

An In-Vitro Study Comparing the GME Handling of Two Contemporary Oxygenators

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Abstract: Gaseous microemboli (GME) are a potential complication of cardiopulmonary bypass (CPB). Though it is difficult to prove that GME is the only major cause of neurological deficits, it may increase the chance of post-operative cognitive dysfunction if not removed. The objectives of this research were to compare LivaNova-Sorin Inspire (Inspire) oxygenator with a Medtronic arterial filter to the Medtronic Fusion (Fusion) oxygenator with and without a Medtronic arterial filter based on each system's ability to handle GME. The Inspire and Fusion systems were evaluated in vitro. GME handling was observed by introducing air in the sampling manifold connected to the venous return at a 60 mL bolus or 1 liter per minute (LPM). The emboli detection

and classification (EDAC) system measured GME preand post-oxygenator/arterial filter. The Inspire with a filter was able to remove a statistically significant greater amount of total emboli per second during the 60 mL bolus and 1 LPM tests than the Fusion with and without an arterial filter. The Inspire with an arterial filter was more efficient in removing GME during a 60 mL bolus and 1 LPM than the Fusion and Fusion with an arterial filter. However, the Fusion with an arterial filter performed better than the Fusion system without the arterial filter. **Keywords:** GME, fusion, inspire, EDAC, microemboli, AF100, Sorin, Medtronic, LivaNova. *J Extra Corpor Technol. 2017;49: 262–272*

Multiple review articles and papers elaborated the effects of gaseous microemboli (GME) and cardiopulmonary bypass (CPB) on patient outcomes (1–10). Although it has been difficult to show a significant relationship between clinical outcomes for patients undergoing cardiac surgery and GME, it is well known that GME plays a role in increasing patient risk and susceptibility to neurocognitive dysfunction (4,8). Because GME are a risk factor for neurological dysfunction, the role of the CPB circuit in handling GME is very important (11,12). The ability of the CPB circuit to eliminate GME through the reservoir, oxygenator, and arterial filter helps to mitigate the risk of neurological dysfunction to patients.

Several studies have examined the ability of CPB circuit components to remove GME in vitro and in vivo. However, there is no conventional way of reporting or studying GME (13–16). The methodology used at the Massachusetts General Hospital (MGH) is simple and provides consistent

results. Our setup can be used to study any institution's CPB circuit for GME handling capabilities.

In this study, we compared the GME handling capabilities of the Inspire 6 reservoir and oxygenator with an external Medtronic arterial filter and the Fusion reservoir and oxygenator with and without an external Medtronic arterial filter. We hypothesized that the Fusion system would perform similarly or even better than the Inspire with the arterial filter. The hypothesis is based on the Medtronic brochure that states the Fusion oxygenator is "indicated for use as both an oxygenator and arterial filter" (17).

MATERIALS AND METHODS

A LivaNova (Sorin) Inspire 6 oxygenator (Sorin Group USA, Inc., Arvada, CO) with reservoir and Medtronic Affinity AF100 (30 micron) arterial filter and Medtronic Fusion oxygenator and reservoir with and without a Medtronic Affinity AF100 arterial filter connected by Medtronic custom tubing (Medtronic Operational Headquarters, Minneapolis, MN) (Reference Table 1) were used for each study. All connections were made with Medtronic tubing coated with Carmeda. A separate LivaNova (Sorin) Inspire 6 oxygenator was used as a degassing oxygenator.

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Table 1. Oxygenator and arterial filter specifications.

	Membrane Oxygenators		Arterial Filter
	Medtronic Fusion	LivaNova-Sorin Inspire	Medtronic AF100
Recommended blood flow rate	1-7 LPM	1-6 LPM	1-7 LPM
Static priming volume	260 mL	191 mL	100 mL
Surface gas transfer fibers	2.5 m ²	1.83 m ²	
Oxygenator material	Microporous polypropylene hollow fibers	Microporous polypropylene hollow fibers	
Coating	Balance	PC phosphorylcoline	Carmeda
Study's nomenclature	"Fusion"	"Inspire"	"Filter"
Reservoir filtration screen size	105 μm	41 + 120 μm	30 μm
Oxygenator filtration type	Depth	Screen	

A Medtronic soft shell venous reservoir was used to help de-air and regulate volume. LivaNova (Sorin) S5 heart lung machine roller pumps were used for each study and calibrated according to manufacturer specifications. A LivaNova (Sorin) XTRA cell salvage device vacuum (Sorin Group USA, Inc.) was used to provide pressure at negative 200 mmHg to the degassing oxygenator gas outlet port. Hospital oxygen was used to provide 100% FiO₂ to each test oxygenator equal to the blood flow for a ratio 1:1. An IEC MB Centrifuge Micro Hematocrit (Thermo Fisher Scientific, Waltham, MA) was used to test for the hematocrit of each study. Two blood samples were collected and centrifuged at 20,000 RPMS for 2 minutes, placed on a Damon IEC Division Micro-Capillary Reader (Damon, Needham, MA), and the hematocrit was calculated. An emboli detection and classification (EDAC) machine (Luna Innovations, Inc., Roanoke, VA) was used to

measure the GME pre-oxygenator and post-oxygenator/ arterial filter.

The Inspire and Fusion systems were setup in parallel and at the same height (Figure 1). We connected two feet of 3/8 inch tubing to the lowest point in the soft shell reservoir to a wye connector two feet from either the Inspire or Fusion venous reservoir inlet. The outlet of each reservoir was connected two feet away to a wye that connected to a 1/2 inch boot running through a roller pump. An EDAC sensor was placed one foot distally to the roller pump and connected to a wye that connected to the inlet of the Inspire and Fusion oxygenator one foot away. All EDAC sensors were covered with Super Sonic Gel to ensure a transmission signal greater than 2,000, which is a number indicative of transmission signal strength with no units. A pressure line was connected to the outlet of the Inspire oxygenator. The Inspire oxygenator purge line was connected to the top of the

Comparison of the total of median emboli per second Pre-Oxygenator during the 60 mL bolus for the Inspire, Fusion, and Fusion Filter

