Diamondback 360° Coronary Orbital Atherectomy System for Treating De Novo, Severely Calcified Lesions: ORBIT II 1-Year Results and Cost Comparison to a Sample of Medicare Hospital Claims

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Potential conflicts of interest

Speaker's name: Jeffrey Chambers

☑ I have the following potential conflicts of interest to report:

Consultant: Cardiovascular Systems, Inc.

Challenges with Calcified Coronary Lesions

Difficult to Treat:

- Prone to dissection during balloon angioplasty or pre-dilatation[1]
- Difficult to completely dilate[2]
- Can prevent adequate stent expansion[3]
- Preclude stent delivery to the desired location[4]

Result in poor clinical outcomes, including higher MACE and angiographic complications.

- Most stent trials excluded patients with moderate to severely calcified lesions
- Most BVS trials are excluding severe coronary calcification[5,6]

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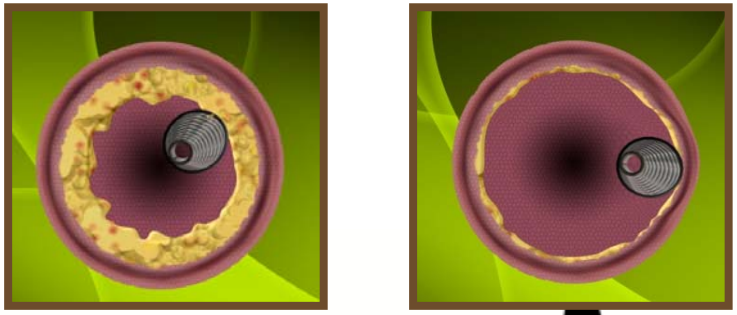
1 Fitzgerald PJ, et al.. Circulation. 1992:86;64-70.
2 Cavusoglu E, et al. Catheter Cardiovasc Interv. 2004;62:485-498.
3 Moussa I, et al. Circulation. 1997;96(1):128-136.
4 Gilutz H, et al. Cathet Cardiovasc Intervent. 2000;50:212-214.
5 Ullah M, et al. Cariovasc J. 2014;6:149-163.
6 ClinicalTrials.gov: NCT01923740, NCT01751906, NCT01977534, NCT01425281, NCT01583608

Orbital Technology for Calcified Coronary Arteries

- ***Differential orbital sanding***
  - Increased speed = Increased centrifugal force
  - Greater centrifugal force = Larger orbital diameter
- ***Continuous flow of blood and saline during orbit***
  - Minimizes thermal injury
  - Potentially decreases no-reflow and periprocedural cardiac enzyme elevation
- ***Different vessel diameters can be treated based on orbiting speed***

Crown will only sand the hard components of plaque

Soft components (plaque/tissue) flex away from crown



Actual results may vary depending on device-to-lumen ratio, run time and speed, and plaque morphology.

