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Efficacy of Dynamic Shoulder Bracing in the Management of Anterior Shoulder Instability

Kristopher S. Nelson
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EFFICACY OF DYNAMIC SHOULDER BRACING IN THE
MANAGEMENT OF ANTERIOR SHOULDER INSTABILITY

by

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Associate of Science, Northwest College, 1994
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An Independent Study
Submitted to the Graduate Faculty of the
Department of Physical Therapy
School of Medicine
University of North Dakota
in partial fulfillment of the requirements
for the degree of
Master of Physical Therapy

Grand Forks, North Dakota
May
1999
This Independent Study, submitted by Kristopher S. Nelson in partial fulfillment of the requirements for the Degree of Master of Physical Therapy from the University of North Dakota, has been read by the Faculty Preceptor, Advisor, and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

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Date 12-7-98
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Finally, I would like to thank my amazing wife for all of her encouragement and support over the past three years. Without you Stacey, this road called PT school would have been much rockier.
ABSTRACT

The purpose of this study was to add to the orthopaedic body of knowledge regarding the efficacy of dynamic shoulder bracing in the management of anterior shoulder instability. Two fresh-frozen cadaveric shoulders were used for testing. One shoulder was used as the “normal” shoulder, while the other was used as the “unstable” shoulder through the creation of a simulated Bankart lesion. Arthroscopic insertion of radiographic markers allowed for assessment of anterior translation of the humerus through the use of x-rays. X-rays were taken with and without shoulder braces applied with the arm in a 90°/90° position. Descriptive statistics were used to analyze the data. Results found during brace testing showed an average increase in anterior translation of 7.4% and 38.7% in the “normal” and “unstable” shoulders respectively. These results seem to show that bracing is ineffective and may in fact be detrimental to those using them. Results will provide healthcare professionals objective information concerning the use of dynamic shoulder bracing in the rehabilitation program of patients with anterior shoulder instability.
CHAPTER I
INTRODUCTION

Introduction

The glenohumeral joint sacrifices stability for a high degree of mobility despite the numerous static and dynamic capsuloligamentous and muscular restraints. Stability is provided by the bony configuration of the joint, the labrum, the capsule and its ligamentous thickenings, the scapular muscles and dynamic control of the rotator cuff.\(^1\) If any one of these restraints fail, it could lead to instability in the shoulder. This article will focus more closely on anterior instability in particular.

Anterior shoulder instability (ASI) accounts for approximately 85%-95% of all shoulder instability problems as a whole.\(^2\) The most common method of anterior dislocation occurs with forcible external rotation while the shoulder is abducted and extended. Controversy remains as to the most effective means of management of the traumatic first-time anterior dislocation. Post-reduction treatment ranges from prolonged immobilization to immediate rehabilitation with pain as the only inhibitor. Only recently has functional bracing entered the scene as a possible tool for conservative management, undoubtedly due to the lack of documented proof of indications, contraindications and efficacy regarding this treatment approach. Despite a substantial amount of testimonial support for the
use of functional bracing, no known scientific studies have provided solid, objective evidence as to the merit of such braces in controlling anterior translation of the humerus during physiologic motions.

**Problem Statement**

Functional bracing for the management of ASI is becoming more common despite the obvious lack of scientific support for such a tool. The ability of such braces to prevent or significantly decrease humeral translation by any means has not been proven on an anatomical level. Allowing athletes with known instability problems to continue to compete using only a functional/dynamic shoulder brace as a means of management may put them at risk for further, increased, or prolonged complications. These braces may provide a false sense of security, which could lengthen healing and recovery time due to subjecting the shoulder to possible harmful conditions. For the safety and security of those using these braces, a controlled scientific study of their effectiveness in limiting passive accessory joint motion during high risk physiologic positions is necessary.

**Purpose of Study**

The purpose of this study is to determine the effectiveness of three commonly used dynamic shoulder braces in the management of anterior shoulder instability through a controlled scientific experiment. The Simply Stable Shoulder Stabilizer, Sawa® Shoulder Brace and Duke Wyre Shoulder Vest will be tested for their ability to limit passive anterior translation of the humerus while the shoulder is held in external rotation and abduction. The use of a cadaveric specimen will afford us the opportunity to look closely at the biomechanics of the shoulder joint during the experiment. Although testimonial evidence provides some reliability as to the effectiveness of these braces, it
does not establish clear scientific proof. This study hopes to help fill the gap in the orthopaedic body of knowledge concerning this point.

**Significance of Study**

The important aspects of this study are easily recognized. First it adds to the objective data concerned with functional bracing in the management of ASI, thus increasing facts concerning the indications, contraindications and efficacy of available braces. This would allow physicians and clinicians to make a more informed decision regarding whether bracing would be beneficial to a particular patient. This would in turn decrease the risk of patients subjecting themselves to harmful conditions brought about by placing a false sense of security in the brace. The data that this study will generate may diminish the potential health risks associated with inappropriate brace use.

**Research Questions**

Question #1: What is the effect of dynamic shoulder bracing in the limitation of passive anterior translation of the humerus with the shoulder held in external rotation and abduction? Can dynamic shoulder bracing replicate the stability provided by normal anatomical structures?

**Hypotheses**

Null Hypothesis: Dynamic shoulder braces do not significantly limit passive anterior translation of the humerus with the shoulder held in external rotation and abduction. Consequently, they do not replicate the stability provided by the anatomical structures that may be compromised in a shoulder with anterior instability.

