Research Article

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Novel Therapeutic Approach for the Treatment of Patients with Reduced Fertility

Saccone Gabriele[1], Paolo Cirillo[2], Umberto Di Maio[3], Antonino Bagnulo[4]* and Maria Potenza[4]

[1]*Centro Delta, Multispecialty Medical Center,, Naples, Italy*

[2]*Department of Advanced Medical and Surgical Sciences, Naples, Italy*

[3]*Shedir Pharma Group SpA, Via Bagnulo, 95 – 80063 Piano di Sorrento (NA), Italy*

[4]*Neilos Srl, Via Bagnulo, 95 – 80063 Piano di Sorrento (NA), Italy*

***Corresponding author:** Antonino Bagnulo, Via Bagnulo 95, 80063, Piano di Sorrento, Naples, Italy

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ABSTRACT

Background: Declining male fertility represents a constantly growing global health problem, with a particularly worrying epidemiological incidence among young subjects.

Objective: Evaluate the clinical efficacy of Priapogen® treatment in improving semen quality in patients with male subfertility of mixed aetiology

Methods: This clinical study enrolled 130 patients with various forms of reduced fertility: oligoasthenoteratozoospermia, asthenozoospermia, teratrozoospermia, oligozoospermia in patients with varicocele, cryptorchidism, hypogonadism and idiopathic infertility. All participants underwent continuous oral therapy with Priapogen® (1 sachet daily) for a total duration of 3 months.

Semen parameters, including ejaculate volume, sperm concentration, total sperm count, progressive motility, morphology and leucocyte concentration, were assessed at baseline (T0) and after 3 months of treatment (T3).

Results: The collected data highlight a statistically significant increase in all the main seminal fluid parameters already after 3 months of treatment (T3). Specifically, ejaculate volume increased by approximately 7%, sperm concentration improved by 31%, total spermatozoa count rose by 51% and morphology increased by 26%. Furthermore, progressive motility showed a significant 27% increase while seminal leucocyte concentration significantly decreased below the pathological threshold.

Conclusion: Priapogen® treatment, nutraceutical supplements based on synergistic substances with targeted antioxidant and anti-inflammatory activity which represent key factors in the pathophysiology of seminal damage, has been shown to be effective in counteracting reduced fertility, through the optimization of both quantitative and qualitative sperm parameters.

Keywords: Oligoasthenozoospermia; Male Fertility; Seminal Fluid; Varicocele

Abbreviations: WHO: World Health Organization; OS: Oxidative Stress; ROS: Reactive Oxygen Species; LH: Luteinizing Hormone; PUFAs: Polyunsaturated Fatty Acids; NAC: N-Acetylcysteine

Introduction

Infertility is defined by the World Health Organization (WHO) as the absence of conception in a couple after at least 12 months of regular, unprotected sexual intercourse. Reduced fertility represents a clinical problem of increasing epidemiological and social relevance, affecting approximately 15% of couples of reproductive ages [1]. In 40–50% of cases, a male factor is present, frequently associated with alterations in sperm quality and quantity, including reduced sperm concentration (oligozoospermia), impaired motility (asthenozoospermia), and morphological abnormalities of spermatozoa (terato-

zoospermia) [2]. The aetiology of reduced fertility is multifactorial. It includes endocrine disorders (such as hypogonadism) in 2–5% of cases, sperm transport disorders (such as post-vasectomy) in 5%, and primary testicular defects in 65–80%. Notably, idiopathic infertility where alterations in semen quality occur without any identifiable systemic, genetic, or organic cause accounts for 10–20% of cases. Environmental factors (stress, smoking, alcohol), metabolic disorders (diabetes, metabolic syndrome), and subclinical urogenital infections also heavily contribute to this landscape. In recent years, biomedical research has increasingly focused on the role of inflammation as a primary pathophysiological mechanism responsible for reduced fertility.

