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13. ABSTRACT *(Maximum 200 words)*

This project intends to (1) Develop predictive methodologies for relating heat patterns observed in the lower limbs of trainees just inducted into the Army to pain syndromes developed during training and (2) Compare the effectiveness of three methods of recording heat patterns in the lower limbs in relating the patterns to pain states. Videothermographs are used to record lower extremity heat patterns of new trainees are recorded while at Ft. Sill's induction station. A second set of recordings are made when the soldiers come to the TMCs for either lower extremity pain or unrelated problems (controls). The patterns are compared with results of standard diagnostic tests and exams. Lower extremity heat patterns from pain patients at FAMC and Ft. Sill which are produced by very accurate but relatively complex and expensive videothermographs are compared with those produced by inexpensive, field useable contact thermographs and electronic thermometers. Funding became available in December, 1989 but did not begin until June, 1990 due to hiring problems at FAMC. During the seven months this project has been in progress we have demonstrated that recruits arriving at their basic training sites have an unexpectedly high rate of abnormal thermograms. We have also that contact thermographs have so many problems visualizing common problem areas that they can not be substituted for videothermographs. However, if a suitable grid system can be developed, single point infrared thermometers would be able to be substituted and are very appropriate for use in the field environment.

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FOREWORD

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RS For the protection of human subjects, the investigator(s) have adhered to policies of applicable Federal Law 45CFR46.

NA In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

Richard C. Ebersole 31 Jan 91

Principal Investigator's Signature Date

Use of body surface heat patterns for predicting and evaluating acute lower extremity pain among soldiers

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Use of body surface heat patterns for predicting and evaluating acute lower extremity pain among soldiers

1. INTRODUCTION:

a. Aim for entire project: To determine the usefulness of surface heat patterns for predicting and evaluating acute lower extremity pain among soldiers. This study contains two overlapping projects. The first uses heat patterns to detect abnormal blood flow patterns in the lower limbs of recruits who have not yet begun their training. The aim of this portion of the study is to develop predictors of problems which develop during training. The second project compares the effectiveness of three methods for recording surface heat patterns in order to determine which might be appropriate for use in the field environment.

b. Hypotheses:

(1) Project one:

(a) That thermography will be an efficient screening tool for predicting which trainees are likely to require treatment for problems in their knees, lower legs, and feet during training. This incorporates the sub-hypothesis that there will be a minimal number of false positive findings in which trainees appear abnormal during initial screening but never require treatment and that there will be a relatively minimal number of false negative findings in which soldiers producing normal thermograms who require treatment for the problems of interest. We predict a relatively high rate of false negatives because many of the solders will injure their knees, lower legs, and feet during training even though they may not have been predisposed to do so.

(b) That thermography will be an effective way to track the resolution of pain in the knees, lower legs, and feet as well as a good predictor of which trainees will experience a reoccurrence of problems in these areas after treatment.

(c) That thermography will be sufficiently efficient to permit design of a study utilizing its predictions to apply preventive measures to selected members of training battalions to increase unit effectiveness.

(2) Project two:

(a) That inexpensive, portable contact thermographs can produce instant Polaroid pictures from two or three standardized views of the feet or legs which attending health care providers can immediately use

to accurately determine the presence or absence of stress fractures.

(b) That beam thermometers can not provide sufficient information about heat patterns in a limb during a reasonably brief session to be of assistance in recognizing the clear patterns produced by stress fractures because there is no way to predict exactly where on the limb differences should occur.

c. Objectives:

(1) project one:

(a) To demonstrate the usefulness of thermography in predicting injuries to the lower limbs during basic training.

(b) To demonstrate the usefulness of thermography for predicting the reoccurrence of lower limb problems occurring during basic training.

(2) project two: To avail the medical practitioner with a field viable, convenient, non-invasive, quick, and accurate modality for the diagnosis of stress fracture in troops by establishing the efficiency of contact thermography and beam temperature monitoring relative to standard tests.

d. Goals for the first year of the project:

(1) Establish system for recording recruits and follow them through their training cycles.

(2) Establish the rates of false positives and abnormalities found during baseline recordings among these troops.

(3) Establish the usefulness of videothermography and thermometers for determining patterns of heat emanating from the lower limbs.

e. Status:

(1) Lower extremity injury rate during basic training: the US Army Research Institute of Environmental Medicine recently completed a review and study of both the incidence and risk factors for injury among Army basic trainees (Jones et al, 1988, Cowan et al 1989). These exhaustive reviews of the literature were combined with detailed studies of actual injury rates among basic trainees. The excellent prospective studies concluded that 51% of females and 27% of males are injured during basic training. Of 124 men and 186 women studied in detail, the men lost 99 days of full training while the women lost 481 days of full training. However,

initial physical fitness was an excellent predictor of injury and when pre-training level of fitness was factored in, the difference between males and females disappeared. The risk of sustaining lower extremity injuries sufficiently severely to significantly interfere with training was 45% for females and 21% for males. Of these, 11% of females and 2 percent of males sustained stress fractures. In a separate study, 129 sustained injuries to their lower extremities which resulted in significant losses of training time. Nine of these were stress fractures. Illness rates were similar for both sexes (after adjustment for gynecological problems) and only caused a loss of 23 and 19 full training days for women and men respectively. The results of these studies parallel the results of the large demographic and clinical studies reviewed by the authors. These rates of injury become especially noteworthy when it is noted that traumatic events initiating the problems are rare. Volpin et al (1989) recently reviewed 105 lower limb pain cases among recruits and found that 54% had stress fractures when diagnosed using technetium scans. Of the remaining recruits without evidence of stress fractures, 74% had anatomical deformities of the lower limb. Thus, lower extremity injury during basic training is a very significant factor in training effectiveness.

(2) Confirmation of the diagnosis of stress fracture: Stress fractures are very difficult to confirm. The study by Volpin et al (1989) discussed above is typical of the vast majority of studies in which x-rays and other techniques are compared in the evaluation of stress fractures. They found that x-rays gave false negative results in 87% of cases documented using scans. The vast majority of stress fractures occur among soldiers who are far from major medical centers having the powerful (as well as heavy, delicate, expensive, difficult and time consuming to use, and immobile) equipment required to perform accurate bone scans. This is the main reason that methods capable of evaluating stress fractures in the field must be identified. It is important to accurately diagnose stress fractures to minimize the amount of time the soldier is away from the unit and to minimize reoccurrence of immobilizing pain due to incorrect treatment. Problems with the use of x-rays for evaluation of stress fractures and the effects of delaying treatment were reviewed by Devereaux et al (1984).

