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ETIOLOGY AND PROGRESSION OF ACUTE MUSCLE TENSION RELATED
LOW BACK PAIN OCCURRING DURING SUSTAINED ACTIVITY
INCLUDING COMBAT TRAINING EXERCISES

ANNUAL REPORT

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13. ABSTRACT (Maximum 200 words) The project is determining relationships between low back muscle tension, amount and type of activity, and onset and intensity of low back pain among people in their normal environments in order to develop preventive and ameliorative measures. The program emphasizes soldiers who are usually pain free in their normal work environments but who experience debilitating low back pain during combat training exercises. Ambulatory recorders are used to record muscle tension, amount of activity, and back pain for 20 hours at a time among civilians in their normal work environments and among soldiers either in garrison or participating in combat training exercises. The test-retest reliability and confidence limits of the system have been established. Relationships between the output of the ambulatory recorder and (a) output of standard instruments and (b) pulling against a standard weight have also been established. Initial evaluation of the results demonstrates that, for people with muscle tension related low back pain, low back muscle tension changes at least a few minutes prior to changes in pain intensity. There is also a definite relationship between participation in field exercises and onset of low back pain among both soldiers who normally do and do not experience back pain.				
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FOREWORD

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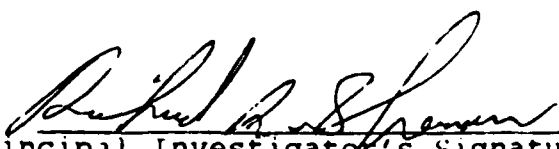

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1. INTRODUCTION:

a. Aim for entire project: Determine relationships between muscle tension, amount and type of activity, and onset and intensity of low back pain among people in their normal environments in order to develop preventive and ameliorative measures. The program emphasizes soldiers who are usually pain free in their normal work environments but who experience debilitating low back pain during combat training exercises. The goals for this year are listed in item "1 d" below.

b. Hypotheses:

(1) Phase One:

(a) That for people with no history of chronic back pain, there are consistent relationships between (1) the intensity and duration of activity being performed, (2) the pattern of paraspinal muscle contraction, and (3) onset of low back pain.

(b) That patterns of muscle tension recorded throughout the normal day in the normal environment will be different for people with (a) low back pain only after physical effort and (b) no recent or significant history of back pain after similar physical effort.

(c) That paraspinal muscle tension becomes elevated prior to the onset of pain

(d) That resolution of back problems related to muscle tension can be predicted by return of muscle tension patterns to normal.

(e) That the information about patterns can be used to predict which soldiers are most likely to be debilitated during combat exercises and that the value of both preventive and post-debilitative treatments can be determined by using the recommended recording techniques.

(2) Phase Two:

(a) That, for soldiers with no histories of back problems, keeping the paraspinal muscles too tense for too long results in low back pain and excess fatigue.

(b) That soldiers with no back problems keep their low back muscles tenser than necessary for longer than necessary during portions of combat training exercises, and, thus, develop more back pain and fatigue than they would if muscles were tensed appropriately.

(c) That teaching groups of soldiers to habitually (rather than consciously) (1) recognize when their low back muscles are tenser than necessary at any given time and (2) to relax them to levels appropriate to the activity being engaged in will result in reduced occurrence of back pain and fatigue along with increased efficiency during combat training exercises.

(d) That the ability to make ambulatory recordings of low back muscle tension which correlate highly with low back pain among people whose pain is related to muscle tension can be utilized to determine how well

treatments for these people are working and whether or not they are working by altering muscle tension patterns.

(e) That cyclobenzaprine HCL (Flexeril) and muscle tension awareness and control exercises can be used to alter muscle tension patterns sufficiently to test the above hypothesis in the above population.

(f) That resolution of back problems related to muscle tension can be predicted by return of muscle tension patterns to normal.

(g) That the information about patterns can be used to predict which soldiers are most likely to be debilitated during combat exercises and that the value of both preventive and post-debilitative treatments can be determined by using the recommended recording techniques.

c. Objectives for Phase One:

(1) To determine whether among people with no history of chronic back pain, there are consistent relationships between (a) the intensity and duration of activity being performed, (b) the pattern of paraspinal muscle contraction, and (c) onset of low back pain.

(2) To determine whether patterns of muscle tension recorded throughout the normal day in the normal environment will be different for people with (a) low back pain only after physical effort and (b) no recent or significant history of back pain after similar physical effort.

(3) To determine whether paraspinal muscle tension becomes elevated prior to the onset of pain for the above types of people.

(4) To determine whether resolution of back problems related to muscle tension can be predicted by return of muscle tension patterns to normal.

(5) To determine whether information about patterns can be used to predict which soldiers are most likely to be debilitated during combat exercises and whether the value of both preventive and post-debilitative treatments can be determined by using the recommended recording techniques.

d. Goals for Phase One:

(1) Establish the test-retest reliability and confidence limits of typical recordings so we can determine how much change there has to be in a signal for it to be considered a real, non-random fluctuation, event.

(2) Establish relationships between standard clinical and laboratory evaluations and field recordings performed in subjects normal work and home environments.

(3) Establish normal and abnormal temporal relationships between movement, type of activity, diagnosis, fatigue, and pain in subjects' normal environments.

(4) Conduct sufficient trials to determine whether the ambulatory recorders have to be modified for use with soldiers operating in the field environment.

e. Status: For the past seven years we have been working with soldiers who experience debilitating pain during combat training exercises which they do not experience while in garrison. Their orthopedic diagnoses

indicate that the pain is probably of muscle tension origin. There is a paucity of objective data available about the relationship between low back pain and low back muscle tension. The literature is contradictory and prolonged treatment success frequently appears to be minimal and random. We performed the first large scale study which demonstrated consistent relationships between paraspinal muscle tension (as reflected by amplitude of bilateral surface EMG) and intensity of low back pain. We are in the process of performing a VA and Army funded study relating patterns of muscle tension to the results of standard diagnostic tests including X-Rays, orthopedic and neurological examinations, surface paraspinal EMGs and the Minnesota Multiphasic Personality Inventory (MMPI). Neither of these studies, nor any data from the literature, can provide information about the etiology of muscle tension problems in the low back which are related to low back pain. Other than the trial data presented below, no one knows what normal and abnormal patterns of muscle tension relative to activity look like in the normal environment. We propose to determine the temporal and intensity relationships between low back pain of muscle tension origin, patterns of paraspinal muscle contraction, and activity by performing continuous recordings of these factors among groups of low back pain subjects in their normal environments. Figure One illustrates the concept of the wearable recorder and Figure Two illustrates the predicted pain - muscle contraction - activity relationships derived from our trial data.

(1) Relationships between pain and muscle tension as recorded using surface electromyography (EMG): Sustained muscle contraction has been shown to produce pain whereas relaxation of the muscles reduces the intensity of the pain (e.g. review by Dorpat and Holmes 1952). Relationships between sustained level of muscle contraction and occurrence of pain in the back are not well understood and the literature is confusing. For example, Basmajian (1981), Wolf and Basmajian (1979), and Kravitz et al. (1981) found that the paraspinal muscles of relaxed low back pain patients were less contracted than those of "normal" controls. Collins et al. (1982) found that in the standing position, the tension in the paraspinal muscles of low back pain subjects were similar to controls. Many other groups have reported similar findings while at least as many have reported just the opposite under apparently similar recording conditions. Hoyt et al. (1981) showed that surface EMGs of low back pain patients differ most from those of normals for the standing positions with low back pain patients being tenser by one third to one half. These types of results have been reported by many others including Grabel (1974) who also found that there were no differences in tension in response to simulated psychological stresses between groups with and without low back pain. Dorpat and Holmes (1952) did find such a relationship among several patients identified as having both high levels of anxiety and back pain. With the important exception of Dorpat and Holmes' few subjects, none of the research groups divided their subjects by diagnosed etiology of their subjects' pain. Many groups (e.g. Cram and Steger, 1983) have found trends toward asymmetry in left vs. right sides of the low back among subjects with low back pain.

