

Improvements in Myocardial Perfusion Observed in Patients Supported with the C-Pulse® Counterpulsation Device

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Purpose

To assess the effect of an investigational implantable counterpulsation device on myocardial perfusion in patients with Class III and ambulatory Class IV heart failure disease with ischemic and idiopathic cardiomyopathy.

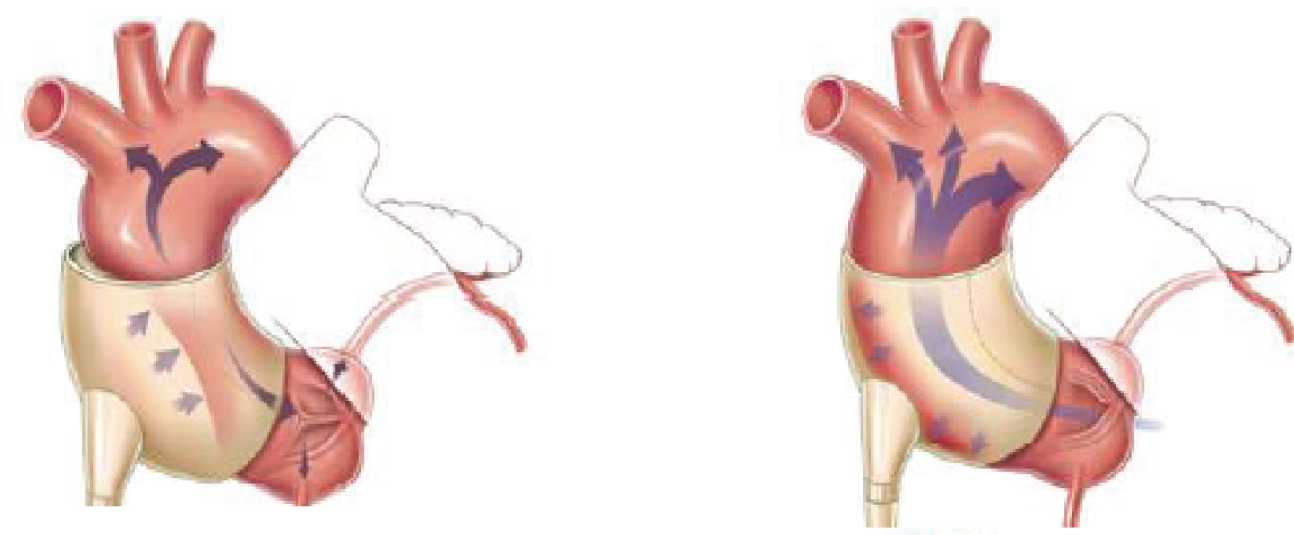


Figure 1. The balloon around the ascending aorta inflates during diastole and starts deflating shortly before ejection, thereby potentially increasing coronary blood flow and decreasing afterload.

We sought to assess changes in myocardial perfusion before and after implantation of the device.

Methods

Three patients (n= 3) with heart failure and functional status NYHA class III underwent device implant. One had an ischemic cardiomyopathy, and two had an idiopathic cardiomyopathy. 99mTc-sestamibi SPECT myocardial perfusion imaging was obtained before implantation, at 1 and 6 months post-implant.

A summed stress score (SSS), a summed rest score (SRS), and a summed difference score (SDS = SSS - SRS) were calculated.

For EU: C-Pulse is CE marked

For Canada: Investigational Device. To Be Used by Qualified Investigators Only.

For US: Caution: Investigational device, limited by United States Law to investigational use.

Results

Nuclear myocardial imaging scans obtained pre- and post-implant of the device shows marked improvement in perfusion abnormalities on 6-month studies as compared with baseline and 1-month post implant (Fig 2). Mean SSS and SRS improved from 20.3 and 16.3 to 8.3 and 5.7, respectively.

These findings were consistent in both ischemic and non-ischemic cardiomyopathy patients, but more pronounced with non-ischemic patients.

