

360° Clinical Series

CSI Clinical Study Bibliography

CSI is leading the industry in providing physicians with the clinical and scientific data needed to support their treatment decisions and provide optimal patient outcomes. The results of the prospective data accumulated to date demonstrate predictable results with repeatable outcomes. They also confirm the clinical and economic relevance of orbital technology in calcific vessels large and small, and in difficult-to-treat disease.

In our ongoing commitment to setting the standard of care for the treatment of vascular disease, CSI will continue its research in the following areas:

- Device safety
- Procedure efficacy
- Long-term durability
- Hospital readmissions
- Economic feasibility/cost effectiveness

Consistent data from more than:



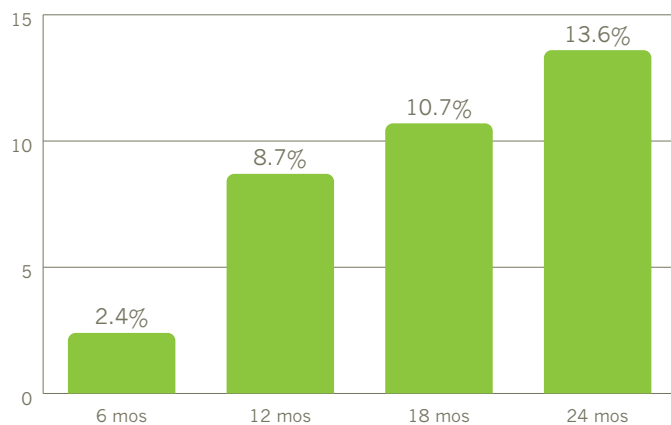
Peripheral IDE Study: Device Safety and Efficacy Established

Study Name	Study Overview	Objective/Endpoints	Key Results	Publication
OASIS Enrollment complete January 2007	<ul style="list-style-type: none"> • Prospective • Single-arm: DB360° • Multi-center (17 sites) • 17 investigators • 124 patients • 201 lesions 	<ul style="list-style-type: none"> • IDE study to gain FDA clearance <p>Primary efficacy</p> <ul style="list-style-type: none"> • Acute reduction in stenosis <p>Primary safety</p> <ul style="list-style-type: none"> • MAEs through 30 days 	<ul style="list-style-type: none"> • Primary endpoints met: <ul style="list-style-type: none"> – 59.4% reduction in stenosis – 4% device related MAEs • 85% lesions = BTK • Clinical improvements sustained at 6 months • ABI increased from 0.69 at baseline to 0.82 (p<0.0001) • 100% limb salvage • Positive symptomatic improvements shown in Rutherford classifications 	<ul style="list-style-type: none"> • Niazi, K. <i>Am J of Cardiology</i>. 2007. Vol. 100 (Suppl 8A), p.45L • Niazi, K. <i>Am J of Cardiology</i>. 2008. Vol. 102 (Suppl 8A), p.229i • Safian, R. <i>Catheterization and Cardiovascular Interventions</i>. 2009. 73:406-412
OASIS Long Term Enrollment complete October 2009	<ul style="list-style-type: none"> • Retrospective • Single-arm: DB360° • Multi-center (12 sites) • 12 investigators • 64 patients • 103 lesions 	<ul style="list-style-type: none"> • Long-term follow-up of OASIS patients • Objective: Review success of orbital treatment out to two years • Endpoints: revascularization, limb salvage rates and ABI 	<ul style="list-style-type: none"> • 2-year data shows durable outcomes in patients treated with the DB360° • TLR = 13.6% • TVR = 15.5% • 100% limb salvage rate maintained (no additional amputations) • Significantly improved ABI: <ul style="list-style-type: none"> – 0.61 at baseline to 0.90 at last followup (p<0.0001) 	<ul style="list-style-type: none"> • Weinstock, B. <i>Am J of Cardiology</i>. 2009. Vol. 104 (Suppl 6A), p.214D

Preservation of Medial Integrity is a *Critical* Predictor of Long-Term Durability:

Less Damage = Less Restenosis¹

Low Re-Intervention Rate with Orbital Treatment



¹ Costa. Molecular Basis of Restenosis and Drug-Eluting Stents. *Circ*. 2005; 111:2257-2273

