Brief Report of a Clinical Trial on the Duration of Middle Ear Effusion in Young Children Using a Standardized Osteopathic Manipulative Medicine Protocol

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Context: Osteopathic physicians have used osteopathic manipulative medicine (OMM) to treat patients with acute otitis media (AOM) and its sequelae (e.g., middle ear effusion [MEE], conductive hearing loss) for more than a century. However, few clinical trials document the efficacy of OMM, perhaps because of various challenges related to OMM clinical trials.

Objectives: To describe a research protocol studying the efficacy of OMM on MEE after an episode of AOM, comment on the feasibility of the protocol and statistical analysis, and report on lessons learned in the first 9 months of the study.

Methods: Dual-site, prospective, randomized, blinded, controlled clinical trial comparing OMM plus standard care to standard care only for MEE after an episode of AOM. Standard care comprised antibiotics and surgery. Patients were aged between 6 months and 24 months, were diagnosed as having AOM, were referred to the study by a participating pediatric provider, and had abnormal tympanogram results on entry into the study. All patients had 5 weekly study visits, and patients in the intervention group received OMM on visits 1 through 3. Patients received weekly tympanogram and acoustic reflectometer readings as well as daily at-home acoustic reflectometer readings for 30 days.

Results: Fifty-six patients were screened, 34 subjects were enrolled, and 26 subjects completed the study protocol in the first 9 months of the study. This resulted in 22 “ears” in the standard care only group and 18 “ears” in the standard care plus OMM group, resulting in 40 cases of AOM studied in the first year of the trial. The OMM treatment protocol was easily administered without serious adverse events. Protocols for interpretation of tympanogram readings and conversion of data for statistical analysis resulted in analyzable data.

Conclusions: The OMM protocol can be administered with no serious adverse events. Subject recruitment is difficult, and a full-time research assistant at the referring site improves subject referral, enrollment, and retention. Accepting only confirmed cases of AOM from trained pediatric providers reduces the patient pool but increases the reliability of the data.

Acutely present, unbearable ear pain is usually due to a middle ear infection (AOM), which can be found in 40% of children 30 days after resolution of a single episode of AOM. Children with persistent MEE have an increased risk of conductive hearing loss later in childhood. In addition, persistent MEE after an episode of AOM is also thought by some experts to contribute to recurrent AOM.

When medical treatment fails, myringotomy with tympanostomy tube placement is recommended for persistent MEE with documented hearing loss. Because of the high prevalence of persistent MEE after AOM, myringotomy with tympanostomy tube placement is now the second most common operation for children in the United States, exceeded only by circumcision in infancy.

The osteopathic medical profession has a long history of using osteopathic manipulative medicine (OMM) in the management of otitis media and its complications, with reported clinical efficacy. Nevertheless, few studies in the peer-reviewed literature regarding the efficacy of manual medicine on pediatric AOM and MEE exist. These studies include one abstract of an osteopathic pilot study, an osteopathic pilot study, an osteopathic clinical trial, a chiropractic retrospective review, and two chiropractic pilot studies. Given the prevalence of otitis media, the serious sequelae of MEE, and the fact that surgery is commonly used to treat patients with this condition, studying the efficacy of manual medicine techniques on pediatric middle ear disease is urgently needed.

In response to this need, we designed a dual-site, prospective, randomized, blinded, controlled clinical trial on the effi-
cacy of a standardized OMM protocol on MEE in young children with AOM. The study design compared the findings of an OMM plus standard care treatment group to a standard care only treatment group. The primary study goal was to determine if a standardized weekly OMM protocol could reduce the duration of MEE after AOM. The second goal was to test the clinical observation that changes in middle ear function can be demonstrated immediately after OMM.

In the present report, we discuss the challenges of OMM trials, describe our study protocol, and report our initial experience with this clinical trial. The present study was registered at ClinicalTrials.gov and assigned number NCT00520039.

