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Research Article

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Clinical Overview of Duplex Guided Balloon Angioplasty of Failing Infrainguinal Bypass Grafts

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Abstract

Background
A comprehensive clinical assessment is conducted by BrosMed Medical Co., Ltd. to thoroughly document the clinical safety, clinical performance, and clinical benefits of the Castor PTA NC Balloon Dilatation Catheter. This meticulous review adheres to the guidelines outlined in the New Medical Device Regulation (MDR) 2017/745/EC, Medical Device Directive (MDD) 93/42/EEC, and the latest version of BS EN ISO 14155:2020. The review was done based on the following intended purpose of this product:

Intended Purpose:
The balloon dilatation catheter is intended to dilate stenoses in the iliac, femoral, iliofemoral, popliteal, infrapopliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent dilatation post-deployment in the peripheral vasculature. The Castor PTA NC Balloon Dilatation Catheter is specifically intended for the treatment of peripheral arterial disease (PAD) and other conditions characterized by arterial stenosis or occlusions. PAD commonly affects the lower extremities, causing reduced blood flow and potentially leading to pain, tissue damage, and impaired mobility. The catheter is used to perform angioplasty, which is a minimally invasive procedure aimed at restoring blood flow in the affected arteries. During the procedure, the catheter is inserted into the artery and advanced to the site of the stenosis or blockage. The balloon portion of the catheter is then inflated, which compresses the plaque or other obstructions, widening the vessel and restoring blood flow.

Features:
The Castor PTA NC Balloon Dilatation Catheter is designed with specific features to facilitate the angioplasty procedure.

Some notable features may include:

Balloon: The catheter includes a balloon at its distal end, which can be inflated to dilate the narrowed artery. The balloon is typically made of a compliant material that can withstand inflation pressures.

Non-Compliant (NC) Design: The catheter may be labeled as ″non-compliant,″ indicating that the balloon is less elastic and more resistant to expansion than a compliant balloon. This property allows for precise and controlled dilatation of the vessel, particularly in cases where resistant or calcified lesions are present.
Catheter Shaft: The catheter has a flexible shaft that allows for easy maneuverability within the vascular system. It is designed to be compatible with standard guide wires and other interventional devices used during the procedure.

Radiopaque Markers: The catheter may have radiopaque markers on its shaft or balloon. These markers enhance the visibility of the catheter under fluoroscopy, enabling the interventional cardiologist to accurately position and deploy the device.

It′s important to note that specific features may vary depending on the manufacturer and model of the Castor PTA NC Balloon Dilatation Catheter. Always consult the device′s Instructions for Use and rely on the guidance of a qualified healthcare professional for proper usage and interpretation.

Objective.

To assess the results of angioplasty and stent placement under duplex guidance for failing grafts.

Methods. Over 22 months, 25 patients (72% males) with a mean age of 74G10 years presented to our institution with a failing infrainguinal bypass. The site of the most significant stenotic lesion was in the inflow in four cases, conduit in 18 cases and at the outflow in 11 cases. All arterial (20) or graft (13) entry sites cannulations were performed under direct duplex visualization. Duplex scanning was the sole imaging modality used to manipulate the guide wire and directional catheters from the ipsilateral CFA to a site beyond the most distal stenotic lesion. Selection and placement of balloons and stents were also guided by duplex. In 11 cases (33%), the contralateral CFA was used as the entry site and a standard approach (fluoroscopy and contrast material) was employed. Completion duplex exams were obtained in all cases.

A comprehensive clinical assessment has been conducted by BrosMed Medical Co., Ltd.to thoroughly document the clinical safety, clinical performance, and clinical benefits of the Castor PTA NC Balloon Dilatation Catheter. This meticulous review adheres to the guidelines outlined in the New Medical Device Regulation (MDR) 2017/745/EC, Medical Device Directive (MDD) 93/42/EEC, and the latest version of BS EN ISO 14155:2020.

The Castor PTA NC Balloon Dilatation Catheter is a medical device used in the field of interventional cardiology. It is primarily designed for percutaneous transluminal angioplasty (PTA) procedures, which involve the dilation of narrowed or blocked blood vessels.

