Use of Spinal Vessel Protection to Facilitate Anterior Revision Surgery

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Introduction

Patients who undergo anterior surgical procedures in the spinal column (cervical, thoracic, or lumbar) face the possibility of needing revision surgery. Whether due to infection, improper positioning of the prosthesis, device failure, adjacent level changes, or continuing symptoms, approximately 15% (range 10%-30%)[1] of spinal fusion surgeries fail and the patient may need a secondary spinal procedure. Careful patient selection and meticulous surgical technique may decrease the need for revision surgery. However, even with these precautions, anterior spinal revision surgery cannot be avoided in many cases.

Revision anterior spinal surgery has inherent risks such as intestinal, neurological, and or vascular injury. To mitigate these risks, access to the spinal disc is usually performed by highly skilled spinal and vascular surgeons who are familiar with the intestinal, neurological and vascular anatomy.[2, 7] Brau, et al reported an overall 11% (7/63) incidence of vascular injury during revision surgery.[3, 4] In addition to the risk of injury to the aorta, the vena cava, and the iliac vessels, these procedures, are also complicated by scarring around the surgical site.[8] Revision surgery presents a significant challenge to the access surgeon, since re-exposure of the spine requires mobilization of the peritoneal sac, which is usually fused to the anterior abdominal wall muscles, as well mobilization of the major vessels and ureter, which are at the time of surgery are encased in fibrous tissue and firmly adhered to each other and the anterior surface of the spine. Sometimes, this can present an enormous problem depending on the type of revision required. Interestingly enough, it has been reported that even at only 10-14 days there is already a capsule surrounding an intervertebral device.[6]

A few papers specifically address the problem of vascular injury. Unfortunately, the results and reported complications vary widely. Nguyen et al[9] reported an 89% incidence of vascular complications at L4-L5 and 40% at L5-S1. Wagner et al[10], on the other hand, report only one vessel injury in 21 revisions of the CHARITÉ artificial disc[5] while Gumbs et al indicate 3% injury.[2] Despite this variance in results, revision surgery is often a complex procedure and, thus, a device that facilitates the procedure and reduces the risk of injury to surrounding tissues, especially blood vessels, would be highly desirable.[11]

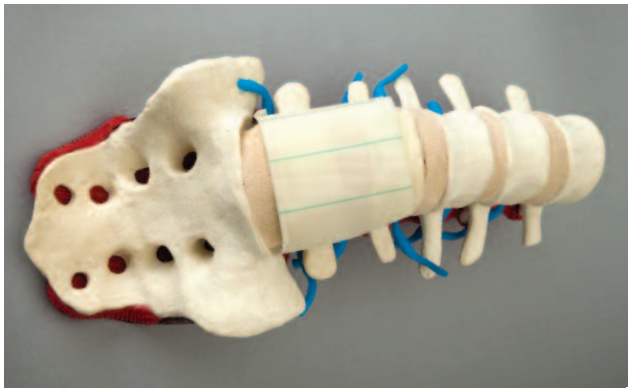
New Products

To address this problem a new class of product, vessel guards, are now available to the spinal surgeon. These products are indicated as a cover for vessels following anterior vertebral surgery. The products that are now commercially available include:

Product Name	Company	Construction	FDA Clearance
Gore Preclude®	Gore Medical	Expanded PTFE	Yes, 510(k)
EnGuard™	Replication Medical	HPAN/Dacron	Yes, 510(k)
Paradís Vaso Shield™	MiMedx Group, Inc.	30 Wt% PVA membrane	Yes, 510(k)

PTFE- polytetrafluoroethylene; HPAN-hydrolyzed polyacrylonitrile; PVA-polyvinyl alcohol

Gore Preclude®—from Gore Medical WebSite.