Phlogistic processes interfere with both steroidogenesis and spermatogenesis, inhibiting the physiological sperm maturation process and inducing a significant reduction in serum testosterone and luteinizing hormone (LH) levels, ultimately impairing conception rates. For instance, during epididymal or accessory gland inflammation, the pathological recruitment of leukocytes into the seminal fluid triggers oxidative pathways and can induce the secretion of anti-sperm antibodies; this phenomenon severely impairs motility, causing agglutination and asthenozoospermia [3]. Oxidative stress (OS) plays an equally critical role in the pathogenic mechanism of sperm damage. OS represents a major cause of reduced male fertility due to the intrinsic vulnerability of spermatozoa to reactive oxygen species (ROS). This specific susceptibility occurs for two main reasons: on the one hand, the sperm cell membrane contains a high percentage of polyunsaturated fatty acids (PUFAs), whose double bonds are easily attacked and degraded by ROS via lipid peroxidation. On the other hand, the limited sperm cytoplasm possesses very few protective antioxidant enzymes capable of counteracting these free radicals [4]. As a result, excessive production of ROS compromises structural functionality, modifies cell membrane fluidity and permeability, induces sperm DNA fragmentation, and drastically reduces fertilizing capacity [5].

Elevated ROS levels are also responsible for lesions affecting genomic and mitochondrial DNA, telomere shortening, Y-chromosome micro-deletions, and alterations in the paternal epigenetic profile [5]. From a clinical perspective, the combination of these factors leads to a marked deterioration of seminal parameters, negatively influencing sperm concentration, motility, and morphology. In light of this evidence, the clinical use of nutraceutical supplements based on synergistic substances with targeted antioxidant and anti-inflammatory activity constitutes an increasingly widespread therapeutic approach in modern urological and andrological practice. The aim of the present study was to evaluate the efficacy of Priapogen® a novel supplement featuring the patented molecular complex F.A.G.® combined with N-acetylcysteine (NAC) and Coenzyme Q10 (CoQ10) on semen parameters in a population of 130 patients with reduced fertility focusing on its ability to counteract oxidative stress and the subclinical inflammation underlying sperm alterations. F.A.G.®, has been found to be involved in cell protection from oxidative stress and inflammation. In cultured human monocytes, F.A.G.®, is non-toxic up to 1 mg/mL and has been shown to inhibit the release of inflammatory cytokines induced by a lipopolysaccharide challenge [6,7]. The acronym F.A.G.®, includes a number of different mixtures obtained by a calibrated mixing of long and short chain fatty acids given to sustain the metabolism of macrophages involved in the inflammatory reaction with the aim of facilitating its resolution and the shift of macrophages to the non-pro inflammatory phase.

Material and Methods

An Italian medical doctor with a specialization in gynaecology and an Italian biologist, enrolled 130 participants in the year 2025 evaluating their clinical manifestations during medical examination. In particular, the participants were selected according to defined inclusion criteria: patients with various forms of reduced fertility oligoasthenoteratozoospermia, asthenozoospermia, teratrozoospermia, oligozoospermia caused by a varicocele, cryptorchidism, hypogonadism and patients with idiopathic infertility. Considering these clinical conditions, a total of 130 patients were enrolled in the present survey; at the first medical examination, the doctors reported for each patient its age, comorbidity and use of pharmacological treatments. At baseline (T0), a comprehensive clinical history was recorded, and a baseline laboratory-conducted semen analysis was performed. The recorded seminal characteristics included: ejaculate volume (mL), sperm concentration (million/mL), total sperm count (million), progressive motility and morphology percentage (%), and leukocyte concentration (million/mL). Then, each participant was administered Priapogen® with a posology of one sachet/day and repeated the sub mentioned semen parameters that were registered from the doctors after the follow-up visit at 3 months (T3).

For both T0 and T3, semen samples were collected after a strict period of sexual abstinence ranging between 3 and 5 days (mean: 3.7 days of abstinence). Semen analyses were performed in accordance with WHO laboratory manual guidelines.

Settings

The clinical survey has been conducted by an Italian medical doctor with a specialization in gynaecology and an Italian biologist, and is based on their clinical experience in patients taking Priapogen®. The retrospective observational survey was conducted in accordance with the Standards of Good Clinical Practice of the European Union and the ethical principles expressed in the Declaration of Helsinki. Data were retrospectively collected in the year 2025. Ethical approval was not necessary according to National Code on Clinical Trials declaration because this data derives from a real-life retrospective study [8]. The aim of the present study was to evaluate the effect of Priapogen® oral administration after three months of treatment (T3) [9].

