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Tomorrow's Technology Today

Adipose derived stem cells (ADSC), the new-kid-on-the-block, have a lot to offer. With a promise of cure, ADSC bring with them a complication-free faster treatment process without any ethical burden. M Neelam Kachhap takes a closer look at the optimism surrounding ADSC

The human quest for knowledge has led to many discoveries, which from time to time has changed our outlook towards our environment and life itself. Stem cells are one such discovery.

Not a single month passes by without a new stem cell research paper being published. Stem cells offer exciting medical promise for repairing or replacing organs that are diseased, damaged or worn out. This promise of repair and regeneration was taken a step further with the advent of Adipose (Fat) Derived Stem Cells (ADSC) which are derived from our own excess body fat.

Much like recycling waste, our excess fat can be processed to give us a better quality of life. Currently used for breast augmentation and reconstruction as well as plastic surgery, ADSC are being researched for most debilitating diseases like Myocardial Infarction (MI), diabetes mellitus and neurodegenerative diseases also.

Growing Interest

There has been growing interest in the promise of ADSC. About eight years ago, 300 scientists from around the world came together to form the International Federation of Adipose Therapeutics and Science Society, to share their knowledge and experience. Subsequently, many researchers in India are also studying the effect of ADSC in various diseases. Researchers feel that a growing number of liposuction procedures prompted the study of ADSC. Expressing his views about this trend Dr Samuel JK Abraham, Director, Nichi-In Centre for Regenerative Medicine (NCRM), Chennai says, "I guess its because of the growing number of liposuction procedures mainly for aesthetic reasons during which significant quantity of adipose tissue is removed, which instead of being discarded, could become a useful source of stem cells, for storage and future applications."



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Added Advantage

Another reason for growing interest in ADSC is the ease of the procedure and advantages over Bone Marrow Derived Stem Cells (BMDSC). According to a review published by Helder, et al ADSC has several advantages over BMDSC, such as easy accessibility; minimal morbidity upon harvest. Additionally, clinically relevant stem cell numbers can be extracted from adipose tissue isolates, potentially eliminating the need for in vitro expansion. Also ADSC have higher stem cell proliferation rates than bone marrow mesenchymal stem cells. The study also states that ADSC show potential for multiple differentiation as they differentiate in vitro and in vivo towards adipogenic, osteogenic, chondrogenic, myogenic, ligamentous and probably, neurogenic, endothelial, hematopoietic and cardiomyogenic phenotypes.

"Clinically, ADSCs have the advantage over their bone marrow-derived counterparts, because of their abundance in numbers – eliminating the need for culturing over days to obtain a therapeutically viable number – and the ease of the harvest procedure itself – being less painful than the harvest of bone marrow. This, in theory, means that an autologous transplant of ADSC will not only work in much the same way as the successes shown using marrow-derived mesenchymal stem cell transplant, but also be of minimal risk to the patient," explains Dr Vijay Sharma, CEO, Kasiak Research, Mumbai.

Adding to this Dr Ramananda S Nadig, CEO, Khoday Stemcell Research & Medical Centre, Bangalore opines, "There is an obvious benefit of ADSC in cardiac disease going by the fact that it is easy to harvest and culture adipose tissue stem cells from the patient himself without subjecting him to invasive procedures of obtaining the stem cells from the bone marrow. This would be even more useful given the fact that following MI one has to wait for sometime before performing bone marrow aspiration."

However, with great discoveries comes great debate. Some researchers think it is too early to talk about the ADSC therapy and want to wait for long-term study results. "Too early to say which therapy is better. Long term studies are essential to prove their efficacy against the bone marrow stem cells which are in clinical practice for bone marrow transplantation as well as primary organ failures for long," says Dr Abraham.

However other surgeons feel that BMDSC may have more merit over ADSC.

