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HEAD AND NECK

Effects of an antiadhesive agent on functional recovery of the greater auricular nerve after parotidectomy: a double-blind randomized controlled trial

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Abstract

Purpose Periauricular sensory deficit occurs frequently after parotidectomy even in cases with preservation of the greater auricular nerve (GAN). This study was performed to evaluate the effects of antiadhesive agent in functional recovery of the GAN after parotidectomy.

Methods Ninety-eight patients undergoing partial parotidectomy for benign parotid tumors were prospectively enrolled in this multicenter, double-blind randomized controlled study and randomly assigned to either the study or control group. Antiadhesive agent was applied in the study group. The results of sensory tests (tactile, heat, and cold sensitivity) and a questionnaire on quality of life (QoL) were acquired at postoperative 1, 8, and 24 weeks after surgery. Clinical parameters, and the results of the sensory tests and the questionnaire, were compared between the two groups.

Results A total of 80 patients were finally enrolled. On sensory evaluation, tactile sensation and warm sensation in the ear lobule, and warm sensation in the mastoid area, showed significant improvement at 24 weeks postoperatively in the study group. There were no significant differences between the two groups on any questions in the QoL questionnaire, at any follow-up time point.

Conclusions Antiadhesive agents have some positive effects on functional recovery of the GAN after parotidectomy. Therefore, applying antiadhesive agents after parotidectomy can reduce discomfort in patients.

Keywords Adhesion · Sensation · Neoplasm · Parotidectomy

Introduction

Parotid surgery is commonly performed for benign and malignant neoplasms, as well as inflammatory and autoimmune conditions. The most important complication that surgeons are concerned with is facial palsy. However, in clinic, the most frequent postoperative complaint of patients is sensory disturbance around the postauricular, preauricular, and lobular areas due to greater auricular nerve (GAN) injury. Traditionally, the GAN is amputated at the inferior margin of the parotid gland during parotidectomy. This technique secures easy access to the parotid gland and prevents the spread of tumor cells [1].

A number of cases of sensory loss have been reported after sacrifice of the GAN, including discomfort when wearing earrings or shaving, and after suffering a burn injury [2, 3]. Although contradictory results have been reported in different studies, and the evidence supporting preservation of the GAN in head and neck surgery remains a matter of debate, several randomized controlled studies and meta-analyses indicated that preservation of the GAN minimizes postoperative sensory disturbance and should be considered as long as tumor clearance is not compromised [4–6].

However, even when preserved, GAN dysfunction can occur due to various reasons such as stretching of the nerve or ischemia. Besides these reasons, extraneural scarring resulting from perineural adhesion can also cause nerve

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dysfunction. Perineural adhesion causes chronic compression or tethering of the nerve to the surrounding tissue, which can in turn cause traction injury and vasospasm of the intraneural vessel. This may lead to ischemia of the nerve, irreversible nerve injury and failure of functional regeneration of the nerve [7, 8]. Therefore, adhesion is recognized as an important complication in the field of peripheral nerve surgery, and various antiadhesive agents have been used to treat it. However, no studies have attempted to identify the effects of antiadhesive agents on the GAN after parotidectomy. This study was performed to determine the effects of antiadhesive agents on functional recovery of the GAN after parotidectomy.

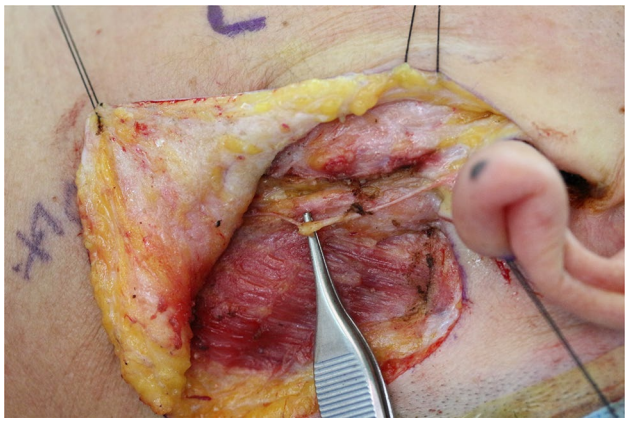

Fig. 1 Intraoperative photograph of preserved greater auricular nerve (GAN)

