

THE PERCUTANEOUS IMPLANT. THE EFFECTS OF DESIGN, HOST SITE AND SURGERY ON THE TISSUE RESPONSE

Akademisk avhandling

Som för avläggande av medicine doktorexamen vid Sahlgrenska akademien, Göteborgs universitet kommer att offentlig försvaras i Föreläsningssal, Biotech Center, Arvid Wallgrens Backe 20, fredagen den 9 mars, 2018, klockan 13.00

av Martin L Johansson

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Avhandlingen baseras på följande delarbeten

- I. Johansson ML, Thomsen P, Hultén L, Halvorsen PS, Fosse E, Edwin B. Integration between a percutaneous implant and the porcine small bowel. *Journal of Biomedical Materials Research Part B: Applied Biomaterials*. 2011;98(1):101-9.
- II. Johansson ML, Hultén L, Peeker R, Jonson O, Thomsen P, Edwin B. Achieving stoma continence with an ileal pouch and a percutaneous implant. *In manuscript*
- III. Shah FA[#], Johansson ML[#], Omar O, Simonsson H, Palmquist A, Thomsen P. Laser-Modified Surface Enhances Osseointegration and Biomechanical Anchorage of Commercially Pure Titanium Implants for Bone-Anchored Hearing Systems. *PLoS One*. 2016;11(6):e0157504. [#]Contributed equally.
- IV. Johansson ML, Eriksson, T, Omar O. The development and ex vivo evaluation of a novel drill system for bone conduction hearing implants. *In manuscript*.
- V. Trobos M[#], Johansson ML[#], Jonhede S, Simonsson H, Hoffman M, Omar O, Thomsen P, Hultcrantz M. The clinical outcome and microbiological profile of bone anchored hearing systems (BAHS) with different abutment topographies – A prospective pilot study. *Submitted for publication*. [#]Contributed equally.
- VI. Johansson ML, Stokroos RJ, Banga R, Hol MK, Mylanus EA, Savage Jones H, Tysome JR, Vannucchi P, Hof JR, Brunings JW, van Tongeren J, Lutgert RW, Banerjee A, Windfuhr JP, Caruso A, Giannuzzi AL, Bordin S, Hanif J, Schart-Morén N, Singam S, Jonhede S, Holmberg M, Cremers CW, Hultcrantz M. Short-term results from seventy-six patients receiving a bone-anchored hearing implant installed with a novel minimally invasive surgery technique. *Clinical Otolaryngology*. 2017;42(5):1043-1048.
- VII. Calon TG, van Hoof M, van den Berge H, de Bruijn AJ, van Tongeren J, Hof JR, Brunings JW, Jonhede S, Anteunis LJ, Janssen M, Joore MA, Holmberg M, Johansson ML, Stokroos RJ. Minimally Invasive Ponto Surgery compared to the linear incision technique without soft tissue reduction for bone conduction hearing implants: study protocol for a randomized controlled trial. *Trials*. 2016;17(1):540.
- VIII. Calon TGA[#], Johansson ML[#], de Bruijn AJG, van den Berge H, Wagenaar M, Eichorn E, Janssen AML, Hof JR, Brunings JW, Joore MA, van Tongeren J, Jonhede S, Holmberg M, Stokroos RJ. Minimally Invasive Ponto Surgery versus the Linear incision technique with soft tissue preservation for Bone Conduction Hearing Implants: A multicentre randomized controlled trial. *Otology & Neurotology*. *Accepted for publication*. 2017. [#]Contributed equally.

**SAHLGRENKA AKADEMIN
INSTITUTIONEN FÖR KLINISKA VETENSKAPER**



THE PERCUTANEOUS IMPLANT. THE EFFECTS OF DESIGN, HOST SITE AND SURGERY ON THE TISSUE RESPONSE

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Abstract

This research project focuses on the multiple challenges associated with implants that breach the skin. The role of device design, host site, and surgical approach on tissue response and outcome are evaluated, experimentally and clinically, for both a stoma port and a bone-anchored hearing system (BAHS). Experimental studies implied the opportunity to integrate a soft-tissue-anchored titanium port with skin and intestine. However, the longevity was challenged by the presence of bacteria and mechanical strains [Paper I, II]. Applying a micro- and nanotopography to a bone-anchored implant, enhanced its biomechanical anchorage in comparison with a machined surface. Further it was found that removal torque was associated with the degree of bone-to-implant contact, whereas the implant stability, at retrieval, was correlated with the bone area [Paper III]. Bench tests demonstrated that during osteotomy preparation, the level and distribution of heat is affected by the drill design, and the drilling and irrigation procedure. Provided that the recommended, standard procedure is followed, the absolute temperatures using either a conventional drill system or a guided drill system are below the threshold for thermally induced tissue damage [Paper IV]. In human studies of BAHS, anaerobic bacteria, but not aerobes, were detected in the tissue already prior to installation. In contrast, after the installation of BAHS, both anaerobic and aerobic (predominantly *S. epidermidis* and *S. aureus*) bacteria were detected on the abutment, in the tissue and in the peri-abutment fluid space, at both three and 12 months [Paper V]. The feasibility of a novel, minimally invasive technique for installing BAHS was demonstrated clinically [Paper VI, VII, VIII]. In a randomized clinical trial, skin sensibility and cosmetics were significantly better and, surgery time and skin sagging was significantly reduced compared with the conventional surgical procedure. At three-months, no significant difference in incidence of inflammation was found between the techniques [Paper VIII].

It is concluded that the device design, host site, and surgical approach are important determinants for the tissue response and clinical outcome of percutaneous systems.