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Correspondence and Communications

Treatment of burn contractures with allogeneic human dermal fibroblasts improves Vancouver scar scale: A phase I/II trial

Dear Sir,

Burn injuries are among the most devastating wounds and represent the fourth most common type of trauma worldwide.[1] Burns that occur across joints often result in contractures resulting in severe aesthetic and functional impairment due to scar contracture. The current standard of care, scar excision followed by skin grafts or flaps, create donor site morbidity and result in a high rate of recurrence. For these reasons, there has been great interest in treatments that do not involve surgery and the risks associated with grafting autologous donor tissue.

Stem cells have been investigated in the use of burn wound healing and scar contracture with promising results.[2] However, the process of harvesting and expanding stem cells poses a challenge to institutions without the necessary research facilities. As an alternative tool, fibroblasts are one of the primary cell types involved in forming and reorganizing scars. Dermal fibroblasts synthesize and deposit new collagen and elastic tissue that are incorporated into the extracellular matrix. Dermal fibroblasts incorporated into scaffolds have been used to treat diabetic non-healing wounds and partial thickness burns with some success. An off-the-shelf, minimally invasive product that can be administered in an office setting would fill this unmet need. ICX-RHY-013 is an injectable investigational medicinal product consisting of allogentic human dermal fibroblasts (AHDF) derived from neonatal foreskin. We hypothesize that the injection of AHDF will reduce scar contracture through collagen remodeling. This is the first study to assess the safety, tolerability, and efficacy of ICX-RHY-013 in mature burn scars.

In Phase I, four healthy female subjects received ICX-RHY-013 injection into stable abdominal scars (non-burn related) in doses up to 5×10^6 cells/cm^2 with a repeat dose at 4 weeks. Scars were excised at 6-8 weeks and underwent H&E staining to evaluate scar architecture and Y-chromosome-targeted FISH to identify remaining donor dermal fibroblasts. In Phase II, nine patients with stable burn scars were injected with: A) single-dose 2.5×10^6 cells/cm^2, B) single-dose 5×10^6 cells/cm^2, or C) 2.5×10^6 cells/cm^2 with repeated dosing at 4 weeks (Figure 1). At 12 weeks, scar analysis (Vancouver Scar Scale VSS, satisfaction with appearance scale SWAP), quality of life questionnaires (CSQ-8, SF-36), and range of motion (ROM) were recorded (Figure 2). In Phase ll, all patients were greater than one year from the date of their injury and a minimum interval of 6 months from the last contracture release.

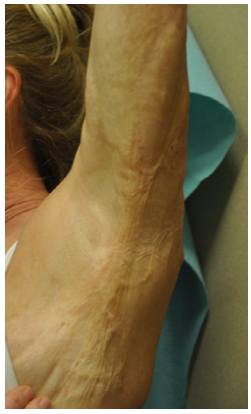

Figure 1 Patient with scar contracture of the left axilla treated with human dermal fibroblasts. Appearance of left axilla prior to treatment.

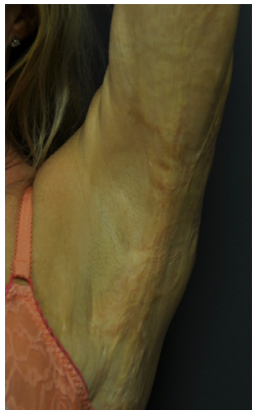

Figure 2 12 weeks following injection.

No serious adverse events were reported. Mild pain, swelling, and redness at the injection site was reported but resolved within 8 hours. In Phase I, H&E stain demonstrated normal scar architecture. FISH analysis demonstrated that the injected cells were cleared by 8 weeks post- procedure, suggesting that the cells enhance collagen and extracellular turnover and then either undergo apoptosis or are cleared by the host.

VSS rating improved significantly from 9.0±1.1 at baseline to 8.1±1.2 at week 12 (p=0.023). The SWAP measures both subjective and social-behavioral aspects of body image (higher scores represent poorer body image).[3] The mean baseline score of 27.8±5.6 improved to 22.0±7.0 at 12 weeks post procedure, however this change did not reach statistical significance (p=0.127). Patients demonstrated high levels of satisfaction throughout the study with no significant difference from 26.8±1.2 at baseline to 27.8±1.8 at week 12 (p=0.228) All patients demonstrated greater range of motion across the contracted joint at 12 weeks following treatment without statistical significance. There was no significant difference with increasing dose.

AHDF injection is safe and well-tolerated. It can be performed in the office without sedation and demonstrates promise as a non-operative treatment for burn scar contractures. Introducing viable neonateal human dermal fibroblasts into dense, constricted, largely acellular scar contractures may synthesize and deposit collagen to allow remodeling of extracellullar matrix.[4] Human fibroblasts exposed to denatured collagen will promote remodeling of the extracellular matrix using matrix metalloproteinases. Furthermore, fibroblasts induce paracrine effects on local keratinocytes and fibroblasts to release cytokines and growth factors integral to stimulating now collagen formation.[5]

Phase I trials for ICX-RHY have been performed in the United Kingdom with minimal adverse events. Phase II trials have followed in the United Kingdom assessing efficacy in treating nasolabial folds and acne scars.[5] Clinical trials utilizing human dermal fibroblast injection for the treatment of epidermolysis bullosa have revealed improved wound healing with no reports of major adverse events. Histologic analysis of patients treated with AHDF for epidermolysis bullosa demonstrate increased levels of collagen up to nine months following treatment despite clearance of the injected fibroblasts around two weeks.[4] This study is limited by the number of subjects and the heterogeneity of initial burn location and functional status.

This study represents the first Phase I FDA clinical trial of ICX-RHY performed in the United States and the first Phase II clinical trial to investigate the use of intradermal injection of human dermal fibroblasts for the treatment of burn scar contractures. Future, randomized, controlled Phase III investigations including a vehicle only group and larger cohorts are needed.

Declaration of Competing Interest

Paul Kemp is the CEO of Intercytex Regenerative Medicine Products. There was no financial support from Intercytex for the research presented.

Funding

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Ethical approval

All methods were in accordance with IRB approval from the University of Pittsburgh Medical Center (PRO10110342) and the FDA (IND# 14527, Clinical trial NCT01564407).

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Targeted Muscle Reinnervation: Does it have a place within the National Health Service (NHS)?

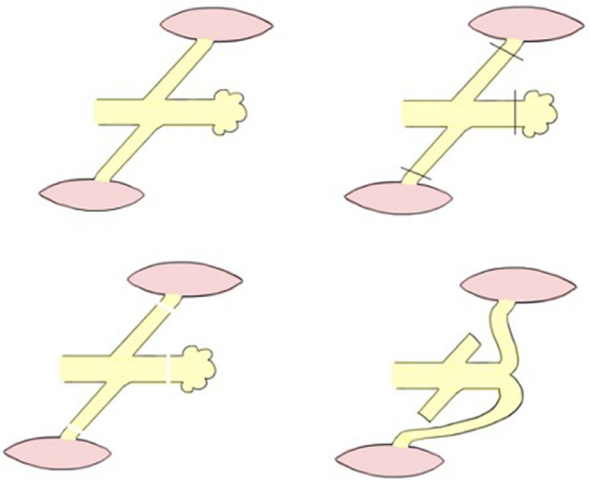

Figure 1 TMR can be conceptualized as a three step procedure. First, the neuroma at the end of the sensory branches is excised. Next, the redundant motor branches innervating the non-functional local muscles are identified and cut. Finally, the cut sensory branches are coapted to the distal cut motor branches.

Dear Sir,

Amputations are performed annually in over a million people worldwide for various indications including tumour excision, reconstruction following trauma, and as a result of vascular and diabetic complications. One major challenge faced by amputees is the phenomenon of post-amputation pain, which can be parsed out into phantom pain and neuropathic pain. The latter is primarily caused by neuromas, which form when the sensory nerves transected during the amputation undergo aberrant, disorganised growth, as they attempt to reach a distal target.

Targeted muscle reinnervation (TMR) is a promising technique for the treatment of post-amputation neuropathic pain and one that is not yet offered in the NHS. The technique involves excision of the sensory neuroma, followed by coaptation of the proximal ends of the transected sensory nerves to the cut motor nerves of nearby non-functional, dennervated muscle targets (Figure 1). TMR likely resolves neuroma pain by providing both a vascularised scaffold for the sprouting nerve axons and a distal target. Although there is a chance of neuroma formation at the cut proximal motor end, this is unlikely to be symptomatic or cause neuropathic pain, as its function is not to signal sense or nociception. A study by Souza et al.[1] reported that 14 of 15 amputees experienced complete resolution of their post-amputation neuropathic pain following TMR and of the patients who had no pre-existing neuropathic pain ($N = 11$), none developed pain after undergoing TMR. In addition, all patients ($N = 26$) were fitted with a prosthesis and 23 patients were able to operate the TMR-controlled prosthesis, demonstrating promising functional outcomes.

In order to consider implementing TMR as the new surgical standard for post-amputation neuromas in the NHS, it must first be shown as consistently more effective than the current treatment. NICE advocates the use of non-invasive pharmacological therapy as first-line management of neuropathic pain, which includes offering a choice of amitriptyline, duloxetine, gabapentin or pregabalin as initial treatment[2]. However, studies have suggested large numbers of patients with neuropathic pain do not receive satisfactory analgesia from pain medications alone or are entirely undertreated with conventional management[3]. This highlights the importance of expanding neuropathic treatment strategies within the NHS.

Other non-surgical management options offered in the NHS for the treatment of post-amputation limb pain include cauterisation and local anaesthetic, fat or Botox injections. Surgical options are limited but include traction neurectomy or neuroma excision followed by deep implantation into local muscle. The former involves nerve release from the soft tissue bed, followed by application of traction as the nerve is surgically cut more proximally. This results in the cut nerve retracting into a muscle and soft tissue bed which protects it from irritation. Inevitably, it often leads to neuroma reformation at the transected site. Dumanian et al.[4] compared the efficacy of TMR with neuroma excision followed by deep implantation into a muscle. The results ($N = 28$) showed a significant improvement of post-amputation pain following TMR and also showed that TMR was superior to the standard neuroma excision in achieving pain-relief. This study invites consideration for a shift towards the use of TMR as the new surgical standard for post-amputation pain within the NHS.

In order to be offered in the NHS, TMR must be cost-effective. No studies to date have effectively weighed the cost of a TMR procedure with the long-term financial costs to the Government and NHS of patients living with inadequately controlled neuropathic pain, which would include the cost of working days lost and decades of pharmacological treatments. As well as financial costs, studies would also need to consider the improvement in quality of life and potential reduction in mental health disease burden in patients undergoing TMR procedures. It is likely that acute TMR performed at the time of amputation would prove to be globally cost-effective as it may prevent the formation of neuroma-associated pain in the first place. For example,

Pet et al.[5] showed that 92% of patients ($N = 12$) were free of palpation-induced neuroma pain following acute TMR vs 87% of patients ($N = 23$) who had delayed TMR. Therefore, acute TMR may reduce the financial and quality-of-life cost associated with neuropathic pain, especially when performed at the time of planned elective amputations such as those carried out for oncological, vascular and diabetic aetiologies.

The literature has shown that TMR is both effective at reducing post-amputation neuropathic pain in the long-term and is superior to alternative surgical options. Therefore, if studies can demonstrate cost-effectiveness of TMR, it may indeed have a place within our National Health Service in the future, alongside complementary pharmacological and psychological therapies.

Ethical approval

Not required

Funding

None

Declaration of Competing Interest

None.

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N/A

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Letter to the editor regarding: Long-term complications of microtia reconstruction: A systematic review

Dear Sir,

With great interest, we have read the article by E M Ronde et al. entitled *Long-term complications of microtia reconstruction: A systematic review*.[1] The authors aimed to analyze long-term complications after auricular reconstruction using autologous costal cartilage (ACC) or porous polyethylene implants, and put forward minimal reporting criteria for future original data studies by performing a systematic review. However, there are several points attracting our attention, and we would like to express some opinions of ours.

Firstly, we believe that the long-term effect of reconstructed ears can be affected by the residual ear condition, the development degree of temporal bone, the thickness and tightness of auriculomastoid skin, the height of temporal hairline, the age of operation, and the surgeon's skills. Besides, the development of costal cartilage in patients with ACC method should also be considered. For microtia patients associated with hemifacial microsomia or previous surgical history of retroauricular mastoid region, the poor conditions of local skin and fascia flaps may also lead to a high incidence of complications. In addition, the gender distribution in this systematic review is not mentioned, we wonder whether the gender difference could also affect the long-term results of reconstructed ears.

From 1959 to 1990, Tanzer and Brent methods were mainly used for ear reconstruction.[2] After 1990, Nagata's method and soft tissue expansion method emerged, and the former had become widely used among countries due to the two-stage operation, fine surgical effect, less technical difficulty, and reliable long-term effect.[3] However, a relatively poor surgical effect was observed on cases with thick or tight postauricular skin. Additionally, the scars and pigmentation in postauricular region are also unacceptable for some patients. For the expanded two-flap method with three stages, it is applicable to various postauricular skin conditions, especially for patients with tight and thick skin. The shortcomings lie in the relatively long treatment period, difficulty of technical control, unstable effect, and long learning period. For the single-expanded flap method with two or three stages, since skin grafting is unrequired,

scars and pigmentation in the donor and recipient site are avoided. However, the long treatment cycle, hard technical control, and unsatisfied results for cases with tight postauricular skin are also observed. Furthermore, the reconstructed ear with insufficient ability to withstand compression and strike make it necessary to worry its long-term safety. Considering those complicated conditions, we have put forward an individualized treatment and achieved the expected results in our center. We adopt the single-expanded flap method if the auriculomastoid skin is loose, and the Nagata's method if the skin is loose and thin. As for the tight skin, the expanded two-flap method is adopted, especially for hemifacial microsomia cases with tight and small skin area. According to our experience, individualized treatment is beneficial to improve the overall effect and the excellent rate of ear reconstruction. Currently, 50% of our cases are treated with the Nagata's method, 27% with the expanded two-flap method, and 23% with the single-expanded flap method.

We thank E M Ronde et al. for this elaborate systematic review for the purpose of analyzing the long-term complications after ear reconstruction and put forward minimal reporting criteria for future original data studies. But further investigation is also required to render it more persuasive.

Funding

None.

Ethical approval

N/A.

Declaration of Competing Interest

No conflict of interest.

