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ORIGINAL ARTICLE

Outcome of Percutaneous Osseointegrated Prostheses for Patients With Unilateral Transfemoral Amputation at Two-Year Follow-Up

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Abstract

Objective: To report outcomes regarding general and specific physical health-related quality of life of treatment with percutaneous osseointegrated prostheses.

Design: Prospective 2-year case-control study.

Setting: University hospital.

Participants: Individuals (N=39; mean age, 44±12.4y) with unilateral transfemoral amputation as a result of trauma (n=23), tumor (n=11), or other cause (n=5). At baseline, 33 of the 39 participants used socket-suspended prostheses.

Intervention: Osseointegrated prosthesis.

Main Outcome Measures: Questionnaire for Persons with Transfemoral Amputation (Q-TFA), Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) physical functioning (PF) and physical component summary (PCS), SF-6D, and Physiological Cost Index (PCI).

Results: At 2 years postimplantation, 6 of 7 Q-TFA scores improved ($P<.0001$) compared with baseline (prosthetic use, mobility, problem, global, capability, walking habits). The walking aid subscore did not improve ($P=.327$). Of the 39 participants, increased prosthesis use was reported by 26, same amount of use by 11, and less use by 2. Improvement was reported in 16 of the 30 separate problem items ($P<.05$). Unchanged items included problems regarding phantom limb pain and pain from the back, shoulders, and contralateral limb. The PF, PCS, and SF-6D improved a mean of 24.1 ± 21.4 ($P<.0001$), 8.5 ± 9.7 ($P<.0001$), and $.039\pm .11$ ($P=.007$) points, respectively. Walking energy cost decreased (mean PCI at baseline, .749; mean PCI at follow-up, .61; $P<.0001$).

Conclusions: Two years after intervention, patients with a unilateral TFA treated with an OPRA implant showed important improvements in prosthetic function and physical quality of life. However, walking aids used and the presence of phantom limb pain and pain in other extremities were unchanged. This information is valuable when considering whether percutaneous osseointegrated prostheses are a relevant treatment option. Archives of Physical Medicine and Rehabilitation 2014;95:2120-7

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A bone-anchored artificial limb is currently an option for select patients with an amputation. Only a few different implant methods are currently used in humans.^{1,2} Thus far, individuals with a transfemoral amputation (TFA) as a result of trauma or tumor have

been the largest group treated. The general aim, regardless of method, is to create the opportunity for prosthesis attachment directly to the bone via an implant protruding into the residual limb, making it possible to wear a prosthesis without a prosthetic socket. This avoids socket-related problems in terms of discomfort, sores/skin irritation, pain, and/or unreliable suspension that have been shown to negatively affect prosthetic mobility and quality of life in large numbers of patients with amputation.³⁻⁶ To achieve bone anchorage, the methods described in this article

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require 2 surgeries with differing implant designs, surgical techniques, and rehabilitation regimens.^{7,8}

The described benefits of bone-anchored prostheses include enhanced comfort, increased range of motion, improved mobility, and fewer visits to the prosthetist compared with socket-suspended prostheses.^{2,9-12} Moreover, increased prosthetic use, improved health-related quality of life (HRQOL), and fewer problems in daily living have been reported.^{13,14} Gait characteristics and implant loading during different activities have been studied.¹⁵⁻¹⁷ However, prospective studies, including studies with larger numbers of patients, have been sparse to date. Brånemark et al¹⁸ recently published the largest prospective study to date on the 2-year outcomes of general and specific HRQOL and success rate in 51 subjects with TFA treated with the OPRA implant system^a in Sweden, the so-called OPRA study. Another recent study from The Netherlands reports prosthetic-related quality of life at 1-year follow-up for 22 subjects with TFA treated with the Integrated Leg Prosthesis implant system.⁸ Both describe significant improvements with regard to greater prosthesis use and improved function compared with the situation before treatment. However, both include patients with unilateral and bilateral TFA, which makes it difficult to generalize the results to the first group. Moreover, detailed results relating to the physical HRQOL outcome assessed in the OPRA study have not yet been reported. In the process of making decisions about whether bone-anchored prostheses are an adequate treatment option for individuals, this kind of information is valuable for patients and clinicians, but it is also valuable in health-economy evaluations. Further, prospective studies reflecting the effectiveness of prosthetic interventions in terms of mobility, daily living, and HRQOL have been recommended.^{19,20}

The aim of the current study is to report the prospective outcome, including details not yet reported, regarding prosthetic function, problems, and physical HRQOL in the subset of individuals with a unilateral TFA included in the OPRA study and followed for 2 years.

