Automated real-time 3D ultrasound mapping of vessels [3D-ULTRAMAN]

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ABSTRACT
The 3D Ultraman project is a collaboration between medical robotics company Vitestro and clinical laboratory Result Laboratorium. During the project, real-time detection of arteries were developed, including a clinical ultrasound-force study as well as training and evaluation of deep learning architectures. In a phase 2 project, these promising algorithms will be further developed and integrated in an ATTRACT phase 2 project. This technology could be the basis for robotic devices autonomously performing a variety of vascular access procedures, enabling new levels of automation in medicine.

Deep learning; blood vessel detection; automation in medicine

1. INTRODUCTION

Vitestro and Result laboratory are developing an autonomous blood drawing device. One challenge in development of this medical device is detection of arteries in real-time to prevent inadvertent arterial puncture. In this project, automated real-time 3D ultrasound detection of arteries was developed using a deep learning framework.

Development of automated real-time 3D detection of arteries and veins offers a myriad of unique applications within the field of medicine. It can lead the way for robotic devices automating medical procedures, such as arterial or intravenous cannulation, or obtaining vascular access. This could reduce healthcare expenditure and patient complications, strongly benefitting European society and economy, because automation can be implemented in healthcare.

During this project the following results were achieved:

- Testing ultrasound force compression software algorithm in hospital to distinguish arteries from veins
- Development, training and testing of several deep learning frameworks automated detection of arteries in ultrasound
- Plan for further optimization and release of deep learning architecture and identifying standalone potential

2. STATE OF THE ART

The COVID-19 crisis has opened our eyes to pressing problems in healthcare: a lack of medical (nursing) personnel and resources, especially in the ICU and emergency departments. The limiting factor in handling the excessive stream of patients is evident: human resources required to perform medical procedures. COVID-19 supercharges our problems, but also highlights enormous opportunities in pushing automation in patient procedures to the forefront.

One particular opportunity is automation of the most common vascular access procedures: placement of peripheral catheters in veins and arteries, as well as peripheral arterial puncture. Intriguingly, peripheral intravenous lines are placed more than a billion times each year on a worldwide basis. Establishing peripheral vascular access is important in emergency departments, ICUs and pre-operative rooms in hospitals, to administer fluids, medications, withdraw blood and monitor patients.

The state of the art in establishing peripheral vascular access is the physician or nurse manually performing the procedure, with or without use of ultrasound technology. However, there are several problems with the current procedure. Primarily, it is resource intensive, requiring significant time of nurses and (specialized) physicians. This puts a strain on personnel and hospital budgets.

For patients, differences in skill between operators can be notable depending on the level of experience. As an example, 60% of all intravenous line placements can be missed in subgroups of patients. [1]

In addition, complications can occur in up to 70% of cases. [2] Phlebitis, infection of the vein, can occur in case

insertion is performed without disinfecting the skin, leading to bacteremia. Other frequent complications are hematoma, pain and extravasation.
In arterial catheter placement, complications include nerve injury, pseudoaneurysm, air embolism and even life-threatening compartment syndrome. [3]

Furthermore, although success rate increases and complication rates drop with the use of ultrasound, this poses new challenges in infection prevention, with the ultrasound probe being a new source of hospital acquired infections, posing new hazards for patients. [4]

3. BREAKTHROUGH CHARACTER OF THE PROJECT

The decreasing costs of (portable) ultrasound and explosion in deep learning potential has created new opportunities for automation of obtaining vascular access. Several research groups worldwide have started to explore development of automated vessel detection using deep learning and robotics with the purpose of establishing intravascular access. [5] [6]

One of the key challenges in developing automated devices, aside from the robotics part, is optimizing image recognition of blood vessels. A core feature is the distinction between different types of vessels, in particular arteries and veins. When placing a line correctly in an automated way, performing correct vessel identification is crucial. This prevents unintended arterial or venous puncture, and ensuing vascular complications. For a medical device that could autonomously place an intravenous catheter, avoidance of arteries would be key to prevent unnecessary complications, propelling its use and clinical acceptance. On the other hand, a device that could obtain arterial blood through automated arterial puncture, guaranteeing arterial puncture and avoiding veins can make a huge clinical difference in acute settings.

Taking the step towards automation of establishing vascular access holds the promise to relieve healthcare systems worldwide and deliver first step towards automation. Using automated ultrasound and robotics enables autonomous procedures that are potentially safer, cheaper and faster than human operators. The promise of using AI as the basis is that image detection will improve over time. This would form the basis for preventing complications such as hematoma, nerve injury or air embolism.
In addition, standardization of procedures would also reflect in effective infection prevention. With each procedure being performed in a similar way, automated cleaning and disinfection could reduce the incidence of hospital acquired infections.
Furthermore, with robotic devices operating autonomously, this reduces the number of nurses required. This would increase the resilience of healthcare systems worldwide: in future pandemics similar to COVID-19, vascular access procedures could be performed by robotic devices with a safe distance, instead of by nurses.