Challenges Specific to OMM Clinical Trials
Several issues common among OMM efficacy studies have the potential to threaten their validity. First, a recurring problem of clinical trials concerns insufficient subject recruitment and retention. Specifically, the possibility of bias in subject retention has been sited as a problem in studies of otitis media.31 Thus, insufficient recruitment and retention affect the statistical reliability and validity of OMM trials.

Second, many OMM clinical studies avoid a standardized OMM protocol. However, a nonstandardized protocol confounds the study results because it is impossible to identify a single factor or group of factors that is consistent among all subjects and related to the outcomes. Even when OMM protocols are used, variations in treatment by different OMM providers may occur. Unlike medications, OMM application is not easily quantifiable, therefore allowing the possibility of patients receiving varying treatment based on the provider. There are rigorous protocols to study and enhance interrater reliability and validity when a manual medicine diagnostic procedure is being performed.32 However, the issue of OMM provider variance is generally addressed by regular standardization training of the OMM providers.33

Third, many OMM trials use subjective measures (eg, patient-reported pain based on Likert-type pain scale) to evaluate the effect of OMM on patient outcomes. Although such measures have value, objective measures are needed to strengthen results and reduce patient bias.

Finally, additional influences, such as certainty of clinical diagnosis and other clinical interventions administered to the patient, need to be controlled so that outcomes can be appropriately interpreted.34 Studies on otitis media in the past have been criticized for using nonstandardized criterion for the diagnosis of AOM or for not differentiating bacterial from viral AOM with those having simply residual fluid in the middle ear.

The protocol described in the present report was designed to address all of these pitfalls in a rigorous study on the effect of OMM on pediatric AOM and MEE.

Methods
The present study was a dual-site, prospective, randomized, blinded, controlled clinical trial on the efficacy of a standardized OMM protocol on MEE in young children with AOM. The study design compared the findings of an OMM plus standard care treatment group to a standard care only treatment group. No sham therapy plus standard care group was used.

The institutional review boards of West Virginia School of Osteopathic Medicine (WVSOM) in Lewisburg and the University of New England College of Osteopathic Medicine (UNE COM) in Biddeford, Maine, approved the study protocol. A Data Safety Monitoring Board (DSMB) was chartered to perform ongoing analysis and ensure patient safety. The research assistant at each site determined patient eligibility for study inclusion. After eligibility was confirmed, the parent or guardian (referred to as parent for the remainder of the present report) provided written consent. Parents were provided with $25 for each study visit to help with travel costs and other expenses for bringing their child to participate in this study.

Setting and Patients
In an attempt to enhance patient recruitment, the protocol was designed using two referral and treatment sites: site A, WVSOM, and site B, UNECOM. Providers from each site were recruited to refer into the study. Both sites shared similar semi-rural locations, academic settings, and patient populations with medium to low socioeconomic status. Instructions and informative flyers and brochures were created and placed throughout the clinics and in examination rooms at both sites. Patient enrollment for year 1 of the study began at both sites September 2007 and ended June 2008. Subject recruitment resumed at site B only in October 2008 and was closed May 2009, as planned. The goal was to capture two winter seasons, when the incidence of AOM and MEE is greater.

Patients were between the ages of 6 months and their second birthday with a confirmed diagnosis of AOM. Diagnoses of AOM were required from a participating referring provider (DO, MD or family nurse practitioner) who used a standard protocol to determine the AOM diagnosis, as described in the following section. Patients were also required to have abnormal tympanogram findings at entry into the study (ie, classification of “B”, “C rising” [C2], “O,” or “unreadable”).

Patients were excluded from the study if they met any of the following criteria: chromosomal abnormalities; major congenital malformations of the head and neck, including torticollis; immunologic abnormalities or deficiencies; any prior ear, nose, and throat surgery for otitis media; or a normal tympanogram on the first study visit. If this was not the child’s first episode of AOM, either 4 weeks had to have elapsed since the completion of antibiotic treatment for a prior episode of AOM, or resolution of the prior episode of AOM had to have been clinically documented.

