

Micro-Flora Research Study - 2010

Specific Micro-Flora Colonies Selected Testing the Survival Percentage Post Medium Exposure over a 24 Hour Period Utilizing the Expertise of ATCC - American Type Culture Collection.

Abstract:

Normal micro-flora constitutes the non-pathogenic bacteria that colonize virtually all surfaces of the human body. Normal flora cause no harm to their host and in fact serve a vital function as a protective barrier that aids in the prevention of infection and colonization of body surfaces by pathogenic microbes. Since 1999, a significant increase in post-operative infections and/or deaths has occurred following placement of nasal-pharyngeal tubes and/or urinary type catheters. This increase in surgical complications may very well coincide with a change in the primary type of lubricant(s) used for intubation, catheter placement and/or OBGYN procedures.

From its introduction in 1931 until production ceased in late 1999, HR Lubricating Jelly was the preferred choice and the industry standard in hospitals, nursing homes, operating rooms and physician's offices. HR Lubricating Jelly is a dye free formulation that does not contain sterilizing bacteriostatic agents. In the past ten years, lubricants containing Chlorhexidine as a sterilizing bacteriostat and/or other chemical formulations such as Polyethylene Glycol (PEG) have filled the void left when HR Lubricating Jelly was no longer available. One possible explanation for the correlation between the increase in surgical complications and the introduction of bacteriostatic-containing lubricants may be the perturbation of the normal flora; bacteriostatic agents kill micro-flora and increase the opportunity for infection at these sites by means of pathogenic microbes. Other possibilities may include water quality and/or ingredient quality used to produce these lubricants whether they be a branded and/or generic.

Studies to address this hypothesis will determine if the increasing number of surgical complications or at least partially, from the replacement of HR Lubricating Jelly with lubricants that could potentially alter to normal occurring floral on the patient. Our goal is to prove that HR Lubricating Jelly is a "benign/gentle" lubricant in that it is micro-flora friendly and safe to use for all OBGYN procedures including PAP Smears as well as Group B Streptococcus cultures.

This test was performed according to the ASTM E 2315e Kill Test and the medium was brought into contact with a known population of microorganisms for a specific period-of-time at a specific temperature. Activity of the test medium was quenched by a neutralizing broth and surviving microorganisms were enumerated. The percent reduction was calculated from initial microorganisms and surviving microorganisms data.

Test Materials:

