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Correspondence and Communications

Botulinum toxin type a intralesional monotherapy for treating human hypertrophic scar in a dose-dependent manner: In an animal model



Dear Sir,

We read with great interest the article entitled “Botulinum Toxin Type A Intralesional Monotherapy for Treating Human Hypertrophic Scar in a Dose-dependent Manner: in an Animal Model”¹ by Li YW et al. in *Journal of Plastic, Reconstructive & Aesthetic Surgery*. In this article, the authors conducted an in vivo experiment on the effect of different doses of botulinum toxin Type A (BTXA) for treating human hypertrophic scar. They concluded that BTXA reduced the severity of hypertrophic scar in a dose-dependent manner by inhibiting proliferation and migration of scar fibroblasts.

In this study, the authors injected different doses of BTXA into the scar tissue, and then implanted them into the back of the same nude mice. We are concerned that the systematic effects would interfere with the results of each intervention group. We believe that each mouse receiving the same dose of BTXA may help reduce bias.

The doses of BTXA intralesional injected to each specimen was 0-2 U. We are afraid that this concentration was too high for a mouse of 25-30 g, since it is equivalent to 4000 U for an adult of 60 kg. Therefore, the clinical transformation of the results is doubtful.

As was described by the authors, the mechanisms of the inhibition of BTXA on fibroblast proliferation and migration need further study. Further research is needed on the effect of BTXA on the biological behaviors of normal dermal fibroblasts.

Declaration of Competing Interest

None declared.

Funding

None.

Ethical approval

Not required.

Reference

1. Li YW, Shan XF, Mao QY, et al. Botulinum toxin type a intralesional monotherapy for treating human hypertrophic scar in a dose-dependent manner: in an animal model. *J Plast Reconstr Aesthet Surg* 2021. doi:[10.1016/j.bjps.2021.03.062](https://doi.org/10.1016/j.bjps.2021.03.062).

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<https://doi.org/10.1016/j.bjps.2021.05.067>

The incidence and risk of involved margins in surgically resected basal cell carcinoma - A multi-centre consecutive case series



Dear Sir,

Introduction

Skin malignancy, specifically basal cell carcinoma (BCC) is the most prevalent cancer in the United Kingdom (UK). Treatment for BCC commonly involves surgical excision with a pre-determined peripheral margin. Oncological clearance is key to preventing local recurrence, with only 1% of BCC's recurring with clear surgical margins versus 31-41% when involved.¹ Recent systematic review evidence however suggests that the proportion of incomplete excisions is higher than previously reported, with significant variation amongst specialists.² Specialist management therefore has the potential to reduce the burden of re-excision, radiotherapy and ongoing surveillance .

Table 1 Basal cell carcinoma types and lesion characteristics.

Subtype	Number of BCCs in study (% total)	Age in years (95% CI)	Depth in mm (95% CI)	Diameter in mm (95% CI)	Ulcerated (% yes)	Perineural invasion (% yes)
Basosquamous	13 (1.3)	74 (70-77)	4 (4-5)	9 (7-11)	2 (0.2)	0 (0.0%)
Infiltrative	166 (16.5)	76 (75-77)	3 (3-3)	12 (11-13)	35 (3.5)	4 (0.4%)
Micronodular	33 (3.3)	74 (72-76)	3 (3-3)	14 (13-15)	3 (0.3)	0 (0.0%)
Morphoeic	29 (2.9)	77 (76-78)	2 (2-2)	12 (11-14)	8 (0.8)	0 (0.0%)
Multinodular	59 (5.9)	73 (72-75)	3 (3-4)	14 (13-16)	12 (1.2)	0 (0.0%)
Nodular	574 (57.0)	76 (75-76)	2 (2-2)	13 (13-13)	58 (5.8)	2 (0.2%)
Nodulocystic	29 (2.9)	77 (75-79)	3 (3-3)	11 (10-12)	2 (0.2)	0 (0.0%)
Polypoid	1 (0.1)	94 (94-94)	8 (8-8)	6 (6-6)	0 (0.0)	0 (0.0%)
Superficial	104 (10.3)	74 (73-75)	1 (1-1)	11 (11-12)	18 (1.8)	0 (0.0%)

Table 2 Percentage frequency of tumour clearance achieved across range of pre-operative peripheral surgical margin values stratified by BCC subtype. Blank cells denote that no margin of that dimension was taken for that subtype.

Subtype	Pre-operative peripheral surgical margin (mm)				
	3	4	5	4-5	5-10
Basosquamous	-	100%	100%	100%	100%
Infiltrative	89%	88%	85%	87%	93%
Micronodular	50%	86%	100%	90%	83%
Morphoeic	-	55%	67%	60%	100%
Multinodular	100%	95%	93%	94%	100%
Nodular	99%	96%	96%	96%	97%
Nodulocystic	100%	90%	100%	94%	100%
Polypoid	-	-	-	-	100%
Superficial	78%	82%	88%	84%	95%

In order to compare datasets between specialist services, high quality robust data within the literature is necessary. The primary aim of this study was to establish the incomplete peripheral margin excision rate at the Welsh Centre for Burns and Plastic Surgery (WCBPS) - a supra-regional plastic surgery service serving 2.3 million people. The secondary aim was to determine whether an association between patient or tumour factors and increased risk of incomplete excision exist.

Methods

We analysed a multi-centre retrospective consecutive case series of patients with a BCC over a three-year period from 03/07/2015 to 19/03/2018, managed with surgical excision using a pre-determined margin. Age, gender, anatomical site, pre-operative margin (mm), peripheral clearance (mm), tumour depth (mm), diameter (mm), BCC subtype, ulceration and peri-neural invasion (PNI) were recorded as were patient, surgical and tumour characteristics. The peripheral margin status was recorded as either clear (≥ 1 mm), close (≥ 0.1 mm to < 1 mm) or involved (0 mm). BCC's with mixed subtypes were excluded to permit stratification into high and low-risk groups. We defined high-risk subtypes as morphoeic, infiltrative, micronodular and basosquamous. Statistical analysis was performed using IBM SPSS Statistics for Windows (v.24, IBM Corp, Armonk, NY). $p < 0.05$ was considered statistically significant.

