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


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).

**LocomotorCapability 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).

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

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

### 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:

![Diagram](image)

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.

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**Results**

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

* 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)