1. Principal Investigator Name:

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NJ COMMISSION ON
SPINAL CORD RESEARCH

Gail F Forrest Ph.D.

2. Name of Organization:

Kessler Medical Rehabilitation Research and Education Corporation

3. Grant Title:

Effect of Body Weight Supported Walking in Incomplete SCI: Physiological and Performance Effects

4. Grant Number

02-0321-SCR-N-0

5. Grant Period Covered by the Report

June 15th, 2002 –June 15th 2005

6. Date of Submission of the Report

8/31/05

1. Specific Aims

The overall goal of this study was to investigate functional locomotion recovery on the treadill and overground after incomplete spinal cord injury (SCI). Specifically, the objective was to evaluate ambulation after incomplete SCI through body weight support (BWS) treadmill training protocol compared to traditional rehabilitation intervention.

To achieve these aims the following parameters were determined at pre and post intervention period:

1. Functional Assessment Measures (Self selected (over ground) average walking velocity).
2. Spatial temporal parameters per gait cycle.
3. Oxygen consumption at maximum and sub-maximum speeds.
4. Kinematics and Electromyography (EMG) activity for multiple gait cycles.

Original Hypotheses:

1. There will be greater improvement in Functional Assessment Measures (eg., Berg Balance scores) due to BWS treadmill training compared to traditional rehabilitation therapy.
2. There will be greater improvement in spatial temporal parameters due to BWS treadmill training compared to traditional rehabilitation therapy.
3. There will be greater improvements in the coordination strategies for the lower extremity during overground walking due to BWS treadmill training compared to traditional rehabilitation therapy.
4. At relative walking speeds on the treadmill there will be a decrease in oxygen consumption due to BWS treadmill training compared to traditional rehabilitation therapy.
5. Due to BWS training EMG firing patterns will be resemble that of normal locomotion.

2. Project Success

We have completed the protocol on 11 people over the 3 year period. We have a large pool of data relevant to electromyography activity (EMG), kinematics, oxygen consumption, autonomic, body composition, bone density, and functional overground data to address the hypotheses cited above and to address many other research questions relevant to BWS. We have just finished testing our final participant. It is our intent to present data related functional outcome, kinematic and muscle activity and body composition. This has been an exciting project to complete.

Functional Assessment Measures or Functional gains:

All participants who entered the study were 100% wheelchair reliant and were at least 12 months post injury (mean 13 ± 2.6). After training all participants in the experimental group could stand (post: maximum standing time =20 ±5 min; pre standing time =0 min) and one individual could walk over ground. Individuals were able to stand by using a standing frame or a walker. The amount of assistance each participant required to stand over ground decreased over time. Furthermore, at the end of the study one participant could stand and point without holding on to a walker or any device. He had moderate assistance at the pelvis and at each knee. This participant was able to reach forward for a distance of 84 cm (Berg Balance test: score 5). When he entered the study he could not stand in a walker and did not have control of equilibrium. Additionally, this participant (in the experimental group) entered the study with an ASIA B classification and after completing the training he had an ASIA C classification. One other participant in the experimental group had a change of motor neurological level for motor from C6 to C7.

The control group received traditional rehabilitation. Two people in the control were able to walk over ground by using a body weight support walker, or braces (mean distance: 40ft ± 10: n=1). None of the people in the control group were able to show the same EMG or muscle activity responses to walking on the treadmill as was shown with experimental. None of the other people in the control group were able to stand with a walker, despite ambulation training as part of the traditional protocol.

Kinematic and Electromyography Activity

In general, all of the people in the experimental group had significant changes in their EMG firing patterns. Before training, all participants (in the control and the experimental group) had irregular muscle firing patterns that did not match the movements of the legs, and often the magnitude of the muscle firing was minimal. Locomotor Training (LT) using BWS started with participants being supported on the treadmill by 60% of body weight. At the end of LT all individuals trained at lower body weight supports (BWS) for most of the 1 hour training session. Significantly, one individual could walk, at 0% BWS for at least 15-20 minutes with very little difficulty.

