

NITINOL STENTS; DEPLOYED IN THE INTERNAL CAROTID ARTERIES; GEOMETRIC EFFECTS

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ABSTRACT... Stents deployed in the carotid arteries cause significant geometric changes in the vessels, influencing the flexibility and torsion characteristics of the vessels, which are aggravated by the high degree of mobility in this area of the body. The influence of these physical characteristics on carotid blood flow could influence the long term performance of the deployed stents. **Objectives:** To evaluate the geometric changes in the carotid arteries after deployment of self expanding nitinol stents. **Settings:** AFIC-NIHD. **Period:** November 2003 to August 2008. **Material & methods:** 45 cases of carotid artery stenting (CAS) done. We selected cases where the stenting to the internal carotid artery (ICA) had been done across the bifurcation of the common carotid artery (CCA) with self expanding nitinol stents, and when DICOM videos that had pre and post stenting images in the same imaging projection were available for analysis. Based on the inclusion criteria 21 videos were selected and deemed fit for taking measurements. The measurement system proposed by Berkefeld et al which involved the measurement of the CCA-ICA (common carotid artery –internal carotid artery) angle and ICA-offset was used. These variables were measured using onscreen measuring software which can measure linear distances and angles after appropriate calibration for each image. **Results:** We did not find any significant changes in the ICA-offset; significant changes in the CCA-ICA angle were noted.

Key words: Stents, Carotid, Nitinol, Geometry

OBJECTIVE

To determine the geometric effects of self-expanding nitinol stents deployed in the internal carotid artery.

MATERIALS AND METHODS

We collected 45 cases of carotid stenting done in AFIC-NIHD done from November 2003 to August 2008. Of these 23 DICOM videos were available for examination. We selected cases where the stenting to the internal carotid artery (ICA) had been done across the bifurcation of the common carotid artery (CCA) with self expanding nitinol stents. Only videos that had pre and post stenting images in the same imaging projection were included in the study. Based on the inclusion criteria 21 videos were selected and deemed fit for taking measurements. The measurement system proposed by Berkefeld et al (discussed later) was used. Two variables were measured: first the CCA-ICA angle; this was measured between the extended mid axis of the CCA and the axis of the initial ICA segment which is terminated by the upper limit of the stenosis. The other variable measured was the ICA-offset. The ICA-offset indicates the maximum linear deviation of ICA tortuosities perpendicular to the extended CCA (midaxis), between the bifurcations and the skull base.(fig 1,2) These variables were measured using onscreen measuring software which can measure linear distances and angles after appropriate calibration

for each image.

RESULTS

Successful stent deployment of appropriate sized stents was achieved in all the cases evaluated with good restoration of distal flow in the carotid vessels. All stents appeared to appose well to the vessel walls. The results are presented in tables I, II.

Table-I. Change in CCA-ICA angle after stenting

	Mean	Std. Deviation
Pre stent angle (degrees)	27.3	13.24
Post stent angle (in degrees)	19.4	8.35

Table-II. Change in offset after stenting

	Mean	Std. Deviation
Pre stent offset (mm)	14.76	8.53
Post stent offset (mm)	11.09	6.64

The mean pre-stent CCA-ICA angle was 27.3o. After stent deployment the mean CCA-ICA angle was 19.4o. The change in the CCA-ICA angle was significant (p value 0.049). The pre-stenting offset was 14.76 mm, and the post stenting offset was 11.09 mm. The change in offset was insignificant.

