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Historic review - ActiGait – a new FES (Functional Electrical Stimulation) improves gait among patients with apoplectic hemiplegia

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Objective: How to introduce a simple FET system for treatment of hemiplegic patients improving their walking and thereby benefit their daily life.

Background: We presented the ActiGait system during the SNS meeting in Tampere, Finland 1992 (Haase et al.). The system was described in 1994 (Sinkjaer et al.) and founded the company "Neurodan" in 1995. In 1999 the first ActiGait system was created at Aalborg University by prof. Thomas Sinkjaer and Mortem Haugland PhD (Haugland). Neurodan was in 2005 bought by the Otto Bock Group and a new series of ActiGait-implantations were initiated in Europe.

For neurosurgeons walking seems to be a trivial and simple motor-function – but is not (Sinkjaer et al., Emborg et al.). Walking implies precise coordination between legs, arms and body. Sensory input from tendons/and skin are important for the posture and balance during walking. Besides the brain directed walking system, a spinal cord automatic system is thus necessary for the walking (Franceschini et al). The ActiGait system serves as an instrument to change the plantar positioned foot (pronated and plantar flexed) found among many hemiplegics into one with a dynamic dorsiflexion. Thereby it changes the walking pattern significantly. We assume this is partly through reflex modulation (Spaich et al). Automatic within-step sensory feedback regulation and not conscious predictive control is the most important factor for achieving a stable walking (Klint R af et al.) Our patient's claims that they feel safer when walking, and they participate in daily life in a much more independent and secure way than before. It is thus not only the speed of walking that increases, but perhaps mostly it is the balance that is improved.

Methods: Demo fra vores kirurgiske manual

Results: The first operated series consisted of 15 ActiGait system implantations treating patients with stable hemiparesis due to vascular brain lesions. This series were carried out in Denmark as a phase 2 trial with. All patients benefitted and there were no nerve injuries based on clinical examination and electrophysiological validation. (Burridge et al.). It must be noted that among our first operated patients, 8 survivors still uses the system today with success. In the summer 2007 further six patients were operated upon in Germany and Denmark. Due to internal wire problems the operations were stopped. After the first cases operated upon in Europe since august 2008, we realized - to our surprise - two severe peroneal nerve lesions. The project was therefore halted until a thorough review and validation had been undertaken within the Otto Bock Group. In this we included validation of biomechanics related to the ActiGait system and MRI scanning of the tissue in the knee region. Following this we learned where the cuff electrode should be positioned, how the sensory branches divides guiding the surgeon to a possible preoperative estimate of correct cuff size and how sensory branches inside the cuff could be

avoided through micro dissection. We have also visualized how much the cuff electrode moves during walking and how normal scar tissue develops around the cuff electrode. Due to these movements it is mandatory that there is no pull on the cuffelectrode from the stimulator body. Since July 2009

- 18 cases have been operated upon in Denmark, Germany, the Netherlands, Luxembourg, Austria and Romania, all awaiting long term follow up's before results are being published. Animations of two

patients walking without and with ActiGait systems illustrate our results.

Conclusion: The simple ActiGait FET system has been used in clinical practice for more than 10 years. The ActiGait system proves reliable and relatively simple to implant providing some essential factors are accepted. The patient's daily life is benefitted with a slight increase in their walking speed in most cases and especially a much better balance is obtained by the ActiGait system.

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