EVALUATION OF CONTEMPORARY OXYGENATOR PERFORMANCE

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AGENDA

- BACKGROUND/GOALS
- BENCH-TOP ANALYSIS
  - GME
- CLINICAL ANALYSIS
  - MULTICENTER EVALUATION OF CONTEMPORARY OXYGENATORS
  - *POST-HOC* ANALYSIS

BACKGROUND

- CARDIAC SURGERY IS COMPLEX
- OUTCOMES ARE THE SUM OF A LARGE NUMBER OF COMPONENTS, BUT GENERALLY SAFE…
  - **WHY?**
    - MANY TECHNOLOGICAL ADVANCEMENTS IN CARDIAC SURGERY
      - SURGICAL/ANESTHETIC PRACTICE
      - PERFUSION PRACTICE/EQUIPMENT
        - INCREASED BIOCOMPATIBILITY: CIRCUIT COATINGS, REDUCED SURFACE AREA
        - REDUCED PRIME: INTEGRATED ARTERIAL FILTERS, SMALLER OXYGENATORS

GOAL

- ***QUALITY ASSURANCE INITIATIVE TO IDENTIFY THE BEST OXYGENATOR FOR OUR CARDIAC SURGERY PATIENTS***

  - **<u>HOW:</u>**
    - **BENCH-TOP AND CLINICAL EVALUATIONS**

SOURCE MATERIAL

- **CLINICAL EVALUATION OF CONTEMPORARY OXYGENATORS**", STANZEL AND HENDERSON, *PERFUSION* 2015
- **"AN *IN VITRO* EVALUATION OF GASEOUS MICROEMBOLI HANDLING BY CONTEMPORARY VENOUS RESERVOIRS AND OXYGENATOR SYSTEMS USING EDAC**", STANZEL AND HENDERSON, *PERFUSION* 2015
- **"IS THERE A RELATIONSHIP BETWEEN PRESSURE GRADIENTS THROUGH CONTEMPORARY OXYGENATORS AND IMMUNE CELL PROLIFERATION DURING CARDIOPULMONARY BYPASS? A PILOT STUDY"**, STANZEL AND HENDERSON, JECT, 2017.
- **"A CLINICAL EVALUATION OF CONTEMPORARY OXYGENATORS: A MULTI-CENTRE EVALUATION"**, *STANZEL, HENDERSON AND O'REILLY. IN PREPARATION FOR SUBMISSION.*

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GASEOUS MICROEMBOLI

- **HARMS OF GASEOUS MICRO EMBOLI**
  - CPB GENERATES GME
    - CAN OBSTRUCT END-ORGAN PERFUSION
  - CEREBRAL ISCHEMIA?
    - POST OPERATIVE DYSFUNCTION, TRANSIENT TO PERMANENT
- **GOALS:**
  - IDENTIFY OPTIMUM CPB PRODUCTS TO PROTECT PATIENTS FROM GME:
    - VENOUS RESERVOIR
    - OXYGENATOR
    - SYSTEM
- EMBOLI DETECTION AND CLASSIFICATION (EDAC™):
  - EVALUATE VARIOUS SIZES OF GME
  - EVALUATE O*VERALL* GME LOAD

GASEOUS MICROEMBOLI

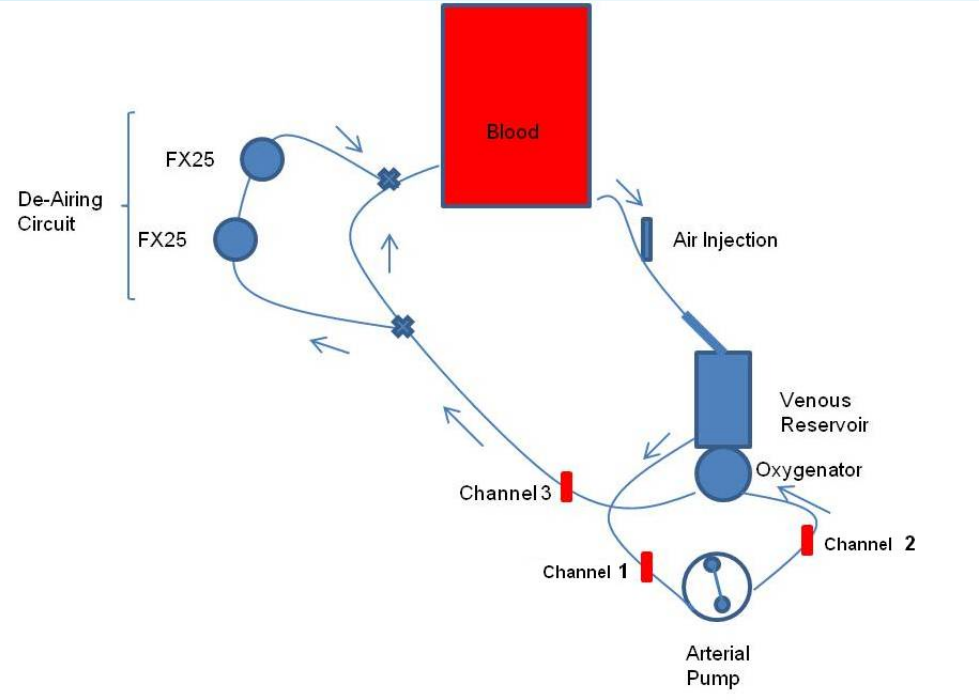
- PRODUCTS:
  - *SORIN SYNTHESIS*
  - *SORIN INSPIRE (6 AND 8)*
  - *TERUMO FX (15 AND 25)*
  - *MAQUET QUADROX-I*

- PARAMETERS:
  - BLOOD:
    - BOVINE
      - 15 L
      - HCT 30 ± 2
      - BE 0 ± 2
      - PH 7.1 – 7.3

- OXYGENATOR SET UP:
  - FLUSHED (3 LPM CO_2 FOR 5 MIN) AND PRIMED AS PER MANUFACTURERS' INSTRUCTIONS
  - 4 LPM FLOW
  - VENOUS RESERVOIR AT MINIMUM OPERATING VOLUME
  - RUN AS PER MANUFACTURERS' INSTRUCTIONS
- AIR INTRODUCTION:
  - 30 SECONDS BASELINE
  - 1 MINUTE OF ROOM AIR (100 CC OVER 1 MINUTE)
- AFTER COMPLETION:
  - CIRCUIT DE-AIRED PRIOR TO NEXT ANALYSIS
  - ONE OF EACH OXYGENATORS
    - 2 RUNS PER OXYGENATOR

