

Biological umbrella can fix hole in heart

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A new technique that uses the body's natural building materials to seal a hole in the heart has been developed and approved for use in Britain, avoiding the need for open-heart surgery or metal implants.

Doctors will be able to deploy an umbrella-like device made of proteins to mend the common defect, which is thought to increase greatly the chance of having a stroke. The implant is eventually absorbed by the body and replaced by the patient's own tissue.

Up to one in four people are thought to be born with a hole between the right and left atrium of the heart, a condition that is also known as patent foramen ovale (PFO). The hole can allow unfiltered blood and fat particles to pass into the arteries and cause blockages.

Most people with PFO do not suffer any symptoms, but over time the hole can affect blood supply to the brain, causing debilitating migraines and possibly strokes. Of the 150,000 Britons who have a stroke each year, up to 40 per cent will have PFO.

Surgeons close up to 1,000 PFOs a year but they believe that by making the operation quicker and less invasive they can help more people.

Trials of the new bioabsorbable implant, known as BioSTAR, found that it effectively sealed holes in more than 50 patients, with no adverse effects reported. Most of the holes were closed within 30 days.

During the procedure, the implant is fed through a catheter in the leg and up to the heart to cover the hole. It is supported by a scaffold of highly purified and very strong collagen, which unfolds either side of the septum like a pair of small umbrellas.

Collagen, which can be derived from pigs, is the main protein used in connective tissue in mammals. It binds quickly to the heart and is easily can be absorbed over time.

Previous devices to treat PFO have been made of metal and polyester, which remain in the heart indefinitely and potentially cause severe health complications. Doctors are using more and more biological materials in surgical procedures. Michael Mullen, a heart consultant at the Royal Brompton Hospital in London, said that patients undergoing the procedure would suffer less pain, have a shorter stay in hospital and recover more quickly than if they had traditional surgery.

"The BioSTAR device allows us to close PFO quickly, effectively and safely," he said. "Crucially, the responses that it triggers mean that patients heal naturally and that minimal foreign material is left behind in the heart.

"Collagen is 25 per cent of our total body protein. It is contained in skin, bones and teeth.

Therefore, using collagen to repair and support parts of the human body makes perfect sense.”

Janet Savage, 61, one of the test patients, said that the operation had rid her of migraines. “I was initially shocked to find out that I had a hole in my heart. It sounds so dramatic but I was only tested for it when I had a mini-stroke and blacked out while driving. I had previously assumed that my migraines were unrelated and just something I had to put up with from time to time, but since having the operation I’ve never felt better.”

David Hildick-Smith, consultant cardiologist at the Royal Sussex County Hospital in Brighton, who also participated in the research, said: “PFO appears to allow blood clots and other debris to clog up arteries in patients, which not only causes strokes but other problems. Using the bioabsorbable device is a radical rethink of a treatment option for migraine but it seems to have shown some very positive results. For a proportion of sufferers, this could end up as a cure for them.”

