THE EFFECT OF RADIAL FORCE ON THE MIGRATION CHARACTERISTICS OF A NEW PERMANENT ARTERIAL DIVERSION DEVICE FOR EMBOLIC STROKE PREVENTION

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ABSTRACT:
A new diversion device (*the Diverter*) was designed to prevent embolic stroke from proximal sources, by implantation at the carotid bifurcation. It diverts emboli away from the internal carotid artery (ICA) into the external carotid artery (ECA). We have previously shown that the diverter, which is a stent like device (Fig. 1), has to be fine structured in order to comply with the diversion demands. This constrain faced us with problems of weak structure (down to 15% of a "common" carotid stents in radial pressure). Our aim was to study the effect of the radial pressure on the migration characteristics of the arterial *Diverter* in the illio-femoral bifurcations of a swine model

Keywords: Implant-Migration, Embolic-Stroke-Prevention, Arterial-Blood-Filtration, Stents-Implantation

INTRODUCTION

The background to this work start with stroke, which is the third leading cause of death and the major cause of disability. In the US alone there are more than 730,000 stroke victims and 4.4 million stroke survivors annually [1]. Stroke is a syndrome of multiple etiologies. Emboli emerging from the heart, aortic arch and the large arteries, mainly carotids, account for about 60% of all stroke cases [2,3]. Atrial fibrillation (AF) is the most important precursor of embolic stroke. More than 2 million Americans have intermittent or sustained AF [4]. Protruding aortic arch atheroma (AAA), prevalent among the elderly, has emerged as an additional common cause of embolic stroke [5]. Plaques located in the aortic arch have been found in 60% of 60 years old patients with ischemic stroke. The association is particularly strong when the plaques are > 4 mm in thickness [6]. AF and AAA often coexist [7]. Currently, the treatment of choice for AF and AAA is anticoagulation with warfarin. The relative risk of stroke can be reduced by 70% in selected subgroups of patients with AF using anticoagulants [8]. However, anticoagulants are contraindicated in about 40% of patients over 65 years old [9]. Moreover, anticoagulation was repeatedly shown to be underused, about 30% of eligible patients [10], and quality of control in routine clinical practice is often poor. Carotid stenosis is a local disease accounting for 9% of stroke [2,3]. Current treatment modalities of carotid stenosis are carotid endarterectomy or carotid stenting, with or without a cerebral protection device. However, these treatments address only transient ischemic attacks and prevention of stroke attributable to carotid stenosis, but not to the prevention of stroke due to emboli originating from the heart or the aortic arch.

Our aim was to study the effect of the radial pressure on the migration characteristics of the arterial Diverter in the illio-femoral bifurcations of a swine model.

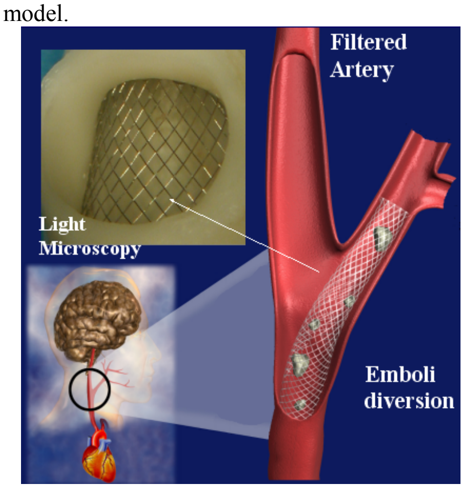
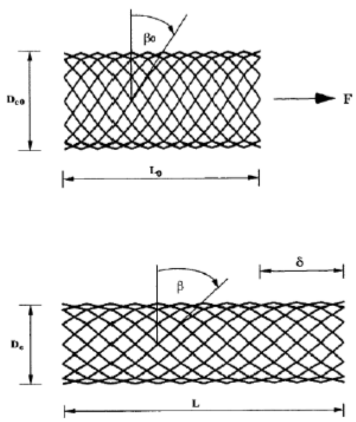


Fig. 1, Proximal emboli sources, and the carotid bifurcation. The Diverter implanted from the CCA to the ECA in the carotid bifurcation.

