COMET

NCT02578381

Randomised Comparison of Simultaneous Data from two Different Pressure Wires:

the COMET trial

Nick Curzen
University Hospital Southampton, UK

Rod Stables
Liverpool Heart & Chest Hospital, UK

on behalf of the COMET Investigators

Financial Disclosures related to this presentation

The COMET trial was funded by an unrestricted research grant from Boston Scientific

The company had no role in the design, performance or analysis of the trial.

Nick Curzen

Speaker fees/consultancy: Boston Scientific, HeartFlow & St Jude Medical in the last 3 years

Unrestricted research support: Boston Scientific & HeartFlow in the last 3 years

Unrestricted educational grant: Volcano Phillips in the last 3 years

Travel sponsorship: Boston Scientific & St Jude Medical in the last 3 years

Rod Stables

Speaker fees/consultancy: Boston Scientific & St Jude Medical in the last 3 years

Unrestricted research support: Boston Scientific & St Jude in the last 3 years

COMET

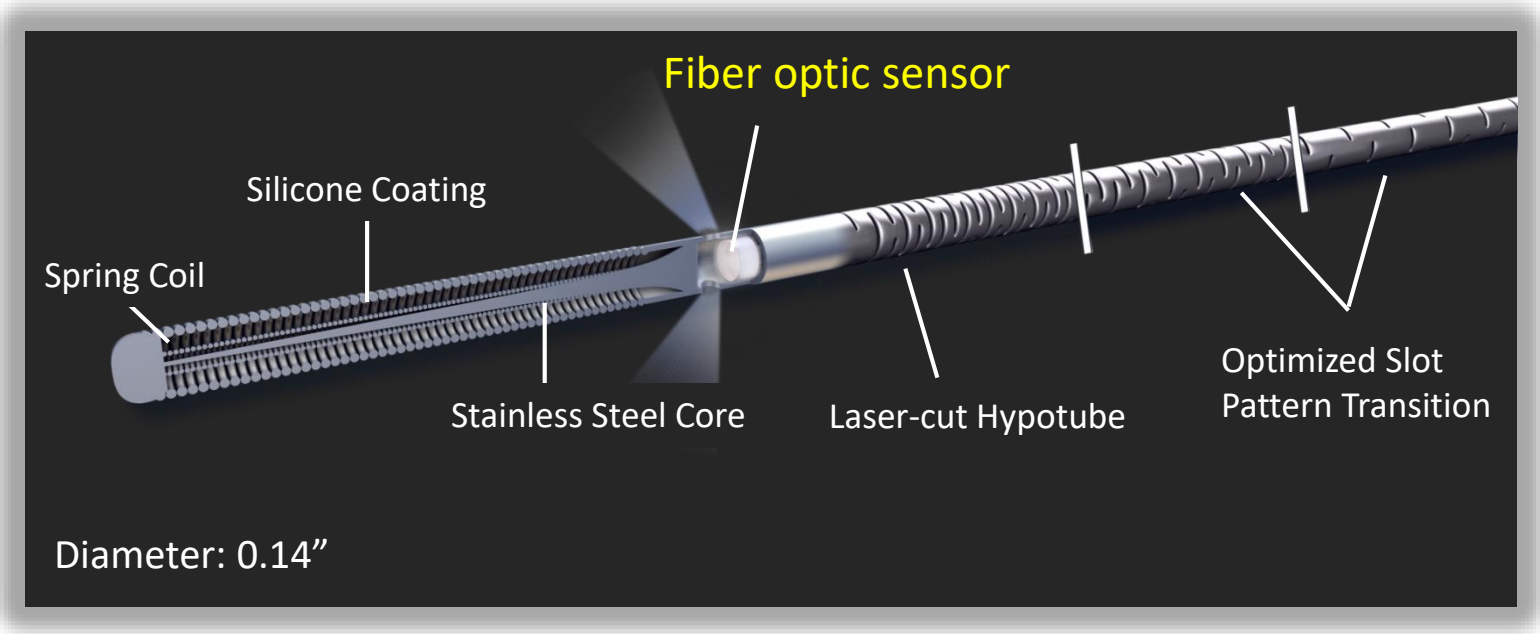
Background & Aim

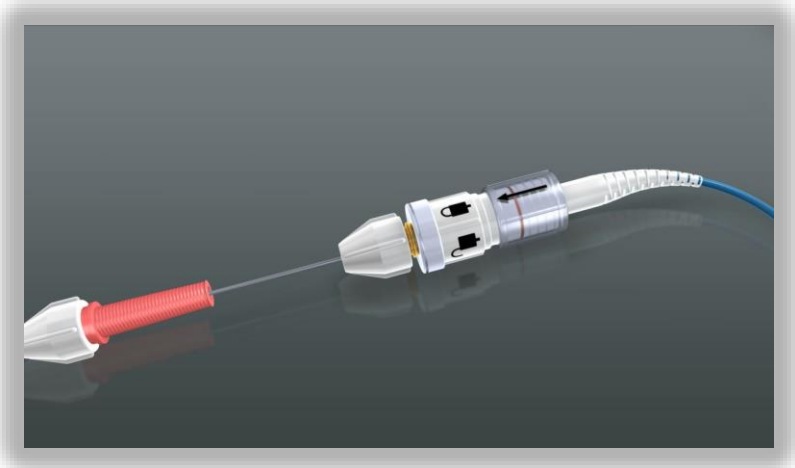
- The evidence base for the use of FFR in the diagnosis and management of patients with chest pain is robust
- Despite this, the uptake of pressure wire (PW) for routine assessment of coronary lesions remains low
- The most established PW systems available in clinical practice are the products of St Jude Medical (SJ) & Volcano Phillips
- Recently, the Boston Scientific *COMET*™ wire received CE Mark and has entered routine clinical practice
- There are, as yet, no suitably powered randomised trials using the PW systematically at the stage of diagnostic angiography and comparing outcome with management based upon angiography alone.
- This is the gap that will be filled by the 1100 patient RIPCORD2 UK trial, which is using the *COMET*™ wire.

The aim of the COMET trial was to assess, in a novel, randomised fashion, the diagnostic performance & drift for *COMET*™ (BS) & St Jude (SJ) PW in a study that allocates patients to simultaneous paired readings using 3 groups:

