Reference

Eva Pröbsting [a], Michael Ernst [a], Harald Böhm [b,c], Thomas Schmalz [a], Veit Schopper [a,d], Barbara Pobatschnig [a], Malte Bellmann [a,c].

Limitations of standard gait models for the precise and accurate evaluation of prosthetic knee joints regarding their functional quality, reliability, reproducibility and safety

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Products

Genium

Major Findings

Comparing the transfemoral gait model (TF) to three standard gait models, namely Plug-in gait (PIG), adapted clinical Cleveland (CC) and 2D model (G2) with patients with transfemoral amputation using the Genium MPK:

→ Standard gait models showed clinically relevant inaccuracies, limiting their suitability for high precision or detailed functional interpretation, only the TF model reliably detected small effects

- Identification of the 4° pre-flexion of the knee at initial contact (Genium specific function) only with TF; other models did not allow a clear distinction

→ The TF model provided measurements closest to the knee angles recorded directly by the prosthetic knee sensor relative to the other models (highest accuracy)

- Across the 18 measured sagittal knee angles, TF outperformed the other gait models in 8 out of 18 (45%), by showing the smallest mean deviation from the sensor data (lowest bias; Figure 1a)

→ The TF model provided the most consistent and reproducible results, so the lowest variability in angles and moments compared to the other models (highest precision)

- Across the 18 measured sagittal knee angles, TF showed the lowest variability relative to the other models; 14 out of 18 (78%) angles were measured with a reproducibility coefficient ≤2° (Figure 1a)

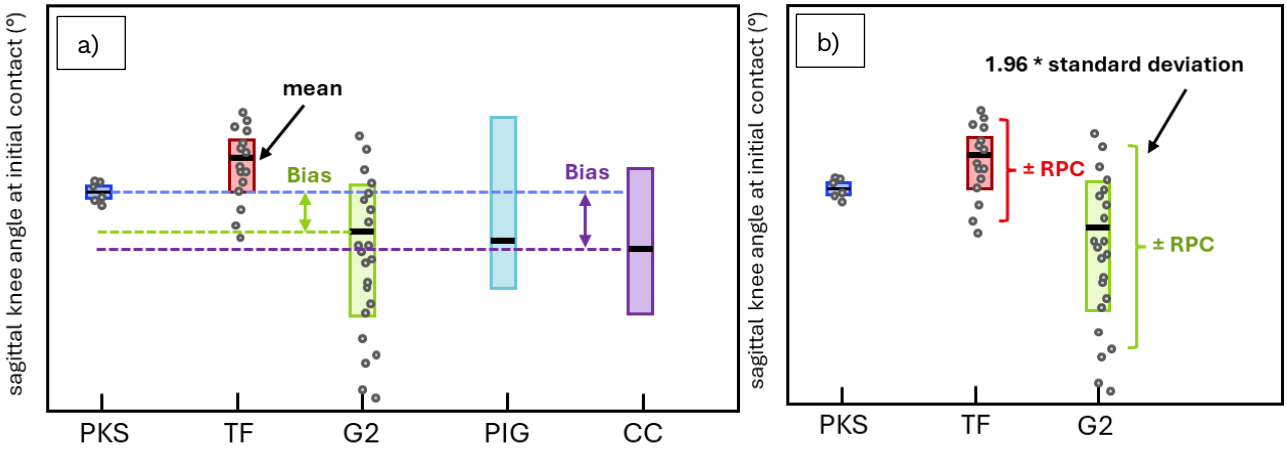


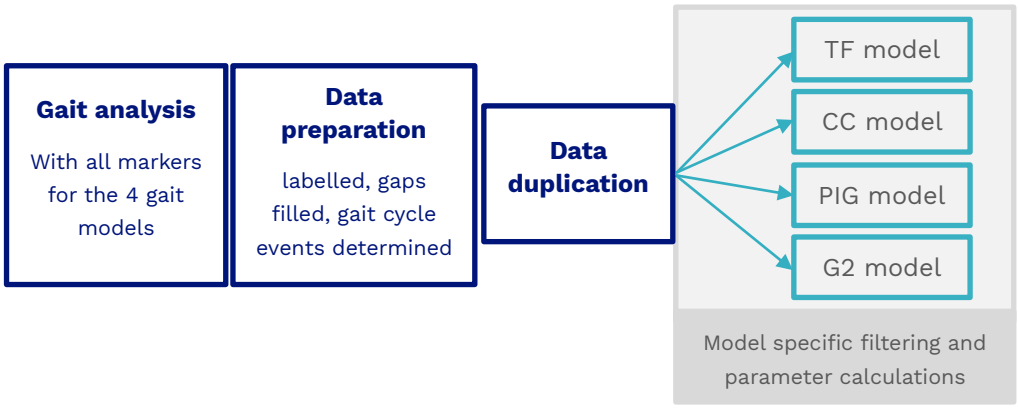
Figure 1. Schematic representation of a) Bias: mean difference between each gait model and the prosthetic knee sensor data - estimates model accuracy, b) RPC = reproducibility coefficient = 1.96*SD (Bland-Altman analysis), represents the range within which 95 % of repeated measurements are expected to fall - estimates model precision; Error classification thresholds of reproducibility coefficient and mean bias: acceptable: ≤ 2°, moderate: 2–5°, concerning: > 5°; PKS: prosthetic knee sensor.

