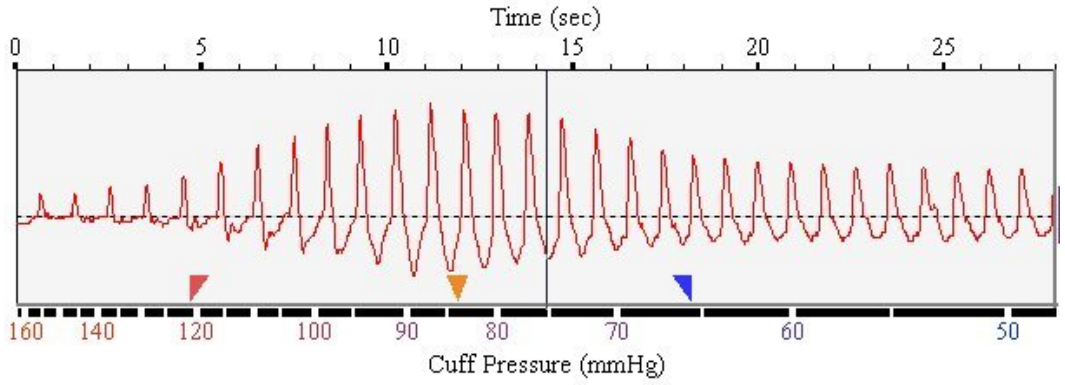
DynaPulse central aortic blood pressure and waveform:

Validation with catheterization - The Pulse Dynamic noninvasive method

Studied at UCSD Medical Center Cath-Lab with results published at American Journal of Cardiology, 1997;80:323-330 by TJ Brinton, et.al., "Development and Validation of a Noninvasive Method to Determine Arterial Pressure and Vascular Compliance", described the DynaPulse method and the comparison of blood pressure and waveform at central aorta area measured to the measurement of left-sided catheterization. Data obtained from 36 subjects, comparing DynaPulse vs Catheterization, showed good agreement for systolic (146+/-4 vs 145+/-5 mmHg), diastolic (80+/-2 vs 77+/-2 mmHg) and MAP (100+/-3 vs 100+/-3 mmHg) with correlation coefficients (r = 0.94, 0.91 and 0.95) respectively. This document further describes the fundamental physics of Pulse Dynamics method and how DynaPulse determines central aortic blood pressure value and waveform, and comparing to catheterization data.

DynaPulse non-invasive method analyzes the complicated cuff-pressure dependent brachial artery pulse waveform at three areas of cuff-pressure, the **supra-systolic** area (above systolic of ~121 mmHg), the **sub-diastolic** area (below diastolic of ~66 mmHg), and the area between systolic and diastolic, the blood pressure measurement, or blood flow-dynamic**,** area, as illustrated in Fig. 1. At supra-systolic, where cuff pressure exceeds the systolic and occluded the brachial artery, therefore cuff can sense up to the aortic point (T-sensing), and at sub-diastolic, where full blood flow through a "straight tube" artery section is assumed, and pulse is sensed by the cuff (S-sensing).

Fig. 1 The DynaPulse (Pulse Dynamics) waveform



Showing below, in Fig. 2 is the conceptual illustration of DynaPulse model, and compared to other methods, catheter, ultrasound and tonameter. Fig. 3 showed the comparison of DynaPulse supra-systolic and sub-diastolic waveforms to simultaneously recorded catheterization pressure pulses. Where supra-systolic waveform resembles the cath-waveform at up-stroke area, and the sub-diastolic resembles the down stroke area. Fig. 4 showed the combined DynaPulse supra-systolic and sub-diastolic waveform and compared to the central aortic pressure waveform obtained from catheterization.

