Review

# Percutaneous Closure Device for the Carotid artery: An integrated review and design analysis

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## ABSTRACT

Endovascular thrombectomies (EVTs) are the current standard of care therapy for treating acute ischemic strokes. While access through the femoral or radial arteries is routine, up to 20% of EVTs through these sites are unable to access the cerebral vasculature on the first pass. These shortcomings are commonly due to tortuous vasculature, atherosclerotic arteries, and type III aortic arch, seen especially in the elderly population. Recent studies have shown the benefits of accessing the cerebral vasculature through a percutaneous direct carotid puncture (DCP), which can reduce the time of the procedure by half. However, current vascular closure devices (VCDs) designed for the femoral artery are not suited to close the carotid artery due to the anatomical differences. This unmet clinical need further limits a DCP approach. Thus, to foster safe adoption of this potential approach, a VCD designed specifically for the carotid artery is needed. In this review, we outline the major biomechanical properties and shortcomings of current VCDs and propose the requirements necessary to effectively design and develop a carotid closure device.

## INTRODUCTION

Stroke is the fifth leading cause of death in the United States, affecting more than 800 000 people annually.[1] The extent of disability is directly related to the duration of the occlusion, as close to 1.9 million neurons are lost per minute during an acute ischemic stroke (AIS).[2] Therefore, diagnosis and treatment of stroke are extremely time sensitive. Endovascular thrombectomy (EVT) is the standard of care therapy and is traditionally performed through the femoral or radial artery.

While current access sites include the femoral and radial arteries,[3–5] failure rates range from 2.2% to 20% due to prohibitive vascular access related to tortuous vasculature, peripheral arterial disease, atherosclerotic arteries, and type III aortic arch.[5] For these patients, recent studies have explored the benefits of accessing the cerebral vasculature directly through the carotid artery.[6–9] Access from a percutaneous, direct carotid puncture (DCP) has demonstrated equivocal functional outcomes with higher reperfusion rates for this patient population.[8 9] Although femoral vascular closure devices (VCDs) are currently used for off-label closure of the carotid arteriotomy, these devices are not ideal nor suitable for the carotid given the risks of cervical hematoma, airway compromise, and potential thromboembolism. Several studies have called for the creation of a carotid closure device (CCD) to target this clinical problem.[6–9]

Here, we provide a brief overview of the biomechanical properties of current VCDs, explore their basic mechanical characteristics and technical limitations for use in the carotid artery, and detail key design requirements for a CCD.

## METHODS

An engineering design analysis following a process of defining a clinical problem, identifying user needs, and creating design inputs were strictly followed.[10] The senior author (RGT) approached a team of biomedical engineers (SB, GR, NJL, JTC, DWP) with a clinical problem of developing a device designed for safe and effective closure of the carotid artery for stroke interventions.

We conducted interviews with over 30 neurointerventionalists, interventional cardiologists, and interventional radiologists across eight institutions within the US to determine the user needs and address the clinical problem. The user needs were divided into four distinct categories: 1) critical engineering requirements, 2) device characteristics, 3) materials, and 4) human factors. Furthermore, user needs within each category were classified by order of importance (High, Medium, Low).

A comprehensive literature review was conducted on PubMed from inception to January 2023 to understand shortcomings associated with current VCDs using the following keywords: vascular closure device, endovascular procedures, percutaneous access, femoral artery, and carotid artery. Two independent reviewers performed the search described. Findings from the literature review were used to develop the design inputs (**figure 1**).

