

The effect of specially designed and managed occlusal devices on patient symptoms and pain: a cohort study

Wayne O. Sletten, DDS, MSD ■ L. Parnell Taylor, DDS ■ Charles J. Goodacre, DDS, MSD ■ Thomas D. Dumont, DDS

There is limited data regarding the benefit of using an occlusal device to help patients resolve a variety of symptoms involving temporomandibular disorder, as well as head, neck, and shoulder pain. The purpose of this study was to evaluate the effect of a carefully adjusted occlusal device on 12 symptoms to determine if there was enough evidence to justify a randomized control trial of this methodology. Splints were designed to ensure a stable, reproducible, mandibular position in a cohort of 157 dental patients with mixed histories of the following 12 symptoms:

temporomandibular joint “pop,” “click,” and lock; jaw, neck, shoulder, and mouth-opening pain; headache; earache; tinnitus; and clenching and grinding of teeth. The results showed significant improvement ($P < 0.001$) in 11 of the 12 symptoms.

Received: March 19, 2014

Accepted: July 2, 2014

Key words: splints, TMD, pain, occlusion, BMAGO

Few areas of study in dentistry's long history have been beset by anecdotes and supposition more than the subject of occlusion and temporomandibular disorder (TMD). The modern era of evidence-based dentistry requires verifiable published scientific evidence. However, when a new procedure is introduced into clinical practice, dentists may tend to rely on its observed results more than formal research. This study attempts to bridge the gap between anecdotal and verifiable research evidence as a precursor to a randomized controlled trial (RCT) testing the procedure.

Although there are still differences of opinion regarding the effect of occlusion upon a patient's pain experience, interocclusal devices have been widely used in the management of occlusion and TMD. They are removable, adjustable, moderately functional, and arguably noninvasive. Acrylic devices can serve as a surrogate dental occlusion, providing a hard interface that may be utilized to observe, test, and treat many dynamic aspects of the dental system. The 3 important functions of an interocclusal device are to facilitate the alignment of orthognathic and adjacent tissues, aid in the investigation of neuromuscular avoidance patterns, and simplify the measurement of occlusal contact sensitivity tolerances. If worn during sleep, properly managed splints can be protective and calming while preventing the destructive outcomes of nocturnal parafunctions (such as bruxing and clenching).¹

A potential benefit to researchers and clinicians is the identification and elimination of parafunction through timely, meticulous adjustments. By eliminating occlusal interferences, splints may assist in reducing head and cervicobrachial pain. This was confirmed by Kirveskari, Kirveskari & Jamsa, and Karppinen et al in their studies on natural dentition adjustments.²⁻⁴ Occlusal devices can also indicate medication-induced parafunctional side effects, serving as a differential diagnosis when the orthopedic cause of disharmony has been removed.⁵ A web-based review of over 70 manuscripts—including RCT splint studies—revealed that in the vast majority of the splint articles reviewed, precise descriptions of design, management, and physiologic goals were missing. For example, while studies by Ekberg & Nilner, Ekberg et al and Nilner & Ekberg showed positive results for TMD appliance therapy, there were few specifics regarding the actual design, adjusting procedures, and splint use.⁶⁻⁸ In general, the studies favorable to splint therapy outnumbered those that were unfavorable, but many of the papers showed minimal and/or insufficient evidence either for or against the use of stabilization therapy when subjected to the close scientific analysis of RCTs. This indecision concerning the usefulness of stabilization therapy was most clearly exemplified in a 2004 article by Al-Ani et al.⁹ Alencar & Becker found that 3 different splints (hard, soft, and nonoccluding), counseling, and self-care equally reduced

