Reference

Klenow, T. D.[1], Lundstrom, R. L.[1], Morris, A.[1], Patterson, S.[2], Simpson, C.[3], Trejo, E. G.[4], & Kannenberg, A[1].

An enhancement of the Genium™ microprocessor- controlled knee improves safety and different aspects of the perceived prosthetic experience for unilateral and bilateral users

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Products

Genium™ and Genium-X3™

Major Findings

With the investigational Genium/X3 compared to previous version of the prosthesis for age-matched unilateral amputees, bilateral amputees as well as the combination of uni- and bilateral amputees (further referred to as “aggregate”):

→ 85% significant reduction in stumble frequency from baseline to final assessments in the combined group

→ 50% significant improvement in patient-reported ease of ADL execution for the bilateral group compared to the unilateral group

→ 57% significant improvement in patient-reported safety of ADL execution for the bilateral group compared to the unilateral group (Figure 1).

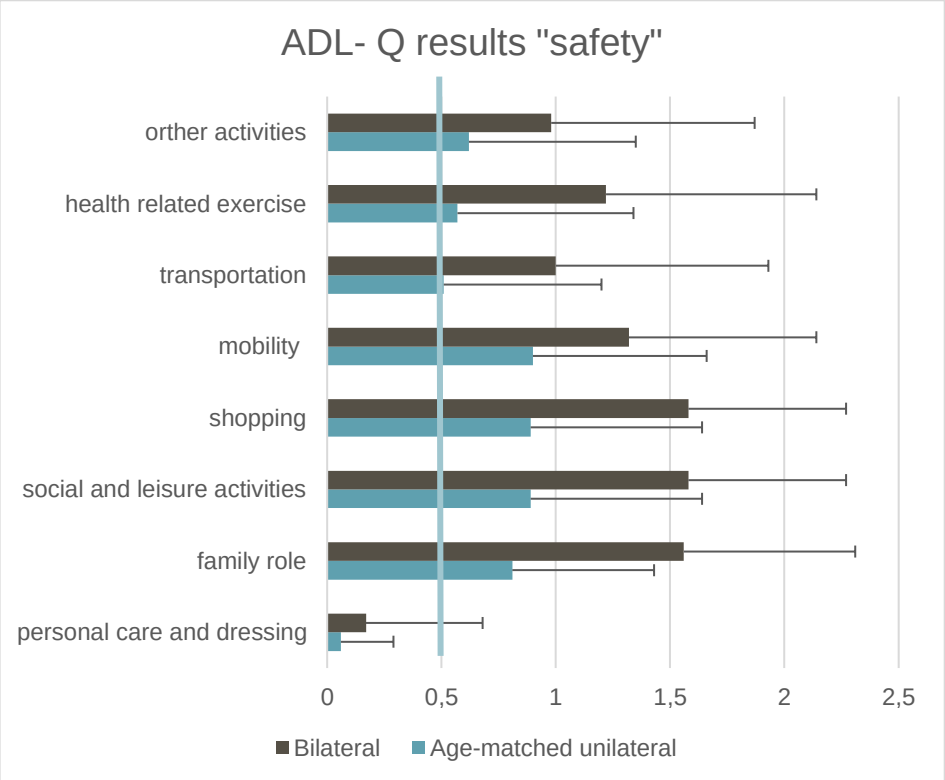

Figure 1. *Comparative ADL-Q results for “safety”; nearly all results showed an improvement (>0) with the new version of Genium/X3 (results above 0.5 denote clinical relevance).*

Population

Subjects:	n=26 (2 female; n=10 in Phase I and an additional 16 in Phase II)
Previous MPK:	Genium or Genium X3
Amputation causes:	Trauma (76,9%), congenital (11,5%), tumor (3,8%), vascular (3,8%), rhabdomyolysis (3,8%)
Amputation level:	Hip disarticulation (n=1) Transfemoral amputation (n=22) Knee disarticulation (n=3)
Mean age:	35.1 ± 12.6 years
Mean time since amputation:	15.0 ± 12.2 years
MFCL:	K2, K3, K4

Study Design

Interventional, non-randomized, non-blinded, pre- to post-test design in two phases. Phase I: Proof of concept testing of developmental ruleset. Phase II: Specific parameter presets for bilateral subjects (Figure 2). Comparisons between baseline and final assessments on the aggregate. A subset of unilateral subjects was age-matched to the group of bilateral subjects for a between-groups analysis.

