ETPrime BETA

ALTERNATIVE THERAPY

Hip hip hurray: homegrown cell therapy Ossgrow is quietly changing the lives of hip-replacement patients

Patients suffering from decomposition of the hip joint have had little recourse save hip implants when the disease reaches an advanced stage. Then there's the risk of painful revision surgeries. A Mumbai-based company's innovation holds out new hope.

Anuj Gupta, Vikas Dandekar 18 Oct 2018

YASH SANGHVI, SATYEN SANGHVI, AND PRATHAP C REDDY OF APOLLO HOSPITAL; REGROW VIA FACEBOOK

Culangattil Mery George was losing hope.

The 61-year-old nurse from Mumbai was diagnosed with avascular necrosis (AVN) of the hip, a progressive disease where blood supply to the hip joint is obstructed, slowly killing the bone. It has four stages, and symptoms such as pain and defective gait are visible from the onset.

Historically, patients with George's condition have had no choice but to sign up for a conventional hip implant. But one episode has shaken up the status quo: shocking stories of medical-device giant J&J's faulty hip implants playing havoc with patients' bodies, and their long, painful wait for justice and compensation. With about 52% market share, J&J leads the total hip replacement (THR) implant market.

Vijay Vojhala, in his forties, was one of the patients who suffered in the J&J mess. He had to undergo revision surgery within 10 years, less than the promised lifespan of a hip implant. Today, Vojhala's movement is restricted, and he has had to give up his sales job.

George decided to take a leap of faith and bet on a different, little-known therapy: autologous adult live-cultured osteoblasts, or Ossgrow, developed by Mumbai-based Regrow Biosciences.

The decision changed her life.
"I have been a hardworking professional all my life," George says. "I would not have recovered and got back to work if it wasn't for Ossgrow."

Regrow: changing treatment modalities through cell therapy
A 30-year veteran of the Indian pharmaceutical industry, Yash Sanghvi spends most of his time at his office in Andheri, a busy Mumbai suburb. For almost three decades, Sanghvi's Satyen Pharmaceuticals has been a major supplier of industrial chemicals, pharmaceuticals, and resins to both global and domestic pharma companies.

However, the Andheri office is reserved for a very different project: developing next-generation therapies.

With a paid-up capital of about INR2.3 crore, the company is a self-funded venture run by Saghvi and his son, Satyen Sanghvi, an MSc in stem-cell technology from the University of Nottingham.

“We started our journey with the aim to fix and repair. We first focused on cartilage and bone for knee and hip. You can’t do any medical intervention here. That is where we come into the picture. That is what we called regenerative medicine,” says the senior Sanghvi. His motivation was his son, who wanted to look beyond his father’s legacy business. “I never wanted to join my father’s business. There were meetings and a lot of trade, but no innovation,” the junior Sanghvi comments on origins of Regrow.

The duo believe cell therapy can offer a personalised solution to many diseases previously considered unforgiving, such as diabetic foot ulcer, cartilage defects of the knee, and AVN.

So much so that they took it upon to themselves to convince all stakeholders, including patients, providers, and regulators. For two years they worked on the cartilage product and then another year and half for the bone product (Ossgrow).

“Our biggest challenge was establishing a market for our product. There was an unmet need. However, we needed to convince all stakeholders about these new products we had. There were no guidelines. We had to write to the CDSCO [The Central Drugs Standard Control Organisation]. At that point, they didn’t understand where it would fit. We made technical presentations. They asked us to record the data till guidelines are published,” recalls Satyen. “Our traction started building once success stories came out. It took a year and half to get through the ethics committee of hospitals interested in taking this up.”

According to a study by the Indian Society of Hip and Knee Surgeons, which evaluated 10,467 patients, AVN is the leading cause of hip-joint failure.

To appreciate the impact Regrow can make, it’s important to understand the evolution of AVN treatment.

There are multiple idiopathic factors and irritants that can lead to obstruction of blood flow, including steroid intake, excessive alcohol consumption, smoking, sickle cell anaemia, lupus, gout, and vasculitis. Lack of blood supply kills osteoblasts and osteoclasts — the cells responsible for regenerating and remodelling the bone in the event of routine wear and tear.

The result: The bone dies a painful death, and the hip joint collapses.

It takes three to five years for the joint to collapse completely and qualify for a total hip replacement. Over 70% of the patients are advised uncemented hip implants. About 80% need a bilateral replacement, while the average life of a surgically implanted hip is only about 15 years. A revision surgery is then needed, and in about 62% of the patients, revision is required due to a loosened implant.

