

Value of Technology

Inequitable patient access to clinically and cost effective medical technology:
Peripheral vascular disease and Crosser® CTO recanalisation system

BACKGROUND

Peripheral vascular disease (PVD) refers to diseases of arteries outside the heart and brain. It occurs when fatty deposits build up in the inner walls of arteries (mainly arteries that lead to the legs and feet) and affect blood circulation. PVD can range from asymptomatic disease, through to pain on walking and limb threatening reduced blood supply that can lead to amputation.

BURDEN OF DISEASE

PVD affects around 12%-14% of the Australian population - around 3 million people.

Chronic total occlusions (CTOs) are found in one third of patients with advanced PVD. CTOs are arterial occlusions that can be greater than 20cm long and are often heavily calcified or extremely fibrotic.

Treatment of CTOs is considered highly challenging. However, failure to treat (revascularise) a CTO often leaves the patient with the more invasive option of bypass surgery, or continuing on costly medical therapy, which may or may not control symptoms. Additionally, leaving a vessel occluded may also have detrimental consequences on long-term survival.

Success rates of minimally invasive CTO procedures are highly variable and largely dependent upon the size and form of the lesion, and operator experience. The main reason for failure is the inability to cross the blockage with a guidewire or inability to re-enter the artery.

Crossing devices are intended to improve the safety and effectiveness of endovascular therapy for CTOs, potentially reducing the need for bypass surgery and amputations.

BENEFITS OF ENDOVASCULAR SURGERY

- More advanced PVD can be treated with minimally invasive endovascular surgery such as:
 - » angioplasty (to widen or clear the blocked vessel using a balloon inside the artery)
 - » angioplasty with stent placement (to support the cleared vessel and keep it open using a metal stent), or
 - » atherectomy (to remove the blockage such as with laser)
- Procedures are performed under local anaesthesia with sedation without the need for a full general anaesthetic and are performed via a needle in the groin.
- Procedures do not require surgical incisions or wounds and require <24 hours in hospital.
- Improved blood flow - the benefits in terms of improved blood flow are realised immediately after the procedure.
- Procedure is extremely well tolerated even by patients who have been told they are too old or frail for conventional surgery.

Figure 2

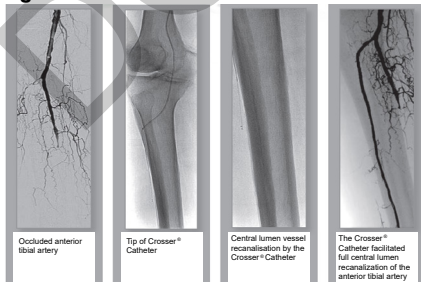


Image: BARD Peripheral Vascular

CROSSER® CTO RECANALISATION SYSTEM

For patients with complete arterial blockages, the CROSSER® CTO Recanalisation Catheter is a catheter system designed to treat patients' CTOs by forming a new channel within a blocked artery for blood to pass through to allow subsequent endovascular treatment options, such as angioplasty and stenting.

The CROSSER® Catheter offers a specialised tip that uses mechanical vibration and cavitation applied directly to the location where plaque has occluded the vessel (Figures 1 & 2). The treatment is delivered throughout the entire length of the blockage until it crosses through the distal CTO cap, restoring central lumen access and blood flow.

The success rate in crossing CTOs that could not be crossed by a guidewire is shown to be 83.5%. Furthermore, no clinical perforations of the artery were observed and average time to cross the lesion was two minutes and six seconds.

ACCESS ISSUES

The Crosser catheter systems are used 10 times more in public hospitals compared to private hospitals.

CROSSER® CTO Recanalisation Catheter is **not currently recognised by the Prosthesis List Advisory Committee (PLAC) as it does not meet their definition criteria of a prosthesis.**

Current financial burden for purchasing CROSSER® CTO Recanalisation Catheters is borne by the treating clinician or the patient to avoid no gap contracts between hospitals and the private health insurance companies.

Cost of CROSSER® CTO Recanalisation Catheter System per procedure is \$3,000 (Table 1).

CTO procedure reimbursement options

There are several MBS item codes that can be used to claim a Crosser CTO procedure (Table 2).

Department of Veterans Affairs (DVA) for CROSSER® procedures
DVA reimburses the use of CROSSER® and have placed the reimbursement code on their list of HIGH COST MEDICAL CONSUMABLES since 2010 - which routinely covers the costs that fall outside the standard procedure fee paid to the hospital for endovascular surgery.

Table 1: Cost of CROSSER® CTO Recanalisation Catheter System per procedure

Item	List Price
CROSSER® CTO Recanalisation Catheter	\$2,500
MICROSHEATH® Peripheral Support Catheter	\$500
Total cost for the system	\$3000

Table 2: MBS codes used for procedures treating CTOs

MBS Codes	Description	List Price
35306	Stent insertion and balloon dilatation	\$2,700
35303	Transluminal balloon angioplasty of more than one peripheral limb	\$3,550
35312	Peripheral arterial atherectomy including balloon dilatation of one limb	\$5,250

Figure 1

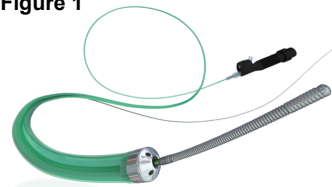


Image: BARD Peripheral Vascular