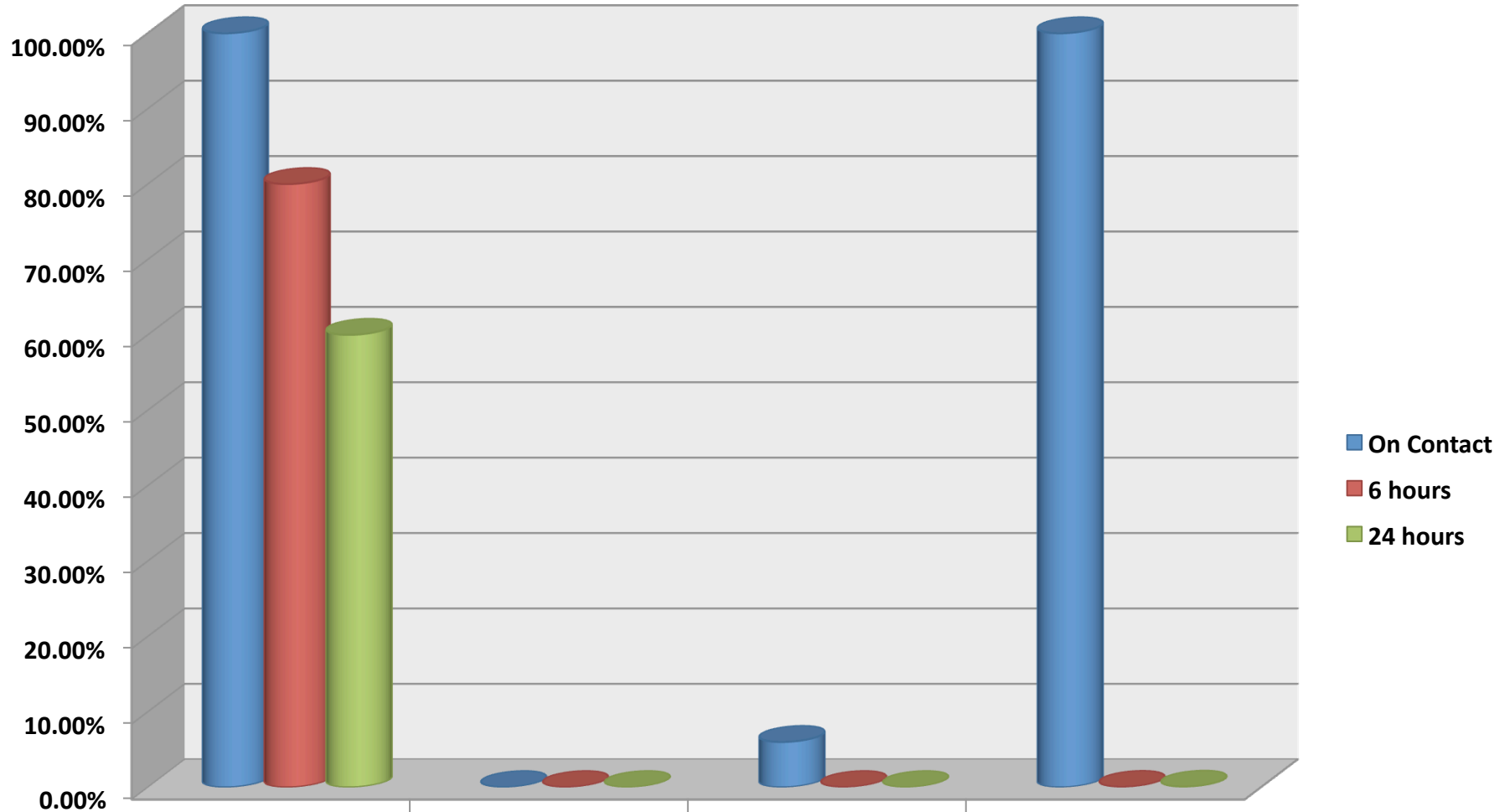
HR Lubricating Jelly – a sterile medical grade lubricant

Surgilube- a lubricant utilizing Chlorhexidine is a bacteriostatic used in lubricants such as "KY" & "KY" Generics Triad Lubricating Jelly - contains PEG-6, PEG-32, PEG-300 & PEG-1450

Medline EZ Lubricating jelly- contains Methylparaben & Propylparaben as a bacteriostatic

