Evaluation of Shoulder Ptosis after Middle Third Clavicle Fractures to Predict Patient Reported Outcomes.

Specific Aims:

Management of displaced midshaft clavicle fractures (DMCFs) is controversial. Historically these fractures have been treated nonoperatively in the vast majority of patients. With the development of modern surgical techniques and the accrual of Level 1 evidence, the paradigm has shifted more towards operative management of many DMCFs to improve union rate, deformity, and functional outcomes. Despite described relative indications for operative management, questions still remain regarding the ideal patient population that benefits from surgery.

DMCFs lead to variable degrees of shoulder ptosis. It is unclear how the degree of shoulder ptosis at the time of injury correlates with shoulder function in patients treated with conservative management. Additionally, it is unclear to which degree of severity for shoulder ptosis at the time of injury identifies patients who would benefit from surgical intervention for improved outcomes.

We hypothesize that among patients with a DMCF, degree of shoulder ptosis at the time of injury can predict which patients will benefit from surgical intervention in terms of patient reported outcomes. We aim to:

1) Establish the reliability and repeatability of measures of shoulder ptosis;

2) Examine the relationships between shoulder ptosis and patient reported outcomes (PROs) among nonoperatively managed patients;

3) Examine the relationships between preoperative shoulder ptosis and PROs in patients treated with surgical management.

Background/Significance:

Fractures of the middle third of the clavicle have historically been treated nonoperatively. This was based upon several landmark studies by Neer and Rowe in the 1960's, which reported nearly universal healing with minimal assessment of PROs. More recent studies have demonstrated between 15-26 % nonunion rate for DMCFs treated conservatively, with a significant amount of patients reporting unsatisfactory results.[1-6] Alternatively, good functional outcomes after conservative management of closed DMCFs have also been reported. [7]

Radiographic parameters at the time of injury are currently used to guide the diagnostic algorithm between surgical versus nonoperative management of DMCFs. Specifically, greater than 100% displacement, significant comminution and shortening greater than 20mm have been cited as relative indications for open reduction and surgical fixation. For patients who elect for conservative management, some degree of shortening and deformity is inevitable.

Shoulder ptosis involves multiplanar deformity in the shoulder girdle.[8] It is best appreciated when the patient is standing and has been described as a drooping and medially displaced shoulder.[9101112] Typically, the injured shoulder also translates and rotates forward (eg, scapular protraction), which is best seen when looking at the patient from above. Visual examination from behind may reveal a prominence of the inferior aspect of the scapula from protraction. A mark from the mid suprasternal notch to the ridge of acromioclavicular joint can be used to measure shortening of the clavicle clinically which may be important to guide decision making between operative versus nonoperative management. Importantly, radiographic measurements of shortening are notably inaccurate, and even when compared to the contralateral side on a bilateral clavicle or chest X-ray, measurements are very sensitive to thoracic rotation. Additionally, the correlation between radiographic measurements of clavicle shortening and multiplanar ptosis is unknown. A classification for shoulder ptosis based upon topographical landmarks at the time of injury that reproducibly correlates with shoulder function would add important information to guide the surgeon when choosing between conservative versus operative management recommendations for patients with DMCF's.

Methods:

Inclusion and exclusion criteria. IRB approval has been obtained to study patients who have sustained DMCFs. The study design will be prospective observational. Inclusion criteria will include patients 18 years of age or older with an isolated closed 100% displaced (as per upright 15 degree cephalic tilt AP clavicle injury radiographs) middle third diaphyseal clavicle fracture. Exclusion criteria will include open fractures or neurovascular compromise, patients with other concomitant injuries, or those with a history of prior fracture of the shoulder girdle or clavicle. Enrolled patients will receive a standard script to describe the advantages and disadvantages of open reduction and surgical fixation versus nonoperative management, and patients will be allowed to choose. The initial clinical examination will be performed within two weeks of injury.

