Influence of resistance training on vascular function, hemodynamic, and perceived exertion responses to fixed submaximal workloads in patients with coronary disease

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Influence of Resistance Training on Vascular Function, Hemodynamic, and Perceived Exertion Responses to Fixed Submaximal Workloads in Patients with Coronary Disease

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Thesis

Submitted to the Department of Health Promotion and Human Performance

Eastern Michigan University

in partial fulfillment of the requirements for the degree of

MASTER OF SCIENCE

in

Exercise Physiology

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March 7, 2018

Ypsilanti, Michigan
Acknowledgments

I would like to thank my greatest supporter Dr. Barry A. Franklin, Ph.D., Program Director of Beaumont’s Preventive Cardiology and Cardiac Rehabilitation Royal Oak, who made this project possible. He offered guidance and support throughout the project. His door was always open for me to ask any questions and receive his expert advice. I am very grateful I had the opportunity to work alongside Dr. Franklin on this research project.

A special Thanks goes to my beloved husband Michael, who accompanied my entire educational path and this project with endless support, patience, and guidance. I could not have done this without you.

I would also like to thank Dr. Phillip Bendick, Ph.D. and Margaret Burr, of Beaumont’s vascular laboratory, who made the inclusion of Flow-mediated Vasodilation (FMD) measurements possible. Margaret Burr did an outstanding job completing all measurements on vascular function. She was always willing and able to accommodate all scheduling requirements and was a delight to work with. Furthermore, I need to thank Dr. Simon Dixon, MD, Chair, Department of Cardiovascular Medicine, who provided funding for FMD testing.

Furthermore, I would like to thank Judy Boura, Biostatistician at Beaumont Health, Diedre Brunk, Clinical Research Nurse, Beaumont Health, and all my wonderful colleagues at Preventive Cardiology and Rehabilitation who helped with blood pressure and heart rate testing often sacrificing their lunch time. Thank you, Dana Haddad, Megan Bowdon, Cindy Haskin-Popp, Emily Balagna, Kaylee Kaeding, Joyce Said, Elizabeth Johnson, and Melissa Kennedy, I could not have done it without you.
Abstract

**PURPOSE:** To determine the impact of superimposed resistance training (RT) in aerobically trained coronary patients on systolic blood pressure (SBP), heart rate (HR), rating of perceived exertion (RPE; 6–20 scale), and rate pressure product (RPP) at fixed submaximal workloads following a 12-week RT intervention. Additionally, pre-and post-RT measures of brachial artery reactivity, an index of endothelial function, were obtained. **METHODS:** Fifteen low risk coronary patients (13 men, 2 women; mean ± SD age = 66.1 ± 5.1 yrs) completed a progressive 12-week RT program that complemented their regular aerobic training regimen. Prior to training, SBP, HR, RPP, and RPE were obtained while subjects performed one set (10 repetitions) of three different exercises (bicep curl [BC], shoulder press [SP], and leg press [LP]) at an intensity ~ 60–80% of 1-repetition maximum. After the training period, testing was repeated while subjects lifted the identical pre-training loads for each exercise following a standardized protocol. Vascular function was assessed by flow-mediated vasodilation (FMD) testing prior to and immediately following the 12-week RT training intervention. **RESULTS:** Lifting the same pre-training loads evoked attenuated responses for all variables (HR, SBP, RPE, and RPP). A statistically significant decrease was shown for RPP ([HR x SBP]/100) during BC (106 ± 27 to 91 ± 22, \( p < .007 \)) and SP (102 ± 24 to 86 ± 17, \( p < .007 \)), whereas the RPP decrease during LP (116 ± 22 to 109 ± 26) did not achieve statistical significance (\( p = .18 \)). RPE for all three exercises decreased significantly (\( p < .0001 \)) following the RT intervention: BC (14.3 ± 2.3 to 9.7 ± 1.6), SP (13.9 ± 1.6 to 9.2 ± 1.5), and LP (14.3 ± 1.4 to 10.3 ± 1.6). Pre-versus-post RT measurements for resting HR and resting SBP were unchanged. Peak FMD responses for the 15 subjects were 12.8% and 10.3% dilation pre- and post-training, respectively (\( p = 0.332 \)). However, 5 of the 15 subjects
showed modest improvements in their post-training time to achieve maximum dilation from a mean of 117 seconds to 81 seconds ($p = .156$). **CONCLUSION:** Among aerobically trained coronary patients, a superimposed resistance training program resulted in decreased hemodynamic and RPE responses to lifting fixed submaximal workloads and improved FMD responses in 5 of the 15 participants.
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CHAPTER 1: Introduction

Traditional cardiac rehabilitation exercise programs have focused mainly on the aerobic aspect of exercise to decrease risk factors associated with coronary artery disease. Before 1990, cardiac rehabilitation programs recommended by the American College of Sports Medicine (ACSM) and the American Heart Association (AHA) did not include resistance training as part of their guidelines (Pollok, Franklin, Balady, Chaitman, Fleg & Fletscher, 2000). However, increasing evidence exists that a fitness program combining aerobic and resistance exercises has not only additional positive effects on muscular strength and endurance, but also on metabolism, psychological well-being, coronary risk factors, and cardiovascular function (Pollok et al., 2000). In 1991 the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) first recommended resistance training as part of a comprehensive exercise program for selected patients with coronary artery disease (Karlsdottir et al., 2002). More recently, cardiac patients, including low- to intermediate-risk and possibly higher risk patients with supervision, have been included in resistance training guidelines (ACSM, 2010). This is a result of research evidence that suggests that resistance training causes similar hemodynamic loads to those observed during aerobic exercise (Karlsdottir et al., 2002).

Resistance training is well known to support the development and maintenance of strength, endurance, power, and muscle mass. More recent research has indicated its beneficial effect on various health factors and chronic diseases (Pollock et al., 2000). Resistance training, in addition to its profound effect on the skeletal muscle system, has been found to have beneficial influence on the prevention of osteoporosis, sarcopenia, lower back
pain, and other disabilities. Additionally, resistance training may positively affect risk factors such as insulin resistance, decreased resting metabolic rate, decreased glucose metabolism, high blood pressure, and high body fat. These conditions are associated with chronic diseases, such as diabetes, cancer, and heart disease (Winett & Carpinelli, 2001).

Furthermore, resistance training contributes to the maintenance of functional abilities especially in most cardiac, frail, and elderly patients (Pollok, 2000).

The ACSM (2010) defines resistance training as “a form of physical activity that is designed to improve muscular fitness by exercising a muscle or muscle group against external resistance”. In the ACSM (2014) guidelines for exercise testing and prescription, the purpose of resistance training for patients with cardiac disease are listed as follows: improve muscular strength and endurance; improve self-confidence; maintain independence; slow age- and disease-related declines in muscle strength and mass; prevent and attenuate the development of other diseases and conditions; such as osteoporosis, type 2 diabetes mellitus, and obesity; increase ability to perform activities of daily living; and decrease cardiac demands of muscular work, such as reduced rate pressure product during daily activities.

Coronary artery patients, similar to healthy individuals, encounter activities of daily living (ADL) that require lifting or carrying moderately heavy loads. Those type of activities do exert a certain amount of strain on the cardiovascular system and elicit hemodynamic responses, such as an increase in heart rate, blood pressure, and myocardial oxygen demand. Thus, patients with coronary artery disease would benefit from resistance training because it improves strength and enables them to lift and carry objects at a lower fraction of their maximal lifting capabilities. It has been demonstrated that improved strength lowers circulatory responses and myocardial oxygen demand required during certain lifting tasks
(Marzolini, Oh, & Brooks, 2012). Rate pressure product (RPP) is a strong hemodynamic predictor of myocardial oxygen demand and provides an estimate of left ventricular function. It is calculated as the product of maximal heart rate and maximal systolic blood pressure (Gobel, Nordstrom, Nelson, Jorgensen, & Wang, 1978). Since lowering the myocardial oxygen demand is especially important for coronary patients, RPP can be used as a variable in the determination of improvements made after a resistance training program was implemented.

Vascular endothelial dysfunction, an imbalance in the regulatory process of smooth muscle tone, inflammation, antithrombosis, and anticoagulation within the blood vessel wall, is an initial step toward atherosclerosis and is associated with hypertension, hyperlipidemia, coronary artery disease, peripheral artery disease, and heart failure (Alley, Owens, Gasper, & Grenon, 2014). According to Vona et al. (2009), “Endothelial dysfunction seems to be particularly relevant in patients with coronary artherosclerosis and acute and chronic myocardial ischemia, and the presence of severe endothelial dysfunction is associated with a less favorable prognosis”. Based on clinical research, exercise training has been accepted as a nonpharmacological treatment option for endothelial dysfunction (Hambrecht et al., 2000). Flow-mediated vasodilation (FMD) is a non-invasive method to evaluate endothelial dysfunction in peripheral arteries using ultrasound measurements. Endothelial function of the peripheral arteries was shown to be closely related to the endothelial function of the coronary arteries by Anderson et al. (1995). FMD testing has been a valued tool in clinical research to assess the effects of exercise on endothelial function in healthy individuals as well as coronary artery patients (Alley, Owens, Gasper, & Grenon, 2014).
**Purpose of the Study**

There is overwhelming evidence from epidemiological and clinical studies that elevated blood pressure is a major risk factor for cardiovascular disease. Resistance training, also known as strength or weight training, is not generally recommended as a sole intervention to decrease resting blood pressure in mildly hypertensive individuals. However, in some previous studies moderate intensity resistance training alone and especially in combination with aerobic exercise has been shown to lower both resting and exercise heart rate and blood pressure. Evidence for the blood pressure-lowering effect is much less compelling for this type of training, as compared with aerobic training. Furthermore, to date, no studies involving coronary patients have investigated the hemodynamic responses to lifting fixed submaximal workloads before and after a structured exercise program, including resistance training. Therefore, the purpose of this study was to examine whether superimposed resistance training in this population can be beneficial in lessening the cardiac demands (i.e., rate pressure product) and rating of perceived exertion to standardized lifting tasks. Because aerobic exercise, with or without concomitant resistance training, has been shown to improve endothelial function, another objective was to investigate the potential independent and additive benefits of resistance training on endothelial function in coronary patients already participating in an exercise-based cardiac rehabilitation program. The primary objective of the present study was to determine whether adjunctive resistance training in coronary patients who are already aerobically exercising will lower resting and exercise (standardized lifting) blood pressures and heart rate responses following 12 weeks of structured, supervised aerobic and resistance training. A secondary objective was to
determine the impact of this physical training regimen on brachial artery reactivity, an index of endothelial function.
Hypothesis

For the purpose of this study, the following hypotheses were proposed:

1. Heart rate response will be attenuated in response to the fixed submaximal workload following the 12-week resistance training program.

