



Medical Devices: Materials, Mechanics and Manufacturing

A novel methodology for the modeling of catheter aspiration in high-fidelity thrombectomy simulations

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Abstract

The development of high-fidelity *in silico* simulations of the endovascular thrombectomy (EVT) procedure, the treatment for acute ischemic stroke, is gaining importance for the possibility of investigating the causes of failure of the clinical procedure and optimizing the treatment. This work proposed a novel methodology for a realistic modeling of the thrombus aspiration in a combined EVT procedure, with stent-retriever and proximal aspiration catheter. In the combined EVT procedure, the thrombus is entrapped in the stent struts and is retrieved towards the aspiration catheter. During the retrieval, the thrombus may rotate, and therefore different portions of its surface are subjected to aspiration forces. An automatic algorithm is implemented allowing to redefine the portion of the thrombus surface subjected to the aspiration pressure in different time points of a high-fidelity finite-element EVT simulation. The algorithm updates at each iteration the loaded portion of thrombus surface, by selecting elements aligned with the vascular centerline. The algorithm is applied in a high-fidelity EVT simulation in a patient-like vascular model, demonstrating the ability of obtaining a realistic simulation of thrombus aspiration.

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1. Introduction

Stroke is the second leading cause of death worldwide, with more than 12 million new cases each year (Feigin et al., 2022). Over 62% of these cases are ischemic strokes, caused by an occlusion in a cerebral artery preventing the blood perfusion of downstream brain tissues. In case of a large vessel occlusion (LVO), i.e. affecting the intracranial internal carotid artery (ICA), the middle cerebral artery (MCA) or the anterior cerebral artery (ACA), the most effective treatment is the endovascular thrombectomy (EVT), a minimally-invasive mechanical treatment aiming at removing the occluding thrombus and restoring the blood flow (Phipps and Cronin, 2020). The procedure can be performed with a stent-retriever, with an aspiration catheter, or with combined techniques using both devices (Munich et al., 2019). A combined EVT technique can be performed using, in combination with the stent-retriever, a proximal aspiration catheter placed at the base of the intracranial ICA (usually a balloon guide catheter, BGC, to stop the antegrade blood flow and facilitate the procedure (Ospel et al., 2020)). In this technique, the stent-retriever, initially crimped in a microcatheter, is deployed at the occlusion location to entrap the thrombus, and is then retrieved to the BGC, whose aspiration facilitates the thrombus removal and avoids the circulation of emboli. A different combined EVT technique uses, in addition to the stent-retriever and the BGC, a distal access catheter (DAC), coaxial with the BGC and navigated to the proximal end of the thrombus. In this technique, the thrombus is entrapped both by the stent-retriever and by the aspiration of the DAC, which are retrieved together, up to the BGC (Ospel et al., 2019).

Despite being currently the standard of care for stroke due to an LVO, there is still a wide interest in optimizing the EVT procedure to increase the success rate and improve the patients' outcome (Ospel et al., 2021). Computational models of the clinical procedure can help understanding the thrombus-device interactions and the causes of failure of the procedure. In recent years, *in silico* models of the EVT procedure with stent-retriever have been proposed (Liu et al., 2021; Luraghi et al., 2021b; Mousavi J S et al., 2021). The credibility of the high-fidelity finite-element model (FEM) proposed in (Luraghi et al., 2021b) was demonstrated through validation with *in vitro* experiments and a patient-specific case (Luraghi et al., 2021a). In (Luraghi et al., 2022a), the same authors proposed a high-fidelity FEM of the combined EVT technique, both with only the BGC and with BGC and DAC.

This work proposes an algorithm for a more realistic FEM modelling of the EVT procedure with stent-retriever and BGC. In (Luraghi et al., 2022a), the aspiration pressure of the BGC was applied to the surface of the proximal end of the thrombus, defined at the initial configuration. However, with this EVT technique, the thrombus entrapped in the stent struts can rotate during the retrieval, therefore the surface exposed to the BGC aspiration pressure may vary throughout the procedure. The novel proposed algorithm allows to automatically redefine the thrombus surface for the application of the aspiration pressure at different time points of the EVT simulation. The novel methodology is applied in a high-fidelity model of a combined EVT procedure in a patient-like vascular model.

