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Correspondence and Communications

A complete lower lip and chin unit resurfacing with expanded cheek flaps: A modified approach with minimal influence on facial cosmetic units

Dear Sir,

Lower lip and chin reconstruction is challenging for plastic surgeons. Small to medium skin defects on lower face can be removed by staged serial excision or be reconstructed with local flaps[1] or submental artery perforator island flaps.[2] Large skin defects are usually needed by full thickness sheet grafts, tissue expansions or free flaps.[3] However, both skin grafts and free flaps are hindered by the poor skin color and texture match. To achieve the ideal reconstruction of lower lip and chin, expanded cheek flap may be the best choice. However, the potential destruction of facial cosmetic units should also be considered. Here, we present a modified technique for a complete lower lip and chin reconstruction as a whole facial aesthetic unit by using an expanded cheek flap.

The study was performed in the Department of Plastic and Reconstructive Surgery, Shanghai Ninth People's Hospital between March 2011 and November 2015. Six female patients with scars or laser-resistant vascular anomalies on their lower lips and chins underwent reconstruction with this technique. During the first-stage operation, 100-or 200-ml rectangular expanders were implanted underneath the overlying skin on one or both sides of the patients' cheeks. The expansion began two weeks after the operation. The mean expansion period was three months. Once adequate tissue expansion had been achieved, the second-stage operation was performed. As the lower lip and chin were planned to be reconstructed as a complete facial unit, the shape of the lower lip and chin were copied to a film to serve as a complete template model. The template model was positioned on the expanded cheek skin with a careful presurgical design, and the bottom side of the template model was aligned with the nasolabial fold. Then, the superficial defects of the lower lip and chin were resected and expanded to the border of the complete lower lip and chin unit. The expander was removed. The expanded cheek skin flap was dissected and rotated to the lower lip and chin (Supplemental figure). The flap had a random blood supply.

Figure 1 A 20-year-old patient was diagnosed with a port wine stain. She received stick isotropy treatment at another hospital when she was very young. Superficial scars were left on her lower lip, chin and left cheek after that inappropriate treatment. (Figure 1a) One 200-ml rectangular tissue expander was inserted underneath her right cheek. In the second stage, the scars on her lower face were fully removed. The lower lip and chin were reconstructed by using the right expanded cheek flap. No lower lip ectropion was observed. No drooping or microstomia was observed. The scar on the lower lip was rotated from the right expanded cheek flap. The transverse scar beside the right corner of the mouth was created for the "dog-ear" revision (Figure 1b).

The donor site was subsequently closed using the remaining expanded cheek skin tissue. The incisions were made within the nasolabial fold, vermilion border and mandibular border. Transverse or oblique linear scars on the cheek were created for "dog-ear" revisions in some cases when needed. Drainage was performed for two days after surgery.

In our study, three patients had one-cheek skin expansion, and the others had two-cheek skin expansions for defects crossing the lower lip and chin units. All the expanded cheek skin flaps survived, and no major complications were observed. None of the patients had lip ectropion. No drooping or microstomia was observed. There were no obvious deformities at the donor sites. All the patients were satisfied with the results (Figure 1).

Many techniques are available for lower lip and chin reconstruction. Local flaps are usually the best option for reconstructing with similar tissue. Modified Karapandzic flaps or extended Karapandzic flaps [4] can reconstruct part or almost all of the lower lip and chin, but some degree of microstomia is inevitable. Therefore, expanded local flaps

with consideration of the facial cosmetic subunits certainly provides a worthwhile option to consider. An expanded neck skin flap may be the mostly used flap for resurfacing the lower lip and chin,[5] but it usually has some drawbacks. Firstly, because of the gravity and the mobility, widen facial scar is common. Secondly, the color of expanded neck is not always matched with the color of face. Thirdly, advancement of the expanded tissue cephalad from the neck to the face carries the risk of lip ectropion either at rest or with neck extension.

Plastic surgeons are usually unwilling to use cheek expansion because it may violate facial aesthetic units. To avoid this potential problem, our approach has two key techniques for the reconstruction of the lower lip and chin by using expanded cheek flaps. One technique is that we reconstructed the chin and lower lip as a complete unit. The scars were hidden in vermilion borders, mandibular borders and marionette lines. Another technique is that the cheek scars are designed to be hidden in the nasolabial folds after closing the donor sites.

In addition to the invisible scars and insusceptible donor sites, one of the advantages of expanded cheek flaps is the minimal risk of lip ectropion because the flaps are rotated from above without gravitational pull and are not affected by the movement of the neck. Additionally, the texture, colour match, and skin appendages of local tissue from the cheeks remain unparalleled by other donor sites. In conclusion, we think expanded cheek flaps are one choice for reconstructing large, superficial defects of the chin and lower lip and should not be ignored.

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Ethical approval

Not required.

Declaration of competing interest

None declared.

Supplementary materials

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Yajing Qiu[1]
Wei Gao[1]
Hui Chen
Gang Ma
Yunbo Jin
Xiaoxi Lin
Department of Plastic and Reconstructive Surgery, Shanghai Ninth People's Hospital, Shanghai Jiao Tong University School of Medicine. PR China

Correspondence to: Xiaoxi Lin and Yunbo Jin, Shanghai Ninth People's Hospital, Shanghai Jiao Tong University School of Medicine, 639 Zhizaoju Road, Shanghai 200011, PR China.
[1]These authors contributed equally to this work.
E-mail addresses: linxiaoxi@126.com, docjinyunbo@126.com

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Pure skin perforator flap direct elevation above the subdermal plane using preoperative ultra-high frequency ultrasound planning: A proof of concept

Dear Sir,

Perforator flaps represents nowadays a gold standard in reconstructive surgery. However, when the aim of the reconstruction is resurfacing rather than creating volume or filling spaces, traditional perforator flaps may result in suboptimal results due to their bulkiness.

In the last decade, thin and superthin perforator flaps became increasingly popular for resurfacing purposes. However, for resurfacing of very thin area of the body such as face, foot, hand, ankle and knee, thin and superthin flaps may result still bulky and a pure skin perforator (PSP) would be optimal to achieve primary reconstruction.

In 1966, Colson and Janvier introduced the concept of skin flap-graft (lambeaux-greffes) by defatting till the dermis level pedicled flaps for hand reconstruction.[1] In the perforator flap Hera, in 2011 Narushima firstly described the pure skin perforator concept for microtia repair using SCIP flap.[2] According to Narushima, the pure skin perforator flap resembles a Wolfe-Kraus full-thickness skin graft nourished by perforators of the SCIP pedicle. The surgical technique reported by the author consist of SCIP flap elevation in retrograde fashion, so that after identifying the SCIP pedicle, the small skin branches are traced till their dermis entry points and residual fat is then resected to achieve a dermis-epidermis only flap. The microdissection technique may require the use of microscope to be safely performed, may result tedious and lengthy. In 2018, Narushima et al. analysed the anatomical vascularity of PSP using intraoperative indocyanine-green angiography interestingly showing that the dermis itself is able to sustain PSP metabolic demand, without the need of preserving any layer of subdermal fat which include the subdermal plexus.[3] In fact, they found direct intradermal linking vessels and arteovenous shunts which allow to both expand the perforasome area as for perforator flap as well as guarantee flap venous drainage.

Our clinical experience with thin and superthin perforator flaps directly elevated along either the Scarpa or Camper Fascia using preoperative ultra-high frequency ultrasound bring us to further investigate if UHF-US may also be applied for PSP.[4]

In this perspective, a total of 54 flap donor-site (21 anterolateral thigh and 33 SCIP flaps) were preoperatively studied using UHF-US (VEVO MD, Sonosite Fujifilm) with 48 and 70 MhZ linear probes in B-mode and Color-Doppler mode. In all cases we were able to locate the main perforator vessels and then trace them till the dermis entry point. By considering the findings of Narushima, we postulated that PSP may be directly elevated using a new plane of elevation, the subdermal layer, if the main dermis piercing branches are precisely located preoperatively, as we usually did for thin and superthin perforator flap. In our experience, UHF-US was able to provide unprecedented clear images of perforator braches directly piercing the dermis, nearby subdermal venules coming from the dermis and connecting to the comitantes perforator venules as well as intradermal arterioles and venules. By using these preoperative findings, PSP were directly harvested above the subdermal plane using the "hot and cold zone" technique reported by Hong JP.[5] All preoperative findings were confirmed intraoperatively. This information goes beyond the ability of angio-CT scan, frequently used in preoperative planning of traditional perforator flaps. Flap perfusion was confirmed clinically and using Indocyanine-green angiography. (Figure 1 and Video).

Our promising preliminary evidence about the feasibility of PSP direct harvesting above the subdermal plane using preoperative planning with UHF-US may further expand freedom in reconstructive surgery and may increase safety, predictability and time-efficiency in PSP flap harvesting.

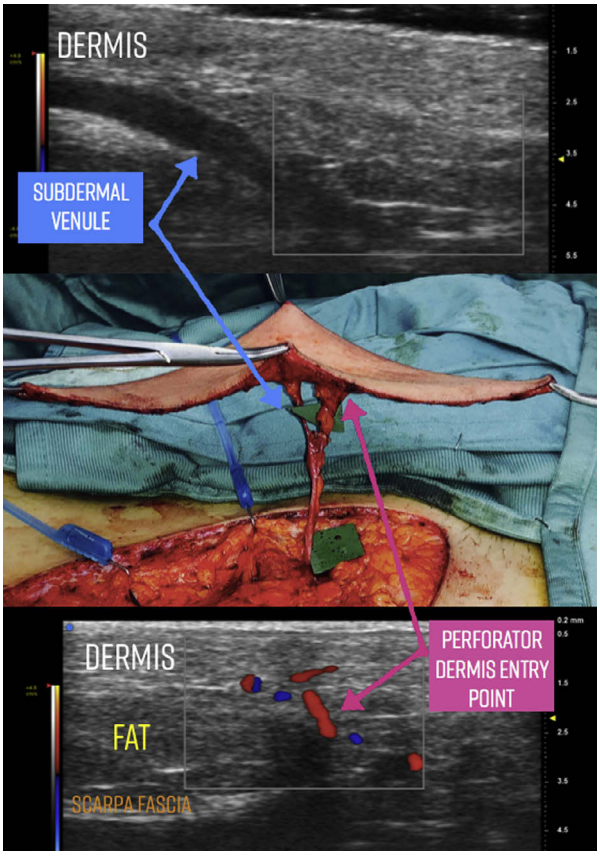

Figure 1 (Above) Subdermal venule with small venule branches directly piercing the dermis and converging into SCIP comitantes venule has been identified using 70 MhZ linear probe. (Center) Intraoperative picture of Superficial Circumflex Iliac Artery Pure Skin Perforator flap harvest based on the perforator dermis entry point and a subdermal venule connecting with the SCIP comitantes vein. (Below) Preoperative planning using ultra-high frequency ultrasound showing the high fidelity findings with the intraoperative ones. Notice the scale on the right side in mm.

Disclosure

None of the authors has a financial interest in any of the products, devices or drugs mentioned in this manuscript.

Conflict of interest

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Supplementary materials

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Giuseppe Visconti, Alessandro Bianchi
Department of Plastic and Reconstructive Surgery, Università Cattolica del "Sacro Cuore" – Fondazione Policlinico Universitario "A. Gemelli" IRCCS – Largo A. Gemelli 8, 00168, Rome, Italy

Akitatsu Hayashi
Department of Plastic Surgery, Kameda Medical Centre, Kamogawa, Chiba, Japan

Marzia Salgarello
Department of Plastic and Reconstructive Surgery, Università Cattolica del "Sacro Cuore" – Fondazione Policlinico Universitario "A. Gemelli" IRCCS – Largo A. Gemelli 8, 00168, Rome, Italy

Correspondence to: Giuseppe Visconti, Department of Plastic and Reconstructive Surgery, Università Cattolica del "Sacro Cuore" – Fondazione Policlinico Universitario "A. Gemelli" IRCCS, largo Agostino Gemelli,8 00169 ROMA, Italy
E-mail address: giuseppe.visconti@policlinicogemelli.it

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Composite ALT flap for structured reconstruction of the abdominal wall: New insights from long-term outcomes in 14 patients

Dear Sir,

Little is known on the long-term performance and functional outcomes in full thickness reconstruction using composite anterolateral thigh (ALT) flaps associated with Vastus Lateralis (VL) and fascia lata (FL) in complex abdominal wall repair (AWR).[1] The role of muscle atrophy and loss of fascia tensile strength over time, potentially influencing abdominal wall stability, still needs to be addressed.

We analyzed long term outcomes of AWR using ALT-VL flaps, focusing on flap properties, flap atrophy over time and the role of a combined mesh.

After selecting all patients who had required AWR using autologous flap reconstruction from May 2003 to June 2017 in our institution, only patients with full thickness defects (including both muscle and fascia) and who benefited of composite anterolateral thigh (ALT+VL) flaps were included. After criteria application we could finally extract from the Department database fourteen patients who benefited from composite ALT-VL reconstructions. Mean age of the 14 patients (8 males, 6 females) was 60±13 years (average ± SD). ALT flaps were tailored depending on the location and transferred as pedicled or free flaps according to defect position and thigh length/trunk ratio (10 pedicled, 4 free).

Composite ALT flaps allowed the reconstruction of all 3 layers in 3-dimensional abdominal defects: vastus lateralis can mimic the rectus abdomini muscle, with the rectus femoris fascia and fascia lata giving continuity to the abdominal fascia on both sides of the flap (Figure 1).

No statistically significant difference in preoperative defect size (both fascia and skin) was present between the two groups of patients ($p = 0.05$). No significant differences in operative time or flap-related complications (all flaps healed uneventfully) were noticed between pedicled or free flaps. Time to complete healing was 20.1 ± 5.36 days (average ± SD) for pedicled flap and 17.75 ± 6.95 day (average ± SD) for free flaps. Average hospitalization time was 23.7 ± 12.27 days (average ± SD) for pedicled flap and 21.5 ± 3.32 day (average ± SD) for free flaps. No statistical difference was present between these groups after analysis.

In order to investigate the relation between flap integrity and clinical outcomes in the long term, volumetric imaging analysis was performed using calculation-imaging program tools on both follow-up CT scans and MRI. In order to avoid unnecessary radiation, tight radiological follow-up was only

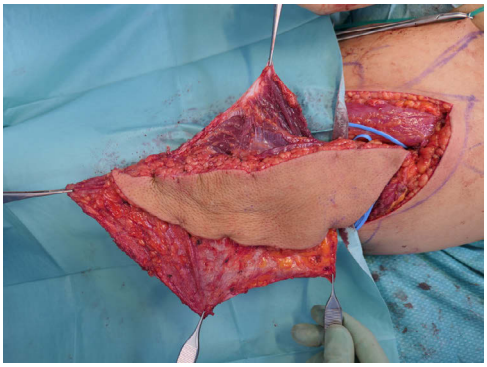

Figure 1 The composite ALT flap includes fascia lata and the vastus lateralis muscle allowing reinforced support while replacing the missing components of the abdominal wall musculature.

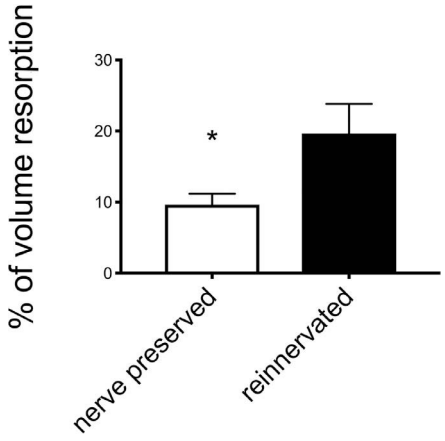

Figure 2 Resorption percentage of flap volume over 12 months comparing flaps with preserved innervation to reinnervated flaps. Values are expressed as average ± SEM ($^{*}p < 0.05$).

performed in patients who had a defect following tumor extirpation at risk of oncological recurrence (9 out of 14 patients). Flap volumes were performed at 3 months, 6 months and every year post-operatively.