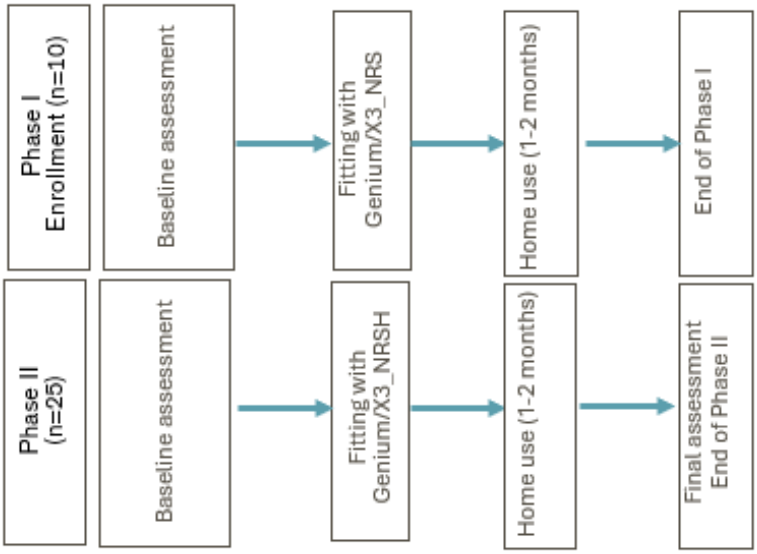

Figure 2. *Study subject flow. NRS = new rule set; NRSH= new ruleset and hydraulics.*

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 the investigational Genium/X3 compared to previous version	Sig.[a,b]
Level Walking	L-test (sec)	**Overall results:** No significant or clinically important difference on aggregate (Δ= -0.5; p= 0.462), or in the age-matched (Δ= -0.1; p= 0.932) and bilateral (Δ= -0.4; p= 0.750) groups. **Between group comparison (*bilaterals vs. age-matched unilaterals*):**	0 --

Category	Outcomes	Results for the investigational Genium/X3 compared to previous version	Sig.[a,b]
		Unilateral subjects were 19,5% faster than the bilateral group at baseline (21.0±4.7 vs. 26.1±4.7; p=0.007) and 18,7% faster at final assessments (20.9±4.6 vs 25.7±4.7;p = 0.027).	
Safety	Subject-reported stumbles	**Overall results:** Self-reported stumbles reduced by 85% on aggregate (Δ= -13.5; p=0.008). No significant difference in age-matched unilateral (Δ= -9,4; p=0.115) or bilateral (Δ= -23.6; p=0.246) groups. **Between group comparison (*bilaterals vs. age-matched unilaterals*):** No significant difference detected.	**++** 0 0
	Subject-reported falls	**Overall results:** A slight, but not significant reduction in fall frequency was detected on aggregate (Δ= -0.42; p=0.133), in the age-matched unilateral (Δ= -0.50 p=0.179) and the bilateral (Δ= -0.17; p=0.713) groups. **Between group comparison (*bilaterals vs. age-matched unilaterals*):** No significant difference detected.	0 0
Safety (Pain)	Numeric Pain Rating Scale (NPRS)	**Overall results:** Low back pain (Δ= -1.0; p= 0.022) and residual limb pain (Δ= -0.6; p=0.002) was significantly reduced on aggregate. A significant reduction in low back pain (Δ= -2.0; p=0.027) and residual limb pain (Δ= -0.9; p=0.020) was also detected in the age-matched unilateral group. No significant differences for low back pain (Δ= -0.3; p=0.593) or residual limb pain (Δ= -0.6; p= 0.109) were detected in the bilateral group. **Between group comparison (*bilaterals vs. age-matched unilaterals*):** No significant difference detected.	**++** **++** 0 0
Activity, Mobility, Activities of Daily Living (ADLs)	Comparative Activities of Daily Living Questionnaire (ADL-Q)	**Overall results:** Clinically meaningful (>0.5) improvements were demonstrated in **ease** of ADL completion in the following domains: - Family Role (aggregate= 0.99±0.86; age-matched unilaterals= 0.74±0.81; bilaterals= 1.56±0.70) - Social and Leisure Activities (aggregate= 1.07±0.74; age-matched unilaterals= 0.89±0.65; bilaterals= 1.51±0.73) - Shopping (aggregate= 1.07±0.74; age-matched unilaterals= 0.89±0.65; bilaterals= 1.51±0.73) - Mobility (aggregate= 0.97±0.78; age-matched unilaterals= 0.88±0.74; bilaterals= 1.25±0.81) - Transportation (aggregate= 0.6±0.76; bilaterals=0.93±0.89) - Health-Related Exercise (aggregate= 0.8±0.82; age-matched unilaterals= 0.73±0.69; bilaterals= 1.05±0.85)	n.a.

