Research Report

# Management of Stress Urinary Incontinence With Surface Electromyography–Assisted Biofeedback in Women of Reproductive Age

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## Background and Purpose

Although surgery has been widely accepted as the treatment of choice for stress urinary incontinence (SUI), there has recently been an increased interest in the conservative management of this condition. The aims of this study were to test the ability of a biofeedback-assisted pelvic-floor muscle exercise (PFME) program to affect symptoms of SUI in premenopausal women and to evaluate a training program that might lead to successful outcomes in a relatively limited number of sessions.

## Subjects

Twenty-six women with SUI were treated with PFME with surface electromyography (sEMG)–assisted biofeedback. All participants were of reproductive age and were treated individually for 12 sessions.

## Methods

Results were evaluated with a 7-day voiding diary, a 1-hour pad test, pelvic-floor muscle strength measurements, sEMG amplitudes, a leakage index, and a quality-of-life questionnaire. These variables were compared before and after the intervention.

## Results

The frequency of urine loss, the occurrence of nocturia, and the number of pads required decreased significantly after the intervention. Objective cure was found in 61.5% of women. There was a significant improvement in the quality of life, in pelvic-floor muscle strength, and in the sEMG amplitudes of all contractions throughout the intervention.

## Discussion and Conclusion

A relatively short-term intervention of PFME with sEMG-assisted biofeedback appeared to be helpful in relieving symptoms of SUI in premenopausal women and represents a reasonable conservative management option.

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Stress urinary incontinence (SUI) is responsible for approximately 50% of the symptoms of urinary incontinence in women between 25 and 49 years of age.[1] Many of these women have active professional and social lives and are likely to be seriously bothered by this condition. It is usually socially embarrassing and can lead to a woman's withdrawal from physical activity, affect her sexual life, and reduce her quality of life.[2]

Surgery has been widely accepted as the treatment of choice for SUI. However, there has recently been an increased interest in the conservative management of this condition.[3-6] Because the initial treatment ideally should be the least invasive with the fewest potential side effects, behavioral methods have been recommended as the first option for the treatment of SUI in many cases.[6] The aim of conservative rehabilitation therapy is to stabilize the urethra by increasing pelvic-floor muscle strength (force-generating capacity). Pelvic-floor muscle strength is important for stabilizing the bladder neck and urethra. Encouraging results obtained with pelvic-floor rehabilitation based on the integral theory recently reinforced this approach.[5] This theory postulates that the pelvic floor is a closely integrated system in which 3-directional muscle forces pull against the pelvic ligaments and fascia to open and close the neck of the bladder and urethra. It is a fundamentally biomechanical concept that strengthening a muscle also will strengthen its insertion point.[5]

Conservative modalities of treatment include pelvic-floor muscle exercise (PFME), vaginal cones, electrical stimulation, and biofeedback. Since Kegel first presented his results, some randomized controlled trials have shown that PFME is more effective than no treatment.[3,4,7] Low cost and lack of side effects are features that make biofeedback and PFME the usually preferred methods of treatment.[5,8,9] Biofeedback is useful in promoting correct contraction control and visualization of muscle activity, because many women are unaware of how to contract their pelvic-floor muscles and need some motivation.[7,10,11]

The results reported in the literature concerning the use of biofeedback in addition to PFME are conflicting. In randomized trials with only older and postmenopausal women, Burns et al[3] and Aksac et al[7] found that 8 weeks of treatment did not result in any clinical differences between groups treated with PFME alone and groups treated with PFME with biofeedback, although both groups improved more than the control group. Conversely, another randomized study with pad test weight as the outcome measure showed a significant improvement in the group using PFME with biofeedback compared with PFME alone.[12]

Pages et al[11] (who did not report the menopausal status of their subjects) compared the effects of PFME with biofeedback and PFME without biofeedback by using an intensive treatment protocol of 5 treatments each week for 4 weeks followed by an unsupervised home exercise program for 2 months. Both groups showed improvements in nocturnal urinary frequency, but only the group using PFME alone improved in terms of daytime urinary frequency. However, the group using PFME with biofeedback demonstrated better self-reported outcomes and higher pressure contractions of pelvic-floor muscles.

