

The New Genium X4 Microprocessor-controlled Knee Joint: How Do Users Benefit from Entirely New Functions in Everyday Life?

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Products

Genium X4

Major Findings

With Genium X4 compared to Genium and Genium X3:

→ **All users preferred the new Genium X4 over the previous Genium / X3**

→ **50% of users reported that Genium X4 required less perceived exertion while walking (the other 50% found it to be equal)**

→ **Improved and safer daily-life performance with Genium X4**

- Clinically relevant improvements in 12 out of 45 activities of daily living (ADL-Q) were rated easier and 13 safer (e.g. pulling open a heavy door, walking in crowded environment, stepping backwards)

→ **Large user-reported benefits in challenging mobility situations**

- Stumble and fall frequency reduced with Genium X4
- Over 50% of users found X4 superior or at least equal:
 - Walking initiation was rated better by 7/7 users
 - Walking backwards was rated better by 6/8 users
 - Walking up ramps was rated better by 5/8 users
- Walking comfort was rated as better by 5/8 users

→ **More effective movement during walking initiation and backwards walking**

- During walking initiation, users could flex the prosthetic knee significantly more (X3: $8.5 \pm 4.6^\circ$; X4: $47.1 \pm 4.7^\circ$; $P = 0.012$)
- Compensatory trunk movements during walking initiation were significantly reduced (lateral trunk lean ROM: X3: $5.4 \pm 3.7^\circ$; X4: $3.8 \pm 3.1^\circ$; $P = 0.025$)
- During backwards walking, a knee flexion limitation can be set between 15° – 30° , which enables an improved acceleration phase, indicated by significantly increased posterior ground reaction force (X3: $4.6 \pm 1.8\%BW \cdot \%Gait\ cycle\ (GC)$; X4: $6.1 \pm 1.4\%BW \cdot \%GC$; $P = 0.027$)

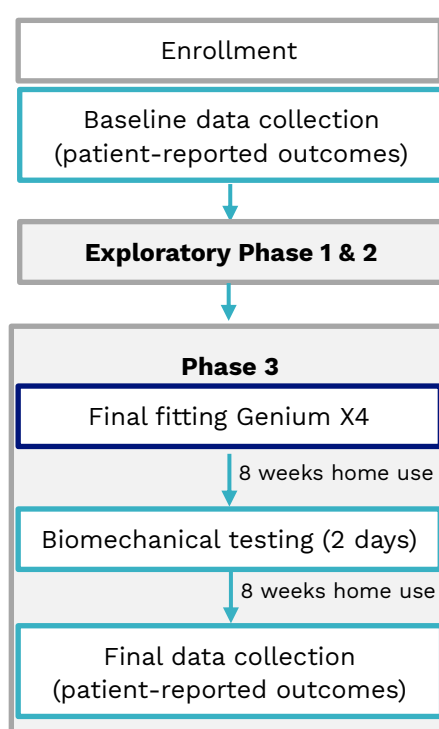
→ **Genium X4 enables an inclination-dependent adaption which produced a more adaptive gait pattern when walking uphill**

- Knee flexion at initial contact increased significantly (X3: $5.1 \pm 1.1^\circ$; X4: $15.4 \pm 2.2^\circ$; $P = 0.027$)
- Reduced compensatory demands observed in the contralateral limb
 - Significantly reduced plantarflexion movement (X3: $20.5 \pm 9.5^\circ$; X4: $17.3 \pm 11.3^\circ$; $P = 0.075$)
 - significantly reduced maximum ankle power (X3: $1.9 \pm 0.7\ W/kg$; X4: $1.5 \pm 0.8\ W/kg$; $P = 0.028$)

Population	Subjects:	8 male participants
	Amputation level:	transfemoral: unilateral (6), bilateral (2) (1 TF/knee disarticulation, 1 TF/TF)
	Previous prosthetics:	Knee: Genium X3 (7), Genium (1) for > 6 months Socket: SI vacuum (2), IC vacuum (5), both (1) Foot: Triton (4), Triton LP, Triton HP, Triton VS, Taleo LP
	Amputation causes:	not reported
	Mean age:	44.1 ± 12.6 years
	Mean weight:	80.0 ± 7.5 kg
	Mean time since amputation:	24.1 ± 14.4 years
	Mean daily prosthetic usage:	12.9 ± 2.6 hours
	MFCL:	K3 (2 unilateral, 1 bilateral), K4 (6 unilateral, 1 bilateral)

Study Design

Pilot clinical trial:



Participants were fit with Genium X4 while retaining the everyday socket and foot. They were involved in testing the device throughout development during phase 1 & 2 for up to three years. Only results from phase 3 are presented (using the final pre-series prototype, identical to commercial device).

