INTRODUCTION
Amputation of a lower extremity results in major changes in a person’s function, body image, and quality of life (Hagberg et al, 2001). It is estimated that less than half of those who require amputations return to work, and the average time to return to work exceeds one year. One-third of all amputees encounter socket-interface problems, leading to reduced prosthetic use and a markedly diminished quality of life. Over the last two decades, a new concept called osseointegration (OI) has emerged; connecting the artificial limb prosthesis to the residual bone. The primary objective of this study was to describe a protocol in detail (OGAAP-1) as a comprehensive strategy for a two-stage OI reconstruction and rehabilitation of lower extremity amputated limbs. The secondary objective was to assess the clinical outcomes in a case series of 50 unilateral transfemoral amputees as a preliminary report on the efficacy of the OGAAP-1 program.

METHOD
Subjects: Prospective data from March 2011 to June 2014, a total of 53 unilateral transfemoral (TFA) amputees were treated using the OGAAP-1. Males (34) and females (16) aged 24-73 (mean 49.4±12) years. Selection criteria: age >18 years, unilateral, TFAs who had socket related problems, or wheelchair bound with non-reconstructable limb pathology. Exclusion criteria included smokers, non-compliance, pregnancy, irradiated affected bone, diabetes, and vasculopathy.

Apparatus: The main outcome measures included the Questionnaire for persons with a TFA (Q-TFA), the Short Form Health Survey 36 (SF-36), K levels, and the Six Minute Walk Test (6MWT) and Timed Up and Go (TUG) tests, pre- and post-operatively.

Procedures: OI reconstruction was performed using either the Integral Leg Prosthesis (ILP) or the Osseointegrated Prosthetic Limb (OPL); titanium press-fit implants, allow bony ingrowth.

RESULTS
Three patients died of unrelated causes, and the remaining 50 treated under this protocol, none were lost to follow-up. Both the post-operative Q-TFA global score (47.82±2.69 to 83.52±2.66, p<0.0001), and the SF-36 physical component summary (37.09±1.41 to 47.29±1.33, p<0.001), were markedly superior to those of the preoperative values. Both the 6MWT (281±19 to 419±20, p<0.0001) and the TUG (14.59±1.19 to 8.74±0.40, p<0.0001), were significantly improved. 23 out of 50 (46%) participants had no adverse events; the other 27 had one or more complications (54%). There were episodes of infection in 21 patients (42%); 13 responded to oral antibiotics alone; 5 responded to IV antibiotics; and surgical soft tissue debridement was required on 3 occasions. Four patients had a post-operative fracture as a result of a fall related to their increased activity levels. Revision of the implant was required in 2 patients; one as a result of an undersized device, and the other as the result of an implant fatigue failure at 3.5 years (96% implant survival).

DISCUSSION
These findings are comparable to, or better than, those reported previously by other groups using alternative implants and rehabilitation protocols. Under the OGAAP-1 protocol the time interval between the initial procedure and fully independent ambulation was approximately 4.5 months. This contrasts markedly with the protracted interval between the initial procedure and independent ambulation previously reported for screw-type osseointegration implants, typically requiring as long as 9 to 12 months. The more rapid completion of reconstruction is likely due to a combination of factors, including the decreased interval between stages and the accelerated progression of weight bearing exercises and rehabilitation.

CONCLUSION
The main objective of this study was to describe in detail the OGAAP-1 clinical protocol and accelerated rehabilitation program for the OI reconstruction of amputees. In this series of 50 unilateral transfemoral patients with a minimum of one-year follow-up, significant improvements were achieved in all of the outcome measures of QOL, ambulation ability, and functional level: QTFA (global score), SF-36 (PCS), K-levels, TUG, and 6MWT.

CLINICAL APPLICATIONS
Osseointegration is a realistic option for primary and secondary reconstruction of non-dysvascular amputees. Observationally, in this study outcomes are improved compared to socket users.

REFERENCES