Methods

The OPRA treatment involves 2 surgeries 6 months apart, followed by a careful increase in implant loading and prosthetic activity over at least 6 months, resulting in a treatment period of about 1 year.^{7,18} The OPRA study is composed of 51 patients treated with 55 implants ($n=45$ unilateral TFA, $n=6$ bilateral TFA of whom 4 were treated bilaterally) enrolled in the study from 1999 through 2007. Specific demographics have previously been described.¹⁸ The OPRA study protocol comprises assessments of function and HRQOL at 3 time points: baseline (prior to the first surgery) and at 1 and 2 years after the second surgery.¹⁸ Patient-reported outcomes were collected using 2 validated questionnaires: Medical Outcomes Study 36-Item Short-Form

Health Survey (SF-36)²¹ and Questionnaire for Persons with Transfemoral Amputation (Q-TFA).²²

The SF-36 is a generic measurement of health composed of 8 subscales and 2 summary component scores. They all evaluate general HRQOL within a range of 0 to 100 points, with 0 indicating poor status and 100 indicating good status.^{21,23} The summary scores are normalized to a mean 50 ± 10 for a healthy population. A preference-based single index measurement of health has been estimated from the SF-36. This measurement, the SF-6D, is constructed from 11 items and is used in health economy evaluations. The SF-6D has been valued by a representative sample of the United Kingdom general population using the standard gamble valuation technique into a scale, where 1 is full health and 0 means death.²⁴ In the current study, the SF-36 subscale of physical functioning (PF), physical component score (PCS), and SF-6D are reported.

The Q-TFA²² evaluates amputation- and prosthesis-specific HRQOL among individuals with TFA and results in 4 main scores: prosthetic use, mobility, problem, and global. All scores result in a value between 0 and 100, where a higher value refers to a better outcome, apart from the problem score, where a lower value means fewer problems. The prosthetic use score constitutes a combination of day of the week and hours per day the patient normally chooses to wear a prosthesis. A score of 100 means that a prosthesis is worn 7d/wk for ≥ 15 h/d, and 0 means not wearing a prosthesis any day of the week. The measurement error is ± 12 points, and a score ≥ 90 is regarded as a very large amount of prosthesis use. The mobility score constitutes the average of 3 subscores: capability, walking aid, and walking habits. All scores range from 0 to 100. The capability subscore includes 12 items on prosthetic function (ie, walking up/down a hill, walking while carrying a tray, sitting in comfort in a low chair) answered with yes, no, or never tried. The walking aid subscore asks about the normative use of walking aids in connection with use of the prosthesis at home and outdoors. In the walking habit subscore, the patient reports how often different predefined walking distances outdoors without stopping have been completed. The problem score includes 30 items on troubles perceived because of the amputation and prosthesis, and each is rated on a 5-point interval scale (0=no trouble; 4=great deal of trouble). The global score includes 3 questions, one of which can be answered regardless of prosthesis use. This single question reports the patient's perception of his/her overall situation as an amputee on 5 levels (extremely poor, poor, average, good, extremely good).

The Physiological Cost Index (PCI) was used to assess energy cost during walking with the prosthesis. In short, it includes measuring heart rate at rest and at a comfortable walking speed in a steady-state condition and results in an index representing the number of extra heartbeats per meter of walking.²⁵ Patients walked indoors at their comfortable speed for 5 minutes supported by their normative choice of walking aid. The PCI protocol has shown acceptable reliability among individuals with lower-limb amputation.²⁶

Although not part of the OPRA study protocol, a description of the prosthesis at each time point was included in the current study. This was recorded by a certified prosthetist and is described in table 1.

All patients included in the OPRA study gave their written informed consent, and the study was approved by the regional ethics board.

