Original Article - Retrospective Study

Clinical evaluation of coverage of open wounds: Polyglycolic acid sheet with fibrin glue spray vs split thickness skin

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ABSTRACT

Purpose: This study aimed to evaluate the coverage of oral wounds using either a polyglycolic acid (PGA) sheet or split-thickness skin grafting (STSG). **Materials and Methods:** A total of 119 cases of wound coverage using a PGA sheet and fibrin glue spray as well as 132 cases of wound coverage cases using STSG were reviewed retrospectively. The site of the excision area, perioperative conditions, and postoperative functional problems were evaluated. **Results:** The PGA group had significantly shorter operation time, earlier start of oral intake, and shorter hospitalization than the STSG group. If the PGA sheet over the wound with exposed bone could be protected by a surgical sprint, oral food intake could be started on the day after surgery at the earliest. When the size of the wound in the buccal excisional area was classified into two groups (<6 or ≥6 cm^2), mouth opening in the STSG group was significantly larger at 3 months postoperatively. When the size of the wound in the tongue and floor of mouth was classified into two groups (<12 or ≥12 cm^2), the STSG group had a significantly higher score in postoperative speech intelligibility. **Conclusion:** Selection of a PGA sheet or STSG based on the consideration of defect size, tumor location, patients' local and general condition and tolerance for surgery could reduce the patients' postsurgical dysfunctional problems.

Keywords: The second operation for tumor recurrence, exposed bony wound, higher aged patients, intraoral surgical defect, oral mucosa, polyglycolic acid sheet, split-thickness skin grafting

INTRODUCTION

At our hospital, the Department of Oral Surgery, Tokyo Medical and Dental School Hospital, we selected polyglycolic acid (PGA) sheet or split-thickness skin grafting (STSG) for covering surgical wounds. However, the sectional evidence was empirical standard based on the reported advantages and our experience of each case. To the best of our knowledge, there are no reports involving a large number of cases on the criteria for selecting a PGA sheet or STSG for the coverage of surgical wounds. In this study, we compared the locations, size of the surgical wound, perioperative course, and postoperative oral functional problems in patients whose surgical wound was covered by either a PGA sheet or STSG. Thus, we evaluated the clinical features of these cases and discussed the selection criteria of the two methods.

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BACKGROUND

Where primary closure of intraoral defects is not possible, pedicle, or free flaps is useful. Alternatives such as mucosal grafts, or skin grafts, are less ideal due to the formation of contractures, which lead to functional disabilities.[1] For oral cavity reconstruction, STSG has been the gold standard for managing medium-sized defects.[2]

STSG have gained popularity as a reconstructive option for defects of the oral mucosa because of the ease of harvesting from a distant site (usually the thigh), the large quantities of skin available for grafting, and better graft survival than a mucosal graft or full-thickness skin graft, due to its thinness.[3] Unfortunately, there are some disadvantages of STSG. It requires additional operating time[3] and the donor site heals by secondary intention with healing taking several weeks.[3] Coverage with STSG necessitates the use of a large tie-over gauze over the wound, which obstructs oral intake.[3]

PGA sheets consist of a nonwoven membrane of polyglactin acid (a homopolymer with a molecular weight of 100,000 dalton). It is fabric that acquires elastic soft properties through a special process. The PGA sheet (Neoveil, Gunze Co., Ltd., Tokyo, Japan) is attached with fibrin glue derived from human blood (Bolheal, Chemo-sero-Therapeutic Research Institute, Kumamoto, Japan).[4] Recently, in the liver and lung surgery, the PGA sheets have been used to cover wounds and prevent bleeding and leakage[5-8] and this method has also been applied for wound coverage in the oral region. There were only a few previous studies involving < 10 cases of the application of a PGA sheet for soft tissue repair such as repair of the upper gingiva,[9,10] lower gingiva,[5,9,10] floor of mouth,[5] buccal mucosa,[5,9] soft and hard palate,[5,9,10] and at the most, 30 cases of coverage of a lingual surgical defect.[1,11,12] Evaluation and analysis of the defect size in studies on a PGA sheet varied among researchers. Rokutanda *et al*. suggested that further controlled studies involving a larger number of patients were needed to confirm the effectiveness of a PGA sheet.[10]

MATERIALS AND METHODS

Patients

A retrospective review of diagnosed patients who underwent oral surgery and wound coverage by a PGA sheet or STSG at the Department of Oral Surgery, Tokyo Medical and Dental School Hospital between April 2001 and February 2016 was conducted. The protocol of this research was approved by our institution and all patients provided informed consent. The study was in accordance with the Declaration of Helsinki. We excluded cases with unclosed orosinusal communications associated with maxillectomy. We also excluded in this study five cases of the hard palate which were left to heal by secondary intention without any covering methods.