Tab. 1. *comparing state of the art versus automated vascular access*

Nurse or physician	Automated vascular access
Intensive FTE	FTE reduction possible
Not scalable	Highly scalable
Difference in skills	Standardized
Risk of complication	Use of image recognition prevents complications
Variable practices infection prevention	Standardized disinfection and cleaning
Variable success rate in difficult cases	Always using ultrasound, advantages for difficult cases

4. PROJECT RESULTS

1) Detecting arteries using force on ultrasound probe

Arteries have a thick vessel wall with small lumen, compared to thin walls in veins with a large lumen. The differences in anatomy facilitate recognition in ultrasound images. Arteries appear rounded in an ultrasound image, and cannot be compressed easily because of the thick vessel wall. In contrast, veins can be compressed easily (figure 1).
With this taken as the basis for the development of artery/vein distinction, an algorithm was developed that would apply force on the vessel through the ultrasound probe. Clinical tests were performed in a Dutch hospital. During these tests, it was investigated whether artery/vein distinction on the basis of force only could be a sufficient method for automatically detecting arteries in real-time.
In total over 300 ultrasound scans were performed on almost 100 patients of all ages.

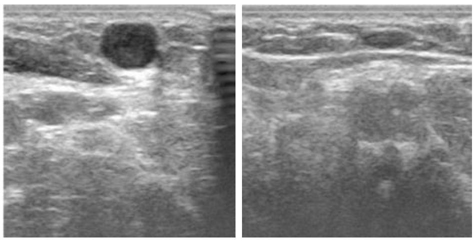

Fig. 1. On the left, an ultrasound image is shown of a vessel in the antecubital fossa. On the right, the same vessel is shown after compression occurs. Because the vessel deforms, it is evidently a vein and not an artery.

Patient data was acquired anonymously and patients gave their consent for joining the study.

It was concluded that while force evidently compresses and can help distinguish veins, it also has a high risk of destabilizing the tracking of vessels. Therefore, focus was shifted towards using a deep learning approach to distinguish arteries from veins in ultrasound images.

2) Deep learning approaches

Deep learning holds the promise to transform the field of image recognition. The following sequence is usually applied when selecting a deep learning architecture:

1. Defining performance requirements: robustness, speed, overfitting, computing power required
2. Prototyping: investigation if a technique/architecture will work, including experimental work
3. Release candidate: model ready to be released. There might be multiple release candidates.
4. Release of model: model released and verified stand-alone
5. Integration of model in device

During the project, several deep learning architectures have been evaluated. An extensive multi-class learning experiment has been performed including hyperparameter optimization and architecture exploration The main results were obtained when using the architecture Mask RCNN, a network introduced by He et al. [7]

Mask RCNN is a network consisting of a backbone and head. The head can be considered to have two different functions:
Region Proposal Network (RPN) - the RPN head finds 'interesting' regions in the image. It proposes the regions to the second part, the Mask Network.
Mask Network: the mask network gets the regions from the RPN and

- Classifies what is in the proposed region (e.g. a vein, an artery or nothing/background)
- Creates a mask that covers the object as good as possible.

The output is so-called instance segmentation: for each object in the image a mask and a classification is made. With instance segmentation it is also possible to have overlapping detections.

Because the Mask-RCNN model was severely overfitting, hyperparameter optimization was performed to improve the learning output of the model. Three augmentation sets were tested, whereas the least impactful augmentation set already prevented overfitting.

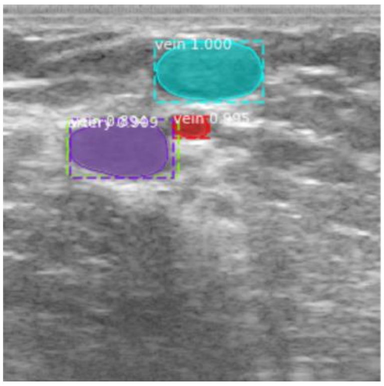

Fig. 2. Below is an example of the MaskRCNN detection. The class name is written next to the object. The number is the confidence of the network that the class is correct (between 0 and 1). The artery is viewed as a different instance as compared to the vein (demonstrated by different color.

No veins were mistaken for an artery. The majority of arteries could be detected using the MASK-RCNN network using the best configurations, see fig. 3 where the percentage of annotations that are detected in different models is shown. To further increase success rate of detection, more training and research is required as well as improving the database annotations. Several other frameworks were identified as potential release candidates, with other capacities such as improved speed compared to the MASK-RCNN.

