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**Physiologic and functional responses of MS patients to body cooling  
using commercially available cooling garments**

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Running Head: Body cooling of MS patients

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**TITLE:** Physiologic and functional responses of MS patients to body cooling using commercially available cooling garments

**ABSTRACT: INTRODUCTION:** Personal cooling systems are widely used in industrial and aerospace environments to alleviate thermal stress. Increasingly they are also used by heat sensitive multiple sclerosis (HSMS) patients to relieve symptoms and improve quality of life. There are a variety of cooling systems commercially available to the MS community. However, little information is available regarding the comparative physiological changes produced by routine operation of these various systems. The objective of this study was to document and compare the patient response to two passive cooling vests and one active cooling garment.

**METHODS:** The Life Enhancement Technology, Inc. (LET) lightweight active cooling vest with cap, the MicroClimate Systems (MCS) Change of Phase garment, and the Steele Vest were each used to cool 13 male and 13 female MS subjects (31 to 67 yr.) in this study. The subjects, seated in an upright position at normal room temperature ( $\sim 22^{\circ}\text{C}$ ), were tested with one of the cooling garments. Oral, right and left ear temperatures were logged manually every 5 min. Arm, leg, chest and rectal temperatures; heart rate; and respiration were recorded continuously on a U.F.I., Inc. Biolog ambulatory monitor. Each subject was given a series of subjective and objective evaluation tests before and after cooling. **RESULTS:** The LET and Steele vests test groups had similar, significant ( $P < 0.01$ ) cooling effects on oral and ear canal temperature, which decreased approximately  $0.4^{\circ}\text{C}$ , and  $0.3^{\circ}\text{C}$ , respectively. Core temperature increased (N.S.) with all three vests during cooling. The LET vest produced the coldest ( $P < 0.01$ ) skin temperature. Overall, the LET vest provided the most improvement on subjective and objective performance measures. **DISCUSSION:** These results show that the garment configurations tested do not elicit a similar thermal response in all MS patients. Cooling with the LET active garment configuration resulted in the lowest body temperatures for the MS subjects; cooling with the MCS vest was least effective. For functional responses, the LET test group performed better than the other two vests.

Key Words: Multiple Sclerosis, Cooling Therapy, Thermal Stress, Rehabilitation

## INTRODUCTION:

Multiple Sclerosis (MS) is one of the most debilitating diseases of our time. Estimates say that 350,000 persons in the U.S. are afflicted with MS. The course of MS is highly diverse varying from slow progression without relapses to fast chronic progression in which the patients deteriorate swiftly, becoming highly incapacitated within one to two years. Characteristic symptoms of MS are also diverse and include lassitude, weakness, incoordination, paralysis, mental disturbances, impaired sensation, and disturbances of vision. Manifestation of symptoms varies with environmental conditions, season of the year, and the patient's activities. A very common complaint from MS patients is a decrease in strength and an onset of fatigue concurrent with increases in climatic temperature and/or core temperature.<sup>1</sup>

Several investigators<sup>2-4</sup> have found that cooling the patient is one way to counteract some of the detrimental effects of increased body temperature. Watson<sup>3</sup> reported that decreasing the core temperature  $\sim 0.5$  °C lessened the effects of elevated temperature and reduced the symptoms of MS. Ways of cooling the MS patient include: immersion in cold water, cold showers<sup>3-4</sup>, ice packs<sup>2</sup>, iced drinks, and the use of an artificial cooling system such as a liquid cooling garment (LCG).

The LCG is the result of technical developments associated with the space program and the need for whole body cooling in adverse work environments.<sup>5</sup> It was first used to provide symptomatic relief of MS patients in 1978, by a UCLA neurologist and NASA's scientists. MS patients in that pilot level study improved their physical performance during walking rehabilitation. Since then, several commercial entities have designed, produced, marketed and sold cooling systems to MS patients. These garments have provided a source of relief and a better quality of life for many patients and their caregivers.

There are two types of cooling systems: active and passive ones. Active systems consist of a liquid cooling garment and a portable chiller or heat exchange unit. Coolant is circulated through the LCG to cool the patient. Heat is extracted from the system by recirculating the outlet

of the LCG to a ice cooled heat exchanger. Passive systems use ice packs placed in pockets within a garment or the evaporation of water at room temperature as the heat exchange mediums. However, in the past 20 years, there has been little quantification or documentation of the physiological effects of such garments on MS patients. Cooling therapy has not been widely accepted by the neurological community primarily due to the lack of formally controlled, statistically significant scientific studies that firmly establish the efficacy of the therapy. Until recently there were only a few studies<sup>6-13</sup> in the formal literature that report on cooling of MS patients and in general all of these studies suffer from various flaws in the experimental design or execution. Conflicting results have also been observed with some investigators finding functional benefits and others reporting no such benefits attributable to cooling.