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A feasibility study of real time dynamic three-dimensional auricular image guidance based on augmented reality

Dear Sir,

The ultimate goal of ear reconstruction for microtia is to obtain perfect match of bilateral auricle. While the fabrication of a framework determines the fine structure, cranioauricular angle and the size of ear, the localization of the reconstructed ear is more important as it determines the overall postoperative outcome. Surgeons commonly use planimetric marker lines for guiding the ear position and making the cartilage framework when performing ear reconstruction, which is often not accurate.[1] Recent advances in augmented reality (AR) technology make it possible to overlay computer-generated images onto patients' bodies.[2] To enhance the aesthetic and symmetric outcomes in patients with microtia, we recently developed a technique by projecting three-dimensional (3D) auricular image to the surgical site using AR technology. By this technique surgeons were able to see 3D structure of the reconstructed ear intraoperatively, which undoubtedly made the guidance for ear reconstruction objectively and more accurately without disturbing the operation room setting.

Here, we explored the procedure of building the real time dynamic three-dimensional auricular image guidance and verified its accuracy to lay the foundation for its application in clinical ear reconstruction in the future.

Computed tomography (CT) data of skulls were obtained from three volunteers (2 males and 1 female; mean age 25.7 years, age range 24–27 years) and built as 3D auricular digital models using ITK-SNAP software (version 3.6.0, USA) and MeshLab software (Version 2016.12.23, Italy). The location of real auricle was obtained through the capture of three infrared motion sensors on the point under the lobe, nasal tip and eyebrow end by infrared tracking device (Natural Point V120: Trio, Opti Tracker Inc., USA) in Motive software (infrared tracking device's supporting software). The 3D auricular image was projected to the corresponding real auricle following the registration of the virtual auricle model and the corresponding real auricle in Unity software (Version 2019.1.1) (Figure 1). The movements of volunteers' head were tracked by infrared motion sensors to achieve real-time tracking and image adjustment.

We evaluated the matching accuracy between 3D auricular image and the corresponding real auricle by calculating

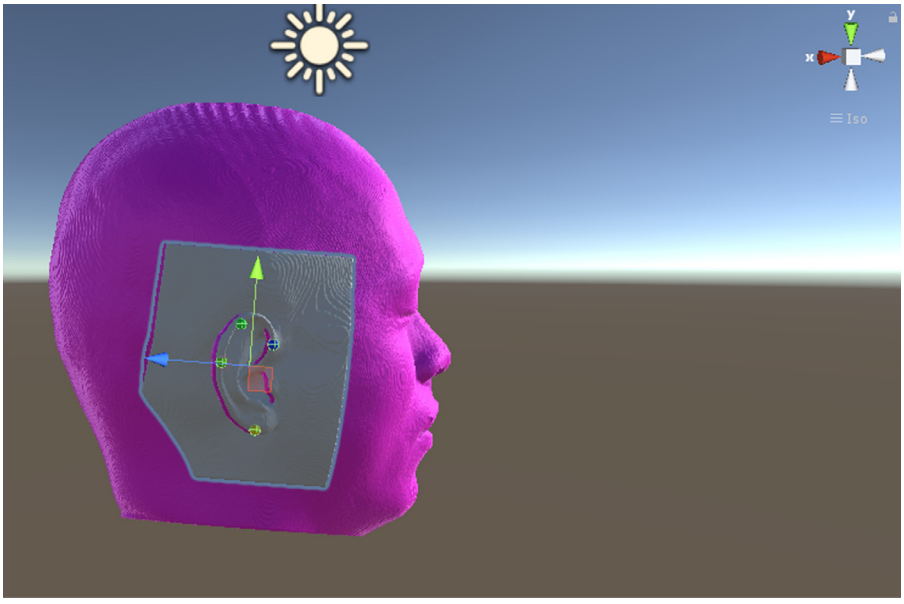

Figure 1 Registration of the virtual auricle with the corresponding real auricle.

Table 1 The average coincidence error rate of the projected auricle image and the real auricle in three volunteers.

	Left ear			Right ear		
mark point	upper	lower	Anterior	upper	lower	anterior
error rate	**2.3%**	**2.6%**	**2.4%**	**2.5%**	**2.4%**	**2.5%**

The average coincidence error rate of the projected auricle image and the real auricle in three volunteers under different rotation angles

	clockwise				counterclockwise	
rotation angle	60°	45°	30°	15°	15°	30°
error rate	16.6%	10.3%	**2.7%**	**2.3%**	3.5%	10.8%

The average image deformation rate of the projected auricle image under different rotation angles

	clockwise				counterclockwise	
rotation angle	60°	45°	30°	15°	15°	30°
error rate	7.0%	4.7%	**2.4%**	**1.6%**	**2.6%**	5.9%

Note: Coincidence error rate = coincidence error between mark points/length of auricle Image deformation rate = average value of the length of projected image auricle /length of real auricle and the width of projected image auricle/width of real auricle.

the coincidence error rate after registration, calculating the coincidence error rate, image deformation and tracking latency during tracking (Table 1). The result showed the registration precision was high, the precision of tracking head movement was high and image deformation was low in a certain rotation range and the image update and motion tracking speed were satisfied and not significant delays were recorded (Figure 2).

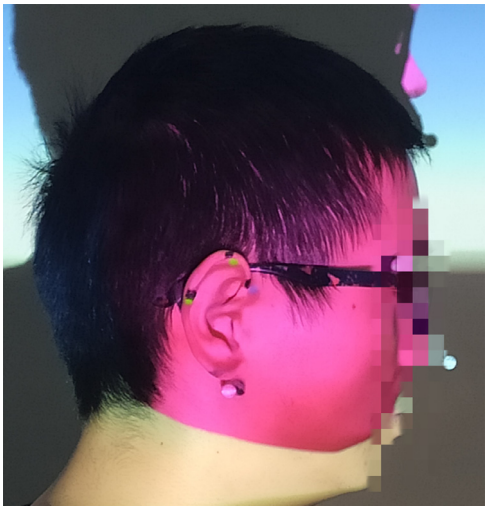

Figure 2 Evaluation of the matching accuracy of the real time dynamic auricular image guidance.

In this study, the auricular image guidance has the following three characteristics: firstly, it is highly consistent with the reconstructed ear (in this study, normal auricle); secondly, it does not affect the operation of surgeons and meet the requirements of the degree of deformation and latency due to the position change intraoperatively; thirdly, patients will not be overburdened physically or economically. The matching error between the auricular image guidance based on AR and the real auricle was lower than the difference between the normal bilateral ears (2.7%), which indicates that this image guidance could be used as the basis for the following clinical study.[3]

As one of limitations to this study, the virtual 3D model cannot be displayed with stereoscopic perception. We will continue to refine our technology to provide an improved visual guidance for ear reconstruction. What is more, only when the problems, including sensor disinfection, occlusion of sight and so on are solved can this technique be applied into clinical ear reconstruction.

Ethical approval

The study conformed to the Declaration of Helsinki and ethical approval was given by the medical ethics committee of Plastic Surgery Hospital, Chinese Academy of Medical Sciences (number 2020-100).

Volunteer consent

Volunteers provided written consent for the participation in this study and the possible publication for photos.

Declaration of Competing Interest

None declared.

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Funding

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A novel microsurgery clamp incorporating the cuff technique for ultrasmall vessel coaptation

Dear Sir,

Microsurgical anastomosis of small vessels is an essential part of reconstructive surgery where the continuity of a vessel is restored. Lymphaticovenous anastomosis, which uses supermicrosurgery to divert the drained lymph fluid to tiny venous ducts helps relieve lymphatic obstruction.[1,2] However, this usually involves the anastomosis of smaller lymphatic vessels around 0.3-0.5 mm diameter, which is technically more challenging.

The cuff technique of vessel anastomosis is commonly used in veterinary microvascular surgery on small animals. This is also seen in Synovis vessel couplers used routinely in vessel anastomoses for flaps.[3] The cuff technique allows eversion of the vessel wall with intima-to-intima contact and reduces vasospasm and external compression of the blood vessels. However, the coupler is not intended for use with veins and arteries having an outside diameter less than 0.8 mm. We have designed a novel double vessel clamp that combines the benefits of a double clamp and the cuff technique, and can be used for suturing very small vessels. It can be used to open both blood vessel lumen ends for quick and easy suturing without suturing the backwall.

Results

Clamp design

Refinements were made to improve the quality and suitability of the device when used *in vivo*. Problems encountered included obtaining the appropriate internal diameter of the double-clamp cuff end. Clamp adjustment under magnification, smoothness, and approximation distance of the clamp ends were also evaluated. Clamp pressure was also adjusted to allow sufficient pressure to stop blood flow but not to cause excessive pressure on vessels. The clamp was also designed to be easily removed from anastomosed vessels using a microsurgery clamp applying forceps (**Figure 1**, **Supp Figure 1**).

Clamp operation

Blood flow is stopped with application of the two ends of the clamp, ensuring that the blood vessel is fully within

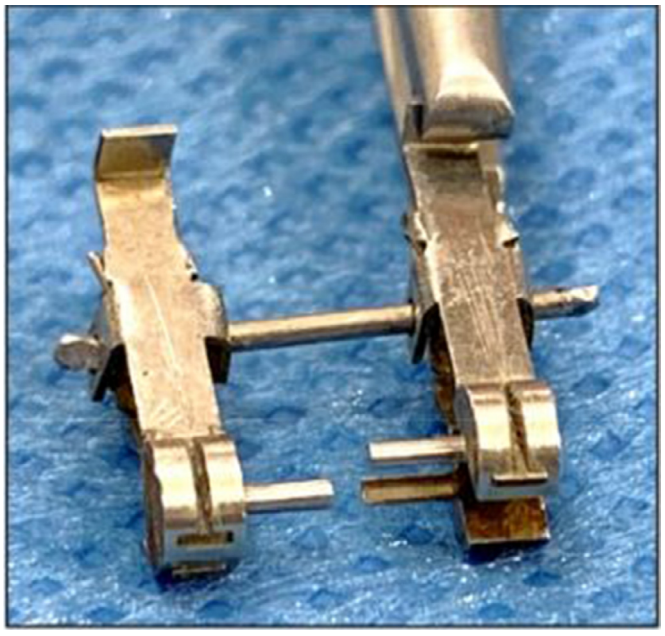

Figure 1 Microvascular double-clamp device with the cuff technique incorporated.

the metal cylinders without catching the walls. Adventitia is trimmed off flush to the vessel lumen. The vessel is then everted and approximated at the edges without tension. A 10-0 nylon monofilament suture was used to perform the anastomosis. Placement of sutures is first performed at the 12 and 6 o'clock positions. Subsequent interrupted sutures are placed between the two points, equally spaced. The clamp is then flipped as normal.

The patency of artery and vein was confirmed by the vascular patency test. A latex injection experiment was also performed to check patency of the anastomosis and perfusion of the limb distal and downstream from the anastomosis (Figure 2). After anastomosis and flowing for several minutes, a fine bore needle was introduced proximally to the anastomosis and latex dye was injected into the femoral artery. Yellow latex was distributed to the arterial blood vessels of the entire flap, and distally to the arterial blood vessels of the thighs, ankle, and toes.

The rats with the anastomosed femoral vessels leading to the skin flap were observed postoperatively for flap survival. Complete healing of the flap was seen on postoperative day 21 indicating that the anastomosis remained after the use of the anastomotic double-clamp device with hand suturing. Flap patency and perfusion of the skin paddle were monitored from body temperature and capillary refill time, which all indicated a healthy skin flap on clinical examination **(Supp. Figure 2A,B)**.

Sections of the anastomosed flaps harvested from the rats were examined histologically with H & E staining. The suture on the exterior did not affect the internal lumen of the anastomosed vessel and there were no abnormalities detected in the architecture of the vessel. Flap tissue showed minimal infiltration of lymphocytes with a smooth intimal segment of the vessel wall. The flap epidermis, hair follicles, fat, and muscle tissues were all intact **(Supp. Figure 2C)**.

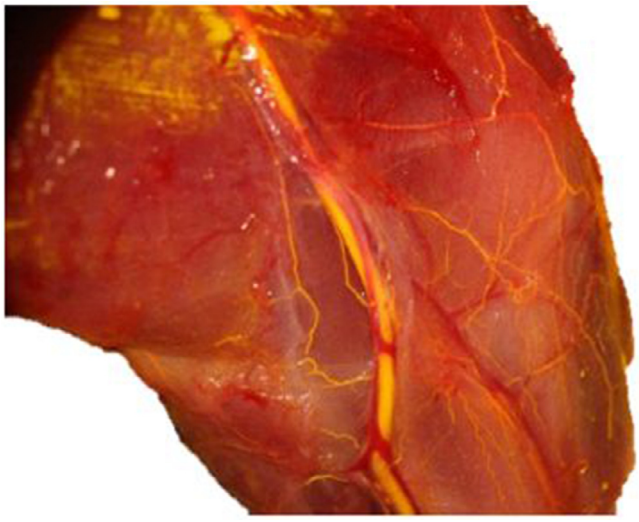

Figure 2 Rat femoral arteries anastomosed utilizing the novel microsurgery clamp with Latex injection demonstrating patency across the anastomosis and the presence of distal flow.

Discussion

This novel microsurgery clamp was applied successfully to the anastomosis of small caliber vessels (the diameter of 0.5–0.9 mm in rats). The clamp can be used for training novices in microsurgery for the anastomosis of small vessels.

To evaluate the efficiency of the device, we compared the hand-sewn anastomosis times between using the device and conventional double clamp. For skilled surgeons, the hand-sewn anastomosis times of rat femoral arteries was around 7.9 $\pm$ 0.2 min and 10.7 $\pm$ 0.6 min using the

device and conventional double clamp, respectively, on video analysis (* $p < 0.05$, Student's t-test, $n = 3$). This suggests that the device can facilitate the anastomosis of small vessels.

A patent application has been approved in Taiwan, demonstrating novelty in the design[4]. We hope that this device will encourage further application of microsurgical coaptation to small vessels applicable in many clinical scenarios. The internal diameter of the device's cuff was designed as 0.3 mm, suggesting that it can be applied for 0.3–0.9 mm diameter of vessels, but not for less than vessels of 0.3 mm ID. It may facilitate and simplify the anastomosis of human lymphatic vessels (0.3–0.5 mm).

Declaration of Competing Interest

The authors declare no conflicts of interest.

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Ethical approval

Animal protocols were approved by the Committee on the Ethics of Animal Experiments of CGMH in Taiwan and the Institutional Animal Care and Use Committee (IACUC) of CGMH in Taiwan under permit numbers IACUC 2018080701 and IACUC 2019010201.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.bjps.2021.09.006.

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Prolonged surgical duration in open craniofacial surgery: Detrimental to cognitive functioning?

