

MAGNETIC RESONANCE ANGIOGRAPHY

Two Ten Patient Pilot Studies



Using Phase

Contrast

Magnetic

Resonance

Imaging

Project I:
Hypertension

Project II:
Headaches

UPPER CERVICAL RESEARCH
FOUNDATION

Introduction and Perspective

Years of clinical evidence suggest that the atlas vertebra misalignment may be related to a negative impact on human nervous system function resulting in chronic health symptoms, conditions and diseases affecting a decrease of quality of life. Within the chiropractic profession, investigation and validation of the mechanisms involved in supporting theories on spinal misalignments are lacking and long overdue.

It has long been suspected that upper cervical spinal misalignments result in altered cerebral blood flow. Correction of the misalignment may produce a 'normalization' of blood flow and a reversal of related patient reported conditions (Scott R et al. 1-8). Accuracy and validity in noninvasive measurement of cerebral blood flow has been limited due to technology.

A new method using Phase Contrast Magnetic Resonance Imaging (MRI) Angiography (PC MRA) now exists that significantly increases accurate valid measurements. Using PC MRA, cerebral arterial and venous blood can be measured in almost every vessel in the brain with an added ability to measure cerebrospinal fluid flow and determine Intra-cranial Pressure (ICP).

It has been proposed to measure all these parameters using PC MRA before and after a NUCCA correction of the atlas misalignment. From these proposed pilot investigations, evidence of mechanisms detrimental to the central nervous system may be discovered.

Changes in cerebral blood flow have been demonstrated by medical research to be connected to a number of medically diagnosed conditions and diseases. With the appropriate tools now available, the effect of the NUCCA atlas correction procedure on cerebral blood flow can be accurately evaluated.

Research Goals

The desired outcome of the blood flow investigations is two fold. Most significant is to discover neural mechanisms involved for two specific conditions involving a large population of our society: migraine headaches and hypertension. The second outcome will attract interest within the scientific community for further investigation of these mechanisms and the funding required to conduct the Gold Standard, Controlled Clinical Research Trials required for validation.

Two studies, each involving ten medically diagnosed patients with Stage I hypertension and ten medically diagnosed patients with migraine headaches are planned. Mechanisms already suspected in migraine headaches and hypertension may be related to in the brain stem nuclei, a critical area that may be involved in the atlas misalignment.

Measurable changes in cerebral blood and cerebrospinal fluid flow may substantiate a neural homeostatic mechanism affected by atlas misalignment in the brain stem nuclei. This research will lay the foundation for further research into the effect of the atlas misalignment on the central nervous system.

