Article

Not peer-reviewed version

Effectiveness of Intraoperative Facial Nerve Monitoring in Submandibular Gland Surgery. A Retrospective Study of a Single Institution

Maria Giulia Cristofaro * , Francesco Ferragina , Giuseppe Tarallo , Angelo Ruggero Sottile , Maria Grazia Ioppolo , Antonella Arrotta , Teresa Chiara De Bartolo , Ida Barca

Posted Date: 3 February 2025

doi: 10.20944/preprints202502.0038.v1

Keywords: benign pathology submandibular gland; marginalis mandibulae branch; postoperative facial nerve paralysis; intraoperative facial nerve monitoring

Article

Effectiveness of Intraoperative Facial Nerve Monitoring in Submandibular Gland Surgery. A Retrospective Study of a Single Institution

Maria Giulia Cristofaro [1,*], Francesco Ferragina [1], Giuseppe Tarallo [2], Angelo Ruggero Sottile [2], Maria Grazia Ioppolo [2], Antonella Arrotta [3], Teresa Chiara De Bartolo [4] and Ida Barca [1]

1 Maxillofacial Surgery Unit, Department of Experimental and Clinical Medicine, Renato Dulbecco Hospital, Magna Graecia University of Catanzaro, Viale Europa, 88100 Catanzaro, Italy
2 Maxillofacial Surgery Operative Unit, Department of Neurosciences, Reproductive and Odontostomatological Sciences, Federico II University of Naples, 80131 Naples, Italy
3 Department of Medical and Surgical Sciences, Anesthesia and Intensive Care, Renato Dulbecco Hospital, Magna Graecia University of Catanzaro, Viale Europa, 88100 Catanzaro, Italy
4 "Magna Graecia" University, Viale Europa, 88100, Catanzaro, Italy
* Correspondence: cristofaro@unicz.it; Tel.: +39-0961-3647271; Fax: +39-0961-3647229

Abstract: Background: The use of intraoperative facial nerve monitoring (IFNM) is becoming more and more frequent, an established intraoperative aid in parotid gland surgery. To date, there are no scientific studies in the literature on the post-operative outcomes of submandibular gland surgery, in particular on post-operative injury of the marginalis mandibulae branch (MMB) that represents the most frequent and feared complication of this surgery, with an incidence of 1-7% of cases. Objective: In this retrospective study, the authors evaluated the incidence of postoperative paralysis of the MMB of the facial nerve (FN)in patients undergoing submandibular sialodenectomy for benign diseases, such as benign tumors and sialolithiasis, from 2014 to 2023, with particular attention to the role of IFNM in this context. Materials and Methods: The retrospective study was conducted at the Maxillo-Facial Department of Magna Graecia University of Catanzaro. The patients were divided into two groups: Group 1 (G1) consisted of subjects who underwent surgery without the use of IFNM and identification and clamping of facial vessels (1 January 2014 to 31 December 2018); Group 2 (G2), consisted of subjects who underwent surgery with IFNM and without identification and clamping of facial vessels (1 January 2019 al 31 December 2023). In G2 employed the Nerve Integrity Monitor (NIMR di Medtronic) and to classify the FN function we used the modified House-Brackmann classification. A descriptive analysis was performed, and univariate and multivariate logistic regression were used to examine the impact of IFNM on surgical timing and the association between deficit of G2 (vs. G1) adjusted for age, sex, smoking status for age, sex, smoking status. The level of statistical significance was set at p value<0.05. Results: A total of 101 patients were included in the study: 50 subjects were assigned to G1 (49.5%, comprising 24 female and 26 male, and 51 subjects were assigned to G2 (50.5%), comprising 21 men and 30 women, the mean age was 55 ± 16 years in the entire patient cohort. In 77% of the cases (n. 78, precisely 38 in G1 and 40 in G2), no facial nerve injury occurred. In 23% of the cases (n. 23, specifically 12 in G1 and 11 in G2), postoperative paralysis of MMB was observed. Of these subjects, nobody had permanent paralysis but only transient dysfuction (of the 12 patients of G1 four demonstrated grade I dysfunction while eight exhibited grade II dysfunction, of the 11 subjects of G2, eight exhibited grade I dysfunction, while three demonstrated grade II dysfunction). After six months the dysfuction of grade II persisted only in five patients of G1. The results of univariate and multivariable linear regression demonstrated that the surgical timing was found to be 99 ± 44 minutes considering the entire cohort of patients, 110 ± 43 minutes for G1 and 92 ± 42 minutes for G2 (Beta = -19, 95% CI -37 to -0.16 and p = 0.048). A longer surgical timing was observed compared to non-smokers (always statistically significant with a p-value of 0.008), suggesting that smoking status may influence the duration of the intervention (Beta = -0,32, 95% CI -0,08 to -0.55 and p = 0.008). Discussion and Conclusions: MMB paralysis represents one of the most frequent complications that can occur also in submandibular gland surgery and IFNM offers to the surgeon a valuable support in identifying the MMB in submandibular sialadenectomy. The use of IFNM can be a valid aid, but its effectiveness always depends on the competence but its effectiveness always depends on the competence of the surgeon.

Keywords: benign pathology submandibular gland; marginalis mandibulae branch; postoperative facial nerve paralysis; intraoperative facial nerve monitoring