Prospective, Randomized Studies: Challenging the Gold Standard

Study Name	Study Overview	Objective/Endpoints	Key Acute Results	Publication
COMPLIANCE 360° Enrollment complete May 2010 <i>Statistical significance achieved in DB360° arm (p< 0.0001)</i>	<ul style="list-style-type: none"> • Prospective • Randomized • DB360° vs. PTA • ATK (Fem-pop) • Multi-center (9 sites) • 9 investigators • 50 patients (25 each arm) • 37 lesions in DB360° arm • 28 lesions in PTA arm 	Primary <ul style="list-style-type: none"> • Restenosis at 6 and 12 months (measured by DUS) or TLR (including the need for bailout stenting) Secondary <ul style="list-style-type: none"> • Procedural success (≤30% residual without MAE) • Lesion success (≤30% residual without stenting) • Change in Rutherford and ABI • TLR/TVR 	<ul style="list-style-type: none"> • Greater number of lesions met angiographic endpoint (≤ 30% residual stenosis). 82.4% versus 17.9% in PTA arm (p< 0.0001) • Lower PTA pressure in DB360° arm. 3.8 atms versus 8.9 atms in PTA arm (p< 0.0001) • Fewer bail-out stents in DB360° arm. 5.9% versus 78.6% in PTA arm (p< 0.0001) 	<ul style="list-style-type: none"> • Dattilo, R. <i>JACC</i>. 2011;57:E1958 • 6- and 12-month results forthcoming in late 2011
CALCIUM 360° Enrollment complete April 2010 <i>Diamondback 360° outperformed PTA in CLI patients</i>	<ul style="list-style-type: none"> • Prospective • Randomized • DB360° vs. PTA • BTK (Pop, tibials) • Multi-center (8 sites) • 8 investigators • 50 patients (25 each arm) • 30 lesions in DB360° arm • 35 lesions in PTA arm 	Primary <ul style="list-style-type: none"> • Acute device success of ≤30% residual stenosis with no dissection grade C-F Secondary <ul style="list-style-type: none"> • Limb salvage • Bailout stenting • TLR/TVR • Major Adverse Events (MAEs) • Change in ABI, Rutherford 	<i>Primary endpoint success: 92.6% in DB360° arm vs. 78.8% in PTA arm</i> Low rate of procedural events DB360° vs PTA <ul style="list-style-type: none"> • Dissections: 3.3% vs. 11.4% • Perforation: 0 vs. 2.9% • Bail-out stent: 6.7% vs. 11.4% Six-month results favor orbital treatment (DB360° vs. PTA) <ul style="list-style-type: none"> • ABI: .81/.97 vs. .70/1.00 (Baseline / 6 months) • Mortality: 0 vs. 16% • Amputation: 8% vs. 12% (minor and major) • Re-intervention: 0 vs. 4% 	<ul style="list-style-type: none"> • Shammas, N. <i>JACC</i>. 2010. Vol. 56/13/Suppl B, p. B95 • Lam, R., et. al. Six-Month Outcomes of Prospective, Randomized CALCIUM 360° Study. <i>New Cardiovascular Horizons</i>, 2011. • 12-month results forthcoming in late 2011

Low Rate of Procedural Events

	OASIS Trial n = 201	CONFIRM I DIAMONDBACK n = 1,138	CONFIRM II PREDATOR n = 1,712	CALCIUM 360° n = 35
Dissection	2.5%	7.6%	7.8%	3.3%
Perforation	1.6%	0.5%	0.4%	0.0%
Bail-out stent due to dissection	2.5%	2.2%	2.5%	6.7%