The objectives of this research were: to document the physiologic responses produced by each cooling vest configuration; to compare the effectiveness of the three cooling vest configurations; and to document relative changes in selected measures of physical capability before and after cooling with each of the three vest configurations.

## **METHODS:**

### **Subjects**

This investigation was conducted at the Institute for Neurology and Neuroscience Research (INNR), Hot Springs, AK, Rocky Mountain Multiple Sclerosis Center's Adult Day Enrichment Program (ADEP), Denver, CO, and the National Aeronautics and Space Administration (NASA), Moffett Field, CA. All subjects provided written informed consent in compliance with the guidelines of The Institutional Review Board of St. Joseph's Regional Health Center in Hot Springs, HealthOne Institutional Review Board in Denver and NASA Ames Research Center's Human Research Institutional Review Board.

Each garment test group consisted of 26 MS subjects, 13 male and 13 female, aged 31–67 years. Most of the subjects had a chronic progressive course of MS (Expanded Disability Status Scale = 0-7.5) and stated that they were heat sensitive. Their physical characteristics are reported

in Table I. The control group consisted of 20 healthy subjects, 12 male and 8 female, aged from 21 to 69 years. They were healthy volunteers tested at Ames Research Center.

All subjects were asked to refrain from ingestion of food, caffeine, smoking, or vasoactive drugs prior to being tested. The number of subjects tested in this experiment was determined from a sample size and power analysis,<sup>14</sup> based upon pilot test data, to provide a 75% mean accuracy of the measured physiologic responses to body cooling with  $\alpha = 0.05$ .

## **TABLE I HERE**

### **Experimental design**

Subjects wore lightweight clothing and were seated in an upright position at normal room temperature ( $\sim 22^{\circ}\text{C}$ ) during the following test sequence: 0-30min., control period without cooling (Control); 30-90min., cooling period while wearing a commercial available cooling garment (Cooling); and 90-135 min., recovery without cooling (Recovery). Each MS subject was given a series of subjective and objective evaluation tests before and after cooling.

Oral, right and left ear canal temperatures, and active cooling system parameters (inlet and outlet temperatures, flow rate, and pressure) were obtained and recorded every five min. during the control, cooling, and recovery phases of each test. Forearm, calf, chest and rectal temperatures, heart rate and respiration rate were recorded continuously on a U.F.I., Inc. Biolog ambulatory monitor. Blood pressure of each MS subject was taken in each of the three test periods.

Prior to the beginning of an active garment test period, the LET system was allowed to run until a constant LCG inlet temperature ( $\sim 15.6^{\circ}\text{C}$ ) was recorded, thus establishing a repeatable baseline. After the subjects donned the active garment, the inlet temperature was ramped down to  $\sim 10.0^{\circ}\text{C}$  within 10 min.

### **Physiological measurements**

A Thermoscan, Inc. San Diego, CA, Pro-1 (Model IR-1) hand held infrared thermometer was used to measure right and left ear canal (Tec) temperatures. A Becton Dickinson and Company Model 524034 (Franklin Lakes, NJ) digital thermometer was used to measure oral temperature (Tor). A U.F.I., Inc. (Morro Bay, CA) Biolog ambulatory monitoring system was used to record the subject's body temperatures, heart rate, and respiration during each seated test sequence. Four U.F.I. 1070 temperature transducers were placed on the subject-- one for chest temperature, one for forearm temperature, one for calf temperature, and one for rectal temperature (Tre). Skin (Tsk) and body (Tbd) temperatures were calculated using Burton's formula.<sup>15</sup> A standard Lead I ECG configuration was used to monitor heart rate. Respiration was monitored using an expandable piezoelectric strap placed around the chest. These data were recorded on a Static "Ram Card", then converted and downloaded to a Personal Computer for analysis.

### **Performance testing**

Before and after cooling, the subjects were asked to subjectively assess their energy level, feeling of pain at various locations on the body, feeling of muscle strength, and cognitive ability. The objective evaluation tests, including hand grip strength, cognition, visual acuity, manual dexterity, and range of motion were also given before and after each cooling session.

