

## Review Article

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# Haemostatic devices in parotid surgery: a systematic review

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## Abstract

**Objective.** The Harmonic Scalpel and Ligasure (Covidien) devices are commonly used in head and neck surgery. Parotidectomy is a complex and intricate surgery that requires careful dissection of the facial nerve. This study aimed to compare surgical outcomes in parotidectomy using these haemostatic devices with traditional scalpel and cautery.

**Method.** A systematic review of the literature was performed with subsequent meta-analysis of seven studies that compared the use of haemostatic devices to traditional scalpel and cautery in parotidectomy. Outcome measures included: temporary facial paresis, operating time, intra-operative blood loss, post-operative drain output and length of hospital stay.

**Results.** A total of 7 studies representing 675 patients were identified: 372 patients were treated with haemostatic devices, and 303 patients were treated with scalpel and cautery. Statistically significant outcomes favouring the use of haemostatic devices included operating time, intra-operative blood loss and post-operative drain output. Outcome measures that did not favour either treatment included facial nerve paresis and length of hospital stay.

**Conclusion.** Overall, haemostatic devices were found to reduce operating time, intra-operative blood loss and post-operative drain output.

## Introduction

Salivary gland tumours represent approximately 5–8 per cent of head and neck tumours.<sup>1,2</sup> Salivary gland cancer is also relatively rare, with a worldwide incidence of 0.5–2.0 per 100 000 people.<sup>2</sup> Approximately 80–85 per cent of salivary gland tumours occur in the parotid gland, and patients with these tumours often undergo parotidectomy.<sup>3</sup> Parotidectomy involves careful dissection because of the gland's dense vascularity and close proximity to the facial nerve.<sup>4</sup> Consequently, intra-operative bleeding can make visualisation more challenging and can contribute to facial nerve injury.<sup>4,5</sup> Facial nerve injury is a known complication of parotidectomy. Traditionally, this surgery has been performed using a steel scalpel and electrocautery. The Harmonic Scalpel® is a widely used alternative in head and neck surgery, including parotidectomy. In contrast to conventional tools, it operates by performing vessel coagulation and tissue dissection simultaneously. This is achieved by ultrasonic vibrations at a frequency of 55 500 Hz to heat tissues, which allows for protein denaturation at temperatures between 55°C and 100°C. As such, there is less thermal transduction to tissue than with electrocautery.<sup>4,6,7</sup> Similarly, the LigaSure (Covidien®) instrument also reduces energy transfer to tissues compared with traditional methods, but it uses bipolar energy as opposed to ultracision to ligate and dissect simultaneously.<sup>8</sup> Current literature suggests that surgical outcomes between the Harmonic Scalpel and LigaSure instruments are comparable in terms of feasibility, intra-operative variables and post-operative variables.<sup>9–11</sup>

The combination of simultaneous dissection and coagulation using these tools has been considered useful in head and neck surgical procedures, including for addressing the intricacies of facial nerve dissection. Yet, some surgeons remain hesitant to use this technology in parotid surgery given the perception that the heat generated could negatively impact facial nerve outcomes.

The use of haemostatic devices has been shown to reduce intra-operative blood loss and to reduce operating time in many head and neck procedures.<sup>5,12–15</sup> A 2009 prospective study of 18 patients who underwent glossectomy found that the Harmonic Scalpel reduced operating time by 16 minutes compared with conventional haemostasis.<sup>16</sup> There have been mixed results with regard to its use in reducing post-operative pain and intra-operative and post-operative bleeding in tonsillectomy.

A retrospective review of 316 tonsillectomies by Walker and Syed and a non-randomised prospective review of 156 tonsillectomies by Morgenstein *et al.* both found no advantage of the Harmonic Scalpel compared with the traditional scalpel and cautery in terms of reducing post-operative pain.<sup>17,18</sup> In contrast, a literature review by Wiatrak and Willging found that the Harmonic Scalpel reduced intra-operative blood loss, post-operative blood loss and post-operative pain in tonsillectomy.<sup>14</sup>

In thyroid surgery, several studies show the Harmonic Scalpel to be superior to traditional methods in terms of reducing intra-operative blood loss and operating time.<sup>12,13,19–21</sup> A randomised controlled trial of 60 patients who underwent total thyroidectomy found that