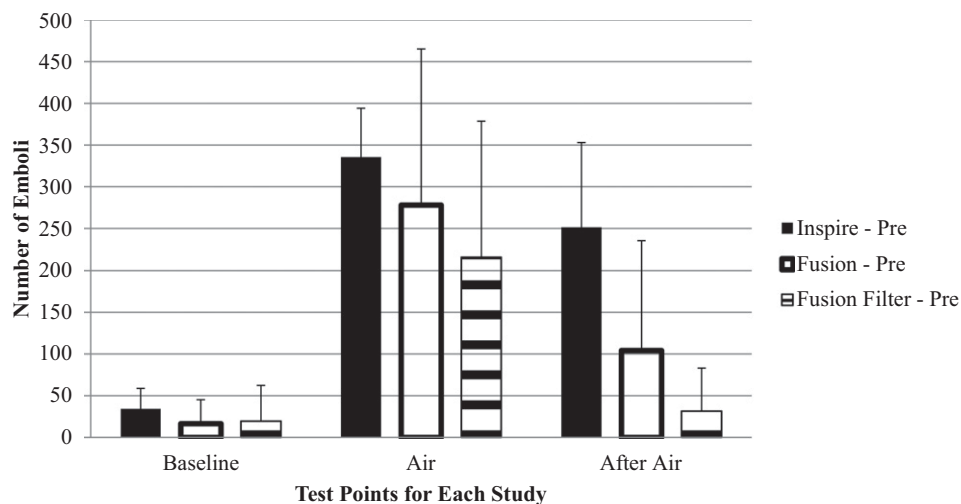


Figure 1. 2-Dimensional depiction of the circuit setup to test the Fusion and Inspire Reservoir and Oxygenator.

Inspire reservoir. The Fusion oxygenator purge line was connected to a stopcock on the inlet of the Fusion reservoir. The outlet of each Inspire and Fusion oxygenator connected up to a separate arterial filter with a bypass line. The arterial filter purge line for the Inspire circuit was connected to the top of the Inspire reservoir. The arterial filter purge line for the Fusion circuit was connected to the stopcock on the venous inlet. The study reservoirs and arterial filters were placed in parallel and at the same height in the circuit. The outlet of each arterial filter setup connected to a wye two feet away that connected to the second EDAC sensor 6 inches away. The EDAC sensor then connected to the degassing oxygenator inlet. The degassing oxygenator purge line was connected to the top of the Medtronic soft shell venous reservoir. The outlet of the degassing oxygenator was connected to the highest fill point in the Medtronic soft shell venous reservoir.

The setups were primed with 3 L of lactated Ringer's solution (Hospira Inc., Lake Forest, IL). Three to four units of expired, packed red blood cells were added to obtain a hematocrit between 24 and 26% and re-circulated throughout the setup at 37°C. When the hematocrit was within range, the Fusion was clamped out accordingly. The Inspire was circulated at 4 liter per minute (LPM), and pressure was applied distally to the second EDAC sensor for an arterial line pressure between 190 and 210 mmHg. Oxygen was provided to the Inspire oxygenator at a rate of 4 LPM with a scavenge line setup on the exhaust port at 4 LPM. The scavenge line mimics current practice at our institution and reduces the buildup of condensation in the oxygenator. Negative 200 mmHg was applied to the exhaust port of the degassing oxygenator. The venous inlet was partially clamped to maintain a reservoir level between 300 and 400 mL. The oxygenator purge line was closed, and the arterial filter purge line was open. When all conditions were met, the EDAC was started and measured for a total of three minutes. The first minute was recorded as Baseline, and then a bolus of 60 mL of air or 1 LPM of air was administered through the sampling manifold into the inlet of the reservoir. The 60 mL bolus of air was administered by hand into the sampling manifold in less than 1 second, and the 1 LPM of air was administered by a roller pump into the sampling manifold at 1 LPM. The second and third minute measured the air handling abilities of the Inspire oxygenator during and after each test. When the 60 mL bolus and 1 LPM were completed three times each, the volume of the reservoir was drained down to zero and the Inspire circuit was clamped out.

The Fusion circuit was unclamped accordingly, leaving clamps proximal and distal to the arterial filter, allowing flow to go through the arterial filter bypass line only. The Fusion had the same test setup as detailed previously. The oxygenator purge line was opened, and the arterial filter purge line was closed. When the 60 mL bolus and 1 LPM

were completed three times each, the arterial filter was unclamped and the arterial filter bypass line was clamped ensuring that the oxygenator purge line and arterial filter purge line were open. The 60 mL bolus and 1 LPM were repeated for another three tests each.

We completed three comparison studies over a year using a total of three Inspire and three Fusion oxygenators. In total, 54 tests were completed that compared the Inspire, Fusion, and Fusion with an arterial filter to a 60 mL bolus or 1 LPM air challenge. All corresponding data were combined and graphed. The first statistical analysis, referred to as Baseline, using a *t*-Test with unequal variances looked at data from the start of recording to right before the first visual increase in GME count (graphically based). The second statistical analysis, referred to as Air, looked at the start of the increase (graphically based) for a duration of 30 seconds for the 60 mL bolus and a duration of 60 seconds for the 1 LPM of continuous air. The third statistical analysis, referred to as After Air, looked at the last 90 seconds after the Air interval for the 60 mL bolus or the last 60 seconds after the Air interval for the 1 LPM. The previously mentioned statistical analysis was completed for the pre-oxygenator and post-oxygenator/arterial filter EDAC sensor for each test (Tables 2 and 3). Percent removal was then calculated from the median emboli count of the pre-oxygenator and post-oxygenator/arterial filter EDAC sensor for each test by finding the difference pre- and post-oxygenator values in sums of 20 data points and averaging the difference (Tables 2 and 3). The Inspire and Fusion median emboli were then plotted on a graph to show the comparison of air handling between the oxygenators during the 60 mL bolus and 1 LPM of continuous air (Figures 2 and 3).

A two tailed *t*-Test with unequal variances in Microsoft Excel was used to test for significant difference between the Inspire, Fusion without an arterial filter (Fusion), and Fusion with an arterial filter (Fusion Filter) systems. The tests were run for a total of 180 seconds segmented into three test points that were statistically analyzed: Baseline, Air, and After Air introduction.

Table 2. Comparison of total median GME counts per second with standard deviation and percent removal in the air test point for the Inspire, Fusion, and Fusion filter for the 60 mL bolus.

	Pre-oxygenator	Post-oxygenator	Percent Removal (%)
	Air (mean ± STD)	Air (mean ± STD)	
Inspire STD	335.47*† ± 58.59	13.72 ± 14.02	95.86 ± 3.23
Fusion STD	277.96‡ ± 187.28	110.72*‡ ± 117.29	61.02 ± 23.84
Fusion filter STD	216.10 ± 162.41	53.88† ± 68.00	76.22 ± 14.44

Data are medians and (interquartile range). STD, standard deviation.

**p* < .05, Inspire vs. Fusion.

†*p* < .05, Inspire vs. Fusion filter.

‡*p* < .05, Fusion vs. Fusion filter.

