Is there really a need for dynamic fusion imaging?

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Disclosures

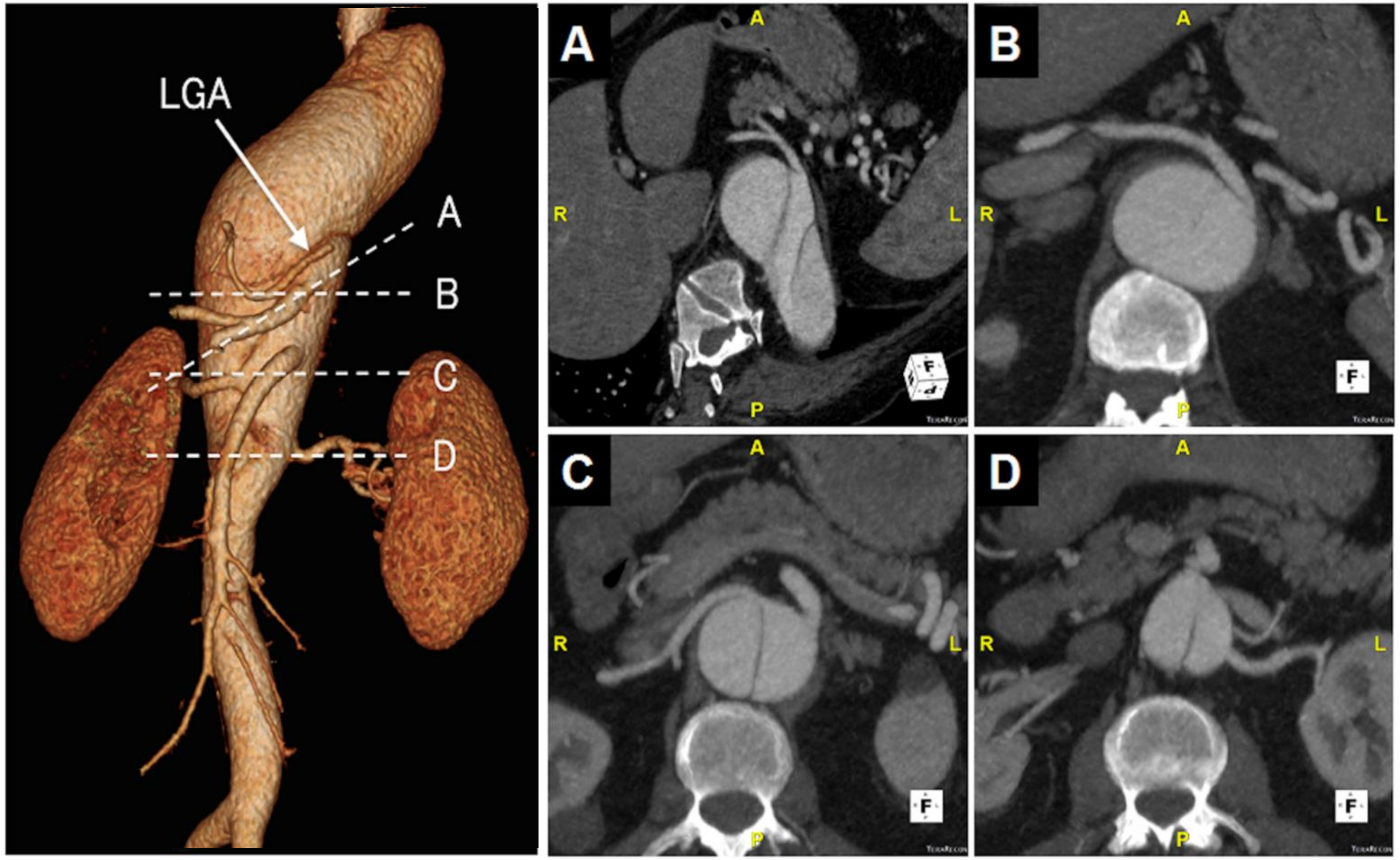
Speaker name: Rachel Clough

I have the following potential conflicts of interest to report:

- ✓ Consultant: Cydar Medical
- ✓ Consultant: GE Healthcare
- ✓ Consultant: Medtronic Digital Surgery

