UNIVERSITÄTS
KLINIKUM
HEIDELBERG

What is the role/added value of mixed/augmented reality to intra-operative imaging in aortic endo procedures ?

Johannes Hatzl, Christian Uhl, Katrin Meisenbacher, Dittmar Böckler

for the research group

Department of Vascular and Endovascular Surgery
University Hospital Heidelberg, Germany

Disclosures and Conflicts of Interest

- **Consultancy**
  - Arsenal, Arterica, BrainLab, Cook, Endologix, Gore, Medtronic, Philips
- **Research grant /research support**
  - BrainLab, Cook, Dietmar-Hopp-Foundation, Gore, Maquet, Medtronic, Siemens
- Advisory Board
  - BrainLab, Endologix, Gore, Medtronic, Philips
- **Paid speaker**
  - Abbott, Cook, Endologix, Gore, Maquet, Medtronic, Siemens
- **Major stokeholder**
  - none

Present Vascular & Endovascular Care: Hybrid OR

Recent technological facilities:

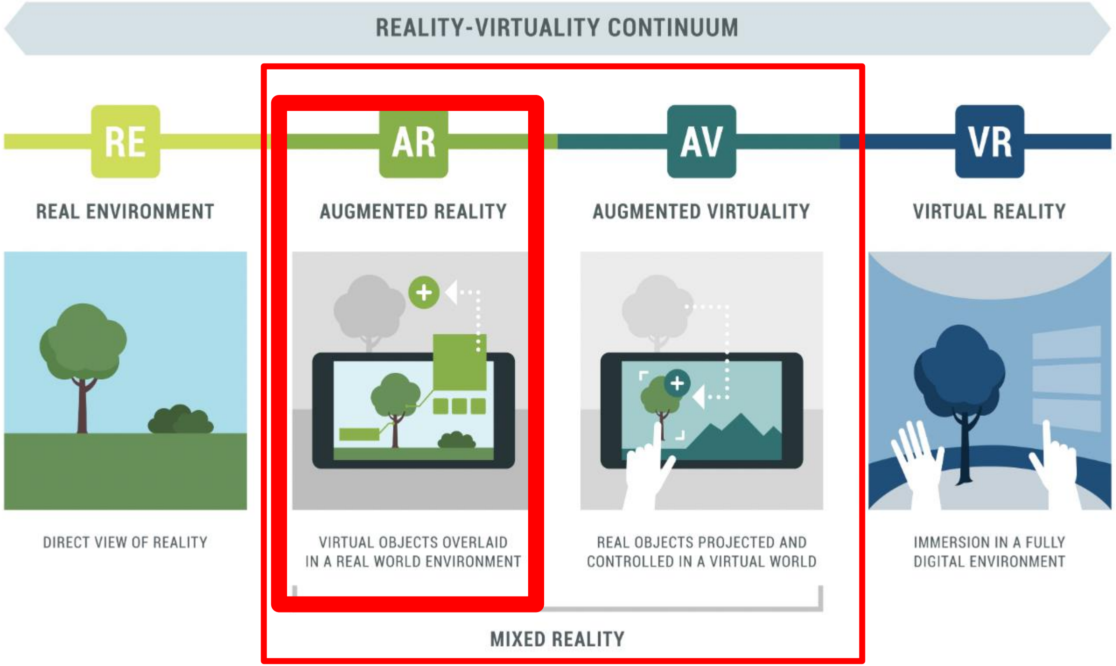
- ➢ Fusion imaging & navigation
- ➢ Cone -beam CT
- ➢ Device tracking technology (FORS)
- ➢ IVUS, CO_2- Angiography
- ➢ Online dosimetry for radiation exposure
- ➢ Dose management programme
- ➢ and more…

Clear Trends in Vascular & Endovascular Surgery

- Non-invasive preoperative diagnostic & planning tools
- Increasing endovascular technologies replacing conventional surgery
- Image guided surgery & intervention
- Implementation of automatic processes using AI, big data, etc.
- Radiation protection and radiation exposure reduction
- Alternative intraoperative imaging modalities

Future Role and Added Value of Mixed / Augmented Reality in Endovascular Therapy?

What is Augmented / Mixed Reality (MxR) ?

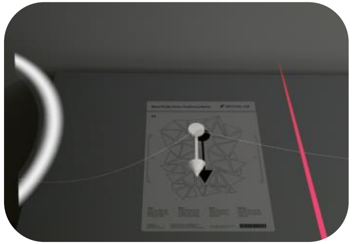


Def.: Mixed Reality (MxR) merges real-world environment and computer-generated content

> Virtual objects are overlaid in a real environment

Mixed Reality Viewer

BRAINLAB



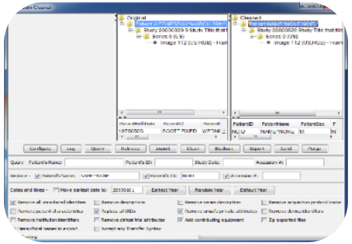
1 DICOM-Data

2 MR-Viewer

3 QR-

4 Position mark

5 Viewing



MxR- **H**ead **M**ounted **D**isplays (HDM)

- Microsoft Hololens2 (Redmont, Washington, USA)

- Magic Leap 1&2 (Plantation, Florida, USA)

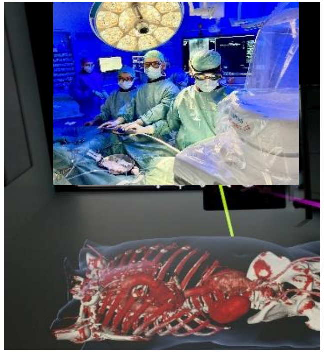
Magic Leap 1

Magic Leap 2 (CE marked 2023)

- Vision Pro (Apple, USA)

Objectives of Mixed Reality Technology in Vascular Interventions

- to augment operators anatomical understanding during interventions using 3D imaging of computed tomography angiography
- **to locate e.g. target vessels in open and endovascular surgery**
- **to plan & to navigate endovascular, robotic, open surgical procedures**
- **to improve procedures regarding time, technical outcome, etc.**
- to reduce radiation and contrast exposure
- to add value for teaching and patient education



Systematic Review for MxR inVascular Surgery

Originalarbeit

Thieme

Mixed Reality in der Gefäßchirurgie – ein Scoping Review

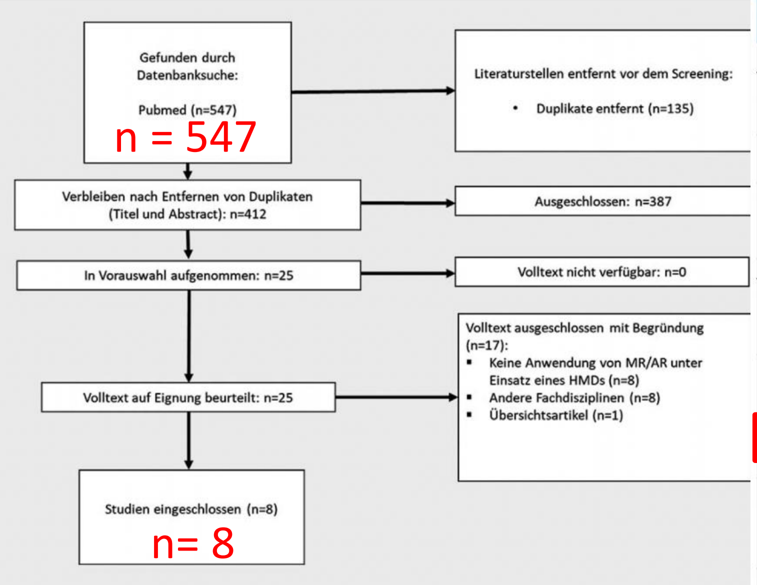
Mixed Reality in Vascular Surgery – a Scoping Review

Autoren

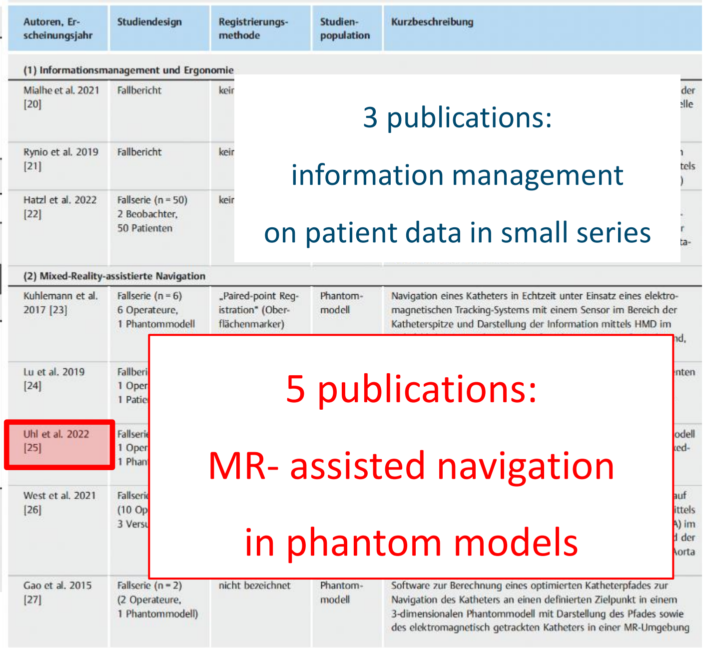
Johannes Hatzl[1], Dittmar Boeckler[1], Katrin Meisenbacher[1], Alexandru Barb[1], Niklas Hartmann[1], Daniel Henning[1], Christian Uhl[1]

