FIBER-OPTIC 0.014” PRESSURE-WIRE: THE OPTOWIRE® AND OPTOMONITOR®

Olivier F. Bertrand, MD, PhD

Associate-Professor of Medicine, Laval University

Adjunct-Professor, Department of Mechanical Engineering, McGill University

Quebec Heart-Lung Institute

Coronary Physiology in the Catheterization Laboratory (9th Edition)- April 23-25, 2015

Coronary Pathophysiology & Microcirculation
ESC Working Group

the radialist

INSTITUT UNIVERSITAIRE DE CARDIOLOGIE ET DE PNEUMOLOGIE DE QUÉBEC

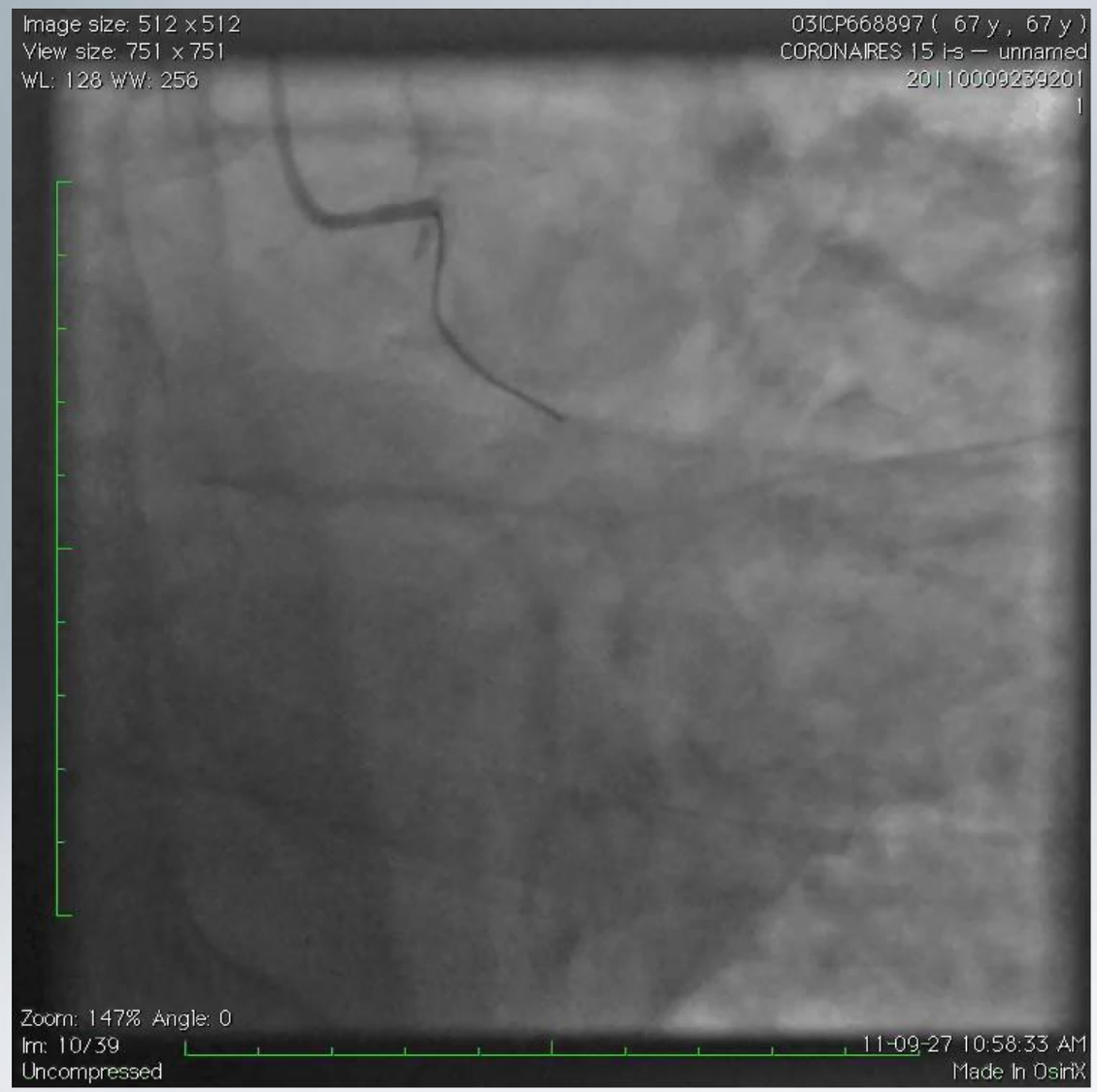
McGill

UNIVERSITÉ LAVAL
International Chair on Interventional Cardiology and Transradial Approach

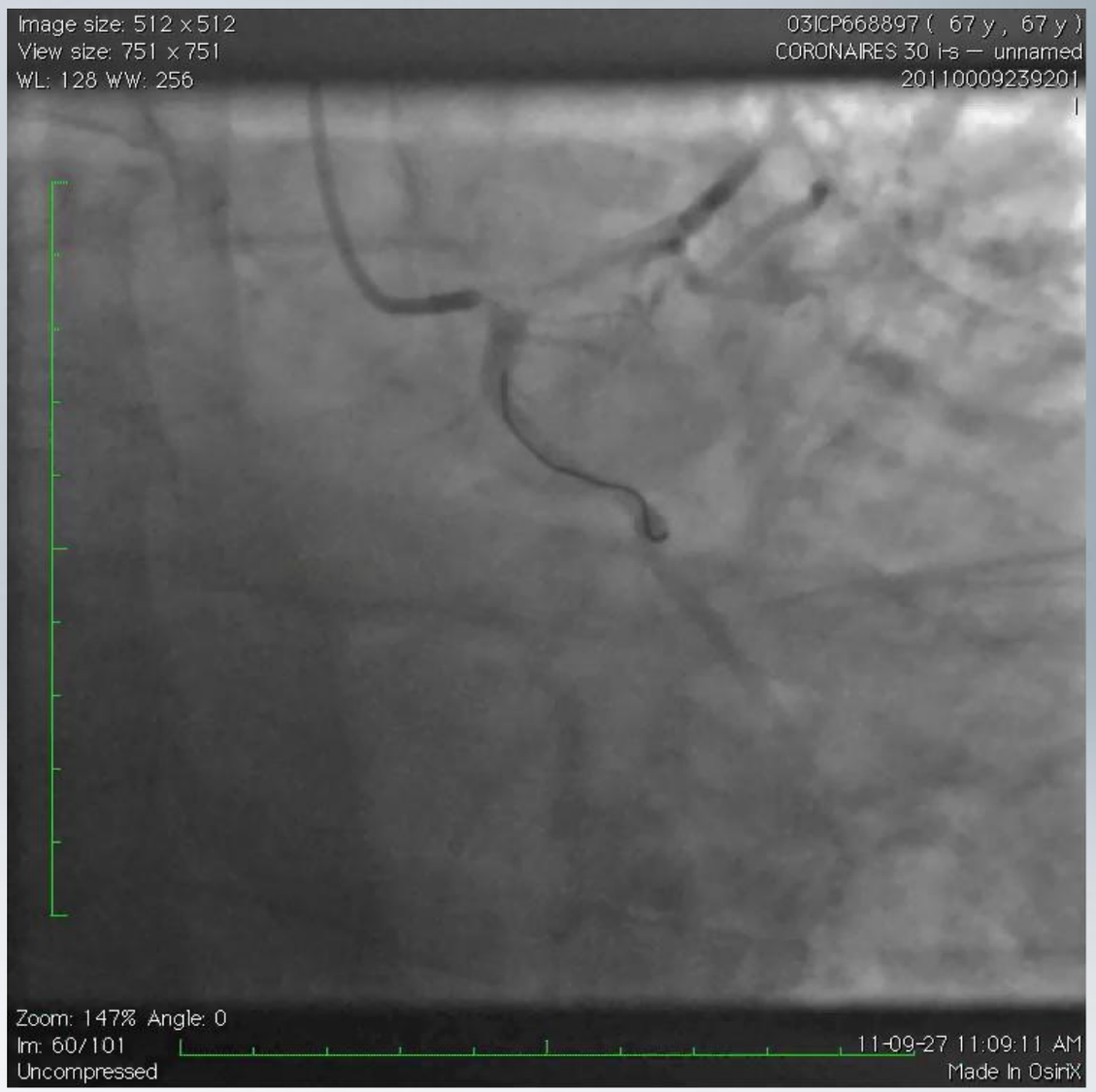
DISCLOSURES

- **Consultant, Opsens**
- **Scientific Director of International Chair in Interventional Cardiology and Transradial Approach**
- **operates www.theradialist.org &**
- **organizes AIM-RADIAL congress (www.aimradial.org)**
- **Chair receives funding from multiple industry and other sources**
- **O_2 FIM study management and data analysis**