### **Cooling System**

The Life Enhancement Technologies LET Mark VII (Redwood City, CA) cooling garment has a fitted fluid patch (Flexitherm™) system, circulating a solution of distilled water and propylene glycol. It can cool two hours at an ambient temperature of 18°C. The vest weighs approximately 1.5 lb.; the heat sink weighs approximately 15 lb. The maximum cooling rate exceeds 1200BTU/hr. This unit is a FDA-approved 510K medical device.

The MCS™ system is a pocketed, nylon vest containing four plastic cold packs. The solution in the cold packs freezer at 18°C and can therefore be frozen in a refrigerator instead of in a freezer. This system provides a 'gentle cool' lasting from 1 to 2 hours, depending on the

environment in which it is used and on the activity level of the individual. The system weighs less than 4.5 lb.

The Steele™ system is a pocketed, cotton vest containing five plastic cold packs. The cold packs must be frozen in the freezer. The cold packs can be (and were) encased in an additional nylon case within the pockets to reduce the severity of the cooling, in order to prevent peripheral vasoconstriction and corresponding elevated core temperatures of subjects. This system provides a cooling period, which lasts from 1 to 3 hours, depending on the environment in which it is used and on the activity level of the individual. The system weighs less than 5 lb.

#### **FIGURE 1A-C HERE**

#### **Statistical analysis**

A repeated-measures analysis of variance (ANOVA), followed by a Tukey post hoc statistical test, was used. All statistical tests were performed using the SYSTAT<sup>14</sup> computer program with the level of significance set at  $P < 0.05$ . Statistical comparisons that were not significant at  $P < 0.05$  are denoted using NS.

#### **RESULTS:**

No significant gender differences were found for MS subjects wearing the same cooling garments. Therefore the male and female data were pooled to represent the physiological changes in response to cooling by the various systems in Table IIA-C and Figures 2A-D.

#### **TABLE II A-C HERE**

Because there is a lack of consensus on how much cooling is necessary to effect a clinical benefit in MS patients, and even less consensus on where or how to measure the temperature change, we measured and/or calculated several body temperatures. The first of these is rectal



temperature, which we measured continuously at a depth of 10 cm and the one we believe is most indicative of the temperature of the body 'core'. We also examined oral and ear temperatures, which are more indicative of temperature changes in the head, and are more likely to be influenced by the presence of a cooling cap. We also measured skin temperature on the calf, chest and forearm, and combined those into a volume-weighted average skin temperature. The outer layers of body tissue -- the 'skin' -- if cooled enough, can serve as a heat sink for the internal 'core'. With very cool skin, the body 'core' temperature (i.e. rectal temperature) can continue to decrease even after the external cooling device is removed. Finally, we calculated each subject's average body temperature, a weighted average of skin and rectal temperatures, using the method of Burton<sup>15</sup>.

Figures 2A through 2D illustrate the thermal responses of the MS subjects to the three tested vest configurations as functions experimental time. For oral and ear canal temperature, no significant differences were found for MCS vest test group. The LET active and Steele passive vests produced similar, significant cooling effects on both  $T_{or}$  and  $T_{ec}$ . Decreases ( $P < 0.01$ ) in the average  $T_{or}$  and  $T_{ec}$  were approximately  $0.4^{\circ}\text{C}$ , and  $0.3^{\circ}\text{C}$ , respectively (Fig 2A and 2B).

As shown on Fig. 2C, the average rectal temperature increased with all three vests, but the change was not significant. The  $T_{re}$  of the MCS vest test group increased (NS) during most of the cooling period, and decreased (NS) to control period values by the end of recovery period. However, the  $T_{re}$  of both the LET and Steele vest female test groups decreased ( $P < 0.01$ ) about  $0.25^{\circ}\text{C}$  at the end of the recovery period.

The average calculated skin temperature changes ( $P < 0.01$ ) for both MCS and Steele test groups were similar during cooling (Fig 2D). The Steele vest test group continued to drop ( $P < 0.01$ ) their  $T_{sk}$  toward the end of 45 min. recovery period. The  $T_{sk}$  of LET test group decreased ( $P < 0.01$ ) to  $1.4^{\circ}\text{C}$  at the end of cooling. Upon removal of the garment  $T_{sk}$  increased significantly ( $P < 0.01$ )  $\sim 0.6^{\circ}\text{C}$  by the end of the recovery period.