Alternate hypothesis: Dynamic shoulder braces do significantly limit passive anterior translation of the humerus with the shoulder held in external rotation and
abduction, possibly providing the ability to replicate the stability provided by the anatomical structures that may be compromised in a shoulder with anterior instability.
CHAPTER II
LITERATURE REVIEW

The shoulder complex is comprised of four joints that function synchronously and allow a high degree of mobility at the sacrifice of stability. Because of this inherent freedom of movement, this joint is dislocated more than all other joints combined in the adult population. The glenohumeral (GH), acromioclavicular (AC), sternoclavicular (SC), and scapulothoracic joints all help contribute to total arm movement. It is essential that normal range of motion take place in all four joints to ensure a fluid, coordinated pattern of motion. The GH joint will be given the greatest attention due to the fact that it is the primary joint associated with anterior instability.

Stability of the Glenohumeral Joint

Osseous Structures

The glenohumeral joint is a multiaxial ball-and-socket synovial joint between the humeral head and glenoid fossa of the scapula. The disproportionate size and lack of congruency of the articular surfaces make the joint inherently unstable. The glenoid fossa is pear shaped and its surface is only one-third to one-quarter that of the humeral head, which means that only part of the humeral head is in contact with the glenoid in any particular position of the joint. Unlike rigid ball-and-socket joints, which possess
inherent bony stability, the glenohumeral joint relies primarily on soft tissue structures for its stability.

**Glenoid Labrum**

The glenoid labrum is a rim of fibrocartilage attached around the margin of the glenoid fossa, acting as an anchor-point for the capsuloligamentous structures.\(^7\) It has been likened to the meniscus of the knee. It adds stability to the socket by increasing the depth by approximately 50%.\(^5\)

**Capsuloligamentous Structures**

The capsule surrounds the joint and is attached medially to the margin of the glenoid fossa and laterally to the circumference of the anatomical neck of the humerus. It is thin and large, allowing 2-3 mm of distraction of the head from the glenoid.\(^8\) The capsule encloses the tendon of the long head of the biceps muscle. The inherent laxity of the capsule allows for the high degree of mobility associated with the GH joint.

The glenohumeral joint is also stabilized by several ligamentous structures. The anterior portion of the capsule is reinforced by the superior, middle, and inferior glenohumeral ligaments. The superior GH ligament runs from the upper part of the glenoid rim and base of the coracoid process to the lesser tuberosity of the humerus. Its primary function is to prevent inferior displacement of the humeral head in the adducted, dependent position.\(^9\)

The middle GH ligament has the greatest variation in size and is absent more frequently than the other GH ligaments.\(^9\) It passes from the anterior margin of the glenoid fossa to the anterior aspect of the anatomical neck of the humerus.\(^10\) The middle GH ligament, along with the subscapularis tendon act as anterior stabilizers of the
glenohumeral joint and function to limit external rotation of the humerus between 0° and 90° of elevation.\textsuperscript{11,12}

The inferior GH ligament is a complex portion of the capsule generally regarded as the structure most critical to glenohumeral joint stability.\textsuperscript{9} It is attached to the anterior, inferior, and posterior margin of the glenoid labrum medially and to the anatomical and surgical neck of the humerus laterally. O’Brien et al\textsuperscript{13} identified three distinct regions of the inferior glenohumeral ligament complex (IGHLC); a distinct anterior and posterior band and an interposed axillary pouch. They suggested that this complex function in a fashion analogous to a hammock supporting the humeral head in the glenoid fossa during abduction and rotation of the shoulder joint.

\textit{Rotator Cuff}

The rotator cuff is the musculotendinous complex formed by the attachment to the capsule of the supraspinatus muscle superiorly, the subscapularis muscle anteriorly, and the teres minor and infraspinatus muscles posteriorly. They provide active support for the joint and can be considered true dynamic ligaments.\textsuperscript{14} They also help to maintain the humeral head within the glenoid fossa during the motions of elevation and rotation, acting as a force couple with the deltoid muscle.

\textit{Neuromuscular Mechanism}

The neuromuscular mechanism that contributes to joint stability is mediated by articular mechanoreceptors and provides the individual with the sensations of kinesthesia and joint position sense.\textsuperscript{15,16} The neurological feedback for the control of muscular actions serves to protect against excessive strain on passive joint restraints and is referred to as joint proprioception. The proprioceptive mechanism is essential for proper joint
function in sports, activities of daily living and occupational tasks.\textsuperscript{17} Following injury to the articular ligaments, disruption to articular mechanoreceptors results in partial deafferentation of the joint. This has been shown to inhibit normal neuromuscular joint stabilization, and it contributes to repetitive injuries and the progressive decline of the joint.\textsuperscript{18,19}

**Factors Predisposing Anterior Instability**

Several factors can contribute to anterior instability of the glenohumeral joint. These include an inadequately sized glenoid fossa, a decreased humeral head retroversion angle, an anteriorly tilted glenoid fossa, a compromised capsule and/or glenoid labrum, or a weakened or deficient rotator cuff mechanism.\textsuperscript{20} Saha\textsuperscript{21} found that if the longitudinal diameter of the glenoid fossa was less than 75\% and the transverse diameter was less than 57\% of the humeral head’s diameter, the glenohumeral joint was more likely to be unstable. He also found an anteriorly tilted glenoid fossa in 80\% of 21 unstable shoulders, while the incidence of this finding in 50 normal shoulders was 27\%.

