

The Impact of a realistic complete Stenting Procedure on the Migration Behaviour: a Numerical Analysis

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ABSTRACT

The migration of the stent graft is one of the main complications of Endovascular aneurysm repair (EVAR). It is closely related to ineffective contact between the endograft ends and the wall of the blood vessel.

In this study, we have developed a realistic stent-graft deployment simulation using the Finite Element Method of 3D nitinol stent in a patient-specific Thoracic Aortic Aneurysm (TAA). This work aims to investigate the impact of the realistic complete stenting procedure by a progressive expanding deployment of the stent graft on the migration behaviour. A comparison of results is investigated between the realistic and non-realistic deployment methods to predict the overall (stent-aorta) biomechanical behaviour. We have also investigated the effect of including the graft material on the mechanical behaviour of the (stent-graft) during the deployment and the contact stability (stent-graft)/aorta after the deployment.

The simulation results show that the realistic deployment method did indeed influence the mechanical behaviour, positioning, and eventually the functioning of the stent-graft when compared with the traditional deployment methods. The impact of adding the fabric tissue to the stent being deployed in an idealized straight centerline on the contact stiffness seems to be modest compared the deployed stent without graft.

Keywords: Aortic aneurysm; Migration; Finite element; Stent design

INTRODUCTION

An aneurysm is defined as enlargement or dilatation of the degenerated aorta. This disease can be considered as a multi-factorial disease with a significant genetic component [1]. The dilatation leads to flow disturbances and changes in wall tension. If left untreated, the aneurysm may rupture leading to death [2].

Endovascular Aneurysm Repair (EVAR) is the alternative and less invasive treatment to conventional open surgery which involves a heavy intervention, large blood loss, and many postoperative complications. The endovascular stent graft is a device used to seal off the aneurysm from inside the aorta and eventually provides a new pathway for blood flow through the region of the aneurysm.

Despite presenting numerous advantages, this technique has not yet been fully validated. Long-term success of (EVAR) is not definitively established as the future data of patients undergoing EVAR are not yet available [2][1]. Migration and Endoleak type I [3] are considered to be the major mechanical related-complications. Endoleak type Ia is defined by the persistent blood flow into the

aneurysm sac that originates from the proximal attachment site wall. Migration is defined as the endograft ends' displacement from its correct position by more than 10mm. Endoleak type I may occur without migration or secondarily to migration [4]. These complications become so manifest when the stent graft is deployed in a complex or tortuous morphology like TAA, the main cause of the early onset of endoleaks type Ia [2] [3]. The stent unconformity to tortuous aortic arc and the high drag forces due to severe angulations [5] lead to ineffective contact between the stent graft and aorta [6] [2]. In addition to the aorta morphology impact, stent design factors like endograft under/over sizing [3] [6] [2], sufficient length of proximal attachment site [7] [2] may also have a major contribution in preventing migration and endoleak Type Ia. Therefore, understanding the mechanical performance of stent graft using realistic numerical simulations is necessary to help in choosing the appropriate stent design for patient-specific aneurysms [8] [9].

Computational mechanics techniques, in particular, the finite element method (FEM) merged with computer-assisted tomography

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(CAT), can be applied to analyze the complete stenting procedure thanks to FEM's efficiency in solving governing differential equations and predicting the overall (stent-aorta) biomechanical response. Many previous studies have investigated, based on 3D FEM, the nitinol stent deployment in a patient-specific aortic aneurysm.

We carried out previous numerical simulations using Computational Solid Mechanics (CSM) in the LaMCoS laboratory [10] [9] [8] to investigate the morphological and stent design factors on the contact stiffness in a realistic (TAA) using finite element method. However, the impact of a realistic progressive stent deployment and graft modeling on the biomechanical behaviour (stent/aorta) has not been fully investigated. TAAs have bary center line curvature in 3D space unlike abdominal aortic aneurysm AAAs, which increases the difficulty of performing FEA simulations because simplistic axisym metric models cannot be used. [11] Has stated that the graft material may contribute to different mechanical behaviour of the nitinol stent during insertion and expansion phase. Very few numerical studies have performed the complete progressive realistic stent deployment in a 3D curved aorta.