CASE STORY

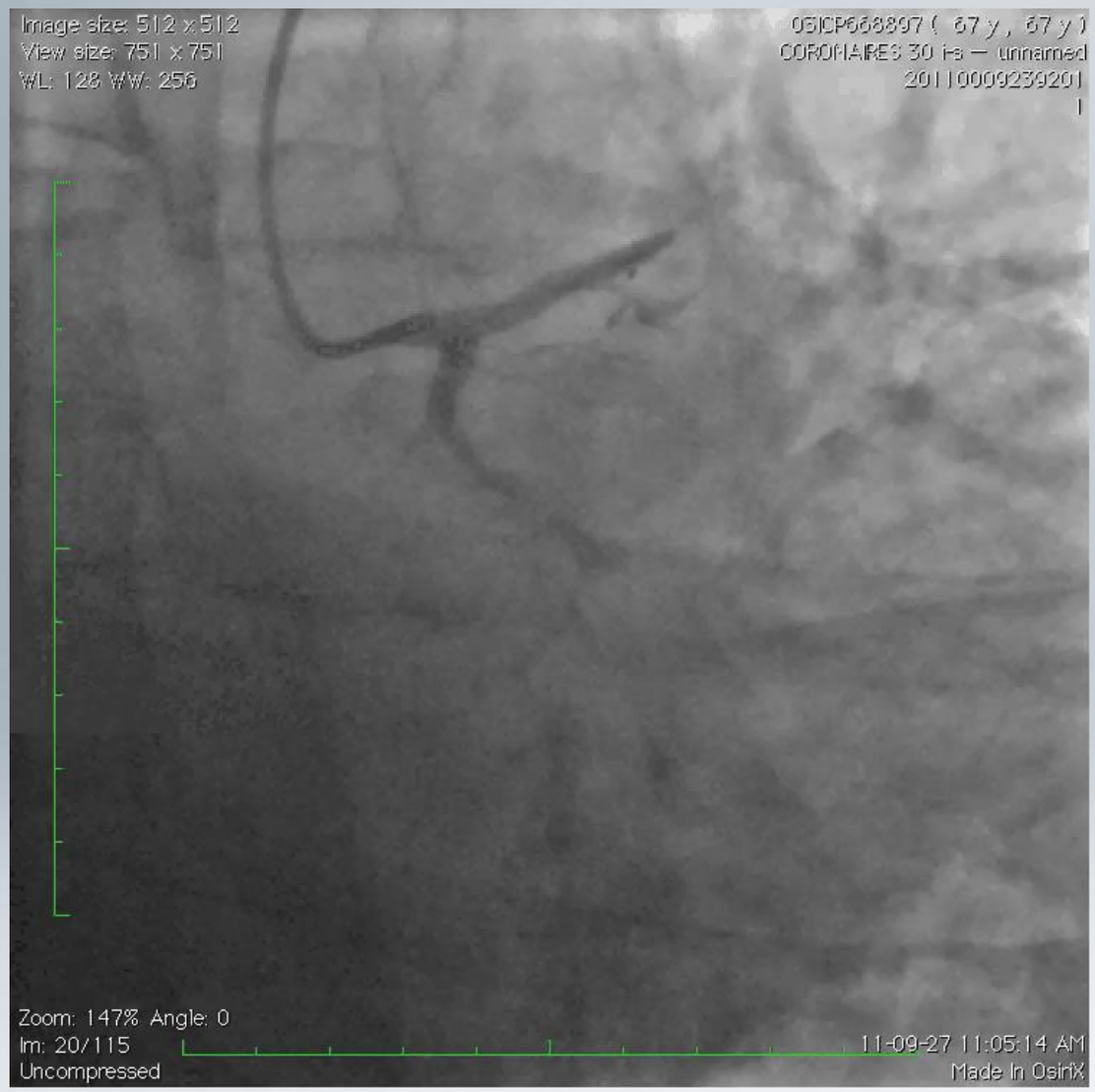


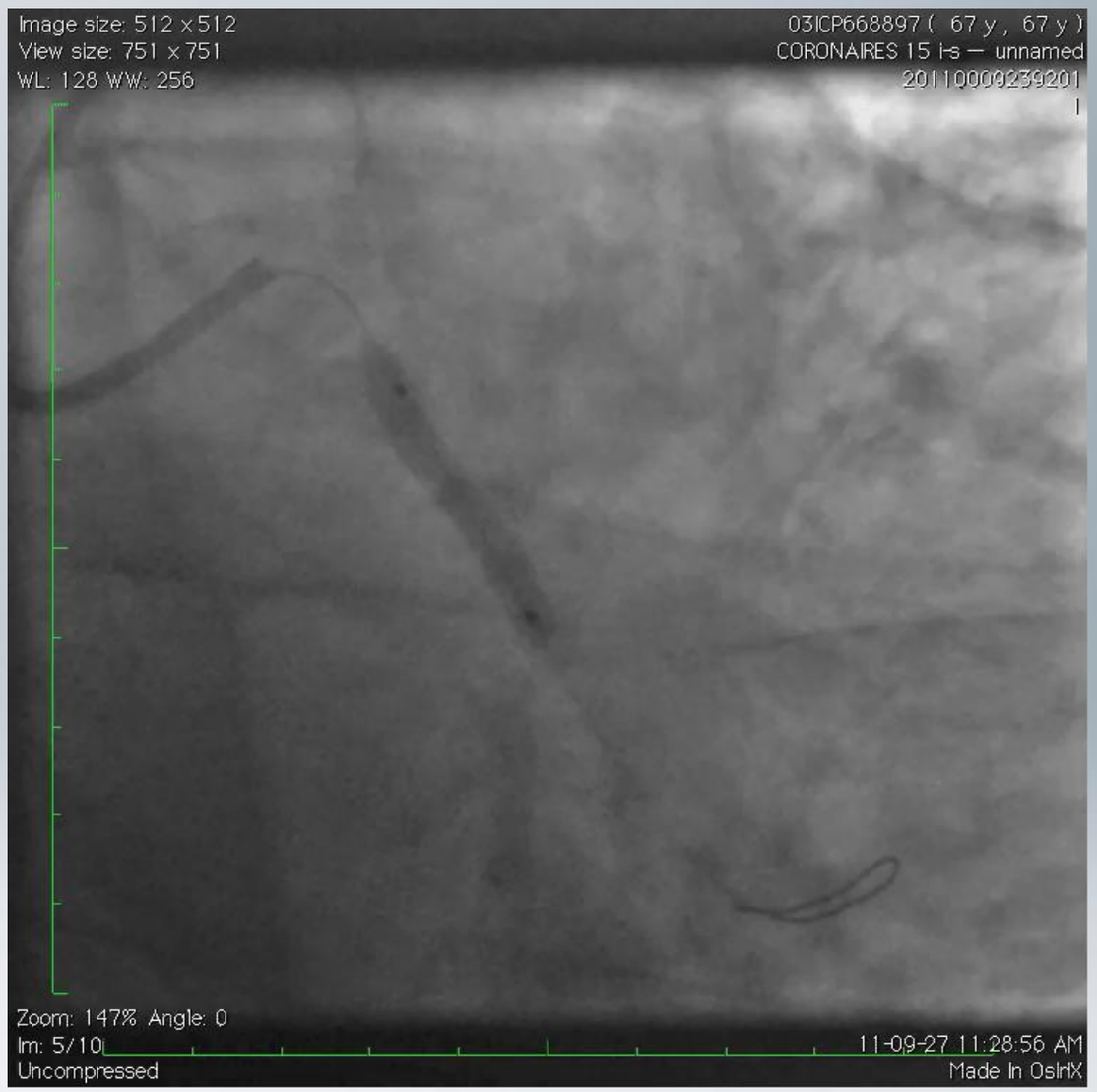
FFR 1



FFR 2

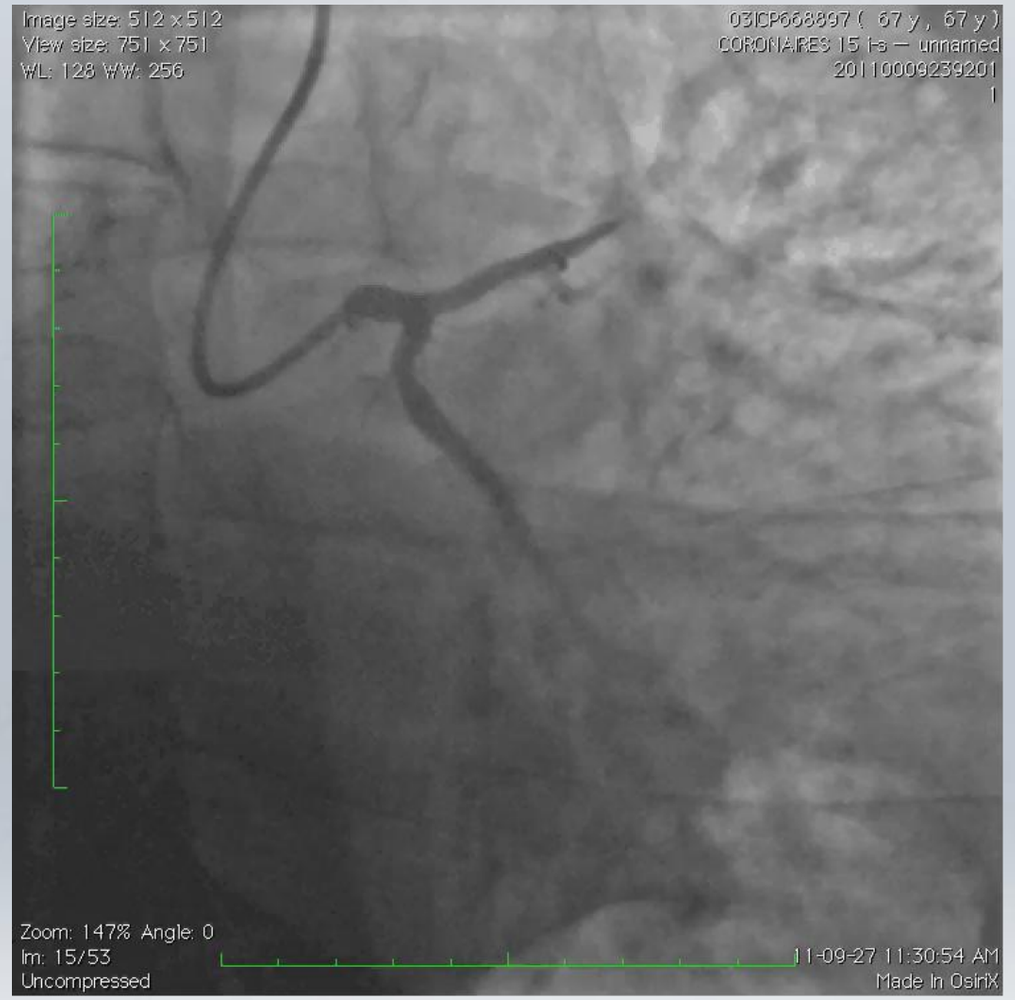
CASE STORY





BMW + direct stenting!

CASE STORY

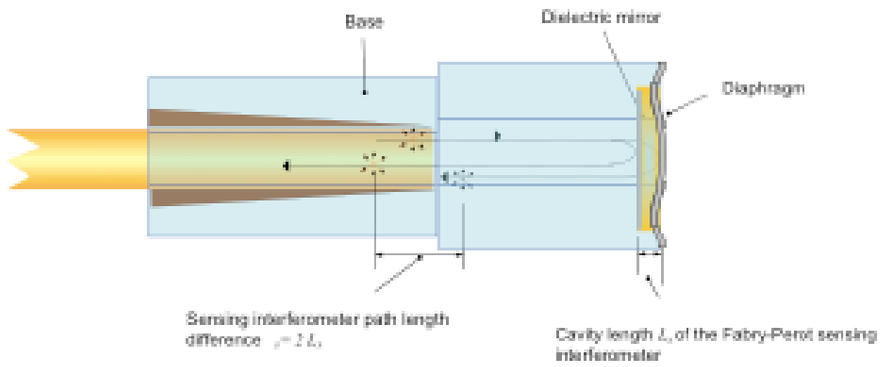


Could we have a floppy-like pressure-wire to reliably and repeatedly assess FFR in any type of lesion and any location ?

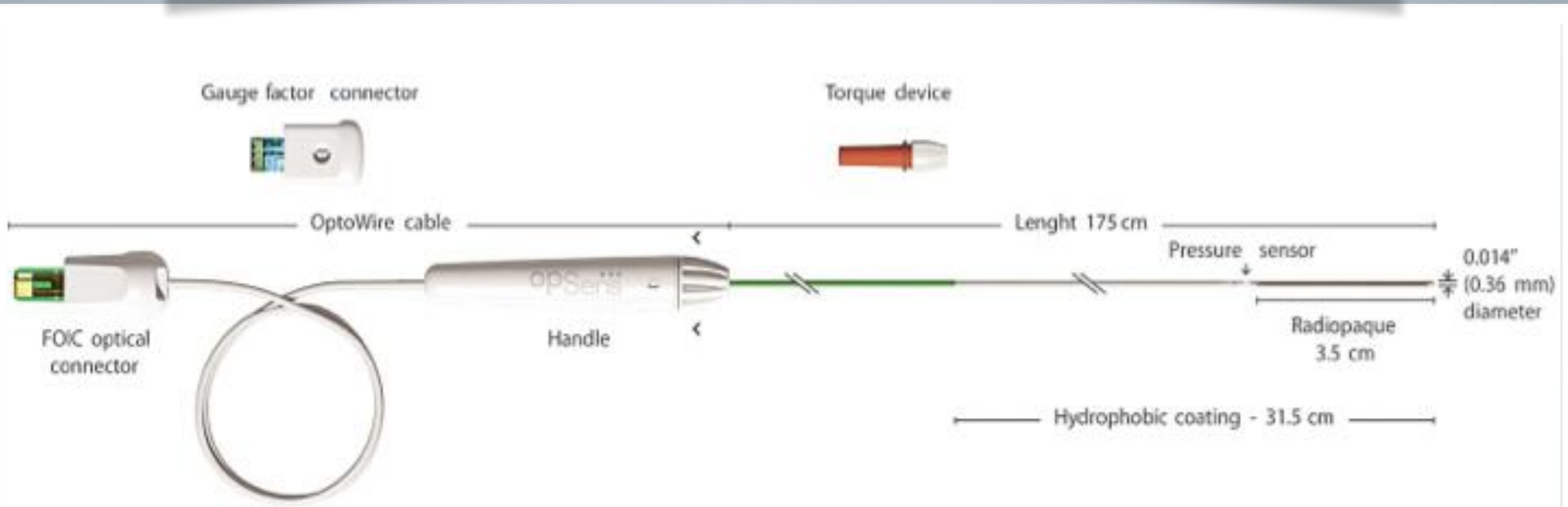
UNMET NEEDS

- FFR wire which performs as a floppy-wire and allows the operator to reach and cross any lesion
- FFR wire must have enough support to work as PCI wire
- FFR wire can be directly hooked up into the cath lab monitoring system (integrated FFR measurements)
- Monitor must be easy to use and allows to print/record results
- Stable and reliable signal upon initial and repeat connexions (multiple lesions assessment /post-PCI measures)

OPTOWIRE DESIGN

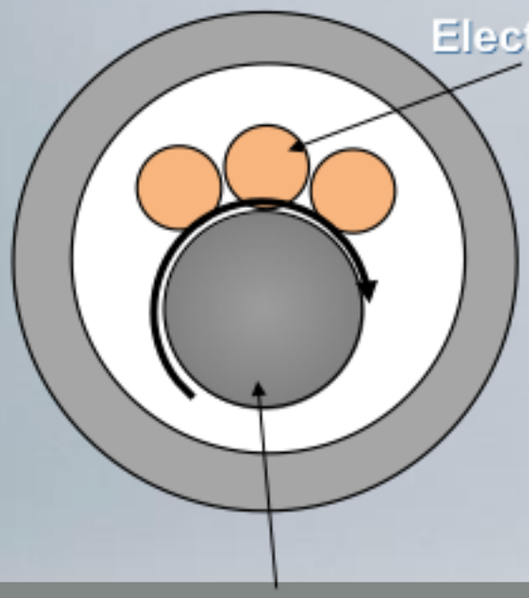


- Unique features - White-light interferometry – Fiber Optic Coherence method (US patent 7.259.862)
- Unique features - Optical MEMS based pressure sensor (US patent 7.689.071 and 8.752.435)



