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Title

Health-related quality of life and safety in persons with a bone-anchored prosthesis: a prospective two-year follow-up cohort study

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Summary

A large amount of people using a SP experience socket-related problems: HRQL is often negatively affected. An OI overcomes these problems and improves HRQL. A tool to assess candidates for OI-surgery is absent. This study examines pros and cons of an OI and explores proper candidate selection.

Introduction/ basics

Persons with a lower limb amputation (LLA) using a socket prosthesis (SP) are often limited by socket-related problems. Consequently, general and disease-specific health-related quality of life (G-HRQL and D-HRQL) are negatively affected. An osseointegrated implant (OI) may solve this problem by elimination of the prosthetic socket (PS) (Figure 1 and 2). We intend to include persons for OI-surgery with a favorable ratio between potential adverse events related to OI-surgery and potential improvement in HRQL. A tool to assess these persons is absent. Aims; 1) Describing change in G-HRQL and D-HRQL in persons with an LLA after OI-surgery and rehabilitation at 6-month, 1-, and 2-year follow-up compared to the preoperative assessment, 2) Identifying subgroups and patterns of potential change in G-HRQL and D-HRQL, 3) Describing 2-year follow-up safety-related outcomes, 4) Establishing an association model for 2-year follow-up change in G-HRQL and D-HRQL.

Material method; implementation/ process

All consecutive persons who underwent OI-surgery in the Radboudumc between May 2014 and April 2020 were eligible for this study. 1) G-HRQL was assessed, from September 2017, using the SF-36 physical component score (PCS) and mental component score (MCS). D-HRQL was assessed, from May 2014, using the Q-TFA global score. Patients not using a prosthesis only

answered one question of the Q-TFA about the current situation as an amputee. 2) Subgroups and patterns were identified using latent class mixed models. 3) Adverse events were analyzed for the entire cohort and included; infection, implant failure (breakage or loosening), stoma problems (hypergranulation/keloid formation or stoma redundant tissue), and periprosthetic fracture. 4) The initial association models included the following factors at baseline: a) G-HRQL; 6MWT, G-HRQL, prosthetic use, amputation level, and age. b) D-HRQL; 6MWT, D-HRQL, prosthetic use, prosthetic comfort, amputation level, BMI, cause of amputation, and age.

Results

In total, 196 persons were eligible for inclusion of which 125 persons were part of the G-HRQL cohort. This preliminary analysis included 131 participants (G-HRQL; n=44, D-HRQL; n=131). At baseline, mean age was 55.1 years, 68% was male, and mean BMI was 29.1. The majority had an unilateral amputation (96%) and trauma was the main cause of amputation (52%). Seventy-two percent of the participants had a TFA, 22% a TTA, 4% a knee-exarticulation, 1% a foot amputation, and 1% received an OI after primary amputation. Nineteen percent of the participants did not use a prosthesis. Preliminary results: 1) The SF-36 PCS (n=44) and the Q-TFA global score (n=131) improved significantly at all timepoints compared to baseline ($p < 0.001$) (Figure 3 and 4). The SF-36 MCS (n=44) did not change significantly at all timepoints compared to baseline ($p = 0.353$). The overall situation as an amputee at each timepoint improved compared to baseline (Figure 5). 2) Subgroups and patterns of this longitudinal change in G-HRQL and D-HRQL have not yet been analyzed. 3) Adverse events have not yet been analyzed. 4) Only low G-HRQL at baseline had a significant association with improvement in G-HRQL between baseline and two-year follow-up and explains 34.6% of the variance of this change in the study population. High 6MWT and low D-HRQL had a significant association with improvement in D-HRQL between baseline and two-year follow-up and explains 43.1% of the variance of this change in the study population.

