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Current News

April 2008: These are the latest articles on Stem Cell Transplant research from Northwestern University

Hematopoietic stem cell transplantation for autoimmune diseases: What have we learned?

Clinical Applications of Blood-Derived and Marrow-Derived Stem Cells for Nonmalignant Diseases

October 2008: I am pleased to announce that we have been joined by a transplantee who had Cancer. Her transplant had to be done with donor cells, and she is very willing to assist Cancer patients who can take advantage of a stem cell transplant. Contact me and I will get you in touch with her.

August 2008: I have past my three year anniversary. I have resumed most of my activities, and am leading a nearly normal life.The traveling continues, and the book is nearly ready! More news on that soon.

April 2008. The ASSIST trial is now primarily being conducted by Dr. Richard K. Burt at Northwestern University in Chicago at this time. More exciting news on new facilities will be forthcoming ,hopefully by the end of the year.
I have sent several patients there, and all have felt that the experience was rewarding.

I reached my two year anniversary in August, 2007. I am

feeling quite well. I did a fair amount of traveling this summer, Colorado, South Dakota, Minnesota, Michigan, New York State, Vermont, Maine, New Hampshire, and Ottawa Canada. The Colorado trip was a bit daunting, and I did need oxygen at those altitudes. In fact, I was the only comfortable one in my party. I am breathing normally and comfortably at home with no supplemental oxygen. I am beginning to cut down some medications, and best of all, I am resuming some of my previous activities, such as quilting and singing.

I attend Pilates class three times a week which greatly helps my breathing. I will be resuming pulmonary rehab in the fall, since it only helps my situation. I continue to speak to any groups who would like to hear about my success, in an effort to reach others.

February, 2007:
A couple of things which may help: If you have Raynauds, use an oven mitt to get things from the freezer. Also as far as gloves are concerned, get gloves that are bigger than your hand. Then, get a thin cotton pair of gloves and use them as liners. You can take the liners out and wash them.A thin cotton pair used as liners will help to keep your hands warm in bitter cold for a comfortable amount of time.

If you have lung problems, such as Pulmonary Fibrosis, etc., there are not stem cell trials yet for these diseases, but there are other clinical trials going on. I plan to have some information up on the site soon, but in the meantime, take a look at clinicaltrials.gov to get a feel for what is out there.

The Type II diabetes study is now in trial.
An article in December issue of Scientific American gives some of the history. More information: clinicaltrials.gov

December 2006: "Arthritis and Rheumatism" published a comparison of the stem cell trials for Scleroderma, comparing SCOT, ASSIST and ASTIS trials.
Review of Stem Cell Transplant Trials

October, 2006

*Type I Diabetes SCT coming soon

*Heart Failure SCT in Trial

*Incontinence SCT Available

*Regenerative Medicine (knee replacement) in trial

REGENERATIVE MEDICINE IN THE NEAR FUTURE

Written by
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Dr. Friedman is a Kidney Specialist and Cell Therapies Physician in West Orange, NJ. He is also Prinicipal Science Administrator of NJ Stem Cell Research and Education Foundation.

Age invites infirmity. Some body parts"wear out," are damaged or destroyed by disease, non use, or trauma. The struggle of those in medicine has been to harness or redirect the natural healing processes of the body and alter the course of disease and repair traumatic injuries. It is ironic that the journey toward longevity and health has redirected scientists to the beginnings of life and the regenerative capacity of the stem cell.

In our lives, we will each experience illness and frailty as the result of decline of cellular functions. It is now recognized that while some organs have the ability to heal and even regenerate themselves, our bodies also rely upon the mobilization of stem cells from our bone marrow to aid in the healing process. This potential for cell regeneration is limited and declines as we age.

The search for alternative sources of regenerative stem cells has converged upon a number of potential sources:

umbilical cord blood and placenta
subcutaneous fat
bone marrow
peripheral blood
embryos

Extraction of stem cells from bone marrow and peripheral blood can be invasive and costly procedures which may carry significant risks. Embryonic stem cells are not currently a viable option due to patients, product liability, potential medical malpractice, legislative and bioethical issues encumbering their use. Liposuction yields a significant number of stem cells and successful extraction of them in large, viable quantities is still in development.

Yet, there are 4 million births and nearly 1 million joint replacement surgeries in the US annually. If routinely collected, bone marrow from joint replacement surgery and stem cells from umbilical cord blood and the placenta would provide unlimited and renewable reserve of stem cells for all persons in need. These facts underlie the basis for the recently passed US Federal legislation goals for Stem Cell banking (US Senate Bill 1317):

Development of an aggregate 150,000 unit bank of stem cells based in the United States to serve as a reservoir for stem cell transplantation for patients with cancer, anemia and metabolic disorders;

Make this reservoir of stem cells units available for treatment of military personnel or civilians injured by radiation;

Support research and development of stem cell therapies to regenerate lost cellular function.

With such a bank, there is nearly a guarantee that each individual would have multiple tissue-matched stem cells available whenever needed. Equally important, patients from ethnic groups or age groups (eg, the elderly,

Asian-Americans, African-Americans, Hispanic-Americans) which currently have great difficulty finding appropriate tissue-matches would more easily find the life-saving stem cell products they need.

Regenerative Medicine

Regenerative medicine is a burgeoning branch of medicine that focuses upon the concept of physiologic "healing" and restoration of function. Since the first successful human stem cell transplant in the US in 1968, the abilities of stem cells to 1. restore a functioning immune system after chemotherapy; 2. incorporate themselves into functioning major organs; and 3. "reset" the immune system and reduce chronic inflammatory states has been cataloged. Currently, the National Institutes of Health has established a national database to follow the immunologic and genomic impact of autoimmune diseases, pregnancy and stem cell transplant upon patients.