---

Introduction

The intraoperative facial nerve monitoring (IFNM) has been extensively studied in parotid gland surgery, proving to be a valuable aid to the surgeon as it reduces the risk of nerve injury and improves postoperative functional outcomes [1,2]. Although these benefits are well documented for parotid surgery [3–5], there is no adequate scientific literature that has evaluated the impact of IFNM in submandibular gland surgery, in particular on one of the terminal branches of the facial nerve (FN), the marginalis mandibulae branch (MMB). This branch, innervating the muscles of the lower lip, is thin and anastomosis with other branches is not always present. Its injury causes motor dysfunction and facial asymmetry, with a significant impact on the patient's quality of life. Lesions of this nerve represent one of the most frequent and feared complications in this type of surgery, which occurs with an incidence of 1-7% of cases, since its superficial position and proximity to the submandibular gland expose it directly during surgery [6]. Sometimes the damage caused to the cervical branch of the facial nerve, which is always posterior to the MMB and whose anatomy is often poorly known, is mistakenly attributed to the MMB lesion. Already in 1964, De Sousa demonstrated electromyographically the importance of the contraction of the platysma muscle in the lowering of the labial commissure and the lower lip [7]. The platysma muscle is involved together with the depressor anguli oris muscle in the balance between elevation and depression forces acting on the labial commissure. It also contributes with the depressor labii inferioris to the lowering of the lower lip, both innervated by the MMB of the FN. The contraction of the platysma muscle, the depressor anguli oris and the depressor labii inferioris is responsible for the expression of sadness, disgust and bitterness and also, in the forced smile, for the exposure of the upper and lower dental arches. Cervical branch lesions of the FN induce asymmetry in these combined movements due to reduced counterbalancing of the elevator commissures labialis on the affected side, which is especially evident when smiling, which is often mistaken for a marginal lesion of the MMB. This asymmetry is found in 35-40% of cases of patients undergoing submandibular sialodenectomy [8], it is transitory and generally resolves within a month of surgery. By respecting some simple technical points during the approach to the submandibular gland, the nerve can be easily spared. In fact, by sparing the posterior part of the muscle in the platysma section, the risk of injury to the cervical branch is reduced to a minimum without in any way hindering the approach to the submandibular space. The most important complication of submandibular gland surgery is therefore due to injury to the MMB of the FN [9]. Since the MMB is a thin nerve, it is often difficult to identify and protect. Many authors recommend identifying the facial artery and vein near the lower border of the mandible and ligating these vessels before pulling them cranially to protect the nerve. However, it is not uncommon for the MMB to run caudally at that site. Although the nerve identification method may seem like a valid protection strategy, problems may arise for the following reasons: nerve identification is often difficult in patients with abundant subcutaneous fat, many patients have multiple MMBs, and finally the MMB is a thin nerve, so dissection alone may cause paralysis. It may be useful during the removal of the submandibular gland not to proceed with the direct identification of the nerve (avoiding its expected course) but to trace its path with the aid of the IFNM. The gap in the literature regarding scientific studies that have addressed iatrogenic damage to the FN in submandibular gland surgery suggests the need for further research to understand whether the introduction of IFNM can offer the

Preprints.org (www.preprints.org) | NOT PEER-REVIEWED | Posted: 3 February 2025 doi:10.20944/preprints202502.0038.v1

same level of protection also in this context, providing surgeons with additional assistance in safeguarding the nerve. In this retrospective study, the authors evaluated the incidence of postoperative paralysis of the MMB of the FN in patients undergoing submandibular sialodenectomy for benign diseases, such as benign tumors and sialolithiasis, from 2014 to 2023, with particular attention to the role of IFNM in this context.

2. Materials and Methods

The retrospective study was conducted at the Maxillofacial Unit of the Magna Grecia University of Catanzaro. The data analyzed concern patients who underwent submandibular sialoadenectomy (1 January 2014 to 31 December 2023) with the use of IFNM compared with those of patients who did not undergo monitoring. This study was approved by the Ethics Committee of the Magna Graecia University of Catanzaro (protocol number 146/2016) and informed consent was obtained from the patients. To mitigate the risk of selection bias, only cases undergoing surgical treatment by two experienced senior surgeons (MGC and IB) were included in the analysis and the choice of device use was random.

Patients were divided into two groups:

- Group 1 (G1), surgical procedures were performed without the use of IFNM and identification and clamping of facial vessels;

- Group 2 (G2), surgical procedures were performed with the use of IFNM and without identification and clamping of facial vessels.

The information, obtained from the medical records and histological examinations, was organized in a database using Microsoft Excel (Version 2017 (Redmond, WA, USA) and included personal data, tobacco/alcohol habits, comorbidities, other interventions performed, histological diagnosis, presence or absence of facial paralysis with involvement of the MMB and surgical timing. Clinical and telephone follow-up collected data on resolution or persistence of paralysis. In this context, the term "permanent paralysis" is used to describe any degree of facial weakness that persists for a minimum of six months following surgery.

The inclusion criteria were as follows:

- patients of both sexes and without age limits, undergoing surgery of the submandibular gland for the presence of submandibular lodge pathologies;

- patients with post-operative histological diagnosis of benign pathology (siaolithiasis, chronic recurrent sialadenitis, benign tumors);

- patients undergoing sialodenectomy of the submandibular gland.

The following exclusion criteria were applied:

- patients with incomplete documentation;
- patients operated on in the same location for other pathology;
- patients with previous deficits affecting the facial nerve;
- patients with malignant tumor

The analysis of the FN function was based on a daily evaluation del MMB and was carried out preoperatively, postoperatively on the first day, and remotely, with photographic documentation. To categorize the FN function the modified House–Brackmann classification system [10] we use a scoring system of levels I to IV of dysfunction, where I indicated no dysfunction, II indicated mild dysfunction, III indicated moderate dysfunction, and IV indicated severe dysfunction (Table 1).

Table 1. The staging of FN function according to the House–Brackmann classification.

Grading	FN Function
I: Normal	No deficit.
II: Mild dysfunction	Slight facial weakness or other mild dysfunction, normal tone and symmetry at rest; complete closure of the eye without effort; slight asymmetry of the mouth when facial movements occur.

Preprints.org (www.preprints.org) | NOT PEER-REVIEWED | Posted: 3 February 2025 doi:10.20944/preprints202502.0038.v1

III: Moderate dysfunction	No facial weakness with synkinesis and complete eye closure and good forehead movement with effort.
IV: Moderate–severe dysfunction	Obvious facial weakness. Incomplete eye closure, no forehead movement, asymmetrical mouth movement, and synkinesis.
V: Severe dysfunction	Little to no ability to smile, frown, or make other facial expressions. The closure of the eye is incomplete, and there is no forehead movement.
VI: Complete paralysis	No facial motion.

