

IUI TABLES AND GRAPHS

Table 1. A comparison of Female Partners participating with their partners in a trial of the ProteX collection device versus a standard specimen cup (SSC)

	Protex n=338	STD	SSC n=357	STD	P value
Age	35.5	5.6	34.8	5.7	0.078
Ovarian Stimulation (%)					0.008
Natural Cycle	8.9		5.0		
Clomid	29.0		38.4		
Letrozole	54.1		49.0		
COH	4.7		6.4		
Tamoxifen	3.3		1.1		

NOTE: ages are trending toward significant difference with ProteX group being older. While treatment protocols are statistically different uncertain how this affects outcome as >80% of patients were treated with either Clomid or Letrozole.

Table 2. A comparison of Male Partners participating with their partners in a trial of the ProteX collection device versus a standard specimen cup (SSC)

	Protex n=338	STD	SSC n=357	STD	P value
Age	37.6	5.6	37.8	5.7	0.618
Days of Abstinence	2.4	2.1	2.1	1.6	0.051
Time from collection to arrive in lab - min	37.6	42.9	33.8	24.0	0.152
Time from Arrival to start of process - min	8.4	10.0	9.3	6.8	0.183
Processing time	28.2	9.7	27.0	8.9	0.104
Total Elapsed time - min	72.7	48.4	70.0	25.7	0.328
Initial Volume - mL	2.5	1.4	2.2	1.2	0.008
Initial Concentration mil/mL	75.3	68.1	68.8	2.6	0.162
Initial Motility (%)	53.0	13.5	48.3	14.9	0.001
Initial Total Motile mil	91.3	94.1	73.0	77.0	0.005
Final Volume - mL	0.5	0.8	0.5	0.2	0.280
Final Concentration mil/mL	88.4	73.6	92.3	80.0	0.525
Final Motility (%)	57.4	31.8	53.7	20.3	0.069
Final Total Motile mil	25.0	22.0	25.0	24.4	0.871

NOTES:

Volumes were higher in the ProteX. Uncertain if this has to do with the collecting at home or not.

As in the IVF study, both the initial motility and Total cells are significantly higher in ProteX (10% and 25%, respectively)

There is a trend toward higher motility post-processing (about 7% numerically higher). This is the result of a post-processing rebound effect where non-motile cells in the SSC regain motility, but any physiological damage would have already taken place.

Interestingly, the final total motile counts are equal, uncertain if this is due to a processing protocol at Columbia where they only put back a certain number of cells.

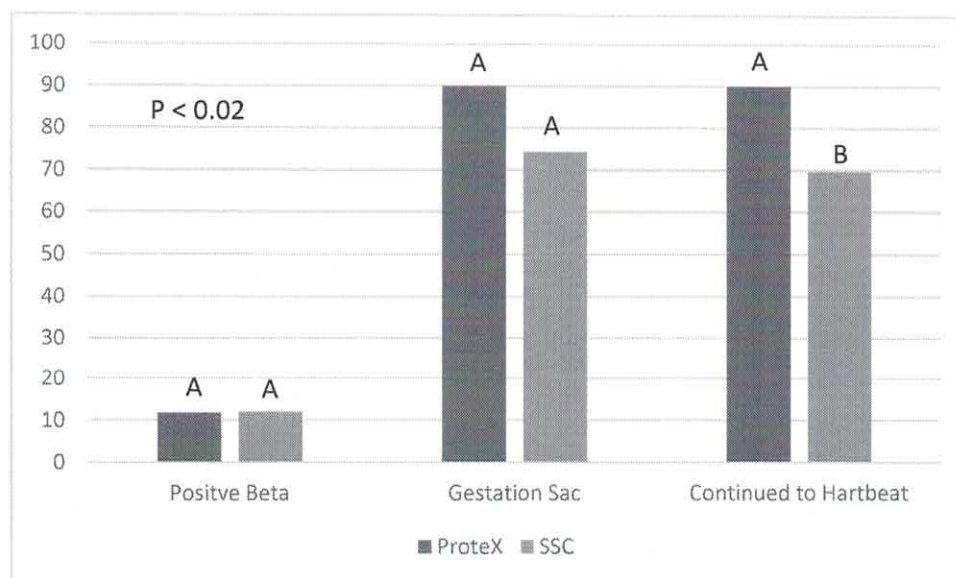


Figure 3. A comparison of pregnancy test outcome (%), pregnancies continuing to sac development (%) and heartbeat (%) in IUI procedures (n= 695) where semen was collected in a ProteX (n=338) versus a standard specimen container (SSC; n=357). Means with different superscripts are statistically different at the P < 0.02 level.