Morkeved et al[13] studied women who were 30 to 70 years of age and who participated in a 6-month training program consisting of 3 sets of 10 contractions performed 3 times each day, with 1 group performing exercise alone and the other group performing biofeedback with exercise. Both groups showed significant improvements in leakage, and both had high objective cure rates, but there was no statistical difference between the groups in any of the outcome measures.

There are also conflicting results in systematic reviews and meta-analyses. In a systematic review, Berghmans et al[14] did not find any evidence that adding biofeedback to PFME was superior to PFME alone. However, De Kruif and van Wegen[15] conducted a meta-analysis that showed a trend toward PFME with biofeedback being more effective than PFME alone. Similarly, in a metaanalysis of 3 studies, Weatherall[16] found that a pooled odds ratio of 2.1 favored biofeedback with PFME over PFME alone, although the 95% confidence interval (0.99-4.4) for the pooled odds ratio did not reach significance.

The value of biofeedback training is controversial in the literature and thus remains an important concern to practicing therapists in this area and to third-party payers. Although the designs of previous studies varied, most involved relatively long-term treatment, included a wide range of ages, and did not consider menopausal status as a criterion for subject inclusion or exclusion.[10,12,13,17] Because we did not find any studies in the literature that considered only reproductive-age women, the aims of this study were to test the ability of a biofeedback-assisted PFME program to affect SUI symptoms in premenopausal women and to evaluate a training program that might lead to successful outcomes in a relatively limited number of sessions.

## Method

### Subjects and Procedure

A total of 26 premenopausal women with symptoms of SUI were enrolled in a protocol of PFME with surface electromyography (sEMG)-assisted

biofeedback at the Department of Physiotherapy of the Centro de Atenção Integral à Saúde da Mulher, State University of Campinas, between October 2003 and June 2004. All women signed a consent form prior to admission. Their premenopausal status was determined by self-report. The symptoms of SUI were mild to moderate and were defined as 2 or more losses of urine a week during physical effort. The initial evaluation included clinical history, pelvic-floor examination, and urine analysis. Exclusion criteria were genital prolapse of grade III (ie, anterior vaginal wall overreaching the hymenal introitus) or previous surgery, pharmacological treatment, physical therapy, or a combination of these for SUI. Multichannel urodynamic testing with a Menuet recorder* was performed to exclude overactive bladder or intrinsic sphincter deficiency.

The mean age of the women enrolled in this study was 42.5 years (range=31-52). The mean body mass index was 27.1 kg/m$^2$ (range=21.2-34.7). The mean duration of symptoms was 5.4 years (range=2-10). One woman was nulliparous, 14 women had had 1 to 3 deliveries, and 11 women had had more than 3 deliveries. Seven women had had cesarean delivery only, whereas 19 had had at least 1 vaginal delivery. Pelvic examination revealed cystocele in 18 women; 16 cystoceles were classified as grade I, and 2 were classified as grade II.[6]

At the initial visit, the subjects individually received verbal information about pelvic-floor anatomy, muscle localization, and function. The biofeedback training was performed with an intravaginal sEMG sensor consisting of bipolar longitudinal electrode plates connected to the biofeedback equipment (MyoTrac 3G†) and an additional sEMG electrode attached to the inferior abdominal wall. The device was designed only for feedback, not for electrical stimulation. The women were instructed to contract their pelvic-floor muscles and relax their abdominal muscles to avoid increasing intra-abdominal pressure. Both the vaginal sEMG output and the abdominal muscle sEMG output were displayed to the subjects on a computer screen. The sEMG data were displayed as line graphs, with a green line corresponding to the signal from the vaginal probe and a red line corresponding to the abdominal muscle sEMG signal, thus providing visual feedback to the subjects.

Participants were treated individually for 40 minutes twice each week for a total of 12 sessions. All subjects performed phasic contractions (fast [3 seconds], followed by 6 seconds of relaxing) and tonic contractions (sustained [10-20 seconds], followed by 20-40 seconds of relaxing). Subjects initially performed 20 phasic contractions and 20 tonic contractions in a supine position and then 10 phasic contractions and 10 tonic contractions each in the sitting and standing positions, for a total of 80 contractions. From sessions 2 to 7, there was a gradual increase in the number of contractions (10 phasic contractions and 10 tonic contractions for each session of the intervention) until the women were able to complete a total of 200 contractions. Therefore, from session 7 until the last session, the women were performing 40 phasic contractions and 40 tonic contractions in the supine position and then 30 phasic contractions and 30 tonic contractions each in the sitting and standing positions.[3,14,17] Participants were not encouraged to perform any sort of home program during the 12 intervention sessions.