Many psychological factors complicate the relationship between reported intensity of low back pain and paraspinal EMG. Psychological influences on perception of pain intensity are especially difficult to evaluate. For this reason, we eliminate all subjects with significantly abnormal psychological patterns from our studies and have all subjects keep logs of their perceived stress intensities. For example, Ahles (personal communication, 1989) reviewed findings from such workers as Flor et al 1985 and Dickson-Parnell and Zeichner 1988 and concluded that personally relevant stressors produce elevations in paraspinal EMG levels which

distinguish low back pain patients from non-pain controls.

We have shown that much of the confusion and high variability in results is caused by (1) recording all of the subjects in only one or two positions regardless of the most painful position and (2) recording the subjects only once without regard to current level of pain. Our laboratory published the first evidence that there is an actual relationship between low back pain intensity and muscle contraction levels (Sherman 1985). We were able to show that a consistent relationship exists because we recorded each subject in many different positions and at many different pain intensities. One hundred and twenty-six subjects participated in the study. Each was recorded while standing, sitting supported and unsupported, prone, bending, and rising. Recordings were performed on days when subjects were at various pain intensities. Each subject reporting pain at the time of recording showed one or more position in which their muscle tension was different from the controls'. When the "low back pain" subjects were recorded without pain, their recordings were similar to those of the controls. For those positions where a subject showed abnormal muscle tension, there was a high correlation between reported pain intensity and number of microvolts showing in the recording over the series of recordings (Spearman's $Rho = 0.92$). Since that time, we have run an additional 256 subjects. Each subject had diagnoses based on thorough orthopedic tests. Our original findings have been confirmed and we have determined that there is a difference in muscle tension between pain free controls, subjects with muscle related back pain, and subjects with diagnoses not related to muscle tension (Arena, et al., 1989). We were also able to show that our electromyographic recording techniques are consistent between recordings so our results are not significantly confused by unrecognized factors (Arena, et al, 1988). Normative data for muscle tension have been developed and reviewed by Wolf et al (1979). However, at this time, the only evidence that muscles' tensing during normal work as related to diagnosed muscle tension pain is from our small trial. No studies other than our trial have been done to determine the duration, pattern, or intensity of muscle tension during normal activities in relation to subsequent onset of pain symptoms.

The critical point here is that we have demonstrated that the level of low back paraspinal muscle contraction increases as low back pain increases not just for people with back pain apparently due only to muscle related problems but for those with very clearly delineated diagnoses not associated with muscle contraction.

(2) Ambulatory monitoring of muscle tension and activity: Studies in which a physiological parameter is continuously recorded among freely moving people away from a laboratory have been done for many years. The simplest systems and those in most common use are the ones for recording blood pressure and electrocardiograms (e.g. Littler et al 1972). Equipment capable of accurately recording muscle tension among freely moving subjects has also been available for many years and is frequently used as part of a biofeedback system to alert people who tense their jaws when they come under stress or who neglect to raise the toe end of the foot sufficiently while walking due to a stroke (e.g. Rugh and Solberg 1974). Monitoring muscle tension among free moving subjects has a variety of problems. The most important one is that background levels of tension can not readily be differentiated from changes in tension due to movement. This becomes especially critical when muscles such as the paraspinals of the low back are being recorded. We avoid this problem by recording both gross - large body movements and acceleration types of movement measures. These measures are then related to the muscle tension signal. The other major problem is how to make a reliable record of muscle tension over a period of several days while the subject is away from a major recording facility. The

commercially available physiological tape recorders which are genuinely wearable in a field environment are good for only 24 hours of continuous recording due to both battery life and tape length problems. They were designed for blood pressure, cardiac or brain wave monitoring and are not able to record an adequate bandwidth for large muscle EMG. The alternative solution is to sum the muscle tension activity level over a set period and have a device such as a printing counter record the amount of activity at the end of each period. This alternative was used in our initial trials and was able to produce the general outlines of the relationship between movement, pain, and muscle tension. However, it was not able to provide sufficiently detailed data on relationships between movement and changes in muscle tension on a movement by movement basis to permit elimination of many artefacts. It was also not possible to determine sufficient detail about changes in activities related to changes in tension patterns because of the difficulty in making frequent notations in a written log necessitated by the lack of moment by moment recordings. Objective recording of intensity, duration, and amount of activity is very important because subjects have been shown to be very inaccurate about how much activity they have engaged in over various periods of time such as would be recorded in hourly logs of activity (e.g. Sanders 1983). When activity is recorded, information such as distance walked is not more important than the size and frequency of movements affecting the muscles being recorded. These types of measures can not be accurately recorded by estimate so we use a mercury cell based movement sensor which records amount as well as frequency of movement. The output goes to the same counter which records muscle tension.

Our own results from using an ambulatory surface muscle tension and movement recorder are detailed in the "work accomplished" section below. We were able to show reliable differences between paraspinal patterns produced while subjects experienced pain and while they were pain free. Patterns produced while subjects were pain free were very similar to those produced by subjects with no current or recent history of low back pain. Feuerstein has gathered some preliminary, unpublished data from brief ambulatory recordings of 16 subjects with mechanical low back pain (Paper presentations: Feuerstein 1986, Feuerstein and Cook 1987). He used equipment which worked similarly to ours but without the capability to accept constant input of log data. Feuerstein's data did not show significant differences in paraspinal activity patterns between control and low back pain subjects. Unfortunately, time commitments prevent him from being active in the field at this time. However, we are in close contact with him and he has read and commented on an earlier draft of this proposal. Thus, we can benefit from his experience and physiological expertise in the area even though he can not be a Co-Investigator.

(b) Supporting evidence that the recording methodology is correct and will provide accurate, useful information: A considerable amount of data has been gathered to show that the readings will (1) be reliable and replicatable, (2) be largely unaffected by normal changes in impedance occurring through the day, (3) not be significantly altered by slight changes in position of sensors required to avoid irritation during week long recordings, and (4) remain proportionate to the amount of exertion done by the back muscles across hours of recordings. Evidence has also been gathered to confirm the choice of bandwidth as being the best possible given the limitations of recording technology.

Our trial results indicate that (a) there are reactive relationships between muscle tension, movement, activity, stress, fatigue, and pain; (b) changes in muscle tension precede changes in pain and fatigue so are causative rather than reactive; and (c) the device is capable of performing the required recording without causing medical problems for the subject or

interfering significantly with performance of normal duties.

BODY:

a. Methods of procedure:

(1) Overview: The study consists of two phases each of which contain two projects. The first phase is still in progress. The first project of the first phase is taking place at Fitzsimons AMC and subjects' normal environments in the Denver area. It (a) is establishing relationships between standard clinical and laboratory evaluations and field recordings performed in subjects normal work and home environments and (b) establishing normal and abnormal temporal relationships between movement, work, fatigue, stress, and pain. The phase began with an extensive in-laboratory evaluation followed by a four day recording period during which the subjects wore the ambulatory recorder during all waking hours. Before participating in the ambulatory recording portion of the study, orthopedic low back evaluations are being performed. After evaluation, each subject wears the muscle tension/motion recording device and logs their pain, fatigue, and stress levels as well as type of activity during all waking hours for four days.

