Reference

Natascha Raisig [1,2,†], Frank Traub [2,†], Per Otto Schüller [3], Andreas Hahn [4], Johannes Schröter [1,2]

Functional Trajectories of Low-Mobility Transfemoral Amputees with a K2-Specialized Microprocessor Knee: An Exploratory Prospective Observational Study.

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Products

Kenevo

Major Findings

With early Kenevo (MPK) provision compared to delayed/no MPK (Kenevo):

→ Early Kenevo provision is associated with superior mobility outcomes over 24 weeks

- Mean change of PLUS-M T-scores from baseline to final follow-up: +9.9 vs −3.0 points (early MPK vs delayed/no MPK)
- Higher T-score at final follow-up for early Kenevo provision (43.6) vs delayed/no MPK (29.1, r ≈ 0.73)
- Clinically meaningful improvement in patient-reported mobility is more frequent with early Kenevo provision - responders (≥MDC_{95}): 63% vs 17% (early MPK vs delayed/no MPK)

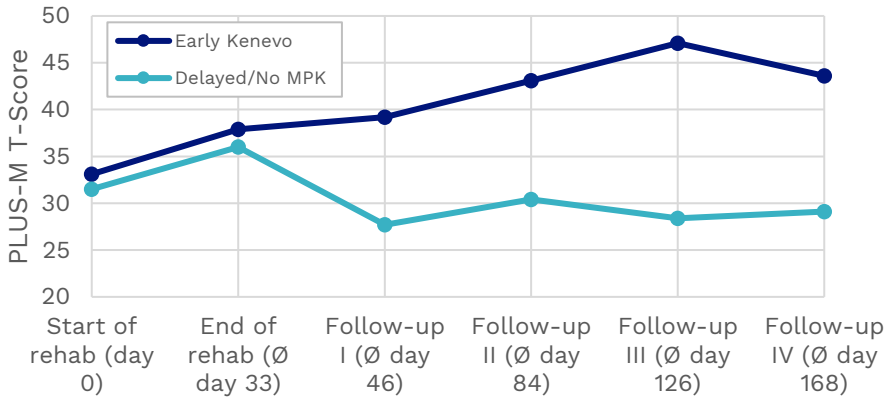


Figure 1. Development of PLUS-M T-Scores over time by prosthetic groups (early Kenevo, delayed/no MPK).

→ Early Kenevo provision leads to higher and sustained improvements in quality of life

- EQ-5D-5L utility at final follow-up: 0.79 vs 0.49 (early MPK vs delayed/no MPK) (effect size r ≈ 0.54), start of rehab from comparable utility scores (0.57 vs. 0.62 (early MPK vs. delayed no MPK)
- EQ-5D-5L VAS at final follow-up: 66 vs 47 (early MPK vs delayed/no MPK), start of rehab from the same VAS of 48 for both groups

→ Early Kenevo provision improves social reintegration, while delayed/no MPK declines

- Reintegration into normal living index at final follow-up: 75% vs 28% (early MPK vs delayed/no MPK, r ≈ 0.81)

- Clinically meaningful improvement in social reintegration more common with early Kenevo provision - responders (≥MCID): 38% vs 20% (early MPK vs delayed/no MPK)

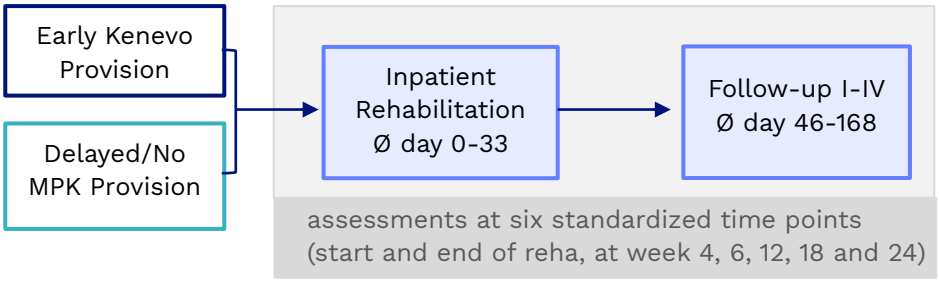
Population

Subjects:	early Kenevo: n=8, 38% female delayed/no MPK: n=6, 33% female
Amputation causes:	early Kenevo: dysvascular 62%, infection 13%, other 25% delayed/no MPK: dysvascular 100%
Median age:	early Kenevo: 68 years (IQR 4) delayed/no MPK: 74 years (IQR 5)
Amputation level:	knee disarticulation, transfemoral
MFCL:	anticipated K1-K2
FCI *:	early Kenevo: 2.0 (IQR 1.0) delayed/no MPK: 2.0 (IQR 0.8)
Median time to first prosthesis:	early Kenevo: 46 days (IQR 16) delayed/no MPK: 26 days (IQR 8)
Median admission time to rehab:	early Kenevo: 39 days (IQR 19) delayed/no MPK: 24 days (IQR 1)

** Functional comorbidity index (FCI) quantifies comorbidity burden at baseline*

Study Design

Exploratory, prospective observational multicenter trial:



Prosthetic knee allocation in the control group followed routine clinical decision-making at the participating rehabilitation clinics and was neither standardized nor randomized. Participants were grouped post hoc into early MPK provision (initial Kenevo) versus delayed or no MPK provision (initial NMPK with/without later transition).

At 6 time points throughout the inpatient rehabilitation and follow-up period data was generated. At the day of admission to the inpatient rehabilitation, a baseline measurement was conducted. Further assessments were performed at the end of the inpatient rehabilitation at week 4, then at 6, 12, 18 and 24 weeks.

