

COMMITTEE MEMBER ESSAYS

09/10/2002

To: MAD Committee Chairman

From: John J. Triano, DC, PhD

The MAD committee was originally charged to answer two questions. Based on discussion and open vote, a consensus of the group was developed to use typical methods to consolidate the literature and review the evidence with respect to moving stylus instruments. The specific questions posed were:

“What is the evidence in the literature of 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?”

Any respondent can manipulate the answers to these questions simply by adjusting the underlying assumptions used in interpreting the data. The result is that different reviewers, legitimately interpreting the evidence from different perspectives will arrive at conclusions having wide variation. As shown in Appendix I⁵ of this report, that variation can range from strongly favorable to strongly unfavorable conclusion for the same piece of literature. The difference between reviewer opinions using the same evidence, then, is a function of context.

As a result, before expressing my opinion regarding the state of the evidence, it is felt an important step to review briefly the context of the questions being raised. For the past 2 decades, the North American health care systems have been struggling with questions of efficacy, effectiveness, costs and safety. Numerous studies and millions of dollars have been expended to review the state of the art and the evidence supporting each segment of the health care system. The overwhelming conclusion is that, with little exception, more than 80% of all health care practice has little to no compelling scientific evi-

dence proving efficacy or effectiveness. The Institute of Health Improvement, founded by Don Berwick, MD, was able to demonstrate that where there is strong evidence (e.g. certain aspects of pediatrics, cardiovascular disease and diabetes) focused effort to review and disseminate knowledge on appropriate care could result in more efficient and less costly care without loss, and in some instances with improvement in, quality of care. The notable exception where no change could be obtained was in the management and care of spine related disorders.

Moreover, when one reviews the literature of “reviews” and “meta-analyses” the invariable conclusion is that all studies show significant weaknesses in methodology. When studies are rank ordered according to type, (e.g. case reports to randomized controlled clinical trials) there is a trend for more generalizable results. However, a poorly constructed or implemented randomized trial has little greater value than a cohort study. Virtually every study has flaws and, thus, it is the preponderance of evidence from repeated efforts among multiple investigative teams that must be used to formulate opinion. When evidence for clearly superior or clearly harmful procedures is available then choice is simple. Unfortunately such choices are rare.

The bar of approval or disapproval of what is considered effective and safe should not be placed higher for a single procedure or technique than it is for any other procedure within the discipline. If such precedent is set, then it is reasonable and prudent for detractors to force all procedures to be viewed under the same precedent.

Finally, a new set of double standards has evolved within health care. Older procedures, technologies, techniques, medicines and surgeries in common use, while under increasing pressure to develop data bases of their own to support their use, are not routinely prohibited or denied. In contrast, new technology and procedures are submitted to a rigorous test of evidence to support their introduction.

The conclusion is that the context exists within the Chiropractic discipline and, indeed within all of medicine, that recognizes the principle that when there is absence of clear evidence, the clinician is afforded the right to decide among available and widely accepted practices in effort to assist his / her patients.

Efficacy

In the context of Chiropractic practice, there are only two modes of treatment that have received a significant amount of higher quality scientific attention. They are unassisted, manual high velocity, low amplitude (HVLA) spinal manipulation for treatment of low back pain, neck pain and headache. The second is HVLA by moving stylus devices (MAD, specifically the Activator).

Within the literature, there is only one pilot study⁷ on the thoracic spine. In the case of asthma, dysmenorrhea and otitis media, not only are studies few but generally negative. Despite that there is no hue and cry for eliminating HVLA or any other form of chiropractic care for these disorders. Indeed the profession responded with general criticism (some justified and other unjustified) of methodology and the claims of clinical benefit. For these disorders, at the practice level, treatment has remained unchanged.

For the evidence on moving stylus devices, the committee found 21 published papers. Five were rated as Class 1 evidence, 3 as Class 2 and 13 were considered Class 3. All of the Class 1 evidence suggested that MAD devices were as effective or superior to their comparisons for causing change in the parameters measured. When compared to manual HVLA procedures, patients were as well off with MAD as with HVLA. When evaluating biological responses, MAD produced statistically greater response in myoelectric activity and blood pressure response than was found in the control groups. Lower class evidence was equally supportive.

In conclusion, while all of these studies are flawed to varying degrees, the preponderance of evidence is that MAD procedures using Activator are as effective as manual HVLA in producing clinical benefit and biological change.

Safety

The question of safety is vital to any health care discipline. Manual spinal treatment has been implicated in

self-limiting, minor complications in up to 12% of the procedures performed,⁸ in a handful of cauda equina syndrome cases⁴ and in serious cerebrovascular complications for less than 0.000001% of procedures. Neither anecdotal nor administrative data base, nor published studies provide information suggesting a higher rate of incident exists with any specific technique.^{1-3,6}

For the evidence on moving stylus devices, the committee found 17 published papers that had information relevant to the topic. Four were rated as Class 1 evidence, 3 as Class 2 and 10 were considered Class 3. 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." Publishing standards expect that reports of care to patients account for adverse effects of the treatment, whether strictly followed or not. In a few of the publications, explicit statement of absence for adverse reaction was made in others comment was absent. One reported 3 cases of alleged adverse event.

There are several problems with the one report. First, it does not follow case study requirements to provide the full case data and clinical information to justify an assertion of relationship. Second, all three cases were selected specifically to claim adverse reaction in contrast to the hundreds of patients that were unselected in the remainder of the literature without a single reported adverse reaction. Third, the article clearly includes a claim of adverse affect from use of the Activator even though the alleged harm had nothing to do with the selection of technique but everything to do with the management decision to fail to refer.

Finally, 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.

In conclusion, the evidence suggests that use of the moving stylus device has no more relative risk than do manual HVLA procedures.

Uses

For the evidence on moving stylus devices, the committee found 30 published papers that had information relevant to the topic. Three were rated as Class 1 evidence, 9 as Class 2 and 18 were considered Class 3.

What is clear from an overview of the evidence on use is that these devices are widely applied to spine related and extremity disorders. They have been used in a broad spectrum of condition severity ranging from simple to complex and with significant co-morbid pathology.

In conclusion, the evidence suggests that there in clinical practice, there is broad application of these procedures.

Education

The evidence table on education consists of 5 studies, all of which were considered Class 3 data. The information provided has little to do with criteria for competency. Rather it is reported that 8 colleges provide training in Activator procedures through elective courses and one college survey reports a desire of 94% of respondents to include training in the curriculum.

In conclusion, it is clear that over half of the North American colleges provide training in these methods. It is recommended that requirements for training empower those trained in and successfully completing programs operated by colleges in the undergraduate curriculum. For those who have had no such training, I recommend that this committee is not the proper venue to make that determination.

The recommendation for requirements to perform procedures not a part of the undergraduate Chiropractic curriculum again carries the issue of setting a consistent and appropriate hurdle. I recommend a separate group, consisting of users of the procedure and College curricula experts be convened to advise on the appropriate criteria. Such a group should avoid the pitfall of setting standards so strict as to create a monopoly on a postgraduate training program. At the same time, there is need to concern the issue of minimum skill of performance and judgment of its application.

