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### DEVELOPMENT OF A HUMAN PENILE TISSUE EXPLANT MODEL TO EVALUATE SAFETY AND EFFICACY OF MICROBICIDE CANDIDATES

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Shattock R., Fischetti L., Fletcher P., Hu Q., Harman S., Mesquita P.

*St George's Hospital Medical School, London, United Kingdom*

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**BACKGROUND:** While much has been learnt about vaginal and/or rectal transmission, factors governing events between exposure of male genital mucosal surfaces and establishment of clinical infection are poorly understood and little is known about the safety and efficacy of potential microbicides for male genital tissue. However, candidate vaginal microbicides may also provide protection to male partners of HIV-1 infected women. Here we present a novel penile tissue explant model to characterise the mechanisms of HIV-1 infection of male genital tissue and evaluate candidate microbicides.

**METHODS:** Male genital tissue was obtained, with consent, from gender reassignment and other surgical procedures. Optimal mucosal explant culture conditions have been determined for glans, urethra (high and low) and transformation zone. In vitro HIV-1 infection was evaluated by measurement of p24 release and proviral formation, furthermore microbicide biocompatibility was assessed by viability assay (MTT) and cytokine production.

**RESULTS:** We have examined the relative susceptibility of different tissue sites (glans, urethra (high and low) and transformation zone). Preliminary studies demonstrate that while all sites are susceptible to HIV-1 infection, glans tissue represents the most active site for viral replication. Blocking studies using co-receptor antagonists demonstrate CCR5 and CXCR4 as the predominant receptors for HIV-1 infection. Early studies of tissue compatibility demonstrate that while nonoxynol 9 and lemon juice are highly toxic for male genital tissue, a range of candidate microbicides show good tissue compatibility. Furthermore, the candidate NNRTI microbicide TMC-120 demonstrates efficient prevention of HIV-1 infection.

**CONCLUSIONS:** The described model may provide an important tool to aid understanding of the determinants of HIV-1 infection of male genital tissue, and may facilitate the successful development of safe and effective microbicides designed to protect both men and women.

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