

# An Assessment of the Usefulness of Kinesiograph as an Aid in the Diagnosis of TMD: A Review of Manfredini et al's studies

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## **ABSTRACT:**

**Aim:** Performing a literature review of publications by Dr. Manfredini et al related to their TMJ injection therapy outcome with conclusions on the clinical utility of computerized measurement devices used in the management of TMD. In addition, reviewing their published opinion on an occlusion: MD vs a biopsychosocial paradigm for TMD. Manfredini et al authored an article published in JADA 2013,<sup>116</sup> the most recent of 12 articles. In all studies, subjects received TMJ injections with an objective measurement outcome criterion; increased maximum mouth opening (MMO) and subjective symptom improvement of pain and chewing function. In 2013 JADA article the Mandibular Kinesiograph, referred to as KG, measured MMO before and after therapy. In 11 prior articles all subject groups with limited mouth opening exhibited very significant increased MMO post-treatment, documenting treatment success using the same 2013 protocol. The 2013 study showed a 1.1mm improved MMO, described as

insignificant. The authors did not critique or explain the aberrant, skewed 2013 outcome data contrasted with their prior studies' which showed overwhelmingly significant increased MMO. Instead, concluding that the MMO recording device was clinically useless. This motivated a literature review of the authors' TMD publications. **Conclusion:** The publications by Manfredini et al, recognized proponents of the psychosocial model of TMD, including the 2013 article, appear to be part of a campaign denying an occlusion: TMD relationship and disparaging the specific computerized measurement devices and dentists using them in the management of their TMD patients using neuromuscular occlusion dental treatment.

Temporomandibular disorders (TMD) comprise a group of musculoskeletal disorders that affect alterations in the structure and/or function of one or more of the following: temporomandibular joints (TMJ), masticatory

muscles, the dentition and its supporting structures, and the complex neuromuscular system attached thereto.<sup>1</sup>

TMD is characterized by generally accepted signs and symptoms of pain, muscle spasm, joint sounds and functional limitation.<sup>2</sup>

Proper diagnosis of TMD is made by the treating dentist and begins with obtaining a patient history, performing a comprehensive clinical examination and imaging studies when indicated. The diagnostic process and treatment plan are greatly enhanced using technologies that can scrutinize the anatomic and functional components of the masticatory system, providing reliable and precise objective measurement data.

Three computerized measurement devices, commonly referred to collectively as Kinesiograph, have been developed to record and analyze, with high degrees of precision, masticatory muscle function (EMG), mandibular movements (CMS), TMJ joint vibrations (ESG), and dental occlusion as dynamic phenomena. According to the American Dental Association (ADA)'s Council on Scientific Affairs, these three measurement devices measure generally accepted signs or symptoms of TMD and aid the dentist in reaching his/her diagnosis of a TMD patient.<sup>3</sup>

*Surface Electromyography* (EMG) is a well-accepted modality which measures the electrical activity of masticatory muscles at rest and in function.

According to the ADA's Council on Scientific Affairs,<sup>3,4</sup> "Surface electromyography, or EMG, is used in dentistry to assess the status of the muscles of mastication.<sup>5</sup> It allows the clinician to assess the resting activity of muscles and determine if muscle spasms are present.<sup>6,7</sup> In particular, EMG instruments measure static and functional muscle activity, including postural hypertonicity and continuous muscle contraction.<sup>7</sup> Evaluation of muscle activity is included among the diagnostic criteria for TMD as given in the ADA Council's Guidelines.... Muscle spasm is included in the counsel's classification system (Section 11.8.3 in

the Appendix), and among the diagnostic criteria is continuous muscle contraction at rest. Surface electromyography is one method that can measure such muscle hyperactivity.... There is considerable agreement among both clinicians and researchers that masticatory muscle activity is increased in symptomatic patients compared to normal subjects, and electromyography is one tool that can be used to study such differences."<sup>8</sup> Therefore, EMG devices "were found to meet the [ADA] Council's Guidelines for Instruments as Aids in the Diagnosis of Temporomandibular Disorders."<sup>4</sup>

A significant body of the scientific literature published in peer-reviewed journals over the past 50 years has concluded that the TMD patient population has an elevated resting EMG muscle activity and weak or asymmetrical functional EMG muscle activity.<sup>9-56</sup> Numerous studies have substantiated the reliability and reproducibility of surface electromyography in the evaluation of the status of the masticatory muscles.<sup>57-68</sup>

*Computerized Mandibular Scanner* (CMS) measures and records in three dimensions mandibular range of motion, direction, velocity and fluidity of jaw movement, rest position of the mandible and dental occlusion, both natural and therapeutic. The integration of surface electromyography of masticatory muscles and electronic jaw tracking is a clinically useful and objective method of quantifying the physical components of temporomandibular disorders in patients screened for treatment and particularly in selecting a therapeutic occlusal position.<sup>69-83</sup>

*Electrosonography* (ESG) records and displays sounds/vibrations of temporomandibular (TM) joints and provides spectral analysis of the recorded sounds/vibrations, identifying their magnitude and specific frequencies produced by mandibular movements during mouth opening and closing with greater precision than stethoscopic auscultation.<sup>84-88</sup>

In addition to measuring the physical and functional signs of TMD, computerized jaw

tracking, electromyography and joint vibration recording devices provide objective documentation of patient pretreatment status, create objective milestones in planning treatment and permit evaluation of treatment outcomes.<sup>89-108</sup>

These three technologies are not free-standing diagnostic devices; they are precision objective measurement instruments, which aid the dentist in establishing a diagnosis and designing treatment. These devices underwent the review processes of the US FDA in 1997 and 1998<sup>109,110</sup> and the ADA's Council on Scientific Affairs in 1986 and 1993<sup>111,112</sup> and were recognized as safe and effective aids in the diagnosis and treatment of patients with temporomandibular disorders.

#### **A Review of Published Studies by Manfredini et. al. on the Efficacy of the Kinesiograph as an Aid in the Diagnosis of Temporomandibular Disorders**

In the study published in the April 2013 issue of the Journal of the American Dental Association<sup>116</sup> Manfredini et al authors studied the effectiveness of their treatment on TMD patients using a Kinesiograph jaw tracking device (Myotronics Inc. Kent, WA, USA). Because the authors' 2013 study results were contrary to the results of other studies, including past studies by Dr. Manfredini et. al., a literature review of the authors' TMD studies that use the Kinesiograph was instituted. The device referenced generically or specifically by its registered trade name, has been the subject of at least four studies by Manfredini et. al.<sup>113-116</sup>

#### **Review of Manfredini et. al.'s 2007 article "The Diagnostic Process for Temporomandibular Disorders"<sup>113</sup>**

In Manfredini et. al.'s 2007 article, the authors performed a literature review and compared various TMD diagnostic procedures and instruments.<sup>113</sup> They opined that "It is well recognized in the literature

that temporomandibular disorders involve the biopsychosocial sphere as well, with chronic pain and functional limitation representing possible sources of interference with daily activities. For this reason, a number of psychosocial instruments have been proposed to assess TMD patients and TMD literature is [sic] plenty of study that have tried to depict a personological profile typical of such disorders. Anxiety, depression and somatization disorders have been associated with TMD symptoms". Note that the referenced psychosocial instruments proposed by the authors are questionnaires to subjectively record the patient's psychosocial state. The article is critical of the use of EMG and jaw tracking instruments because "no direct relationship between pain and EMG levels has been well documented". The article concludes that "EMG-based instruments and jaw tracking devices have no place in the diagnostic process for temporomandibular disorders due to the impossibility to correlate instrumental signs with patients' symptoms and to their poor reliability and repeatability". The authors made this conclusion even though the American Dental Association's Council on Scientific Affairs had cited extensive scientific publications to support their conclusion that Myotronics devices "measure generally accepted signs or symptoms of TMD".<sup>3</sup> Admittedly, these devices do not measure pain. Further, the authors state in their 2010 article that "TM disorders are characterized by restriction, deviation or deflection of mouth opening path."<sup>117</sup> The reference provided by the authors in their 2013 article defines the TMD/TMJ as a disorder characterized by "limited mandibular movement, spasm in the masticatory musculature and... clicking/popping noise in the TMJ."<sup>2</sup> These signs and symptoms of TMD, that are defined by the authors themselves in their publications, can be effectively and accurately measured and recorded by Myotronics devices.