Volumetric measurements and imaging confirmed flap stability over time, assuring coverage, support and avoiding dead space. As expected, free re-innervated flaps showed a significant volume loss when compared to their pedicled innervated counterpart's (**9.67 ± 2.78 in pedicled group vs 22 ± 2 in free transfer group; values expressed as average ± SD) (Figure 2). In our series resorption did not influence the stability of reconstruction as this seemed to be more influenced by the reconstitution of an effective fascia layer associated with meshes, rather than by muscle bulk. Despite excellent flap outcomes in terms of coverage and re-establishment of anatomical layers, the long-term outcome of these reconstructions showed that even a resistant tissue component like the fascia lata undergoes progressive stretch under continuous intrabdominal pressure. The almost total absence of rectus abdomini muscle to contrast intrabdominal pressure had probably a further role in bulge recurrence.

Three patients out of 14 (2 free and1 pedicled flaps reconstructions, 21%) presented abdominal bulging at 35 months follow-up. Interestingly, abdominal bulge did not impact significantly on quality of life, with similar clinical scores from abdominal wall functional questionnaires (HerQLes), and only one patient required a secondary mesh placement.

If defect size did not influence the choice of flap (pedicled v/s free), defect location could influence the reconstructive choice as pedicled transposition to the upper abdominal quadrant is limited by the thigh length/trunk ratio.[2] When defects were multiple, or extending caudocranially, free flaps guaranteed better insetting possibilities and were preferred.

Despite the severity of the repaired full thickness defects in this series, the recurrence hernia rate compared favorably with the literature (particularly considering the bridging repair).[3-5] Flap atrophy varied between pedicled and free flaps, but did not seem to have significant repercussions on abdominal wall stability, at least from a clinical point of view.

In conclusion, the composite nature of the antero-lateral thigh flap, when harvested with the vastus lateralis muscle and vascularized fascia lata, can mimic abdominal wall structures, allowing an anatomical and functional reconstruction of the abdominal wall, by establishing a continuity between remnant patient fascia layers and vascularized fascial extensions of the flap. The use of mesh should be associated to flap reconstructions to allow for highest possible durability of the results.

Disclosures

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Pietro G. di Summa, William Watfa
Department of Plastic, Reconstructive and Hand Surgery, University Hospital of Lausanne (CHUV), Lausanne, Switzerland

Salvatore Giordano
Department of Plastic and Reconstructive Surgery, Turku University Hospital, Finland

Leslie Elahi-Rausis
Department of Thoracic Surgery, University Hospital of Lausanne (CHUV), Lausanne, Switzerland

Olivier Bauquis
Department of Plastic, Reconstructive and Hand Surgery, University Hospital of Lausanne (CHUV), Lausanne, Switzerland

Dieter Hahnloser
Department of Visceral Surgery, University Hospital of Lausanne (CHUV), Lausanne, Switzerland

Wassim Raffoul
Department of Plastic, Reconstructive and Hand Surgery, University Hospital of Lausanne (CHUV), Lausanne, Switzerland
E-mail address: pietro.di-summa@chuv.ch

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Surgical cost implications of the AJCC v8 staging system for melanoma and the melanoma in focus consensus statement

Dear Sir,

The introduction of the new American Joint Committee on Cancer (AJCC) guidelines for cutaneous melanoma in January 2018 **(AJCC version 8**) has redefined stage 1b melanoma. The Breslow thickness has dropped to 0.75 mm because this is now reported rounded to the nearest 0.1 mm, with mitotic rate no longer a criterion for upstaging to 1b from 1a.[1,2] Furthermore, the recent UK Melanoma Focus consensus statement has made recommendations that all patients with a pT1b primary melanoma in the UK should be considered for SLNB, especially where the primary tumour has ≥2 mitoses or lymphovascular invasion. The guidelines particularly emphasise that a negative result would downstage patients to stage 1a but a positive result would upstage the patient to stage 3a, observing that *"in either case the post-treatment clinical surveillance will be significantly altered"*.[3] We have undertaken an analysis of the projected change in costs to our unit following the adoption of the new AJCC v8 classification for melanoma in light of the recent melanoma focus consensus statement.

Table 1 Numbers of stage 1 patients.

Stage	AJCC v7	AJCC v8
1	596	614
1a	428	436
1b	**168**	**178**

Methods

We interrogated the prospectively maintained, anonymised St George's melanoma database for all patients treated for cutaneous melanoma from January 2010 (the date of the introduction of AJCC v7) to July 2016. Results are presented for the total number of primary tumour stage pT1a and pT1b patients under both the AJCC v7 and AJCC v8 classification systems. The number of additional patients now eligible for SLNB under AJCC v8 (i.e. Breslow 0.8–1.0 mm without ulceration) were analysed. We further analysed results for those no longer eligible for SLNB under the new AJCC v8).

In order to estimate the resultant changes in cost with AJCC v8, we obtained tariffs for sentinel node biopsy and outpatient follow up clinics from our coding team, and modelled the likely number of appointments required for a patient to complete five years of surveillance follow-up for stage 1b disease.

Results

From January 2010 to July 2016, 1012 patients were treated for cutaneous melanoma within our Unit. A total of 596 patients were stage 1 under the AJCC v7 system. When AJCC v8 is applied to the database this increases to 614 (Table 1).

SLNB outcomes

Using AJCC v7, 168 patients were stage 1b, therefore eligible for SLNB. Of these, 99 (59%) chose to undergo the investigation, and seven were positive (7%). Of these seven patients there were no recurrences and no mortalities at mean follow up of 5.3 years.

In order to estimate the likely SLNB positivity rate for pT1b patients in our patient population using AJCC v8, we interrogated our database for all patients who underwent SLNB who satisfied only the AJCC v8 definition of tumour stage 1b. Within this cohort of 178 patients 89 SLNBs were

Table 2 Tariff costs for SLNB and outpatient follow-up.

Cost of SLNB	Cost of 1 year follow-up	Cost of 5 year follow-up
£2097	£512	£1792

performed, of which six were positive (7%). Of these six patients one died of metastatic melanoma; the primary tumour was 1.03 mm, non-ulcerated, MR1. The remaining five were alive and free of disease at mean follow up of 6.0 years.

A secondary analysis was performed to look at those patients previously offered SLNB who would no longer be eligible (i.e. those patients who were stage 1b under AJCC v7 who are now stage 1a under AJCC v8). There were 72 patients in this group, of which 35 underwent SLNB and four were positive (11%), there were no mortalities or local recurrences at mean follow up of 7.3 years.

Cost analysis

Overall, ten more patients would have been classified as stage 1b under the AJCC v8 guidelines than v7. Within our database 59% of eligible patients underwent SLNB; thus we have extrapolated that six of these additional patients would potentially have had a SLNB. A key feature of AJCC v8 is that tumour stage pT1b patients who have a negative SLNB are subsequently downstaged to pathological stage 1a, with 5-year overall survival of 99% reducing the duration of follow up surveillance required from 5 years to 1 year.[3,4] The rate of positive SLNB for AJCC v8 tumour stage pT1b patients in our cohort was 8%, therefore we have inferred that 5 of these 6 patients could be downstaged to disease stage 1a following a negative SLNB.

The tariff costs for our unit for both SLNB (based on the tariff for a day case patient of £2097) and tariff per outpatient appointment (£128 for a plastic surgery outpatient appointment) are summarised in Table 2.

Overall the cost of an additional 6 SLNBs would be £12,582. This surgical cost is offset by the potential reduction in outpatient clinic attendances by downstaging five patients with negative SLNBs to stage 1a. The cost of five year follow up for a stage 1b patient is £1792 for a total of 14 clinical visits, based on 4 appointments per year for the first 2 years and 2 appointments per year for the remaining 3 years; the cost for one year follow up for a stage 1a patient is £512, therefore the potential cost saving is £6400. However, it is important to highlight that one of the key aims of the recent melanoma focus consensus statement was to highlight the importance of potentially upstaging more patients to stage 3a by expanding the criteria for offering SLNB, making more patients eligible for a range of adjuvant oncological therapies, the costs of which considerably exceed any variations in surgical costs.[3,5]

Over the 6.5 year study period we estimate that the overall surgical cost difference had AJCC v8 been used instead of AJCC v7 would be just £6182 more.

Discussion

Regarding potential costs of changing from AJCC v7 to AJCC v8 there is a small increase in the number of patients eligible for SLNB, with an overall potential additional 10 patients over the 6.5 year period of our study meeting the criteria for upstaging their primary tumour to pT1b. The surgical costs of providing additional SLNBs are substantially offset by the reduction in follow-up appointments required because of the potential to downstage those patients with a negative SLNB to stage 1a. However, overall costs to the NHS are likely to increase with wider patient eligibility for oncological therapies as a result of increasing numbers of patients being upstaged to 3a.

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Conflict of interest

None.

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D.R. Thomson
I.C.C. King
L. Cooper
J. Odili
B.W.E.M. Powell
Department of Plastic Surgery, St George's Hospital, London, United Kingdom
E-mail address: david.thomson@stgeorges.nhs.uk

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Outcome reporting in breast reconstruction

Dear Sir,

We read with great interest the systematic review published by Wagner et al. on evaluating the complication profiles in pre-pectoral breast reconstruction alone versus pre-pectoral with acellular dermal matrix (ADM) or mesh.[1] We would like to raise some important issues compromising the interpretation of the data.

The authors report overall complication rates for infection (2.6%), seroma (5.1%), hematoma (2.4%), implant loss (3.3%), mastectomy flap necrosis (5.4%), and NAC necrosis (2.7%). However, we argue that such reporting of complications is somewhat less useful, as there is no stratification according to clinical management (i.e. conservative/non-operative or operative intervention). A more useful and accepted classification is that proposed by Clavien-Dindo,[2] with clear grades of complication, and should be used for reporting. Similarly, complications should be clearly defined *a priori*, with evaluation of grades of fat necrosis, seroma and degree of partial flap necrosis. The authors did stratify capsular contracture as per the Baker's classification.

Furthermore, there is no evaluation of patient reported outcomes (PROs). PROs form a key component of the reconstructive breast surgery core outcome set.[3] Evaluation of quality of life, using validated tools like the BREAST-Q,[4] should be mandatory for comprehensive assessment of the treatment intervention. Omission of PRO evaluation renders the findings of systematic review incomplete. Complication rates may not always correlate with PROs as purported by our group previously.[5] It is also worth noting that no articles were included in the review beyond the year 2017, and hence, the findings from the review may not be the most up to date.

We commend the authors for carrying out this work, however there is a perennial and urgent need to enhance the reporting of outcomes in the breast reconstruction literature. Mandatory requirement by journal editors for authors to ensure adequate reporting of breast reconstruction core outcome set and defining complications *a priori* will enhance reporting quality and interpretation of the data. This, in turn, will reduce inter-study heterogeneity in outcome measurement and facilitate meta-analysis.

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Declaration of Competing Interest

AK is an Associate Editor of *Systematic Reviews* Journal.

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Ankur Khajuria
Kellogg College, University of Oxford, Oxford, UK
Department of Surgery & Cancer, Imperial College London, UK

Afshin Mosahebi
Division of Surgical & Interventional Sciences, University College London, UK

Corresponding author at: Department of Surgery & Cancer, Imperial College London, UK.
E-mail address: ankur.khajuria09@imperial.ac.uk

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A case series of breast reconstruction for amastia in a family with ectodermic dysplasia

Dear Sir,

Ectodermic dysplasia (ED) is used to designate a group of pathological conditions characterized by congenital defects that involved two or more of the ectodermal-derived structures, comprising sparse hair (hypotrichosis), abnormal or missing teeth (hypodontia or anodontia)[1] and inability to sweat (hypo or anhidrosis). Anomalies including breast or nipples are also described.

In these patients, who are already very physically stigmatized by dental and capillary agenesis, the mammary

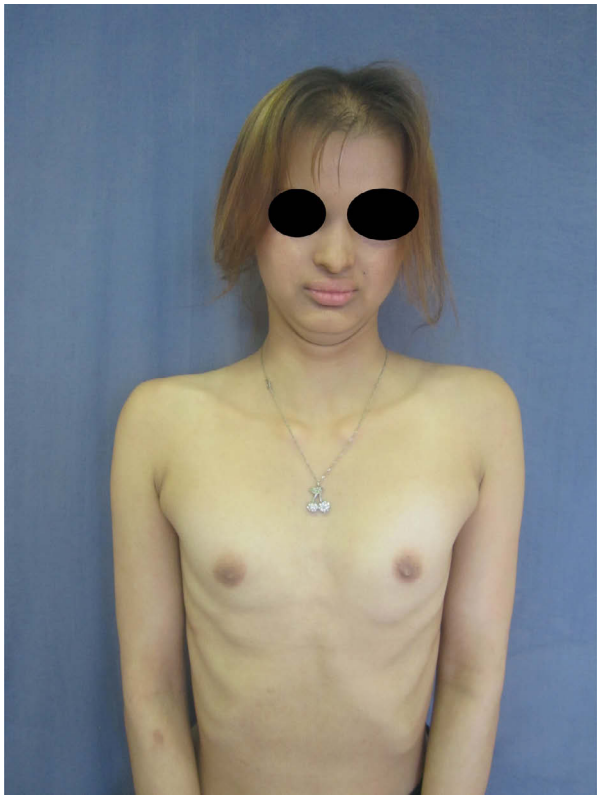

Figure 1 Patiente 1 before reconstruction. She presented an ectodermal dysplasia phenotype with complete amastia. No areolar disorder was noticed.

Figure 2 Patiente 1. 6 months after bilateral prostethic reconstruction.

anomaly reinforces psychosocial impact and isolation. The management of these cases can often be difficult and most have been treated with tissue expansion and the use of implants.

Following the STROBE guidelines, we reported here the cases of three patients issue of the same family with ectodermal dysplasia and mammary aplasia associated with various form of PAM malformation. These three teenagers had a major difficulty in female identification and self-confidence that motivated their consultation in plastic surgery. They were proposed a prosthetic one stage implant reconstruction.

The first patient (Figure 1) presented a complete bilateral breast aplasia associated with a small pectus. There was no disorder in the areolar region and no inframammary fold.

It was decided to install a 205 g silicone smooth round prosthesis, in a retro-pectoral position. A bilateral cutaneous inframammary fold incision was made at the level of the medial side of the PAM, length of 4–5 cm, 9 cm below the nipple with the skin stretched (Figure 2).

The second patient presented also a complete breast aplasia bilaterally, but this case was accompanied with a complete areolar region agenesis: a complete amastia.

Here it was decided to put in a 310 g textured round prosthesis in a retro-pectoral position. As areolar region did not exist, we centered the incision in the middle of the inframammary fold. After 6 months, a bilateral areola-tattoo was performed

The third patient, first cousin of patient 1 and 2 presented a complete mammary aplasia with areolar asymmetry. It was decided to put in a 310 g textured round prosthesis in retro-pectoral position.

Patients were followed up for 18 months and at each clinical examination the results were photographically documented.

They were satisfied with the result as well as the surgeon.

Amastia is a rare congenital deformity, characterized by uni- or bilateral absence of breast and nipple-areola complex defects. In 1886, Hutchison was the first to described a case of amastia associated with congenital ectodermal defects but it was Burck and Held who first described this association in female patients.[2]

There are several possibilities for breast reconstruction: direct to implants augmentation, pre-expansion followed by implant augmentation, autologous tissue transfers or association of tissue and implant. The indication depends on the patient morphology and wishes, clinical examination particularly skin laxity and surgeon dexterity.

In this series our patients were young (minor) and very thin (BMI less than 18), so there was no possibility of autologous reconstruction.

