

Clinical Research Summary

The Harmony®: Early Fitting of Transtibial Amputees with Unhealed Residual Limb Wounds

According to the most recent update by the Amputee Coalition (2012), close to two-million persons with limb loss reside in the United States, and of those, 54% of their amputations were a result of vascular disease.^{1,2} Furthermore, in 2009, hospitals reported costs related to limb loss as being greater than 8.3 billion dollars.^{1,3}

When there is Presence of Unhealed Wounds

Until recently, standard practice was to delay the prosthetic fitting until the residual limb was in good condition and could withstand the forces generated by the prosthesis. In his research, VanVelzen (2005) found that ideally, the surgical wound from the amputation must be healed, the stump matured and conically shaped, and there should be no remaining edema when the prosthesis is fit.^{4,5,6}

Persons with transtibial limb loss have (4X) greater likelihood of successful prosthetic use than persons with higher-level amputations.⁶ However, they are also more likely to experience skin complications on the residual limb.^{7,8} Presence of ulcers or unhealed surgical wounds may delay prosthetic rehabilitation and increase the need for medical treatment.^{6,9}

As a result, it has been suggested that there are benefits to accelerating the initiation of rehabilitation after amputation surgery.^{10,11}

One way that this may be achieved when there are wound-healing issues is by early fitting with a vacuum-assisted socket system (VASS), such as the Harmony® Vacuum System.

Early Fitting with Prompt Ambulation Using the Harmony® Vacuum System

A randomized controlled trial recently published by Trallesi, et al,⁷ evaluated fitting of the Harmony® System on subjects with open ulcers/wounds (n=10) compared to fitting a standard suction socket (n=10) after wounds were healed to 1cm² (control group). Subjects were either limited community ambulators (MFCL-2) or full community ambulators (MFCL-3), average age 61.3±13.2, with recent admission to the rehabilitation hospital after transtibial amputation due to dysvascular cause.

A twelve-week rehabilitation program was initiated for all subjects and additional follow-up conducted at weeks 28 and 36. **First Steps:** Harmony® users took their first step at 16±8.6 days, while the control group took their first step at 58.6±24.7 days (p=0.012). **Independent Walking:** At week 12 all Harmony® users were independent walkers, while only 5 in the control group were independent (p=0.001). **Prosthetic Use:** At 2-months the Harmony® group used their prostheses 62 hours/wk. (mean), while the control group used theirs 12 hours/wk. (p=0.003). At 6 months, prosthetic use was 80 hours/wk. for the Harmony® group compared to 59 hours/wk. for the control group; however, results were no longer significant (p=0.191). **Locomotor Capability Index (LCI):** At week 12 the median LCI score for the Harmony® group was 42 (maximum score possible) versus 21 for the control Group (p=0.002). **Drop-outs:** Three subjects dropped out of the control group (one each at 4 weeks, 6 weeks, and 16 weeks) and one dropped out of the Harmony® group at 20 weeks. **Wound Healing and Pain:** Considering the difference in prosthetic use between the two groups, one would expect the

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Harmony® users to experience increased pain and possibly less healing. However, wound-healing and pain perception scores were not statistically significant between the groups. **Conclusion:** The authors concluded that that early use of the Harmony® in the presence of open ulcers/wounds did not impede healing, nor did it increase pain.

When Compared to Amputees without Ulcer/Wound Healing Failure

An earlier study by Brunelli,¹² conducted at the same rehabilitation facility, reported on 24 transtibial amputees; 7 subjects with ulcer/wound healing failure fit with the Harmony® and 17 subjects with no ulcer/wound healing failure fitted with a standard PTB socket (PTB Group).