Clinically, shoulders with weakened muscles, cuff tears, shallow glenoid fossae, and labral defects have compromised stability from lack of concavity compression.\textsuperscript{22} Concavity compression refers to the stability gained by compressing the humeral head into the concave glenoid fossa.

**Management of Anterior Shoulder Instability**

*Conservative Approach*

This section will focus primarily on the conservative management for patients with first time anterior dislocations. In the past, immobilization was advocated for several weeks to allow for early healing of the injured tissue. Investigators have
documented that the incidence of recurrent instability is not affected by the type or length of glenohumeral immobilization.\textsuperscript{23} Currently, the trend in rehabilitation is toward earlier protected motion and strengthening activities in conjunction with stabilizing exercises for the rotator cuff musculature to re-establish voluntary stability of the humeral head within the glenoid fossa. Dines and Levinson\textsuperscript{24} have devised a six-phase progressive rehabilitation program for the conservative treatment of anterior instability. It can be adapted for both acute dislocation and chronic instabilities. It should be emphasized that each individual patient’s response to therapy will vary, making it essential to individualize the treatment program according to subjective complaints and objective findings. A summary of the goals for each phase of the rehabilitation program can be found in Appendix A.

Historically, little attention has been given to the role of the neuromuscular mechanism following injury.\textsuperscript{17} A rehabilitation program that addresses the need for restoring normal joint stability and proprioception cannot be constructed until one has a total appreciation of both the mechanical and sensory functions of articular structures. Simply restoring mechanical restraints or strengthening the associated muscles neglects the coordinated neuromuscular-controlling mechanism required for joint stability, especially during the sudden changes in joint position common to functional activities.\textsuperscript{17} Therefore, proprioceptive training should be included in the rehabilitation regimen prescribed following injury to the shoulder.

\textit{Surgical Approach}

In some cases where conservative management fails, surgical intervention may be necessary in order to stabilize the glenohumeral joint. Ideally, the surgical intervention
should include the following goals: (1) restoration of static glenohumeral stability, (2) elimination of pain, (3) restoration of adequate range of motion and normal strength, (4) restoration of function, and (5) ability to participate in an aggressive post-surgical rehabilitation program. Some of the most common surgical procedures used today are the Bankart procedure, the Bristow operation, and the Putti-Platt procedure. It is beyond the scope of this article to explain the surgical procedures used in these approaches. Please refer to an overview of each procedure from Blackburn. It should be noted that the conservative management mentioned previously could be implemented post-surgically as a means of rehabilitation.

**Shoulder Bracing**

Functional bracing has not been a prominent tool for managing anterior shoulder instability, primarily because indications, contraindications, and efficacy remain undocumented. In addition, a definitive brace that is comfortable, that allows for adequate function, and that maintains glenohumeral joint stability has yet to be developed. Braces currently on the market act either to limit glenohumeral motion to a "vulnerable-free zone," or to provide a stabilizing compressive force to the joint or both. It is questionable as to whether it is possible to prevent anterior instability by either of these means, while maintaining adequate functioning. This concern is of most importance to athletes in which shoulder mobility is essential. Since it has been estimated that 75% of anterior dislocation injuries occur during athletics, this population comprises the majority of those affected. Bracing may provide a false sense of security, possibly subjecting the patient to further or increased injury.
Bracing is potentially of value to provide proprioceptive feedback, control pain, promote stability in the joint, and enhance the performance of the joint. Braces may also place specific limits on the patient’s range of motion, keeping the shoulder in a “vulnerable-free zone.” Bracing could potentially protect a previous surgery or postpone or avoid the need for surgery altogether.

In a study conducted by Harding et al, a review of the most commonly used braces was done. Braces were analyzed for containment method, construction, comfort, cosmesis, cost, and convenience of application. A variety of problems were encountered, including sacrifice of comfort for function, interference with breathing, the use of moisture intolerant material, difficulty of fitting the patient and lack of adaptability to anterior instability to name a few. The search for the ideal brace that allows full range of motion, adequate functioning and maintains stability continues.
CHAPTER III
MATERIALS & METHODS

Specimen History

One fresh-frozen human cadaveric torso stored at -20 degrees Celsius was obtained from the donor banks of Anatomical Service Inc. in Rosemont, IL. The specimen donor was a 78 year old male whose cause of death was cardiovascular disease. No previous history of shoulder pathology was known upon shipment. The specimen was tested for and cleared of HIV and HBV prior to shipment.

Shoulder Preparation/Arthroscopy

The specimen was thawed at room temperature for 48 hours prior to experimentation. Using standard precautions, arthroscopic investigation of the glenohumeral joint was performed to ensure no history of shoulder pathology. With the specimen in the supine beach-chair position, the right shoulder was entered through a standard posterior-lateral glenohumeral arthroscopic portal. Using a 4.0 mm arthroscope, good visualization of the GH joint was obtained. Looking anteriorly, the glenolabrum was intact as well as the biceps tendon and its attachment to the superior labrum. The glenohumeral surface did not reveal any evidence of arthrosis. There was a robust middle glenohumeral ligament as well as an intact anterior inferior glenohumeral ligament on the anteroinferior portion of the GH joint. Looking superiorly, the superior
labrum was intact and lateral to the biceps tendon, the supraspinatus and infraspinatus attachments to the humeral head were observed intact. The arthroscope was then placed in the anterior portal to check the competency of the inferior GH ligament and it was visualized intact. The subscapularis recess was examined and devoid of any loose bodies, and there was no identifiable detachment of the posteroglenolabrum.