A 7-day voiding diary was completed twice during the study, before sessions 1 and 12. To quantitatively evaluate the results, a standardized 1-hour pad test was performed before and after the intervention. *Objective cure* was defined as 1 g or less of leakage after the intervention.[7,18] *Subjective cure* was graded by participants' self-evaluation of their condition after the intervention as "cured," "almost cured," "improved," "unchanged," or "worse."[4] Pelvic-floor muscle strength was assessed by vaginal palpation and perineometry (vaginal squeeze pressure). Vaginal palpation was performed by 2-finger palpation, and contractions were graded as 0 ("none"), 1 ("weak"=<1 second), 2 ("moderate"=1-5 seconds), or 3 ("strong"=>5 seconds).[19] Perineometry was performed by use of an air-filled silicone sensor connected to a portable perineometer with a pressure transducer (Peritron 9300V‡).[20] All women were encouraged to contract the pelvic-floor muscles, and the maximum contraction pressure was recorded.

All participants underwent sEMG evaluation of pelvic-floor muscle activity before the intervention and at sessions 6 and 12 of the intervention. The vaginal sEMG sensor and biofeedback equipment were the same as those used to perform the intervention (MyoTrac 3G), and the electrical activity of muscles was recorded in microvolts. An adapted sEMG assessment of pelvic-floor muscle activity consisted of an initial rest period of 60 seconds and then a phasic contraction, a tonic contraction of 10 seconds, and a tonic contraction of 20 seconds.[21] The sEMG

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‡ Cardio-Design Pty Ltd, PO Box 6407 BC, Baulkham Hills, New South Wales 2153, Australia.

values for phasic and tonic contractions were obtained as mean amplitudes during each contraction.

The leakage index, a tool designed to evaluate a woman's perceived stress incontinence, consists of a 5-point scale (1="never," 5="always") used to evaluate 13 types of physical activity known to trigger urine leakage.[22] This index was applied before and after the intervention. The King Health Questionnaire also was applied to assess a woman's quality of life.[23] After the intervention, all participants also graded their condition: "cured," "almost cured," "improved," "unchanged," or "worse."[4] All procedures and measures were performed by the same physical therapist.

### Data Analysis

Because sEMG measurements were obtained at 3 times, initially a repeated-measures analysis of variance on ranks was performed with the Friedman test. Additionally, a Wilcoxon signed rank test was applied to compare the values before the intervention and after the intervention. Absolute frequencies were calculated to describe the percentages of reduction and remission. Statistical significance was defined as $P<.05$. Data analysis was performed with the SAS software package (version 8.2).[§]

## Results

On the basis of the 7-day diary, there was no change in voiding frequency. However, the frequency of urine loss, the occurrence of nocturia, and the number of pads required significantly decreased by the end of the intervention (Tab. 1).

Twenty-two women (84.6% of the 26 enrolled women) showed a reduction of 50% or more in the frequency of urine loss. Ten women (38.5%) reported complete remission of this symptom, and 4 women had an improvement of less than 50% in the frequency of urine loss.

Objective cure was achieved in 16 women (61.5%). On the basis of the amount of leakage in grams, 18 women achieved improvement of at least 75%, 4 women achieved improvement of between 50% and 74%, and the remaining 4 women achieved improvement of less than 50% in urine leakage.

There was a significant improvement in pelvic-floor muscle strength, as evaluated both by vaginal palpation and by perineometry. The results showed an increase of 15 cm $H_2O$ in the maximum pressure contractions (Tab. 2).

Concerning pelvic-floor muscle strength, 20 women (76.9%) had contractions classified as grade 0 ("absent") or 1 ("weak") before the intervention. After the intervention, almost all women (92.3%) had contractions classified as grade 2 ("moderate") or 3 ("strong"), demonstrating an upgrade of at least 1 grade after PFME with sEMG-assisted biofeedback.