We only performed STSG for all the oral surgical defect which was so large that primary closure was not possible yet it did not require pedicle or free flap transplantation before 2010. After 2010, we selected mainly STSG if postoperative severe scar contracture and dysfunctional problems such as speech disability and reduction of mouth opening were anticipated. We also mainly used a PGA sheet with fibrin glue to cover localized exposed bony wounds, the cases which already had observed severe scar contracture and severe trismus that was predicted potential difficulty in STSG via intraoral approach, the cases which have problems in general condition and tolerance for surgery and for the cases that declined STSG after 2010.

Polyglycolic acid sheet and fibrin glue spray protocol

The PGA group protocol was similar to those reported by Takeuchi *et al*.[1] and Shinozaki *et al*.[5] During the preoperative informed consent process, we explained to each patient the risk of blood-borne diseases with the use of fibrin glue.

After achieving wound hemostasis, a small amount of fibrin glue (fibrinogen) was sprayed onto the wound. Next, the wound was covered with a PGA sheet which had been cut to the same size as the resected area, and a mixture of fibrin glue and thrombin was sprayed onto the sheet and the surrounding area using a specialized spray kit. All operations were performed by expert oral surgeons (n = 7).

Postoperatively, the patient was fed through a nasal tube to prevent the sheet from dislodgement. If the PGA sheet could be protected with a surgical splint, the patient started oral intake shortly after the surgery. Healing started from around the wound edges, and the PGA sheet peeled off at the epithelized portion. The peeled PGA sheet was cut off.

Split-thickness skin grafting protocol

The STSG protocol was based on that described by Chick.[13] Tissue (0.015 inches thick) was harvested from the anterior upper thigh, and the donor site was covered with gauze, which was left in place for an average of 3 weeks until epithelialization occurred. The basement membrane of the harvested skin faced the surgical wound, and it was sutured. Medicated gauze was used to compress and fix the grafted skin. Postoperatively, the patient was fed through a nasal tube, and oral intake was started after the medicated gauze was removed.

Analysis

All clinical data such as tumor type, location, operation time, volume of intraoperative bleeding, number of days of use of pain relievers, number of postoperative days before the start of oral intake, and hospitalization time were obtained from the patient's medical records.

The lengths (major and minor axes) were obtained from the patient's medical records and pathological reports of the surgical specimen. The excision area (cm^2) was calculated using the formula proposed by previous studies:[1,9] major length (cm) × minor length (cm) × $\pi/4$ of the surgical specimen.

To assess postoperative functional problems, we evaluated the mouth opening in the postoperative period before (approximately 2 weeks) and after hospital discharge (approximately 3 months) in buccal excision cases. For lingual and floor of mouth excision cases, postoperative speech intelligibility was evaluated.

Speech intelligibility

Speech intelligibility was evaluated using Furuya's speech articulation test.[14] Each patient pronounced 100 Japanese syllables that were listed randomly on a test sheet and five listeners who were unfamiliar with the patient assessed each pronunciation attempt. Speech intelligibility scores are expressed as mean percentages of correct responses recorded by the five listeners.

Statistics

Continuous data were compared between the PGA and STSG groups using ANOVA, Mann–Whitney U-test and Kruskal–Wallis test. Categorical data were analyzed with an m × n Chi-squared test and Fisher's test. The value of $P < 0.05$ was considered statistically significant.

