

# HELIX 3D Hip Joint System



Quality for life

## Clinical Study Summaries

This document summarizes clinical studies conducted with the Helix 3D hip joint system. The included studies were identified by a literature search made on PubMed and within the journals Der Orthopäde, JPO Journal of Prosthetics and Orthotics, Orthopädie-Technik and Technology & Innovation.

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# 1 Overview table

The summaries are organized in three levels depending on the detail of information. The overview table (Level 1) lists all the relevant publications dealing with a particular product (topic) as well as researched categories (e.g. level walking, safety, activities, etc). By clicking on individual underlined categories, a summary of all the literature dealing with that category will open (Level 2).

For those interested to learn more about individual studies, a summary of the study can be obtained by clicking on the relevant reference (Level 3).

Reference		Category									
		Functions and Activities								Participation	Environment
Author	Year	<u>Level walking</u>	<u>Stairs</u>	<u>Ramps, Hills</u>	<u>Uneven ground Obstacles</u>	<u>Cognitive demand</u>	<u>Metabolic Energy Consumption</u>	<u>Safety</u>	<u>Activity Mobility ADL</u>	<u>Preference Satisfaction QoL</u>	<u>Health economics</u>
<u>Ludwigs</u>	2013	x	x	x					x		
<u>Galledrat*</u>	2013	x								x	
<u>Nelson*</u>	2011	x									
<u>Ludwigs</u>	2010	x									
<u>Blumentritt</u>	2008	x									
<b>Total number</b>		5	1	1	0	0	0	0	1	1	0

\* Case report

## 2 Summaries of categories

On the following pages you find summaries of categories researched in several studies (e.g. level walking, stairs, etc.). At the end of each summary you will find a list of reference studies contributing to the content of the particular summary.

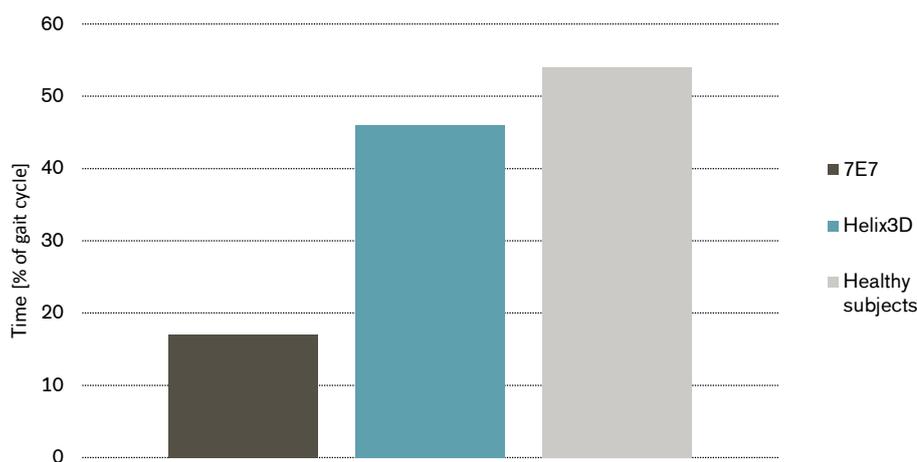
# Level Walking

## Major Findings

With Helix<sup>3D</sup> Hip Joint System compared to other prosthetic hip joints:

- **Increased safety and higher stability due to generation of only hip extension movements during the whole stance phase.**
- **Gait pattern closer to contralateral limb.**
- **Increased symmetrical knee flexion during swing phase.**
- **Reduced range of motion of pelvic tilt by 5° could help alleviate spinal pain syndromes.**

### Maximum hip extension angle is reached later in stance phase with Helix<sup>3D</sup>



Ludwigs et al. (2010)

## Clinical Relevance

The main aim of a prosthesis is the restoration of function. For lower extremities the most important function is ambulation. It has influence on the mobility grade of the subject, the participation of life and, therefore, general quality of life. Furthermore, a natural gait pattern is pursued, since it prevents the sound side from higher or inappropriate loads due to compensatory movements.

## Summary

Biomechanical analysis showed that with Helix<sup>3D</sup> during the entire stance phase only extension sagittal moments act on the hip. In comparison, with 7E7 also flexion moments were measured which leads to a potential for prosthesis collapse (Ludwigs et al 2010). Helix<sup>3D</sup> presents therefore an improved safety potential compared to 7E7. Furthermore, with Helix<sup>3D</sup> the maximum extension angle of the hip joint is reached at the end of stand phase (46% of gait cycle) whereas it is reached with 7E7 already at 17% of gait cycle. This leads to a decreased hip angular velocity of the extension movement in stance phase with Helix<sup>3D</sup> compared to 7E7 and a more natural gait pattern (Ludwigs et al 2010). The maximum extension knee angle is reached smoother through a hydraulic dampening mechanism in Helix<sup>3D</sup>. Additionally, the flexion movement in swing phase is smoother with Helix<sup>3D</sup> compared to 7E7 indicated through a decreased maximum hip angular velocity (Ludwigs et al. 2010 and Blumentritt et al. 2008). Swing phase initiation is supported since hip flexion movement starts right at the beginning of stance phase enabled through the polyurethane elements in Helix<sup>3D</sup> (Blumentritt et al. 2008).

The gait pattern with Helix3D is closer to the contralateral side than 7E7. This is achieved due to increased toe clearance with Helix<sup>3D</sup> compared to 7E7 based on an increased maximum knee flexion angle in swing phase as well as due to an increased maximum knee flexion angle in stance phase (Ludwigs et al. 2010).

Maximum mean range of pelvic tilt is decreased by 5° when using Helix3D compared to 7E7. The reduction of range of motion in the anterior/posterior tilt could help reduce spinal pain symptoms, which hip disarticulation and hemipelvectomy amputees are often confronted with (Ludwigs et al. 2010).

