BIOFEEDBACK AS A CLINICAL TOOL IN THE CONTROL OF ESSENTIAL HYPERTENSION

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ABSTRACT

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Because of the potential far-reaching implications of learned control of autonomic bodily functions, the field of biofeedback is growing rapidly. Nevertheless, the usefulness of biofeedback in general, and, in particular, its effectiveness in the reduction of elevated blood pressure has yet to be demonstrated. Results of studies using biofeedback to lower blood pressure are often contradictory. In addition, many of the succesful studies exhibit methodological problems and/or the presence of uncontrolled confounding variables. Controlling for these difficulties, we attempted to demonstrate whether biofeedback could be a clinically useful tool in the treatment of essential hypertension. Despite near optimal conditions of feedback, reinforcement, and attentional factors, our six hypertensives did not show a significant reduction in systolic blood pressure from baseline levels. We then attempted to use self-monitoring biofeedback in combination with relaxation training and compared the results with each treatment used separately. While there was a significant reduction of distolic blood pressure, it was across sessions regardless of treatment. These results are consistent with the fact that many very different treatment approaches produce the same results. The possibility that all these approaches are simply demonstrating habituation to the measurement of blood pressure per se is then discussed.

ACKNOWLEDGEMENTS

To Zalman, my ever-elusive but always helpful mentor and supervisor, but most especially to my Dvoraleh, the most important person in my world and the most beautiful person in THE world.

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INTRODUCTION

Until the late 1960's, it was assumed that acquiring voluntary control of autonomic bodily functions was virtually impossible. Thus, Kimble (1961) stated the very widespread belief that "for autonomically mediated behaviour the evidence points unequivocally to the conclusion that such responses can be modified by classical, but not instrumental, training methods." In spite of this, people have long been fascinated with reports that Indian yogis could voluntarily slow their heartbeat, increase their body temperature, or survive with very little oxygen. It is thus not surprising that when Neil Miller and his associates began to report successes in instrumentally training autonomic responses in curarized rats (Miller & Dicara, 1967; Miller & Carmona, 1967; Miller & Banauzizi, 1968; and Miller 1969), interest and enthusiasm were high and very rapidly the field of biofeedback and self-regulation came into being.

One of the projected applications of biofeedback is in the treatment of essential hypertension. This disease is estimated to effect between 25% and 30% of the U.S. population (National Center for Health Statitics, 1964a, 1964b, 1966; Stamler, Stamler, Riedlinger, Algera & Roberts, 1976; Sheps & Kirkpatrick, 1975) and it is associated with increased risk of coronary artery disease and cerebrovascular accidents

(Kannel, Dawber, Kagan, Revotskie & Stokes, 1961; Kannel, Schwartz & Macnamara, 1969) the major cause of death in the United States today (United States Department of Health, 1967). Self regulation of blood pressure and, in particular, the ibility to voluntarily lower blood pressure levels would, therefore, constitute a major breakthrough with very far reaching benefits to hypertensive patients.

Many studies investigating the effectiveness of biofeedback in lowering blood pressure have been reported (e.g. see Blanchard & Young, 1974; Schwartz, 1973; and Schwartz & Shapiro, 1973). However many of these experiments have used normal subjects. Typically in these reports, half the subjects were reinforced for lowering their blood pressure and the other half were reinforced for increasing their blood pressure (Shapiro, Tursky, Gershon & Stern, 1969; Shapiro, Tursky & Schwartz, 1970a; Shapiro, Tursky & Schwartz, 1970b; Schwartz, Shapiro & Tursky, 1971; Shapiro, Schwartz & Tursky, 1972). A common methodological flaw in these studies is that they usually reported only a significant difference between the group reinforced to increase blood pressure and the group reinforced to decrease blood pressure. However, when a random reinforcement control group was added (Shapiro et al, 1970a) neither experimental group was significantly different from the control group. Furthermore, the magnitude of change in

blood pressure displayed by both experimental groups was small - typically 5mmHg or less.

Some studies have used a clinical population diagnosed as essential hypertensives. Although Schwartz and Shapiro (1973) and Miller (1975), using hypertensives, both failed to get reductions in diastolic blood pressure; in another study done by Benson, Shapiro, Tursky and Schwartz (1971), five out of seven subjects showed significant decreases in their systolic blood pressure, with the average decrease for the entire group being 16.5mmHg. Elder, Ruis, Deabler and Dillenkoffer (1973) were successful in lowering the diastolic blood pressure of their six subjects receiving feedback and reinforcement by an average of approximately 20%. However, both these experiments exhibit methodological flaws. Thus, even though Benson et al. (1971) continued to record blood pressure changes in up to five separate baseline sessions (representing 7500 blood pressure determinations), the Elder et al. (1973) study uses only 20 readings taken over a 40 minute period as their baseline. Furthermore, though Sackett, Haynes and Gibson (1975) estimated that among hypertensive patients non-compliance (i.e. not taking prescribed medication) may be over 50%, neither of the above studies controls for the issue of compliance since no monitoring of medication - either before or during the study - was reported.

It is entirely possible, therefore, that subjects assumed to be taking medication may not in fact have been doing so prior to the experiment but began to do so after entering the study. Not controlling for the issue of compliance, therefore, confounds the results and makes them uninterpretable.

In summary, many studies attempting to lower blood pressure via biofeedback have used normal subjects and reported minimal or no changes. Some studies using a clinical population of essential hypertensives also report no reductions. Others report success in lowering high blood pressure but either use inadequate baselines or fail to control for the possibility of increased compliance with drug therapy during the course of the study. The present thesis therefore attempted to determine whether, using a meaningful baseline and eliminating the question of compliance, biofeedback would produce clinically useful results in the treatment of essential hypertensives.

EXPERIMENT 1

The first experiment addressed the question of whether biofeedback can be a viable technique in the treatment of essential hypertension. It thus attempted to determine whether biofeedback can produce medically (not just statistically) significant reductions in the blood pressure levels of essential hypertensives, reductions sufficient to bring the blood pressure to within or close to normal range. The present study was also designed to determine whether reductions in blood pressure are possible using equipment that could be readily available to the average clinician, and whether the effects will be durable enough to last over a period of time.

METHOD

SUBJECTS

Subjects were solicited via newspaper advertisements and notices on local university bulletin boards (see Appendix A). All respondents filled out a detailed questionnaire (see Appendix B) and were screened by a participating medical doctor to ascertain a) that the subject was an essential hypertensive and not suffering from some other disorder of which elevated blood pressure is a sympton; b)

that the subject was not taking any medication for his hypertension or any other medication such as tranquilizers, birth control pills, etc. that effect blood pressure level (this will rule out the question of compliance raised by Stone and DeLeo, 1976, in interpreting results) and c) that the subject would not be changing his lifestyle in any way that might effect his blood pressure (e.g. dieting, increased exercise, etc.) for the duration of the study. Medical screening included urinanalysis, intravenous pylograms and peripheral vein renins. In addition, all subjects accepted for the study were required to leave a deposit of $20.00 which would be forfeited if the subject failed to complete the study.

