This document summarizes clinical studies conducted with the Harmony Socket 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. healing, limb volume fluctuation, etc.). By clicking on individual 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).

<table>
<thead>
<tr>
<th>Reference</th>
<th>Year</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Author</td>
<td></td>
<td>Body Function</td>
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<tr>
<td></td>
<td></td>
<td>Wound Healing</td>
</tr>
<tr>
<td>Samitier</td>
<td>2014</td>
<td></td>
</tr>
<tr>
<td>Kahle¹</td>
<td>2014</td>
<td>x</td>
</tr>
<tr>
<td>Kahle</td>
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<td>x</td>
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<tr>
<td>Hoskins²</td>
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<tr>
<td>Traballesi</td>
<td>2012</td>
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<tr>
<td>Sanders²</td>
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<td>x</td>
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<td>Klute</td>
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<tr>
<td>Ferraro</td>
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<td>Brunelli</td>
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<td>Street¹</td>
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<td>Goswami</td>
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<td>Beil</td>
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<td>Board</td>
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<tr>
<td>Total number</td>
<td>4</td>
<td>6</td>
</tr>
</tbody>
</table>

1) Review Article  2) Case Series
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.
Wound Healing

**Major Findings**

With vacuum-assisted socket system (VASS) compared to other socket systems:

- **Even in the presence of unhealed wounds the prosthesis can be worn.**
- **The wounds show a strong trend to heal also when prosthesis is in use.**

**Wound healing occurs while using VASS**

Patient 72 years old, cause of amputation was nonhealing ulcer, diabetes mellitus type II, fitted with a vacuum-assisted socket system (VASS). (Hoskins et al., 2014)

**Clinical Relevance**

Prosthesis should provide adequate environment and thereby keeping the residual limb healthy and free of wounds. Early prosthesis fitting is crucial to obtain great patient autonomy and mobility (Traballesi et al., 2012). Delayed rehabilitation can lead to a deterioration of balance, muscle endurance, strength, flexibility and coordination. Moreover delayed prosthesis fitting is the main cause of increased costs for rehabilitation after amputation.

**Summary**

With the VASS healing occurs while the amputee is able to use the prosthesis for ambulation. In contrast, other modes of suspension normally require the residual limb to be out of the prosthesis for healing to take place. This difference is based on following. (I) With the VASS movement of the limb relative to the socket is reduced which leads to minimal physical stress as peak pressure and shear forces. (II) Increased blood flow (Street, 2002) has the potential to improve limb health since blood is the delivery system that provides the limb with oxygen, nutrients and immune cells, and removes wastes.

Hoskins et al. reported that wound closure occurred within all subjects in an average time of 177 days while the prosthesis is in use. A high variation in time was observed in the range of 40 to 390 days which is based on heterogeneity in health conditions, wound severity, and compliance in terms of wound care and prosthesis use (Hoskins et al., 2014). These results are in accordance to Brunelli et al. (2009): Wound healing occurred in all subjects while using VASS within 9 months.


Limb Volume Fluctuation

**Major Findings**

With vacuum assisted socket system (VASS) compared to other socket systems:

- **Prevents volume loss of the residual limb during activity**
  - Residual limb volume increased 3.7% with VASS
  - Residual limb volume decreased 6.5% with suction socket system (SSS)

- **Limb volume change is more positive than with pin suspension system (PSS) during activity**
- **Net gain of limb volume is achieved with under-sized, neutral and over-sized socket design after activity**

**Increased stump volume with VASS after walking**

![Graph showing stump volume change with VASS and SSS](image)

Volume of residual limb before and after 30 minutes of walk was measured for vacuum-assisted socket system (VASS) and suspension socket system (SSS). (Board et al., 2001)

**Clinical Relevance**

One of the most important benefits of the VASS is that limb volume is maintained throughout the day. With other suspension systems, the residual limb loses volume as fluid gets pushed out of the limb during stance phase. As a result, the socket fit is less consistent and users need to remove prosthesis multiple times/day while attempting to manage volume changes with additional sock layers.

**Summary**

VASS shifts the fluid balance in the residual limb to one of maintenance or a slight gain by driving less fluid out of the limb during stance phase and drawing more fluid in during swing phase. An increase in the residual limb volume by 3.7% after 30 min of walking was observed with VASS, whereas the residual limb volume decreased by 6.5% with the suction socket system (Board et al., 2001). A case report demonstrated that 2 out of 3 subjects showed an increase in limb fluid volume during activity by 1.2%, respectively 0.4%. Moreover, 3 out of 3 subjects showed a more positive limb volume change during activity compared to pin suspension system (PSS) (Sanders et al., 2011).

A study investigating the effect of different socket sizes measured a change of the fluid balance of the residual limb towards a net gain for all socket sizes during walking. The improved fluid balance is independent of socket size. Nevertheless a tight socket is crucial to make the VASS work as well as for safety reasons. (Goswami et al., 2003).
Beil et al. (2002) proposed that drawing more fluid in based on the 27% increase of negative pressure in swing phase is probably most responsible for volume maintenance. The drop in pressure is hypothesized by Street (2006) to be the result of the anchored liner. Thus tissues elongate, tissue pressure drops and therefore fluid is drawn into the limb.

References of summarized studies


↑ Back to overview table
Pain

Major Findings

With vacuum assisted socket system (VASS) compared to other socket system:

→ No change in pain perception even if prostheses use is more intense or residual limb volume is increased
→ Improves pain control even in the presence of wounds

Pain during walking with the prosthesis is decreased with VASS

<table>
<thead>
<tr>
<th>Pain level</th>
<th>Max pain</th>
<th>10</th>
<th>9</th>
<th>8</th>
<th>7</th>
<th>6</th>
<th>5</th>
<th>4</th>
<th>3</th>
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</tbody>
</table>

Visual analog scale [score]

Pain during walking after one month and after nine months wearing vacuum-assisted socket system (VASS) or a patellar-tendon bearing prosthesis (PTB). Subjects with wound healing failure were enrolled in VASS group, whereas subjects without wound healing failure were enrolled in PTB group. (Brunelli et al., 2009)

Clinical Relevance

If pain is not influenced by the occurrence of wounds, early prosthesis fitting and rehabilitation start before completed wound healing is possible. Early prosthesis fitting is crucial to obtain great patient autonomy and mobility (Traballesi et al., 2012).

Summary

There are multiple features of the VASS which have a positive effect on residual limb pain: I) residual limb volume maintenance and reduced pistoning results in minimization of skin irritations and breakdown. II) Mechanical stress, which is the major cause of pain, is reduced through smaller shear stress and through reduced pressure during stance phase. In practice this was confirmed by Brunelli et al. (2009): Subjects on VASS showed improved pain control after 1 month and after 9 month compared to subjects on patellar-tendon bearing (PTB) prosthesis. These results are even more remarkable, considering that only subjects with wound healing failure were included in the VASS group and only subjects without wound healing failure in the PTB group. Traballesi et al. (2012) could not find any difference in pain reported by subjects with wound healing failure between VASS group and the suction suspension system (SSS) group, even though subjects on VASS reported a longer prostheses use per day.

A study investigating the effect of different socket sizes, showed, that the increase in residual limb volume through an over-sized socket size, didn’t result in a change in pain perception (Goswami et al., 2003).

