0008-3194/2004/152–179/$2.00/©JCCA 2004

Report

A review of the literature pertaining to the efficacy, safety, educational requirements, uses and usage of mechanical adjusting devices Part 2 of 2

Shane H Taylor, DC* Chairman
Nicole D Arnold, BSc, DC**
Lesley Biggs, PhD†
Christopher J Colloca, BS, DC††
Dale R Mierau, DC, FCCS, MSc**
Bruce P Symons, BSc, MSc, DC¶
John J Triano, DC, PhD, FCCS(C)(H)¶¶

Over the past decade, mechanical adjusting devices (MADs) were a major source of debate within the Chiropractors' Association of Saskatchewan (CAS). Since Saskatchewan was the only jurisdiction in North America to prohibit the use of MADs, the CAS established a committee in 2001 to review the literature on MADs. The committee evaluated the literature on the efficacy, safety, and uses of moving stylus instruments within chiropractic practice, and the educational requirements for chiropractic practice. Following the rating criteria for the evaluation of evidence, as outlined in the Clinical Guidelines for Chiropractic Practice in Canada *(1994), the committee reviewed 55 articles – all of which pertained to the Activator. Of the 55 articles, 13 were eliminated from the final study. Of the 42 remaining articles, 6 were rated as class 1 evidence; 11 were rated as class 2 evidence and 25 were rated as class 3 evidence.*

In this article – the second in a series of two – we review the results of uses and usage, safety and educational requirements. Of the 30 articles designated under the category of usage, 3 were rated as Class 1 evidence; 9 studies were classified as Class 2 evidence

Au cours de la dernière décennie, les appareils à mise au point mécanique (MAD) ont été une source majeure de débat au sein de l'Association des chiropraticiens de Saskatchewan (CAS). Comme la Saskatchewan était la seule juridiction nord-américaine à interdire l'utilisation des appareils à mise au point mécanique, l'Association a mis sur pied, en 2001, un comité chargé de revoir la documentation de ces appareils. Ce comité a évalué la documentation selon l'efficacité, la sécurité et l'utilisation d'instruments palpeurs mobiles dans la chiropractie et les exigences académiques de la pratique chiropratique. Suivant les critères d'évaluation lors de l'appréciation des preuves, tel que décrits dans les Directives cliniques des pratiques chiropratiques du Canada (1994), le comité a révisé 55 articles, tous en relation avec le Activator. Sur les 55 articles, 13 ont été éliminés de l'étude finale. Sur les 42 articles restants, 6 ont été classés dans les éléments de preuve de classe 1; 11 dans les éléments de preuve de classe 2; et 25 dans les éléments de classe 3.

Dans cet article, le second d'une série de deux, nous examinons les résultats de l'évaluation des utilisations, de la sécurité et des exigences scolaires. Sur les 30

* Private practice of chiropractic, Regina, SK, Canada.
** Private practice of chiropractic, Saskatoon, SK, Canada.
† Department of Women's and Gender Studies, University of Saskatchewan, Saskatoon, SK, Canada.
†† Private practice of chiropractic, Phoenix, AZ, USA.
¶ Private practice of chiropractic and Human Performance Lab, Faculty of Kinesiology, University of Calgary, Calgary, AB, Canada.
¶¶ Chiropractic Division, Texas Back Institute, Plano, TX and University of Texas, Arlington Biomedical Engineering Program, USA.
Thank you to the Chiropractors' Association of Saskatchewan for funding of this project.
Submit reprint requests to the Chiropractors' Association of Saskatchewan, 3420A Hill Avenue, Regina, SK, Canada S4S 0W9.

and 18 were rated as Class 3 evidence. Overall the committee reached consensus that in clinical practice, there is broad application of these procedures. A minority report was written arguing that the reviewer was unable to reach a conclusion about the use of the Activator Instrument other than it is used as a clinical and research tool.

Of the 16 studies that dealt either explicitly or implicitly with safety, 4 were Class 1 evidence; 3 were Class 2 evidence and 9 were Class 3 evidence. Overall the committee reached consensus that the evidence supports that the Activator instrument is safe and has no more relative risk than do manual HVLA procedures. A minority report was written arguing that there is no evidence either to support or refute the view that MAD is safe.