After LT, all individuals had muscle activity [in the rectus femoris (RF), bicep femoris (BF), tibilias anterior, (TA), and gastrocnemius (G)] that was appropriate to the leg stepping movement and many of the muscles examined increased their magnitude of firing. Specifically, preliminary data has demonstrated higher EMG RMS amplitudes after LT [Pre vs post (60%BWS): LBF: 19.64±.23 vs 43.76 ±5.10uV; LR: 19.64 ± 1.36 vs 43.76 ± 1.13uV; LG:3.96 ± 1.29 vs 23.73 ± 1.01uV]. Furthermore, our data illustrates that for the RF, BF, and TA the EMG activity were more rhythmical and less tonic after the LT. None of these changes were seen in the control group. After traditional therapy, there was no change in muscle amplitude or mean burst duration for any of the individuals in the control group.

These results demonstrate the effectives of Locomotor Training (LT) for changes in neural and muscle activity. Early, analyses has shown that walking at lower BWS increases the burst duration and the amplitude of muscle activity.

Importantly, all of the individuals in the experimental group were classified as ASIA B or C and all were 100% wheel chair reliant. After training, these participants were able to walk on the treadmill (with and without BWS) and their leg muscle activation during stepping was close to normal firing patterns, however, these participants were not walking over ground. An important question to ask is what else is needed to be able to further facilitate muscle function to be able to walk over ground?

Figure 1 and Figure 2 (page 6) illustrate the changes in muscle fining patterns after training for a control participant (who received traditional therapy) and an experimental participant (who received LT) .

Autonomic data progress

Autonomic data

All the data for the seated data (paced and unpaced breathing) have been analyzed for all the subjects who have completed the study. These results have shown variable outcomes among both the control and experimental populations. Refer to Figure 3 through Figure 10 (page 7), for results on variables such as the mean heart rate (HR), mean blood pressure (BP), low frequency HR, and high frequency HR. The sit to stand data has been processed to ensure its integrity but no particular method of analysis has yet been chosen. The walking autonomic data is currently being processed in multiple fissions by looking at a linear fit of the changing heart rate. This data will also be processed using either short time Fourier transform or wavelet transform. These joint time frequency analysis methods will enable us to observe the changes in heart rate variability. This will be used as indication of the changes with in the two branches of the autonomic nervous system as the subject walks at different speeds and body weight support.

Bone Density and Body Composition.

The study has provided excellent pilot data to look at the effects of dynamic vertical loading on bone and body composition for those individuals who have been 100% wheel chair reliant since onset of injury. Our preliminary data illustrates that after training, the experimental group (n=5) gained 15 % (±0.26 %) lean body mass in the legs compared to the controls (n=3) who lost 10% (±0.55%) in the legs. We have collected BMD pilot data for total body, spine, leg, hip, and knee for the control group and the experimental group. BMD data analyses is ongoing.

3. Project Challenges

A definite challenge for this study was the high number of medical issues that is inherent with a person following a spinal cord injury. Subsequently, the time line for productivity has been greatly affected. A continual challenge was replace those skilled individuals who left the HPMAL and who were part of the study team. Additionally, the original grant did not budget adequately for the cost of trainers and cost of analyzing data.

4. Plans to continue for ongoing research

a) Our results in this study demonstrated changes in EMG burst duration and amplitude that closely resmbled normal walking patterns on the treadmill, however our participants who were mostly ASIA B individuals (and a few ASIA C participants - 100% wheel chair reliant) were not walking overground independently after the locomotor training using body weight support (LTBWS). After spinal cord injury, there is a great amount of bone loss and muscle atrophy. Perhaps there is a relationship between the loss in muscle and lack of functional gains. Therefore, I am interested in investigating a multi-modality approach where one group of particpants with SCI will have electrical stimualtion (ES) and LTBWS. With the repetitive step training I hypthosize that there will be more an increase in amplitude of EMG when compared to LTBWS alone and subsequently will promote more functional independent overground walking gains.

b) Our results for lean body mass (LBM) and fat mass illustatrated that after LTBWS there is an increase in LBM in the legs. However, there are limitations to our design by using only DEXA measurements. I wish to further investigate the changes in lean mass (and muscle volume) by using MRIs and calculating muscle tension (or potential torque).

c) Our results suggested an attentuation of bone mineral density after training. However, there are limitations to our design by using only DEXA measurements. I wish to further investigate the effect of LTBWS on the bone by looking at markers for bone resorption and for bone formation

d) To further examine bone and LTBWS I wish to implement a multi-modality approach of investigating the effect (on bone retention) of combining a bisphosphonate drug and LTBWS.