List of abbreviations:

HRQOL	health-related quality of life
PCI	Physiological Cost Index
PCS	physical component summary
PF	physical functioning
Q-TFA	Questionnaire for Persons with Transfemoral Amputation
SF-36	Medical Outcomes Study 36-Item Short-Form Health Survey
TFA	transfemoral amputation

Table 1 Prosthetic components

Prosthetic Details	Baseline (N=35)	1-y Follow-Up (N=39)	2-y Follow-Up (N=39)
Category of knee joint component			
Polycentric cadence responsive knee	10 (29)	12 (31)	10 (26)
Polycentric knee	0 (0)	1 (3)	0 (0)
Single-axis cadence responsive knee	20 (57)	20 (51)	23 (59)
Single-axis friction knee	0 (0)	6 (15)	6 (15)
Single-axis stance-locking knee	5 (14)	0 (0)	0 (0)
Category of foot component			
Dynamic foot	26 (74)	29 (74)	28 (72)
Multiaxis foot	4 (11)	10 (26)	11 (28)
Single-axis foot	5 (14)	0 (0)	0 (0)
Prosthetic socket design			
Quadrilateral	11 (32)*	NA	NA
Ischial Containment Socket	20 (59)		
Marlo Anatomical Socket	3 (9)		
Suspension type			
Vacuum (skin suction)	24 (69)	NA	NA
Vacuum with liner	1 (3)		
Liner with pin or string lock	10 (29)		
Prosthetic weight (kg)	3.9±0.52, 4.0 (2.5–5.0)†	3.9±0.43, 3.85 (2.9–4.9)‡	3.9±0.48, 3.9 (2.9–4.9)‡

NOTE. Values are n (%) or mean ± SD, median (minimum–maximum). Missing values are the result of no information on prosthesis details at baseline or not recorded at the assessment.

Abbreviation: NA, not applicable.

* n=34.

† n=33.

‡ n=38.

Statistical evaluation

Demographic data are presented as n (%), mean, and median. For descriptive purposes, outcome data are presented for all 3 time points: baseline, 1 year postimplantation, and 2 years post-implantation. Analyses of differences are presented to compare data between baseline and 2-year follow-up. For patient-reported data, nonparametric analyses were used. Differences in scores were analyzed using the Wilcoxon signed-rank test. For analyses of differences in single items, the sign test was used. Because of the risk of multiple comparisons, the Bonferroni-Holm method²⁷ was used to adjust *P* values in the analyses of changes in each of the 30 Q-TFA problem items. The paired Student *t* test was used for analyses of differences in the PCI. The significance level was set at *P* < .05. SPSS version 21^b was used for all statistical calculations.

Results

The results showed that 6 of 45 subjects with a unilateral TFA were not followed for 2 years for varying reasons (implant removed because of complications: n=3, deceased: n=1, lost to follow-up: n=1, withdrawn because of problems with contralateral limb: n=1).¹⁸ As a result, the data reported in this study are based on 39 subjects (17 men, 22 women) with unilateral TFA. The amputation was the result of trauma (n=23), tumor (n=11), or other cause (n=5). The mean age at amputation was 31±14.8 years, and mean age at inclusion was 44±12.4 years. Seven (18%) had ≥1 additional disabilities causing a functional

limitation (foot injury: n=3, knee injury: n=1, transtibial amputation: n=1, paralytic arm: n=2). The length of the residual limb was classified as long in 4 cases (10%), medium in 27 cases (69%), and short in 8 cases (21%).²⁸ At inclusion, 33 subjects (85%) used socket-suspended prostheses, whereas 6 (15%) were not using prostheses. The subjects were citizens from 3 European countries (Sweden: n=21, Norway: n=12, Spain: n=6).

At the 2-year follow-up, 38 of the 39 subjects reported using the bone-anchored prosthesis. One individual did not use the prosthesis at all because of loading pain, and the implant was subsequently found to have loosened and was removed.

Patient-reported outcomes in terms of the SF-36 (PF, PCS, SF-6D) and all Q-TFA scores are presented in table 2. Compared with baseline, the results showed statistically significant improvements (*P* < .0001) in all Q-TFA scores except the Q-TFA walking aid subscore. The mean improvement in PF, PCS, and SF-6D was 24.1±21.4 (*P* < .0001), 8.5±9.7 (*P* < .0001), and .039±.11 (*P* < .007), respectively.

A very high Q-TFA prosthetic use score (≥90) was reported by 11 subjects (28%) at baseline, and 23 (61%) and 27 subjects (69%) at 1 and 2 years, respectively. The individual change in prosthesis use, based on a change exceeding ±12 points, between the 2-year follow-up and baseline showed that 26 subjects (67%) reported more use, 11 (28%) reported the same amount of use, and 2 (5%) reported less prosthesis use. Of the 2 cases reporting less use, one was not able to use the prosthesis at all because of pain, and the other case used the prosthesis less because of a hip fracture causing delayed rehabilitation.