2.1. Surgical Technique

In both patient groups, submandibular sialodenectomy was performed under general anesthesia, with standard practice procedures previously established in our clinical setting. One hour before the start of surgery, patients were administered intravenous midazolam at a dose of 1 to 5 mg. After adequate preoxygenation and denitrogenization, anesthesia was induced with propofol 2 mg/kg intravenously (i.v.) as a bolus (for sedation) in combination with a single reduced dose of rocuronium (0.3 mg/kg). Analgesia was provided by continuous infusion of remifentanil at a rate of up to 1 mcg × kg/min. The surgical technique used was transcervical submandibular sialodenectomy. The cervical skin incision was made 3 cm from the lower margin of the mandible, parallel to it and about 4-5 cm long, in a natural crease of the neck. The incision runs from the anterior border of the sternocleidomastoid muscle to the submental area, the skin and platysma are incised and the upper and lower flaps are raised respectively to the lower margin of the mandible and below the submandibular gland [11]. The dissection then proceeds from the superficial cervical fascia to the gland, the facial vessels are identified and tied and clamped to ensure protection of the MMB of the FN. In the subjects of G2 the mapping or "blind" stimulation of the surrounding tissues the MMB was performed by using the probe (Medtronic) at no more than 2mA, without proceeding with the identification al clamp of the facial vessel. A blunt dissection of the gland is performed from back to front, identifying the lingual nerve, Wharton's duct and hypoglossal nerve. The Wharton's duct is then ligated, the gland is removed, hemostasis is carefully checked and sutured in layers. In G2 the device used for IFNM was the Nerve Integrity Monitor (NIM®) (Medtronic, Fridley, MN, USA), which is one of the most widely used monitoring devices in thyroid surgery. The device provides audiovisual information based on electromyographic (EMG) activity resulting from intraoperative nerve stimulation. It consists of a recording electrode and a monopolar or bipolar nerve stimulation probe connected to a pulse generator. In parotid surgery four recording electrodes are used, while in submandibular gland surgery a single channel is sufficient to monitor the muscular response of the orbicularis oris, innervated by the MMB of the FN. Immediately after intubation to verify that the facial electrode is correctly placed we perform a tapping test of this muscle and observing a response wave in the monitor due to this stimulation.

At the end of the intervention in the patients of the G2, the system generated a report containing the electromyographic tracings that was inserted in the medical record. In the post-operative period, the patients were monitored for possible complications, including deficits of the FN, in particular of its MMB. Patients who developed a FN injury were referred to a rehabilitation program in collaboration with the Physical Medicine and Rehabilitation Department of the "Renato Dulbecco" University Hospital in Catanzaro and subsequently subjected to follow-up checks.

Statistical Analysis

The dataset was subjected to statistical analysis using R software. A descriptive analysis was performed, and univariate and multivariate logistic regression models were used to examine the likelihood of patients developing a postoperative deficit depending on whether or not they underwent IFNM. In addition, univariate and multivariate linear regression models were used to examine the impact of monitoring on surgical time. The level of statistical significance was set at p value<0.05.

Preprints.org (www.preprints.org) | NOT PEER-REVIEWED | Posted: 3 February 2025 doi:10.20944/preprints202502.0038.v1

The dataset included demographic information and details of surgical procedures performed, comorbidities, histological diagnoses, and postoperative FN function. Subsequently, data on the recovery or permanence of facial paralysis were collected through clinical and/or telephone follow-up. In this context, the term "permanent paralysis" is used to describe any degree of facial weakness that persists for a minimum of six months following surgery.

Results

From 1 January 2014 to 31 December 2023, 104 patients underwent submandibular sialodenectomy at the Maxillofacial Unit of the Magna Grecia University of Catanzaro, of which 101 met the inclusion criteria, while 3 patients were excluded because they had been operated on in the same location for another pathology.

Of the 101 patients, 45 (44,5%) were female and 56 (55,4%) were male. Of these 101 patients, 50 (49,5%) were G1 and 51 (50,5%) patients were G2.

Of the 50 G1 patients, 24 (48 %) were female and 26 (52%) were male, while of the 51 G2 patients, 21 (41%) were female and 30 (59%) were male.

The mean age was 55 ± 16 years in the entire patient cohort, 56 ± 16 years in G1, and 54 ± 15 years in G2.

All patients underwent submandibular sialoadenectomy (100%), of which 50 were in G1 (49.5 % of the total patients in G1) and 51 in G2 (50.5 %), according to the surgical technique described.

The length of hospital stay is 5.19 ± 1.93 days considering the entire cohort of patients, while it is equal to 5.24 ± 2.20 days for G1 and 5.14 ± 1.64 for G2 (Figure 1).

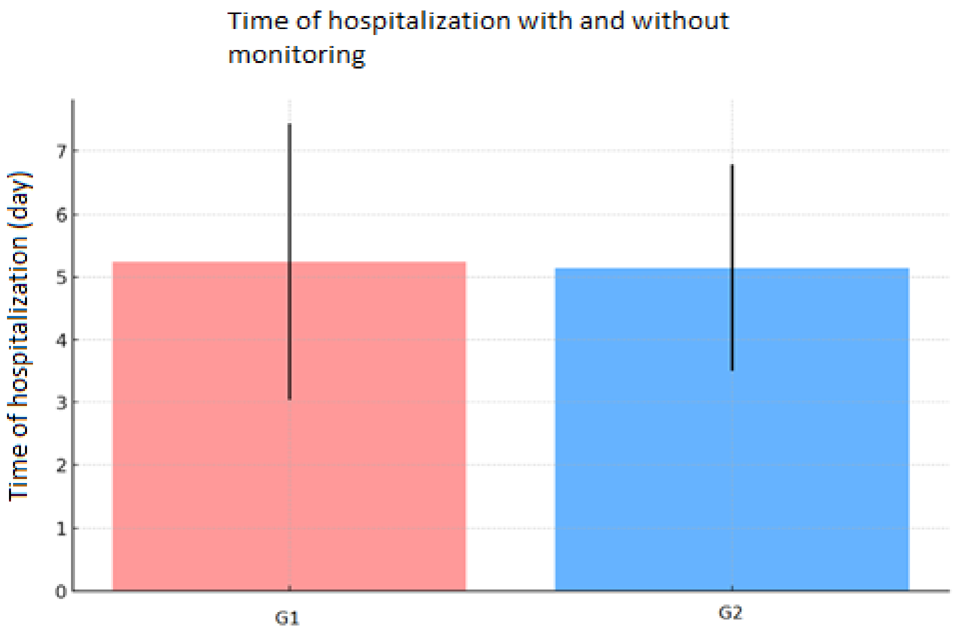

Figure 1. Length of hospital stay: The mean length of hospital stay was similar for both groups, with minimal differences.