Once all structures had been determined to be normal, an accessory anterior portal was made, and a 7 mm cannula was inserted into the interval medial to the biceps tendon and superior to the subscapularis tendon. Using a 15-blade, the entire anterior glenolabrum was detached from the 12 o’clock position down to the 6 o’clock position. It was detached completely off the glenoid and was free and resembling a traumatic Bankart lesion. Once this was accomplished, two 3 mm Mitek suture anchors were inserted, one at the 12:30 position on the superior aspect of the glenoid and one on the humeral head just lateral to the biceps tendon with the arm maximally externally rotated.

Once this was accomplished, the arthroscope and instruments were removed and the same diagnostic examination was performed on the left shoulder. Through the posterior portal, the left shoulder showed an intact glenoid labrum, as well as competent biceps and rotator cuff tendons. No changes of arthrosis were noted on the glenohumeral surface. The inferior and middle glenohumeral ligaments were intact also. The posterior glenoid labrum revealed no signs of pathology. At this point, the Mitek anchors were placed in the same position as they were on the right shoulder. The arthroscope and instruments were then removed and the sequential testing was started.
Shoulder Brace Testing

At this time a portable C-arm x-ray machine was used to obtain radiographic images of the right (simulated Bankart lesion) glenohumeral joint. The x-rays were taken from a superior angle with respect to the shoulder (see Figure 1). Manual stabilization of the torso was applied during shoulder movements to limit unwanted positional changes of the specimen during testing. A base-line image was obtained in the absence of a shoulder brace. For the base-line, the shoulder was abducted to approximately 90 degrees and was externally rotated to a point having the forearm, with the elbow at 90 degrees, parallel to the C-arm of the x-ray machine (see Figure 1).

Each brace was then applied according to instructions provided by the brace manufacturer. Both the Simply Stable shoulder stabilizer and the SAWA Shoulder Brace allowed us to achieve a comparable amount of abduction and external rotation as was applied during the base-line x-ray. A radiographic image of the GH joint was then taken in the same manner as previously described. The Duke Wyre shoulder vest limited the achievable amount of abduction to approximately 65-70 degrees, while allowing the same amount of external rotation as previously described. An x-ray was taken for comparison to the other braces and the base-line. The left shoulder was tested in the same manner for the baseline and all three braces to determine the effect on anterior translation in a "normal" shoulder.

Determining Anterior Translation

Anterior translation was defined as the amount/distance of anterior excursion measured between the two radiographic markers in a direction parallel to the glenoid
Figure 1. Setup of X-ray Machine and Cadaveric Specimen During Shoulder Brace Testing
fossa. On the x-rays taken of the shoulder joint, a line was drawn parallel to the glenoid fossa. From this line, two additional lines were drawn perpendicular to it, each intersecting one of the two radiographic markers on the x-ray. Then the distance was measured between these two lines to determine the amount of anterior translation of the humerus (see Figure 2).

**Figure 2.** Method of Measuring Anterior Translation on X-rays. (a) Line parallel to glenoid fossa. (b,c) Lines intersecting radiographic markers, perpendicular to line (a). Anterior translation distance was measured between lines (b) and (c). (Adapted from Zuckerman and Matsen).20

**Data Analysis**

Descriptive statistics were used to compare the difference in translation of the humerus with each individual brace in place and in the absence of a brace. Comparisons were made between the amount of translation before and after the simulated Bankart lesion was implemented. A generalized comparison was also made between the "unstable" shoulder and the "normal" shoulder.
CHAPTER IV

RESULTS

Results showing amount of anterior translation measured with each brace applied and in the absence of a brace for both the right ("unstable") and left ("normal") shoulders are summarized in Table 1. These values were compared to determine any decrease in anterior translation between the trials with braces and the "baseline" trial with no brace applied. The average change in translation distance was +1.43 mm for the right shoulder and +0.20 mm for the left shoulder, demonstrating an average increase in translation with the braces applied. The average percent increase in translation from the baseline value was considerably greater on the right ("unstable") shoulder when compared to the left ("normal") shoulder.
# TABLE 1

Anterior Translation of the Humerus Recorded During Brace Testing

<table>
<thead>
<tr>
<th>BRACE TESTED</th>
<th>SHOULDER TESTED</th>
<th>ANTERIOR TRANSLATION (mm)</th>
<th>% CHANGE FROM BASELINE</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Brace; &quot;Baseline&quot;*</td>
<td>R</td>
<td>3.7</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>L</td>
<td>2.7</td>
<td>N/A</td>
</tr>
<tr>
<td>Simply Stable Shoulder Stabilizer</td>
<td>R</td>
<td>5.0</td>
<td>+35.1%</td>
</tr>
<tr>
<td></td>
<td>L</td>
<td>2.8</td>
<td>+3.7%</td>
</tr>
<tr>
<td>Sawa® Shoulder Brace</td>
<td>R</td>
<td>5.5</td>
<td>+48.6%</td>
</tr>
<tr>
<td></td>
<td>L</td>
<td>2.8</td>
<td>+3.7%</td>
</tr>
<tr>
<td>Duke Wyre Shoulder Vest</td>
<td>R</td>
<td>4.9</td>
<td>+32.4%</td>
</tr>
<tr>
<td></td>
<td>L</td>
<td>3.1</td>
<td>+14.8%</td>
</tr>
</tbody>
</table>

* The baseline value for the right shoulder was established after the implementation of the simulated Bankart lesion
CHAPTER V
DISCUSSION

Conservative methods of managing anterior shoulder instability depend on the severity and nature of the injury. Typically, treatment includes relief of acute symptoms, protection, regaining of normal range of motion, strengthening activities, and stabilizing exercises for the rotator cuff musculature.\textsuperscript{24} Traditionally, however, functional shoulder bracing has had little or no role in the management of anterior shoulder instability, which becomes especially evident when compared with management of knee problems.\textsuperscript{26} Lack of knowledge concerning indications, contraindications, and efficacy constitutes the main reason. Recently, functional bracing has become a more prominent tool, despite the obvious lack of scientific research available to substantiate its effectiveness.

