



# Partial Removal of the Submaxillary Gland for Aesthetic Indications: A Systematic Review and Critical Analysis of the Evidence

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## Abstract

**Background** Neck aesthetics is an essential feature for a youthful attractive appearance. Deep neck surgery involving partial resection of the submandibular gland (SMG) has been a controversial issue in aesthetic surgery given its challenging technique and potential risks. The aim of this review is to evaluate the safety and efficacy of partial SMG resection in patients undergoing aesthetic neck surgery.

**Methods** We undertook a systematic review of the literature and analysis of studies reporting surgical outcomes and complications of partial SMG resection from Medline, Cochrane and Google Scholar databases from 1950 to March 30, 2019. Two independent reviewers conducted titles and abstracts screening and data extraction. Data were analyzed using mixed methods appraisal tool and a clinical impact score.

**Results** Six studies including 602 patients who underwent 1200 partial SMG resections were included. All studies reported aesthetic improvement according to Ellenbogen aesthetic neck ideals. Hematoma related to partial SMG resection was encountered in one case (0.08%), hematoma related to cervicofacial skin flap was encountered in 26 cases (1.4%), sialoceles happened in 16 cases (1.3%), transient marginal mandibular nerve weakness occurred in

86 cases (4.7%). No mortalities, permanent motor nerve damage or dry mouth were reported. The clinical impact score was positive for five out of the six reports.

**Conclusion** Partial SMG resection in patients undergoing aesthetic neck surgery may represent an effective procedure to enhance neck aesthetics and is associated with minor, self-limiting complications. Future controlled studies with prospective evaluation of aesthetic outcome and patient-reported outcome measures are needed.

**Level of Evidence III** This journal requires that authors assign a level of evidence to each article. For a full description of these Evidence-Based Medicine ratings, please refer to the Table of Contents or the online Instructions to Authors [www.springer.com/00266](http://www.springer.com/00266).

**Keywords** Submandibular gland · Facelift · Necklift · Facial rejuvenation · Neck rejuvenation · Limited scar facelift

## Introduction

A body of opinion led by Bruce Connell advocated contouring deep subplatysmal structures for aesthetic purpose [1–16]. Among the proposed procedures, partial resection of the hypertrophic submandibular gland (SMG) was probably the most controversial topic [17, 18]. Concerns about difficulty to control major bleeding from distant submental access were raised: The aesthetic outcome VS potential risks were pointed out with calls to abandon the procedure [17].

The aim of this study was to systematically review the literature to determine risks specifically related to aesthetic SMG partial resection.

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## Materials and Methods

### Literature Search

We conducted a systematic search on Medline, Cochrane and Google Scholar databases between 1950 and 2019. Results were limited to human studies in the English language reporting on submandibular gland resection for aesthetic indications and clearly documenting aesthetic benefit outcome (patient or physician reported) and complications. The following search strategy was applied:

((("submandibular gland"[MeSH Terms] OR ("submandibular"[All Fields] AND "gland"[All Fields]) OR "submandibular gland"[All Fields]) OR submental[All Fields]) OR cervicomental[All Fields]) AND ((((((("rejuvenation"[MeSH Terms] OR "rejuvenation"[All Fields]) OR ("esthetics"[MeSH Terms] OR "esthetics"[All Fields] OR "aesthetic"[All Fields])) OR ("cosmetics"[Pharmacological Action] OR "cosmetics"[MeSH Terms] OR "cosmetics"[All Fields] OR "cosmetic"[All Fields])) OR ("lifting"[MeSH Terms] OR "lifting"[All Fields])) OR contouring[All Fields]) OR ("surgery, plastic"[MeSH Terms] OR ("surgery"[All Fields] AND "plastic"[All Fields]) OR "plastic surgery"[All Fields] OR ("plastic"[All Fields] AND "surgery"[All Fields]))) AND "humans"[MeSH Terms]).

### Inclusion Criteria

All relevant articles in which study participants underwent partial SMG resection for aesthetic purposes were reviewed. We included prospective and retrospective observational studies, case series and case reports that included the technique, aesthetic advantage and complications for the entire cohort.

### Exclusion Criteria

We excluded articles not reporting sample size, SMG resection for indications other than aesthetic (sialolithiasis, tumors, etc.), SMG resection not reporting surgical technique, not accounting for all complications, face neck lift articles without SMG resection and cadaveric studies.

