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Abstract

Objective

During endovascular aneurysm repair (EVAR), complex iliac anatomy, is a source of complications such as unintentional coverage of the hypogastric artery. The aim of our study was to evaluate ability to predict coverage of the hypogastric artery using a biomechanical model simulating arterial deformations caused by the delivery system.

Methods

The biomechanical model of deformation has been validated by many publications. The simulations were performed on 38 patients included retrospectively, for a total of 75 iliac arteries used for the study. On the basis of objective measurements, two groups were formed: one with "complex" iliac anatomy (n=38 iliac arteries), the other with "simple" iliac anatomy (n=37 iliac arteries). The simulation enabled measurement of the lengths of the aorta and the iliac arteries once deformed by the device. Coverage of the hypogastric artery was predicted if the deformed renal/iliac bifurcation length (Lpre) was less than the length of the implanted device (Lstent-measured on the post-operative CT) and non-deformed Lpre was greater than Lstent.

Results

Nine (12%) internal iliac arteries were covered unintentionally. Of the coverage attributed to peri-operative deformations, 1 case (1.3%) occurred with simple anatomy and 6 (8.0%) with complex anatomy (p=0.25). All cases of unintentional coverage were predicted by the simulation. The simulation predicted hypogastric coverage in 35 cases (46.7%). There were therefore 26 (34.6%) false positives. The simulation had a sensitivity of 100% and a specificity of 60.6%. On multivariate analysis, the factors significantly predictive of coverage

were the iliac tortuosity index (p=0.02), the predicted margin between the termination of the graft limb and the origin of the hypogastric artery in non-deformed (p=0.009) and deformed (p=0.001) anatomy.

Conclusion

Numerical simulation is a sensitive tool for predicting the risk of hypogastric coverage during EVAR and allows more precise pre-operative sizing. Its specificity is liable to be improved by using a larger cohort.

INTRODUCTION

The widespread uptake of endovascular aneurysm repair (EVAR) for abdominal aortic aneurysms (AAAs) has given rise to complications specific to this technique. The most well-known complications are those that occur a while after the surgical procedure, such as endoleaks. However, there are some complications that can occur during the procedure itself and are independent of both the technique employed and the surgeon. These are complications specifically linked to use of stent grafts for treating aortic disease, given that such procedures attempt to achieve the closest fit possible between the patient's anatomy and the implanted device. In the last few years, planning tools such as sizing software have advanced considerably, providing several reconstructions and advanced measurements that permit a better appreciation of the patient's anatomy and hence optimization of device selection and the operative strategy to use.

Currently, complex anatomy represents the primary challenge for stent graft treatments given that the size of the eligible patient population is only limited by anatomy. Complex anatomy is problematic not only for the durability of the seal but also because, during the procedure, the rigid ancillary tools required to implant the stent graft cause some degree of anatomical deformation, which can modify the anatomy as perceived, or even precisely measured, before the procedure and as used to select the device to implant.

More specifically, the anatomy of the iliac arteries is highly variable between patients, with features such as calcification, tortuosity and angulation, which can also be present together. These arteries are subject to the greatest stress when the stent graft is placed (1) and can give rise to specific complications such as unintentional coverage of the internal iliac artery — this complication illustrates the above-mentioned paradox: although pre-operative anatomy is studied in detail to allow optimal selection of the stent graft, there are no specific tools

available with which to predict the behavior of the landing zones, particularly when the stent graft is definitively delivered.

In previous work (2,3), we showed that a numerical finite element simulation enabled quantification and localization of peri-operative deformations and, after comparing pre-operative and actual, peri-operative data in 28 patients, we could conclude that we had a reliable and validated biomechanical model for predicting peri-operative deformation. The aim of the present study was to evaluate the predictive performance of this model with regard to unintentional coverage of the internal iliac artery during placement of an aortic stent graft in the treatment of AAA.

MATERIALS AND METHODS

The protocol and informed consent form were approved by the local institutional review board, and all subjects gave informed consent. This was a retrospective study that compared the anatomy of iliac arteries defined in two groups: “simple anatomy” vs. “complex anatomy”. Each iliac was considered as a specific case. Iliac arteries were assigned to one of these two groups on the basis of their anatomic complexity, as determined using the Society for Vascular Surgery’s severity grading system (4), described below.

Analysis of pre-operative CT scan and definition

Measurements used to categorize patients

For each patient, the centerlines of the vasculature were extracted from the pre-operative CT scan (EndoSize®; Therenva, France). Pre-operative CT data were analyzed and the following variables were calculated in order to describe pre-operative iliac morphology and to use the SVS grading system:

- Iliac tortuosity index: the ratio between the length as measured by the centerline and the length of the shortest, straight-line path
- Maximal iliac angulation: measured using a 3D reconstruction
- Percentage of iliac calcification: determined using a specific measuring tool based on grayscale values of the Hounsfield scale (5)

A severity grade of 0 to 3 was assigned to each calculated value, as per Chaikof’s standards.

