Reference

Hahn A, Lang M, Stuckart C.

Analysis of clinically important factors on the performance of advanced hydraulic, microprocessor-controlled exo-prosthetic knee joints based on 899 trial fittings

Medicine (Baltimore), 2016, 95(45)e5386.

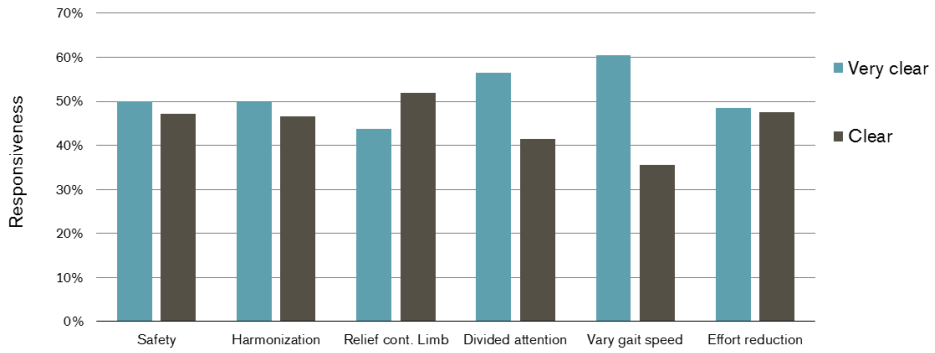
Products

Genium®, C-Leg®, mechanical knee joints

Major Findings

- → **Overall responsiveness exceeded 90%** after 1 week trial fitting**.** Genium responders span a wide range of demographic and epidemiologic characteristics.
- → **Investigated variables failed to exhibit classifying power.** Eligibility decisions for the patient based on such variables only (e.g. mobility grade, comorbidities, BMI and over 50 more) might thus be unjustified.
- → **Single and multiple regression models** detected influences of mobility grade, residual limb conditions, socket type, use of liners, vacuum technology, dynamic foot and others on likelihood to improve performance indicators.
- → **Trial fittings** may pose a very appropriate method to investigate individuals' potential to benefit from Genium. Bias in the sample is estimated to be below 5%.
- → Trial outcomes vary in sensitivity**. Variation of gait speed, perception of toileting and reciprocal stair ascent** exhibit the highest number of sensitive confounders in their respective categories (functional benefits (FB), subject perception (SP) and advanced maneuvers (AM), respectively).
- → **C-Leg walkers profit from an upgrade to Genium** in advanced maneuvers and subjects' perception categories**.**

Responsiveness to Functional Benefits (FB) variable subgroup

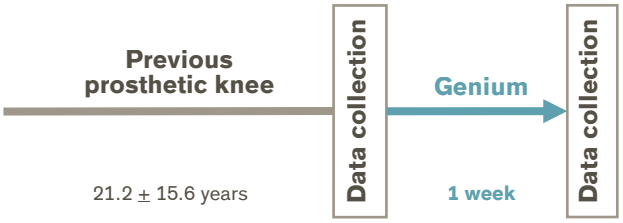


Population

Subjects:	899
Previous prosthetic knee:	C Leg (689), mechanical hydraulic knees (38), pneumatic knees(22), other polycentric (19), 4-bar knees (15), brake knees (9), locked knees (2).
Amputation causes:	68.9% trauma, 15.4% tumor, 6% vascular disease.
Amputation level:	80.1% TF, 18.9% KD.
Mean age:	49.0 ± 12.9 y.
First prosthesis since:	21.2 ± 15.6 y.
MFCL:	12.5% K2, 64.1% K3, 22.8% K4.

Study Design

Retrospective, cross-sectional cohort analysis.



Data from routine trial fittings was retrieved from customer support service, from 272 prosthetic clinics between 2011 and 2015. Influence of clinical variables (i.e. mobility grade) on performance indicators (functional befits (FB), subjects perception (SP), advanced manoeuvring (AM)) were analysed using single and multiple linear and logistic regression modelling. FB by prosthetist and SP by patient were assessed on 5 point Likert scales. The upper two ratings of the Likert scale were defined as being respondent. Advanced manoeuvres were categorized by the prosthetist non-ordinally and dichotomized for analysis. The number of statistically relevant confounders were identified in each performance-indicating category. Clinical significance was derived by regression estimate (e).

