

# Evaluation of Female Condom 2 lubricant

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# Overview

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- Female Condom 2 (FC2)
- Lubricant types
- How does FC2 compare?



# Why study FC2 lube?

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- The FC is being offered to women in many microbicide clinical trials.
- The availability of the FC is increasing.
- The FC is coated with a lubricant similar to male condoms.
- Would this lubricant impact any clinical trial safety parameters?

# Female Condom 2

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- The female condom is a thin sheath or pouch worn by a woman during sex.
- It entirely lines the vagina to prevent pregnancy and sexually transmitted diseases including HIV.
- Female Condom 2 is made of nitrile.





# Female Condom 2

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- The condom satchel contains ~1.2 to 1.4 grams of lube.
- The lube is polydimethyl siloxane fluid also known as Silicone oil commonly used on male condoms.
- We tested the FC2 lube for safety and anti-HIV activity.

# Formulation Characteristics

Lubricant	Osmolality (mmol/kg)	pH	Viscosity (cps, 10 rpm @ 25°C)
Semen	321	8.1	4
PRÉ	502	7.3	1683
KY Jelly	2510	4.5	5913
ID Glide	3150	5.2	751
Elbow Grease	3865	5.7	3159
Astroglide	6113	4.0	207
FC2 lube	NA	NA	330
Wet Platinum	NA	NA	145

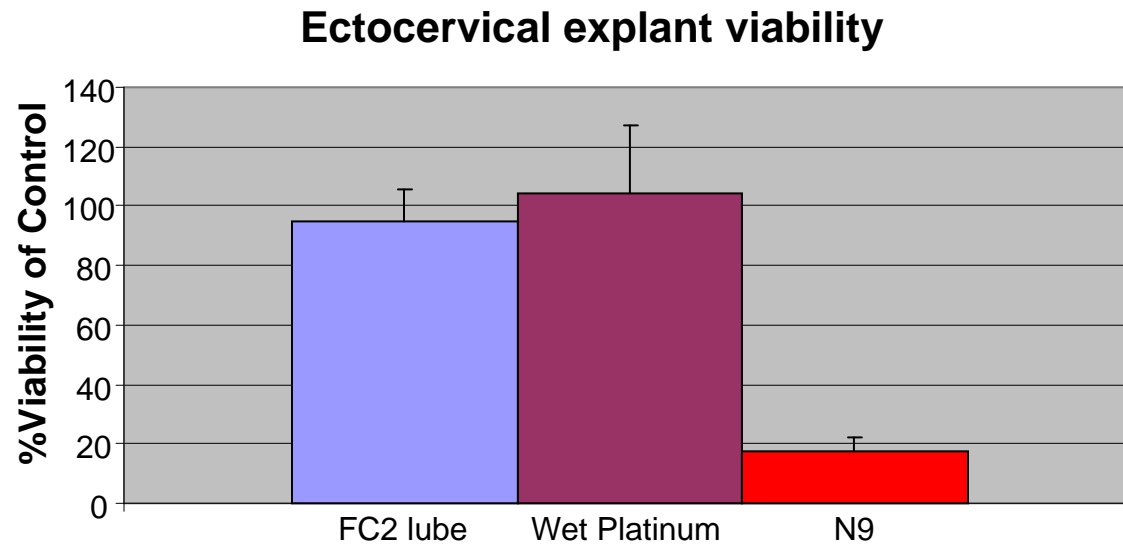


# FC2 Lube Testing

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- Does the FC2 lube effect tissue viability?
- Does the FC2 lube impact the epithelium?
  - Evaluate permeability of stratified epitheilium
  - Tissue histology
- Does the FC2 lube have anti-HIV activity?

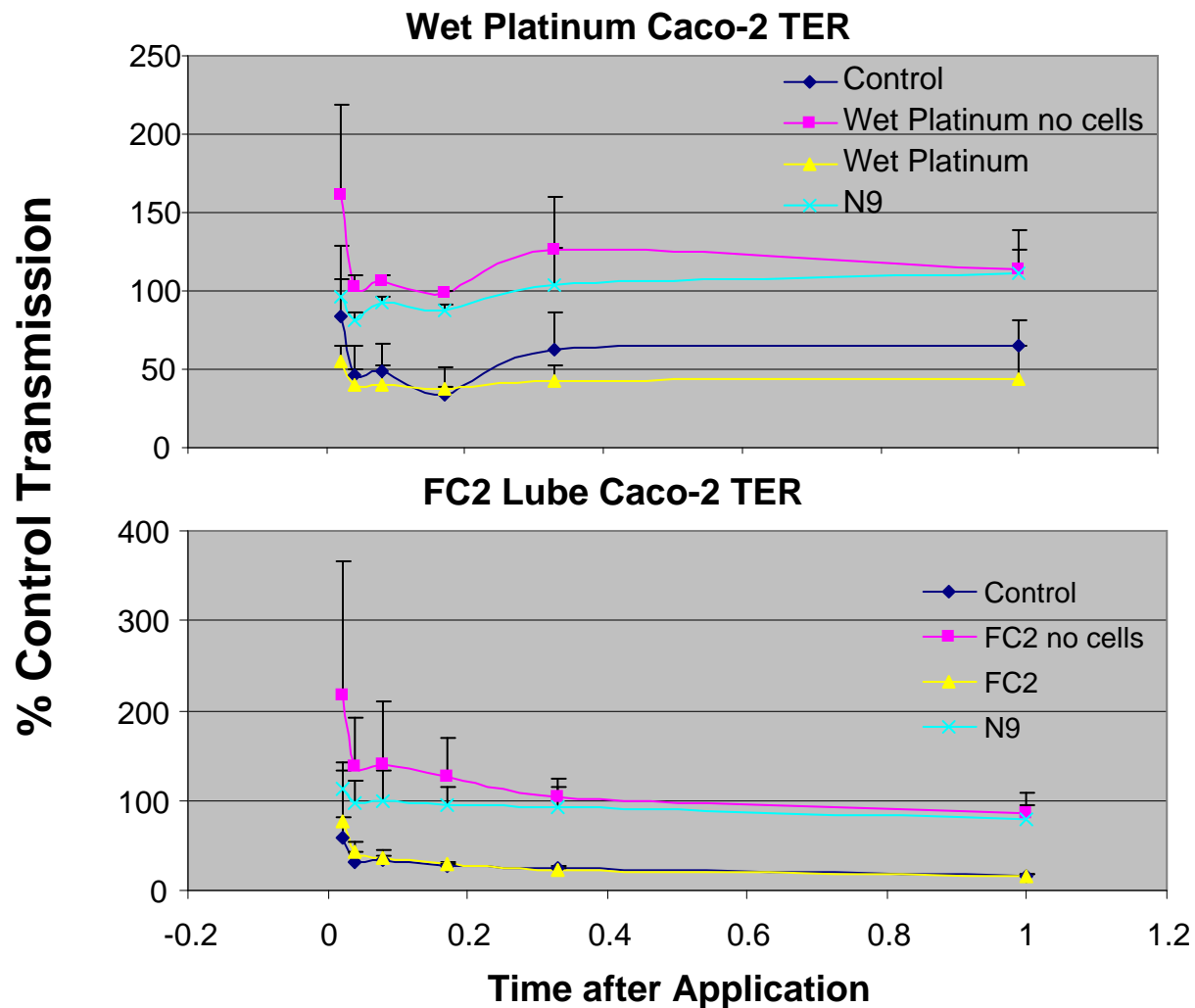
# Does the FC2 lube effect tissue viability?