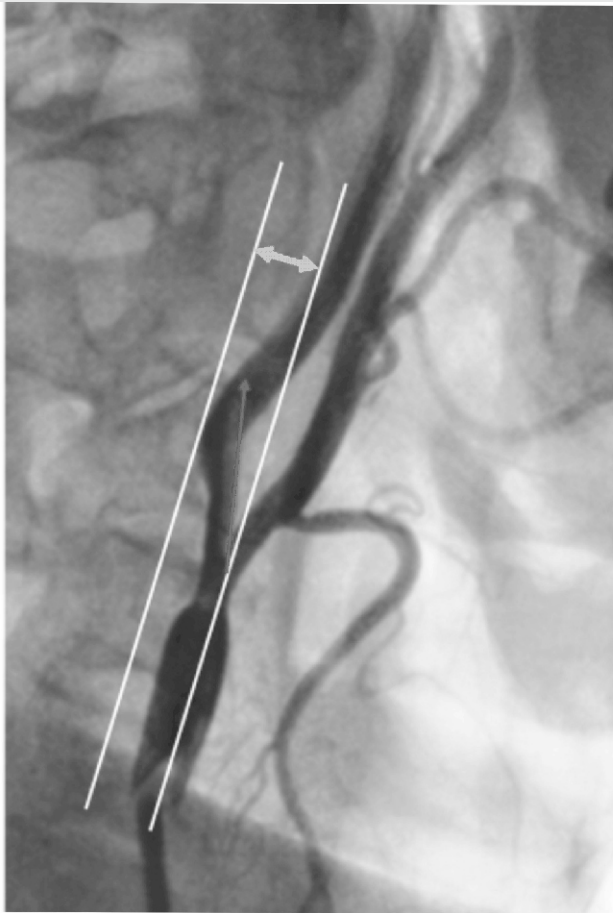


Figure-1.

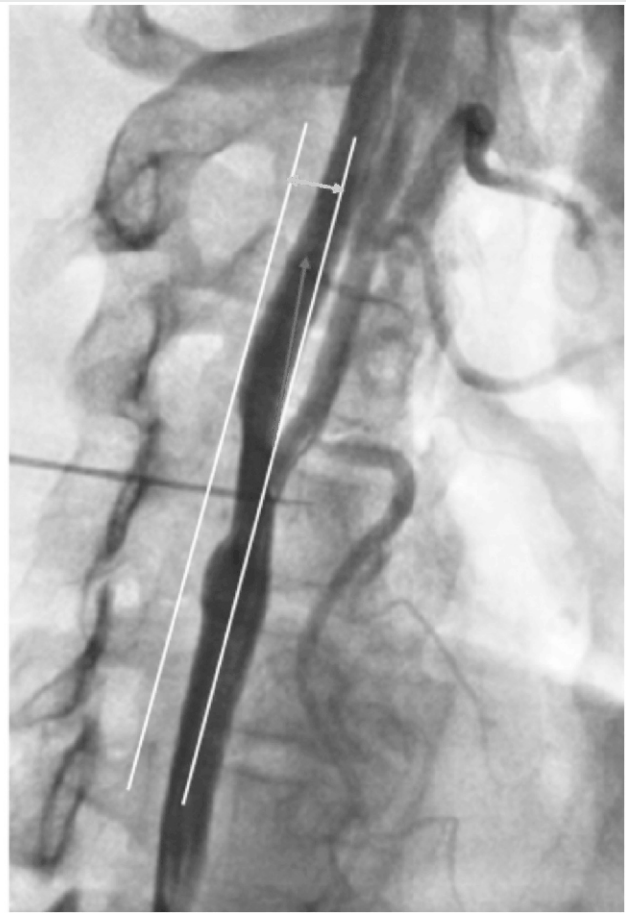


Figure-2.

Figure 1,2. The CCA-ICA angle, is measured between the extended mid axis of the CCA (white line) and the axis of the initial ICA segment (red line) which is terminated by the upper limit of the stenosis. The ICA-offset indicates the maximum linear deviation of ICA tortuosities perpendicular to the extended CCA (midaxis), represented by the yellow double arrow. Fig 1 and 2 represent pre and post stent images.

DISCUSSION

The carotid bifurcation is located in a highly mobile part of the human body. Considerable motion of the carotid artery is present during head movements. One study which assessed the influence of head position on carotid bifurcation hemodynamics showed that cross sectional areas and shapes of the vessels were influenced only slightly by head rotation but the vessel positions did change; and the wall shear stress on the outer wall of the carotid bulb decreased, which is an adverse hemodynamic phenomenon¹. This has important implications for carotid stent implants. While CAS has been advocated potentially safe, cost effective and less