RESULTS

We included 205 patients (108 men, 97 women) who received a PGA sheet or STSG. Wound closure was performed with a PGA sheet and fibrin glue spray in 119 cases (58 men, 61 women) or with STSG in 132 cases (74 men, 58 women). In 25 of 119 cases of the PGA sheet coverage and 35 of 132 cases of STSG, the procedures were performed for repeated surgeries for the same patient who had tumor recurrences or multiple carcinomas of the oral mucosa. Median age at the time of surgery in the PGA and STSG groups was 70.0 years (range, 24–93 years) and 69 years (range, 21–90 years) ($F = 0.47$, $P = 0.49$).

Tumor type in excised specimens

The type of tumor at excision sites that were covered with the PGA sheet and fibrin glue spray were leukoplakia (22 cases), benign tumor (13 cases, comprising 9 cases of pleomorphic adenoma, and 1 case each of myoepithelioma, pigmented nevus, cavernous hemangioma, and papilloma), and squamous cell carcinoma (SCC) (84 cases).

The type of tumor at excision sites covered with STSG were leukoplakia (19 cases), benign tumor (5 cases, comprising 3 cases of fibrous hyperplasia, and 1 case each of desmoid-type fibromatosis, and pleomorphic adenoma), and 108 cases of SCC.

Tumor location

The most common location of a PGA sheet and fibrin glue spray coverage was the hard palate (30/119 cases, 25.2%), followed by the lower gingiva (22/119 cases, 18.5%). The most common location of STSG was the buccal mucosa (44/132 cases, 33.3%), followed by the lower gingiva (38/132 cases, 28.8%). Hard palate lesions were covered with only a PGA sheet and fibrin glue spray. The distributions of the locations are shown in Table 1.

Differences in the mean size of excision area between the polyglycolic acid and split-thickness skin grafting groups

The mean size of the excision area is shown in Table 2. Except for soft palate lesions, the excision areas that received STSG was significantly larger than those covered by a PGA sheet (ANOVA, $F = 9.78$, df = 1; $P < 0.01$). In terms of tumor site, buccal cases covered with STSG were larger than those covered by a PGA sheet (ANOVA, $F = 5.33$, df = 1; $P = 0.02$).

Differences in operation time, volume of bleeding during surgery, number of days of use of pain relievers, numbers of postoperative days before start of oral intake, and hospitalization time

Differences in operation time, volume of bleeding during surgery, number of days of use of pain relievers, number of postoperative days before start of oral intake, and hospitalization time were compared between the PGA and STSG groups [Table 3].

Table 1: Tumor location

	PGA group (*N*=119)	STSG group (*N*=132)
Tumor location		
Tongue	18	20
Floor of mouth	7	22
Lower gingiva	22	38
Upper gingiva	18	4
Buccal mucosa	21	44
Hard palate	30	0
Soft palate	3	4

N=Number of the cases

Table 2: The mean size of the excision area covered by PGA or STSG (*N*=251)

	Excision area (cm²) Mean±SD (*n*)		*p*
	PGA group (*N*=119)	STSG group (*N*=132)	
Tumor location			
Tongue	8.80±6.89 (18)	11.77±5.80 (20)	0.17
Floor of the mouth	12.30±5.87 (7)	12.69±4.92 (22)	0.86
Lower gingiva	8.17±5.18 (22)	11.02±5.26 (38)	0.09
Upper gingiva	10.96±7.04 (18)	8.34±3.16 (4)	0.48
Buccal mucosa	7.10±5.30 (21)	10.22±4.88 (44)	0.02*
Hard palate	7.23±5.41 (30)	No cases	-
Soft palate	10.79±15.90 (2)	9.06±2.14 (4)	0.83

SD=Standard deviation; N=Number of the cases; *=Statistically significant

Table 3: Comparison of operative time, volume of bleeding during surgery, number of days of NSAID use postoperatively, number of days before start of oral intake, and length of hospitalization between PGA and STSG groups

	PGA group (*N*=119) Mean±SD	STSG group (*N*=132) Mean±SD	*P*
Variable			
Operation time (hours)	1.25±0.86	2.22±1.04	<0.01*
Volume of bleeding during surgery (ml) Median (range)	40.10±22.50	52.11±4.59	0.35
Number of days of NSAID use (days)	4.0 (0-28)	4.5 (0-30)	0.23
Number of postoperative days before start of oral intake (days)	6.0 (0-23.0)	9.0 (3-30)	<0.01*
Length of hospitalization (days)	13.0 (0-107)	23.0 (9-127)	<0.01*

