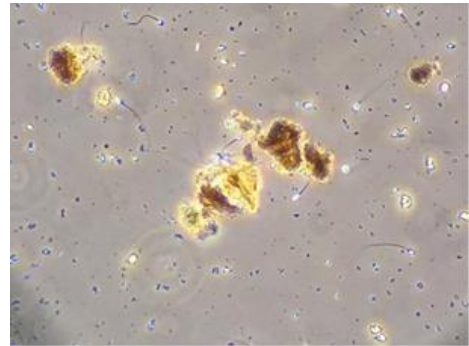


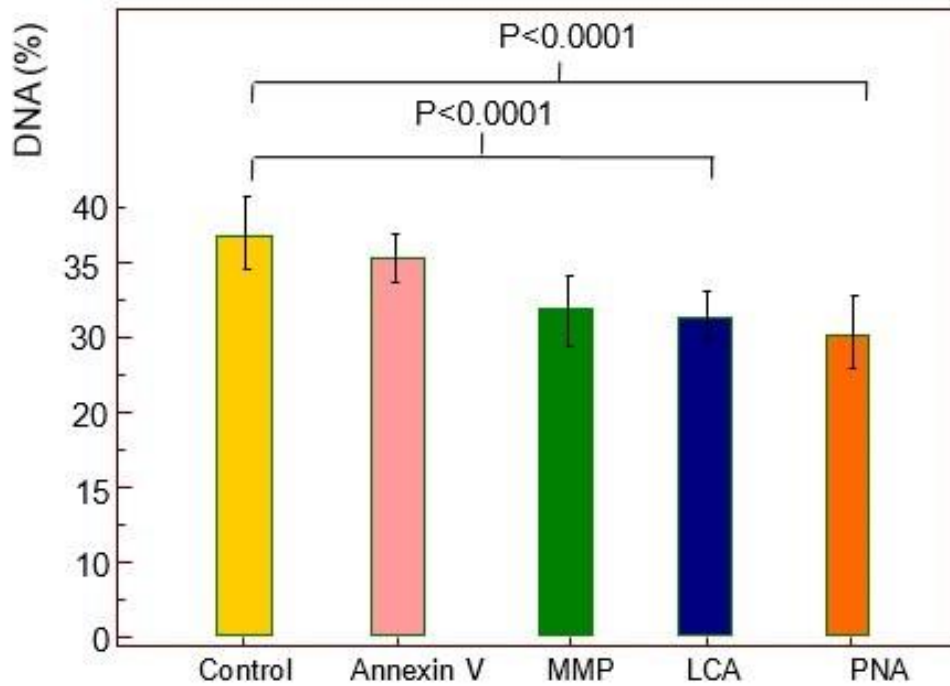
Magnetic Activated Sperm Enrichment (**MASE**) client Feedback



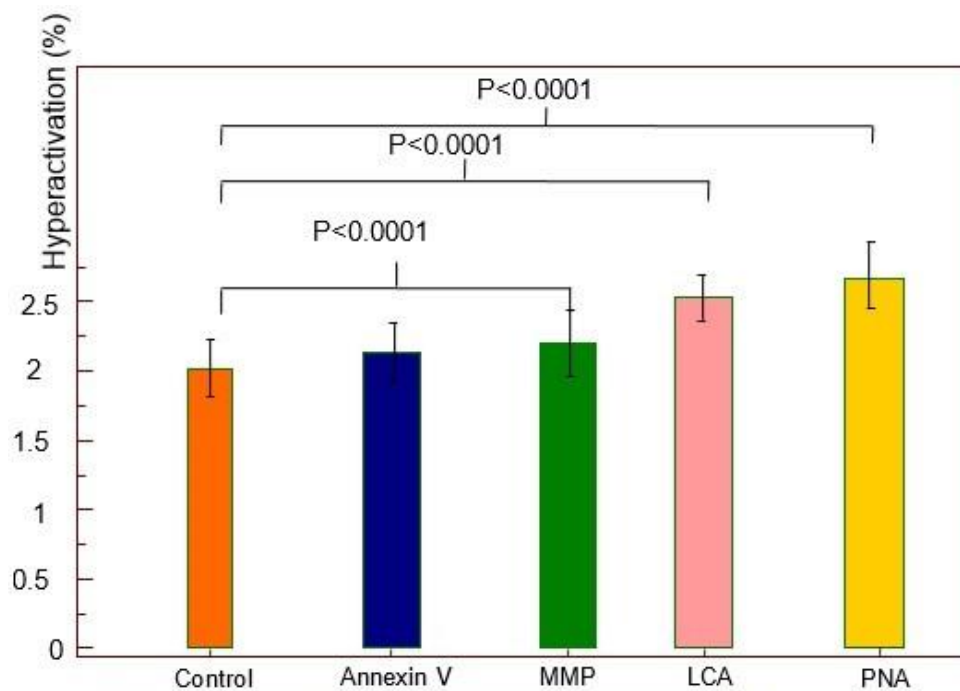
Cell Sorting Reagent

Preclinical Trial (Human Spermatozoa) 2017

Study Conducted in South Africa (Western Cape University in 2017) by PhD. Salem Shalaweh, M.Med.Sci (ART) Khaled Raouf, PhD. Henry Clemente, PhD. G Von Der Horst & PhD. Ismael Alfourtia at Western Cape University Hospitals. (n=25) a preclinical study for patients undergoing treatment for conception with high DNA fragmentation. Each of the MASE ligands were tested alone against control. Study showed significant reduction in DNA fragmentation, ROS plus elevation in motility & hyperactivation compared to control.



