







# Which Technologies To Replace X-Ray in the Near Future

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#### Disclosures & Conflicts of Interest

- Consultancy
  - Arsenal, Arterica, Brainlab, Cook, Endologix, Gore, Medtronic
- Research Grant /research support
  - Brainlab, Cook, Gore, Maquet, Medtronic, Siemens
- Advisory Board
  - Endologix, Gore, Medtronic, Siemens
- Paid speaker
  - Cook, Endologix, Gore, Maquet, Medtronic, Siemens
- Major stokeholder
  - none







### The Future Goals in Endovascular Therapy



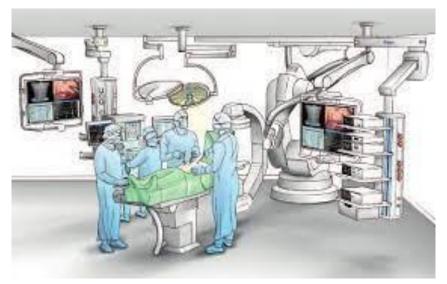
- ➤ Mitigate radiation exposure
- > Advance navigation imaging
- > Improve outcome
- Protect patient and "caregiver"





### From X-Ray Image guided to AI-guided Surgery











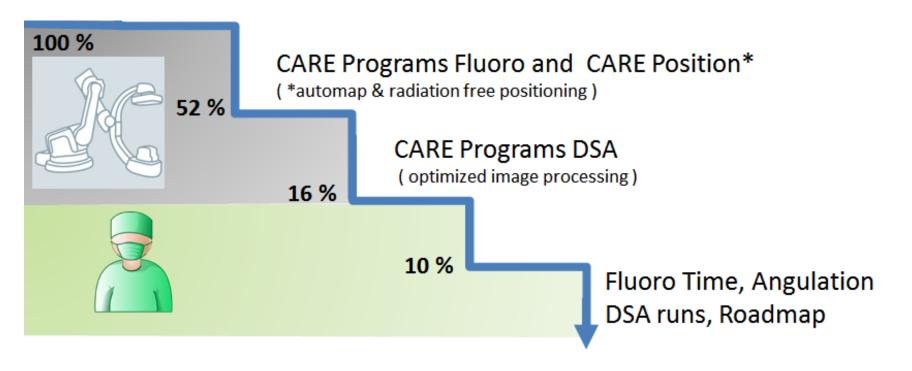
### Recent Hybrid OR Working Conditions 2021







### Efforts Lowering Radiation Exposure







### Clear Trends in Vascular/Endovascular Surgery

- ➤ Non-invasive preoperative diagnostic tools
- > Increasing endovascular technologies replacing conventional surgery
- > Image guided surgery & intervention becoming standard of care
- Establishing alternative intraoperative imaging modalities (CO<sup>2</sup>, IVUS)
- > Implementation of automatic processes using AI, digitalization, big data
- > Radiation protection: Dose Management System
- ➤ Vision of a x ray free Hybrid-OR or angio-suite







#### 3D - 4D - 5D Ultrasound



JACC: Cardiovascular Imaging
Volume 12, Issue 3, March 2019, Pages 500-515

State-of-the-Art Paper

## 3-Dimensional Echocardiography in Imaging the Tricuspid Valve

Denisa Muraru MD, PhD <sup>a, b</sup>, Rebecca T. Hahn MD <sup>c</sup>, Osama I. Soliman MD <sup>d</sup>, Francesco F. Faletra MD <sup>e</sup>, Cristina Basso MD <sup>a</sup>, Luigi P. Badano MD, PhD <sup>a, b</sup> 尽 <sup>⊠</sup>

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https://doi.org/10.1016/j.jcmg.2018.10.035

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#### Summary

<u>Tricuspid regurgitation</u> (TR) is an independent predictor of death. Lately, emerging technologies for the treatment of TR



#### Author manuscript

Transplantation, Author manuscript; available in PMC 2018 June 01.

Published in final edited form as:

Transplantation. 2017 June; 101(6): 1344-1352. doi:10.1097/TP.000000000001206.

#### New Dimensions in Renal Transplant Sonography: Applications of 3-Dimensional Ultrasound

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"Albert Einstein College of Medicine, Department of Epidemiology & Population Health, Bronx, NY

#### Abstract

**Background**—The aim of this study is to demonstrate the usefulness of adding 3-dimensional (3D) ultrasound in evaluation of renal transplant vasculature compared to 2-dimensional (2D) Duplex ultrasound.