For the first patient we had no problem to put 205 g, so we agreed to put more for her sister with per-operative difficulties to dissect and distend the skin. We still managed to put 310 g but, at a distance we can note apparition of many stretch marks on the skin. For the cousin, there was no particular problem with the same volume inserted, however the skin was more flexible. In the particular case of the

second patient, a pre-expansion could have been discussed. Thus we think that preoperative skin examination seems essential to ask the indication of the technique and discuss the volume to be implanted.

The two techniques have ever been studied and approved for breast reconstruction in this pathology.[3,4]

As Klinger et al.,[5] our main concern about one-stage reconstruction by implant was the presence of a very thin skin and a possible hypotrophy of pectoralis muscle that could imply cutaneous sufferance or implant migration.

In our experience, patients' skin was not particularly thin without abnormalities.

There was also no problem of coverage by the pectoral muscle, which is not of ectodermal origin that is why we finally choose for this option with intraoperative confirmation of this clinical impression.

To our knowledge, this is the first article where three patients from the same family with ED were treated.

It is particularly interesting because it shows that in the same family with probably the same genetic anomaly the mammary phenotype can be variable and shows three different mammary dysplasia with varying degrees of cutaneous involvement whereas the dental and appendages lesions were relatively identical.

This case series illustrates the safety and satisfactory outcomes of prosthetic reconstruction without previous tissue expansion in a family of young women with various forms of congenital mammary abnormalities associated with ectodermal dysplasia.

The role of the plastic surgeon in the management of patients suffering from this anomaly of the body lining.

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Ethical approval

Not required.

Declaration of competing interest

None declared.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.bjps.2019.07.011.

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J. Laloze
Department of Plastic, Reconstructive and Aesthetic Surgery, Rangueil University Hospital, Toulouse, France
Department of Maxillo-facial, Reconstructive Surgery and Stomatology, Limoges University Hospital, Dupuytren University Hospital, 2, Avenue Martin Luther King, 87042 Limoges, France

B. Chaput
Department of Plastic, Reconstructive and Aesthetic Surgery, Rangueil University Hospital, Toulouse, France

J. Usseglio-Grosso
Department of Maxillo-facial, Reconstructive Surgery and Stomatology, Limoges University Hospital, Dupuytren University Hospital, 2, Avenue Martin Luther King, 87042 Limoges, France

J.L. Grolleau
Department of Plastic, Reconstructive and Aesthetic Surgery, Rangueil University Hospital, Toulouse, France

C. Pienkowski
Department of Pediatric, Purpan Children Hospital, Toulouse, France

T. Meresse
Department of Plastic, Reconstructive and Aesthetic Surgery, Rangueil University Hospital, Toulouse, France
Department of Plastic and Reconstructive Surgery, Cancer University Institute of Toulouse Oncopole, Toulouse, France

Corresponding author at: Department of Maxillo-facial, Reconstructive Surgery and Stomatology, Limoges University Hospital, Dupuytren University Hospital, 2, Avenue Martin Luther King, 87042 Limoges, France.
E-mail address: jeromelaloze@etu.unilim.fr

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Preserved nipple erectile function after free nipple areolar complex transplantation

Dear Sir,

It is generally believed that sensory innervation and preservation of nipple erectile function are lost after free nipple areolar complex (NAC) transplantation. We, however, would like to present a case that already reported 'restored' nipple erectile function two weeks after free NAC transplantation following bilateral mastectomy and breast free flap reconstruction and this function remained consistent throughout two years follow up.

The mechanism underlying nipple erection is not fully understood, however several studies suggest (autonomous) innervation to govern nipple erectile function.[1-3] Therefore, patients are generally informed that sensation and erectile function of the nipple will definitely be lost after NAC transplantation or NAC reconstruction. Although the areola itself is important in nipple erection,[3] the contractile function is also locally organized in the nipple itself, as demonstrated by 42% of cases retaining nipple erection in the donor nipple after composite nipple grafting.[4] Moreover, our case clearly underlines that local factors play a role in restoration of nipple erectile function after free NAC reconstruction when using autologous nipple tissue.

A 33 year old woman with a known BRCA1 mutation and vitiligo underwent an elective bilateral mastectomy and immediate reconstruction with bilateral Deep Inferior Epigastric Perforator (DIEP) free flap surgery in our hospital in 2016. During the mastectomy the NAC was harvested as a full thickness graft from both breasts. After DIEP flap reconstruction, with a monitor island caudally from the new nipple areolar location, the NAC grafts were reinserted on the partially de-epithelialized DIEP flap. Compression gauzes were kept in place until the patient was discharged in good health after 5 days. Two weeks postoperatively, the patient already reported and demonstrated preserved nipple erectile function which occurred upon cold exposure and touch. Nipple erection induced by sexual arousal, however, did not exist anymore. Six months after breast reconstruction the monitor skin islands were surgically removed and a minor dogear correction was performed of the abdominal flanks. After nine months nipple erectile function was still present (Figure 1) despite absent sensation of the skin of the reconstructed breasts. The patient was very content with both the esthetic aspect as well as the restored nipple function of her reconstructed breasts.

Our case clearly demonstates that local tissue organization is essential in NAC erectile function: it is virtually impossible that the observed restored nipple erection was due to autonomous innervation since (a) free NAC transplantation results in discontinuation of innervation at both NAC as well as free-flap/thoracic level, (b) the NAC graft was transplanted on a denervated DIEP flap, (c) the erectile function was already present 2 weeks after surgery and (d) no sensible reinnervation occurred to the NAC in the 2 years follow-up period.

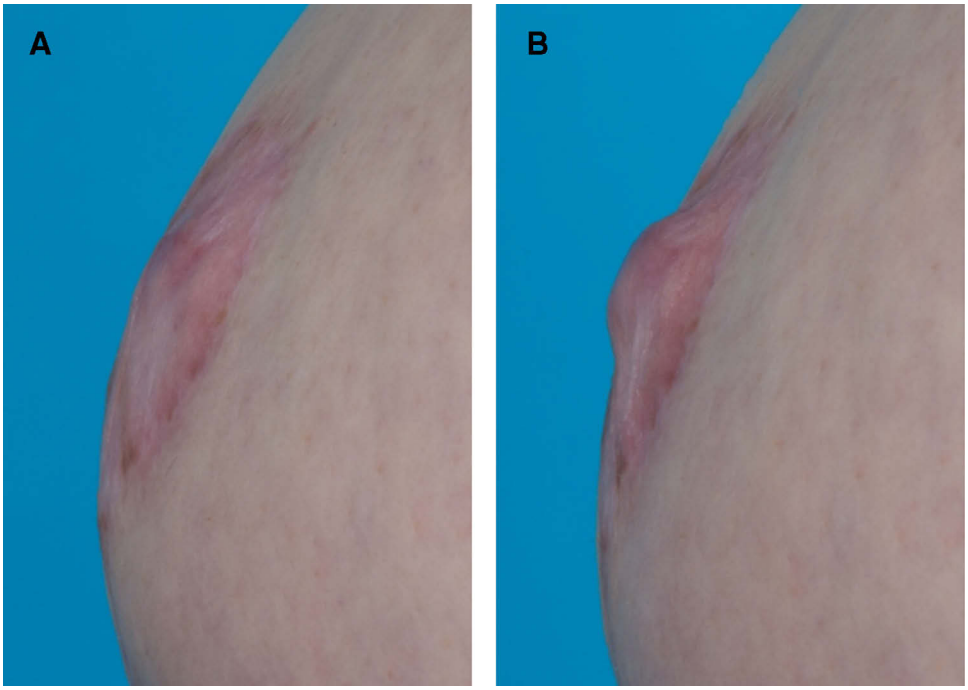

Figure 1 Evaluation of nipple erectile function. **(A).** Resting nipple surface in neutral condition immediately after removal of bra. **(B).** Erectile nipple when exposed to cold room temperature or after tactile stimulation. Left nipple is depicted as example, both nipples responded independently of each other with erection to tactile and temperature stimulation.

Although nipple erection was preserved in our patient by tactile and temperature stimuli, sexual arousal could not induce erection. Erection by sexual arousal therefore probably is the only erectile function requiring sympathetic nervous system activation.

In conclusion, as observed in our case, it seems possible that nipple erectile function can be preserved after free NAC transplantation. The potential of preserving erectile function after NAC transplantation warrants further investigation and may in the near future be a subject to be discussed among potential candidates of direct breast reconstruction after mastectomy.

Conflict of interest

None.

Funding

None.

Consent

The principles outlined in the Declaration of Helsinki have been followed and written informed consent was obtained from the patient for publication of this communication and the accompanying images.

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E.L. de Vrij
Plastic Surgery, University Medical Center Groningen, Groningen, the Netherlands
Clinical Pharmacy and Pharmacology, University Medical Center Groningen, University of Groningen, Groningen, the Netherlands
Surgery, Martini Hospital Groningen, Groningen, van Swietenplein 1, 9728 NT Groningen, the Netherlands

B. van der Lei, M.A. Huijing
Plastic Surgery, University Medical Center Groningen, Groningen, the Netherlands
E-mail address: e.l.de.vrij@umcg.nl

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Cost-effectiveness of pre-pectoral implant-based breast reconstruction: A pilot comparative analysis

Dear Sir,

Implant-based breast reconstruction (IBR) is the most common reconstructive procedure after mastectomy.[1] Over the last decade, the introduction of Acellular Dermal Matrices (ADMs)/synthetic meshes has driven a change in practice from total submuscular implants to sub-pectoral implants. In the last 5 years, pre-pectoral approach to IBR with complete ADM/mesh cover is gaining popularity as an alternative to sub-pectoral IBR given its reported benefits in terms of postoperative pain, animation deformity and possibly aesthetic outcome.[2]

Avoiding dissection of muscular structures has anticipated advantages of reduced operative time and postoperative pain, and hence of a shorter patient recovery with reduced length of hospital stay (LoS). Theatre occupation time and LoS are both relevant factors, together with consumables and re-admissions/re-operations and outpatient attendances related to postoperative complications, in determining the cost to any health service of an IBR.

To our knowledge, there are no studies in the literature analysing the cost-effectiveness of pre-pectoral IBR in comparison with the sub-pectoral approach. We used initial data of a single oncoplastic breast surgeon, who introduced pre-pectoral approach to mesh-supported -BR in immediate setting in a UK university hospital, to perform a cost comparison analysis.

Previously published Manchester cost analysis in sub-pectoral IBR was used as a reference.[3] This analysis had used the NHS reference costs for year 2011–2012 as a proxy for hospital costs and considered the number of outpatient attendances (ultrasound scans, seroma drainage), re-admissions/re-operations and the cost of the ADM as additional variables. We updated the data from this study using the NHS reference costs for year 2015–2016,[4] and included data on LoS in the cost analysis.

A retrospective review of first 10 consecutive patients undergoing immediate one-stage pre-pectoral IBR under the care of the senior author (AA) was performed. Patients' demographics, co-morbidities, BMI and neoadjuvant/adjuvant treatments were analysed. The cost analysis used the same criteria applied to the sub-pectoral group.

One-stage immediate pre-pectoral breast reconstruction with implant and Braxon™ (porcine ADM) was performed in 10 patients (11 breasts). Patients' mean age and BMI were 53.9 (39–73) years and 24.9 (18.3–30.1) respectively. 2 patients had neoadjuvant chemotherapy and 3 received (and 1 awaiting) post mastectomy radiotherapy (PMRT). Mean operative time (from skin incision to closure) for unilateral IBR was 216 min (146–273) with a trend towards reduced time in latter cases; the bilateral case took 295 min. Average LoS was 0.6 nights (1 night for 6 patients, the remaining

Table 1 Patients' characteristics.

	CUH bilateral pre-pectoral ($n=1$)	Manchester bilateral sub-pectoral ($n=13$)	CUH unilateral pre-pectoral ($n=9$)	Manchester unilateral sub-pectoral ($n=11$)	*P* value*
Mean age	58	43 (27-64)	53.4 (39-73)	51 (38-66)	-
Co-morbidities	0	4	0	2	0.592
Mean operating time (min)	295	220 (165-274)	216 (146-273)	152 (102-225)	-
Mean length of stay (nights)	0	6.2 (3-14)	0.66 (0-1)	3.1 (2-5)	-
Mean drain duration (days)	7	14 (6-18)	6.66 (4-8)	13 (1-21)	-
Complications	0	13	2	4	0.492
Seroma drainages	0	6	1	3	0.368

CUH: Cambridge University Hospitals.
* chi-square test.

Table 2 Cost comparison analysis.

Tariffs (£)	CUH bilateral pre-pectoral ($n=1$)	Manchester bilateral sub-pectoral ($n=13$)	CUH unilateral pre-pectoral ($n=9$)	Manchester unilateral sub-pectoral ($n=11$)
Index Procedure	2413	49,842	23,679	32,065
Excess bed days	0	18,096	0	8338
USS	0	726	484	242
Seroma aspiration	0	363	121	726
Unplanned operations/admissions	0	11,781	1120	0
ADM	4200	44,026	18,900	16,586
ADM for unplanned procedures	0	4512	0	0
Average cost	6613	9637	4923	5269

CUH: Cambridge University Hospitals; USS: Ultrasound scan.

4 were day-cases including the bilateral). Drain was kept on average for 6.7 (4-8) days; ultrasound was performed in 4 patients and seroma aspiration was necessary for 1 patient. One PMRT patient had a single episode of cellulitis during adjuvant chemotherapy requiring IV antibiotics; post-chemotherapy, she completed PMRT with no issues at 18 months follow-up.

Although a complete statistical analysis was not possible (continuous variables were not analysed because the full dataset of the Manchester paper was not available), the mean operating time was longer in our series (295 vs. 220 min and 216 vs. 156 min for bilateral and unilateral reconstructions respectively), whereas LoS was markedly shorter for both bilateral and unilateral IBR (0 vs. 6.2 nights and 0.66 vs. 3.1 nights respectively). There were no statistical differences in the number of patients with co-morbidities and postoperative complications. (Table 1).

Results of the cost analysis are shown in Table 2. Bilateral pre-pectoral IBR appears to be less costly than sub-pectoral reconstruction, with a potential saving of approximately £3000 (6613 vs. 9637). The potential saving is mainly related to the difference in LoS: the pre-pectoral reconstruction was performed as a day-case procedure (tariff: £2413),[4] whereas the sub-pectoral reconstructions were all performed as elective inpatients (tariff: £3834 + excess bed days cost).[4] The difference in costs in case of unilateral IBR is less (approximately £350).

There is emerging volume of literature, albeit small volume and short-term, suggesting that pre-pectoral IBR as a technique regardless of implant or mesh type appears to be a safe and well tolerated technique, with a shorter recovery time and a rate of early post-operative complications no worse than sub-pectoral including following PMRT.[5]

Further reduction in operative time (trend present in data) is anticipated as the surgeon and team gather experience leading to additional savings. This pilot cost analysis shows that pre-pectoral IBR has a potential cost benefit compared with sub-pectoral IBR, especially for bilateral reconstructions. However, it is limited by small numbers and by the use of the data from a 6-year-old study for the sub-pectoral control group, that may not be representative of the current practice in the UK, including LoS data. Although not conclusive, we believe that this work might open a debate and stimulate further research interest in this still unexplored topic.

Ethical statement

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Conflict of interest: We declare that there is no actual or potential conflict of interest in relation to this article. All the authors have no financial or personal relationship with

other people or organizations that could inappropriately influence (bias) this work.