### Data Collection

Two independent reviewers (FB and IAK) read the titles and abstracts of retrieved articles. The full text was then retrieved. The following data points were recorded: author(s), year of publication, incision approach, SMG

resection technique, benefit outcome and complications including hematoma (secondary to SMG partial resection or to the face–neck flap dissection), sialoma, transient or permanent marginal mandibular nerve (MMN) injury and dry mouth.

### Data Analysis

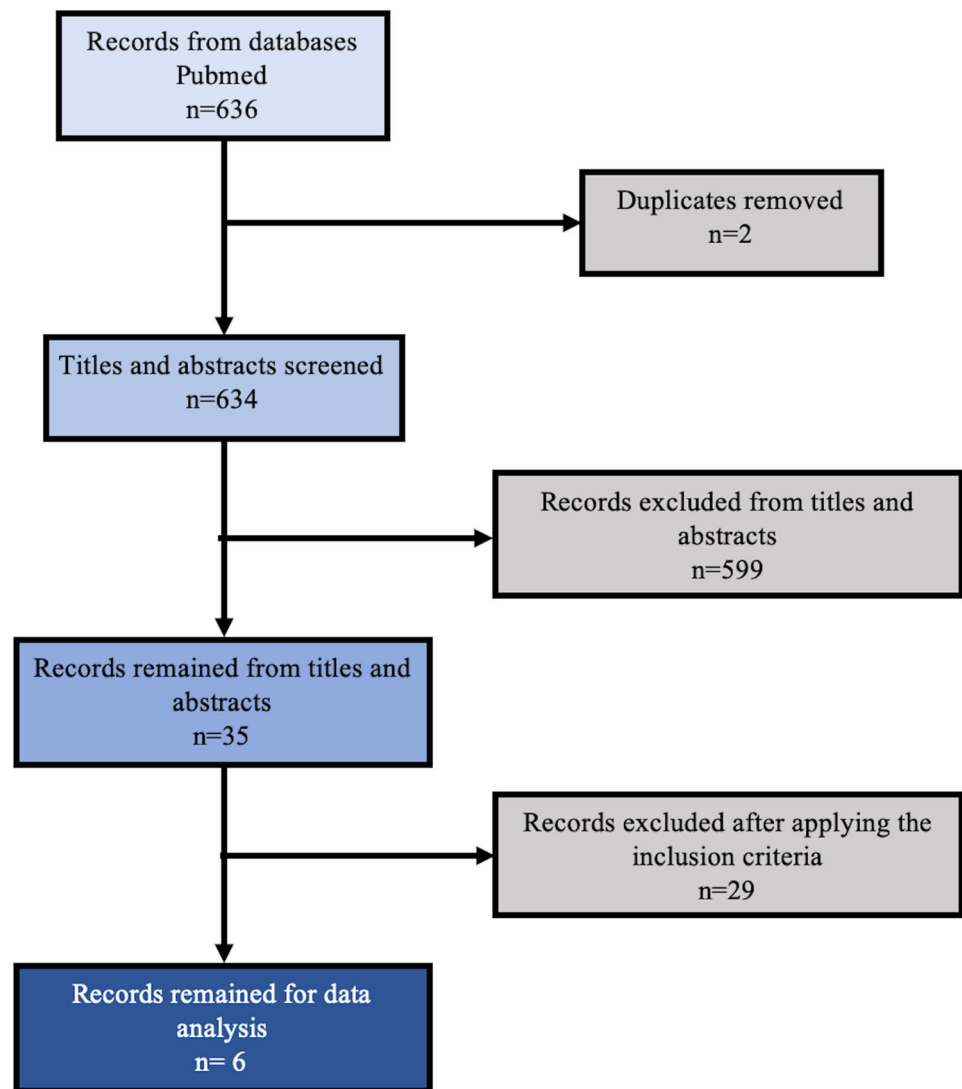
The quality of papers was appraised using the hierarchy of Centre for Evidence-Based Medicine [19] and the Mixed Methods Appraisal Tool [20]. Paper selection flowchart is depicted in Fig. 1. Data from the selected studies were extracted and tabulated according to the criteria mentioned above. Included studies were rated according to a clinical impact (CI) score (Table 1), which consisted of seven components with varying weighting. The papers were finally classified in a simple traffic light system of three levels to reflect high (green), moderate (yellow) and low (red) clinical impact.

