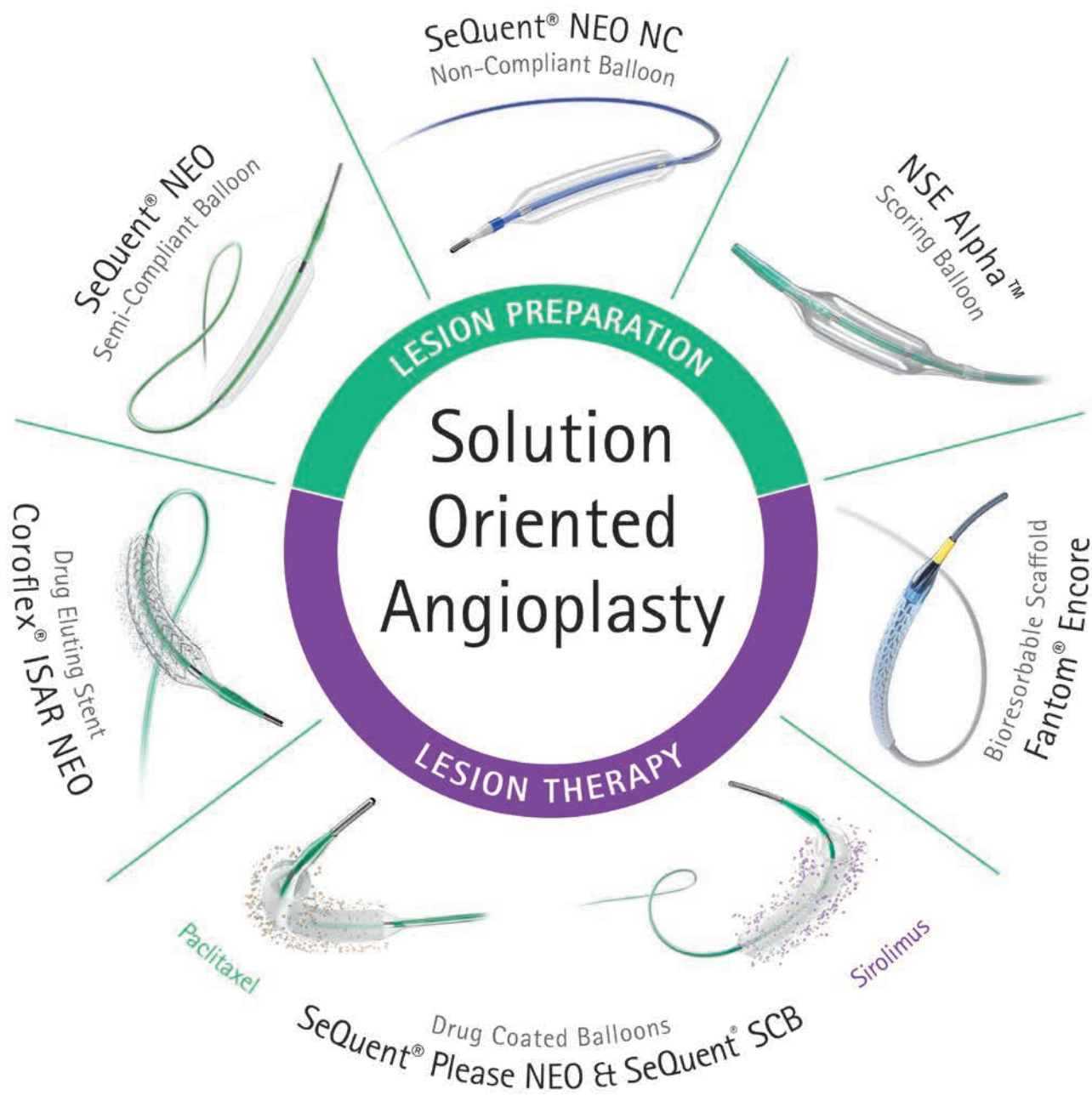




Clinical Evidence

NSE Alpha™
Scoring Balloon Catheter



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Subgroup Analysis NSE Alpha™ vs. POBA for Lesion Preparation in De Novo Lesions

