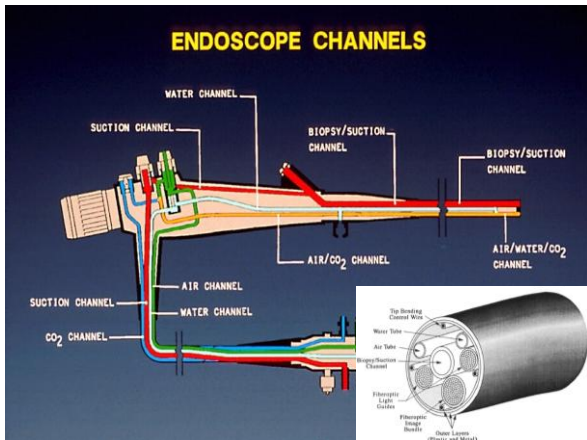




Preliminary study measuring ATP Bioluminescence as a means of validating the decontamination process of the gastrointestinal endoscopes

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GI ENDOSCOPES

- Widely used in diagnostic and therapeutic procedures
- Endoscope contamination during use (10^9 - 10^5)
- Semi critical item- requires at least high-level disinfection
- Inappropriate cleaning and disinfection has lead to cross-transmission
- Though the incidence remains very low, endoscopes represent a risk of disease transmission



TRANSMISSION OF INFECTION

- Gastrointestinal endoscopy
 - >250 infections transmitted
 - *Salmonella* sp. and *P. aeruginosa*
 - Clinical spectrum ranged from colonization to death (~4%)
 - Bronchoscopy
 - >90 infections transmitted
 - *M. tuberculosis*, atypical *Mycobacteria*, *P. aeruginosa*
- Spach DH et al Ann Intern Med 1993; 118:117-128



Endoscope Reprocessing: Quality Assurance

- Quality reprocessing is checked by performing routine Microbiological cultures according to the GENCA guidelines (2008)
- All GI endoscopes (except Duodenoscopes) should be monitored every 3 months
- Negative results are not available till 7 days
- This protocol continues to threaten the safety of patients undergoing endoscopy
- Therefore more rapid and practicable method is desirable



ATP Bioluminescence

- ATP is found in organic matter and living cells including bacteria
- This technology utilizes the light producing reaction between ATP, luciferin and luciferase to estimate levels of ATP in a sample
- Luminometer machine converts the number of photons in to Relative Light Units (RLUs)
- This linear transformation makes the readings from these systems quantifiable
- The result is available in less than 2 minutes
- This method is widely used in **Food Industry** to check cleaning



How many GI Endoscopes procedures (Colonoscopes, Duodenoscopes, Gastroscopes) performed per year??

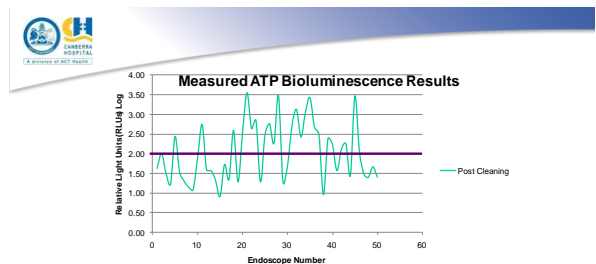
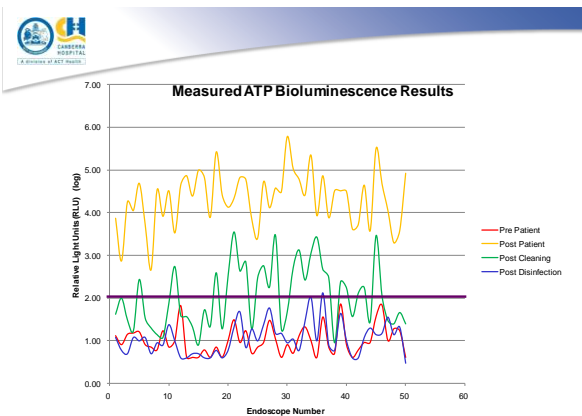
During 2009-2010 4,200 procedures were performed using 6 colonoscopes, 4 Duodenoscopes and 4 Gastroscopes.