Table 3. Comparison of total median GME counts per second with standard deviation and percent removal in the Air test point for the Inspire, Fusion, and Fusion filter for the 1 LPM of continuous air.

	Pre-oxygenator Air (mean ± STD)	Post-oxygenator Air (mean ± STD)	Percent Removal (%)
Inspire STD	307.73 ± 35.73	14.06 ± 14.13	95.38 ± 3.83
Fusion STD	368.55* ± 89.92	240.52*‡ ± 105.55	32.70 ± 29.08
Fusion filter STD	364.06† ± 89.45	147.24† ± 99.92	55.48 ± 31.29

Data are medians and (interquartile range). STD, standard deviation.
 **p* < .05, Inspire vs. Fusion.
 †*p* < .05, Inspire vs. Fusion filter.
 ‡*p* < .05, Fusion vs. Fusion filter.

RESULTS

The total median GME count per second pre-oxygenator in the Baseline test point during the 60 mL bolus for the Inspire, Fusion, and Fusion Filter was 34.36 ± 24.39, 16.48 ± 28.76, and 19.67 ± 42.52, respectively (Figure 2). The Inspire GME count was significantly higher (*p* < .001) at Baseline when compared with the Fusion and Fusion Filter, whereas the Fusion and Fusion Filter were not statistically different. The total median GME count per second post-oxygenator in the Baseline test point for the Inspire, Fusion, and Fusion Filter was 1.99 ± 2.97, .85 ± 1.57, and .75 ± 1.90, respectively (Figure 3). Similarly to the pre-oxygenator, the GME count at Baseline for the Inspire was significantly higher (*p* < .001) at Baseline than the Fusion and Fusion Filter, whereas the Fusion and Fusion Filter were not statistically different.

The total median GME count per second pre-oxygenator in the Air test point during the 60 mL bolus for the Inspire, Fusion, and Fusion Filter was 335.47 ± 58.59, 277.96 ± 187.28, and 216.10 ± 162.41, respectively (Table 2). The GME count at Air for the Inspire was significantly higher (*p* < .001) compared with the Fusion and Fusion Filter while Fusion was significantly higher (*p* < .001) than the Fusion Filter (Figure 2). The total median GME count post-oxygenator for the Inspire, Fusion, and Fusion Filter was 13.72 ± 14.02, 110.72 ± 117.29, and 53.88 ± 68.00, respectively (Table 2). The GME count for the Inspire was significantly lower (*p* < .001) compared with both Fusion and Fusion Filter, and the Fusion Filter was significantly lower (*p* < .001) compared with the Fusion. Percent removal was calculated by the sum of 30 pre-oxygenator data points minus the sum of 30 post-oxygenator data points then dividing that by the sum of the pre-oxygenator data points. Out of 19 different summed data points, the average percent difference for the Inspire, Fusion, and Fusion Filter is 95.86 ± 3.23%, 61.02 ± 23.84%, and 76.22 ± 14.44%, respectively (Table 3). The Inspire significantly (*p* < .05) removed more GME than the Fusion and Fusion Filter, whereas there was a significant difference (*p* < .05) between the Fusion and Fusion Filter over percent removal.

The total median GME count per second pre-oxygenator in the After Air test point during the 60 mL bolus for the Inspire, Fusion, and Fusion Filter was 251.40 ± 101.43, 104.16 ± 131.78, and 31.69 ± 51.56, respectively (Figure 2), suggesting that GME count for the Inspire was significantly higher (*p* < .001) compared with the Fusion and Fusion Filter, whereas the Fusion was significantly higher (*p* < .001)

Comparison of the total of median emboli per second Post-Oxygenator during the 60 mL bolus for the Inspire, Fusion, and Fusion Filter

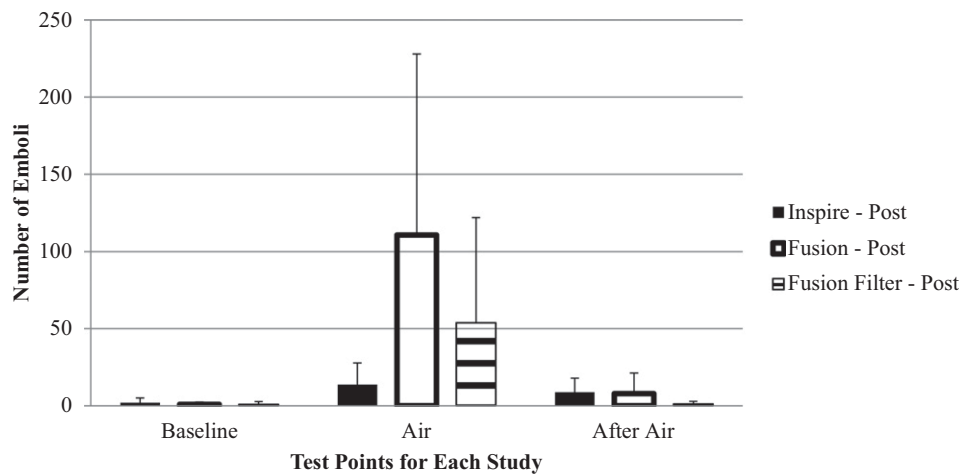
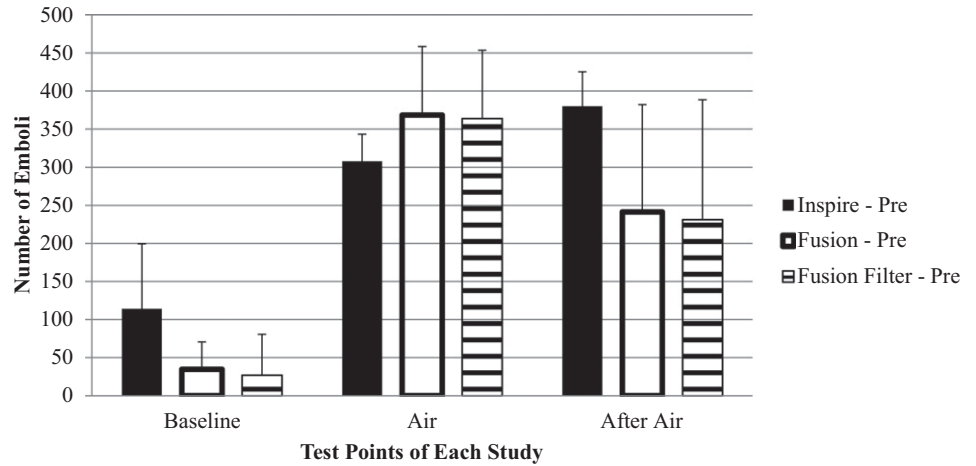


Figure 2. Comparing the pre-oxygenator of total median emboli per second of the Baseline, Air, and After Air introduction during the 60 mL bolus of air challenge for the Inspire, Fusion, and Fusion with an arterial filter. Pre-oxygenator the Inspire had a significantly greater total median emboli count than the Fusion and Fusion Filter in the Baseline, Air, and After Air test points.