(3) Use of patterns of heat emanating from the body's surface as an aid to medical diagnosis: The use of heat emanating from the body's surface to detect disease processes is of ancient origin. The recent application of modern videothermographic methodology to detect near surface blood flow patterns is simply a refinement of the older techniques of feeling the body's surface. Videothermographs look very much like television cameras and work in a parallel way. The basic difference is that heat emanating from the body's surface is recorded rather than light

reflecting off of it as is done with traditional light television. Thus, the system is safe and non-invasive as nothing goes to or touches the subject. Over the last ten years, great strides have been made in increasing the resolution and sensitivity of medical videothermography systems while decreasing their size and operational complexity. For example, the Inframetrics 600M color thermograph can differentiate between temperatures as little as 0.15 degrees C apart and can visualize areas ranging from one square centimeter to the entire body at once. The unit can quantify differences in heat and record on Polaroid and 35 mm film as well as videotape. A special computer interface/software package permits quantified comparison of many images simultaneously. The device fits on a 2 X 3 foot cart when it is in its "ready to use" configuration. An absolute temperature reference always appears on the screen so the actual temperature of an object being viewed is always known and day to day comparisons can be made. Contact thermographs consist of a plastic screen about 18 inches on a side which is pressed against the part of the body to be visualized. The screen contains closely spaced pixels of chemicals which change color at different temperatures. Thus, a color image representing body heat is produced from the color at each pixel. These devices are very limited in temperature range and can not be used for long term recordings because the pressure of the plastic screen against the body changes the surface heat patterns.

Medical thermography is still in its infancy but has become accepted medical practice in several areas. Its most common medical use has been in finding objective evidence for reported pain not detectable by other means. For example, positive thermograms are acceptable in court as sufficient to establish the presence of low back disorders causing low back pain (Raskin et al. 1976, Wexler 1981, and Breckler 1980). Thermography has been used for differential diagnosis of reflex sympathetic dystrophy (Uematsu et al. 1981), rheumatic diseases (Ring 1975), insensitive feet and stumps (Bergtholdt and Brand 1975), diabetic myopathies (Cronin 1975), chronic pain of unknown origin (Hendler, Uematsu, and Long 1982); and as a screen for appropriate amputation level, breast cancer, and cardiovascular disease (Winsor and Winsor 1975), and referred pain (Hobbins 1982). Although no excellent, blinded, comparative technique studies have been performed, thermography has recently been accepted by the AMA as a valid method for assisting in the diagnosis of many conditions and as a primary method for confirming presence of reflex sympathetic dystrophy. Papers such as those by Goodman et al (1985) and Devereaux et al (1984) indicate that thermography is consistently of value in diagnosing stress fractures when compared with results of bone scans (the gold standard for demonstrating the presence of stress fractures). The technique is rapidly gaining wide acceptance for this use.

We have been using videothermography for over six years in a clinical research setting and have found that it is consistently reliable for

detecting lower extremity pain problems (Sherman et al 1987). We are currently using thermography to elucidate mechanisms through which phantom limb and body pain are manifested (Sherman 1984, Sherman et al 1986, Sherman et al 1987) and as part of an evaluation of new methods for diagnosis of low back pain (Funded VA merit Review) and lower limb pain. We feel that thermography can grow to be a powerful tool in aiding the early detection and evaluation of status for many disorders which have changes in near surface blood flow among their manifestations.

Typical thermographic studies of chronic pain patients usually either follow one or two subjects through a series of evaluations (Sherman 1984) or show the results of one evaluation for a small group of patients with similar diagnoses (Sherman et al 1986). Unfortunately, virtually all articles on the use of thermography for evaluation of chronic pain are very similar in spite of the number of years the technique has been in use and the extensive claims made for its efficacy in detection and demonstration of various pain syndromes discussed above. Other than our own work (e.g. Sherman et al 1987), We have not been able to locate any blind, controlled studies in which such variables as intrasubject change with both time and pain intensity were taken into account. Uematsu is the leading investigator and reviewer in this field (1976) and has published papers (Uematsu 1985, Uematsu et al 1988) in which the stability of temperature differences in paired extremities are compared. Green et al (1986) found a five percent false positive rate when three blinded thermographers evaluated thermograms of 100 normal subjects. Feldman and Nickoloff (1984) have published the first major set of thermographic standards for normal peoples' upper backs and arms we are aware of. Although subjects were thermographed only once, the study was large enough to permit definition of the expected range of normal but not expected intrasubject variability. Their paper discusses asymmetries and lists other thermographic studies using normal controls. Harway (1986) has discussed some of the methodological issues involved in making good thermographic recordings of the extremities. His paper summarizes the work in this area to date.

Parr et al. (1985) followed Raynaud's syndrome subjects over time. Drummond and Lance (1984) took sequential pictures of cluster headache patients through the course of a headache and have data on the same patients both when in pain and when pain free. This method of gathering data contrasts with the study of the same disorder by Kudrow (1985) who used large numbers of subjects observed once to gather significant information. Both of these studies provide excellent data. However, they make use of a technique which has not really been demonstrated to be sufficiently free of methodological problems to insure that the data are replicable and reflective of underlying physiological parameters. In short, there does not seem to be more than tantalizing evidence that thermography is a valuable clinical technique for evaluation of pain. The proposed studies will fill virtually all of the gaps in determining whether

thermography is a valuable tool for predicting onset of lower limb problems and detecting stress fractures.

BODY:

a. Overview: The basic structure of the program was presented in the introduction and is illustrated in Figure One on the next page.

b. Subjects:

(1) Number, age, source, and sex: The subjects will be soldiers just entering basic training at Ft. Sill and soldiers who are non-trainee patients at FAMC. Our pilot studies with soldiers indicate that almost all experiencing pain in the lower extremities will show abnormal thermograms, so the number of subjects will be predicated on the need to establish a rate of false positives and negatives (sensitivity of the technique). We will not be able to predict exactly how many subjects will be required until power analysis techniques are applied to initial data. However, we do know from our pilot data that no less than 100 subjects actually reporting pain in each of the three study areas could be useful in establishing sensitivity. For study one, since a minimum of twenty percent of trainees experience pain in these areas which is not due to obvious trauma, and each initial training battery has about 180 trainees, we will have to screen a minimum of 9 training batteries before training begins to insure that sufficient trainees subsequently report to health clinics for treatment of pain in the lower extremities which occurred during training. Based on our and others' experience in soliciting participation in minimal risk studies, we anticipate that a minimum of 95% of the trainees will agree to participate in the study. The number of batteries screened may have to be increased to ten if the number of trainees agreeing to participate falls substantially below this rate. This will not effect the total number of subjects participating in the study. This will require a minimum of one year with the likely requirement for continued data gathering and reduction for a second year if we use one thermograph. This fits well with the availability of our professional resources. For study two, Our pilot data indicates that although 100 subjects would be sufficient to establish the efficiency of the technique, the need to clearly differentiate between the results of three heat sensing techniques as well as between relatively physically stable soldiers at FAMC and relatively physically labile trainees at Ft. Sill will require an additional hundred subjects and fifty controls from each site. The subjects will be male and female soldiers between the ages of 18 and 40.