Background Significance

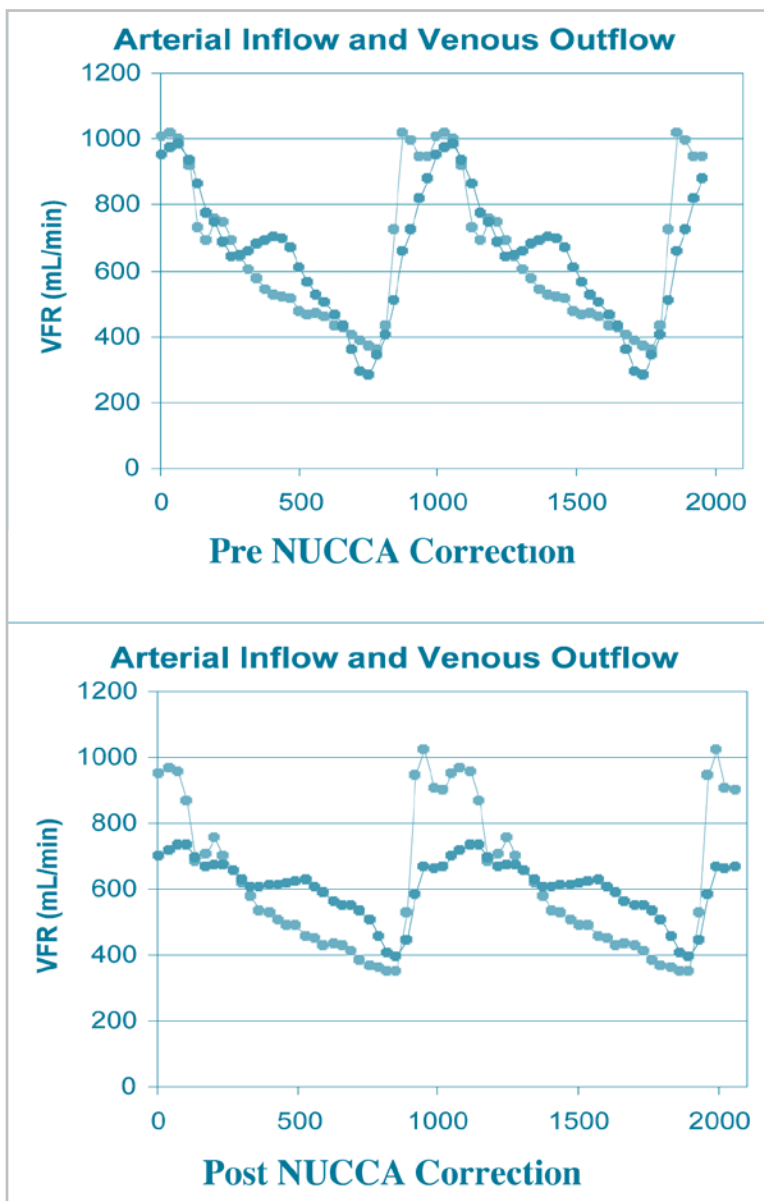
The publication of the NUCCA hypertension study in the Journal of Human Hypertension, May 2007, created a demand for more research in this "Atlas Phenomena." Two important areas requiring immediate investigation involve the explanation of a possible physiologic mechanism behind the atlas correction, the development of a screening tool to determine the prevalence of atlas misalignment in the US population. Of enormous importance, is the identification of who can benefit from an atlas correction, especially those diagnosed with chronic conditions such as hypertension, migraine headaches, chronic fatigue and fibromyalgia.

One surprising result of the hypertension study involves an unchanged heart rate resulting from the reduction of blood pressure. Since this did not occur, a central (in the brain) or central nervous system mechanism mediated this response. This indicates a change in blood flow patterns to the areas in brain stem regulating blood pressure.

It is suspected that a change in blood flow in the Posterior Inferior Cerebellar Artery (PICA) that circulates to the Nucleus Tractus Solitarius (NTS) in the brain stem could be the mechanism involved in altering the function of the nervous system. The NTS serves as a collection center of sensory nerves coming into the brain and determines which 'messages' are important and where they need to be 'delivered' in the brain. Blood pressure is one of those messages.

Case Study Results

A pilot study using Phase Contrast has recently concluded revealing startling evidence of changes in the cerebral blood flow after a NUCCA correction. The subject with a 20 year history of intractable headaches (migraine) occurring three to four times a week was studied. A PC MRA imaging study was obtained before the standardized NUCCA protocol evaluation. After the NUCCA procedure, a post PC MRA study was performed. The changes in venous outflow are represented graphically below.



Note in the post correction graph, the venous outflow has decreased.

MRA HYPERTENSION PROJECT

The article published in the Journal of Human Hypertension suggesting a relationship of atlas misalignment and hypertension has aroused the attention of the medical community. The investigation involves an examination of changes in cerebral blood flow pre and post atlas correction in relation to measured blood pressure for a diverse ethnic group diagnosed with Stage I hypertension.

The significance of this study will provide information about the mechanisms involved in the reduction of blood pressure resulting from the correction of the misalignment of the atlas, head and cervical spine.

PRINCIPAL INVESTIGATORS AND CREDENTIALS

George Bakris, MD, *Professor of Medicine, University of Chicago, Director, Hypertension Center*

Dr. George Bakris specializes in the diagnosis and reduction of high blood pressure, particularly in complicated or refractory cases. His internship and residency was at the Mayo Clinic where he specialized in Clinical Trial Research Design. He is the author of over 340 journal articles. He served on the 2003 the Joint National Committee on Blood Pressure and Hypertension setting guidelines for classification and treatment of hypertension. Dr. Bakris contributed his expertise to the NUCCA hypertension study.