5. Plans to continue this research

I wish to further develop this line of research to investigate:

- The effect of using locomotor training with body weight support (LTBWS) on decreasing bone loss after SCI.
- the effect of combining LTBWS with a drug (bisphosphonate) on decreasing bone loss after SCI
- The effect of LTBWS on decreasing muscle loss after SCI.
- The effect of using LTBWS with muscle electrical stimulation on decreasing muscle loss after SCI.
- The effect of LTBWS on muscle atrophy and/or on improvement in functional gains.
- The effect of using LTBWS with functional electrical stimulation (given during the treadmill walking session) for the improvement of muscle atrophy and/or functional improvement.
- The effect of using fine wire electrodes (afferent electrical stimulation) during stance and swings during treadmill and overground walking.

Previously, I have submitted a NIH R21 grant. It is my intent to submit a K grant series in December 2005.

6. List of presentations, abstracts, publication, and chapters

Presentations:

2004 Bentson, S, Reiman, J, Forrest, GF, Sisto, SA . Autonomic Nervous System Response to Locomotor Training with Body Weight Supported Treadmill Walking in Individuals with Incomplete SCI Presentation at 30th Annual Northeast Bioengineering Conference.

2004 Forrest GF, Sisto SA, Schmidt M. Preliminary Findings of clinical Trials using body weight supported treadmill walking in SCI. The principal investigator presented the preliminary findings (kinematic, EMG, autonomic, and metabolic data) at a training course at the American Congress of Rehabilitation Medicine Conference.

2004 Forrest, GF, Sisto, SA, Kirshblum S, Harkema, S, Wilen, J Bond, Q, Bentson, (2004). Body Weight supported walking for SCI: Increased body weight loading promotes greater muscle activation. Combined Sections Meeting (American Physical Therapy Assoc.).

2005 Forrest, GF, Sisto, SA Kirshblum S, Wilen, J, Bond, Q,BS, Bentson, S Harkema, S. The Effects of Locomotor Training on Neural and Muscle Activation. International Society of Biomechanics/American Society of Biomechanics,

2005 Forrest, GF, Sisto, SA Kirshblum S, Wilen, J, Bond, Q, BS, Bentson, S Harkema, S. The Effects of Locomotor Training on Body Composition, Bone Density.

<u>Publications:</u>

Forrest, GF, Sisto, SA, Harkema, S, Wilen, J Bond, Q, Bentson, (2004). The Effects of Locomotor Training on Muscle activation, Body Composition, Bone. Resubmitted to Journal of Spinal Cord Medicine.

<u>Publications in Preparation</u>:

The Effects of Locomotor Training on Body Composition and Bone Density.

Forrest, GF PhD, Asselin PA., Bauman, W, Sisto, SA, Kirshblum S , Bond, Q, , Harkema, S.

Comparison of Locomotor Training and Traditional rehabilitation

Forrest, GF PhD, Asselin PA., Barbeau, H., Sisto, SA, Kirshblum S , Bond, Q, , Harkema, S.

Locomotor Training: Volitional movement compared to manual assisted movement

Forrest, GF PhD, Asselin PA, Barbeau, H., Sisto, SA, Kirshblum S , Bond, Q, , Harkema, S.