FIGURE ONE — STRUCTURE OF THE PROGRAM

USE OF BODY SURFACE HEAT PATTERNS FOR PREDICTING AND EVALUATING ACUTE LOWER EXTREMITY PAIN AMONG SOLDERS

STUDY ONE
Predictive efficiency of thermography for lower limb injuries

1,620 trainees in 9 training batteries asked to participate as they arrive during fill week.

baseline one - performed as trainees arrive and are waiting for final assignment to training.

baseline two - performed at the end of fill week.

soldiers who never report to sick call: normative data base : soldiers reporting to sick call for any reason

200 trainees not attending sick call for lower limb pain or trauma act as controls for lower limb pain group

all trainees attending sick call due to non-traumatic lower limb pain

suspect stress fracture? yes / no

controls in study one. thermograms & lower limb exam at each visit orthopedic surgeon, 50 of controls simultaneously act as controls for study two.

thermograms, lower limb exam by podiatrist & videothermograms, pain diagram, biomechanical evaluation, and all required tests at each visit.

STUDY TWO
Efficiency of thermography for diagnosis of stress fractures in the lower limbs

a. STRESS FRACTURE SUSPECTS: 200 patients suspected of having stress fractures (approximately 150 soldiers at FAMC in stable level of physical condition and 50 trainees at Ft. Sill to provide a comparison of stable vs. changing physical condition)

2 sessions approximately one week apart: contact thermography, videothermography, heat scan, and physical exams by an orthopedic surgeon and a podiatrist.
+
one X-ray & bone scan

b. 100 CONTROLS:
(1) 50 normal volunteers from the same groups as the "physically stable" stress fracture group at FAMC
(2) 50 controls for the "physically labile" trainees drawn from the

Two sessions approximately one week apart:

contact thermograms, heat scan, lower limb physical exam as above. NO x-rays or bone scans.

(2) Inclusion and exclusion criteria: For trainees at Ft. Sill, the only entrance criterion is willingness to participate in the study while the only exclusion criterion is being in overall good health. For soldiers at FAMC, the entrance criteria are (a) being within the age limits, (c) not being a trainee, and (c) being suspected of having a NEW stress fracture.
The exclusion criteria are (a) having any significant medical problem other than the suspected stress fracture, (b) not being relatively physically stable, (c) having a skin problem which would preclude use of contact thermography, and (d) having a history of stress fractures.

(3) Subject identification: During participation, subjects will be identified by their names and social security numbers because experimental data have to be related to results of standard medical tests. However, all records relating experimental results to subjects' names and numbers will be kept locked in a file cabinet at each participating site. At the end of participation, a code number will replace the names and social security numbers on each record. The key relating the code to the subjects' names and social security numbers will be kept locked in the PIs' files. This is necessary in case valuable clinical data is produced by the study which should be shared with the subjects.

(4) Subject assessment: see the following evaluation section.

(5) Risk to benefit ratio: maximum benefit to minimum risk. There are no risks involved in having heat recordings made of the intact skin surface. All other tests are required by the physical condition and would be performed regardless of whether the subject was participating in a study. At Fort Sill, no unit training time will be wasted as all evaluations will be performed during the three day initial in-processing period or while waiting for appointments at the troop medical clinic. At FAMC, The subjects' only contact with research evaluations will be two ten minute, harmless recording sessions. All other tests and examinations are standard at both sites.

(6) Precautions, corrective actions, and special care: none.

b. Project medications: none.

c. Evaluations:

(1) Thermographic recordings for study one: Subjects will be recorded in large groups in a temperature regulated environment with drafts reduced to a minimum. Subjects will be barefoot and wearing short pants. Each will wait for the session while laying down with the bottom of the feet in the air for a minimum of 15 minutes to allow body temperature to stabilize. Smoking and use of caffeine and alcohol are normally prohibited for several hours before a thermogram because they effect near surface

blood flow. Control of these factors during the baseline sessions is largely beyond our control. However, trainees are normally not permitted to smoke or drink alcoholic beverages and we will request that they not use caffeine for an hour before the baseline and medical clinic sessions. Trainees who are secretly smoking or drinking alcohol are not likely to stop at our request. We do not feel that lack of control of these factors will invalidate the study because there would be the same lack of control when the technique is actually used to predict which trainees will are more likely to report lower limb dysfunctions. Privacy is not an issue as only the legs are exposed. At the end of the equilibration period, the bottom of the feet will be thermographed using an Inframetrics model 600M videothermograph. The instrument is capable of resolving temperature differences of 0.1 degrees Celsius and is sensitive to the heat created by blood flow patterns (spectral range of 8 - 12 micrometers) up to 1.5 cm. deep. Thus, all heat sources in a structure as thin as a foot would be visible but only a diffuse reflection of heat sources deep in the leg are directly visible. The device produces either grey tone or color images on a television screen. The video images are recorded on videotape and Polaroid photographs for later computer analysis at FAMC. Sensitivity is adjusted so that the computer can differentiate between 0.1 degree C levels. However, during the actual analysis, differences of less than 0.5 degrees will be discounted as they are within the range of normal variation (see the introduction). The model 600M thermograph has an internal temperature reference so day-to-day changes in temperature can be objectively related. After the bottom of the feet are thermographed, the subject will stand up and the tops of the feet and the front and side of the legs will be thermographed while the back of the legs are equilibrating. The backs of the legs will be thermographed after all standard tests are completed so the back of the legs can be equilibrating during the tests. Similar thermographic recordings will be made of all recruits reporting to sick call with non-traumatic lower extremity pain at each visit while they are waiting to be seen. As detailed in the introduction, a series of recruits reporting to sick call without lower extremity problems will be recorded in the same way.

