STEM CELLS FROM FAT-- A NEW MODEL FOR REGENERATIVE MEDICINE AND STEM CELL TREATMENT CENTERS

The stem cell age is here and is rapidly evolving. The media is saturated with stories and there is so much hype and promises about stem cell wonders and cures. As clinicians, we are starting to see the potential of cell therapy to achieve organ replacement and repair and eventually we will see "stem cells in a bottle" as cell based therapies obtain FDA approval for various indications. These therapies will take years to decades and hundreds of millions of dollars before they are widely available. Coexisting, and in parallel to this mainstream stem cell research efforts based on evidence based medicine, there exists another clinical industry of stem cell treatment clinics offering cell therapies derived from adipose tissue. For various reasons, these centers are gaining acceptance and popularity in recent years. The main reason is that some of these centers have good science and ethics and are offering patients treatment options that they cannot obtain in many traditional doctor's offices. Second, is that many patients want access to regenerative therapies but cannot afford to go overseas where such treatments are more widely available. Third, the regulatory issues that prevent doctors from growing and "manipulating" cells do not apply to same day surgical procedures that permit physicians to transfer tissues rich in stem cells to damaged areas of the body. Surgeons have been promoting healing by moving different tissues around the body since the field was created and FDA tissue handling rules recognize this aspect of medical care. This permits these clinics to use stem cells from autologous fat (from one's own body) which is readily accessible, painlessly acquired, and not at risk for disease transmission.

Our project got started in 2010. Colleagues in Asia gave my partner, Dr. Mark Berman, an internationally recognized expert on fat grafting procedures, a simple way to procure adult mesenchymal stem cells from lipoharvest fat in the form of stromal vascular fraction SVF. We understood that since SVF is obtained from autologous tissue in the operating room on the same day, the cell deployment falls under the auspices of a "lipo-transfer" surgical procedure and is not regulated as a laboratory procedure by the FDA. All medications and devices used in the procurement are FDA approved but used "off-label." The entire procedure is really no different than bladder replacement surgery for example where small bowel is used to replace bladder tissue, or a bypass surgery where a vein from the leg is transferred to the heart to form an artery. My partner and I quickly realized that we had valuable technology at our disposal but that we would had to use it judiciously. We set up California Stem Cell Treatment Center for the investigational use of stromal vascular fraction and we obtained Institutional Review Board IRB approval to study the safety and efficacy of our deployments. IRB's are governed by the Office of Human Research Protections (a division of HHS). We created an educational website and a multispecialty team since we were looking at treating conditions that required expertise beyond our scope such as cardiac and orthopedic diseases. Our educational website (www.stemcellrevolution.com) explains that this is patient funded research and that patients would in fact bear the full cost of their care. We used information and deployment techniques that we obtained from our veterinary colleagues and from reputable centers overseas to optimize our outcomes. We coined the term "*cell surgery*" since our surgical procedure

has no laboratory or manufacturing component and we wished to distinguish ourselves from the pharmaceutical model of regenerative medicine in which the aim is to monetize a stem cell product as a biologic drug for global distribution. After all, we were clinicians providing our patients with a surgical regenerative treatment, not a product that comes with a label. We have now performed over 1000 cases at our treatment center with extraordinary safety and no adverse effects and our safety data mimics that seen from the worldwide SVF experience. We have seen astonishing results in wound healing, cardiac function recovery, nerve repair, disease mitigation and arthritis mitigation and treatment of crippling back pain. Many patients have delayed or avoided joint replacement by having SVF deployments. We have helped patients with Peyronies disease (penile scarring with no effective therapy). We have provided relief for numerous patients with debilitating autoimmune diseases. The uses and various methods of deploying SVF are continually growing.

Two years ago, with the understanding that it is important to teach our technology to other interested physicians, we started training select physicians to use our techniques to isolate SVF and incorporate it in their practices and we formed a translational research network that includes 65 centers in the United States and also centers as far away as Asia, South Africa, South America and New Zealand. We called the project the Cell Surgical Network. All Network physicians are performing cell surgery using identical protocols that we developed in our centers over the past 4 years and all are collecting outcomes data in our online advanced database. We have presented our data all over the world including at the prestigious World Stem Cell Summit in 2013.

SVF deployment is a disruptive technology. A technology that allows surgeons to tap the human storehouse of healing cells , taking them from fat and making them "bio-available" for disease mitigation. Many clinicians in the United States and Europe are waiting for the pharmaceutical industry to provide cell based therapeutics but those will come from a laboratory after a prolonged regulatory process. Others have chosen to use the surgical techniques of stem cell procurement and the knowledge that we have accumulated here and overseas to benefit our patients today.

As with any new industry, many clinics have entered the fray, including some without adequate knowledge and training but interested in riding the regenerative medicine wave. Their websites are full of testimonials and irresponsible claims. It is important for physicians and consumers to understand that not all stem cell clinics should be painted with the same broad strokes. Those committed to data collection, that emphasize training, and have IRB oversight should set examples for a model of how we can accelerate the quality of regenerative medicine. The Cell Surgical Network was the first organization to aspire to these goals and continues to promote our vision of quality regenerative care. We have served as advisors to autologous stem cell policy makers in numerous countries including Australia, the European Union, and China. As patient advocates, our vision is to have safe and cost effective cell based therapies available soon to everyone in the world. A vision we get closer to achieving every day.