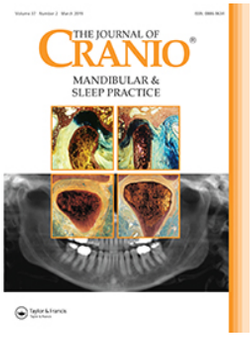

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The effect of specially designed and managed occlusal devices on patient symptoms of tinnitus: A cohort study

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ABSTRACT

Objective: Bioesthetic maxillary anterior guided orthoses (BMAGOs) were designed and adjusted to establish the mandibular location referred to as stable seated condylar position SSCP. This study demonstrates treatment efficacy of this device on tinnitus.

Methods: All patients had histories of temporomandibular disorder (TMD), head, neck and shoulder pain. Each patient wore the BMAGO at all times, eating, talking and sleeping with it functioning as a surrogate occlusion. Patients were seen every two weeks for adjustments. They were provided a self-reporting numeric rating scale (NRS) beginning each visit. NRS scores ranged from 0 to 10, with 10 being the highest intensity pain for 12 TMD symptoms including tinnitus.

Results: A significant decrease of tinnitus symptoms (p<.001) were recorded for all effected patients by visit #12.

Conclusions: These findings firmly support symptomatic reduction of tinnitus.

KEYWORDS

BMAGO; MAGO; TMD pain; tinnitus; seated stable condylar position; (SSCP); optimum occlusion; Occlusal Device

Introduction

A review of existing literature reveals a lack of consistency, or agreement, in occlusal device therapies [1–5]. Prior to the article by Sletten [6], there has been no singular occlusal device design and adjustment protocol published in the scientific world that is based on clearly defined objectives as they relate to an optimal natural stomatognathic model (Figure 1). The authors feel this is because there is no officially accepted theory or model of occlusion [7]. The only literature touting this model comes from publications that do not stand up to the rigors of peer reviewed journals [8–15].

Current dental thought is making a concerted effort to move into the realm of evidence based dentistry (EBD) in making clinical treatment choices. Clinicians must never forget that EBD, first, is that of observation and clinical experience. This precedes all of the random controlled trials (RCTs), meta-analyses, and statistical proofs.

Asserting that an optimum model of occlusion exists is based on the clinical observations and practice of clinicians over the past 27–30 years [8–15].

Dental occlusal concepts have sometimes been based on random supposition, observation, anecdotal opinions, and invention with very little being accomplished in terms of defining occlusion as it relates to the biology of existent pristine adult dental systems.

Pokorney [7] alludes to this fact where over 10,000 articles from the early twentieth century forward were studied in a systematic review of occlusion literature. Limited research has been published describing the optimum biologic interrelationship between jaw function, tooth function, and mechano-receptive guidance [16].

A previously published article by Sletten [6] shows compelling evidence that when stable seated condylar position (SSCP) is achieved, using a surrogate occlusion on a specially designed and adjusted occlusal device known as a bioesthetic maxillary anterior guided orthosis (BMAGO), a large number of head, neck, and temporomandibular disorder (TMD) symptoms are resolved with a very high degree of significance and predictability ($p < 0.001$).

The only symptom not accorded credibility in Sletten's original study was that of tinnitus, due to a lack of power in the sample size. Also, it was unclear from the data gathering points of Sletten as to what this symptom reduction looked like over time [6]. By measuring every appointment, this paper now demonstrates the trend of

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Figure 1. Forty-three-year-old patient demonstrating ideal dental system.

the BMAGO's significance, as well as providing the power necessary to make the results significant and predictable.

The authors define SSCP as that moment when the BMAGO adjustments are not required for three consecutive visits. In other words, this "surrogate occlusion" is stable to evaluation of occlusal contacts with 8 μm shim stock. Patient affirmation of "an even touch," through "feel and feedback," verifies this "touch" has not changed over time. Further, due to the adjustment protocol, the condyles can be said to be fully seated and stable, anatomically. This adjustment protocol, based on observed dynamics of optimal dental systems [8–15], differentiates the BMAGO from other occlusal devices in use.

Tinnitus has been an enigmatic condition that has confounded clinicians for over a century. The American Tinnitus Association states, "Tinnitus incurs significant personal, social and financial cost, both for individual patients and for society at-large [17]." Papers have been written attempting to correlate tinnitus and costs to society [17,18]; tinnitus and depression [19,20]; tinnitus and sleep [19]; and tinnitus with suicide [20–23]. Loprinzi [19] makes the case for tinnitus, when it is personally disturbing to the patient at bedtime, to intervene in order to reduce exacerbation of depression. Seo [23], when looking at the relationship of tinnitus and suicide notes, observed that those patients with tinnitus had a higher incidence of suicide ideation and suicide attempts when compared to a population without tinnitus. Lewis [19], in a rebuttal letter to the editor for Jacobsen, points out in his studies of 1992 and 1994 to be careful in drawing a direct relationship of tinnitus to suicide.