Results

A total of 3203 lesions were identified in the study period, with 1007 lesions in 860 patients available for analysis after excluding those with missing data. Table 1 demonstrates demographic and lesion characteristics. A 4 mm pre-operative surgical margin was most commonly utilised (37%), with 76% of lesions excised with a peripheral margin of either 3 mm, 4 mm or 5 mm. No lesions were managed using Mohs micrographic surgery.

A significant association between male gender ($p = 0.001$), presence of ulceration ($p = 0.001$), histological subtype (morphoeic, infiltrative and superficial, $p = 0.001$) and incomplete excision is seen. High-risk anatomical sites (central face, peri-orbital eyes, nose, lips and ears), age, or tumour diameter were not associated with an increased risk of incomplete peripheral margin excision.

Pre-operative surgical peripheral margin and the peripheral margin clearance rates were compared across all BCC histological subtypes. The percentage frequency tumour clearance was summated across varying pre-operative peripheral surgical margins and stratified by BCC subtype (Table 2). Ordinal regression (anatomical site, diameter, and pre-operative peripheral margin as covariates) demonstrated a significant odds ratio for an involved margin when morphoeic, superficial and infiltrative lesions were compared with nodular BCC (odds ratio 11.001, 5.452 and 3.004 respectively).

Discussion

The peripheral incomplete excision rate of 7.6% in this cohort is in line with many other published studies, although lower than the recently reported 11%.² These figures are higher than those previously reported from national dermatology audits, with an incomplete peripheral margin rate as low as 1.8%.^{3, 4} The one national plastic surgery audit of BCC excision rates, performed during COVID-19, demonstrated a higher incomplete excision rate of 4.6%.⁵ This may be attributed to greater complexity in relation to anatomically site and tumour size.

Comparison between peripheral margin clearance with documented peripheral surgical margin shows that the rate of complete peripheral excision is strongly influenced by the histological subtype. High-risk lesions tend to have ill-defined borders that make it harder to clinically determine where the tumour ends and therefore where to plan the margin from. Morphoeic subtypes, followed by superficial and infiltrative lesions presented the highest risk of close or involved margins in our series. This is in keeping with the literature, with morphoeic lesions having a lower respective excision rate for the same surgical margin compared to other subtypes (3 mm margin, 66%; 5 mm margin, 82%; 13-15 mm margin, > 95%).

Some anatomical sites are known to confer a higher risk for incomplete excision, such as the temple, medial canthus, nose and ears. Interestingly, in this study we did not find a correlation with anatomical site and risk of incomplete peripheral margin clearance.

Strengths of the study include the large sample size and consecutive nature of patient recruitment, which limits selection bias. The retrospective nature of the study is a confounding factor in this aspect of study design and as such prospective data collection would mitigate this bias. Additionally, the grade of operating surgeon and use of loupe magnification were not included as a co-variate in our regression model.

Conclusion

We present the largest multi-centre study of incomplete BCC excision rates and the risk of involved margins of any plastic surgery service in the UK. The proportion of incomplete excision in our series is lower than that reported by meta-analytic data.

Authorship

All listed authors contributed to; 1) conception and design, acquisition of data, analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; 3) final approval of the version to be published; 4) agreement to be accountable for all aspects of the work.

Financial support

There was no specific funding for this study.

Conflicts of interest

None.

Institutional ethical approval

None.

Reporting standards

STrengthening the Reporting of OBServational studies in Epidemiology (STROBE).

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<https://doi.org/10.1016/j.bjps.2021.08.012>

Bridging the digital divide among advanced age skin cancer patients



Dear Sir,

The COVID-19 pandemic has ushered in an increasingly digital age. Innovative technologies (e.g. artificial intelligence for skin cancer screening) and new models of care (e.g. telemedicine services allowing patients to send images of suspicious lesions to their clinicians) have been crucial in allowing skin cancer patients to meet pandemic-related challenges.¹ While health information technology (HIT) use among skin cancer patients has significantly increased within the past decade, there remains a “digital divide” in both the access to and utilization of HIT across various demographics of skin cancer patients.² We consider that the technological advances made during the pandemic, while potentially beneficial for skin cancer management, may also have the unintended consequence of exacerbating this digital divide.

In recent years, there has been increased discussion surrounding the use of artificial intelligence to diagnose and monitor potentially malignant skin lesions. While these technologies have traditionally been designed for clinician use, researchers and public health advocates have begun to explore the potential for their use by patients, which may allow for greater convenience of and access to care. In a study by Sangers and colleagues exploring the barriers to and facilitators of use of artificial-intelligence driven mobile health applications for skin cancer screening among the Dutch general population,³ the authors concluded that creation of low-cost, privacy-friendly, and easy-to-use mobile health applications may encourage adoption of these technologies for skin cancer screening. Integration of mobile health technologies into skin cancer care certainly represents a promising and innovative approach toward facilitating early skin cancer detection. However, given the aforementioned digital divide, increasing adoption of skin cancer screening applications alone may be unlikely to reach the target audience demographic.

Skin cancer tends to occur in patients of advanced age.^{1,2} In one study, only 17.0% of individuals ages 65-79 currently owning a smartphone or tablet were interested in using a health-related application to obtain health information.⁴ In another retrospective analysis of the National Health Interview Survey, an annual survey of United States households, skin cancer patients age >65 were the least likely age group to utilize HIT, which included using a computer to schedule healthcare appointments, look up health information online, communicate with providers, or fill prescriptions.² Furthermore, plastic surgery and dermatology practices have rapidly invested in and expanded upon their telemedicine services due to the COVID-19 pandemic.⁵ Given the high incidence of skin cancer in the elderly and the likely perpetuation of clinical changes related to telemedicine expansion, we believe that investing in the infrastructure to bridge

the digital divide among skin cancer patients represents an equally pressing priority to the continued development of technological advances aimed at skin cancer management.