WIRES STRUCTURE

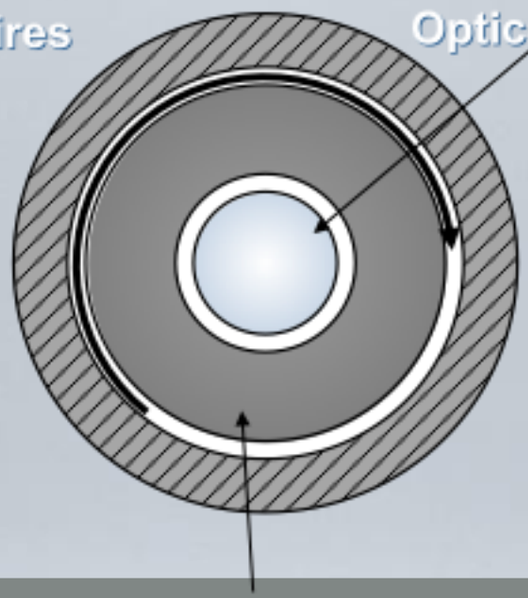
Pressure Guidewire



Core Wire (SS)
Thin – low torque
Eccentric - whipping

0.0035’’-0.0055’’

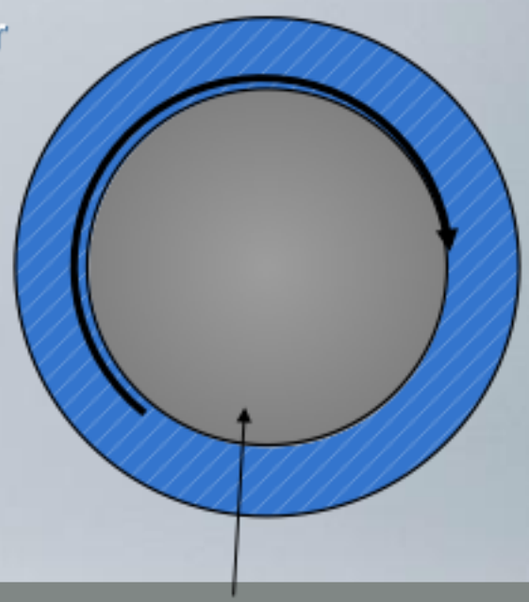
OptoWire



Hollow Wire (NiTi)
Large – High torque
Concentric – No whipping

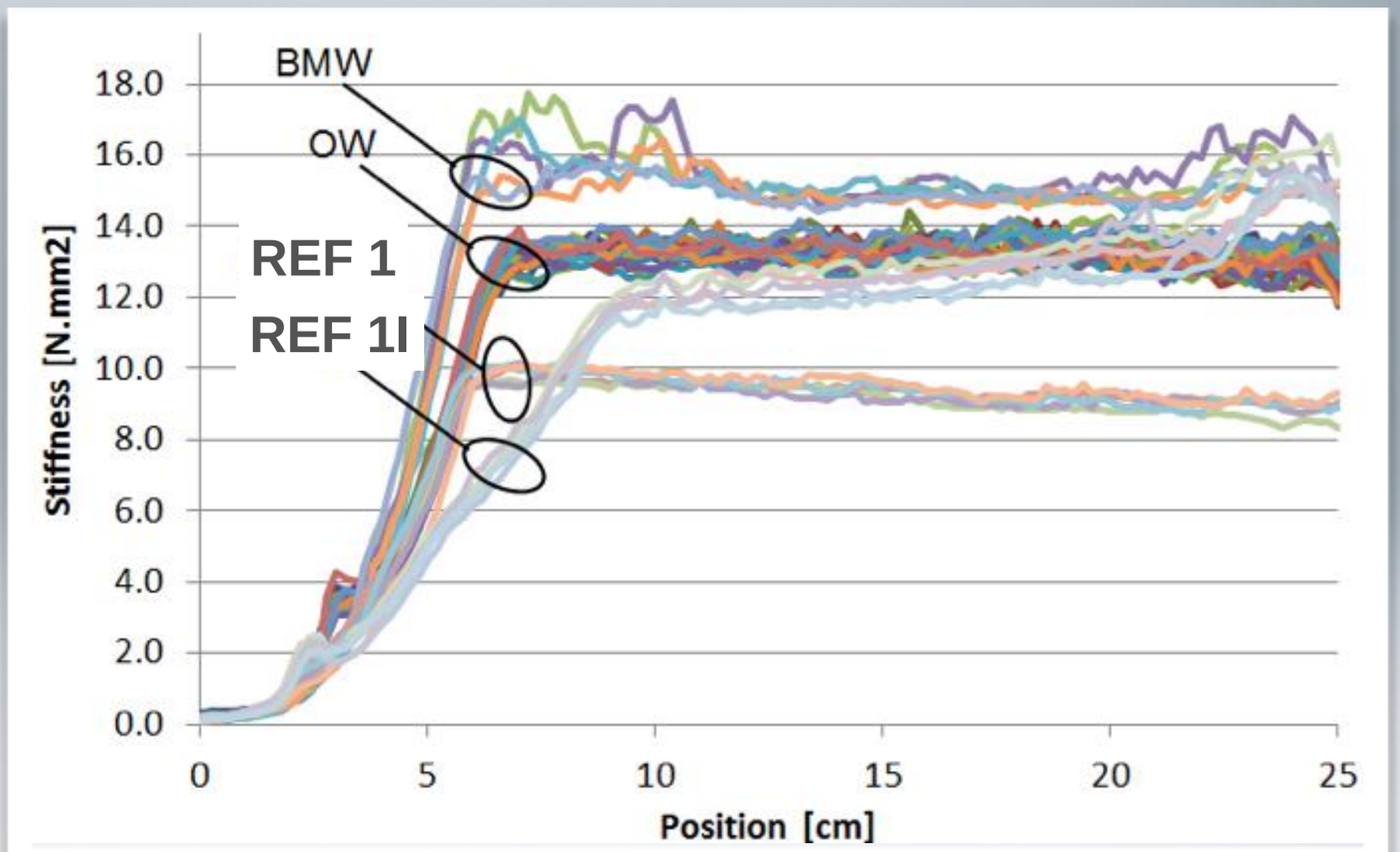
0.009’’-0.0075’’

