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Original Article / Özgün Makale

Evaluation of 3D printed carotid anatomical models in planning carotid artery stenting

Karotis arter stent planlamasında 3D baskılı anatomik karotis modellerin değerlendirilmesi

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ABSTRACT

Background: We aimed to investigate the potential role of three-dimensional printed anatomical models in pre-procedural planning, practice, and selection of carotid artery stent and embolic protection device size and location.

Methods: A total of 16 patients (10 males, 6 females; mean age 75.6±4.7 years; range, 68 to 81 years) who underwent carotid artery stenting with an embolic protection device between January 2017 and February 2019 were retrospectively analyzed. The sizing was based on intraprocedural angiography findings with the same brand stent using distal protection device. Pre-procedural computed tomography angiography images used for diagnosis were obtained and modeled with three-dimensional printing method. Pre-procedural and three-dimensional data regarding the size of stents and protection devices and implantation sites were compared.

Results: Measurements obtained from three-dimensional models manually and segmentation images from software were found to be similar and both were smaller than actually used for stent and embolic protection device sizes. The rates of carotid artery stenosis were similar with manual and software methods, but were lower than the quantitative angiographic measurements. Device implantation sites detected by the manual and software methods were different than the actual setting.

Conclusion: The planning and practicing of procedure with three-dimensional models may reduce the operator-dependent variables, shorten the operation time, decrease X-ray exposure, and increase the procedural success.

Keywords: Carotid artery, embolic protection device, Mimics software, printing, stenting, three-dimensional.

ÖZ

Amaç: Bu çalışmada üç boyutlu baskılı anatomik modellerin işlem öncesi planlanan, uygulama ve karotis arter stent ve emboli önleme cihazının boyut ve yerleşiminin belirlenmesindeki muhtemel rolü araştırıldı.

Çalışma planı: Ocak 2017 - Şubat 2019 tarihleri arasında emboli önleme cihazı ile karotis arter stentleme yapılan toplam 16 hasta (10 erkek, 6 kadın; ort. yaş 75.6±4.7 yıl; dağılım, 68-81 yıl) retrospektif olarak incelendi. Boyut, distal önleme cihazı kullanılarak aynı marka stent ile işlem sırası yapılan anjiyografi sonuçlarına göre belirlendi. Tanıda kullanılan işlem öncesi bilgisayarlı tomografi anjiyografi görüntüleri elde edildi ve üç boyutlu baskı yöntemi ile modellendi. Stent ve önleme cihazlarının boyutu ve implantasyon bölgelerine ilişkin işlem öncesi ve üç boyutlu veriler karşılaştırıldı.

Bulgular: Stent ve emboli önleme cihazı boyutları, manuel üç boyutlu modelden ve yazılımdan segmentasyon görüntülerinden elde edilen ölçümler için benzer ve asıl kullanılanlardan küçük idi. Karotis arter darlığı oranı da, manuel ve yazılım yöntemler ile benzerdi; ancak, kantitatif anjiyografik ölçümlere kıyasla daha düşük idi. Manuel ve yazılım modelleri ile tespit edilen cihaz implantasyon yerleri, gerçekte kullanılandan farklı idi.

Sonuç: Üç boyutlu modeller ile işlemin planlanması ve uygulanması, operatöre bağımlı değişkenleri azaltabilir, ameliyat zamanını kısaltabilir, radyasyon maruziyetini düşürebilir ve işlem başarısını artırabilir.

Anahtar sözcükler: Karotis arter, emboli önleme cihazı, Mimics yazılımı, baskı, stentleme, üç boyutlu.