The present paper is a follow-up to our previous papers [10] [9] [8]. The main goal of this work is to explore how a realistic gradual deployment of the stent in a 3D specific-patient TAA may impact the mechanical behaviour of the stent's struts during deployment (insertion and expansion phase). In particular, we investigated the proximal contact stability and proximal placement of the stent's struts with respect to the aorta after deployment in a short-term fixation frame. The graft impact on the contact stiffness was also investigated for a progressive simulation deployment in an idealized straight aorta. The contact stiffness was evaluated using the standard Coulomb frictional model.

MATERIALS AND METHODS

Patient specific TAA and stent graft models

The FEM patient-specific TAA and stent models were the same as for the previous work [8] [9]. In this case, the degree of anisotropy is modest and can be ignored [12]. Using the generalized Mooney-Rivlin hyperelastic constitutive model, the aorta material behaviour is considered as an isotropic hyperelastic and nearly-incompressible. The nitinol super elastic behaviour was assigned to the stent [13]. The finite elements discretization was developed using Abaqus C3D8R element for both aorta and stent.

In this study, the Polyethylene terephthalate (PET) fabric was considered with 0.3mm wall thickness. The graft was discretized with linear shell elements and modeled as an orthotropic elastic material using Lamina material model. We considered the orthotropic behaviour in plane constraints with two bending (in both longitudinal and circumferential direction). The graft tissue is attached to the stent using Tie-constraints (no friction or relative slip). All the orthotropic material properties and the bending rigidities characterized by [14] (Table 1) were used and implemented in Abaqus software.

FEM stent deployment procedure

We have adopted two progressive deployment methods, Virtual Gradual Expansion in Subsets (VGES) and a Realistic Sliding

Deployment (RSD) method. For both methods, a program routine using Processing was developed and modified to calculate the needed nodal displacement to comprise the aorta centerline in the insertion and the expansion phases into subsets.

Following on from the previous deployment method, i.e. Virtual Gradual Expansion in Subsets (VGES), which was inspired by the work of [14], of a pure boundary condition subset approach and employed in our prior work [8], a new method has been developed to gradually deploy the stent in a 3D curved aorta. In (VGES), we first activated stent/aorta contact before re-expansion and then expanded successively the segments (in multiple simulation steps) to a diameter greater than that of the aorta. The over sizing stent value was 15%. The general contact algorithm was used for the interactions between all model components. The isotropic Coulomb friction model was adapted to describe the tangential behaviour [8] with a coefficient of friction (stent/aorta) $\mu=0.05$. All the performed deployment simulations are illustrated in Table 2.

The contact stability ratio $\bar{F}_{cs} = \bar{r}_{eq} / \mu p, 0 \leq \bar{F}_{cs} \leq 1$, which defines the stick/slip behaviour between stent and aorta [8] was evaluated at both attachments sites at the first moment of interaction and when the stent was fully deployed. The bigger the value, the smaller the pullout forces needed to dislodge the stent from its attachment site which leads to migration.

Because of the high nonlinearity inherent in the simulation (large deformation, material nonlinearity, complex contact problems), and the interest in the dynamic effects of the expansion, the use of an explicit dynamic analysis is particularly suited to this problem. Commercial software ABAQUS / Explicit 6.13 has been used with mass scaling technique [15] [16] to perform the simulations.

Figure 1 shows compression, deformation, and expansion in subsets of the catheter with stent and aorta (VGES).

