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ORIGINAL ARTICLE

Walking Ability and Quality of Life in Subjects With Transfemoral Amputation: A Comparison of Osseointegration With Socket Prostheses

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Abstract

Objective: To investigate walking ability and quality of life of osseointegrated leg prostheses compared with socket prostheses.

Design: Prospective case-control study.

Setting: University medical center.

Participants: Subjects (N=22) with transfemoral amputation (1 bilateral) referred to our center because of socket-related skin and residual limb problems resulting in limited prosthesis use. Their mean age was 46.5 years (range, 23−67y) and mean time since amputation was 16.4 years (range, 2−45y). Causes of amputation were trauma (n=20) and tumor (n=2).

Intervention: Implantation of an osseointegration prosthesis (OIP).

Main Outcome Measures: Global score of the Questionnaire for Persons With a Transfemoral Amputation (Q-TFA), prosthesis use, 6-minute walk test (6MWT), Timed Up & Go (TUG) test, and oxygen consumption during treadmill walking.

Results: With the socket prosthesis, the mean ± SD Q-TFA global score, prosthesis use, 6MWT, TUG, and oxygen consumption were 39±4.7 points, 56±7.9h/wk, 321±28m, 15.1±2.1 seconds, and 1330±310mL/min, respectively, and significantly improved with OIP to 63±5.3 points, 101±2.4h/wk, 423±21m, 8.1±0.7 seconds, and 1093±361mL/min, respectively.

Conclusions: Osseointegration is a suitable intervention for persons whose prosthesis use is reduced because of socket-related problems. Subjects with OIP significantly increased their walking ability and prosthesis-related quality of life.

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Approximately one third of individuals with transfemoral amputation have chronic skin problems associated with the socket of their prosthesis.[1-3] These skin problems often cause serious limitations in mobility and quality of life.[3-6] Despite new materials and improved socket designs, skin problems remain an important burden because the skin in weight-bearing areas of the socket is not always resistant to the pressure and friction caused by the socket during ambulation. Bone anchorage of the artificial limb is an intervention that avoids these problems. With this technique, the prosthesis is transcutaneously attached to the human skeleton by osseointegration using an intramedullary implant into the femur (fig 1). Attaching prostheses to the skeleton by osseointegration is now relatively well established in dentistry[7,8] and has begun to be established in the field of extremity amputation.[9-15] The suggested advantages of a bone-anchored prosthesis are direct prosthesis control and improved stability, better fixation, maximum sitting comfort, larger hip range of motion, quick donning and doffing,[13,16] better body perception,[17] osseoperception,[18-20] increased walking ability,[21] improved functional capacity,[22,23] and an overall increase in quality of life.[13,17,24] To date, there are 2 implants for bone-anchored prostheses used in humans: the Integrated Leg Prosthesis,[10-12,a] used in this study and hereafter referred to as osseointegration prosthesis (OIP); and the Osseointegrated Prosthesis for the Rehabilitation of Amputees (OPRA).[9,14,b] OIP was introduced in The Netherlands in 2009, and between May 2009 and May 2011, 22 participants were prospectively studied with respect to walking ability and quality of life. The surgical protocol

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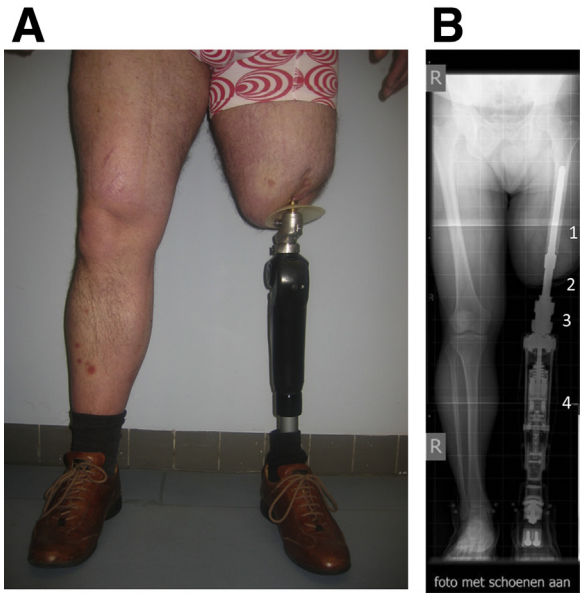

Fig 1 (A) Frontal view of subject with OIP. (B) Radiograph of a subject with OIP: 1, intramedullary implant; 2, transcutaneous unit; 3, click-safety adapter; 4, microprocessor-controlled prosthesis. The subject in A is not the same as the subject in B.

and postoperative care were adopted from publications of Aschoff et al.[10-12] The aim of this study was to investigate whether walking ability and quality of life of subjects with OIP are superior to walking ability and quality of life of the same persons with conventional socket prostheses.

