OPEN FORUM

Body Contouring

A Prospective, Open-Label Study to Evaluate Functional Changes Following Electromagnetic Muscle Stimulation of Abdominal Muscle

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Aesthetic Surgery Journal Open Forum 2023, 1–7

https://doi.org/10.1093/asjof/ojad045
www.asjopenforum.com

OXFORD UNIVERSITY PRESS

Abstract

Background: Electromagnetic muscle stimulation (EMMS) is an effective, well-tolerated noninvasive body contouring treatment for strengthening, toning, and firming the abdomen.

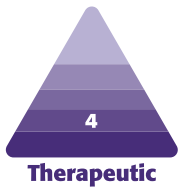
Objectives: In this study, functional changes following abdominal EMMS treatment wereevaluated.

Methods: In this prospective, open-label study, adults received 8 abdominal EMMS treatments (2 treatments on nonconsecutive days/week over 4 weeks). Follow-ups occurred 1 month (primary endpoint), 2, and 3 months postfinal treatment. Effectiveness endpoints included improvements from baseline on Body Satisfaction Questionnaire (BSQ; primary endpoint), core strength (timed plank test), abdominal endurance (curl-up test), and Subject Experience Questionnaire (SEQ). Safety was evaluated throughout.

Results: Sixteen participants (68.8% female) were enrolled, with a mean age of 39.3 years and a mean BMI of 24.4 kg/m^2; 14 participants completed the study per protocol. Mean BSQ scores were significantly improved from baseline (27.9) to the 1-month follow-up (36.6; $P < .05$). Core strength and abdominal endurance were significantly greater at the 1-, 2-, and 3-month posttreatment time points than at baseline ($P < .05$). Frequently cited reasons for seeking EMMS treatment included a desire to feel stronger (100%; $n = 14/14$) and to improve athletic performance (100%; $n = 14/14$). SEQ responses 3 months posttreatment showed that most participants reported feeling stronger (92.9%) and motivated to receive additional EMMS treatments (100%) and work out to maintain treatment results (100%). The majority of participants (>78%) reported being "satisfied" or "very satisfied" with abdominal treatment 1 month posttreatment. One device- and/or procedure-related adverse event of menstrual cycle irregularity was reported in 1 participant and was mild in severity.

Conclusions: EMMS treatment of the abdomen is associated with functional strength improvements and high patient satisfaction.

Level of Evidence: 4



Editorial Decision date: May 19, 2023; online publish-ahead-of-print May 25, 2023.

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Minimally invasive body contouring procedures continue to grow in popularity. While many of these procedures primarily target reductions in adipose tissue, targeting the underlying muscle through muscle stimulation devices can also effectively improve body tone and shape. The therapeutic use of nonvolitional electrical and electromagnetic muscle stimulation to aid in injury recovery, strengthen skeletal muscle, and prevent muscle atrophy goes back several decades.[1–6] In recent years, however, similar devices have started being applied for aesthetic use in the clinical setting.

CoolTone (ZELTIQ Aesthetics Inc., an AbbVie Affiliate; Pleasanton, CA), an electromagnetic muscle stimulation (EMMS) device, is FDA-cleared for strengthening, toning, and firming the muscles of the abdomen, buttocks, and thighs. With EMMS, a magnetic field induces current at the level of the muscle, causing sustained, nonvolitional muscle contractions, while also avoiding the skin, fat, and bone due to their comparatively weak conductive properties.[5–7] Multiple studies have demonstrated the safety and effectiveness of EMMS devices for aesthetic improvements, high patient satisfaction, and physical improvements such as increased muscle thickness.[8–14] However, it is not known whether these aesthetic changes are accompanied by functional changes, such as changes in strength and endurance. The goal of this study was to evaluate the extent of functional change following stand-alone EMMS treatment of the abdomen over a 3-month period.

METHODS

Study Design

This was a prospective, nonrandomized, open-label study conducted on healthy adult volunteers at a single site in the United States between March 4, 2020, and May 18, 2021. The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki and in accordance with local regulatory requirements. Informed consent was obtained from all participants at screening. This study was registered at clinicaltrials.gov (NCT#04506307). The study comprised 13 visits, including screening and 8 EMMS treatments; follow-up visits occurred 4 days, 1 month, 2 months, and 3 months after the final treatment.

