

A RESEARCH DESIGN TO EVALUATE ULTRASOUND IN
PATIENTS WITH SHOULDER STIFFNESS

by



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A Thesis

Submitted to the School of Graduate Studies

in Partial Fulfilment of the Requirements

for the Degree

Master of Science

McMaster University

July 1980

A RESEARCH DESIGN TO EVALUATE ULTRASOUND

MASTER OF SCIENCE (1980)
(Health Care Research Methods)

McMaster University

TITLE: A Research Design to Evaluate Ultrasound in
Patients with Shoulder Stiffness

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NUMBER OF PAGES: vii, 84

ABSTRACT

The objective of this thesis is to propose a methodology of the evaluation of the effectiveness of therapeutic ultrasound and exercise in physiotherapy outpatients with shoulder stiffness. The comparison group is to obtain exercise alone. The results of the study are to be analysed using an analysis of covariance with suspected confounding variables as the covariates.

ACKNOWLEDGEMENTS

I wish to thank Helen Saarinen, Barbara Gowitzke and Robert Magee who all played important roles in guiding my development prior to entry into the programme.

I wish to pay a debt of gratitude to Peter Tugwell, Pat Caulfield and Harry Shannon for their guidance, support and patience in the development of this thesis.

I wish also to thank John V. Basmajian for his comments as external reader.

Also, I wish to thank Adrienne Marks who expertly typed the final draft of this thesis.

Finally, I wish to thank Diane for putting up with a certain moody individual for almost every night for two years.

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CHAPTER 1

INTRODUCTION

The following text provides a research design aimed at answering the question: Is a treatment programme of ultrasound and exercise more effective than exercise alone, when applied to physiotherapy outpatients with shoulder stiffness? Shoulder stiffness which is also known as frozen shoulder or adhesive capsulitis is commonly seen in major medical centre physiotherapy practices (at least 25 cases per year). Therapeutic ultrasound is the most frequently used electrotherapy modality in a physiotherapy practice. It is believed to be of value in joint contractures resulting from tightness or scarring of capsular tissues, however, no randomized clinical trials have been employed to demonstrate this benefit. Ultrasound equipment is costly and treatment requires continuous patient-therapist contact. By carrying out this study the effectiveness of the modality in combination with exercise on shoulder joint stiffness can be ascertained.

The text is organized in a manner as to offer the reader initially information on the shoulder joint and considerations of frozen shoulder. This in turn is followed by a section on the treatment of frozen shoulder with special reference to ultrasound and exercise. After this appears the bulk of the text which focuses on the research design and methodological considerations. This section is followed by a chapter on statistical analyses. Finally, there appears a brief section on ethics which is followed by a summary.

CHAPTER 2

BACKGROUND CONSIDERATIONS OF FROZEN SHOULDER

2.1 Introduction

This chapter provides the reader with an overview of the relevant anatomy of the shoulder complex, the pathology and pathomechanics of frozen shoulder. Also included are descriptive statistics on frozen shoulder including sections on causation and the clinical course of the condition. This information is presented in order to provide the reader with a baseline knowledge of frozen shoulder in order to facilitate the reading of subsequent chapters.

2.2 Anatomy of The Shoulder

2.2.1 Static

The shoulder girdle is composed of the humerus, scapula, clavicle, sternum and ribs. The glenohumeral, scapularhumeral, acromioclavicular, scapulocostal, sternoclavicular, costosternal and costovertebral joints are all important in allowing full shoulder movement (Cailliet, 1974).

It is the glenohumeral joint to which the term frozen shoulder or adhesive capsulitis applies and it is for this reason that the text will offer a more extensive account of its anatomy.

The glenohumeral joint is the articulation between the glenoid fossa of the scapula and the head of the humerus. The glenoid fossa is shallow and somewhat pear shaped. It is covered with articular hyaline cartilage with the circumference being further protected by a

flat rim of fibrocartilage known as the glenoid labrum. This structure acts both to cushion the fossa against the impact of the humeral head and to deepen the fossa to aid in stabilizing the glenohumeral joint. The head of the humerus represents a third of a sphere. Its axis forms with the axis of the shaft of the humerus an angle of approximately 135° and with the frontal plane an angle of approximately 30° (Kapandji, 1970).

The glenohumeral capsule is the ligmentous structure which attaches the humerus to the scapula. The capsule is variable in its configuration but it generally originates from the circumference of the glenoid labrum and the bone surrounding it and inserts distally on the superior aspect of the anatomical neck of the humerus and into the periosteum of the humeral shaft. The capsule is thickened anteriorly by the superior, middle and inferior glenohumeral ligaments. These ligaments and the recesses formed between them have been shown to be somewhat variable (DePalma, 1954). The capsule is also reinforced anteriorly by the coracohumeral ligament.

Lining the joint capsule is a synovial membrane. This membrane blends with the articular cartilage on the head of the humerus and extends to the bicipital groove and is reflected over the biceps tendon.

In addition to the capsule, the glenohumeral stability is further enhanced by a group of muscles known as the rotator cuff. Thus, posterior dynamic stability is offered by teres minor and infraspinatus muscles, superior stability by the supraspinatus muscle and anterior dynamic stability offered by the subscapularis muscle.

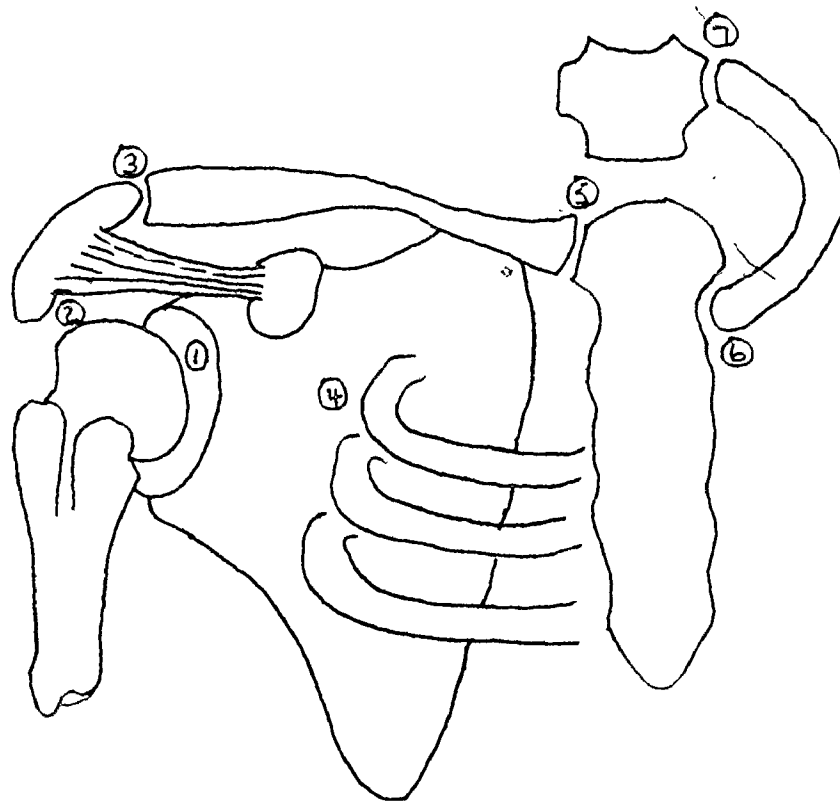


Fig. 2.1 Illustration of seven joints: the glenohumeral, scapularhumeral, acromioclavicular, scapulocostal, sternoclavicular, costosternal and costovertebral.

2.2.2 Dynamic

The shoulder joint is considered to be a multi-axial ball and socket joint with three degrees of freedom (Gardner, Gray, O'Rahilly, 1969). Movements permitted to occur at the shoulder joint are: flexion, extension, abduction, adduction, medial and lateral rotation and circumduction. In order to permit the humerus to move into elevation a simultaneous occurrence of abduction of the arm and depression of the humeral head is required to prevent impingement of the greater tubercle on the coracoacromial ligament.

The arm can be fully abducted and elevated overhead to produce a range of motion of 180° . Of this 180° , 120° of it is considered to occur at the glenohumeral joint and 60° due to scapular rotation (Gardner, Gray, O'Rahilly, 1969; Cailliet, 1974). Thus, for every 15° of elevation a glenohumeral joint contribution of 10° and a scapular contribution of 5° is considered to constitute normal scapulo-humeral rhythm.

2.3 Historical Overview of Frozen Shoulder

Duplay (1872) first described a condition which differed from arthritis in its symptoms and clinical course. At that time it was believed the subacromial bursa to be responsible for causing the pain and dysfunction of the shoulder. Codman (1934) observed that shoulder pain and stiffness could occur without apparent exogenous influences and he classified this condition separately from periarthritis of the shoulder. Codman's name for this condition was "frozen shoulder"--a term which was generally accepted and used synonymously with restrictive

humero-scapular periarthrititis. Codman believed the condition to be caused by tendonitis of the short rotators of the shoulder. Neviaser (1945) demonstrated that the joint capsule was the site implicated in frozen shoulder. Presently shoulder stiffness occurring as a result of capsular contracture and adhesions, is known as frozen shoulder, adhesive capsulitis or restrictive humero-scapular periarthrititis.

2.4 Frozen Shoulder Pathology

Neviaser (1945) has described the pathologic changes in patients with "frozen shoulder" as being a thickening and contracture of the joint capsule which becomes adhered to the humeral head. Also present are microscopic reparative inflammatory changes in the capsule with the possibility of chronic inflammation denoted by fibrosis and perivascular infiltration.

Nelson (1952) and Harmon (1958) both reported finding of significantly reduced joint volumes in patients with "frozen shoulder" when compared to normal shoulders. Lundberg (1969) states that the volume of the joint is related to the severity of the disease.

Lundberg (1970) has demonstrated an increased concentration of glycosaminoglycan in the capsule of frozen shoulders compared to normal shoulders. The significance of this fact is presently unknown.

Radiological examination reveals no abnormalities other than osteopenia or cystic change in the head of humerus (Lundberg, 1968). Arthrography demonstrates a decrease in the volume of the joint capsule and a loss of the normal axillary pouch.

2.4.1 Patho-Mechanics

The contracture of the joint capsule produces a functional limitation of movement which Cyriax (1976) describes as a capsular pattern. This pattern is identified by an overall restriction of glenohumeral joint range with abduction being limited more than flexion and external rotation being limited more than internal rotation.

2.5 Descriptive Statistics

2.5.1 Minimum Incidence

Due to inadequate sampling procedure no true estimate of prevalence can be presented. Lundberg (1969) reported for the year of 1965; 72 cases were recorded in the hospital of Malmö. The population at risk was determined to be 3,400 which results in a minimum prevalence estimate of 2%.

2.5.2 Sex and Age Distribution

In 232 cases of frozen shoulder Lundberg (1969) reported that 58% were female and 42% male. The mean age at onset was 52± a standard deviation of 7 years for women and 55± a standard deviation of 7 years for men. Codman (1934) stated that in 100 cases of frozen shoulder, 58 were women with an average age of 52 years. Stratford (1980) found in 23 cases of frozen shoulder 52% were female and 48% male. The mean age for the females was 60± a standard deviation of 7 years and for the males 58± a standard deviation of 7 years. Hamer (1976) reported that in 31 cases of frozen shoulder 16 were female and 15 male. The combined mean age was 59 years with a range of 41 to 75 years.