(2) Body heat evaluations for study two: The videothermography will be performed exactly as stated for study one. Sessions will be in a temperature controlled environment and subjects will be prohibited from smoking and using caffeine for two hours prior to the test. Subjects will be prohibited from using alcohol for twelve hours prior to the test. After each view is taken, the beam thermometer will be run along the surface just photographed by the videothermograph and measurements will be taken along the distal-proximal midline of the surface at approximately 2.5 cm intervals. After the beam thermometer has been run across the surface, the contact thermograph will be pressed against the surface and a grey-tone

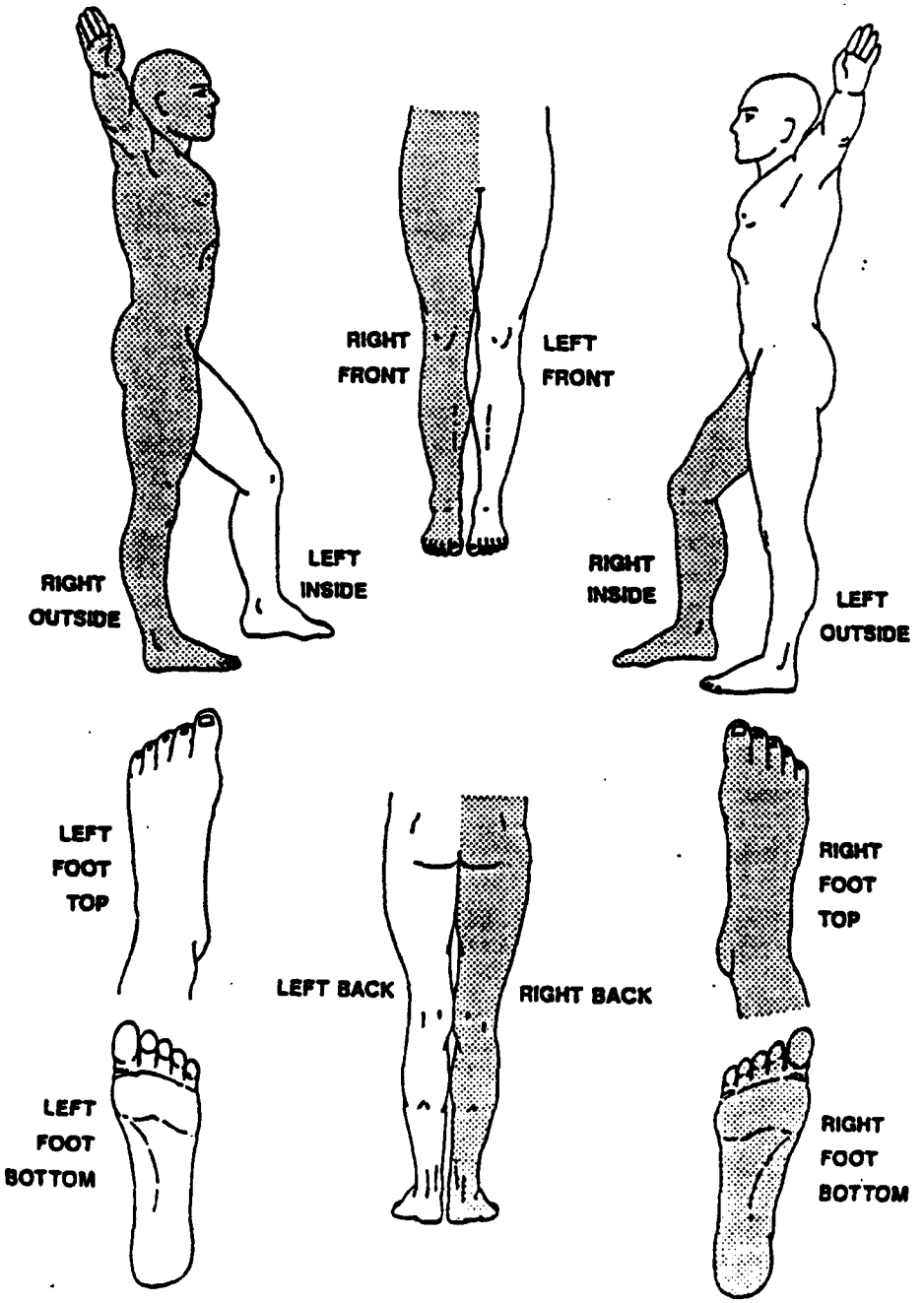
videotape will be made of the image produced. This will permit computer comparison of the images produced by the contact and video thermographs.

(3) Other evaluations: All other evaluations for both studies are the standard, clinical, podiscopic, and biomechanical evaluations required for evaluation of pain in the lower extremities. The podiscopic evaluations will be filmed so the data can be directly compared to the thermographic data. Every subject in study two and during the "sick call" phase of participation in study one will be examined by according to criteria set by an orthopedic surgeon and a podiatrist and will fill in a diagram (Figure Two on the next page) of the lower extremities indicating location, description, and intensity of the pain. Every subject suspected of having a stress fracture will have both x-rays and a bone scan. These tests are now standard for this condition at both FAMC and Ft. Sill so are not part of the experimental evaluation.

(4) Schedule of evaluations and interrelationships between the two studies: See the figure for details of subject assignment and scheduling. The key interrelationship between the studies is that when trainees at Ft. Sill who are participating in study one (predictive value of thermography) and are suspected of having stress fractures, will also participate in study two (thermographic evaluation of stress fractures). Fifty of the trainee control subjects from study one will also serve as

FIGURE TWO LOWER EXTREMITY DIAGRAM

Trainees reporting lower extremity pain indicate the location, intensity, and description of their lower extremity pain on the diagram each time they report for sick call.



controls for the trainees in the stress fracture study. All of the Ft. Sill trainees in the stress fracture study will be recorded at Ft. Sill so a contact thermograph and a heat beam meter will be located at Ft. Sill as well as at FAMC.

Because training batteries are filled fairly quickly, the baseline thermograms for the entire battery will have to be taken over a period of only a few days. The "half time" thermography technician will work full time during the period that a battery is filling. There will then be about a week when few trainees report for sick call from that battery with appropriate disorders so the technician will be off for a week to make up for working full time the previous week. The technician will then work half time at the TMC to cover morning sick call for the battery until its members graduate. The technician will not perform thermographic recordings of trainees having traumatic injuries to the lower extremities but will note who they are so their baseline thermograms can be examined. At that time, the cycle of recordings will be repeated.

d. Data Evaluation:

(1) Thermographic data: All data will be reduced and analyzed using the thermal computer interface and program as well as the statistical programs and resources at FAMC. Intrasubject thermograms of the lower limbs including the feet are compared with adjacent and non-painful contralateral areas to determine differences in pattern of temperature and in the actual temperature at several points. Intersession differences are calculated from actual temperature differences between painful and pain free areas using a special computer program at FAMC. Half a degree is the amount of normal variability, so none of the data is considered to include reliable differences unless differences in temperature greater than half a degree are consistently present. Intersubject comparisons are made the same way. Each thermogram is rated by the computer as normal or abnormal depending on whether significant (greater than 0.5 degrees) asymmetries are found. The heat beam readings are evaluated the same way. Thus, a heat beam recording is considered abnormal if corresponding readings from the painful and non-painful sides are more than half a degree different.

