HeartFlow®

HeartFlow Plaque Analysis I REVEALPLAQUE Study

HeartFlow AI-Plaque Analysis demonstrated excellent accuracy in quantification and characterization of coronary atherosclerosis as compared to Intravascular Ultrasound (IVUS).*

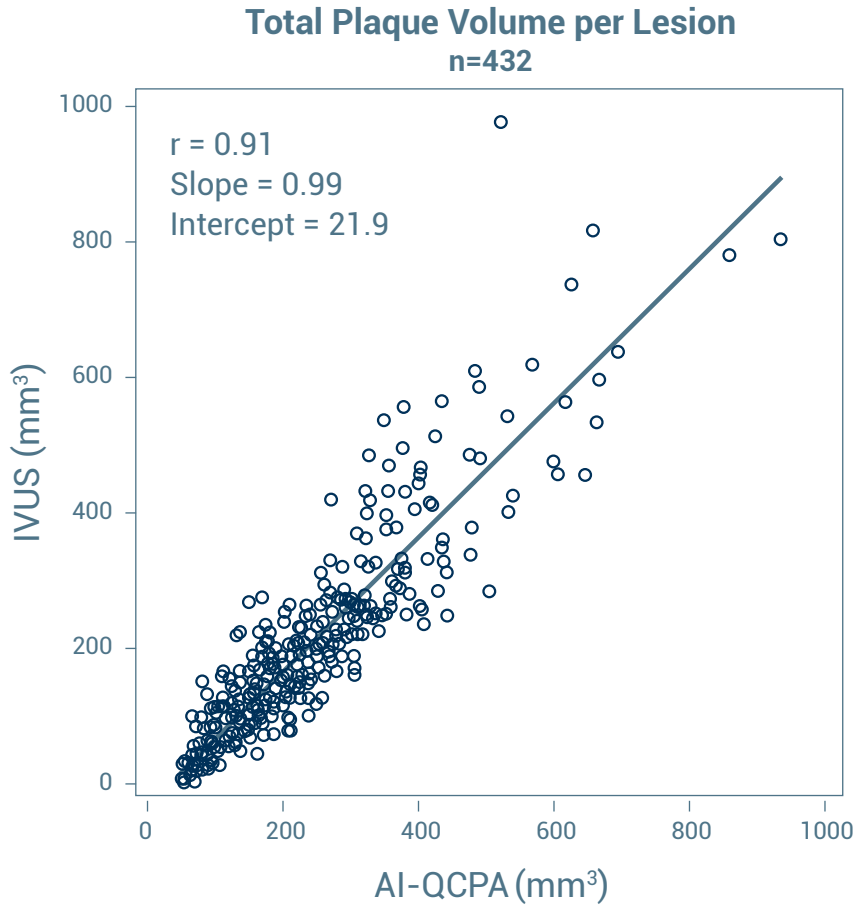
STUDY OBJECTIVE

Large, global, prospective study, enrolling 258 patients across 15 sites with independent, blinded, core lab adjudication to determine accuracy of HeartFlow's AI-Plaque Analysis vs IVUS.

KEY RESULTS:

HeartFlow AI-Plaque Analysis is highly accurate compared to IVUS, the invasive gold standard, in quantification and characterization of coronary plaque by demonstrating a total plaque volume correlation coefficient of 0.91 per lesion and 0.99 slope, indicating consistent and high correlation across the range of data.

Total plaque volume demonstrated **95% agreement with IVUS.**



Total Plaque Volume

95%

Agreement with IVUS*

STUDY ENDPOINTS

Significant correlation and high accuracy compared to IVUS was observed for total plaque volume on a per vessel-segment level, as well as for calcified, non-calcified vessel, and lumen volumes on a per lesion and per vessel-segment level.

PLAQUE TYPE	CORRELATION PER LESION (n=432)	
	PEARSON	ICC
Total Plaque Volume	0.91	0.95
Calcified Plaque Volume	0.91	0.95
Non-calcified Plaque Volume	0.87	0.93
Lumen Volume	0.93	0.95
Vessel Volume	0.94	0.96

STUDY DESIGN

REVEALPLAQUE only included patients with high IVUS image quality, resulting in an accurate comparison to IVUS. The final statistical analysis was conducted with 237 patients, accounting for 432 lesions and 245 IVUS pullbacks.

STUDY CONCLUSIONS

- The HeartFlow AI-Plaque Analysis demonstrated excellent accuracy in identifying total plaque volume, plaque sub-types on a per lesion and per vessel-segment level compared to IVUS.
- The rigorous design of the REVEALPLAQUE study demonstrated HeartFlow's AI-Plaque Analysis is highly accurate compared to IVUS, the invasive gold standard.

* REVEALPLAQUE Study, presented at SCCT 2023.

Legal Disclaimer: The information provided by the HeartFlow FFR_{CT} Analysis and Plaque Analysis is intended to be used in conjunction with the patient's clinical history, symptoms, and other diagnostic tests, as well as the clinician's professional judgment. The HeartFlow FFR_{CT} and Plaque Analysis may not be appropriate for all patients. See their respective indications for use for more information.

The HeartFlow FFR_{CT} Analysis has received FDA Clearance, is CE-Marked, and is commercially available in the United States, Europe, Japan, and Canada. The Plaque Analysis has received FDA Clearance and is commercially available in the United States.

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