

The use of Operio over critical zones
and instruments
to reduce air-borne contamination
at intravitreal eye injections

A study from an eye clinic in a
Swedish University Hospital
October 2015



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Objective of the measurements

The objective is to determine if Operio reduces air-borne colony forming units (e.g. bacteria), hereafter referred to as CFU, during intravitreal injections near the surgical site and over instruments. Comparison shall be made to ambient air in the room without the clean air flow from Operio, here referred to as Reference.

Measurement method

Measurements on the bacteria occurrence over the critical zone and instruments were carried out during 23 authentic eye injections at a Swedish University Hospital in Sweden, in October 2015. Prior to using the air zone unit on patients, a simulated measurement took place in June 2015 at the same location. This report includes and compares results from both the simulated measurement and the authentic surgical procedures.

CFU – Bacteria sampling

The bacteria sampling was carried out by using an active CFU sampler and sterile agar plates of 55 mm that later were incubated in 32°C for 72 hours. The air was sampled over the instruments and as near the injection site as possible. Reference values were sampled outside the critical zone and at various locations in the room. At each measurement cycle 1m³ of air was sampled for 10 minutes. The CFU sampler was not covered with sterile drapes but was handled very delicately not to get in touch with the critical zones. CFU = Colony Forming Unit.

Particulate sampling

To evaluate the effect of the HEPA filtrated air flow, particulates were sampled near the injection site as well as in the ambient area for reference. Particulate sizes in the intervals > 0.5 µm and > 5.0 µm are sampled in the air and it takes approximately 1 minute to sample 0.1 foot³. These sizes of particulates are of interest since studies have shown a direct relation between the amount of particulate and its possibility of carrying bacteria.

Endpoints

The primary outcome is to determine the CFU level in the air at the surgical site and over instruments. The time frame is up to one week after the sampled air.

Conditions

The ventilation system in the examination room consisted of air inlet and air outlet installed in the ceiling. An air conditioner was placed at the floor level but with the air outlet positioned away from the air zone unit Operio to avoid air disturbances. The critical zones were supplied with HEPA filtered air from the air zone unit Operio, positioned to protect both sterile instruments and the injection site from contamination of falling particulates. The examination room had an approximate size of 200 ft². Altogether 3-4 people were present in the room and any activity from people moving around in the room was low. Doors were only opened to let in and out patients.

Summary of measurement results

CFU mean values for simulated and authentic eye injections

Date	Samples	Measurement site	Operio mean* value	Reference mean* value	Difference
15th of June	2	Simulated injection	1	90	90
6th of October	27	Injection patient 1-23	0.4	48.2	120

**Full test records are presented in the appendixes.*

Particulate mean values for simulated and authentic eye injections

Date	Samples	Measurement site	Operio mean* value		Reference mean* value		Difference	
			Part >0.5µm	Part >5 µm	Part >0.5 µm	Part >5 µm	Part >0.5 µm	Part >5 µm
15th of June	12	Simulated injection	2.6	0.16	1262	58.66	485	367
6th of October	31	Injection patient 1-23	1.1	0	747.1	33	680	> 33

**Full test records are presented in the appendixes.*

Conclusion

The test results clearly show that there is a significant difference in the occurrence of bacteria and particulates when the injection site and instruments are provided with particulate free air from the air zone unit Operio compared to the ambient air in the room.

The bacteria counting result showed that the difference was as prominent as 120 times for authentic injections, with a mean value less than 1 CFU over the critical zone and instruments compared to a mean value of 48 CFU's in the ambient air. The simulated injection differed 90 times, but this was based on only two measurements. The difference between the simulated and authentic situation was not prominent.

To verify that efficiency from the HEPA filtrated air, particulates was sampled simultaneously. From a particles point of view, the difference was apparent to. The air was found to be 421 times cleaner over the critical zone for particulates of sizes > 0.5 µm. Particulates of sizes 5 µm could not be detected. The particulates are of interest since a low amount of particulates will have a low CFU count. However, the reverse does not apply since not all particulates carry bacteria.