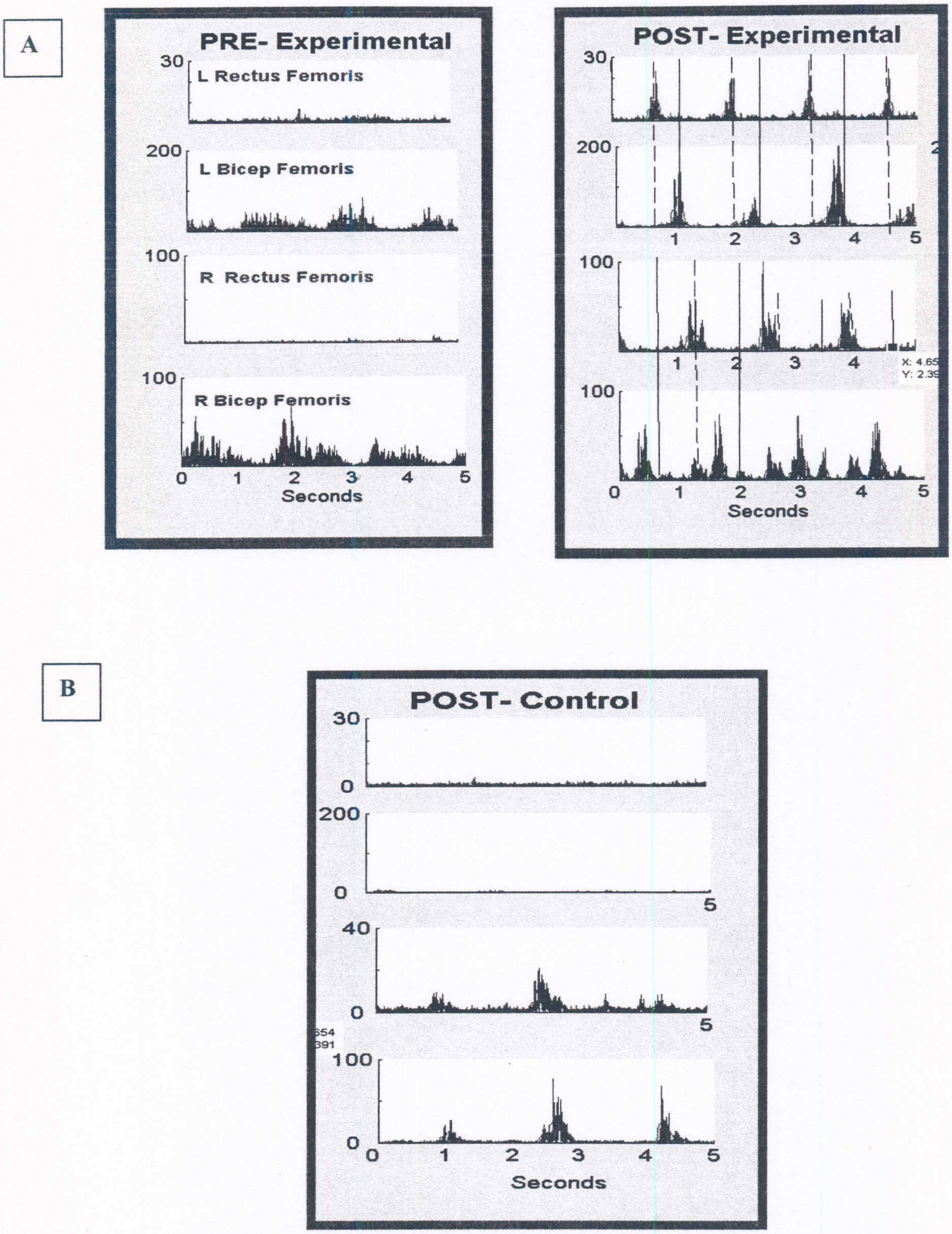
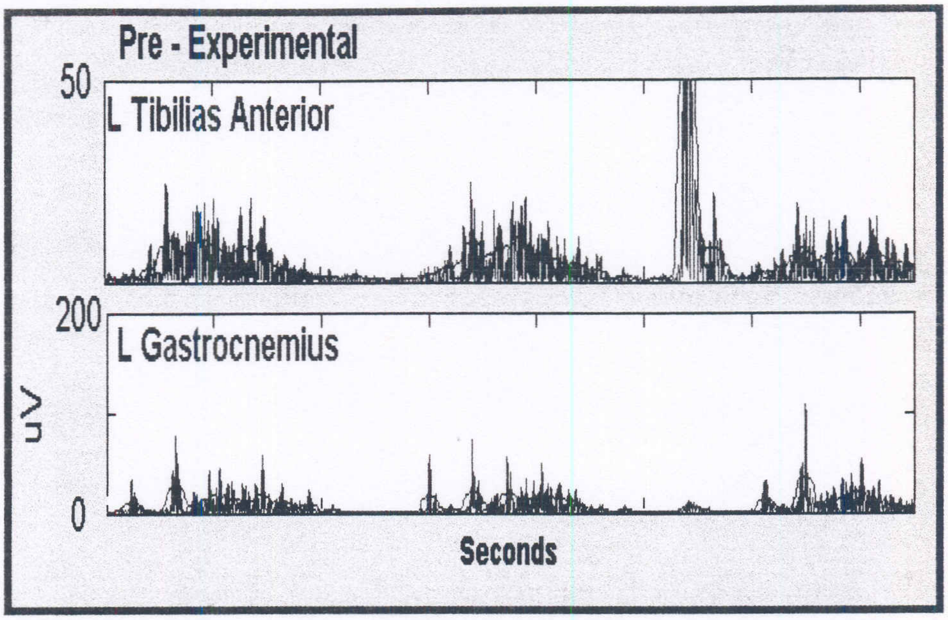