invasive procedure for the treatment of carotid artery stenosis; a stent could work as planned in a particular head position, however changes in head position could affect wall shear stress values predisposing to a milieu conducive to restenosis. Studies using MRI have shown that following stenting across the carotid bifurcation, sharp ICA angulations occur at the distal stent junction; there is a negative effect on the flexibility and rotational capacity of the vessel. The angulations are aggravated by forward bending of the head. Both the CCA and ICA are subjected to considerable torsion shear with the head turned left and right². These changes in the carotid anatomy are not accommodated by the current carotid

stent designs. Another study evaluated the effects of head movement on morphology and flow dynamics in patients who had undergone CAS with those who had carotid endarterectomy. There was a significant increase in ICA angulation in CAS patients if the head was bent forward; this was not observed in CEA patients. This angulation change did not lead to significant acute changes in cerebral blood flow. The study did not evaluate any chronic effects³.

These mobile features of the carotid artery may hamper the long term results of CAS with alteration in cerebrovascular blood flow, potentially causing CAS to take a backseat in the treatment of carotid artery stenosis.

Although features of stent flexibility are documented *ex vivo*, the stented section of the carotid artery shows complete lack of flexibility. A study of 13 stents has shown that all stents become significantly stiffer upon deployment⁴. Flexibility and torsion studies of 5 stents before and after deployment *in vitro* were done and then compared with the torsion in the bare expanded stents⁵. The results indicated that the flexibility of the current stents decreases after deployment in the carotid arteries, irrespective of their flexibility in the bare state. It must be reiterated that these changes can influence the long term performance of these stents.

Norimitsu et al investigated the effects for 5 different types of stents deployed in 40 simplified pulsatile perfused silicone models of the carotid bifurcation, which incorporated elastic properties of the real carotid arteries. All stents deployed were chosen according to the nominal diameter of the carotid vessel and bridged the external carotid artery origin as well as a consecutive curve at the initial segment of the internal carotid artery. The study measured CCA-ICA angle and ICA-offset, in the models after deployment of stents. The older braided stents modified the course of the model vessel and straightened the angulation and circumscribed curve of the ICA, which was transformed into a larger C-shaped bow. The segmented nitinol stents did not lead to significant changes in the geometry of the carotid bifurcation and the ICA curve. The Wallstent clearly reduced the CCA-ICA angle as well as the ICA deviation

(offset) perpendicular to the CCA axis, whereas the newer nitinol stents induced less reduction of the angle and minimal changes of the ICA offset. The ICA angle between both limbs of the ICA curve increased markedly with the use of braided stents. The segmented nitinol stents induced negligible widening of the ICA angle. No major differences could be detected among the three different subtypes of nitinol stents. This experiment suggested that improved conformity of the segmented nitinol stents may improve recanalization results in cases with tortuous anatomy or abrupt changes of the vessel diameter. Separation between the stent segments can be a focus for subsequent plaque protrusion, and this discontinuity between the stent modules might induce irregular flow patterns. In curved vessels segments of nitinol stents protrude into the vessel wall; this is a potential source of emboli, as well as a source for other devices such as guidewires or embolic protection umbrellas to get hung up on the stent during withdrawal⁶.

In our study we used the measurement system proposed by Berkefeld et al⁷. It measures the CCA-ICA angle and ICA- offset before and after CASs. This system was applied to 224 digital subtraction angiogram images and it corresponds to the visual changes in carotid artery angulation and tortuosity before and after CAS, and provides a basis for geometric evaluation evaluation of CAS.

Our study was unique in that unlike previous studies which applied the measurement system to silicon models we applied the measurements to human angiographic studies. In our study we found that there was a significant change in the CCA-ICA angle after deployment of self-expanding nitinol stents, however, there was not a significant change in the ICA-offset. We feel however, that the sample size should be larger to further emphasize the significance or otherwise of these measurements undergoing carotid stenting. Further studies need to be done involving newer stent designs.

CONCLUSIONS

CAS is a leap forward in the treatment of both intra and extra cranial atherosclerotic carotid artery disease; however the geometric effects of these stents in a highly mobile area of the body cannot be ignored. Whether

these stent effects have any bearing on the long term patency of the stents is another question that remains unanswered? Future research needs to be directed towards development of more malleable materials that will conform well to the anatomy of the human carotid vessels, and accommodate all movements, and deformations.

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