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Assessment of Flow Quantity and Capture Efficiency of a Distal Protection Device

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Abstract

Purpose: A distal protection device (DPD) is used to perform carotid artery stenting (CAS) more safely. The DPD requires high debris capture efficiencies and proper blood flow quantities to prevent slow flow. The flow quantity and debris capture efficiency of the Filterwire EZ (EZ) and Angioguard XP (XP) were assessed.

Methods: We created virtual models of the common carotid artery (CCA), the internal carotid artery (IC) and the external carotid artery (EC) and generated a pulsatile flow. A 50% or lower IC level of flow was defined as slow flow. DPDs were placed in the IC, and virtual debris was injected until slow flow occurred. Cellulose porous beads (CPBs) were used as virtual debris. The CPBs were administered until slow flow occurred, and the CPB dose, the number of missed CPBs and the ratio of missed CPBs to the total dose were compared.

Results: The dose at which the CPBs caused slow flow was significantly higher in the EZ group, and the number of missed CPBs and the ratio of missed CPBs to the total dose were significantly lower in the EZ group.

Conclusion: Compared with the XP, safer CAS procedures can be performed with the EZ device, because it provides higher blood flow quantities and has higher capture efficiencies.

Key words: **Distal protection device, Flow quantity, Capture efficiency, Carotid artery stenting, Virtual model**

Introduction

Carotid artery stenting (CAS) has been evaluated as a substitute for carotid endarterectomy (CEA). CAS has been performed for patients for whom CEA is risky [1),2),3)] or for randomly assigned patients,[4)] and the results were found to be comparable to those of CEA. To perform CAS more safely, a distal protection device (DPD) is often used. The debris caused by CAS procedures increases the risk of cerebral embolism and slow flow. Slow flow during CAS correlates with a poorer prognosis [5)]. The DPD needs to provide sufficient debris capture and maintain the proper flow to the central nervous system. However, to the best of our knowledge, while the efficacy of debris capturing by injecting certain amounts of virtual debris has been studied previously, there have been no reports focused on slow flow [6)–9)].

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In this study, we examined the flow quantities of DPDs by injecting virtual debris. We examined two DPDs that were available at the time of the experiment in Japan.

Materials and methods

The Angioguard XP (XP) (Cordis, a Johnson & Johnson company) and the Filterwire EZ (EZ) (Boston Scientific) were used (Fig. 1). The pore size of the XP is 110 μm and that of the EZ is 80 μm.

Using 4 mm diameter silicon tubes, we created virtual models of the common carotid artery (CCA), the internal carotid artery (IC) and the external carotid artery (EC), and generated a pulsatile flow with physiological saline. The pulsatile flow was set to 60 times/min using an EYELA ROLLERPUMPRP RP2100. The flow quantity was measured each minute at the outlet of the IC by a cylinder. After the IC flow became stable, DPDs were placed in the IC, and the IC flow quantity was measured. After the DPDs were placed and the IC flow became stable, virtual debris was injected from just proximal to the DPD (Fig. 2). Cellulose porous beads (CPBs) were used as the virtual debris (Fig. 3) because they have uniform porous structures and sizes. The 230 μm in diameter CPBs, which are the smallest size that exceeds the pore size of the filters, were selected for this experiment. Because the CPBs are uniform, the number of CPBs can be calculated based on the weight. In this study, 0.01 g was equivalent to 40,000 units of CPBs and 0.43 cc of physiological saline. Thirty micrograms of CPBs (230 μm) were dissolved in 50 mL of contrast agent and injected at 300 mL/hour. A

