Reference

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Degree of Safety Against Falls Provided by 4 Different Prosthetic Knee Types in People With Transfemoral Amputation: A Retrospective Observational Study

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Products

MPKs including C-Leg, Genium and Kenevo vs. NMPKs

Major Findings

With MPKs compared to NMPKs (locked knees (LK), articulating mechanical knees (AMK) and fluid-controlled knees (FK)):

→ Significant association between the knee category and falls with the prosthesis (p=0.038[b])

- Significant difference in the rate of falling between FK and MPKs - Highest rate of falling with FK with 2.81 falls per 1000 days vs. 1.15 falls per 1000 days with MPKs (p = 0.014[a])
- Non-significant but clinically relevant differences between the knee categories FK, AMK, and LKs with and without PS-weighting (falls incidence rate[b] for LK = 1.07, AMK = 1.63, FK = 2.81, MPK = 1.15)

[a]*after propensity score (PS) weighting*

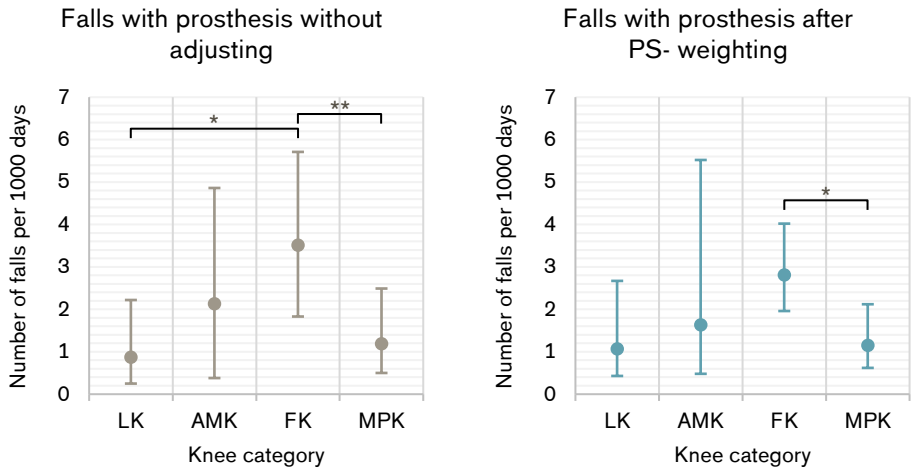

Figure 1: Fall incidence rates (IRs) (95% CI) per knee category. IRs are calculated for falls that occurred while the individual was wearing the prosthesis, without adjusting for confounding effects and after propensity score (PS) weighting. Horizontal lines marked with asterisks indicate statistically significant differences between couples of knee categories. (Legend: *p < .05, **p < .001)

→ Fall incidence rate (IR) on FK higher in patients at first prosthetic outfitting

- Incidence rate ratio (IRR) of 0.47 for prosthetic renewal compared to the first prosthesis provision indicates that the fall incident rate for renewals is less than half of the rate for first prosthesis provision (p = 0.004)
- FK may be too complex to use at first provision and does not provide safety mechanisms

Population

Subjects:	815 subjects (97 = female, 718 = male),
Hospitalizations:	1486 (n = 1352 from male, n = 134 from female)
Amputation level:	unilateral transfemoral, knee disarticulation
Prosthesis type:	MPK (n = 260), FK (n = 334), LK (n = 189), AMK (n = 83), not available (n = 30)
MPK fitting types[b]	C-Leg/C-Leg Compact (67%), Genium (13%), Genium X3 (2%), Kenevo (1%), Rheo Knee (4%), Hybrid Knee (4%), Undefined (9%)
Amputation causes:	Traumatic (77.4%), vascular disease (15.4%), cancer (3.4%), infectious disease (2.6%), congenital (1.3%)
Mean age:	58.1 ± 14.7 years

[b] *breakdown from journal supplemental material providing prosthetic knee grouping for included hospital stays*

Study Design

Retrospective, observational study design (using data from INAIL Prosthesis Centre in Budrio):

Eligibility - Eligible patients were defined as all hospitalizations of individuals with TF or KD amputation aged over 18 years, admitted as an inpatient at INAIL Prosthesis Centre between 2011 and 2017. During the inpatient rehabilitation the patients were fitted with a prosthesis.

