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Original research

Predicting flow diverter sizing using the AneuGuide™ software: a validation study

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ABSTRACT

Background Stent sizing remains a challenging task for flow diverter implantation because of stent foreshortening. In this study, we aimed to quantify the change in length after implantation and assess the error in length prediction using AneuGuide™ software.

Methods In a retrospective cohort of 101 patients with 102 aneurysms undergoing treatment with a pipeline embolization device (PED; Covidien, Irvine, California, USA), we used AneuGuide™ software to obtain measured lengths (ML) and calculated lengths (CL) after stent implantation. Stent elongation was defined as the ratio of ML-LL to the labeled length (LL). Simulation error was defined as the ratio of the absolute value of CL-ML to ML. The correlation and consistency between ML and LL and between ML and CL were analyzed using Pearson's correlation test and the Bland–Altman plot. Statistical significance was set at $p < 0.05$.

Results The mean elongation of ML was 32.6% (range 26.3–109.2%). Moderate consistency was observed between LL and ML ($p = 0.74$, $p < 0.001$). With the AneuGuide™ software, the mean simulation error was 6.6% (range 0.32–21.2%). Pearson's correlation test and the Bland–Altman plot showed a high correlation and consistency between ML and CL ($p = 0.96$, $p < 0.001$).

Conclusion Labeled length provides only a low reference value for predicting the actual length of the flow diverter after implantation. The high consistency between ML and CL obtained from AneuGuide™ software shows its great potential for the optimization of the flow diverter sizing process.

INTRODUCTION

Patients with intracranial aneurysms (IAs) account for 1 in 50 of the global population.¹ The annual rupture rate of IA is 0.95%, which is the leading cause of spontaneous subarachnoid hemorrhage with a mortality of approximately 50%.² Intervention for unruptured aneurysms can effectively reduce the risk of rupture. Flow diverters (FDs), such as the pipeline embolization device (PED; Covidien, Irvine, California, USA), present a new concept for the treatment of IAs and show great potential.

In contrast with traditional coiling techniques, FDs mainly show an immediate therapeutic response by redirecting blood flow past the IA into the distal vessel because of its high metal coverage along the artery segment and then achieves a permanent cure of the aneurysm through the endothelialization process.³ However, these are

highly affected by the size and deployment of FDs. Previous studies have reported that oversizing or undersizing of an FD could result in accidental coverage of lateral branches, eccentric stenosis in the distal end, or poor wall apposition, which could further lead to lateral branch occlusion, endo-leak formation, overgrowth of neointima, and in-stent stenosis.^{4–8}

To date, the main approach to FD sizing is to measure the length and diameter of the target segment of an artery on two-dimensional (2D) or three-dimensional (3D) DSA. Guidelines for both unruptured and ruptured IAs indicate that the treatment of IAs should be performed at high volume centers.^{9–10} This implies that, for this approach, selection of the appropriate size depends mainly on the experience of the operator. However, device behavior during endovascular implantation may not be what was envisaged before surgery. Additionally, tortuous structures, severe wall irregularities, varying diameters of the arteries, and poor visibility also increase the difficulty. All of these indicate the necessity of an effective and efficient tool to assist neurointerventionists in IA treatment, particularly in FD sizing and FD positioning preoperatively. Thus we developed real time braided stent sizing software, AneuGuide™ (ArteryFlow Technology, Hangzhou, China), to aid clinicians in choosing braided stent size and improve the intervention process.

In this study, we aimed to preliminarily validate AneuGuide™ in a clinical setting by quantitatively assessing the accuracy of the predicted stent length after deployment. We hypothesized that the predicted FD length after virtual FD deployment using AneuGuide™ corresponds more closely to the actual FD length after deployment than the labeled FD length.

METHODS

Study population

This retrospective study was conducted at Beijing TianTan Hospital, China. A total of 101 consecutive patients with 102 saccular aneurysms treated with a PED were enrolled. The medical history (including sex, age, comorbidities, and complications) and angiographic IA data of the patients were obtained. The study was approved by the institutional research ethics board of Beijing TianTan Hospital. The requirement for informed consent was waived owing to the retrospective nature of the study.

