

# **The Effect of Bioesthetic Splints on Patient Symptoms and Pain: A Cohort Study**

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## **ABSTRACT**

**Statement of problem.** There is limited data regarding an effective reproducible standard for occlusal devices (splints) in helping patients diminish multiple symptoms involving temporomandibular disorders (TMD), head, neck and shoulder pain.

**Purpose.** To evaluate the effect of a Bioesthetic Maxillary Anterior Guided Orthosis (BMAGO) splint on twelve different patient symptoms.

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**Material and methods.** BMAGO splints were designed, placed and managed with stable seated condylar position (SSCP) as a goal for treatment in a cohort of 157 symptomatic dental patients with histories of TMD, head, neck and shoulder pain. This group included numerous post orthodontic and previously treated TMD/pain cases. The form and functional relationships found in optimal natural dental systems were used as a goal for treatment. The patients were provided a self-reporting Numeric Rating Scale (NRS) each visit ranging from zero to ten with ten being the highest intensity pain level for the 12 symptoms: TMJ pop, TMJ click, TMJ lock, jaw pain, headache, neck pain, shoulder pain, earache, ear ring (Tinnitus), clenching, grinding, and opening pain. Data was gathered for this study from the first, sixth, twelfth, and eighteenth visits.

**Results.** There was highly significant improvement ( $p < .001$ ) in eleven of the twelve symptoms. The number of patients (power) with ear ring (tinnitus) limited the ability to determine if a significant effect occurred with this symptom.

**Conclusions.** There were highly significant reductions in the symptoms of temporomandibular and/or head, neck and shoulder pain when a BMAGO hard surface occlusal device (splint) was used. Further research using prospective clinical randomized controlled trials (RCTs) is desirable.

**Clinical Implications.** The BMAGO splint described in this article and the clinical techniques associated with its design and management provided symptom and pain reduction in the dental system (DS) and adjacent tissues.

## INTRODUCTION

The history of dentistry has included several different concepts of occlusion and there continues to be differences of opinion related to the effect or lack thereof of tooth contact upon symptoms and/or pain some patient's experience. Of the many services rendered in dentistry, acrylic resin interocclusal appliances (splints) have been widely used in the management of occlusion, TMD and patient pain. They are removable, adjustable, moderately functional and arguably noninvasive. They also can serve as a surrogate dental occlusion.

Acrylic resin splints provide a hard, but softer than teeth interface, that may be utilized to observe, test and treat many dynamic aspects of the dental system (DS). Three

important functions are: (1) they can facilitate structural alignment of orognathic and adjacent tissues, (2) aid investigation of neuromuscular avoidance patterns and (3) simplify the measurement of occlusal contact sensitivity tolerances. Properly designed and managed splints can be protective and calming if worn during sleep in preventing the destructive outcomes of nocturnal parafunction in the form of bruxing and clenching.<sup>1</sup>

A potential benefit that remains controversial to researchers and some clinicians is identification and elimination of parafunction through timely, meticulous splint adjustments. Splints, by taking away occlusal interferences, could likely affect the results of head and cervicobranial symptom reduction as achieved by Kirveskari and Karppinen on natural dentition adjustments.<sup>2,3,4</sup> It has been stated that splints can reveal medication induced parafunctional side effects<sup>5</sup> through surface markings serving as a differential diagnosis when the orthopedic cause of disharmony has been removed. Unfortunately, these uses of “splints” have not been well validated in the literature. An internet review of 70+ manuscripts including random controlled trial (RCT) splint studies using key words: “oral splint/appliance, TMD therapy” and “dental occlusal stabilizing splints” revealed that in the vast majority of these “splint” articles, precise descriptions of design, management and physiologic goals were missing. For example, while numerous studies by Ekberg and Nilner<sup>6,7,8</sup> were considered effective in TMD appliance therapy, there were few specifics regarding the actual design, adjusting procedures and splint use. Seemingly, a common theme in the literature is that a “splint” is a generic tool with an assumed known form and function that is randomly applied to an oral system to see what happens. In general, the studies favorable to splint therapy outnumbered those unfavorable, but many of the papers showed minimal and/or insufficient evidence for or against the use of stabilization therapy when subjected to the close scientific analysis of RCTs. The Cochrane Collaboration<sup>9</sup> most clearly exemplified that opinion. Alencar and Becker found that three different splints; hard, soft and non-occluding, counseling and self care equally reduced symptoms using the Mod-SSI test.<sup>10</sup> However, Donovan et al in a 1966-2006 literature review of intraoral devices found that “hard occlusal devices have good evidence of modest efficacy in the management of painful TMD”.<sup>11</sup> Similar conclusions were arrived at in both an abstract by Dupont and Brown reviewing the literature from 1855-2006<sup>12</sup> and also a position paper on temporomandibular disorders by the International College of Cranio-Mandibular Orthopedics in 2011.<sup>13</sup> Splint care in essentially all of the references studied was generated as a therapy device in reaction to TMD and not for purposes of DS

alignment in preparation for a diagnosis and treatment plan. Therefore, no solid standard for splint care pro or con could be discerned in the authors literature review. Perhaps a “splint” protocol with clear, optimal, physiologic treatment goals along with well-defined design and management could provide plausible therapeutic evidence for effectively dealing with the very sensitive and reactive dentognathic system. A simple test by any dentist can demonstrate common human occlusal awareness. If a prebond resin is applied to a molar stamp cusp occlusal contact point, blown down as thin as possible and light cured, the patient will identify that precise spot immediately upon the first closure. If the resin is left in place for 5-10 minutes, the mandible will adapt away from the prematurity to make the bite fit better. That example of sensitivity and response is produced with a 5-10 micron thick<sup>14</sup> prematurity of prebond resin on the tip of a molar cusp. **Therefore, human proprioceptive awareness demands highly specific operator management complete with a defined objective and patient input to align, seat and stabilize the condyles in the glenoid fossae.**

