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First Human Trial of a Bioengineered Part Human and Part Porcine Liver

In June of 2025 at Intermountain Medical Center in Murray, Utah a patient was surgically connected to an external bioengineered liver. The implanted miroliverELAP ® had been bioengineered to perform the liver functions that this patient's failing liver could no longer provide. The patient who received this surgery, did not meet the criteria to be placed on the liver transplant list. This bioengineered organ was developed by scientists and doctors at Miromatrix; a subsidiary of United Therapeutics. The miroliver itself, when the bioengineering process was completed had a DNA match that made it almost human. This liver assist will hopefully be a major step forward towards Miromatrix's ultimate goal, which is the creation of fully transplantable human organs.

The miroliver is the first bioengineered organ to be approved for stage 1 human trials. In these trials liver organs will be implanted outside of the patient's body and properly connected to the patient's circulatory system. Proper placement and blood flow is critical for the miroliver to properly perform its biological functions. If the data from this first surgery and future surgeries, successfully meet the criteria set forth in the study one would expect that Miromatrix will receive approval to start testing other organs. Photo 1 shows many organs in bioreactors being readied for future transplantation.

Photo 1 Credit: Miromatrix

This US gov website can provide you with more information on participant criteria, the 8 participating hospitals (including Mayo Clinic in Minnesota and Mount Sinai in New York), and what bench marks the doctors and researchers at Miromatrix will need to achieve for the stage 1 study to be successful. https://www.clinicaltrials.gov/study/NCT06285253?term=miromatrix&rank=4

The bioengineering procedure that was used to create these organs is fascinating. In an over simplification of the process one can describe their bioengineering as a two-part process that begins with Perfusion Decellularization which removes what makes the organ genetically pig. Once part one is completed part two of the process Perfusion Recellularization begins and it makes the organ genetically almost human.

Perfusion Decellularization

To transform a pig organ into a partially human organ the company created a decellularization process that removes the porcine cells from the organ so only a protein scaffold of the organ exists. They perform this operation by pumping a mild detergent through the arteries of the organ so that the solution flows through even the smallest capillaries to dissolve all the porcine cells. These cells are washed out of the organ through the organ's veins.

Perfusion Recellularization

The protein scaffold at this point in the process contains the structure, arteries, capillaries, veins, and mechanical properties of the organ. Basically, everything but the functioning cells that are needed to remove harmful substances from the body's bloodstream. To bring the organ back to life they created an automated system that infuses live human cells using the circulatory system that remains intact in the organ scaffold. They infuse the cells that form the inner lining of blood vessels and also infuse healthy stem cells that come from human donors. These donors might be a sibling, parent, or people from a doner registry. Human STEM cell therapy is already an FDA approved treatment for certain cancers and other diseases.

Recellularization takes place over time in a bioreactor. Perfusion of all the cell types that are found in a functioning organ is created from stem cells that grow and mature as they are pumped through the organ's arteries, capillaries, and veins. That these researchers, bioengineers, and doctors found a way to coax the STEM cells to develop into the needed cells is truly amazing. In the bioreactor the STEM cells slowly mature forming all the necessary cell types to perform the function of a human organ. Photo 2 shows a kidney that is almost ready to be transplanted in an animal study.

Photo 2 Credit: Miromatrix

Perhaps human trials of full organs is not so far into the future. Miromatrix has already successfully transplanted full bioengineered organs into animals. The results from these surgeries could soon become the basis for them to file for approval for full organ human trials.

Taking it a Step Further

Topics for student research and class presentations: (STEM Cell Therapy) (Cloning) (Genetic Engineering) (Synthetic Biology) (CRISPR Gene Editing) (Vaccines vs Antibiotics)

Alan Pierce, EdD, CSIT is a technology education consultant. Visit www.technologytoday.us for past columns and teaching resources