Patients were enrolled in the study within 3 days of receiving the diagnosis of AOM and were followed for 30 days. All patients received standard medical care from their referring
provider for the duration of their enrollment in the study. Parents were directed to refrain from having their children receive OMM or other manual therapies outside of the study protocol for the duration of the study.

Referrals
We recruited referring pediatric providers (osteopathic physicians [DOs], allopathic physicians [MDs], and family nurse practitioners) from the pediatric departments at each site and provided extensive education regarding study protocol. To ensure reliability of the diagnosis of AOM in children referred to the study, all referring providers were required to follow peer-reviewed algorithms for the diagnosis and management of otitis media (Figure 1). All referring providers signed a statement agreeing to adhere to these guidelines and abide by the study protocol. There were 5 referring providers at both sites. However, 3 of the providers at site A left the area within the first 2 months of the study.

To further standardize pre-enrollment diagnosis and treatment, parents were not allowed to self-refer their children into the present study. Only referrals from the specified pediatric providers were accepted. Referring providers did not participate in any other aspect of the study protocol and did not receive any monetary reimbursement or incentive for participation.

Patient Recruitment and Retention
A research assistant was hired at each site with the primary responsibility of recruiting and retaining patients and conducting the study protocol. Secondary responsibilities consisted of ensuring compliance with overall study protocols, creating a manual of procedures (site A), and participating in research education (site B).

Site A hired a part-time pre-professional school (physician assistant) student. This research assistant (E.B.) maintained a flexible work schedule and was on call at all times. She was contacted by the pediatric department when a potential study participant was referred and then either met with the parents or arranged to contact the parents later to discuss the study and enroll the patient if the patient was eligible and the parent agreed.

Site B developed a different model for the research assistant by creating a student osteopathic research fellowship within the UNECOM Department of Osteopathic Manipulative Medicine for each year of the study. During the year of the fellowship, each student participated in research-based and OMM educational activities, received tuition forgiveness for the year of the fellowship, and a stipend supplemented by the original grant. A third-year osteopathic medical student was chosen for this position and was stationed in the referring pediatric clinic full time. The research assistant at site B (J.V.) interacted with the clinic staff and physicians daily, reminding them of the study. When referrals were made, the site B research assistant was immediately available to discuss the study with the parents and enroll the patients.

Randomization and Blinding
Enrolled subjects were randomly assigned to the intervention (ie, OMM and standard care) or control (standard care only) groups using Research Randomizer (Geoffrey C. Urbaniak and Scott Plous; http://www.randomizer.org). Three groups of randomization tables were generated for each site, and the last ones were used. Each patient at each site had a unique number. As each site enrolled patients sequentially into the study, they were randomly assigned to either the intervention or control group.

The investigators were blinded as to all data collected and patient outcomes but not to patient group assignment; referring providers were blinded as to patient group assignment and study outcomes; parents were blinded as to patient data at each study visit; and the audiologist was blinded as to site, subject number, visit number, ear (right or left), date, whether it was pre- or posttreatment of the audiograms read, and patient outcomes. The research assistants and the statistician were not blinded to any aspect of the study.

Office Visits and Interventions
All patients had weekly study visits for 30 days, resulting in 5 study visits per patient. At the initial visit, demographic information was obtained. All parents were given an acoustic reflectometer (AR), were instructed in its use by the research assistant at each site, and were asked to measure and record their child’s AR readings daily for the duration of the study. At each study visit, MEE was evaluated with three tympanogram tracings from each ear, one AR reading from each ear, and a parent questionnaire on visits 2 through 5. This questionnaire asked about change in the following items since the last visit: child’s sleep pattern; over the counter medications used; if the parent felt comfortable with taking AR recordings; and any unusual behavior noticed in the previous week.