Institut

1 Klinik für Gefäßchirurgie und Endovaskuläre Chirurgie, Universitätsklinikum Heidelberg, Heidelberg, Deutschland

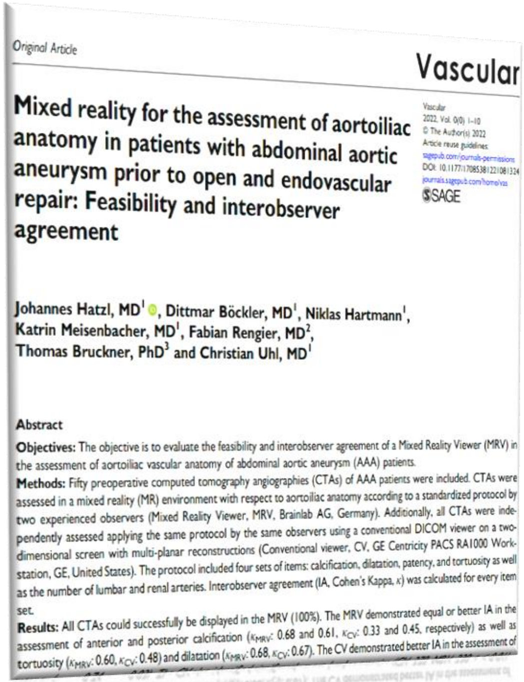


Hatzl J. , Uhl U, Böckler D, Zentralbl. Chir, Oct.. 2022



Autoren, Erscheinungsjahr	Studiendesign	Registrierungsmethode	Studienpopulation	Kurzbeschreibung
(1) Informationsmanagement und Ergonomie				
Mialhe et al. 2021 [20]	Fallbericht	kein		
Rynio et al. 2019 [21]	Fallbericht	kein		
Hatzl et al. 2022 [22]	Fallserie (n = 50) 2 Beobachter, 50 Patienten	kein		
(2) Mixed-Reality-assistierte Navigation				
Kuhlemann et al. 2017 [23]	Fallserie (n = 6) 6 Operateure, 1 Phantommodell	„Paired-point Registration" (Oberflächenmarker)	Phantommodell	Navigation eines Katheters in Echtzeit unter Einsatz eines elektromagnetischen Tracking-Systems mit einem Sensor im Bereich der Katheterspitze und Darstellung der Information mittels HMD im
Lu et al. 2019 [24]	Fallberi… 1 Oper… 1 Patie…			
Uhl et al. 2022 [25]	Fallserie… 1 Oper… 1 Phan…			
West et al. 2021 [26]	Fallserie… (10 Op… 3 Versu…			
Gao et al. 2015 [27]	Fallserie (n = 2) (2 Operateure, 1 Phantommodell)	nicht bezeichnet	Phantommodell	Software zur Berechnung eines optimierten Katheterpfades zur Navigation des Katheters an einen definierten Zielpunkt in einem 3-dimensionalen Phantommodell mit Darstellung des Pfades sowie des elektromagnetisch getrackten Katheters in einer MR-Umgebung

Feasibility Studies to Assess Anatomy of AAAs


Original Article

Vascular

Mixed reality for the assessment of aortoiliac anatomy in patients with abdominal aortic aneurysm prior to open and endovascular repair: Feasibility and interobserver agreement

Vascular
2022, Vol. 0(0) 1–10
© The Author(s) 2022
Article reuse guidelines:
sagepub.com/journals-permissions
DOI: 10.1177/17085381221081324
journals.sagepub.com/home/vas
SAGE

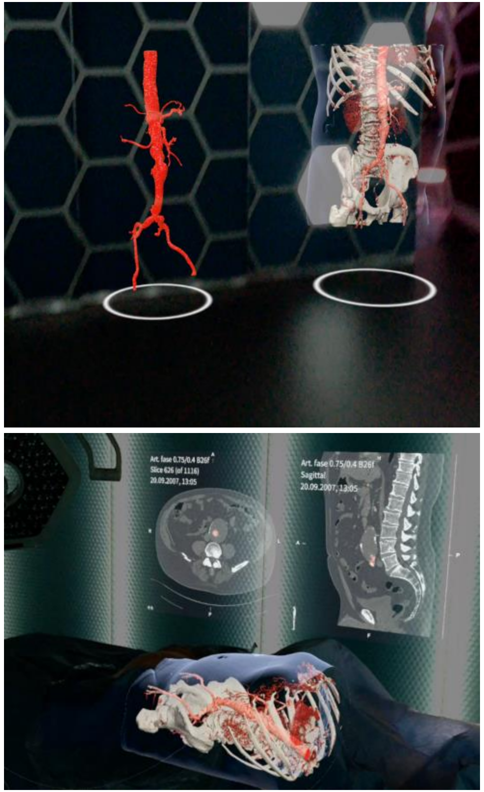
Johannes Hatzl, MD[1], Dittmar Böckler, MD[1], Niklas Hartmann[1], Katrin Meisenbacher, MD[1], Fabian Rengier, MD[2], Thomas Bruckner, PhD[3] and Christian Uhl, MD[1]

Abstract

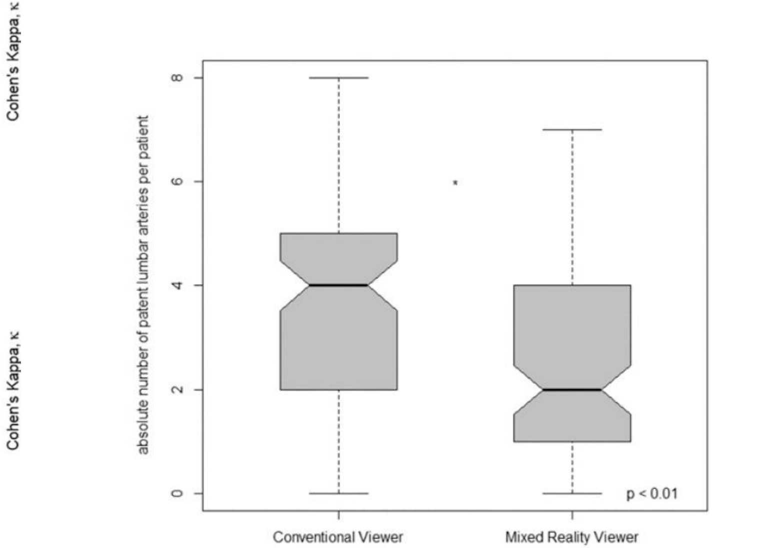
Objectives: The objective is to evaluate the feasibility and interobserver agreement of a Mixed Reality Viewer (MRV) in the assessment of aortoiliac vascular anatomy of abdominal aortic aneurysm (AAA) patients.

Methods: Fifty preoperative computed tomography angiographies (CTAs) of AAA patients were included. CTAs were assessed in a mixed reality (MR) environment with respect to aortoiliac anatomy according to a standardized protocol by two experienced observers (Mixed Reality Viewer, MRV, Brainlab AG, Germany). Additionally, all CTAs were independently assessed applying the same protocol by the same observers using a conventional DICOM viewer on a two-dimensional screen with multi-planar reconstructions (Conventional viewer, CV, GE Centricity PACS RA1000 Workstation, GE, United States). The protocol included four sets of items: calcification, dilatation, patency, and tortuosity as well as the number of lumbar and renal arteries. Interobserver agreement (IA, Cohen's Kappa, κ) was calculated for every item set.

