

Chapter 20
**Enhanced External Counterpulsation (EECP):
A Non-Invasive Out-Patient Procedure to Revascularize
the Heart Muscle Without Open Heart Surgery**

Fouad I. Ghaly, M.D.

President and Founder, Longevity & Rejuvenation Clinics of California

ABSTRACT

The heart and cardiovascular system play such pivotal roles in maintaining our overall health and fitness that taking measures to ensure heart health is vital to any anti-aging or longevity program. In a 2005 study published in *Heart Failure Monitor*, Gielen *et al* noted the striking similarities between aging and chronic heart failure, including “exercise intolerance, reduced cardiac functional reserve during exercise, and loss of skeletal muscle mass as a result of inflammation and catabolism.” They also described vascular aging as a “progressive decrease in flow-mediated, endothelium-dependent vasodilatation” and showed that aging of the cardiovascular system could begin in individuals as young as 25-35 years of age. In addition, Lakatta and Levy state in a 2003 paper published in *Circulation*, “There is a continuum of expression of cardiac structural and functional alterations that occurs with age in healthy humans, and these age-associated cardiac changes seem to have relevance to the steep increases in LVH, chronic heart failure, and AF seen with increasing age.” It is clear that taking steps to maintain cardiovascular health is an essential component of any Longevity or Rejuvenation Program.

No matter how much we may wish otherwise, the fact remains that we cannot stop time. But is there anything that we can do to stop or even reverse the harmful effects that aging and atherosclerosis have on the heart and cardiovascular system? Fortunately, there is. Enhanced External Counterpulsation (EECP) is a 50-year-old, non-invasive technology that has proven to be a safe and effective alternative or complement to invasive, high-risk procedures such as angioplasty and bypass surgery. Unlike these conventional treatments that target individual blockages, EECP treats heart disease as a chronic system-wide illness. By recruiting and helping to develop new collateral blood vessels, EECP maximizes blood flow to the heart, as well as throughout the entire body.

INTRODUCTION

Cardiovascular disease affects more than 70 million people in the US and is the leading cause of death for American men and women, accounting for nearly 1 million fatalities every year. One of the great dangers of heart disease is that it can take 10 to 20 years to develop. While there are certain genetic risk factors that can predispose one to the development of heart disease – such as diabetes, hypertension, familial hyperlipidemia, high levels of homocysteine, and auto-immune or inflammatory processes – as well as acquired lifestyle risk factors, such as smoking, improper nutrition, sedentary lifestyle, obesity, stress, and type II diabetes – coronary artery disease still often goes undetected until the heart and circulatory system have been seriously compromised. Therefore, an individual may experience no warning signs, not even pain, until he or she suffers a heart attack. I refer to this as the “Clinton Syndrome.” As a former President and one of the most powerful men on earth, Bill Clinton had access to state-of-the-art healthcare and a yearly “Presidential” physical exam. Yet, the tests administered to him did not detect the coronary artery disease that resulted in his recent heart attack.

In the United States alone, approximately 4.6 million people suffer from chronic heart failure, and it is estimated that this number is increasing by 550,000 people per year. Even with conventional medical and surgical management, the outlook for these patients is not good. After diagnosis, men suffering from heart failure have a median survival of only 1.7 years, and women have a median survival of only 3.2 years. Furthermore, heart disease is a leading cause of premature and permanent disability among working adults in the US. The economic impact of cardiovascular disease is staggering: this single health issue will cost the US approximately \$400 billion this year, including healthcare expenditures and lost productivity due to disability and death.

Conventional Management of Heart Disease

Traditionally, strategies for managing cardiovascular disease have focused on the modification of risk factors (poor diet/nutrition, lack of exercise, smoking), medication, and surgical procedures such as angioplasty and bypass surgery, which treat the illness as a “plumbing problem” and focus on opening or bypassing blockages in the vessels of the heart. Despite these interventions, 20% of patients who receive stents, 54% of patients who receive angioplasty, and 8% of patients who receive bypass surgery require repeat surgeries/procedures within a few years, and a significant number of people continue to suffer from frequent, severe, and disabling angina. It is clear that if we rely on these strategies alone, we will continue to fail these people.