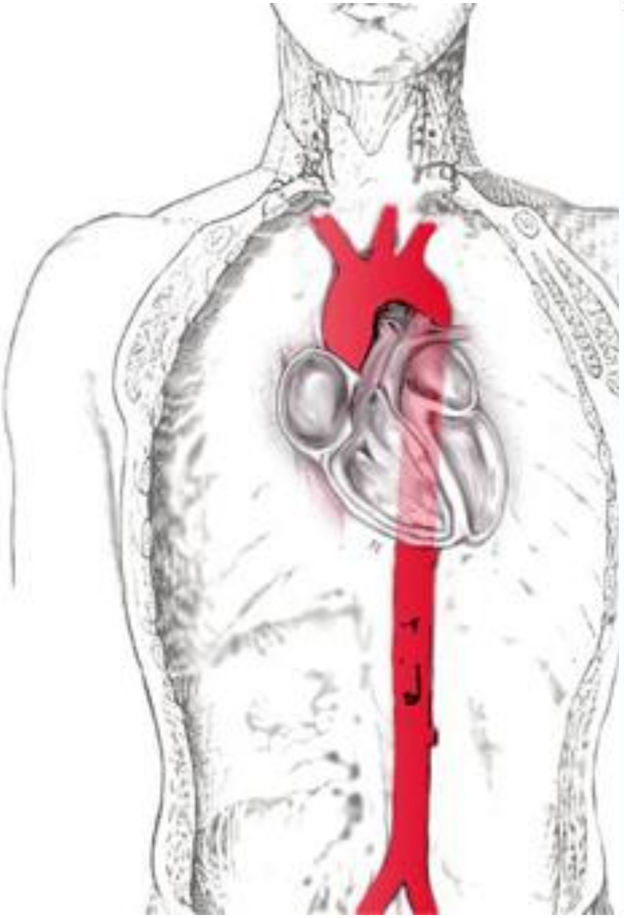
Complex 3D, patient-specific anatomy

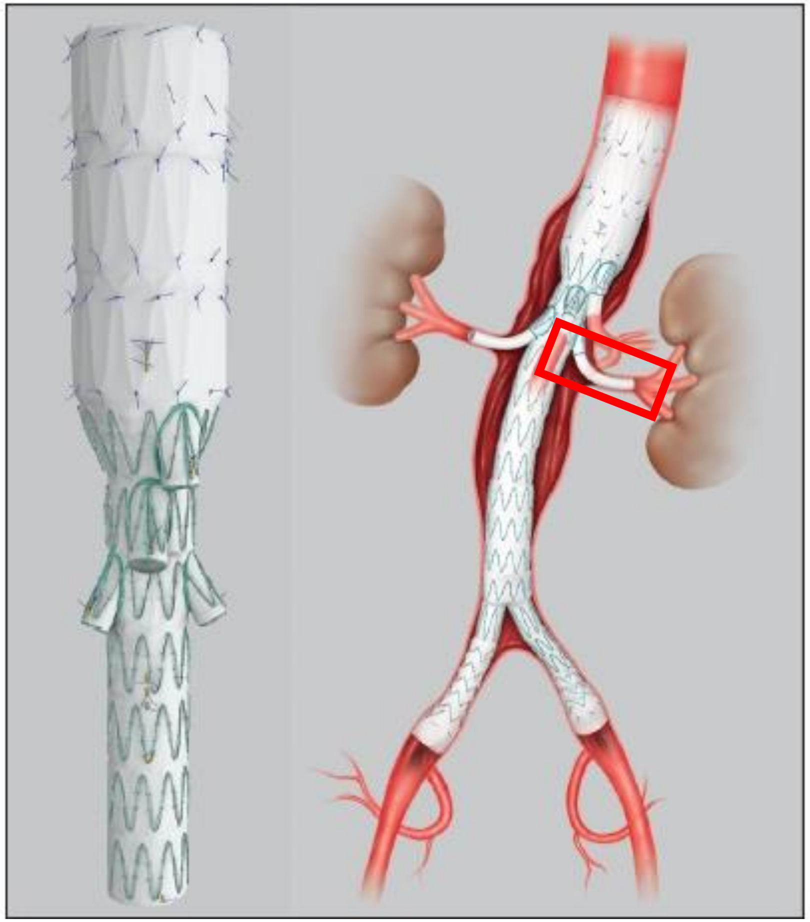
Chronic aortic dissection

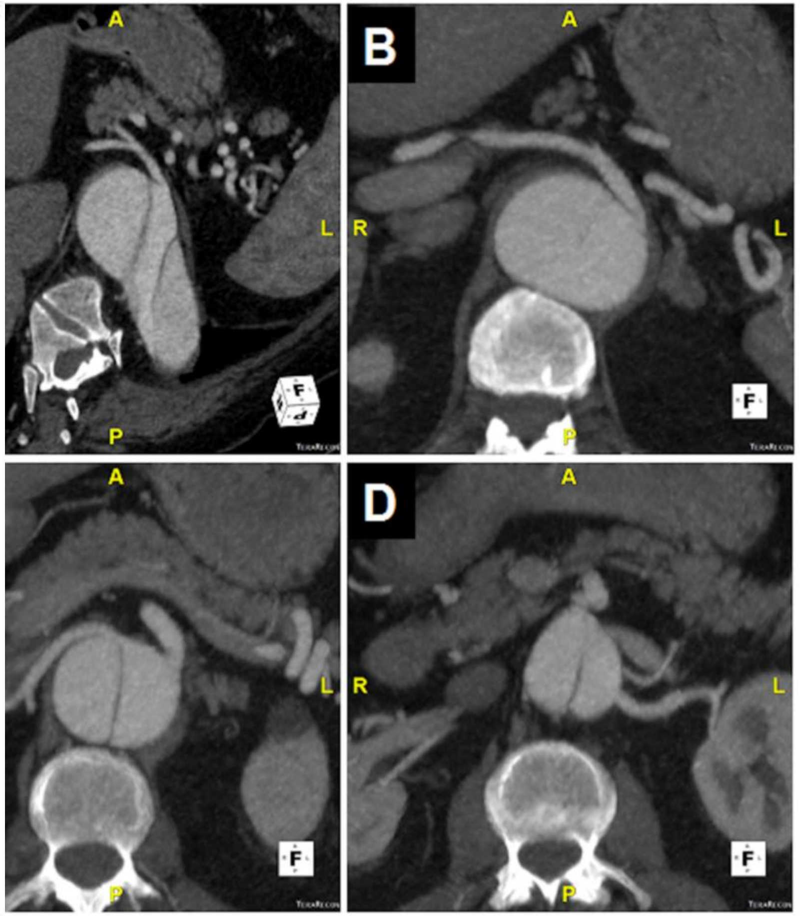


Complex 3D, patient-specific anatomy

Treatment



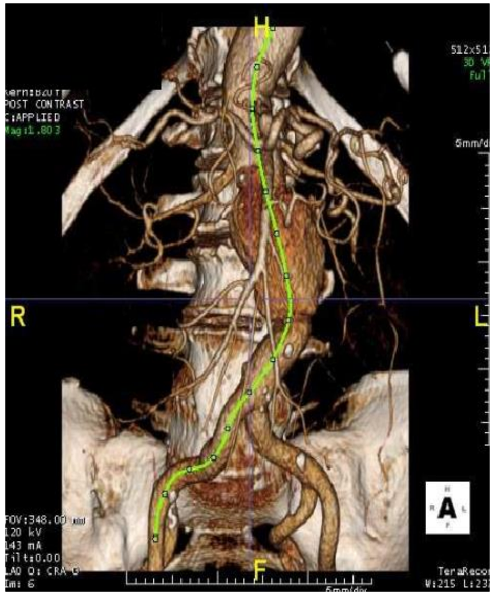


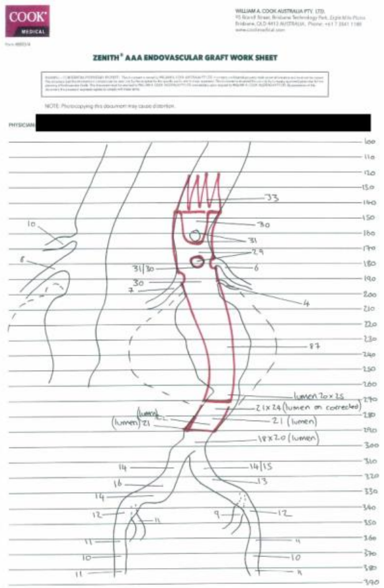


Problem

Precise plans but poor view of soft tissues and 3D anatomy during surgery

Before surgery