No difference was detected in self-selected walking velocity between Helix<sup>3D</sup> and 7E7 (Ludwigs et al 2010). A 10 meter walk test showed a trend towards increased walking velocity with Helix<sup>3D</sup> compared to an old hip system (Ludwigs et al 2013). Furthermore, a case study showed that the subject could improve gait speed with Helix<sup>3D</sup> by 90% relative to 7E7, measured by a 2-minute walk test (Nelson & Carbone 2011). Another group conducting the 2-minute walk test reported that two out of three subjects increased walking speed with Helix<sup>3D</sup> compared to 7E7 (Gailledrat et al. 2013).

Nelson & Carbone (2011) observed a subject over a 15-week period starting with the day of Helix<sup>3D</sup> fitting. Time used to perform the timed up and go (TUG) test decreased progressively over the 15 weeks by 35%. Therefore risk of falling decreased when the subjects got used to Helix<sup>3D</sup>. However, gait speed measured by a 2-minute walk test did not change over the 15-week time period.

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## References of summarized studies

Blumentritt, S., Ludwigs, E., Bellmann, M., & Boiten H. (2008). Das neue Hüftgelenk Helix 3D. *Orthopädie-Technik*, (5), 1–6.

Gailledrat, E., Moineau, B., Seetha, V., DeAngelis, M., Saurel, B., Chabloz, P., . . . Pérennou, D. (2013). Does the new Helix 3D hip joint improve walking of hip disarticulated amputees? *Annals of Physical and Rehabilitation Medicine*, 56(5), 411–418. doi:10.1016/j.rehab.2013.05.001

Ludwigs, E., Bellmann, M., Schmalz, T., & Blumentritt, S. (2010). Biomechanical differences between two exoprosthetic hip joint systems during level walking. *Prosthetics and Orthotics International*, 34(4), 449–460.

Ludwigs, E., Kannenberg, A., & Wüstefeld, D. (2013). Evaluation of the Benefits of a New Prosthetic Hip Joint System in Activities of Daily Function in Patients after Hip Disarticulation or Hemipelvectomy. *Journal of Prosthetics and Orthotics*, 25(3), 118–126.

Nelson LM, & Carbone NT. (2011). Functional Outcome Measurements of a Veteran With a Hip Disarticulation Using a Helix 3D Hip Joint: A Case Report. *Journal of Prosthetics and Orthotics*, 23(1), 21–27.

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# Stairs

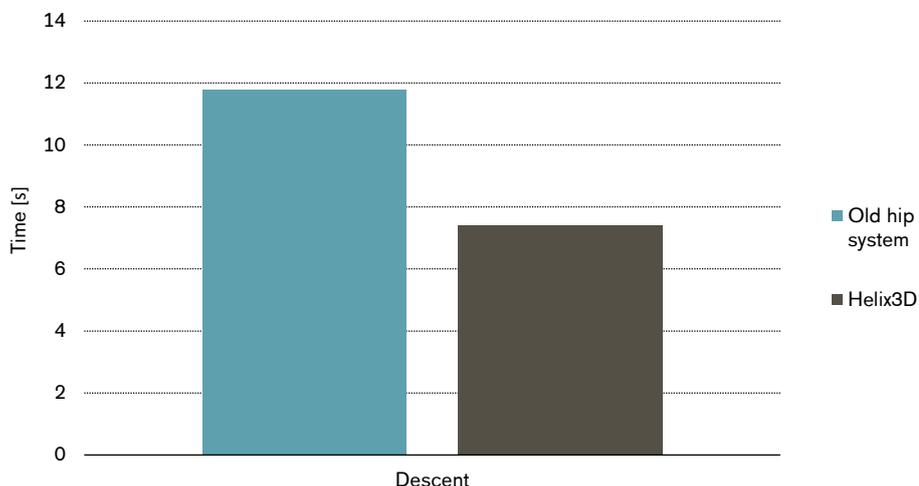
## Major Findings

With Helix<sup>3D</sup> Hip Joint System compared to other prosthetic hip joints:

→ **Velocity increased by 37% when descending**

→ **Stair descent was possible using the step-over-step strategy**

### Decreased time required to descend stairs with Helix<sup>3D</sup>



Ludwigs et al. (2013)

## Clinical Relevance

Stair ambulation is an activity that is important for amputees with an activity level ranging from K2 to K4. Being able to ascend and descend stairs is a requirement to participate in daily life. Common ways of measuring amputee's ability to ambulate stairs include stair ascent and descent strategy, use of handrail and/or use of an assistive device. Since stair ascent strategy is for hip disarticulated and hemipelvectomy amputees restricted to step-by-step strategy based on missing hip muscles, studies focus mostly on stair descent assessment. Measuring the time required to complete stair descent task can be done as part of a clinical mobility assessment.

## Summary

The time required to complete the stair descent task decreased by 37% when using Helix<sup>3D</sup> Hip Joint System compared to an old hip system. Furthermore, all of the 10 subjects were able to descend the stairs with a step-over-step strategy. In comparison, only 2 subjects were able to do so with their old hip system (Ludwigs et al. 2013). Both improvements are not only the beneficial effect of Helix<sup>3D</sup> but can also be explained by the effect of the change from non-microprocessor controlled knees to C-Leg. With the old hip system, 23% subjects were using C-Leg, whereas with Helix<sup>3D</sup> 100% of subjects. The acclimatisation period for Helix<sup>3D</sup> was determined as the time the subjects need to feel adjusted to the new prosthesis and was around 11 weeks.

## References of summarized studies

Ludwigs, E., Kannenberg, A., & Wüstefeld, D. (2013). Evaluation of the Benefits of a New Prosthetic Hip Joint System in Activities of Daily Function in Patients after Hip Disarticulation or Hemipelvectomy. *Journal of Prosthetics and Orthotics*, 25(3), 118–126.

