

# Sustained drug retention after paclitaxel-coated balloon angioplasty for superficial femoral artery disease: Follow-up intravascular imaging

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## Abstract

A 63 year-old woman with claudication underwent endovascular therapy for diffuse stenosis of the right superficial femoral artery in our hospital. We performed paclitaxel-coated balloon angioplasty using the IN.PACT™ Admiral™ and achieved acceptable results. After 42 days, we performed follow-up optical frequency domain imaging for the right superficial femoral artery lesion treated with paclitaxel-coated balloon and observed several high-intensity regions with attenuation on the lumen surface. Sustained drug availability is a notable characteristic of paclitaxel-coated balloon. To the best of our knowledge, this is the first report on the visualization of sustained drug retention on the lumen surface using follow-up optical frequency domain imaging after paclitaxel-coated balloon angioplasty in a human patient with superficial femoral artery disease.

## Keywords

Paclitaxel-coated balloon, superficial femoral artery disease, optical frequency domain imaging, optical coherence tomography

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## Introduction

The use of a paclitaxel-coated balloon (PCB) has improved the clinical outcomes of endovascular therapy (EVT) for superficial femoral artery (SFA) disease.<sup>1</sup> Paclitaxel is an antiproliferative drug with anti-inflammatory effects.<sup>2</sup> A previous study using a rabbit model of atherosclerosis demonstrated that paclitaxel was transferred into arterial walls of atherosclerotic lesions.<sup>3</sup> The IN.PACT™ Admiral™ (Medtronic, Dublin, Ireland), which is one of the new-generation PCBs with a paclitaxel dose density of 3.5 µg/mm<sup>2</sup> and urea as the excipient, was found to result in sustained drug availability and a prolonged antiproliferative effect in the SFA of swine.<sup>4</sup> Several studies involving the human coronary artery observed the attachment of paclitaxel to the vessel wall after PCB angioplasty and healing of dissections at

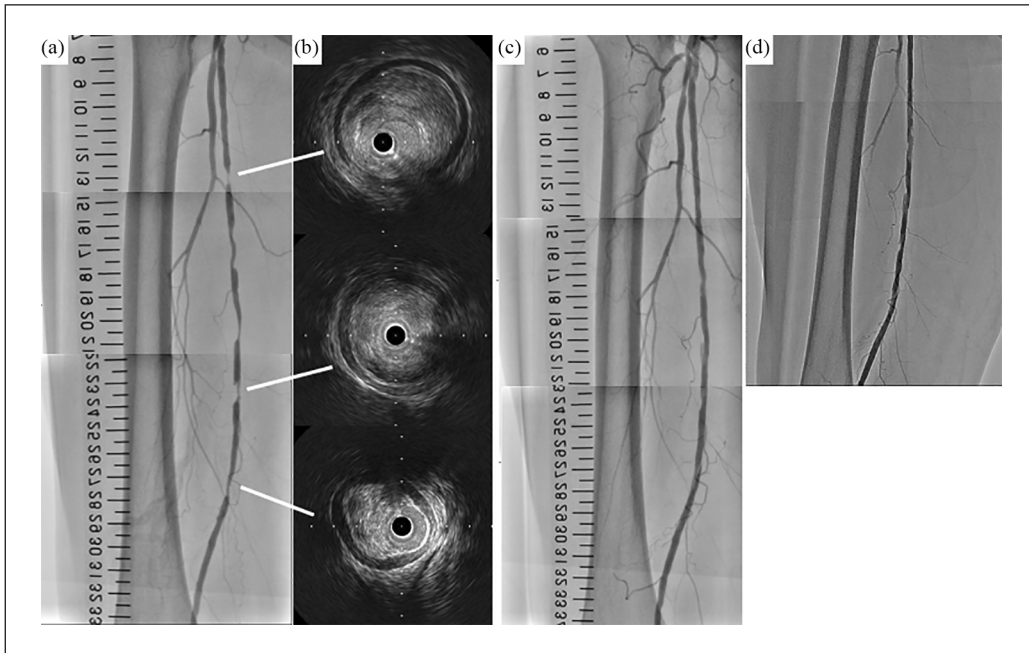
the mid-term follow-up using frequency domain optical coherence tomography.<sup>5,6</sup> However, data regarding the use of PCB for SFA disease are scarce. Here, we report the visualization of sustained drug retention on the lumen surface of the SFA using follow-up optical frequency domain imaging (OFDI) after PCB angioplasty using the IN.PACT™ Admiral™ in an elderly woman with bilateral SFA disease.

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**Figure 1.** (a) Preoperative angiography of the right SFA, (b) preoperative intravascular ultrasound findings, (c) final angiography after PCB angioplasty using the IN.PACT™ Admiral™ for right SFA disease and (d) follow-up angiography of the right SFA at 42 days after the procedure.