Charles Woodfield, D.C., R.Ph., *Life West College of Chiropractic, Haywood, CA*

Dr. Woodfield received his training at UNC-Chapel Hill School of Pharmacy and Palmer College of Chiropractic. While studying at Palmer, he conducted a clinical trial remaining after graduation to conduct other trials on chronic neck pain. He was instrumental in establishing the Practice Based Research Network. He has conducted NUCCA upper cervical chiropractic research since 1996 in conjunction with Dr. Marshall Dickholtz, Sr. and Dr. Bruce Bell. He was the primary developer of the NUCCA hypertension study protocol and major contributor to the final published paper.

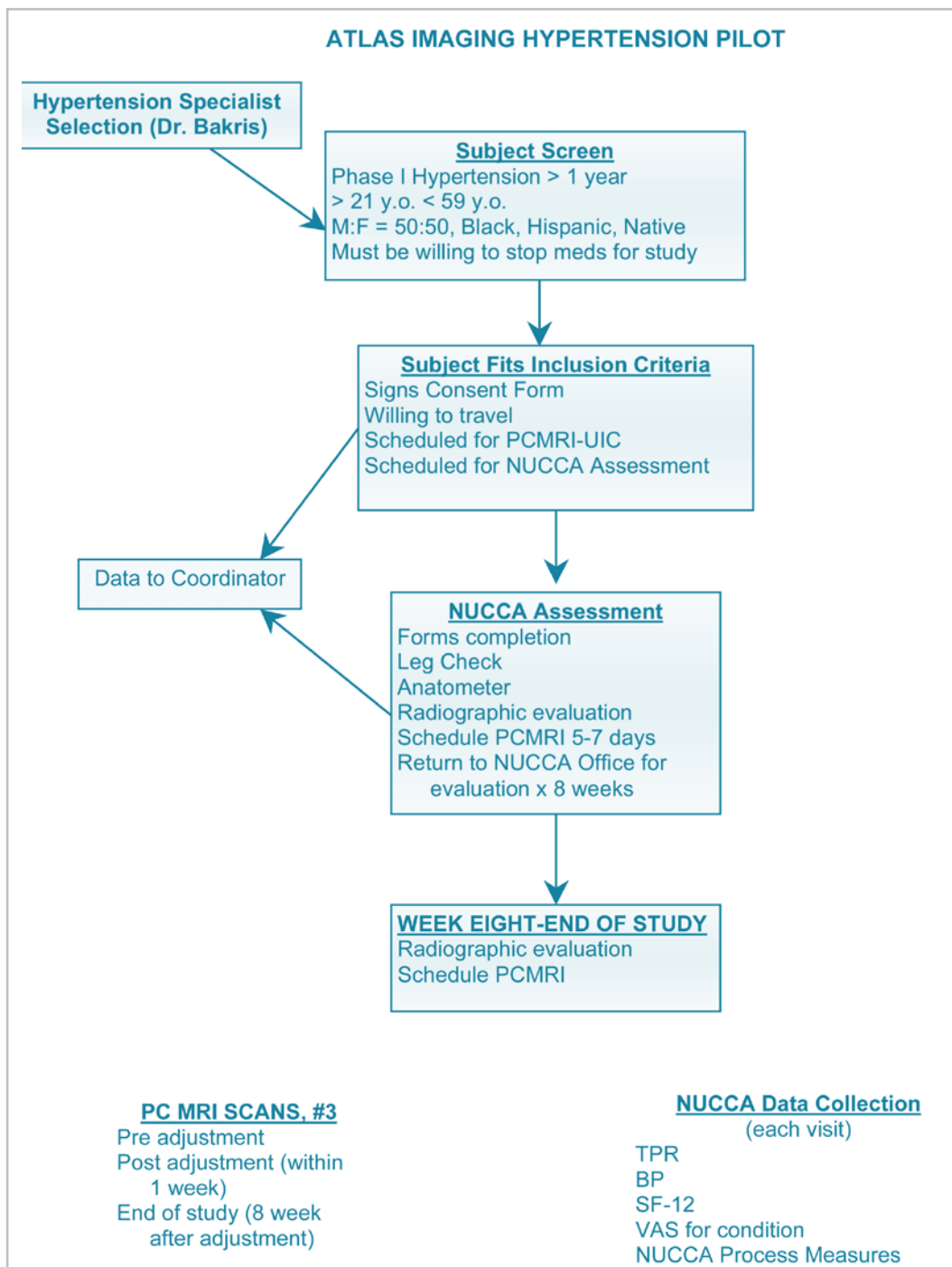
Noam Alperin, Ph.D., *Associate Professor of Medical Physics. Head, MRI Research Lab, Department of Radiology, University of Illinois at Chicago.*