(a) BS-BS; (b) SJ-SJ; (c) BS-SJ*

*(Group C sub-randomisation for wire to be passed first)


Fiber optic sensor
Silicone Coating
Spring Coil
Stainless Steel Core
Laser-cut Hypotube
Optimized Slot
Pattern Transition
Diameter: 0.14”



Primary Hypothesis

Is the magnitude of the difference observed in paired simultaneous recordings of coronary pressures any different with the use of BS & SJ PW when compared to 2 x SJ PW ?

Statistical Considerations

100 patients – measuring FFR in 1.5 vessels per case = 150 vessels examined

In each vessel: Baseline Pd/Pa + FFR = 300 paired observations (ie 100 in each group)

For the primary outcome (Magnitude of delta SJ/SJ v Magnitude of delta BS/SJ):

assuming a control delta of 0.01 (SD 0.03) for 2 groups, each of 100 paired sets

we have 90% power to detect a difference of 0.0135

Precision Method:

For an observed mean difference of 0.01

Associated 95% CI for this point estimate would be (0.0041 - 0.016):

Method

- ✓ Ethical approval granted for written informed consent in cases in whom FFR is clinically indicated
- ✓ Elective & NSTACS
- ✓ Web based randomisation after diagnostic angiography
- ✓ 2 centres (Southampton & Liverpool)
- ✓ Patients randomised to one of 3 paired wire options:
  - BS - BS n of Patients = 37 n of Paired Readings = 90
  - SJ - SJ n of Patients = 34 n of Paired Readings = 90
  - BS - SJ n of Patients = 35 n of Paired Readings = 108

  (BS/SJ sub-randomised for wire to be passed first)

- ✓ For each vessel, 4 simultaneous pressure recordings were taken with the wires at exactly the same position…

1. Equalisation at the guide catheter tip
2. Baseline Pd/Pa at the target measurement site in the distal vessel
3. FFR at the target measurement site (steady state maximum hyperaemia using iv adenosine)
4. Final Pd/Pa at the guide catheter tip (for estimation of "drift")

