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***Stellenbosch University doctors perform first successful penile transplant in the world***

In a ground-breaking operation, a team of pioneering surgeons from Stellenbosch University (SU) and Tygerberg Hospital performed the first successful penile transplant in the world.

The marathon nine-hour operation, led by Prof André van der Merwe, head of SU’s Division of Urology, was performed on 11 December 2014 at Tygerberg Hospital in Bellville, Cape Town. This is the second time that this type of procedure was attempted, but the first time in history that a successful long-term result was achieved.

“South Africa remains at the forefront of medical progress,” says Prof Jimmy Volmink, Dean of SU’s Faculty of Medicine and Health Sciences (FMHS). “This procedure is another excellent example of how medical research, technical know-how and patient-centred care can be combined in the quest to relieve human suffering. It shows what can be achieved through effective partnerships between academic institutions and government health services.”

Van der Merwe was assisted by Prof Frank Graewe, head of the Division of Plastic Reconstructive Surgery at SU FMHS, Prof Rafique Moosa, head of the FMHS Department of Medicine, transplant coordinators, anaesthetists, theatre nurses, a psychologist, an ethicist and other support staff.

The patient, whose identity is being protected for ethical reasons, has made a full recovery and has regained all function in the newly transplanted organ.

“Our goal was that he would be fully functional at two years and we are very surprised by his rapid recovery,” says Van der Merwe. The end result of the transplant was the restoration of all the patient’s urinary and reproductive functions.

“It’s a massive breakthrough. We’ve proved that it can be done – we can give someone an organ that is just as good as the one that he had,” says Graewe. “It was a privilege to be part of this first successful penis transplant in the world.”

“Western Cape Government Health (WCGH) is very proud to be part of this ground-breaking scientific achievement,” says Dr Beth Engelbrecht, head of the WCGH. “We are proud of the medical team, who also form part of our own staff compliment at Tygerberg Hospital. It is good to know that a young man’s life has been significantly changed with this very complex surgical feat. From experience we know that penile dysfunction and disfigurement has a major adverse psychological effect on people.”

The procedure was part of a pilot study to develop a penile transplant procedure that could be performed in a typical South African hospital theatre setting.

“There is a greater need in South Africa for this type of procedure than elsewhere in the world, as many young men lose their penises every year due to complications from traditional circumcision,” explains Van der Merwe.

Three years ago the 21-year-old recipient’s penis had to be amputated in order to save his life when he developed severe complications after a traditional circumcision. Although there are no formal records on the number of penile amputations per year due to traditional circumcision, one study reported up to 55 cases in the Eastern Cape alone, and experts estimate as many as 250 amputations per year across the country.

“This is a very serious situation. For a young man of 18 or 19 years the loss of his penis can be deeply traumatic. He doesn’t necessarily have the psychological capability to process this. There are even reports of suicide among these young men,” says Van der Merwe.

“The heroes in all of this for me are the donor, and his family. They saved the lives of many people because they donated the heart, lungs, kidneys, liver, skin, corneas, and then the penis,” says Van der Merwe. Finding a donor organ was one of the major challenges of the study.

The planning and preparation for the study started in 2010. After extensive research Van der Merwe and his surgical team decided to employ some parts of the model and techniques developed for the first facial transplant.

“We used the same type of microscopic surgery to connect small blood vessels and nerves, and the psychological evaluation of patients was also similar. The procedure has to be sustainable and has to work in our environment at Tygerberg,” says Van der Merwe.

This procedure could eventually also be extended to men who have lost their penises from penile cancer or as a last-resort treatment for severe erectile dysfunction due to medication side effects. As part of the study, nine more patients will receive penile transplants.

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Please find additional information below.

**Additional Information**

**Technical details of the transplant**

In preparation of the transplant, the surgeons used cadaver studies to identify key blood vessels, nerves and other structures in the penis that have to be connected to ensure normal function.

When the organ was harvested from the donor, the entire penis was carefully dissected keeping blood vessels, nerves and other connecting structures intact. These were carefully marked and connected to the recipient’s correlating tissue 10 hours later during the transplant.