As we transition into the post-pandemic clinical landscape, plastic surgeons, dermatologists, and other clinicians involved in the management of skin cancer must actively encourage eHealth literacy among their older patients. Simpson and Kovarik present excellent suggestions for engaging geriatric patients via telemedicine.⁵ Helpful interventions might include creating patient education materials describing how to perform medical tasks using a smartphone or computer (e.g. creating an account through the electronic medical record), engaging advanced age patients at time of surgery (e.g. iPads in the room loaded with patient educational videos for post-operative care), and utilizing telemedicine platforms that allow for multiparty encounters which permits older patients the opportunity to attend online visits with a trusted health advocate.^{2,5} These recommendations would help optimize virtual skin cancer care across all demographics, and would especially target the generally lower eHealth literacy of older adults.

The use of artificial intelligence and associated technological advances to improve early detection of skin cancer is undoubtedly an important aspect of the ever-changing field of digital health. While it is necessary to reduce barriers to use of mobile health screening applications and similar new technologies for the care of skin cancer patients, we must first establish a framework allowing for the equitable distribution of practices related to digital health expansion in the post-pandemic era. Only then can we facilitate optimal utilization of these innovative technologies by their intended patient population.

Declaration of Competing Interest

The authors report no conflicts of interest relevant to this work.

Financial disclosure

The authors report no funding sources relevant to this work.

Ethical approval

Not required.

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<https://doi.org/10.1016/j.bjps.2021.08.009>

Three-dimensional measurement and analysis of botulinum toxin A injection for improving the aesthetic appearance of upper lip



Dear Sir,

The thickness of lips gradually decreases with increasing age and progressive shrinkage of subcutaneous tissue. Meanwhile, a large number of fine wrinkles appear, giving people a sense of oldness, which seriously affects the aesthetics of lips¹; some fillers, such as non-permanent hyaluronic-acid dermal fillers and autologous fat, are often used to resolve this problem, although this method often causes bruising, swelling, and pain in lips. In addition, some people have too much exposure of gum tissue in the anterior maxilla when smiling, known as “gummy smile,” which not only affects appearance but also becomes a psychological burden. In 2010, Mazzuco and Hexsel developed different botulinum toxin injection methods based on the exposed gum area.² BTX A has been proven effective in treating gummy smile. However, there are still many patients who are dissatisfied with an unnatural smile after injection. To further improve the shape of lips with minimal treatment risk has become an issue that needs to be resolved urgently in clinics.

Twenty-four participants were included in this study. Inclusion criteria were as follows: (1) Medicis Lip Fullness Scales score (MLFS) 1 (very thin) or 2 points (thin); (2) Wrinkle Assessment Scale for Upper Lip Lines (WASULL) 5 (extreme), 4 (severe) or 3 (moderate); and (3) with or without gummy smile (gum exposure above the central incisor \geq



Figure 1 A 40-year-old male patient with mixed gummy smile. Gum exposure above the central incisor was 3.5 mm, and gum exposure above the canine was 5.5 mm.

3 mm when smiling). In this study, BTX A (Botox, 100 U/ml) was diluted to 40 U/ml with saline and the injection sites were between lip peak and corner of the mouth, or thinner upper lip when smiling naturally, 1,2 mm from the upper lip margin. All patients received injections at four sites, 1,2 U at each site. The evaluation was performed before operation and 1, 2, 4, 8, 12, 16, 20, and 24 weeks after operation. Treatment success was defined as an increase in MLFS of ≥ 1 grade and a decrease in WASULL of ≥ 1 grade. For the improvement in lip fullness, the treatment success rate was 62.5% at the second week, and 100% at the fourth week. For the improvement in fine wrinkles around the mouth, the treatment success rate was 79.17% at the second week and 100% at the fourth week. It was also found that the treatment effect could last for about 20-24 weeks. The change in the thickness of upper red lip, distance from upper lip to nasiomental line, and nasolabial angle were obtained using three-dimensional (3-D) photography. These indicators significantly changed 4 weeks after injection ($P < 0.05$). For gummy smile 2 weeks after injection, average gum exposure above the central incisor changed from 3.75 ± 0.68 mm to 1.00 ± 1.13 mm, average gum exposure above the canine changed from 4.15 ± 0.71 mm to 0.9 ± 1.13 mm, and the difference was statistically significant ($P < 0.05$), a typical case as shown in [Figures 1](#) and [2](#). No allergic reactions and severe adverse reactions were noted.

Botulinum toxin relaxes the orbicularis oris and stretches the upper lip skin. Meanwhile, the upper lip skin appears tight because of relatively increased amount of lip tissue. These might be the reason behind lip fullness and wrinkle improvement.³ The efficacy duration was approximately 24 weeks, which is consistent with the efficacy duration of BTX A. We found that the combined use of 3D photography and computer modelling measurement can significantly improve the limitations of traditional two-dimensional data, increase the diversity of research results, and make better and more complete use of clinical data, which is worthy of consideration.⁴ In this study, the improvement rate of gummy smile was 100% 2 weeks after injection. One of the possible mechanisms is inhibition of fusion of the orbicularis oris and levator labii superioris near the lip, thereby inhibiting some degree of hyperfunction of the levator labii superioris. The other possible mechanism is that after the



Figure 2 Two weeks after injection of BTX A, gum exposure above the central incisor was -1.5 mm and that above the canine was -1 mm.

orbicularis oris relaxes, the contents of upper lip are released and the thickness of upper lip increases, thus covering overexposed gums; the two sides work together to improve the subjects' gummy smile.⁵ Future studies with a larger sample size should further investigate and confirm the effect of botulinum toxin injection on the overall aesthetic improvement of lips.

Ethical approval

Not required.

Funding

2020 Military Medical Science and Technology Project for Youth Training and Incubation (20QNPY097).

Declaration of Competing Interest

The authors have no financial interest to declare in relation to the content of this article.

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<https://doi.org/10.1016/j.bjps.2021.06.005>

Prospective clinical trial comparing barbed dermal suture and interrupted suture closure of the anterolateral thigh flap donor site in a Taiwanese population based on the Vancouver scar scale and the patient and observer scar assessment scale



Dear Sir,

The anterolateral thigh (ALT) flap is ideal for soft tissue reconstruction. Most of donor sites can be primarily closed. Boca¹ showed that flap width-to-thigh circumference (WtTC) ratio is reliable parameter. All cases can be primarily closed if flap WtTC ratio is $<16\%$.

