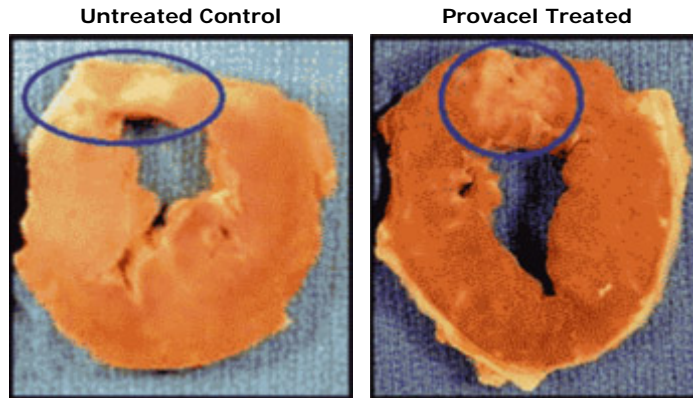


Repairing Hearts with Universal Adult Stem Cells

Osiris Therapeutics' Technology Saves Billions of Dollars and Millions of Lives.



The circled region denotes extent of scar in each image. Dense scar formation and wall thinning is seen in control hearts. In contrast, scar is limited and ventricle wall thick in hearts of MSC-treated animals. Source: Osiris Therapeutics, Inc.

The Challenge—More than 7 million Americans suffer from heart disease, at a cost topping \$100 billion annually. Once the heart muscle is damaged, decline is inevitable without costly, risky surgery or lifelong drug therapies.

In 2001, Osiris Therapeutics, Inc. wanted to develop mesenchymal stem cells (MSCs) for heart therapy but needed support for the next step, growing MSCs into heart muscle, in this technically risky venture. The company applied for and received an ATP award that allowed it to extend its promising work to heart muscles.

The Outcome—During the three-year project, Osiris demonstrated that in animals:

- MSCs grew into muscle when injected into the heart, without having to be cultured outside the heart.
- MSCs could be injected through a catheter to the heart or could be introduced intravenously.
- The body did not reject the new tissue, as is customary during organ transplants. This meant that expensive, risky, lifelong drug regimens to keep the body's immune system from reacting could be eliminated forever.

In 2003, Boston Scientific Corporation, a leading manufacturer of medical devices, joined with Osiris to commercialize MSCs for heart therapy. Their first therapeutic, Provacel, entered the Food and Drug Administration's second phase, human clinical testing, in March 2005. If approved, Provacel would save millions of dollars and improve the quality of life for millions of people with heart disease.

The Phase I human trials showed that treatment with Provacel significantly improved irregular heartbeat, premature ventricular contractions, lung function, and other critical indicators as well as the overall condition of people who had had heart attacks. There were no patient deaths and no significant side effects.

Others have taken note of Osiris's success. The company has acquired numerous patents, and investors continue to show interest in this promising therapy. Osiris regularly publishes and makes presentations on its heart disease research at conferences. A researcher on the ATP-funded project won the Heart Failure Society's Young Investigator Award in 2004. In 2005, Osiris gained \$29 million in venture capital, ranking fourth in venture capital attraction in Maryland. An August 2006 initial public offering capitalized the company at nearly \$300 million, making it the world's second-largest public stem cell company.

Partnering Organization:	Osiris Therapeutics, Inc., Baltimore, MD
Project Duration:	3/1/1998 – 2/28/2001
Project Cost:	\$1.8M ATP cost-share; \$2.5M industry cost-share
Project Brief:	http://jazz.nist.gov/atpcf/prjbriefs/prjbrief.cfm?ProjectNumber=97-07-0049
Project Status Report:	http://statusreports.atp.nist.gov/reports/97-07-0049.htm Research conducted March 2006