

# Evaluation of Bacterial and Fungal Growth in a Primed ECMO Circuit



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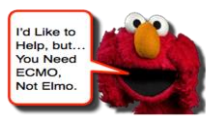
# Disclosure

- I have no disclosures



# Overview

- Background
- Methods
- Results
- Conclusion



**Is it safe to leave an ECMO circuit primed?**

Perfusion 2015, Vol. 30(1) 47-49  
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DOI: 10.1177/0885066614264892

**A Weinberg,<sup>1</sup> B Miko,<sup>2</sup> J Beck,<sup>1</sup> M Bacchetta<sup>3</sup> and L Mongero<sup>1</sup>**

**SAGE**

- 30 days
- Rising needs for ECPR and rapid deployment primed circuits
  - Survival rate vs Discharge rate
    - Adults: 38% vs 29%
    - Peds: 54% vs 41%
    - Neonates: 64% vs 40%
- Increase in cost
  - Disposables: \$2,200-\$15,000
- Help improve response time while keeping cost down and preserving primed ECMO circuits longer



**Wet-priming extracorporeal membrane oxygenation device maintains sterility for up to 35 days of follow-up**

F. Naso,<sup>1</sup> A. Gandaglia,<sup>1</sup> P. Balboni,<sup>2</sup> F. Zanella,<sup>3</sup> R. Danesin,<sup>4</sup> M. Spina<sup>5</sup> and G. Gerosa<sup>1</sup>

Published online 2018  
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DOI: 10.1177/0885066618781111  
jicm.sagepub.com

- 8 circuits and 3 groups. Dideco PMP oxygenator/Revolution
  - R circuits (n=3)
    - Continuously circulated circuits, sampled every 7 days for 35 days at 37° C
  - NR circuits (n=3)
    - Non-circulated circuits, placed at 37° C, sampled every 7 days for 35 days
    - Circuits were circulated for 15 mins prior to each sample
  - P circuits (n=2)
    - Added 5 ml of E.Coli
    - Sampling times 3, 6, 19, 21 and 24 days
    - Visual count of E.Coli concentration



## Methods

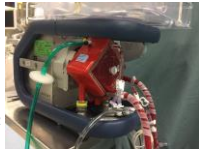
Circuit	Circuit Type	Primed Setup Time (days)	Wet Sterile Testing (weeks)	Sampling Intervals (weeks)	Function Tested
1	CardioHelp	0	12	Baseline, 2, 4, 5-12	No
2	CardioHelp	60	4	8, 10, 12	No
4	CardioHelp	263*	12	Baseline, 2, 4, 6, 8, 10, 12	No
3	Two-Base	30	8	4, 6, 8, 9, 10, 11, 12	No
5	Two-Base	60	4	8, 10, 12	No
6	Two-Base	60	4	8, 10, 12	Yes
7	Two-Base	60	4	8, 10, 12	Yes

\* Dry set up time



## Methods

- **Circuit 1**
    - Sterility
      - CardioHelp, no manipulation
      - Wet primed for 12 weeks
        - Sampled bag solution, Prime solution, weeks 2, 4, 5-12 for 12 weeks
      - Remained in OR pump room for sampling, draped
- **Circuit 2**
  - Sterility
    - CardioHelp with standard NCH setup
    - Wet primed for 8 weeks prior to testing
      - Sampled at weeks 8, 10 and 12 from prime date
    - Remained in OR pump room for sampling, draped



## Methods

- **Circuit 4**
  - NCH Rapid Deployment Circuit setup
    - CardioHelp
    - Dry for a year
      - Removed cardioplegia setup prior to wet priming
      - Housed in the OR pump room, draped
    - Sampled every 2 weeks for 12 weeks



## Methods



- **Circuit 3 and Circuit 5**
  - NCH Non-Cardiac Setup
    - Two base Pediatric Rotaflow/Quadrox-i setup
    - Circuit 3 was primed for 4 weeks prior to sampling; and circuit 5 was primed for 8 weeks prior to sampling
      - Housed in non-cardiac storage room, not draped
    - Both circuits were sampled every 2 weeks for 12 weeks



## Methods

- **Circuit 6 and Circuit 7**
  - NCH Non-Cardiac Setup
    - Two base Pediatric Rotaflow/Quadrox-i setup
    - Primed for 8 weeks prior to sampling
      - Housed in non-cardiac storage room, not draped
    - Sampled every 2 weeks for 12 weeks
  - Function
    - Tested in the OR with second oxygenator in line used as a "de-oxygenator" using expired human blood