Comparison of the total of median emboli per second Pre-Oxygenator during the 1LPM for the Inspire, Fusion, and Fusion Filter

Figure 3. Comparing the post-oxygenator/arterial filter of total median emboli per second of the Baseline, Air, and After Air introduction during the 60 mL bolus of air challenge for the Inspire, Fusion, and Fusion with an arterial filter. Post-oxygenator/arterial filter the Inspire had a significantly greater total median emboli count than the Fusion and Fusion Filter in the Baseline and After Air test points. However, the Fusion and Fusion Filter had a significantly greater total median emboli count than the Inspire in the Air test point.



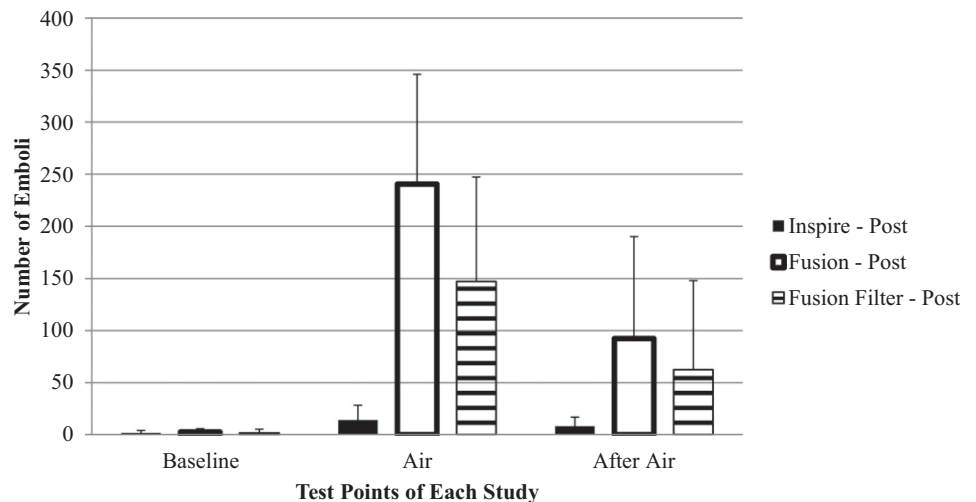
compared with the Fusion Filter. The total median GME count post-oxygenator during the 60 mL bolus for the Inspire, Fusion, and Fusion Filter was 8.83 ± 9.11 , 7.85 ± 13.34 , and 1.07 ± 1.80 , respectively (Figure 3). The Fusion Filter was significantly lower ($p < .001$) compared with both Inspire and Fusion, whereas the Inspire and Fusion were not significantly different.

The total median GME count per second pre-oxygenator in the Baseline test point during the 1 LPM of continuous

air for the Inspire, Fusion, and Fusion Filter was 114.16 ± 85.35 , 34.66 ± 35.95 , and 26.82 ± 53.89 , respectively (Figure 4). At Baseline, the GME count for the Inspire was significantly higher ($p < .001$) compared with Fusion and Fusion Filter, whereas the Fusion was significantly higher ($p < .002$) compared with the Fusion Filter. The total median GME count post-oxygenator/arterial filter for the Inspire, Fusion, and Fusion Filter was 1.49 ± 2.41 , 2.50 ± 3.14 , and 1.48 ± 3.67 , respectively (Figure 5). At Baseline,

Comparison of the total of median emboli per second Post-Oxygenator during the 1LPM for the Inspire, Fusion, and Fusion Filter

Figure 4. Comparison of pre-oxygenator of total median emboli per second of the Baseline, Air, and After Air introduction during the 1 LPM of air challenge for the Inspire, Fusion, and Fusion Filter. Pre-oxygenator the Inspire had a significantly greater number of total median emboli than the Fusion and Fusion Filter in the Baseline and After Air test points. However, the Fusion and Fusion Filter had a significantly greater number of total median emboli than the Inspire in the Air test point.