A Non-Invasive Strategy for the Management of Heart Disease

Enhanced External Counterpulsation (EECP) is a completely non-invasive therapy, which causes minimal, if any, patient discomfort. Approved by the FDA and covered both by Medicare and by most major health plans, a typical course of treatment of EECP costs only \$6,000. This is merely a fraction of the cost of angioplasty or bypass surgery, which can cost between \$20,000 and \$100,000.

Despite the fact that many consider EECP a “low-tech” procedure, research has documented conclusively that this treatment significantly reduces mortality in the setting of acute myocardial infarction and/or cardiogenic shock. Furthermore, patients who undergo EECP use less nitroglycerine and experience fewer anginal episodes. Many patients report complete resolution of their angina. Additionally, when combined with conventional treatments, EECP will enhance their overall effectiveness.

This chapter will discuss the merits of Enhanced External Counterpulsation (EECP) as a safe and effective non-invasive procedure that has been clinically proven to reduce or eliminate the symptoms of heart disease over a much longer term than conventional therapies.

HISTORY OF EECP

EECP is not a new invention. In fact, the basic theory and techniques of counterpulsation were developed more than 50 years ago by researchers at Harvard University and the Massachusetts General Hospital. These scientists sought to capitalize upon well-known hemodynamic and physiologic principles, by using them in the clinical setting to improve the care of patients with cardiovascular disease.

Like any other muscle in the body, the heart depends upon a robust blood supply for the provision of oxygen and nutrients. As the coronary arteries and their tributaries penetrate and traverse the wall of the heart to deliver blood to the innermost portions of the muscle, the high pressures that are generated during systole are more than sufficient to impede, stop or even reverse the flow of blood through some of these vessels. Consequently, unlike the rest of the body, the heart receives approximately 80% of its blood supply during *diastole*, while it is at rest.

The amount of oxygen that the heart uses to sustain its work is determined by the heart rate, contractility (a measure of the force of each contraction), and systolic wall tension (also referred to as “afterload”). The amount of oxygen that is supplied to the myocardium is proportional to coronary blood flow, which is determined by diastolic blood pressure and coronary perfusion pressure. Based upon these facts, it follows that the ratio of myocardial oxygen supply to myocardial oxygen consumption is increased by lowering systolic blood pressure (systolic unloading) and/or by increasing diastolic blood pressure (diastolic augmentation). These physiologic principles are the basis for Counterpulsation (CP) Therapy.

The first attempts at CP utilized a femoral artery cannula, which was attached to an extracorporeal pump. The pump withdrew blood from the circulation during systole and returned it during diastole. This technique was shown to increase coronary artery blood flow and to reduce the workload and, subsequently, the oxygen consumption of the left ventricle. Unfortunately, the pumping mechanism resulted in an unacceptable amount of hemolysis, making this technique unsuitable for clinical use. This work led to the development of an *internal* CP device known as the intra-aortic balloon pump (IABP). This device, basically a catheter with a balloon attached to its end, was inserted through the femoral artery and advanced to the descending aorta. By inflating the balloon during diastole, the IABP was shown to increase blood flow and oxygen to the heart through the coronary arteries. By deflating the balloon just before systole, both afterload and the heart’s overall workload were reduced. Not only did the IABP provide immediate relief to patients whose hearts were ischemic due to diseased coronary vessels, it also

stimulated both the recruitment and the development of collateral vessels around the heart, providing new and permanent pathways for the delivery of blood and oxygen.