Therefore, the conclusion of the authors' 2007 literature review that "EMG-based instruments and jaw tracking devices

have no place in the diagnostic process for temporomandibular disorders” is contrary to the conclusions of other studies, especially in view of the definitions of TMD signs and symptoms documented in the authors own publications.

**Review of Manfredini et. al.’s 2011 article  
“Surface electromyography of jaw muscles and  
kinesiographic recordings: diagnostic accuracy  
for myofascial pain”<sup>114</sup>**

Never having previously published stating the use of the Kinesiograph, Dr. Manfredini conducted a so called research with a Myotronics K6 device and published this 2011 negative article in the *Journal of Oral Rehabilitation (JOR)*. According to the authors “Except for clenching parameters during clenching tasks, all the other outcome EMG parameters and KG [Kinesiograph] measures did not reach acceptable levels of sensitivity and specificity”. This study used the Sensitivity/Specificity argument that has been used by anti-instrumentation authors over the past 25 years to discredit the scientific credibility, utility and the efficacy of physiologic measurement devices as aids in the diagnosis and treatment of TMD.

Under the banner of the requirement of high “sensitivity and specificity” for “diagnostic instruments”, Manfredini et al. summarily dismissed the scientific credibility of measurement devices and concluded that because these devices cannot rule in/rule out TMD, they have no diagnostic value or clinical utility.

Interestingly, the authors concluded that the measurement of maximum mouth opening (MMO) with the Kinesiograph (KG) “did not reach acceptable levels of sensitivity and specificity” and should not be performed for the evaluation of TMD patients. The authors reached this conclusion even though reduced MMO is a universally accepted sign of TMD and Manfredini et al selected it as the only objective outcome parameter to assess the effectiveness of their TMD treatment in 2013 and in all their past 11 TMD

studies. See the review of the authors’ past TMD studies later in this article.

*Sensitivity* is the probability that the diagnostic test result can correctly identify the existence of the disease when the disease is present. *Specificity* is the probability that the test result can correctly identify that the disease does not exist when the disease is not present. A low sensitivity would result in false negative finding and a low specificity would result in a false positive finding. While *sensitivity* and *specificity* can be useful in their application to determine the effectiveness of certain diagnostic procedures when the disease is clearly defined such as tuberculosis, they are not appropriate criteria in evaluation of diagnostic procedures when applied to multi-faceted multi-presentational disorders, such as TMD. Based on an understanding of the complex multifaceted nature of TMD, no single free standing instrument or device can successfully make a diagnosis of every form of TMD. Notably, Myotronics, the manufacturer of the physiologic monitoring devices, about which Manfredini and et al have written, does not claim that their device is a free standing diagnostic device.

Even though the Myotronics device is not promoted as a free-standing TMD diagnostic device, a significant body of literature published in peer reviewed journals over the past 50 years has documented the support for its efficacy as a valuable aid in the diagnosis of TMD patients.<sup>3-108</sup> In medicine, there are many devices considered valuable as diagnostic aids such as radiographs and MRI that are not free-standing diagnostic devices. Myotronics K7 device provides valuable objective data, which together with patient’s history and clinical examination findings, aid the treating dentist in arriving at a diagnosis, treatment planning, treatment monitoring and outcome evaluation. In spite of its approved FDA intended uses and the ADA Seal of Acceptance (when the Seal programs were in effect), anti-instrumentation authors lead by Dr. Charles Greene<sup>118-120</sup> and Dr. Danielle Manfredini have used the sensitivity/specificity argument, in publications that are often

referenced in other publications to discredit the use of Myotronics devices.

**Review of Manfredini et. al.'s 2012 article  
"Kinesiographic recordings of jaw movements  
are not accurate to detect magnetic resonance-  
diagnosed temporomandibular joint (TMJ)  
effusion and disk displacement: findings from  
a validation study"<sup>115</sup>**

In this 2012 article, Manfredini et. al. used a Myotronics "jaw tracking" device to record the Mandibular movement of 31 TMD patients to diagnose joint disease i.e. disk displacement with/without reduction and effusion of the TM joints.

The authors attempted to use the measurements of the movement of the jaw to diagnose whether the patients had joint effusion!! The authors' action is not different than a physician using an imaging device to conclude that the patient has high cholesterol, when in fact the blood analysis of the patient shows low cholesterol. The physician would then use the sensitivity and specificity of his arbitrarily reached diagnosis to conclude that the imaging device has no usefulness in the diagnosis of high cholesterol! The physician and his anti-instrumentation colleagues then reference this article in their future studies in a context to convey that the device "does not detect clinical symptoms". That was precisely the case when an anti-instrumentation author published an article titled "Warning: Diagnostic tools proven to be inaccurate", referencing this Manfredini et. al article.<sup>120</sup>

In a published letter to the Editor of the *Triple O Journal* titled "Manfredini et. al.'s study uses Myotronics K6 device contrary to the device's published indications for use"<sup>121</sup>, Myotronics responded:

"1)The study design is flawed and its conclusions are false and misleading because the authors used the K6 jaw tracking device in a manner grossly

contrary to the manufacturer's published indications for use to reach diagnosis of specific classification of the TM joint disease. Myotronics, Inc. (myotronics.com) has not promoted the use of its jaw tracking devices to diagnose joint disease nor are we aware of a dentist who uses the information obtained from a jaw tracking device for such purpose. Indications for use are clearly documented in the device's promotional literature and our web site. To design and publish a study that is grossly contrary to the device's intended use, to reach a conclusion regarding the clinical usefulness of a device, can only be explained by the authors' political agenda to intentionally disparage the product and deceptively deny its valid utility in a dental practice.

Incredibly, the authors compared the sensitivity and specificity of their arbitrarily and inaccurately reached diagnosis from their interpretation of jaw tracking measurements to the diagnosis reached from the MRI data obtained from the patients and concluded as follows: "The findings do not support the usefulness of jaw tracking devices in dental practices that diagnose and manage temporomandibular disorders"!!

2) Even if the authors study design was valid, they would not have been able to make a meaningful scientific conclusion simply because the K6 instrument used in this study, purchased in January 1992, has never been calibrated. The K6 was announced to owners as requiring calibration every 3 years. Myotronics and its Italian distributor have no record of calibration, or any type of service since purchased 21 years ago. The authors described the K6 as "a commercially available device", even though the K6 was discontinued and replaced by the K7 in



2001. Interestingly, lack of calibration of this device is evidenced in Figure 3 of the article. When such a pattern is obtained, the device is nearly always in need of calibration or its sensor array is not placed symmetrically on the patient's face. This is another example of the authors' lack of understanding of our technology, at best, or intentional misuse of our device's instruction for use, at worst.