Lewis says suicide is a far more complex issue and to be careful in attaching causality to tinnitus. The author further goes on to say people with depression "are less resilient," but does not agree, necessarily, that tinnitus caused the depression or suicide issues.

Parker [24] and Gelb [25] outline the many possible causal relationships for tinnitus, citing many works dating to the 1920s and 1930s and up through the time of publishing in 1995 and 1997, respectively. The authors make the case for embryological, neurological, muscular, and structural defects that can lead to, or contribute to, tinnitus. Costen [26] was probably the first to attempt to define tinnitus as a syndrome. All the early authors attempted to relate anatomical features and functions as to why ontological/TMD problems might be true.

Later, in the chronology of the literature, Loughner [27], Schmidt [28], Siessere [29], Senciman [30], and Eckerdal [31] again delve into the anatomical dissections of the TMJ and auditory complex, describing and demonstrating the proximities of nerves, vessels, bone, fissures, ligaments, and muscles to one another. Senciman demonstrated movement of the malleus when the anterior maleolar ligament was stretched through its connection to the medial capsule via the petro tympanic fissure and spheno-mandibular ligament.

Many are aware of the atypical pain referral patterns from myofascial trigger points [32]. The pain referral pattern of a non-vital mandibular molar referring pain to a maxillary molar is also well known [33]. It then becomes plausible to accept the possibility of atypical pain patterns occurring within the intricate and intimate anatomical

and neurological complexities surrounding the temporomandibular joints, the inner ear, and cranial nerves. Figures 2 and 3 demonstrate just how closely related the anatomical features are in this area. The petro-tympanic fissure and the connection of the retro-discal tissues to the inner ear shown in these figures is an example [31]. Further, these figures illustrate the concept of just how interrelated and complicated the diagnosis and treatment of cranio-cervical pain can be.

Fernandez [34] and Bernhardt [35] show a clear predictive relationship existing between TMD pain symptoms and tinnitus. Further, Fernandez reported sleep bruxism (SB) alone had no relationship to tinnitus unless accompanied with painful TMD symptoms. This may be due to SB being regulated more from a central nervous system regulatory response than peripheral. Certainly, SB has a relationship to other aspects of TMD symptoms [36]. Also, this may explain why patients taking selective serotonin re-uptake inhibitors (SSRIs) have concomitant SB 44% of the time [37].

The prevalence of tinnitus in TMD patients has been reported. De Felicio [38] and Bernhardt [39] reported the prevalence of tinnitus in TMD patients at 60%. Parker and Chole [24] noted that patients with TMD also had tinnitus 59% of the time. Bush [40] reported the prevalence of tinnitus with TMD to be 38%. Salvetti [41] asserts tinnitus issues rise to 85% in patients with TMD.

Bush [40] and Erlandsonn [42] both reported one-half to two-thirds of their patients' moderate tinnitus symptoms were relieved by stomatognathic treatments. Unfortunately, treatment for the severe tinnitus symptoms was not as effective.

Bernhardt [39] and Attanasio [43] also called for a TMD screening when performing a diagnostic survey for tinnitus patients. This screening could possibly identify which patients with tinnitus could not be helped via occlusal device therapies.

When studying the TMD literature regarding therapeutic results, those of the bio-psycho-social treatment philosophy [1–3] assert a 40–50% reduction in symptoms, or $p < 0.05$ as success. The authors feel, with evidence of 95–100% therapeutic success, the BMAGO should be studied on its compelling biologic merits [6]. The BMAGO design and adjustment process is based on occlusal contact and functional guidance observed in adult dentitions with very little tooth wear, seen in Figure 1. Clinicians achieve the most therapeutic success when the BMAGO is adjusted to SSCP according to the protocol that follows. In other words, maximum BMAGO occlusal contact must become coincident with SSCP [6,9]. Coupling this with patient certified "even" anterior and posterior centric contacts, along with mechano-receptive guidance (seen in Figure 4), the temporomandibular symptoms of popping, clicking, locking (structural symptoms);