Participants

Eligible participants were healthy male and female adults aged 22 to 65 years with a BMI ≤ 30 kg/m^2 at screening and no weight changes exceeding 5% of body weight in the preceding month. The participants agreed to maintain their weight within 5% of baseline by not making any major changes in diet or exercise routine during the course of the study and agreed to have photographs taken of the treatment area during the scheduled time periods. The participants also agreed to refrain from any new abdominal muscle training exercises during the course of the study.

Participants were excluded if they had a history of recent surgical procedure(s) in the area of intended treatment where muscle contractions could disrupt the healing process; needed to have or had a known history of subcutaneous injections administered into the treatment area (eg, heparin, insulin) within the month before screening; had an intrauterine contraceptive device inserted or removed within the month before screening; had an abdominal hernia, pulmonary insufficiency, fever, cardiac disorder, malignant tumor, growth plate in the treatment area, or metal or electronic implants in or adjacent to the treatment area; or had been diagnosed with a seizure disorder or Grave's disease. Participants were also not eligible if they were pregnant, were planning to become pregnant in the next 9 months, were currently lactating, or were lactating in the previous 6 months. Participant data were excluded from effectiveness analyses if their weight change was $\geq$5% of total body weight at the 1-month follow-up visit or if they did not receive all 8 EMMS treatments.

Treatment

Each participant received 8 EMMS treatment sessions to the abdomen over a 4-week period, with 2 sessions each week and at least 2 days between each treatment. During each treatment session, the participants were made to lie in the supine position with the EMMS device strap beneath their abdomen and 1 or 2 (depending on if the width of the participant's torso allowed) applicators were placed centrally on the abdomen and secured with the strap (Supplemental Figure[15]). Each treatment cycle was 30 min in duration, and the intensity of muscle stimulation delivered by the device was adjusted throughout to ensure that the participants felt comfortable. All treatments were carried out with an FDA-cleared EMMS device (CoolTone; ZELTIQ Aesthetics Inc., an AbbVie Affiliate, Pleasanton, CA, USA).

Primary Endpoints

Participants completed the Body Satisfaction Questionnaire (BSQ) at baseline before treatment; after the fourth, sixth, and eighth EMMS sessions; and at the 1-, 2-, and 3-month follow-up visits. The BSQ measures participants' perceptions of the shape and appearance of the abdomen using a set of 10 dichotomous word pairs (eg, firm vs wobbly).[5,6,8,10] Each of the 10 word pairs is rated on a 5-point semantic differential scale from 1 (most negative) to 5 (most positive), with the total score ranging from 10 to 50. An increase in

Table 1. Demographics and Baseline Characteristics

Parameter	Value
Sex, *n* (%)	
Female	11 (68.8)
Male	5 (31.3)
Mean age, years (range)	39.3 (26-61)
Weight, lbs (range)	147.7 (120.9-193.3)
BMI, kg/m^2 (range)	24.4 (20.5-29.8)
Race, *n* (%)	
Asian	6 (37.5%)
Black or African American	1 (6.3%)
Native Hawaiian or Other Pacific Islander	1 (6.3%)
White	6 (37.5%)
Other	2 (12.5%)
Fitzpatrick skin phototype, *n* (%)	
I/II	1 (6.3%)
III/IV	13 (81.3%)
V/VI	2 (12.5%)
Mean treatment intensity, % (range)	
4th treatment	95.6% (57.0%-100.0%)
6th treatment	100.0% (100.0%-100.0%)
8th treatment	100.0% (100.0%-100.0%)

the BSQ score reflects a participant's perceived improvement in appearance. The primary effectiveness endpoint was the change in participant perception of body shape, as measured by the BSQ at the 1-month follow-up.

Safety was monitored throughout the study by documenting device- and procedure-related adverse events (AEs), including serious device-related AEs (SADEs), and clinical assessment of the treatment area to assess pain. The primary safety endpoint was the frequency of AEs, including SADEs.