For children in the intervention group, MEE was evaluated by the research assistant at each visit as above. In addition, a second series of tympanogram and AR readings were taken immediately after administration of the OMM treatment protocol, which was performed on visits 1 through 3. The AR and tympanogram are described further under “Outcome Measurements.” Children in the standard care control group did not receive OMM.

Figure 1. American Academy of Pediatrics’ and American Academy of Family Physicians’ guidelines for the diagnosis of acute otitis media. Patients had to meet the criteria for each of the three items

1. Otalgia, pulling at ear, irritability, otorrhea, or fever
2. Presence of middle ear effusion (MEE): bulging tympanic membrane, air fluid level, or otorrhea
3. Signs and symptoms of middle ear inflammation: erythema of tympanic membrane or otalgia that interferes with sleep or normal activity

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1. Treatment of the sacroiliac joints bilaterally using balanced ligamentous tension (BLT)\textsuperscript{35}—The child is supine. The physician contacts the sacrum just medial to the sacroiliac joint with the fingers of one hand and contacts the anterior superior iliac spine with the palmar surface of the other hand. The sacrum is stabilized as the innominate is positioned in anterior and posterior rotation, inflare and outflare, until balanced ligamentous tension is achieved. This position is maintained until tissue relaxation occurs.

2. Treatment of thoracolumbar junction and diaphragm using myofascial release technique (MFR)\textsuperscript{36}—The child is supine. The physician is seated beside the child. The physician places one hand across the chondral masses of the lower ribs and the other hand across the spinous processes of the lower T12 and L1 vertebrae. Alternatively, a hand can be placed on either side of the lower rib cage. The thoracolumbar fascia is gently moved into its superior-inferior, rotation, and sidebending restrictions, applying steady force until tissue relaxation is noted.

3. Treatment of the rib cage using MFR\textsuperscript{36}—The child is either seated or supine. The physician contacts the rib cage posteriorly at the angles with one hand and anteriorly with the other. The thumbs lie along the lateral aspect of the same ribs. A gentle anterior-posterior compression is applied between the two hands until there is a slight decrease in tissue tension. Then the ribs are tractioned laterally. The tissue release is followed until it is completed.

- OR -

3b. Treatment of the rib cage using BLT\textsuperscript{35}—The child is supine. With one hand the physician contacts the rib medial to its angle. The other hand contacts the spinous processes of the two corresponding vertebrae. The rib is tractioned laterally. The physician applies a gentle force to the spinous process to rotate the vertebrae into the restrictive barriers until balanced tension is achieved. This position is maintained until tissue relaxation occurs.

4. Treatment of cervicothoracic area (thoracic inlet) using MFR\textsuperscript{36}—The child is supine. The physician places his or her hands across the top of the patient’s shoulders, contacting the upper ribs anteriorly with the finger tips and posteriorly with the thumbs. The physician applies fascial rotation by simultaneously moving one hand anteriorly and the other posteriorly. The cervical fascia is rotated into its restrictive barrier and a steady force is applied until there is a tissue release.

5. Treatment of cervical area using BLT\textsuperscript{35}—The child is supine. The physician sits at the head of the table. The physician contacts the articular pillar of the superior vertebrae with one hand and the adjacent inferior vertebrae with the other. Rotation and sidebending can be introduced using this contact. The vertebrae are moved through sidebending and rotation to achieve balanced tension. This position is held until there is a release in tissue tension. The procedure is applied to C7 through C3 vertebrae.

6. Treatment of craniocervical junction using suboccipital inhibition\textsuperscript{36}—The child is supine. The physician sits at the head of the table. The occiput is held in the palms of the physician’s hands with the fingers aligned inferior to inion. The physician lifts his or her fingertips into the suboccipital muscles until the muscles relax.