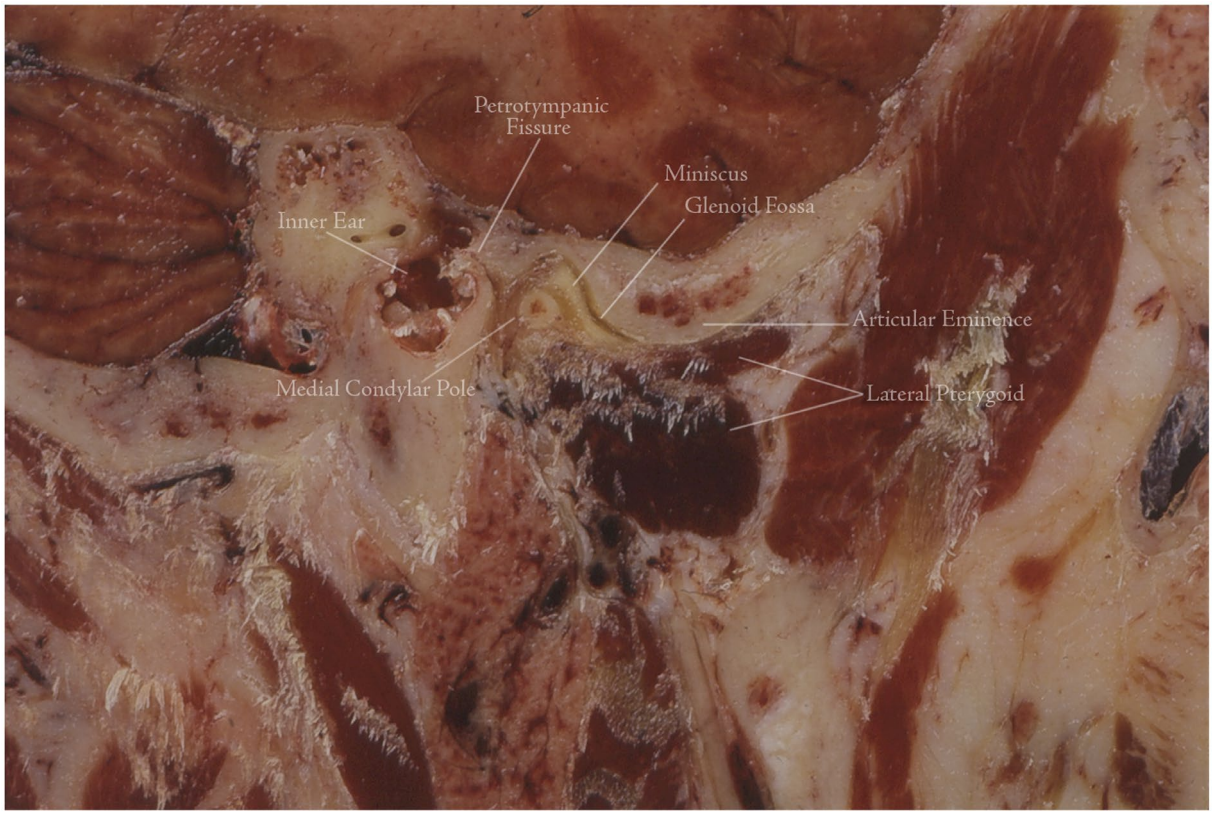
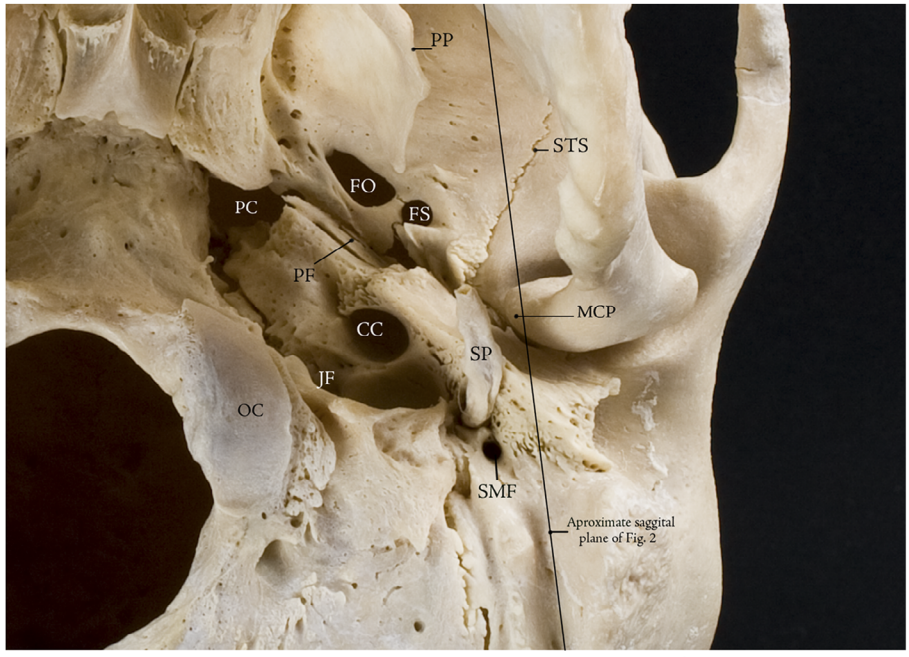


Figure 2. Frozen skull, sagittal section, showing petro-tympanic fissure.