Category	Outcomes	Results for the investigational Genium/X3 compared to previous version	Sig.[a,b]
		- Other Activities (aggregate= 0.7±0.76; age-matched unilaterals= 0.65±0.70; bilaterals= 0.91±0.82); as well as in **safety** of ADL completion in the following domains: - Family Role (aggregate= 1.08±0.81; age-matched unilaterals= 0.81±0.62; bilaterals= 1.56±0.75) - Social and Leisure Activities (aggregate= 1.1±0.78; age-matched unilaterals= 0.89±0.75; bilaterals= 1.58±0.69) - Shopping (aggregate= 1.1±0.78; age-matched unilaterals= 0.89±0.75; bilaterals= 1.58±0.69) - Mobility (aggregate= 1.02±0.81; age-matched unilaterals= 0.9±0.76; bilaterals= 1.32±0.82) - Transportation(aggregate= 0.63±0.79; age-matched unilaterals= 0.51±0.69; bilaterals= 1.00±0.93) - Health-Related Exercise (aggregate= 0.8±0.84; age-matched unilaterals= 0.57±0.77; bilaterals= 1.22±0.92) - Other Activities (aggregate= 0.71±0.77; age-matched unilaterals= 0.62±0.73; bilaterals= 0.98±0.89).	
		Between group comparison (*bilaterals vs. age-matched unilaterals*): The bilateral group reported 50% greater improvement in ease (p = 0.009) and 57% greater improvement in safety (p = 0.009) of ADL execution compared to the unilateral group. In the activity categories, the bilateral group improved more than the unilateral group with statistically significant relative improvements in **ease** in the following domains:	**++**
		- Family Role (1.56±0.70 vs. 0.74±0.81; p = 0.0006) - Social and Leisure Activities (1.51±0.73 vs. 0.89±0.65; p = 0.0001) - Shopping (1.51±0.73 vs. 0.89±0.65; p = 0.0001) - Mobility (1.25±0.81 vs. 0.88±0.74; p = 0.0004) - Transportation (0.93±0.89 vs. 0.49±0.69; p = 0.027); as well as in **safety** in the following domains:	**++** **++** **++** **++**
		- Family Role (1.56±0.75 vs. 0.81±0.62; p = 0.0005) - Social and Leisure Activities (1.58±0.69 vs. 0.89±0.75; p = 0.00008) - Shopping (1.58±0.69 vs. 0.89±0.75; p = 0.00008) - Mobility (1.32±0.82 vs. 0.9±0.76; = 0.0001) - Transportation (1.00±0.93 vs. 0.51±0.69; p = 0.021) - Health-Related Exercise (1.22±0.92 vs. 0.57±0.77; p = 0.004) - Other Activities (0.98±0.89 vs. 0.62±0.73; p = 0.043)	**++** **++** **++** **++** **++** **++**
	Utilization of MPK function	**Between group comparison (*bilaterals vs. age-matched unilaterals*)**: Subjects in the bilateral group reported greater utilization of optimized stair ascent and stepping over obstacles compared to the age-matched unilateral group.	n.a.

