

# Sustained Blood Pressure Reduction by Baroreflex Hypertension Therapy with a Chronically Implanted System:

## 3 Year Data from the Rheos DEBuT-HT Study in Patients with Resistant Hypertension

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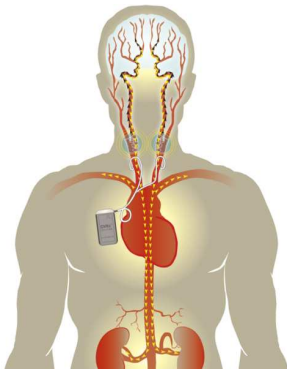
### Introduction

The Device Based Therapy of Hypertension (DEBuT-HT) study uses an implantable pulse generator and electrodes implanted around the carotid sinus to electrically activate the carotid baroreflex (Rheos® System). The long-term ( $\geq 3$  year) blood pressure (BP) data in a cohort of patients who underwent chronic Rheos therapy were analysed to assess the extent of sustained pressure reduction.

### Methods

All subjects had drug-resistant hypertension with a systolic BP  $>160$  mmHg and were on a stable medication regimen of 3+ drugs which included a diuretic. A total of 45 subjects were implanted with the Rheos System, which remained turned off for 1 month. The system was then activated throughout follow-up. A total of 17 subjects currently have paired data through the 3 year time point.

The Rheos System is designed to electrically activate the carotid baroreceptors, the body's natural BP sensors. When the baroreceptors are activated, signals are sent through neural pathways to the brain and interpreted as a rise in BP. The brain works to counteract this perceived rise in BP by sending signals to the heart, blood vessels and kidneys to reduce BP.



BP and heart rate (HR) readings were taken pre-implant and at least yearly through 3 years of active therapy. The efficacy endpoint was defined as a decrease of at least 10 mmHg in office systolic BP.

### Results

**Table 1** presents subject characteristics. Prior co-morbidities include MI (18%), stroke (18%), diabetes (29%), coronary artery disease (12%), dyslipidemia (59%), and diastolic dysfunction (41%).

**Table 1. Subject Characteristics (N=17)**

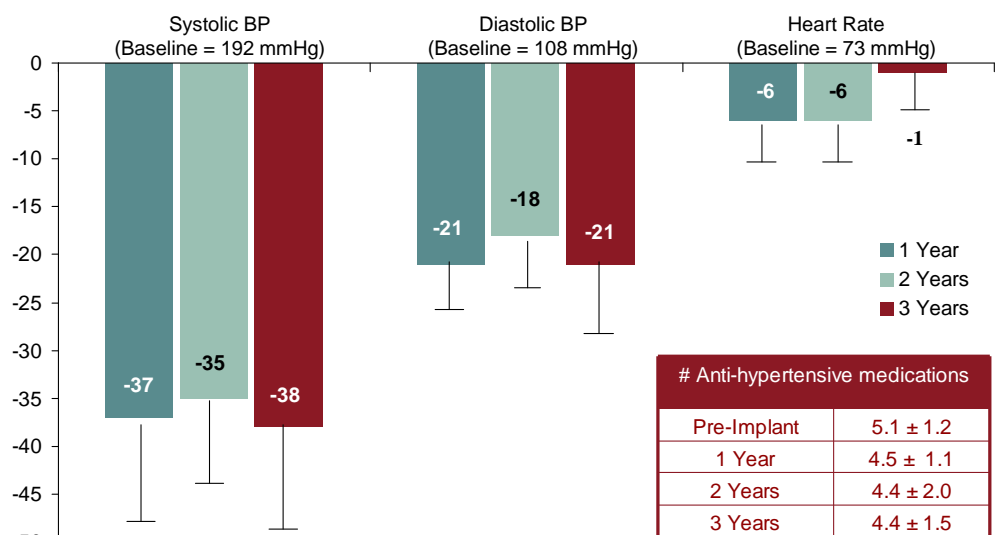
Gender (% male)	59%
Race (% Caucasian)	100%
Age (mean years $\pm$ SD)	54.4 $\pm$ 7.9
BMI (mean kg/m <sup>2</sup> $\pm$ SD)	30.7 $\pm$ 6.1
# Anti-hypertensive Meds (mean $\pm$ SD)	5.1 $\pm$ 1.2
Office Systolic BP (mean mmHg $\pm$ SD)	191.5 $\pm$ 36.4
Office Diastolic BP (mean mmHg $\pm$ SD)	108.3 $\pm$ 20.3
Office Heart Rate (mean mmHg $\pm$ SD)	72.8 $\pm$ 12.7

**Figure 1** shows office BP reductions attained at 1 year are sustained through 3 years. The reductions at 3 years were 38/21 mmHg. All p-values for BP were  $<0.01$ . Seventy-six percent of subjects attained a drop in systolic BP of at least 10 mmHg. The average number of antihypertensive medications decreased during first year of follow-up and then stabilized.

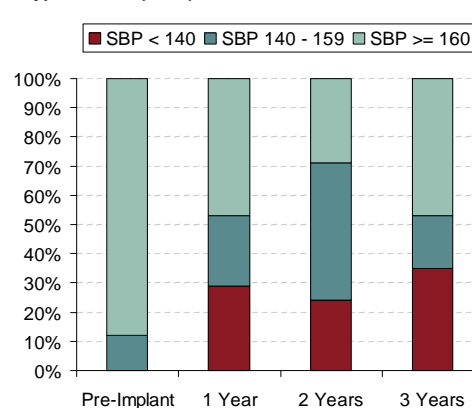
**Figure 2** shows 30% of subjects achieve a systolic BP  $<140$  mmHg within 1 year of implant. This percentage is continued with continued therapy.

**Figure 3** shows 24-hour ambulatory systolic BP reductions at 1 year are increased at 2 years. Data for only 8 subjects are available. The reduction at 2 years was 24 mmHg ( $p < 0.01$ ).

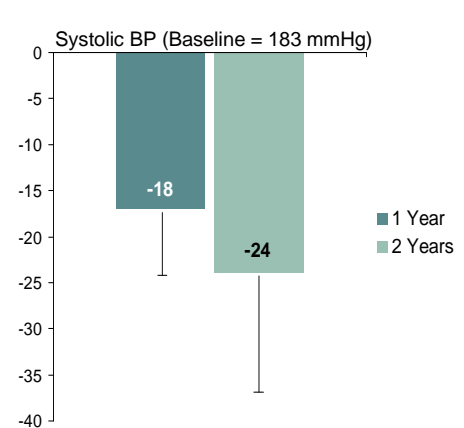
**Figure 1. Reduction in office BP and HR (N=17)**



**Figure 2. Percentage of Patients at Different Stages of Hypertension (N=17)**



**Figure 3. Reduction in ambulatory BP (N=8)**



### Conclusions

The Rheos System is a novel implantable device for the chronic treatment of resistant hypertension. These 3-year results indicate that the response to the Rheos System therapy is sustained and support a device-based approach to blood pressure control as a therapeutic option in patients with resistant hypertension.