3) The authors created an imaginary and false performance standard and subjected the measurement equipment to tests based on their own test standard. It is no surprise that the authors have concluded that the measurement equipment has failed to meet the test standard!

4) The title of Manfredini et. al.'s article is misleading, selected to include a Myotronics device's trade name, imply far reaching conclusions regarding the "usefulness" of the device and to provide a convenient reference for future anti-instrumentation authors, evident in the references, to perpetuate their campaign to undermine the value of diagnostic aid devices. Again, the authors' use of the K6 device was grossly contrary to the device's indications for use.

5) If the authors' objective was to undertake a legitimate study of joint function, it is puzzling why our ESG joint vibration measurement device was not used. Even an ESG device can not classify the TMJ dysfunction in the narrow categories diagnosed by the authors."

Using jaw tracking measurements to diagnose TMJ joint disease shows the authors' lack of knowledge regarding the clinical utility of a jaw tracking device or its manufacturer's published and approved intended use. The publication of this article demonstrates that the authors performed a blatantly flawed study, which they used to discredit the scientific credibility of a measurement and diagnostic aid device.

**Review of Manfredini et. al.'s 2013 article "An assessment of the usefulness of jaw Kinesiography in monitoring temporomandibular disorders: correlation of treatment-related kinesiographic and pain changes in patients receiving temporomandibular joint injections."<sup>16</sup>**

In this 2013 article, published in the Journal of the American Dental Association (JADA), Manfredini et. al. used a Myotronics K6 jaw tracking device on a group of temporomandibular disorder (TMD) patients who received a specific arthrocentesis treatment. Note the word "usefulness" inserted in the title of this article.

The authors collected jaw motion information including maximum mouth opening from the patients before and after treatment. Manfredini et. al. reported that the maximum mouth opening measured by the K6 after treatment did not increase significantly, concluding that "At the end of treatment we found no correlation between the clinical variables and any of the KG [K6] variables" and "KG [K6] is not useful in monitoring the disease in the clinical setting"

Supported by numerous scientific studies, a reduced maximum opening of the mouth is universally accepted as a sign of TMD and increase in maximum mouth opening after treatment is frequently used by investigators to assess the effectiveness of the treatment.

Because the authors' study results were contrary to the results of other published studies, including past studies by these authors, a literature review of the authors' past arthrocentesis studies was conducted. The hypothesis was that if the authors' past arthrocentesis studies investigated the effect of the same treatment intervention as in the 2013 JADA published study on substantially the same TMJ osteoarthritis patient population mix as the JADA study, then the earlier studies would have yielded the same results i.e. no significant increase in the maximum opening of the mouth after treatment.

## MATERIALS AND METHODS:

A comprehensive literature search in the National Library of Medicine's Pubmed data base (Pubmed.com) and Biomed Experts data base (biomedexperts.com) for each author's past publications list was performed, followed by a search of the authors' identified publications on the use of arthrocentesis with Hyaluronic Acid (HA) injections for the treatment of TMD patients with TMJ osteoarthritis, with each article authored by at least one of the five 2013 JADA article authors. All publications identified as a result of this search strategy were obtained and reviewed. To ensure the inclusion of all of the authors' related past studies, the references for the identified publications were also reviewed.

### Results of the Literature Search of the authors' past Arthrocentesis studies

The search strategy yielded a total of eleven very similar studies to the 2013 JADA article published from 2002 to 2012 on the use of arthrocentesis with Hyaluronic Acid (HA) injections for the treatment of osteoarthritis of the TMJ in TMD patients, each authored by at least one of the five JADA article authors.<sup>122-132</sup> According to the authors, their 2013 JADA study's treatment protocol was the same as that described in their 2007 study<sup>124</sup> and their earlier studies that investigated the effects of arthrocentesis. The eleven studies investigated twenty patient groups with TMJ degenerative disorder/osteoarthritis as specified in the 2013 JADA study:

- With minor exceptions, all studies had the same treatment protocol i.e. Arthrocentesis with 1 ml HA injection, once a week for five weeks as used in the 2013 JADA study.
- Pain relief and chewing ability were the subjective outcome parameters and maximum mouth opening was the objective outcome parameter used for the evaluation

of treatment effectiveness as in the 2013 JADA study.

- The sex and age distribution of the patients were very similar to those of the 2013 JADA article.

Even though the authors of the 2013 JADA study had recorded the maximum mouth opening (MMO) as well as other mandibular movement measurements, our review was limited to the study of MMO because MMO was the only outcome parameter that was used in all of the authors' past 11 studies. The review of the MMO in these studies provides a valid analysis of the authors' work because the JADA study had concluded that "No significant changes were described in any of the KG [K6] variables at the end of treatment".

Exhibit 1 lists the summary (patient population mix, intervention, before and after treatment MMO and conclusions) of the authors' past 11 studies in comparison to the 2013 JADA study.

*Table 1* lists the increase in MMO after treatment in millimeters and in percentages for the 12 studies.

*Table 2* shows the increase in the Maximum Mouth Opening (MMO) in all studies conducted by the authors when before treatment MMO showed a restriction in opening ( $MMO \leq 37.0$  mm).

*Table 3* shows the patient population mix (number of patients, mean age and the ratio of female to the total study population) of the JADA study in comparison to the patient population of the authors past studies when before treatment MMO showed a restriction in opening ( $MMO \leq 37.0$  mm).

*Table 4* shows the increase in the after treatment MMO of the 2013 JADA study versus the MMO of the authors past studies when before treatment MMO showed a restriction in opening ( $MMO \leq 37.0$  mm)

*Table 5* shows the Z-test statistical comparison of the 2013 JADA study MMO increase versus the MMO increases of the authors' past studies.