SD=Standard deviation; N=Number of evaluated cases; *=statistically significant

Operative time, volume of bleeding during surgery, number of postoperative days before the start of oral intake, and length of hospitalization were significantly less in the PGA group. Statistically significant differences were found in operative time (hours) (ANOVA, $F = 55.13$, df = 1; $P < 0.001$), number of postoperative days before start of oral intake (ANOVA, $F = 42.94$; df = 1; $P < 0.001$), and length of hospitalization (ANOVA, $F = 15.06$, df = 1; $P < 0.01$).

Complications

Partial necrosis was observed in 15 cases in the STSG group (15/122 i.e. 12.3%).

With regard to postoperative functional problems, buccal excision cases were diagnosed with trismus if mouth opening (interincisor distance) in the postoperative period before hospital discharge (approximately 2 weeks) was <3.0 cm despite the mouth opening in the preoperative period was ≥3.0 cm. In this analysis, we excluded the cases which already had observed a reduction of mouth opening (<3 cm) caused by previous oral surgeries because those cases could not be defined as postoperative dysfunctional problems caused by covering wound with a PGA or STSG. In buccal excision cases which had trismus in the postoperative period before hospital discharge (median, 12.5 days; range 8–21), 11 (11/44 i.e. 27.5%) received STSG and eight received a PGA sheet (8/21 i.e. 38.1%). Based on buccal wound size (<6 cm^2 and ≥ 6 cm^2), we separated patients into two groups to compare mouth opening in the postoperative period before hospital discharge (median, 12.5 days; range, 8–21) between the PGA and STSG groups [Table 4]. Differences in mouth opening between the PGA group and STSG group were not significant in the postoperative period before hospital discharge (ANOVA, $F = 0.31$, df = 1, $P = 0.59$). Mouth opening in both groups was larger than 3.0 cm in the postoperative period after hospital discharge (median, 88.5 days; range, 74.0–113.0) relative to that before discharge. The mouth opening in the STSG group was significantly larger (ANOVA, $F = 9.59$, df = 1, $P = 0.008$). In both postoperative periods, no significant differences in excision area were observed, and no interaction between the wound covering method and excision area was noted [Table 4].

With regard to postoperative speech disability, speech intelligibility was evaluated in the postoperative period (median, 20.2 days; range, 11–28). In this analysis, we excluded the cases which already had observed speech intelligibility <80.0 caused by previous oral surgeries because those cases could not be defined as postoperative dysfunctional problems caused by covering wound with a PGA or STSG. When the excisional area of the wound in the tongue and floor of mouth was classified into groups (<12 cm^2 and ≥12 cm^2), the score for postoperative speech intelligibility in the STSG group was significantly higher (ANOVA, $F = 250.30$; df = 1; $P = 0.04$). No significant differences in excision area were observed, and no interaction between the wound covering method and excision area was noted [Table 5].

Polyglycolic acid sheet dislodgment of the wound on the exposed bone

The PGA sheet on the upper gingiva, the lower gingiva, and the hard palate were protected by a surgical sprint. No cases of a PGA sheet dislodgment occurred.

The incidence of wound infection

All cases were administered antibiotic therapy (2000 mg cephem antibiotic i.v. per day) during the operative day and postoperative 1–5 days in the hospital and (300 mg cephem antibiotic p.o. per day) after the intravenous administration. No infection of surgical wound occurred in all the studied cases.

DISCUSSION

Application of a polyglycolic acid sheet

Yonezawa *et al*. observed histopathological changes in sections of the wound that had been covered with a PGA sheet and suggested that a new epithelium formed over the wound.[11] Tie-over fixation was not required if the PGA sheet was fixed by fibrin glue spray and it tightly covered the wound and remained secure until epithelialization is achieved.[12] The PGA sheet did not act as a scaffold but served only as a simple dressing to relieve pain and protect the wound postoperatively.[12] There were no morphological or functional abnormalities on completion of epithelialization, and no carcinogenic material was present.[12]