## RESULTS

### User needs

User needs were determined from the informative interviews with clinicians and classified into several categories: critical engineering requirements, device characteristics, materials, and human factors. All the critical engineering requirements were classified as *high* importance. These include the ability to achieve rapid hemostasis while avoiding additional punctures in the carotid wall and reducing the risk of thromboembolic complications. Among the device

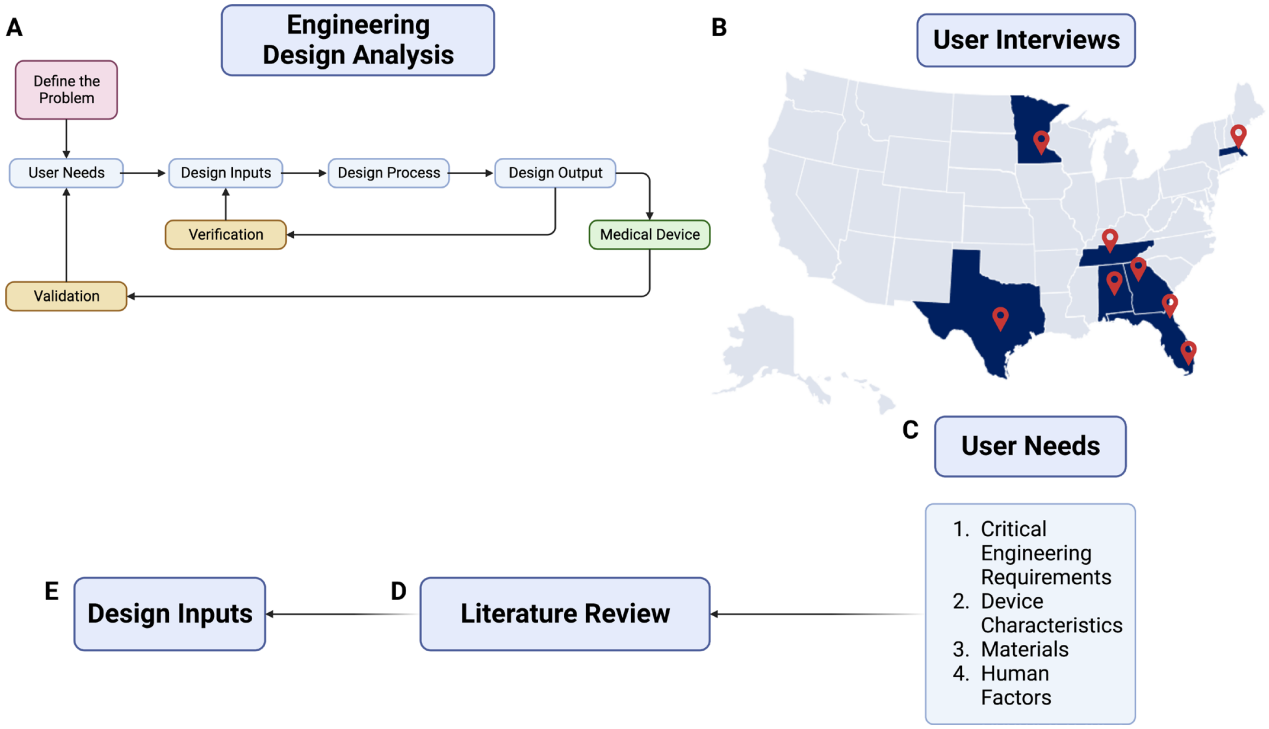


**Figure 1** Outline of the methodology that was taken to obtain the design inputs. (A) overview of a general engineering design process, adopted from the Food and Drug Administration design control guidance for medical device manufacturers; B) US map with highlighted location of the user interviews that were conducted; C) user needs stratified by category; D–E) literature review conducted on the user needs to generate design inputs. *Created with BioRender.com*.

characteristics, the most important factor was to limit the distal length of the device to prevent crossing the carotid bifurcation. Following this, maintaining compatibility with existing 6–8 French sheaths and micro guidewires were classified as *medium* importance. The materials of the intra- and extravascular components that need to be considered for a CCD are classified as *high* importance. Intravascularly, components should be rigid, low-profile, and non-thrombogenic, while extravascular components should be focused on promoting thrombogenicity to enhance rapid hemostasis. Lastly, human factors are needed to incorporate tactile and visual feedback mechanisms for the user, however, these are of *low* importance.