No significant differences were found for the average body temperature responses of the MCS vest test group. The  $T_{bd}$  decreased ( $P < 0.01$ )  $\sim 0.5^{\circ}\text{C}$  for the LET vest test group at the

end of cooling. Tbd for the Steele vest test group decreased ( $P<0.01$ )  $\sim 0.3^{\circ}\text{C}$  at the end of recovery period.

#### **FIGURE 2 A-D HERE**

Table III shows the various performance measures by number of subjects that improved, remained the same, or degraded after cooling for each of the three vests. The subjective measures (energy level, muscle strength, and cognitive ability) are taken from subject interviews after the cooling period. The remaining indices are measures of both cognitive and physical assessment tests that were given before and after each cooling period.

#### **TABLE III HERE**

Figures 3A-C gives the delta means  $\pm$  S.E. for the performance measures of each vest test group. All of the performance measures except handgrip strength showed no significant difference between male and female subjects. As shown in Fig. 3A, with cooling, grip strength performance improved for MS female subjects wearing the LET active vest ( $P<0.01$ ), and the MCS passive vest ( $P<0.05$ ). Grip strength did not significantly improve for any of the MS male subject vest test group, which is consistent with our previous findings on head and neck cooling<sup>16</sup> of MS patients.

#### **FIGURE 3A-C HERE**

Figure 3B shows the subjective evaluation results of each test group after 60 min. of cooling. Overall, the MS subjects felt that the LET active vest provided the most improvement ( $P<0.01$ ) in their energy level, muscle strength, and cognitive ability. The Steele passive vest provided less improvement ( $P<0.05$ ) during cooling. Figure 3C illustrates the objective

performance measures. Again, the LET active vest produced the most improvement in vision acuity ( $P < 0.05$ ), mini mental test ( $P < 0.01$ ), and motion range evaluation ( $P < 0.01$ ). After cooling, the MS subjects wearing the Microclimate and Steele passive vests, did not significantly improve on most of the objective performance measures except for timed alphabet ( $P < 0.01$ ).

## **DISCUSSION:**

The NASA work published to date on the use of artificial cooling garments on both healthy subjects and MS patients has provided some insight into the causes of some of these varied results. We have found that proper fit of the garment to the individual patient and the use of a garment temperature/time profile that precludes vasoconstriction, caused by the initial contact of a very cold garment with the body surface, are both critical parameters that must be controlled in order to get reproducible results.

No unusual or unexpected results were found during the performance of the above series of experiments. Most of the MS patients found the cooling periods to be a relief and often remarked that they felt less fatigued, could see better, and had more control over their muscular movements. The maximum decrease in rectal temperature observed in any of our experiments was less than  $1.0^{\circ}\text{C}$ .

These results show that the garment configurations tested do not elicit a similar thermal response in all MS patients. There is a great deal of variance among individuals. The LET active garment configuration was most effective in decreasing body temperatures of the MS subjects. The LET active garment system used in this study included a cooling cap, which may account for some of the differences in subject response to the three garments, especially in the oral and ear canal temperature changes. The thermal effect of the Steele passive vests appears to be nearly equivalent to that of the LET active vest. The MCS vest was least effective in decreasing body temperatures of the MS subjects.

Considering all subjects, the various subjective and quantitative assessment measures favor the LET active vest as being the system that provides the most functional benefit to our

subject population, as tested in our protocol. The MCS passive vest and the Steele passive vest were both less effective than the active garment in improving the performance of the MS subjects in this study.

It is difficult to recommend one vest for use by all MS patients; all have characteristics that warrant their use under particular circumstances. An active vest offers more control of the cooling profile used on a subject. This control is useful because there is a large variance among individuals in the amount of external cooling that will induce constriction. When peripheral vessels constrict, blood is shunted to the body core, and core temperature rises. To facilitate nerve impulse conduction in MS patients, we want to lower the temperature of the CNS, not raise it<sup>16</sup>. With an active garment one is able to customize the system-cooling rate for a given subject so that rectal temperature does not increase. This can be accomplished by varying the coolant temperature flowing to the garment, or by decreasing the coolant temperature gradually so as to prevent constriction. With an active system the cooling profile could be optimized for each subject to compensate for individual subject response.

