

Conceive Plus™

A Novel, Physiologically Important Ca²⁺ and Mg²⁺ 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 Ca²⁺ and Mg²⁺ ion Containing Non-Spermicidal Vaginal Lubricant

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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 Ca²⁺ and Mg²⁺ 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 Ca²⁺ and Mg²⁺ 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 Ca²⁺ and Mg²⁺ 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

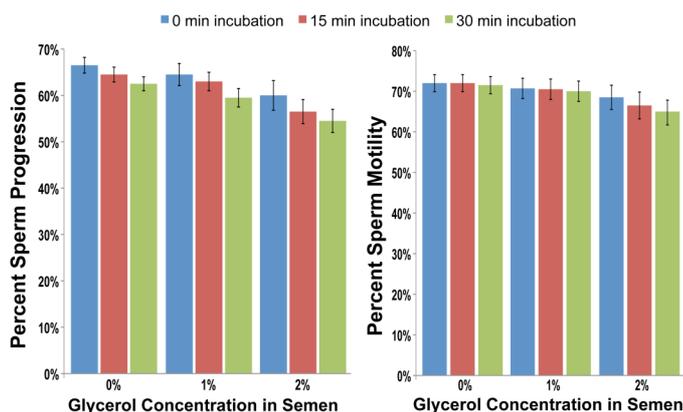
The *in vitro* assays used in this study were according to literature protocols and followed the published WHO criteria. Some of the assays were conducted in a blinded fashion by independent third parties on a fee-for-service basis. Optimum media was used as a control in all assays. The newly designed water-based lubricant that has balanced pH and osmolality and that contains Ca²⁺ and Mg²⁺ ions was compared to the control optimum media in all assays.

Background

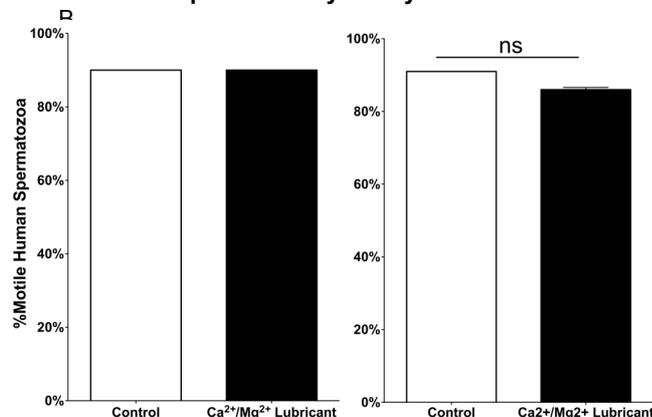
Importance of Ca²⁺ and Mg²⁺ Ions

- Calcium and Magnesium ions are naturally present in human semen and cervical fluids.
- Presence of Calcium in human semen was shown as early as 1942 by Huggins *et al.* (Ref 1).
- Ca²⁺ and Mg²⁺ ions are critically important for the viability and function of sperm and eggs.
- Sperm has an absolute requirement for Calcium to undergo acrosome reaction in preparation for egg fertilization (Ref 2).