Table 4: Mouth opening (interincisor distance) in the PGA and STSG groups

	Mouth opening (interincisor distance) in the postoperative period before hospital discharge (median, 12.5 days; range, 8-21)		Mouth opening (interincisor distance) at postoperative period after hospital discharge (median, 88.5 days; range, 74.0-113.0)	
	PGA Mean±SD (*n*)	STSG Mean±SD (*n*)	PGA Mean±SD (*n*)	STSG Mean±SD (*n*)
Excision area (cm^2)				
≤6.0	2.25±0.58, (6)	2.35±0.38 (5)	3.01±0.38 (6)	3.56±0.39 (5)
>6.0	2.08±0.25 (2)	2.16±0.30 (6)	3.00±0.35 (2)	3.57±0.30 (6)
	F	*P*[a]	*F*	*P*[a]
Main effect of covering method	0.31	0.59	9.59	0.008[b]
Main effect of the size of excision area	0.01	0.93	0.006	0.941
Interaction between covering method and the size of excision area	0.96	0.35	0.013	0.91

SD=Standard deviation; N=Number of evaluated cases; [a]*P*-value determined using analysis of variance (ANOVA) [b]$P<0.05$

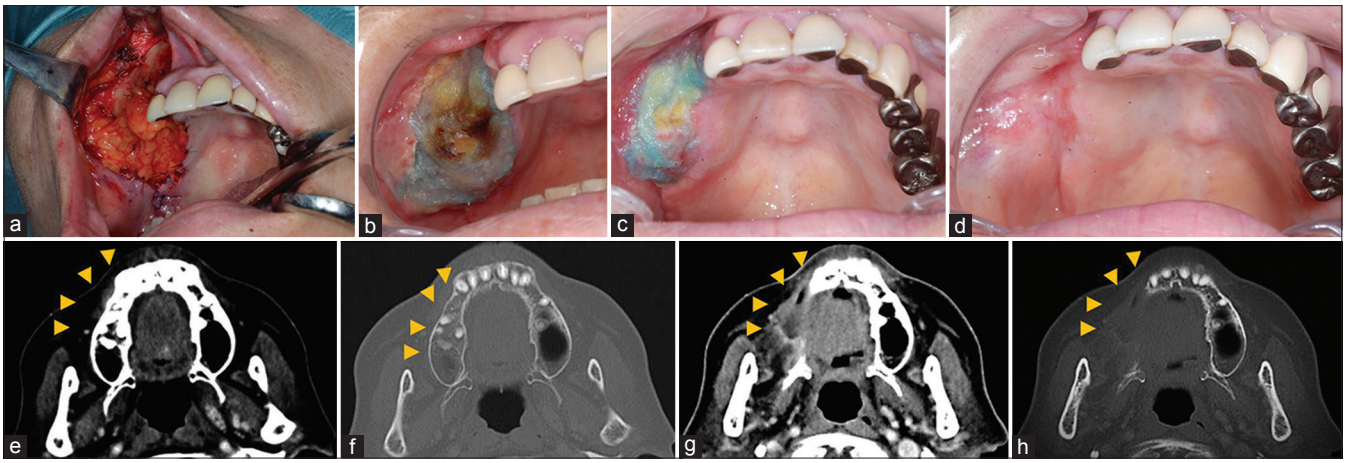

Figure 1: The patient was a 75-year-old woman with squamous cell carcinoma of the right side of upper gingiva. TNM stage was T2N0M0, Stage II. A right partial maxillectomy was performed. Orosinusal communications emerged and we performed soft tissue closure of orosinusal communications using a buccal fat pad flap and a polyglycolic acid attachment over the fat pad and exposed alveolar bone (a). The polyglycolic acid sheet was protected with a surgical splint. The patient was fed through a nasal tube during postoperative 2 days and started oral intake. Intraoral photograph after postoperative 2 weeks (b) and after 3 weeks were displayed (c). The polyglycolic acid sheets remained partially and peeled around the wound edges. Mucosa of the surrounding of the wound was epithelialized and was completely epithelialized at the point of postoperative 2 months (d). From preoperative axial computed tomography scan of the mandible in soft tissue window (e) and in bone window (f) of the buccal alveolus of the right maxillary from premolars' to molars' region (yellow arrows) the expansive soft tissue mass or cortical bone destruction were not found (yellow arrows). Axial computed tomography scan of the mandible in soft tissue window (g) and in bone window (h) of the right maxillary region 6 months after partial maxillectomy (yellow arrows) were displayed

