INNOVATION IN OR VENTILATION CONCEPTS: Stress Testing Temperature-controlled Air Flow

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ABSTRACT

Despite 60 years of evidence supporting the correlation between airborne contamination and surgical site infection (SSI), little innovation in OR ventilation technology has occurred since the 1960s. The higher the number of colony forming units (CFU) of bacteria the higher the risk of an SSI. This risk increases with use of implants, which are particularly susceptible to contamination. It is also widely understood that the people in the room are the primary source of airborne bacterial contamination. As the number of people and movement in the room increases, airborne CFUs rise. Door openings have also been shown to increase airborne microbial levels. Ventilation is the first defense against airborne contamination.

In contrast to the US, in Europe standards which limit airborne contamination in the OR have been promulgated. The scope of this work was to measure the performance of Temperature-controlled Air Flow (TcAF), a more recent ventilation concept, against the Dutch standard1,2 for OR air quality. TcAF utilizes air that is 1.5 o below ambient room temperature. The temperature gradient results in a reliable, gravity driven vertical downflow throughout the room.TcAF maintains ultraclean (<10 CFU/m3)3 conditions in the entire room as opposed to conventional Laminar Air Flow which provides a limited clean zone around the operating table, only.

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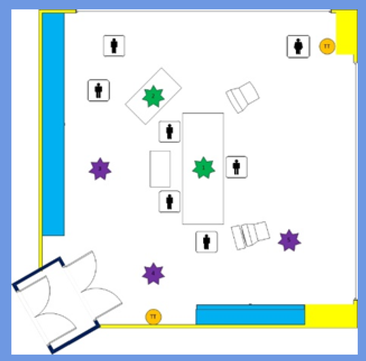
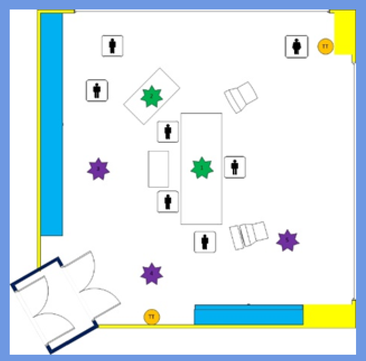
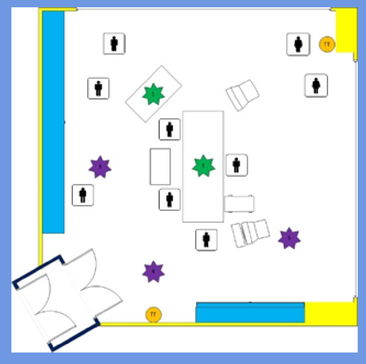
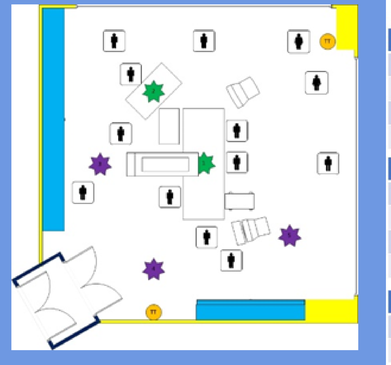








Results procedure 1

0,5 µm	Sterile zone		Periphery		
Level	1	2	3	4	5
High	0	14.125	15.538	15.891	1.059
Low	0	1.765	0	0	0
Average	0	5.841	3.391	3.009	37

5,0 µm	Sterile zone		Periphery		
Level	1	2	3	4	5
High	0	2.407	1.412	1.765	353
Low	0	0	0	0	0
Average	0	360	360	507	7

Area	1	2	3	4	5	Average
Wound	3 cfu/m³	0 cfu/m³	0 cfu/m³	0 cfu/m³	0 cfu/m³	0,6 cfu/m³
Instruments	1 cfu/m³	1 cfu/m³	1 cfu/m³	2 cfu/m³	1 cfu/m³	1,2 cfu/m³

Results procedure 2

0,5 µm	Sterile zone		Periphery		
Level	1	2	3	4	5
High	0	18.010	178.339	145.143	16.951
Low	0	0	0	0	0
Average	0	2.600	13.200	10.203	808

5,0 µm	Sterile zone		Periphery		
Level	1	2	3	4	5
High	0	2.118	2.825	2.472	706
Low	0	0	0	0	0
Average	0	286	743	669	51

Area	1	2	3	4	5	Average
Wound	0 cfu/m³	0 cfu/m³	0 cfu/m³	0 cfu/m³	0 cfu/m³	0 cfu/m³
Instruments	1 cfu/m³	0 cfu/m³	1 cfu/m³	0 cfu/m³	1 cfu/m³	0,6 cfu/m³