(2) Statistical associations: For study one, the two baseline thermograms performed on each trainee will be compared with each other to establish the normal level of variability for the individual. All of the baseline thermograms will be evaluated to establish the rate of "positive" findings and normal variability in an asymptomatic group. When trainees come to sick call for non-traumatic leg pain, their thermograms will be compared with their baseline thermograms and subsequent thermograms taken at subsequent visits to sick call to evaluate individual changes from baseline and changes as the problem resolves. The thermograms will be divided into groups depending on the final diagnosis for each trainee and

an attempt will be made to identify characteristics for each diagnosis. If the attempt appears successful based on computer identification of patterns, a group of five raters who are not aware of the diagnoses or of which set of thermograms relates to which diagnosis will attempt to sort individual thermograms into categories. See Sherman et al, 1987 for a detailed explanation of this technique and the associated statistical analysis.

Thermograms of trainees reporting to sick call for non-pain and trauma related problems (e.g. colds) will be related to their baselines to establish the expected differences due to training. Their thermograms will be related to those of the above trainees reporting lower leg pain to ascertain group differences. If there are no differences between the baseline thermograms of the trainees being seen for colds and etc. and those not reporting to sick call at all, the baseline thermograms of all trainees not having lower extremity pain will be considered equivalent in the analysis. The rate of false positives for the asymptomatic population will be calculated from the thermograms taken of these clinic controls. The rate of false positives and negatives for the symptomatic trainees will be calculated based on relationships with standard tests and reports of pain.

The efficiency of a test is frequently defined as the percentage of patients correctly classified as diseased or healthy (number of true positives plus true negatives divided by the number of tests times 100). We use efficiency as a measure of test effectiveness because it combines sensitivity and specificity in one measure. It is extremely sensitive to both false positives and false negatives which are of great interest to any evaluation of thermography. When relationships between report of pain and heat are evaluated, nonparametric Spearman's rank order correlation are used. A rank order test is required because pain ratings are entirely subjective and there is no way to be sure that the difference in pain between a zero and one rating is the same amount of difference between a four and a five. Nor is there any reason to think that any two people would either rate their pain the same or that the amount of change for one person would be rated exactly the same way an identical change would be rated by someone else. In other words, a "two" for one person could be a "five" for someone else. If both experienced the same degree of change in pain intensity, one might rate the change as from two to three while the other might rate the change as being from five to eight. For the same reasons, there would be virtually no validity to comparing pain - temperature change correlations between people. As this study is attempting to establish the predictive value of thermography, the most important tests are the non-parametric correlations between heat patterns, type and intensity of disorder reported, pain intensity and duration, and time lost from training. Of far less importance are the co-variate analyses and correlations which will factor out physical problems, height - weight - body fat ratios, location, description, and intensity of pain, and foot

characteristics recorded during the examinations. Knowing how these factors effect the data may help explain variability in the key correlations and thus make the results more powerful but will not make them more meaningful. This is because there would be little value to screening baseline thermograms if a full battery of examinations of far greater than the usual detail have to performed also for the thermograms to be interpreted. In other words, the thermograms will have to stand as alone as possible for them to be valuable predictive tools.

The baseline thermograms of trainees having traumatic injuries to the lower extremities will be related to the other physical examinations done during the baseline period and to the thermograms of trainees who did not report lower extremity pain or trauma to determine whether the thermograms were different in any way.

For study two, the rate of false positives and negatives for each heat sensing technique will be calculated as described above by comparing the results of the particular heat test for a group of subjects with the results of the individuals' bone scans (our "gold standard"). This calculation will give the efficiency of each thermographic technique. The efficiencies of the three techniques and the rates of true positive findings will be compared using an analysis of variance. X-ray results will be compared with bone scans the same way. The true positive heat thermograms will be analyzed in detail to identify key sites where the heat beam sensor might be applied to produce replicable, positive identifications.

All data will be kept on computer disk and/or in hard copy for 15 years after completion of the study. The key relating the data to specific individuals will be kept locked in the PIs' files until it is destroyed at the completion of the study.

RESULTS TO DATE:

a. Funding became available in November, 1989 and, after numerous delays already detailed in prior reports, staff were finally hired by June so the project has actually been in progress for only seven months.

b. Results of project one to date:

(1) Subjects: Data from 247 recruits has been reduced. Thirty-four of them developed lower limb pain problems and had repeat thermograms done in the TMC.

(2) Baseline: of the 247 baseline recordings, only 121 were within accepted normal limits. Ninety-four had abnormalities on the bottom of the feet. Of these, fifty-six had other lower limb abnormalities as well. Thirty-two had abnormalities in other areas of the lower limbs but normal

feet.

(3) Clinic Visits: Nine "control" subjects who visited the clinic due to problems not related to the lower limbs or to circulation (e.g. colds) were videothermographed. Of the five that produced abnormal thermograms, all had produced abnormal ones during the baseline. Of the four producing normal ones, two had been abnormal during the baseline period.
Four subjects were diagnosed as having pattelo-femoral joint syndrome. All showed abnormal thermograms during the evaluation. Three had already shown abnormal thermograms during the baseline evaluation. Two subjects were evaluated for potential stress fractures. One produced a normal thermogram and one an abnormal one. The same pattern was present during the baseline. Three subjects were seen for general foot pain. All were abnormal when seen in the clinic. One had been abnormal at the baseline. Of nine subjects seen for knee pain, six produced abnormal thermograms. Of these, four were already asymmetrical during the baseline. Of the three producing normal thermograms, one had produced an asymmetrical thermogram during the baseline period. Two subjects were seen for plantar fasciitis. Both produced abnormal thermograms. One had been abnormal during the baseline period. One subject was seen for heel blisters. The thermograms were abnormal both during the baseline and the clinic visit. One subject was seen for tendonitis who produced normal thermograms at both the baseline and the clinic visit.

c. Results of project two to date:

(1) Subjects: Forty-five subjects were recorded at total of 109 times. Eleven had knee pain, nine had pain throughout most of one leg in combination with back pain, four had stress fractures, three had RSD, four had peripheral nerve damage (sciatic, peroneal, sural, mixed with lower limb weakness), two ankle pain, two plantar warts, and two generalized leg pain with no know etiology. The others were pain free controls.