Outcomes and data collection. All patients will complete a Brophy/Marx shoulder activity level questionnaire (to asses baseline function), Quick DASH, and a survey asking importance of shoulder cosmesis at the initial visit. Demographic data such as age, sex, BMI, handedness, expectations, and comorbidities will be documented. At subsequent encounters, patients will take a Quick DASH survey. In addition to collection of PROs, radiographic, manual, and topographic data will also be collected within 2 weeks from injury, and at 6, 12, and 52 weeks post-injury or operation. Patients will receive AP upright dedicated bilateral clavicular radiographs with 15 degree cephalic tilt. Radiographic measurements for clavicle length, cortical diameter, and superior/inferior displacement will be made on both the injured and uninjured sides, and measurements will be correlated to manual and topographical data. Clavicle shortening will be measured as defined by the technique described by Lazarides et al[13]. A tape measure will be used to record the following manual measurements of surface anatomy on both the injured and uninjured side: 1) mid-sternal notch to AC joint, 2) posterolateral border of the acromion to C7 spinous process, and 3) posterolateral border of the acromion to the inferior angle of the scapula. Every patient encounter will also have documentation of 1)VAS pain score, 2) current narcotic use related to the shoulder in morphine equivalents, 3) return to work/sports status, and 4) complications i.e. malunion[14], nonunion, infection, wound dehiscence, hardware failure.

We will utilize a novel three-dimensional topographical scanner (Structure Sensor, Occipital Inc., CO, USA) to quantify the relationships of the injured and uninjured shoulder girdles. This system uses a scanning sensor to capture the three-dimensional shape of a subject. These data can then be uploaded to a computer and analyzed using the accompanying photogrammetric software for measurements and has been validated in a demonstration (see Figure 1) We intend to employ this technology to topographically analyze the shoulder girdle for precise three-dimensional measurements anatomical relationships related to shoulder ptosis. Four specific anatomical landmarks will be tagged: 1) midsternal notch, 2) superior/anterior aspect of the ac joint, 3) C7 spinous process, 4) inferior angle of the scapula. Distance and the angles formed between the landmarks will be determined with the analysis software.

All manual and topographical measurements will be performed with the patient standing with arms at their side in neutral rotation and shirt off. The manual and topographical measures will both be performed twice by the resident and also by the attending for each patient, with the order of the modality being randomized for every encounter. For the radiographic measurements, the resident and surgeon will each perform the measurements twice separated by a span of two weeks to avoid recall bias. Both raters will be blinded to their original and counterpart's measurements

Ultimately, we will compare PRO's between operative versus nonoperative groups with respect to a comparable degree of shoulder ptosis upon presentation.

Aim 1 analysis. Inter- and intra-rater reliability for each of the radiographic, manual, and topographic measurements will be assessed by calculating intraclass correlation coefficients (ICCs) with 95% confidence intervals. ICCs range from 0 to 1 with 1 indicating perfect reliability. Acceptable reliability will be defined as an ICC of at least 0.8.

Aim 2 analysis. Descriptive statistics will be presented as frequencies and percentages for categorical variables and means and 95% confidence intervals for continuous variables (or with medians and interquartile ranges if non-normally distributed). Data distributions will be assessed visually with histograms and quantile-quantile plots. Shoulder deformity will be calculated as the differences in each of the radiographic, manual, and topographic measures between the injured and noninjured sides for each patient. The nature of the relationships between shoulder deformity and the change in PROs from baseline to each subsequent follow-up will first be assessed visually through scatterplots. If linear, relationships between the shoulder displacement measures and the change in PROs will be assessed with simple linear regression. If non-linear, appropriate data transformations and/or non-linear statistics will be employed as needed. Threshold values of shoulder displacement upon presentation beyond which patients have poorer outcomes will be determined through error minimization of iterative piecewise regression models.

Aim 3 analysis. The analysis for Aim 3 will parallel that for Aim 2. All analyses will be conducted with SAS version 9.4 (Cary, NC, USA), with a two-sided level of significance of $\alpha = 0.05$.

Sample size and recruitment. For Aim 1, a sample size of at least 55 patients will enable estimation of the ICC to within confidence interval width of 0.2 at a level of significance of 0.05. For Aims 2 and 3, a sample size of 44 in each of the treatment groups (88 total) will provide at least 80% power to detect a correlation of 0.45 or stronger via linear regression with a level of significance of 0.05. Adding an additional 15% to account for potential loss to follow up brings the final number to 100 total patients (50 conservatively managed, 50 surgically managed).

Based on our clinical experience, we expect roughly an 80% enrollment rate, and we expect that 50% of our patient population will choose surgical management. Given the number of DMCF patients seen in our clinic, we should achieve our desired recruitment goal within 8-9 months.

