Intelligent image fusion for intraoperative navigation

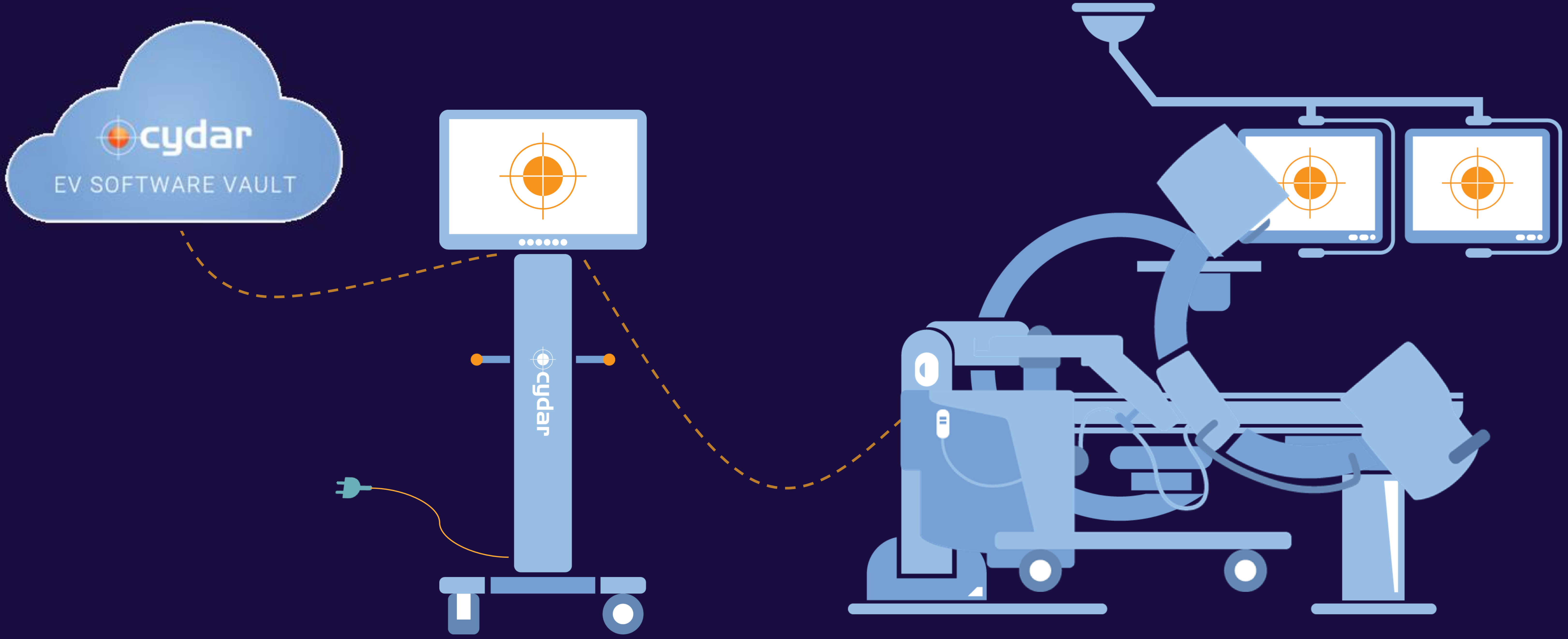
Making Image Fusion Simple, Accurate and Reliable

Tom Carrell
Vascular Surgeon
Founder and CEO Cydar

Cydar Medical

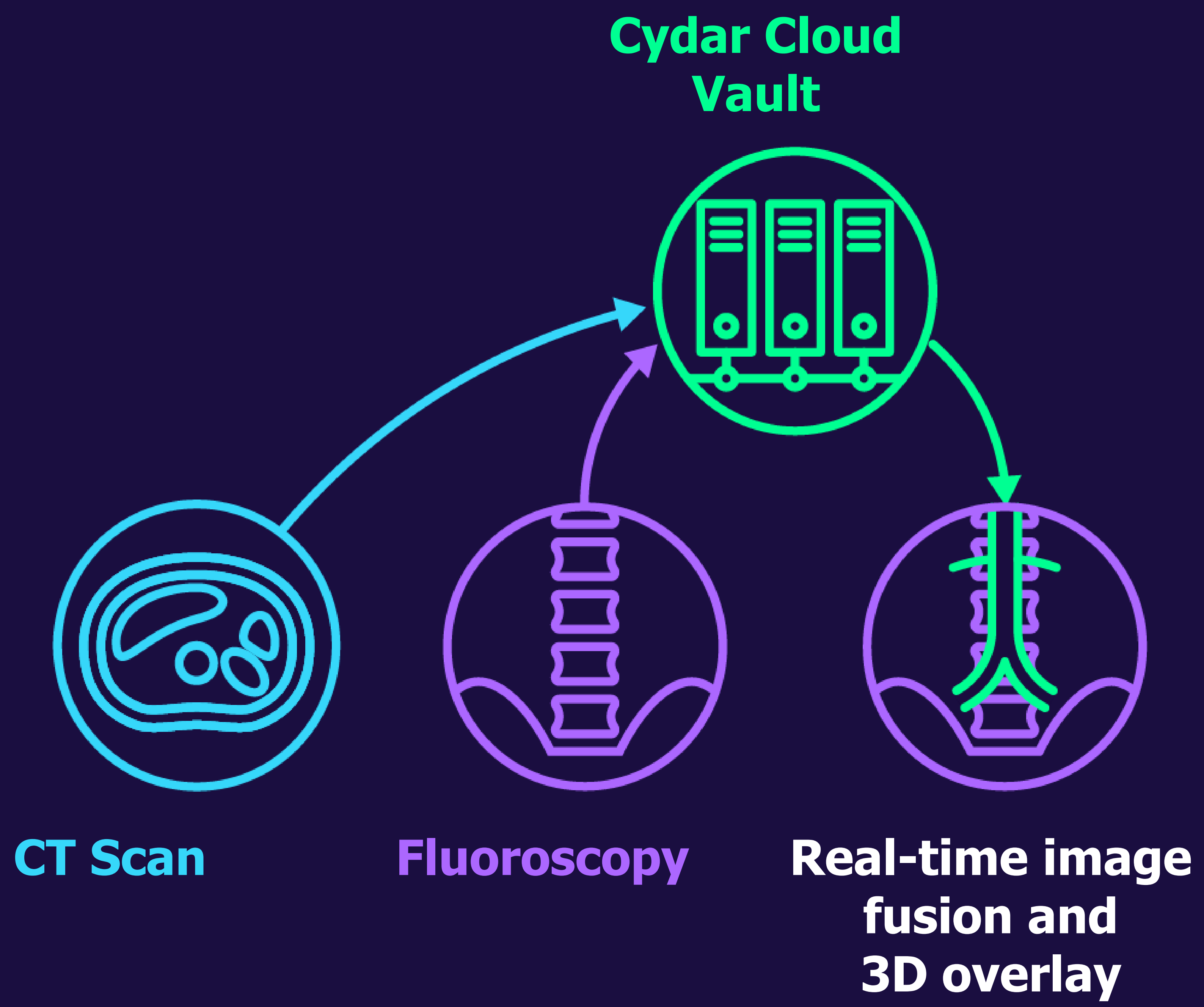
Uses images only. No special hardware.

Fixed or mobile C-arm. Any manufacturer. Flat screen or Image Intensifier



Why cloud?