The second project consists of using the recorders with troops who regularly participate in field combat exercises. Groups of ten soldiers at a time will be recorded for two weeks (separated by six weeks as above) while in garrison, throughout their exercise, and for an additional two weeks after they return from the field. Half of the soldiers will be selected from among those with a history of experiencing back pain during field exercises but not in garrison while the other half will be from the same units matched as closely as practical for actual job performed during the exercise, sex, age, and medical background.

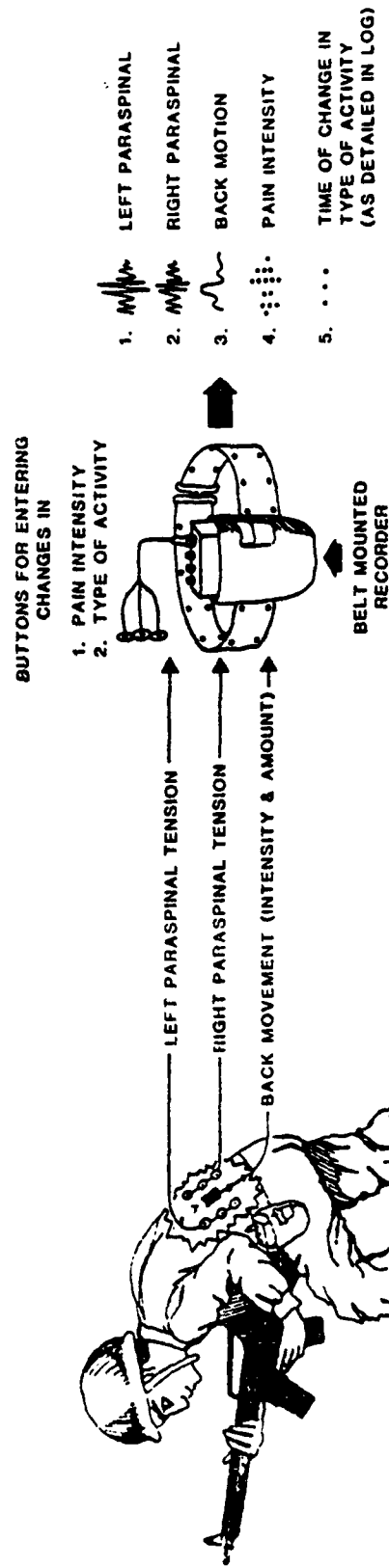
The second phase of the program is described below.

(2) The Device: Figure one depicts a soldier wearing the movement/tension recorder on his belt as well as the form the raw data is stored in for eventual transfer to the laboratory's main computer. The device was designed by Dr. John Searle (Chief of Biomedical Engineering at the Medical College of Georgia) and by the principal investigators based on experience with a very primitive commercially available wearable EMG recorder and the trial device described in the background section above. The finalized device's ability to function in the field environment and the lack of complications due to its use were also described above. Since movement and EMG are recorded independently but simultaneously on a second by second basis, it is possible to examine the dynamic relationships between them. The recorder consists of three modules. The mechanisms through which the device accurately records two channels of surface EMG proportional to muscle tension from the paraspinal muscles of the low back and back movement are described in the publication. This publication also includes details on signal storage and evaluation, on calibration of the recorder, and on how changes in pain intensity are logged onto the recorder.

FIGURE ONE

WEARABLE MUSCLE TENSION • MOVEMENT • PAIN RECORDER

INPUT ————— STORAGE DEVICE ————— OUTPUT TO COMPUTER
AFTER 24 HOURS



(3) Subjects in phase one:

We used power analysis to calculate the number of subjects for each group based on the variability we found between pain free and low back pain subjects in our laboratory study of low back muscle tension (Sherman 1985) and on the average difference in EMG readings for subjects recorded when in moderate pain and when pain free in the above study. We would need thirty subjects per group to assure us of an 85 percent probability of being able to distinguish between the groups at a 0.05 level of significance. However, the data from our trials with the device were somewhat more variable and suggested that at least 40 subjects would be required for each group. We only had sufficient data from six trial subjects as opposed to data from 90 experimental subjects who participated in the 1985 study and the set in our current work so we have more confidence in the variability estimates of the Sherman 1985 study. We have opted to compromise at using 35 subjects per group. If we find a trend which almost reaches significance we will run four extra subjects in the key sub-groups to determine whether the difference is actually significant. Since all participants will be relatively healthy, we will attempt to use medical history only as a third co-variate.

c. Inclusion/exclusion criteria and examination: All subjects will be essentially in good health other than their back pain. Previous experience has proven that we can not utilize people with either complex medical problems or with behavioral complications in these high density recording studies. Each subject being screened for participation in phase one (including no pain controls) will be given a complete orthopedic physical evaluation. The orthopedic evaluation includes several tests designed to identify potential malingerers (e.g. the Hoover test and head pressing). Subjects showing strong "functional" components on the MMPI will also be eliminated from the study. Inclusion criteria for each group are specified in Appendix A.

Subjects being screened for participation in phase two will all be members of combat units who have no significant problems in their medical histories. The participating orthopedic surgeon will give each a screening examination. Any subject who reports pain during the field exercise will be examined at the time of report by the research PA or orthopedic surgeon accompanying the unit throughout the exercise.

d. Subject availability: All of the subjects in phase one's project one will be people eligible for care at Fitzsimons Army Medical Center who live in the Denver area, meet the above requirements, and are willing and available to perform the required tasks. Fitzsimons sees active duty military from all services and their family members. Our experience with recruiting from this population for the low back pain evaluation studies discussed above showed that we can get sufficient numbers of relatively young, healthy people who regularly perform physically demanding tasks as part of their regular occupations.

The subjects in project two will be from combat units stationed at Fort Carson. The command at Fitzsimons has communicated formally with the command at Fort Carson about this proposed study so we know that we are both expected and welcome.

(4) Log: The log's format forms Figure Two. It consists of a small pad which fits into the wearable recorder's pouch. There is one pad for each day of participation. At each hour (as designated by the signal from the recorder) or whenever a recorded parameter changes, the subject notes the status of all parameters in the log. The parameters recorded are stress, fatigue, and type of activity.

Pain is recorded directly on the wearable device. Exact specifications

For rating each parameter are explained to the subject and appear on the back of each page of the log. Pain will be rated on a scale of zero to ten where zero is no pain and ten is so much that the subject could not imagine more pain if it had to be borne for one more second. Fatigue will be rated on a scale of zero to ten where zero is no fatigue and ten is so much that the subject collapsed from it. Intensity of stress responses to individual classes of stressors identified during psychological screening as being those the subject is most likely to show paraspinal EMG responses to is rated similarly. We chose one hour log intervals because we felt that this was the most frequent that we could expect any group busy with other activities to fill it out. Our experience and that of many others who have had subjects keep logs over a period of many days indicates that an hourly log will not be kept accurately unless the participants are encouraged frequently by a monitor and are reminded to log in at every hour. The timer's tone will remind the subjects to make their notations at the appropriate times.