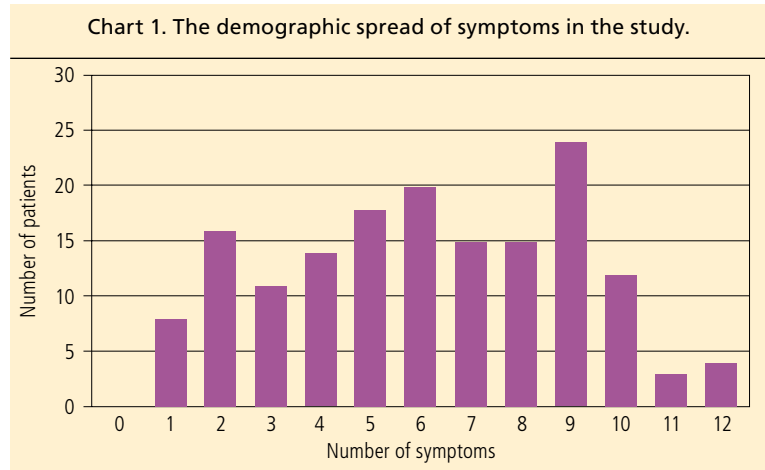
TMD symptoms.¹⁰ However, in a 1966-2006 literature review of intraoral devices, Donovan et al found that “hard occlusal devices have good evidence of modest efficacy in the management of painful TMD.”¹¹ Similar conclusions were found by Dupont & Brown in a review of literature from 1855-2006 and a position paper on TMD by the International College of Cranio-Mandibular Orthopedics in 2011.^{12,13} Splints were originally generated as therapy devices in reaction to discomfort and/or deformity and not for dental system alignment in preparation for a diagnosis.¹⁰⁻¹³ No published research was found validating a common standard for splint care in relation to dental system alignment.

The authors conducted informal chairside tests by intentionally placing a 5-10 μm thick prematurity using bonding resin. The splint used in these tests was intended to very quickly activate neuromuscular avoidance by the patient, even with a prematurity as miniscule as 5-10 μm . A splint protocol with clear, optimal, physiologic treatment goals and a well-defined design and management plan could provide an effective process for dealing with a complex dentognathic system.

It has been proposed that people with the most ideal natural dental systems can help serve as a model for splint design and function.¹⁴ These dental systems exhibit 3 main attributes: a coincident relationship between maximum intercuspation (MI) with positive incisor contact and



Fig. 1. Anterior view of a 48-year-old patient's mouth indicating optimal dentostomatic health: little wear, excellent guidance, and maximum intercuspation equating to centric relation (CR).



stable condylar position (SCP), incisive and canine guidance that disallows posterior tooth contact until final closure, and minimally worn teeth.¹⁴ These findings in nature are referred to as *optimal biologic dental system principles* (Fig. 1).

Materials and methods

Knowledge of optimal biologic dental systems determined the form and management of the splint used in this study: a *bioesthetic maxillary anterior-guided orthosis* (BMAGO). A numeric rating scale (NRS) for symptom intensity was recorded every visit over the course of each patient's splint therapy.

The cohort analysis consisted of 157 symptomatic dental patients with mixed histories of TMD, head, neck, and shoulder problems seeking care at a private practice dental clinic over an 8-year period. A significant portion of this population had experienced previous orthodontic and TMD/pain treatments, including various splints and pharmaceuticals. All patients in this study completed the prescribed therapy regimen. There were 12 men (8%) and 145 women (92%), ranging in age from 15 to 74 (median 40.2) years. BMAGO splints were placed in each patient. The patients' BMAGOs were adjusted at 2 week intervals until mandibular positional stability was achieved.

Each patient required a variant number of adjustment appointments to achieve the treatment goals. The range was 4-34 visits. Each appointment began with the patient completing a self-reported NRS ranging from 0 (no symptoms) to 10

(highest intensity level) for each of the following 12 symptoms: temporomandibular joint (TMJ) "pop," "click," and lock; jaw, neck, shoulder, and mouth-opening pain; headache; earache; tinnitus; and clenching and grinding of teeth. Chart 1 depicts the number of declared symptoms for each patient at his/her initial visit. A recorded NRS score ≥ 5 from 1 of the 12 symptoms at the first visit was needed for the patient data to be included in this demographic analysis.

Demographics of a multisymptom population

This process enabled the clinician to track symptom sensitivity as perceived by the patient. Only the NPR scores from Visits 1, 6, 12, and 18 are presented. The exact length of treatment time was different for each patient, with an average time of 6 months from the start of the protocol to condylar stabilization. The severity of the malocclusion, state of the TMJ, age, and compliance of the patient were all factors that determined the amount of time necessary to position and stabilize the mandible for diagnosis.