Linking data, high-performance computing and AI in real-time



General Data Protection Regulation

CERTIFIED ISO 13485

Information Security Management ISO 27001 Certified

NHS Digital

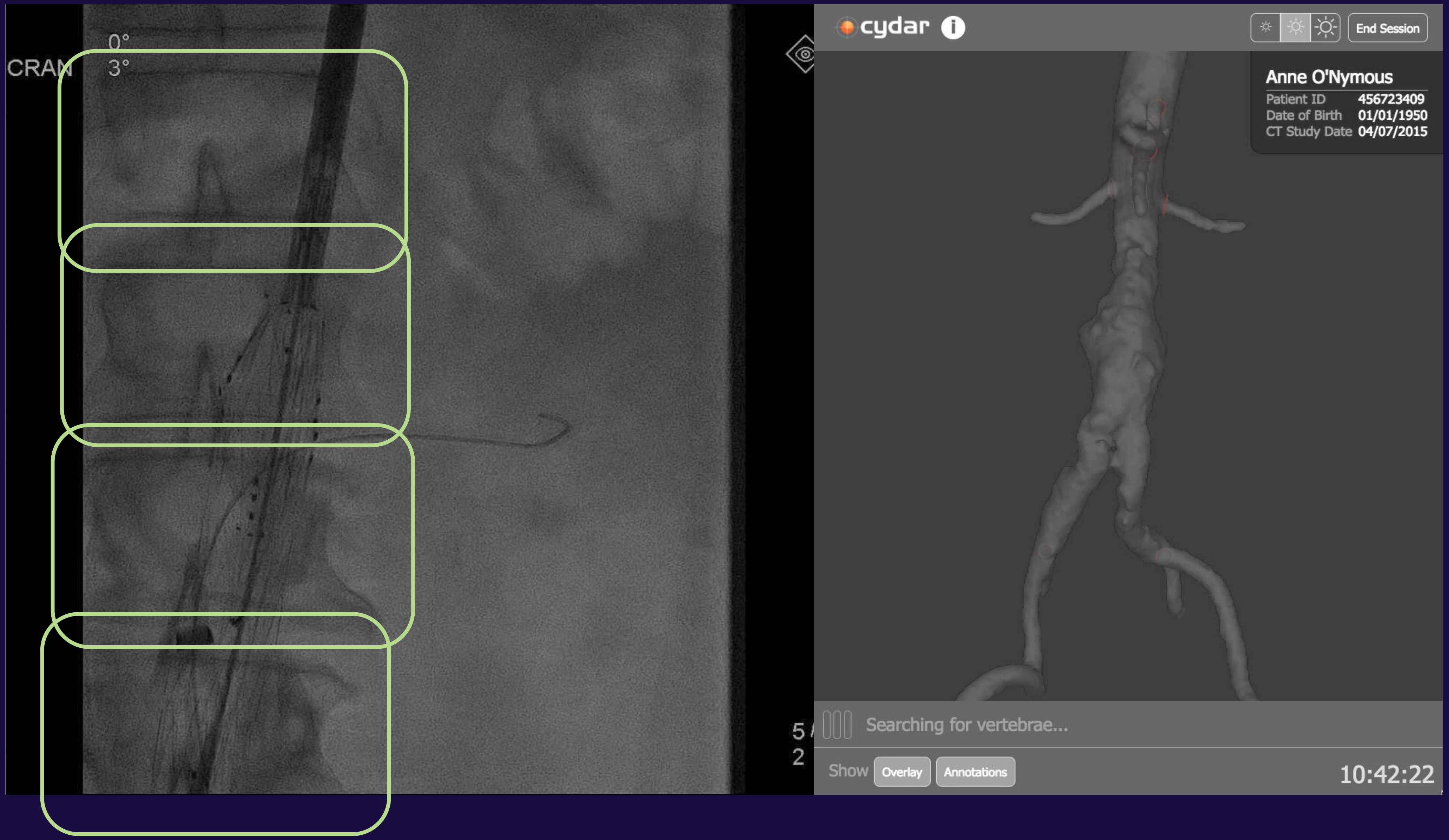
HIPAA COMPLIANT

FDA CE

Cydar EV rigid overlay - How it works

How it works 1: Image-based tracking

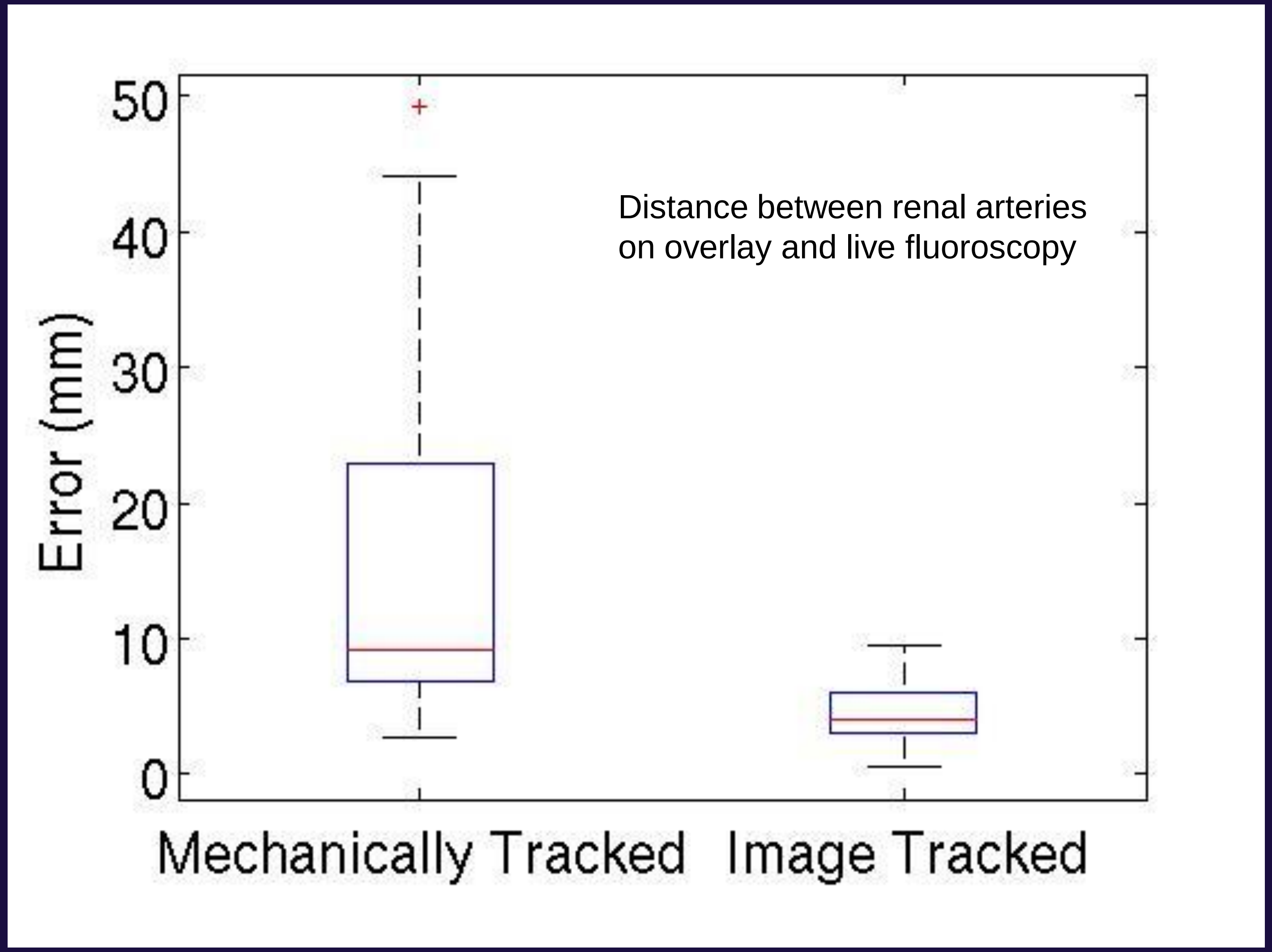
Uses the patient's skeleton as the frame of reference for Cydar EV rigid overlay

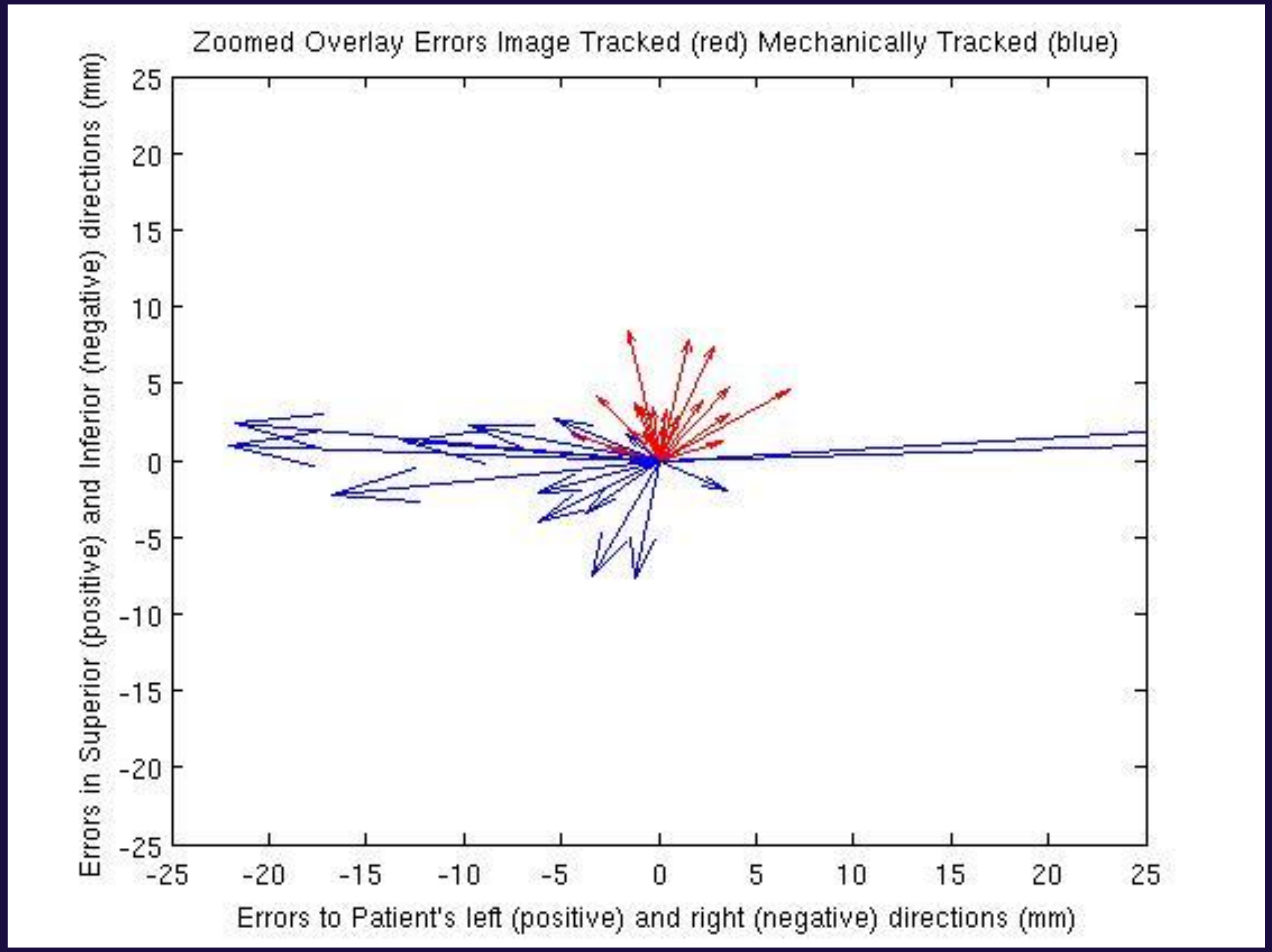


- Computer Vision continuously watches X-ray images on the screen
- If it can confidently identify (>99.8% confidence) two or more vertebrae, a 3D overlay automatically appears
- Never gets tired! Maintains accuracy and reliability throughout the procedure