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Figure 1 Workflow of AneuGuide™. (A) Reading of three-dimensional rotational angiography images. (B) Segmentation and reconstruction of vessels. (C) Calculation of centerline and setting of landing zone. (D) Virtual stenting and visualization. (E) Sizing of braided flow diverter stent. (F) Three parameters provided by the software.

Image acquisition

All patients with pre- and post-treatment 3D-DSA were diagnosed using the Siemens Artis Zee System (Siemens Healthcare, Erlangen, Germany) or Innova IGS 630 (GE Healthcare, Boston, USA). The matrix size of all frames was 512×512 with a pixel spacing of 0.391 mm. Size selection and deployment of the PED were performed by a panel of expert interventional neuroradiologists. The proximal and distal ends of the FD were marked on the 2D sequences of post-treatment images by two interventional neuroradiologists with more than 15 years of experience.

Virtual deployment

AneuGuide™ is a real time sizing tool developed by Artery-Flow Technology to assist clinicians in selecting braided stents. The workflow of AneuGuide™ comprises five steps, as shown in figure 1.

First, preoperative 3D rotational angiography images of the vasculature are read by the software (figure 1A). The vessel model is then reconstructed based on the level set segmentation method, which is a robust approach and has been applied widely in the area of medical image segmentation. Considering the efficiency of the subsequent steps, the region of interest is extracted with a sphere (figure 1B), and the centerlines (figure 1C) are then generated by connecting the centers of the maximum inscribed spheres. The landing zone of the stent is set by manually selecting two points on the target centerline. Once the landing zone is confirmed, the software computes all of the necessary geometrical parameters associated with the centerline. These parameters include the diameter of the maximum inscribed sphere, cross sectional area of the vessel, tangential vector, normal vector, and curvature at each point. Based on these geometrical data, the software calculates the morphology of the stent and proposes a recommendation (figure 1D). Finally, the results of different models, sizes, and

landing zones can be shown and compared (figure 1E), and contours of three critical parameters, apposition, coverage, and pore density, are provided for reference.

Notably, the woven features of braided stents are directly visualized in AneuGuide™, which reflects the relationship between the braiding angle and geometrical parameters, such as vessel diameter and curvature. The whole process, from image reading to stent sizing, takes about 2 min with an iMac (3.0 GHz, 6-Core, Intel Core i5, 8 GB memory), which makes it feasible for intraoperative applications.

Measured length and calculated length

To measure stent length after implantation, the distal and proximal ends of the stent were marked on the 2D post-treatment image, and the corresponding points on the centerline were picked up during simulation. The recommendation of AneuGuide™ included three dimensions (labeled diameter, labeled length (LL), and final length), and the final length in this situation was equal to the length between the two points, which was then used as the measured length (ML). In the case shown in figure 2, an ML of 20.33 mm was obtained.

The calculated length (CL) was readily obtained by selecting the exact dimensions of the stent implanted while keeping the distal end unchanged. In the case shown in figure 2, a PED with a labeled diameter of 3 mm and an LL of 20 mm was selected from the menu. Then, a CL of 19.63 mm was obtained.

Data analysis

In each case, LL, ML, and CL of a PED were recorded, and two parameters, elongation and error, were computed to assess the foreshortening behavior of the PED and the accuracy of the software.

Elongation: The elongation of each stent after implantation was calculated as follows:

Figure 2 Measured length and calculated length of the braided stent. Measured length was obtained by calculating the centerline length between the distal point and proximal point, and calculated length was obtained by fixing the distal point and calculating the deployed length of the used stent.

$$\text{elongation} = \frac{(ML - LL)}{LL \times 100\%} \quad (1)$$

Error: the simulation error of AneuGuide™ for each case was defined as the absolute value of the difference between CL and ML divided by ML.

$$\text{error} = \text{abs} \left(\frac{(CL - ML)}{ML} \right) \times 100\% \quad (2)$$

Statistical analysis

All statistical analyses were performed with NumPy and SciPy, two widely used packages of Python for data analysis. The association and the degree of agreement between ML and LL and between ML and CL were analyzed using Pearson's correlation test and the Bland–Altman plot. Statistical significance was set at $p < 0.05$.