Measurements used to test simulation performance

The distance between the lowest renal artery and the ostium of the internal iliac artery measured using the centerline was called L_{pre}. This length corresponded to the maximum

theoretical deployment zone of the stent graft without coverage of collaterals (renal or internal iliac arteries).

Analysis of post-operative CT scan

Centerlines were also extracted, with the stent graft in place, from the post-operative CT scan at 1 month. The first measurement, $L_{post,}$ was the length from the lowest renal artery to the ostium of the internal iliac artery. The second measurement, L_{stent}, was the length from the lowest renal artery to the distal extremity of the graft limbs; this length corresponded to the length of the stent graft in situ.

Group formation

Patients were included in a non-interventional clinical research protocol, accepted by the institutional review board of Rennes University Hospital (April 2016) and the French national data protection agency (CNIL). Patients were included either prospectively (written consent obtained over a 12-month inclusion period) or retrospectively (a letter was sent to these patients and they did not provide written objection to retrospective participation in the study). All patients eligible for endovascular repair of an AAA with a 3rd-generation stent graft could be included. Patients who died or with intentional coverage of the internal iliac artery, decided pre-operatively, were excluded. Patients whose CT scans had a slice thickness greater than 1 mm and/or showed heterogeneous arterial enhancement of the aorta and the iliac arteries were not included. The selection of the stent graft was completely independent of the study, being entirely at the surgeon's discretion.

In order to achieve the same number of patients in both groups, the complex anatomy group was formed first. These patients had to have a severity grade of 2 or 3 for at least one of the three measured iliac variables for one or both of their iliac arteries. When a complex anatomy patient was selected, the next patient (in terms of the procedure date) was selected for the

simple anatomy group if they fulfilled the criteria, namely a severity grade of 0 or 1 for the three measured iliac variables for both iliac arteries.

Numerical simulation

The modeling and simulation method used was described then validated in two previous publications using peri-operative data from 28 patients.

Using the simulation system, it was possible to model the configuration of the vascular tree deformed by the presence of rigid guide wires and the delivery system (using the patient's pre-operative CT scan). A simulation was performed for each patient, on the right then on the left sides. Next, the deformed vascular tree was analyzed in terms of centerline length. The renal-hypogastric length after insertions of the rigid guide wire and delivery system was measured on both sides: L_{peri}. This length could then be compared to the implanted device in situ (L_{stent}).

Prediction of residual length

The post-operative residual length (length of uncovered iliac artery) was calculated as the difference between Lpost and Lstent and corresponded to the zone of the common iliac artery not covered by the stent graft. A negative value represented coverage of the internal iliac artery. The simulated residual length, computed from the model of the aorta deformed by the presence of the stent graft delivery system and rigid guide wire, was also computed. The post-operative residual length was analyzed by a statistical predictive model in order to identify the potential predictive variables from pre-operative anatomical and numerical simulation data.

Prediction of internal iliac coverage

The simulation predicted coverage of the internal iliac on the basis of two essential conditions: the deformed renal/iliac bifurcation length (L_{peri}) was less than the length of the

implanted device (L_{stent}); and L_{pre} was greater than L_{stent}. If L_{pre} was less than L_{stent} and L_{peri} less than L_{stent}, then a sizing error had occurred (Figure 1).

Statistical analysis

The first analysis focused on the prediction of the post-operative residual length. Univariate analyses were used to estimate the influence of pre-operative and simulation parameters.

Descriptive analysis and univariate analysis were performed using the $\chi 2$ test, Fisher's test, Student's test or Pearson correlation, as appropriate. Parameters with a significance lower than 0.2 were included in a multivariate analysis performed using multiple linear regression and an iterative approach to select the best attributes.

The second analysis gave rise to a simple strategy for evaluation based on a pre-operative simulation of risks. By focusing on the presence or absence of coverage (post-operative residual length < 0), the goal was to identify the subgroups of patients at high risk of complications. The residual lengths predicted by simulating insertion of stiff tools were directly used for risk stratification. The confusion matrices and ROC curves were thus calculated using a threshold set at 0 for the estimated lengths.

Analyses were performed with the software program R (The R foundation for statistical computing, 2009).

RESULTS

The study included 38 patients (mean age: 77.8 ± 8.1 years). Given that one patient had received an aortomonoiliac stent graft, a total of 75 iliac arteries were studied and simulated, 66 of which (88%) were from men. Thirty-seven and thirty-height iliac arteries (49.3%) were assigned to the simple and complex anatomy groups, respectively (Table 1). There were no significant differences in implanted stent grafts between groups (Table 2, p=0.065).

