

INCONTINENCE

Barbara Woolner, RN, Fellow, BCIA-C, CCCN

Describe incontinence in its various forms and biofeedback's role in helping to strengthen the muscle groups involved.

My own definitions of the various types of incontinence are derived from the available literature and follow the Clinical Practice Guideline on Urinary Incontinence in Adults: Acute and Chronic Management. "Urinary Incontinence can be caused by anatomic, physiologic and pathologic (genitourinary) factors affecting the urinary tract, as well as external (non-genitourinary) factors." Urge incontinence, frequently called overactive bladder, is the involuntary loss of urine associated with a strong desire to void (urgency). Stress Incontinence presents clinically as the involuntary loss of urine during coughing, sneezing, laughing or other increases in intra-abdominal pressure. Patients with mixed incontinence exhibit symptoms of both stress and urge incontinence. One symptom (urge or stress) is usually more bothersome to the patient than the other.

Biofeedback plays a major role in helping patients acquire more functional pelvic muscles whether it is through strengthening, reducing excessive muscle activity or using the muscles appropriately. To patients who have little or no sense of the pelvic floor, biofeedback may be the only way to first identify the correct muscle for exercising. For those with weak muscles the information provided by the biofeedback acts as an external proprioceptive aid until the muscles begin to gain strength and generate more internal sensation. An often-overlooked problem is lack of coordination with other muscle groups and/or inappropriate pelvic muscle use during elimination. Biofeedback is, in my opinion, the best and sometimes the only way to reverse the problem. I agree with a recent publication from The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), "Biofeedback takes the guesswork out of pelvic muscle training."

In the evolving field of healthcare, biofeedback, as a treatment and evaluation tool, is playing an increasingly important role. Biofeedback is used by a diversity of health professionals to treat an ever-lengthening list of conditions. Health professionals such as psychiatrists, psychologists, nurses, physiatrists, physical and occupational therapists and physicians in various specialties have come to use biofeedback either independently or as an adjunctive technique with positive results.

The Expert Series is an on-going series of interviews with leading clinicians in the field of biofeedback lending the insights and techniques they have acquired through many years of practice.

Thought Technology is very pleased to be part of this educational project. For over 25 years, Thought Technology has been committed to making biofeedback more accessible through innovation in technology and educational initiatives.

The Expert Series interviewed Barbara Woolner, RN, Fellow, BCIA-C, CCCN

Barbara Woolner is certified in both continence care and biofeedback and specializes in the behavioral treatment of urinary incontinence and related pelvic muscle disorders. Since 1988, she has provided continence care in a variety of settings including urology, urogynecology, colon-rectal surgery and geriatrics. As Chairperson for the SUNA/WOCN Continence Coalition, her testimony during HCFA's Medicare Advisory Panel Hearings on Biofeedback was instrumental in achieving a positive national reimbursement policy for biofeedback to treat urinary incontinence.



"sEMG can help identify inappropriate muscle substitution patterns and thus refine therapeutic exercise prescription."

Barbara Woolner
RN, Fellow, BCIA-C, CCCN

Tell me about yourself and your involvement with SUNA, the HCFA ruling and other organizations.

I've been a member of SUNA, the Society of Urologic Nurses and Associates, for almost as long as I've provided continence care. In 1991, SUNA, along with the Wound, Ostomy and Continence Nurses (WOCN) and a couple of other professional organizations, sponsored the first Multi-Specialty Nursing Conference on Continence. I've presented my work with biofeedback and urinary incontinence (UI) at each of these bi-annual conferences, since. The interest in continence care has increased to the degree that the conference is now held annually. WOCN now certifies nurses in continence care and has held two conferences specific to the topic in the last 3-4 years.

In 1997 a continence nurse specialist from California, Marta Krissovich, came up with the idea of forming a coalition of professional organizations to help improve the quality of care in patients with UI. The SUNA/WOCN Continence Coalition (CC) was created and I was approached to serve in an advisory capacity. One of the first items on the Coalition agenda was to seek consistent reimbursement for biofeedback to treat UI and to reinstate coverage for pelvic floor electrical stimulation. Biofeedback coverage had heretofore been handled according to regional carrier discretion. Clinicians were paid to perform the service in some states, and not in others. The inconsistency in reimbursement was not only frustrating but very unfair since it denied standard of care to patients in some geographic areas. Pelvic floor stimulation had been a non-covered item since 1994. The Coalition developed a Position Statement on Reimbursement for Biofeedback that was circulated to various professional organizations dealing with incontinence. This single effort generated support of that Position Statement by several organizations. Others developed their own statements in support of biofeedback.