2. Blood pressure response will be attenuated in response to fixed submaximal workload following the 12-week resistance training program.

3. Rate pressure product will be decreased in response to fixed submaximal workload following the 12-week resistance training program.

4. Rating of perceived exertion will be lower in response to fixed submaximal workload following the 12-week resistance training program.

5. Endothelial function will improve after the 12-week resistance training program.
CHAPTER 2: Literature Review

Cardiovascular Disease

According to the Mayo Clinic (2014) “cardiovascular disease (CVD) generally refers to conditions that involve narrowed or blocked blood vessels that can lead to a heart attack, chest pain (angina) or stroke”. Cardiovascular disease and coronary heart disease (CHD) are often used interchangeably. CHD is the result of coronary artery disease, which starts in early childhood and is defined as the buildup of plaque in the arteries that supply the heart muscle. Over time, coronary artery disease can lead to coronary heart disease as the progression of plaque buildup continues. As the plaque continues to grow, eventually it will start to limit the blood flow to the heart muscle, also called ischemia. A healthy life style free of or with limited risk factors can help to slow the progression of coronary artery disease and hopefully prevent coronary heart disease (AHA, 2015). Mozaffarin et al. (2014) demonstrate the importance of prevention by summarizing statistics on cardiovascular disease,

Cardiovascular disease is the leading global cause of death, accounting for 17.3 million deaths per year, a number that is expected to grow to more than 23.6 million by 2030. Nearly 787,000 people in the U.S. died from heart disease, stroke and other cardiovascular diseases in 2011. Cardiovascular diseases claim more lives than all forms of cancer combined. About 85.6 million Americans are living with some form of cardiovascular disease or the after-effects of stroke. Heart disease is the No. 1 cause of death in the world and the leading cause of death in the United States, killing over 375,000 Americans a year. Heart disease accounts for 1 in 7 deaths in the U.S. From 2001 to 2011, the death rate from heart disease has fallen about 39 percent–but the burden and risk factors remain alarmingly high. (Mozaffarin, et al., 2014)
Profound clinical and statistical research has identified various factors that increase the risk for coronary heart disease. Primary risk factors significantly increase the risk while contributing factors are only associated with increased risk. Risk factors that are not modifiable include: age, gender, and family history. High cholesterol and triglyceride levels, high blood pressure, diabetes and pre-diabetes, overweight and obesity, smoking, unhealthy diet, stress, and insufficient physical activity are considered modifiable, either through lifestyle changes or medication treatment (AHA, 2012).

**Benefits of Exercise/Physical Activity**

Research findings suggesting the positive effects on risk factors associated with CHD can be explained by measurable physiological changes caused by regular exercise. Mainly, exercise modifies several risk factors associated with the disease, as it reduces body weight, blood pressure, heart rate, and LDL cholesterol, and it increases insulin sensitivity, which is associated with the development of diabetes. Furthermore, it raises HDL cholesterol level, which is considered a negative risk factor for heart disease if the value is ≥ 60 mg/dl. Regular exercise will increase a person’s muscular strength and the body’s ability to transport and use oxygen, also called maximal oxygen consumption or aerobic capacity. Regular daily physical activities can be performed with less fatigue, which may be measured as perceived physical exertion (RPE), as a person’s ability to transport and utilize oxygen improves. Research has confirmed that exercise improves the ability of blood vessels to dilate in response to exercise or hormones. Improved vascular wall function enhances the ability of providing oxygen to the working muscles including the heart muscle (Meyers, 2003).

Numerous studies have been conducted investigating relative risks, morbidity, and mortality rates associated with physical inactivity. Sesso, Pfaffenbarger, and Lee (2000) found
a 10% significant risk reduction for individuals who expend ≤ 4,200 kj/wk. Furthermore, they were able to proof that physical activity has a positive effect on other risk factors. These findings led to the conclusion that only vigorous, not moderate, physical activity decreases those risks.

Moreover, Shiroma and Lee (2010), in the Surgeon General report, indicated a 20–25% risk reduction with moderate amount of physical activity, and a 30–35% reduction through vigorous physical activity. Their exercise guidelines have been based on those findings, which recommend at least 300 minutes of moderate physical activity per week or 150 minutes per week of vigorous aerobic physical activity (Shiroma & Lee, 2010).

Costill, Branam, Moore, Sparks, and Turner (1974) investigated the effects of physical training in men with CHD by conducting a randomized control trail using graded treadmill exercise testing. The results have demonstrated that a supervised training program for patients with CHD and for individuals with a low fitness capacity significantly improves exercise capacity.

Profound evidence exists that regular physical activity is associated with a decreased risk of morbidity and mortality of coronary heart disease for both men and women, as well as positive effects on co-existing risk factors. Although more recent studies do exist, more research needs to be conducted on resistance training and its role in cardiovascular health promotion.
Health Benefits of Resistance Training

As described by McCartney and McKelvie (1996), resistance exercise is a combination of static and dynamic contractions, the proportions of each varying in accordance with the degree of effort required to lift the weight. At the beginning of the movement an isometric contraction occurs until the muscle force exceeds the weight of the object to be lifted. A dynamic concentric contraction during the raising of the weight is followed by a dynamic eccentric contraction during the lowering phase and then a relaxation phase between successive lifts.

Winett and Caprinelli (2001) investigated various benefits of resistance training in their review study on potential health benefits of resistance training. The authors reviewed studies mainly involving middle-age to older men and women, and found that resistance training had a positive effect on risk factors associated with osteoporosis, cancer, diabetes, and cardiovascular disease. No variances were seen in the percentage change by age or sex.

Regarding weight and body fat loss the authors concluded that resistance training may play an important role in maintaining weight loss by increasing lean body mass. They argued that caloric restriction and aerobic exercise alone may compromise lean body mass along with lowering resting metabolic rate. Furthermore, they presented a study investigating the effects of exercise on central obesity which showed a 40% reduction in visceral fat in middle-aged, obese men following a low caloric diet and participating in low-volume resistance training (Winett & Carpinelli, 2001). Central obesity is related to clustering cardiometabolic
risk factors, as it increases the risk of developing insulin resistance, glucose intolerance, abnormal lipid profiles, and hypertension (McCartney & McKelvie, 1996).

According to Winnet and Caprinelli (2001), several studies, however not completely consistent, have shown that resistance training can increase HDL cholesterol. Additional health—related benefits of resistance training reviewed by the authors included the maintenance of functional capacities, prevention of osteoporosis, sarcopenia, low back pain, and other disabilities. Furthermore, they found that studies consistently showed that resistance training decreases blood pressure, heart rate, and rate pressure product. These variables may be at greater importance for patients with cardiovascular disease.

**Cardiac Rehabilitation**

Over the last decades cardiac rehabilitation has shifted its focus from simple monitoring for the safe return to physical activities to patient education, individually tailored exercise prescription, risk factor modification, and the psychological and overall well-being of cardiac patients (Mampuya, 2012). A typical cardiac rehabilitation program includes cardiovascular monitoring, physical exercise, dietary counseling, smoking cessation, stress management, and health education opportunities. According to the National Heart, Lung, and Blood Institute (NHLBI, 2013) the benefits of cardiac rehabilitation include reduced overall mortality, risk of future cardiac complications, and the risk of dying from a myocardial infraction; symptom relief and reduced medication need to treat chest pain; decreased hospital re-admission for cardiac complications; improved overall health by reducing risk factors associated with cardiovascular disease; and improved quality of life.
Cardiac rehabilitation consists of three phases. Phase I, the inpatient phase, is started while the patient is still in the hospital. Due to much shorter hospital stays with modern cardiology, the focus in this phase is set on early mobilization to make self-care possible by discharge, and brief counseling about the nature of illness, treatment, risk factors identification and management, and home exercise guidelines. Phase II is a supervised ambulatory outpatient program that usually consists of 18 to 36 electrocardiogram (ECG) monitored exercise sessions mainly focusing on safety and screening for any adverse signs or symptoms during aerobic exercise. Most programs offer an optional resistance training component for eligible patients. Additionally, risk factor identification and modification are part of Phase II, as well as various health education opportunities. Phase III is a maintenance program that emphasizes physical fitness and additional risk-factor reduction with less or no medical surveillance dependent upon if home exercise or a supervised program is chosen by the patient (Mampuya, 2012).

Resistance training has become an essential part of cardiac rehabilitation especially during the maintenance phase. Specific resistance training guidelines for cardiac patients have been established by the ACSM and AHA. Both encourage the inclusion of a resistance program in combination with aerobic exercise for cardiovascular patients. Moderate-to-high resistance training (40%–80% 1 RM) can be performed safely if the patient is showing no signs of anginal symptoms, ischemic changes on ECG, abnormal hemodynamic responses, and complex dysrhythmias. More specifically, contraindications to strength training include unstable angina, uncontrolled hypertension (systolic BP ≥ 160 mmHg and/or diastolic 100 mmHg), uncontrolled dysrhythmias, unevaluated recent history of heart failure, severe stenotic or regurgitant valvular disease, and hypertrophic cardiomyopathy. As an additional
pre-requisite for the inclusion into a resistance program, patients with myocardial ischemia or poor left ventricular function should have a cardiorespiratory fitness level of > 5 METs or 6 METs (ACSM, 2010).

