
Reference

Brunelli S, Averna T, Delusso S, Trallesi M.

Fondazione Santa Lucia, Rome, Italy.

Vacuum assisted socket system in trans-tibial amputees: Clinical report

Orthopädie-Technik Quarterly, English edition, 2009; II:2-8.

Products

Vacuum-assisted socket system* (VASS) vs Patellar-tendon bearing prosthesis (PTB)

* TEC, later acquired by Otto Bock and sold as Harmony

Major Findings

With VASS compared to PTB:

→ **Wound healing occurs even when prosthesis is in use**

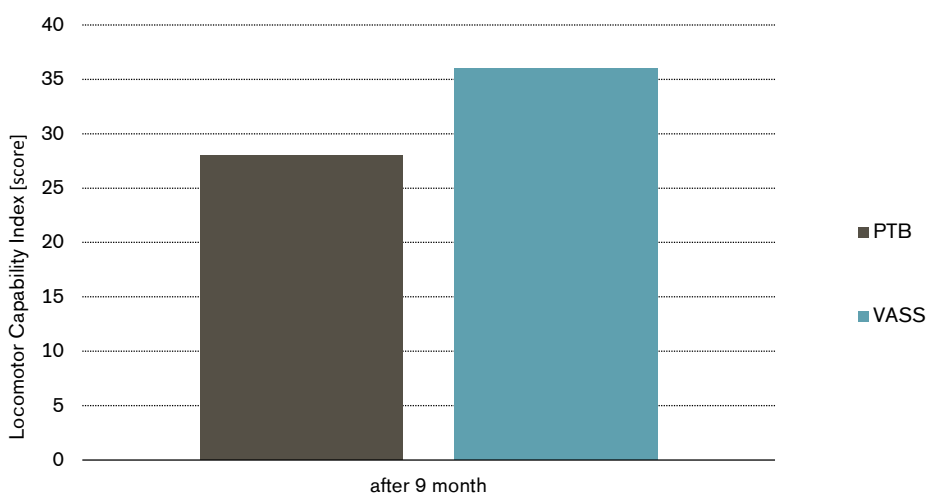
All subjects using VASS showed a complete wound healing after 9 months

→ **Allows for prosthesis use for at least 8 hours per day even when the stump presents unhealed wounds**

→ **Mobility tends to be improved by 29%**

Caution: Methodological problem since inclusion criteria in two study groups differed (subjects with wound healing failure in VASS group and subjects without wound healing failure in PTB group).

Increased mobility with VASS



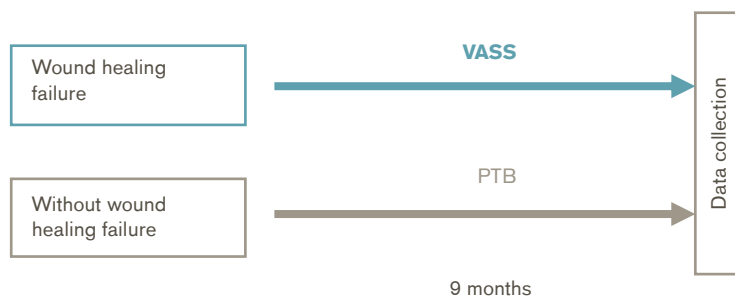
Locomotor Capability Index (LCI) is a mobility index with a maximum score of 42. Measurements were conducted with a vacuum-assisted socket system (VASS) or a patellar-tendon bearing prosthesis (PTB).

Population

Subjects:	24 transtibial amputees
Previous socket system:	Patellar-tendon bearing prosthesis
Amputation causes:	Dysvascular
Mean age:	62 ± 11 yrs in VASS group, 67 ± 11 yrs in PTB group
Mean time since amputation:	not reported
MFCL:	K2 – K3

Study Design

Interventional, parallel design:



Subjects with wound healing failure after amputation or chronic dermal ulceration of the stump were enrolled in VASS group. Subjects without wound healing failure after amputation or chronic dermal ulceration of the stump were enrolled in PTB group.

Results

Body Function				Activity			Participation	Others	
Wound Healing	Limb Volume Fluctuation	Pain	Comfort, Limb Health	Level Walking	Balance	Activity, Mobility, ADLs	Preference, Satisfaction, QoL	Pistoning	Pressure Measurement

Category	Outcomes	Results for VASS compared to PTB	Sig.*
Wound Healing	Digital photographs. Localization, description, type and size of wound, skin ulcers, scars or necrosis, trend of wound healing and residual limb health were reported	With VASS a complete healing of the wounds was achieved after 9 months in all subjects (n=7).	n.a.
Pain	Pain during walking by Visual Analogical Scale (VAS)	Pain tended to be decreased by 34% (4.6 vs 7 with a max score of 10).	+
Activity, Mobility, Activities of daily living (ADLs)	Locomotor Capability Index (LCI)	Level of locomotion capabilities tended to be increased by 29% (36 vs 28 of a max score of 42).	+

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

Author's Conclusion

"We can assert that patients fitted the VASS Harmony had an excellent compliance with the prosthesis and all of them showed an improvement in wound healing. The major advantages observed in VASS group patients are: 1) possibility to use the prosthesis even when the stump presents unhealed wounds; 2) a strong trend to healing of these wounds, 3) better walking autonomy with less pain compared to patients fit PTB sockets. The amputees fit with Harmony referred a good balance, stability and control over the prosthesis due to improved proprioception and the awareness the patient has of his or her leg in space. It can be fit earlier after amputation and it may help to heal stump wounds." (Brunelli et al. 2009)

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