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KOL testings demonstrate Felix™ System outperforms DGC

Key points:

- **Two publications have recently been released in globally significant journals, *Andrology* and the *Journal of Assisted Reproduction and Genetics,* on the Felix™ System by key opinion leaders (KOLs) evaluating the device.**
- ***In vitro* results from both publications demonstrate that the Felix™ System outperforms the density gradient centrifugation (DGC) method, the most globally common sperm preparation method for IVF procedures.**
- **These peer reviewed papers underpin the utility of the device, enhance commercialisation discussions and will add to future regulatory filing material.**

Australian-based reproductive biotechnology company, Memphasys Limited (ASX: MEM) is pleased to announce the first publications of study findings by key opinion leaders (KOLs) of the Felix™ System - a patented, automated device for quickly and gently separating high quality sperm from a semen sample for use in human IVF procedures.

Overview of published findings

A published article entitled "Spermatozoa isolation with Felix™ outperforms conventional density gradient centrifugation preparation in selecting cells with low DNA damage" featured in *Andrology,* the official journal of the American society of Andrology and European Academy of Andrology, on 11th January 2023.

The article can be accessed via the link https://doi.org/10.1111/andr.13384

The research was conducted by renowned French genetics reproduction and development lab (GReD), supported by the University Clermont Auvergne (UCA), and led by Professor Joel Drevet, an international leader in mammalian andrology ("the KOL").

The KOL studied 29 human semen samples which were analysed fresh and after DGC or Felix™ System preparation and were monitored by sample volume, sperm count, total motility, progressive motility, sperm DNA fragmentation using the Sperm Chromatin Structure Assay ("SCSA") and sperm DNA oxidation.

Results of the study highlighted spermatozoa preparation with Felix™ System "significantly improved spermatozoa fractions with higher progressive motility, lower sperm DNA fragmentation, and lower sperm DNA oxidation compared with raw semen and DGC-prepared spermatozoa".[1]

The article noted that the study data supported spermatozoa preparation by the Felix™ system "as it allows selection of spermatozoa with the highest progressive motility as well as the lowest nuclear/DNA damage."

[1] Pauline Villeneuve, Fabrice Saez, Elisa Hug, Areski Chorfa, Rachel Guiton, Benoit Schubert, André Force, Joël R. Drevet, 2023, "Spermatozoa isolation with Felix™ outperforms conventional density gradient centrifugation preparation in selecting cells with low DNA damage", *Andrology* pp 1-12.

The article concluded that “These improved sperm parameters, along with the fact that the Felix™ separation process is very fast and highly standardized, should be of great interest to the assisted reproduction technologies industry.”

In addition, another article entitled “A comparison between the Felix™ electrophoretic system of sperm isolation and conventional density gradient centrifugation: a multicentre analysis”, has been published in *Journal of Assisted Reproduction and Genetics*, an official journal of the American Society for Reproductive Medicine.

The article can be accessed via the link https://doi.org/10.1007%2Fs10815-022-02680-0

Supported by Memphasys, the research was conducted and collaborated across five KOLs namely:

- Monash IVF, Australia
- Andrology Center, India
- The Ronald O. Perelman and Claudia Cohen Center for Reproductive Medicine, USA
- GeneraLife IVF, Sweden
- Reproductive and Genetic Hospital, People’s Republic of China

The KOLs compared the quality of the sperm populations isolated by the Felix™ System and DGC in terms of processing time, sperm concentration, motility, vitality, and DNA integrity as assessed by 3 methods: SCSA, Halo, and TUNEL.

Across all KOLs, 112 comparisons were performed with findings highlighting the Felix™ system “is a positive technical development capable of isolating suspensions of highly motile spermatozoa in a fraction of the time taken by conventional procedures such as DGC.”[2]

Four of the five centres reported a significant improvement in DNA integrity relative to DGC (one reported no statistical difference but both methods selected sperm with low DNA damage). The Felix ™ system isolates sperm in a standardised 6-minute preparation time whereas clinical DGC protocols vary between sites but generally took around 40 minutes to complete.

This announcement has been approved for release by the board of Memphasys Limited.

ENDS

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[2] Farnaz Shapouri, Tara Mahendran, Mirudhubashini Govindarajan, Philip Xie, Olena Kocur, Gianpiero D. Palermo, Hassan W. Bakos, Aisling Ahlström, Gunilla Caisander, Bo Xu, Shun Bai, Sarah Lambourne & R. John Aitken, 2022, “A comparison between the Felix™ electrophoretic system of sperm isolation and conventional density gradient centrifugation: a multicentre analysis”, *Journal of Assisted Reproduction and Genetics* pp 83-95

About Memphasys:

Memphasys Limited **(ASX: MEM)** is a reproductive biotechnology company specialising in developing and commercialising novel medical devices, diagnostics and media for application to human and animal reproduction.

Website: www.memphasys.com