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Results

After three months of continuous treatment with Priapogen®, a generalized and statistically significant improvement was recorded across all evaluated seminal parameters. As illustrated in Figure 1, the mean ejaculate volume increased by approximately 7%, reaching optimal physiological levels. Concurrently, the sperm concentration per millilitre expanded by 31%. This was accompanied by a robust increase in the total spermatozoa count per eiaculate of approximately 51%, yielding an optimal mean absolute count of approximately 42 million spermatozoa. Progressive motility is a vital functional characteristic of ejaculated human spermatozoa that directly governs their capacity to penetrate cervical mucus, migrate through the female reproductive tract, and ultimately fertilize the oocyte [6]. Following Priapogen® administration, an optimal and statistically significant increase of 27% in progressive motility was achieved at T3 compared to baseline values, markedly upgrading the overall kinetic profile of the cohort. After three months of treatment with Priapogen®, the morphology had also improved by as much as 26% compared with the baseline value, in line with the reference parameters of 4% (T0) (Figure 2).

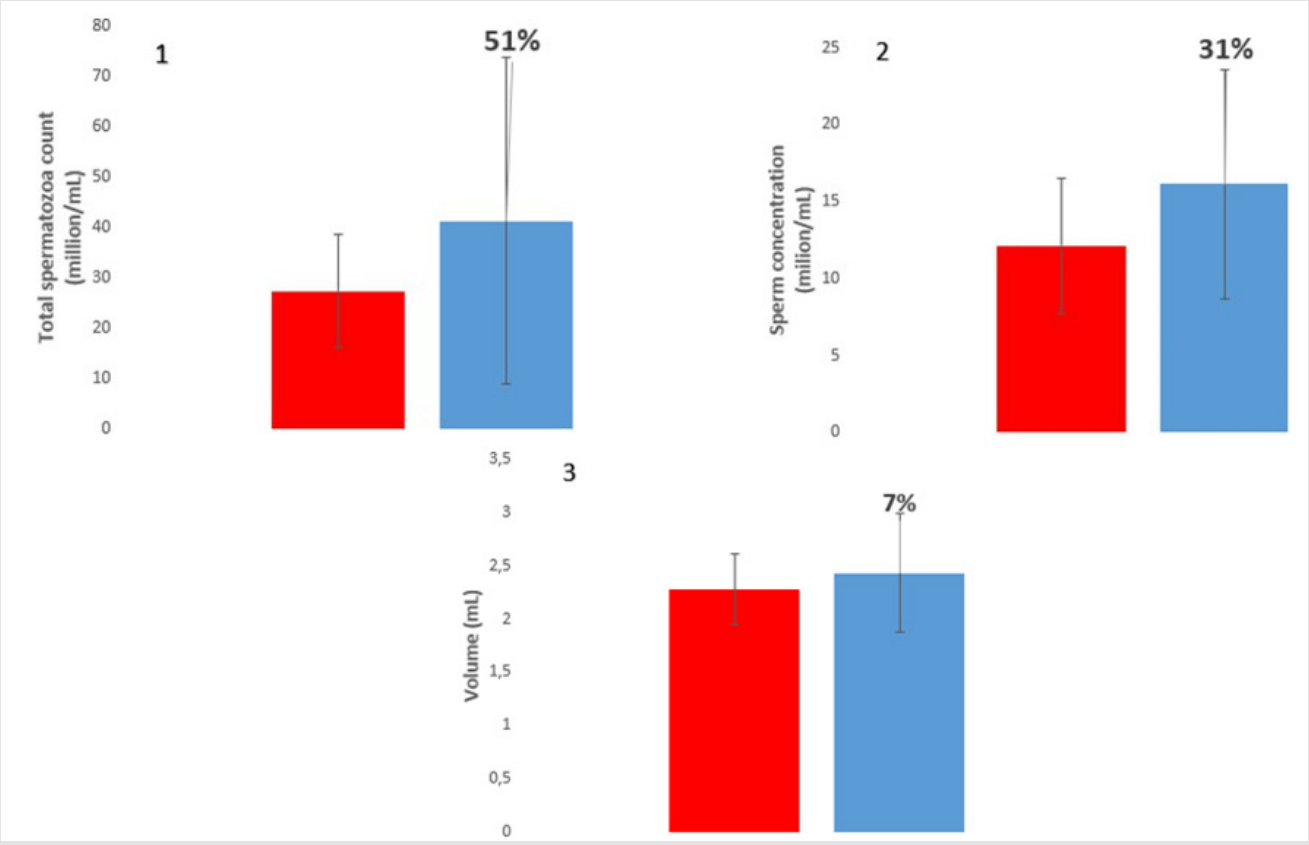

Figure 1: Spermiogram results in terms of: Total spermatozoa count (million/mL) (1) sperm concentration (millions/mL) (2) and volume (mL) (3), at T0 (red) and after three months of treatment with Priapogen® (blue). Data are expressed as mean ± standard deviation.