Once a patient is cleared for strength training a supervised resistance training orientation should be conducted emphasizing proper lifting technique, safe breathing pattern, and exercise prescription. While lifting, patients should not exceed an effort of 11–13 on the RPE scale. The initial load should allow 12–15 repetitions (40%–60% of 1 RM). Low-risk patients may progress to 8–12 repetitions (60%–80% 1 RM). Loads may be increased by 5% increments (2–5 lb/week for arms and 5–10 lb/week for legs) when patients can comfortably lift 12–15 repetitions. Due to possible elevated blood pressure (BP) response, the rate pressure product (RPP) should not exceed that of the endurance exercise. Two to four sets should be performed for each major muscle group. However, especially for novice lifters, one set can elicit strength gains. Resistance training should be performed 2–3 times/week at non-consecutive days with at least 48 hours of rest (ACSM, 2010).

**Rate of Perceived Exertion (RPE)**

The rate of perceived exertion scale, invented by Borg, is a means of rating the level of exertion subjectively during exercise. The RPE scale is related to exercise heart rates and oxygen consumption (VO\(_2\)), as it takes the linear rise of heart rate and VO\(_2\) during exercise into account. The initial scale is set from 6 to 20 and the revised scale from 0 to 10, which also reflects non-linear changes in lactate and ventilation during exercise. It is widely used in the cardiac rehabilitation setting and during cardiorespiratory stress testing. The studies reviewed for this paper refer to the original RPE scale of 6–20. A rating of no exertion corresponds to 6 on the RPE scale, and a rating of 20 corresponds to the maximal level of
exertion (Heyward, 2010).

Most studies evaluating the effects of resistance do not include the RPE scale to determine training effects, possibly due to its subjective nature. Moreover, most studies have not evaluated strength gains by comparing fixed absolute loads, in which a decrease in RPE would be expected after the training periods. Instead, strength gain and fitness capacity were measured in terms of relative workloads or by assessing changes during aerobic testing.

Wood et al. (2001) investigated concurrent cardiovascular and resistance training in older healthy adults. The 36 participants were randomly assigned to a control group or three exercise groups. All exercise groups trained for 12 weeks doing either resistance training alone (RT), cardiovascular training alone (CVT), or cardiovascular/resistance training combined (CVT and RT). Before and after the training periods, the subjects performed a submaximal exercise test (GXT), a five-repetition maximal strength test (5 RM), and a functional fitness test. Variables of interest included RPE, heart rate, blood pressure, mean arterial pressure, rate pressure product, 5 RM strength scores, and functional fitness scores. RPE values were measured during each stage of the submaximal tests but were not considered during the 5 RM test or the functional fitness test. RPE scores during the second stage of GXT were used to assess training effects. The results showed a significant decrease in RPE for all training groups during the second stage of the GXT with the changes being similar for each group.

The studies evaluated for this review primarily used the RPE scale during aerobic functional testing as an additional variable during the various stages. Nevertheless, patients are likely to use their rate of perceived exertion during regular resistance training to determine suitable initial loads and load progression as they perceive the initial loads to be
“easier” to lift. Furthermore, during lifting tasks as part of activities of daily living (ADL), individuals usually decide on personal ability to lift an object based on perceived effort level. Therefore, the RPE scale can be a valuable variable to be measured as resistance training effects are assessed. However, RPE measurements might be limited by its subjectivity. Wosornu, Bedfordt, and Ballantyne (1996) conducted a study on the comparison of the effects of strength and aerobic exercise training on exercise capacity and lipids after coronary artery bypass surgery. They argued that perceived exertion is an acceptable substitute for heart rate monitoring. A patient at the end of a program might continue unsupervised exercise and needs to decide on the level of that exercise by relying on their symptoms, rather than their heart rate. Therefore, during the training sessions, no heart rate or cardiovascular monitoring was conducted. During training patients were expected to be at their perceived exertion level, as recommended by the ACSM.

**Heart Rate (HR)**

Heart rate measures how often the heart beats in a minute. A heart rate of less than 60 bpm is considered bradycardia (slow rate), 60 to 100 bpm normal rate, and a heart rate greater than 100 bpm is considered tachycardia (fast rate). Resting heart rate should not be considered a cardiorespiratory measure, as there is a wide variability in resting heart rate in the population. A low resting heart is not always suggestive of high cardiorespiratory fitness, although resting heart rates of highly trained individuals may be as low as 28 to 40 bpm. Especially among cardiac patients, low resting heart rates might be caused by medications. However, changes in resting heart rate or heart rate response to identical absolute workloads can be indicative of cardiorespiratory improvement (Heyward, 2010).
Numerous studies have investigated the effects of resistance training, including measuring resting and exercising heart rate, before and after an applied resistance training program. A study by Pierson et al. (2001), investigating the effects of combined aerobic and resistance training versus aerobic training alone in cardiac rehabilitation, found that submaximal heart rates were lower among subjects that were trained with a combination of aerobic and resistance training.

Twenty coronary patients were randomly assigned to either an aerobic training only group (AE) or a group combining aerobic and resistance training (AE+RT). The study was conducted over a 6-month period in which all patients exercised 30 min aerobically three times per week and the AE+RT group performed an additional two sets of strength training exercises. Each patient performed a treadmill GXT in order to measure ventilator threshold before the training period. Strength gain, changes in body composition, and submaximal exercise efficiency were measured. The exercise efficiency at submaximal workloads was measured during a 10-minute constant load walk on the treadmill at workloads that corresponded to their ventilator threshold measured during the GXT. Heart rate, blood pressure, rate of perceived exertion, rate pressure product, VO_{2peak}, and VO_{2vt} were measured.

In regard to heart rate, the researchers found a significant decrease in resting HR in the AE+RT group but not in the AE group. Furthermore, at steady state exercise conditions during the constant load walk test heart rate was also found to be significantly decreased in the AE+RT group but not in the AE group. A significantly greater change in HR was found in the AE+RT group compared to the AE group. The researchers concluded that a combination of resistance and aerobic training results in reduced cardiovascular demand at a fixed submaximal aerobic exercise load. A similar study by Maiorana et al. (2000) examining the
effects of combined aerobic and resistance training in CHF patients showed a 10% reduction in HR at submaximal aerobic work levels after the training. Moreover, findings described by Wosornu, Bedfordt, and Ballantyne (1996) showed a significant decrease in resting heart rate as well as during submaximal aerobic workloads in coronary patients after strength training.

McCartney, McKelvie, Martin, Sale, and MacDougall (1993) investigated the effects of a 12-week strength training program on heart rate and blood pressure among older healthy males during 10 repetitions of diverse weight lifting exercises. The 15 subjects that were included in the study were required to complete three supervised weight training sessions per week. Intrabrachial arterial pressure and HR were continuously measured during the exercises before and after the training period. The subjects were lifting weights at the intensity of 60–80% of 1 RM pre- and post-training with the corresponding load changes. The results showed a marked decrease in HR after the training period as the subjects were lifting 80% of their pre-training 1 RM. The HR response was similar after training during lifting 60%, 80%, and 100% of the post-training 1 RM when compared to the pre-training values when the same relative, but lighter, absolute load was lifted. The authors stated that the strength gain found corresponds to other research on both young and old healthy subjects, and patients with coronary artery disease. They were able to show attenuated circulatory responses during lifting with the trained muscle. Additionally, it supports the use of resistance training in older adults if the effects can be transferred to ADL using the trained muscle (McCartney et al., 1993). Using the RPE scale could have been a beneficial addition to the study results since it could have given insight on how the subject perceived their improvement and a possible relation to the impact on ADL.
Blood Pressure

Throughout the vascular system blood exerts pressure on vessel walls, which is greatest in the arteries and is referred to as blood pressure. It is the force the blood exerts on the arterial walls and is dependent upon the amount of blood pumped by the heart and the resistance to blood flow. Normal blood pressure is < 120/80 mmHg and is expressed as systolic (SBP) over diastolic blood pressure (DBP). Systolic pressure is the pressure exerted on the artery walls as the left ventricle pumps the blood during ventricular systole. Diastolic pressure is lower and represents the pressure during diastole as the heart muscle relaxes (Powers & Howley, 2009).

Hypertension is one of the primary risk factors associated with cardiovascular disease (CVD); (Corrick, Hunter, Fisher, & Glasser, 2013). Hypertension is a condition in which the long-term force of blood against the artery walls is increased to a point at which it may cause heart problems, including heart disease. It is determined both by the amount of blood the heart pumps and the amount of resistance to blood flow in your arteries. Headley (2012), in an article for ACSM, classifies hypertension as follows: “an individual is diagnosed as having hypertension if their seated blood pressures on two separate occasions exceed a systolic (SBP) reading of 140 mmHg or a diastolic (DBP) reading of 90 mmHg.”

Aerobic exercise has been proven to be effective lowering blood pressure. A comprehensive meta-analysis involving aerobic endurance and resistance training studies and their effect on blood pressure reduction has found that aerobic endurance training alone resulted in an averaged decrease in blood pressure of 3.0/2.4 mmHg. Although less data were available, the results showed that resistance training of moderate intensity can reduce blood pressure (3.5/3.2mmHg) (Fagard, 2006). According to the National High Blood Pressure
Education Program, “it has been estimated that a 5 mmHg reduction of SBP in this population would result in a 14 percent overall reduction in mortality due to stroke, a 9 percent reduction in mortality due to CHD, and a 7 percent decrease in all-cause mortality” (Chobanian et al., 2004).