Six subjects who met the above criteria and who were able and willing to meet the study schedule were chosen. The subjects were five men and one woman with a mean age of 39.5 years (standard deviation = 6.7) who had all been diagnosed as essential hypertensives by their family physician. This diagnosis was verified in each case by the consulting physician through the medical screening described above. Blood pressure readings were taken during the initial intake interviews and ranged from 138/90 to 160/102.

All subjects came to the psychology laboratories of Concordia University three times a week for six weeks. Each

subject was assigned a fixed hour of the day and all his sessions took place at that hour to avoid the blood pressure changes that are associated with different times of the day. Since the major purpose of this study was to determine the clinical viability of an optimal biofeedback package, we were not concerned with possible mediational effects, whether these be muscular, central or cognitive. Furthermore, all elements associated with biofeedback were included in the training sessions with an attempt to optimize the contribution of each. Thus the treatment package included a) visual feedback of systolic blood pressure, b) verbal and monetary reinforcement and c) maximum placebo factors including the constant presence of two experimenters and the use of imposing equipment.

EQUIPMENT

Equipment used in the study was comprised of 1) Bonn-SP sphygmomanometer and pulse rate measure (TOA Electronics and Optical Company, Ltd., Tokyo, Japan), 2) Feedback thermometer BFT 302 (Biofeedback Technology, Garden Grove, California), and 3) Feedback myograph BFT 401 (Biofeedback Technology, Garden Grove, California). The sphygmomanometer is capable of taking blood pressure and pulse rate measurements once every 25 to 40 seconds depending on the bleed-off

speed used and the pulse rate of the subject. While this is far less than the number of determinations obtainable with the feedback system described by Tursky, Shapiro and Schwartz (1972), that system is relatively complex and requires highly skilled personnel to maintain its operation and it is thus beyond the scope of the average clinician. However, following the finding by Brenner, Kleinman and Goesling (1969) that the degree of cardiovascular control is a direct function of the amount of augmented sensory feedback provided during training, we attempted to maximize the amount of blood pressure information fed back to the subjects within the constraints of the monitoring system used. The temperature and EMG measurements, while not germaine to the present study, were included to maximize equipment placebo effect.

PROCEDURE

During each session, the subject was seated in a semi-reclining position and the blood pressure cuff, thermistor, and EMG electrodes were attached. Two experimenters were in the room at all times - one to measure blood pressure and (during training sessions) project its value on a screen and, where appropriate, provide reinforcement. The other experimenter recorded temperature and EMG level at the time

of each systolic blood pressure determination. The subject then sat quietly for 10 minutes to allow blood pressure to stabilize. For the next 40 minutes, blood pressure measurements were taken approximately every 40 seconds. For the first three sessions, no feedback was given to the subject, and these readings were taken as the subjects' baseline measure. During the next 15 sessions, after each determination of systolic blood pressure, the actual numerical value was projected on a screen directly in front of the subject. The actual blood pressure readings were used rather than the binary feedback often used in such studies (e.g. Benson et al., 1971; Shapiro et al., 1969; Shapiro et al., 1970a; Shapiro et al., 1970b) since direct feedback was shown to be superior by Blanchard, Young, Haynes and Kallman (1974).

Before beginning the 15 training sessions, each subject was informed that his actual systolic blood pressure level would be displayed on the screen in front of him after each determination; that monetary reward would be provided for reductions in blood pressure level and that each amount earned would be displayed on the screen. He was also told that he was to try to lower the number on the screen - i.e. his systolic blood pressure - in any way that he could.

Reinforcement was given as follows: the mean of each 10

blood pressure readings was used as the base for reinforcement during the following 10 readings (this modified shaping procedure was used since Miller, 1969, obtained changes of 20%-with shaping as compared to 5% without). For each reading which was lower than the last base by one mmHg, the experimenter said "good" immediately after displaying the numerical value on the screen and, in addition, displayed "5¢" on the screen to indicate that this amount was earned by the reduction in blood pressure. For each reading which was lower by two or three mmHg, the experimenter said "very good" and displayed "10¢" on the screen. If the reading was lower by four mmHg or more, the experimenter said "excellent" and displayed "15¢" on the screen.

RESULTS

Means of systolic blood pressure per session were calculated for each subject (for actual scores, see Appendix C) and a repeated measures analysis of variance was performed yielding a highly significant between sessions effect (see Table 1). To determine where the significance lay, a Scheffe test was performed showing a significant difference between the first three and the last three treatment sessions ($F = 1141.3$; critical value, .05, = 1047.09; $p < .05$). However

TABLE 1

SOURCE TABLE - REPEATED MEASURES ANOVA, SESSIONS BY SUBJECTS

SOURCE	SUM OF SQUARES	D.F.	MEAN SQUARE	F
TOTAL	9127.02	107		
ROW (BETWEEN SUBJECTS)	5571.92	5	1114.38	
COLUMN (BETWEEN SESSIONS)	1588.68	17	93.45	3.095**
R X C (ERROR)	2566.42	85	30.19	

there was no significant difference between the three baseline sessions and the 15 treatment sessions (F=.90). While individual differences between the means of the three baseline sessions and the means of the last three treatment sessions ranged from -16.8mmHg to +5.4mmHg with an average change of -4.9mmHg (see Table 2), the difference here too was not statistically significant (F=213.7).

Since there was no significant change in systolic blood pressure from baseline level, the projected follow-up was not carried out.