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Report to the MAD Committee of the CAS

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September 11, 2002

I. Efficacy

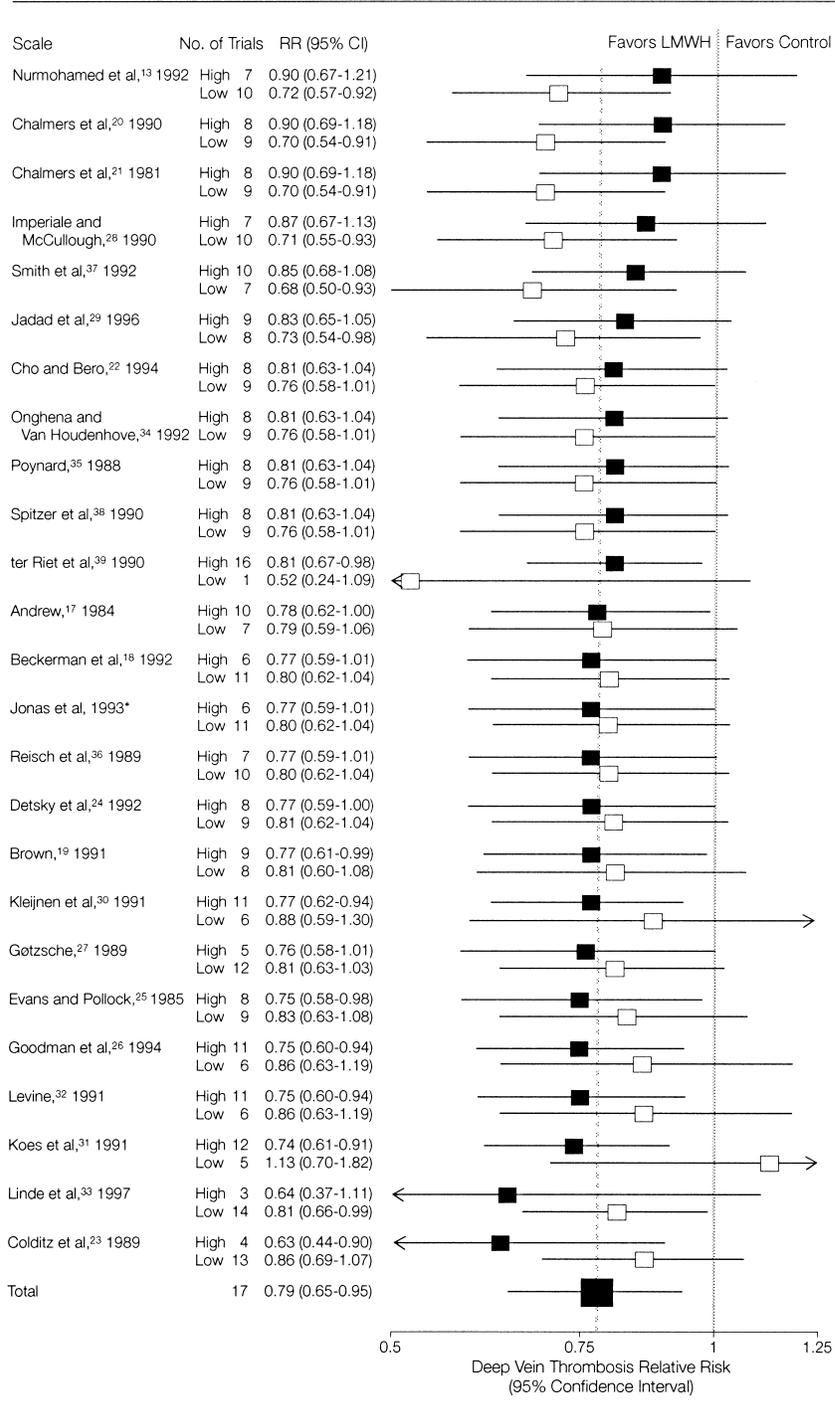
The MAD committee classified 5 of the papers reviewed as Class I evidence; numbers 6, 8, 28, 31 and 54. All studies except study #54 were described, by the authors, as pilot studies to pave the way for larger clinical trials of the effect of Activator instrument on spine pain conditions. Study #54 was a clinical trial of the effect of treatment with the activator instrument on anxiety and blood pressure.

Three papers were classified as Class II evidence; numbers 13, 17, 43. Papers #13 and #43 were basic science experimental papers that reported the results of force application by the activator instrument and the effect of the application of the activator instrument on sEMG responses respectively.

Paper #17 was a two period crossover design to compare flexion distraction treatment to a placebo (Activator instrument set to 0). The authors stated that the results of the study were useful to plan a randomized controlled study using a placebo chiropractic treatment.

Appendix I

Results From Sensitivity Analyses Dividing Trials⁵ in High- and Low-Quality Strata, Using 25 Different Quality Assessment Scales



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A. Basic Science Studies

Papers #13 and #43 are important basic science studies. Neither included any investigators from Activator Methods Inc., nor did they disclose any funding from NICR.

Herzog et al. (#43) studied the relationship between pre-load and peak forces during spinal manipulative therapy (SMT). They studied treatment to the cervical, thoracic and lumbar spine. Cervical spine treatment methods included Gonstead technique, a rotational thrust and a treatment with the Activator instrument. The authors concluded that preload and eventual peak load forces differed between manual and instrument generated treatments. The authors reported a significant correlation between peak force, preload force and change in force during manual manipulation. This correlation was not present between pre-load and change in force for the activator treatments. The data points (Figure 7C) for the change in force for the activator instrument were not correlated ($r = 0.19$). Change in force seemed to vary, independent of the preload force, for the activator instrument. Change in force is likely exclusively dependent on the mechanical spring device when the spring device is set at the constant, maximal value. A setting on activator instrument to a less than maximum may not provide enough change in force from pre-load to delta F to provide a treatment physiological treatment effect.

Symons et al. (#13) studied volunteers without symptoms. The sEMG response rate in the activator group was inconsistent. Manual SMT elicited a 100% response rate while Activator mediated responses were in the 68% range. They concluded that a reflex response elicited by treatment with an Activator instrument is quantitatively and qualitatively different than the response elicited by a manual treatment and that the physiologic and clinical relevance of the reflex response they observed remains unknown.

B. Clinical studies

Studies #6 and #8 were funded by NICR.

Cervical spine pain was studied in a group of subjects by Wood, Colloca and Matthews (#6) and Yurkiw and Mior (#28).

Keller and Colloca (#8) and Gemmel and Jacobson (#31) studied low back pain.

1. Number of patients/subjects studied

The number of patients/subjects included in the studies of the effect of the activator instrument on musculoskeletal conditions:

	N	number treated with activator
Low Back Pain		
8. Keller and Colloca	40	20
31. Gemmel and Jacobson	30	15
	70	35
Cervical spine pain		
6. Wood Colloca Mathews	30	15
28. Yurkiw and Mior	14	7
	44	22
Total	114	57

A total of 57 patients/subjects with musculoskeletal conditions were treated with the Activator instrument in studies classified as Class I.

Yurkiw and Mior (#28) documented 5 randomized controlled clinical trials of cervical spine manipulation. If one supposes that 1/2 of those patients/subjects were exposed to manual techniques, approximately 144 patients/subjects were studied with this type of clinical trial using manual technique (as of 1996) compared to 22 using the activator instrument as of 2003.

2. Clinical indication used to direct treatment

The prone leg length test was used as the clinical test used to identify the location of the spine treated by the Activator instrument in studies #6 and #8. It is not clear if this test was also used for the other treatment groups in these studies. Haas et al. (#40, #41) concluded that the prone leg length test is neither reliable nor reproducible as a method to determine levels of the spine to treat. The use of the prone leg length test to identify the levels treated in studies #6 and #8, in spite of the published results by Haas et al. in papers published 1993, draws the reader to the recommendation on page 265 of paper # 6 in which the author stated 'data collection should be done by a blinded examiner to decrease the chance of examiner bias'.