Results: All CTAs could successfully be displayed in the MRV (100%). The MRV demonstrated equal or better IA in the assessment of anterior and posterior calcification (κ_{MRV}: 0.68 and 0.61, κ_{CV}: 0.33 and 0.45, respectively) as well as tortuosity (κ_{MRV}: 0.60, κ_{CV}: 0.48) and dilatation (κ_{MRV}: 0.68, κ_{CV}: 0.67). The CV demonstrated better IA in the assessment of



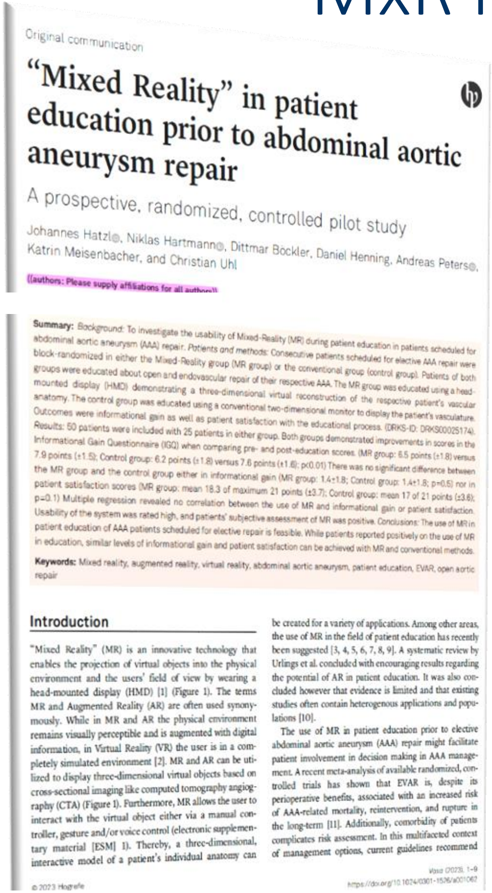
	Conventional viewer		Mixed Reality Viewer		
	Mean (SD)	Total	Mean (SD)	Total	*p* value*
Lumbar arteries	3.8 (2.1)	379	2.4 (1.9)	239	<0.01
Renal arteries	2.3 (0.8)	231	2.4 (0.8)	236	0.16



Hatzl J, Böckler D, Hartmann N et al. Mixed reality for the assessment of aortoiliac anatomy in patients with abdominal aortic aneurysm ment. Vascular 2022. doi:10.1177/17085381221081324: 17085381221081324. doi:10.1177/17085381221081324

MR-Viewer better describe dilatation, calcification and tortuosity , but not patency

MxR in Patient Education prior AAA Tx



Original communication

"Mixed Reality" in patient education prior to abdominal aortic aneurysm repair

A prospective, randomized, controlled pilot study

Johannes Hatzl, Niklas Hartmann, Dittmar Böckler, Daniel Henning, Andreas Peters, Katrin Meisenbacher, and Christian Uhl

((authors: Please supply affiliations for all authors))

Summary: *Background:* To investigate the usability of Mixed-Reality (MR) during patient education in patients scheduled for abdominal aortic aneurysm (AAA) repair. *Patients and methods:* Consecutive patients scheduled for elective AAA repair were block-randomized in either the Mixed-Reality group (MR group) or the conventional group (control group). Patients of both groups were educated about open and endovascular repair of their respective AAA. The MR group was educated using a head-mounted display (HMD) demonstrating a three-dimensional virtual reconstruction of the respective patient's vascular anatomy. The control group was educated using a conventional two-dimensional monitor to display the patient's vasculature. Outcomes were informational gain as well as patient satisfaction with the educational process. (DRKS-ID: DRKS00025174). Results: 50 patients were included with 25 patients in either group. Both groups demonstrated improvements in scores in the Informational Gain Questionnaire (IGQ) when comparing pre- and post-education scores. (MR group: 6.5 points (±1.8) versus 7.9 points (±1.5); Control group: 6.2 points (±1.8) versus 7.6 points (±1.6); p<0.01) There was no significant difference between the MR group and the control group either in informational gain (MR group: 1.4±1.8; Control group: 1.4±1.8; p=0.5) nor in patient satisfaction scores (MR group: mean 18.3 of maximum 21 points (±3.7); Control group: mean 17 of 21 points (±3.6); p=0.1) Multiple regression revealed no correlation between the use of MR and informational gain or patient satisfaction. Usability of the system was rated high, and patients' subjective assessment of MR was positive. Conclusions: The use of MR in patient education of AAA patients scheduled for elective repair is feasible. While patients reported positively on the use of MR in education, similar levels of informational gain and patient satisfaction can be achieved with MR and conventional methods.

Keywords: Mixed reality, augmented reality, virtual reality, abdominal aortic aneurysm, patient education, EVAR, open aortic repair

Introduction

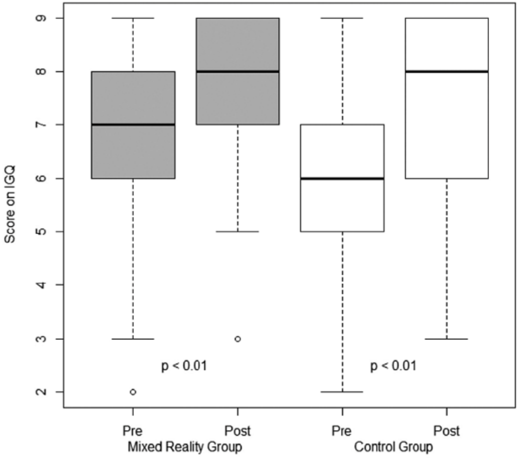
"Mixed Reality" (MR) is an innovative technology that enables the projection of virtual objects into the physical environment and the users' field of view by wearing a head-mounted display (HMD) [1] (Figure 1). The terms MR and Augmented Reality (AR) are often used synonymously. While in MR and AR the physical environment remains visually perceptible and is augmented with digital information, in Virtual Reality (VR) the user is in a completely simulated environment [2]. MR and AR can be utilized to display three-dimensional virtual objects based on cross-sectional imaging like computed tomography angiography (CTA) (Figure 1). Furthermore, MR allows the user to interact with the virtual object either via a manual controller, gesture and/or voice control (electronic supplementary material [ESM] 1). Thereby, a three-dimensional, interactive model of a patient's individual anatomy can be created for a variety of applications. Among other areas, the use of MR in the field of patient education has recently been suggested [3, 4, 5, 6, 7, 8, 9]. A systematic review by Urlings et al. concluded with encouraging results regarding the potential of AR in patient education. It was also concluded however that evidence is limited and that existing studies often contain heterogenous applications and populations [10].

The use of MR in patient education prior to elective abdominal aortic aneurysm (AAA) repair might facilitate patient involvement in decision making in AAA management. A recent meta-analysis of available randomized, controlled trials has shown that EVAR is, despite its perioperative benefits, associated with an increased risk of AAA-related mortality, reintervention, and rupture in the long-term [11]. Additionally, comorbidity of patients complicates risk assessment. In this multifaceted context of management options, current guidelines recommend

© 2023 Hogrefe

Vasa (2023), 1–9
https://doi.org/10.1024/0301-1526/a001062

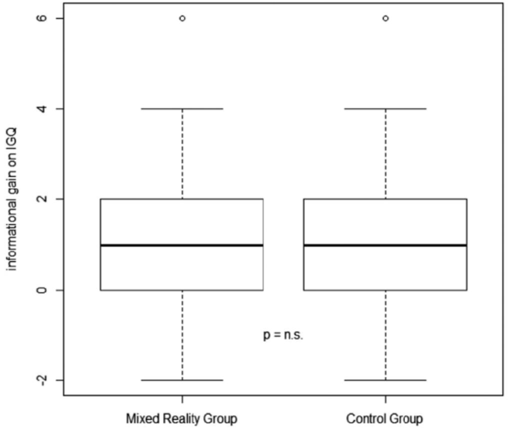
Hatzl J, Böckler D, Uhl C et al VASA 2023



	Score pre-education	Score post-education	p value*
MR group (mean ± SD)	6.5 ± 1.8	7.9 ± 1.5	<0.01
Control group (mean ± SD)	6.2 ± 1.8	7.6 ± 1.6	<0.01

*Wilcoxon test for two paired samples.

Figure 4. Scores on the Informational Gain Questionnaire (IGQ) pre- and post- patient education in the MR- and control group.



	MR group	Control group	p-value*
Informational gain (mean ± SD)	1.4 ± 1.8	1.4 ± 1.8	0.5

*Mann Whitney U test for two unpaired samples.

Figure 5. Informational gain in the MR- and control group according to the Informational Gain Questionnaire (IGQ).

Mixed Reality assisted Vessel Puncture

Journal of Imaging

Article

MDPI

Mixed-Reality-Assisted Puncture of the Common Femoral Artery in a Phantom Model

Christian Uhl †, Johannes Hatzl *,†, Katrin Meisenbacher, Lea Zimmer, Niklas Hartmann and Dittmar Böckler

Department of Vascular and Endovascular Surgery, University Hospital Heidelberg, Im Neuenheimer Feld 420, 69120 Heidelberg, Germany; christian.uhl@med.uni-heidelberg.de (C.U.); katrin.meisenbacher@med.uni-heidelberg.de (K.M.); lea.zimmer@gmail.com (L.Z.); niklas.hartmann@med.uni-heidelberg.de (N.H.); dittmar.boeckler@med.uni-heidelberg.de (D.B.)
* Correspondence: johannes.hatzl@med.uni-heidelberg.de
† These authors contributed equally to this work.

Abstract: Percutaneous femoral arterial access is daily practice in a variety of medical specialties and enables physicians worldwide to perform endovascular interventions. The reported incidence of percutaneous femoral arterial access complications is 3–18% and often results from suboptimal puncture location due to insufficient visualization of the target vessel. The purpose of this proof-of-concept study was to evaluate the feasibility and the positional error of a mixed-reality (MR)-assisted puncture of the common femoral artery in a phantom model using a commercially available navigation system. In total, 15 MR-assisted punctures were performed. Cone-beam computed tomography angiography (CTA) was used following each puncture to allow quantification of positional error of needle placements in the axial and sagittal planes. Technical success was achieved in 14/15 cases (93.3%) with a median axial positional error of 1.0 mm (IQR 1.3) and a median sagittal positional error of 1.1 mm (IQR 1.6). The median duration of the registration process and needle insertion was 2 min (IQR 1.0). MR-assisted puncture of the common femoral artery is feasible with acceptable positional errors in a phantom model. Future studies should aim to measure and reduce the positional error resulting from MR registration.