Additional Effectiveness Endpoints

Participants completed the Subject Experience Questionnaires (SEQs) to assess their motivation for receiving EMMS treatment at baseline and at all posttreatment follow-up visits to assess effectiveness from their perspective. Abdominal endurance and strength changes were measured using the American College of Sports Medicine (ACSM) paced curl-up test and a prone plank test, respectively, which have been used previously to assess abdominal strength

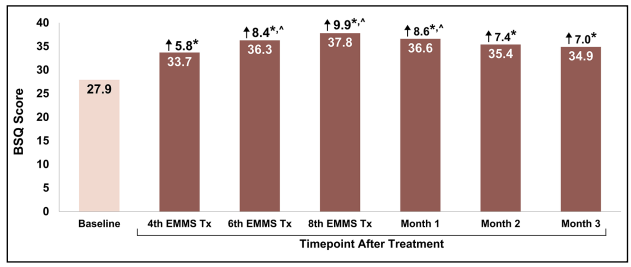

Figure 1. Body Satisfaction Questionnaire (BSQ). Mean BSQ scores for the abdomen at baseline; immediately after the fourth, sixth, and eighth treatments; and at Months 1, 2, and 3 after the final treatment. Possible scores range from 10 to 50, with an increase in score reflecting a participant's perceived improvement in appearance. The arrows represent the mean change from baseline in the BSQ score. *$P < .05$ vs baseline; ^$P < .05$ vs fourth electromagnetic muscle stimulation (EMMS) treatment. $n = 14$. Tx, treatment.

endurance, including after muscular stimulation.[6,16–18] For the paced curl-up tests, the participants were made to lie in a supine position on a mat with the knees bent to 90°, as measured with a goniometer. Their arms were at their side, with the palms facing down, and with the middle fingers touching a piece of tape. A second piece of tape was placed 8 cm (for those who were ≥45 years) or 12 cm (for those who were<45 years) from the first piece of tape. The participant's trunk flexion ability could also be used to determine the distance (8 or 12 cm) to the second tape. The participants completed slow, controlled curl-ups to lift the shoulder blades off the mat (the trunk makes a 30° angle with the mat) in time with a prerecorded tape or metronome at a tempo of 40 curl-ups per minute. They performed as many curl-ups as possible without pausing. The test was terminated when the participants were no longer able to keep up with the pace of the metronome or when their fingers could not reach the second piece of tape. For the prone plank test, the participants were instructed to lie straight with the elbows parallel to each other and directly under the shoulders. While in this position, a horizontal reference rod or band was placed so that it touched their lower back. They held this "plank" position while touching the reference rod for as long as possible. The assessment ended when the participants no longer touched the reference rod or lowered themselves to the mat. The total hold time (in seconds) was measured for each participant. For both tests, all participants were trained during their initial orientation before any baseline assessments to eliminate the bulk of the learning effect.

Statistical Analyses

Demographic data are summarized descriptively. For continuous data (eg, age), the mean, standard error, and minimum and maximum are described. Where appropriate,

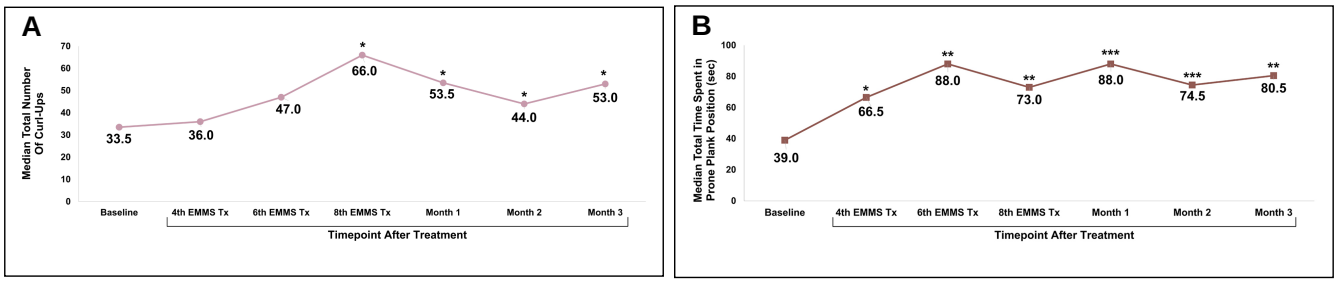

Figure 2. Abdominal endurance and core strength tests. Median performance on the (A) paced curl-up and (B) prone plank tests. $^{*}P < .05$; $^{**}P < .01$; $^{***}P < .001$ vs baseline. $n = 14$, except at the post sixth electromagnetic muscle stimulation (EMMS) treatment visit when 1 participant did not complete the curl-up test due to an adverse event. Individual results were variable. Min and max for curl-up test: baseline (1-157); Month 1 (21-344); Month 2 (17-350); Month 3 (11-360). Min and max for the prone plank test: baseline (13-165); Month 1 (49-200); Month 2 (50-184); Month 3 (48-229). Tx, treatment.