3. Sources of error

a. Sample size

The effect of small sample size on the results and conclusions of such studies is well summarized on page 455 of the study by Gemmel et al. (#31). They performed a power calculation and predicted that a sample size of 1200 would be required to detect a statistical difference, if there was one, between Activator adjusting and Meric adjusting.

Yurkiw and Mior (#28) studied the clinical effects of the Activator instrument compared to manual adjusting on pain, range of motion and cervical spine range of motion. They did not use the prone leg length method to determine the location of the spine to be treated. They documented a treatment effect for both interventions (no control) but no difference in the two groups. This result is not surprising; in fact it should be expected with hands on intervention (given the strong tendency toward a placebo response and the Hawthorne effect with these types of interventions) and the low number of subjects (Type II error). These authors fully disclosed the preliminary nature of their study. Yurkiw and Mior (#28) also performed a power calculation and estimated samples sizes between 147 and 7874 subjects depending on which range of motion of the cervical spine one compared.

b. Inherent sources of error

The study by Hawke et al. (#17), classified as Class II evidence, can be interpreted as a study of the placebo and the Hawthorne phenomena in trials of manual treatment of low back pain. The activator instrument was used as a method of providing a 'sham' or placebo treatment. Hawkes et al. (17) documented a treatment effect for the activator even though the instrument was set to 0 (i.e. no impulse). Hawke et al. even documented an adverse reaction to treatment with the Activator instrument (increased symptoms) even though the impulse setting was set to 0. The treatment effect for the activator in the Hawkes et al. study (#17) might be equivalent to that published in the other clinical trials using the Activator instrument as a treatment modality rather than a placebo. The result of small improvement for everyone involved in a trial, regardless of the intervention used, can be expected in studies with such a strong potential for placebo or Hawthorne effect and such a small sample size (Type II error).

c. Measurement error

Wood et al. (#6 – pp 264)) alerted readers to a critical point regarding the measurement of spine range of motion with the CROM. The CROM scale is divided into 2-degree increments. Also, Yurkiw and Mior (28 – pp 161) alerted the reader to the possibility of a margin of error due to 'inherent examiner testing'. Therefore one could assume at least a ± 2 degrees margin of error, although the margin of error is likely greater due to error inherent in examiner testing.

d. Measure of central tendency

Wood et al. (#6) reported median differences pre and post treatment at 4 and 6 degrees for rotation and 6 and 10 degrees for lateral bending. It is not clear why the investigators chose to compare pre and post treatment medians rather than means; both are reported. Table One documented significant differences in pre-treatment range of motion values between the instrument thrust group and the manual thrust group and differences (in some cases in excess of 2 degrees) between the mean value and the median value.

4. The indirect effect of treatment on anxiety and blood pressure

The study by Yates et al. (#54) was a good design with adequate methodology and data analysis. However, this study cannot be considered more than a pilot study for reasons documented by the authors on page 487. A major problem, identified by the authors, is that the diagnosis of hypertension was not made using standard clinical criteria. In other words, it is not known whether or not the subjects had true hypertension. Therefore, the precision of the method of diagnosis for the clinical condition being treated (independent variable) was not adequate. This has significant ramifications with respect to extrapolation the results of this study to the management of patients with the condition of hypertension. The authors concluding remarks offer suggestions for further study, including a method of blinding the activator clinician to whether the activator instrument was 'on' or 'off'

5. Summary

Deciding which treatment is better than another in a clinical trial is difficult, even if one can effectively blind the patient, the examiner and the treatment provider. The real

difference in effect size may be small, the heterogeneity of subjects large (the true diagnoses can differ widely even though the clinical presentation may be similar (i.e. pain and decreased range of motion) and the external variables may be many (including placebo effect and Hawthorne effect) so very large sample sizes are required. The published sample size estimates, based on separate power analyses by Gemmel and Jacobson (#31), and Yurkiw and Mior (#28), vary between 147 and 7800 subjects. These values exceed, by a large number, the 22 subjects with neck pain and 44 subjects with low back pain treated using the Activator instrument documented in the clinical studies reviewed by this committee.

When one considers instrument margin of error, examiner margin of error, pre-treatment differences between groups, small sample sizes and potential for error associated with the use of median rather than mean values (rounding error and reduction of the effect of outliers) the reported results must be accepted as preliminary. The authors put a fine a point on it. Wood et al. concluded that 'a randomized controlled clinical trial in a similar patient base with a larger sample size is necessary to verify the clinical relevance of these findings'. Keller and Colloca (#8 – page 592) also made this statement. Yurkiw and Mior (#28) clearly identify their study as a pilot study.

C. Conclusion

The material presented to this committee by way of literature published in peer-reviewed journals is not sufficient in quality or quantity to draw a conclusion about the efficacy of the activator instrument. The authors of the clinical studies classified as Class I all make the statement that the published work was one of a preliminary study to form the basis of a larger, more robust study. Furthermore, they conclude that the results cannot be used to address clinical relevance. This structured review of the literature does not provide a reason for the members of this committee to disagree with those authors judgment of their own work. The present literature about the Activator instrument does not allow one to draw a conclusion about whether the instrument is efficacious or not efficacious. Thus, there is insufficient evidence to support the use of the Activator instrument on patients.

II. Safety

With respect to risk assessment, case reports, case stud-

ies, case series, and most blinded randomized clinical trials can only alert us to the possibility of risk. These studies are not designed to, and cannot address the issue of safety or risk assessment, even if the stated purpose of the study is to address safety or adverse effects. One must use analytic observational designs, with the expressed purpose and design of risk assessment (like a cohort or a case control design) to quantify risk. A randomized controlled trials design can be used if it is big enough. These are basic principles in epidemiology and are well accepted.

A. Method of risk calculation

If a case study can't quantify risk, it cannot quantify the lack of risk. Again, to quantify risk (or the lack of risk) requires more than a series of case reports. One might argue that a series of case reports is the equivalent to a cohort study. However, that is not true. A cohort study is analytic: cases are incepted into the study by exposure status (in this instance it would require randomly selecting cases exposed to activator vs. some other treatment). In a randomized control design, the exposure would be randomly allocated to subjects (RCTs and cohorts are similar, except the former is experimental: the investigator controls the exposure allocation). An adverse reaction is a rare outcome so neither an RCT or cohort design would be efficient (too many subjects are required in the study to collect enough adverse reactions to estimate the risk). The best design would be a case control design because subjects are incepted into the study by their case status (i.e., cases have had an adverse reaction already and controls are matched on other confounders to cases). One could then look back at their exposure status, such as: Were they treated before the adverse reaction and did the controls have the same rate of treatment? A series of cases would not have the power to estimate a rare outcome or to quantify the risk.