Results. The overall technical success was 97% (32/33 cases). In only one case, the outflow stenotic lesion in the plantar artery could not be traversed with the guidewire due to extreme tortuosity. Overall local complications rate was 6% (two cases). One vein bypass pseudoaneurysm caused by rupture with a cutting balloon was repaired by patch angioplasty and one SFA pseudoaneurysm at the puncture site required open repair. Overall 30-day survival rate was 100%. Overall 6- month limb salvage and primary patency rates were 100 and 69%, respectively.

Clinical Performance: The clinical trials conducted on the Castor PTA NC Balloon Dilatation Catheter demonstrate its efficacy in achieving successful percutaneous transluminal angioplasty procedures. These trials show that the catheter effectively dilates narrowed arteries, restoring blood flow and potentially alleviating symptoms associated with peripheral arterial disease (PAD). The catheter′s design, including the non-compliant balloon and radiopaque markers, contributes to its precise placement and controlled dilatation during procedures. Overall, the clinical performance of the catheter supports its intended use in addressing arterial stenosis or occlusions.

Clinical Safety: The clinical trials conducted on the Castor PTA NC Balloon Dilatation Catheter have also assessed its safety profile. The catheter's non-compliant design aids in controlled dilatation, potentially reducing the risk of overexpansion related complications. Additionally, the compatibility of the catheter with standard guide wires and interventional devices contributes to procedural safety. The trials demonstrate that the catheter can be safely used in various arterial territories, with the potential to improve blood flow and alleviate symptoms associated with PAD.

Clinical Benefits: The Castor PTA NC Balloon Dilatation Catheter offers several clinical benefits based on the literature review and clinical trials. These benefits include:

Effective Dilation: The catheter's balloon design enables efficient dilation of narrowed arteries, enhancing blood flow restoration. Precision and Control: The non-compliant balloon design allows for precise and controlled dilatation, particularly in challenging cases involving resistant or calcified lesions. Improved Visibility: Radiopaque markers enhance catheter visibility during procedures, aiding accurate placement and deployment. Minimally Invasive: The catheter's minimally invasive nature reduces patient trauma and recovery time compared to more invasive procedures. It is life sustaining device Conclusions. Duplex guided endovascular therapy is an effective modality for the treatment of failing infrainguinal arterial bypasses. In accordance with MDR 2017/745 and MDD 93/42/EEC regulations, the Castor PTA NC Balloon Dilatation Catheter′s clinical performance, safety, and benefits have been evaluated through literature review and clinical trials. The device′s design and intended use align with its clinical outcomes, making it a valuable tool for interventional cardiologists in treating peripheral arterial disease and related conditions.

Keywords: Duplex Guided Balloon Angioplasty, Infrainguinal Bypass Grafts, Radiopaque markers

Introduction

The high-resolution images and accurate hemodynamic information provided by modern duplex scanners makes them a reliable tool for intraoperative and postoperative surveillance of infrainguinal bypasses.[1–10] Moreover, timely repair of bypass stenoses may improve graft patency and limb salvage rates.[11–13] Balloon angioplasty has been shown to have similar results to surgical repair of graft stenoses.[14–19] Endovascular techniques traditionally employ the use of contrast arteriography and fluoroscopy, Johnson *et al.* attempted to augment this approach with duplex scanning to monitor the hemodynamic success of balloon angioplasties of failing infrainguinal bypasses.[20]

In our recently published reports, we extended the application of ultrasound from diagnostic to therapeutic. The feasibility of duplex guidance for femoral– popliteal and infrapopliteal balloon angioplasties using Castor PTA balloon catheter (Brosmed medical Co. Ltd.) in patients with renal insufficiency was demonstrated in an attempt to avoid use of nephrotoxic contrast agents and radiation exposure.[21,22] To further explore the limitation and advantages of duplexguided balloon angioplasty (DGBA), we describe the use of duplex guidance for balloon angioplasties of 33 failing infrainguinal bypasses.