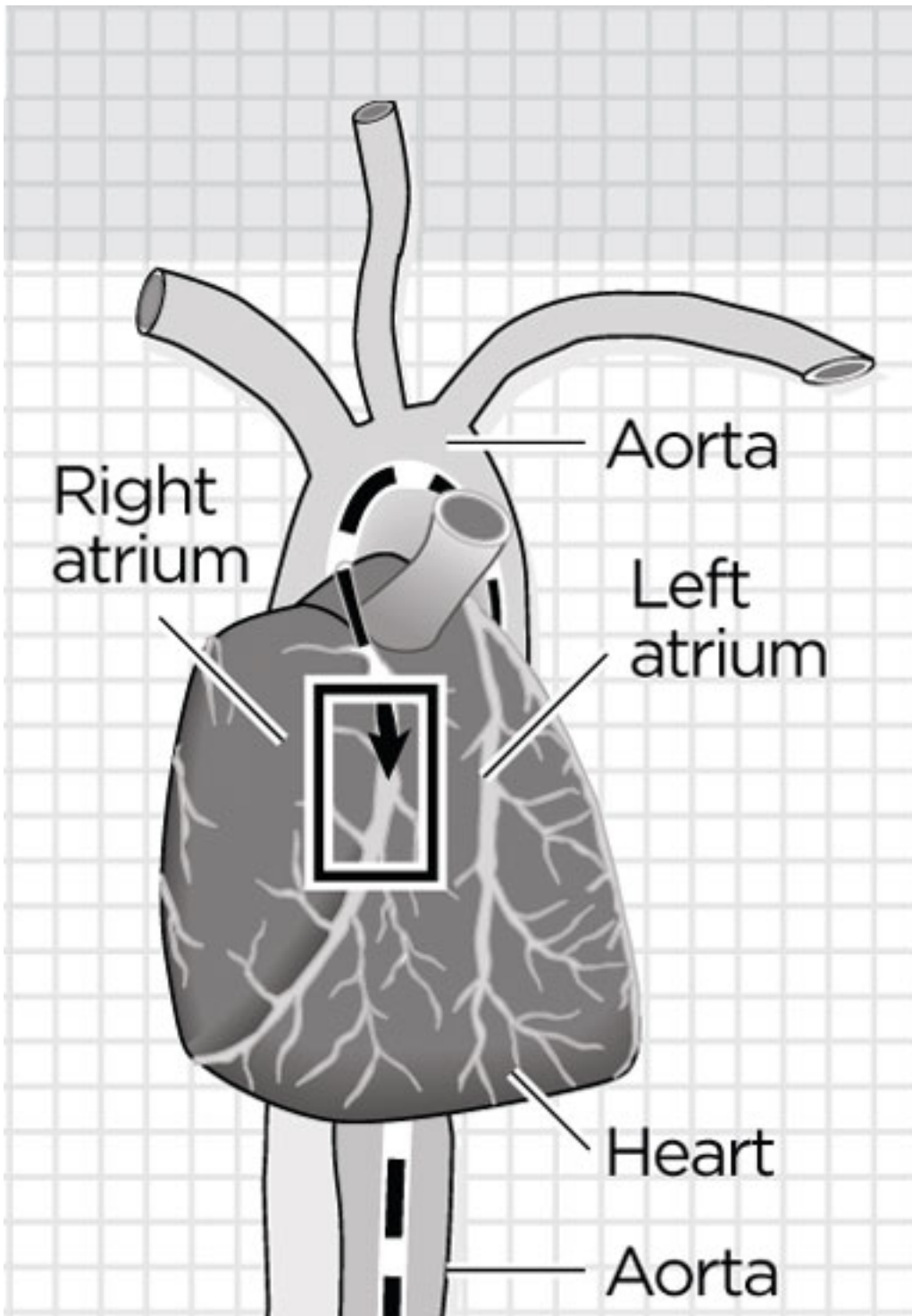
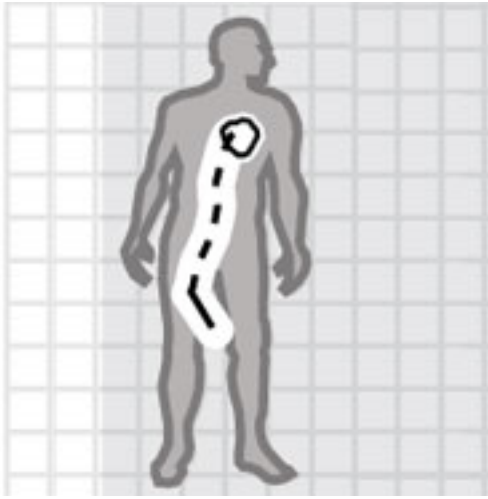
The foramen ovale is a small hole located in septum between the upper chambers of the heart. It occurs naturally in a foetus as it develops in the womb, to speed up the travel of blood through the heart. As a developing baby does not use its own lungs to supply oxygen-rich blood, deriving it instead from its mother through the umbilical cord. The foramen ovale allows blood to flow from the right side of the baby’s heart to the left side, without having to go via the lungs.