Dear Sir,

Studies suggest that brief surgical interventions early in life do not negatively affect cognitive functioning[1,2]. However, preclinical studies suggest that exposure to anesthetics for ≥2 h can cause neuronal apoptosis, potentially affecting cognitive functioning[3]. We assessed the independent associations between cognitive outcome and surgical and anesthesiologic factors by measuring cognitive performance in children who previously underwent open craniofacial surgery.

Table 1 Baseline characteristics, perioperative factors, and postoperative factors.

Baseline characteristics	
Severity of trigonocephaly (degrees)	99.2 ± 5.1 (range: 88.1–109.3)
Age at time of surgery, months	11 ± 4.4 (range: 5–20)
Extracranial congenital anomalies, *n*	11/52
Perioperative factors	
Blood loss, ml/kg	80.8 ± 40.2 (range: 20.1–211.5)
Blood products administered	
Total, ml	535.9 ± 365.8 (range: 40–1647)
Platelets, ml	16.1 ± 52.5 (range: 0–254)
Plasma, ml	99.7 ± 134.5 (range: 0–556)
Erythrocytes, ml	438.1 ± 232.2 (range: 40–1220)
Low hematocrit (≤20%), *n*	0/52
Acidosis (arterial blood pH ≤7.35), *n*	36/50
Low O_2 saturation levels ($SatO_2$ <80%), *n*	0/52
Surgical duration, minutes	185.0 ± 33.1 (range: 110–280)
MAC-minutes	220.9 ± 52.8 (range: 114–406)
Postoperative factors	
Hours recovering in the intensive care unit	26.1 ± 9.2 (range: 18–74)
Low hematocrit (≤20%), *n*	0/52
Acidosis (arterial blood pH ≤ 7.35), *n*	17/48
Hypotension, *n*	0/50
Clinically significant venous air embolism, *n*	0/52
Postoperative infection, *n*	1/52
Sepsis, *n*	0/52
Readmission to intensive care, *n*	0/52

Except where indicated otherwise, data are presented as the mean ± SD.

All children who underwent open cranioplasty for radiologically confirmed metopic stenosis under the age of two at Erasmus University Medical Center from June 1990 through August 2005 were approached. Patients with other primary morphogenic defects associated with cognitive dysfunction and patients who underwent another surgical procedure prior to measuring cognitive assessment were excluded (Figure S1). The study included 52 patients (Table 1) and was approved by a Medical Ethics Committee. All patients' parents provided written informed consent.

Surgical duration was defined as the interval between the first incision and placement of the final skin suture. Cumulative exposure to anesthetic (0.3–1.5% isoflurane with or without 70% N_2O) was measured in MAC-minutes, with 1 MAC-minute equal to the concentration equivalent of 1 MAC of anesthetic for the patient's age for 1 min.

Cognitive outcome was measured using the age-specific subtest short forms of the Wechsler Intelligence, Visual-Motor Integration (VMI), Visual Perception (VP), and Motor Coordination (MC) tests.

Correlations were analyzed using Pearson's correlation coefficient or Spearman's rank correlation coefficient. Ordinary linear regression models were used to investigate the effects of surgical parameters on cognitive functioning. Using a stepwise approach, the effects of surgical duration and MAC-minutes were estimated, and potential confounders with a p-value <0.2 were included in linear regression models (Table S1). Final model selection was based on adjusted R-squared values.

The associations between cognitive functioning and surgical parameters, as well as potential confounders, are summarized in Table S2. The mean (±SD) IQ score was 102.5 ± 20.9. Mean age at assessment was 8.1 ± 3.3 years and was not correlated with IQ score (Pearson's rho=−0.1; $p = 0.50$). IQ scores did not differ significantly either between or within the IQ assessment tools (ANOVA $F = 0.31$; $p = 0.73$). Mean VMI score was 94.9 ± 15.0, and age at VMI assessment was not associated with VMI score (Pearson's rho=−0.03; $p = 0.83$). Mean VP and MC subtest scores were 101.1 ± 19.5 and 89.2 ± 16.9, respectively, with no association between either subtest and age.

Surgical duration was negatively associated with IQ score (B=-0.20; $p = 0.04$) (Figure S2). When surgical duration was taken into account, MAC-minutes had no added effect on IQ scores (B=−0.07; $p = 0.24$). No potential confounders altered the effect of surgical duration on IQ score. The final regression model—including surgical duration and controlling for differences in MAC-minutes—explained 17% of the variance in IQ scores (adjusted R-squared=0.13). This model suggests that each 30-min increase in surgical duration was associated with a 6.0-point decrease in IQ score. The results regarding the relationships between cognitive functioning and surgical parameters are summarized in Table 2.

We found no significant correlation between VMI score and either surgical duration (B=−0.13; $p = 0.08$) or MAC-minutes (B=−0.06; $p = 0.19$) or total VMI score. In addition, we found no effects among the possible confounding factors.

The negative association between surgical duration and IQ supports the widely held hypothesis that the release of inflammatory cytokines such as IL-1, IL-6, and TNF-alpha during surgery can adversely affect cognitive functioning

Table 2 Association between cognitive outcome and surgical duration and MAC-minutes.

	IQ score				VMI motor score			
	β	95% CI		p-value	β	95% CI		p-value
Surgical duration	−0.20	−0.40	−0.01	0.04	−0.13	−0.27	0.01	0.08
MAC-minutes	−0.07	−0.19	0.05	0.24*	−0.06	−0.15	0.03	0.19*

The potential confounders described in Table S2 had no discernible effect on the association between surgical duration and any of the dependent variables. When included in this model, none of these relationships was significantly associated with the dependent variables.

via molecular and cellular processes in both neurons and glial cells, including synaptic plasticity, neurogenesis, cellular migration, and cellular differentiation [4]. This may be particularly relevant in open cranial vault surgery, given that several cytokines—including IL-1, IL-6, and TNF-alpha—can cross the blood-brain barrier and given that the brain is close to the surgical site, where cytokine concentrations can increase 100[4]. The sole clinical study supporting this hypothesis found a weak negative association with total surgical duration among 70 children who underwent surgery for various craniosynostotic defects[5].

Preclinical studies suggest that anesthesia exceeding 2 h during peak brain development can cause neuronal apoptosis and cognitive decline[3]. Interestingly, a clinical study involving young children found a significant negative association between exposure to anesthetic and neurodevelopment[5].

Further studies are needed to confirm that cognition is affected by cytokines and/or surgical duration, factors that can be minimized by applying pharmacological interventions that reduce the immune response and/or shortening the procedure, for example by concentrating care in high-volume surgical centers. Prospective studies examining neuropsychological functions combined with detailed information regarding surgery-related trauma such as surgical duration, blood loss, and cytokine release are needed in order to determine the effect of surgery—particularly open craniofacial surgery—on specific domains of cognitive functioning in pediatric patients.

In conclusion, we report that the duration of open cranial vault surgery in children under 2 years of age was negatively associated with subsequent cognitive functioning in this study. Additional studies are warranted in order to confirm this finding, determine additional potential risk factors and possibly identify clinically relevant protective factors.

Declaration of Competing Interests

All authors report no conflicts of interest.

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Financial disclosure

All authors report having no financial relationships to disclose relevant to this article.

Authors' Contributions

Joris J.B. van der Vlugt: initiated the study, conceptualized and designed the study, recruited the patients, carried out the final analysis, and wrote the manuscript. **Robert R.J. Coebergh van den Braak** collected the clinical data and wrote the manuscript. **Jacques J.M.N. van der Meulen** initiated the study and critically reviewed and revised the manuscript. **Steven E.R. Hovius** reviewed and revised the manuscript. **Frank C. Verhulst** provided critical input regarding the cognitive assessments and critically reviewed and revised the manuscript. **Jolanda M.E. Okkerse** conducted the cognitive assessments and critically reviewed and revised the manuscript. **André I. Wierdsma** provided critical input regarding the statistical analysis and critically reviewed and revised the manuscript. **Steven A. Kushner** provided critical input regarding the study and critically reviewed and revised the manuscript. **Markus Klimek** provided critical input regarding the anesthesiology and critically reviewed and revised the manuscript.

Supplementary materials

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Postoperative apex dorsal displacement after open reduction and internal fixation using locking plate for proximal first metacarpal fracture: A multivariate analysis

Dear Sir,

Open reduction and internal fixation (ORIF) using a locking plate is effective in first metacarpal fracture treatment.[1] Locking plates could provide fixation rigidity, thus enabling patients to initiate early active mobilisation.[2]

However, Diaconu et al. reported poor outcomes and high secondary displacement rates after ORIF with locking plates for first metacarpal fractures following our clinical experience (Supplement).[3] Studies have shown that fractured first proximal metacarpal shafts tend to be pulled and flexed by flexors, abductors, and thenar muscles, causing postoperative apex dorsal displacement (ADD) (Supplementary).[4,5] It remains unclear whether the rigidity provided by locking plate fixation could prevent postoperative ADD, especially after osteosynthesis, during the treatment of first proximal metacarpal fractures. Moreover, comparative analyses between plate and K-wire fixation assessing differences in their postoperative outcomes have not been performed. Thus, we performed a retrospective cohort study examining consecutive 42 thumbs treated with locking plates or K-wires. We excluded patients with bilateral injuries, Bennett fractures, and partial intra-articular fractures: those presenting prior to epiphyseal arrest and those with follow-up periods $<$8 weeks.

Prognostic factors, such as age, sex, preoperative displacement angle, implant used, fracture type (intra- or extra-), and casting duration, were analysed. We measured the postoperative ADD angle—defined as the numerical difference between the postoperative ADD angle and the angle at the final follow-up examination—on lateral radiographs (Figure 1). The postoperative ADD angle was included as the primary outcome in the multivariate linear regression analysis to identify significant prognostic factors. To identify the implications of preventing postoperative displacement, details of techniques and implants used during osteosynthesis were also reviewed, and their effect on postoperative displacement was determined.

Similarly, Pearson's product-moment correlation coefficients (CCs) were calculated to evaluate the relationships of age, preoperative displacement, and casting duration with the postoperative displacement angle. The mean age at injury, follow-up period, preoperative ADD, and postoperative displacement angle was 43 years, 25 weeks, 17.4°, and 8.5°, respectively. Regarding the preoperative displacement angle, no significant difference was found between these two groups (mean displacement, plate vs. pinning: 21.3 vs. 15.3; $p = 0.19$). The affected thumbs were cast for an average of 12.9 days. Although increased age (CC, 0.336) and preoperative displacement (CC, 0.527) showed a significant positive correlation with the postoperative displacement angle, casting duration was negatively correlated with this angle (CC, −0.116). Univariate and multivariate linear regression analyses showed that plate fixation and larger preoperative displacement were significant negative prognostic factors for postoperative displacement (total $R^2 = 0.4823$) (Table 1). In the K-wire pinning procedure, temporary pinning of the trans-carpometacarpal joint improved outcomes (mean displacement, 7.6 vs. 4°). Regarding plate choice, the use of rectangular three-dimensional (3D) plates (mean displacement, 3.5 vs. 15.5°) with 2.3-mm screws (mean displacement, 12.8 vs. 18.3°) was a positive prognostic factor for small postoperative displacement. Five out of six patients whose thumbs showed postoperative displacement $>$20° were treated with a plate, and all of the plates were bent without any screw loosening.

In summary, a positive correlation was identified between advanced age, greater preoperative ADD, and postoperative displacement. Preoperative ADD and a specific treatment choice (i.e., plate fixation) were observed as prognostic factors for postoperative displacement. Trans-carpometacarpal joint temporary pinning and the use of rectangular 3D plates with 2.3-mm screws presented a reduced postoperative displacement.

Table 1 Linear regression analysis of postoperative displacements.

				Univariate analysis		Multivariate analysis	
	Mean (95% CI)	Sample size (%)	Mean displacement (95% CI)	Estimate (95% CI)	p value	Estimate (95% CI)	p value
Patient age							
	43 (36.2-49.1)			0.08 (−0.06-0.22)	0.27		
Sex							
Female		7 (17)	8.0 (4.9-11.1)	-	-		
Male		35 (83)	11.1 (2.5-19.8)	1.79 (−5.77-9.36)	0.63		
Intra-articular fracture							
-		27 (64)	9.5 (5.8-13.3)	-	-		
+		15 (36)	6.8 (2.3-11.3)	−3.70 (−8.96-1.56)	0.16		
ORIF							
K-wire		27 (64)	5.6 (2.9-8.3)	-	-	-	-
Plate fixation		15 (36)	13.9 (8.3-19.5)	6.23 (0.75-11.70)	0.03	6.49 (1.84-11.13)	≤0.01
Casting duration							
	12.9 (7.7-18.1)			0.07 (−0.10-0.23)	0.43		
Preoperative displacement							
	17.4 (13.1-22.8)			0.28 (0.10-0.46)	≥0.01	0.29 (0.13-0.46)	≤0.01

CI, confidence interval; ORIF, open reduction and internal fixation.

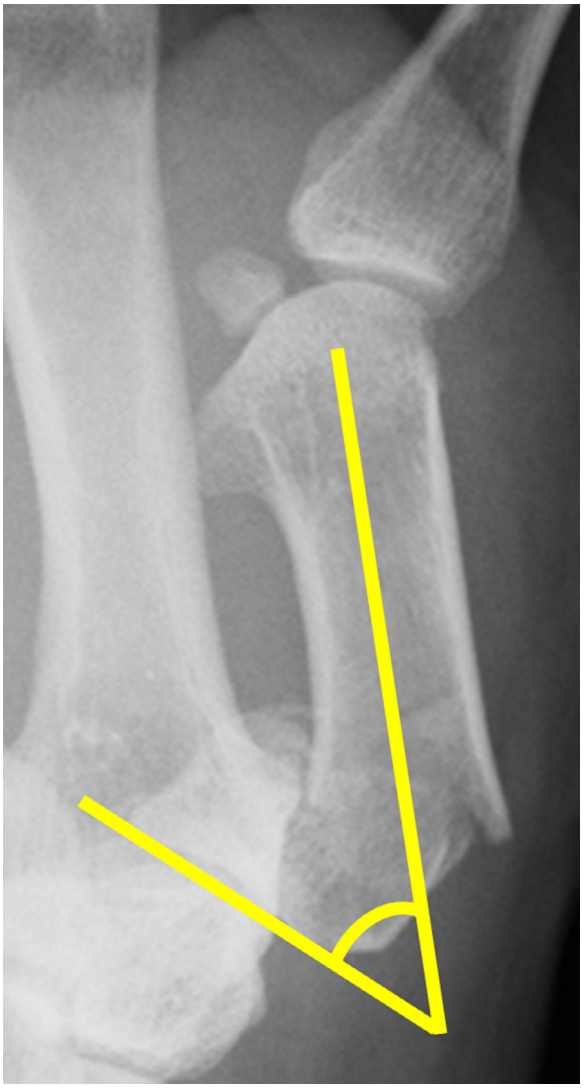

Figure 1 Measurement of displacement angle.
We defined apex dorsal displacement angle as the angle between the axis of the metacarpal shaft and the base of the metacarpal bone.