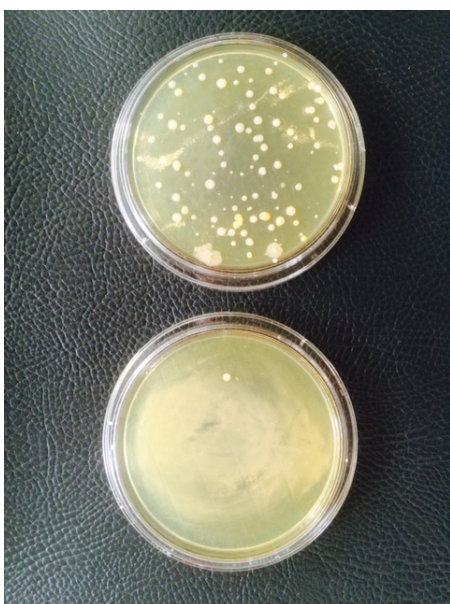
A typical recommendation is that the CFU value for clean surgery should be less than 10. Since the air zone unit Operio showed a mean result of less than 1 CFU at 22 CFU measurements when sampled in the critical zone, this is well within the recommendation. In conclusion, it is considered to be statistically valid that the particulate free air from the air zone unit Operio is very effective to use over the critical zones to reduce the levels of airborne bacteria carrying particles which could be a cause for post-operative infections.

Appendix 1 – Measurement record 12th of June 2015

CFU measurement at simulated eye injection

Test equipment		Airflow m³/min	
SAS Super ISO		1m ³ /10 min	
Filter manufacturer Batch no 1503302936		Agar plate substrate TSA+TW+LEC	
Date 12th of June 2015		Responsible for test Toul Meditech AB	
Operation room Examination room approx 200 ft ²		Type of surgery Simulated eye injection	
Incision start	Wound closing	Clothing Mertex	

No	Start	Stop	Door openings	People present	Sample	Comment	Total cfu per plate	Count date
Reference Plate 1				3	Reference ambient air	Centre of the room	90	16/6
Plate 2				3	Clean zone	Simulated injection site	1	16/6
Comment	Result for incubate plates see below							



Top – The agar plate from the ambient air without Operio has approx. 90 CFU / m³ air.

Bottom – The agar plate from the simulated injections site has with the use of Operio has 1 CFU / m³ air.

Appendix 2 – Measurement record 12th of June 2015

Particulate counts at simulated eye injections

Test equipment		Airflow m³/min	
Aerotrak TSI		1 fot ³ /1 min	
Date		Responsible for test	
6th of October 2015		Toul Meditech AB	
Operation room		Type of surgery	
Examination room approx 200 ft ²		Simulated eye injection	
Incision start	Wound closure		Clothing
			Mertex

No	Time	Measurement site Operio		Measurement site Reference		Comment
		Part >0.5µm	Part >5 µm	Part >0.5 µm	Part >5 µm	
1		2	0			Injection site/instruments
2		0	0			
3		3	0			
4				1167	62	Reference ambient air
5				1412	78	
6				1051	42	
7		0	0			Injection site/instruments
8		4	0			
9		7	1			
10				1312	67	Reference ambient air
11				1408	54	
12				1221	49	
	Mean value	2.6	0.16	1261.83	58.66	
	Highest value	7	1	1412	78	

485 times

Appendix 3 – Measurement record 6th of October 2015

CFU measurement at 23 authentic eye injections

Test equipment		Airflow m³/min	
SAS Super ISO		1m ³ /10 min	
Filter manufacturer Batch no LOT 1503302936		Agar plate substrate TSA + TW +LEC	
Date 6th of October 2015		Responsible for test Toul Meditech AB	
Operation room Examination room approx 200 ft ²		Type of surgery Intravitreal injection, Lucentis & Eylea	
Incision start Started at 8:05	Wound closure Continued to 15:20		Clothing Mertex

Type of surgery	Intravitreal eye injections	Number of patients	23
Duration of surgery	10 minutes/patient	Age of patient	70-85 years
Location of air delivery	40” from injection site, from right side	Gender	M/F
OR room	Procedure room		

No	Start	Stop	Door openings	People present	Sample	Comment	Total cfu per plate	Count date
Plate 1	8:05	8:15		4	Reference	Reference	42	11/10
Plate 2	8:16	8:26	1	4	Operio	Patient 1	2	11/10
Plate 3	8:27	8:37	1	4	Operio	Patient 2	0	11/10
Plate 4	8:40	8:50	1	4	Operio	Patient 3	0	11/10
Plate 5	8:52	9:02	1	4	Operio	Patient 4	2	11/10
Plate 6	9:05	9:15	1	4	Operio	Patient 5	0	11/10
Plate 7	9:15	9:26	1	4	Operio	Patient 6	0	11/10
Plate 8	9:30	9:40	1	4	Operio	Patient 7	0	11/10
Plate 9	9:48	9:58	1	4	Operio	Patient 8	0	11/10
Plate 10	10:10	10:20	1	4	Reference	Reference	24	11/10
Plate 11	10:28	10:38	1	4	Operio	Patient 9	1	11/10
Plate 12	10:40	10:50	1	4	Operio	Patient 10	0	11/10
Plate 13	10:51	11:01	1	4	Operio	Patient 11	0	11/10
Plate 14	11:02	11:12	1	4	Operio	Patient 12	1	11/10
Plate 15	11:13	11:23	1	4	Operio	Patient 13	0	11/10