Methods

Patients

Over the last 22 months, 25 patients (72% males) with a mean age of 74G10 years (range 48–89 years) presented at our institution with 33 failing infrainguinal bypasses in 26 limbs. All patients had preoperative graft duplex scans, which identified at least one hemodynamically significant stenosis in the inflow artery, bypass conduit or outflow artery. Hemodynamically significant stenosis was defined as R70% diameter reduction measured by color image and confirmed with PSV ratio of R3. Primary procedures were performed in 20 cases, 1st redo angioplasty in six cases, 2nd redo angioplasty in six cases and 3rd redo in the remaining case. Associated risk factors such as hypertension, diabetes, renal insufficiency (serum creatinine level R1.5 mg/dl), coronary artery disease and smoking were present in 84, 68, 60, 48 and 44% of cases, respectively. A total of 33 attempted balloon angioplasties (27 vein; six PTFE) were included in this study. Twelve vein grafts were common femoral artery (CFA) to popliteal artery

(PA) (six) and infrapopliteal (six) bypasses, 10 were superficial femoral artery (SFA) to PA (three) and infrapopliteal (seven) bypasses and the remaining five were PA to PA (two) and infrapopliteal (three) bypasses. Of the six PTFE grafts four were CFA to popliteal (two) and infrapopliteal (two) bypasses and the remaining two were superficial femoral artery to popliteal bypasses. Bypass operations were performed from 3 to 78 months prior to the current procedure (mean 26G22 months).

Preoperative evaluation

None of the patients in this series were subjected to preoperative contrast arteriography. All patients underwent preoperative graft duplex scans in our vascular laboratory. Our duplex scan protocol included visualization of the ipsilateral infrainguinal inflow arteries, entire bypass conduit and outflow artery. After color and/or power imaging, spectral analysis was routinely obtained from the following points: proximal artery, proximal anastomosis, proximal, mid and distal bypass conduit, distal anastomosis and distal artery. Additional images were taken from areas of stenosis identified by color imaging and confirmed by peak systolic velocity (PSV) step-up. Balloon angioplasty was recommended for severe stenoses defined as R70% diameter reduction measured on color and/or power image and confirmed by PSV ratio R3 (Fig. 1). A single stenosis was demonstrated in 18 cases (55%) and multiple (range 2–5, mean 1.8G1.1) stenoses were present in the remaining 13 cases (45%). The site of the most significant stenotic lesion was at the inflow in four cases, conduit in 18 cases and at the outflow in 11 cases. Highest PSVat the stenotic areas were registered and compared before and after the procedure. Bypass volume flows (VF) were also recorded.