FIGURE TWO

EXAMPLE OF ONE DAY LOG BOOKLET WHICH IS CARRIED IN THE RECORDER POUCH

cover page	:	page 1
H#	TIME	EVENT
RATING		
24 HOUR	1	stress
LOW BACK PAIN LOG		fatigue
		act chng
1. YOUR NAME: _____	:	_____
2. DATE YOU STARTED THIS LOG:	:	_____
day / month / year	:	-----
3. DAY OF WEEK LOG STARTED: _____	:	2 stress
	:	fatigue
4. EMG COUNT WHEN LOG STARTED:	:	act chng
_____	:	_____
5. MOVEMENT COUNT WHEN LOG STARTED:	:	-----
_____	:	3 stress
6. TIME WHEN LOG STARTED: _____	:	fatigue
	:	act chng
REMEMBER TO FILL IN THE TIME OF	:	_____
EACH ENTRY.	:	-----
RATING INSTRUCTIONS ARE ON BACK	:	4 stress
OF EACH PAGE.	:	fatigue
TURN ALARM OFF ONLY FOR SLEEP.	:	act chng

(5) Events during ambulatory recording: During phase one, each subject wears the device during all waking hours continuously for four days. Every day, the technician will meet the subject at a prearranged place to replace the sensors, check the subject for irritation, check the functioning of the unit, replace the memory module, and debrief (and encourage) the subject. Subjects will log their pain intensity into the recorder using the buttons provided each time it changes.

During phase two, each subject will wear the recorder as described above before the exercise to establish a reactivity baseline. They will wear it throughout the exercise and for one week after the exercise to evaluate patterns when under physical and mental stress and during resolution.

(7) Statistical considerations: The electromyographic, movement, and pain intensity data are stored on chips in the wearable recording device and are transferred automatically to the main computer for further manipulation and reduction by the software which is provided with the interface unit. Data from the logs will be entered into the computer by the technicians. It should be noted that the surface EMG signal is somewhat different for each individual due to differences in physical conditioning, skin thickness, and etc. so comparisons between individuals are minimized by using repeated measures designs both in the study structure itself and in the analysis. Since comparisons are made of pattern changes within individuals rather than across subjects, the differences in the signal do not effect the analysis.

For purposes of analysis, the study structure is a three level repeated measures block design with two groups. For each group (pain and no pain), subjects are measured during four day sessions and different intensities of work (the repeated measures). Intergroup data from each of the repeated measures as well as change scores between them will be evaluated using either a non-parametric or parametric analysis of variance depending on the distribution and nature of the data. Relationships between pain, muscle tension, and activity will be evaluated using multiple regression analyses. Temporal relationships between changes in movement, both channels of surface EMG, and pain will be evaluated using cross-lag correlations. We recently used this technique with similar longitudinal data from both headache patients and amputees. We found it sensitive to predicting which variable or combination of variables consistently change before others. Differences between groups for each variable pattern will be evaluated using Mann-Whittney "U" tests because the data are usually not normally distributed and are non-parametric in nature. Frequency occurrence data will be evaluated using Chi Square techniques. We plan to compare the two recording weeks and changes in patterns using a repeated measures analysis of variance. If we can not match work types for members of all groups we will use covariate analysis to reduce the effects of those differences on the EMG data. The ratio techniques utilized for the pilot study will not be used for the main analysis. We utilize DB3+ for data storage and both SPSS and Statpack Gold for data reduction on our IBM, Compaq, and Zenith "AT" computers.

RESULTS TO DATE:

a. Funding became available in November, 1989 so the project has actually been in progress for only 18 months. The first phase of the study was originally designed to require two years because of recognized limitations in technician and equipment time. Data gathering was initially well ahead of schedule until the technician who was performing the ambulatory recordings left in mid September after becoming ineffective over a month

before that. CPO managed to replace this technician on 26 January 1992 (after about four months) so the data gathering portion of the study is now somewhat behind schedule. Thus, it will require the full two years originally estimated to complete the first phase of the study

b. Test - Retest Reliability and Confidence intervals:

There is little use attempting to interpret data from recordings extending across days and different activities if the device making the recordings is not shown to reliably produce substantially similar numbers when the same activities are repeated both sequentially and across days. Similarly, there is no realistic way to know whether a change in a parameter is meaningful if confidence limits for repetitions of the type of activity being recorded have not been established. Without knowing the confidence limits, there is no way to know whether a change is within the normal limits of variability or beyond the expected range.

(1) Test - retest reliability and confidence intervals for normal subjects performing normal tasks: The variations from five repetitions of four tasks (walking 350 feet on a flat surface, walking up 21 stairs, walking down 21 stairs, and sitting still in a recliner for one minute.) repeated on two successive days by two normal subjects were calculated. The results are printed in Table One. They indicate that the 95% confidence limits are similar for different subjects (when corrected for different base levels of activity) and that average output is very similar across repetitions of tasks done both sequentially and across days. Thus, changes in the data exceeding half of the mean activity are virtually always outside the 95% confidence limits. This was the exceedingly conservative estimate we used when reducing the raw data from our subjects. As is detailed in the next section, differences normally exceeded 3 or 4 times the average level.

(2) Relationships between output from the recorder and structured tasks: It is vital to establish the variability between recordings of highly replicable tasks within subjects or no estimate can be made of whether differences seen on environmental recordings are simply expected variability or actual changes. It is equally important to know how different people are likely to be when performing the same task so determinations can be made as to whether different recordings actually reflect different patterns. Fifteen subjects participated in tasks where they (a) pulled back against a ten pound spring, (b) bent over to about 30 degrees and held at that angle for 30 seconds, and (c) walked on a flat surface. The results of their recordings are presented in Table Two. As can be seen from part "A" of the table, intersubject recordings differ so much for the same task that only relative amounts of change can be used to compare subjects. However, as can be seen from part "B", subjects vary very little when repeating a task so relatively small changes are meaningful. The confidence intervals for each subject are used when determining whether a change is random or not.

TABLE TWO

RELATIVE REPLICABILITY OF RECORDINGS
DURING STRUCTURED TASKS

A. Intersubject differences

Each task was recorded for 30 seconds. Numbers are in microvolts. The variability of recordings made by a standard Coulbourn, laboratory psychophysiological recording device is compared with variability of recordings made by the ambulatory recorder. The subjects all have abnormally functioning low back muscles and have low back pain.

USE:	PULLING AGAINST TEN POUNDS				WHILE BENT 30 DEGREES		WHILE WALKING	
	COULB		AMB RCDR					
SUB #	lft	rt	lft	rt	left	right	left	right
1	28	55	34	17	23	84	62	51
2	9	11	11	9	71	83	47	40
3	4	5	7	11	44	49	45	42
4	23	11	38	23	80	49	46	35
5	29	17	14	16	67	70	64	128
6	16	12	14	17	67	54	38	34
7	8	9	8	14	71	53	62	50
8	art	50	12	9	71	68	29	31
9	11	21	10	21	34	47	28	41
10	12	11	19	14	88	86	53	46
11	15	16	33	art	76	77	61	221
12	14	14	11	10	51	52	37	45
13	11	11	2	17	14	116	9	61
14	31	18	28	18	99	79	46	35
15	8	4	11	13	53	57	38	34

B. Inter-trial differences while using the ambulatory recorder

Each task was recorded for two independent ten second intervals. During each interval, average EMG was recorded each second so each of the ten second intervals is an average of ten recordings. Standard deviations are shown after the means. Numbers have been kept as recorded rather than being transformed into microvolts.