In the RSD method, a progressive and gradual catheter retraction

Table 1: Material Properties of the Polyethylene terephthalate material.

longitudinal Young's modulus E_A , MPa	225+10%
circumferential Young's modulus E_c , MPa	1000±10%
Poisson's ratio ν_c	0.2
Shear modulus G , MPa	3.6
Longitudinal ultimate strain $\epsilon L/R$	0.23
Circumferential ultimate strain $\epsilon R/c$	0.18
Longitudinal bending stiffness D_L 0^4	4
Circumferential bending stiffness D_c 0^4	18

Table 2: deployment simulations of stent 2.

Deployment Simulation (VGES) & (RSD)	I
(Angulated proximal neck without graft)	(Stent2)
Proximal attachment site length(mm)(PASL)	$D_{2p} = 21$
Distal attachment site length(mm)(DASL)	$D_{2D} = 18$
Oversizing value (O %)	15%
Tangential Contact Behavior (coefficient of friction)	$\mu=0.05$
(Non-Angulated proximal neck with a graft)	(Stent2)
Proximal attachment site length(mm)	$D_{1p} = 18$
Distal attachment site length(mm)	$D_{1D} = 15$
Over sizing value (0%)	15%
Tangential Contact Behavior (coefficient of friction)	$\mu=0.05$

was simulated allowing a realistic expansion stent release to the diameter of the aorta. By combining the catheter translation results and the assembly parameters, a complete FEA model containing the stent, aorta, and catheter was created, and deployment of the stent using the (RSD) method was obtained as seen in Figure 2.

To investigate the impact of the graft on the mechanical behaviour of the (stent-graft) and the contact stiffness at the attachment sites during a realistic progressive deployment see Figure 3, a

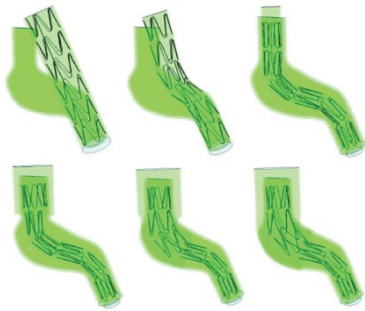


Figure1: Compression, deformation, and expansion in subsets of the catheter with stent and aorta (VGES).

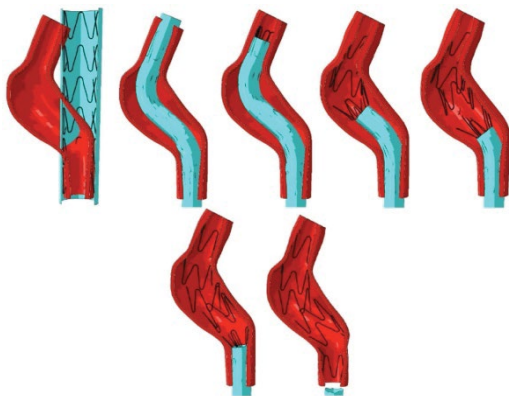


Figure2: Stent deployment with sliding catheter along the barycenter line (right to left, top to bottom).

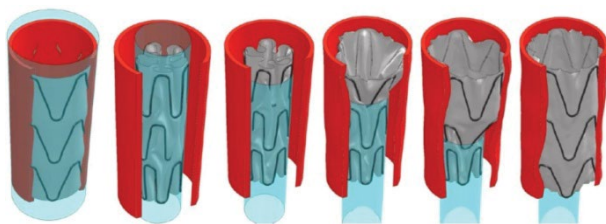


Figure3: Stent graft deployment by catheter translation.

20% oversized stent was deployed in an ideal straight aorta. The obtained results were compared with our previous results [8]

RESULTS

The (VGES) method's convergence was sensitive to the number of subsets. An optimal number of subsets should be found for any other stent size or aorta geometry to ensure convergence. This leads to the focus on the development of the Realistic Sliding Deployment (RSD) method.

(VGES) simulation induced slightly smaller values of stresses in the vessel compared to the traditional deployment method with 60° proximal angulations after full deployment of the first circle of struts [8]. The maximum value of Von Mises stresses was 0.043 MPa vs. 0.05 MPa at the proximal site. A slight increase of 2.19 % of contact stability was found in the proximal site compared to its value with the traditional deployment 0.91 vs 0.89. When all the stent's struts were deployed, the contact stability values were almost identical for both simulation methods.