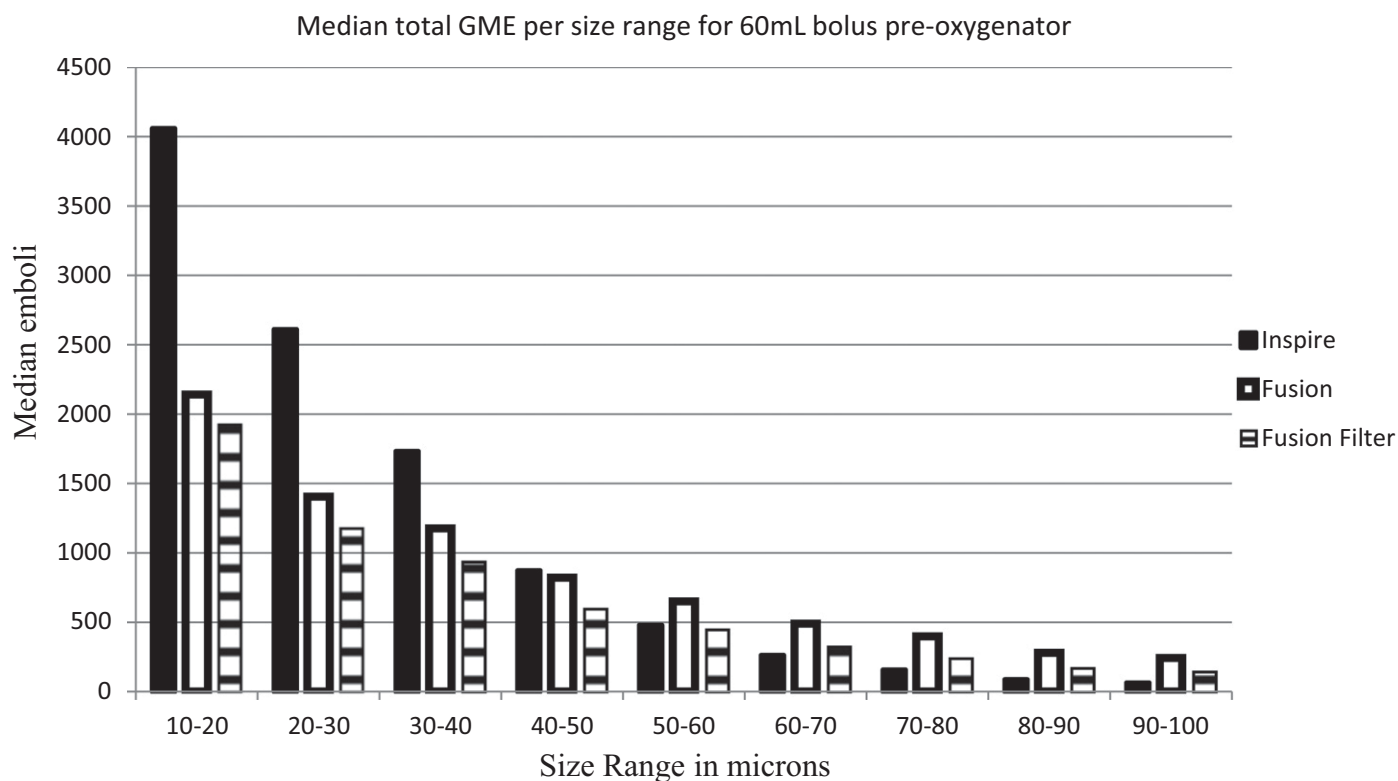


Figure 5. Bar graph of the median total emboli count per size range (0–100 μm) post-oxygenator/arterial filter for the Inspire, Fusion, and Fusion Filter in the Air test point during 1 LPM of continuous air.

the GME count for the Fusion was significantly higher ($p < .001$) compared with the Inspire and Fusion Filter.

The total median GME count per second pre-oxygenator in the Air test point during the 1 LPM of continuous air for the Inspire, Fusion, and Fusion Filter was 307.73 ± 35.73 , 368.55 ± 89.92 , and 364.06 ± 89.45 , respectively (Table 3). The GME count for the Inspire was significantly lower ($p < .001$) compared with both Fusion and Fusion Filter while the Fusion and Fusion Filter were not significantly different. The total median GME count post-oxygenator for the Inspire, Fusion, and Fusion Filter was 14.06 ± 14.13 , 240.52 ± 105.55 , and 147.24 ± 99.92 , respectively (Table 3). The GME count for the Inspire was significantly lower ($p < 0.001$) compared with both Fusion and Fusion Filter, whereas the Fusion Filter was significantly lower ($p < .001$) compared with the Fusion. Percent removal was calculated by the sum of 30 pre-oxygenator data points minus the sum of 30 post-oxygenator data points then dividing that by the sum of the pre-oxygenator data points. Out of 19 different summed data points, the average percent difference for the Inspire, Fusion, and Fusion Filter are $95.38 \pm 3.83\%$, $32.70 \pm 29.08\%$, and $55.48 \pm 31.29\%$, respectively (Table 3). The Inspire significantly ($p < .05$) removed more GME than the Fusion and Fusion Filter while there was no significant difference between the Fusion and Fusion Filter over percent removal.

The total median GME count per second pre-oxygenator in the After Air test point during the 1 LPM of continuous air for the Inspire, Fusion, and Fusion Filter was 8.01 ± 8.81 , 92.46 ± 98.08 , and 62.38 ± 85.80 , respectively (Figure 5). The GME count for the Inspire was significantly lower ($p < .001$) compared with both Fusion and Fusion Filter, and the Fusion Filter was significantly lower ($p < .001$) than the Fusion.

The total GME count was characterized 10–100 microns (μm) pre-oxygenator in the Air test point for the 60 mL bolus of air (Figure 6). The Fusion Filter had a significantly lower ($p < .001$) number of emboli for size ranges 50 μm and less compared with the Inspire, whereas the Fusion had a significantly lower ($p < .001$) number of emboli for size ranges 10–40 μm compared with the Inspire. The Inspire had a significantly lower ($p < .001$) number of emboli for size ranges 70–100 μm compared with the Fusion. The Fusion and Fusion Filter were not significantly different throughout all size ranges pre-oxygenator.

The total GME count was characterized 10–100 μm post-oxygenator/arterial filter in the Air test point during the 60 mL bolus (Figure 7). The Inspire had significantly lower

