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**Animal Model Study of a New Patient Lubricant's  
Effect on In Vitro Fertilization & Embryo Development**

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Experiments were done to evaluate in vitro fertilization and embryo development following sperm exposure to products used to lubricate devices in fertility medicine including: KY Gel, Aquasonic Ultrasound Gel and Pre' (a new Patient Lubricant recently cleared for use during fertility interventions).

Bovine in vitro fertilization and embryo culture methods are standard and have been proposed as an excellent model for gamete toxicity studies (ReprodBioMed Online 2002;4:170-5).

In this study, cryopreserved bull sperm (from a single bull) were routinely washed, resuspended in a TALP medium and placed into one of 5 treatments. These included: 1) Control sperm in medium alone; or sperm medium suspensions with the following added (v/v) 2) 10% Pre' lubricant; 3) 50% Pre' lubricant; 4) 10% KY; or 5) 10% Aquasonic Gel.

Sperm were incubated in treatments for 30 min at body temperature, and placed into fertilization wells with mature oocytes (1 x 10<sup>6</sup> sperm cells per well).

At 8 hrs, putative zygotes were transferred into embryo culture medium and further incubated. At 32 hr of culture, dividing embryos were counted (% fertilization in each treatment).

Final development rates were evaluated on Day 7 (post IVF) to determine the % of total oocytes that had developed to the morula or blastocyst stage. ANOVA was used to compare the % fertilization of oocytes & the % of normal embryo development resulting from sperm in each treatment (as seen in Table below, data are mean +/- sd). In Vitro Fertilization & Embryo Development After Sperm Exposure



Treatment	Total Oocyte Number	% Fertilized Oocytes (+ sd)	% Embryos Developing (+ sd)
Control Medium	80	61(5)a	40(9) a
Pre' 10%	80	60(8)a	39(8) a
Pre' 50%	80	59(6)a	43(10) a
KY 10%	80	23(6)b	6(5)b
Aquasonic10%	80	0c	0c

a,b,c denote means that differ within column by  $p < 0.0001$  (ANOVA).

Pre' Patient Lubricant did not interfere with the ability of sperm to fertilize oocytes or support embryo development in vitro (using a bovine model) even at high concentrations.

Conversely, KY and Aquasonic significantly impacted the ability of sperm to fertilize oocytes, and allow normal embryo development.