Study method to evaluate ATP as a rapid test

- Endoscopes (50)
 - Gastroscopes (26)
 - Duodenoscopes (5)
 - Colonoscopes (19)
- Endoscopes Flushes
 - Pre Patient (Pre Pt)
 - Post Patient (Post Pt)
 - Post Clean (Post Cl)
 - Post Disinfection (Post Dis)
- Microbiological Culture- Blood agar (35° C), Chocolate agar (35° c), MacConkey agar (35° c) for 7 days
- ATP Test- Aqua-Trace ATP Test (3M Biotrace International Bioproduct)
- Failure if ATP result - >100 RLUs (Hensen & Hilgenhoner et al 2008)

Measured ATP Bioluminescence result (RLUs) across the procedure

	Pre Patient	Post Patient	Post Cleaning	Post Disinfection
Average	15	55,324	432	18
MIN	4	452	8	3
MAX	73	594,016	3,555	134

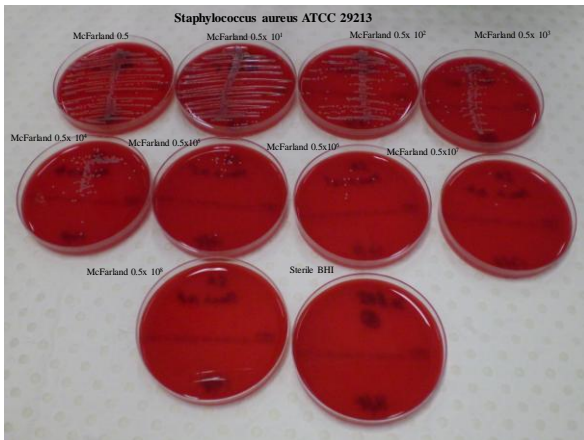


Post Cleaning	>100 RLUs	< 100 RLUs
Sample No	26	24
Culture Positive	10	14



Investigation of Post cleaning Problem??

- How was the Post cleaning specimen collected?
- Collected after manual cleaning of the endoscope with "Cleantec"- Proteolytic Enzyme Detergent
- Does this reaction inhibit the ATP luciferin/Luciferase reaction??
- Checked the ATP value
 - Known organism (Gram positive, negative, Candida albicans, Atypical Mycobacteria)
 - Known concentrations (McFarland 0.5 up to 8 times diluted)
 - Diluted with either DW and "Cleantec" solution
- ATP value was same



Investigation of Post cleaning problem?? Cont:

- Checked the ATP swabs with known ATP negative/positive controls
- Positive controls – showed low reading (< 1000 RLU). Why??
- Where is the problem??
 - The ATP Swabs
 - The Luminometer Machine
 - The ATP positive controls
- The problem was with the ATP swabs
- New ATP swabs
 - Checked with known ATP negative/positive controls
 - Checked with known organisms of known concentrations



St.BHI + S.aureus-ATCC 29213(Diluted in St. DW)

	SA BHI McF 0.5	x10 ¹	x10 ²	x10 ³	x10 ⁴	x10 ⁵	x10 ⁶	x10 ⁷	x10 ⁸	St BHI	St DW
Bact/ ml	1.5x10 ⁸	x10 ⁷	x10 ⁶	x10 ⁵	x10 ⁴	x10 ³	x10 ²	x10 ¹	1	0	0
ATP/ RLU	81,198	26,575	10,427	1,137	651	108	61	21	22	5,462	20
CFU/ ml	>1000	>1000	>500	>250	162	19	9	3	0	0	0

St.BHI + E.coli -ATCC 25922 (Diluted in St. DW)

	EC BHI McF 0.5	x10 ¹	x10 ²	x10 ³	x10 ⁴	x10 ⁵	x10 ⁶	x10 ⁷	x10 ⁸	St BHI	St DW
Bact/ ml	1.5x10 ⁸	x10 ⁷	x10 ⁶	x10 ⁵	x10 ⁴	x10 ³	x10 ²	x10 ¹	1	0	0
ATP/ RLU	84,840	40,208	8,677	1,316	344	129	79	69	40	4,812	21
CFU/ ml	>1000	>1000	>500	>250	92	37	5	1	0	0	0



New ATP Swabs

- The investigations were carried on
 - *Staphylococcus aureus* ATCC 29213
 - *Enterococcus faecalis* ATCC 29212
 - *Escherichia coli* ATCC 25922
 - *Pseudomonas aeruginosa* ATCC 27853
 - *Candida albicans* ATCC 10231
 - *Mycobacterium fortuitum* ATCC 6841



Conclusions

- ATP test is not a sterility test
- ATP results vary between different organisms
- Sensitivity level varies between 10,000-1,000 organisms/ml (Culture sensitivity varies between 100-10 organisms/ml)
- ATP is a reasonable indicator of contamination but not as good as culture
- Good indicator to check the level of manual cleaning before automatic washer/disinfecter cycle
- May be a valuable point of care testing prior to the insertion, but further studies needed



Lessons Learnt

- Though ATP is a rapid test, it is not as good as Microbiology cultures
- Mandatory to carry out positive/negative controls with **known ATP controls**

Limitations of the study

Lack of investigations for viruses and non microbial (organic) contamination



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Thank You