Replication Medical's EnGuard™

With each product, a biocompatible, biomaterial-based membrane is inserted at the conclusion of the index surgical procedure. The membrane is designed to prevent the infiltration of tissue around the surgical site and surrounding blood vessels. By preventing fibroblast penetration, vascular wall attachment to the membrane is minimized and reoperation is thereby facilitated. All of the products take advantage of non-resorbable biocompatible polymers that are permanents implants. So if revision surgery is required, the vessel guard would be visible to the surgeon and mobilization of the necessary tissues, organs, and vessels would be facilitated.

Method of Use

After conclusion of the anterior spinal surgical procedure, prior to releasing retraction of the vessels, an appropriate sized vessel guard is placed directly anterior to the vertebra. The vessel guard can be stabilized to the surrounding soft tissue, periosteum or directly to the vertebra(e) using suture. Retraction of the vessels is then released and they are allowed to lie anterior to the vessel guard. Verification of pulsatile blood flow and direct visualization of venous return is made.

In the anterior cervical spine, the vessel guard is similarly placed directly anterior to the vertebra(e) and posterior to the esophagus. If so desired, the vessel guard can be placed anterior to the carotid sheath as well. Alternatively, the vessel guard can be placed directly over an anterior cervical plate again posterior to the esophagus.

Clinical Results

Because Replication Medical's EnGuard™ and MiMedx's Paradís Vaso Shield™ devices are so new (2009 FDA clearance) there is no published clinical data available at this time. However, there is some clinical data for Gore Medical's Preclude® device . For example when 14 orthopaedic surgeons were asked the following questions their responses were very positive:

Question	Yes	No
Did the Gore ePTFE membrane facilitate the revision surgery?	14	0
Did the Gore ePTFE membrane protect the vessels during the approach/ exposure of the anterior spine?	13	1
Did the Gore ePTFE membrane provide a clear plane of dissection against the vasculature during the approach/exposure of the anterior spine?	14	0

Gore also reports data on 21 revision surgeries with an average time to revision of 9 months with a range of between two days and 30 months. The results were very positive. For example in 81% of the cases the surgical time to access the spine was between 30 and 60 minutes and in 76% of the cases there was less than 100cc of blood lost. Finally, Gore also reports plane of dissection data:

Plane of Dissection Near Vessels

Clearly Visible	Moderately Visible	Moderately Obstructed	Totally Obstructed
70%	30%	0%	0%

Vessel Mobility Near the Anterior Spine

Clearly Mobile	Moderately Mobile	Moderately Immobile	Totally Immobile
52%	39%	9%	0%

Gore ePTFE Membrane Ease of Dissection From Vessels

Easy	Moderately Easy	Moderately Difficult	Difficult
78%	18%	4%	0%

Extent of Tissue Attachment to the Gore ePTFE Membrane

None	Minimal	Some	Significant
39%	52%	9%	0%

It is hoped and anticipated that Replication Medical, Inc. and MiMedx Group will publish similar results as soon as they become available so that a suitable comparison of products can be made.

Conclusions

There is a definite risk of blood vessel injury while accessing the spine in preparation for anterior revision surgery. This is due mainly to the development of fibrotic tissue at the initial surgical site. This tissue complicates mobilization of the peritoneal sac which is usually fused to the anterior abdominal wall muscles. Further, mobilization of the major vessels and ureter is also made more difficult because at the time of surgery they are encased in fibrous tissue and firmly adhered to each other and the anterior surface of the spine. Thus, the high percentage of revision surgeries, the risk of vessel damage and the added complexity of the procedure due to scar tissue have created a need for a device that will both protect the spinal blood vessels and facilitate reoperation by forming a permanent visible barrier or plane separating the blood vessels from the surgical site These new products seem to be very successful in meeting this need as they appear to be easy to use and quite effective in facilitating anterior revision surgery.

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[13] Without a vessel guard exposure time can be 3 times as long as the initial exposure. One cannot put an absolute value on the time involved as every procedure and patient varies.

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⚠Refer to the instructions for use supplied with product for specific information on indications for use, contraindications, warnings, precautions, adverse reaction information, and sterilization.
WARNING: The safety and effectiveness of this device for reducing the incidence, severity and extent of post-operative adhesion formation have not been established.