The Steele and MCS passive vests have certain advantages that should be noted. It requires no heat sink or power and weighs less than the active system. It is more portable and easier to use by MS subjects whose manual dexterity or strength is impaired and it also costs less. Unfortunately, the operating temperature of a specific passive vest can not be varied; it is the melting temperature of the fusible compound in the 'ice' packs. This temperature may not be optimal for everyone; it may induce constriction for some, and it may not be cold enough to cool others significantly. One can add insulation to the ice packs so as to provide a gentler cooling, and possibly avoid constriction. One can use the ice packs without insulation to provide a higher cooling rate if needed. All tests of the Steele vest in this investigation were performed using the insulation pouches provided by the manufacturer. As purchased, when compared to the active system, the Steele vest and the MicroClimate vest are relatively inflexible in their temperature range.

**SUMMARY:**

- Oral, ear canal, rectal and skin temperatures of MS subjects wearing the LET active vest decreased the most.

- Oral, ear canal, and rectal temperatures of MS subjects wearing the MCS passive vest were not significantly decreased during any phase of the investigation.

- Oral and ear temperatures are not reliable indicators of changes in core temperature.

- The LET active vest generally produced the greatest improvement on most of the subjective and objective performance measures.

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Table I. Physical characteristics of male and female MS patients (Mean  $\pm$  SD)

Garment	MS subjects	Age(yr.)	Height(cm)	Weight(Kg)
LET	Males (13)	50.1 $\pm$ 8.6	179.3 $\pm$ 5.6	81.0 $\pm$ 9.9
	Females (13)	48.8 $\pm$ 9.7	164.5 $\pm$ 6.5	73.5 $\pm$ 13.4
MCSP	Males (13)	47.4 $\pm$ 6.7	175.8 $\pm$ 9.1	77.8 $\pm$ 14.3
	Females (13)	42.9 $\pm$ 5.3	163.7 $\pm$ 5.5	58.1 $\pm$ 12.2
Steele	Males (13)	44.1 $\pm$ 8.2	179.0 $\pm$ 6.6	86.0 $\pm$ 16.6
	Females (13)	49.7 $\pm$ 11.7	163.7 $\pm$ 5.9	62.8 $\pm$ 11.4

Table IIA. Physiologic responses of MS patients wearing LET active garment

Physiologic Responses:	Control Period (Mean $\pm$ SD)	Delta from Control to End of Cooling	Delta from Control to End of Recovery	Minimum Temperature
Oral Temp. ( $^{\circ}$ C)	36.62 $\pm$ 0.31	-0.21 **	-0.40 **	-0.64 **
Ear Temp. ( $^{\circ}$ C)	36.14 $\pm$ 0.52	-0.09	-0.33 **	-0.52 **
Rectal Temp. ( $^{\circ}$ C)	36.59 $\pm$ 0.95	-0.00	-0.15	-0.25 **
Skin Temp. ( $^{\circ}$ C)	32.64 $\pm$ 1.03	-1.41 **	-0.74 **	-1.57 **
Body Temp. ( $^{\circ}$ C)	35.29 $\pm$ 0.74	-0.46 **	-0.35 **	-0.57 **

\*\* Decrease significantly ( $P < 0.01$ ) different from mean of control value

Table IIB. Physiologic responses of MS patients wearing MCS passive garment

Physiologic Responses:	Control Period (Mean $\pm$ SD)	Delta from Control to End of Cooling	Delta from Control to End of Recovery	Minimum Temperature
Oral Temp. ( $^{\circ}$ C)	36.52 $\pm$ 0.37	-0.11	-0.13	-0.48 **
Ear Temp. ( $^{\circ}$ C)	36.23 $\pm$ 0.44	-0.07	-0.09	-0.40 **
Rectal Temp. ( $^{\circ}$ C)	36.83 $\pm$ 0.76	0.08	-0.00	-0.18 **
Skin Temp. ( $^{\circ}$ C)	32.59 $\pm$ 1.04	-1.57 **	-0.48 **	-0.77 **
Body Temp. ( $^{\circ}$ C)	35.40 $\pm$ 0.70	-0.11	-0.16	-0.32 **

\*\* Decrease significantly ( $P < 0.01$ ) different from mean of control value

Table IIC. Physiologic responses of MS patients wearing Steele passive garment

Physiologic Responses:	Control Period (Mean $\pm$ SD)	Delta from Control to End of Cooling	Delta from Control to End of Recovery	Minimum Temperature
Oral Temp. ( $^{\circ}$ C)	36.61 $\pm$ 0.35	-0.14 **	-0.34 **	-0.56 **
Ear Temp. ( $^{\circ}$ C)	36.34 $\pm$ 0.51	-0.15 **	-0.26 **	-0.41 **
Rectal Temp. ( $^{\circ}$ C)	36.78 $\pm$ 0.45	0.06	-0.12	-0.21 *
Skin Temp. ( $^{\circ}$ C)	33.06 $\pm$ 1.12	-0.50 **	-0.73 **	-0.84 **
Body Temp. ( $^{\circ}$ C)	35.55 $\pm$ 0.54	-0.14 *	-0.34 **	-0.40 **

