

Sperm Motility Following Contact with “Fertility” Lubricants Available in Australia

Common vaginal lubricants such as KY[®], Astroglide[®] and Replens[®] have been reported in numerous medical studies to harm sperm on contact and should not be used when couples are trying to conceive, even at very low concentrations (*Tagatz et al., 1972; Goldenburg & White, 1974; Frishman et al., 1992; Miller et al., 1994; Kutteh et al., 1996; Anderson et al., 1998; Agarwal et al., 2008*). In general, products with glycerin (or glycerol) as an ingredient can be toxic to sperm and should be avoided (*Tulandi & McInnes, 1984*).

Independent medical studies (Cleveland Clinic in the US and Faber Foundation in Switzerland), have reported that only the lubricant Pre~Seed[®] did not damage sperm motion or genetic material (DNA), as compared to other lubricants tested (*Agarwal et al., 2008; Vargas et al., 2008*). Pre~Seed[®] (INGfertility, Valleyford, WA, USA) claims that it does “not harm sperm” and was specifically developed for use when couples are trying to conceive. Pre~Seed[®] is distributed in Australia by Lullaby Conceptions Pty Ltd. Pre~Seed’s mild, isotonic formula has also been shown to cause less irritation than other lubricants, with physicians recommending it for any sensitive woman, not just those trying to conceive (*Adriaens & Remon., 2008*).

Recently, another lubricant has been introduced into Australia with claims of creating “an optimal environment for sperm” , for trying to conceive couples. However no independent studies could be found to confirm the effect of this product on sperm function. Furthermore, no studies were found comparing sperm function following exposure to these two “fertility” lubricants. For the purpose of this report we have name the other lubricant “x-brand”.

Objective: The present study was done to compare sperm motility (swimming) following incubation with two lubricants marketed in Australia and targeted toward couples who are trying to conceive.

Methods:

The methods of this study are similar to those previously published (*Agarwal et al., 2008*). Semen samples were obtained from normal healthy donors at a regional sperm bank (Northwest Andrology & Cryobank, Spokane, WA, USA), whose personnel also completed all aspects of the study. All samples met normal World Health Organization criteria (*WHO Manual, 1999*). Each specimen was produced by masturbation without lubricant into a sterile plastic container after a recommended abstinence period of 48 – 96 hours. Specimens were allowed to liquefy and then processed within 30 minutes. Samples from 10 men were evaluated in each treatment as follows.

Treatment of sperm samples with lubricants

Each sperm sample was diluted 1:4 with Human Tubal Fluid medium + 10% human serum albumin, divided into 900 µl aliquots, and placed into tissue culture wells. Pre~Seed[®] or X-brand was then added respectively to aliquots to achieve final concentrations of 10% (V/V) of each lubricant. Another aliquot served as the control, with no lubricant added. Specimens were incubated in treatments for 30 minutes at 37°C and 5% CO₂ in 95% humidity.

Determination of sperm motility

The percentages of progressively motile sperm after 30 minutes were determined by an operator who was blind to treatment. Specifically, 10µl samples from each treatment (Pre~Seed[®], X-brand or control medium) were placed on prewarmed slides, and covered with a

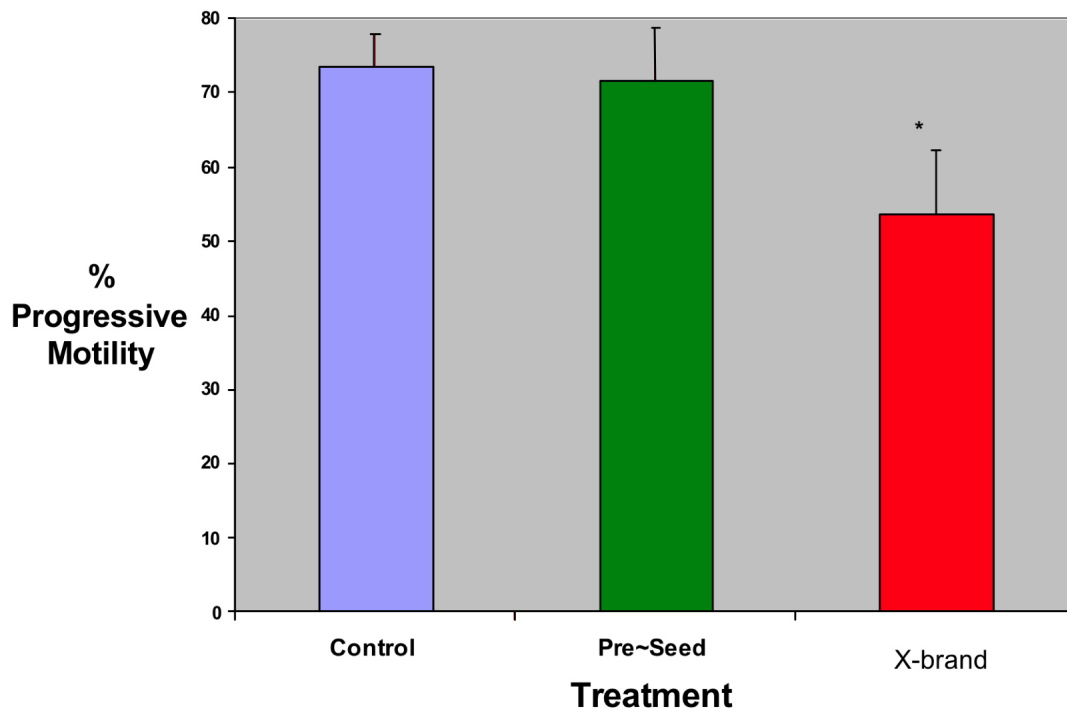
coverslip. Evaluations of the percentage motility and overall progression (speed of the sperm) were performed according to WHO guidelines using an inverted phase contrast microscope (Olympus IMT2, Olympus, Corp., Lake Success, NY). Progressively motile sperm were those regarded as a + b forms as indicated by WHO guidelines. Sperm motility after 30 minute exposure to 10% lubricant in each treatment was compared to sperm motility in the control medium using Analysis of Variance (ANOVA). The a priori level of statistical significance was $p < 0.05$.