Since the 12 categories shared some similarities, they were placed into 4 subgroups. These subgroups were *structural* (Group 1): pop, click, and lock TMJ symptoms; *functional* (Group 2): clenching, grinding, and mouth-opening pain; *pain* (Group 3): headache, earache, and shoulder/neck/jaw pain; and *tinnitus* (Group 4). Even though the BMAGO dramatically reduced the symptom of tinnitus in the sample, Group 4 was

dropped from the analysis due to the small size of the sample, which prohibited it from being statistically predictive.

BMAGO fabrication and clinical adjustment

The goal of a BMAGO stabilization splint is dictated by the optimal biologic dental system principles. The device will establish SCP through regular adjustments, allowing muscle function to normalize and provide for the best possible positioning of the condyles in the glenoid fossae.

The technique used in this protocol begins by initially recording the condylar position in centric relation (CR). Condylar and mandibular positional changes invariably occur during BMAGO therapy. With malocclusions, it is assumed the jaws have adapted for best fit of the teeth, thus the condyles are most likely not ideally positioned in the fossae. By carefully relaxing and bimanually manipulating the mandible, a beginning CR allows the condyles to move toward a more seated position, that is, closer to being seated in the glenoid fossae.¹⁵ In almost all malocclusions, the initial or starting CR position has been found to be a less seated and, therefore, significantly different position than after BMAGO therapy. The commitment to stabilize the condyles is based on the CR and MI being very close or coincident to SCP, as found in optimal biologic dental systems.

The BMAGOs were made using clear methyl methacrylate resin. First, maxillary and mandibular casts were fabricated. The maxillary casts were mounted on an articulator using an average axis facebow.¹⁶ The



Fig. 2. Photograph of CR-articulated casts using discluded CR registration.



Fig. 3. Photograph of the patient's smile showing the shim challenge phase of the adjustment process.

mandibular casts were then mounted to the maxillary casts using open CR occlusal registrations (Fig. 2).

The articulator was opened until 2 mm separated the closest point between the maxillary and mandibular casts. The splint base was then fabricated on the maxillary cast. The BMAGO is fitted to the maxilla because it furnishes the most stable platform for anterior and lateral mechanoreceptive guidance.¹⁷

The incisal edges of the mandibular incisors provide a mechanoreceptive input that aids in positioning and stabilizing the mandible, as observed in optimal dentitions. Therefore, anterior acrylic resin centric occlusal stops were developed that engaged only the 4 mandibular incisors in CR. Next, a low-angle ramp for smooth central incisor/intrusive guidance on the splint base was shaped. To expedite the seating process, initially no posterior occlusal contact distal to the incisors was provided. The BMAGOs were then fitted and adjusted on each patient so that the 4 mandibular incisors all touched evenly, with each incisor holding 8 μ m thick shim stock in a centric occlusal closure. Enkling et al found that subjects can discern a 14.2 μ m central occlusal prematurity.¹⁸ As previously stated, the authors of this study have found that subjects are more sensitive at the 5-10 μ m level of sensitivity. The BMAGO technique calls for interactive patient input as a key element in gaining an absolute evenness of the mandibular front 4 incisor closing contacts. Each patient is asked where the first point of contact is, and the BMAGO is adjusted until the patient cannot discern

a contact difference. The condition becomes apparent when all 4 mandibular incisors contact evenly and feel “like a line” to the patient. Beside the positional benefits derived from this beginning form of occlusal engagement, significant symptomatic improvement has previously been proven with the more abbreviated anterior nociceptive trigeminal inhibitory (NTI) jig in a study conducted for the US Food and Drug Administration.¹⁹

Once seated, the patients were instructed to wear their occlusal device 24 hours/day, 7 days/week—including while speaking, eating, and sleeping—and *only* removing the BMAGO for brushing, flossing, and cleaning. They were instructed to do so until mandibular positional stability was established. Patient compliance with this curriculum is the key to success with BMAGOs. The BMAGO must become the patient’s “teeth” so the proprio/mechanoreceptive input is not mixed with different occlusal contact signals. Empirical experience has taught that the protective nature of the central nervous system (through the neuromusculature) will hold back complete condylar seating if it senses that the existent malocclusion will be used in any way. Stability of the mandible is determined when the locations of the occlusal contacts have not required adjustment for a minimum of 3 weeks.

In this study, the BMAGO, with anterior-only stops, was initially worn for 2 days, after which the patient returned to have the 4 incisor contacts rechecked for evenness and adjusted if necessary. The authors have found that the simultaneous

uniform contact of the 4 incisor contacts—once established without posterior input—will serve as a valuable guide in assessing both condylar movement and stability throughout the process. The mandibular 4 incisor contact position acts as a constant with the condyles being the moveable variables.

