

COST-EFFECTIVENESS OF ACCEL-HEAL IN MANAGING CHRONIC NON-HEALING VENOUS LEG ULCERS IN THE UK

^{1,2}Julian F Guest, ¹Riza R Taylor, ¹Erikas Sladkevicius ¹Catalyst Health Economics Consultants, Northwood, Middlesex UK; ²Postgraduate Medical School, University of Surrey, Guildford, Surrey, UK.

INTRODUCTION

- Electric stimulation has acquired a substantial body of evidence to support its use in wound management [1,2].
- Delivery of electric stimulation to a chronic wound requires a device that can pass an electrical current across the wound bed. One such device is Accel-Heal which emits a specific sequence of micro-current electrical pulses which interact with biological processes that have become static within a chronic non-healing wound.
- The aim of this study was to assess the potential cost-effectiveness of using Accel-Heal plus compression bandaging compared to compression bandaging alone in patients with chronic non-healing venous leg ulcers (VLU), from the perspective of the UK's National Health Service (NHS).

METHODS

Markov Model

- A 5-month Markov model was constructed depicting the management of chronic, non-healing VLUs of >6 months duration in the UK (Figure 1).
- The model considers the decision by a clinician to continue with a patient's previous standard care (i.e. compression bandaging alone) or to treat with Accel-Heal plus compression bandaging.

Model Inputs

- The model was populated with clinical outcomes and healthcare resource use obtained from a clinical evaluation of a cohort of 21 patients treated with Accel-Heal.
- In the clinical evaluation, patients' ulcer sizes were measured at different time points and at different frequencies. Time-series forecasting was undertaken to interpolate and extrapolate each patient's ulcer size, using moving averages, to provide a continuous estimate of wound size over a period of 20 weeks from the start of Accel-Heal treatment. This forecasting predicted which Accel-Heal-treated ulcers would either heal, improve, remain unchanged or get worse and the rate of healing.

- The treatment patterns, clinical outcomes and resource use of patients in the clinical evaluation had remained unchanged in the 6 months preceding the start of Accel-Heal therapy. Hence, it was assumed that these would continue to remain unchanged in the next 5 months had they not been treated with Accel-Heal. Therefore, patients' treatment patterns, clinical outcomes and resource use in the period preceding the start of Accel-Heal therapy and those treated with placebo were used as a proxy for treatment with compression bandaging alone.

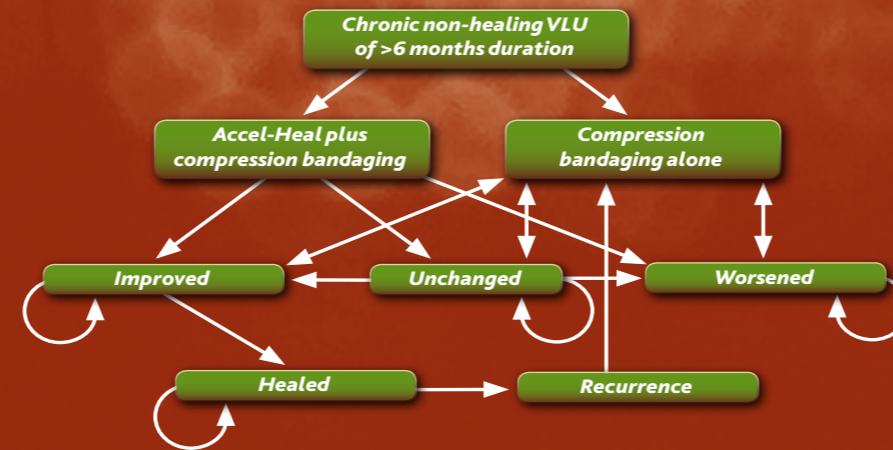
Model Outputs

- Published utilities for VLUs [3] were assigned to the respective states in the model and unit costs at 2008/09 prices [4-5] were assigned to the estimates of healthcare resource use in the model.
- The model was used to estimate:
 - The expected 5-monthly healthcare costs of a patient receiving either Accel-Heal plus compression bandaging or continuing with compression bandaging alone.
 - The expected effectiveness of each treatment at 5 months.
 - The expected number of quality-adjusted life years (QALYs) associated with each treatment at 5 months.
 - The cost-effectiveness of Accel-Heal plus compression bandaging compared to compression bandaging alone at 5 months (i.e. the cost per QALY gained) from the perspective of the UK's National Health Service (NHS).
- The base-case analysis assumed that patients only received 3 units of Accel-Heal at a cost of £40 per unit.