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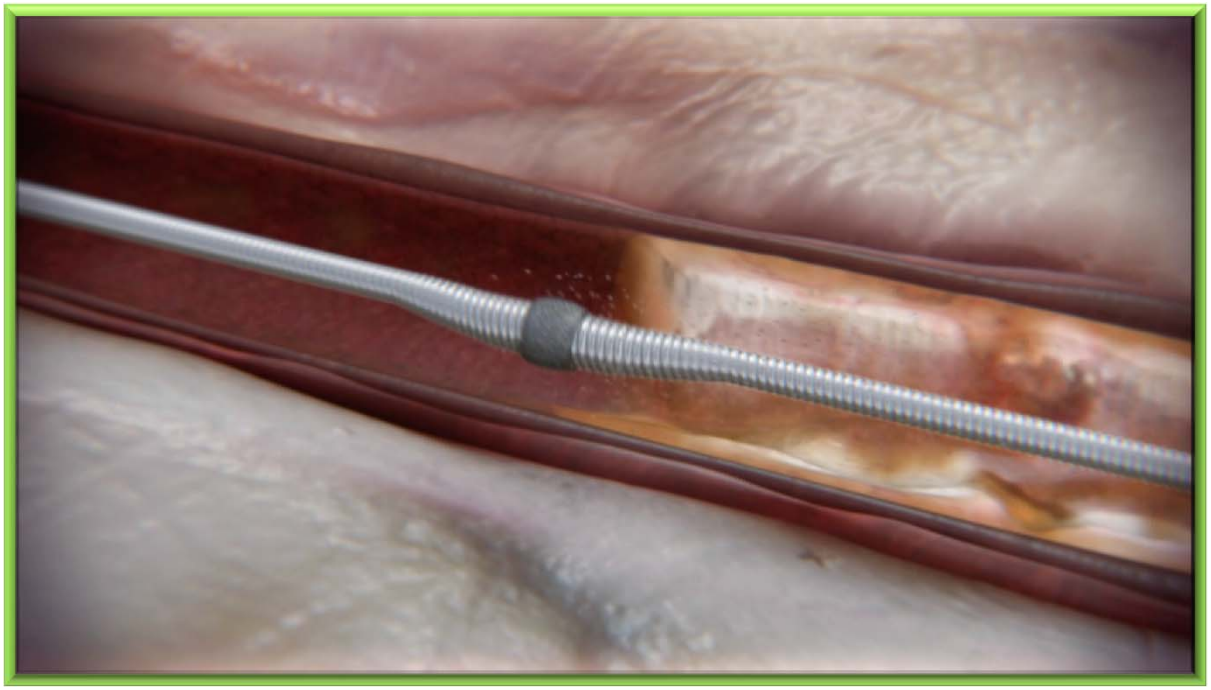
DIAMONDBACK 360° CORONARY ORBITAL ATHERECTOMY SYSTEM MOA



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ORBIT II STUDY DESIGN

To evaluate safety and efficacy of the coronary orbital atherectomy system (OAS) to prepare *de novo,* severely calcified coronary lesions for enabling stent placement

Prospective, multi-center trial

Single arm - FDA recommendation as there were no FDA-approved percutaneous treatments for patients with severely calcified lesions

- **443 patients enrolled in 49 U.S. sites**
- **1 year follow-up (N=433/440)**

Key Inclusion Criteria:

- The target lesion must have fluoroscopic or IVUS evidence of severe calcium:
  Presence of radiopacities noted without cardiac motion prior to contrast injection involving both sides of the arterial wall with calcification length of at least 15 mm and extend partially into the target lesion or presence of ≥ 270° of calcium at one cross section via IVUS
- The target vessel reference diameter ≥ 2.5 mm and ≤ 4.0 mm and lesion must not exceed 40 mm in length

Key Exclusion Criteria:

- Diagnosed with chronic renal failure (CR >2.5 mg/dl) unless under hemodialysis
- Evidence of current LVEF ≤25%
- More than 1 lesion requiring intervention unless the lesions are staged
- In-stent treatment
- Target lesion is an ostial location, bifurcation or has a ≥ 1.5 mm side branch
- Target lesion has thrombus or dissection
- Angio evidence of dissection prior to initiation of OAD

***Most previous stent Clinical Trials Excluded patients with moderate to severe calcified lesions**

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ORBIT II: DEMOGRAPHICS & LESION/VESSEL CHARACTERISTICS

Demographics	N=443
Male	64.6%
Age (yrs)	71.4
History of diabetes mellitus	**36.1%**
History of CABG	**14.7%**
History of dislipidemia	91.9%
History of hypertension	91.6%
Smoker (current or previous)	66.1%
Vessel & Lesion Characteristics	**N=440**
Mean pre-procedure target lesion length	18.9 mm
Mean pre-procedure minimum lumen diameter	0.5 mm
Mean pre-procedure percent stenosis	**84.4%**
Types of stents	**n=542**
BMS	**11.4%**
DES	88.2%

ORBIT II STUDY OBJECTIVE 1
EFFICACY

Demonstrate that the OAS successfully facilitates stent deployment in severely calcified coronary lesions

