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Significance & Hypothesis/Techniques: For transfemoral amputees, osseointegrated prosthetics present an alternative to a traditional socket interface, by anchoring an external prosthesis to an implant fixed in the residual femur, thereby reducing issues with socket wear. Early studies report improved ambulation and quality of life. We conducted a prospective study, recording patient-reported outcomes (PROs) and adverse events in 21 patients with transfemoral amputations who underwent placement of a percutaneous bone anchored prosthesis using the Osseointegrated Prostheses for the Rehabilitation of Amputees (OPRA)™Implant System.

Innovation: OPRA™is the first FDA-approved osseointegrated implant for transfemoral amputees in the United States. OPRA™has three major components: the fixture, abutment, and abutment screw, which attaches to an external prosthetic leg through using a connecting device (Axor II). The continuous connection between the implant and external prosthetic leg allows OPRA™to bypass problems commonly reported with socket prostheses, such as pain and discomfort.

Approach: Our prospective study examined functional and patient-reported outcomes in 21 of 23 patients who completed the 2-staged OPRA™ procedure and had at least 2 years of postoperative follow-up. A retrospective chart review was performed to analyze re-operations and complications among this cohort until present-day. Patient-reported outcomes (PROs) collected through Q-TFA, OPUS, and EQ5D at baseline and 24 months were compared using the Wilcoxon Signed Rank Test.

Results: The mean age at Stage 1 surgery was 50 years [range: 21-65yrs] and the most common indication for amputation was trauma [n = 14; 67%]. Soft tissue infections [n = 11; 52%] were the most common complication and did not require reoperation (Table 1), followed by soft tissue redundancy [n = 12; 48%], three (14%) of which required reoperation. Twenty-one reoperations were performed in 15 patients, eight (33%) due to deep infection, three (14%) of which were explantations. Unexpected dislodgement or release of the AXOR II failsafe device occurred in nine (43%) patients, resulting in four falls. Additional issues including popping and clicking, or issues with loosening and tightening the Axor device in 13 (62%) patients. The cohort experienced improvements across all Q-TFA domains, EQ-5D-5L index values and EQ VAS scores from baseline to 2-year follow-up (Figure 1). Additionally, OPUS Device and Service satisfaction scores also improved over this time period.

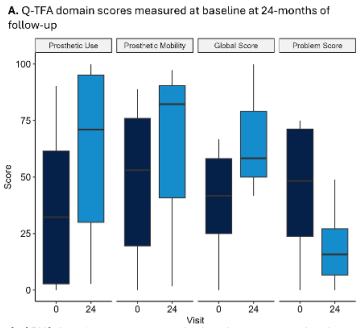
Discussion & Impact: Patient reported outcomes across the Q-TFA, EQ-5D-5L, EQ VAS, and OPUS show improvements in prosthetic use and mobility, and overall health and wellbeing among patients with unilateral transfemoral amputations who received the OPRA™ implant. Fifteen (67%) of patients required reoperation, largely due to infection or soft tissue redundancy. Sixty-two percent of our patients experienced issues with the AXOR II connector, which complicated their rehabilitation, ambulation, and increased the risk for falls. Despite these concerns, patients report fewer problems and greater usage of their prosthesis. Ultimately, osseointegrated implants offer an alternative to traditional sockets for patients with transfemoral amputations, but have high re-operation rates and mechanical issues, as well as a need to reduce infection risk, to maximize function and quality of life for patients who use the OPRA™system.

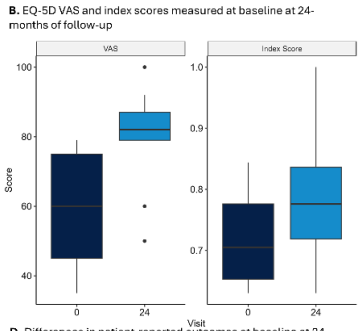
Table 1. Complications and Reoperations

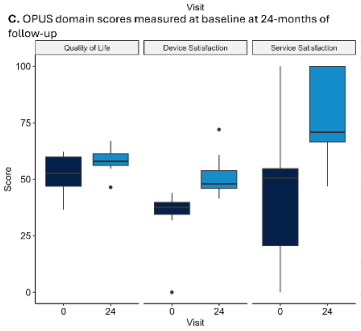
Category and type	Number of Complications (% of total cohort, n=21)	Reoperation (% of total cohort, n=21)
Infection	40 (62%)	
Superficial	28 (52%)	0
Deep[1]	12 (33%)	8 of 12 (24%)
Soft tissue envelope	16 (62%)	
Redundancy	12 (48%)	5 of 12 (14%)
Necrosis	1 (5%)	0
Dehiscence	1 (5%)	1 of 1 (5%)
Hematoma	1 (5%)	0
Ulcer	1 (5%)	0
Mechanical	14 (48%)	
Abutment[2]	6 (29%)	6 of 6 (29%)
Abutment screw	5 (24%)	2 of 5 (10%)
Graft screw and/or washer	3 (14%)	0
Periprosthetic fracture	3 (14%)	
Intertrochanteric	2 (10%)	2 of 2 (10%)
Femoral neck	1 (5%)	1 of 1 (5%)
Other	4 (19%)	
Pain	2 (10%)	2 of 2 (10%)
Heterotopic ossification	1 (5%)	1 of 1 (5%)
DVT and PE	1 (5%)	0

[1]Three patients underwent explantation
[2]Two patients underwent reoperation due to having a deep infection along with a loose abutment. Both patients were explanted.

Figure 1. Patient Reported Outcomes (Baseline and at 24 months Follow-Up)







D. Differences in patient-reported outcomes at baseline at 24-months of follow-up

	Baseline	24 Months	Difference	p-value[1]
Q-TFA, N = 11				
Prosthetic Use	32.3 (2.8, 61.5)	71.0 (30.0, 95.2)	5.5 (1.4, 43.4)	0.011
Prosthetic Mobility	53.0 (19.6, 76.0)	82.2 (40.8, 90.5)	9.2 (1.1, 29.6)	0.054
Global Score	41.7 (25.0, 58.2)	58.3 (50.0, 79.2)	16.7 (12.7, 33.3)	0.0078
Problem Score	48.3 (23.7, 71.2)	15.8 (6.7, 27.1)	-25.4 (-38.4, -15.3)	0.0059
EQ-5D, N =10[2]				
Index Score	0.72 (0.65, 0.78)	0.78 (0.72, 0.92)	0.08 (-0.02, 0.14)	0.058
VAS	60.0 (45.0, 75.0)	82.0 (79.0, 87.0)	12 (5.0, 35.0)	0.022
OPUS, N = 10				
Quality of Life	52.6 (47.0, 59.8)	57.9 (56.1, 61.2)	4.5 (0.8, 9.4)	0.014
Device Satisfaction	37.5 (34.5, 39.7)	48.0 (45.9, 53.8)	13.5 (10.8, 19.8)	0.0019
Service Satisfaction	50.5 (20.7, 54.7)	70.9 (66.5, 100.0)	42.7 (17.3, 50.5)	0.014

[1]Wilcoxon Signed Rank Test; [2]One patient was missing VAS; all scores are presented as median (interquartile range)