## Osseointegrated Implants for Transfemoral Amputees: Radiographic Evaluation of Bone Remodeling

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**Purpose:** Osseointegration is a novel method to overcome persistent socket prosthetic issues in amputees by anchoring a transcutaneous implant directly onto the skeletal residuum. Although similar technologies have been widely applied in the area of hip and knee arthroplasty, little evidence exists in the literature reporting the bone remodeling effects of osseointegrated implants. Stress shielding results in the reduction of bone density due to the implant removing the stress that is usually exerted on the bone, which greatly reduces implant stability. This study investigates the bone remodeling effect and quantifies it in 2 of the most common osseointegration implants.

**Methods:** This is a prospective study of 50 patients with transfemoral amputations, consisting of 35 males and 15 females, aged 20-73 years (mean 48.2) at surgery, with minimum 2-year follow-up. Two implants, the Integral Leg Prosthesis (ILP) and Osseointegrated Prosthetic Limb (OPL), with differences in tapering, coating and bone ingrowth regions, were examined. Radiographs were taken at 6 months, 1 year, 2 years, and 5 years post surgery. The surrounding bone was defined using inverse Gruen zones and graded into 5 levels of bone growth or resorption.

**Results:** Results obtained at 1 and 2-year follow-ups were compared to the 6-month follow-up values as a baseline. Significant bone growth near the proximal zones of the implant was observed on patients with the ILP implant. This was accompanied by significant resorption toward the distal end indicating the occurrence of stress shielding. The OLP implant demonstrated much more uniform bone density throughout the length of the implant.

**Conclusion:** Overall, the patterns of bone remodeling after osseointegration showed similarities to those seen on hip stems with a press-fit design. Of the 2 osseointegration implants examined in this study, the OLP implant exhibited less stress shielding effects and is expected to provide better long-term stability.

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.