TABLE 2

DIFFERENCE BETWEEN THE MEANS OF THE THREE BASELINE SESSIONS AND THE MEANS OF THE LAST THREE TREATMENT SESSIONS

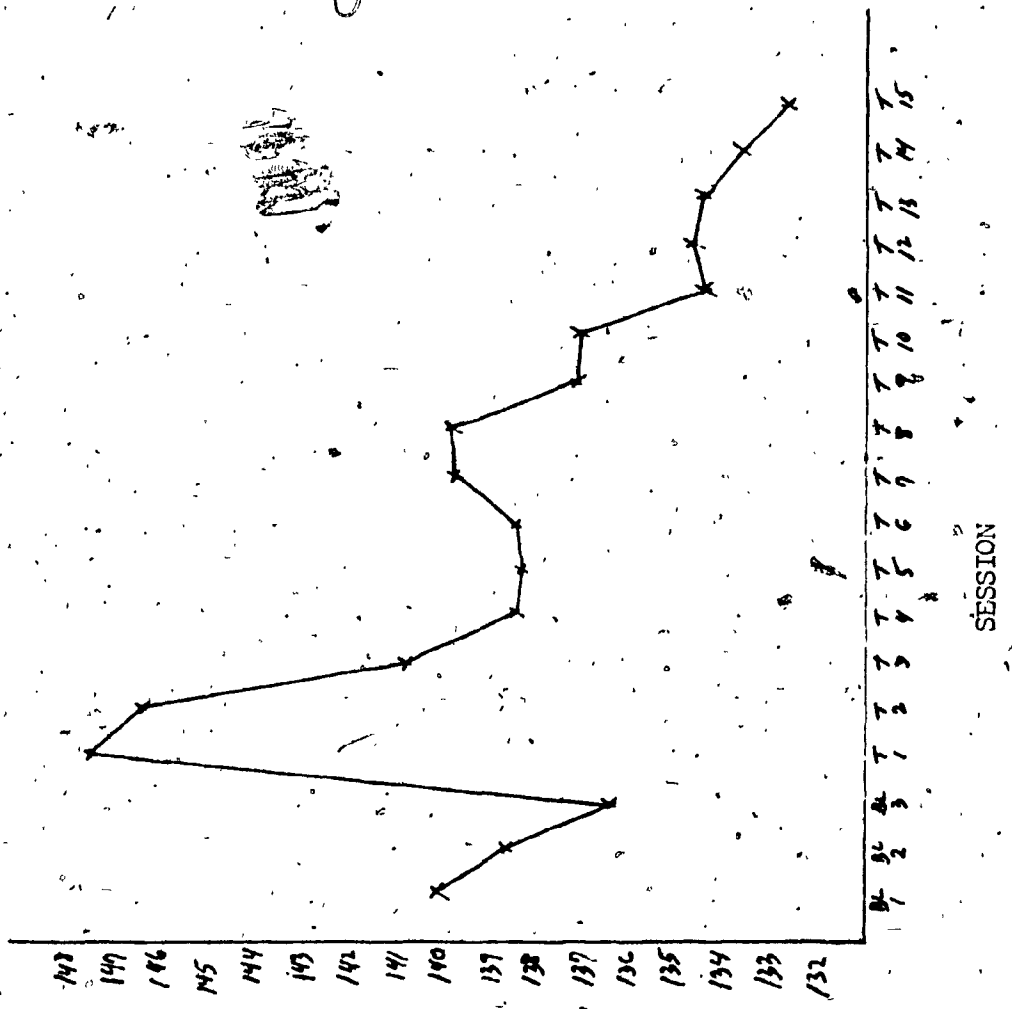
SUBJECT	$\bar{X}BL_{1,2,3}$	$\bar{X}T_{13,14,15}$	TREATMENT MINUS BASELINE
1	141.1	124.3	-16.8
2	138.8	141.2	+ 2.4
3	148.6	143.4	- 5.2
4	136.4	126.6	- 9.8
5	139.0	133.7	- 5.3
6	126.6	132.1	+ 5.4
MEAN FOR ALL 6 Ss:	138.4	133.5	- 4.9

DISCUSSION

The graph of mean systolic blood pressure for all six subjects (see Figure 1) showed a marked increase in systolic blood pressure during treatment session one as compared to the three baseline sessions. The curve then gradually declines until the last three sessions reach a mean level of 4.9mmHg lower than the mean of the three Baseline sessions. While this decrease is not significant, the decrease from the first three to the last three training sessions is. Thus, if we were to look at just the decline over treatment sessions (from the first three to the last three), we would see a highly significant change with a mean decrease of 11.3mmHg! Obviously this decline does not show a decrease in systolic blood pressure as a result of biofeedback, since the three baseline sessions and the last three treatment sessions are not significantly different from one another. What it does show is the importance of examining change in relation to an adequate baseline. The humping effect that we obtained at the beginning of treatment is similar to the effect reported by Paskewitz and Orne (1973) in alpha feedback training. As Orne (personal correspondence - Appendix D) points out, putting someone in a learning situation tends to raise, in the initial

phase, the physiological parameters measured. The subject then subsequently "learns" to volitionally reduce that parameter until it reaches the level of the original baseline. Orne (Appendix D) further suggests that "this type of effect is more clearly evident when the learning situation is one which tends to cause a change in the parameter being investigated." It is likely, then, that the feedback and demands introduced in the first treatment sessions were the cause of the initial hump.

Overall, in spite of close to optimal conditions of feedback, reinforcement and equipment placebo, we failed to show any significant decline in average systolic blood pressure.



MEAN SYSTOLIC BLOOD PRESSURE FOR
ALL SIX SUBJECTS

FIGURE 1

MEAN SYSTOLIC BLOOD PRESSURE FOR ALL
SIX SUBJECTS AS A FUNCTION OF SESSIONS.

EXPERIMENT 2

Given the lack of results with biofeedback alone, it was decided to run a second study using a different type of biofeedback and to compare the results with a relaxation group and a combination of of biofeedback - relaxation group. To avoid the humping effect obtained in the first experiment, it was decided to use a different type of paradigm - one which would not involve differences between baseline and treatment recording sessions.

Patel (1973) obtained reductions in blood pressure in 16 out of 20 hypertensives using a combination of yoga and biofeedback. She assumed that the results were due essentially to the biofeedback alone, the yoga simply making the feedback more effective by allowing the subject to concentrate more carefully on his blood pressure changes. It has, however, been demonstrated that relaxation training alone can lead to substantial decreases in blood pressure (Benson, Marzetta & Rosner, 1974; Benson, Rosner, Marzetta & Klenchuk, 1974; Blackwell, Henenson, Bloomfield & Mogenheim, 1975; Brody, Luborsky & Kron, 1974; Jacobson, 1939; Paul, 1969; Tasto & Shoemaker, 1973). Benson (unpublished data, reported in Onesti, Fernandes & Kim, 1976) and Benson & Greenwood (1976) in fact have indicated that even where

biofeedback seemed to be successful, the key factor was probably relaxation and not biofeedback. We decided, therefore, to use relaxation to compare with biofeedback.

