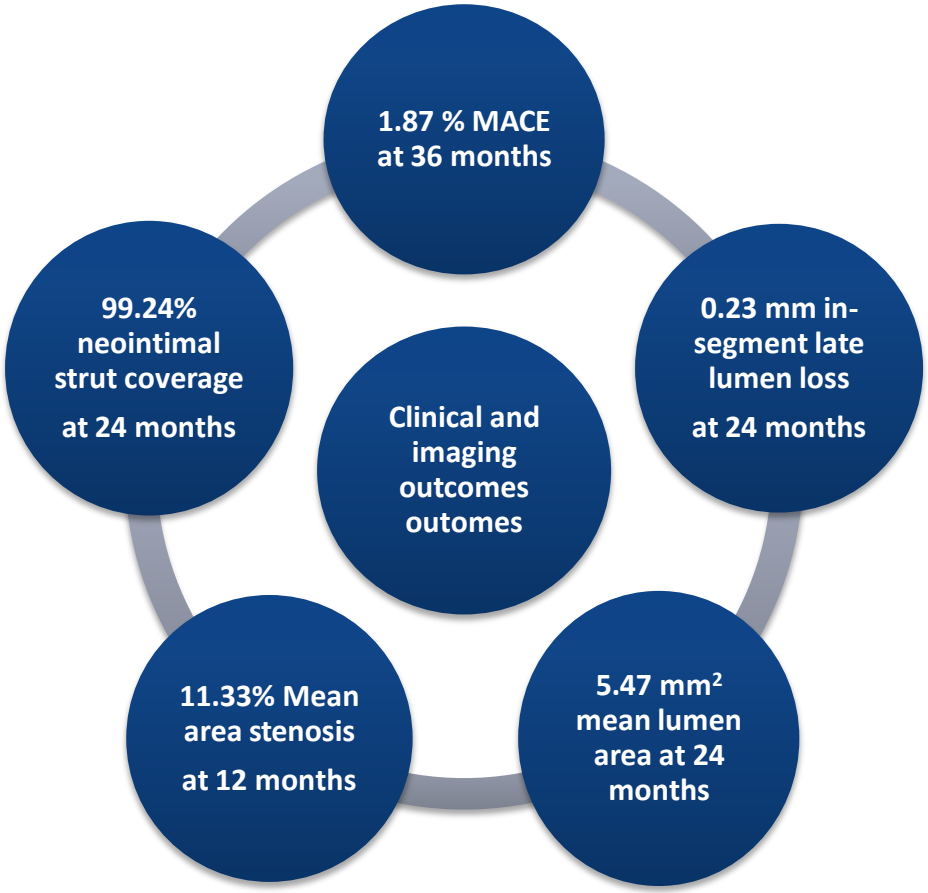
MeRes-1 Study

Study Highlights

- Principal Investigator: Dr. Ashok Seth
- The MeRes-1 was first-in-human, single-arm, prospective, open-label, multicentre trial of MeRes100™ sirolimus-eluting BioResorbable Vascular Scaffold System (BRS) in treating de novo native coronary artery lesions
- Three-year clinical and two-year multimodality imaging including QCA, OCT and IVUS analysis at 6 and 24 months; CTA imaging at 12 months
- MeRes-1 study demonstrated the favourable safety and effectiveness of MeRes100 BRS clinical outcomes at three-year follow-up and multimodality invasive imaging at two-year follow-up

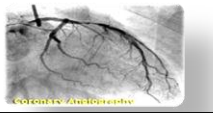


❖ Study Design

First-in-human, single-arm, prospective, multicentre study

A total of 108 patients were enrolled at 13 sites

Clinical follow-up at 30 days, 6 months, 12 months, 24 months and 36 months post-procedure

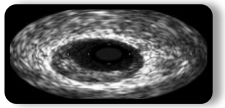


Angiographic follow-up at 6 and 24 months

Analysed by: Cardiovascular Research Centre, Sao Paulo, Brazil

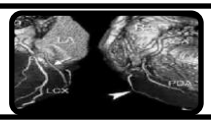
OCT at 6 and 24 months

Analysed by: Cardialysis BV, Rotterdam, the Netherlands



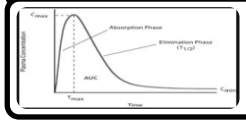
IVUS at 6 and 24 months

Analysed by: Cardialysis BV, Rotterdam, the Netherlands



CTA imaging at 12 months

Analysed by: Cardialysis BV, Rotterdam, the Netherlands



Venous blood samples were collected at pre-dose and 12-time points after implantation of the scaffold