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Emanuele Garreffa
Amit Agrawal
The Cambridge Breast Unit, Addenbrooke's Hospital, Cambridge University Hospitals NHS Foundation Trust, Hills Road, Cambridge CB2 0QQ, UK
E-mail addresses: amit.agrawal@addenbrookes.nhs.uk, amitagrawal@doctors.org.uk

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Targeted breast re-innervation (TBR) for post-mastectomy pain

Dear Sir,

Chronic pain following mastectomy, a recognized entity with a reported incidence up to 60%, has a documented detrimental impact on quality of life.[1] The treatments for chronic neuropathic pain have varied efficacy and typically require long-term pharmacologic therapy with their associated risks and costs.[2] Recently, there has been an increased interest in the surgical treatment of certain pain conditions, most notably chronic phantom limb pain following amputation. The proposed surgical treatment, targeted muscle re-innervation (TMR), identifies cut sensory nerves and connects them to non-functional muscle motor nerves.[3,4] This, in essence, provides a target for the injured nerve and reciprocal feedback that keeps the nerve from "sensing" injury or irritation. This approach has been shown to improve all aspects of nerve and phantom pain. As mastectomy is essentially an amputation of the breast, it is likely that post-operative breast pain is of a similar pathology. The innervation of the breast has been well described both anatomically and using anesthetic nerve blocks and imaging. One of the key nerves providing sensation to the breast is the 4th anterolateral Intercostal nerve. This nerve has been used as a putative target for autologous tissue innervation.[5] However, its use as a target for neuropathic pain has yet to be described. In the migraine literature, pre-operative nerve blocks have been shown to be useful adjuncts in both the diagnosis and treatment of peripheral nerve related pain. To that end, this is the first report and description of using a pre-operative nerve block as both a diagnostic and technical adjunct in post-reconstruction breast pain.

Herein we describe three patients with chronic post-mastectomy pain treated with targeted breast re-innervation (TBR).

Patient 1 is a 57-year-old female who had previously undergone subpectoral immediate reconstruction with tissue expanders. Over the course of her expansion, she developed worsening pain to the point of considering discontinuing reconstruction. She described the pain as "unbearable" and that it was if her "ribs were breaking". Using a routine visual analogue scale, her pain was 10/10 at pre-operative visits prior to her second stage. Given these concerns, as well as potentially providing more medialization of the implants, we discussed that at her second stage; we would switch from a subpectoral to a pre-pectoral position. This would allow for correction of implant placement and identification of the nerves that were the source of her pain to allow for neurolysis and nerve graft connection to the skin.

On the day of surgery, the patient's pain was 7/10 on VAS score. The patient was asked to identify the point of maximal pain using one finger and a mix of methylene blue and 1% lidocaine was injected at each pre-marked site. After the nerve block, her pain decreased from 7/10 to 0/10 bilaterally. During the procedure, the external marking, as well as the methylene blue dye, helped identify the potential nerve (Figure 1). The nerve was readily identified beneath the serratus, 17 cm from midline on the left, 15 cm from midline on the right and 10 cm from the axilla bilaterally. The nerve was 1.5 mm in diameter on the left and 2 mm on the right. The nerve was neurolysed as required and dissection under the rib was not required. A 70 mm $\times$ 2 mm cadaveric nerve graft was used to coapt the nerves following neurolysis from the underside of the serratus. The distal end of the nerve graft was connected to the subcutaneous inferior mastectomy flap. To do so, the distal end of the cadaveric nerve is divided into its fascicles on the back table. A 40 $\times$ 50 mm nerve protector is divided in half and then the fascicles are placed such as to offset the nerve protector that it directs the distal ends towards the mastectomy flap. The nerve and protectors are secured using fibrin glue. A 2-0 prolene suture is then used to pierce the mastectomy flap from the outside, carried through the nerve protector on the lateral aspect and a "U" stitch is performed to bring the construct up to the flap after being pulled from the

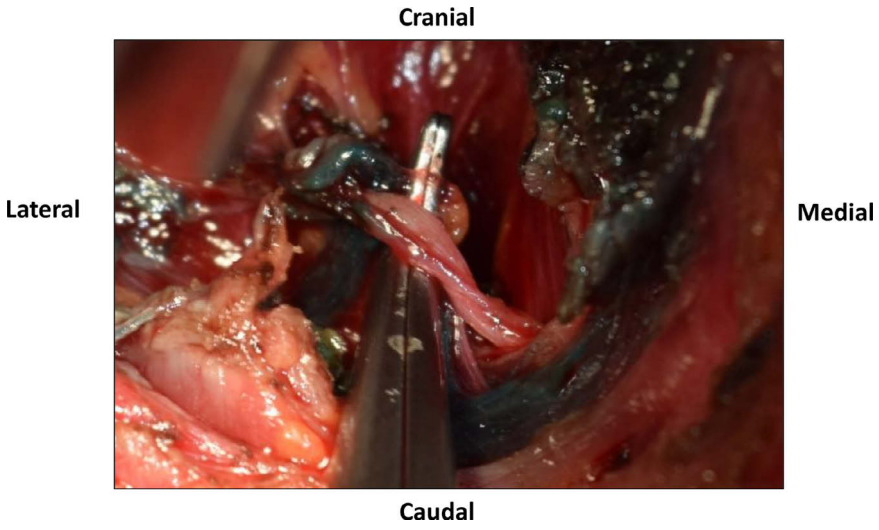

Figure 1 Isolation of nerve with pre-operative localization and nerve block in combination with methylene blue.

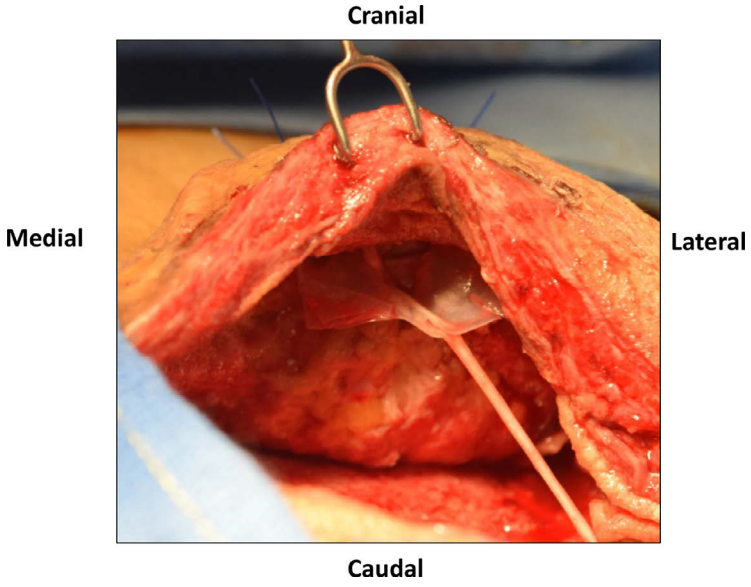

Figure 2 Demonstration of parachute technique to connect nerve graft and conduit to mastectomy flap.

inside of the mastectomy flap to the skin. A similar stitch is performed on the medial aspect, and then the entire construct is parachuted into the mastectomy flap and tied down (Figure 2). The external sutures are removed at 2 weeks. At more than four weeks post-operatively, the patient is pain free and is happy with her reconstruction. Further sensory testing will be performed to determine the efficacy of the sensate reconstruction.

Patient 2 is a 38-year-old female who presented to clinic with chronic left breast pain after bilateral tissue expander to permanent implant reconstruction. At the time of consultation, she requested improvement in the appearance of her breasts as a primary concern. A pocket exchange was performed, but the patient still had persistent left sided breast pain. A nerve block performed at the site of maximal tenderness resulted in a VAS decrease from 7 to 2/10. She subsequently underwent TBR in a similar fashion with a post-operative decrease in pain.

Patient 3 is a 63-year-old female who underwent mastectomy and delayed tissue expander insertion required due to being on Humira at time of mastectomy. While pain was not her primary concern, she noted an uncomfortable feeling with pain levels 5/10 and no breast sensory feedback. She underwent delayed tissue expander insertion, neurolysis and nerve grafting in a similar fashion. Her discomfort decreased from 5 to 0/10 post-operatively and she has had subjective improvement in sensation. She has since undergone delayed DIEP reconstruction and has maintained positive pain outcomes.

All patients were given a similar post-operative regimen including opioids as needed for pain control, flexeril as needed for muscle spams and scheduled gabapentin. Quantities were prescribed for three days at which point over-the-counter regimens were encouraged and adequate. Post-operatively, patients were instructed on early sensory training through self-massage.

While this is an early and merely technical description, the use of a pre-operative block in combination with methylene blue is useful in two distinct ways. A positive responder to a pre-operative nerve block can help diagnose and potentially predict success following a surgical procedure. Secondly, a thorough understanding of the anatomic location of the targeted nerve in conjunction with a visual cue during surgery can assist in a quick and efficacious dissection to increase technical success and decrease operative time. Neuromas were not identified in any patient, but redirection of the sensory nerve through coaptation with a cadaveric nerve graft and redirection to the mastectomy flap resulted in decreased pain post-operatively. Additionally, all neurolysis was performed superficially and no dissection was required beneath the rib. While further study is necessary, a description of these techniques can allow for others to consider this as a potential adjunctive therapy in the setting of neuropathic pain following breast reconstruction. In conclusion, a pre-operative diagnostic nerve block can help elucidate targets for controlling post-mastectomy neuropathic pain with the added potential of allowing for improved sensation to the breast.

Disclosures

None.

Conflict of interest

None.

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James Gatherwright
Division of Plastic Surgery, MetroHealth, 2500 Metrohealth Drive, Cleveland, OH 44109, United States

Rebecca Knackstedt
Department of Plastic Surgery, Cleveland Clinic, Cleveland, OH, United States
E-mail address: jgatherwright@gmail.com

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The electrocardiogram is not affected in women who underwent breast reconstruction by tissue expanders

Dear Sir,

Women with breast cancer are often offered to undergo immediate or delayed breast reconstruction surgery (BRS). Reconstructed women with prosthesis may complain of chest pain related to the surgery or to other conditions including coronary ischemia. Many women have risk factors of coronary artery disease (CAD) including diabetes, hypertension and others as well as chemotherapy or radiotherapy, all increase the risk of CAD.[1] To our knowledge no studies have examined the effect of BRS on the electrocardiogram (ECG) which is a major tool in the evaluation of chest pain or other cardiac symptoms. Therefore, it is of vast importance to recognize if BRS affect the ECG signal.

This study has been conducted in Carmel Medical Center, Haifa, Israel between January 2009 and January 2017 and has been approved by the institutional ethical committee.

All women who underwent two-stage breast reconstruction surgery were reviewed retrospectively. The first stage consisted of a mastectomy and immediate insertion of tissue expander followed by a second stage operation of an insertion of permanent silicone breast implants. The tissue expanders were of the Backer type (Mentor Worldwide, CA, USA). Therefore, we could compare their baseline ECG prior to the first stage with the ECG prior to the second stage. Clinical variables such as age, medical history and type of the breast disease have been collected. A single experienced cardiology consultant reviewed all ECGs. Each ECG record interpretation has included several parameters such as rhythm, PR interval, voltage, QT interval, arrhythmias, T wave inversion, ST elevation or depression, RR interval and conduction.

Continuous variables were expressed as mean ± standard deviation and compared using paired Student's T test. Continuous variables without normal distribution were presented as median (interquartile range). Categorical

Table 1 Baseline demographic and surgical characteristics of the women included in the study.

Age- mean ± SD	51 ± 9.5
Neoadjuvant therapy-n (%)	4 (16)
Diabetes- n (%)	4 (13)
Hyperlipidemia- n (%)	9 (29)
Hypertension- n (%)	4 (13)
Family history of breast cancer- n (%)	13 (42)
Operation	
Left mastectomy- n (%)	5 (16)
Right mastectomy- n (%)	9 (29)
Bilateral mastectomy- n (%)	17 (55)
Axillary lymph node dissection- n (%)	12 (39)

Table 2 ECG parameters prior and following breast reconstructive surgery.

ECG parameters	Pre-BRS	Post-BRS	P value
Patients in sinus rhythm-n (%)	31 (100)	31 (100)	1
Heart rate - mean ± SD (bpm)	81 ± 14	81 ± 14	0.9
PR interval - msec (±SD)	165 ± 17	168 ± 19	0.3
QRS axis- degrees ± SD	35 ± 22	31 ± 24	0.4
QRS duration - msec ± SD	90 ± 7	90 ± 7	0.5
Mean voltage score- mv ± SD	17 ± 6	17 ± 4.5	0.8
QTc- msec ± SD	421 ± 45	427 ± 26	0.42

BRS- Breast Reconstruction Surgery; msec - milliseconds.
Mean voltage score was calculated as the voltage amplitude in Lead L2+V5.

variables were expressed as percentages. All tests were two-sided with a significance level of 0.05.

31 women were included in this study and their ECGs were analyzed (Table 1). The mean age was 51 years old (SD ± 9.5 years). Most of the women (17, 55%) underwent bilateral mastectomy, while 14 women had left or right mastectomy. The second stage surgery was performed after complete recovery and completion of adjuvant therapy. None of the women included in this study had a history of ischemic heart disease. Four women (13%) had mild asymptomatic valvular disease (mild mitral regurgitation in two and mild aortic regurgitation in two). Coronary risk factors were found in up to third of the patients, including diabetes (13%), hypertension (13%) and hyperlipidemia (29%). The Median difference in the ECG recording time was 19 months (IQR, 10.5, 28 months). All patients were in sinus rhythm. No change has been found between the two ECGs in each operated woman (Table 2). During a mean follow up of 5.2 ± 1.9 years, 9 women (29%) were admitted to a hospital due to possible cardiac symptoms which included chest pain in five women, dyspnea in one, weakness in one, epigastric pain in one and hypertensive crisis in one woman. Diagnostic workup included ECG for all admitted women, cardiac enzymes in six, echocardiography in two women and chest computer tomography to exclude pulmonary embolism and coronary disease in two. Two patients had a diagnosis of atypical chest pain and required no further evaluation except for the ECG. None of the patients was diagnosed with an acute coronary syndrome.

Our study did not find any evidence of ECG changes which were related to BRS. The effect of BRS on ECG recording is an important clinical question since many of these women are at risk for cardiac disease, whether due to their comorbidities, or due to the effects of the cancer treatment medication such as Doxorubicin and Trastuzumab and radiotherapy which have the most deleterious effect on the heart.[1]

The surface ECG signal reflects both the heart electrical activity and the surrounding conductivity. According to the low of Ohm, any decrease in the medium resistance is expected to decrease the surface voltage. Emphysema, pericardial effusion and obesity[2–4] have been shown to alter the ECG signal. The effect of Saline or Silicone breast implants on the ECG signal has not been tested.

A recent abstract by Bun et al.[5] evaluated the possibility that breast implants might influence the ECG. This report which compared between ECG of 25 healthy women with breast implants and 20 healthy women without breast implants has found high incidence of ECG abnormality. However, significant disagreement was noticed between the two electrophysiologists who reviewed the ECGs i.e. 57% Vs. 38%.

To our knowledge this is the first study to demonstrate that breast reconstruction employing tissue expanders does not interfere with the ECG. Therefore, any ECG changes following BRS should be regarded as suspicious for cardiac condition and should not be related to the breast reconstruction surgery. Further clinical studies are warranted to consolidate our results.

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Conflicts of interest

None declared.

Ethical approval

This study has been approved by the institutional ethical committee.

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Aviv Kramer
Department of Plastic Surgery, Carmel Medical Center and the Bruce and Ruth Rappaport Faculty of Medicine, Technion- Israel Institute of Technology, Haifa, Israel

Asaf Danon[1]
Unit of Electrophysiology, The Division of Cardiology, Carmel Medical Center and the Bruce and Ruth Rappaport Faculty of Medicine, Technion- Israel Institute of Technology, Haifa, Israel

Eyal Franco, Issa Metanes, Yaron Har-Shai
Department of Plastic Surgery, Carmel Medical Center and the Bruce and Ruth Rappaport Faculty of Medicine, Technion- Israel Institute of Technology, Haifa, Israel

Correspondence to: Yaron Har-Shai, Department of Plastic Surgery, Carmel Medical Center, Haifa 2126343, Israel.
[1]This author contributed equally to this work as the first author.
E-mail address: yaron07@yahoo.com

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Evaluation of trainee performance in microsurgical procedures

Dear Sir,

Acquisition of microsurgical expertise is integral to plastic surgical training. The United Kingdom Certificate of Completion of Training requires surgeons to perform 27 free tissue transfers and 35 microvascular anastomoses during their training; a goal challenging to trainees and trainers alike given reduced training hours, complexity of cases, and consequences of flap failure.