Clinically, all patients showed NYHA class improvements from III to II at 1 month. At 6 months, one patient remained at NYHA class II, while two continued to improve to NYHA I.

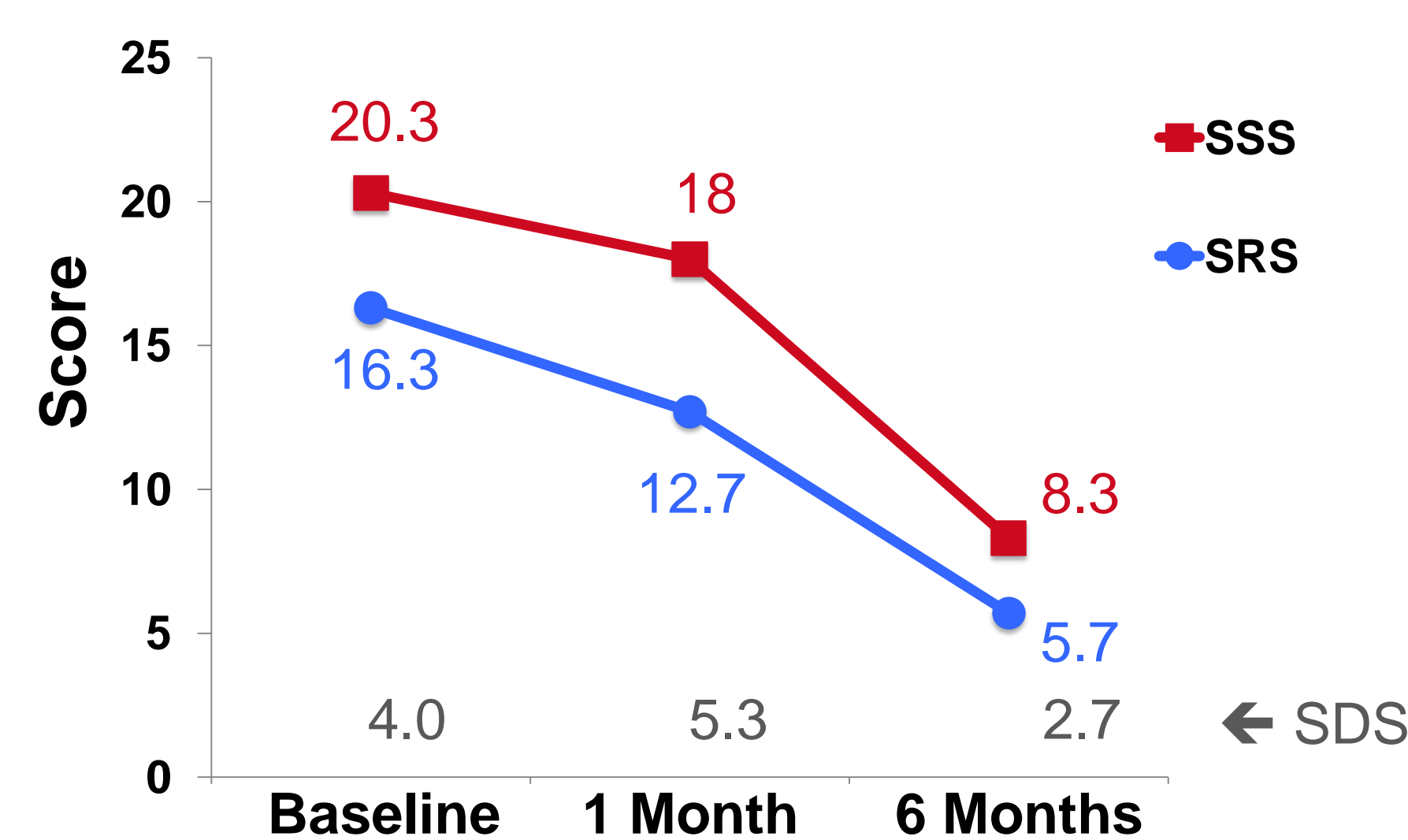


Figure 2. SPECT myocardial perfusion imaging (MPI) Stress-Rest scoring

99mTc-sestamibi SPECT myocardial perfusion imaging (MPI) at baseline and 6-month shows improvement in myocardial perfusion compatible with the expected mechanism of action of the device.