It is proposed that people with ideal natural dental systems help serve as a model for splint design, management and a goal for therapy. They exhibit three main attributes: (1) **a coincident relationship between maximum intercuspation (MI) and stable, seated condylar position (SSCP)**<sup>15</sup>, (2) **incisive and canine guidance** (vertical and horizontal overbites) that disallows posterior tooth contact until final closure and as a result, (3) **minimally worn teeth**. These findings are referred to as the Optimal Biologic Dental System Principles. Other findings in this group often include: A Class I jaw and dental relationship, very little restorative dentistry, excellent periodontal health, and no history or evidence of temporomandibular joint problems. These exceptional individuals can be found in all age groups. (Fig.1)



Fig. 1 A 48 year old patient with little wear, ideal guidance and MI equating to CR exemplifies optimal DS health.

Cognizance of this optimal biologic DS should influence the form and management of a splint. The splints used in this series of patient treatments were designed to facilitate as closely as possible the qualities of ideal jaw relationships and are termed “Bioesthetic Maxillary Anterior Guided Orthoses” (BMAGOs). Because of the many anecdotal benefits reported using this type of splint, it was decided to create a more objective study by officially recording baseline pain symptoms using the Numeric Rating Scale (NRS) from a cohort of patients and monitoring them throughout their splint therapy.

## **METHODS AND MATERIALS**

The cohort analysis consisted of 157 **symptomatic** dental patients with mixed histories of TMD, head, neck and shoulder problems gathered at a private practice dental clinic over an 8 year period. A significant portion of the population had experienced previous orthodontic and TMD/pain therapies including splints and pharmaceuticals. All the patients in this study completed the BMAGO therapy. There were 12 males and 145 females (92%) ranging in age from 15-74 with an average age of 40.2 yrs. BMAGO splints were placed in each patient using a design and technique to be described. Patients in this study were under close splint supervision with the BMAGO being adjusted at approximately two week intervals until mandibular positional stability was achieved.

Each appointment began with the patient completing a self reported NRS ranging from zero (no pain) to ten (the highest pain level) for each of the following twelve symptoms: TMJ pop, TMJ click, TMJ lock, jaw pain, headache, neck pain, shoulder pain, earache, ear ring (Tinnitus), and pain on clenching, grinding and opening. The graph below (Fig. 2) depicts the number of declared symptoms, out of 12, for each patient of the cohort study at their initial visit. To be counted, a pain intensity level of **5 or more** was necessary using the NRS (0-10) on the first visit prior to BMAGO treatment.

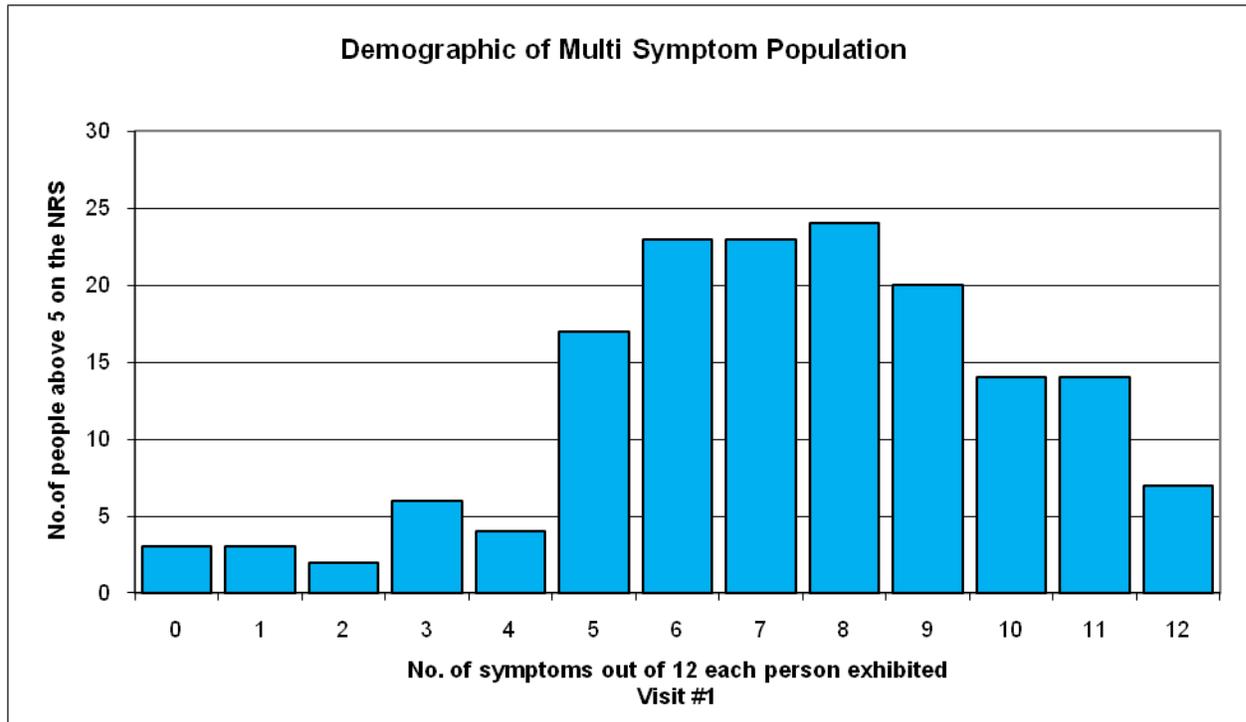


Fig. 2

This process enabled the clinician to track symptom sensitivity as perceived by the patient. For this article, only the numbers from the 1<sup>st</sup>, 6<sup>th</sup>, 12<sup>th</sup> and 18<sup>th</sup> visits are depicted. This study is unique in that the quest for condylar stability was driven by that attribute and the form and function of optimally healthy dental systems. The exact length of treatment time was different for each patient with the average time for completing the protocol being 6 months. The severity of the malocclusion, the state of the TMJs, the age and compliance of the patient were all factors that determined the amount of time necessary to positionally stabilize the mandible for diagnosis.

