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# Issues in Emerging Health Technologies

## The Heart Laser™: Transmyocardial Revascularization Treatment of Angina Pectoris

### The Technology

The Heart Laser™, a new surgical cardiac laser system, is used in the treatment of severe angina pectoris.<sup>1,2</sup> The chest pain experienced by those with angina pectoris can be due to ischemic heart disease. Chest pain occurs when the heart muscle does not receive an adequate supply of oxygenated blood. This is often a result of cholesterol plaque formation in coronary arteries which can lead to heart attack.<sup>3</sup>

The process of transmyocardial revascularization (TMR) uses laser technology in an attempt to restore blood flow to previously ischemic (oxygen deprived) heart tissue, thereby reducing the symptoms of angina.<sup>1,4</sup> Using The Heart Laser™, TMR is performed on a beating heart through a small incision on the left chest wall. A single pulse from the high-energy, carbon dioxide laser creates between 20 and 40 one-millimeter-wide channels through the ischemic heart muscle into the left ventricle, restoring blood flow to oxygen-starved myocardium. The laser is synchronized with the heartbeat and automatically fires when the ventricle is filled with blood. Remaining laser energy is absorbed by the blood, preventing damage to other heart tissue.<sup>5</sup> Evidence suggests that the outer channel heals, while the inner part of the channel remains open, allowing blood to perfuse from the left ventricle into the new channels.<sup>6</sup> The symptoms of angina are reduced by exposing ischemic myocardium to oxygenated blood. The method by which this treatment works is an enigma. However, it is thought that previously ischemic myocardium is reperfused through the lasered channels, or that new blood vessels are formed.<sup>6,7</sup>

### Regulatory Status

The Heart Laser™ by PLC Medical Systems Inc., was approved for use in transmyocardial revascularization treatment of severe angina pectoris on August 20, 1998, by the Food and Drug Administration.<sup>1,2</sup>

### Patient Group

End-stage coronary artery disease is a therapeutic challenge, as an increasing number of patients cannot be adequately managed by medication or effectively treated by conventional surgical or catheter-based procedures.<sup>5</sup> A cineangiogram is necessary to determine initial candidacy for the procedure.

In Canada, ischemic heart disease accounts for 56% of deaths due to cardiovascular disease.<sup>8</sup> In the absence of Canadian data, approximately 150,000 Americans have end-stage coronary artery disease, of which an estimated 80,000 qualify for TMR annually.<sup>2,5</sup>

The Heart Laser™ is indicated for the treatment of patients with class 3 or 4 stable angina not amenable to medical treatment and conventional coronary revascularization, according to the Canadian Cardiovascular Society (CCS) classification system for angina.<sup>1</sup> Most patients treated with The Heart Laser™ in clinical trials had already received at least one bypass surgery and posed high risk for reoperation. For medical reasons, these patients were not expected to benefit from angioplasty.<sup>1</sup>

### Current Treatments

Conventional treatment of coronary artery disease includes medication, bypass surgery and angioplasty. Traditional medicinal therapies for angina consist of short and long-acting nitroglycerin preparations,  $\beta$ -blockers, and calcium channel antagonists. Coronary artery bypass graft (CABG) is a conventional surgical procedure used to open blocked coronary arteries.<sup>3</sup> Percutaneous transluminal coronary angioplasty (PCTA), a less invasive, percutaneous procedure, may be used to achieve the same outcome.<sup>3</sup>

## Potential Cost

In the absence of Canadian data, PLC's The Heart Laser™ sells for \$400,000 US; the disposables for each procedure sell for \$1,500 US. PLC is willing to negotiate placement contracts with hospitals willing to pay an upfront fee of \$25,000 US for the laser, with a per-procedure charge of \$3,500 US to cover the cost of disposables.<sup>2</sup> The operation takes approximately two hours to complete and does not require a heart-lung machine. The average hospital stay following TMR ranges from 5 to 7 days and is generally less than the recovery time following CABG, the traditional means of treatment.<sup>5</sup>

