A new voice for larynx cancer patients

Thanks to further development in EUREKA project E! 2614 NEWVOICE, larynx cancer sufferers will be given better post-operative options in the future, helping them speak more naturally and improve their quality of life after surgery.

When recovering from a laryngectomy, advanced larynx cancer patients often have difficulty in regaining the natural quality of speech they once had. Devices and techniques have been developed including a one-way shunt valve that creates a new airway connection between the lungs and the vocal cavities. By closing the tracheal opening with a finger, exhaled air passes through the shunt valve to the oesophagus, where soft tissue structures serve as a substitute voice. Unfortunately with this system, voice quality still remains poor and the process creates a mental barrier, forcing patients to literally point to their handicap. Partners involved in EUREKA E! 2614 NEWVOICE developed a new voice-producing shunt prosthesis that produces a voice with sufficient loudness, adjustable fundamental frequency and natural intonation.

"The research was carried out so that the speaking capacity of our patients could be improved," says project leader Professor Bart Verkerke, from the BioMedical Engineering Department at the University Medical Centre Groningen in the Netherlands. "We also investigated how we were going to improve the lifetime and fixation of the devices. Initially most of the NEWVOICE participants had been involved in E! 723 ARTIFICIAL LARYNX, which as its name suggests, focused on developing an artificial larynx with a voice-restoring device. It allowed the team to gain enough expertise in medical devices to improve the rehabilitation process that was to be developed in NEWVOICE.

E! 2614 NEWVOICE started in April 2002, with a budget of 3 million euro. The main partners were based in Germany, the Netherlands, the UK and the Czech Republic, while project advisers came from Spain and Italy. Now a finished project, it claims success in three key areas of research including material coatings, a new voice-producing element and new fixation systems.

The first success was reproducing the voice after surgery, and then producing new materials for the devices and improving fixation system, one of the most important components. The material coating is already being sold around the world," says Verkerke.

Quality speech for all

Finding the same quality of voice as before, was one the first challenges facing researchers. When the project began, the voice-producing element of the project seemed to cause a particular problem for female patients who had trouble emitting the lower pitch of the voice created by the shunt. They tended to speak in a weak and breathy voice. “A sound generator has now been designed based on the principle of two parallel-placed membranes oscillating in the air flow. The resulting sound pressure waves send the air into the vocal tract and the patient can convert these vibrations into speech,” explains Verkerke.

Clinic-ready product prototypes were developed based on theoretical and experimental research. In addition, the research was carried out so that the speaking capacity of our patients could be improved.

Professor Verkerke - University Medical Centre Groningen, the Netherlands

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experimental scale model studies. They were placed into a shunt valve and tested successfully in two clinics.

With patients now able to speak more naturally, how could the shunt valve fixation system be improved? A new fixation method was developed, fixed to the skin or to the tracheo-stoma with an intra-tracheal device.

However, the tissue-implant surface is subject to potential damage because of the motion of soft tissue in the neck and the pressure of inserting the device. It was necessary to create a protein coating onto the implant that was able to improve fixation. The three materials that were used for the implant design including titanium, polypropylene, and silicone rubber. The research team studied cell adhesion to a number of human fibroblasts. The collated data indicated that a proper protein coating could be beneficial for improving fixation strength.

Making the device last longer
A critical problem facing the project team was also that food and fluid passing the shunt valve had a tendency to form a biofilm, causing the shunt valve to malfunction and be replaced every four months. “We tried to make valves from surface coatings and silicone materials that would increase the longevity of the device,” explains Verkerke.

The initial task of the project was to improve the silane coating on the voice box prostheses. Dutch company Medin supplied standard silicone rubber button shunt valves. Even though not all objectives were met the project created a new shunt valve that will last considerably longer than current models available. The results of the clinical work are expected to lead to potential commercial benefits for Medin.

“It will take us a few years for the prototype to become a product that can be used by the medical world but...