The twelve categories were placed into four subgroups designated as Structural, Functional, Pain and Tinnitus. The Structural Group consisted of pop, click and lock symptoms in the TMJ. The Functional Group included clenching, grinding and opening. The Pain Group consisted of headache, earache, shoulder, neck and jaw pain. Tinnitus was analyzed as a separate subgroup.

### **BMAGO Fabrication and Clinical Adjustment**

The goal of a BMAGO/ stabilization splint is to establish SSCP through regular adjustments that allow 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 recording the condylar position in centric relation (CR). Condylar and thus mandibular positional changes invariably occur during BMAGO therapy. With malocclusions, it is assumed that in MI, the jaws have adapted to fit the teeth together and the condyles most likely are not ideally positioned in the fossae. By carefully relaxing and bimanually manipulating the mandible, a *beginning* CR position is facilitated. The condyles are therefore in a different location and closer to being appropriately positioned.<sup>16</sup> The *initial* or *starting* CR has been found to be a less seated and different position than SSCP after BMAGO therapy in most malocclusions. That may partially explain condylar instability following some comprehensive dentistry using CR as a treatment position. ***The commitment to stabilize the condyles is based on CR and MI being very close or coincident to SSCP as found in outstanding natural dental systems.***

The BMAGOs were made using clear methyl methacrylate resin. Fabrication began by making impressions and pouring maxillary and mandibular casts. The maxillary casts were mounted on an articulator using an average axis face bow.<sup>17</sup> The mandibular casts were then mounted to the maxillary casts using either open occlusal or Roth power *centric relation* (CR) registrations. (Fig.3)

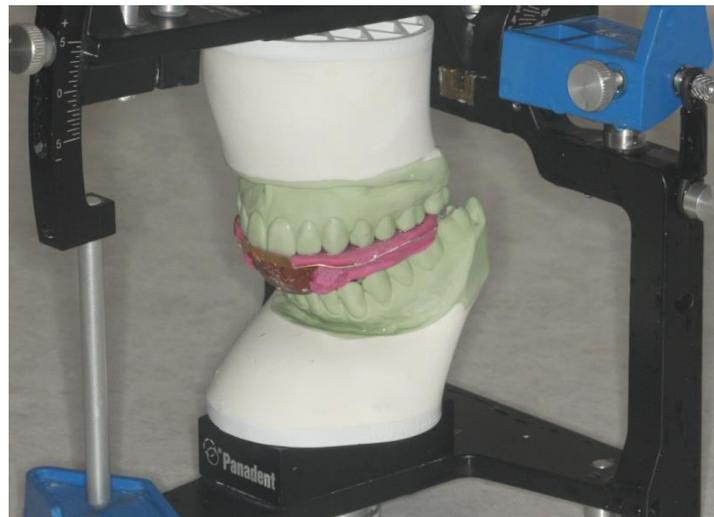


Fig. 3 Mounted models with an open bite registration in CR  
(Panadent Corporation, Grand Terrace, CA)

The articulator was opened with the incisal pin until about 2mm separated the closest approximation of the maxillary and mandibular occlusal surfaces. That close proximity is usually found between the most posterior teeth. The splint base was then

fabricated on the maxillary cast. The BMAGO is fitted to the maxilla because it furnishes the most stable platform upon which anterior and lateral proprioceptive guidance can be constructed for the ever mobile, adapting mandible.<sup>18</sup>

It is proposed that the incisal edges of the mandibular incisors will provide mechanoreceptive input that aid in positioning and stabilizing the mandible as observed in exceptional dentitions. Therefore, anterior acrylic resin centric occlusal stops are developed that engage only the four mandibular incisors in CR and also include a low angle ramp for smooth central incisor (protrusive/intrusive) guidance on the splint base. To jumpstart the seating process, initially no posterior occlusal contact distal to the incisors is provided. The BMAGOs are then fitted and adjusted on the patient so that the four mandibular incisors all touch evenly with each incisor holding 8 micrometer thick shim stock in centric occlusal closure. Enkling et al tells us that humans can discern a 14.2 micrometer prematurity.<sup>19</sup> We know it is a least that from the prebond resin experiment previously cited. Therefore, the technique calls for interactive patient input as a key element in gaining absolute “evenness” of the mandibular front four 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. That condition becomes apparent when all front four contacts touch 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 also been proven with more abbreviated anterior nociceptive trigeminal inhibitory (NTI) appliances having similar limited occlusal contacts in a study conducted for the U.S. Food and Drug Administration.<sup>20</sup>

***Once seated, the patients begin 24/7 wear; speaking, eating, and sleeping with their appliance, ONLY removing the BMAGO for brushing, flossing and cleaning until mandibular positional stability is established. Patient compliance with this curriculum is the key to success with BMAGOs. The BMAGO must become the patients “teeth” so the proprioceptive 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 judged to be achieved when the locations of the occlusal contacts have remained stable on the BMAGO not requiring adjustment for a minimum of 3 weeks.

