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


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 $16.4 \pm 8.6$ days after starting the rehabilitation program regardless of wound healing. Conversely, subjects on SSS had to wait for substantial wound healing ($\text{wound area} \leq 1 \text{ cm}^2$) until prosthesis fitting ($58.6 \pm 24.7$ days). It is a common clinical practice to authorize the use of a SSS only when the stump is healed.

Results

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