BMW

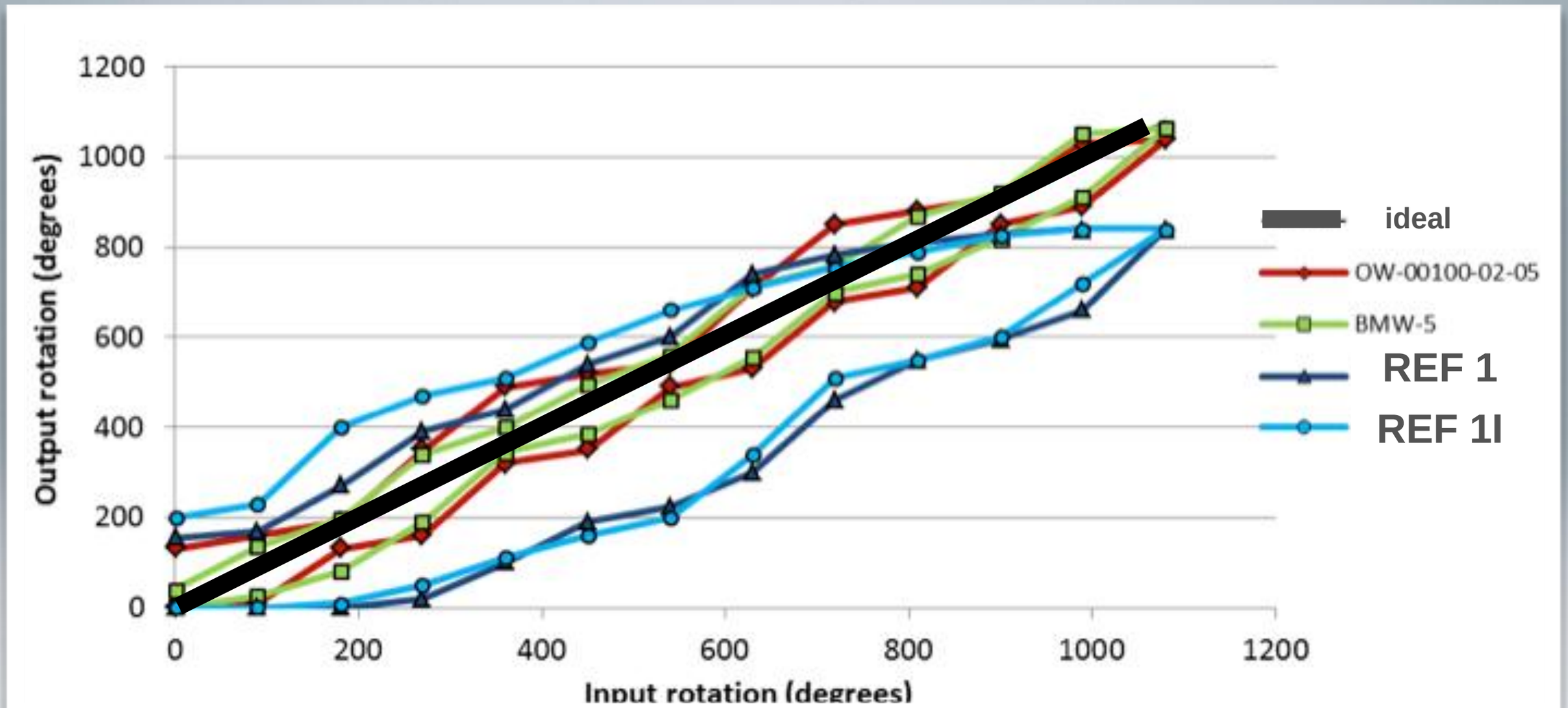


Core Wire (NiTi)
Large – High torque
Concentric – No whipping

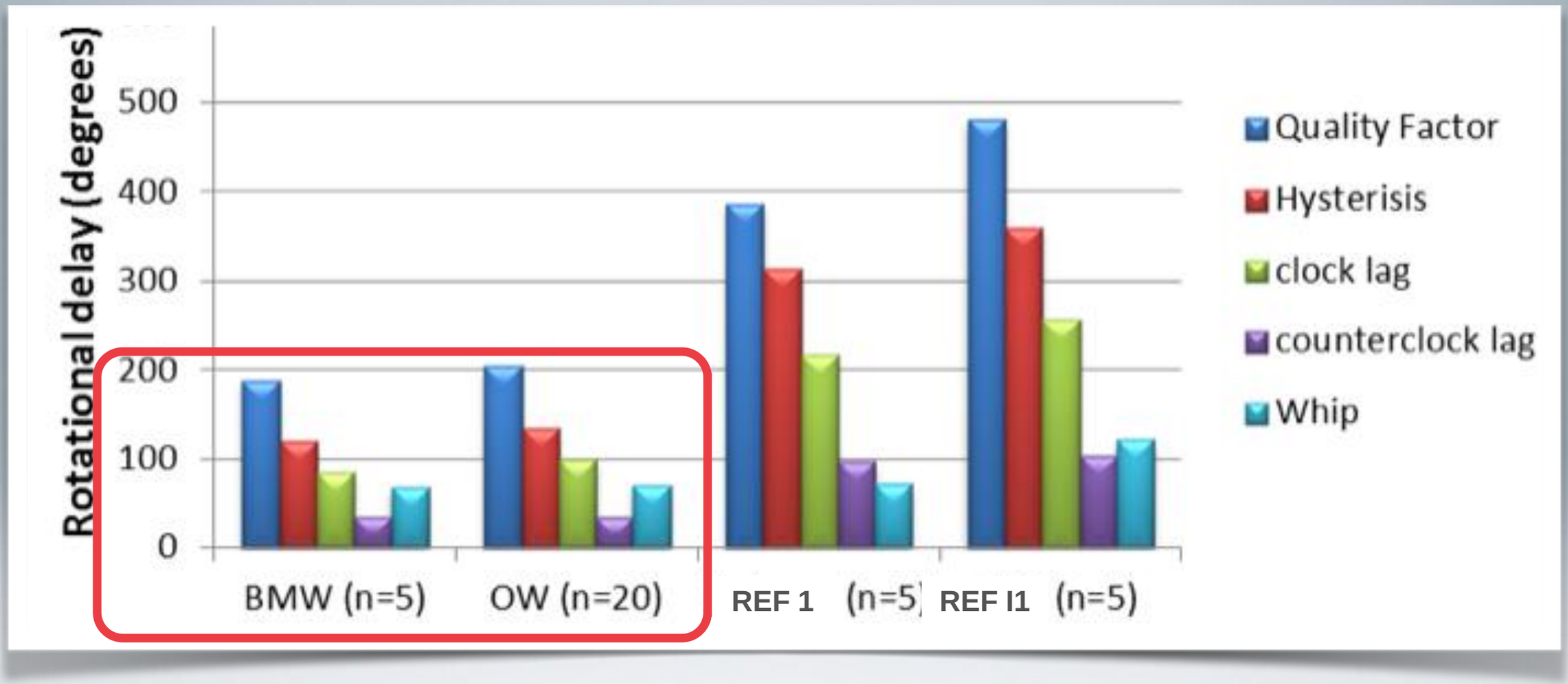
FLEXIBILITY TESTING



TORQUABILITY TESTING

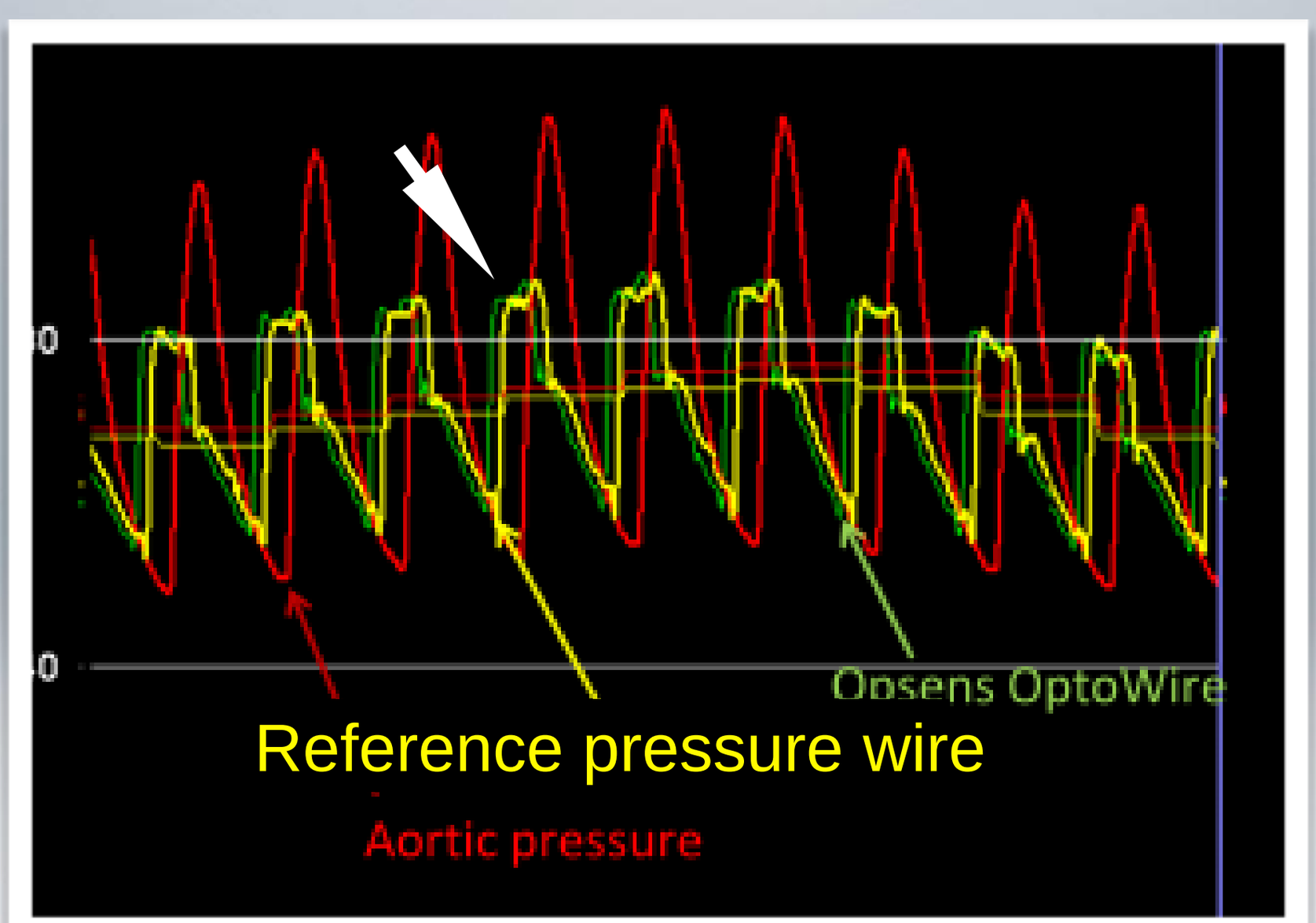


TORQUABILITY TESTING



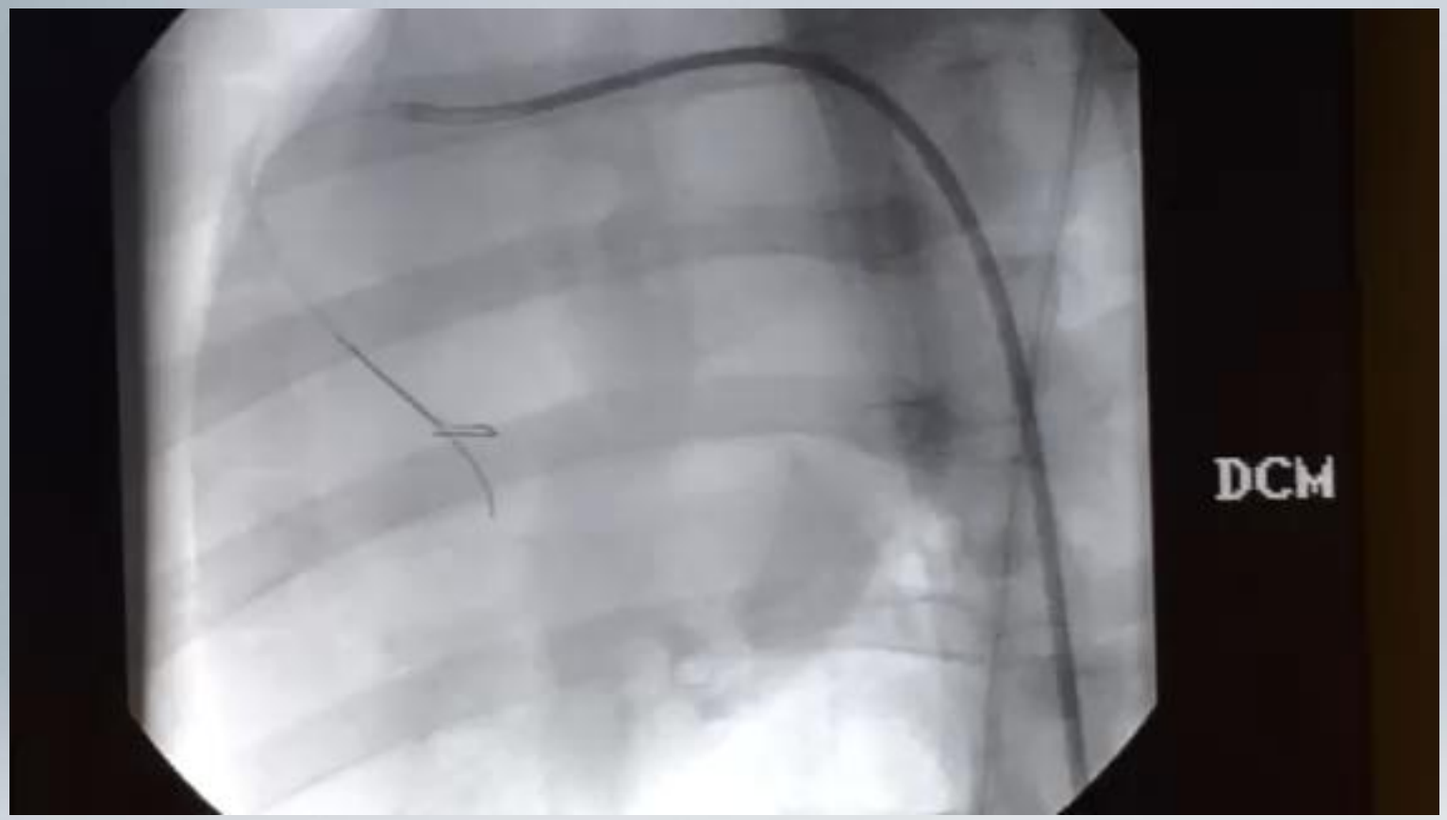
CONNECTIVITY

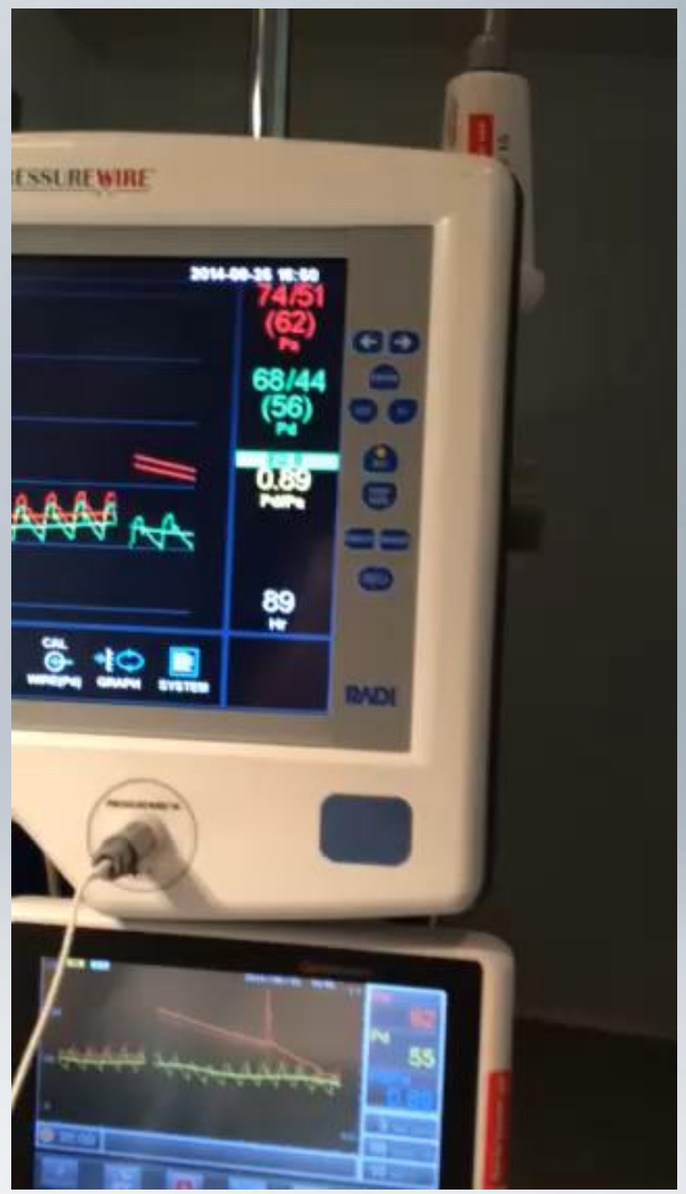
ANIMAL (PIG) TESTING



GLP Testing completed in November 2013 at Accelab (Montreal)