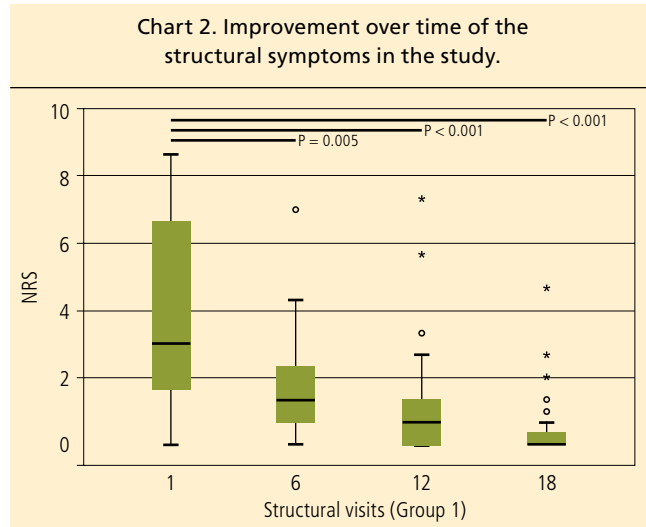
Autopolymerizing acrylic resin was then added to the left and right posterior platforms of the splint from the canines to the most posterior molar. The patient was instructed to lightly close, touching the front 4 contacts until the initial resin polymerization was complete. The splint was then immersed in a warm water pressure pot for complete polymerization. Posterior stops representing the buccal cusp tips of the mandibular posterior teeth were adjusted (using black Mylar occlusal ribbon) until there was equal light contact. Incisor and canine guidance were marked on the splints with red Mylar and carefully adjusted.

Cuspal anatomy is not used on the BMAGO. Most condyles can be seated and stabilized for diagnosis with even, functional, mandibular, posteribuccal cusp tip contact on the splint. While anterior-contact-only deprogramming appliances have been shown to be symptomatically effective, it has been found empirically that an equalized functioning posterior contact is necessary to establish condylar seating and stabilization.²⁰

Adjustments were made every 2 weeks utilizing the “shim challenge.” A thickness-adjustable anterior deprogrammer was made, consisting of 4 shims of soft tinfoil



Fig. 4. Photograph of the fully adjusted bioesthetic maxillary anterior-guided orthosis with centric contacts in black and excursive marks in red.



held together with shim wax (76.2 μm each) (Fig. 3). The patient was instructed to make 2 firm taps (with black Mylar) in CR on the shims on the right and left sides of the BMAGO. Any occlusal contact marks were lightly reduced using a fine straight hand-piece acrylic resin laboratory bur. The process was repeated until the tapping did not produce any posterior marks. Then 1 shim was peeled away, and the process continued until very light, even, occlusal contact marks remained after the final shim was removed. Because of high interocclusal sensitivity, the patient was continually engaged during the process to assess the evenness of the posterior and incisal contacts. Once equal tactile contacts on the BMAGO were coincident with CR, the appointment was completed.

At the beginning of each appointment, the 4 incisal contacts were assessed for evenness. An uneven anterior contact indicated avoidance of a premature posterior contact due to condylar seating. At the point that even, simultaneous contacts between the splint and the 4 mandibular incisors were re-established, the condyles were again considered seated with occlusal contact equaling CR. This process was repeated at each visit until no condylar change was apparent for >3 weeks. The dental system was then considered stable enough to diagnose.

The mandibular to cranial base relationship occurring on the splint is the equivalent of achieving MI in a dentition coincident with CR. This eventually

becomes a SCP over multiple visits, a relationship previously noted in outstanding dental systems. Recent research “found a significant correlation between MI-CR discrepancy and signs and symptoms of TMD,” indicating the potential benefit of this coincident relationship as a treatment goal.²¹ In this study, excursive movements were marked with red Mylar at each appointment, establishing canine and central incisor guidance with related posterior clearance during mandibular movements. All other excursive marks were eliminated as shown (Fig. 4).

Jaw position, occlusal contact between the mandibular teeth and the BMAGO with bimanual jaw manipulation, chin point guidance, and hands-free closure should all feel the same to the patient whether laying down or sitting up at the end of each appointment.