In this study, the splint with anterior only stops was initially worn for 2 days after which the patient returned to have the four incisor contacts rechecked for evenness and adjusted if necessary. Experiential findings show that simultaneous uniform contact of the four incisor contacts, once established without posterior input, will serve as a valuable guide in assessing both condylar movement and stability throughout the process. ***Therefore, the mandibular four incisors provide the baseline mandibular contact position, acting as a constant with the condyles being the moveable variables.***

Auto polymerizing acrylic resin is then added to the left and right posterior platforms of the splints from the canines to the most posterior molar. The patient is then instructed to lightly close, touching the front four contacts until the initial resin polymerization is complete. The splint is then submerged in a pressure pot for complete polymerization. Posterior stops representing the buccal cusp tips of the mandibular posterior teeth are then adjusted until there is equal light contact when using black Mylar Accufilm (Midwest Dental, Wichita, Texas). Incisor and canine guidance's are marked on the splints with red Mylar Accufilm and carefully adjusted. Cuspal anatomy is not used on the BMAGO. Most condyles can be seated and stabilized for diagnosis with even, functional, mandibular, posterior buccal cusp tip contact on the appliance. ***While 'anterior contact only' deprogramming appliances have been shown to be symptomatically effective,<sup>21</sup> it has been found empirically that equalized functioning posterior contact is necessary to seat and stabilize the mandible.***

In the process of seating and stabilizing the condyles, adjustments were made approximately every 2 weeks utilizing the "shim challenge". A thickness adjustable anterior jig deprogrammer is made that most often consists of 4 shims of .003 inch (76.2 microns) thick dead soft tinfoil held together with shim wax (Fig.4).



Fig. 4 BMAGO shown peeling off one of the four .003 in tinfoil shims serving as an adjustable jig

The patient is then instructed to make two firm taps in CR on the shim jig with black accufilm on the right and left sides of the BMAGO. Any occlusal contact marks are lightly reduced using a fine straight hand piece acrylic resin laboratory bur and the process repeated until the tapping does not produce any posterior marks. Then one shim is peeled away and the process continued until very light, even occlusal contact marks remain after the final shim is removed. Again, because of high interocclusal sensitivity, the patient is continually questioned during the process to assess the “evenness” of the posterior and incisal contacts. Once equal tactile contacts on the BMAGO are achieved, centric occlusion (CO) and CR are coincident and the initial appointment is completed.

At the next appointment the four incisal contacts are again assessed for evenness. ***It is observed that incisor unevenness is an adaptive result (avoidance) of premature posterior contact caused by condylar seating movement.*** Shims are then reapplied and the splint is adjusted ***posteriorly*** until even, simultaneous, 8 micrometer tolerant contacts between the splint and the four mandibular incisors are re-established. The condyles are again considered seated with CO equaling CR at that moment in time. This process is repeated at each visit until no condylar change is apparent for 3+ weeks. The dental system is then considered stable enough to diagnose. This mandibular to cranial base relationship is the splint equivalent of achieving MI (CO) coincident with CR which eventually becomes SSCP, a stable center of rotation 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”<sup>22</sup> indicating the potential benefit of this coincident relationship as

a treatment goal. Excursive movements were then marked with red accufilm establishing canine and central incisor guidance with related posterior clearance during mandibular movements. All other excursive marks were eliminated. (Fig.5)



Fig. 5 Ideal BMAGO occlusal markings after each shim challenge visit. Centric contact is shown in black and excursive movements in red

Jaw position and 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 non-parametric Friedman Test was applied using the null hypothesis: There would be no significant difference in patient's symptomatic response between the 1st and 18<sup>th</sup> visits. Probability (p) values ( $> .05$  not significant,  $< .005$  highly significant) were calculated with Box plot graphs used to visually depict the numerical data.

## RESULTS

The null hypothesis stating: "There would be NO significant change in symptoms in Groups (1) Structural, (2) Functional or (3) Pain and (4) Tinnitus from visit 1 thru visit 18" was rejected. Highly significant improvement ( $p < .001$ ) was shown in categories (1), (2) and (3). Tinnitus is included in this paper because of the dramatic results achieved using the BMAGO. What occurred with this symptom happened in the first six visits and is incidental to the purpose of this project. The power (size) of the sample limited any ability to call it predictive even with a significance level at  $p = .05$ .

In all the statistical box plots (Figs. 6-9) there was a significant decrease in the inter quartile range for the various conditions as the visits advanced from 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: Structural- 4.0 to 0.33, Functional- 7.0 to 1.67, Pain- 6.0 to 1.25 and Tinnitus- 3.0 to 0.0 (by Visit #6).

Group (1) Structural Joint Problems (average of Pop, Click, and Lock)

(1) The observed range of self-reported symptom intensity was between 0 and 9 on the NSSS. The inter quartile range (IQR) representing half of patients treated was from 1.85 to 6.7. The dark line represents the median pain intensity which was 3 for pop, click and lock complaints.

(2) The mean rank of response among the 4 visits (1st, 6th, 12th, and 18th) did not stay the same (Friedman test,  $df = 3$ ,  $p < .001$ ). There was a highly significant steady decrease in patient symptom response.

(3) Post Hoc Results: The least significant measurement ( $p=.005$ ) occurred between visits 1 vs 6. The ranges of high significance were recorded between visits 1 vs 12 and visits 1 vs 18 ( $p < .001$ )