7. Venous sinus drainage technique\textsuperscript{36}—The child is supine. The physician is seated at the head of the table. The physician’s fingertips are aligned along the superior nuchal ridge of the occiput with the fifth fingers at inion. A slight anterior and lateral pressure is applied until there is a change in tissue texture. The physician’s fingertips are then aligned on both sides of the occiput on a cephalocaudad axis. A slight anterior and lateral pressure is applied until there is a change in tissue texture. The physician then crosses the thumbs to contact the parietal bones on opposite sides of the sagittal suture starting at lambda. A slight inferior and lateral pressure is applied until there is a change in tissue texture. The thumbs are moved anteriorly along the sagittal suture and the technique is repeated. The finger tips are then aligned on each side of the metopic suture. A slight posterior and lateral pressure is applied until there is a change in tissue texture.

8. Occipital decompression technique\textsuperscript{36}—The child is supine. The physician is seated at the head of the table. The physician’s fingertips contact the occiput such that the index fingers contact the mastoid portion, the middle fingers are aligned with occipital condyles, and the ring fingers are on the supraocciput. A gentle traction of the occiput is applied posteriorly and then laterally while resisting movement at the mastoid portions until a slight tissue tension release is felt in the occiput equally bilaterally.

9. Sphenobasilar symphysis decompression technique\textsuperscript{36}—The child is supine. The physician is seated at the head of the table and applies a posterior temporal or frontal-occipital hand hold is used. The physician gently decompresses the SBS by moving the sphenoid greater wings anterior-superior and the occiput posterior-inferior until a tissue texture release is felt bilaterally.

Figure 2. Standardized osteopathic manipulative medicine protocol used in the present study.

Both sites had daily availability of OMM providers, who could provide same-day treatment to subjects enrolled that day. All OMM providers used in the study were practicing osteopathic physicians who were faculty members of the departments of osteopathic principles and practice (WV SOM) or osteopathic manipulative medicine (UNE COM) at the participating academic institutions. All of the DOs provided OMM to children regularly in their practices. The OMM providers were selected and trained by the principle investigator (K.M.S.) at site A or co-investigator (J.E.C.) at site B. Monthly OMM standardization sessions were held at each site. There were 3 trained OMM providers at each site. Treatment providers were blinded to the clinical course of the subject.

**Standardized Treatment Protocol and Providers**

The osteopathic manipulative medicine (OMM) treatment protocol was developed in consultation with the principle investigator of a previous study exploring the effect of OMM on otitis media.\textsuperscript{28} Our OMM protocol consisted of nine routine techniques, which have been described in standard reference texts\textsuperscript{35,36} and are summarized in Figure 2. The protocol used myofascial release and balanced ligamentous tension tech-
niques to the pelvis, abdominal diaphragm, torso, and cervical area as well as osteopathy in the cranial field. Parents were enlisted to entertain their children during the OMM protocol, which lasted approximately 15 to 30 minutes.

**Outcome Measurements**

All data collection, management, and entry were performed by the research assistant at each site for each year of the study. Each research assistant at each site gathered data obtained from face-to-face verbal interviews with parents, outpatient tests performed during the study visits, and logs completed by the parents and converted the information into numeric format, entered it into SPSS, encrypted it, and then sent it to an independent statistician at a different institution.

Tympanograms measure MEE by recording the ability of the tympanic membrane to vibrate at different pressures. Standardized protocols exist to determine if the middle ear is likely to be filled with fluid. The “A” and “C sharp” (C1) type tympanograms are considered normal, “O” indicates a tympanic membrane perforation, “not readable” is not classifiable, and “B” and “C rising” (C2) are abnormal. There were 3 tympanograms taken from each ear at each visit, and a second set of 3 tympanograms taken from each ear immediately following the OMM protocol for the first three study visits for those patients in the intervention group. All tympanograms taken from both ears at each visit were stored on a separate Tympanogram Data Collection Form (TDCF), which was created for the present study. All TDCCFs from both sites were numbered (T1, T2, etc). A separate file was created, linking the numbering (T number) to the site, subject number, visit number, ear (right or left), date, and whether it was pre- or posttreatment. All the above identifiable information was removed from the TDCCFs, which were then sent to the audiologist for interpretation. The blinded audiologist selected the best (ie, most healthy) tympanogram for each ear for each visit and assessed each tympanogram in four categories: equivalent ear canal volume (VEA), tympanometric peak pressure (TPP), PeakYa (static admittance), and gradient, in accordance with standard protocols.