2. Materials and Methods

2.1. Algorithm for thrombus aspiration modeling

The algorithm for the automatic definition of the thrombus surface for the application of the catheter aspiration is based on periodically restarting the FEM aspiration simulation, solved using the finite-element solver LS-DYNA (ANSYS, USA). A schematic representation of the algorithm is provided in Fig. 1. The algorithm requires the definition of a shell mesh representing the outer surface of the thrombus, and the discretization of the vessel centerline with beam elements. Moreover, the number of simulation restarts N_r is chosen based on the desired time interval dt for the update of the thrombus surface for the application of aspiration.

In the initial configuration, a set of elements is selected on the thrombus end in proximity to the aspiration catheter for the application of the aspiration pressure (details about the simulation settings will be provided in the next section). The FEM simulation is launched and stopped after a time interval dt . The generated output files are analyzed for the update of the loaded thrombus surface. This is done by following four main steps: 1) identify the closest beam element of the centerline to the thrombus surface, using the beam connectivity to select the centerline elements in the direction of the aspiration; 2) define the centerline direction using the extreme points of the identified beam element; 3) define the normal vectors to each element of the shell mesh defining the outer surface of the thrombus, and for each normal vector compute the scalar product with the centerline direction, to select the thrombus elements with angle between

the normal vector and centerline direction below a chosen value; 4) redefine in the simulation settings the thrombus surface for the application of the aspiration pressure. The simulation is restarted from the last configuration, and runs for another interval dt . The process is repeated until the desired number of restarts Nr is reached and the simulation continues until the imposed termination time.

The whole procedure is made completely automatic through Python codes, which manage both the algorithm for the redefinition of the loaded surface and the restart of the simulation in the computational facility.

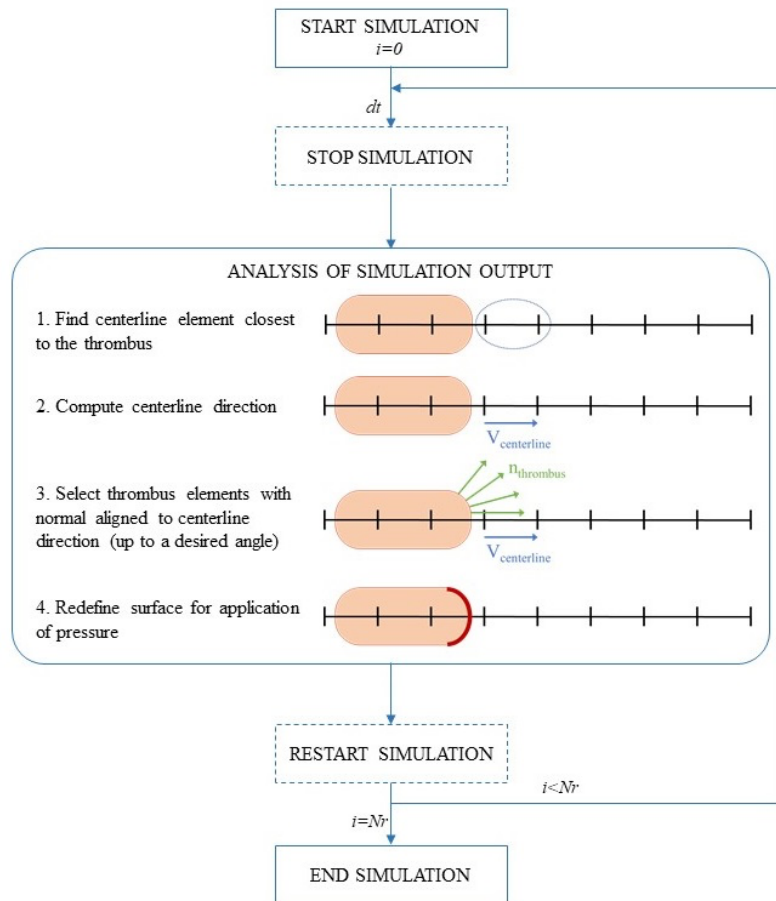


Fig. 1. Algorithm for the update of the thrombus surface for the application of the aspiration pressure (i =iteration; Nr =number of simulation restarts; dt =time interval between each surface update).