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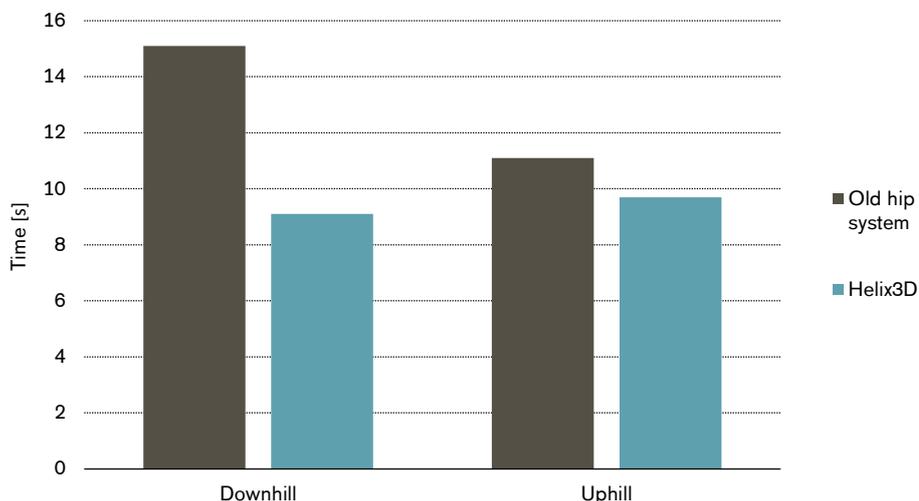
# Ramps / Hills

## Major Findings

With Helix<sup>3D</sup> Hip Joint System compared to other hip prostheses:

- Increased walking velocity when walking down ramps by 40%
- Trend towards increased walking velocity when walking up ramps by 13%

### Decreased time required to walk up and down ramp with Helix<sup>3D</sup>



Ludwigs et al. (2013)

## Clinical Relevance

Similar to stairs, ramps and hills need to be navigated by amputees with a wide range of activity levels to be able to participate in daily life. Evaluating the time needed to complete a ramp task can be part of a clinical mobility assessment.

## Summary

The time required to walk down a ramp decreased by 40% with Helix<sup>3D</sup> Hip Joint System compared to an old hip system. Furthermore, there was a trend towards decreased time required to walk up a ramp by 13% with Helix<sup>3D</sup> Hip Joint System. Both of these improvements not only result from the change of the previous hip prosthesis to Helix<sup>3D</sup> but are also affected by the change from a non-microprocessor controlled knee to C-Leg. The acclimatisation period for Helix<sup>3D</sup> was determined as the time the subjects need to feel adjusted to the new prosthesis and was around 11 weeks (Ludwigs et al. 2013).

## References of summarized studies

Ludwigs, E., Kannenberg, A., & Wüstefeld, D. (2013). Evaluation of the Benefits of a New Prosthetic Hip Joint System in Activities of Daily Function in Patients after Hip Disarticulation or Hemipelvectomy. *Journal of Prosthetics and Orthotics*, 25(3), 118–126.

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# Activity / Mobility / Activities of daily living (ADLs)

## Major Findings

With Helix<sup>3D</sup> Hip Joint System compared to other prosthetic hip joints:

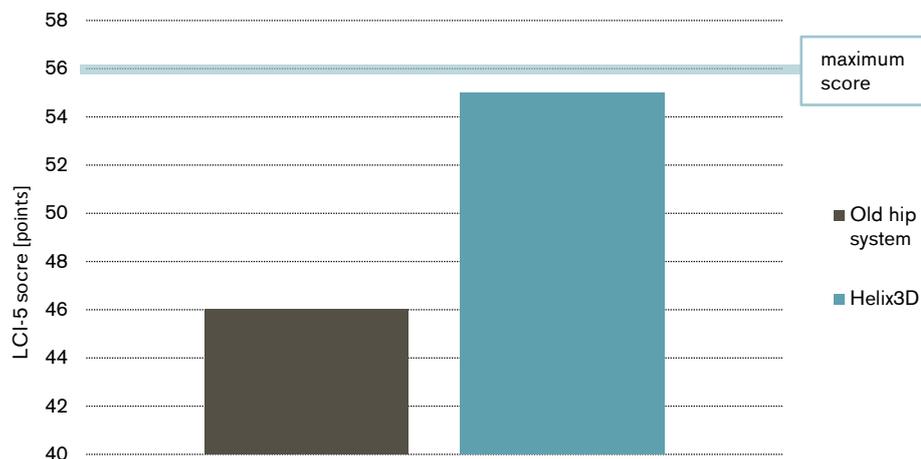
→ **Mobility and independence increased by 20%**

→ **74% less subjects dependent on caregivers**

→ **43% less subjects need walking aids**

→ **Improved walking ability**

### Improved LCI-5 score with Helix<sup>3D</sup>



LCI-5 score assesses the mobility and independence of lower-limb amputees based on 14 activities of daily living (ADLs). The maximum possible score is 56 points. Ludwigs et al. (2013)

## Clinical Relevance

With activities of daily living (ADLs) information is gathered on one hand side about the independency of amputees. Self-care activities and activities to live independently in a community are included in this part. On the other hand side, information about participation is gathered. Furthermore, assessment of ADLs is tool to detect avoidance of activities which can lead to an increase of comorbidities such as obesity and depression.

## Summary

The LCI-5 score improved from 46 points when using an old hip system to 55 points when using Helix<sup>3D</sup>, whereas 56 points represent the maximum possible score. Improvements in the subscore 'advanced ambulation skills' was reported. The subscore 'basic ambulation skills' stayed unchanged. The improvement of mobility and independence was confirmed by further findings: Four out of seven MFCL K2 subjects improved to MFCL K3 and one out of one MFCL K1 subjects improved to MFCL K2 with the use of Helix<sup>3D</sup>. The number of subjects that depend on help from relatives or caregivers was reduced from 4 to 1 out of 13 subjects. Moreover, 4 out of 7 subjects, which depended on a walking aid, showed a reduction in the support of waking aids with Helix<sup>3D</sup> compared to old hip systems. At the one year follow-up, 3 out of 7 subjects showed even a further reduction of the support of walking aids (Ludwigs et al. 2013).

Not only the overall functional assessment specific for the use of a hip prosthesis, but also each of the assessed functions by itself, was rated as improved with Helix<sup>3D</sup> compared to an old hip system. Namely the improved functions are comfort while standing, safety at loading response, ease of initiation of swing phase, walking velocity, safety while standing, reaching the extension stop, and starting to walk from a

standing position. In conclusion, the walking ability is improved with C-Leg (Ludwigs et al 2013).