Statistical analysis

The nonparametric Friedman test was applied using the null hypothesis that there would be no significant difference in each patient’s symptomatic response between the Visit 1 and Visit 18. Probability (P) values (>0.05, not predictive; <0.005, highly predictive) were calculated with box plot graphs to visually depict the numerical data.

Results

The null hypothesis applied to Groups 1, 2, and 3 from Visits 1-18 was rejected, as highly predictive improvement ($P < 0.001$) was shown.

In all the statistical box plots (Charts 2-4) there was a significant decrease in the interquartile range (IQR) for the various conditions from Visits 1-18. As the therapy progressed, the reported range of symptom intensity for the cohort decreased on the high end of the range from Visits 1-18 as follows: Group 1, from 4.0 to 0.33; Group 2, from 7.0 to 1.67; and Group 3, from 6.0 to 1.25.

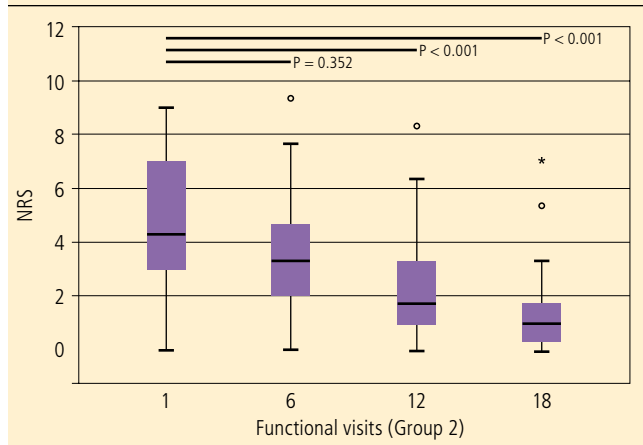
Group 1 structural TMJ symptoms (pop, click, and lock)

The observed range of self-reported symptom intensity was between 0 and 9 on the NRS. The IQR (representing half of patients treated) was from 1.85 to 6.7 (Chart 2). The dark line in the chart represents the median pain intensity of 3.0 for the TMJ complaints. The mean rank of response among the 4 visits (Visits 1, 6, 12, and 18) did not stay the same (Friedman test, $df = 3$, $P < 0.001$). There was a highly significant steady decrease in patient symptom response. According to *post hoc* results, the least significant measurement ($P = 0.005$) occurred between Visits 1 and 6. The ranges of high significance were recorded between Visits 1 and 12 and Visits 1 and 18 ($P < 0.001$).

Group 2 functional symptoms (clench, grind, and mouth-opening pain)

The observed range of self-reported symptom intensity was between 0 and 9.5 on the NRS. The IQR of complaints was

Chart 3. Improvement over time of the functional symptoms in the study.



3.0 to 7.0 with a median of 4.2 (Chart 3). The mean rank of response among the 4 visits did not stay the same (Friedman test, $df = 3$, $P < 0.001$). There was a dramatic steady decrease in the patient symptom response. The *post hoc* results showed significantly less intensity of functional symptoms in the later visits compared to earlier visits ($P < 0.05$); the results for Visits 1 and 6 were $P = 0.352$, whereas the results for Visits 1 and 12 and Visits 1 and 18 were $P < 0.001$.

Group 3 pain (average of headache, neck, shoulder, and earache)

The observed range of self-reported symptom intensity was between 0 and 10 on the NRS. The IQR of complaints was 2.0 to 6.0, with a median of 4.0 (Chart 4). The mean rank of response among the 4 visits did not stay the same (Friedman test, $df = 3$, $P < 0.001$). A highly predictive steady decrease in the patient response level was recorded. The *post hoc* results demonstrated significantly less intensity of pain symptoms in the later visits compared to earlier visits ($P < 0.001$).

Charts 5-8 visually depict the progressive reduction of symptoms per person in the BMAGO care population, starting from Visit 1 (baseline) through Visits 6, 12, and 18.