B. Precision

One could consider the concept of precision that was suggested by a member of the committee. For example, if one has 50 case reports and no adverse outcome, one could estimate the lower confidence interval for the estimate of risk. A rule of thumb is $3/n$: $3/50 = 0.06$. This means that as many as 6% might have an adverse outcome in this small study. This method of prediction of adverse

reaction is sometimes used to determine risk of a surgical procedure, but it isn't really a good way. By this method, one could get an estimate, associated with activator treatment, by summing all individual participants in published case reports, case series, cohort studies and clinical trials in which the Activator was used to treat a patient/subject with a defined condition. This number would become the denominator. For our purposes we can pick a number, say 300: $3/300 = .01$. This calculation provides an estimate of an adverse reaction at 1%. In 1996, Yurkiw and Mior (#28) documented 5 clinical trials in which manual manipulation was used as a treatment. If one assumes that $\frac{1}{2}$ of the patients in those trials were assigned to manual treatment, the number of subjects would be 133. The number of subjects in clinical trials in this review using the Activator instrument for the treatment of neck pain is 22.

A flaw with this method of evaluating risk and safety of an intervention such as the Activator instrument (with a relatively small number of published papers) is clearly the artificial nature of the way the denominator is 'chosen', i.e. a calculation that is based on the number published cases. This may lead to a conclusion about the Activator instrument that defines it as relatively unsafe relative to other treatments simply because of the paucity of published cases. There has clearly been more case reports published for manual adjusting than adjusting with the Activator instrument. Thus, method of calculating the chance of an adverse reaction that was proposed has an inherent bias toward manual manipulation over the Activator instrument irrespective of the true risk.

C. Likelihood of Benefit

A final consideration in the assessment of risk, safety and probability of adverse reaction, is the likelihood of benefit. This committee was asked to review the literature published about the Activator instrument. The quality and quantity of this literature does not allow one to reach a conclusion, either that it is efficacious or it is not efficacious, about the efficacy of the Activator as a method of treating patients. Thus the argument: why accept any risk without clear evidence for benefit?

III. Educational requirements

The decision to include or exclude a treatment or intervention from a curriculum should be based on the information available in the published literature.

- The prone leg length test that is used as a method of determining areas of the spine to be treated using the Activator Method dates back to the work of Van Rumpt and Deerfield in the 1950's and 1960's. Recently, this test was shown to be neither valid nor reproducible (Haas et al. #40, #41).
- The result of this review of the literature supports the conclusion that there is not enough evidence to support, or not support, use of the Activator instrument for the treatment of patients

These points should be taught, or at least debated, at colleges of chiropractic.

IV. Usage

The Activator instrument was developed in the 1960's by two chiropractors who modified a dental instrument to reduce the physical demand of chiropractic practice when they became unable withstand the physical demands of busy chiropractic practice. Its use has grown and it is now reportedly widely used by chiropractors and others who treat the spine (including massage therapists). Some interpret this widespread use to confirm that the instrument is efficacious and safe. However, this review of the literature supports the conclusion that the existing literature is not conclusive. One is struck by the fact that after 40 years of development of the Activator Instrument, there is acceptable clinical data on only 57 patients/subjects. A conclusion regarding the clinical utility of the Activator instrument cannot be made from the literature reviewed. This conclusion is consistent with that of the authors of the published clinical studies, who clearly state that their papers are preliminary or pilot studies.

The clinical literature about the Activator instrument cannot be used to support the use of the Activator instrument for patient care.

Mechanical Adjustive Devices Committee Essay
Bruce P. Symons, MSc, DC
September 2002

Preamble

Most members of this committee will echo the sentiment that research in the area of mechanical adjustive devices (MAD) is poor and needs further investigation. Nevertheless, the data appear generally but weakly supportive of MAD. This conclusion is clear based on the quantity rather than quality of the evidence in the literature; if one simply tabulates all of the papers and adds up the checks and minuses, they will be positive. However, I find interesting to note what is NOT in the literature. There are no reports of any adverse effects, incorrect usage or lack of efficacy (alone or in comparison to manual manipulation) for MAD in the literature. Most clinicians will agree that there is an inherent risk in any therapeutic intervention, regardless of how benign it is. Therefore, I find it scientifically alarming that the literature is collectively neutral or supportive of MAD; there are no negative reports.

In this essay I will strive for brevity, and will give my opinions as definite conclusions. The interested reader can peruse the Appendices included at the end of this report for the full description and analysis of any given manuscript.

Safety

There were a total of 16 studies defined by the MAD committee as addressing Safety. These studies consisted of 4 RCTs (Class 1 evidence), 3 experimental studies (Class 2 evidence), 6 case reports (Class 3 evidence), and two reviews. It is important to note that none of these studies sought to directly evaluate the safety of MADs as a primary objective listed in the manuscript – the evidence for safety was derived as a secondary objective of the manuscript. Nevertheless, taken together with the biomechanical behavior of MADs described under the subcategory of Use and/or Usage, there was weak but unequivocal evidence, both experimental and clinical, to support the safety of MADs in the hands of trained personnel.

Education

There were only 5 studies defined by the MAD committee as addressing Education. All of these studies consisted

of Class 3 evidence. It is important to note once again that none of these studies sought to directly evaluate the educational requirements for using MADs as a primary objective listed in the manuscript – the evidence was derived secondarily. There is moderate evidence to support education in the use of MAD in chiropractic educational institutions. However, these institutions vary in the level of MAD expertise they impart to their students, and there was no evaluation of clinical competency.

Efficacy

There were a total of 21 studies defined by the MAD committee as addressing Efficacy. These studies consisted of 5 RCTs (Class 1 evidence), 2 clinical trials (Class 2 evidence), 2 experimental studies (Class 2 evidence), 11 case reports (Class 3 evidence), and one review. It is important to note that the authors of the RCTs generally considered their trials as “preliminary” in their discussion and conclusions, and therefore the results should be interpreted as such. The majority of these studies compared MADs, specifically the Activator device, to traditional, conservative, high-velocity/low-amplitude spinal manipulative therapy. There was no evaluation of MADs as a stand-alone therapeutic modality. Overall, there was weak and equivocal evidence, which was largely clinical and non-experimental, to support the efficacy of MADs.

Use and/or Usage

There were a total of 30 studies defined by the MAD committee as addressing Use and/or Usage. These studies consisted of 3 RCTs (Class 1 evidence), 2 clinical trials (Class 2 evidence), 6 experimental studies (Class 2 evidence), and one case series (Class 2 evidence). In general, it is estimated that 31–44% of the chiropractors practising in Canada utilize MADs in a minority (< 50%) of their patients. Also under the subcategory of Use and/or Usage were a significant number of basic scientific studies investigating the biomechanics of MADs. Overall, there was weak and equivocal evidence, both clinical and experimental, to support the usage of MADs.

Conclusion

I support the conditional use of MAD as a therapeutic option available to the chiropractic clinician. The conditions are:

- 1 there must be proof of adequate education and training

in the use of MADs for any individual chiropractor, similar to the proof required for acupuncture certification;

- 2 MADs should not be used as a replacement for manual manipulation, but rather as a therapeutic adjunct; and
- 3 the CAS should not endorse the use of MADs, but rather permit it, based on the literature

**Summary of the Literature on MAD
Regarding Efficacy, Safety, Usage and Education
Submitted by Lesley Biggs
September 12, 2002**

Summary of the Literature on Efficacy

Of the 21 studies examining efficacy either implicitly or explicitly, 5 were RCT (Class 1 Evidence), 2 were experimental (Class 2 Evidence), 2 were clinical trials (Class 2 evidence), 11 were case studies and 1 was a review of the literature.

