

Fertility Treatment Outcomes Using NovoSort Processing Method vs. Standard Density Gradient

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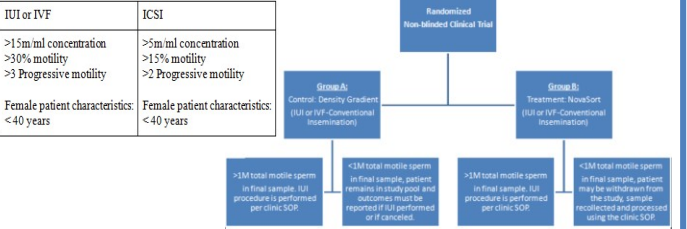
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PURPOSE & OBJECTIVES

The **first** aim of this study is to validate the efficacy of ProteX collection container and NovoSort for semen processing to demonstrate significant improvement in semen parameters compared to the density gradient (motility pre-processing, concentration and motility post-processing) translating to improved pregnancy rates for in vitro fertilization using ICSI, IVF, or IUI treatments. **Second**, we seek to assess NovoSort and ProteX device performances in various procedural contexts applicable to patients in reproductive medicine or obstetrics and gynecology, while reducing the need for extensive staff training.

MATERIALS & METHODS

This was a multi-center prospective study of 172 IUI and 59 IVF with ICSI autologous treatments analyzed between December 2024- March 2025. Patients undergoing fertility treatment requiring sperm preparation (IUI, IVF, ICSI) who met the inclusion criteria, were randomly assigned to have their semen prepared using either the NS/PX system or the laboratory's standard sperm collection cup and isolation technique, the density gradient (DG).



All samples underwent an initial semen analysis evaluating multiple parameters to include volume, concentration, % motility and a post processing analysis to include concentration and % motility. For the control group, samples were overlaid on a density gradient and centrifuged for 15 mins at 1500RPM followed by a wash for 8 minutes at 1500 RPM. For the test group, the NS device containing wash media was inserted in the ProteX cup and left undisturbed for 15 minutes for ICSI and 30 minutes for IUI and IVF-Conventional Insemination treatments. Final samples (0.5ml for IUI and full volume for IVF-ICSI) from both groups were used per standard protocol for assigned treatments. Data was analyzed using Chi Square and Student's T-Test.

RESULTS

Data were pooled from all four sites for statistical analysis. One site was unable to provide clinical outcomes. A second site performed on limited IVF using the NovoSort, so those cycles were also eliminated from analysis. Therefore, their data was not included in the final analysis. This left a total of 172 IUI and 59 IVF cycles with ICSI which met data criteria and were in final statistical analysis.

Table 1 demonstrates the semen aspects of the IUI Study. The NovoSort performed at least as well as the SSC/Gradient in the recovery of motile cells for and IUI procedure. Further, while having equal recovery rates (P = 0.656), the NovoSort recovered significantly more Total Motile Cells Compared to the SSC/Gradient (**Figure 1**; P < 0.001). Additionally, while the cells collected in the SSC initial demonstrated a trend toward higher percentage of cells with a 3-4 forward progression compared to the NovoSort (81.3 vs.. 90.7% respectively; P = 0.067). Cells recovered from the NovoSort had higher rates of forward progression post-processing (93.5 vs. 100%; P < 0.001). Initial Pregnancy Rates were similar between the two collection devices (**Figure 2**; P < 0.820).

Table 2 demonstrates the semen aspects and embryo aspects of the IVF-ICSI Study. As with the IUI Study, the NovoSort performed at least as well as the SSC/Gradient in the recovery of motile cells and embryo development as the SSC/Gradient Treatment. There was a trend (P = 0.0520) for greater number of euploid embryos on a per patient basis of those tested with PGT (**Table 2**). Limited Pregnancy data (N=17) shows a numerical but not significantly higher pregnancy rate in patients using the NovoSort (**Figure 3**). Finally, evaluating euploid embryo development per-embryo, rather than per patient, there are significantly (P < 0.001) more normal embryos in the NovoSort group. With only 42/102 (41.2%) embryos from the gradient sperm being classified as euploid, while 69/114 (60.0%) of embryos derived from NovoSort were classified as euploid.

TABLE 1
Male demographics and semen characteristics of men participating in IUI treatment and whose semen was process using the ProteX/NovoSort vs. Density gradient processing .