Plate 16	11:26	11:36	2	4	Operio	Patient 14+15*	1	11/10
Plate 17	11:37	11:47	1	4	Operio	Patient 16	0	11/10
Plate 18	11:50	12:00	1	4	Reference	Reference	100	11/10
Plate 19	13:03	13:13	2	4	Reference	Reference	46	11/10
Plate 20	13:14	13:25	2	4	Operio	Patient 17	0	11/10
Plate 21	13:25	13:35	1	4	Operio	Patient 18	0	11/10
Plate 22	13:40	13:50	1	4	Operio	Patient 19	0	11/10
Plate 23	13:52	14:02	1	4	Operio	Patient 20	1	11/10
Plate 24	14:08	14.18	1	4	Operio	Patient 21	1	11/10
Plate 25	14:22	14:32	1	4	Operio	Patient 22	0	11/10
Plate 26	14:33	14:43	1	4	Reference	Reference	29	11/10
Plate 27	15:10	15:20	1	4	Operio	Patient 23	0	11/10
Mean value Operio							0.4	
Highest value Operio						120 times	2	
Mean value Reference							48.2	
Highest value Reference							100	
Comment	Results for incubated agar plates with the correspondent number see below. * Patient 14+15 is the same patient and had double injections.							

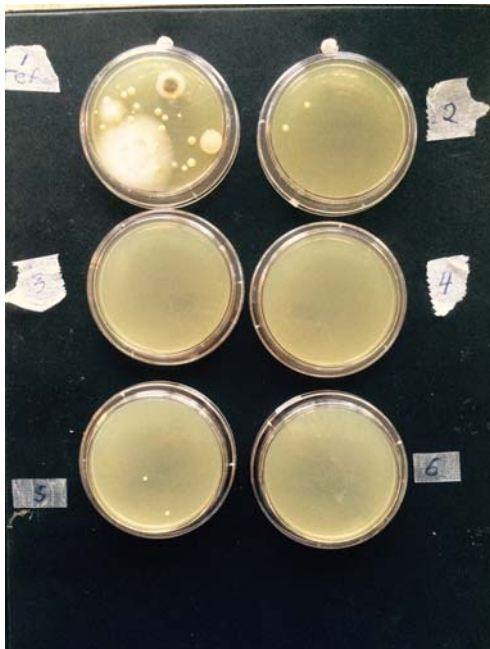


Plate 1-6

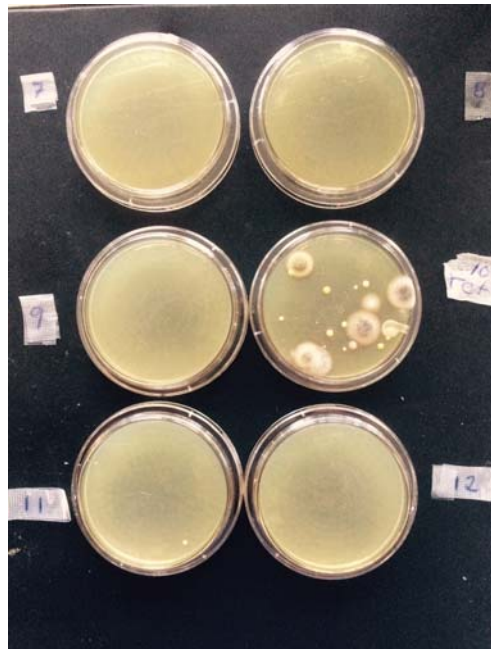


Plate 7-12

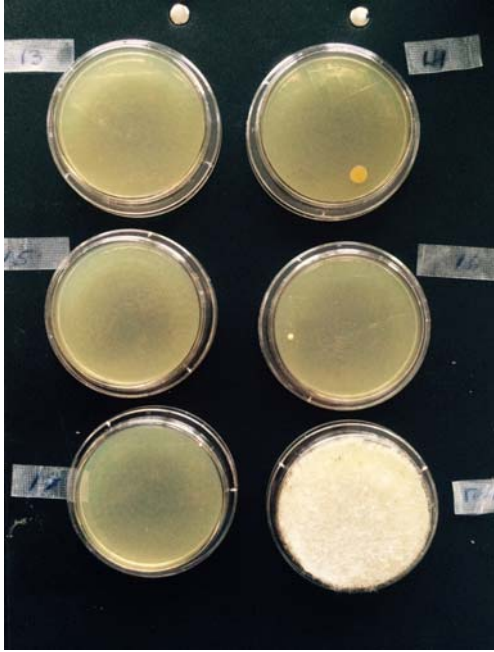


Plate 13-18

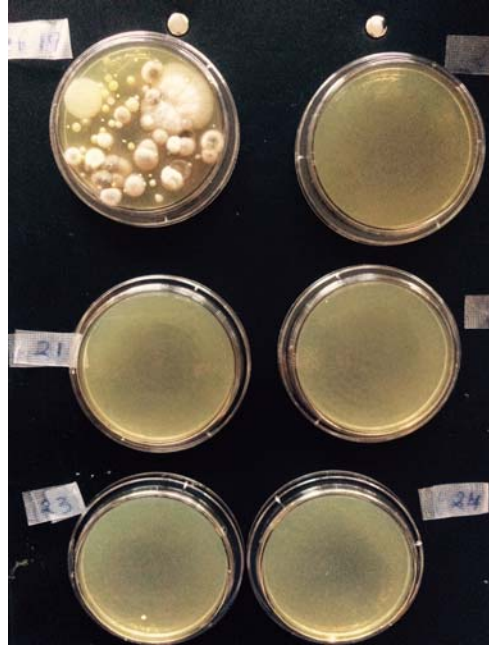


Plate 19-24

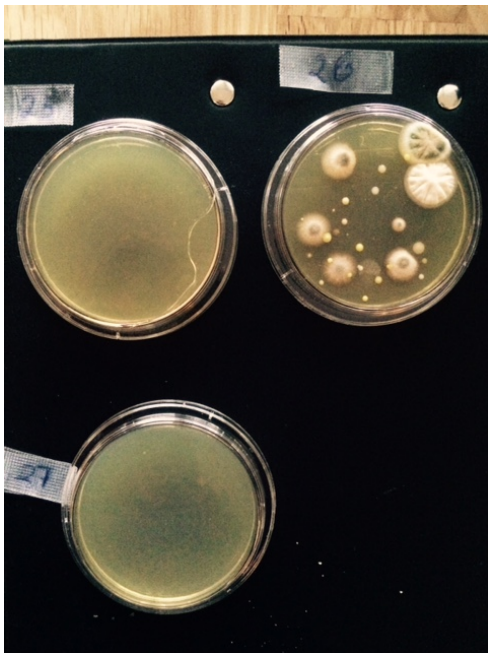


Plate 25-27

Appendix 4 – Measurement record 6th of October 2015

Particulate counts at 23 authentic eye injections

Test equipment		Airflow m³/min	
Aerotrak TSI		1 fot ³ /1 min	
Date		Responsible for test	