NOTES:

Both groups had equal number of positive pregnancy test (12%)

There was a trend toward more gestational sacs in those couples using the ProteX (P = 0.07)

More couples (29% more) using the ProteX reached heartbeat (90% of those with a positive pregnancy test; P < 0.02)

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T-TEST GROUPS=trt(0 1)
/MISSING=ANALYSIS
/VARIABLES=female male Initial_volume Initial_concentration Initial_motility
Initial_total_motile final_volume final_concentration final_motility final
_total_motile
time_collection_recieved time_received_start_processing time_start_finish_
processing
total_elapsed_time
/CRITERIA=CI(.95).

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T-Test

Group Statistics

	trt	N	Mean	Std. Deviation	Std. Error Mean
female	.00	357	34.8880	4.58304	.24256
	1.00	338	35.4734	4.12500	.22437
male	.00	357	37.8207	5.66443	.29979
	1.00	338	37.6036	5.60756	.30501
Initial_volume	.00	352	2.2158	1.24226	.06621
	1.00	336	3.3814	16.51001	.90069
Initial_concentration	.00	352	68.8153	52.86838	2.81789
	1.00	336	75.3034	68.09192	3.71472
Initial_motility	.00	352	48.3159	14.86566	.79234
	1.00	336	53.0018	13.53253	.73826
Initial_total_motile	.00	352	72.9697	77.00523	4.10439
	1.00	336	110.5569	364.18010	19.86765
final_volume	.00	352	.4973	.20242	.01079
	1.00	336	.5426	.75827	.04137
final_concentration	.00	352	92.2563	79.98424	4.26317
	1.00	336	88.4344	73.60584	4.01553
final_motility	.00	351	53.7407	20.34498	1.08593
	1.00	336	57.4328	31.82280	1.73608
final_total_motile	.00	350	24.7074	24.46955	1.30795
	1.00	334	24.9960	21.95108	1.20111
time_collection_recieved	.00	352	33.7528	24.04231	1.28146
	1.00	322	37.5590	42.92504	2.39212

Group Statistics

	trt	N	Mean	Std. Deviation	Std. Error Mean
time_received_start_processing	.00	347	9.2709	6.83550	.36695
	1.00	332	8.3976	10.01562	.54968
time_start_finish_processing	.00	349	27.0487	8.94976	.47907
	1.00	334	28.2126	9.74847	.53341
total_elapsed_time	.00	348	70.0000	25.71076	1.37824
	1.00	327	72.6728	43.49304	2.40517

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means
		F	Sig.	t
female	Equal variances assumed	2.322	.128	-1.767
	Equal variances not assumed			-1.772
male	Equal variances assumed	.195	.659	.508
	Equal variances not assumed			.508
Initial_volume	Equal variances assumed	2.281	.131	-1.321
	Equal variances not assumed			-1.291
Initial_concentration	Equal variances assumed	8.795	.003	-1.400
	Equal variances not assumed			-1.392
Initial_motility	Equal variances assumed	2.236	.135	-4.317
	Equal variances not assumed			-4.327
Initial_total_motile	Equal variances assumed	4.247	.040	-1.893
	Equal variances not assumed			-1.853

Independent Samples Test

		t-test for Equality of Means		
		df	Sig. (2-tailed)	Mean Difference
female	Equal variances assumed	693	.078	-.58542
	Equal variances not assumed	691.244	.077	-.58542
male	Equal variances assumed	693	.612	.21718
	Equal variances not assumed	691.619	.612	.21718
Initial_volume	Equal variances assumed	686	.187	-1.16560
	Equal variances not assumed	338.621	.198	-1.16560
Initial_concentration	Equal variances assumed	686	.162	-6.48802
	Equal variances not assumed	631.800	.165	-6.48802
Initial_motility	Equal variances assumed	686	.000	-4.68588
	Equal variances not assumed	684.471	.000	-4.68588
Initial_total_motile	Equal variances assumed	686	.059	-37.58716
	Equal variances not assumed	363.572	.065	-37.58716