Prediction of post-operative residual length

Parameters related to iliac anatomy and patient demographic data were included in the univariate analysis (Table 3), along with the pre-operative and simulated residual lengths. From the usual pre-operative anatomical and demographic variables, only the iliac angle score ($R = 0.33$, $p = 0.04$) could predict the post-operative residual length. The simulated residual length showed higher predictive value ($R=0.75$, $p<0.001$) than the pre-operative residual length ($R = 0.62$, $p < 0.001$). In the multivariate analysis, four variables were shown to be significantly predictive: the pre-operative residual length (p=0.009), the simulated residual length (p=0.001), the tortuosity score (0.0224) and the angulation score (0.0587). There was a high correlation between the simulated and post-operative residual length (Figure 2).

Prediction of internal iliac coverage

Among the 75 iliac arteries, there were 9 cases (12%) of unintentional internal iliac coverage, two of which were due to sizing error. Of the 7 cases attributed to peri-operative deformation, 1 (1.3%) occurred in the simple anatomy group and 6 (8.0%) in the complex anatomy group (p=0.25). After comparison of the real and simulated situations, there was a correspondence between simulated and real internal iliac coverage (Figure 3). All iliac arteries covered accidentally were also covered in the simulation. The sensitivity of the simulation was 100%.

196 The simulation predicted internal iliac coverage in 35 cases (46.7%). Hence there were 26
197 (34.6%) patients who had internal iliac coverage in the simulation but not in reality. The
198 specificity of the simulation was 60.6%. Coverage of the internal iliac artery (yes/no) via the
199 difference in the residual length after insertion of the delivery system/length of the stent graft
200 in situ (L_{post}) was predicted with an area under the curve of 0.91 (Figure 4).

201

DISCUSSION

In this article, we describe the use of simulation to predict a complication during the surgical procedure. The simulation models deformable anatomy (a property of soft tissues such as arteries) and its interactions with rigid materials. The current version of the numerical model focuses on the consequences of deformation during the aortic endovascular procedure, which are two-fold. First, by reducing arterial length, deformations have an impact on calibration. This illustrates the paradox of current practice whereby planning is based on an arterial volume that has different dimensions when the stent graft is deployed. This paradox is a source of complication and error. The exact quantification of deformation-related shortening is difficult and not based on statistical data. Coverage of internal iliac arteries is responsible for buttock claudication and even pelvic ischemia (6–9) so must be avoided at all costs, but it presents enormous planning challenges in complex anatomy. Such coverage could be related to a sizing error, as occurred with two patients included in the present study, but it is more often related to deformations of the aortoiliac vasculature caused by insertion of rigid material such as the rigid guide wire and the stent graft delivery system.

In our study, we set ourselves the task of predicting the residual length of the common iliac artery, i.e. the length not covered by the stent graft, because it is one of the variables that every surgeon intuitively attempts to control for when choosing the length of the stent graft to implant. To achieve a realistic model, we decided to determine the length of the stent graft on the basis of the post-operative CT scan rather than using the value in the catalog. There is indeed a difference between catalog length and in situ length. Our study showed that no single anatomical variable is able to predict the post-operative residual length without the aid of simulation. The most predictive variable was the residual margin between the extremity of the graft limb and the ostium of the internal iliac, in an aorta deformed by the stent graft delivery

system. This result highlights the utility of simulation when planning EVAR. Finally, in this study of a highly specific clinical complication — coverage of the internal iliac — the results showed that simulation alone is capable of predicting this risk with a robust model (ROC curve). The clinical relevance of this study was to predict coverage of the internal iliac artery. All cases of unintentional coverage were predicted by the numerical simulation. In clinical practice, this simulation model could play an important role in reducing iliac complications during EVAR procedures.

Whittaker *et al.* (10) proposed an algorithm to predict the length of the stent graft modified during the EVAR procedure; however their model was based on pre- and post-operative CT data, whereas peri-operative data are more precise for preventing and predicting peri-operative complications. Iliac tortuosity is known to be a source of complications during or after EVAR and represents a difficult aspect of the procedure. In our previous works (2,3), we showed that the reliability of our model extended to complex cases. Conformation of aortic stent grafts has already been studied by comparing *in vitro* or *in vivo* models with a numerical simulation (11–13), and it was shown that stent graft behavior could be anticipated from the anatomy, notably in cases of complex anatomy.

The second consequence of deformation during EVAR procedures concerns the precision of rigid registration in fusion imaging. It is currently accepted in several articles (1,14) that deformation represents the leading source of registration error when the pre-operative CT scan is laid over the 2D fluoroscopic image. It is the primary factor limiting fusion imaging. With the aid of a numerical deformation model, the precision of fusion can be improved, helping to achieve precise positioning of the graft limbs (Figure 5).

Another approach to gain precision would be to perform intra-operative length measurements, using for instance a calibrated pigtail catheter after the introduction of stiff guide-wire, and integrate these data into new predictive models or refine previous ones.