The surgical timing was found to be 99 ± 44 minutes considering the entire cohort of patients, 110 ± 43 minutes for G1 and 92 ± 42 minutes for G2 (*Figure 2*).

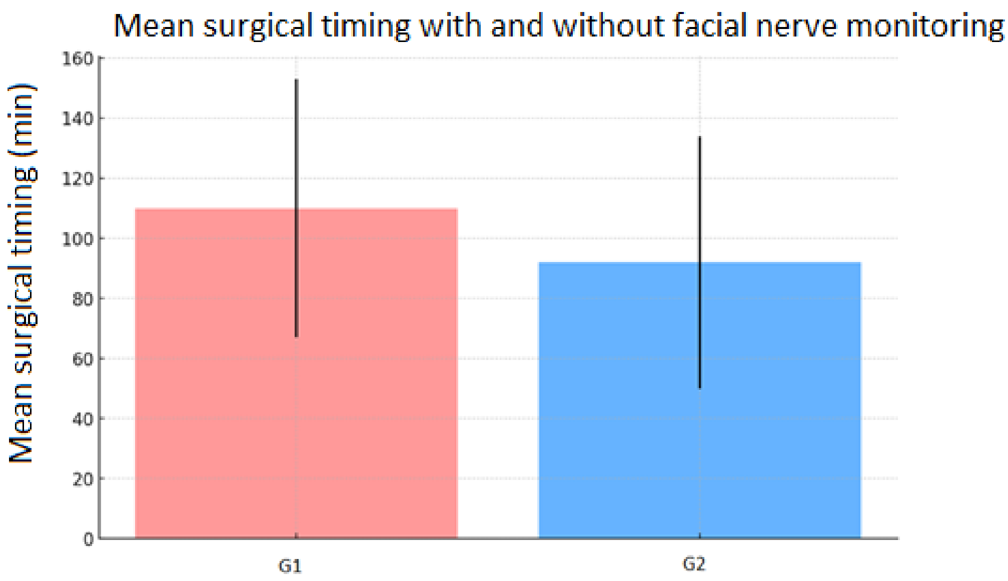

Figure 2. The mean surgical timing in the two groups.

As regards smoking status, in the entire cohort of patients, 53 (52%) were non-smokers, 14 (14%) were ex-smokers and 34 (34%) were smokers; in G1, 32(64%) patients were non-smokers, 5 (10%) were ex-smokers and 13 (26%) were smokers; while for G2, 21 patients (41%) were non-smokers, 9 (18%) were ex-smokers and 21 (41%) were smokers. (*Figure 3*).

Preprints.org (www.preprints.org) | NOT PEER-REVIEWED | Posted: 3 February 2025 doi:10.20944/preprints202502.0038.v1

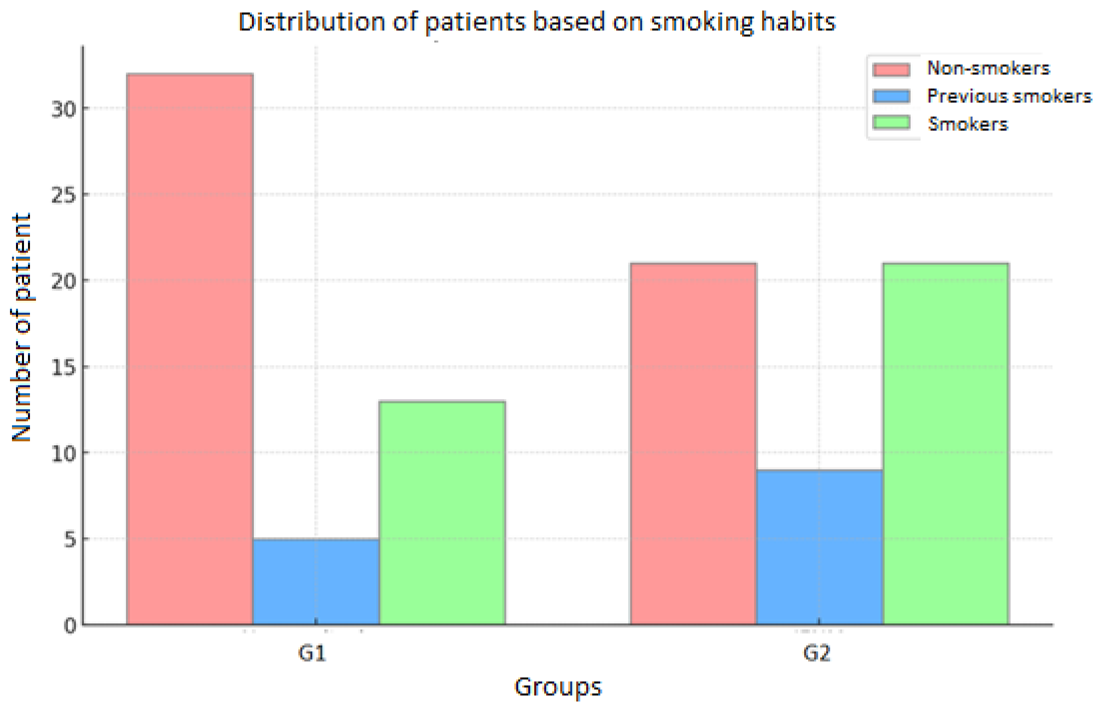

Figure 3. Distribution of patients according to smoking in G1 and G2.

The diagnosis was divided into three categories: sialolithiasis, benign tumour and other pathologies (sialadenitis, follicular hyperplasia, Kuttner tumor). Patients operated for sialolithiasis were a total of 78 (77%), of which 46 belonged to G1 (59% of the total patients in G1) and 32 to G2 (41% of the total patients in G2). Patients operated for neoplasia were 10 (10%), of which 4 belonging to G1 (40%) and 6 (60 %) to G2, larger than 2 cm in size, with intraparenchymal localization, with preoperative cytological diagnosis of pleomorphic adenoma confirmed with postoperative histological examination. Patients with another diagnosis were a total of 13 (12 % of the total patients), of which 5 of G1 (38% of the total patients in G1), while the remaining 8 belonged to G2 (61% of the total patients in G2). (Table 2)

Table 2. Characteristics of the patient cohort of G1 and G2.