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 early Kenevo vs. delayed/no MPK *	Sig.[a,b]
Activity, Mobility, Activities of Daily Living (ADLs)	**PLUS-M K2**	**Trajectory** During inpatient rehabilitation both groups demonstrated improvement with a non-significant difference. During follow-up, the early Kenevo group showed continuous improvements, whereas the delayed/no MPK group demonstrated more variable and less sustained trajectories. T-scores were significantly higher in the early Kenevo group at all follow-ups ($p \leq 0.05$), but after Holm adjustment, only the difference at the final follow-up remained significant. Large effect sizes ($r \approx 0.69$-0.79) support the clinical relevance of these findings.	

	Early Kenevo	Delayed/no MPK	Effect size (r) [d]	raw	Holm [c]
Start of rehab (day 0)	33.1 (25.7-40.5)	31.5 (16.9-46.0)	0.03	0	0
End of rehab (Ø day 33)	37.9 (31.2-44.7)	36.0 (24.4-47.7)	0.12	0	0
Follow-up I (Ø day 46)	39.2 (29.4-49.1)	27.7 (20.7-34.8)	0.69	++	0
Follow-up II (Ø day 84)	43.1 (35.6-50.5)	30.4 (14.7-46.1)	0.79	++	0
Follow-up III (Ø day 126)	47.1 (34.1-60.2)	28.4 (19.7-37.0)	0.79	++	0
Final follow-up (Ø day 168)	43.6 (38.3-48.8)	29.1 (22.3-35.9)	0.73	++	++

Mean change from baseline to final follow-up (reported in Discussion section) Kenevo +9.9 pts Delayed/no MPK -3.0 pts	n.a.
Responder analysis Patients achieving MDC/MCID thresholds at final follow-up: - early Kenevo: 5 out of 8 patients (63%) - delayed/no MPK: 1 out of 6 patients (17%)	n.a.
Trajectory At baseline health utility values were comparable between groups. During follow-up the early Kenevo group showed a sustained increase whereas the delayed/no MPK group exhibited overall lower values with greater variability.	n.a.

	Early Kenevo	Delayed/no MPK	Effect size (r) [d]
Baseline	0.57 (0.11-1.03)	0.62 (0.39-0.85)	0.07

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Category	Outcomes	Results for early Kenevo vs. delayed/no MPK *			Sig.[a,b]
		Final follow-up (Ø day 168)	0.79 (0.61-0.98)	0.49 (0.21-0.77)	0.54
	EQ-5D-5L VAS	**Trajectory** The baseline EQ-5D-5L VAS values were comparable. The early Kenevo group demonstrated higher VAS scores compared to the more variable and lower values of the delayed/no MPK group.			n.a.
			Early Kenevo	**Delayed/no MPK**	**Effect size (r) [d]**
		Baseline	48 (14-81)	48 (30-66)	0.01
		Final follow-up (Ø day 168)	66 (45-86)	47 (14-80)	not reported
	Social reintegration (RNLI)	**Trajectory** (assessed only during follow-up) At the first follow-up RNLI values were higher in the early Kenevo group. During follow-up the early Kenevo group showed a continued increase whereas the delayed/no MPK group exhibited overall lower values with greater variability trending to toward decline.			n.a.
			Early Kenevo	**Delayed/no MPK**	**Effect size (r) [d]**
		Follow-up I (Ø day 46)	63 (53-74)	41 (21-62)	0.63
		Final follow-up (Ø day 168)	75 (60-91)	28 (18-38)	0.81
		Responder analysis Patients achieving MDC/MCID thresholds at final follow-up (MCID ≥7% compared to first baseline measurement): - early Kenevo: 3 out of 8 patients (38%) - delayed/no MPK: 1 out of 5 patients (20%)			n.a.

[a] no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.); significance set at p<0.05; trends set at 0.1>p>0.05

[b] p-values should be interpreted with caution due to small sample size;

[c] Holm-adjustment was applied for multiple comparisons across time points.

[d] Effect sizes (r) indicate magnitude of group differences (small ≈ 0.1, moderate ≈ 0.3, large ≥0.5) and support interpretation of clinical relevance.

* results displayed as: Continuous variables: mean (95% CI) for approximately normally distributed data and as median with interquartile range (IQR) for non-normally distributed data. Categorial variables as absolute and relative frequencies (*n*, %).

Author's Conclusion

"In this exploratory cohort, early provision of a K2-specific MPK was associated with more favorable functional trajectories compared with delayed or no MPK provision. However, due to substantial methodological limitations, including small sample size, missing data, and non-randomized

treatment allocation, these findings should be considered hypothesis-generating only. Future adequately powered prospective studies are required to determine whether the timing of MPK provision influences rehabilitation outcomes in low-mobility transfemoral amputees." (Raisig, 2026)

Author's Affiliation

[1] MEDIAN Rehab-Center Wiesbaden Sonnenberg, 65191 Wiesbaden, Germany; johannes.schroeter@median-kliniken.de

[2] Department of Orthopaedics and Traumatology, University Medical Centre of the Johannes Gutenberg University Mainz, 55131 Mainz, Germany; frank.traub@unimedizin-mainz.de

[3] MEDIAN Clinic Flechtingen, 39345 Flechtingen, Germany; per.schueller@median-kliniken.de

[4] Ottobock Healthcare Products GmbH, 1110 Vienna, Austria; andreas.hahn@ottobock.com

† These authors contributed equally to this work.