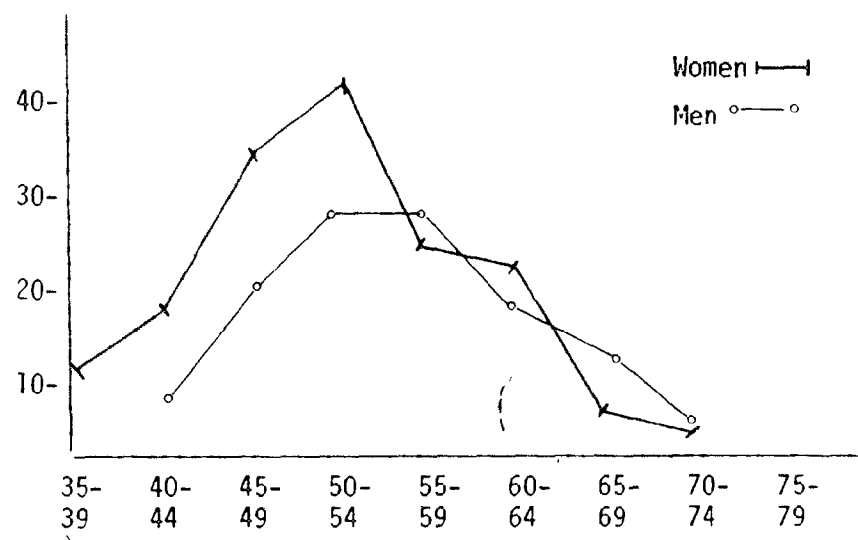


Fig. 2.2 Age and sex distribution (Lundberg, 1969)

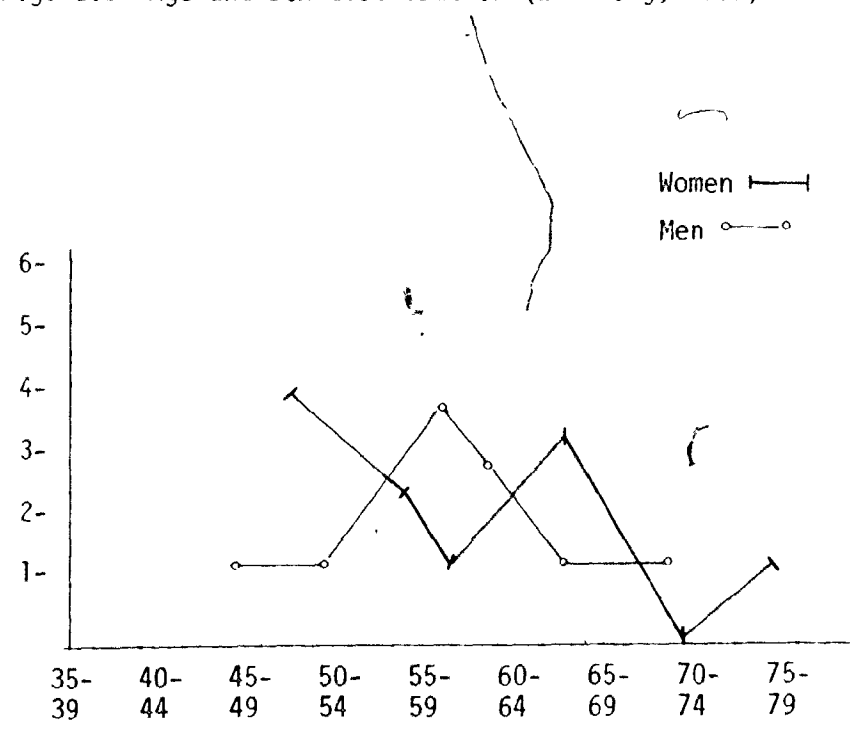


Fig. 2.3 Age and sex distribution (Stratford, 1980)

Note: a line graph rather than a bar graph is used to more clearly indicate the differences between sexes.

2.5.3 Side Involved

Dickson and Crosby (1932) found the right shoulder to be involved more often in cases of periarthritis of the shoulder. Lippman (1951) and DePalma (1952) found the left shoulder to be involved most frequently. These studies did not specify whether the distribution was different for males or females. Lundberg (1969) reported a statistically significantly greater number of left sided involvement in women and a marginally greater number of right sided involvement in men. The literature does not specify involvement with regards to the dominant limb.

2.5.4 Bilateral Involvement

Grey (1978) reported bilateral shoulder involvement in 4 of 21 cases (19%). Lundberg (1969) stated that 35 of 206 cases (17%) demonstrated bilateral involvement.

2.6 Causation

The literature traditionally divides frozen shoulder into two categories. The first category is known as Primary or Idiopathic frozen shoulder and the second category is referred to as Secondary frozen shoulder.

The literature does not provide strong methodology to determine causation for frozen shoulder. The reports to be presented are descriptive in nature and clearly are not as rigorous as studies designed to provide risk or odds ratios (Mausner and Bahn, 1974).

Lundberg (1969) described that in cases of Primary frozen shoulder there would appear to be an increased risk for individuals between the age of 40 and 60 years. He also stated that 25% of the

cases with Primary frozen shoulder had cervical pain. No estimate of the prevalence of cervical pain in a comparable population without frozen shoulder is provided. Therefore, it is difficult to determine whether an association between cervical pain and Primary frozen shoulder exists. Lundberg (1969) goes on to suggest an association between individuals with Primary frozen shoulder and diabetes. From his investigation he provides us with a diabetic prevalence rate of 6% for individuals with Primary frozen shoulders and compares this to a prevalence rate of 2% in the general population in the south of Sweden as presented in 1958. While an odds ratio in excess of 3 can be computed, one must be hesitant to accept this association due to the distemporality in data collection. Also there is no mention of adjustment for age or sex. Johnson (1959) suggests a high incidence of Primary frozen shoulder in institutionalized patients with pulmonary tuberculosis. However, there is insufficient data available to calculate a risk or odds ratio.

In cases with Secondary frozen shoulder two descriptive causal scenarios emerge. The first scenario describes those cases in which the cause is believed related to previous trauma to the shoulder (Simon, 1975; Bateman, 1978; Moseley, 1969). The second scenario describes those cases in which the cause is believed related to immobilization of the shoulder (Moseley, 1969; Cailliet, 1974; Lundberg, 1969). While both of these explanations demonstrate biological plausibility and consistency in reportings, the data required to calculate a strength of association is not provided in the literature.

2.7 Clinical Course

The clinical course of frozen shoulder can be divided into four

stages. The first stage is characterized by pain which is present both at rest and during activity. This pain is often increased at night (Welfing, 1969; Simm, 1975). This stage is followed by a mild lessening of pain and an increase in glenohumeral stiffness (Welfing, 1969). Two to three months following the onset the shoulder has become quite stiff and discomfort is only felt at the extremes of range (Moseley, 1969). In most cases this stage gives way to a progressive return in mobility and function.

In most cases the condition is considered to be self-limiting and usually function is returned anywhere from 6 to 36 months (Moseley, 1969; Grey, 1978; Quin, 1965).

CHAPTER 3

FROZEN SHOULDER AND TREATMENT MODALITIES

3.1 Introduction

This chapter provides a literature review of clinical trials in which ultrasound was evaluated as a treatment modality for frozen shoulder. This review is provided as the basis for justifying why the question as to ultrasound's potential benefit has not been firmly established to date. Also included in this chapter is a review of therapeutic exercise and alternate forms of treatment of frozen shoulder.

3.2 Treatment of Frozen Shoulder

3.2.1 Ultrasound

Lehmann (1954) reported on a prospective cohort non-randomized clinical trial in frozen shoulder patients comparing ultrasound with microwave diathermy with exercise and massage being common to both groups. The dosage of ultrasound varied from 2.5 to 14.0 watts total. By dividing the area of the sound head, this would approximately convert to .5 to 2.4 watts/cm². The duration of treatment was from 5 to 10 minutes with two-thirds of the treatment being offered to the shoulder and the other third paravertebrally. Patients were matched with regards to duration of treatment with the average number being 8 days. The two treatment groups were comparable with regards to age, duration of symptoms, sex and starting shoulder angle. The total number of patients treated were 78 per group. The results indicated a mean gain in shoulder flexion range of motion of $27.4^{\circ} \pm 2.3^{\circ}$ with ultrasound and $16.1^{\circ} \pm 1.5^{\circ}$ with

microwave diathermy. This result is significant statistically and also suggestive of clinical significance. The positive features of Lehmann's study were the comparability of the treatment groups and the seemingly appropriate sample size. Prominent features which detract from Lehmann's finding are the lack of randomization and apparent lack of blinding of evaluators. Either of these two features could create a bias which could have influenced the results. Also, Lehmann's outcome measure seems lacking in rigor. He does not appear to follow his patients to full functional range nor does he measure shoulder function.

Mueller (1954) reported on a prospective cohort non-randomized clinical trial comparing the treatment effects of ultrasound with that of placebo ultrasound in patients with stiff shoulders. Eight patients were assigned to the treatment group by their physician and the 7 placebo patients were selected by the therapist. Patients were assessed after 10 treatments of receiving a dose of 2 watt/cm^2 for 5 minutes. The assessor was apparently blind as to the type of treatment the patient received. No statistical or clinically significant differences between groups were demonstrated. The outcome measure used was based on the patient's subjective complaints (1/3 total score) and estimated goniometric measurements (2/3 total score). The only methodologic strength present in this study is that of blinding of the assessor. The weaknesses of the study are many. The lack of randomizing patients to treatment groups provides an opportunity for allocation bias. Secondly, it would appear that the placebo patients had no knowledge that they may potentially be receiving a placebo treatment. This ethical issue must be corrected in any further studies. Thirdly, there is no indication

as to the comparability of the groups with respect to age, sex, duration of symptoms and starting angle of shoulder movement. No inclusion-exclusion criteria are stated. The area of the shoulder to which the ultrasound was given is not stated. The outcome measures are not rigorously stated, leaving a question to their validity and reliability. The end-point for the measurement, 10 days after commencing treatment, is artificially too short. Lastly, the number of patients chosen are too small to demonstrate anything but gigantic differences between groups.

Quin (1969) has reported on a non-randomized cohort-type clinical trial in which he prospectively compares the effects of ultrasound and exercise to x-ray therapy and exercise with a retrospective group receiving heat and exercise in patients with frozen shoulders. Ultrasonic treatment was given to the anterior, lateral and posterior surfaces of the shoulder using an intensity of 0.5 W/cm^2 . The duration of each treatment is not stated, however, the regime was carried out three times per week for 2 months. An unreported number of patients in both the ultrasound and x-ray group also received courses of shortwave diathermy followed by a more rigorous course of exercise. Patients were followed up at monthly or two-monthly intervals until they were pain free and had full shoulder movement. No mention was made as to how pain and shoulder movement was measured or to whether it was measured by an observer blind to the patient's treatment group. Fifteen patients are reported on in each group. The mean total duration of disability for the ultrasound group was 11.73 months compared to 12.13 months for the x-ray therapy group. The historical controls had a mean

disability duration of 11.13 months. The main weaknesses of this study are: lack of randomization, lack of controlling for cointervention, lack of rigor in reporting on the measurement techniques, the apparent lack of blinding of the investigator, no reference on comparability of groups, insufficient sample size and the use of a historical control group. Lack of statistical or clinical significance among groups could be due to any of the factors alone or in combination.