The MRI Research Lab, founded by Dr. Alperin in 1996, is one of the leading research groups in the country studying brain biomechanics. The MRI Research Lab in the Department of Radiology provides an interdisciplinary research environment. Dynamic motion-sensitive MRI techniques are used to characterize the relationships between blood flow and cerebrospinal fluid pulsation in the brain. This research is funded by the National Institutes of Health.

Terry Lichtor, M.D., Ph.D., *Department of Neurosurgery, Rush University Medical Center*

Dr. Lichtor received his degrees from the University of Chicago. He completed an internship in general surgery at Mayo Clinic, a residency in neurological surgery and a fellowship in molecular neurobiology at the University of Chicago. His research interests are focused on projects concerning the development of MRI methods to non-invasively measure intracranial pressure and determining cerebral blood flow.

Dr. Marshall Dickholtz, Sr., *Adjusting Doctor,* is the founding director of both the National Upper Cervical Chiropractic Association (NUCCA), and the Upper Cervical Research Foundation (formerly NUCCRA), for which he served a long, laudable term as its president. Dr. Dickholtz's recent hypertension study, printed in the *Journal of Human Hypertension*, May 2007, demonstrates the NUCCA correction of the atlas misalignment reduces blood pressure.



ESTIMATED COSTS

Phase Contrast				
MRI Pilot-Hypertension				
10 subject feasibility study				
Imaging Costs-UIC Facility	\$2,000.00			
	per study X 30	\$60,000.00		\$60,000.00
Personnel Costs				
NUCCA Researcher	\$750 X 10 Subjects	\$7,000.00		
	\$30 X 80 subject visits	\$2,400.00		
Subject data & procedures	115 hours X \$35.00	\$4,025.00		
Nurse (RN)				
Project Administrator	5% time	\$15,000.00		
PC MRI Physicist				
	20% time	\$30,000.00		
Neurology Research PC MRI				
	5% time	\$12,500.00		
Project Coordinator				
	40% time	\$20,880.00		
Statistician Consult				
	\$125 x 20 hours	\$2,500.00		
		\$94,305.00		\$94,305.00
			Subtotal:	\$154,305.00
Indirect Costs				
University of Illinois-Chicago -or- Administrating Insitution (2% of 90K)	\$1,800.00			\$1,800.00
UCRF (7% of 173K)	\$11,921.00			\$11,921.00
Subject Expenses				
	\$1,000.00 X 10 subjects			\$10,000.00
Coordination Travel				
	2 trips-ORD x \$1,000			\$2,000.00
Presentation Costs				
	\$4,000.00			\$4,000.00
			Grand Total:	\$184,026.00
			Cost Estimate:	\$184,026.00

MRA MIGRAINE HEADACHE PROJECT

A relationship between the atlas misalignment and headaches has been suggested by years of clinical evidence. By measuring the cerebral blood flow before and after an upper cervical correction of the atlas vertebra using the NUCCA procedure one of the mechanisms may have been discovered to understand why the patient's headaches were significantly diminished.

This is a larger study using the same imaging of the vasculature and cerebrospinal fluid of the cranial vault used in the one patient pilot project for intractable headache. This study continues the investigation into the mechanism involved when the NUCCA atlas correction exerts an effect on the autonomic nervous system and headaches.

PRINCIPAL INVESTIGATORS AND CREDENTIALS

Bruce Bell, M.D.

Dr. Bell has lead investigation into the mechanism of the NUCCA correction for over 20 years. In conjunction with Drs. Dickholtz, Sr. and Woodfield, several projects have been conducted culminating with the NUCCA Hypertension project. His wisdom and vision have inspired progress into the physiologic mechanism behind the NUCCA correction.