References of summarized studies


## Comfort and Limb Health

### Major Findings

With vacuum assisted socket system (VASS) compared to other socket systems:

- **Trend towards increased limb health**
  - 38% less blisters
  - 8% less redness of the skin

- **Improvements in comfort**

### Decreased comfort restricting factors with VASS

![Graph showing decreased comfort with VASS](image)

Problems experienced in users of vacuum-assisted socket system (VASS) and pin suspension system (PSS) (n=13) after wearing each system at least 30 days. (Ferraro, 2011)

### Clinical Relevance

Comfort is the basis for a successful prosthesis use. As a result of comfort, prosthesis use per day may increase which further leads to improved confidence of amputees and quality of life.

### Summary

Ferraro (2011) showed an increase in comfort with VASS compared to pin suspension system (PSS) based on a trend towards improved limb health such as less blisters and less redness of the skin. Furthermore, it is known, based on experience in praxis, that VASS reduces or eliminates minor skin problems such as folliculitis and recurring cysts (Street, 2006).

A study investigating the effect of different socket sizes with VASS, demonstrated that even the volume gain by using over-sized socket does not cause discomfort or reddening of the skin (Goswami et al., 2003). Only Klute et al., (2011) reported contrary results; residual limb health decreased with VASS compared to pin suspension system (PSS). These results can probably be explained by an inappropriate socket fit due to changes in residual limb volume that were not accommodated by necessary socket modifications in the first months of using VASS.

In a study investigating the effect of different socket types in combination with electronic VASS on transfemoral amputees, subjects reported higher comfort with brimless socket design instead of the ischial ramus containment (IRC) socket design (Kahle et al., 2014).

### References of summarized studies


**Level Walking**

**Major Findings**

With VASS compared to other socket systems:

- **Improvements in walking velocity**
  - Walking velocity improved by 11% measured by a 6 min walking test
  - Time required to complete timed up and go (TUG) test decreased by 19%

- **More symmetrical gait pattern compared to suction socket system**
  - Step length symmetry improved by 62%
  - Trend towards more symmetrical stance duration

**Decreased time to complete TUG with VASS**

![Bar chart showing decreased time to complete TUG with VASS](chart.png)

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. (Samitier et al., 2014)

**Clinical Relevance**

A poor fit of the prosthesis is associated with spending less time on the amputated limb because the amputee is less confident of control over and position of the prosthesis. Thus, maintaining a good fit is important to symmetrical gait.

**Summary**

Walking velocity improved with VASS by 11% relative to previous socket designs measured by a 6 minute walking test. Furthermore, time to complete the time up and go test (TUG) decreased by 19% (Samitier et al., 2014).

The VASS improved symmetry in stance duration and, consequently, step lengths were also more symmetrical (Board et al., 2001). The improved gait parameters of the VASS suggest the existence of a better fit compared to the suction system. Further, a proper fit affords the amputee better control by providing sufficient perception.
<table>
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<th>References of summarized studies</th>
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Balance

**Major Findings**

With vacuum assisted socket system (VASS) compared to other socket systems:

- **Improvements in balance and stability during activities**
  
  Berg balance scale score improved by 7.2%
  
  Time required completing four square step test decreased by 18%
  
  Activities-specific balance confidence (ABC) score improved by 23%

- **Decreased risk of falling**

**Decreased risk of falling with VASS**

The four square step test (FSST) was performed in subjects with mobility level K2 and K3. A time of 24 s or longer indicates an increased risk of falling in transtibial amputees. (Samitier et al., 2014)

**Clinical Relevance**

A good balance is important for stability during activities and to minimize the risk of falls. The Berg Balance Scale (BSS) is designed to evaluate balance. Scores range from 0 – 56 points, with higher scores reflecting a greater ability to balance. Another tool to measure balance is the activities-specific balance confidence (ABC) scale. A high score correlates with high grade of mobility and reduced limitations caused by a fear of falling. The four square step test (FSST) is a test to assess risk of falling among amputees.

**Summary**

Several balance assessment measurements have shown an improvement with VASS compared to other socket systems: Berg balance scale score improved by 7.2% with VASS compared to previous socket designs. Time required completing the four square step test decreased by 18% with VASS compared to previous socket designs (Samitier et al., 2014). Furthermore, activities-specific balance confidence (ABC) scale increased by 23% with VASS compared to pin locking suspension system (Ferraro, 2011).

Improved fit and linkage of the socket with decrease in pistoning when using VASS lead to an increase in balance and control compared to other socket designs. This may result in a lower risk of falling which correlates with survey results, where 31% of patients reported less falls when using VASS. However, these results didn’t reach significance (Ferraro, 2011).

**References of summarized studies**


Activity, Mobility, Activities of daily living (ADLs)

**Major Findings**

- **Higher mobility and better locomotion capabilities are achieved**
  - In K3 subjects: Locomotor capability index (LCI) increased by 19%
  - In subjects with wound healing failure: LCI increased by up to 100% at week 12

- **Prosthesis use is increased**
  - In K2 subjects: prosthesis use is increased by 7.4%
  - In subjects with wound healing failure: fivefold increase after 2 months

- **86% of subjects reported increased walking times compared to pin suspension system (PSS)**

- **31% of subjects reported less falls than with PSS**

**Improved mobility with VASS**

Patients were randomly fitted with either vacuum-assisted socket system (VASS) or suction socket system (SSS). All subjects had presence of wound failure as a surgical complication or an ulcer at the start of the study. Subjects on SSS discontinued prosthesis use until their wounds were almost healed (wound surface area <1 cm²). This is the reason why locomotor capability index (LCI) is constantly increasing for SSS whereas it is already at the maximum score of 42 at 12 weeks for VASS. (Traballesi et al., 2012)

**Clinical Relevance**

Prosthesis fitting is the only way patients with lower limb amputation can regain the ability to walk and find new independence in the activities of daily living. An increased grade of mobility is crucial to reach a satisfying quality of life.

**Summary**

Mobility, measured by locomotor capability index (LCI), improved in MFCL K3 subjects with VASS compared to previous socket system by 19% (Samitier et al., 2014). When investigating mobility in patients with wound healing failure, patients on VASS reached already 12 weeks after fitting a maximum score in the LCI. In contrast, patients on suction socket system (SSS) reached a score of 21 which can be explained that subjects had to discontinue prosthesis use until a complete wound healing was reached. Moreover, improvements in clinical mobility with VASS were observed at all later follow-ups up to week 36 (Traballesi et al., 2012).

These results were confirmed by a study comparing VASS to a patellar-tendon bearing prosthesis (PTB). The LCI score tended to be improved by 29% with VASS.
after a 9 months period, even though only patients with wound healing failure were enrolled in the VASS group (Brunelli et al., 2009).

Prosthesis use increased in MFCL K2 subjects with VASS compared to previous socket system by 7.4% (Samitier et al., 2014). A fivefold increase in prosthesis use was reached with VASS compared to SSS in subjects with wound healing failure (Traballesi et al., 2012). Furthermore, 86% of subjects reported increased walking time when fitted with VASS compared to pin suspension system (PSS). When prosthesis is worn more often, patient’s confidence increases which leads furthermore to a decreased incidence of falls. 31% of subjects reported less falls with VASS compared to PSS (Ferraro, 2011).

Only one study demonstrated decreased activity with VASS compared to pin suspension system measured by number of steps (Klute et al., 2011). However, these results have to be looked at with caution. A dropout rate of 75% of subjects indicates insufficient amounts of socket checks, which are necessary with VASS based on a decrease in residual limb volume.