   BS Drift estimation in 142 vessels; SJ Drift estimation in 137 vessels

Results- between wire comparison

Primary Outcome

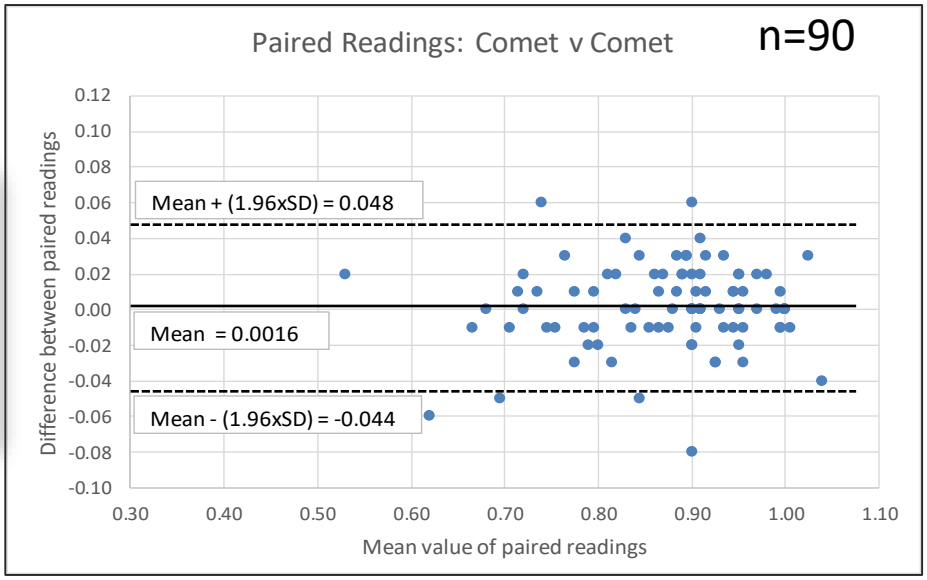
Observed absolute Δ

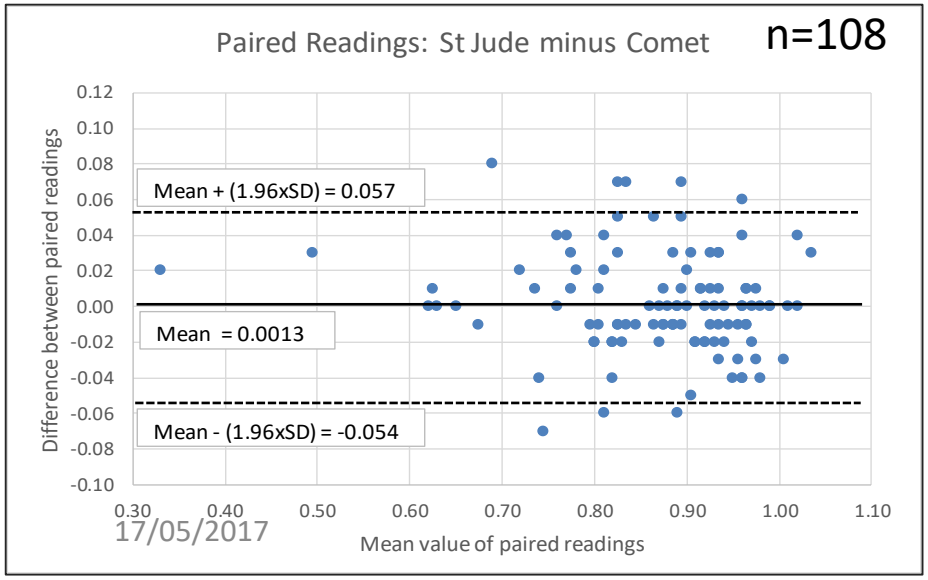
(irrespective of sign - Median and IQR)

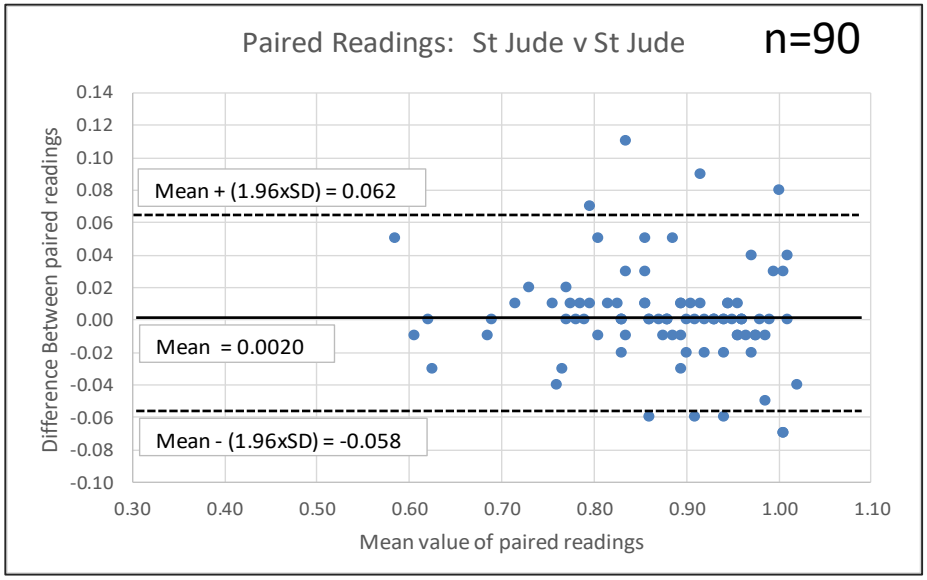
BS-SJ Median = 0.01 IQR (0.01 – 0.0225)