GASEOUS MICROEMBOLI

- SET-UP:

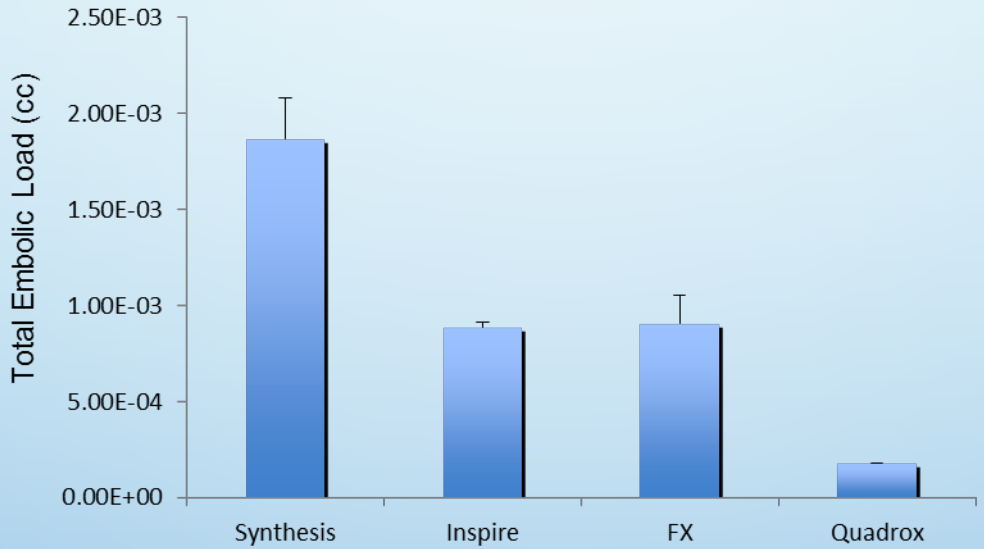


- GME DETECTION
  - CHANNEL 1: DISTAL VENOUS RESERVOIR
  - CHANNEL 2: DISTAL ARTERIAL ROLLER PUMP
  - CHANNEL 3: DISTAL OXYGENATOR

- PROCEDURE:
  - BASELINE GME ESTABLISHED (<10 EMBOLI/6 SECONDS)
  - AIR INJECTION
    - 100 CC ROOM AIR OVER 1 MINUTE THROUGH STOPCOCK IN VENOUS LINE
  - GME DATA RECORDED DURING AIR INJECTION THEN FOLLOWING 3 MINUTES

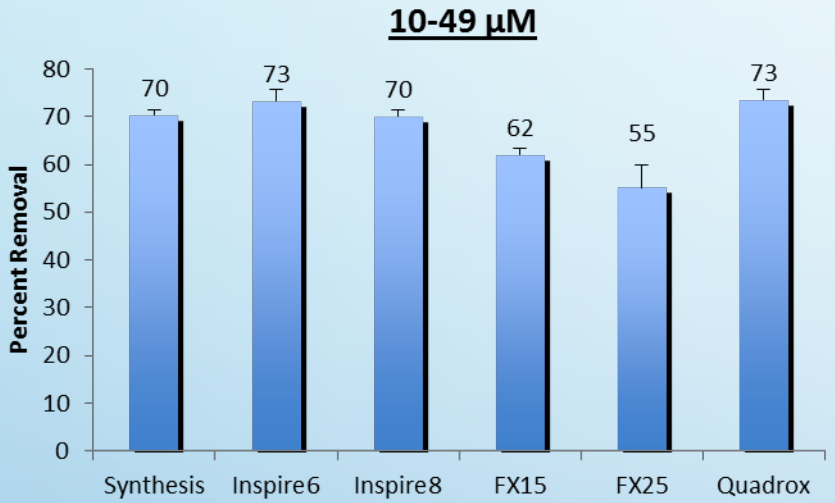
GASEOUS MICROEMBOLI

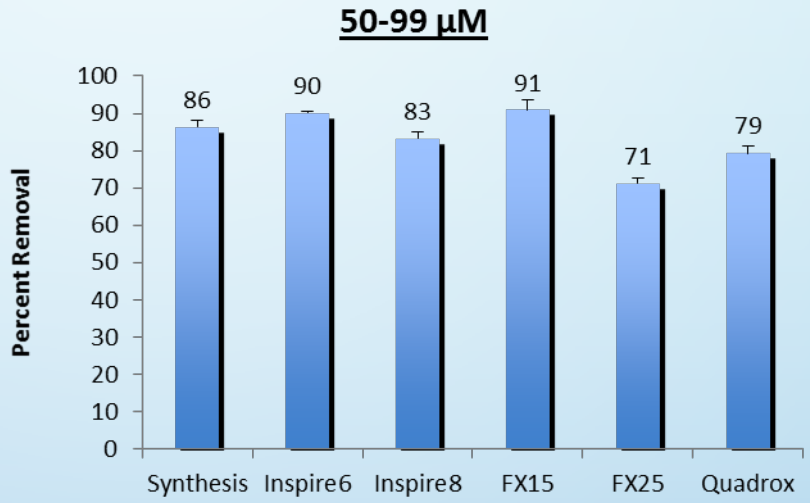
Reservoir:

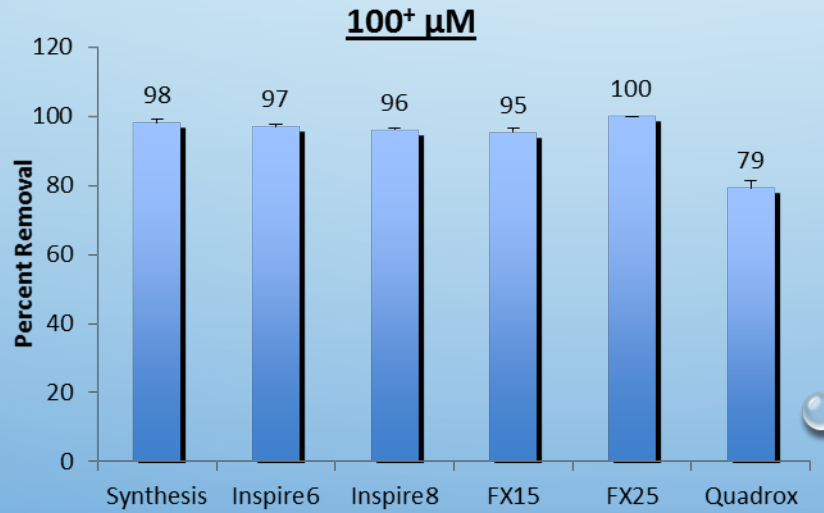


GASEOUS MICROEMBOLI

Oxygenator:

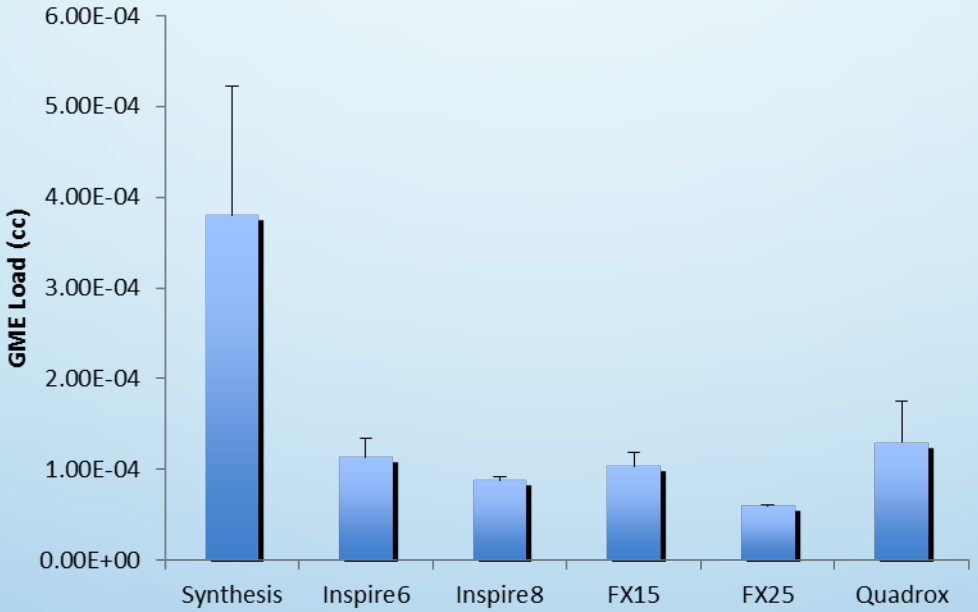






GASEOUS MICROEMBOLI

Total System:



GASEOUS MICROEMBOLI

- CONCLUSIONS:
  - VARYING ABILITY TO REMOVE GME
    - RESERVOIR: MAQUET SUPERIOR
    - OXYGENATOR: COMPARABLE, EXCEPT MAQUET WITH 100 MM+ GME
    - SYSTEM: SYNTHESIS INFERIOR
  - NEWER TECHNOLOGY HAS IMPROVED GME HANDLING

AGENDA

- BACKGROUND/GOALS
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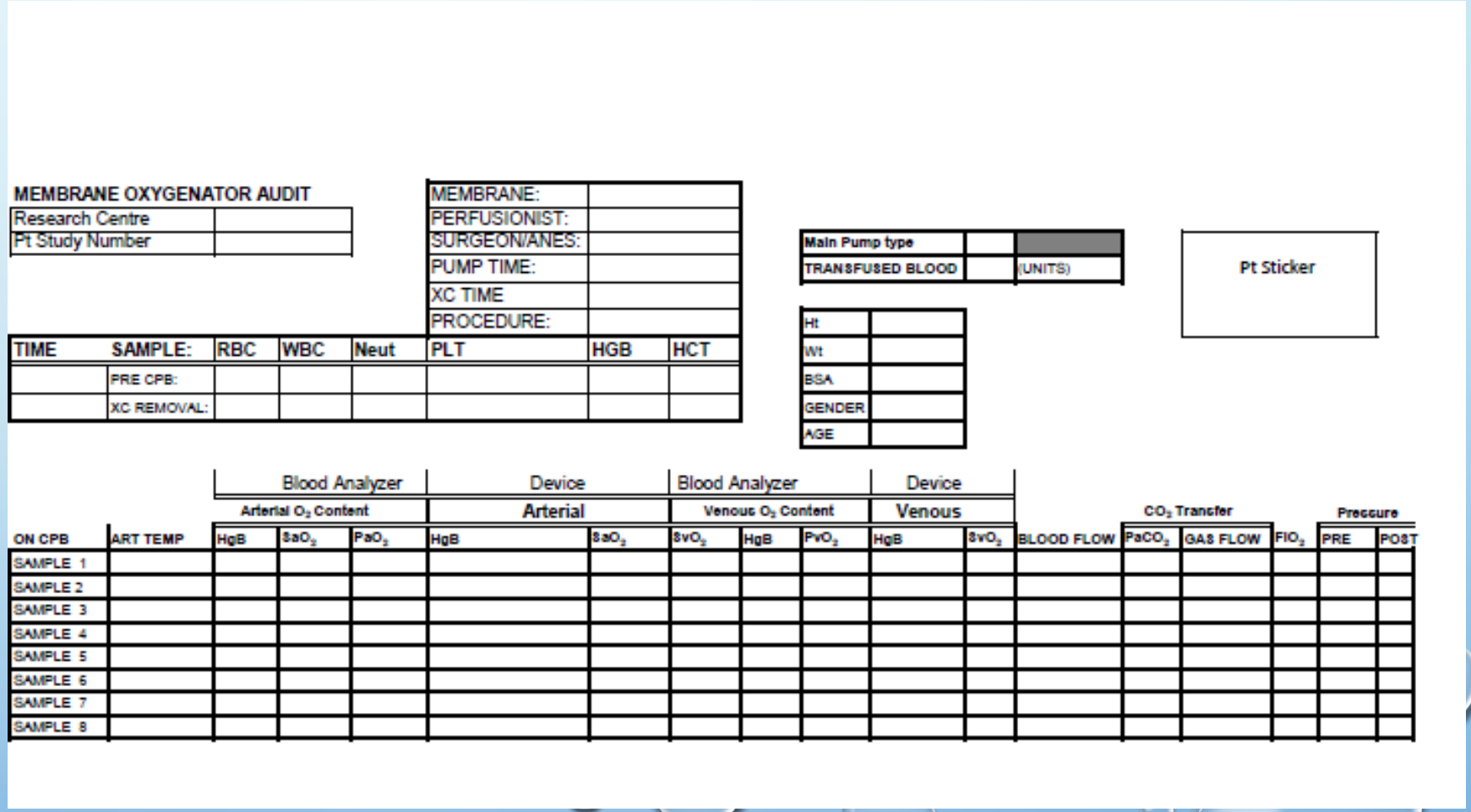
  - MULTICENTER EVALUATION OF CONTEMPORARY OXYGENATORS
  - *POST-HOC* ANALYSIS