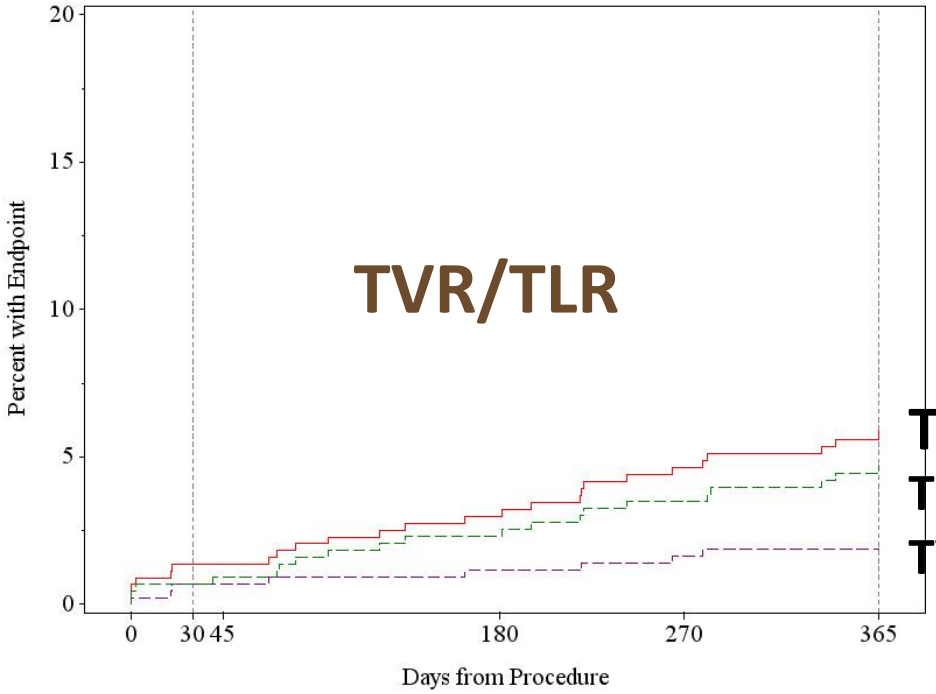
Successful Stent delivered:	**97.7%**
Less than 50% residual stenosis:	**98.6%**

ORBIT II STUDY OBJECTIVE 2
SAFETY

Demonstrate that the OAS is safe in treating *de novo,* severely calcified coronary lesions.

	30 Days	Change from 31 Days to 1 Year
Cardiac Death	0.2%	2.8%
TVR	1.4%	4.5%
MI	9.7%	0.0%
Q-Wave MI	0.9%	0.0%
Non-Q Wave MI (3X CK-MB)	8.8%	0.0%
MACE	10.4%	6.0%
MI (SCAI definition: 10X CK-MB)	2.0%	0.0%

ORBIT II: 1-Year Outcomes
TVR/TLR



TVR/TLR: 5.9%
TLR: 4.7%
TVR (non-TLR): 1.9%

PREDICTORS OF 1-YEAR MACE

Univariable Analysis of 1 year MACE	OR [95% CI]	P-value
Gender (male vs. female)	**1.04 [0.64, 1.69]**	**0.8813**
Age (yrs), one unit increase	**1.01 [0.98, 1.03]**	**0.6549**
Weight (lbs), one unit increase	**1.00 [0.99, 1.00]**	**0.5568**
Height (in), one unit increase	**1.01 [0.96, 1.07]**	**0.6725**
BMI, one unit increase	**0.98 [0.94, 1.02]**	**0.3134**
History of dyslipidemia	**0.77 [0.35, 1.68]**	**0.5115**
History of hypertension	**2.16 [0.68, 6.85]**	**0.1924**
History of stroke/TIA	**0.95 [0.41, 2.20]**	**0.9092**
History of MI	**0.99 [0.56, 1.72]**	**0.9587**
History of angina	**0.81 [0.47, 1.37]**	**0.4291**
History of CABG	**1.89 [1.10, 3.26]**	**0.0214**
LVEF (%), one unit increase	**0.99 [0.97, 1.02]**	**0.5229**
eGFR/renal function, one unit increase	**0.99 [0.99, 1.00]**	**0.2171**
OR>1: Increase in the odds of angiographic complication with an increase of one unit in predictor.		