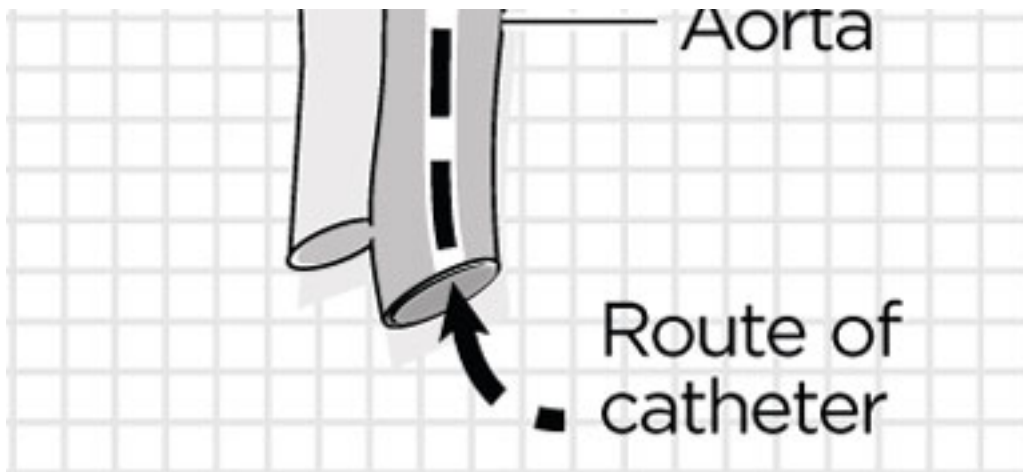
Normally, the foramen ovale closes at birth when increased blood pressure on the left of the heart forces the opening to close. But in some people, with PFO, the septum does not close properly. The defect generally manifests itself as a flap valve, only opening during certain conditions when there is more pressure inside the chest.

— A “living laboratory” in the shape of a mouse with human liver cells could soon be helping drug companies to develop new products. The mouse is able to live normally with 90 per cent of its liver repopulated by human cells. The cells function as if they were inside a human patient, producing all the same blood-clotting factors and proteins. They can be used to study the way compounds are biologically processed in the body and tolerated - essential for any form of drug development. Scientists hope that the mouse, produced at Oregon Health and Science University, will soon become the “gold standard” for both investigating drug metabolism and new ways of tackling liver infections such as hepatitis and malaria.

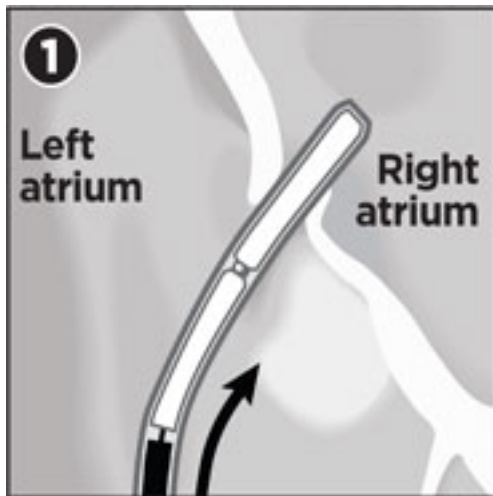
How it works

Device is inserted by catheter through artery in the groin

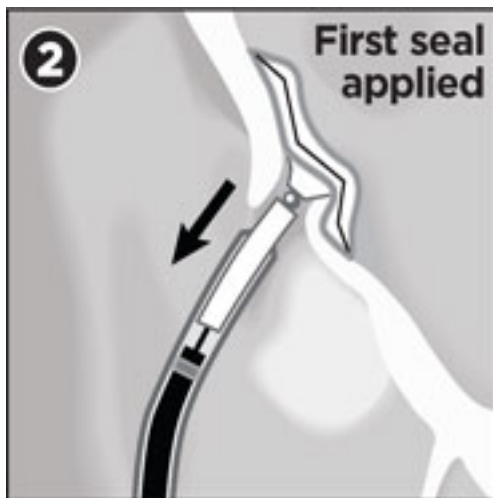




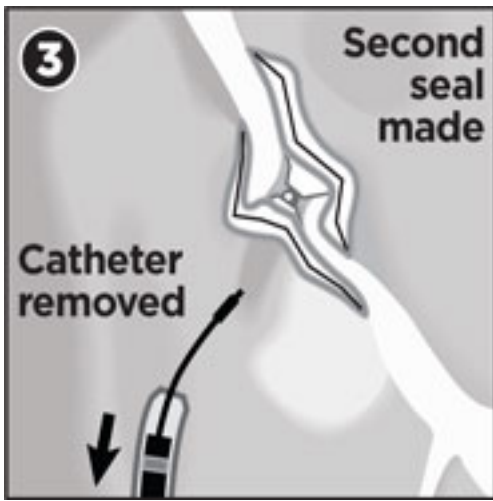
A collagen device is advanced to midway through the hole



Umbrella-like structure is then released, making first seal of hole



A second umbrella seals hole. Catheter is removed



- One in four people has a hole in the heart, which usually closes over at birth
- 90-95 per cent of an implant to seal the hole can be absorbed and replaced by a patient's own tissue
- This closes the hole permanently, reducing the risk of stroke