2.2. Combined EVT simulation in patient-like vessel

The algorithm for the update of the thrombus surface for applying the aspiration pressure was integrated in a high-fidelity simulation of a combined EVT procedure, with a stent-retriever and a BGC.

A computer-aided design (CAD) model of a patient-like vascular branch, complete with ICA, MCA and ACA, was provided by Cerenovus, Johnson&Johnson (Ireland) (Fig. 2a). The model was discretized with quadrilateral rigid elements of 0.35 mm average size. The vascular centerline was discretized with beam elements of 0.2 mm.

A thrombus model was placed at the bifurcation of the MCA. The thrombus diameter was set to occlude 90% of the vascular lumen. The thrombus was modeled with a length of 10 mm and a 100% fibrin – 0% red blood cells composition. The quasi-hyperelastic foam material formulation available in LS-DYNA was used (Kolling et al., 2007), which determines the material parameters directly from a given stress-strain curve (Fig. 2b), interpolated from experiments carried out on human *ex vivo* thrombi, as detailed in (Luraghi et al., 2021a). The thrombus was discretized

with tetrahedral elements of 0.2 mm average size (following an analysis on the element size reported in (Luraghi et al., 2022b, 2021b)). The connectivity of the triangular shell elements in the outer surface of the thrombus is stored, necessary for the surface update algorithm.

The BGC (2.3 mm diameter) and the microcatheter (0.5 mm diameter) for the stent delivery (respectively black and blue in Fig. 2a) are discretized with quadrilateral rigid elements (0.35 mm average size). A model of the EmboTrap II (Cerenovus) stent-retriever was created (Fig. 2c) based on the CAD model provided by the company, and discretized with beam elements with rectangular section and 0.2 mm length (a sensitivity analysis was performed in (Luraghi et al., 2021b)). The nickel-titanium material was modeled with the shape memory material model available in LS-DYNA, with parameters calibrated as explained in (Luraghi et al., 2021b).

The EVT simulation is made of four main steps:

1. Stent crimping and microcatheter tracking: the stent-retriever is crimped inside a straight 0.5 mm diameter microcatheter by imposing the movement of the stent tip. At the same time, the microcatheter is displaced inside the vessel to reach the position shown in Fig. 2a, and pushes the thrombus against the vessel wall. A contact with 0.4 friction coefficient is defined between thrombus and vessel wall.
2. Stent tracking: the crimped stent is displaced inside the microcatheter to reach the thrombus position.
3. Stent deployment: the stent is deployed by progressively removing the contacts with the microcatheter. A contact with 0.2 friction coefficient is defined between stent and thrombus, and a frictionless contact between stent and vessel wall.
4. Retrieval and aspiration: the stent-thrombus complex is retrieved along the vessel towards the BGC, by imposing the movement of the stent tip. At the same time, the aspiration pressure is applied to the portion of the thrombus surface closest to the BGC. The pressure is applied as a function of the distance of the thrombus from the BGC: the applied pressure is hypothesized to start having an effect on the thrombus when it is less than 10 mm far from the BGC. From this distance, the applied pressure grows linearly from 0 to 10 kPa exerted by the BGC (in the range of catheter aspiration pressures reported in (Chitsaz et al., 2018)).

Further details about the simulation settings can be found in (Luraghi et al., 2021b) and (Luraghi et al., 2022a).

The algorithm for the update of the thrombus surface for the aspiration is applied with a total of $Nr = 10$ restarts of the simulation, with intervals $dt = 50$ ms starting from the retrieval phase. The loaded surface of the thrombus is selected considering elements with an angle $< 30^\circ$ with the centerline direction.