6th of October 2015		Toul Meditech AB	
Operation room		Type of surgery	
Examination room approx 200 ft ²		Intravitreal injection, Lucentis & Eylea	
Incision start	Wound closure	Clothing	
Start from 8:05	Continued to 15:20	Mertex	

No	Time	Measurement site Operio		Measurement site Reference		Comment
		Part >0.5µm	Part >5 µm	Part >0.5 µm	Part >5 µm	
1	10:20			403	11	No patient in the room
2	10:21	0	0			No patient in the room
3	10:22			529	30	No patient in the room
4	10:24	0	0			No patient in the room
5	10:25			622	37	No patient in the room
6	10:28			1045	37	Patient 9
7	10:30			1049	39	Patient 9
8	10:35			657	26	Patient 9
9	10:45			856	30	Patient 10
10	11:00	2	0			Patient 11
11	11:01	3	0			Patient 11
12	11:03			762	29	Patient 12
13	11:10	0	0			Patient 12
14	11:11			647	30	Patient 12
15	11:27			762	29	Patient 14
16	11:28	2	0			Patient 14
17	11:37			669	44	Patient 16
18	11:38	1	0			Patient 16
19	13:05			1092	37	No patient in the room
20	13:06	2	0			No patient in the room
21	13:27			694	32	Patient 18
22	13:28	0	0			Patient 18
23	13:40			880	36	Patient 19
24	13:42	1	0			Patient 19
25	14:00			798	32	Patient 20

26	14:05			962	42	No patient in the room
27	14:06	1	0			No patient in the room
28	14:23			1021	46	Patient 22
29	14:24	0	0			Patient 22
30	15:15			1263	34	Patient 23
31	15:16	2	0			Patient 23
	Mean value	1.1	0	747.1	33.3	
	Highest value	3	0	1263	46	

680 times