In the RSD method, the main observation was the existence of rapid collisions between stent and aorta walls due to the strain energy stored from compression. This was due to the release of a stent strut on its own, undamped by the expansion of the catheter as in previous methods [18,19]. These elastic collisions resulted in the expected differences in strut's position of the stent due to the inertia during release. The convergence and stability of this method were more sensitive to the low speeds of the catheter translation, than the high speeds. This can be explained by the fact that at low speeds, the stent strut undergoes high deformations due to the contact between the edge of the opening of the catheter and the struts. At high speeds, this edge-to-surface contact is minimal, and the catheter retracts before the struts fully accelerate radially.

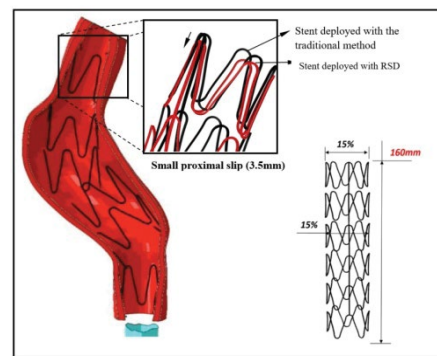


Figure 4: Stent slip after full deployment (RSD)

Table 3: Slip-stick behaviour results of different deployments methods.

Stent 2 (160mm)- PASL=21- DASL=18					
Simulation deployments		VEGS	RSD	RSD	Traditional deployment
Oversizing (O %)=15%					
Tangential contact behavior $\mu=0.05$					
(\bar{f}_{cs})		No graft	No graft	With graft	No graft
	Proximal neck	0.9(ASD)	0.82 (ASD)	0.83	0.89
		0.91 (1 st SSD)	0.88vs(1 st SSD)		
	Distal neck	0.86	0.83	0.89	0.98
Average normal contact forces (N)	Proximal neck	0.1	0.14	0.1	0.09
after deployment	Distal neck	0.12	0.15	0.1	0.1

RSD simulation resulted in better contact stability with an 8.5% improvement in the proximal site, compared to its value with the traditional deployment 0.82 vs 0.89 when All the Stent is Deployed (ASD), see Table 3. More importantly, the results also showed that stent2 slipped 3mm compared to the stent's position with the traditional deployment as illustrated in the Figure 4.

RSD simulation showed a progressive increase in deformation and stresses in the aorta from the proximal to the distal attachment site.

The simulation of the stent-graft being deployed from the catheter, using a simple translation of the catheter along the straight centerline axis, was successful as shown in Figure3. The proximal contact stability was slightly bigger compared to its value with the traditional deployment and zero proximal angulations [8] with the traditional deployment 0.83 vs 0.80. The impact of including the graft on the mechanical behaviour of the stent/aorta was minimal.

DISCUSSION

This study has confirmed the feasibility of using FEA simulations of stent-graft (SG) deployment in aneurysm models with realistic geometries. The originality of this work is that SGs were realistically deployed in an aneurysm while following its curvature. Several clinical aspects could eventually be quantified and prove that it has the potential for clinical applications in surgical practice.

(VGES) simulation results have a relatively minor impact on the aorta mechanical behaviour and contact stability. The slight increase in the contact stability value can be explained by the super plastic recovery mitigation of the first circle of struts as all the other circles of struts still did not recover their entire potential strain energy of super plastic recovery (reference). The deployment position was identical compared to the stent's position with the traditional deployment. When all the stent's struts were deployed, the contact stability values were almost identical for both simulation methods. This result is expected as the stent eventually will recover its entire super plastic energy in both RSD & (VGES) simulations.