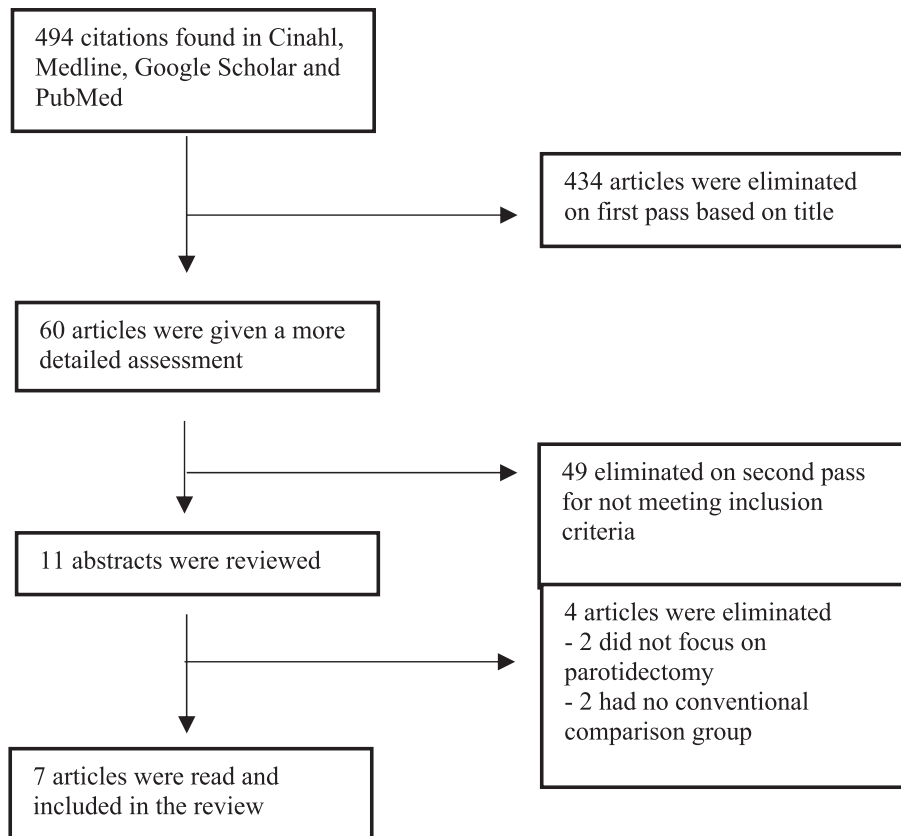


Fig. 1. Diagram showing a systematic review of the literature.

the Harmonic Scalpel reduced operating time by 37 minutes compared with conventional haemostasis, the operating cost of the Harmonic Scalpel was 85 dollars less than conventional haemostasis and the Harmonic Scalpel also reduced post-operative pain.<sup>22</sup>

However, there are few studies that focus specifically on the use of haemostatic devices in parotidectomy. Of these, even fewer have compared the frequency of facial nerve injury during parotidectomy between haemostatic devices and traditional scalpel and cautery. Our objective was to perform a review of the literature and subsequent meta-analysis of studies that have compared these methods in parotidectomy with an emphasis on outcomes of facial nerve injury.

## Materials and methods

A systematic review of the literature was performed. Seven studies were identified that compared the use of haemostatic devices with traditional methods in parotidectomy. Six of the selected studies focused on the use of the Harmonic Scalpel, and one study by Hahn and Sørensen compared the LigaSure small jaws (Covidien) instrument to traditional scalpel and cautery.<sup>8</sup> The purpose of including two distinct but similar devices in our study is to increase our sample size as there are a limited number of studies that specifically focus on parotidectomy.

Demographic data and tumour data were collected where available, as were data for the following outcome measures: temporary facial paresis, operating time, intra-operative blood loss, post-operative drain output and length of hospital stay. A subsequent meta-analysis was performed only for data on superficial parotidectomy.