Table 5: Comparison of speech intelligibility score between PGA and STSG groups

	PGA Mean±SD (*n*)	STSG Mean±SD (*n*)
Excision area (cm2)		
≤12.0	97.22±0.66 (13)	92.13±10.10 (7)
>12.0	95.89±1.97 (4)	91.40±2.50 (12)
	F	***P*[a]**
Main effect of covering method	250.30	0.04[b]
Main effect of excision area	11.64	0.18
Interaction between covering method and the size of excision area	0.016	0.90

SD-Standard deviation; N=Number of evaluated cases [a]*P*-value determined using analysis of variance (ANOVA) [b]$P<0.05$

It was anticipated that PGA sheets would gradually shrink or peel from the area surrounding the wound as epithelialization progresses. In most cases, the sheet should remain on the wound area for 3–4 weeks[1] [Figure 1], which would prevent postoperative scar contracture[9,12] and postoperative oral dysfunction from occurring.[15] Infection of the nonepithelialized granulated wound after early detachment of a PGA sheet results in severe postoperative scar contraction.[16] Although the PGA sheet is a foreign material placed in the oral cavity, we consider the wound infection was protected by antibiotic therapy at the operative day and during the postoperative days. There are only a few preliminary studies with a small number of cases of a PGA sheet coverage of exposed bone.[5,9,10,12]

Our result suggested that the optimal wound size for the use of a PGA sheet with fibrin glue without severe postoperative complications was 10.96 cm^2 in the upper gingiva, 8.17 cm^2 in the lower gingiva, and 7.23 cm^2 in the hard palate.

In our study, if the PGA sheet could be protected by a surgical sprint, which prevents the PGA sheet from peeling off, oral food intake could be started on the day after surgery at the earliest and within 4 days after surgery at the latest.

These times were earlier than those of the STSG group. The PGA sheet is soft and flexible and could be shaped more easily to cover complicated shapes.[12] It would be appropriate to cover an intraoral, geometrically complex wound with bone exposure with a PGA sheet protected by a surgical splint. Our result indicated that the PGA sheet coverage of the exposed bone is an effective treatment, as previously reported.[10]

Our result showed that median age at the time of surgery with a PGA sheet was a tendency to be higher than the age in STSG group and also the PGA group had significantly shorter operation time, less days of use of pain relievers, and shorter hospitalization. The PGA sheet method avoids donor site morbidity and is associated with shorter surgical and hospitalization time. Our study had sectional bias in deciding the surgical method. However, the result insisted that the application of a PGA sheet to the higher aged patients who have a poor general condition and low tolerance for surgery was one of the effective methods without surgical complications.

Application of split-thickness skin grafting

In spite of the areas covered with STSG were larger than those covered by a PGA sheets, our analysis of postoperative dysfunctional problems such as reduction of mouth opening and presence of articulation disorder revealed that the disorders in the STSG group tended to be milder. The PGA sheet over the mobile intraoral soft tissue had the problem of early detachment from the wound and scar contraction[9,16] even if a PGA sheet was not easily detached from the open wounds with exposed bone. On the other hand, STSG that were placed onto the intraoral mucosa