References


Preference, Satisfaction, Quality of Life

**Major Findings**

With vacuum-assisted socket system (VASS) compared to other socket systems:

- **Trend towards improved satisfaction in limited community ambulators after only 4 weeks of use**
  SAT-PRO showed tendency to be improved by 13%

**Trend towards improved satisfaction with VASS in limited community ambulators**

<table>
<thead>
<tr>
<th>SAT-PRO scale [score]</th>
<th>Previous socket</th>
<th>VASS</th>
</tr>
</thead>
<tbody>
<tr>
<td>31</td>
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<td>24</td>
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</table>

Satisfaction was measured by SAT-PRO Questionnaire. It consists of 15 categories and lower scores represent higher satisfaction. (Samitier et al 2014)

**Clinical Relevance**

Satisfaction of a person with a device is important as it contributes to its acceptance and usage. It is influenced by other categories and can therefore be seen as a summary of possible activities, independence and perceived safety. SAT-PRO scale is a self-administered questionnaire to determine the subject’s satisfaction with the use of the prosthesis.

**Summary**

MFCL K2 subjects showed a trend towards increased and K3 subjects showed a trend towards decreased satisfaction with VASS compared to subject’s previous socket system. As observed in other socket studies, even when a functional improve was measured, subjective evaluation of the new socket only showed small differences compared to the socket system the subjects were familiar with. It is likely that some patients need more time to adapt to the use of a new device than is provided in studies. Furthermore, subjects, especially K3 subjects, had already a high satisfaction score with the previous socket system and therefore it is difficult to reach an improvement (Samitier et al 2014). In the study of Klute et al (2011) besides short acclimatisation period and high initial score, a probability for not sufficient socket checks are responsible for the increased frustration with VASS.

In a study investigating the effect of different socket types in combination with VASS on transfemoral amputees, all subjects preferred the brimless socket design instead of the ischial ramus containment (IRC) socket design (Kahle et al 2014).
<table>
<thead>
<tr>
<th>References of summarized studies</th>
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</table>

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Pistoning

**Major Findings**

With vacuum-assisted socket system (VASS):

- **A better fit of the socket is achieved during walking compared to a suction socket system**
  
  Pistoning of the liner decreased by 80%
  Pistoning of the tibia decreased by 18%

- **A better fit of the socket is achieved during weighting and unweighting the prosthesis compared to pin suspension system**
  
  Pistoning decreased by 83%

**Decreased pistoning with VASS**

![Graph showing decreased pistoning with VASS](image)

For mean displacements of the liner and tibia from the socket, the unloaded conditions were subtracted from the loaded conditions. Vacuum-assisted socket system (VASS) was compared to suction socket system (SSS). (Board et al 2001)

**Clinical Relevance**

Good socket fit results in comfort of the amputee, health of the skin and the effective transfer of forces from the residual limb to the socket, such that the amputee has better control over the prosthesis and can perform daily activities without damaging tissue or experiencing pain.

**Summary**

A better socket fit is achieved with VASS compared to a suction socket system, measured by reduced liner displacement (80% lower) and tibia displacement (18% lower) relative to the socket (Board et al 2001). Also Klute et al (2011) showed that the changes of distance between the prosthesis and the residual limb was decreased with VASS (1 mm) compared to the pin suspension system (6 mm). Therefore, a better fit is maintained with a vacuum condition.

A study investigating the effect of different socket types in combination with electronic VASS on transfemoral amputees, showed, that the vertical movement tended to be decreased by 44% with brimless compared to ischial ramus containment (IRC) socket design (Kahle & Highsmith 2014).
References of summarized studies


Back to overview table
Pressure Measurement

Major Findings

With vacuum-assisted socket system (VASS):

- **Positive pressure (compression of the residual limb) is reduced in stance phase compared to suction socket system**
  - Pressure impulse decreased by 7%
  - Peak pressure decreased by 4%

- **Negative pressure (elongation of the residual limb) is increased in swing phase compared to suction socket system**
  - Negative pressure impulse increased by 27%
  - Negative peak pressure increased by 27%

- **Medial brim pressure decreased by 41% with brimless compared to ischial ramus containment (IRC) socket design for transfemoral amputees**

### Decreased positive pressure impulse and increased negative pressure impulse with VASS

During stance phase pressure (compression) impulse values and peak pressure values were measured with five contact sensors. During swing phase pressure (elongation) impulse values and peak pressure values were measured with one air pressure sensor. Vacuum-assisted socket system (VASS) was compared to suction socket system (SSS). (Beil et al 2002)

Clinical Relevance

External pressures applied to the skin affect the volume of the residual limb. Positive pressures decrease the volume of the limb (fluids are forced out) while negative pressures increase limb volume (fluids are drawn in). To maintain a proper fit during the day, it is important to keep volume fluctuations as minimal as possible.

Summary

With VASS positive pressure on residual limb is reduced in stance phase (Beil et al 2002) and therefore pushes less fluid out of the limb. During swing phase negative pressure is increased (Beil et al 2002) and more fluid is pulled into the limb. This combination prevents daily volume loss of the residual limb. As a result, the socket fit is more consistent.

A study investigating the effect on different socket types in combination with electronic VASS on transfemoral amputees, showed, that the medial brim pressure was reduced by 41% with brimless compared to ischial ramus containment (IRC) socket design (Kahle & Highsmith 2014).
References of summarized studies


[Back to overview table]
3 Summaries of individual studies

On the following pages you find summaries of studies that researched Harmony Socket 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.
The benefits of using a vacuum-assisted socket system to improve balance and gait in elderly transtibial amputees

Journal of Prosthetics and Orthotics. Epub.

With VASS compared to previous socket:

**MFCL K2 subjects**
- Improvement of prosthesis use by 7.4%
- Balance increased by 15%
- Trend towards decreased risk of falling
  
  Trend towards improvements in timed up and go test (TUG) by 15%

**MFCL K3 subjects**
- Decreased risk of falling
  
  Timed up and go test (TUG) improved by 22%
- Walking velocity increased by 15% and mobility by 19%
- Increased balance by 19%
- Subjects tend to more satisfied
- Time of prosthesis use tends to be increased

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.

| Reference | Samitier BC, Guirao L, Costea M, Camós JM, Pleguezuelos E.  
| Hospital de Mataró, Barcelona, Spain. |

| Products | Vacuum-assisted socket system* (VASS) vs other socket system  
| * Harmony P2 & HD |

| Major Findings | With VASS compared to previous socket:  
| MFCL K2 subjects |  
| - Improvement of prosthesis use by 7.4%  
| - Balance increased by 15%  
| - Trend towards decreased risk of falling  
| Trend towards improvements in timed up and go test (TUG) by 15% |

| MFCL K3 subjects |  
| - Decreased risk of falling  
| Timed up and go test (TUG) improved by 22%  
| - Walking velocity increased by 15% and mobility by 19%  
| - Increased balance by 19%  
| - Subjects tend to more satisfied  
| - Time of prosthesis use tends to be increased |

| Population | Subjects: 16 unilateral, transtibial amputees  
| Previous socket system: not reported  
| Amputation causes: 100% peripheral vascular disease  
| Mean age: 65 ± 10 yrs  
| Mean time since amputation: 5.2 ± 2.2 yrs  
| MFCL: 37.5% K2, 62.5% K3 |

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.
Study Design

Interventional, pre- to post-test design:

- Previous socket
- VASS
- Data collection
- 4 weeks acclimatisation

Results

<table>
<thead>
<tr>
<th>Category</th>
<th>Outcomes</th>
<th>Results for VASS compared to previous socket</th>
<th>Sig.*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level Walking</td>
<td>Timed up and go (TUG) test</td>
<td>All: Time to complete the task decreased by 19% (11.6 vs 14.3 s). K2: Trend towards decreased time to complete task (13.0 vs 15.3 s). K3: Time to complete the task decreased by 22% (10.7 vs 13.7 s)</td>
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<tr>
<td></td>
<td></td>
<td>6 min walking test (6MWT)</td>
<td>All: Walking velocity improved by 11% (0.89 vs 0.80 m/s). K2: Trend towards improved walking velocity (0.76 vs 0.73 m/s). K3: Walking velocity improved by 15% (0.97 vs 0.84 m/s).</td>
</tr>
<tr>
<td>Balance</td>
<td>Berg Balance Scale (BBS)</td>
<td>All: Balance improved by 7.2% (average scores 49.1 vs 45.8). K2: Trend towards improved balance (47.3 vs 45.5). K3: Balance improved by 9% (average scores 50.1 vs 45.9).</td>
<td>++</td>
</tr>
<tr>
<td></td>
<td>Four square step test (FSST)</td>
<td>All: Time to complete the test was decreased by 18% (15.0 vs 18.2 s). K2: Time to complete the test was decreased by 15% (17.4 vs 20.6 s). K3: Time to complete the test was decreased by 19% (13.5 vs 16.7 s).</td>
<td>++</td>
</tr>
<tr>
<td>Activity, Mobility, ADLs</td>
<td>Locomotor Capabilities Index (LCI)</td>
<td>All: Trend towards improved mobility (average score 47.4 vs 43.3). K2: Trend towards decreased mobility (average score 44.2 vs 46.2) K3: Mobility improved by 19% (average score 49.4 vs 41.6)</td>
<td>++</td>
</tr>
<tr>
<td></td>
<td>Houghton Scale</td>
<td>All: Trend towards improved prosthesis use (average score 9.9 vs 9.3). K2: Prosthesis use improved by 7.4% (average score 9.7 vs 9.0). K3: Trend towards improved prosthesis use (average score 10.0 vs 9.5).</td>
<td>+</td>
</tr>
<tr>
<td>Category</td>
<td>Outcomes</td>
<td>Results for VASS compared to previous socket</td>
<td>Sig.*</td>
</tr>
<tr>
<td>------------------</td>
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<td>---------------------------------------------</td>
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</tr>
<tr>
<td>Preference, Satisfaction, QoL</td>
<td>SAT-PRO Scale</td>
<td>All: No difference in satisfaction. K2: Trend towards increased satisfaction. K3: Trend towards decreased satisfaction.</td>
<td>0+−</td>
</tr>
</tbody>
</table>

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

**Author's Conclusion**

"In conclusion, the Harmony® P2 & HD is a useful device in dysvascular transtibial amputees over 50 years of age. In our study, use of the VASS improved balance, gait and transfers in patients with MFCL-3 mobility grade and balance and prosthesis use in patients with MFCL-2 activity level. In patients with a lower activity level, the use of an additional distal valve in the socket should be considered." (Samitier et al. 2014)
Kahle JT, Orriola JJ, Johnston W, Highsmith MJ. School of Physical Therapy and Rehabilitation Sciences, University of South Florida, Tampa, FL.

The effects of vacuum-assisted suspension on residual limb physiology, wound healing, and function: A systematic review


**Products**

Vacuum-assisted socket system* (VASS)

* different suppliers

**Major Findings**

With VASS:

- Allows for early fitting without inhibiting wound healing or increasing pain
- Residual limb volume increased by 3.7% during walking
- Twofold increase in symmetry of step length and stance duration compared to suction socket system
- Decreased risk of stumbles and falls
  
  Activities-specific balance confidence scale (ABC) score increased by 23% compared to pin suspension system
- Reduced pistoning compared to suction socket system and pin suspension system
- Pressure impulse was decreased by 7.5% in stance phase and increased by 27% in swing phase compared to suction socket system

### Improved residual limb physiology with VASS compared to other socket systems

![Graph showing improved residual limb physiology with VASS compared to other socket systems](image-url)

Studies related to residual limb physiology include categories limb volume fluctuation (n=3), pistoning (n=1) and pressure measurement (n=1). Included were studies comparing VASS to other socket systems.

**Population**

Subjects: 60 transtibial and 10 transfemoral amputees
Mean age: 49 yrs

**Study Design**

Review Article
## Results

<table>
<thead>
<tr>
<th>Category</th>
<th>Results for VASS</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wound Healing</td>
<td>VASS allows for early fitting without inhibiting wound healing.</td>
<td>Traballesi et al 2012</td>
</tr>
<tr>
<td>Limb Volume Fluctuation</td>
<td><strong>The residual limb volume increased 3.7% with VASS and decreased 6.5% with the suction socket system after walking for 30 min (n=10).</strong>&lt;br&gt;With VASS the residual limb mean volume increased by 92, 93, and 58 cc in the undersized, neutral, and oversized socket (n=7) after physical activity.&lt;br&gt;No difference in volume of the residual limb between VASS and pin suspension system after walking for 30 min (n=5).</td>
<td>Board et al 2001</td>
</tr>
<tr>
<td>Level Walking</td>
<td><strong>Twofold increase in symmetry of step length and stance duration with VASS compared to suction socket system.</strong></td>
<td>Board et al 2001</td>
</tr>
<tr>
<td>Balance</td>
<td><strong>Improvement of Activities-specific balance confidence scale (ABC) score by 23% with VASS compared to pin suspension system.</strong></td>
<td>Ferraro 2011</td>
</tr>
<tr>
<td>Activity, Mobility, Activities of daily living (ADLS)</td>
<td><strong>Locomotor Capability Index (LCI) was increased with VASS compared to suction socket system during a 12 week rehabilitation program (LCI score 42 vs 21) including subjects with open ulcer.</strong>&lt;br&gt;<strong>Less step activity when utilizing VASS compared to pin suspension system.</strong></td>
<td>Traballesi et al 2012</td>
</tr>
<tr>
<td>Pistoning</td>
<td><strong>Pistoning was reduced with VASS compared to pin suspension system (13 mm vs 64 mm).</strong></td>
<td>Klute et al 2011</td>
</tr>
<tr>
<td>Pressure Measurement</td>
<td><strong>Medial proximal pressure was reduced when using brimless compared to ischial ramus containment (IRC) socket design with VASS.</strong></td>
<td>Kahle and Highsmith 2014</td>
</tr>
<tr>
<td></td>
<td><strong>Pressure impulse was reduced by 7.5% and peak positive pressure was reduced by 4.2% with VASS compared to suction socket system during stance phase. Pressure impulse was increased by 27%, average pressure was increased by 25% and peak pressure was in-</strong></td>
<td>Beil et al 2002</td>
</tr>
<tr>
<td>Category</td>
<td>Results for VASS</td>
<td>Reference</td>
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<tr>
<td></td>
<td>creased by 27% with VASS compared to suction socket system during swing phase.</td>
<td></td>
</tr>
</tbody>
</table>

