Biobrane versus Duoderm for the treatment of intermediate thickness burns in children: a prospective, randomized trial
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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
The health technologies studied were Biobrane (Bertek Pharmaceuticals Inc. Morgantown), a biocomposite wound dressing, and Duoderm (ConvacTec Inc., Bristol-Myers Squibb Co., New York City), an occlusive hydrocolloid dressing, for the treatment of small, intermediate thickness burns in children.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised paediatric patients between 3 and 18 years of age with superficial or mid dermal partial thickness burns covering less than 10% of the total body surface area. Burns involving face, hands, feet or the perineum were excluded.

Setting
The interventions were provided by a secondary care provider in an inpatient setting. The geographical location of this study was the USA.

Dates to which data relate
The dates between which the effectiveness and resource data were collected were not reported. Cost comparisons using 1999 costs and 2002 costs were reported separately.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample that provided the effectiveness data.

Study sample
A power analysis was performed prior to enrolment to determine the sample size necessary for 80% power. The authors reported that 72 consecutive patients who met the inclusion criteria were enrolled. None were reported to have refused consent for randomisation. Thirty-seven were randomly assigned to the Duoderm dressing group and 35 to the Biobrane dressing group. All enrolled participants completed the study.

Study design
The study was a single-centre, prospective, randomised controlled trial. The method of randomisation was not reported.
Blinding of the patients and clinicians does not appear to have been attempted. It would appear that patients were followed up to complete re-epithelialisation, as assessed by a burn surgeon or nurse.

**Analysis of effectiveness**
The time taken for complete re-epithelialisation and the aggregate pain scores on the Oucher or visual analogue scales (depending on patient age) were used in the analysis of effectiveness. The groups were not shown to be comparable in terms of the population demographics or the mechanism of injury.

**Effectiveness results**
Patients in the Duoderm group demonstrated complete re-epithelialisation at a mean of 11.21 (+/- 6.5) days, compared with 12.24 (+/- 5.1) days for those in the Biobrane group, (p=0.47).

The mean aggregate pain score was 2.37 (+/- 2.27) in the Duoderm group and 2.36 (+/- 2.62) in the Biobrane group, (p=0.993).

**Clinical conclusions**
There was no significant difference in the time to healing or in the pain scores between the two groups.

**Measure of benefits used in the economic analysis**
The authors did not derive a summary measure of benefit. In effect, a cost-consequences analysis was performed. See 'Analysis of Effectiveness' for the clinical outcomes measured. The benefits were not discounted.

**Direct costs**
The study reported the costs to the hospital of the dressing material in the two groups. The unit costs were not reported. The costs were reported as the mean costs (+/- standard deviation) per patient. Cost comparisons using 1999 and 2002 prices were reported separately. The costs were not discounted.

**Statistical analysis of costs**
The groups were compared using an independent sample t-test.

**Indirect Costs**
The productivity costs were not considered.

**Currency**
US dollars ($).

**Sensitivity analysis**
Mean values with standard deviations were reported.

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

**Cost results**
At 2002 prices, the mean cost of Biobrane was $21.57 (+/- 19.56) for a 5x5 dressing and $40.62 (+/- 10.39) for a 5x15
dressing. The cost was $5.33 (+/- 3.94) for thin Duoderm and $12.82 (+/- 5.49) for thick Duoderm, (p<0.001).

**Synthesis of costs and benefits**
The costs and benefits were not combined.

**Authors’ conclusions**
Duoderm and Biobrane provide equally effective treatment of second-degree burns in the paediatric population. No significant difference could be demonstrated in healing time or pain control. However, Duoderm is statistically less expensive than Biobrane and can be considered a first-line treatment option for intermediate thickness burn wounds in children.

**CRD COMMENTARY - Selection of comparators**
A justification was provided for the technologies compared. They were both commonly used in the authors’ setting but their relative merits were unknown. The authors noted that there were other products on the market. You should decide if the products compared here represent valid comparators in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis was based on a randomised controlled trial. Power calculations were performed to ensure that the size of the study sample was adequate. The authors described the mechanism of injury in the children, thus enabling readers to form a reasonable impression of the extent to which their own patients are comparable with those in this study. The fact that the patients were enrolled sequentially (rather than selectively) may provide the reader with some reassurance that the sample was typical of the study population. The authors reported that every patient eligible for the study consented to randomisation. The method of randomisation was not reported and the patient groups were not shown to be comparable demographically at baseline. The nature of the intervention would have prevented blinding of the patients and the clinicians. However, the blinding of researchers who scored pain should have been possible. This possibility was not discussed but it would have helped minimise potential bias in the data analysis. It was not reported how often in the day the wounds were inspected for healing, but time to healing was reported in decimal days. If inspections were carried at fixed times once or twice a day, the decimal days reported may be a function of the time of injury in relation to the fixed time for inspection of wounds.

**Validity of estimate of measure of benefit**
The authors did not derive a summary measure of benefit. In effect, a cost-consequences analysis was performed. You should decide if the measures of effectiveness adequately captured the health outcomes of the products.

**Validity of estimate of costs**
The study reported the mean costs of the dressing in the two groups. No attempt was made to evaluate the costs of nursing and physician time or other costs of hospitalisation. As it turns out, the duration of healing was identical in both groups but this could not have been assumed at the start of the study. The authors described the mean costs for each of the two types of Biobrane dressing and two types of Duoderm dressing used. However, they did not report the quantities of the four dressings used. This hinders the generalisability of the results. Since the costs were incurred during less than 1 year, discounting was not relevant and was not performed.

**Other issues**
The generalisability of the results is limited because the costs and the quantities were not reported separately. The authors discussed their findings in the context of other studies comparing different dressings for burns. The authors did not report the results selectively and their conclusions reflected the scope of the study.
Implications of the study
Duoderm is statistically less expensive than Biobrane and can be considered a first-line option for intermediate thickness burns in children. The authors suggested that future studies evaluating newer products must be compared with the currently most efficacious products such as Duoderm.

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