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**References of  
summarized studies**

Ludwigs, E., Kannenberg, A., & Wüstefeld, D. (2013). Evaluation of the Benefits of a New Prosthetic Hip Joint System in Activities of Daily Function in Patients after Hip Disarticulation or Hemipelvectomy. *Journal of Prosthetics and Orthotics*, 25(3), 118–126.

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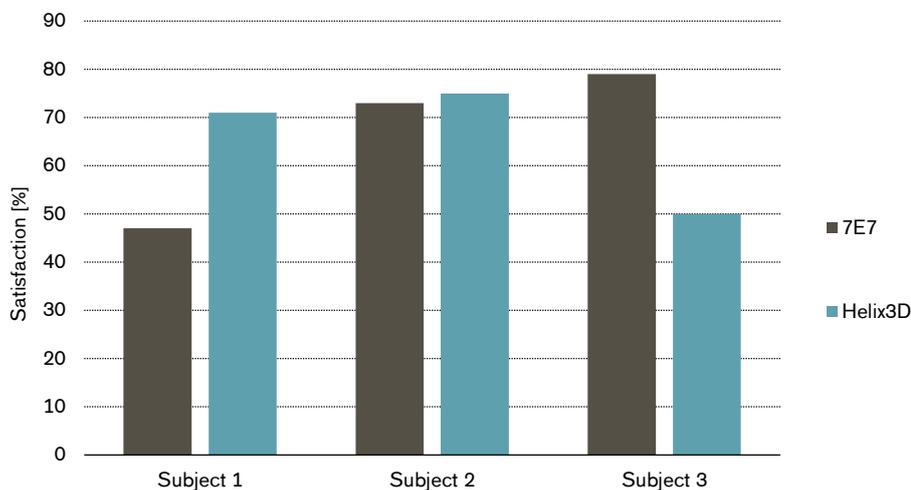
# Preference / Satisfaction / Quality of Life (QoL)

## Major Findings

With Helix<sup>3D</sup> Hip Joint System compared to 7E7:

→ **Increased satisfaction in 2 out of 3 subjects after only 4 days of using Helix<sup>3D</sup>**

### Increased satisfaction in 2 out of 3 subjects with Helix<sup>3D</sup>



Satisfaction was measured after 4 days of using Helix<sup>3D</sup> (Gailledrat et al. 2013).

## Clinical Relevance

Satisfaction and quality of life can be measured to determine the general well-being of a person. They are influenced by other categories and can therefore be seen as a summary of possible activities, independence and perceived safety. Satisfaction can be measured by using the SatPro questionnaire. It includes 15 items estimating comfort, facility to use, and effectiveness of the prosthesis. The result is presented as a satisfaction score expressed in percentage.

## Summary

The satisfaction was increased for 2 out of 3 subjects after 4 days of using Helix<sup>3D</sup> compared to 7E7 by 51%, respectively 3%. 2 out of 3 subjects reported that moving with Helix<sup>3D</sup> is more difficult than with the 7E7 (Gailledrat et al. 2013). These unsatisfying results are based on the prosthetic set up applied in study: As stated by the authors, the prosthetic set up of the Helix<sup>3D</sup> prosthetic hip system was not in compliance with the methods recommended by the manufacturer (Ottobock). Furthermore, since it takes time for subjects to get used to the hydraulic control of Helix<sup>3D</sup>, 4 days of acclimatisation period might have been too short.

## References of summarized studies

Gailledrat, E., Moineau, B., Seetha, V., DeAngelis, M., Saurel, B., Chabloz, P., . . . Pérennou, D. (2013). Does the new Helix 3D hip joint improve walking of hip disarticulated amputees? *Annals of Physical and Rehabilitation Medicine*, 56(5), 411–418. doi:10.1016/j.rehab.2013.05.001

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## 3 Summaries of individual studies

On the following pages you find summaries of studies that researched Helix 3D hip joint system. You find detailed information about the study design, methods applied, results and major findings of the study. At the end of each summary you also can read the original study authors' conclusions.

## Reference

Ludwigs E, Kannenberg A, Wüstefeld D.

Research Department, Otto Bock HealthCare GmbH, Göttingen, Germany.

# Evaluation of the Benefits of a New Prosthetic Hip Joint System in Activities of Daily Function in Patients after Hip Disarticulation or Hemipelvectomy

Journal of Prosthetics and Orthotics 2013; 25(3):118-126.

## Products

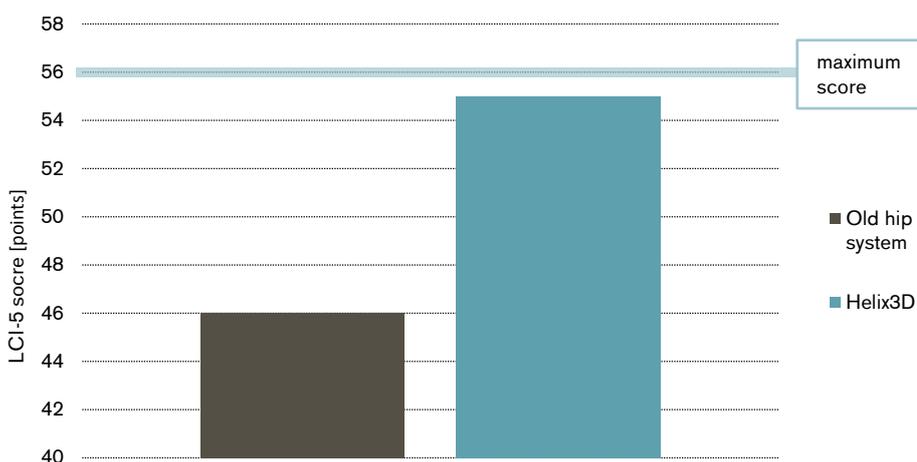
### Helix<sup>3D</sup> vs old hip system

## Major Findings

With Helix<sup>3D</sup> Hip Joint System compared to old hip system:

- **Increased mobility and independence by 20%**
- **Increased walking velocity when descending stairs by 37% and when walking down ramps by 40%**
- **Less need for walking aids and for help of caregivers**

### Improved mobility and independence with Helix<sup>3D</sup>



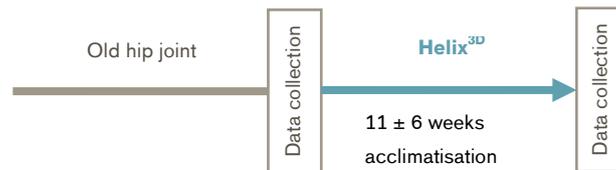
Locomotor Capability Index 5 (LCI-5) score assesses the mobility and independence of lower-limb amputees based on 14 activities of daily living (ADLs). The maximum possible score is 56 points.