\*\* Decrease significantly (P<0.01) different from mean of control value

\* Decrease significantly (P<0.05) different from mean of control value

Table III. Post-cooling performance measures by number of subjects

	LET			MCS			Steele		
	Improved/	Same/	Worsened	Improved/	Same/	Worsened	Improved/	Same/	Worsened
Energy Level	14	11	1	10	12	4	8	12	6
Pain Evaluation	5	8	13	1	10	15	3	11	12
Muscle Strength	11	15	0	10	14	2	6	16	4
Cognitive Ability	11	13	2	5	17	4	8	12	6
Hand Grip	13	0	8	13	1	7	11	0	10
Timed Alphabet	16	0	10	20	1	5	20	0	6
Vision Test	14	10	2	8	12	6	11	10	5
Mini Mental	18	5	3	14	5	7	12	8	6
Finger to Nose	6	17	3	10	11	5	16	0	10
Finger Tap	14	3	9	12	1	13	9	0	17
Motion Evaluation	21	2	3	13	6	7	14	3	9

## ends for Illustrations

Fig. 1 - Cooling system; A - LET portable cooling system, B - MicroClimate systems™ change of phase vest, C - Steele™ Passive Cooling Vest

Fig. 2 - Relative change (difference from mean of control) in thermal responses

2A oral temperature vs. elapsed time

2B ear canal temperature vs. elapsed time

2C rectal temperature vs. elapsed time

2D skin temperature vs. elapsed time

■ LET active vest, ● MCS passive vest, ▲ Steele passive vest, ❖ significant difference (P<0.01) from mean of control for LET test group, ⊙ significant difference (P<0.01) from mean of control for MCS test group, ✚ significant difference (P<0.01) from mean of control for Steele test group

Fig. 3 – Performance measures for each of the vest

3A Female and male delta hand grip

3B Subjective performance measures

3C Objective performance measures

\* significant difference (P<0.05) after cooling, \*\* significant difference (P<0.01) after cooling