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

**Author's Conclusion**

“The strongest evidence supporting the clinical outcomes of VASS for the prosthetic user was in the topic of residual limb (RL) physiology. There is currently limited evidence supporting the use of VASS regarding wound healing and function. The mechanical principles of VASS applied to prosthetic use may have physiological and functional merit. Applying the associated principles to prosthetic design may create alternative interface design configurations for both the transtibial amputees and the transfemoral amputees.” (Kahle et al. 2014)
Kahle JT, Highsmith M.
School of Physical Therapy and Rehabilitation Sciences, University of South Florida, Tampa, FL

Transfemoral sockets with vacuum-assisted suspension comparison of hip kinematics, socket position, contact pressure, and preference: Ischial containment versus brimless


**Electronic vacuum-assisted socket system** (eVASS)
* ePulse, Otto Bock

**Major Findings**

With brimless compared to ischial ramus containment (IRC) socket design:

- **Improved comfort**
- **Preference of all subjects**
- **Medial proximal average skin pressures decreased by 41%**
- **Vertical movement of the socket showed a tendency to be reduced by 44%**

Pressure on skin recorded with sensors during gait for both brimless and ischial ramus containment (IRC) socket design. Sensors were placed on medial proximal and distal lateral position of the residual limb between skin and liner.

**Population**

- **Subjects:** 9 transfemoral amputees
- **Previous socket system:** 33% brimless, 67% IRC
- **Amputation causes:** 78% trauma, 11% sarcoma, 1% vascular disease
- **Mean age:** 41.2 ± 14.5 yrs
- **Mean time since amputation:** 9.1 ± 10.3 yrs
- **MFCL:** not reported
Study Design

Interventional, randomized crossover design:

Results

<table>
<thead>
<tr>
<th>Category</th>
<th>Body Function</th>
<th>Activity</th>
<th>Participation</th>
<th>Others</th>
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<tbody>
<tr>
<td>Wound Healing</td>
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<tr>
<td>Limb Volume Fluctuation</td>
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<td>Pain</td>
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<tr>
<td>Comfort, Limb Health</td>
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<tr>
<td>Level Walking</td>
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<td>Balance</td>
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<tr>
<td>Activity, Mobility, ADLs</td>
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<tr>
<td>Preference, Satisfaction, QoL</td>
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<td>Pistoning</td>
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<tr>
<td>Pressure Measurement</td>
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</tr>
</tbody>
</table>

### Category: Comfort, Limb Health

**Outcomes**
- Questionnaire about comfort

**Results for brimless compared to IRC socket design**
- Higher comfort in sitting and standing.
- Decrease in phantom pain.
- Increase in hip range of motion.
- Less urogenital interference.
- Ease in walking.

**Sig.***
- n.a.

### Category: Level Walking

**Outcomes**
- X-ray to measure hip angle

**Results**
- Trend towards increased femoral abduction in double support.
- Trend towards increased femoral abduction in stance phase.
- Trend towards increased femoral adduction in swing phase.

**Sig.***
- +

### Category: Preference, Satisfaction, Quality of Life (QoL)

**Outcomes**
- Questionnaire about preference

**Results**
- All subjects preferred the brimless socket design.

**Sig.***
- n.a.

### Category: Pistoning

**Outcomes**
- X-ray to measure medial wall height, vertical and lateral socket movement

**Results**
- Increased mean lateral shifting (1.6 cm vs 1.2 cm).
- Decreased mean vertical movement (1.4 cm vs 2.5 cm).

**Difference in position of the mean medial wall of the socket relative to the distal-most aspect of the ischial tuberosity:**
- 3.3 cm distal for brimless socket
- 1.1 cm proximal for the IRC socket

**Sig.***
- –
- +
- +

### Category: Pressure Measurement

**Outcomes**
- One proximal-medial and one distal lateral sensor to record pressures of 15 gait cycles

**Results**
- The peak/stance average pressure in the medial proximal aspect of the socket decreased by 41% (190 mmHg vs 322 mmHg).
- The peak/stance average pressure in the distal lateral aspect tended to be increased by 18% (222 mmHg vs 188 mmHg).
- The single greatest peak pressure value in the

**Sig.***
- ++
- –
- +
<table>
<thead>
<tr>
<th>Category</th>
<th>Outcomes</th>
<th>Results for brimless compared to IRC socket design</th>
<th>Sig.*</th>
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<tbody>
<tr>
<td></td>
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<td>medial proximal aspect tended to be decreased by 2.6 (819 mmHg vs 841 mmHg).</td>
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<td>The single greatest peak pressure value in the distal lateral aspect tended to be increased by 38% (751 mmHg vs 543 mmHg).</td>
<td>−</td>
</tr>
</tbody>
</table>

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

**Author’s Conclusion**

“Elimination of the brim may be a clinically viable choice of socket for TFAs because the brimless design was equivalent to the IRC in the area of coronal hip angle, vertical movement, and lateral shifting. Mean peak stance skin pressure was less in the medial proximal aspect of the brimless design. All other peak and mean skin pressures were shown to be equivalent when comparing the brimless design with the IRC. The brimless design was reported to be more comfortable than the IRC design in short-term preference.” (Kahle et al. 2013)
Using vacuum-assisted suspension to manage residual limb wounds in persons with transtibial amputation: a case series


**Products**

**Vacuum-assisted socket system** (VASS)

* Harmony, Otto Bock (5 subjects); LimbLogic VS, Willow Wood (1 subject)

**Major Findings**

With VASS:

- Wound closure is obtained while using the prosthesis
- Allows for prosthetic fitting and walking despite the presence of an open residual limb wound with large surface area

**Wound healing occurs while using VASS**

![Graph showing wound healing process](image)

Wound healing process shown for one representative subject. Subject was instructed to wear prosthesis as much as possible given any pain they may experience and not to limit their activities.

**Population**

- Subjects: 6 transtibial amputees
- Previous socket system: not reported
- Amputation causes: 67% ulcer, 16.5% ischemia, 16.5% trauma
- Mean age: 66.5 ± 5.5 yrs
- Mean time since amputation: 8.0 ± 9.1 yrs
- MFCL: not reported
Study Design

Case series:

![Diagram showing VASS fitting leading to wound healing with data collection every 1-2 weeks.]

Results

<table>
<thead>
<tr>
<th>Body Function</th>
<th>Activity</th>
<th>Participation</th>
<th>Others</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wound Healing</td>
<td>Limb Volume Fluctuation</td>
<td>Pain</td>
<td>Comfort, Limb Health</td>
</tr>
</tbody>
</table>

**Category** | **Outcomes** | **Results for VASS** | **Sig.**
--- | --- | --- | ---
Wound Healing | Documentation of wound surface area using digital photographs | Wound closure was achieved for all 6 subjects within an average time of 177 ± 113 days while using the VASS. Variability in time to heal is based on heterogeneity in health conditions, wound severity, and compliance in terms of wound care and prosthesis use. | n.a. |

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

**Author’s Conclusion**

“We observed closure of residual limb wounds in six subjects with unilateral transtibial amputation while wearing VAS sockets. The results of this case series contribute to the growing body of evidence that suggests that VASS prostheses may be used while managing residual limb wounds in persons with transtibial amputation. The results suggest that a well-fitting socket with VASS in compliant individuals does not preclude wound healing and that wound closure is possible without limiting or halting activities.” (Hoskins et al. 2014)

[Back to overview table]
Residual limb wounds or ulcers heal in transtibial amputees using an active suction socket system. A randomized controlled study