Collier et al. (2011) investigated sex differences of hemodynamics and arterial stiffness following a 4-week resistance versus aerobic exercise training in individuals with pre-hypertension and stage 1 hypertension demonstrated similar results than those described in the meta-analysis by Fagard (2006). For men the results at rest demonstrated a decrease of 4 mmHg in SBP and a 3 mmHg reduction of DBP after aerobic training. For women resting SBP decreased 5 mmHg and DBP 3 mmHg. After resistance training, women also demonstrated a reduction in resting SBP and DBP. Interestingly, the reduction in DBP was significantly greater in women compared to men (10 versus 2 mmHg). The authors concluded that both aerobic and resistance training reduce resting blood pressure and are a beneficial addition to the treatment of hypertension (Collier et al., 2011).

In contrast, the above-mentioned study by Wood et al. (2001) only showed a reduction in resting SBP after aerobic training but not resistance training or a combination thereof. No changes in DPB were shown across all training groups. At submaximal aerobic workloads, however, there was a significant decrease of DBP in the aerobic and the resistance group, but not in the combined group (Wood et al., 2001). Measurements of hemodynamic responses during resistance training exercises could have been a valuable addition to the study results.

As previously mentioned, McCartney et al. (1993) investigated weight training effects of the circulatory response during weight lifting in older adults. With regard to blood
pressure, they were able to show a significant decrease in both SBP and DBP after training while the subjects were lifting pre-training loads at 80% of 1 RM. During lifting post-training, 80% of 1 RM blood pressure responses were the same as those generated during pre-training which corresponded to lighter weights. It was concluded that an increase in strength results in attenuated blood pressure results when the identical load is lifted since after training a reduced relative effort is required (McCartney et al., 1993).

**Rate Pressure Product**

Rate pressure product (RPP) is a strong hemodynamic predictor of myocardial oxygen demand and provides an estimate of left ventricular function. It is calculated as the product of maximal heart rate and maximal systolic blood pressure (Gobel et al., 1978). As mentioned above, the study conducted by Wood et al. (2001) did not show any decrease in SBP or HR during the submaximal exercise test after the training period for all groups. As a result, no decrease in RPP was produced during submaximal exercise after the resistance training period. However, the findings did show a significant decrease in RPP at rest after the training in all exercise groups, as each exercise group showed significant reductions in at least one of the two variables (Wood et al., 2001).

In contrast, the study by Pierson et al. (2001) showed a significant decrease in both HR and RPP under steady state submaximal exercise conditions in the group combining aerobic and resistance training but not in the aerobic only group. Neither group showed any significant reduction in SBP, which led the researches to the conclusion that the decrease in RPP was due to the decrease in HR rather than SBP. The same was found for post-training resting values (Pierson et al., 2001). Similar observations were made by Wosornu et al.
McCartney et al. (1993), who studied the effects of resistance training on circulatory response during weight lifting, found that maximal RPP was lower after training during the lifting of identical absolute pre-training loads for all exercises. However, the differences were only significant during the double-leg press exercise. This could be explained by the fact that the largest decrease in HR and SBP was recorded during the double-leg press exercise. Furthermore, after training, RPP was found to be the same during lifting post-training loads and lifting lighter pre-training loads.

**Endothelial Function and Flow-Mediated Vasodilation**

The endothelium of the blood vessels has various important functions, including the regulation of vascular smooth muscle tone, thrombosis and anticoagulation control, promotion of intra-arterial permeability, and inflammation control (Alley, Owens, Gasper, & Grenon, 2014). Furthermore, various substances are released by the endothelium to regulate vascular dilation and constriction. The release of nitric oxide (NO) from the endothelial has been studied in great detail, as it acts as a main mediator in the maintenance of vascular tone (Harris, Nishiyama, Wray, Richardson, 2010). Risk factors such as aging, smoking, obesity, dyslipidemia, hypertension, hyperglycemia, and a genetic predisposition to early atherosclerosis are associated with endothelial dysfunction (Widlansky, Gokce, Keaney, & Vita, 2003). Vascular endothelial dysfunction is an impairment of the regulatory process of smooth muscle tone, inflammation, antithrombosis, and anticoagulation within the blood vessel wall, and is an initial step toward atherosclerosis. (Alley et al., 2014). Thus, assessing endothelial function has become of great interest in the medical research field for prognostic
purposes. Moreover, the evaluation of endothelial dysfunction seems to be a respected option in the assessment of treatment outcomes.

Flow-mediated vasodilation (FMD) testing is a non-invasive method to evaluate endothelial function of the peripheral arteries using Doppler ultrasound measurements (Harris et al., 2010). Endothelial function of the peripheral arteries was shown to be closely related to the endothelial function of the coronary arteries by Anderson et al. (1995). Due to its non-invasive nature and relatively simple procedure, it has become the most prevalent method in clinical research for the evaluation of vascular endothelial function (Harris et al., 2010). A more invasive option to measure endothelial function directly in the coronary arteries involves the intracoronary infusion of acetylcholine in the combination of angiography to evaluate vascular response to the infusion (Alley et al., 2014). A healthy endothelium should demonstrate vasodilation in response to acetylcholine infusion or increased blood flow, by releasing vasodilator agents such as NO. Patients with endothelial dysfunction demonstrate impaired FMD and vasoconstriction rather than normal vasodilation, likely due to loss of NO effects (Widlansky, Gokce, Keaney, & Vita, 2003).

During FMD testing, the percent change in brachial artery diameter is measured during a period of reactive hyperemia, an increase in blood flow after temporary interruption. Using an ultrasound probe, the baseline diameter and blood velocity of the brachial artery are measured at the antecubital fossa of the forearm while the subject is laying in a supine position. Using a blood pressure cuff, the blood flow will be occluded for at least 5 minutes by inflating the cuff 30–50 mmHg above the subject’s systolic blood pressure. Multiple measurements of the arterial diameter and blood velocity are recorded at various time segments during cuff release and post cuff release. Baseline and percentage change in
diameter, as well as shear rate, are documented. Percent FMD is defined as “the change in arterial diameter after occlusion in response to hyperemia, over baseline diameter” (Alley et al., 2014). Studies reviewed by Alley et al. (2014) suggest a percent FMD of 6–10% for healthy adults and a percent FMD of 0–5% in patients with CAD using brachial artery FMD testing.

Based on clinical research, exercise training has been accepted as a nonpharmacological treatment option for endothelial dysfunction (Hambrecht et al, 2000). Widlansky, Gokce, Keaney, and Vita (2003) support that view, and concluded through research that,

Exercise is an important lifestyle factor that reduces cardiovascular risk, and exercise has been repeatedly shown to improve endothelial vasomotor function in healthy subjects and in disease states including hypertension, congestive heart failure, and CAD. These effects appear to be mediated in large part by increased NO bioavailability and may be greatest in vascular beds exposed to repetitive increases in blood flow during exercise, which includes the coronary circulation for all types of exercise.

A study investigating specific types of training (aerobic, resistance, and the combination) and the effects on endothelial function among patients with recent myocardial infarction found that endothelial function improved independent of the type of exercise training. In this study, 209 (male and female) patients, who had been referred to cardiac rehabilitation after a first uncomplicated acute myocardial infarction, completed baseline and follow up measurements. The subjects were randomly assigned into four groups differentiating different exercise types: aerobic only, combination of aerobic and resistance,
resistance only, and no regular physical activity. The aerobic only group exercised four times a week for 4 weeks on a cycle ergometer for 60 min. The aerobic/resistance group alternated two aerobic and two resistance training sessions per week. The resistance training group completed 4 sessions of controlled resistance exercises a week. The control group avoided regular physical activity during the four weeks.

Endothelial function was assessed by measuring brachial artery reactivity via FMD testing prior to the training period and 4 weeks after the completion, as well as 4 weeks after detraining. The results during baseline measurements showed no significant difference in FMD between all groups. FMD was found to be significantly lower compared to values considered normal, suggesting endothelial dysfunction. Follow-up testing after the initial 4 weeks showed a significant increase in FMD for all exercise groups. The control group also improved FMD but to a much lesser extent than the training groups. Testing was repeated after a 4-week detraining period, which included no structured physical activity sessions. FMD was found to be significantly lower compared to the results at the end of the trainings period. According to the study results, the researchers concluded that “the present study demonstrates that all types of exercise (aerobic, resistance, and their combination) are safe and effective strategies for correcting endothelial dysfunction in patients after a recent myocardial infarction” (Vona et al., 2009).

In comparison, a prospective study conducted by Hambrecht et al. (2000), using a different more invasive method, also showed an improvement in coronary endothelial function in coronary artery patients after a 4-week aerobic exercise program by measuring the changes in vascular diameter in response to the intracoronary infusion of acetylcholine via angiography. The protocol included the random assignment of 19 CAD patients (male)
with endothelial dysfunction to either an exercise group or an inactive control group. Patients in the exercise group exercised daily for 20 minutes on a bicycle ergometer, whereas the control group continued a sedentary lifestyle.

Before and after the 4-week training period, all patients including the inactive group underwent angiography to study the effects of the direct infusion of various pharmacological agents including saline, acetylcholine, adenosine, and nitroglycerin. The exercise group showed a reduction in coronary-artery constriction by 48% in response to acetylcholine infusion compared to baseline measurements before the exercise training. Furthermore, the exercise training led to a 96% increase in blood flow velocity compared to baseline. No significant difference was shown in the control group. The exercise and control group showed similar responses to the NO infusion, the vasodilatory response remained virtually unchanged for both groups. Coronary blood flow reserve (mean peak flow velocity after administration, divided by the velocity at rest) was assessed by adenosine infusion, which showed a significant improvement of a 29% change in the exercise group. Results did not significantly differ after 4 weeks from results of the baseline study in the control group. According to these results, the researchers concluded that exercise training partially improves endothelial function of large coronary and resistance vessels in patients with coronary artery disease (Hambrecht et al., 2000).