Our study has several limitations. The number of patients is small; it is probable that a greater number of patients would improve the robustness of the model (its specificity, among other aspects). The incidence of complex anatomy was low and we were not able to include more patients from our center fulfilling the study criteria. There may also be a selection bias, as patients with too complex iliac anatomy could have undergone open surgery. However, at our center, since the emergence of 3rd-generation stent grafts, iliac access has not been a contraindication to EVAR, with the exclusion of iliac occlusion. At our center, contraindications to EVAR only concern the proximal neck (length < 10 mm). Improvements in the profile of stent grafts have allowed procedures with stenosed and tortuous access vessels, sometimes with additional steps such as paving and cracking when applicable. This is why we did not retrospectively include patients at our center treated with 2nd-generation stent grafts. Complex anatomy therefore represents a veritable clinical challenge. Obviously, there are solutions for better appreciating deformations, for example taking peri-operative iliac measurements using graduated markings on the rigid guide wire, but this technique carries with it the risk of parallax error, which is greater with tortuous iliac arteries.

One unresolved issue, whose existence provides the impetus for us to continue working on numerical simulation, is the behavior of the iliac artery after delivery of the stent graft and withdrawal of the rigid guide wire. In our practice, we have observed that sometimes the anatomy (even sometimes tortuous anatomy) reverts to its initial form and sometimes it does not. This behavior is multifactorial and probably difficult to predict because it also depends on the implanted stent graft and its biomechanical characteristics. Our simulation model should therefore simulate delivery of the stent graft, and take into account the overlapping of

different modules and the different brands of stent graft. Reaching this point requires a significant technical and scientific leap forward. This is why we initially decided that data from deformation by one guide wire and one delivery system were sufficient to develop a reliable, robust and precise tool for predicting peri-operative arterial behavior. Other applications under study include the displacement of ostia of renal and gastrointestinal arteries during placement of a fenestrated stent graft, which poses problems, not only for sizing, but also for peri-operative positioning of the stent graft and catheterization. Transfer to other centers remains a problem. However it is possible to simplify the model without sacrificing precision so that it becomes less time-consuming to use and can be integrated into sizing programs used routinely in clinical practice.

CONCLUSION

Evaluation of surgical risk is a constant concern for surgeons. Numerical simulation provides precise information about arterial biomechanical behavior during implantation of an aortic stent graft. Complex anatomy is associated with a higher incidence of peri-operative iliac complications due to deformation. Simulation models deformations and could provide quantitative information that would reduce the risk of complications.

Acknowledgments

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Legends for figures

Figure 1: Definition of prediction of coverage. Lpre is the renal- iliac length without deformation, Lperi is the same length adjusted by simulation and after deformation, and Lstent is the length of the stentgraft in situ measured on postoperative CT scan.

Figure 2

Prediction of the post-operative (real) residual length: calibration plot

Figure 3

Distribution of false positive (FP), true positive (TP), false negative (FN) and true negative (TN), based on the post-operative (real) and simulated (predicted) residual length.