Accuracy and Reliability of Image-Based Tracking:

Residual errors are soft tissue deformation (by stiff wires, stents etc.)





Eur J Vasc Endovasc Surg (2016) ■, 1–9

A Comparison of Accuracy of Image- versus Hardware-based Tracking Technologies in 3D Fusion in Aortic Endografting

A.E. Rolls [a,b], B. Maurel [a], M. Davis [a], J. Constantinou [a], G. Hamilton [a], T.M. Mastracci [a,b,*]

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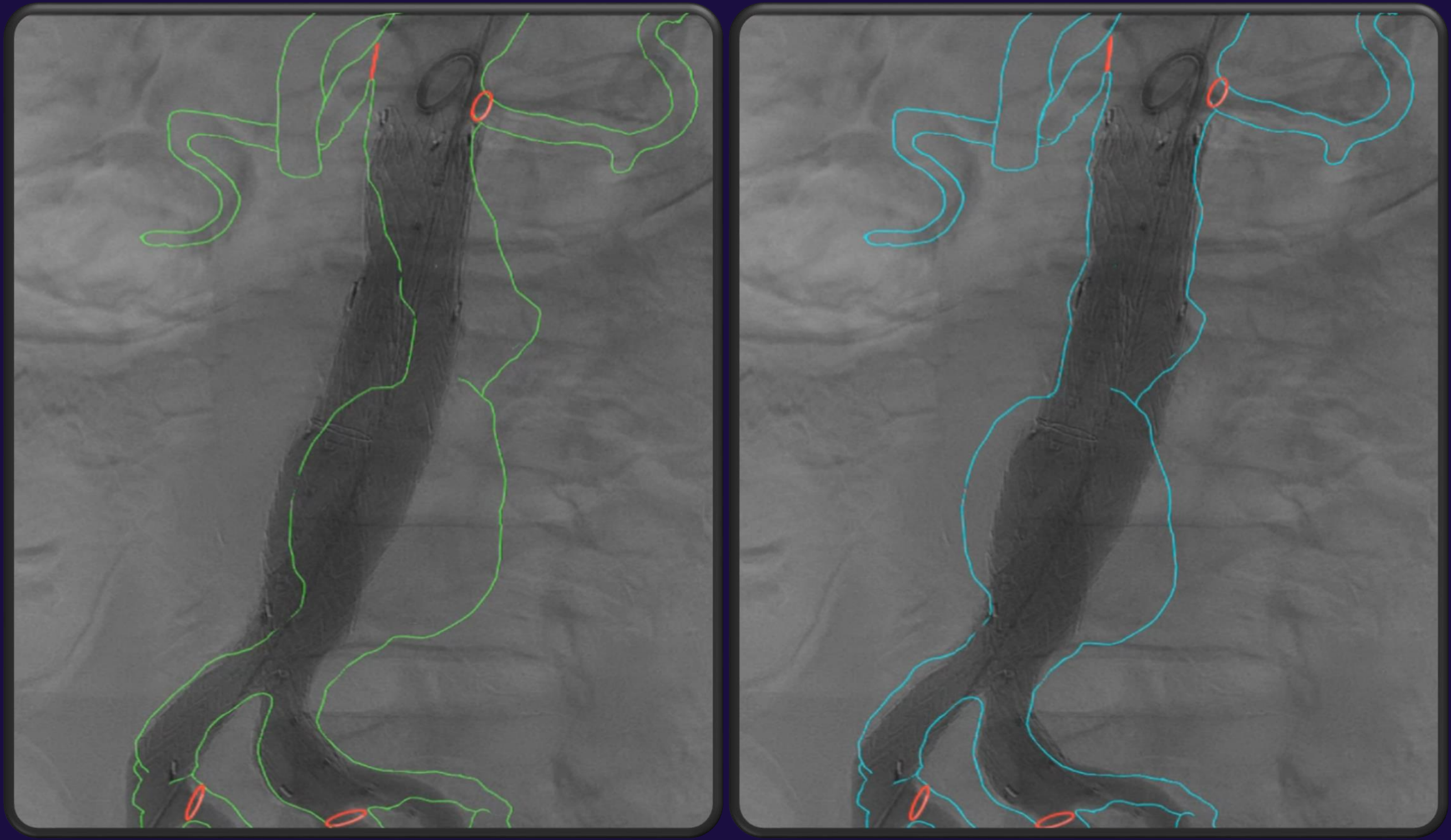
How it works 2: Automatic correction for postural changes

Machine learning ('AI') detects posture change and adjusts the pre-operative anatomy

How it works 3: Soft tissue Deformation:

Accurate Cydar EV rigid overlay is the foundation for Dynamic Morphology Correction



