

# ***The RESTOR Study***

**RESTOR: R stent Efficacy and Safety Trial by Orbus  
Six Month Angiographic and Clinical Follow-up Results**



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## **RESTOR: R stent Efficacy and Safety Trial by Orbus Six Month Angiographic and Clinical Follow-up Results**

Orbus Medical Technologies (Orbus) has concluded its first Quantitative Coronary Angiography (QCA) clinical registry of the R stent - the "R stent Efficacy and Safety Trial by ORbus" or the RESTOR study. The results of the RESTOR study have shown that the R stent premounted on the Talos rapid exchange PTCA delivery system is both safe and effective for the treatment of de novo lesions in native coronary vessels. This study was conducted at two world renowned clinical sites in the field of Percutaneous Coronary Intervention (PCI), both of which are located in the Netherlands: The Heart Center Rotterdam and the Amphia Hospital Breda. The management of this study and the evaluation of the data was conducted by Cardialysis, B.V., an independent Clinical Research Organization (CRO) and QCA core laboratory.

RESTOR was designed to assess the clinical efficacy of the R stent by measuring both clinical and angiographic parameters of the stent's performance for a period of six months (210 days). The primary endpoint of this study was MACE (Major Adverse Cardiac Events – cardiac death, myocardial infarction, CABG, and TLR- target lesion revascularization). The secondary endpoints of RESTOR included post-procedural in-stent percent diameter stenosis, angiographic success, percentage DS, MLD and restenosis rate at six months, and major bleeding and/or major vascular complications at hospital discharge - 30 days and six months.

This study encompassed a two-center, prospective, non-randomized registry enrolling 121 patients with de novo lesions up to 25 mm in length that have been treated with an R stent in native coronary arteries ranging from 2.75 – 4.0 mm in diameter. Patient enrollment was initiated in April 2000, and completed in December 2000. The stents used were 3.0, 3.5, and 4.0 mm in diameter and ranged in length from 9 to 28 mm. In accordance with the protocol, lesions were predilated with an angioplasty balloon prior to stent implantation.

The patients enrolled in the RESTOR study were 75.2% male and had an average age of 58.8 years. Of this population, 62.5% presented with CCS III or IV angina, and 39.7% had previously experienced a myocardial infarction prior to the intervention. The index lesions had an average reference diameter of 2.84mm and a minimal lumen diameter of 0.98mm. In addition, 64% of all lesions treated were Type B2 or C.

The results of this study are very comparable with the best data produced to date on other coronary stents (see Table 1). Angiographic success (<30% in-stent diameter stenosis by QCA) was achieved in 100% of the cases attempted with an R stent. While procedural success (angiographic success + freedom of MACE prior to discharge) was achieved in 97.5% of all cases attempted with the study device. These parameters attest to the deliverability, conformability, and scaffolding provided by the R stent upon implantation.



**Table 1: MACE/ TLR Study Comparison**

Study Name	MACE (up to 30 days)	MACE (up to 210 days)	TLR (up to 210 days)
Ravel Control	Not published	27.1%	23 %
Benestent I	Not published	20.1%	10 %
ROSE	4.2%	19.2%	10 %
DUET	5.1%	17.2%	14 %
SOPHOS	4.0%	16.0%	9 %
Finess II	1.9%	13.5%	10 %
Benestent II	3.9%	12.8%	8 %
Musik	7.0%	12.1%	7 %
RESTOR	3.3%	12.4%	10 %

The 30 day MACE rate of this study was 3.3% (all of these events occurred prior to patient discharge based on non target lesion or procedural complications not involving the R stent), while the primary endpoint of six month MACE was 12.4%. This includes two cases of CABG which were due to one index and one non-index lesions and one non-cardiac death. Within the 210 days only four MI's were reported - all of which were non-Q wave.

As a result of the range of stent lengths evaluated during this study, restenosis could not be statistically evaluated and thus was not an endpoint of this registry. However, based on the 104 patients who participated in the six month angiographic follow-up, a binary restenosis rate of 20% was calculated by the core laboratory after QCA analysis. In addition, the MLD at six months was determined to be 1.85mm and a late loss index of 0.51 was found within the stented population. These values compare quite favorably to other clinical studies conducted by Cardialysis on other coronary stents based on the reference diameter (RD) and lengths of stents implanted (see Tables 2 & 3).

**Table 2: QCA Comparison**

Study Name	RD (mm)	MLD pre (mm)	MLD post (mm)	MLD @ follow-up	Loss Index	Restenosis Rate (%)
Ravel Control	2.64	1.06	2.55	1.85	0.51	26
RESTOR	2.84	0.98	2.64	1.85	0.51	20
ROSE	2.88	0.97	2.52	1.86	0.47	21
Benestent II	2.90	1.08	2.69	1.89	0.80	16
DUET	2.91	1.00	2.61	1.87	0.48	16
SOPHOS	2.94	1.00	2.69	1.91	0.49	18
Benestent I	2.96	1.07	2.48	1.82	0.65	22
Finess II	2.96	1.04	2.67	1.89	0.50	17
Musik	3.04	1.13	2.90	2.12	0.45	10

The data on the R stent collected in the RESTOR study are encouraging when compared to other clinical studies using competitive coronary stent designs, despite the longer lesions and smaller reference diameters of the patients treated. The safety and efficacy of the R stent for the treatment of single de novo coronary lesions in patients with angina pectoris at 210 days has clearly been demonstrated by the high event-free (MACE) survival, angiographic, and procedural success rates.



**TABLE 3: Comparable Cardialysis Monitored Coronary Stent Studies**

Study Name	Device	Sponsor	Lengths Utilized	Comments
Ravel Control	BX Velocity	J&J	18mm	All lesions predilated prior to stent implantation
Benestent I	Palmaz-Schatz	J&J	15mm	262 patients treated with stents (randomized trial N=520 balloon vs. stent)
ROSE	beStent	Medtronic	15mm	120 patients enrolled
DUET	Multilink	Guidant	8, 13, 18, & 28 mm	More than 90% of the stents implanted were $\leq$ to 18mm in length
SOPHOS	BiodivYsio	Biocompatibles	15 mm	200 patients treated with 15mm phosphorylcholine-coated stent with 6 month angiographic follow-up
Finess II	NIR	Boston Scientific	9 & 16mm	156 patients enrolled
Benestent II	Palmaz-Schatz	J&J	10, 15 & 20mm	An open, randomized, controlled, multi-center clinical trial with a 12 months follow-up period including 824 patients
Musik	Palmaz-Schatz	J&J	15mm	IVUS guided stent restenosis study
RESTOR	R stent on Talos	Orbus Medical Technologies	9, 13, 18, 23 & 28 mm	67% of stents were $\geq$ 18 mm

Our warmest thanks to the investigators and the research nurses for their excellent work, attention to details, and superb treatment of the patients in this study. We are looking forward to collaborating with you in our future clinical programs.



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