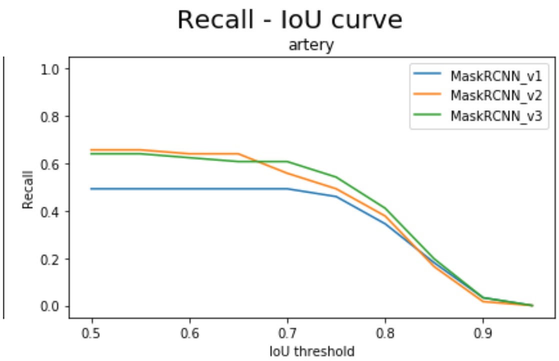

Fig. 3. The Recall - IoU curve shows which percentage of annotations are detected (Recall) vs. the amount of overlap a detection should have with the annotation (IoU threshold).

5. FUTURE PROJECT VISION

5.1. Technology Scaling

To scale the technology to TRL 5-7, a plan has been created to further experiment with other deep learning architectures, finding release candidates and releasing these candidates. As of writing, the first step has been taken to annotate a complete ultrasound image database with a new annotation tool, including expert review. This already would greatly improve in the performance of selected deep learning networks. Once a candidate is released, integration of the algorithms can occur in the autonomous blood drawing device that Result Laboratorium and Vitestro are developing. If this is successful, the deep learning technology would already reach even beyond TRL 7. Furthermore, to determine the potential for a standalone case, this integration could also serve as a basis for understanding the potential of using this technology in development of wide variety of other vascular access devices.

5.2. Project Synergies and Outreach

In ATTRACT phase 2, we want to the optimize the technology with the right consortium. With our current clinical partner Result Laboratorium, the first step would be to collect a far greater amount of clinical data in a varied population, as an enormous amount of heterogeneity can be seen in the arm of patients. Then, the data should be annotated with use of experts. By only this, the performance of the 3D Ultraman technology is already expected to vastly increase.
In addition, this consortium would require a company or university research lab specializing in deep learning. This partner will help Vitestro to optimize the algorithm to ensure detection is very fast (real-time) and accurate.

To facilitate public dissemination, a clear plan will be created with the partnering consortium. One way to enable dissemination is to focus on the scientific output and clinical potential of this application. However, this is not the only way. Result Laboratorium and Vitestro already have close interactions with patients and hospitals, dissemination will also include creating media (e.g. 3D animations) to explain this new innovation and understand the response of nursing personnel. Furthermore, videos could be made and shared on social media of the research and potential of this technology for automation in intensive care and emergency departments.

5.3. Technology application and demonstration cases

We strongly believe that with this 3D Ultraman technology of automated blood vessel detection, we can take the first step towards the fully autonomous hospital of the future, moving from human resources to machine resources in medicine. This brings concrete societal value in the area of Health and Well-being.
Demonstration cases would actually involve clinical trials, invasive or non-invasive, in the relevant hospital departments involved. Outcome of this demonstration would be to demonstrate the feasibility of robotic vascular access for ubiquitous procedures.
If proven feasible, the trained deep learning technology can be the foundation technology for robots that can autonomously place catheters in veins and arteries, and perform other kinds of vascular access procedures in the emergency department and ICUs. With AI at its core, these systems will improve with each procedure, yielding expert quality. This can improve outcome for patients and safety.

5.4. Technology commercialization

To commercialize the 3D Ultraman technology, both Vitestro and Result can play their part.
No such steps have been taken in this direction, although the main project Vitestro and Result are working on is being commercialized with investment from public and private stakeholders, and it is expected that for the 3D Ultraman technology this experience will greatly help. As Vitestro already has a large ecosystem of innovative hospitals across Europe, this will form the basis for adequate deployment and commercialization. If required, strategic partnerships can be closed to further stimulate adoption, for example which larger medical technology companies.

5.5. Envisioned risks

Main risks of the phase 2 project are related to acceptation of this technology by patients and nursing personnel. By testing from an early stage in the hospital, we can fully understand what is required in design to stimulate adoption. In addition, the eventual technology challenge will be to develop an algorithm that is reliable, fast and accurate, delivering a consistent performance. By partnering up with both deep learning research labs and hospitals, we expect the technology challenge is solvable. In addition, there will be regulatory challenges to obtain certification for deep learning based medical device applications. By engaging notified bodies for CE marking in an early stage, we can mitigate these risks.

5.6. Liaison with Student Teams and Socio-Economic Study

To facilitate student teams, Vitestro has already provided an experienced person in phase I to facilitate understanding of the 3D Ultraman technology and generating new ideas for societal challenges outside the medical field. In phase II, the consortium will also be happy to enable student teams.

Vitestro and Result could enable expert interviews in phase 2, with their diverse networks in the robotic/AI and clinical fields. In addition, it could facilitate workshops demonstrating technology.

To enable the socio-economic study both partners can contribute by providing interviews, giving demonstrations and leveraging its direct network.

6. ACKNOWLEDGEMENT

Authors thank the teams at Result Laboratorium and Vitestro, in particular the phlebotomy department and its management for the kind help received.

This project has received funding from the ATTRACT project funded by the EC under Grant Agreement 777222.

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