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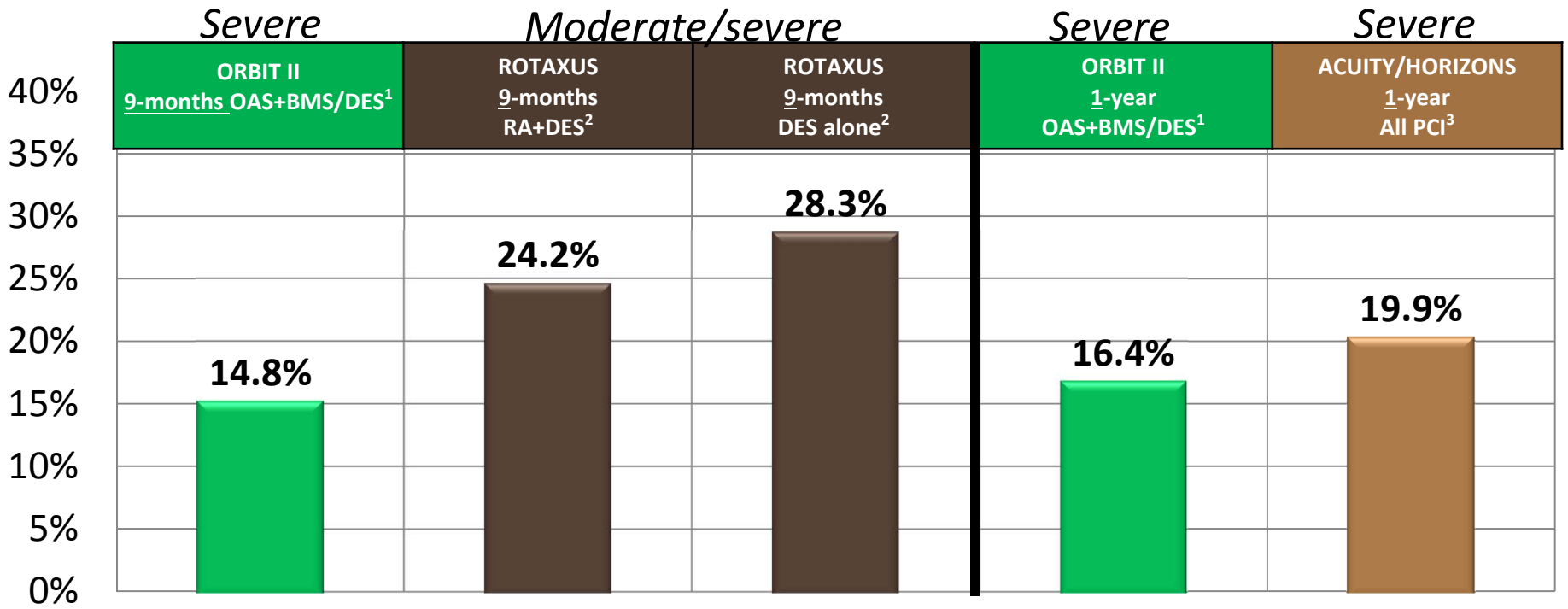
9-12 Months MACE in Patients with Severe Coronary Calcium



1. Chambers, 2014, Data on file at CSI, ORBIT II, 100% severely calcified lesions
2. Abdel-Wahab 2013, EuroPCR, ROTAXUS, ~50%/50% moderate/severely calcified lesions, and Abdel- Wahab, 2013 JACC:CI
3. Genereux, 2013, TCT, ACUITY/HORIZONS Subanalysis, 100% severely calcified lesions

