

Short Term Study Data Shows ExMI™ Treatments Successful: Early Long Term Results Reveal Good Durability



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ORLANDO, FL - Our center recently evaluated the safety and efficacy of Extracorporeal Magnetic Innervation, or ExMI™, as a treatment for urinary incontinence in women. As part of enrollment, women underwent a complete history, physical, multi-channel urodynamic evaluation, urethroscopy, cystoscopy, standardized provocative pad test and perineal strength test. A validated quality of life questionnaire and urinary flow volume chart were also obtained. With the exception of urethroscopy and cystoscopy, all tests were repeated after the study for comparison.

Fifty-eight women completed a six-week course of therapy, which consisted of two 20-minute treatment sessions per week. Based on our initial work-up, we determined that the majority of these patients had genuine stress urinary incontinence. In addition, most were post-menopausal, and a large number had cystoceles. About one third had a previous hysterectomy, and half were on hormone replacement therapy.

Following therapy, significant reductions occurred in pad weight, number of pads used daily and documented leakage during Valsalva. In addition, quality of life scores obtained after treatment were markedly improved, increasing from 49 to 70 (based on a scale of 100). At the eight-week follow-up, symptoms of incontinence had improved in 88% of patients. At 12 and 24 weeks, 55% and 51% of patients, respectively, reported they were still satisfied with the results of their treatment. Eighteen-month follow-up calls have been initiated to determine the long-term satisfaction levels of patients who have undergone ExMI treatment, and early results have revealed a continuing high level of patient satisfaction.

Our experience with ExMI therapy to this point has been favorable, and the treatment is in active use on our patients. Since ExMI requires no patient effort and is painless and non-invasive, it offers a viable treatment option for many women suffering from urinary incontinence.

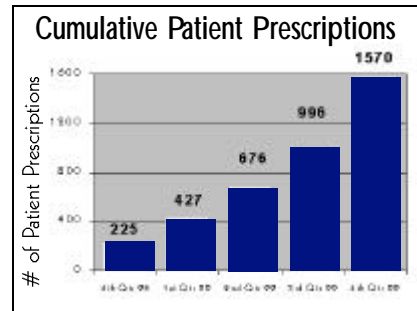
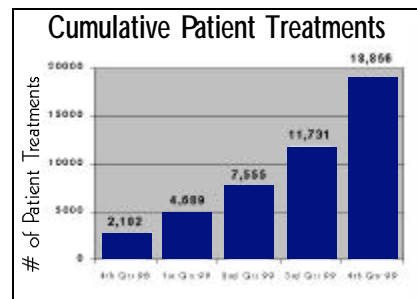
18 New Payors Reimburse ExMI™

Every week new payors are added to the list of those who reimburse for NeoControl® treatments. The list is compiled from Neotonus' billing records and successes reported by physicians' offices. Payors new to the list include:

- American Medical Security
- Atlantic Health Plans - Charlotte
- BC/BS Teachers and State Employees NC
- BC/BS of California
- BC/BS of Oregon
- BC/BS of South Carolina
- CNA Health Partners
- CNA Health Care
- Fieldcrest PCN
- Fortis
- Kirke Van Orsdel, INC.
- MAMSI
- MEDCOST Preferred
- MEDCOST Primenet
- NCAS MEDCOST
- NC State Health Plan
- Ohio Carpenters Health & Welfare Fund
- Private Health Care Systems
- Trigon Key Care/Med South
- Wellpath

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Fourth Quarter Clinical Utilization Increases 70+ % Over Previous Quarter



NeoControl® treatments exceeded 18,800 and prescriptions topped 1,500 through Dec. '99, a 70%+ quarterly increase over the previous quarter, setting a rapid pace for growth in the utilization of ExMI™.

The graphs to the left represent the first five quarters of routine clinical use of ExMI, excluding research study patients.

New ACOG Screening Guidelines Include Urinary Incontinence

"For all women beginning at age 19, the routine screening history taken by physicians should include questions about both urinary and fecal incontinence," according to the recently released "Primary and Preventive Care: Periodic Assessments" by the American College of Obstetricians and Gynecologists (ACOG). The document updates previous ACOG recommendations on the screening, evaluation and counseling women should receive from their OB/GYN based on their age and risk factors.