We use biofeedback in combination with drug therapy for many individuals with urge incontinence (overactive bladder) with the goal of discontinuing the medication when the behavioral treatment begins to take effect.

The Continence Coalition was a catalyst for what became an intense and organized effort to achieve equity in patient care.

By 1998, the Health Care Financing Administration (HCFA) had been approached by Coalition leaders and a dialogue between the CC and HCFA representatives

was ongoing. HCFA is the arm of government responsible for coverage policy decisions for Medicare beneficiaries. Responding to new congressional guidelines, HCFA was bound to creating a more public forum for their policy and decision-making processes. Biofeedback and pelvic floor electrical stimulation (PFS) became the first two medical technologies to undergo this public process. As part of the dialogue the CC was asked to prepare utilization parameters for biofeedback and PFS for review by HCFA. Coalition Chair, Diane Smith, approached me to reference and edit a draft of this document. The one-day commitment I expected evolved into my eventual chairing of the CC when Diane became a part of the HCFA Medicare Coverage Advisory Committee. Eighteen months of effort culminated in HCFA's announcement of a positive national coverage decision for biofeedback to treat UI. More than a dozen other professional organizations, their leaders, spokespersons, and members participated in a sustained and united assault until the sought-for outcome was announced.

Tell us about your work with biofeedback in the treatment of incontinence.

I was a nurse anesthetist for 23 years; retired in 1986 and after a couple of years of exploring less stressful and leisurely areas of interest I pursued certification in biofeedback. I was exposed to biofeedback in the '70s through a continuing education course and had been captured by its power to help individuals make changes in their physiology. I had read the literature, especially Kathryn Burgio's work, and looked around to find no one in my geographic area performing the service. With the help of a couple of inter-

ested parties I began to treat incontinent patients with biofeedback and have never veered from the path. I was fortunate in working with some very supportive individuals from the beginning and gained early experience with a widely diverse patient population. Though the largest part of my work has always been with women in peri-menopause and menopause, I had the honor of working with frail elders for over a period of 6 years. Since there was such a paucity of information being generated in the early 90's about biofeedback for incontinence in that age group I had the opportunity to present my work at some very prestigious meetings including the International Continence Society, American Geriatric Society and a National Institute of Health (NIH) sponsored conference on UI in the frail elderly. Though I am often associated with only my biofeedback work with geriatric patients, I presented a paper on Biofeedback for Severe Lower Urinary Tract Dysfunction at the International Continence Society as early as 1993. This paper was based on case studies of much younger women.

For the past 5 years I have worked almost exclusively with a uro-gynecologist and that has been a very comfortable fit in terms of being able to provide services on several different fronts. We use biofeedback in combination with drug therapy for many individuals with urge incontinence (overactive bladder) with the goal of discontinuing the medication when the behavioral treatment begins to take effect. Biofeedback is especially effective with those patients. Teaching these patients to inhibit urgency and abort incontinent episodes by using their pelvic muscles is as exciting to me, now, as it was over 10 years ago when I first realized how effective the technique could be! Approximately 25% of patients with stress urinary incontinence that we see in the practice require surgery for anatomical correction of their problem. For those patients, biofeedback is recommended pre-operatively to begin pelvic muscle rehabilitation (PMR) that will continue after the surgical correction. Anyone having even a little experience in this

field recognizes the fact that many individuals have dual incontinence though initially they may not disclose the fecal incontinence. I get referrals from gastroenterologists and colon-rectal surgeons for fecal incontinence and I've had some exciting results working with patients referred for fecal incontinence after gracilis muscle transposition operations. This is very advanced PMR that would have been impossible without biofeedback. I also treat pediatric patients with voiding dysfunctions and, though not currently working with male patients, I've had quite good success with post-prostatectomy patients in the past.

Describe your input into the creation of TTL's sensors and software.

