CELL SURGICAL NETWORK™

Dear Potential Affiliate,

Introduction

The rise of Regenerative Medicine may well be one of the great technological advances of the turn of the 21st Century. In the cyber age, cell medicine information spreads faster than genuine knowledge and expectations for medical cures outpace current technology. Most of the resources devoted to advancing regenerative medicine have been channeled from government grants and pharmaceutical company research into basic laboratory work. Although basic laboratory science research is vital, one must consider the role of translational research in making progress in bringing technology from the "bench to the bedside." Working in this manner, many of the great historical advances in medicine were obtained by thoughtful and courageous clinicians.

Clinical knowledge of some of the practical applications of stem cell treatments have come mostly from international sources and the United States is severely lagging. At this time in the United States, most of the clinical trial work is designed to evaluate stem cells as a drug since the studies are designed by an industry whose model is to market something in a bottle to the masses. Hucksters and offshore enterprises of dubious quality have exploited this clinical vacuum. But there is another way.

Enormous quantities of mesenchymal stem cells in a rich soup of growth factors have been serendipitously identified in human fat as "stromal vascular fraction (SVF)." This rich storehouse of autologous adult mesenchymal regenerative cells can be harnessed and deployed through a surgical procedure that is a type of "fat transfer." American physicians must embrace the concept that a person's own cells from their fat are not an investigational biologic drug but instead, they are a surgical tool in the physician's armamentarium to fight disease. This ability to use one's own cells to treat degenerative disease without pharmaceuticals is what we have termed "The Stem Cell Revolution®." As physicians and scientists, we must apply academic rigor to the evaluation of safety and efficacy of our techniques. We must develop and hone surgical procedures within our "scope of practice" to exploit the fascinating regenerative properties of SVF and advance our knowledge of cellular healing. Professional research networks can catalyze this process under Institutional Review Board (IRB) approved protocols by standardizing techniques and providing a platform for sharing data efficiently.

History of our organization

In early 2008, using equipment designed by Dr. Hee Young Lee in South Korea, Dr. Mark Berman, a cosmetic surgeon and an international expert in fat transfer, began isolating concentrated fat for cosmetic uses. With Lee's technology and further consideration after visits in Japan with Dr. Katoro Yoshimura and others, he quickly realized the therapeutic potential of SVF for degenerative diseases based on extensive animal studies and clinical work in the US, Europe and Asia. Later in 2010, a GMP grade of collagenase became commercially available from Roche Laboratories and techniques for isolation of SVF continued to advance. Dr. Berman, in collaboration with Dr. Tom Grogan, a board certified orthopedic surgeon, began using intra-articular injections of SVF for various orthopedic uses and found that their experience matched the positive outcomes described in the literature. Dr. Berman began collaborating with Dr. Elliot Lander, a board certified Urologist, to develop research protocols to test for safety of various methods of SVF deployment. Dr. Lander and Dr. Berman created California Stem Cell Treatment Center® as a vehicle for patient funded research. Protocols have been developed to treat orthopedic, urologic, cardiovascular, pulmonary, auto-immune, wound care, and several other disease entities. The center is founded on a multi-specialty team approach to patient care. More than 1000 patients have received SVF deployment at California Stem Cell Treatment Center (CSCTC®) and the Cell Surgical Network™. An IRB approved study of adverse events has been initiated and is registered with Clinicaltrials.Gov. Additionally, a clinical research coordinator is employed to monitor the patient registry to collect valuable data and a huge online database is actively collecting outcomes data.

Mission

The mission of the Cell Surgical Network™ is to provide care for people suffering from diseases that may be alleviated by access to adult stem cell based regenerative treatment. As such we hope to advance the field of "Cell Surgery" and teach other physicians techniques that they can use to bring regenerative medicine into their practices.

Current Practices

Our affiliates operate their own independent stem cell treatment centers where they work with multidisciplinary teams of physicians to provide investigational SVF therapy to patients that have been carefully screened. Our surgical procedures can be conducted completely under local anesthesia (with rare exception IV sedation or general can be employed). The patient is prepped and draped and a sterile environment is maintained

throughout the procedure. We utilize GMP grade collagenase and the TimeMachine™ equipment made by Medikhan to harvest and prepare the fat via a mini-liposuction procedure. This is done under a completely closed system that we developed specifically for cell surgery. The equipment is reasonably priced and the disposables are likewise affordable. We believe that not only does our technique satisfy FDA 1271 exemptions; it is a surgical procedure and would not even be under the jurisdiction of the FDA. The liposuction segment of the procedure takes 10 – 15 minutes and the processing takes another hour or so. At that point the cells (SVF) can be deployed.

