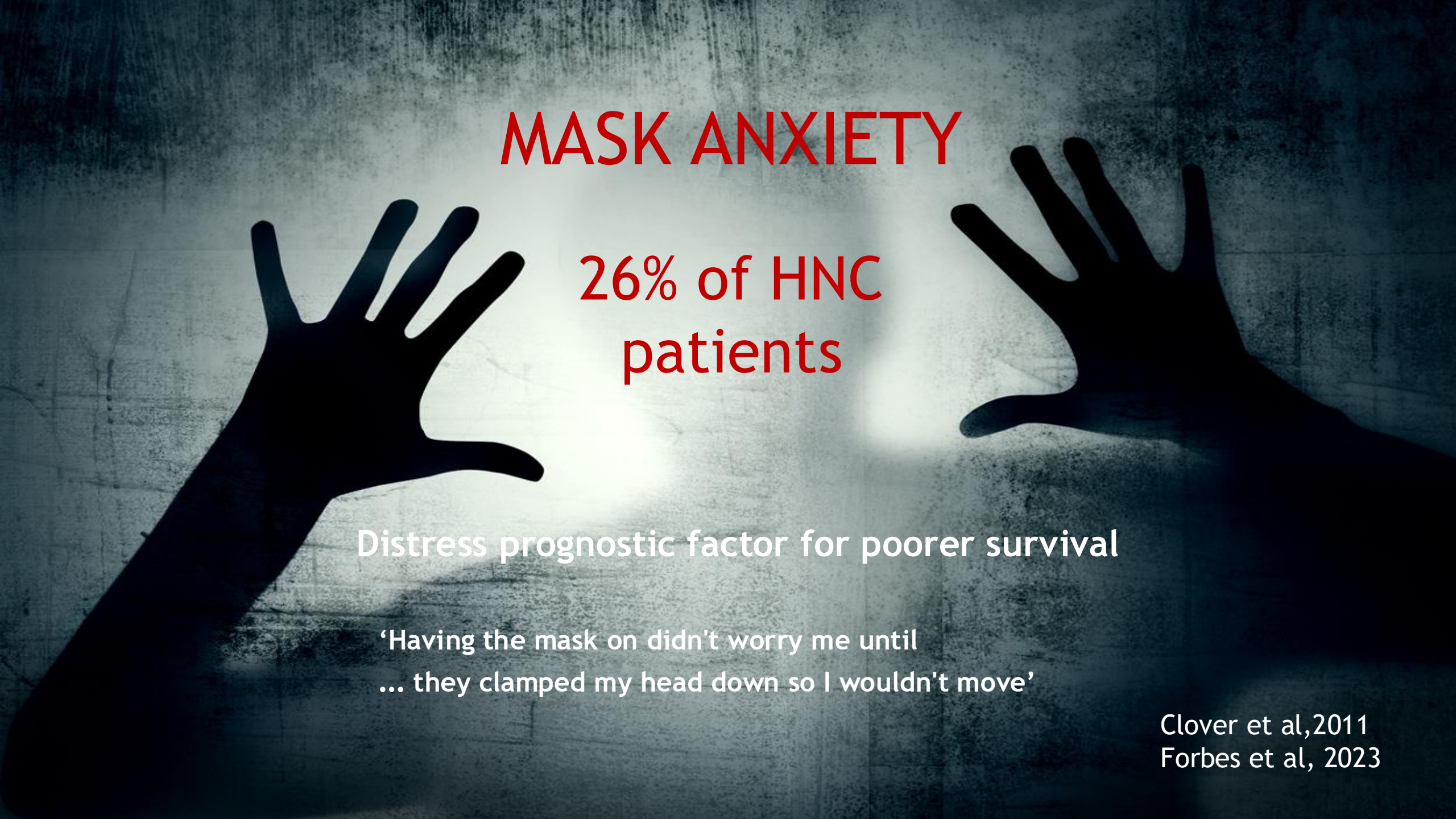
- Travel kindly covered by VisionRT to speak today

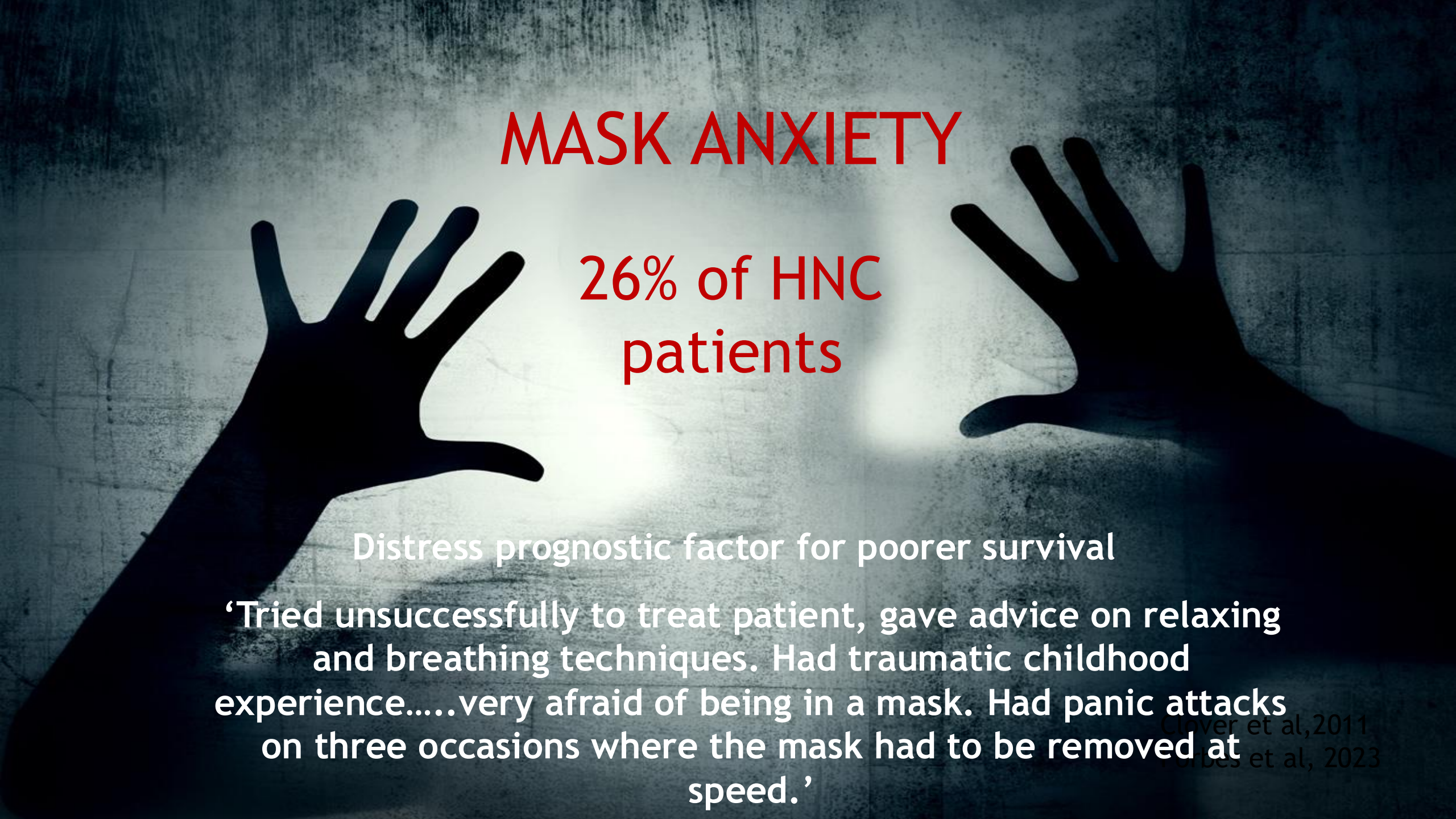
- Masks provided by Orfit Industries but no input in study concept, design or analysis

ST. LUKE'S RADIATION ONCOLOGY NETWORK

- SLRON:
  - St. Luke's Hospital
  - St. James's Centre
  - Beaumont Centre
- Radiotherapy, Brachytherapy and Nuclear Medicine
- 6 CT-simulators across 3 sites
- 14 linear accelerators across 3 sites
- ~5500 RT patients per year




MASK ANXIETY
26% of HNC patients
Distress prognostic factor for poorer survival
‘Having the mask on didn't worry me until
... they clamped my head down so I wouldn't move’
Clover et al,2011
Forbes et al, 2023



MASK ANXIETY

26% of HNC patients

Distress prognostic factor for poorer survival

‘Tried unsuccessfully to treat patient, gave advice on relaxing and breathing techniques. Had traumatic childhood experience…..very afraid of being in a mask. Had panic attacks on three occasions where the mask had to be removed at speed.’

Clover et al,2011
Tribes et al, 2023

REPORTS OF PRACTICAL
ONCOLOGY AND
RADIOTHERAPY

SCAN ME

Unmasking anxiety: a head-to-head comparison of open and closed masks in head and neck cancer radiotherapy

Aisling M. Glynn, Rachel Harwood, Bill Garrett, Dean Harper, Mary Dunne, Jill Nicholson, Guhan Rangaswamy, Fran Duane, John Armstrong, Orla McArdle, Sinead Brennan

ABSTRACT

Background: Facemasks accurately immobilise patients with head and neck cancer (HNC) receiving radiotherapy (RT). However, such masks are associated with treatment related distress, a prognostic factor for poorer survival. Open masks offer increased comfort and patient satisfaction. We investigated whether open masks could immobilise patients without affecting treatment accuracy.

Saint Luke's Radiation Oncology Network

Reports of Practical Oncology and Radiotherapy 2024, Vol 29, N0 2, : 219–227
DOI: 10.5603/rpor.99905

Importance of Ph 3 RCT in evaluating new technology

With SGRT we wanted to:

- Reduce the complexity of treatment setup
- Track patient motion with < 1mm accuracy
- Enable reduced immobilisation options (3-point)
- Maximise patient comfort
- Move to 3mm H&N margins with confidence

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SGRT: REGION OF INTEREST (ROI) DESIGN STRATEGY

Initial pilot aims:
- Ensure optimal ROI approach
- Inform staff training on OPEN trial ROI based tracking strategies

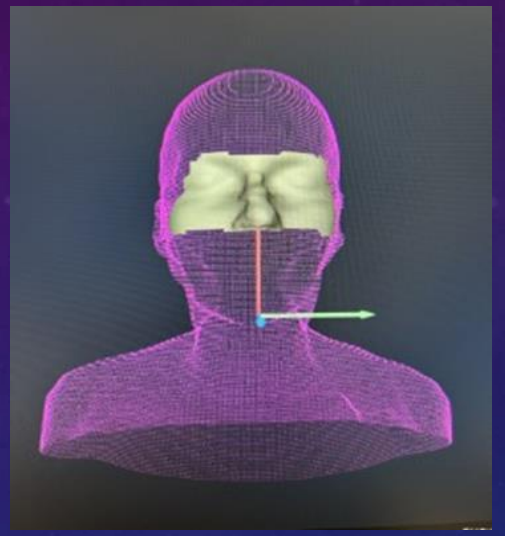
Final approach for OPEN: dual ROI workflow!