"The bone marrow has relatively less number of mesenchymal stem cells but it has a different cocktail of stem cells, namely endothelial progenitor and haematopoietic stem cells. It also has abundant quantity of growth factors which are necessary for cell proliferation and differentiation. This cocktail of different cells helps in multiplication of these cells. It has been seen that more pure the cell types, poorer are the results," explains Dr Himanshu Bansal, Medical Director, Anupam Hospital, Uttarakhand. Having worked on comprehensive treatment with autologous tissue like BMDSC, sural nerve graft, nasal olfactory tissue and omental transposition for treatment of spinal cord injury, Dr Bansal also says, "All indications served by mesenchymal stem cells of bone marrow can be served by ADSC like spinal cord injury, neurodegenerative disorders, cardiomyopathies, avascular necrosis of bone. Also ADSC are easy to isolate via less invasive process."

Process Simplified

The process as described by various researchers is fairly simple. Doctors perform liposuction to remove a portion of fat about the size of a medium potato from, for example, the abdomen. They then extract the stem cells and then inject them into diseased tissue. There's no chance of rejection since the cells come from the patient. The extract from liposuction may contain either a mixture of cells or can be pure stem cell, as required by the procedure. All this is achieved in less time and with minimum discomfort to the patient.

Problem Solved : Cells at the Point-of-Care



Utility Galore

The safest procedure to use ADSC and adipose derived regenerative cells is cosmetic surgery for facial reconstruction and facial defect repair. The process has been approved in Europe and Japan and is now being used in India. This is followed closely by breast augmentation and reconstruction, wound healing as well as treatment of radiation lesions and Crohn's disease. One of the first surgeon to use this therapy Dr Anup Dhir, Senior Consultant, Apollo Hospital, Cosmetic Plastic Surgeon & Andrologist and Secretary Indian Association of Aesthetic Plastic Surgeons says, " Fat grafting with adult stem cells and regenerative stem cells can rejuvenate the skin. Usually fat grafting is done in two to three sittings; however with this procedure once you add these cells the number of fat grafting required is less. The ADSC helps increase fat survival and improves result." He recently used this process on a 24-year-old patient who had a windscreen injury to the right side of her face at the age of three. Since then, she underwent a number of surgeries, but her disfigurement and scars had not healed satisfactorily. However, after the procedure the patient has shown marked improvement at four months.

Says Dr Dhir, "A lot of improvement was seen in this patient. In the last four months, scars have become so much lighter that its barely noticeable. ADSC stimulates angiogenesis (formation of new blood vessels) and thus fills cavities and improves scars. There is nothing artificial, nothing synthetic so no side effects. Plus this therapeutic application is a well established procedure."

"I was a part of adipose tissue derived stem cell trial in spinal cord injury and critical limb ischemia. We could not have a large number of subjects because of cost considerations, but the results were encouraging in spinal cord injury. However in critical limb ischemia results were poor as compared to good results of other studies with bone marrow derived stem cells," laments Dr Bansal.

"A 32-year-old patient with complete spinal cord injury showed phenomenal improvement after stem cells injection from adipose derived source. His bladder and bowel control and walking index improved significantly over a six month period. Three out of seven patients with spinal cord injury showed improvement. We will compare this result with a present ongoing trial with bone marrow cells," Dr Bansal further adds.

Apart from these cases, Mumbai based Kasiak Research is using ADSC for idiopathic pulmonary fibrosis. "Kasiak has a novel technique for the isolation of ADSCs and the pilot studies so far have yielded encouraging results. The turn around in patients with terminal conditions such as IPF would be the highlight, but would also like to share the potential of this therapy in diabetic foot ulcers," informs Dr Sharma.

Apart from this, there are a number of trials investigating applications in ischemic heart disease around the world. Six-month results from a 14-patient heart attack trial in the Netherlands and Spain showed not only a reduction in the size of the heart injury, but also improvements in the amount of blood supplied to the heart muscle and the amount of blood the heart can pump. Data from a second trial, a 27-patient chronic heart disease study in Spain, showed a reduction in the amount of damage in the left ventricle. It also showed that patients receiving stem cells had better oxygen consumption and improved ability to perform physical activity.