Tympanograms were classified into one of the following seven categories and converted into the respective numeric format for data analysis:

- **Type A**—1
- **Type B Flat**—2
- **Type B Wide**—3
- **Type C Sharp**—4
- **Type C Rising**—5
- **Open**—6
- **Not Readable**—7

Any change from B (flat or wide) or C rising to A or C sharp was considered favorable. To analyze the extent to which subjects’ tympanograms changed from “non-A/non-C sharp” to “A/C sharp” during the 30 days of observation, chi-square analyses using SAS statistical software (version 9.2; SAS Institute Inc, Cary, North Carolina) was computed by cross-tabulating the treatment group by the favorable/unfavorable changes in tympanograms readings.

The AR is a simple hand-held device that measures the ability of the tympanic membrane to reflect sound. The AR has been validated as a reliable measure of MEE. This device is designed to be used by physicians and parents. It predicts the likelihood that there is fluid in the middle ear on a Likert scale of one to five, with one and two being low probability of middle ear fluid, and five being high probability of middle ear fluid. The first date of a reading of “1” or “2” was considered the date of effusion resolution.

The tympanogram and AR data were analyzed to determine change in middle ear functioning immediately after the OMM protocol in the intervention group. These changes in readings were compared by treatment by Chi-square analysis using SAS statistical software version 9.2. To analyze the data from the AR readings regarding duration of MEE during the 30-day period, survival analyses using the Kaplan-Meier method computed the differences between the groups on the amount of time elapsed from day one to MEE recovery, as judged by the AR readings, on each ear.

**Results: Preliminary Report**

**Enrollment and Retention**

After the first 9 months of the present study, 56 patients were screened, 34 subjects were enrolled, and 26 subjects completed the study protocol, resulting in 40 cases of AOM studied. During this period, site A screened 18 patients referred into the study and enrolled 7 and site B screened 38 patients referred and enrolled 27 patients (Table 1). Site A had 39% of referred subjects enroll in the study and site B had 71%. Overall, 61% of the subjects screened for to the study were enrolled for participation.

During the first 9 months of the study, the investigators had a 76% patient completion rate. The most common reason for non-enrollment resulted from expiration of the enrollment period. The most common reason for subject drop out was failure to attend appointments (Table 2). No subject drop was due to an adverse event. Most subjects assigned to the intervention group received OMM from more than one osteopathic physician (Table 3).

<table>
<thead>
<tr>
<th>Site</th>
<th>Screened, No.</th>
<th>Enrolled, No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site A</td>
<td>18</td>
<td>7 (39)</td>
</tr>
<tr>
<td>Site B</td>
<td>38</td>
<td>27 (71)</td>
</tr>
</tbody>
</table>

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**Table 1**

Duration of Middle Ear Effusion in Young Children: Percentage of Screened and Enrolled Patients at 9 Months

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**Table 2**

Duration of Middle Ear Effusion in Young Children: Percentage of Screened and Enrolled Patients at 9 Months

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**Table 3**

Duration of Middle Ear Effusion in Young Children: Percentage of Screened and Enrolled Patients at 9 Months
**Table 2**
Duration of Middle Ear Effusion in Young Children: Patient Exclusion, Enrollment, and Completion, No.