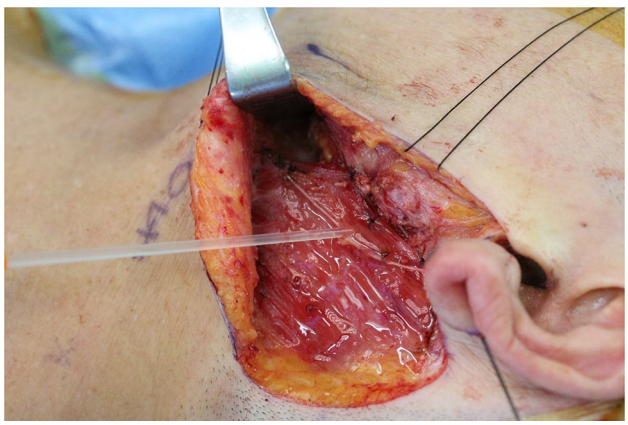

Fig. 2 Intraoperative photograph of application of the antiadhesive agent to the GAN and surrounding areas

Materials and methods

Study design

This was a multicenter double-blind randomized controlled study. The study protocol was registered, reviewed, and approved by the Clinical Research Information Service (CRIS) of the National Research Institute of Health of the Korean government (CRIS registration No. KCT002026, trial No. XC15DIMI0085K). Five head and neck surgeons from five different hospitals affiliated with the Catholic University of Korea participated in this study. Between September 2016 and January 2018, 98 patients older than 18 years, undergoing partial parotidectomy for benign salivary gland tumors and consenting to participate in the clinical trial, were initially enrolled in this study. Bilateral parotid gland tumors, diagnosis of malignant tumors before and after surgery, undergoing chemotherapy or irradiation of the head and neck region, a history of injury close to the auricle, and central/peripheral nervous disease or psychiatric disease were the exclusion criteria. After enrollment, patients were dropped from the study if they elected to stop participating in the trial at any time, if the pathology report revealed malignancy after parotidectomy, or if any adverse response occurred. Following approval by the Institutional Review Board of The Catholic University of Korea, Seoul, Korea, all patients provided written informed consent to participate in the study. Patients were randomized into the study group or control group using a web-based randomized allocation protocol. Randomization was performed after completion of hemostasis and before wound closure. Each surgeon opened the allocation envelope after hemostasis at the end of surgery. Therefore, surgeons did not know the patient group assignments, thus avoiding any bias. No information regarding randomization was provided to the patient or sensory examiner, in accordance with the double-blind study protocol. Partial parotidectomy was performed by five head and neck surgeons. However, the posterior branch of the GAN was carefully preserved during surgery in all cases (Fig. 1), and a Jackson-Pratt drain was uniformly inserted into the surgical wound to calculate the amount of discharge. Antiadhesive agent (Mediclore®; Daewoong Pharmaceutical, Korea) was applied to the GAN and surrounding areas in the study group patients just before wound closure, whereas no agent was applied to the patients in the control group (Fig. 2). After surgery, tumor volume (calculated as horizontal diameter × vertical diameter × height on pathology report; cm^3) and total amount of drainage (mL) were calculated.

The enrolled patients visited the clinic five times during the clinical trial. The first visit occurred at any time within 8 weeks before surgery. The second visit was on the day of the operation. The third, fourth, and fifth postoperative follow-up visits were at 1, 8, and 24 weeks after surgery, respectively. At each visit, the patients underwent history-taking, including previous medical disease and medications, and vital signs were also checked. During the follow-up period (third, fourth, and fifth visits), patients underwent

sensation check and adverse response checks, and were asked to complete the questionnaire on quality of life (QoL). An overview of the study schedule is presented in Table 1.

Sensory checks and questionnaire

Sensory checks were performed by designated ear, nose, and throat (ENT) doctors of each hospital, who were blinded to the results of randomization. The examiners were not involved in the operation, but only in the work performed when the patient visited the clinic, such as history-taking, sensory check, completing the questionnaire, etc. Tactile sensation and thermal sensitivity were evaluated. We divided the skin innervated by the GAN into seven areas: (1) preauricular superior; (2) preauricular inferior; (3) angle of the mandible; (4) helix and concha; (5) ear lobule; (6) retroauricular area; and (7) mastoid-lateral neck (Fig. 3) [9]. Sensory check was performed first on the healthy non-operated side and subsequently on the operated side. Sensitivity on the operative side was classified as follows: class 0, no sensitivity; class 1, reduced sensitivity; and class 2, normal sensitivity compared to the non-operated side.