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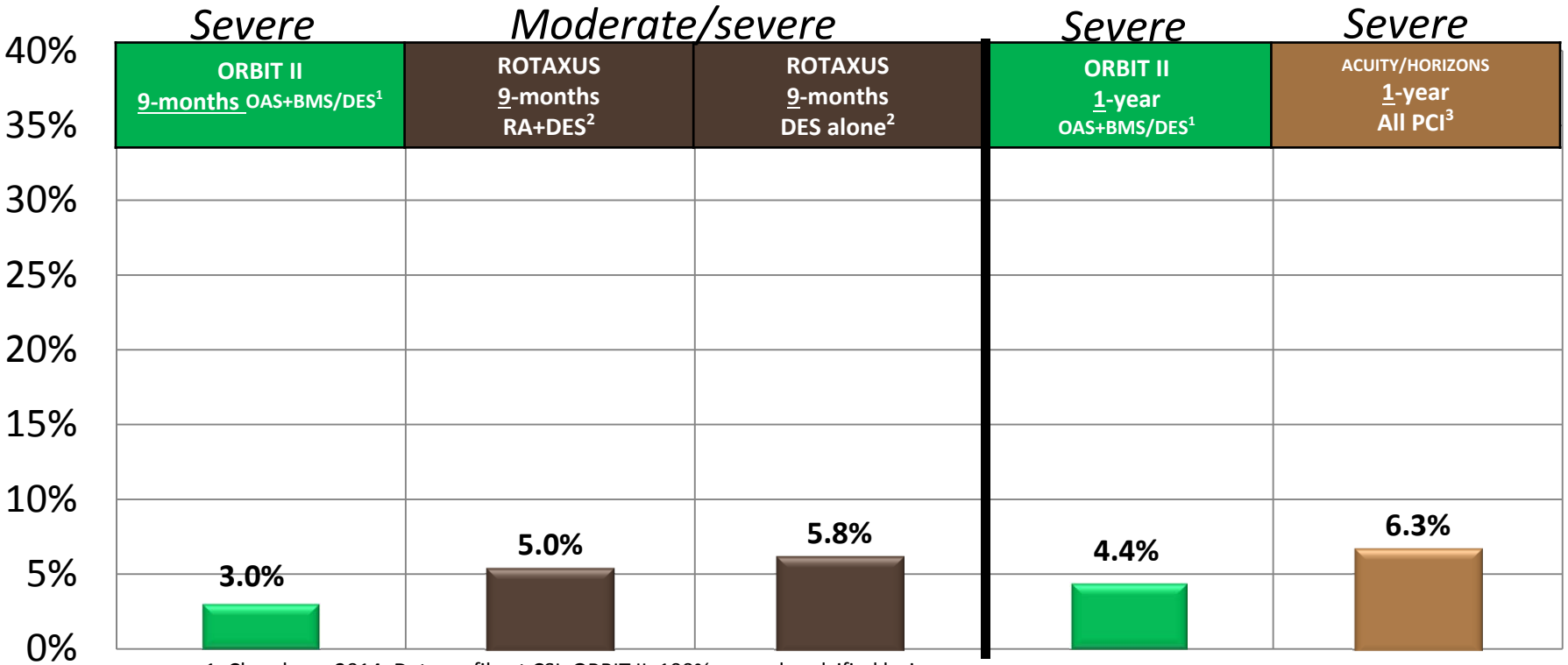
ALL-CAUSE MORTALITY