Gutman and Benson (1971) demonstrated that the pattern of responses in labile hypertension reflects a repeatedly activated "fight or flight" reaction related to stressful environmental events. This preparation for somatic action is similar to anticipation of active exercise (Obrist, Webb, & Sutterer, 1970) which involves increased muscle tension in preparation for aggression or withdrawal. Schwartz and Shapiro (1973), therefore, suggest that it would seem fruitful to explore techniques attempting to reduce sympathetic activity in aggressive anxiety situations by teaching patients to relax somatically. This notion is further supported by Datey, Deshmuck, Davli & Vineker (1969) who demonstrated that yogic exercises, which were designed to produce complete mental and physical relaxation, significantly reduced blood pressure in hypertensive patients. Schwartz and Shapiro (1973) further suggest that a combined treatment approach using both relaxation training and direct blood pressure control techniques (i.e. biofeedback) may be better than either one alone in that the biofeedback directs one's attention to the abberant system and possibly increases one's awareness

and control of it. Furthermore, Schwartz and Shapiro (1973) suggest that biofeedback might be used as a monitor -i.e. not to be directly controlled but rather as an indicant of success in other areas. Thus, by means of the feedback, especially if made available in the patient's normal environment, the patient may learn to recognize what kind of thoughts, feelings, situations and actions lead to increased blood pressure as well as how successful he is in changing his lifestyle and/or environment in order to reduce the blood pressure. Shoemaker and Tasto (1975) make essentially the same suggestion. "Another area of investigation which is pertinent to environmental factors involves testing the extent to which the subject can control his environment in order to lower his blood pressure. The patient may gain increasing control over environmental factors which precipitate his blood pressure, or the patient may, in some way, adjust to the environmental factors" (page 40).

In summary, relaxation alone has been shown to be effective in reducing blood pressure, and it has been suggested that a combination of relaxation and biofeedback, especially self-monitored biofeedback, may be more effective than either alone. (It is possible, of course, that the biofeedback procedure used in this study may more properly be considered self-monitoring.) The second part of this thesis, therefore, attempted to show whether a combination of biofeedback in the patient's

normal environment and training in progressive muscle relaxation is effective in reducing the blood pressure levels of essential hypertensives and whether it is more effective than either biofeedback or relaxation alone.

METHOD

Subjects were again solicited via newspaper advertisements and notices on local university bulletin boards. All the respondents filled out a detailed medical history questionnaire (Appendix D) to ascertain a) that the subject was an essential hypertensive and not suffering from some other disorder of which high blood pressure is a sympton; b) that the subject was not taking any medication for his hypertension or any other medication such as tranquilizers, birth control pills, etc. that effects blood pressure level (again to rule out the question of compliance raised by Stone and DeLeo, 1970, in interpreting results); and c) that the subject would not be changing his lifestyle in any way that might effect his blood pressure (e.g. dieting, increased exercise, etc.) for the duration of the study. In addition, all subjects accepted for the study were required

to leave a deposit of fifty dollars which would be forfeited if the subject failed to complete the study.

SUBJECTS

The sixteen subjects who met the criteria for admission to the study consisted of eight men and eight women with a mean age of 42.5 years (standard deviation = 11.0) who had all been diagnosed as essential hypertensives by their family physician or by the consulting physician. Since Schwartz and Shapiro (1973) suggest that it might be difficult to lower blood pressure in people with chronic hypertension, we attempted to use subjects who had not previously been or who had just recently been diagnosed as hypertensive. The average length of time for all subjects since the original diagnosis of hypertension was 2.8 years (standard deviation = 3.1)

All subjects came to the psychology laboratories of Concordia University once a week for seven weeks. Each subject was assigned a fixed hour of the day, and with few exceptions, all his sessions took place on the same day of the week at the same time of day to avoid the blood pressure changes that are associated with different times of the day. The subjects were assigned in random order to one of three

groups: 1) combination feedback - relaxation, 2) feedback alone, and 3) relaxation alone.

PROCEDURE

During each recording session, the subject was seated in a semi-reclining position and the blood pressure cuff was attached. The subject then sat quietly for 10 minutes to allow blood pressure to stabilize. For the next 25 minutes, blood pressure readings were taken at approximately 40 second intervals for a total of 35 readings per session. The first three sessions served as baseline sessions. Following the third session, subjects in the combination feedback - relaxation group were given an audio tape cassette containing instructions for progressive muscle relaxation and a sphygmomanometer adapted for self-measurement. They were instructed to listen to and follow the instructions on the relaxation tape once a day, keeping a record of the time of day the exercises were done. They were also instructed to measure and keep a record of their blood pressure three times a day - morning, early afternoon and evening. Following the fourth session, subjects were taught a brief ritualized relaxation procedure and instructed to use the procedure when-

ever experiencing stress (in addition to the full relaxation exercises once daily). Subjects in the feedback alone group were given a sphygmomanometer and identical instructions regarding its use, but were not given the relaxation tape nor the ritualized relaxation instructions. The relaxation alone group was given the relaxation tape and the ritualized relaxation instructions, but not the sphygmomanometer.

EQUIPMENT

The equipment consisted of 1) for measuring blood pressure in the laboratory - Bonn SP sphygmomanometer and pulse rate measure (TOA Electronics and Optical Company, Ltd., Tokyo, Japan); 2) for blood pressure measurements taken by subjects at home or work - Do-It-Yourself Stethescope Aneroid Blood Pressure Unit #1010 (Hartz Standard Health Care Supply Company, Montreal, Canada), and 3) Relaxation Exercises Cassette (Behavior Media, Montreal, Canada).

RESULTS

Despite random assignment, group baseline means differed from one another (for actual mean scores of each subject for each session, see Appendix F). Since we were interested in change relative to baseline, all scores were converted into percent of mean baseline. (Table 3 lists percent of mean baseline as well as actual mean scores for each of the three experimental groups.) A two way analysis of variance with repeated measures on one factor was performed and yielded a significant between sessions effect for diastolic blood pressure. A Scheffe test showed a significant difference between mean baseline and the four treatment sessions ($F=200.8$; critical value, .05, = 181.6; critical value, .01, = 264.2; $P < .05$), between mean baseline and last two treatment sessions ($F=296.5$; $P < .01$), but not between mean baseline and first two training sessions ($F=74.9$; $P > .05$), nor between the first two and last two training sessions ($F=110.0$; $P < .05$). There was no significant interaction effect nor significant difference between groups on either systolic or diastolic blood pressure nor was there a significant between sessions effect for systolic blood pressure (see Tables 4 and 5).