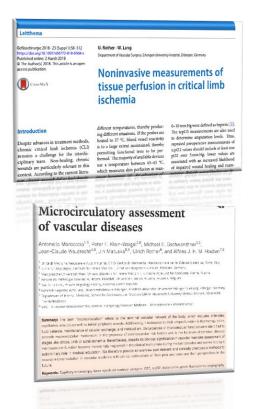
Quelle: www.9Monate.de





#### Radiation Free ICN - Angiography

#### Tissue perfusion & mikrocirculation in Critical Limb Ischemia (CLI)



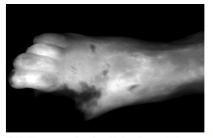


Fig. 2 ▲ Fluorescence angiography with indocyanine green (SPY system, NOVADAQ, STRYKER, Kalamazoo, USA) following hallux amputation

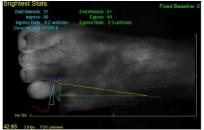
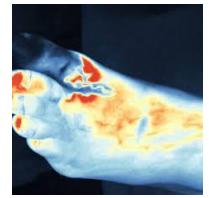
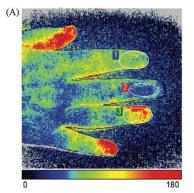
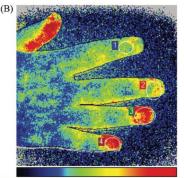


Fig. 3 ▲ Quantification of fluorescence angiography with indocyanine green (SPY-Q, NOVADAQ). Fluorescence intensity is quantified using a 256 gray scale, thereby enabling inflow and outflow to be assessed













### New MR-Technology in PAOD

**Table 2.** Novel MRI techniques for peripheral artery disease.

Technique	Contrast	Advar
First-pass gadolinium enhanced perfusion	Yes	Semision a time
Arterial spin labeling	No	Quan excell poral
Blood-oxygen-level dependent MRI	No	High thigh t
Phosphorus-31 magnetic resonance spectroscopy	No	Reproductions
Creatinine chemical exchange saturation transfer	No	Spatia ment





Mathew RC et al Vascular Medicine 2018;23:143-152

### FORS (Fibre Optic Real Shape)





#### First in Human Clinical Feasibility Study of Endovascular Navigation with Fiber Optic RealShape (FORS) Technology

Josef A. van Hernexarden \*, Marthen M. Jansen ', Inversion P.A. Vonken ', Tripole Biomene Tuke ', Baland W.M. Ballens ', Gen J. de Borg '

Department of Vascular Surgery, University Medical Center Utrache, Utrache, the Netherlands Department of Yacuser Surging, University Medical Contant Universit, threath, the National Department of Radiology, University Medical Contant Universit, Universit, the National Operations Systems Rederland, Sest, the National Systems Rederland, Sest, the Nati

#### WHAT THIS PAPER ADDS

Fiber Optic RealShape (FORS) technology is a new method to visualise endovascular guidewires and catheters inside the body in 3D, in real time. FORS functions as an add on to conventional fluoroscopy and uses integrated multicore optical fibres to track and visualise the entire devices based on light rather than X-ray. This paper contains the first in human use of FORS technology in (regular and complex) endovascular acrtic repair and peripheral lesion repair. This exploratory study demonstrates the feasibility and potential of this technology in clinical practice and forms a foundation for future clinical research.

Objective: Endovascular procedures are conventionally conducted using two dimensional fluoroscopy. A new technology platform, Fiber Optic RealShape (FORS), has recently been introduced allowing real time, three dimensional visualisation of endovascular devices using fiberoptic technology. It functions as an add on to conventional fluoroscopy and may facilitate endovascular procedures. This first in human study assessed the feasibility of FORS in clinical practice.

Methods: A prospective cohort feasibility study was performed between July and December 2018. Patients undergoing (regular or complex) endovascular aortic repair (EVAR) or endovascular peripheral lesion repair (EVPLR) were recruited. FORS guidance was used exclusively during navigational tasks such as target vessel catheterisation or crossing of stenotic lesions. Three types of FORS enabled devices were available: a flexible guidewire, a Cobra-2 catheter, and a Berenstein catheter. Devices were chosen at the physician's discretion and could comprise any combination of FORS and non-FORS devices. The primary study endpoint was technical success of the navigational tasks using FORS enabled devices. Secondary study endpoints were user experience and fluoroscopy time

Results: The study enrolled 22 partents: 14 EVAR and eight EVPLR patients. Owing to a technical issue during start up, the FORS system could not be used in one EVAR. The remaining 21 procedures proceeded without device or technology related complications and involved 66 navigational tasks. In 60 tasks (90.9%), technical success was achieved using at least one FORS enabled device. Users rated FORS based image guidance "better than standard guidance" in 16 of 21 and "equal to standard guidance" in five of 21 procedures. Fluoroscopy time ranged from 0.0 to 52.2 min. Several tasks were completed without or with only minimal X-ray use.