A positive point was awarded for level of evidence of IV and above and another point for confirmation of efficacy by either patients or surgeons. A minus point was awarded for each major complication, i.e., hematoma, sialoma, permanent marginal mandibular nerve injury or permanent dry mouth. Mortality was awarded three negative points. The articles were then assigned a composite score and a color code: Red for scores of – 6 to – 1 indicates a risky procedure with no clear benefit. Amber indicates a score of 0 for procedures with no risk and questionable benefit. Green indicates a score of 1–2 for procedures that have a positive benefit/risk ratio.

## Results

The search strategy yielded a total of 636 articles. After removal of duplicates and screening the titles and abstracts, a total of 35 articles were found in the initial search. After applying the inclusion and exclusion criteria, a total of six eligible reports were identified [6, 18, 21–24] (Fig. 1). Full texts were obtained and clinical data were tabulated accordingly (Table 2).

The studies reported covered the period from 1991 to 2019 and included a total of 1200 glands resected in 602 patients. Five of the six articles reported the SMG partial resection group within a wider group of aesthetic face and neck lift where the SMG was not resected. This served as a quasi-control group when complications were reported separately. A total number of 1814 of patients were included in this wider group.

**Fig. 1** SMG partial resection systematic review paper selection flowchart**Table 1** Clinical Impact Score (CI)

	Criteria of clinical impact score	Weighting
Quality of recommendation	LOE	1
Aesthetic outcome	Efficacy—clinician or patient assessment	1
Safety of procedure	Hematoma	− 1
	Sialoma	− 1
	Permanent facial nerve injury	− 1
	Permanent dry mouth	− 1
	Mortality	− 3

Scoring metrics: For each identified study, an overall clinical impact score can be calculated based on weighted grades of a few criteria for each relevant domain. The score is composed of the sum of grades. One positive point was awarded for level of evidence of IV and above and another point for confirmation of efficacy by either patients or surgeons. A minus point was awarded for each major complication, i.e., hematoma, sialoma, permanent marginal mandibular nerve injury or permanent dry mouth. Mortality was awarded three negative points. The articles were then assigned a composite score and a color code: red for scores of − 6 to − 1 indicates a risky procedure with no clear benefit. Amber indicates a score of 0 for procedures with no risk and questionable benefit. Green indicates a score of 1–2 for procedures that have a positive benefit/risk ratio

**Table 2** Clinical data from the selected articles

Author	Year of publication	Period	Cases with SMG partial resection	Total cases with face/neck lift	Number of individual SMG resected	TECHNIQUE	LOE	Hematoma related SMG Study Group	Hematoma related to lift subcutaneous flaps	Complications comments	Sialocele	MMNT	MMNP	DRY MOUTH	Score
De Pina 6	1991		8		12	Direct submandibular access(transcutaneous or transplatysma incision after skin elevation)	IV	0	0	No fistula formation or any other complication encountered	0	0	0	0	2
Bravo 21	2013		21	27	42	SM approach	IV	0	0	no hematoma encountered	2	0	0	0	1
Feldman 22	2014	2004 2013	129	522	258	SM approach	IV	0	14	0% from SMG resection 14(2,7%) from lift	1	50	0	0	1
Auersvald 23	2014	2011 2014	240	240	480	SM approach	IV	0	2	The majority of hematoma and sialoma cases were encountered in the first 25 cases performed without haemostatic net	6	3	0	0	1
Mendelson 18	2015	2002 2013	112	736	224	SM approach identification and ligation of central artery	IV	1	1	life threatening (8th case in the serie) : pulsatil bleeding from central artery	5	5	0	0	0
Auersvald 24	2016	2011 2015	92	289	184	SM approach	IV	0	9	215 cases reported in earlier publication were excluded	2	28	0	0	1
TOTAL			602	1814	1200	-		1 (0.08%)	26 (1.4%)	-	16 (1.3%)	86 (4.7%)	0%	0%	

Included studies were rated according to a clinical impact score and classified in a simple traffic light system of three levels to reflect high (green), moderate (yellow) and low (red) clinical impact

## Surgical Technique

One out of the six studies used a direct approach either transcutaneous or transplatysmal incision after lateral skin elevation and an extracapsular dissection of the gland [6]. All other five reports used a submental route, medial subplatysmal dissection and intracapsular dissection [18, 21–24].