We analyzed cases in the prospectively populated microsurgery database from a single unit, between December 2017 and December 2018. Intraoperative data, flap outcomes, and patient characteristics were compared between two groups. Operative steps were coded as Consultant-delivered, Trainee supervised by a scrubbed Consultant (STS) or Trainee with a supervisor unscrubbed (STU).

One hundred and one adults received 103 flaps during the study period. Patients' mean age was 49 (SD = 16). There were no significant difference in patient demographics or flap type between Consultant-delivered and Trainee led cases. Overall, 27 cases (22%) were entirely Consultant delivered. Trainee with scrubbed Consultants raised 25 flaps (26%), prepared the recipient vessels in 17 cases (19%) and performed the microvascular anastomosis in 29 cases (32%). Trainees with the unscrubbed supervisors raised 18 flaps (19%), 14 recipients prepared (15%) and 13 flaps anastomosed (14%). The median ischaemia was 68 minutes for Consultants, 76 minutes for Trainee with STS, and 68 minutes for Trainees with STU ($p = 0.3$). The total operative time was not difference between groups ($p = 0.1$). Eight patients returned to theatre for flap salvage (6%) and 5 flaps failed (4%), neither of which were associated with trainee involvement ($p = 0.6$).

Accepting the complexity of many of these cases and the variables that can occur in surgical outcomes we found no detrimental effects of trainee led microsurgery and hope to encourage this further.

Declaration of Competing Interest

N/A

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J. Smith
Department of Plastic and Reconstructive Surgery, Leeds Teaching Hospitals Trust, Leeds, UK

R.G. Wade
Leeds Institute for Medical Research, University of Leeds, Leeds, UK

R. Clancy, D. Wilks
Department of Plastic and Reconstructive Surgery, Leeds Teaching Hospitals Trust, Leeds, UK

Correspondence author: James Smith, Leeds General Infirmary, Plastic Surgery, Great George Street, Leeds, United Kingdom
E-mail address: james.smith@doctors.org.uk

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Plastic surgery trainees, GDPR and the eLogbook: Are we doing it all wrong?

Dear Sir,

The Pan-Surgical eLogbook is the primary logbook for plastic surgery trainees in the UK. The Joint Committee for Surgical Training expects trainees to keep their eLogbook updated throughout training in order to demonstrate the surgical competences required for completion of training.[1] At the time of writing, over 43 million operations have been logged in eLogbook by 33,000 surgeons of all specialties. With this amount of patient information stored outside NHS servers, it is important to consider our duties as trainees to safeguard patient data, especially in light of the General Data Protection Regulation (GDPR) and its UK implementation, the Data Protection Act 2018.

In this context, three main questions should be considered: firstly, whether eLogbook information constitutes personal data; secondly, whether trainees are considered Data Controllers and, if so, need to be registered with the Information Commissioner's Office as required by law; thirdly, whether separate consent must be obtained from patients to record their details on eLogbook.

Is the information entered into eLogbook "Personal Data"?

According to Article 4 of the GDPR, personal data is any direct or indirect information related to an identified or identifiable natural person; this may include something as simple as an identification number. As the definition includes "any information", what constitutes personal data should be interpreted in the broadest possible terms. ELogbook entries clearly fall into this definition, as they contain not only patients' hospital numbers, but also their date of birth, date of surgery, operation type, supervising consultant, possible complications, and free text. Access to this information could therefore be used to identify individual patients.

Are plastic surgery trainees Data Controllers?

A Data Controller is a natural or legal person who, alone or jointly with others, determines the purposes and means of personal data processing. Prior to GDPR, the status of eLogbook users was open to interpretation.[2] However, this has now been clarified by eLogbook's updated terms and conditions where it is expressly stated that eLogbook users are Data Controllers, a role they share with the four Royal Colleges of Surgeons.[3] Therefore, trainees must be registered with the Information Commissioner's Office, which is the UK's National Data Protection Authority. Registration costs £40 per annum and failure to register is a civil offence (it was a criminal offence under previous legislation).

How many plastic surgery trainees are registered with ICO?

Even though the ICO register is public,[4] it is difficult to know exactly how many UK plastic surgery trainees are on it, as trainees' details are, themselves, protected under GDPR. However, the author is a senior plastic surgery trainee in Scotland with access to details of the Scottish trainee cohort. This enabled him to search the ICO register and get a measure of the situation in Scotland. As of May 2019, only 5 out of 36 Scottish plastic surgery trainees (14%) held ICO registration. Even allowing for the fact that some trainees might be registered under a company name, this number is still low. In contrast, 32 out of 51 (63%) plastic surgery consultants currently working in the NHS in Scotland are registered with ICO; this likely reflects the fact that consultants need ICO registration to be able to work privately.

Is separate consent required for eLogbook?

Under GDPR Article 9, health data are "special category data" (previously "sensitive personal data") and therefore require a higher level of protection, meaning Data Controllers must have both a lawful basis for processing them and explicit consent from the data subjects to use them. This immediately raises several questions: how realistic is it for trainees to obtain separate consent from patients, bearing in mind the average trainee needs at least 2100 operations to finish training? [1] Is verbal consent enough? Are NHS patients different than private patients? None of these questions are easy to answer, especially in the absence of specific guidance by the ICO or any legal precedent. However, both private and NHS patients should expect the same safeguarding standards and, from an ethical perspective, all patients should have the autonomy to decide how their personal information is processed. Whether that means obtaining verbal consent or amending pre-existing consent forms is outwith the scope of this paper, but trainees need to be aware of this added legal obligation and incorporate it in their practice.

In summary, the GDPR makes it clear that plastic surgery trainees that use eLogbook in the UK are Data Controllers and, as such, should be registered with ICO. ICO registration is still very low amongst trainees and this is something that the Training Deaneries should take steps to improve. Trainees in the UK should be aware that explicit patient consent is a legal requirement for processing sensitive data. International trainees that use eLogbook should also be familiar with GDPR and local legislation in the countries where they practice.

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Conflicts of interest

None.

Ethical approval

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Nikolaos Arkoulis
Department of Plastic and Reconstructive Surgery, Ninewells Hospital and Medical School, Dundee DD2 1SY, United Kingdom
E-mail address: narkoulis@nhs.net

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Does 3D printing really guide surgeons in having a more satisfying rhinoplasty result?

Dear Sir,

Introduction

Aesthetic surgeries may help people to increase their self-esteem. Due to complexity of procedure, sometimes surgeons cannot persuade them about the outcomes and ultimate shape of the nose and face after surgery. Having an assessment of facial landmarks, or applying scales to demonstrate the expected outcome, such as Rhino Scale[1] would be remarkable.

Consultations before surgery provide opportunities to understand a person's psychosocial condition and expectations to consider them. Jacques Joseph was probably the first who started image morphing and explaining the expected surgical changes by drawing on black and white photographs of patients before surgery.[2] Nowadays, this has developed into digital imaging. Generally, 2D and 3D digital imaging are used for aesthetic consultations to make expectations more realistic.

In this study we investigated a new method. This method combines 2D digital imaging with 3D prints to make molds based on the person's desired shape of the nose before surgery. During surgery, the surgeon creates the ultimate shape of the nose with these 3D guides to make sure it is exactly as it was requested by the person.

Materials and methods

42 people who wanted to undergo septorhinoplasty signed an informed consent and took consulting sessions before the surgery to see how their nose would look like after the surgery in the digital images. The surgeon planned the procedure based on the person's expectation and the created 3D print by the technician who made the model guides with 3D printers using Poly-Ethylene-Tetra-Phthalate-Glycol (officially approved material) to show the finally accepted, designed shape of the nose.

All the steps of a standard rhinoplasty were undertaken during the surgery. Disinfected model guides were used to check the desired results with axial (profile) and basal guides and with the final guide at the end of surgery (Figure 1). Minimal extra jobs were done as needed to have smooth surfaces and curves as it was desired by the participants before the surgery. The incisions were closed if the surgeon was satisfied. 15 months after the surgery all participants completed a questionnaire regarding this process.

Results

All participants completed the forms before the surgery and the questionnaire 15 months after the surgery. 78.6% believed that this method helped to be aware of the final result. 88.1% confirmed the eventual shape was similar to the provided image. 78.6% were satisfied with the predicted results that were according to their desire. However, 29.6% complained about its expensiveness and mentioned that it is not cost-efficient (Table 1).

Discussion

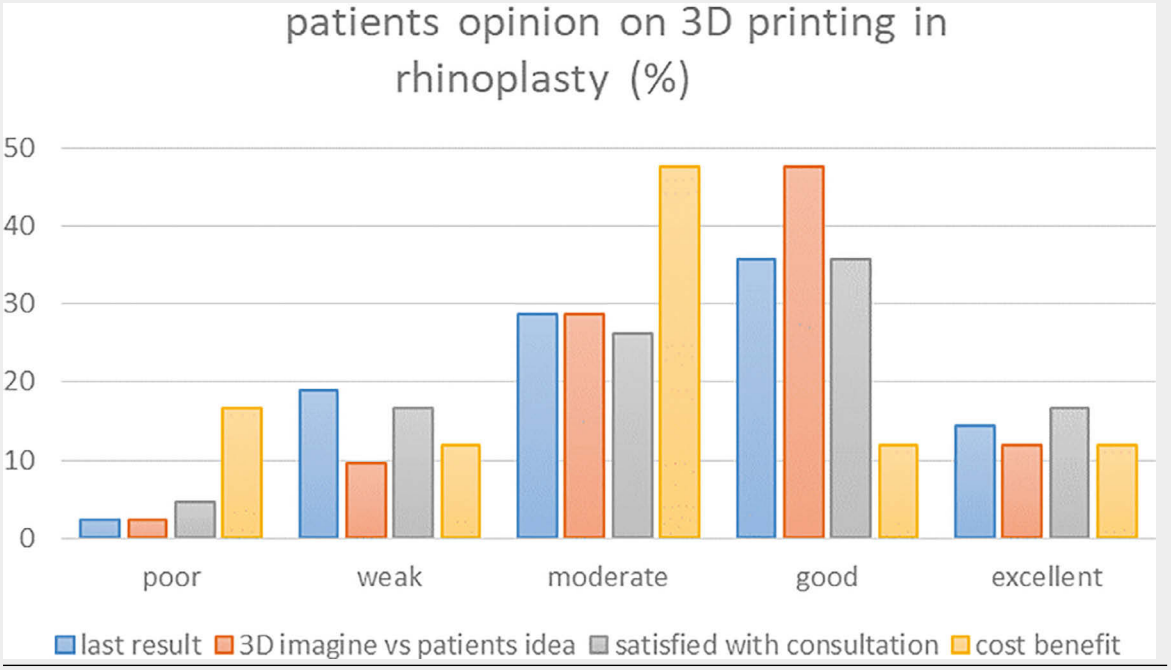
We designed a method to achieve more satisfaction of rhinoplasty using 3D imaging and printing. This process started with a consulting session in which the person sat next to the surgeon and technician to design a new picture of his/her nose and discuss the possibility of the procedure. The participants were informed about their possible constraints. After getting the final agreement on the nose shape, the technician took the picture and made three – basal, profile (axial) and final – surgical guides with a 3D printer. The surgeon made the last required minimal changes.

Amirlak and colleagues consider 3D printing as a useful instrument in modern septorhinoplasty.[3] Likewise, we used 3D model guides with improved modifications to do all the requested details desired by the participants.

Antón de Vez and Jover have sought "patient specific model" on 10 people to remove dorsal humps in rhinoplasty which can be reached by 3D computed tomography imaging,

Figure 1 Checking the nose shape in perioperative field with surgical guides. Left upper row: check with final guide before operation; middle upper row: check with axial guide before operation; right upper row: check with basal guide before operation. Left lower row: check with final guide at the end of surgery; middle lower row: check with axial guide at the end of surgery; right lower row: check with basal guide at the end of surgery.

Table 1 Patients opinion on 3D printing in rhinoplasty (%).



nasal anthropometries, and resection devices.[4] We provided basal, final and profile guides, which enabled us to manage dorsal hump and basal view or even tip jobs. Moreover, we tried this method on 42 people who evaluated the result 15 months after the surgery.

Less than 12% of participants complained a little about the eventual outcome. Still they were somehow satisfied with their nose as it was similar to what they had expected from the consulting sessions. The reason might be that they may have expected outcomes not discussed previously. We had only two cases of revision due to remained dorsal hump.

Our patients paid an extra $100–$150 for the consulting sessions plus imaging and molds. Only 29.6% complained about this added charges. Bekisz et al. introduced their 3D printed guides for approximately $5 in each set of home-made molds which is low-cost,[5] but we believe that improve

in manufacturing can make our method less expensive in the future.

The surgeons are familiar with rhinoplasty techniques and possible results, but patients expect different outcomes that cannot be easily explained exactly to surgeons. 3D images and 3D model guides can help surgeons to persuade people about the desired outcome and to consider their expectations with more detail.

Declaration of competing interest

None declared.

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Ethical approval

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Supplementary material

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.bjps.2019.07.025.

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Javad Rahmati
Plastic and Reconstructive Surgery Ward, Valiasr Hospital, Imam Khomeini Hospital Complex, Tehran University of Medical Sciences, Bagherkhan St., Towhid Sq., Tehran, Iran

Plastic and Reconstructive Surgery Ward, Razi Hospital, Tehran University of Medical Sciences, Tehran, Iran

Nafiseh Malekmohammadi
Faculty of Midwifery, Islamic Azad University, Tehran Medical Sciences, Tehran, Iran

Hojjat Molaei
Plastic and Reconstructive Surgery Ward, Valiasr Hospital, Imam Khomeini Hospital Complex, Tehran University of Medical Sciences, Bagherkhan St., Towhid Sq., Tehran, Iran
Plastic and Reconstructive Surgery Ward, Sina Hospital, Tehran University of Medical Sciences, Tehran, Iran

Corresponding author at: Plastic and Reconstructive Surgery Ward, Valiasr Hospital, Imam Khomeini Hospital Complex, Tehran University of Medical Sciences, Bagherkhan St., Towhid Sq., Tehran, Iran.
E-mail address: hmolaei@sina.tums.ac.ir

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Letter to the editor—Zygomatico-orbital artery: The largest artery in the temporal area

Dear Sir,

We read with great interest the article entitled "Zygomatico-orbital artery: The largest artery in the temporal area" by Choi et al.[1] The paper found that zygomatico-orbital artery bifurcates from the external carotid artery, rises and crosses the zygomatic arch anterior to the porion. The zygomatico-orbital artery mean diameter was 2.52 mm. Figure 1(A) described by the author showed the detailed course of the zygomatico-orbital artery.[1]

The study demonstrated that zygomatico-orbital artery started from point 1 on the external carotid artery in Figure 1(A) displayed by Choi et al.[1] However, after discussed with radiologist and anatomist for anatomic relationship and imaging features, we found that the external carotid artery displayed in Figure 1(A) is more likely to be a vein. It is pertinent to note that the external carotid artery begins lateral to the upper border of the thyroid cartilage. With a little curved and spiral, external carotid artery first ascends slightly forwards and then inclines backwards and a little laterally, to pass midway between the angle of the mandible and the tip of the mastoid process. Behind the condyle neck of the mandible, it divides into its terminal branches, the maxillary arteries and superficial temporal. As external carotid artery ascends, it diminishes rapidly in caliber. The external jugular vein is thicker than the exter-

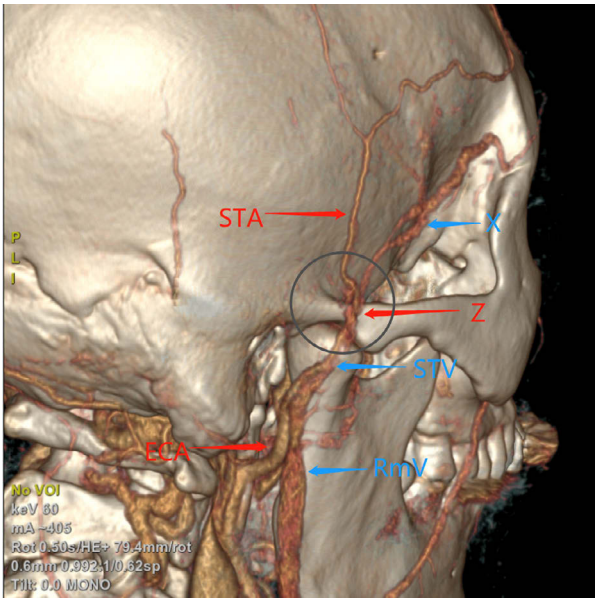

Figure 1 Relationship between X-vessel ("zygomatico-orbital artery" described by the author), external carotid artery, retromandibular vein and superficial temporal vein. ECA: External Carotid Artery; STA: Superficial Temporal Artery; STV: Superficial Temporal Vein; RmV: Retromandibular vein; Zone Z: The base of the zygomatic arch; X-vessel: "Zygomatico-orbital artery" described by Choi et al.