Of the RCT studies, Wood, Colloca, Mathews (2001) compared standard Diversified technique to MFMA in the treatment of cervical dysfunction in a sample of 30 patients. They found no statistical differences between the two groups; both groups showed significant improvement during the treatment phase and at a one month follow-up. Cervical ROM showed statistically significant changes for both groups during the treatment phase, but the differences between groups was not significant at the end of treatment or one month following. In a pilot study ($n = 14$) of patients with unilateral neck pain, Yurkiw and Mior (1996) found no statistically significant differences on left and right lateral flexion scores, and VAS scores differences for patients receiving MAD and SMT treatments. Although the trend was toward clinical improvement, this was not statistically significant. Similarly, Gemmell and Jacobson (1995) found in sample of 30 patients no statistical differences between Meric and Activator adjustments in reducing acute low back pain. Yates, Lamping, Abram, and Wright (1988) conducted a study ($n = 21$) of patients 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); a control group (which received no treatment). The

study found significant differences between the Active Treatment Condition Group, and the Placebo and Control groups, resulting in lower systolic blood pressure scores for the Active Treatment Condition. In addition, the study found significant lowered states of anxiety for the Active Treatment Condition and Control groups.

A cohort study ($n = 18$) conducted by Hawk, Azad, Phongphua and Long (1999) indicates that the role of placebos needs to be examined more thoroughly. 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 treatments; a somewhat greater improvement occurred in most cases with the active treatment. In a descriptive case series study of 10 patients suffering whiplash, Osterbauer, Derickson, Peles, De Boer, Fuhr and Winters (1992) found a statistically significant decrease in overall mean pain scores and increased range of motion. In case series study of 10 patients, Osterbauer, De Boer, Widmaier, Petermann and Fuhr (1993) found a statistically significant difference in VAS scores and Oswestry Index scores after receiving MFMA SMT. The majority, but not all patients, reported a decline in back pain and increased function; these improvements remained stable at a one year follow-up.

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. Symons, Herzog, Leonard, Nguyen (2000) found in a sample of 9 patients resulting in 83 observations that AAI thrusts delivered to the entire spine elicited an 68% positive response rate overall; however, positive responses varied across the spine ranging from 94% for sacroiliac SMT thrusts to 50% for cervical thrusts. Herzog, Kawchuk and Conway (1993) found no significant correlation between preload and ΔF forces for treatments using the Activator instrument whereas four of the five manual techniques a significant correlation between preload and ΔF was found.

Improved clinical outcomes were reported for patients suffering from post-surgical neck syndrome (Polkinghorn and Colloca, 2001), coccygodynia (Polkinghorn and Colloca, 1999), lumbar disc herniation (Polkinghorn and Colloca, 1998), frozen shoulder (Polkinghorn, 1995), frozen shoulder with metastatic carcinoma (Polkinghorn,

1995), plantar fasciitis (Polkinghorn, 1995), torn medial meniscus (Polkinghorn, 1994), two cases of bell's palsy (Frach, Osterbauer, and Fuhr, 1992), otitis media (Phillips, 1992), and sciatic neuropathy and lumbar disc herniation (Richards, Thompson, Osterbauer, 1990). Of these studies, 5 studies (Polkinghorn and Colloca, 1999; Polkinghorn and Colloca, 1998; Polkinghorn, 1995a, 1995b, 1995c;) suggested that MFMA SMT may provide an alternative when there are contraindications to using manual SMT.

Conclusion

Overall, the RCT, cohort and descriptive case studies, and single case reports regarding the efficacy of MFMA SMT indicates that AAI, like other SMT techniques, has a positive effect on clinical outcomes. The findings of the RCT studies do not indicate that MFMA is more or less efficacious than other SMT techniques. However, the literature is dominated by case studies (52.4% or 11/21) which provide limited data on efficacy since no comparative data is available. In addition to the low number of RCT trials and cohort studies, this latter group of studies are characterized by small sample sizes. These studies are presented as pilot studies; a full-scale RCT has yet to be published. Finally, the authors of these studies point to other types of problems which limit the interpretation of the data including Type 11 errors (Yurkiw and Mior, 1996), confounding variables (use of other therapies/treatments along side SMT) (Frach, Osterbauer, Fuhr, 1992), the lack of 'blindedness' of the experimenters leading to the 'Hawthorne' effect (Yurkiw and Mior, 1996), and the placebo effect (Azad, Phongphua and Long, 1999; Yates, Lamping, Abram, and Wright, 1988).

Summary of Evidence regarding Safety

Of the 16 studies that dealt either explicitly or implicitly with safety, 4 were randomized control trials (Class 1 evidence), 3 were experimental studies – one of which appeared as a book chapter – (Class 2 evidence), 6 were case studies (Class 3 evidence), two were reviews of the literature appearing in a book chapter and journal article respectively (Class 3 evidence), and 3 were deemed not applicable.

Of the RCTs, none directly measured safety per se; no injuries were reported. Wood, Colloca and Mathews (2001) conducted a pilot study ($n = 30$) comparing manu-

al versus mechanical adjusting devices (MAD). No statistical differences were found between the groups; both groups showed statistical improvement on the questionnaires and there was equal effectiveness between the manual and mechanical adjusting groups during the treatment phase and at a one-month follow-up. Similarly, Yates, Lamping, Abram, and Wright (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); a control group (which received no treatment). The study found significant differences between the Active Treatment Condition Group, and the Placebo and Control groups, resulting in lower systolic blood pressure scores for the Active Treatment Condition. In addition, the study found statistically significant lowered states of anxiety for the Active Treatment Condition and Control groups. 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. Finally, Gemmell and Jacobson (1998) compared the Toftness diagnostic tool to manual palpation to detect subluxations in 85 patients. Both groups were treated with AAI. No statistically significant differences in pain location accuracy was found between the two procedures.

In the experimental studies which provided a theoretical model of small vertebral motions (Solinger, 2000), or examined the dynamic response of the spine during spinal manipulation (Fuhr, Green, Colloca, Keller, 1997) and the biomechanical characteristics of five common spinal manipulative methods (Kawchuk and Herzog), safety was not studied; no injuries were reported.

Case studies reported by Polkinghorn and Colloca (2001), Polkinghorn and Colloca (1998), (Polkinghorn, 1995), Phillips (1992), Richards, Thompson, Osterbauer (1990) that patients responded positively to AAI treatment. In contrast, Nykolation 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. In at one of these cases, the competency of the practitioner to deliver MFMA SMT would seem to be at issue.

Conclusion

Of the 50 articles reviewed by this committee, and of the 12 studies which were deemed to deal with safety, there are no Randomized Control Trials or cohort studies which deal directly with safety. Safety can only be implied from clinical and experimental studies where MFMA SMT has been applied to a subject. The vast majority of these studies have reported positive results; and with the exception of the case study by Nykolation and Mierau (1999), no injuries resulting from using MAD have been reported. Lack of evidence is neither proof that MAD are harmful or safe.

Summary of the Literature on Usage

Of the 30 articles designated under the category of usage, 3 (10%) are RCT studies (Class 1 Evidence); 2 (6%) are cohort studies (1 of which is a clinical study while the other is an experimental study); 6 (20%) are experimental studies; and 1 (3.3%) is a descriptive case series. These latter 9 (30%) studies were classified as Class 2 Evidence. The remaining Class 3 studies consisted of 4 (10%) literature reviews/commentary; 11 case reports 36.7%; 1 (3.3%) case series; 1 (3.3%) cohort non-crossover study and 1 (3.3%) hypothetical case study.

