**•Safety of Osseointegrated Prosthesis for Transfemoral Amputees**

*Munjed Al Muderis, MB ChB, FRACS, FAOrthA[1]; Guy Raz, MD[1]; Michael Edwards[2]; Henk van de Meent, MD, PhD[2];* ***Jan Paul Frölke, MD, PhD***[2]*;*
*[1]School of Medicine, University of Notre Dame Australia, Sydney, New South Wales, Australia;*
*[2]Radboud University Nijmegen Medical Center, Nijmegen, The Netherlands*

**Purpose:** Osseointegration is a known concept to avoid problems related to the socket-body interface for transfemoral amputees. With this technique the prosthesis is transcutaneously attached to the distal femoral shaft by osseointegration using a retrograde intramedullary implant. Although osseointegration has been proven to significantly increase walking ability and prosthesis-related quality of life, the risk of potential complications prevents further introduction to a larger scale, so far. In this study we report on complications to determine potential risk factors in the first 2 years after implantation.

**Methods:** After IRB approval, two university hospitals in Australia and the Netherlands conducted a prospective clinical cohort study to analyze all consecutive subjects with transfemoral amputation (3 bilateral) who underwent implantation of osseointegrated femoral prosthesis (ILP Ortho Dynamics GmbH, Lubeck, Germany) with 2 years follow-up. All complications were prospectively registered and classified. Potential risk factors for complications were determined including gender, age, duration after amputation, cause of amputation, comorbidity including body mass index, smoking behavior, and length of stoma.



**Results:** Complications occurred in 26 of 47 subjects (55%) during the first 2 years after osseointegrated femoral prosthesis. 26 patients had 101 events. 88 events were graded as a minor event not requiring surgery. 11 patients had major complications requiring surgical

| N=47 | No/Mild complications n=36 (77%) | Adverse Effects which required surgery n=11 (23%) | P |
|---|---|---|---|
| Gender m/f | 30/6 | 6/5 | 0.0484 |
| Mean age (years) | 46.94 | 45.86 | 0.83 |
| Mean duration after amputation (years) | 17.06 | 15.00 | 0.77 |
| Cause trauma/neoplasia/other | 27/6/3 | 8/0/3 | 0.074 |
| Mean follow-up (months) | 24.81 | 25.71 | 0.71 |
| Smoking status no/yes | 34/2 | 7/4 | 0.0074 |
| Length of stoma (cm) | 4.66 | 4.29 | 0.50 |
| Prosthetic use (hrs per week) | 104.25 | 93.43 | 0.026 |
| 6 min walking test (m) | 413.38 | 434.86 | 0.93 |

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intervention (23%): 2 patients underwent exchange of intramedullary implant and 9 other patients underwent surgical corrections for recurrent peri-implant soft-tissue irritation with pain. No septic loosening of implant was identified. Risk factors that might have contributed to these complications included smoking, and female gender (see table).

**Conclusion:** Complications related to the osseointegrated leg prosthesis do occur but the suffering and disabilities are relatively mild. Infectious events are superficial and can be managed with intensive local irrigation and antibiotics. Strict patient selection and adherence to exclusion criteria may reduce complication rate.