Figure 1: A. A typical profile for left and right thigh muscles before and after training (60%BWS, 1.6mph). The dotted line represents toe off, the solid line represents foot contact. **B** A Control profile for the same muscles. Amplitude EMG is uV



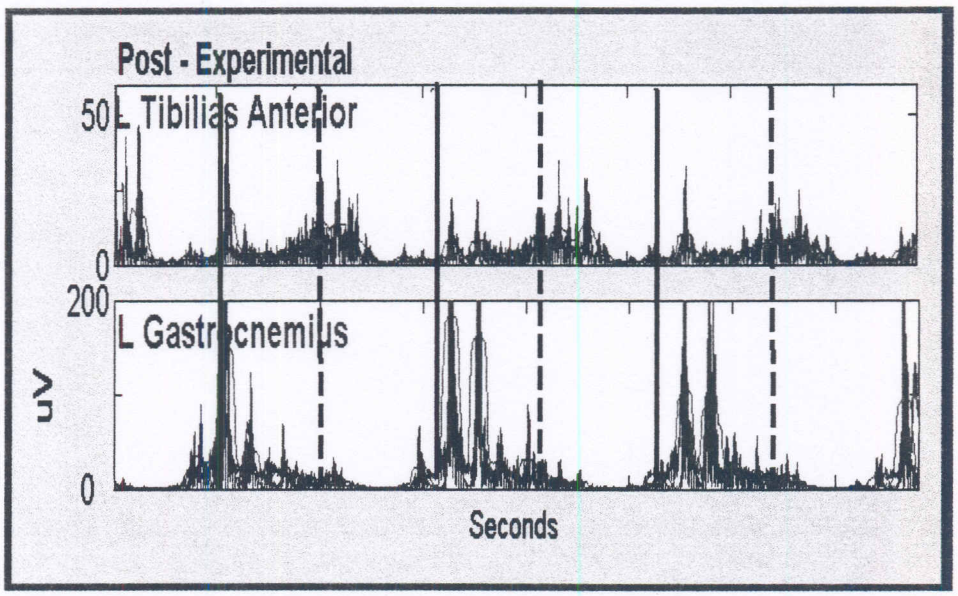


Figure 2: A. A typical profile for left and right lower leg muscles before (60%BWS, 1.6mph) and after (0% BWS 1.6mph) for a 5 second period. The dotted line represents toe off, the solid line represents foot contact. Before training the anterior and posterior muscles were firing at the same time. After training the Left gastrocnemius and the left tibilias anterior were firing alternatively and the firing patterns were appropriate for the leg movement. Amplitude is uV.

Figure 3. Mean HR (unpaced)

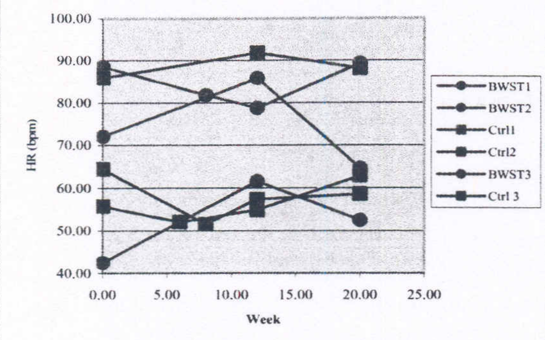


Figure 4. Mean HR (paced)