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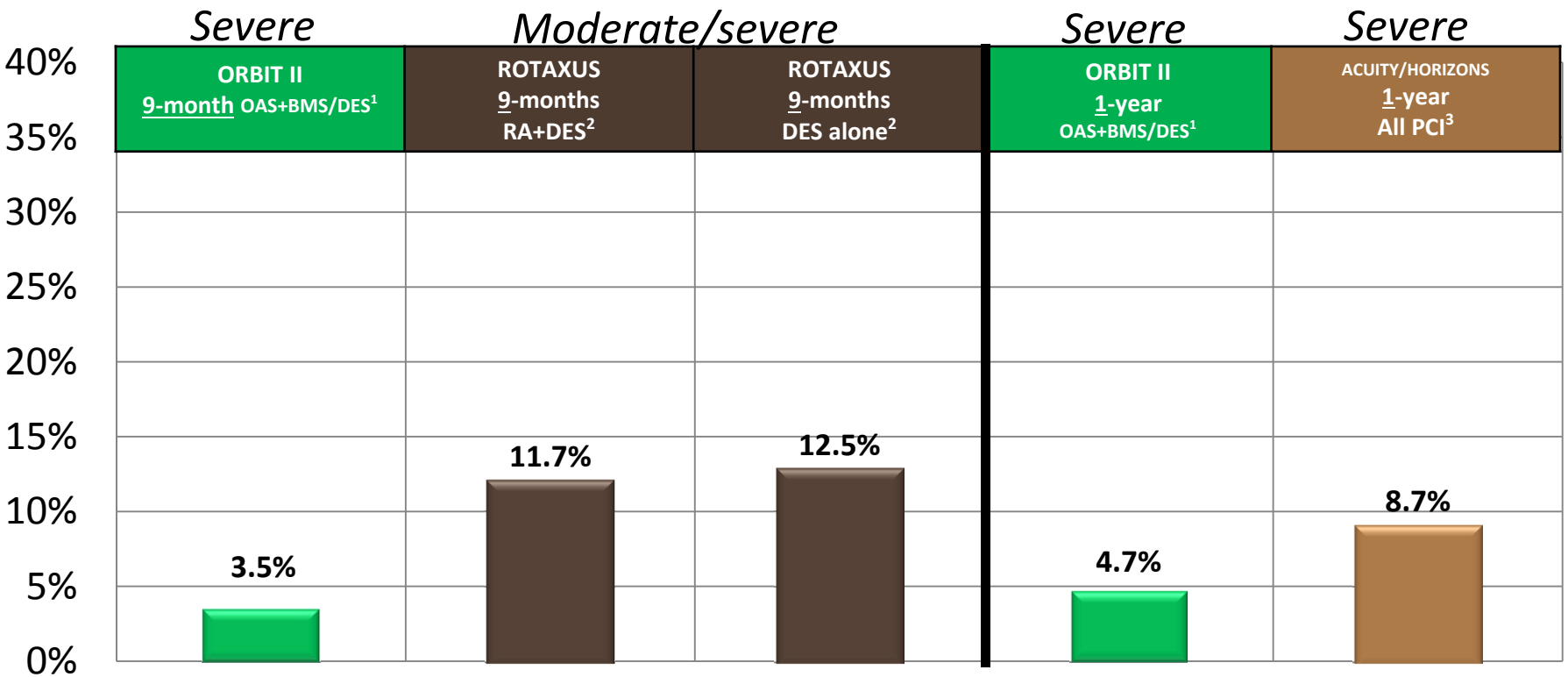
TARGET LESION REVASCULARIZATION



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ORBIT II ECONOMIC ANALYSIS: ASSESSING THE IMPACT ON MEDICAL CARE RESOURCE USE AND COST

- **Elderly (> age 64) ORBIT II patients (n=297)** were compared to a sample of elderly Medicare coronary stent patients with reported calcification.

- The **Medicare comparison** sample was drawn from the 100% Standard Analytical File for the period September 2011 through December 2012. The base case analysis was restricted to **calcification patients (n= 308)** from **hospitals (n=17)** reporting more than 10% of **stent patients with calcification** during this initial period.

- The ORBIT II and Medicare comparison sample were **comparable in terms of baseline characteristics**.

Variable/measure	ORBIT II (n=297)	Medicare (n=308)
Age (years)	74.6	75.0
Age distribution (%)		
65-74	52.6	60.1
75-84+	47.1	33.4
85+	0.3	6.5
Gender (% female)	37.0	34.7
Charlson Comorbidity Index (mean)	1.1	2.6
Percentage outpatient	48.2	55.8

Disclaimer: Example only based on national estimates. Actual reimbursement rates may vary. Estimated Medicare national average overhead.

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ORBIT II ECONOMIC ANALYSIS

Variable/measure	Medicare (n=308)	ORBIT II (n=297)	Difference/Savings
Mean stent procedure unadj. costs	$17,579	$14,381	$3,198
Median stent procedure unadj. costs	$14,604	$12,099	$2,505
Mean length of stay (outpat=0)	5.46	2.00	3.46
Median length of stay (outpat=0)	4.0	1.0	3.0
Mean length of stay (outpat=1)	2.97	2.00	0.97
Median length of stay (outpat=1)	1.0	1.0	0.0

- In the adjusted base case comparison, the ORBIT II patients experienced a shorter mean length of stay by 1 to 3 days depending on assumptions about outpatient stays. Considering both inpatient and outpatient procedures, **mean costs were lower by $3,198 (p=0.003)**

- However, after adjusting for differences in age, gender, and comorbidities mean costs were 17% (P<0.001) lower in ORBIT II patients compared to Medicare patients, or approximately $2,600-$2,700.