Keywords: mixed reality; virtual reality; vascular surgery; vascular access; femoral artery; endovascular

check for updates

Citation: Uhl, C.; Hatzl, J.; Meisenbacher, K.; Zimmer, L.; Hartmann, N.; Böckler, D. Mixed-Reality-Assisted Puncture of the Common Femoral Artery in a Phantom Model. J. Imaging 2022, 8, 47. https://doi.org/10.3390/jimaging8020047

Academic Editors: Jean Sequeira, Sebastien Mavromatis and Erwan Maigret

Received: 31 December 2021
Accepted: 14 February 2022
Published: 16 February 2022

Publisher's Note: MDPI stays neutral with regard to jurisdictional claims in published maps and institutional affiliations.

Copyright: © 2022 by the authors. Licensee MDPI, Basel, Switzerland. This article is an open access article distributed under the terms and conditions of the Creative Commons Attribution (CC BY) license (https://

1. Introduction

Percutaneous puncture of the common femoral artery (CFA) is a frequently used technique to gain arterial vascular access and is applied in a variety of medical specialties such as vascular surgery, cardiology, interventional radiology, and neuroradiology. The technique of femoral arterial puncture has changed in recent decades. Initially the optimal puncture site was determined by palpation of the pulse and the location of the CFA relative to the femoral head in projection radiography. In recent years the use of sonography with real-time two-dimensional visualization of the target vessel has become the gold standard. Although the use of sonography has reduced the complication rate after femoral arterial access, there are still relevant puncture-associated complications in 3–18% of cases today [1,2]. Complications during vascular arterial access mainly arise from suboptimal localization of the puncture site, in addition to the quality of the targeted vessel (diameter, calcification). Inadvertent puncture of the superficial femoral or profound femoral arteries can result in false aneurysms, local dissections with subsequent lower limb ischemia or bleeding complications [2,3]. Puncture of the external iliac artery proximal to the femoral ligament can result in catastrophic retroperitoneal hemorrhage, which is associated with high morbidity and mortality [4–6]. Arterial puncture of severely calcified vessel areas can lead to local vascular injury and failure of vascular closure devices, which often leads to

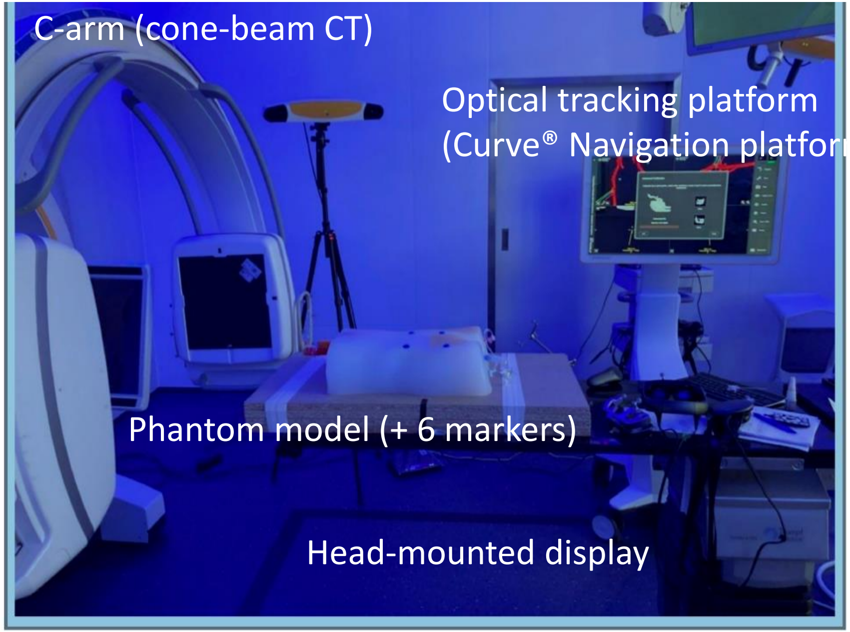
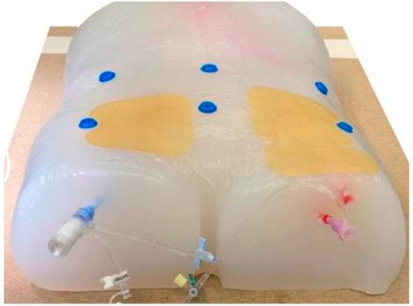
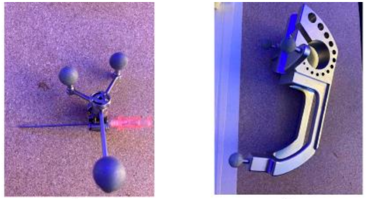
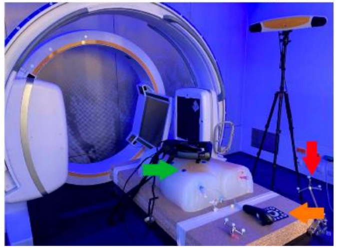


Figure 3. Experimental set-up: Phantom model (center), X-ray device (Siemens Cios alpha Siemens Healthcare GmbH, Erlangen, Germany) for cone-beam CTA (left), Curve® Navigation (Brainlab AG, Munich, Germany) for optical tracking with tripod camera system and work (background), and HMD on the O.R. table (right).







Results - Mixed Reality assisted Vessel Puncture

Journal of Imaging

Article

MDPI

Mixed-Reality-Assisted Puncture of the Common Femoral Artery in a Phantom Model

Christian Uhl †, Johannes Hatzl *,†, Katrin Meisenbacher, Lea Zimmer, Niklas Hartmann and Dittmar Böckler

Department of Vascular and Endovascular Surgery, University Hospital Heidelberg, Im Neuenheimer Feld 420, 69120 Heidelberg, Germany; christian.uhl@med.uni-heidelberg.de (C.U.); katrin.meisenbacher@med.uni-heidelberg.de (K.M.); lea.zimmer@gmail.com (L.Z.); niklas.hartmann@med.uni-heidelberg.de (N.H.); dittmar.boeckler@med.uni-heidelberg.de (D.B.)
* Correspondence: johannes.hatzl@med.uni-heidelberg.de
† These authors contributed equally to this work.

Abstract: Percutaneous femoral arterial access is daily practice in a variety of medical specialties and enables physicians worldwide to perform endovascular interventions. The reported incidence of percutaneous femoral arterial access complications is 3–18% and often results from suboptimal puncture location due to insufficient visualization of the target vessel. The purpose of this proof-of-concept study was to evaluate the feasibility and the positional error of a mixed-reality (MR)-assisted puncture of the common femoral artery in a phantom model using a commercially available navigation system. In total, 15 MR-assisted punctures were performed. Cone-beam computed tomography angiography (CTA) was used following each puncture to allow quantification of positional error of needle placements in the axial and sagittal planes. Technical success was achieved in 14/15 cases (93.3%) with a median axial positional error of 1.0 mm (IQR 1.3) and a median sagittal positional error of 1.1 mm (IQR 1.6). The median duration of the registration process and needle insertion was 2 min (IQR 1.0). MR-assisted puncture of the common femoral artery is feasible with acceptable positional errors in a phantom model. Future studies should aim to measure and reduce the positional error resulting from MR registration.

Keywords: mixed reality; virtual reality; vascular surgery; vascular access; femoral artery; endovascular

check for updates

Citation: Uhl, C.; Hatzl, J.; Meisenbacher, K.; Zimmer, L.; Hartmann, N.; Böckler, D. Mixed-Reality-Assisted Puncture of the Common Femoral Artery in a Phantom Model. J. Imaging 2022, 8, 47. https://doi.org/10.3390/jimaging8020047

Academic Editors: Jean Sequeira, Sébastien Mavromatis and Erwan Maigret

Received: 31 December 2021
Accepted: 14 February 2022
Published: 16 February 2022

Publisher's Note: MDPI stays neutral with regard to jurisdictional claims in published maps and institutional affiliations.