TABLE 3

MEAN SYSTOLIC AND DIASTOLIC BLOOD PRESSURE READINGS FOR EACH GROUP - AS RAW SCORES AND AS % OF BASELINE

	MEAN ACROSS BASELINE	TREATMENT 1	TREATMENT 2	TREATMENT 3	TREATMENT 4
			BIOFEEDBACK GROUP		
ALL 5 Ss ($\bar{X}$)	140.5/93.7	138.6/92.9	138.7/94.0	134.6/89.7	136.9/91.4
AS % OF BASELINE		98.6/99.1	98.7/100.3	95.8/96.7	97.4/97.5
			RELAXATION GROUP		
ALL 6 Ss ($\bar{X}$)	148.1/98.3	143.2/94.3	144.4/96.4	144.3/91.6	144.1/91.3
AS% OF BASELINE		96.7/ 95.9	97.5/98.1	97.4/93.3	97.3/92.9
			BIOFEEDBACK PLUS RELAXATION GROUP		
ALL 5 Ss ($\bar{X}$)	147.7/98.4	143.1/93.7	141.0/93.9	141.4/92.8	145.0/93.8
AS % OF BASELINE		96.9/95.2	95.5/95.4	95.7/94.4	98.2/95.3

TABLE 4

SOURCE TABLE FOR SYSTOLIC BLOOD PRESSURE - TWO WAY ANOVA WITH REPEATED MEASURES ON ONE FACTOR

SOURCE	SUM OF SQUARES	D.F.	MEAN SQUARES	F
TOTAL	1853.7	79		
BETWEEN SUBJECTS	944.3	15		
CONDITIONS	21.8	2	10.9	.15
ERROR B.	922.5	13	71.0	
WITHIN SUBJECTS	909.4	64		
TRIALS	118.2	4	29.6	2.1
TR. X COND.	43.2	8	5.4	.38
ERROR W.	748.0	52	14.4	

TABLE 5

SOURCE TABLE FOR DIASTOLIC BLOOD PRESSURE - TWO WAY ANOVA WITH REPEATED MEASURES ON ONE FACTOR

SOURCE	SUM OF SQUARES	D.F.	MEAN SQUARES	F
TOTAL	2126.3	79		
BETWEEN SUBJECTS	800.5	15		
CONDITIONS	116.5	2	58.3	1.11
ERROR B.	684.0	13	52.6	
WITHIN SUBJECTS	1325.8	64		
TRIALS	327.2	4	81.8	4.60*
TR. X COND.	75.6	8	9.5	.53
ERROR W.	923.0	52	17.8	