Hamer (1976) reported on a cohort type non-randomized clinical trial in which patients with frozen shoulder were treated with ultrasound and exercise or ice and exercise. The ultrasonic dosage was 0.5 W/cm^2 for 5 to 8 minutes, with the exact location of where the sound head was applied not being stated. This treatment was offered twice weekly. The outcome measures used were pain and limited rotation with the measuring technique being specified. The pain measurement was obtained by a blinded observer but no reference is made on this point as to the range measurement. The two groups were comparable on age and sex distribution and the duration of symptoms were somewhat shorter in the ultrasound group. The end-point for the patients is not clearly stated and thus the results are difficult to interpret. The major limitations in this study were lack of randomization, failure to clearly specify the end-points and a small sample size (15 and 16 per group).

3.2.2. Summary

The major limitations in trials involving patients with frozen shoulders and treated with ultrasound are many. The major fault is that none of the studies have used random allocation in the assigning of patients to treatment groups. Failure to do so may result in a bias

favouring the ultrasound group in Lehmann's (1954) paper and the alternative group in the remaining three papers. The differences in ultrasonic dosage, duration of application and site of application may have also influenced the results in each study and thus differences in reporting. Ultrasound has been described as an adjunct to exercise therapy and thus the type and extent of the exercise cointervention could account for differences in reporting. The lack of rigor in determining the extent to which the outcome measures are valid and reliable is also a factor in determining the impact of the studies reported on. Likewise, the end-points for the studies are not clearly defined. In many of the studies the evaluator was not blinded as to treatment groups. This could result in further bias either in favour of or against ultrasound. The sample size used in 3 of the four studies are too small. Lastly, none of the analyses included an adjustment for potential confounding variables.

Given the insufficiencies in the literature to date, the value of ultrasonic therapy in the treatment of frozen shoulder has been neither supported nor refuted. In order to determine the extent to which ultrasound is of benefit to patients with frozen shoulders, a clinical trial using random allocation of patients seems essential. Furthermore, attention must be given to validating the outcome measures, defining the end-points, carefully describing the exercise programme to be used in conjunction with the treatment, and reducing or eliminating all forms of bias associated with measurement. Finally, a sample size must be selected capable of demonstrating clinically significant differences (should they exist) and analyses performed to control for potential confounding variables.

Table
SUMMARY OF STUDIES OF ULTRA

	Design	Bias Safe- guards	Factors Checked For Compara- bility of Groups	Sample Size	Area of U.S. Application
LEHMANN (1954) U.S. & Microwave	Cohort non- ranomized	No	Yes age sex restric- tion duration of symptoms	73 per group	Shoulder, specific area not specified
MUELLER (1954) U.S. placebo	Cohort non- randomized	No	None stated	8-U.S. 6-Placebo	Shoulder specific area not specified
QUIN (1969) U.S. - x- ray + (heat)	Cohort non- randomized	No	Yes duration of symptoms	15 per group	Shoulder -anterior -lateral -posterior
HAMER (1976) U.S. - ice	Cohort non- randomized	No	Yes age sex	Total of 31	Shoulder specific area not specified

3.1

SOUND FOR STIFF SHOULDERS

Compliance	Outcome Measure	End-point defined	Combined Treatment	Results	Drop-out Analyzed
?	Passive joint range	No	Massage and exercise	U.S. better than micro-wave	?
?	1/3 pain 2/3 R.O.M. estimate	No	None	No difference	?
?	Time to full recovery	No	Exercise (and some heat)	No difference	?
?	Pain change Lack of movement change	No	Exercise	No difference	?

3.3 Ultrasound

Ultrasonic energy is a form of mechanical energy produced by sound waves of frequencies greater than 16 kilohertz. Therapeutically, ultrasonic energy is produced by way of the piezo-electric effect. Here, by applying a voltage across a crystal the crystal is excited and a natural vibration occurs. The sound waves produced are longitudinal compression waves, with the movement of particles in the medium occurring parallel to the direction of the wave propagation. The propagation of ultrasound is dependent on a medium being present, thus, propagation cannot occur in a vacuum. Ultrasonic frequencies used for physio-therapeutic purposes range between 0.8 and 1.0 megahertz with the most common frequencies being between 0.86 and 0.875 megahertz. Output intensities of 3 watts per square cm and less are used therapeutically. Schwann (1972) reported an effective depth of penetration of ultrasound at a frequency of 1.0 megahertz and a transducer head diameter of 3 centimeters to be 4 centimeters. The effective depth of penetration is considered to be an intensity which is half of that applied to the skin.

3.3.1 The Device and Application

Therapeutically, ultrasonic waves are produced by feeding the output from a high frequency oscillator to a crystal with a natural frequency similar to that of the oscillator. The crystal is located in the head of a transducer and the sound waves are applied to the patient by stroking the transducer over the area of the patient to be treated.

An acoustic coupling agent is applied between the transducer and the patient to ensure that a high percentage of the sound waves are transmitted to the patient.

3.3.2 Thermal Effects

The absorption of sound waves produces a heating effect. Maximum heat is generated at the interface of tissues, such as between fat and muscle, and at the periosteum. The production of heat causes increased cell activity and vasodilation resulting in an increased blood supply.

3.3.3 Mechanical Effects

The wave vibration produces a loosening of adhesion formations (Scott, 1968; Watkins, 1972) and also increases the permeability of the cell membranes which accelerates fluid interchange and absorption. Excess intensities of ultrasound applied in a stationary manner have been shown to produce tissue disruption resulting and cavitation animals (Licht, 1972). Proper application of therapeutic ultrasound has not been shown to produce these effects in humans.

3.3.4 Indications

Scott (1968) suggests that ultrasound is indicated in both traumatic and inflammatory conditions. Lehmann (1972) states that ultrasound is most effective in treating joint contractures resulting from tightness or scarring of the capsule. Scott (1968) and Watkin (1972) both agree that ultrasound is of benefit in treating contractures and scar tissue.

3.3.5 Contraindications

Lehmann (1972), Scott (1968) and Watkins (1972) all agree that therapeutic ultrasound should not be given about the brain, spinal cord, eye, heart, reproductive organs, epiphysis of growing bones and over areas of impaired circulation.

3.4 Exercise

Therapeutic exercise can be grossly divided into two categories. The first category deals primarily with maintaining or increasing joint mobility and the second category deals with improving muscle function (strength and endurance).

Gardiner (1971) states that relaxed passive movements maintain but do not increase mobility. She goes on to state that in order to increase mobility forced passive movements or manipulation are required. Paris (1979) offers a rationale for the above statement.

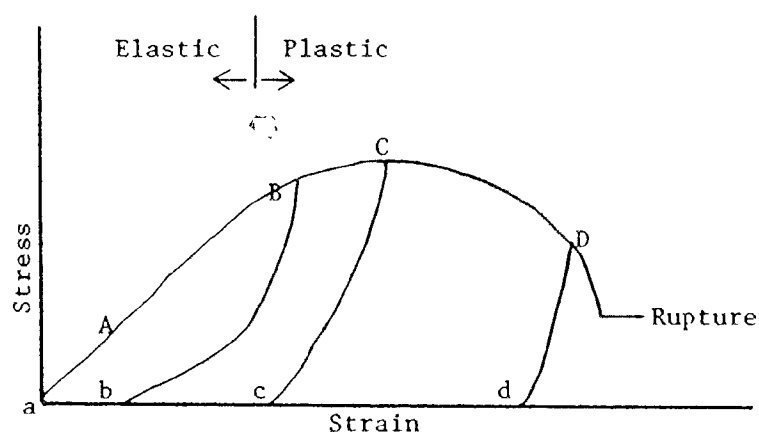


Fig. 3.1 Stress-Strain Curve for connective tissue

When a force is applied to connective tissue, an elongation or deformation of the tissue will occur. If the deformation is within the elastic portion of the curve, the tissue will return to length "a" when the force is removed.

If, however, sufficient force is applied to the tissue, the plastic range will be entered and when the force is removed a permanent deformation of the tissue will have occurred. By referring to Fig. 3.1.

it can be seen that by applying a force of B a permanent deformation of b will occur; likewise, by applying a force of C a permanent deformation of c will occur. Thus, when mobilizing a joint with the intent of increasing range of motion the plastic range must be entered. Excessive application of force, point D, will produce further immediate deformation, 'd', however, side effects such as inflammation, pain and spasm are likely to produce immobilization and a decreased range over the next several days. Thus, when mobilizing using forced passive movements without anaesthetic and medical management to reduce the inflammatory response, the plastic range must be entered but not abused. This would correspond to point C in Fig. 3.1.

3.5 Muscle Training

Muscle training is used to improve three parameters of muscle function: strength, power and endurance. Strength is a measure of the force produced by the muscle and is expressed in units of pounds, dynes and newtons. Power is a measure of the rate of doing work, with the respective units being foot-pounds per second, dyne-centimetres per second and newton-metres per second. Endurance is a measure of the ability to carry out a task repeatedly.

Muscle work is traditionally divided into three categories. Concentric muscle work occurs when a muscle shortens in the process of overcoming a resistance. Eccentric muscle work occurs when a muscle lengthens due to an applied force which is greater than the applied muscle force. Static muscle work occurs when a muscle contracts with no change in length occurring.

DeLorme (1945) reported that low-repetition, high resistance exercise produces strength (which DeLorme incorrectly calls power) and high-repetition, low resistance exercise produces endurance. Astrand (1970) is in agreement with this statement. Berger (1962) demonstrated in a trial where 177 freshman and sophomore male students were divided into 9 different types of exercise groups that those individuals in the group that trained with 3 sets of six repeat maximal lifts demonstrated statistical as well as clinically significant increases in strength compared to the other 8 groups. Test-retest measurements in this trial produced a reliability coefficient of 0.97. There is no mention as to whether the subjects were stratified and randomly assigned or whether the evaluators were blind with regards to treatment groups.

3.6 Alternative and Complementary Adjuncts to Treatment

These areas will be briefly mentioned to form a background for exclusion criteria, stratification and confounding variables.

3.6.1 Injection Therapy

Lee (1973) reported no significant difference between treatment groups receiving local hydrocortisone and exercise and those receiving infra-red irradiation and exercise. Quin (1965) reported that while a treatment group receiving hydrocortisone injections, heat and exercise may have experienced some relief in pain when compared to a heat and exercise group there was no difference in the rate of restoration of full shoulder movement. These statements are in agreement with Cyriax and Troiser (1953) and Glyn and Newton (1958). Lloyd-Roberts and French

(1959) reported that hydrocortisone as used in their trial when combined with manipulation and physical methods reduced the total disability period when compared to physical methods with and without oral cortisone. This statement is in general agreement with Crisp and Kendall (1955). It should be noted that the disagreement indicated above could be due to: differences in diagnostic criteria, differences in injection sites or techniques, different cointerventions or differences in follow up and outcome measures.

3.6.2 Analgesics

Lee (1973) reported that a treatment group receiving only analgesics progressed significantly slower than treatment groups receiving heat and exercise or hydrocortisone and exercise. Hazleman (1972) reported in a retrospective study that frozen shoulder patients receiving analgesics only did not significantly differ in their mean deviation of incapacity when compared to groups treated by injection, physiotherapy and manipulation.

3.6.3. Manipulation

Lundberg (1969) demonstrated in a trial where patients were randomly allocated to a manipulated group and control group that the manipulated group progressed at a rate which was both clinically and statistically significantly higher than the control group. The values specific are in degrees per month and are 14.5 and 23.2 for the control and manipulated group respectively. The hospitalized manipulated group had a mean improvement of 94.3° per month.

