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3D Stent Graft Guidance based on Tracking Systems for Endovascular Aneurysm Repair

Abstract: In endovascular aneurysm repair (EVAR) procedures, the stent graft navigation and implantation is currently performed under a two-dimensional (2D) imaging based guidance requiring X-rays and contrast agent. In this work, a novel 3D stent graft guidance approach based on tracking systems is introduced. A calibration method and the visualization of the stent graft guidance are described. The tracking based stent graft guidance is evaluated by conducting an EVAR procedure on a torso phantom using a stent graft system equipped with an optical fiber and three EM sensors. The physicians were able to navigate the stent graft to the landing zone, and to place and implant it as intended using the introduced guidance. This showed that the application of the stent graft guidance is feasible in a clinical environment and promising for the reduction of radiation and contrast agent.

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1 Introduction

Endovascular aneurysm repair (EVAR) procedures are minimal invasive interventions, where a stent graft is implanted into the aneurysm region. The current gold standard for navigating the inserted instrument inside the human body are two-dimensional (2D) fluoroscopy and digital subtraction angiography. Moreover, contrast agent is administered to visualize the current vessel volume and to verify the correct implantation of the stent graft.

This imaging based guidance has several drawbacks. First of all, it offers a 2D view of the inserted instruments and the depth information is missing. As a result, the navigation of the inserted instruments is challenging, which can result in prolonged procedures. Second, the imaging is based on X-rays and thus the surgical team as well as the patient are exposed to ionizing radiation during the intervention. Third, the commonly used iodine contrast agents carry health risks like nephrotoxicity [1]. These burdens may increase further in the future, as screening studies show an increase in EVAR procedures [2].

Ideally, the physicians would like to have a real-time three-dimensional (3D) guidance without those disadvantages. A 3D tracking based guidance may overcome these problems. Such tracking systems are electromagnetic (EM) sensors [3], which can be used to track the position and orientation (pose) of medical instruments, and multicore fibers [4], which allow measurements of the current shape with fiber optical shape sensing (FOSS). Both technologies use small and thin sensors, and thus can be easily integrated into endovascular devices.

Combining FOSS with EM tracking, the benefits of both tracking systems are utilized and the current 3D shape positions of the inserted instrument inside the human body can be tracked. In previous works, the authors already introduced approaches on combining both technologies [5,6]. In this manuscript, we describe a novel approach for a 3D guidance of the stent graft integrated into a stent graft system based on the tracked shape of the instrument. A method for calibrating the shape is introduced and the visualization during usage is described. The stent graft guidance was evaluated in an EVAR procedure conducted on a torso phantom.

2 Material and Methods

2.1 Stent graft guidance

In the next sections, the steps for the shape calculation and visualization are introduced. This allows to both visualize the 3D shape positions of the stent graft system as well as the integrated stent graft.

The located shape obtained from the optical fiber and the EM sensors is used as input for this approach. First, a spatial calibration of the stent graft to the tracking systems has to be done. When this calibration is done, the located shape of the stent graft can be determined and it is visualized suitable for the physician.

2.1.1 Incoming tracking data

With the method introduced in [5,6], we obtain the located shape of the stent graft system. The resulting shape points obtained in the preoperative CT Scan are represented as a point set

$$\hat{S}^{CT} = \{ \hat{S}_0^{CT}, \dots, \hat{S}_n^{CT} \} \tag{1}$$

with $n = 760$ and $\|S_i^{CT} - S_{i+1}^{CT}\|_2 = 0.5\text{mm}$ distance in between, because the fiber has 38 cm shape sensing length and 20 interpolated positions were calculated per centimeter.

2.1.2 Stent graft shape calibration and calculation

The stent graft shape $\hat{St}^{CT}$ is a subset of the tracked shape $\hat{S}^{CT}$

$$\hat{St}^{CT} = \{\hat{S}_{j_{start}}^{CT}, \hat{S}_{j_{start}+1}^{CT}, \dots, \hat{S}_{j_{end}-1}^{CT}, \hat{S}_{j_{end}}^{CT}\} \subset \hat{S}^{CT}, \tag{2}$$

as shown in Figure 1. To obtain the correct shape subset, a calibration between the tracked shape and the stent graft has to

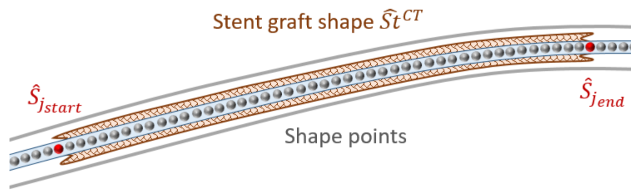

Figure 1: The stent graft shape $\hat{St}^{CT}$ in relation to the whole tracked shape $\hat{S}^{CT}$. The start and end of the stent graft shape corresponds to $\hat{S}_{j_{start}}^{CT}$ and $\hat{S}_{j_{end}}^{CT}$ of the shape $\hat{S}^{CT}$.

be done, where the start and end indices j_{start}, j_{end} are determined.