Of the 5 studies that dealt with educational requirements, all were Class 3 evidence. Overall the committee reached consensus that there was no evidence in the literature with respect to educational requirements to form any conclusions. A minority report was written offering opinion that there is evidence with respect to educational requirements.
(JCCA 2004; 48(2):152–179)

KEY WORDS: Activator, mechanical adjusting device.

articles figurant dans la catégorie utilisation, 3 ont été classés dans les éléments de preuve de classe 1, 9 dans les éléments de preuve de classe 2 et 18 dans les éléments de preuve de classe 3. Les membres du comité ont convenu unanimement qu'il y a une large application de ces procédures dans la pratique clinique. Un rapport minoritaire allègue que l'évaluateur n'a pas été en mesure d'en arriver à une conclusion au sujet de l'utilisation de l'activateur à d'autres fins que d'outil clinique et de recherche.

Sur les 16 études qui traitent explicitement ou implicitement de la sécurité, 4 ont été classées dans les éléments de preuve de classe 1, 3 dans les éléments de preuve de classe 2 et 9 dans les éléments de preuve de classe 3. Les membres du comité ont convenu unanimement que les éléments de preuve confirment que l'activateur est sécuritaire et qu'il ne présente pas plus de risque relatif que les procédures manuelles GVFA. Un rapport minoritaire fait valoir qu'il n'existe aucune preuve pour confirmer ou réfuter le point de vue selon lequel les appareils à mise au point mécanique sont sécuritaires.

Les 5 études portant sur les exigences scolaires ont toutes été classées dans les éléments de preuve de classe 3. Les membres du comité ont convenu unanimement qu'il n'existe aucune preuve dans la littérature permettant de tirer des conclusions en ce qui concerne les exigences scolaires. Un rapport minoritaire est d'avis qu'il existe des preuves en ce qui a trait aux exigences scolaires.
(JACC 2004; 48(2):152–179)

MOTS CLÉS : Activator, appareils à mise au point mécanique.

Introduction

A comprehensive introduction, methods and statistics section was published in part one, JCCA 2004; 48(1):74–108. In brief, a committee was struck by the Chiropractors' Association of Saskatchewan to perform a literature review on the efficacy, uses and usage, safety and educational requirements of mechanical adjusting devices.

After reviewing the CAS motion, the committee decided that the following questions needed to be answered:

What is the evidence in the literature on efficacy, safety, and uses of moving stylus instruments within chiropractic practice?
If evidence exists, what are the educational requirements for moving stylus instruments within chiropractic practice?

The section on efficacy was presented in the previous article. This article reviews the literature with respect to uses and usage, safety and educational requirements of

MADs. As was the case for the category of efficacy, evidence tables[a] were created for usage or uses, safety, and educational standards.

RESULTS

Summary of the literature on use and usage

Of the 30 articles designated under the category of usage, 3 are Randomized Controlled Trials (RCT) studies[1–3] (Class 1 Evidence); 2 are cohort studies[4,8] (1 of which is a clinical study while the other is an experimental study); 6 are experimental studies[5–7,9–11]; and 1 is a descriptive case series.[12] These latter 9 studies were classified as Class 2 Evidence. The remaining Class 3 studies consisted of 4 literature reviews/commentary which were deemed not applicable to this report[14,17,21,25]; 11 case reports[13,16,18–20,22–24,26,28,30]; 1 case series[27]; 1 cohort non-crossover study which was deemed not applicable to this report[15] and 1 hypothetical case study.[17]

Clinical treatment

Class 1 Evidence

Of the RCT studies, Wood, Colloca and Mathews (2001) compared standard Diversified technique to MFMA in the treatment of cervical dysfunction in a sample of 30 patients.[1] They did not report a statistically significant differences between the two groups. Both groups were reported to show significant improvement in outcomes during the treatment phase and at a one month follow-up. Statistically significant changes were reported in cervical ROM for both groups during the treatment phase. The differences between the groups were not different at the end of the treatment period or one month following.