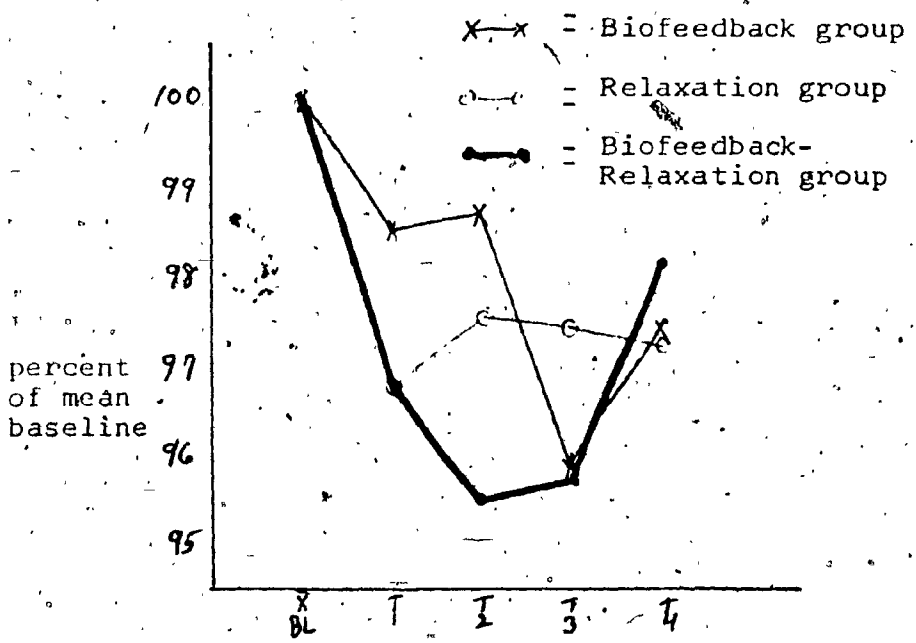


FIGURE 2

SYSTOLIC BLOOD PRESSURE FOR ALL THREE GROUPS - PERCENT OF MEAN BASELINE BY SESSION

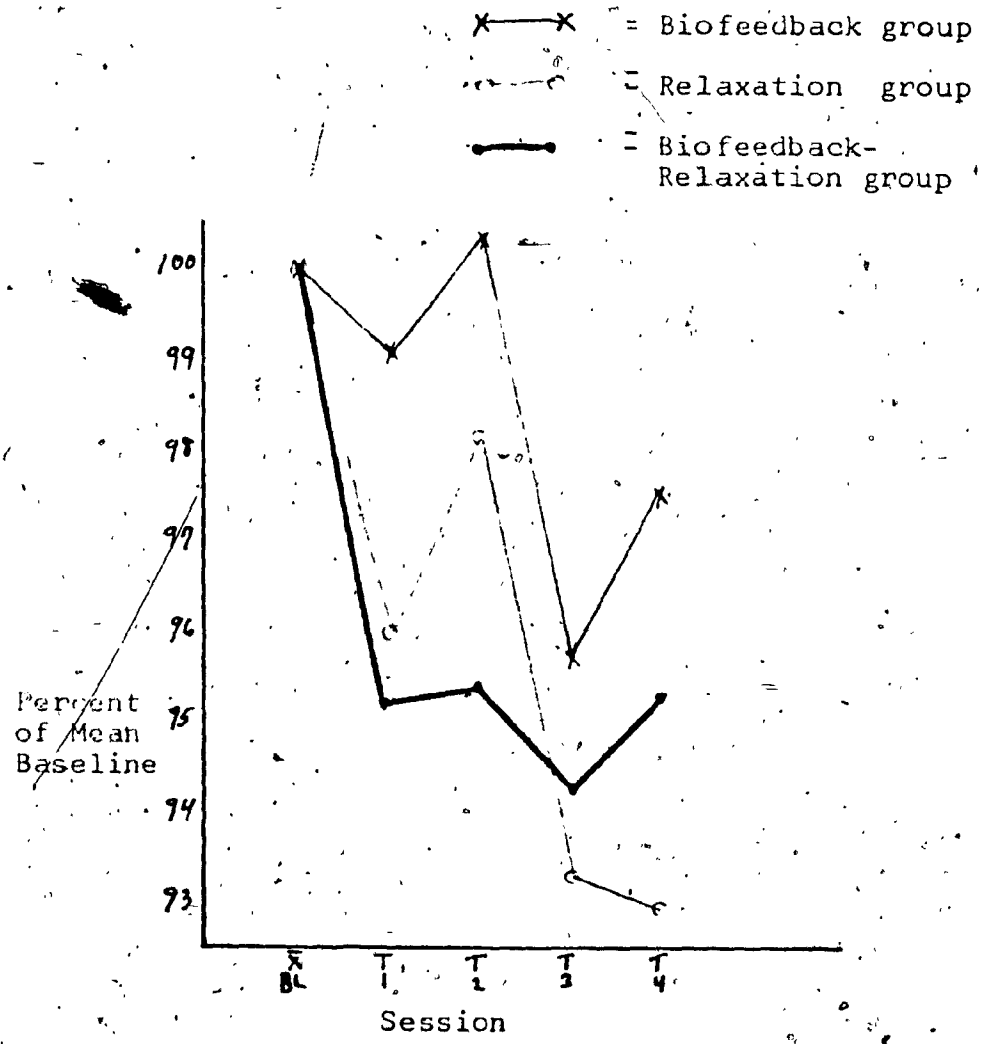


FIGURE 3

DIASTOLIC BLOOD PRESSURE FOR ALL THREE GROUPS - PERCENT OF MEAN BASELINE BY SESSION

DISCUSSION

That the three groups did not differ significantly from one another is graphically illustrated by Figures 2 and 3. Even on diastolic blood pressure where changes did occur, it took place from baseline to treatment, irrespective of experimental condition. Thus, the effects of biofeedback and relaxation were the same, and even combining the two treatments did not produce a different effect.

The lack of results using biofeedback is actually not surprising. One is hard pressed to suggest that the few biofeedback studies that have reported successes in reducing blood pressure have, in fact, demonstrated that the reductions were due to the biofeedback! For even if we ignore the confounding elements present in almost all these studies (medication, compliance, inadequate baselines etc.; e.g. Benson et al.;1971; Elder et al.; 1973;Schwartz et al., 1971; Shapiro et al., 1970b; Shapiro et al., 1969), we are still left with the overall impression which the present study supports: which technique is used matters little, if at all. Thus, significant reductions in blood pressure levels have been reported using not only biofeedback and relaxation but also drug placebo (Grenfell, Briggs &

Holland, 1963), hospitalization (Krifcher, Moustas & Shapiro, 1965; Moustas et al., 1976), instruction alone (Redmond et al., 1974, Shapiro et al., 1972), acupuncture (Tam & Yiu, 1975), or simply having nurses rather than doctors measure the blood pressure (Moustas et al., 1971, Pickering, 1966). In effect, regardless of the procedures used to bring about the reduction, all the studies that have shown successful reductions in blood pressure over a period of time may, in reality, simply be demonstrating a process of habituation to the laboratory situation or to the act of blood measurement itself! Shapiro, Schwartz and Benson (1974) report the case of a patient who, after nine biofeedback training sessions, reduced his diastolic blood pressure from 110mmHg to 85mmHg but was recorded again at 110mmHg when he returned to his physician for a second physical examination. It seems likely that this patient was simply habituating to the laboratory situation, but was unable to transfer his "learning" to the medical examination. It is not at all unreasonable to suggest that had the patient spent the same amount of time and sessions having his blood pressure measured with or without feedback by his physician, he would have recorded lowered blood pressure readings in the doctor's office as well! The

present author and Zalman Amit experienced similar results in the treatment of an essential hypertensive patient using biofeedback, relaxation and reassurance. The patient was, over a period of time, successful in lowering his blood pressure at the clinic and, to some extent at home, but always got high readings at his doctor's office!

That the doctor or experimenter can be a pressor stimulus has been well documented by Hunman, Engel & Bickford (1962) and by Kain, Hinman & Sokolow (1964). Moustas et al (1967) have suggested that perhaps mere hospitalization reduces blood pressure because of the fact that the taking of blood pressure per se becomes a less stressful experience. "It becomes a routine experience, done regularly throughout the day, and not a "test" for the patient, i.e. he need not present a favorable blood pressure to the examining physician..." (page 681) Liberman (1962) has suggested that this may represent an extinction of a "conditional response."

It seems reasonable, then, to suggest that the important component in vitually all the studies that have demonstrated reductions in blood pressure - whether using

biofeedback, relaxation, placebo, hospitilization, instuctions or acupuncture - may, in fact, be simply a combination of habituation to blood pressure measurement and directional task awareness. Thus Redmond et al., 1974, got reductions in blood pressure in those subjects simply instructed to lower blood pressure and increases in blood pressure in those subjects instructed to raise blood pressure. Similiarly Bergman and Johnson, 1971 and 1972, obtained significant changes in heart rate appropriate to directional instructions without feedback, while the addition of feedback did not augment the response to instruction!

CONCLUSION

Neil Miller, who provided the impetus for much of the current interest in biofeedback, has recently stated (1974) that "unfortunately, as frequently happens with a new technic, reports by the popular media, and also by salesmen for do-it-yourself equipment, have presented hopeful expectations that run far ahead of proved facts." (page 684). This seems to remain the state of affairs up to the present. Impressive claims by biofeedback equipment manufacturers in every issue of the American Psychological Association Monitor and in various medical journals as well as articles in the lay press all continue to bolster the impression that the effectiveness of biofeedback as a clinical tool is a proven fact.

Perhaps the time has come to go beyond the cautious "maybe" statements of Miller and others (e.g."..... much hard work remains to be done before we can make definite statements about the therapeutic value of biofeedback training", Miller, 1975, page 248). Perhaps the time has come to admit that, to date, no study has yet shown biofeedback to be the prime factor in the control of high blood pressure, nor has any study, to date, shown biofeedback (in

the few instances where it brought some results) to be superior to at least four or five other less costly and less time consuming techniques.

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APPENDIX A: Solicitation of subjects

WORRIED

ABOUT HIGH

BLOOD PRESSURE?

MEMBERS OF CONCORDIA UNIVERSITY'S DEPARTMENT OF PSYCHOLOGY WILL MEASURE YOUR BLOOD PRESSURE. IF IT IS ELEVATED, YOU MAY BE ELIGIBLE TO PARTICIPATE IN A STUDY OF THE REDUCTION OF BLOOD PRESSURE USING BIOFEEDBACK.

IF INTERESTED, CALL 879-4463 BETWEEN 9 AND 5.

APPENDIX B: Subject questionnaire, experiment 1.

NAME _____

ADDRESS _____

PHONE NUMBER: HOME _____ WORK _____

DATE OF BIRTH _____ SEX: F _____ M _____

OCCUPATION _____

HAVE YOU EVER BEEN TOLD THAT YOU HAVE HIGH BLOOD PRESSURE?

YES _____ NO _____

IF YES, HOW LONG AGO?

_____MONTHS _____YEARS

IF YES, WERE YOU TREATED?