The idea for the Thought Technology Ltd. (TTL) sensors evolved from my search for a more comfortable sensor. One of the biggest difficulties I encountered in my first few years of pelvic floor biofeedback was in creating patient comfort during evaluation and treatment. The sensors available at the time were uncomfortable and limited patient positions to a reclining or supine position. Since most incontinent individuals experience leaking more often while standing or in a sit-to-stand situation I have long favored training in an upright, seated position. It's been my experience that biofeedback is reinforced when the patients' proprioception of his/her pelvic floor is enhanced by being in a seated position. I'd played around with designs in my head and, when the opportunity arose, I discussed the need and the rough idea with Dr. Hal Myers. I sketched my design idea and he and his design and engineering team went to work. Several months later, we had a prototype very close to my original concept. The vaginal sensor was tested with more than 400 women and the rectal sensor with about 100 men. The clinical tests proved what we had hoped for, the sensors were quite comfortable and readily accepted by patients, allowing me to treat them in a more functional manner than had ever been possible before.

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The unique design of the sensor allows the patient to sit comfortably, with sensor in place, and to get up and down from a seated position. When correctly positioned, the labia closes around the "T" portion of the sensor, holding it in place in a standing position. I frequently use the rectal sensor in older or virginal women who have smaller vaginal openings. In several thousand patient visits for UI or fecal incontinence I can count on one hand the patients who have been unable to use the sensor.

TTL's Myotrac 3 and 3G EMG devices have software components designed specifically for pelvic floor evaluation and re-education. After my collaboration with TTL in the sensor design, I acted as a consultant in the development of hardware and software for a dedicated continence instrument. At the time, most biofeedback manufacturers were simply using their existing EMG software for pelvic floor biofeedback, an often unsatisfactory practice due to certain engineering specifications of the instrument. According to Basmajian's work, the weak and damaged pelvic floor muscles often produce signal frequencies falling into ranges below 80 Hz. Many instruments failed to take this into consideration, resulting in the failure to detect the weak signal from a pelvic muscle contraction. One of my recommendations was to design the instrument with a bandwidth that would encompass those lower frequencies. This particular part of the instrument design makes it particularly sensitive to very weak muscle activity. The software used in several instruments on the market at the time, averaged the amplitude of "work" and "rest" periods. I suggested work/rest periods be measured separately, to provide the clinician with a more realistic measure of change. The software of TTL's continence instruments is particularly friendly to novice clinicians. Guidance is available each step of the way for beginning practitioners in the form of text, describing upcoming sections of the protocols. In order to make these instruments suitable for both novice and

experienced clinicians, three separate protocols were included in the software to provide the broadest range of use. One was designed to allow clinicians the greatest flexibility in creating a variety of situations for pelvic floor evaluation, including fast and slow fiber recruitment and release during work and rest. Accessory muscle to target muscle ratio information is available as well as standard deviation measures for stability of the signal. The second protocol allows the clinician to specify patient-specific work/rest criteria along with individualized threshold levels. The last one is an open display of either one or both EMG signals, permitting the clinician to work very specifically in any number of areas that don't require saving of data. The EMG signals can be viewed in a number of ways, providing feedback that is easy for the patient to understand. The reporting part of the software was designed to include information commonly found in SOAP (Subjective, Objective, Action, Plan) notes that are standard for most medical treatment encounters. The SOAP notes are arranged so the clinician has only to fill in the blanks for the most pertinent continence data, saving time and creating a standard way of reporting. Not only did I enjoy playing a part in creating the system, I've thoroughly enjoyed using it.

What are the key features to consider when using biofeedback for continence?

If I were in the market for a biofeedback system for pelvic muscle work, the primary feature I would demand would be a bandwidth that encompasses the low frequencies necessary to detect weak pelvic muscle activity. This means a minimum bandwidth of 35 – 350 HZ. Secondly I would look for a system that allows me to make changes appropriate to specific patient needs such as "on the fly" setting of thresholds, changes to scale and type of feedback. Further, I would look for an instrument developed by a manufacturer with experience in EMG and an understanding and appreciation for the needs of the clinical community.

Is a pressure sensor necessary?

Pressure feedback for pelvic floor was a creation of Dr. Arnold Kegel. We're appreciative of his work, but more than 50 years of technology have created systems far more sophisticated. Pressure is used extensively in the colon-rectal and Gastroenterology fields for anal-rectal manometry. As I see it, the major drawback to the use of pressure in pelvic muscle work is the lack of baseline information that provides a plethora of information useful to the clinician. I've had scores of patients that would not have benefited from biofeedback without the information I've been provided by EMG about the state of the pelvic muscles at rest. For this reason alone, I don't find pressure useful.