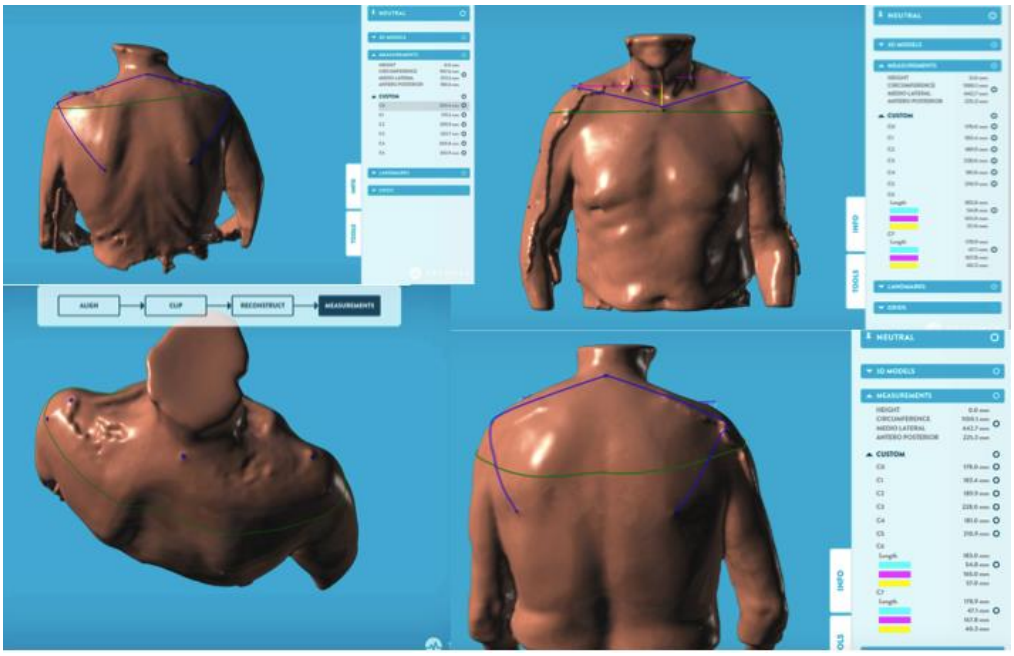
Challenges:

There are several challenges to this study. Collection of topographical measurements requires the use of a novel technology that has not yet been validated for analyzing shoulder ptosis. We do not anticipate this being a problem, as this technology was specifically designed to accurately recreate surface anatomy as a three dimensional diagram. Another challenge may be preventing bias in the patient's decision to choose whether or not to undergo surgery. We will control for this bias by reciting a standard script explaining the risks and benefits of both approaches to every patient. Ultimately the choice of treatment will be up to the patient. A randomized control trial would be the only way to truly limit this bias and would be our next investigative step after completion of this feasibility study.

Resident role:

The resident will be the principal investigator on this grant. He was responsible for the development of this proposal. He is responsible for maintaining compliance with the IRB, recruitment of patients and will oversee data collection and analysis. He will have the primary responsibility of drafting and submitting the resultant manuscript to the Journal of Orthopaedic Trauma.

Figure 1: Demonstration of 3D scanning technology with anatomical measurements in a patient with a displaced midshaft clavicle fracture.



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Names of specific individuals and names of institutions should NOT be in the body of the budget.

BUDGET

SALARIES AND WAGES (List all personnel for whom money is requested)	% effort on project	Requested from OTA (round to $)
Research Coordinator	20 %	$ $ 10,000
Computer technician to analyze topographic data	10 %	$ 5,000
	%	
	%	
Fringe Benefits _____% of Salaries and Wages Salaries and Wages plus Fringe Benefits	TOTAL	$ 15,000

PERMANENT EQUIPMENT (append justification)	
3D Scanning Hardware (Camera, Ipad, Video processing computer)	$ 4,500
3D Scanning Software	$ 500
Subtotal	$ 5,000

CONSUMABLE SUPPLIES (exclude animals and animal care)	
Subtotal	$ 0

ANIMALS AND ANIMAL CARE	
Subtotal	$ 0

ALL OTHER EXPENSES	
Subtotal	$ 0

TOTAL DIRECT COSTS $ 20,000