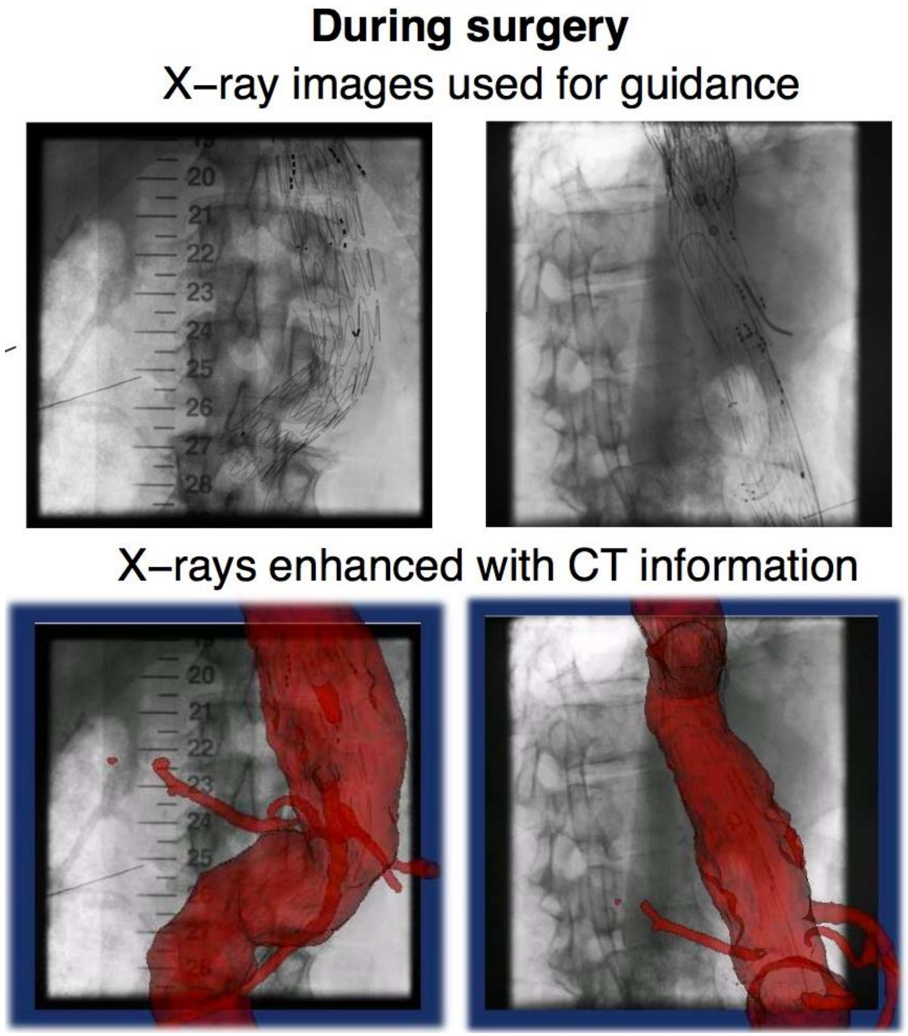




Diagnostic 3D CT scan used to plan surgery

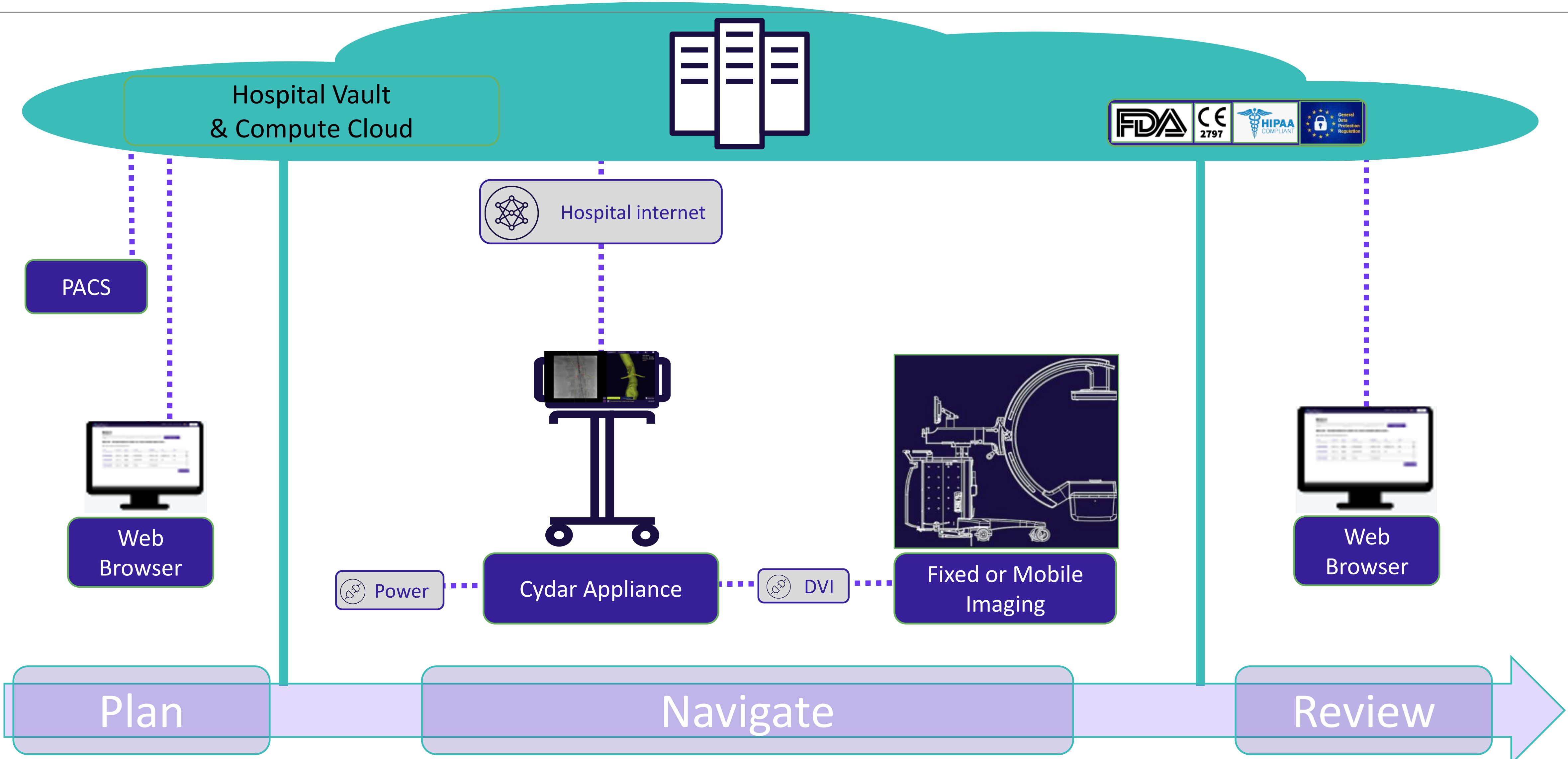
Cydar Maps

In-theatre guidance | Dynamic image fusion



CYDAR MEDICAL

Cydar Maps system architecture

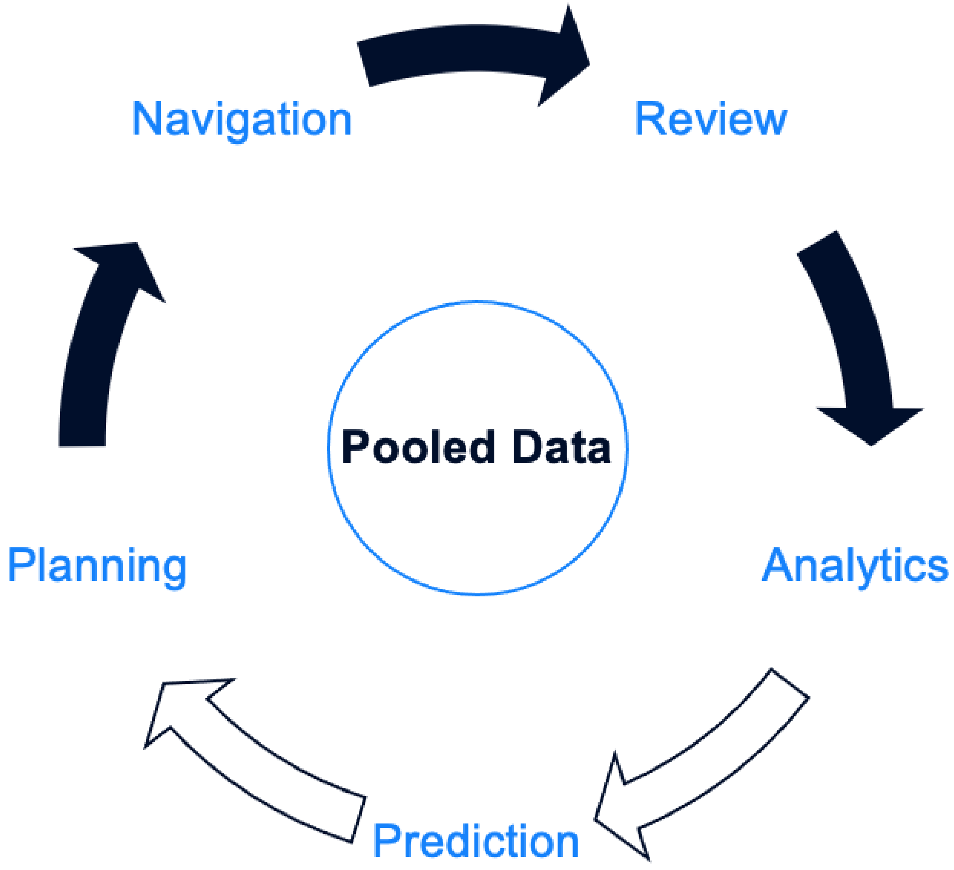


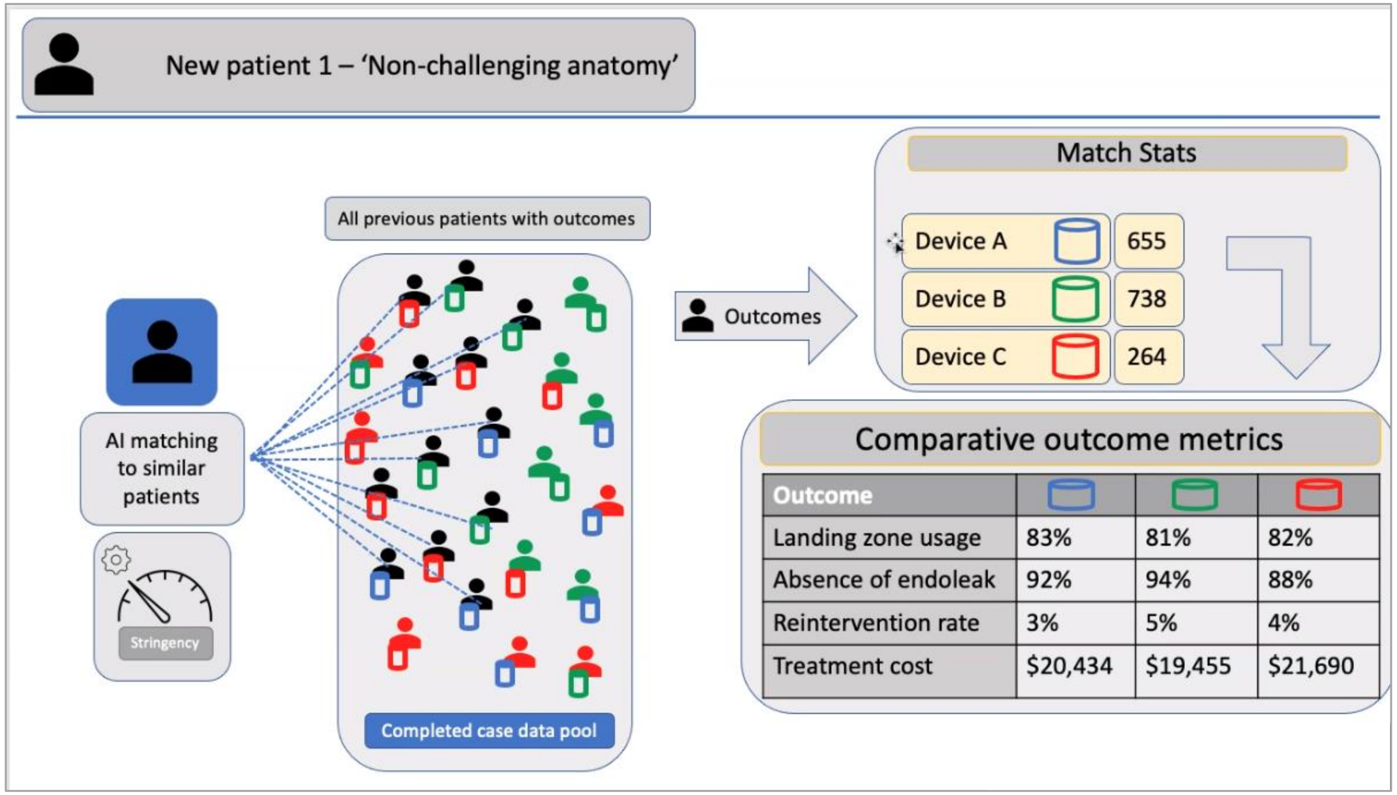
Value of cloud technology

- Easy access: case plans, intra-operative recordings, all CTA data
- Collaboration: case-planning, intra-operative screen-sharing