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Despite technical advancements in carotid artery stenting (CAS), there are still ongoing challenging issues.[1] Variants of carotid arterial system in terms of geometrical and spatial course and aortic arch variability are widely reported.[2-5] In addition, a wide range of instruments used during the procedure may confuse the operator when and where to use which. Therefore, 87 to 99% success rates have been reported.[2,3] Although pre-procedural planning is of utmost importance to overcome difficulties, the most optimal imaging modality for decision making is still unclear.[5,6]

Computed tomography (CT) and magnetic resonance imaging (MRI) are used for decision making in stent and embolic protection device (EPD) sizing at experienced centers. However, these modalities are mostly used for diagnosis, and sizing is solely based on angiography which is performed during implantation.[6-9]

Inappropriate sizing of stent and EPD (length and diameter), inappropriate design of stent, and inadequate coverage of the lesion by the stent may result in peri-procedural ischemic events.[10-14] Therefore, prespecification of preferences becomes a useful overall risk marker.[10,15,16]

Three-dimensional (3D) printing was first described by Charles Hull in 1986. It is a fabrication technique used to transform digital images into physical objects in a layer-by-layer approach where images from CT or MRI (digital imaging and communication in medicine [DICOM] files) are converted to a standard tessellation language (STL) file by software and finally printed by stereolithography (a special form of laser printing).[17-24] This software also enables us to make more accurate surface-to-surface virtual measurements without printing. Although anatomical studies for educational purposes with 3D printing have been done in carotid arteries, there is no studies available regarding pre-procedural planning, practicing, and device selection.[14]

In this study, we aimed to evaluate optimal carotid artery stent and EPD sizes and implantation sites using 3D printed anatomical models and its software.

PATIENTS AND METHODS

In this retrospective study, a total of 16 patients (10 males, 6 females; mean age 75.6±4.7 years; range, 68 to 81 years) who underwent CAS with EPD at Medical Park Izmir Hospital, Izmir, Turkey between January 2017 and February 2019 were included. The study group consisted of the patients stented throughout the study period. Having a high-risk surgery is the main indication for CAS. The procedures were performed by a single experienced interventionist. The Medtronic SpiderFX EPDs (Covidien, Mannsfield, MA, USA), sized 3.0-7.0 mm, were used as distal protection filters with the Medtronic Protégé RX (Medtronic Inc., Minneapolis, MN, USA) self-expanding straight and tapered stents of 6×20 mm to 10×60 mm in sizes. Stent and EPD size selection were based on two-dimensional (2D) angiographic images, and quantitative angiography performed during implantation. Pre-procedural CT images (Toshiba Aquilion One Vision Edition 640 slice Dynamic volume tomography; Canon Medical Systems, California, CA, USA) were used for diagnostic purposes (Figure 1). All procedures were performed by catheters and wires, which were suitable for aortic, carotid, and stenotic segment anatomies and through the femoral artery. The selection was based on the interventionist's spatial perception of 2D angiographic images and clinical knowledge during the procedure.

The patients' preoperative volumetric CT images were analyzed retrospectively and modeled with 3D printing where the DICOM files (Figure 1) on axial,

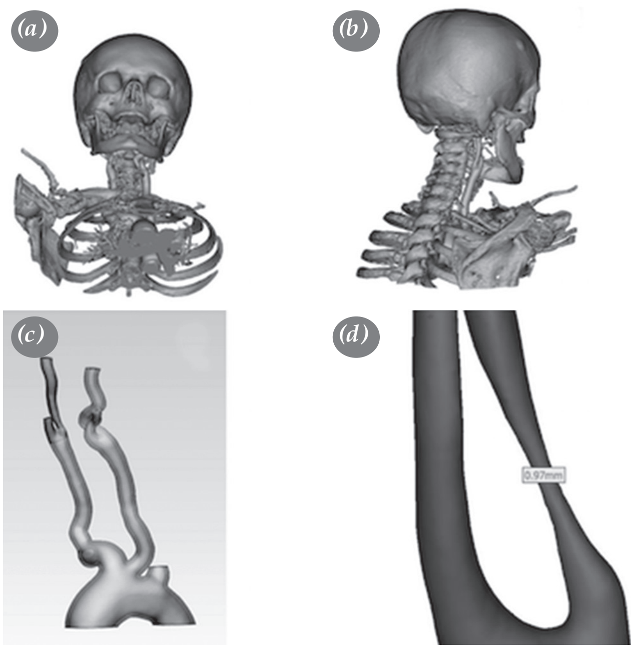

Figure 1. (a) Computed tomography angiographic (volumetric) anterior view of carotid arteries. **(b)** Computed tomography angiographic (volumetric) lateral view of carotid arteries. **(c)** 3D segmentation digital model of carotid arteries wall and lumens via mimics software. **(d)** 3D segmentation digital flow model of internal carotid narrowing via mimics software.