Yates et al. (1988) conducted a study (n = 21) of patients with elevated blood pressure who were randomly assigned to one of three conditions, active treatment (which received a chiropractic adjustment delivered by AAI); a placebo group (which received a sham adjustment delivered by an AAI delivered in the off position); and a control group (which received no treatment).[3] The study found significant differences between the active treatment condition group, the placebo and control groups. Lower systolic blood pressure scores were reported for the active treatment group. In addition, lowered states of anxiety were reported for the active treatment group and control groups but the placebo group demonstrated an elevated state of anxiety.

Class 2 Evidence

In a descriptive case series study of 10 patients suffering whiplash, Osterbauer et al. (1992) found a statistically significant decrease in overall mean pain scores and increased range of motion.[12] A cohort study (n = 18) conducted by Hawk et al. (1999) found that the role of placebo effect needs to be examined more thoroughly.[8] In a comparison of flexion-distraction table technique with the AAI set on 0 used to perform a sham adjustment, they found that VAS and GWBS scores improved with both the treatment and the control groups.

Class 3 Evidence

In case series study of 10 patients, Osterbauer et al. (1993) found a statistically significant difference in VAS scores and Oswestry Index scores after receiving MFMA SMT.[27] The majority, but not all patients, reported a decline in back pain and increased function; these improvements remained stable after a one year follow-up.

Improved clinical outcomes were reported in case studies of patients suffering from post-surgical neck syndrome[13], ccocygodynia[16], lumbar disc herniation[19], frozen shoulder[22], frozen shoulder with metastatic carcinoma[23], plantar fascitis[24], torn medial meniscus[26], otitis media[28], and sciatic neuropathy and lumbar disc herniation[30]. Of these studies, 5 studies suggested that MFMA SMT may provide an alternative when there are contraindications to using manual SMT.[13,19,22–24] In addition, based on one case study, Polkinghorn (2001) suggests that MFMA may be effective when a patient's condition was initially aggravated by manual manipulation.[20] Byfield (1991) also suggested, based on one case study, that the Activator may have some advantages over the toggle thrust since it provides "a consistent, controlled force."[29]

In contrast to the case studies demonstrating positive outcomes, Nykoliation and Mierau (1999) reported on three different case studies (two of which had led to malpractice actions) where the delivery of MAD SMT was associated with adverse effects for the patient.[18] In at least one of these cases, the competency of the practitioner to deliver MFMA SMT would seem to be at issue.

a The evidence tables for efficacy can be found on the JCCA website.

Basic science studies on use and usage

Class 1 Evidence

In a cohort study (n = 40) measuring Lumbar sEMG output, Keller and Colloca (2000) found significant differences between the Active treatment group (MFMA SMT), and the Sham and Control groups.[2] It showed that mechanical lumbar adjusting creates short term maximal voluntary contraction of the lumbar paraspinal musculature immediately following treatment.

Class 2 Evidence

In his review of the literature, Gleberzon (2000) found that 43.6% of Canadian chiropractors utilize Activator methods.[6] Kopansky-Giles and Papadopoulous (1995) found that 31.4% of chiropractors utilized Activator methods for 1–25% of their patients.

Herzog, Kawchuk and Conway (1993) found no significant correlation between preload and ΔF forces for treatments using the Activator instrument whereas a significant correlation between preload and ΔF was found among four of the five manual techniques.[11] Similar results were found by Kawchuk and Herzog (1993).[10]

In a cohort study (n = 22), Colloca and Keller (2001) examined the spine stiffness and neuromuscular reflex responses using MFMA SMT.[4] They reported that in patients with frequent or constant LBP symptoms, there was a greater spinous process stiffness index compared to the SP stiffness index of subjects with only occasional or no LBP symptoms. The high chronicity group also reported significant greater scores on the VAS, Oswestry Index and perceived health status.

In an experimental study (n = 20), Colloca and Keller (2001) examined surface electromyographic reflex responses in response to MFMA.[5] They found consistent, but relatively localized, reflex responses to the localized, MFMA thrusts delivered to the thoracolumbar spine and SI joints.

