

Turning over a new leaf in the treatment of intracranial aneurysms

The eCLIPs device is now being studied in the EESIS trial, an open label, prospective, multicentre, single-arm, post marketing study evaluating the safety, technical feasibility, and efficacy of the eCLIPs family of products for the treatment of bifurcation intracranial aneurysms. Here, the trial's principal investigator, Joost de Vries (Radboud University, Nijmegen, Netherlands), speaks to *NeuroNews* about the eCLIPs device and how it is different from other devices used to treat intracranial aneurysms.

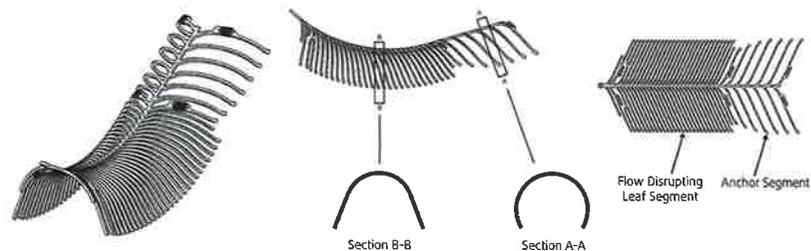
What are the features of the eCLIPs device?

The eCLIPs device is a self-expanding, nickel-titanium, implantable noncircumferential device with platinum radiopaque markers. The device has two discrete sections: an anchor segment designed to conform to the arterial walls beside the neck of a bifurcation aneurysm, and a leaf segment (aneurysm cover) with moveable ribs, designed to allow a coil delivery catheter to pass through the implanted device so as to deliver detachable coils. The leaf segment is designed to divert blood flow and reduce

the jet effect into the aneurysm, thus reducing the chances of aneurysm recurrence, in a manner similar to current flow-diverter devices. The greater density of the leaf segment of the eCLIPs device also provides a scaffold for progressive neointimal growth over the aneurysm neck.

How has the device changed and developed since its inception to now?

This second-generation device differs from the first generation device (published in 2008) in that it is not balloon mounted, it



eCLIPs device



Joost de Vries

comes in a single size suitable for parent vessels ranging from 2.0 to 3.25mm in diameter, and it does not circumferentially cover any of the parent vessel.

A newer, smaller profile version is in development.

How is the eCLIPs device different from other devices used to treat intracranial aneurysms?

Unlike other intravascular devices the eCLIPs is a noncircumferential device, thereby not jailing bifurcation side branches. The leaf segment that covers the aneurysm neck has a low porosity of 70% (or metal coverage of 30%) comparable to flow diverters. In contrast to flow diverters, however, the low porosity is only present at the aneurysm neck. Furthermore, the leaf segment can be passed with a standard microcatheter to coil the aneurysm. Typically the device is used in conjunction with coils.

What is the current experience with the eCLIPs device?

All patients treated with the eCLIPs device are documented in a prospective registry. Recently the initial experience in the first 33 patients was published (Chiu AH, De Vries J, O'Kelly CJ, Riina H McDougall I, Tippett J, Wan M, de Oliveira Manoel AL, Marotta TR. The second-generation

eCLIPs Endovascular Clip System: initial experience. *J Neurosurg.* 17:1-8, 2017).

An initial group of patients was treated starting June 2013 in Canada due to their "no other therapeutic option" status (Canada's Special Access Programme). These patients had particularly complex lesions (recurrent symptomatic giant basilar tip aneurysms). A second group of patients were treated after CE mark status was obtained.

Two periprocedural transient ischaemic attacks and two asymptomatic thrombotic events occurred.

Twenty-one patients had a follow-up at an average of eight months and 17 (81%) sustained a modified Raymond-Roy Classification (MRRC) class of I or II angiographic result. No worsening of MRRC was recorded. So far in total 52 patients have been treated with the eCLIPs device.

As the device is intended to treat bifurcation aneurysms, could it potentially address a currently unmet need?

Follow-up after eCLIPs implantation revealed no cases of worsening MRRC, which is a well-documented issue following stent-assisted coiling. This could reflect the flow-disrupting effect of the eCLIPs device.

The eCLIPs device is now being studied in the EESIS trial. The primary outcome measures being assessed are: absence of a major territorial stroke or death (procedural) at 30 days, absence of a major territorial stroke or neurological death between 30 days and 12 months, complete aneurysm occlusion (Raymond 1) at six months, and complete aneurysm occlusion (Raymond 1) at 12 months. Investigators aim to enrol 60 patients at ten centres in Europe.

de Vries told *NeuroNews* that so far seven patients have been enrolled in the trial, with an estimated end date of mid-2019.