## Findings of the literature review

### Current Food and Drug Administration (FDA) approved VCDs for the femoral artery

A total of 12 articles from the literature review were included in our analysis.[11–22] There are three basic principles that can be used to classify VCDs for the femoral artery: suture-based, extravascular-based, and compression-based.[11–18]

The most common suture-based VCDs are the Perclose ProGlide and the Prostar XL (Abbott Vascular, CA, USA), both of which close the vessel tightly through additional puncture sites and sutures. While Prostar XL is designed for closure of cardiac procedures requiring large access sites, Perclose is commonly used for routine neurointerventional procedures with an 8 French access.

There are several extravascular-based VCDs that perform a mechanical closure of the vessel opening and some that use an absorbable extravascular component. Starclose (Abbott Vascular, CA, USA) is one of the VCDs that implements a mechanical closure by clipping the arteriotomy and creating additional puncture sites in the vessel wall. The most common extravascular VCDs place a collagen or gel-like substance extravascularly to induce hemostasis. These include the MynxGrip (Cordis, FL, USA), Exoseal (Cordis, FL, USA), and Vascade (Cardiva Medical, CA, USA). These devices are broadly used given their simplicity, especially for routine angiograms with a smaller 5–6 French access.

Compression-based VCDs exhibit the most robust mechanism, with compressive forces from both the extravascular and intravascular surfaces driving its closure. Some compression-based devices, such as the Angio-Seal (Terumo Medical, NJ, USA), implement a sturdy intravascular component, while others such as the Celt ACD (Vasorum, Dublin, Ireland), offer sturdy components on both sides of the vessel. Angio-Seal is the most used device, touted for its simplicity and reliability for many percutaneous femoral artery approaches.[11]

A summary of the advantages and disadvantages of these three most common VCDs is listed in detail in table 1.

## Design inputs

The user needs along with findings from the literature review informed the design inputs according to four core categories. The user needs, design inputs and associated metrics per input are detailed in table 2.

An engineering analysis of the current VCDs is essential to provide an objective framework for the suitability of their components for carotid closure. The CCD should be able to safely close the carotid artery without posing any additional risk to stroke patients following an EVT.

**Table 1** Advantages and disadvantages of the most common VCDs

| Perclose ProGlide | | MynxGrip | | Angio-Seal | |
|---|---|---|---|---|---|
| **Advantages** | **Disadvantages** | **Advantages** | **Disadvantages** | **Advantages** | **Disadvantages** |
| Complete closure of the arteriotomy | Creates additional punctures | Induces thrombosis extravascularly | Occlusion of the vessel on deployment | Induces thrombosis extravascularly | High-profile intravascular component |
| No intravascular components | Device crosses the carotid bifurcation | | Lack of a compressive mechanism; no rigid intra- and extravascular components | Compressive mechanism with both intra- and extravascular components | Lack of a rigid extravascular component |

## Critical engineering requirements

Current VCDs average a leakage rate of less than 0.32 mL/sec post-closure.[19–21] Although this might be tolerated by patients following femoral access, the risks associated with carotid access are potentially life-threatening. Specifically, for a CCD to be unique and more effective than current VCDs, it should first minimize residual bleeding from the carotid artery into the surrounding extravascular space, achieving close to 0 mL/sec of blood flow.[19] Carotid bleeding from the arteriotomy site can lead to hematoma formation and induce cerebral ischemia from reduced blood flow, as well as possible obstruction of the airways. To mitigate blood loss, some crucial aspects of the device are that it should achieve rapid hemostasis and prevent the formation of emboli at the intraluminal component of the device.

