

Title of Proposal

Randomized, controlled trial of posterior C1-2 fusion versus bracing alone for treatment of type II odontoid process fractures in the elderly

Investigators**Institutions****Grant Category****Hypotheses**

This prospective study addresses one of the most controversial topics in the treatment of cervical spine trauma: the management of type II odontoid process fractures in the elderly. It is our hypothesis that surgical treatment will result in improved functional outcome measures, neck pain and mortality rates as compared with nonsurgical management. Furthermore, we hypothesize that surgical treatment of odontoid process fractures will limit hospital re-admissions and development of medical complications secondary to prolonged immobilization in a cervical orthosis and delayed surgery related to late fracture displacement, which are often associated with non-operative care. Additionally, data from this study will be useful in identifying patient-specific predictors of improved outcome which can be used to optimize treatment algorithms and more effectively counsel patients who sustain these injuries.

Study Proposal/Methods

This prospective, randomized, controlled study (n=200) will be performed across 10 tertiary-referral academic spine centers over an 18-month period. To be enrolled, patients will be ≥ 65 years of age, present with a type II odontoid process fracture from traumatic injury <90 days prior to enrollment, have undergone no previous fracture treatment and have no cognitive impairment which would require the use of a health care proxy to enroll in the study.

Clinical data collected will include patient demographics, co-morbidities and injury mechanism. Patient reported outcome measures collected preoperatively as well as at 3,6 and 12 month post-operatively will include: Short Form 12-Item Survey (SF-12), Neck Disability Index (NDI) and Visual Analogue Scale (VAS) for pain. Complications will be recorded based on a list of 19 anticipated complications which was previously formulated for this patient population. Events such as reoperation, cohort crossover leading to operative intervention for the braced group and patient deaths will be recorded. This clinical data is already obtained as part of the standard of care at participating institutions which will minimize administrative support needed to complete this study.

Institution Board Review will be sought for this study and consent will be obtained from all study participants prior to enrolment. All data will be stored in a study specific database and statistical support for data analysis will be provided onsite.

Significance of Project

Type II odontoid process fractures are the most common cervical spine injuries in patients age 65 and older and represent the majority of cervical fractures in patients older than 80. With these demographic groups growing in North America as the baby boom generation ages, establishing an evidence based treatment algorithm for these injuries will become an important aspect of cervical spine health. Although it has been the subject of numerous studies, the treatment of type II odontoid process fractures remains controversial, in part because of criticism suggesting that the largest prospective cohort study on this patient population was compromised by selection bias. Careful attention to the design and execution of a randomized, controlled trial can address the equipoise related to treatment of type II odontoid process fractures and provide definitive guidance for surgeons treating these patients.

Previous Work in this Area

The investigators have completed a substantial body of work on this topic but feel strongly that the proposed study can supersede all previous efforts in terms of providing meaningful guidance to spine surgeons treating patients with type II odontoid fractures.

The investigators played leadership roles in the previously mentioned prospective cohort study of type II odontoid process fractures (PMID 23595072) which suggested operative treatment was superior to nonsurgical treatment in terms of Neck Disability Index, and SF-36 bodily pain scores. More than 20% of patients initially treated nonsurgically crossed over into the surgical group. Derivative studies from this data set established the effect of nonunion on morbidity and mortality (PMID 24335630), described mortality rates for patients in operative and nonoperative groups (PMID 23354104), and modeled risk factors predictive of outcomes (PMID 23459135). A final manuscript still in production further stratifies patient outcome by decade of life. Several other retrospective studies and review papers have been published by the investigators on this topic.

Budget

Centralized research nurse, 50% effort	\$
Local research support, \$3,000/site x 9 sites	\$
<u>Statistical Analysis</u>	<u>\$</u>
Total	\$