Locomotor Capability Index (LCI): Subjects were measured using LCI to determine prosthetic use. At nine months, the Harmony® group scored 36±6.7 on the LCI compared to the PTB group which scored 28±4.2. **Pain Perception:** Subjects were measured using the Visual Analog Scale (VAS) for pain perception. VAS scores were favorable for the Harmony® group both at 1 month (6.3±2.2 compared to 7.5±2.5) and at 9 months (4.6±1.3 compared to 7±1.8). **Conclusion:** The authors concluded that patients fit with the Harmony® were compliant in its use, and their ulcers/wounds improved during the study.

Large Wound Case Study

Traballesi⁴ also reported on a 60 year-old, dysvascular, transtibial amputee with a 43.5cm² category IV wound on his residual limb. Measurements included the LCI for prosthetic use, the Barthel Index (BI) for functional independence, and digital photos of the wound for healing. The subject wore the Harmony® 8 hours per day for 4 months and participated in outpatient gait therapy.

Results: Despite having such a large open wound, when tested using the Harmony®, the subject's LCI score was 41 and BI was 85. Additionally, after 3-4 hours of continuous ambulation and standing

activities, VAS (pain) score was 0. At the end of 4 months, the wound area was reduced to 28cm², which equated to a 34% reduction in wound area.

- ¹ Amputee Coalition. Limb loss statistics. <http://limblossawareness.org/about-llam/limb-loss-statistics/index.php>.
- ² Ziegler-Graham K, MacKenzie EJ, Ephraim PL, et al. Estimating the prevalence of limb loss in the United States: 2005 to 2050. *Arch Phys Med Rehabil*. 2008;89(3):422-429.
- ³ HCUP Nationwide Inpatient Sample (NIS). Healthcare Cost and Utilization Project (HCUP). Rockville, MD: AHRQ; 2009.
- ⁴ Traballesi M, Aversa T, Delusso AS, Brunelli S. Trans-tibial prosthesis in large area of residual limb wound: Is it possible? A case report. *Disability and Rehabilitation: Assistive Technology*. 2009;4(5):373-375.
- ⁵ Van Velzen AD, Nederhand MJ, Emmelot CH, Ijzerman MJ. Early treatment of trans-tibial amputees: Retrospective analysis of early fitting and elastic bandaging. *Prosthet Orthot Int* 2005;29:3-12.
- ⁶ Gauthier-Gagnon C, Grise MC, Potvin D. Predisposing factors related to prosthetic use by people with a transtibial and transfemoral amputation. *JPO*. 1998;10(4):99-109; Waters RL, Mulroy S. The energy expenditure of amputee gait. *Gait and Posture*. 1999;9(3):207-231; Bowker JH, Michael JW (ed): In: Atlas of limb prosthetics: Surgical, prosthetic and rehabilitation principles. St. Louis: Mosby Year Book, 1992;381-387.
- ⁷ Traballesi M, Delusso AS, Fusco A, et al. Residual limb wounds or ulcers heal in transtibial amputees using an active suction socket system. A randomized controlled study. *Eur J Phys Rehabil Med* 2012;48:1-2
- ⁸ Dudek NL, Marks MV, Marshall SC, Chardon JP. Dermatologic conditions associated with use of lower extremity prosthesis. *Arch Phys Med Rehabil*. 2005;86:659-663
- ⁹ Meulenbelt HE, Geertzen JH, Jonkman MF, Dijkstra PU. Determinants of skin problems of the stump in lower-limb amputees. *Arch Phys Med Rehabil*. 2009;90:74-81
- ¹⁰ Munin et al. Predictive factors for successful early prosthetic ambulation among lower-limb amputees. *J Rehabil Res Dev*. 2001;38:4
- ¹¹ White SA, Thompson MM, Zickerman AM, et al. Lower limb amputation and grade of surgeon. *Br J Surg* 1997; 84(4): 509-11.
- ¹² Brunelli S, Aversa T, Delusso AS, Traballesi M. Vacuum assisted socket system in trans-tibial amputees: Clinical report. *Orthopädie-Technik Quarterly, English edition*. 2009; 11:2-4