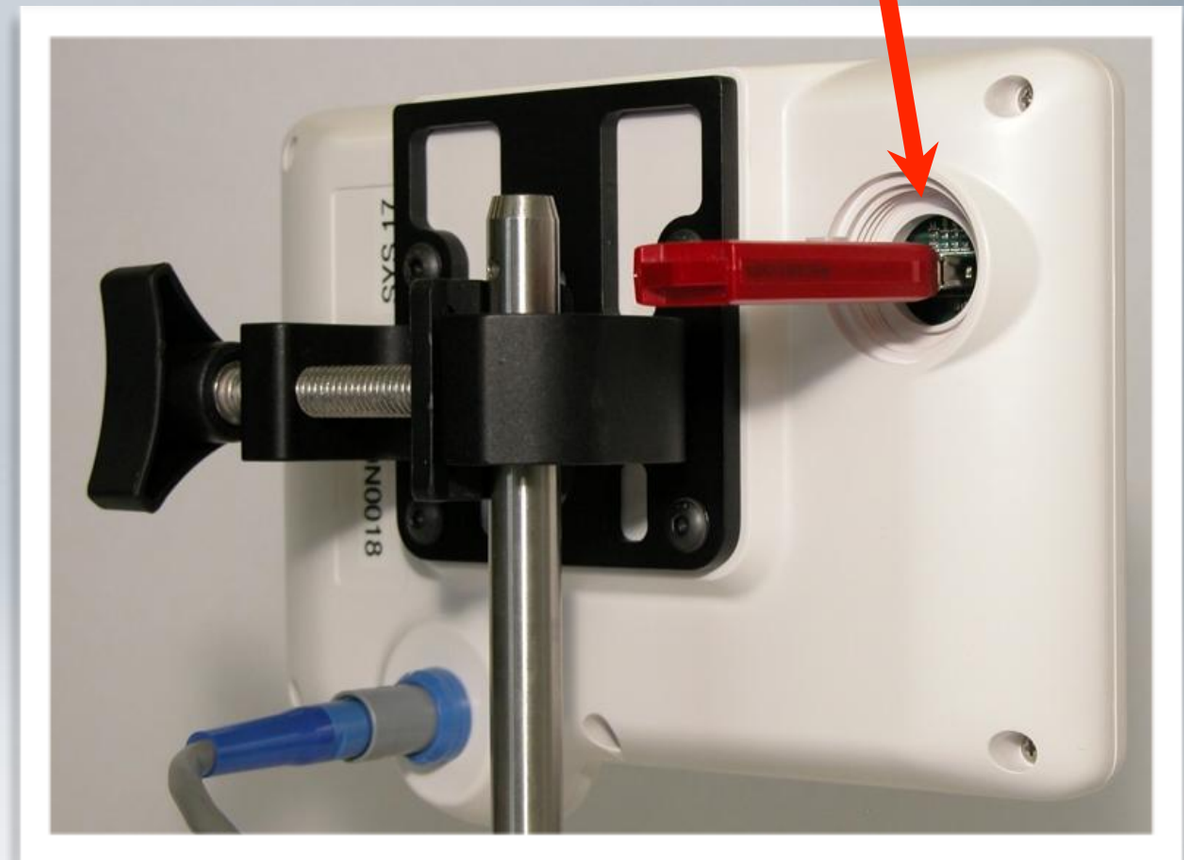
ANIMAL (PIG) TESTING





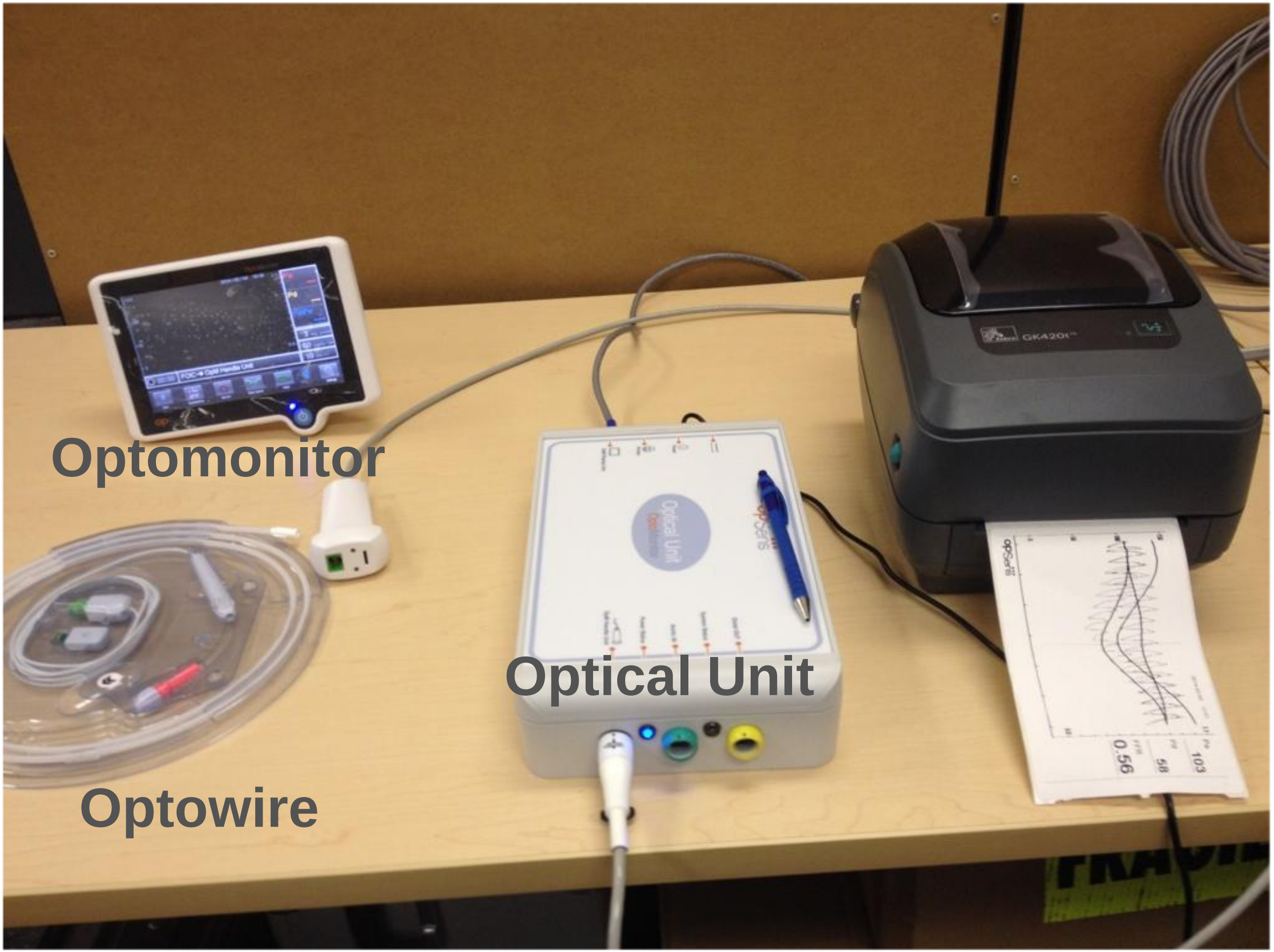
Prolonged parallel pressure monitoring in pig coronary model-Accelab (Montreal)

