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Title
Safety and effectiveness of Bone Anchoring Device for Artificial Limbs (BADAL X) in lower limb amputees: A prospective two-year follow-up cohort study

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Summary
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Introduction/ basics
Previous risk-benefit studies of bone anchored/osseointegration devices for prosthetic attachment have predominantly included transfemoral amputatees. Currently almost half of the candidates referred to our center for bone anchored prosthetic treatment have either short femoral remnants or a transtibial amputation. For these individuals a new press-fit bone anchoring device was developed including a curved and gamma type femur implant and a anatomically shaped press-fit tibia implant. The aim of this study was to present the adverse events, prosthesis wearing time and health-related quality of life. The one year follow up data of this identical cohort previously were published in PLoS One by Atallah et al in 2020.

Material method; implementation/ process
All consecutive individuals treated between March 2015 and June 2018 with curved femur implants (BADAL X OFI-C or OPL) indicated for amputees with long femoral remnant, gamma type femur implant (BADAL X OFI-Y) indicated for amputees with a short femoral remnant, or tibia implant (BADAL X OTI) indicated for the transtibial amputees, were eligible for this study. Safety was evaluated by counting all adverse events from the medical records at prospectively planned follow-up visits. Infectious adverse events were graded as: grade 1 and 2 for respectively low- and high-grade soft tissue infection, grade 3: deep bone infection, grade 4: septic implant loosening. Effectiveness was measured by the Prosthetic Use Score (PUS; range 0-100) and prosthesis related quality of life; Global Score (GS; range 0-100). These

effectiveness measures were extracted from the Questionnaire of persons with trans-femoral amputation (Q-TFA) at baseline before surgery and at two-year follow-up.

Results

Ninety of 91 individuals were included (mean age: 54±14 yrs, 26 females); treated with 53, 16 and 21 respectively OFI-C, OFI-Y and OTI. Follow up results were derived from 91 and 83 subjects at respectively one and two year follow up. Safety: In the first year, the number of grade 1, 2, 3 and 4 infections were respectively 11, 10, 0 and 1 events. In the second year, the number of grade 1, 2, 3 and 4 infections were respectively 3, 2, 1 and 0 events. Other adverse events reported in the second year after implantation were stoma/myogenic pain, nerve/phantom pain, hip-joint pain, and proximal femur fracture in respectively: 20, 12, 3 and 2 subjects. Reported device failures were DCA breakages in 4 subjects. Broken DCAs were revised and the two years implant survival was 99%. Effectiveness: At baseline mean ±SD and median (25th to 75th PCTL) Q-TFA PUS and GS were 52±39, 52(7-90) and 40±19, 42(25-50) and improved significantly to respectively 85±25 (63% increase), 100 (90-100) and 6 6±20 (65% increase), 75 (50-75) at two-year follow-up.

Discussion/ conclusion; conclusion for the practice

The number of soft tissue infectious adverse events sharply decreases in the second year after implantation. Stoma- and myogenic-pain in the residual limb remains an issue in 22% of all included subjects but is well counterbalanced by an enormous increase in patient reported prosthetic use (63%) and prosthesis related quality of life (65%).

References

Safety, prosthesis wearing time and health-related quality of life of lower extremity bone-anchored prostheses using a press-fit titanium osseointegration implant: A prospective one-year follow-up cohort study. Atallah R, van de Meent H, Verhamme L, Frölke JP, Leijendekkers RA.PLoS One. 2020 Mar 9;15(3