Fig. 2 The conceptual physical model of Pulse Dynamic method

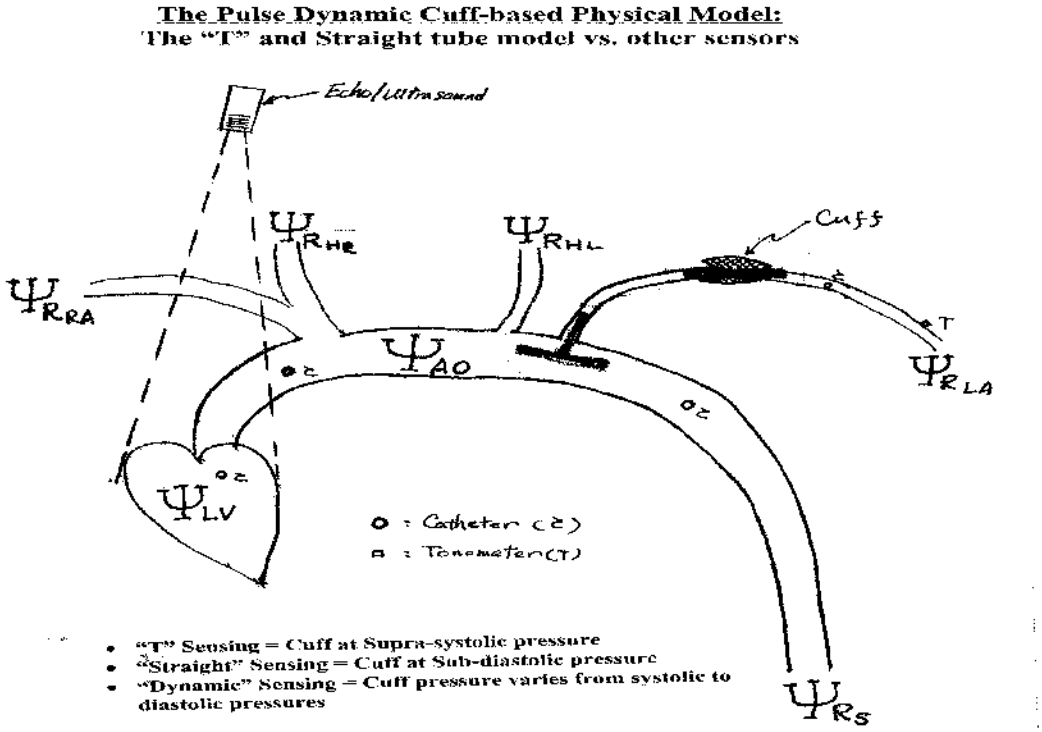
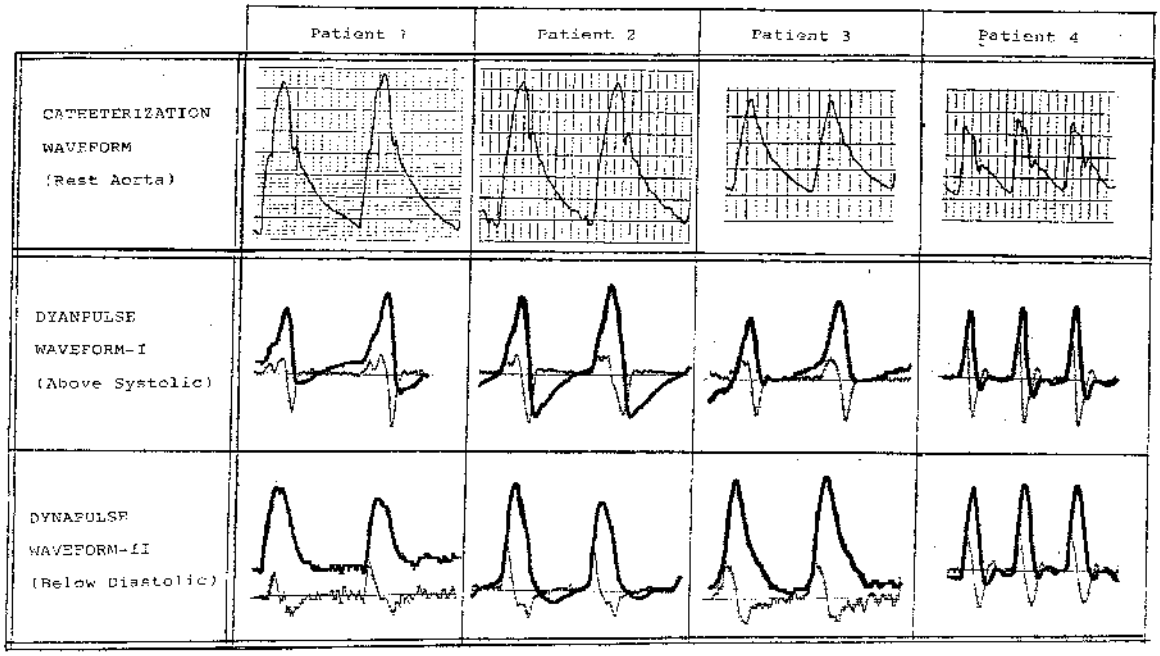