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

* TEC Harmony

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

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
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 ≤ 1 cm²) 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

<table>
<thead>
<tr>
<th>Category</th>
<th>Outcomes</th>
<th>Results for VASS compared to SSS</th>
<th>Sig.*</th>
</tr>
</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>
</tr>
<tr>
<td></td>
<td></td>
<td>VASS showed progressive healing, whereas SSS showed a high degree of healing around week 20.</td>
<td>n.a.</td>
</tr>
<tr>
<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>
</tr>
<tr>
<td>Activity, Mobility, Activities of daily living (ADLs)</td>
<td>Locomotor Capability Index (LCI) for walking capabilities</td>
<td><strong>LCI-score increased by 100% (42 vs 21 points) at week 12.</strong> With VASS 100% of subjects were able to walk independently, whereas with SSS only 50% at week 12.</td>
<td>++</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Improved clinical mobility was observed at all later follow-ups.</td>
<td>+</td>
</tr>
<tr>
<td>Interview: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. 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.</td>
<td>++</td>
<td></td>
</tr>
</tbody>
</table>
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)

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)
Sanders JE, Harrison DS, Myers TR, Allyn KJ. University of Washington-Bioengineering, Seattle, WA, USA.

Effects of elevated vacuum on in-socket residual limb fluid volume: Case study results using bioimpedance analysis


Products

Vacuum-assisted socket system* (VASS) and electronic vacuum-assisted socket system** (eVASS) vs Suction socket system (SSS) and Pin suspension system (PSS)

*Harmony, Otto Bock
** ePulse, Otto Bock; eVAC, Smith Global

Major Findings

With VASS and eVASS:

→ 3 out of 3 subjects showed a more positive limb volume change during activity compared to PSS

The difference in limb fluid volume change between VASS and PSS was up to 1.7%.

→ 2 out of 3 subjects showed an increase in limb fluid volume during activity

The limb fluid volume increase was 1.2%, respectively 0.4%

Caution: This article includes 7 case reports. Subjects were tested with different protocol and different vacuum systems.

Limb volume changes over session are more positive with VASS

The session was composed of 2 min sitting, 5 min standing, 5 min treadmill walking, 2 min sitting, 5 min standing, and 5 min treadmill walking. The volume change was calculated by subtracting the fluid volume after the second walk from the fluid volume at the outset of the first stand. The test session was performed with vacuum-assisted socket system (VASS) and pin suspension system (PSS). Case 5 and 6 were fitted with electronic VASS and case 7 was fitted with mechanical VASS.
Subjects: 7 transtibial amputees

Previous socket system: 71% PSS, 14% VASS, 14% neoprene suspension system

Amputation causes: 86% trauma, 14% ulcer

Mean age: 46 ± 14 yrs

Mean time since amputation: 7.4 ± 7.5 yrs

MFCL: 14% K1, 28% K3, 57% K4

Study Design

7 case studies:

Results

<table>
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<tr>
<th>Category</th>
<th>Outcomes</th>
<th>Results for VASS</th>
<th>Sig.*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limb Volume Fluctuation</td>
<td>Extracellular fluid volume changes measured by bioimpedance: With the difference in response of different biological structures to electrical current, fluid volumes can be determined.</td>
<td>For two out of three subjects, limb fluid volume during walking with VASS increased by 1.2%, respectively by 0.4%. The limb volume change during walking with SSS was comparable.</td>
<td>n.a.</td>
</tr>
<tr>
<td></td>
<td>3 min walking with SSS, 3 min walking with VASS, 2 min sitting, 3 min walking with VASS, 3 min walking with SSS (n = 3)</td>
<td>For all three subjects, limb fluid volume during the test session tended to be more positive with VASS compared to PSS. The difference in limb fluid volume change between VASS and PSS was up to 1.7%.</td>
<td>n.a.</td>
</tr>
<tr>
<td></td>
<td>2 min sitting, 5 min standing, 5 min walking, 2 min sitting, 5 min standing, 5 min walking. Test session performed with both VASS and PSS (n = 3)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

Author's Conclusion

“This series of case studies on seven subjects showed that some subjects demonstrated less decrease (or more increase) in limb fluid volume using sockets with elevated vacuum compared with suction sockets or lock-and-pin suspension sockets, while others did not. Some measures of limb fluid volume changed consistently, while others did not. A number of variables may affect limb fluid volume change. When designing future research studies, investigators need to consider these variables in study design, particularly when comparing elevated vacuum to another socket design.” (Sanders et al. 2011)
Vacuum-Assisted Socket Suspension Compared With Pin Suspension for Lower Extremity Amputees: Effect on Fit, Activity, and Limb Volume


Products

Vacuum-assisted socket system* (VASS) vs pin suspension system (PSS)

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

Major Findings

With VASS compared to PSS:

→ A better fit of the residual limb in the socket is achieved during weighting and unweighting prosthesis

Limb pistoning decreased by 83%

Caution: From 20 enrolled subjects only 5 completed the study. 3 subjects withdrew before study started, 12 withdrew during study. This was probably caused by poor socket fit. Since residual limb volume decreases in first months after using VASS, the socket volume has to be checked on a regular basis and adjusted as necessary.

Decreased pistoning with VASS

Pistoning was defined by the change of distance between prosthesis and residual limb while subjects weighted and unweighted their prosthesis.

Population

Subjects: 5 transtibial amputees
Previous socket system: Pin suspension system (PSS)
Amputation causes: 80% trauma, 20° dysvascular
Mean age: 56 ± 9 yrs
Mean time since amputation: 13 ± 15 yrs
MFCL: not reported
## Study Design

Interventional, randomized crossover design:

![Study Design Diagram]

## Results

<table>
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<tbody>
<tr>
<td><strong>Limb Volume Fluctuation</strong></td>
<td>Residual limb volume was measured before and after a 30 min walk with a limb scanning system</td>
<td>No difference in limb volume, independent of exercise.</td>
<td>0</td>
</tr>
<tr>
<td><strong>Comfort, Limb Health</strong></td>
<td>Questionnaire about sweat, smell, volume changes, rashes, ingrown hairs, and blisters. A score of 100 indicates the best outcome.</td>
<td>Residual limb health decreased by 14% (77 vs 90 points) after having used the socket for 4 weeks.</td>
<td>n.a.</td>
</tr>
<tr>
<td><strong>Activity, Mobility, Activities of daily living (ADLs)</strong></td>
<td>Activity level, measured by total number of steps</td>
<td>Activity level decreased by 48% (38,000 vs 73,000 steps per two weeks).</td>
<td>-- --</td>
</tr>
<tr>
<td></td>
<td>Questionnaire about ability to walk in general, in close spaces, on stairs and ramps, in urban environments, and on slippery surfaces. A score of 100 indicates the best outcome.</td>
<td>Difficulty to ambulate increased by 31% (67 vs 95 points) after having used the socket for 4 weeks.</td>
<td>n.a.</td>
</tr>
<tr>
<td><strong>Preference, Satisfaction, QoL</strong></td>
<td>Questionnaire about frustration (frequency of occurrence and rating). A score of 100 indicates the best outcome.</td>
<td>Frustrating increased by 53% (43 vs 91 points) after having used the socket for 4 weeks.</td>
<td>n.a.</td>
</tr>
<tr>
<td><strong>Pistoning</strong></td>
<td>Changes of distance between prosthesis and residual limb when weighted and unweighted prosthesis was measured using a 12-camera motion analysis system</td>
<td>Limb pistoning decreased by 83% (1 vs 6 mm).</td>
<td>++</td>
</tr>
<tr>
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**Author's Conclusion**