## Methods

Culture Tests	Clinical Relevant Examples
<b>Sterility culture</b> <i>Identifying aerobic organisms</i>	Enterobacteriaceae, Pseudomonas sp., Staphylococcus sp., Streptococcus sp.
<b>Anaerobic culture</b> <i>Identifying anaerobic organisms</i>	Bacteroides sp., Fusobacterium sp., Porphyromonas sp., Prevotellasp., Clostridium sp., Peptostreptococcus sp., and Propionibacterium sp.
<b>Fungal culture</b> <i>Identifying Filamentous fungi or yeast</i>	Aspergillus, Penicillium, Cladosporium, Mucor, Rhizopus, Absidia, Trichophyton and Microsporium Yeast: Candida sp.



## Methods



Circuit	Circuit Type	Primed Setup Time (days)	Wet Sterile Testing (weeks)	Sampling Intervals (weeks)	Function Tested
1	CardioHelp	0	12	Baseline, 2, 4, 5-12	No
2	CardioHelp	60	4	8, 10, 12	No
4	CardioHelp	263*	12	Baseline, 2, 4, 6, 8, 10, 12	No
3	Two-Base	30	8	4, 6, 8, 9, 10, 11, 12	No
5	Two-Base	60	4	8, 10, 12	No
6	Two-Base	60	4	8, 10, 12	Yes
7	Two-Base	60	4	8, 10, 12	Yes

\* Dry set up time



## Results-Circuit 1

Circuit 1	Results			
	pH	Sterility culture	Anaerobic culture	Fungal culture
Bag Soln	6.812	NG	NG	NG
Prime Sample	6.787	NG	NG	NG
Week 2	6.848	NG	NG	NG
Week 4	6.834	NG	NG	NG
Week 5	6.957	NG	NG	NG
Week 6	6.921	NG	NG	NG
Week 7	6.864	NG	NG	NG
Week 8	6.901	NG	NG	NG
Week 9	6.926	NG	NG	NG
Week 10	6.891	NG	NG	NG
Week 11	6.915	NG	NG	NG
Week 12	6.886	NG	NG	NG

\*\* No Growth= NG



## Methods



Circuit	Circuit Type	Primed Setup Time (days)	Wet Sterile Testing (weeks)	Sampling Intervals (weeks)	Function Tested
1	CardioHelp	0	12	Baseline, 2, 4, 5-12	No
2	CardioHelp	60	4	8, 10, 12	No
4	CardioHelp	263*	12	Baseline, 2, 4, 6, 8, 10, 12	No
3	Two-Base	30	8	4, 6, 8, 9, 10, 11, 12	No
5	Two-Base	60	4	8, 10, 12	No
6	Two-Base	60	4	8, 10, 12	Yes
7	Two-Base	60	4	8, 10, 12	Yes

\* Dry set up time



## Results-Circuit 2

Circuit 2	Results			
	pH	Sterility culture	Anaerobic culture	Fungal culture
Week 8	6.846	NG	NG	NG
Week 10	6.873	NG	NG	NG
Week 12	6.931	NG	NG	NG

\*\* No Growth= NG



## Methods



Circuit	Circuit Type	Primed Setup Time (days)	Wet Sterile Testing (weeks)	Sampling Intervals (weeks)	Function Tested
1	CardioHelp	0	12	Baseline, 2, 4, 5-12	No
2	CardioHelp	60	4	8, 10, 12	No
4	CardioHelp	263*	12	Baseline, 2, 4, 6, 8, 10, 12	No
3	Two-Base	30	8	4, 6, 8, 9, 10, 11, 12	No
5	Two-Base	60	4	8, 10, 12	No
6	Two-Base	60	4	8, 10, 12	Yes
7	Two-Base	60	4	8, 10, 12	Yes

\* Dry set up time



## Results-Circuit 4

Circuit 4	Results			
	pH	Sterility culture	Anaerobic culture	Fungal culture
Prime Sample	6.697	NG	NG	NG
Week 2	6.768	NG	NG	NG
Week 4	6.793	NG	NG	NG
Week 6	6.845	NG	NG	NG
Week 8	6.786	NG	NG	NG
Week 10	6.826	NG	NG	NG
Week 12	6.837	NG	NG	NG