Comparing the force-time and force-frequency of AAI with the electronic PCB hammer, Keller, Colloca and Fuhr (1999) suggested that the AAI may be effective in assessing the dynamic mechanical behaviour of the vertebral column.[7]

Nathan and Keller (1994) measured lumbar intervertebral motion patterns following MFMA SMT and determined the frequency of PA stiffness.[9] Based on the findings of three subjects, the authors suggest that AAI, along with impedance analysis, may be used to quantify the mechanical response of normal and abnormal spine.

Conclusions

After reviewing the literature and much debate, the committee reached consensus (5 to 1) that with respect to uses and usage the evidence supports that the Activator is widely applied to spine related and extremity disorders. They have been used in a broad spectrum of conditions severity ranging from simple to complex and with significant co-morbid pathology. It is also clear that the device is widely used by chiropractors across North America. In conclusion, the evidence suggests that in clinical practice, there is broad application of these procedures.

Minority Report on Usage
Dale Mierau DC, MSc, FCCSC
October 4, 2002

The quantity and quality of evidence in the literature reviewed was not sufficient for one to reach a conclusion about the efficacy and safety of the Activator instrument. There are 2 reports in the reviewed literature about the use of the Activator Methods (Gelberzon, 2000; Gelberzon, 2001). These reports described the use of the Activator instrument in the context of the Activator Method of treatment. Activator Methods teaches and promotes the use of the prone leg length test as a test to identify areas of the spine for treatment and as an outcome measure for treatment. Two well designed studies, one a prospective double blind cross-over trial of a diagnostic test and the other a prospective, double blind clinical trial of a diagnostic test, reported that the prone leg length test was "not found to be viable for identifying vertebrae to be adjusted" or as useful as an outcome measure to assess the effectiveness of the adjustment. (Haas et al., 1993; Haas et al., 1993).

The committee agreed to review the published literature about the Activator instrument and not Activator Methods. Since the only published literature about the use of the Activator is in the context of Activator Methods technique, I am unable to reach a conclusion about the use of the Activator Instrument other than it is used as a clinical and research tool. The indications, contraindi-

cations for the use of the Activator Instrument as a clinical tool, and the efficacy and safety of its use are unclear, not documented or unknown.

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Summary of the literature on safety

Of the 16 studies that dealt either explicitly or implicitly with safety, 4 were randomized control trials[1–4] (Class 1 evidence), 3 were experimental studies[5–7] – one of which appeared as a book chapter – (Class 2 evidence), 6 were case studies[9,11,12,14–16] (Class 3 evidence), two were reviews of the literature appearing in a book chapter[8,13] and journal article respectively[10] (Class 3 evidence). The latter 3 were deemed not applicable to this report.

In order to consider the evidence presented as related to safety, the reader must assume as stated on the evidence table "In the absence of epidemiological data, case report or case series reporting no adverse reaction are as valid as those that report adverse reaction." (See appended essay by Dr. Triano) Publishing standards expect that reports of care to patients account for adverse effects of the treatment, whether strictly followed or not.

Class 1 Evidence

A review of the Class 1 evidence relating to safety has been including under the subheadings of efficacy, and use and usage. They include studies by Wood, Colloca and Mathews (2001)[1], Keller and Colloca (2000)[2], Gemmel and Jacobson (1998)[3] and Yates et al. (1988)[4]. Safety was not directly measured in any Class 1 evidence but it was important to note that no injuries were reported during these trials.

Class 2 Evidence

In the experimental studies which provided a theoretical model of small vertebral motions done by Solinger (2000)[5], or examined the dynamic response of the spine during spinal manipulation by Fuhr et al., (1997)[6] and the biomechanical characteristics of five common spinal manipulative methods by Kawchuk and Herzog (1993)[7], safety was not directly studied. However, the biomechanical data comparing the loads from use of Activator versus those of HVLA clearly demonstrate that, properly applied, there is no biological feasible means to cause injury with this device. It has been demonstrated that the force-time profiles of moving stylus instruments have characteristics of producing less force and do so over a much faster time interval inasmuch, as the impulse derived from a moving stylus device is of a lesser amplitude and shorter duration when compared to traditional manual type spinal manipulation.