We demonstrated a significant correlation between preoperative and postoperative displacements. Although preoperative displacement angle can be inaccurate because it is not 'fixed,' the presence of highly displaced fractures implies severe comminution on the dorsal side of the fractured bone. Therefore, the possibility of postoperative displacement can be estimated before surgery based on this correlation.

Casting duration did not correlate with postoperative displacement; this could have resulted from selection bias because surgeons may have used casts when the bone was unstable. The negative effects of postoperative casting on outcomes cannot be established; however, we can assert that postoperative casting cannot prevent postoperative displacement. Our findings suggested the use of rectangular 3D plates with 2.3-mm screws to prevent postoperative displacement after plate fixation. Although we chose 2.0 mm or, more frequently, a 1.5 mm plate for the fixation of metacarpal fracture because of the fragment size, this choice could cause postoperative apex dorsal angulated displacement.

Despite the relatively short follow-up period, limited sample size, biases caused by the study's non-randomised design and inaccuracy of radiographic measurement, we identified the negative effect of using locking plate fixation for first proximal metacarpal fractures, with high rates of postoperative displacement observed. Our findings suggested that we should not be overly confident regarding the rigidity of locking plate fixation; K-wire fixation with temporary pinning of trans-carpometacarpal joint or locking plate fixation with a rectangular 3D plate and 2.3-mm screws might be superior for preventing postoperative displacement in such fractures. Future cadaveric or mechanical-test studies would validate our findings, contributing to the selection of this treatment.

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Ethical approval

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Declaration of Competing Interest

None.

Supplementary materials

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Distal interphalangeal contracture in Dupuytren's disease

Dear Sir,

In advanced stages of Dupuytren's disease a limitation of flexion or a hyperextension deformity of the distal interphalangeal joint (DIP) joint can occurs whilst a flexion contracture is rare and has been reported in 9 cases in the English literature and 14 cases in a non-indexed German journal[1]. Its etiopathogenesis is debated and some authors propose a lateral and a retrovascular cord as the structures involved but their origin from Cleland's ligament, Grayson's ligament, the natatory ligament, the spiral band or the *abductor digiti quinti* is unclear[2]. We present our experience and discuss the etiopathogenesis of the DIP contracture.

This single-centre retrospective study used a survey of three seniors surgeons regarding the management of DIP contracture during 8 years throughout operative reports. The surgeons described the position of the structures involved in DIP contracture and tried to link these structures with what they thought was either Cleland's ligament or natatory cord. Thirty-nine cases equally distributed between the surgeons were found, twenty-four men and fifteen women with an average age of 57 years. The little finger was affected in twenty-four cases, the ring finger in eleven cases, the middle and the index fingers in two cases each. Average contracture was 40° (range 20-100°) and was isolated in eight patients (one middle finger, three ring fingers and four little fingers). The other patients had an associated proximal interphalangeal joint (PIP) contracture.

DIP contracture was caused by a retrovascular cord in 35 cases, the continuation of the lateral cord in 3 cases and by the lateral band from the *abductor digiti quinti* continuous with a retrovascular cord in one patient [Figure 1].

Isolated DIP flexion contracture was secondary to a retrovascular cord. In concomitant PIP contractures there was an expansion of the lateral cord that joined the retrovascular cord. At the distal phalanx, the cord usually ended laterally to the neurovascular bundle, but in some cases, it passed above the neurovascular bundle to end more medially [Figure 2].

Full DIP extension was achieved when preoperative DIP contracture was $\leq$ 30° (28 cases). Severe cases ($\geq$100°) had an average residual loss of extension of 30° (11 cases).

Millesi (1967) described fourteen cases of DIP contracture: one isolated, four with an associated PIP involvement and nine with a palmar involvement. Although, as in Millesi's and Barton's series, we found this DIP involvement often associated with a PIP contracture, we did not find any palmar involvement. We found an isolated DIP involvement in eight patients whilst it has been reported only in isolated cases in four publications[1]. Takase explains this impairment as a "reverse pattern" with a contracture developing from distal to proximal[1].

Two structures are responsible for DIP contracture: the lateral cord and retrovascular cord. The lateral cord extends between the skin and the neurovascular bundle. It inserts distally on the skin and tendon sheath at the base of the middle phalanx and is considered as the pathologic involvement of the lateral digital fascia. For Hurst (2011), this lateral cord is formed proximally from the coalescence of the natatory ligament and the spiral band and causes DIP contracture by a distal extension of the cord beyond the PIP[2]. In Millesi's series, all patients presented a cord lateral to the neurovascular bundle that pushed it towards the median axis.

The retrovascular cord described by Thomine originates from the retrovascular band and extends to the distal pha-

This work should be attributed to: Institut de la main Jouvenet, 6 Square Jouvenet, Paris, France.

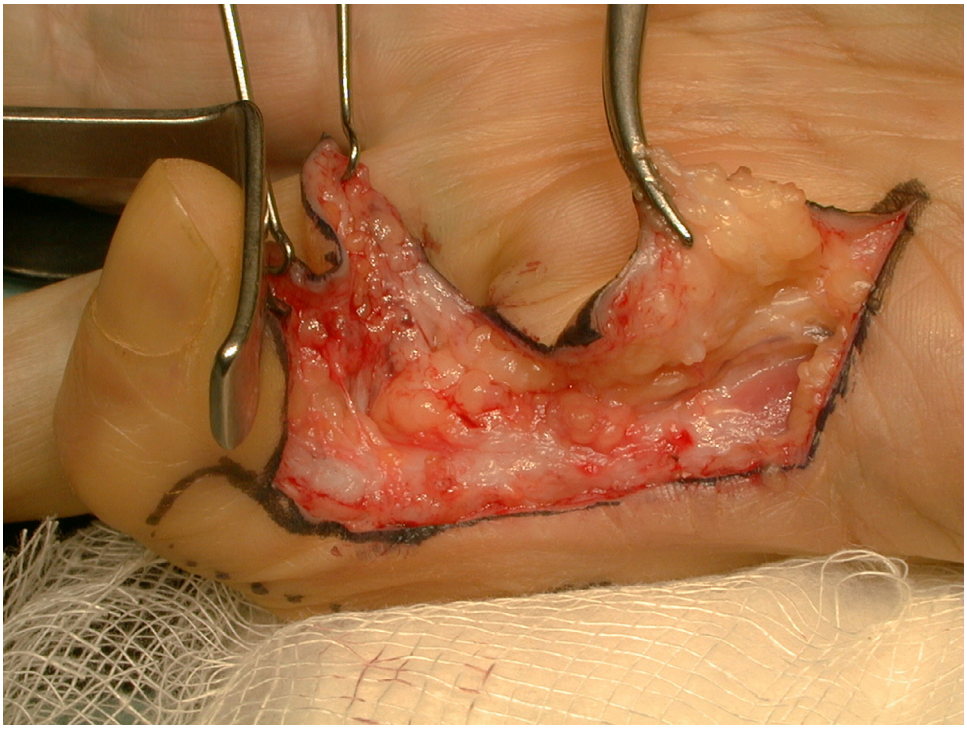

Fig. 1 Intraoperative visualisation of the pathologic tissue arising from *abductor digiti quinti* and ending at the distal interphalangeal joint (DIP).

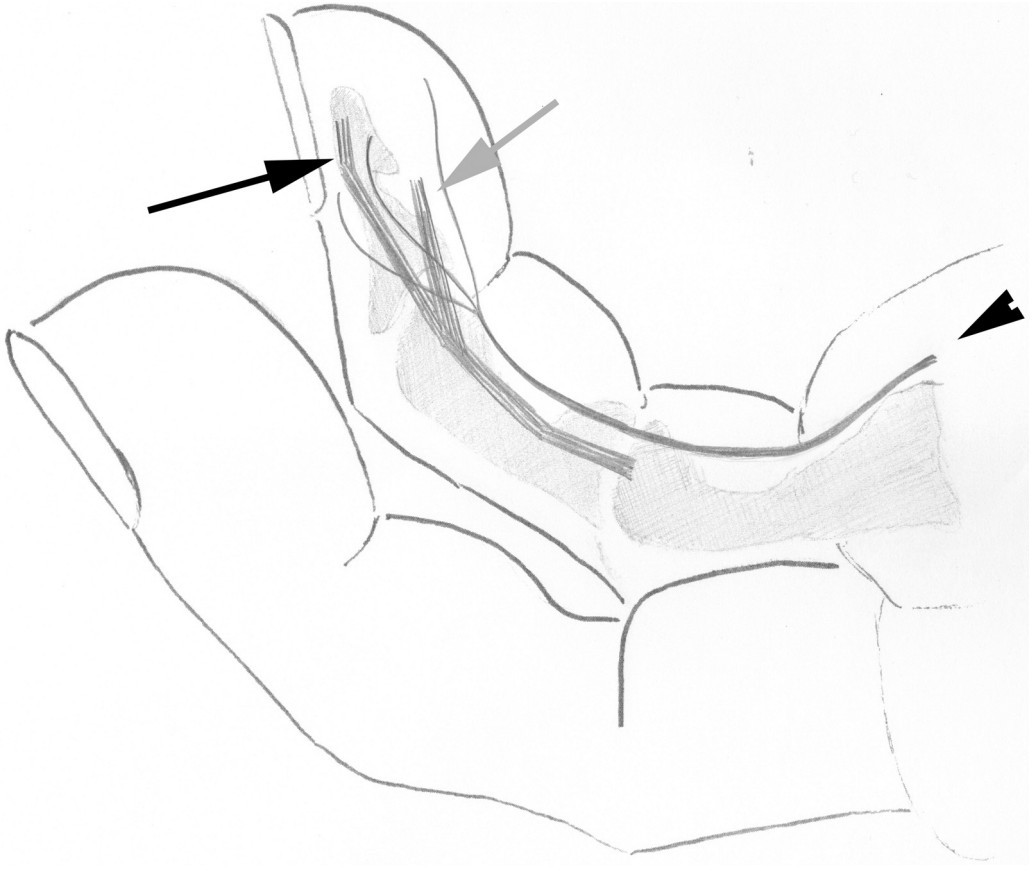

Fig. 2 Schematic drawing of the intra-operative lesions on a distal interphalangeal joint (DIP) contracture. The neurovascular bundle (arrowhead) is pushed medially by the cord that ends lateral to it (black arrow) or sometimes passes over the neurovascular bundle (white arrow). Both endings can be associated. (Drawing by Dr Sylvie Carmès).

lanx as a thickening of the posterior fibrous sheath that encircles the neurovascular bundle. Zancolli and Cozzi failed to find an anatomical structure and the neurovascular bundle was said to extend in a tunnel formed by the volar and dorsal distal fibrous septa of the natatory ligament as stated by Thomine who consider that the retrovascular cord is equivalent to Cleland's ligament. Other authors consider that this structure is separated from the transverse Cleland's ligament and thus could lead to DIP hyperextension contracture[2].

The major controversy is that Cleland's ligament is considered as a transversal structure disease running from the phalanx to the skin, while Thomine considered it as a longitudinal structure with elective zones of fixation to the phalanx[2]. To our belief, the retrovascular cord and the lateral cord are the same thickening of the ligaments that encircles the neurovascular bundle, known as Cleland's ligament posteriorly, and Grayson's ligament anteriorly. Besides, Zancolli stated: "The lateral cord…produces flexion contracture of the DIP joint. This is a retrovascular cord".

Thomine explained the high incidence of DIP contracture of the little finger by the retrovascular cord which merges with the *abductor digiti quinti* whilst White (1984) showed that the lateral cord arose from the ulnar side of the finger from the *abductor digiti quinti*. We believe this is the same structure with different names.

A retrovascular cord and an extension of the lateral cord are probably the same structures that encircles the neurovascular bundle responsible for DIP contracture. Nevertheless, the few reports available are case studies published before 2000 and our speculations are based on our retrospective survey study. Detailed reports are required to clearly understanding this involvement as complete excision of the pathological tissue is mandatory to improve results particularly in severe deformities.

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Addressing the safety of hyaluronic acid dermal filler injections during the SARS CoV-2 pandemic worldwide vaccination

Dear Sir,

We recently read the American Society of Plastic Surgeons (ASPS) guidance concerning FDA reported adverse events in patients with dermal fillers receiving the SARS-CoV-2 mRNA vaccine [4]. Since the importance regarding the safety of aesthetic procedures and the current worldwide pandemic, we decided to address the safety of hyaluronic acid (HA) dermal filler procedures during the SARS CoV-2 vaccination campaign.

Data from literature investigates possible (HA) dermal filler adverse events related to the SARS CoV-2 vaccine. For instance, Gotkin et al. recently addressed the question and designed a survey in order to detect correlations between soft tissue filler injections and any of the SARS CoV-2 vaccines globally available. The data collected did not support any increased risk of developing soft tissue filler adverse reactions associated with the SARS CoV-2 vaccines compared to other previously described triggers [1] . By contrast, in their study, Munavalli et al. presented the first reported cases of delayed inflammatory reactions (DIR) to hyaluronic acid (HA) dermal filler injections after SARS CoV-2 vaccine inoculation [2]. Among these, two cases were related to mRNA-1273 (Moderna) vaccine and one case to BNT162b2 (Pfizer) inoculation (Munavalli). The patients presented lo-

calized symptoms such as primarily edema, erythema, tenderness, swelling. Moreover, formation of painful indurated plaques and nodules occurred in one case requiring treatment with hyaluronidase. The authors believe that the DIR of dermal filler was triggered by the exposure to the SARS CoV-2 spike protein, which could explain the local reaction to HA filler. All the reported reactions were temporary and resolved within a few days.

Given this background, the ASPS recommendation states that patients should not be discouraged from receiving the SARS CoV-2 vaccine. However, patients should be adequately informed before undergoing the aesthetic procedures and a complete medical anamnesis should be obtained before the aesthetic procedure.

However, we notice that Rice et al. performed a review of the literature addressing the same question. They suggest that providers may consider a 4–8 week window (before or after) between the SARS CoV-2 vaccine and HA filler injections for the general population. Moreover, this window should be potentially longer for patients with autoimmune risk factors or immunologic disorders, and those with previous dermal filler reactions [3].

It is of paramount importance to encourage all our patients to abide by the vaccine schedule.