**Table 2** Design inputs for a carotid closure device.

| | User need | Design input | Metric |
|---|---|---|---|
| Critical Engineering Requirements | Minimal residual bleeding | Flow rate of blood into the extravascular space | 0 mL/sec (±0.1)[30] |
| | Does not create additional emboli | Intra-arterial pressure to cause dislodgement | Up to 220 mmHg systolic pressure[19] |
| | Rapid hemostasis | Time to deploy the device | < 1 min for deployment<br>< 1 min for hemostasis[20] |
| | Minimize additional puncture sites | Number of puncture sites | ≤ 2 punctures[11] |
| | Lower failure rate than competitors | Failure rate for establishing hemostasis | < 1.30%[21] |
| Device Characteristics | The distal end of the device must not cross the carotid bifurcation | Length of the distal portion of the device | < 5 cm[22] |
| | Close an 8F puncture site | Inner diameter of the device | ID=2.67 mm (±0.1 mm)[11] |
| | Compatibility with existing access sheaths | Inner diameter of the device | ID=2.67 mm (±0.1 mm)[11] |
| | Maintain vascular access through a guidewire | Inner diameter of the device | ID=2.67 mm (±0.1 mm)[11] |
| Materials | Biocompatible, thrombogenic extravascular component | Thrombogenic material | Collagen[11] |
| | Biocompatible, non-thrombogenic intravascular component | Non-thrombogenic material | Poly-lactic-acid (PLA)[11] |
| Human Factors | Provide feedback on the lumen location | Visual/tactile feedback on lumen contact | Labeled markers and a step-by-step guide to ensure proper deployment[11] |

## Device characteristics

A safe CCD should not cross the carotid bifurcation to avoid complications related to a potential carotid plaque, thus the length of the distal end of the CCD should be less than 5 cm, which is the minimum distance from the beginning of the carotid to the bifurcation point.[22]

Furthermore, the CCD should be able to close the 6–8 French access site securely.[11] Alternatively, the CCD can be designed with its own sheath that could be exchanged with the existing sheath, necessitating a hollow center for the guidewire. Compatibility with existing equipment will facilitate easier and faster adoption into clinical practice.

## Materials

To facilitate effective closure and prevent risks to the patient, the materials used should complement the function of the device. Intravascularly, components should be non-thrombogenic and low-profile to minimize the risk of thromboembolic complications. Poly-lactic-acid (PLA) is a proven bio-compatible, non-thrombogenic material for intravascular components.[11] Extravascular components need to have thrombogenic properties to promote rapid hemostasis; however, they should be coupled with a safety component to prevent their displacement to the intravascular space. The literature suggests that collagen is the safest and most widely used thrombogenic material for extravascular applications.[11] Angio-Seal, for example, utilizes a PLA-based intravascular anchor as well as an extravascular collagen plug that are both absorbed by the body within 90 days.

## Human factor considerations

Human factor considerations are intended to make the CCD safe, intuitive, and effective for the user. Current VCDs use a variety of feedback mechanisms to facilitate proper deployment and inform better positioning of the device. To provide tactile feedback and approximate the intravascular wall, Perclose utilizes a footplate, MynxGrip utilizes a balloon, and Angio-Seal utilizes an anchor. To provide visual feedback, Angio-Seal and Perclose have openings on the intraluminal portion of the device which allows blood to flow from the intraluminal space to the exterior upon lumen contact.[11] Additionally, there are measurement markers along the side of Angio-Seal that reflect the depth of the device, facilitating proper deployment. This feedback is essential to provide visual feedback for optimal deployment of the device regardless of variations in tissue thickness. Finally, including a step-by-step numerical guiding system will help to mitigate confusion and ensure proper deployment.

### Regulatory considerations

A CCD can be classified as an FDA Class II device due to several existing predicate devices. This reduces the financial burden of creating and testing such a device and can allow for CCDs to enter the market within a few years.

## DISCUSSION

### Percutaneous transcarotid access

Cerebral angiography procedures date back to the early 1960s, when the percutaneous transcarotid access was first described as a routine, first-line access point.[23] As the field evolved, safer access sites were explored and the transfemoral and transradial approach gained popularity.[23 24] These approaches are now the standard of care for neuroendovascular procedures. There is a growing body of evidence that has demonstrated the benefits of the transfemoral or transradial approach. However, bovine arch, type II and III aortic arch, tortuous vasculature, and occlusive disease of proximal vasculature are some reasons that preclude a successful EVT from these access sites.[7 9 25] Despite newer flexible radial guide catheters, these anatomical limitations may still render the DCP necessary.