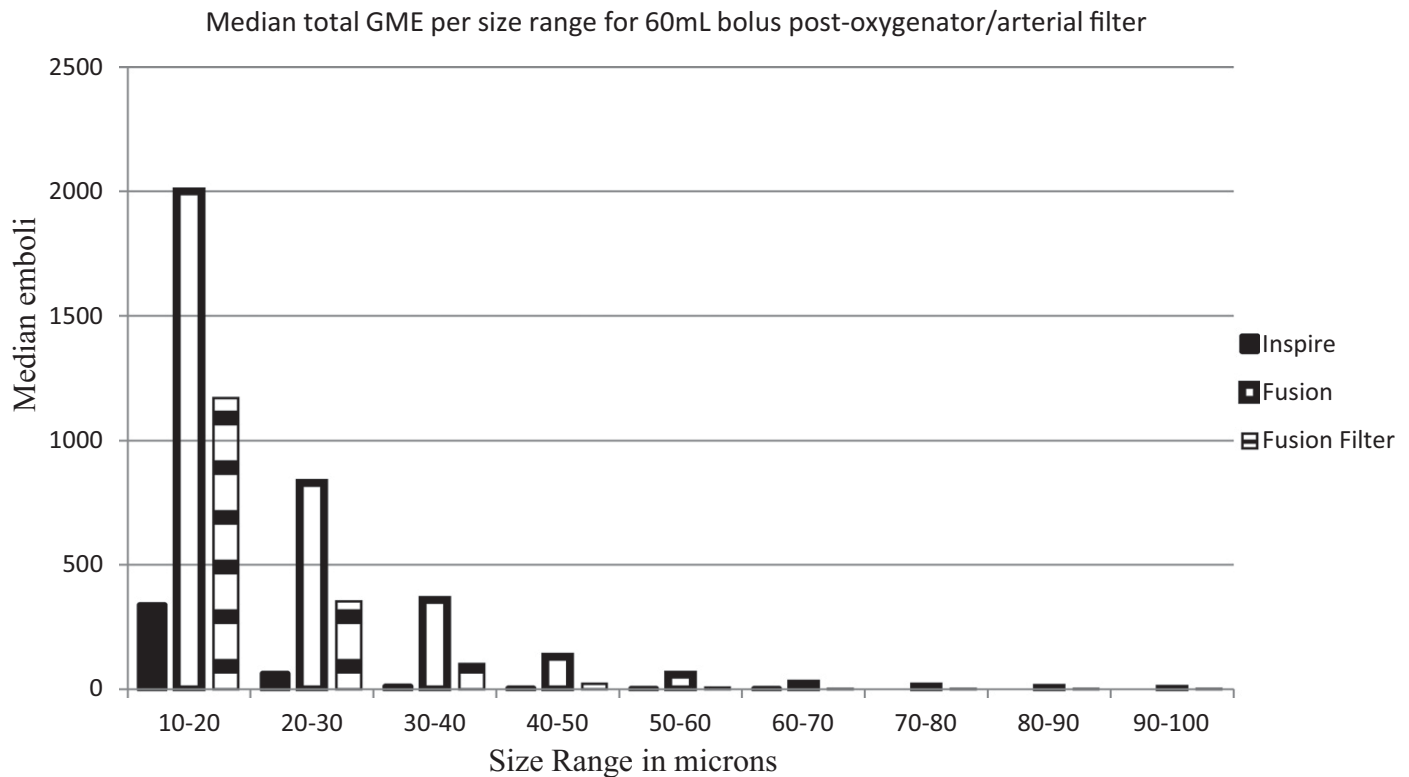


Figure 6. Bar graph comparing the median total emboli count per size range (0–100 μm) pre-oxygenator for the Inspire, Fusion, and Fusion Filter in the Air test point during the 60 mL bolus.

($p < .001$) number of emboli against the Fusion in all size ranges 10–100 μm and the Fusion Filter for size ranges 10–60 μm . The Fusion Filter had a significantly lower ($p < .001$) number of emboli compared with the Fusion for size ranges 30–100 μm while the Fusion and Fusion Filter were not significantly different in size ranges less than 30 μm post-oxygenator/arterial filter.

The total GME count was characterized 10–100 μm pre-oxygenator in the Air test point during the 1 LPM of continuous air (Figure 8). The Inspire had a significantly lower ($p < .001$) number of emboli for size ranges 40–100 μm compared with the Fusion and 50–100 μm compared with the Fusion Filter. The Fusion and Fusion Filter had a significantly lower ($p < .001$) number of emboli for size range 10–20 μm compared with the Inspire. The Fusion and Fusion Filter were not significantly different for all size ranges pre-oxygenator.

The total GME count was characterized 10–100 μm post-oxygenator/arterial filter in the Air test point during the 1 LPM of continuous air (Figure 9). The Inspire had a significantly lower ($p < .001$) number of emboli for all size ranges compared with the Fusion and Fusion Filter. The Fusion Filter had significantly lower ($p < .001$) number of emboli for size ranges 20–100 μm compared with the Fusion, whereas the Fusion and Fusion Filter were not significantly different in emboli count for size ranges less than 20 μm post-oxygenator/arterial filter.

DISCUSSION

Published guidelines recommend minimizing the CPB circuit to reduce hemodilution and minimize blood transfusions (18,19). However, a potential consequence of shrinking the CPB circuit has reduced time to remove GME. Perfusionists need to ensure that the efficacy and efficiency of CPB circuits are not lost with the reduction in prime volume. Several investigators, including those at the MGH, have conducted research focused on GME and CPB components (13–16). The MGH test circuit setup is very easy and can be easily replicated and provides consistent results. Also, it provides a consistent and reliable understanding of how a specific circuit handles GME in an in-vitro setting.

The Fusion oxygenator with an arterial filter was more efficient at removing GME at size ranges 30–100 μm during the 60 mL bolus and 20–100 μm during the 1 LPM of continuous when compared with the Fusion without an arterial filter. In addition, the efficiency was not different between the two systems for GME less than 30 μm for the 60 mL bolus or less than 20 μm with the 1 LPM. The arterial filter provided added protection from GME greater than 20 μm leaving the oxygenator, but did not contribute to removing GME less than 20 μm . Based on the significant difference between sizes of 20–100 μm compared with the Fusion with and without an arterial filter, it can be