Unique Proposition

Recently Apollo Hospital, Hyderabad announced that they would be using a unique equipment to bring stem cell therapy from bench-to-bed-side. The Celution system, patented by the US based Cytori Therapeutics, is the only medical device approved in Europe that offers hospitals and clinics the ability to extract stem and regenerative cells from fat (adipose) tissue in a sterile, cost-effective manner without time consuming manual processing. Dr Sudhakar Prasad, Senior Consultant, Plastic & Cosmetic Surgeon, Apollo Hospitals in a press release said, "Apollo physicians have already performed several Celution system based cell-enriched fat grafting cosmetic procedures such as breast augmentation and facial rejuvenation in Hyderabad and Delhi as part of the initial evaluation of the technology." He further added that this will bring in major advantages to patients particularly in areas of breast augmentation, face lifts and wound healing.



According to Cytori, Celution System is a point-of-care device that standardises and automates the extraction of naturally occurring stem and regenerative cells from the patient's fat tissue, the richest source of stem and regenerative cells in the body. Cytori's celution system is CE marked in the European Union for use in breast reconstruction, augmentation and other cosmetic and reconstructive procedures, said Apollo Hospitals. "A key advantage to ADSCs and Celution cell therapy technology is cell numbers, point-of-care and real-time access," says David Oxley, Vice President, Emerging Market Sales, Cytori Therapeutics, US.

In addition to the above therapy, hospitals around the world are using Celution under physician initiated clinical trials to address such diseases as urinary incontinence, Parry-Romberg Syndrome, liver and kidney ischemia and HIV facial wasting.

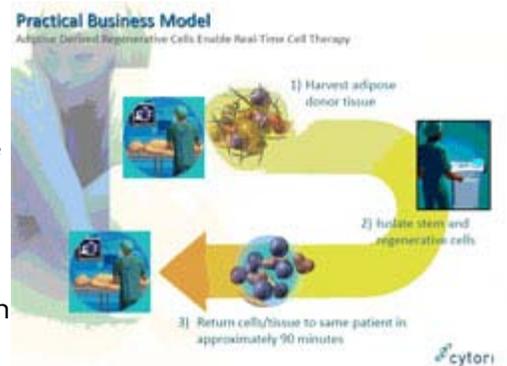
Talking about the equipment Oxley further explains, "Celution system enables the surgeon in the operating room to harvest, process and deliver his or her patient's own stem and regenerative cells to treat a wide variety of ischemic diseases. Apart

from being the largest known source of stem and regenerative cells in the human body, fat is also a much easier source of tissue to harvest from patients in the operating room than bone marrow. That's why Cytori has designed its technological innovation around fat and the needs of an operating room – easy source of tissue to extract, largest known sources of stem and regenerative cells to draw from and efficient for surgeons who demand real-time use across a wide variety of ischemic diseases."

"If the surgeon wants clinical grade regenerative cells to treat his or her patient without disruption of patient flow, operating room delay, or risk of tissue rejection, then Celution is the platform of choice," he further adds.

Apolitical Cells

Researchers are of the opinion that ADSC are easy to use as there are no ethical issues involved as compared to embryonic stem cells. As ADSC come from the patients themselves and not from embryos that are destroyed in the process of extracting their stem cells, their use bypasses the ethical dilemmas that divides many researchers. "Against embryonic stem cells, its needless to say that adipose tissue derived cells have no ethical issue of destruction of a potential life for harvesting stem cells," explains Dr Abraham



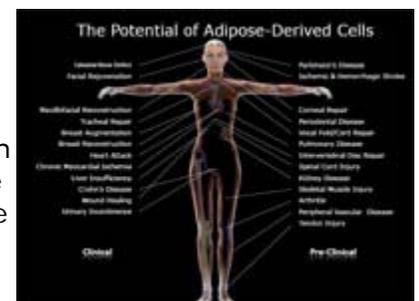
Cost Consideration

The procedure is expensive yet, not very expensive compared to the existing procedures. New technology does incur cost. "The cost of any stem cell therapy is almost the same as any conventional surgical procedure. It would perhaps cost as much as Rs 50,000-75,000 for one course of stem cell therapy and the number of courses and duration would obviously depend on patient improvement. The cost of therapy will depend on procedures involved in procuring the stem cells, harvesting, culturing and characterisation including quality control of all procedures. With increase in numbers and scale of operations the cost will come down over time," explains Dr Nadig.