Characteristics	**Total number = 101**	**G1 N = 50**	**G2 N = 51**
Age (years)	55 ± 16	56 ± 16	54 ± 15
Sex (female)	45 (45%)	24 (48%)	21 (41%)
Hospitalization (days)	5,19 ± 1,93	5,24 ± 2,20	5,14 ± 1,64
Surgical timing (minutes)	99 ± 44	110 ± 43	92 ± 42

Preprints.org (www.preprints.org) | NOT PEER-REVIEWED | Posted: 3 February 2025 doi:10.20944/preprints202502.0038.v1

Characteristics	Total number = 101	G1 N = 50	G2 N = 51
Smokers			
No smokers	53 (52%)	32 (64%)	21 (41%)
Ex smokers	14 (14%)	5 (10%)	9 (18%)
Smokers	34 (34%)	13 (26%)	21 (41%)
Diagnosis			
Sialolithiasis	78 (77%)	46 (59%)	32 (41%)
Benign tumour (pleomorphic adenoma)	10 (10%)	4 (40%)	6 (60%)
Other (sialadenitis, follicular hyperplasia, Kuttner tumor)	13 (12%)	5 (38%)	8 (61%)

The descriptive analysis of the postoperative paralysis demonstrated that 78 patients (77%) of the entire cohort did not report paralysis, in particular 38 (76%) of G1 and 40 (78%) of G2.

Twenty-three patients (23%) of the entire cohort exhibited varying degrees of paralysis, in particular 12 patients (24%) of G1 and in 11 patients (22%) of G2, but none of the patients reported permanent paralysis.(Table 3)

Table 3. Postoperative paralysis rates in the two groups.

Characteristics	Total number = 101	G1 N = 50	G2 N = 51
Post-surgery deficit			
No deficit	78 (77%)	38 (76%)	40 (78%)
Deficit Day One	23 (23%)	12 (24%)	11 (22%)
Deficit after three months			
No deficit	92 (92%)	43 (86%)	50 (98%)
Deficit	8 (8%)	7 (14%)	1 (2%)

Preprints.org (www.preprints.org) | NOT PEER-REVIEWED | Posted: 3 February 2025 doi:10.20944/preprints202502.0038.v1

Characteristics	Total number = 101	G1 N = 50	G2 N = 51
Deficit after six months			
No deficit	96 (95 %)	45 (90 %)	51(100%)
Deficit	5 (5 %)	5 (10%)	

On the day following surgery 12 subjects of G1 exhibited varying degrees of paralysis and in particular four demonstrated grade I dysfunction while eight exhibited grade II dysfunction. Of the 11 subjects of G2, eight exhibited grade I dysfunction, while three demonstrated grade II dysfunction.

After three months all the patients of both groups with grade I dysfunction no longer exhibited any dysfunctions. Of the patient with grade II dysfunction in eight persisted the dysfuction (seven of G1 and one of G2), after six months the dysfuction of grade II persisted only in five patients of G1.

The data presented in Table 4.

Table 4. FNI assessed by House–Brackmann classification.

DAY	G1	No Facial Paralysis	G2	No Facial Paralysis
Day 1	Gr I: 4/12 Gr II: 8/12	38	Gr I: 8/11 Gr II: 3/11	40
Days 90	(Gr II): 7/12	43	Gr II: 1/11	50
Days 180	(Gr II): 5/12	45		51

Regarding locoregional postoperative complications, edema was observed in 30 subjects (29.7 %) which resolved on average after five days and treated with corticosteroids only when considered clinically significant, the minor emorrhages were not treated, wound infection was noted in 5 subjects (4.9%) treated with antibiotics.

Statistical investigations were conducted to evaluate the correlation between variables of interest. For all analyses performed, a significance level α of 5% and a confidence interval (CI) of 95% were considered. The first test conducted is the univariate and multivariate logistic regression for the baseline deficit. The odds ratio (OR) for G2 (vs. G1) in relation to baseline deficit is 0.87 ($p = 0.8$), indicating that monitoring does not have a significant association with the reduction in risk of postoperative deficit (Table 5)

Table 5. Univariate logistic regression for the association between baseline deficit and IFNM, in G2 vs G1.

Characteristic	**OR**	**95% CI**	***p-value***
G2 (vs. G1)	0.87	0.34, 2.22	0.8

The second test involved the multivariate regression analysis, always considering G2 vs G1, but adjusted for age, sex, smoking status and vascular ligation. The OR remains non-significant with a value of 0.73 and $p = 0.5$ (Table 6).

Preprints.org (www.preprints.org) | NOT PEER-REVIEWED | Posted: 3 February 2025 doi:10.20944/preprints202502.0038.v1

Table 6. Multivariate logistic regression for the association between baseline deficit and G2 (vs. G1) adjusted for age, sex, smoking status.

Characteristic	**OR**	**95% CI**	***p-value***
G2 (vs. G1)	0.73	0.26, 1.96	0.5
Age (years)	1.01	0.98, 1.05	0.5
Females (vs. Males)	2.24	0.73, 7.41	0.2
No smokers			
Ex smokers	3.64	0.79, 17.0	0.093
Smokers	1.66	0.44, 6.26	0.4

This OR value indicates that patients in G2 have a 27% lower probability ((0.73 – 1) *100) of developing a postoperative deficit compared to those in G1, but this effect is not statistically significant since the resulting p-value is above the pre-set threshold of 0.05. Considering age (expressed in years), the OR value of 1.01 means that each year of age is associated with a 1% increase in the probability of developing a post-operative deficit, but even in this case the effect is minimal since the corresponding p-value = 0.5 indicates that age does not have a significant statistical effect. When considering gender (female vs. male), OR = 2.24 indicates that female patients are 2.24 times more likely to develop a postoperative deficit than male patients. Again, the effect is not statistically significant as the p-value = 0.2 and greater than 0.05. Considering the condition of ex-smoker vs. non-smoker, an OR value of 3.64 is observed, suggesting that ex-smokers are 3.64 times more likely to develop a post-operative deficit compared to non-smokers. The p-value = 0.093, although close to the value of 0.05, does not reach the threshold of significance. As for smoking vs non-smoking status, the OR is 1.66, so smokers have a 1.66 times higher probability of developing a post-operative deficit compared to non-smokers, but the effect is not statistically significant (p-value = 0.4).