“The VASS resulted in a better fitting socket as measured by limb pistoning, although the clinical relevance of the small but statistically significant difference is difficult to discern. Treadmill walking had no effect, suggesting that a skilled prosthetist can control for daily limb volume fluctuations using conventional, nonvacuum systems. Participants took approximately half as many steps while wearing the VASS, which, when coupled with their subjective responses, suggest a patient preference for the PSS. The need for fewer check sockets and a shorter time to obtain an adequate fit suggest a clinician preference for the pin suspension.” (Klute et al. 2011)
Outcomes Study of Transtibial Amputees Using Elevated Vacuum Suspension in Comparison With Pin Suspension


Vacuum-assisted socket system* (VASS) vs Pin locking suspension system (PSS)

*supplier unknown

With VASS compared to PSS:

- **Decreased risk of falling**
  - Balance increased by 23%

- **86% of subjects reported an increased walking time**

- **Trend towards increased limb health**
  - 38% less blisters
  - 8% less redness of the skin

The Activities-specific Balance Confidence (ABC) rates the balance confidence for performing activities. The marked part (scores of 67 or lower) indicates a greater risk of falling in the elderly.

Subjects:
- 13 transtibial and transfemoral amputees

Previous socket system:
- Pin locking suspension system

Amputation causes:
- not reported

Mean age:
- not reported

Mean time since amputation:
- ≥ 6 months

MFCL:
- K2, K3, K4
Study Design

Interventional, pre- to post-test design:

<table>
<thead>
<tr>
<th>Study Design</th>
<th>Data collection</th>
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</thead>
<tbody>
<tr>
<td>PSS</td>
<td>≥ 30 days</td>
</tr>
<tr>
<td>VASS</td>
<td>≥ 30 days</td>
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Results

<table>
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<tr>
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<tr>
<td>Comfort, Limb Health</td>
<td>Questionnaire about perception of comfort and skin breakdown</td>
<td>Subjects reported</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td></td>
<td>46% less pistoning,</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>38% less blisters,</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>8% less redness of the skin.</td>
<td></td>
</tr>
<tr>
<td>Balance</td>
<td>Activities-specific Balance Confidence Scale (ABC)</td>
<td>ABC score increased by 23%.</td>
<td>++</td>
</tr>
<tr>
<td></td>
<td>(n = 9 transtibial amputees)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Activity, Mobility, Activities of daily living (ADLs)</td>
<td>Questionnaire about activity and falls</td>
<td>86% of subjects reported increased walking time.</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td></td>
<td>31% of subjects reported less falls.</td>
<td></td>
</tr>
</tbody>
</table>

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

Author's Conclusion

“Due to more intimate fit of the socket, more secure hold, and decrease in pistoning with the vacuum system, lower incidence of predicted future falls can be achieved. Moreover, fewer skin problems and therefore increased comfort may account for the increased walking times.” (Ferraro 2011)
Vacuum assisted socket system in trans-tibial amputees: Clinical report


Brunelli S, Averna T, Delusso S, Traballesi M.
Fondazione Santa Lucia, Rome, Italy.

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
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

<table>
<thead>
<tr>
<th>Category</th>
<th>Outcomes</th>
<th>Results for VASS compared to PTB</th>
<th>Sig.*</th>
</tr>
</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>
</tr>
<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>
</tr>
<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>
</tr>
</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)
Vacuum Suspension and its Effects on the Limb
Orthopädie Technik 2006; IV: 2-7.

Major Findings

With VASS:

- Pistoning is reduced through a tight fit of socket and liner.
- Limb pressures and shear forces are reduced and therefore wound degeneration is reduced.
- Limb volume loss during the day is prevented.
- Healthier environment is maintained.

Suspension force created by VASS

The sum of the axial components of the liner anchoring forces creates an exceptionally large suspension force. The value of 70 kg is reached with an average size limb (33 cm proximal circumference) and vacuum (~78 kPa). Since extraction forces of daily activities hardly exceed 10 kg, separation between the liner and the socket is not caused.

Population

not reported

Study Design

Review Article
### Results

<table>
<thead>
<tr>
<th>Category</th>
<th>Results for VASS</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limb Volume Fluctuation</td>
<td>With VASS the limb stays hydrated and positively keyed to the socket. Patients identify daily volume maintenance as a major advantage of VASS. It was proposed that drawing more fluid in because of the additional 27% drop in pressure is probably most responsible for volume maintenance.</td>
<td>Board (2001) and Goswami (2003)</td>
</tr>
<tr>
<td>Comfort, Limb Health</td>
<td>VASS reduces or eliminates minor skin problems such as folliculitis and recurring cysts. Less physical abuse as reduced pressures, reduced shear forces and a tight fit as well as increased blood flow are explanations for the improved limb health.</td>
<td>n.a.</td>
</tr>
<tr>
<td>Pistoning</td>
<td>Based on the vacuum, the liner and therefore the skin are no longer able to separate from the socket. This leads to a positive global connection of the liner with the socket which is maintained throughout the day. To achieve a proper fit, a socket that closely matches the shape of the limb and adding fillers to maintain close contact are required. Eliminating separation between the liner and the socket improves the patient’s proprioception and control over the prosthetic leg.</td>
<td>n.a.</td>
</tr>
</tbody>
</table>

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

### Author’s Conclusion

"Vacuum suspension is simply the removal of air molecules from the sealed air space in a valve suspension system. The resulting vacuum has one direct physical effect; it anchors the liner to the socket. The large suspension force, ~70 kg, created by the axial components of the liner anchoring forces prevents separation between the liner and socket. This provides the amputee with unmatched linkage that improves his/her spatial awareness and control over the prosthesis. With this elimination of pistoning, limb pressures and shear forces are reduced, providing the limb with a healthier environment. Unlike all other modes of suspension, vacuum suspension prevents the limb volume during the day. So, a healthier environment is maintained throughout the day. The global pumping effect of the cyclic positive and negative pressures during walking increases circulation and fluid exchange, and probably plays a role in improving limb health and wound healing." (Street 2006)
Goswami J, Lynn R, Street G, Harlander M. Health, Physical Education, Recreation and Sport Science, St. Cloud University, Minnesota, USA

Walking in a vacuum-assisted socket shifts the stump fluid balance


**Vacuum-assisted socket system** (VASS)

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

**Major Findings**

With VASS:

- Fluid balance of the residual limb is changed towards a net gain for all socket sizes and therefore a better fit of the socket is achieved
  - For under-sized socket, limb volume increased by 92 cc
  - For neutral socket, limb volume increased by 93 cc
  - For over-sized socket, limb volume increased by 58 cc

**Stump Volume Change**

Average changes in volume from the initial stump volume after 18 minutes walking in the under-sized, neutral and over-sized sockets. The predicted changes are based on the volume available to the stump in the respective sockets.

**Population**

- Subjects: 7 transtibial amputees
- Previous socket system: not reported
- Amputation causes: Trauma or congenital
- Mean age: 45 yrs (27 – 66 yrs)
- Mean time since amputation: ≥ 3 yrs
- MFCL: not reported
The study was designed to determine the effect of socket size on the stump volume fluctuation when walking. Therefore volume differences of -8% for under-sized, 0 for neutral and 8% for over-sized socket sizes from the liner volumes were investigated.