Copyright: © 2022 by the authors. Licensee MDPI, Basel, Switzerland. This article is an open access article distributed under the terms and conditions of the Creative Commons Attribution (CC BY) license (https://

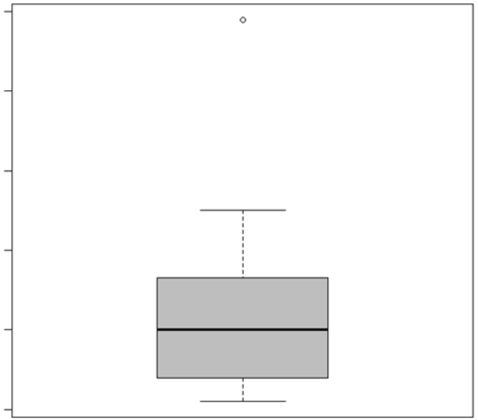
1. Introduction

Percutaneous puncture of the common femoral artery (CFA) is a frequently used technique to gain arterial vascular access and is applied in a variety of medical specialties such as vascular surgery, cardiology, interventional radiology, and neuroradiology. The technique of femoral arterial puncture has changed in recent decades. Initially the optimal puncture site was determined by palpation of the pulse and the location of the CFA relative to the femoral head in projection radiography. In recent years the use of sonography with real-time two-dimensional visualization of the target vessel has become the gold standard. Although the use of sonography has reduced the complication rate after femoral arterial access, there are still relevant puncture-associated complications in 3–18% of cases today [1,2]. Complications during vascular arterial access mainly arise from suboptimal localization of the puncture site, in addition to the quality of the targeted vessel (diameter, calcification). Inadvertent puncture of the superficial femoral or profound femoral arteries can result in false aneurysms, local dissections with subsequent lower limb ischemia or bleeding complications [2,3]. Puncture of the external iliac artery proximal to the femoral ligament can result in catastrophic retroperitoneal hemorrhage, which is associated with high morbidity and mortality [4–6]. Arterial puncture of severely calcified vessel areas can lead to local vascular injury and failure of vascular closure devices, which often leads to

Hatzl J, Böckler D. et al, Journal of Imaging 2022

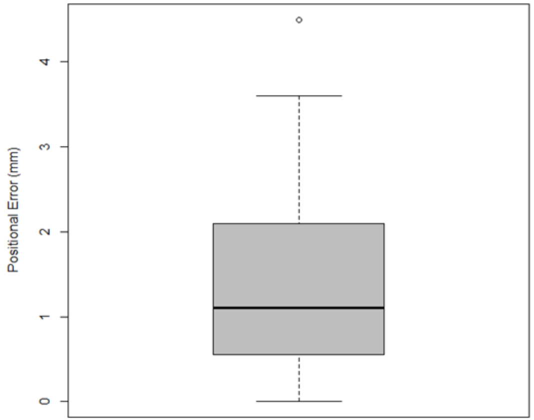
Technical success rate 93.3%

Accuracy +/- 1mm



Axial

1.0 mm (IQR 1.25)

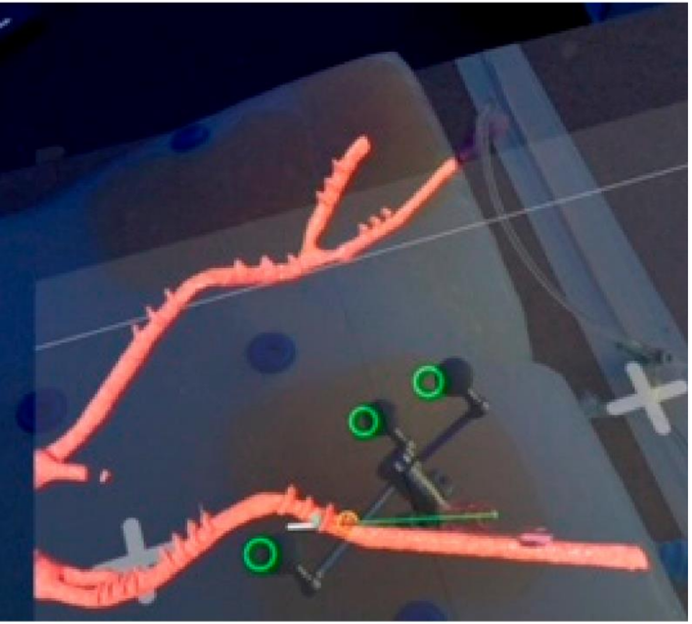


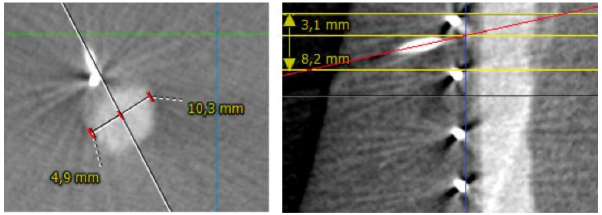
Sagittal

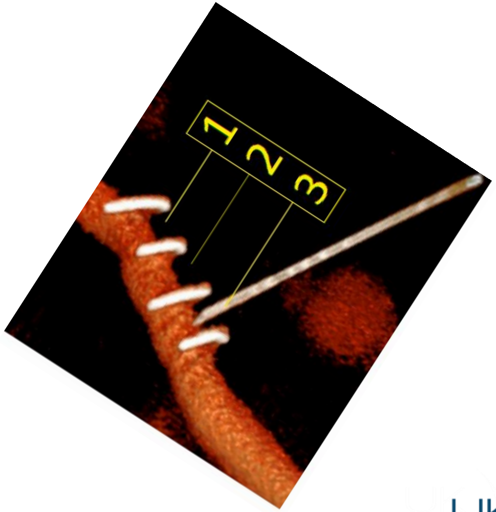
1.1 mm (IQR 1.55)

Uhl C, Hatzl J, Meisenbacher K, Zimmer L, Hartmann N, Böckler D. Mixed-Reality-Assisted Puncture of the Common Femoral Artery in a Phantom Model. J Imaging. 2022 Feb 16;8(2):47. doi: 10.3390/jimaging8020047. PMID: 35200749; PMCID: PMC8874567.

Observer's point of view of CFA Puncture in Phantom



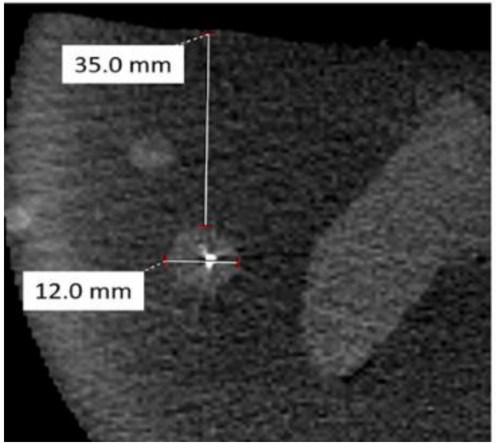


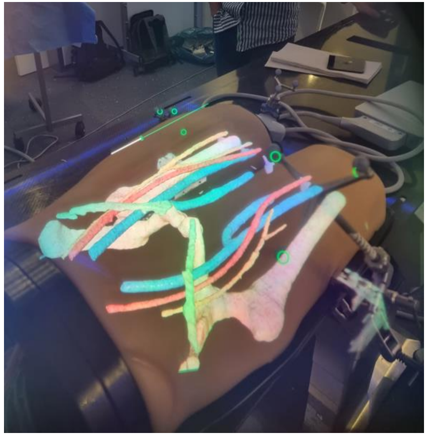


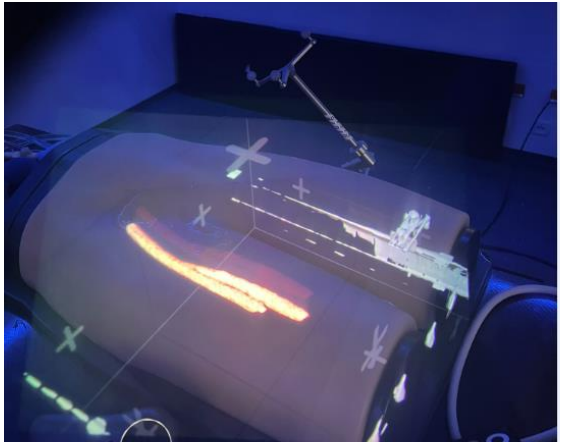
Sonography-registered MxR-assisted CFA access

Potential benefits:

- No superficial markers needed
- can be repeated multiple times if patient position changes (no new CT/cone beam CT, no radiation)
- focus on region-of-interest







Sonography-registered MxR-assisted CFA access

Basic Science, Imaging and Technology

Journal of Endovascular Therapy
1–8
© The Author(s) 2023
Article reuse guidelines: sagepub.com/journals-permissions
DOI: 10.1177/15266028231208640
www.jevt.org
Sage

A New Method for Common Femoral Arterial Access Using a Mixed Reality–Assisted Technique on a Phantom Model

Johannes Hatzl, MD[1], Daniel Henning[1], Niklas Hartmann[1], Dittmar Böckler, MD[1], and Christian Uhl, MD[1]

Abstract

Purpose: The purpose of this study was to investigate the technical feasibility and usability of a mixed reality (MiR)-assisted common femoral arterial (CFA) access technique using a sonography-assisted registration method.