Subsequently, a univariate and multivariate linear regression was performed for surgical timing, which shows that facial nerve monitoring is significantly associated with a shorter surgical time. In the univariate regression, G2 has a surgical time reduced by approximately 19 minutes compared to G1 (with a p-value = 0.048). (Table 7)

Table 7. Univariate linear regression for the association between surgical timing and IFNM (G2 vs. G1).

Characteristic	**Beta**	**95% CI**	***p-value***
G2 (vs. G1)	-19	-37, -0.16	0.048

This effect remains statistically significant even in multivariate regression, where the association is even stronger (p-value = 0.004), even after adjusting for variables such as age, sex, smoking status.

Furthermore, among smoking patients, a longer surgical timing was observed compared to non-smokers (always statistically significant with a p-value of 0.008), suggesting that smoking status may influence the duration of the intervention (Table 8).

Table 8. Multivariate linear regression for the association between surgical timing and G2 (vs G1) adjusted for age, sex, smoking status.

Preprints.org (www.preprints.org) | NOT PEER-REVIEWED | Posted: 3 February 2025 doi:10.20944/preprints202502.0038.v1

Characteristic	**Beta**	**95% CI**	***p-value***
G2 (vs. G1)	-0.28	-0.46, -0.09	0.004
Age	0.00	0.00, 0.01	0.7
Females (vs. Males)	-0.02	-0.23, 0.19	0.9
No smokers			
Ex smokers	0.09	-0.20, 0.39	0.5
Smokers	0.32	0.08, 0.55	0.008

Considering G2 vs. G1, Beta is -0.28 indicating that IFNM is associated with an average reduction of 0.28 minutes in surgical timing; the p-value of 0.004 less than 0.05 indicates that this reduction is statistically significant. If, instead, we consider age (in years), Beta is 0.00, it means that age has no effect on surgical timing, but in this case the p-value equal to 0.7 indicates that this data is not statistically significant. Taking into account gender (female vs. male), the Beta coefficient of -0.02 indicates that women have a slightly shorter surgical timing (0.02 minutes) than men, but the effect, in addition to being practically zero, is not statistically significant since p-value = 0.9.

Considering ex-smoker status (vs. non-smoker), Beta is 0.09, so ex-smokers have a slightly longer surgical timing (by 0.09 minutes), but the effect is small and not statistically significant with a p-value of 0.5.

Considering, instead, the status of smoker vs. non-smoker, Beta is 0.32, therefore smokers have a significantly longer surgical timing of 0.32 minutes compared to non-smokers; this data is instead statistically significant since the p-value is 0.008.

Finally, a boxplot and a scatterplot were constructed to graphically represent the relationships of interest.

The boxplot (Figure 5) is used to visualize the distribution of a data set and its quartiles. In this graph, the vertical axis represents the surgical timing (expressed in minutes), while the horizontal axis shows the variable post-operative deficit with two categories: “No deficit” and “Deficit” and the data are divided into G1 and G2.

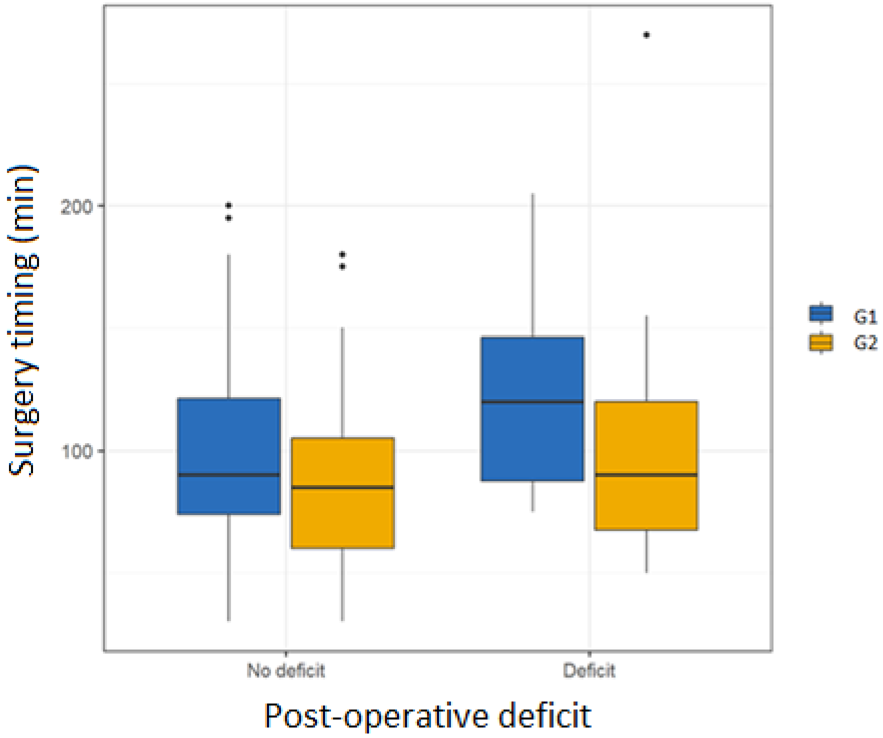

Figure 5. Boxplot showing how surgical timing is significantly reduced in patients undergoing IFNM regardless of postoperative deficit.

Each boxplot shows the distribution of data for a combination of postoperative deficit and nerve monitoring. The horizontal line within each box represents the median surgical timing.

The edges of the box correspond to the first and third quartiles (the length of the box therefore represents the central 50% values of the data). The vertical lines (whiskers) extend to the minimum and maximum values, excluding outliers (represented as black dots outside the whiskers), i.e., values that deviate significantly from the rest of the data. This graph is useful for comparing surgical times between patients with and without deficits, and for examining the effect of intraoperative monitoring. The graph shows that patients subjected to facial nerve monitoring during surgery, had shorter surgical times regardless of postoperative deficit.

The scatterplot (Figure 6) displays the duration of surgery over the time period considered (from 2014 to 2023): the vertical axis represents the time of surgery (in minutes) and the horizontal axis shows the year in which the interventions were performed.

Each dot represents a surgery, with the size and color indicating the completion category. The black trend line represents linear regression, which helps visualize the change in surgery duration over time. It is useful for analyzing any trends over time in surgery duration, taking into account the type of surgery. n this scatterplot the points have been slightly shifted to display the entire cohort, given the high number of patients with equal operating time. It is noted that there is a significant decrease in surgical time over the years.