Tactile sensitivity was tested using a monofilament esthesiometer (Gillis W. Long Hensenis Disease Center, Carville, LA) by pressing the center of each area with the tip of the filament. Cold sensitivity was tested by holding the finger of a latex glove filled with iced water against the center of each area. Heat sensitivity was evaluated using the tip of a steel spoon warmed in boiling water for 5 s and left for 15 s at room temperature until reaching 45 °C. Each area was tested twice consecutively for tactile, cold, and heat sensitivity and then compared to the contralateral area.

At the end of the sensory evaluation, a QoL questionnaire was administered (Fig. 4). We used the Korean translation of the questionnaire, validated by Patel et al. [10]. This questionnaire, consisting of eight questions, was designed to measure outcomes after GAN sacrifice during parotidectomy. Question 1 is a multiple choice question on the nature of discomfort felt by the patient. Question 7 is an open question regarding how the discomfort interferes with the patient's daily life. All other questions deal with the severity of patients' subjective discomfort and its effect on QoL. A 7-point ordinal response scale was used for questions to ensure high reliability, where a low score indicates less severe, shorter duration pain or discomfort that has only a minor impact on daily life.

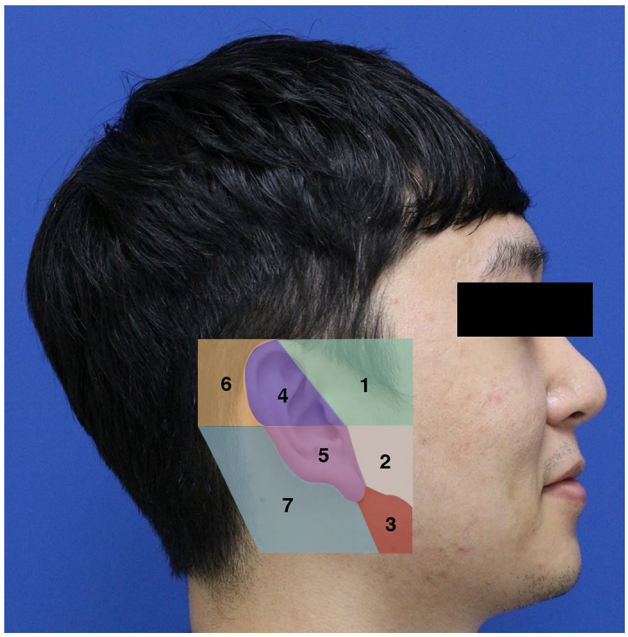

Fig. 3 Division of the auricle and periauricular areas innervated by the GAN. (1) Preauricular superior area (2) preauricular inferior area (3) angle of the mandible (4) helix and concha (5) lobule (6) retroauricular area (7) mastoid area

Statistical analysis

Statistical analysis was performed using SPSS software (version 14.0; SPSS Inc., Chicago, IL). The Chi-square test and

Table 1 Overview of the study schedule

	Visit 1 screening	Visit 2 operation	Visit 3 Post-op 1 week	Visit 4 Post-op 4 week	Visit 5 Post-op 24 week
Informed consent	O				
History-taking	O				
Randomization		O			
Apply antiadhesive agent		O			
Vital sign check	O	O	O	O	O
Sensory check			O	O	O
Questionnaire			O	O	O
Check for adverse events		O	O	O	O
Drainage amount check		O			

Fig. 4 Quality of life questionnaire validated by Patel et al. [12]

Thank you for taking the time to answer the following questions regarding your parotid surgery. Please answer as accurately as possible.

1) Please check any of the following sensations you may be experiencing around your ear or neck since your surgery.

- ❑ Stinging
- ❑ Abnormal sensation
- ❑ Burning
- ❑ Lack of feeling
- ❑ Pain
- ❑ Lack of sensitivity
- ❑ Discomfort
- ❑ Hypersensitivity

If you did not check any of the above, you may stop here.
Otherwise, please complete the remainder of the survey.

2) How often have you experienced any of the above sensations within the past month?