Unsatisfied hypertrophic scar occurs around 19% ². Theoretically, possible risk factors include tension, suture material, body mass index (BMI), and WtTC. Vancouver Scar Scale (VSS) and Patient and Observer Scar Assessment scale (POSAS) are scientific tools for linear scar evaluation³. However, there is no study demonstrated predominant factor of scar formation in ALT flap donor site based on VSS and POSAS. Nylon is traditionally available suture material, and barbed suture is newly time-saving one.

This study was designed to compare the esthetic results between 4-0 nylon and 3-0 V-Loc 90 barbed suture (VLoc, Covidien, North Haven, CT, USA). The VLoc was used in clos-

Table 1 Determining Factors Contributing to The Scores of Vancouver Scar Scale and Patient and Observer Scar Assessment Scale.

VLoc (6-12 month)	N = 36		P_POSAS		O_POSAS		Scar Width	
	VSS (Correlation)	p value	(Correlation)	p value	p value	p value	(Correlation)	p value
Age	-0.246	0.108	-0.036	0.818	-0.159	0.301	-0.287	0.059
Body mass index	0.191	0.215	0.221	0.15	0.138	0.371	-0.027	0.861
ALT width	-0.242	0.113	-0.28	0.065	-0.121	0.436	-0.162	0.294
ALT length	-0.31	0.041	-0.289	0.057	-0.207	0.177	-0.155	0.316
M point circumference	0.191	0.214	0.081	0.601	0.028	0.856	-0.196	0.202
m point circumference	0.118	0.444	0.15	0.33	-0.009	0.955	-0.146	0.344
W/M ratio	-0.288	0.058	-0.258	0.09	-0.091	0.558	0.008	0.957
W/m ratio	-0.261	0.087	-0.312	0.04	-0.088	0.57	-0.01	0.951

Nylon (6-12 month)	N = 32		P_POSAS		O_POSAS		Scar Width	
	VSS (Correlation)	p value	(Correlation)	p value	p value	p value	(Correlation)	p value
Age	-0.004	0.981	-0.055	0.74	-0.055	0.738	-0.277	0.087
Body mass index	-0.025	0.879	-0.102	0.535	-0.033	0.841	-0.062	0.708
ALT width	0.011	0.948	-0.116	0.481	-0.04	0.81	-0.037	0.823
ALT length	-0.103	0.533	-0.122	0.461	-0.184	0.262	-0.207	0.205
M point circumference	-0.048	0.771	0.852	-0.301	0.001	0.996	0.07	0.673
m point circumference	0.008	0.961	-0.03	0.855	0.03	0.856	0.084	0.609
W/M ratio	0.045	0.786	-0.049	0.769	-0.014	0.931	-0.053	0.748
W/m ratio	0.001	0.995	-0.058	0.724	-0.051	0.759	-0.083	0.617

VSS: Vancouver Scar Scale.

POSAS: patient and observer scar assessment scale.

P_POSAS: POSAS scores provided by patient.

O_POSAS: POSAS scores provided by observer.

W/M ratio: WtTC of M point.

W/m ratio: WtTC of m point.

Statistics: Pearson Correlation test.

Table 2 Two Staged Follow-up for Scar Evaluation.

	VLoc	Nylon	95% Confidence Interval	p- value
0-6 month	N = 39	N = 34		
	Mean ± SD (Range)	Mean ± SD (Range)		
VSS score	3.72 ± 2.15 (0-8)	6.59 ± 1.84 (2-9)	(-3.81-1.93)	0.000
P_POSAS	11.56 ± 3.24 (7-24)	18.79 ± 7.61 (7-38)	(-10.06-4.40)	0.000
O_POSAS	15.51 ± 6.66 (7-38)	26.44 ± 8.83 (8-42)	(-14.63-7.22)	0.000
7-12 month	N = 36	N = 32		
	Mean ± SD (Range)	Mean ± SD (Range)		
VSS score	2.75 ± 2.44 (0-10)	5.19 ± 2.73 (1-11)	(-3.69-1.19)	0.000
P_POSAS	11.42 ± 6.12 (7-33)	16.41 ± 5.31 (7-28)	(-7.78-2.20)	0.001
O_POSAS	14.83 ± 8.45 (7-49)	26.81 ± 11.21 (9-59)	(-16.75-7.20)	0.000
Scar width (mm)	5.31 ± 3.42 (2-14)	8.28 ± 3.26 (1-15)	(-4.60-1.35)	0.000

VSS: Vancouver Scar Scale.

POSAS: patient and observer scar assessment scale.

P_POSAS: POSAS scores provided by patient.

O_POSAS: POSAS scores provided by observer.

Statistics: independent t-test. SD: standard deviation.

ing donor site of ALT flap for head and neck cancer reconstruction. All deep sutures were made with interrupted 2-0 and 3-0 vicryl in same tension-free method. Prospective clinical trials comparing VLoc and nylon for 92 ALT flaps in 90 consecutive patients were performed (May 2016-February 2017). Patient profile included age, sex, BMI, and width and length of ALT flap.

The desired flap width, midpoint between anterior superior iliac spine and superior lateral border of patella (*M* point circumference), midpoint of designed ALT flap (*m* point circumference), and WtTC ratio were recorded before surgery. This study hypothesized that greater WtTC ratio will cause more tension and contribute to worse scar based on the study by Boca¹. Therefore, circumferences of the *M* and *m* points were recorded before harvesting of ALT flap. The flap width was evaluated by pinch test. Every case was prospectively enrolled if WtTC ratio (<16%) meets criteria. Post-operative care includes sterile tape coverage and neomycin with gauze dressing. The sterile tapes and nylon were removed in postoperative week 2. Patients were asked to use sterile tape for scar care for 6 months. All cases were followed up in postoperative months 1-6 and 7-12. Two well-trained plastic surgeons recorded widest scar width, completing VSS and POSAS questionnaire. The outcome assessment was not double-blinded. Statistical Analysis were conducted using Pearson correlation test for risk factors, and independent *t*-test for numerical data. The China Medical University Hospital Ethics Committee approved this study, and patients gave written informed consent.

Included in this study were 92 ALT flaps in 90 patients (May 2016 to February 2017). The VLoc (72.0%; 36/50) and nylon groups (76.2%; 32/42) completed two-stage follow-up. Factors in basic patient profile were normally distributed except for sex (female predominated VLoc group). One flap failure occurred and no donor site complications (e.g., wound infection, dehiscence, and seroma) existed.