Charles Woodfield, D.C., R.Ph., *Life West College of Chiropractic, Hayward, CA*

Dr. Woodfield received his training at UNC-Chapel Hill School of Pharmacy and Palmer College of Chiropractic. While a student at Palmer, he conducted a clinical trial remaining after graduation conducting other trials in chronic neck pain. He was instrumental in establishing the Practice Based Research Network. He has conducted NUCCA upper cervical chiropractic research since 1996 in conjunction with Dr. Dickholtz, Sr. and Dr. Bruce Bell. He was the primary author of the NUCCA hypertension study protocol and major contributor to the final published paper.

Ben Nager, M.D.

Board certified in neurology, Dr. Nager provides his expertise in the autonomic nervous system in verification of the migraine headache diagnosis.

Noam Alperin, Ph.D., *Associate Professor of Medical Physics. Head of MRI Research Lab, Department of Radiology, University of Illinois at Chicago.*

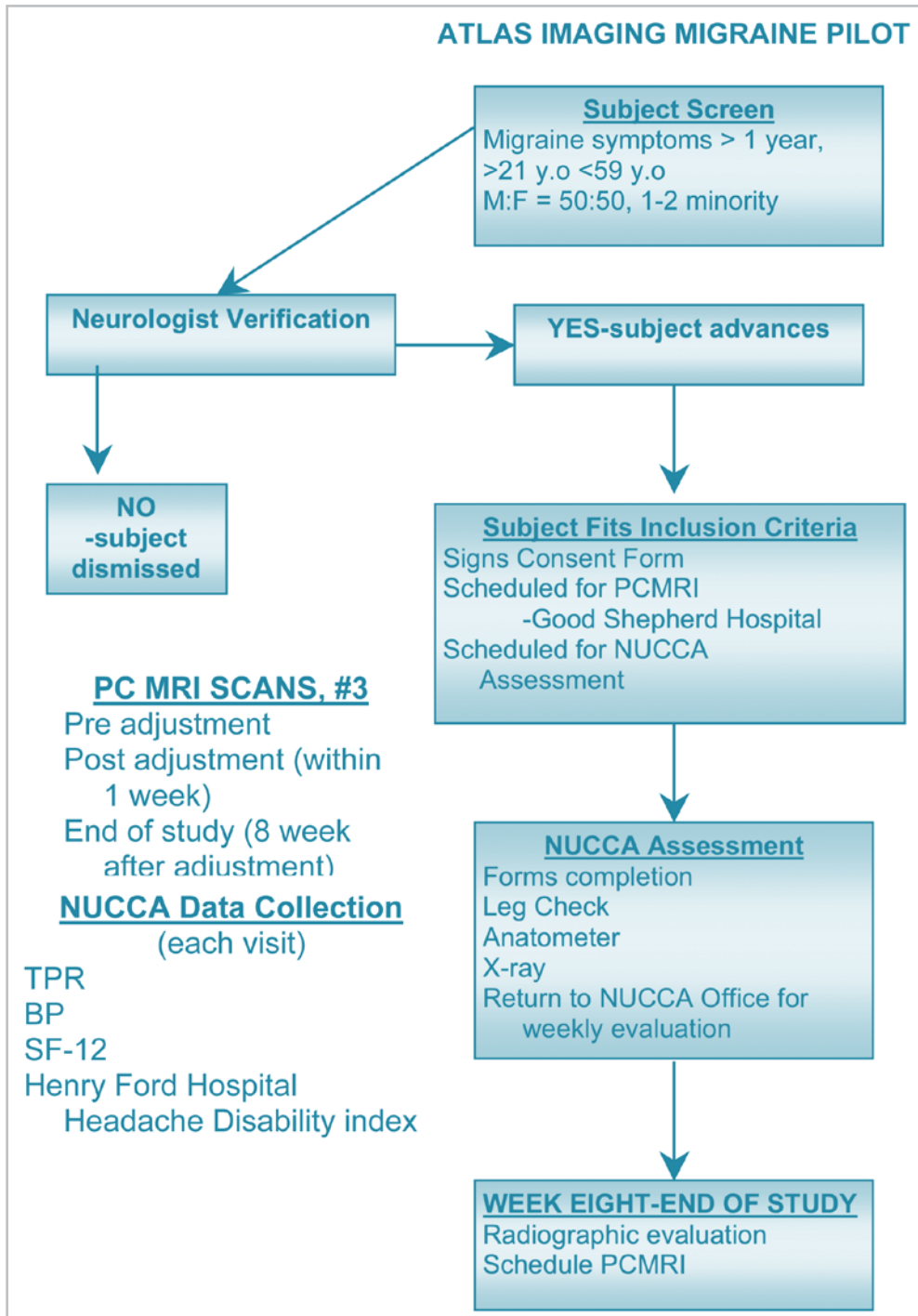
The MRI Research Lab, founded by Dr. Alperin in 1996, is one of the leading research groups in the country studying brain biomechanics. The MRI Research Lab in the Department of Radiology provides an interdisciplinary research environment. Dynamic motion-sensitive MRI techniques are used to characterize the relationships between blood flow and cerebrospinal fluid pulsation in the brain. This research is funded by the National Institutes of Health.