1- Never
2- Almost none of the time
3- A little bit of the time
4- Some of the time
5- A good bit of the time
6- Most of the time
7- Always

3) How long does it last?

1- Up to 1 minute
2- Up to 10 minutes
3- Up to 30 minutes
4- Up to 60 minutes
5- Up to 12 hours
6- More than 1 day
7- All the time

4) How much does it bother you?

1- Not at all
2- Almost none
3- A little
4- Somewhat
5- A good amount
6- A lot
7- A tremendous amount

5) How large is the affected area?

1- Smaller than the size of a penny
2- About the size of a penny
3- About the size of a quarter
4- About the size of a half-dollar
5- Larger than the size of a half-dollar

6) How much does it interfere with your daily activities?

1- Not at all
2- Almost none
3- A little
4- Somewhat
5- A good amount
6- A lot
7- A tremendous amount

7) How does it interfere with your daily activities? (shaving, combing your hair, etc.)

8) How often are you worried or concerned about any of the above sensations?

1- Never
2- Almost never
3- A little bit of the time
4- Some of the time
5- A good bit of the time
6- Most of the time
7- All of the time

independent *t* test or Mann–Whitney *U* test was used to compare the sensory scores of each subsite, and the questionnaire scores, between the study and control groups at each postoperative time point. Continuous variables are expressed as the mean ± standard deviation, and $P < 0.05$ was taken to indicate statistical significance.

Results

Among the 98 patients initially enrolled, 80 finally completed the follow-up and were included in the analysis. Among the 18 patients dropped from the study, 11 were excluded after enrollment due to malignant pathology after surgery, and 7 dropped out of the trial voluntarily during the follow-up period. The 80 patients included in the analysis consisted of 55 males and 25 females with a mean age of 53.75 ± 13.19 years (range 21–79 years). The study group consisted of 46 patients (57.5%) and the control group had 34 patients (42.5%). The most common pathologies were pleomorphic adenoma (52.5%) and Warthin's tumor (35%). Most patients underwent parotidectomy via modified facelift incision (57 patients, 71.3%) followed by modified Blair incision ($n = 20$, 25%) and single cervical transverse incision ($n = 3$, 3.8%). The mean tumor volume was 15.34 ± 22.91 cm^3 (range 0.39–168.0 cm^3). Sex distribution, age, pathology,

incision, tumor volume, and drainage amount were not significantly different between the two groups. Demographic characteristics are summarized in Table 2.

On sensory evaluation, improvements in tactile sensation and warm sensation in the ear lobule, and warm sensation in the mastoid area at 24 weeks postoperatively were greater in the study group than the control group. Other areas showed no significant differences in tactile, cold, or warm sensation between the two groups at any follow-up time point (Table 3).

According to the questionnaire survey, the most common symptom associated with GAN injury after parotidectomy was "lack of feeling" (154 responses), followed by "discomfort" (83 responses), "abnormal sensation" (79 responses), "stinging" (71 responses), "lack of sensitivity" (68 responses), "pain" (33 responses), and "hypersensitivity" (6 responses). Analysis according to groups showed similar results (Table 4). Questions scored using the 7-point ordinal scale (questions 2, 3, 4, 5, 6, and 8) showed gradual improvement of patients' subjective symptoms in both groups (Fig. 5). However, there were no significant differences in responses to any questions between the two groups at any follow-up time point (Table 5).

Discussion

GAN is the largest superficial branch of the cervical plexus, providing sensory innervation to the skin overlying the parotid gland, external ear, and posterior auricular region. The cervical plexus gives rise to multiple superficial cutaneous branches in addition to the GAN, including the lesser occipital, transverse cutaneous, and supraclavicular nerves, generally originating from the posterior aspect of the sternocleidomastoid muscle (SCM) into the so-called Erb's point. The GAN arises from the anterior branch of the second and third cervical nerves or directly from the latter, passes around the posterior margin of the SCM, and ascends from the muscle to divide into the posterior and anterior branches at the inferior margin of the parotid gland [11]. The anterior branch passes through the inferior pole and innervates the skin of the face and the angle of the mandible that covers the parotid gland. The posterior branch travels from the rear boundary of the parotid gland through subcutaneous tissue to the mastoid process and the posteroinferior surface of the auricle. It controls skin sensation in the auricle, through which fine branches pass to reach the collateral part of the auricle, innervating the ear lobule and concha [12]. Sensory