- Face ROI for initial set up

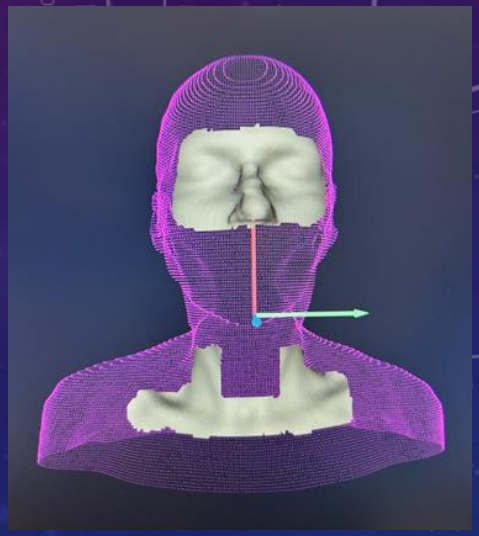
- Composite ROI for real time tracking during RT

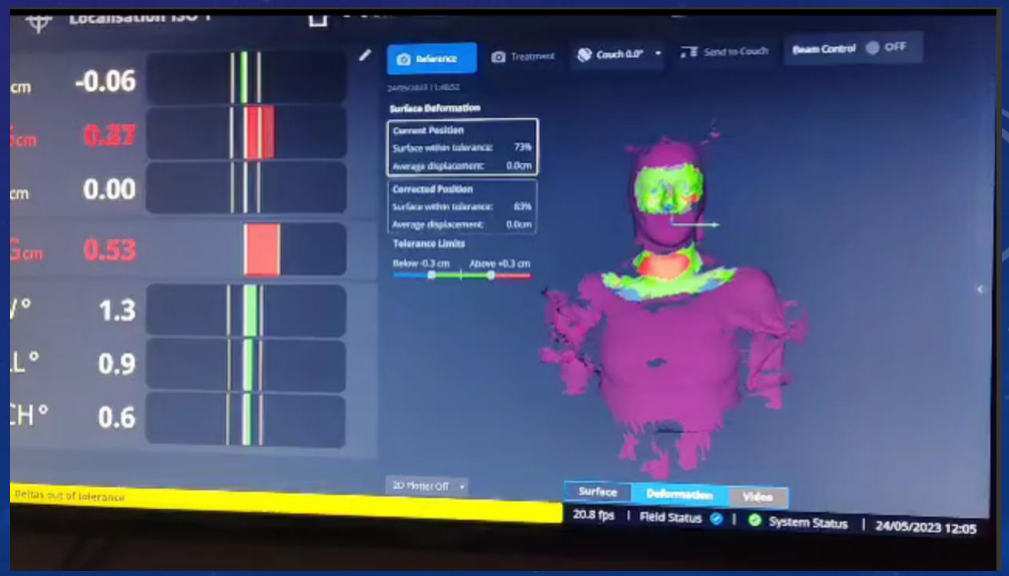
Real Time Deltas
Set up with 2mm and 2deg

Face ROI



Composite ROI

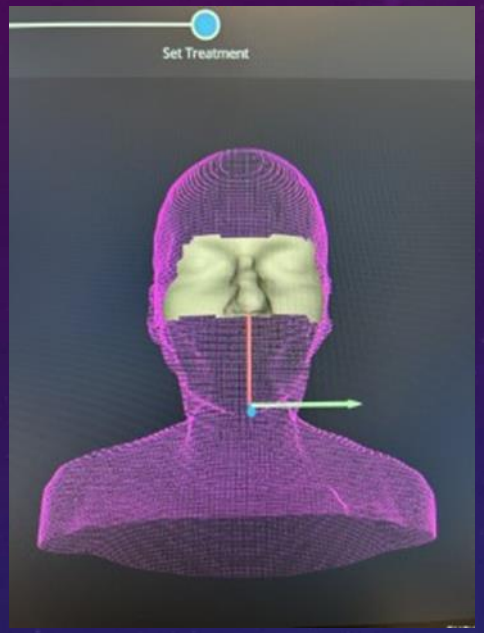




visionrt

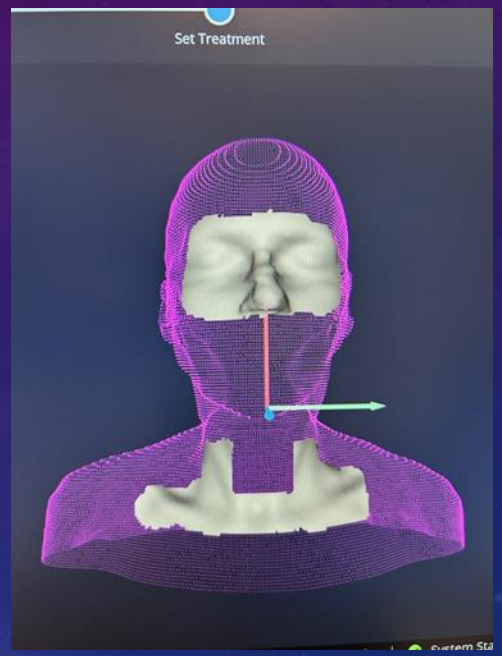
OPEN TRIAL: ROI APPROACH

1st - FACE ROI - Setup



- Used for Set up Only
- Get the face as close to zero in all directions first. Move the bed.
- Postural video tab for guidance (neck inflection)
- Place mask on patient and ensure within tolerance

2nd - Composite ROI - Treatment



- Final setup & treatment monitoring ROI (beam held).
- Ensure thorax in tolerance, try not to move the bed - move the patient first
- Use deformation workspace for shoulders

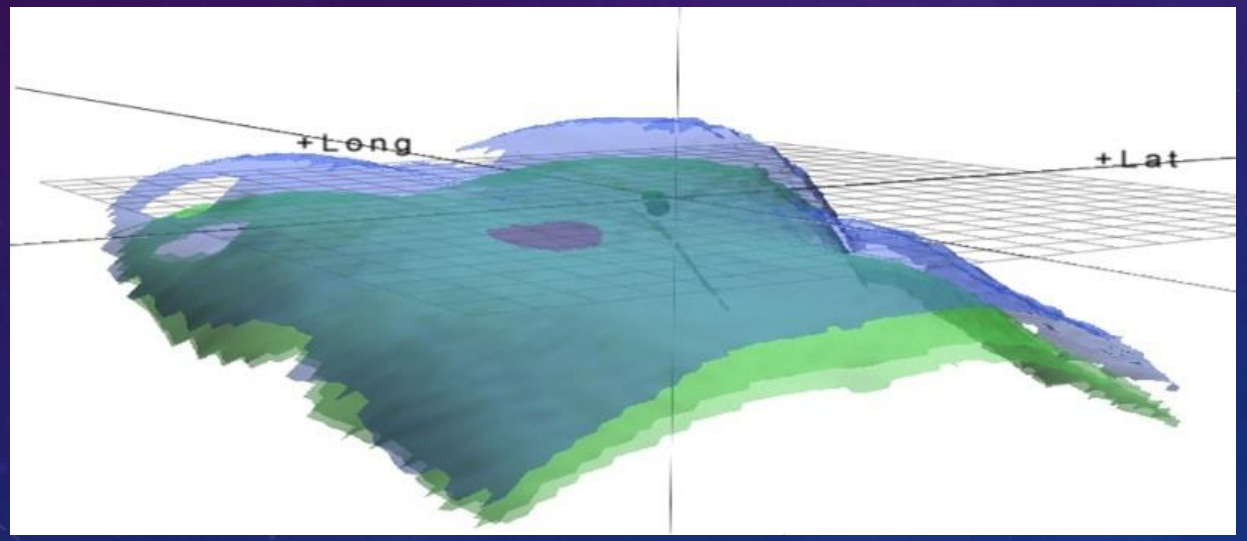
General guidance given to RTTs:

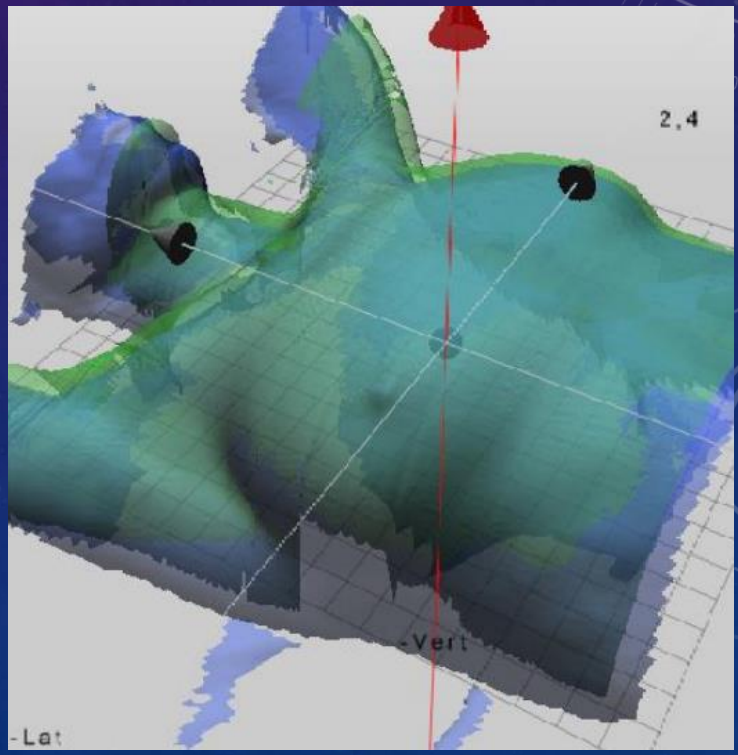
1. All ROI's should extend laterally across face & exclude mouth/lips
2. Include stable surfaces (ie clavicles and nose)
3. Exclude immobilisation devices, clothing etc.
4. All ROI's can be modified for each patient during treatment (eg. come off swelling/skin reaction)

OPEN face ROIS are quite small….
Did we capture “Good” topography?