MULTICENTER CLINICAL EVALUATION

- IN 2015, HALIFAX CONDUCTED SMALL CLINICAL EVALUATION OF CURRENT OXYGENATOR AND NEW OXYGENATORS
- METRICS
    - PRIME
    - GAS EXCHANGE
    - PRESSURE GRADIENTS
    - EFFECTS ON BLOOD ELEMENTS
- SIGNIFICANT DIFFERENCES
- ARE THESE REPRODUCIBLE?
    - SMALL MULTICENTRE EVALUATION USING THE SAME PROTOCOL
        - HYPOTHESIS:
            - ***DATA FROM OTHER CENTERS AGREE WITH INITIAL EVALUATION***

MULTICENTER CLINICAL EVALUATION

- PARTICIPATING CENTERS:
  - HALIFAX
  - NEW BRUNSWICK
  - LONDON
- OXYGENATORS:
  - FX25
  - INSPIRE-8
  - QUADROX-I
- N = 100
- STATISTICS
  - CATEGORICAL DATA
    - FISCHER'S EXACT TEST
  - QUANTITATIVE DATA
    - ANOVA WITH BONFERRONI CORRECTION



MEMBRANE OXYGENATOR AUDIT

Research Centre	
Pt Study Number	

MEMBRANE:	
PERFUSIONIST:	
SURGEON/ANES:	
PUMP TIME:	
XC TIME	
PROCEDURE:	

Main Pump type	
TRANSFUSED BLOOD	(UNITS)

Pt Sticker

Ht	
Wt	
BSA	
GENDER	
AGE	

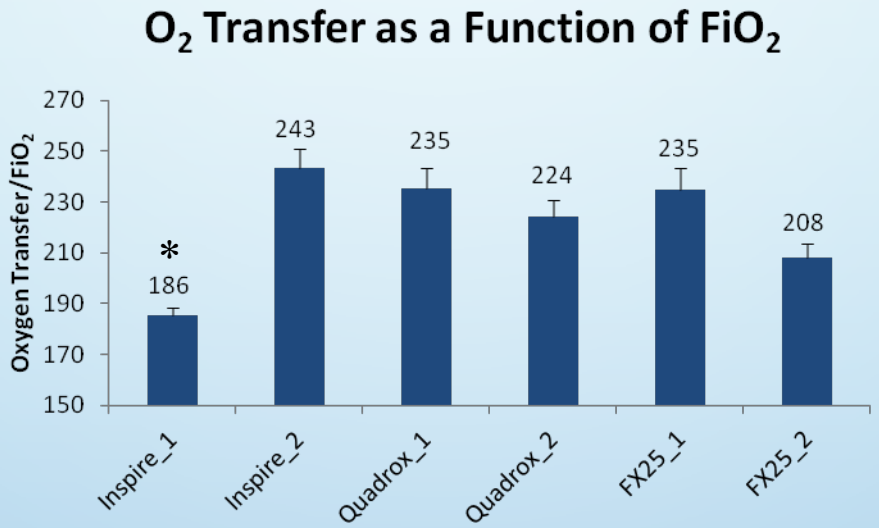
TIME	SAMPLE:	RBC	WBC	Neut	PLT	HGB	HCT
	PRE CPB:						
	XC REMOVAL:						

		Blood Analyzer			Device		Blood Analyzer			Device							
		Arterial O_2 Content			Arterial		Venous O_2 Content			Venous			CO_2 Transfer			Preccure	
ON CPB	ART TEMP	HgB	SaO_2	PaO_2	HgB	SaO_2	SvO_2	HgB	PvO_2	HgB	SvO_2	BLOOD FLOW	$PaCO_2$	GAS FLOW	FIO_2	PRE	POST
SAMPLE 1																	
SAMPLE 2																	
SAMPLE 3																	
SAMPLE 4																	
SAMPLE 5																	
SAMPLE 6																	
SAMPLE 7																	
SAMPLE 8																	