❖ Study Results

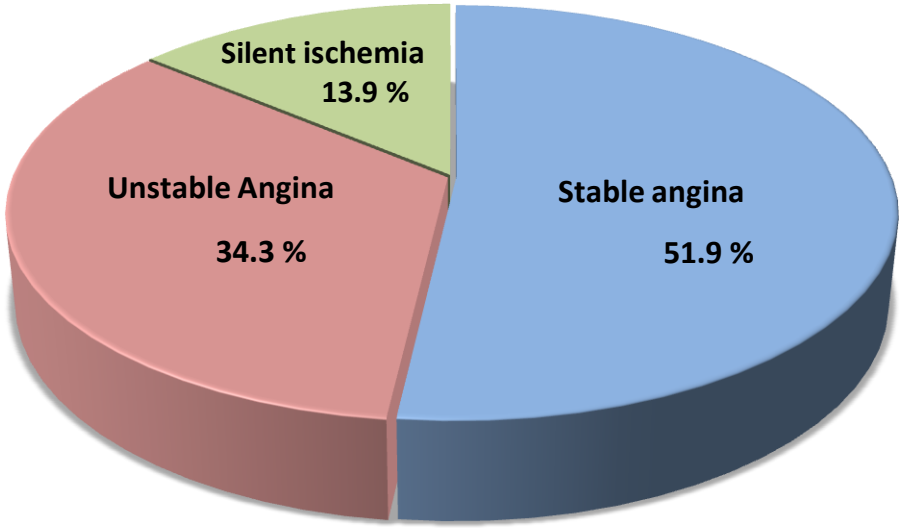


Figure 1: Cardiac Status

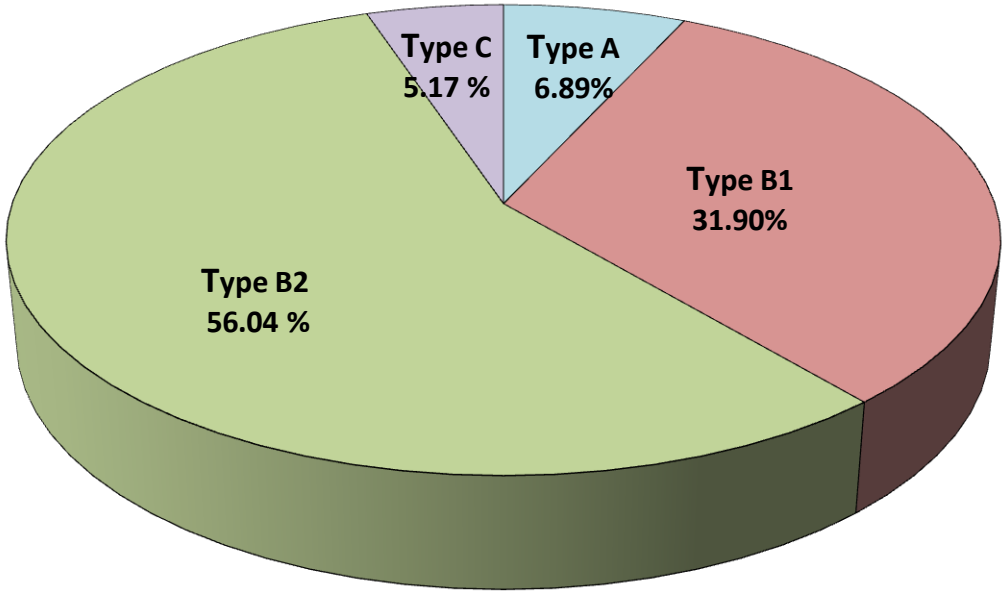
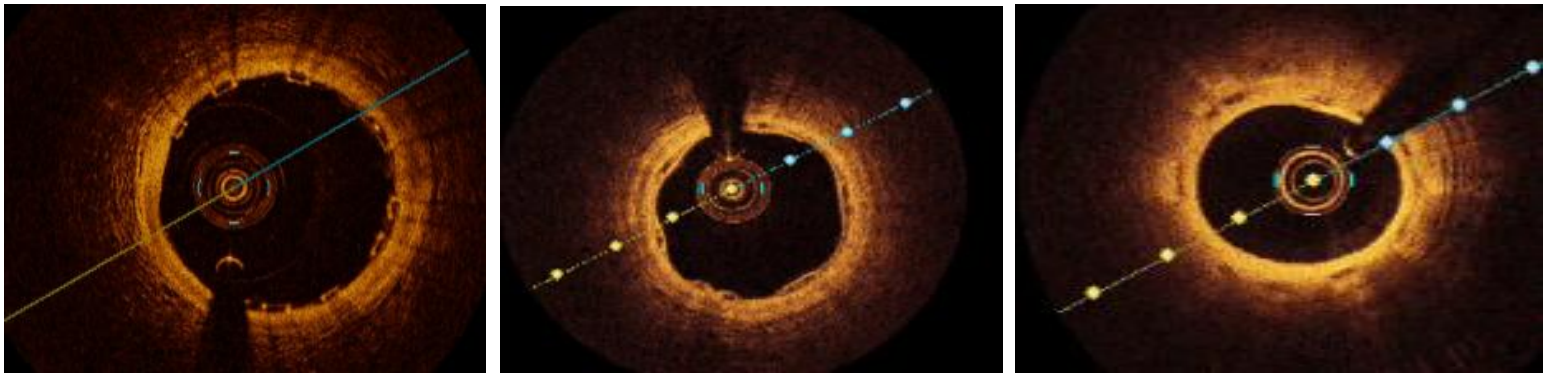