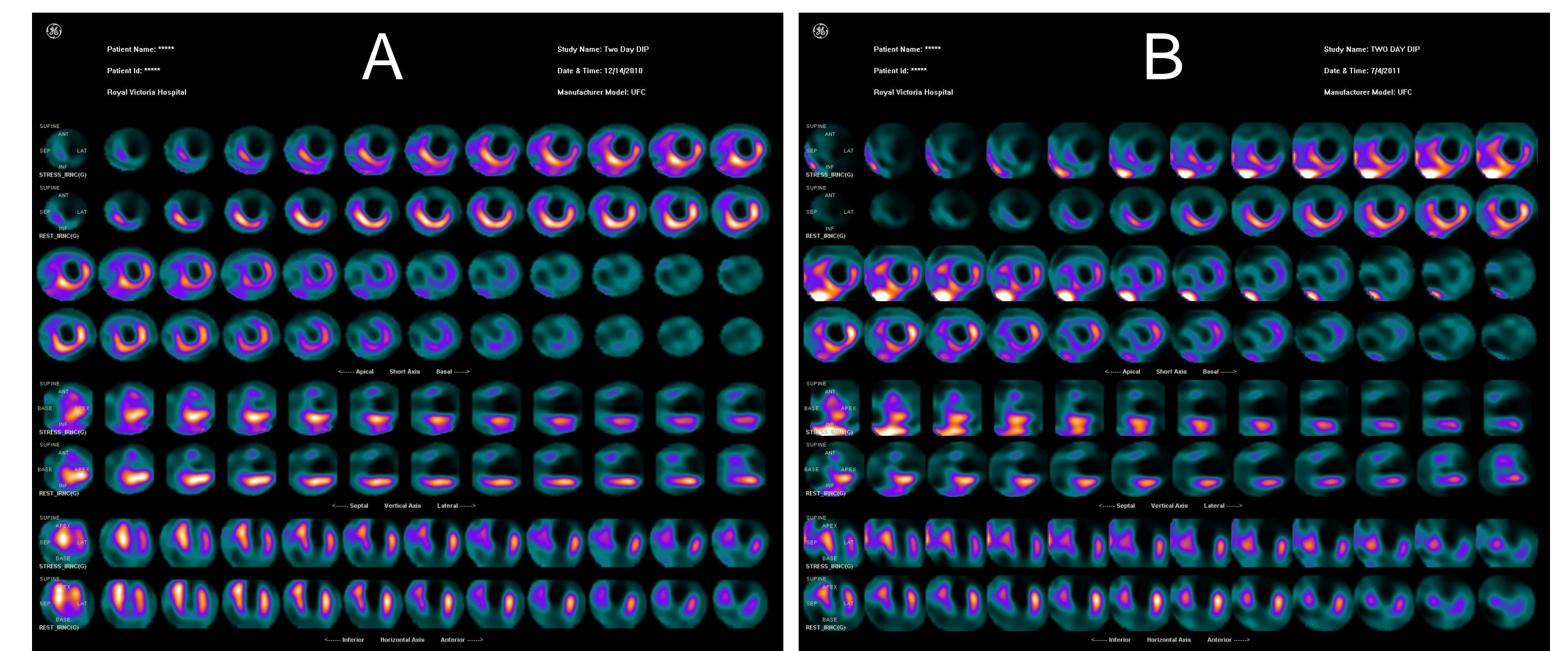


Figure 3. Patient 1. Ischemic cardiomyopathy. A. Baseline. B. 6-month.