MULTICENTER CLINICAL EVALUATION

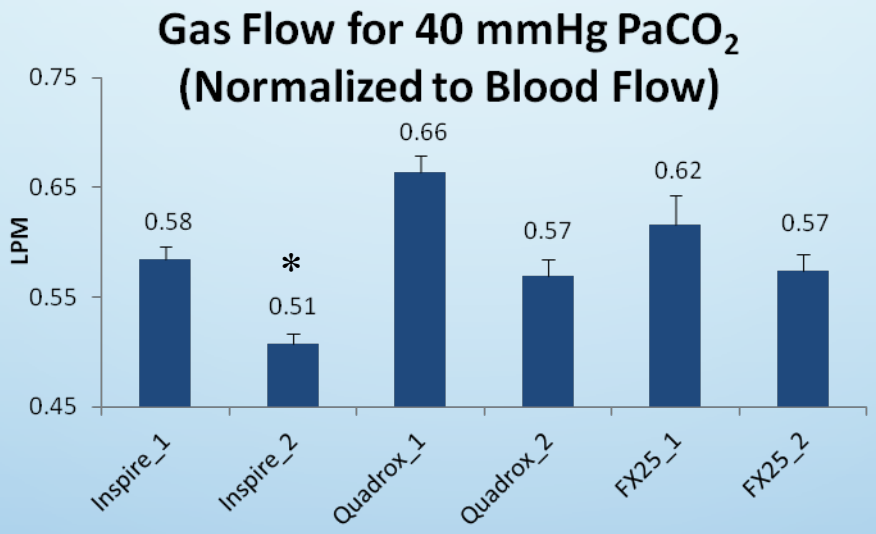
- NO DIFFERENCES IN PATIENT OR CASE DEMOGRAPHICS

MULTICENTER CLINICAL EVALUATION



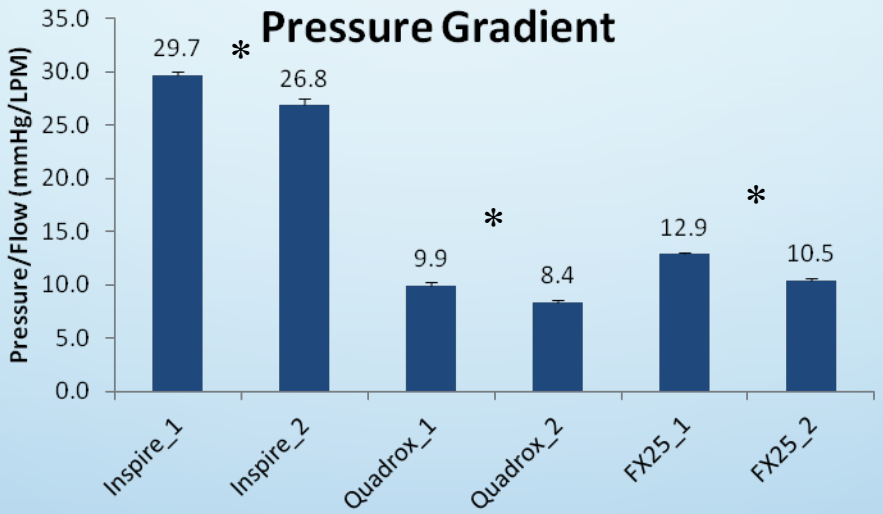
Inspire_1 had lowest O_2 transfer (except FX25)

MULTICENTER CLINICAL EVALUATION



Inspire_2 required lower gas flow than Quadrox_1 to achieve 40 mmHg $PaCO_2$

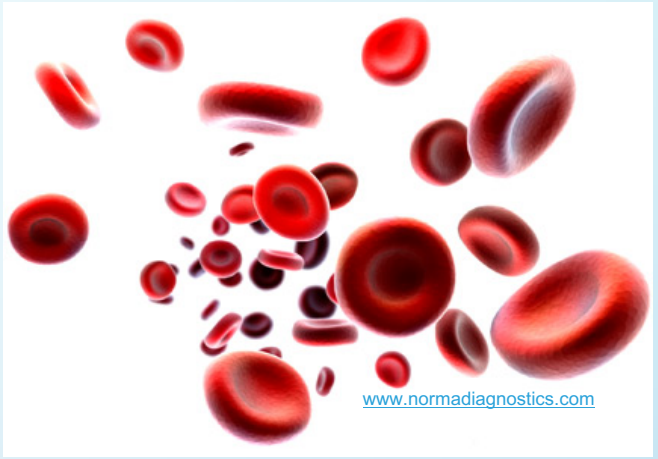
MULTICENTER CLINICAL EVALUATION



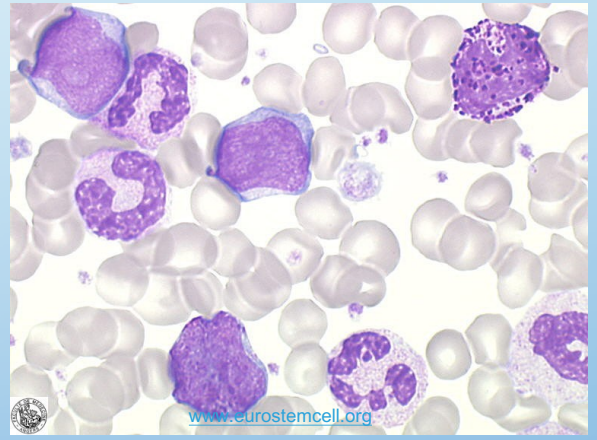
Inspire > FX25 > Quadrox

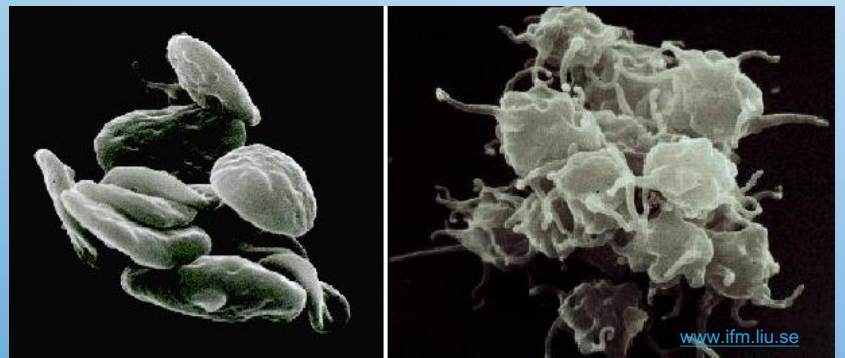
HEMATOLOGY

- CORE LABORATORY SERVICES (QEII)



- SAMPLES:
  - POST-HEPARIN, PRE-CPB (BASELINE)
  - POST-CROSS CLAMP
- PARAMETERS:
  - HEMOGLOBIN, PLATELETS, WHITE BLOOD CELLS
- EVALUATION:
  - NORMALIZED TO ‘POST-HEPARIN’ VALUE
    - % BASELINE