Cydar EV
Rigid overlay

Cydar EV DMC
Non-rigid adjustment

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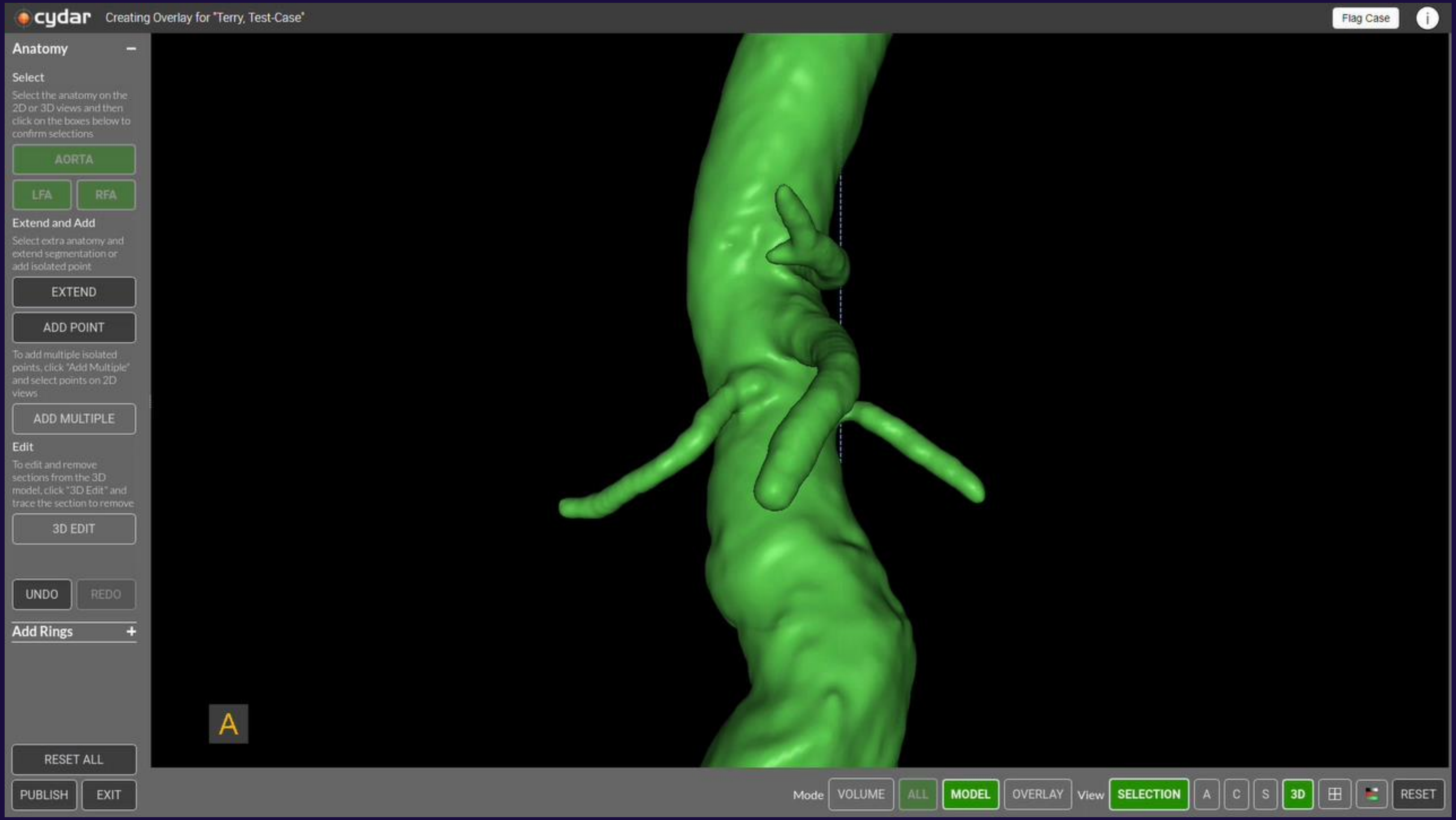
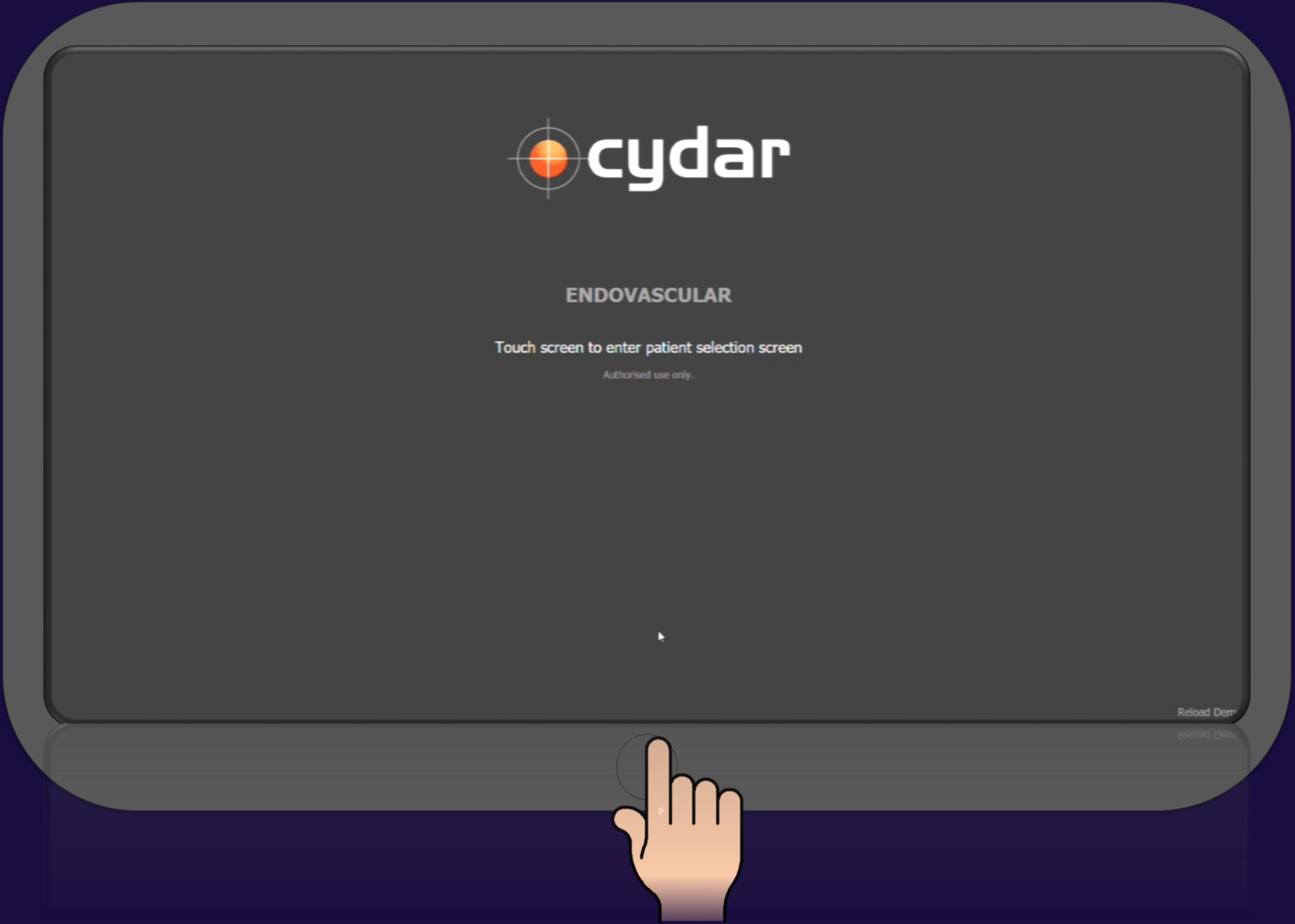
Clinical Workflow