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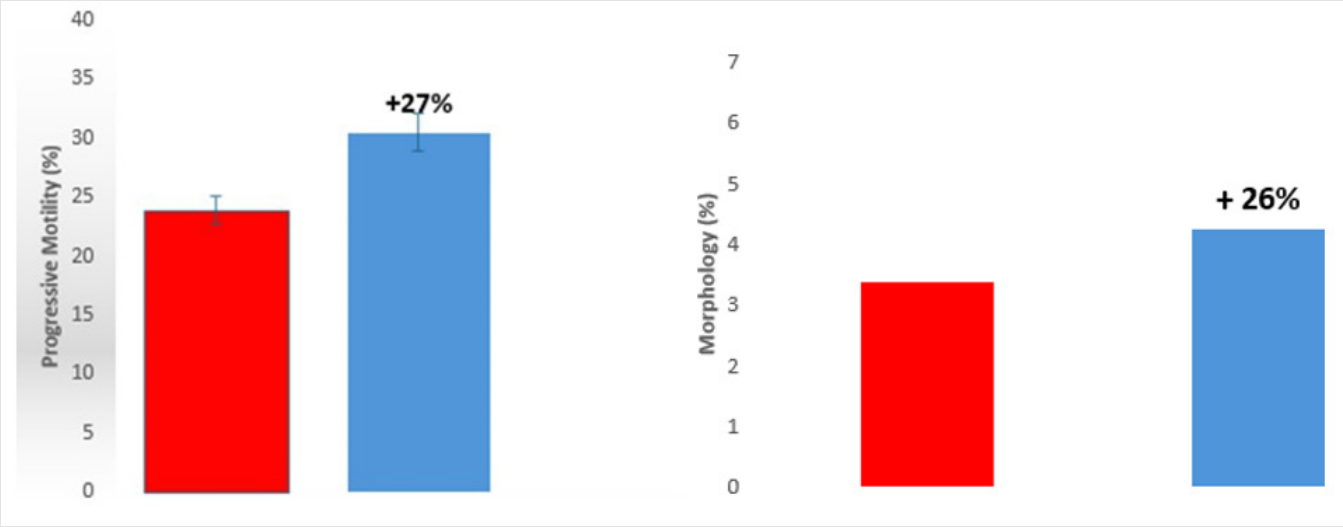

Figure 2: Spermiogram results in terms of the progressive motility (%) and morphology (%) at T0 (red) and after three months of treatment with Priapogen® (blue). Data are expressed as mean ± standard deviation.

Finally, the nutraceutical treatment exerted a powerful healthy effect on seminal inflammatory metrics. At baseline (T0), the patient cohort presented a pathological mean leukocyte concentration exceeding 1.0 million/mL, which represents the critical cutoff threshold defined by the World Health Organization for leukocytospermia. Following the 3-month therapeutic cycle with Priapogen®, mean leukocyte concentration dropped significantly, falling well below the pathological threshold value and demonstrating a clear resolution of seminal inflammation (Figure 3).

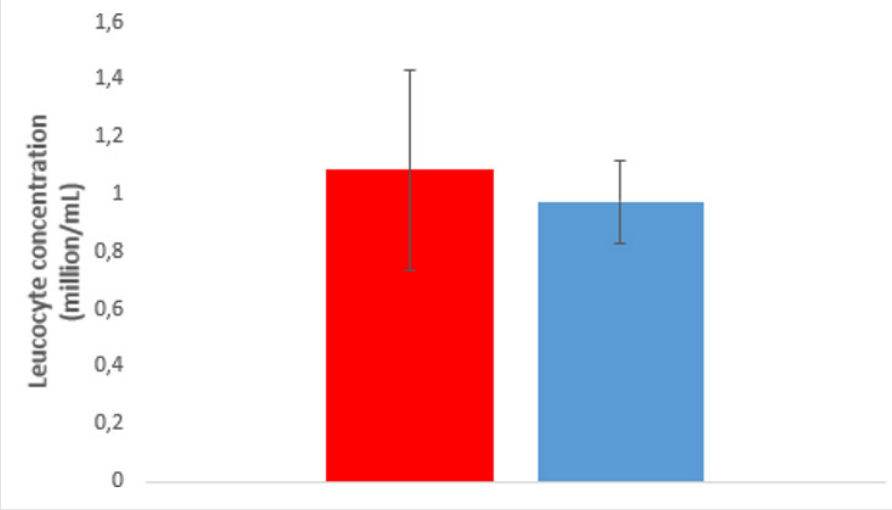

Figure 3: Leucocyte concentration (million/mL) at T0 (red) and after three months of treatment with Priapogen® (blue). Data are expressed as mean ± standard deviation.