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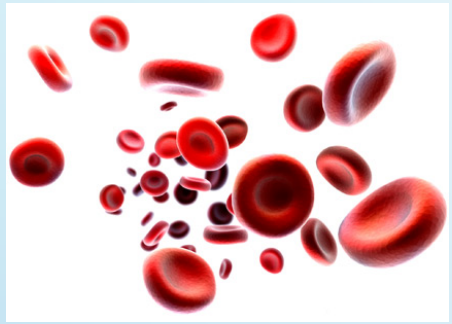
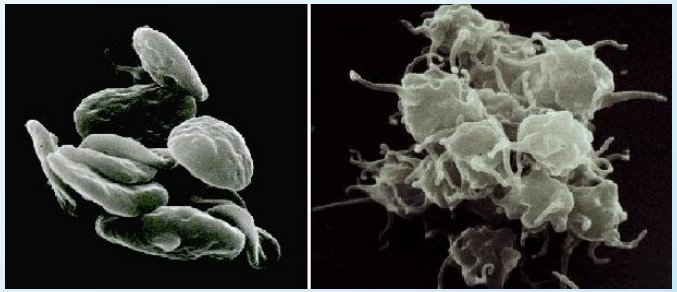
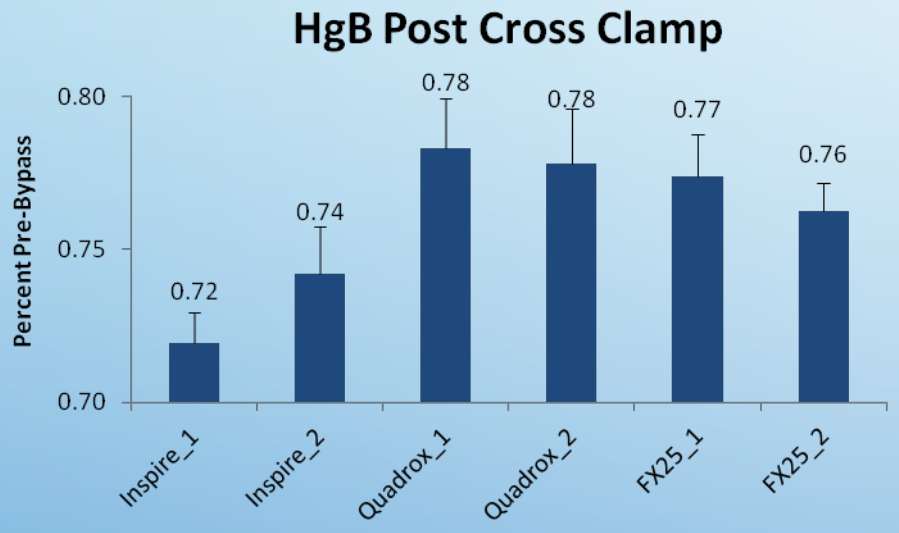
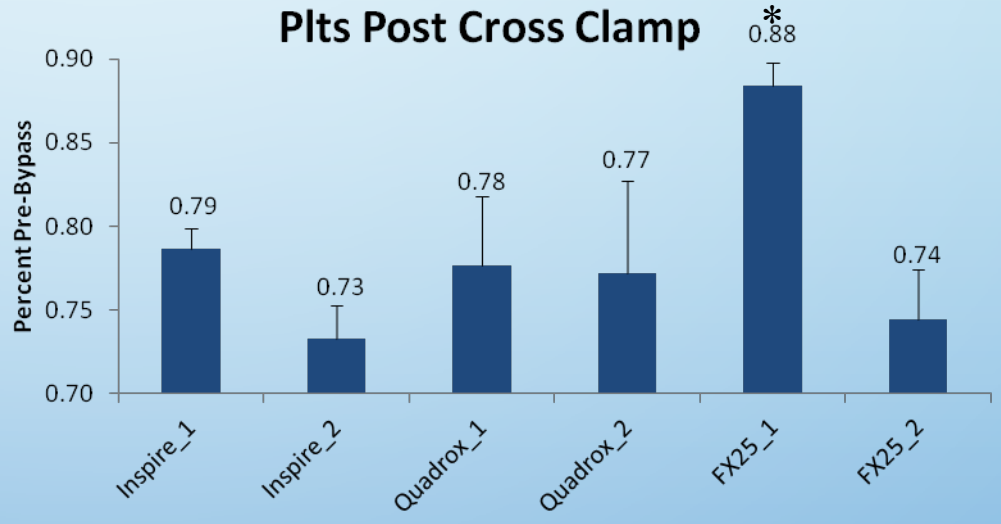




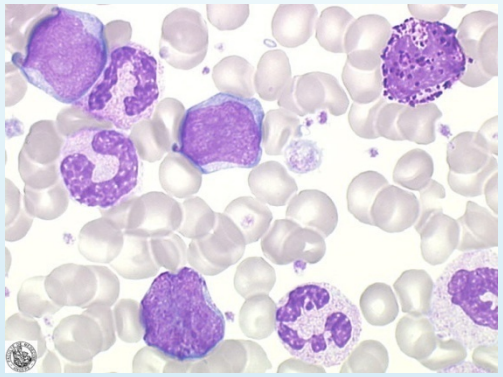


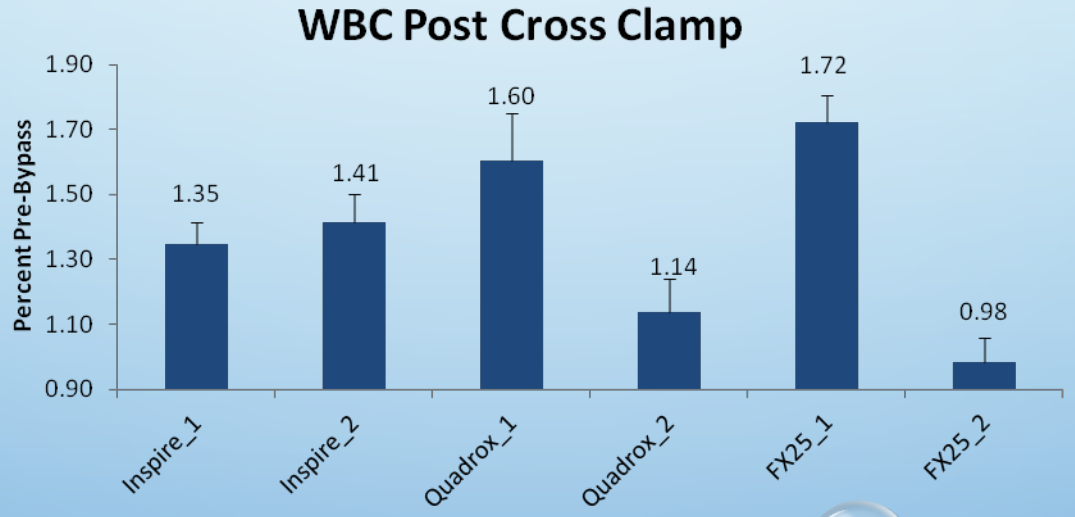


Inspire_1 < FX25_1

FX25_1 had greatest Plt retention

MULTICENTER CLINICAL EVALUATION





FX25_1 > Inspire_1, Quadrox_2 and FX25-2
Quadrox_1 > FX25_2

MULTICENTER CLINICAL EVALUATION

- CONCLUSIONS
  - OBSERVED UNEXPECTED DIFFERENCES TO INITIAL EVALUATION
    - GAS EXCHANGE
    - HGB
    - PLT
    - WBC
  - WHY?
    - DIFFERENCES IN CLINICAL PRACTICE?
    - WHAT ARE THEY…?

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UNDER PRESSURE?