Figure 4

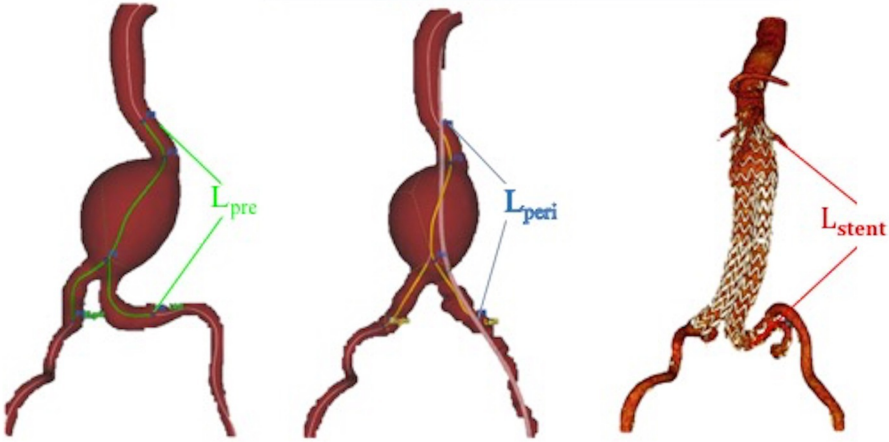
ROC curve using logistic regression

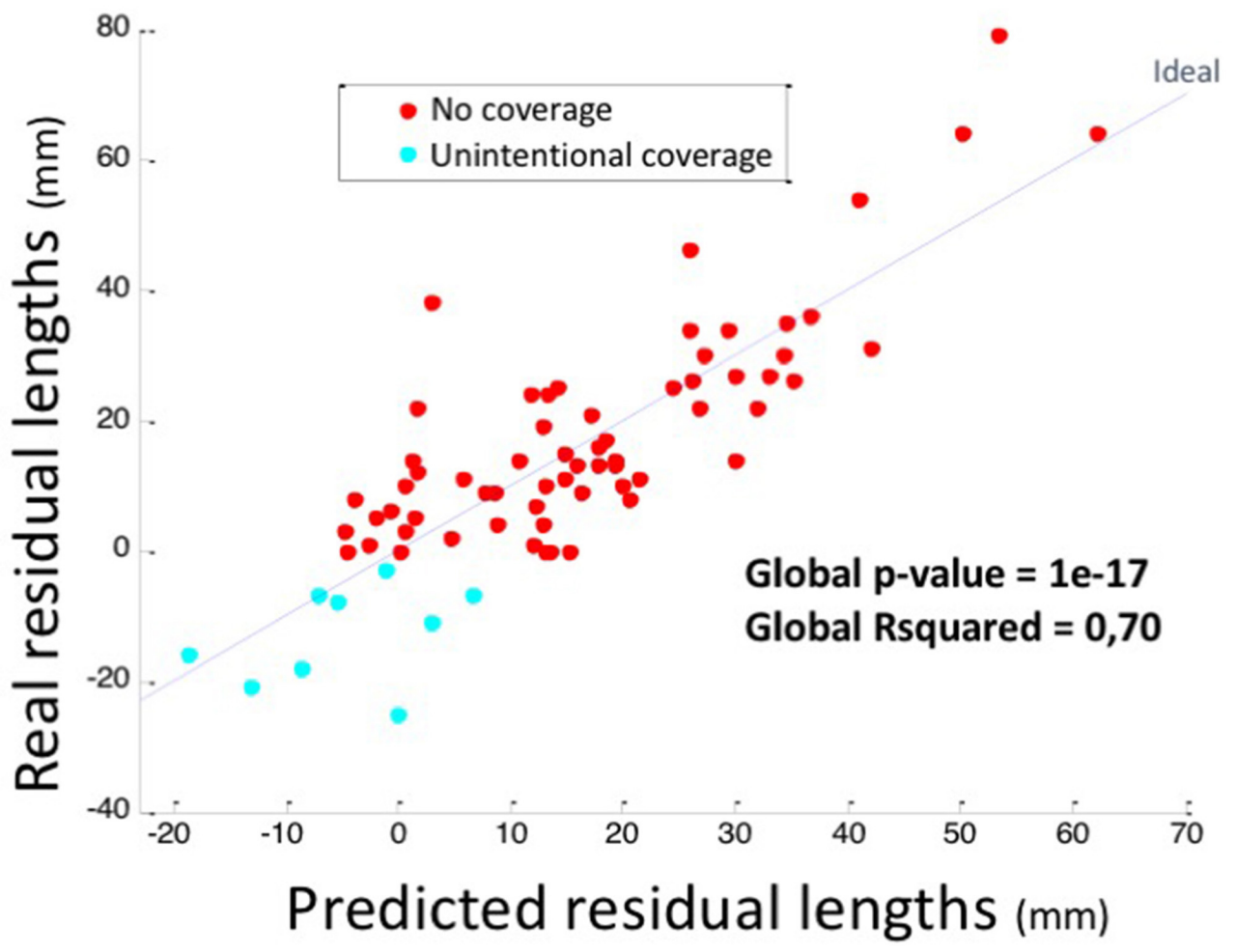
Figure 5

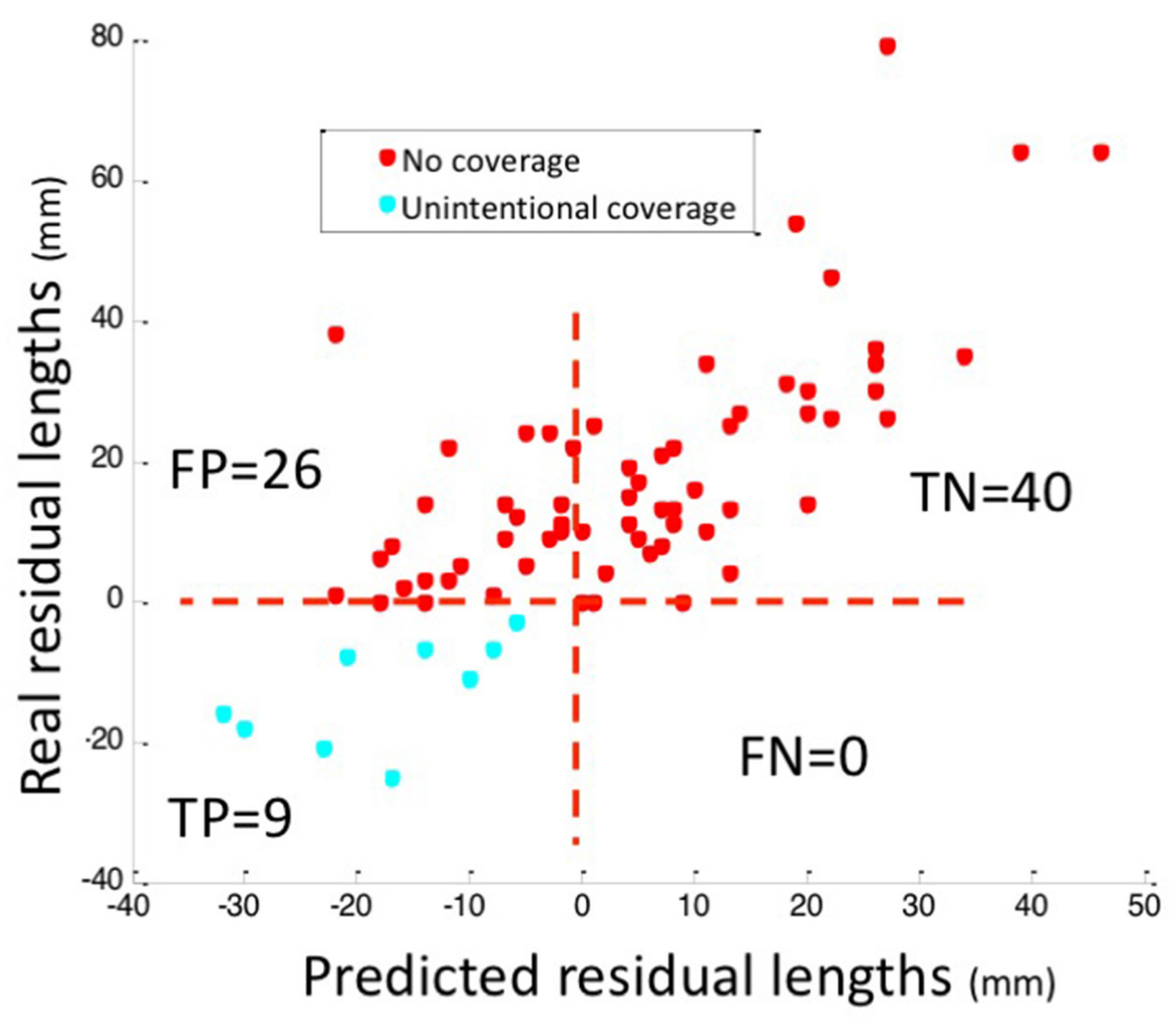
Application of simulation in endovascular navigation for fusion imaging. Fluoroscopic image with the fusion of the 3D preoperative anatomy without deformation (A) and the same image with deformation