- Automatic remote software upgrade
- 24/7 remote support

Global experience | Data-driven clinical decision support

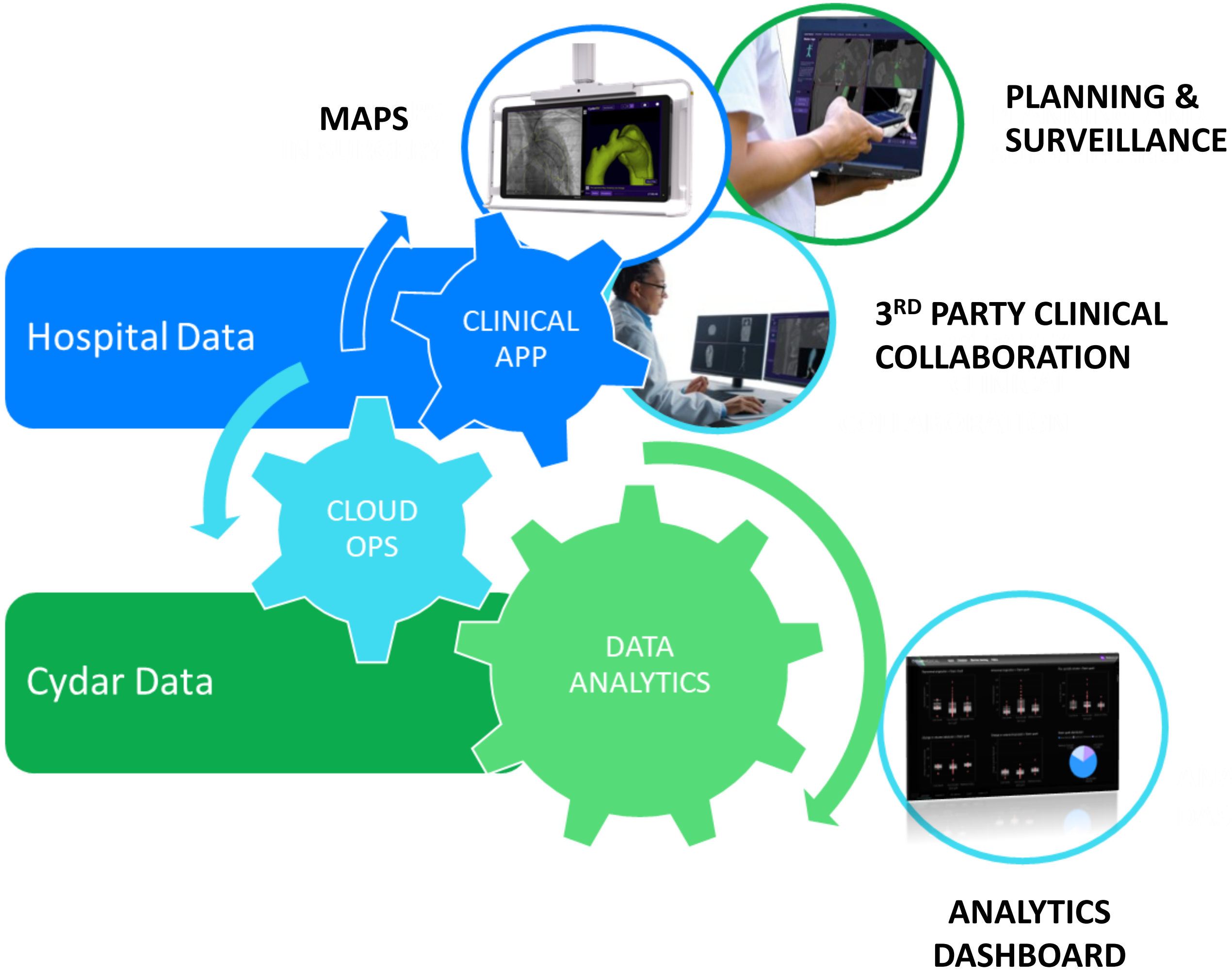
Improved patient outcomes





Inter-relationship of clinical application with analytics

Improved patient outcomes



Cydar Maps
Software-as-a-Medical Device (FDA & CE cleared)

- Informs individual patient care
- Identified data (patient, hospital, clinician)