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

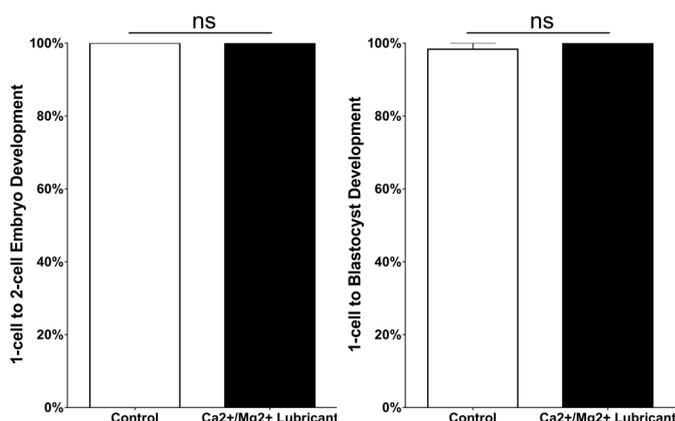


A. Human Sperm Motility Assay

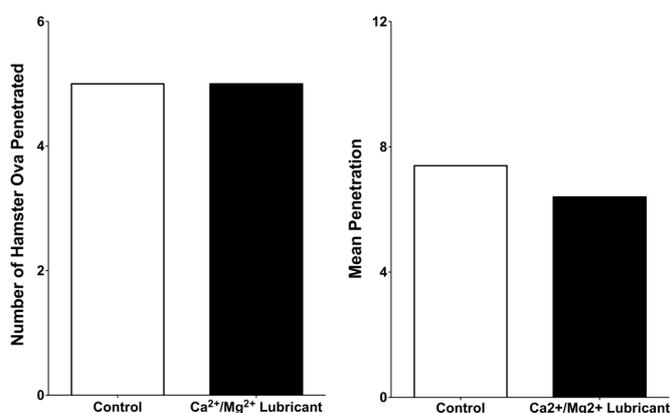


Novel Ca²⁺/Mg²⁺ lubricant (Sasmar Conceive Plus™) does not harm human sperm viability or motility

B. Mouse Embryo Assay

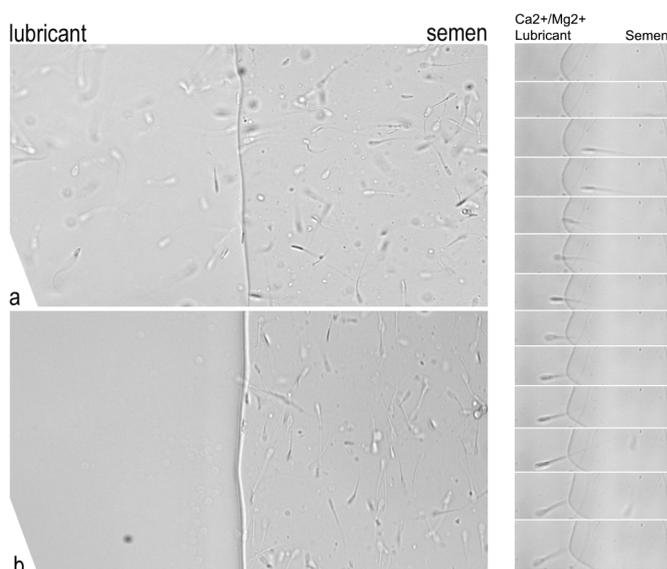


Novel Ca²⁺/Mg²⁺ lubricant (Sasmar Conceive Plus™) does not harm embryo development



Novel Ca²⁺/Mg²⁺ lubricant (Sasmar Conceive Plus™) does not hinder human sperm velocity or penetration of hamster ova

D. Lubricant Barrier Assay



Novel Ca²⁺/Mg²⁺ lubricant (Sasmar Conceive Plus™) does not create a barrier against motility of sperm

Conclusions

- Sasmar Conceive Plus™ contains the physiologically important Ca²⁺ and Mg²⁺ ions to better mimic the natural fertile cervical fluids. It is water-based and has balanced pH and osmolality.
- *In vitro* tests shows that the unique Ca²⁺ and Mg²⁺ 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 Ca²⁺ and Mg²⁺ containing lubricant does not affect embryo development to the blastocyst stage.
- This non-spermicidal, Ca²⁺ and Mg²⁺ 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

² Evans JP, Florman HM. The state of the union: the cell biology of fertilization. Nat Cell Biol. 2002 Oct;4 Suppl:s57.

³ Huggins G and Preti G, Volatile constituents of human vaginal secretions, Am J Obstet Gynecol, 1976 Sep 1;126(1):129-36.

⁴ Preti G, Huggins G and Silverberg G, Alterations in the organic compounds of vaginal secretions caused by sexual arousal, Fertil Steril 1979;32:47-54.

⁵ Huggins G and Preti G, Vaginal odors and secretions, Clinical Obstetrics and Gynecology, 1981; 24; 355-377.

⁶ Owen D and Katz D, A vaginal fluid simulant, Contraception, 1999Feb;59(2):91-5.

⁷ Tulandi T, McInnes RA. Vaginal lubricants: effect of glycerin and egg white on sperm motility and progression in vitro. Fertil Steril, 1984;41:151.

⁸ Critser JK, Huse-Benda AR, Aaker DV, Arneson BW, Ball GD. Cryopreservation of human spermatozoa. III. The effect of cryoprotectants on motility. Fertil Steril. 1988 Aug;50(2):314.

⁹ Goldenberg RL, White R. The effect of vaginal lubricants on sperm motility in vitro, Fertil Steril, 1975; 26:872.

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

www.conceiveplus.com