PP = Pterygoid Plate; STS= Sphenotemporal Suture; MPC= Medial Condylar Pole; SP= Styloid Process; SMF= Stylomastoid Foramen; JF= Jugular Fossa CC= Carotid Canal; OC= Occipital Condyle; PF=Petrotympanic Fissure; FS= Foremen Spinosum; FO= Foremen Ovale; PC=Pterygoid Canal.

Figure 3. Skull osteology showing proximity of joint facets, osseous sutures, neurovascular foramina, and muscle attachments.

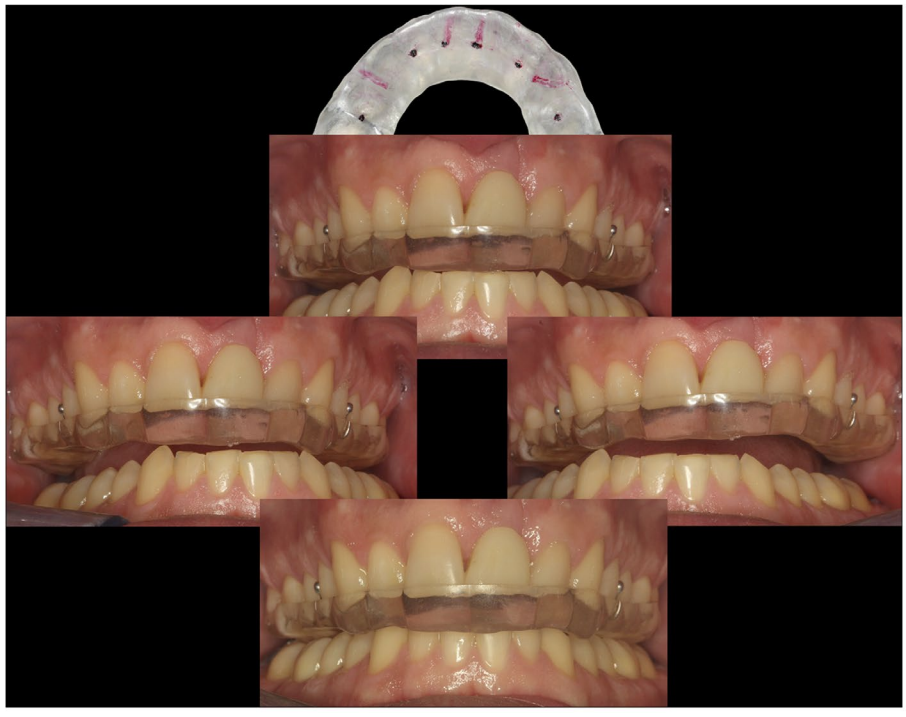


Figure 4. Functional example of a bioesthetic maxillary anterior guided orthosis (BMAGO).

mouth opening pain, clenching and grinding (functional symptoms); headache, earache, shoulder/neck/jaw pain (pain symptoms); and, tinnitus will become minimal or nonexistent [6], as noted in the original article. Thus, the BMAGO design and the specific protocol of wearing and adjustment, has demonstrated this efficacy in consistently reducing head, neck, and TMD symptoms in this cohort of patients.

The purpose of this study was to demonstrate the efficacy of utilizing a BMAGO for treatment of tinnitus. Sletten discovered, in the first paper, that the 12th symptom (ear ringing/tinnitus) almost disappeared by the first

data gathering point (visit #6). While the reduction of the symptom was highly significant ($p < 0.001$), the number of patients in that study did not have enough power to make it predictive.

Materials and methods

Patient selection for this study involved evaluating a private practitioner's TMD practice. At the beginning of each visit to the office, the patients individually recorded their symptoms using a numeric rating scale (NRS). The records were evaluated, and symptomatology intensities were recorded on a spreadsheet. These symptoms were rated from 0 with no symptoms, to 10 equaling the worst possible symptoms.

Twelve symptoms were tested with this NRS. These were: tinnitus, pop, click, lock, clenching, grinding, opening, headache, neck ache, shoulder pain, neck pain, and jaw pain.

Inclusion criteria for this study focused only on the BMAGO effects regarding the symptom of tinnitus during the first 12 weeks of treatment. Two hundred-eight patient charts were analyzed for this analysis using the NRS results. Sixty-four patients demonstrated some level of tinnitus.