Conclusion: Real time navigation using FORS technology is safe and feasible in abdominal and peripheral endovascular procedures. FORS has the potential to improve intra-operative image guidance. Comparative studies are needed to assess these benefits and potential radiation reduction.

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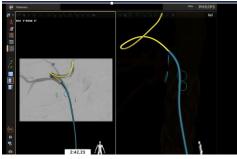
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in recent decades, an enormous shift has occurred from open operations to fluoroscopically guided endovascular interventions. However, fluoroscopically guided navigation Mail Close A. van has several important limitations. While guidewires and catheters are being manipulated in a 3D space, these movements are presented to the physician in a 20 projection. This limits the ability to estimate the spatial



Figure 1. The Fiber Optic RealShape (FORS) system with workstation (1), trolley (2), docking base (3), docking top that connects to the FORS enabled devices (4). The FORS enhanced devices are visualised in context of an anatomical roadmap on the screen (5). Copyright © (2020) Koninklijke Philips N.V. All rights reserved.



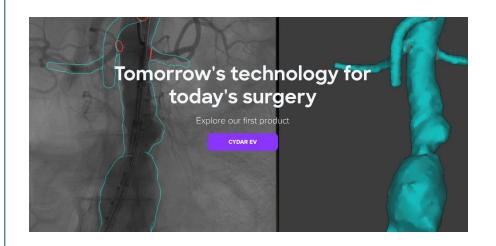






# Cydar® Surgical Augmented Intelligence (Cydar Medical, Cambridge, UK)

CYDAR EB =Cloud AI based technology computer vision and machine learning technology to advance surgical visualisation and decision-making in theatre

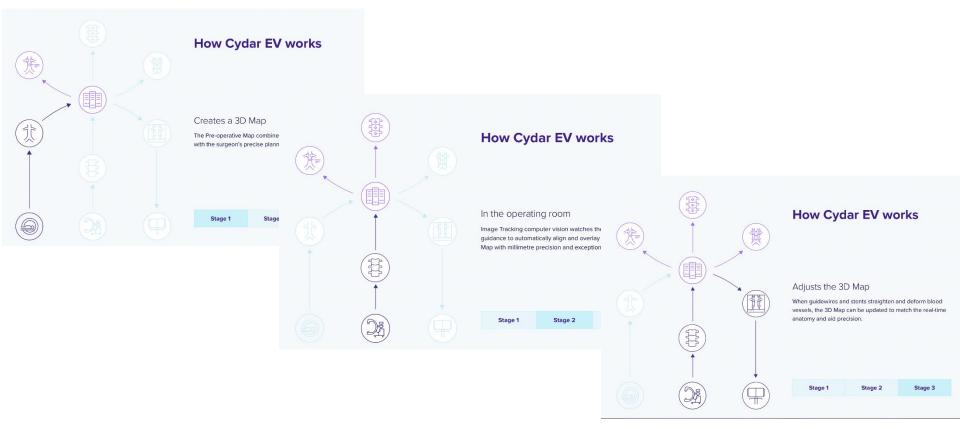


Source: www.cydarmedical.com





## How Cydar® EV Works

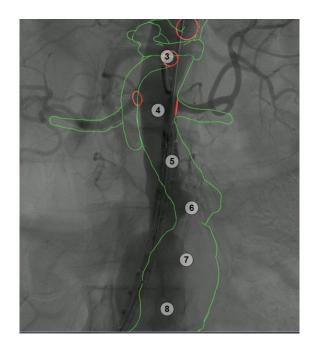


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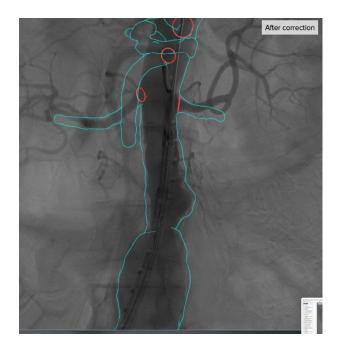