Sensitivity Analyses

- Probabilistic and deterministic sensitivity analyses were undertaken to identify how the cost per QALY gained with Accel-Heal plus compression bandaging would change by varying different parameters in the model.

Figure 1: Markov model depicting the management of chronic, non-healing VLUs of >6 months duration with Accel-Heal plus compression bandaging compared to compression bandaging alone. The arrows depict the possible movement of patients between the different health states.



RESULTS

Clinical Outcomes

- At the start of the clinical evaluation, patients' mean age was 69.2 years, 62% were female and the age of their wound was a mean 2.0 years. By allowing for the probability of recurrence [6], 36% of patients in the Accel-Heal group is expected to be healed by 5 months compared to 9% of those treated with compression bandaging alone (Figure 2).

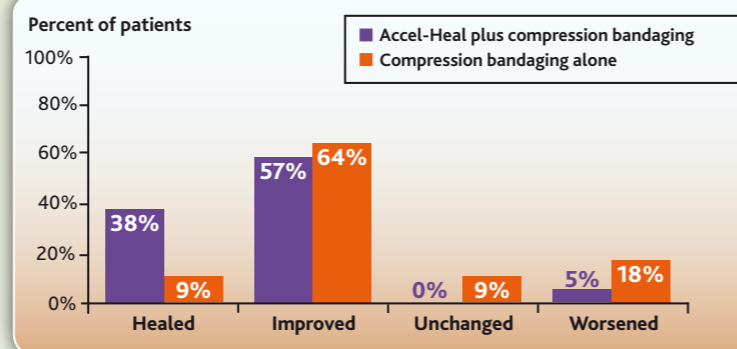


Figure 2: Expected effectiveness at 5 months.

- Using Accel-Heal is expected to lead to 0.316 QALYs (95% CI: 0.315, 0.316), whereas use of compression bandaging alone is expected to lead to 0.299 QALYs (95% CI: 0.298, 0.299).
- Hence, using Accel-Heal is expected to lead to a 6% increase in health gain of 0.017 QALYs (95% CI: 0.017, 0.017) at 5 months after the start of treatment.

Resource Use and Corresponding Costs

- Use of Accel-Heal plus compression bandaging instead of compression bandaging alone is expected to lead to a 27% reduction in the requirement for nurse visits (from a mean 49.0 to 35.9 visits per patient) over the first 5 months after the start of treatment (Figure 3), thereby potentially releasing 13 nurse visits per patient for alternative use within the system.

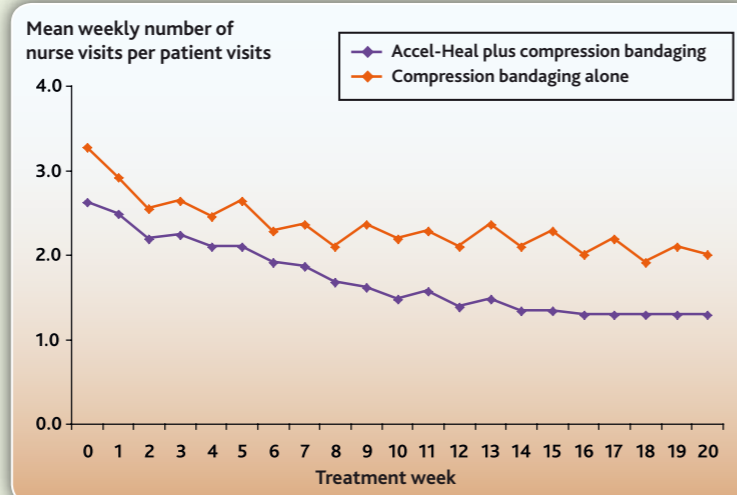


Figure 3: Expected number of nurse visits over 5 months.

- By assuming that patients only receive 3 units of Accel-Heal and an acquisition cost of £40 per unit, the total 5-monthly cost of managing patients with Accel-Heal plus compression bandaging was estimated to be £748.9 (95% CI: £746.1; £751.8) (Figure 4).

- Using compression bandaging alone is expected to lead to a 5-monthly cost of £879.9 (95% CI: £876.4; £883.4) (Figure 4).
- Nurse visits are the primary cost driver in both the Accel-Heal and compression bandaging group, accounting for 67% and 77% respectively of the total healthcare cost (Figure 4).
- Accel-Heal accounts for 16% of the total healthcare cost in the Accel-Heal group (Figure 4).
- Bandages, dressings and emollients account for the remainder of the healthcare costs in both groups (Figure 4).