SCAN ME

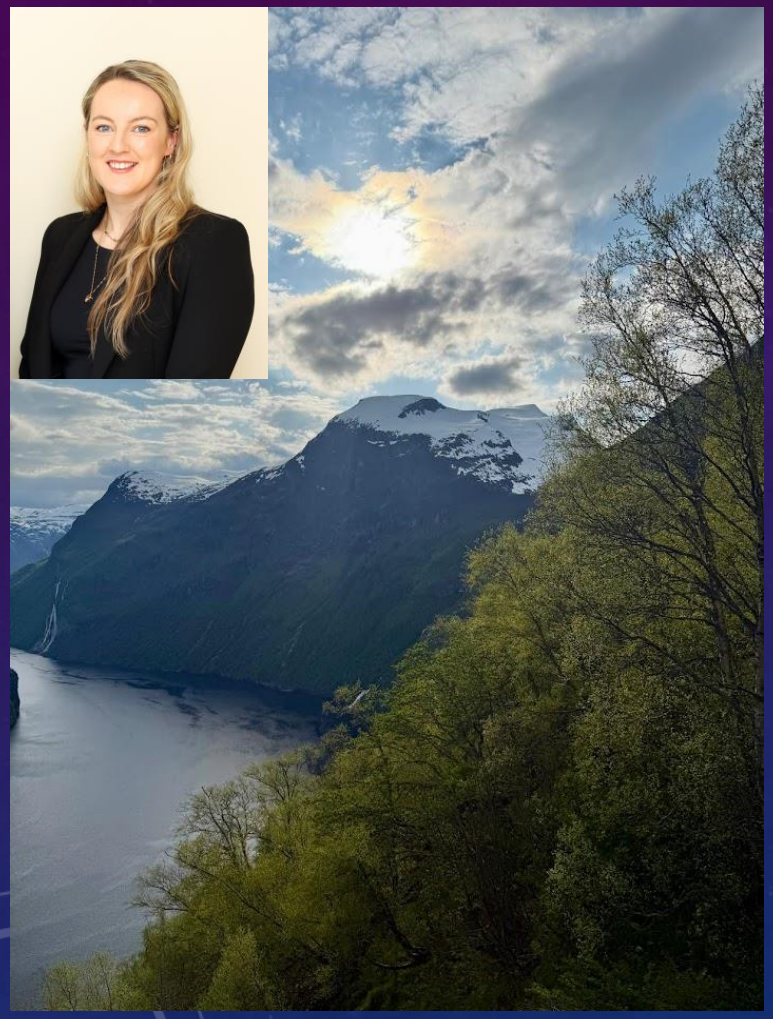
- ROI: Region of Interest (ROI) is a defined area on the patient's body surface that is used to monitor and guide treatment delivery
- The ROI should include **suitable topography** for accurate SGRT **surface registration**
- Currently: Qualitative guidance & experience!!

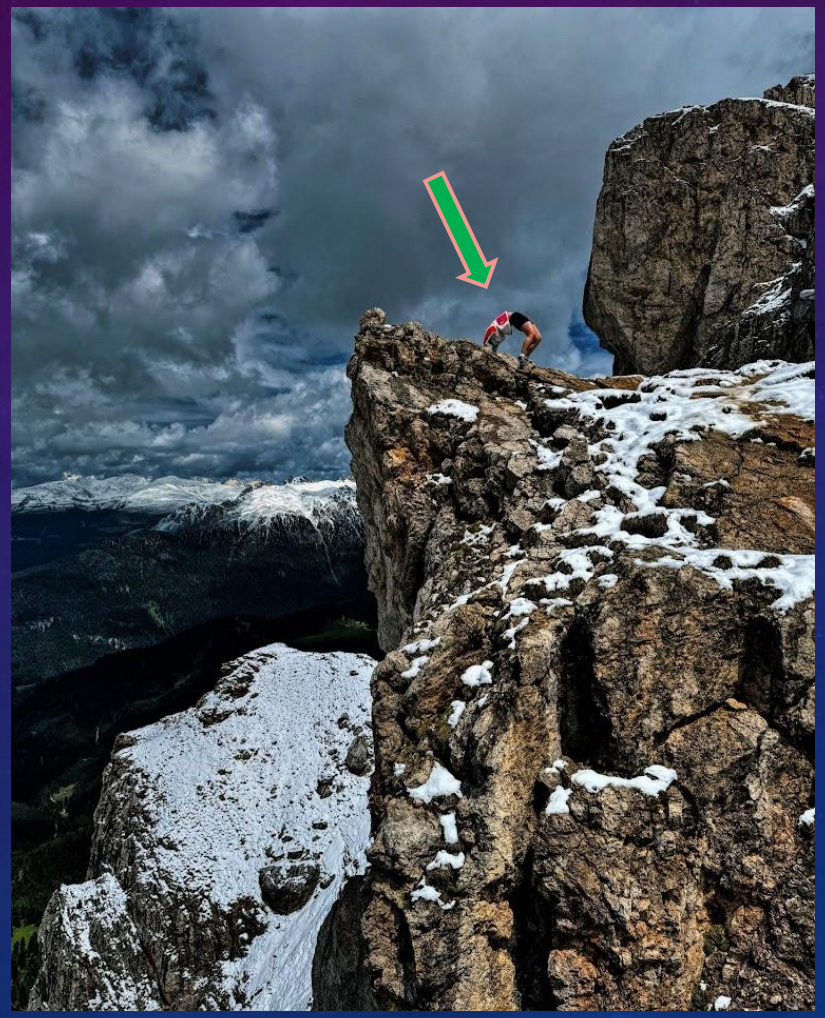




TOPOGRAPHICAL METRICS: “SURFACE TOPOGRAPHY”

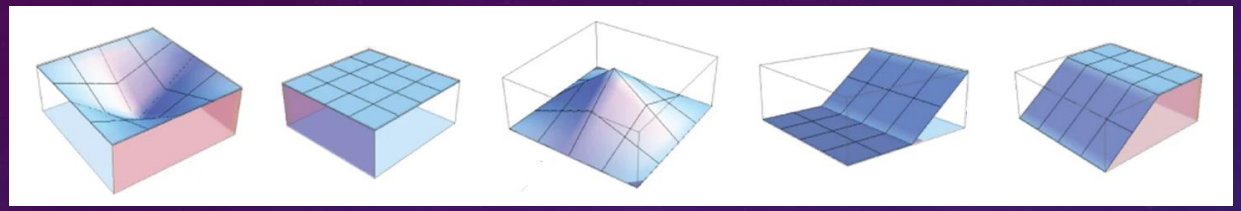
SCAN ME





SGRT – WHAT IS “GOOD TOPOGRAPHY”?

SCAN ME



Slope (0-90)
Aspect (0-360)

Vector Ruggedness Measure (VRM) – fine structure
Terrain Ruggedness Index (TRI) – local structure
Topographic Position Index (TPI) – regional structure

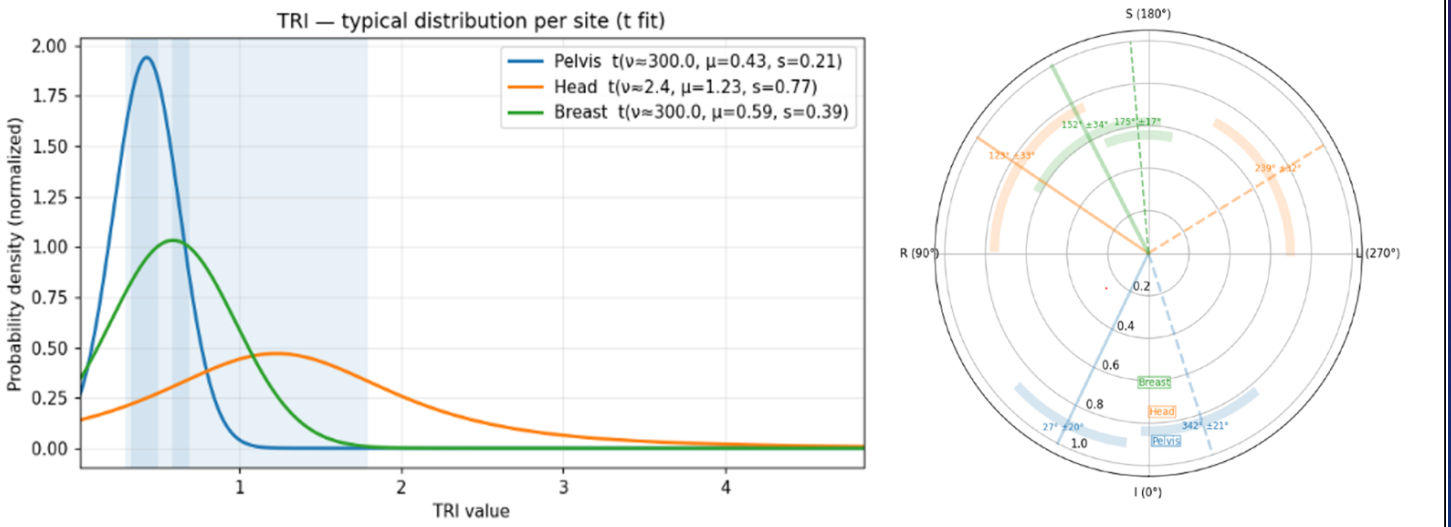


Figure 1. Comparison of surface topography metrics for the Pelvis, Head, and Breast regions. Left: Distributions of the Terrain Ruggedness Index (TRI). Right: Aspect distribution rose plots showing the dominant aspect directions (lines) and IQR ranges (bands).