## Assessment of Aesthetic Benefit

Two studies used Ellenbogen's criteria of a youthful neck [18, 24]. These include distinct submandibular border, subhyoid depression, visible thyroid cartilage bulge, visible anterior SCM border, cervico-mental angle of 120°–150° and submental-SCM angle 90° [2]. Two studies referenced elements of Ellenbogen's criteria, namely the importance of the delineation of the mandible and cervico-mandibular angles in their assessment [6, 21]. The other two utilized a more global aesthetic assessment of the neck contour and its durability as a goal for neck rejuvenation [22, 23]. No study used patient-reported outcome measures to evaluate the aesthetic outcome.

## Complications

### Hematoma

In all six studies, hematoma specific to the SMG partial resection cases were referred to specifically. One study reported a single incident of SMG resection-related hematoma giving an overall incidence of 0.08%. This case was the sole reported life-threatening hematoma [18]. Five out of the six studies reported cervicofacial flap-related hematoma occurring in 26 patients giving an overall incidence of 1.4% [18, 21–24].

### Sialocele

Five out of six cases reported sialoma as a complication occurring in a total of 16 cases (1.3%) [18, 21–24]. In one of the six studies, the author reported two sialomas in 21 patients (10%) who underwent partial SMSG resection [21]. This was the highest rate of saliva leakage reported. Both were successfully treated with transcutaneous drainage.

### Marginal Mandibular Nerve Injury

Four studies reported transient MMN injuries in 86 patients giving a total incidence of 4.7%, the largest complication encountered [18, 22–24]. These resolved between 72 h and

8 months. There were no cases of permanent MMN injuries.

### *Dry Mouth*

None of the studies reported permanent dry mouth occurring as a result of SMG resection.

### **Clinical Impact Score**

Five out of the six reports had a high clinical impact score of SMG resection, and one had intermediate scores.

## **Discussion**

### **Surgical Technique**

The first description of partial SMG resection for aesthetic indication was performed through a direct submandibular access either transcutaneous or transplatysmal after lateral skin elevation [6]. SMG dissection was performed through the extracapsular plane. Such visible incision is no longer acceptable [18, 25], and most surgeons use the submental



**Fig. 2** 3D “frozen” photograph (clay) representing a youthful attractive standard of mandibular–neck interface. It exhibits the first Ellenbogen’s visual criteria: The distinct inferior mandibular border, which translates visually in a smooth continuous shadow that stretches below the full length of the mandible from the chin to the mandibular angle

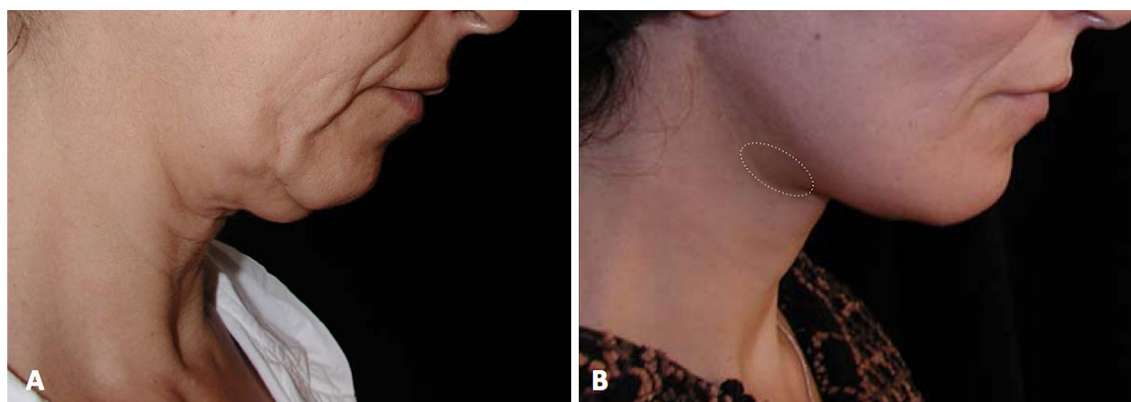
approach along with an intracapsular dissection of the gland [18, 21–24].