The RSD stent graft deployment with zero proximal angulations showed a slight decrease in contact stiffness. This can be explained by the slight mitigation of the graft against the stent's struts outward forces during the deployment. In this case, the fabric resistance limits the stent super plastic recovery. The work done by [20] showed that the graft plays a crucial functional role in stent deployment, especially in curved aneurysms such as TAAs. At the vessel's outer curve, forces pull consecutive stents apart, but the fabric stretching quickly limits this displacement. Therefore, stent application on the arterial wall seems to remain adequate at the outer curve. At the vessel's inner curve, increasing angulations approaches consecutive stent struts closer together, up to possible over-lapping. At this point, fabric resistance limits stent overlap and the further load is transformed into radial deformation of the Z-stents at the level of the vessel curvature [19].

In this work, the influence of a graft material was performed in a simplified straight geometry in order to minimize the complexity of the numerical simulation. Therefore, this part of the simulation remains to be developed and to be compared with the other results such as those published by Perrin et al [21].

The RSD simulation resulted in better contact stability with an

8.5% improvement in the proximal site after full stent deployment (ASD). In addition, the super plastic recovery behaviour was different compared to the tradition deployment method. Special attention should be given to the stent design in order to minimize the reported 3 mm migration with (RSD).

LIMITATIONS

A significant amount of R&D is still needed before this tool will be available to the clinical physician. Further refinement such as the addition of anchorage systems at the proximal end and better representation of sutures between textiles and stents is needed. In this work, we believe that the blood flow impact can be ignored when compared to the normal forces applied by the spring action when the stent has just been deployed. Modeling the blood flow using fluid-structural interaction [21] [22] would be necessary to confirm the risk of endoleaks and to assess the consequences of kinks. The arterial wall could include anisotropy [23], calcifications, and thrombus Patient-specific constitutive mechanical properties could also be better characterized using dynamic imaging for more accurate patient-specific results. The results of the simulated stent grafts in patient-specific aneurysms should be compared to clinical studies with post-operative CT-scans.

CONCLUSION

In this research project, a novel realistic stent-graft deployment method was proposed and developed. This consisted of gradually deploying the stent by either sliding the catheter or expanding it in subsets. The present study suggests that precise and relevant information on SG behaviour deployed within arterial models may be provided by numerical simulation. This can be used to better anticipate the formation of kinks at the edges of arteries as described in [19]

With these new methods, more realistic and stable simulations can be obtained than with previous deployment techniques. The RSD deployment method, which was more stable, did indeed influence the mechanical behavior, positioning, and eventually, the functioning of the stent-graft when compared with the traditional deployment methods.

The work on improving patient-specific simulation techniques will help improve medical treatments of aneurysms using stents. This tool was created to be easily adapted to any aneurysm geometry and stent size or design, thus opening a wide range of research possibilities where these techniques can be applied and for this deployment technique to become the new norm in stent FEA deployment. The present model has interesting applications in the field of preclinical testing of new SG prototypes. FE analyses have the advantage of infinite possibilities of models of various SGs and aneurysm configuration. While modeling in test bench experiments is restricted by the limited quantity of available prostheses and aneurysm models.

Another major application would be patient-specific prediction of EVAR intra and/or post-operative complications. Previous works have started working toward this ultimate goal [23].

This tool will eventually allow researchers to improve the design and choice of patient-specific stents, which, during endovascular deployment, would behave more closely to the behaviour predicted

by the numerical simulations. This could be confirmed only after intensive clinical and experimental verifications.

HIGHLIGHTS

Two novel deployment methods were developed as part of this research work: VGES: Virtual Gradual Expansion in and RSD: Realistic stent deployment by translating the catheter along the barycentre line of the aorta.

VGES was considered unstable and the need to find the optimal number of subsets to ensure convergence. This led the focus on the development of (RSD) method.

The RSD deployment method, which was more stable, did indeed influence the mechanical behaviour of the stent-graft when compared with the traditional deployment methods.

The impact of including the graft on the mechanical behaviour of the stent/aorta was minimal.

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