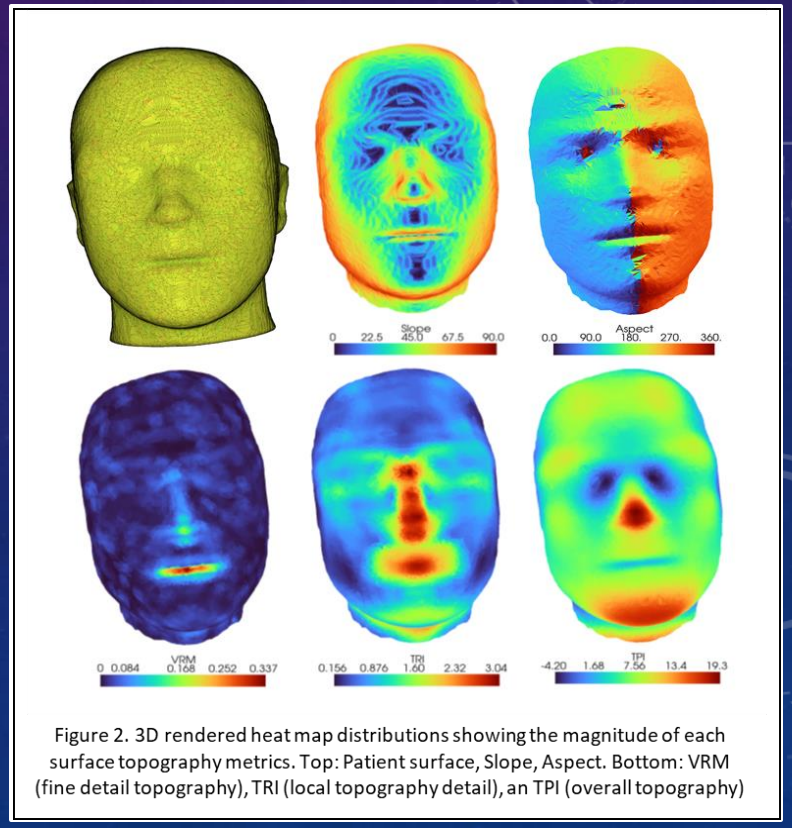
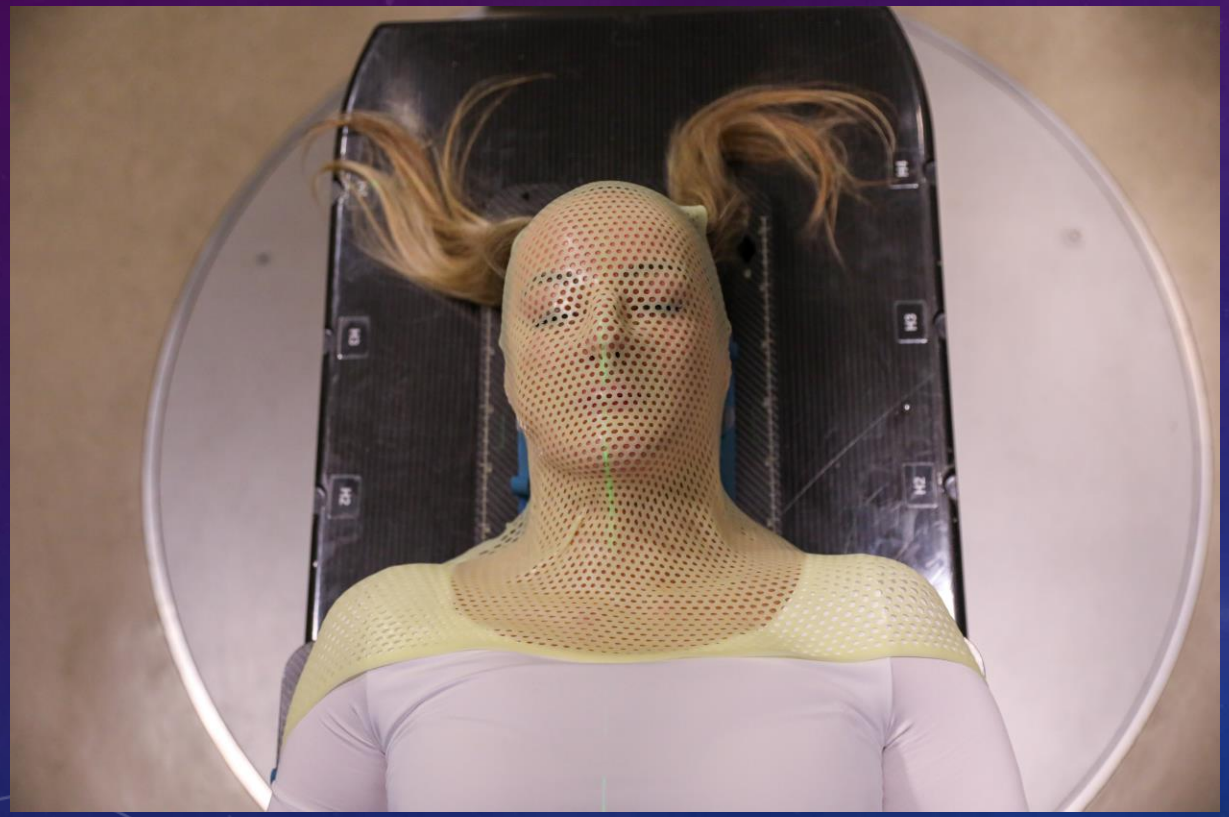
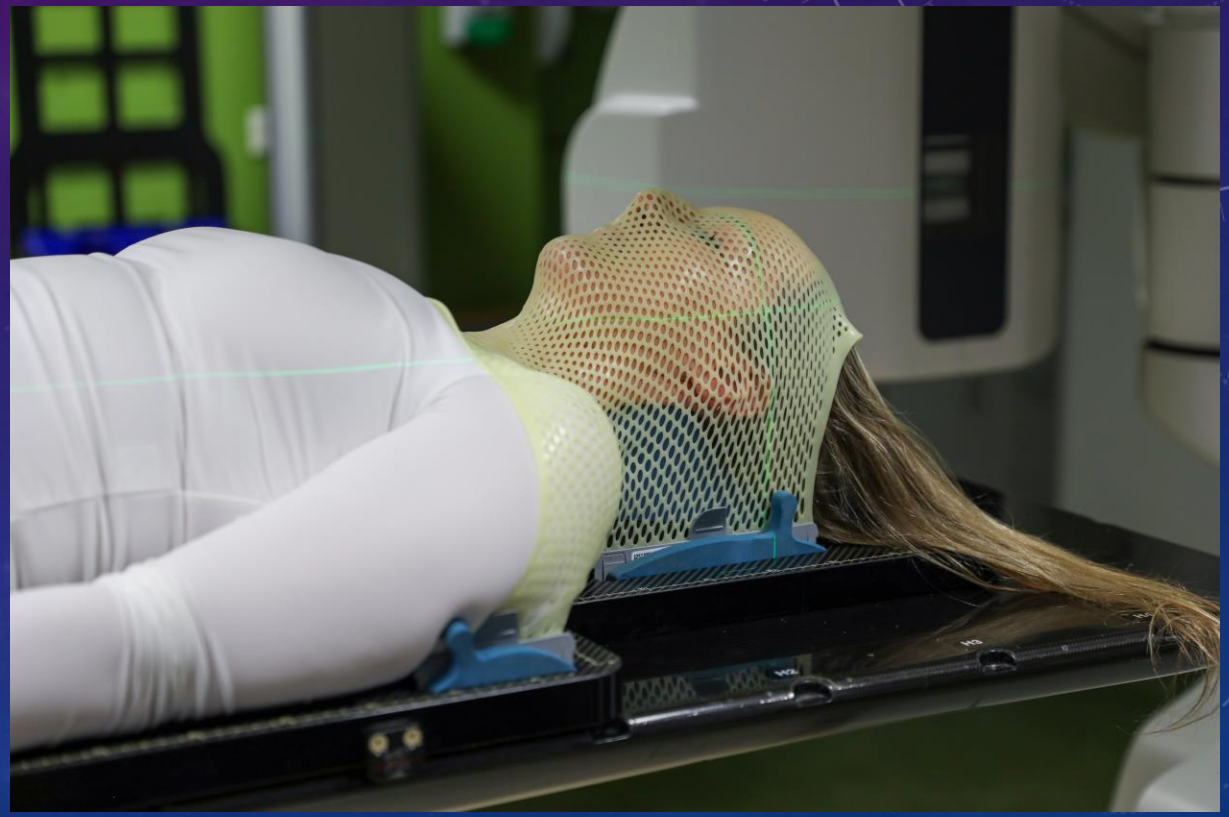


Figure 2. 3D rendered heat map distributions showing the magnitude of each surface topography metrics. Top: Patient surface, Slope, Aspect. Bottom: VRM (fine detail topography), TRI (local topography detail), an TPI (overall topography)

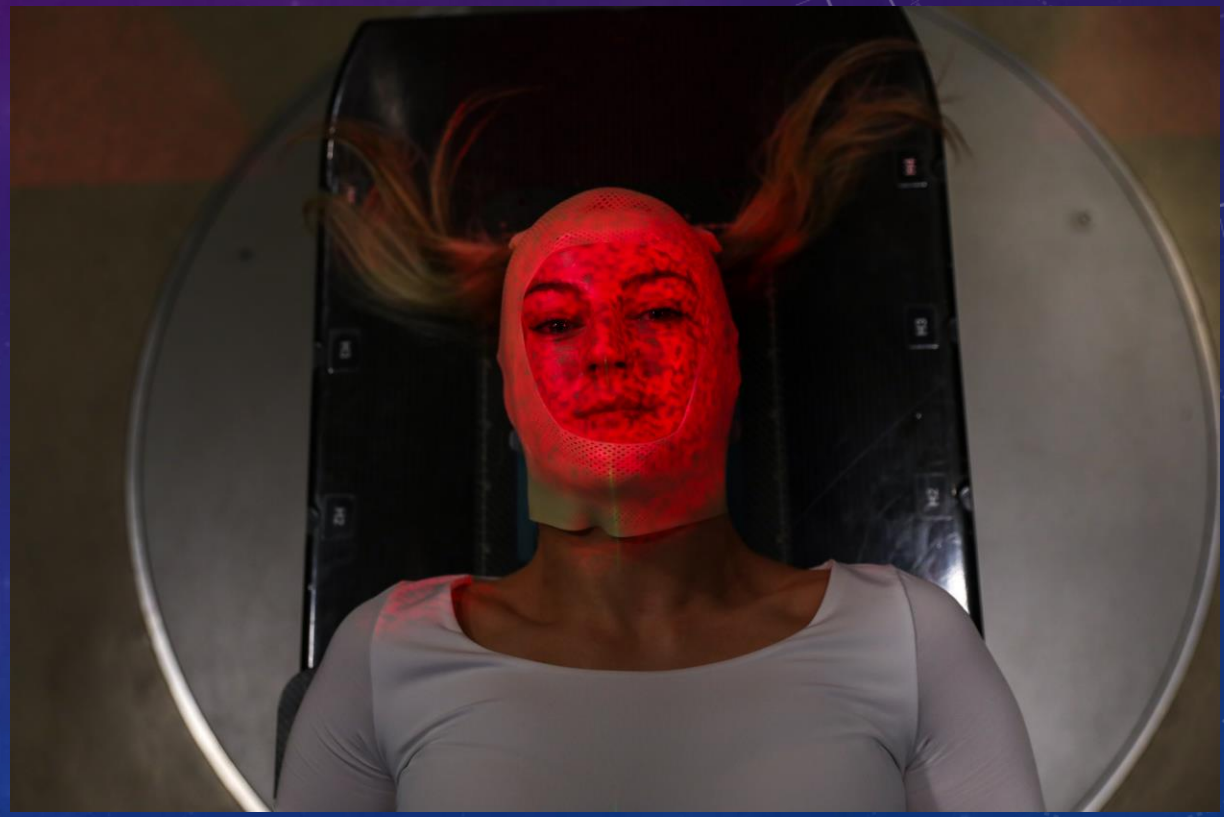
Result: Even small ROIs in the facial region give good surface topography. Nasal bridge = important