SJ-SJ Median = 0.015 IQR (0.01 – 0.03)

(p = 0.61 Mann-Whitney test)







Results - Drift

Primary Outcome

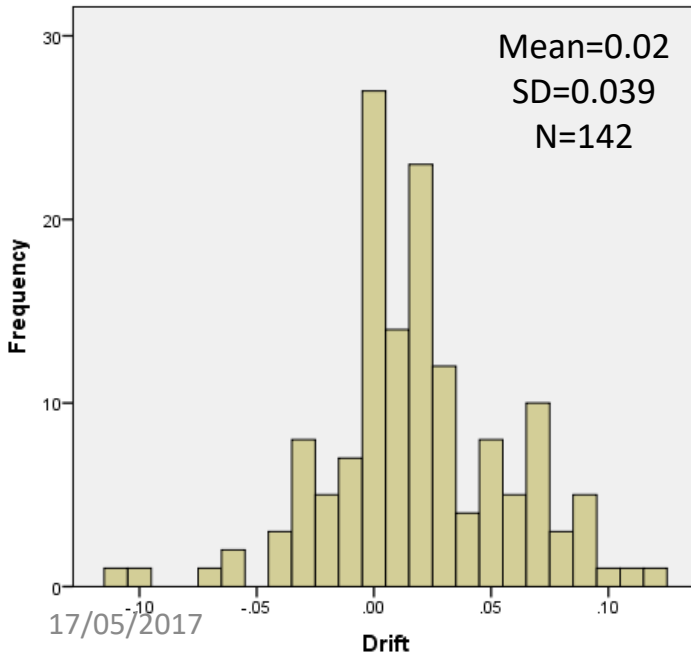
Observed absolute Δ from Pd/Pa=1.0 at equalisation

(irrespective of sign - Median and IQR)

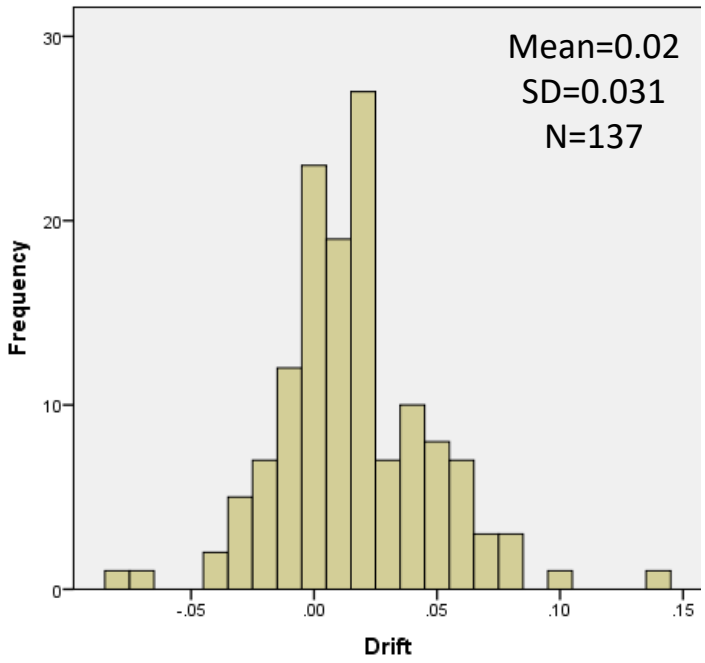
Boston	Median = 0.02	IQR (0.01 – 0.05)
St Jude	Median = 0.02	IQR (0.01 – 0.04)

(p = 0.14 Mann-Whitney test)