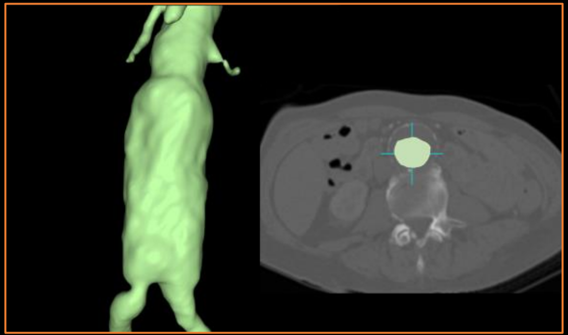
Cydar Data for new Insights

- ≈10GB new data generated by AI (DL and computer vision) per patient pathway
- Highly structured
- Globally pooled
- Unidentifiable with respect to geography, hospital, clinicians, and patients

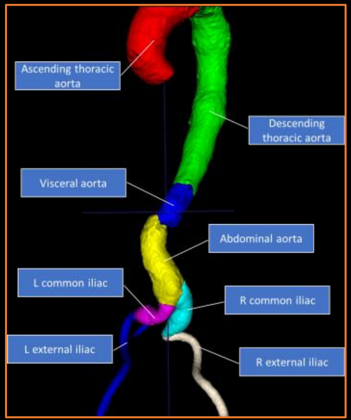
Cydar analytics

Combined AI functions

Deep learning segmentation and image classification of Cydar 3D and 2D image data
Analysed with fully automated deterministic algorithms (e.g. angles, curvatures, areas and volumes)

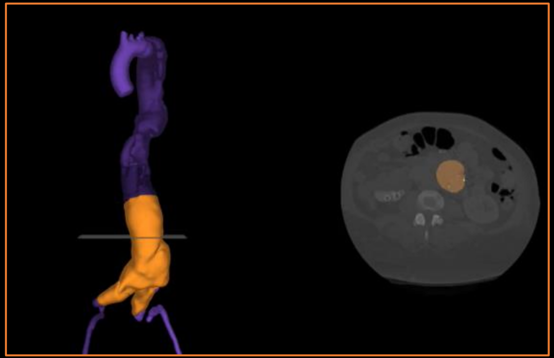


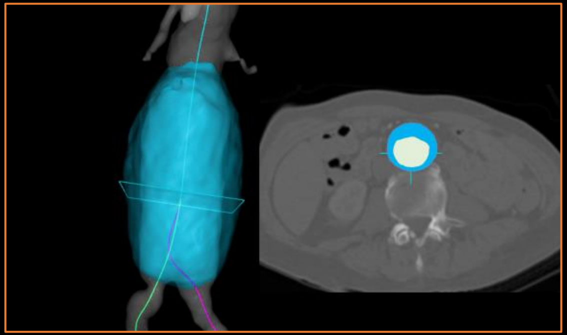
Lumen segmentation



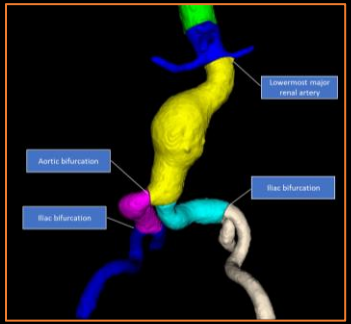
Anatomical regions

Device classifiers

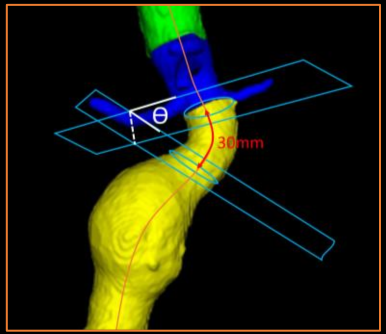




Thrombus segmentation



Reference points



Virtual wires

Combined functions
AAA sac example:

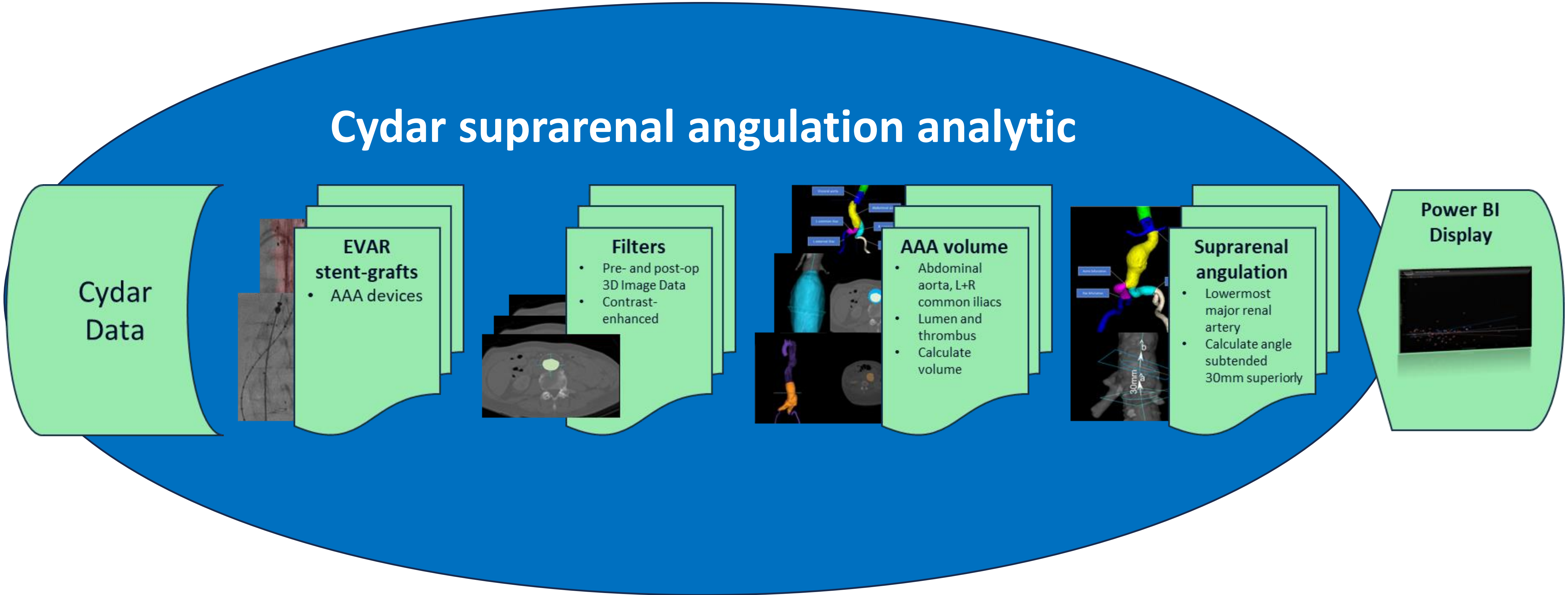
1. Segment lumen and thrombus between lowest major renal artery and iliac bifurcations
2. Measure volume

Analytics pipeline distils meaningful insights

Improved patient outcomes

Example insight:

In steep supra-renal neck angles, what does the data show about outcomes with different EVAR devices?



