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Effect of microfluidic sperm separation versus standard sperm washing processes on fertilization rates, blastocyst development and euploidy rates among all infertility patients

Biography

Glen Adaniya, PhD, HCLD, ELD serves as the ART Laboratory Director at Ovation Fertility Indianapolis (2018), formerly Midwest Fertility Specialists (since 1998). He earned a bachelor's degree in Biomedical Engineering from Northwestern University (1983), and attained his MS and PhD at the University of Illinois, Chicago. (1992). Dr. Adaniya began his career as a senior embryologist at the Center for Assisted Reproduction at Brigham & Women's Hospital, where he was jointly appointed to the faculty of the Harvard Medical School.

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Study question:

Our goal was to determine if the ZyMōt microfluidic sperm separation device effectively improved ICSI sperm selection and subsequent embryo development applied to a general IVF patient population.

Summary answer:
Utilization of a ZyMōt device to process all IVF semen samples (untested for Sperm DNA Fragmentation, SDF) revealed no overall benefit to embryo outcomes.

What is known already:
The natural sperm filtering actions of cervical/uterine crypts has been mimicked by a new microfluidic sperm separation device (ZyMōt). Its microporous filter and channels help separate the most motile sperm with normal morphology without centrifugation. In turn, not only does the ZyMōt device claim to reduce procedure-induced reactive oxygen species (ROS) associated with causing SDF, it selectively isolates healthier, progressively motile sperm with lower SDF. Pilot studies suggest that the higher chromatin integrity (i.e., lower SDF) attained for IVF use improves fertilization, embryo morphology and blastocyst euploidy rates. We aimed to test the ZyMōt's proposed developmental benefits.

Study design, size, duration:
A prospective, randomized, multicenter, sibling oocyte study was conducted with 86 consenting

patients possessing ≥10 oocytes. Non-DFI tested ejaculates underwent a split processing treatment: 1) Control washing procedures (density gradient separation or swim-up) or 2) Treatment - ZyMōt swim out. Each sample was then used to inseminate an equal number of sibling oocytes. Resulting blastocyst were biopsied and NGS tested. Euploid (non-mosaic) embryo selection for ET was randomized. Chi-squared analysis was performed to assess differences($p<0.05$).

Participants/materials, setting, methods:
Upon informed consent, partner sperm was processed in parallel by 1) either density gradient centrifugation (DGC) at OF-IN(n=26), OF-OH(n=19) and OF-LA(n=18) or a swim-up wash procedure (OF-TN,n=23); or 2) a 0.85µ ZyMōt device. After removal of cumulus/coronal cells by hyaluronidase, half of the mature oocytes were randomly allocated to ICSI with Control sperm and the other half with ZyMōt sperm. Fertilization, embryo culture and biopsy were performed using the clinic's standard protocols.

Main results and the role of chance:
Table. ICSI cycle embryo development outcomes following standard sperm washing procedures (Control) or the use of a microfluidic sperm separation device (ZyMōt)

Treatment:	ZyMōt	Control
Number of Oocytes	787	777
Fertilization rate (% 2PN)	604 (76.7%)	592 (76.2%)
Blastocyst rate (%>2BB)	296 (49.0%)	282 (47.6%)
Euploidy rate	165/283 (58.3%)	151/265 (57.0%)
Mosaicism rate	25/283 (8.8%)	31/265 (11.7%)

There were no statistical differences observed between the ZyMōt or Control sperm processing methods. Although some normal variation between labs was observed, there were also no differences between the control DGC and swim-up methods. Clinical pregnancy outcomes are still being evaluated, but preliminary results reveal no advantage to the ZyMōt treatment. To date, intrauterine pregnancies are trending upward($p>0.1$) for the Control groups (21 of 30, 70%) in contrast to 18 of 37 (48.6%) in the ZyMōt group.

Limitations, reasons for caution:
Male factor patients with known elevated SDF were not selected for this multi-center trial. Therefore, we can not speak to the potential improvements ZyMōt may elicit. However, it is possible that selection of normal, progressive sperm for ICSI, plus the repair capacity of oocytes, is sufficient to promote normal development.

Wider implications of the findings:
We do believe the ZyMōt device may have a useful application in infertile men with elevated SDF, yet it is equally possible that an ICSI sperm selection alone allows for the immobilization and injection of highly progressive, morphologically normal sperm as seen in this study of typical infertility patients.

Keywords:
ZyMot
sperm wash
fertilization
blastocyst
aneuploidy