Table 2 Results of self-reported general and specific HRQOL in terms of SF-36, SF-6D, and Q-TFA scores

Score	Baseline	1-y Follow-Up	2-y Follow-Up	P (baseline–2y)
SF-36				
PF	35.7±21.3, 30 (0–85)	59.0±18.9, 60 (15–85)	60.0±21.4, 60 (10–90)	<.0001
PCS	32.1±9.1, 30.5 (18–55)	40.5±10.2, 42 (24–62)*	40.5±9.8, 42 (19–57)	<.0001
SF-6D	.653±.094, .65 (.44–.84)	.682±.091, .70 (.41–.84)*	.692±.108, .71 (.43–.87)	.007
Q-TFA				
Prosthetic use score	52±36.7, 71 (0–100)	83±20.2, 90 (0–100)*	84±24.2, 90 (0–100)	<.0001
Mobility score	56±16.2, 56 (19–81) [†]	66±16.8, 70 (17–91) [‡]	69±16.1, 74 (30–91)*	<.0001
Capability subscore	58±16.2, 58 (25–83) [†]	79±19.6, 83 (0–100) [‡]	83±14.5, 83 (42–100)*	<.0001
Walking aid subscore	75±24.3, 83 (33–100) [†]	69±24.6, 83 (5–100) [§]	75±22.1, 83 (33–100)	.327
Walking habit subscore	36±18.5, 35 (0–75) [†]	51±17.7, 50 (10–80) [§]	50±22.5, 57.5 (0–85)*	<.0001
Problem score	43±19.1, 43 (5–77) [†]	15±8.8, 13 (2–40) [§]	16±11.3, 13 (1–49)*	<.0001
Global score	38±18.5, 33 (8–92) [†]	75±16.4, 75 (42–100) [§]	76±17.4, 75 (33–100)*	<.0001

NOTE. Values are mean ± SD, median (minimum–maximum) or as otherwise indicated. Unless otherwise stated, n=39. Calculation of scores of Q-TFA has previously been published.²² Each score results in a value between 0 and 100. Q-TFA mobility score (and subscores for capability, walking aid, and walking habit), problem score, and global score cannot be calculated if prosthesis is not used at least 1d/wk.

* n=38.

† n=33.

‡ n=36.

§ n=35.

|| n=37.

Figure 1 illustrates the patients' perception of the overall situation regardless of prosthesis use (1 item in the Q-TFA global score). The situation was rated as good or extremely good by 11 subjects (28%) at baseline and 31 subjects (79%) at the 2-year follow-up. Figure 2 illustrates the percentage of patients reporting less, the same, or more trouble for each item in the Q-TFA problem score at 2 years when compared with baseline. Significantly less trouble was reported in 16 of the 30 items, and no item was reported to be significantly more troublesome at follow-up. The Q-TFA walking habit subscore at baseline showed that 7 of 33 subjects (21%) had walked ≥500m outdoors at least several days per week during the last 3 months, and this figure increased to 20 (56%) of 36 patients at 1 year and 20 (53%) of 38 patients at

2 years. Figure 3 illustrates the longest walking distance that had been covered at least several days per week.

Results from the PCI are presented in table 3. Energy cost was significantly reduced at 2 years ($P<.0001$) compared with baseline among the subset of 27 subjects that performed the measurement on both occasions (see table 3). There was no significant difference in heart rate at rest or walking speed between assessments, whereas the heart rate was reduced while walking with the bone-anchored prosthesis ($P=.006$).

There was no change in prosthetic weight between assessments. After treatment, prosthetic knee components with single-axis friction and multiaxis feet were more commonly used (see table 1).