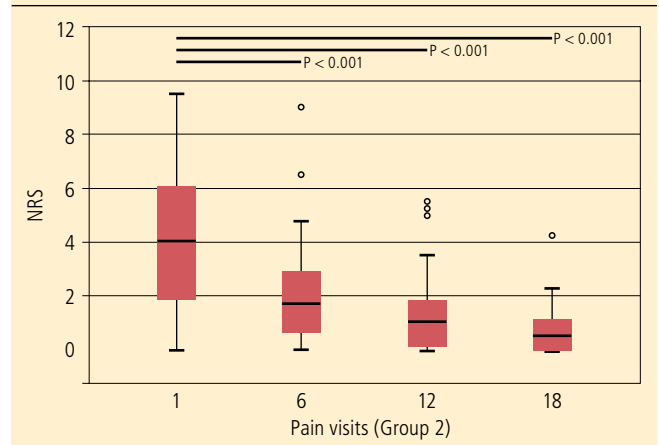
Discussion

The cohort results demonstrate that the BMAGO splint used for mandibular stabilization can provide highly predictive

symptom reduction ($P < 0.001$) in dentognathic and adjacent systems. This efficacy may have been due to the SCP and specific parameters required for the cited design, management, and patient compliance for the BMAGO. These findings may help serve as a starting point to establish what Harrel & Nunn suggested as the next step towards establishing “an evidence based approach to occlusal treatment that is reproducible among clinicians so that it can be standardized for optimal results.”²² The BMAGO appliance process is very specific. The protocol tracks each individual “biologic response” and can take up to 9 months, depending upon the complexity of the dental system treated. The object is to align the condylar articulation for each patient between the mandible and cranial base in preparation for orthognathic diagnosis and treatment. To the authors’ knowledge, the appliance protocol presented here has been developed and refined through empirical chairside applications by practitioners for over 20 years.

This study attempts to bridge the gap between anecdotal and science-based research. It is hoped this will improve the practice standard for hands-on, patient-based, dental system care. This system offers a new paradigm for dental system diagnosis and treatment and a context for how it can be rendered. With optimal biologic dental system principles as a guide, a detailed plan for a distinct treatment destination can be developed and

Chart 4. Improvement over time of the pain symptoms in the study.



implemented.²³ The primary use of the BMAGO has been to utilize that optimal blueprint to position and stabilize the condyles. The intention of this study was to document the favorable side effects of the BMAGO process on symptomatic patients. However, the general reduction in symptoms speaks not only to the validity and effectiveness of an optimal health model as a specific goal for treatment but also to the connectivity between the dental and adjacent tissue systems.

A review of the 157 patient records revealed that 90% of this group proceeded with treatment after stabilization and diagnosis. The full spectrum of procedures, from conservative subtractive coronoplasty to orthognathic surgical procedures, was employed to fulfill the optimal biologic dental system principles. Those who did not continue with treatment were encouraged to wear the BMAGO nightly for preventative protection. The review also disclosed that there was no return of symptoms with this group in the posttherapy reports after >8 years of using BMAGO applications. Groups 1, 2, and 3 demonstrated a dramatic decrease in symptom intensity when comparing Visit 1 and Visit 18. The phenomenon is consistent with what clinicians have empirically reported when treating these types of pain patients with BMAGOs.

The results of this study also show the potential benefit of using BMAGO therapy for a differential diagnosis. When symptoms are not affected by

Chart 5. The demographic spread of symptoms at Visit 1.

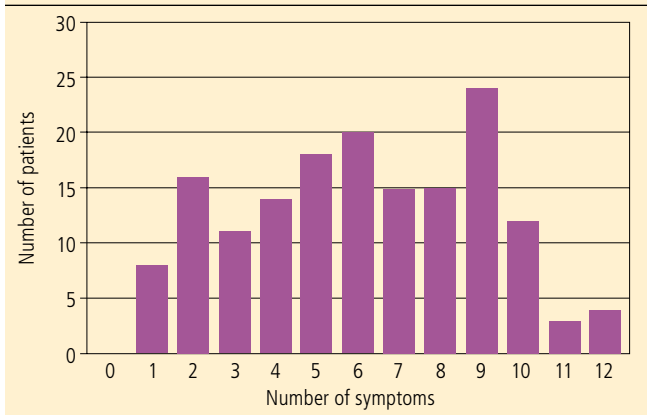


Chart 6. The demographic spread of symptoms at Visit 6.