Analytics pipeline distils meaningful insights

Improved patient outcomes

Example insight:

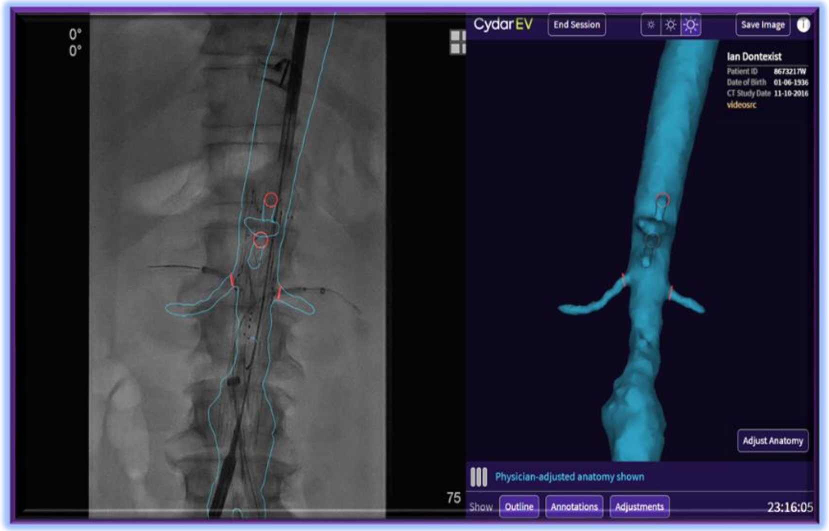
In steep supra-renal neck angles, what does the data show about outcomes with different EVAR devices?

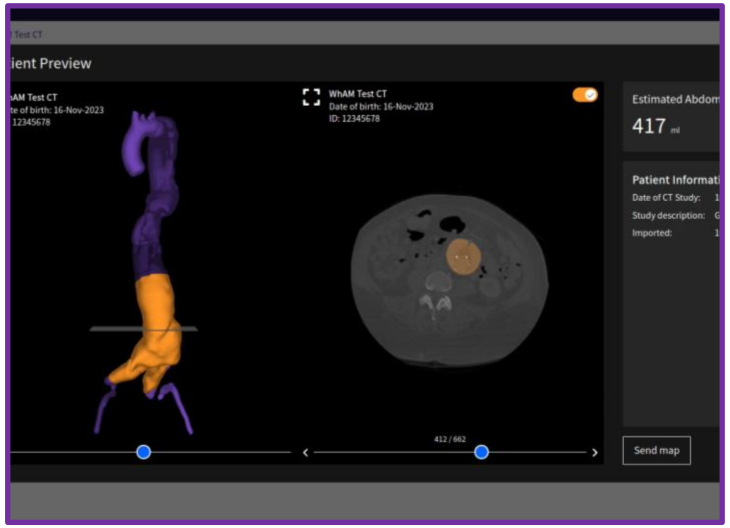
Cydar analytics demo

- Real data, real functionality
- Small sample size for demo purposes
- Fractional change in sac volume on y-axis. Device type of x-axis
- Slider top right filters dataset by suprarenal angulation

Cydar Maps

End-to-end clinical application





- BUILDS A 3D MAP FOR SURGERY: GUIDEWIRES, INTENDED DEVICE POSITIONS, GEOMETRY, MARKERS
- AI COMPARES ANATOMY TO DYNAMIC GLOBAL POOL OF MATCHED DATA: AWARENESS OF ANATOMICAL EXTREMES
- SECURE REMOTE COLLABORATION

- FULLY AUTOMATED OVERLAYS FROM ARCH TO FEMORALS, STEEP LAO-RAO, CRANIAL-CAUDAL
- ALWAYS ACCURATELY ALIGNED WITH SKELETON
- MAP UPDATES TO MATCH VESSEL DEFORMATION
- SECURE LIVE REMOTE COLLABORATION

- AUTOMATIC PACS VIGILANCE AND PROCESSING OF POST-EVAR CT SCANS
- ANEURYSM SAC VOLUME CALCULATION AND DISPLAY OF VOLUME TRENDS OVER TIME

PLAN

NAVIGATE

REVIEW

IS THERE REALLY A NEED?

Current data

Independent case-control studies in UK and US

From the Society for Vascular Surgery

A prospective observational trial of fusion imaging in infrarenal aneurysms

Blandine Maurel, MD, PhD,[a,b] Teresa Martin-Gonzalez, MD, PhD,[a] Debra Chong, MD,[a] Andrew Irwin, MD,[a] Guillaume Guimbretière, MD,[b] Meryl Davis, MD,[a] *and* Tara M. Mastracci, MD, MSc, FRCSC, FACS, FRCS,[a]
London, United Kingdom; and Nantes, France

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 p… as air kerma and dose-area p…

Results: For… …ents. No significant differences w… …e (wire to wire) and fluoroscopy … …fferences between groups (*P* = … (8.9-85.9) Gy cm², compared with the fusion group, 12.4 (7.5-23.4) Gy cm² (*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

Overall 50% reduction in radiation dose in standard EVAR

IF09.

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

Kevin W. Southerland, Uttara Nag, Megan Turner, Brian Gilmore, Richard McCann, Chandler Long, Mitchell Cox, Cynthia Shortell. Duke University Medical Center, Durham, NC

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

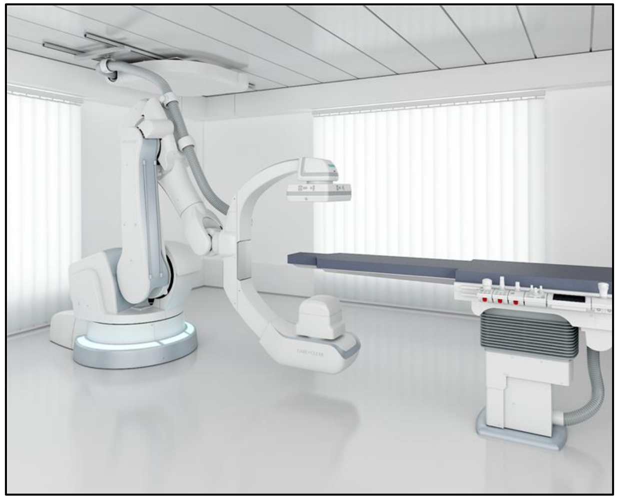
Overall
30% reduction in radiation
20% shorter procedure times
in mixed standard and complex EVAR

J Vasc Surg, 2018;68:1706-13, J Vasc Surg, 2018;67:e61

Current data

Accuracy | Confidence

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



Hardware-based tracking

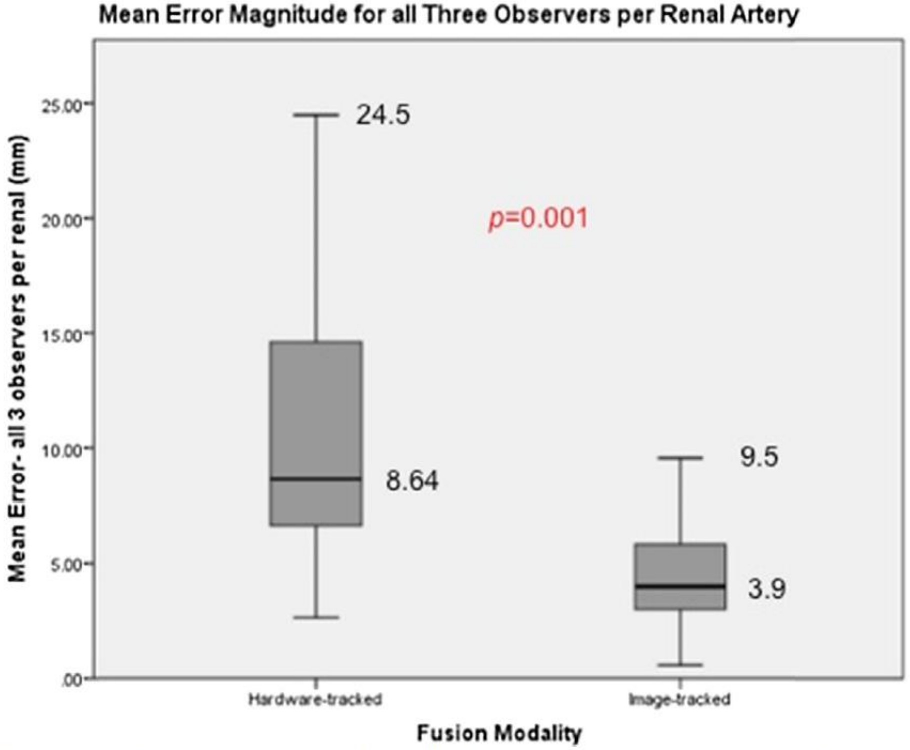


Image-based tracking
(Cydar EV software)

