

# The direct extravascular calcium interruption arterial procedure technique for heavily calcified vessels

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## ABSTRACT

Severely calcified lesions continue to plague endovascular interventions by negatively affecting the acute and long-term results. A new technique was developed to allow balloon crossing or to treat persistent recoil. In the direct extravascular calcium interruption arterial procedure technique, an artery forceps is percutaneously introduced to modify the plaque after conventional techniques have failed. In this initial experience, the direct extravascular calcium interruption arterial procedure technique was successful as a bailout option in patients in whom balloon crossing was impossible or recoil was untreatable even with high-pressure balloons. (*J Vasc Surg Cases and Innovative Techniques* 2020;6:369-73.)

**Keywords:** Peripheral arterial disease; Critical limb-threatening ischemia; Recoil; Percutaneous transluminal angioplasty; Technique; Lesions; Calcification; Infrapopliteal; Infringuinal

Severely calcified lesions are difficult to treat with endovascular techniques.<sup>1,2</sup> These lesions are highly prevalent in elderly patients and in diabetics, in whom endovascular treatment is preferred.<sup>3</sup> Heavily calcified lesions are difficult to cross and are a hurdle to optimal dilation.<sup>1</sup>

Ichihashi et al<sup>4</sup> developed a technique of percutaneous direct needle puncture of calcified plaque (PIERCE). In this technique, the calcified lesion is percutaneously punctured with a needle, causing a crack in the lesion to facilitate the passage of the device through the lesion.<sup>4</sup> It is a simple and inexpensive technique but is not always successful, partly because of mobility of the vessel.

We developed a novel extension of the PIERCE technique that we termed the direct extravascular calcium interruption arterial procedure (DECIAP). This technique involves percutaneously crushing and therefore modifying the calcified plaque to allow balloon passage or

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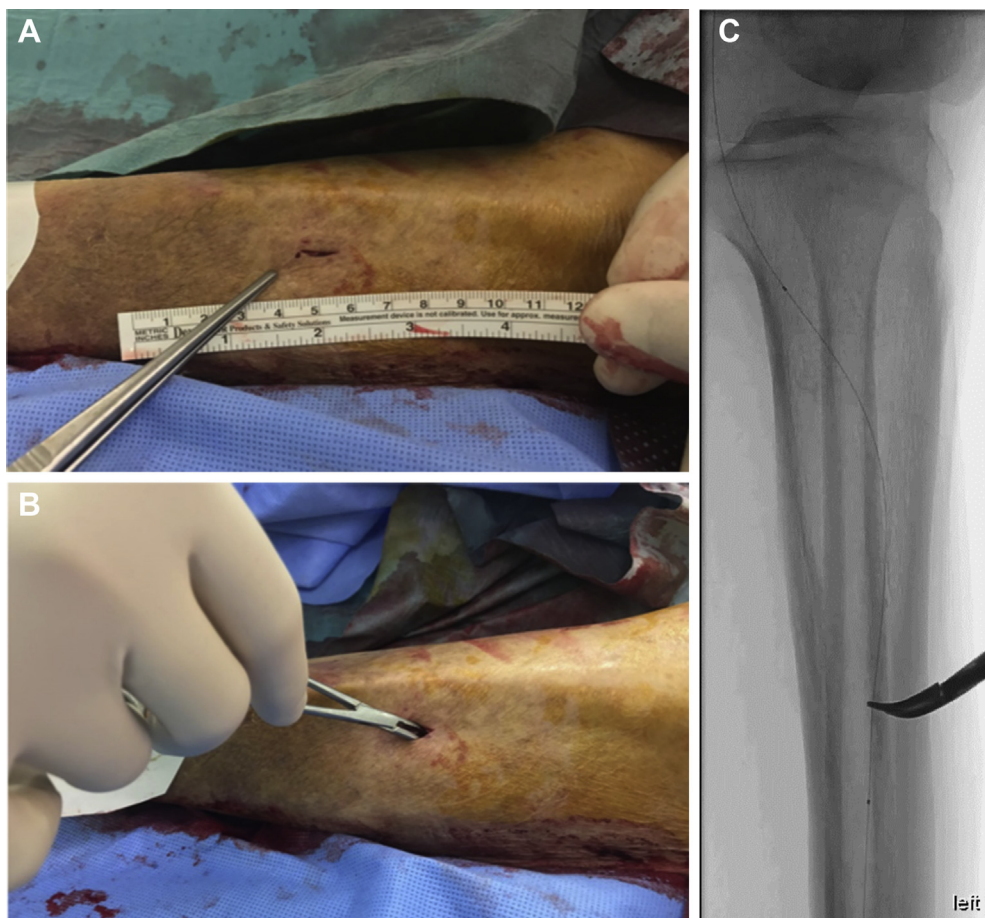
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**Fig 1.** Recoil was seen despite high-pressure non-compliant balloon angioplasty.

