Title

Transfemoral bionic bone-anchored prostheses: What is the margin of safety of load applied by state-of-the-art components?

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Summary

This study showed that the margin of safety of the load applied during daily activities on osseointegrated implant by transfemoral bone-anchored prostheses fitted with selected state-of-the-art components is unlikely to challenge the integrity of healthy residual bone and fixation coupling.

Introduction/ basics

Microprocessor-controlled knees (MPKs) and energy storing and return (ESAR) feet increase efficacy of transfemoral bone-anchored prostheses (BAP), particularly mobility and quality of life.[1, 2] In principle, the design of state-of-the-art components could contribute to increase safety of BAPs (e.g., auto adaptive stance and swing control, stumble recovery and push off functions).[3, 4]

However, little is known about the relationship between fitting of state-of-the-art BAP and load-related adverse events (e.g., infections, loosening, periprosthetic fracture, incidence of fall, breakage of implant parts, removal of implant) (Figure 1).

This study aimed at testing the hypothesis that the forces (F) and moments (M) applied on long (LG), anteroposterior (AP) and mediolateral (ML) axes of the implant by Rheo Knee XC and Pro-Flex XC or LP feet (OSSUR, Iceland) during standardized daily activities have a margin of safety unlikely to challenge the integrity of healthy bone/fixation coupling.

Material method; implementation/ process

BAP-users with transfemoral amputation (TFA) ambulated with an instrumented prosthesis including a connector, a transducer, MKP Rheo Knee XC and ESAR Pro-Flex XC or LP feet as well as their own footwear.[5]

The minimum and maximum load applied on the implant were measured using an iPecsLab (RTC, USA) while participants performed straight level walking, ascending and descending ramp and stairs at a self-selected comfortable pace in non-experimental facilities.

Safety was represented by the factor of safety (FoS= High impact load / absolute maximum load measured during daily activities) and margin of safety (MoS=FoS-1). The high impact loads were based on internal constrains applied on femur of able-bodied during running calculated by Edwards et al (2008).[6]

The use of prosthesis during daily activities was deemed safe when MoS#3 based on the assumption it was sufficient to prevent compromising the integrity, let alone catastrophic failure, of the healthy bone/fixation coupling.

Results

A total of 13 TFAs participated in this study including two females and 11 males fitted with press-fit osseointegrated implant in Australia between Sept 2017 and Aug 2018 (57+/-14 years, 1.78+/-0.08 m, 86.31+/-18.03 kg, 25.921+/-4.734 kg/m2, 17+/-19 years since amputation, 2+/-2 years since osseointegration, 28.38+/-5.69 cm residuum length or 63+/-11% of sound thigh).[5]

This cohort represented approximately 3.25% and 1.3% of the population of TFA fitted with BAP in Australia and worldwide, respectively.

A total of 2,127 steps was analysed. The cadence ranged between 36+/-7 and 47+/-6 strides/min.

The overall minimum and maximum load applied on the osseointegrated implant across all activities ranged between -298 N and 1,322 N or -28 %BW and 161 %BW on FLG, -358 N and 388 N or -31 %BW and 34 %BW on FAP, -56 N and 133 N or -7 %BW and 16 %BW on FML, -22 Nm and 20 Nm or -2 %BWm and 2 %BWm on MLG, -52 Nm and 24 Nm or -6 %BWm and 3 %BWm on MAP,-67 Nm and 88 Nm or -9 %BWm and 11 %BWm on MML, respectively.

As detailed in Table 1, the MoS across all forces and moments ranged between 5 N and 20 %BW as well as 7 Nm and 24 %BWm, respectively.

Discussion/ conclusion; conclusion for the practice

This study provided new evidence suggesting safety of transfemoral BAP fitted with selected state-of-the-art components. It showed that MoF>4 for all forces and moments. This confirmed the hypothesis that the regular daily use of the components tested (i.e., Rheo Knee XC, Pro-Flex XC or LP feet) could hardly be held responsible for mechanical damages of healthy bone/fixation coupling (e.g., periprosthetic fracture).

This study paved the way for further investigations of possible safety benefits of BAP fitted with state-of-the-art components to perform higher impact activities such as running, cycling, lifting load, wearing backpack (e.g., return to active duty in military).[7]
Altogether, this work was a worthwhile contribution toward a better understanding of potential benefits of specific state-of-the-art knees and feet to improve clinical outcomes of direct skeletal attachments for the increasing population of individuals suffering from limb loss considering bionic solutions.