RESULTS

Patient characteristics

A total of 101 consecutive patients with 102 aneurysms treated with a PED at a hospital were enrolled. Only one patient had two aneurysms in each of the bilateral carotid arteries treated with PED.

Mean age of the patients was 55.7 years, and 76 (74.5%) were women. The aneurysms were located in the internal carotid artery (91/102, 89.2%), anterior cerebral artery (1/102, 0.98%), middle cerebral artery (3/102, 2.9%), and vertebral artery (7/102, 6.9%). The mean artery diameter was 3.4 mm, and the mean size of the IAs was 7.1 mm. All IAs were wide necked. Details of baseline information are shown in table 1.

Labeled length and measured length of PED

Online supplemental table 1 shows the results of the elongation observed between LL and ML for the cases studied. Changes of

Table 1 Baseline information for the whole population

Population characteristics	
Women (n (%))	76 (74.5)
Mean age (years)	55.7
Hypertension (n (%))	37 (36.3)
History of cerebral ischemia (n (%))	8 (7.8)
Diabetes (n (%))	7 (6.9)
Hyperlipidemia (n (%))	9 (8.8)
Smoking (n (%))	14 (13.7)
Drinking (n (%))	6 (5.9)
Location of aneurysm (n (%))	
Internal carotid artery	91 (89.2)
Vertebral artery	7 (6.9)
Anterior cerebral artery	1 (1.0)
Middle cerebral artery	3 (2.9)
Size of aneurysm	
Large (>10 mm) (n (%))	17 (16.7)
Small (≤10 mm) (n (%))	85 (83.3)
Mean size (mm)	7.1
Labeled length of PED (n (%))	
14 mm	1 (1.0)
16 mm	13 (12.7)
18 mm	14 (13.7)
20 mm	35 (34.3)
25 mm	27 (26.5)
30 mm	7 (6.9)
35 mm	5 (4.9)
Labeled diameter of PED (n (%))	
2.5 mm	1 (1.0)
3 mm	3 (2.9)
3.25 mm	3 (2.9)
3.5 mm	7 (6.9)
3.75 mm	14 (13.7)
4 mm	25 (24.5)
4.25 mm	14 (13.7)
4.5 mm	22 (21.6)
4.75 mm	8 (7.8)
5 mm	5 (4.9)
Post-processing (n (%))	
Yes	11 (10.8)
No	91 (89.2)

PED, pipeline embolization device.

up to 109% with respect to LL in stent length occurred, with a mean change of 32.6%. The most frequently used LLs of PEDs were 20 mm (35, 34.3%) and 25 mm (27, 26.5%). The mean MLs of the 20 mm PED and 25 mm PED were 27.4 mm and 31.1 mm, respectively. The greatest elongation was observed in the group with an LL of 14 mm. Also, the mean elongations of PEDs with and without post-processing operations were calculated. Most PEDs became longer after deployment inside the vessel. Only eight PEDs (7.8%) showed shortening changes

compared with LL. Pearson's correlation test showed a moderate correlation between LL and ML ($p=0.74$, $p<0.001$) (figure 3A).

Calculated length and measured length of PED

Online supplemental table 2 summarizes the differences between CL and ML in the present study. The average error was 6.6% (range 0.32–21.2%). No statistically significant differences were observed. Pearson's correlation test showed an extremely strong correlation between CL and ML ($p=0.96$, $p<0.001$) (figure 3B). Bland–Altman analysis showed great consistency between CL and ML (figure 3C). Figure 3E–F shows the box plots of the length error between CL and ML in the whole cohort, subgroups of patients with an aneurysm size >10 mm or ≤10 mm, and subgroups of patients with or without a post-processing operation.