Currently, DCP is used as a potential bailout technique in the case of transfemoral or transradial access failure.[6–9] The traditional attitude surrounding access sites has been to avoid a DCP due to increased risk and morbidity for the patient. Recent studies have demonstrated the added benefit of performing an EVT through a DCP. Yu *et al*[9] retrospectively analyzed their series of 126 patients, 13 (10.3%) of whom received a DCP after a failed transfemoral approach. There were no differences in functional outcomes for patients undergoing DCP compared with non-DCP controls. Cord *et al*[6] reported that 20/352 (5.7%) patients with prohibitive vascular access underwent a DCP. Dumas *et al*[7] described the Carotid Artery Puncture Evaluation (CARE) study and evaluated the safety of a DCP for patients after a failed transfemoral approach across 45 sites in Europe. Although the incidence for a DCP was low (108/28149 patients; 0.39%), there was a high complication rate in the DCP cohort (18.5%) which was attributed to the absence of an effective closure device.

As EVT indications and accessibility continue to expand globally, there is an increasing need to reduce the time elapsed between stroke onset and reperfusion. In light of this transformative care centered on time and efficiency, our field is faced with the challenge of maximizing the tools in our armamentarium to continue optimizing stroke care. The use of a DCP has evolved over time; however, it has recently garnered renewed attention for EVT.[6–9 25] While we do not anticipate the transcarotid approach to supplant traditional approaches, given the expanding indications for EVT and the drive to minimize the time between stroke onset and EVT, the adoption of a DCP may progressively increase over time once a safe and effective CCD is available.

### Issues with carotid artery closure

Manual compression has traditionally been the most common way to achieve hemostasis following removal of the access sheath. This, however, has major implications for use in a DCP given the required pressure on the carotid artery and the airways for securing hemostasis, with risks of cervical hematoma and airway compromise. While current VCDs are designed to achieve adequate hemostasis for femoral access, they are not designed for the carotid artery and their use in stroke victims with DCP is not optimal.

### Why are current VCDs unable to work in the carotid?

The complications related to the deployment of VCDs can be detrimental to patients if they occur in the carotid artery.[26] While every VCD is designed with specific mechanisms and variable advantages and disadvantages, none of them accounts for the specific anatomy of the carotid artery. Perclose is unable to safely close a carotid puncture due to its long distal end which can pass into the intracranial vasculature, risking further complications.[22] Also, the additional needle punctures in the vessel wall might result in bleeding, especially in patients on anticoagulants or following IV thrombolytics, which can lead to cervical hematoma. Unlike other access sites, cervical hematomas can result in compression of the airways and the carotid artery, ultimately posing additional risks to patients.

MynxGrip has a short distal component and might be safe to advance distally within the internal carotid artery; however, the PEG sealant can be easily displaced leading to extravasation, especially in coagulopathic patients, and those on antiplatelet and anticoagulant medications.[27 28] External devices that require mechanical compression to induce hemostasis are not ideal for use in the neck due to the risk of compromising the flow within the carotid and impairing ventilation during cervical compression.

Lastly, although existing devices with an intravascular anchoring component like Angio-Seal are very effective for a femoral closure, they pose unique risks when used in the carotid. Specifically, large, and high-profile intravascular anchors have an increased risk of altering the flow dynamics in the carotid and causing thromboembolic complications, which could lead to a stroke.[29 30]

### Design considerations for a CCD

In this study, the shortcomings of current VCDs were determined based on interviews with neurointerventionalists and a comprehensive literature review. The collected datapoints were used to develop key design inputs for creating a successful CCD.

