

Study Protocol

**An Evaluation of Cervical Spine
Ligamentous Instability After
Acceleration/Deceleration Injury**

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Protocol

1. Project Title:

An evaluation of cervical spine ligamentous instability after acceleration/deceleration injury.

2. Investigator(s):

Principal Investigator: Henry J. Griffiths, MD
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3. Abstract:

The use of radiographic imaging in acceleration/deceleration injury to the soft tissues of the cervical spine remains mostly unreported. The purpose of this study is to determine the incidence of ligamentous injury in patients who suffer neck pain and stiffness at least 4 weeks after sustaining an acceleration/deceleration injury as a result of a motor vehicle accident (MVA). Magnetic Resonance Imaging (MRI) will be utilized along with the Steven L. Rhodes MR Device to facilitate flexion and extension views. Magnetic field exposure from the MRI is extremely safe for the subject and does not utilize radiation. This study does not involve providing medical treatment for the injury. It only involves patients giving permission for the MRI imaging center to share the MRI reports from their procedure with the investigators, for the purpose of research. Subjects who present to the Shands Jacksonville Emergency Department with neck pain and who fit the inclusion and exclusion criteria, and who may require additional follow-up care, including MR imaging, will be given research study advertisements.

4. Specific Aims:

The purpose of this investigation is to determine the incidence of ligamentous injury (objectively determined by MRI) in patients who suffer neck pain and stiffness at least 4 weeks after sustaining an acceleration/deceleration injury as a result of a motor vehicle accident (MVA). We will also attempt to correlate the patients' clinical diagnosis with the radiology (MRI) interpretation. To accomplish this, we will request copies of the patient's imaging studies, from those patients who receive MRI's with flexion and extension views.

We hypothesize that there will be quantifiable ligament laxity in a subset of the population studied.

5. Background and Significance:

In an article from Australia published in 1997, radiologists, a neurologist and family practitioners performed MRI on 29 patients who had sustained a whiplash-type injury. This was repeated on 19 of the patients 6 months following injury. Apart from spondylosis found in 11 patients, loss of lordosis found in 7 patients, the only major abnormality found was one patient to have a small syrinx. The authors were unable to correlate the MR findings with the clinical symptoms in any of the patients.

In a comparative study between 40 subjects with neck sprain (patients with acceleration/deceleration injury), and 20 age and gender matched controls, Borchgrevink, et al., found no statistically significant differences between MRI of the brain and cervical spine in the injured group and in the control group. With respect to the patient group, 19 (47%) had various types of postural abnormalities including slight straightening of the lordosis in 11 patients (27%), and complete straightening of the lordosis in 3 patients (8%). This pathology was found in 25 of the patients and 15 of the volunteers. In the patients, reduced signal in the disc was found in 12 (30%) and disc protrusion was found in 13 patients (32%) as well as in 6 controls and that is 30%. Spondylosis was found in 10 patients (25%) but the word spondylosis was not defined. The authors commented that neck stiffness was found in 42% of the patients at 6 months, neck pain in 22%, and headache in 33%, but they did not repeat the MR scans.

In one of the first articles comparing the MR findings with the clinical symptoms in a group of whiplash trauma patients, Petterson, Hildingsson and colleagues found no relationship between the two. However, they did find that 26 of 39 consecutive patients (66%) with acceleration/deceleration-type injuries had abnormalities on MRI. Mild ventral disc bulging was seen in 16 patients (40%) and dorsal disc bulging was seen in 18 patients (46%) of which 1 was considered severe and 7 were considered moderate. Actual spinal stenosis was found in 3 patients. One patient had a muscle rupture, which was visible on MRI. The authors postulated that the disc changes were age related, rather than a result of the trauma.

In a review article published in the *European Journal of Radiology* in 1996, Van Goethen and co-authors reviewed the etiology, classification, symptoms and imaging findings in acceleration/deceleration injury, including the use of plain films (as well as extension/flexion views), CT and MR imaging. In their discussion, they recommend the use of MRI and prophetically suggest the use of dynamic MRI.

Thus, the next step is to objectively evaluate the presence of ligamentous injury with flexion/extension MRI.

6. Research Plan:

Patients who present to the Shands Jacksonville Emergency Department with neck pain and who are evaluated by University of Florida Department of Emergency Medicine physicians and who fit inclusion/exclusion criteria will be informed about the research study, upon discharge from the Emergency Department. Inclusion/exclusion criteria includes any adult (> 18 years), involved in a MVA, who was evaluated for cervical spine injury and who was found to have no fracture. Each prospective subject will be given a letter and reminder card informing them that they can call a telephone number if they require additional care following their MVA. All patients who are in need of advanced imaging will be scheduled for Magnetic Resonance Imaging (MRI) at one of a number of selected imaging facilities (based on a location convenient to the patient). As with any patient needing additional medical care, their insurance company will be charged for the MRI and medical treatment, and the unpaid balance will be the responsibility of the patient.

Patients who elect to receive additional treatment at the specified facility, and who are in need of an MRI (based on clinical decisions at the facility) will then be asked if their protected health information can be shared with the investigators.

One thousand subjects who receive MRIs as part of their clinical care will be recruited to serve as subjects. Each subject will receive a series of views obtained by MRI to evaluate ligamentous injury, including 1 axial sequence and 3 sagittal sequences. The Steven L. Rhodes MR Device will be used to facilitate flexion and extension views. The patient will be consented by trained staff from the imaging facility and a copy of the MRI images, as well as the radiologist's interpretation, will be transported by a member of the research staff to the Principal Investigator along with a signed copy of the consent form. Three copies of written informed consent will be obtained; the patient's copy, the imaging facility's copy (who will obtain the consent), and the investigator's copy which will accompany the MRI images and report.

Data will be analyzed with descriptive data. The dependent variables are:

- Percent of patients who show signs of ligamentous injury via flexion and extension MRI.
- Correlation (percent of agreement) between clinical diagnosis (provided by clinicians who are not members of the research team) and radiology interpretation.

7. Potential Health Risks:

There are no known risks to these subjects as a result of their participation in this research protocol.

8. Potential Health Benefits:

There are no direct health benefits to the subjects as a result of their participation in this research protocol. This protocol only serves to furnish the research team with the results of already obtained imaging studies for the purposes of research. This protocol does not include the provision of medical services.

9. Potential Financial Risks:

There are no financial risks to the subjects as a result of their participation in this research protocol. This protocol only involves sharing health information (imaging studies which have already been obtained for diagnosis and treatment) for the purposes of research.

10. Potential Financial Benefits:

There are no direct financial benefits to the subjects as a result of their participation in this research protocol.

11. Conflict of Interest:

There are no conflicts of interest as it relates to any of the investigators and this protocol.

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