The mid-1960s saw the development the first *external* CP device. Taking advantage of the same physiology as the IABP, researchers designed a system that was extra-corporeal and completely non-invasive. This machine consisted of large, steel chambers that housed inflatable cuffs, which were part of a hydraulic circuit. The cuffs were wrapped around subject's calves, thighs and buttocks and were inflated and deflated in synchrony with diastole and systole, respectively. As observed with intravascular or internal CP, external CP resulted in increased coronary blood flow and decreased left ventricular work and oxygen consumption. Unlike internal CP, however, external CP afforded the additional benefit of increased venous return (preload). In clinical application, external CP was shown to improve survival rates for patients with acute myocardial infarction, cardiogenic shock, and angina pectoris, but the results were not obtained consistently and the technique did not gain much favor among clinicians. In addition, these initial results were significantly overshadowed by the even more impressive successes achieved through coronary artery bypass grafting and angioplasty, as these procedures were invented and refined in the 1970s.

Studies in China

Although interest in counterpulsation waned in the US, physicians in China remained very interested in the therapy. The medical establishment in China appreciated the cost-effectiveness of CP, and they felt that the principles of the therapy were congruent with the philosophy of Eastern medicine, which seeks treatments that aid and enhance the body's innate ability to heal itself. In the 1970s, Zheng and colleagues refined the technology behind external CP, ushering in the era of *enhanced* external counterpulsation or EECP. The hydraulic system that had been used to inflate and deflate the lower extremity cuffs in prior models was replaced with a pneumatic system, which made the system much less cumbersome. Their most important improvement to the procedure, however, was that their system was computerized and programmed to inflate the sets of cuffs sequentially, from the calves to the buttocks. This modification ensured that blood would flow retrograde, back toward the heart and the coronary vessels, during diastole. In the early 1980s, they reported on their extensive experience in treating angina with EECP. EECP reduced the frequency and severity of anginal symptoms during normal daily functions and exercise, furthermore, these benefits were sustained for years after therapy, in some cases.

By 1990, there were 1,800 EECP centers operating in China, and a study of more than 6,000 patients reported that this treatment had resulted in improvement for 90% of participants.

Another study by Xu *et al* showed that 74% of EECP patients experienced improvement in symptoms of heart disease seven years after completing treatments and were four times less likely to suffer death from heart disease than patients treated with medication alone. This was extraordinary news for the medical world.

The United States Takes Notice

These results prompted a group of investigators (Lawson WE, Hui JCK, Soroff HS, *et al*) at the State University of New York at Stony Brook (SUNY) to undertake a number of open-label studies with the EECP system between 1989 and 1996 to see if they could reproduce the Chinese results, using both objective and subjective endpoints. Eighteen patients who suffered from debilitating angina, despite surgical intervention and medication, received 35 one-hour sessions of EECP over a period of 7 weeks. At the end of these treatments, all eighteen patients showed improvement in angina. Results showed that sixteen patients (89%) could perform their normal daily activities without symptoms, twelve (66%) tested completely normal on nuclear stress tests following treatment, showing that normal blood flow had been reestablished in the heart, and two (11%) had stress tests that, while still abnormal, were significantly improved. Stress test results were unchanged in four patients (22%). A three-year follow up study by Lawson WE, Hui JCK, Zheng ZS, *et al* showed that eleven (79%) of participants still remained symptom free. The only treatments the subjects had received during that time had been adjustments to their medications and additional EECP treatments (8 patients).

By 1995 enough of a body of research had accumulated for EECP to receive FDA approval as a treatment for chronic stable angina, cardiogenic shock, and for use during a heart attack. Most recently, in June of 2002, the FDA approved the use of EECP for congestive heart failure.

The Gold Standard: The MUST-EECP Trial

For many years critics claimed that no double-blind studies existed to prove the effectiveness of EECP, but this changed in 1995 when Vasomedical began a large, randomized, controlled, double-blinded clinical trial called the Multicenter Study of Enhanced External Counterpulsation (MUST-EECP). Cardiologists at seven leading university hospitals, including Columbia, Yale, and Harvard, conducted research on 139 participants. Half of these patients received thirty-five real EECP treatments and the other half received thirty-five placebo treatments (cuffs squeezing only minimally while the patient lay on the treatment bed).