Fig. 1A LET Portable Cooling System



Fig. 1B - MicroClimate Systems™ Change of Phase Vest



Fig. 1C Steele™ Passive Cooling Vest

**Fig. 2 RELATIVE CHANGE IN THERMAL RESPONSES**

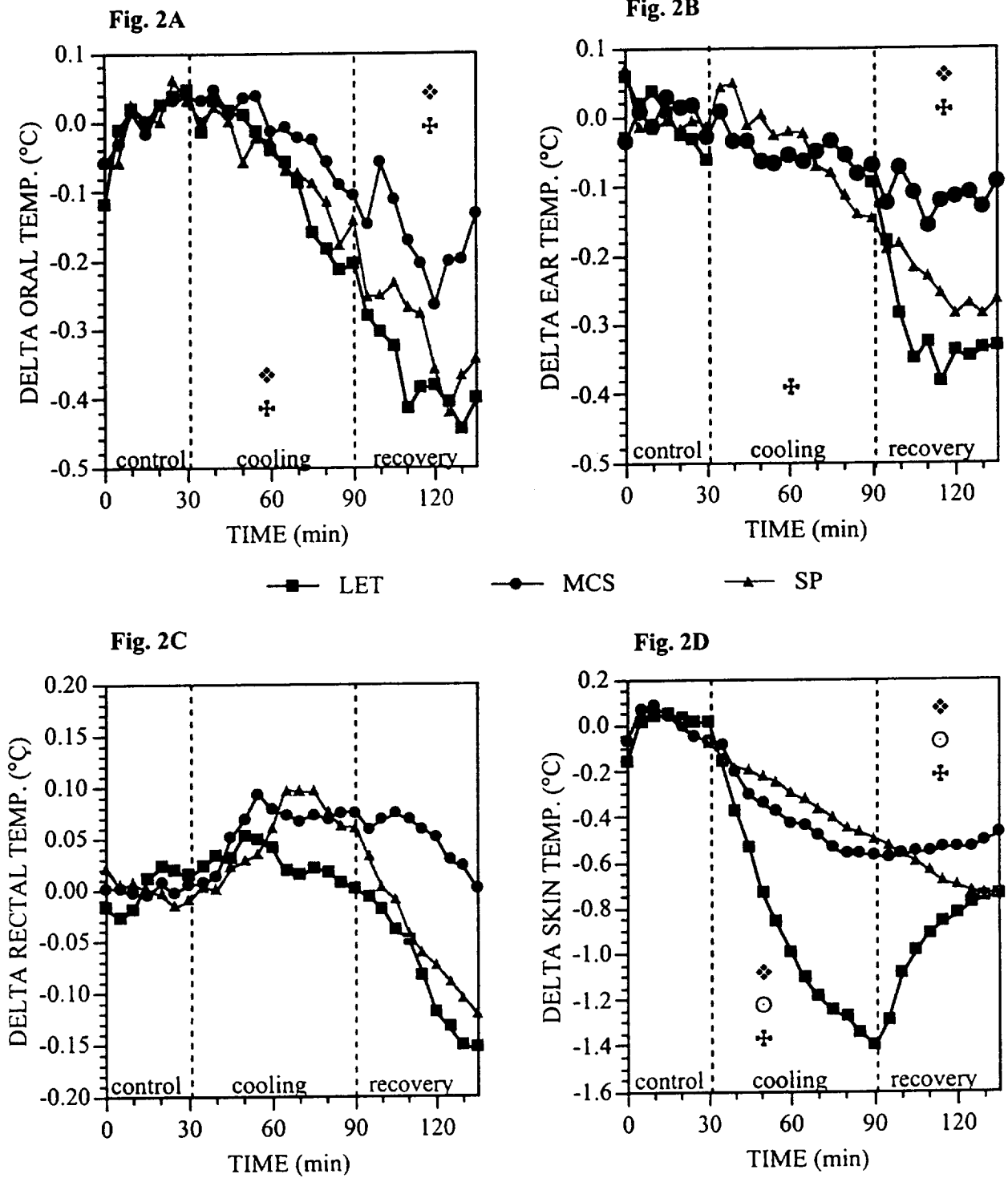