Results procedure 3

0,5 µm	Sterile zone		Periphery		
Level	1	2	3	4	5
High	706	9.535	12.007	19.423	5.297
Low	0	0	0	0	0
Average	21	1.681	3.905	6.427	974

5,0 µm	Sterile zone		Periphery		
Level	1	2	3	4	5
High	353	1.412	6.709	2.118	1.059
Low	0	0	0	0	0
Average	7	162	618	669	88

Area	1	2	3	4	5	Average
Wound	0 cfu/m³	0 cfu/m³	0 cfu/m³	0 cfu/m³	0 cfu/m³	0 cfu/m³
Instruments	2 cfu/m³	2 cfu/m³	1 cfu/m³	1 cfu/m³	2 cfu/m³	1,6 cfu/m³

Results procedure 4

0,5 µm	Sterile zone		Periphery		
Level	1	2	3	4	5
High	5.660	13.066	7.062	12.007	3.884
Low	0	353	0	0	0
Average	1.195	5.426	5.589	5.623	944

5,0 µm	Sterile zone		Periphery		
Level	1	2	3	4	5
High	706	2.825	1.765	2.118	1.412
Low	0	0	0	0	0
Average	28	590	821	645	135

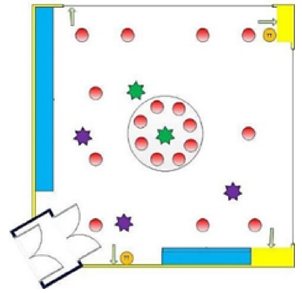
Area	1	2	3	4	5	Average
Wound	3 cfu/m³	0 cfu/m³	0 cfu/m³	0 cfu/m³	1 cfu/m³	0,8 cfu/m³
Instruments	6 cfu/m³	7 cfu/m³	5 cfu/m³	7 cfu/m³	9 cfu/m³	6,8 cfu/m³

METHODOLOGY

In the Netherlands, ORs in which infection-prone surgeries are performed, may have a maximum of ≤ 10 CFU/m3 and are required to maintain a mean value of ≤ 5 CFU/m3. This is one of the most rigorous standards for OR air quality in the world. Four surgical procedures were simulated to stress the performance of the system. For each procedure, particle measurements were carried out at 5 positions and microbiological (CFU) measurements at 2 positions (instrument table/periphery and wound).

The 4 surgical procedures included:
1. Knee surgery
2. Open abdominal surgery
3. Caesarean section
4. Trauma surgery on the upper leg

Each successive procedure was designed to increase the stress on the TcaF system.



Surgical procedure 1: Presence of 6 personnel, 2 instrument tables and a minimum heat load (surgical and anaesthesia equipment). During the 52 minute procedure there were 6 door openings.

Surgical procedure 2: Presence of 7 personnel, 2 instrument tables and a minimum of heat load. There were 12 door openings during the 53 minute procedure.

Surgical procedure 3: Presence of 9 personnel, 2 instrument tables and extra heat load. During the 52 minute procedure there were 8 door openings.

Surgical procedure 4: Presence of 13 personnel, 2 instrument tables, addition of a Bair Hugger and use of imaging equipment, maximum heat load and a maximum amount of equipment. During the 50 minute procedure there were 36 door openings. In this procedure, the movement of personnel exceeded standard procedures. Procedure 4 was a deliberate attempt to put maximum stress on the system.

CONCLUSION

Even under the extreme conditions simulated in Procedure 4, the system was able to maintain <10CFU/m3 throughout the entire room. CFU levels are higher for this procedure than for the others because the OR was full with people and equipment turned on to maximum heat loads. Personnel were moving fast and not according to routine protocols. Our conclusion is that the system is robust and disturbances have a minimum impact on functionality.

Unlike conventional LAF systems, TcAF is able to maintain <10CFU/m3 throughout the entire room. This is particularly important given that previously sterilized items such as instruments and implants are often staged in the periphery of the room. The size of the clean zone with a typical LAF system leaves scant room for instrument tables. Personnel in TcAF rooms also report a higher level of comfort as these systems are quieter and produce fewer cold draughts.

References

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2. Addendum Dutch Orthopaedic Society “Verenigingsstandpunt NOV betreffende de eisen voor een klasse 1+ operatiekamer”, April 2022;
3. Teknisk specification SIS-TS 39:2012: “Microbiological cleanliness in the operating room – Preventing airborne contamination – Guidance and fundamental requirements”, April 2013