Discussion/ conclusion; conclusion for the practice

We intend to include persons for OI-surgery with a favorable ratio between potential adverse events related to OI-surgery and potential improvement in HRQL. As adverse events were not analyzed in this preliminary analysis, a favorable ratio is not known yet. However, the

review of Atallah concluded that major complications (e.g. infection and failure) are rare in transfemoral bone-anchored prosthesis (BAP). Minor complications (e.g. soft tissue infections/ complications) are common. As 72% of our participants have a TFA, we do not expect many major complications. No conclusion were given regarding complications in TTA due to underreporting. By eliminating the PS and thus corresponding problems, HRQL is positively influenced. However, this positive change is based on heterogeneous populations, not on individuals. Personalized care becomes increasingly important in healthcare. Therefore, subgroups and patterns for change in HRQL needs to be analyzed. This type of analysis has not been previously described in OI literature. To our knowledge this is the first study which developed association models for improvement in G-HRQL and D-HRQL in persons with a BAP. In conclusion, G-HRQL PCS, D-HRQL, and the overall situation as amputee at 2-years after surgery improved compared to baseline. Therefore persons are most eligible for OI-surgery if they have a high age, a high score on the 6MWT, and a low G-HRQL and D-HRQL at baseline. These findings are helpful to optimize patient selection.

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Image: Image 1. Radiographs of osseointegration implants a. TF OI b. TT OI_250.PNG