The end-point used by Lundberg was 160° of shoulder flexion, however, it is not explicitly stated whether all subjects reached this

end-point. Furthermore, Lundberg does not report on whether the assessment was performed by an observer "blinded" to the patient's treatment group. The manipulation process is described in the article. Lundberg (1969) further states that the groups were comparable on sex distribution and side involvement. He goes on to say that an analysis of covariance was performed using the initial range of motion and the duration of symptoms prior to manipulation as the covariant factors. He reports that the significant difference in favour of the manipulated group was preserved, however, he does not provide the figures. Lundberg (1969) goes on to state that no significant difference was noted when comparing the mean total duration of dysfunction.

^

CHAPTER 4

RESEARCH DESIGN

4.1 Introduction

This chapter presents the actual design for the proposed randomized clinical trial. The trial is one which primarily studies effectiveness rather than efficacy since it is addressed at those individuals to whom treatment is offered rather than those who fully comply with treatment.

Initially a time table for the study and a patient flow diagram within the study are presented. This is followed by the research questions which are accompanied by a set of definitions useful in reviewing the text. This in turn is followed by a step-by-step description of the study design with special reference to methodological issues and strategies involved in dealing with these issues.

4.2 Research Questions

The primary question to be posed is: Is a treatment programme of ultrasound and exercise more effective than exercise alone, when applied to physiotherapy out-patients with shoulder stiffness? This primary question can be divided into two elements based on the Outcome measures of interest. The first element asks: Is a treatment programme of ultrasound and exercise more effective than exercise alone, as measured by the duration of treatment in weeks to reach 160° of passive shoulder flexion when applied to physiotherapy out-patients with shoulder stiffness? The second element asks: Is a treatment programme

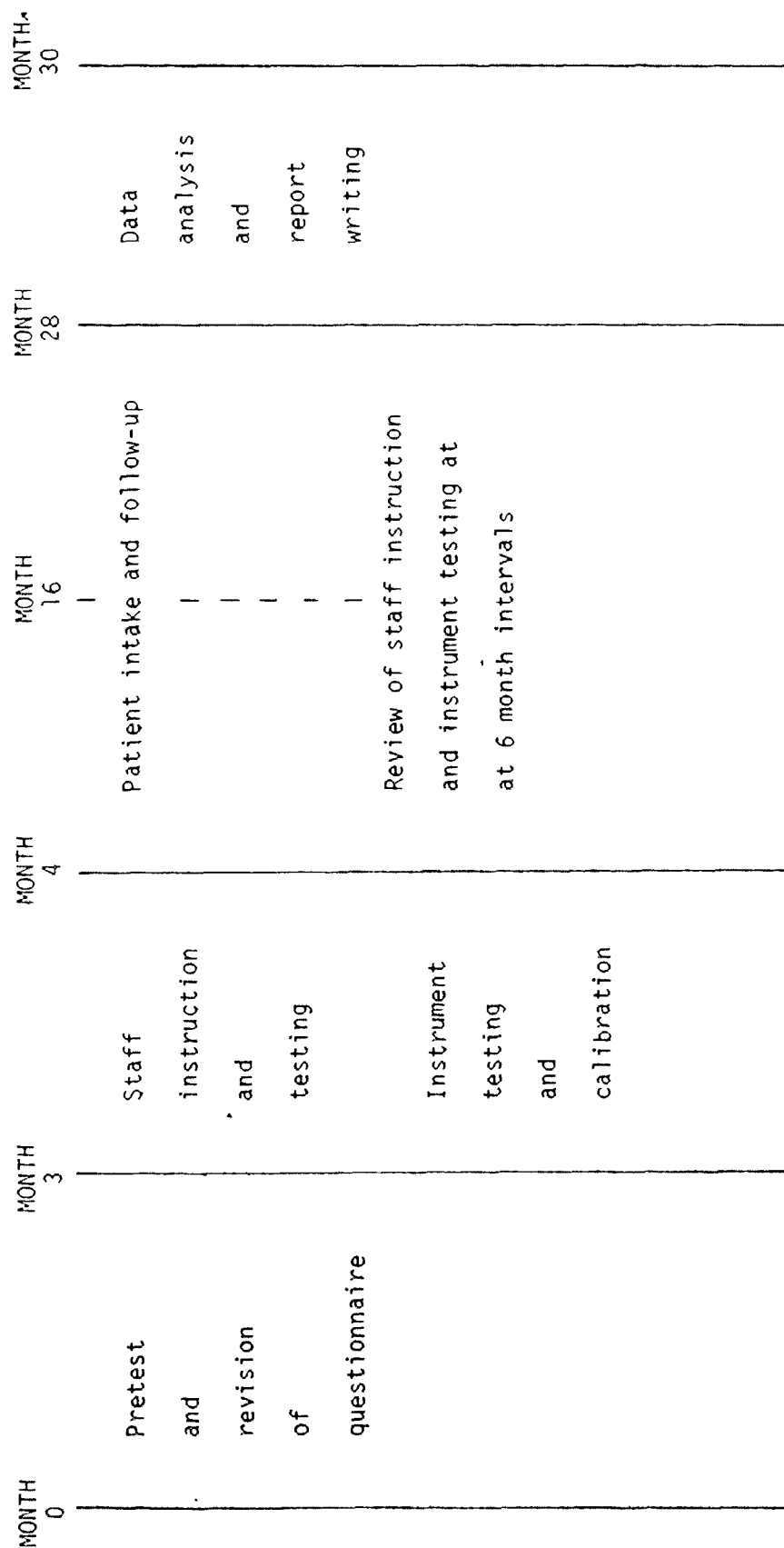


Fig. 4.1 Study time table

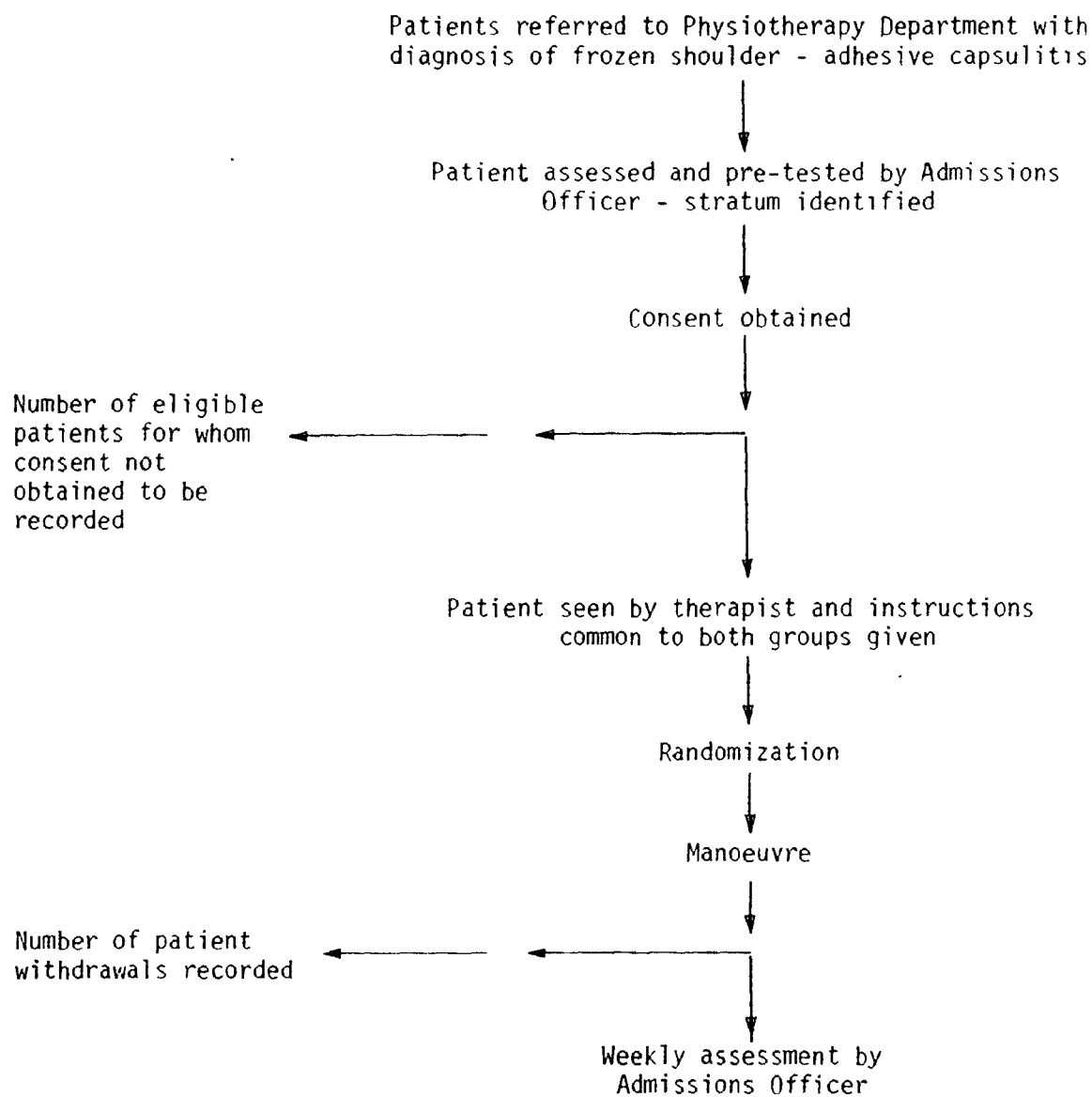


Fig. 4.2 Patient flow

of ultrasound and exercise more effective than exercise alone, as measured by the duration of treatment in weeks required to obtain full physical function as measured by the questionnaire provided in Appendix 1, when applied to physiotherapy out-patients with shoulder stiffness?

4.3 Definitions

- 1) Shoulder Stiffness: A shoulder in which movement, both active and passive is restricted in a capsular pattern. Also referred to as "Adhesive Capsulitis" and "Frozen Shoulder".
- 2) Physical Function Questionnaire: A questionnaire designed to measure physical function and change in physical function of the shoulder. Its content is presented in Appendix 1.
- 3) Exercise: This refers to shoulder exercise, both active and passive in nature. It will be described more fully in the manoeuvre.
- 4) Ultrasound (also referred to as therapeutic ultrasound): This is a form of diathermy used to produce therapeutic effects. The unit to be used in this study operates at a frequency of .875 MHz . Its operation principles have been described in the literature review and its mode of application will be described in the manoeuvre.
- 5) Capsular Pattern of the Shoulder: A restrictive pattern in which abduction is limited greater than flexion (by approximately 10°) and external rotation is limited greater than internal rotation (by approximately 5-8°).

- 6) Active Movement: Movement performed or controlled by the voluntary action of the patient's muscles.
- 7) Passive Movement: Movements which are produced by an external force during muscular inactivity.
- 8) Assisted Exercise: When muscle strength or co-ordination is inadequate to perform a movement an external force is applied to compensate for the deficiency.
- 9) Sustained Stretch: A passive or assisted stretch held at the end range of a movement for 20 seconds.
- 10) Flexometer: This is a device used to measure changes in joint angles. Its units are degrees.
- 11) Electrogoniometer: Is an instrument which generates an electrical output signal proportional to an angular change in a patient's joint.

4.4 Patient Population

The target population to which the sample will ideally be generalized are all patients with the diagnosis of frozen shoulder - adhesive capsulitis fulfilling the admission criteria for this study.

4.5 Admission Criteria

To be admitted into the study each patient must fulfill all inclusion criteria and none of the exclusion criteria. All potential subjects will be screened for all inclusion and exclusion criteria.