2-sided *t*-tests with $\alpha = 0.05$ or the Mann–Whitney test were used. Safety data are summarized descriptively.

RESULTS

Participants

A total of 16 participants were enrolled and received at least 6 treatments; these participants were included in the safety population. Fourteen participants who completed all 8 EMMS treatments and the 3-month final follow-up visit were included in the per protocol population for effectiveness analyses ($n = 1$ withdrew consent after the sixth treatment due to a family member with possible SARS-CoV-2 exposure; $n = 1$ could not complete the seventh and eighth treatments or attend the 4-day follow-up due to local SARS-CoV-2 guidelines). Two male participants received 2 simultaneous cycles at each treatment session.

In the safety population ($n = 16$), participants had a mean age of 39.3 years (range: 26-61 years) and the majority of the participants were female ($n = 11$; 68.8%) (Table 1). The majority of the participants ($n = 13$; 81.3%) had Fitzpatrick skin phototypes III/IV and were predominantly Asian ($n = 6$; 37.5%) and White ($n = 6$; 37.5%). The participants had a mean weight of 147.7 lbs (range: 120.9-193.3 lb) and mean BMI of 24.4 kg/m^2 (range: 20.5-29.8 kg/m^2).

Effectiveness

Mean overall BSQ scores ($n = 14$) were significantly improved from baseline (27.9) to the 1-month follow-up (36.6; $P < .05$). At all other time points posttreatment, mean BSQ scores were significantly improved from baseline ($P < .05$; Figure 1).

Abdominal endurance, as measured by the median number of curl-ups completed at a pace of 40 curl-ups per minute, was significantly improved from baseline (33.5; range, 1-157) to the 1-month postfinal treatment visit (53.5; range, 21-344; $P < .05$). The median number of completed curl-ups remained significantly higher than baseline at the 2- and 3-month postfinal treatment follow-ups ($P < .05$; Figure 2A). The median percentage improvement from baseline in curl-up performance, calculated based on participant-level percentage changes from baseline, was 140.7% at the 1-month postfinal treatment visit and remained >100% at the 2- and 3-month postfinal treatment visits.

Core strength, as measured by the time spent in a prone plank position, was significantly improved from baseline (39 s; range, 13-165 s) to the 1-month postfinal treatment visit (88 s; range, 49-200 s; $P < .001$) and remained greater than baseline at the 2- and 3-month postfinal treatment follow-ups ($P < .01$; Figure 2B). The median percentage improvement from baseline in the time spent in a prone plank, calculated based on participant-level percentage changes from baseline, was 94.6% at the 1-month postfinal treatment visit and remained >90% at the 2- and 3-month postfinal treatment visits.

The reasons for seeking EMMS treatment most frequently cited by the participants ($n = 14$) included a desire to feel stronger (100%), to improve athletic performance (100%), and to appear more toned (85.7%) (Table 2). SEQ responses at 1-month postfinal treatment ($n = 14$) (Table 3) showed that most participants reported feeling stronger (92.9%) and feeling that their athletic performance had improved (71.4%). The participants also reported feeling that their abdominal tone was improved (85.7%) and feeling motivated to receive additional EMMS treatments (78.6%) and motivated to work out to maintain treatment results (100%). Similar responses were seen at the 2- and 3-month follow-up visits. The majority of the participants also reported being “satisfied” or “very satisfied” with abdominal treatment at the 1-month (78.6%) and 3-month (92.9%) postfinal treatment time points, and the most common response was “satisfied” at all time points after the final treatment (Figure 3).