Table 1

Review of the Manfredini et. al Studies On the Use of Arthrocentesis with Hyaluronic Acid (HA) injections in TMD (Temporomandibular Disorders) Patients with TMJ Degenerative Disorders/Osteoarthritis					
Study's Authors and Year	Population	Intervention	Maximum Mouth Opening in mm		Authors Conclusions
			Before Treatment	After Treatment	
Manfredini, D., Favero, L., Michieli, M., Salmasso, L., Cocciolo, F., Guarda-Nardini, L. 2013	34 patients with TMJ osteoarthritis 32 F, 2 M with mean age of 55.7	<b>Protocol:</b> Arthrocentesis with 1 mL HA injection (once a week for 5 weeks) <b>Outcome Parameters</b> <b>Subjective:</b> TMJ pain (VAS), chewing ability (VAS) <b>Objective:</b> Max mouth opening (mm)	35.0	36.1	"Significant changes were described at the end of treatment for clinical variables (outcome parameters), chewing ability and pain level." "None of the KG [K6] parameters we investigated was able to indicate treatment changes in patients with TMJ osteoarthritis." "Parameters for mouth opening were not related to changes in pain level and chewing ability." "These findings suggested that jaw KG [K6] is not useful in monitoring the disease in the clinical setting."
Guarda-Nardini, L., Cadornì, C., Frizziero, A., Ferronato, G., Favero, G., Manfredini, D. 2012	38 patients with TMJ osteoarthritis Patients were assigned to 2 groups Group A: 17 patients with average age of 48 years (14 females) Group B: 18 patients with average age of 53 years (16 females)	<b>Protocol:</b> Arthrocentesis with 1 mL HA injection (once a week for 5 weeks) Group A received medium molecular weight HA Group B received low molecular weight HA <b>Outcome Parameters</b> <b>Subjective:</b> Pain at rest and at chewing (VAS), functional limitation (LTS) <b>Objective:</b> Max mouth opening (mm)	Group A 36.9 Group B 36.7	41.6 40.5	"At the end of the follow-up period, all the outcome variables improved in both groups of patients."
Guarda-Nardini, L., Olivo, M., Ferronato, G., Salmasso, L., Bonini, S., Manfredini, D. 2012	76 patients with TMJ osteoarthritis 23 under 45 years (20 females) 28 45-65 years (24 females) 25 over 65 years (21 females)	<b>Protocol:</b> Arthrocentesis with 1 mL HA injection (once a week for 5 weeks) <b>Outcome Parameters</b> <b>Subjective:</b> Pain at rest and at chewing (VAS), functional limitation, mastication efficiency and subjective efficacy <b>Objective:</b> Max mouth opening (mm)	Under 45 years 39.87 45-65 years 36.55 Over 65 years 39.14	41.0 42.7 42.0	"Mouth opening values were not significantly improved, given that baseline values were already within the range of normality." "Significant effect of the treatment on the symptoms"
Manfredini, D., Rancitelli, D., Ferronato, G., Guarda-Nardini, L. 2012	60 patients with TMJ osteoarthritis 51 females, 9 males with mean age of 50.1 years Patients were assigned to 5 patient groups	<b>Protocol:</b> Each patient group received one of six treatment protocol of arthrocentesis with or without additional drugs <b>Outcome Parameters</b> <b>Subjective:</b> Pain at rest and at chewing (VAS), chewing efficiency (VAS) <b>Objective:</b> Max mouth opening (mm)	Group A 38.1 Group B 34.7 Group C 37.1 Group D 42.5 Group E 40.1	45.1 46.4 48.2 44.6 44.3	"All protocols were associated with positive outcomes."
Review of the Manfredini et. al Studies On the Use of Arthrocentesis with Hyaluronic Acid (HA) injections in TMD (Temporomandibular Disorders) Patients with TMJ Degenerative Disorders/Osteoarthritis					
Study's Authors and Year	Population	Intervention	Maximum Mouth Opening in mm		Authors Conclusions
			Before Treatment	After Treatment	
Guarda-Nardini, L., Ferronato, G., Manfredini, D. 2011	78 patients with TMJ osteoarthritis assigned to 2 groups Single Needle: 33 females, 5 males with mean age of 54.2 years Two Needle: 37 females, 3 males with mean age of 56.9 years	<b>Protocol:</b> Arthrocentesis with 1 mL HA injection (once a week for 5 weeks). The SN patient group received single needle arthrocentesis and the TN patient group received two needle arthrocentesis <b>Outcome Parameters</b> <b>Subjective:</b> Pain at rest and at chewing (VAS), chewing efficiency (VAS), functional limitation <b>Objective:</b> Max mouth opening (mm)	Single - Needle Group 40.2 Two - Needle Group 37.0	44.2 41.0	"In both treatment groups significant improvement with respect to baseline levels were achieved in all outcome variables."
Ch. 26 of the Book "Current Concepts on Temporomandibular Disorders", Manfredini, D., 2010	References Manfredini et al Studies	References Manfredini et al Studies	References Manfredini et al Studies		"Arthrocentesis has been proven to be effective in increasing the range of jaw motion."
Guarda-Nardini, L., Manfredini, D., Ferronato, G. 2009	31 patients with DDR and arthralgia 25 female, 6 males, with mean age of 42.4 yrs.	<b>Protocol:</b> Arthrocentesis with 1 mL HA injection (once a week for 5 weeks) <b>Outcome Parameters</b> <b>Subjective:</b> Pain at rest and at chewing (VAS), functional limitation and subjective efficacy <b>Objective:</b> Max mouth opening (mm)	39.57	44.97	"Marked improvements with respect to baseline values in all the outcome variable." "Objective parameter, jaw range of motion, improved significantly."
Guarda-Nardini, L., Manfredini, D., Ferronato, G. 2009	14 patients with TMJ osteoarthritis 10 females, 4 males with mean age of 56.9 years	<b>Protocol:</b> Arthrocentesis with 1 mL HA injection (once a week for 5 weeks) <b>Outcome Parameters</b> <b>Subjective:</b> Pain at rest and at chewing (VAS), functional limitation and subjective efficacy <b>Objective:</b> Max mouth opening (mm)	37.8	37.5	"Range of motion values remained quite unchanged. This finding may be due to the fact that baseline range of motion values were already within the range of normality."
Guarda-Nardini, L., Manfredini, D., Stefano, M., Staffieri, A., Marioni, G. 2009	50 patients with TMJ osteoarthritis 17 over 65 years, all females with mean age of 72.7 years 33 equal or under 65 year, 29 females, 3 males with mean age of 51.1 years	<b>Protocol:</b> Arthrocentesis with 1 mL HA injection (once a week for 5 weeks) <b>Outcome Parameters</b> <b>Subjective:</b> Pain at rest and at chewing (VAS), functional limitation <b>Objective:</b> Max mouth opening (mm)	Patients > 65 years 36.7 Patients ≤ 65 years 37.8	40.5 42.0	"All parameters of treatment efficacy markedly improved in both groups."
Manfredini, D., Bonini, S., Arboretti, R., Guarda-Nardini, L. 2009	76 patients with TMJ osteoarthritis Unspecified age and sex	<b>Protocol:</b> Arthrocentesis with 1 mL HA injection (once a week for 5 weeks) <b>Outcome Parameters</b> <b>Subjective:</b> Pain at rest and at chewing (VAS), functional limitation and subjective efficacy <b>Objective:</b> Max mouth opening (mm)	37.9	42.1	"Statistically significant improvement in the range of motion of the jaw."
Guarda-Nardini, L., Stefano, M., Brombin, C., Salmasso, L., Manfredini, D. 2007	25 patients with TMJ osteoarthritis 23 females, 2 males with mean age of 60.7 years	<b>Protocol:</b> Arthrocentesis with 1 mL HA injection (once a week for 5 weeks) <b>Outcome Parameters</b> <b>Subjective:</b> Pain at rest and at chewing (VAS), functional limitation and subjective efficacy <b>Objective:</b> Max mouth opening (mm)	36.9	42.4	"Marked improvements in all outcome parameters."
Review of the Manfredini et. al Studies On the Use of Arthrocentesis with Hyaluronic Acid (HA) injections in TMD (Temporomandibular Disorders) Patients with TMJ Degenerative Disorders/Osteoarthritis					
Study's Authors and Year	Population	Intervention	Maximum Mouth Opening in mm		Authors Conclusions
			Before Treatment	After Treatment	
Guarda-Nardini, L., Masiero, S., Marioni, G. 2005	3 groups of 20 patients with TMJ degenerative disorders Group A: (20 F, 0 M, mean age 50) Group B: (19 F, 1 M, mean age 51) Group C: (16 F, 4 M, mean age 46)	<b>Protocol for Group A:</b> Arthrocentesis with 1 mL HA injection (once a week for 5 weeks) <b>Protocol for Group B:</b> Bite Plane occlusal appliance <b>Protocol for Group C:</b> No treatment <b>Outcome Parameters</b> <b>Subjective:</b> Pain at rest and at chewing (VAS), functional limitation and subjective efficacy <b>Objective:</b> Max mouth opening (mm)	37.7	44.7	"Significant improvement in all outcome parameters."
Guarda-Nardini, L., Tilo, R., Staffieri, A., Beltrame, A. 2002	10 patients with degenerative TMJ disease: 9 F, 1 M, mean Age of 49.3 yrs	<b>Protocol:</b> Arthrocentesis with 1 mL HA injection (once a week for 5 weeks) <b>Outcome Parameters</b> <b>Subjective:</b> Pain at rest and at chewing (VAS) and functional limitation <b>Objective:</b> Max mouth opening (mm)	36.5	41.4	"Significant improvement in all outcome parameters maintained over time."
VAS: Visual Analog Scale LTS: Likert Type Scale		M: Male F: Female			