USE:	PULLING AGAINST TEN POUNDS		WHILE BENT 30 DEGREES		WHILE WALKING	
	first	second	first	second	first	second
SUB #						
1	2.9(.43)	1.4(.39)	10.2(.56)	8.8(1.0)	6.7(.74)	6.9(.79)
2	3.1(.66)	3.1(.45)	12.8(7.3)	23.9(1.8)	11.7(2.9)	10.5(2.2)
3	2.0(.38)	1.9(.38)	13.0(.98)	12.6(1.3)	8.6(1.5)	8.1(1.4)
4	1.3(.47)	1.2(.42)	7.8(.72)	8.1(1.2)	8.2(.89)	7.7(.74)
5	6.8(.41)	6.7(.70)	14.2(.93)	14.5(1.3)	8.0(1.1)	8.3(1.6)
6	2.5(.51)	2.4(.59)	12.4(1.9)	11.5(1.9)	11.4(2.9)	11.7(2.4)
7	2.5(.50)	2.5(.57)	11.5(.66)	12.5(.76)	6.6(1.0)	6.9(1.6)
8	1.4(.50)	1.5(.50)	12.7(2.6)	no rcd	10.9(2.1)	11.1(1.7)
9	2.2(.38)	2.0(.35)	13.3(.99)	12.2(.73)	4.0(.89)	5.3(.99)
10	1.8(.42)	1.8(.42)	5.9(.43)	6.2(.37)	5.1(.92)	4.9(.74)
11	2.7(.48)	2.3(.45)	15.9(1.3)	15.8(1.2)	9.8(1.4)	9.3(.88)
12	6.4(.78)	5.5(.70)	14.2(.81)	13.2(.98)	10.2(1.8)	11.5(1.6)
13	1.9(.32)	1.9(.32)	9.4(4.3)	9.6(4.6)	6.3(1.1)	7.0(1.5)
14	3.0(.56)	3.0(.67)	24.7(1.3)	17.1(4.5)	11.1(2.7)	11.0(1.7)
15	4.8(.52)	5.1(.43)	18.8(.87)	16.9(1.2)	7.8(1.4)	8.6(1.7)

(3) Relationships between output from standard laboratory recording equipment and the ambulatory recorder: If the ambulatory recorder produces significantly different numbers than a standard recorder, such as the Coulbourn system in our laboratory, the numbers produced by the ambulatory recorder are open to doubt. Fifteen subjects pulled against a ten pound spring for two ten second intervals while being recorded by the Coulbourn system. They then repeated this task while being recorded by the ambulatory recorder. The number of microvolts shown by the Coulbourn system do not correlate well with those produced by the ambulatory recorder ($p = 0.21$). However, this is probably due to the tasks being done at different times. We will repeat this test while recording simultaneously.

(4) Confidence intervals during calibration of ambulatory recorders across time, channels, and recorders: It is impossible to compare recordings made on different days with different ambulatory recorders, or even to compare the results of one channel with another unless the likely amount of difference between recordings is known. We calculated this for ideal, in-laboratory conditions by using differences in 89 calibration signals recorded for the above studies. Before each recording session, a 100 microvolt, 80 cycle signal was recorded for three ten second intervals on both our standard, in-laboratory recording system (Coulbourn) and the ambulatory recorders. The above studies took place over a period of months and utilized both channels of many recorders. Differences in the recordings are due to differences in the recorders, environmental conditions, and the attachment process. The standard Coulbourn system's 99 percent confidence interval around a mean of 105.8 was 104.01 - 107.55 while that of the ambulatory recorders was 17.95 - 18.05 around a mean of 18.00. Thus, the ambulatory recorders do not vary more than standard laboratory equipment and we can be 99 percent certain that differences of more than 0.10 are real.

c. Environmental Recordings:

(1) Project one (local subjects recorded in their normal environments): Fifty-three of the 70 projected subjects have completed participation in both the ambulatory recordings and the baseline comparisons in which the results from the ambulatory recorder are compared with the outputs from standard, in-laboratory, physiological recorders while subjects are making controlled movements and working to preset numbers of pounds. Of these 53, 11 had no histories or current reports of low back pain and were normal upon examination; two were diagnosed as having intermittent low back pain due to disk-nerve entrapment problems while two had continuous pain due to the same diagnosis; 33 were diagnosed as having intermittent back pain due to muscle tension/mechanical problems while four had continuous pain due to the same diagnosis; and one had continuous pain due to arthritis. Data from the ten patients completed since the mid-year report have not been mathematically reduced. However, the graphs show the same predictive relationship between change in ENG followed by change in pain reported for the initial group when the pain is related to muscle tension.

The most outstanding result continues to be that the recordings look very different for subjects with different diagnoses of low back pain. Visual inspection alone is sufficient to differentiate controls from people with back pain due to muscle spasm. Although we have only four cases of people with back pain due to disk or arthritic problems, these recordings also look very different from those of people with muscle spasms. Among people with muscle spasm related back pain, the muscle tension level is relatively loosely related to activity. It increases from several minutes to 3/4 hour before pain increases and decreases about the same duration prior to a decrease in pain. Several examples of temporal relationships between pain

and muscle tension are depicted in Figure Three and the data are summarized in Table Three.

(2) Results of project two (recording soldiers participating in field combat training exercises at Ft. Carson): Twenty-six soldiers from the fourth infantry division (mechanized) were recorded for between three and four days while in garrison followed by a four to five day break and then recorded during their exercises. Four soldiers had no histories of back pain either while in garrison or in the field, three had histories of pain in both locations but no current pain, eight had current pain in both locations, and eleven had pain only when in the field environment. All of the soldiers reporting pain had the diagnosis of low back strain. The demographics of the participants are summarized in Table Four. Initial evaluation of the data shows that the relationship between pain and muscle tension is maintained among soldiers participating in field exercises. The data comparing temporal relationships between low back muscle tension and pain from recordings of soldiers made in garrison with those made in the field during combat exercises are summarized in Table Five. The data have only been roughly analyzed at this time. Of all the possible temporal combinations of pain - tension relationships, those in which changes in EMG predict same direction changes in pain predominate. The other combinations (e.g. change in pain predicting change in tension or increase in one factor predicting a decrease in another) appear to be randomly scattered through the data. It is strikingly clear that soldiers experience more pain during FTXs than in garrison. This holds true for soldiers who do not normally report pain in either location.

d. Complications during attempts to establish control measures: One of the vital control groups which needs to be recorded consists of people who are have intermittent pain elsewhere then in the back which is not related to low back muscle tension. This permits us to factor out changes in muscle tension related to changes in overall muscle tension caused by stress, which is, in turn, caused by the pain. Unless this relationship is accounted for, changes in muscle tension which are observed in the low back may be caused by changes in stress caused by changes in low back pain rather than being directly related to the low back pain. A multitude of studies have shown that there are clear relationships between changes in stress responses and occurrence of "muscle contraction" or "migraine" headache pain but there is no relationship between amount of paraspinal, trapezius, or frontal area muscle activity and occurrence of these problems. Thus, we felt that this was an ideal group to use as stress - pain controls. We recorded six subjects with "muscle tension" headaches, six with "migraines" and two with a combination of both. Subjects were recruited from patients receiving medical care at FAMC. Prior to participation, every subject was evaluated by a neurologist in order to diagnose the type of headache and to reduce the likelihood that unrecognized problems were contributing to headache activity. Subjects were also screened for psychological variables and did not participate if their MMPIs were abnormal. Their demographics are summarized in Table Six.

