



A Comparison of Manual and Three-Dimensional Modalities in Predicting Nellix Polymer Volume

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Purpose: Achieving an effective seal with the Nellix endovascular aneurysm system is dependent on filling the stent bags with an appropriate volume of polymer. Calculating this volume preoperatively is essential and can be performed manually or using three-dimensional (3D) software. The aim of this project was to compare the accuracy of these two methods relative to the actual polymer volume used.

Materials and Methods: Consecutive patients undergoing Nellix aneurysm repair were included in this retrospective study. Operation notes were analysed for the polymer volume used intra-operatively. Predicted volumes for all patients had been calculated on picture archiving and communication system (PACS) using a manual 'segmental cylinder' method. Computed tomography angiograms were then re-analysed using the Synapse 3D PACS update. The difference between groups was assessed using a paired t-test.

Results: Twenty-eight patients were included in the analysis; 26 men (92.9%) and 2 women (7.1%); median age 80.9 years (interquartile range, 72.5-84.5 years). The mean volume of polymer used was 103 mL. The mean manual-derived prediction was 100.1 mL ($P=0.365$) and 3D-derived prediction 110.2 mL ($P<0.001$). Manual prediction led to an average 2.8% underestimate of polymer volume whilst 3D prediction led to an average 7.0% overestimate.

Conclusion: Calculating predicted polymer volume for the Nellix system is more accurate using a manual approach than the 3D alternative. Whilst this method is more time-consuming, there is no significant difference when compared to the actual volume used. Quicker 3D software predictions can be utilised, but their tendency to overestimate should be recognized and taken into account during planning.

Key Words: Endovascular sealing, Nellix graft, Polymers, Computed tomography, Three-dimensional

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INTRODUCTION

Endovascular aneurysm sealing (EVAS) is a novel alternative to endovascular aortic aneurysm repair in the treatment of aneurysmal disease of the abdominal aorta.

The Nellix system consists of two identical catheter-

based devices with a 10-mm flow lumen being created by two balloon-expandable polytetrafluoroethylene-covered cobalt-chromium stents. The stents are surrounded by polyurethane endobags. The system used for management of abdominal aortic aneurysm (AAA) repair and the idea of having endobags which are filled with a polymer that hard-

ens and sets within the aneurysm sac is to prevent type 2 endoleak.

Calculating this polymer volume preoperatively is important to ensure adequate stocks are defrosted for the procedure and the bags are not significantly over- or under filled.

There are two ways of measuring the volume: manual and three-dimensional (3D)-derived. Each involves quantifying the aneurysm flow lumen and subtracting the stent volume to give an estimate of polymer requirements.

The aim of this project was to compare the accuracy of manual and 3D-derived predictions relative to actual polymer volume used in EVAS cases.

MATERIALS AND METHODS

Consecutive patients undergoing Nellix aneurysm repairs at a single vascular institute over one year (2016-2017) were included in this retrospective study.

Institutional Review Board approval was waived on all data analysis and patient consent was not obtained, given that all data are anonymous and no patient identifiers are collected plus retrospective nature of the study.

The manual method involves splitting an aneurysm into rudimentary cylindrical-shaped segments based on computed tomography (CT) morphology. The height and radius

of the cylinders can be measured on coronal and axial image slices. Each cylinder volume is then calculated using the formula $V = \pi r^2 h$ and total luminal volume predicted by combining individual cylinders. Measurements were made using the flow lumen and ignoring thrombus (Fig. 1).

The 3D-derived method uses Synapse picture archiving and communication system (PACS) updates to automatically calculate the volume of contrast within an aneurysm. After importing CT angiogram series into Synapse, a 3D reconstruction of the aneurysm is formed. The contrast within the flow lumen is automatically stained orange and the software to calculate aneurysm luminal volume uses this. Again, thrombus is ignored by this method (Fig. 2).