Due to a lack of safety data with regards to the causal link between the SARS CoV-2 vaccination and the delayed inflammatory reaction on the filler injection site, it seems crucial for the scientific community to achieve a consensus on:

- Whether it is appropriate to delay an elective HA dermal filler procedure in patients undergoing the SARS CoV-2 vaccination.
- The number of the interval weeks required before and after the I and II dose of vaccination.
- Whether the same precautionary rule applies to every vaccination.

In addition, we have to consider the need for a second dose of Moderna and Pfizer vaccine up to three months after the first vaccine dose. Moreover, the recent new vaccine from Astrazeneca, which requires an interval of up to three-months between the first and the second dose, could extend the precautionary interval even more [5]. This scenario could appear even more complicated if we take into consideration that the SARS CoV-2 vaccine might require a boosted dosage within six months. Do we need to suspend treating our patients with fillers for the time being?

We believe that a consistent protocol for the collection of the patient's medical history, focused on any present conditions and previous immunological disorders or reactions, is the key factor to eventually postpone a filer implant.

For all the reasons expressed so far, we recommend that this issue to be taken into consideration from all the aesthetic medicine societies in order to reach a global consensus.

Declaration of Competing Interest

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Ethical approval

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Inferior lateral tunneling (ILT) composite separation technique

Dear Sir,

Oscar Ramirez published his "Component separation" technique for closure of abdominal-wall defects in 1990[1]. Further refinements of the component separation technique are still in progress worldwide. According to the standard method of "anterior component separation" described by Ramirez, the external oblique aponeurosis should be divided 1–2 cm lateral to the linea semilunaris after skin flap elevation. It can be combined with the retromuscular (Rives-Stoppa-Wantz) repair which has been proclaimed to be the gold standard for open ventral hernia repair by the America Hernia Society. By this technique, dissection of the posterior rectus sheath is from 0.5 cm of the medial edge of rectus abdominis, laterally to the linea semilunaris - the place of the anterior-posterior rectus sheath junction. It provides an extra medial advancement of the rectus abdominis complex of 1–2 cm per side. This technique was described as an excellent adjunct to the anterior component separation. Combination of those techniques allows retro muscular mash placement sufficient to repair defects of 10–12 cm. The technique can be performed to repair even recurrent hernias after a prior anterior component separation when a mesh covers the prior external oblique releases[2]. On the other hand, posterior component separations (incision of the posterior leaflet of the internal oblique) and TAR procedures (transversus abdomens release) should not be combined simultaneously with any type of anterior release.

For plastic surgeons familiar with the angiosome theory, preservation of the abdominal skin periumbilical perforators is a logical step further. But which way to proceed? First, modification made by Butler[3] - the Minimally Invasive Component Separation (MICS) use bilateral transversal access tunnels in the supraumbilical area, ruffly from the middle of the laparotomy wound, and then two separate longitudinal tunnels for anterior component separation. Second, the Periumbilical Perforator Sparing (PPS) Component Separation technique by Dumanian[4] has additional bilateral subcostal incisions to make anterior component separation and involves a transverse incision about 6–8 cm in length made at the inferior aspect of the rib cage. Finally, turning the discussion to panniculectomy and abdominal wall reconstruction (AWR), a simultaneous panniculectomy is advocated by Nahabedian[5] and a separate subcostal incisions for the anterior release again.

We propose that the anterior release for AWR procedure is executed with an inferior lateral tunneling approach (from inguinal, panniculectomy site) without compromising the circulation to Huger's zone III of the abdominal wall with subcostal incision. Technically ILT offers a much easier and straightforward plane to perform anterior muscular separation when compared to MICS described by Butler which requires two curved J shape tunnels that are difficult to directly visualize. Comparing our technique to the PPS Component Separation method described by Dumanian, the ILT is a modification of the technique but with two key advantages to point out. The ILT technique eliminate the need for an unsightly and potentially vascularly compromising subcostal scar. It preserves the circulation to Huger's zone III of the abdominal wall (flank region). The benefit is a reduced complication rate of wound dehiscence at the inverted T and medial region to 2 dehiscence out of 18 patients in the ILT group comparing to 11 complications out of 26 patients in the skin flap elevation group (standard anterior release). During the average follow up period of 23 months (range 1–50 months) we did not have any case of hernia recurrence (0/44, 0%).

The most of our AWR procedures (37/44, 84%) include panniculectomy. Inferior lateral tunneling for anterior release through the lateral parts of the panniculectomy excision is technically straightforward. First sharp dissection is performed, followed by blunt manual dissection (relatively avascular zone) (Fig. 1,2). With the help of an L-shaped retractor with integrated light source, a long handle scalpel, constant medial traction of the rectus sheath by the surgical assistant and appropriate positioning of the operating table (Trendelenburg position) it is possible to cut the external oblique aponeurosis 1–2 cm lateral to the semilunar line superiorly from the costal margin down to the inguinal ligament sparing periumbilical and also subcostal vascular supply of the overlying abdominal skin. The retro muscular (Rives-Stoppa-Wantz) dissection to the linea semilunaris is taken from the medial part of the wound. To fix the mesh (intermediate-weight, polypropylene, PPE) in a retrorectal subly position under physiologic tension we use Reverdin needle approaching from the inferior tunnel lateral to the linea semilunaris placing the full thickness transmusculofascial sutures (0-Polypropylene). In four cases requiring management of the 'open abdomen', we use the same technique of inferior tunneling (after Barker vacuum packing usually applied by abdominal surgeons) without removing the sheet as microbiologically "safe" plane and by direct medial fascial closure without mesh. All the patients use the same post operative protocol with early ambulation and abdominal binding for 6 weeks.

Presented at: 11th Annual Abdominal Wall Reconstruction (AWR) 2019 organized by MedStar Health, Jun 06 - 08, 2019 at Grand Hyatt Washington

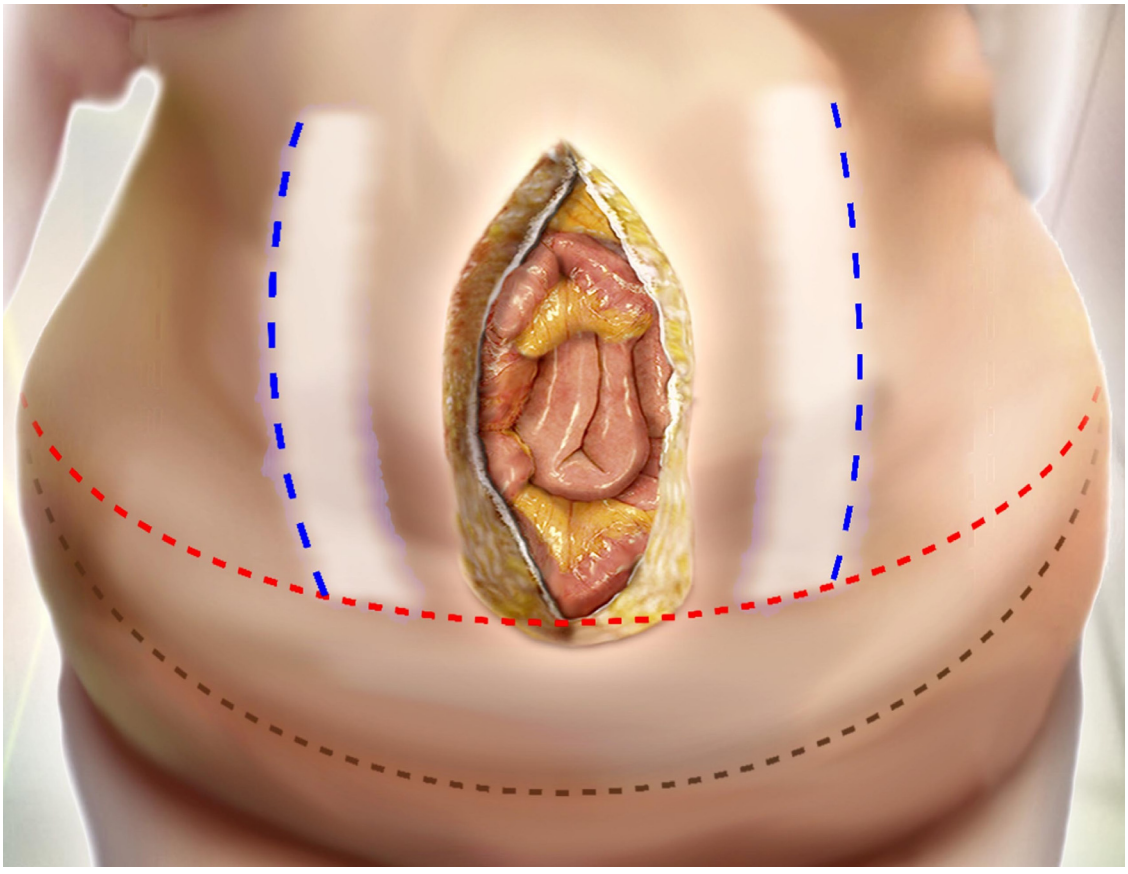

Fig. 1 Schematic drawing – Inferior Lateral Tunneling - plane of dissecton (light color tunnel) and anterior release (blu dots) from the paniculectomy site (cranial margin - red doted and caudal margin- brown doted).

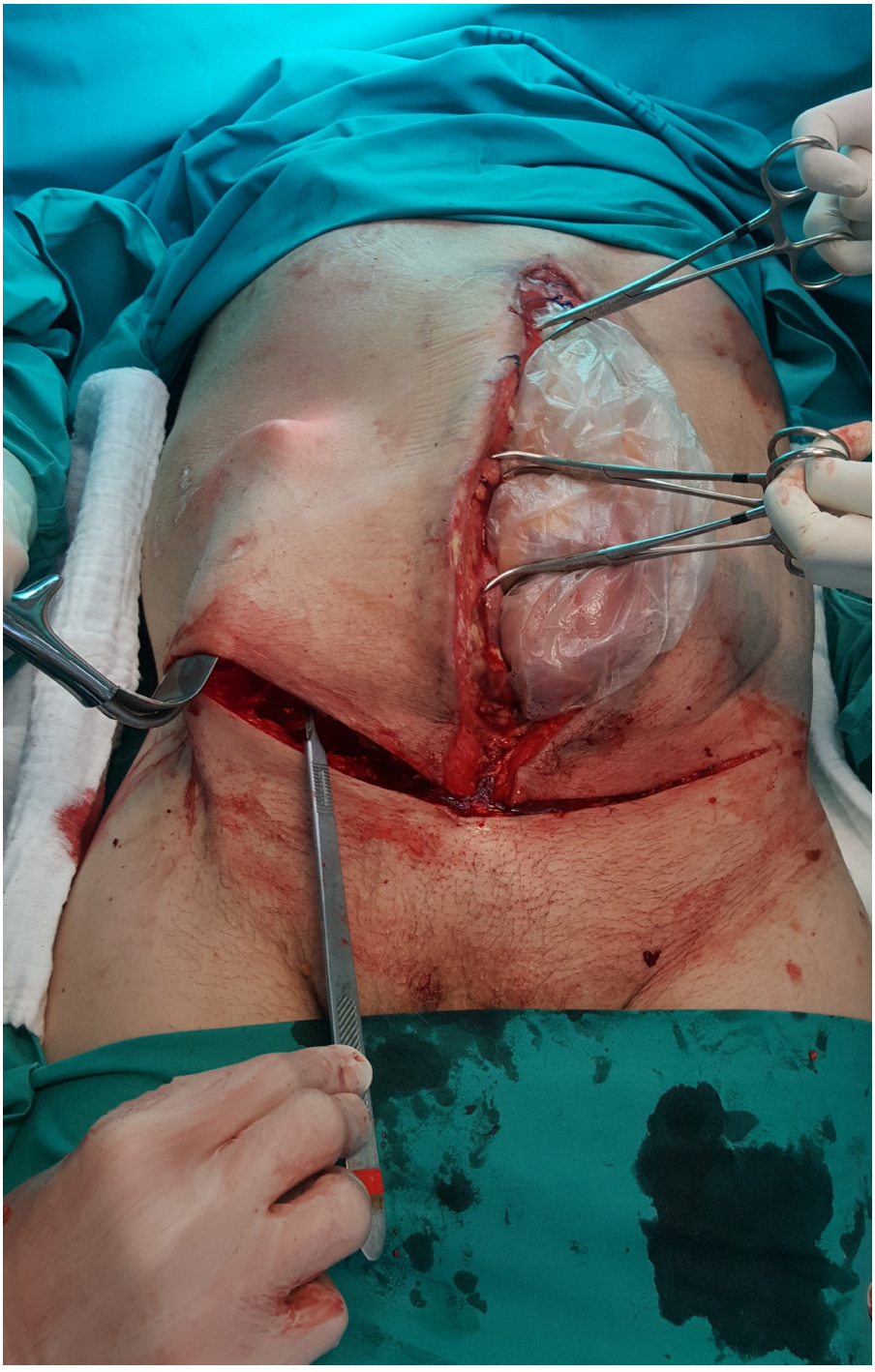

Fig. 2 Barker vacuum packing for open abdomen "in situ", with the help of L-shape retractor with integrated light source, long handle scalpel, constant medial traction of the rectus sheath by surgical assistant and proper position of the operating table (slightly Trendelenburg position) it is possible to cut the external oblique aponeurosis 1–2 cm lateral to the linea semilunaris superiorly from the costal margin and inferiorly down to the inguinal ligament sparing periumbilical and subcostal vascular supply of the abdominal skin.

Declaration of Competing Interest

None declared.

Funding

None.

Ethical approval

Not required

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A letter to the editor: Sentinel lymph node biopsy for Merkel cell carcinoma—A UK-wide perspective

Dear Sir,

Merkel Cell Carcinoma (MCC) is a rare, cutaneous, highly aggressive neuroendocrine malignancy of the skin.[1] Whilst its incidence remains low, it appears to be increasing, with rising cases noted in the United Kingdom (UK).[2] Whilst ultraviolet light and immunosuppression are prominent risk factors, its risk increases exponentially with age, which may in part account for the increasing incidence with an ever-growing elderly demogrpahic.[2] The latest 5-year relative survival rate of MCC is 70%, and mortality remains high despite latest research advancements.[3] Therefore, there remains a need for improved therapeutic planning and effective treatment.

Sentinel lymph node biopsy (SLNB) is used to stage MCC. A positive SLNB has been shown to correlate with both reduced survival and increased recurrence.[4, 5] However, there remains controversy as to on which patients, when, and why SLNB ought to be used and whether or not this has any impact on the treatment provided and subsequent patient outcome. In order to address this and inform future practice, a national survey as performed to establish current practice relating to the use of SLNB in MCC (**Table 1.**).