FIGURE THREE:

Examples of temporal relationships
between
changes in pain and muscle tension

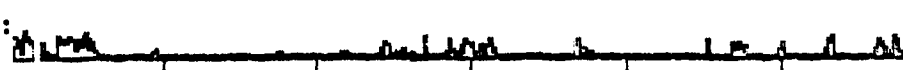
Pain due to muscle spasm:

muscle tension: 
(Left & Right)

pain: 9

90 min/div: 0

Pain due to arthritis:

muscle tension: 
(Left & Right)

pain: 9

90 min/div: 0

Pain due to disk problem:

muscle tension: 
(Left & Right)

Pain: 9

90 min/div: 0

Table Three

Summary of low back muscle tension - pain relationships

DIAGNOSTIC CATEGORY	SUB #	# SES	# HRS SES	PAIN INTENS RANGE	PAIN CHARACTER	EMG CHNG THEN PAIN (# events X av # min)	PAIN CHNG THEN EMG	PN & EMG CHNG SIMULT	PAIN CHNG NO CHNG EMG
muscle tension related pain	A1	4	6	0 - 2	int/sharp	5 X 15	1 X 60	2	0
	A2	3	10	0 - 7	int/sharp	10 X 30	0	1	0
	A3	3	9	0 - 9	int/sharp	11 X 30	1 X 20	1	3
	A4	1	11	1 - 3	int/dull	1 X 1	5 X 3	0	2
	A7	3	7	0 - 9	int/dull	4 X 10	2 X 12	9	4
	A9	3	7	0 - 9	int/sharp	7 X 15	3 X 4	9	1
	A10	3	5	no chng	int/dull	no chng			
	A11	4	6	0 - 8	int/sharp-burn	12 X 7	3 X 4	8	6
	A13	4	9	0 - 9	int/sharp	27 X 8	5 X 6	9	8
	A14	2	12	0 - 6	cont/sharp	10 X 9	2 X 6	2	3
	A15	2	7	1 - 9	int/stiff	9 X 6	1 X 1	2	3
	A17	2	11	0 - 7	cont/burn-stab	9 X 8	1 X 2	3	1
	A18	4	9	1 - 9	int/stiff-tght	23 X 6	1 X 0.75	2	5
	A21	4	6	0 - 9	int/stiff-dull	7 X 14	0	4	4
	A24	4	9	0 - 9	int/stiff	20 X 6	3 X 5	22	7
	A25	1	6	0 - 7	cont/sharp-stab	4 X 6	1 X 23	0	0
combined with:									
disk	A12	3	9	2 - 9	int/sharp-stab	14 X 10	0	4	8
osteoper	A16	1	7	2 - 8	cont/stif-shrp	5 X 6	0	2	1
disk only	A5	4	8	2 - 8	cont/stab	11 X 5	9 X 10	16	9
	A26	3	9	0 - 8	cont/shrp-stff	3 X 2 *8 X 4*	1 X 1	3	2
arthritis	A19	4	12	0 - 9	cont/dull-stab	0	0	13	6
controls who noted minor backache	A6	3	6	0 - 2	ache	1 X 16	2 X 5	0	0
	A8	3	7	0 - 9(3)	ache	7 X 1	2 X 5	2	1
	A23	2	7	0 - 3	ache	7 X 5	1 X 6	3	4
	A22	2	5	0 - 5	ache	2 X 5	0	1	0

* EMG decreased before pain increased & vice versa (opposite of usual pattern)

TABLE FOUR

SOLDIERS RECORDED DURING COMBAT TRAINING EXERCISES

Description of Pain				Character	Type	Intensity
SB	Sex	Age	Diagnosis			
B1	M	27	Low back strain	intermittent	sharp	severe
B2	M	23	Low back strain	constant	dull	mild
B3	M	18	Low back strain	intermittent spastic	stiffness	moderate
B4	M	24	Low back strain	intermittent	stiffness	mild
B5	M	24	Low back strain	intermittent	dull	mild
B6	M	22	Low back strain	constant stiffness	sharp	moderate
B7	M	33	Low back strain	constant	dull	mild
B8	M	21	Low back strain	intermittent	stiffness	moderate
B9	M	22	Low back strain	no pain	n/a	n/a
B10	M	22	Low back strain	intermittent dull	stiffness	moderate
B11	M	25	No pain	control	n/a	n/a
B12	M	19	Low back strain	intermittent	stiffness	moderate
B13	M	22	Low back strain	constant	dull	moderate
B14	M	34	Low back strain	constant	dull	moderate
B15	M	23	Low back strain	intermittent	spastic	severe
B16	M	24	Low back strain	no pain	n/a	n/a
B17	M	19	Low back strain	constant stabbing	stiffness	severe
B18	M	19	No pain	control	n/a	n/a
B19	M	18	No pain	control	n/a	n/a
B20	M	23	Low back strain	no pain	n/a	n/a
B21	M	25	Low back strain	constant stiffness	sharp	moderate
B22	M	24	Low back strain	intermittent	stiffness	mild
B23	F	25	Low back strain	intermittent stiffness	dull	mild
B24	M	38	Low back strain	constant	spastic	severe
B25	M	34	Low back strain	intermittent stiffness	dull	moderate
B26	F	25	No pain	control	n/a	n/a

Pain intensity scale (0-9): 0-No Pain, 1-2 mild, 3-5 moderate, 6-8 severe, and 9 excruciating.

TABLE FIVE

TEMPORAL RELATIONSHIPS BETWEEN EMG AND PAIN

AMONG SOLDIERS RECORDED BOTH

DURING COMBAT EXERCISES AND IN GARRISON

Predictions of change in tension and pain
(all pain (significant pain))

SB	Usual pain	garrison			:	field		
		EMG predicts pain	Other relation- ships	Random	:	EMG predicts pain	Other relation- ships	Random

Soldiers who usually experience pain both in garrison and in the field

B2	mild	0	6(4)	0	:	5(5)	5(3)	3
B6	moderate	5(1)	7(5)	0	:	40(40)	51(48)	2
B7	mild	1(1)	13(10)	0	:	10(10)	13(2)	1
B13	moderate	2(1)	3(3)	0	:	7(7)	4(2)	0
B14	moderate	8(8)	19(19)	15	:	3(3)	1(1)	5
B17	severe	0	11(11)	0	:	22(21)	47(43)	0
B21	moderate	2(2)	8(6)	0	:	0	3(3)	0
B24	severe	0	1(0)	0	:	2(2)	2(0)	0

Soldiers who usually experience pain mainly in the field

B1	severe	0	3(0)	0	:	5(5)	11(7)	1
B3	moderate	3(3)	3(0)	1	:	7(7)	8(8)	0
B4	mild	3(3)	4(1)	0	:	2(2)	1(0)	0
B5	mild	3(3)	5(5)	0	:	10(10)	8(8)	0
B8	moderate	8(8)	21(21)	3	:	15(15)	14(14)	14
B10	moderate	1(1)	5(5)	1	:	18(18)	50(50)	3
B12	moderate	6(6)	9(9)	7	:	5(5)	7(5)	0
B15	severe	0	0	0	:	3(3)	3(1)	0
B22	mild	2(2)	2(1)	0	:	2(2)	7(7)	3
B23	mild	0	1(1)	0	:	0	4(0)	0
B25	moderate	6(5)	10(6)	1	:	7(7)	30(28)	8

Soldiers who do not usually report significant pain during participation
but have histories of pain

B9	none	18(18)	44(44)	0	:	5(3)	11(8)	6(0)
B16	none	15(15)	44(44)	3	:	16(16)	31(31)	4(0)
B20	none	3(3)	9(9)	7	:	8(8)	27(27)	0