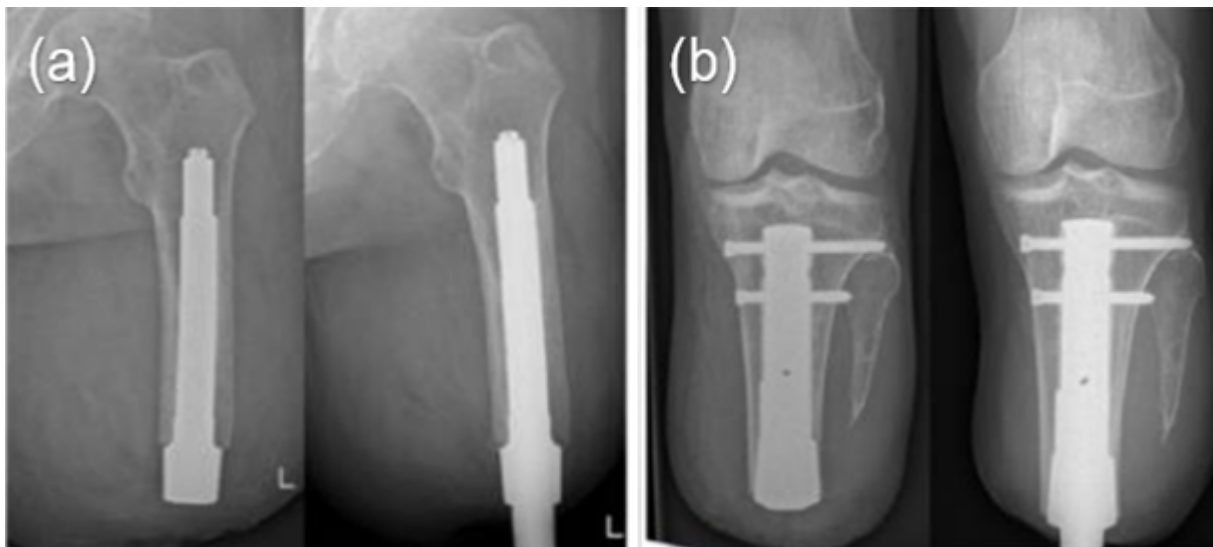


Image: Image 2. Bone-anchored prostheses. Left TF BAP. Right TT BAP_251.png



Image: Image 3. G-HRQL at each timepoint. Whisker 95% CI _252.PNG

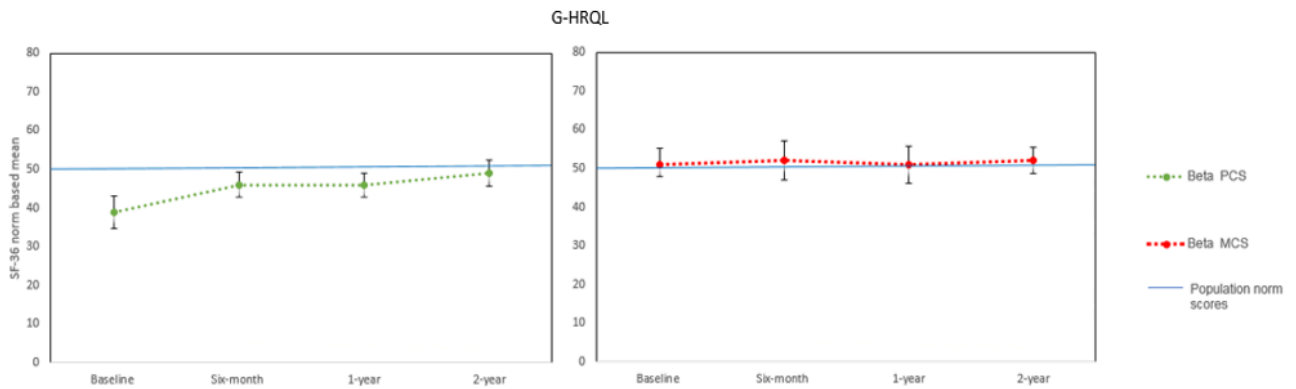


Image: Image 4. D-HRQL at each timepoint. Whisker 95% CI_253.PNG

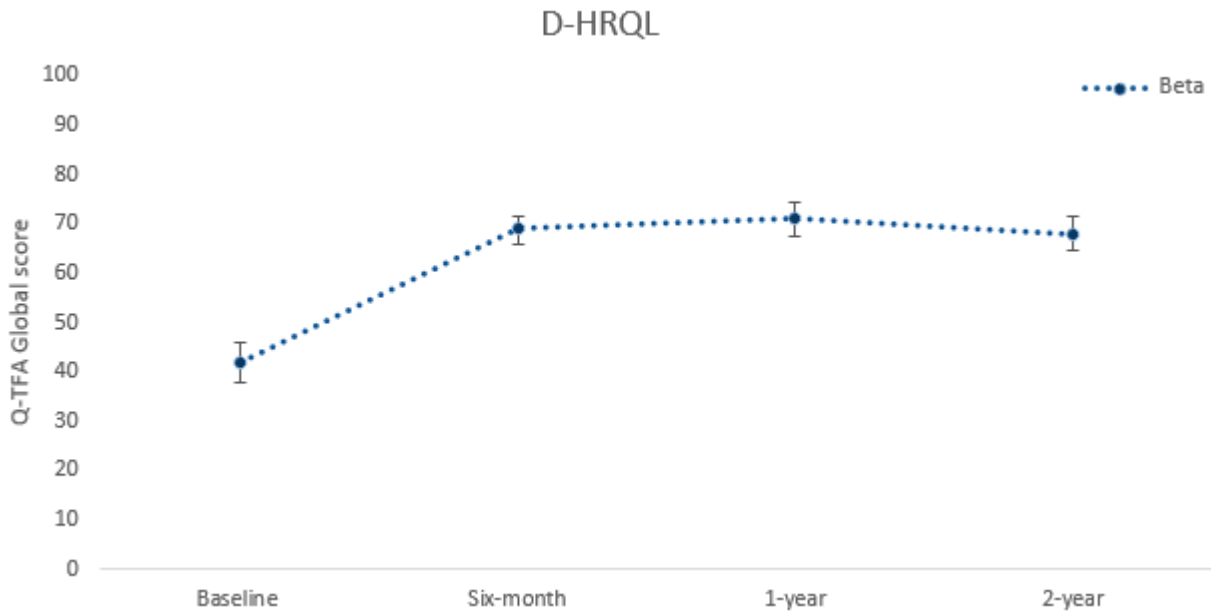


Image: Image 5. Answers to the single question on the patients overall situation as an amputee at each timepoint_254.PNG