Results

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

Category	Outcomes	Results for Genium®	Sig.*
Level walking	Harmonization of gait pattern (FB)	FB total responsiveness: 96.36% very clear: 49.76% clear: 46.6 % # of detected sensitive confounders: 10	++
	Capability to vary gait speed (FB, SP)	FB total responsiveness: 96.05% very clear: 60.57% clear: 35.48% # of detected sensitive confounders: 22	++
		SP total responsiveness: 83.20% very clear: 52% clear: 31.2% # of detected sensitive confounders: 11	++
		Impacted by mobility grade e: 0.36, $p < 3x10^{-26}$, $r^2 = 0.13$	++
	Reduction of overall effort (FB)	FB total responsiveness: 96.03% very clear: 48.45% clear: 47.58% # of detected sensitive confounders: 13	++
	Walking backwards (SP, AM)	SP total responsiveness: 90.78% very clear: 64.90% clear: 25.88 % # of detected sensitive confounders: 5	++
		AM responsiveness safety: 92.28% # of detected sensitive confounders: 16	++
	"Door Test" (AM)	AM responsiveness safety: 88.35 %	++

Category	Outcomes	Results for Genium®	Sig.*
	Abrupt change of walking direction	# of detected sensitive confounders: 13	
Stairs	Descent (SP, AM)	SP total responsiveness: 66.82 % Very clear: 38.30 % Clear: 28.52% # of detected sensitive confounders: 13	++
		AM responsiveness safety: 70.52 % # of detected sensitive confounders: 20	++
	Ascent (reciprocal) (SP, AM)	SP total responsiveness: 88.64% very clear: 63.10% clear: 25.54 % # of detected sensitive confounders: 12	++
		AM responsiveness safety: 32.81 % # of detected sensitive confounders: 25	++
Ramps, Hills	Descent (SP, AM)	SP total responsiveness: 85.78% very clear: 59% clear: 26.78 % # of detected sensitive confounders: 6	++
		AM responsiveness safety: 70.86 % # of detected sensitive confounders: 21	++
	Ascent (SP, AM)	SP total responsiveness: 86.03% very clear: 57.40% clear: 28.63 % # of detected sensitive confounders: 9	++
		AM responsiveness safety: 74.53 % # of detected sensitive confounders: 14	++
	Standing (SP)	SP total responsiveness: 95.69% very clear: 76.60% clear: 19.09 % # of detected sensitive confounders: 11	++
Uneven ground, Obstacles	Crossing Obstacles (SP, AM)	With prosthetic side first SP total responsiveness: 92.36% very clear: 65.90% clear: 26.46% # of detected sensitive confounders: 8	++
		With contralateral side first SP total responsiveness: 85.32% very clear: 54% clear: 31.32% # of detected sensitive confounders: 5	++
	Stepping on Obstacles (SP)	# detected sensitive confounders: 10	++
Cognitive Demand	Divided Attention (FB)	FB total responsiveness: 98.05% very clear: 56.57% clear: 41.48% # of detected sensitive confounders: 18	++
	Dual Tasking (SP)	# detected sensitive confounders: 14	++
Metabolic Energy Consumption	Carrying objects with visual obstruction (SP, AM)	SP total responsiveness: 82.83% very clear: 51.30% clear: 31.53%	++

Category	Outcomes	Results for Genium®	Sig.*
		# detected sensitive confounders: 9	
		AM responsiveness safety: 87.74% # detected sensitive confounders: 11	++
	Carrying heavy loads (SP, AM)	SP total responsiveness: 82.40% very clear: 51% clear: 31.40% # detected sensitive confounders: 6	++
		AM responsiveness safety: 72.73% # detected sensitive confounders: 14	++
Safety	Safety (FB)	FB total responsiveness: 97.04% very clear: 49.94% clear: 47.10% # detected sensitive confounders: 14	++
Activity, Mobility, Activities of Daily Living (ADLs)	Change of mobility grade	FB total responsiveness: 96% very clear: 57.10% clear: 38.90% # detected sensitive confounders: 14	++
	Toileting (SP)	# detected sensitive confounders: 18	++

* no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)

Author's Conclusion

"Responders to Genium trial fittings span a wide range throughout the entire investigated variables. **None of those variables nor their combination seem to qualify as predictor for an individual response to a performance indicator**. This is confirmed for mobility grade and further includes age, etiology, residual limb conditions, and comorbidities. BMI fails to exhibit statistical significance. Decision making processes that rely on those variables without appropriately considering the subjects' individual potential and capabilities do not seem to be supported by these findings. As no data is available supporting such approaches, the denial of access to advanced technology based on such variables may indeed be questionable. **A threshold value for walking capacity cannot be excluded and may pose a component of a possible predictor**. Future research may consider a minimum walking capacity as a component of a predictive instrument.

Toileting was identified as the most responsive indicator in the subject's perception. Difficulties associated with this specifically demanding task may be insufficiently considered and may play a more important role when deciding upon the appropriate prosthetic components. Future protocols for trial fittings may consider limiting the number of performance indicators to those with high differentiating power. Subjects having previously been fitted with C-Leg show benefits when fitted with Genium. Most of these benefits can be found in perception and advanced manoeuvres among which is stairs ascent. Liners and the use of a higher dynamic response foot further contribute to a better utilization of functional benefits." (Hahn et al., 2016).