General Statements

In his review of the literature, Gleberzon (2000) found that a significant proportion of Canadian chiropractors utilize Name techniques including Activator methods. He found that overall 43.6% of practicing chiropractors use Activator methods. Kopansky-Giles and Papadopoulos in 1995 found that 31.4% of chiropractors utilized Activator methods for 1–25% of their patients (cited in Gleberzon, 2000: 162). Gleberzon (2001), Cooperstein (1997) Osterbauer, Fuhr, Keller, (1995) have conducted reviews of Activator Methods and provide summaries of studies conducted to date of publication. These studies have been re-reviewed by the MAD committee.

Clinical Treatment

Of the RCT studies, Wood, Colloca, Mathews (2001) compared standard Diversified technique to MFMA in the treatment of **cervical dysfunction** in a sample of 30 patients. They found no statistically significant differences between the two groups; both groups showed significant improvement during the treatment phase and at a one

month follow-up. Cervical ROM showed statistically significant changes for both groups during the treatment phase, but the differences between the groups was not significantly different at the end of treatment period or one month following. Yates, Lamping, Abram, and Wright (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); a control group (which received no treatment). The study found significant differences between the Active Treatment Condition Group, and the Placebo and Control groups, resulting in lower systolic blood pressure scores for the Active Treatment Condition. In addition, the study found significant lowered states of anxiety for the Active Treatment Condition and Control groups.

In a descriptive case series study of 10 patients suffering **whiplash**, Osterbauer, Derickson, Peles, De Boer, Fuhr and Winters (1992) found a statistically significant decrease in overall mean pain scores and increased range of motion. In case series study of 10 patients, Osterbauer, De Boer, Widmaier, Petermann and Fuhr (1993) found a statistically significant difference in VAS scores and Oswestry Index scores after receiving MFMA SMT. 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. A cohort study ($n = 18$) conducted by Hawk, Azad, Phongphua and Long (1999) indicates that the role of placebos needs to be examined more thoroughly. 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 treatments; somewhat greater improvement occurred in most cases with the active treatment.

Improved clinical outcomes were reported in case studies of patients suffering from post-surgical neck syndrome (Polkinghorn and Colloca, 2001), coccygodynia (Polkinghorn and Colloca, 1999), lumbar disc herniation (Polkinghorn and Colloca, 1998), frozen shoulder (Polkinghorn, 1995), frozen shoulder with metastatic carcinoma (Polkinghorn, 1995), plantar fasciitis (Polkinghorn, 1995), torn medial meniscus (Polkinghorn, 1994), two cases of bell's palsy (Frach, Osterbauer, and Fuhr, 1992),

otitis media (Phillips, 1992), and sciatic neuropathy and lumbar disc herniation (Richards, Thompson, Osterbauer, 1990). Of these studies, 5 studies (Polkinghorn and Colloca, 1999; Polkinghorn and Colloca, 1998; Polkinghorn, 1995a, 1995b, 1995c;) suggested that MFMA SMT may provide an alternative when there are contraindications to using manual SMT. In addition, based on one case study, Polkinghorn (1998) suggests that MFMA may be effective when a patient's condition was initially aggravated by manual manipulation. Byfield also (1991) suggests, also based on one case study, that the Activator may have some advantages over the toggle thrust since it provides "a consistent, controlled force".

In contrast to the case studies demonstrating positive outcomes, Nykolation 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. In at one of these cases, the competency of the practitioner to deliver MFMA SMT would seem to be at issue.

An Assessment Tool for Physiologic Measures (See Appendix 1 for more detail.)

The AAI has been used to measure lumbar sEMG (Keller and Colloca, 2000); preload and ΔF forces (Herzog, Kawchuk and Conway, 1993; Kawchuk and Herzog (1993)); reflex response rates (Symons, Herzog, Leonard, Nguyen (2000)); lumbar stiffness and neuromuscular reflex responses (Colloca and Keller, 2001); electromyographic reflex responses (Colloca and Keller, 2001); lumbar intervertebral motion patterns (Nathan and Keller; 1994). Keller, Colloca and Fuhr (1999) suggested that the AAI may be effective in assessing the dynamic mechanical behaviour of the vertebral column.

Appendix 1: An Assessment Tool for Physiologic Measures

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

and Herzog (1993). Symons, Herzog, Leonard, Nguyen (2000) found in a sample of 9 patients resulting in 83 observations that AAI thrusts delivered to the entire spine elicited an 68% positive reflex response rate overall; however, positive responses varied across the spine ranging from 94% for sacroiliac SMT thrusts to 50% for cervical thrusts.

In a cohort study ($n = 22$), Colloca and Keller (2001) examined the lumbar stiffness and neuromuscular reflex responses following MFMA SMT. They found that in patients with frequent or constant LBP symptoms, there was a significantly increased spinous process stiffness index in comparison with 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. They found consistent, but relatively localized, reflex responses to the localized, MFMA thrusts delivered to the thoracolumbar spin and SI joints. In 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. Nathan and Keller (1994) measured lumbar intervertebral motion patterns following MFMA SMT and determined the frequency of PA stiffness. Based on the findings of 3 subjects, the authors suggest that AAI, along with impedance analysis, may be used to quantify the mechanical response of normal and abnormal spine.

Summary of the Literature on Education

Five studies included a reference to educational issues. All were categorized as Class 3 evidence.

As of 1990, Osterbauer and Fuhr identified 7 schools which offered Activator Methods either as an elective and/or postgraduate course.

Accredited Colleges and Types of Instructional Offerings in Activator Methods Chiropractic Technique (Osterbauer and Fuhr, 1990: 174. Table 2).

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

Evidence of demand for courses in Name techniques generally and Activator Methods in particular can be found in a study conducted by Gleberzon (2000). In his review of the literature, Gleberzon (2000) found that a significant proportion of Canadian chiropractors utilize Name techniques including Activator methods. He found that overall 43.6% of practicing chiropractors use Activator methods. Based on student assignments ($n = 263$) investigating "Name Techniques", Gleberzon (2000) found that 94% of the assignments recommended, inter alia, the inclusion of Activator Methods in CMCC's curriculum.

Based on one case report, Polkinghorn (1998) suggests that MFMA may be effective when a patient's condition was initially aggravated by manual manipulation. Polkinghorn (1998) 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.

Conclusion

There is virtually no literature indicating the nature of educational training (length of course, number of hours, credentials of trainers etc.) in MFMA SMT.

Since there are no full-scale RCT or even cohort studies which have examined the efficacy, safety, and usage, it would be premature at this time to recommend the inclusion of MFMA SMT into the curriculum of accredited educational institutions.

However, the literature suggests that many chiropractors in Canada and the United States use MFMA SMT. Given interest in MFMA SMT, it would seem that a full-scale RCT of MFMA SMT technique examining efficacy and safety would seem an appropriate course of action.

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Mechanical Adjusting Device Committee Essay
Christopher J. Colloca, D.C.

Questions: What is the evidence in the literature of 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?**

Operating Definitions:

Class 1: Evidence provided by one or more well-designed controlled clinical trials; or well-designed experimental studies that address reliability, validity, positive predictive value, discriminability, sensitivity, **efficacy or safety**.

Class 2: Evidence provided by one or more well-designed uncontrolled, observational clinical studies, such as case-control, cohort studies, etc; or clinically relevant basic science studies that address reliability, validity, positive predictive value, discriminability, sensitivity, specificity, **efficacy or safety**; and published in refereed journals.

Class 3: Evidence provided by expert opinion, descriptive studies or case reports **on the topics of safety or efficacy**.