Class 3 Evidence

Case studies reported that patients responded positively to AAI treatment.[9,12,14–16] In contrast, Nykoliation and Mierau (1999) reported on three different case studies (two of which had led to malpractice actions) where the delivery of MAD SMT was associated with adverse effects for the patient.[11] In at least one of these cases, the competency of the practitioner to deliver MFMA SMT would seem to be at issue.

Conclusion

After reviewing the literature and debate, the committee came to consensus (4 to 2) that the evidence supports that the conclusion that the Activator instrument is safe and has no more relative risk than do manual HVLA procedures. The committee again would like to caution that the literature available is weak but unequivocal and that there have been no studies that looked directly at safety. A study designed to specifically look at safety is required to better understand the safety of MADs.

Minority Report on Safety
Submitted by Dale Mierau DC, MSc, FCCSC
and Lesley Biggs, PhD
Submitted October 4, 2002

Since there were no studies evaluating the safety of the Activator instrument, we believe that **there is no evidence either to support or refute** the view that MAD is safe. The best that can be said is that no injuries were reported, other than 3 adverse effects reported in one case series (Nykoliation and Mierau, 1999).

We do not agree with the statement, "In the absence of epidemiological data, case report or case series reporting no adverse reaction are as valid as those that report adverse reaction." This statement was a source of debate and finally disagreement, even before the stage at which the individual essays were written and discussed. As indicated in the Report, this statement is an assumption yet to be tested; in essence, it represents a null hypothesis (i.e. it is a research question). We are not able to find an equivalent statement or concept in any epidemiological or clinical literature. We were able to find citations to suggest that the rate of adverse reactions to treatment are underreported and a major policy concern. (See special issue of the British Medical Journal, 320, 18 March 2000; Cochrane Reviewers Handbook 4.1.4, October, 2001; National Steering Committee on Patient Safety, (2002); Sackett et al., 1985). This view is consistent with the last statement in the section of the report on safety: "The committee again would like to caution that the literature available is weak but unequivocal and there have been no studies that looked directly at safety. A study designed to specifically look at safety is required". We agree with this latter statement and interpret it to mean that the literature published on the Activator instrument is not of sufficient quantity or quality to draw a conclusion about the safety of the instrument. This is the reason for our vote of "not enough evidence" as opposed to a vote that the evidence in the literature supports that the Activator is safe.

Other Comments

1 The scientific approach to investigating the probability of risk is the same as that for investigating potential benefit (efficacy). The best method for both is a randomized controlled trial. However, in the field of treatment for musculoskeletal conditions the probability of an adverse reaction (risk) may be very remote, or the adverse effect may be temporary and benign. In such a case the trial would need to be very large to capture even one adverse effect. By convention, to be 95 % confident of observing one or more adverse reactions to an intervention, one must follow three times the reciprocal of the true adverse reaction rate (that is if the true adverse reaction rate is 1/1000 then investigators would have to follow 3000 treated patients to be 95% confident of finding at least one adverse reaction). Given the size of a sample required, RCTs are not often used to study adverse reactions unless the risk is very high or the adverse reaction is death or chronic disability. The next best method is to use a cohort study in which one group received the treatment and one did not. One could then follow the cohorts over time and count the number of adverse reactions in each group. However, one cannot assign causality with a cohort or case control study of risk any more than one can draw a conclusion about efficacy.
2 The notion that one can simply count up the number of reports without adverse effects and those with adverse effects and draw a conclusion about the safety of the intervention has no basis. The rationale for this statement is:
   i Adverse effects to treatment are underreported (National Steering Committee on Patient Safety, (2002); Cochrane Reviewers' Handbook, 2001).
   ii Simply counting up instances of an adverse effect or lack of one gives no insight into other variables, bias and confounders, which can assist to define causation (Haldeman et al, 1999; Sackett et al. 1985).
   iii The term 'adverse effect' may mean different things to different clinicians and hold different meanings for patients.