Independent Samples Test

		t-test for Equality of Means		
		Std. Error Difference	95% Confidence Interval of the Difference	
			Lower	Upper
female	Equal variances assumed	.33137	-1.23603	.06519
	Equal variances not assumed	.33042	-1.23417	.06333
male	Equal variances assumed	.42780	-.62275	1.05711
	Equal variances not assumed	.42768	-.62252	1.05688
Intital_volume	Equal variances assumed	.88256	-2.89845	.56724
	Equal variances not assumed	.90313	-2.94205	.61084
Initial_concentration	Equal variances assumed	4.63575	-15.58999	2.61394
	Equal variances not assumed	4.66258	-15.64405	2.66801
Initital_motility	Equal variances assumed	1.08534	-6.81686	-2.55489
	Equal variances not assumed	1.08297	-6.81223	-2.55953
Initial_total_motile	Equal variances assumed	19.85963	-76.58011	1.40580
	Equal variances not assumed	20.28718	-77.48211	2.30779

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of
		F	Sig.	t
final_volume	Equal variances assumed	1.535	.216	-1.080
	Equal variances not assumed			-1.059
final_concentration	Equal variances assumed	3.893	.049	.651
	Equal variances not assumed			.653
final_motility	Equal variances assumed	1.786	.182	-1.820
	Equal variances not assumed			-1.803
final_total_motile	Equal variances assumed	2.810	.094	-.162
	Equal variances not assumed			-.162
time_collection_recieved	Equal variances assumed	6.326	.012	-1.436
	Equal variances not assumed			-1.403
time_received_start_processing	Equal variances assumed	8.772	.003	1.332
	Equal variances not assumed			1.321
time_start_finish_processing	Equal variances assumed	.519	.471	-1.626
	Equal variances not assumed			-1.623
total_elapsed_time	Equal variances assumed	8.192	.004	-.979
	Equal variances not assumed			-.964

Independent Samples Test

		t-test for Equality of Means		
		df	Sig. (2-tailed)	Mean Difference
final_volume	Equal variances assumed	686	.280	-.04526
	Equal variances not assumed	380.446	.290	-.04526
final_concentration	Equal variances assumed	686	.515	3.82182
	Equal variances not assumed	685.089	.514	3.82182
final_motility	Equal variances assumed	685	.069	-3.69203
	Equal variances not assumed	565.561	.072	-3.69203
final_total_motile	Equal variances assumed	682	.871	-.28856
	Equal variances not assumed	679.425	.871	-.28856
time_collection_recieved	Equal variances assumed	672	.152	-3.80617
	Equal variances not assumed	494.435	.161	-3.80617
time_received_start_processing	Equal variances assumed	677	.183	.87330
	Equal variances not assumed	581.312	.187	.87330
time_start_finish_processing	Equal variances assumed	681	.104	-1.16386
	Equal variances not assumed	669.837	.105	-1.16386
total_elapsed_time	Equal variances assumed	673	.328	-2.67278
	Equal variances not assumed	522.334	.335	-2.67278

Independent Samples Test

		t-test for Equality of Means		
		Std. Error Difference	95% Confidence Interval of the Difference	
			Lower	Upper
final_volume	Equal variances assumed	.04190	-.12752	.03700
	Equal variances not assumed	.04275	-.12932	.03880
final_concentration	Equal variances assumed	5.86786	-7.69932	15.34295
	Equal variances not assumed	5.85654	-7.67712	15.32075
final_motility	Equal variances assumed	2.02903	-7.67588	.29183
	Equal variances not assumed	2.04773	-7.71412	.33006
final_total_motile	Equal variances assumed	1.78029	-3.78406	3.20695
	Equal variances not assumed	1.77578	-3.77524	3.19812
time_collection_recieved	Equal variances assumed	2.65126	-9.01191	1.39958
	Equal variances not assumed	2.71374	-9.13804	1.52571
time_received_start_proces sing	Equal variances assumed	.65560	-.41395	2.16056
	Equal variances not assumed	.66091	-.42475	2.17136
time_start_finish_processin g	Equal variances assumed	.71562	-2.56895	.24122
	Equal variances not assumed	.71696	-2.57163	.24390
total_elapsed_time	Equal variances assumed	2.73074	-8.03458	2.68902
	Equal variances not assumed	2.77207	-8.11857	2.77300

CROSSTABS

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/TABLES=trt BY pregtest sac hp
/FORMAT=AVALUE TABLES
/STATISTICS=CHISQ
/CELLS=COUNT ROW COLUMN TOTAL

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/COUNT ROUND CELL.