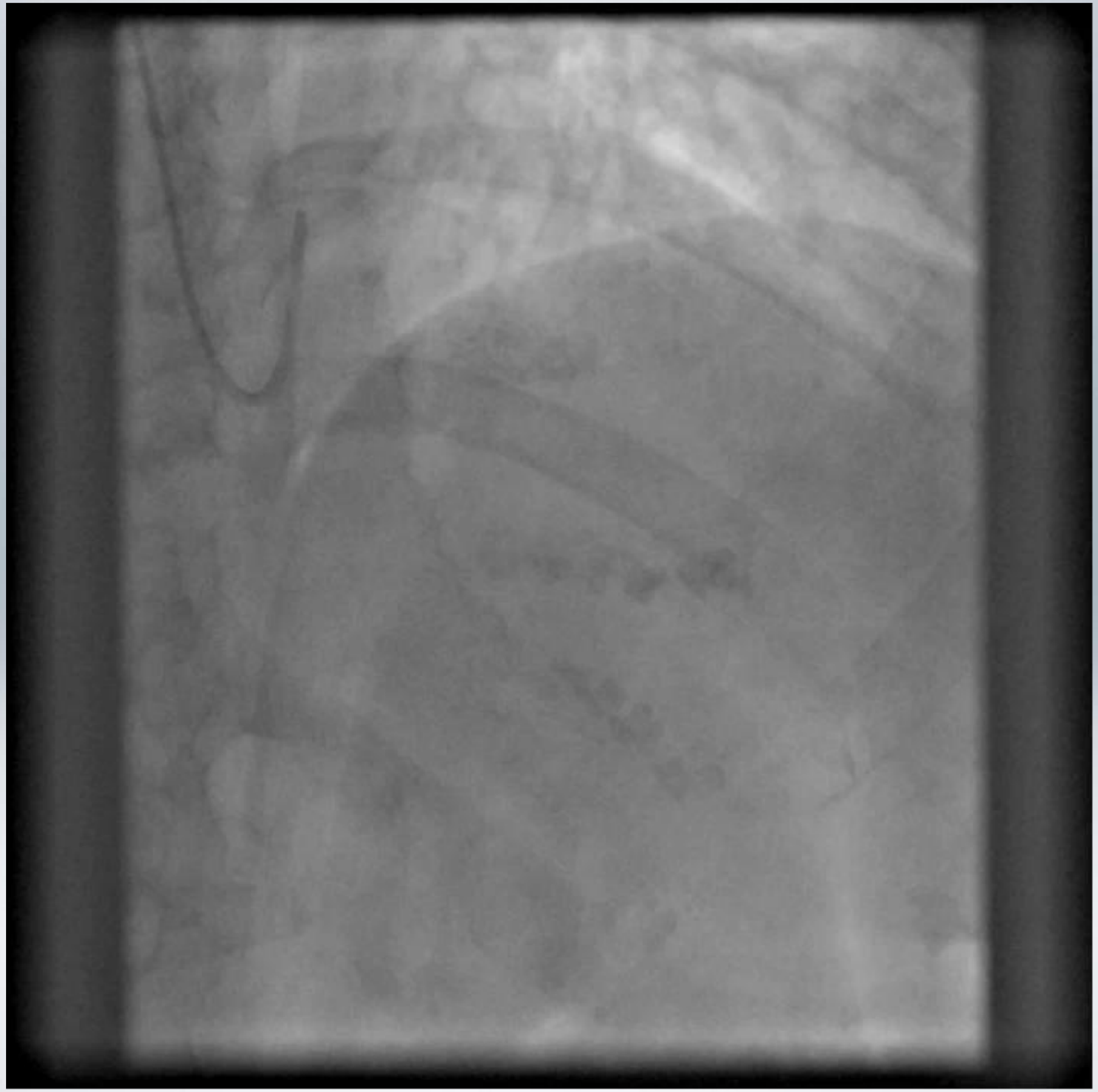
OPTOMONITOR®

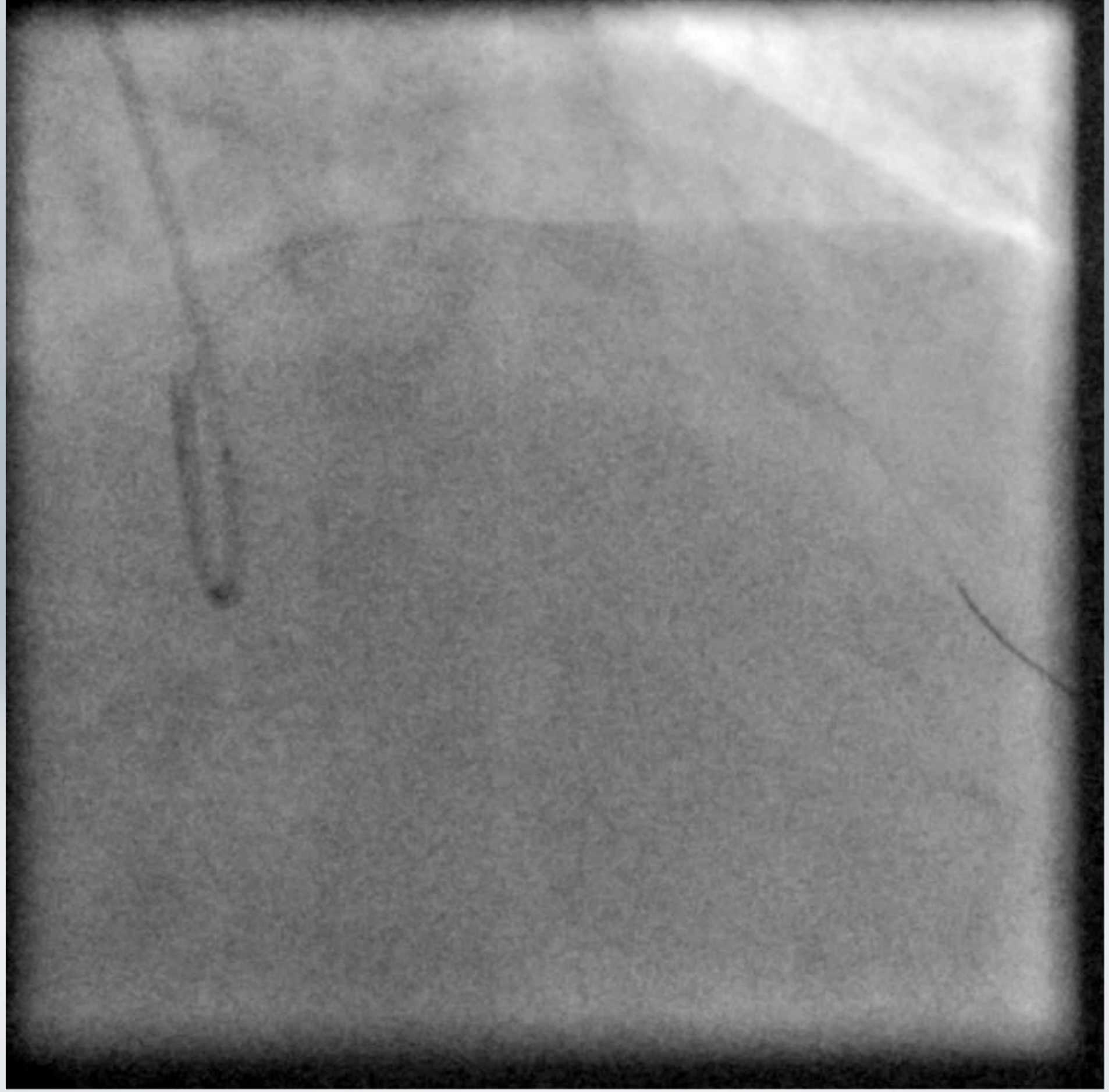


Front **Back**

Up to 1h data recording


Optomonitor
Optical Unit
Optowire





O_2- OBJECTIVES

- **To assess the performance of Opto-wire to cross any type of coronary lesion, except CTOs and thrombotic lesions**

- **To assess the ease and reliability (drift ?) to obtain Pre- and/or Post-PCI FFR values**

- **To evaluate the performance of Optowire as PCI wire**

STUDY POPULATION (N =27)

Age	**65 +/- 10**
Male	**17 (63%)**
Hx MI	**10 (37%)**
Hx PCI	**10 (37%)**
Stable angina	**10 (37%)**
Unstable angina	**12 (44%)**
NSTEMI	**5 (19%)**
Diabetes	**9 (33%)**
Hypertension	**24 (89%)**
Dyslipidemia	**24 (89%)**
Smoker (current)	**6 (35%)**

Presented at TCT 2014: Late-breaking New Technologie

STUDY POPULATION (N =27)

Access (radial/ulnar)	**25/2 (100%)**
Diagnostic catheter	**6 (14%)**
Guiding catheter	**37 (86%)**
5Fr	**41 (95%)**
6Fr	**2 (4.7%)**
Vx diseased (1/2/3)	**17 (62%)/5 (19%)/5 (19%)**
Lesions	**LM: 3 (7%)**
	LAD-Diag: 20 (47%)
	Cx-Mg: 12 (28%)
	RCA: 8 (19%)
Ejection Fraction	**57 +/- 8%**
Procedure duration (min)	**45 [33-71]**
Contrast volume	**138 +/- 62 ml**

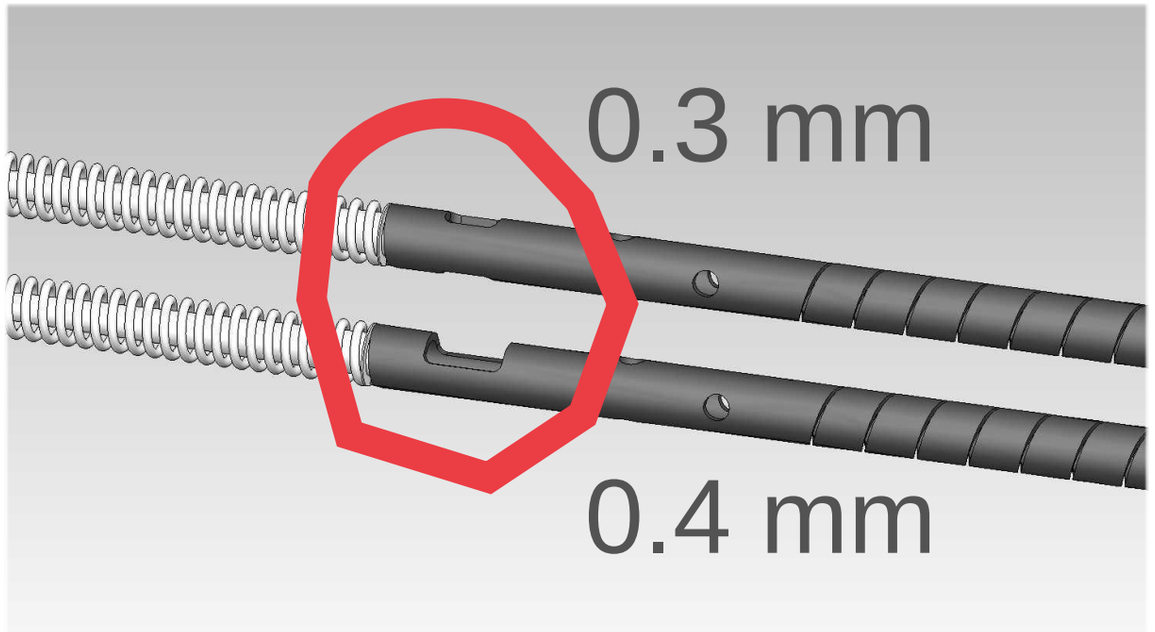
FFR ONLY OR PRE-PCI

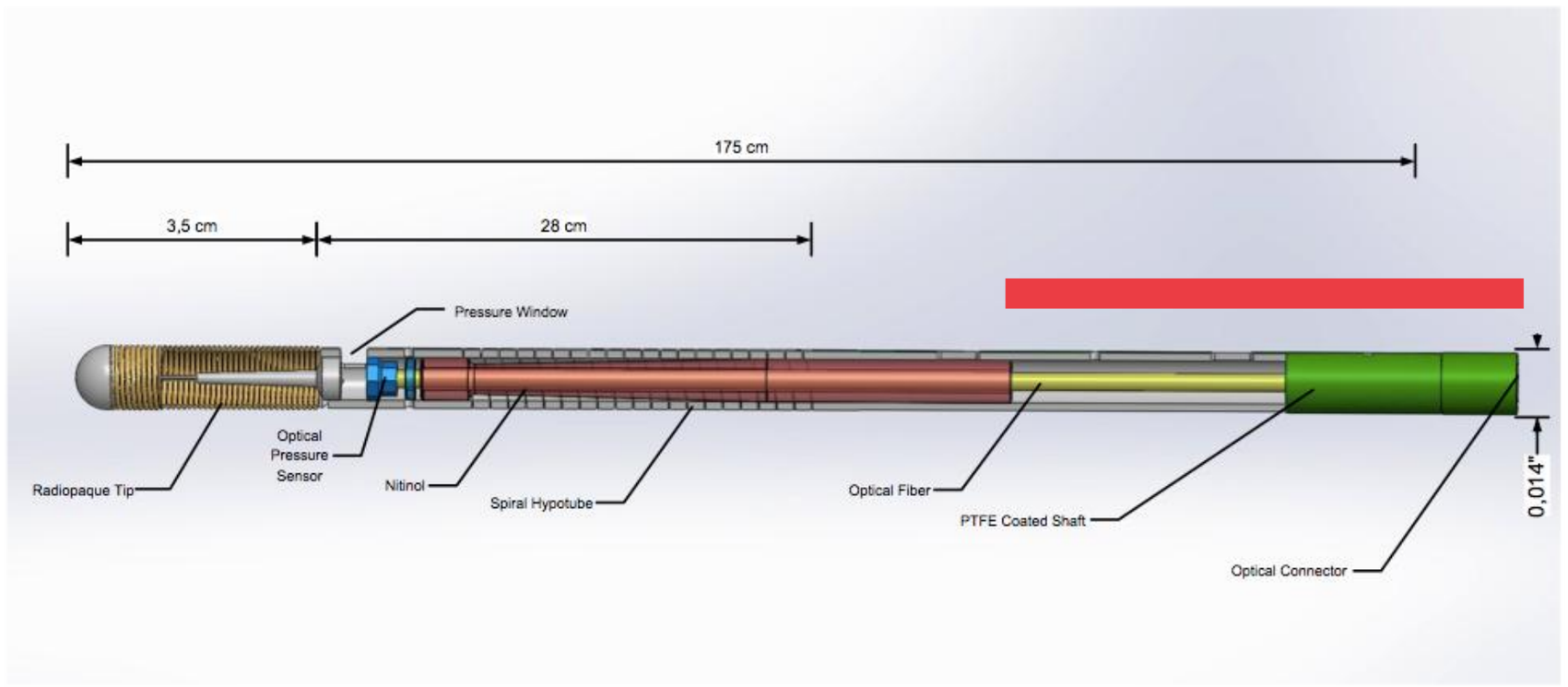
	Measurements
N	50 FFR/36 sites
% diameter stenosis	60 [40-80]
Lesion	Type A: 4 (9%)
	Type B1: 23 (53%)
	Type B2/C: 16 (37%)
Reference Diameter (mm)	2.73 +/- 0.37
Baseline Pd/Pa	0.87 +/- 0.13
(300 µg IC adenosine)	0. 78 +/- 0.14
Pressure at proximal pull-back	0.99 +/- 0.03
Pressure after reconnection	0.99 +/- 0.03

FFR POST-PCI

N	**24 FFR/19 sites**
Lesions	**LAD-Diag: 14 (60%)**
	Cx: 7 (30%)
	RCA: 2 (10%)
Number of stents (DES/BVS)	**1.2 +/- 0.6**
Stent diameter (mm)	**2.68 +/- 0.38**
Stent length (mm)	**19.8 +/- 7.2**
Largest balloon (mm)	**2.8 +/- 0.4**
Max pressure (ATM)	**20.5 +/- 5.2**
Angiographic Success	**23 (100%)**
Pd/Pa baseline	**0.90 +/- 0.07**
FFR (300 µg IC adenosine)	**0.83 +/- 0.08**
Pressure at proximal pull-back	**0.97 +/- 0.02**
Pressure after reconnection	**0.97 +/- 0.02**