4.5.1 Inclusion Criteria

- 1) Total forward flexion (elevation) of the shoulder is

restricted to 135° or less.

- 2) The restriction of the glenohumeral joint is capsular in nature. (Abduction is limited greater than flexion. External rotation is limited greater than internal rotation).
- 3) Pain is aggravated by shoulder movement and relief is obtained by a reduction or cessation of shoulder movement (Bateman, 1978; Cailliet, 1974).
- 4) Informed consent obtained.

4.5.2 Exclusion Criteria

- 
- 1) X-rays indicating arthritic changes with osteophyte formation or erosion present on either the glenofossa or humeral head.
 - 2) The patient has undergone manipulation to the shoulder within the past year.
 - 3) Fracture to the greater tubercle in the past year as indicated by medical records or x-ray examination.
 - 4) Fracture to the proximal 1/3 (as indicated by the overall length of the humerus) of the humerus in the past 12 weeks.
 - 5) Co-existence of neurological disorders involving the shoulder as diagnosed by the referring physician.
 - 6) Impairments of the blood supply to the shoulder.
 - 7) A history of open surgical procedures at the shoulder.
 - 8) Shoulder dislocation in the past year.
 - 9) Co-existence of lesions* to the rotator cuff, subacromial

bursa, bicipital tendon, inflammatory joint disease and cervical spondylosis leading to shoulder pain. (The diagnostic criteria for the above are outlined in Cyriax's Textbook of Orthopaedic Medicine, pp. 180-228, 1976)

4.6 Sample

The sample will consist of all patients fulfilling the admission criteria presenting at the institutes taking part in the study during the length of the trial. The sample will consist of consecutive patients collected in a serial fashion.

4.7 Physician Compliance

Since the referrals to the physiotherapy departments involved in the study and the continuation of the patients on treatment will be largely dependent on the referring physician, every effort will be made to secure and retain his co-operation. Prior to commencing the study a form letter explaining the nature of the study will be sent to all frequently referring physicians as well as physicians belonging to the local medical society. Correspondence will also accompany all patient follow-up visits with the referring physician. This correspondence will also request new data pertaining to the medical management of the patient's shoulder.

*Excluded until soft tissue (contractile) lesion resolved.

4.8 Prognostic Stratification

Prognostic stratification is one technique available to ensure that known or suspected confounding variables are distributed relatively equally between treatment groups prior to administration of the treatment. A confounding variable is a variable that is a) extraneous to the question being asked, b) a risk factor or determinant for the outcome of interest and c) is associated with exposure to the putative cause. Confounding can destroy the validity of a study and must therefore be avoided.

Factors initially considered for stratification were as follows: duration of symptoms prior to treatment, starting shoulder angle in degrees of flexion, etiology, sex, age, medication, injection and institutions. Due to a lack of decisiveness and rigor in the literature a method was developed using a multiple regression procedure to identify potential confounding variables for the Outcome measures of interest. This procedure consisted of a retrospective chart review of 23 patients fulfilling the diagnostic criteria for this study. These patients represented all patients seen through the Physiotherapy Department at McMaster University Medical Centre over a duration of nine months (April 1979 to December 1979) fulfilling the diagnostic criteria. All of these patients were treated with active, active-assisted and passive exercise. Data were gathered on the following factors: duration of symptoms prior to treatment, total duration (onset of symptoms to 160° of shoulder flexion, measured in weeks), starting angle of shoulder flexion (angle measured on first visit), etiology (divided into primary and secondary), sex, age, and duration

Since no data on injection or medication was available for multiple regression analysis and the findings presented in the literature review are not decisive, injection status of the shoulder will not be stratified for.

In summary, stratification will be performed for:

- This constitutes a total of $(2 \times 2) 4$ strata or 2 strata per institute.

4.9 Randomization

Randomization will be performed to reduce the risk of patients being allocated to treatment groups in a systematic way resulting in a bias. Randomization also provides the best known way to handle unknown confounding variables. In this investigation randomization will be performed for each stratum using a table of random numbers. The randomization sequences as determined by the table will be recorded in sealed envelopes and a set kept at each institute.

Patients who meet the admission criteria will be randomly assigned to either the ultrasound-exercise group or exercise group following stratification. Upon identifying a patient for the study, the Admissions Officer will open the next sealed envelope representing the patient's stratum. The contents of the envelope will consist of a paper with either a zero or a one which corresponds to the two settings on the randomization switch on the machine. (It should be noted that during the study the ultrasound machines will be used for the study patients only.) The Methods Officer will record the patient's name and randomization coding in a book under the appropriate stratum heading.

4.10 Sample Size

In determining sample size for an investigation of this type, there are three primary parameters which must be considered. The first two parameters are error types and the third parameter is the noise to signal ratio. A Type I error would be committed if the null hypothesis (no difference between treatments) was falsely rejected. A Type II

error would be committed if the null hypothesis was accepted when in fact the alternate hypothesis (a difference exists between treatments) was true. The noise to signal ratio is a value which considers the closeness of measures within each treatment group which is the noise and the difference between the two treatment groups which is the signal. Since the signal appears in the denominator of this relationship, the larger the signal the smaller the sample size required. Conversely, as the noise appears in the numerator the larger the noise, the larger the sample size required.

In planning a trial the investigator must decide on the risk he is willing to take when considering the two error types. In this investigation the risk of committing either types of error will be considered to have equal importance when interpreting the outcome. A one-sided alpha value of 0.05 and a one-sided beta value of 0.05 will be used.

From the literature review no firm values for either the signal or noise were obtained for the outcomes of interest in this study. A survey of physiotherapy clinicians suggests that a 30% reduction in treatment duration would constitute a clinically meaningful difference between treatments. This survey consisted of interviewing 18 physiotherapists who were familiar with both ultrasound and the condition known as frozen shoulder.

In order to obtain estimates of the signal and noise, a retrospective chart review was performed. Five subjects treated with ultrasound and exercise were identified and six subjects treated with exercise only were identified. Since there are two outcomes of interest

in this study, the signal and noise values will not necessarily be the same for both. Also, since the questionnaire on shoulder function was not developed when the patients used in the survey were present, no direct values for sample size based on physical function can be calculated. An estimate of this value will be used to approximate this sample size. This estimate is based on the duration of treatment to obtain 160° of passive shoulder flexion. The rationale for using this substitution is presented in Appendix 4.

The formula to be used in the calculation of sample size for both Outcome measures is expressed in Equation 1 (Armitage, 1974).

Equation 1

$$n > 2 \left\{ \frac{(\alpha_1 + \beta) \sigma}{\Delta} \right\}^2$$

Substituting the values obtained in Appendix 5 for the delta and pooled standard deviation, Equation 1 now becomes equation 1.1 for Outcome measure 1 (treatment duration in weeks to 160° of passive shoulder elevation).

Equation 1.1

$$n > 2 \left\{ \frac{(1.65 + 1.65) 3.41}{3.65} \right\}^2$$

n > 19

This yields a sample size of 20 subjects per group. Based on the rationale presented in Appendix 4 this figure will also serve as an estimate of sample size for Outcome measure 2.

The total sample size required excluding drop outs will be

forty subjects based on the calculations in equation 1.1.

4.11 Patient Intake

Based on the sample size calculation in Equation 1.1, forty patients will be required for this investigation. Using a maximal acceptable refusal/withdrawal rate of 20% a total patient intake of forty-eight patients would be required. Based on a retrospective survey by Stratford (1980) approximately thirty suitable patients are seen at a major medical centre per 12 month period. In order to arrive at the number of centres to take part in the study and the duration of the study, the following factors were considered. As the number of centres increase the cost due to travel, (organization and follow-up clinics) equipment and personnel increases. The duration that the average therapist spends at any one institute is approximately two to 3 years. As the number of centres increase so does the risk of inter-centre variation with respect to measurement techniques. For these reasons it is decided to use two centres for the study. (Tentatively these centres would be Chedoke-McMaster Hospital, McMaster Division and Hamilton General Hospital.) This would result in a patient intake period of one year.

4.12 Treatment

4.12.1 Rationale for Combined Treatment

In this clinical trial the addition of ultrasound to the standard treatment of exercise will be evaluated to see whether or not this combined treatment is more effective than exercise alone. No

randomized clinical trials have appeared in the literature on the question being posed. Several cohort studies have been reported in the literature (Quin, 1969; Hamer, 1976; Lee et al, 1973; Lehmann, 1954; Mueller, 1954) and have been discussed in the literature review. The consensus of these reports suggest that ultrasound is best used as an adjunct to exercise rather than being complete in itself. Therefore, for the purpose of this clinical trial, the combined treatments will be evaluated.

4.13 Combined Treatment Group

4.13.1 Ultrasound Application

Therapeutic ultrasound dosage is dependent on three factors:

Output intensity, Duration of application and speed at which the sound head is passed over the treatment site (Reid and Cumming, 1973; Faus, 1969). The dosage to be used for the shoulder joint capsule will be a continuous intensity of 1 watt/square cm for a duration of five minutes (Knock and Krauth, 1972). The shoulder will be divided and treated in three areas: anterior, inferior and posterior. Each area will receive a 5 minute treatment per session. The treatment programme will consist of three treatments per week with at least one day off between two of the 3 treatments. The device to be used is a Sonostat* 733 with the modification of an extra switch to allow for "therapist and patient blinding". The coupling agent to be used is Aquasonic Gel[®]†. The sound head will be pre-warmed in 38°C water for 15 seconds prior to

*Sonostat 733 (Siemens)

†Aquasonic 100 (Parker Laboratories)

patient contact.

4.13.2 Exercise Programme

The exercise programme will be divided into two sections. The first section will deal with exercises to be performed while in attendance at physiotherapy and the second section will describe the home exercise programme.

The physiotherapy programme will consist of a warmup two-minute pendular type exercise (Codman, 1934). This will be followed by a pulley auto-assisted exercise routine which will consist of six sustained stretches in flexion followed by 6 sustained stretches in abduction. This will be followed by a similar series of passive sustained stretches performed by the therapist. Also included in this series will be six sustained stretches for internal and external rotation. All of the sustained stretches will be held for twenty seconds followed by a 20-second rest interval. The rest interval between exercise sets will be three minutes. The patient will finish up with an active/active-resisted strengthening programme throughout the active range at the shoulder. This will consist of three groups with 6 repetitions per group at maximal loads (Astrand and Rodahl, 1970; Gardiner, 1971). This exercise programme will be done immediately following the ultrasound treatment.

The home exercise programme will consist of a warmup of one-minute pendular type exercise. This will be followed by a pulley auto-assisted exercise routine as previously discussed. Following the auto-assisted routine the patient will perform six sustained stretches for external and internal rotation with the aid of a towel. This

technique is similar to drying one's back with a towel. The last home exercise of the set will be an active-resisted routine throughout active range holding one full soup can. This routine will consist of 3 groups with six repetitions per group. The set of home exercises will be performed twice daily on days when therapy is not attended and once daily when therapy is attended.

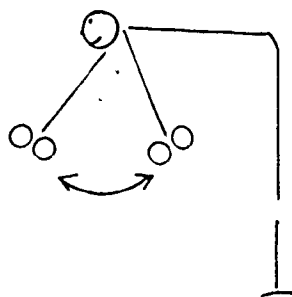
4.14 Exercise Group

This group will receive a similar contact time with the pre-warmed ultrasonic application, however, the output will be off. The exercise programmes while in attendance at therapy and at home will be identical to the combined treatment group.