	NovoSort (N=103)	Gradient (N=169)	P value
Male Age (yrs)	34.40	35.10	0.410
Initial Volume (mL)	2.50	2.60	0.840
Initial Concentration (mil/mL)	52.20	43.80	0.031
Initial Motility (%)	61.80	58.10	0.076
Initial Total Motile Count (mil)	79.00	63.70	0.065
Final Volume (mL)	1.00	0.60	0.001
Final Concentration (mL)	18.80	23.40	0.046
Final Motility (%)	88.90	85.30	0.120
Final Total Motile Count (mil)	17.80	12.40	0.006
% Recovery	26.40	24.90	0.656

TABLE 2
Male demographics and semen characteristics, and female demographics and cycle outcomes of men and women participating in IVF treatment and whose semen was process using the ProteX/NovoSort vs. Gradient processing.

	NovoSort (N=28)	Gradient (N=31)	P value
Male Age (yrs)	36.70	36.70	0.985
Initial Volume (mL)	2.80	2.70	0.776
Initial Concentration (mil/mL)	47.90	52.40	0.294
Initial Motility (%)	63.50	60.00	0.363
Initial Total Motile Count (mil)	70.10	86.10	0.634
Final Volume (mL)	1.11	0.56	0.001
Final Concentration (mL)	12.90	28.30	0.003
Final Motility (%)	86.70	81.70	0.080
Final Total Motile Count (mil)	13.30	14.00	0.470
% Recovery	19.00	21.50	0.654
Female Age (yrs)	34.90	33.90	0.283
# Oocyte Retrieved	14.70	17.50	0.149
# ICSI	12.30	14.30	0.182
# Fertilized	10.70	12.70	0.162
# Normal Fertilization	9.70	10.60	0.332
# Cryo	5.20	5.10	0.466
% Cryo	50.70	40.20	0.101
# Euploid*	3.60	3.00	0.238
% Euploid	60.90	45.10	0.052

* of those tested with PGT

CONTACT INFORMATION

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RESULTS

FIGURE 1
A comparison of total motile sperm concentrations of semen samples process using a NovoSort (N = 102), vs. using a standard gradient (N=169).

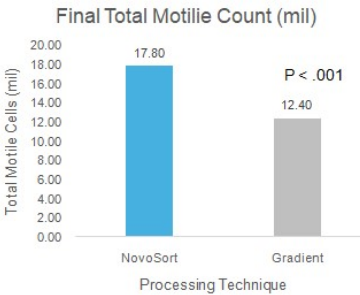


FIGURE 2
A comparison of IUI pregnancies rates of semen samples process using the ProteX/NovoSort (N = 102), vs. using a standard gradient (N=169).

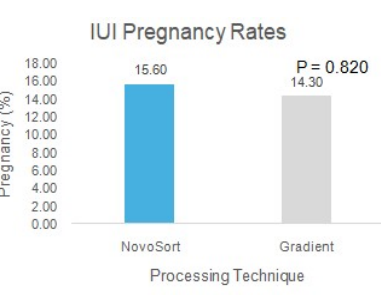


FIGURE 3
A comparison of current initial IVF pregnancies rates of couples processing their semen samples a NovoSort (N = 13), vs. using a standard gradient (N=10).

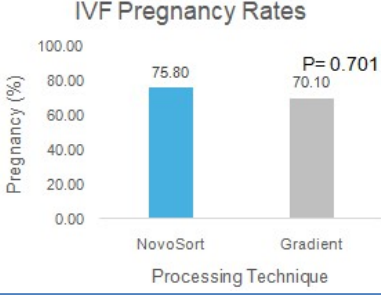
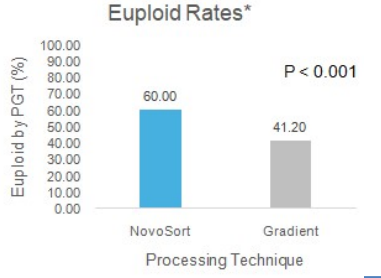


FIGURE 4
Percentage of normal PGT results of couples following processing their semen samples in the ProteX/NovoSort (N = 184), vs. using a standard gradient (N=144) calculated without regard to source of embryo.



CONCLUSIONS

Data from this study validate the NovoSort as a viable means of semen recovery for infertility treatments requiring sperm processing. The device produces at least equal or better semen parameters than DG. Despite the lower total motile cells (TMC) in the ICSI study, given the limited 15 min processing time for the Novosort, the treatment provided more than adequate motile cells for the ICSI procedures. Data from the IUI arm suggests equal sperm recovery and improved TMC when sample is processed for 30 mins. Initial pregnancy rates are at least equal (and numerically higher in the NovoSort treatments) between the processing techniques. The data also suggest embryos conceived with semen processed with the NovoSort device may be healthier, supporting the concept that a better collection and processing environment leads to healthier sperm and more euploid embryos. An added benefit of PX/NS is the continuous handling of the semen specimen in one device and a simple processing test, thereby reducing chain of custody errors.

ACKNOWLEDGEMENTS

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REFERENCES

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