

## Osseointegrated Prosthetic Limb for Amputees: Over 10 Years' Experience with More Than 100 Cases

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**Purpose:** The Osseointegrated Prosthetic Limb (OPL) was introduced in 1999. Prior to its advent all prostheses consisted of stump and socket mechanisms, which did not change dramatically since Ambroise Paré introduced lower limb prostheses in 1529. These socket prostheses failed to address a few major requirements of normal gait. Our hypothesis was that using an osseointegrated prosthetic limb will result in superior function of daily activities, without compromising patients' safety.

**Methods:** This is a prospective cohort study, of our first 100 OPL cases operated between 1999 and 2013 in two centers: Lübeck, Germany and Sydney, NSW, Australia, by the two principal surgeons acquainted with this technology. Both centers used similar strict exclusion criteria, and followed equivalent surgical technique. We collected demographic as well as surgical details, and postoperative complications. In addition, patients' outcome measurement included: Objective functional, as well as subjective surgeon assessment, and Short Form-36 and Q-TFAs (Questionnaires for Persons with a Transfemoral Amputation). The results were statistically analyzed to compare socket versus OPL outcome.

**Results:** 78 amputees were operated on by the German center, and 37 in the Australian center, totaling 115 patients. Eight patients (six German, two Australian) had a bilateral implantation. Average age at amputation for both centers was 33 years (range, 3-76), at implantation 44.3 years (range, 17-76). Average period from amputation to implantation was 13 years (range, 0-46). Traumatic amputations occurred in 61 patients (78%) in Germany, and 28 (76%) in Australia. Infection was the second most common cause for amputation consisting of 10% of cases in Germany and 12% in Australia. Neoplasia was the cause for amputation in similar rates in both centers (10%). In addition 4% in Germany had a vascular etiology, and 2% congenital malformation in Australia. Both K scores, and Timed Up and Go tests have shown improved results for OPL compared to socket prostheses, with high significance ( $P = 0.0006$ , and  $P = 0.0149$ , respectively). Six-minute walking tests did not show significant improvement. Patients' questionnaire scores have improved as well with statistically significance.

**Conclusion:** This study shows favorable results for OPL treatment for above-knee as well as below-knee amputees, compared to socket prostheses. Our experience with over 100 patients has revealed encouraging results with a major improvement in patient functionality and quality of life, and a low rate of complications.

- The FDA has not cleared this drug and/or medical device for the use described in this presentation (i.e., the drug or medical device is being discussed for an "off label" use). For full information, refer to page 600.