Biomechanical test conditions included (8-10 valid trials for each condition):

- Level walking (slow, medium, fast self-selected speed, and with small steps) (20m walkway)
- Walking initiation with prosthetic side
- Walking backwards
- Walking up ramps (10°, 7m)

Biomechanical tests were conducted on 2 consecutive days (day 1: Genium X4, day 2: previous knee: Genium / X3)

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 X4 vs. Genium / X3	Sig. ^a
Level Walking	Walking on level ground	- Across different gait velocities, the maximum swing phase knee flexion angle was more consistent on the prosthetic side (X3: 5.4 ± 3.9°/m/s; X4: 3.3 ± 3.3°/m/s; <i>P</i> = 0.547)	0
		- Lower self-selected slow velocity (X3: 1.06 ± 0.08 m/s; X4: 0.94 ± 0.21 m/s; <i>P</i> = 0.457)	0

Category	Outcomes	Results for Genium X4 vs. Genium / X3	Sig. ^a																												
		○ slightly higher maximum swing phase knee flexion angle at slower velocity (X3: 64.1 ± 5.6°; X4: 64.9 ± 5.8°; <i>P</i> = 0.576)	0																												
		- With small steps (<40cm): higher maximum swing phase knee flexion angle (X3: 52.5 ± 6.6°; X4: 54.8 ± 7.4°; <i>P</i> = 0.176)	0																												
	Walking initiation	Initiating walking on the prosthetic side (left for bilateral): - Significantly higher maximum swing phase knee flexion angle (X3: 8.5 ± 4.6°; X4: 47.1 ± 4.7°; <i>P</i> = 0.012) - Reduced maximum pelvic tilt on the prosthetic side (X3: 10.9 ± 2.5; X4: 9.9 ± 3.1; <i>P</i> = 0.123) - Reduced maximum lateral trunk lean to the contralateral side (X3: 4.7 ± 4.0; X4: 3.9 ± 3.4°; <i>P</i> = 0.161) - Significantly reduced lateral trunk lean ROM (X3: 5.4 ± 3.7°; X4: 3.8 ± 3.1°; <i>P</i> = 0.025)	++ 0 0 --																												
	Walking backwards	Bilateral subjects: - Backwards acceleration: both prosthetic knees remained below 15° knee flexion (minimum knee flexion limitation in the new X4 function) Unilateral subjects: - Significantly reduced maximum knee flexion angle during stance phase on the prosthetic side (X3: 35.4 ± 7.1°; X4: 16.3 ± 0.6°; <i>P</i> = 0.028) - Higher maximum of the posteriorly directed ground reaction force on the prosthetic side (X3: 15.6 ± 2.8%BW; X4: 18.0 ± 2.4%BW; <i>P</i> = 0.173) - Prolonged acceleration phase - Significantly increased impulse (X3: 4.6 ± 1.8%BW·%GC; X4: 6.1 ± 1.4%BW·%GC; <i>P</i> = 0.027)	n.a. -- 0 n.a. ++																												
Ramps, Hills	Walking up a ramp (10°)	- Significantly increased knee flexion angle at IC on the prosthetic side (X3: 5.1 ± 1.1° X4: 15.4 ± 2.2°; <i>P</i> = 0.027) - For unilateral users during contralateral stance phase (20%–40%gc):: ○ Reduced plantarflexion movement (X3: 20.5 ± 9.5°; X4: 17.3 ± 11.3°; <i>P</i> = 0.075) ○ Significantly reduced maximum ankle power (X3: 1.9 ± 0.7 W/kg; X4: 1.5 ± 0.8 W/kg; <i>P</i> = 0.028)	++ - --																												
Safety	Stumble and fall frequency (self-reported outcome)	Reduced stumble and fall frequency with Genium X4 <table><tr><th colspan="2"></th><th>never</th><th>once</th><th>2-5 times</th><th>>5 times</th></tr><tr><td rowspan="2">Stumble</td><td>Genium / X3</td><td>4</td><td>1</td><td>2</td><td>1</td></tr><tr><td>Genium X4</td><td>5</td><td>1</td><td>2</td><td>0</td></tr><tr><td rowspan="2">Falls</td><td>Genium / X3</td><td>5</td><td>1</td><td>2</td><td>0</td></tr><tr><td>Genium X4</td><td>8</td><td>0</td><td>0</td><td>0</td></tr></table>			never	once	2-5 times	>5 times	Stumble	Genium / X3	4	1	2	1	Genium X4	5	1	2	0	Falls	Genium / X3	5	1	2	0	Genium X4	8	0	0	0	n.a.
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Category	Outcomes	Results for Genium X4 vs. Genium / X3	Sig. ^a																								