\*\* No Growth= NG



- Rapid Deployment Circuit
- Worse case scenario

## Methods



Circuit	Circuit Type	Primed Setup Time (days)	Wet Sterile Testing (weeks)	Sampling Intervals (weeks)	Function Tested
1	CardioHelp	0	12	Baseline, 2, 4, 5-12	No
2	CardioHelp	60	4	8, 10, 12	No
4	CardioHelp	263*	12	Baseline, 2, 4, 6, 8, 10, 12	No
3	Two-Base	30	8	4, 6, 8, 9, 10, 11, 12	No
5	Two-Base	60	4	8, 10, 12	No
6	Two-Base	60	4	8, 10, 12	Yes
7	Two-Base	60	4	8, 10, 12	Yes

\* Dry set up time



## Results-Circuit 3

Circuit 3	Results			
	pH	Sterility culture	Anaerobic culture	Fungal culture
Week 4	6.839	NG	NG	NG
Week 6	6.635	NG	NG	NG
Week 8	6.853	NG	NG	NG
Week 9	6.838	NG	NG	NG
Week 10	6.857	NG	NG	NG
Week 11	6.84	NG	NG	Rare Amt of Probable Geotrichum
Week 12	6.682	NG	NG	NG

\*\* No Growth= NG



## Methods



Circuit	Circuit Type	Primed Setup Time (days)	Wet Sterile Testing (weeks)	Sampling Intervals (weeks)	Function Tested
1	CardioHelp	0	12	Baseline, 2, 4, 5-12	No
2	CardioHelp	60	4	8, 10, 12	No
4	CardioHelp	263*	12	Baseline, 2, 4, 6, 8, 10, 12	No
3	Two-Base	30	8	4, 6, 8, 9, 10, 11, 12	No
5	Two-Base	60	4	8, 10, 12	No
6	Two-Base	60	4	8, 10, 12	Yes
7	Two-Base	60	4	8, 10, 12	Yes

\* Dry set up time





## Results-Circuit 5

Circuit 5	Results			
	pH	Sterility culture	Anaerobic culture	Fungal culture
Week 8	6.86	NG	NG	NG
Week 10	6.865	NG	NG	NG
Week 12	6.87	NG	NG	NG

\*\* No Growth= NG



## Methods



Circuit	Circuit Type	Primed Setup Time (days)	Wet Sterile Testing (weeks)	Sampling Intervals (weeks)	Function Tested
1	CardioHelp	0	12	Baseline, 2, 4, 5-12	No
2	CardioHelp	60	4	8, 10, 12	No
4	CardioHelp	263*	12	Baseline, 2, 4, 6, 8, 10, 12	No
3	Two-Base	30	8	4, 6, 8, 9, 10, 11, 12	No
5	Two-Base	60	4	8, 10, 12	No
6	Two-Base	60	4	8, 10, 12	Yes
7	Two-Base	60	4	8, 10, 12	Yes

\* Dry set up time



## Results-Circuit 6

Circuit 6	Results			
	pH	Sterility culture	Anaerobic culture	Fungal culture
Week 8	6.819	NG	NG	NG
Week 10	6.785	NG	NG	NG
Week 12	6.82	NG	NG	NG

\*\* No Growth= NG



## Results-Circuit 7

Circuit 7	Results			
	pH	Sterility culture	Anaerobic culture	Fungal culture
Week 8	6.86	NG	NG	NG
Week 10	6.865	NG	Lab Error	Lab Error
Week 12	6.87	NG	NG	NG

\*\* No Growth= NG



## Results

Arterial blood gas results for circuit 6 & 7

	pH	pCO2	pO2	BE	Temp	SvO2
<b>0.5-1.0</b>						
Baseline	7.41	39	199	0	35.4	100
90	7.42	39.9	200	0	35.4	100
180	7.43				35.4	100
270	7.4				35.4	100
360	7.43				35.4	100
<b>1.0-1.0</b>						
Baseline	7.57				35.4	100
90	7.42				35.4	100
180	7.43				35.4	100
270	7.38				35.4	100
360	7.44				35.4	100
<b>2.0-1.0</b>						
Baseline	7.56				35.4	100
90	7.48				35.4	100
180	7.46				35.4	100
270	7.44				35.4	100
360	7.48	30.4	234	0	35.4	100