No significant correlation existed between scar score and age, BMI, ALT width, and *M* and *m* point circumferences. Neither flap width to *M* (*W/M* ratio) nor to *m* ratio (*W/m* ratio) was found to correlated with final scar (Table 1). The result does not support the initial hypothesis wherein greater tension was derived from higher BMI, wider ALT width, and higher WtTC ratio which does not contribute to the worsening of thigh scar in ALT flap donor site. VLoc showed significantly better cosmetic results (Table 2). In VSS, results in postoperative 1-6 months (VLoc vs. nylon, 3.72 ± 2.15 vs. 6.59 ± 1.84 ; $p = 0.000$) and postoperative 7-12 months (VLoc vs. nylon, 2.75 ± 2.44 vs. 5.19 ± 2.73 ; $p = 0.000$) showed significant difference. When using POSAS, VLoc also achieved better score either by patient (P_POSAS) or observer (O_POSAS). P_POSAS (VLoc vs. nylon, 11.56 ± 3.24 vs. 18.79 ± 7.61 ; $p = 0.000$) and O_POSAS (VLoc vs. nylon, 15.51 ± 6.66 vs. 26.44 ± 8.83 ; $p = 0.000$) at postoperative 1-6 months, P_POSAS (VLoc vs. nylon, 11.42 ± 6.12 vs. 16.41 ± 5.31 ; $p = 0.001$) and O_POSAS (VLoc vs. nylon, 14.83 ± 8.45 vs. 26.81 ± 11.21 ; $p = 0.000$) at postoperative 7-12 months were also significantly better in the VLoc group. The mean final scar width at postoperative 7-12 months in VLoc group is significantly reduced around 3 mm than nylon group.

Limitations include small sample size and significant selection bias (female predominated and additional financial

burden 60 USD in VLoc group). Also, patients were excluded if pinch test indicated primary closure impossible.

In conclusions, VLoc is a safe, cosmetic, and time-saving material in the closure of ALT flap donor site. Based on VSS and POSAS, this is the first study providing an objective evaluation of thigh scar. Two-staged follow-up in a year significantly provide better scar scores both by the patient and physicians.

Funding

None.

Ethical approval

Not required.

Declaration of Competing Interest

None.

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<https://doi.org/10.1016/j.bjps.2021.06.015>

Obstructive sleep apnea after pharyngeal flap surgery for velopharyngeal insufficiency in cleft patients



Dear Sir,

We investigated the incidence and severity of obstructive sleep apnea (OSA) in cleft patients who underwent pharyngeal flap surgery (PFS) for velopharyngeal insufficiency (VPI) at long-term postoperatively and determined the effect of age at PFS on them. OSA is one of the most serious complications of PFS.¹ Many authors investigated OSA in cleft patients after PFS (Supplementary Data, Table S1). To our knowledge, there has been little literature on OSA with a longer follow up (mean 6.0 years) after PFS in cleft patients.

A retrospective study was conducted on cleft patients who underwent PFS in Affiliated Hospital of Qingdao University from 2007 to 2017. All patients underwent the procedure by one senior surgeon. The following exclusion criteria were used: (1) syndromic patients (e.g., vela-cardio-facial syndrome, Pierre Robin sequence), or systemic abnormalities, (2) patients with craniofacial abnormalities, or adenotonsillar hypertrophy, (3) Obese patients identified by BMI, (4) patients who failed to cooperate with medical personnel. A total of 82 patients were enrolled in this study. Participants were divided into two groups according to the age at PFS. Thirty patients who were equal to or greater than 18 years old when receiving PFS were included in the adult group, and 52 patients who were under 18 years old when receiving PFS were included in the child group. The general information of the two groups of patients was shown in Table 1. An overnight polysomnography (PSG) (Respironics, Inc., Murrysville PA) was recorded on each patient. The performance of PSG was at least 1.2 years (mean 6.0 years) after PFS. Apnea-hypopnea index (AHI) measured by PSG was used as indicator to evaluate the incidence and severity of OSA. The lowest arterial O₂ saturation (LSaO₂) was also recorded. The criteria to determine the presence of OSA in adults and children were quite different.² In adults, AHI values greater than or equal to five was considered abnormal. Severity was categorized as mild (5 ≤ AHI < 15), moderate (15 ≤ AHI < 30), or severe (AHI ≥ 30). In children, AHI values greater than or equal to one was considered abnormal. Severity was categorized as mild (1 ≤ AHI < 5), moderate (5 ≤ AHI < 10), or severe (AHI ≥ 10). Data analysis was performed using SPSS 20 (SPSS Inc, Chicago, IL) software and the level of significance was set at $p < 0.05$. Written informed consent for this study was obtained from the patients.

Speech assessments were performed by a professional speech pathologist. The surgeons also engaged the patients in conversation to determine the severity of hypernasality. Then, the patients received nasopharyngoscopy to confirm the diagnosis of VPI. The choice of surgical approach is de-

Table 1 Statistics of general information on patients in both groups.

	Adult group	Child group
Patient (n)	30 (16 M, 14F)※	52 (25 M, 27F)
Type of cleft (n)	15	21
Isolated cleft palate	9	20
Unilateral cleft lip with palate	6	11
Bilateral cleft lip with palate	8	5
Technique of palatal repair (n)	7	16
Von-Langenbeck	5	18
Furrow palatoplasty	-	10
Two-flap	10	3
Two-flap + vomer mucoperiosteal flap		
Unknow (operated elsewhere)		
The age of PFS (y)	23.3 ± 4.2	8.9 ± 4.1
Follow-up time (y)	5.9 ± 2.2	6.1 ± 2.1

※M=male, F=female.

Table 2 Polysomnographic data.