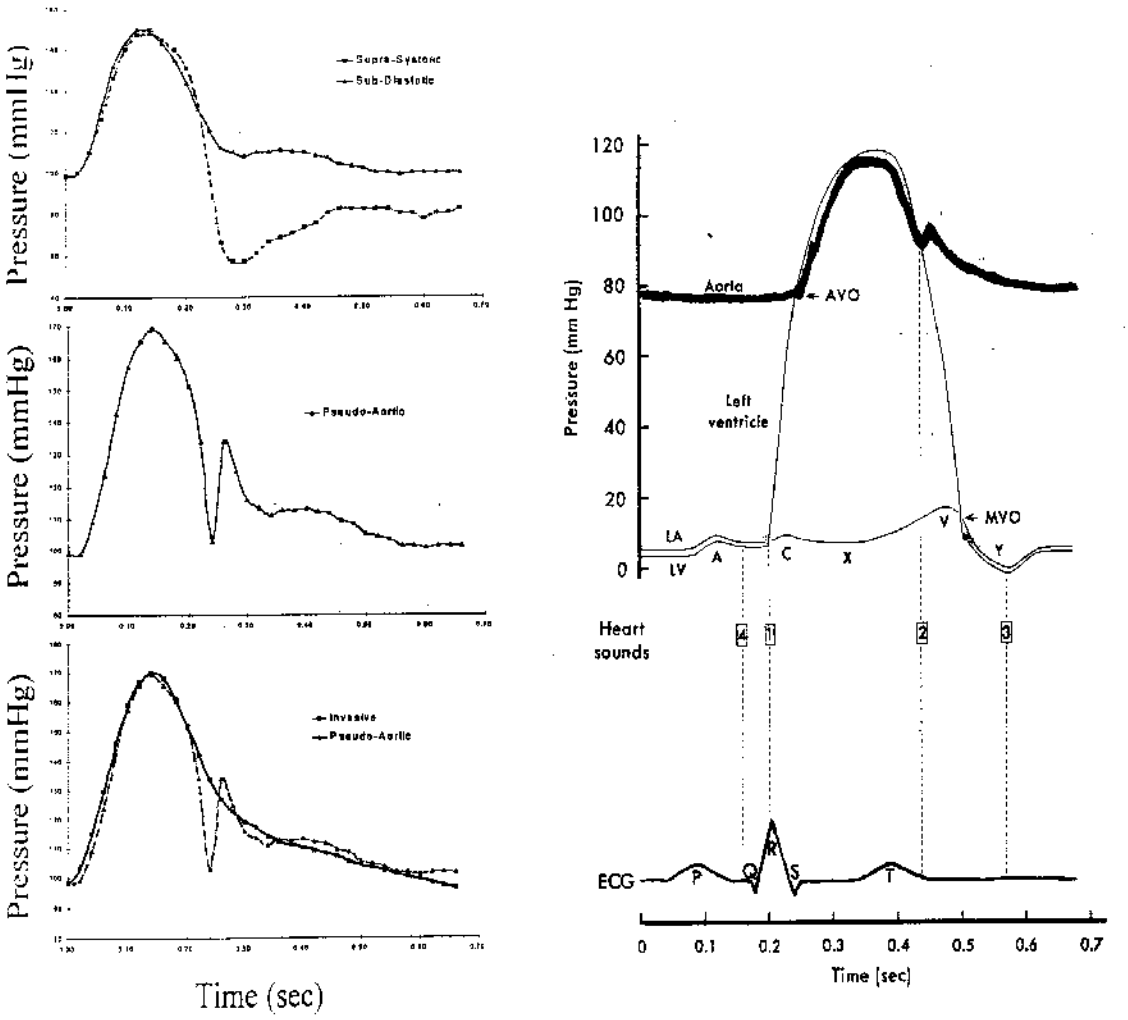
Fig. 3 DynaPulse waveforms vs. catheterization waveform