ARM A: 5 POINT CLOSED MASK

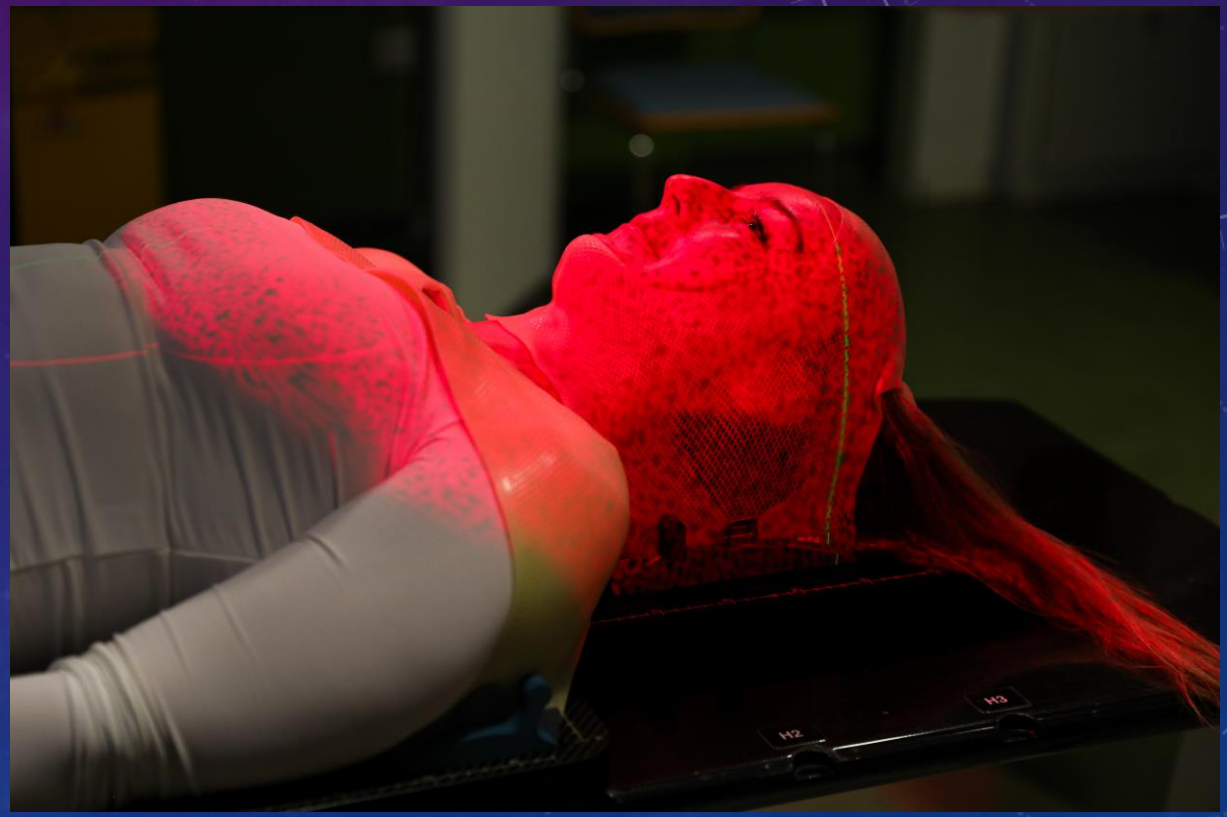




ARM B: 3 POINT OPEN MASK

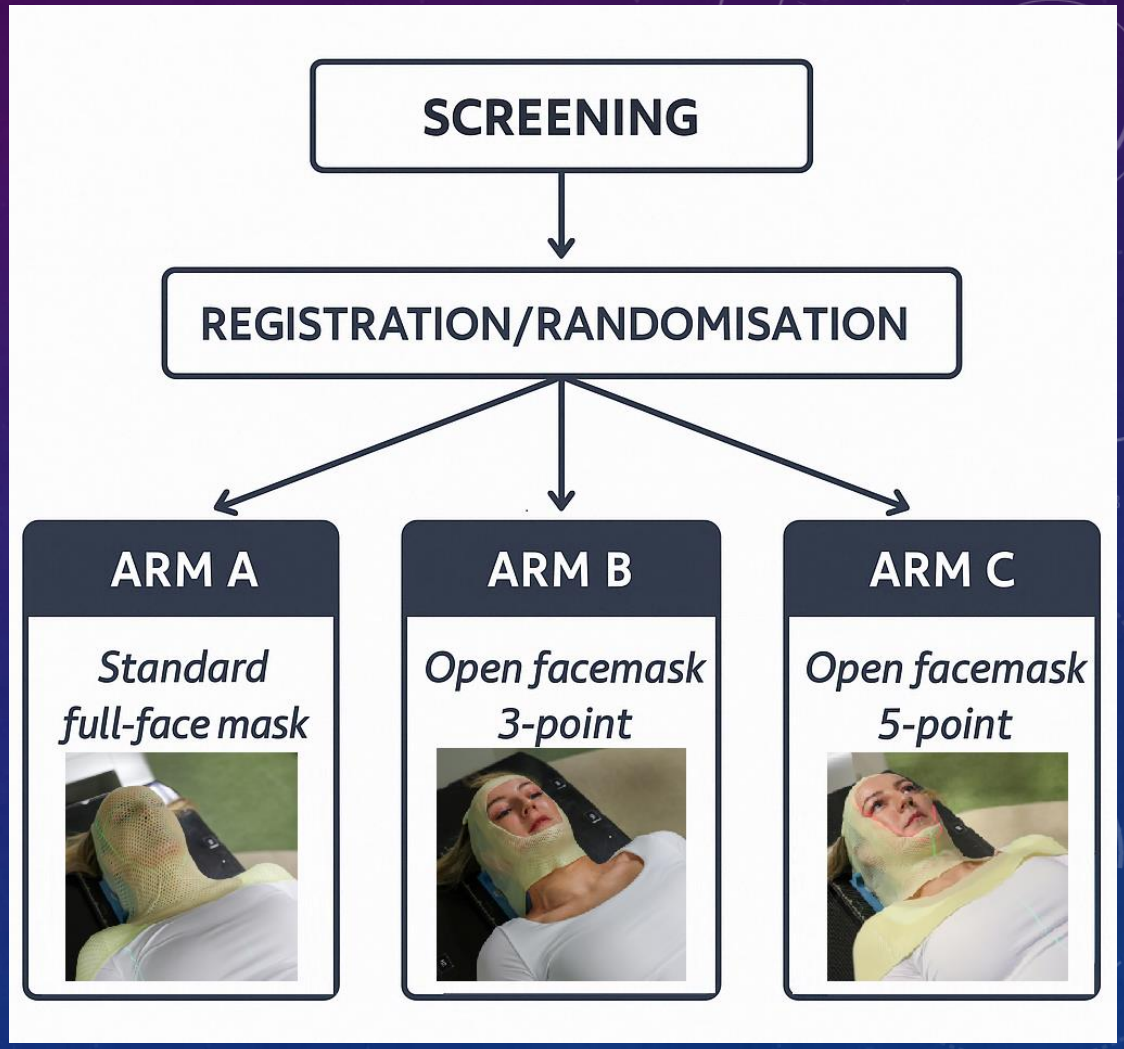


ARM C: 5 POINT OPEN MASK



OPEN TRIAL: METHODS

- Largest randomised trial of Open faced masks: N= 230
- Included radical RT for head and neck cancer pts
- **Excluded pts with known claustrophobia**
- Randomised 1:1:1
- Combination of frequentist & Bayesian statistics
- Automated data parsing pipelines & analysis scripts using Python



ClinicalTrials.gov: NCT06327139
Protocol Accepted for Publication: HRB Open Access Journal

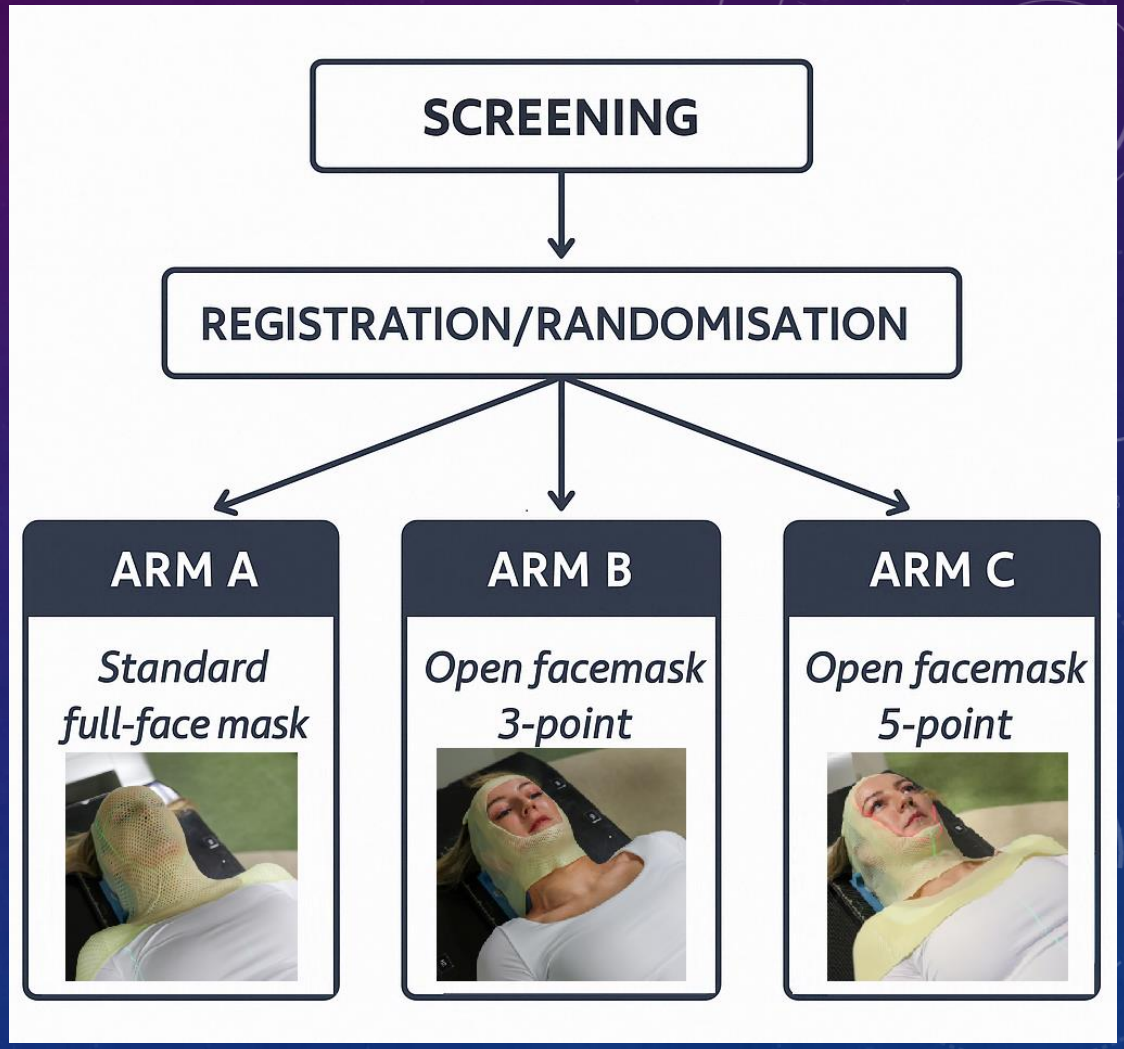
OPEN TRIAL: METHODS

Primary Objectives:

1. Compare the setup accuracy of three different types of masks

Secondary Objectives:

1. Compare patients' distress levels, comfort, tolerability & overall experience
2. Evaluate potential advantages of Surface Guided Radiotherapy (SGRT) as a tool for intra-fraction motion monitoring compared to CBCT imaging
3. Assess impact on treatment set up time and use of resources on the treatment unit



ClinicalTrials.gov: NCT06327139
Protocol Accepted for Publication: HRB Open Access Journal

WHAT EXACTLY IS INTRA-FRACTION MOTION

"Set-up and motion that occurs during a single treatment fraction delivery"

2.1.7 Intrafractional verification

This evaluates the set-up and motion *during* a single treatment fraction delivery.