(2) Comparative test routine and rationale:
Three forms of thermography were compared: video thermography, contact thermography, and surface temperatures taken by an infrared thermometer. Video thermography is the state of the art in thermography and provides detailed and accurate picture of the heat that reflects off a body. This was considered the standard by which the other two forms of thermography were measured.
The subjects were first video thermographed, then had surface temperatures taken, and lastly had contact thermograms taken. The procedures were done in this order to eliminated any false patterns that might have been produced by the contact thermograph since it involves holding an inflated pillow against the skin for up to 30 seconds. Video thermography involves no physical contact to the patient. This prevents the apparatus itself from influencing the results and eliminates the need to take additional

infectious disease precautions. The field of vision of the video thermograph camera allows a small area to be viewed, such as a patient's toes only, or an area the size of an entire leg can be viewed. This allows one to scan a large area readily or to observe a small area for detailed thermographic patterns. The videothermograms taken are continuously videotaped so that the data observed is always recorded. The video thermograph machine provides a color gradient at the base of the video screen that show what color corresponds to what temperature. The color gradient can be adjusted so that each variation in color represents a temperature difference of 0.25 degrees C. The machine is accurate to 0.1 degrees C and can give a temperature of a specific area being thermographed. The infrared thermometer was used with a modified tip so that the thermometer would constantly be held a uniform distance of about 1 Cm. over the skin's surface. Temperatures were taken of a point on one side of the body, and then immediately the temperature was taken at the corresponding area of the body. The temperatures were then recorded on a body diagram. The temperature differences observed with this method are very similar to the temperature differences observed with the video thermograph, but the following may account for why some temperature differences may vary. The video thermograph camera is like a video camera and projects everything in a two dimensional plain. For areas such as the top of the feet that were not thermographed flat to the camera due to their shape, the temperatures observed with the video thermograph may be different than those taken with an infrared thermometer. This is because the infrared thermometer is always held the same distance from the skin with no angle. The video thermograph shows a very detailed picture of exactly where temperatures are observed. This makes it very easy for the thermographer to concentrate on the specific areas that are effected. The exact point at which the temperature difference is the greatest can easily be detected and recorded. With the infrared thermometer, temperatures were taken at set areas and may not have always reflected the point where the greatest temperature could be observed. This may have diminished the temperature differences observed with the surface temperatures.

There were standard areas where the surface temperatures were always taken. The areas chosen allowed us to map out a relatively detailed picture of heat patterns of the leg and foot area. With more attention to the task of developing a set method for taking surface temperatures of lower limbs, this form of thermography could be exceptionally useful, in the assessment of lower limb pain. The contact thermograph system is a series of flexible pillow detectors containing crystals that change color to correspond to a specific temperature. The pillow has a transparent window, allowing the thermographic image to be observed and photographed. The contact thermograph system has eight detector pillows so that thermographic images of a wide range of temperatures can be recorded.

Similar to the video thermograph, the contact thermograph has a color scale on each window that states what temperature each color corresponds to. This is determined by calibration at the manufacturer. Temperature differences that are required to produce the various colors do not occur in standard set increments, but the differences between each color can vary from 0.3 degrees C to 1.1 degrees C. The manufacturer claims this method is accurate to within 0.2 degrees C. Since beginning the study we have had to have the system recalibrated once. This is because the crystals will "drift" and the temperature required to produce a specific color can change over time. The procedure of taking a thermograph with this method involves holding the detector against the patient's skin for about 20 seconds. Then the detector is pulled away from the patient to flatten the pillows surface so that the image can be photographed. The thermographic image changes as the detector is taken off the patient's body. If there is a camera malfunction or a time delay the picture will change or be completely lost. Since the pillow detector had to be in a flat position to be photographed without glare, the image appears in a slightly distorted shape, thus the thermographic information may also be distorted. There were patients that were seen with a condition that was too painful for the patient to withstand even the light pressure of the detector against the skin preventing us from being able to use the contact thermograph. Also, if a patient had an open skin wound, rash, or a fresh surgery scar this procedure was not performed. At the early stages of the study we tried to get a contact thermograph of the entire leg and foot area. The size of the individual pillow detectors is about 12 inches by 9 inches. Due to the shape of the leg and foot areas, only a fraction of the area can be thermographed at a given moment. We found that the edges of the detectors would cool the skin and produce a cold line across the skin in the areas that it touched. This prevented us from being able to thermograph the entire leg area. This method alone can not give a thorough thermographic image of the lower limb area.

A specific pillow is chosen so that ideally the majority of the thermographic image should appear in the center of the pillow's temperature range. This was often difficult if not impossible. Often a patient's body would be to cold to be observed in the range of even the pillow with the lowest temperature detecting ability. The leg and foot areas often have temperature differences that are greater than a few degrees. With some patient's, the left and the right side could not be observed with the same pillow. This tells us that there is a temperature difference but does not allow us to determine what that difference is. Although the pillows are calibrated to match up a specific color to its assigned temperature, often the same body area would produce a different temperature reading with the use of a different pillow. This may not be that critical of a factor since relative differences from right to left are what we are trying to determine. However, since the study to date has shown that temperature

differences may occur in the lower limbs that are too great to fit in the range of a single detector, this method is not an effective or accurate diagnostic measurement. The detector pillows needed to be inflated in order to produce the thermographic image. The pillows are not air tight and lose air quickly and constantly need to be re-inflated. The system comes with warnings not to over inflate the detector pillows, as this would permanently damage their capabilities. The system does not have any pressure gauges or other measurements to determine what the optimal air pressure should be inside the detector pillows.
Certain areas of the lower limbs could fit within the field measured by the detectors such as the bottom of the feet. If both the right and left feet are relatively symmetrical in temperature, and there was not much variability in the temperature of the foot from heel to toe, then a relatively clear picture could be obtained. The thermographic trends observed when an adequate thermographic image was obtained followed the trends seen with the other forms of thermography. Contact thermography may be most useful at measuring thermographic patterns qualitatively on a small flat surface of the body.

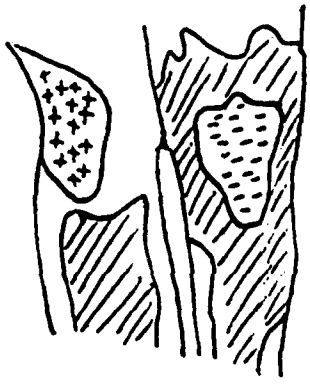
(3) Results of comparisons of the three techniques:
The videothermograph was consistently simple to use and could visualize all required areas. For those regions upon which the pillow could be pressed, the contact thermograph always showed a difference when the videothermograph showed one. However, the actual amount of difference was usually not calculable to the problems discussed above. Thus, the device could be used to pick up problems but not to track their progress across sessions. The infrared thermometer always showed the same temperatures as the videothermograph and could measure the temperature virtually instantly anywhere on the limbs with equal ease. It has none of the problems which make the contact thermograph cumbersome and ineffective. However, it only reads one temperature at a time rather than producing a multitemperature picture of the limb. In order to use the temperatures generated by the thermometer, many measurements must be made on each limb. The measurements must be made of exactly paired areas of the limbs or the measurements are useless. An illustration of temperature differences is produced by noting differences onto a picture of a limb which is overlaid by a grid. This takes longer than taking a videothermogram but about the same amount of time as it takes to use the contact thermograph. This is because the contact thermograph's pillows have to be changed and adjusted frequently. The following figures illustrate typical problems which arise when attempting to utilize the contact thermograph and provide a comparison of its output to that of the videothermograph.