Discussion

Clinical management of patients with reduced male fertility remains a significant challenge in reproductive medicine, particularly due to the multifactorial nature of its etiology, which ranges from poor lifestyle choices (such as smoking and alcohol consumption) to structural, metabolic, and endocrine pathologies. While semen analysis represents the diagnostic cornerstone of couples' infertility evaluation, effective therapeutic interventions capable of safely and robustly upgrading seminal parameters are still a subject of intense debate, with existing literature often offering conflicting or contradictory results. In this clinical scenario, the findings of the present study demonstrate that a three-month oral administration of the innovative nutraceutical Priapogen® leads to a significant and clinically meaningful improvement in all key seminal parameters within a cohort of 130 patients with reduced fertility. A principal finding of our investigation is the remarkable increase in sperm concentration (+31%) and total spermatozoa count (+51%) after three months of treatment. This specific temporal framework perfectly aligns with the human spermatogenetic cycle, which requires approximately 74 days for full development.

This synchronization suggests that the bioactive components of Priapogen® exert a protective and supportive effect directly during the critical physiological phases of sperm proliferation and differentiation. The molecular rationale behind these results can be traced back to the targeted, synergistic action of its ingredients. Priapogen® uniquely combines high-dosage antioxidants specifically N-acetylcysteine (NAC) and Coenzyme Q10 (CoQ10) with the patented F.A.G.® (Fatty Acids Group) molecular complex. It is well-established that oxidative stress, arising from an imbalance between excessive ROS generation and available local antioxidant defenses, acts as a primary pathological driver of idiopathic male infertility. Antioxidants like CoQ10 constitute an indispensable component of the mitochondrial electron transport chain within the sperm midpiece, directly bolstering cellular bioenergetics and ATP synthesis. Concurrently, NAC acts as a direct ROS scavenger and a fundamental intracellular precursor for glutathione synthesis, thereby safeguarding fragile developing spermatids from oxidative membrane and DNA injury. In addition to quantitative metrics, qualitative parameters showed crucial clinical enhancements. Progressive motility expanded by 27%, crossing a threshold that is vital for cervical mucus penetration and regular oocyte fertilization. This action is given by the integration of CoQ10, which directly optimizes the mitochondrial energy of sperm, increasing motility. Furthermore, the stabilization of membrane integrity is supported by the F.A.G.® molecular complex which, thanks to the specific quantitative mixture of fatty acids, biomodulates sperm inflammation. Another key parameter is morphology, which increases by as much as 26 % after three months of treatment.

This parameter measures the shape of the sperm by analysing the head, midpiece and tail; according to the World Health Organisation (WHO) and the Kruger criteria, the threshold for normality is 4%. Another highly relevant outcome of this study is the corrective effect of Priapogen® on seminal inflammation. At baseline (T0), the cohort exhibited a mean leukocyte concentration indicating leukocytospermia (about 1 million/mL). Seminal leukocytes are recognized as a massive source of pathological ROS production in semen, often linked to silent, subclinical urogenital track inflammation. Following three months of treatment, leukocyte counts significantly dropped below the WHO threshold. This anti-inflammatory resolution is robustly mediated by the F.A.G.® complex, which is explicitly engineered to modulate inflammatory pathways and reduce leukocyte recruitment. By down-regulating local inflammatory states and subsequent leukocyte-driven oxidative stress, Priapogen® establishes a significantly more favorable microenvironment for sperm survival, structural preservation, and functional longevity.

Conclusion

In conclusion, the oral administration of Priapogen® for three months has a beneficial effect on all sperm parameters and on the various causes of reduced fertility, successfully alleviating both oxidative stress and seminal inflammation, Its innovative formulation, combining powerful anti-inflammatory the patented molecular complex F.A.G.® with high dose established antioxidants, achieved significant improvements in sperm concentration, total spermatozoa count, progressive motility, morphology and seminal leukocyte levels.

These findings support the clinical role of Priapogen® as a valuable, noninvasive first-line oral therapy to support and improve sperm quality in men with reduced sperm concentration and motility.

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