Materials and Methods: A total of 60 CFA punctures were performed on a phantom model by 2 observers. Thirty punctures were performed using MiR (MiR group) and 30 punctures were performed using a conventional sonography-guided access procedure (control group). In the MiR group, a virtual object was created based on a computed tomography (CT) angiography scan of the model and registered to the physical patient in an MiR environment utilizing a software prototype that allowed registration based on a sonography scan. Positional error assessment encompassed 4 measurements using cone beam CT scans: (1) distance of the needle tip to the centerline, (2) distance of the needle entry site from the mid-level of the ostium of the profound femoral artery, (3) angle of entry of the needle in coronal, and (4) sagittal planes. Technical success rates as well as positional errors were compared between both groups. In addition, the usability of the system was assessed according to the system usability scale (SUS).

Results: Technical success was 96.7% and 100% in the MiR and control groups, respectively. The median distance between the needle tip and the centerline was 3.0 (interquartile range [IQR]: 2.0–4.6) in the MiR group and 3.2 mm (IQR: 2.3–3.9) ($p=0.63$) in the control group. Similarly, the median distance from the needle entry site to the mid-level of the ostium of the profound femoral artery was 3.0 mm (IQR: 2.0–5.0) in the MiR group and 4.5 mm (IQR: 2.0–7.8) ($p=0.18$) in the control group. The median coronal angles of needle entry were 7.5° (IQR: 6–11) and 6° (IQR: 2–12) ($p=0.13$), and the median sagittal angles were 50° (IQR: 47–51) and 51° (IQR: 50–55) ($p<0.01$) in the MiR and control groups, respectively. The mean SUS score provided by both observers was 51.3.

Conclusion: The feasibility of an MiR-assisted CFA access technique could be demonstrated on a phantom model. Further studies are needed to investigate the technique beyond phantom model experiments and in different anatomical settings.

Clinical Impact

This study demonstrates the technical feasibility of a Mixed-Reality-assisted common femoral arterial access procedure on a phantom model. The positional accuracy was comparable to a conventional sonography-guided technique. However, there are several limitations that need to be resolved prior to potential implementation into clinical practice. Further studies are needed to investigate its performance beyond phantom model experiments and the prototypical application requires further technical refinement to increase its usability.

Keywords
mixed reality, vascular access, endovascular, augmented reality, navigation, vascular surgery

Introduction

There are several techniques used to perform common femoral arterial (CFA) access for a wide variety of indications. Traditionally, CFA access relies on palpation of the femoral pulse and anatomical landmarks such as the superior iliac spine, the pubic tubercle, and the inguinal crease with or without fluoroscopic visualization of the femoral head. However, the safety of these techniques is compromised due to the inconsistent nature of anatomical landmarks such as the relation of the inguinal crease to the inguinal ligament, especially in unexperienced hands. In addition, anatomical

Hatzl J, Henning D, Hartmann N, Böckler D, et al.
Journal of Endovascular Therapy. 2023;0(0).
Ahead of print

- 60 CFA punctures in a phantom by two observers
- N=30 conventional sonography (control group) versus n= 30 MxR
- using cone beam CT scans of phantom and prototype software

➢ Endpoints:

  ➢ Technical success rate

  ➢ System stability

  ➢ Positional error assessment encompassed 4 measurements

  – (1) distance of the needle tip to the centerline,
  – (2) distance of the needle entry site from themid-level of the ostium of the profunda femoral artery,
  – (3) angle of entry of the needle in coronal, and
  – (4) sagittal planes.

Results of Sonography-registered MxR-assisted CFA access

Journal of Endovascular Therapy
Journal of Endovascular Therapy
1–8
DOI: 10.1177/15266028231208640
www.jevt.org
Sage
© The Author(s) 2023
Article reuse guidelines: sagepub.com/journals-permissions

A New Method for Common Femoral Arterial Access Using a Mixed Reality–Assisted Technique on a Phantom Model

Johannes Hatzl, MD[1], Daniel Henning[1], Niklas Hartmann[1], Dittmar Böckler, MD[1], and Christian Uhl, MD[1]

Abstract

Purpose: The purpose of this study was to investigate the technical feasibility and usability of a mixed reality (MiR)-assisted common femoral arterial (CFA) access technique using a sonography-assisted registration method.
Materials and Methods: A total of 60 CFA punctures were performed on a phantom model by 2 observers. Thirty punctures were performed using MiR (MiR group) and 30 punctures were performed using a conventional sonography-guided access procedure (control group). In the MiR group, a virtual object was created based on a computed tomography (CT) angiography scan of the model and registered to the physical patient in an MiR environment utilizing a software prototype that allowed registration based on a sonography scan. Positional error assessment encompassed 4 measurements using cone beam CT scans: (1) distance of the needle tip to the centerline, (2) distance of the needle entry site from the mid-level of the ostium of the profound femoral artery, (3) angle of entry of the needle in coronal, and (4) sagittal planes. Technical success rates as well as positional errors were compared between both groups. In addition, the usability of the system was assessed according to the system usability scale (SUS).
Results: Technical success was 96.7% and 100% in the MiR and control groups, respectively. The median distance between the needle tip and the centerline was 3.0 (interquartile range [IQR]: 2.0–4.6) in the MiR group and 3.2 mm (IQR: 2.3–3.9) (p=0.63) in the control group. Similarly, the median distance from the needle entry site to the mid-level of the ostium of the profound femoral artery was 3.0 mm (IQR: 2.0–5.0) in the MiR group and 4.5 mm (IQR: 2.0–7.8) (p=0.18) in the control group. The median coronal angles of needle entry were 7.5° (IQR: 6–11) and 6° (IQR: 2–12) (p=0.13), and the median sagittal angles were 50° (IQR: 47–51) and 51° (IQR: 50–55) (p<0.01) in the MiR and control groups, respectively. The mean SUS score provided by both observers was 51.3.
Conclusion: The feasibility of an MiR-assisted CFA access technique could be demonstrated on a phantom model. Further studies are needed to investigate the technique beyond phantom model experiments and in different anatomical settings.

Clinical Impact
This study demonstrates the technical feasibility of a Mixed-Reality-assisted common femoral arterial access procedure on a phantom model. The positional accuracy was comparable to a conventional sonography-guided technique. However, there are several limitations that need to be resolved prior to potential implementation into clinical practice. Further studies are needed to investigate its performance beyond phantom model experiments and the prototypical application requires further technical refinement to increase its usability.

Keywords
mixed reality, vascular access, endovascular, augmented reality, navigation, vascular surgery

Introduction

There are several techniques used to perform common femoral arterial (CFA) access for a wide variety of indications. Traditionally, CFA access relies on palpation of the femoral pulse and anatomical landmarks such as the superior iliac spine, the pubic tubercle, and the inguinal crease with or without fluoroscopic visualization of the femoral head. However, the safety of these techniques is compromised due to the inconsistent nature of anatomical landmarks such as the relation of the inguinal crease to the inguinal ligament, especially in unexperienced hands. In addition, anatomical

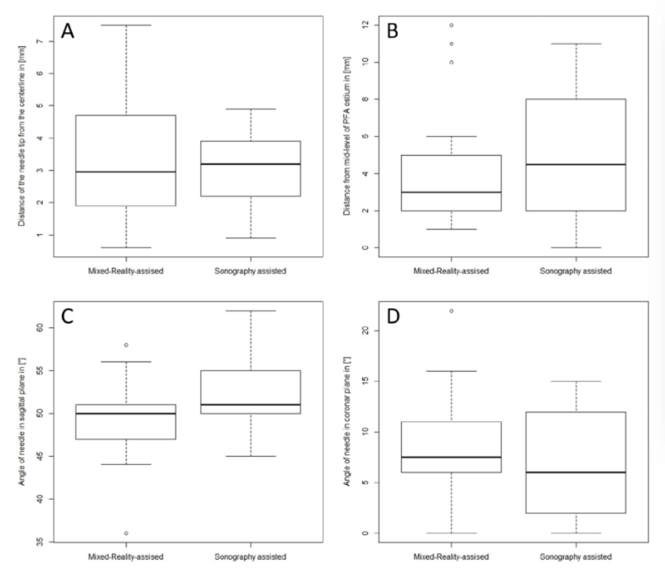


Figure 5. Positional errors: (A) Distance of the centerline to the needle tip in the axial plane. (B) Distance of the needle entry point from the mid-level of the profound femoral artery (PFA) ostium on the centerline. (C) Insertion angle in a sagittal plane. (D) Insertion angle in a coronal plane.

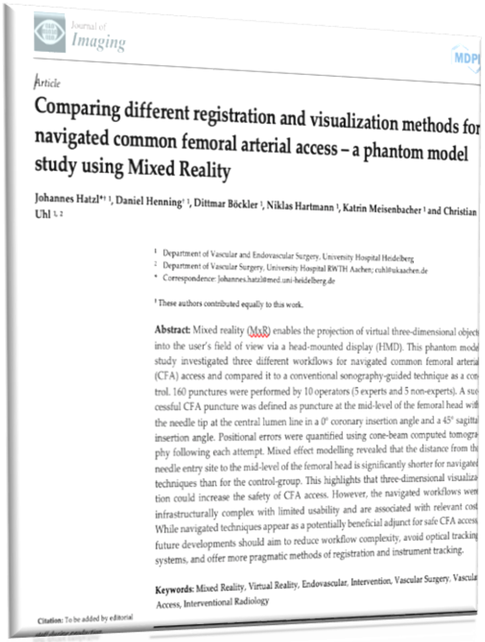
Table 1. Measurements of Positional Errors.