## Literature review and study selection

An electronic search of the literature was conducted for citations on the use of haemostatic devices in parotidectomy

using the following databases: Google Scholar, PubMed, Cinahl and Medline. Keywords included: parotidectomy, scalpel, facial nerve and injury. Studies reviewed were published no earlier than 2000. This time frame corresponds approximately with the widespread adoption of these devices into surgical practice. Relevant studies were identified and reviewed independently by two reviewers (L Allen and S M Taylor). A total of seven studies were selected for analysis based on the inclusion criteria (Figure 1).

## Inclusion criteria

Studies that met inclusion criteria measured facial nerve outcomes in parotidectomy for haemostatic devices and traditional scalpel and cautery. Other outcome measures, including operating time, intra-operative blood loss, post-operative drain output and length of hospital stay were favourable but not required. All studies included were published in English between 2000 and 2018. Studies excluded were those that did not evaluate facial nerve outcomes or did not compare the use of haemostatic devices to traditional methods.

No inclusion criteria were defined for the type of study (i.e. retrospective or prospective), type of surgery (i.e. partial or total parotidectomy) or the type of surgical pathology (i.e. benign or malignant), although these data were collected where available. Studies must have been published as full reports: conference abstracts and letters to the editor were not included. Four of the studies were non-randomised retrospective reviews, two were non-randomised prospective reviews and one was a randomised prospective review. Exclusion criteria for participants in all except two studies included: prior parotid surgery, concurrent neck surgery and prior facial nerve weakness. The exceptions are the studies by Salami *et al.*,<sup>23</sup> who did not specify prior facial nerve weakness, and Hahn and Sørensen,<sup>8</sup> who did not specify any of the

three criteria but who measured facial nerve function using House–Brackmann grading pre- and post-operatively.

### Analysis

Data for the described outcome measures in total and superficial parotidectomy were compiled using Microsoft Excel® spreadsheet software (version 16.10; Table 1). Analysis was only performed for superficial parotidectomy data. Specifically, a meta-analysis of combinable studies was performed, and heterogeneity was assessed for each outcome. Random effects models, tests of heterogeneity and forest plots were generated.

### Results

Seven studies were included with a total of 675 patients: 372 patients were treated with haemostatic devices, and 303 patients were treated with traditional scalpel and cautery. Mean age ranged from 50.8 to 55 years in the studies that reported mean age, and mean tumour size ranged from 2.2 to 3.2 cm in reporting studies (Table 2). Outcomes with statistical significance for superficial parotidectomy included operating time, intra-operative blood loss and post-operative drain output ( $p < 0.01$  for all three outcomes). Outcome measures that did not favour either treatment included facial nerve paresis and hospital stay (Figures 2–5).

#### Temporary facial paresis

Of the seven studies included in the review, five had separate superficial parotidectomy data for the temporary facial paresis outcome. These studies were combined, and the odds ratio was calculated as the effect size. The heterogeneity was moderate for these data ( $I^2 = 44$  per cent); therefore, a random effects model was used. The odds ratio estimate was 0.40 (95 per cent confidence interval (CI), 0.13 to 1.21), which did not significantly favour either treatment ( $p = 0.11$ ; Figure 2).

#### Operating time

Of the seven studies included in the review, four had separate superficial parotidectomy data for the operating time outcome. These studies were combined, and the mean difference was calculated as the effect size. The heterogeneity was substantial for these data ( $I^2 = 71$  per cent); therefore, a random effects model was used. The mean difference estimate was  $-28.95$  minutes (95 per cent CI,  $-39.04$  to  $-18.86$ ), which significantly favoured treatment using haemostatic devices ( $p < 0.01$ ; Figure 3).

#### Intra-operative blood loss

Of the seven studies included in the review, four had separate superficial parotidectomy data for the intra-operative blood loss outcome. These studies were combined, and the mean difference was calculated as the effect size. The heterogeneity was considerable for these data ( $I^2 = 92$  per cent); therefore, a random effects model was used. The mean difference estimate was  $-38.87$  ml (95 per cent CI,  $-48.54$  to  $-29.20$ ), which significantly favoured treatment using haemostatic devices ( $p < 0.01$ ; Figure 4).

#### Post-operative drain output

Of the seven studies included in the review, three had separate superficial parotidectomy data for the post-operative drain

output outcome. These studies were combined, and the mean difference was calculated as the effect size. The heterogeneity was substantial for these data ( $I^2 = 76$  per cent); therefore, a random effects model was used. The mean difference estimate was  $-25.98$  ml (95 per cent CI,  $-26.33$  to  $-25.64$ ), which significantly favoured treatment using haemostatic devices ( $p < 0.01$ ; Figure 5).