FIGURE THREE

INTERPILLOW CALIBRATION PROBLEMS WHICH PREVENT USE OF CONTACT THERMOGRAMS FOR DETERMINING ABSOLUTE DIFFERENCES BETWEEN LIMBS WHICH ARE OF TOO DIFFERENT TEMPERATURES TO BE VISUALIZED ON THE SAME PILLOW

The color polaroid pictures produced by the thermographs have been traced so that their patterns will show on xeroxed copies of this report. Different temperatures are shown by different patterns of crosshatching. Significant asymmetries are shown when paired areas of the limbs have different patterns.

Videothermogram showing both limbs. The areas shown by pluses and minuses are 5.4 degrees different. Differences of this magnitude are common and changes must be tracked in order to determine progress toward resolution of the problem.



Contact thermograms taken of the same limbs moments later. Two pillows had to be used to get both limbs into range of the pillows. The important point here is that the limb shown at the left of each drawing is in range for both pillows. It shows as 29.1 degrees in the left picture (the Xs) and as 29.7 degrees in the right picture (the dots). This common problem means that we can not determine the actual difference between two limbs when the two have to be visualized on different pillows.

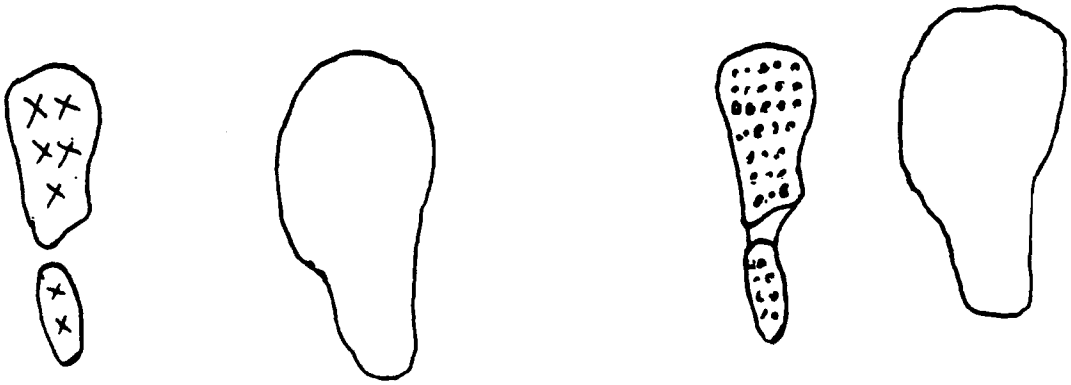


FIGURE FOUR

EFFECT OF THE CONTACT THERMOGRAPH FRAME
ON ABILITY TO PROPERLY VISUALIZE AREAS

The redrawn videothermogram on the left shows a crucial area in crosshatching which happened to be about the same size as the dark marks left on the skin by the frame of the contact thermograph shown on the right. These frame marks prevent proper visualization of an entire limb without waiting for the marks to fade over a period of about ten minutes. This makes the evaluation take so long that it is impractical.

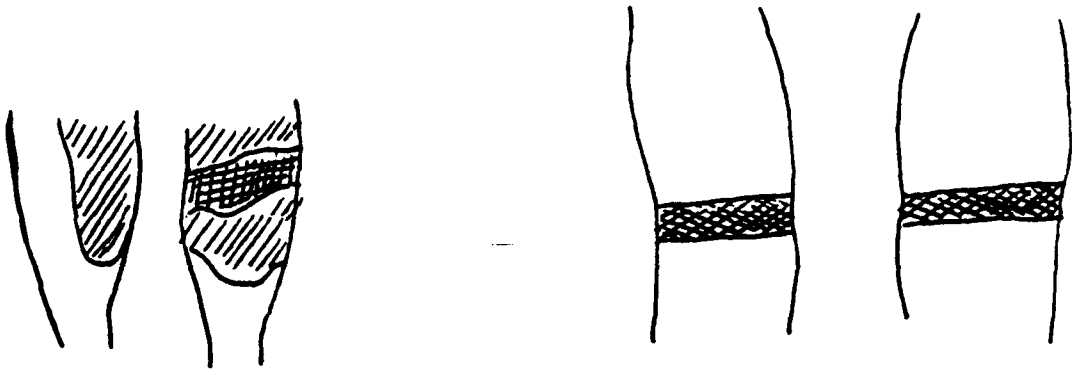
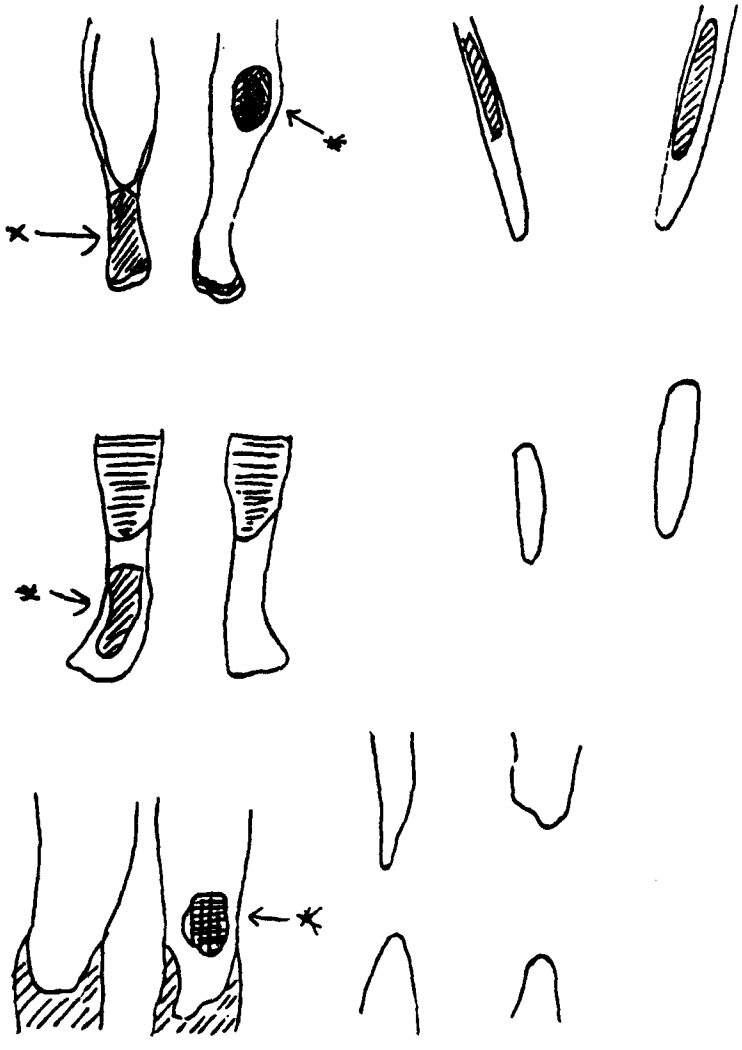