Who might benefit from doing cell surgery?

Adult mesenchymal stem cells within SVF are currently being used in the treatment of a host of degenerative diseases including orthopedic conditions, cardiac, pulmonary, and urologic. Auto-immune diseases and certain neurologic problems such as muscular dystrophy and MS may benefit from cell therapy. Protocols exist for ED, lichen sclerosis, peyronies disease, interstitial cystitis, neuropathy and critical limb ischemia. New protocols are constantly being developed including hair restoration, male and female incontinence, and macular degeneration, to name a few. In close collaboration with China's leading stem cell facility, WA Optimum Health Care in Shanghai, new protocols in anti-aging, autism, TMJ disorders, hepatitis repair and other areas continue to emerge. Network candidates include groups consisting of various combinations of cosmetic and plastic surgeons, orthopedic surgeons, internists, cardiologists, urologists, gastroenterologists, wound care experts, family physicians, pain management doctors, sports medicine physicians, and other specialties.

Why affiliate with Cell Surgical Network™?

Establish your practice as a cutting edge research oriented member associated with a well-established practice of like-minded collaborating physicians. Joining the Cell Surgical Network™ will enable your practice to participate in our research network and benefit from the extensive experience we have developed over the past 3 years doing cell surgery.

Affiliate Network Organization

California Stem Cell Treatment Center has used its knowledge, influence, brand reputation, and web presence to launch an affiliate network of Stem Cell Treatment Centers under the banner of the Cell Surgical Network™ (CSN).

In order to support the affiliate network, CSN™ will provide marketing support, training services and financial resources for select medical practices on a national level in strategic markets through brand licensing agreements.

Contracting practices will be able to use the "Stem Cell Treatment Center" name to market their quality and affiliation. A typical center might be called "The New York Stem Cell Treatment Center, an affiliate of the Cell Surgical Network™."

We will provide physician affiliate clients around the United States with a number of different services including: technology and IP transfer, training, education and support for physicians and staff, access to research protocols including the CSCTC™ IRB, website presence, access to a very powerful university quality research database that collects outcomes from all sites, access to preferred pricing network for equipment, PR and marketing benefits including geographic referral leads and practice development tools. Our network affiliation also includes stem cell deployment malpractice coverage benefits for affiliates and their independent contractors.

Affiliate clinics will be expected to strictly abide by the rules and recommendations of the brand licensor regarding FDA claims, adherence to research protocols and ethics, strict adherence to IRB approved equipment usage, careful accounting and business practices, and quality control.

Affiliates will pay no fees to be in the Network, but must agree to use only CSN approved equipment and purchase disposable kits from the Cell Surgical Network™.

RESPONSIBILITIES OF CELL SURGICAL NETWORK AFFILIATES

CSN will license its intellectual property and research protocols through a brand license agreement to affiliates who wish to participate in our research network.

1. Licensees will be expected to adhere strictly to CSN research protocols.
2. Licensees will be expected to adhere to CSN standards of quality and ethical conduct and provide compassionate patient care within their scopes of practice.
3. Licensees will be expected to avoid all claims and testimonials in advertising. TV or news shows are acceptable as long as only factual information is presented and patients can be allowed to appear to present their experiences. Print and video advertisements should otherwise be restricted to informing the public that the practice is involved in investigational IRB approved regenerative medicine studies and direct people to the website.
4. Licensees will make best efforts to form a multi-disciplinary team of experts that is qualified to treat the diseases that they plan to treat with SVF. Teams require that at least one member has expertise in liposuction and teams may consist of cosmetic surgeons, plastic surgeons, orthopedics, pain specialists, sports medicine experts, etc. Team members may participate as independent contractors of the practice. Cell harvesting can be performed by the licensee or outsourced to an independent contractor. The team member who has appropriate expertise in the area of disease should perform the cell deployment. For example, treatment of cardio-pulmonary disorders should be performed in collaboration with a contracted internal medicine physician. The contracting physician may review candidacy applications or perform the actual injection.
5. Licensees will be expected to follow price guidelines (to be provided) to avoid competition for patient enrollment within the network. It is understood that early in the center's development phase, substantial financial discounts may be offered for procedures, however, it is legal and prudent to adhere to the pricing structure as closely as possible.
6. Licensees will be diligent in registering all patients into the research registry since data accumulation is essential and must be rigorous. Cell Surgical Network™ will bear the cost of the database.
7. Licensees will agree to use the IRB approved consent and all standardized forms for patient care and data collection. Licensees will agree to use the official database to follow outcomes and adverse events diligently.
8. Licensees are encouraged to share with the network information or any ideas that may improve patient quality of care.