Adult group (n = 30)	n	AHI(/h)	LSaO ₂ (%)
Normal	24	1.6 ± 1.0	91 ± 2
Mild OSA	6	9.7 ± 2.8	88 ± 3
Moderate OSA	0	-	-
Severe OSA	0	-	-
Child group (n = 52)	n	AHI(/h)	LSaO ₂ (%)
Normal	26	0.5 ± 0.3	92 ± 3
Mild OSA	10*	2.5 ± 1.2	91 ± 3
Moderate OSA	10	2.6 ± 0.9	90 ± 4
Severe OSA	6	7.8 ± 1.3	88 ± 4
	0	-	-

*Ten patients in the child group became adult after PFS, and none of the 10 patients had OSA.

vided by the speech pathologist after discussion with the senior surgeon. For patients with a velopharyngeal closure rate of less than about 0.7, PFS was recommended.³ The patient obtained a narrow, medium, or wide pharyngeal flap, which was decided by the size of the velopharyngeal space and the amount of movement of the soft palate wall as well as lateral pharyngeal, as documented with nasopharyngoscopy. The width of the narrow flap usually is half (50%) of the posterior pharyngeal wall, the medium flap is two-thirds (66%), and the wide flap is 90% to 100%. The pharyngeal flap was performed using a superiorly based flap. In each patient the soft palate was split in the midline and the flap was inset with layered closure. The turnover soft palate nasal mucosal flap was used to line the raw surface of the pharyngeal flap. The donor site was uniformly closed.

The results of PSG were shown in Table 2. The more severe OSA is, the lower LSaO₂ is. There was no significant difference in the incidence of OSA between two groups ($P = 0.289$). OSA was diagnosed in 20% (6/30) of the adult group and 31% (16/52) of the child group. It is worth men-

tioning that 10 adult patients who underwent PFS in childhood have no OSA. It may be that PFS when done during childhood is unlikely to result in OSA as an adult. However, this still needs large sample studies to further confirm. There was not noticeable difference between these two groups in severity of OSA ($P = 0.079$). Six patients in the adult group had mild OSA. In the child group, 10 patients were found to have mild OSA and 6 patients had moderate OSA. There were no patients in either group with severe OSA.

Pharyngeal flap is known to cause reduction in airway dimensions.^{1,3-5} The senior surgeon routinely paid more attention to patients with airway obstruction before the surgery and advised them to stop the procedure. Therefore, we can consider that the preoperative incidence of OSA in the patients in this study must be extremely low.

Finally, based on an analysis of the data from this study, we concluded that some cleft patients still had OSA in a long period (mean 6.0 years) after PFS and the age at PFS was unrelated to the incidence and severity of OSA. Due to OSA remains high for a long period after surgery, in future practice, we will narrow the indications for PFS to reduce the incidence of airway complications. Through further clinical study, the best therapeutic protocol will be explored.

Declaration of Competing Interest

There are no conflicts of interest to disclose.

Financial support

This work was funded by Grant from [Natural Science foundation of Shandong Province](#) (Grant Number: ZR2015HM022).

Ethical approval

This study has been reviewed and approved by the Institutional Review Board of the Affiliated Hospital of Qingdao University (No. 2018-KQHMWK-02). Additionally, this study is in accordance with the World Medical Association Declaration of Helsinki, as well as subsequent amendments.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:[10.1016/j.bjps.2021.06.009](https://doi.org/10.1016/j.bjps.2021.06.009).

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<https://doi.org/10.1016/j.bjps.2021.06.009>

Lengthening temporalis myoplasty: A question of access



Dear Sir,

The temporalis transfer has been used for restoration of symmetry and movement in facial palsy patients for many years. The original Gillies technique¹ (1934) involved turning down the mid-section of the temporalis muscle and lengthening it by means of fascia lata strips. This created a significant bulge over the zygomatic arch, especially on clenching teeth, and left a depression in the temporal donor site. McLaughlin² described an orthodromic tempo-



Figure 1 The question-mark shaped incision is marked within the hairline over the temporal fossa and extended to the preauricular area if required. Here this female patient's hair is separated into fields, bunched and then braided or knotted.



Figure 2 Appearances at 9 months post-op. The question-mark scar is well-concealed and not easily noticeable, even with a receding hairline in this male patient.

ralis transfer in 1953 that avoided these issues, but still required fascial extensions to reach the oral commissure and nasolabial fold. Labbé (1997) further modified the orthodromic temporalis transfer, so as to retain the advantages of the McLaughlin technique but obviate the need for fascia lata extensions, and called his technique Lengthening Temporalis Myoplasty (LTM)^{3,4}. This procedure has since become well established as a reliable, single-stage muscle transfer for facial reanimation. A modification of the original LTM (version 2) was subsequently described in 2009.⁵

Version 1 (v1) of Labbé's technique utilises a classic bicoronal scalp incision to expose the temporalis muscle and the zygomatic arch, and osteotomise the zygomatic arch and coronoid process of the mandible. A nasolabial incision is used to attach the temporalis tendon to the upper lip and oral commissure. The bicoronal incision requires shaving a 2 cm strip of the patient's hair from behind the level of the helix on one side, all the way to the other ear. The hair is braided on either side and the incision line is made above the insertion of the helix across to the other side. Sub-galeal forehead flap dissection is then performed anteriorly all the way up to 1-2 cm above the orbital rim to access the temporalis muscle. Whilst a bicoronal approach provides ample access to the upper and middle thirds and lateral skull, its potential disadvantages are increased bleeding, sensory (supratrochlear/supraorbital) nerve damage, prolonged operating time, and a long scar in the scalp.

Version 2 (v2) altered the surgical approach by using a hemi coronal rather than bicoronal incision, since in this version the anterior most fibres of the temporalis muscle are left attached to the overlying skin. The nasolabial fold incision is used in this instance to both osteotomise the coronoid process and fix the temporalis tendon, and the zygomatic arch is not sectioned. Though the scalp incision is shorter than a bicoronal incision, considerable undermining of the scalp in the subgaleal plane is still required and unilateral sensory nerve injury can occur.

In our unit, we use a question-mark shaped incision rather than a hemi coronal incision to access the temporalis muscle in version 2 (v2) of the Labbé procedure. We exclusively perform the v2 procedure, and have never needed to convert to v1 (Figures 1 and 2).

We have used our modified approach to version 2 of lengthening temporalis myoplasty in well over a hundred patients since July 2009, and feel that it confers the following advantages:

The "question-mark" incision does not require any hair to be shaved, and the resultant scar is well-hidden and barely visible in the long-term. In fact, this incision has also been used in several men with receding hairlines without being too prominent. There have been no incidences of scar or scalp alopecia.