There are no known scientific studies that have attempted to determine the efficacy of such braces regarding control of anterior translation of the humerus during stress testing. Also, no studies have investigated the effect of shoulder bracing on proprioception, muscle recruitment, or concavity compression. Therefore, a comparison of the use of functional knee braces in the anterior cruciate ligament-deficient knee may be helpful. Knee bracing is widely used to protect a reconstructed or partially torn ACL by attempting to decrease strain in that ligament.
Wojtys, Kothari, and Huston investigated the effect of knee bracing on neuromuscular function, anterior tibial translation, and isokinetic performance. They showed that all braces tested decreased anterior tibial translation. In a trial where muscles were relaxed, with braces applied, anterior tibial translation was decreased by an average of 33.1% from baseline. In a trial in which the hamstring, quadriceps, and gastrocnemius muscles were contracted in order to resist the displacing tibial force, anterior tibial translation was decreased by an average of 80.1% from baseline with the braces applied.

This last point brings about an interesting comparison that can be suggested regarding functional knee bracing and shoulder bracing. There is little doubt that a well-conditioned neuromuscular and musculoskeletal system can improve the function of an ACL-deficient knee. Several investigators have documented the importance of good hamstring muscle function in preventing abnormal anterior tibial translation in stable and unstable knees. Similarly, can the muscles that provide stability to the shoulder joint through compression, namely the rotator cuff interval, efficiently limit anterior translation of the humerus in the presence of pathologic instability? Since functional bracing can at best only assist the body's natural stabilizing mechanisms, a knowledge of these stabilizing mechanisms is crucial.

A study by Apreleva et al suggested that dynamic stability could be maintained by the rotator cuff muscles even when the anterior aspect of the capsule is divided and the anterior portion of the labrum is separated. This suggests that even in the presence of a large Bankart lesion, if the rotator cuff is functioning properly, stability would not be compromised. It should be noted that the most common method of anterior dislocation is
forcible external rotation with the arm abducted. This study did not simulate this kind of environment, which allows one only to speculate on the rotator cuff's ability to stop subluxation or dislocation within that type of testing environment.

Knee bracing has been shown to increase proprioception in subjects with normal knees during a dynamic tracking task.\textsuperscript{31} Results of this study showed that there was an improvement of 11% in tracking when subjects wore a knee sleeve type brace. Despite the lack of scientific proof regarding proprioceptive changes noted in the shoulder with bracing, a similar improvement in tracking and position sense might be assumed by those who prescribe braces as part of the rehabilitation regimen. This possible increased "awareness" in the joint may be partly responsible for the testimonial support for the use of shoulder bracing.

Our study looked at the effect braces had on controlling passive anterior translation of the humerus with the arm held in abduction and external rotation. This could possibly help to explain why anterior translation increased with the application of braces. The force required to maintain the arm in the testing position may have been greater with the braces applied, due to the inherent function of the braces to provide resistance to motion. We also did not simulate recruitment of the rotator cuff muscles, looking only at the static stabilizing mechanisms of the joint. The results of this study suggest that functional bracing does not effectively limit passive anterior translation of the humerus with the arm in abduction and external rotation. Therefore, the braces tested do not appear to be able to replicate the stability provided by those anatomical structures which are often compromised due to pathology.
Limitations of Study

Looking at this investigation retrospectively shows several limitations to the study. Limitations arose mostly due to the experimental nature of this study. The small sample size, the method by which data was gathered, and the inability to create a more "real-life" environment for testing all limit the strength and reliability of the study.

Since data was obtained for only two shoulders, only descriptive statistics could be used. With such a small sample size we were only able to speculate on the significance of the data obtained. A larger sample size would afford the researcher the opportunity to determine the actual statistical significance of values that were recorded. In doing so, this would strengthen and increase the reliability of the study.

The method by which data was gathered posed some problems in terms of its objectivity. X-rays were taken of the glenohumeral joint, allowing visualization of the radiographic markers that were inserted into the humeral head and glenoid fossa. It was then necessary to determine the position of the glenoid fossa on the x-ray, which was somewhat subjective. Previous studies analyzing translation of the humerus have used magnetic tracking devices to record the data.\textsuperscript{30} Using a device such as this, having reliability of the data collection method already established, would add to the depth of the study.

One of the most common limitations to any study of this nature is the inability to create a testing environment that truly mimics real life. In testing the effectiveness of shoulder braces on their ability to help restore normal kinematics in the unstable shoulder, several considerations should be made. Aspects such as pain and proprioception can not be included when using a cadaveric specimen. Muscle
recruitment, method of force production, and type of pathology mimicking instability are all things that can be simulated or controlled for in some capacity. In our study we did not simulate muscle involvement, such as in the study by Apreleva et al. Since the dynamic restraints work in conjunction with the static stabilizers to control translation of the humerus, simulating muscle involvement would make the testing environment more life-like.