This means over their lifetime, an AVN patient may have to go under the knife two to three times. It is a lot of pain and suffering. The economic burden is not only on the patient but on the health system as well.

Some 15 years ago, doctors had limited options. They had to wait for the joint to become defunct and then cut it open to replace it. However, the science has evolved. If detected early, a regressive joint can be treated, and the progression of the disease can be halted. For many THR patients, this opens up the chance to heal without putting their bodies through the trauma of repeat surgeries.

This is the disruption Regrow is eyeing.

Backed by clinical data on its cell-based therapies, the company has convinced the Indian drug regulators, and, in 2017, won the Maharashtra Food and Drug Administrator's nod for two key products: Ossgrow, and autologous adult live cultured chondrocytes, or Cartigrow.

"While the symptoms of AVN are prominent during the early stages and therefore easily diagnosed, neither patients nor treating doctors have much choice other than palliative care," says Charul Bhanji, technical director at Regrow Biosciences. "Unfortunately, the disease is allowed to progress, [so that] the joint is bad enough to be replaced. With Ossgrow, we can change that."

How Ossgrow works

Ossgrow is nothing but the patient's own osteoblast (cells responsible for bone creation) taken from a healthy site in their body, cleaned, and reinserted at the affected site. The autologous implant reproduces the same cells at the targeted site without any significant modification.

Of course, all this is easier said than done. First, the inclusion criteria for Ossgrow are quite stringent. Not every AVN patient is eligible for implant. Only stage 1 and 2 AVN patients are recommended after careful examination of the idiopathic factors and counselling.

The procedure itself is complicated. However, the trickier part is the logistics. Donor sample from the patient needs to be extracted via biopsy at the hospital, transferred to the lab under temperature and infection control, cultured in a controlled environment, and then transferred back to hospital with the same care. Regrow has chosen leading logistics provider FedEx to ensure reliable execution.

"It works well for patients with early-stage AVN. We clean up the affected area, restore blood supply, implant the patient's own osteoblast, and allow the bone to heal itself. It can control disease progression and in some cases cure it, provided the patient doesn't abuse alcohol or take steroids or any other irritant," says Bhanji.

Ossgrow has been administered on 287 patients so far. Clinical data from retrospective study of 172 patients, prospective study of 14 patients, and post-launch study of 101 patients shows promising results. Clinical outcomes of safety and efficacy study were measured through improvement in pain and functional scores, such as Harris Hip Score (HHS), Oxford Hip Score (OHS), Visual Analogue Scale (VAS) and X-ray, MRI, and CT scan.

Advantage Ossgrow

Property	Metal implant	Autologous cells
Type of Implant	Metal – ceramic, cobalt-chromium, titanium; unnatural, foreign part in the body	Patient's own cells – personalised and natural
Safety and efficacy	Metal leaching and rusting; can lead to infection and implant loosening; leads to recurring joint pain	No reported toxicity issues since autologous (FDA-approved phase III clinical trials)
Cost efficiency	Requires revision surgery after primary replacement; repeated costs for surgery, doctor visits, hospital charges, and pain-management medication	One-time procedure; less effort; fewer hospital visits; limited doctor consultation
Time efficiency	Repeated surgeries required; more time spent in hospital and pain management	One-day procedure; OT time reduced; no revision required
Durability	Lifetime of metal implant limited; up to 10-15 years for revision and re-revision surgeries	One-time surgery offers lifetime cure; back to normal daily-life activities

Source: *ET Prime research*

Economic benefits of Ossgrow

With Ossgrow, patients can gain at least 10-15 pain-free quality-adjusted life years. International research studies have reported a long-term shelf life of osteoblasts for osteonecrosis of up to 20 years.

The procedure is cost-effective too: Patients eligible for Ossgrow are likely to lead a healthy life at less than a fifth of the cost of THR.