Efficacy

The Mechanical Adjusting Device (MAD) Committee identified twenty-one peer-reviewed articles relevant to the issue of efficacy of moving stylus instruments in chiropractic practice. Through consensus, the MAD Committee determined that of the twenty-one articles, five met criteria for Class 1 Evidence, three were defined as Class 2 Evidence, and thirteen met the criteria of Class 3 Evidence. Studies relevant to the efficacy of moving stylus instruments in chiropractic practice are numerous, including basic science research investigations and spanning a variety of clinical conditions with different evidence weightings.

Class 1 Evidence. Two separate studies have found improvements in neck pain, disability and improved cervical spine range of motion associated with chiropractic adjustments delivered by means of mechanical adjusting devices (Wood, Colloca and Matthews, 2001, Yurkiw and

Mior, 1996). It should be noted that in both of these studies, no significant differences were found in outcomes for patients receiving chiropractic care by means of traditional manual chiropractic adjustments or chiropractic adjustments delivered by means of moving stylus instruments. Both of these studies were limited by the small sample sizes of subjects participating in the research protocol making them both prone to Type II error. Another study also compared the immediate effect of chiropractic adjustments delivered using the MERIC technique (Manual) and instrument delivered (Gemell and Jacobson, 1998) in acute low back pain patients. The results of this study found no significant difference between MERIC and Activator adjustments in reducing acute low back pain ($F = .005$, $df = 2,27$, $p = .941$). Keller and Colloca (2000) found a 21% increase in trunk muscle strength as measured by electromyography in patients receiving instrument delivered chiropractic adjustments and no statistically significant differences in a sham-adjustment and control groups. Last, a randomized controlled trial conducted by Yates et al. (1988) reported statistically significant decreases in blood pressure among those patients receiving chiropractic adjustment to the upper thoracic spine with an activator adjusting instrument as compared to those receiving a sham treatment with the same device set to the "off" position, and a control group receiving no treatment.

Class II Evidence. Basic science research comprises the three studies rated as Class II Evidence. One investigation has demonstrated physiologic responses associated with Instrument delivered spinal adjustments (Symons et al. 1999). Another study has attempted to quantify the pre-load and peak forces associated with moving stylus instruments (Herzog, Kawchuk, and Conway, 1993) and a moving stylus device has been found to be effectively used in a research setting "detuned" as a placebo (Hawk et al., 1999).

Class III Evidence. Case reports were identified most commonly among Class III evidence relevant to instrument delivered chiropractic adjustments. Anecdotal evidence from case reports include encouraging clinical outcomes cases including post-surgical neck syndrome, lumbar disc herniation, coccygodynia, torn medial meniscus, frozen shoulder (adhesive capsulitis), plantar fasciitis, cervical disc protrusion, pain associated with mixed metastatic carcinoma, sacroiliac joint syndrome, Bell's

Palsy and neck pain among whiplash patients.

Safety

Evidence relating to the safety of moving stylus instruments include research characterizing the force-time profiles of a chiropractic adjusting instrument (Kawchuk & Herzog). In this and a number of other studies, 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, the impulse derived from a moving stylus device is of a lesser amplitude and shorter duration as compared to traditional manual type spinal manipulation.

Only one case report study in the literature notes adverse effects associated with the use of a moving stylus device (Nykoliati and Mierau). Co-founding variables associated with treatment limit the interpretation of the moving stylus device to be suspect of the cause of the adverse reactions. Moreover, as was agreed by the MAD Committee, there are numerous reports in the literature which discuss the use of moving stylus instruments that have not reported any adverse effects with its use.

Uses

The usage of moving stylus instruments has been reported in comprehensive surveys of the chiropractic profession in North America and Australia. "Activator," for example, has been found to be in use from 20–58% across Canada depending on the province surveyed (Christensen, 1993). In the United States, "Activator" has been reported to be in use by over 50% of practices. Government agencies such as Medicare under the U.S. Department of Health and Human Services proclaims that "spinal adjustment by means of a chiropractic "Activator" meets the requirements of manual manipulation outlined in the Medicare Carriers Manual section 2251.1.

The use of moving stylus instruments has been reported in the literature in the treatment of a variety of clinical conditions. Evidence from the literature reports the use of moving stylus instruments in the treatment of low back pain, neck pain and dysfunction, post-surgical neck syndrome, lumbar disc herniation, coccygodynia, torn medial meniscus, frozen shoulder (adhesive capsulitis), plantar fasciitis, cervical disc protrusion, pain associated with mixed metastatic carcinoma, sacroiliac joint syndrome, Hypertension, Bell's Palsy and neck pain and

neck dysfunction, among whiplash patients.

Educational Requirements

Doctors of chiropractic are regulated through their respective National, State, and Provincial licensing boards to perform spinal manipulation and/or chiropractic adjustments. The minimum educational requirements for the use of moving stylus instruments are thus successful completion of licensing. Moving stylus instrument adjusting techniques are included as core-curricula, and as elective courses in several chiropractic colleges in the United States, Canada, and around the World. A survey conducted at a Canadian Chiropractic College noted that a high percentage of students desired to learn techniques that include moving stylus instrument usage (Gleberzon). Council on Chiropractic Education (CCE) sponsored post-graduate educational courses also provide educational training to doctors of chiropractic in the use of moving stylus instruments.

Mechanical Adjusting Device Committee Report By Nicole Arnold, D.C.

Efficacy

Wood, Colloca, Matthews⁶ article compared manual and mechanical adjusting devices. The study found that each method was effective for treating cervical dysfunction. This suggests that manual and mechanical adjusting devices are equally suitable for treating complaints of cervical dysfunction. This article was treated as class one evidence and did not have any serious design flaws, other than it is difficult to blind the patient as to which treatment group that they were placed in with the techniques so vastly different.

It was demonstrated that maximal voluntary contraction of the lumbar paraspinals was increased according to EMG measurements following Activator adjusting. This Keller and Colloca⁸ article was categorized as Class one. It is uncertain if the patients were randomized into treatment, sham and control groups. It was also obvious to the control group that they were the control. This article is an interesting demonstration of the various factors mechanical adjusting devices, and potentially manual adjusting, can effect.

This pilot study by Yurkiw and Mior²⁸ had a very small

sample size, as a result, this increased the risk of statistical errors. It was a comparison of mechanical and manual adjusting techniques and the measurement of interest was there effect on cervical lateral flexion. The study concluded that pre and post lateral cervical flexion measurements for both groups were improved. Comparison between the two groups was statistically insignificant. The patient base was recruited from an existing chiropractic patient base, so they could not be blinded to which adjustment technique that they were receiving. It is again demonstrated that there is equal effectiveness between manual and mechanical adjusting.

Gemmell and Jacobson³¹ compared manual and mechanical adjusting in a low back pain patient population. There was a statistically significant difference in the variables measured pre and post treatment, but not between the techniques. Because of the small sample size there is potential for statistical error.

Yates, Lamping, Abram and Wright⁵⁴ demonstrated a short term decrease in systolic and diastolic blood pressure readings immediately following spinal mechanical adjusting. This portion of the study is significant for its role in showing that there can be visceral responses to chiropractic adjustments as well as somatic. Anxiety scores were decreased in the treatment and control groups. The placebo group showed an increase in anxiety scores.