Table 2

<b>Maximum Mouth Opening (MMO) Before and After Treatment Documented in 12 Manfredini et. al Studies on the use of Arthrocentesis with Hyaluronic Acid (HA) injections in TMD Patients with TMJ Degenerative Disorders/Osteoarthritis</b>						
<b>Study's First Author and Year</b>	<b>Patient Group</b>	<b>Maximum Mouth Opening in mm</b> <b>Before Treatment    After Treatment</b>		<b>Increase in MMO (mm)</b>	<b>Percentage of Increase (%)</b>	<b>Authors Conclusions</b>
Manfredini, D. 2013	1	35.0	36.1	1.1	3.1	"Parameters for mouth opening were not related to changes in pain level and chewing ability."
Guarda-Nardini, L. 2012	2	Group A 36.9	41.6	4.7	12.7	"At the end of the follow-up period, all the outcome variables improved in both groups of patients."
	3	Group B 36.7	40.5	3.8	10.4	
Guarda-Nardini, L. 2012	4	Under 45 years 39.87	1.0	N/A	N/A	"Mouth opening values were not significantly improved, given that baseline values were already within the range of normality."  "Significant effect of the treatment on the symptoms"
	5	45-65 years 36.55	42.7	6.15	16.8	
	6	Over 65 years 39.14	42.0	2.86	7.3	
Manfredini, D. 2012	7	Group A 38.1	45.1	7.0	18.3	"All protocols were associated with positive outcomes."
	8	Group B 34.7	46.4	11.7	33.6	
	9	Group C 37.1	48.2	11.1	29.8	
	10	Group D 42.5	44.6	2.1	4.9	
	11	Group E 40.1	44.3	4.2	10.5	
Guarda-Nardini, L. 2011	12	Single - Needle Group 40.2	44.2	4.0	9.9	"In both treatment groups significant improvement with respect to baseline levels were achieved in all outcome variables."
	13	Two - Needle Group 37.0	41.0	4.0	10.8	
Guarda-Nardini, L. 2009	14	39.57	44.97	5.4	13.6	"Objective parameter, jaw range of motion, improved significantly."
Guarda-Nardini, L. 2009	15	37.8	37.5	N/A	N/A	"Range of motion values remained quite unchanged because baseline range of motion values were already within the range of normality."
Guarda-Nardini, L. 2009	16	Patients > 65 years 36.7	40.5	3.8	10.4	"All parameters of treatment efficacy markedly improved in both groups."
	17	Patients ≤ 65 years 37.8	42.0	4.2	11.1	
Manfredini, D. 2009	18	37.9	42.1	4.2	11.1	"Statistically significant improvement in the range of motion of the jaw."
Guarda-Nardini, L. 2007	19	36.9	42.4	5.5	14.9	"Marked improvements in all outcome parameters."
Guarda-Nardini, L. 2005	20	37.7	44.7	7.0	18.6	"Significant improvement in all outcome parameters."
Guarda-Nardini, L. 2002	21	36.5	41.4	4.9	13.4	"Significant improvement in all outcome parameters maintained over time."
<b>Number of studies prior to the 2013 JADA study</b> 11	<b>Number of patient groups</b> 20	<b>Range of MMO (mm)</b> <b>Before Treatment    After Treatment</b> 34.7 – 42.5    37.5 – 48.2				

Table 3

**Increase in Maximum Mouth Opening (MMO) After Treatment Documented In Manfredini et. al studies on the use of Arthrocentesis with Hyaluronic Acid (HA) injections in TMD Patients with TMJ Degenerative Disorders/Osteoarthritis when Before Treatment MMO Showed a Restriction in Opening (MMO ≤ 37.0 mm)**

Study Authors, Title and Year Published Number of Patients, Mean Age and Ratio of Female Patients	Maximum Mouth Opening (mm)		Increase in MMO After Treatment (mm)	Increase in MMO After Treatment %
	Before Treatment	After Treatment		
Manfredini D, Favero L, Michieli M, Salmaso L, Cocilovo F, Guarda-Nardini L. An assessment of the usefulness of jaw kinesiography in monitoring temporomandibular disorders. 2013 Patient Group 1: N = 34 MA = 55.7 F = 94%	35.0	36.1	1.1	3.1%
Guarda-Nardini L, Cadorin C, Frizziero A, Ferronato G, Manfredini D. Comparison of 2 Hyaluronic Acid Drugs for the Treatment of Temporomandibular Joint Osteoarthritis. 2012 Patient Group 2: N = 17 MA = 48 F = 82% (Group A) Patient Group 3: N = 18 MA = 53 F = 89% (Group B)	36.9	41.6	4.7	12.7%
	36.7	40.5	3.8	10.4%
Guarda-Nardini L, Olivo M, Ferronato G, Salmaso L, Bonnini S, Manfredini D. Treatment effectiveness of arthrocentesis plus hyaluronic Acid injections in different age groups of patients with temporomandibular joint osteoarthritis. 2012 Patient Group 4: N = 28 MA = 55 F = 86%	36.55	42.7	6.15	16.8%
Manfredini D, Rancitelli D, Ferronato G, Guarda-Nardini L. Arthrocentesis with or without additional drugs in temporomandibular joint inflammatory-degenerative disease: comparison of six treatment protocols 2012 Patient Group 5: N = 9 MA = 50.1 F = 85%	34.7	46.4	11.7	33.6%
Guarda-Nardini L, Ferronato G, Manfredini D. Two-needle vs. single-needle technique for TMJ arthrocentesis plus hyaluronic acid injections: a comparative trial over a six-month follow up. International J Oral and Maxillofacial Surgery. 2011 Patient Group 6: N = 40 MA = 56.9 F = 92.5%	37.0	41.00	4.0	10.8%
Guarda-Nardini L, Manfredini D, Stifano M, Staffieri A, Marioni A Intra-articular injection of hyaluronic acid for temporomandibular joint osteoarthritis in elderly patients. 2009 Patient Group 7: N = 17 MA = 72.7 F = 100%	36.7	40.5	3.8	10.4%
Guarda-Nardini L, Stifano M, Brombin C, Salmaso L, Manfredini D. A one-year case series of arthrocentesis with hyaluronic acid injections for temporomandibular joint osteoarthritis. 2007 Patient Group 8: N = 25 MA = 60.7 F = 92%	36.9	42.4	5.5	14.9%
Guarda-Nardini L, Tito R, Staffieri, Beltrame A. Treatment of patients with arthrosis of the temporomandibular joint by infiltration of sodium hyaluronate: a preliminary study. 2002 Patient Group 9: N = 10 MA = 49.3 F = 90%	36.5	41.4	4.9	13.4%
<b>Min. Increase in MMO in Studies prior to 2013 JADA study</b>			<b>3.8 mm</b>	<b>10.4%</b>
<b>Average Increase in MMO in Studies prior to 2013 JADA study</b>			<b>5.6 mm</b>	<b>15.4%</b>
<b>Max. Increase in MMO in Studies prior to 2013 JADA study</b>			<b>11.7 mm</b>	<b>33.6%</b>
N = Number of patients in the study F = Ratio of the number of female patients to total number of patients MA = Mean age of the patients in the study, in years				