#### Length of hospital stay

Of the seven studies included in the review, two had separate superficial parotidectomy data for the days of hospital stay outcome. These studies were combined, and the mean difference was calculated as the effect size. The heterogeneity was unable to be assessed for this analysis due to all patients in one study having the same length of stay (two days); therefore, a random effects model was used. The mean difference estimate was therefore essentially the mean difference from the Salami *et al.*<sup>23</sup> study which was  $-2.20$  days (95 per cent CI,  $-2.59$  to  $-1.81$ ), which did not significantly favour either treatment ( $p = 0.32$ ; not shown).

Quality of evidence for included studies was evaluated using the Modified Newcastle-Ottawa Quality Assessment Scale for Cohort Studies (Table 3). All studies were of good quality with three to four of four possible stars in the selection domain and one of two possible stars in the comparability domain and two to three of three possible stars in the outcome domain.

### Discussion

Statistically significant outcomes favouring the use of haemostatic devices over traditional methods were intra-operative blood loss, operating time and post-operative drain output. These findings are consistent with current literature supporting the use of haemostatic devices in head and neck surgery. However, our findings specifically address the advantages of these devices in parotidectomy. Interestingly, our results do not show that they are superior to traditional methods in terms of reducing facial nerve injury, but our results do strengthen existing literature that shows haemostatic devices reduce operating time and intra-operative blood loss. From a clinical standpoint, the importance of limiting blood loss intra-operatively is important with regards to facial nerve dissection. That is, visualisation is key for facial nerve preservation. Limiting intra-operative blood loss and improving surgical field visualisation may contribute to a reduction in operating time: two findings that are consistent in the literature. However, further studies are needed to clarify our findings and this correlation.

It is also important to consider the impact of haemostatic devices on operating costs. For example, the Harmonic Scalpel is relatively expensive because of upfront costs and disposability. However, studies have demonstrated greater or comparable cost-effectiveness between the Harmonic Scalpel and conventional instruments used in head and neck surgery because of the reduction in operating time.<sup>16,24–26</sup> Similarly, our analysis shows that haemostatic devices reduce operating time, which may justify their cost. However, this was not an outcome measured in this study, and further research is needed to clarify the cost-effectiveness of these devices in head and neck surgery.

The results of this study demonstrate a benefit for the use of haemostatic devices in terms of reducing post-operative drain output but not for reducing length of hospital stay. To our