Soldiers who do not usually report significant pain during participation
and do not have histories of pain

B11	none	6(6)	0	0	:	2(2)	11(11)	0
B18	none	3(0)	7(0)	1(0)	:	2(1)	4(2)	17
B19	none	6(6)	7(7)	1	:	4(4)	10(8)	11
B26	none	1(0)	1(0)	0	:	0	0	2(0)

TABLE SIX

HEADACHE CONTROL SUBJECTS

SUB #	DX	SEX	AGE	EMG/PAIN RELATION	# RECORDINGS
1	Tension	F	37	No relationship observed	5
2	Tension	F	58	No relationship observed	3
3	Tension	F	31	Increased EMG before	5
4	Tension	M	33	High EMG Spikes during increase in headache	1
5	Tension	M	50	Lower EMG after pain increased from 0 TO 1	2
6	Tension	M	37	No relationship observed	4
7	Migraine	M	22	No relationship observed	4
8	Migraine	M	59	Increase in EMG before increase in pain	7
9	Migraine	F	50	No relationship observed	2
10	Migraine	F	65	No relationship observed	4
11	Migraine	M	48	No relationship observed	4
12	Migraine	M	63	Increase in EMG before increase in pain	3
13	Combined T & M	M	67	Low points of EMG are lowest on no pain days and after pain decreased	3
14	Combined T & M	F	51	No relationship observed	2

The ambulatory monitor was attached to each subject at the beginning of the day by lab personal. Subjects wore it throughout the day in their normal environments. The EMG sensors were placed over both the right and left trapezius muscles. The motion sensors were attached to the back of the neck and the anterior left shoulder. Subjects were instructed to wear the recorders for their waking hours and disconnect them prior to sleeping. They were encouraged to indicate changes in pain intensity and activity at the time these variables changed. The recorder produced a tone every hour until a key was depressed indicating current pain intensity and activity. The subjects wore the recorder for up to 5 days, consecutively if possible. They were recorded for enough days to get a representation of both headache and headache free periods and/or periods when headache pain changed.

We found a consistent (repeated) relationship between increases and decreases in pain intensity and EMG level among half of the subjects. In two of these subjects, one diagnosed with tension headaches and the other with migraine, trapezius EMG consistently increased before an increase in pain and remained elevated while pain intensity was elevated. Typical relationships are illustrated in Figure Four. The migrainer experienced a decrease in EMG before pain intensity decreased, and the subject with tension headaches showed a decrease in EMG at the time pain intensity decreased. In the third subject, a tension headache sufferer, the reported pain level fluctuated between two and three and high spikes were observed only when the subject reported a pain level of three. In the fourth subject, who had mixed tension and migraine headaches, EMG reached lower levels during pain free recordings than before and during reports of headache pain. In the fifth subject, a tension headache sufferer, EMG decreased after pain increased from zero to one. There was no apparent relationship between trapezius EMG and report of pain intensity in the remaining eight subjects (three with tension headaches, four with migraine headaches, and one with mixed tension and migraine headaches).

This unexpected finding has complicated our study since we can not differentiate between generalized musculoskeletal stress responses to non-muscle related pain. We will look for a different control group. However, we need to try to understand why we have found pain - muscle tension relationships that the rest of the research community has searched diligently for over several decades but has never found. This is important because many soldiers do suffer from headaches which decrease their performance effectiveness. If it turns out that changes in muscle tension do cause some headaches, and that the change in muscle tension is related to the types of activity being engaged in, we should study the relationship in order to find ways to reduce the occurrence of headaches.

Most studies compared muscle contraction levels during both painful and pain free periods among subjects diagnosed as having muscle contraction headaches. Some studies compared muscle contraction levels in subjects with no recent history of headaches and subjects with muscle contraction headaches. These studies were performed in controlled laboratory or clinical settings and looked at only brief periods of time. If a stressor was introduced in the laboratory it was an artificial situation. Studies in the literature comparing trapezius EMG and headache pain have shown no set relationship between them. These studies have taken place in laboratory settings and represent a cross-sectional view. Our data shows that the temporal relationship between trapezius EMG and headache pain may be exceptionally complex and may include subgroups exhibiting a variety of relationships between EMG and headache pain intensity. One possible

subgroup may include individuals who experience an increase in trapezius EMG prior to and during headache pain. The relationships between EMG and headache pain intensity may provide an explanation for possible different etiologies resulting in headache pain.

d. Publication resulting from project:

Sherman RA, Arena JG, Searle JR, Ginther JR: Development of an ambulatory recorder for evaluation of muscle tension related low back pain and fatigue in soldiers' normal environments. Military Medicine 156: 245-248, 1991.

CONCLUSIONS: We have the first objective evidence ever gathered showing a very clear predictive relationship between changes in back muscle tension and changes in pain intensity. Because the data were gathered in over 93 subjects having a variety of diagnoses over multiple sessions and at different pain levels as well as during a wide variety of activities, there can no longer be any doubt that in many instances increases in back muscle tension precede increases in pain by many minutes and that decreases in muscle tension predict decreases in pain. The amounts of change in pain and muscle tension are approximately proportionate and are usually independent of changes in movement. Thus, it is highly likely that (1) treatments of muscle tension related low back pain can be optimized by maximizing their ability to change patterns of low back muscle tension and (2) the ambulatory recorder is an excellent way to track effectiveness of treatments. These hypotheses should be experimentally evaluated as soon as possible to permit determining which treatments actually produce the best results and not only return soldiers to duty more quickly but permit them to be more comfortable while working during the period when they still have significant back pain but have returned to duty. This later evaluation is critical because most people with intermittent back pain do not become so debilitated by it that they are constantly off duty but, rather, function in considerable pain with reduced mobility and effectiveness.

PLAN FOR PHASE TWO:

(1) Project 1 - centered at Ft. Carson: This project will use the information gathered in the first phase to assist in testing "muscle tension recognition and control training" to prevent onset of excess fatigue and low back pain among soldiers participating in combat training exercises. The first phase of the study showed that there are indeed relationships between increased muscle tension and back pain. Literature detailed in the initial protocol demonstrated that "muscle tension recognition and control training" is effective for teaching people to recognize abnormal levels of muscle tension for a given situation and for bringing the tension to appropriate levels without having to think about the problem. These methods combine home use of tape recorded progressive muscle tension training techniques with group based muscle tension biofeedback and relaxation training.

Method: We propose to have a half time psychophysiology technician stationed at Ft. Carson. Dr. Ginther and the technician will identify and screen male and female soldiers between the ages of 18 and 40 with no medical back problems or other significant medical problems from units participating in combat training exercises who either (a) have no history of back pain during combat exercises or (b) have back pain during combat exercises but not in garrison. The initial phase of the study showed that it is impractical for one technician to perform ambulatory recordings on more than eight soldiers at once while they are participating in combat exercises because of the difficulty in keeping track of them. It is also difficult to train more than eight people at a time in the required muscle tension awareness and control skills because more people cannot be monitored effectively or brought together at one time. We propose to (a) perform ambulatory recordings of low back muscle tension, movement, and pain intensity (as detailed in the original protocol) on groups of eight

solders for twenty hours per day for four days while they participate in combat training exercises to gather baseline data on each soldier, (b) train these soldiers in muscle tension awareness and control techniques, and then (c) record them again during their next combat exercise to determine how their patterns of muscle tension, pain, fatigue, and combat effectiveness have changed from the first recording. The group phase of the training will be offered both during and after regular duty hours so that individual schedules can be accommodated. If necessary, soldiers will be trained individually. The clinic/group phase of the training will be held in either the troop area or the hospital, depending on the local command's wishes. This phase requires four, one hour long classes held about once per week and a fifth half hour "brush-up" class after the home phase of the training. Soldiers will be given 15 minute long tape recorded muscle tension awareness exercises to perform at "home" twice per day for approximately six weeks. Since people learn at different rates, as long as eight weeks may be required for some people to reach standard, accepted control criteria. Soldiers who do not reach training criteria will be dropped from further participation.