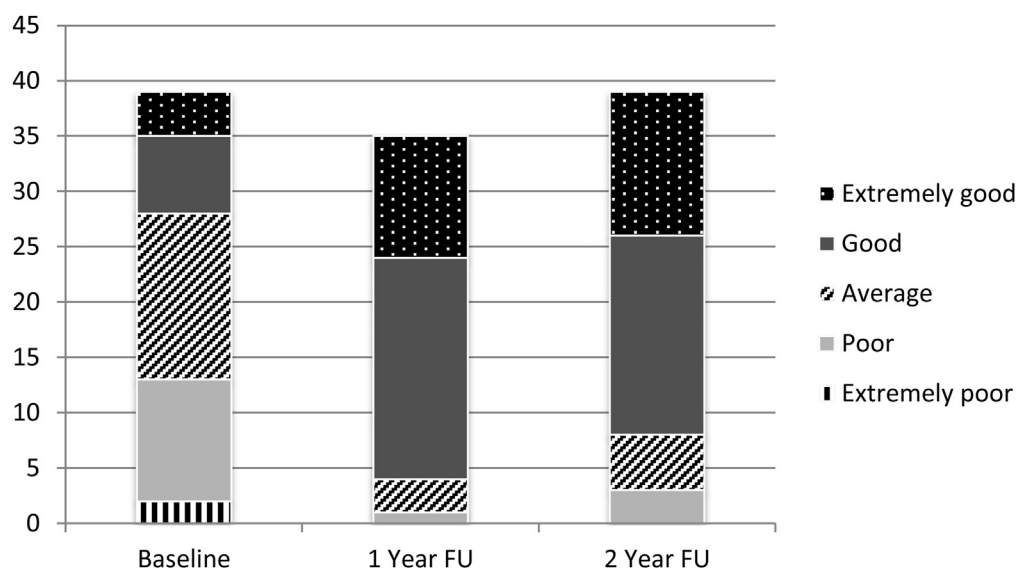


Fig 1 Amputee status regardless of prosthesis use at baseline and 1- and 2-years postimplantation FU. Number of answers for each category of the single question included in the Q-TFA global score. Abbreviation: FU, follow-up.