	Mixed reality–assisted	Sonography-assisted	p value[a]
Distance of the needle tip to the centerline (mm)	3.0 (IQR: 2.0–4.6)	3.2 (IQR: 2.2–3.9)	0.63
Distance of the needle entry site from the mid-level of the PFA ostium (mm)	3.0 (IQR: 2.0–5.0)	4.5 (IQR: 2.0–7.8)	0.18
Angle of the needle in the sagittal plane (°)	50 (IQR: 47–51)	51 (IQR: 50–55)	0.005
Angle of the needle in the coronal plane (°)	7.5 (IQR: 6–11)	6 (IQR: 2.3–12)	0.13

Technical success rate :
MxR : 96.7%
Ultrasound: 100%
Similar usibility and accuracy

Hatzl J, Henning D, Hartmann N, Böckler D, et al. Journal of Endovascular Therapy. 2023;0(0).

Comparison of Different Registration Methods for Vessel Access



Journal of Imaging — MDPI

Article

Comparing different registration and visualization methods for navigated common femoral arterial access – a phantom model study using Mixed Reality

Johannes Hatzl*[†] [1], Daniel Henning[†] [1], Dittmar Böckler [1], Niklas Hartmann [1], Katrin Meisenbacher [1] and Christian Uhl [1,2]

[1] Department of Vascular and Endovascular Surgery, University Hospital Heidelberg
[2] Department of Vascular Surgery, University Hospital RWTH Aachen; cuhl@ukaachen.de
* Correspondence: johannes.hatzl@med.uni-heidelberg.de

[†] These authors contributed equally to this work.

Abstract: Mixed reality (MxR) enables the projection of virtual three-dimensional object into the user's field of view via a head-mounted display (HMD). This phantom mode study investigated three different workflows for navigated common femoral arteria (CFA) access and compared it to a conventional sonography-guided technique as a control. 160 punctures were performed by 10 operators (5 experts and 5 non-experts). A successful CFA puncture was defined as puncture at the mid-level of the femoral head wit the needle tip at the central lumen line in a 0° coronary insertion angle and a 45° sagitta insertion angle. Positional errors were quantified using cone-beam computed tomography following each attempt. Mixed effect modelling revealed that the distance from th needle entry site to the mid-level of the femoral head is significantly shorter for navigated techniques than for the control-group. This highlights that three-dimensional visualization could increase the safety of CFA access. However, the navigated workflows were infrastructurally complex with limited usability and are associated with relevant cost While navigated techniques appear as a potentially beneficial adjunct for safe CFA access, future developments should aim to reduce workflow complexity, avoid optical tracking systems, and offer more pragmatic methods of registration and instrument tracking.

Keywords: Mixed Reality, Virtual Reality, Endovascular, Intervention, Vascular Surgery, Vascula Access, Interventional Radiology

Citation: To be added by editorial

Hatzl J, Henning D, Böckler D, et al.
Journal of Imaging 2024; Ahead of print

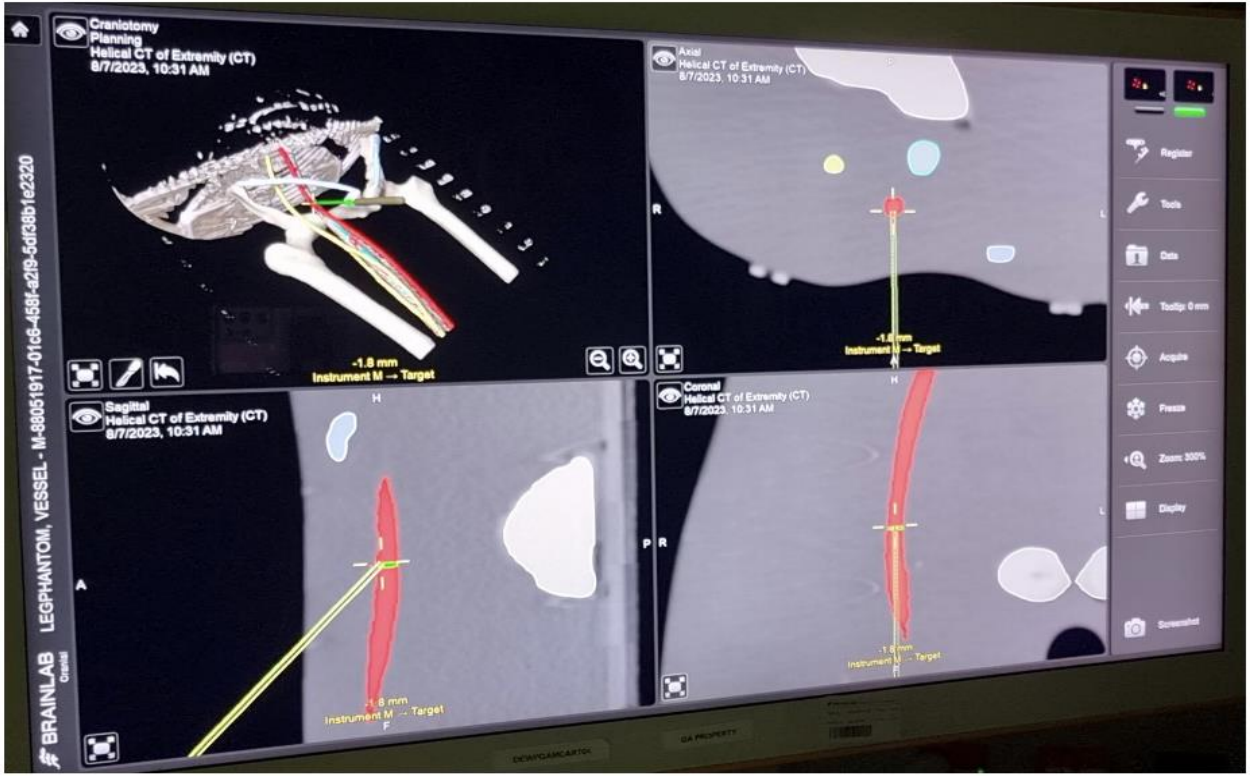
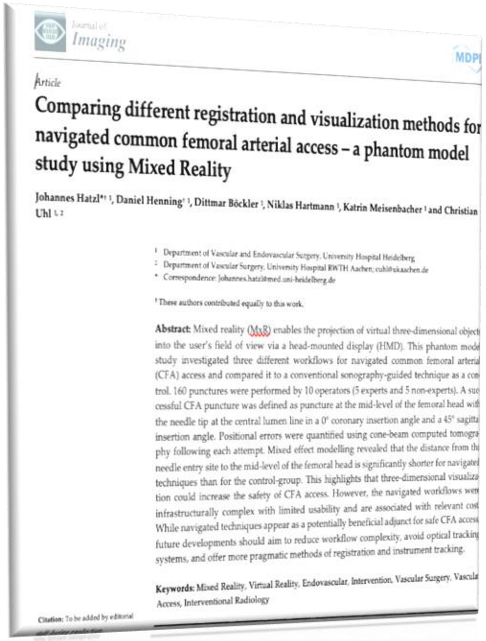


Figure 5. Monitor-visualization. The needle is represented in axial plane as well as coronal and sagittal reconstructions. The green line represents the optimal trajectory for the operator to follow.

RESULTS: Different Registration Methods for Vessel Access



Journal of Imaging

MDPI

Article

Comparing different registration and visualization methods for navigated common femoral arterial access – a phantom model study using Mixed Reality

Johannes Hatzl*† 1, Daniel Henning† 1, Dittmar Böckler 1, Niklas Hartmann 1, Katrin Meisenbacher 1 and Christian Uhl 1, 2

1 Department of Vascular and Endovascular Surgery, University Hospital Heidelberg
2 Department of Vascular Surgery, University Hospital RWTH Aachen; cuhl@ukaachen.de
* Correspondence: Johannes.hatzl@med.uni-heidelberg.de

† These authors contributed equally to this work.

Abstract: Mixed reality (MxR) enables the projection of virtual three-dimensional object[s] into the user's field of view via a head-mounted display (HMD). This phantom mode[l] study investigated three different workflows for navigated common femoral arteria[l] (CFA) access and compared it to a conventional sonography-guided technique as a con[-]trol. 160 punctures were performed by 10 operators (5 experts and 5 non-experts). A suc[-]cessful CFA puncture was defined as puncture at the mid-level of the femoral head wit[h] the needle tip at the central lumen line in a 0° coronary insertion angle and a 45° sagitta[l] insertion angle. Positional errors were quantified using cone-beam computed tomogra[-]phy following each attempt. Mixed effect modelling revealed that the distance from th[e] needle entry site to the mid-level of the femoral head is significantly shorter for navigate[d] techniques than for the control-group. This highlights that three-dimensional visualiza[-]tion could increase the safety of CFA access. However, the navigated workflows wer[e] infrastructurally complex with limited usability and are associated with relevant cost[s]. While navigated techniques appear as a potentially beneficial adjunct for safe CFA access[,] future developments should aim to reduce workflow complexity, avoid optical tracking systems, and offer more pragmatic methods of registration and instrument tracking.