There was a significant increase in the sEMG amplitudes of all contractions throughout the intervention ($P<.0001$). The mean (±SD) values for the phasic contractions were 20.9 μV (±2.7) before the intervention, 28.3 μV (±3.0) at session 6, and 31.7 μV (±3.0) at session 12. The mean (±SD) values for the 10-second tonic contractions were 15.1 μV (±2.0) before the intervention, 23.4 μV (±2.5) at session 6, and 28.1 μV (±2.8) at session 12. The mean (±SD) values for the 20-second tonic contractions were 13.4 μV (±1.8) before the intervention, 20.9 μV (±2.1) at session 6, and 24.1 μV (±2.2) at setion, the values for the phasic contractions and for the 10- and 20-second tonic contractions were significantly dif-

**Table 1.**
Seven-Day Voiding Frequency, Frequency of Urine Loss, Occurrence of Nocturia, and Number of Pads Used Before and After Intervention (N=26)

| 7-d Diary | $\bar{X}$±SD | | P[a] |
|---|---|---|---|
| | Before Intervention | After Intervention | |
| Voiding frequency | 47.8±18.3 | 48.9±11.3 | .2878 |
| Frequency of urine loss | 14.8±17.0 | 3.2±4.2 | <.0001 |
| Occurrence of nocturia | 11.1±11.1 | 5.6±3.1 | .0012 |
| No. of pads used | 6.0±8.1 | 1.0±2.1 | .0014 |

[a] Determined by Wilcoxon signed rank test. Statistical significance was set at $P<.05$.

**Table 2.**
Pelvic-Floor Muscle Strength Evaluated by Vaginal Palpation and Perineometry Before and After Intervention (N=26)

| Pelvic-Floor Muscle Strength Evaluation Method | $\bar{X}$±SD | | P[a] |
|---|---|---|---|
| | Before Intervention | After Intervention | |
| Vaginal palpation (grade) | 1.0±0.8 | 2.4±0.6 | <.0001 |
| Perineometry (maximum contraction [cm $H_2O$]) | 24.5±16.0 | 40.0±17.0 | <.0001 |

[a] Determined by Wilcoxon signed rank test. Statistical significance was set at $P<.05$.

[§] SAS Institute Inc, PO Box 8000, Cary, NC 27511.

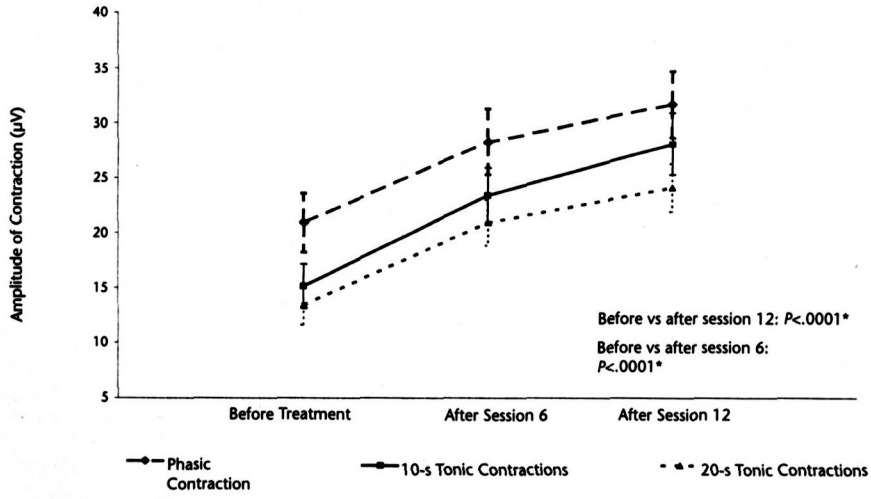


**Figure 1.**
Surface electromyography amplitudes (in microvolts) for phasic contractions and for 10- and 20-second tonic contractions before the intervention, after session 6, and after session 12 (N=26). Values are reported as mean±standard error. *P values were determined by Wilcoxon signed rank test. Statistical significance was set at $P<.05$.

ferent from the initial values ($P<.0001$) (Fig. 1).

Figure 2 shows the leakage index values before and after the intervention. The corresponding means (±SD) were 3.52 (±0.83) and 1.66 (±0.63), respectively. This difference was statistically significant ($P<.001$).

Quality of life, as evaluated by the King Health Questionnaire, showed a significant improvement in all score domains, with the exception of personal relationships. The results for the score domains are shown in Table 3.