The shape and location of the incision allows direct access and visualisation of the subjacent temporal fossa and temporalis muscle, with minimal dissection and undermining required.

No sensory nerves to the scalp are disrupted.

In our hands, using the Gillies plane to separate the temporalis muscle from the zygomatic arch is quicker and easier than the Labbé approach.

We propose our "question-mark" incision as a useful alternative to the hemi coronal incision in the v2 lengthening temporalis myoplasty. We also recommend the Gillies plane as a quick and easy alternative to subperiosteal dissection when separating the temporalis muscle from the zygomatic arch in v2.

There were no complications specifically related to our access incision.

Funding

None.

Ethical approval

Not required.

Declaration of Competing Interest

None declared.

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<https://doi.org/10.1016/j.bjps.2021.06.014>

Indocyanine green angiography in breast reconstruction surgery: A systematic review of cost-analysis studies



Dear Sir,

Mastectomy skin flap necrosis (MSFN) is a major complication after skin- or nipple-sparing mastectomy with a prevalence of 11-24%.¹ Indocyanine green angiography (ICGA) has been used in the last ten years in breast reconstruction surgery. ICGA involves real-time fluorescence imaging utilising a near-infrared camera after intravenous administration of the fluorophore, indocyanine green. There has been evidence that it has greater sensitivity than just clinical assessment to identify skin flaps with reduced perfusion.

Given the significant financial burden of healthcare costs on patients and the healthcare system, it is important to examine technologies from a cost-effectiveness perspective. Although the utility of ICGA has been increasing in breast reconstruction surgery, the cost-effectiveness of its use remains in question.¹⁻⁵ We conducted a systematic review to evaluate the cost-effectiveness of ICGA in breast reconstruction surgery.

Electronic databases Ovid MEDLINE, PubMed, Web of Science, and the Cost-Effectiveness Analysis (CEA) Registry were systematically searched using Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Publications up until October 20, 2020 were evaluated. Five studies were included for final analysis (Figure 1). The results of a quality analysis by the CEA Registry were only available for one of the included studies which had a score of 4 out of 7 (Table 1).⁴ Due to varying methods of cost analyses a meta-analysis was not performed.

The study by Mirhadara (2019) compared 206 immediate implant-based breast reconstructions performed using ICGA to a historical cohort that did not use ICGA. Routine use of ICGA decreased MSFN rate from 12.4% to 6.3% as well

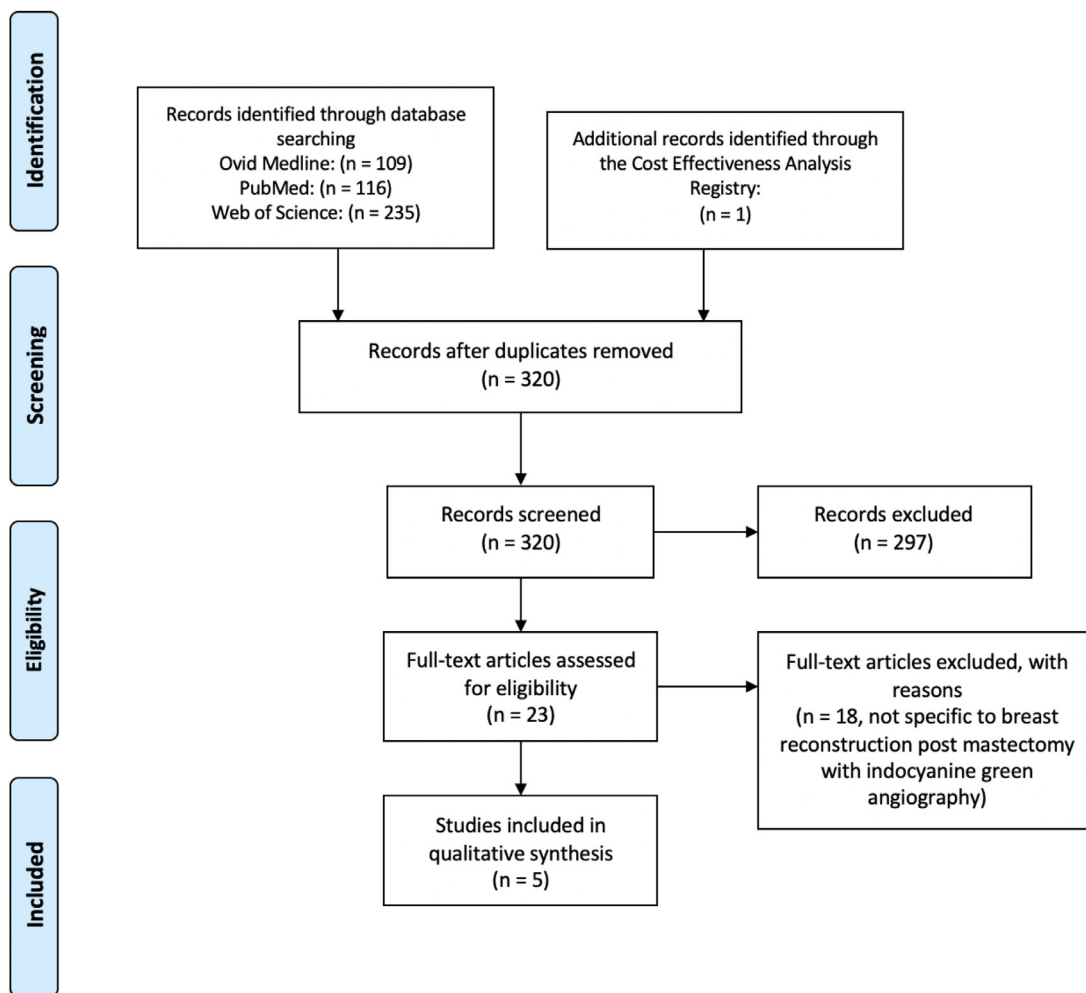


Figure 1 PRISMA Flow chart of systematic literature search.

Table 1 Summary of cost-analysis studies evaluating ICGA in breast reconstruction.