The effect of each particle used in our mixture on DNA Fragmentation versus control
(Western Cape university hospital study 2017)



The effect of each particle used in our mixture on Hyperactivation versus control
(Western Cape university hospital study 2017)

	Control	1 µg/ml Annexin V	1 µg/ml MMP	1 µg/ml LCA	2 µg/ml PNA	1 µg/ml PNA	ANOVA (P value)
ROS (%)	40.35±4.19	39.60±4.12	35.95±4.75	35.30±4.48	34.45±3.26	37.80±2.68	<0.001

The effect of each particle used in our mixture on ROS reduction after separation versus control
(Western Cape university hospital study 2017)

Clinical Trial (IUI feedback Human) 2017

Table. IUI Case trials done in Libya May 2018 by Dr.Salem Shalaweh (Phd) & Dr.Ghalia Milad (M.D. Obs & Gynae)

	PRE NP TREATMENT COUNT	Pre NP Total Motile Ratio	Pre NP Progressive Motility	Pre NP Normal Forms (Verified by staining)	After Dilution & NP Treatment Count	After NP Treatment Total Motile Count	After NP Progressive Motility	After NP Normal Forms (Verified by staining)	Infection Post IUI Procedure	Pregnancy Outcome
Case 1	150	70	0	10	4	95	60	30	No	+ve
Case 2	40	75	0	10	5	100	70	20	No	-ve
Case 3	40	20	0	5	4	80	15	10	No	-ve
Case 4	60	70	0	5	5	80	5	7	No	+ve
Case 5	35	70	5	3	4	95	35	15	No	-ve
Case 6	50	75	10	2	5	85	15	20	No	-ve

Clinical Trial (ICSI feedback Human) 2017

Table. Patient Demographics for study (n=80 Treated cases with MASE prior to ICSI)

Age (years)	28.55 ± 0.74
BMI (kg/m ²)	28.7 ± 0.86
Duration of infertility (years)	5.82 ± 0.37
Basal FSH (IU/L)	5.80 ± 0.19
Antral Follicle count	10.2 ± 0.47
Total FSH / HMG	2321 ± 56
PCOS: n (%)	23 (29%)
Male factor: n (%)	35 (44%)
Tubal factor: n (%)	22 (27%)
No. Oocytes collected	19.82 ± 0.54
No. Mature oocytes: (mean)	17.60 ± 0.34

Table. Study main findings (n=80 Treated cases with MASE prior to ICSI)

	Sperm Processing Method		Odds Ratio (95% CI)	P value
	Clemente Nano Particles (n=80) %	Contr Density Gradient (n=80) %		
Fertilization rate 2PN oocytes injected MII oocytes (%)	452/683 (66%)	492/724 (68%)	0.92 (0.74 - 1.15)	0.48
Cleavage rate Cleaved Embryos/ fertilized oocytes (%)	449/452 (99%)	478/492 (97%)	4.38 (1.25 - 15.36)	0.0118
Top Quality Day 3 Embryos/fertilized oocytes (%)	391/452 (87%)	347/492 (97%)	2.68 (1.92 - 3.73)	< 0.0001
Compaction rate Compacted Day 3 Embryos/fertilized oocytes (%)	287/452 (63%)	117/492 (28%)	5.58 (4.20 - 7.39)	< 0.0001
Blastocyst formation rate Blastocysts/ fertilized oocytes (%)	352/452 (78%)	322/492 (65%)	1.88 (1.41 - 2.52)	< 0.0001
High quality blastocysts from fertilized Embryos (%)	319/452 (71%)	138/492 (28%)	6.15 (4.64 - 8.16)	< 0.0001
Cryopreservation rate: Vitrified blastocysts / fertilized Embryos (%)	290 / 452 (64%)	245 / 492 (50%)	1.80 (1.39 - 2.34)	< 0.0001
DNA Fragmentation method of testing	<i>DNA Fragmentation tested by Halo Technology</i>	<i>DNA Fragmentation tested by Halo Technology</i>		
DFI mean / processing method	6.982 ± 2.05	15.89 ± 3.07		< .0001