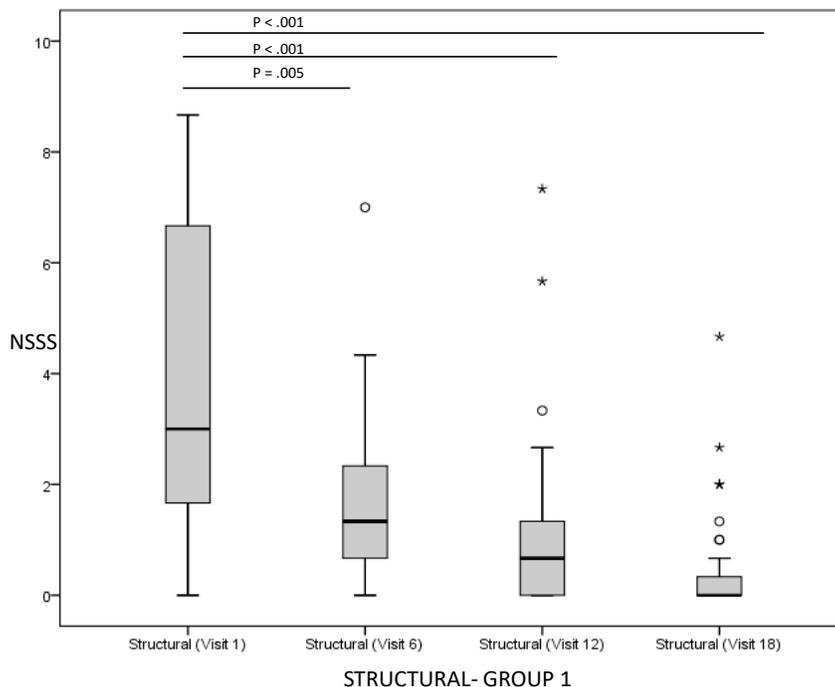


Fig.6

Group (2) Functional Issues (average of clench, grind and open)

- (1) The observed range of combined functional symptoms was from 0-9.5, on the NRS, while IQR of complaints was 3.0 to 7.0 with the median being 4.2.
- (2) The mean rank of response among the 4 visits did not stay the same (Friedman test,  $df = 3$ ,  $p < .001$ ). There was a highly significant steady decrease in the patient symptom response.
- (3) Post Hoc Results: Later visits demonstrated significantly less intensity of functional symptoms compared to earlier visits ( $p < .05$ ). Visits 1 vs 6 ( $p = .352$ ), visits 1 vs 12 and visits 1 vs 18 ( $p < .001$ ).

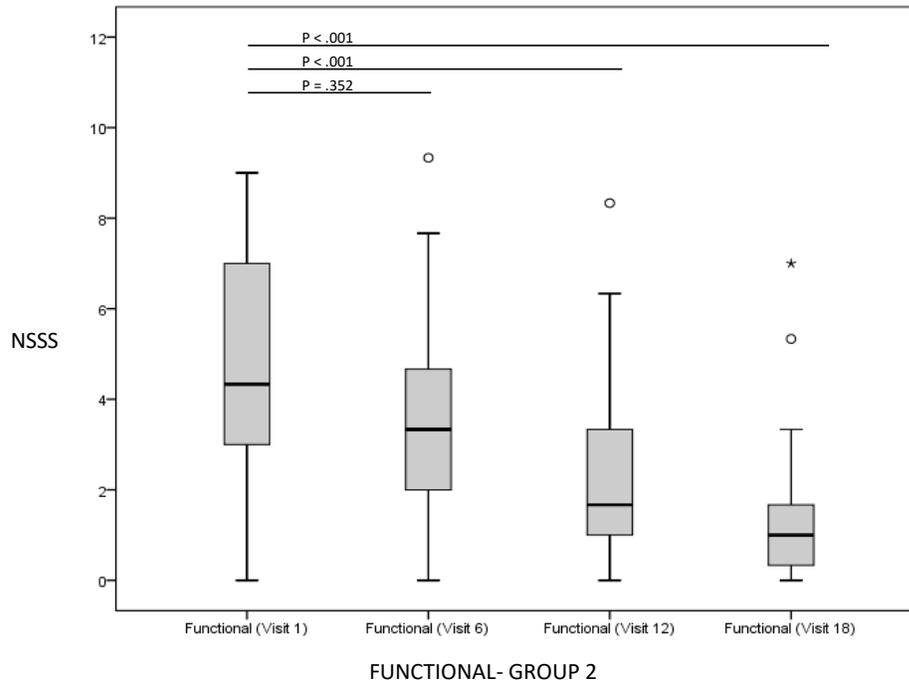


Fig.7

Group (3) Pain (average of Headache, Neck, Shoulder, Earache)

- (1) The observed range for the combined symptoms of pain on the NRS was from 0-10. The IQR was from 2-6 with a median of 4.
- (2) The mean rank of response among the 4 visits did not stay the same (Friedman test,  $df = 3$ ,  $p < .001$ ). A highly significant steady decrease in the patient response level was recorded.
- (3) Post Hoc Results: All later visits demonstrated significantly less intensity of pain symptoms compared to earlier visits ( $p < .05$ ) Comparing visits 1 vs 6, 1 vs 12, or 1 vs 18, ( $P < .001$ ).