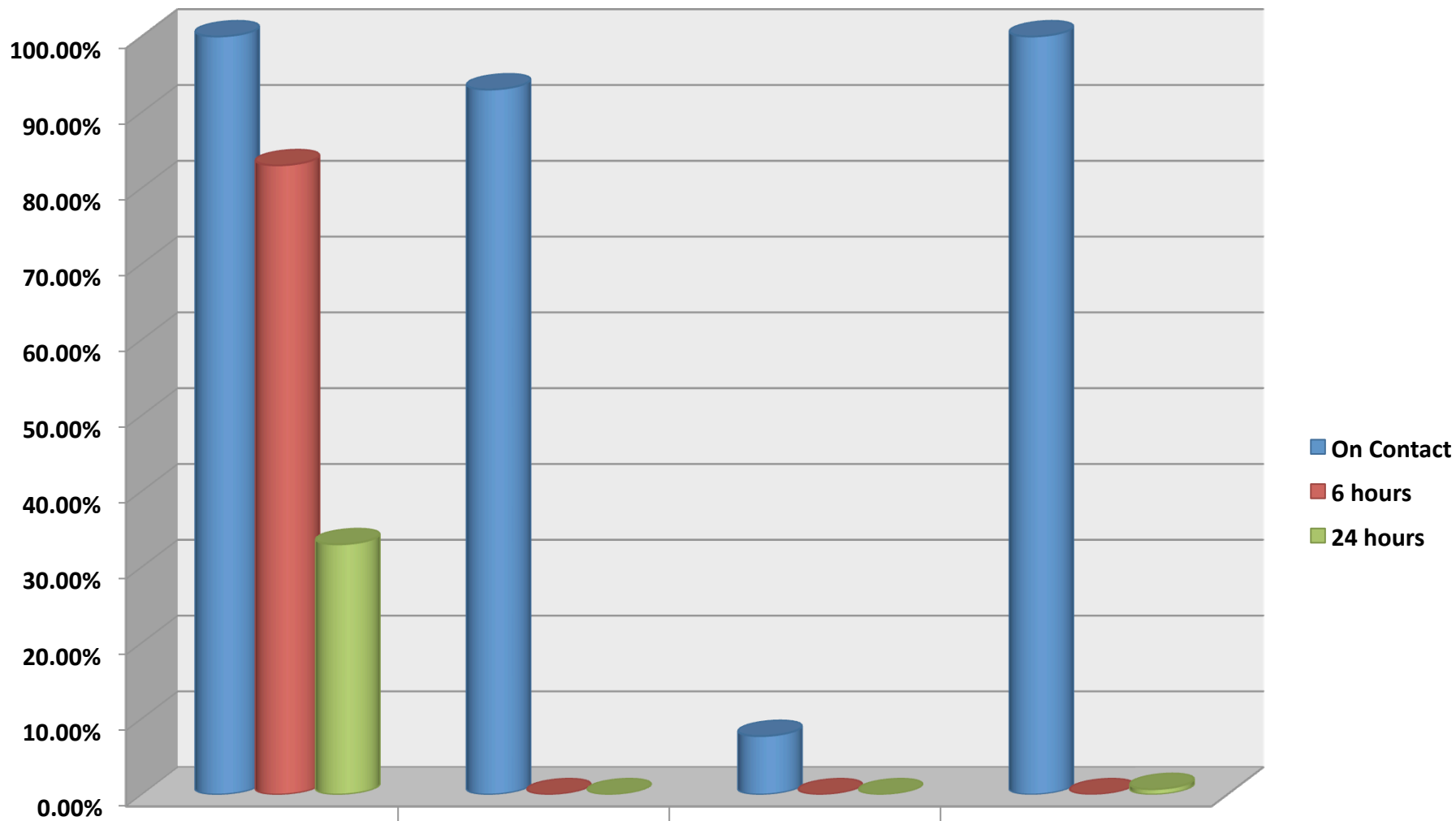
A Nutrient Rich Medium - "Control Group" a nutritional resource for micro-organisms to feed/proliferate