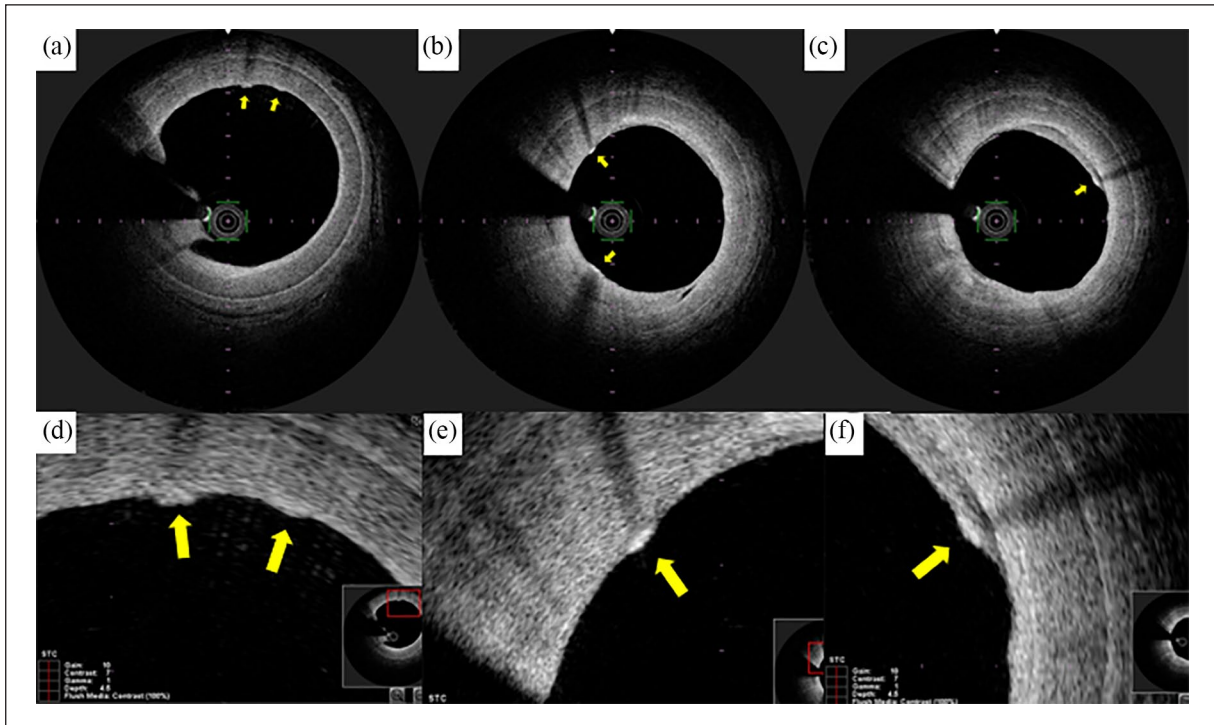
## Case

A 63-year-old woman with claudication and a history of hypertension and diabetes mellitus was scheduled to undergo EVT for bilateral SFA disease. At first, we planned EVT for diffuse stenosis of the right SFA. We introduced a 6-Fr sheath via the ipsilateral common femoral artery. Angiographically, there was no severe calcification, and the lesion length was approximately 160 mm (Figure 1(a)). Preoperative intravascular ultrasound revealed a fibrous plaque without severe calcification at the lesion site (Figure 1(b)). We performed balloon angioplasty using a 3.0/200-mm balloon, followed by angioplasty using two 4.0/150-mm PCBs (IN.PACT™ Admiral™). Final angiography showed some dissection, although there was no remarkable residual stenosis (Figure 1(c)). After 42 days, we performed EVT for the left SFA along with follow-up angiography and OFDI (Lunawave; Terumo Corporation, Tokyo, Japan) for the right SFA. Although dissection was still observed in follow-up angiography, there was no restenosis at the treated site (Figure 1(d)). Follow-up OFDI demonstrated several high-intensity regions with attenuation on the lumen surface (Figure 2(a)–(c)). High-power field images showed the high-intensity regions more clearly. There was no apparent neointimal hyperplasia over these regions (Figure 2(d)–(f)).

## Discussion

A previous study evaluating different PCB technologies in a swine model demonstrated a sustained tissue concentration

of paclitaxel for up to 60 days and subsequent neointimal inhibition.<sup>4</sup> However, there are no follow-up intravascular imaging data to confirm prolonged antiproliferative effects after PCB angioplasty for SFA disease. To the best of our knowledge, this is the first report on the visualization of sustained drug retention on the lumen surface using follow-up OFDI after PCB angioplasty, which was performed with the IN.PACT™ Admiral™, in a human patient with SFA disease. Our follow-up OFDI demonstrated findings similar to those observed on optical coherence tomography images obtained after PCB angioplasty (SeQuent Please™, B. Braun, Melsungen, Germany and NIPRO Corporation, Japan) for coronary artery disease in a previous study.<sup>5</sup> The authors discussed that the high-intensity superficial regions probably represented a mixture of iopromide and paclitaxel. On the contrary, the IN.PACT™ Admiral™ uses urea as an excipient, which is critical for delivering and sustaining paclitaxel in vessel walls. We consider that histological evaluation is necessary to confirm what these high-intensity regions truly represent. Unfortunately, OFDI is not usually available for EVT in our daily practice; therefore, we were unable to record OFDI data after the procedure. As a result, the amount of drug attached to the lumen wall after the procedure and that during the follow-up evaluation could not be compared. Nevertheless, we consider that our findings will be useful for evaluation of the mechanism underlying the long-term efficacy of PCB angioplasty for SFA disease in the future. Further studies should confirm whether our findings are associated with a prolonged antiproliferative effect and the prevention of clinical restenosis.



**Figure 2.** (a–c) OFDI images acquired at 42 days after PCB angioplasty using the IN.PACT™ Admiral™ for SFA disease and (d–f) high-power field images.

There are several high-intensity regions with attenuation on the lumen surface (arrows).

## Conclusion

In summary, we described a case wherein follow-up OFDI at 42 days after PCB angioplasty using the IN.PACT™ Admiral™ for SFA disease exhibited sustained drug retention on the lumen surface. Although sustained drug availability is one of the notable characteristics of PCBs, further studies are required to evaluate the efficacy of this feature.

## Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

## Ethical approval

Our institution does not require ethical approval for reporting individual cases or case series.

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## Informed consent

Written informed consent was obtained from the patient(s) for their anonymized information to be published in this article.

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