# Cydar® Surgical Augmented Intelligence (Cydar Medical, Cambridge, UK)



Before correction



After correction

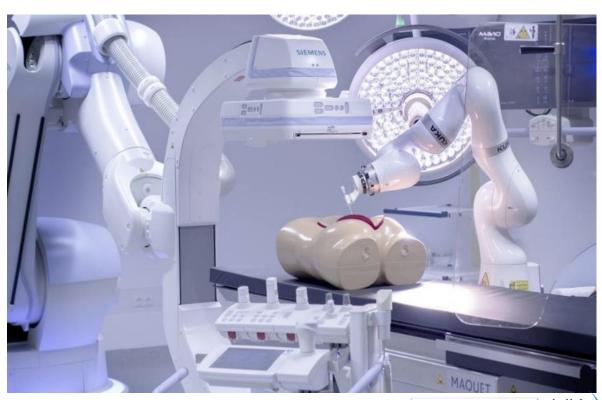
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## Robotic









### "Operator out of OR" – Intervention







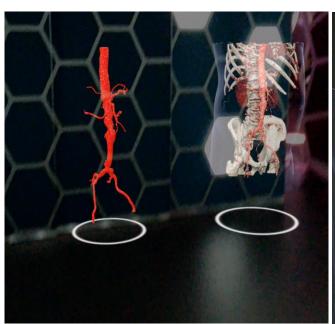
# Mixed Reality

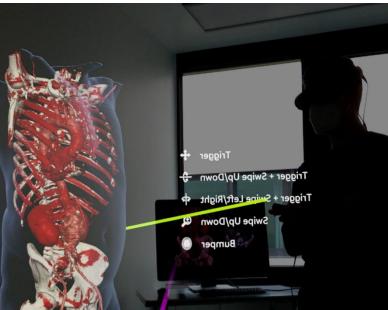






## Mixed Reality











### Mixed Reality – First Publications



Contents lists available at ScienceDirect

Journal of Biomedical Informatics journal homepage; www.elsevier.com/locate/yjbin



Use of mixed reality for surgery planning; Assessment and development



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- Department of Diagnosis: Physics, Odo Dissersey Hospital, Soptimenton 20, 0272 Odo, Norsey Department for Pedicaric Cordicings, Only Debersary Hospital, Superconnect 20, 0272 Only, Notway
- Department of Computer Science, NTNU, Televologicum 22, 2015 Garok, Narway
- Department of Surgery N1, Yannus State Medical Department, Yannus, Armenia
- \* Department of Reputation createfully Surgery, Oslo University Hasperd, Sugarinensisses 20, 0072 Oslo, Norway Department of Informatics, University of Only, Gausti-dollars 23 8, 0273 Only, Narvey

#### ARTICLE INFO

#### Krywords Mixed reality

ABSTRACT

Meticulous preoperative planning is an important part of any surgery to achieve high levels of precision and avoid complications. Conventional medical 2D images and their corresponding three-dimensional (3D) reconstructions are the main components of an efficient planning system. However, these systems still use flat screens for visualisation of 3D information, thus losing depth information which is crucial for 3D spatial under standing. Currently, cutting edge mixed reality systems have shown to be a worthy alternative to provide 3D information to clinicians. In this work, we describe development details of the different steps in the workflow for the clinical use of mixed reality, including results from a qualitative user evaluation and clinical use cases in laparoscopic liver surgery and heart surgery. Our findings indicate a very high general acceptance of mixed reality devices with our applications and they were consistently rated high for device, visualisation and interaction areas in our questionnaire. Furthermore, our clinical use-cases demonstrate that the supports perceived the HoloLens to be useful, recommendable to other surgross and also provided a definitive answer at a multidisciplinary team meeting.

#### 1. Introduction

Visualisation of medical images of organs in 3D is gaining importance in healthcare, especially for surgical procedures. Understanding the patient-specific 3D-anatomy helps surgeons to better prepare for (e.g. vessels, parenchyma and lesions for liver and chambers, septa surgery, thus delivering better treatment to patients. Currently, conventional volumetric images such as contrast-enhanced magnetic resonance (MR) and computed tomography (CT) images are used to plan surgery. These high-quality medical images provide excellent discrimination properties, which are necessary to differentiate anatomical structures and understand highly variable morphologies like, for instance, in congenital heart disease. However, these 3D volumetric images are still viewed as 2D slices leaving important depth information behind, which may be insufficient for complex cases. By planning

surgery using 2D slices, surgeons have to create the 3D model in their minds, with obvious potential flaws [1].