November 12, 1999

Mr. Michael W. Aertker, M.S.E.
Mr. Ted Hammond, RN

Dear Mike:

I wanted to take this opportunity to sincerely thank you and Ted for the beneficial treatment I received from the magnetic therapy chair. Please let this letter serve as my sincere testimonial as to how well this treatment worked on my chronic pain. As you are aware, I have been seriously suffering for over four years now with extreme pain in my groin area due to complications from my vasectomy surgery. I have seen several physicians, none of whom could explain, nor diagnose the reason for the pain; offered no hope and told me that I would have to live with the pain. I was devastated! However, I refused to accept this and with the help of my loving, supportive wife (as it greatly affected her too), I forged on, always seeking relief from my pain.

“I am more comfortable in my clothes and my mood and sleeping habits have improved significantly. The process was so simple and quick – no fuss.” J.S.

Finally! My prayers were answered. My wife, who works as a nurse at Children's Hospital, learned about the magnetic chair and its treatment from Ted Hammond (entrepreneurial nurse). She also learned of a wonderful Urologist named Dr. Susan McSherry (whom I have adopted as my new doctor for life – she is terrific...takes her time to explain things and genuinely cares for her patients). After seeing Dr. McSherry, I was able to begin the magnetic treatments.

So I embarked on my journey, traveling twice a week from New Orleans to Covington, Louisiana to begin my magnetic chair treatments. After 16 sessions, my pain has significantly diminished (on a scale of 1-10, it has gone from a 9 to a 1), extremely mild and tolerable. Although it has not been completely eradicated, I'm extremely pleased and satisfied with my results. I am more comfortable in my clothes and my mood and sleeping habits have improved significantly. The process was so simple and quick – no fuss.

I highly recommend these treatments for men who may be in the same or similar circumstances and are living with pain; either due to embarrassment or with no hope of an alternative. We need more Urologists like Dr. McSherry, who believe and are not afraid to explore other bold avenues of treatment.

I'm a "new" person, with a happier, healthier look at life!
Best of luck with this new procedure.

Very truly yours,
J.S.

December 7, 1999

Dear Dr. Butler,

I've recently finished my treatments with the NeoControl chair and wanted to share with you my personal feelings regarding this type of therapy. I can honestly say that it is the most painless treatment I have experienced – ever! And aside from being painless, I didn't even need to undress for it – what more could a person ask for.

I truly hope that anyone weighing the options of NeoControl vs. surgery or any other major form of treatment chooses to use the NeoControl chair. Seeing the type of results that it brings makes me wish that it would have been available as a choice before either of the two surgeries that I had to experience – which still left me with unsatisfactory results.

I don't really know what else to say, except to say thank you for bringing this wonderful new technique to your office and to Brenda for taking me through the therapy period. She was so easy to talk with about what I was experiencing; she is a true asset to your office.

I will be continuing to speak with Brenda in the coming months and will be coming in to the office to be evaluated by her to make sure we are staying on track. But, things are so much better than they have been in a long, long time. Simple things in my every day life that have been complicated by my bladder problems – like my one hour drive to work, and various other things – are simple again. It has made such a difference in my life – you can't imagine how incredibly happy that makes me.

“Simple things in my every day life that have been complicated by my bladder problems – like my one hour drive to work, and various other things – are simple again.” W.K.

If you ever have a patient who is not sure about going through this treatment or wants to hear first-hand from someone who has experienced the NeoControl therapy, please feel free to contact me. I would recommend it in a heartbeat. Like I said before, I truly wish that this was an option that I could have had instead of surgery.

Sincerely,
W.K.

Editor's Note: Current FDA labeling for NeoControl® includes stress, urge and mixed urinary incontinence in women.

Neotonus Launches Multi-Center Study To Evaluate ExMI™ for Treatment of Post-Prostatectomy Urinary Incontinence

By Yvonne Greene, M.D., Clinical Manager, Neotonus

In January 2000, Neotonus launched the first study to explore ExMI™ as a non-invasive treatment for urinary incontinence among men who have undergone radical prostatectomy for prostate cancer. More than 330,000 men are diagnosed with prostate cancer each year, many of whom will require prostate surgery, which is the leading cause of male incontinence. Of those who undergo a radical prostatectomy, it is estimated that up to 63 percent will experience a lack of bladder control six months or longer following surgery.