Multicenter randomized controlled trial of PCB vs. POBA in SVD



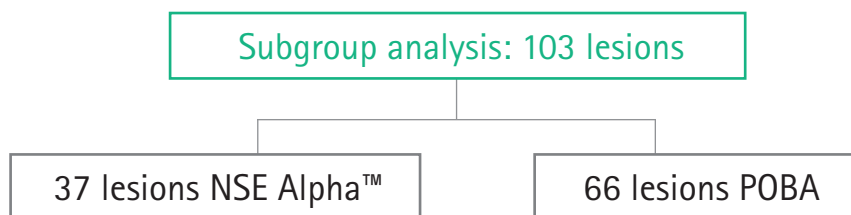
Conclusion

The incidence of composite acute event was significantly lower in the NSE group.

Methods

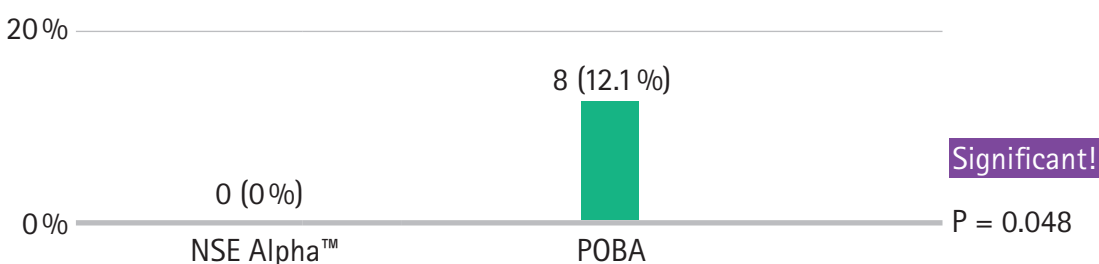
- 135 patients with de novo lesions treated with PCB (Paclitaxel Coated Balloon) or POBA
- Subgroup analysis: in PCB group 103 patients were treated
- Pre-Dilatation was performed:
 - In 37 lesions with NSE balloon
 - In 66 lesions with POBA

PubMed – Click here
<https://pubmed.ncbi.nlm.nih.gov/28589231/>



Results

- Composite events after Lesion Preparation



Combination of NSE Alpha™ & SeQuent® Please NEO in ISR and De Novo Lesions

Systematic scoring balloon lesion preparation for drug-coated balloon angioplasty in clinical routine: results of the PASSWORD observational study

Conclusion

The routine use of a non-slip element scoring balloon catheter to prepare lesions suitable for drug-coated balloon angioplasty is associated with high procedural success rates and low TLF rates in de novo lesions.

Methods

- Systematic use of scoring balloon angioplasty (SBA) prior to DCB angioplasty
- Unselected, non-randomized patient population. Prospective, all-comers study
- 481 patients (496 lesions) were recruited:
 - ▶ De novo lesions (78.4%, 377)
 - ▶ BMS-ISR (4.0%, 19)
 - ▶ DES-ISR (17.6%, 85)
- **Primary endpoint:** TLF at 9 months
- SBA was performed for lesion preparation

PubMed – Click here

<https://pubmed.ncbi.nlm.nih.gov/32274746>



Results

- Overall accumulated TLF rate: 3.0% (14/463)
- Overall accumulated TLR rate: 1.9% (9/463)
- Significantly higher TLR rates in
 - ▶ BMS-ISR group: 5.3%, 1/19
 - ▶ DES-ISR group: 6.0%, 5/84
- In de novo lesions, the TLF rate was 1.1% (4/360) and the TLR rate was 0.8% (3/360)

NSE Alpha™ for Lesion Preparation Prior DCB and DES

Clinical outcomes of drug-coated balloons in coronary artery disease unsuitable for drug-eluting stent implantation



Conclusion

For lesions that are unsuitable for stent implantation, stent-less intervention using a DCB should be considered initially. The present study also highlighted that lesion preparation is key to a successful DCB strategy.