Results: Exposing sperm to a 10% solution of Pre~Seed® for 30 minutes of culture caused no change in the percentage of motile sperm as compared to that seen in the control medium without lubricant (Figure 1). The mean percentage of motile sperm (\pm SD) following Pre~Seed® contact was 72 (2)%, while 74 (2)% of the sperm in the control medium were motile.

In contrast, sperm exposed to the X-brand lubricant had a statistically significant reduction ($p < 0.001$) in the percentage of motile sperm, with only 54 (2)% being motile versus the 72 (2) % or 74 (2)% seen in Pre~Seed® or the control treatments (respectively). Overall, sperm incubated with Pre~Seed® maintained 99% of the motility observed in the control treatment (no lubricant), whereas sperm in X-brand only retained 72% of the motility observed with control treatment.

The mean speed of progression for sperm (graded 0 to 4) also was significantly lower for sperm in X-brand as compared to sperm in either Pre~Seed® or the control ($P < 0.0001$).

Figure 1. Mean percent progressively motile sperm with no lubricant present (control), or following 30 min exposure to 10% concentrations of lubricants sold as “safe for use while trying to conceive” in Australia.



* Indicates average sperm motility significantly worsened following exposure as compared to other treatments ($p < 0.001$).

Conclusion: The two lubricants in this study are sold in Australia with claims of not harming sperm and are specifically promoted for use by couples who are trying to conceive. However, the two lubricants differed in their effect on sperm motility. Specifically, one of the lubricants decreased average sperm motility in normal sperm samples by over 25%. Such a decrease in motility could be a critical factor for men with already low sperm motility or compromised function.

Decreases in sperm motility in culture have been associated in other studies with decreases in the sperm cell's ability to penetrate cervical mucus or to fertilize eggs (*Sharrara et al., 1995; Mortimer, 1997*). In contrast, Pre~Seed® which maintained sperm motility in this study, has also been shown to support normal fertilization and embryo development in laboratory studies (*Wright & Clifton, 2008*). Specifically, researchers at Washington State University found that concentrations as high as 50% Pre~Seed® did not change in vitro fertilization or embryo development outcomes using an animal model. In contrast, other lubricants, which decreased sperm motility, also caused a decrease in fertilization and embryo development. This difference may be due in part, to the fact that Pre~Seed® does not harm sperm chromatin or DNA material (*Agarwal et al., 2008*), whereas all other lubricants tested caused a decline in sperm chromatin quality. Lubricants claiming to be “safe for use while trying to conceive” should be required to complete and report outcomes of studies on fertilization and embryo development with their product, as well as verification of sperm chromatin quality after contact.

The 10% concentration of lubricant used in this study, may be low compared to actual product concentrations achieved when used by couples at home. However, this 10% concentration allows assessment of the lubricant's impact on sperm function without inadvertent bias against a product based on viscosity or thickness. Lubricating gels are more viscous (thicker) than the culture medium, sperm are routinely incubated in, and that was used as the control in this study. Sperm swimming through a viscous lubricant-medium mixture will show a slower forward motion, even though the substance is not toxic. This is due to a physics phenomenon known as the Reynold's Number effect (*Podolsky et al., 1993; Mortimer, 2002; Dillon et al., 2007*). It would be similar to comparing swimming speeds of two neighbors in a pool of water versus a pool of molasses, obviously the person in the molasses will swim more slowly. Mixing a test lubricant in a one to one ratio with semen or media, as has been done in some studies, is not a measure of the toxicity effect of the lubricant; it is a measure of the Reynold's Number effect of the lubricant's viscosity. Diluting the lubricant to 10%, as reported here, allows for differences in sperm function to appear based on formulation, and thus, better reflects actual deleterious effects on sperm motility.

Guidelines and requirements for testing lubricants claiming to not harm sperm need to be developed and enforced by regulatory bodies such as the TGA in order to protect consumers. Claims of a product being “sperm-safe” and/or “safe while trying to conceive” are not marketing statements, but are actual medical claims that could adversely impact consumers if the claims are not valid. A body of evidence in published studies states that the use of most lubricants is contraindicated (or medically ill advised) when couples are trying to conceive, because they may interfere with conception (*Tagatz et al., 1972; Goldenburg & White, 1974; Frishman et al., 1992; Miller et al., 1994; Kutteh et al., 1996; Anderson et al., 1998; Agarwal et al., 2008*). Therefore, lubricants should be avoided when trying to conceive, unless the product has been independently tested and proven to not harm sperm or impact their function. The results of such testing should be mandatorily reviewed by regulatory bodies and made available for public

assessment. Products which can support such claims should then be allowed to offer labeling of “safe for use when trying to conceive”.

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