CLINICAL EVALUATION AND USER EXPERIENCES - VITROLIFE LABWARE DISHES

Vitrolife has recently introduced an assortment of Labware products consisting of dishes, test tubes and pipettes. All products are developed and toxicity tested specifically for IVF purposes. Five of the dishes have a new design: square with ramped wells and a flat bottom for optimal temperature control. These dishes have been clinically evaluated in two different ways: i) two clinics used the dishes in their daily work and studied embryo development and resulting clinical pregnancy rate. ii) Twenty clinics used the dishes and scored their usability and user friendliness compared to the dishes they traditionally use in the clinic.

Material and Methods

The dishes were evaluated and scored in relation to the dishes the clinics traditionally use i.e embryo tested dishes from BD (Falcon) and Nunc (Nunclon). The comparisons are retrospective.

Evaluation of clinical performance

Clinic A evaluated the performance of the dishes for both fresh and cryopreserved cleavage stage embryos as well as for blastocysts. Data was also analysed according to age, <40 years and all ages. Elective single embryo transfer, eSET, was performed in >90% of all patients below 40 years of age.

Clinic B evaluated the dishes on fresh cleavage stage embryos. 1.2 embryos per patient were transferred in the Vitrolife group and 1.3 embryos in the "traditional dish" group. There were no differences regarding hormone replacement regimens, age, number of oocytes retrieved etc between patient groups in either clinic.

Evaluation of usability

Usability and user friendliness of the dishes were scored on a scale 1-6 where 6 means highest usability. Each dish was given an individual score. Score above 3.5 means that the dish was considered more user friendly and of higher usability than the dish normally used by the clinic.

Results

Clinic A

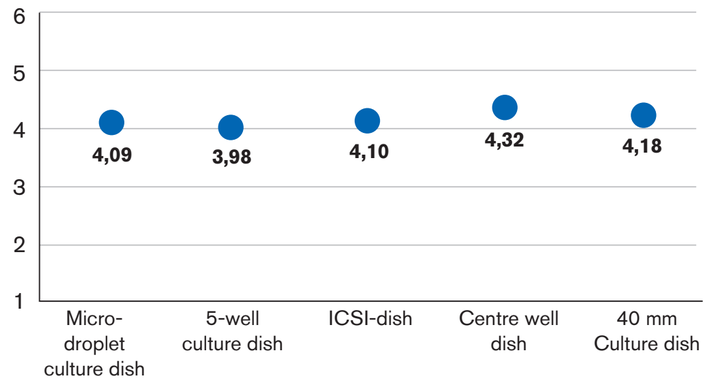
Table 1 shows the clinical pregnancy rates (CPR) for the different subgroups
Graph 1 shows the clinical pregnancy rate (%) for Vitrolife dishes and for traditional dishes, respectively, divided into sub-groups

Clinic B

Table 2 shows the clinical pregnancy rate (CPR) for Vitrolife dishes compared to traditional dishes.
Graph 2 shows the clinical pregnancy rate (%) for Vitrolife dishes and for traditional dishes, respectively.

Scoring of dishes

The figure below shows the separate scores for the five different dish types. The results from the twenty clinics have been combined. A score above 3.5 indicates that the dish has a higher usability than the dish traditionally used.



Conclusion

5 new dishes specifically developed and toxicity tested for IVF were evaluated by two clinics regarding clinical performance. The results at both clinics show that Vitrolife Labware are safe and support treatment success when used for clinical IVF. In addition, twenty clinics gave the dishes a higher score of usability than their traditional dishes showing that the new dish design is at least as user friendly as other dish types commonly used for IVF.

Table 1.