Patient data were de-identified at the practice, therefore maintaining the HIPPA compliance obligated to the practitioner. Expedited IRB approval was obtained. Only numerical data was presented for analysis.

The BMAGO, based on optimally functioning natural occlusal orthognathic systems [8–15], provided the platform for helping these patients toward a significant reduction in symptoms [6].

The symptomatology of the 12 TMD markers used in assessing patient improvement was evaluated by having each of the patients self-report their own symptoms on a NRS at the beginning of their appointments. These patients required a variable number of appointments to achieve therapeutic clinical success. Again, tinnitus was the primary interest in this retrospective study. The authors have focused on how each progressed toward relief of symptoms during the early stages of therapy.

The fabrication and adjustment of the BMAGO follows a specific protocol to achieve SSCP.

An open bite centric relation (CR) record is made to articulate earbow mounted casts. Once the mounting and casts are verified for accuracy, the articulator is opened to a vertical clearance of the closest opposing teeth of 2–3 mm, and the incisal pin is locked down. The BMAGO is fabricated with only the four incisors touching upon closure. The anterior intrusive ramp, should be 90 degrees to the long axis of the lower incisors, leaving the required clearance posteriorly. The mouthpiece should fit snuggly without rocking or discomfort. Of major importance with this device, besides patient comfort, is how it is modified and adjusted. Seating/stabilizing of the condyles involves delivering the device with the four lower incisors evenly occluding. This is verified first by 8 µm shim stock, but most importantly, a certification by the patient of absolute evenness. Every patient is capable of discerning an 8 µm prematurity. The patient will point to the lower tooth touching first. That mark will be lightly adjusted until it is not premature (according to the patient). This process continues until the patient cannot discern a prematurity. There being no posterior contact discourages the neuromuscular avoidance pattern from activating; thus, the mandible's arc of closure becomes uninhibited. Gentle bi-manual manipulation [44] facilitates producing even front four occlusal contact. When the patient can't tell which front tooth touches first, and biting contact feels like "a line," they are dismissed to wear the BMAGO for 2–3 days, 24/7, with anterior incisor contact only, taking it out only to clean it. At the next visit, if there has been any condylar seating, the front four contacts will not be as even as they were. The surrogate occlusion of the BMAGO reveals that any condylar settling will change the way the teeth contact the anterior ramp. Thus, the same process is repeated. Once the anterior occlusal discrepancy, created by condylar seating, is identified and adjusted, posterior resin is added to both right and left sides and adjusted to flat plane posterior occlusion with lateral canine guidance.

In order to be certain the patient is actually adjusted correctly, and not demonstrating an occlusal avoidance pattern, 3–5, 0.003 in.-thick tinfoil shims are applied with shim wax to the anterior ramp of the BMAGO. Direct application of shims to the BMAGO provides the patient with instant deprogramming. The patient is then instructed to lightly tap together a few times. Any posterior occlusal contact would be considered a prematurity and is very lightly removed. Also, if any posterior occlusal contact marks were previously noted in the resin, they should be removed immediately. Once the posterior no longer marks with indicator mylar, a shim is removed. This process is repeated until all shims are removed and the patient contacts on all teeth are in centric occlusion, except the laterally sensitive canines, holding 8 µm shim stock. Once achieved, the patient is interviewed as to what touches first. Contacts should be absolutely "even." When this is true, the patient is dismissed to be seen again at the next visit. Occurring over a series of appointments, the NRS and the tin shim procedures are repeated until the patient reports even contact for three consecutive appointments.

The protocol for how the BMAGO is made and adjusted is distinctly different from other occlusal device therapies. These differences are as follows:

(1) It is worn 24/7 for the duration of treatment and removed only to clean.
(2) The patient relationship is important in their self-reporting of symptoms via the NRS. They will also tell the clinician, upon questioning, if they are even or uneven in their occlusion. An anterior prematurity usually indicates a subtle posterior prematurity on the contralateral side.
(3) Repeating the "shim challenge," previously described, allows the clinician to predictably determine when SSCP is achieved.

Once SSCP is determined, an accurate diagnosis and treatment of the orthognathic system can be made.

The nonparametric Friedman test was applied. The null hypothesis assumed there would not be any difference in NRS responses between appointments 1 and 12, as applied to tinnitus. Probability (p) values (>0.05, non-predictive; <0.005, highly predictive) were applied to box plot graphs to show the numeric data recorded.

Results

The null hypothesis applied to the tinnitus symptoms was dismissed. With a power size of 64, the BMAGO was highly predictive in reducing the symptoms of tinnitus. Even in adjusting for multiple tests, the "p" value was found to have a significance of ($p < 0.001$) from 1 to 11 visits.