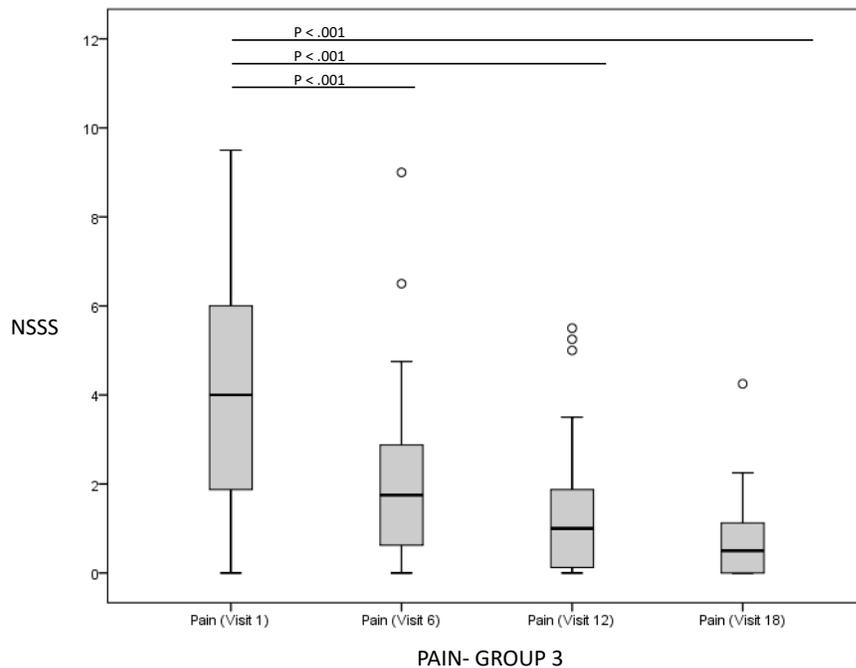


Fig.8

#### Group (4) Tinnitus

Of the 157 patients observed, tinnitus was found in 38 (24.2%) patients. This percentage is in keeping with incidence of tinnitus being reported by Soghy, et al<sup>23</sup> and Bush<sup>24</sup> reporting 20% and 33% respectively

(1) The observed range for the combined symptoms of Tinnitus on the NRS was from 0-10 while the interquartile range (IQR) was from 0-3 with a median of 0.

(2) Though the mean rank of response among the 4 visits was statistically similar, a dramatic decrease was observed in the range of response between Visit 1 and Visit 6. (Friedman--- test,  $df = 3$ ,  $p = .056$ .)

(3) Post Hoc Results: No statistically significant changes in symptoms occurred following visit #6. However, later visits demonstrated significantly less intensity of pain compared to earlier visits when the range was observed.

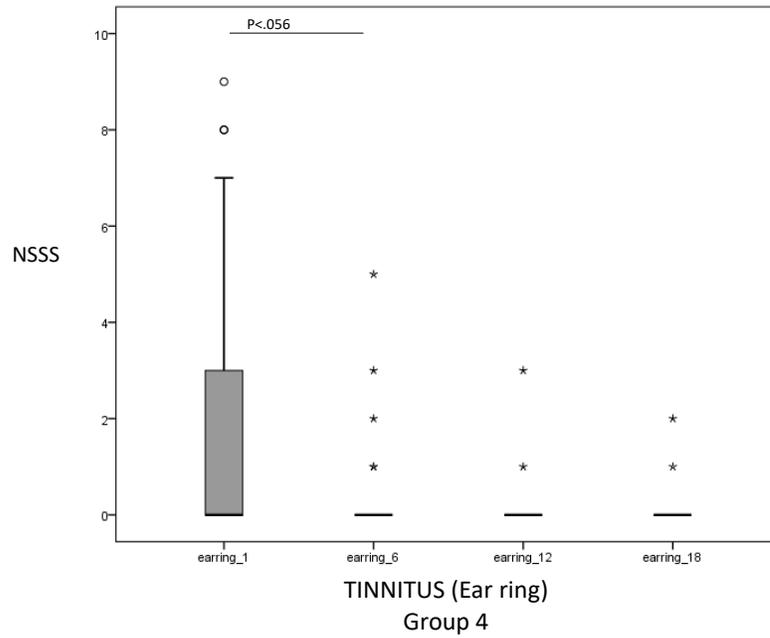


Fig. 9

The following graphs visually depict the progressive reduction of symptoms in the study population per person from the 1<sup>st</sup> through the 6<sup>th</sup>, the 12<sup>th</sup> and the 18<sup>th</sup> visits. (Fig. 10)