Actual polymer volumes used intra-operatively and manual predicted volumes were recorded from operation notes and planning documents. Preoperative CT angiograms were then re-analysed using the Synapse 3D PACS update to calculate 3D-derived predictions.

1) Statistics

Data were statistically described in terms of mean standard deviation, and range, or frequencies (number of cases) and percentages when appropriate. Comparison between the different estimation methods and the operative real volume was done using paired t-test in normally distributed

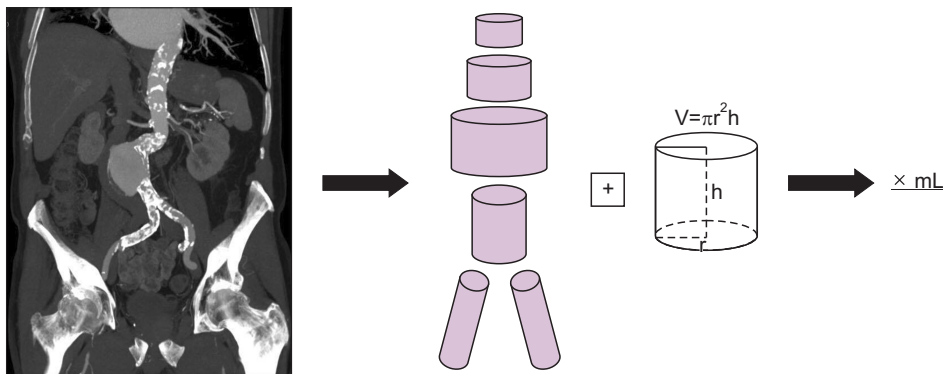


Fig. 1. Manual method for calculating Nellix polymer volume.

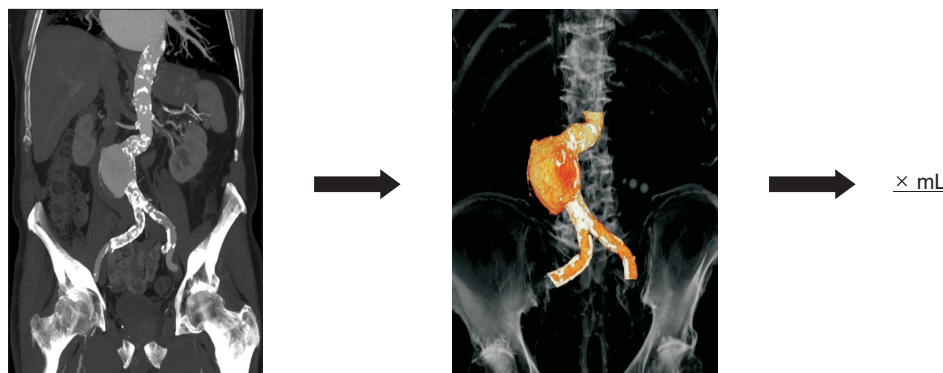


Fig. 2. Three-dimensional-derived method for calculating Nellix polymer volume.

data and Wilcoxon signed rank test for paired (matched) samples when data are not normally distributed. For comparing categorical data, Chi-square (χ^2) test was performed. Exact test was used instead when the expected frequency is less than 5. Correlation between various variables was done using Pearson moment correlation equation for linear relation in normally distributed variables and Spearman rank correlation equation for non-normal variables/non-linear monotonic relation. A P-value less than 0.05 was considered statistically significant. All statistical calculations were done using computer program IBM SPSS Statistics ver. 19.0 software (IBM Co., Armonk, NY, USA) release 15 for Microsoft Windows 2006 (Microsoft, Redmond, WA, USA).

RESULTS

Twenty-eight patients were included in the analysis; 26 men (92.9%) and 2 women (7.1%); median age 80.9 years (interquartile range, 72.5-84.5 years). Twenty-six patients underwent an elective AAA repair (92.9%) out of them 2 chimney EVAS (7.1%) has been done and 2 patients had an emergency EVAS for rupture AAA (7.1%) (Table 1).