Table 2 Demographic data

Characteristics	Control group ($n=34$)	Study group ($n=46$)	P value
Sex			0.478
Male	24 (70.6%)	31 (67.4%)	
Female	10 (29.4%)	15 (32.6%)	
Age (years)	53.03 ± 13.71	54.28 ± 12.92	0.907
Tumor volume (cm^3)	14.23 ± 17.11	16.15 ± 26.41	0.234
Drainage amount (mL)	57.91 ± 54.31	66.15 ± 62.45	0.452
Incision			0.715
Modified facelift	23 (67.6%)	34 (73.9%)	
Modified Blair	10 (29.4%)	10 (21.7%)	
Transverse	1 (2.9%)	2 (4.3%)	
Pathology			0.513
Pleomorphic adenoma	18 (52.9%)	24 (52.2%)	
Warthin's tumor	14 (41.2%)	14 (30.4%)	
Basal cell adenoma	0	2 (4.3%)	
Intraparotid lymph node	1 (2.9%)	1 (2.2%)	
Salivary duct cyst	0	2 (4.3%)	
Branchial cleft cyst	1 (2.9%)	0	
Lymphoepithelial cyst	0	1 (2.2%)	
Lymphangioma	0	1 (2.2%)	
Oncocytic cystadenoma	0	1 (2.2%)	
Wound complication			
Infection	1 (2.9%)	0	0.242
Seroma	3 (8.8%)	4 (8.7%)	0.984
Wound dehiscence	0	1 (2.2%)	0.387
Bleeding or hematoma	1 (2.9%)	1 (2.2%)	0.828

Table 3 Comparison of sensory scores for each subsite and follow-up period between the two groups

Area	Sensation	Postoperative follow-up period (weeks)	*P* value
Preauricular superior	Tactile	1	0.948
		4	0.253
		24	0.246
	Warm	1	0.539
		4	0.250
		24	0.564
	Cold	1	0.192
		4	0.118
		24	0.521
Preauricular inferior	Tactile	1	0.778
		4	0.677
		24	0.492
	Warm	1	0.223
		4	0.621
		24	0.259
	Cold	1	0.819
		4	0.662
		24	0.198
Angle of the mandible	Tactile	1	0.245
		4	0.421
		24	0.281
	Warm	1	0.369
		4	0.310
		24	0.281
	Cold	1	0.331
		4	0.289
		24	0.311
Helix and concha	Tactile	1	0.226
		4	0.229
		24	0.119
	Warm	1	0.645
		4	0.382
		24	0.803
	Cold	1	0.250
		4	0.298
		24	0.401
Ear lobule	Tactile	1	0.070
		4	0.069
		24	0.029*
	Warm	1	0.192
		4	0.097
		24	0.002*
	Cold	1	0.815
		4	0.244
		24	0.193
Retroauricular area	Tactile	1	0.813
		4	0.411
		24	0.262
	Warm	1	0.616
		4	0.170
		24	0.128
	Cold	1	0.252
		4	0.193
		24	0.244
Mastoid	Tactile	1	0.331
		4	0.170
		24	0.118
	Warm	1	0.148
		4	0.063
		24	0.005*
	Cold	1	0.077
		4	0.397
		24	0.178

*$P < 0.05$

loss due to damage of the GAN not only creates discomfort, but can also lead to injury as a result of the lack of pain signaling as a defense mechanism [2, 3].

When performing parotidectomy, the anterior branch of the GAN is typically amputated at the inferior margin of the SCM. The posterior branch of the GAN can be either mobilized and preserved or sacrificed to expose the posterior and inferior aspects of the gland [13]. In cases with preservation and mobilization of the posterior branch of the GAN, this nerve should be dissected off from the surrounding tissues, and retracted during surgery to secure an adequate surgical field. This procedure causes neuropraxia, resulting in hypoesthesia or anesthesia of the innervated areas. The degree and area of sensory deficit generally seem to decrease every 3 months during the first year, with most patients showing no anesthesia after 12 months [14]. However, a long-term follow-up study indicated that sensory deficits commonly last longer despite GAN preservation [9].