Patients received treadmill stress tests both before and after receiving each EECP treatment. Following treatments, the participants in the group who had received EECP were able to exercise significantly longer without symptoms or change to their EKG, had less angina symptoms, and used less nitroglycerin. This proved that they had more blood and oxygen circulating through their hearts. Both at the completion of the thirty-five-hour course of treatments and when patients were retested one year later, those who had actually received EECP continued to show sustained improvement in their ability to work and perform daily activities. They also reported less pain, more energy, greater ability to socialize, less anxiety and depression, and lower levels of angina (Arora *et al*).

The results of the MUST-EECP study were presented at the annual Scientific Sessions of the American Heart Association in November of 1997 and the American College of Cardiology in March of 1998. The *Journal of the American College of Cardiology*, a major peer-reviewed medical journal, published the results of the MUSTEECP trial in June 1999.

In 1999, Medicare began paying for EECP treatments. Since then, most major private health insurance companies have followed suit.

Currently, more than 800 physicians in the US use EECP therapy to treat approximately 19,000 patients annually who suffer from chronic angina and heart failure. With a success rate of approximately 80% and an annual growth rate of over 30%, EECP therapy is one of the fastest-growing medical procedures in the country. More than 80 articles published in leading medical journals document significant benefits to patients suffering from angina and congestive heart failure, including symptom relief, increase in functional capacity, and improved quality of life.

HOW DOES EECP WORK?

Patients usually receive EECP treatment for 35 hours, divided into one or two 60-minute treatment sessions five days per week. Patients who undergo two treatment sessions in one day require rest between sessions. Treatment is administered on a padded table, where three sets of electronically controlled inflation and deflation valves are located. These valves are connected to adjustable cuffs that are wrapped firmly, but comfortably, around the calves, the lower thighs, and the upper thighs and buttocks. Patients wear special pants during the sessions to minimize the possibility of skin irritation.

Inflation and deflation of the cuffs is triggered by the patient's EKG signal. At the onset of diastole, the cuffs inflate rapidly and sequentially, starting from the calves and proceeding upward to the buttocks. This increases diastolic pressure; thereby increasing coronary artery perfusion pressure and blood flow to the heart muscle. Compression of the veins in the lower extremities also increases the volume of blood returned to the right side of the heart (preload). Simultaneous deflation of the cuffs just prior to the onset of systole lowers peripheral vascular resistance –thereby decreasing afterload, cardiac work, and oxygen consumption – and increases cardiac output. The net effect of these physiologic changes is to increase the supply of oxygen to the heart, while decreasing cardiac oxygen demand.

This result is possible because the body has its own solution to an inadequate blood supply caused by stenosed or occluded coronary arteries. When a coronary vessel is severely narrowed, the body's natural response is to increase the amount of blood flowing to the heart by opening up smaller branches of nearby arteries. These smaller arteries form a network of vessels known as the "collateral circulation," which can serve to create detours around points of occlusion. Significant obstruction in one or more coronary arteries can create a pressure difference between areas of the heart that are perfused and those that are not. Repeated and pulsed increases in blood pressure during diastole may stimulate both the opening and the formation of new collateral channels across this pressure gradient within the heart, resulting in increased blood supply to ischemic tissues.

The development and enhancement of a collateral circulation is particularly important in the heart where it may be lifesaving. However, collateralization is a gradual process, and not everyone has the

same ability to develop these networks. EECF appears to stimulate the natural process of developing collateral circulation. In addition, there are likely other, as yet unexplained, mechanisms that contribute to the long-lasting effects of EECF.

Mechanism of Action

While the exact mechanisms by which EECF produces clinical improvement remains unknown, there are two primary hypotheses that have been discussed in the clinical literature.