YES _____ NO _____

ARE YOU PRESENTLY BEING TREATED?

YES _____ NO _____

IF SO, WHAT MEDICATION ARE YOU TAKING? _____

_____

Results of experimints have suggested that people can learn to control their blood pressure level without the use of medication. The purpose of this study is to assess the most effective way of lowering blood pressure using feedback procedures.

If you fulfill the criteria for admission in this study,

your responsibility will involve the following:

A) A testing session including tests like cardiogram, chest x-ray, and urine analysis performed at the Royal Victoria Hospital.

B) Availability for three training sessions per week lasting 50 minutes each, always at the same hour of the day. These sessions will last for a period of six weeks from the end of June to the middle of August.

C) You may also be requested to return for three follow-up sessions around November of this year.

The training sessions will take place at the behavioral laboratory of Concordia University. Your blood pressure will be measured automatically for approximately 40 minutes per session while you sit quietly. No medication or invasive techniques will be employed.

If you have any doubt to your availability for the entire duration of the experiment, please do not volunteer. If you think that you can fulfill the above requirements, please complete the following questionnaire.

We thank you for your co-operation.

MEDICAL INQUIRY

1. Do you have a family doctor? Yes_____ No_____
2. If yes, please give his name: _____
3. Have you seen him in the last month_____ 3 months_____
   5 months_____ 1 year_____ none of these_____
4. If necessary, may we communicate with him? yes____ no____

5. Are you now being treated for any disorder? yes____ no____

6. If yes, what disorder?_____

7. In the past month have you taken any medication like:
vitamins_____ birth control pills_____
anti-allergy_____ anti-asthma_____ diuretics_____
tranquilizers_____ cold preparations_____

8. Do you follow any special diet: diabetic_____
low calory_____ low cholesterol_____ low salt_____
low fat_____ high protein_____ vegetarian_____

9. Have you gained_____ lost_____ weight in the past
3 months_____ 1 year_____. Amount_____.

10. If you have lost weight, has this weight loss been intentional? yes_____ no_____

11. Do you intend to lose weight this summer? yes____ no____

12. Do you change your diet in the summer? yes_____ no_____
If yes, explain:_____
_____

13. Do you exercise regularly? yes_____ no_____. If yes, explain:_____

14. Do you anticipate increasing your exercising this summer? yes_____ no_____. If yes, explain:_____
_____

15. (For females) Are you now pregnant? yes_____ no_____

16. Are you aware of having had or having any of the following diseases?
iodine allergy_____ kidney disease_____
heart disease_____ thyroid disease_____
diabetes_____

strokes_____ chronic diarrhea_____

nose bleeds_____ migraine headaches_____

17. Have you ever had a cardiogram? yes____ no____ ?____

18. If yes, was it reported to be normal? yes____ no____

19. Have you ever had a heart attack? yes_____ no_____

20. Has anyone in your family ever had a heart attack? yes_____ no_____. If yes, what is the person's relation to you?_____

21. Does anyone in your family have diabetes? yes_____ no_____. If yes, what is the person's relation to you?

_____

22. If yes, are they on regular insulin treatment? yes_____ no_____

23. Has anyone in your family ever had a stroke? yes_____ no____. If yes, what is the person's relation to you?

_____

APPENDIX C

Mean systolic blood pressure for each subject on each of the treatment sessions and mean baseline for each subject.

SUBJECT	Mean of the 3 baseline sessions	T1	T2	T3	T4	T5
1	141.1	142.9	139.4	134.9	131.8	131.6
2	138.8	147.8	148.6	144.8	146.9	142.2
3	148.6	158.8	162.9	145.5	148.3	148.5
4	136.4	150.3	144.6	131.0	131.0	124.7
5	139.0	143.1	143.6	145.4	133.6	142.7
6	126.7	140.9	138.9	142.9	138.9	139.5

SUBJECT	T6	T7	T8	T9	T10	T11
1	131.0	131.9	142.5	130.7	130.7	119.9
2	139.6	142.2	141.7	135.3	132.2	139.5
3	160.2	163.0	154.9	157.7	156.1	150.2
4	123.2	124.9	123.8	128.2	134.2	120.5
5	138.1	140.6	138.8	136.7	138.6	138.4
6	137.5	135.8	132.3	133.4	129.9	137.3

SUBJECT	T12	T13	T14	T15
1	120.9	124.3	125.1	122.3
2	143.9	144.0	139.6	140.1
3	149.2	149.6	147.1	140.4
4	120.9	126.5	125.1	128.3
5	137.1	134.3	135.3	131.5
6	136.4	134.2	130.3	131.7

APPENDIX D

Pennsylvania Hospital THE INSTITUTE
111 NORTH FORTY-NINTH ST., PHILADELPHIA PA 19139
Unit for Experimental Psychiatry
MARTIN T. ORNE, M.D., PH.D., DIRECTOR

University of Pennsylvania
Department of Psychiatry

February 2, 1977

Rabbi Mordechai Glick
Concordia University
Applied Psychology Center
1374 Sherbrooke Street, West
Suite #6
Montreal; Quebec H3G 1M8
Canada

Dear Rabbi Glick:

Some time ago you wrote to me concerning a study of essential hypertension and blood pressure. You are quite correct that I have for a long time emphasized a tendency to confuse baseline shifts with effective specific training.

In many biofeedback situations the initial baseline, if taken under fairly relaxed circumstances, will be indicative of an individual's characteristic response. However, if he is put into a "learning situation" there is a dramatic change. He subsequently "learns" to volitionally change his physiological parameter until it approaches the level of the original baseline.

This type of phenomenon was described by Paskewitz and myself with alpha feedback training where the initial baseline obtained in a totally dark room is, of course, far higher than the baseline obtained in a dimly lit room as one begins biofeedback training. As a consequence of training, the subject eventually is able to increase alpha density until it approaches his initial baseline. This type of effect is more clearly evident when the learning situation is one which tends to cause a change in the parameter being investigated. Thus, the presence of light tends to increase alpha density much as the situation of measuring blood pressure tends to increase the blood pressure in many patients.

I do not mean to imply that this is the only kind of change one can produce with biofeedback; rather that this type of change should be recognized for what it is and not be confused with a true effect.

Sorry about the delay in answering. With best regards,

Very sincerely,

Martin T. Orne, M.D., Ph.D.

MTO:mcw

P.S. I would be grateful for a copy of any work you are doing in this area.

APPENDIX E: Subject questionnaire, experiment 2

NAME _____

ADDRESS _____

PHONE NUMBER: HOME _____ WORK _____

DATE OF BIRTH _____

SEX: F _____ M _____

OCCUPATION _____

Have you ever been told that you have high blood pressure?

yes _____ no _____

If yes, how long ago?

