

# **EIS Clinical Pre-Study of Stress-Related Erectile Dysfunction**

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## **Site of Investigation**

St. Louis Hospital  
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## **Final Report**

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## **Summary**

A test group of 37 male patients with erectile dysfunction (ED) undergoing consultation in the Andrology Department at St. Louis Hospital (Paris) were measured by a device called the Electro Interstitial Scanner (EIS) System.

All the patients presented neurovegetative dystonia with high stress levels and an increased level of catecholamine. None of the patients was undergoing treatment and no pathology was present.

The objective was to test the specificity and sensitivity of the ElectroScanGram (ESG), a graph generated by the EIS System, in reference to a patient database with stress-related ED and a control group of 30 subjects without evidence of stress.

## **Hypotheses**

The study was based on the following hypotheses:

1. The ESG graph can be used as a marker of stress and neurovegetative dystonia.

This hypothesis was validated by the statistical results:

A statistical study of the database (Mean Plot: Whisker using STATISTICA version 6.0) indicated that four values (2, 4, 15, and 17) of the ESG graph showed a sensitivity of 84% (IC calculated to 95%) in the stressed ED group, compared to the control group, with a specificity of 87% (IC calculated to 95%).

2. The number of patients for this study is sufficient for a statistical analysis in order to calculate a level of specificity for the ESG graph.

This hypothesis was validated for the calculation of the specificity. However, for more accuracy regarding sensitivity, a meta analysis is necessary.

**Justification**

Since the introduction of sildenafil citrate (Viagra®), increased reporting of erectile dysfunction has occurred, opening the way for more conversation on this controversial issue and most likely leading to increased prescribing of sildenafil. However, the origin of this problem is multifaceted, and treatment with sildenafil includes cardiovascular contraindications.

The EIS System was placed in the Andrology Department of St. Louis Hospital to begin a clinical investigation on erectile dysfunction (ED) related to significant stress. It is important to note that the patients were not diagnosed with any other pathology and were not undergoing treatment.

**The EIS System**

The principle of the EIS System is the measurement of the conductivity of interstitial fluid locally and in vivo using the technique of bioelectric impedance. The EIS System uses DC current for access to interstitial fluid data. <sup>(16)</sup>

This measurement uses six tactile electrodes:

- Two on the forehead
- One on each hand
- One on each foot

From these six electrodes, 22 tissue volumes are measured and are recorded on a graph. The graphic display of the conductivity values of these 22 volumes is the ElectroScanGram (ESG).

**Tested hypotheses**

The questions raised for investigation were:

1. Would the EIS System offer the possibility of providing a marker for patients with stress or neurovegetative dystonia?
2. Would the number of patients in this study be sufficient for a statistical analysis in order to calculate specificity and sensitivity compared to a reference graph?

**STUDY CONDITIONS****Site of investigation**

The recordings took place in the Andrology Department at St Louis Hospital from January 7, 2005, to April 20, 2005.

**Subjects excluded**

Excluded from testing were patients who:

- Had skin lesions in contact with the electrodes or excessive perspiration
- Had been fitted with pacemakers
- Were unable to be seated
- Had been fitted with metal pins or prostheses in the lower limbs or joints
- Were missing one or more limbs
- Were undergoing specific treatments or taking certain medications (e.g., hypertensives, anticoagulants, etc.)
- Had a pathology that would have an influence on an erection

**Patients recruited**

Two groups of patients were established:

- **Group 1:** A control group of 40 men in supposed good health. This group was recruited from hospital employees and their families. These subjects had no pathology, no ED disorders, and were not taking medications.
- **Group 2:** All the patients in this group displayed chronic ED and evidence of stress. Like the control group subjects, these patients had no diagnosed pathology and were undergoing no treatment.

The patients at St. Louis Hospital were addressed either by their practitioner or by direct consultation in the Andrology Department.

**Number of patients**

Forty male patients were selected in Group 1. They ranged in age from 23 years to 59 years. Thirty-seven male patients were selected to participate in Group 2 of this study. They ranged in age from 17 years to 60 years.

**Enlightened consent**

After the safety aspects and benefits of the study were presented to the patients, they signed an enlightened consent form.

