A blinded, randomised, controlled trial of stapled versus tissue glue closure of neck surgery incisions

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ABSTRACT

INTRODUCTION Cosmetic acceptability of scar and neck mobility are important outcomes after collar line incision for neck surgery. This randomised, controlled trial compares these parameters in closures using tissue glue (Dermabond™, Ethicon, UK) and skin staples.

PATIENTS AND METHODS Patients requiring a collar line incision were randomised to receiving tissue glue or staples for skin closure. Time for closure to be completed was recorded. Mobility of the neck was assessed using a visual analogue scale at 48 h and 1 week after surgery. At 6 weeks, cosmetic appearance was assessed using a linear 1–10 visual analogue scale by the patient, surgeon and an independent blinded assessor. Results were compared using appropriate statistical tests.

RESULTS Glued ($n = 14$) and stapled ($n = 15$) closures were performed for hemithyroidectomy ($n = 8$ versus 6), sub-total thyroidectomy ($n = 2$ versus 4), total thyroidectomy ($n = 1$ versus 4) and parathyroidectomy ($n = 3$ versus 1). Closure with tissue glue took significantly longer than with staples (mean, 95 versus 28 s; $P < 0.001$). Neck mobility scores were comparable at 48 h and 1 week (mean, 4.8 versus 4.4; $P = 0.552$; and 2.7 versus 2.6; $P = 0.886$). Cosmetic appearance at 6 weeks was comparable when patient (mean, 1.7 versus 1.8; $P = 0.898$), surgeon (mean, 2.6 versus 2.3; $P = 0.633$) and independent assessment (mean, 1.4 versus 1.9; $P = 0.365$) was performed.

CONCLUSIONS The use of glued skin closure may increase the duration of surgery but acceptable neck mobility and wound cosmesis can be achieved by the more rapid application of stapled skin closure in cervicotomy incisions.

KEYWORDS

Wound closure – Neck incision – Skin staples – Tissue glue

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Acceptable wound cosmesis and neck mobility are important outcomes following cervicotomy. Methods of skin closure vary in published series and are largely the result of surgeon choice based upon the need for a rapid, economic and reproducible technique of skin apposition. Recent advances in skin closure include the use of skin staples and tissue glues. Though each of these modalities has been evaluated against standard sutured methods in randomised clinical trials, no such comparison between these methods has been performed following cervicotomy. This blinded, randomised, controlled trial seeks to address this by comparing the speed and cosmetic results of cervicotomy closure using tissue glue or skin staples.

Patients and Methods

The trial protocol was reviewed and approved by local research ethics committee. The study population comprised

patients undergoing primary cervicotomy for thyroid or parathyroid surgery at a single district general hospital. Primary outcome measure was time taken to complete skin closure. A power calculation yielded that 30 participants were required based on a halving of closure time with 80% power, an allocation ratio of 1:1 to glue and staple groups and a two-sided significance test at the 5% level. Secondary outcomes were neck mobility, scar cosmesis score and peri-operative adverse event rates. Inclusion criteria were planned primary thyroid or parathyroid surgery in patients of the age and ability to give informed consent, with no known allergies to the products to be used and agreeing to randomisation procedure. Exclusion criteria were secondary neck surgery, history of poor compliance with medical treatments, allergy to products to be used or inability to give informed consent for inclusion or randomisation. Potential participants were identified at outpatient visits when the decision for surgical excision was

made and received written study information. Informed consent was obtained during a pre-operative assessment visit and documented on dedicated forms distinct from the generic operative consent form. Randomisation to glue or stapled closure was performed following induction of general anaesthesia by random envelope allocation.

Surgery was performed by the same consultant surgeon using standard techniques of thyroid and parathyroid resection. Briefly, following apposition of the strap muscles of the neck and closure of platysma using interrupted absorbable sutures (Vicryl™; Ethicon, Johnson and Johnson, Belgium), skin closure was applied. For both stapled and glued closure, tissue forceps were placed at the lateral ends of the incision. Gentle lateral traction on these accurately apposed the skin edges allowing staples (Visistat®; Weck Closure Systems, USA) to be applied at 5-mm intervals or tissue glue (Dermabond™, Ethicon) application to the dried skin surface. Following glue application, continued gentle traction with tissue forceps allowed the glue to dry with apposed skin edges as per the manufacturer's instructions. The time taken for skin closure was recorded and identical dressings (Mepore®; Mölnycke Healthcare, Sweden) were applied to facilitate further blinded assessment. Patients received a standard postoperative protocol and analgesic regimen to achieve tolerance of fluids and diet prior to discharge.

Neck mobility was assessed at 48 h, 1 week and 6 weeks by patient self-assessment, the operating surgeon and the blinded assessor using a 10-point linear visual analogue scale (VAS). Cosmesis of the scar was assessed by the patient, surgeon and blinded assessor after 6 weeks using a similar 10-point scale.

All data were encrypted and stored on a password-secured PC until completion of follow-up. The blind was then broken and analysis was performed using Version 11.0 of Statistical Package for Social Sciences (SPSSv11.0; IL, USA) run on Windows XP.

Frequencies of independent dichotomous nominal variables were compared using a chi-squared test (χ^2) except where expected values were < 5 where a Fisher's exact test was employed. Means of independent quantitative ordinal variables were compared using Student's *t*-test. All analyses used a 5% degree of statistical significance. Values for ordinal and continuous variables are expressed as mean differences $\pm$ 95% confidence intervals of the difference.

Results

Thirty patients were recruited and 29 successfully randomised. Fourteen had glue closure and 15 had stapled closure of cervicotomy. The distribution of operations performed were comparable and included thyroid lobectomy ($n = 8$ versus 6), subtotal thyroidectomy ($n = 2$ versus 4), total thyroidectomy ($n = 1$ versus 4) and parathyroidectomy ($n = 3$ versus 1; Fig. 1).