**AAMI Standards**  
 pH:  
 pCO2:  
 pO2:  
 BE:  
 Temp:  
 SvO2:

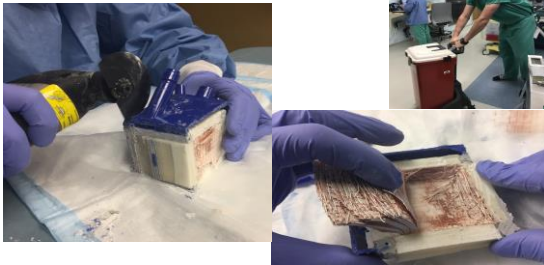


## Scanning Electron Microscope

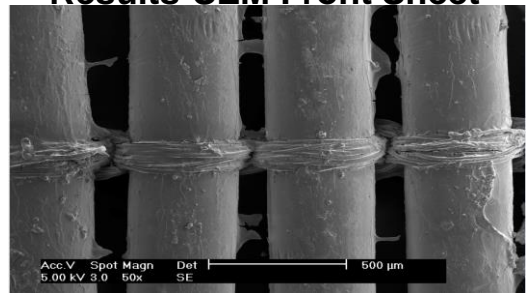
- Circuit 3
- Drying process
  - 100% EtOH for 5 mins, 3 times
  - Open to air for 1 week- dry time
- Cut open the membrane
  - Collected samples from the front, middle and back of fiber bundle
  - Two sheets each section
  - Placed in sterile containers
- Gold plated
- SEM at Ohio State University Department of Engineering



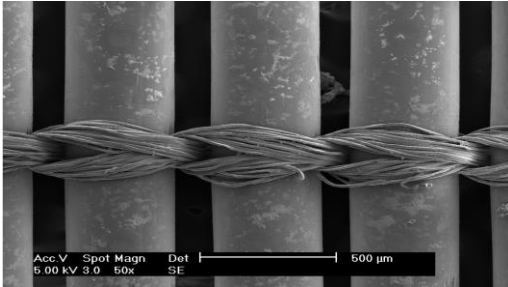
## SEM



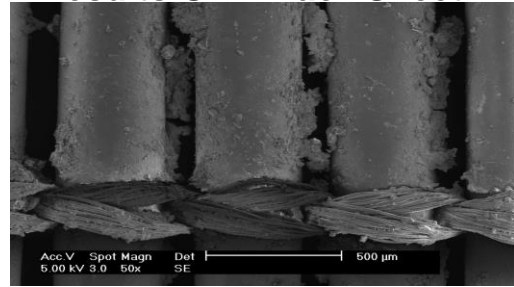
## Results-SEM Front Sheet



## Results-SEM Middle Sheet



## Results-SEM Back Sheet



## Conclusion

- Two separate circuit configurations, showed no anaerobic, aerobic or fungal growth after 12 weeks
- Oxygenator function was preserved on two circuits using AAIM standards
- No disturbance in membrane integrity by SEM
- As a result a change in our clinical practice occurred, allowing wet primed ECMO circuits to be utilized on patients for 60 days



Questions?

*Special thank  
you to my  
coworkers*





# Methods



Circuit	Circuit Type	Primed Setup Time (days)	Wet Sterile Testing (weeks)	Sampling Intervals (weeks)	Function Tested
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6	Two-Base	60	4	8, 10, 12	Yes
7	Two-Base	60	4	8, 10, 12	Yes

\* Dry set up time

- Primed with standard electrolyte solution with sodium gluconate
  - 1.5 L
- Open gas port
  - With a 0.22 µm filter in R and NR circuits
- Incubated in a hot-room (constant 37°C)
  - Unmoved with limited access
- Monitored pH levels
- Tested for Enterobacteriaceae, Staphylococcus and Fungi (both mold and yeast)



# Results

Arterial blood gas results for circuit 6

	pH	pCO2	pO2	BE	Temp	SvO2
<b>0.5-1.0</b>						
Baseline	7.48	39.6	194	5	34.1	100
90	7.5	34	195	4	35.1	100
180	7.45				35.1	100
270	7.44				35.3	100
360	7.4				35.4	100
<b>1.0-1.0</b>						
Baseline	7.55				34.2	100
90	7.54				35.2	100
180	7.47				35.3	100
270	7.49				35.2	100
360	7.46				35.3	100
<b>2.0-1.0</b>						
Baseline	7.59				34.8	100
90	7.58				35.2	100
180	7.55				35.3	100
270	7.54				35.2	100
360	7.52	27.2	179	-1	35.4	100

**AAMI Standards**

pH: 7.35-7.45

pCO2: 35-45

pO2: 100-500

BE: -2 to +2

Temp: 36-37.5

SvO2: 70-100