OPTOWIRE 001 VS 002

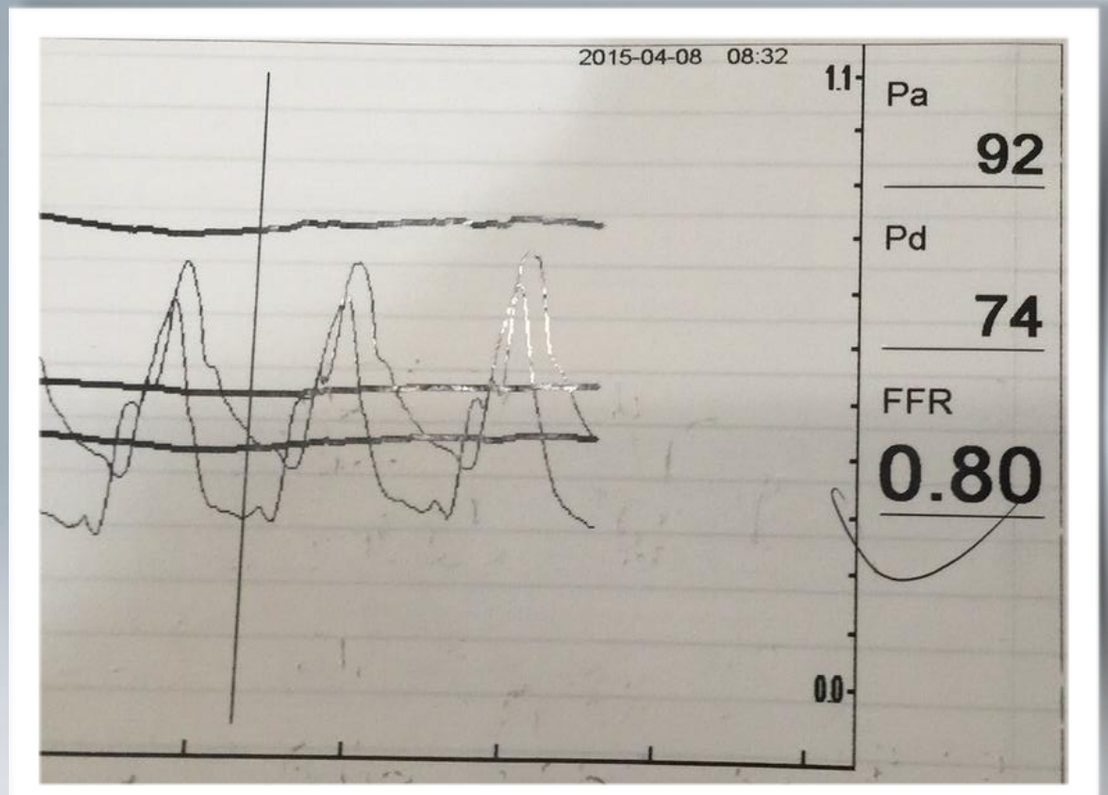


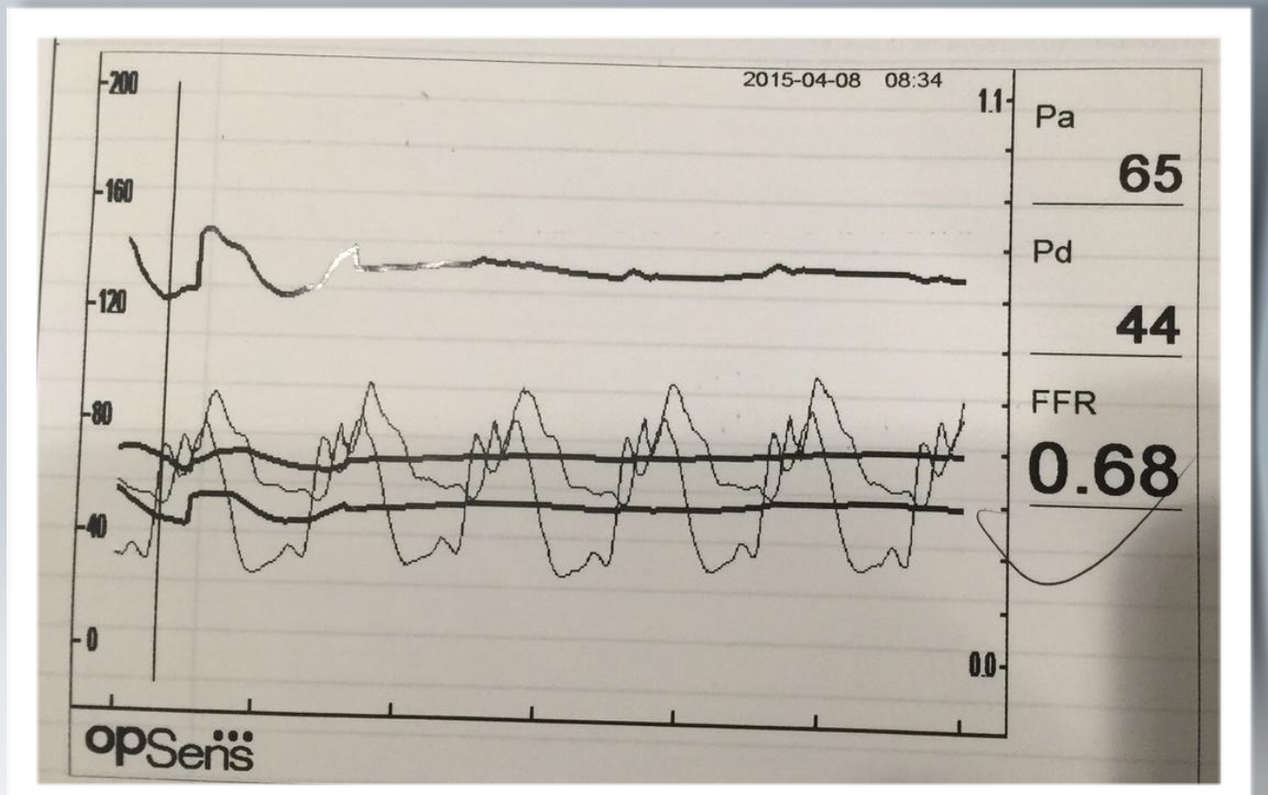


RAO CAUDAL VIEW

RAO CRANIAL VIEW

LAD ASSESSMENT

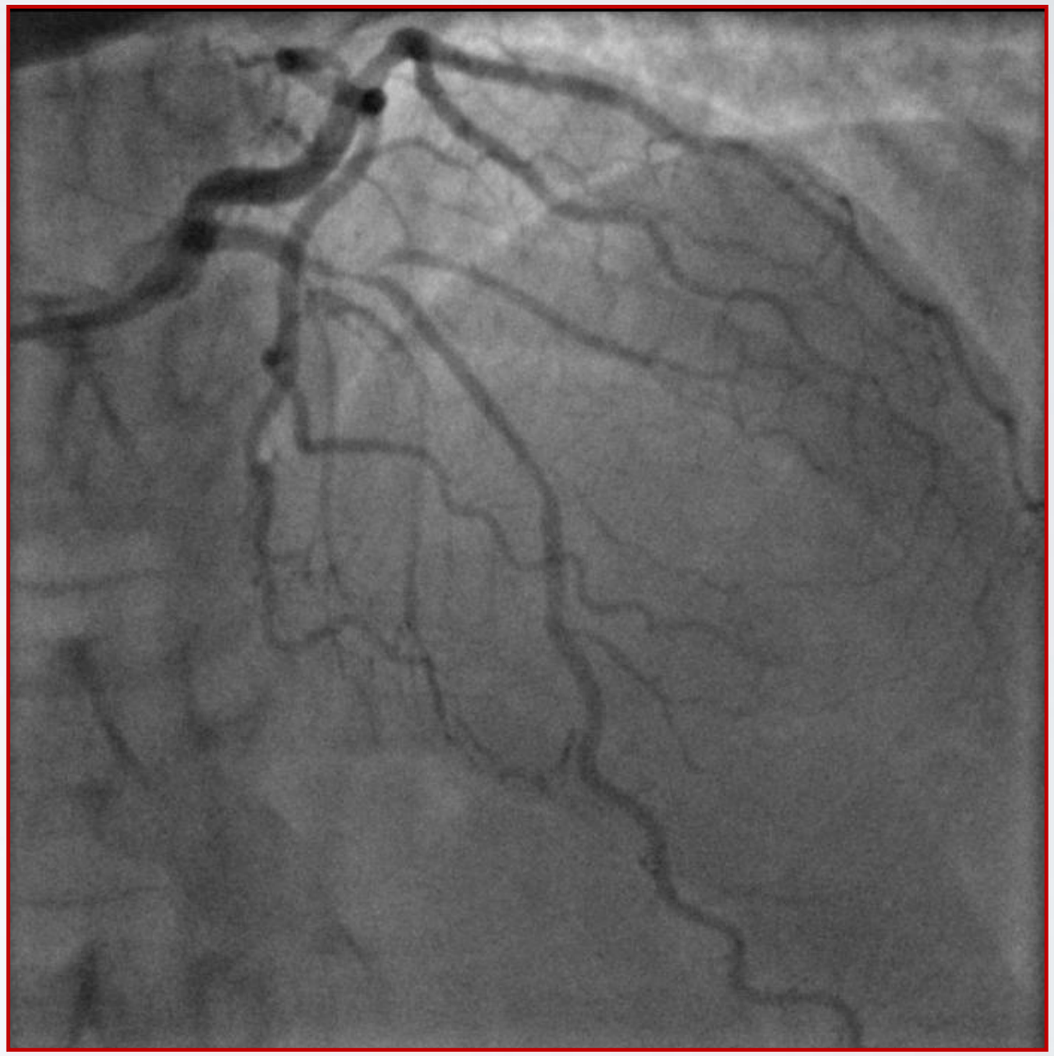




D.R.J. 55 Y/O MALE
86 KG – 1,79 CM – 26,8 KG/M²

Risk factors:

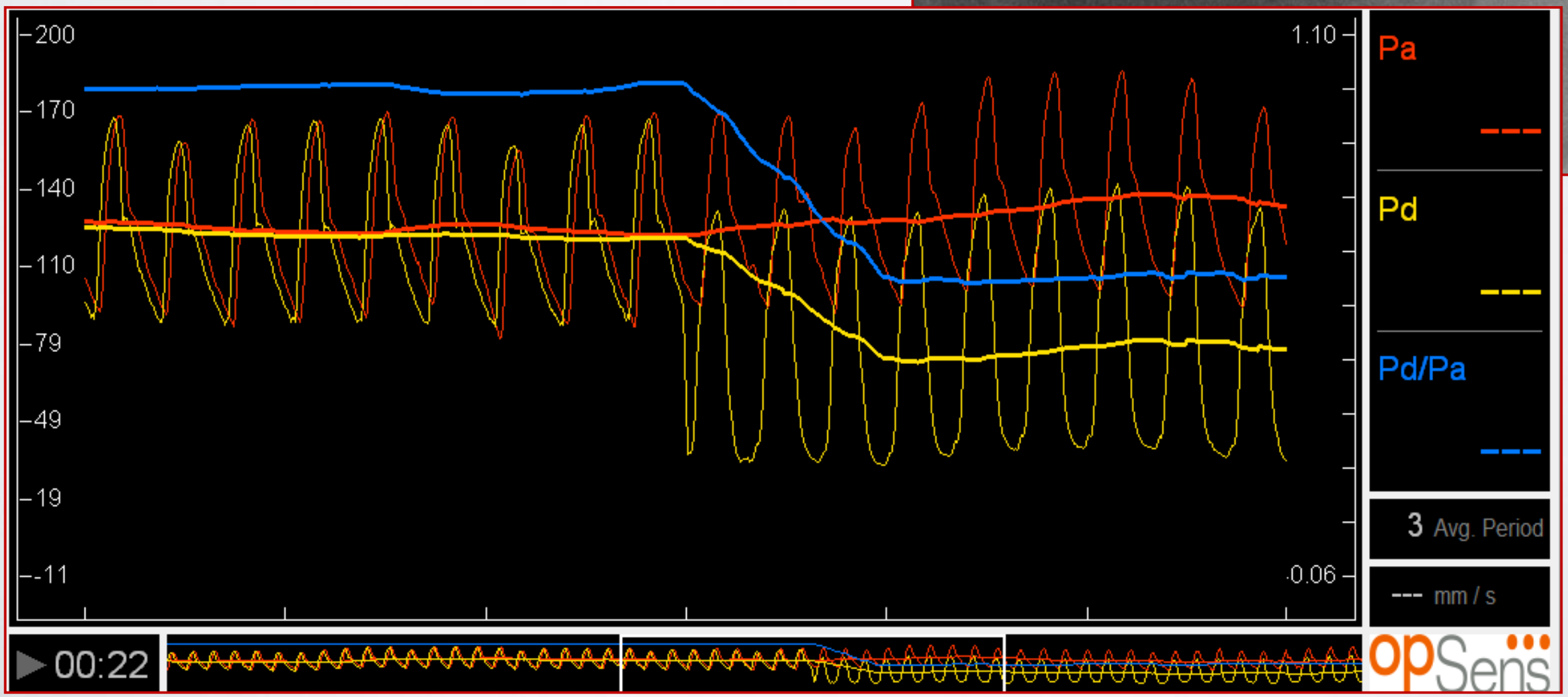
- Dyslipidemia
- Family history of CAD
- Hypertension
- Diabetes mellitus type 2 ?
- Obesity