References

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Figure 1. Overview of the relationship between load-related adverse events (e.g., infections, loosening, periprosthetic fracture, incidence of fall, breakage of implant parts, removal of the implant) and efficacy of bone-anchored prostheses relying on osseointegrated implant.

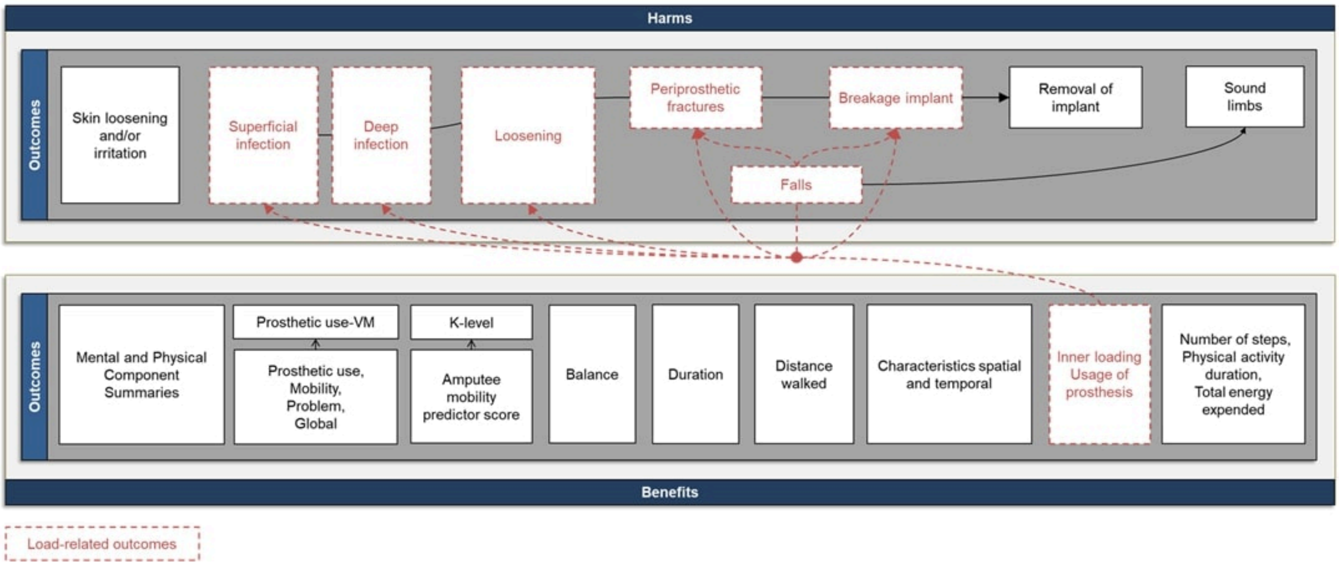

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Table 1. Factor of safety (FoS) and margin of safety (MoS) of three components and forces (F) in N and %BW and moments (M) in Nm and %BWm applied on the long (LG), anteroposterior (AP) and mediolateral (ML) axes of the fixation for cohorts of 13 participants fitted with state-of-the-art ÖSSUR components compared to high impact load applied on the mid-shaft of able-bodied femur during running reported in Edward et al (2008).[6] BW: percentage of the bodyweight (%BW).

	Edwards et al (2008)		State-of-the-art			
	Mean	SD	Mean	SD	FoS	MoS
FLG (N)	6,675.08	454.50	737.72	146.36	9.05	8.05
FAP (N)	698.71	61.05	108.45	48.14	6.44	5.44
FML (N)	1,031.11	108.54	91.70	43.63	11.24	10.24
MLG (Nm)	108.54	6.78	5.34	2.47	20.32	19.32
MAP (Nm)	210.29	13.57	21.93	9.87	9.59	8.59
MML (Nm)	149.24	20.35	25.00	14.00	5.97	4.97
Mean	1,478.83		165.02		10.44	9.44
SD	2,571.56		283.60		5.23	5.23
FLG (%BW)	984.00	67.00	89.06	9.29	11.05	10.05
FAP (%BW)	103.00	9.00	13.03	4.75	7.90	6.90
FML (%BW)	152.00	16.00	11.01	4.44	13.81	12.81
MLG (%BWm)	16.00	1.00	0.64	0.26	24.95	23.95
MAP (%BWm)	31.00	2.00	2.63	1.06	11.79	10.79
MML (%BWm)	22.00	3.00	2.92	1.32	7.53	6.53
Mean	218.00		19.88		12.84	11.84
SD	379.08		34.25		6.40	6.40