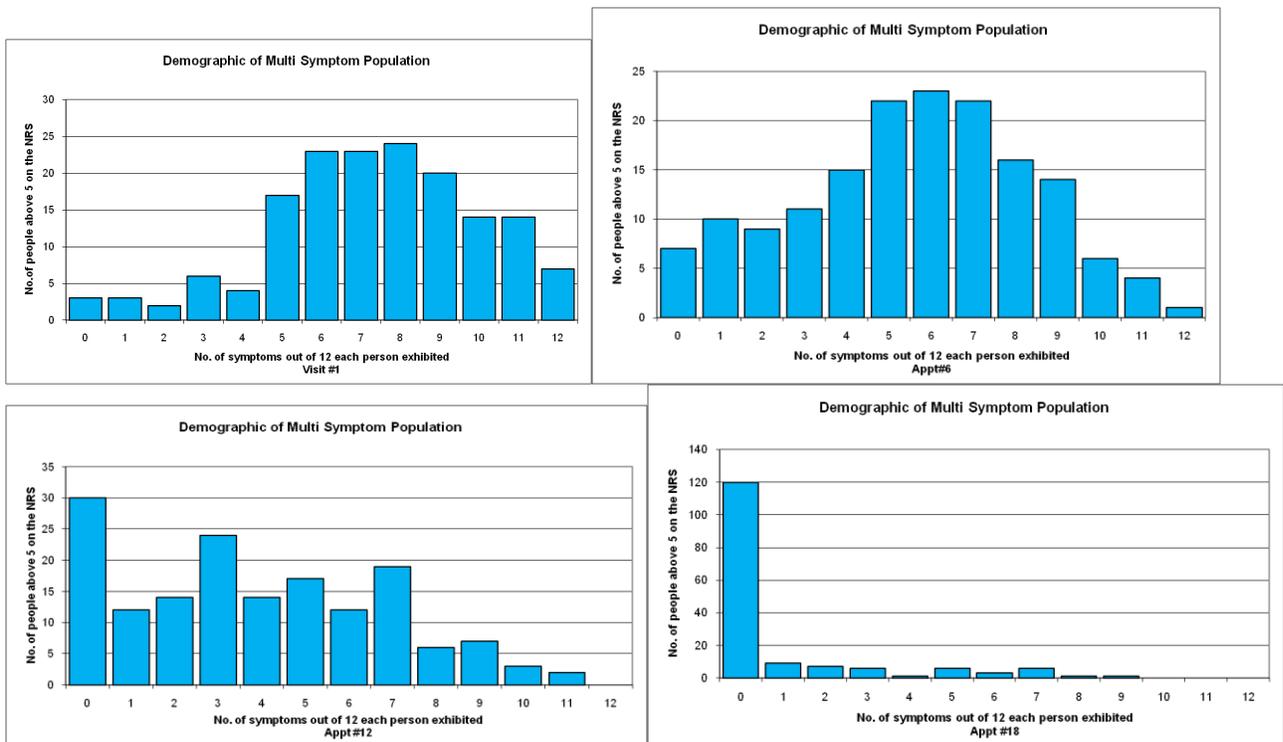


Fig. 10

## DISCUSSION

The study of this cohort appears to demonstrate that the BMAGO splint used for mandibular stabilization can provide highly significant ( $p < .001$ ) symptom reduction in dentognathic and adjacent systems. This is due primarily to the physiologic goal of SSCP and specific parameters required for design, management and patient compliance cited with the BMAGO. These findings begin to answer the call to action voiced by Harrel and Nunn to establish “an evidence based approach to occlusal treatment that is reproducible among clinicians so that it can be standardized for optimal results.”<sup>25</sup> The previously described BMAGO appliance process is very specific. In summary: After the initial 2-day period of even mandibular incisal contact, it must be worn on the maxilla in full occlusal contact guiding mandibular incisors and cuspids 24/7. That includes sleeping, talking AND eating, the primary conscious driving force for condylar seating. Shims are essential for immediate deprogramming and facilitation of incremental adjustments every 2 weeks (in this study) until CO and CR are coincident between the BMAGO and the mandibular teeth. Ideally all occlusal contacts should hold 8 micron thick leaf gauge after each visit. This process continues until the condyles stop moving for a period of 3 weeks. That protocol tracks each individual “biologic response” and usually takes from 3- 9 months depending upon the complexity of the DS treated. Working at that close level is always necessary in treating the brain protected, neurologically sensitive, highly reactive and adaptive DS. The object is to align the occlusal articulation for each patient between the mandible, maxilla and cranial base in preparation for orognathic diagnosis and treatment. The appliance protocol presented here has been developed and refined through empirical applications by practitioners, chair side, for over 20 years. This manuscript presents an attempt to initiate the process of officially bridging the gap between valid experiential/anecdotal and experimental/scientific information to improve the practice standard for hands-on patient-based DS care. The optimal occlusal health model offers a new paradigm for DS diagnosis and treatment and a context for how it can be rendered. With existence-based ideal form and function as a guide, a detailed plan for a distinct treatment destination can be developed and implemented.<sup>26</sup> The primary use of the BMAGO has been to utilize that blueprint to seat and stabilize the condyles. The intention of *this* study, however, was to measure the often related and observed favorable side effects of the BMAGO process on symptomatic patients. 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 responsive interrelationships and connectedness of nature found between the DS and the adjacent tissues. Review of the 157 patient records revealed that 90% of this group proceeded with treatment after stabilization and diagnosis to the full spectrum of comprehensive procedures from conservative subtractive coronaplasty to extensive restorative, orthodontic, orthognathic surgical procedures

and various combinations of each to fulfill the optimal biologic DS principles. Those who did not continue with treatment were encouraged to wear the BMAGO nightly for continued preventative protection. The review also disclosed that the return of symptoms was less than 5% with this group in the post therapy reports after 8+ years of using BMAGO applications. Groups 1, 2 and 3 demonstrated a dramatic decrease in symptom intensity when comparing the first with the eighteenth visits. This phenomenon is typical of what clinicians have unofficially reported when treating these types of pain patients with BMAGOs. Early symptom relief occurring in the Tinnitus Group (4) is not predictive in this study due to (1) the median being at zero by visit #6 and (2) a small population sample. A separate study is ongoing to analyze what happened in the first twelve weeks of treatment in this cohort to determine predictability. Many literature references exist showing increased incidence of tinnitus in the TMD population as compared to the “normal” population. Efficacy of occlusal splint therapy in reducing otolaryngological symptoms, along with the causes alluded to earlier are seemingly as conflicting as treating TMD itself. The results of this study also show the potential benefit of using BMAGO therapy for a differential diagnosis. When symptoms are not affected by the previously mentioned procedures, they are not likely due to an orthopedic mandible to cranial base /dental occlusion interface problem. Diagnostic energy can then be directed elsewhere. Techniques for proper delivery of the BMAGO process may require training. The highly significant reduction of symptoms presented here while observational, should represent enough of an evidence basis<sup>27</sup> to warrant critical appraisal through further research with the BMAGO in the form of prospective clinical RTCs.

## **CONCLUSIONS**

Based on this cohort study of 157 patients with symptoms of TMD, head, neck and shoulder pain, the following conclusions are offered:

1. The design, management and optimal physiologic goal of SSCP using the BMAGO intraoral splint presented herein produced highly significant symptom and pain reductions in eleven out of twelve examined symptoms.
2. The eleven symptoms where highly significant reduction occurred were TMJ pop, TMJ click, TMJ lock, jaw pain, headache, neck pain, shoulder pain, ear ache, clenching, grinding, and pain on opening.
3. Tinnitus was the symptom where significant reduction in intensity was recorded, but not predictive due to the power (size) of the sample represented.

4. The BMAGO as an intricate, adjustable, noninvasive interface where biology and technology meet provides new opportunities for a deeper understanding of the human dental system.
5. Further research is in order on the BMAGO using prospective RCTs.

