Vascular Closure Devices

Provisional Patent

Biodesign Innovation: Team 10

Inventors

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BACKGROUND OF INVENTION

1. Field of invention

The present invention is related to closure of vascular access openings created during percutaneous vascular procedures.

2. Prior Art

The field of vascular closure devices is dense and several decades old. The problem of vascular closure has been addressed by many devices and methods. The efficacy and complication rates of the commonly used ones are pretty consistent and considered to be comparable to that of manual compression. Here we will discuss prior art and freedom to operate issues as they directly apply to the concepts covered by this provisional patent. The four aspects of our design for which prior art relevant to vascular closure exists include: catheter balloons, method of deployment of the device, vascular closure or repair with a vascular patch and valve/port vascular devices.

A review of the prior art shows that in the vast majority of proprietary applications balloons are used inside the artery as a means to apply pressure to the inner walls of an artery to dilate the lumen of an artery. Our present invention proposes to use a balloon catheter passed along a guide wire to dilate an arteriotomy after initial arterial access. Patents which describe balloons being used in physical forms similar to our concept may need to be further assessed to determine our freedom to operate, but our preliminary assessment suggests that they will not create any limitations. For example, US Patent #4950276 describes the use of a balloon as a dilator, but the dilation effect is with respect to vessels constrained by prosthetic banding devices and the patent claims do not appear to apply beyond that usage environment. Similarly, US Patent #5868778 includes a claim around the insertion of a balloon apparatus through an introducer which is disposed in the blood vessel opening. This claim is relevant to our proposed device design, but the ensuing application of the balloon is different from our design and similar to other prior art in terms of its use of a separate sealing method (in this case, a procoagulant). US Patent # 4748982 is also relevant as it describes a balloon dilation catheter that is passed along a guidewire, but might not restrict freedom to operate as it is not specifically designed for dilation for vascular access.

Vascular closure devices utilize many different methods to deploy the device in the patient. Our device is attached to the introducer sheath and inserted in the patient along with the introducer sheath near the beginning of the procedure. US patent #6461364 describes a clip and fastener vascular closure

apparatus that is delivered by way of the introducer sheath. This patent is relevant to the specific method of introduction of our vascular closure devices but, focus on specific closure devices in the claims that is different than ours.

Vascular patches are common alternative to simple repair with sutures to repair vascular incisions. However a preliminary search of US patents did not yield any patents that describe percutaneously deployed vascular patches or patches that also provide vascular access. US patent #5100422 describes a PTFE blood vessel patch that is attached to the blood vessel by way of sutures. This is the most relevant patent to our PatchPort patch concept. US patent #4164045 describes an implantable artificial vascular graft or patch material that is similar to the proposed material for our device, but also does not describe a patch that provides access and closure.

Valves are widely used as medical devices in vessels, especially in heart repair and for ports to access various portions of the vasculature. However, a search of the US patent databases does not yield any IP that directly speaks to the use of a valve as closure device. Among the notable patents are US patent #6042569 assigned to Vasca, Inc. which describes a vascular cannula with a pressure-responsive valve for implantation into a blood vessel subcutaneously. US patent # 5149327 assigned to Terumo and US patent #5149327 assigned to Hiroaki Oshiyama describe a medical valve used in conjunction with a catheter. Finally, there are many patents describing valve ports for accessing blood vessels, such as US patent # 7056316 which outlines valved ports for accessing blood vessels and other body lumen.

DESCRIPTION OF INVENTION

I. PatchPort

Description of the device

The PatchPort device includes components that provide controlled opening, maintained access and solid vascular closure all with one device. Closure of arteriotomies up to 22F is achieved by placement of a vascular patch. Opening is achieved by a specialized access balloon that also contains an endplate that is deployed upon inflation to determine correct positioning of the PatchPort patch. The PatchPort patch provides both acute vascular access and long term vascular closure by way of two overlapping retractable elastic membranes. The patch is positioned during the access process and engaged to the overlying tissue around the arteriotomy using tines. It and the introducer sheath provide an access point for the working tools of the relevant clinical procedure. When the procedure is done the tools are removed along with the sheath and the patch is left behind, sealing the arteriotomy.