_____months _____years

If yes, were you treated?

yes _____ no _____

Are you presently being treated?

yes _____ no _____

If so, what medication are you taking?

_____

Results of experiments have suggested that people can learn to control their blood pressure level without the use of medication. The purpose of this study is to assess the most effective way of lowering blood pressure without drugs.

If you fulfill the criteria for admission to this study, your responsibility will involve the following:

A) Availability for one session per week lasting

one hour or less. The sessions will begin in the middle of January and will continue for five weeks.

B) Committment to carry out certain brief procedures during the course of your normal day. These procedures will be fully explained to you during your first session.

C) Agreement to leave a deposit of $50 during your first session, which will be returned to you at the end of your last session. The purpose of this deposit is to ensure that, if you begin the study, you will carry it through to completion.

D) You may also be requested to return for a follow-up session in March or April.

The sessions will take place at the behavioral laboratories of Concordia University. At each session, your blood pressure will be measured automatically for approximately 20 minutes while you sit quietly. In addition, part of the first two sessions will involve training in certain procedures that will be carried out by you daily. No medication, unpleasant or invasive techniques will be employed.

If you have any doubt as to your availability for the entire study, please do not volunteer. If you think you can fulfill the above requirements, please sign below and complete the questionnaire on the following pages.

I am interested in participating in the blood pressure reduction study outlined above.

Signature_____ Date_____

MEDICAL INQUIRY

1. Do you have a family doctor? yes_____ no_____
2. If yes, please give his name:_____
3. Have you seen him in the last month____ 3 months____
   5 months_____ 1 year_____ none of these_____
4. If necessary, may we communicate with him? yes___ no___
5. Are you presently being treated for any disorder?
   yes_____ no_____
6. If yes, what disorder?_____
7. In the past month have you taken any medication like:
   vitamins_____ birth control pills_____
   anti-allergy_____ anti-asthma_____
   water pills_____ tranquilizers_____
   cold preparations_____
8. Do you follow any special diet? diabetic_____
   low calory_____ low cholesterol_____
   low salt_____ low fat_____
   high protein_____ vegetarian_____
9. Have you gained_____ lost_____ weight in the past
   3 months_____ 1 year_____. Amount_____.
10. If you have lost weight, has this weight loss been intentional? yes_____ no_____
11. Do you exercise regularly? yes_____ no_____

12. Do you anticipate increasing or decreasing your exercising over the next two months? yes____ no____
If yes, explain:_____
_____

13. For females: Are you pregnant? yes_____ no_____

14. Are you aware of having or having had any of the following diseases? kidney didease_____ iodine allergy_____
thyroid disease_____ heart disease_____
diabetes_____ strokes_____
chronic diarrhea_____ nose bleeds_____
migraine headaches_____

15. Have you ever had a cardiogram? yes____ no____ ?____

16. If yes, was it reported to be normal? yes____ no____

17. Have you ever had a heart attack? yes_____ no_____

18. Has anyone in your family ever had a heart attack?
yes_____ no_____

19. Do you smoke? yes_____ no_____. If yes, how many cigarettes per day?_____

20. Do you anticipate changing your smoking habits over the next 2 months? yes_____ no_____

21. Does anyone in your family have diabetes? yes____ no____

22. Has anyone in your family ever had a stroke? yes___ no___

APPENDIX F

MEAN SYSTOLIC AND DIASTOLIC BLOOD PRESSURES READINGS OF EACH SUBJECT FOR EACH SESSION.

SUBJECT	BL 1	BL 2	BL3	T1	T2	T3	T4
			BIOFEEDBACK GROUP				
1	127.5/93.3	124.4/90.5	124.8/88.7	124.5/95.1	130.8/100.3	125.7/91.2	130.1/96.5
2	132.1/95.1	134.4/85.9	127.3/98.3	134.4/87.1	127.3/79.8	127.2/82.6	134.0/95.0
3	171.2/100.5	172.2/104.1	179.6/106.5	168.9/103.2	166.4/105.3	157.6/98.1	153.7/91.5
4	142.7/100.2	120.1/84.1	119.3/83.9	118.5/87.2	118.7/86.2	118.1/87.0	123.2/88.0
5	143.3/89.5	144.7/93.1	143.6/91.9	146.7/92.0	150.3/98.3	144.3/89.5	143.6/86.0
Group Mean	143.4/95.7	139.2/91.5	138.9/93.8	138.5/92.9	138.7/94.0	134.6/89.7	136.9/91.4
			RELAXATION GROUP				
6	119.7/88.6	114.4/92.4	116.1/88.0	114.8/91.9	111.9/87.2	109.1/86.2	104.0/81.8
7	177.0/99.3	148.1/87.0	---	134.9/84.2	149.6/88.0	133.1/84.1	141.7/84.5
8	133.7/93.7	141.3/106.5	131.0/97.9	135.3/100.7	136.4/101.6	131.6/89.1	129.8/92.4
9	183.6/103.4	187.4/97.7	180.7/97.1	189.3/90.6	186.9/100.3	193.1/87.8	194.8/93.5
10	122.8/92.4	130.3/98.1	129.3/92.6	125.0/87.9	120.6/89.0	134.6/91.4	125.7/83.8
11	167.7/110.5	173.3/116.6	165.1/110.0	160.9/110.4	160.7/112.1	164.5/110.8	168.4/111.5
Group Mean	150.8/98.0	149.1/99.7	144.4/97.1	143.2/94.3	144.4/96.4	144.3/91.6	144.1/91.3

(cont'd.)

APPENDIX F (cont'd.)

SUBJECT	B11	B12	B13	[illegible]	T2	T3	T4
	BIOFEEDBACK PLUS RELAXATION GROUP						
12	156.6/105.1	145.2/100.0	157.4/103.1	152.4/99.1	141.9/102.3	149.5/104.5	164.5/107.4
13	148.4/100.1	151.7/96.7	137.3/89.2	142.3/91.3	135.8/83.6	149.1/88.9	141.3/91.7
14	159.3/106.1	152.4/109.6	146.5/102.1	144.1/103.8	154.7/102.7	142.3/103.0	150.7/100.2
15	126.0/95.8	122.0/90.6	124.7/90.2	120.6/86.5	115.7/90.5	119.2/89.4	120.5/86.7
16	169.0/101.8	160.2/96.1	159.2/89.8	155.8/87.7	157.1/90.4	146.7/78.1	148.1/82.7
Group Mean	151.9/101.8	146.3/98.6	145.0/94.9	143.1/93.7	141.0/93.9	141.4/92.8	145.0/93.8