### **Assessment of Aesthetic Outcome**

Aesthetic outcome after SMG partial resection has been criticized [17]. Sharp mandibular angle and submandibular hollowing are negative outcomes that may occur after aggressive cervical surgery. These complications may also arise from an ill-conceived surgical planning where the goal is to accomplish a “slightly concave” submental area [11]. This highlights the need for objectivity in aesthetic results’ assessment. An ideal standard against which results may be judged and compared seems to be essential [26–29]. Ellenbogen described the ideal neck in six visual criteria [2], among which, a distinct inferior mandibular border appears to be the most important. It translates visually in a smooth continuous shadow that stretches below the full length of the mandible from the chin to the mandibular angle (Fig. 2).

Bravo divided the submandibular shadow in three zones [30]. This subdivision has the merit to link each zone to the anatomical structures susceptible to disrupt the continuity of submandibular shadow and to address those structures specifically. For instance, submandibular shadow under the body of the mandible (Bravo’s Zone II) may be disrupted by two structures: the jowl and the SMG. The former may be addressed by direct excision, liposuction or SMAS lateral re-suspension. Enlarged SMG may benefit from cervical platysma tightening [31, 32] or basket gland suspension [33] when the gland is ptotic and/or moderately hypertrophic.

However, larger hypertrophic glands pose a different challenge: The spatial location of a firm-uncompressible gland between the strong-thick mylohyoid muscle superiorly and the weaker often attenuated-degenerative platysma muscle inferiorly [34] does not allow to relocate permanently the gland under the mandibular border: The balance of forces clearly favors the mylohyoid muscle. The results of SMAS suspension and platysma plication are ephemeral, lasting for only a few months [33] even when deep platysma muscle dissection is performed and traction sutures are applied medially at the level of the SMG [35, 36]. Partial surgical resection of the segment of the gland that cannot be permanently confined under the mandible seems to be the only solution, restoring submandibular shadow continuity, hence improving jawline distinctiveness and definition. Therefore, in the process of comparing postoperative results to the ideal standard, any remaining deviations from that ideal can be pointed out. Suboptimal partial glandular resection may result in a remaining cervical bulging and translates visually as an interruption of submandibular shadow continuity in



**Fig. 3** **a** Pre-op photograph of a 60-YO patient prior to neck lift comprising subplatysma fat contouring and partial SMG resection, **b** 9 months post-op photograph shows a substantial improvement. However, in order to be a purist in relation to Ellenbogen's visual criteria, a slight cervical bulging persists (dotted oval) under the body

of the mandible secondary to suboptimal partial glandular resection. It translates visually as an interruption of submandibular shadow continuity in Bravo's zone II. It may eventually be corrected by further resecting the disrupting segment of the gland. An over-resection of the SMG may result in an abnormally large concavity under the body of the mandible and translates visually as an exaggerated submandibular hollowing in zone II. It may eventually be corrected by microfat grafting in the concave area, restoring submandibular softness. This could be easily performed in the pre-platysmal plane to avoid bringing the cannula in close intimacy to the vascular network surrounding the remaining gland (Fig. 4).

The question as to the relevance of the evaluation of neck aesthetic by having the patient gaze downward has been raised [17]. The aesthetic assessment of the neck in the sole neutral position seems to be inadequate. A patient does not undergo surgery so that her/his appearance improves in a limited number of postures and positions. The primary criteria of face-neck interface's aesthetic, i.e., the smooth continuous shadow stretching below the full length of the mandible from chin to mandibular angle may better be evaluated in all normal postures of everyday life, and downward head flexion (Connell's view) is one among them (Fig. 5). We strongly believe that face-neck aesthetic assessment should be evaluated in all possible views. Photographic documentation in upward view of the patient's neck and dynamic-video evaluations recently introduced by Auersvald and Auersvald [37] seem to bring more accuracy to aesthetic evaluation of the head and neck (Fig. 5).

Finally, it was noted that none of the reports included a validated patient-reported outcome measure (PROM) to appraise the aesthetic outcome. PROMs are an essential component of modern evidence-based medicine that is particularly lacking in aesthetic practice [38].