In contrast, a study by Kitzman et al. (2013) showed no significant difference in brachial artery FMD after 16-week endurance exercise program in older patients with heart failure and preserved ejection fraction (≥ 50%). Sixty-three patients were randomized into either an exercise group, which exercised aerobically for one hour three times per week over
a 16-week period, or the control group which did not exercise. Both groups were tested at baseline, at eight weeks, and after 16 weeks. Fifty-four subjects completed the full protocol.

Subjects in the exercise group showed a significant increase in VO$_2$peak after the 16-week training period, and the results were significantly greater compared to the control group. However, the results for brachial artery FMD showed no significant differences between the groups for baseline brachial FMD, and no significant change in FMD was revealed after the 8 or 16 weeks intervention for both groups. The results actually showed a slight decrease in FMD in the exercise group. It was concluded that exercise training in patients with heart failure and preserved ejection fraction improves VO$_2$peak without changing brachial artery FMD, suggesting that FMD might not be a crucial component of exercise intolerance in this population (Kitzman et al., 2013). However, compared to the previously mentioned studies, patients with a history of hyperlipidemia, smoking, coronary, cerebrovascular, or peripheral artery disease were excluded from the study due to the effects of atherosclerosis on arterial function.

Summary

To summarize, abundant studies have investigated the influence of resistance training on strength gain, health benefits, functional capacity, cardiorespiratory fitness, circulatory responses (HR, BP and RPP), and much more. Furthermore, several populations have been investigated, including older individuals and cardiac patients with various comorbidities. For the purpose of this review, studies examining the circulatory responses to resistance training were included. All studies showed an attenuation in circulatory responses following a resistance training program. However, different results were produced for diverse variables, measuring circulatory responses, and circumstantial variations. Most studies evaluated the
post resistance training changes in circulatory responses during submaximal aerobic exercise testing and focused mainly on strength gains during strength testing. In contrast, the author of the present study is only aware of one study, by McCartney et al. (1993), that has tested the circulatory responses during actual weight lifting, giving an insight on changes in heart rate, blood pressure, and rate pressure product while lifting. These researchers focused their study on older adults. To the best of the author’s knowledge, no study has investigated the circulatory responses in cardiac patients during weightlifting after the inclusion of a resistance training regime to an already existing aerobic exercise program. Vasculature and circulatory responses may differ in this population due to medications and disease progress. Therefore, more research needs to be done to investigate the effects of resistance training on circulatory responses during weight lifting in cardiac patients. Abundant research has been conducted investigating the effects of exercise on endothelial function using various methods including FMD testing. Numerous studies showed an improvement in endothelial function after an exercise program had been implemented. Although training period length, sample sizes, populations, and type of exercise differed, most studies showed a positive effect of exercise on endothelial function. For the purpose of this study, the interest lies in examining the effects on endothelial function when implementing a resistance training regime to an already existing aerobic training program in CAD patients.
CHAPTER 3: Methodology

Study Population

Fifteen subjects have been included in the study. Eligible subjects were selected from a pool of Beaumont’s Phase 3 cardiac rehabilitation participants who responded to a flyer outlining a study overview. Low-risk patients diagnosed with coronary artery disease (CAD) who were focusing primarily on aerobic exercise and were not participating in regular/heavy resistance training were included in the study.

Eligibility Criteria

Inclusion criteria included an exercise capacity $\geq 5$ metabolic equivalents (METs), signifying the ability to increase energy expenditure at least five times above resting level, based on the subjects most recent peak or symptom-limited exercise test. If no exercise test data were available, subjects were required to have a submaximal training load of $> 3$ METs based on their current exercise training workload. Eligible “low-risk” subjects were included if their left ventricular ejection fraction was $\geq 40\%$. Moreover, subjects were required to have a history of coronary artery disease (i.e., diagnosis of CAD, previous myocardial infarction, percutaneous coronary revascularization, coronary artery bypass surgery, angina pectoris, or combinations thereof).

Subjects were excluded from the study if they had any signs or symptoms of myocardial ischemia or threatening ventricular arrhythmias. Furthermore, any subjects that had baseline electrocardiogram abnormalities including, but not limited to, frequent arrhythmias (frequent premature ventricular contractions or atrial fibrillation) and pacemaker rhythm, which preclude an accurate assessment of the heart rate response during standardized
lifting tasks, or had orthopedic limitations due to severe arthritis or any musculoskeletal injury were excluded from the study. Patients with gait instability or any other balance/coordination limitations were also excluded from participation in the study. Additionally, subjects with any other serious medical conditions that would prohibit their full participation and completion were excluded. Subjects that were regularly participating in moderate to heavy resistance training leading up to this study were not eligible to participate.

The eligibility criteria were evaluated through chart review, including medical history and Phase 2 and Phase 3 cardiac rehabilitation records as well as patient interviews.

**Testing Protocol**

**Hemodynamic and RPE testing.** Prior to initial testing, an individual resistance-training practice session was conducted with each subject to familiarize him or her with the eight resistance training exercises included in the study protocol. The session focus was on proper technique, breathing, and posture during weight lifting. Additionally, the session served as an aid to determine the appropriate weight load for each exercise.

During the initial testing, subject’s resting and exercise (lifting) blood pressure, heart rate, and rating of perceived exertion were obtained using sphygmomanometer, electrocardiogram telemetry unit, and Borg rating of perceived exertion scale (6–20).

Following a 10-minute aerobic warm-up on the treadmill at 2 mph 0% grade, subjects performed three resistance exercises: unilateral bicep curl, unilateral overhead shoulder press, and bilateral leg press. Dominant arm was used during unilateral exercises and all exercises were completed in a seated position with back support to standardize the protocol. Subjects completed a warm-up set for each exercise of 12 repetitions corresponding to rating of perceived exertion 10–11 (fairly light) at approximately 50% of testing load. Bicep curl and
overhead shoulder press were performed using free weights, whereas the leg press was performed on a resistance machine (Quantum Leg Press). Following a 2-minute rest period, the subjects performed a second set at an intensity allowing only 10 repetitions corresponding to 60–80% of the 1 repetition maximum and rating of perceived exertion of 12–13 (somewhat hard). Blood pressure, heart rate, and rating of perceived exertion were obtained immediately before completion of this set. Lastly, after the completion of the 12-week training period, the testing was repeated while subjects lifted the exact same pre-testing loads for each exercise following the same standard protocol.

Pre- and post-testing were completed at the same time of day. Additionally, subjects were required to take their medications daily at the same time including pre- and post-testing days as well as during the training period. Furthermore, subjects were asked to refrain from caffeine on the testing days prior to their appointment. Protocol was not controlled for diet and fluid consumption.

**Brachial Artery Reactivity Testing (Flow Mediated Dilation).** Each subject was resting in a supine position for at least 10 minutes to reach hemodynamic and vasomotor stability. To begin the protocol, blood pressure was measured and recorded using a sphygmanometer. The brachial artery of the right arm was visualized in a longitudinal scan 2–6 cm above the antecubital fossa, with the site marked using a skin marker, using a 12 MHz linear matrix array transducer (GE Ultrasound Logiq E9 system). Angle-corrected pulsed Doppler spectral velocity analysis was used only to ensure not a vein but the brachial artery was visualized. Then, using M-mode imaging, the diameter of the brachial artery was recorded in real time over three consecutive cardiac cycles. The end-diastolic vessel diameter was measured in millimeters for each cycle using the ultrasound system electronic calipers,
and the results were averaged to a single value. After baseline measurements were taken, a blood pressure cuff was inflated on the upper arm to a pressure at least 20 mmHg above systolic pressure for 5 minutes. During active hyperemia, further measurements of brachial artery end-diastolic diameter were taken at 15, 30, and 45 seconds and at 1, 1.25, 1.5, 2, 2.5, 3, 4 and 5 minutes post cuff release, using the same technique at the same marked site used for baseline measurements. Flow-mediated vasodilation was calculated as the maximum absolute and relative increase in brachial diameter change during reactive hyperemia.

**Surveys.** Subjects completed the PHQ 9 depression screener, Duke Activity Status Index (DASI), and Dartmouth COOP Health screener. Each survey was completed before the initial testing and again following the completion of the 12-week training period.

**Training Intervention**

Subjects were instructed to complete at least two, but not more than three, supervised resistance-training sessions each week over a 12-week period, as a complement to their aerobic exercise regimen. Compliance was defined as completion of at least 21 sessions within 12 consecutive weeks or at least 24 sessions within 14 consecutive weeks. The resistance training regimen consisted of eight different exercises: leg press, bicep curl, overhead shoulder press, chest press, tricep extension, lat-pull down, leg extension, and leg curl. Exercises were conducted on a combination of multi-station resistance-training machines, cable station machines, and free weights. Subjects were required to complete two sets of 10 repetitions for each exercise at an intensity corresponding to 60–80% of the 1 repetition maximum and rating of perceived exertion of 12–13. All subjects were instructed on proper body form; proper breathing techniques (avoiding Valsalva maneuver); and the importance of warm-up before lifting (10 min), cool-down (5 min), and post-exercise
stretching (5–10 min). Furthermore, subjects were encouraged to gradually progress workloads throughout the training sessions in order to maintain relative exercise intensity as strength improves. Weight should be added if the subject is able to complete two or more repetitions over the assigned goal repetitions (10 repetitions) in the second set for two consecutive workouts. Estimated load increase for upper and lower body exercises was set to not exceed 2.5–5 lbs and 5–10 lbs, respectively.

