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A fix for real time delivery in stem cell therapy

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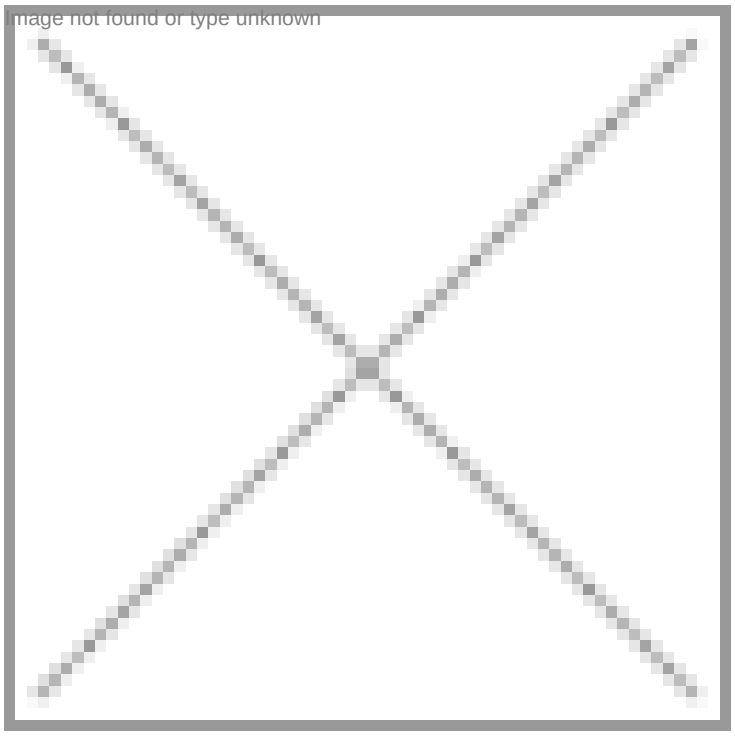
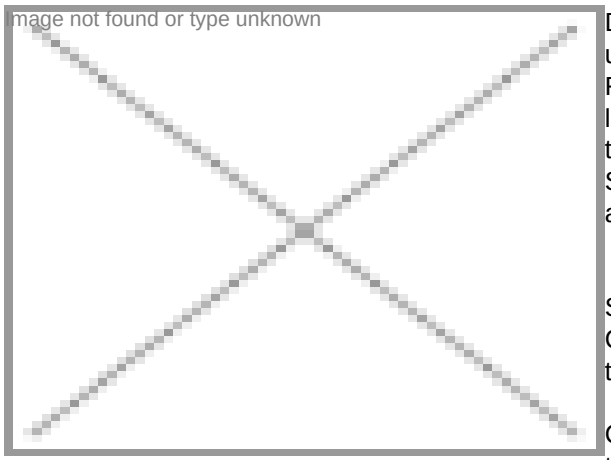


A therapeutic model by US-based Cytori Therapeutics can process human fat and derive adipose-derived adult stem and regenerative cells for repair and restoration of damaged tissues in an hour's time



Dr Anup Dhir, a senior consultant and surgeon in New Delhi, recently undertook a facial rejuvenation procedure on a 58-year-old patient. Rather than putting her through tedious and time-consuming procedures, like plastic surgery, he opted for an unconventional method. He pulled the fat from her abdomen and used a medical device called Celution System to process the fat for cell-enriched graft. The processing took around an hour and Dr Dhir completed the entire treatment procedure on

So far, India has had 10 such cases where doctors have used the Celution System, a product of US-based company Cytori Therapeutics, to process human fat and derive adipose-derived adult stem and of damaged tissues.

Contrary to the popular belief that adult stem cells can only be found in the bone marrow, a team of experts at Cytori proved the potential of ADRCs to repair or restore lost and damaged tissues and organs. Derived from adipose tissues, these cells hold key advantages over stem and regenerative cells from other sources. The team proved that these ADRCs contain a higher frequency of stem cells than any other autologous adult stem cell source and can be harvested with minimal pain and discomfort through a simple, minimally invasive liposuction procedure performed under local anesthesia, which takes 20-30

minutes. Lastly, they can be processed quickly to yield stem cells in a sterile, automated system.

The genesis

Ten years ago, when the standard procedure to derive stem cells was culturing the cells derived from a patient in a tissue culture media, the team at Cytori was looking at a different therapeutic model, which would largely focus on real time delivery of the patient's own ADRCs. The model was to also look at cutting down time, between the period when cells are extracted from a patient, isolated and processed, till the time when these stem cells are administered to the patient for treatment, cost-effective.