## Projected Rate of Diffusion

With FDA clearance, PLC marketed The Heart Laser™ to hospitals with open-heart surgery programs. The system is installed at 105 sites worldwide, including 33 investigational sites in the United States.<sup>2</sup> On October 8, 1998, PLC Systems Inc. entered an exclusive agreement with a unit of GE Capital to provide a broad array of financing alternatives to U.S. hospitals interested in acquiring PLC's The Heart Laser™ System in the field of TMR.<sup>9</sup> GE Capital Trans Leasing, a unit of GE Capital's Vendor Financial Services, specializes in working with medical equipment manufacturers and dealer/distributors. They agreed to provide financing options in connection with PLC, the only company

thus far to have received FDA approval of a TMR product for commercialization. This relationship will enable PLC to offer a range of financing and leasing alternatives to a target market of more than 900 hospitals, and provides PLC with a non-dilutive source of capital to finance placements of The Heart Laser™ system.<sup>9</sup>

## Concurrent Developments

In September of 1998, Eclipse Surgical Technologies, Inc. announced that the Circulatory System Devices Panel of the FDA will review the Pre-Market Approval application for Eclipse's Transmyocardial Revascularization laser system on October 27, 1998.<sup>10</sup>

## Adverse Effects

The use of the PLC laser is limited to surgeons trained in its use and to patients with severe angina who cannot be helped by other means. The FDA warns that laser revascularization poses a risk of heart attack, irregular heartbeat and stroke. Patients are required to sign an informed consent form. Ten percent of patients in clinical trials had major cardiac arrhythmia, and 3% of patients died within a month following the procedure.<sup>1</sup> TMR use in patients with refractory, unstable angina has resulted in operative mortality rates of 12% and 12 month mortalities of 22.4%.<sup>14</sup>

## Assessing the Evidence

Over 4,000 patients have been treated with TMR by carbon dioxide laser since 1990.<sup>12</sup> A nonrandomized phase II trial was conducted in 1995 and a

randomized controlled phase II trial was also completed. Two hundred patients with end-stage coronary disease and severe angina not amenable to conventional revascularization took part in each trial. The class of angina and evidence of reversible ischemia based on myocardial perfusion scans was evaluated preoperatively. Eighty percent of patients showed significant improvement in angina class status, and 30% had no symptoms of angina one year following the procedure.<sup>13</sup> Greater than two thirds of all patients significantly improved more than two angina classes (CCS) as well as reduced hospitalization.<sup>5</sup>

Sixty-one patients were treated with CO<sub>2</sub> laser in a TMR-trial at Hamburg University.<sup>12</sup> TMR improved the clinical status of 80% of laser-treated patients, while 8.2% did not benefit as evaluated using the CCS classification system for angina. 9.8% died according to 6-month clinical follow-up data. A reduction in angina grade was observed in 22 patients 12 months post-TMR. Clinically, TMR improved cardiac function in patients with severe ischemic cardiac disease, but pathophysiological data and morphological features from myocardium could not explain the phenomenon.<sup>12</sup>

TMR may reduce long-term mortality compared to maximum medical therapy according to preliminary data from the last phase III FDA study in a randomized group of patients.<sup>14</sup> The presence of laser channels reaching at least 1 cm into apical or supra-apical left ventricular myocardium has been demonstrated in TMR patients using ultrasound imaging technology following injection of an echo contrast agent.<sup>6</sup> Distinctive color doppler patterns indicative of ongoing perfusion were repeatedly visualized up to two years following TMR with The Heart Laser<sup>TM</sup>.<sup>6</sup>

## Implementation Issues

The evidence to date is limited. It would be of benefit to conduct further clinical trials to evaluate long-term effectiveness of the procedure. It may be appropriate to compare the TMR procedure with drug therapy, or

as an adjunct to bypass surgery. There is the potential for major adverse events such as cardiac arrhythmia or premature death. Therefore, the use of the PLC laser is restricted to surgeons trained in its use and to patients with severe angina not amenable by other means. Informed consent is required from patients prior to undergoing the procedure.

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