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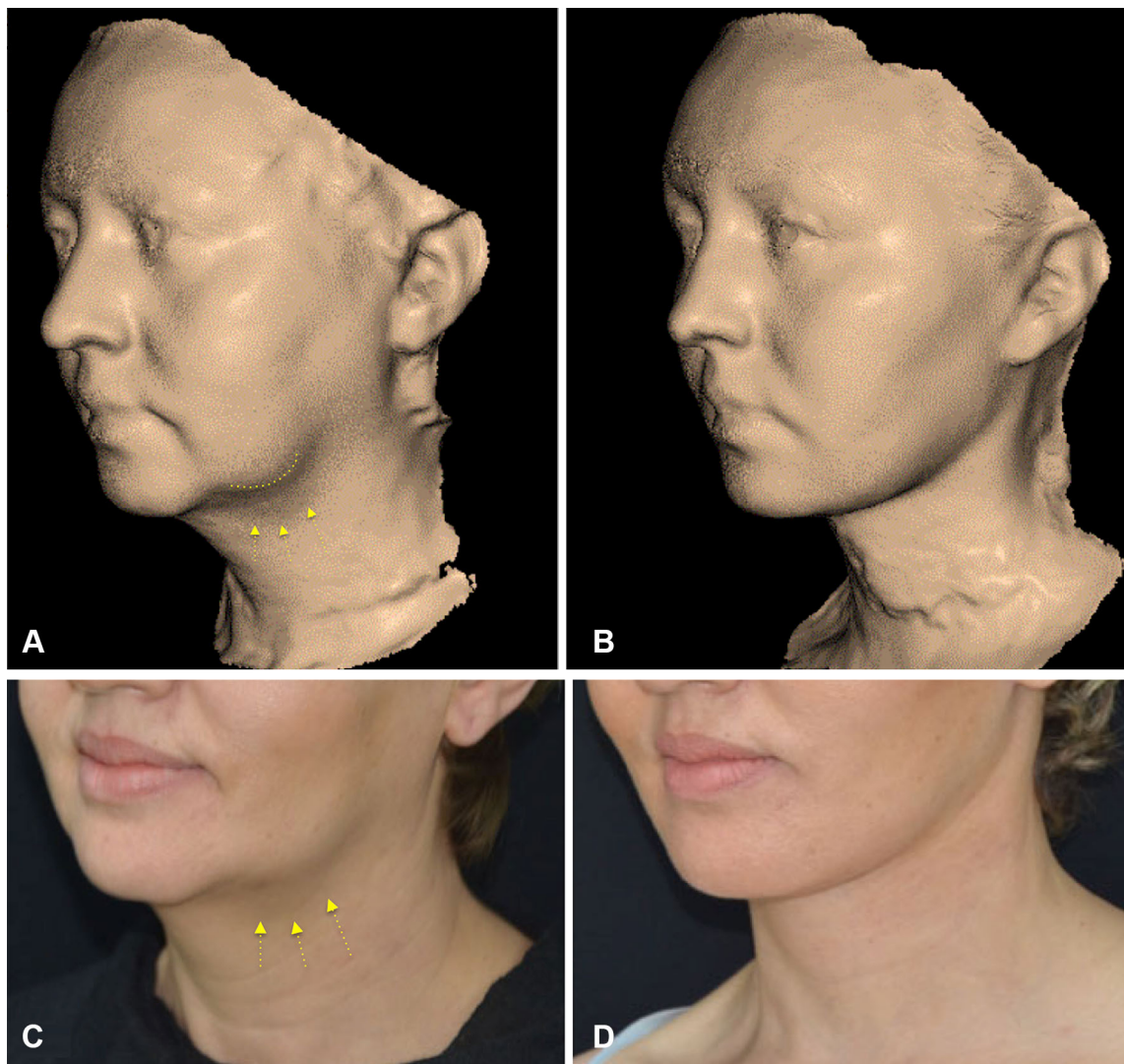
## Complications

### Hematoma

SMG surgery through the submental incision is challenging. It may be one of the reasons why authors who pioneered this technique emphasized the importance of being "highly trained and very experienced" to perform such an advanced procedure [4, 5, 12]. These warnings may have been a disincentive factor for unprepared surgeons to perform SMG resection which may explain a surprisingly low complication rate despite the difficulty of the procedure as well as a limited number of published case series: Only 602 patients were included in this review since its description in 1991.

SMG resection was criticized for both safety and poor aesthetic outcome. A concern to control robust hemorrhage from the limited and distant submental access to the gland was pointed out [17]. Significant variations of glandular blood supply and vein diameters exist, and their three-dimensional relationships have been recently documented by O'Daniel [39]. These should be well understood by surgeons before engaging in such an advanced procedure. A single case of life-threatening hematoma related to SMG partial resection was reported [18]. It happened at the beginning of the authors' experience: the 8th of 112 consecutive patients. No further case of major postoperative bleeding was reported in their series.