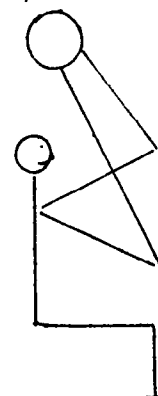
4.15 Assessment and Treatment Variation

If the patient, assessments and therapeutic manoeuvres are to be administered by more than one person, care must be taken to ensure that the inter-assessor-therapist differences are not large enough to spuriously influence the outcome. These differences can be minimized by developing strategies in advance to deal with sources of variation.

i) Evaluator Variation is liable to occur between the four evaluators representing the 2 study centres. In order to minimize this variation, prior to the study and at six-month intervals during the study, special clinics will be arranged. These clinics will consist of encounters between a simulated patient and each of the four evaluators (2 per centre). The simulated patient will present four different simulations (Frozen Shoulder, Supraspinatus Tendonitis, A-C joint



Pendular Exercise



Pulley auto-assisted exercise

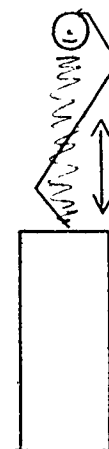
Internal-external exercise
using a towel

Fig. 4.3 Active and active-assisted exercises

sprain, Bicipital Tendonitis) to each evaluator in a pseudo-clinical setting. The evaluator will be scored on whether they would admit this patient to the study. A perfect score is required in order to accept an evaluator for the study.

In addition to the patient simulation based on diagnoses, the clinic will also include simulations on joint measurement. The testing protocol for this procedure is outlined in Appendix 8. Boone (1978) demonstrated that joint ranges are measured more reliably when measured by the same observer. For this reason one observer will measure the ranges at each centre, thus totalling 2 observers. A back-up observer will also be trained for each centre to carry out the measurements should the primary observer not be available.

ii) Treatment Variation is likewise likely to occur between the four (2 per centre) therapists at the centres partaking in the study. The simulated patient technique will also be used with them in order to minimize treatment variation. This procedure will consist of the therapist teaching the simulated patient the home exercise routine and administration of a treatment. The therapist will be evaluated by the simulated patient using the form presented in Appendix 9.

The simulated patient approach to be used is similar to that outlined by Barrows (1964, 1968) and Burri (1976). For the present study it has been selected over using real patients as the signal created by the simulated patient can be ensured to be the same for all tested; patient (simulated patient) discomfort is not likely to be an issue; one simulated patient can be used for all simulations (no change with time, e.g. 6-month follow-up) and the simulated patient can be trained

to provide feedback to the therapist.

4.16 Biases Relating to Patient Assessment and Treatment

A bias represents a systematic deviation from the truth. The results of a clinical study may be markedly altered by bias occurring in the evaluator, the one who administers the treatment or even the patients themselves. In order to reduce the risk of bias, the following steps will be taken in this study.

The therapist administering the treatment will not know which of the positions on the randomization switch represents the "on" position. If the therapist strongly desired they could break the code by putting the sound head in water and adjusting the randomization switch until an output was visualized. For this reason the treatment therapist will not perform the assessment.

Like the treatment therapist the evaluator will be blind as to which treatment the patient is receiving. Also, this person will have no direct contact with the ultrasound machine making it more difficult for him to break the code. While the evaluator may expect the patients to improve with time, since he is blinded to the treatments this effect, if present, would be expected to act equally for both groups.

With normal ultrasonic treatment the sound head becomes mildly warm. This effect could bias both the patient and therapist. In order to overcome this effect, the sound head will be placed in 38°C water for 15 seconds prior to treatment. With the friction developed due to the sound head moving over the skin during treatment, the sound head will remain mildly warm for the duration of the treatment. The temperature

difference will not be clinically perceivable to the patient.

4.17 Summary of the Patient Evaluation Procedure

The initial assessment of patients referred to the Physiotherapy Department will be conducted by the evaluator (hereafter referred to as the Admissions Officer) at each institute. If the patient fulfills the admission criteria they will be provided with a self-administered questionnaire (Appendix 1). Ongoing assessments of the patient which will consist of measuring and recording shoulder flexion and administering the questionnaire on a weekly basis will be performed by the Admissions Officer. This procedure will continue until an end-point for the patient has been reached.

4.18 Patient Compliance

Patient compliance can be considered to be the extent to which the patient's behaviour (adherence to the therapeutic programme) coincides with the clinical prescription. Compliance is worth following in a clinical trial as it alone or in association with other variables may influence outcome.

The total patient compliance in this study will be a composite measure of the frequency of patient attendances at therapy and the frequency of the home exercise programme. The frequency of attendances at therapy will be recorded by the therapist. In addition to this, the patient will be given a log book and asked to record in it daily exercise frequency, medications or injections taken and exercise performed in addition to that prescribed.

While the log method of observing compliance may be of questionable validity it would appear to represent the most practical method short of direct observation of the patient's home exercise programme.

4.19 • Outcome Measurements

The true end-point of this study will be 160° of passive forward shoulder elevation and full function as measured by the questionnaire.

The literature is not in general agreement as to which outcome measure(s) are best suited to evaluate shoulder dysfunction. A collection of outcome measures used to date consist of subjective questioning (Müller, 1953; Quin, 1969), total time taken for full recovery (Lloyd-Roberts and Finch, 1959), mean duration of symptoms (Hazelman, 1972), improvement in passive rotation (Hamer, 1976), gain in range of motion following 8 days of treatment (Lehmann, 1954), an aggregate of active and passive ranges for 6 weeks of treatment (Lee, 1973) and the rate at which the range of motion is increased to 160° of shoulder flexion (Lundberg, 1969).

When considering an outcome measure or measures appropriate, one should first consider the patients presenting complaints. In the case of a patient with a "frozen shoulder" the primary reasons for seeking help are a stiff and occasionally painful shoulder which fails to function properly. From the patient's standpoint it would seem important that the outcome measure looks at mobility, discomfort and function.

The rationale for using ultrasound as an adjunct to the existing forms of treatment is that it is believed to increase the mobility of a joint when capsular tightness or adhesions are present (Lehmann, 1954). Since ultrasound is claimed to reduce capsular tightness and not at

increasing muscle strength it would appear from a technical standpoint that passive range of motion would be of paramount importance.

Lee, et al (1973) report that increased movement at the shoulder in one direction correlates highly with increased movements in all other directions. (Lundberg (1969) also reports a relationship between total shoulder elevation and internal rotation. Lundberg (1969) also reports that humero-scapular elevation has a strong relationship with total shoulder elevation in subjects with frozen shoulder (based on 66 subjects $r = -81$). This value demonstrates a strong correlation which does not strongly differ from one. Clinically, total shoulder elevation is measured as opposed to humero-scapular range primarily due to convenience. It would also appear that the increased accuracy obtained by measuring humero-scapular range can only be detected with the use of x-rays (Lundberg, 1969).

Since ultrasound is used in the belief that it affects the capsule and does not directly facilitate muscle strengthening a passive range measurement will be taken. In order to simplify the measuring procedure, the 6 movements which occur at the shoulder will be represented by a single measure of forward elevation. The first Outcome measure will be the length of treatment in weeks to reach 160° of passive shoulder flexion (forward elevation).

Improving the passive range of motion is not enough however to satisfy the patient, for it is limited function which is his chief complaint. The second Outcome measure will be the length of treatment in weeks to full functional recovery as measured by the questionnaire (Appendix 1).

4.20 End-points

The true endpoint of this study will be 160° of passive forward shoulder elevation and full function as measured by the questionnaire.

4.20.1 Special Cases

In order to minimize bias when analyzing the data special end-points will be declared at this point in time.

- 1) Fifty-two weeks of treatment within the study (if the true end-points have not been met previously).
- 2) Withdrawals prior to meeting the true end-points will be charged as having 52 weeks of treatment within the study.
(Refer to End-point within the analyses section.)

4.21 Instrumentation

The instruments referred to in this section will be used to either provide the treatment (ultrasound) or measure the outcome (flexometer and indirectly the questionnaire). Faulty instrumentation in either of these two areas is liable to lead to false conclusions about the treatment groups. For this reason safeguards must be taken to ensure that the instruments operate in an accurate, precise and unbiased manner.

4.21.1 Ultrasound

Potential problems which may arise with the ultrasound equipment are an output which is not accurate. This may be as a direct result of the output itself or indirectly related due to faulty timing circuitry. For these reasons the output and timers of all ultrasonic equipment will be calibrated prior to the study and at six month intervals during the study.

4.21.2 Flexometer

Similar problems of accuracy may be common to the flexometers also. For this reason the same make of flexometer (+Leighton Flexometer) will be used at all centres. All flexometers will be checked against the gold standard electrogoniometer prior to the study and at six month intervals in order to ascertain their level of accuracy.

The electrogoniometers' accuracy will be tested against a jig.

4.21.3 Questionnaire

Prior to the final acceptance of the questionnaire, it must be pre-tested and judged acceptable. The criteria for acceptability of the questionnaire are: validity, reliability, sensitivity to change, simplicity of administration and acceptability to both the therapist and patient.

4.21.3.1 Drafting the Questionnaire

A panel of five physiotherapists and 7 patients with shoulder problems contributed to the question pool. The questions were refined and referred back to the panel for approval. Approval for each individual item required unanimous agreement from the panel of 12. This was often obtained after rephrasing several similar questions. Nine items were approved and appear in Appendix 1.

4.21.3.2 Pre-testing of the Questionnaire

The questionnaire is to be pre-tested and revised if necessary in the three month period immediately preceding admission of the first patient into the trial. It is expected that the questionnaire will be tested on 50 shoulder patients during this time by combining the four centres taking part in the trial.

+Trademark

4.21.3.3 Validity

This refers to the extent to which the response to items on the questionnaire reflect the truth.

i) Concurrent Validity is a sub-classification of criterion validity. It is studied when both the predictor and criterion rating are obtained within the same time frame. Concurrent validity will be demonstrated within the pre-test by having approximately half of the patients partaking in the pre-test to actually demonstrate their ability with respect to the items on the questionnaire.

ii) Content Validity refers to the extent to which items appearing on the questionnaire reflect the domain of activities which represent shoulder function. Content validity has in part been obtained as it has been accepted by the panel of therapists and patients. During the period of the pre-test, further therapist and patient opinions will be gathered and modifications made if required.

4.21.3.4 Reliability

This refers to the stability of patient responses on each item. The extent to which each item is reliable will be obtained by using a test-retest approach. The retest will be performed within 3-5 days of the original test when the therapist has indicated that no significant change has occurred. Twenty-five patients partaking in the pre-test will be retested. A Kappa value of 0.6 will be required for each item in order for it to be accepted for the final questionnaire.

4.21.3.5 Sensitivity to Change

This refers to the extent to which the questionnaire will be able to detect important changes in shoulder function. Approximately

twenty-five patients partaking in the pre-test will be re-administered the questionnaire when the therapist feels a significant change in shoulder function has occurred.

4.21.3.6 Scoring of the Questionnaire

For the purpose of the pre-test each item will have four potential responses; Yes, Yes with difficulty, No, No--but not due to the shoulder. These divisions have been chosen to provide the investigator with more information compared to the conventional Yes - No responses.

At this point in time (prior to the results of the pre-test) each item will be considered to have the same weight. Tentatively this would seem to be a responsible course to take since a complete absence of 'No' responses is required for full function as measured by the questionnaire.

