

Reprint, 2019

Evaluation of the effect of supplementation with SUPRAMEN[®] on the improvement of semen quality parameters in men with reduced fertility

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Introduction

According to the World Health Organization (WHO) infertility is the inability to get pregnant during the 12 months of regular intercourses of a couple for conceptual purposes¹. It affects up to 20% of couples in Poland and in the world. It is estimated that among infertile couples the male factor accounts for 25% up to even 60%^{2,3,4,5}. The male infertility factor may be associated with sperm parameters abnormalities, such as: azoospermia, necrospermia, oligozoospermia, asthenozoospermia, teratozoospermia, oligoasthenoteratozoospermia. Decreased sperm parameters may be caused by an improperly balanced diet and nutrient deficiencies. The studies have shown that the deficiency of certain substances, such as zinc, selenium, copper, vitamin E, L-carnitine, N-acetyl-L-carnitine, coenzyme Q10, lycopene or myo-inositol¹⁰ correlates with abnormalities of motility, number, morphology and function of sperm cells. In the last two decades there have been numerous clinical studies analysing the influence of antioxidant supplementation on human fertility^{6,7,8}.

The positive effect of administration of various substances with proven effect on the improvement of sperm parameters, hormonal profile and percentage of acquired pregnancies has been confirmed. The subject of this study is the assessment of the effect of supplementation with SUPRAMEN® on the improvement of the quality of basic ejaculate quality parameters i.e. viscosity, volume, morphology, motility, abundance, and viability of sperm cells.

Methodology

The study included a group of 100 men aged 25-35 whose body mass index (BMI) was 17-35. Men with normospermia, azoospermia, aspermia and smokers were excluded. Each of the subjects received SUPRAMEN® for three (3) months. Two measurements of semen parameters were performed in each patient (visit 0 – measurement I) and after 3 months of supplementation with SUPRAMEN® (measurement II). Results of the pre- and post-supplemental semen analysis were compared according to WHO criteria 2010¹. The analysis included as many as seven parameters: ejaculate volume and viscosity, sperm cells concentration, general and progressive motility and their morphology. The study was not completed for 16 males; 9 of them reported the need to include antibiotic therapy, as the reason for termination of the study, which would impair the credibility of the results obtained during the control examination, and the remaining 7 of them did not attend a semen examination.

Results

The study included a group of 84 men. The results presented in tables (1-5) and in the charts determine the change size for the total group (Figures 1.a-5.a) and for the individuals whose result in the first measurement was below the standard according to WHO criteria 2010 (charts 1.b-5.b). The results with the p value of



<0.05 (less than 0.05) are marked in red, which indicate a statistically significant change in the analysed values (or statistically significant difference between groups – in case of group comparison, or statistically significant dependence of variables – with further chi-square when analysing the "improvement" of results). To evaluate the distribution of results, the t-student test was used for related and unrelated variables, and in the case of abnormal distribution of results, non -parametric tests (Wilcoxon and Mann-Whitney).

Morphology

Table 1

		Ν	М	Me	Min.	Max.	Q1	Q3	SD	Group comparison
Total group	Measurement I	84	3.93	3.8	0.0	18.0	2.0	5.0	3.10	Z ^A = 1.439
	Measurement II	84	4.16	4.0	0.0	20.0	3.0	5.8	2.94	p = 0.150
Subjects	Measurement I	42	1.82	2.0	0.0	3.5	1.0	3.0	1.19	Z ^A = 3.302
norm	Measurement II	42	2.95	3.0	0.0	8.0	1.0	4.0	2.15	p = 0.001
The size of the change	Total group	84	0.23	0.0	-15.0	12.0	-0.5	1.5	3.32	
	Outside the norm	42	1.13	1.0	-3.0	7.0	0.0	2.0	2.01	Z ^B = 2.880 p = 0.004

N - number of people, M - average, Me - median, Min. - minimum value, Max. - maximum value, Q1 - lower quartile, Q3 - upper quartile, SD - standard deviation, ZA - analysis of Wilcoxon matched pairs test, ZB - Mann-Whitney U test result, p - statistical significance





Chart 1b. Morphology in measurement I and II (group with a value below the norm in I measurement).



Morphology I [%] Morphology II [%]

Sperm concentration

Table 2

		N		N/ -	N.C.	Mari	01	01	60	Group
		IN	IVI	ivie	IVIIII.	IVIdX.	QI	US	50	comparison
Total group	Measurement I	84	66.07	12.4	0.7	492.8	6.8	92.9	96.31	Z ^A = 2.587
rotal group	Measurement II	84	85.11	15.5	4.5	853.1	9.2	98.0	148.09	p = 0.010
Subjects	Measurement I	50	7.47	7.1	0.7	14.0	4.4	10.4	3.59	Z ^A = 4.585
norm	Measurement II	50	13.32	9.5	4.5	79.4	8.0	14.6	14.33	p < 0.001
The size of the change	Total group	84	19.05	2.3	-174.4	760.2	-2.0	10.5	117.98	
	Outside the norm	50	5.85	2.3	-3.7	71.8	0.7	4.3	14.39	Z ^B = 0.296 p = 0.767

N - number of people, M - average, Me - median, Min. - minimum value, Max. - maximum value, Q1 - lower quartile, Q3 - upper quartile, SD standard deviation, ZA - analysis of Wilcoxon matched pairs test, ZB - Mann-Whitney U test result, p - statistical significance



Chart 2a. Sperm concentration in measurement I and II (total group).