Methods

Subjects with transfemoral amputation recruited for this study were referred to the outpatient clinic from the university medical center. All subjects were referred because socket-related skin and residual limb problems were contributing to limited prosthesis use. An inclusion criteria instrument for OIP was developed based on the following items: prosthesis use, prosthetic mobility, problems, and global score of a Dutch translation of the Questionnaire for Persons With a Transfemoral Amputation (Q-TFA) (table 1).[25] The socket and prosthetic alignment were evaluated by a rehabilitation physician. In cases where patients were functionally limited because of an inadequate prosthesis, the prosthesis was improved using accepted standard-of-care approaches. Prosthetic components were the same for the socket prosthesis and the OIP. Subjects with a residual femur length shorter than 8cm (proximal reference measure: the lesser trochanter), subjects with amputations caused by diabetes or vascular disease, and subjects with a medical history of severe cognitive or psychiatric disorders were excluded from the study. All participants gave their written informed consent. The regional medical ethics committee approved that the study protocol conforms to the Helsinki Declaration (nr NL32086.091.10).

List of abbreviations:

OIP	**osseointegration prosthesis**
OPRA	**Osseointegrated Prosthesis for the Rehabilitation of Amputees**
PWS	**preferred walking speed**
Q-TFA	**Questionnaire for Persons With a Transfemoral Amputation**
SF-36	**Medical Outcomes Study 36-Item Short-Form Health Survey**
6MWT	**6-minute walk test**
TUG	**Timed Up & Go**

Table 1 Inclusion criteria for OIP

Current socket prosthesis	
1. Reviewed by a rehabilitation physician and approved (fitting and alignment)	Yes ○
Prosthetic use and walking distance with socket prosthesis	
2. Prosthetic use <50h/wk	Yes ○
3. Walking distance <2km (can do, with or without walking aids)	Yes ○
Influence on quality of life	
4. Have you been considerably unable to rely on the prosthesis being securely fastened?	Yes ○
5. Has the prosthesis made it considerably uncomfortable to sit down?	Yes ○
6. Has the prosthesis considerably given rise to sores, chafing, or skin irritation?	Yes ○
7. During last summer, have you been considerably troubled by heat/sweating when wearing the prosthesis?	Yes ○
8. Would you summarize the problems you experience with your current prosthesis as considerable?	Yes ○
OIP is indicated if question 1 is answered yes and if at least 4 other questions are answered yes.	

Before OIP surgery, participants underwent preoperative evaluation using their socket prosthesis. Evaluation with OIP was performed 12 months after surgery and completion of OIP rehabilitation. Quality of life was evaluated with the Q-TFA including prosthesis use (in hours per week) and global score (range, 0−100).[25] Prosthesis use was calculated using the Q-TFA subitem prosthesis use by multiplying the average number of hours per day by 7. Walking ability was measured with the 6-minute walk test (6MWT), which measures the distance a person is capable of walking in 6 minutes, and with the Timed Up & Go (TUG) test, which measures the duration, in seconds, necessary to get up from a chair, walk 3m, go back to the chair, and sit down again.[26] Oxygen consumption, in milliliters per minute, was measured during treadmill walking at preferred walking speed (PWS). The PWS was the same for both the pre- and postoperative measurements. During treadmill walking, participants used handrail support for balance and security. Oxygen uptake was measured continuously during treadmill walking using a gas analyzer[c] with a face mask placed over the mouth and nose. Oxygen uptake was monitored during treadmill walking.[27] All measurements were executed on a single occasion preoperatively and then again postoperatively. The participants started with the TUG, then the 6MWT, followed by the oxygen consumption test. All participants were allowed to use walking aids in the pre- and postoperative tests.

Surgery

The OIP was implanted in a 2-step surgery.[10-12] In all participants, the residual femur was shortened to 20cm proximal of the contralateral knee joint space. This distance was used to establish

equal heights of rotation axes of the sound and prosthetic knee joints. The operation was performed with pre- and postoperative administration of antibiotics. Postoperatively, participants were hospitalized for wound care and intravenous administration of antibiotics for 5 days. Six weeks after the first operation, a stoma was created in a second operation by cutting the skin and soft tissue shaft with a circular knife and bolting the transcutaneous OIP unit into the implant. After the second operation, participants received instructions on how to clean and care for their stoma before being discharged from the hospital.