As previously mentioned, the most common method of anterior dislocation of the shoulder occurs when the head of the humerus is levered anteriorly as the arm is driven posteriorly, while in abduction and external rotation. In our study the arm was manually held in a position of abduction and external rotation, applying only enough force to maintain the desired position. This component of the experiment reveals the inherent inability of research investigations to mimic the type of environment within which pathology is elicited.

Suggestions for Future Studies

In order to add to the reliability and strength of this study, a few items should be considered. First, the use of a larger, younger (age eighteen to forty) sample size would allow for a more reliable comparison to the patient population likely using shoulder bracing as a component of their management of anterior instability.

Second, a means of more closely simulating “real life” conditions would add to the strength of the investigation. The forces that act upon the shoulder joint to cause instability or dislocation are likely much greater than those simulated in testing situations. Greater force production used during the investigation would help to mimic the kinds of forces that are likely to be encountered during athletics. It may be beneficial for future
researchers to consider simulating a typical injury that may result in anterior dislocation, such as when a quarterback is hit forcefully on the arm as he is attempting to throw the football (arm in abduction and external rotation). Also, if muscle simulation could be implemented, similar to that performed by Apreleva et al., it would allow for a more "life-like" testing environment.

Third, an investigation of the effect of bracing on proprioceptive changes in the shoulder would be beneficial. It has been shown that significant shoulder kinesthetic deficits occur after anterior glenohumeral joint dislocation. An investigation of the ability of shoulder braces to improve proprioception during closed and/or open kinetic chain activities would be helpful. If proof of increased kinesthetic awareness could be documented it would provide support for the use of shoulder braces in the management of unstable shoulders. This may suggest that bracing can be effective functionally in the active patient population without being effective during passive physiological testing.

Finally, it would be beneficial to determine a means of measuring anterior translation of the humerus non-invasively. For instance, one investigation used a knee laxity testing device to assess anterior-posterior translation of the shoulder. This would allow for a more in depth investigation to take place, providing the opportunity to screen subjects before testing. If live human subjects were used, all factors associated with glenohumeral stability, including proprioception, muscle recruitment, and static restraints, could be accounted for. This would permit the researcher to perform follow-up studies after a specific rehabilitation program was performed. It may also provide a means of determining when anterior laxity in the shoulder is sufficient to require surgery,
as is the case when using the KT-1000 arthrometer in diagnosing laxity in anterior cruciate ligament-deficient knees.
In summary, the results from our study suggest that functional shoulder bracing does not appear to limit passive anterior shoulder translation during physiologic motion. Although limitations of this study were recognized, we believe it to be of significant importance to future researchers concerned with this area in orthopaedics. It poses a serious question about shoulder bracing with respect to the management of shoulder instability. It also aims to generate further investigation into this void in the orthopaedic body of knowledge.

Despite the obvious lack of documented proof regarding indications, contraindications, and efficacy of functional shoulder braces currently on the market, they continue to be used. It is hoped that if these braces are used, it will be done so cautiously, and in conjunction with a proper rehabilitation program while under the supervision of a physician. Ultimately, the search for a shoulder brace that is comfortable, that allows for adequate function, and that maintains glenohumeral joint stability remains.
APPENDIX A

Phase Goals for Conservative Management
Rehabilitation Protocol
Summary of Phase Goals for Conservative Management

Phase I Goals
- Protect and rest the shoulder
- Decrease pain and edema
- Prevent limitation of wrist and elbow motion
- Strengthen scapular muscles manually

Phase II Goals
- Increase pain-free motion of the shoulder
- Strengthen scapular muscles through closed-chain activities
- Strengthen rotator cuff and deltoid muscles isometrically in plane of scapula
- Strengthen latissimus dorsi from 90° forward flexion to neutral

Phase III Goals
- Increase shoulder external rotation range of motion
- Restore scapulohumeral rhythm
- Strengthen rotator cuff and deltoid muscles isotonically in plane of scapula
- Initiate biceps brachii strengthening

Phase IV Goals
- Restore full shoulder range of motion
- Continue to strengthen scapular and rotator cuff muscles, stressing eccentric component
- Incorporate upper extremity endurance training
- Initiate proprioceptive training

Phase V Goals
- Strengthen rotator cuff in overhead position
- Initiate an upper body strengthening program
- Initiate isokinetic strengthening exercises and plyometric exercises
- Monitor endurance and normal muscle flexibility

Phase VI Goals
- Eliminate any strength deficits
- Prepare for return to activity
APPENDIX B

Institutional Review Board Approval
X EXPEDITED REVIEW REQUESTED UNDER ITEM ___8___ (NUMBER[S]) OF HHS REGULATIONS

____EXEMPT REVIEW REQUESTED UNDER ITEM _____ (NUMBER[S]) OF HHS REGULATIONS

UNIVERSITY OF NORTH DAKOTA HUMAN SUBJECTS REVIEW FORM
FOR NEW PROJECTS OR PROCEDURAL REVISIONS TO APPROVED PROJECTS INVOLVING HUMAN SUBJECTS

PRINCIPAL INVESTIGATOR: David Reiling, M.S., P.T. and Kristopher S. Nelson    TELEPHONE: (701)777-2831 DATE: 07/01/98

ADDRESS TO WHICH NOTICE OF APPROVAL SHOULD BE SENT: 501 North Columbia Road P.O. Box 9037 Grand Forks, ND 58202-9037


PROJECT TITLE: Efficacy of Dynamic Shoulder Bracing in the Management of Anterior Shoulder Instability

FUNDING AGENCIES (IF APPLICABLE): Philip Q. Johnson, M.D., P.C.