The effect of intrafractional movement can be accounted for in treatment margins and, if significant, can be reduced using the following methods:

- Terminating the treatment beam if movement occurs outside predefined tolerances
- Timing the treatment beam to ensure delivery of radiation coincides with a known position of the patient's internal anatomy (gating)
- Restricting variation in the position of internal anatomy.

Intra-fraction motion is the variability seen in multiple images acquired in rapid succession during the delivery of a radiation treatment beam. Intra-fraction error is considered to be random, as the variations seen in multiple images acquired during one beam-on period are typically related to factors such as patient movement and internal organ motion during the treatment fraction. Random intra-fraction error is the variability averaged across all the images taken on one day and compared with the averaged error of all the fractions where images were obtained.8

Michalski et al. 2012

The results were defined by one of two categories; the measurement difference between images within a fraction (intra-fraction motion); and the measurement difference of images between fractions (inter-fraction motion). The latter of these categories also included a comparison with the digitally reconstructed radiograph (DRR) produced from each patient's planning CT scan.

Jones et al. 2015

Intrafractional tumor motion was quantified in 84 patients using cine MRI.

Mean maximum tumor motion was 2.4 mm in feet-head and 1.8 mm in anterior–posterior.

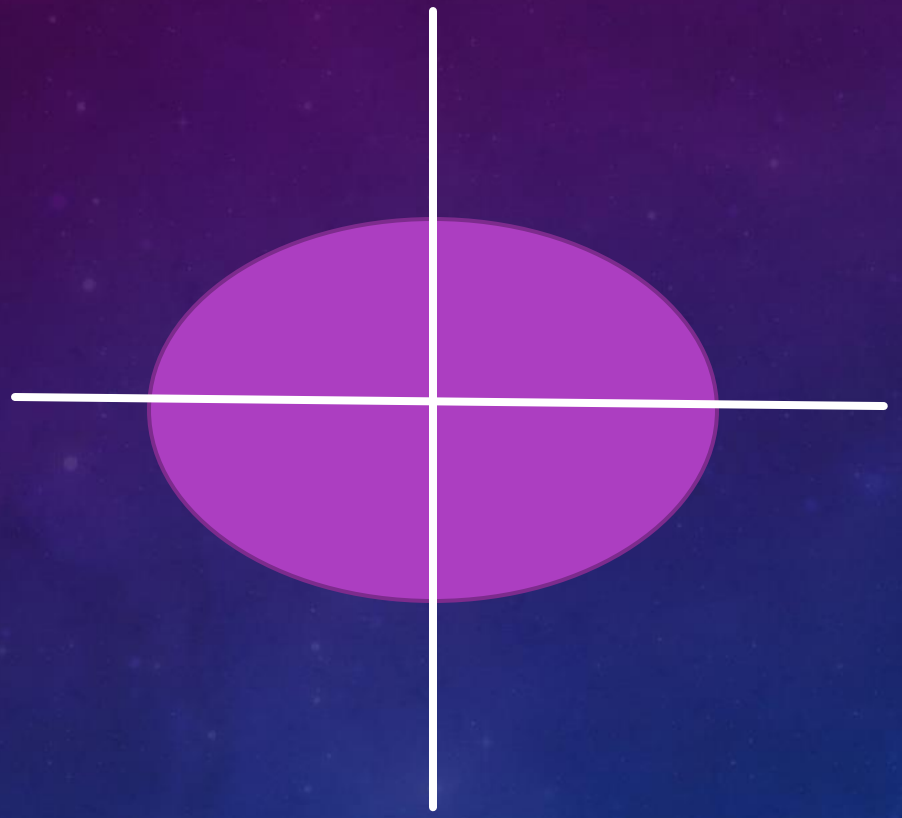
Bruijnen et al. 2019

Several other studies have evaluated the effect of intrafraction motion on the dosimetry of SRS plans, though previous studies have used a radiographic method to measure motion by acquiring the images at the end of the fraction, thus making it not truly intrafraction.[28,29] These methods only provide a snapshot of the patient position and do not provide continuous monitoring as SGRT does; the patient position at time points other than the imaging procedure is unknown. A recent

RD Foster et al, 2023

INTRA-FRACTION MOTION

Set-up and motion that occurs during a single treatment fraction delivery



Start position: (0,0)

???

End position: (-2,-2)

CBCT → Treatment → CBCT

RESULTS:
INTRAFRACTION MOTION - A SYNERGISTIC APPROACH

SCAN ME

- Pre-planned interim safety analysis
- First 56 patients (Closed: 18, 3-point open: 18, 5-point open: 17)
- Intrafraction motion assessed using both weekly pre + post CBCT, and daily SGRT synergistically
  - CBCT - deviations in translational + rotational dimensions based on bony alignment
  - SGRT - continuous monitoring of surface motion
- Bayesian analysis to determine the equivalence across mask types and measurement techniques