Rehabilitation

Two weeks after the second operation, participants began with weight-bearing exercises using a short pylon attached to the transcutaneous unit. Weight feedback was provided by a scale. During the first week, participants were allowed to bear 50% of their body weight on the implant. This was gradually increased to full body weight-bearing during the second week. Four weeks after the second surgery, the prosthesis was attached to the transcutaneous unit using a click-safety adapter,[d] and a progressive loading rehabilitation program initiated. Rehabilitation consisted of gradually increasing the amount of weight-bearing on the implant and locomotion exercises. In 2 weeks, participants were allowed to bear their full body weight on the implant. Rehabilitation was performed twice a week in OIP group training sessions of 2 hours' duration. The average rehabilitation period was 6 to 8 weeks.

Data analysis

Pre-post values of prosthesis use, 6MWT, TUG, and oxygen consumption were analyzed using the Student paired *t* tests. The Q-TFA global score was analyzed with the Wilcoxon test. Data analysis was performed using SPSS software.[e] Data are presented as mean ± SD, median, minimum and maximum values. Statistical significance was set at $P<.05$.

Results

Between May 2009 and May 2011, 22 subjects who had undergone transfemoral amputation because of trauma (n=20) or a tumor (n=2) participated in this study. Twenty-one participants had unilateral transfemoral amputation, and 1 participant had bilateral transfemoral amputations. The mean age ± SD of the study group was 46.5±10.7 years (range, 23–67y) and included 18 men and 4 women. At the time of inclusion, the participants were at an average ± SD of 16.4±14.8 years after amputation (range, 2–45y). Two participants were not able to complete the preoperative walking tests. All participants completed the postoperative walking tests. Three participants used mechanical knee joints, and 19 participants used microprocessor-controlled knee joints in their prostheses. There were no participants lost to follow-up.

Compared with the socket prosthesis, all participants significantly improved prosthesis use and prosthesis-related quality of life (table 2). The Q-TFA global score with OIP was significantly higher (68%) than with a socket prosthesis. Prosthesis use significantly improved by 45%, from 56h/wk with the socket prosthesis to 101h/wk with OIP, and in 6 minutes participants with OIP walked significantly further (27%) than with the socket prosthesis. In the TUG test, participants with OIP were significantly faster (44%) than with the socket prosthesis. With an OIP, TUG completion took 8 seconds, whereas 15 seconds was required with the socket prosthesis. During walking on a treadmill at PWS, participants with OIP used significantly less oxygen (18%) compared with the socket prosthesis.

During the 12-month follow-up period, 8 participants had mild infections of the soft tissue at the OIP skin-penetration area. The average 6MWT and prosthesis use of participants with soft tissue infections was 436m and 99h/wk, respectively. These values did not differ statistically from those of participants without infections—412m and 105h/wk, respectively (Student *t* test: $P=.29$ and $P=.27$, respectively).

Discussion

In this prospective case-control study, we report that OIP improved walking ability and quality of life in subjects with transfemoral amputation who initially presented with socket prosthesis–related skin and residual limb problems. In summary, subjects with OIP were capable of walking further faster while using 18% less energy. In addition, they had significantly better prosthesis-related quality of life compared with their previous situation with the socket prosthesis. Participants with OIP used their prosthesis 14h/d, which is approximately the maximum time for prosthesis use during daytime hours.

The participants in this study were selected based on their poor prosthesis use and socket prosthesis–related limitations. Whether the average subject without socket prosthesis–related limitations will benefit from OIP is not clear. In 2004, Hagberg et al[25] reported a Q-TFA global score ± SD of 62±21 points in 156 individuals using a transfemoral socket prosthesis. In 2009, we performed a pilot study (unpublished data) in 14 individuals with

Table 2 Walking ability and prosthesis-related quality of life

	Socket		OIP		
Measure	Mean ± SD	Median (Min–Max)	Mean ± SD	Median (Min–Max)	*P*
Q-TFA global score (0–100)	39±4.7	42 (8–75)	63±5.3	75 (42–100)	.001
Prosthesis use (h)	56±7.9	56 (1.5–108.5)	101±2.4	98 (56–108.5)	<.001
6MWT (m)	321±28	326 (230–470)	423±21	427 (323–613)	.002
TUG (s)	15.1±2.1	11 (6.3–29.3)	8.1±0.7	7.3 (4.9–15.3)	.002
Oxygen PWS (mL/min)	1330±310	1306 (801–1991)	1093±361	1084 (300–1714)	.001