## Population

Subjects:	11 disarticulation and 2 hemipelvectomy amputees
Previous prosthesis:	69% 7E7, 23% littig hip, 8% 4-bar-knee joint mounted in revers
Amputation causes:	not reported
Mean age:	17 – 71 yrs
Mean time since amputation:	not reported
MFCL:	8% K1, 54% K2, 38% K3

## Study Design

Observational, pre- to post-test design:



For most of the subjects not only the prosthetic hip joint was changed, but also the prosthetic knee joint; With the old hip joint, 23% of subjects were using C-Leg and 77% of subjects were using non-microprocessor controlled knees. With Helix<sup>3D</sup>, all subjects were using C-Leg.

## Results

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 Helix <sup>3D</sup> compared to an old hip system	Sig.*
Level Walking	10 m walk test (n=10)	Walking velocity tends to be increased from 0.76 to 0.83 m/s.	+
Stairs	Time to walk down eight steps (n=10)	<b>Time required completing the task decreased by 37%.</b>  All subjects walked down with the step-over-step strategy when using Helix <sup>3D</sup> . With the old hip system, only 2 subjects were able to do so.	<b>++</b>  n.a.
Ramps, Hills	Time to walk up and down a ramp (11° grade) (n=10)	<b>Time required walking down a ramp decreased by 40%.</b> Time required walking up a ramp decreased by 13%.	<b>++</b> +
Activity, Mobility, Activities of daily living (ADLs)	LCI-5 (14 ADLs)	<b>Score improved by 20% (from 46 to 55).</b>  No changes in subscore 'basic ambulation skills'. <b>Improvements in subscore 'advanced ambulation skills'.</b>	<b>++</b>  0 <b>++</b>
	Questionnaire containing 6 activities that are demanding for hip disarticulation and hemipelvectomy amputees	<b>Improvement in score.</b>	<b>++</b>
	Determination of mobility level	1 out of 1 MFCL K1 subject improved to MFCL K2. 4 out of 7 MFCL K2 subjects improved to MFCL K3.	n.a.
	Functional assessment specific for the use of a hip prosthesis	All of the assessed functions were rated as improved: <b>Comfort while standing</b> <b>Safety at loading response</b>	<b>++</b> <b>++</b>

Category	Outcomes	Results for Helix <sup>3D</sup> compared to an old hip system	Sig.*
		<b>Ease of initiation of swing phase</b>	<b>++</b>
		<b>Walking velocity</b>	<b>++</b>
		<b>Safety while standing</b>	<b>++</b>
		<b>Reaching the extension stop</b>	<b>++</b>
		<b>Starting to walk from a standing position</b>	<b>++</b>
		<b>The overall assessment is improved.</b>	<b>++</b>
	Independence and walking aid	Subjects needed help from relatives or caregivers was reduced from 4 to 1 subject out of 13.	n.a.
		7 subjects needed walking aid with the old hip system. 4 out of 7 subjects showed a reduction in the support of walking aids with Helix <sup>3D</sup> . At the one year follow-up, 3 out of 7 subjects showed even a further reduction in the support of walking aids.	n.a.

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

#### Author's Conclusion

"In summary, the results of the LCI-5, the functional assessments, and walking velocity demonstrate significant improvements with the Helix<sup>3D</sup> Hip Joint System as compared with conventional pelvic socket prostheses. This suggests that increased mobility and independence offered by this new prosthetic system with Helix<sup>3D</sup> Hip Joint, C-Leg, instructions for the prosthetic alignment, and recommendations for the pelvic socket may improve the outcome of the amputee's rehabilitation." (Ludwigs et al. 2013)

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## Reference

Gailledrat E, Moineau B, Seetha V, DeAngelis MP, Saurel B, Chabloz P, Nougier V, Pérennou D.

Department of Physical Medicine and Rehabilitation, Grenoble University Hospital, Institute of Rehabilitation, France.

# Does the new Helix 3D hip joint improve walking of hip disarticulated amputees?

Annals of physical and rehabilitation medicine 2013; 56(5):411-418.

## Products

### Helix<sup>3D</sup> vs 7E7

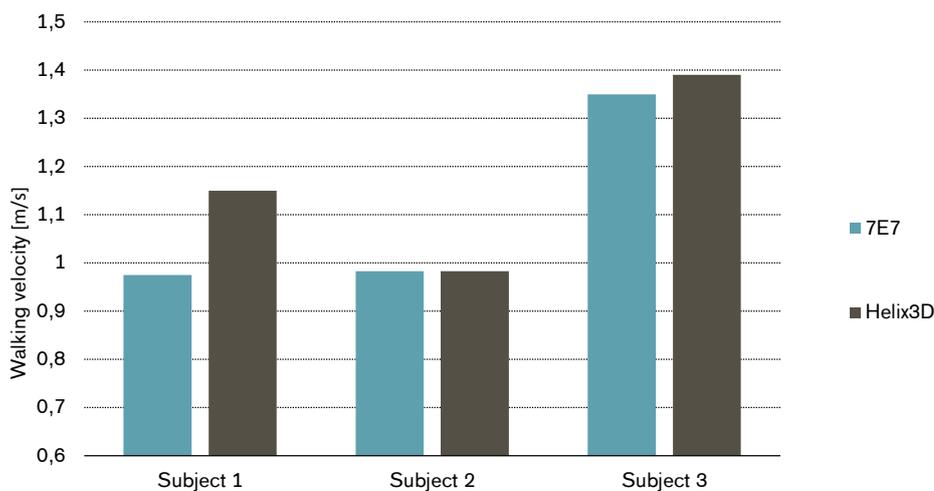
## Major Findings

With Helix<sup>3D</sup> Hip Joint System compared to 7E7:

- **Increased satisfaction for 2 out of 3 subjects**
- **Increased walking velocity for 2 out of 3 subjects**
- **Increased length of single limb support on prosthetic side for 2 out of 3 subjects**

Caution: The prosthetic set up of the Helix<sup>3D</sup> prosthetic hip system was not in compliance with the methods recommended by the manufacturer (Ottobock). Moreover, 4 days of acclimatisation period might have been too short to evaluate Helix<sup>3D</sup>, since it takes time to get used to the hydraulic control system.

### Increased walking velocity only after 4 days of using Helix<sup>3D</sup>



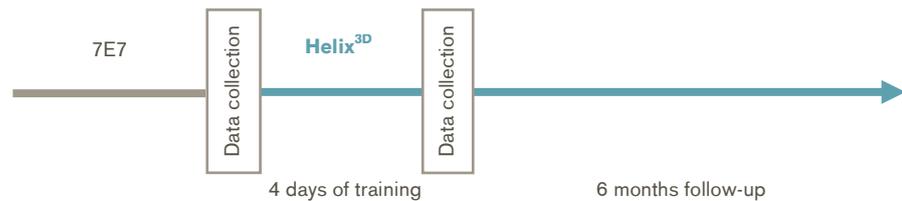
Walking velocity was determined by the two minute walk test.

## Population

Subjects:	3 hip disarticulated amputees
Previous prosthesis:	7E7
Amputation causes:	67% trauma, 33% osteosarcoma
Mean age:	37 yrs
Mean time since amputation:	not reported
MFCL:	not reported

## Study Design

Clinical case report:



Only one out of three subjects continued with the follow-up. No measurements were taken after the follow-up period since the amputee showed an ischiatic wound.

## Results

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 Helix <sup>3D</sup> compared to 7E7:	Sig.*
Level Walking	Two minute walk test (TMWT)	Distance increased for 2 subjects by 18% and 3%. Unchanged distance for one subject.	n.a.
	Motion analysis	Length of single limb support on prosthetic side relative to gait cycle increased for 2 subjects by 11% and 1.6%.	n.a.
	Walking aid	Number of subjects who use a cane when ambulating decreased from one to none.	n.a.
Preference, Satisfaction, Quality of Life (QoL)	Satisfaction Questionnaire (SatPro)	Increased score for 2 out of 3 subjects. For one subject the score increased by 51%, for the other subject by 3%.	n.a.

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

## Author's Conclusion

"This three cases study showed that experimental and clinical assessments and satisfaction scales must be associated for the validation of technical innovations in amputees. It also suggested the need for further developments of the Helix<sup>3D</sup> equipment protocol before getting clinically relevant for hipdisarticulated amputees. A prolonged training period might be also necessary to improve confidence in the prosthesis equipped with Helix<sup>3D</sup>, especially when equipping hip-disarticulated patients used to another prosthesis." (Gailledrat et al. 2013)

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## Reference

Nelson LM, Carbone NT.

Department of Veterans Affairs, Prosthetics and Sensory Aids Service, New York, USA.

# Functional Outcome Measurements of a Veteran With a Hip Disarticulation Using a Helix 3D Hip Joint: A Case Report

Journal of Prosthetics and Orthotics 2011; 23(1):21-27.

## Products

Helix<sup>3D</sup> vs 7E7

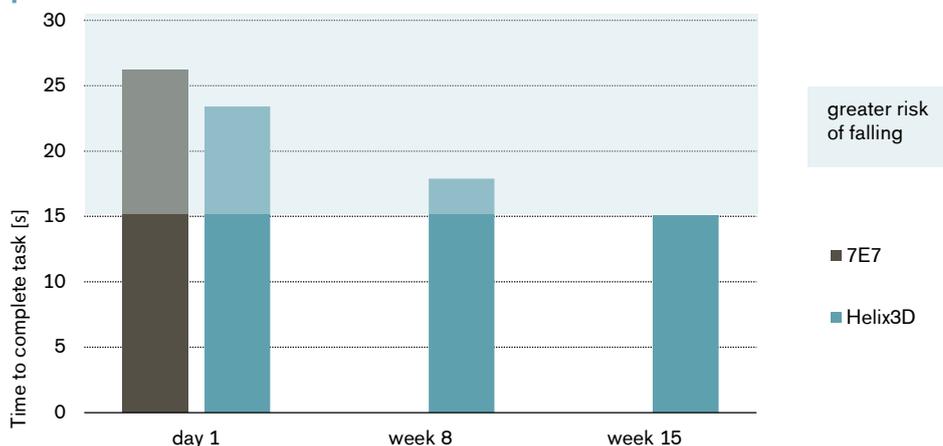
## Major Findings

With Helix<sup>3D</sup> Hip Joint System:

→ **Decreased risk of falling over 15-week time period based on improvements in timed up and go test (TUG) by 35%**

→ **Walking speed increased by 90% compared to 7E7**

### Progressively improving time to complete TUG over test period



The timed up and go test (TUG) includes standing up from a chair, walking 3 meters, turning around, walking 3 meters, sitting down.

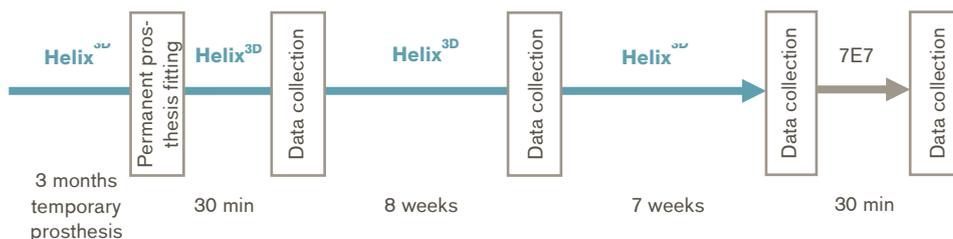
The marked part indicated a greater risk of falling assessed from a healthy geriatric population.