% Viable Microflora Post Lubricant Exposure Lactobacillus Acidophilus



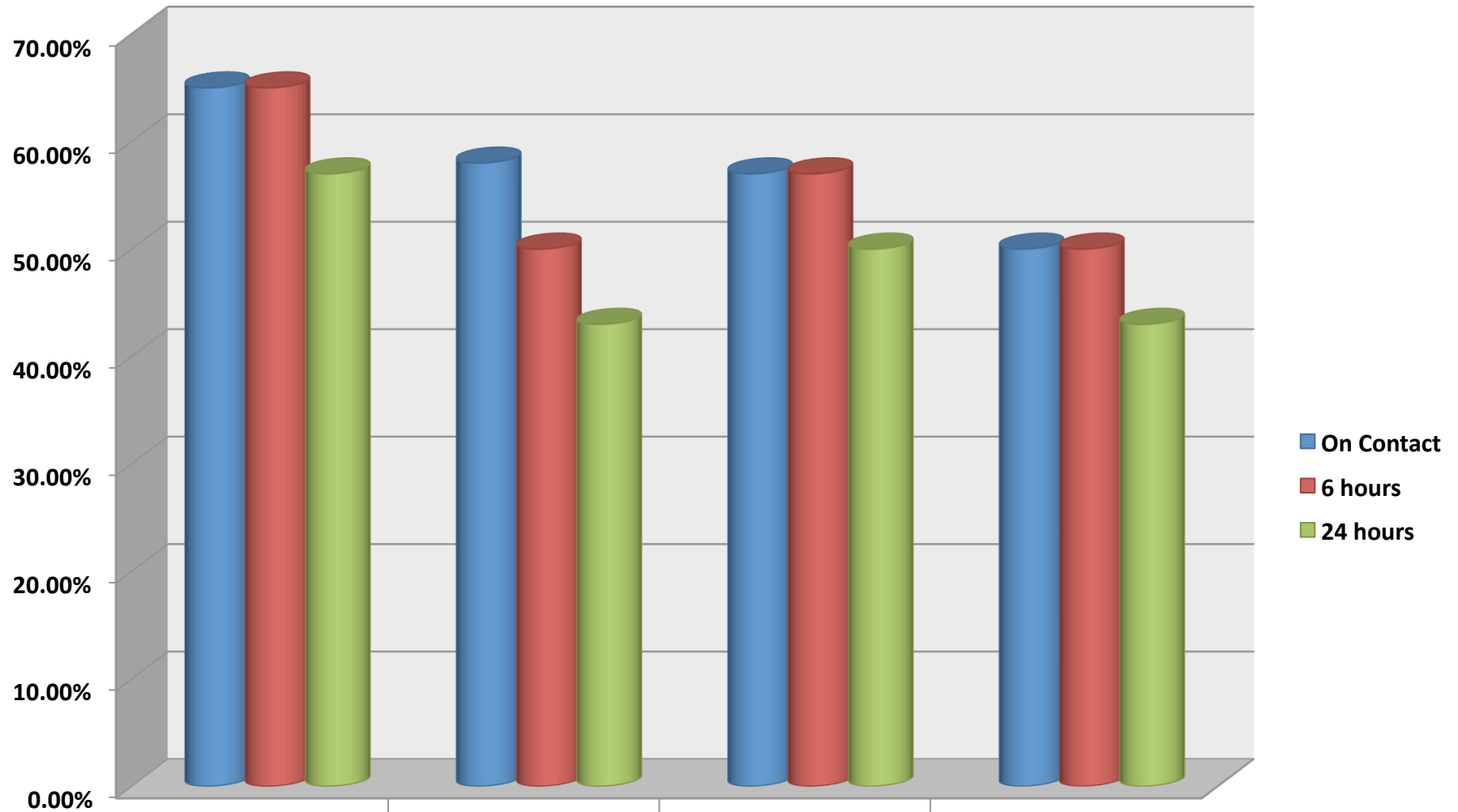
	HR® Lubricating Jelly	Surgilube®	Triad® Lubricating Jelly	Medline EZ Lubricating Jelly
On Contact	100.00%	0.01%	6.00%	100.00%
6 hours	80.00%	0.01%	0.01%	0.03%
24 hours	60.00%	0.01%	0.01%	0.06%