Figure 2: Lesion Characteristics (ACC/AHA Classification)

❖ **OCT Analysis**



Post-procedure OCT **6 –month FU OCT** **2–year FU OCT**

Figure 3: OCT images of the implanted scaffold at post-procedure, 6 months and 24 months follow-up

❖ **QCA Analysis**

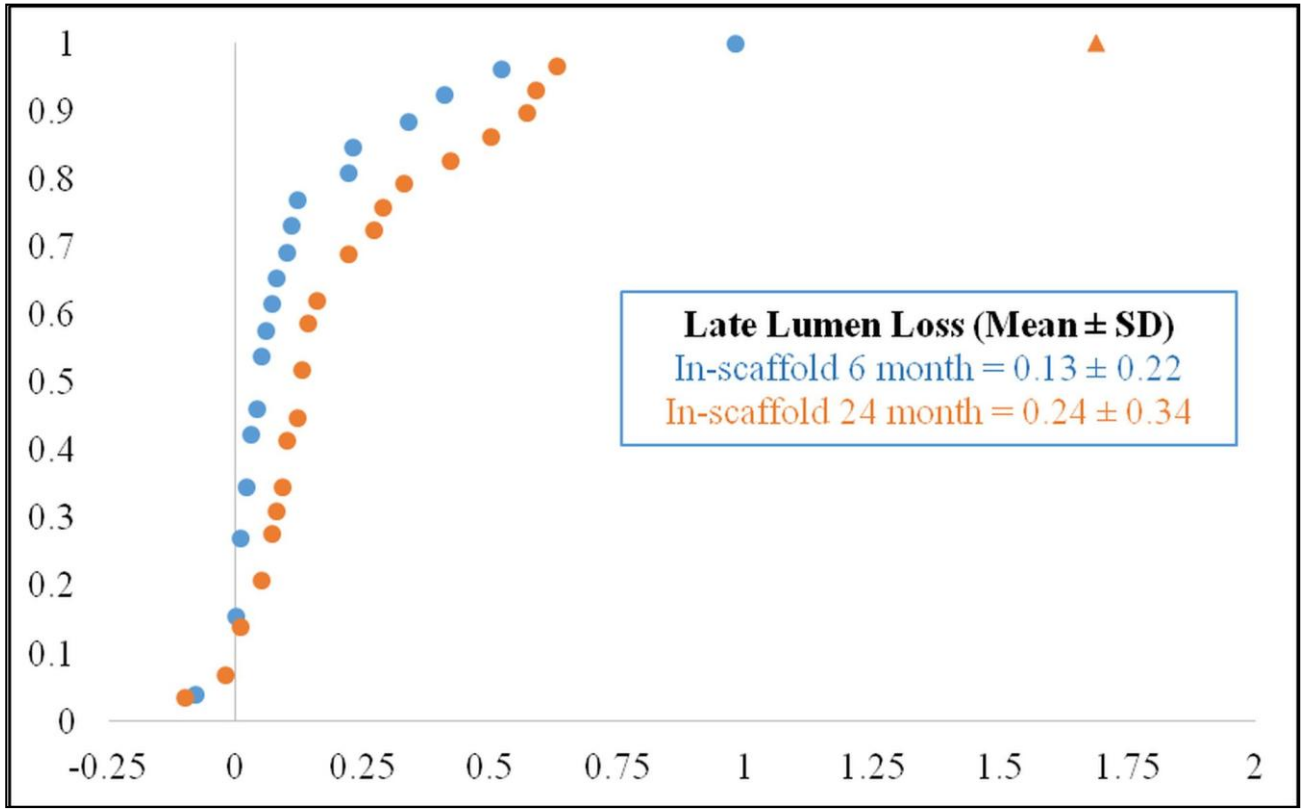