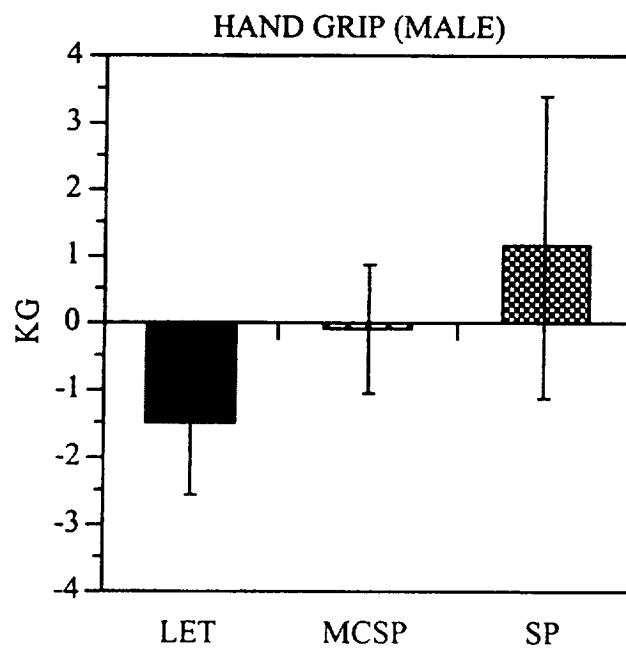
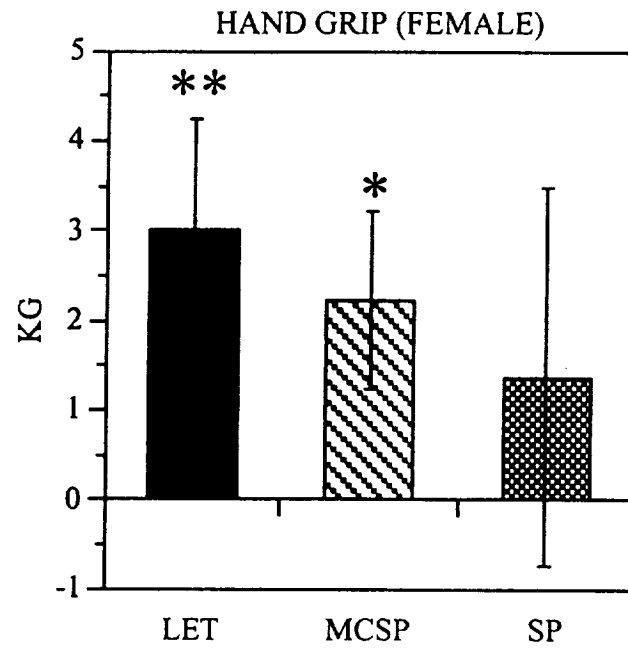
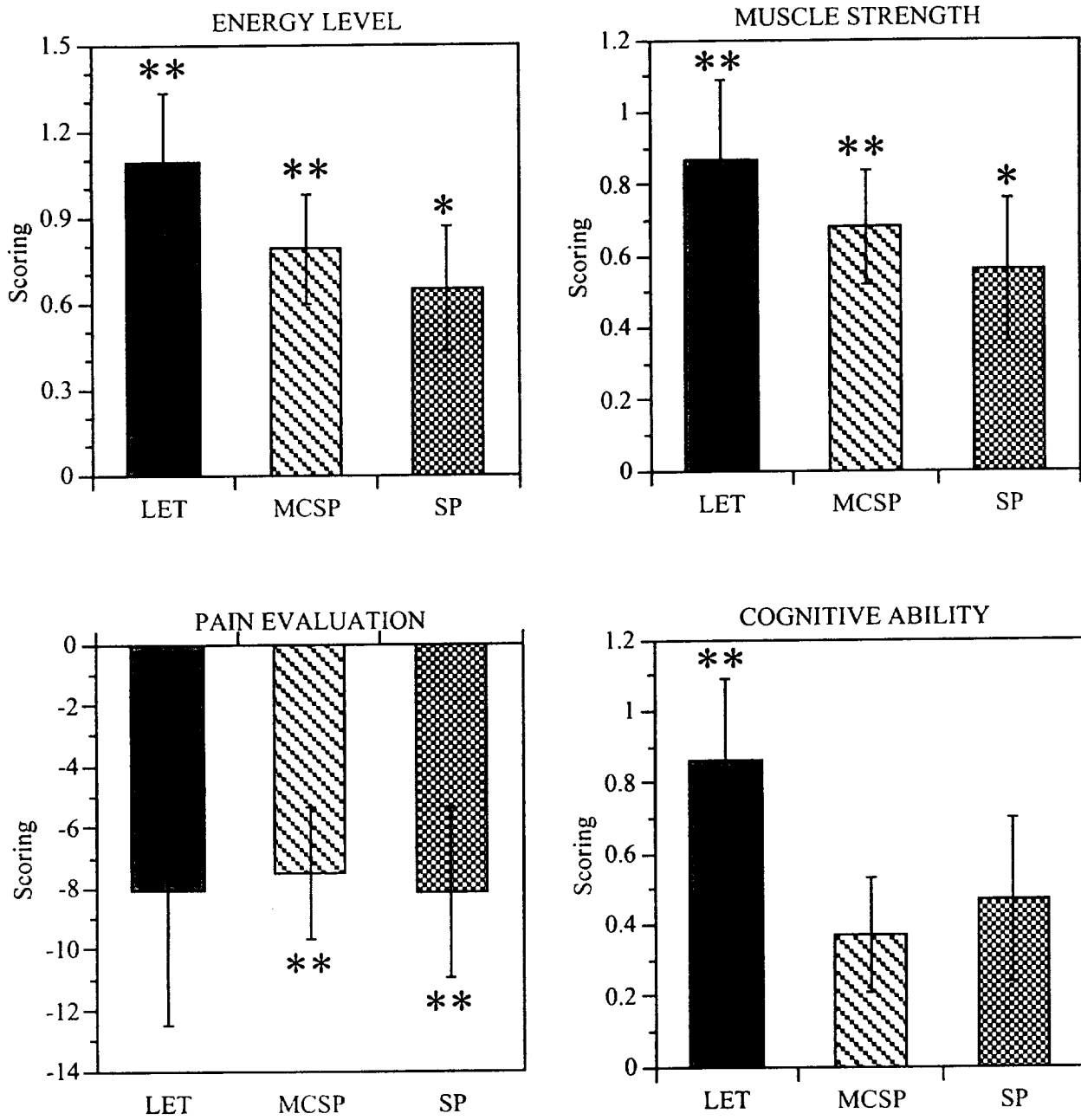


Fig. 3A DELTA HAND GRIP STRENGTH



**Fig. 3B SUBJECTIVE PERFORMANCE MEASURES**

**Fig. 3C OBJECTIVE PERFORMANCE MEASURES**