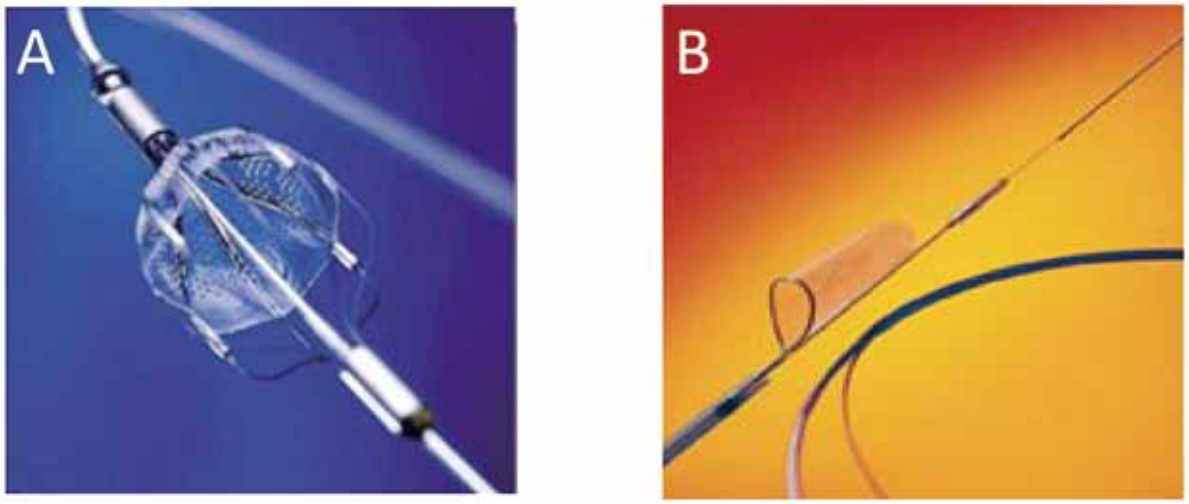

Figure 1. The distal protection devices (DPD) tested *in vitro*.
A: Angioguard XP
B: Filterwire EZ

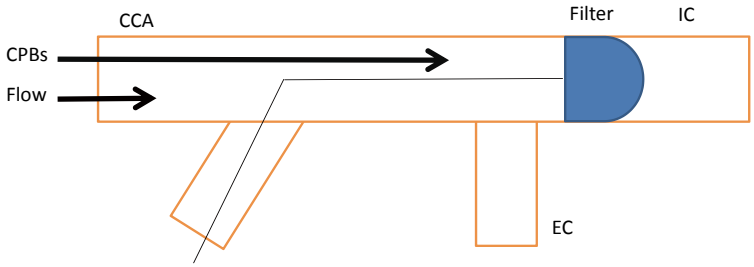

Figure 2. A schematic drawing of the in vitro set-up of the experiment.
CCA: common carotid artery
IC: internal carotid artery
EC: external carotid artery
CPBs: cellulose porous beads

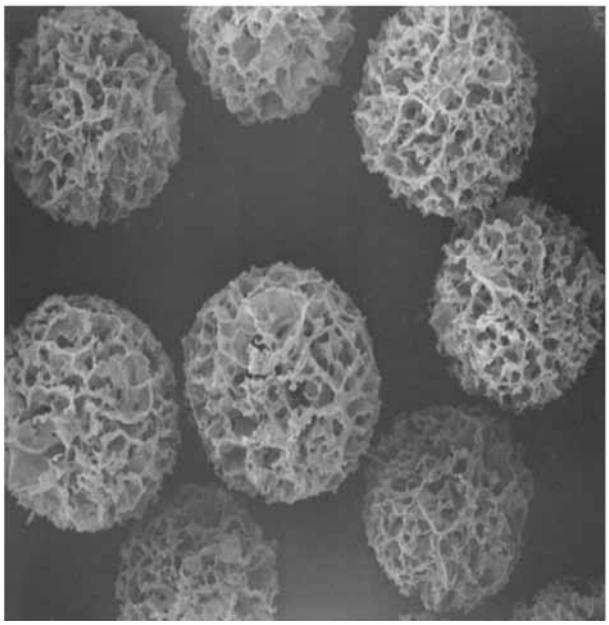

Figure 3. A micrograph of the CPBs.

filter that measured the CPBs that failed to be captured was placed separately at the outlet of the IC. After the experiment, images of the filters were taken with a digital camera, and the number of CPBs trapped by the filter was measured.