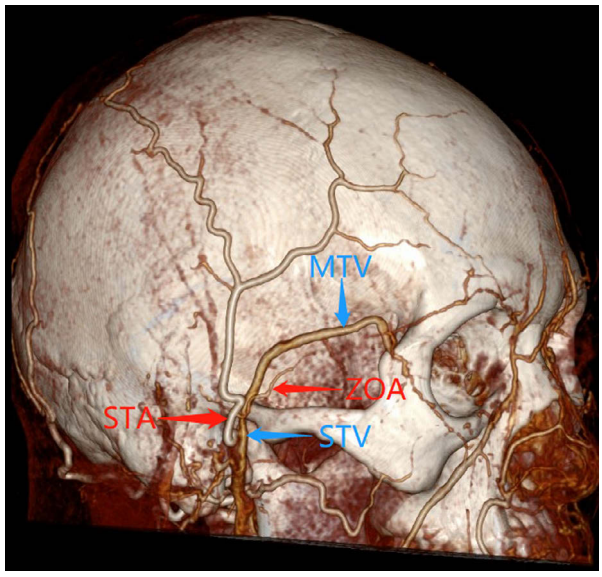

Figure 2 Course of middle temporal vein and the zygomatico-orbital artery. STA: Superficial Temporal Artery; STV: Superficial Temporal Vein; ZOA: Zygomatico-orbital artery; MTV: Middle Temporal Vein.

nal carotid artery. It begins near the mandibular angle, descends from the angle of mandibular to the midclavicle, running obliquely and superficially to the root of the neck. The vein is formed by the union of the posterior division of the posterior division of the retromandibular vein with the posterior auricular vein. Retromandibular vein is formed by the union of the superficial temporal vein with maxillary vein at condyle neck of the mandible. The superficial temporal vessels are superficially and longitudinally arranged at the base of the zygomatic arch (zone Z in the figures below). The superficial temporal vein is located on the superficial surface of the superficial temporal artery.[2] Based on the course and diameter of the blood vessel, we suspect that the "external carotid artery" in Figure 1(A) displayed by Choi et al. is more likely to be the "superficial temporal vein".

Reference method mentioned in the article, we collected and analyzed image data of patients who underwent contrast-enhanced 3D facial or neck CT for the diagnosis of vessel patency in the maxillofacial or neck region.[1] The following Figure 1 showed the relationship between X-vessel ("zygomatico-orbital artery" described by the author), external carotid artery, retromandibular vein and superficial temporal vein. Superficial temporal vein was thicker than the superficial temporal artery. Moreover, veins were located more superficial. Therefore, we are more certain that the "external carotid artery" in Figure 1(A) displayed by displayed by Choi et al. is actually the superficial temporal vein. Moreover, it is apparent that the X-vessel joins the vein. As a result, we can confirm that the X-vessel is a vein, not the true "zygomatico-orbital artery".

In addition, we strongly suspect that the X-vessel is the middle temporal vein. Jung et al. demonstrated that the middle temporal vein joins the superficial temporal vein. It was located 23.5 mm and 18.5 mm above the zygomatic arch at the jugale (where the temporal and frontal processes of the zygomatic bone meet) and the zygion (the most lateral point on the zygomatic arch), respectively. The diameter of the middle temporal vein range from 2.0 mm to 9.1 mm.[3] In contrast, we found that the course and diameter of the X-vessels measured by Choi et al. are similar to those of the middle temporal vein. Figure 2 showed the course of middle temporal vein and the zygomatico-orbital artery. Middle temporal vein joins the superficial temporal vein. Besides, the zygomatico-orbital artery in this figure started from superficial temporal artery.

In summary, we strongly doubt the "zygomatico-orbital artery" described by Choi et al. should be the middle temporal vein. However, more information is still needed to confirm the detailed course and diameter of zygomatico-orbital artery.

Declaration of Competing Interest

None.

Founding

None.

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Shuo Liu[1]
State Key Laboratory of Oral Diseases & National Clinical Research Center for Oral Diseases & Department of Cosmetic and Plastic Surgery, Oral and Maxillofacial Surgery, West China Hospital of Stomatology, W China Coll Stomatol, Sichuan University, Chengdu 610041, China

Lingjun Liu[1]
Department of Radiology, West China Second Hospital, Sichuan University, Chengdu 610041, Sichuan, China

Hang Wang
State Key Laboratory of Oral Diseases & National Clinical Research Center for Oral Diseases & Department of Cosmetic and Plastic Surgery, Oral and Maxillofacial Surgery, West China Hospital of Stomatology, W China Coll Stomatol, Sichuan University, Chengdu 610041, China

Corresponding author.
[1]These authors contributed equally to this work.
E-mail address: dr.hangwang@hotmail.com

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Reossification of the skull base after fronto-orbital advancement for craniosynostosis

Dear Sir,

Fronto-orbital advancement (FOA) is one of the accepted first-line surgical procedure for craniosynostosis. The aims of FOA are to expand the anterior cranial fossa, provide protection for the globe, and to contour the forehead. However, one of the disadvantages of FOA is the development of a bony gap behind the advanced segments, especially when FOA is performed in older patients.[1] In the absence of reossification, this may lead to functional issues.

Although, reossification of the cranium after FOA, with and without distraction osteogenesis, has been evaluated in the literature,[2-4] to the best of our knowledge, reossification of the gap of the skull base, including the orbital roof, has not been previously assessed. The skull base is necessary to separate the nasal cavity from the dura. Additionally, an orbital roof defect may result in pulsatile proptosis.

In this study, we retrospectively evaluated postoperative bone formation in the gap of the skull base and investigated the correlations between reossification and clinical factors. This study received approval from the relevant institutional ethics review board.

Between 2006 and 2015, the patients with nonsyndromic craniosynostosis who underwent FOA with or without distraction osteogenesis were included in this study. Patients were grouped into under 24 months and over 24months, and the latter group was done with distraction (Figure extra). The distraction protocol was to activate the device at a rate of 1.0 mm/d after a 5-day latency period. The internal distractors were removed after 6 months consolidation period.

Among them, computed tomography (CT) scans were obtained immediately after surgery, immediately after distraction, and 1-year post-surgery using a 320-detector row CT.

The amount of advancement was measured immediately after surgery using CT based on the width of the bone defect at the centre of the upper orbital rim. The mean of both sides was used to determine the amount of advancement. The reossification area was determined from the bone defect of the skull base (Figure 1). The differences in bone defect from immediate post-op and 1 year post-op were used to determine the reossification area. For plagiocephaly, we compared regenerated bone at the orbital roof in the affected and unaffected sides.

As a result, 13 cases of unicoronal synotosis, 12 cases of metopic synostosis, and 6 cases of bicoronal synostosis were included in this study (Table 1, Figure 2).

In patients with unicoronal synostosis, the reossification in the affected and unaffected sides was compared. The advancement lengths were lower in the unaffected side than the affected side ($p < 0.05$) for all operative ages because the affected side is always advanced to a greater degree. The mean reossification ratio in the affected and unaffected sides in patients under 12 months indicated almost complete reossification. The reossification rates in the affected and unaffected sides in patients over 24 months were $93.7 \pm 2.2\%$ and $93.3 \pm 2.2\%$, respectively, and this difference was not significant ($p = 0.79$). Reossification ratios in the affected and unaffected sides in patients 12-24 months and over 24 months were $81.9 \pm 9.2\%$ and $93.7 \pm 5.1\%$, respectively, and this difference was significant ($p < 0.05$).

In patients with metopic synostosis, patients under 12 months obtained more than 90% reossification. Although the advancement lengths in each group did not differ significantly, the reossification in patients aged 12-24 months was $89.6 \pm 2.3\%$, which was significantly worse than in patients under 12 months ($p < 0.05$). In contrast, in patients over 24 months who underwent distraction, reossification was $96.0 \pm 0.7\%$, which was significantly better than

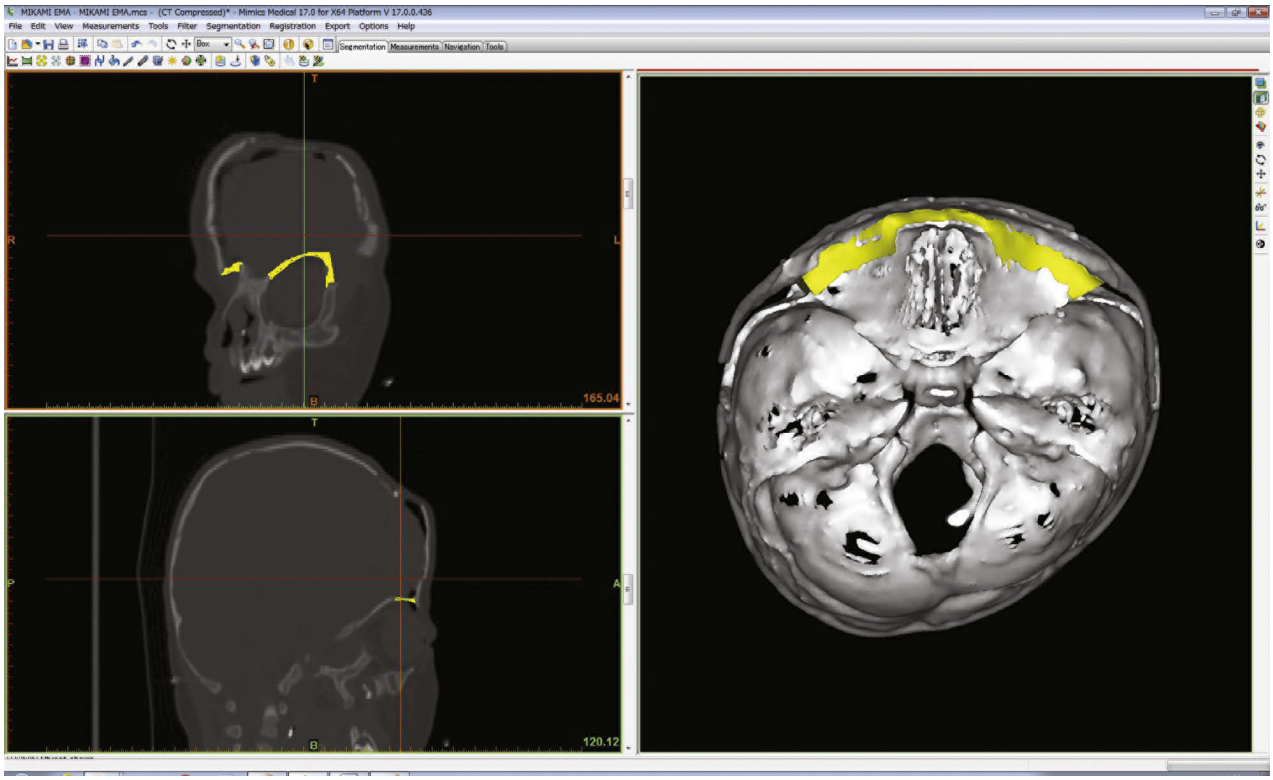

Figure 1 Measurement view using Mimics® software (Materialise, Leuven, Belgium) to calculate skull base defects.

Table 1 Reossification ratio in each etiology.

	Operative age		
	< 12 month[a]	12-24 months[a]	> 24 months[b]
Plagiocephaly (No.)	4	5	4
Mean operative age (month)	8.5 ± 3.0	18.0 ± 2.0	37.3 ± 12.0
Amount of advancement			
Affected side (mm)	13.2 ± 0.7	11.5 ± 0.9	11.8 ± 0.8
Unaffected side (mm)	8.8 ± 1.2	7.6 ± 0.4	8.1 ± 0.6
Reossification ratio			
Affected side (%)	99.7 ± 0.58	81.9 ± 9.2	93.7 ± 2.2
Unaffected side (%)	99.6 ± 0.67	93.7 ± 5.1	93.3 ± 2.2
Trigonocephaly (No.)	6	3	3
Mean operative age (month)	8.8 ± 2.1	16.0 ± 3.0	24.3 ± 0.6
Amount of advancement (mm)	11.8 ± 1.1	11.4 ± 1.0	11.5 ± 1.8
Reossification ratio (%)	98.2 ± 2.5	89.6 ± 2.3	96.0 ± 0.7
Brachycephaly (No.)	5	1	0
Mean operative age (month)	9.2 ± 1.8	15	-
Amount of advancement (mm)	16.9 ± 1.1	16.9	-
Reossification ratio (%)	95.6 ± 2.8	88.7	-

[a] Performed FOA without distraction osteogenesis.
[b] Performed FOA with distraction osteogenesis.

reossification ratios obtained in patients aged 12–24 months ($p < 0.05$). There was no significant difference between the reossification ratios in patients aged 12–24 months, who did not undergo distraction osteogenesis, and patients over 24 months, who did undergo distraction osteogenesis ($p = 0.10$).

In bicoronal synostosis, the amount of advancement was significantly larger than the other nonsyndromic patients ($p < 0.01$). Although, the reossification ratio in patients over 12 months was 88.7%, and lower than patients under 12 months (95.6 ± 2.8), the difference was not significant ($p = 0.10$) because of the small sample size.

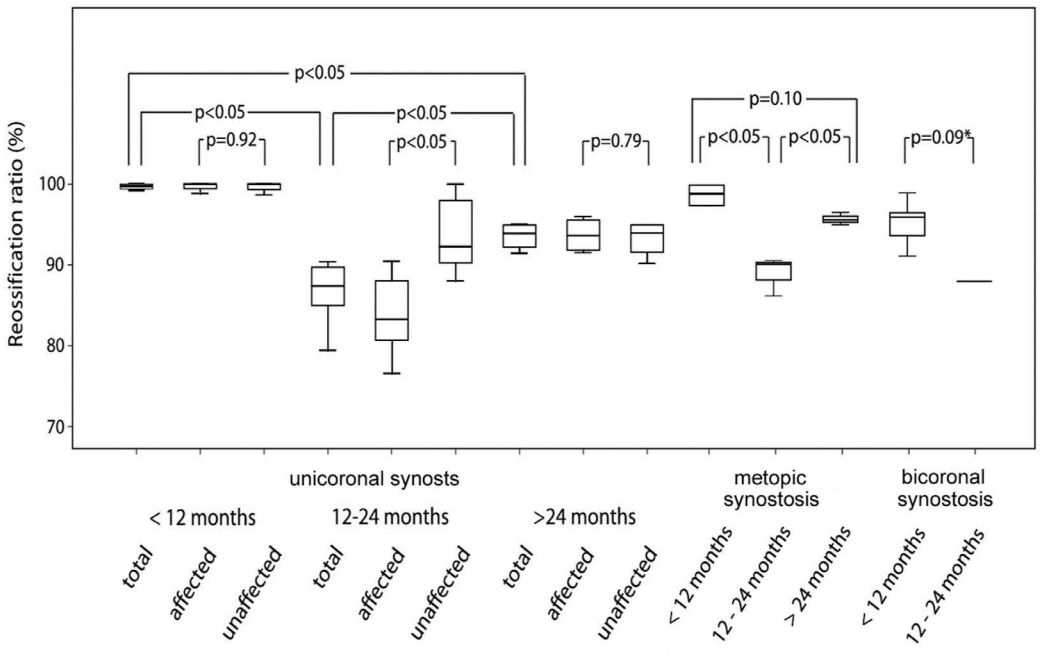

Figure 2 Reossification ratios in patients for each etiology.