A total of sixty-four centres were contacted by telephone and emailed a questionnaire on the use of SLNB in MCC (see appendix 1). Sixteen (25%) centres responded and, of these, eight (50%) did use SNLB and eight (50%) did not. The majority of centres saw 10 or fewer cases of MCC per year ($n = 10$; 62.5%), five (31.25%) saw between 11 and 20 cases, and only one centre (6.25%) saw greater than 20, noting a considerable increase in the number of cases their centre had seen in the previous 2 years.

Of those centres which did use SLNB, specific patient criteria were applied to assess the suitability of its use. Performance status and frailty scores were taken into consideration: more frail patients were less likely to be offered SLNB as they were less likely to be suitable for subsequent radical surgery (such as lymphadenectomy) or adjuvant/neoadjuvant therapy. One centre (6.25%) offers SLNB for MCCs of the trunks and limbs, but not of the head and neck. Similarly, another centre reported that SLNB is offered to all patients who are suitable for both surgical management of the lymph node basin and other adjuvant therapies. One centre reported that SLNB does not change their surgical resection margin or plan for radiotherapy but a positive SLNB results in referral to medical oncology for discussion of adjuvant immunotherapy and enrolment in clinical trials. Only one skin cancer MDT reported using SLNB only in patients who had a good performance status and who had initial clear staging on computerised tomography (CT). Amidst all of these factors, patient choice was also always taken into consideration.

The result of the SLNB guided treatment in the same way in the majority of centres which used SNLB. If SNLB was positive, adjuvant therapy to target the positive lymph node basin (depending on site and nodal burden) and/or further surgery after an MDT discussion which included a specialist oncologist was considered. Radiotherapy to the positive nodal basin was the most common adjuvant therapy ($n = 7$; 87.5%). (NB: Once centre commented that they offer adjuvant nodal irradiation without pathological evidence of disease from SLNB.)

Of those centres which did not use SLNB in MCC, the most common reason (reported by $n = 5$; 62.5%) was the

Table 1 A Table to illustrate the responses on the use of sentinel Lymph node biopsy in Merkel cell carcinoma of different skin cancer multi-disciplinary teams across the United Kingdom.

Centre Number	Number of MCCs per Year	Use SNLB (Y/N)	If so, to all patients with MCC?	Specific criteria on use of SLNB in MCC?	Does SNLB guide treatment in MCC?
1	10 or less	N	N/A	N/A	N/A
2	10 or less	N	N/A	N/A	N/A
3	11 – 20	Y	N	Y	Y
4	10 or less	Y	Y	N	Y
5	10 or less	Y	N	Y	Y
6	10 or less	N	N/A	N/A	N/A
7	10 or less	N	N/A	N/A	N/A
8	10 or less	Y	N	Y	Y
9	10 or less	N	N/A	N/A	N/A
10	10 or less	N	N/A	N/A	N/A
11	10 or less	Y	N	Y	Y
12	11 – 20	Y	N	Y	Y
13	11 – 20	N	N/A	N/A	N/A
14	11 – 20	N	N/A	N/A	N/A
15	11 – 20	Y	N	Y	Y
16	Greater than 20	Y	N	Y	Y

NB: Centres have been anonymised to protect confidentiality of responses.

current lack of evidence demonstrating a clear benefit. They commented that MCCs are very high risk tumours with high mortality rates and that data shows a high rate of nodal disease relapse even in those patients with negative SLNB. Consequently, with poor evidence and unclear guidance on its use, two centres (12.5%) commented that they are unable to secure tariffs/funding for its use, resulting in no capacity or commissioning for nuclear medicine and theatre time for SLNB in MCC. One centre (6.25%) did not use SLNB in MCC if disease was limited to in-situ disease. One centre planned on introducing SLNB for MCC, but currently could not accommodate this due to the related increase in workload capacity of surgeons and the local pathology department in processing samples. This department is intending to introduce SNLB to guide decisions on further surgery and consideration for adjuvant radiotherapy.

In conclusion, the incidence of MCC is increasing and accurate staging techniques are required to risk-stratify patients who may benefit from further surgery and adjuvant treatment. Whilst this study is limited by an incomplete response rate across skin cancer MDTs in the UK, it has demonstrated a wide variation in practice regarding SLNB in the management of MCC. Further work should focus on determining whether SLNB is truly of benefit in this patient group.

Declaration of Competing Interest

None of the authors have not conflicts of interest to declare.

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N/A

Appendix 1. MCC QUESTIONNAIRE FOR SKIN CANCER MDTs

1 How many Merkel Cell Carcinomas (MCCs) does your unit see, approximately, in a year?
   a 10 or less
   b 11 and 20
   c Greater than 20
2 Do you offer SLNB for MCC?
3 If your unit does offer SLNB for MCC, do you offer it to all patients with MCC?
4 If not, how do you choose the patients to whom you do offer SLNB for MCC? Do you use specific criteria and, if so, what are these criteria and why these criteria?
5 For those to whom you do not offer SLNB for MCC, why do you not?
6 Does the result of the SLNB for MCC guide your treatment of the MCC?
7 If so, in what way does SLNB for MCC guide your treatment? (e.g. decision to treat with surgery, radiotherapy, neoadjuvant therapy etc.)
8 If you do not offer SLNB for MCC, please briefly elaborate (1–2 sentences) why not.

Thank you very much for your time in answering our questionnaire.

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Continuing to establish the relationship between anatomical location of cutaneous head and neck melanoma primaries and locoregional sites of metastasis: A consideration of a new anatomical site, drainage to multiple and non-adjacent neck levels, and the impact on the selectivity of neck dissection

Dear Sir,

We read with interest Dale et al's excellent paper which suggests melanoma primaries of the posterior head may be amenable to selective neck dissection (SND), due to more consistent patterns of lymph node drainage[1]. Following the Checkmate 238[2] and KEYNOTE-054[3] studies, prognostic benefits of adjuvant immunotherapy in stage III melanoma are evident. Completion lymphadenectomy (CLN) does not afford a survival benefit[4], therefore is no longer routinely performed. However, patients that present with macroscopic disease may benefit from lymph node dissection (LND), before offering adjuvant immunotherapy. LND may also benefit those who relapse whilst on, or following systemic therapy by gaining locoregional control. SND demonstrates favourable morbidity[5] and may reduce operative time. The impact of neck dissection comprehensiveness on prognosis is unclear. We review the link between anatomical location of primary melanomas as described by Dale et al and lymphatic levels of the neck involved in metastasis for our own patient cohort, with the addition of the neck as a separate anatomical region, where primaries were frequently sited in our patients.

A retrospective analysis of 126 consecutive head and neck melanomas treated at one UK tertiary centre between 2004-2021. Clinical records, imaging (lymphoscintigraphy/SPECT), and pathology reports were reviewed. Patients were grouped by primary anatomical location as per Dale et al (anterior, lateral, posterior)[1], with the additional neck primaries category. Where sentinel node neck levels were not documented postoperatively, they were determined on imaging by the senior author.

Of 126 patients, average age 66.3 years, equal gender distribution (male:female, 68:58), 109 had identifiable nodes. Neck levels were documented in 82 patients, 27 determined from imaging. Sixty-six primaries were anteriorly located, 19 laterally, 7 posteriorly and 17 on the neck. An average of 1.88 nodes were excised per patient (range 1-5).

Results demonstrate that anterior and neck primaries may drain to any level within the neck. One posterior primary, three neck, five lateral and 11 anterior (17%) had drainage to more than one level. Of particular note is 7.4% (n=8/108) primaries drained to non-adjacent levels. Furthermore, we identified drainage to occipital and mastoid nodes from lateral and posterior primaries.

Our study demonstrates similar findings to Dale et al in that no patients with a posterior primary drained to level I.

Anterior primaries in both our cohort and Dale et al's, demonstrated similar patterns of distribution of drainage to each level: I, II III most commonly involved and levels IV and V least commonly. Whilst infrequent, drainage to these levels is consistent across both studies. Consequently, excluding these levels in SND could result in small numbers of nodal recurrences.

Our lateral primaries drained only to the parotid, level II and Level V. This contrasts Dale et al's findings where all levels were involved. Of particular note is that our lateral primaries involved drainage to nodes outside of the usual neck dissection levels, drainage to multiple levels and non-adjacent levels. Consequently, we would be cautious to recommend SND for lateral primaries.

Furthermore, we would advocate caution in SND for neck primaries, as nodal distribution was fairly even across all levels and included the parotid.

There are limitations to our study. It is retrospective and data was retrieved from a variety of sources. We accept drainage patterns identified on lymphoscintogram may not be equivalent to patterns of metastatic spread through cervical lymph nodes. However, our data corroborates previ-

Data presented as virtual poster at 10th World Congress of Melanoma/17th EADO Congress 15-17th April 2021: Journal of Plastic and Reconstructive Surgery

Table 1 Number of patients metastasising to neck lymphatic levels and the parotid gland, as well multiple or non-adjacent levels, from grouped melanoma sites.

Anatomical Group	Institution	Total number primary melanoma	Lymphatic Level								
			Level I	Level II	Level III	Level IV	Level V	Parotid	Other	>2 Levels	>3 Levels	Non adjacent Level
Anterior	Hull	**65**	**5**	**39**	**6**	**3**	**2**	**22**	**0**	**8**	**3**	**3**
	Dale et al	33	8	19	7	2	2	18				
Lateral	Hull	**19**	**0**	**12**	**0**	**0**	**3**	**7**	**2***	**5**	**0**	**3**
	Dale et al	11	2	6	4	5	2	4				
Posterior	Hull	8	**0**	**3**	**0**	**0**	**3**	**0**	**2****	**1**	**0**	**1**
	Dale et al	11	0	3	3	2	9	3				
Neck	Hull	17	2	4	3	1	5	2	0	3	0	1

*Other sites for lateral primaries included mastoid and Occipital Chain.
**Other sites for posterior primaries included occipital chain.

ous studies that show head and neck cutaneous lymphatic drainage can be unpredictable. Furthermore, our findings are broadly similar to Dale et al's as we saw no spread to level I from posterior primaries, suggesting it is safe to spare this level in SND for this cohort. We also demonstrate infrequent drainage to levels IV and V from anterior primaries. Consequently, this may inform decisions on an individual patient basis when considering risks and benefits for SND versus CND.

We have added to the discussion by including data on neck primaries, demonstrating unpredictable drainage and highlighting data on nodes outside of the usual neck levels. We emphasise the importance of considering drainage to multiple nodal levels when planning neck dissection, in particular patients with non-adjacent levels.

Table 1.

There is still clearly a role for nodal excision in the management of melanoma. More information is required to clarify whether this should be highly selective: removing only macroscopic disease, selective: removing identifiable disease, or comprehensive: removing all potentially involved nodal tissue in the neck and parotid. This study confirms the unpredictability of cutaneous head and neck nodal drainage which often involves the parotid and multiple, potentially non-adjacent nodal levels. Consequently, the risks and benefits of performing SND versus CND must be determined on an individual patient basis until more information is available. We would recommend the prospective collection of data from multiple units undertaking neck dissection for melanoma to identify the safest management.

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Ethical approval

N/A.

Declaration of Competing Interest

None

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Free nipple grafts for immediate autologous breast reconstruction: Expediting the reconstructive journey

Dear Sir,

Reconstruction after breast cancer surgery is usually a staged restorative journey and not commonly a single surgical event. Immediate autologous breast reconstruction for patients undergoing a mastectomy has been proven safe and is associated with high satisfaction rates. However, revisional surgery usually follows[1]. Preserving the skin envelope allows maintaining the shape and footprint of the breast and even the nipple-areola complex (NAC). Nipple-sparing mastectomy (NSM) with immediate reconstruction is now commonly performed where oncologically safe, as preservation of the NAC has shown to have a positive impact on the aesthetic outcome and the psychological well-being of patients[2].

However, it is challenging to offer NSM to patients with ptotic breasts due to the high risk of nipple necrosis, as the mastectomy violates any potential dermal pedicles that would allow repositioning the NAC. Traditionally, a monitoring paddle for the underlying free flap would be fashioned in the NAC desired position, which could later be used to reconstruct the nipple using a local flap. Tattooing of the nipple and areola would be then offered as a third procedure.

The COVID-19 pandemic led to a significant disruption in this reconstructive pathway, as elective surgeries were cancelled during the first wave[3]. When breast reconstruction services were re-started later in 2020, operating lists were scarce and therefore, strategies that would avoid further revision surgery were preferred. We hereby present the outcomes of a prospective series of patients with ptotic breasts who underwent therapeutic mastectomies with immediate reconstruction with buried microsurgical flaps and free nipple grafts with the aim of reducing the need for further revisional surgery following breast reconstruction.

The NAC graft was harvested from the mastectomy specimen using a standard nipple marker and preserved in a saline-soaked gauze. Once the free flap was revascularized and secured in the breast footprint, the native breast skin was then re-draped and adjusted as necessary, using wise pattern incisions. The free nipple graft was routinely placed on a de-epithelialised area of the mastectomy flap. If there is any concern regarding the vascularity of this bed, the NAC would be placed directly on the de-epithelialised free flap. Graft inset was performed with 4-0 Vicryl Rapide (Ethicon. NJ, USA) and secured with quilting sutures. A bolster foam dressing is applied with a tie over using 3-0 Prolene (Ethicon. NJ, USA). Free flaps were monitored using GEM venous flow couplers (Synovis Surgical Innovations. MN, USA). Graft checks were done in the dressing clinic at one week as the standard follow up for breast reconstruction patients.

A retrospective review of our prospective autologous breast reconstruction database was undertaken, identifying 24 patients who had a total of 25 free nipple grafts as part of their microsurgical breast reconstruction between 1st July 2020 and the 1st July 2021. Twenty-three of these had immediate, unilateral reconstructions using a deep inferior epigastric artery perforator (DIEP) flap and one bilateral DIEP flap reconstruction. Patients had a mean age of 55 years of age and a body mass index of 29.1. All patients had Regnault grade II and III ptosis. None were diabetic or smokers at the time of surgery.

Mean flap weight was 472 g with ischaemia times that ranged from 52 to 90 min. Of these 24 patients, 16 also had a symmetrising breast reduction or mastopexy for the contralateral breast, with an average operative time of 5 h and 10 min. All flaps were buried with no external skin paddle and there were no flap failures. Only one patient presented failure of the free nipple graft due to seroma formation and healed satisfactorily by secondary intention. None of these patients has requested further revision surgery so far. Three patients underwent adjuvant radiation therapy and developed minor hypopigmentation of the grafted NAC, but only one patient requested tattooing to address this.