4.22 Co-intervention

This is the performance of additional screening, diagnostic and therapeutic procedures upon the experimental group. These procedures must be avoided unless the same procedures are performed with equal vigour upon members of the comparison group. Patients will be asked to avoid additional exercise (both type and duration). Should they find themselves performing additional exercise they will be asked to record the type, frequency and duration in their log book.

4.23 Contamination

This is the administration of the same or related therapeutic manoeuvre to the comparison group. This would occur if the comparison

group received ultrasonic therapy. Since the therapists are blinded as to treatment this will be difficult to follow. However, the therapists will be asked to record the position the switch was actually in when the ultrasonic treatment was performed.


CHAPTER 5

STATISTICAL ANALYSES

This chapter provides the reader with the hypotheses to be tested as well as the statistical analyses to be performed on the data. The analyses described include a Student's 't' test to be used when the sample variances are equal and unequal. Also included are adjustment and analyses of covariance techniques which will be used post hoc in order to control for potential confounding variables. Separate analyses will be performed for both Outcome measures specified. Due to sample size considerations, it will be necessary to combine strata within each treatment group when performing the analyses.

5.1 The Hypotheses

A) The Null Hypotheses

- 
- i) The ultrasound and exercise group will not be better than the exercise group as measured by Outcome measure 1.
 - ii) The ultrasound and exercise group will not be better than the exercise group as measured by Outcome measure 2.

B) One-Sided Alternate Hypotheses

- i) The treatment effect will be significantly greater as measured by Outcome measure 1, in the ultrasound and exercise group compared to the exercise group.

- ii) The treatment effect will be significantly greater as measured by Outcome measure 2, in the ultrasound and exercise group compared to the exercise group.

The null hypotheses will be rejected at an alpha level of 0.05. A one-sided test will be used since we are specifically interested in determining whether the combined treatment is superior to the exercise treatment.

5.2 Primary Analyses

The primary statistical test to be applied to the results will be a 't' test for independent samples. An 'F' test will be performed to test the assumption of equal variances (Equation 5.1).

Equation 5.1

$$F = \frac{S_{us}^2}{S_{ex}^2}$$

If the variances are determined to be equal, the formula presented in Equation 5.2 will be applied. The p value is determined by referring to the t distribution with $n_{us} + n_{ex} - 2$ degrees of freedom (sample Table and Calculations appear in Appendix 7).

Equation 5.2

$$t = \frac{\bar{X}_{us} - \bar{X}_{ex}}{\sqrt{S^2 \left(\frac{1}{n_{us}} + \frac{1}{n_{ex}} \right)}}$$

Should the F statistic yield a value indicating a difference in variances between groups, the formula in Equation 5.3a will be used in the analysis. The significance test of the null hypothesis will be based on the t'' statistic which approximates the standardized normal deviate when n_{us} and n_{ex} are reasonably large.

Equation 5.3a

$$t'' = \frac{\bar{x}_{us} - \bar{x}_{ex}}{\sqrt{\frac{s^2_{us}}{n_{us}} + \frac{s^2_{ex}}{n_{ex}}}}$$

The degrees of freedom associated with t'' is approximated by employing the formula in Equation 5.3b.

Equation 5.3b

$$d.f = \frac{(n_{us}-1) \frac{s^2_{us}}{n_{us}} + (n_{ex}-1) \frac{s^2_{ex}}{n_{ex}}}{\frac{s^2_{us}}{n_{us}} + \frac{s^2_{ex}}{n_{ex}}}$$

5.3 Secondary Analyses

Secondary analyses of the data will be performed to adjust or control for imbalances between treatment groups. The primary adjustment technique to be used is an Analysis of Covariance. The actual analysis of covariance regression model takes the form of that presented in Equation 5.4 excluding the term in parentheses. Here, age, starting angle, duration of symptoms, sex and etiology are referred to as the

Equation 5.4

$$y = \beta_0 + \beta_1 \text{ age} + \beta_2 \text{ starting angle} + \beta_3 \text{ duration of symptoms} + \beta_4 \text{ sex} + \beta_5 \text{ etiology} + \beta_6 \text{ group} \left[+ \beta_7 \text{ age} \times \text{group} + \beta_8 \text{ starting angle} \times \text{group} + \beta_9 \text{ duration of symptoms} \times \text{group} + \beta_{10} \text{ sex} \times \text{group} + \beta_{11} \text{ etiology} \times \text{group} \right]$$

covariates and group is represented by a dummy variable indicating the two treatment groups. While the term presented in parenthesis, referred to as the interaction term, is not formally included in the analysis of covariance, it must be tested to determine whether it contributes significantly to the model. If it does contribute to the model an interaction is said to occur and the analysis of covariance technique cannot be used to adjust the data. If such is the case, the following adjustment technique will be used.

Kleinbaum and Kupper (1978) offer an alternate adjustment technique referred to as the Z-Score method of adjustment. Here the adjustment procedure takes into account differences in the variability of the dependent variable in the various covariate categories. The text will outline an adjustment for starting angle of shoulder elevation

Equation 5.5.

$$Z = \frac{y_i - \bar{y}_i}{S_i}$$

followed by a test of significance between treatment groups having adjusted for starting angle of shoulder elevation. By referring to

Equation 5.5 \bar{y} would represent the mean starting angle of shoulder elevation for a given starting angle of shoulder elevation range, y is the observed value of starting angle of shoulder elevation and S indicates the standard deviation of the given starting angle of shoulder elevation range. "i" indexes the starting angle of shoulder elevation range. The entire data (both groups) would be divided into starting angle of shoulder elevation ranges and standardized deviations (Z) would be calculated for each observed values using the formula presented in Equation 5.5.

To determine whether the treatment groups differ significantly in adjusted scores the formula presented in Equation 5.6 would be used.

Equation 5.6

$$Z = \frac{(\bar{z}_{us} - \bar{z}_{ex})}{\sqrt{\frac{s^2_{z_{us}}}{n_{us}} + \frac{s^2_{z_{ex}}}{n_{ex}}}}$$

Where \bar{z}_{us} and \bar{z}_{ex} are the mean two scores for ultrasound-ex. and exercise groups respectively, $s^2_{z_{us}}$ and $s^2_{z_{ex}}$ are the sample variances for the ultrasound-ex. and exercise groups respectively and n_{us} and n_{ex} are the number of observations in the ultrasound-ex. and exercise groups respectively.

5.4 Analyses and End-points

The end-points have been previously defined in Section 4.20.

An analysis will be carried out on all potentially confounding variables to determine if the withdrawals and those who fail to meet the true end-point differ from those who do meet the end-point.

Two analyses will be performed and reported on. The first analysis will include all withdrawals as being treated for 52 weeks and they will be analysed and charged against their respective treatment group. The second analysis will be performed with all withdrawals removed from the data.

Table 5.1
DUMMY TABLE ILLUSTRATING DATA PRESENTATION

Subject #	Age	Sex	Shoulder Flexion Starting Angle	Limb Involved R - L	Limb Involved Dominant Yes - No	Duration of Symptoms in weeks	Previous Episodes Yes - No	History of Trauma	Injection (cortisone) Yes - No	Co-existing Medical Problem	Duration to Functional Recovery in weeks	Duration to 160° of Shoulder Elevation in weeks
1	56	M	84°	R	Yes	8	No	Yes	Yes	No	9	8
14	47	F	112°	L	Yes	6	No	No	No	Diabetes	8	11
27	63	F	77°	R	No	12	Yes	No	No	No	13	6

CHAPTER 6

ETHICAL CONSIDERATIONS

Patients participating in this study will do so only after informed consent is obtained. The patients will be free from assault and any risk which may be present will be no greater than that incurred attending physiotherapy outside this study. The patient's privacy and confidentiality will be ensured. The patients have the right to refuse to be part of the study and to withdraw at any time without affecting their physiotherapy treatment or the attitude towards them by the therapist. (Consent form is presented in Appendix 6).

CHAPTER 7

SUMMARY--INTERPRETATION OF OUTCOMES

Should the results of this clinical trial demonstrate a clinically and statistically significant difference in favour of the combined treatment group, the results would support the use of ultrasound as an adjunct to exercise for patients fulfilling the admission criteria for this study. An alternative explanation for this finding may be a Type I error which is likely to be committed one in 20 times. A statistically significant difference may occur which is not clinically significant if the actual standard deviation and delta values are proportionally smaller than those estimated.

An alternative situation may be a clinically and statistically significant result favouring the ultrasound-exercise group for Outcome measure 1 and a non-statistically significant results for Outcome measure 2. An explanation for this finding may consider that while ultrasound-exercise showed a better ability to decrease the duration of treatment in weeks to reach 160° of passive shoulder elevation (forward flexion) the exercise portion of the regime was inadequate to provide the patient with the muscle strength to utilize the obtained passive range. This may reflect on the strengthening regime itself or the patients' compliance with the regime.

If the results were to demonstrate a clinically and statistically significant difference in favour of the combined treatment group for Outcome measure 2 and not for Outcome measure 1 one might consider whether those patients in the combined treatment group were more adept

at incorporating "trick" movements into their activities of daily living.

Finally, should no difference be evident between treatment groups for both Outcome measures, one might argue that no strong evidence exists to suggest the combined treatment group to be superior to the exercise group. Clinically this may reduce physiotherapy departments operating costs as perhaps the quantity of ultrasound machines may be reduced. Also, this may provide for increased efficiency of the departments as the length of direct therapist-patient contact time would be reduced by 15 minutes per patient. Alternatively, a finding of no significant difference between treatment groups may result due to a Type II error (like the Type I error this is likely to occur one in 20 times). If this were the case, repeated trials using a similar design would be the tool to pick this up.

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APPENDICES

PART 1

This sheet will be filled out by the admissions officer on the patient's initial visit.

PATIENT'S NAME TODAY'S DATE

AGE SEX OCCUPATION

INSTITUTE

STRATA >90° <90°

ANGLE OF FLEXION ON INITIAL VISIT

LIMB INVOLVED right () left ()

DOMINANT LIMB right () left ()

DURATION OF SYMPTOMS IN WEEKS

Was this episode preceded by trauma or excessive use? No ()

Yes ()

→ If Yes, how?

.....

Has this shoulder ever been injured before? No ()

Yes ()

Has the opposite shoulder ever experienced similar stiffness?

No ()

Yes ()

PREVIOUS TREATMENT: Manipulation with G.A. Yes () No ()

Injection to shoulder Yes () No ()

→ If Yes, when?

.....

PART 1 (continued)

Does the patient have any co-existing medical problems? No () Yes () ☒

→ If Yes, identify them

.....

.....

PART 2

The following self-administered questionnaire will be completed by the patient on the initial visit and at weekly intervals thereafter until all questions in PART 2 are answered negatively or until 52 weeks of treatment are completed. Questions are adapted from the McMaster Health Index (Chambers, 1976) and patient-therapist question pool referred to in the text.

DIRECTIONS: Please answer each question by putting a check (✓) in the proper box. We are interested in knowing about several activities involving your shoulder. We would be interested in knowing if you are able to do the following activities and if so whether you have difficulty in doing them due to your shoulder problem.

	YES	YES WITH DIFFICULTY	NO	NO--BUT NOT DUE TO THE SHOULDER
<u>Today are you able to:</u>				
Reach above shoulder level	()	()	()	()
Reach behind your back	()	()	()	()
Cook, dust or do light housework	()	()	()	()
Shave or put on your make-up	()	()	()	()
Dress or undress yourself	()	()	()	()
Clean the floor, garden or shovel snow	()	()	()	()
Put your hand in your back pocket or reach behind your seat	()	()	()	()
Put on a pullover sweater by yourself	()	()	()	()
Comb your hair or scratch the back of your head	()	()	()	()

APPENDIX 2

The following data were extracted retrospectively from the medical records of 23 patients with frozen shoulder (Stratford, 1980).