Note: Typical aortic sclerosis/stenosis with cath-waveform showed, at up-stroke, negative dP/dt or "augmentation", in Patient 1 and 2, which also shown in DynaPulse Waveform-I (above systolic).

Fig. 4

Right: The concept of Aortic-to-LV pressure contour fitting for transformation
Left: Comparison of a convoluted DynaPulse pulse to a Cath-aortic waveform



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Note to DynaPulse and DAC users: In addition to the above described central aortic blood pressures (end-systolic, end-diastolic and MAP) that measured by DynaPulse, DynaPulse 5200A/Pathway and DAC report (Sample report attached below) also calculate and provide the equivalent auscultatory (K1/K4) systolic/diastolic blood pressure values.

By SS Chio 031308

(Sample)

DynaPulse Hemodynamic Profiling Report:

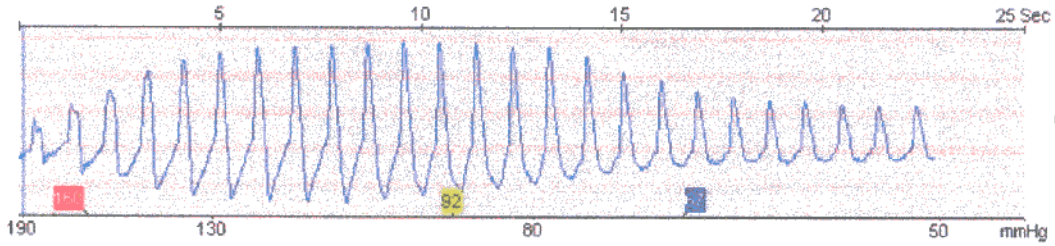
Hemodynamic Report

First ◀ Previous **Measurement Time: 1/26/2008 15:53** Next ▶ Last

SSC Trial - Physician Name: n/a n/a

Patient ID:
Patient Name:
Birthdate | Sex: 2/22/1945 | Male
Measurement Time: 1/26/2008 15:53
Body Mass Index (BMI): 24.2

Auscultatory eq. Sys.(K1)/Dia.(K4)
153 / 75 mmHg
HR: 65 bpm



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The red, yellow and blue markers are for End Sys., MAP and End Dia.

		[Normal Range(Male)*]
CENTRAL BP PARAMETERS		
End Systolic (mmHg)	160	[105 - 143]
End Diastolic (mmHg)	67	[54 - 83]
MAP (mmHg)	92	[70 - 101]
PP (mmHg)	93	[39 - 72]
CARDIAC PARAMETERS		
LV Ejection Time (sec)	0.295	[0.207 - 0.388]
LV dP/dt Max (mmHg/s)	1,568	[847 - 1506]
LV Contractility (1/s)	16.16	[12.39 - 19.08]
Cardiac Output (L/min)	4.73	[4 - 8]
Cardiac Index (L/min/m^2)	2.68	[2.5 - 4.2]
Stroke Volume (mL)	72.6	[60 - 130]
Stroke Vol Index (mL/m^2)	41.1	[30 - 65]
SYSTEMIC VASCULAR PARAMETERS		
SV Compliance (mL/mmHg)	0.78	[1.02 - 2]
SV Resistance (dynes/sec/cm^5)	1,555	[770 - 1500]
BRACHIAL ARTERY PARAMETERS		
BA Compliance (mL/mmHg)	0.049	[0.056 - 0.132]
BA Distensibility (%/mmHg)	3.74	[4.38 - 9.28]
BA Resistance (kdynes/sec/cm^5)	279	[80 - 317]

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