Reference, country, year of cost analysis	Comparison	Methods	Quality score*	Total cost difference	Limitations	Conclusions
Mirhaidari (2019) ² , US, 2014-2015	Implant-based breast reconstruction with ICGA versus without	- Retrospective review - 126 patients (206 reconstructions) in ICGA group versus 117 patients (194 reconstructions) in non-ICGA group - Costs based on itemized bills and Medicare Reimbursement CPT codes	N/A	- Gross cost savings of \$396,453 - Net savings of \$185,753 in favour of ICGA	- Retrospective study - Use of a historical control group as a comparison	ICGA was cost-effective in reducing incidence of MSFN, implant loss, and overall reoperation rate
Duggal (2014) ³ , US, 2009	Implant-based or autologous breast reconstruction with ICGA versus without	- Retrospective review - 184 patients in ICGA group versus 184 patients in non-ICGA group - Costs of reoperations and associated hospital stays calculated	N/A	\$610 per patient saved in favour of ICGA	- Retrospective study - Use of a historical control group as a comparison	ICGA use reduced costs due to a decrease in unexpected reoperations and hospital admissions costs
Chatterjee (2013) ⁴ , US, 2011	Autologous breast reconstruction with ICGA versus without	- Literature review - 152 reconstructions in ICGA group versus 1497 reconstructions in non-ICGA group - Complication rate probabilities combined with Medicare Reimbursement CPT codes and utility estimates for complications	4	\$774 per patient saved and \$3517 per QALY gained in favour of ICGA	Literature predates modern microsurgical techniques so complication rate estimates for ICGA non-use were likely high	ICGA was cost-effective in free autologous breast reconstruction
Kanuri (2013) ⁵ , US, 2004-2011	Implant-based breast reconstruction with no comparison	- Retrospective review - 508 patients (710 reconstructions) - Cost of treating implant loss and MSFN estimated and compared to the cost if ICGA was theoretically used	N/A	Cost savings per case were \$2099 for smokers, \$5162 for BMI >30, and \$1893 for mastectomy weight >800 g	- Retrospective study - Based on assumption that positive and negative predictive values of ICGA are 100%	- ICGA was not cost-effective if used routinely on all patients undergoing implant-based breast reconstructions - ICGA use was cost-effective for high-risk patients
Chattha (2017) ¹ , US, 2012-2014	Implant-based or autologous breast reconstruction with ICGA versus without	- Retrospective review of a large database - 107,005 patients in ICGA group versus 3315 patients in non-ICGA group	N/A	\$9080 per patient in favour of not using ICGA	- Retrospective study - Small percentage of the whole cohort had ICGA use	ICGA use was associated with higher debridement rates and higher costs

Indocyanine green angiography (ICGA), Mastectomy skin flap necrosis (MSFN), United States (US), Body mass index (BMI), Not available (N/A), Quality-adjusted life year (QALY), Current Procedural Terminology (CPT).

*Quality score rated on scale of 1-7 by the Cost-Effectiveness Analysis Registry.

as implant loss and unplanned reoperation rates. ICGA use prevented MSFN in 13 breasts resulting in gross cost savings of \$396,453 and net savings of \$185,753.²

Similarly, the study by Duggal (2014) compared 184 patients who underwent implant-based or autologous breast reconstruction using ICGA to a historical control cohort. Routine ICGA use decreased MSFN incidence by 10% and unexpected reoperations by 8% resulting in overall savings of \$614 per patient.³

The analysis by Chatterjee (2013) also concluded that ICGA was cost-effective. Of note, the calculated cost of ICGA per procedure was \$1295 which was significantly greater than other studies. This study reviewed the literature to identify MSFN and flap loss rates with and without ICGA use in free autologous breast reconstruction. There was a \$3517 per quality-adjusted life-year (QALY) gained in favour of ICGA. The added cost of \$3517 per patient life-year gained of perfect health demonstrated that ICGA can improve clinical outcomes with reasonable costs. A limitation of the study was that some of the literature searched predates modern microsurgical techniques and so estimates of complication rates for ICGA non-use were likely high. Their study also concentrated on autologous free flaps and did not take into account the added costs of breast implants.⁴

These studies contradict the findings of Kanuri (2014) who found that routine ICGA use in immediate implant-based reconstruction was not cost-effective if used indiscriminately on any patient. 710 immediate implant-based breast reconstructions without ICGA were analysed. The cost of theoretical ICGA use would exceed the cost of treating MSFN with the additional cost per case of MSFN prevented being \$1537. ICGA use was only cost-effective in patients at high risk of MSFN. Cost savings per case of MSFN prevented was \$2099 in smokers, \$5162 in patients with body mass index (BMI) >30, and \$1893 in patients with mastectomy weight >800 g.⁵

Comparing these studies, the universal theme is that ICGA is a cost-effective technology, being an objective measure in addition to our current gold standard of clinical judgement.²⁻⁵ The Chattha (2017) study was the only study that reported higher costs associated with ICGA using a database of 110,320 patients. There were higher debridement rates seen in patients who had ICGA use. This resulted in more reoperations and an increase of \$9080 per patient with ICGA use. A limitation of this study was that only a small percentage (3%) of the whole cohort used ICGA.¹

All included studies reviewed were retrospective and used variable cost-analysis methods which make it difficult to compare their outcomes. All studies were conducted in the United States and based on their cost codes which may not be applicable worldwide. Future studies in the other countries could be performed utilising local cost codes.

Given the economic pressures that the healthcare system faces it is important to evaluate technologies not only

for clinical outcome but also from a cost-benefit perspective. Although there is a paucity of cost-analysis studies, based on current data, ICGA use is cost-effective. There is conflicting data on whether ICGA use is cost-effective when performed routinely or only in patients at high risk for MSFN. Future prospective analyses are needed to better establish its cost-effectiveness to assist in deciding to adopt this technology in routine clinical practice or reserve it for certain indications.

Funding

N/A.

Ethical approval

Not required.

Declaration of Competing Interest

None.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:[10.1016/j.bjps.2021.08.013](https://doi.org/10.1016/j.bjps.2021.08.013).

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Plastic, Reconstructive and Aesthetic Surgeons.

<https://doi.org/10.1016/j.bjps.2021.08.013>