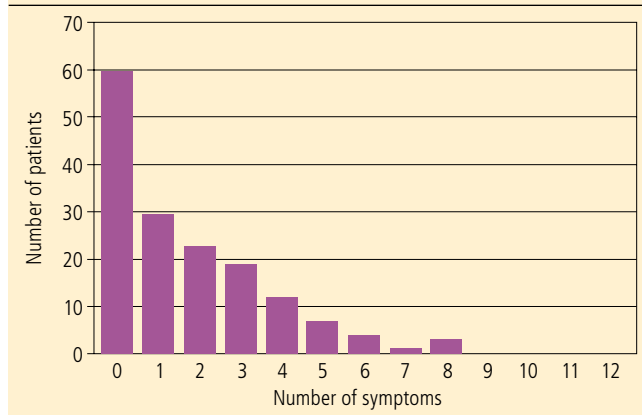


Chart 7. The demographic spread of symptoms at Visit 12.

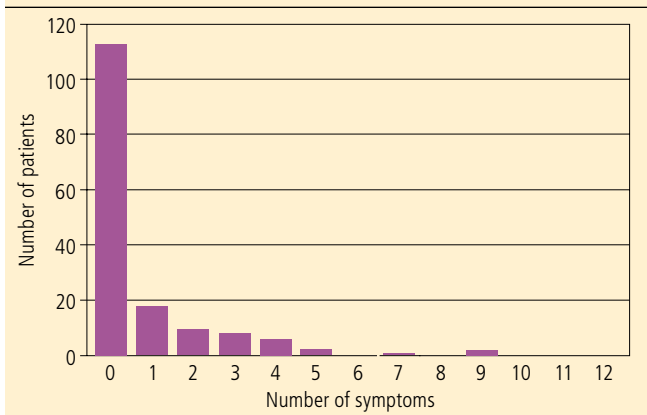
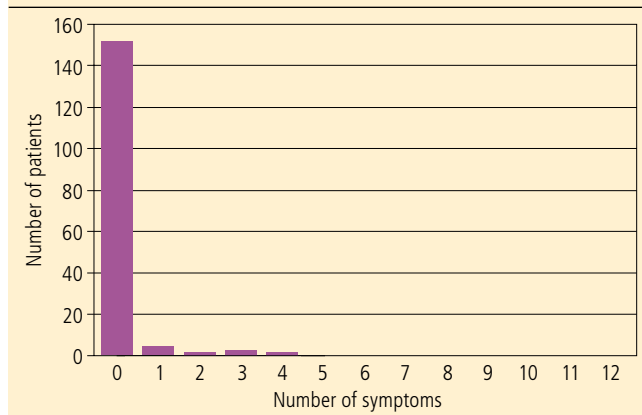


Chart 8. The demographic spread of symptoms at Visit 18.



the previously mentioned procedures, they are not likely due to an orthopedic mandible to cranial base/dental occlusion interface problem. Techniques for proper delivery and management of the BMAGO require training. The dramatic reduction of symptoms presented here, while anecdotal, should represent enough of an evidence basis of health improvement to warrant BMAGO research in the form of prospective clinical RCTs.²⁴

Conclusion

This cohort study of 157 patients with symptoms of TMD and/or head, neck, and shoulder pain found that the design, management, and optimal physiologic goal of achieving a stable SCP using the BMAGO intraoral splint produced highly predictive symptom reductions in 11 of the 12 examined symptoms.

The symptoms that exhibited highly significant reductions were TMJ pop, click, and lock; jaw, neck, and shoulder pain; headache and earache; and clenching, grinding, and mouth-opening pain. Further research, in the form of RCTs, is necessary on the BMAGO.

Author information

Dr. Sletten is in private practice in Albert Lea, Minnesota, and is an assistant professor, Department of Orthodontics, University of Minnesota, Minneapolis. Dr. Taylor is an associate professor, Department of Restorative Dentistry, Loma Linda University School of Medicine, California, where Dr. Goodacre is a professor. Dr. Dumont is in private practice in Ashland, Oregon, and a faculty member at the OBI Foundation for Bioesthetic Dentistry, Medford, Oregon.

Acknowledgments

The authors would like to thank Udo Oyoyo, PhD, for his statistical expertise. This paper was presented at the Roth Williams International Association of Orthodontists, Paris, France, in October, 2012. It was also presented at the Orognathic Bioesthetics International Annual Meeting, Las Vegas, Nevada, in November, 2012.

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