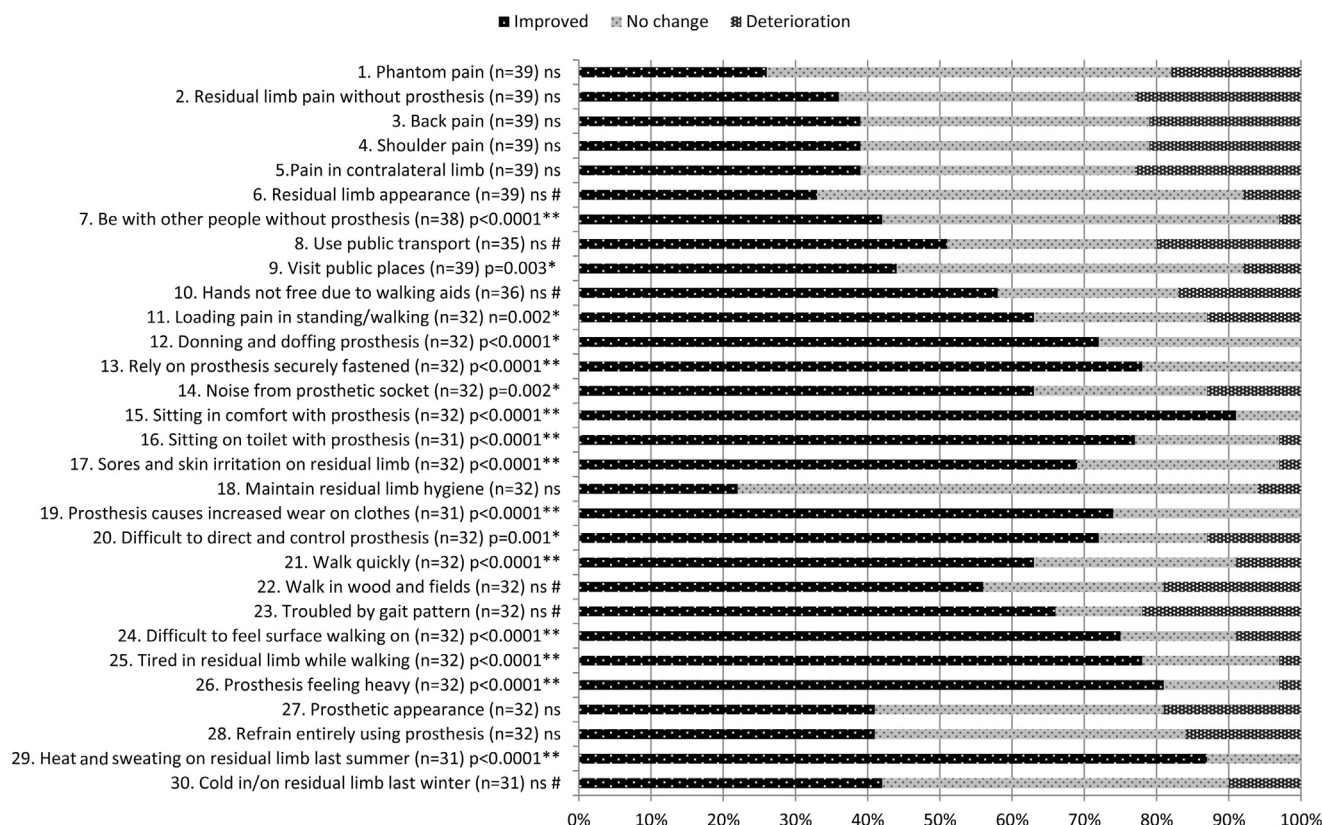


Fig 2 Percentage of subjects reporting improvement, no change, or deterioration for each item in the Q-TFA problem score at 2-year follow-up compared with baseline. Items 1 through 10 are related to problems regardless of prosthesis use, and items 11 through 30 are related to problems in connection with prosthesis use. The degree of the problem for each item was rated as 0 (no trouble), 1 (slight trouble), 2 (moderate trouble), 3 (considerable trouble), and 4 (great deal of trouble). Exact *P* values are calculated before the adjustment for multiple comparison. Abbreviation: NS, nonsignificant after adjustment for multiple comparison. *Adjusted *P* value, *P*<.05. **Adjusted *P* value, *P*<.001. #Item with significant difference before adjustment for multiple comparison.

Discussion

This prospective study focused on individuals with a unilateral TFA treated with osseointegration and followed for 2 years. The results confirm earlier publications reporting that patients treated with the OPRA show important improvements with regard to prosthetic mobility and HRQOL.^{13,14} In the evaluation of whether or not a bone-anchored prosthesis is an adequate treatment alternative, the patient should be given detailed realistic information, including possible benefits and complications. Complications in terms of infections, implant loosening, and mechanical failures constitute key information of this kind and have previously been reported.^{7,18,29} However, the aim of the current study was to report more detailed information on physical HRQOL and functional outcomes of patients with a unilateral TFA treated with the OPRA.

Most of the 39 subjects reported very high prosthesis use at follow-up, and the prosthetic use score was significantly improved compared with baseline (see table 2). Van de Meent et al⁸ presented similar results at the 1-year follow-up of 22 subjects with Integrated Leg Prostheses. Daily prosthesis use for ≥ 15 hours is in fact rarely described at all among individuals with socket-suspended TFA prostheses^{3,30-33} and reflects one of the main benefits of bone-anchored prostheses. However, not every single subject reported such a large degree of prosthesis use, and 2 subjects (5%) reported a decrease compared with baseline.

Another main benefit of bone-anchored attachments is a decline in socket-related problems resulting in a lower Q-TFA problem score (see table 2) and a statistically significant improvement in 16 of the 30 items (see fig 2). Improved items, as shown in figure 2, include less trouble with sitting, reliability of prosthesis suspension, donning prostheses, and sweating of the residual limb during the summer. This improvement in everyday living was confirmed by an in-depth interview-based study of 13 individuals treated with the OPRA.¹⁴ However, items with no significant change should be noted and include problems with regard to phantom limb pain and pain in other parts of the body (back, shoulders, contralateral leg) (see fig 2). Pain of this kind has frequently been described as bothersome to individuals with amputations.^{6,33-36} Other items not rated as being changed related to maintaining residual limb hygiene and residual limb appearance. This shows that the daily cleaning of the implant-skin penetration area and the protruding screw sticking out of the limb are not reported as troublesome after treatment. Finally, about 80% reported fewer problems with regard to the prosthesis feeling heavy (see fig 2, item 26), despite the fact that the prosthesis weight was unchanged between assessments (see table 1). This suggests a difference between prosthesis anchorage and suspension to the residual limb.

The increase in walking habits (see table 2 and fig 3) constitutes another key outcome. Geertzen et al³⁷ argued that individuals with lower-limb amputations need to be able to walk at least 500m for adequate independence. In a meta-analysis, Penn-