Methods

- Retrospective study
- 118 de novo lesions that were not suitable for DES implantation (very small vessel lesions, patients with planned non-cardiac surgery, high bleeding risk [HBR] patients, lesions that easily develop stent fracture)
- Primary endpoint: TLR
- Secondary Endpoint: Rate of suboptimal lesion preparation before DCB treatment
- Optimal lesion preparation was defined as:
 - ▶ TIMI flow grade 3
 - ▶ Minor coronary dissection
 - ▶ Residual stenosis $\leq 30\%$
- NSE Alpha™ was used for lesion preparation

118 patients

Inclusion criteria:

- (1) **small vessel** (diameter ≤ 2.0 mm);
- (2) non-cardiac **surgery planned** or **high bleeding risk**;
- (3) lesions at risk of **stent fractures**;
- (4) **> 50% diameter stenosis in side branch** in bifurcation

Lesion preparation

Semi-compliant / cutting balloon /
rotablation / NSE Alpha™ (SBA)

115 patients

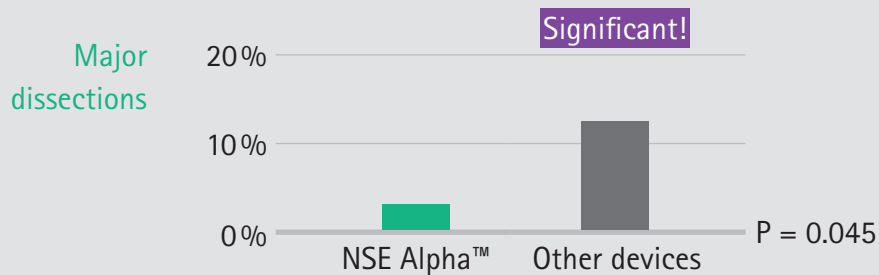
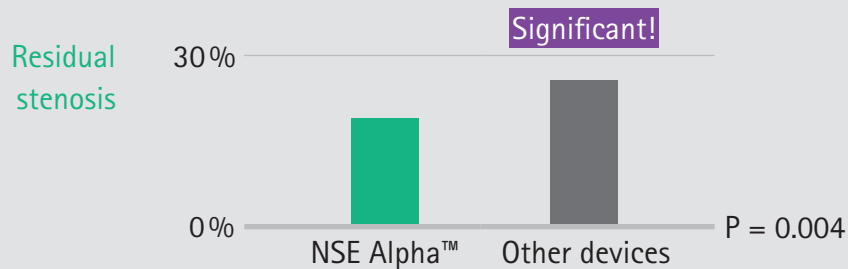
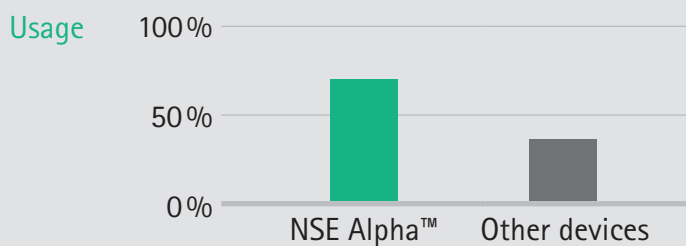
DCB-only

3 patients

Unacceptable
angiographic result

Results

- Rate of suboptimal lesion preparation: 2.5% → 115 patients were treated with a DCB
- TLR at 8 months: 8 patients (7.0%)
- The present study found that achieving optimal lesion preparation with a debulking device and NSE balloon were key to a low incidence of TLR in such lesions.



PubMed – Click here
<https://pubmed.ncbi.nlm.nih.gov/29899199/>



NSE Alpha™ for Fibrocalcific Lesion

Midterm clinical outcomes of non slip element (NSE) scoring balloon for treating fibrocalcific coronary lesions in realworld patients



Conclusion

Use of NSE scoring balloon prior 2nd generation DES is safe with good procedural results. There was a clinical benefit associated with NSE in terms of acute and midterm clinical outcomes in patients with fibrocalcific lesions.