Number of soldiers and statistics: Both individual and group variability in muscle tension - pain relationships can be estimated from the first phase of the study. Power analysis techniques for repeated measures (baseline vs. post training period for each soldier) multi-level (no pain group vs. group with pain only during combat exercises) evaluations of mixed non-parametric (pain ratings and fatigue ratings) and parametric (movement and muscle tension) time lagged correlational data are not available. However, a standard power analysis on simplified forms of the data indicates that 20 groups (10 with pain during field exercises and 10 without) of eight subjects each should be enough to give an 95 percent chance of detecting a difference at $p = 0.05$ between the groups. This is more subjects than required to detect a difference between baseline and post-training recordings within groups. The exact statistical methods proposed for analysis of the data were detailed in the original protocol.

(2) Project 2 - centered at FAMC: The progress reports for the first phase of this project contained evidence that people with muscle tension related back pain show clear patterns in which muscle tension recorded in the normal environment increases prior to increases in pain and decreases prior to decreases in pain. We should be able to use this information to test the ability of treatments for muscle tension related low back pain to actually alter patterns of low back muscle tension. We propose to test this hypothesis by using two simple treatments already shown to be moderately effective for back pain diagnosed as being due to muscle tension which supposedly work at least partially by reducing muscle tension in the low back.

Methods: The study design has to be oriented towards repeated measures because of the huge inter-subject variability demonstrated in the first phase of the protocol. Participants will be limited to those low back pain patients examined by Dr. Place who have no significant medical problems other than back pain, are between the ages of 18 and 40 (to match the soldiers in the Ft. Carson study), are eligible for care at FAMC, have no evidence of any cause for low back pain other than muscle tension problems, have maintained about the same level and pattern of pain for at least one year, and do not produce any abnormal patterns on the MMPI (Minnesota Multiphasic Personality Inventory). These requirements are necessary so we can avoid as much variability as possible due to (a) pain being caused by a variety of problems not related to muscle tension (which would probably not change with changes in muscle tension patterns), (b) unstable baselines in

which frequency and intensity of pain episodes might change randomly with respect to the interventions, and (c) psychological reactions to environmental stress which are likely to influence perception of pain intensity and, thus, confuse reports of pain relative to muscle tension. People who have had any form of biofeedback or relaxation training, who cannot use cyclobenzaprine, or who cannot stop taking medications which might influence pain perception or muscle tension will not be able to participate. We propose to work with subjects who have more or less constant low back pain and with those who experience pain only during and after physical exertion. We propose to (a) perform ambulatory recordings of these people for four days while they are not taking any medications (and after any washout period required), (b) give each a two week trial of cyclobenzaprine (10 mg., 3X/day = 30 mg. day) with the last four days recorded on the ambulatory recorder, (c) train each subject using muscle tension recognition and control exercises as described for the combat soldiers, and (d) perform a final four day ambulatory recording of those subjects who reach control criteria. Subjects will be warned about cyclobenzaprine's common side effects and will be told to stop using the medication if they occur to an annoying degree.

Number of subjects and time course of the study: As explained for the first study, a standard power analysis is impossible due to the complexity of data gathering techniques and of the data themselves. However, the data from the first study showed that a 35% change in muscle tension is virtually always predictive of a subsequent change in pain. If we set a 35% change in muscle tension reactivity as the amount of difference required to differentiate between treatments, we should need about 60 subjects per group to be 95% sure of differentiating between the three recording periods at $p = 0.05$ if there are differences. Because differences between the two groups may be more due to differences in complex patterns rather than simply elevation of changes, we really cannot estimate how many people we will need to differentiate between the groups until we run at least the first ten in each group. If more subjects are required than we can feasibly run during the proposed duration of the study, we will modify the design or request additional time to perform the study. The first phase showed that it is impractical to have more than eight subjects using the recorders at any one time. As each subject's participation is between ten and twelve weeks long (depending on how long it takes to reach control criteria), even if new subjects are started while others are not using the recorders during their training period, only 69 subjects can be run in a year by one technician. Thus, the study will require two years to perform given an initial three month start up period to hire and train a technician.

c. Additional study: The finding that some headaches may be caused by increases in back muscle tension which consistently occur prior to changes in either perceived pain or stress, is important because it may permit development of methods for avoiding the onset of debilitating headaches which reduce unit performance. We will work with staff at MRDC to determine whether we should propose an addendum to this study or an entirely new study to investigate this relationship.

d. Administrative recommendation: When MRDC funds projects at Army MEDCENS, consideration should be given to beginning the funding cycle when staff and equipment are actually available. For example, this project was funded in December of 1989 but CPO at FAMC did not permit us to bring staff on until June of 1990. This means that we had only seven months to perform the first year's worth of work and had to return salary funds to MRDC.

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APPENDIX A

DIAGNOSTIC CRITERIA FOR PLACING SUBJECTS INTO GROUPS

Note that these are key features. We will use them very conservatively along with clinical judgement. We will NOT include a subject rather than have one who might not clearly fit into the designated group.

A. Pain only after physical exertion which is diagnosed as being due to muscle tension related problems:

1. Must NOT meet the following criteria:

a. INTERVERTEBRAL DISC DISORDER:

- (1) Patient should have more (over 50%) leg pain than back pain.
- (2) Positive tension signs (such as straight leg raising test) must be present.
- (3) Results of EMG/NCV positive for lower extremity radiculitis/radiculopathy.
- (4) Pain increased on flexion of the lumbosacral spine.
- (5) Findings of diminished or absent reflex in the lower extremities, diminished muscle strength in lower extremities, or altered sensibility in the lower extremities (These are usually not required for the diagnosis but are included to insure exclusion of problematical cases.)
- (6) CT scan & myelogram consistent with HNP.

b. DEGENERATIVE ARTHROSIS, SPONDYLOLYSIS, SPONDYLOLISTHESIS:

- (1) Radiographic findings consistent with spondylolysis, spondylolisthesis, or degenerative arthritis. This would include facet arthrosis, osteophyte formation, disc space narrowing, anterior/posterior displacement of one vertebral body on another, fracture or defect of the pars interarticularis, and abnormal motion on X-ray.
- (2) Back pain greater than lower extremity pain.
- (3) Palpable tenderness or trigger points localized to the back or buttock region.
- (4) Pain worsened by cold or wet weather.

2. May meet the following criteria for SOFT TISSUE INJURY; MUSCLE STRAINS AND LIGAMENT SPRAINS:

- a. Absence of signs or symptoms of lower extremity radiculitis or radiculopathy as above.
- b. Pain localized to the back and/or buttock area.
- c. Normal routine radiographs of the spine.
- d. EMG/NCV results not compatible with radiculitis or radiculopathy.
- e. Palpable tenderness and/or trigger points localized to the back or buttock region.

B. No history or current complaint of back pain:

The subject must not meet any of the criteria for the above problems.

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