Category	Outcomes	Results for the investigational Genium/X3 compared to previous version	Sig.[a,b]
	Activities-specific Balance Confidence (ABC) Scale (%)	**Overall results:** Improvements in the ABC scale were detected on aggregate (Δ= +2.2; p=0.201) and in the age-matched unilateral group (Δ= +4.4; p=0.164). In the bilateral group, the results decreased with -1,2% (Δ= -1.2; p=0.400). The results were not significant.	0
		Between group comparison *(bilaterals vs. age-matched unilaterals)*: No significant result detected	0
	Prosthetic Limb Users Survey of Mobility (PLUS-M) (T-score)	**Overall results:** T-scores decreased on aggregate (Δ= -0.2; p= 0.783) and among bilateral users (Δ= -3.4; p= 0.249). In the age-matched unilateral group, t-score improved (Δ= +2.2; p= 0.426), but none of the results were significant.	0
		Between group comparison *(bilaterals vs. age-matched unilaterals)*: No significant result detected	0
	Study-specific questionnaire (SSQ)	**Overall results:** Significant improvements were demonstrated on aggregate in the following domains: - +13,4% in walking safety (8.4±2.6 to 9.7±0.6; p = 0.046) - +13,5% in walking comfort (8.3±2.1 to 9.6±0.6; p= 0.002) - -6.7% in exertion during walking (3.0±2.2 to 1.8±1.1= -1.2; p= 0.012) - -4.1% in concentration during walking (2.4±1.8 to 1.7±1.4; p= 0.006) - +10,5% in standing comfort (8.5±1.8 to 9.5±0.8; p= 0.015) - +7.5% in sitting comfort (8.7±2.3 to 9.4±1.2; p= 0.039) - +18.6% in stability standing on ramps (7.0±2.1 to 8.6±1.7; p= 0.001) - +16.3% in overall prosthesis safety (8.2±2.8 to 9.8±0.4; p= 0.009).	++
		The age-matched unilateral group demonstrated significant improvements in the following domains: - -9.8% in exertion during walking (3.2±2.0 to 1.7±0.7; p= 0.041) - -8.3% in concentration during walking (2.2±1.3 to 1.2±0.7; p= 0.024) - +11.3% in walking comfort (8.6±0.9 to 9.7±0.4; p= 0.020) - +13,8% in stability standing on ramps (8.1±1.5 to 9.4±0.8; p=0.031).	++
		No significant results were detected in the bilateral group.	0
		Between group comparison *(bilaterals vs. age-matched unilaterals)*:	0

Category	Outcomes	Results for the investigational Genium/X3 compared to previous version	Sig.[a,b]
		The unilateral group reported lower scores on perceived concentration while walking at the final assessments (1.2±0.7 vs 2.3±2.2; p = 0.026). No other significant differences were shown.	

[a] no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)
[b] p value after post hoc Bonferroni correction did not
significance set at p<0.05; trends set at 0.1>p>0.05
effect sizes classified by authors as small (<0.3), moderate (>0.3 and <0.5) or large(>0.5)

Author's Conclusion

"This study evaluated the implementation of a ruleset and hydraulics upgrade as well as bilateral parameter presets to the Genium™ and Genium-X3™. Marked reductions in stumbles, residual limb pain, and back pain were shown overall. These reductions were driven by the results of the subjects with unilateral amputation who also showed improvements in comfort, exertion, and concentration while walking. Improvements in patient-reported ease and safety of completing ADLs were shown overall and were driven by the results of the subjects with bilateral amputation who had significantly greater relative improvements compared to the unilateral users. Finally, performance of the MPKs did not decrease following the enhancement." (Klenow et al., 2024)

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