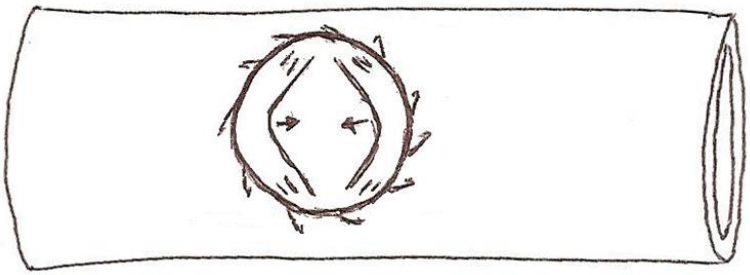
Process of use

The closure process begins with opening of the arteriotomy. A balloon is attached to the dilator or sheath used to make the arteriotomy. It then is inflated to dilate the arteriotomy to the desired size and to deploy a traction endplate. Next the balloon is partially deflated after inserting a working sheath with the PatchPort patch attached. Once the sheath is inserted the endplate is snugged against the inner wall of the artery and the sheath (with the PatchPort patch attached) is pushed as close as possible to the arteriotomy. The tines of the PatchPort patch are engaged to the tissue just outside of the arteriotomy by

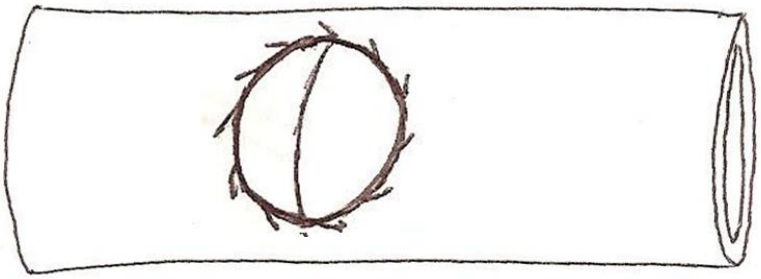
rotating the sheath. After the PatchPort patch is engaged the balloon is deflated and removed. With solid access achieved and the patch in place, the tools are then passed through the sheath. After the procedure is completed the tools and sheath is removed. When the sheath is removed the port, which is created by two overlapping flexible membranes that are stretched open, closes sealing the patch and achieving hemostasis.

DRAWINGS

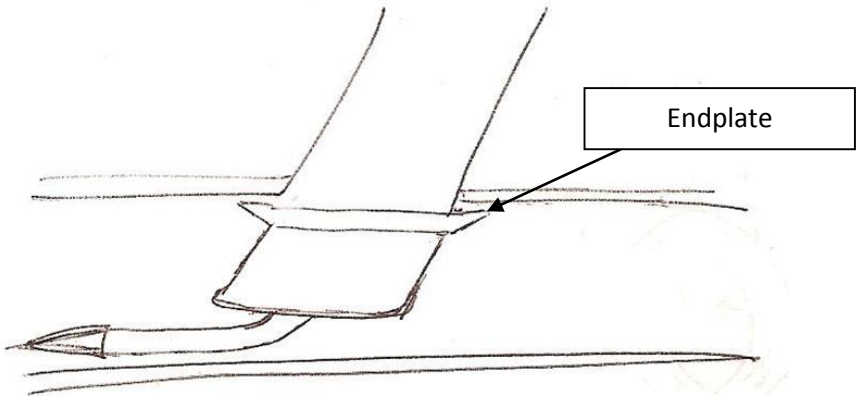
The following drawings describe the invention and its process of deployment.



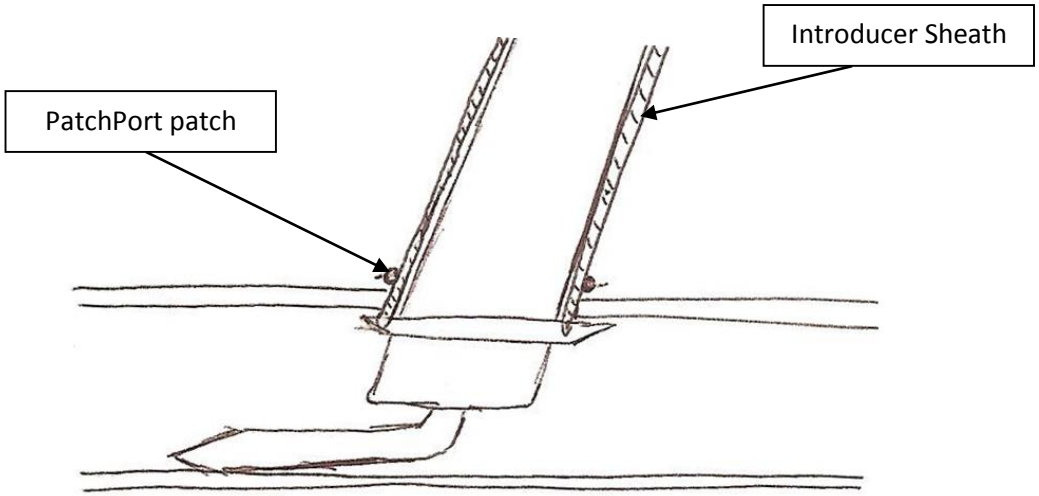
PatchPort patch prior to removal of sheath. Note dual membranes retracting after removal of sheath.