3D: Three-dimensional.

coronal, and sagittal plan were converted to STL files (segmentation images) by Mimics Innovation Suite 21 Software (Materialise, Leuven, Belgium, CE 0120 Certification) (Figure 2). The arterial lumen and wall were created with data processing via manual smoothing and hollow command in design module (3-matic). Then, the STL files were exported to 3D printer (Formlabs Form 2, Formlabs Inc., MA, USA, and Laser Specifications: EN 60825-1:2007 certified) and printed using resin. The 3D models were treated with the wash and cure process and detached from the support points. All 3D models were prepared at the Middle East Technical University Technocity, BTECH Company facility on May 2019. The optimal stent length and diameter and EPD size were evaluated manually with a digital caliber on the physical model and 3D printing software on the digital model. These values were statistically compared with the actual used stent and EPD sizes from the patient records based on 2D angiography images (Figures 2 and 3). The percentage of carotid artery narrowing was calculated by the North American Symptomatic Carotid Endarterectomy Trial method

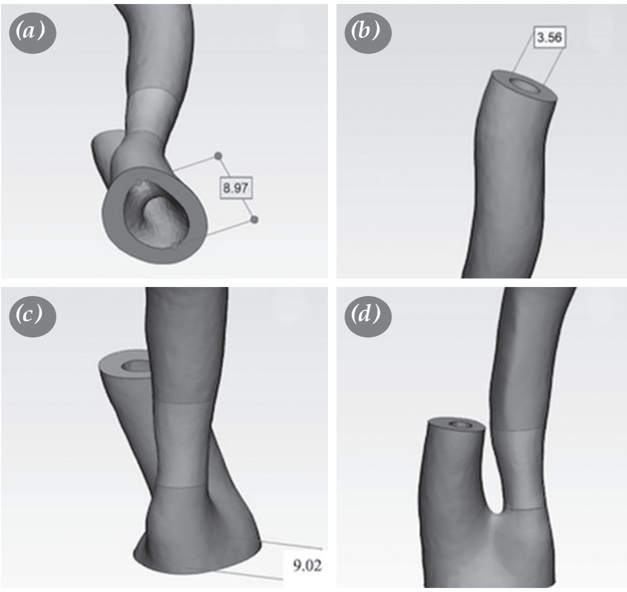

Figure 2. Measurements of Digital 3D printing models with 3D printing software (Mimics/3-matic) modules. **(a)** Proximal internal carotid artery inner diameter. **(b)** Distal internal carotid artery inner diameter. **(c)** Proximal internal carotid artery outer diameter. **(d)** Carotid bifurcation

3D: Three-dimensional.

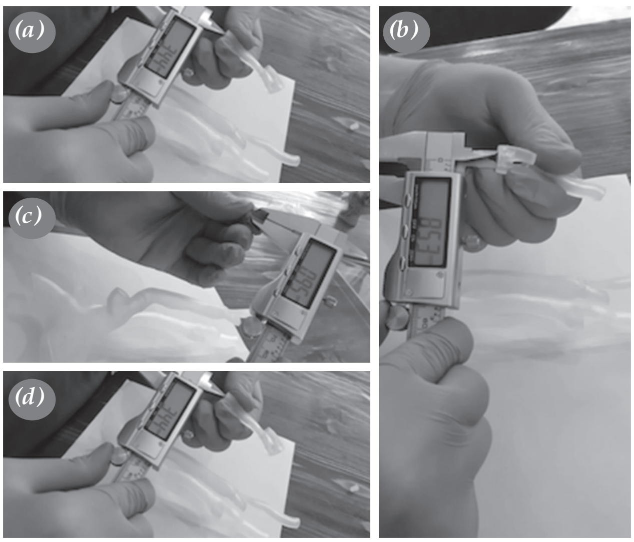

Figure 3. Manuel measurements of 3D printed physical models with a digital caliper. **(a)** Distal internal carotid artery inner diameter measured with a digital caliper. **(b)** Proximal internal carotid artery inner diameter measured with a digital caliper. **(c)** Carotid narrowing lumen diameter with a digital caliper. **(d)** Distal internal carotid artery inner lumen diameter measured with a digital caliper.