## REFERENCES

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- <sup>1</sup> Klasser GD, Greene CS, Lavigne GJ. Oral appliances and the management of sleep bruxism in adults: A century of clinical applications and search for mechanisms. *Int J Prosthodont* 2010; 23:453-462.
- <sup>2</sup> Kirveskari, P, Jamsa, T. Health risk from occlusal interferences in females, *European Journal of Orthodontics* 2009; 31: 490-495.
- <sup>3</sup> Kirveskari, P. The role of occlusal adjustments in the management of temporomandibular disorders, *Oral Surg Oral Med Oral Pathol Radiol Endod* 1997; 83: 87-90
- <sup>4</sup> Karpinen, K, Eklund, S, Suoninen, E, Eskelin, M, Kirveskari, P. Adjustment of dental occlusion in treatment of chronic cervicobranial pain and headache, *Journal of Oral Rehabilitation* 1999; 26: 715-721.
- <sup>5</sup> Obisesan, O. Drug Induced Bruxism, *U S Pharm.*, 2005; 1: HS21-26.
- <sup>6</sup> Ekberg, EC, Nilner, M. A 6- and 12-Month Follow-up of Appliance Therapy in TMD Patients: A Follow-up of a Controlled Trial, *International Journal of Prosthodontics* Nov 2002; 15: 564-570.
- <sup>7</sup> Ekberg, EC, Vallon D, Nilner M. The Efficacy of Appliance Therapy in Patients with Temporomandibular Disorders of Mainly Myogenous Origin. A Randomized, Controlled, Short-Term Trial, *Journal of Orofacial Pain* 2003; 17:133-139.
- <sup>8</sup> Nilner, M, Ekberg, EC. Short-term Effectiveness of a Prefabricated Occlusal Appliance in Patients with Myofacial Pain, *Journal of Orofacial Pain* 2008; 22: 209-218.
- <sup>9</sup> Al-Ani, MZ, Davies SJ, Gray RJM, Sloan P, Glenny AM. Stabilisation splint therapy for temporomandibular pain dysfunction syndrome (Review), *The Cochrane Collaboration, The Cochrane Library, John Wiley & Sons Publishing*, 2009 Issue 1.
- <sup>10</sup> Alencar JR, F. ,Becker, A. Evaluation of different occlusal splints and counseling in the management of myofascial pain dysfunction, *Journal of Oral Rehabilitation* 2009; 36: 79-85
- <sup>11</sup> Donovan, TE, Anderson, M, Becker, W, Cagna, DR, Hilton, TJ, Rouse, J. Annual Review of Selected Scientific Literature, *Journal Pros. Dent.*, Oct. 2011; 106: 246
- <sup>12</sup> Dupont, J.S., Brown, C.E. General Dentistry: Occlusal Splints from the Beginning to the Present. *cranio.com* 2006; 24:
- <sup>13</sup> Temporomandibular Disorders: A position paper of the international college of cranio-mandibular orthopedics. *Cranio* 2011; 29:237-44.
- <sup>14</sup> Optibondxtr-techbulletin-35221. pdf (application/pdf Object.

- 
- <sup>15</sup> Hunt K. Bioesthetics: The Study of Beauty in Life. *Dentistry Today* 1996; 15: 48-55.
- <sup>16</sup> Cordray, F. Three-dimensional analysis of models articulated in the seated condylar position from a deprogrammed asymptomatic population: A prospective study. Part 1, *Am Journal of Orthodontics & Dentofacial Orthopedics* 2006; 129: 619-630
- <sup>17</sup> Lee RL, Pagan WJ. *Panadent Professional Articulator System Instruction Manual*. 1986;p. 51-94
- <sup>18</sup> Schindler HJ, Turp JC. Functional characteristics of the jaw musculature: clinical implications for the management with occlusal splints, *Journal of Craniomandibular Function* 2008; (Sample issue): 9-23.
- <sup>19</sup> Enkling N, Nicolay C, Utz KH, Jöhren P, Wahl G Mericske-Stern R. Investigating interocclusal perception in tactile teeth sensibility using symmetric and asymmetric analysis, *Clin Oral Investig*. 2009 Oct 9, 19816719
- <sup>20</sup> Shankland WE. Migraine and tension-type headache reduction through pericranial muscular suppression: a preliminary Report, *Cranio*, 2001; 19:269-78.
- <sup>21</sup> Stapelmann H, Turp J. The NTI-tss device for the therapy of bruxism. temporomandibular disorders, and headache – Where do we stand? A qualitative systemic review of the literature, *BMC Oral Health* 2008, 8:22 doi:10.1186/1472-6831-8-22
- <sup>22</sup> Shu Shu He, Xiao Deng, Peter Wamalwa, Song Chen. Correlation between centric relation-maximum intercuspation discrepancy and temporomandibular joint dysfunction, *Acta Odontologica Scandinavica*, 2010; 68: 368-376.
- <sup>23</sup> O.A. Sobhy,A.R. Koutb, F.A. Abdel-Baki, T.M. Ali, I.Z.El Raffa & A.H. Khater. Evaluation of aural manifestations in temporo-mandibular joint dysfunction, *Clinical Otolaryngology*, 2004; 29: 382-385.
- <sup>24</sup> Bush, F.M. Harkins, S.W. and Harrington, W.G. Otolgia and adverse symptoms in temporo-mandibular disorders, *Ann. Otol. Rhinol. Laryngol*. 1999; 108: 884-891.
- <sup>25</sup> Harrel, SK, Nunn, ME. The effect of occlusal discrepancies on periodontitis II Relationship of occlusal treatment to the progression of periodontal disease, *J Periodontol* 2001; 72: 495-505.
- <sup>26</sup> Lee R.L. Esthetics and its relationship to function, In: Rufenacht C.R. *Fundamentals of Esthetics*, Chicago, IL: Quintessence Publishing; 1990.p. 137-209.
- <sup>27</sup> Matthews DC, Hujuel PP. A practitioner’s guide to developing critical appraisal skills. *JADA* , July, 2012; 143:784-786

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