Is electrical stimulation necessary?

Not in my practice. Although I've had the ability to use electrical stimulation for at least the past 9 years, I have seldom found a reason to do so. With an instrument sensitive enough to detect low frequency EMG signals, I rarely find a patient who cannot be trained with EMG alone. I believe the prevalence of electrical stimulation used by some clinicians arises from the inadequacies of their biofeedback instrument to detect low frequency signals. When an EMG signal shows no response, they inappropriately determine the patient is at fault and rely on electrical stimulation to help the patient identify the pelvic muscles. If the engineering of the instrument is adequate, this approach is probably not necessary. Again, this goes back to the bandwidth designed into the instrument.

What μV range should one be looking at that would be considered normal?

Well, I've had patients who've become completely dry with EMG μV amplitudes as low as 1 μV above baseline and others who've been far less successful with readings as high as 30 μV over baseline. So, I don't think we can

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look at numbers as our guideline, rather the change that occurs with the biofeedback PMR. Remember, muscle function is dependent on many things and the capacity for change is quite different among individuals. Some patients with relatively good muscle function need the help biofeedback can provide to teach them better coordination and to use the muscles more effectively and at the appropriate time. Others need the motivation it provides in seeing the changes they can make on the computer screen before they are actually benefiting from symptom reduction.

What is the success rate with biofeedback for incontinence? We heard that you had an 80% success rate with people over 80. How does it work for different age groups?

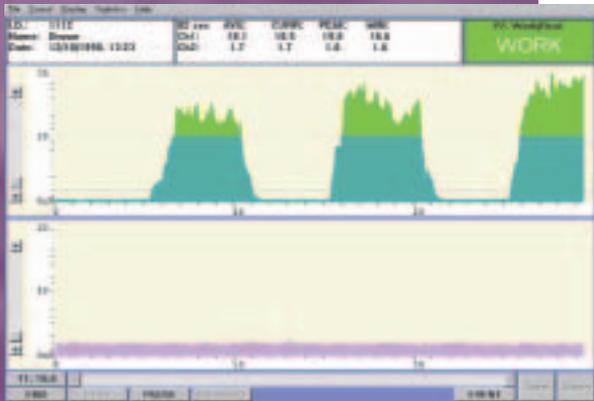
The literature reports a broad range of success, up to 85%. One has to look at the techniques being used and the experience and training of the clinician to more clearly evaluate the data. My success rate of symptom reduction in frail elderly women, average age 87 years, was 62% as reported in 1994 at "Managing Incontinence in Elderly Dependent Institutionalized and Community Dwelling Persons: An Agenda for Research and Care" sponsored by UCLA/Jewish Homes for the Aged, Center for Gerontological Research and supported by the National Institutes for Health. Urologist Dr. Pat O'Donnell reported an identical success rate, 62%, in elderly male patients at the same conference. In my uro-gynecologic practice my success rate is 87% in symptom reduction. I actually had my data analyzed by an independent statistical consulting firm in January of 2000 and was pleased that the results they reported confirmed by own crude analysis. I reported this data at the 5th Multi-Specialty Conference on Continence. The success rate in elderly patients is, as one might imagine, somewhat less than for a younger, healthier population. I'm not familiar with reported data in pediatric work but I've had excellent results in 8-10

year old patients with dysfunctional voiding related incontinence.

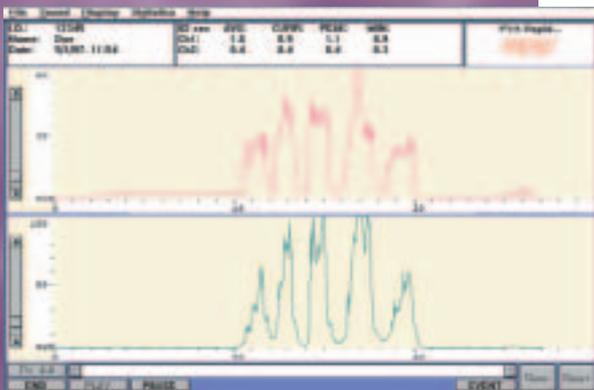
We know you have been teaching for the Biofeedback Foundation of Europe (BFE). Can you give us some insight into what one would expect at a biofeedback training course for incontinence?