3D: Three-dimensional.

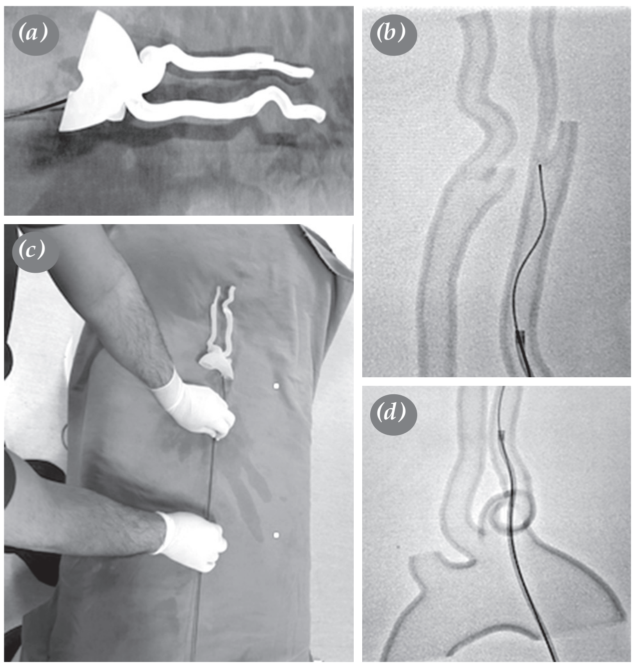

Figure 4. Manual practice with different catheters, wires on 3D physical models in both non-sterile environment and under X-ray tube. **(a)** Left common carotid artery cannulation with guiding catheter in non-sterile environment. **(b)** Cannulation of common carotid artery and crossing the internal carotid narrowing via guide wire under angiographic guidance in anteroposterior view. **(c)** Left internal carotid artery cannulation with guiding catheter in non-sterile environment. **(d)** Cannulation of common carotid artery and crossing the internal carotid narrowing via guide wire under angiographic guidance in lateral view.

3D: Three-dimensional.

in both physical model and digital model. This was compared to 2D angiographic measurements from quantitative angiography. To gain a better understanding of the spatial geometry of lesions, practice with 3D printed models was performed by the interventionist under X-ray in a non-sterile environment using different catheters and wires (Figures 4 and 5).

A written informed consent was obtained from each patient. The study protocol was approved by the Medical Park Hospital Ethics Committee. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Statistical analysis

Statistical analysis was performed using the PASW for Windows version 17.0 software (SPSS Inc., Chicago, IL, USA). Continuous variables were expressed in mean ± standard deviation (SD) or median (min-max), while categorical variables were expressed in number and percentage. The Friedman two-way analysis of variance (ANOVA) was used to test the significance difference. A *p* value of $p<0.05$ was considered statistically significant.

RESULTS

Eight patients had a preoperative ischemic event. Pre-dilatation was performed in eight patients and post-dilatation was performed in three patients. There were four post-procedural ischemic events of which three were transient and one was permanent.

Measurements of each carotid stent diameter and length and EDP device size were similar for manual measurements via a digital caliper and segmentation images via the measurement module of Mimics software ($p>0.05$, Table 1). However, these measurements were lower than the actual implanted carotid stent diameter and length and EDP device based on 2D angiography images during implantation ($p<0.001$, Table 1). A bias toward the use of oversized stent and EPD were

