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## **Promising Results for Islet Cell Transplantation to Treat Diabetes May Lead to Potential Cure**

***Interventional radiology technique provides safe and reliable delivery of cells to the liver  
without surgery***

Salt Lake City, Utah (March 28, 2003) – Early data shows that transplanting healthy, insulin producing islet cells by infusion into the portal vein to the liver enables uncontrolled type 1 diabetic patients to become insulin free, according to data presented here today at the 28<sup>th</sup> Annual Scientific Meeting of the Society of Interventional Radiology. “This work is the collaborative effort of transplant specialists and interventional radiologists. This early data shows that if we can get enough healthy islet cells to the liver, diabetes patients could potentially be cured,” says Richard Owen, M.D., interventional radiologist at the Alberta Hospital. The islet cells become rapidly engrafted into the liver and secrete insulin almost immediately. The study shows that the interventional radiology delivery technique provides reliable and safe access to the liver, and together with islet cell separation techniques and immunosuppressive treatment, offers a significant development in the treatment of type 1 diabetes.

Interventional radiologists specialize in performing minimally-invasive treatments using guided imaging to treat diseases without surgery. Using ultrasound or fluoroscopic guidance, a needle is placed through the skin to a branch of the right portal vein, where the cells are infused. “Interventional radiology allows the cells to be placed directly where they need to engraft to begin producing insulin for the patient. This minimally invasive technique is a safe, accurate and practical means of delivery in the hands of a skilled interventional radiologist,” says Dr. Owen, in his scientific presentation

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*New Frontiers in Interventional Radiology.* The portal vein is the site of islet implantation because of the ease of technical access combined with cumulative data indicating that this route is the safest and most durable route for transplantation. The procedure is well within the capability of all interventional radiologists, and with adequate cell separation and purification, the procedure and clinical results of this study should be reproducible.

### About The Study and Islet Cell Transplantation

Forty-eight patients had 90 transhepatic portal vein islet cell transplantation procedures for type 1 diabetes. Twenty-two patients had two transplants, 10 patients had three transplants, and sixteen patients had a single transplant. In most cases, more than one transplant is required to obtain a sufficient number of islets to become insulin independent. On average, only about 5,000 islet equivalents per kilogram can be obtained from one donor pancreas. Successful islet cell infusion was achieved in all cases by the interventional radiologist. All of the patients who received more than 9000 islet equivalents per kilogram became insulin independent. One year later, twenty-one of the twenty-six patients that have received the full number of islets (81 percent) are insulin free. Most importantly, they are now metabolically stable.

“The people who took part in this trial had labile diabetes, which is dangerously unstable metabolic control. They could no longer tell when they had dangerous lows in blood sugar and had to test continuously. These patients were losing consciousness off and on, were at risk for diabetic coma, and were afraid to go to sleep at night, for fear that they would not wake up. Islet transplantation has given them their lives back,” says Owen.

### Treatment Availability

This is a very active area of research and the Alberta hospital in Edmonton, Canada is one of several hospitals in the United States and Canada with islet cell transplantation programs. Although not yet available outside of a clinical trial, multi-national trials using the Edmonton protocol are now in progress. This treatment is still being studied and is reserved for diabetics who have unstable diabetes to such an

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extent that the risks of transplantation are considered less than the risk of uncontrolled diabetes.

Recent developments in tailored immunosuppression for islet transplant recipients, combined with the delivery of sufficient islets, has led to rejuvenated enthusiasm for clinical islet transplantation as a potential therapeutic option for selected patients with type 1 diabetes. This enthusiasm is based on current insulin independence rates at one year exceeding 80 percent, combined with the minimal morbidity of the interventional approach for implantation. Improved safety, avoidance of major surgery, rapid hospital discharge and return to normal activity has been a major advantage of this approach, making the procedure attractive to patients.

These new success rates are very encouraging. Prior to these recent developments, the previous success rates were about 7 to 14 percent. There are still limitations to the procedure. Isolating the cells from a donor remains a highly technical and labor intensive process. If a large enough number of islets can be isolated then they are transplanted. This early work shows that if we can get enough healthy islet cells to the liver, diabetic patients could potentially be cured of their need for insulin.

### About the Society of Interventional Radiology

An estimated 5,000 people are attending the Society of Interventional Radiology 28<sup>th</sup> Annual Scientific Meeting in Salt Lake City. The Society represents interventional radiologists — physicians who specialize in minimally invasive, targeted treatments performed using guided imaging. Interventional radiology procedures are a major advance in medicine that do not require large incisions – only a nick in the skin about the size of a pencil tip – and offer less risk, less pain and shorter recovery times compared to surgery. Interventional radiologists pioneered modern medicine with the invention of angioplasty, the first catheter-delivered stent and the coronary angiography technique most used worldwide -- state of the art treatments that are commonplace in medicine today. More information can be found at [www.SIRweb.org](http://www.SIRweb.org).

**Interviews are available by contacting the press office on site at 801-534-4753.**

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