Pelvic Floor Disorders

Project Title:

Pelvic Floor Pain and Surface Electromyography (SEMG)

Primary Investigators:

Howard I. Glazer, Ph.D.
Clinical Associate Professor
Psychiatry and Obstetrics and Gynecology
Cornell University Medical College
Address: 2166 Broadway #6D, New York, N.Y. 10024
Tel: (212) 832-0477
Fax: (212) 371-6102
Email: DrGlazer@att.net

Project Summary:

The proposed research project is a multi-national effort, designed to develop a pelvic floor muscle surface electromyographic database to be used in the differential diagnosis of essential vulvar disorders. Previous research using SEMG biofeedback have documented encouraging results.

Previous Research:

For previous research, please visit www.vulvodynia.com.

Primary Investigators and Co-investigators:

The primary investigator worldwide is Dr. Howard Glazer, at Cornell University in the United States. He is supported by a network of co-investigators and clinician researchers who will supervise and carry out data collection in up to 30 sites worldwide. Other participating countries include Australia, Canada, France, Germany, Israel, the Netherlands, Norway, Sweden, the United Kingdom and the United States. Co-investigators are responsible for securing national funding in each country and for data analysis and preparation for publication of the results of the national data.. Country coordinators are responsible for identifying appropriate data collection sites and supervising data collection to assure adherence to the research protocol. Dr. Glazer will supervise data collection worldwide and will be primarily responsible for data analysis and preparation for publication worldwide.

Data Collection Sites:

Data for this project will be collected in locations in each country. A healthcare professional at each data collection site a will be trained in the research protocol. Initial training will consist of attendance at a two-day workshop focusing on essential vulvovaginal pain disorders and the incorporation of SEMG technology for diagnostic and rehabilitative purposes.

Subjects:	Each data collection site will be asked to find a number of subjects for the research over a 2-3 year period. All subjects will be diagnosed with essential vulvar pain. All will present at least moderate pain based on a specific pain questionnaire and clinical diagnosis.
Procedures:	Subjects who are identified as eligible for (and who consent to) the research will need to undergo an assessment, including an SEMG evaluation prior to beginning their course of treatment. A quality of life tool will also be used to monitor their attitudes regarding pelvic pain and their treatment outcomes.
Budget:	The BFE project manager is responsible for preparing the budget with the co-investigator and country co-coordinator for each country. The application will request funding to reimburse participating facilities (data collection sites) for the following items: 1. Therapist costs 2. Unigel electrodes 3. Vaginal or rectal sensors 4. Photocopying and incidental expenses including telephone calls 5. A single SEMG biofeedback device with accompanying software. The Biofeedback Foundation of Europe is supporting the project through an equipment subsidy/rebate on the deployment of SEMG biofeedback devices with accompanying software and training at approved and qualified data collection sites.
Equipment:	The MyoTrac3 SEMG biofeedback equipment selected for use in this project is manufactured and distributed by a Canadian Company, Thought Technology Ltd., based in Montreal. The company applies and maintains a quality system program that conforms to ISO 9001-1994, EN46001-1996, MDD93/42/EEC, USFDA QSR-1996 and Health Canada Medical Device Regulations at all levels of the company. The MyoTrac3 with customized software will be utilized exclusively to minimize variability due to instrumentation.
Ethics:	Country coordinators/co-investigators will submit ethics applications at appropriate sites prior to initiating the research.