A randomized trial of two irremovable off-loading devices in the management of plantar neuropathic diabetic foot ulcers

Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Two devices for the treatment of plantar neuropathic diabetic foot ulcers were examined. One was a total contact cast (TCC), while the other was a removable cast walker rendered irremovable (irremovable TCC).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised diabetic patients who had chronic, non-ischaemic, non-infected University of Texas Stage 1A or IIA ulcers. All patients had moderate to severe neuropathy, with a loss of protective sensation, defined as a neuropathy disability score of at least 6 and a biothesiometer vibration perception threshold score of at least 25 volts at the apex of the hallux on the affected side. Patients were excluded if they had clinical evidence of active infection at the ulcer site, or active Charcot neuroarthropathy. They were also excluded if they had significant peripheral arterial disease (defined as an absent dorsalis pedis or posterior tibial pulse), an inability to walk, or if they did not meet the inclusion criteria.

Setting
The setting was a hospital. The economic study was carried out in the USA.

Dates to which data relate
The dates to which the effectiveness and resource use data related were not reported. The price year was not given.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients as that used in the clinical study.

Study sample
Power calculations were carried out in the preliminary phase of the study. These showed that the study had a power of 95% to detect a 5% difference in the proportion of patients with healed ulcers at or before 12 weeks, and a 35% power to detect a 25% difference in complication rates. A sample of 41 patients was identified and included in the analysis.
There were 21 patients (71% men) in the irremovable TCC group and 20 (65% men) in the TCC group. The mean age of the patients was 50.7 years (age range: 29 - 65) in the irremovable TCC group and 51 years (age range: 23 - 65) in the TCC group. It was not stated whether some patients refused to participate, or were excluded for any reason from the initial study sample.

**Study design**
This was a prospective, randomised clinical trial that was, presumably, carried out at a single centre. The patients were allocated to study groups using a prepared random number table. The length of follow-up was 12 weeks. Overall, 7 patients were lost to the follow-up assessment (4 in the irremovable TCC group and 3 in the TCC group). Reasons for loss to follow-up were not reported. The outcome assessment was not blinded.

**Analysis of effectiveness**
The analysis of the clinical study was conducted on an intention to treat basis. However, results were also reported for when patients lost to follow-up were not taken into consideration. The outcome measures used in the clinical study were:

- the proportion of patients with ulcers that healed in less than or equal to 12 weeks;
- the median healing times for patient with ulcers healing in the 12-week period;
- the frequency of complications (defined as any potential side effect from the treatment);
- the weight of the devices; and
- the times of placement and removal of the devices.

The study groups were comparable at baseline in terms of the demographics and clinical characteristics.

**Effectiveness results**
The proportion of patients with ulcers that healed in less than or equal to 12 weeks was 74% (+/- 45) in the TCC group and 80% (+/- 41) in the irremovable TCC group, (p=0.65). Excluding patients lost to follow-up, the corresponding proportions were 93% (+/- 26) and 94% (+/- 24), (p=0.97).

The median healing time for patient with ulcers healing in the 12-week period was 5 weeks (first quartile 3 - third quartile 7) for the TCC group and 4 weeks (first quartile 3 - third quartile 7) for the irremovable TCC group.

The frequency of complications was 65% with TCC and 38% with irremovable TCC, (p=0.09). The analysis showed a relative risk reduction (RR) of 41% with irremovable TCC and an absolute RR of 27% (95% confidence interval, CI: 4.3 - 58). Most of the complications were simple local skin maceration. When episodes of maceration were excluded, the complication rates dropped to 46% in the TCC group and 13% in the irremovable TCC group. This corresponded to a relative RR of 71% and an absolute RR of 33% (95% CI: -1.2 - 67; p=0.06). One amputation (a single toe amputation) was observed in each group.

The medium-sized irremovable TCC weighed 1.1 kg in comparison with 1.5 kg for the TCC, (p=0.0009).

The large-sized irremovable TCC weighed 1.4 kg (p=0.5 compared with the TCC).

The mean time for placement was 12.4 (+/- 1.9) minutes (range: 6.9 - 15.7; 95% CI: 11.7 - 13.11) for the TCC and 7.6 (+/- 1.6) minutes (range: 5.3 - 12.5; 95% CI: 7.1 - 8.1) for the irremovable TCC, (p<0.0001). This represented a 39% reduction (95% CI: 33 - 47) in time with the irremovable TCC.

