

Better quality of life for stoma patients

A new concept of continent ileostomy that will dramatically change the patient's quality of life.

OstomyCure AS, a Norwegian company, has developed this groundbreaking concept.

Mats Cardell is the project manager for the company's activities in Kista and he says that the idea originated about ten years ago in a hospital in Norway:

“The basic idea came from a Norwegian nurse. The idea spread and OstomyCure was established as a spin-off to the hospital, and then developed the idea further” explains Mats Cardell who has been working with the implant for almost five years.

Mats Cardell sits in his office as he describes the background to the idea. On one wall of the office are a number of surgery images that reveal in detail what it looks like when patients are newly operated and the implant is in place in the abdomen. A small tube of titanium, a few centimeters in diameter and



with a mesh structure, sticks out half a centimeter through the patient's abdominal

wall. Mats Cardell points to the images and explains that the mesh structure makes it easier for the skin to grow into the implant.

Every year, in Europe, ten thousand patients receive a permanent ileostomy (25 000 worldwide). The reasons can vary, but two common ones are Crohn's disease and ulcerative colitis, both of which are inflammatory bowel diseases. Another reason is cancer. For many stoma patients, everyday life involves many inconveniences, and even if the stoma has saved their life, the mental stress that patients must deal with cannot be overlooked.

The stoma bag can leak, make embarrassing noises, smell bad and cause skin irritations and infections. Life for many stoma patients means difficult situations at times where their stoma controls their lives.

“For many patients, having to walk around all day with a bag on their stomach filled with feces that must be changed regularly is experienced as very unpleasant. Then there is also a group of people who have problems with leakage or ruptures around the stoma” says Ulf Gunnarsson, professor at Umeå University and chief physician at Norrland University Hospital.

The new solution (implant and lid) will make life easier, more comfortable and increase the quality of life for many of these patients. It will also dramatically reduce skin problems as the device only need to be cleaned with tap water and no disinfectants or adhesives will be used.

“The idea is that these patients should be able to use the toilet almost like people without a stoma” explains Ulf Gunnarsson.

The implant consists of a small tube of titanium implanted into the abdomen where the intestine and soft tissue grow into it. The implant then becomes an extension of the intestine, and sticks out a few millimeters on the outside of the abdomen where it is sealed with a lid that the patient can open to drain whenever necessary. The lid quite simply

functions as a stopper. In the usual stoma patient, the intestine is instead extended a few centimeters through the abdominal wall and ends in a bag that adheres to the stomach. The bag must be emptied at regular intervals and the adhesive can cause skin irritations.

Surgical implant

“You can really see in the pictures how the skin has grown onto the implant; it is incredibly well integrated with the tissue” Mats Cardell explains.



He tells us more about the background and how, soon after its establishment, OstomyCure started looking for collaborations. Among others the company collaborated with the University of Gothenburg. This is where former professor Per-Ingvar Brånemark worked, known for his ground-breaking work with securing implants in the body, mainly in the dental field and implantable hearing devices. At the University of Gothenburg, there is also broad knowledge of how titanium is compatible with the human body.

After a few years of work and collaboration, a first model was ready and after a number of successful animal experiments, the first clinical trials were conducted in 2009-2011. Seven patients received the implant, three of which still have their implants today. Professor Ulf Gunnarsson was one of the surgeons involved.

“I participated in four of the seven implant operations and I was also part of the group of experts who reviewed the outcomes. We came to the conclusion that there were a number of things that needed development” But in spite of the fact that it was not entirely perfect, the patients who still have their implants love them and absolutely do not want to remove them.

Mats Cardell agrees with this:

“No, we were not entirely satisfied with the product, but many patients loved it!”

Several challenges

Both Ulf and Mats talk about challenges and changes that are being made prior to producing the latest TIES III model. The challenge is to get the implant to integrate properly and remain sealed:

“In itself titanium as a material causes no problems in the body. A problem arises if the implant does not integrate correctly with the skin and the underlying tissue. This can cause inflammation” explains Ulf Gunnarsson and Mats Cardell adds:

“There are other implants that also stick out of the body, for example, dental implants, but the difference is that these integrate into bone. This implant needs to integrate into soft tissues, which makes it a bit more complicated. There is not as much experience surrounding implants intended to integrate into soft tissue.”

Getting the implant to integrate with the soft tissue is one of the challenges that OstomyCure has worked on a lot in recent years. The new TIES III model has even better integration with the body than the previous model. OstomyCure has used 3D technology to manufacture the new model. The porous structure all over the implant promotes the integration of the device. Mats Cardell says that this will also make production easier:

“With the 3D-manufacture, the basic material is a powder that melts when we shoot laser beams at it. In this way, the product is built up layer by layer, which means that the



manufacturing process is much smoother, and the surface of the product is better suited. It no longer consists of parts welded together like the first implants were made; instead, it is just one solid piece,” he says, and continues:

“The surface is very important for how well the implant grows into the body. This manufacturing method will have a big impact on the end result.”

In the development of the latest TIES III model, OstomyCure has worked a great deal with the research institute Swerea:

“For example, they have helped to measure the number of pores in the material to investigate how solid it is, as well as analyzed its composition. The material must be clean and free from impurities” explains Mats Cardell.

Coming closer to the market

The new implant is in clinical trials for CE-marking and building further experience.

“With this implant on the market, everyday life will be much easier for a large group of people with problems and discomfort” says Ulf Gunnarsson.

The clinical study for ileostomy patients is ongoing at the University Clinic AHUS in Lillestroem, Norway. Primary Investigator is Prof Tom Oeresland.

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