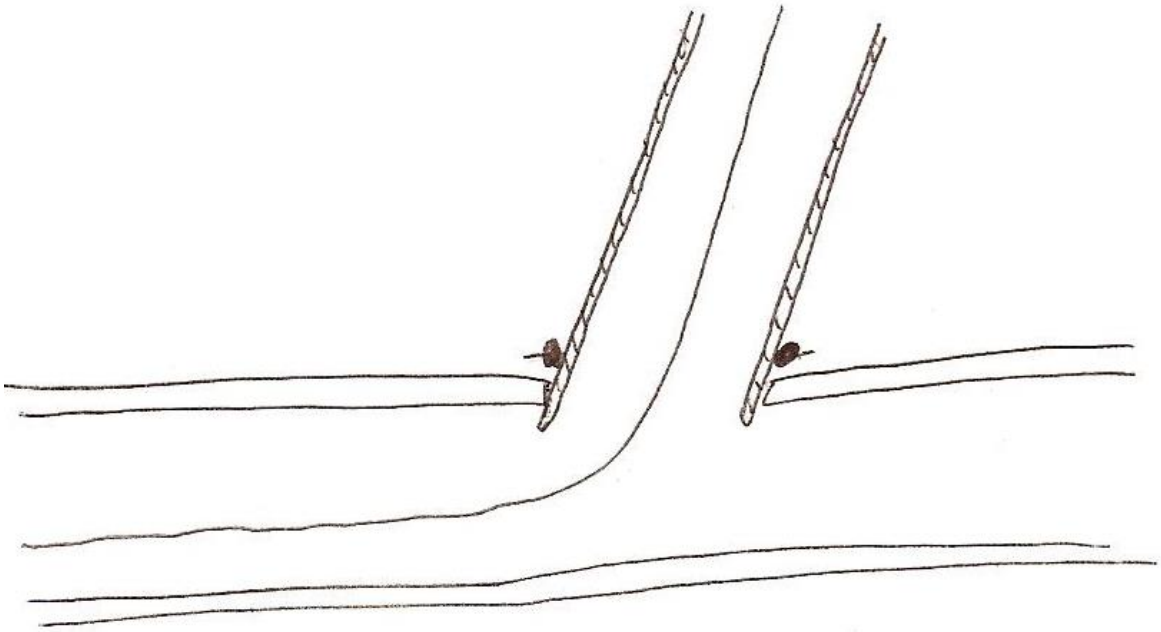
Top view of the PatchPort after procedure.



Side view of artery after dilation of arteriotomy is complete. Note the balloon endplate pulled against the inner wall of the artery.



Cross section view during the procedure when theiIntroducer sheath is inserted with the PatchPort patch attached. Note the sheath is pushed against the endplate ensuring correct placement of the patch.



Access achieved with guidewire passing through the sheath.

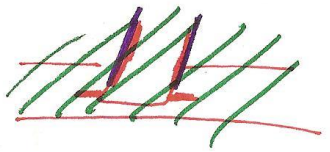
(1) Midway through dilation insert balloon dilator

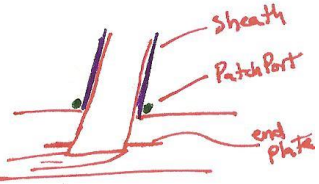
(2a) inflate balloon dilator to dilate the arteriotomy to the desired size & to deploy traction endplates.

(2a)

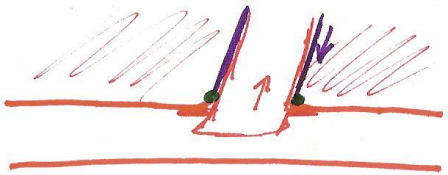
← inflated balloon has a traction endplate attached allowing for correct positioning..

(3) ~~Pull the balloon dilator~~ Partially deflate the balloon dilator after inserting working sheath with patch port.

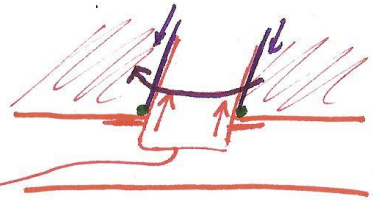




(4) Once the sheath is ~~deep~~ inserted the end plate is snuggled against the inner wall of the artery + the sheath (with patch port attached is pushed against the outer wall of the artery. This will ~~help~~ ensure that the patch port is as close to the arteriotomy as possible.



(5) While maintaining the smushing force the sheath is rotated, engaging the tines of the patch port.

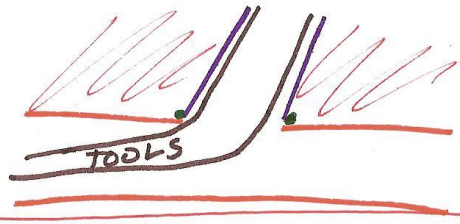


top view

tines

Patch port

(6) After the patch port is engaged.. the balloon is deflated + removed .. then the tools are passed for the procedure.



(7) When the procedure is complete the sheath is removed and the patch port leaflets seal the arteriotomy

Microsoft interactive Future interface