Conceive Plus™
A Novel, Physiologically Important Ca\textsuperscript{2+} and Mg\textsuperscript{2+} ion Containing Non-Spermicidal Vaginal Lubricant.

Data presented here is derived from the following poster presented at the 2009 Annual Meeting of the American Society for Reproductive Medicine (ASRM):

Development of a Novel, Physiologically Important Ca\textsuperscript{2+} and Mg\textsuperscript{2+} ion Containing Non-Spermicidal Vaginal Lubricant
J. Kurtz\textsuperscript{1,2}, E. Willmer\textsuperscript{1,2}, B. Nikolic\textsuperscript{1,2}, and V. Gupta\textsuperscript{1,4}
\textsuperscript{1}Aquatrove Biosciences, Inc., Miami FL; \textsuperscript{2}Emmanuel College, Boston MA; \textsuperscript{3}Massachusetts General Hospital, Harvard Medical School, Boston MA; \textsuperscript{4}Miller School of Medicine, University of Miami, Miami FL

Fertility and Sterility, Volume 92, Issue 3, Supplement 1, September 2009, Pages S212-S213

Introduction
Exposure to over-the-counter spermicidal lubricants results in rapid loss of sperm viability and motility. The combination of suboptimal pH, osmolality, and various additives in these lubricants results in sperm damage and an inability of the sperm to penetrate into the cervix, thereby negatively impacting conception.

A novel water-based lubricant containing essential Ca\textsuperscript{2+} and Mg\textsuperscript{2+} ions and optimal pH and osmolality manufactured and marketed as Sasmar Conceive Plus™, has been designed to better mimic the natural fertile cervical fluids to alleviate the problem of vaginal dryness and to assist couples trying-to-conceive.

Abstract
Objective:
The primary objective of this study was to evaluate the performance of the novel calcium and magnesium containing non-spermicidal vaginal lubricant (Sasmar Conceive Plus™) using established in vitro assays. It also measured the effectiveness of Sasmar Conceive Plus™ in maintaining sperm viability and motility, as compared to optimum control medium. Trying to conceive couples seek a vaginal lubricant that mimics natural fluids and is not toxic to the sperm.

Results and Conclusions:
The physiologically important Ca\textsuperscript{2+} and Mg\textsuperscript{2+} ions have been incorporated into a new water-based, pH and osmolality balanced vaginal lubricant to better mimic the natural fertile cervical fluids. This scientifically designed non-spermicidal lubricant does not harm viability or motility of human sperm as compared to treatment with the optimum culture medium alone.

It does not create a barrier against sperm motility. Data shows that the new Ca\textsuperscript{2+} and Mg\textsuperscript{2+} containing lubricant does not hinder the process of egg fertilization and does not harm embryo development to the blastocyst stage. Thus, it is an ideal lubricant for assisting with the needs of couples trying-to-conceive.

Methods
The in vitro assays used in this study were according to literature protocols and followed the published WHO criteria. Some of the assays were conducted in a blinded fashion by independent third parties on a fee-for-service basis. Optimum media was used as a control in all assays. The newly designed water-based lubricant that has balanced pH and osmolality and that contains Ca\textsuperscript{2+} and Mg\textsuperscript{2+} ions was compared to the control optimum media in all assays.

Background
Importance of Ca\textsuperscript{2+} and Mg\textsuperscript{2+}Ions
- Calcium and Magnesium ions are naturally present in human semen and cervical fluids.
- Presence of Cain human semen was shown as early as 1942 by Huggins et al. (Ref 1).
- Ca\textsuperscript{2+} and Mg\textsuperscript{2+} ions are critically important for the viability and function of sperm and eggs.
- Sperm has an absolute requirement for Ca ions to undergo acrosome reaction in preparation for egg fertilization (Ref 2).

Glycerol Does Not Harm Human Sperm
(Applied from Reference 7)

![Graph showing percent sperm progression and percent sperm motility at different glycerol concentrations](image)

A. Human Sperm Motility Assay

![Graph showing novel Ca\textsuperscript{2+}/Mg\textsuperscript{2+} lubricant (Sasmar Conceive Plus™) does not harm human sperm viability or motility](image)
B. Mouse Embryo Assay

Novel Ca\(^{2+}\)/Mg\(^{2+}\) lubricant (Sasmar Conceive Plus™) does not harm embryo development

Novel Ca\(^{2+}\)/Mg\(^{2+}\) lubricant (Sasmar Conceive Plus™) does not hinder human sperm velocity or penetration of hamster ova

D. Lubricant Barrier Assay

Novel Ca\(^{2+}\)/Mg\(^{2+}\) lubricant (Sasmar Conceive Plus™) does not create a barrier against motility of sperm

Conclusions

- Sasmar Conceive Plus™ contains the physiologically important Ca\(^{2+}\) and Mg\(^{2+}\) ions to better mimic the natural fertile cervical fluids. It is water-based and has balanced pH and osmolality.
- *In vitro* tests show that the unique Ca\(^{2+}\) and Mg\(^{2+}\) containing lubricant is non-spermicidal and does not harm viability or motility of human sperm.
- Sasmar Conceive Plus™ does not create a barrier against sperm motility.
- Sasmar Conceive Plus™ does not hinder the process of fertilization between mouse ova and sperm that are exposed to this lubricant.
- The new Ca\(^{2+}\) and Mg\(^{2+}\) containing lubricant does not affect embryo development to the blastocyst stage.
- This non-spermicidal, Ca\(^{2+}\) and Mg\(^{2+}\) containing lubricant is ideally suited for assisting with the needs of couples trying-to-conceive.

1. Huggins C, Scott WW, and J Heinen JH, Chemical composition of human semen and of the secretions of the prostate and seminal

This novel lubricant is being manufactured, distributed and marketed by SASMAR as Sasmar Conceive Plus™. Detailed product information is available

www.conceiveplus.com