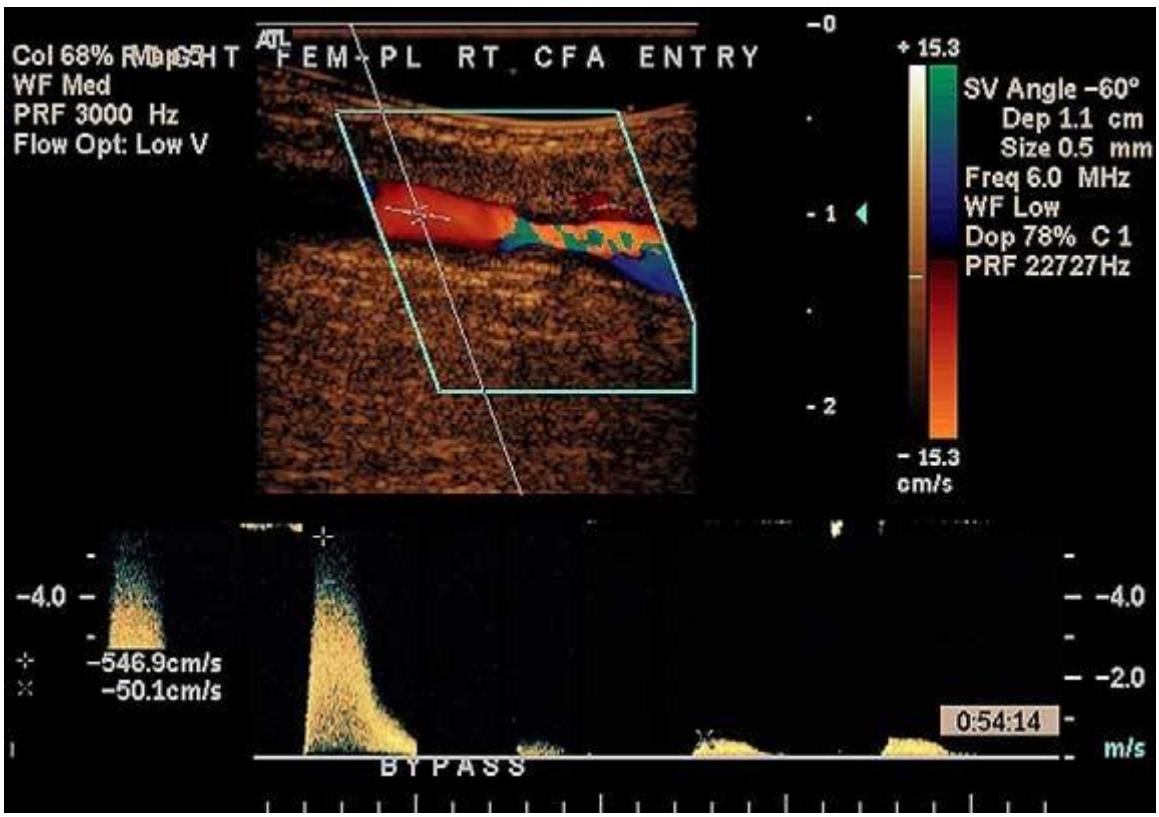

Fig. 1. Spectral analysis of the distal anastomosis of the femoral to plantar artery vein bypass graft confirmed critical stenosis by PSV ratio of O10 (547 cm/s over 50 cm/s).

Technique

We used an ATL HDI 5000 scanner (Phillips Medical Systems, Bothell, WA) with SonoCTw in all cases. A linear 4–7 MHz probe inserted in a sterile plastic cover with coupling gel was utilized for artery and graft insonation on the thigh and calf. In addition, a compact linear 7–15 MHz 'hockey stick' probe allowed detailed visualization of more superficial arterial structures at the ankle and foot for bypasses to the dorsalis pedis and plantar arteries (seven cases) and for very superficial grafts (seven cases). Two cases required the use of a curved 2–5 MHz transducer to visualize distal anastomosis of the femoral to above the- knee PA bypass in obese patients. All procedures were performed in the operating room under local anesthesia of the puncture site (an equal mixture of 1% lidocaine and 0.5% sensorcaine) and light sedation during inflation of Castor PTA balloon angioplasty catheter. All access sites cannulations were done under direct duplex visualization. Short 6 Fr (23 cases), 5 Fr (eight cases) or 4 Fr (two cases) sheaths were chosen based on the profiles of anticipated balloons. Overall, 22 cases (67%) were completed in an antegrade fashion and the remaining 11 (33%) through a contralateral access. Twenty procedures were performed through the ipsilateral (nine cases) or contralateral (11) femoral puncture. The remaining 13 angioplasties were carried out through direct graft puncture (nine venous and four PTFE). Duplex scanning was the sole imaging modality used to manipulate the 0.035 in. Glidewire (Boston Scientific Corporation, Natick, MA 01760, USA) supported by either 5 Fr Selective Bern catheter (Boston Scientific Corporation, Natick, MA 01760, USA) or 5 Fr Angled Taper Glidecathw (Terumo Medical Corporation, Somerset, NJ 08873, USA) directional catheter from the ipsilateral access site to the distal outflow artery.

Four (36%) of 11 cases with contralateral CFA punctures, did not require contrast use due to cannulation of their ipsilateral iliac artery with fluoroscopy guidance only. Two of these patients had elevated serum creatinine (2.3 and 2.4 mg/dl, respectively).In the remaining seven cases (64%), a standard approach (fluoroscopy and contrast material) was employed to reach the ipsilateral CFA and proximal anastomosis of the bypass. Five of these patients had normal serum creatinine levels. Their aorto-iliac arteriograms were performed with 10 cm3 of Visipaquee (Amersham Health, Princeton, NJ). The remaining two patients with elevated creatinine levels (2 and 2.1 mg/dl, respectively) were subjected to aorto-iliac arteriograms with non-ionic contrast material (10– 15 cm3 of Magnevistw, Berlex Laboratories, Wayne, NJ).

We used 4, 5 and 6 mm Castor PTA balloon (Brosmed medical Co. Ltd,). balloons in various lengths according to the extent of the lesions and artery/bypass diameter as measured by duplex. Tri Wedge PTA scoring balloons (Brosmed medical co Ltd,). (Fig. 2) were used in 16 cases (48%).23,24 Castor and Tri Wedge PTA scoring balloons use required an exchange of a 0.035 guide wire for a finer one (0.018 or 0.014 in.) which was also done under duplex control.

