# "Low Echoic Area" around stent after bare and drug-coated stenting or stent graft placement for superficial femoral artery disease

SAGE Open Medical Case Reports Volume 9: 1–5 © The Author(s) 2021 Article reuse guidelines: sagepub.com/journals-permissions DOI: 10.1177/2050313X211014519 journals.sagepub.com/home/sco

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#### Abstract

Restenosis after stent implantation in femoropopliteal lesions is still big issue. However, restenosis has been reduced by the recent new drug-eluting stent "Eluvia" (Boston Scientific, Marlborough, MA, USA). However, it was reported that "low echoic area (LEA)" finding around stent by ultrasound that they called "aneurysmal degeneration," but no blood flow was identified outside the stent was confirmed after Eluvia implantation. In this report, we describe the similar findings that were observed after other types of stents (S.M.A.R.T. bare-nitinol stent (Cordis Corporation, Hialeah, FL, USA), Zilver PTX drug-coated stent (Cook Medical, Bloomington, IN, USA), and Viabahn stent graft (W. L. Gore & Associates, Newark, Delaware, USA)) for superficial femoral artery disease. These findings did not change to "aneurysmal change" during the follow-up.

#### Keywords

Aneurysmal degeneration, low echoic area, femoropopliteal segment, stent, duplex ultrasound

Date received: 7 August 2020; accepted: 13 April 2021

# Introduction

Reduced restenosis and favorable outcomes have been reported by the latest drug-eluting stent "Eluvia" (Boston Scientific, Marlborough, MA, USA).<sup>1-4</sup> However, there is a potential safety concern of the finding of "low echoic area (LEA)" around stent by ultrasound after Eluvia implantation. It is reported as an "aneurysm formation."<sup>5</sup> Whether this finding is specific after Eluvia placement remains unclear.

In this report, we describe the similar findings that were observed after other types of stents or stent graft for superficial femoral artery (SFA) disease and these findings did not change to "aneurysmal change" during follow-up period.

## Case

#### Case I: 73-year-old male

For patients with intermittent claudication due to the right SFA occlusion, S.M.A.R.T. stent (Cordis Corporation, Hialeah, FL, USA) was implanted (Figure 1(a)). No complications were confirmed after the procedure, but a surface echo on the following day showed an LEA around the stent implanted in the proximal SFA (Figure 1(b), arrow). No blood flow signals were confirmed within the LEA. He was not aware of symptoms. Three-month follow-up, surface echo also revealed the similar findings of the LEA, and no changes were confirmed. In addition, he was not aware of any symptoms up to 3-year follow-up (Figure 1(c), arrow).

# Case 2: 72-year-old male

For claudicant with the left SFA occlusion, Viabahn stent graft (W. L. Gore & Associates, Newark, DE, USA) was implanted (Figure 2(a)). One month later, he came to our hospital again because of pyrexia and pain of the proximal SFA. A surface echo showed an LEA around the Viabahn in the proximal SFA (Figure 2(b), arrow). No blood flow signals were observed within the LEA. After the treatment with corticosteroids, his symptom has been improved. At 6 months, the regression of the LEA around Viabahn was

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Figure 1. Seventy-three-year-old male treated with bare-metal stent. (a) S.M.A.R.T. stent was implanted. (b) Next day, a "low echoic area" was shown in the proximal SFA (arrow). (c) Three months later, the "low echoic area" findings were similar (arrow).



**Figure 2.** Seventy-two-year-old male treated with Viabahn stent graft. (a) Viabahn stent graft was implanted. (b) One month later, a "low echoic area" around the Viabahn was shown. But, no blood flow signals were observed. (c) After the steroid treatment, the regression of the "low echoic area" was observed. (d) At 18 months, the "low echoic area" almost disappeared.



**Figure 3.** Seventy-two-year-old male treated with bare-metal stent. (a) Right SFA occlusion before procedure. (b) After the conventional balloon angioplasty, major dissection was found. (c) Intravascular ultrasound showed dissection of 180 degrees. (d) The proximal lesion was treated with bailout stent and the distal lesion was treated with drug-coated balloon. (e) The procedure was completed after favorable blood flow. (f) Next day, a "low echoic area" around the stent that corresponded to the medial dissection. (g) There was no blood flow in the "low echoic area." (h) It was difficult to identify the presence of "low echoic area" at distal lesion treated with drug-coated balloon.

found (Figure 2(c), arrow). Subsequently, the steroid dose was tapered off and then discontinued. At 18 months, the LEA almost disappeared (Figure 2(d), arrow). Although 4 years has passed, the LEA remains disappeared with no recurrent symptom.

#### Case 3: 72-year-old male

The claudicant patient due to the right SFA occlusion was admitted to our hospital (Figure 3(a)). When conventional balloon angioplasty was performed after the guidewire passage, major dissection was found in the proximal SFA (Figure 3(b)). Intravascular ultrasound (IVUS) showed medial dissection of 180 degrees (Figure 3(c), arrow). Therefore, S.M.A.R.T. stent was implanted as the bailout stenting, and the distal lesion was treated with drug-coated balloon (DCB) (Figure 3(d)). The procedure was completed after favorable blood flow (Figure 3(e)). Next day, an LEA due to dissection was shown (Figure 3(f)). There was no blood flow in the LEA (Figure 3(g)). This LEA has been gradually reduced and disappeared within 1 year. On the contrary, since the border of the lumen wall of distal unstented site was unclear, it was difficult to identify the presence of LEA in the DCB-treated lesion (Figure 3(h)).