Subject	Total Duration Onset of Symptoms to 160° (in weeks)	Total Duration of treatment (in weeks)	Pt's Age	Pt's Sex	Total Duration of Symptoms prior to treat- ment (in weeks)	Etiology	Flexion Starting Angle
1	63	60	75	0	3	0	15
2	88	36	63	1	52	0	95
3	40	12	62	0	28	0	110
4	12	6	61	1	6	1	110
5	55	17	58	0	38	1	100
6	38	18	55	1	20	1	120
7	54	34	56	1	20	0	75
8	39	17	54	0	22	0	95
9	46	23	53	0	23	1	110
10	49	15	54	0	34	1	85
11	21	15	51	1	6	1	110
12	30	10	47	1	20	1	105
13	29	11	66	1	18	1	115
14	33	7	60	1	26	1	110
15	28	15	56	1	13	0	80
16	36	11	65	0	25	1	70
17	44	4	58	1	40	0	90
18	34	31	55	0	3	0	30
19	18	12	72	1	6	0	55
20	8	6	54	0	2	1	95
21	9	4	65	0	5	0	115
22	44	4	59	0	40	1	90
23	45	5	68	0	40	0	95

Sex = 1 if male; 0 if female

Etiology = 1 if Primary (Idiopathic)

0 if Secondary (Secondary to trauma or immobilization)

APPENDIX 3

MULTIPLE REGRESSION PROCEDURE

In order to identify potential variables that are associated with outcome, the following multiple regression procedure was adopted. The decision rule is to consider a variable for stratification if the step-wise F to enter value has a corresponding p value $\leq .05$.

Regression Statement 1. The Outcome measure, duration of treatment was regressed with sex, age, etiology, starting angle in degrees of flexion and duration of symptoms.

Table A3.1

OUTPUT AFTER STEP 1 OF REGRESSION PROCEDURE

Source	D.F.	SS	M.S.	F.	p
Shoulder flexion starting angle	1	1585.58	1585.58	14.42	$p < .005$
$R^2 = .4072$					
Residual	21	2308.33	109.92		

F to enter on next step

	F	p
Duration of Symptoms	.076	$p > .05$
Age	.041	$p > .05$
Sex	.259	$p > .05$
Etiology	1.467	$p > .05$

APPENDIX 4

Since the questionnaire was not available for the patients on whom the retrospective chart review was performed no direct measure of consistent physical function can be obtained. Therefore, one cannot estimate the sample size required for Outcome measure 2 (duration to full function as measured by the questionnaire) based on the chart review. A substitute measure has therefore been used to approximate the estimate of the parameters required for a sample size calculation for Outcome measure 2.

The steps taken to obtain the substitute measures will now be outlined. First of all a convenience sample of 12 patients with limited shoulder mobility were asked to complete the questionnaire. At the same time their passive shoulder flexion was measured by a therapist (the same therapist in each case) who had no knowledge of the questionnaire response. To determine whether there was a correlation between the two measures the data were subjected to Spearman's Rank Difference Correlation (Table A4.1).

Table A4.1

RAW AND RANKED DATA FOR CORRELATION

Subject	Passive Flexion Angle	Questionnaire # of No Responses	Ranks		Rank Difference (D)	D ²
			Angle	Responses		
1	30°	8	1	1	0	0
2	85°	6	2.5	3	.5	.25
3	85°	5	2.5	5.5	2.5	6.25
4	92°	6	4	3	1.0	1.0
5	95°	6	5.5	3	2.5	6.25
6	95°	5	5.5	5.5	0	0
7	102°	4	7	7	0	0
8	136°	3	8	8	0	0
9	146°	1	9	10	1	1.0
10	157°	1	10	10	0	0
11	160°	0	11.5	12	.5	.25
12	160°	1	11.5	10	1.5	2.25
						$\Sigma D^2 = 17.25$

Rank Difference Correlation (Issac, 1978)

$$= 1 - \frac{6 (\Sigma D^2)}{N (N^2 - 1)}$$

$$= 1 - \frac{6 (17.25)}{12 (144 - 1)}$$

$$= .939$$

$$p < .01$$

The 'p' value would suggest that there is a strong correlation between passive shoulder flexion and function as measured by the

questionnaire. Based on this correlation, the delta and standard deviation estimates used in the sample size calculation for Outcome measure 2 (Appendix 5.B) were obtained by using the time in weeks from the initial physiotherapy encounter to 160° of shoulder flexion.

APPENDIX 5.A

This appendix develops the calculation of the delta and sample standard deviation values for Outcome measure 1 (directly) and Outcome measure 2 (inferred). Table A5.1 presents the duration of treatment in weeks to obtain 160° of passive shoulder elevation (forward flexion) for five patients treated with ultrasound and exercise and 6 patients treated with exercise alone. These subjects were matched for age (within 10 years) and starting angle (greater than or equal to 80° and less than 80° of shoulder flexion). The data were gathered based on a retrospective chart review.

Table A5.1
DURATION OF RECOVERY IN WEEKS AS MEASURED
BY PASSIVE SHOULDER FLEXION

Subject Number	Ultrasound & Exercise Group	Subject Number	Exercise Group
1	10	6	11
2	11	7	17
3	6	8	15
4	4	9	12
5	4	10	11
		11	7

The mean value for the ultrasound and exercise group is 7 weeks and the mean treatment for the exercise group is 12.16 weeks. By referring to the text it was decided that a delta value equivalent to a 30% improvement over the exercise group would be considered clinically

significant. This results in an improvement of 3.65 weeks. The pooled standard deviation is equal to 3.41 weeks.

APPENDIX 5.B

This appendix develops the calculation of the delta and sample standard deviation values for Outcome measure 2. It should be remembered that these calculations are based on the duration of physiotherapy treatment from the initial visit to 160° of shoulder flexion. The rationale for this substitution is covered in Appendix 4. Table A5.2 presents the duration of recovery in weeks from the initial physiotherapy visit to 160° of shoulder flexion. These results were taken from the same subjects presented in Table A5.1.

Table A5.2

DURATION OF RECOVERY OF PASSIVE SHOULDER FLEXION IN THE
ULTRASOUND-EXERCISE GROUP AND EXERCISE GROUP

Subject Number	Ultrasound & Exercise Group (weeks)	Subject Number	Exercise Group (weeks)
1	10	6	17
2	11	7	11
3	6	8	7
4	4	9	15
5	4	10	12
		11	11

The mean value for the ultrasound and exercise group is 7 weeks with a standard deviation of 3.32 weeks. The mean value for the exercise group is 12.16 weeks with a standard deviation of 3.48 weeks. Using a delta value equivalent to a 30% improvement over the exercise group, a value of 3.65 weeks (30% of 12.16) is obtained. The pooled variance is equal to 11.66 or a pooled standard deviation of 3.41 weeks.

APPENDIX 6

CONSENT FORM FOR THE STIFF SHOULDER STUDY GROUP

The purpose of this study is to compare the effectiveness of two treatment techniques which are commonly used in physiotherapy. The present consent is given with the understanding that I may withdraw from the study at any time. I understand that I will be asked to participate in either the exercise group or the ultrasound and exercise group without my knowing which group I'm in. I also understand that the following procedures may be carried out:

1. I will be asked to participate in an exercise programme both at therapy and at home.
2. My progress will be monitored by means of a questionnaire and shoulder range measurement on a weekly basis.
3. I may receive ultrasonic treatment which is comfortably warm.
(NOTE: ultrasonic therapy has been used for the past 25 years and no adverse effects are known to occur when used within the precautions designated within this study.)

At present neither of these two forms of treatment have been shown to be superior to the other. Should this study demonstrate one form of treatment to be superior, this knowledge will be used to benefit others in the future. All data collected in this study will be handled in a confidential manner and patients will not be identified in any publications.

I understand that I may withdraw from this study at any time after having signed this consent. Refusal to sign the consent form will in no way affect the treatment I receive in physiotherapy services, nor will withdrawal from the study compromise my case.

DATED

Patient signature

Witness signature

I have explained the nature of the project to the patient.

Signature _____

APPENDIX 7

Sample calculation based on Outcome measure 1

Table A7

SAMPLE VALUES FOR DURATION OF TREATMENT IN WEEKS
TO 160° OF PASSIVE SHOULDER FLEXION

Ultrasound & Exercise	Exercise
10	17
11	11
6	7
4	15
4	12
	11

$$\bar{X}_{us} = 7 \text{ weeks}$$

$$\bar{X}_{ex} = 12.16 \text{ weeks}$$

$$S_{us} = 3.32 \text{ weeks}$$

$$S_{ex} = 3.48 \text{ weeks}$$

pooled variance = 11.66

Test for variance equality:

$$F = \frac{S_{ex}^2}{S_{us}^2}$$

$$= \frac{3.48^2}{3.32^2}$$

$$F = 1.098$$

With $\alpha = .05$; $F_{.95,5,4} = .135$; $F_{.025,5,4} = 9.36$

Since 1.098 is between .135 and 9.36 we accept the null hypothesis of equality of variances and proceed with the "t" test using a pooled variance.

$$t_{n_{us} + n_{ex} - 2} = \frac{\bar{X}_{us} - X_{ex}}{\sqrt{S^2 \left(\frac{1}{n_{ex}} + \frac{1}{n_{us}} \right)}}$$

$$t_9 = \frac{7 - 12.16}{\sqrt{11.66 \left(\frac{1}{6} + \frac{1}{5} \right)}}$$

$$t_9 = -2.49$$

$p < .05$ one sided at 9 degrees of freedoms.

APPENDIX 8

A pre-study training session will be held for all admissions officers involved in the study. The goal of this training session is to reduce the inter-therapist flexion measurement variation.

In order to minimize the variation in the passive shoulder flexion measurement the following standardization procedures will be adopted:

1. The patient will be positioned with his/her back, shoulders and seat square to the wall.
2. The flexometer will be strapped to the arm.
3. The arm will be passively elevated into flexion until a firm resistance is present.
4. The weighted arm on the flexometer will be locked and the device read.
5. The reading will be immediately recorded on the data form.

The testing procedure will be carried out on a simulated patient with an electrogoniometer strapped to the arm as a goal reference. Each therapist will perform 3 sets of five measures (Set 1: 18°, 84°, 107°, 135°, 158°; Set 2: 27°, 59°, 90°, 124°, 148°; Set 3: 16°, 71°, 88°, 127°, 164°) corresponding to various positions in the range of shoulder flexion. Each therapist (admissions officer) must be within 3° of the reference standard on each measurement of all three sets before being cleared to participate in the study. This would result in a maximum inter-observer variation of 6°.

Similar training sessions will be held at six month intervals for the duration of the study.

SIMULATED PATIENT--EVALUATION FORM OF THERAPIST

Area	Satisfactory	Unsatisfactory	Comments
Order of Instruction.	()	()	
<u>ULTRA SOUND</u>			
Preheat	()	()	
Dosage	()	()	
Timer setting	()	()	
Conduction medium	()	()	
<u>CLINIC EXERCISE</u>			
Warm up	()	()	
Pulley	()	()	
Passive stretch	()	()	
Active resisted	()	()	
<u>HOME EXERCISE</u>			
Warm up	()	()	
Pulley	()	()	
Passive stretch	()	()	
Active resisted	()	()	
Frequency of home programme	()	()	