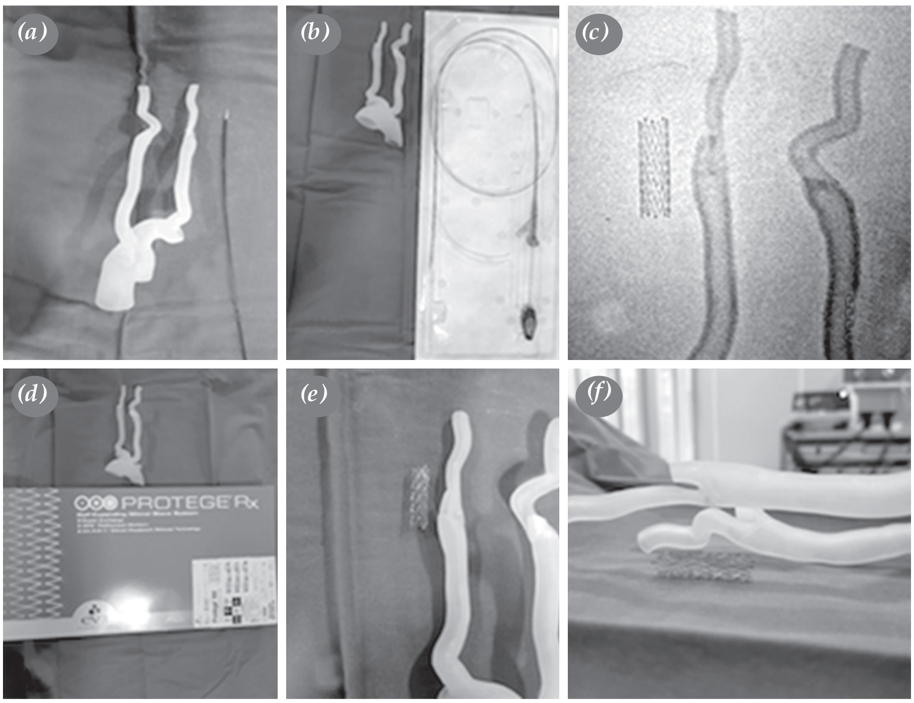

Figure 5. Manual practice with different size of embolic protection device, catheters, wires and stents on 3D physical models in both non-sterile environment and under X-ray tube. **(a)** Practice with different size of embolic protection device in non-sterile environment. **(b)** Practice with different size of embolic protection devices and stents in non-sterile environment. **(c)** Image of carotid stent and 3D digital model under angiographic image. **(d)** Practice with Protégé stent. **(e)** Practice with Protégé stent in antero-posterior view. **(f)** Practice with Protégé stent in lateral view.

3D: Three-dimensional.

Table 1. The actual and estimated (optimal) measurements of sizes of carotid stents and EPDs

	Measurement methods						
	3D printed models		Preoperative 2D angiography		Mimics software segmentation images		
	Median	25^{th}-75^{th} percentile	Median	25^{th}-75^{th} percentile	Median	25^{th}-75^{th} percentile	*p*
Stent diameter (mm)	6	6-7	8	7-8	6	(6-7	χ^2= 29.39 0.001
Stent length (mm)	30	20-40	60	40-60	30	22.50-40	χ^2= 27.40 0.001
EPD size (mm)	4	4-5.75	8	7 -8	4	4-5	χ^2= 29.69 0.001
Estimated stenosis (%)	0.80	0.75-0.87	0.89	0.83-0.97	0.80	0.76-0.86	χ^2= 27.26 0.001

3D: Three-dimensional; 2D: Two-dimensional; EPD: Embolic protection device.

detected. Estimated carotid narrowing percentages were similar in both manual and software methods, but lower than the quantitative angiography measurements ($p<0.001$, Table 1).

DISCUSSION

Although CAS is a widely performed interventional procedure, sizing and selection of devices are still ongoing issues. Proper sizing of device bears a high degree of correlation to success of procedure and decrease mortality and morbidity.[2,3] Undersizing may result in partial plaque coverage and inadequate revascularization, whereas oversizing may cause extensive endothelial damage and vasospasm.[6,11] Another important issue is distal protection device sizing where oversizing may result in vasospasm and undersizing may lead to embolization of the debris from the site of intervention, resulting in cerebrovascular events.[11,12] Placing the EPD at an adequate distance from the lesion and in a straight part of the distal lumen is also crucial to prevent devastating ischemic events and guarantee the procedure success.[2,3,6] In daily practice, the interventionist estimates the carotid stent diameter and length and EPD size using quantitative angiography images performed during implantation which have shortcomings due to the 2D nature of the imaging technique.[8] Evaluation of the lesion size for stent and distal vascular bed size for EPD with volumetric CT and MRI images give some advantages over 2D angiography. However, inadequate 3D reconstruction and poor resolution of images compared to 3D print software and printed models may decrease the success rates. In our study, we also demonstrated these shortcomings where sizing for the stent length and size and EPD size were similar for 3D printed and software-based measurements, but were smaller than the actual implanted sizes. We also documented a tendency for oversizing which may adversely affect the success rates as mentioned above.