“We were unable to use one of the recipient’s major blood vessels which was destroyed by the same infection that caused the patient to lose his penis three years ago,” explains Prof Frank Graewe, head of the Division of Plastic and Reconstructive Surgery at Stellenbosch University’s Faculty of Medicine and Health Sciences. “So we rerouted a blood vessel from the patient’s lower abdomen to the perineum where we connected it to the new penis.”

The surgeons connected three blood vessels (each between 1mm and 2mm in diameter) to ensure sufficient blood flow to the transplanted organ, two dorsal nerves (also between 1mm and 2mm in diameter) to restore sensation, the urethra which enables the recipient to urinate through the penis, and the corpus cavernosum, which will allow the patient to obtain an erection.

The delicate surgery used to connect small blood vessels and nerves are performed using microscopes (microsurgery). “At Tygerberg Hospital we do a lot of microsurgery during reconstructions after breast, head and neck cancers,” says Graewe.

The patient has been back in theatre to correct minor complications, to re-establish the blood supply of one of the arterial anastomosis that was blocked, for drainage of a hematoma and to repair a small fistula of the urethra.

**Immunosuppression**

Immunosuppression is a key component of a successful organ/tissue transplant. “As soon as you put a foreign object into a person, the body’s natural instinct is to reject it. Immunosuppression helps to prevent the body from rejecting the transplanted organ,” says Prof Rafique Moosa, head of the Department of Medicine at Stellenbosch University’s Faculty of Medicine and Health Sciences. All transplants, except where the same person’s own tissue, or that of an identical twin is used, requires immunosuppression.

“Because there are no guidelines on this type of transplant, we based our treatment on other composite tissue transplants such as hand and face transplants,” says Moosa. Transplants where several types of cells are involved (muscle, nerve, blood vessels, etc.) require stronger immunosuppression treatment than transplants of organs involving fewer cells, for example, kidneys.

The immunosuppression drugs used for the penile transplant, although not usually used as a first-line treatment, are available in state facilities and are generally used for kidney transplant patients.

Although the drug doses are progressively lowered, transplant patients have to take immunosuppression medication for the rest of their lives – even if the patient made a full recovery.

**Ethical considerations**

The investigators proactively sought to cover all ethical aspects of the study and were granted permission from Stellenbosch University’s Health Research Ethics Committee (HREC) in 2011. They closely consulted with ethicists as well as the HREC throughout the design and conduct of the study.

According to Dr Nicola Barsdorf, head of Health Research Ethics at the FMHS, the research team adequately addressed the important ethical issue of therapeutic misconception (the risk that a research participant may not fully understand that this treatment is only experimental). “The patient was repeatedly counselled over an extended period of time on the potential benefits and risks of the procedure. He had a clear understanding of the experimental nature of the transplant and after multiple, comprehensive discussions about the voluntary nature of his participation, provided his informed consent,” explains Barsdorf.

The research also met the ethical benchmark of social justice as it would benefit all sectors of society. “The research was conducted in partnership with local public health structures and will be delivered to the people who need it most,” says Barsdorf. “Once the surgery is made broadly available it will be offered in state facilities and be accessible to vulnerable groups that are often unable to afford or access state of the art health care.”

**Psychological aspects of transplant**

All patients considered for the study had to undergo extensive psychological evaluation to determine whether they were mentally fit to receive a transplant. Organ transplantation could have a negative psychological effect when patients that can’t associate with the organ.

**Other penile replacement options**

Current surgical options for patients include penis reconstruction with free tissue transfer. For this procedure skin tissue (“flap”) is taken from the arm, reconstructed into a penis, and attached to the body. A prosthesis can be implanted in order to allow sexual intercourse, but is expensive (around R100 000) and may develop complications. However, unlike the transplant, with a reconstruction a patient cannot conceive naturally.

**The first attempted penis transplant in 2006**

In 2006, surgeons from Guangzhou General Hospital in China for the first time transplanted a penis from a donor to a 44-year old man who had lost his penis in an accident. However, two weeks after the operation surgeons had to remove the organ. Although it showed no signs of rejection by the body, reports claim that it was removed for psychological reasons.

**Ends**