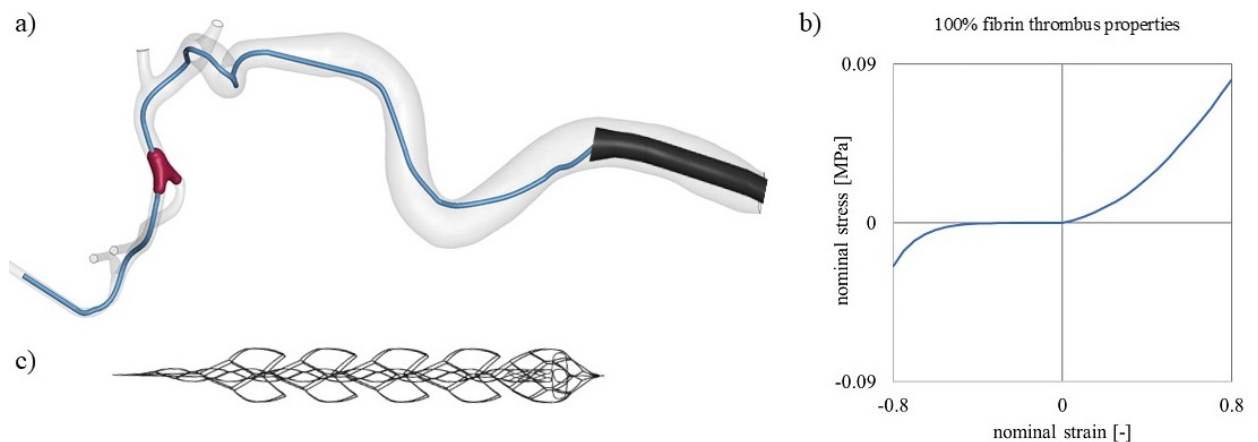


Fig. 2. a) Finite-element model for the combined EVT simulation in a patient-like vessel; b) Stress-strain curve for the definition of the thrombus material; c) Finite-element model of the EmboTrap II stent-retriever.

3. Results

Fig. 3 shows the results of the combined EVT simulation in the patient-like vascular model, from the deployment of the stent (frame 1) to the final retrieval of stent and thrombus inside the BGC (frame 6). These simulation frames clearly show the rotation of the thrombus during the procedure. The proposed algorithm allowed to select the proper portion of thrombus surface for the application of the aspiration pressure in each restart of the simulation (Fig. 4). The effect of the aspiration pressure on the thrombus is visible from frame 4, when the thrombus is closer to the BGC.