CONFIRM 360° Series: Predictable, Repeatable Results in Real-World Usage

Study Name	Study Overview	Objective/Endpoints	Key Results	Publication
CONFIRM I DIAMONDBACK Enrollment complete March 2010	<ul style="list-style-type: none"> • Prospective, acute registry • Multi-center (57 sites) • 84 investigators • 728 patients • 1,138 lesions • All patients treated with DB360° included 	<ul style="list-style-type: none"> • Demonstrate the value of changing lesion compliance with the Diamondback 360° • Validate DB360° safety and efficacy results • Acute procedural success 	<ul style="list-style-type: none"> • Challenging patients enrolled (36% renal disease, 61% diabetic) • Challenging lesions treated (87% calcified, 77 mm average lesion length) • Entire leg treated (36% BTK, 46.5% ATK, 17.5% Pop) • Predictable, reproducible efficacy. Stenosis 88% pre-DB360°, 10% residual post DB360°, and low-pressure PTA if needed • Predictable, reproducible, extremely low rate of procedural events • 0.5% perforations • 1.2% abrupt closure • 0.7% macro-embolization • Low bail-out stent rate due to dissection: 2.2% 	<ul style="list-style-type: none"> • Dattilo, R. <i>JACC</i>. 2010. Vol. 56/13/ Suppl B, p. B95
CONFIRM II PREDATOR Enrollment complete December 2010	<ul style="list-style-type: none"> • Prospective, acute registry • Multi-center (122 sites) • 153 investigators • 1,127 patients • 1,712 lesions • All patients treated with Predator 360° included 	<ul style="list-style-type: none"> • Validate acute safety and efficacy results of the Predator 360° • Acute procedural success 	Preliminary real-world results demonstrate: <ul style="list-style-type: none"> • Typical PAD population demographics • CLI and claudicants treated • 82% lesions moderately-severely calcified • 73 mm average lesion length • Entire leg treated (31% BTK, 52% ATK, 17% Pop) • Low rate of procedural events (0.4% perforations, 3.9% slow flow, 1.4% abrupt closure, 2.1% macro-embolization) • Low bail-out stent rate due to dissection: 2.5% 	<ul style="list-style-type: none"> • Publication underway
CONFIRM III OUTFLOW Currently enrolling	<ul style="list-style-type: none"> • Prospective, acute registry • Multi-center (up to 200 sites) • Up to 1,200 patients • No inclusion or exclusion criteria • Consecutive patients treated with any current version of DB360° 	<ul style="list-style-type: none"> • Emphasize data collection of inflow + outflow treatment <ul style="list-style-type: none"> – Treat the leg as a system – Restore flow to runoff (tibial) vessels – Confirm performance of orbital PAD treatment in modifying resistant plaque in the entire leg – Low-pressure adjunctive PTA – Low rate of dissections and bail-out stenting anticipated • Contribute descriptive procedural data to large and growing database 	<ul style="list-style-type: none"> • Study underway 	<ul style="list-style-type: none"> • Study underway

Physician-Initiated Studies

Study Name	Study Overview	Objective/Endpoints	Key Results	Publication
Amputation Prevention (Mustapha) Enrollment complete January 2010	<ul style="list-style-type: none"> Retrospective Single arm: DB360° Single center 32 patients 	<ul style="list-style-type: none"> Restore flow in patients previously scheduled for amputation Included patients with occlusions in all three runoff vessels to foot 	<ul style="list-style-type: none"> All patients left cath lab with palpable or Doppler pulse Patency maintained in 100% of patients that returned for staged procedure within 6 weeks Limbs saved in all 32 patients 	<ul style="list-style-type: none"> Mustapha, J. <i>ISET</i>. 2010
DB360° vs PTA in Infrapopliteal (Patlola) Enrollment complete October 2009	<ul style="list-style-type: none"> Prospective Randomized DB360° vs. PTA Single center 150 patients (80 DB360° arm, 70 PTA arm) 	<ul style="list-style-type: none"> Compare orbital PAD treatment versus balloon therapy in infrapopliteal lesions 	<ul style="list-style-type: none"> Higher rate of bailout stenting with PTA (5% in DB360° arm vs. 45% in PTA arm) Higher rate of restenosis with PTA (15% in DB360° arm vs. 62.5 in PTA arm) 	<ul style="list-style-type: none"> Patlola, et.al. <i>Am J of Cardiology</i>. 2009. Vol. 104 (Suppl 6A), p. 24D-25D
Predator 360° (Makam) Single-Center, Long-Term Results Enrollment complete May 2011	<ul style="list-style-type: none"> Prospective Single arm: DB360° Single center 46 patients 57 lesions 	<ul style="list-style-type: none"> Evaluate the long-term durability of plaque modification with the next-generation Diamondback 360° Predator PAD System 	<ul style="list-style-type: none"> The Predator modified lesion compliance in resistant plaques as demonstrated by the need for a low-pressure adjunctive balloon (5.3 atm for an average of 2.3 minutes) Bail-out stenting was not needed in this challenging patient population 1 dissection reported 5 patients (8.8%) returned for retreatment of the target lesion within 12-months 	<ul style="list-style-type: none"> Makam, P. Guedes, R. Use of the Predator 360° Orbital PAD System in a High Volume Clinical Practice. <i>New Cardiovascular Horizons</i>. 2011.