We conducted a preliminary experiment prior to this study. The XP and EZ were placed in separate experimental models, and CPBs were injected into them both. We assessed whether the flow was stopped or not. Despite unlimited injections of CPBs, complete stoppage of flow did not occur, and the minimum flow quantity was 25% of the flow quantity before placement of both devices. Based on this experiment, a 50% decrease in the flow quantity compared to that recorded pre-placement was defined as slow flow.

Five experiments were performed with the XP and EZ. We compared the following three elements between them by t-tests（XP and EZ）; 1）CPB dose required to induce slow flow（injectable index）, 2）the number of uncaptured CPBs and 3）the ratio of uncaptured CPBs to the total dose of CPBs（uncaptured ratio）.

Results

The flow quantity of the IC was 100 mL/min under stable conditions without the DPD. The IC flow quantity was 100 mL/min in the EZ and 90 mL/min in the XP under stable conditions after DPD placement. Neither of the DPDs could capture all of the virtual debris completely（Table 1）.

The injectable index of the EZ（4.46 mL±1.06（mean±SD））was significantly higher than that of the XP（2.7 mL±0.12）（P=0.02）. The number of uncaptured CPBs by the EZ（19.4 units±19.0（mean±SD））was significantly less than that by the XP（87.6 units±51.0）（P=0.02）. The uncaptured ratio of the EZ（0.20%±0.19（mean±SD））was significantly lower than that of the XP（1.35%±0.79）（P=0.03）.

Table 1 Injectable index and uncaptured ratio

Angioguard XP				
	CPB dose（ml）	Number of CPBs	Number of missed CPBs	Uncaptured ratio
1st	2.9	6960	74	1.06
2nd	2.7	6480	149	2.30
3rd	2.6	6240	11	0.18
4th	2.7	6480	112	1.73
5th	2.6	6240	92	1.47
mean±SD	2.7±0.1	6480±293	87±51	1.34±0.79

Filterwire EZ				
	CPB dose（ml）	Number of CPBs	Number of missed CPBs	Uncaptured ratio
1st	4.0	9600	47	0.49
2nd	2.8	6720	16	0.24
3rd	5.2	12480	2	0.02
4th	5.1	12240	29	0.24
5th	5.2	12480	3	0.02
mean±SD	4.4±1.0	10704±2534	19±19	0.20±0.19

SD : standard deviation, CPBs : Cellulose porous beads

Discussion

In this study, we evaluated the ability of preserve the flow quantity and the CPB capture rate of two DPDs. With regard to the ability of the DPDs to capture virtual debris, the amount of debris passing through the DPDs was significantly lower with the EZ. We think that the amount of debris passing through the DPDs was associated with the adhesion between the DPDs and blood vessels. The EZ's rate of adhesion to blood vessels was higher, and the gap between the filters and blood vessels was smaller compared with those of the XP, and the amount and the ratio of uncaptured particles were also lower [6]. Although stop flow often occurs during CAS in the clinical situation, we could not generate stop flow in this study. We assume that this was because not only by embolic material, but also various other factors, such as the blood viscosity, coagulation factors and vascular spasms, affect the flow in the clinical situation. In this study, the flow quantity was more preserved in the EZ compared to the XP. This phenomenon can probably be attributed to the flow resistance caused by the filter structures [7), 9)]. The injectable index was significantly higher in the EZ. The capacity for debris capturing, which was attributed to the basket size, of the EZ exceeds that of the XP. Therefore, the EZ has more space for water to pass through, even if the debris is captured by the basket.

When slow flow during CAS is confirmed, the occurrence of perioperative complications within one month is estimated to be five times higher [4)]. DPDs that maintain the blood flow are desirable to ensure safer surgeries.

Based on our findings, CAS using the EZ appears to be safer than that using the XP, because it provides higher blood flow quantities and higher capture efficiencies, although our experiments were performed under simulated conditions that did not completely mimic the clinical situation.

Conclusion

Compared to the XP, CAS can be performed more safely with the EZ, because it provides higher blood flow quantities and higher capture efficiencies for debris.

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