Regarding subjective cure, 23 women (88.5%) reported an improvement: 6 (23.1%) considered themselves "cured," and 17 (65.4%) considered themselves "almost cured." No woman considered her condition to be "unchanged" or "worse" after the intervention.

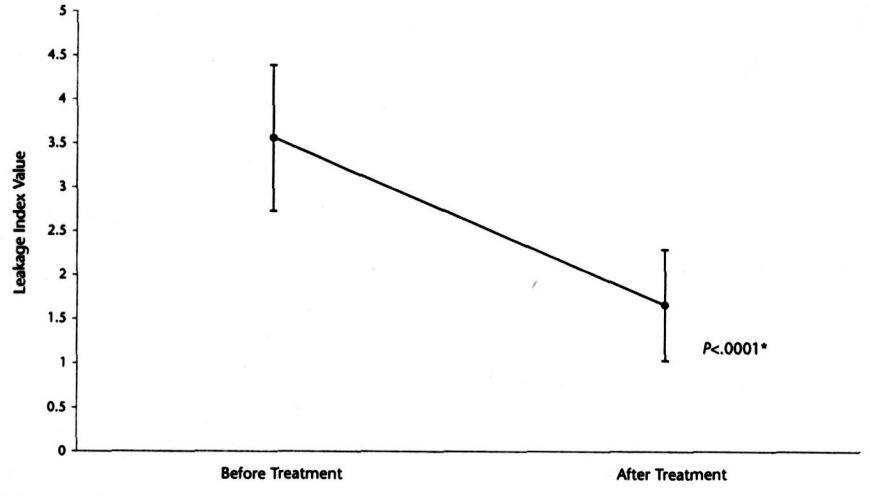


**Figure 2.**
Leakage index values before and after the intervention (N=26). Values are reported as mean±standard error. *P value was determined by Wilcoxon signed rank test. Statistical significance was set at $P<.05$.

## Discussion

The present study showed that a relatively short-term intervention of PFME with sEMG-assisted biofeedback appeared to be helpful in relieving the symptoms of SUI in premenopausal women. These results are in agreement with data published in the literature on the effect of PFME with biofeedback.[8,11,12,24-26] Most of these studies, however, failed to take a subject's age or hormonal status into consideration.

It is important to emphasize that the lack of a control group was an important limitation of the present study. No control group was used because this was an initial evaluation of the performance of this approach at our institution, and some randomized studies[3,7] have shown no improvement in the condition of subjects in a control group. In addition, other factors, such as a placebo effect and a Hawthorne effect, might have influenced our results, that is, a significant positive effect that has no causal basis in the theoretical motivation for the intervention but that is apparently attributable to the effect on the participants of knowing that they were being studied in connection with the outcomes measured. However, the large improvement found in the women in the present study warrants consideration.

The present study included only women who were of reproductive age and who had adopted conservative therapies as the initial treatment for SUI. Most urologists and gynecologists do not consider reproductive age and potential future in childbearing as a contraindication to anti-incontinence surgery.[27] However, reports regarding the negative

**Table 3.**
Comparison of Scores on Domains of the King Health Questionnaire Before and After Intervention (N=26)

| Qality-of-Life Domain | $\bar{X}\pm SD$ | | $P^a$ |
|---|---|---|---|
| | Before Intervention | After Intervention | |
| General heath perception | 49.4±23.9 | 26.9±15.6 | .0015 |
| Incontinence impact | 78.2±28.1 | 32.5±30.5 | .0001 |
| Role limitation | 75.0±27.1 | 13.4±22.6 | <.0001 |
| Physical limitation | 72.4±29.4 | 15.3±24.4 | <.0001 |
| Social limitation | 38.2±28.5 | 6.4±14.6 | <.0001 |
| Personal relationships | 60.5±33.8 | 41.6±16.6 | .0679 |
| Emotions | 58.9±33.8 | 14.1±24.6 | .0001 |
| Sleep/energy | 33.9±23.8 | 6.4±16.3 | .0001 |
| Severity measures | 66.9±19.6 | 22.3±24.2 | <.0001 |

[a] Determined by Wilcoxon signed rank test. Statistical significance was set at $P<.05$.

effects of surgical procedures on subsequent pregnancies have been published. Casper et al[28] reported on 4 women who had pregnancies complicated by a prior Burch or Marshall-Marchetti-Krantz procedure. Lynch et al[29] reported a pregnancy complicated by a sling procedure, resulting in urethral obstruction, pyelonephritis, and a recurrence of incontinence. Determining which surgical procedure offers the greatest benefit to a woman who expresses her desire for future childbearing is difficult.