To reduce the risk of such a potentially life-threatening bleeding, Feldman described a tactic "to maintain control at all time" during partial gland resection [22]. It consists of inserting a transcutaneous traction suture in the caudal aspect of the SMG. The assistant pulls the external suture inferiorly, which exerts an inferior traction on the gland. This maneuver allows the surgeon to free one hand. In his



**Fig. 4** Same patient as Fig. 2. **a** 3D “frozen” photograph (clay) of a 50-YO patient. She doesn’t present the youthful-attractive head/neck separation. Submandibular shadow is limited to the submental area and continues laterally around the jowl in a broken-chaotic fashion. Dotted curve underlines the jowling; arrows point to the SMG component of bulging under the body of the mandible (Bravo’s zone II). **b** Seven months post-op photograph displays a clear separation at the head/neck interface. A distinct submandibular border is

identifiable, which translates visually in a smooth continuous shadow below the full length of the mandible from the chin to the mandibular angle. **c** Pre-op 2D photograph of the same patient. Arrows point to the SMG component of bulging under the body of the mandible (Bravo’s zone II). **d** Seven months post-op two-dimensional photograph of the same patient. Surgical procedure performed by Fahd Benslimane, Casablanca, Morocco

series of 129 patients, hematomas, which occurred on 14 patients (2.7%) and needed surgical evacuation, were all related to the wide cervical subcutaneous dissection. No deep hematoma related to gland resection causing postoperative airway problems was reported.

Auersvald and Auersvald described an innovative technique to avoid blood accumulation in the subplatysmal space after SMG partial resection [23]. It consists of a quilting suture leaning and sealing the platysma against the remaining SMG and the mylohyoid muscle with the aim to obliterate the dead space and avoid hematoma. This led to elimination of major cervicofacial hematoma and SMG

resection-related hematoma in 711 cases operated on since their introduction of the hemostatic net into their practice [37].

#### *Sialoma*

Glandular postoperative leakage after partial resection has been encountered in five out of the six reports. In all cases, the leak was amenable to conservative management. Auersvald and Auersvald proposed that salivary leakage might benefit from the same hemostatic quilting suture by forcing the SMG secretions to drain inside the mouth as



**Fig. 5** **a** Pre-op of a 62 YO patient. The side view photograph does not exhibit the traditional youthful-attractive face/neck separation. The cervical cylinder presents a widening in its upper portion. The short submandibular shadow is limited to the submental area, interrupting its course at the anterior aspect of the jawl. Arrows point to the SMG component of bulging under the body of the mandible (Bravo's zone II). **b** Nine months post-op photograph exhibits a clear separation at the head/neck interface. The upper cervical cylinder has been narrowed resulting in an elongated neck and a more acute cervico-mandibular angle. The submandibular shadow has been elongated, stretching beyond the cervico-mandibular angle. However, in order to be purist in relation to Ellenbogen's visual criteria, the submandibular shadow is not smooth: The submental area exhibits irregularities, calling for further evaluations in other postures. **c** Pre-op Connell's view exhibits an anterior fall of cervical tissues, a full/wide cervical cylinder in its upper portion and an obtuse cervico-mandibular (CM) angle, a chaotic/short submandibular shadow and two additional major cervical horizontal lines in the lower neck along with other minor lines. **d** Post-op Connell's view exhibits a narrowing of the upper cervical cylinder, an acute CM angle, an elongated submandibular shadow stretching from chin to the mandibular angle with no additional cervical lines. However, submandibular shadow is not "perfectly smooth," exhibiting a "two-level" shadow at the transition submental/intracervical shadow, calling for further evaluations in other postures. **e** Pre-op Auersvald's view exhibits a marked submental crease which extend laterally in the lower face, multiple chaotic vertical/oblique lines intersecting with horizontal lines at the lower third of the neck and multiple chaotic horizontal lines at the lower neck along with multiple small-fine rhythides. (Black ovals indicate SMG bulging location.) **f** Post-op Auersvald's view exhibits disappearance of the submental crease, the vertical/oblique lines and horizontal lines at the lower neck. There is a substantial improvement of the small-fine rhythides in lower neck and in skin quality. The upward Auersvald's view presents the advantage of examining and assessing the under-jaw aesthetic and submental scar quality. In this case, the lack of smoothness observed in both side and Connell's view can be better appreciated and related to poor skin elasticity and poor submental scar quality. Scar revision is indicated for further improvement. **g, h** Understanding how central cervical skin migrates superiorly and posteriorly "inside" the newly created central neck (Connell's concept) and not laterally although lateral traction and skin resection were performed. The lower cervical moles at the level of superior cervical line (white circles) indicate that migration didn't occur laterally as their post-op position didn't change in the sagittal plane in relation to upper mole 1 (at the level of submental crease) and upper mole 2 lateral to the naso-labial fold (black circles). Surgical procedure performed by Fahd Benslimane, Casablanca, Morocco