Postulated Mechanism of Action #1:

- Raised transmural pressure gradients open “latent” conduits
- Both arteriogenesis and angiogenesis occur
- Increased shear forces stimulate growth factor release, capillary sprouting and endothelial migration
- Nitric oxide levels are increased while endothelin levels diminish
- Restoring flow reserve

Postulated Mechanism of Action #2:

- 35 hour-long periods of cardiac assist rest the myocardium
- Myocyte metabolism switches back from free fatty acid energy supply toward glucose utilization
- Neurohumoral signals are “normalized,” permitting improved arterial compliance and arteriolar reactivity
- Oxygen demand is reduced as oxygen efficiency is improved

Clinical Benefits

Positive vascular benefits:

DECREASED Endothelin - Potent vasoconstrictor	Werner <i>et al.</i> 1998 Wu GF <i>et al.</i> <i>Circulation</i> 1999
DECREASED BNP - Promotes diuresis -Released with LV dysfunction	Urano <i>et al.</i> <i>JACC</i> Jan 2001 Masuda, <i>et al.</i> , <i>Euro Heart J</i> 2001
INCREASED Nitric Oxide -Potent vasodilator	Xiao-Xian Qian <i>et al.</i> 1999 Wu GF <i>et al.</i> <i>Circulation</i> 1999 Qian XX <i>et al.</i> <i>J Heart Dis</i> 1999 Masuda D. <i>et al.</i> <i>Eur Heart J</i> 2001
INCREASED VEGF -Promotes angiogenesis	Masuda <i>et al.</i> <i>Euro Heart J</i> 2001
INCREASED ANP -Promotes diuresis	Kho <i>et al.</i> Endocrine Society's 82 nd Annual Meeting 2000 Masuda <i>et al.</i> <i>Euro Heart J</i> 2001

Additional clinical benefits:

- Improvement in peak oxygen consumption (Soran *et al*)
- Increased ejection fraction (Gorscan *et al*, Suresh *et al*, Strobeck *et al*)
- Increased cardiac output (Gorscan *et al*, Suresh *et al*)
- Decreased heart rate (Gorscan *et al*)
- Improvement in exercise times (Soran *et al*)
- Improvements in quality of life (Soran *et al*)
- Reduction in CCS angina classification immediately after therapy (Arora *et al*)
 - Up to 85% decrease at least 1 class
 - Up to 54% decrease at least 2 classes
- Decreased anginal episodes and nitroglycerin use (Suresh *et al*, Int. EECP Pat. Reg.)
- Improvement sustained for up to 5 years (Feldman, Lawson, Cohn *et al*)

WHO IS A CANDIDATE FOR EECP?

Many patients have questions about whether or not they are candidates for EECP. Since it is a non-invasive and completely safe therapy, the good news is that *everyone* is a candidate for EECP. EECP is especially appropriate for nearly all those who suffer from heart disease. This includes individuals who have irregular heartbeats or pacemakers, patients who have recently undergone invasive cardiac procedures, individuals with blood clots in their legs, people who take Coumadin, and those who suffer from peripheral vascular disease. There is no risk that EECP can cause a defibrillator or a pacemaker to malfunction, or that this treatment will cause any irregularities in heart rhythm. Patients who have received recent angioplasty, surgery for stent placement, or cardiac catheterization can receive EECP without risk and can start treatments as early as one week following these procedures, when groin tenderness has subsided.

Those suffering from poor leg circulation from peripheral vascular disease will also do well with EECP, although it may take a longer time period for them to see results, because of a smaller volume of blood in the lower extremities to pump back toward the heart.

In addition to helping patients with heart disease, EECP is ideal for people who wish to improve their level of cardiovascular health and fitness.

Are There Risks To Receiving EECP?

While there are no dangers or risks involved in receiving EECP, there are certain conditions that require caution when considering this therapy:

1. Severe aortic insufficiency
2. An abdominal aortic aneurysm greater than 5 cm in diameter
3. Malignant Hypertension
4. Deep vein thrombosis
5. Hemophilia
6. Pregnancy
7. Fever
8. An open leg wound
9. Superficial phlebitis

The majority of these conditions are either temporary or treatable, and EECP can be initiated once they have resolved or been treated.