Cydar Vault

Converts preoperative CT Scans into 3D model of surgical plan

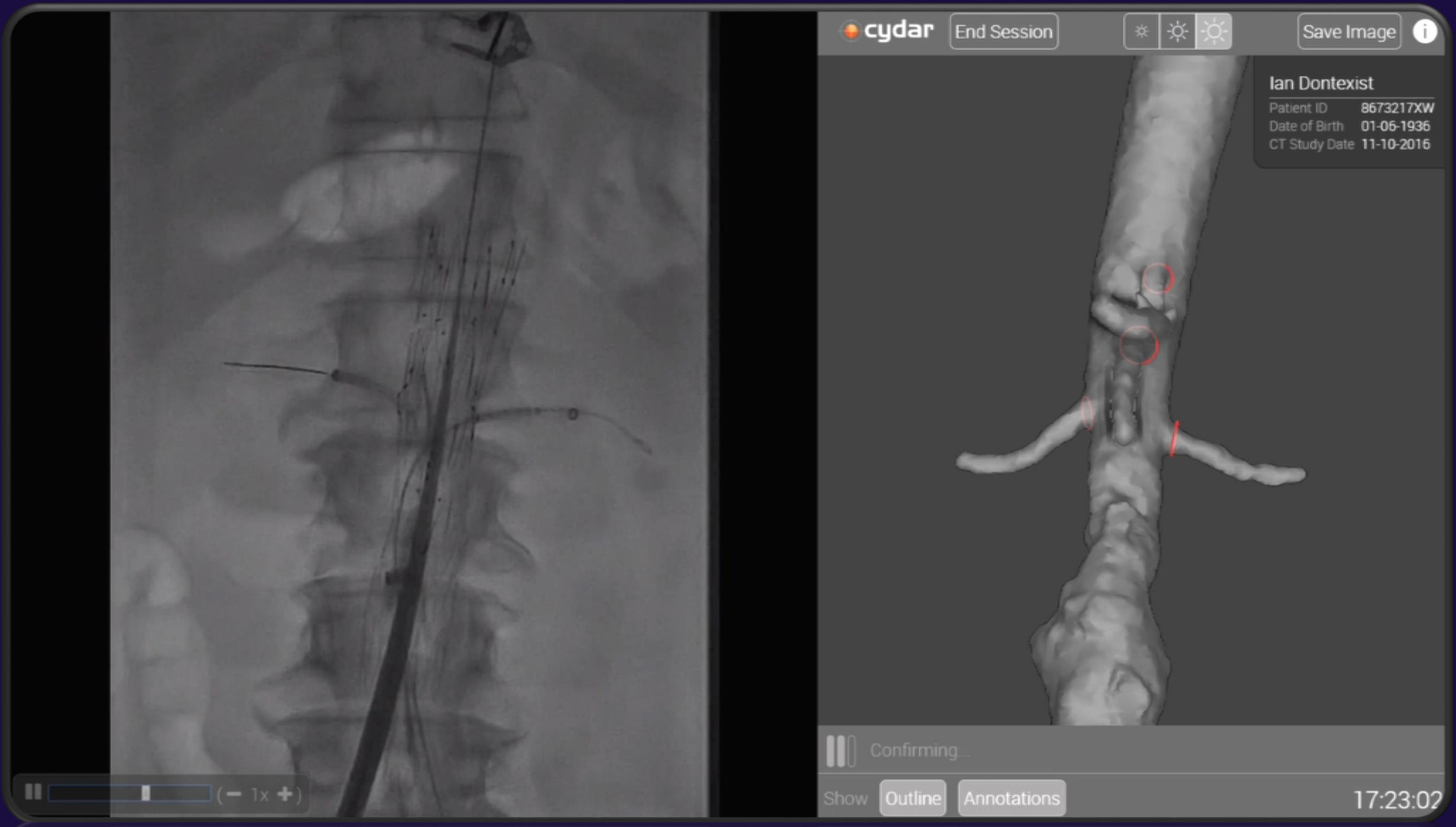


Clinical workflow: Intraoperative



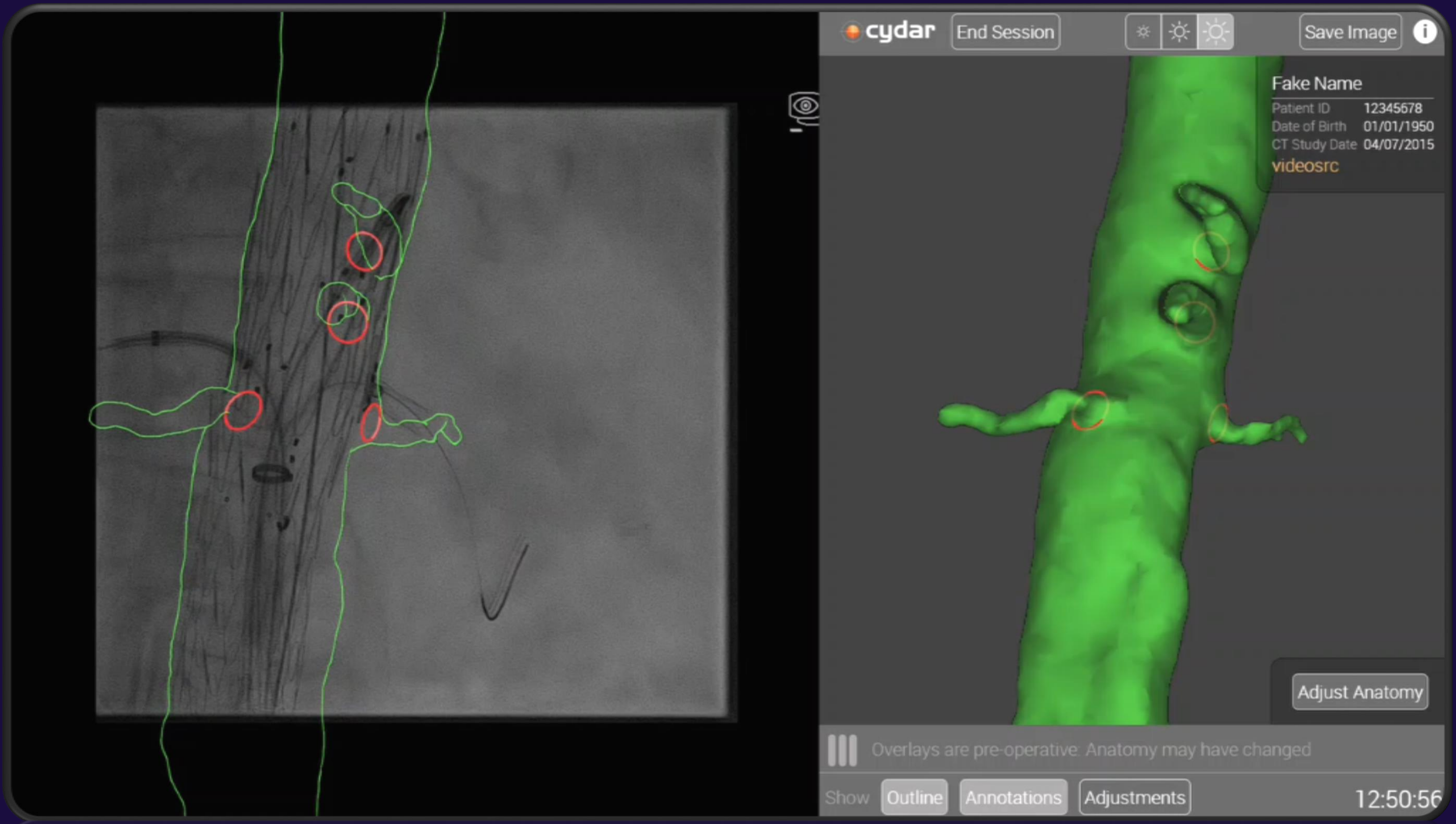
Cydar EV

AI tracks the patient tirelessly for millimetre-precision throughout the procedure



Cydar Dynamic Morphology Correction

Updates 3D soft tissue model to account for deformation caused by wires, stents etc…




RAO 13°
CRAN 8°
75
cydar
End Session
Save Image
Fake Name
Patient ID 12345678
Date of Birth 01/01/1950
CT Study Date 04/07/2015
videosrc
Adjust Anatomy
Overlays are pre-operative: Anatomy may have changed
Show
Outline
Annotations
Adjustments
20:43:03

How CYDAR makes image fusion simple

Reduces your workload

- No special set-up required
  - no AP and lateral X-ray
  - no spin/cone beam CT
- No technologist required
- Cloud means always updated

- Can be used with
  - Flat-panel detector
  - Image intensifier
  - Mobile C-arms
  - Fixed fluoroscopy systems

Clinical evidence

Clinical evidence – clinical impact

From the Society for Vascular Surgery

A prospective observational trial of fusion imaging in infrarenal aneurysms

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ABSTRACT

Objective: Use of three-dimensional fusion has been shown to significantly reduce radiation exposure and contrast material use in complex (fenestrated and branched) endovascular aneurysm repair (EVAR). Cydar software (CYDAR Medical, Cambridge, United Kingdom) is a cloud-based technology that can provide imaging guidance by overlaying preoperative three-dimensional vessel anatomy from computed tomography scans onto live fluoroscopy images both in hybrid operating rooms and on mobile C-arms. The aim of this study was to determine whether radiation dose reduction would occur with the addition of fusion imaging to infrarenal repair in all imaging environments.

Methods: All patients who consented to involvement in the trial and who were treated with EVAR in our center from March 2016 until April 2017 were included. A teaching session about radiation protection and Cydar fusion software use was provided to all operators before the start of the fusion group enrollment. This group was compared with a retrospective cohort of patients treated in the same center from March 2015 to March 2016, after a dedicated program of radiation awareness and reduction was introduced. Ruptured aneurysms and complex EVAR were excluded. Preoperative and perioperative characteristics were recorded, including parameters of radiation dose, such as air kerma and dose-area product. Results were expressed in median and interquartile range.

Results: Forty-four patients were prospectively enrolled and compared with 21 retrospective control patients. No significant differences were found in comparing sex, body mass index, and age at repair. The median operation time (wire to wire) and fluoroscopy time were 90 (75-105) minutes and 30 (22-34) minutes, respectively, without significant differences between groups ($P = .56$ and $P = .36$). Dose-area product was nonsignificantly higher in the control group, 21.7 (8.9-85.9) Gy cm^2, compared with the fusion group, 12.4 (7.5-23.4) Gy cm^2 ($P = .10$). Air kerma product was significantly higher in the control group, 142 (61-541) mGy, compared with 82 (51-115) mGy in the fusion group ($P = .03$). The number of digital subtraction angiography runs was significantly lower in the fusion group (8 [6-11]) compared with the control group (10 [9-14]); ($P = .03$). There were no significant differences in the frequency of adverse events, endoleaks, or additional procedures required.

Conclusions: When it is used in simple procedures such as infrarenal aneurysm repair, image-based fusion technology is feasible both in hybrid operating rooms and on mobile systems and leads to an overall 50% reduction in radiation dose. Fusion technology should become standard of care for centers attempting to maximize radiation dose reduction, even if capital investment of a hybrid operating room is not feasible. (J Vasc Surg 2018;■:1-8.)

Keywords: EVAR; Automated overlay; Advanced imaging guidance software; Radiation exposure; Imaging fusion

IF09.

Image-Based Three-Dimensional Fusion Computed Tomography Decreases Radiation Exposure, Fluoroscopy Time, and Procedure Time During Endovascular Aortic Aneurysm Repair

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Objective: Although endovascular aneurysm repair (EVAR) has minimal perioperative morbidity and mortality, it is still associated with increased radiation exposure and contrast material use. Three-dimensional (3D) fusion computed tomography (CT) technology has the potential to revolutionize endovascular management of aneurysms by mitigating radiation exposure. Currently available 3D fusion devices use hardware-based (ie, operating table) tracking to position the overlay on the fluoroscopic image. This can be labor-intensive and lead to inaccurate overlay. Recently, our institution implemented a novel cloud-based 3D fusion system, which has been shown in prior studies to be highly accurate. This system uses the patient's vertebral anatomy rather than the operating table to register and produce the overlay, and it can be used with any imaging system, including C arm. The purpose of this study was to investigate the impact of this new 3D fusion system on EVAR.

Methods: Our institutional database was reviewed to identify patients who underwent elective EVAR or fenestrated EVAR. Patients treated using 3D fusion CT were compared with patients treated in the immediate 6 months before the implementation of 3D fusion CT at our institution. Primary end points included the patient's radiation exposure, contrast material use, fluoroscopy time, and procedure time.

Table. Comparison of radiation dose, fluoroscopy time, contrast material volume, and procedure time for all endovascular aneurysm repair (EVAR) and fenestrated EVAR patients with and without intraoperative three-dimensional (3D) fusion computed tomography (CT)

	Before 3D fusion CT	After 3D fusion CT	*P* value
Radiation dose, mGy	3006	2112	.015
Fluoroscopy time, minutes	36.8	27.9	.022
Contrast material volume, mL	78	73.9	.183
Procedure time, minutes	163.7	127.5	.007

Results: A total of 108 patients (67 before vs 41 after 3D fusion CT implementation) underwent EVAR or fenestrated EVAR from October 2016 through December 2017. There was a significant decrease in radiation exposure (3006 vs 2112 mGy; $P = .015$), fluoroscopy time (36.8 vs 27.9 minutes; $P = .022$), and procedure time (163.7 vs 127.5 minutes; $P = .007$) with cloud-based digitally registered intraoperative 3D fusion CT. There was no difference in contrast material use (78 vs 73.9 mL; $P = .183$) between the two groups (Table).