The shape is calibrated by "visiting" the start and end position of the stent graft with an EM tracked pointer. In a first step, the stent graft system is fixed, and the shape is measured with the tracking systems. Afterwards, a stylus equipped with a calibrated EM sensor is used to point to the starting position and the measured position $\hat{T}_{Stylus}^{EM}$ is acquired.

The start point of the stent graft shape can be determined as the shape point of $\hat{S}^{EM}$ which is nearest to the measure stylus tip:

$$j_{start} = \underset{i \in \{0,\dots,n\}}{\arg\min} \left\| \hat{S}_i^{EM} - \hat{T}_{Stylus}^{EM} \right\|_2 \tag{3}$$

The end position of the stent graft can be obtained in the same way. After the calibration step was conducted, a guidance of the stent graft can be done by using the determined indices.

2.1.3 Visualization

During the procedure, the tracked shape positions are shown in the preoperative CT scan. The whole shape of the instrument is visualized as a thin black curve. The stent graft shape is highlighted as a red curve in the visualization, because this information is most important for navigating and correctly placing the stent graft at the landing zone.

Currently, surgeons use marker rings in fusion imaging as an add-on technology [7] to facilitate the stent graft placement by highlighting the desired landing zone in the three-dimensional CT dataset, however it is not yet part of the gold standard navigation. The start and end marking rings can be placed along the chosen centerline insertion path C. During the procedure, these markers are displayed when navigating the stent graft. As a result, the surgeon can assess the possible landing zone to guarantee technical success of the procedure.

2.2 Stent graft system and stent graft

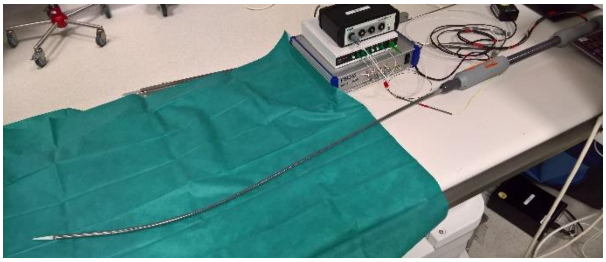

Figure 2: The stent graft system with tracking systems and stent graft integrated in the front.

A stent graft system (E-vita THORACIC 3G, Jotec GmbH, Hechingen, Germany) was disassembled and the integrated stent graft was removed. Afterwards, a multicore fiber (FBGS Technologies GmbH, Jena, Germany) inserted in a metallic capillary tube (400µm diameter, AISI 304L) was integrated. Moreover, three Aurora Micro 6 degree-of-freedom EM sensors (9mm, diameter: 0.8mm}; Northern Digital Inc., Waterloo, Canada) were integrated at the first 25 cm of the stent graft system. Everything was covered with shrinkage tubing and fixated. After the calibration step of the integrated tracking systems was done, a stent graft suitable for the thoracic aneurysm of the phantom was integrated. The resulting stent graft system is shown in Figure 2.

2.3 Torso Phantom

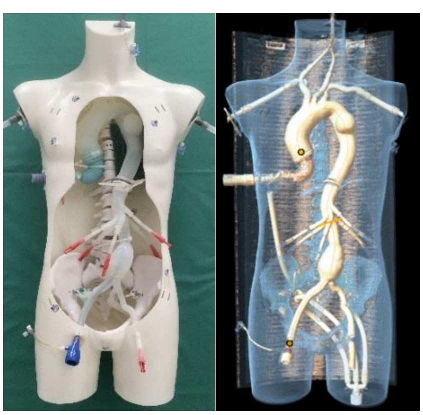

Figure 3: Image (left) and preoperative CT scan (right) of the torso phantom.

A custom-made torso phantom including a realistic vessel system was developed, as shown in Figure 3. The integrated 3D printed aortic vessel is based on patient-specific data and is made of silicone. The vessel system can be entered through the introducer sheath to the right femoral artery. Seven metallic markers (The Suremark Company SL10, diameter: 1mm) were placed on the outer cover of the phantom for the EM calibration.

2.4 Experimental Setup

Before the experiment, a preoperative CT scan (Figure 3) of the phantom filled with water and contrast agent (ratio 1:10) was acquired. Then, the vessel system was segmented and the position of the metallic markers were determined for the EM calibration.

As preparation of the experiment, the workstation and the tracking devices were set up and connected. Then, the stent graft calibration was conducted. Afterwards, the phantom was filled with water, placed such that all markers were in the measurement volume of the EM system and connected to a pump for simulating blood flow. Then, the EM tracking system was calibrated and, finally, all calibration parameters were loaded for the guidance.