Figure 4: Late lumen loss at 6 and 24 months follow-up

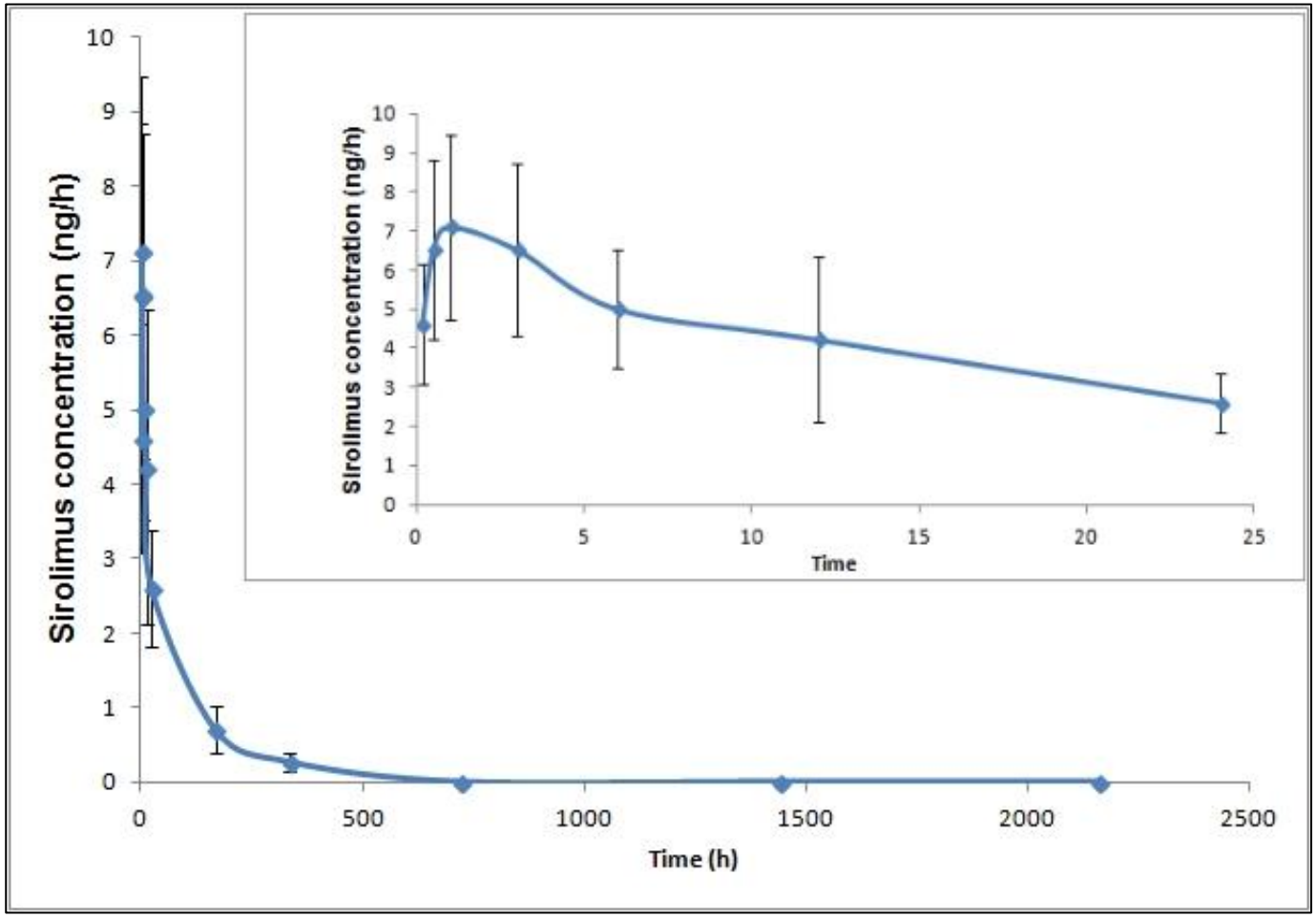


Figure 5: Pharmacokinetic profiles (concentration versus time profile) of sirolimus over 90 days after implantation

❖ References

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