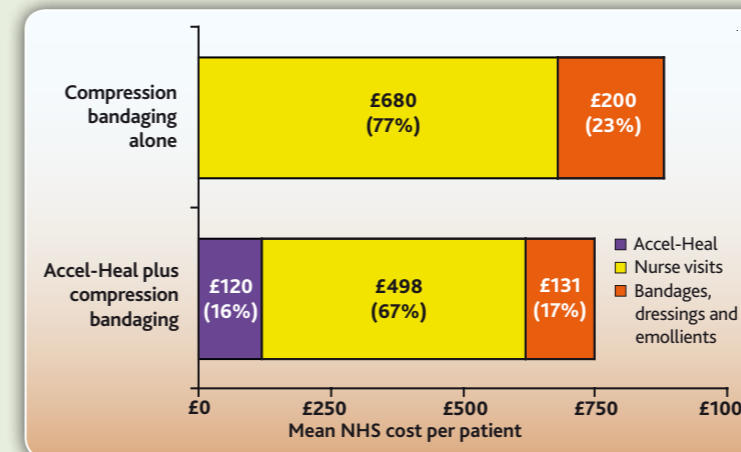


Figure 4: Distribution of expected NHS costs.

Cost-Effectiveness Analysis

- Use of Accel-Heal is expected to lead to a cost reduction of £131.0 (95% CI: £126.8; £135.1) over 5 months and a 6% improvement in health gain of 0.017 QALYs at 5 months.
- Hence, Accel-Heal is expected to afford the NHS a dominant treatment since the cost per QALY gained was an estimated -£7,696.
- Probabilistic sensitivity analyses demonstrated that at a cost of £40 per unit of Accel-Heal, it is likely that 98% of a cohort would be cost-effectively treated with Accel-Heal up to a threshold of £20,000 per QALY.
- Deterministic sensitivity analyses showed that the relative cost-effectiveness of Accel-Heal plus compression bandaging is very sensitive to the acquisition cost of Accel-Heal, the number of units per treatment and the number of nurse visits in both groups. The relative cost-effectiveness of Accel-Heal plus compression bandaging was relatively insensitive to changes in healing rates and recurrence rates.

Net Resource Implications and Budget Impact

- The current population in the UK is 61.8 million people. Assuming the prevalence of VLUs is 0.2% [7], that would equate to 123,600 people with a VLU per annum. Assuming that 38% of the wounds are long-term non-healing of >6 months duration [8], that would equate to ~47,000 people in the UK with a long-term non-healing VLU of >6 months duration.
- If all 47,000 patients with a hard-to-heal VLU were treated with Accel-Heal plus compression bandaging (3 units @ £40 per unit) instead of compression bandaging alone, the expected net impact to the NHS would be:
 - 15% reduction in NHS costs (£6.2 million) over the first five months of treatment, from £41.3 to £35.2 million.
 - 27% reduction in the number of nurse surgery visits (0.6 million) over the first 5 months of treatment, from 2.3 to 1.7 million nurse visits.

DISCUSSION

- The clinical basis of the model was a clinical evaluation of Accel-Heal among a relatively small sized group of patients at one centre.
- Due to the nature of the clinical data set and lack of a prospective comparator, the model may not be predictive of the incremental differences in clinical outcomes and resource use that will be seen in clinical practice when Accel-Heal becomes routinely available.
- Since the analysis is based on the treatment patterns at one centre the levels of healthcare resource use observed in the analysis may not be indicative of the UK as a whole.
- The analysis estimated the cost and consequences of managing chronic, non-healing VLUs over 5 months and does not consider the potential impact of the wounds that remained unhealed beyond that period.
- The analysis was unable to consider the impact of other factors that may affect the results, such as co-morbidities, underlying disease severity, pathology of the underlying disease, dressings and bandages that patients received.
- The model excluded costs incurred by patients and indirect costs borne by patients or society.
- Notwithstanding this, Accel-Heal's acquisition cost is expected to be offset by a reduction in the requirement for nurse visits, thereby releasing NHS resources for alternative use within the system.

CONCLUSION

- Accel-Heal plus compression bandaging potentially affords the NHS a cost-effective treatment compared to compression bandaging alone in the management of chronic non-healing VLUs of >6 months duration. However, this is dependant on the number of Accel-Heal units per treatment, the unit cost of Accel-Heal, and the number of nurse visits. Generation of a robust, comparative clinical data set is a prerequisite for a more definitive estimation of the cost-effectiveness of Accel-Heal.

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