The class one literature reviewed all verify that MAD's are just as effective for the treatment of cervical and low back pain/ dysfunction as manual (Meric/ Diversified) adjusting techniques. This is critical because typically manual techniques utilize more force than MAD's. The same number of treatments gave the same improvements. It also shows that MAD's are effective at producing a visceral response.

Symons, Herzog, Leonard and Hguyen¹³ demonstrated that 68% of activator thrusts elicited a reflex muscular response, as measured by EMG. A sham MAD adjustment did not evoke a response 100% of the time. Compared to previous studies of manual adjusting which gave reflex responses 100%. This difference may possibly be explained by the broader contact of the manual techniques and that the patient position is not always kept in the neutral position with manual adjusting.

Hawk, et al.¹⁷ tried to determine the various placebo effects. The study found positive results in decreasing

pelvic pain. It lacked a control group to validate the results. With patient recruitment happening within a chiropractic teaching facility, some of the patients were able to discriminate between the treatment and sham adjustments. The results of this study are not applicable to the question of this committee. The treatment technique of choice was flexion – distraction. Activator, at the zero setting, was used for the sham.

Herzog, et al.⁴³ demonstrated a relationship between preload and peak thrusting forces during different manual adjusting techniques. The Activator did not show a significant correlating relationship between preload and peak thrust forces. Assumably, because the spring applies the thrust and not the technician. The peak force values for the Activator compared to the manual techniques were lower. As mentioned earlier, with utilizing less force the MAD is still able to produce equivalent clinical results.

Osterbauer, et al.⁴⁴ showed that acute and chronic whiplash patients improved cervical lateral flexion with rotational coupling following a treatment program of six week duration. This was considered a class two study because it lacked a control group.

Unlike the class one evidence, the subject of the class two articles is varied. The Activator is used for different reasons – at times for treatment and in other studies for placebo. The Activator consistently shows that it is effective in providing a response.

Class three evidence describes case reports. Improvement in clinical conditions under MAD adjustments include: failed cervical surgery syndrome, coccygodynia, lumbar disc herniation, adhesive capsulitis, adhesive capsulitis with metastatic cancer, plantar fasciitis, torn medial meniscus, SI joint dysfunction, Bell's Palsy, otitis media, sciatic neuropathy. Cooperstein²⁶ reviews numerous case studies where the Activator has been beneficial.

There may be clinical situations where manual adjusting is contraindicated but MAD is not. For example, manual side posture adjusting of the lumbar spine may increase the risk of herniation in an acute patient. MAD adjusting keeps the patient in the neutral position, therefore not adding additional stress to compromised structures.

The evidence supports the statement that the Activator MAD is efficacious.

Use and Usage

Wood, et al.⁶ demonstrates in this article that equal clinical results are produced utilizing mechanical and manual techniques. Both treatment groups showed equal improvements in cervical dysfunction.

Keller, et al.⁸ shows that mechanical lumbar adjusting creates short term maximal voluntary contraction of the lumbar paraspinal musculature immediately following treatment. This finding may play an important role in further determining the multi-faceted effects of adjusting on recovering from low back pain.

Herzog, et al.⁴³ comments on the how manual adjusting provides feedback to the chiropractor of the patient's joint end feel and accordingly the amount of force estimated necessary to provide a successful adjustment. This sensory feedback is not available with MAD, but it may not be required due to the significantly lower peak forces generated.

Yates, et al.⁵⁴ demonstrated that both temporary reductions in systolic and diastolic blood pressures immediately following adjusting. Mixed results were received on anxiety scores following MAD adjusting. This is an interesting result. Herzog, et al.⁴³ referenced an article that stated minimum 400 N of force was necessary to evoke an immune response during a spinal adjustment. Yet, Yates was able to illicit a temporal visceral response with MAD adjusting below the stated threshold.

Class one evidence, in this category, shows benefits involving somatic and visceral uses for MAD's.

Colloca and Keller³ demonstrated that there was increased spinous process stiffness in patients that have low back pain compared to asymptomatic study participants. There was also increased neuromuscular reflexes associated with Activator adjusting in the symptomatic participants compared to the asymptomatic counterparts.

Colloca and Keller⁵ similar study EMG recordings were taken to monitor if neuromuscular reflexes were evoked adjusting certain spinous and transverse processes. This work is similar to the article completed by Symons, et al.¹³ These studies may lay the groundwork for future development of improved treatment for low back pain/dysfunction.

Gleberzon¹⁴ recommends, based on student assignments, that brand name techniques should be taught within the chiropractic college curriculum.

Keller, et al.¹⁶ showed that the AAI was able to give

consistent forces when applied to a steel beam.

Hawk, et al.¹⁷ in this article the Activator was used as the sham adjustment compared to the active treatment of flexion – distraction.

Nathan and Keller³⁵ demonstrated, using the Activator, that the spinal stiffness and mobility of the lumbar spine is different in normal, degenerative and retrolisthesed conditions.

Kawchuk and Herzog⁴² studied the relationship of five commonly used chiropractic techniques and their thrust/force relationships. They found similarities and differences between the techniques and did not clinically comment on the significance of their findings. The Activator technique was found to have a similar slope (relating to mean thrust duration) but of decreased magnitude. As anticipated this difference is probably due to the construction and mechanism of action of the instrument.

Osterbauer, et al.⁴⁴ found that Activator was beneficial in improving cervical biomechanics in a whiplash treatment group.

The majority of the articles presented under class two evidence involve basic science experiments. Using MAD's the articles show that it is capable of producing a measurable effect – neuromuscular reflexes, changes to cervical spinal biomechanics, or spinal mobility and stiffness.

Class three articles deal with reviews of literature and case studies that demonstrate that there are multiple areas within the practice of chiropractic that mechanical adjusting devices are capable of being utilized producing a clinically positive result.

The evidence supports that there are clinical situations where MAD's are appropriate for use/usage.

Safety

All of the articles, with the exception of one, did not report and injury or adverse reaction to MAD adjusting. The case series article by Dr's Nykolation and Mierau (20) involved two injury cases that were resolved legally. Since neither of these files originated within either of the author's private practices there was little description of the actual files and full details were not incorporated into the report. One of the cases comes from a private practice file. This case's problem lies with improper case management rather than with the technique used.

It stands to reason that if a technique can provide bene-

fit, that it must be able to potentially harm as well. It is recommended throughout various articles reviewed that the best way to decrease potential risk of injury is through proper and adequate training.

The evidence provided is convincing that the MAD is safe if used with proper training and clinical judgement.

Education

It is recommended that users of the Activator Adjusting devices receive training in its use. As noted in the study conducted by Colloca, Keller, Gunzberg, Vandeputte and Fuhr¹⁰ there is preliminary evidence to show that increased specificity to the segment adjusted and the directions of the vectors of force will show affect the amplitudes of the action potentials.

Gleberzon¹⁴ in his article recommends that the chiropractic colleges include the teaching of named techniques within the chiropractic curriculum. He states that the students are requesting it and that a large majority of the practicing chiropractors are using it.

Pocklington²² relates in his case study and further commentary that AMCT is an effective alternative to managing cases that are aggravated through manual adjusting techniques. He includes within the article comparisons between manual and ACMT adjusting. Notably he describes how the AAI thrust is quicker than the manual and faster than the muscle stretch reflex.

It has been mentioned numerous times that ACMT is taught within the D.C. curriculum or the postgraduate curriculum of many accredited colleges. Cooperstein (26)

There should be guidelines established to set minimum competency levels for chiropractors who are interested in utilizing MAD techniques within their chiropractic practices.