Start position

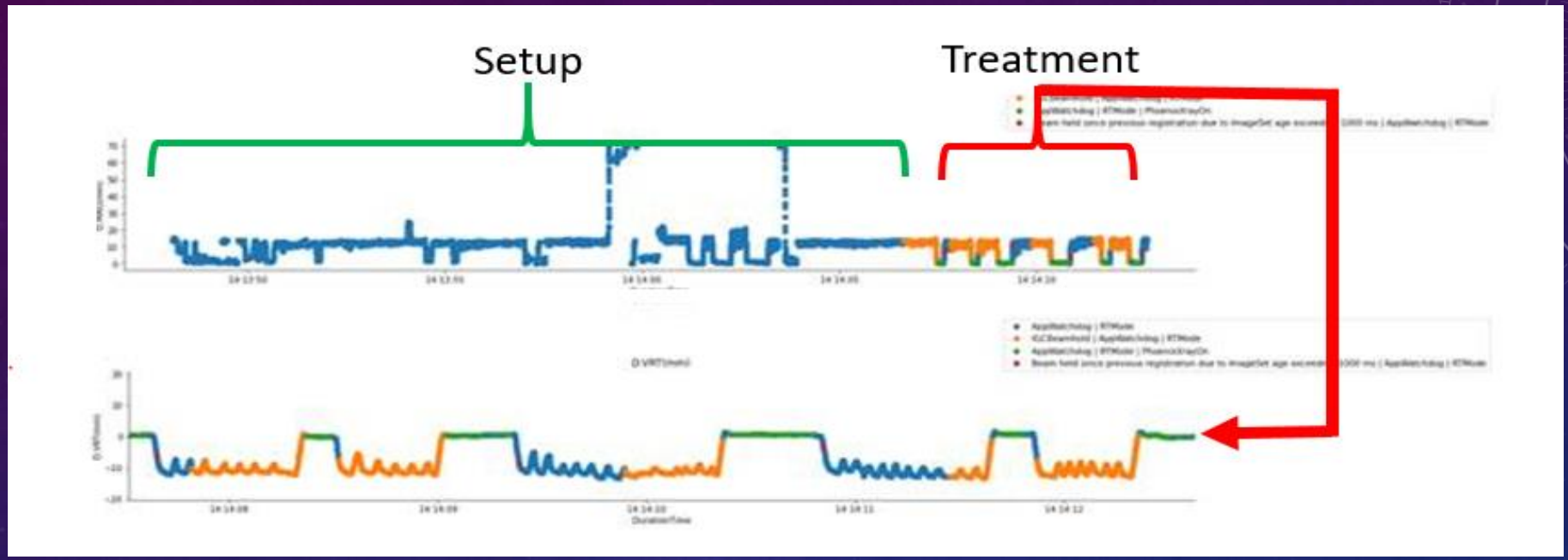
During Treatment

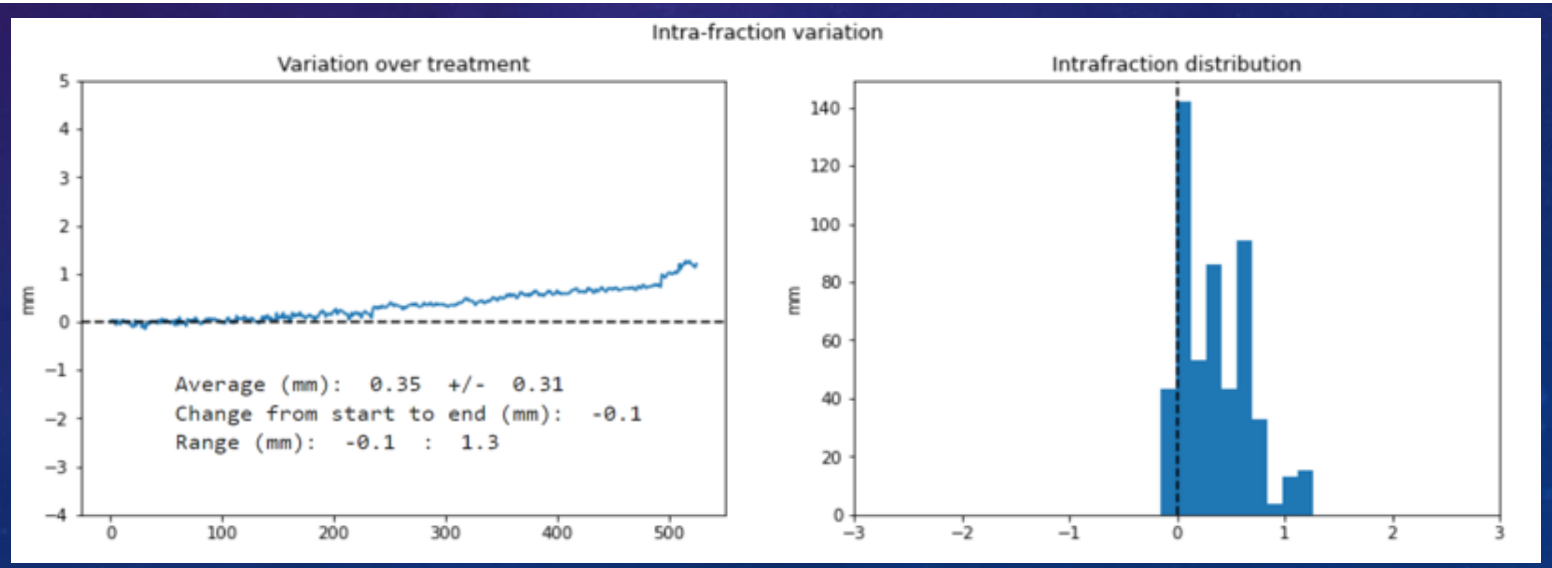
End position

CBCT — SGRT — CBCT

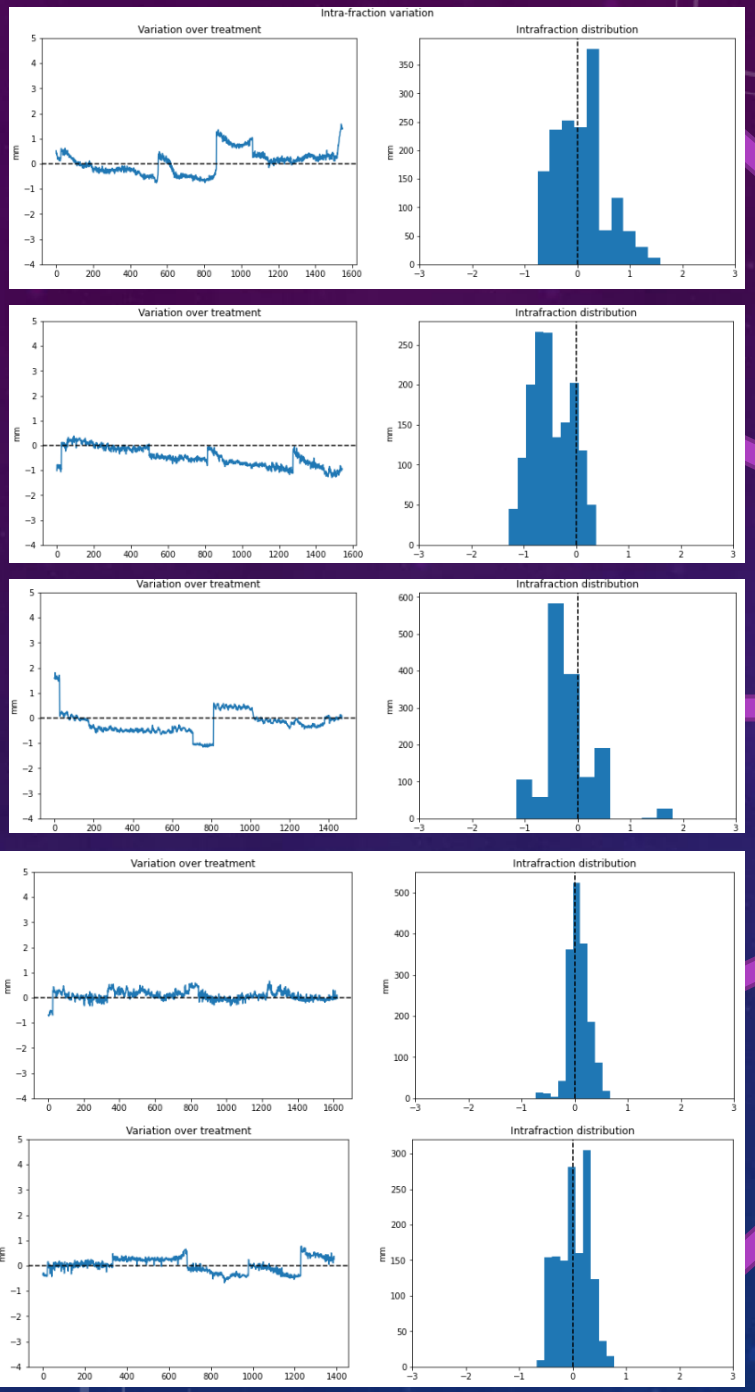
SGRT INTRA-FRACTION VARIATION: SINGLE FRACTION

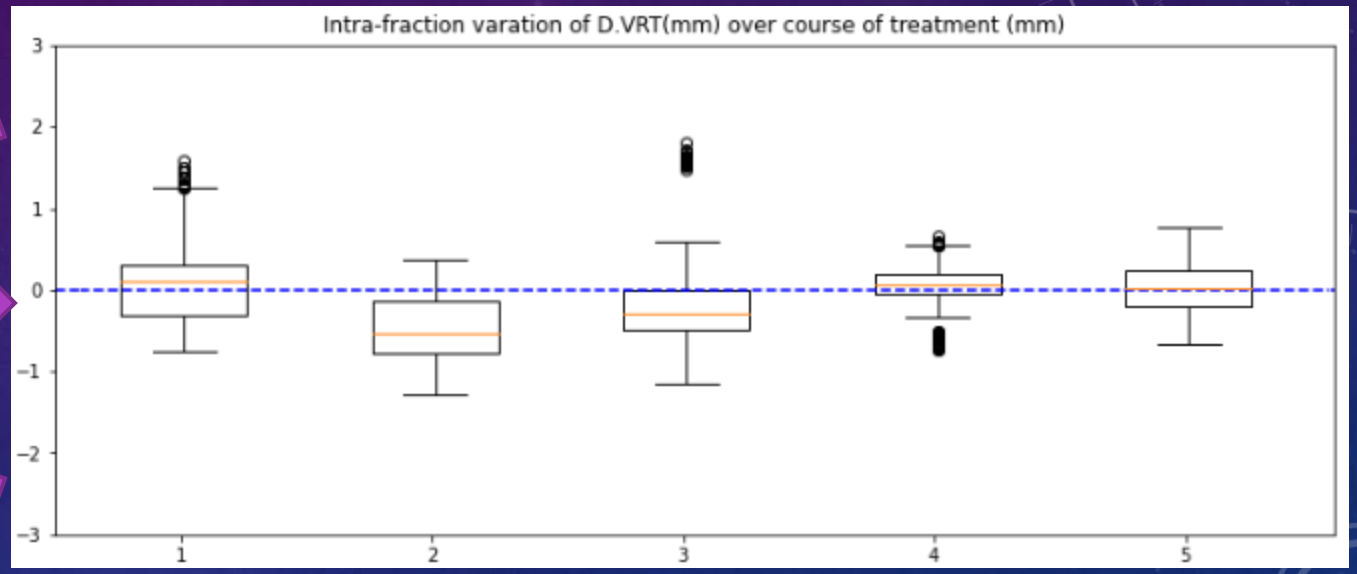
RTD file export



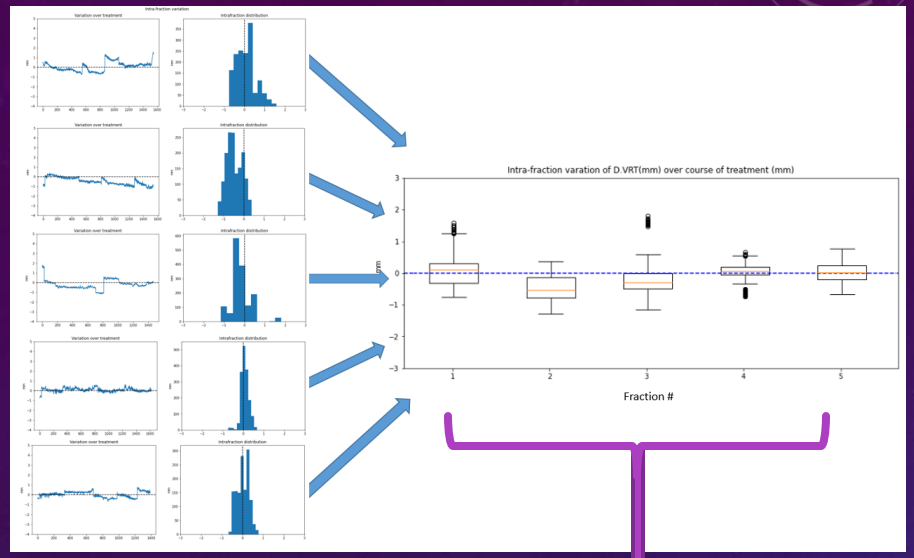


SGRT Intra-fraction variation: Multiple fractions



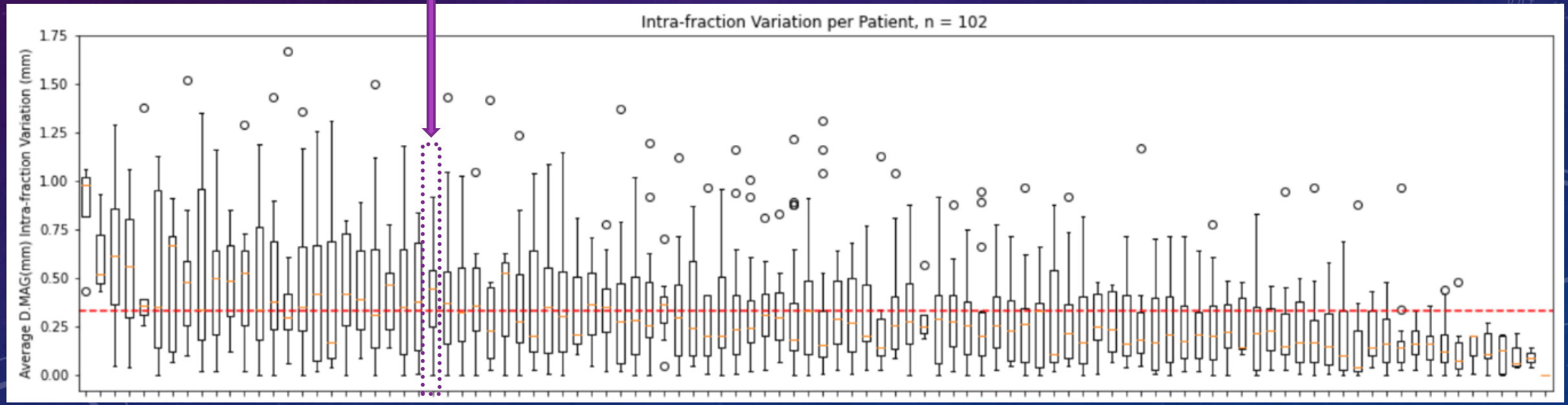


Intra-fraction variation: Multiple patients



SGRT data allows for robust quantification of motion:

- **Fraction aware features**
- **Overall motion description during beam-on**



D.Mag(mm)

RESULTS: INTRAFRACTION MOTION

Open-face masks show intrafractional stability comparable to closed masks.