to treat persistent recoil. This report describes the technical aspects of the DECIAP technique performed in four patients.

This study was conducted according to the principles of the Declaration of Helsinki and approved by the Institutional Review Board. Informed consent was obtained from all patients.



**Fig 2.** The direct extravascular calcium interruption arterial procedure (DECIAP) technique. **A**, A 1-cm incision is performed directly over the lesion. **B**, Artery forceps is introduced and positioned above the lesion, as confirmed on an angiogram. **C**, The jaws of the forceps are opened 2 to 3 mm apart, and the walls of the artery are crushed gently (the jaws are not fully closed) between the jaws of the forceps.

## CASE REPORT

From August 2017 to September 2018, four patients underwent the DECIAP technique, which was performed as a bailout procedure to ensure angiographic success. The DECIAP technique was performed in patients with Rutherford class 5 or class 6 chronic limb-threatening ischemia with the inability to cross a stenotic or occlusive lesion with a low-profile balloon after initial wire passage or with persistent recoil of  $\geq 50\%$  after high-pressure balloon angioplasty or stenting (Fig 1). The DECIAP technique was performed in the infrapopliteal vessels ( $n = 3$ ) and in the superficial femoral artery (SFA;  $n = 1$ ).

**Procedural details.** All patients were prepared for angioplasty according to the institutional protocol and were pretreated with aspirin (100 mg) before the procedure. All patients underwent a popliteal nerve block for periprocedural and postprocedural pain relief. General anesthesia was used if popliteal anesthesia alone was insufficient. Antegrade access to the femoral artery was obtained, and a 5F or 6F sheath was placed. Systemic anticoagulation was performed with 3000

units of intra-arterially administered unfractionated heparin followed by 1000 units per subsequent hour of intervention according to institutional protocol.

Percutaneous transluminal angioplasty was performed in a standard fashion. SFA lesions were crossed using a 0.018-inch moderate-support guidewire, and infrapopliteal lesions were crossed with a 0.014-inch moderate-support guidewire. When antegrade crossing failed, retrograde access was performed. A low-profile balloon was inserted to cross and to predilate the lesion. High-pressure balloons were used to treat recoil. A stent was inserted when there was  $\geq 50\%$  recoil or dissection.

The PIERCE technique<sup>4</sup> was performed when the balloon was unable to cross the lesion or when recoil could not be treated by a high-pressure noncompliant balloon. This was performed with 16-gauge needles. The decision to use the PIERCE technique before DECIAP was left to the discretion of the operator.

**DECIAP technique.** Before DECIAP, a low-profile balloon was placed just above the lesion to cross the lesion or to perform balloon-assisted hemostasis. In cases of infrapopliteal lesions, a



**Fig 3.** Angiogram results with a high-pressure non-compliant balloon after the direct extravascular calcium interruption arterial procedure (DECIAP) technique. The lesion is successfully dilated at a lower pressure.

1-cm incision was performed directly over the lesion (Fig 2). A curved surgical artery forceps was introduced, and blunt dissection of the soft tissue was done to arrive just above the surface of the artery. This was confirmed on angiography in two views. The lesion was localized at the center of the fluoroscopy field view to minimize parallax error.