Functional recovery after peripheral nerve injury is sometimes unsatisfactory. Several factors are responsible for incomplete recovery, including extraneural scarring and perineural adhesion. There have been attempts to reduce epineural scarring and peripheral adhesion after peripheral nerve surgery in the fields of plastic and orthopedic surgery, and many studies have reported positive effects of various antiadhesive agents on functional recovery after peripheral nerve injury. In an animal study, use of hyaluronic acid-carboxymethylcellulose membrane as an antiadhesive showed favorable effects in terms of reducing extraneural adhesion and promoting nerve regeneration in rabbits at 3 months

Table 4 Summary of questionnaire scores regarding subjective symptoms associated with GAN injury

Postoperative week	Stinging			Abnormal sensation			Lack of feeling			Pain			Lack of sensitivity			Discomfort			Hypersensitivity		
	1	8	24	1	8	24	1	8	24	1	8	24	1	8	24	1	8	24	1	8	24
Control group	11	15	13	14	8	9	27	27	17	8	3	4	18	14	2	18	17	5	0	0	1
Study group	9	14	9	22	12	14	32	27	24	12	3	3	20	10	4	21	14	8	2	2	1
Total	20	29	22	36	20	23	59	54	41	20	6	7	38	24	6	39	31	13	2	2	2

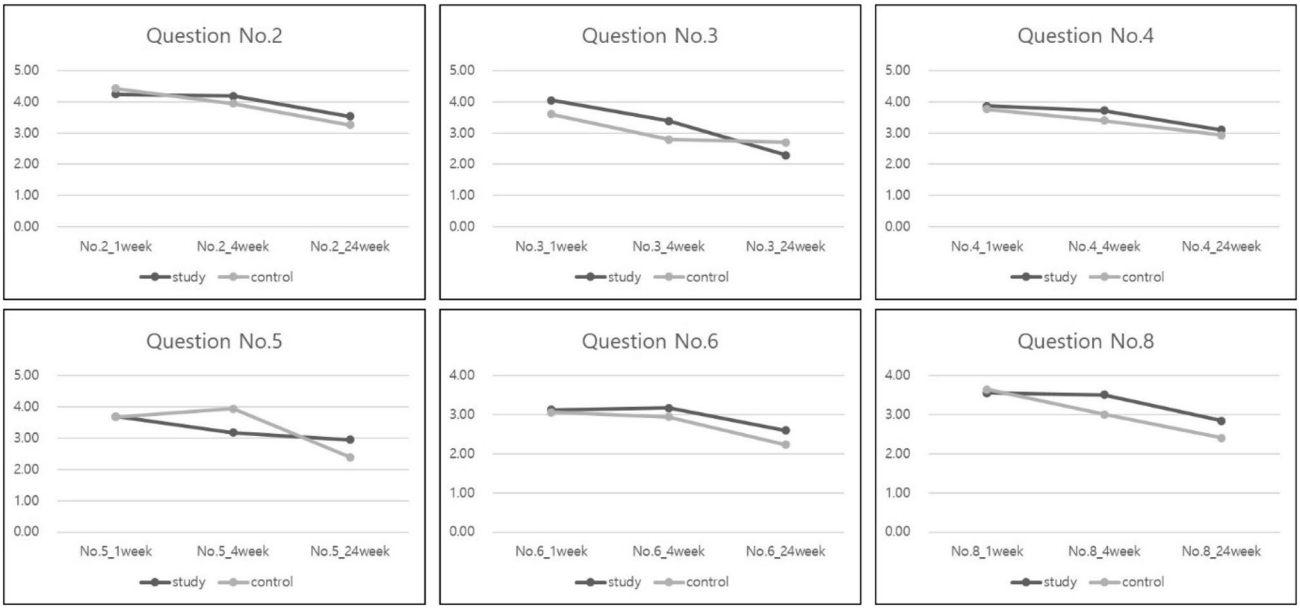

Fig. 5 Temporal trends of questions with ordinal response data. Mean values for each follow-up period are shown

after sciatic nerve repair [15]. In the field of nerve surgery, antiadhesive agents act as physical barriers and can reduce peripheral nerve adhesion and epidural fibrosis, and promote functional nerve regeneration [16–18]. Based on these findings, we applied antiadhesive agent to the GAN after parotidectomy. There have been no previous reports regarding the effects of antiadhesive agents on functional recovery of the GAN after parotidectomy.