If $L_{stent} > L_{peri}$ AND if $L_{stent} < L_{pre}$ = ***prediction of coverage***

If $L_{stent} > L_{pre}$ = ***sizing error***




Ideal
No coverage
Unintentional coverage
Global p-value = 1e-17
Global Rsquared = 0,70
Real residual lengths (mm)
Predicted residual lengths (mm)
80
60
40
20
0
-20
-40
-20
-10
0
10
20
30
40
50
60
70


No coverage
Unintentional coverage
FP=26
TN=40
FN=0
TP=9
Real residual lengths (mm)
Predicted residual lengths (mm)
80
60
40
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0
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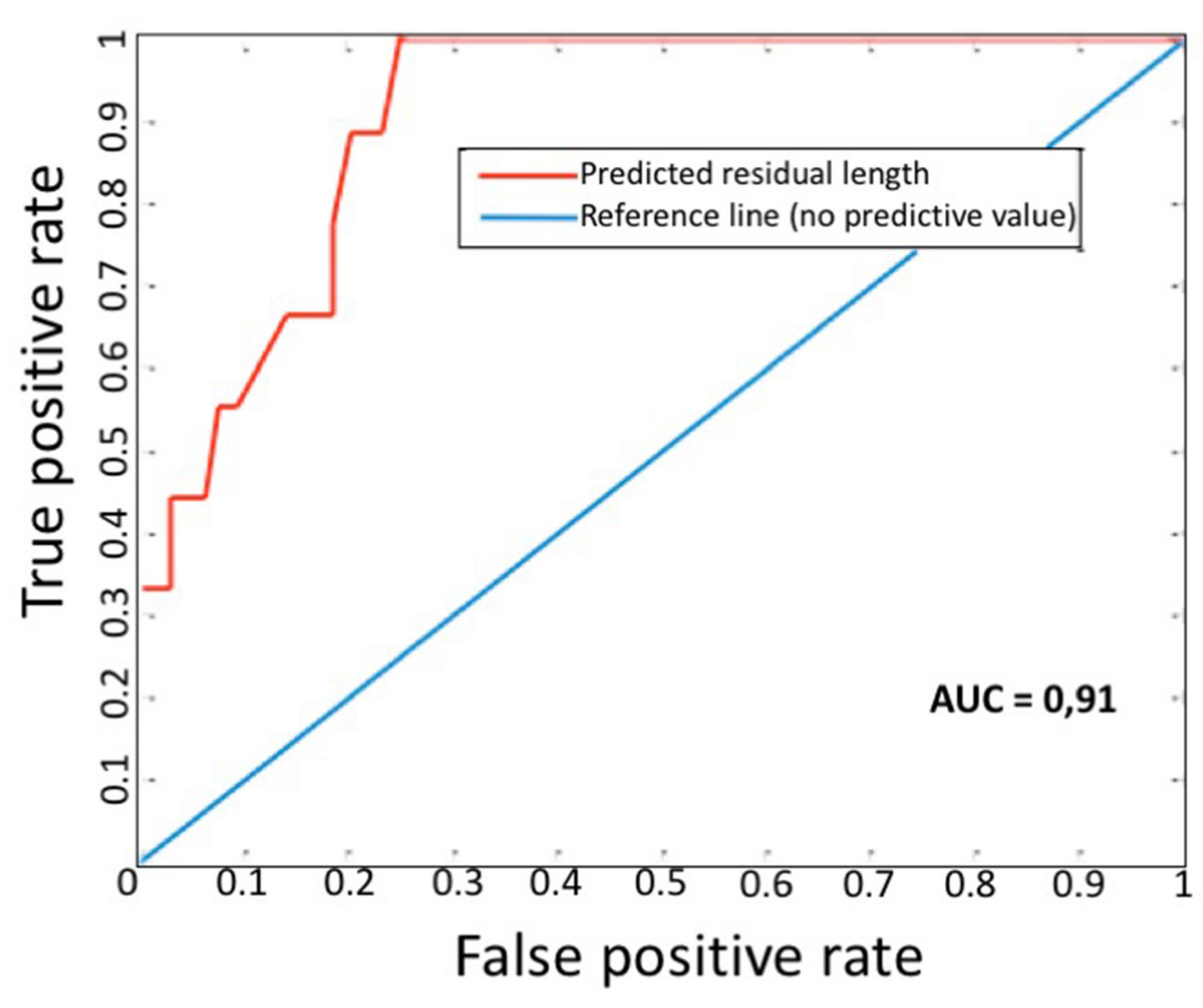
-30
-20
-10
0
10
20
30
40
50