Adjusting for multiple tests, the only range not having a predictive significance was from visit #6 to visit #11, with an adjusted value ($p = 0.356$). With no adjustment for multiple tests, the "p" value was significant at ($p = 0.005$).

This should come as no surprise when the boxplots are studied (Figure 5). Much of the success in tinnitus reduction occurred earlier in the treatment. The statistical boxplot graphs show a significant decrease in the inter-quartile range (IQR) as well.

Half of the patient population is contained within the box in the middle of the graph. The darker line in the middle separates the lower inter-quartile range from the upper. In other words, that line is the mean. Interestingly, by visit #6, half of the population no longer has tinnitus. By visit #11, even the upper quartile group, 75% of patients no longer have reportable symptoms of tinnitus.

Also, the population base of tinnitus patients to the cohort equaled 30.7%. This is in the range of tinnitus patients reported in other studies [6,24,38,39,43].

Discussion

The importance of dental occlusion profoundly affecting adjacent anatomical and physiologic systems has been quite obscure if not essentially unknown up to and including the present health culture. The teeth are the hardest tissues of the body. They have a tactile acuity of less than 8 μm when occluding 600–2000 times/day during

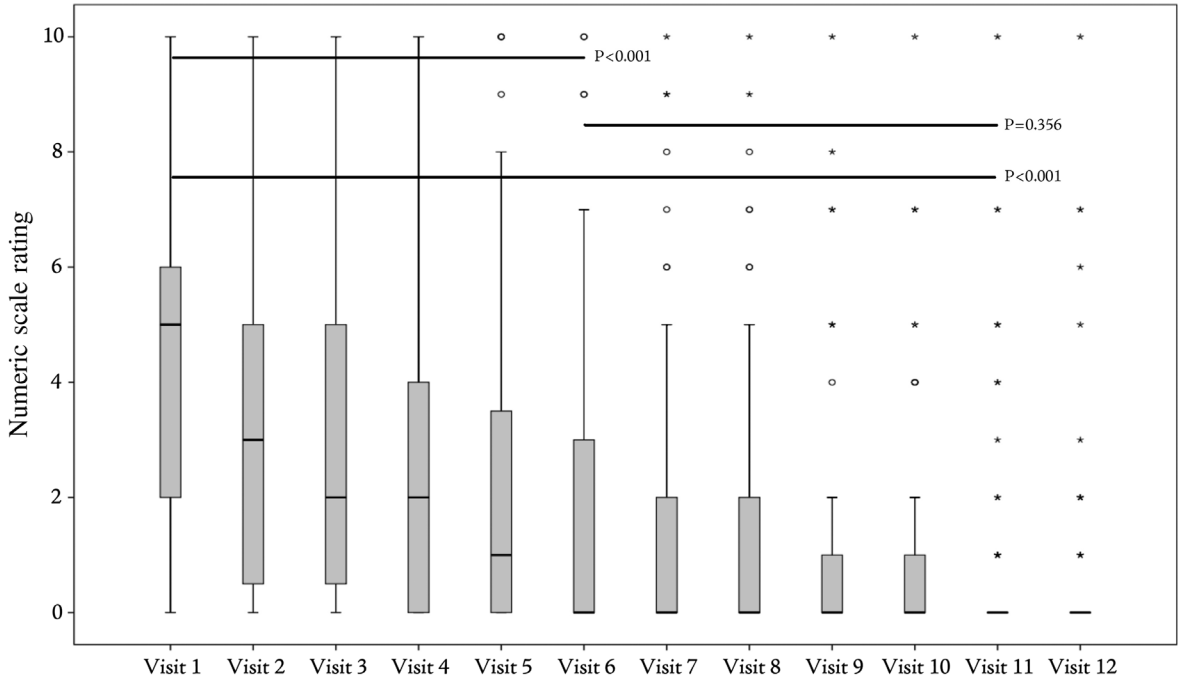


Figure 5. Boxplot graph of results.