The results of this study revealed positive effects of antiadhesive agent on the GAN after parotidectomy. Among seven subsites and three different sensations, tactile sensation and warm sensation in the ear lobule and warm sensation in the mastoid area showed significant improvement at 24 weeks postoperatively. Preauricular and mastoid areas (areas 1–3 in Fig. 3) are innervated by the anterior branch of the GAN, and this branch is almost always sacrificed during parotidectomy. It was clear that these areas did not show sensory improvement in either group. Among the areas innervated by the posterior branch of the GAN, sensory recovery in the ear lobule was most prominent in this study. In daily practice, when evaluating patients after parotidectomy, one of the main types of discomfort reported is sensory loss at the ear lobule. In addition, a previous study comparing sensation between GAN preservation and sacrifice indicated that the most significant difference in sensation occurred in the lobular region [5]. Therefore, our results showing significant improvement at 6 months postoperatively in tactile and warm sensation in the lobular region in patients treated with antiadhesive agent are important.

The questionnaire results indicated that the most frequent complaint among patients after GAN injury was “lack of feeling” in both groups. In serial analysis, the scores on the questionnaire showed improvement in both groups, indicating that subjective symptoms improved over time regardless of the use of the antiadhesive agent. There was no significant difference in QoL between the two groups at any follow-up time point. This may have been because significant sensory recovery occurred only in selected areas (lobule and mastoid area) and for certain types of sensations (tactile and warm sensation) at 6 months. Other studies indicated no significant difference in QoL between patients with sacrifice compared to preservation of the GAN [19–21]. Therefore,

Table 5 Comparison of mean questionnaire scores for each follow-up time point between the two groups

Question number, time point	Study group	Control group	*P* value
2, 1 week	4.24	4.42	0.641
2, 4 weeks	4.18	3.94	0.457
2, 24 weeks	3.53	3.26	0.715
3, 1 week	4.05	3.59	0.851
3, 4 weeks	3.38	2.79	0.777
3, 24 weeks	2.29	2.70	0.551
4, 1 week	3.86	3.76	0.156
4, 4 weeks	3.71	3.39	0.196
4, 24 weeks	3.09	2.93	0.465
5, 1 week	3.68	3.67	0.099
5, 4 weeks	3.17	3.93	0.492
5, 24 weeks	2.94	2.39	0.500
6, 1 week	3.12	3.06	0.587
6, 4 weeks	3.16	2.94	0.590
6, 24 weeks	2.59	2.23	0.238
8, 1 week	3.55	3.64	0.229
8, 4 weeks	3.50	3.00	0.146
8, 24 weeks	2.84	2.40	0.134

despite functional recovery of the GAN, use of the antiadhesive agent had no effect on patients' QoL.

There was no difference in total amount of drain between the two groups. Although the same partial parotidectomy was performed, five different surgeons participated in this study, and the tumor volume and extent of surgery differed in all cases. Therefore, comparison of the total amount of drainage may not be meaningful. However, as the mean tumor volume was not significantly different between the two groups, the effects of antiadhesive agent on bleeding control and the amount of discharge could be assessed and were found to be minimal. There were no adverse reactions or complications related to application of the antiadhesive agent in any of the patients, at any follow-up time point. Therefore, the antiadhesive agent can be applied safely in patients with parotidectomy.

To our knowledge, this is the first study to evaluate the effects of antiadhesive agent on functional recovery of the GAN after parotidectomy. Although only observed in selected areas at 6 months after surgery, the antiadhesive agent had a positive effect on functional recovery of the GAN and reduced postoperative discomfort. Although we did not directly evaluate the degree of adhesion of the GAN or the antiadhesive effect of the agent (which would have been impossible), considering the results of other studies evaluating the antiadhesive effects of antiadhesive agents in nerve surgery, it was assumed that our positive results were due to the antiadhesive effect of the antiadhesive agent, which prevented perineural adhesion and enhanced functional regeneration of the GAN.

This study was limited by the relatively short follow-up period (6 months). Previous long-term follow-up studies indicated that sensory morbidity was improved even after 1 year [9, 19, 22]. Further studies with longer follow-up periods would allow more precise determination of the effect of antiadhesive agents on functional recovery of the GAN after parotidectomy.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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