BTG Crossing Device Study

Novel CenterCross™ and MultiCross™ devices for the treatment of infrainguinal chronic total occlusions: initial single-center experience

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Patients

- **n= 53**
- **Patients not amenable to attempts at crossing using standard guidewires**
- **Chronically occluded infrainguinal arteries**

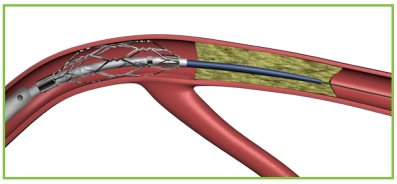
Objectives

Recanalize chronically occluded infrainguinal arteries using the MultiCross™ or CenterCross™ device:

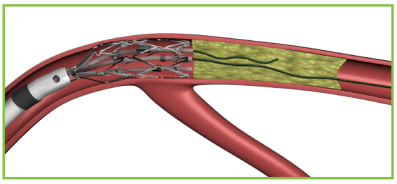
- **Efficacy – ability to cross lesions with use of these devices**
- **Safety – freedom from bleeding, distal embolization, vessel perforation, dissection or need for emergency surgical intervention.**

Methods

- A contralateral retrograde or ipsilateral femoral access was obtained in patients with infrainguinal chronic lesions
- Intravenous unfractionated heparin was used to attain an activated clotting time >250 seconds
- After attempts to use conventional wires to cross occlusion failed, CenterCross™ or MultiCross™ catheters were used to assist the advancement of a guidewire across the occlusion
- No other conventional crossing devices were attempted before using CenterCross™/MultiCross™
- CenterCross™ or MultiCross™ catheters were used to advance a guidewire across the lesion
- All patients received intravenous hydration before and after the procedure, aspirin 325 mg before the procedure and thienopyridine after the procedure
- After the procedure, all patients were monitored overnight in a post-procedure observation unit and discharged the next day if stable



CenterCross™



MultiCross™

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The CenterCross and CenterCross ULTRA Catheters are intended to be used in conjunction with steerable guidewires to access discrete regions of the coronary and peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices beyond stenotic lesions, including chronic total occlusions (CTOs).

The MultiCross Support Catheter is intended to be used in conjunction with steerable guidewires to access discrete regions of the coronary or peripheral vasculature and for guidewire exchange beyond stenotic lesions, including chronic total occlusions (CTOs).

FDA Clearance: The CenterCross™, CenterCross ULTRA and MultiCross™ Catheter is intended to be used in conjunction with steerable guidewires to access discrete regions of the coronary and peripheral vasculature. They may be used to facilitate placement and exchange of guidewires and other interventional devices.

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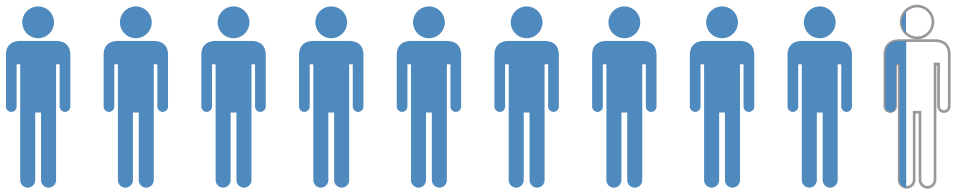
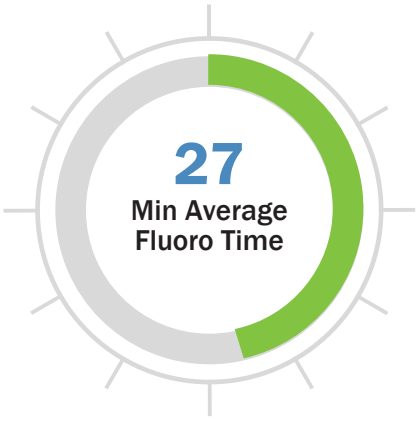
PATIENT CHARACTERISTICS AND SAFETY

- High prevalence of comorbid conditions including hypertension (98%) and hyperlipidaemia (87%)
- 77% of patients had an intermediate to high bleed risk
- 26% of patients had a previous amputation
- Safety Outcomes: 1.9% (1) distal embolizations and 3.8% (2) arterial perforations



92.4%
Crossing Success



CONCLUSION

The MultiCross™ and CenterCross™ devices were effective and safe for the recanalization of peripheral chronic lesions that were not amenable to conventional guidewires.

The CenterCross and CenterCross ULTRA Catheters are intended to be used in conjunction with steerable guidewires to access discrete regions of the coronary and peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices beyond stenotic lesions, including chronic total occlusions (CTOs).

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