The use of free nipple grafts has previously been reported by Egozi et al., including a series of 13 cases with a graft take rate of 70%[4]. We adopted this technique in the context of a pressured National Health Service with almost 5 million people are awaiting hospital treatment[5]. In these difficult circumstances, optimising resources by avoiding subsequent operations seems a reasonable course of action. More importantly, it benefits the patients to complete their reconstructive journey without having to waiting for a second and third interventions, which can take place months and even years later.

We conclude that free nipple grafts for patients with large ptotic breasts undergoing mastectomy with immediate autologous reconstruction is safe and can provide good aesthetic outcomes (Figures 1 and 2). It also significantly shortens the reconstructive journey of these patients whilst

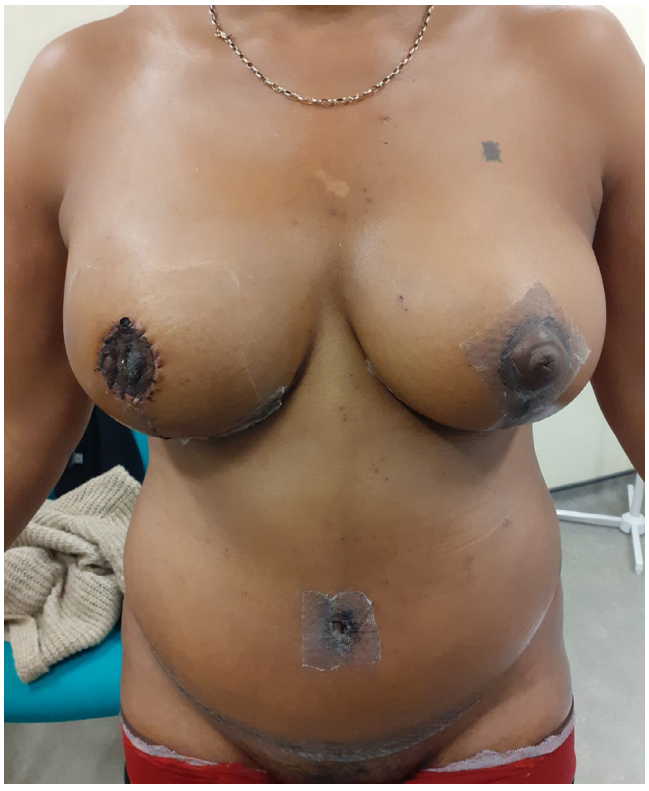

Figure 1 42-year old female patient who underwent right mastectomy and immediate reconstruction with a buried DIEP flap and a free nipple graft. A left breast reduction was done at the same time. Photograph shows an early result at 1 week after surgery.

reducing the burden on NHS waiting lists. In addition, careful collaboration with breast surgeons ensures the oncological safety of the procedure .

Declaration of Competing Interest

The authors do not have any conflicts of interest to disclose.

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Ethical Approval

This is a service evaluation project and therefore does not require ethical approval

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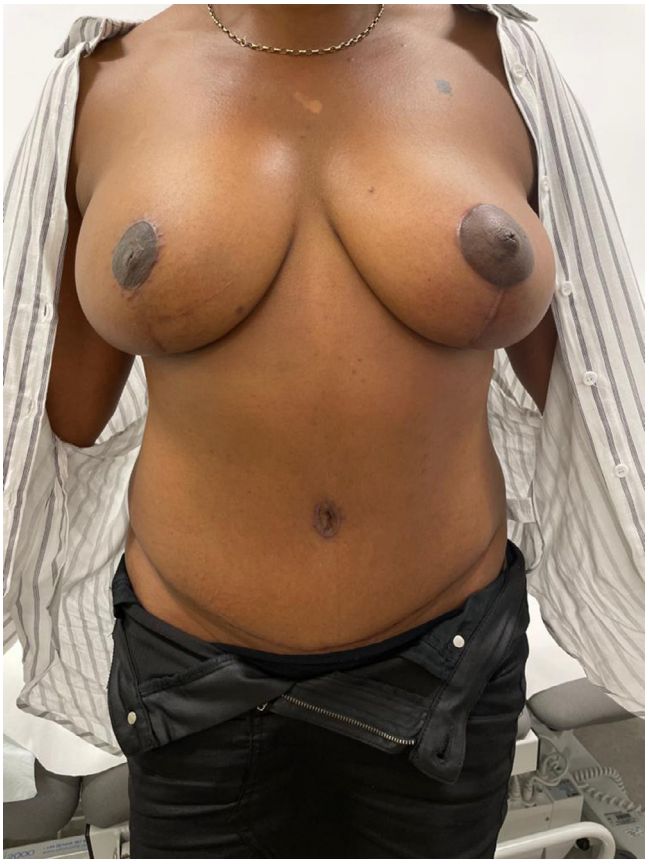

Figure 2 Same patient at 6 weeks after her operation.

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Sexual well-being in transgender patients: Could gender confirming-chest surgery be enough?

Dear Sir,

We read with interest the article by Agarwal et al. entitled "Quality of life improvement after chest wall masculinization in female-to-male transgender patients: A prospective study using the BREAST-Q and Body Uneasiness Test", published in January 2018 in the *Journal*.[1] We commend the authors for contributing with this relevant work to an aspect of plastic surgery that is often neglected: transgender patient care. Their prospective study assessed the impact of mastectomy on body image, physical well-being, sexual satisfaction and chest satisfaction using the BREAST-Q and BUT-A questionnaires.

The importance of gender-confirming chest surgery in improving the well-being of transgender patients is nowadays well established.[2,3] The research of Agarwal et al. added evidence to the improvement of many aspects of trans-male patients' life after gender-confirming chest surgery.[4] Moreover, they highlighted the need to assess long term outcomes as 6-month follow-ups may not reflect long-term attitudes.

When it comes to gender-confirming chest surgery, questions may arise if such procedure may impact alone sexual well-being in transgender male and female patients and if short term outcomes last overtimes.

From October 2019 up to August 2020, all transgender female and male patients eligible for gender-confirming chest surgery in our institution were asked to file two questionnaires preoperatively, at 4- and 12-month post-op (10 trans-female patients and 13 trans-male patients). The first one, BREAST-Q, evaluated the aesthetic aspect of the surgery, while the second, BESAQ, reported body-image awareness during sexual intercourse.

All trans-female patients underwent breast augmentation surgery with round micro-textured silicone implants inserted by inframammary incision and positioned retroglandular (Fig. C). Depending on the patient's anatomy and aspirations, two different mastectomy techniques were performed to masculinise the chest of trans-male patients: 5 patients underwent concentric circular technique mastectomy (Fig. B), and 8 patients underwent free nipple graft technique mastectomy (Fig. A).[5]

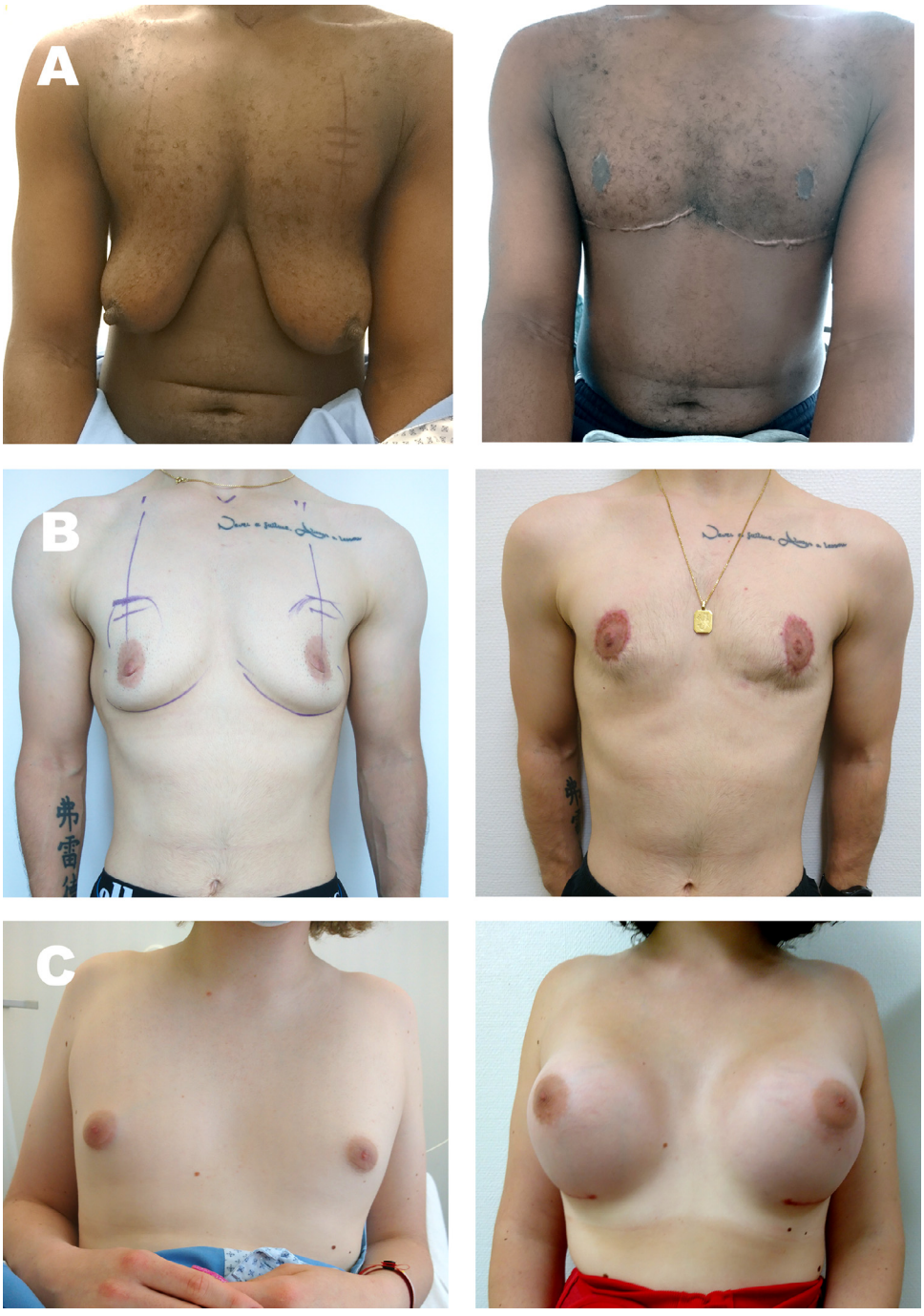
Questionnaires' results confirmed a significant improvement of the psychosocial well-being and patient's satisfaction with breast/chest aesthetic in both trans-male and trans-female patients already at 4-month post-op compared with pre-op ($p < 0.05$). Between 4 and 12-month post-op, statistical analysis did not show noteworthy differences in psychological well-being and chest/breast aesthetic satisfaction in either group.

Regarding the body-image awareness during sexual intercourse, a significantly higher mean score was found in the trans-male group at 4-month post-op compared to pre-op (51.08% $\pm$ 20.21% at 4-month post-op vs. 32.77 $\pm$ 21.68% pre-op, values expressed as average $\pm$ SD, p^{*}). This score was further enhanced at 12-month post-op. These results are consistent with Agarwal et al., suggesting that trans-male patients could be reassured of having satisfying results regarding sexual well-being already 4- to 6-month post-op and lasting over time.

Interestingly, the trans-female group did not show improvement of body image awareness during sexual intercourse at 4-month post-op compared to pre-op values ($p > 0.05$). It is only at 12-month post-op that a significantly higher score was found in this group with mean scores of 81.00 $\pm$ 8.83% at 12-month post-op vs 32.50 $\pm$ 19.59% pre-op (average $\pm$SD, p^{***}). This time-lapse before obtaining an improvement of sexual well-being could be explained by the need for transgender females to undergo surgical sex reassignment as the majority underwent vaginoplasty between the 4-month post-op and the 12-month post-op assessments. These findings add evidence to the need of longer follow-up amongst trans-female patients.

In conclusion, transgender male and female patients obtain maximal improvement in aesthetic satisfaction and psychosocial well-being already at 4-month post-op. In our experience, transgender males achieve the maximal improvement of sexual well-being at 4-month post-op without undergoing phalloplasty, while transgender females, despite breast augmentation, appear to have the need to complete their transition by a vaginoplasty in order to improve their sexual well-being. Nevertheless, a higher number of long-term outcomes assessments is necessary to obtain stronger evidence.

Fig. 1



A: Trans-men free nipple graft technique mastectomy. B: Trans-men concentric circular technique mastectomy. C: Trans-female breast augmentation. All figures represent preoperative view and 6 months postoperative view.

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Ethical approval

Swiss ethic ID 2019-01,226

Declaration of Competing Interest

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Management of orbital dystopia in neurofibromatosis type I☆

Dear Sir,

Neurofibromatosis type 1 (NF1), formerly known as von Recklinghausen disease, is a relatively common autosomal dominant disorder. The skeletal signs include scoliosis and sphenoid wing dysplasia, and bony distortion may occur in some patients with NF1.[1] As the result of the sphenoid dysplasia, the bony orbit is enlarged in the classic egg-shaped orbital deformity, and the globe is displaced downwards.[2] Defects of the sphenoid wing may also occur.

Orbital tumour debulking, anterior levator resection, and lateral canthus formation are commonly performed for mild orbital dystopia in orbitofacial neurofibromatosis. For severe orbital dystopia, orbital exenteration and a prosthetic eye are ultimately required for cosmesis.[3] However, to obtain satisfactory cosmetic results, orbital exenteration is an agonizing choice and is awkward because of emotional input from the patient.

In this paper, we describe our challenge in managing the severe orbital dystopia of orbitofacial neurofibromatosis without orbital exenteration, using orbital osteotomy and tumour debulking.

Between 2012 and 2017, 11 patients with orbitofacial neurofibromatosis were treated. amongst them, vertical orbital osteotomy and tumour debulking were performed for two male patients (aged 21 and 23 years). The amount of vertical movement required by the orbit was predetermined using three-dimensional computed tomography (3D-CT).

The operation was performed through a bicoronal incision with subperiosteal exposure of the cranio-orbital skeleton and a frontal craniotomy. A gingival incision for exposure of the maxilla was also performed.

After the orbital box osteotomy, the tumour tissue which occupied the retro-orbital space was excised. The orbit was then translocated superiorly and fixed at the new position. The frontal bone resected for superior translocation was grafted into the defect space of maxilla.

A pericranial flap was obtained and provided an extra barrier between the intracranial cavity and the frontal bone and sinonasal tract.

Neither patient had any complications, including infection, cerebrospinal fluid leak, or haematoma.