Safely Restores Flow in Challenging Patients*

Long Lesions
69 mm
 (mean)

Small Vessels
40%

Heavily Calcified Arteries
86%

*Compilation of CSI Clinical Results (Peripheral and Coronary)

Prospective Safety Study

Study Name	Study Overview	Objective/Endpoints	Key Results	Publication
CLEAR 360° Enrollment complete March 2009	<ul style="list-style-type: none"> • Prospective • Single-arm: DB360° • Multi-center (4 sites) • 4 investigators • 31 patients • 42 lesions 	<ul style="list-style-type: none"> • Demonstrate safety of orbital treatment <p>Primary endpoint:</p> <ul style="list-style-type: none"> • Clinically significant hemolysis defined as: <ol style="list-style-type: none"> 1) presence of laboratory evidence of hemolysis AND 2) presence of any significant clinical event post treatment 	<ul style="list-style-type: none"> • Safety of orbital PAD treatment confirmed • Clinically significant hemolysis not reached in any subject 	<ul style="list-style-type: none"> • Mody, K. <i>JACC</i>. 2010. Vol. 56/13/Suppl B, p. B95 • Staniloae, C. <i>J Endovasc Ther</i>. 2011;18:57-63

Prospective European Safety and Efficacy Study

Study Name	Study Overview	Objective/Endpoints	Key Results	Publication
PAD II Enrollment complete January 2007	<ul style="list-style-type: none"> • Prospective • Single-arm: DB360° • Multi-center (7 sites) • 7 investigators • 66 patients • 86 lesions 	<ul style="list-style-type: none"> • European feasibility study • Confirm safety and efficacy of DB360° in additional patients prior to US market approval <p>Primary safety endpoint:</p> <ul style="list-style-type: none"> • Procedural success: <30% residual stenosis with DB360° + adjunct therapy 	<ul style="list-style-type: none"> • DB360° is safe and effective for treating PAD • 90.7% achieved <30% residual stenosis • 55% reduction in stenosis with DB360° • Significantly improved ABI (0.61 at baseline to 0.84 at last followup, p<0.0001) 	<ul style="list-style-type: none"> • CE mark for peripheral indication received • Scheinert, D. <i>Am J of Cardiology</i>. 2008. Vol. 102 (Suppl 8A), p. 230I

Coronary Studies: The Future of Coronary Intervention

Study Name	Study Overview	Objective/Endpoints	Key Results	Publication
ORBIT I* Enrollment complete July 2008	<ul style="list-style-type: none"> • Prospective • Single arm: DB360° • Multi-center (2 sites in India) • 4 investigators • 50 patients • 50 lesions 	<ul style="list-style-type: none"> • Coronary safety and efficacy feasibility study <p>Primary endpoint:</p> <ul style="list-style-type: none"> • Composite of target vessel failure either during treatment or at followup 	<ul style="list-style-type: none"> • Orbital atherectomy can be safely used in calcified coronary lesions with a low rate of complications <ul style="list-style-type: none"> – Conclusions contributed to FDA approval for ORBIT II study in US – 30-day MACE (6%) – Cardiac death (0%) – Non Q-wave MI (6%) – Q-wave MI (0%) 	<ul style="list-style-type: none"> • Parikh. <i>JACC</i>. 2009. Vol. 53, No. 10, Suppl A, p. A20
ORBIT II* Currently enrolling 2011	<ul style="list-style-type: none"> • Prospective • Multi-center (up to 50 US sites) • 429 patients 	<ul style="list-style-type: none"> • Evaluate safety and performance of orbital coronary system in de novo, severely calcified lesions to gain FDA clearance <p>Primary safety endpoint:</p> <ul style="list-style-type: none"> • 30-day MACE <p>Primary efficacy endpoint:</p> <ul style="list-style-type: none"> • Procedural success in facilitating stent delivery with final residual stenosis of <50% and no in-hospital MACE 	<ul style="list-style-type: none"> • Study underway 	<ul style="list-style-type: none"> • Study underway

*The Diamondback 360° Coronary System is under clinical investigation and is currently not commercially available in the U.S.