EECP TREATMENT PROTOCOLS

Diagnostic Protocols

The diagnostic protocols administered to a patient being for EECP are identical to those administered to any patient suspected of heart disease:

1. A comprehensive metabolic panel
2. A lipid panel, including testing for levels of lipoprotein A and lipoprotein B, fibrinogen, platelet count, homocysteine, and folic acid
3. Testing for C-reactive protein

4. Resting EKG and Stress EKG
5. An echocardiogram
6. Radio-nucleotide Imaging
7. EBT (electron beam tomography) with calcium scoring
8. Coronary angiogram

Follow-up Testing and Evaluation

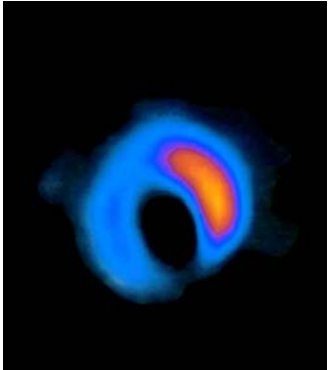
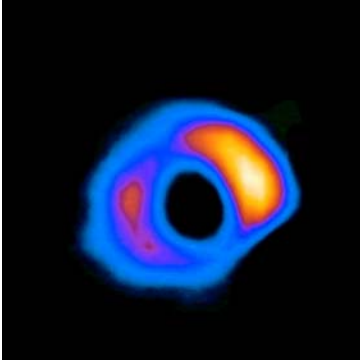
While the effects of EECp can last anywhere from three to five years, cardiovascular disease is progressive. Therefore, every six months following EECp, patients should receive the following tests and evaluations to ensure that the therapeutic benefits are maintained:

1. Cardiac echo
2. Treadmill (stress test EKG)
3. Comprehensive metabolic panel
4. A lipid panel, including testing for levels of lipoprotein A and lipoprotein B, fibrinogen, platelet count, homocysteine, and folic acid

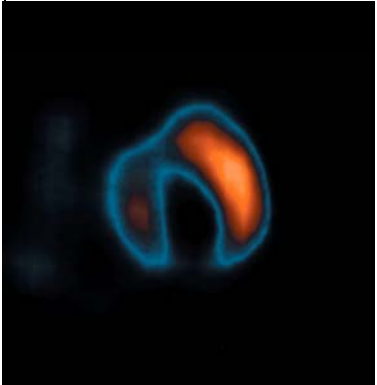
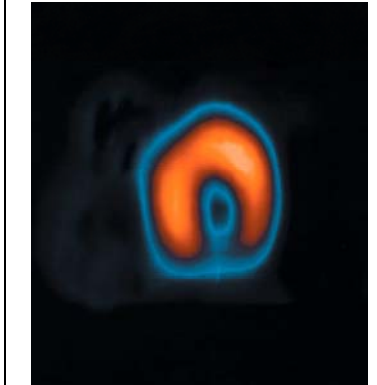
CASE HISTORIES OF EECp PATIENTS

To more thoroughly understand the effectiveness of EECp and its many applications, it is useful to examine some case histories published in Strobeck *et al.*

Case History #1: Angina

<ul style="list-style-type: none"> • Patient 27-year-old male, family history of hyperlipidemia • Evaluation <ul style="list-style-type: none"> - Presented with exertional angina pectoris - 1.5-2.0 mm horizontal ST segment depression on exercise treadmill test - 100% occlusion of mid-right coronary artery - 100% occlusion of med-left anterior descending coronary artery - 95% blockages in both proximal mid-right coronary artery and small branch of left circumflex coronary artery - Patient not considered suitable for interventional therapy • Outcome Following 35 one-hour sessions of EECp: <ul style="list-style-type: none"> - angina completely eliminated at normal levels - post-treatment radionuclide stress testing showed marked Improvement 	<p style="text-align: center;">Before EECp</p>  <p style="text-align: center;">After EECp</p> 
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Case History #2: Coronary Artery Disease with Diabetes