## Population

Subjects:	1 unilateral, disarticulated amputee
Previous hip prosthesis:	Helix <sup>3D</sup> (temporary prosthesis)
Amputation causes:	gunshot
Mean age:	30 yrs
Mean time since amputation:	6 months
MFCL:	not reported

## Study Design

### Case study:



## Results

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 Helix <sup>3D</sup>	Sig.*
Level Walking	Timed up and go (TUG)	Progressively improving test time during the 15-week time period: 23.4 s at the day of prosthesis fitting, 17.9 s at 8 weeks, 15.1 s at 15 weeks.  Improved test time (23.4 s) compared to 7E7 (26.2 s) at the day of prosthesis fitting.	n.a.
	2-minute walk test	No changes in distance covered over the 15-week time period: 128.6 m at the day of prosthesis fitting, 125.0 m at 8 weeks, 129.0 m at 15 weeks. Therefore gait speeds of 1.08, 1.04 and 1.07 m/s were reached.  Distance covered (128.6 m) was increased by 90% compared to 7E7 (67.6 m) at the day of prosthesis fitting and therefore gait speed improved to 1.08 m/s compared to 0.56 m/s with 7E7.	n.a.

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

## Author's Conclusion

"The veteran with a hip disarticulation in this case report showed improvement in TUG times using the Helix Hip 3D, C-Leg, and Trias foot prosthesis during the 3-month course of physical therapy and prosthetic care. The veteran also ambulated at a speed that has been determined to indicate independence in ADLs, successful community ambulation, and a decrease in the chance of hospitalization when using the Helix Hip 3D prosthesis. As per the functional outcome measures, the veteran did not achieve the same level of functional independence with the trial of the single axis 7E7 hip joint. Future studies should consider measuring gait symmetry through kinematic analysis and energy expenditure while ambulating with the Helix 3D hip joint when compared with a single-axis hip joint." (Nelson & Carbone 2011)

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## Reference

Ludwigs E, Bellmann M, Schmalz T, Blumentritt S.

Research Department, Otto Bock HealthCare GmbH, Göttingen, Germany

# Biomechanical differences between two exoprosthetic hip joints systems during level walking

Prosthetics and Orthotics International 2010; 34(4):449-460.

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## Products

### Helix<sup>3D</sup> vs 7E7

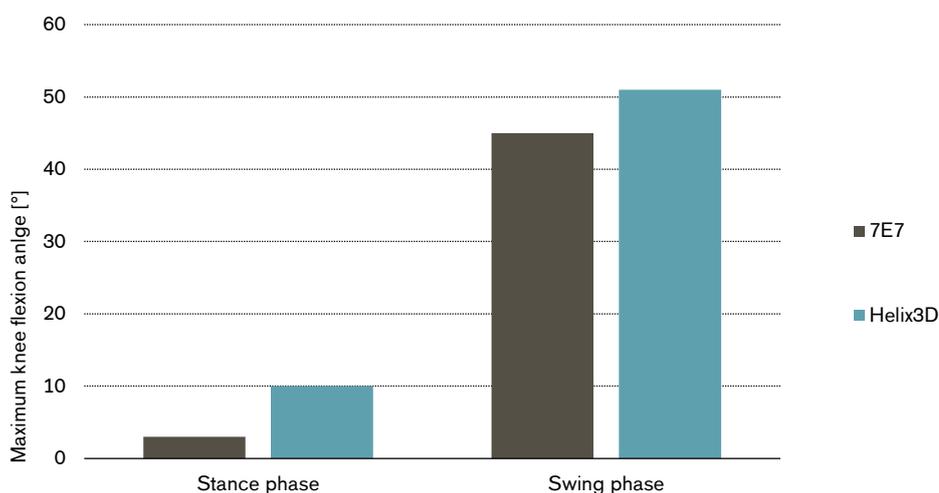
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## Major Findings

With Helix<sup>3D</sup> Hip Joint System compared to 7E7:

- **Increased safety and higher stability due to generation of only hip extension movements during the whole stance phase.**
- **Gait pattern closer to contralateral limb.**
- **Increased symmetrical knee flexion during swing phase.**
- **Reduction of range of motion of pelvic tilt by 5° could help alleviate spinal pain syndromes.**

### Increased maximum knee flexion angle with Helix<sup>3D</sup>



Maximum knee flexion angle during stance and swing phase was measured when subjects walked at self-selected walking velocity. 1 out of 6 subjects used a walking aid on the contralateral side.

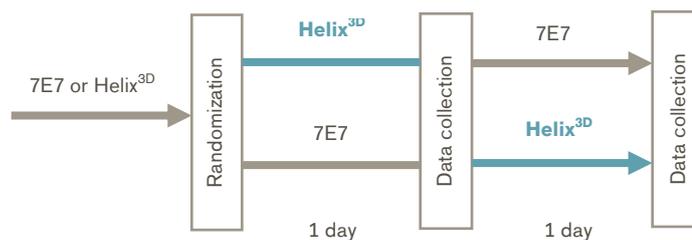
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## Population

Subjects:	6 unilateral, hip disarticulated amputees
Previous hip prosthesis:	67% 7E7, 33% Helix <sup>3D</sup>
Amputation causes:	67% tumour, 17% congenital, 17% infection
Mean age:	41 yrs ( $\pm$ 14 yrs)
Mean time since ambulation:	not reported
MFCL:	not reported

## Study Design

Interventional, randomized crossover design:



## Results

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 Helix <sup>3D</sup> compared to 7E7	Sig.*
Level Walking	Self-selected walking velocity	No difference.	0
	Motion analysis	<p>No difference in step length on the contralateral side, neither on the prosthetic side.</p> <p><b>Mean maximum external sagittal hip moments within first 20% of gait cycle (beginning stance phase) result in extension moments with Helix<sup>3D</sup> and in flexion moments with 7E7.</b></p> <p><b>Maximum extension hip angle is reached later in stance phase (at 46% vs 17% of gait cycle).</b></p> <p>With Helix<sup>3D</sup> hip flexion movement starts immediately after maximum extension is reached, whereas with 7E7 flexion movement is initiated after 70% of gait cycle.</p> <p><b>Decreased maximum hip angular velocity of extension movement in stance phase (94 °/s vs 160 °/s).</b></p> <p><b>Decreased maximum hip angular velocity of flexion movement in swing phase (-64 °/s vs -98.5 °/s).</b></p> <p>Sagittal knee moments within the first 20% of gait cycle (beginning stance phase) result in flexion moments with Helix<sup>3D</sup> and in only short flexion moments with 7E7 between 0 and 5% and between 15 and 25% of gait cycle.</p> <p><b>Increased maximum knee flexion angle in stance phase (10° vs 3°).</b></p> <p><b>Increased maximum knee flexion angle in swing phase (51° vs 45°).</b></p>	<p>0</p> <p>0</p> <p>++</p> <p>++</p> <p>n.a.</p> <p>++</p> <p>++</p> <p>n.a.</p> <p>++</p> <p>++</p>

Category	Outcomes	Results for Helix <sup>3D</sup> compared to 7E7	Sig.*
		<b>Decreased difference in maximum knee flexion between the prosthetic and sound side during swing phase.</b>	<b>++</b>
		<b>Decreased maximum mean range of pelvic tilt (20° vs 25°).</b>	<b>++</b>

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

### Author's Conclusion

"The results of this investigation confirm significant enhancements with regards to the gait pattern of hip disarticulation patients when walking with the new Helix<sup>3D</sup> Hip Joint in comparison to the 7E7 hip joint. These enhancements include:

- Improved hip extension control and polycentric design offer increased security during stance phase with respect to uncontrollable hip motion;
- Longer, more natural period of hip extension during stance phase;
- More constant hip flexion movement during swing phase;
- Increased knee flexion during stance phase;
- Increased knee flexion during swing phase;
- Significant reduction in the range of pelvic tilt.

Hence, the Helix<sup>3D</sup> Hip Joint System provided a gait pattern more similar to that of able bodied persons than the uniplanar 7E7 design." (Ludwigs et al. 2010)

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**Reference**

Blumentritt S, Ludwigs E, Bellmann M, Boiten H.

Otto Bock HealthCare GmbH, Research, Duderstadt, Germany

## The new Hip Joint Helix<sup>3D</sup>

Orthopädie Technik 2008; 59(8):345-349.

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**Products****Helix<sup>3D</sup> vs 7E7**

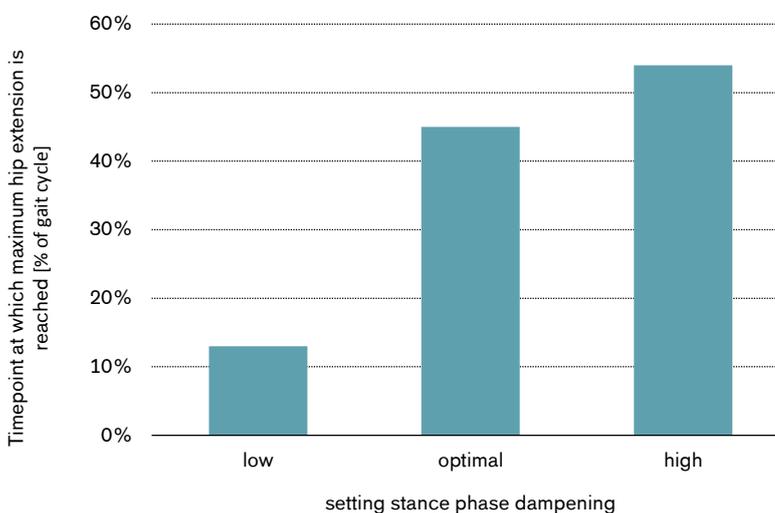
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**Major Findings**

With Helix<sup>3D</sup> Hip Joint System compared to 7E7:

- **Increased toe clearance**
- **Timepoint of maximum hip extension angle in gait cycle as well as step length can be adjusted by swing phase and stance phase settings**
- **Supported swing phase initiation**
- **Pelvis tilt reduced by around 6°**

### Maximum hip extension angle depends on settings of stance phase dampening



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**Population**

Subjects:

18 disarticulation and 3 hemipelvectomy amputees for assessment of prosthetic fit  
6 disarticulation amputees for biomechanical motion analysis

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**Study Design**

Technical report and description of first experiences when subjects walked with test prosthesis

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## Results

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 Helix <sup>3D</sup> compared to 7E7	Sig.*
Level Walking	Motion analysis	<p>Pelvic tilt over gait cycle is reduced by around 6°.</p> <p>Maximum extension hip angle in stance phase is reached smoother through hydraulic dampening. Based on the settings of the stand phase dampening, the maximum extension hip angle is reached between 13% and 54% of the gait cycle.</p> <p>Allows for knee flexion angle in stance phase.</p> <p>Hip flexion movement starts right at the beginning of stance phase based on the polyurethane elements and therefore swing phase initiation is supported.</p> <p>Knee and hip joint flexion in swing phase occurs simultaneously and therefore toe clearance is ensured.</p> <p>Subjects reported that the combined movement of the hip joint, meaning flexion and rotation, is in particular useful during stance phase when walking slowly.</p> <p>With changing the settings of swing phase dampening, step length can be adjusted.</p>	n.a.

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

### Author's Conclusion

"First results and experience gained by biomechanical gait analysis studies as well as trial fittings conducted with a total of 21 disarticulation or hemipelvectomy patients are reported. During ambulation the pelvis position in stance phase is controlled and pelvis tilt reduced. The initiation of swing phase is supported. Interaction between hip and knee joint (C-Leg) allows enhanced shock absorption at weight acceptance, causes stance phase flexion and provides for more toe clearance during mid swing phase." (Blumentritt et al. 2008)

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