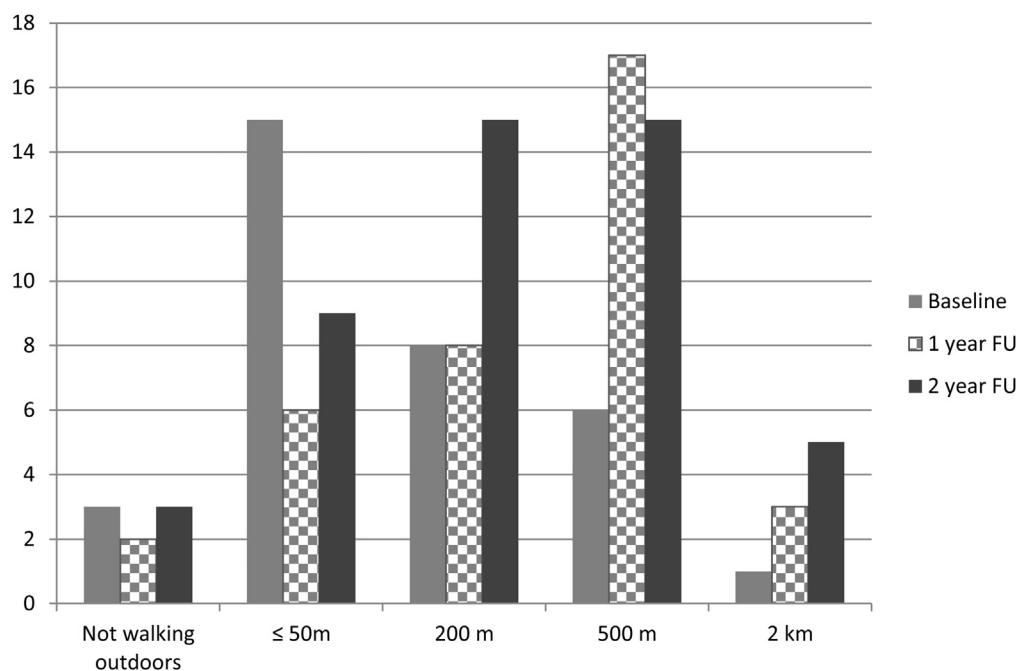


Fig 3 Self-reported longest walking distance outdoors without stopping, being covered daily or several days per week during the last 3 months at baseline and 1- and 2-year FU. The number of subjects is reported. Abbreviation: FU, follow-up.

Barwel³¹ showed that 55% of individuals with a unilateral TFA as a result of trauma ($n=203$) had that ability. In the current study, only 21% reported that they had walked 500m without stopping several days per week at baseline. This increased to >50% at follow-up. However, there are differences between ability and performance (can walk, have walked). Despite more walking, many patients used a walking aid, and the walking aid subscore showed no change between assessments (see [table 2](#)). During the PCI, subjects used their normative walking aid. At baseline, 40% walked unaided compared with 17% and 35% at 1 and 2 years, respectively (see [table 3](#)). However, a single support (1 stick/crutch) was chosen more frequently after treatment (20.5%, 47%, 47%, respectively) (see [table 3](#)). Frequent use of walking aids has previously been described in individuals with lower-limb amputations,^{20,38} and the results suggest that bone-anchored TFA prostheses are not different in this perspective. On the contrary, in our experience, individuals who walked unaided before treatment might be more concerned about risking a mechanical implant complication (eg, because of a fall) and may choose to use a single support for safety when walking longer distances. Recently, Schaffalitzky et al³⁹ stated that minimizing the use of walking aids was not an important outcome with regard to prosthesis use. Instead, improved quality of life and comfort while walking and sitting were reported as important outcomes.³⁹ This is in line with the benefits of bone-anchored prostheses.

The PCI showed reduced energy cost at 2-year follow-up compared with baseline (see [table 3](#)). This is in line with the reduced energy consumption recently shown for bone-anchored Integrated Leg Prostheses.⁸ Details of the PCI assessment showed no difference in resting heart rate or speed but showed lower heart rate while walking (see [table 3](#)). Hypothetically, the reduced PCI reflects less demand to control the prosthesis. Moreover, the slower speed and more frequent use of walking aids at 1 year (see [table 3](#)) reflect that many patients are still in a rehabilitation phase after 1 year.

Clinical trials should include general and specific measurements of HRQOL. The SF-36 is a general measurement that is frequently recommended,⁴⁰ and with regard to the OPRA study, all SF-36 scores have previously been reported.¹⁸ In the current study, we opted to include only the PF and PCS because they are the main SF-36 scores reflecting physical HRQOL. In a recent publication,⁴¹ SF-36 scores were reported for 241 patients (including 33 with amputation) an average of 5 years after a wartime extremity vascular injury. They reported that the mean scores for the PF and PCS were 42.3 and 43, respectively. Our scores at baseline were lower (PF: 35.7, PCS: 32.1), but at 2 years the PF score was substantially higher (60) and the PCS was at approximately the same level (40.5) (see [table 2](#)). In general, our PF and PCS scores at baseline are in line with or lower than those previously reported for similar groups of patients (with amputations or limb-sparing surgery). At follow-up the situation is reversed, meaning that the scores are in line with or higher than those previously reported.^{3,31,32,42,43} To our knowledge, the SF-6D has not been previously described for individuals with amputations. The mean improvement in the SF-6D in the current study was .039. Based on the minimally important difference for the SF-6D reported in 2 different publications (.033 and .041),^{44,45} an improvement of this size can be regarded as important.