$\tau > 75$ dynes/cm^2: **Leukocytes**

Sublytic granule release, adhesion, aggregation and phagocytosis

- SHEAR STRESS IN AN OXYGENATOR (T)= $\{(\eta \times Q_{blood} \times \Delta P)/(V_{prime})\}$

Where:

η = absolute viscosity

Q_{blood} = blood flow

ΔP = pressure drop

V_{prime} = prime volume

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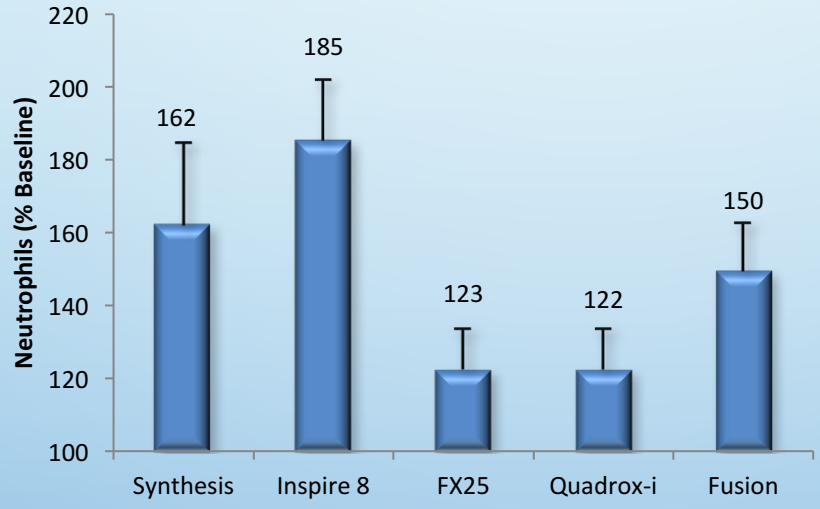

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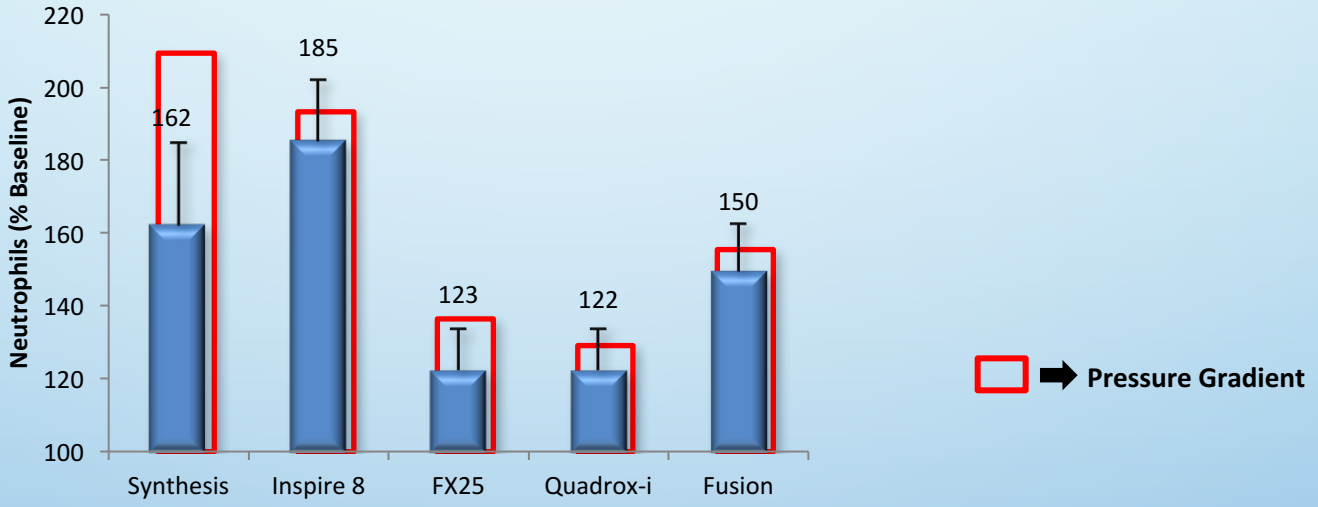
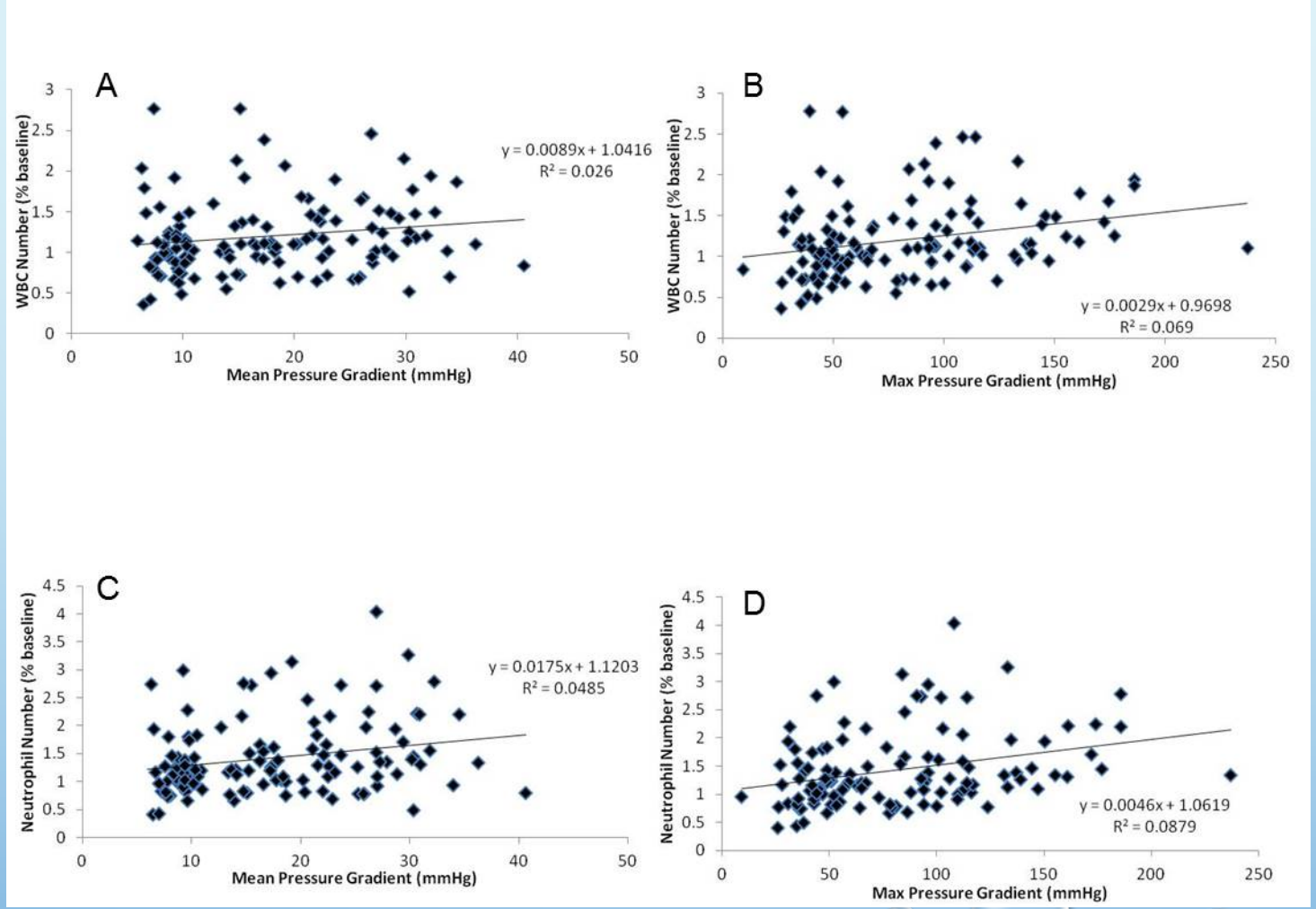


