

## Use of skin staplers in head and neck surgery: prospective clinical study

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### Health technology

The use of skin staplers (Proximate Plus MD 35 Wide, Ethicon Endo-Surgery) versus conventional suturing (using a 3-0 monofilament nylon) for skin closure in head and neck surgery. The staples and sutures were both removed on the seventh postoperative day.

### Type of intervention

Other: Surgery.

### Hypothesis/study question

The aim of the study was to determine the effectiveness and costs associated with skin closure using staplers, compared with conventional sutures, in head and neck surgery. Conventional sutures appear to have been implicitly chosen as the comparator. The perspective of the study was not reported.

### Economic study type

Cost-effectiveness analysis.

### Study population

The study population comprised patients with tumours of the head and neck who underwent resections of pharyngeal and laryngeal tumours combined with neck dissections. Specific inclusion and exclusion criteria were not reported.

### Setting

The setting was tertiary care. The economic analysis was conducted in Zagreb, Croatia.

### Dates to which data relate

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

### Source of effectiveness data

The effectiveness data were derived from a single study.

### Link between effectiveness and cost data

The costing was not carried out on the same sample of patients as that used in the effectiveness study.

### Study sample

The use of power calculations was not reported. The 50 consecutive patients included in the study were randomly assigned to the two groups. There were 25 patients in the skin stapler group and 25 in the conventional suturing group. The study sample was not shown to be representative of the study population.

### Study design

This was a randomised controlled trial that was conducted in a single centre. The duration of follow-up was 6 weeks after surgery. No loss to follow-up was reported. The method used to randomise the patients to the study groups was not reported. Two surgeons who were blinded to the method of skin closure assessed the clinical examinations.

### Analysis of effectiveness

The analysis of the clinical study was conducted on an intention to treat basis. The health outcomes used were the speed of suturing, wound healing result, cosmetic result and complications (wound dehiscence, infection, allergic reaction, or fistula formation). The speed of suturing was calculated as the time for skin closure per centimetre of wound. Healing and cosmetic results were assessed by clinical examination 6 weeks postoperatively and were rated as good, satisfactory, or poor. The criteria for good healing were unremarkable scar with well-adapted edges in the skin level.

The demographics and clinical characteristics of the study sample were not reported.

### Effectiveness results

The average wound closure speed was 18.9 (+/- 1.4) cm/minute with staplers and 1.9 (+/- 0.4) cm/minute with interrupted sutures,  $p < 0.001$ ). Thus, the closure speed was 10 times greater with staplers than with conventional suturing.

Healing was good in both groups. Twenty-one patients were rated as good and 4 as satisfactory in the stapler group, versus 20 (good) and 5 (satisfactory), respectively, in the sutured group. Healing was complete by the time the sutures and staples were removed.

There was no statistically significant difference between the groups in terms of cosmetic appearance.

There were no complications in either group.

### **Clinical conclusions**

Closure speed was faster with staplers than with sutures, while both procedures achieved similar healing results and cosmetic appearance.

### **Measure of benefits used in the economic analysis**

The time for skin closure appears to have been used as the summary measure of benefit in the economic evaluation. This measure of benefit was directly obtained from the clinical analysis.

### **Direct costs**

The perspective adopted was not reported. The direct costs included only the costs of the suturing material (including monofilament, round needle and staples). The authors did not provide any additional details of the cost analysis. The unit costs and the quantities of resources used were not presented separately. The price year was not reported. The resource use data appear to have been derived from actual data gathered by the authors. The sources of the unit costs and prices were not reported. Discounting was not relevant and none was reported. The direct costs reported were the incremental costs per average wound length (30 cm) closed by skin stapler in comparison with conventional closure.

### **Statistical analysis of costs**

A statistical analysis of the costs was not carried out.

### **Indirect Costs**

The indirect costs were not included.

### **Currency**

US dollars (\$)

### **Sensitivity analysis**

Sensitivity analyses were not performed.

### **Estimated benefits used in the economic analysis**

The authors reported that for the average wound length of 30 cm, the skin stapler would save 13 minutes of time for skin closure in comparison with conventional suturing.

### **Cost results**

The difference in cost between the stapler suture and conventional suture was \$3.00 for a 30-cm wound length.

### **Synthesis of costs and benefits**

The estimated costs and benefits were not combined.

### **Authors' conclusions**

Skin staplers significantly reduced wound closure time and yielded similar cosmetic results, with no complications and with only a slightly higher cost for the suturing material.

### **CRD COMMENTARY - Selection of comparators**

The choice of the comparator (conventional suturing in head and neck surgery) was justified as being current practice, even though the authors stated that skin staplers had been used in their institution for more than 6 years. You should decide whether it represents a valid comparator in your own setting.

### **Validity of estimate of measure of effectiveness**

A randomised controlled study was performed, which was appropriate for the study question. Power calculations were not carried out. The sample size was small, hence the study might not have had adequate statistical power to detect significant differences in the outcomes, notably cosmetic appearance. The study groups were not shown to be comparable at baseline, thus confounding factors might have influenced the effectiveness results. The outcomes assessment was performed blinded, therefore no assessment bias should have occurred. Data came from a single centre and, consequently, the study sample might not have been representative of the study population.

### **Validity of estimate of measure of benefit**

The summary benefit measure used in the economic analysis may have been appropriate for the specific interventions analysed, but it will not enable the results to be compared with those from different health care interventions.

### **Validity of estimate of costs**

The perspective of the study was not stated, thus it was not possible to assess whether all the relevant categories of costs were included in the analysis. However, it appears that some relevant costs have been omitted from the analysis. For example, the analysis did not include the cost of personnel time for suturing, so the costs might have been underestimated. Details of the unit costs, quantities of resources and the price year were not reported. This limits the transferability of the economic analysis to other settings and limits reflation exercises. The cost estimates appear to have

been derived from the authors' setting, hence the results may not be generalisable to other settings. Discounting was not carried out since the costs were incurred during less than 2 years. The main drawback of the cost analysis was that the authors provided a limited cost analysis, which lacked detail, and statistical and sensitivity analyses were not performed on the costs. Consequently, the internal and external validity of the costing analysis may be low.

### **Other issues**

The generalisability of the results was not addressed. The authors commented that, while in this study patients did not experience complications, other studies have detected such complications. However, no further comparisons were made with the findings from other studies, nor were any additional limitations of the study reported. The results were not reported selectively and the conclusions reflected the scope of the study. Sensitivity analyses were not performed to account for variability in the cost or effectiveness data. Consequently, caution should be exercised when extrapolating the study results to different contexts.

### **Implications of the study**

The authors recommended the use of skin staplers in head and neck surgery.

### **Source of funding**

None stated.

### **Bibliographic details**

Grgic M, Ivkic M. Use of skin staplers in head and neck surgery: prospective clinical study. *Journal of Otolaryngology* 2002; 31(3): 137-139

### **PubMedID**

[12121014](#)

### **Other publications of related interest**

Medina dos Santos LR, Freitas CA, Hojaij FC, et al. Prospective study using skin staplers in head and neck surgery. *American Journal of Surgery* 1995;170:451-2.

### **Indexing Status**

Subject indexing assigned by NLM

### **MeSH**

Esthetics; Head and Neck Neoplasms /surgery; Humans; Prospective Studies; Statistics, Nonparametric; Surgical Staplers; Treatment Outcome; Wound Healing

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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.