	Vitrolife dishes		Traditional dishes	
	Number of patients	CPR	Number of patients	CPR
Fresh cleavage stage embryo transfers, all ages	100	45.0%	140	39,3%
Age <40 years	75	52.0%	107	45.8%
Fresh blastocyst transfers, all ages	48	60,4%	69	46,4%
Cryopreserved cleavage stage embryo transfers, all ages	43	60.4%	111	39.6%
Age <40 years	36	66,7%	93	40,9%
Crypreserved blastocyst transfers, all ages	41	61,0%	108	40,7%

Graph 1. Clinical pregnancy rate

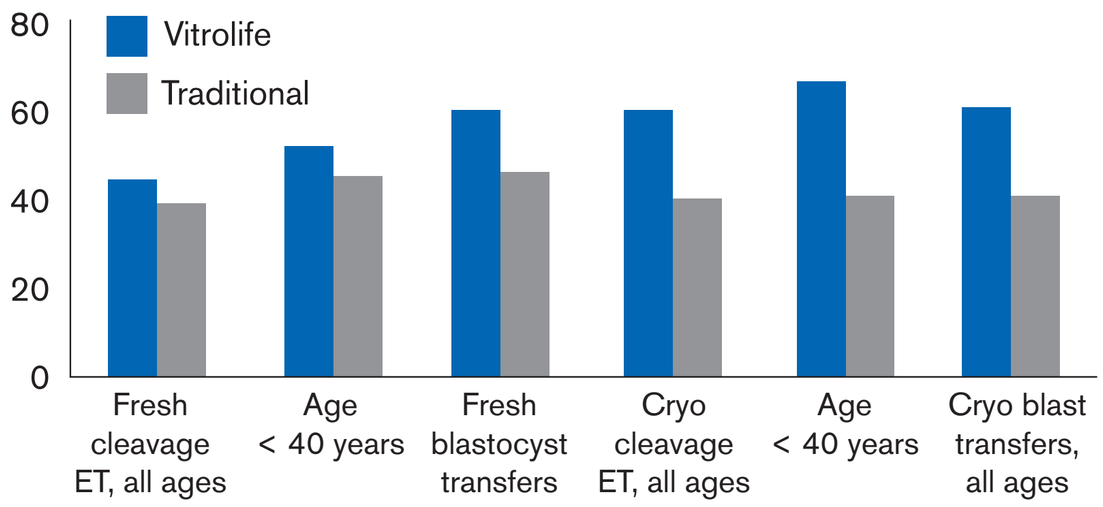
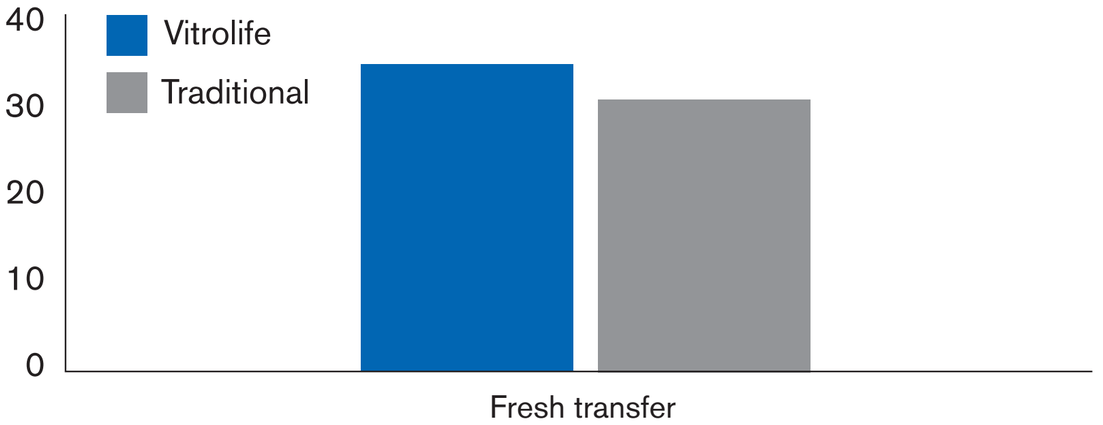


Table 2.

	Vitrolife dishes		Traditional dishes	
	Number	Rate	Number	Rate
Patients	310	NA	313	NA
2PN fertilised	1686	67,1%	1756	70,4%
Cleaved embryos	1735	102,9%	1707	97,2%
Clinical Pregnancies	107	34,5%	96	30,7%

Graph 2. Clinical pregnancy rate



Microdroplet dish | **5-well dish** | **Centre well dish** | **ICSI dish** | **40 mm culture dish**

REFERENCE
HertART 2013. Data on file.

Vitrolife