The United States Food and Drug Administration approved 3D print software for medical purposes which provides more precise measurements not only with digitally structured 3D objects, but also 3D printed real models. The measurements are closer to reality and enable preoperative practice possible in non-sterile environment.[17,23] Therefore, preoperative planning of the procedure with 3D printed models is possible. This, in turn, leads to a decrease in the procedural time, radiation exposure of both the operator and patient, thereby, reducing complications, mortality, and morbidity.[14,17,23] The aortic arch type, crossing lesion in the tortuous vessel, inadequate catheter back-up, catheter-wire selection, and placing protection device can be also handled by pre-procedural practice and planning.[17] In this context, we attempted to demonstrate the importance of 3D printing in pre-procedural evaluation and documented deviances with 3D printed models and digitally created models via the print software.

The current European Society of Cardiology (ESC) guidelines define indications for carotid interventions and are based on stenosis percentage and symptomatology.[25] In particular, borderline lesions pose a confusion. Therefore, accurate measurements are vital. This study also revealed a tendency to overestimate stenosis percentage with 2D angiography. We believe that a more precise decision for identification of the lesion severity is possible with 3D printed models.

Device selection based on 3D printing measurements (manual or software) allows the operator making more precise decisions.[14,17,23] In our study, we demonstrated the importance of pre-procedural planning with 3D printing providing more accurate understanding of 3D spatial anatomy of vessel and lesion morphology. Moreover, preoperative printed models enabled performing preoperative practice in a non-sterile environment by increasing the operator self-confidence and giving him/her an opportunity to find out which maneuvers would be the best for the procedure. Although our study was mainly designed for finding out the optimal device size and placement sites, it also gave us an opportunity to practice on 3D models. If the method could have been employed pre-procedurally and the study was conducted prospectively, more accurate sizing may have been achieved and the outcomes of stenting may have been more favorable than the actual results. However, further large-scale, prospective, randomized-controlled studies are needed to comment on this subject and on possible comparison of the stent results employing this model with surgery.

Nonetheless, this study is retrospective in nature which may have led to bias. Prospective studies using pre-procedural planning with the model and comparing the results with actual results would be more valuable. In addition, the cost of the model is another limitation. Each model takes about 6 h to print which costs around €300. Although the model may not be cost-effective currently, with wide use of the model, the cost is expected to decrease. Also, the method may prevent further interventions by enabling more accurate sizing.

In conclusion, our study demonstrated the importance of newly developing technologies and collaboration of medicine and engineering. It may be concluded that three-dimensional printing is a useful way for choosing the optimal size of the stent and embolic protection device and their placement sites in carotid interventions. Carotid artery stents and embolic protection device systems develop in parallel to industry and engineering. In addition, three-dimensional printing technology has been evolving with the advancement in software, printers, and printing materials. To decrease mortality and morbidity and to increase the procedural success, novel modalities such as three-dimensional printing can be integrated to interventional medicine via collaboration of engineers and interventionists. Nonetheless, to test these hypotheses, there is still a need for further prospective, randomized-controlled studies in this area. Based on our study results, we conclude that the importance of pre-procedural planning is of utmost importance and the use of three-dimensional printed anatomic models provide the interventionist practice before the procedure and allows him/her to become ready for possible issues and complications. In this way, more accurate sizing and localization may be possible which may increase the operator expertise and decrease complication rates and morbidity and mortality, eventually.

Declaration of conflicting interests

The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

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