MATERIALS AND METHODS

Two groups of biocompatible Diverters, composed of multiple fine wire meshes, were implanted in the illio-femoral bifurcations of female swine. Group A (n=22) consisted of an average radial pressure approximately 40% of "common" carotid stents, and group B (n=21) of an average radial pressure of ~20% of "common" carotid stents. The radial pressure was calculated using mechanical analytic models that we have developed (Fig. 2), and the theoretical graph (Fig. 3) was drawn, and compared with the testing data considering the range of arterial diameters and tapering in swine anatomy. The Diverters' location was evaluated using angiography and by specimen harvesting up to 18 weeks post device implantation.



$$F = 2Nw^{*}\left(\frac{GI_P}{k_3}\left(\frac{2\sin\beta}{k_3} - k_1\right) - \frac{EI\tan(\beta)}{k_3}\left(\frac{2\cos(\beta)}{k_3} - k_2\right)\right)$$

$$k_1 = \frac{\sin(2\beta_0)}{D_0} \;;\quad k_2 = \frac{2\cos^2(\beta_0)}{D_0} \;;\quad k_3 = \frac{D_0}{\cos(\beta_0)}$$

$$D_O = \frac{D_N \cos(\beta_0)}{\cos(\beta_N)} \;;\quad L = L_0 + \delta = L_O\left(\frac{\sin(\beta)}{\sin(\beta_0)}\right)$$

Fig. 2, The *Diverter 's* elongation under load F and the relevant mathematical relations.

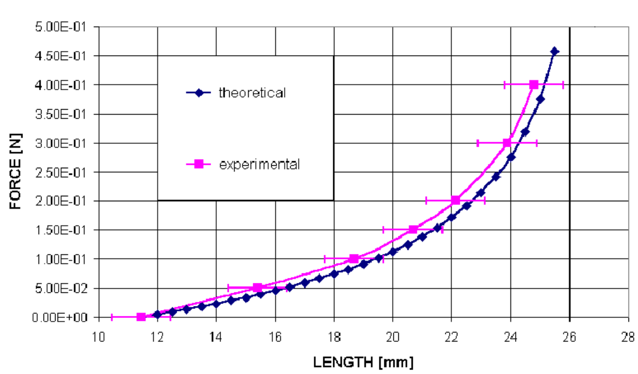


Fig. 3, A sample depicting the length versus the axial load and the compliance with the theoretical model.

RESULTS

In spite of the extremely low radial forces in the two groups, no migration was observed by angiography (Fig. 4) prior to harvesting in all cases. Following animal sacrifice, little shortening of the Diverter was found due to artery diameter growth, but still no migration was observed.

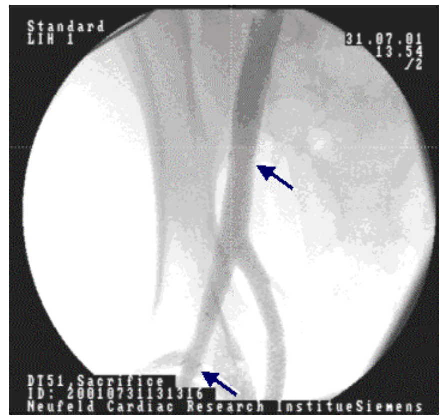


Fig. 4, Angiography depicting the implanted bifurcation in-vivo and the location of the Diverter (between the arrows)

CONCLUSIONS

Implantation of a permanent arterial Diverter made of fine wire with very low radial force is feasible without migration. These preliminary findings give hope to a novel therapy for patients at high risk of embolic stroke from proximal sources, and may serve as a new potential vascular approach for this devastating disease.

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