Colorectal explant viability being determined

Dezzutti, C.S. unpublished results

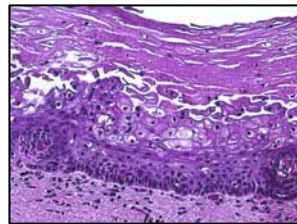
# Does the FC2 lube impact the epithelium?



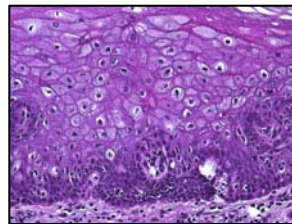
Dezzutti, C.S. unpublished results

# Does the FC2 lube impact the epithelium?

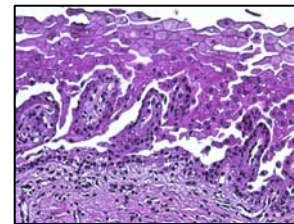
Ectocervical explants



Control



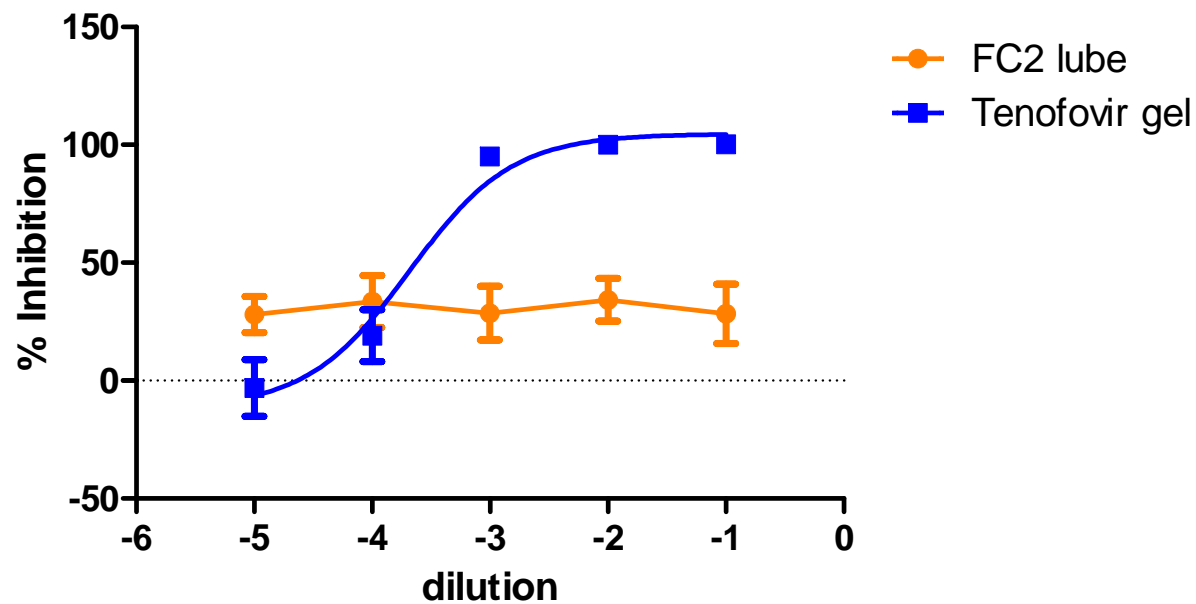
FC2 lube



N9

Colorectal explants are in progress

# Does the FC2 lube have anti-HIV activity?



Dezzutti, C.S. unpublished results

# Summary

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- Does the FC2 lube effect tissue viability?
  - NO
- Does the FC2 lube impact the epithelium?
  - Evaluate permeability of stratified epitheilium
    - NO
  - Tissue histology
    - NO
- Does the FC2 lube have anti-HIV activity?
  - NO



# We can say...

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- The FC2 lube appears to be safe and does not have any residual anti-HIV activity
- The FC2 appears to be safe to use in microbicide clinical trials.

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