

Reference

Traballesi M, Delussi AS, Fusco A, Iosa M, Averna T, Pellegrini R, Brunelli S.
Fondazione Santa Lucia, Rome, Italy.

Residual limb wounds or ulcers heal in transtibial amputees using an active suction socket system. A randomized controlled study

European Journal of Physical and Rehabilitation Medicine 2012; 48(4):613-23.

Products

Vacuum-assisted socket system* (VASS) vs Suction socket system (SSS)

* TEC Harmony

Major Findings

With VASS compared to SSS:

→ **Complete wound healing is not a prerequisite for prosthesis fitting and use**

Time until prosthesis fitting is more than three times shorter

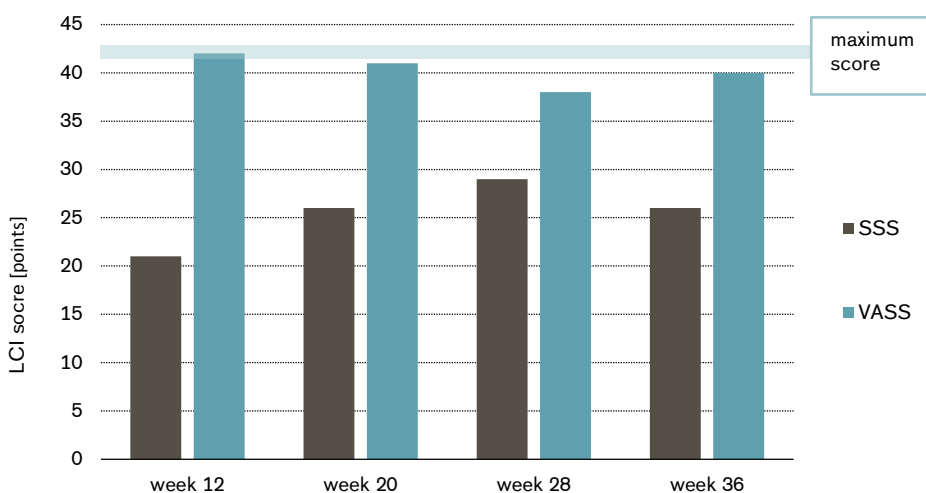
→ **Increased mobility**

Locomotor capability index was increased by up to 100%

Up to double as many subjects are able to walk independently

→ **Fivefold increase in time prosthesis was used**

Improved mobility with VASS



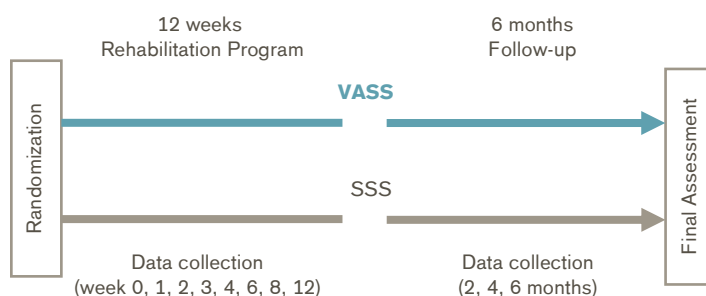
Locomotor capability index (LCI) assesses the mobility of lower-limb amputees. The maximum possible score is 42 points.

Population

Subjects:	16 transtibial amputees
Previous socket system:	not reported
Amputation causes:	100% dysvascular
Mean age:	61.3 ± 13.2 yrs
Mean time since amputation:	not reported
MFCL:	K2 – K3

Study Design

Interventional, randomized parallel study design:



Only subjects with presence of a wound dehiscence as a surgical complication or an ulcer were included. The in-patient rehabilitation program started a few days after amputation or after the occurrence of a new residual limb wound. Subjects on VASS were able to start walking with the prosthesis 16.4 ± 8.6 days after starting the rehabilitation program regardless of wound healing. Conversely, subjects on SSS had to wait for substantial wound healing (wound area $\leq 1 \text{ cm}^2$) until prosthesis fitting (58.6 ± 24.7 days). It is a common clinical practice to authorize the use of a SSS only when the stump is healed.

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 SSS	Sig.*
Wound Healing	Computerized tool to assess size of ulcers/wounds	Faster mean wound healing rate (percentage of reduction of both wound area and perimeter) between week 3 and week 20.	n.a.
		VASS showed progressive healing, whereas SSS showed a high degree of healing around week 20.	n.a.
Pain	Pain perception (Visual Analogue Scale)	No difference in pain at week 20 and week 36.	0
Activity, Mobility, Activities of daily living (ADLs)	Locomotor Capability Index (LCI) for walking capabilities	LCI-score increased by 100% (42 vs 21 points) at week 12.	++
		With VASS 100% of subjects were able to walk independently, whereas with SSS only 50% at week 12.	++
		Improved clinical mobility was observed at all later follow-ups.	+
		Interview: Time until prosthesis fitting and number of hours of prosthesis use per week	Time until prosthesis fitting was more than 3 times shorter (16 vs 59 days) since wound healing is not a requirement with VASS. Fivefold increase in time prosthesis was used (62 hrs/week vs 12 hrs/week) after two months.
	Prostheses use remained higher for the entire follow-up period.	+	

Category	Outcomes	Results for VASS compared to SSS	Sig.*
* no difference (0), positive trend (+), negative trend (-), significant (++)/(--), not applicable (n.a.)			
Author's Conclusion	"When open residual limb wounds are present, use of a prosthesis with VASS may be effective for early ambulation recovery with no substantial pain and no inhibition of wound healing." (Traballesi et al. 2012)		

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