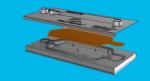


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WHAT IS ALREADY KNOWN?

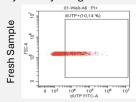
Before any assisted reproduction treatment, sperm selection is required. There are several sperm selection techniques, the most commonly used are swim-up and density gradients. Both techniques involve centrifugation, which exposes the sperm to a high level of reactive oxygen species that can lead to increased DNA fragmentation. In addition, both techniques require many steps, which are time-consuming and increase the risk of error. Currently, microfluidics emerges as a method which avoids centrifugation and increase the efficiency.

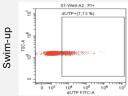
STUDY QUESTION AND SUMMARY ANSWER

Can a sperm selection device based on microfluidics and permeable membrane improve IVF laboratory Key Performance Indicators (KPIs) compared to the swim-up technique? The microfluidic group achieved a significant increase in the usable blastocyst rate, as well as a significant improvement in blastocyst morphology and embryo morphokinetics.

MATERIAL AND METHODS

This sibling, double-blinded, prospective study enrolled 100 patients (mean age: 38.23 ± 4.31 years) at IVI Valencia. Each semen sample was equally divided and processed either by conventional swim-up or by the SwimCount™ Harvester (SCH), a novel membrane-based microfluidic device. Subsequently, half of the mature oocytes of each patient were microinjected with the semen selected by microfluidics, while the remaining half received semen processed by swim-up. Sperm quality was assessed according to WHO 2021 criteria, including concentration, motility, morphology, vitality, chromatin stability, and DNA fragmentation, the latter measured by flow cytometry using TUNEL assay.





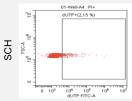


FIGURE 1: Representative example of sperm DNA fragmentation analysis using the TUNEL assay.

Embryos were cultured in time-lapse system and morphokinetic parameters were exported (t2: time to 2 cells, t3: time to 3 cells, t4: time to 4 cells, t5: time to 5 cells, tB: time to blastocyst formation). Usable blastocysts were those transferred or vitrified for future use. Embryo quality was evaluated following ASEBIR criteria, with embryos classified as grades A and B considered of highest quality. In this study, two artificial intelligence (AI) tools were employed: Future Fertility Magenta, to assess occyte quality, and Life Whisperer Viability (LWV), to predict the implantation potential of the resulting embryos. Trophectoderm biopsy for ploidy analysis was performed.

RESULTS

Sperm concentration was significantly higher in the SCH group 6.5×10⁶/ml compared to the swim-up group 3.0×10⁶/ml (p<0.001). However, progressive motile sperm percentage was slightly higher in the swim-up group 98.0% in comparison to SCH 97.0% (p=0.025). In contrast, the total progressive motile sperm count was also higher in the SCH group 5.0×106, compared to swim-up 2.4×106 (p<0.001). Sperm vitality showed no statistically significant difference between groups (p=0.846). Nevertheless, the proportion of morphologically normal sperm was higher in the SCH group 7.0%, compared to swim-up 6.0% (p<0.001). The percentage of spermatozoa with correct stability of the chromatin structure showed significantly higher values in the SCH group 91.0%, than in the swim-up group 90.0% (p=0.009). Additionally, DNA fragmentation was significantly lower in the SCH group (SCH: 3.30%; swim-up: 5.61%; p=0.047).

Inspite of using sibling oocytes, an AI tool was employed to assess the quality of each oocyte objectively. Analysis of the scores generated by this tool showed that oocyte quality was statistically comparable between the SCH and swim-up groups. This homogeneity supports the robustness and reliability of the findings presented. The use of the SCH device was associated with a statistically significant increase in the usable blastocysts rate and the goodquality blastocysts rate (grades A and B) per mature microinjected oocyte, whereas no significant differences were observed for fertilization or euploidy rates per embryo biopsied, as illustrated in Figure 2. Moreover, the time to blastocyst formation (tB) was significantly reduced in the SCH group, although no significant differences were observed for the AI-generated score, as shown in Table 1.

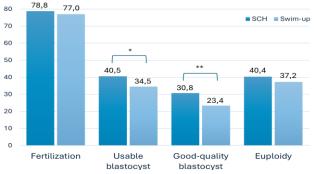


FIGURE 2: Comparison between the SCH device and swimup for laboratory KPIs

| | SCH Median [IQR] | Swim-up Median [IQR] | p-Value |
|-----|--------------------------|--------------------------|---------|
| t2 | 26.33 h [23.87–28.51] | 26.23 h [24.09–28.10] | 0.9159 |
| t3 | 36.40 h [32.25–39.50] | 36.48 h [33.10–39.06] | 0.7883 |
| t4 | 37.89 h [34.80–41.39] | 38.07 h [35.10–40.84] | 0.8496 |
| t5 | 47.96 h [43.26–53.26] | 48.24 h [42.79–52.50] | 0.5432 |
| tB | 106.95 h [101.25-115.10] | 109.46 h [103.30-115.69] | 0.036* |
| LWV | 5.70 [1.40–8.00] | 4.60 [1.27–7.40] | 0.1892 |
| | | | |

Table 1: Comparison between the SCH device and swim-up for morphokinetics parameters (t2, t3, t4, t5, tB) and Al score (LWV).

WIDER IMPLICATIONS OF THE FINDINGS

Comparing Swim-up with the new microfluidic device for sperm selection, the device simplifies the process by reducing steps and improves the sperm quality. Regarding laboratory's KPIs, microfluidics significantly increased the usable blastocyst rates, improved embryo quality and reduced the time to blastocyst formation.

LIMITATIONS

Although the study shows an improvement in key performance indicators (KPIs), future research should narrow inclusion criteria to focus on patients with high sperm DNA fragmentation and poor oocyte quality, such as those of advanced maternal age or elevated body mass index (BMI).

STUDYING FUNDING

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