The multi-center, placebo-controlled trial will be led by principal investigator Dr. Ajay Nehra of the Mayo Clinic in Rochester, Minn. Co-investigators will include Dr. Rodney Appell of the Cleveland Clinic in Cleveland, Ohio; Drs. Alan Wein and Eric Rovner of the University of Pennsylvania; Drs. William Ellis and Paul Lange of the University of Washington; Dr. Kurt McCammon of Eastern Virginia Medical School; and Dr. Thomas Keane of Emory University School of Medicine in Atlanta. ExMI treatment will be compared to placebo utilizing outcome measures of dynamic pad weight tests, voiding diaries and quality of life surveys. The cross-over design will allow patients in the placebo arm to have the opportunity for actual treatment.

ExMI™ Scientific Calendar: First Half 2000

The scientific and clinical basis of ExMI™ therapy will be explored in a number of upcoming forums:

January 2000, AUA Meeting of the Minds: Urogynecology, New York.

A Wein, *ExMI for Female Urinary Incontinence*

January 2000, SUNA Multi-specialty Conference, Nashville

J Gammony, *Results of ExMI Research at Morton-Plant*

February 2000, Update in Gynecologic Urology, St. Thomas

PK Sand, *ExMI: North American Experience*

A Bourcier, *ExMI: European Experience*

May 2000, American Urological Association, Atlanta (Submissions)

PK Sand, *Factors Influencing Success of ExMI*

T Bavendam, *Quality of Life Data After ExMI Treatment*

H Bruschini, *ExMI: Brazilian Experience*

Ongoing ExMI™ Research Studies

Geriatric Study. Case Series, Uncontrolled, Assisted Living Facilities. Principal Investigator: Dr. Joseph Ouslander (Atlanta, GA, USA)

ExMI vs. Pelvic Floor Muscle Exercise. Prospective, Randomized, Single-Blinded, Single Site. Principal Investigator: Dr. Peter Gilling (Tauranga, New Zealand)

ExMI For Urinary Incontinence. Randomized, Multi-Center, Placebo-Controlled. Principal Investigators: Dr. L. Cardozo (UK), Dr. C. Smith (UK), Dr. P. Costa (France), Dr. B. Jacquetin (France), Dr. W. Schaefer (Germany), Dr. B. Schuessler (Switzerland), Dr. A. Weil (Switzerland), Dr. E. Cruciani (Italy)

ExMI vs. Tolterodine. Randomized, Cross-Over, Single Site. Principal Investigator: Dr. Alfred Bent (Baltimore, Maryland, USA)

ExMI For Chronic Pelvic Pain (Male). Prospective, Double-Blinded, Randomized, Controlled. Principal Investigators: Dr. Carolyn Smith (London, United Kingdom)

ExMI For Treatment Of Urinary Incontinence (Phase IV). Open Label Design, Evaluation of Durability of Treatment and Dose Requirements. Principal Investigator: Dr. Stephen Carlan (Orlando, Florida, USA)

ExMI In The Treatment Of Post-Prostatectomy Incontinence. Multi-Center, Single-Blinded, Placebo-Controlled. Principal Investigators: Dr. Ajay Nehra (Rochester, MN, USA); Dr. R. Appell (Cleveland, OH, USA); Dr. W. Ellis and Dr. P. Lange (Seattle, WA, USA); Dr. K. McCammon (Norfolk, VA, USA); Dr. A. Wein and Dr. E. Rovner (Philadelphia, PA, USA); Dr. T. Keane (Atlanta, GA, USA)

ExMI™ Success Factors Data Well Received at IBS

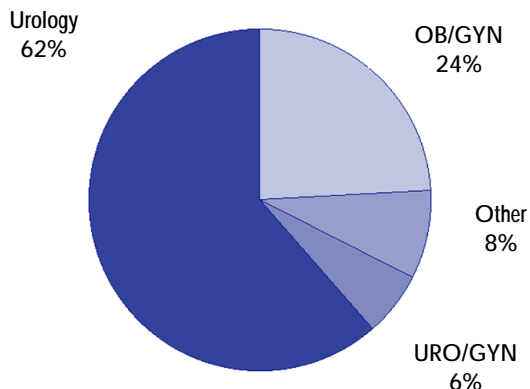
Washington, DC – Dr. Peter K. Sand from Evanston Continence Center in Illinois was asked to submit a manuscript to be published in the Proceedings of the recent International Bladder Symposium (IBS), held in Washington, DC in November. The text will further elaborate factors influencing success as analyzed from six-month follow-up data from a multi-center clinical trial of ExMI™. The abstract was presented to attendees of the IBS during an oral poster presentation, and reprints are available from Neotonus upon request.