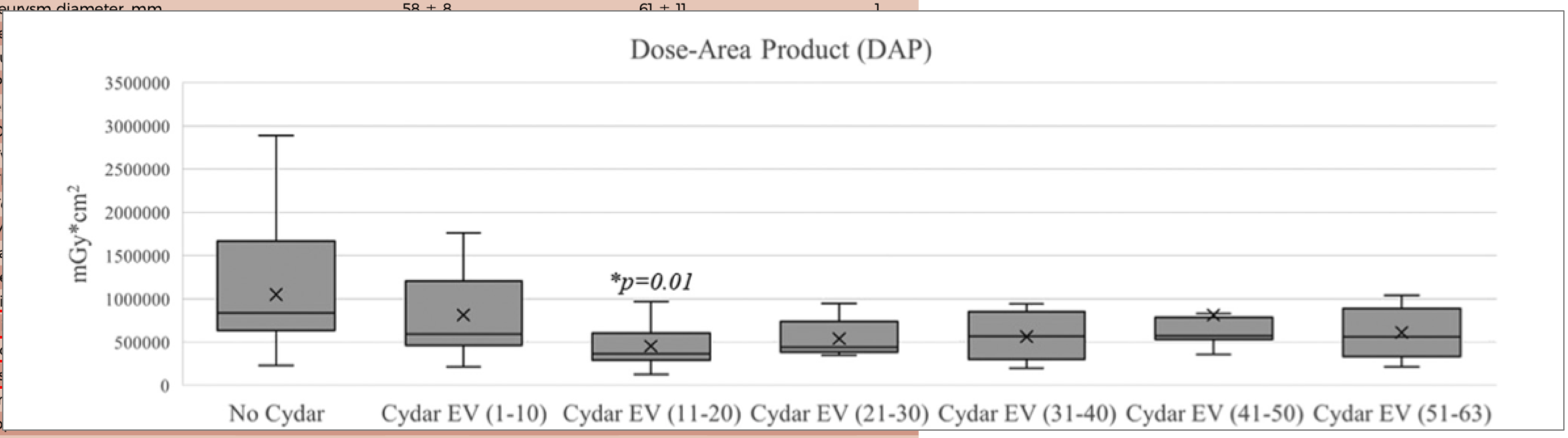
Eur J Vasc Endovasc Surg, 2016;52:323-31

Current data

FEVAR | Learning curve | Sustained reduction in radiation exposure

	Cydar EV		
Variable	No (n = 53)	Yes (n = 63)	*P* value
Aneurysm details			
Aneurysm diameter, mm	58 ± 8	61 ± 11	.1
Ane			
Ju			
P			
Ste			
C			
T			
T			
T			
M			
Opera			
Ope			
Esti			
Iod			
Flu			
Dos			
Cur			
Posto			
Length of stay, days	3 (1-73)	4 (1-58)	.9
Length of ICU stay, days	1 (1-43)	2 (1-24)	.4
Major adverse postoperative events	19 (36)	30 (48)	.3

ICU, Intensive care unit.
Data presented as mean ± standard deviation or number (%).
Boldface *P* values represent statistical significance.

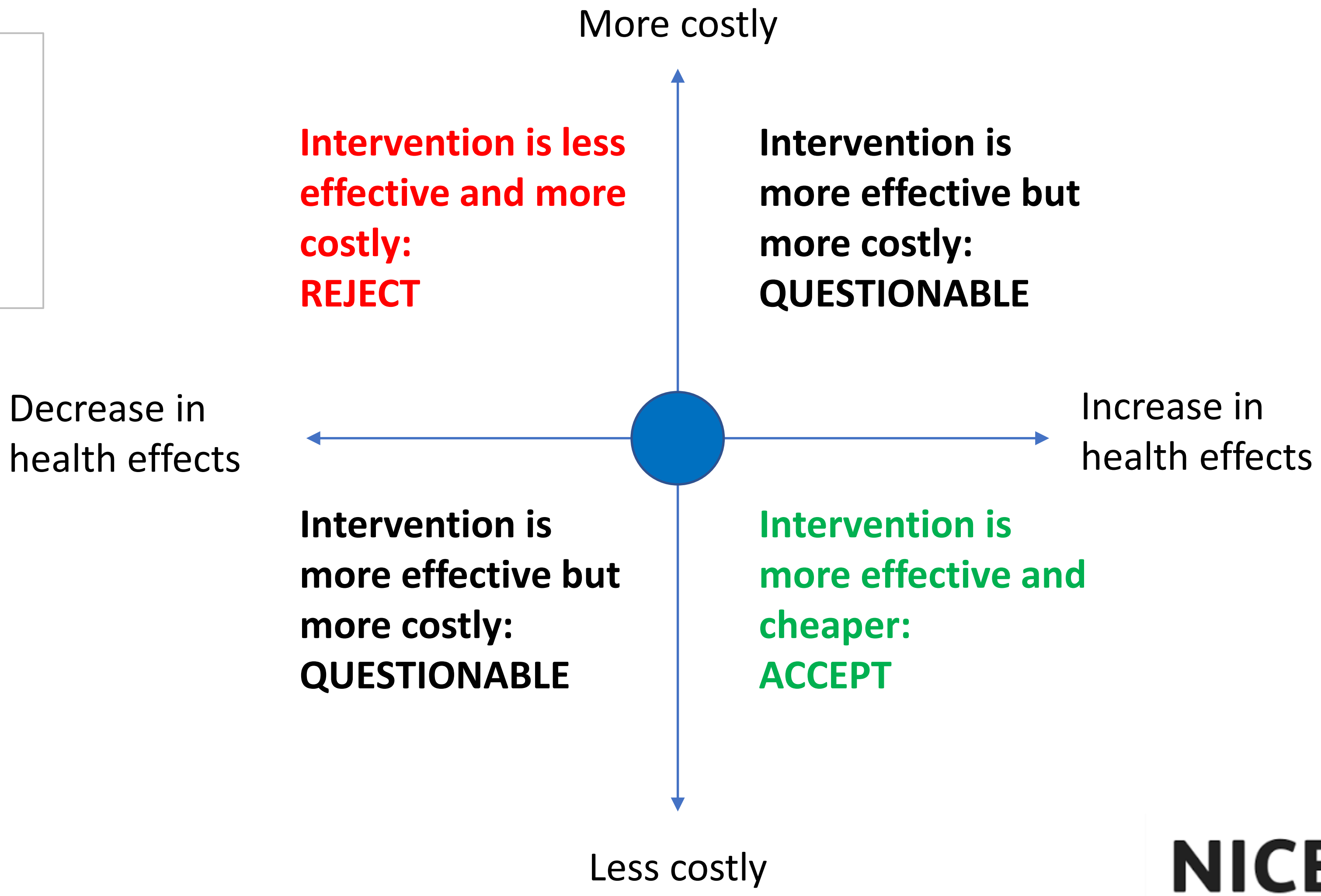


J Vasc Surg, 2023; 77:366-373

NICE Appraisal

NHS is an efficient and effective healthcare system. Resource stretched.