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Summary of the literature on educational requirements

Five studies[1–5] included a reference to educational issues. All were categorized as Class 3 evidence. In general, this information has little to do with criteria for competency. Rather these studies provide information about which colleges provide training in Activator procedures through elective courses (Osterbauer and Fuhr, 1990: 174. Table 2).[5] Eight schools provide such training, and are listed below:

Cleveland/KC: elective course
Life College: elective and postgraduate courses
Life/West: elective and postgraduate courses
Logan: elective course
New York: elective course
Palmer/Davenport: elective and postgraduate courses
Parker: elective course

A number of authors concluded that MAD methods should be included in the undergraduate or postgraduate curriculum of chiropractic colleges. In a college survey investigating Name techniques ($n = 263$), Gleberzon (2000) found that 94% of respondents recommended, inter alia, the inclusion of Activator Methods in Canadian Memorial Chiropractic Colleges's curriculum and that a significant proportion (43%) of Canadian chiropractors utilize Name techniques including Activator methods.[2] It has been mentioned several times that Activator Methods is taught within the DC curriculum or postgraduate curriculum of many accredited colleges.[4]

Based on one case report, Polkinghorn (1998) suggests that MFMA may be effective when a patient's condition was initially aggravated by manual manipulation.[3] Polkinghorn reinforced the need for chiropractors to be trained adequately in manipulative skill. Based on their findings that 'distractive and compressive loads have resulted in

differing neurophysiologic sensitivity, Colloca et al., (2000) recommend that practitioners should receive mechanosensitive education and training in terms of force vector application during chiropractic technique applications.[1]

Conclusion

After reviewing the literature and after debate consensus was reached (5 to 1) that there was no evidence in the literature with respect to educational requirements to form any conclusions. The members felt that with no evidence available to reach any conclusions about educational requirements, and anything they wrote would simply be opinion.

Minority Report
Educational Requirements For Moving Stylus Instruments Within Chiropractic Practice

Christopher J. Colloca, D.C.
Private Practice of Chiropractic, Phoenix, AZ, U.S.A.

Our committee was asked to review the literature and answer the question, *"What are the educational requirements for moving stylus instruments within chiropractic practice?"* Upon this review, the majority of the Mechanical Adjusting Devices (MAD) committee determined that there wasn't evidence available to determine the educational requirements for moving stylus instruments within chiropractic practice. I am pleased to have the opportunity to provide a minority opinion to be included in this report to clarify issues that I believe to be relevant to this matter.

In consideration of the question of the educational requirements of moving stylus instruments, both the literature and the law should be considered. Moving stylus instruments are taught as part of the core curriculum or as an elective course in several Council on Chiropractic Education (CCE) accredited chiropractic college curricula.[1] In addition, educational coursework involving the use of moving stylus instruments is also taught as part of CCE accredited post-graduate educational coursework that satisfies license renewal requirements for both State and Provincial chiropractic licensing agencies.[1]

The literature demonstrates that moving stylus instruments are popular in use in chiropractic practice. Data from the United States, Canada, and Australia note that moving stylus instruments are in use by a majority of doctors of chiropractic, ranging in the upwards of 62% usage on 21% of patients.[2] The popularity of moving stylus instruments in chiropractic practice is consistent with their acceptance by state and provincial guidelines within the United States (Mercy)[3] and Canada (Glenerin).[4] Inherently in their formal chiropractic education, doctors of chiropractic are trained and subsequently licensed to perform manual treatments to the human frame. Moving stylus instruments are defined as mechanical force, manually assisted thrust procedures[3–5] which meet the definitions of such educational training requirements for which doctors of chiropractic are licensed according to the CCE requirements.

In summary, although there appears to be no standardized language regarding the educational requirements for using moving stylus instruments in chiropractic practice, it appears that the training requirements for the use of such devices falls under the scope of the doctor of chiropractic license in performing manual treatments. Moreover, the educational requirements necessary for the doctor of chiropractic to understand the multitude of issues involving manual technique application of forces to the human body are inherent in the chiropractor's license to practice. Just as doctors of chiropractic are licensed to utilize manual force, mechanically assisted devices (drop-tables or flexion-distraction tables) under their scope of practice, chiropractors are also licensed to use moving stylus instruments based upon the educational requirements of the chiropractic license.

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Kyoto 2005 – International Multidisciplinary Scientific Symposium

Biological and Applied Aspects of Somato-Autonomic Interactions

Kyoto University, Kyoto, Japan April 8, 9 – 2005

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