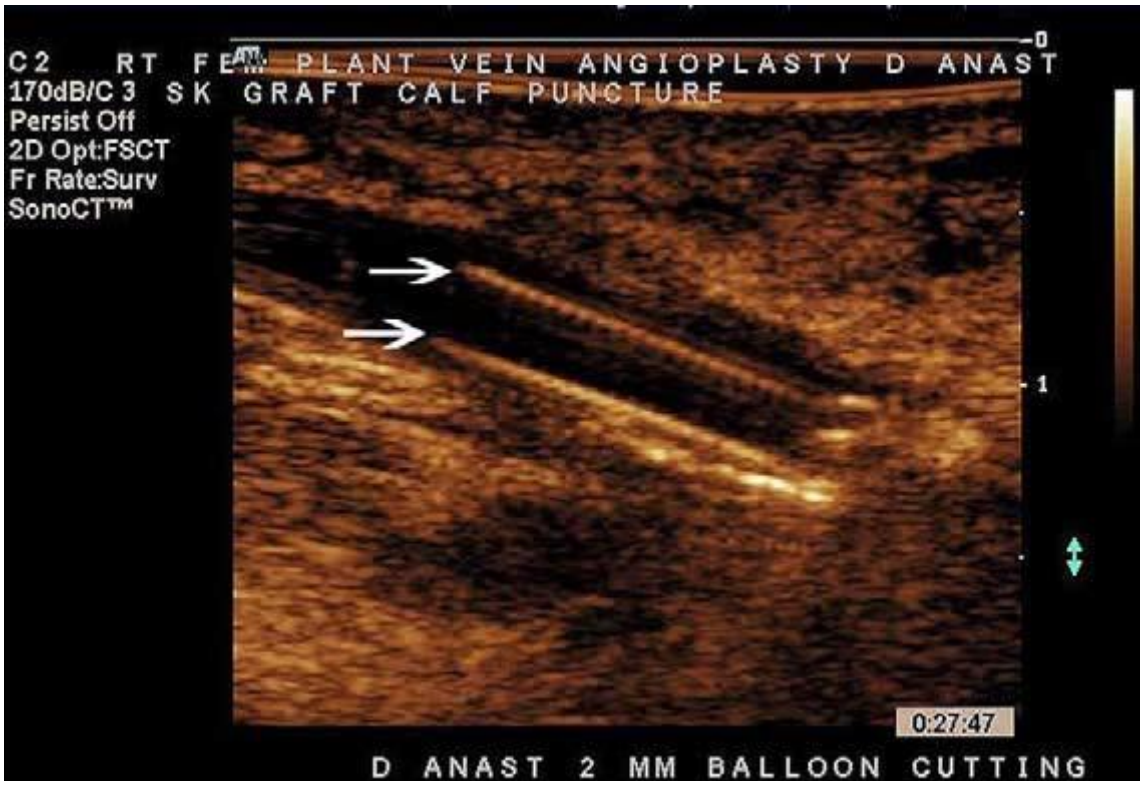

Fig. 2. Tri Wedge PTA scoring balloon (2 mm diameterX15 mm length) positioned and inflated across the stenosis depicted in Fig. 1. White arrows point to balloon's blades.

Completion duplex exams following the preoperative protocol were obtained in all cases after removal of the balloon angioplasty catheter. Biplanar scanning (sagittal and transverse) was used for identification of residual stenoses or recoils. All suspected defects were evaluated by direct diameter reduction measurement on color and/or power image and spectral analyses including PSV step-up. Technical success was defined as absence of PSV ratio R2 along the bypass as well as its inflow and outflow arteries. Repeat inflations with larger balloons (if allowed by the adjacent artery or bypass diameter) or cutting balloons were used for treatment of residual stenoses and/or recoil.

Bypass volume flow (VF) measurements were obtained immediately after procedure completion and after intra-arterial administration of 30 mg of papaverine hydrochloride. VF average value GSD as well as ranges were calculated and compared for each time point. Intraoperative contrast arteriograms were not used in this series.

Follow-up

Graft duplex scans were performed prior to hospital discharge. Patients were scheduled to come for a follow up visit including a physical exam and a graft duplex scan in the outpatient office within a month after the procedure and every 3 months thereafter. Graft occlusions or significant restenosis requiring a repeat procedure (diameter reduction O70% confirmed by PSV step-up R3) were reported.

Statistical analysis

Arterial patency life tables (Kaplan–Meier survival test) were calculated using GraphPad Prism version 4.00 (GraphPad Software, San Diego, CA 92121, www. graphpad.com).