The mean time for removal was 3.6 (+/- 0.8) minutes (range: 2 - 5.3; 95% CI: 3.4 - 3.8) for the TCC and 2.3 (+/- 0.6) minutes (range: 1.4 - 4; 95% CI: 2.1 - 2.5) for the irremovable TCC, (p<0.0001). This represented a 36% reduction.
Clinical conclusions
The effectiveness analysis showed that comparable healing rates and healing times were observed with the TCC and irremovable TCC. However, the irremovable TCC was associated with significantly shorter times for placement and removal of the device, and there was a strong trend for lower complication rates in patients fitted with this device.

Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used in the economic evaluation. In effect, a cost-consequences analysis was carried out.

Direct costs
Discounting was not relevant since the costs were incurred during a short timeframe. The unit costs were not presented separately from the quantities of resources used. The health services considered in the economic evaluation were cast changes, materials (e.g. local dressings, cast padding, fibreglass cast material, elastic wraps and cast boots) and cast technician salary. The cost/resource boundary adopted in the study was not explicitly stated. Resource use was estimated using patient-level data that were derived from the sample of individuals included in the clinical trial. The source of the cost data was presumably the authors' institution. The price year was not reported.

Statistical analysis of costs
The costs were treated deterministically.

Indirect Costs
The indirect costs were not considered in the economic evaluation.

Currency
US dollars ($).

Sensitivity analysis
Sensitivity analyses were not carried out.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The direct cost of a treatment course was $210.67 with TCC and $158.47 with irremovable TCC (difference $52.20; 24.8%).

Synthesis of costs and benefits
A synthesis of the costs and benefits was not relevant since a cost-consequences analysis was performed.

Authors' conclusions
The irremovable total contact cast (TCC), for the treatment of superficial plantar diabetic foot ulcers, was as efficacious as the standard TCC in healing and was associated with no more or possibly fewer complications. It also
took less time to place or remove, and was cheaper.

**CRD COMMENTARY - Selection of comparators**
The authors justified the choice of the comparators, with the TCC representing the 'gold' standard and the irremovable TCC representing an alternative treatment option. You should decide whether they are valid comparators in your own setting.

**Validity of estimate of measure of effectiveness**
The effectiveness evidence came from a clinical trial, which was appropriate for the study question. The internal validity of the study was enhanced by some robust aspects of the design. For example, the justification of the sample size (which was powered to detect statistically significant differences in the main outcome measures), the randomised allocation of treatment, the use of intention to treat as the basis for the analysis of the clinical outcomes, and the comparability of the patient groups at study entry. However, the authors acknowledged that the sample size was relatively small. Blinding was not performed because, owing to the nature of the devices, it was not feasible. The evidence presumably came from a single institution, thus caution is required when extrapolating the results of the clinical study to other centres.

**Validity of estimate of measure of benefit**
No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted. Please refer to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

**Validity of estimate of costs**
The perspective adopted in the analysis was unclear. It appears that only those costs relevant to the service provider have been included in the analysis. The unit costs, quantities of resources used and price year were not reported. The costs were presumably obtained from the authors' institution, although it was not explicitly stated. The costs were not treated stochastically and were specific to the study setting. Sensitivity analyses were not carried out.

**Other issues**
The authors did not make extensive comparisons of their findings with those from published studies, stating instead that their study was the first randomised comparison of the irremovable TCC and TCC. It was also noted that the results from a parallel study supported the superiority of the irremovable TCC. The issue of the generalisability of the study results to other settings was not addressed and sensitivity analyses were not performed. This reduces the external validity of the analysis. Some limitations of the analysis were highlighted, such as the small sample of patients and the fact that the casts would not be appropriate for all patients.

**Implications of the study**
The study results supported the use of an irremovable TCC for the treatment of superficial plantar diabetic foot ulcers. The authors stressed that further research, using a large sample of patients, should be carried out to corroborate their findings.

**Source of funding**
None stated.

**Bibliographic details**
Other publications of related interest


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Subject indexing assigned by NLM

MeSH
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