**Table 1.** Literature comparing outcomes in parotidectomy

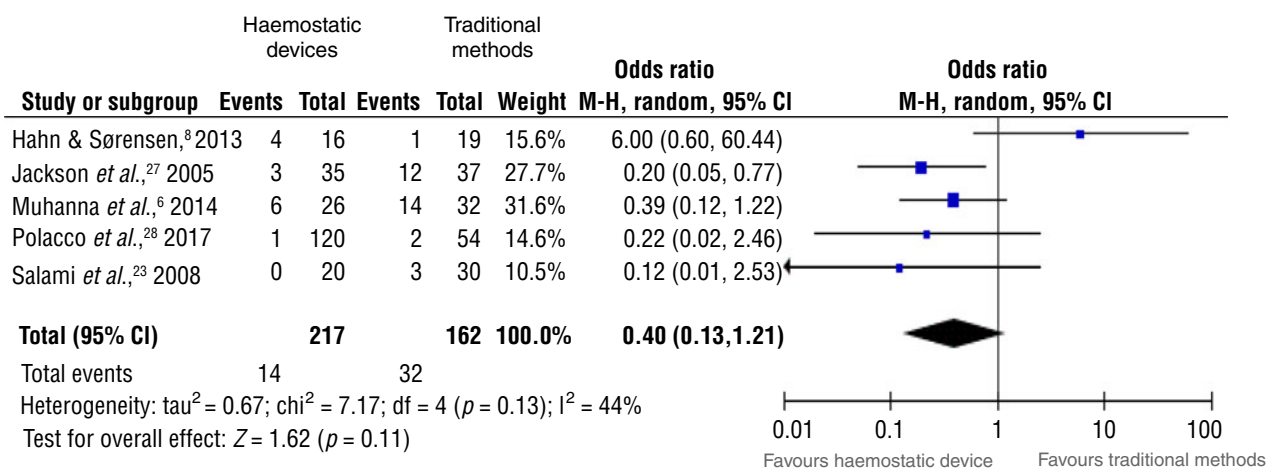
Surgery	Study design	Instrument	Patients ( <i>n</i> )	Temporary paresis (%)	Operating room length (minutes ± SD)	Drain output (ml ± SD)	Blood loss (ml ± SD)	Hospitalisation (days ± SD)
Superficial parotid								
– Hahn & Sørensen, <sup>8</sup> 2013	NRPS	HD	16	4 (25)	128 ± 44	–	40 ± 22	2.0 ± 0
		SC	19	1 (5)	155 ± 26	–	115 ± 34	2.0 ± 0
– Jackson <i>et al.</i> , <sup>27</sup> 2005	NRRR	HD	35	3 (9)	–	–	38 ± 4	–
		SC	37	12 (32)	–	–	68 ± 12	–
– Muhanna <i>et al.</i> , <sup>6</sup> 2014	NRRR	HD	26	6 (23)	137 ± 19	74 ± 38	–	–
		SC	32	14 (59)	163 ± 22	68 ± 22	–	–
– Polacco <i>et al.</i> , <sup>28</sup> 2017	NRRR	HD	120	1 (1)	216 ± 42	24 ± 15	28 ± 19	–
		SC	54	2 (4)	234 ± 54	43 ± 36	76 ± 52	–
– Salami <i>et al.</i> , <sup>23</sup> 2008	NRPS	HD	20	0 (0)	157 ± 1	46 ± 1	38 ± 1	5.1 ± 0.4
		SC	20	3 (15)	195 ± 1	72 ± 1	64 ± 1	7.3 ± 0.8
Total parotid								
– Polacco <i>et al.</i> , <sup>28</sup> 2017	NRRR	HD	59	1 (2)	240 ± 42	35 ± 30	38 ± 21	–
		SC	22	1 (5)	288 ± 78	33 ± 20	85 ± 55	–
Superficial and total parotid								
– Deganello <i>et al.</i> , <sup>21</sup> 2014	RPS	HD	43	7 (16)	147 ± 40	69 ± 52	–	3.9 ± 1.2
		SC	65	26 (40)	152 ± 54	78 ± 81	–	4.7 ± 1.4
– Jackson <i>et al.</i> , <sup>27</sup> 2005	NRRR	HD	44	8 (18)	184 ± 58	48 ± 36	38 ± 4	–
		SC	41	13 (32)	201 ± 41	48 ± 22	66 ± 11	–
– Polacco <i>et al.</i> , <sup>28</sup> 2017	NRRR	HD	179	2 (1)	–	–	–	–
		SC	76	3 (4)	–	–	–	–
– Yang <i>et al.</i> , <sup>29</sup> 2017	NRRR	HD	44	2 (5)	65 ± 17	62 ± 32	35 ± 9	3.8 ± 1.1
		SC	50	5 (10)	89 ± 20	89 ± 51	55 ± 10	4.7 ± 1.2

SD = standard deviation; NRPS = non-randomised prospective review; HD = haemostatic device; SC = scalpel and cautery; NRRR = non-randomised retrospective review; RPS = randomised prospective study