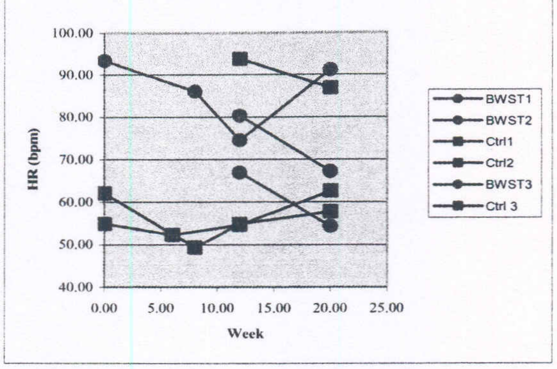


Figure 5. Mean SBP (unpaced)

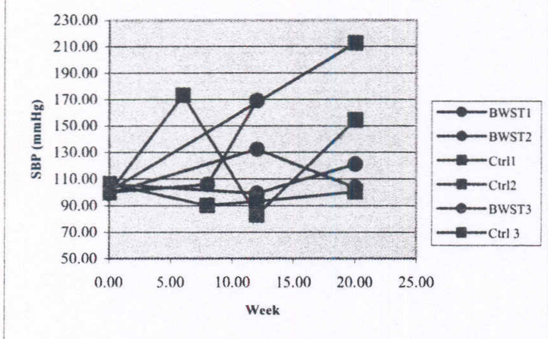


Figure 6. Mean SBP (paced)

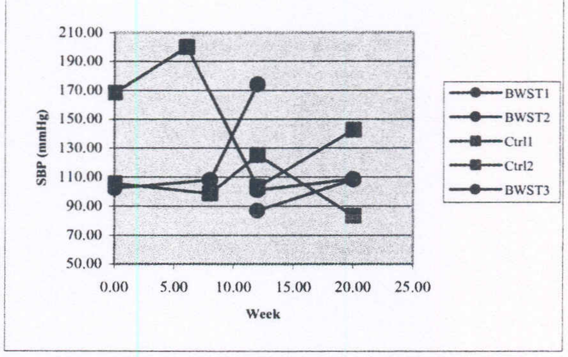


Figure 7. LF HR (unpaced)

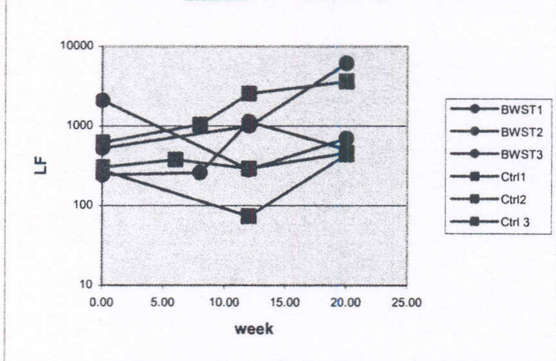


Figure 8. LF HR (paced)

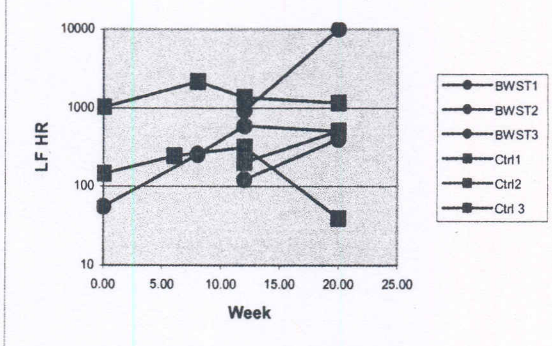


Figure 9. HF HR (unpaced)

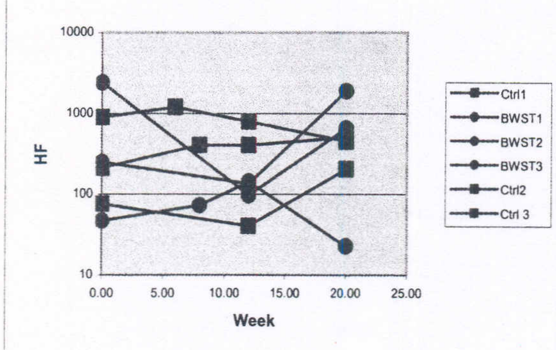


Figure 10. HF HR paced