First, a soft guide wire was inserted and navigated to the target region under fluoroscopy. A standard catheter was pushed over and the soft guide wire was replaced with a stiff guide wire. Afterwards, the catheter was removed and the stent graft system could be inserted. Then, the stent graft guidance was used to navigate and place the stent graft to the landing zone in the thoracic aorta. Finally, the stent graft was implanted and a 2D fluoroscopic image was acquired to check, whether the stent graft was implanted correctly.

3 Results and Discussion

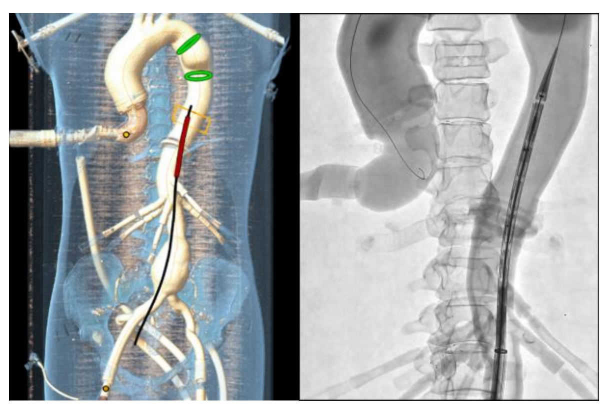

Figure 4: A screenshot of the tracking based guidance (left) and a fluoroscopy image of the gold standard guidance (right).

The data received from the tracking systems was sampled with 10 Hz and hence, the measured 3D shape positions could also be updated in this frequency. As a result, the physicians obtained a real-time feedback of the stent graft system and stent graft movements inside the vessel system.

A comparison of the stent graft guidance based on tracking systems and the standard fluoroscopy based guidance is shown in Figure 4.

The first advantage of the tracking based guidance is that the field of view is larger as the field of view obtained with the fluoroscopy imaging. The whole preoperative scan can be viewed and the tracked 3D shape positions are visible. Using the standard image guidance, the C-Arm has to be moved to the current region of interest and this not necessary when using the tracking based guidance. Another advantage is the visualization. The 3D shape positions of the tracked stent graft system and the stent graft are clearly visible in the preoperative scan together with marker rings. In the fluoroscopy image, however, all information is visible in grayscale. But the tracking based guidance has the disadvantage, that the current intraoperative anatomical structure is not visible, since everything is visualized in the preoperative scan. Intraoperative changes or movements of the anatomical structure are thus not recognized.

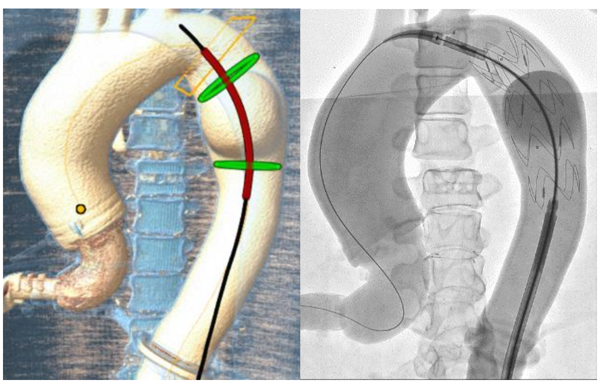

Figure 5: The view of the stent graft guidance before implantation (left) and the fluoroscopic image after implantation (right).

The physicians placed the stent graft using the tracking based guidance. The image of this situation is shown in the left image of Figure 5. According to the image, the stent graft shape is located in both marking rings and should cover the whole aneurysm region. Afterwards, the stent graft was implanted and the resulting 2D fluoroscopy image is shown in the right image of Figure 5. It illustrates that the stent graft was implanted as intended by the physicians and that it bridges the aneurysm region. This result shows that the stent graft guidance was feasible and that it could be used successfully by the physicians.

4 Conclusions

This study introduced a 3D stent graft guidance based on tracking systems and compared it with the current standard guidance. For this purpose, a multicore fiber and three EM sensors were integrated into the front of a stent graft system. An EVAR procedure was conducted on a silicone thoracic aorta inside a torso phantom using the tracking based guidance for navigating and implanting the stent graft.

The results showed that the tracking based guidance provided the 3D position information suitable visualized and in real-time without the disadvantages of the standard 2D fluoroscopy based guidance. The stent graft implantation was successfully conducted by the clinicians, which is a promising first clinical result. Since intraoperative anatomical changes are not visible, this guidance is most suitable for applications were no or only small movements are expected.

In future work, the focus will be on a more extensive, clinical validation and further adaptions for clinical use.

Author Statement

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