Safety of Osseointegrated Prosthesis for Transfemoral Amputees

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Background/Purpose: Although osseointegration has been demonstrated to improve walking ability and prosthesis-related quality of life in patients with transfemoral amputations suffering from socket-related complications, the risk of potential infectious complications has limited wider introduction to date. We report on the incidence of infection in the first 2 years after implantation and investigate potential risk factors.

Methods: Two university hospitals conducted a prospective cohort study to analyze all consecutive subjects with transfemoral amputation who underwent implantation of osseointegrated femoral prosthesis between 2011 and 2013. Infections were prospectively reported and classified using a standardized protocol (Table). Patient and clinical characteristics (gender, age, time since amputation, cause of amputation, and comorbidities including BMI [body mass index], smoking behavior and length of stoma) were recorded and relative risk (RR) and 95% confidence intervals (95% CIs) calculated to identify potential risk factors.

Results: Of 89 procedures in 84 patients (5 bilateral) performed, a total of 45 infections in 31 (34%) procedures in 29 (35%) patients were reported at median follow-up of 28 months (range, 12-65). In group A 21 Infections were classified as: 15 grade 1A, 5 grade 1C, and 1 grade 3C. Group B comprised 24 infections: 15 grade 1A. 8 grade 1C, one grade 2C. Overall, 13 (14%) of procedures in 13 patients had grade 1B-C infection. 3 of 6 (50%) smokers and 10 of 23 (43%) of women had at least one infection (RR 1.5, 95% CI 0.6-3.5; RR 1.4, 95% CI 0.8-2.5, respectively).

Conclusion: One-third of patients had at least one diagnosis of infection. The majority of infections (30, 65%) were mild, classified as superficial and managed with oral antibiotics. Infections occur but not serious, only 1% results in implant failure. Further research is required to identify risk factors to determine appropriate patient selection criteria and optimal infection prevention strategies to reduce the complication rate.

See pages 47 - 108 for financial disclosure information.

Symptoms	Grade	Action
Soft Tissue infection		
Cellulitis with signs of Inflammation (Redness, Swelling, Warmth, Stinging Pain, Pain which increase on Loading, Tense	1A	Oral antibiotics
	1B	Parenteral antibiotics
	1C	Surgical intervention
Osteitis		
X Ray (Periosteal Bone Reaction +/- evidence of Osteitis - Sequestrum and Involucrum)	2A	Oral antibiotics
	2B	Parenteral antibiotics
	2C	Surgical intervention
Implant failure/osteomyelitis		
X Ray (Loosening)	3A	Oral antibiotics
	3B	Parenteral antibiotics
	3C	Surgical intervention