Population

Subjects:	19 male participants
Amputation level:	transfemoral (18), knee disarticulation (1)
Previous prostheses:	Genium, Genium X3 with ESR feet
Mean age:	52 ± 12 years
Mean weight:	81 ± 10 kg
Mean height:	1.8 ± 0.1 m

Study Design

Multicenter cross-sectional study:



Gait analyses in two gait laboratories (1) 12-meterwalkway, 12 optoelectronic cameras, (2) 13-meter walkway, 8 cameras; both had 2 force plates installed.

Measurement:

- at level ground; comfortable, slower and faster walking speed
- comparator: everyday prosthesis with personalized settings
- prosthetic knee sensor (PKS) provided reference data
- markers of the tested gait models were attached simultaneously (n=58)

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 Genium	Sig.
Level Walking	Walking speed (m/s)	Mean walking speed was: Slow: 0.95 ± 0.015 Self-selected: 1.23 ± 0.17 Fast: 1.56 ± 0.21	n.a.
	Prosthetic knee angle (Mean sagittal angle)	**Root mean square error (RMSE [1]):** - RMSE between the prosthetic knee sensor (PKS) and the models were all relatively small compared to the overall knee RoM	n.a.

Category	Outcomes	Results for Genium	Sig.
		- RMSE was smallest at slow walking speed and highest at fast speed for all models For normal walking speed RMSE was lowest for the TF model:	

model	RMSE (°)
TF	1.7 ± 0.6
G2	2.1 ± 1.0
CC	3.2 ± 1.5
PIG	3.3 ± 1.0

	Bias [2] as measure of accuracy: - Lowest mean bias was most frequently found for TF (TF 45%, PIG 35%, G2 15%, CC 5%) - All mean bias were within ≤2° for TF, PIG, G2 - 5% of CC mean bias were >2°	n.a.

	Reproducibility coefficient (RPC [3]) as measure of precision:
	- Lowest RPC was shown with TF model for every discrete parameter → highest precision.
	- RPC values ≤2° (small) were observed in:
	  o G2 and CC: 1% of RPCs
	  o PIG: 17% of RPCs
	  o TF: 78% of RPCs
	- RPC values >2° (moderate) were observed in:
	  o G2 and CC: 89% of RPCs
	  o PIG: 50% of RPCs
	  o TF: 22% of RPCs
	- RPC values >5° (clinically concerning) were observed in:
	  o PIG: 33 % of RCPs
	  o CC: 11 % of RPCs
		n.a.

	Detection of 4° pre-flexion at initial contact TF model was the only model of the four that could clearly identify the Genium specific Preflex-function of the prosthetic knee.	n.a.
Prosthetic knee moment (normalized to weight)	**Root mean square error (RMSE [1]):** - RMSE between PKS and the four models was smallest at slow and highest at fast speed. At normal walking speed RMSE was lowest for the TF model:	n.a.

model	RMSE (Nm/kg)
TF	0.05 ± 0.02
CC	0.06 ± 0.02
G2	0.08 ± 0.02
PIG	0.13 ± 0.04

Category	Outcomes	Results for Genium	Sig.
		Bias [2] as measure of accuracy: Lowest mean bias for the peak moments occurred most frequently with 33% in: TF, PIG and G2 (CC showed in no peaks the lowest mean bias)	n.a.
		Reproducibility coefficient (RPC [3]) as measure of precision: Model Precision is highest for TF model, as the RPC is the lowest compared to the other three models for every peak moment.	n.a.

[1] **RMSE = root mean square error:** calculated for the sagittal knee angle and knee moment curves between the prosthetic knee sensor data (as predictor) and the different models (as estimator)

[2] **Bias**: mean difference between each gait model and the prosthetic knee sensor data - estimates model accuracy

[3] **RPC** = reproducibility coefficient = 1.96*SD (Bland-Altman analysis), represents the range within which 95 % of repeated measurements are expected to fall - estimates model precision

Error classification thresholds of reproducibility coefficient and mean bias**:** acceptable: ≤ 2°, moderate: 2–5°, concerning: > 5°.

Author's Conclusion

"The new model, specifically developed for the analysis of above-knee amputees, shows in summary the most precise and accurate data of sagittal knee angle and moment compared to the other gait models analyzed in this study. These parameters are key indicators for evaluating prosthetic knee joints in terms of function, reliability, reproducibility, and safety. The 2D-calculated results are comparable to the more complex standard gait models.
The accuracy and precision of the data are influenced by the segment definition and the use of reference data gained from a neutral standing posture." (Pröbsting, 2025)

Author's Affiliation

[a] Ottobock SE & Co. KGaA, Clinical Research and Services – Biomechanics, Annastraße 33-35, 37075 Göttingen, Germany

[b] Orthopaedical Childrens Hospital, Aschau im Chiemgau, Biomechanical Lab, Germany

[c] HAWK University of applied sciences and arts Göttingen, Germany

[d] German Sport University Cologne, Germany