Conclusions: The results of this study demonstrate that the use of intraoperative image-based 3D fusion CT during EVAR decreases radiation exposure, fluoroscopy time, and procedure time. This novel technology has the potential to improve clinical outcomes, to reduce costs, and to broaden the application of 3D fusion imaging.

Author Disclosures: M. Cox: Nothing to disclose; **B. Gilmore:** Nothing to disclose; **C. Long:** Nothing to disclose; **R. McCann:** Nothing to disclose; **U. Nag:** Nothing to disclose; **C. Shortell:** Nothing to disclose; **K. W. Southerland:** Nothing to disclose; **M. Turner:** Nothing to disclose

Clinical and health economic impacts

Evidence for strong benefits

DUKE UNIVERSITY MEDICAL CENTER

Strong Data to Support Adoption & Usage

Procedure	Average Procedure Time[1] (mins)	3D Overlay Time Saving[2, 3] (%)	New Procedure Time (mins)
Complex	360	**17.5**	297
Standard	110	**27.8**	79

Complex Case - Without 3D Overlays

Procedure	Cases per Day	OR Time (mins)	Time Over (mins)	Charges[4] (USD)	Potential Additional Revenue per Day (USD)
Complex	1	360	60	$165,541	
Standard					
TOTAL			60	$165,541	$0

Complex Case - With 3D Overlays

Procedure	Cases per Day	OR Time (mins)	Time Over (mins)	Charges[4] (USD)	Potential Additional Revenue per Day (USD)
Complex	1	297		$165,541	
Standard	1	79		$101,876	
TOTAL			44	$267,417	$101,876

Standard Case - Without 3D Overlays

Procedure	Cases per Day	OR Time (mins)	Time Over (mins)	Charges[4] (USD)	Potential Additional Revenue per Day (USD)
Complex	0	0			
Standard	3	330			
TOTAL	3	330	90	$305,628	$0

Standard Case - With 3D Overlays

Procedure	Cases per Day	OR Time (mins)	Time Over (mins)	Charges[4] (USD)	Potential Additional Revenue per Day (USD)
Complex	0	0		$0	
Standard	5	397		$509,380	
TOTAL			23	$509,380	$203,752

	Non-Cydar (n = 83)	Cydar (n = 36)	P
Radiation dose (mGy)	2894 (2454)	2395 (1924)	0.118
Radiation dose > 2Gy	41 (49.4)	17 (47.2)	0.827
Fluoro time (min)	35.7 (25.6)	31.5 (20.4)	0.171
Contrast volume (mL)	80.4 (34.4)	73 (39.6)	0.169
Procedure time (min)	**163.0 (94.0)**	**133.4 (57.5)**	**0.038**
Intra-op endoleak	16 (19.3)	8 (22.2)	0.713
LOS (d)	3.7 (8.0)	1.6 (1.8)	0.087
30-d mortality	3 (3.6)	0 (0.0)	0.248
Post-op endoleak	18 (21.7)	6 (16.7)	0.531
Postop Cr	**1.5 (1.3)**	**1.1 (0.4)**	**0.004**
30-d Cr	**1.4 (1.3)**	**1.1 (0.3)**	**0.011**

- **Statistically significant reduction in:**
  - Procedure time – 23 minutes for standard cases, 51 minutes for complex cases; this translates into increased OR case volume, and additional revenue
  - Postoperative Cr
  - 30-d Cr
- **Reduction trends in:**
  - Radiation dose, Fluoro time, Contrast volume, Endoleak, LOS

When using Cydar EV:

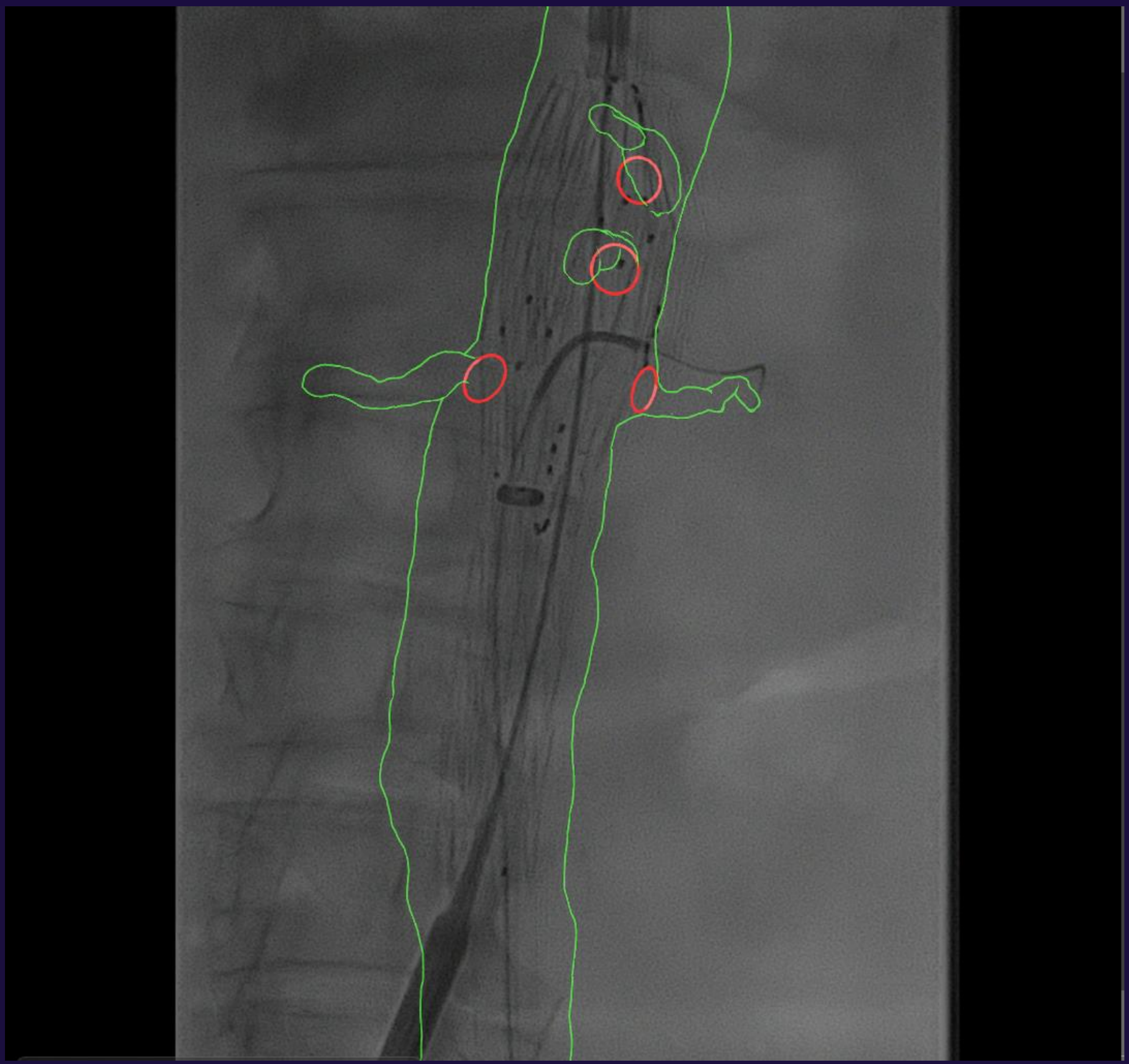
- Statistically significant 30-60 minute (17.5 to 27.8%) reduction in procedure duration
- Time savings translated into increased OR case volume and a potential increase in revenue of $100k-200k per operating room per day
- Statistically significant improvement in patients' renal function
- Lower radiation exposure for staff and patients

Improvement in clinical outcomes:

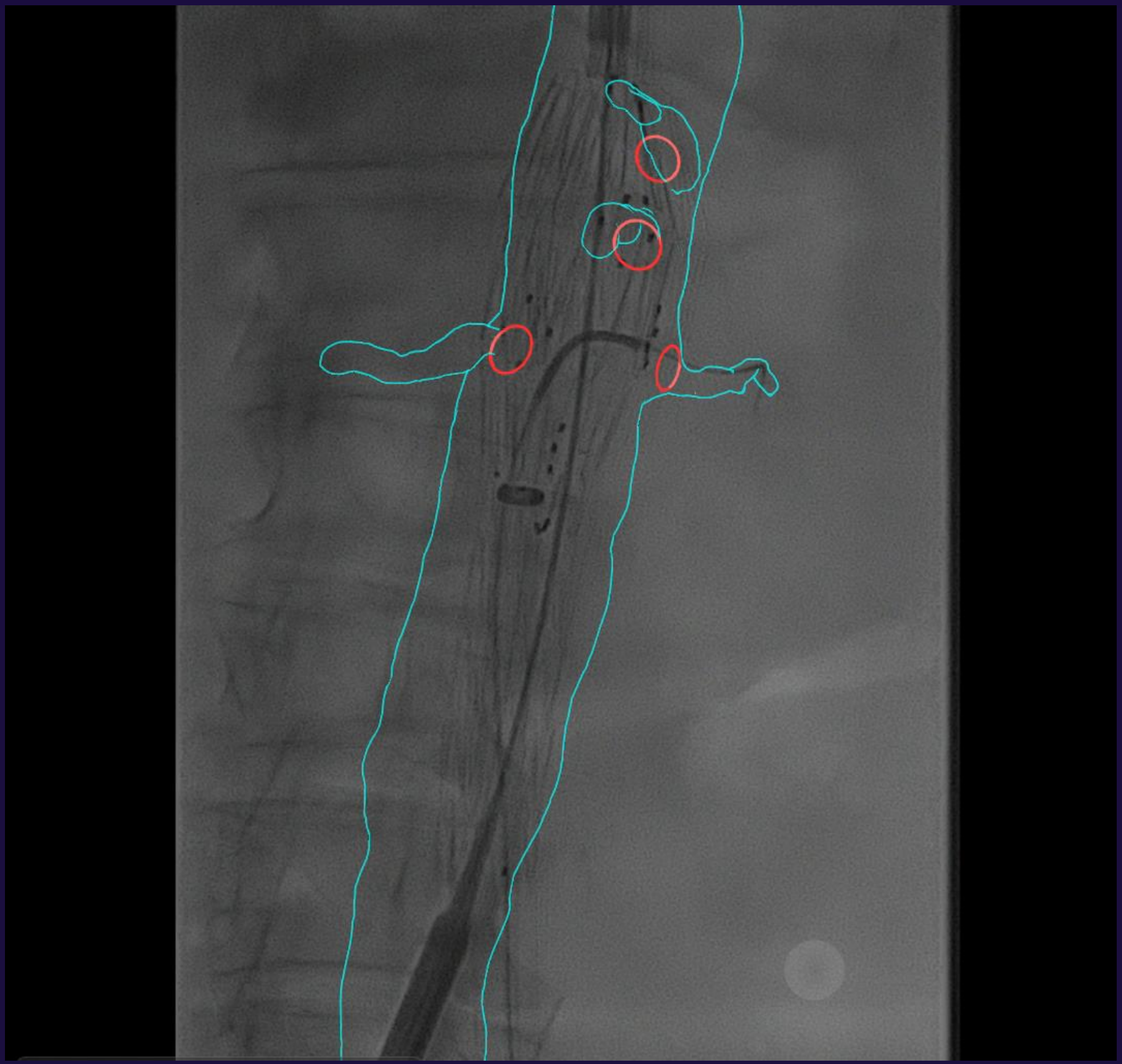
- Technical success; length of stay (LOS); mortality; long-term renal function