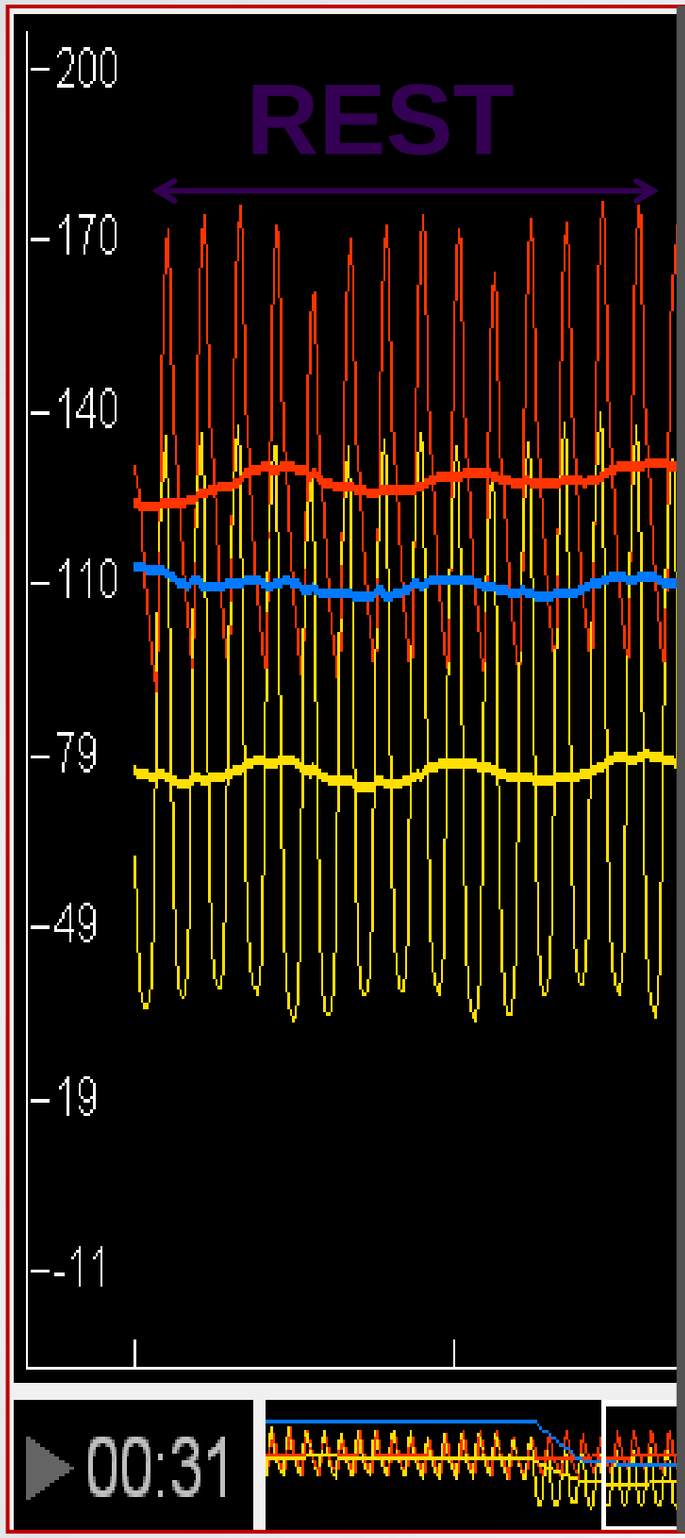
Clinical presentation (April 2015):

- NSTEMI

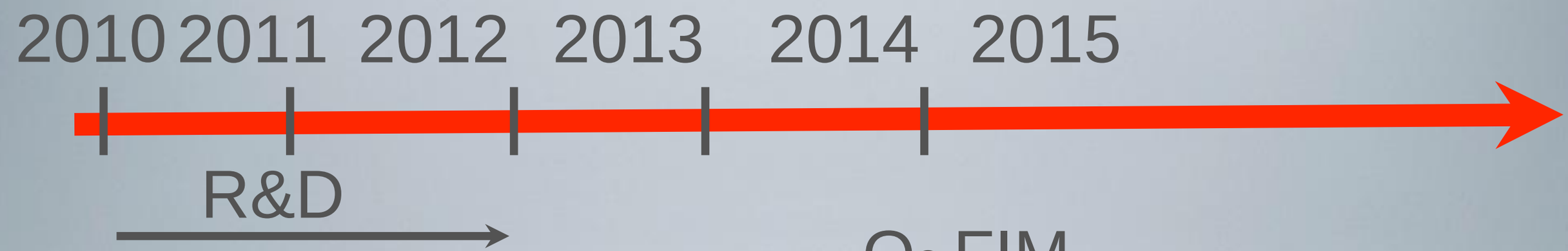
Cardiovascular Center Aalst



Cardiovascular Center Aalst



TIME FRAMES



Optowire & Optomonitor

O_2 FIM Study (Canada)

Animal Testing

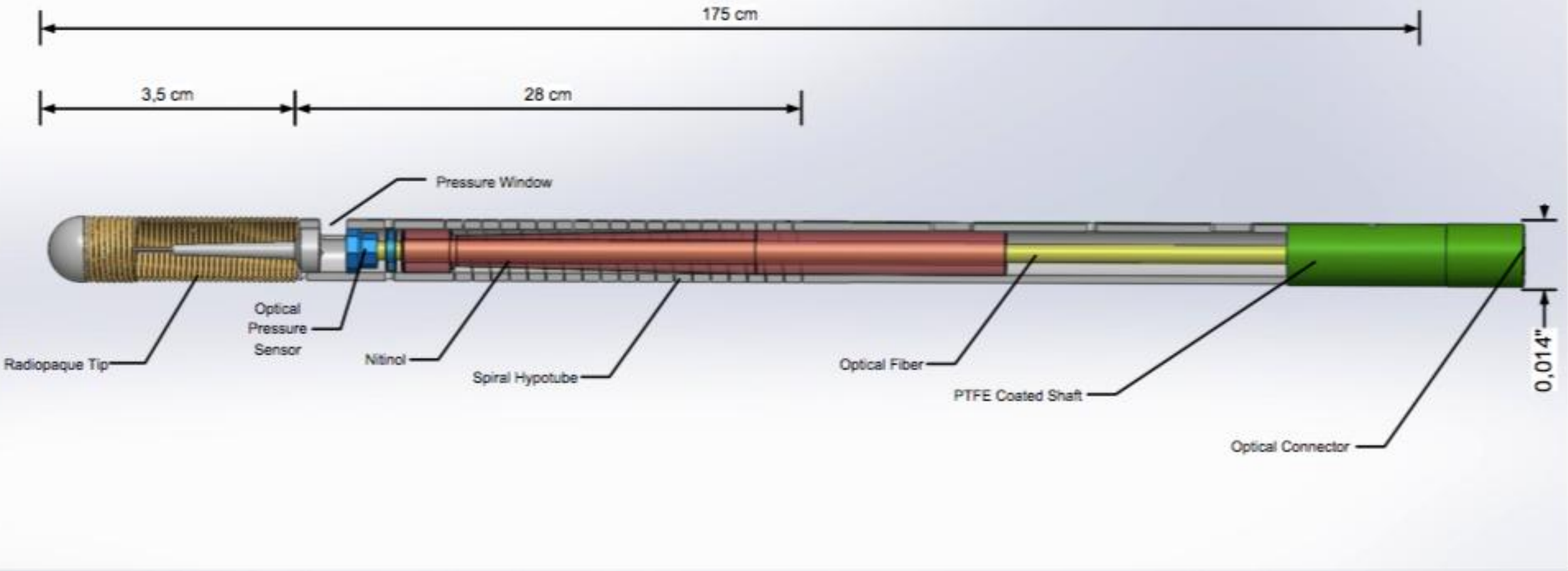
Q4:Japan approval

Q2:CE- Mark
FDA (510k) pending

Canada pending

LV ANGIOGRAM

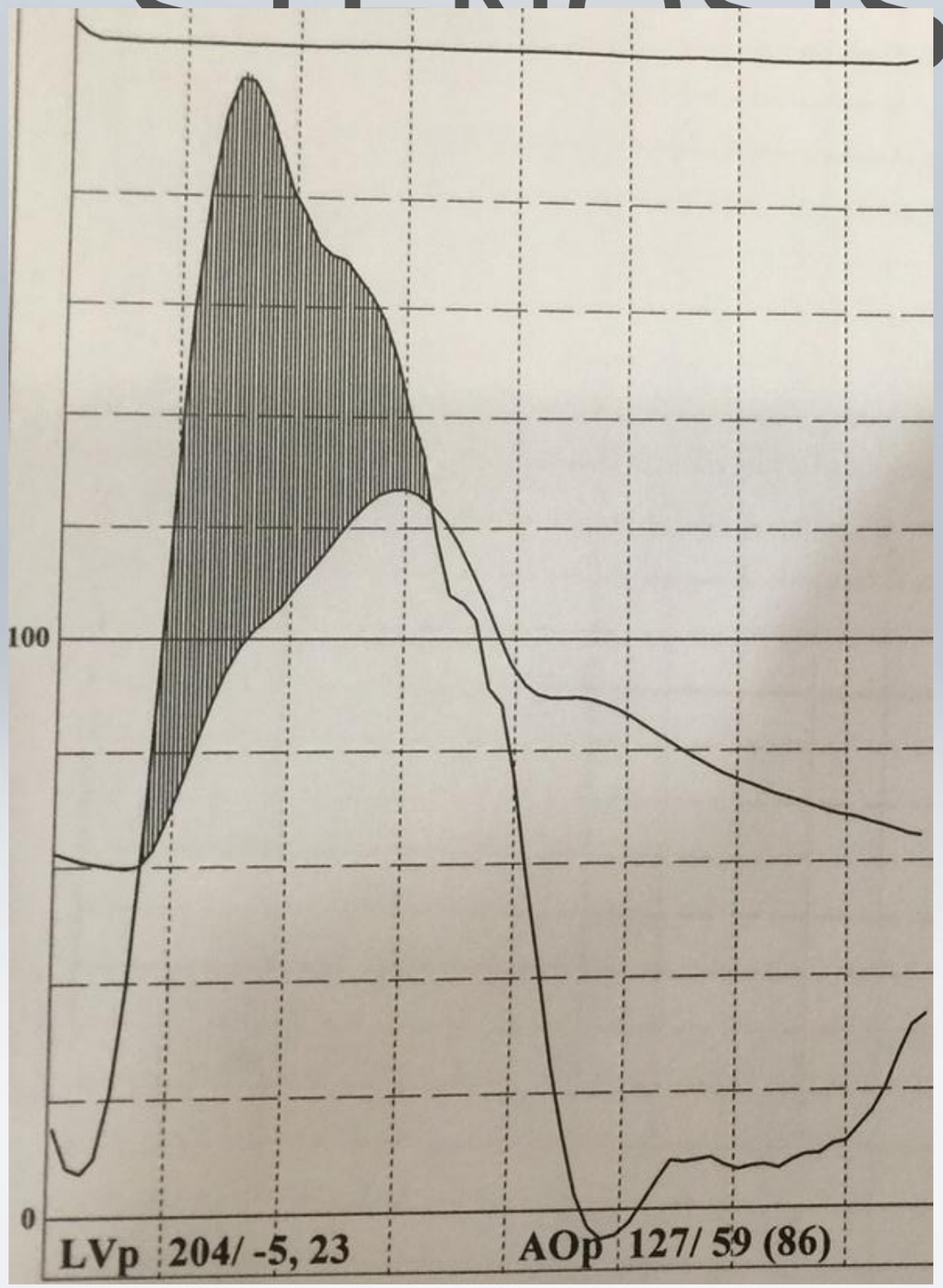
STRUCTURE


175 cm
3,5 cm
28 cm
Pressure Window
Radiopaque Tip
Optical
Pressure
Sensor
Nitinol
Spiral Hypotube
Optical Fiber
PTFE Coated Shaft
Optical Connector
0,014"

FFR WIRE INTRA-LV

DUAL PRESSURE

SEVERE AORTIC STENOSIS



ECHO REPORT

Rapport Echo Adulte

Identification: [redacted]	**Date de l'examen :** 2015-04-08 14:06	**Taille:** 166 cm	**N°dossier:** 720060
Né(e) le: 1950-03-13 (yyyy-MM-dd)	**Localisation patient:** 2e ND HEMO	**Poids:** 106 kg	**PA:** 117/70 mmHg
Age: 65 an(s)	**Sexe:** Masculin	**SC**: 2,1 m^2	**FC:** 84
Raison de l'examen: Évaluer valve aortique			

Synthèse

Sténose valvulaire aortique : sévère.
Gradient transaortique maximal: 101 mm Hg.
Gradient transaortique moyen: 60 mm Hg.
L'appareil valvulaire aortique est tricuspide et non bicuspide.
Aorte ascendante de calibre normal.
Remodelage concentrique du VG.
Le septum interventriculaire est sigmoïde.
Un gradient de pression intraventriculaire gauche de 80 mm Hg a été mesuré.

Ventricule gauche

Le ventricule gauche est d'une taille globalement normale. Remodelage concentrique du VG. La masse du V
été mesurée à 103.4 g/m2. (N hommes:<116 ; HVG légère 116-131, modérée 132-148, sévère >148). Un
intraventriculaire gauche de 80 mm Hg a été mesuré. Le septum interventriculaire est