# Case 4: 71-year-old male

For claudicant patient due to the left SFA occlusion, Zilver PTX stent (Cook Medical, Bloomington, IN, USA) was implanted (Figure 4(a)). No complications were occurred after the procedure, but a surface echo on the following day showed an LEA around the stent implanted in the proximal SFA (Figure 4(b), arrow). There was no blood flow signal within the LEA. He was not aware of any symptoms. Follow-up echo at 6 months, 1 year, and 2.5 years showed the similar findings of LEA. No change and no symptom



Figure 4. Seventy-one-year-old male treated with drug-coated stent: (a) Zilver PTX stent was implanted. (b) Next day, a "low echoic area" around stent was shown. (c) Six-month follow-up. (d) One-year follow-up. (e) 2.5-year follow-up.

	Table I.	Patients	and lesion	charact	eristics
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	Case I	Case 2	Case 3	Case 4
Age (years)	73	72	74	71
Sex	Male	Male	Male	Male
Indication	Claudication	Claudication	Claudication	Claudication
Lesion	Long SFA CTO	Long SFA CTO	Long SFA CTO	Long SFA CTO
Stent	S.M.A.R.T	Viabahn	S.M.A.R.T	Zilver PTX
Guidewire passage	Intraluminal	Intraluminal	Intraluminal	Intraluminal
When was it detected?	Next day	I month	Next day	Next day
Location	Stenting site	SFA prox	SFA prox	Stenting site
Symptom	(-)	Pain	(-)	(-)
Doppler signal out of stent	(-)	(-)	(-)	(-)
Additional treatment	(-)	Steroid	(-)	(-)
Clinical course	No change	Improvement after steroid	Disappearance during 6 months	No change
Follow-up period	3 years	4 years	2.5 year	3 years
Restenosis	(-)	(-)	(-)	(-)
Stent thrombosis	(-)	(-)	(-)	(-)

SFA: superficial femoral artery.

were observed during the follow-up period (Figure 4(c)–(e), arrow).

### Discussion

We reported four cases of LEA surrounding stents after stent placement of various types. Table 1 shows the respective cases. The cause of these cases may represent localized: (1) elastic membrane, (2) edema associated with inflammation, and (3) dissected lumen. In Cases 1 and 4, the findings were noted on the following day after stent implantation, and they did not largely change with time. Therefore, the LEA around the implanted stent may be seen from the image of elastic membrane-based structures, and thus evaluated more easily based on the clearer border with the lumen as a result of stent implantation.

Next, fever and pain at stented site were observed in Case 2. These symptoms might be caused by inflammation like post-implantation syndrome. However, pathological study is needed to confirm these clinical findings.

Finally, the findings in Case 3 may be seen from the image of the dissections that were formed during the procedure. Since the dissected lumen corresponded to the area and almost disappeared during the follow-up, it was thought to be healed and resolved.

Further investigation is needed to confirm whether "low echoic are" surrounding stent is really "aneurysmal change" as reported and this finding is specific after only Eluvia placement. Recently, it was reported that prolonged paclitaxel exposure after Eluvia implantation may contribute to the differential vascular responses. In this report, medial layer disruption and aneurysmal vessel degeneration were observed in vitro.<sup>6</sup> Two-year clinical follow-up data support these concerns.<sup>7</sup> These features should be confirmed by pathology and in vivo imaging of human femoral arteries to determine their clinical significance. Additional details on how the lesions were crossed, any adjunctive therapy such as atherectomy, balloon size, and the inflation pressures are also required to understand other contributing factors which could result in the LEA findings.

# Conclusion

Although "LEA around stent" by ultrasound was reported as "aneurysmal degeneration" after Eluvia stent, the similar findings were also observed after other types of stents or stent graft placement for SFA disease in this report. And these findings were not growing up to aneurysmal change during follow-up period.

### **Author contributions**

Y.S. contributed to the conception and data collection. Y.S. and K.A. contributed to the drafting of manuscript.

#### **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.

#### Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

#### **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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#### References

- 1. Müller-Hülsbeck S, Benko A, Soga Y, et al. Two-year efficacy and safety results from the IMPERIAL randomized study of the Eluvia polymer-coated drug-eluting stent and the Zilver PTX polymer-free drug-coated stent. *Cardiovasc Intervent Radiol* 2021; 44(3): 368–375.
- Gray WA, Keirse K, Soga Y, et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxelcoated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): a randomised, non-inferiority trial. *Lancet* 2018; 392: 1541–1551.
- Golzar J, Soga Y, Babaev A, et al. Effectiveness and safety of a paclitaxel-eluting stent for superficial femoral artery lesions up to 190 mm: one-year outcomes of the single-Arm IMPERIAL long lesion substudy of the Eluvia drug-eluting stent. *J Endovasc Ther* 2020; 27(2): 296–303.
- Soga Y, Fujihara M, Tomoi Y, et al. One-year late lumen loss between a polymer-coated paclitaxel-eluting stent (Eluvia) and a polymer-free paclitaxel-coated stent (Zilver PTX) for femoropopliteal disease. *J Atheroscler Thromb* 2020; 27: 164–171.
- Bisdas T, Beropoulis E, Argyriou A, et al. 1-year all-comers analysis of the eluvia drug-eluting stent for long femoropopliteal lesions after suboptimal angioplasty. *JACC Cardiovasc Interv* 2018; 11: 957–966.
- Sakamoto A, Torii S and Jinnouchi H. Vascular response of a polymer-free, paclitaxel-coated stent (Zilver PTX<sup>®</sup>) versus a polymer-coated, paclitaxel-eluting stent (Eluvia<sup>®</sup>) in healthy swine femoropopliteal arteries. *J Vasc Interv Radiol* 2021; 4: 014.
- Stavroulakis K, Torsello G, Bosiers M, et al. 2-year outcomes of the eluvia drug-eluting stent for the treatment of complex femoropopliteal lesions. *JACC Cardiovasc Interv* 2021; 14: 692–701.