From our results, we demonstrated that for patients who underwent FOA without distraction, age was one of the factors influencing reossification. Previous studies have also demonstrated that increased age of the patient at surgery is associated with incomplete reossification.[2] However, on this study, we have demonstrated that older children undergoing FOA with distraction, achieve higher rates of reossification.

Also, it is thought that the amount of advancement is one of the factors in reossification from the results of unicoronal synostosis.

In conclusion, our study is the first report on reossification that focused on the skull base after FOA. Apart from fronto-facial monobloc advancement,[4] FOA with distraction is rarely performed outside of Japan. However, FOA with distraction should be considered in patients of all ages with varying amounts of advancement, which is often seen in syndromic craniosynostosis.

Declaration of Competing Interest

None.

Financial disclosure and products

None of the authors has a financial interest in any of the products, devices, or drugs mentioned in this manuscript

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.bjps.2019.07.005.

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Yoshiaki Sakamoto
Department of Plastic and Reconstructive Surgery, Keio University School of Medicine, 35 Shinanomachi, Shinjuku-ward, Tokyo 160-8582, Japan

Tomoru Miwa, Kazunari Yoshida
Department of Neurosurgery, Keio University School of Medicine, 35 Shinanomachi, Shinjuku-ward, Tokyo 160-8582, Japan

Kazuo Kishi
Department of Plastic and Reconstructive Surgery, Keio University School of Medicine, 35 Shinanomachi, Shinjuku-ward, Tokyo 160-8582, Japan
E-mail address: ysakamoto@z8.keio.jp

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Does non-activated platelet-rich plasma (PRP) enhance fat graft outcome? An assessment with 3D CT-scan in mice. Letter to editor

Dear Sir,

We carefully read the last article of Atashi et al. recently published in JPRAS entitled "Does non-activated platelet-rich plasma (PRP) enhance fat graft outcome? An assessment with 3D CT-scan in mice".[1] We would like to congratulate the authors for this exhaustively documented experimental study. Indeed, the idea to increase fat graft retention using PRP and growth factors it contains is a popular topic in aesthetic and reconstructive field. More than a dozen pre-clinical studies since 2013, trying to investigate this point have been identified without any consensus. The adjuvant potential of PRP on adipose tissue is still lacking of objective data and needs evidence-based assertions. In this context, this work is a reliable contribution to our general knowledge of PRP effects and we would like to raise several points.

First, the study of Dr Atashi and colleagues is one of the scarce studies using volume assessment by imaging. The quality of the 3D reconstruction of the fat grafts should be underlined and whether Computerized Tomography Scan (CT) or Magnetic Resonance Imaging (MRI) have to be used can be discussed but one of these techniques should be preferred as objective volume assessment criteria rather than macroscopic measurement, ultrasound or liquid overflow method. MRI spectrometry can also be used to investigate water/fat ratio into the graft and assess the tissue viability.[2]

Secondly, experimental studies investigating PRP-fat mixture should systematically report two essentials parameters describing the injected products and allowing comparison between these kinds of studies. Thus, we previously define (i) the percentage of PRP volume in the mixture and (ii) the dose of platelets per volume of mixture as gold standards in fat-PRP mixture description. In this case, the authors used a 80% fat – 20% PRP and a mean platelets dose of 48 million of platelet per milliliter of mix. Literature review shows that these parameters range from 0.15 to 300 million of platelets per milliliter of mix, that could explain the contradictory results of some pre-clinical studies. Interestingly, the only double-blinded, placebo-controlled randomized trial that compared the use of fat alone vs PRP-fat mix for facial rejuvenation did not show any benefit from PRP addition in terms of skin elasticity or graft volume maintenance.[3] Authors suggested that high platelet levels may be counterproductive, possibly because they trigger undesirable cellular differentiation or ASC differentiation toward a fibroblast-like phenotype.

The last interesting point concerns the quantity of injected product in mouse model. This aspect is discussed by the authors trying to justify discrepancies in volume with Hersant's study[4] as they have respectively injected 0,5 ml vs 1 ml per site. We would like to highlight the recent article of Kokai et al.[5] recommending not to inject human fat graft bigger than 0.3 ml in immunosuppressed mice model. Indeed, they observed that volume retention reflected tissue health in 0,3 ml grafts although central oil cysts were still present in 1 ml grafts by 18 weeks.

The clinical and experimental results on this topic is widely controversial. Atashi's work is a great model of fat – PRP in vivo experimentation with objective data. Thus, we take the opportunity of this study to provide to cell-based therapy researcher guidelines for future publications, as such:

- Using volumetric analysis of fat graft by imaging and reconstruction.
- Providing information on proportion of fat – PRP mix and platelets dose/mL of mix.
- Targeting an injection of 0.3–0.5 cc in mouse model to limit central fat necrosis and optimize volumizing effect.

Funding

None.

Declaration of Competing Interest

None.

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Maxime Abellan Lopez, Baptiste Bertrand
Plastic, Reconstructive and Aesthetic Surgery Department, La Conception Hospital, 147 Bd Baille, 13005 Marseille, France

Aurélie Daumas
Culture and Cell Therapy Laboratory, CICBT 1409, La Conception Hospital, 147 Bd Baille, 13005, Marseille, France

Dominique Casanova
Plastic, Reconstructive and Aesthetic Surgery Department, La Conception Hospital, 147 Bd Baille, 13005 Marseille, France

Jérémy Magalon, Florence Sabatier
Culture and Cell Therapy Laboratory, CICBT 1409, La Conception Hospital, 147 Bd Baille, 13005, Marseille, France
E-mail address: maxime.abellanlopez@gmail.com

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Transversus abdominis release in the treatment of subcostal incisional hernias

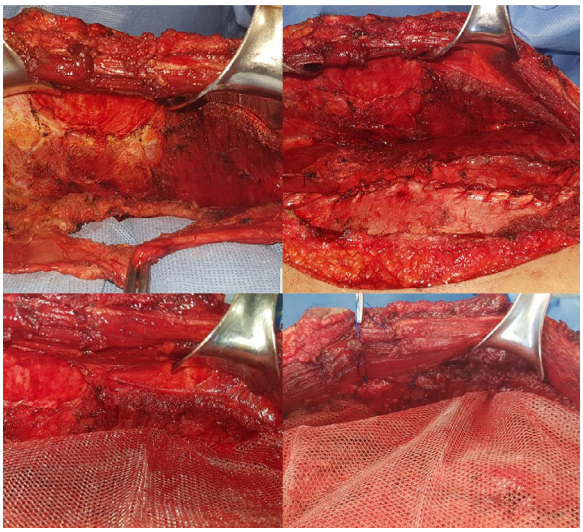

Figure 1 (Upper left): a TAR dissection through the midline demonstrates a subcostal defect both at the level of the posterior fascia (lateral border of posterior rectus sheath – medial border of transversalis fascia), and at the level of the muscles (between the lateral edge of the rectus muscle and the medial border of the three lateral muscles). (Upper right): The subcostal hernia defect and the midline defect created during surgery have been closed with polyglactin 910 sutures at the level of the posterior fascia to reconstruct a visceral sac.
(Lower left): Placement of a wide macroporous medium-weight polypropylene retromuscular mesh with great overlap over the posterior fascia. (Lower right): The subcostal defect at the level of the muscles has been closed with polypropylene sutures.

Dear Sir,

Subcostal incisions are used primarily in hepato-pancreato-biliary procedures due to their excellent exposure of upper abdominal structures, ease of closure of the abdominal wall layers and their reduced incidence of incisional hernias compared to midline incisions. Nonetheless, subcostal hernias – when they occur – pose a substantial clinical problem, and are considered as "complex defects".[1] In 2009, Stumpf et al. performed dissections on cadavers and stated that, in the treatment of subcostal hernias "…the layer between the external oblique muscle and the internal oblique muscle is the ideal place to position the mesh with adequate overlap".[2] Two years later, we advocated the use of anterior component separation to close medium to large-sized subcostal hernias.[3] In 2014, Gauduchon et al., described their approach to subcostal hernias, placing a mesh either in the plane between the external oblique and the costal cartilage, or intraperitoneally.[4] De Oliveira Peres et al., advocated the use of the supra aponeurotic onlay technique in 24 patients with subcostal hernias.[5] Since January 2015, we have adopted the transversus abdominis release (TAR) technique for reconstruction of the abdominal wall in 19 patients with subcostal incisional hernias. A midline incision is performed to gain access to the abdominal cavity. Intra-abdominal adhesions are lysed and the herniated content is reduced. Retro-rectus dissection is performed bilaterally, as well as division of the medial fibres of the transversus abdominis muscles to expose the fascia transversalis bilaterally to the level of the psoas muscles, caudally to expose the Cooperś ligaments, and cephalically to expose the xyphoid (Figure 1, upper left). The hernia defect at the level of the transversalis fascia and the lateral aspect of the posterior rectus sheath is closed with a running 2-0 polyglactin 910 (Vicryl, Ethicon) suture; also, the medial borders of both posterior rectus sheaths are closed in the midline at the posterior-most layer (Figure 1, upper right). A 30 × 30 cm macroporous 75 g/cm^2 polypropylene mesh (Parietene, Medtronic) is placed in a retromuscular fashion and fixed to both Cooper's ligaments and to the xyphoid with 0 polydioxanone (PDS, Ethicon) (Figure 1, lower left). The hernia defect at the level of the lateral border of the rectus muscle and the medial border of external oblique, internal oblique and transversus abdominis muscles is closed with a running 0 polypropylene (Prolene, Ethicon) suture (Figure 1, lower right) Two 19-French drains are placed and a bilateral transversus abdominis plane block is performed by infiltrating ropivacaine and dexamethasone. The midline fascia is closed with a running 0 polypropylene (Prolene, Ethicon) suture and the skin is closed in three layers of 3-0 polyglecaprone (Monocryl, Ethicon) (Figure 2). Obesity was present in 32% of patients, and 21% were smokers. Hernias were recurrent in 47% of all patients. Average hernia size was 13 × 11 cm with mean loss of domain of 17%. Median postoperative follow-up was 13 months. Compared to our group of patients with midline incisional hernias treated with the same technique, patients with subcostal defects had a longer postoperative in-hospital stay (11 days vs 7

Figure 2 Pre and post-operative pictures of a patient with a left subcostal hernia treated with the TAR technique through a midline incision.

days; $p = 0.000006$), more postoperative local abdominal wall complications, such as seroma, haematoma, and wound infection (21% vs 4%, $p = 0.004$), and a higher recurrence rate (21% vs 4%; OR 6.13, CI 1.01–36.9; $p = 0.004$). Of note, taking into account exclusively the group of patients with subcostal hernias, postoperative recurrence rate was significantly higher in patients who developed immediate postoperative local abdominal wall complications compared to those patients who did not develop such complications (75% vs 7%; OR 42, 95% CI 2.01–877.5; $p = 0.01$). These outcomes allow us to confirm that subcostal hernias should be regarded as "complex". This sceneario represents an area of opportunity, where prevention may play an important beneficial role. This may be accomplished with the addition of a mesh in the closure of the initial procedure, and avoidance of excessive weight gain in patients undergoing surgical treatment of hepato-pancreto-biliary diseases. Also, surgeons need to weight the benefits of a subcostal incision with the risks posed when an incisional hernia is developed in such location. In this regard, a word of caution is proposed. Even when incisional hernias occur less often after the use of subcostal incisions than with midline incisions, subcostal hernias are *per se* complex defects and their repair is associated to a worse outcome, than that experienced by patients with midline defects.

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Antonio Espinosa-de-los-Monteros
Stephanie Hernandez-Camacho
Alberto Saldivar-Luna
Mariam Rela
Department of Plastic Surgery, Instituto Nacional de Ciencias Medicas y Nutricion "Salvador Zubiran", Vasco de Quiroga 15, Tlalpan, CP 14000, Mexico City, Mexico
E-mail address: aedlms@hotmail.com

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Are fasciocutaneous flaps adequate in the reconstruction of grade 3 and 4 sacral sores? - A retrospective volumetric study using artec 3D scanner

Dear Sir,

Introduction

Pressure ulcers are amongst the commonest challenges faced by reconstructive surgeons on a daily basis. Grade III and IV presacral pressure sores require reconstruction by fasciocutaneous,[1] musculocutaneous,[2] perforator flaps[3] and sometimes free tissue transfer. Very few options will remain if major flaps like musculocutaneous flaps are already utilized, in case the patient develops a recurrence. Numerous studies have debated the choice of fasciocutaneous versus musculocutaneous flaps but none have used any relevant objective methods to logically show the advantage of one method over another. Our aim is to use the 3D Artec scanner to quantitatively establish the adequacy of fasciocutaneous flaps for pressure sores of pre-sacral region.

Materials and methods

Ten paraplegic patients with pre-sacral pressure sores of grade III and IV were selected. The sores were sequelae of spinal cord injury or Potts spine with satisfactory general condition. All patients were subjected to an initial debridement followed by application of negative pressure wound therapy for around 10 days. The surgery was done under local anesthesia with proper precautions and anesthetist backup. Wound shape was converted to a rhomboid shape. 3D scanning using the Artec scanner with DICOM images in INVIVO 6.93, was carried out meticulously to measure the

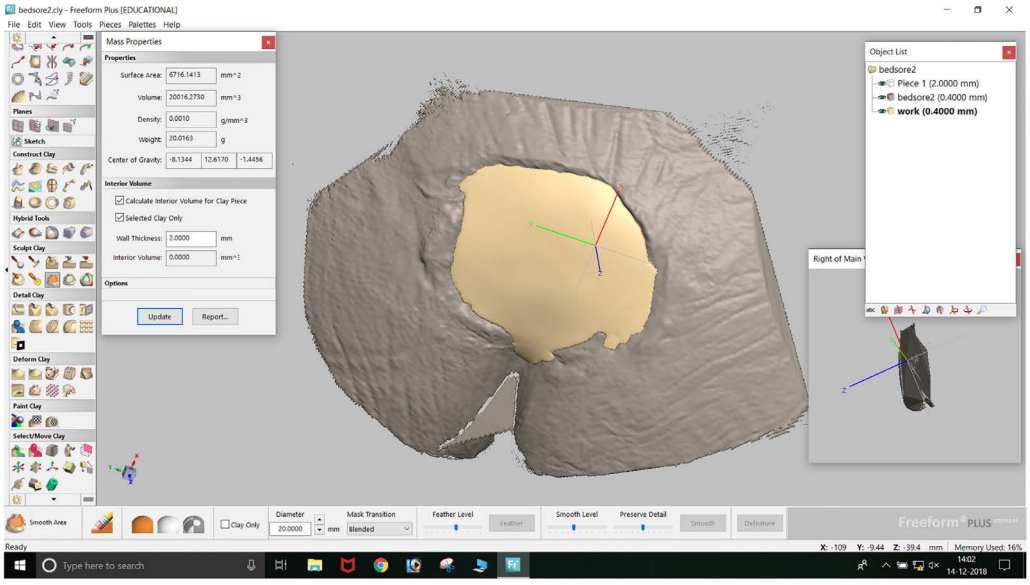

Figure 1 Wound defect volume assessment using Artec 3D scanner.