NAFC Board Meeting Spotlights ExMI™ Data

Atlanta, GA – Dr. Niall Galloway from Emory University School of Medicine in Atlanta presented six-month data from a multi-center clinical trial of ExMI™ at the National Association for Continence (NAFC) Annual Board Meeting in October. Dr. Galloway presented the latest clinical results, factors influencing success with ExMI and quality of life information. Attendees at the meeting included physicians, clinicians and industry leaders committed to improving the lives of those with bladder control problems.

1999 ExMI™ Treatment Utilization Profile by Practice Type

1999 ExMI Treatments by Practice Type

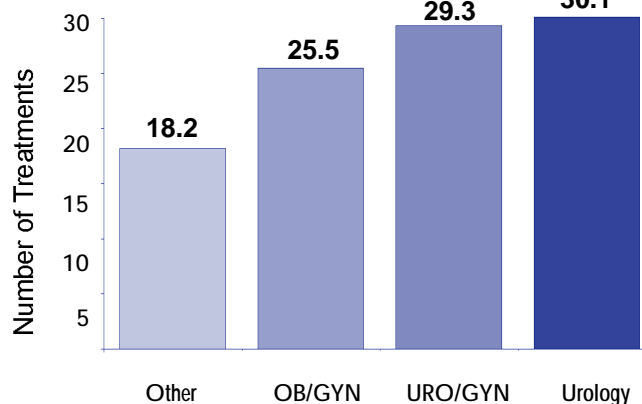


The majority of ExMI™ treatments in 1999 were administered by Urologists (62%), while OB/GYN offices performed 24% of treatments. Urogynecologists accounted for 6% of treatments, and Other (therapy centers, clinics) comprised 8%.

When evaluating the average number of monthly treatments in 1999 according to practice type, Urologists and Urogynecologists performed roughly the same number of treatments per month at 30.1 and 29.3, respectively. OB/GYNs followed closely at 25.5 treatments per month, while Other settings administered an average of 18.2 treatments per month. Although currently performing a relatively smaller number of total treatments, Urogynecologists are performing nearly as many treatments per month as Urologists, and this trend is expected to continue.

**Based on compiled data from more than 15,000 treatments during 1999; data on file at Neotonus, Inc.*

1999 Average Monthly ExMI Treatments by Practice Type



Neotonus Co-Sponsors NAFC Patient Support Groups

Research from the National Association for Continence (NAFC) has shown that people with bladder control problems consider social isolation to be one of their top concerns. In recognition of this concern, Neotonus has agreed to co-sponsor the NAFC Take Control Support Group Program, which provides tools for health care providers and consumers who want to initiate incontinence support groups in their area. Neotonus has provided an unrestricted grant to NAFC to help fund the program, which includes starter kits consisting of a year's worth of meeting materials for 20 participants. Information on NeoControl® is included in the program of the third meeting of a twelve meeting series.

ExMI™ Presentations Made Easy

Have you been asked to make a presentation to your colleagues, patients or community about NeoControl® Pelvic Floor Therapy? Could you use a simple explanation of how the technology works, the scientific principles upon which it is based and its clinical applications?

If the answer to any of these questions is "yes", then Neotonus has prepared an easy to use presentation with a sample script. You may call your Customer Service representative and request either 35mm slides for a traditional presentation, or a PowerPoint version of the slides on CD-ROM. The digital version operates on PC-based systems and requires the operator to have MS PowerPoint 97 or above.

Editor's Note: INSIGHTS IN INNERVATION (ISSN 1523-8180) is produced bimonthly as a service to NeoControl users. If you have additions, corrections or would like to contribute to a future issue, please contact Kathleen Bowley at kbowley@neotonus.com, (770) 428-7356 or (800) 895-4298. For more information, visit our website: www.neocontrol.com.

Payors Reimburse ExMI (Continued from Page 1)

Previously reported payors who have reimbursed for ExMI are:

- Aetna Managed Choice
- Anthem (Southcare)
- BC/BS of Albany, NY
- BC/BS of GA
- BC/BS of Illinois
- Central State SW/SE (Health and Welfare Fund)
- Cigna
- Cigna HMO of Atlanta
- Coresource
- Employer's Mutual (Orange Co. Public Schools)
- First Health
- First Integrated Health
- GEHA (Southcare)
- General American
- The Guardian
- Health Net
- Humana
- Jefferson Pilot
- Mailhandlers
- Medical Mutual of Ohio
- NY Lifecare
- Principal Financial (Southcare)
- Promina
- Prucare
- Prudential
- UHC of GA
- Unicare
- Wausau