

# 7 Early Fertility Trials of Semen Collection Device Previously Demonstrated to Improve Semen Parameters and Pregnancy Rates in Animal Models

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## OBJECTIVE

It is well documented that sperm are susceptible to shock during processing which often induces biochemical pathways leading to cell death. Previous animal studies from this lab suggest a modification of the collection technique (Device for Improved Semen Collection; DISC) can prevent activation of these pathways, yielding larger, more motile pools of sperm for treatment and resulting in higher pregnancy rates. The objective of the present study was to evaluate the DISC in humans.

## DESIGN

Lab-based trials in donors and infertility patients.

## MATERIALS AND METHODS

Donors collected in a standard specimen cup (SSC) and the DISC. The samples were then processed and cultured for 24 hours. Aliquots were taken, over time, for semen analysis using CASA, and biochemical assessment, including: acrosomal status, lipid peroxidation, mitochondrial membrane potential (MMP) and DNA damage. A preliminary clinical trial was then conducted comparing the DISC to SSC. Couples undergoing IUI alternated semen collections between the DISC and SSC for up to 6 cycles.

## RESULTS

Donor samples collected in the DISC exhibited improved semen parameters when compared to the SSC: viability ( $p < 0.005$ ), motility rates ( $p = 0.066$ ), path velocities ( $p = 0.061$ ), progressive velocity ( $P < 0.05$ ), and motility index ( $p < 0.034$ ). Further, cells collected in the DISC had more intact acrosomes ( $p < 0.017$ ) and retained higher MMP ( $p < 0.004$ ). 24 couples completed 51 IUI cycles (26 SSC vs. 25 DISC). As in the donor trial, samples from the DISC trended to have higher motility ( $p = 0.063$ ) and progressive velocity ( $p = 0.057$ ). There were 9 pregnancies (17.6%) with equivalent results in the DISC vs. SSC, 4 vs. 5 ( $p = 0.762$ ). However, while 100% of the pregnancies in the DISC delivered, only 40% in the SSC did ( $p = 0.058$ ).

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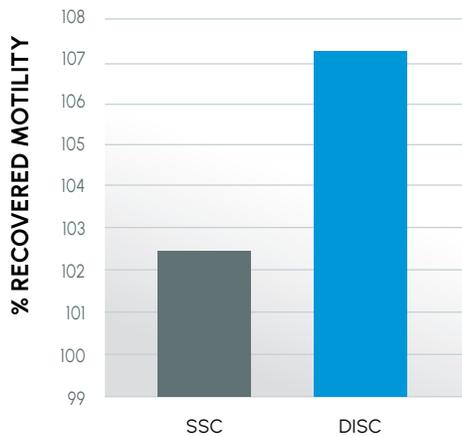
## CONCLUSIONS

As in the animal studies, results suggest improved semen quality from the DISC. Larger numbers are needed to determine if improved semen quality will lead to the increased pregnancy rates seen in other species.

## SUPPORTED BY

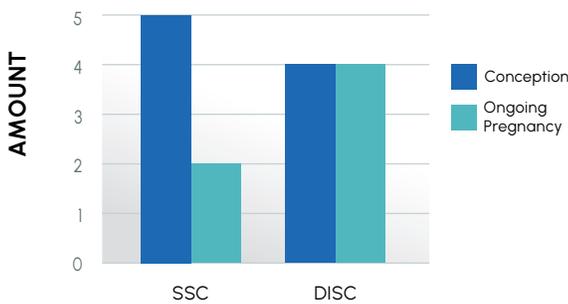
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**FIGURE 1** Rate of Post-wash Sample Recovered Motility



Rate of post-wash sample recovered motility (% of pre-wash motility / % post-wash motility) from a SSC versus the DISC. There was a trend ( $p = 0.06$ ) toward increased rates of post-wash recovery.

**FIGURE 2** Conceptions and Ongoing Pregnancies



Conception rates ( $p = 0.83$ ) and ongoing pregnancies ( $p < 0.02$ ) from semen collected in a standard specimen cup (SSC) versus a new device for improved semen collection (DISC)

Knowing that both the protective properties of ProteX and the addition of media yield biochemically and physiologically healthier sperm, researchers naturally questioned if healthier sperm result in healthier pregnancies. A very small trial of only 24 patients was undertaken to evaluate if ProteX is equivalent to standard collection methods. It was found that across all patients that 5% more motile sperm were recovered post-wash when patients used ProteX.

As expected with this sample size, there was no difference in conception rate. What was not expected by the team was that while over half of the patients who conceived using the standard cup experienced a miscarriage, all patients who conceived using ProteX had a live baby, suggesting that healthier sperm result in healthier pregnancies.

INSIGHTS

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