% Viable Microflora Post Lubricant Exposure Lactobacillus Crispatus



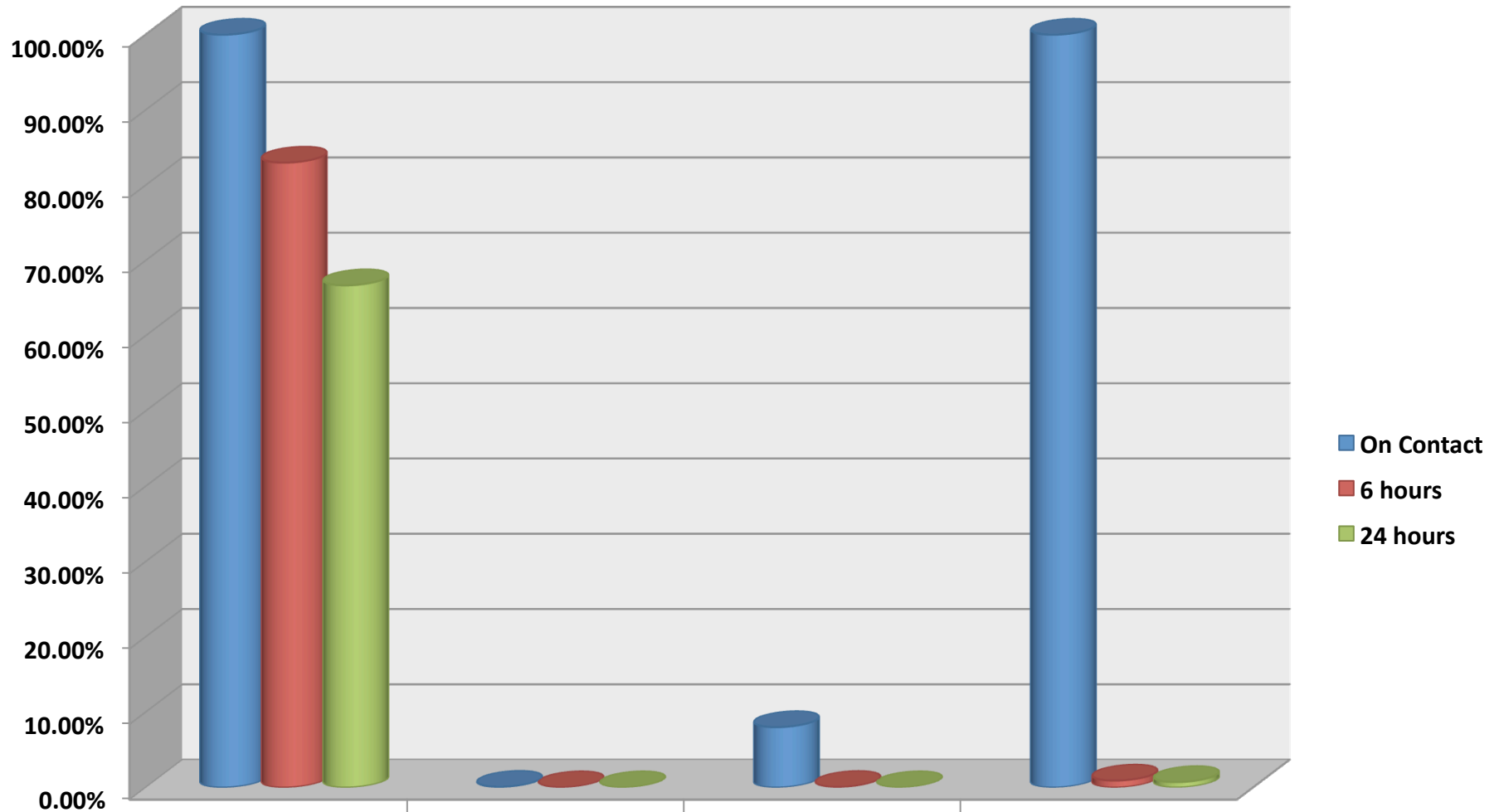
	HR® Lubricating Jelly	Surgilube®	Triad® Lubricating Jelly	Medline EZ Lubricating Jelly
On Contact	100.00%	93.00%	7.70%	100.00%
6 hours	83.00%	0.01%	0.01%	0.01%
24 hours	33.00%	0.01%	0.01%	0.70%