NOTE. Q-TFA, prosthesis use, and locomotion parameters of subjects using socket prostheses (preoperative assessment) compared with OIP prosthesis (postoperative assessment). The Q-TFA score and prosthesis use were pre- and postoperatively assessed in 22 subjects. The 6MWT, TUG, and oxygen consumption test were preoperatively assessed in 20 subjects and postoperatively in 22 subjects.
Abbreviations: Max, maximum; Min, minimum.

transfemoral amputation visiting our clinic for repeated prescription of a socket prosthesis. In this pilot group, the Q-TFA global score with socket prosthesis was 61±16.9 points. Both of these results are similar to the Q-TFA global score of OIP subjects in this study (63±5.3 points); however, regarding prosthesis use, the pilot group reported 89h/wk, while the OIP group reported 101h/wk. This indicates that individuals with transfemoral amputation who do not experience specific prosthesis-related functional limitations still may benefit from OIP, particularly with regards to hours of prosthesis use.

In 2008, Hagberg et al[13] published the first prospective outcome study in 18 subjects with transfemoral amputation and OPRA. During a 2-year follow-up, 1 subject had pain and implant loosening, and 6 subjects had been forced to temporarily abstain from the OIP because of pain or superficial infections. The remainder of participants in this Swedish study (n=17) reported an average Q-TFA global score of 72 points, which was an improvement of 36 points when compared with that for the socket prosthesis. These Q-TFA global scores are 9 points higher than our results (Q-TFA global score, 63 points), and the reason may be that the follow-up period in Hagberg's group was 1 year longer. In the first year after OIP implantation, participants are more likely to have soft tissue infections, stoma irritation, or residual limb pain. We assume that these complications may explain the lower estimation of the quality of life in our group compared with the results reported by Hagberg.[13]

Study limitations

In this study, the prosthesis use item of the Q-TFA was calculated differently from that reported by the developers of the Q-TFA.[25] We chose to calculate the prosthesis use in hours instead of points because presentation in hours is easier to interpret than points.

In this study, we did not report in detail about adverse events such as infection rates and technical failures because 1-year follow-up is insufficient time to reliably study these aspects of osseointegration. Infections of the soft tissue in the skin-penetration area of the OIP as reported in this study were successfully managed with intensive cleaning with hydrogen peroxide and sometimes antibiotics. In this study, we did not observe deep infections/osteomyelitis or implant failures. There were no subjects who had to abstain from using the OIP. Based on these observations we think that a bone anchorage prosthesis is a safe and satisfactory alternative to a socket prosthesis. Nevertheless, larger studies with longer follow-up are necessary to substantiate this claim. In a subsequent study we plan to investigate adverse events of osseointegration in a larger population with longer follow-up.

The use of walking aids during walking tests was not measured in this study. We measured the walking aid score but did not record which patient used a walking aid in the pre- and posttests.

A lower limb amputation has previously been reported to influence mainly the physical dimensions of the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36).[25] In this study, the Q-TFA was used instead of a more general health survey questionnaire because the scores of the Q-TFA are associated with SF-36 dimensions primarily reflecting physical health.[25]

Conclusions

Osseointegration is a suitable intervention for individuals with transfemoral amputation performed because of trauma or tumor, who have reduced prosthesis use as a result of socket-related residual limb/skin problems. In 1-year follow-up, subjects with OIP significantly increased walking ability and prosthesis-related quality of life.

Suppliers

a. Orthodynamics Ltd, Industrial Park, Bourton on the Water, Gloucestershire, GL54 United Kingdom.
b. Integrum AB, Krokslätts Fabriken 50, 43137, Mölndal, Sweden.
c. Cosmed Srl, Via del Piani di Monte Savello 27, 00041 Pavona di Albano, Rome, Italy.
d. OTN bv, De Weertjes 1120, 6605 RD Wychen, The Netherlands.
e. IBM Corp, 1 New Orchard Rd, Armonk, NY 10504-1722.

Keywords

Amputation; Function; Osseointegration; Prosthesis; Quality of life; Rehabilitation

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