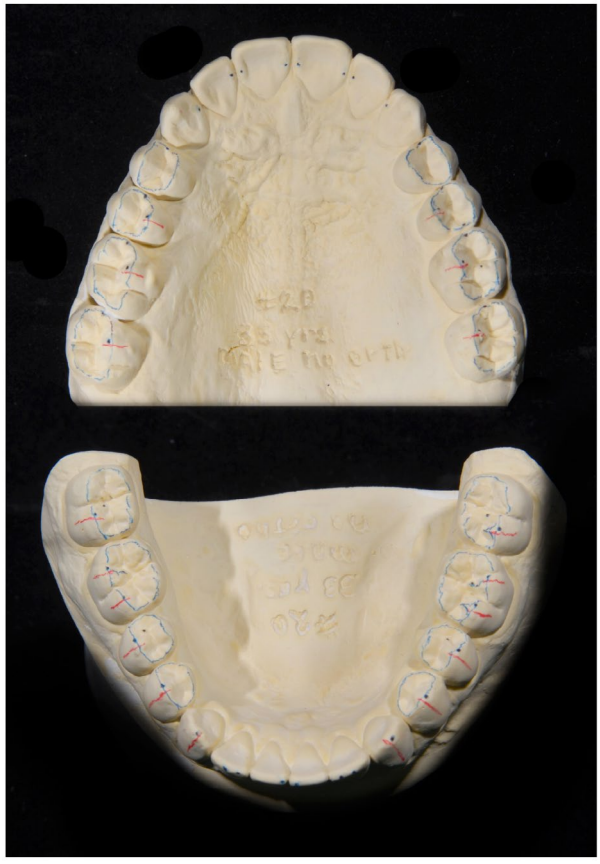


Figure 6. Thirty-eight-year-old, casts of optimal occlusion-occlusal view.

swallowing and other touching functions. Two questions become apparent: (1) Does malocclusion generally adversely influence the health of the surrounding tissues? (2) Are the BMAGO effects reversible? The current study, as well as that of Sletten [6], has affirmed both questions.

Lee [9] was the first to observe tooth wear as being an initial disease process. The author was the first to postulate the existence of an optimum biologic model for the stomatognathic system. Simply put, this model exists because there are people with three observed, mutually held anatomical features: (1) Their condyles are in SSCP with co-incident MIP = CR = CO. (2) They demonstrate biologic tooth form with minimal wear. (3) Anterior/lateral and intrusive guidance is present in these people. Commonly, anterior coupling occurs within the range of 2–3 mm overjet and 2–4 mm overbite. When these three principles have been met, dental chewing systems have been observed to last a lifetime with minimal wear to the teeth. No research to date has promoted this model, other than the predictive results achieved from Sletten [6] and this paper.

Close scrutiny of the casts in photos (Figure 6) reveals a dental system of a 38-year old with an optimal occlusion. Noteworthy is the ideal biologic form to the teeth with the overjet and overbite previously described (Figure 7). The minimal numbers of tooth-to-tooth contacts can be observed, as well as their point sizes. Most interesting are the contacts touching convex to convex surfaces. The natural ideal dental anatomy is interesting for how it departs from invented occlusal configurations.

Beyron [45], in 1969, actually advocated a similar occlusal scheme, though it was not as sophisticated as presented by what nature has created. Another observation is the amount of space that actually exists between the contacts, allowing for efficient chewing of food and

Figure 7. Thirty-eight-year-old, casts of optimal occlusion, MIP view/overbite and overjet.

provision for sluiceways for food to escape without tooth collision.

The BMAGO provides a surrogate occlusion that fulfills two of the three principles. It delivers tactile contacts, but not biologic tooth form.

The purpose of Sletten's original study [6] was to evaluate BMAGO effects on all 12 symptoms, including tinnitus. Two things occurred: (1) Tinnitus disappeared by the second data gathering point (visit 6 or 12 weeks) and was not predictive. (2) The remaining 11 symptoms did not achieve predictive clinical relief until well after visit 12 (3 months) and even as far along as visit 18 (36 weeks). To study tinnitus, it became necessary to study the BMAGO effects weekly, in the first 24 weeks at each visit. This enabled adding new patients to the cohort, due to the passage of time in the practice. These additions to the cohort yielded a tinnitus power sample large enough to be predictive. The purpose of this study was to analyze the BMAGO effects on tinnitus. Sletten's [6] paper, which studied the effects of the BMAGO on the other 11 symptoms, required a much longer time frame for their resolution.

Further, because these data come from a fulltime practice with special emphasis on treating TMD issues, very few patients chose not to immediately proceed to definitive treatment (< 5%). Those patients not proceeding with definitive care were encouraged to continue using the BMAGO as a nighttime device. This further supports the assertion that the BMAGO is reversible in its effects.

Interestingly, when used as a nighttime device, clinicians experienced with the BMAGO can observe subtle changes occurring in the stomatognathic system from what is recorded on this device. They have come to appreciate that maybe subconscious bruxism is more a response to the effects of "sleep-malocclusion" than bruxism. As the jaws relax and occlusal contact occurs in the act of swallowing, any prematurity detected will activate the protective neuromuscular avoidance pattern known as sleep bruxism. The teeth on the softer BMAGO resin will record the prematurity and subsequent jaw movements. The BMAGO will also reveal the CNS response when SSRIs are being used. The effects of any nocturnal malocclusion can be observed on the BMAGO at subsequent re-care visits and can be adjusted. Living individuals do, in fact, have continuous micro changes taking place as their soft tissues adapt to the subtleties of their new stable position. The BMAGO facilitates efficient management of these living realities.