Results

Technical success

Overall technical success was 97% (32/33 cases). In only one case, the stenotic lesion at the bypass outflow could not be traversed with the guidewire due to extreme tortuosity. Two arterial dissections of the inflow arteries (SFA) causing severe stenoses were treated successfully with self-expanding stents placed under duplex guidance. No stents were placed along the bypasses conduit with a Tri Wedge PTA scoring balloon was repaired by patch angioplasty and one CFA pseudoaneurysm at the puncture site required open repair after two unsuc- cessful attempts of thrombin injections.

Intraoperative and early postoperative complications

Overall local complication rate was 6% (two cases). One vein bypass pseudoaneurysm caused by rupture with a Tri Wedge PTA scoring balloon was repaired by patch angioplasty and one CFA pseudoaneurysm at the puncture site required open repair after two unsuc- cessful attempts of thrombin injections.

Hemodynamic findings

PSV obtained at the stenosis decreased in all 32 successful cases from preoperative 426G152 cm/s (range 191–807 cm/s) to 99G27 cm/s (range 57–152 cm/s) after angioplasty. Comparison of graft VF before the procedure, immediately after its completion and after intra-arterial administration of papaverine is depicted in Table 1.

Table 1. Comparison of bypass volume flows (VF) obtained before balloon angioplasty procedure (A), immediately after its completion (B) and after intra-arterial administration of 30 mg papaverine (C)

Bypass VF (ml/min)	A	B	C	P1* value	P2 † value
Range	9-144	20-241	52-677		
MeanGSD	59G35	124G68	283G175	!0.0001	!0.0001

*P1 vale represents comparison of VF between columns A and B
† P2 vale represents comparison of VF between columns B and C

Patency and limb salvage rates

Average follow up was 10G6 months (range 1–22 months). Overall 6-month limb salvage and primary patency rates were 100 and 69%, respectively. Three of nine patients (33%) whose vein bypasses were punctured directly developed restenosis at the puncture site.

One transmetatarsal amputation was performed for a patient in whom the distal anastomosis angioplasty failed due to tortuosity. This patient's popliteal to plantar artery vein bypass occluded 5 months after the angioplasty attempt.

Procedure duration

DGBA duration ranged from 15 to 100 min (mean 36 minG18, median 33 min).

Discussion

Recurrent stenoses of infrainguinal bypasses have been shown to be a major limiting factor of this procedure.12,14,25 Open repair of failing bypasses is a durable treatment option. More recent reports advocate the use of endovascular management for this problem. Historically, all endovascular interventions required use of

contrast material and fluoroscopic guidance. Our study demonstrates the possibility of duplex guidance for these procedures.

Since, duplex imaging allows accurate assessment of the arterial wall as opposed to conventional arteriography, it can offer unique advantages as compared to those performed with fluoroscopy. Direct visualization of the entry site ensures precise placement of arterial puncture needle and avoidance of posterior wall bleeding, dissections and other arterial injuries. Arterial calcifications localization helps locate an appropriate entry site. This technique is particularly beneficial in obese patients and scarred groins where arteries become difficult to palpate. We did not encounter technical difficulties while obtaining access for procedure through ipsilateral or contralateral CFA, SFA or bypass conduit.

We note that three out of nine vein bypasses punctured directly developed subsequent stenosis at the sheath entrance site, which probably deserves further review. Because the numbers are small, limited conclusions can be drawn from this observation. Nevertheless, based on our findings, we now try to avoid direct access to a vein bypass unless it is absolutely necessary. Given that fluoroscopy does not continuously assess the intraluminal location of the sheath, guidewire, balloons and stents, operative mishaps may complicate the procedure course. Fluoroscopic guidance of endovascular procedures is often based upon the expected course of the vessels or bypasses and may sometimes be misleading. Duplex guidance helps avoid passage of the guidewire into the branches and possible perforation and plaque dissections.

The interventions performed under ultrasound guidance have another distinct advantage: exact placement of the balloons and stents due to its tremendous magnification capabilities. This magnification can be performed without an increase in radiation time and intensity as would be required for fluoroscopy-guided interventions. The diameter of the vessels to be ballooned or stented can be measured by the duplex scanner with a precision of a 1/10th of a millimeter. This measurement accuracy can be especially important when using scoring balloons.[23,24] In fact, in almost 50% of the cases, we used scoring balloons, mostly for focal lesions in vein bypasses and calcified distal arteries. Although one patient developed bypass rupture necessitating open repair with patch angioplasty, we were, overall, satisfied with the ability of this device to dilate the bypass or the artery without further recoil.