Jonathan Brown, D.C.

Graduate of Logan College of Chiropractic, Dr. Brown trained under Dr. Dickholtz, Sr. and assisted in the Hypertension project. Dr. Brown has assisted Dr. Bell and will continue his role as the adjusting doctor in the migraine study.

Terry Lichtor, M.D., Ph.D., *Department of Neurosurgery, Rush University Medical Center*

Dr. Lichtor received his degrees from the University of Chicago. He completed an internship in general surgery at Mayo Clinic, a residency in neurological surgery and a fellowship in molecular neurobiology at the University of Chicago. His research interests are focused on projects concerning the development of MRI methods to non-invasively measure intracranial pressure and determining cerebral blood flow.



ESTIMATED COSTS

Phase Contrast				
MRI Pilot-Migraine				
10 subject feasibility study				
Imaging Costs-	\$1,000.00			
Good Shepherd Hospital	per study X 30	\$30,000.00		\$30,000.00
Personnel Costs				
NUCCA Researcher	\$400 X 10 Subjects	\$4,000.00		
	\$30 X 80 subject visits	\$2,400.00		
Subject data & procedures	115 hours X \$35.00	\$4,025.00		
Nurse (RN)				
Project Administrator	10% time	\$30,000.00		
Neurologist Confirmation	\$300 X 10 Subjects	\$3,000.00		
PC MRI Physicist	10% time	\$15,000.00		
Neurology Research PC MRI	5% time	\$12,500.00		
Project Coordinator	40% time	\$20,880.00		
Statistician Consult	\$125 x 20 hours	\$2,500.00		
		\$94,305.00		\$94,305.00
			Subtotal:	\$124,305.00
Indirect Costs				
Good Shepherd Hospital-(7% of 60 K)	\$4,200.00			\$4,200.00
UCRF (7% of 130 K)	\$9,121.00			\$9,121.00
Coordination Travel				
	2 trips ORD x \$1,000			\$2,000.00
Presentation Costs	\$4,000.00			\$4,000.00
			Grand Total:	\$143,626.00
			Cost Estimate:	\$143,626.00

REFERENCE LIST

Scott, R., et. al. "The Impact of Chiropractic Adjustments on Intracranial Blood Flow: A Pilot Study." *JVSR*, (2007): 1-8.

Alperin, N., et al. "Relationship between total cerebral blood flow and ICP measured noninvasively with dynamic MRI technique in healthy subjects." *Acta Neurochir.Suppl* 95 (2005): 191-93.

ADDITIONAL UCRF RESEARCH

FINITE ELEMENT SPINAL MODELING PROJECT

The Spinal Model project specifically addresses what is biomechanically normal by employing a powerful non-destructive engineering method utilizing computers and sophisticated software developed to determine how forces impact the spine. This process not only offers an understanding of biomechanical problems seen in the human spine, it also suggests how best to use biomechanics in correcting these problems. As a result, NUCCA researchers are able to use their vast clinical knowledge and understanding to identify actual problems from practice experience and transform the problem-related information into useful biomechanical equivalents in the model.