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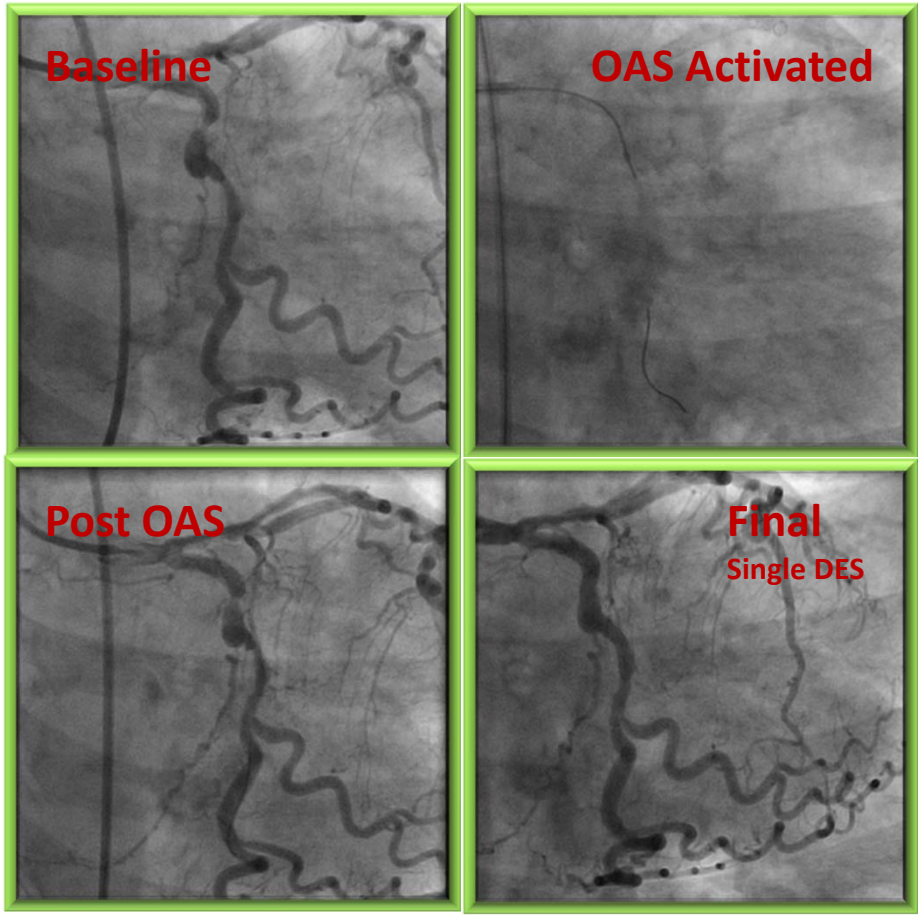
ORBIT II CASE EXAMPLE

- Female, 70 years old
- History of DM, smoker, dyslipidemia, HTN, EF 50%, Positive stress test
- LCX Lesion length 24 mm



- 1.25 mm Crown With Electric OAD
- Low Speed, 15 Seconds
- High Speed, 15 Seconds

Conclusions

- **The Diamondback 360 Coronary Orbital Atherectomy System is the first FDA approved novel technology to treat severely calcified lesions.**
- **At 1-year, the ORBIT II study reported a higher freedom from TVR/TLR rate (94.1%) compared to previously reported rates (81.7%-91.3%), though more severely calcified lesions were included in the ORBIT II study.[1,2]**
- **ORBIT II study also reported high freedom from cardiac death (1yr, 97.0%) and freedom from MACE (1yr, 83.6% and 31days-to-1yr, 94.0%) rates.**
- **Considering both inpatient and outpatient procedures, mean costs were lower by $3,198 (p=0.003) in ORBIT II patients compared to Medicare patients.**
- **Using the Diamondback 360 Coronary OAS as a lesion preparation tool prior to stent implantation offers patients with severely calcified coronary lesions a new treatment option with potential cost benefits.**

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