The jaws of the forceps were opened 2 or 3 mm apart. The forceps was then advanced deeper, and the walls of the artery were gently crushed between the jaws of the forceps. Successful crushing of the artery was assumed when deviation of the wire was seen in response to the crushing. The movement was performed in a slow, deliberate “kneading” fashion along the length of the lesion. The lesion was crossed with a balloon for balloon hemostasis for 3 minutes. Control angiography was then performed. If any extravasation was seen, prolonged balloon-assisted hemostasis was applied for 3 minutes more. Final balloon angioplasty was performed with a high-pressure non-compliant balloon. The balloon was sized on a 1:1 basis on outer wall direct visualization vs sizing based on luminal diameters of the normal vessel (Fig 3).

Skin closure was performed with 3-0 interrupted Prolene sutures (Ethicon, Somerville, NJ). After the procedure, heparin was partially reversed at the discretion of the operator. The same technique was applied in the SFA lesions. Procedural details are summarized in the Table.

## RESULTS

A total of four patients were treated with the DECIAP technique. The indications to use the DECIAP technique were failure of crossing with a low-profile balloon (Armada XT [Abbott Vascular, Abbott Park, Ill];  $n = 2$ ), recoil after stenting ( $n = 1$ ), and recoil after high-pressure balloon (JADE [OrbusNeich, Hong Kong];  $n = 1$ ). The technique was performed by vascular surgeons with broad experience in endovascular techniques. After the DECIAP technique, final angioplasty was performed with the JADE balloon with a pressure between 16 and 20 atm in three patients and a Mustang balloon (Boston Scientific, Marlborough, Mass) with a pressure of 24 atm in one patient.

**Procedural outcomes.** After the DECIAP technique, optimal balloon angioplasty (recoil of  $<30\%$ ) was successfully achieved in all patients. In two patients, no residual stenosis was seen on final angiography. In the other two patients, angiographically insignificant residual stenosis of 30% was seen. A small perforation occurred in one patient at the area of the artery where the DECIAP technique was performed. This was resolved with prolonged ballooning for another 3 minutes. One patient died of sepsis 6 days after the procedure. No other adverse events were recorded in the 30 days after the procedure.

No angiographic evidence of distal embolization was seen in any of the patients. Postprocedural surveillance ultrasound imaging did not reveal any aneurysmal change of the vessels treated with DECIAP. One patient required a clinically driven reintervention because of an occlusion that was detected 3 months after the initial procedure. No other reinterventions were performed in the other three patients during the length of follow-up. The ischemic wounds present before the procedure healed at days 87, 113, and 131. In one patient, no wound healing occurred because of death at day 6. All stab incisions made to perform the DECIAP procedure healed during the time of follow-up.

## DISCUSSION

DECIAP is an adaptation of a technique that has been described in open surgery to enable clamping of an artery or stitching of an artery in severe calcification. It is an accessible procedure to perform as a bailout option to cross heavily calcified lesions. Other plaque-cracking techniques have been reported by Kawarada et al<sup>6</sup> and Dias-Neto et al.<sup>7</sup> Karawarda et al<sup>6</sup> described the percutaneous intravascular cracking technique. In this technique, the stiff tail of a guidewire is used to crack severely calcified chronic total occlusion lesions. Dias-Neto et al<sup>7</sup> described a retrospective study of the “pave-and-crack” technique in which the lesion is first “cracked” in preparation for the “pave” with a stent. This technique is done by aggressive high-pressure or cutting balloon angioplasty and would therefore not be applicable if

