# The Diagnostic Gap

*Limitations of 2D Angiography May Lead to Increased Clinical Risk*

"Leave nothing behind" is a clinical mantra that many clinicians falsely limit to reduced stent utilization. In reality, this concept emerged during surgical endarterectomies and was in reference to elimination of luminal plaque burden – thus leaving no plaque behind. This foundational principle has been shown to translate to significantly improved laminar flow surfaces and favorable patency at 5 years[1].

In the majority of percutaneous procedures for PAD therapy, angiography is often the sole diagnostic tool used to determine residual plaque burden, however, the limitations of fluoroscopy to truly identify residual plaque are well documented[2]. In Avinger's most recent study – VISION – we investigated the resulting differences between the diagnostic lesion length as measured by fluoroscopy and the OCT guided treatment length. Thus, the term 'Diagnostic Gap' defines this difference: OCT Length – Fluoroscopy Length, and can been seen in the exemplary case (Figure 1A).

Taking a further look into the data, Figure 1B reveals that an average Diagnosis Gap of ~19mm was measured across all lesions (n=198) when comparing Fluoroscopy vs. OCT treatment lengths during the VISION trial. Moreover, in an effort to identify the clinical implications of this under-treatment, we examined patients who required target lesion revascularization (TLR). Figure 1C demonstrates, a difference in Diagnostic Gap between TLR and Non-TLR patients – potentially providing a link between under treatment and restenosis/TLR. The clinical implications of this under-treatment is significant because the underestimate of plaque burden may prevent patients from receiving the necessary treatment required. Support for our hypothesis is based on the following coronary/peripheral clinical data:

1) On average, only **39.7% of target plaque volume is removed** from directional coronary atherectomy[3]
2) Residual plaque burden ≥46% is correlated with a **4.4-fold greater restenosis risk increase**[4]

To the best of our knowledge, this is the first clinical study to present the Diagnostic Gap and its correlation with long-term outcomes of TLR in PAD. We already knew of OCTs capacity to accurately characterize plaque demographics[5], however, we now have data which suggests that OCT will allow our physicians to significantly treat plaque burden beyond diagnostic lesion boundaries, and potentially reduce or eliminate this known risk factor for arterial restenosis.

Figure 1: (A) Exemplary Case Demonstrating the Diagnostic Gap; (B) VISION data comparing the lesion length assessment via fluoroscopy and OCT; (C) comparison between the values of the Diagnostic Gap in Non-TLR and TLR lesions
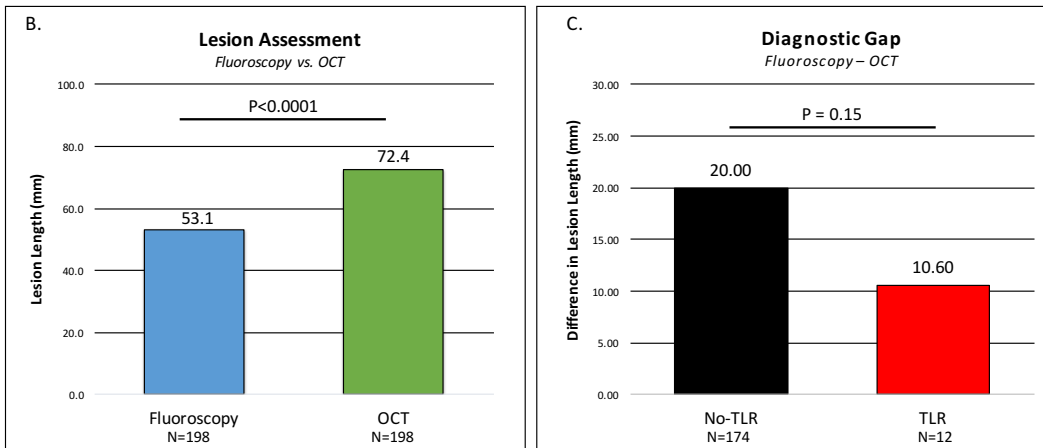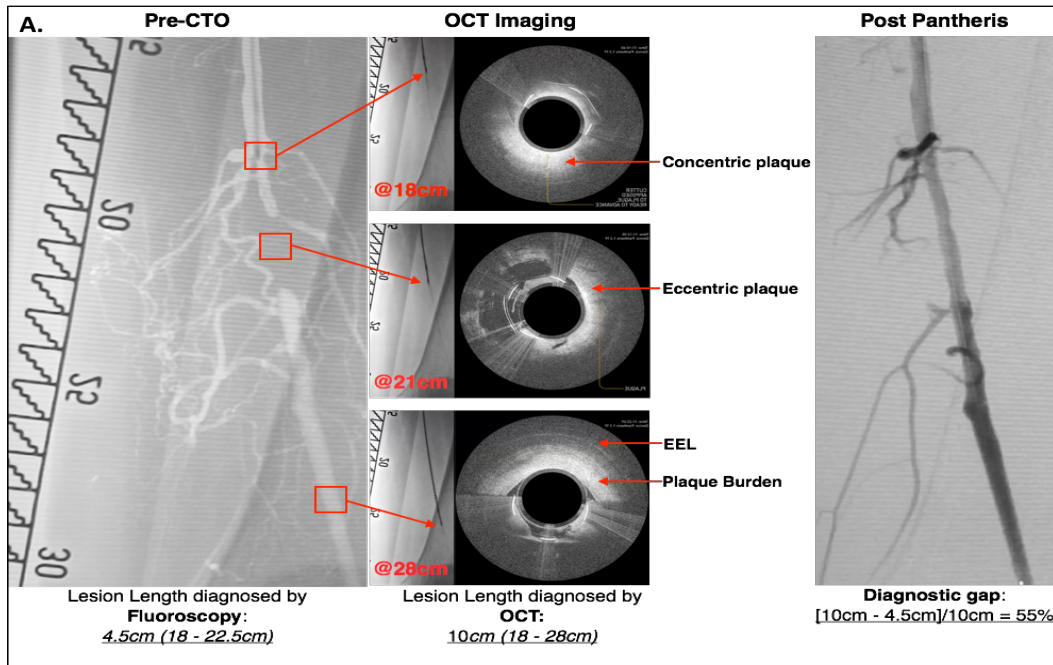
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