Case Examples: Standard EVAR

Case Examples: Deformable anatomy

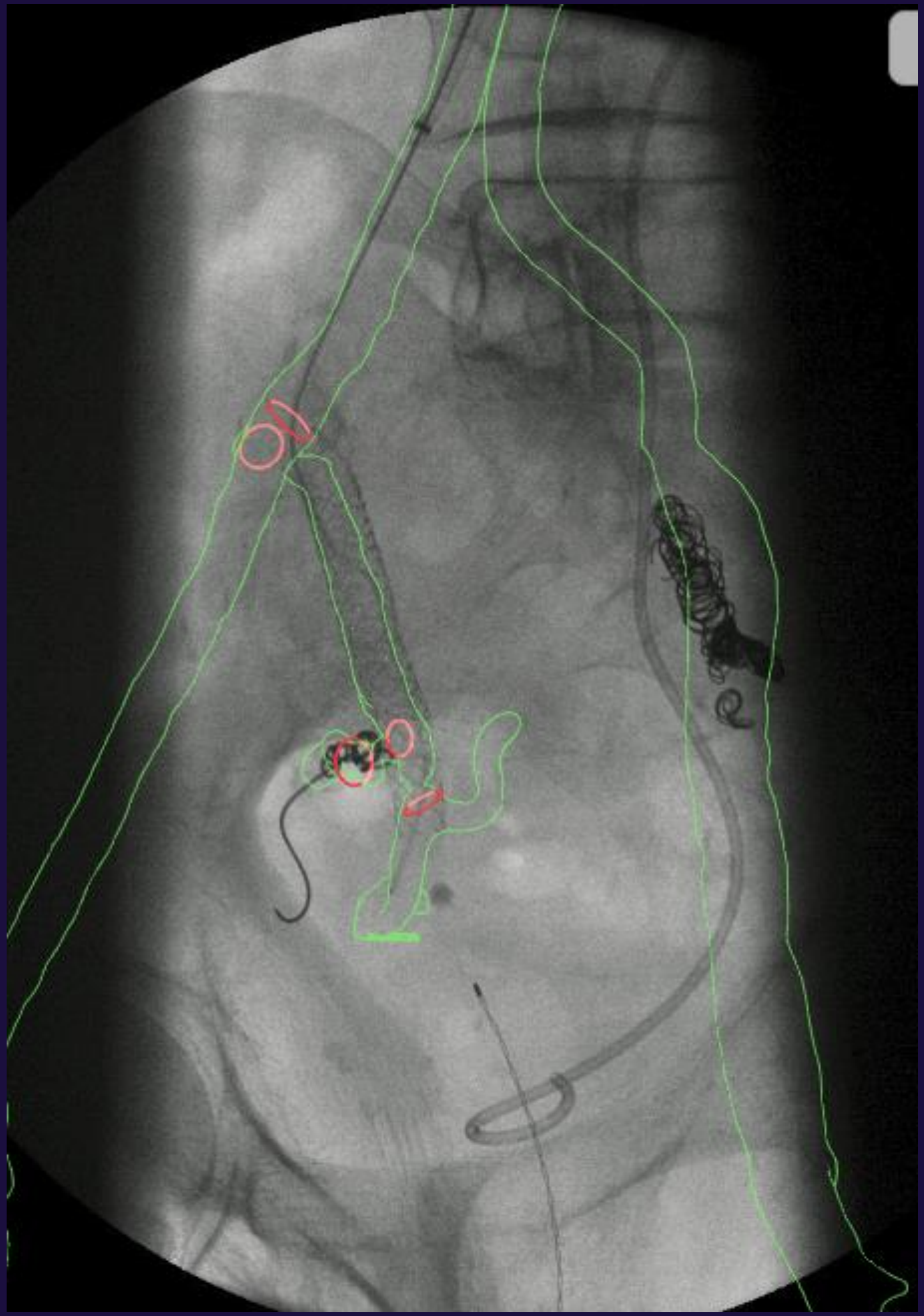


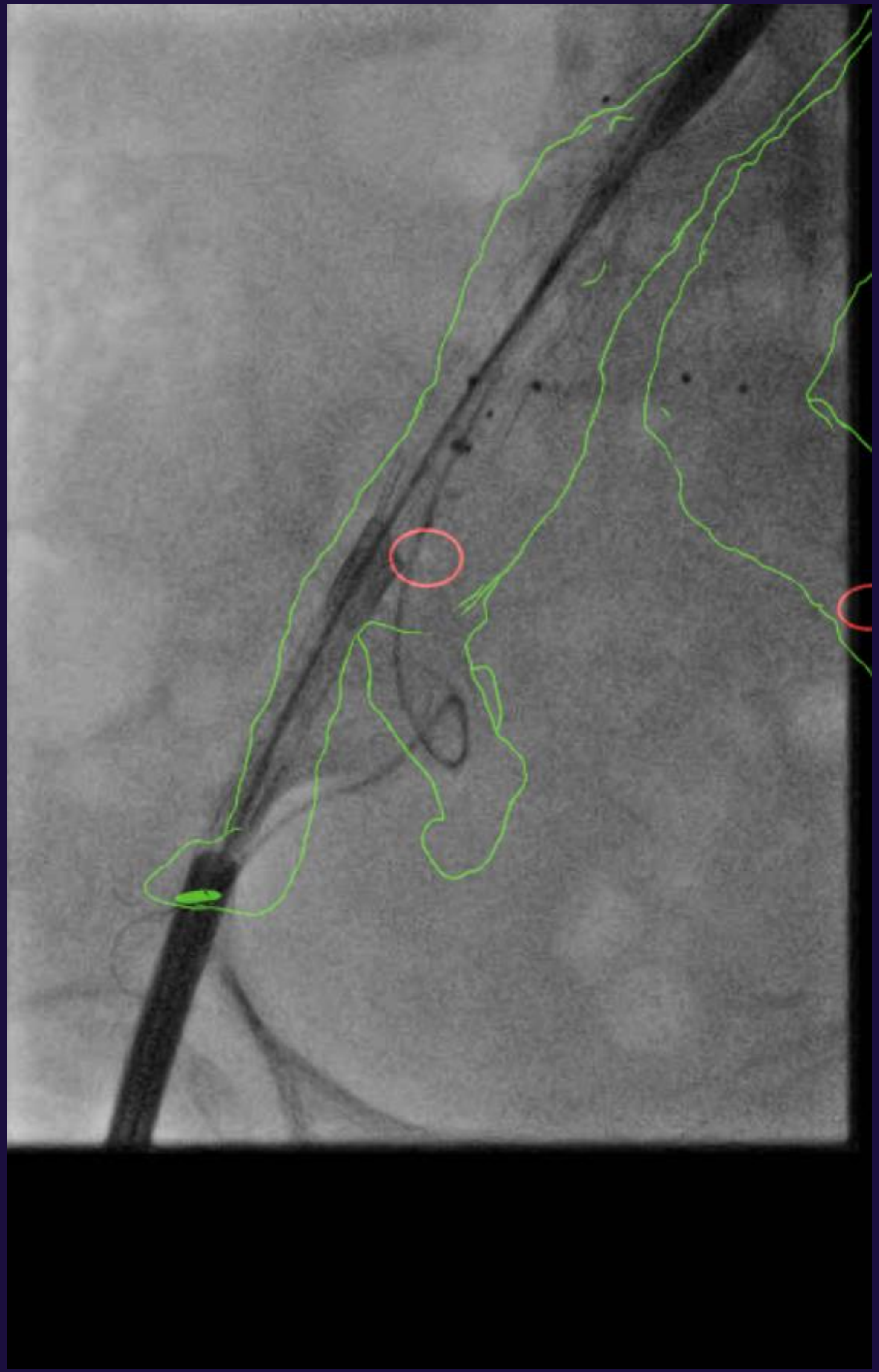
Rigid overlay of pre-operative anatomy



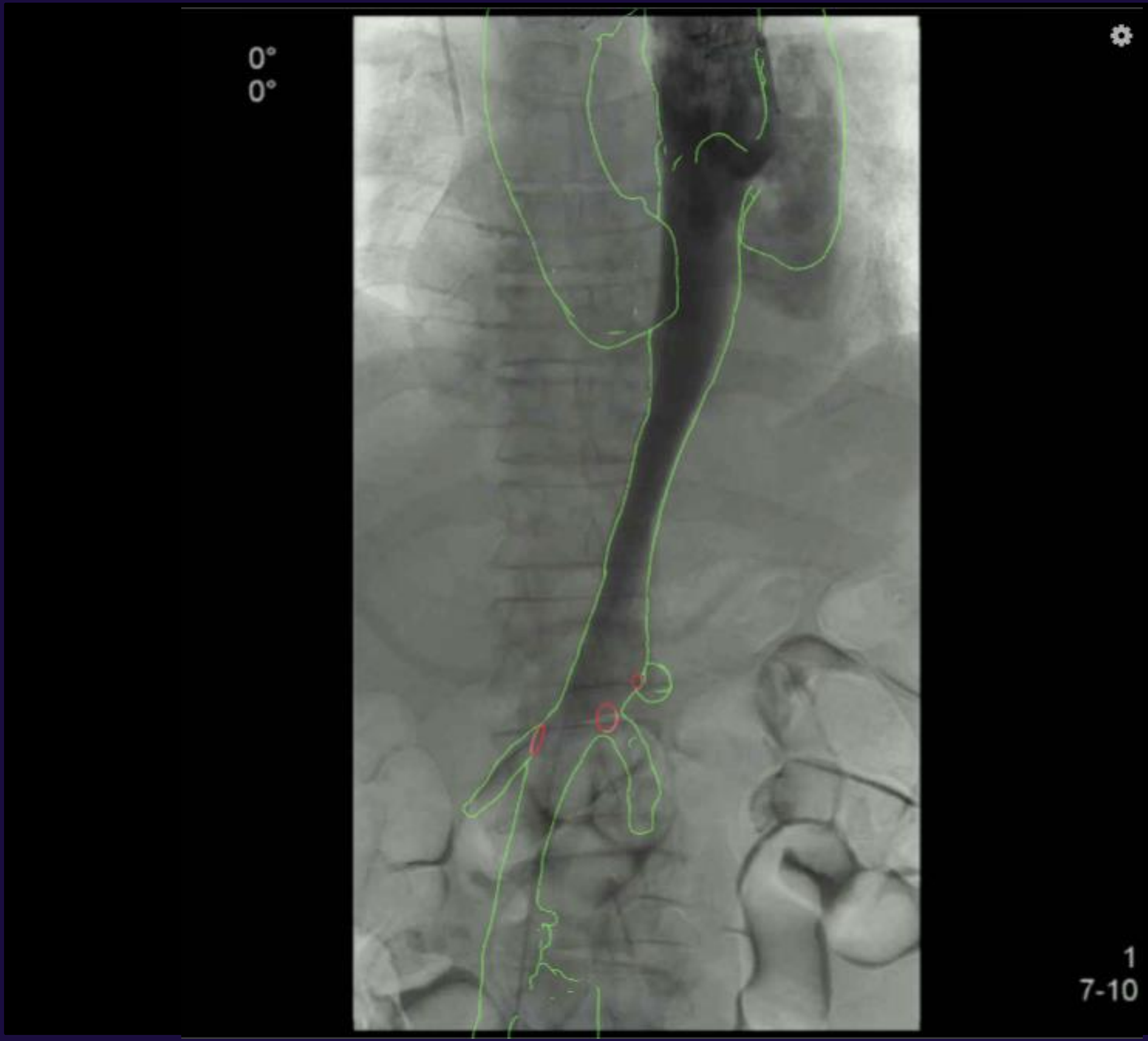
Non-rigid adjusted overlay

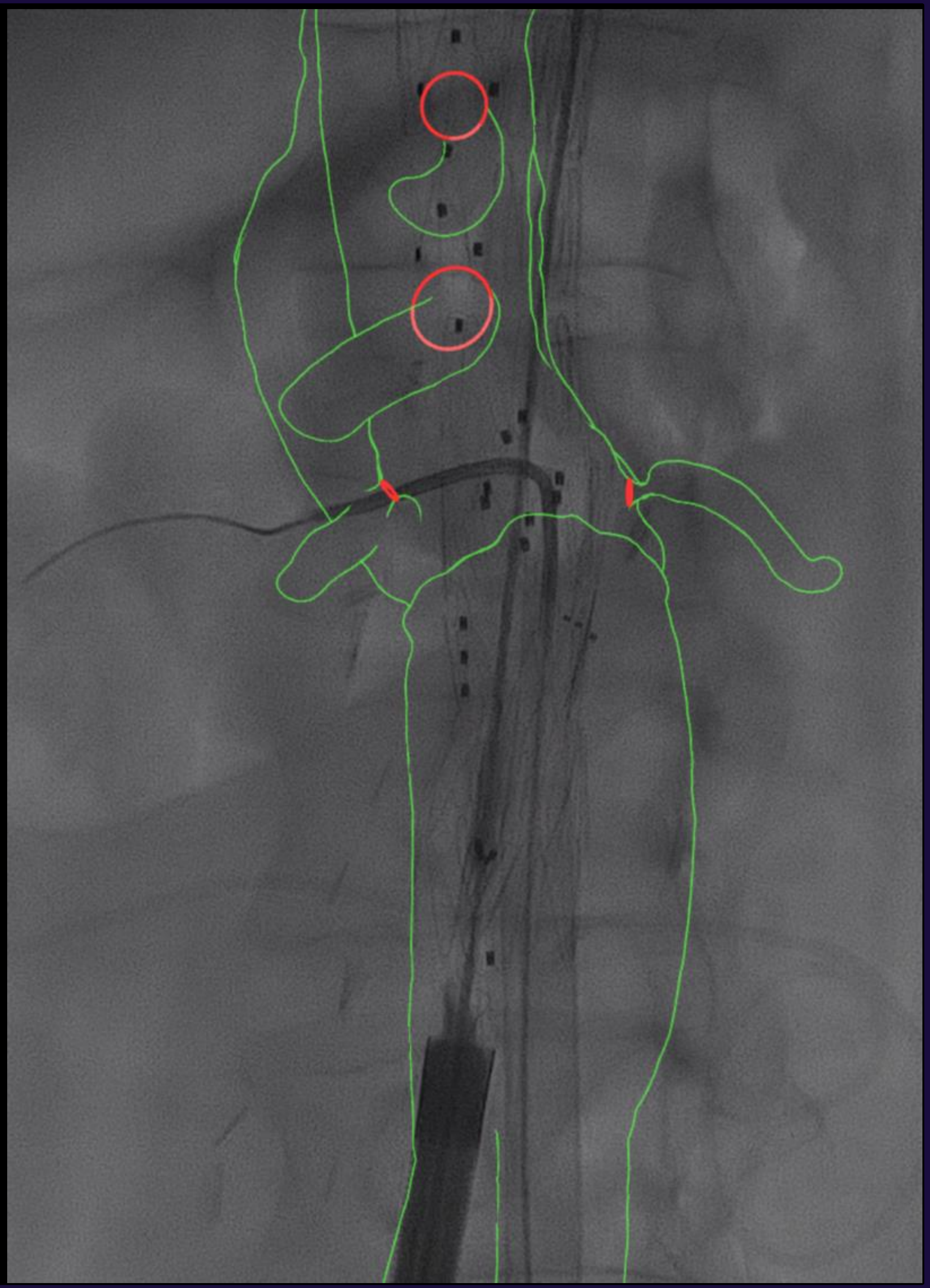
Case Examples: Iliac anatomy





Case Examples: Dissection





Thank you

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