TYPE OF PROJECT (Check ALL that apply):

  X NEW PROJECT  ___ CONTINUATION  ___ RENEWAL  _____ DISSERTATION OR THESIS RESEARCH  ____ X

  SEARCH PROJECT

  ___ CHANGE IN PROCEDURE FOR A PREVIOUSLY APPROVED PROJECT

DISSERTATION/THESIS ADVISER, OR STUDENT ADVISER: Dave Reiling, M.S., P.T.

PROPOSED PROJECT:  ____ INVOLVES NEW DRUGS (IND)  ___ INVOLVES NON-APPROVED USE OF DRUG

___ INVOLVES A COOPERATING INSTITUTION

IF ANY OF YOUR SUBJECTS FALL IN ANY OF THE FOLLOWING CLASSIFICATIONS, PLEASE INDICATE THE CLASSIFICATION(S):

  _ MINORS (<18 YEARS)  _ PREGNANT WOMEN  _ MENTALLY DISABLED  _ FETUSES  _ MENTALLY RETARDED

  _ PRISONERS  _ABORTUSES  _ UND STUDENTS (>18 YEARS)

IF YOUR PROJECT INVOLVES ANY HUMAN TISSUE, BODY FLUIDS, PATHOLOGICAL SPECIMENS, DONATED ORGANS, FETAL MATERIAL, OR PLACENTAL MATERIALS, CHECK HERE  X

IF YOUR PROJECT HAS BEEN WILL BE SUBMITTED TO ANOTHER INSTITUTIONAL REVIEW BOARD(S), PLEASE LIST NAME OF BOARD(S):

Status: ___ Submitted; Date _____________ ___ Approved; Date ______________ ___ Pending

1. ABSTRACT: (LIMIT TO 200 WORDS OR LESS AND INCLUDE JUSTIFICATION OR NECESSITY FOR USING HUMAN SUBJECTS.

The purpose of this study is to further enhance the knowledge of the efficacy of dynamic shoulder bracing in the management of anterior shoulder instability. It has been proposed that functional bracing provides an effective means of managing shoulder instability as an alternative
to other conservative and surgical approaches. However, current literature includes no scientific studies to support such a claim. Most studies show that the average age of patients having anterior shoulder dislocations is the early 20s. It has been documented that 75% of such injuries occur during athletics, with 85% of those injured being male. It is hypothesized by this researcher that the braces currently on the market do not efficiently limit accessory joint motion during high-risk physiological movements (i.e. external rotation while in abduction). This poses possible adverse affects to a substantial share of this country's population. Dr. Philip Q. Johnson will fund and supervise a controlled scientific study that will help to determine the true effectiveness, or lack there of, in using dynamic shoulder braces to manage shoulder instability. A cadaveric study is the only reasonable means of collecting the crucial data necessary to fill this gap in the current knowledge base.

PLEASE NOTE: Only information pertinent to your request to utilize human subjects in your project or activity should be included on this form. Where appropriate attach sections from your proposal (if seeking outside funding).

2. PROTOCOL: (Describe procedures to which humans will be subjected. Use additional pages if necessary.)

One fresh-frozen cadaveric torso will be purchased from the Anatomy and Service Company in Rosemont, Illinois. Demographic information such as gender, age, and previous shoulder pathology will be determined before purchasing the specimen. It is our intent to obtain a young (less than 40 years of age), male cadaver with no previous history of shoulder pathology. The supplying company maintains confidentiality of specimens beyond the demographic data mentioned above; however, any demographic data collected will be kept for three years after completion of this study then stored to maintain donor confidentiality in accordance with IRB guidelines. The donor specimen will be thawed and prepared using universal precautions and sterile technique. The specimen will be mounted in an upright position onto a wooden platform. Metal rods will be inserted up from the platform through the clavicles to provide support. An intramedullary rod will be inserted into the shaft of the humerus. This rod will be fixed to a machine that will provide the simulated physiologic motion of external rotation while the arm is abducted to 90 degrees.

Fuji, pressure-sensitive contact film will be inserted into the glenohumeral joint space between the humeral head and anterior glenoid rim. Humeral translation will then be measured through the use of the contact film as the arm is externally rotated while in abduction. A simulated Bankart lesion will be implemented at this time to simulate anterior instability. Humeral translation will again be measured with no brace and with each brace to be tested. Testing will be administered at the University of North Dakota Department of Anatomy under the supervision of Dr. Philip Q. Johnson.

Care will be taken during the experiment to store all discarded and used tissues according to waste containment policies. Following completion of the experiment, all of the cadaveric specimens will be incinerated by the University of North Dakota School of Medicine and Health Sciences Anatomy Department using standard incineration procedures. Results of testing will be statistically analyzed to determine the effectiveness of the braces in the prevention of humeral translation and as a means of managing anterior shoulder instability.
3. BENEFITS: (Describe the benefits to the individual or society.)

Results from this study will further enhance the body of knowledge concerning dynamic shoulder bracing in the management of anterior shoulder instability. Currently, no scientific studies have been done to provide support for the use of such braces. With this knowledge, surgeons will be able to more effectively determine if bracing is an alternative to surgery. We anticipate that the braces currently on the market do not effectively limit accessory motion in the shoulder during high-risk physiological movements. If this is in fact true, it may put the patient or athlete at risk for further or increased complications in the future, including recurrent episodes of dislocation.

