Effects of Upper Extremity Immobilization and Use of a Spinner Knob on Vehicle Steering: A Prospective Study In Patients with Distal Radius Fractures

Specific Aims (250 words maximum): (In this section please define the clinical or basic science problem that exists that deserves investigation. Provide a null hypothesis and specific aims. It should be brief and concise.)

The ability of an injured person to safely drive an automobile while immobilized in an upper extremity cast or splint is not well defined. While driving is a multifactorial process, it can be assumed a faster reaction time and higher degree of steering accuracy correlates with safer driving. A steering wheel spinner knob may be an effective assistive device to aid with one handed driving while immobilized.

The aims of the study are to investigate the effects of upper extremity injury and immobilization on patients' steering ability. We also aim to evaluate the effectiveness of a steering wheel spinner knob to assist with one-handed driving.

Null Hypothesis

1. Patients with a distal radius fracture immobilized in a cast or splint do not have any differences in steering reaction time or accuracy acutely, sub-acutely or after the patient returns to functional baseline.
2. Patients with a distal radius fracture immobilized in a cast or splint, do not differ in steering reaction time or accuracy with and without use of a steering wheel spinner knob.

Background & Significance (350 words maximum): if preliminary data is available, include here. Briefly present the impact you think your research might have on orthopaedic trauma clinical practice or for future research effects.

The use of upper extremity immobilization is common in orthopaedic practices. The ability of a person to safely drive a car following an upper extremity injury while immobilized is disputed. [(1)] One survey found that a majority of orthopaedic surgeons (76%) did not have a consistent return to driving policy.[(2)] A second survey found there to be inconsistent opinions regarding whether patients with an upper extremity fracture treated in a cast should be allowed to drive.[(1)] The state of art in the field relies largely on expert opinion and several small studies in healthy volunteers analyzing the effects of upper limb immobilization on driving safety (including our own unpublished work).[(3-7)]

Our research group has recently completed a pilot study in healthy volunteers analyzing steering reaction time and accuracy.[(7)] Twenty healthy, right-hand dominant participants (ten males/ten females) were recruited for this cross-over trial. All had valid driver licenses and no upper extremity deficits. Five conditions were tested: no immobilization (control), right arm immobilized with an off-the-shelf removable wrist splint, right arm immobilized with an above elbow sugar-tong splint and the two immobilized conditions combined with a steering wheel spinner knob. Steering reaction time and steering accuracy were measured in a driving simulator (DriveSafety™, CDS-250). The order of the test conditions was counterbalanced in blocks of ten to minimize learning effects and bias. Subjects were randomized to the order of conditions. Overall, we found that immobilization with or without use of a spinner knob does not significantly affect steering reaction time. However, immobilization with or without use of a

spinner knob does have a negative effect steering accuracy. Accuracy was not found to be dependent on the type of immobilization.

To our knowledge, there has not been a study examining acutely injured patients. While the extremity is immobilized, the role injury and pain play in driving ability is unknown and is the impetus for this research project. The results will hopefully assist physicians to better counsel patients with upper extremity injuries on when it is safe to return to driving.

Research Design and Method (1,000 words maximum): Give a brief review of your study design and research method (as one would in an abstract for a meeting presentation).

There are many variables that dictate driving ability. Accidents are rare events and therefore are difficult to study. Two quantifiable variables that may be influenced by upper extremity immobilization are steering accuracy and steering reaction time. It can be assumed a higher degree of steering accuracy or faster reaction time correlates with safer driving.

The study subjects will be acutely injured patients with distal radius fractures treated with surgery. Sample size will be 25 patients. Study sample size is based on power calculations using variability information from pilot data and assuming a significant clinical effect threshold with immobilization of 1.5 times decrease in steering accuracy (α=0.05).

Inclusion criteria: acute distal radius fracture treated with surgery, valid driver's license. Exclusion criteria: non-drivers, multitrauma, open fractures, contralateral upper extremity disability, and previous ipsilateral upper extremity functional deficit.

Baseline information will be collected including: Age, years of driving experience, history of driving while immobilized, history of spinner knob use, AO /OTA fracture classification and hand dominance.

Steering accuracy will be evaluated using a driving simulator (DriveSafety™, CDS-250 with SimClinic™ software and Learning Basic Controls expansion module). The simulator consists of an authentic automotive cab (Ford Focus, automatic transmission) linked to three side by side visual display monitors for 110 degrees of field of view. Steering wheel, pedal sensors and data collection software provide continuous real-time data at 60Hz.