Over the years, my teaching has evolved in such a way that I present concepts I feel are needed to effectively use biofeedback in PMR. I don't present a cookbook-approach, rather the course is structured to provide basic information on the types of incontinence and other disorders as they relate to the pelvic floor. Attendees are given a foundation of information about basic anatomy and physiology of the lower urinary tract and pelvic musculature, what's normal and what's not, i.e. types and causes of incontinence. I then present basic principles of biofeedback specifically needed for PMR work and an introduction to EMG instrumentation that defines what is important in instrument selection. This background information, followed by a good dose of behavioral techniques, mandatory to working with incontinent individuals, all leads up to the very practical approach to EMG evaluation and training of the pelvic muscles. I always recruit a volunteer from the attendees to act as a patient, while I demonstrate my technique in pelvic muscle evaluation. After, the demonstration attendees are familiarized with the biofeedback instrument and guided through conducting evaluations on each other. Most participants actively engage in this portion of the workshop that I believe to be critical to their learning process. Once all have had the opportunity to work with equipment, I discuss the EMG characteristics of pelvic muscle dysfunction and segue into the principles of pelvic muscle training to tie everything together. More hands on with equipment is interspersed, as required by the needs of the particular group. I make every effort to make the workshops practical and to customize the workshops to the needs of the individual attendees and their particular working environments.

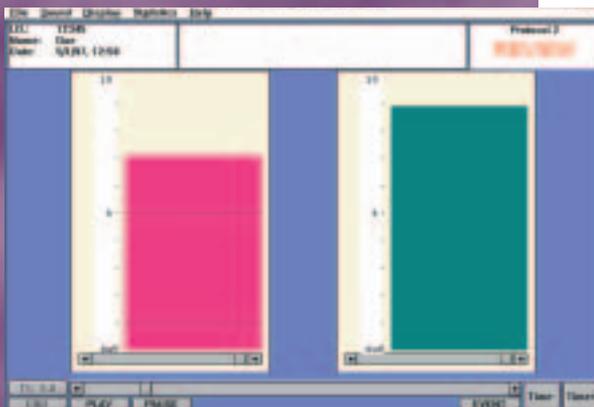
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Quick flicks assess speed of onset and release to view both pelvic floor function and accessory muscles for co-contractions.



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With Thought Technology's line of Incontinence equipment, you can pick up activity at 0.1 microvolts, providing the vital information you need.

Our devices and sensors were designed by highly skilled engineers as well as clinicians working and teaching in the field.

Our vaginal and rectal sensors are designed to ensure accuracy. The T-bar and longitudinal sensor plates for same direction placement ensure consistency in the patients' use of the sensor, so that they are measuring the same muscles each time.

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Our Continence software lets you extend your ability to assess and train pelvic floor muscles with custom protocol configurations:

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MyoTrac 3™



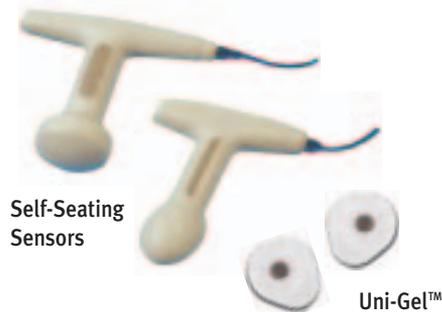
A highly sensitive, dual-channel, sEMG feedback device, the MyoTrac 3 allows you to monitor two muscle sites simultaneously. Customized patient care is easy with our exclusive continence software. You have the flexibility to tailor applications for your diverse patient population. Its sleek design connects easily with your laptop or desktop PC, turning it into a continence clinic.

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An easy-to-use, single-channel, sEMG training device, the battery-operated U-Control allows your patients to practice pelvic-floor contraction exercises in the comfort of their own homes. Daily practice with sEMG feedback enhances a patient's recovery time and your ability to help them. With both visual & audio feedback and easy to set thresholds the U-Control is the perfect portable pelvic floor trainer.

Sensors



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Self-Seating Sensors

For single patient use with either the U-Control or MyoTrac 3, our uniquely designed sensors are remarkably comfortable, durable, and reusable. The T-bar design and longitudinal sensor plates ensures better placement, and superior long term results. Recommended by leading clinicians in the field.

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