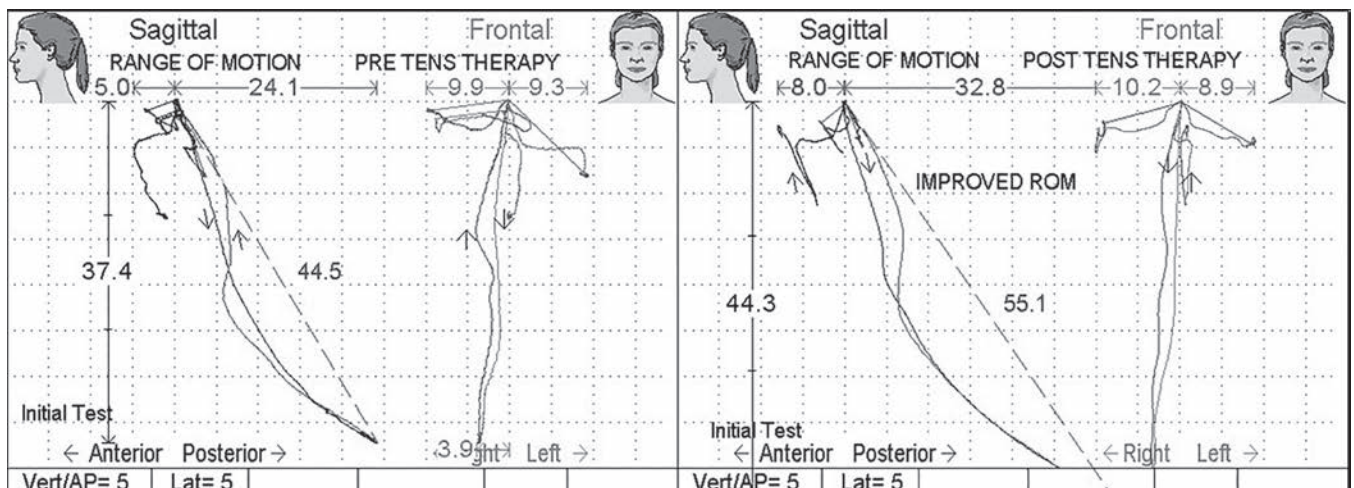
Table 4

Comparison of patient population of the 2013 JADA study versus that of 7 previous Manfredini et. al Arthrocentesis studies that showed Before Treatment restriction in max. mouth opening (MMO ≤ 37.0 mm)			
Manfredini et. al Arthrocentesis studies	Number of Patients	Mean Age of Patients (years)	Ratio of Female to the Total Study Population
2013 JADA Study	34	55.7	94%
Studies Prior to 2013 JADA Study (Range)	9-40	48-72.7	82%-100%
Studies Prior to 2013 JADA Study (Average)	27	55.7	89.6%

Table 5

Comparison of the increase in Maximum Mouth Opening (MMO) of the Previous Manfredini et. al Studies Versus the increase in the 2013 JADA Study When Before Treatment MMO showed a restriction in opening (MMO ≤ 37.0 mm)	
Min. MMO Increase of pre 2013 studies as a percentage of MMO increase of the 2013 JADA study	3.8 mm/1.1mm = 342%
Average MMO Increase of pre 2013 studies as a percentage of MMO increase of the 2013 JADA study	5.6 mm/1.1mm = 509%
Max. MMO Increase of pre 2013 studies as a percentage of MMO increase of the 2013 JADA study	11.7 mm/1.1mm = 1,064%

Figure 1



**DISCUSSION:**

The authors' 2009 study titled "Short-term effects of arthrocentesis plus viscosupplementation in the management of signs and symptoms of painful TMJ disc displacement with reduction. A pilot study" investigated the effect of arthrocentesis on a patient group with the diagnosis of disk displacement.<sup>128</sup> This study was excluded from our review since the objective was to investigate the authors' past studies on patients with TMJ osteoarthritis. All other patient groups in the authors past studies had a diagnosis of TMJ Osteoarthritis, the same as the patient group in the 2013 JADA study.

It should be noted that the computed averages in *Table 2* and *Table 4* were based on arithmetic averages and were not weighted by sample size or stratified by gender. The authors' measured increases in maximum mouth opening (MMO) in their 2002 to 2013 studies listed in *Table 1* showed considerable variation. The uniformity of increases in MMO in studies prior to the 2013 JADA study improved when patient groups with before treatment MMO showed a restriction in opening (MMO < than 37.00mm). If patient group 5 is excluded due to the small sample size of this group, the increase in the MMO in these studies ranges from 3.8mm to 6.15mm.

The review of the authors' past studies (Exhibit 1 and *Table 1*) shows that two patient groups, out of the 20 patient groups, did not experience an after treatment increase in their MMO. The authors explained that "this was due to the fact that baseline range of motion values were already within the range of normality."

Since the authors had hypothesized that when the baseline range of motion is "within the range of normality" a significant after treatment increase in MMO can not be expected, we selected a cut off MMO of 37.0 mm or below to only include patient groups with a restriction in mouth opening, as in their JADA study. A total of 7 of the authors' past studies (8 patient groups) had patients with mean MMO of

Table 6

<b>Two-tailed Z-test: Comparison of the 2013 JADA study Maximum Mouth Opening (MMO) Increase vs. the MMO Increases of the authors' previous studies</b>	
<b>Patient Groups</b>	<b>Increase in MMO after Treatment (mm)</b>
<b>Patient Group 1 (JADA Study)</b>	1.1
Patient Group 2	4.7
Patient Group 3	3.8
Patient Group 4	6.15
Patient Group 5	11.7*
Patient Group 6	4.0
Patient Group 7	3.8
Patient Group 8	5.5
Patient Group 9	4.9
<b>Mean of MMO Increases of Patient Groups 2-9 and Standard Error</b>	4.7 (0.90)
<b>Significance (p value) Comparison of Patient Group 1 vs. Patient Groups 2-9</b>	0.000069
*Patient Group 5 was excluded due to small sample size	

37.0mm or below. The increase in the MMO of their 2013 JADA study was compared with those of the 7 past studies (*Table 2*). The patient mix (number of patients, mean age and the ratio of female to male patients) of the 2013 JADA study was compared with those of the authors 7 past studies. It was not possible to perform a statistical comparison of the patient population of the 2013 JADA study with the patient population of the authors' past studies, since the authors did not provide the standard deviation for patients' ages in their studies. Nevertheless, it is evident from the comparison of the range and mean of the ages and the ratio of females to the total study population (*Table 2* and *Table 3*), that the population of the 2013 JADA study was substantially similar to that of the 8 patient groups in Manfredini et al.'s past studies. Interestingly, the mean age of the 2013 JADA study was 55.7 years, which is precisely the same as the mean age of the 8 patient groups in the authors' past studies, underscoring the substantial similarities of the patient groups in all of the authors' arthrocentesis studies. This is not unexpected since it is quite possible that a number of 2013 JADA patients had participated



in several past arthrocentesis studies conducted by the authors.

In summary, an objective analysis of Manfredini et. al.'s studies that are documented in *Table 1*, *Table 2* and *Table 3*, shows that the patient populations mix and treatment intervention employed in the JADA 2013 study were substantially the same as those of the past 11 arthrocentesis studies that the authors had conducted from 2002 to 2012. It was expected that the authors would have found similar results in their earlier studies as in the 2013 JADA study.