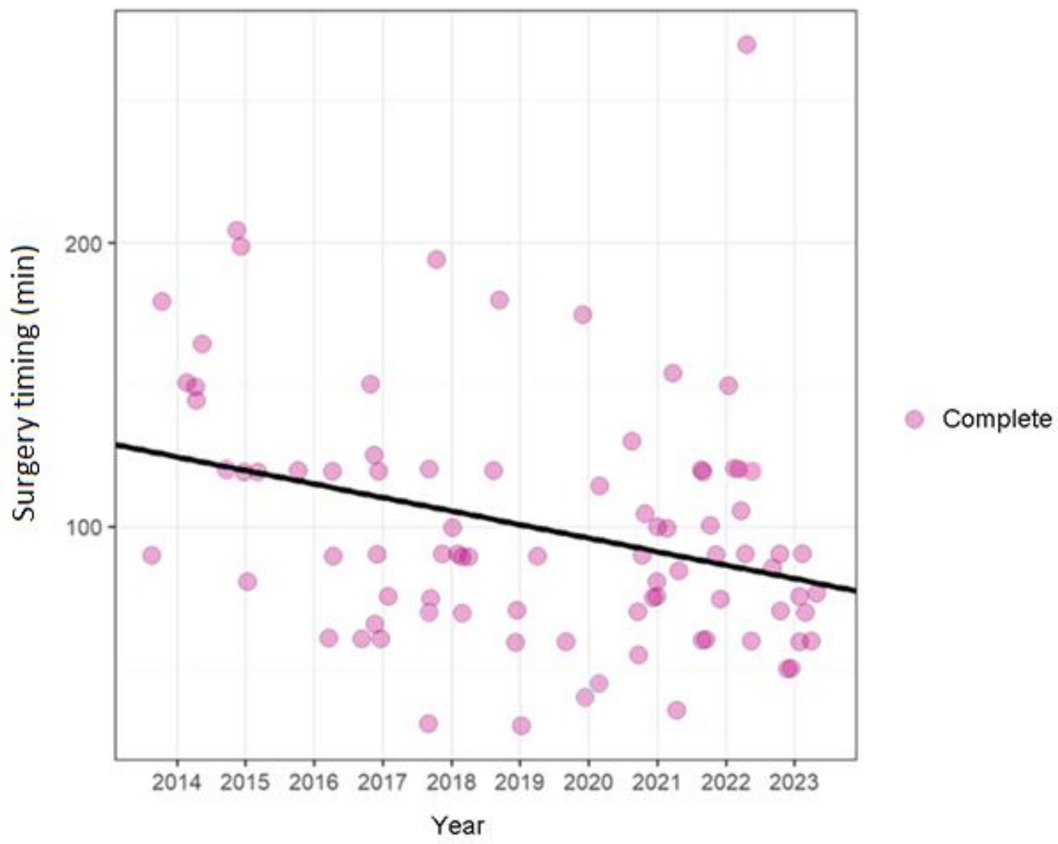

Figure 6. Scatterplot shows how there is a significant decrease in surgical timing over the years.

Discussion

The IFNM supports the surgeon in identifying the FN, reporting any accidental manipulation or stimulation, tracing its path and providing indications on the possible functional outcome of the FN after the operation. It is believed that such monitoring helps to reduce temporary paralysis, promptly warning of potential damage such as stretching or compression, which could compromise the nervous microcirculation. [10,11]

Although there are several international guidelines and consensus statements on the clinical use of IFNM for the recurrent laryngeal nerve IORLNM) e in otologic and skull base surgery [12–14], no such standardized protocols on the use and interpretation of IFNM have been published to date in parotid gland surgery and even less in submandibular gland surgery.

Infact regarding IFNM in submandibular gland surgery, the current literature does not provide conclusive evidence demonstrating a direct link between the use of this monitoring and the reduction in the incidence of post-operative deficits, particularly of the MMB [15]. Although some studies have suggested that monitoring may be useful in protecting the FN [7,16,17], the available results are not sufficient to establish a statistically significant correlation. Numerous investigations have shown that postoperative rates of facial paresis may be similar for patients undergoing intraoperative facial nerve monitoring and for those who are not.

It is important to note that the authors excluded patients with primary or metastatic malignant tumors of submandibular gland from the study because they can infiltrate the branches of the FN requiring a radical surgical strategy.

Both univariate and multivariate logistic regression analyses conducted in the study did not highlight a statistically significant correlation between the use of IFNM and a significant reduction in the risk of FN deficiency after submandibular sialodenectomy (OR = 0.87, 95% CI from 0.34 to 2.22

and p = 0.8 in univariate logistic regression, OR = 0.73, 95% CI from 0.26 to 1.96 and p = 0.5 in multivariate logistic regression).

This study presents the most relevant evidence in the scientific literature demonstrating a higher percentage of patients undergoing IFNM (G2) reported a complete resolution of deficits in a short time than G1 patients as well as a statistically significant reduction in surgical timing.

In particular, it was seen that in G2 the percentage of patients with post-operative deficit at three months decreased from 22% (11 patients) of the total patients of G2 (51) to 2% (1 patients), while in G1 the percentage decreased from 24% (12 patients) of the total patients of G1 (50) to 14% (7 patients) and after six months, grade II dysfuction persisted in five patents of G1.

Furthermore, univariate and multivariate linear regression analyses found that IFNM was associated with a statistically significant reduction in surgical timing, with an average of approximately 19 minutes less than operations performed without monitoring, as evidenced by univariate linear regression (Beta = -19, 95% CI -37 to -0.16 and p = 0.048). This surgical timing saving could represent a concrete advantage in terms of operative efficiency, potentially reducing the risk of complications related to longer surgical timing. A longer surgical timing was observed compared to non-smokers (always statistically significant with a p-value of 0.008), suggesting that smoking status may influence the duration of the intervention (Beta = -0,32, 95% CI -0,08 to -0.55 and p = 0.008).

Of course the design of prospective study will allow to identify the potential benefits of IFNM also in the surgery of benign pathology of the submandibular gland in reducing the severity of the lesions and shortening the recovery period from transient post-operative paralysis.