Cost comparison of Ossgrow and total hip replacement

Cost head	Ossgrow	Cemented implant
Implant	87,000	2,10,000
Medicine	3,500-4,000	3,500-4,000
Doctor consultation	3,000-4,000	>10,000-15,000
Diagnostics	2,000-4,000	>10,000-15,000
Revision surgery	Not required	2,50,000-3,00,000

All figures in INR

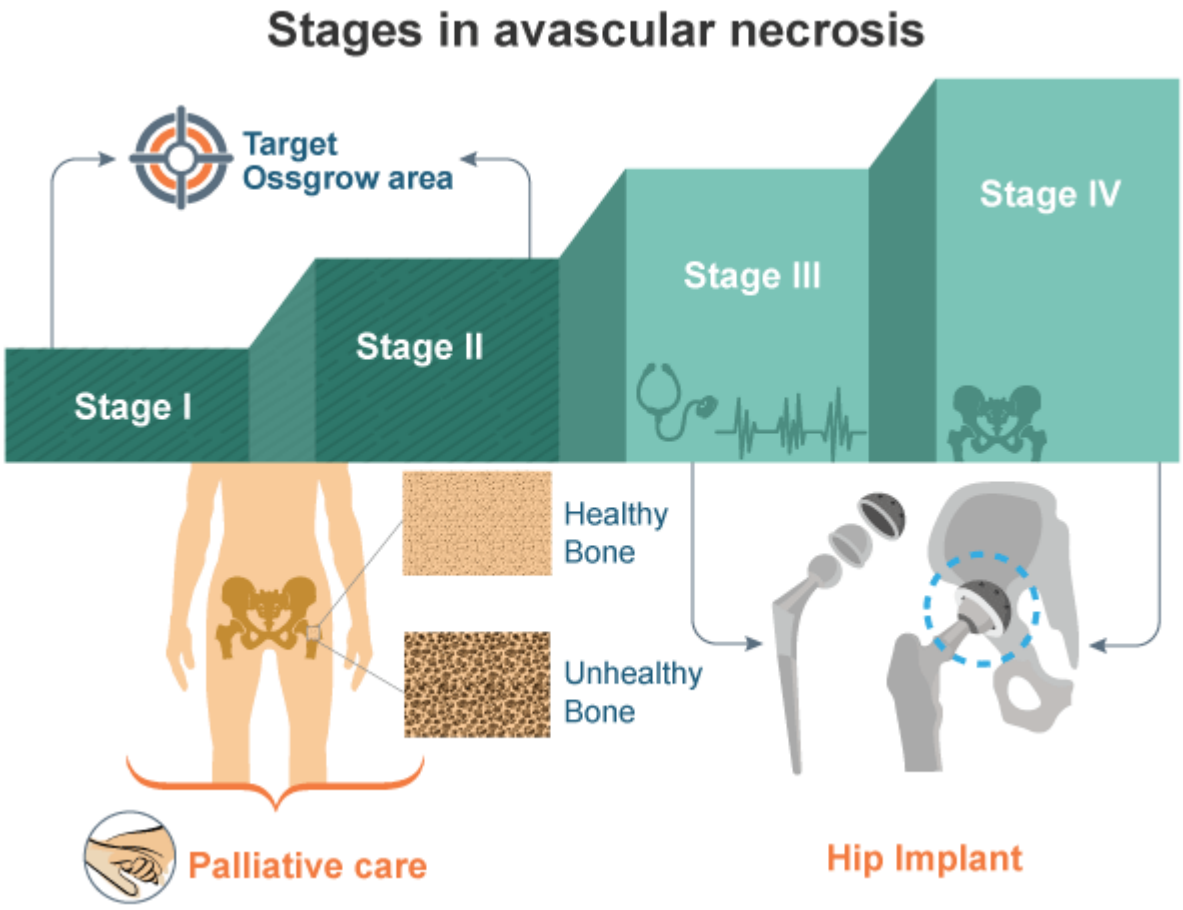
Source: *Regrow Biosciences; Apollo Hospital*

Market potential of Ossgrow

In India, in 2017, nearly 87,000 patients were recommended THR. Of these, about 43,000 patients were recommended THR due to AVN. Of these, about 30%-40% were in the early stages — the addressable market for Ossgrow.

Hence, annually, 13,000-17,000 patients may qualify for Ossgrow.

According to Apollo Hospitals, the cost of Ossgrow and related procedures is approximately INR87,000, excluding biopsy. So, the annual revenues from Ossgrow in India alone can be INR130.5 crore (assuming all patients eligible are given the treatment).



“It can be a billion-dollar drug, globally,” says the junior Sanghvi. “The potential is huge. Right now, we don’t have competition. We have already been given drug status in India, which gives us a lead time of at least three years. We are getting ready to file for approvals in the US and the EU by early next year.”

(*Graphics by Abdul Shafiq*)