	Safety (self reported outcome)	Safety perception was rated as good as or better with Genium X4 relative to their previous Genium / X3 <table> <tr> <th></th><th>X4 safer</th><th>X4 as safe as own knee joint</th><th>Own knee joint safer</th></tr> <tr> <td>Feeling of safety</td><td>2</td><td>6</td><td>0</td></tr> <tr> <td>Safety issues:</td><td>1</td><td>7</td><td>0</td></tr> <tr> <td>Safety when stumbling</td><td>1</td><td>7</td><td>0</td></tr> <tr> <td>Fear of falling</td><td>1</td><td>7</td><td>0</td></tr> <tr> <td>Perceived safety while walking</td><td>2</td><td>6</td><td>0</td></tr> </table>		X4 safer	X4 as safe as own knee joint	Own knee joint safer	Feeling of safety	2	6	0	Safety issues:	1	7	0	Safety when stumbling	1	7	0	Fear of falling	1	7	0	Perceived safety while walking	2	6	0	n.a.
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Activity, Mobility, Activities of Daily Living (ADLs)	ADL Questionnaire *	32 activities of 45 were rated easier and safer with Genium X4 compared to the previous knee (>0.0 mean rating) Reaching the clinical relevance threshold (>0.5 mean rating) for 12 (easier) and 13 (safer) activities Highest-rated activities regarding ease of use (>0.75 mean rating): - Walking up ramps, stepping backwards, walking around in a small space (mean rating: 0.88) - Walking in a crowded environment, going for a walk (mean rating: 0.75) Highest-rated activities regarding safety (>0.75 mean rating): - Riding a bicycle/motorcycle (0.86; mean rating 1.14 for health-related exercise cycling) - Walking up ramps, stepping backwards (mean rating: 0.75)	n.a.																								
Preference, Satisfaction, Quality of Life (QoL)	Preference	All subjects preferred Genium X4 over their previous knee joint. Recurring reasons: - Better modes - More intuitive while walking - Feels lighter - Improved sensitivity to initiate swing phase	n.a.																								
	Effort and comfort (study-specific questionnaire)	Rated “better” with X4 than their previous knee were: - Perceived exertion while walking (by 4 out of 8 subjects) - Walking comfort (by 5 out of 8 subjects) (one subject reported less back pain with Genium/X3) All aspects were rated as at least as good.	n.a.																								
	Movement situations (study-specific questionnaire)	Half or more of the subjects rated the following movement situations better with Genium X4 than their previous knee: - Walking up ramps (5/8), - Walking down ramps (4/8), - Walking upstairs (4/8), - Riding a bike (4/5; only five patients were generally able to ride a bike), - Walking initiation (7/7; one patient did not answer), - Walking backwards (6/8)	n.a.																								

Category	Outcomes	Results for Genium X4 vs. Genium / X3	Sig. ^a
		(one subject reported a deterioration while walking on uneven ground and walking with stance phase flexion)	

^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

* ADL Questionnaire rating: values > 0.0: easier/safer with the Genium X4

Author’s Conclusion	“The Genium X4 features more advanced control algorithms than its predecessor, offering greater individualization to user needs and improved functional adaptations for various movement situations. Patient-reported outcomes have shown notable improvements, primarily linked to the new functions. These findings align with the biomechanical analysis, which indicates more natural movement patterns and reduced compensatory strategies during walking initiation and walking up inclines. Overall, the Genium X4 provides users with further increased safety, enhanced functionality, and an improved daily-life experience.” (Köhler, 2026)
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