The number of adverse events were comparable between glue and stapled groups ($n = 1$ versus 0). This arose from glue becoming adherent to the dressing resulting in a wound dehiscence after a dressing change. This resolved uneventfully after primary closure using skin staples.

Tissue glue closures took significantly longer than stapled closures (mean difference, $67 \text{ s} \pm 42$ to 91 s ; Fig. 2).

Neck mobility assessment at 48 h and 1 week were comparable in both groups (mean differences, 0.5 ± -1.1 to 2.0 and 0.1 ± -1.3 to 1.5 ; Fig. 3).

Scar cosmesis assessment by both patient, surgeon and independent blinded assessor at 6 weeks were comparable for both groups (mean differences, -0.1 ± -1.2 to 1.1 , 0.3 ± -0.9 to 1.4 , and -0.5 ± -1.6 to 0.6 , respectively; Fig. 4).

Figure 2 Time taken for cervicotomy closure.

Discussion

Cervicotomy skin closure techniques vary widely in the reported literature and the choice lies largely with the surgeon based on experience. Critical to the choice of method is the need for rapid application, accurate skin apposition, economy and reproducibility. However, of paramount importance is the need to achieve excellent cosmesis and postoperative neck mobility given the conspicuous site and considerable morbidity associated with a poor result.

In 1991, Matthews and Briant¹ advocated a randomised, controlled trial comparing the use of tissue glue with standard methods of skin closure following thyroid surgery to

confirm their findings of a reduced hospital stay where glue was used. To date, this retrospective case control study remains the only comparison of tissue glue with a standard method of skin closure for cervicotomy.¹

A recent Cochrane database systematic review of eight randomised controlled trials concluded that tissue adhesives are an acceptable alternative to standard wound closure for repairing simple traumatic lacerations; there was no significant difference in cosmetic outcome between tissue adhesives and standard wound closure, or between different tissue adhesives. Tissue adhesives were advocated to decrease procedure time and pain, albeit with a small, but statistically significant, increased rate of dehiscence.²

The first study comparing tissue glue with standard suturing techniques in long surgical incisions demonstrated comparable rates of wound healing by day 10, with a tendency to reduced wound infection rates in the group closed with glue.⁵ Subsequently, cosmetic results comparable with conventional wound closure have been attained in breast surgery,⁴ paediatric surgery^{5,6} and laparoscopic port site closure.^{7,8} Furthermore, glue closure is faster compared to subcuticular suturing of incisions in inguinal hernia repair⁹ and in body contouring surgery.¹⁰

The first cyanoacrylate glues comprised short-chain molecules with low breaking strength and a brittle consistency which left them prone to fracturing.^{11,12} Their use was restricted to low-tension wounds where little tensile strength was required in the closure material¹⁵⁻¹⁶ and *in vitro* studies demonstrated a low wound tensile strength compared to monofilament sutures.^{11,12} Recently, longer chain cyanoacrylates have been introduced with improved tensile strength and more powerful adhesion of wound edges. Dermabond™, used in this study is 2-octylcyanoacrylate. This longer chain cyanoacrylate is a combination of monomers and plasticisers. Its 5-dimensional wound breaking strength is 4 times that of *n*-2-butylcyanoacrylate and it polymerises in an exothermic reaction on contact with fluid forming a strong bond. Animal studies suggest its tensile strength to be superior to adhesive tape strips, equivalent to subcuticular suturing but inferior to skin staples, and its use in high tension wounds is not recommended.¹⁷ This was reinforced clinically by Bernard *et al.*,¹⁸ who demonstrated an improved cosmetic outcome where suturing was used to close wounds involving tissue excision resulting in higher wound tension.

The cyanoacrylates are safe for clinical use with no reports of adverse effects or carcinogenicity.^{15,14,19} Indeed, they may have some beneficial antimicrobial properties, especially against Gram-positive organisms.²⁰⁻²²

The use of skin staples continues to generate debate and a considerable number of randomised clinical trials have failed to demonstrate a consistent benefit of this method of skin closure over sutured techniques. Though rapid to apply, the overwhelming consideration must be for patient comfort, satisfaction, cosmesis and functional outcome, and no study has reported staples to be superior to other methods of skin closure using these outcome measures. Indeed, recent studies have implicated skin staples with increased rates of wound complication and infection compared with subcuticular suturing.²³

This study demonstrates that the use of tissue glue for cervicotomy skin closure has no benefit over the use of staples. Use of tissue glue prolonged operating times but achieved neck mobility and wound cosmesis scores comparable to stapled closures.

Furthermore, though not within the remit of this study, it is likely that stapled closure can be achieved more economically

that glued closure. It is the authors' experience that cervicotomy closure can be attained using a single disposable unit of skin staples whereas glued closure occasionally required the use of multiple glue packs which may elevate costs of skin closure up to 5-fold. Similarly, Shamiyeh *et al.*²⁴ demonstrated that the use of skin adhesive was 14 times that of sutured closure and 40 times that of adhesive dressings in varicose vein surgery. A randomised controlled trial by Zempsky *et al.*²⁵ achieved similar cosmetic results with reduced cost using adhesive tape closure *versus* tissue glue in facial lacerations in children.

Conclusions

The authors advocate that skin staples should be favoured over tissue glue for the closure of cervicotomy wounds as equivalent cosmetic and functional outcomes are attained in a shorter operative duration. However, surgical technology is likely to yield a method of skin closure which achieves excellent cosmesis and function with reduced cost. A future randomised controlled trial comparing such a method with current closure techniques should include a cost-benefit analysis to determine both clinical efficacy and beneficial cost savings.

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