The present study revealed a significant improvement in the weekly frequency of urine loss: 84.6% of women showed an improvement, although only 10 women (38.5%) reported a complete remission of symptoms. Our results are in agreement with previously published data for rates of cure and improvement that ranged from 69% to 85%.[11,25] The protocols of these studies included longer treatment times or treatment associated with sEMG-controlled biofeedback home training. Instead of long-term treatment, we applied a protocol of 12 sessions without additional home training. Our results suggest that success can be achieved with relatively fewer physical therapy sessions.

A significant decrease in the amount of urine leakage in the pad test was found in the present study, showing that 61.5% of women were dry. These results are in agreement with the findings of other trials, which reported rates ranging from 58% to 80%.[8,12,13,26] Some of these studies used a pad test with a standardized bladder volume, which is known to be more reliable than the use of a pad test without a standardized bladder volume.[13] However, because of local restrictions, we did not perform the pad test with a standardized bladder volume. The objective cure rate was higher than the subjective cure rate (61.5% versus 23.1%, respectively). This finding may indicate that an individual's impression does not always reflect the objective cure and may not be in agreement with the results of the pad test. On the other hand, the pad test may have been subject to bias caused by the participant's knowledge of the procedure after the first test.

The evaluation of pelvic-floor muscle strength by vaginal palpation and perineometry is a very simple method of measuring the success of therapy. In the present study, both techniques revealed a significant increase in pelvic muscle strength. At the initial vaginal palpation, 20 women (76.9%) were unable to satisfactorily contract their pelvic-floor muscles. This figure is similar to data reported in the literature.[30] However, after the intervention, almost all of the women (92.3%) were able to satisfactorily contract these muscles, and the contraction pressures, as measured by perineometry, were 2 times higher. These findings suggest that one of the probable benefits of sEMG biofeedback is the acquisition of appropriate pelvic-floor muscle contractions. An advantage of biofeedback is that it may facilitate this specific physiologic response, which would otherwise be difficult to detect, and it permits the visualization of low-amplitude and low-strength contractions.[17]

In addition, the greatest increase in sEMG amplitudes was found between intervention sessions 1 and 6, whereas the mean increase from sessions 6 to 12 was not significant. On the basis of these results, we can hypothesize that biofeedback may be useful for achieving faster improvement at the beginning of the intervention. The latter may be a desirable feature, particularly when access to physical therapy is difficult and expensive. Similar results were described by Berghmans et al.[10]

One criticism of PFME has been that the lengthy duration of treatment for SUI may affect adherence to this therapy. Some women may find it difficult to perform the exercises on a regular basis.[31] However, we had no dropouts, perhaps because of the relatively small number of sessions in our study protocol. However, Glavind et al[24] concluded that the long-term effect of therapy with biofeedback was better than that of

PFME alone because the patient's motivation for training was higher. We believe that this motivation is related not only to the frequency of sessions but also to the treatment credibility and to the interest and ability of both the instructor and the patient.

Quality of life has become an important outcome measure in clinical trials of treatment for incontinence. All participants in the present study were of reproductive age, and some authors have reported that younger women with this condition report a greater loss of quality of life than older women.[2] Younger women tend to be more socially, economically, and sexually active, a situation that probably contributes to a greater negative effect of SUI on their quality of life. We observed a significant improvement in the quality of life for women after the intervention, particularly with regard to factors related to limitations (in physical and social activities) and to severity measures.

## Conclusion

A relatively short-term intervention of PFME with sEMG-assisted biofeedback appeared to be helpful in relieving the symptoms of SUI in premenopausal women. This approach represents a reasonable conservative option for the management of SUI in women of reproductive age.

Ms Rett and Dr Simoes provided concept/idea/research design. Ms Rett, Dr Simoes, Dr Herrmann, and Dr Pinto provided writing. Ms Rett provided data collection, and Ms Morais provided data analysis. Dr Simoes provided project management. Dr Marques provided subjects and facilities/equipment.

This study was approved by the Institutional Review Board of the School of Medicine, UNICAMP.

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