Concentration I [%] Concentration II [%]

Chart 2b. Sperm concentration in measurement I and II .



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General motility

Table 3

		N	М	Me	Min.	Max.	Q1	Q3	SD	Group comparison
Total group	Measurement I	84	34.76	35.0	3.0	68.0	21.0	50.0	16.97	Z ^A = 2.037
	Measurement II	84	38.38	37.0	5.0	79.0	29.0	47.0	15.64	p = 0.042
Subjects outside the norm	Measurement I	56	24.05	24.0	3.0	39.0	15.0	35.0	11.02	Z ^A = 3.540
	Measurement II	56	31.11	30.0	5.0	79.0	21.0	37.0	13.54	p < 0.001
The size of the change	Total group	84	3.62	3.0	-25.0	60.0	-5.0	7.0	13.61	
	Outside the norm	56	7.05	4.0	-23.0	60.0	-1.0	13.0	14.32	Z ^B = 3.191 p = 0.001

N - number of people, M - average, Me - median, Min. - minimum value, Max. - maximum value, Q1 - lower quartile, Q3 - upper quartile, SD - standard deviation, ZA - analysis of Wilcoxon matched pairs test, ZB - Mann-Whitney U test result, p - statistical significance

Chart 3a. General motility in measurement I and II (total group).

Chart 3b. General motility in measurement I and II (group with a value below the norm in I measurement).







Progressive motility

Table 4

		Ν	М	Me	Min.	Max.	Q1	Q3	SD	Group comparison
Total group	Measurement I	84	26.34	26.0	0.0	70.0	12.0	39.0	16.22	Z ^A = 1.443
	Measurement II	84	29.20	28.0	1.0	69.0	17.0	42.0	16.14	p = 0.149
Subjects outside the norm	Measurement I	57	16.23	17.0	0.0	31.0	8.0	25.0	9.45	Z ^A = 2.664
	Measurement II	57	22.07	21.0	1.0	69.0	13.0	28.0	13.32	p = 0.008
The size of the change	Total group	84	2.86	1.5	-38.0	55.0	-4.0	10.0	13.16	
	Outside the norm	57	5.84	3.0	-11.0	55.0	-4.0	10.0	12.81	Z ^B = 2.729 p = 0.006

N - number of people, M - average, Me - median, Min. - minimum value, Max. - maximum value, Q1 - lower quartile, Q3 - upper quartile, SD - standard deviation, ZA - analysis of Wilcoxon matched pairs test, ZB - Mann-Whitney U test result, p - statistical significance

Chart 4a. Progressive mobility in measurement I and II (total group). value below the norm in I measurement).

Chart 4b. Progressive mobility in measurement I and II (group with a









Vitality

Table 5

		Ν	М	Me	Min.	Max.	Q1	Q3	SD	Group comparison
Total group	Measurement I	84	58.79	58.0	31.0	85.0	50.0	70.0	14.61	Z ^A = 2.037
	Measurement II	84	60.49	62.0	30.0	92.0	50.0	69.0	14.53	p = 0.042
Subjects	Measurement I	41	45.80	47.0	31.0	57.0	38.0	53.0	7.86	T = -3.747
norm	Measurement II	41	50.98	51.0	30.0	77.0	41.0	62.0	12.51	p = 0.001
The size of the change	Total group	84	1.70	2.5	-32.0	24.0	-4.0	7.0	9.92	
	Outside the norm	41	5.17	4.0	-9.0	24.0	-1.0	12.0	8.84	Z ^B = 2.287 p = 0.022

N - number of people, M - average, Me - median, Min. - minimum value, Max. - maximum value, Q1 - lower quartile, Q3 - upper quartile, SD - standard deviation, ZA - analysis of Wilcoxon matched pairs test, ZB - Mann-Whitney U test result, p - statistical significance



Chart 5a. Vitality in measurement I and II (total group).

Chart 5b. Vitality in measurement I and II (group with a value below the norm in I measurement).

The correct post-treatment viscosity was observed in 78% (N = 66) subjects. The average semen volume in all patients (N = 84) after treatment was 4.17 ml, which means that the median was in compliance with WHO standards.

Summary

The following charts show the percentage of individuals with improved tested parameter after 3 months supplementation with SUPRAMEN ®.



Conclusions

In all subjects with a parameter value below the norm, the parameter improved by a statistically significant value, although not all results obtained were within the normal range. In the semen samples analysed, an upward trend was observed in all sperm parameters tested, which may suggest that longer supplementation will allow the complete normalization of the above mentioned parameters. The study confirmed the beneficial effect of supplementation with SUPRAMEN® on the improvement of sperm quality parameters in men with a parameter values below the norm.

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