DISCUSSION

FDs, typically as braided stents, have the advantage of high metal coverage and high pore density, which can help restore local blood flow of the aneurysmal lesion, thereby inducing thrombosis formation inside the sac. Additionally, the woven design of braided FD stents makes it easy to conform to the tortuous geometry of the intracranial vessels. However, the foreshortening behavior makes FD stent sizing a challenge. The FD stent has the risk of falling into the sac if it is too short or covering the collateral vessels if it is too long. The traditional approach to FD stent sizing is to plot several straight lines on the 2D angiographic picture or 3D virtual rendering to measure the length of the target vessel. Then, the proximal and distal sizes of the target vessel are measured. Based on the measured geometric information and the manufacturer's guidelines, the clinician chooses an FD stent long enough under normal conditions to fulfill the length requirement after deployment. This is a coarse approximation method and depends largely on the experience of the clinician. Virtual stenting methods have been proposed to flatten the learning curve of stent sizing.

The finite element method (FEM) is the most widely used technique in industrial and scientific fields. It converts a body of continuum into finite regular elements assigned simple trial functions, thus turning the problem into determining the coefficients of the trial functions by solving the extremum value of a function. FEM can provide the most accurate result even in the simulation of clinical practices, such as push/pull operations, if precise mechanical behaviors of the stent and vessel are inputted.^{7 8 11 12} However, completing one calculation usually takes several hours, thus making it unsuitable for intraoperative clinical use.

To improve efficiency, researchers have developed another type of virtual stenting method based on the spring mass model.^{13–16} The woven structure of a braided stent is modeled with a tube consisting of mass points and springs. The final deformed stent is controlled by the pseudo forces in the springs and the pseudo interaction between the mass points and vessel boundary. This method, compared with FEM, can save considerable computational costs. However, several shortcomings limit its clinical application. For example, this method cannot reflect the foreshortening behavior of braided stents, thus requiring that the size of the stent should be input as a priori. Additionally, the mechanism of this method always results in inaccurate perfect apposition between the stent and vessel lumen.

The geometrical deployment method, involving only geometrical calculations, has great prospects for clinical application. This method is based on the assumption that the stent cross section always tends to be circular and inscribed to the local

Figure 3 (A) Results of Pearson correlation test of labeled nominal length (LL) and measured length (ML). Results of Pearson's correlation test (B) and the Bland–Altman plot (C) of ML and calculated length (CL). Box plots of the length error between ML and CL in the whole cohort (D), subgroups of patients with large or small aneurysms (E), and subgroups of patients with or without a post-processing operation (F).

vessel lumen under the natural state. The core idea to realize the geometrical deployment is to divide the stent into a series of tubular segments and align them one by one along the centerline with each segment inscribed in the vessel lumen. When the vessel lumen is locally large, for example at the aneurysm neck, the deformation of the stent segment is constrained by its maximum diameter under a stress free state. Compared with spring mass models, this approach is suitable for fast preoperative stent sizing. First, its core algorithm includes the foreshortening mechanism, which enables the method to predict the deployment of a chosen stent or recommend a stent based on the chosen landing zone. Second, the circular cross section is a reasonable assumption validated with *in vivo* observations, and for self-expanding braided stents, depicting their natural deployment is more objective. Artificial correction during the procedure is difficult to predict. As a result, natural deployment can provide a baseline for clinicians to make a better plan for stent size and necessary corrections.

Commercially available software with embedded geometrical deployment methods include Sim&Size (Sim&Cure, France)^{17 18} and Ankyras (Galgo Medical SL, Spain).^{19 20} Sim&Size provides a workflow similar to that of AneuGuideTM. In a retrospective study that enrolled 189 patients, procedures performed with the software were reported to have a lower rate of corrective intervention (9% vs 20%, $p=0.036$), shorter intervention duration (46 min vs 52 min, $p=0.002$), lower median radiation dose (1150 mGy vs 1558 mGy, $p<0.001$), and shorter stent length (14 mm vs 16 mm, $p<0.001$).¹⁸ However, validation of the accuracy of the software has not yet been revealed. Ankyras is another similar sizing tool for FDs. To the authors' best knowledge, Ankyras is performed by technicians of the company, and there

is a need for data transfer between companies and hospitals. In a validation study published in 2018, researchers performed an error analysis of 82 patients and found a mean error of 7.6%.¹⁹ Both can predict the final length of FDs after implantation and visualize the local apposition and metal coverage ratio.