Methods

- 92 patients with de novo fibrocalcific lesions
- NSE for lesion preparation prior to 2nd generation DES treatment
- Quantitive coronary angiography (QCA)
- **Primary Endpoint:** MACE (Cardiac Death, MI, Ischemia-driven revascularization) at 30 days and 9 months
- **Secondary Endpoint:** TVR, TLR and stent thrombosis at 30 days and 9 months

PubMed – Click here
<https://www.jacc.org/doi/10.1016/j.jcin.2016.12.105>



Results

- Composite events after Lesion Preparation

	30 Days	9 Months
MACE	2.08 %	6.2 %
TLR	0 %	2.08 %

Elegant Study: NSE Alpha™ Prior DCB for ISR Treatment

Effect of combination of non-slip element balloon and drug-coating balloon for in-stent restenosis lesions

Conclusion

- LLL similar between NSE Alpha™ and non-compliant group
- However, NSE Alpha™ pre-dilatation has advantages such as the reduction in balloon slippage and in geographical miss during the procedure.

Methods

- Patients with one or more in-stent restenosis
- Treated with paclitaxel coated balloon. Pre-dilation with
 - ▶ NSE Alpha™ (NSE group)
 - ▶ Non-compliant balloon (POBA group)
- 105 patients in each group
- Multicenter: 17 hospitals
- **Primary endpoint:** Late Lumen Loss at 8 months.

PubMed – Click here
<https://pubmed.ncbi.nlm.nih.gov/31248751/>



Results

	NSE Group	POBA Group	P-Value
Late Lumen Loss	0.28 mm	0.27 mm	0.750
@8 months	+/- 0.45 mm	+/- 0.38 mm	0.002
Balloon Slippage	7.9%	22.9%	0.002
Geographical miss	6.9%	21.9%	0.040

NSE Alpha™ after Rotational Atherectomy

Prognostic impact of scoring balloon angioplasty after rotational atherectomy in heavily calcified lesions using second-generation drug eluting stents: A multicenter registry-based study



Conclusion

Additional Scoring Balloon Angioplasty following Rotational Atherectomy was associated with significant lower MACE incidence in patients undergoing Rotational Atherectomy with a small-sized burr. Scoring Balloon Angioplasty was proven to be an independent predictor for MACE with a significant low hazard ratio.

Methods

- Clinical events were evaluated of patients with PCI using rotational atherectomy (RA) for heavily calcified lesions
- Total of 307 patients received DES after RA were analyzed and divided into
 - ▶ Scoring Balloon Angioplasty (SBA) group (n=96)
 - ▶ Conventional balloon angioplasty (CBA) group (n=211)
- Subgroup:
 - ▶ 82 patients in SBA after small burr (SBA-SB)
 - ▶ 189 patients in CBA after small burr subgroup (CBA-SB)
- **Study endpoints:** MACE at 3 years, TVR, TLR

Results

	SBA-SB	CBA-SB	P-Value
MACE	12.2%	30.7%	0.001
TVR	6.1%	16.4%	0.022
TLR	3.7%	12.7%	0.022

PubMed – Click here
<https://pubmed.ncbi.nlm.nih.gov/31201059/>



Leopard-Crawl Technique

Efficacy of Lacrosse NSE using the "leopard-crawl" technique on severely calcified lesions

Conclusion

The bench model verified the dilatation effect of the NSE balloon, and the leopard-crawl technique was proven to be an effective strategy to cross the lesion. The design of the NSE balloon aids this lesion crossing technique and is therefore able to effectively create a controlled dilatation of the calcified lesion for successful lesion crossing.

Challenges

- Difficulties in stent delivery and under expansion are associated with calcified lesions
- Preparation of calcified lesions prior to stent implantation is important to facilitate stent delivery allowing homogenous stent expansion
- The NSE balloon catheter provides an effective scoring effect for pre-dilatation
- Interventions for severely calcified lesions are typically more challenging

Solution oriented method

- One method for overcoming the obstacles faced by difficult stent implantation or DCB angioplasty is the use of the "leopard-crawl" technique
- Low inflation pressure is used to create a wedge into the calcification to subsequently advance the catheter during balloon deflation so that catheter delivery across the stenosis is facilitated
- This technique is well suited for the NSE balloon due to its unique catheter design

PubMed – Click here
<https://pubmed.ncbi.nlm.nih.gov/24088433/>



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