**Risks and Benefits**

The present research protocol superimposes regular, progressive resistance training to the physical conditioning regimen of cardiac patients that were participating in aerobic exercise only (Phase 3 cardiac rehabilitation). The addition of resistance training to an endurance exercise program is a standard of care component of cardiac rehabilitation for eligible patients. Only Phase 3 participants who were eligible for resistance training and met the inclusion criteria were included in the study. All testing measurements were noninvasive and involved minimal risk, including assessment of blood pressure and heart rate during standardized lifting, and flow-mediated vasodilation evaluations. There was a potential risk of skin irritation due to electrode placement for the telemetry system and from the gel used for ultrasound imaging. Additionally, the inflation of the blood pressure cuff bore the risk of discomfort as it tightened around the arm; patients on anticoagulant medications were at increased risk of bruising.

Following data collection, hemodynamic and perceived exertion responses were evaluated to determine if regular resistance training, when superimposed on ongoing aerobic training, can further lower cardiac demands (heart rate and blood pressure) and rating of perceived exertion during standardized lifting in this cardiac population. Each subject, if they
chose, was provided data related to their participation and benefits related to the study, including pre-vs. post-blood pressure, heart rate, rating of perceived exertion, and electrocardiogram responses to standardized lifting loads. Also, results from flow-mediated vasodilation were provided.

Moreover, this study provided information on the hemodynamic (heart rate and blood pressure) responses and flow-mediated vasodilation to resistance training and provided selected coronary patients with an additional option for improving exercise tolerance.

**Data Analysis**

Descriptive statistics were analyzed on all data collected, including electrocardiographic, hemodynamic, and perceived exertion responses at a standardized submaximal workload (lifting). The means +/- SD (if normally distributed), medians, 25th, 75th percentiles, and minimum and maximum were given for all continuous variables and the counts and percentage frequencies for categorical or class variables. The primary objective of changes in hemodynamic responses were evaluated with sign tests, which were dependent on the normality of the differences from pre-vs. post-measurements in heart rate, systolic blood pressure, diastolic blood pressure, and rating of perceived exertion responses. Statistical significance was set at $p < .05$. The highest resistance training loads obtained during Week 12 was compared to the initial loads obtained at baseline again using sign tests due to the distribution of the differences. Change variable was categorized as; $< 0$ or decrease is -1, 0 or no change is 0, and $> 1$ or increase is 1. Additionally, Spearman correlations were examined between the change in load variables to corresponding hemodynamic and RPE variables for each exercise. Cohen’s d analysis was used to evaluate effect size. Paired Student’s $t$ test was
used for the evaluation of pre-and post-FMD measurements using SAS for Windows® 9.3, Cary NC for the analysis.
CHAPTER 4: Results

Subject Criteria

Of the 27 patients who responded to the study advertisement, 16 passed the screening process and were provided with the study information sheet, outlining the study details. Due to the low risk nature of the study protocol, patients consented to participation by acknowledging the information sheet. One patient was discontinued from the study due to ECG changes that caused difficulties in accurately assessing heart rate during testing. Fifteen subjects with a mean age of 66.13 ± 5.07 yrs completed the study protocol without any adverse events and appropriate attendance (sessions: 27.40 ± 5.23; weeks: 12.07 ± 0.26). Weight and BMI ranged from 140.8–240lbs and 20.2–34 kg/m$^2$ respectively. There was no statistical difference ($p = .09$) comparing pre-and post-training weight and BMI measurements (weight: 192.53 ± 28.24 to 188.93 ± 27.29 lbs; BMI: 27.71 ± 3.84 to 27.18 ± 3.64 kg/m$^2$). All subjects had been previously diagnosed with CAD and were regular participants of phase 3 cardiac rehabilitation. Descriptive statistics of subject characteristics at time of study begin can be found in Table 1.
Table 1. Descriptive Subject Characteristics

<table>
<thead>
<tr>
<th>Subjects (N=15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
</tr>
<tr>
<td>Male</td>
</tr>
<tr>
<td>Age (yrs)</td>
</tr>
<tr>
<td>Height (inches)</td>
</tr>
<tr>
<td>Weight (lbs)</td>
</tr>
<tr>
<td>BMI (34kg/m²)</td>
</tr>
<tr>
<td>LVEF (%)</td>
</tr>
<tr>
<td>Session (of 24 sessions)</td>
</tr>
<tr>
<td>Weeks (of 12 weeks)</td>
</tr>
</tbody>
</table>

**Medical History**
- Coronary Artery Disease 100%
- Myocardial Infarction 46.7%
- PCI /Stent 80.0%
- CABG 33.3%
- Angina 13.3%
- Hypertension 86.7%
- Hyperlipidemia 100%
- Type 2 Diabetes 33.3%

**Medications**
- Anticoagulant (incl. Aspirin) 100%
- Beta-blocker 80.0%
- ACE/ARB 46.7%
- Vasodilating Agents (Nitrates) 6.8%
- Diuretics 13.3%

Values are % or mean ± SD. LVEF= left ventricular ejection fraction, PCI=percutaneous intervention, CABG= coronary artery bypass graft, BMI= body mass index, ACE=angiotensin-converting-enzyme inhibitor, ARB=Angiotensin II Receptor Blockers.
Weight Lifting Capacity

The progressive weight training program was comprised of eight exercises including the three exercises used for testing of hemodynamic and RPE responses to fixed submaximal loads: bicep curl (BC), shoulder press (SP), and leg press (LP). The additional training exercises included triceps extension (TE), chest press (CP), lateral pull-down (LatP), leg curl (LC), and leg extension (LE). When the load change was assessed using sign tests, all exercises showed a statistically significant load increase ($p < .0001$): BC (12.93 ± 2.91 to 18.87 ± 4.27 lbs), SP (9.27 ± 2.05 to 15.73 ± 4.40 lbs), LP (170.0 ± 29.28 to 220.0 ± 31.90 lbs), TE (46.33 ± 10.43 to 80.67 ± 25.27 lbs), CP (37.67 ± 10.15 to 62.33 ± 19.54 lbs), LatP (52.33 ± 11.32 to 80.33 lbs), LC (45.33 ± 11.25 to 62.00 ± 13.20 lbs), and LE (42.00 ± 18.21 to 64.00 ± 19.57). The largest weight load change was shown for the TE with a percent change of 74.1% followed by the SP with 69.8%. The LP showed the smallest load increase with a change of 29.4% followed by the LC with 36.8%. BC showed an average increase of 45.9%. Spearman correlations were examined between the change in the load variable with the changes in the corresponding HR, SBP, DBP, RPP and RPE. The only statistically significant correlation was the negative correlation between load change and RPE change for BC ($-0.58260$) and LP ($-0.52210$).

Hemodynamic and RPE Responses

When resting values during pretraining testing were compared to values at 12 weeks of training intervention, including seated HR, SBP, DBP, and RPP, no statistical significant change could be shown. Lifting of the same pre-training loads evoked attenuated responses for all variables (HR, SBP, DBP, RPE, and RPP). A statistically significant decrease was shown for RPP during BC ($106 ± 27$ to $91 ± 22$, $p < .007$) and SP ($102 ± 24$ to $86 ± 17$, $p <$
.007), whereas RPP decrease during LP (116 ± 22 to 109 ± 26) did not achieve statistical significance ($p = .18$). Nevertheless, Cohen’s $d$ analysis revealed a small clinical effect for RPP during LP ($d = 0.3$). A medium to large effect size was yielded for BC ($d = 0.6$) and SP ($d = 0.8$) exercises. Attenuated responses in HR, SBP, and DBP were shown for all exercises but were only statistically significant for DBP during SP (74 ± 14 to 65 ± 10, $p < .09$).

Although not all values were statistically significant, $d$-values revealed a small effect on HR for all exercises and a medium to large effect on SBP for BC and SP and a small effect for the LP. RPE for all three exercises decreased significantly ($p < .0001$) following the RT intervention: BC (14.3 ± 1.6 to 9.7 ± 1.6), SP (13.9 ± 1.6 to 9.2 ± 1.5), and LP (14.3 ± 1.4 to 10.3 ± 1.6). Results showed a very strong practical effect on RPE. Table 2 and 3 show all results for hemodynamic and RPE measurements at rest and during exercise.

**Table 2.**

**Hemodynamic/RPE Responses at Rest**

<table>
<thead>
<tr>
<th></th>
<th>Pre</th>
<th>Post</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HR</td>
<td>57.73±7.16</td>
<td>56.33±7.69</td>
<td>0.42</td>
</tr>
<tr>
<td>SBP</td>
<td>113.47±12.29</td>
<td>113.60±19.63</td>
<td>0.61</td>
</tr>
<tr>
<td>DBP</td>
<td>69.33±9.25</td>
<td>62.13±12.01</td>
<td>0.12</td>
</tr>
<tr>
<td>RPP</td>
<td>65.65±11.57</td>
<td>63.31±9.32</td>
<td>1.00</td>
</tr>
</tbody>
</table>
Table 3.
Hemodynamic/RPE Responses During Exercise