<table>
<thead>
<tr>
<th>Status</th>
<th>Site A</th>
<th>Site B</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Referred</td>
<td>18</td>
<td>38</td>
<td>56</td>
</tr>
<tr>
<td>Excluded</td>
<td>10</td>
<td>13</td>
<td>23</td>
</tr>
<tr>
<td>Time commitment</td>
<td>0</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Enrollment period expired</td>
<td>9</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>Enrolled</td>
<td>7</td>
<td>27</td>
<td>34</td>
</tr>
<tr>
<td>Dropped Out</td>
<td>4</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>Completed</td>
<td>3</td>
<td>23</td>
<td>26</td>
</tr>
</tbody>
</table>

**Interim Analysis**
The DSmB convened June 2008 and reviewed the study reports and AR data analysis from the first 15 subjects to complete the study. They reported that there was no reason to recommend cessation of the study; there were no recommended changes to the study; the data was in an adequate form at for statistical analysis, study protocols, and procedures; and data collection forms were appropriate for the desired function.

The primary investigator (K.M.S.), co-investigator (J.E.C.), referring physicians, OMM providers, audiologist, and parents have remained blinded to the outcomes.

**Comment**
Subject referral and enrollment were less than anticipated during the first 9 months of this trial. A factor affecting site A was the loss of three of the five committed referring providers within the first 2 months of the study.

A second factor, which was learned during the first 9 months of the present study, was that to generate and retain referred patients, it is important to have a research assistant stationed full time at the referring providers clinic in order to be a constant reminder of the study, and to enroll patients on the date of referral. The full-time research assistant stationed full time at the referring providers clinic, 16 additional subjects were completed during year 2, resulting in 22 additional cases of AOM. It is clear that getting patients referred into the study is a critical factor in success of any clinical trial, and our experience has shown that factors that increase the number of referrals likewise increase the number of patients enrolled. We recommend that future investigators plan for adequate funding to enhance subject recruitment and recognize that subject recruitment for this prevalent disease is extremely difficult.

Another factor that we believe has reduced the pool of potential patients for our study is the rigorous inclusion criteria, which were established in order to meet criticisms of prior otitis media studies, in which the certainty of diagnoses was questioned.33

**Conclusion**
We reported on preliminary experience with a dual-site, prospective, randomized, blinded, and controlled clinical trial on the effect of OMM on the duration of MEE following an episode of AOM in young children for 30 days immediately following OMM and during 30 days, using tympanogram and acoustic reflectometer readings as outcome measures. We conclude that the study’s OMM protocol can be administered to this subject group with no serious adverse events and that the data is analyzable. Subject referral was slower than expected because of a number of factors, including loss of referring providers at one site, half-time research assistant support at one site, and the rigorous inclusion criterion.

Reporting the final outcomes of this study is planned later this year. We are publishing our experience before analysis and publication of the final study results to allow other osteopathic physicians and researchers to evaluate this standardized protocol in their practices and provide their feedback regarding its clinical efficacy. Also, by reporting our lessons learned thus far, other researchers in this field may be able to better plan to avoid barriers encountered in the present study. A full copy of the manual of procedures is available from the primary investigator upon request.

**Acknowledgments**
We would like to thank the following individuals who provided invaluable assistance in the conduct of the present clinical trial: des Anges Cruser, PhD, research education director for the national Osteopathic Research Center, for her assistance during the design phase of this study; Miriam Mills, MD, upon whose research study this project is based, for her assistance in the design of the OMM protocol and the tympanogram analysis; Hollis H. King, DO, PhD, for serving as chairperson of the DSmB; and Scott Dean, PhD, for his assistance with statistical analysis of the data.


Editor's Note: In this article, the authors use the term osteopathy in the cranial field to describe the palpatory techniques and osteopathic manipulative treatment used to assess cranial dysfunction and to treat patients for such dysfunction. The authors use osteopathy in the cranial field because it is a more universally used term than cranial osteopathic manipulative medicine and osteopathic medicine in the cranial field, which are the terms preferred by the style guidelines of JAOA—The Journal of the American Osteopathic Association.