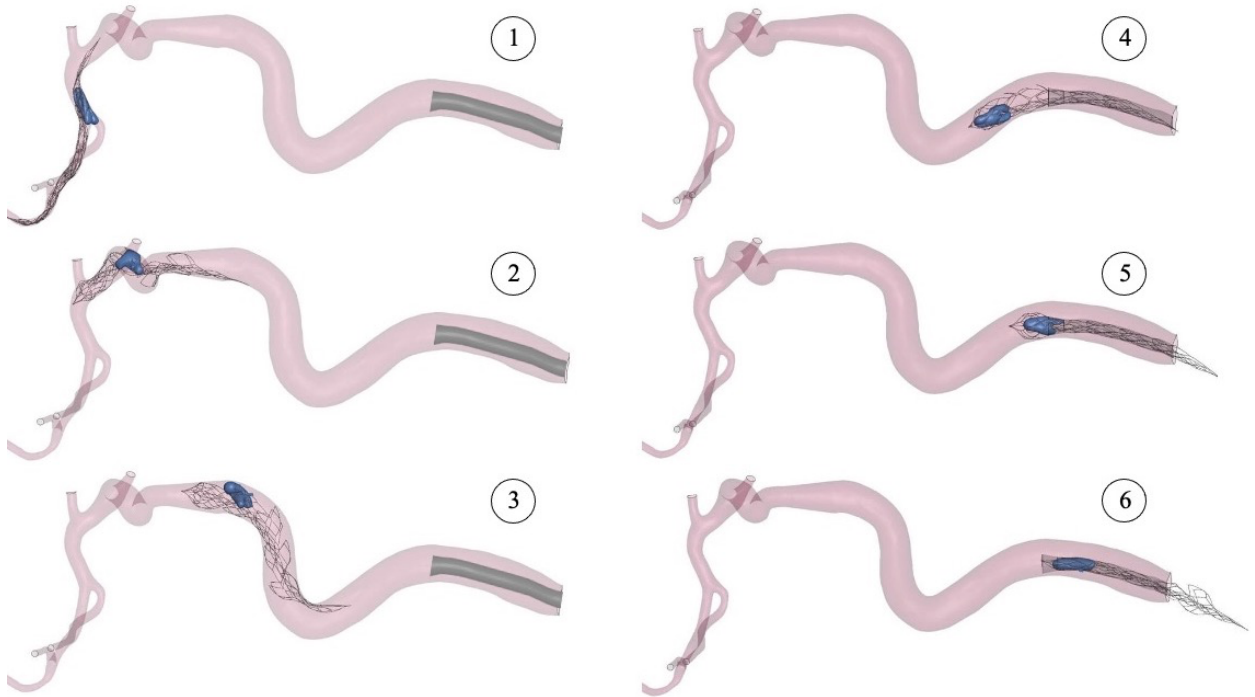


Fig. 3. Results of the combined EVT simulation in the patient-like vessel.

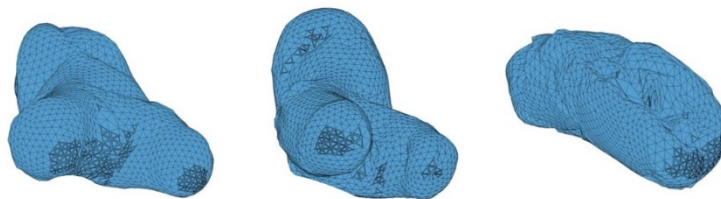


Fig. 4. Different selected portions of the thrombus for the application of the aspiration pressure in different time points of the simulation (the selected elements are contoured in black).

4. Discussion

In this work, an automatic algorithm was developed for a realistic application of the aspiration pressure exerted by the BGC in a combined EVT simulation. The use of *in silico* simulation of the EVT procedure is gaining much relevance for the investigation of the thrombus-device interactions and for understanding the causes of unsuccessful outcomes. While several computational studies can be found in the literature replicating the EVT procedure with only

stent-retriever (Bridio et al., 2021; Liu et al., 2021; Luraghi et al., 2021b, 2021a; Mousavi J S et al., 2021), only one study proposed the implementation of high-fidelity simulations of the EVT with aspiration catheters (Luraghi et al., 2022a). This work is intended to provide a methodology to improve the modeling of the thrombus aspiration, in particular for the case of EVT performed with stent-retriever and BGC.

The algorithm was applied in a high-fidelity simulation of EVT with stent-retriever and BGC in a patient-like model of the cerebral vasculature. In this case, there was an evident rotation of the thrombus during the retrieval phase (Fig. 3), and the developed algorithm allowed to properly select the portion of thrombus surface subjected to the aspiration pressure (Fig. 4).

The results of this study demonstrated the applicability of the implemented algorithm for a realistic simulation of the catheter aspiration. To verify the feasibility of the methodology, some assumptions were made, in particular on how the aspiration pressure of the BGC is transferred on the thrombus surface. The aspiration is assumed to have an effect on the thrombus when it is less than 10 mm far from the BGC, and to grow linearly with the decreasing distance from the BGC. This assumption needs to be verified in future works, possibly implementing computational fluid dynamics simulations and evaluating the pressure transferred to the thrombus surface at various distances from the aspiration catheter. Additionally, the aspiration pressure of the BGC was here assumed of 10 kPa. This value was chosen as reasonable for an EVT procedure, but can be varied to evaluate the effect of different applied aspiration pressures.

Finally, after this applicability study, the proposed methodology will need to be validated with *in vitro* EVT experiments or patient-specific cases. A successful validation of this methodology would allow to model high-fidelity EVT procedures with aspiration with structural FEM simulations, avoiding fluid-structure interaction approaches, which are more computationally demanding.

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