Safety

A total of 7 AEs occurring in 6 participants were reported during the study; of these, 6 were mild in severity and 1 was

Table 2. SEQ at Baseline—Reasons for Seeking EMMS Treatment

Statement	*N*	%
I want to feel stronger	14/14	100.0
I want to feel more energetic	8/14	57.1
I want to improve my athletic performance	14/14	100.0
I want to appear more slim	12/14	85.7
I want to appear more toned	12/14	85.7
I want to look better in my clothes	10/14	71.4
I want to feel more confident	10/14	71.4
I want to look more youthful	6/14	42.9

Table lists the number and percentage of participants choosing *agree* or *strongly agree* with each statement as a reason for seeking EMMS treatment from the baseline SEQ. Note that the participants could have selected multiple statements. SEQ, Subject Experience Questionnaire; EMMS, electromagnetic muscle stimulation.

moderate. This included 1 device- and/or procedure-related AE of menstrual cycle irregularity that was reported in 1 participant and was mild in severity; the participant experienced a heavier flow volume with clotting during 1 of her cycles within the study that was unusual for the participant and was considered possibly related to the device/procedure. The remaining 6 AEs were considered unrelated to the device or procedure. All AEs resolved without intervention by the end of the study.

DISCUSSION

This prospective, nonrandomized, open-label study is the first to show improvements in functional strength and endurance after EMMS treatments to the abdomen. Multiple participant-reported outcome measures also showed that body satisfaction, as well as self-reported strength, muscle tone, and motivation, were significantly improved by EMMS treatment, and treatment outcomes satisfied many of the participants' stated reasons for seeking abdominal EMMS treatment. EMMS treatments were well tolerated by the participants.

The primary endpoint of this study was met, with significant increases in mean participant-rated BSQ scores 1 month after the final EMMS treatment versus baseline. The majority of the participants also reported being "satisfied" or "very satisfied" with treatment. Importantly, increases in BSQ scores and high participant satisfaction persisted through the 3-month follow-up period. These data support previous studies showing similarly positive participant experiences with abdominal EMMS treatments,[8–10] suggesting that EMMS produces consistent, lasting improvements in self-rated aesthetic perception.

Table 3. SEQ After Treatment—Overall Treatment Experience

Statement	4 Days post final treatment (%)	1 Month follow-up (%)	2 Month follow-up (%)	3 Month follow-up (%)
I feel stronger	92.9	92.9	78.6	92.9
My athletic performance has improved	64.3	71.4	78.6	71.4
I feel more energetic	50.0	42.9	71.4	35.7
I feel like my posture has improved	35.7	42.9	35.7	35.7
I feel like my abdominal muscle tone has improved	78.6	85.7	85.7	85.7
I feel more confident	64.3	64.3	64.3	57.1
I am happier with my overall appearance	78.6	71.4	71.4	64.3
My clothes feel better	42.9	57.1	50.0	57.1
My clothes look better	35.7	42.9	50.0	57.1
I feel motivated to follow up with additional treatments to maintain these treatment results	71.4	78.6	78.6	100.0
I feel motivated to work out and maintain these results	100.0	100.0	92.9	100.0

Table lists the percentage of participants choosing *agree* or *strongly agree* with each statement. $n = 14$. SEQ, Subject Experience Questionnaire.

Other participant-reported outcome measures showed agreement between participants' stated treatment goals (eg, to appear more toned) and treatment outcomes. Indeed, all study participants reported a desire to feel stronger and to improve their athletic performance as reasons for seeking EMMS treatment, and the majority of the participants reported 1 month posttreatment that they felt stronger (92.9%) and that their athletic performance had improved (71.4%). The participants also reported feeling motivated to follow up with additional EMMS treatments in order to maintain the results (78.6%) and to work out to maintain the positive results (100%). As with BSQ scores and overall satisfaction, positive responses on posttreatment SEQ were also maintained throughout the 3-month posttreatment follow-up period. Similar findings were

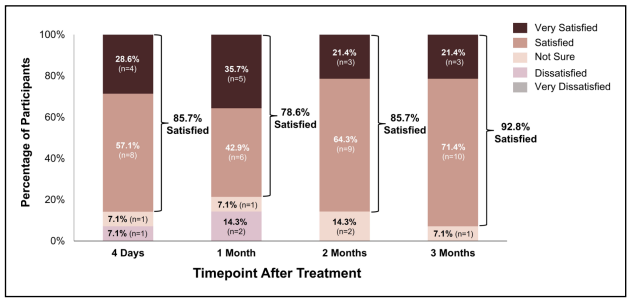

Figure 3. Overall satisfaction with electromagnetic muscle stimulation (EMMS) treatment. Participants were asked to rate their overall satisfaction with the treatment results on a 5-point Likert scale from *Very Dissatisfied* to *Very Satisfied*. $n = 14$.