<table>
<thead>
<tr>
<th></th>
<th>BC</th>
<th></th>
<th>SP</th>
<th></th>
<th>LP</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre</td>
<td>Post</td>
<td>Pre</td>
<td>Post</td>
<td>Pre</td>
<td>Post</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HR</td>
<td>71.4 ± 13.5</td>
<td>69.1 ± 11.8</td>
<td>0.61</td>
<td>0.2</td>
<td>71.6 ± 11.9</td>
<td>67.5 ± 8.6</td>
</tr>
<tr>
<td>SBP</td>
<td>149.1 ± 27.6</td>
<td>132.4 ± 23.6</td>
<td>0.013 *</td>
<td>0.7</td>
<td>143.2 ± 25.1</td>
<td>127.7 ± 19.4</td>
</tr>
<tr>
<td>DBP</td>
<td>75.7 ± 16.7</td>
<td>67.0 ± 10.9</td>
<td>0.092</td>
<td>0.6</td>
<td>74.4 ± 14</td>
<td>64.5 ± 9.9</td>
</tr>
<tr>
<td>RPP</td>
<td>106.2 ± 27</td>
<td>91.3 ± 22.2</td>
<td>0.007 *</td>
<td>0.6</td>
<td>102.3 ± 23.9</td>
<td>86.2 ± 16.9</td>
</tr>
<tr>
<td>RPE</td>
<td>14.27 ± 2.6</td>
<td>9.7 ± 1.6</td>
<td>&lt;0.0001 *</td>
<td>2.4</td>
<td>13.9 ± 1.60</td>
<td>9.2 ± 1.5</td>
</tr>
</tbody>
</table>

*p-value significant (<0.05), d=Cohen’s d, HR=heart rate, SBP=systolic blood pressure (mmHg), DBP=diastolic blood pressure (mmHg), RPP=rate pressure product (HR*SBP/100), RPE=rate of perceived exertion (Borg 6-20)

Vascular Function (FMD)

Overall as a group, FMD in response to reactive hyperemia showed the expected behavior of a gradual increase leading to a peak at approximately 90 seconds after the onset of increased flow, with a gradual decline over the following 2 to 3 minutes (Figure 1). There were no significant differences in the group response when pre-training and post-training were compared. Peak FMD responses for the 15 subjects were 12.8% and 10.3% dilation pre- and post-training, respectively (\( p = 0.332 \)). Three subgroups were identified in this small sample of subjects. The first was a group of five subjects with a normal response both before and after training which closely mimicked the group as a whole (Figure 2). These subjects showed no significant change comparing pre-and post-values. The second group was comprised of five subjects who were noted to have a somewhat delayed response to
hyperemic flow during pre-training testing, reaching a peak response at approximately three minutes after the onset of hyperemic flow. These subjects showed modest improvement in their post-training time to achieve maximum dilation from a mean of 117 seconds to 81 seconds ($p = .156$) and are further described in Figure 3. The third group of three subjects had a relatively abnormal response to hyperemic flow prior to training and demonstrated similar results after training intervention, with the vasodilatory response never having a clearly identified peak. Their response was one of a slow early dilation which then appeared to plateau for approximately two minutes and then gradually fell off (Figure 4).

Figure 1. Group Response.
Figure 2. Subgroup (5 subjects) normal response.

Figure 3. Subgroup (5 subjects) abnormal pre and normal post.
Figure 4. Subgroup (3 subjects) Abnormal Pre and Post

Surveys

Subjects were asked to complete three questionnaires before and after the training period including, PHQ 9 depression screener, Duke Activity Status Index (DASI), and Dartmouth COOP Health screener. No statistical significant change was shown for the PHQ9 depression screener (1.27 ± 1.16 to 0.80 ± 0.94, \(p = .34\)). All subjects scored below any of the diagnostic categories for depression (score ≥ 5) with the highest score being 4 and the lowest 0. The DASI scores, which represent a rough estimate of functional capacity, improved from pre-to post training evaluation (50.62 ± 12.39 to 53.32 ± 8.89). However, the change did not achieve statistical significance (\(p = .13\)). Comparing pre-and post-training scores for the Dartmouth health screener a significant change was shown (15.73 ± 3.49 to 13.73 ± 2.43, \(p= .039\)). This screener consists of nine categories, including ratings for physical fitness, feelings, daily activities, social activities, change in health, overall health,
social support, quality of life, and pain. The greatest improvement was shown in the “pain”
category followed by “overall health”. The smallest improvement was revealed in the
category “social activities” followed by “feelings”.

CHAPTER 5: Discussion

Effects of resistance training on hemodynamic responses are often evaluated by maximal or submaximal aerobic exercise testing. This practice allows for evaluation of overall improvement in fitness capacity and circulatory responses to aerobic activity. However, less insight can be revealed on the direct effect of training on hemodynamic responses during actual lifting tasks. This study design is unique in that it is evaluating hemodynamic responses during actual weight lifting tasks among coronary patients. In this study HR, BP, RPP, and RPE were obtained during submaximal standardized lifting tasks to evaluate the direct effect of training on cardiac demand. To the best author’s knowledge, only McCartney et al. (1993) investigated weight-training-induced attenuations of circulatory responses while weight lifting; however, McCartney et al.’s study participants were older healthy males, unlike the present study in which participants were coronary patients. Like healthy individuals, coronary patients encounter tasks during activities of daily living (ADL) that require lifting or carrying moderate to heavy loads, which elicit an increase in myocardial oxygen demand by increasing heart rate and blood pressure. The results of this study demonstrate that patients with coronary artery disease benefit from additional resistance training, as it improves strength and enables lifting at a lower fraction of maximal lifting capabilities, causing decreased cardiac demand due to attenuated HR and BP responses. This is especially important for cardiac patient as they are at higher risk for future cardiac complications, especially during high-intensity activities.

Hemodynamic Responses

In this study, heart rate and blood pressure were measured before and after training intervention during three exercises including bicep curl (BC), shoulder press (SP), and leg
press (LP). The results revealed attenuated responses in heart rate (HR) and systolic blood pressure (SBP) during all exercises. Although statistical significance was only reached for SBP during BC, a significant decrease in RPP could be shown for BC and SP. A small to medium effect on HR, SBP, and RPP was shown for all exercises, indicating a positive clinical effect of resistance training on hemodynamic responses. Results during LP showed attenuated responses; however, statistical significance was not reached. Participants were aerobically training prior to study begin predominately engaging in weight-bearing exercises, likely diminishing the training effect for the lower extremities which may explain weaker effects on HR, BP, and RPP during LP compared to BC and SP. Unlike these results, the study conducted by McCartney et al. (1993) showed the largest decrease in HR and SBP during the double leg LP. Furthermore, RPP decreased during single arm BC, single leg LP, but the differences were only significant during double leg LP. Those subjects might have been novice endurance and resistance training exercisers at the study beginning, which could explain the greater effects during the LP compared to this current study. Furthermore, the study design is very similar to this current study; however, in McCartney et al.’s study, BP was measured directly via catheterization measuring intrabrachial artery pressure compared to using regular sphygmomanometer measurement used in this study, which increased the possibility of intrarater variability and decreased reliability.

A study conducted by Wood et al. (2001) investigated concurrent cardiovascular and resistance training in older healthy adults and found no decrease in RPP during submaximal aerobic exercise testing after the training periods that included either resistance training only or a combination of aerobic and resistance training. However, comparable results to this current study might have been generated if HR and BP would have been measured during
actual weight lifting in addition to submaximal aerobic testing. Moreover, their findings revealed a significant decrease in RPP at rest after training in all exercise groups, in contrast to this current study which showed no significant decrease in HR, BP, and RPP at rest. In the current study, the subject pool consisted of well-aerobically trained subjects with a moderate to high fitness capacity, which could explain the smaller improvement of resting hemodynamic values compared to the results produced by Wood et al., where subjects did not participate in a training program prior to the study’s beginning. Also, 80% of the study population in this current study was taking beta-blockers, which influence resting and exercise HR and BP.

The study by Pierson et al. (2001) showed a significant decrease in both HR and RPP under steady state submaximal exercise conditions in a group combining aerobic and resistance training. However, the study did not show any significant reduction in SBP, which led the researchers to the conclusion that the decrease in RPP was due to the decrease in HR rather than SBP. The same was found for post-training resting values. Similar observations were made by Wosornu et al. (1996), who showed a decrease in HR but not in SBP during submaximal aerobic exercise, nevertheless producing a significant reduction in RPP. These findings are incongruent with the current findings of this study in which SBP seemed to have a greater influence on RPP than HR, which yet again comparing circulatory responses during lifting tasks to those elicited during aerobic exercise is likely to produce different findings.

**RPE Ratings**

During lifting tasks as part of ADL, individuals usually decide on their personal ability to lift an object based on their own perceived effort level. During weightlifting exercises individuals are dependent upon the use of RPE or rating of effort level to determine
suitable initial loads for a given set of repetitions and load progression, especially in populations where 1 RM testing is not appropriate such as cardiac patients. Therefore, the RPE scale is a valuable tool used for the assessment of training effects as well as for training purposes. However, RPE measurements might be limited by subjectivity and its reliability on user interpretation.

The results of this study revealed a very significant decrease in RPE responses to submaximal fixed loads, with the changes being similar for each exercise. Subjects perceived the identical absolute load as much lighter after the progressive resistance training as a result of reduced relative effort. Effect size analysis showed a strong effect of resistance training on how the participants perceived the exact same weight prior to intervention compared to after training completion. RPE has not been included in most studies evaluating the effects of resistance training, possibly due to its subjective nature. The above-mentioned study by Wood et al. (2001) included RPE measurements during pre-and post-aerobic graded exercise testing but did not consider these during the 5 RM test or the functional fitness test. The results showed a significant decrease in RPE for all training groups with the changes being similar for each group.

ACSM uses the Borg RPE scale (6–20) for aerobic and resistance training prescriptions for all populations including cardiac patients, as well as, guidelines for stress testing and fitness assessments. Wosornu, Bedfordt, and Ballantyne (1996) argued that perceived exertion is an acceptable substitute for heart rate monitoring, which is used during cardiac rehabilitation for exercise prescription in conjunction with RPE, as patients at the end of a program might continue unmonitored exercise and need to rely on their symptoms rather than their HR to decide on intensity level. Therefore, during the training sessions no heart
rate or cardiovascular monitoring was conducted and patients were expected to be at their perceived exertion level, as recommended by the ACSM. Future studies should consider using the RPE scale as tool in assessing training effects as it can give insight on subjects perceived effort level and translates to activities of daily living.