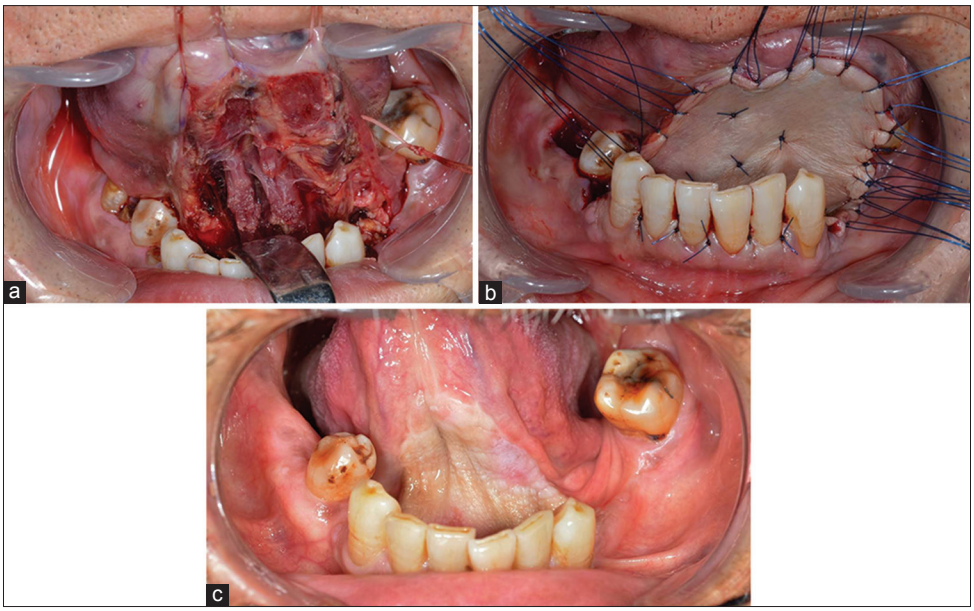

Figure 2: The patient was a 66-year-old man with squamous cell carcinoma of the middle side of mouth floor. TNM stage was T1N0M0, Stage I. The leukoplakia surrounding the tumor was observed. A tumorectomy of mouth floor was performed (a) and STS (split-thickness skin) harvested from the anterior upper thigh was grafted (b). A medicated gauze was used to compress the grafted skin during postoperative 7 days. The grafted skin over the lower alveolar bone was yet weak and the patient was fed through a nasal tube during postoperative 10 days before oral intake started. Intraoral photograph was displayed at the point of postoperative 1 year (c). Tongue movement was almost the same as the preoperative motion

adapted the cytoarchitecture of stratified squamous epithelium of the oral mucosa [Figure 2].[17] These grafts had postoperative mucosal extensibility and could prevent severe postoperative dysfunctional problems better than a PGA sheet method. If the size of the wound in the buccal area was ≥ 6 cm^2 and the size of the wound in the tongue and floor of the mouth was ≥ 12 cm^2, then STSG would be better for covering the wound.

Previous studies have reported graft failure of 2% for intraoral STSG.[2] STSG for geometrically complex occasionally becomes necrotic because the medicated gauze could not tightly compress and fix the graft to the underlying tissue.

Sectional criteria of the polyglycolic acid sheet and split-thickness skin grafting

The irregular anatomy and scar formation after wide *en bloc* resection of the oral mucosa occasionally results in severe postoperative dysfunction and anatomical deformity. We included patients that had a second operation for tumor recurrence, 25 of the total of 119 PGA surgeries and 35 of 132 surgeries. However, in those secondary operations for such as tumor recurrence, postoperative functional problems did not disturb the patients' satisfaction.

Each method has advantages and disadvantages. A PGA sheet combined with STSG could be effective for covering an open wound after a wide *en bloc* resection of a geometrically complex mucosal lesion or after repeated surgeries of the oral mucosa that had irregular anatomy and scar formation postoperatively. The appropriate use of a PGA sheet or STSG could resolve these problems.

Our study is the first one that was compared and discussed a PGA sheet and STSG covering method by large series. However, the major weakness of this retrospective study is that the two groups (PGA and STSG) were not randomized and the selection criteria for covering with a PGA sheet or STSG should be further studied and discussed by another study approach such as a randomized controlled trial.

CONCLUSION

Our result suggested that the optimal wound size for use of a PGA or STSG without severe postoperative complications. In particular, the PGA sheet was considered to beneficial for covering open wounds with exposed bone. STSG over the mobile intraoral soft tissue prevents from the severe scar contraction. The PGA group had a shorter operation time, less intraoperative bleeding, and shorter hospitalization. The selection of a PGA sheet or STSG should be determined based on the defect size, tumor location and patients' general condition and tolerance for surgery. Our study gives the beneficial information to give informed consent and education to the patients before surgery and to develop the further study for selection criteria of the covering soft tissue with a PGA sheet or STSG to improve postoperative dysfunctional problems, quality of life and patients' satisfaction, and patients' prognosis.

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Conflicts of interest

There are no conflicts of interest.

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