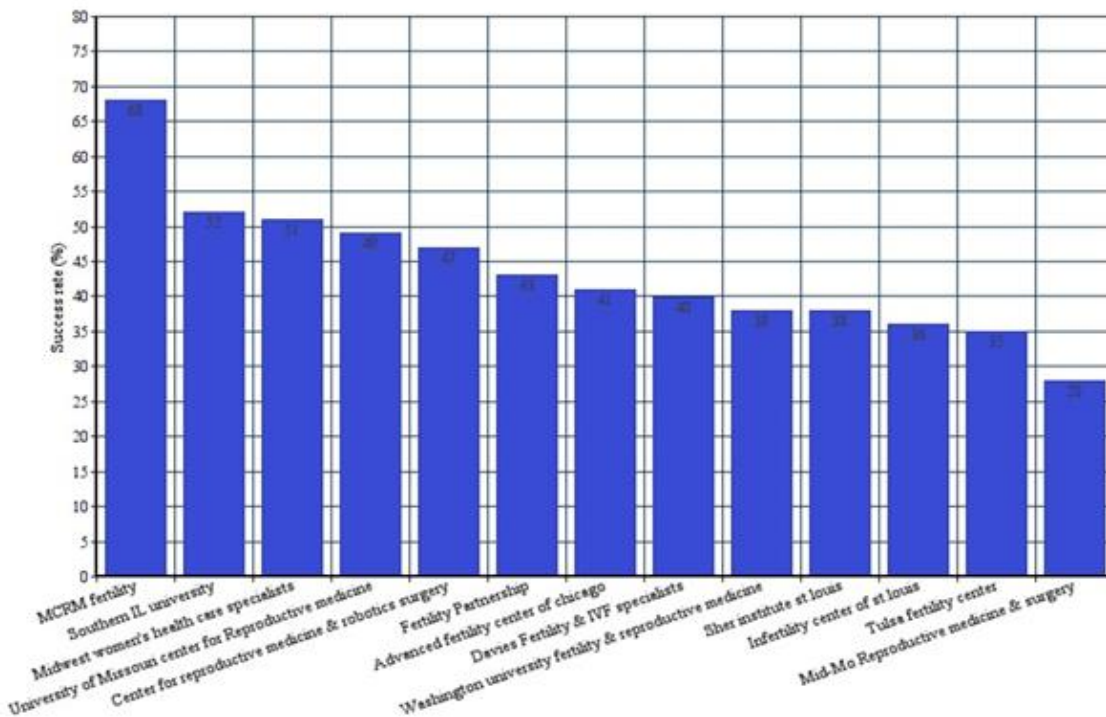
Ongoing - Clinical Trial (ICSI feedback Human) 2018

Magnetic Assisted Sperm Enrichment						Density Gradient Treatment Alone				
No.	Total	Fertilized	D3 TQE	Blastocyst	ET	Total	Fertilized	D3 TQE	Blastocyst	ET
1	7	6	3	3		9	6	4	3	2
2	9	9	2	m		9	9	0	m	m
3	7	5	3	0		9	8	6	4	2*
4	15	10	8	m		13	12	8	m	m
5	15	14	9	7	2*	m	m	m	m	m
6	11	11	10	6	2	m	m	m	m	m
7	6	6	5	5	1*	5	4	1	1	m
8	7	5	3	m		7	5	3	m	m
9	4	4	3	2	m	4	4	1	3	1
10	6	3	2	2	1*	7	5	3	4	1*
11	10	7	7	m	m	9	6	6	m	m
sum	97	80	55	25		72	59	32	15	
rates		82%	69%	31%			81.90%	54%	25%	

- The labelled m stands for either cancelled or frozen cycle.
- The labelled grey reported positive pregnancy while the * sign indicate the embryo was transferred from which category of treatment (MASE or DG).
- Embryo transfer coming out from the MASE treatment pre-fertilization was not encouraged until case 5.
- Starting case 6 the embryologist conducting the fertilization and transfer of embryos started using the 1month old batch instead of the first batch (4-5 months old).
- Number of blastocysts retrieved from MASE compared to DG alone are 25:15 which is considered highly significant.
- Other cases pregnancy in the table still not completely monitored due to lack of compliance of reporting by the patient.

Recent success rates across the state of Illinois comparing one center using our technology in sperm selection (MCRM Fertility clinic) vs. other clinics in the same state. The [Centers for Disease Control and Prevention \(CDC\)](#) compiles and publishes data regarding individual assisted reproductive technology (ART) centers as well as Society for Assisted Reproductive Technologies (SART) .

Comparing success rates for MCRM Fertility, a fertility Clinic using our particles vs other clinics not using the same technology in the same state



MCRM fertility Link for our bio-separation technology

<https://www.mcrmfertility.com/2018/07/02/could-magnetic-nanoparticle-selection-lead-to-sex-selection-in-ivf/>

<https://www.mcrmfertility.com/treatment-options/in-vitro-fertilization-ivf/sperm-selection/#nanobead>

General resources regarding the technology

Effects of magnetic-activated cell sorting on sperm motility and cryosurvival rates

- <https://www.ncbi.nlm.nih.gov/pubmed/15866582>

Clinical outcomes of magnetic activated sperm sorting in infertile men candidate for ICSI.

- <https://www.ncbi.nlm.nih.gov/pubmed/29363381>

Magnetic-activated cell sorting for sperm preparation reduces spermatozoa with apoptotic markers and improves the acrosome reaction in couples with unexplained infertility.

- <https://www.ncbi.nlm.nih.gov/pubmed/20150175>

Clinical outcomes of magnetic activated sperm sorting in infertile men candidate for ICSI.

- <https://www.ncbi.nlm.nih.gov/pubmed/20150175>

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