The engineering-problem in finite element analysis is represented by what is called a finite element model. In a finite element model, the geometry of the structural component is divided into small parts/mesh. Each of these small parts is called an “element” and the points where these small parts connect to each other is called a “node”. Appropriate material properties are assigned to each element. Therefore, intuitively, as the size of the element becomes smaller, the model more closely represents the actual material continuity that exists.

NUCCA PRACTICE BASED RESEARCH

Practice based research (PBR) networks are designed to provide missing links in high quality chiropractic research by utilizing the controlled environment of the doctor’s practice. The individual practitioner collects information from the patient to determine a working diagnosis and treatment plan, and uses specific outcome measures to assess the patient’s improvement.

Methods to collect this data without disrupting the functioning of the office can provide a vast database of information used to document needed evidence that NUCCA chiropractic care is an effective and valid healthcare choice. This study offers key demographic information describing the patient population that utilizes NUCCA care and also provides evidence of improvements in quality of life.

The Hypertension study conducted in the NUCCA practice of Dr. Marshall Dickholtz, Sr. utilized a Practice Based Research protocol. This study was a culmination of over 10 years of PBR experience that began with simply collecting information from his patients. As his research skills and motivation developed, participation in the research Gold Standard, a Randomized Controlled Clinical Trial was realized. The results are published in the prestigious medical Journal of Human Hypertension.

VALIDATION OF THE SUPINE LEG CHECK

It is vital for the successful validation of the NUCCA atlas correction procedure to have a reliable screening test to determine if the atlas is misaligned. Such a test is the Supine Leg Check (SLC) as described by NUCCA’s founder, Dr. Ralph Gregory. This test is easy to teach, easy to learn and inexpensive to perform.

The National Institute of Health is interested in this technique and has requested a study to confirm its validity. The SLC will be utilized in the NIH National Health and Nutrition Examination Survey (NHANES) which is an in-depth investigation of the health status of the various communities it studies. The SLC will be used to determine how many people in certain focus regions have a short leg, a clear indication of a misaligned atlas and possible related health and well-being issues.

INTER & INTRA EXAMINER X-RAY RELIABILITY

The orthogonal radiograph exam is the primary means by which the atlas misalignment and correction are evaluated. The radiograph is used to measure the exact degree of misalignment allowing determination of a viable correction strategy. In the realm of scientific investigation, the radiograph provides documented objective evidence confirming the newly adjusted position of the atlas. The same measurements used to identify the misalignment are used to determine the success of the correction.

This NUCCA study process requires candidates to submit films for review by certified practitioners providing an ideal situation where radiographs are screened for usability and sent to other certified doctors for review. Films can be easily sent between reviewers for inter reliability verification as well as having them review the same series again and determine the degree of agreement. This study will be research investigating the work of Board Certified NUCCA practitioners who have demonstrated both competency and proficiency. It is designed to help overcome the bias that remains from earlier theories and hypotheses suggesting that misalignment of spinal vertebrae are not measurable on X-ray.

CERVICOGENIC TEMPORAL MANDIBULAR DISORDER

Chiropractic and dental literature suggest an association between Temporal Mandibular Disorders, commonly called TMJ or TMD, and cervical chiropractic. This study therefore, is designed to provide an understanding of the interconnections between TMD and malposition of the atlas. In addition to providing an understanding between TMD and atlas malposition, this project is also expected to determine the optimal way in which dentists and upper cervical chiropractors can work together for the benefit of the patient. The question to be answered is: "Does a malposition of the upper cervical spine change the dental occlusion or bite? For example, if the atlas is corrected and not malpositioned, does that decrease the number of adjustments needed on dental occlusion and appliances? Clinical observations to date support the view that increased spinal stability and dental function are seen with patients using an integrated approach to dental care. The cervical spine-jaw-head modeling at the University of Toledo will be used to interpret what is seen dentally and chiropractically and will provide a biomechanical model relating TMD and misaligned cervical vertebrae.

For Complete Project Descriptions, Please Visit www.ucrf.org

The Upper Cervical Research Foundation is devoted to the evolution of healthcare and impacting change that truly makes a difference. We need many partners to realize this vision and invite you to help us continue our tradition of supporting educational initiatives and innovative research to promote optimal well-being. Lend your hand to change. It's a remarkable work in progress!