The conclusions of all 11 studies by Manfredini et. al. that investigated 20 patient groups were reviewed finding that the maximum mouth opening increased “significantly” and “markedly”, in the authors own words, in all patient groups, correlating with improvements in pain and chewing ability, when the baseline data showed a limitation in mouth opening (*Exhibit 1* and *Table 1*).<sup>122-</sup>

<sup>132</sup> Treatment related improvements in pain and chewing ability were reported to be coincident with significant increases in maximum mouth opening, precisely the reason why the measurement of MMO was chosen by the authors as the only “objective outcome parameter” to assess the effectiveness of the treatment in all their past studies. The authors must have been convinced of the “usefulness” of a measurement device in evaluating treatment outcome by using it over and over in all 11 studies over a span of 10 years. The measurement device used in the authors’ past studies was not specified. Yet, when they used a Myotronics K6 device in their 12<sup>th</sup> study (the 2013 JADA study), they reportedly did not record a significant increase in the maximum mouth opening concluding that the K6 is “not useful in monitoring the disease in the clinical setting.”

### ***Statistical Analysis***

To assess the probability of obtaining a 1.1 mm increase in the MMO after treatment (as reportedly measured by the authors), in view of the authors previous study results of MMO increases, the following statistical analysis was performed:

It is safe to assume that if the number of patients in each patient group is large enough, the MMO increases for all the authors’ studies follow a normal distribution and the Central Limit Theorem (CTL) can be used since the patient groups come from virtually the same population and they are subjected to the same treatment protocol, as previously established. Our null hypothesis was whether the authors’ JADA study MMO mean came from the same distribution of MMO means as their previous studies. The statistical significance level was set at  $p < 0.05$ .

Only patient groups with a minimum sample size of 10 patients were considered, resulting in the exclusion of Patient Group 5 from our analysis (*Table 2* and *Table 5*). The mean of the MMO increases of the 7 patient groups with 10 or more patients was 4.7 mm with a standard error of 0.90 mm. The patient groups we used to calculate the parameters of the distribution of the means were not all of the same sample size. However, the CLT holds for any reasonable sample size, provided the underlying distribution is normal.

Given a normal distribution with a mean of 4.7 mm and standard error of 0.90 mm, we conducted a two-tailed Z-test to test the hypothesis that the reported MMO increase of Patient Group 1 (mean MMO of 1.1 mm) came from the same distribution. The resulting p-value of the comparison of Patient Group 1 (JADA article) versus the distribution of means of previous studies is 0.000069. Since the p-value is less than 0.05, we reject the hypothesis that the data from Patient Group 1 came from the same distribution of means as the previous studies (*Table 5*). We conclude that the probability of the authors’ obtaining an MMO increase of 1.1 mm, as reported in their JADA study, is 69 in one million or about one in 15,000.

It should be noted that while Manfredini et al performed numerous statistical analyses on the data collected from the K6 Kinesiograph, they ignored the most basic element when studying the utility of a precision measurement device: that the device be used according to the manufacturer’s



operating instructions. Such instructions specify that the Kinesiograph be re-calibrated every three years. The authors used a device that was manufactured in 1992, with an 18 year overdue re-calibration schedule.

**Comparison of the Increase in the MMO of the 2013 JADA study versus that of the Manfredini et. al.'s prior 11 studies, When Before Treatment MMO showed a restriction in opening (MMO  $\leq$  37.0 mm)**

*Table 4* and *Table 5* underscore the absurdity of the results and conclusion of the 2013 JADA article, in comparison to the MMO results documented in Manfredini et. al.'s prior 11 studies when before treatment MMO showed a restriction in opening (MMO  $\leq$  37.0 mm):

- The minimum after treatment increase in MMO in their prior studies was 3.8 mm, which is 342% of the 1.1 mm MMO increase reportedly measured by the authors in their 2013 JADA study.
- The average after treatment increase in MMO in their prior studies was 5.6 mm, which is 509% of the 1.1 mm MMO increase reportedly measured by the authors in their JADA study.
- The maximum after treatment increase in MMO in their prior studies was 11.7 mm, which is 1064% of the 1.1 mm MMO increase reportedly measured by the authors in their 2013 JADA study.
- The probability of the authors' obtaining an MMO increase of 1.1mm, as reported in their 2013 JADA study, is about one in 15,000.

Interestingly, the authors failed to explain or even disclose why the results of their 2013 JADA study was so completely different in terms of improved maximum mandibular opening from the results of their 11 very similar studies since 2002 with the same treatment protocol, nearly

the same patient sex and age distribution as in the past studies. The only reference the authors made to their past studies was to convey that their JADA study had the same treatment protocol and outcome parameters as their past studies. It is troubling why the authors did not question the accuracy and validity of their 2013 JADA study results in light of their past similar arthrocentesis studies all of which had contrary conclusions.

In Chapter 9 of his 2010 book, Dr. Manfredini writes "there are two main reasons for individuals with TMD to seek treatment: The presence of pain and a severe limitation in mouth opening"<sup>133</sup>. He adds "Thus the clinicians must focus their diagnostic efforts on the treatment-seeking signs and symptoms, i.e. pain and limited mouth opening. The evaluation of mouth opening and the comprehensive assessment of pain should be the target for all clinicians treating TMD patients.... The perfect diagnostic instrument should allow detecting jaw motion limitations". In Chapter 26 of the same book Manfredini et. al write that "arthrocentesis has been proven to be effective in increasing the range of mandibular motion and improving patient management in patients with internal derangement and inflammatory-degenerative disorders."

These statements explain the authors' rationale for measuring the maximum mouth opening in all of their 11 arthrocentesis studies that investigated 20 patient groups.

So, in spite of the authors' numerous past publications that had substantiated the "usefulness" of the measurement of maximum mouth opening in the diagnosis and management of all TMD patients, the authors not only did not question the validity of their 2013 JADA results and conclusion with an explanation of why their results and conclusion were contrary to those of their past publications, they did not even including all of their pertinent publications in their 2013 JADA article's reference list.

Analysis of the 2013 JADA article's results, in light of the authors' past publications, demonstrates that the 2013 JADA study was flawed

and from its title appears to have been conducted to attack the “usefulness” of Myotronics manufactured diagnostic aid devices and to discredit the neuromuscular occlusion dentists who use them, rather than to support their therapeutic intervention as published many times before.

### **A review of publications by Dr. Manfredini et. al. on TMD diagnostic aid devices**

To assess the objectivity of the authors in performing literature reviews and studies on the efficacy of physiologic measurement devices, a comprehensive literature search in the National Library of Medicine’s Pubmed data base (Pubmed.com) and Biomed Experts data base (biomedexperts.com) was performed for the publications authored by the leading author of the 2013 JADA study, Dr. D. Manfredini. An additional search of the thus selected articles was made to identify the TMD related publications of this principal author. This research identified 16 articles and a book published by Dr. Manfredini.<sup>113, 133-147</sup>

A review of these publications demonstrates that Dr. Manfredini has been publishing a series of literature reviews, studies and a book since 2003 promoting the psychosocial model of TMD, while attacking the TMD/Occlusion association and the clinicians who treat TMD primarily conservatively and according to the occlusion model of TMD. Dr. Manfredini’s published articles have promoted the association between “psychosocial variables” of stress, depression/anxiety/somatization and TMD, denying the occlusion role as an important factor in predisposition, precipitation and perpetuation of TMD.