An advantage of AneuGuideTM is that it provides a far more real visualization, which is attributed to its unique algorithm. This feature not only improves user experience, but also makes it possible for researchers to output a model for computational fluid dynamics, which maintains both high accuracy and low computational cost. AneuGuideTM also provides the contour of the pore density, which is an important complement to the metal coverage ratio.

The LL of the stent is the reference length provided by the manufacturer. However, it is different from the actual deployed length of the stent *in vivo*. This does not meet the requirement of high precision in interventional clinical practice because stents are often difficult to retrieve after complete release. In this study, we defined elongation to compare the real length *in vivo* to the LL provided by the manufacturer. Mean elongation was 32.6% (range -26.3% to 109.2%). This result indicates that, on the one hand, FD stents have good ductility and adaptability to complex intracranial vascular morphology; in contrast, LL is not a reliable indicator of real stent length.

To calculate stent length accurately, we developed real time stent sizing software, AneuGuideTM. We defined ML and CL, which represented the length of the stent after implantation *in vivo* and the length simulated by AneuGuideTM software, respectively. The mean error between ML and CL was 6.6% (range 0.32% – 21.2%). However, CL remained a far more accurate predictor of actual length than LL. In some cases, such as artery

stenosis combined with aneurysms and tandem aneurysms, which have more complex vascular configurations, real time stent sizing software may show greater potential in the clinical setting.

In our center, post-processing operations, such as J wire angioplasty, bumping, and balloon angioplasty, were only applied when the stent was poorly unfolded, or the stent was poorly adhered to the wall. In this study, only 11 patients underwent a post-processing operation. The simulation error in patients with post-processing operations was smaller. This result is attributed to the purpose of post-processing, which is to ensure that the state of the stent after deployment is closer to the ideal natural state. The result of our software simulation is exactly the result of the natural release of the stent. For larger aneurysms, we set up a subgroup according to whether aneurysms were larger than 10 mm. The simulation results for large aneurysms exhibited a larger error than those for other aneurysms. The reason for this finding is the usually large neck segment of large aneurysms. In this neck segment, configuration of an FD is not as determinable as that in the parent vessel, and ensuring that the calculated centerline in this segment is strictly consistent with that in the real procedure is difficult. Another reason is that our algorithm assumes that any part of an FD can fully expand to its free state if it is unconstrained by the vessel wall. However, under actual circumstances, there should be a transition zone between the crimping and expanding parts. This means that there is a lack of consideration of the mechanical behavior of the metal wires and the woven structure. Additionally, the segment of the FD under the aneurysm neck is easily affected by the push/pull operations.

The study had several limitations. First, the study was performed retrospectively. We only analyzed the pre-deployment stent selection and post-deployment stent status using the available medical records and imaging data. Second, we included only patients with PED treatment. Third, we excluded patients with fusiform/dissecting aneurysms because the centerline of the vessel in the luminal part of the parent artery obtained by the current algorithm was not consistent with the centerline of the stent, and the morphology of the stent in the luminal part of the fusiform/dissecting aneurysm was greatly influenced by the pushing and pulling operation of the surgeon. This resulted in a significant difference between the natural release results simulated by the software and the actual results.

CONCLUSIONS

Real time preoperative virtual sizing technique has great potential in FD treatment. In the present study, preoperative sizing with AneuGuide™ software resulted in a more accurate prediction of FD length compared with labeled length. AneuGuide™ software may help clinicians improve the treatment of IAs using FD.

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Contributors AHL and JPX conceived and designed the study. JF and AHS provided a final overview of the paper and revised the manuscript. XCL and JGC collected

the data. XBH was responsible for quality control. XT and YJS conceived the project, analyzed the data, and wrote the paper. AHL is responsible for the overall content. All authors helped organize the study and carried out the research. All authors read and approved the final manuscript.

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