High pressure-drop oxygenators may be pro-inflammatory?

UNDER PRESSURE?



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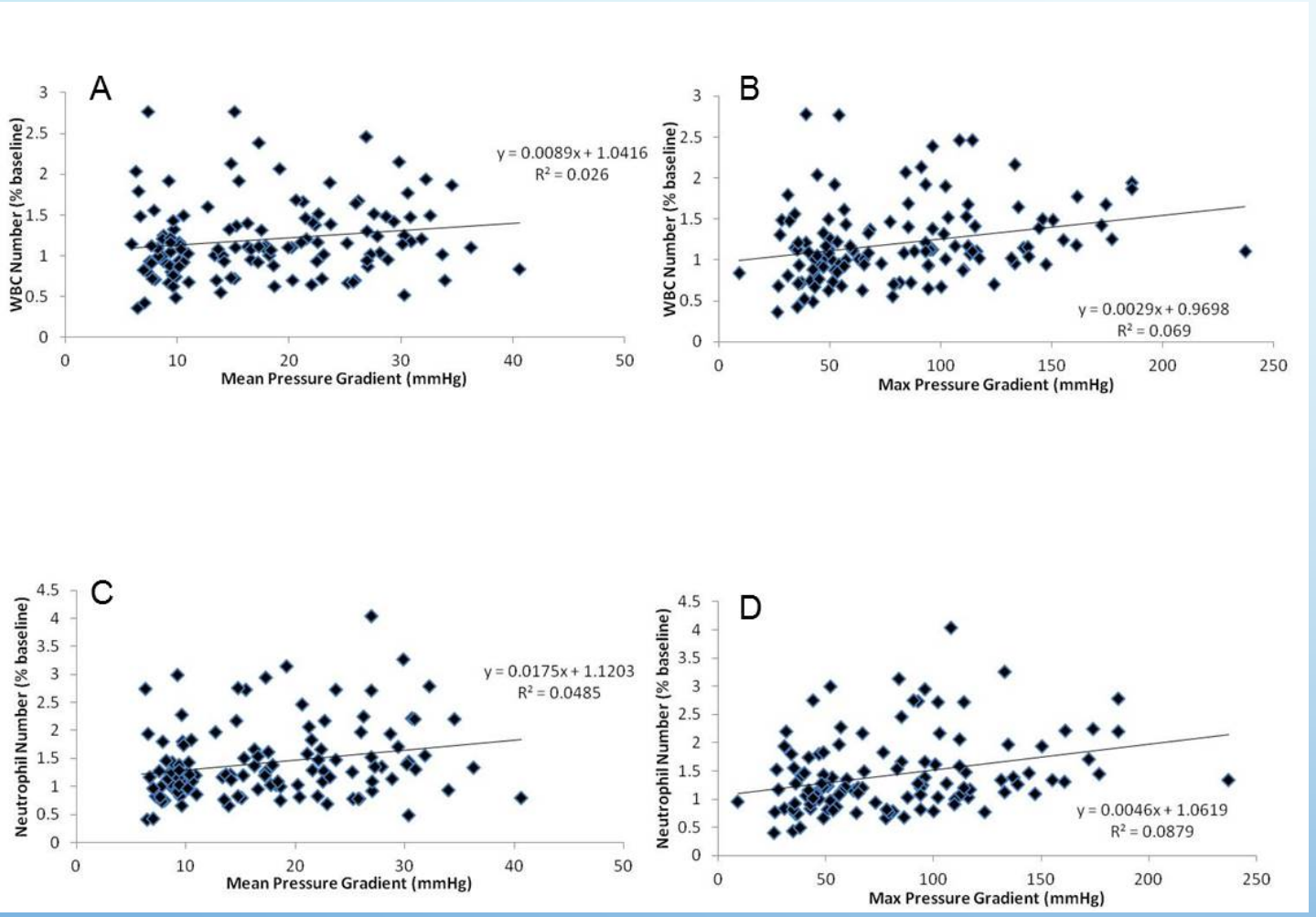

- NO CORRELATION BETWEEN PRESSURE AND IMMUNE CELL PROLIFERATION ON CPB
- <u>CONCLUSION:</u>
  - OTHER FACTORS RESPONSIBLE
  - COATINGS
  - OXYGENATOR DESIGN
  - ?

CONCLUSIONS

- MODERN TECHNOLOGY HAVE IMPROVED GME REMOVAL
- DIFFERENCES IN CLINICAL PERFORMANCE
- GAS EXCHANGE, CBC
- PRESSURE DROP NOT RESPONSIBLE FOR DIFFERENCES IN IMMUNE CELL INCREASES

FUTURE GOALS

- ANSWER THE QUESTION: WHY THE DIFFERENCES IN CLINICAL PERFORMANCE?
  - INCREASING NUMBER OF PARTICIPATING CENTERS
- ONGOING QUALITY ASSURANCE
  - TRACK OXYGENATOR PERFORMANCE
  - ESTABLISH A BASELINE AND ASSESS IMPACTS OF CHANGE IN PRACTICE
- RE-INVIGORATE INTEREST IN PERFUSION RESEARCH

THANK YOU

- CSCP CMOC
- BILL HILL, LANCE MITCHELL AND NSHA PERFUSION STAFF
- CHRIS MACKAY AND LHSC PERFUSION STAFF
- HNH PERFUSION STAFF