reported in a recent retrospective analysis of participant experience with EMMS treatment.[10]

In this study, the authors also assessed whether self-reports of EMMS treatment improving abdominal strength and tone were accompanied by measurable changes in strength and endurance. To do this, the ACSM paced curl-up and prone plank tests were conducted to measure endurance and strength, respectively, at baseline and after treatment. There were significant improvements from baseline in abdominal strength (prone plank test) at all time points through the 3-month study period. Abdominal endurance (paced curl-up test) was significantly improved from baseline after 8 EMMS treatments; although the magnitude of improvement was slightly lower in the assessments 1, 2, and 3 months after EMMS treatment, performance remained statistically significantly greater than at baseline for all of these later time points. The data from both tests showed variability at all time points, which may be due to the small study population and the range of abilities at baseline; to account for this variability, median values for core strength and abdominal endurance tests were used for the analysis. Additionally, the participants were trained on how to correctly perform each test at their initial orientation session to minimize the influence of the learning effect on performance. However, both the median number of curl-ups and the median time spent in a prone plank were significantly greater after EMMS treatment than at baseline. Additionally, examining performance on the individual level showed that improvement from baseline was >50% for the majority of the participants ($n = 11/14$), and at least half of the participants showed >100% improvement, representing a doubling in performance, on both tests at the 1-month posttreatment assessment. This is the first study in which both objective standardized and self-reported measures of abdominal strength and endurance following EMMS treatment were used; importantly, there is concordance between the different assessment types, lending additional credence to EMMS as an effective means of abdominal strengthening. The present findings support a recent study of a neuromuscular electrical stimulation device that reported similar increases in abdominal strength posttreatment using the ACSM tests, including the same paced curl-up test used here.[19]

In line with previous studies,[8,9] EMMS treatment was well tolerated, with a total of 7 reported AEs. One participant experienced 1 device- and/or procedure-related AE of menstrual cycle irregularity; this event was mild in severity. The remaining 6 AEs were considered not related to the device or procedure, and no SAEs or SADEs were reported.

Limitations

A potential limitation of this study is the small sample size; however, significant and long-lasting increases in functional measures of strength and endurance, as well as self-rated improvements in body satisfaction, were seen at all posttreatment time points. Another potential limitation of this study is that participant screening did not control for baseline variability in abdominal strength and endurance; however, the majority of the participants showed >50% improvement from baseline at the 1- and 3-month posttreatment visits, and this may provide a more "real-world" representation of treatment results. Although we report overall positive results following EMMS treatment, the small study size does preclude additional analyses based on participant demographics (eg, age, BMI) that may influence outcomes. Additionally, this study has limited follow-up, and it is not known whether the aesthetic and functional improvements after EMMS treatment are maintained beyond 3 months posttreatment. Although a multitude of factors (eg, baseline fitness level, age, activity levels) likely contribute to the time course of strength and endurance loss following the final EMMS treatment, the authors agree that it is reasonable to expect improvements in strength and endurance to persist ~8 to 10 weeks after the last treatment, followed by a slow decline back to baseline. Future controlled and real-world studies with longer follow-up times and larger sample sizes are warranted to address these outstanding questions.

CONCLUSIONS

The data from this prospective study show that EMMS treatment for body contouring of the abdomen is well tolerated, associated with high levels of participant satisfaction, and produces not only aesthetic improvements, but also lasting increases in abdominal strength and endurance.

Supplemental Material

This article contains supplemental material located online at www.asjopenforum.com.

Disclosures

Dr Bachelor is the Medical Director for Zeltiq Aesthetics, Inc., an AbbVie company (Pleasanton, CA) and principal investigator for the Innovation Research Center (Pleasanton, CA). Dr Kilmer is a paid consultant and advisory board member for AbbVie Inc. (North Chicago, IL) and has received research support from AbbVie Inc. Dr Porcari is a paid speaker and consultant for AbbVie Inc. Ms Gamio is an employee of AbbVie and may own AbbVie stock.

Funding

The design, study conduct, and financial support for the study were provided by Allergan plc (Dublin, Ireland) before its acquisition by AbbVie Inc. (North Chicago, IL). AbbVie was involved in the interpretation of data, review, and approval of the publication. Medical writing and editorial assistance were provided to the authors by Sarah J. Cross, PhD, of AbbVie, and funded by AbbVie Inc.

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