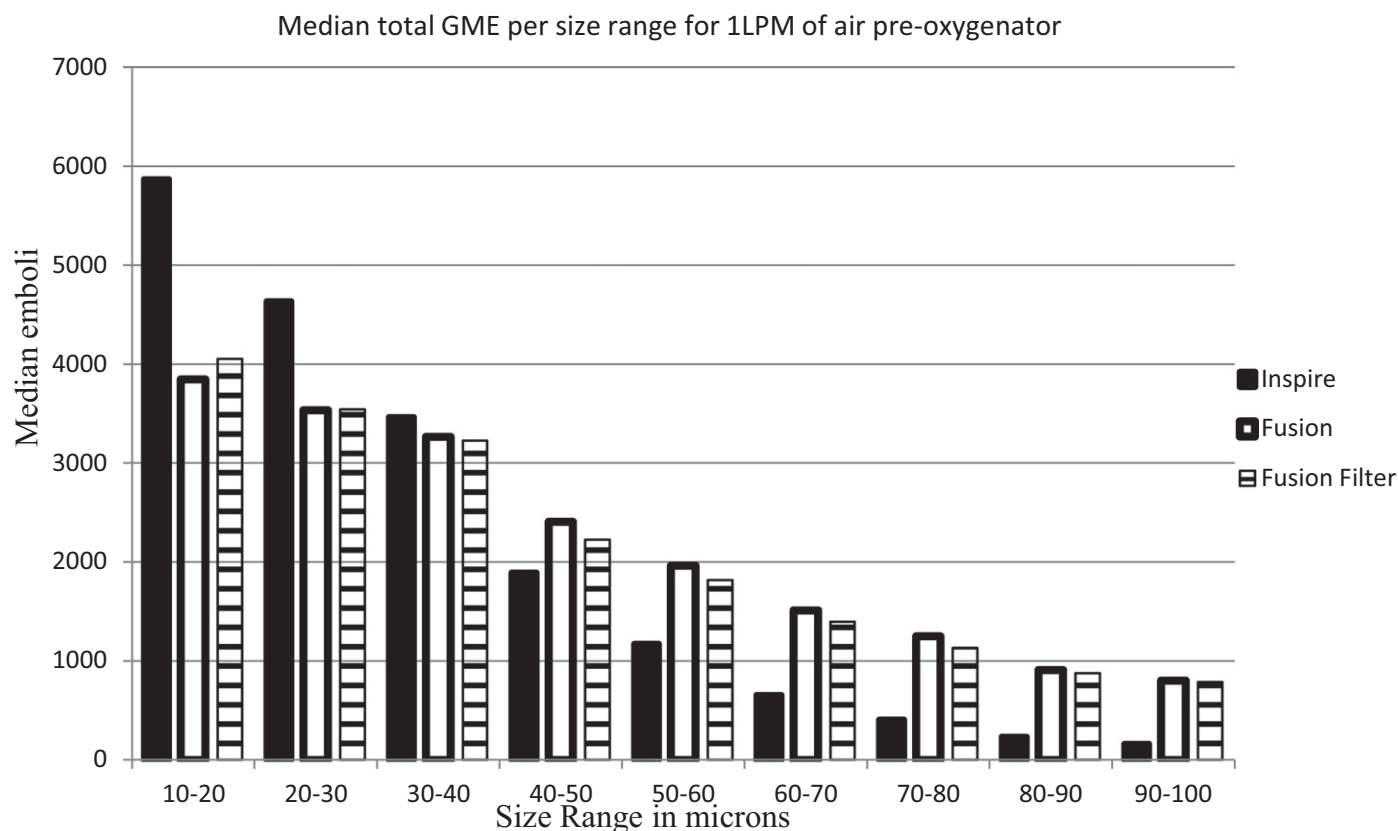


Figure 7. Bar graph comparing the median total emboli count per size range (0–100 μm) post-oxygenator/arterial filter for the Inspire, Fusion, and Fusion Filter in the air test point during the 60 mL bolus.

hypothesized that the 25 μm depth filtration of the Fusion oxygenator did not effectively remove GME greater than 25 μm .

The Fusion without an arterial filter and the Fusion with an arterial filter pre-oxygenator had a greater number of GME greater than 40 μm and greater than 50 μm for both 60 mL bolus and 1 LPM of continuous air, respectively. The large GME can be contributable to the 105 μm filtration screen size for the Fusion reservoir outlet. Post-oxygenator for the Fusion without an arterial filter showed that the oxygenator increased the number of GME less than 20 μm . It can be postulated that the Fusion reservoir maintains the size of GME greater than 20 μm introduced into the circuit while the Fusion oxygenator breaks down the GME to 20 μm or less, and the Fusion oxygenator having a low pressure drop (17) allows for GME less than 20 μm to be passed to the patient and not removed by system. The Inspire oxygenator outperformed the Fusion with and without an arterial filter for the Air test point in the 60 mL bolus and 1 LPM of continuous air by having a lower GME count post-arterial filter even though the Inspire oxygenator had a higher number of GME less than 20 μm pre-oxygenator. Based on company brochures, the Inspire has a long blood path and high pressure drop (20), whereas the

Fusion is shown to have a short blood path and low pressure drop (17). The differences in pressure and blood path length might be why the Inspire is able to remove more GME than the Fusion.

Surprisingly, the Inspire pre-oxygenator had significantly higher GME count per second when compared with the Fusion with and without an arterial filter at the Baseline and After Air test points, even with a reservoir level between 300 and 400 mL. The reservoir level was very important to the amount of pre-oxygenator GME captured when collecting data for the Fusion. The higher GME count for the Inspire can be explained by three different variables. First reason is that the Inspire reservoir outlet has a smaller filtration screen at 41 μm . The second reason is that the structural feature of the Inspire venous inlet is a straight tube that drops from the top of the reservoir to the 200 mL level. Because of this configuration, air is trapped within the tube and is continuously broken into smaller pieces over time, which could be the possible explanation of why the Inspire had a significantly greater number of GME less than 20 μm pre-oxygenator in the 60 mL bolus and 1 LPM. Also, this explanation shows that the reservoir level for the Inspire should have no effect on removing GME in the reservoir.

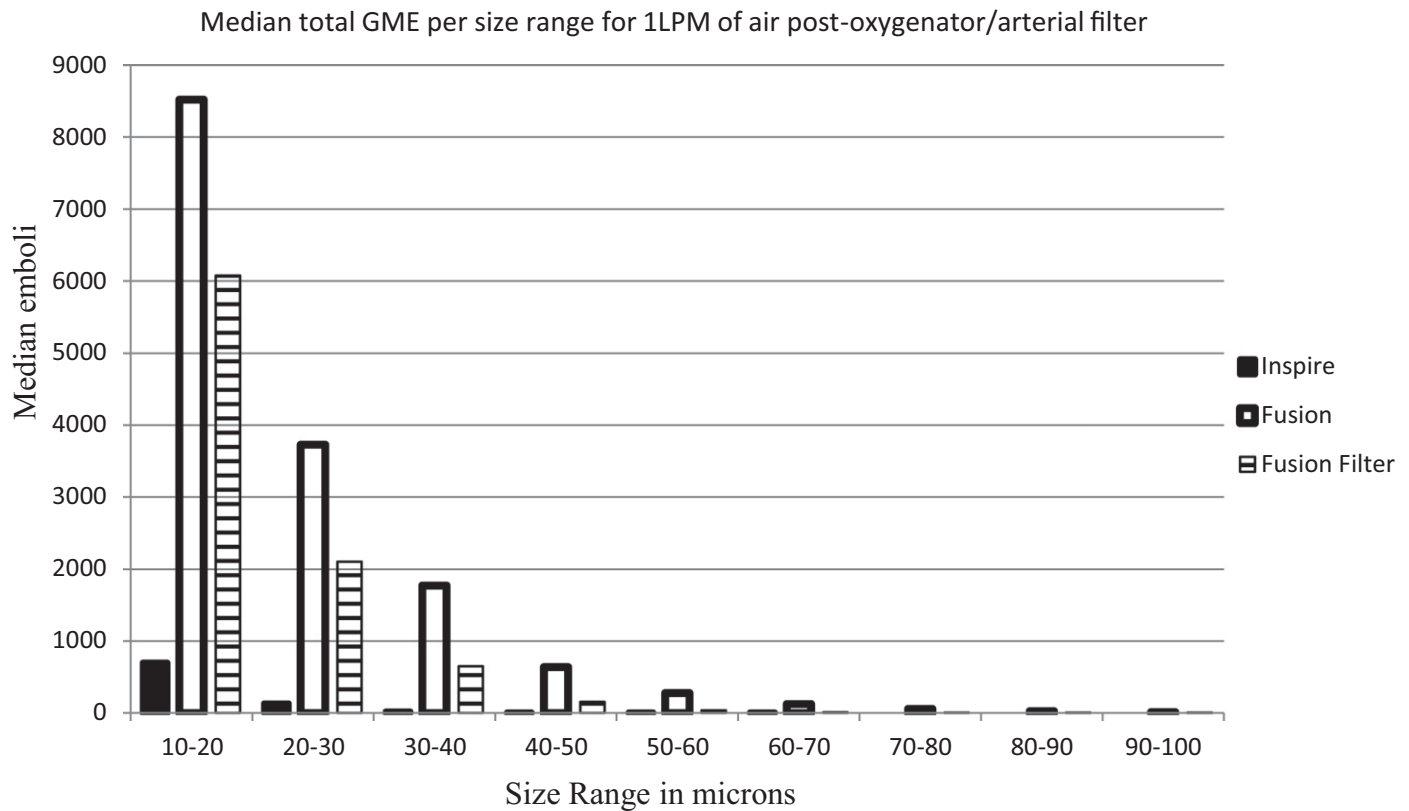


Figure 8. Bar graph of the median total emboli count per size range (0–100 μm) pre-oxygenator for the Inspire, Fusion, and Fusion Filter in the Air test point during 1 LPM of continuous air.