Patients will be tested at two time points while immobilized: acutely following a distal radius fracture surgery (0-10 days, post-op wrist splint) and sub-acutely (4-6 weeks, removable wrist splint). The patients will be tested again following cast or splint removal when function should return to baseline (control, approximately at 3-4 months). At each time point, the testing will be repeated both with and without a steering wheel spinner-knob in a randomized, counterbalanced cross-over study design. Comparison will be made between time points and to healthy controls from our pilot study. Testing will occur at least four hours after last narcotic dose.

The simulator will capture the following steering test scenarios for each patient and at each study time point: Reaction Timer Steering, Steering Chase Medium and Steering Chase Hard. The Steering Chase scenario measures steering accuracy. The study patient will be given an initial practice run through for familiarization to the simulator testing. All testing will be performed by occupational therapists trained in driver rehabilitation.

Reaction Timer Steering involves the patient turning the wheel as quickly as possible in the direction of an arrow (right or left) that appears on the screen. The time between the arrow appearing and the moment the steering wheel is turned in the correct direction is measured. The scenario includes an initial practice set, followed by twenty test responses that are averaged for analysis.

Steering Chase involves the patient following a target zone as it moves around a virtual steering wheel on a programmed course and speed. The course includes multiple changes in direction and up to two full turns of the wheel in either direction. Each patient will complete the test three times for two different degrees of difficulty, medium and hard. Hard has a smaller target zone and faster moving target. The outputs are steering accuracy, determined by total number of errors, where an error is each incidence the wheel is outside the target zone.

During testing, video of the participants will be used to subjectively observe steering ability, assess use of the immobilized extremity and perform root cause analysis of steering errors. Based on pilot data, we suspect that with immobilization errors would be more likely to occur at steering hand cross-over points and may be less likely with the steering wheel spinner knob.

Patients will be surveyed at each time point about opioid use and difficulty of steering with and without the spinner knob. Responses to a visual analog scale will be collected both at the beginning and end of testing at each time point. Grip strength will be collected at each time point. Disabilities of the Arm Shoulder and Hand (DASH) and range of motion of the injured extremity will be collected at the final time point.

Hypothesis 1 will be analyzed using a repeated measures ANOVA comparing immobilized performance acutely, sub-acutely and at final follow-up. Hypothesis 2 will be analyzed using a 2X3 (spinner-knob use X time) repeated measures ANOVA with appropriate paired comparison follow-up tests (paired samples t-tests). Prior to all analyses, data will be investigated for outlier responses and to ensure that the assumptions of parametric statistical analyses are met. Non-parametric tests may be required for certain dependent variables (e.g. response time outcomes) which tend to have a skewed distribution.

Role of the Resident (200 words maximum): Thoroughly describe the role the resident will play in the research project, including development of the proposal, data collection and analysis and formulation of the manuscript.

The resident, Lyle Jackson is responsible for the study from concept through completion. The initial study idea was Dr. Jackson's. He has taken the lead with the multidisciplinary team (including orthopaedic surgeons, occupational therapists, and driving researchers from a local university based automotive research center) to develop and conduct the previous pilot study.

He is responsible for protocol development, data dictionary, and data collection form development. While simulator data collection will be conducted by occupational therapists, Dr. Jackson will assist with patient recruitment and collection of other research data. Dr. Jackson will prepare data for data analysis and will work closely with the statistical research staff for the analysis. Dr. Jackson will also be responsible for final manuscript preparation.

The project should be able to be completed in approximately 12 months. It is a realistic expectation for project completion given the number of patients with distal radius fractures treated at our institution by our traumatologists and hand surgeons. Traumatologists treated 29 distal radius fractures surgically in 2012 (not including hand surgeons). If necessary, other faculty orthopaedists will be utilized for patient recruitment. This will allow completion of the study during Dr. Jackson's residency.

References

1. Rees JL, Sharp RJ. Safety to drive after common limb fractures. Injury. 2002 Jan;33(1):51-4.

2. Chen V, Chacko AT, Costello FV, Desrosiers N, Appleton P, Rodriguez EK. Driving after musculoskeletal injury. addressing patient and surgeon concerns in an urban orthopaedic practice. J Bone Joint Surg Am. 2008 Dec;90(12):2791-7.