True positive rate
False positive rate
Predicted residual length
Reference line (no predictive value)
AUC = 0,91
0
0.1
0.2
0.3
0.4
0.5
0.6
0.7
0.8
0.9
1

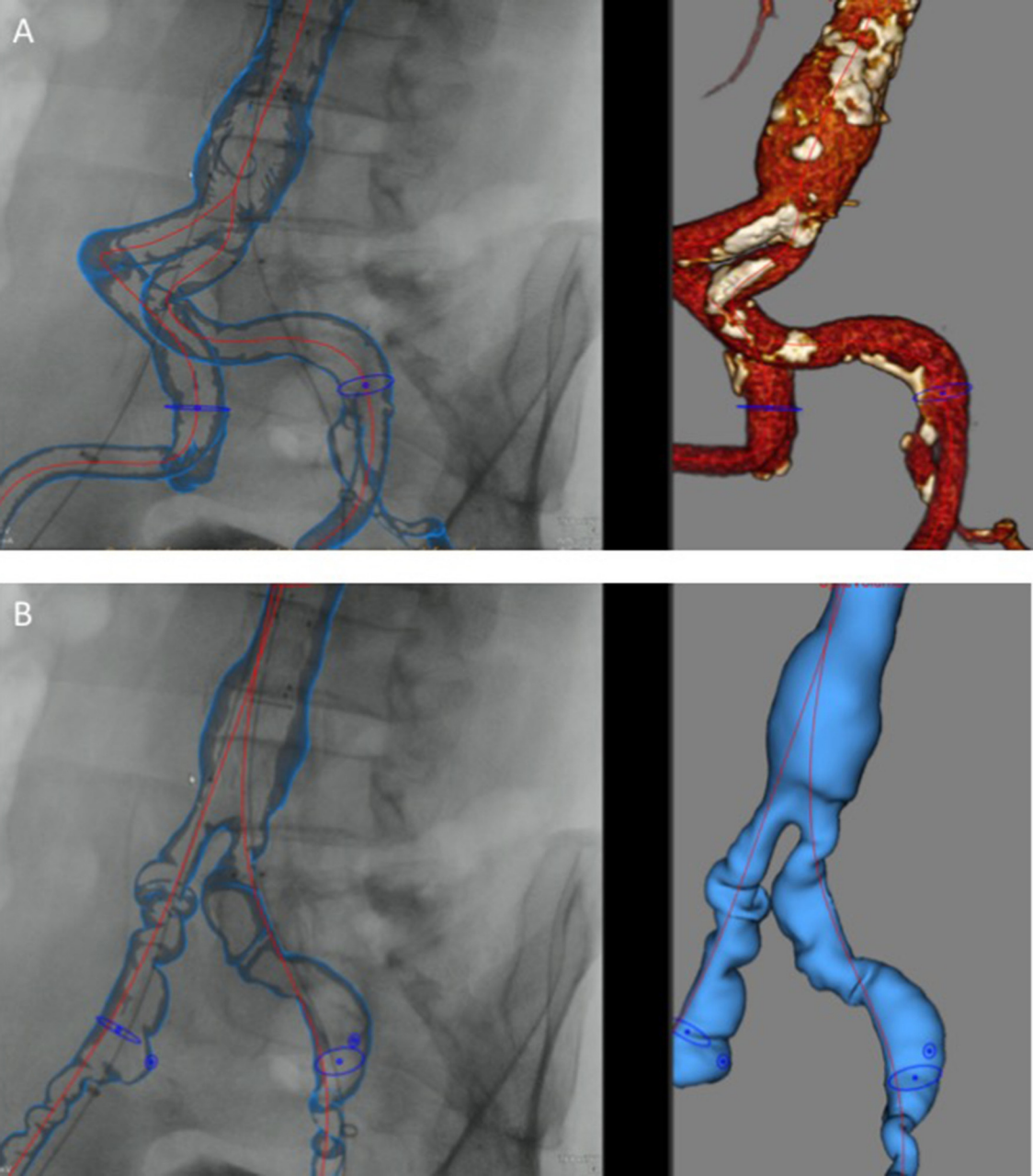

A
B

Table 1: Descriptive analysis: comparison of demographic and anatomical parameters between groups

	Simple anatomy (n=37)	**Complex anatomy (n=38)**	***p***
Pre-operative aorto-iliac length (cm, mean ± SD)	176.9 ± 17.9	194.6 ± 21.2	<0.01
Age (Years, mean ± SD)	77.1 ± 8.2	77.8 ± 8.1	0.45
Sex (male, number (%))	31 (83,8%)	35 (92,1%)	0.15
Iliac tortuosity index (mean ± SD)	1.34 ± 0.09	1.54 ± 0.17	<0.01
Tortuosity score (number (%))			<0.01
0 (index<1.25)	6 (16.2%)	2 (5.3%)	
1 (1.25<index<1.5)	31 (83.8%)	10 (26.3%)	
2 (1.5<index<1.6)	0 (0%)	14 (36.8%)	
3 (index>1.6)	0 (0%)	12 (31.6%)	
Maximal iliac angle (mean ± SD)	142 ± 13.27	107.58 ± 19.83	<0.01
Iliac angle score (number (%))			<0.01
0 (160°-180°)	3 (8,1%)	0 (0%)	
1 (121°-159°)	34 (91.9%)	11 (28.9%)	
2 (90°-120°)	0 (0%)	19 (50%)	
3 (<120°)	0 (0%)	8 (21%)	
Iliac calcifications (mean ± SD)	20% ± 0.15	16% ± 0.14	<0.01
Calcification score (number (%))			<0.01
0 (none)	0 (0%)	4 (10.5%)	
1 (<25% vessel length)	28 (75.7%)	26 (68.4%)	
2 (25% - 50% vessel length)	7 (18.9%)	8 (21.1%)	
3 (>50% vessel length)	2 (5.4%)	0 (0%)	

Table 2: Repartition of the implanted stentgrafts according to groups

	Cook - Zenith alpha	Endologix - AFX	Gore - Excluder C3	Medtronic - Endurant II
Simple anatomy	10	4	6	17
Complex anatomy	12	3	0	23
Total	22	7	6	40

Table 3: Prediction of the post-operative residual length: univariate analysis.

	total (n=75)	***p***
Pre-operative aorto-iliac length (cm, mean ± SD)	185.9 ± 21.4	0.06
Age (Years, mean ± SD)	77.4 ± 8.1	0.57
Sex (male, number (%))	66 (88%)	0.34
Iliac tortuosity index (mean ± SD)	1.44 ± 0.17	0.73
Tortuosity score (number (%))		0.09
0 (index<1.25)	8 (10.7%)	
1 (1.25<index<1.5)	41 (54.7)	
2 (1.5<index<1.6)	14 (18.7%)	
3 (index>1.6)	12 (16%)	
Maximal iliac angle (mean ± SD)	125 ± 24.27	0.12
Iliac angle score (number (%))		0.04
0 (160°-180°)	3 (4%)	
1 (121°-159°)	45 (60%)	
2 (90°-120°)	19 (25.3%)	
3 (<120°)	8 (10.7%)	
Iliac calcifications (mean ± SD)	18% ± 0.15	0.51
Calcification score (number (%))		0.35
0 (none)	4 (5.3%)	
1 (<25% vessel length)	54 (72%)	
2 (25% - 50% vessel length)	15 (20%)	
3 (>50% vessel length)	2 (2.7%)	
Pre-operative residual length*	24.5 ± 19.9	<0.01
Simulated residual length**	0.5 ± 17.9	<0.01

* Difference between Lpre and Lstent
** Difference between Lperi and Lstent