% Viable Microflora Post Lubricant Exposure Lactobacillus Fermentum



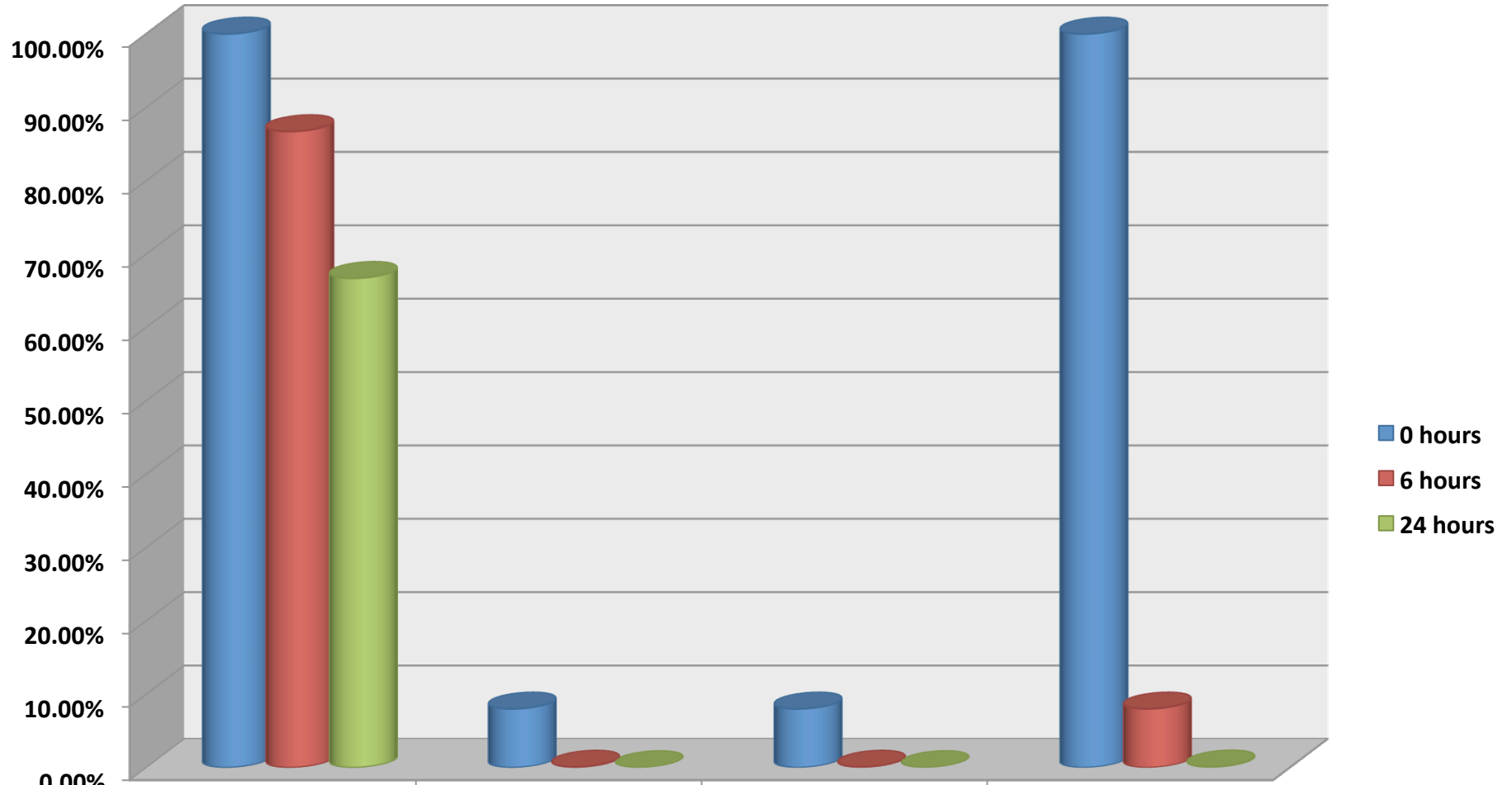
	HR® Lubricating Jelly	Surgilube®	Triad® Lubricating Jelly	Medline EZ Lubricating Jelly
On Contact	65.00%	58.00%	57.00%	50.00%
6 hours	65.00%	50.00%	57.00%	50.00%
24 hours	57.00%	43.00%	50.00%	43.00%

% Viable Microflora Post Lubricant Exposure Lactobacillus Delbruekii



	HR® Lubricating Jelly	Surgilube®	Triad® Lubricating Jelly	Medline EZ Lubricating Jelly
On Contact	100.00%	0.07%	8.00%	100.00%
6 hours	83.00%	0.01%	0.05%	0.90%
24 hours	66.70%	0.01%	0.01%	0.70%

% Viable Microflora Post Lubricant Exposure Lactobacillus Gasseri



	HR® Lubricating Jelly	Surgilube®	Triad® Lubricating Jelly	Medline EZ Lubricating Jelly
0 hours	100.00%	8.00%	8.00%	100.00%
6 hours	86.70%	0.07%	0.07%	8.00%
24 hours	66.70%	0.01%	0.01%	0.10%

Results

In conclusion, HR Lubricating Jelly in its present state offers a very limited nutrient resource; this would also include all Medical type lubricants. With that said, at 24-hours HR Lubricating Jelly had a 60+% viable response, whereas at 48 hours, the micro-flora had expired. In most cases, the three (3) comparative lubricants killed the micro-flora within minutes of exposure