Alternatively, the 3D-reconstructions or segmented 3D-models of the volumetric medical images based on different tissue categories and vessels for heart, etc.) can be used for better visualisation, simplifying the understanding of the patient anatomy [2,3]. Visualising these segmented 3D models in real 3D could provide the surgeons with a better anatomical overview. This could greatly impact the decisionmaking process and lead to different and better decisions in surgical

Mixed reality, which is the merging of real and virtual worlds where physical and digital objects co-exist and interact in real-time, has already shown to provide better 3D information to surgeons

\* This article was originally published in Journal of Biomedical Information X. Journal of Biomedical Information X is you discustined and the article is equilibried here for the reader's convenience. For citation purposes, please use the publication details of this article: Journal of Biomedical Informatics, U.S.

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https://doi.org/10.1016/j.yjbins.2020.100077

Available online 03 September 2020 1532-0464/© 2020 The Authors. Published by Elsevier Inc.

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Viewer







Mixed Reality Viewer









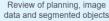


planning

















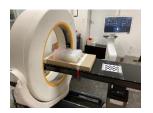


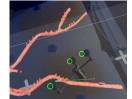


### Mixed Reality – Preliminary Experience in HD



- ➤ Medical education ✓
- ➤ Patient edication ✓
- ➤ Case planing
- > Intraoperative navigation &









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VEITH 2021: Researchers present ex vivo demonstration of fluoroscopy-free complex AAA stent placement

November 2021 • 379



Gustavo Oderich at the VEITH 2021 podium

"I think this represents the beginning of the end of an era where we have to use lead to perform these procedures." Those were the words delivered by Gustavo Oderich, professor and chief of vascular and endovascular surgery at UTHealth's McGovern Medical School in Houston, USA, as he demonstrated the results of an ex vivo experiment in which the emerging Intra-Operative Positioning System (IOPS) imaging technology from Centerline Biomedical was used "totally radiation-free."

Oderich was speaking during the 2021 VEITHsymposium (16-20 November, Orlando, USA). He was displaying for the audience how he and colleagues used a 3D-printed aortic model, and performed a

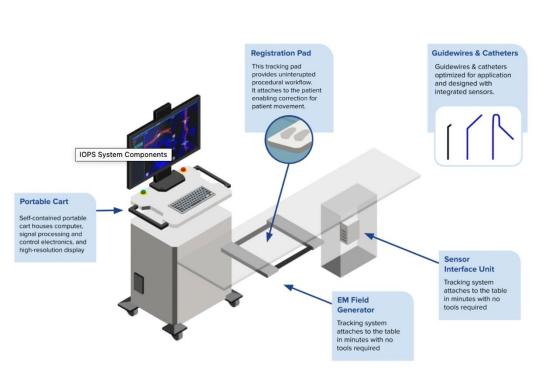


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### IOPS® Technology (Centerline Biomedical, Cleveland Clinic)

#### **IOPS®** Components



Endovascular portable

high quality 3D Image

GPS like navigation with

intraoperative

positioning

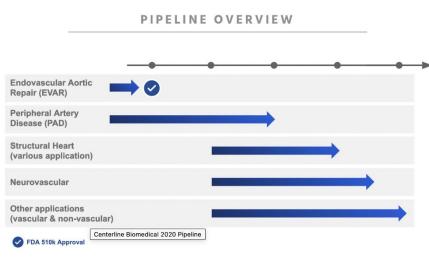
Source: www.centerlinebiomedical.com





### Future Scenario with IOPS® Technology





\*The HoloLens is currently not cleared for use with IOPS by FDA

Source: www.centerlinebiomedical.com





# First Case at Memorial Hermann & UT Health Houston July 29th 2021



Source: www.centerlinebiomedical.com





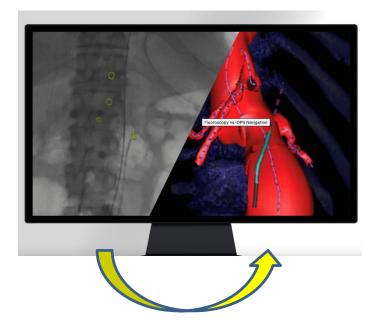
#### Summary

- "Endovascular First" is daily clinical practice in many sites
- > X -ray fluoroscopy based imaging is still current golden standard
- > Low dose programmes, fusion imaging etc. reduced radiqtion exposure
- Mitigating X-Ray radiation in Endovascular Tx is the new holy grail
- Fiber optic technology, AI, mixed reality are "the new kids on the block"
- > Preop. Imaging technology to reduce x-ray for patients (3D-5D US in VS)





# The "near future" is now! New technolgies are in our hands...



... to replace X Ray today!