Current uses of stem cells for cancer treatment only "scratches the surface" of clinical utility. Publications regarding stem cells and their potential uses for treatment of stroke, heart disease, liver disease, arthritis, diabetes,and other common conditions have begun to permeate medical and scientific literature. Stem cells represent a potential "treasure chest" for treatment of a multitude of diseases. Regenerative Medicine targets reversal of the root cause of disease: loss of cell function.

Arthritis is one of the leading causes of disability amongst Americans. There are millions of new cases of Arthritis diagnosed annually in the US and it is one of the most frequent causes of personal and work-related disability. Joint replacement is the treatment of choice when medical and surgical modalities fail. The success of joint replacement is tempered by the realities of perioperative morbidity and mortality as well as the finite longevity of all joint protheses. Stem cell-based regeneration of synovial tissue

may delay or eliminate the need for joint replacement surgery.

Heart Disease remains one of the leading causes of morbidity and mortality amongst Americans. There are 500,000 new cases of congestive heart failure (CHF) diagnosed annually in the US. CHF is the single most utilized hospital admission diagnosis in the state of NJ and one of the most expensive. Currently, whole-organ heart transplantation is the treatment of choice when medical and interventional cardiology modalities fail. The success of heart transplantation is tempered by the realities of organ rejection and the adverse effects of immunosuppressants. Stem cells transforming into new, functional myocardiocytes could stave off the need for heart transplantation and supplement existing medical treatment for patients with CHF.

Autoimmune diseases such as Scleroderma have always been intriguing and humbling diseases to understand and treat--they often have minds of their own, flaring for inexplicable reasons and quieting down for unapparent reasons.

2006--Where Are We Now?

Because of the courage of some of you, I have been privileged to be able to witness the benefits of stem cells in the treatment of this awesome illness. As a transplant physician, my awakening came in 1998. Faced with the reality the more and more people needed life-saving or life-enhancing transplants, the American Society of Transplantation began to invite some of the most prominent human stem cell researchers to present to nearly 5,000 transplant physicians.We were left with these thoughts about stem cells:

Could this be our way through the heart, liver, and pancreas organ shortages?

Could these cells be used to coax the immune system into accepting a donor's transplanted organ?

Could these cells be used to replace brain, spinal

cord and other as yet untransplantable organs?

Could the expertise of organ transplanter and oncology/stem cell transplanters bring stem cells safely to human clinical trials?

So where are we now in 2006? First and foremost, at the highest levels of government, the stem cell "shot heard round the world" was fired that last week of December 2005 when the US Senate passed Senate Bill 1317--Bone Marrow and Cord Blood Cell Transplant Program. The value of stem cells in the treatment of human diseases is now being realized in over 100 different diseases. As of 2005, human clinical treatment of SCLERODERMA with stem cells is a real option for those who have not sufficiently benefited from medications used in the treatment of Scleroderma.

Microchimerism: An Investigative Frontier in Autoimmunity and Transplantation

Written by
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Microchimerism

STEM CELL TRANSPLANTATION FOR SCLERODERMA

Written by

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Dr. Traynor and Dr. Burt participate in the ASSIST trial;
several centers across the US participate in the SCOTT trial.
It is important to know that your center has experience with HSCT for Scleroderma and to ask about any deaths among transplant patients.

At Northwestern University and the University of Massachusetts over the last 3 years, Ann Traynor and Richard Burt and their colleagues have performed 11 stem cell transplants for scleroderma. All of the 11 patients are alive, and all have been able to discontinue using oxygen and all have markedly improved skin scores. This single armed trial continues to treat patients at this time. We will soon open a "randomized trial" comparing transplant to treatment with cytoxan. Individuals who are randomized (assigned to one treatment or the other randomly, as by flipping a coin) to standard cytoxan and fail to respond well to the cytoxan will be able to proceed with stem cell transplant treatment.

While our anecdotal evidence thus far suggests that stem cell transplant may offer hope for scleroderma and its progression, the only way to be sure that this treatment is truly superior to the treatments that are more commonly available, and that it is acceptably safe, is to compare the outcomes of similar patients treated by stem cell transplant or treated by another reasonably aggressive approach.

The Food and Drug Administration encourages us to perform a "randomized trial" to compare two treatments in order to determine the relative safety and efficacy of the stem cell transplant approach. Randomization is like

flipping of a coin, where each patient gets assigned to either the transplant arm or to the more standard, aggressive treatment. It goes without saying that, if one arm begins to show clear superiority and safety, the study should be terminated and that treatment should become standard treatment.

From this type of comparison the general public, the FDA and all scleroderma patients can appreciate whether one treatment is superior and is sufficiently safe. Ethically there are two major concerns with a trial of this kind: first, that individuals with scleroderma must not be encouraged to enter treatments that are unduly risky, because they are "desperate to find something that works" and two, that, if stem cell transplant does appear more effective and safe in such a comparison, that individuals be allowed to move quickly from the "standard of care" treatment to stem cell transplant before their disease progresses.

Currently the FDA has approved two randomized, comparative trials for scleroderma, both of which compare stem cell transplant to cytoxan alone, in the United States. Different transplant centers choose to participate in one trial of the other, largely based on their opinion of the preparative regimen (the high dose therapy) used in the transplant arm. The two trials are named the ASSIST trial and the SCOT trial.

	ASSIST TRIAL	SCOTT TRIAL
Both trials compare:	HSCT vs standard Cytoxan	HSCT vs standard Cytoxan
They differ in high dose Therapies given	High dose Cytoxan and Campath antibody	High dose Cytoxan and Total Body Irradiation
Crossover allowed?	Yes	Not yet