FIGURE FIVE

EFFECT OF THE CONTACT THERMOGRAPH'S INABILITY TO VISUALIZE
HIGHLY CURVED SURFACES
ON ITS ABILITY TO DETECT CRITICAL ASYMMETRIES

The redrawn videothermograms on the left show the critical areas of asymmetry where marks on one limb are different from those on the pair in the same area. Note that the contact thermograph failed to make images of the critical areas because the curve was too great for the pillow to wrap around or get into. The top two images are of the front of the legs with the front of the ankles and sides of the legs missing in the contact thermograms. The bottom drawing is of the back of the legs with the backs of the knees missing in the contact thermographic views.



CONCLUSIONS:

a. Conclusions based on data gathered to date:

(1) Study One: There is a strong trend toward asymmetrical thermograms produced during the baseline predicting asymmetrical thermograms at clinic visits. However, insufficient subjects have participated to be able to predict which patterns are likely to predict that specific trainees are likely to experience problems during their training. The unexpectedly high rate of abnormal thermograms of the feet produced during the baseline (relative to similar controls) indicates that either these trainees are unusual or that they are doing something to themselves just before coming on active duty. Discussions with local recruiters and with training personnel indicate that many recruits try to get into shape for basic training by doing vigorous exercises to which they are not accustomed starting one or two weeks prior to leaving for basic training. This is not enough to do them any real good but would produce the abnormal patterns we are seeing. We will test this hypothesis during the second year of the study as described below.

(2) Study Two: The contact thermograph was a very surprising disappointment. It is very poorly constructed and cumbersome or impossible to use as required. It can not visualize important areas which have greatly curved surfaces such as the front of the ankles and the back of the knees. Although it is initially enticing to see an apparent image of the extremity's heat produced on a screen, the limitations of that image make it useless for the Army's needs both in the field and in fixed facilities. Due to the very limited number of degrees each pillow is sensitive to, most of the image does not appear. Neither of our sets of contact thermogram pillows are properly calibrated so the readings from one pillow can not be related to the readings on the one above or bellow it along the temperature range. This means that no absolute difference between two limbs can be generated in the frequent case where the temperatures of the limbs are so different that each has to be visualized using a different pillow. The infrared thermometer costs only a few hundred dollars and will probably be available at each field site since it can take body temperatures virtually instantly without risking contamination of the instrument by touching the patient. We are able to produce a picture of temperature asymmetries using this device as quickly as can be done using the contact thermograph. The difference is that differences between the limbs must be noted on a picture of the subject's limb rather than just referring to a photograph of an image. However, the notations produce an accurate assessment of the asymmetries while the contact thermograms just give a vague notion of problems at best. We will spend much of the study's second year developing ways to make a pectoral grid system which can be used by untrained personnel to produce accurate temperature evaluations of the lower limbs

within five minutes.

b. Plan for second year of project: We are one month into the project's second year. We will continue recording trainees as they arrive for basic training and when they come to the TMC. However, we will also record 100 similar people at the MEPS station when they have their physical examinations up to six months before they come on active duty as part of the delayed entry program. We have contacted the MEP command for permission to perform the study. This will give us an idea of whether our trainees are actually an abnormal subgroup of the general population or whether they are damaging themselves in an unsuccessful effort to prepare for the rigors of basic training. The additional work caused by the unexpectedly high rate of abnormal thermograms and the need to do a project at a MEP station means that we have to bring our half time technician at Ft. Sill up to 3/4 time. This will cost $3,440. If the current budget can not accommodate this increase, we will send a separate request for additional funds. These funds are available in the current budget because a second project for Ft. Sill has recently been funded which provides funding for TDYs between Ft. Sill and FAMC. We will combine the trips to save money.
We will change our in laboratory procedures so that the infrared thermometer is used prior to taking videothermograms of the subjects' limbs and will not use the contact thermograph at all. As patterns of clinical interest are at least three cm square, we will develop a grid pattern having pores of this size which can be used by untrained personnel to pick up all important asymmetries using the infrared thermometer. Results will be checked with the videothermograph to determine whether any important asymmetries are missed. If the thermometer can be used with a grid to produce accurate assessments in an evaluation requiring less than five minutes, we will recommend that this procedure be adopted for all field TMCs.

c. Plan for follow-on project (increase in scope): As stated in the initial funding request, this project was originally conceptualized and approved by HSC as having two parts. The first part is the one currently funded by MRDC. We have waited until determining whether the first part would be successful prior to proposing the second part to MRDC. The second part is actually a combination of two projects (again). We will continue working with trainees at Ft. Sill but will use the information from those baseline thermograms which the first phase show to be highly predictive of development of specific problems to institute preventive measures for those trainees showing the patterns. We will then determine the resulting change in rates of unit debilitation. The straightforward methodology for this study will be somewhat complicated because we also need to use the data from the baseline thermograms as part of a study in which we will give every other training battery inserts for their combat boots and sneakers.

We will determine whether the batteries receiving the inserts have less injuries, less lost time due to clinic visits, better scores on their PT tests, and less abnormal heat patterns then do batteries not receiving the inserts.
The other project in the follow-on study will take place at FAMC. It is designed to determine whether all fixed medical facilities should have a videothermograph available to help assess and objectively track the progress toward resolution (or otherwise) of lower limb syndromes which the videothermograph is shown to be sensitive to during phase one.
As this is intended to be a contiguous follow-on to the currently funded first phase of the study, we propose to begin it in January. As recommended by staff at RADII, a full protocol describing the program will be submitted during the next several months. We hope funding will be contiguous so staff do not have to be rehired. We can not perform this study without continued funding from MRDC.

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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