Conclusion

MMB paralysis represents one of the most frequent complications that can occur also in submandibular gland surgery and IFNM offers to the surgeon a valuable support in identifying the MMB in submandibular sialadenectomy. This retrospective study demonstred that IFNM represent an efficace methods in reduncing the risk of dysfuction of MMB. In particular this approach allows method both in the faster functional recovery as well as in terms of reduction of surgical timing, potentially reducing the risk of complications related to longer surgical times long. In light of the results obtained, the authors strongly recommend the use of IFNM in surgery of benign lesion of submandibular gland. It is important to emphasize, however, that the use of monitoring systems should never replace the experience, anatomical knowledge and decision-making ability of the surgeon. Technology can be a valid aid, but its effectiveness always depends on the competence and judgment of the physician, who remains the central figure in ensuring the success of the intervention and the well-being of the patient.

References

1) Tirelli G.; Bergamini PR.; Scardoni A., Gatto A., Boscolo Nata F. and Marcuzzo AV., Intraoperative monitoring of marginal mandibular nerve during neck dissection. *Head & neck,* 2018. May;40(5):1016-1023. doi: 10.1002/hed.25078. Epub 2018 Feb 1.
2) Savvas, E.; Hillmann, S.;Weiss, D.; Koopmann, M.; Rudack, C.; Alberty, J. Association Between Facial Nerve MonitoringWith Postoperative Facial Paralysis in Parotidectomy. *JAMA Otolaryngol.–Head Neck Surg.* 2016, 142, 828.
3) Cristofaro M.G., Colangeli W, Ferragina F, Tarallo G, Sottile AR, Ioppolo MG, Arrotta A, Barca I. Facial Nerve Injury after Extracapsular Dissection for Benign Parotid Tumors with and without Intraoperative Monitoring: A Retrospective Study of a Single Center. *Diagnostics (Basel)*. 2024 Sep 12;14(18):2017. doi: 10.3390/diagnostics14182017.
4) Turhal, G.; Hepkarsi, S.; Ozturk, K. The potential applicability of facial nerve monitoring as a navigation tool in parotid gland surgery. Braz. J. Otorhinolaryngol. 2023, 89, 230–234
5) Duque, C.S.; Londoño, A.F.; Duque, A.M.; Zuleta, J.J.; Marulanda, M.; Otálvaro, L.M.; Agudelo, M.; Dueñas, J.P.; Palacio, M.F.;Dionigi, G. Facial nerve monitoring in parotid gland surgery: Design and feasibility

 doi:10.20944/preprints202502.0038.v1

assessment of a potential standardized technique. *World J. Otorhinolaryngol.–Head Neck Surg. 2023, 9, 280–287.*

6) Cammaroto G., Vicini C., Montevecchi F. Bonsembiante G., Meccariello L., Bresciani L., Pelucchi S. and Capaccio P. Submandibular gland excision: From external surgery to robotic intraoral and extraoral approaches. *Oral Dis* 2020 Jul;26(5):853-857. doi: 10.1111/odi.13340. Epub 2020 Apr 20.
7) Righini C.A., Petrossi J. , E. Reyta E., Atallaha I. An original submandibular approach technique sparing the cervical branch of the facial nerve. *Eur Ann Otorhinolaryngol, Head Neck Dis* (2014) 131, 143—146
8) Silver NL., Chinn SB, Bradley PJ. and Weber RS. Surgery for Malignant Submandibular Gland Neoplasms. *Adv Otorhinolaryngol* 2016:78:104-12.

doi: 10.1159/000442130. Epub 2016 Apr 12.

9) Kikuoka Y.; Kawata R.; Higashino M.; Terada T.; Haginomori SI. Operative technique for benign submandibular gland mass without identifying the mandibular branch of the facial nerve. *Auris Nasus Larynx 45 (2018) 1221–1226*
10) House, J.W.; Brackmann, D.E. Facial Nerve Grading System. *Otolaryngol. Adv Otorhinolaryngol* 2016:78:46-52. doi: 10.1159/000442124. Epub 2016 Apr 12.
11) A. Sanfurgo De Carvalho; R. Aperecido Dedivitis; M.A. Ferrari De Castro.Submandibular gland excision. Ressecção da glândula submandibular *Rev. Col. Bras. Cir. 2015; 42(1): 014-017*
12) Wu C.W., Dionigi G., Barczynski M., Chiang F.Y., Dralle H., Schneider R., Al-Quaryshi Z., Angelos P., Brauckhoff K., Brooks J.A. International neuromonitoring study group guidelines 2018: Part II: Optimal recurrent laryngeal nerve management for invasive thyroid cancer—Incorporation of surgical, laryngeal, and neural electrophysiologic data. Laryngoscope. 2018;128:S18–S27. doi: 10.1002/lary.27360
13) Schneider R., Randolph G.W., Dionigi G., Wu C.W., Barczynski M., Chiang F.Y., Al-Quaryshi Z., Angelos P., Brauckhoff K., Cernea C.R. International neural monitoring study group guideline 2018 part I: Staging bilateral thyroid surgery with monitoring loss of signal. Laryngoscope. 2018;128:S1–S17. doi: 10.1002/lary.27359.
14) Wilson L, Lin E, Lalwani A. Cost-effectiveness of intraoperative facial nerve monitoring in middle ear or mastoid surgery. Laryngoscope. 2003;113:1736-1745
15) Duque, C.S.; Londono, A.F.; Duque, A.M.; Zuleta, J.J.; Marulanda, M.; Otálvaro, L.M.; Agudelo, M.; Duenas, J.P.; Palacio, M.F.;Dionigi G. Facial nerve monitoring in parotid gland surgery: Design and feasibility assessment of a potential standardized technique. *World J. Otorhinolaryngol.Head Neck Surg.* ***2023****, 9, 280–287*
16) Zieli ’ nski, M.; Sowa, P.; Adamczyk-Sowa, M.; Szl˛ezak, M.; Misiołek, M. Assessment of Intraoperative Facial Nerve Monitoring in Patients Undergoing Partial Parotidectomy. *BioMed Res. Int. 2022, 2022, 3318175*
17) Lin B., Lu X., Shan X., Zhigang L. and Cai Z. Preoperative percutaneous nerve mapping of the mandibular marginal branch of the facial nerve. *J Craniofac Surg.* 2015 Mar;26(2):411-4. doi: 10.1097/SCS.0000000000001408.