**Table.** Patients' characteristics and procedural details

	Patient 1	Patient 2	Patient 3	Patient 4
Age, years	83	83	73	80
Sex	Female	Female	Male	Female
Comorbidity	HT, HL, DM, CVA	HT, HL, DM, IHD	HT, HL, DM, CKD	HT, HL, DM, AF
Body mass index, kg/m <sup>2</sup>	21.5	21.5	23.6	28.5
Rutherford class	5	5	5	5
Indication for DECIAP	Unable to cross with low-profile balloon	Recoil of SFA post-stenting 50% recoil	Unable to cross with low-profile balloon	Recoil with high-pressure balloon
PIERCE technique	Not performed	PIERCE failed	PIERCE failed	PIERCE failed
Target vessel	ATA	SFA	ATA	ATA
Anesthesia	Regional	Regional	Regional	Regional converted to general
Stenosis or occlusion	90% diffuse stenosis, entire length of ATA	70% diffuse stenosis, whole SFA	90% diffuse stenosis, entire length of ATA	Occlusion, lower two-thirds of ATA
TASC lesion	C	C	C	D
PARC classification of calcification <sup>5</sup>	Severe	Severe	Severe	Moderate
Guidewire	0.014-inch PT2 <sup>a</sup>	0.018-inch V18 <sup>a</sup>	0.014-inch Command ES <sup>b</sup>	0.014-inch PT2
Crossing	Antegrade only	Antegrade only	Antegrade only	Retrograde
Balloons used to cross or to efface lesions before DECIAP	Armada XT <sup>b</sup> 1.5 × 20 mm	Mustang <sup>a</sup> 6 × 80 mm, 24 atm	Armada XT 1.5 × 20 mm	JADE <sup>c</sup> 3 × 120 mm, 24 atm
Balloon used for final angioplasty	JADE 2.5 × 120 mm, 16 atm	Mustang 6 × 80 mm, 24 atm	JADE 3 × 120 mm, 20 atm	JADE 3 × 120 mm, 20 atm
Heparin	3000 units	3000 units	3000 units	3000 units
Heparin reversal	Protamine, 20 mg	Protamine, 20 mg	Protamine, 20 mg	No reversal
Length of follow-up, days	87	6	131	113

AF, Atrial fibrillation; ATA, anterior tibial artery; CKD, chronic kidney disease; CVA, cerebrovascular accident; DECIAP, direct extravascular calcium interruption arterial procedure; DM, diabetes mellitus; HL, hyperlipidemia; HT, hypertension; IHD, ischemic heart disease; PARC, Peripheral Academic Research Consortium; PIERCE, percutaneous direct needle puncture of calcified plaque; SFA, superficial femoral artery; TASC, TransAtlantic Inter-Society Consensus.

<sup>a</sup>Boston Scientific, Marlborough, Mass.  
<sup>b</sup>Abbott Vascular, Abbott Park, Ill.  
<sup>c</sup>OrbusNeich, Hong Kong.

balloon crossing is not initially achieved. New treatment modalities, such as lithotripsy, aim to fracture the calcium intravascularly. Although this might be a solution for heavily calcified lesions, its use is accompanied by increased costs, and the safety and efficacy are poorly studied in infrapopliteal arteries.<sup>8</sup>

In our series, the DECIAP technique was used to allow a small low-profile balloon to cross the lesion and to perform predilation or to treat persistent recoil. No major procedure-related events occurred during or after the procedure, and the equipment necessary for the procedure is already present in the interventional suite and therefore does not require capital investment of consoles used in some atherectomy systems.

There are a few drawbacks of the DECIAP technique. The technique is somewhat invasive and may cause injury to surrounding structures. Nerve injury, artery

rupture, distal embolism, guidewire fracture, arterial occlusion, arteriovenous fistula, venous thrombosis, bleeding, and infection are all potential risks, most of which were not observed in our study. This technique might not be feasible in obese patients or in arteries that are in a deeper location, for example, proximal to mid SFA and deep posterior tibial or peroneal artery. In addition, the potential for stent fracture exists, but because of our limited experience, we are unable to advise on safety. None of the mentioned risks was seen in our series.

## CONCLUSIONS

In this initial experience, the DECIAP technique was successful as a bailout option in patients in whom balloon crossing was impossible or recoil was untreatable even with high-pressure balloons. The necessary

equipment to perform the technique is readily available. More research is needed in a larger population of patients to clarify the safety and long-term efficacy of the DECIAP technique.

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