Practitioners treating patients with head and neck pain have achieved varying success relieving their patients of tinnitus, as well as other TMD symptoms. If systemic, neurologic, inner ear, and aging processes are ruled out, BMAGO therapy should be considered, since the patients in this study achieved successful resolution of their tinnitus. There may be severe types of tinnitus that likely would not be helped with a BMAGO. The outliers seen within the boxplot graph are evidence of this.

As with the previously published paper on the BMAGO, "The effect of specially designed and managed occlusal devices on patient symptoms and pain: a cohort study," the authors again assert there is an optimum biologic dental system health model of occlusion and function [6,8,10]. This model is built into the BMAGO. By establishing a SSCP, coincident with even occlusal contact, as well as facilitating anterior mechano-receptive guidance [16], major symptomology disappears [6]. Once these parameters are established in treating patients' orthognathic issues, their health invariably improves. Maybe the lack of an optimal health model, as it pertains to the stomatognathic system, is why Ebrahim's [46] 2016 systematic review of the literature on splint therapy admits to inconsistent results. The paper indicates only moderate success with splints relieving TMD symptoms.

The authors of the present study again assert there has been no defined optimal stomatognathic model to treat toward. Now, with the optimal model defined by Lee [9] and this paper, there is a specific splint protocol that is precise and predictable in its methods.

To the authors' knowledge, no other paradigm speaks to definitively achieving the parameters outlined above [7]. The BMAGO is designed to emulate the elements of an ideal stomatognathic system, with the exception of biologic tooth form. This device acts as a model to facilitate improved health.

Quoting Sletten [6], "When symptoms are not affected by previously mentioned procedures [with the BMAGO], they are not likely, due to an orthopedic mandible to cranial base/dental occlusion interface problem." In those cases, the BMAGO facilitates a differential diagnosis, so co-morbid issues can be considered. Further, the protocol of fabricating, delivering, and adjusting a BMAGO does require specific training and practice.

The current dominating theme in dental literature favors the medical management model in TMD therapy. In fact, one Author [48] went so far as to attach the label, "unethical" to treating patients orthognathically by specially trained dentists. This prevailing mindset leaves little opening to patients who might be helped, even cured, rather than "managed" with ongoing drug therapies, physical therapy and psychotherapy [47,48]. Admittedly, there may be those patients who require those services. However, to relegate everyone to the biopsychosocial realm of treatment, without a complete understanding or experience of how an ideal orthognathic system functions and adapts, could be considered unethical as well.

Clinicians treating TMD patients with success over the last 27 years, while using the BMAGO process, have

come to appreciate that treatment in this realm of TMD is not "either/or," but, rather, "both/and" problem solving [8–15]. In other words, there is room for both biopsychosocial and a stomatognathic approach to treatment. If the desire to achieve long lasting positive results for patients is the goal, maybe the dental profession should open the plausible door to understanding the optimal dental system model of health [9].

Conclusion

Significant reductions in the symptoms of tinnitus were recorded when the BMAGO was used in accordance with the clinical protocol. Clinical implications of the splint specified in *General Dentistry*, March/April, 2015 and the clinical techniques associated with its design and management, provided symptom and pain reduction in the dental system and adjacent tissues for 12 TMD symptoms [6]. These implications can now be extended, with predictability, to symptomatic reduction of tinnitus as well.

The authors agree with Bernhardt [39] and Atanasio [43] in their call to screen patients for occlusal/physical contributors for their tinnitus. The results obtained within this study echo results from other studies, with two major exceptions:

(1) This present study asserts that an optimal health model of occlusion does exist, and, it is time to study healthy dental form and function, rather than disease alone. Even Siessere [29] says, "… the integrity of a complex joint such as that of the jaw is the result of a balance interaction of soft tissue and bony structures."
(2) The data seems to suggest overwhelming predictability of results when the stomatognathic system is in balance. This balance is achieved when the role of the teeth in stabilizing the dental system is recognized, as well as respecting the "… soft tissue and bony structures [29]."

A prospective random clinical trial would be the next step in further validation, plus in-depth analysis of existent unworn adult dental systems.

Contributors

L. Parnell Taylor performed the literature review, prepared the references, citations and figures. Taylor, DDS, wrote the main body of the paper. Tom Dumont, DDS, provided editorial support and literature citations as well. Sletten, DDS, retrieved the data and made the spread sheet from which the analysis was made. Sletten also made editorial contributions.

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Disclosure statement

No potential conflict of interest was reported by the authors.

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