Keywords: Mixed Reality, Virtual Reality, Endovascular, Intervention, Vascular Surgery, Vascula[r] Access, Interventional Radiology

Citation: To be added by editorial

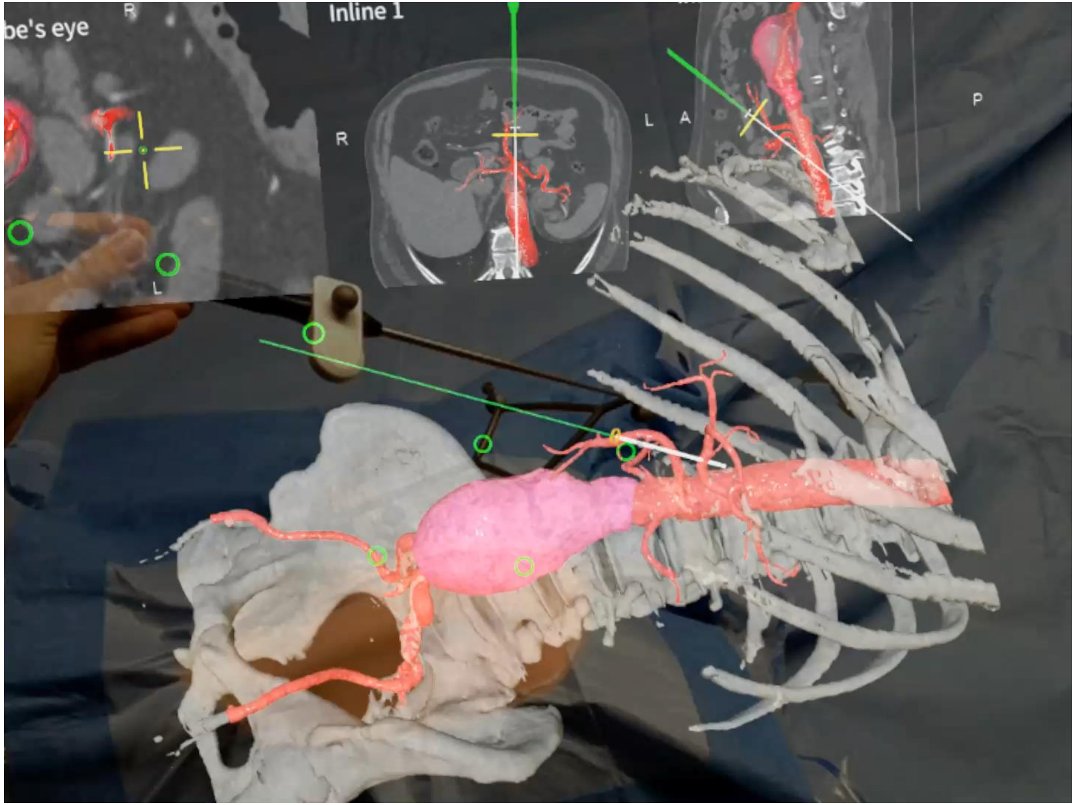
Hatzl J, Henning D, Böckler D, et al.
Journal of Imaging 2024; Ahead of print

- Overall technical success rate: 91.1%

Technical success (n=158)	Expert	Non- Expert	P-value
overall	98.7 %	83.5%	0.002
control	100%	95.5%	1.0
navigated	98.3%	79.9%	0.003
workflow 1	100%	75%	
workflow 2	100 %	80%	
workflow 3	94.7%	84.2%	

> MxR navigated techniques show beneficial adjuncts for save vessel access

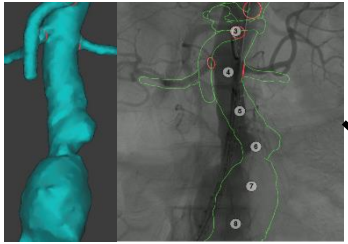
Next Step: MxR assisted Device Tracking & Navigation in endovascular aortic repair



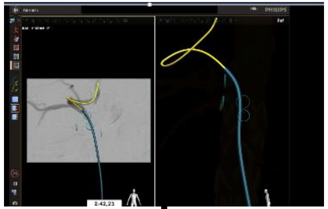
Recent Limitations of MxR

- Still experimental use in phantoms
- Results not ransferable to real patients sofar
- Vascular deformation / distorsion effects
- Impaired visualization of small vessels
- Registration and tracking errors
- Processing capacities of large data set

Working Place of the Future – the Role of MxR

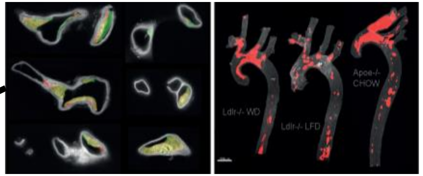


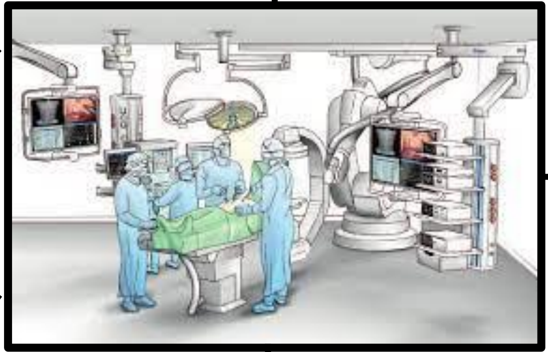
Cydar ® Surgery
Augmented Intelligence
Cydar

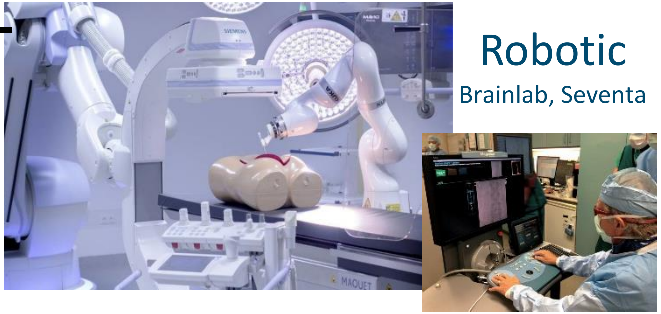


FORS ®
Philips

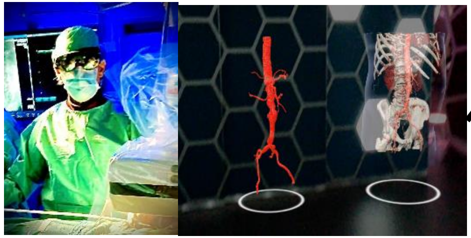
AI – Imaging e.g.
Carotid plaque







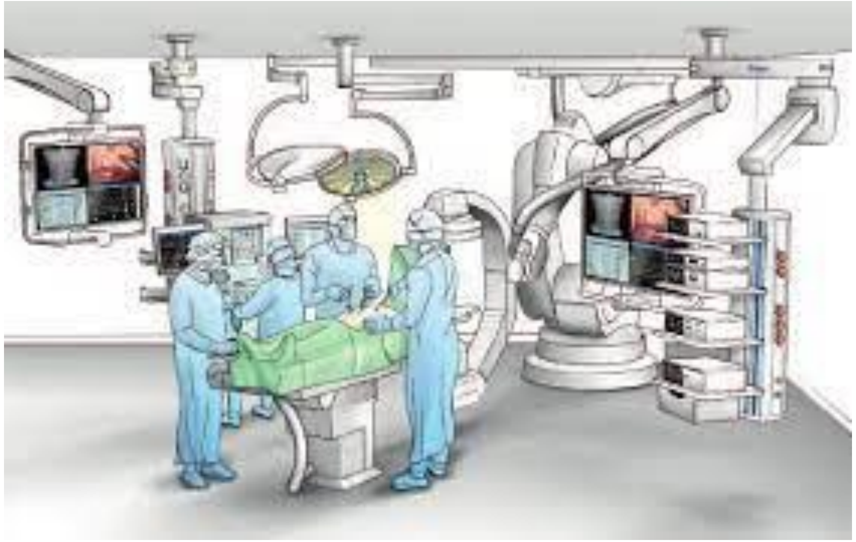
Robotic
Brainlab, Seventa



Mixed Reality
BrainLab & MagicLeap

IOPS®
centerlinebiomedical.com

From Image guided to AI-guided guided surgical workplace



Summary and Conclusions

- MxR > number of applications in endovascular & vascular surgery
- MxR-assisted anatomy assessment is feasible with high accuracy
- MxR-assisted vascular access is successfully demonstrated in phantom model studies
- Technological developments such as next-generation HMDs, alternative registration methods will increase feasibility and performance of MxR
- Further advances are required to overcome recent limitations
- Bringing MxR into hybrid OR *as a "standard visualization tool"* is still in an early stage