MPI at baseline shows a perfusion defect involving the mid to distal anterolateral, anterior and anteroapical walls, the apex and the distal inferior and inferolateral walls with partial reversibility in the distal inferior and inferolateral walls at rest. At 6-months post-implant, there is improvement in perfusion in the distal inferior and inferolateral walls.

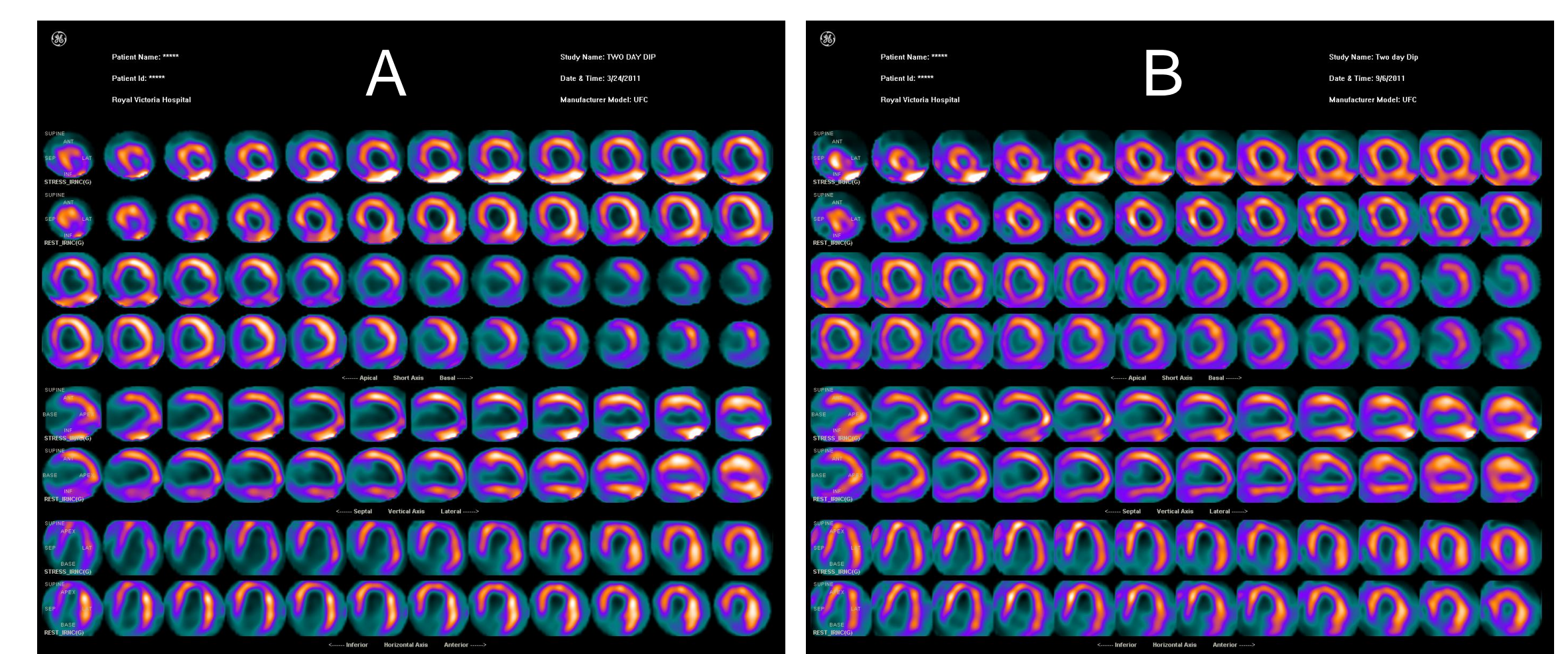


Figure 4. Patient 2. Non-ischemic cardiomyopathy. A. Baseline. B. 6-month.

MPI at baseline shows an extensive perfusion deficit in the entire inferolateral wall, the distal anterolateral wall, the septum and the apex, predominantly reversible at rest. At 6-months post-implant, these reversible perfusion abnormalities are no longer present and the perfusion is relatively homogenous throughout all of LV myocardial territories.