**Monitoring**

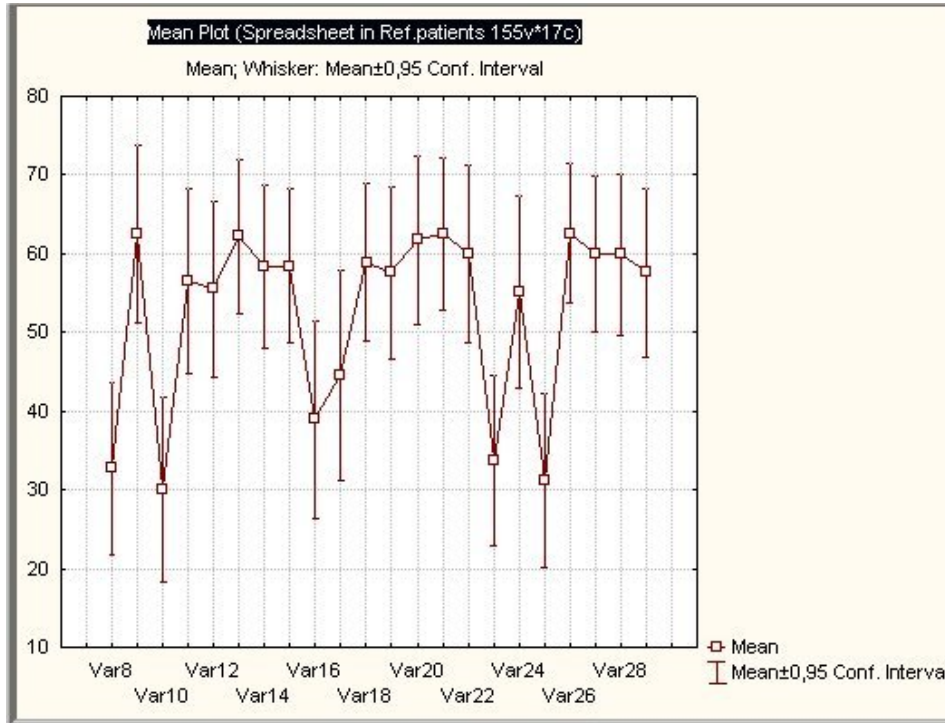
Measurements were taken by the sponsor of the study, Mr. Albert Maarek.

**Confidentiality**

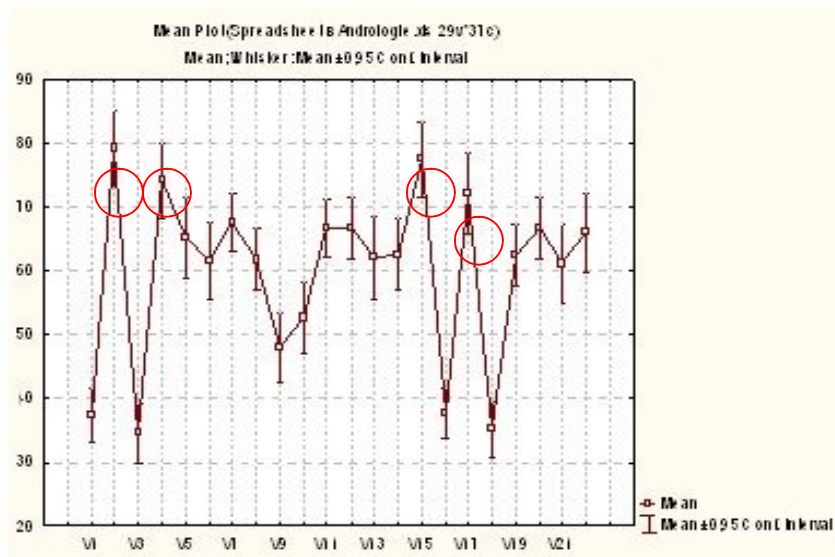
Due to patient confidentiality, identities of all the patients were kept anonymous and each patient was numbered by date of examination. Only clinical data were mentioned for each patient.

**RESULTS**

See below the statistical result analysis of the ESG graph carried out with the method Mean Plot: Whisker (program STATISTICA, version 6.0.) These graphs represent the average of the ESG graph of the two groups of patients.



**Group 1: Control group**



**Group 2: ED patients (Summary plot)**

The results of the graph group with stress and ED and the ESG graph of the control group determine a sensitivity of 84% (IC calculated to 95%) and a specificity of 87% (IC calculated to 95%). This sensitivity and specificity are related to the high values of the volumes 2, 4, 15 and 17 of the ESG graph.

## CONCLUSIONS

This study shows, with very high specificity, that the marker of stress, neurovegetative dystonia, and undoubtedly an important catecholamine rate should be the volumes 2, 4, 15 and 17 of the ESG graph. Hypothesis 1 is validated.

The number of patients (37) appears to be sufficient to determine the levels of specificity and sensitivity. Hypothesis 2 is also validated.

However, a future meta analysis with the recording of more pathologies will determine with more precision the sensitivity of obtained results.

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