The mean volume of polymer used was 103 mL. The mean manual-derived prediction was 100.1 mL (P=0.365) and 3D-derived prediction 110.2 mL (P<0.001). Manual prediction led to an average 2.8% underestimate of polymer volume whilst 3D prediction led to an average 7.0% overestimate (Table 2, 3).

Manual calculations took longer time comparing to 3D-

derived calculations particularly in tortuous and less fusiform aneurysms.

DISCUSSION

EVAS is a simple endovascular technique that permits more rapid aneurysm exclusion than a bifurcated modular system, but there is a learning curve and adaptations in technology and deployment techniques with time, which means that there is a relative paucity of high-quality pub-

Table 1. Demographics, AAA anatomy and device type

Value	Patient (n=28)
Age (y)	80.9±5.596
Male	26 (92.9)
Aortic aneurysm neck length	
<15 mm	2 (7.1)
>15 mm	26 (92.9)
Asymptomatic AAA	26 (92.9)
Symptomatic AAA	1 (3.6)
Rupture AAA	1 (3.6)
Type of repair	
EVAS	26 (92.9)
Ch-EVAS	2 (7.1)

Values are presented as mean±standard deviation or number (%). AAA, abdominal aortic aneurysm; EVAS, endovascular aneurysm sealing; Ch-EVAS, chimney endovascular aneurysm sealing.

Table 2. Difference between manual and 3D volume in comparison to real volume

	Minimum	Maximum	Mean	SD
Age (y)	70	92	80.86	5.596
Manual volume (mL)	47	186	100.14	37.115
3D volume (mL)	52	225	110.18	45.560
Real volume (mL)	34	214	103.00	46.600
Manual volume % difference (mL)	-29	41	1.11	15.643
3D volume % difference (mL)	-8	53	9.48	11.501

3D, three-dimensional; SD, standard deviation.

Table 3. Paired samples test

		Paired differences					t	df	P-value
		Mean	Standard deviation	Standard error mean	95% confidence interval-difference				
					Upper	Lower			
Pair 1	Manual volume-Real volume	-2.857	16.436	3.106	-9.230	3.516	-0.920	27	0.366
Pair 2	Three-dimensional volume-Real volume	7.179	7.399	1.398	4.310	10.048	5.134	27	0.000

df, degrees of freedom.

lished outcome data [1].

Outcomes in the industry-sponsored US pivotal trial and the EVAS Forward Global Registry seem encouraging [2]. However, caudal migration and type 1 endoleak has been a concern as Nellix device does not have active fixation and device stability is achieved from stent and endobags complex occupying all of the available space [3].

Precise estimation of polymer volume required to fill the aneurysm space might help to reduce the incidence of graft migration, as it is the main pillar for stability of Nellix graft. The goal of this retrospective study is to compare 3D and manual calculation of polymer volume to real intraoperative polymer volume in order to identify the most accurate method for calculation of polymer volume. Knowing the right volume of polymer preoperatively will help to achieve device stability and also reduce the cost of the procedure by decrease the amount of polymer used.

There is no statistically significant difference between manually calculated polymer volumes and actual volumes

used in Nellix EVAS cases. In contrast, 3D-derived predictions for polymer volume overestimate the amount required by almost 7% and are significantly different from the actual volumes recorded ($P < 0.001$).

The reason why the 3D method overestimates the volume of polymer is unknown, few studies have discussed the tendency of 3D CT reconstruction to overestimates the size of the aortic aneurysm sac [4]. It might also be related to the characteristics of the polymer material.

Manual calculations are time consuming, particularly in tortuous and less fusiform aneurysms, whereas 3D-derived calculations can be performed quickly regardless of the aneurysm morphology.

In conclusion, calculating predicted polymer volume for the Nellix system is more accurate using a manual approach than the Synapse 3D alternative. If the 3D software is used, its tendency to overestimate should be recognized and taken into account during planning.

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