"We started off with cell culture of stem cells because that was the norm at that time. But then we realized that cell culture was not the only route. Ideally, there are three weeks between harvesting the cells and treating the patient. For some diseases, it may work but, clearly, not for all. Also, culturing to a great extent changes the properties of the patient's cells," says Dr John Fraser, principal scientist at Cytori Therapeutics.

The core team at Cytori spent nearly $300 million for working on methodologies to derive ADRCs from human fat. They divided their work into two areas. One was to develop systems on how these ADRCs would work on patients and the other was to bring out a medical device.

"We first developed manual systems, which could cover the entire process of harvesting, processing and isolating, in five hours, in a closed system that was clinically more appropriate. We then realized that this process could be faster and came up with a device that allowed the entire process to be completed in 60-90 minutes," recalls Dr Fraser. "Through this device, we could give autologous cells in real time."

Dr Fraser believes that the Cytori ADRC therapy has an upper hand over other forms of cell therapy because it would enable surgeons with real-time, point-of-care access to a patient's own ADRC, offers no risk of rejection phenomena by the body, has no costly laboratory requirements, and there are no operating room time and work flow delays. Cytori ADRC therapy is cells harvested from a patient for the same patient within the same procedure.

In addition, it enables the harvested ADRCs to be mixed with adipose extracted for use as grafts to create a cell-enriched graft for immediate re-implantation into the same patient. These enhanced fat grafts enjoy long-term retention and are, therefore, a far better, natural alternative to artificial implants for breast reconstruction or augmentation.

Opportunity in India

Top officials from the company believe that India has a basket of market opportunities to offer to Cytori Therapeutics (for Celution in particular) with the cosmetic surgery market being the prime focus area. Around 31 per cent of India's medical tourism business today comes from cosmetic surgery and statistics from ISAPS survey reveal that eight percent (683,160 cases) of surgical and 2.4 percent (211,540 cases) of non-surgical procedures were conducted by Indian doctors last year.

Advantages of Celution System

- Improved graft survival and predictable outcome
- Addition of ADRC to fat graft improves graft survival
- Automated standardized cell & tissue processing
- Cell-enhanced graft produced in approx 90 min

"We believe that there is a burgeoning consumer demand for natural soft tissue filler that is both safe and effective. Consumers are seeking alternatives to silicone breast implants and synthetic fillers, such as Botox and hyaluronic acid. Worldwide, this alternative appears to be one of the fastest growing areas of plastic and

In a span of six months, the company has conducted 10 procedures using the Celution System in India across four institutions, including private hospitals like Fortis and Apollo (Hyderabad and New Delhi, respectively), which includes cases of facial rejuvenation and facial reconstruction. "India is a fast growing market and is presently ready for medical devices that require low-cost operations. In such a context, we think that our device is very relevant because India's healthcare system is understaffed in terms of technicians and nurses. Moreover, a lot of time and resources go in training them. This is a device that the doctor can operate himself," says Mr Rohit Nand, principal consultant (India), Cytori Therapeutics.

The company has set up a marketing and sales office in Mumbai with five people. "We are looking at partnering with private and public hospitals to bring regenerative medicine to India. We expect to increase our investment as more hospitals adopt this new technological platform for their patients. We have the capability of rolling out 20 centers and, in 2011, we are looking at 10 such centers," says Dr Fraser.

Pricing strategy

In India, Cytori Therapeutics is looking at two distinct segments of the population. While one segment constitutes of top-level

patients willing to pay any price for high-end therapies, there is also the rising middle class that cannot be ignored. Hence, the task in a country like India is to find an appropriate pricing strategy. “Nobody can come here and replicate the same model that they have applied in markets like the US. We offer the same treatment at a lower price of ₹1.95 lakh and we will get to a point where we will be competitive. You can’t just sell the device, you need to sell the service too,” adds Mr Nand.

The company has formulated a price band for emerging markets, like India. “The price of this product in the emerging markets is $225,000. But this price is a package of products and services that we offer and comes with professional staff and surgeons, technicians, engineers, training and follow-up training. A surgeon can’t just walk into our center to buy this product. We have to invest a lot of resources and time in training them,” says David Oxley, vice president of emerging market sales and marketing, Cytori Therapeutics.

The future Cytori products have been used at more than 150 institutions in more than 30 countries and have treated more than 3,000 patients. In India, Cytori will introduce a host of cell therapies across the country based on current CE Mark-approved cell therapies in Europe. These would include cell therapy in the area of burn repair, scar remodeling, and wound healing to Crohn’s disease, cosmetic and reconstructive surgery indications, including breast reconstruction, breast augmentation, facial reconstruction/defect repair, buttock augmentation. During the medium term, Cytori will also expand the use of the Celution cell therapy platform by addressing acute and chronic heart disease.

— **Nayantara Som** in Mumbai