Enrollment - Only hospitalizations with signed informed consent from the patient for data treatment for research purposes were enrolled.

Data Collection - Prosthetic knee safety was evaluated based on the occurrence of falls during inpatient rehabilitation while wearing the prosthesis. The patients received theirs first prosthesis during admission for the inpatient rehabilitation, as the outcome. Data were retrieved from patient electronic health records and paper medical records.

The prosthetic knee models fitted were grouped into 4 categories:

- locked knees (LK – 237 locked knees and 14 more functional knees with manual lock),
- articulating mechanical knees (AMKs – 73 friction-brake and 38 4-bar knees with friction swing control),
- fluid-controlled knees (FK – 344 multiaxial knees with fluid swing control and 113 hydraulic stance and swing control knees), and
- microprocessor-controlled knees (MPK – 583 knees in total with breakdown provided in the Population section above).

Results

Functions and Activities								Participation	Environment
Level walking	Stairs	Ramps, Hills	Uneven ground, Obstacles	Cognitive demand	Metabolic Energy Consumption	**Safety**	Activity, Mobility, ADLs	Preference, Satisfaction, QoL	Health Economics

Category	Outcomes	Results for MPKs vs. NMPKs	Sig.[c]
Safety	Risk factors for falls	Significant risk factors for falls with prosthetic use were:	
		• Use of antidepressants (IRR = 3.23, p = 0.0001)	++
		• Use of antiepileptics (IRR = 2.74, p = 0.0005)	++

Category	Outcomes	Results for MPKs vs. NMPKs	Sig.[c]
		• Reason for rehabilitation training: prosthetic renewal (IRR=0.47) vs. first prosthesis provision (p = 0.004) • Time from amputation (IRR = 0.78, p = 0.002) • Amputation cause (p = 0.05) → IRR with respect to cancer: infectious disease = 1.29, congenital = 0.57, traumatic = 0.43 and vascular disease = 0.22 No association with age or sex	++ ++ ++ 0
		Propensity score model[b] was fitted with significant participants risk factors for falls. The maximum mean effect size after PS-weighting over these variables was 0.102 (good balance)	n.a.[b]
	Incidence rate (IR) for falls with prosthesis per 1000 patient days	**LK** | **AMK** | **FK** | **MPK** | **All** 0.87 | 2.13 | 3.51 | 1.19 | 2.08	n.a.
		The knee category was significantly associated with falls with a prosthesis (p = 0.001) before PS weighting.	++
		• FKs have higher fall rate than LKs (p = 0.013) • FKs have higher fall rate than MPKs (p = 0.009)	++ ++
	IR for falls with prosthesis per 1000 patient days PS-weighted	**LK** | **AMK** | **FK** | **MPK** 1.07 | 1.63 | 2.81 | 1.15	n.a.
		The knee category was significantly associated with falls with a prosthesis (p = 0.038[b]) after PS-weighting.	++[b]
		• FKs have significant higher fall rate than MPKs (p = 0.014) • Non-significant but clinically relevant differences between the knee categories – highest fall rate in FKs of all knee joints, followed by AMK, MPK and LK (difference between MPK and LK was neglectable).	++ n.a.

[a] no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)
[b]after propensity score (PS) weigthed

Author's Conclusion

"FK (Fluid-controlled prosthetic knees) expose people with transfemoral amputation to higher risk of falling relative to MPK (microprocessor-controlled knees) during rehabilitation training. These findings are based on a wide cohort of individuals, mostly with traumatic amputation. Future research should investigate the relative efficacy of prosthetic devices on individuals with different social and clinical profiles and assess the generalizability of our findings outside the rehabilitation setting." (Palumbo et al., 2022)

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