Comparative clinical study of the sure-closure device with conventional wound closure techniques

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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
Sure-closure device in complex wound problems.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis

Study population
Patients presenting complex wounds with multiple etiologies. The age range was 1 to 83 years. 67.5% of the sample were male. Preoperative antibiotics were used on 40% of patients. Patients were grouped as follows: group A - patients with lower torso injuries without bone exposure; group B - patients with lower torso injuries with bone exposure; and group C - patients with upper torso injuries.

Setting
Hospital. The study was carried out in Pittsburgh, Pa, USA.

Dates to which data relate
Not stated.

Source of effectiveness data
Single study.

Link between effectiveness and cost data
Costing was undertaken retrospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
No power calculations were reported. Forty patients were evaluated. The Sure-closure device was used in 24 patients with the remaining 16 were managed by conventional approaches.

Study design
Non-randomised trial with concurrent controls. The duration of follow-up was 3 months.
**Analysis of effectiveness**
The basis of the analysis (intention to treat or treatment completers only) was not clearly stated. The main health outcomes used in the analysis were the percentage of primary closures and postoperative complications (partial necrosis of the skin edges, hypertrophic scars, keloids at 1 and 3 months follow-up, and infection). The patients’ ages varied from 3 to 82 years in the control group and 1 to 73 in the device group. Preoperative antibiotics were used in 8 out of 16 patients in the control group and 8 out of 24 in the device group.

**Effectiveness results**
Primary closure was obtained in all 24 patients in the device group. None of these patients had postoperative complications. Patients who had delayed stretching (1 to 3 days) tolerated the procedure well. Infection was noted in 2 of the control patients but was not seen in any of the device patients.

**Clinical conclusions**
The sure-closure device can be a valuable adjunct to the existing techniques for wound closure and should be kept in mind for the closure of some tight wounds where extra skin length would enable primary wound closure.

**Measure of benefits used in the economic analysis**
The main health outcomes used in the analysis were the percentage of primary closures and postoperative complications (partial necrosis of the skin edges, hypertrophic scars, keloids at 1 and 3 months follow-up, and infection).

**Direct costs**
Resource use quantities were not reported separately from costs which, in turn, were only reported graphically. The costs included: operating room time, operating room supplies, anaesthesia, monitoring, recovery room time, wound care supply, pharmacy charges, and room and board. No cost dates were given. The source of data was the finance department of the "respective hospitals".

**Statistical analysis of costs**
Two-tailed Student t test was used to analyse differences in mean costs between groups.

**Indirect Costs**
Not considered.

**Currency**
Not stated.

**Sensitivity analysis**
Not performed.

**Estimated benefits used in the economic analysis**
Primary closure was obtained in all 24 patients in the device group. None of these patients had postoperative complications. Patients who had delayed stretching (1 to 3 days) tolerated the procedure well. Infection was noted in 2 of the control patients but was not seen in any of the device patients.
Cost results
A cost reduction trend was associated with the sure-closure method (p<.05). The total cost was reported in the form of a graph and therefore, the following figures represent the CRD Reviewer's approximations: the mean device group patient, 15,000; control group patient, 8,000.

Synthesis of costs and benefits
Since the intervention turned out to be the dominant strategy, no synthesis of costs and benefits was presented.

Authors' conclusions
The sure-closure device can be a valuable adjunct to the existing techniques for wound closure and should be kept in mind for the closure of some tight wounds where extra skin length would enable primary wound closure.

CRD Commentary
The study results are unlikely to be internally valid due to the selection biases associated with the non-random nature of the study design and the low numbers in the study. Furthermore, the differences in demographic characteristics between groups were not properly analysed. The cost analysis lacked adequate detail and the dates for the resource use (as well as effectiveness) data collection were not provided. The price year was not reported.

Implications of the study
Given the uncertainties in the data, further studies are needed before strong, justified conclusions can be reached. Randomised control trials are desirable to address the cost-effectiveness of treatment options in complex wound closure.

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