**Survey Outcomes**

Questionnaires were used to evaluate the impact on ADL, functional fitness capacity, and overall well-being of the participant. The surveys did not quite reflect the positive feedback given by participant through conversation during and after the training was completed. The DASI, which gives a rough estimate of fitness capacity, showed small improvements comparing pre-and post-scorings. The high initial scores predicted no or small improvement, which was not surprising since the subject pool consisted of low-risk patients with no orthopedic limitations and moderate to high fitness capacities. Similar results were shown for the PHQ 9 depression screener. Participants scored low at the initial evaluation and improved only minimally after the completion of training. All subjects were aerobically trained through their Phase 3 cardiac rehabilitation participation. Thus, the favorable initial scores confirm the positive outcome of cardiac rehabilitation as it is perceived by the patient. The Dartmouth health screener scores improved significantly after training was complete. This screener consists of nine categories, which include questions regarding physical fitness, health, social activities, and pain. Looking at each category separately the greatest change was seen in the category rating pain followed by overall health. An improvement in overall pain or health ratings can be impacted by various factors and might not be directly related to the training effect. However, according to Winnet and Caprinelli (2001), several studies showed the health benefits of resistance training, including maintenance of functional

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capacities, prevention of osteoporosis, sarcopenia, low back pain, and other disabilities. Future studies should include questionnaires that specifically geared toward functional capabilities during ADL, especially if the target group does not consist of novice exercisers.

**Vascular Function (FMD)**

Vascular endothelial dysfunction is an impairment of the regulatory process of smooth muscle tone, inflammation, antithrombosis, and anticoagulation within the blood vessel wall (Alley et al., 2014). Vona et al. (2009) found that, “endothelial dysfunction seems to be particularly relevant in patients with coronary artherosclerosis and acute and chronic myocardial ischemia, and the presence of severe endothelial dysfunction is associated with a less favorable prognosis”. Based on clinical research, exercise training has been accepted as a nonpharmacological treatment option for endothelial dysfunction (Hambrecht et al, 2000).

Hambrecht et al. (2000) conducted a study on coronary artery patients with endothelial dysfunction, investigating the effect of a 4-week aerobic training program, and found a significant improvement in endothelial function and a significant difference between the exercise group and the inactive control group. Likewise, Vona et al. (2009) found significant improvements in endothelial function after a 4-week training intervention when they compared three exercise groups including aerobic only, combination of aerobic and resistance, and resistance only with an inactive group. They concluded that endothelial function improvements are independent upon the exercise type. Including these studies, most investigations of training effects evaluate untrained subjects. In this current study, the impact of the addition of resistance training to an already existing aerobic exercise regimen on endothelial function was investigated.
The results showed that average FMD in response to reactive hyperemia for the 15 subjects was normal, with peak FMD responses at 12.8% and 10.3% dilation pre- and post-training, respectively. No significant difference in the group response could be shown when pre-training and post-training values were compared. Vast improvements in endothelial function were unable to be generated partially due to the normal initial response prior to the training intervention. Nevertheless, a subgroup of five subjects out of the small sample of 15 were noted to have a somewhat delayed response to hyperemic flow during pre-training testing and revealed normalized readings during post-training measurements, which could indicate a positive effect of adjunctive resistance training on patients with abnormal endothelial function. However, the sample size of this study was too small to reach a distinct conclusion. To compare, Vona et al. (2009) in the above-mentioned study included 209 subjects. On the other hand, Hambrecht et al. (2000) could show significant results for only 19 patients. In contrast to other studies, direct measurements of the coronary arteries function were taken via angiography, which can produce more accurate results compared to brachial artery reactivity testing.

No studies have seemingly examined the effects of additional resistance training on endothelial function in coronary patients who are already participating in an aerobic exercise program. Future research should aim for larger sample sizes, including mainly patients who show signs of endothelial dysfunction prior to a training intervention. Additionally, the aerobic activity of the participants should be well controlled to reduce confounding variables. Moreover, a future study protocol should tightly control for diet and medication intake. Further research on the positive effects of resistance training on vascular function in coronary
patients could add another incentive for professionals to prescribe resistance training and could motivate more patients to try it.

Limitations

As mentioned above, this study is limited by its small sample size, mainly due to a small pool of eligible candidates. Resistance training is an important component of cardiac rehabilitation and is prescribed for most patients unless contraindications advise against it. Therefore, the number of suitable subjects, who were not already including resistance training in their routine and fulfilled all other eligibility criteria, was small. Furthermore, this led to the inability to include a control group for comparison of training effect. While progression of resistance training was recorded during study period, the possible changes in aerobic activity were neither evaluated nor controlled. Since all patients were cardiac rehabilitation patients, it would have been unethical to halt aerobic training progression during the study period. Thus, a possible effect of increased aerobic activity on study results cannot be precluded. Blood pressure testing was performed using sphygmomanometer and multiple testers were involved, which can affect accuracy and test-retest reliability. However, the use of catheterization to measure intrabrachial arterial pressure, as it was used in McCartney et al.’s study (1993) was not feasible for the low-risk protocol of this study. It cannot be assumed that a longer training period would not have improved the study outcome; however, 12 weeks are consistent with other study protocols. Research suggests that FMD measurements should be taken under fasting conditions since the consumption of high-fat and high-carbohydrate meals can cause attenuated FMD responses. Furthermore, vitamin supplementation and other medications especially those targeting the cardiovascular system may confound results (Harris et al., 2010) In this study it was not feasible for subjects to
refrain from their cardiac medications for $\geq 4$ half-lives as recommended, and food intake and vitamin supplementation were also not controlled for. When creating a protocol for future studies, researchers should consider these limitations to reduce confounding variables.

**Conclusion**

The present findings indicate a superimposed resistance training program results in decreased hemodynamic and RPE responses to lifting fixed submaximal workloads among aerobically trained coronary patients. According to the results, it is feasible to conclude that cardiac demand decreases after progressive resistance training when identical absolute but relatively lower loads are lifted after training is complete. This can be especially beneficial during ADL, as resistance training improves strength and enables lifting objects at a lower fraction of maximal lifting capabilities. Although resting heart rate and blood pressure decreased slightly after the training period, a significant change could not be demonstrated, leading to the conclusion that the addition of resistance training among well-controlled cardiac patients does not impact resting heart rate or blood pressure significantly. FMD measurements revealed a normal average group response, and no difference could be found between pre- and post-measurements. The normal pre-training results support other study findings that indicate favorable endothelial function in coronary patient who participate in an aerobic exercise training program. However, five subjects were identified who had a somewhat abnormal FMD response before the training period and showed modest improvement after training was complete. This could indicate that the addition of a resistance training to an already existing aerobic training regimen could have a positive effect in coronary patients with initial endothelial dysfunction. Future research is necessary to
investigate the true effects of superimposed resistance training on vascular function among coronary patients.
References


National Heart, Lung and Blood. (2013). What are the benefits and risks of cardiac rehabilitation?. Retrieved 12 June, 2015, from


http://doi.org/10.1006/pmed.2001.0909

http://doi.org/10.1097/00005768-200110000-00021

Appendix: IRB Approval Letter

October 28, 2016

Kerstin Grafe

Beaumont Health System - Cardiovascular Medicine - Cardiac Rehabilitation

IRB#: 2016-296
Protocol Title: Resistance Training Study N/A
Influence of Resistance Training on Vascular Function, Hemodynamic and Perceived Exertion Responses to Fixed Submaximal Workloads in Patients with Coronary Disease
Sponsor: Investigator-Initiated

Dear Kerstin Grafe,

It has been determined that the above referenced project with waiver of consent documentation, involves no more than minimal risk to human participants per the code of federal regulations. It is further determined that this research satisfies the conditions for a Waiver of HIPAA Authorization.

Action: Approved under Expedited Review
Category: **Category 4**: Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing; **Category 7**: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

**Approval Date:** October 28, 2016  
**Expiration Date:** 10/27/2017  
**Renewal Cycle:** 12 months

IRB approval was granted for:

- Information Sheet, Version Date: 10/21/16  
- Consent provider’s names: Kerstin Grafe, Megan Bowden, Cindy Haskin-Popp, and Barry Franklin  
- Protocol (Version 1.1), version date: 10/05/2016  
- Recruitment Flyer  
- Screening and Eligibility Checklist  
- Outpatient Adult Fall Risk Assessment

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Beaumont® HEALTH SYSTEM  
Research Institute  
Institutional Review Board

- Data Sheet Training Period  
- Dartmouth COOP Health Survey  
- Duke Activity Status Index (DASI)  
- PHQ9-Nine Symptom Checklist (Depression Screen)  
- Testing Session Data Tool  
- Approved number of participants to be enrolled: 15 (Consent 50 to enroll 15)  
- Age range of participants: 18 years of age or older  
- The following Vulnerable Participant Population(s) will be incidentally included as study participants has been determined appropriate:
Economically or Educationally Disadvantaged individuals  ○ Students/Trainees/Staff

Any amendment or change to the protocol must be reviewed and approved by the IRB prior to initiation.

The following must be reported to the IRB: All Unanticipated Problems, all instances of study article (medication or device) error, enrollment of participants not meeting enrollment criteria, any change to the protocol, any deviation from the protocol that affects the health or safety of a study participant, and study termination.

A Progress Report must be submitted to the IRB, and undergo review and approval prior to 11:59 PM on 10/27/2017. Failure to do so will result in a lapse of IRB approval. Research activity for this project may not continue after the expiration date.

If you have questions or concerns, please contact Denise T Cunningham, RN, MSN, CCRC, CIP at (248) 551-8551 or Denise.Cunningham@beaumont.org

Sincerely,

Graham Krasan, MD
Chairperson

Institutional Review Board/dc