3. Chong PY, Koehler EA, Shyr Y, Watson JT, Weikert DR, Rowland JH, et al. Driving with an arm immobilized in a splint: A randomized higher-order crossover trial. J Bone Joint Surg Am. 2010 Oct 6;92(13):2263-9.

4. Gregory JJ, Stephens AN, Steele NA, Groeger JA. Effects of upper-limb immobilisation on driving safety. Injury. 2009 Mar;40(3):253-6.

5. Stevenson HL, Peterson N, Talbot C, Dalal S, Watts AC, Trail IA. An objective assessment of safety to drive in an upper limb cast. J Hand Surg Eur Vol. 2012 Jun 28.

6. Kalamaras MA, Rando A, Pitchford DG. Driving plastered: Who does it, is it safe and what to tell patients. ANZ J Surg. 2006 Jun;76(6):439-41.

7.[Authors redacted]. Effects of upper extremity immobilization and use of a spinner knob on vehicle steering. In manuscript preparation.

OTA Resident Research Grant Budget Sheet

Budget cannot exceed $20,000

Submitting a budget over this amount disqualifies your application for consideration

- Salaries and Wages: Enter name, percentage of time on project and salary requested as well as fringe benefits charged to the grant. Please also state what each person will be doing.
- Permanent Equipment: Justification to be appended.
- Consumable Supplies: Excludes animals and animal care.
- Animals and Animal Care: Justify all requests where need is not apparent.
- All Other Expenses**:** Charges for overhead are not covered by OTA Grants. No indirect costs will be funded.

SALARIES AND WAGES (List all personnel for whom money is requested)	% Of Time on this project	Requested from OTA Funds (Omit Cents)
Research Coordinator time	5%	$1761
	%	
	%	
	%	
Fringe Benefits _22.66__% of Salaries and Wages Salaries and Wages plus Fringe Benefits	TOTAL	$2159

PERMANENT EQUIPMENT (Justification to be appended)	
2 video cameras, cords, mounts, etc	$835
Hand Grip Dynamometer	$260
Subtotal	$1095

CONSUMABLE SUPPLIES (Exclude animals and animal care)	
Subtotal	

ANIMALS AND ANIMAL CARE	
None	
Subtotal	

ALL OTHER EXPENSES	
Patient stipend, $100 per patient x 25 patients	$2500
Software changes for scenario upgrades (DriveSafety™)	$2000
Driving Simulator use fee ($125 per session, 25 patients, 3 sessions each)	$9375
Subtotal	$13,875

TOTAL DIRECT COSTS $17,129

Budget Justification:

Salaries and Wages

Salary is requested for Rebecca Snider, BS, Clinical Trials Research Coordinator. Mrs. Snider will be responsible for maintaining regulatory documentation for the study. Additionally, Mrs. Snider will aid the investigators in screening individuals for study participation. Mrs. Snider currently works approximately 30 hours per week. She is expected to spend 5% of her time, approximately 1.5 hrs per week on this study at $22.57 per hour. The fringe benefit rate for 2014 is estimated at 22.66%. Her estimated salary is $1760.46 + $398.92, for a total salary and fringe rate of $2159.38.

Permanent Equipment
Video cameras with mounts will need to be purchased in order to video each individual during the driving exercises. These are necessary to evaluate the use of the immobilized extremity during the driving tasks. Also, the video will allow for analysis of outlier data, to determine if a potentially unsafe driving behavior led to the outlier data.

The estimate for the camera equipment are as follows
2x GoPro Hero3 Silver - $300 each
1x GoPro Hero3 Remote - $70
2x GoPro Naked Frame Mount - $40 each
2x GoPro Tripod Mount - $7.50
Total: ~$835

Grip strength at each time point will be measured with a Hand Grip Dynamometer: estimated cost $260 from medical equipment supplier. A study specific Hand Grip Dynamometer will be used to ensure uniformity in testing between subjects.

Consumable Supplies
None
Animals and Animal Care
None

All other expenses
Each participant will receive a stipend for participation. $20 on the completion of the 1st and 2nd sessions and $60 on the completion of the 3nd session, for a total of $100 per patient for 25 patients totaling $2500.

The use fee for the driving simulator will be $125 per session. ($125 per session x 3 sessions x 25 patients= $9375.