Taken as a whole, the generally poor findings at baseline (eg, low prosthesis use, low PF score) indicate that this subset of individuals included in the OPRA study had a difficult situation before treatment, consistent with the indications for the OPRA treatment. From this perspective, the high degree of prosthesis use and small number of problems after treatment can be regarded as even more impressive.

Study limitations

Study limitations include the shortcomings of any self-reported measurement with regard to the subjective nature of the data

Table 3 Results of the PCI during 5 minutes of walking indoors at a comfortable speed

Variable	Baseline (n = 30)	1-y Follow-Up (n = 36)	2-y Follow-Up (n = 34)	P (baseline–2y)
Heart rate at rest	76±11.3, 74 (54–115)	76±10.8, 74 (57–99)	76±9.9, 76 (55–96)	NS
Heart rate at work*	117±16.6, 118 (92–156)	111±17.2, 109 (78–185)	110±13.1, 111 (68–134)	.006
Distance during 5min walk	280±63.7, 274 (132–403)	264±63.0, 253 (140–367)	290±66.6, 292 (114–390)	NS
Comfortable walking speed	56.1±12.7, 54.7 (26.4–80.6)	52.8±12.6, 50.6 (28.0–73.4)	57.9±13.3, 58.4 (22.8–78.0)	NS
PCI†	0.749±0.247, 0.735 (0.330–1.260)	0.702±0.346, 0.615 (0.300–1.770)	0.610±0.237, 0.555 (0.240–1.470)	<.0001
Walking aid used‡				
No aid	12 (40)	6 (17)	12 (35)	NT
1 stick/crutch	8 (20.5)	17 (47)	16 (47)	NT
2 sticks/crutches	8 (20.5)	2 (33)	6 (18)	NT
Other aid	2 (5)	1 (3)	0 (0)	NT

NOTE. Values are mean ± SD, median (minimum–maximum); n (%); or as otherwise indicated. Reason for missing values at baseline includes no prosthesis (n=5), could not fit the prosthesis on day of assessment (n=1), and other reasons (n=3). Reason for missing values at 2 years includes other disease or pain in other part of the body on day of assessment (n=3), not using prosthesis at all because of loading pain (n=1), and other reason (n=1).

Abbreviations: NS, not significant; NT, not tested.

* Heart rate at work was calculated from the last 3 minutes during 5 minutes of walking to enable a steady-state condition.

† PCI was calculated by heart rate at work – heart rate at rest/comfortable walking speed.

‡ Subjects were instructed to use the walking aid they would normally choose if walking for 5 minutes without stopping. The walking aid used was registered.

captured. Moreover, the group of participants is still fairly small and because some outcome measures demand prosthesis use, results for an even smaller number were presented in separate parts of this study. In some cases, components were changed between assessments (see table 1), which might have influenced the results. Future research needs to evaluate the influence of different kinds of prosthetic components on mobility with bone-anchored prostheses. Finally, 2 years cannot be regarded as long-term follow-up in light of limb loss being a lifelong disability. However, to our knowledge, there is no other prospective study of individuals treated with bone-anchored TFA prostheses that has presented results for a larger group or a longer period. Larger studies with a longer follow-up are definitely needed when it comes to bone-anchored amputation prostheses.

Conclusions

This prospective study showed increased and large-scale daily prosthesis use, reduced problems, improved mobility, including more walking and decreased energy cost, and improved physical HRQOL in individuals with a unilateral TFA treated with the OPRA implants and followed over 2 years. However, there was no significant change in use of walking aids, trouble reported with regard to phantom limb pain, and pain problems from the back, shoulders, and contralateral limb compared with baseline. Taken as a whole, this is important information for patients and clinicians when considering whether any bone-anchored, and particularly osseointegrated, TFA prosthesis could be a treatment option. In addition, results from the SF-6D can form basis for a health-economy evaluation of the OPRA treatment.

Suppliers

- Integrum AB, Kroksläts Fabriker 50, 43137 Mölndal, Sweden.
- IBM Corp, 1 New Orchard Rd, Armonk, NY 10504-1722.

Keywords

Artificial limbs; Osseointegration; Quality of life; Rehabilitation

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