<ul style="list-style-type: none">• Patient 72-year-old male, history of diabetes, gout, hypertension, triple-vessel coronary artery disease (CAD)• Evaluation<ul style="list-style-type: none">- Presented with stable angina- Previously declined bypass, maintained on medication- Stress test suggested progression of CAD- Severe hypoperfusion of inferior wall and apex with stress perfusion• Outcome Following 45 one-hour sessions of EECF:<ul style="list-style-type: none">- Post-treatment stress testing revealed marked improvement in myocardial perfusion- Patient showed increased exercise ability- Chest pain symptoms were eliminated- Patient no longer required nitroglycerin	<p style="text-align: center;">Before EECF</p>  <p style="text-align: center;">After EECF</p> 
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Case History #3: Congestive Heart Failure

- **Patient**

Elderly male, two previous myocardial infarctions, previous bypass surgery

- **Evaluation**

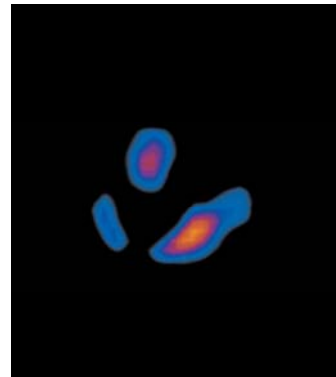
- Ischemic cardiomyopathy
- Progressive angina with minimal exertion
- Maintained on medical therapy

- **Outcome**

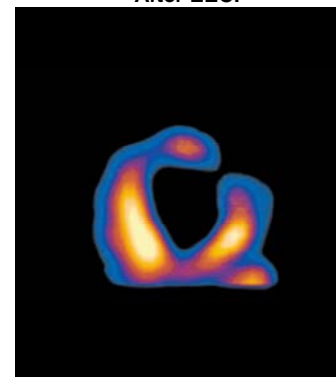
Following 35 one-hour sessions of EECp:

- Left ventricular ejection fraction (LVEF) increased by 80% (20% to 36%)
- Functional status and chest pain improved markedly
- Post treatment stress test showed improved cardiac perfusion and function

Before EECp



After EECp



CONCLUDING REMARKS

It is time for us to rethink how we manage cardiovascular disease and promote cardiovascular health. While traditional procedures such as angioplasty and bypass surgery are able to target individual blockages, they do nothing to address the underlying pathology of cardiovascular disease, as this is a systemic illness. Therefore, in order for a therapy to provide a lasting benefit, it must address the circulatory system as a whole. Over the last 50 years, EECp has proven to be a safe, effective, and noninvasive means of accomplishing this goal, even for patients with severe, life-shortening conditions such as congestive heart failure. Patients undergoing EECp do not have to endure long hospital stays or lengthy periods of recuperation. They often begin to experience relief from angina and exercise intolerance as rapidly as halfway through the course of their therapy. If symptoms reoccur, patients can receive additional sessions of EECp immediately, without fear of injury.

Not only is EECp a safe and effective therapy for those who suffer from cardiovascular disease, it also holds great promise for assisting in the management of other common illnesses, including diabetic neuropathy and retinopathy, erectile dysfunction, hypertension, kidney disease, memory disorders, peripheral vascular disease, Parkinson's disease, and macular degeneration. In addition to the therapeutic benefit that it provides, EECp greatly improves the overall *quality* of patients' lives, by giving them more energy and an enhanced ability to work, perform daily tasks and exercise, thus allowing them to enjoy a greater sense of well-being.

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ABOUT THE AUTHOR

Fouad Ghaly, M.D., serves on the scientific boards of the British Society of Anti-Aging Medicine and the European Society of Anti-Aging Medicine. Board-certified in anesthesiology and anti-aging medicine, he has been practicing EECP and anti-aging medicine since 1997 through Longevity & Rejuvenation Clinics and his website, www.Prolongyouth.com. An international lecturer, he has spoken about EECP at universities, medical centers, and conferences.