Dr. Manfredini is the author and the editor of the 2010 book titled *Current Concepts on TMD*<sup>133</sup> with contributing author, Dr. Charles Greene, a recognized anti-instrumentation, anti-occlusion author and a psychosocial proponent. On the back cover of his book Dr. Manfredini states “High-quality literature supports the abandonment of biomechanical and instrumental approaches to TMD diagnosis and management in favor of an exhaustive biopsychosocial assessment.” He adds

“...and importantly, it seems that the view of TMD as occlusion-related is hard to eradicate from the primary practitioner community.” He implies that TMD/occlusion association should be purged from dentistry.

Dr. Manfredini’s book is dedicated to advancing TMD as a psychosocial disorder, and documents citations and excerpts from several negative articles reportedly regarding the lack of efficacy of jaw tracking and EMG devices in the diagnosis of TMD. Dr. Manfredini is the sole author of several chapters including two that are titled “Psychosocial Assessment” and “Introduction to TMD Diagnosis”. A contributor to Dr. Manfredini’s book, Dr. Charles Greene, a section editor of JADA is also a published proponent of the biopsychosocial basis of TMD and an opponent of the occlusion: TMD connection philosophy and computerized measurement devices.<sup>118-120</sup>

As a recognized proponent of the psychosocial model of TMD with a long history of Dr. Manfredini’s anti-instrumentation publications, it is evident that Dr. Manfredini did not intend to conduct a study nor perform a literature review that are supportive of the “usefulness” of the Myotronics measurement devices.

In their response to the 4 published letters sent to the JADA Editor regarding the 2013 JADA article, Manfredini et. al called the letters a “collection of old defensive arguments about neuromuscular dentistry”<sup>148</sup>, further reinforcing the fact that the authors are attacking “neuromuscular dentists” who perform conservative treatment of TMD patients based on neuromuscular occlusion principles using precise computerized measurement devices. In a broader sense, the authors are attacking those who believe in the occlusion model of TMD by attacking the devices that many use.

### **Dr. Manfredini et. al.’s 2013 JADA article and its historical perspective related to his past publications**

The titles of Dr. Manfredini et. al.’s 3 studies are intentionally selected to include a Myotronics

manufactured device with its registered trade name, i.e. K6 or KG (Kinesiograph) and imply or outright state the conclusions regarding the “usefulness” or “accuracy of the” device as a TMD diagnostic aid. This has provided a convenient reference for anti-instrumentation authors, including the JADA Section Editor<sup>118-120</sup>, to perpetuate their campaign to undermine the value of the diagnostic aid devices.

In his 2012 article titled “Dental Occlusion, body posture and temporomandibular disorders: where are we now and where are we headed for”<sup>145</sup>, Dr. Manfredini writes:

“The scientific communities’ skepticism towards the potential usefulness of technological devices in the TMD field concerns their adoption as stand-alone diagnostic tools to intercept purported occlusal and postural abnormalities that, in the users’ intentions, need to be corrected. Such a typical chain of events, which characterizes some so-called philosophies to approach the dental profession (e.g. neuromuscular dentistry, dental kinesiology and osteopathy) is not scientifically sound and is a source of unjustified over treatments, with subsequent huge biological and financial costs.

In conclusion, there is no evidence for the existence of a predictable relationship between occlusal and postural features, and it is clear that the presence of TMD pain is not related with the existence of measurable occluso-postural abnormalities. Therefore, the use instruments and techniques aiming to measure purported occlusal, electromyographic, kinesiographic or posturographic abnormalities cannot be justified in the evidence-based TMD practice”.

These two paragraphs document Dr. Manfredini’s objective in discrediting Myotronics measurement devices as aids in the diagnosis

of TMD and discrediting dentists who utilize neuromuscular occlusion principles employing these diagnostic aid devices in their practice --along with patient examination and other instruments-- to diagnose and treat TMD patients conservatively with occlusal appliances. Dr. Manfredini asserts that the neuromuscular dentists (NM) are using devices that provide useless measurements, which lead to misdiagnosis, over treatment and unnecessary treatment. In fact NM dentists do not use these devices as “stand-alone” diagnostics nor do they use the information to “over treat” the patient and alter their occlusion unnecessarily with “subsequent huge biological and financial costs”, as purported by Dr. Manfredini.

Myotronics current K7 device is advertised as “The comprehensive Instrument for Precise Occlusal Evaluation” and is used by many of the neuromuscular dentists who use neuromuscular occlusion principles and procedures in treating TMD patients. Neuromuscular occlusion is a physiologically and objectively measured occlusion, incorporating relaxed masticatory muscle function with dental occlusion. These clinicians use Myotronics instruments and other devices for objective evaluation of the occlusion, jaw and masticatory muscle function (*Figure 1*).

For over twenty five years a small group of dentists and psychologists, positioned in universities, have waged a campaign designed to discredit dentists who use computerized measurement devices in the treatment of TMD and in other restorative procedures involving any occlusal treatment of TMD. They have waged a relentless effort in the ADA, FDA, in governmental agencies, professional forum and in the courts against dentists and devices manufactured by Myotronics that are used to record physiologic parameters relevant to TMD as aids in the diagnosis of TMD, supplementing patient examination, history and other diagnostic information including imaging.

The small, well published minority in the dental profession, who oppose the validity of the TMD/Occlusion association, do so to bolster support

for their Biopsychosocial paradigm for their own purposes. Using JADA and other respected journals, they promote their concepts without any objective measurement documentation to prove the veracity of their own treatment protocols. The treatment they promote consists of providing no-treatment while waiting for a supposed self-limiting disorder to resolve or their recommendation of ameliorative home self-care, psychological/psychiatric and/or pharmacological management of a chronic pain state. The Biopsychosocial proponents have long denied the etiological role of dental occlusion in TMD. They extend their denials to dentists who treat TMD through occlusal therapies, some of whom use objective computerized measurement devices to scrutinize mandibular function, dental occlusion, masticatory muscle and temporomandibular joint function and specifically to the ADA recognized devices that are used to provide these clinically valuable and relevant physiological measurements. The goal of this article is to inform the dental profession about these important issues which ultimately affect dentists' Freedom of Practice for the benefit of our patients.

## CONCLUSIONS:

Manfredini et al have conducted and published a long series of studies primarily concerning treatment for intracapsular TMJ disorders. They have broadened their scope to include denial of an occlusion: TMD connection as well as a posture: occlusion: TMD connection. In addition, they have used some of these articles to deny the usefulness of certain computerized measurement devices employed by dentists in the management of TMD. In their most recent study, their results regarding a positive therapeutic effect of injection therapy into the TMJ's on increasing maximum mandibular opening (MMO) was minimal. This is in sharp contrast with the significantly larger increases in MMO reported in all their previous jaw studies and those of others. Rather than scrutinizing and critiquing their 2013 data, they instead concluded

that the device used to measure MMO had no clinical utility.

These reviews of the scientific literature substantiate that the publications of Manfredini et. al. are part of a long campaign by the authors to discredit an occlusion: TMD etiologic and therapeutic connection and to disparage the specific computerized measurement devices and denigrate the dentists who use them in the management of their patients with TMDs. As recognized proponents of the biopsychosocial (psychosocial) model of TMD, it is evident that the authors did not perform an objective study on the use of diagnostic aid devices in their 2013 article or the positive association between dental occlusion and TMD in all of their publications for over a decade, nor did they perform a comprehensive review of the scientific literature which includes articles demonstrating the efficacy of diagnostic aid devices.

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