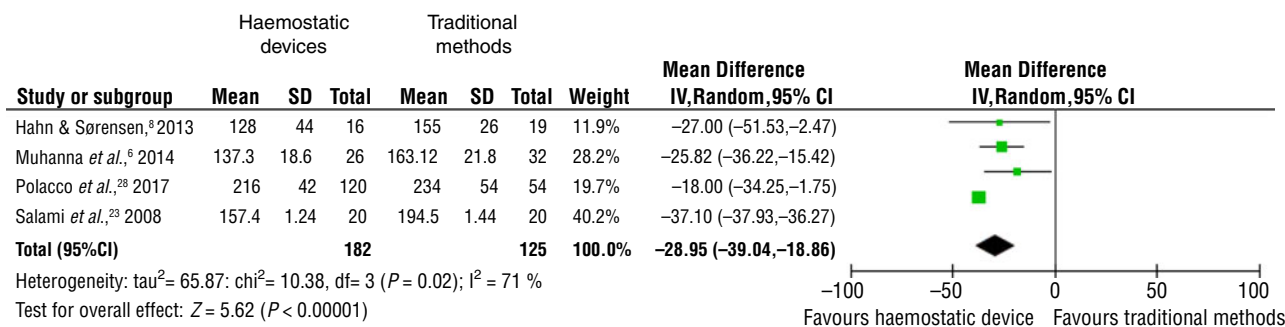
**Table 2.** Patient characteristics

Study	Haemostatic devices (n)		Traditional methods (n)		Age (mean (range; years))	Mean tumour size (cm)	
	Male	Female	Male	Female		HD	SC
Deganello et al., <sup>21</sup> 2014	20	23	29	36	55 (4–48)	2.8 ± 1.1	2.9 ± 1.3
Hahn & Sørensen, <sup>8</sup> 2013	6	10	12	7	55 (28–85)	2.2 (1.5–3.4)	2.2 (1.7–2.6)
Jackson et al., <sup>27</sup> 2005	21	23	32	9	50.8 (15–82)	3.0 (1.5–7)	3.2 (1–7)
Muhanna, <sup>6</sup> 2014	12	14	15	17	53.6 (19–79)	–	–
Polacco, <sup>28</sup> 2017	87	92	34	42	–	–	–
Salami et al., <sup>23</sup> 2008	–	–	–	–	–	–	–
Yang 2017 <sup>29</sup>	21	23	24	26	–	2.9 ± 1.2	2.8 ± 1.1

HD = haemostatic device; SC = scalpel and cautery



**Fig. 2.** Forest plot of the odds ratio of temporary facial paresis after superficial parotid surgery using haemostatic devices versus traditional methods. Calculated using a random effects model. The size of the square represents the weight of the study with larger squares representing the studies with greater precision. The centre of the diamond represents the estimated effect size and direction of the effect, and the ends of the diamond represent the confidence interval. M-H = Mantel–Haenszel; CI = confidence interval



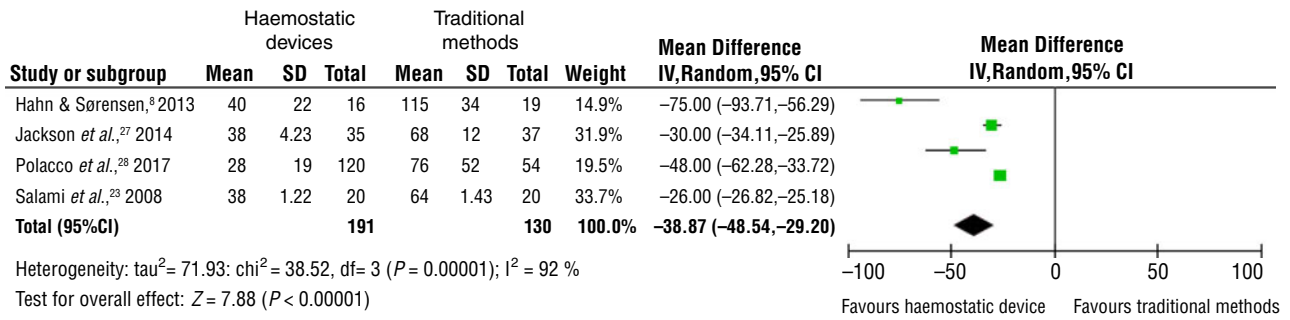
**Fig. 3.** Forest plot of the mean difference of operating time for superficial parotidectomy surgery between haemostatic devices versus traditional methods. Calculated using a random effects model. The size of the square represents the weight of the study with larger squares representing the studies with greater precision. The centre of the diamond represents the estimated effect size and direction of the effect, and the ends of the diamond represent the confidence interval. SD = standard deviation; IV = inverse variance; CI = confidence interval

knowledge, this is the largest meta-analysis to date that measures these outcomes in parotidectomy. We plan to add significant data to the literature in the near future as the senior author (S M Taylor) has performed over 50 superficial parotidectomy procedures with the Harmonic Scalpel without the use of a post-operative drain. All patients had combined sternocleidomastoid flaps with pressure dressings, and all