Adding to this Dr Sharma says, "The cost would be determined once the trials have been successfully completed, but a good estimate would be Rs 1. 5 lakh."

Impact

As can be seen, this therapy would positively impact the outcome of many diseases. Maybe in the years to come people will queue up for fat donation drives much like they queue up for blood donation now-a-days. The basis of this therapy is an autologous cell, which may be a stepping stone now yet in future it would encompass a broad array of technologies. Some researchers have



compared this to the computer age before software and applications. People knew the computer was a powerful tool but did not have methods to harness its potential. However, today pretty much everything runs on computer software and its progenies.

Similarly, ADSC have the potential to impact our lives, if new tools and technologies for therapy are developed using this platform. Summing up the impact Dr Dhir says, "If it lives up to its initial expectation it will give rise to another dimension in medicine. Its application will be far more impactful in heart, knee and spinal indications."

Caution Amid Optimism

While many researchers are hopeful of ADSC therapy, some experts urge caution, saying it's too early to know whether these cells will be as good as other types of stem cells. Primary concerns are related to the scientific pitfalls of stem cells giving rise to cancer, which is being studied by researchers. Another theoretical concern is that ADSC may cause fat to develop in grafted tissue. Studies to dismiss or support these theories have to be elucidated. Dr Bansal says, "ADSC therapy should be carried as clinical trial in few patients (maximum 20) in which sound preclinical data exists. Once the results are encouraging it should be published and a placebo-controlled, multicentric clinical trial on more number of patients should be done before taking it up as therapy."

In summary, ADSC are promising and very lucrative therapy option for some patient population. Only time can tell if ADSC will live-up to its initial promise. However, at present it is helping heal patients with no other viable treatment options.

Further reading

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Celution : Cell Therapy at the Point-of-Care



Celution System

A surgeon harvests a small amount of adipose tissue from the patient, or fat as it is more commonly known. The surgeon then places the fat into the Celution system. The system then processes the fat and in 90 minutes provides the surgeon with a five cc heterogeneous population of the patient's own regenerative cells to be used to treat an ischemic disease. This five cc syringe of autologous regenerative cells can be mixed back with the patient's fat cells to create a cell-enriched fat graft, or used independently depending on the presenting case. Celution system is a combination of capital equipment and a per-patient consumable set. The system was designed for the operating room or cardiac cath lab and designed to vertically integrate into the operating room workflow. The system is the culmination of a decade of research and development that is now being used through Europe, Japan, the US and India.

Celution has been reviewed and approved for use in Europe by CE Mark. The Celution 800/CRS System is indicated for:

- Plastic & Reconstructive Procedures to replace, repair, reconstruct, or augment
- Surgical soft tissue defects (defect up to 150 mL in size and augment up to 260 mL of volume), Such as those seen in the breast due to mastectomies and lumpectomies
- Liposuction defects, such as those seen in the abdomen, back, thighs and buttocks
- Congenital asymmetry of soft tissues, such as those seen in the breast, buttocks and face
- Soft tissue wasting disorders, such as those affecting the hands and face

The Celution 800/GP System is indicated for:

- General surgery procedures to facilitate healing in: rectal and vaginal fistulae in Crohn's disease

Adipose (fat) tissue-derived regenerative cells (ADRCs) obtained using the Celution System demonstrated a statistically significant improvement in cardiac functional capacity (MVO₂) at 18 months in PRECISE trial for chronic myocardial ischemia. New data from this trial were presented at the American Heart Association Scientific Sessions 2010 in Chicago by Co-Principal Investigator Emerson C. Perin, MD, PhD, Director, Clinical Research for Cardiovascular Medicine and Medical Director, Stem Cell Centre, Texas Heart Institute.