saliva drains by a pressure gradient [23]. This may in turn explain the very low postoperative sialoma rate in the largest reported series of this review: only two patients out of 307 (0.7%).

#### *MMN Motor Injury*

The largest encountered complication was MMN transient weakness occurring in 4.7% of the cases [18, 21–23]. It was not possible to delineate if this was related to SMG resection or to the technique or extent of the cervicofacial flap elevation in all reports. That said, the injury resolved in



all cases between 72 h and 8 months. There were no cases of permanent MMN injuries.

### *Dry Mouth*

Concerns have been raised about the importance of salivary secretion from the SMG. However, there was no case of permanent dry mouth occurring as a result of SMG partial resection.

### **Clinical Impact Score**

Applying evidence-based medicine to aesthetic surgery is challenging [40]. High-level evidence articles related to the question of this systematic review were lacking. Accordingly, meta-analysis was not possible to perform due to the heterogeneity of identified reports. We attempted a synthesis of the collected data to assess their potential applications in daily-informed decision-making and clinical usefulness. A clinical impact score was designed based on relevant criteria: the quality of recommendation and relevant clinical outcome (Table 1). The score consisted of components with varying weighting: level of evidence (LOE), MMAT score, clinician-directed efficacy (aesthetic outcome confirmation) and safety (reported complications).

The interpretation of the CI score was partitioned into three levels to reflect high (score > 0)—green, moderate (score of 0)—yellow and low (score < 0)—red clinical impact. A high score would correlate the study's quality, outcomes and safety's characteristics with decision-making. A low score would indicate study's weaknesses and doubtful clinical impact. This is an indicative reference guide based on current knowledge, but further high-quality studies should be performed to produce stronger evidence and clear guidelines.

### **Need of Large Series**

The importance for reporting large consecutive case series, standardized surgical technique and accurate data was stressed [17]. When these reservations were made, de Pina and Quintas [6] would have published their series of eight cases. This systematic review reports a total of 602 verified cases available in the literature to this date. Thoughtful tactics such as external suture traction have been described to control the surgical field during glandular resection [22]. The innovative hemostatic net applied to the remaining SMG and surrounding space also seems to be effective [23].

The results from this systematic review seem to indicate no justification for abandoning the procedure in patients who would benefit from it: five out of six reports had a favorable clinical impact outcome of SMG resection. There

were no fatalities in any of the reported series. Transient sialocele and marginal mandibular nerve injury where self-limiting. They must be disclosed in patients' informed consent. A single life-threatening bleed from SMG partial resection was reported. The hemostatic net which consists in platysma suture quilting against the remaining gland and mylohyoid muscle to seal the dead space seems to be a promising technique as the authors didn't report any major hematoma from gland resection in the largest series of SMG resection [24]. Higher-level evidence is still pending for further safety assessment and wider acceptance of the procedure.

### **Conclusion**

In patients seeking aesthetic neck improvements, and where the indication is present, partial SMG resection can be offered as an effective intervention as part of the deep cervical lift. The procedure should be proposed with a full informed consent of potential complications. These are minor and self-limiting in the majority of cases. To discern the exact added value of partial SMG resection in aesthetic neck surgery, large powered controlled trials with prospective objective evaluation of aesthetic outcome and patient-reported outcome measures are needed.

### **Compliance with Ethical Standards**

**Conflict of interest** The authors declare that they have no conflicts of interest to disclose.

**Human and Animal Rights** This article does not contain any studies with human participants or animals performed by any of the authors.

**Informed Consent** For this type of study, informed consent is not required.

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