“Provides similar or greater benefits at a similar or lower overall cost than the comparator(s)”



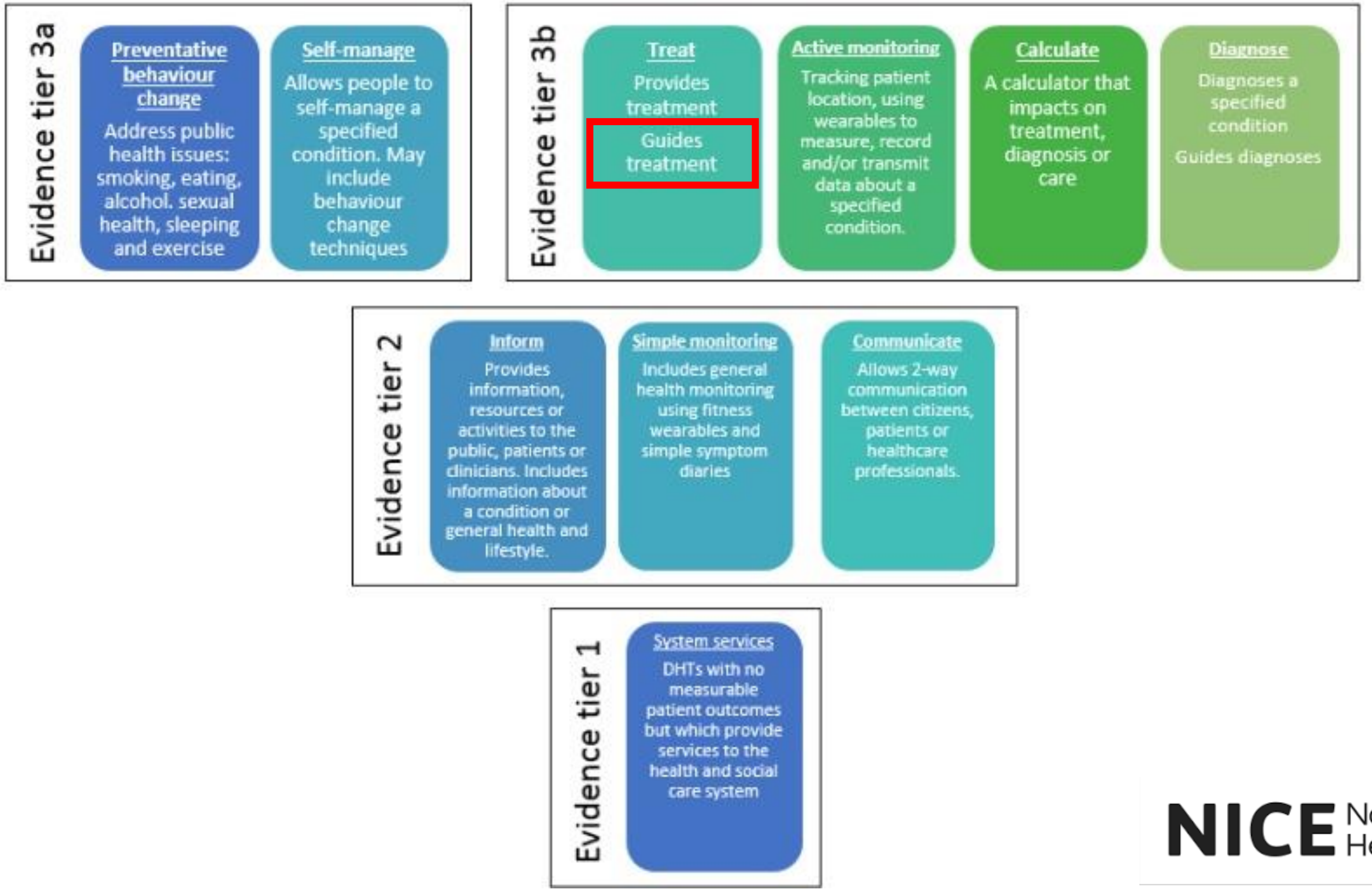
● Comparator

NICE National Institute for Health and Care Excellence

NICE Digital Evidence Framework

Digital health technology to guide treatment

Figure 1 DHTs classified by function and stratified into evidence tiers



NICE Digital Evidence Framework

High quality RCT

Table 6 Evidence for effectiveness standards for tier 3b DHTs

Evidence category	Minimum evidence standard	Best practice standard
Demonstrating effectiveness.	High quality intervention study (experimental or quasi-experimental design) showing improvements in relevant outcomes, such as: • diagnostic accuracy • patient-reported outcomes (preferably using validated tools) including symptom severity or quality of life • other clinical measures of disease severity or disability • healthy behaviours • physiological measures • user satisfaction and engagement. Generic outcome measures may also be useful when reported alongside condition-specific outcomes. The comparator should be a care option that is reflective of the current care pathway, such as a commonly used active intervention.	High quality randomised controlled study or studies done in a setting relevant to the UK health and social care system, comparing the DHT with a relevant comparator and demonstrating consistent benefit including in clinical outcomes in the target population, using validated condition-specific outcome measures. Alternatively, a well-conducted meta-analysis of randomised controlled studies if there are enough available studies on the DHT.

Research Award

ARIA

Randomised controlled trial investigating the role of a cloud-based, artificial intelligent image fusion system to guide endovascular aortic repair

Award ID:
NIHR201004

Active Award

Plain English Summary:

An aortic aneurysm is an abnormal swelling of the main artery of the body, the aorta. When the aneurysm reaches a certain size it can burst like a balloon. To prevent this a device called a stent-graft, which is a metal frame (stent) coated with a special fabric (graft) is introduced in a key-hole procedure called endovascular aortic surgery . Approximately 5,000 patients have t...

Read more

Abstract:

Research question Can a novel type of medical device comprised of real-time cloud computing, AI and computer vision, improve the clinical and cost-effectiveness of X-ray guided surgery? Background X-ray fluoroscopy-guided surgery is a large and growing segment of the minimally-invasive surgery market, but is limited by 2D imaging that visualises soft tissues po...

Read more

Chief Investigator(s):
Dr Rachel Clough, Mr Tom Carrell

Co-investigators:
Dr Yanzhong Wang, Miss Caroline Murphy, Ms Joanna Kelly, Professor Janet L Peacock, Professor John Deanfield, Professor Julian Scott, Professor Stephen Palmer

Award:
£1,811,927.00

Contracting Organisation:
King's College London

FUNDED BY
NIHR | National Institute for Health Research

Study design

Prospective, multi-centre, two-armed, randomised controlled trial

Multi-centre, 2-armed, RCT

Patients listed for endovascular repair of AAA/TAAA

↓

Screening
- Baseline CT imaging
- Clinical assessment

↓

Consent
- EQ-5D questionnaire

↓

Stratification

1:1 Randomisation
- N=340

↓

Conventional surgery
Standard fluoroscopy imaging
- EQ-5D questionnaire

3D-image-guided surgery
Cydar fusion imaging
- EQ-5D questionnaire

↓

6-12 week follow up
- CT imaging
- Outpatient review
- EQ-5D questionnaire

↓

1 year follow up
- CT imaging
- Outpatient review
- EQ-5D questionnaire

10 recruiting sites
Evidence-based site selection
Duration 3 years

Power calculation, 90% power, 2-sided 5% difference

Procedure duration (min(SD)):

2D fluoroscopy	132.1(69.2)	22.5 min
Cydar	109.6 (34.2)	

(J Vasc Surg, 2018;67:e61)

End-points
1°: procedure time
2°: radiation & contrast exposure, QoL, consumables, LoS, technical success

NICE National Institute for Health and Care Excellence

ARIA trial progress

213 patients, total required = 340

Conclusion

- Dynamic fusion imaging has the potential to revolutionise the information available to clinicians for endovascular repair
- The dynamic database grows and evolves with real-world use
- ARIA trial will provide data on clinical-, technical- and cost-effectiveness
- Submission to NICE to understand the true value of this technology