As endovascular cases are becoming a more important part of the vascular surgeons' practice, it is logical to assume that radiation exposure becomes a significant hazard to the operating or interventional room staff and surgeons or interventionists.[26] Duplex guidance eliminates this risk factor for everybody involved in the procedure. Conceivably, patients with impaired renal function and elevated serum creatinine levels or diabetics may benefit the most from ultrasound guidance due to lack of exposure to contrast materials.[27,28]

We cannot undervalue the significance of the presence of an experienced and well-trained registered vascular technologist during this procedure. The person performing duplex guidance of balloon angioplasties must have extensive experience in duplex mapping of infrainguinal and aorto-iliac arterial segments as well as be able to recognize different endovascular tools and devises on the ultrasound image.

The most noted limitations of duplex guidance include non-visualization of the lumen in severely calcified vessels, limited field of view and depth limitation. However, as we have previously cited, with a few innovative and intuitive maneuvers, we can obtain the necessary information. This is possible with severely calcified vessels using multiple projections and SonoCT. Although each individual field of view is limited by probe width, we have previously demonstrated that the entire arterial tree from aorta to pedal vessels can be reliably visualized using duplex arteriography.[29] Deeper located bypass segments (distal anastomosis of the femoral to above the knee bypasses in two obese patients) were successfully

assessed with an abdominal C2-5 MHz probe in this series.

We have thus far restricted our interventions to the infrainguinal vessels since precise visualization of the iliac arteries is more difficult due to depth limitations and gas interposition. Whenever access to the failing bypass was only available through the contralateral lower extremity (one third of the cases), fluoroscopy was used with or without contrast administration for negotiating the wire in the iliac arteries.

One other important benefit of duplex guidance is real-time hemodynamic monitoring of the intervention. For example, hemodynamic significance of dissections or recoils can be easily assessed by the PSV ratio. We also measured bypass volume flows as they have been suggested to play an important role in predicting bypass patency.30 Completion duplex scans were performed at the end of every case: to confirm technical adequacy of the procedure; to help assess significance of residual stenoses and to rule-out distal embolization.

In our practice, duplex scanning has evolved from an essential diagnostic and surveillance tool to an integral part of endovascular interventions.21,22 The approach described in the present article represents an extended use of duplex guidance to avoid and/or minimize the use of contrast material and radiation exposure in patients undergoing infrainguinal bypasses. Based upon our preliminary experience, we suggest that this technique can be safely and effectively used. Further follow-up is recommended to evaluate long-term patency of duplex-guided balloon angioplasties for failing infrainguinal bypasses.

Clinical Performance: The clinical trials conducted on the Castor PTA NC Balloon Dilatation Catheter demonstrate its efficacy in achieving successful percutaneous transluminal angioplasty procedures. These trials show that the catheter effectively dilates narrowed arteries, restoring blood flow and potentially alleviating symptoms associated with peripheral arterial disease (PAD). The catheter's design, including the non-compliant balloon and radiopaque markers, contributes to its precise placement and controlled dilatation during procedures.

Overall, the clinical performance of the catheter supports its intended use in addressing arterial stenosis or occlusions.

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Clinical Benefits: The Castor PTA NC Balloon Dilatation Catheter offers several clinical benefits based on the literature review and clinical trials. These benefits include:

Effective Dilation: The catheter's balloon design enables efficient dilation of narrowed arteries, enhancing blood flow restoration. Precision and Control: The non-compliant balloon design allows for precise and controlled dilatation, particularly in challenging cases involving resistant or calcified lesions. Improved Visibility: Radiopaque markers enhance catheter visibility during procedures, aiding accurate placement and deployment. Minimally Invasive: The catheter's minimally invasive nature to more invasive procedures. It is life sustaining device.

Conclusions

Duplex guided endovascular therapy is an effective modality for the treatment of failing infrainguinal arterial bypasses. In accordance with MDR 2017/745 and MDD 93/42/EEC regulations, the Castor PTA NC Balloon Dilatation Catheter's clinical performance, safety, and benefits have been evaluated through literature review and clinical trials. The device's design and intended use align with its clinical outcomes, making it a valuable tool for interventional cardiologists in treating peripheral arterial disease and related conditions.

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