A representative case is shown in Figure 1. This patient is a 23-year-old male with orbitofacial neurofibromatosis. Unilateral pulsating exophthalmos due to a bone defect at the greater wing of the right sphenoid bone was recognised. right orbit was enlarged and dislocated.

After the orbital box osteotomy and orbital tumour debulking, the orbit was elevated by 8 mm, and the orbital roof reconstructed using a split bone graft from the frontal bone.

Six months after the box osteotomy, the neurofibroma at the upper eyelid remained. We recommended tumour and levator resection for the right eyelid ptosis, and the patient was satisfied with the aesthetic result.

With advances in craniofacial surgery, the transcranial approach has become a more practiced and standardized technique.[4] However, orbital dystopia in sphenoid wing dysplasia associated with NF1 is complicated. Although skull base reconstruction was performed, orbital dystopia sometimes remains in severe orbitofacial neurofibromatosis.

To correct the orbital dislocation, bow osteotomy is performed for orbital dystopia. However, to our knowledge, vertical orbital correction for severe orbital dystopia in NF1 has not previously been assessed.

Skull base reconstruction and tumour debulking could be performed for pulsating exophthalmos. However, in severe orbitofacial neurofibromatosis, facial asymmetry due to detachment of lateral canthus and enlargement of orbit is remaining. By performing box osteotomy and reattachment of the canthus ligament, an acceptable facial contour could be obtained.

The disadvantage of this procedure is that it is difficult to obtain excellent aesthetic result using only this procedure. In severe cases of upper lid infiltration with ptosis, lower lid infiltration, and conjunctival infiltration were involved. tumour resection and blepharoplasty were thus necessary for aesthetic reasons. However, the hope in those severe patients is to improve the dislocation of the orbit.

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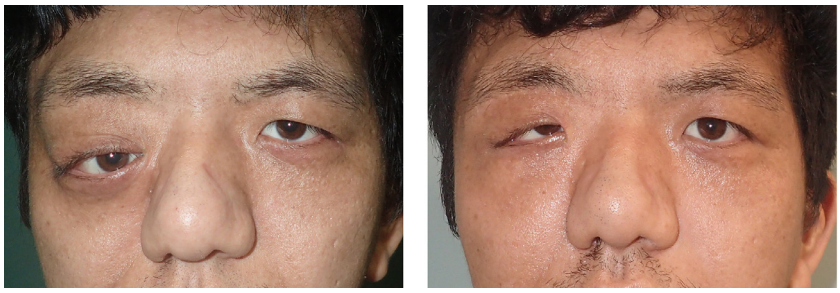

Figure 1 A representative case of a 23-year-old male with right orbitofacial neurofibromatosis. (left) Preoperative frontal view. Unilateral pulsating exophthalmos due to a bone defect at the greater wing of the right sphenoid bone was identified. His right orbit was enlarged and dislocated. (right) Two years' postoperative frontal view. The orbit was elevated by 8 mm through orbital box osteotomy and orbital tumour debulking. The patient was satisfied with the aesthetic result, although his right eyelid continued to droop.

By correction of the orbit alone, the patients were satisfied with the results because the deformity of the eyelid could be camouflaged by wearing sunglasses or an eyepatch.

In conclusion, vertical orbital correction is useful for orbital dystopia in severe orbitofacial neurofibromatosis type I.

Declaration of Competing Interest

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Financial Disclosure and Products

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Ethical Approval

The protocol of this study was approved by the institutional research ethics board of Keio University hospital (approval number 20190287).

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Continuing professional development whilst shielding

Dear Sir,

On 23 March 2020, at the start of the first UK COVID-19 lockdown, clinically vulnerable individuals were instructed by the government to shield.[1] This applied to vulnerable doctors including 1343 doctors in training[2] and has resulted in 216 days of shielding away from clinical duties, patients and supervisors.

This work has not been presented at any meetings with wholly or in part.

Table 1 Enablers and pre-requisites for working from home staff.

Theme	Detail
Trainee's IT	• Availability of a fast and reliable broadband connection at home
Trust IT	• Access to hospital systems through a Virtual Private Network or other access gateway
	• Availability on the hospital systems of referral letters, clinic letters, results of investigations, radiology and other ancillary documentation
Management support	• Adequate NHS hardware in clinics, including webcams and computers of sufficient speed to run modern video programmes, preferably with dual-monitor setups
	• Support from departmental management to navigate the approvals and adjustments that are required to equip the trainee with all that they need to work from home
Supervision	• Consultants' and trainees' familiarity with remote video systems, including those designed for remote video clinics (such as Attend Anywhere) and those used for MDTs/other departmental meetings (such as Zoom, Microsoft Teams or Google Meet)
	• Clear supervisory arrangements with nominated and agreed consultant ownership of "registrar remote clinics"
	• Flatter hierarchies: consultants happy to discuss clinical work, for example ad hoc case discussions, clinic debriefs etc

The impact on staffing and patient care from those suddenly required to shield was substantial. The UK government body, Health Education England (HEE), who are responsible for training, noted trainees were not "sick" and recommended they continue to engage in clinical work. Despite this unprecedented situation, there was no uniform formula for such a large proportion of the workforce to suddenly start to work from home (WFH).

Trainees shielding reported feelings of guilt, frustration, anxiety and loneliness,[3] along with concerns about delays to training and career progression. There are a number of opportunities to ensure training continues. We present our experience from a large UK plastic surgery department with personal perspective from a shielding trainee and a local lead for training. We offer recommendations that we hope may be useful for trainees faced with situations where they are unable to undertake face-to-face clinical work, but where there is the opportunity for remote working.

Enablers & pre-requisites

The key to successful WFH is summarised in Table 1. This revolves around the IT infrastructure, remote access passes to hospital systems and help from non-clinical and clinical staff. Supervisors should ensure they have access to and are familiar with the latest trust software for remote consultations to allow participation of WFH trainees.

Opportunities for continue professional development during shielding

There are a number of activities that those shielding can be involved with depending on local provision. These are summarised in Table 2. Opportunities for professional development may seem difficult to achieve, but each allows the individual to guide their learning to personal development objectives. Cumulatively this allows for greater self-directed learning, but does not compensate for face-to-face clinics or time in theatre.

Most clinical opportunities are through outpatient clinics and these form the basis for workplace-based assessments. Before clinic, the role of the trainee should be discussed. In fully remote video clinics, the trainee may be better as an observer to avoid more than one clinician speaking. In consultant face to face clinic a multiscreen set up can allow the trainee to be more involved, for example by guiding examination. It is important that the consultant is familiar with the video systems available and complies with the trust's IT policy. Recommendations for online clinical engagement should be adhered to. Our patients have viewed the remote attendance of the trainee as positive, interesting and have had no concerns.

Proof of professional development & supervision

UK guidance from HEE advises that an appropriate professional development plan should be devised reflecting the opportunities available.[1,5] A diary of opportunities missed and gained should be kept up to date whilst WFH and uploaded to the surgical portfolio for progression review as well as any learning events attended including the certificate of attendance.

HEE also recommends that supervisors need to be proactive whilst engaging with shielding trainees to stop the feeling of 'out of sight, out of mind'. This is achieved by agreeing a set of goals early with regular check-ins, appraisal of progress and review of goals, and attention to the pastoral and emotional elements of shielding. These meetings should be documented on the surgical portfolio. Before return to work any outstanding training and personal issues should be addressed and whether any enhanced supervision should be implemented on return.

Across the UK, clinical supervision for trainees has been reported to be variable. Ideally for each clinical opportunity an appropriate supervisor should be sought, whether this is the trainees own clinic or attending a consultant's clinic

Table 2 Opportunities for delivering clinical care and for continued professional development.

Theme	Recommendation for engagement
Outpatient activity Training rating: good	• Clinic participation must be tailored to the patient groups and the trainee's level of experience / independence • Participation at consultant-led video clinics can be either observational or through actively leading the consultation • Attendance is possible as an observer
Multidisciplinary team meetings Training rating: excellent	• Ideally those shielding should be encouraged to take an active role by preparing patients' notes, imaging and histology where appropriate • These opportunities can also be recorded on the trainee's e-portfolio for review at progression meetings
Triaging referrals Training rating: average	• Involvement in this process offers those shielding the opportunity to understand referral pathways, to develop skills in clinical prioritisation and to identify cases to see in clinic
Discharge letters Training rating: average	• In centres that have electronic case notes and prescribing, those who are shielding may be able to write discharge letters and take-home prescriptions. We would not recommend this as this work is vulnerable to omission of relevant details and we would advocate the team physically seeing the patient each day doing this task
Audit, quality improvement & research Training rating: excellent	• Shielding can give protected time to complete audit, quality improvement and research tasks • The particular project should be considered in detail as there are limitations in the information that is available remotely • These opportunities contribute to completion of training requirements • Given the restrictions in face-to-face meeting sizes, audit and research meetings, are now often via an online platform, allowing an assessment of audit to be completed
Organising & delivering teaching Training rating: excellent	• During the pandemic, the virtual webinar has become more popular[4] and involvement in teaching in this format can be on a local, regional or national level both in the trust, for external groups or even for local Universities • The latter also provides further opportunities for further development including interviewing applicants, writing exams or examining clinical skills • Contacting your departmental/ hospital lead for teaching, local university or even national trainee group will guide you towards medical education opportunities
Webinars & conferences Training rating: excellent	• There are a number of webinars, both in and outside of working hours run through national (eg JPRAS journal club, PLASTA) and international groups (Eg ICOPLAST) • A number of national and international meetings have moved to an online format, often at a reduced price to the traditional meeting • Study leave and budget can be utilised for these opportunities

virtually, this allows for contemporaneous discussion about cases and opportunity for assessment.

Through the e-learning for health care portal in the UK there is an e-learning programme for supervisors and shielding trainees as well as a module for when this cohort returns to work.[5]

Psychological impact

WFH creates a number of challenges psychologically as well as clinically. The lack of face-to-face contact with colleagues and patients resulted in feelings of unequal distribution of tasks, namely that while WFH I was not completing my equal share of the work. Through perseverance attending clinic remotely I found there were ways that I could contribute such as requesting scans and imaging ahead of time, chasing letters from other health care professionals and booking tests during the consultation through my remote log on. Maintaining motivation for self study and solo clinics was also difficult. Through open and frank discussions with trainers about patients, arranging 'de-brief' sessions for case-based discussions helped reduced feelings of isolation and gave drive to read around topics.

Conclusion

Shielding provides a number of unique challenges for trainees and supervisors. It requires the trainee to be organised and motivated to actively seek out a diverse range of learning opportunities. It also enables trainees to direct their own learning to areas they have a personal interest in or require development. With the increasing face to face component in clinics, this can reduce the role of the shielding trainee and adding to feelings of frustration and isolation. However, engagement of trainers and supervisors in the commitment to continued professional development can help improve this. Support is also crucial from the managerial team in the department to help prepare opportunities (such as clinics), identify supervisors and provide contacts to enable remote access to the hospital systems.

Currently there is no guidance from the UK Royal Colleges nor speciality groups about supporting this cohort of trainees. While there can feel like a plethora of challenges for all involved it is essential to remember that this cohort are still members of the team and must not be forgotten. The pandemic has created a number of challenges but WFH has also allowed trainees to develop skills, contribute to the team and continue to provide good patient care.

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Ethical approval

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Conflict of interest statement

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The use of Personal Protective Equipment during the COVID-19 pandemic: The effects on surgical wounds healing after parotid gland surgery

Dear Sir,

The coronavirus disease 2019 (COVID-19) is a viral infection caused by SARS-CoV-2, which spread around the world from December 2019 and caused over 4 million deaths around the world. Despite advances in pharmacological treatments and the actual coming of the vaccine, self-protection by the use of facemasks still remains the main way to prevent and control the infection and to reduce the transmission of the virus [1]. Compelling data now demonstrate that community mask wearing is an effective non-pharmacologic intervention to reduce the spread of this infection, especially as source control to prevent spread from infected people and as protection to reduce wearers' exposure to infection [1,2]. But the use of masks is not without discomfort: Cotrin et al. [2] showed that the patients reported feel shortness of breath, feel discomfort in the ears due to the elastics, dermatitis/skin problems and esthetic issues.

The aim of our study was to underline that the chronic use of mask in patients who underwent to parotid surgery for benign neoplasia with a preauricular approach, seems to retard the surgical wounds healing.

Preauricolar surgical approach to the parotid gland is a very common for the removal of parotid lesions. This approach involves a skin incision in the preauricular region with extension to the ear lobe and continues in the mastoid region according to the type of flap needed for the various types of surgery [3]. This means that both the superior and

Table 1

	No Dehiscences	Dehiscences	Total
Group A (NO COVID-19)	81	3	84
Group B (COVID-19)	59	11	70
Total	140	14	154

inferior loop of Personal Protective Equipment (PPE) are in contact with the wound.

Commonly the wound healing consists in four overlapping stages: hemostasis, inflammation, proliferation and finally maturation and/or remodeling. In particular, during the angiogenesis and maturation phases, any trauma to the area of skin involved in surgery will lead to the destruction of the small and delicate sprouting vessels that repopulate the dermis with the result of dehiscence. Any disruptions in healing such as infection or dehiscence itself will lead to a compromised wound that enters a stage of secondary healing, that is more prone to infection and pathological scarring [4].

So, during the pandemic, we observed in the postoperative time a significant increase in dehiscence and inflammation of surgical wounds after parotid gland surgery for benign lesions. In fact we registered 13.75% cases of parotid region dehiscence after benign neoplasia surgery, compared with the literature data of 2–3% of cases [5]. We therefore hypothesized a possible correlation between the frictional trauma due to the loop of the masks and the delay of healing and dehiscence of the surgical wounds of parotid region.

Our hypothesis was supported by the statistical analysis conducted on 154 patients who were treated with a preneural parotidectomy or extracapsular dissection for benign parotid tumors by using a preauricular approaches. These patients were divided into two groups: Group A) 84 patients treated before the pandemic (March 2019-March 2020); Group B) 70 patients treated during the pandemic (March 2020- March 2021) who were therefore forced to wear a mask.

We recorded a total of 3 surgical wound dehiscences in group A and 11 in group B (Table 1).

The statistical analysis of the data was performed using a chi-square test (Microsoft Excel 16.16.27 Version) and comparing the obtained values with the chi-square standard distribution tables.

We thus obtained that the number of parotid regions dehiscences after surgery, obtained during the pandemic, is statistically higher than in the period preceding the covid-19 (chi-square value 6,81).

Thus we confirmed our hypothesis of correlation between the use of a mask and the parotid region dehiscence: we suggest to our patients to use the PPE with mask loop clips, or extenders, to avoid any frictional trauma that can retard healing wounds.

Declaration of Competing Interest

None declared.

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Ethical approval

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