THE BADAL X-PROTECT

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The BADAL X™ is a bone-anchored implant for limb prosthesis attachment, thereby posing an alternative to socket-extended prostheses. Amputees that experience issues with their socket, for example chafing, may consider such an implant. The BADAL X™ is anchored to the bone through a process called osseointegration (Brånemark, 1985). On the side to which the prosthesis is attached, the implant protrudes the skin, creating a stoma. This permanent stoma results in increased infection risks (Atallah et al., 2018). Infections cause pain and discomfort to the patients, and increase the risk of implant failure. Additionally, amputations caused by vascular disease are currently a contraindication to receiving the implant because of the accompanying infection risks (Leijendekkers et al., 2017). The aim of this thesis is to reduce infection risks through a BADAL X™ redesign. The accompanying research question is as follows: *How can the infection risks at the interface of the soft tissue and the extramedullary head of the BADAL X™ be reduced through a redesign?* To this end, an iterative approach called Action Research is used (Coghlan and Brannick, 2010). The main framework consists of four iterations. During the upcoming sections, iterations one to four are summarised. Lastly, a summary of the discussion and conclusions is provided.

During the first iteration, bacterial colonisation is researched. The most important conclusions are that bacterial adhesion is mainly depended on thermodynamical processes and topographical surface modifications (Zheng et al., 2021). Furthermore, adding bactericidals and impairing biofilm formation lead to decreased bacterial colonisation. From this, design ideas are derived using BioTRIZ, a biomimicry design method derived from TRIZ, introduced by Vincent et al. (2006). At the end of iteration one, it is decided to expand the analysis and adjust the idea generation approach.

During the second iteration, the host immune response is analysed. The most important conclusion is that protein adsorption causes a Foreign Body Response (Franz et al., 2011, Anderson et al., 2008). This implies that the immune system needs to divide its resources and consequently less bacteria are cleared. Additionally, production methods for reducing bacterial adhesion and modulating the immune response are researched. Several manufacturing approaches to nano surface modifications are found. Additionally, it is concluded that hydrogels are often used for immunomodulatory design (Vishwakarma et al., 2016). From the analysis of iteration one, iteration two, and background information of the implant, a list of requirements is constructed. This list of requirements is used as a starting point for ideation, which consists of both ideation sketching and BioTRIZ idea generation. From ideation, three concept directions are derived. The first concept direction is nearest to the current implant design and uses a hard and smooth coating to minimise interaction with the surrounding tissue. This may be complemented using increased hydrophilicity, charge, or metal ions. The second concept employs a nanopattern, optionally biodegradable and loaded with metal ions. The last concept uses a hydrogel coating, either degradable or long-term.

During the third iteration, a concept decision is made. For concept grading, the List of Requirements is adjusted and used. From concept grading follows that the hydrogel concept receives most points. Subsequently, more research on hydrogels is performed. From this analysis and the List of Requirements, several functions for the redesign are

Figure 1: Detailed sketch of the BADAL X-Protect implant.

derived. These functions are used as a starting point for a morphological scheme. Using this morphological scheme, three sub-concepts are derived. Again, the List of Requirements is used to rank the concepts. The concept with the most points is a chemically self-healing tetra-hydrogel of either PEG or a zwitterionic hydrogel. This hydrogel is loaded with metal ions to yield bactericidal effects during the first weeks of wound healing. Additionally, the hydrogel forms a seal to block bacteria from entering through the stoma. The concept is called the BADAL X-Protect, and the sealing itself is called the Protect Sealing.

During the last iteration, the concept is further developed. To identify practical issues, final sketches are made. From these sketches, the final considerations are listed and according design decisions are made. These include dimensions and production. With respect to dimensions, it is decided to cover 25 mm of the extramedullary head with the coating. The coating thickness is approximately 1 mm. With respect to production, it is decided that the coating is applied during production using a mussel-inspired adhesive (Cheng et al., 2017) and dipcoating. Lastly, companies producing comparable products are investigated. The companies that are regarded include Novagenit®, DePuy Synthes, DSM, and DermaRite.

In conclusion, The BADAL X-Protect with Protect Sealing is recommended as a redesign of the BADAL X™ to reduce infection risks. Summarised, this is a tetra-hydrogel seal made of PEG or a zwitterionic polymer with chemical self-healing functional groups, loaded with bactericidal particles. It is dipcoated with a mussel-inspired adhesive onto 25 mm of the extramedullary head with a 1 mm thickness. Several open questions and additional recommendations are relevant in further development of the concept. These include synthesising and testing chemical compositions of the sealing, calculating and testing the interfacial stress caused by further material inflation in moist environments, testing production techniques, testing damage resistance and lifespan of the material, researching cleaning considerations, considering partnerships, and marketing and insurance considerations.

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