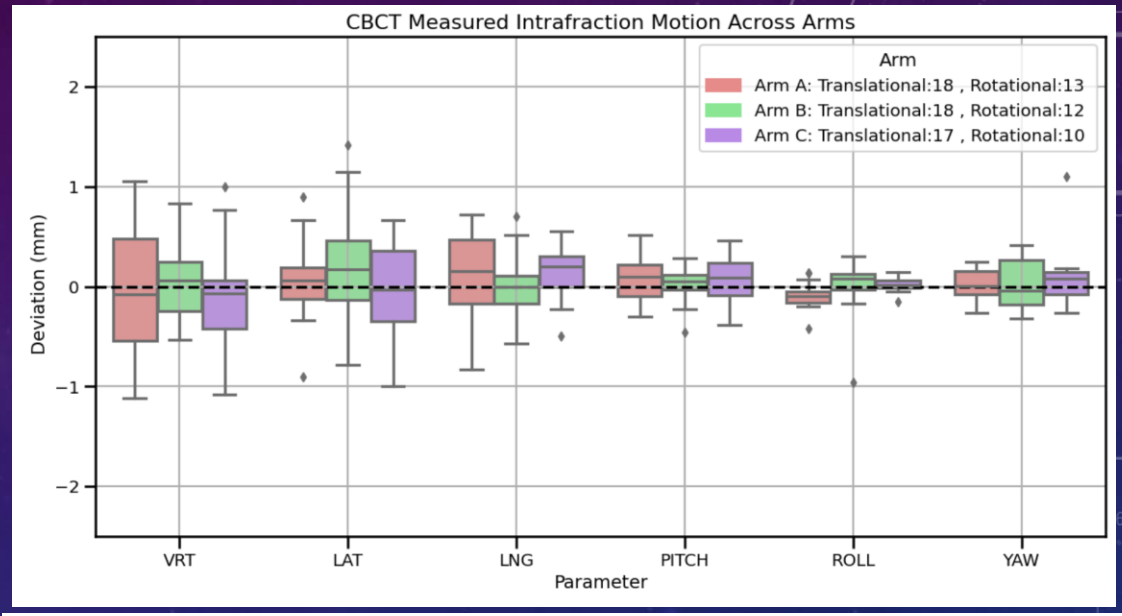
- Mean CBCT deviations < 0.4mm and 0.2 deg
- SGRT 95th percentile deviations: 0.4 mm; 0.8 deg

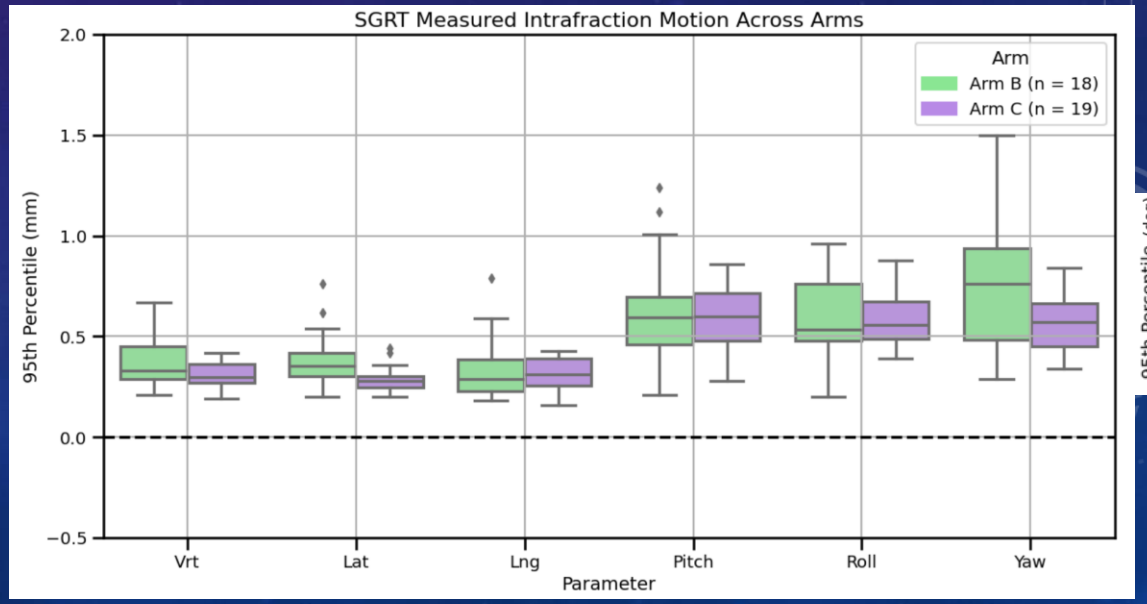
- Bayesian analysis: no clinically significant differences

- Margins consistent across masks, validated by SGRT data
- However, SGRT revealed transient deviations missed by CBCT!

Confidence that SGRT was allowing us to capture patient positional variation when it mattered most: during treatment

SCAN ME





OPEN OUTCOME: PRACTICE CHANGE IN SLRON

"was so tight, couldn't breath through mouth,..breath using nose instead. took a while to get used ...was panicking first 2 days but got used to it on day 3"

"hard to tolerate.....some times it is unbreathable"

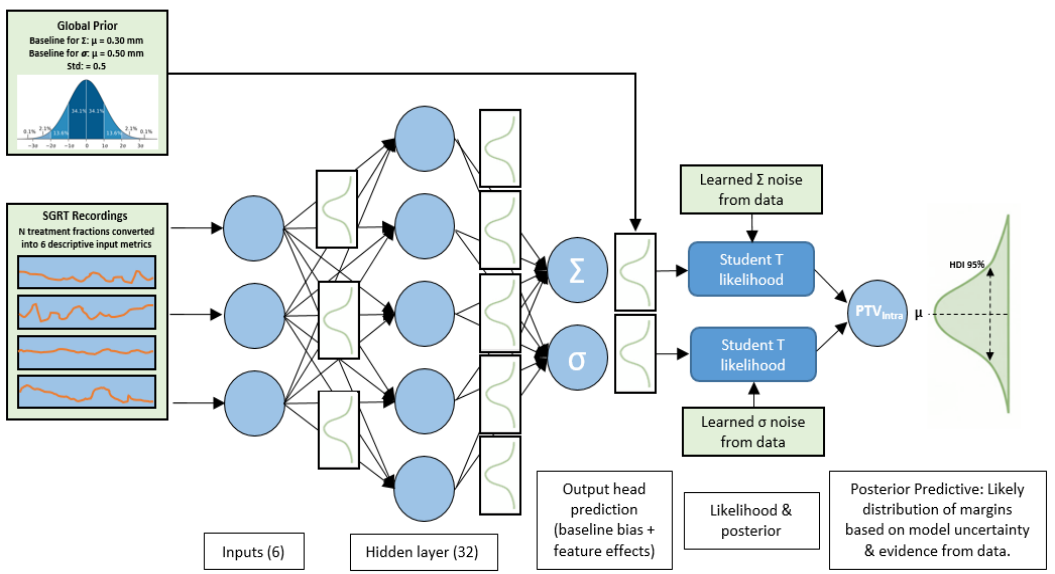
"I got the one with the open face.....It's brilliant. ....It's very easy. I was amazed at how easy it was"

ARM A: 5 point CLOSED mask

ARM B: 3 point OPEN mask

WHATS NEXT?
SHOULD ALL H&N PATIENTS GET THE SAME POPULATION MARGIN?

*Not yet published



Bayesian neural network (BNN) for prediction. Features pass a shared 32-unit hidden layer; two heads output positive means for the systematic (Σ) and random (σ) components. Priors are anchored to institutional H&N data; observation noise uses a log-scale Student-t with learned spreads based on variability of training data. Margins are posterior-predictive draws with 95% HDI.

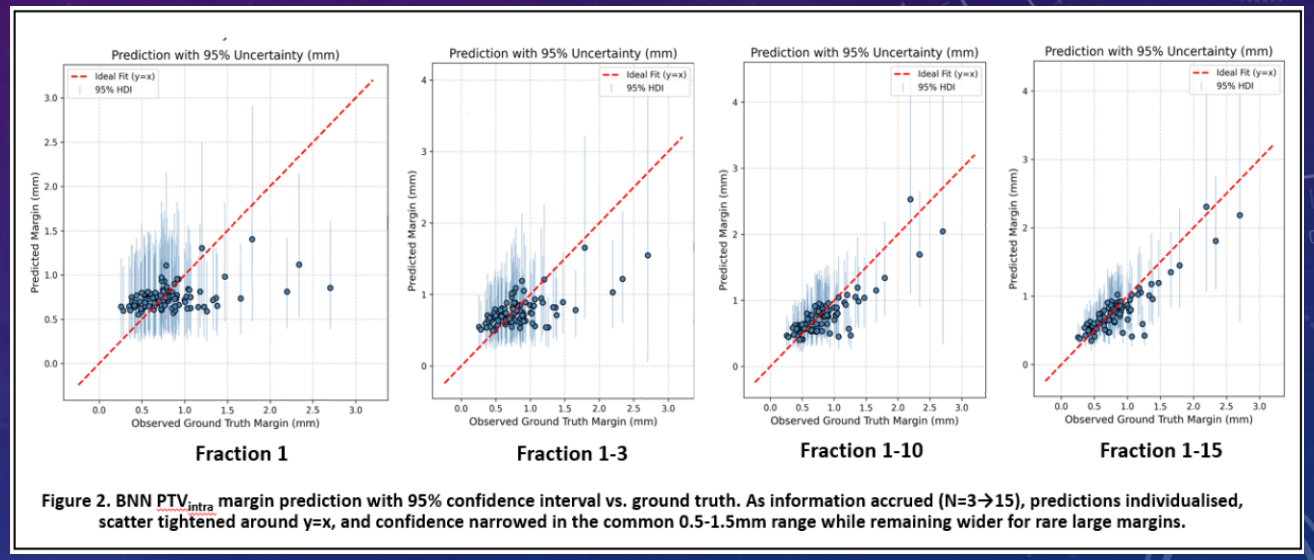


Figure 2. BNN PTV_{intra} margin prediction with 95% confidence interval vs. ground truth. As information accrued (N=3→15), predictions individualised, scatter tightened around y=x, and confidence narrowed in the common 0.5-1.5mm range while remaining wider for rare large margins.

Using AI and Bayesian statistics with continuous monitoring to personalise intrafraction motion management (PTV margins) with clinically informative uncertainly

WHAT CONTINUOUS SGRT MONITORING ADDS IN A RANDOMIZED PHASE III TRIAL?

- Allowed us to robustly and confidently move to OPEN facemasks
- Quantified motion when it matters most – during treatment!
- Detected outliers that pre-/post- imaging missed
- Personalises motion:
  - Fraction motion, patient motion and population motion variation
  - Enables us to trial a move to a personalised margin for H&N using a BNN AI approach.
- Even small facial ROIs give good surface topography

Thank you to the SLICR Fellows Dr. Jill Nicholson, Samantha Ryan & Claire Fitzpatrick, and the team at SLRON.