### Results

<table>
<thead>
<tr>
<th>Category</th>
<th>Outcomes</th>
<th>Results for VASS</th>
<th>Sig.*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limb Volume Fluctuation</td>
<td>Alginate casting method: marked limb was casted in an alginate-water mixture. The impression of the stump thus formed, was filled with water. The volume of water determined the limb volume.</td>
<td>Post-walk stump volumes were increased relative to the volumes available in the sockets for all socket sizes: For undersized socket size stump volume increased by 92 cc For neutral socket size stump volume increased by 93 cc For oversized socket size stump volume increased by 58 cc Therefore, the fluid balance of the stump was changed towards a net gain for all socket sizes.</td>
<td>++</td>
</tr>
<tr>
<td>Pain</td>
<td>Questioned about pain after walk with over-sized socket</td>
<td>No pain resulted from the volume gain following the walk in the over-sized socket.</td>
<td>n.a.</td>
</tr>
<tr>
<td>Comfort, Limb Health</td>
<td>Questioned about discomfort after walk with over-sized socket</td>
<td>No discomfort or reddening of the skin resulted from volume gain following the walk in over-sized socket.</td>
<td>n.a.</td>
</tr>
</tbody>
</table>

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

**Author’s Conclusion**

“A custom-fit, VASS minimizes or prevents the acute volume loss normally observed after donning the recommended 4-6% under-sized socket. This shift in fluid balance ensures that a good fit is maintained during the day in ambulatory trans-tibial amputees.” (Goswami et al. 2003)
Beil TL, Street GM, Covey SJ. Human Performance Laboratory and the Department of Mechanical and Manufacturing Engineering, St. Cloud State University, MN, USA

**Interface pressures during ambulation using suction and vacuum-assisted prosthetic sockets**


**Major Findings**

With VASS compared to SSS:

- **Positive pressure (compression of the residual limb) is reduced in stance phase**
  - Pressure impulse decreased by 7%
  - Peak pressure decreased by 4%

- **Negative pressure (pull on the residual limb) is increased in swing phase**
  - Negative pressure impulse increased by 27%
  - Negative peak pressure increased by 27%

**Decreased positive pressure impulse and increased negative pressure impulse with VASS**

During stance phase pressure impulse values measured with five contact sensors. During swing phase values measured with one air pressure sensor. Measurements were conducted with a vacuum-assisted socket system (VASS) and with a suction socket system (SSS).

**Population**

- **Subjects:** 9 unilateral, transtibial amputees
- **Previous socket system:** total-surface weight bearing socket
- **Amputation causes:** not reported
- **Mean age:** 46 yrs (33 - 65 yrs)
- **Mean time since amputation:** 18 yrs (6 - 32 yrs)
- **MFCL:** not reported
Study Design

Interventional, randomized crossover design:

Subjects walked 20 meters with one socket system, changed to the other socket system and walked 20 meters. This was repeated three times.

Results

<table>
<thead>
<tr>
<th>Body Function</th>
<th>Activity</th>
<th>Participation</th>
<th>Others</th>
<th>Pressure Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wound Healing</td>
<td>Limb Volume Fluctuation</td>
<td>Pain</td>
<td>Comfort, Limb Health</td>
<td>Level Walking</td>
</tr>
<tr>
<td>Pressure Measurement</td>
<td>Outcomes</td>
<td>Results for VASS compared to SSS</td>
<td>Sig.*</td>
<td></td>
</tr>
<tr>
<td>Pressure Measurement</td>
<td>Data from 5 force-sensing resistors (for positive pressure) and 1 air pressure sensor (for negative pressure) during 5 steps at 4 km/h</td>
<td>Stance phase (compression of the residual limb):</td>
<td>Pressure impulse decreased by 7%. Peak pressure decreased by 4%.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Swing phase (pull on the residual limb):</td>
<td>Magnitude of negative pressure impulse increased by 27%. Magnitude of negative average impulse increased by 25%. Magnitude of negative peak pressure increased by 27%.</td>
<td></td>
</tr>
</tbody>
</table>

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

Author's Conclusion

“Use of the VASS changes the positive and negative pressures exerted on the residual limb during ambulation. Pressure impulse and peak positive pressures are reduced during the stance phase, while the magnitude of the impulse, average, and peak negative pressures is increased during the swing phase.” (Beil et al. 2002)
A comparison of trans-tibial amputee suction and vacuum socket conditions


Major Findings

With VASS compared to SSS:

- **Volume loss of the residual limb is preserved during activity**
  - Residual limb volume increased by 3.7% during 30 min walking

- **A better fit of the residual limb in the socket is achieved during walking**
  - Pistoning of the liner decreased by 80%
  - Pistoning of the tibia decreased by 18%

- **Improvement of gait symmetry**
  - Step length symmetry improved by 62%

![Graph showing increased residual limb volume with VASS after walking](image)

Percentage changes in volume before and after 30 minutes of walking. Measurements were conducted with a vacuum-assisted socket system (VASS) and a suction socket system (SSS).

Population

- **Subjects:** 11 unilateral, transtibial amputees
- **Previous socket system:** not reported
- **Amputation causes:** Trauma
- **Mean age:** 45 yrs (32 – 64 yrs)
- **Mean time since amputation:** 15.2 yrs (6 – 41 yrs)
- **MFCL:** not reported
Interventional, randomized crossover design:

**Results**

<table>
<thead>
<tr>
<th>Category</th>
<th>Outcomes</th>
<th>Results for VASS compared to SSS</th>
<th>Sig.*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Limb Volume Fluctuation</strong></td>
<td>Alginate casting and water displacement procedure before and after walking for 30 min</td>
<td>With VASS limb volume increased by an average of 3.7% during walking for 30min.</td>
<td>++</td>
</tr>
<tr>
<td></td>
<td></td>
<td>With SSS volume decreased by an average of 6.5% during walking for 30min.</td>
<td>++</td>
</tr>
<tr>
<td><strong>Level Walking</strong></td>
<td>Cinematography during walking test: Step length and stance duration. Data analysed using a symmetry index formula</td>
<td>Step length symmetry improved by 62%.</td>
<td>++</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Trend towards more symmetrical stance duration.</td>
<td>+</td>
</tr>
<tr>
<td><strong>Pistoning</strong></td>
<td>X-ray before and after applying two different static draw loads to displace the prosthesis distally</td>
<td>Liner displacement decreased by 80% (0.1 vs 0.5 cm).</td>
<td>++</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tibia displacement decreased by 18% (3.3 vs 4.0 cm).</td>
<td>++</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tissue elongation increased by 7% (4.5 vs 4.2 cm).</td>
<td>+</td>
</tr>
</tbody>
</table>

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

**Author’s Conclusion**

Proper socket fit is crucial for the comfort of the amputee, health of the skin, and performance of the prosthesis. Maintaining a good fit is difficult with the total surface bearing suction socket (SSS) because the pressure that provides a good fit causes daily volume loss in the stump. As volume is lost and the fit deteriorates, the skin is thought to be subjected to higher pressure and shear forces, and possible ulceration. Drawing a high vacuum on the interface space prevents volume loss or, in some cases, causes a gain in volume. A vacuum also reduces pistoning of the stump and tibia within the socket when statically loaded. Therefore, a vacuum condition maintains a better fit and may reduce irritation of the skin. In addition, a vacuum improves gait symmetry., (Board et al. 2001)