INTRODUCTION
The etiology, incidence, and types of infections associated with osseointegrated (OI) prostheses are not well described for lower-limb amputees (Tabanella G, et al., 2009). Two previously published studies involved the OPRA System, and reported a very low (<3%) risk of deep infection leading to implant removal. The first study was a 5-year prospective of 39 patients, and reported only one patient with an infection leading to implant removal after 3 years. A subsequent prospective study of 51 patients reported a 55% cumulative incidence of superficial infections at 24 months, with implant removal due to infection in only one patient. In Australia and the Netherlands a macro-porous press-fit type of implant allows a novel protocol of OI surgery and accelerated rehabilitation. Data regarding the infectious and non-infectious adverse events associated using this particular implant has not previously been reported. The main goal of this study was to develop a classification system specifically for OI related infections that includes both clinical and radiological signs enabling prospective reporting of the true incidence of these events, as well as a means to assess their severity.

METHOD
Subjects: A total of 86 patients aged 25-81 (47) years were included. Selection criteria: age >18 years, unilateral, trans-femoral amputees who had socket related problems including wheel-chair bound patients with short stump non reconstructable limb pathology. Exclusion criteria included smokers, psychological instability, non-compliance, diabetes, and vasculopathy.

Procedures: OI reconstruction was performed using either the Integral Leg Prosthesis or the OI Prosthetic Limb (OPL) titanium implants specifically designed for press-fit fixation, allowing bony in growth.

Data Analysis: Odds ratios were calculated to assess the association between patient gender, smoking status, and the presence of complications. An independent two-sample t-test was performed to test for a difference inpatient and surgical characteristics measured as continuous variables between patients with and without complications. A p-value <0.05 was significant.

RESULTS
Patients were followed up for a median of 34 (24-71) months, during which 31 patients had an uneventful course without any complications. Of the remaining 55 patients, 25 had minor complications but no infections. A total of 24 patients developed infections, but all of these were either grade 1 or grade 2 and did not necessitate surgery. During the period of the study, no patients developed grade 3 or grade 4 infections. Other adverse events requiring intervention were observed in 26 patients, including: inadequate OI with replacement of implant (1); stoma hyper-granulation (17); implant breakage (2); breakage of the dual cone component safety pins (3); and proximal femur fractures (3). There was a significant association between gender and risk of severe infection with women having more than a 6-fold increase in risk (OR 6.5, 95% CI 1.1-38.15). A BMI > 25, was associated with a significant 3-fold higher risk of a mild infection (OR 3.47, 95% CI 1.16-10.39). Smokers had a 7-fold higher risk of a recurrent infection (OR 7.5, 95% CI 1.32-42.35).

DISCUSSION
This study represents the largest prospective cohort evaluation of transfemoral amputees treated with press-fit OI implants reported to date. A comprehensive classification for infection related to OI systems including treatment criteria was introduced and used to assess the safety of these press-fit type OI. Mild infection and irritation of the soft tissue in the skin penetration area are common, but successfully managed with simple measures. This multicenter study indicates that severe infections resulting in septic implant loosening are rare, and were not observed in this cohort. These findings suggest careful soft tissue handling and appropriate intervention as indicated can successfully limit the potential risk of deep infection that might otherwise be associated with OI.

CONCLUSION
Mild infection and irritation of the soft tissue in the skin penetration area are common and successfully managed with simple measures. Severe infections resulting in septic implant loosening are rare. These findings indicate careful surgical soft tissue handling is essential.

CLINICAL APPLICATIONS
Osseointegration is a safe procedure for the primary and secondary reconstruction for all non-dysvascular amputees. Adverse effects are similar to those associated with other implant procedures, such as hip and knee replacement.

REFERENCES
Safety of osseointegrated implants for transfemoral amputees: A multicentre prospective cohort study

Al Muderis, M1,2,3, Bosley, B3, and Kahle, JT4
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