Boston Comet



St Jude



SUMMARY

✓ We have used a novel method for comparison of 2 diagnostic devices

✓ The magnitude of the difference between BS & SJ wires is no greater than between a pair of SJ wires

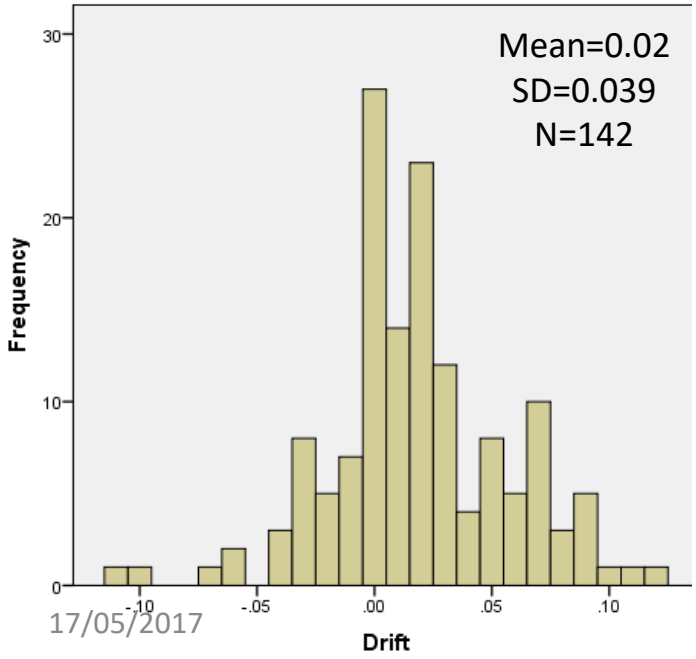
✓ Both types of PW tested in this trial exhibit a small degree of drift, but there is no significant difference between the magnitude of this drift observed using either wire

CONCLUSION

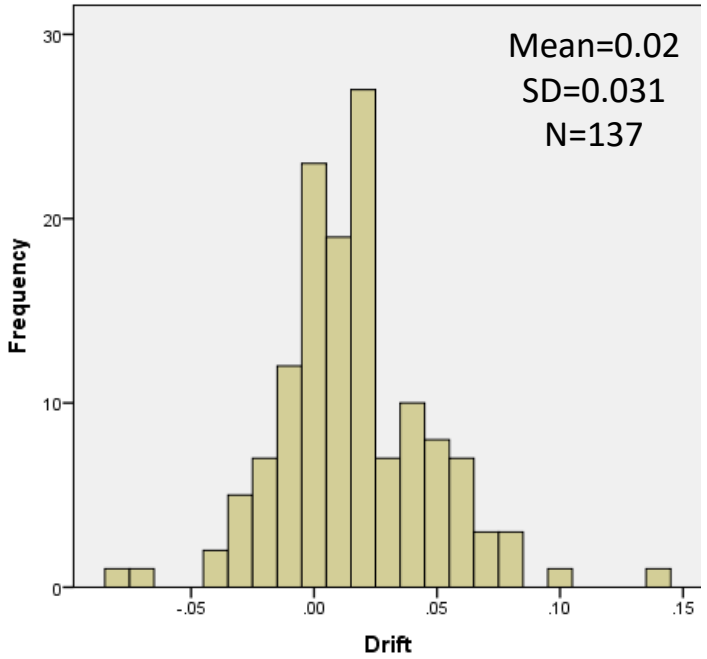
There is no significant difference in performance between the COMET & SJM PW

COMET Trial…. The Known Unknowns

Boston Comet



St Jude



How much drift is too much?

Should we routinely measure drift?

If so, what should we do about it?

17/05/2017

ACKNOWLEDGEMENTS

University Hospital Southampton NHS
NHS Foundation Trust

Research Staff: Zoe Nicholas, Sam Gough, Judy Radmore, Karen Banks, Julie Bigg,
Interventionists: Michael Mahmoudi, Simon Corbett, James Wilkinson, John Rawlins, Alison Calver, Iain Simpson
Catheter Lab Staff: especially Irvin , Phil Banks, Sarah Kingston & the cardiac physiology team

Liverpool Heart and Chest Hospital NHS
NHS Foundation Trust

Research Staff: Mostafa Elguindy, Ian Kemp, Jan Barton, Alexandra Thompson, Christine Mars
Interventionists: John Morris, Mike Fisher, Jow Mills
Catheter Lab Staff: especially Paul Wright, Emer Burton & the cardiac physiology team