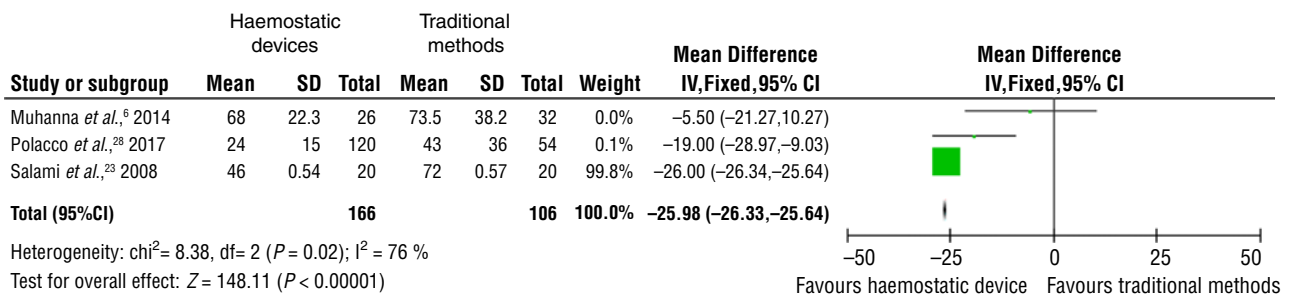
patients with one exception were discharged home the day following surgery.

**Study limitations**

None of the studies used for meta-analysis were randomised controlled trials. Care was taken to ensure comparability of



**Fig. 4.** Forest plot of the mean difference of intraoperative blood loss during superficial parotidectomy surgery between haemostatic devices versus traditional methods. Calculated using a random effects model. The size of the square represents the weight of the study with larger squares representing the studies with greater precision. The centre of the diamond represents the estimated effect size and direction of the effect, and the ends of the diamond represent the confidence interval. SD = standard deviation; IV = inverse variance; CI = confidence interval



**Fig. 5.** Forest plot of the mean difference of post-operative drain output (millilitres) following superficial parotidectomy surgery between haemostatic devices versus traditional methods. Calculated using a random effects model. The size of the square represents the weight of the study with larger squares representing the studies with greater precision. The centre of the diamond represents the estimated effect size and direction of the effect, and the ends of the diamond represent the confidence interval. SD = standard deviation; IV = inverse variance; CI = confidence interval

**Table 3.** Modified Newcastle-Ottawa quality assessment scale for cohort studies: evaluation of included studies

Study	Selection ****	Comparability **	Outcome ***	Total *****
Deganello <i>et al.</i> <sup>21</sup>	****	*	***	*****
Hahn & Sørensen <sup>8</sup>	****	*	***	*****
Jackson <i>et al.</i> <sup>27</sup>	****	*	**	*****
Muhanna <i>et al.</i> <sup>6</sup>	****	*	**	*****
Polacco <i>et al.</i> <sup>28</sup>	****	*	***	*****
Salami <i>et al.</i> <sup>23</sup>	***	*	**	*****
Yang <i>et al.</i> <sup>29</sup>	****	*	***	*****

\*Number of points per article in reference to the total points possible per category as indicated in each column title

the data being combined. However, given the small number of studies included and the amount of heterogeneity, especially where the I<sup>2</sup> value was greater than 60 per cent, these estimates should be interpreted with caution.

Although our results did not clearly lend favour to the use of haemostatic devices for facial nerve preservation, vigilance should be taken when interpreting our results because of bias toward publishing in support of haemostatic devices. This bias may be present in the existing literature and could be due to surgeons' preference for a particular operative method or device, which may therefore influence this analysis. Our results do highlight the need for further research to more clearly define the role of haemostatic devices in facial nerve preservation.

**Conclusion**

The use of the Harmonic Scalpel and LigaSure small jaws, when compared with traditional instruments, likely play a

role in reducing operating time and intra-operative blood loss in parotidectomy, but they do not appear to impact frequency of facial nerve injury. Another advantage may be reducing post-operative drain output. The impact of these devices on cost effectiveness in parotidectomy remains unclear.

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**Competing interests.** None declared

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