

Update On The Current Status Of A Catheter Aortic Septotomy Device For Treating Aortic Dissections By Cutting The Septum From Below: Yes, There Is A Downside To Other Septotomies That Cut The Septum From Above

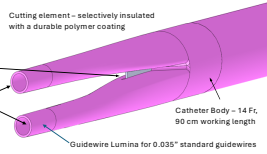
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I have no conflict of interest

The numerical and experimental work for this catheter was done in my engineering lab at the U of Michigan by my research associate Khalid Khanafer PhD and two PhD candidates, Marty Schlicht PhD and Ambroise Duprey MD, PhD

The Catheter for Retrograde Septectomy

- A cutting electrode to deliver RF power housed between 2 flexible tips
- The flexible tips-for the guidewires- slide into each of the 2 lumina of the dissected aorta, leading the cutting element to the edge of the septum

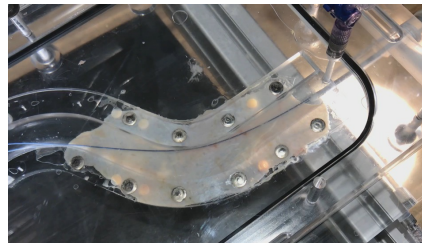


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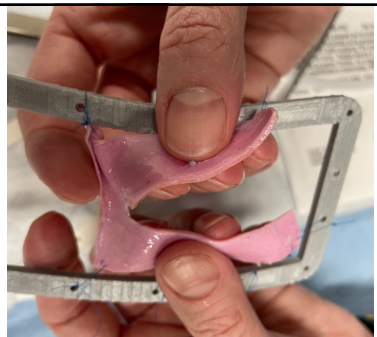
Septectomy in an aortic model



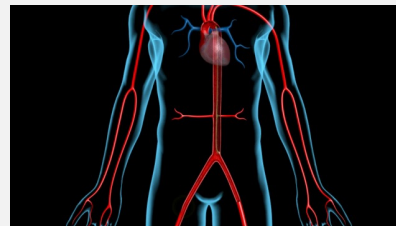
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A full-thickness human aorta cleanly divided by the RF catheter



Device Overview – Simulation



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Our catheter was designed for two purposes:

- 1-To facilitate the placement of an endograft in a chronic AD
- 2- As the primary treatment of acute, complicated AD

Endograft Treatment of a CHRONIC Dissection

Since 2014, various centers have reported using *ad hoc* fenestration techniques to create a segment of aorta with a single lumen to facilitate the attachment of an endograft. These septectomies were done using:

- Balloon inflation at the septum. (Mehta et al. Faure et al)
- Antegrade wire-saw technique (Geisler et al)
- Antegrade pulling of wire connected to electrocautery (Kabbani et al, Timaran et al.)

These *ad hoc* techniques can lead to complications:

Mechanical disruption of the septum by balloon or wire causes a tear of unpredictable length and orientation

Both the cheese-wire technique and the balloon disruption may result in wadding of the distal aorta by intimo-intimal intussusception and in occlusion of the aortic branches by elements of the divided/ruptured flap.

Treatment of complicated ACUTE Aortic Dissection:

- (1) To restore inflow into dissected branch vessels
- (2) The septectomy- by equalizing the pressure in both lumina reduces/avoids the later risk of developing an aneurysm

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Clinical corroboration of the last hypothesis:

(1) 1940 patients who underwent aortoiliac endarterectomy **never** developed an aneurysm of the endarterectomized aorta. (Euro J Vasc Endovasc 2010;39:460-71)
The wall left after aortic endarterectomy, similar to the lateral wall of the false lumen, does not dilate. In an AD, within minutes, the now thinner FL wall dilates 10-12% (Laplace). But, any further dilation into an aneurysm, months to years later, will be the consequence of a differential of pressure between the lumina

(2) 80 reported patients who had an **open** surgical fenestration to treat a complicated AD with visceral/ leg ischemia did not develop an aneurysm in the fenestrated aorta after 10 years

It can be surmised that fenestration, by equalizing the pressure in both lumina, prevents the formation of aneurysm

The human studies of our catheter will be carried out at the Frankel Cardiovascular Center (U of Michigan) by Dr J Eliason and at Mass General Hospital (U of Harvard) by Dr M. Eagleton