4. RISKS: (Describe the risks to the subject and precautions that will be taken to minimize them. The concept of risk goes beyond physical risk and includes risks to the subject’s dignity and self-respect, as well as psychological, emotional or behavioral risk. If data are collected which could prove harmful or embarrassing to the subject if associated with him or her, then describe the methods to be used to insure the confidentiality of data obtained, including plans for final disposition or destruction, debriefing procedures, etc.)

No risks to the subject exist due to the fact that they are no longer living. Also, personal demographic data regarding the cadaveric specimen will not be included in the study. Information regarding age, gender, and previous shoulder pathology may be specified prior to purchasing the specimen. Any demographic information obtained will be kept confidential and stored for a period of three years after completion of the study in the physical therapy department at the University of North Dakota.

A minor risk to the researchers exists due to the potential of disease transmission. To negate this risk, universal precautions, emphasizing a sterile environment, will be utilized by all personnel involved with the actual testing of the cadaveric specimen. Also, all specimens are tested for and confirmed negative for hepatitis A, B, and C and HIV.

5. CONSENT FORM: A copy of the CONSENT FORM to be signed by the subject (if applicable) and/or any statement to be read to the subject should be attached to this form. If no CONSENT FORM is to be used, document the procedures to be used to assure that infringement upon the subject’s rights will not occur. Describe where signed consent forms will be kept and for what period of time.

In accordance with IRB guidelines, all study results and demographic data collected from the cadaveric specimen will be stored in the student advisor’s office for a period of three years after completion of the study, after which they will be destroyed.

6. For FULL IRB REVIEW forward a signed original and thirteen (13) copies of this completed form, and where applicable, thirteen (13) copies of the proposed consent form, questionnaires, etc. and any supporting documentation to:

Office of Research & Program Development
University of North Dakota
Grand Forks, North Dakota 58202-7134

On campus, mail to: Office of Research & Program Development, Box 7134, or drop it off at Room 105 Twamley Hall.
For **EXEMPT** or **EXPEDITED REVIEW** forward a signed original and a copy of the consent form, questionnaires, etc. and any supporting documentation to one of the addresses above. The policies and procedures on Use of Human Subjects of the University of North Dakota apply to all activities involving use of Human Subjects performed by personnel conducting such activities under the auspices of the University. No activities are to be initiated without prior review and approval as prescribed by the University's policies and procedures governing the use of human subjects.

**SIGNATURES:**

__________________________  __________________________
Principal Investigator Date

__________________________  __________________________
Project Director or Student Adviser Date

__________________________  __________________________
Training or Center Grant Director Date
July 1, 1998

Institutional Review Board
Office of Research & Program Development
University of North Dakota
Grand Forks, ND 58202-7134

Dear Board Members:

The following memo is in regards to the attached proposal brought forth to the IRB in April. It was approved on May 6, after which time a few changes have become apparent. With regards to the section entitled PROTOCOL, the third paragraph should now read as follows:

Radiographic markers will be inserted into the humeral head and anterior glenoid rim and used in conjunction with x-ray to determine the amount of humeral translation that occurs during external rotation with the arm abducted to 90 degrees. A simulated Bankart lesion will be implemented at this time to simulate anterior instability. Again using x-ray techniques, humeral translation will be measured before and after each shoulder brace is applied. Testing will be administered at Dakota Heartland Hospital in Fargo, ND under the supervision of Dr. Philip Q. Johnson, M.D., P.C.

Thank you for your consideration of these changes to the project entitled *Efficacy of Dynamic Shoulder Bracing in the Management of Anterior Shoulder Instability* (Project Number: IRB-9805-298).

Sincerely,

Kristopher S. Nelson

cc: Dave Relling, M.S., P.T., Advisor
REPORT OF ACTION: EXEMPT/EXPEDITED REVIEW
University of North Dakota Institutional Review Board

DATE: May 6, 1998 PROJECT NUMBER: IRB-9805-298

David Relling, M.S., P.T.

NAME: Kristopher S. Nelson DEPARTMENT/COLLEGE: Physical Therapy

PROJECT TITLE: Efficacy of Dynamic Shoulder Bracing in the Management of Anterior Shoulder Intensity

The above referenced project was reviewed by a designated member for the University's Institutional Review Board on May 6, 1998 and the following action was taken:

☑ Project approved. EXPEDITED REVIEW NO. __________
    Next scheduled review is on May 1999

☐ Project approved. EXEMPT CATEGORY NO. __________ No periodic review scheduled unless so stated in the Remarks Section.

☐ Project approved PENDING receipt of corrections/additions. These corrections/additions should be submitted to ORPD for review and approval. This study may NOT be started until final IRB approval has been received. (See Remarks Section for further information.)

☐ Project approval deferred. This study may not be started until final IRB approval has been received. (See Remarks Section for further information.)

☐ Project denied. (See Remarks Section for further information.)

REMARKS: Any changes in protocol or adverse occurrences in the course of the research project must be reported immediately to the IRB Chairperson or ORPD.

PLEASE NOTE: Requested revisions for student proposals MUST include adviser's signature.

cc: D. Relling, Adviser

Signature of Designated IRB Member
UND's Institutional Review Board

Date 5/6/98

If the proposed project (clinical medical) is to be part of a research activity funded by a Federal Agency, a special assurance statement or a completed 310 Form may be required. Contact ORPD to obtain the required documents.

(1/98)
REFERENCES