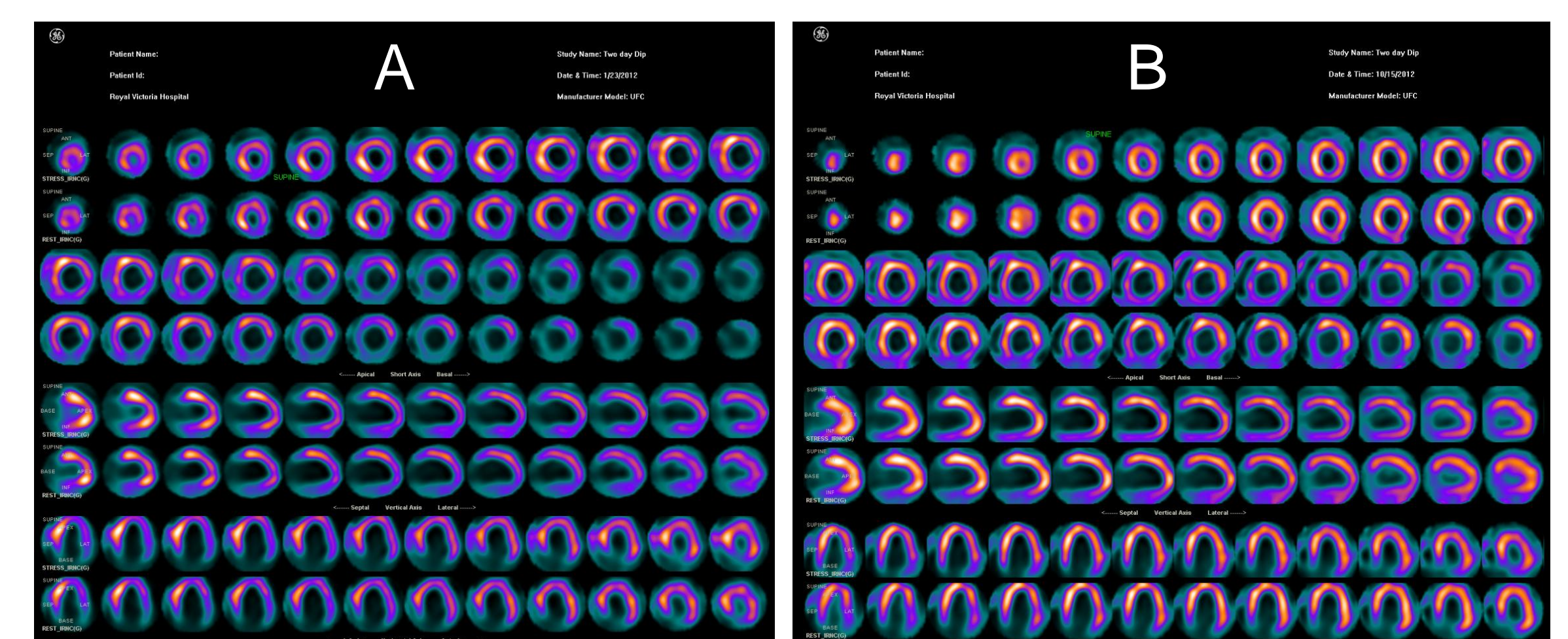


Figure 5. Patient 3. Non-ischemic cardiomyopathy. A. Baseline. B. 6-month.

MPI at baseline shows a large moderate perfusion defect involving the inferior and lateral walls. This is predominantly reversible at rest in the anterolateral wall and fixed in the remainder of the perfusion defect. At 6-months post-implant, there has been significant improvement at the site of the perfusion defect and reversibility is no longer apparent.

Conclusion

99mTc-sestamibi SPECT imaging in ambulatory patients implanted with the C-Pulse device suggest improvement in myocardial perfusion as a mechanism of action for this form of therapy. These benefits are present in both ischemic and idiopathic forms of cardiomyopathy. These findings warrant further similar testing in a larger numbers of patients.