Critical engineering requirements include the ability to achieve rapid hemostasis while avoiding additional punctures in the carotid wall and reducing the risk of thromboembolic complications. The distal end of the device that is introduced within the carotid to secure deployment should be less than 5 cm to prevent crossing the carotid bifurcation and should maintain compatibility with existing 6–8 French sheaths and 0.014-inch microwires. It is preferable to use intra- and extravascular components to maximize the ability to achieve hemostasis. Intravascular components should be rigid and low-profile. The intravascular component should be derived from non-thrombogenic materials, such as metal (eg, titanium, cobalt, platinum, etc.) or PLA to prevent distal embolization. Careful consideration may be given toward designing the intravascular component as a single piece to further prevent distal embolization: a component that traverses from the intravascular space, through the lumen and into the extravascular space. The extravascular component should be designed to promote rapid hemostasis; collagen was noted as one of the most widely used thrombogenic materials. In order to reduce and potentially eliminate extravasation, a rigid PLA extravascular component designed to couple the extravascular collagen may be necessary to prevent displacement of any device component. Lastly, visual/tactile feedback during deployment is essential to help with accurate and optimal deployment at the epicenter of the arteriotomy site. This will hopefully guarantee a secure and reliable closure while allowing minimal complications to facilitate adoption into clinical practice.

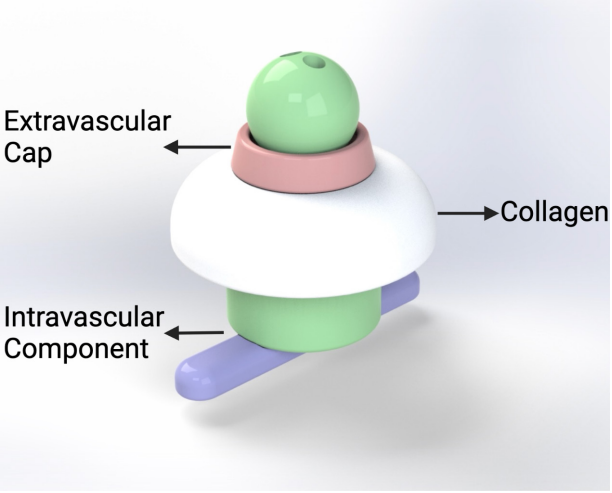


**Figure 2** Proposed carotid closure device. Intravascular component to secure device against the lumen, collagen to act as a thrombogenic extravascular plug, and a rigid extravascular cap to secure the collagen in place.

### Proposed carotid closure device

After implementing a thorough engineering design analysis of the current VCDs, we are proposing that an ideal CCD would have the components shown in figure 2. These components are a) sturdy, low-profile, non-thrombogenic intravascular component b) thrombogenic, extravascular plug c) rigid, extravascular component to secure the extravascular plug.

The key standards with safety and efficacy criteria investigated in this article are essential for developing a secure CCD. A novel device will likely increase the safety of direct carotid access in selected patients with challenging routine endovascular access. Once developed, the safety and efficacy of such a device need to be demonstrated in basic settings and subsequently implemented in clinical trials before routine clinical use. This will hopefully expand the window of EVT to benefit patients with hostile anatomy where routine approaches fail to achieve benchmark standards in terms of timing and success rates. It might also benefit other intracranial procedures where the carotid artery can be used as a primary site for safe and reliable vascular access. Once available and given the safety profile by the FDA, the device could be adopted by other fields, such as interventional cardiology and radiology.

## LIMITATIONS

This study has several limitations, given its qualitative and non-randomized design. The user needs determined from user interviews were subjective based on each interventionalist's personal experience. However, these interventionalists have years of expertise and this is a necessary step in the identification of flaws in current designs and key points for future directions. Further studies are needed to evaluate the design inputs proposed here through in-vitro and in-vivo animal testing. Further adoption into clinical practice will require sufficient safety demonstrated in clinical trials.

## CONCLUSIONS

Currently, there are no vascular closure devices designed specifically for the carotid artery, discouraging the use of a DCP for EVT. In this review, the major biomechanical properties and shortcomings of current closure devices are investigated with an objective analysis of their suitability for carotid closure. Additionally, we propose the key design requirements necessary to effectively design and develop a carotid closure device.

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