MARKETING BULLETIN
ANCHOR Dec. 2016

The Angiolite stent demonstrated **good clinical performance**, high procedural success and markedly **low rate of angiographic restenosis and target lesion failure at 6 months.** OCT data showed **low degree of neointimal proliferation** as well as **low rate of strut malaposition.**

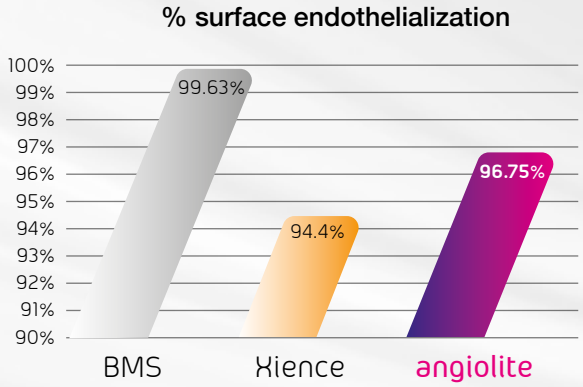
Post-Intervention, 3- and 6-Month Follow -Up QCA

	3-month	6-month
Pre-PCI	**n=28**	**n=70**
RVD, mm	3.01 ± 0.50	3.08 ± 0.67
MLD,	0.77 ± 0.32	0.90 ± 0.37
DS, %	73.6 ± 11.6	70.2 ± 12.0
Lesion Lenght, mm	14.3 ± 5.8	13.0 ± 5.3
Post-PCI	**n=28**	**n=70**
RVD	2.99 ± 0.44	2.90 ± 0.58
MLD, mm	2.73 ± 0.44	2.66 ± 0.48
DS, %	7.4 ± 11.0	6.3 ± 12.7
Follow-up	**n=21**	**n=56**
In-stent MDL, mm	2.67 ± 0.42	2.56 ± 0.53
In-segment MLD, mm	2.07 ± 0.46	2.28 ± 0.59
In-stent DS, %	4.1 ± 15.1	8.8 ± 9.1
In-stent late loss, mm	0.03 ± 0.24	0.07 ± 0.37
In-stent binary restenosis, n (%)	0	0
In-segment binary restenosis, n (%)	1 (4.7)	0

Anchor study 3 & 6-month follow-up showed that Angiolite stent is proving its very **high efficacy**, mainly supported by a **binary restenosis of 0%**, a **very low in-stent late lumen loss** 0,07 mm. Safety is also supported by a **very low target lesion failure rate (1%)**, caused by **1% of target lesion revascularization**.

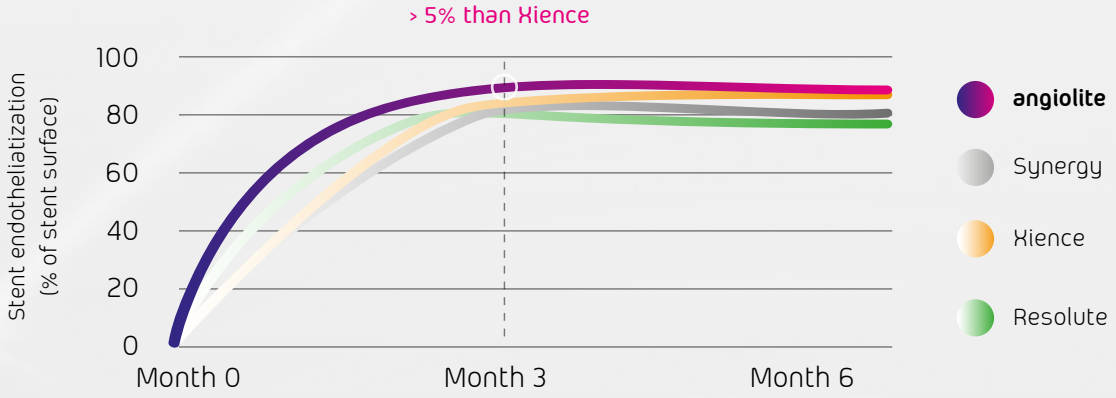
Meta-analysis of preclinical and clinical studies

Pre-Clinical study of Angiolite confirmed safety and states that Angiolite has improved endothelization rates vs Xience. The accuracy of strut coverage evaluated by OCT has been validated in pre-clinical studies.



In the clinical trials, such as TRANSFORM-OCT Bioresorbable polymer Everolimus eluting stent (SYNERGY™) vs Durable polymer-based zotalimus eluting stent (RESOLUTE Integrity™) the rate of covered struts was 79,1% for Synergy and 78.4% for Resolute. In COMPARATIVE TRIAL at 3-month follow-up the endothelialization rate for Xience was 81,5%. The results obtained with Angiolite, where the covered struts rate is 86.3%, are considered to be better compared to the other studies.

QCA results of Angiolite showed an in-stent late lumen loss of 0.07 mm and binary restenosis of 0%. In comparison, the LongOCT study had an in-stent late lumen loss of 0.46 mm for Endeavor Sprint and 0.17 mm for Resolute, and binary restenosis of 18.18% for Endeavor and 0% for Resolute. In ISAR-TEST 6 OCT, in-stent late lumen loss was 0.31 mm for Cypher and 0.11 mm for Xience, while binary restenosis 15.88% for Cypher and 4.6% for Xience. The Ultimaster OCT study from Terumo also has very low LLL and restenosis rate (0,9%). However, its small number of patients (21), does not allow drawing any firm conclusions concerning clinical outcomes.



Unique study features

More than 30% of diabetic patients in the ANCHOR study vs >20% of patients with diabetes in the competition trials.

Patients with diabetes mellitus have a less positive clinical outcomes at one year after successful stent placement as compared to the nondiabetic patients. Cardiovascular risk factors are more prevalent in diabetic patients, a worse clinical outcome in this group of patients could be expected, therefore impacting the global ANCHOR results.

Nevertheless, Angiolite stent still demonstrated highly positive outcomes, even compared to less risky patient population.

The ANCHOR study results confirm the safety and efficacy of the Angiolite SES from iVascular (LVD Biotech) for the treatment of patients with de novo lesions

Potential Q&A

Not a randomized study

There are two options to answer this question. First one is that **most OCT studies aren´t randomized** and second that the ANCHOR study is the **first OCT** prospective evaluation of exploratory efficacy and clinical performance of the new DES Angiolite. Then, there is an ongoing randomized Angiolite trial in the process and the 1-month follow up will be presented in the beginning of 2017.

Small number of patients

During the ANCHOR study 75 patients were treated with Angiolite while during the TRIAL WITH SYNERGY only 22 patients were implanted with DES and in COMPARATIVE TRIAL, where 36 patients were treated with Xience DES (Everolimus). If we compare all these numbers, it brings us to the conclusion that the **ANCHOR trial has the highest number of patients** compared to others OCT studies.

No 1 year QCA data

OCT is a powerful tool for evaluating delayed healing and reendothelialization after stent implantation in living patients. The coverage of stent struts evaluated by OCT at 3 months is strongly associated with late-DES thrombosis. Our 6-months thrombosis rate (0%), with optimal endothelialization, can be perceived as a strong predictor to long term highly positive outcomes.

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