The third reason is the location of the purge line on the top of the venous reservoir may have caused a “splashing effect” at the venous outlet creating more GME. However, the Fusion with and without an arterial filter started with a lower number of GME pre-oxygenator and had significantly higher GME post-oxygenator/arterial filter during each challenge. The Fusion with and without an arterial filter were significantly different pre-oxygenator for 60 mL bolus in the Air test point because the Fusion reservoir level was very difficult to maintain between 300 and 400 mL while the bolus was being administered. This is proven by the insignificant difference between both systems’ pre-oxygenator in the Air test point during the 1 LPM.

Because the EDAC machine and supplies are no longer in production, we propose that the study be repeated by another hospital using the Bubble Counter BC100 (GAMPT, Merseburg, Germany) and similar circuit setup and technique. It should be taken into account that De Somer et al. (21) showed that at 3 LPM the EDAC captured 38% total GME while the Gampt BC100 only captured 18%. Also, because of the limited stock of supplies, we were only able to monitor two sites on the circuit. A more robust comparison of arterial filter capabilities could be carried out by measuring both before and after the filter.

We were unable to fully quiet the system, which is seen in the Baseline data. We did not use fresh frozen plasma in our prime, which may have decreased the resistance through the oxygenator allowing for a decrease in the removal of GME. However, the normal range for plasma viscosity is 1.10–1.30 mPa at 37°C (22), whereas lactated Ringer’s solution viscosity is 1.0 mPas (23). Consequently, our solution of expired red blood cells and lactated Ringer’s solution had a slightly lower viscosity than whole blood diluted to 25% at 37°C. Also, we did not include the real flow out of the oxygenator between the Inspire and the Fusion, which makes a difference because the Fusion oxygenator would have seen a lower flow rate with the oxygenator purge line open. Lastly, we did not monitor the inlet and outlet pressures of the oxygenator to have a comparison of pressure drop during each study to validate the manufacture statements (17,20).

In conclusion, the Inspire oxygenator with an arterial filter was more effective than the Fusion oxygenator with and without an arterial filter in removing GME. Although the arterial filter helped to remove the emboli larger than 20 μm shown by the comparison of the Fusion systems, it was not able to remove GME less than 20 μm .

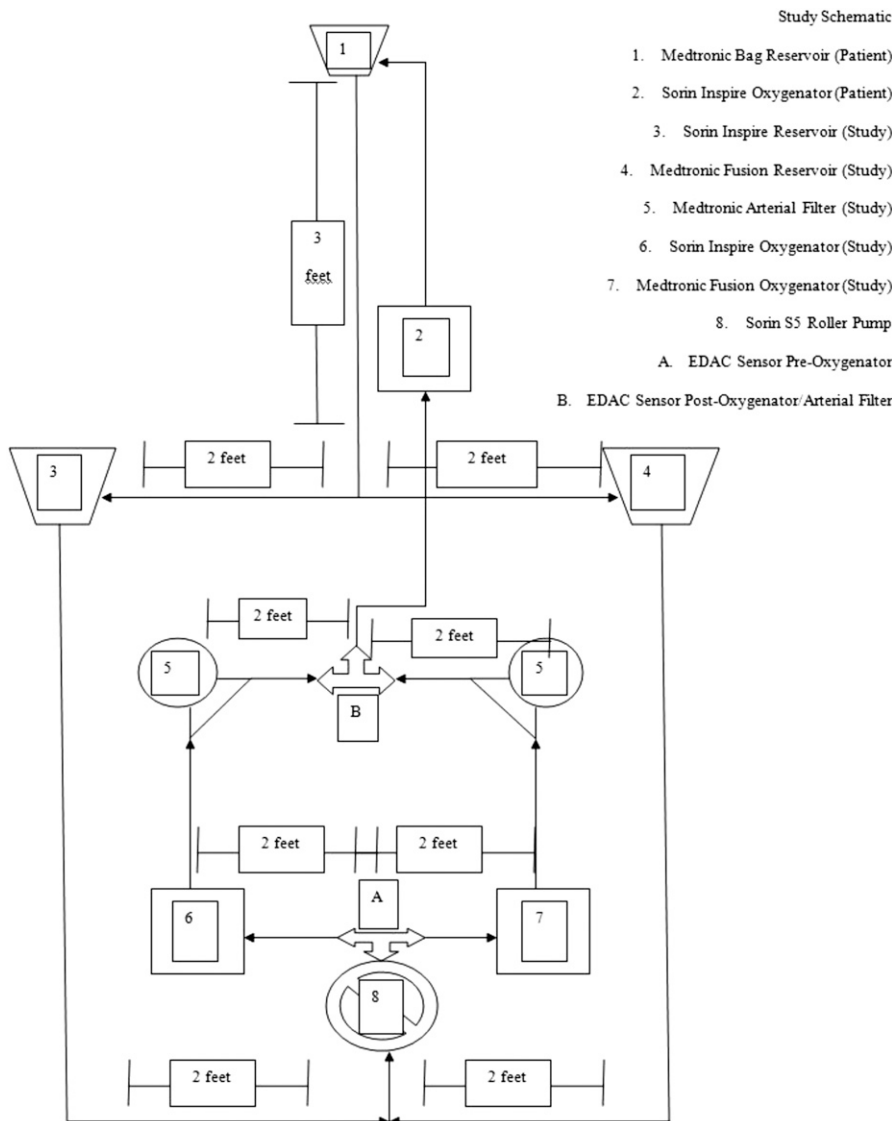


Figure 9. Comparison post-oxygenator/arterial filter of the total median emboli per second of the Baseline, Air, and After Air introduction during the 1 LPM of air challenge for the Inspire, Fusion, and Fusion with an arterial filter. Post-oxygenator/arterial filter the Fusion had a significantly greater number of total median emboli than the Inspire and Fusion Filter in the Baseline test point, and the Inspire had a significantly greater number of total median emboli than the Fusion Filter in the Air test point, and the Fusion had a significantly greater number of total median emboli than the Inspire in the After Air test point, and the Fusion had a significantly greater number of total median emboli than the Fusion Filter in the After Air test point.

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