Table 1 Paired *T* test - wound depth and flap thickness (*t*-value is −0.13296, the *p* value is 0.447. The result is not significant at $p < 0.05$).

Wound depth (mm)	Flap thickness (mm)	Wound volume (mm^3)	Flap volume (mm^3)
13.62	15.39	20,016	19,772
11.82	17.02	28,785	41,447
26.55	16.57	235,663	147,559
12.76	11.32	26,434	23,781
10.69	12.54	59,759	70,008
25.17	21.2	15,530	130,903
12.5	14.2	3388	53,876
33.5	43.86	802,202	1050,893
11.58	12.22	28,455	30,077
16.24	15.34	23,444	22,785

Paired *T* test - defect volume and flap volume (*t*-value is −0.12978, the *p* value is 0.449. The result is not significant at $p < 0.05$).

defect size including area, depth at the centre and at the edge, and total volume. Then a local fasciocutaneous flap (Reading man/Rhomboid flap) planned and raised and scanning was repeated for the raised flap to measure the area, thickness at the base and the distal part and thence the volume was calculated based on an average of the depth measurements along with the calculated area. The age of patient, gender, size of the sore, primary pathology, any postoperative complication was documented along with the longest time of follow up. Paired *T* tests to compare the wound defect volume and the flap volume.

Results

At the end of 10th day of VAC, the sores measured on an average 58.25 cm^2 +/− SD 68.07 (14.43-239 cm^2). All patients underwent fasciocutaneous flaps with good postoperative results. The wound healed in all patients in 15 days. Average time taken for the reconstruction was 42.5 min +/− SD 8.24 min. (Table 1) The volumetric analysis (Figure 1), carried out showed that depth of the defect matched well with the fasciocutaneous flaps raised to resurface them. In addition, the volume of the flap was also adequate for the defect showing the adequacy of the flap. Paired T test comparing wound depth and Flap thickness showed *p* value of 0.449, which was insignificant proving that there was no significant difference between wound depth and flap thickness. Paired *t*-test comparing the defect volume and flap volume revealed a *p* value of 0.448, thus proving that there is no significant difference between their volumes. None of these patients developed wound dehiscence or recurrence of their sore in their average follow up of 15 months.

Discussion

Stage III or IV pressure sores/ulcers need surgical reconstructions. The reconstructive flaps, which are available for the management of pressure sores, can be fasciocutaneous,[1] musculocutaneous,[2] or perforator flaps.[3] Rarely free tissue transfers have been utilized.

The choice[4] of fasciocutaneous flaps and musculocutaneous flaps in reconstruction of pressure ulcer is always controversial. The sacral area and other such pressure points normally comprise of a bone, covered with fascia, subcutaneous tissue and skin, and hence it would be anatomically normal to use fasciocutaneous flaps to reconstruct the defects in these areas than musculocutaneous flaps.

We are in consensus with fasciocutaneous flaps and argue against the use of musculocutaneous flaps in the primary management of sacral sores. The points in favour are as follows.

1. Easy to elevate.
2. Associated with less blood loss.
3. Provides same durability of cover if not greater compared to the musculocutaneous flaps.
4. In addition, considering the high rate of recurrence, these flaps preserve the option of further muscle flaps in future.

Our study is novel as it has used volumetric analysis of defect and flap volume using the 3 D software[5] to establish that these defects are comparative in volume to the volume of the fasciocutaneous flaps used to resurface after analyzing the measurements. This has helped to support our argument of using fasciocutaneous flaps instead of the more tedious musculocutaneous flaps in reconstructing sacral defects in a more objective manner.

Conclusion

To sum up, this article presents yet another study to show that in pressure ulcer management, the reconstructive ladder concept must be respected. Whenever possible simple flaps must be utilized so that the more complex flaps are available for use in case of future complications such as recurrence which are so common in these patients, that too in a situation where the results of both flap options are equivocal.

Conflict of interest

None.

Funding

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Madhubari Vathulya*
Department of Burns and Plastic Surgery, All India Insititute of Medical Sciences, Rishikesh, Uttarakhand, India

Pankaj Kandwal
Department of Orthopaedics, All India Insititute of Medical Sciences, Rishikesh, Uttarakhand, India

Praveen A.J.
Department of Burns and Plastic Surgery, All India Insititute of Medical Sciences, Rishikesh, Uttarakhand, India

* Corresponding author.
E-mail addresses: madhubari@yahoo.co.in, madhubarivathulya079@gmail.com, pankajkandwal27@yahoo.com, viperpraveen@gmail.com

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Chest wall reconstruction following iatrogenic Eloesser-type wounds: The rush algorithm

Dear Sir,

Although myocutaneous flaps have been utilized in thoracic reconstruction for more than a century, there is no standardized method to reconstruct Eloesser wounds—a significant cosmetic and functional burden for patients.[1] The goals of chest wall reconstruction include restoring chest wall rigidity, preserving pulmonary mechanics, protecting intrathoracic organs, minimizing donor site morbidity, providing durable wound coverage, and temporizing overt thoracic deformity.[2] The investigators undertook a pilot series of three chest wall reconstruction procedures to describe the feasibility of a simple algorithm specifically for flap reconstruction of Eloesser-type wounds with excellent aesthetic and functional results.

The Rush Algorithm uses the reconstructive ladder in Eloesser wounds (Figure 1). The latissimus dorsi flap is utilized first due to its versatility. Its arc of rotation can also be improved with rib resection, provided chest wall stabil-

Elemental parts of this work were presented at: Rush University Medical Center, Division of Plastic and Reconstructive Surgery Grand Rounds, March 9, 2018.

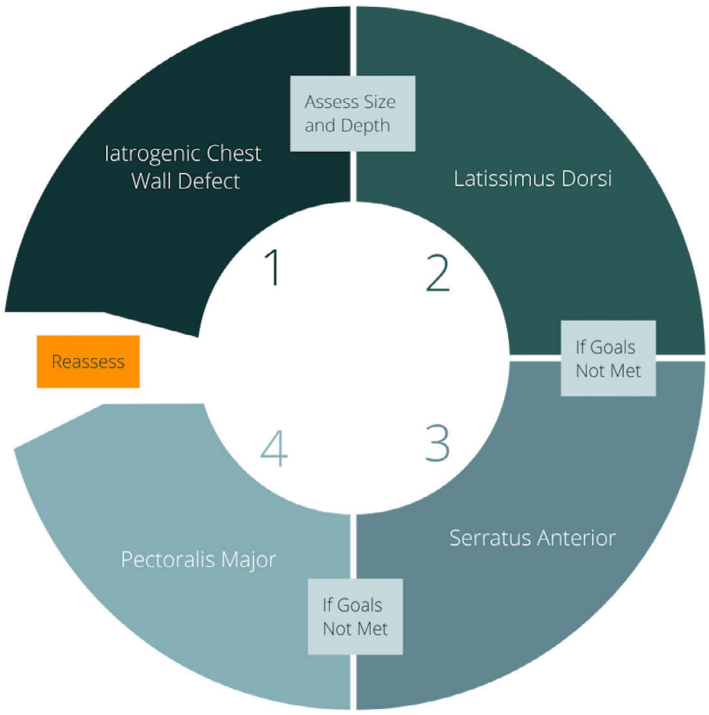

Figure 1 Graphic representation of the proposed Rush Chest Wall Reconstructive Algorithm for Eloesser flap defects.

ity is maintained. The serratus anterior is used second for additional soft tissue coverage and is elevated either as a separate flap or alongside the latissimus to ensure flap viability. If rib resection has resulted in an unacceptable chest wall contour or if thoracic dead space is still an issue, a pectoralis major flap is elevated third and rotated posteriorly. At the end of the operation, two thoracostomy tubes are placed, generally one apical and one along the diaphragm, to prevent fluid accumulation and to decrease thoracic potential space. Two additional drains are placed in the subcutaneous space.

Case 1 involved repairing a 62-year-old man's draining thoracic wound from a modified Eloesser flap used to control a Mycobacterium avium-*intracellulare* empyema. A latissimus flap was complemented with an overlying serratus flap and used to achieve closure of bronchopleural and thoracocutaneous fistulae. A residual chest wall defect was successfully obliterated with a pectoralis major flap (Figure 2). Case 2 involved a 50-year-old man with a chronically draining bronchopleural fistula due to a prior thoracotomy with decortication. A latissimus flap was used to close the bronchopleural fistula and a serratus flap then successfully obliterated the remaining thoracocutaneous fistula leaving no spatial defect. Case 3 involved a 70-year-old female with a chronic thoracocutaneous fistula following a right upper lobectomy via thoracotomy for lung malignancy. A latissimus flap was successful in closing her thoracocutaneous fistula and also fully obliterated the anatomical defect.

Post-operative physical exam in all cases demonstrated stability of chest wall dynamic movement with improved contour and complete resolution of thoracocutaneous fistulae. Follow up chest X-rays visualized persistence of intrathoracic muscle flap bulk and resolution of bronchopleural fistulae. Subjectively, patients reported increased quality of life, related to eliminating arduous dressing changes. No patients experienced major complications, defined as infection, seroma, hematoma, prolonged hospital stay, readmission, or return to operating room.

The latissimus dorsi, serratus anterior, and pectoralis major flaps have remarkable versatility and have been described with historical success in both chest wall reconstruction and in the closure of bronchopleural fistulae since the 1980s.[3] Strategically layering flaps in combination has been described in definitively closing large defects for decades.[4] The proposed algorithm builds on this history, providing a straightforward approach to deal with these defects that may be beneficial in optimizing outcomes, standardizing repairs, and simplifying reconstructive strategy. It presents a cumulative approach for using these pedicled myo[cutaneous] flaps and allows the surgeon to continually assess and treat three main facets of these wounds: defect size, depth, and intrathoracic/thoracocutaneous fistulae.

The latissimus flap is the first step and can theoretically cover the entire ipsilateral chest. Subscapular trunk and thoracodorsal arterial anatomy are the basis for choosing the latissimus as the initial flap. Retrograde blood flow via the serratus branch allows this flap to be used even with an injured thoracodorsal artery—potentially the case with an Eloesser wound. The linked nature of latissimus and serratus flaps through this bridging vasculature allows the serratus flap to work naturally as the second step flap, potentially completing reconstruction. The pectoralis major flap is the

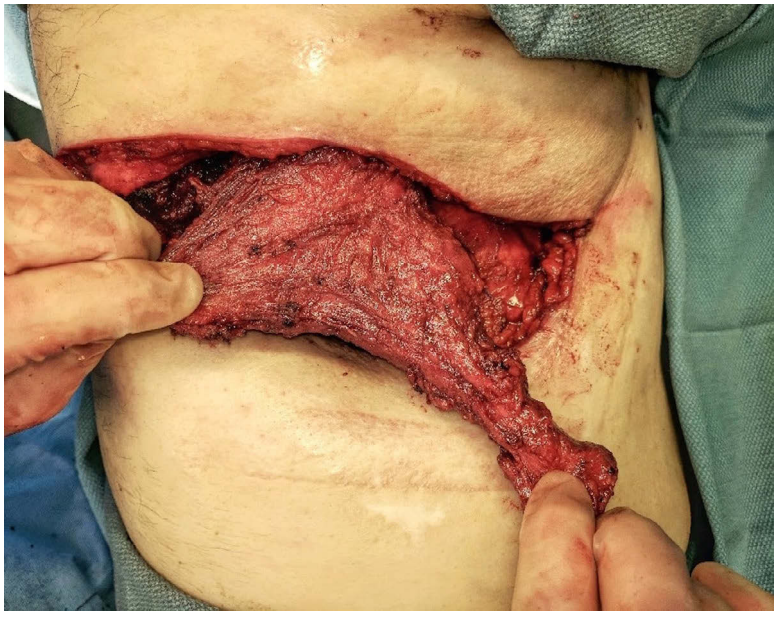

Figure 2 Intra-operative photo of the pectoralis flap used in Case 1 to help obliterate the residual spatial defect of an Eloesser wound iatrogenically created to control a refractory empyema.

third step (if needed) and can be used to definitively obliterate any residual fistulous or spatial defects. Reaching the Eloesser wound may involve releasing humeral attachments and creating a turnover pectoralis flap based on segmental blood supply via the internal mammary and intercostal perforator vessels.[5]

The Rush Chest Wall Reconstruction Algorithm is an easy step-wise approach for utilizing the latissimus dorsi, serratus anterior, and pectoralis major flaps for reconstruction of complex Eloesser-type chest wounds. It allows for continual intra-operative reassessment of the residual defect and adaption to individual patient needs. Excellent functional and aesthetic results were achieved in this pilot series. We believe it is a practical method and may be safely applied to these wounds. Additional studies are needed to confirm this, but its utility as a framework for surgical planning appears to be valid.

Conflict of interest

No authors listed on this manuscript submission have any financial or personal relationships with other people or organizations that might inappropriately influence their work.

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Aaron Lee Wiegmann
David A Hill
Thomas Q. Xu
Anuja K. Antony
Keith C. Hood
Department of Surgery, Division of Plastic and Reconstructive Surgery, Rush University Medical Center, 1625 W Harrison St, Chicago, IL 60612, United States
E-mail address: Aaron_L_Wiegmann@rush.edu

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Bringing the end-of-the-bed assessment to the multidisciplinary team in outpatient pre-tibial laceration management

Dear Sir,

Five in 1000 UK emergency department attendances are pre-tibial lacerations, in frail, older patients.[1,2] Hospital admission is expensive, with associated morbidity and dependence.[3] Mobilisation does not impede pre-tibial laceration healing, so community convalescence is encouraged.[1] For wounds deemed unlikely to heal within 4–6 weeks, due to non-viable tissue or their depth and area, surgery is facilitated by outreach nurses, reporting to a weekly, consultant-led multi-disciplinary team (MDT).[1] Local anaesthetic (LA) daycase or short stay admissions are organised ±− sedation, spinal, regional or general anaesthetics.

Patient assessment entails an outreach nurse-filled pro forma, performed in the community, with wound photographs.[2] Patients are usually co-morbid and polypharmaceutical,[1,3] therefore anaesthetically 'risky'. However, denying surgery to those who may benefit, through excessive attribution of risk, also carries morbidity. To the remote MDT, communicating the intuitive feel for the patient overall, is difficult. We aimed to establish whether an end-of-the-bed patient photograph could support the assessment of anaesthetic risk.

All pre-tibial laceration patients over the age of 70 (or with significant co-morbidities) were included, over eight months, with appropriate clinical governance permissions. They were assessed per protocol in the community, with an additional end-of-the-bed photograph taken for consenting patients. All patients requiring surgery with sedation, general, regional or spinal anaesthetic were identified, and their notes retrospectively reviewed. Their pre-operative information and wound photograph were shown to five anaesthetists, blinded to the patient's clinical outcome, who assigned the patient's fitness for surgery and their confidence in their accurate assessment on a Likert scale, Canadian Study of Health and Aging Clinical Frailty Scale score and ASA grade. They repeated this, having reviewed the end-of-the-bed image. Finally, they reviewed the anaesthetic records from surgery, and considered whether the end-of-the-bed photograph plus pro forma represented the patient during the admission. Paired students' t-tests were used, with $p < .05$ taken as significant.

Forty-six patients were identified; Twelve were excluded due to inaccessible/incomplete notes, and ten for lack of consent. Twenty-four patients were included, 83% female of average 82 years old (range 61–95), with five (2–8) co-morbidities taking 7 (2–16) medications. 30% had LA with sedation, 30% general, 26% regional, and 13% spinal anaesthetic. While in 33 (27% of) assessments, the anaesthetist upgraded the perceived perioperative risk after reviewing the photograph, the mean perceived perioperative risk was downgraded after seeing the end-of-the-bed photograph from 43.6 to 51.2 (where 0 is high and 100 is low risk, $p<.0001$). The anaesthetists felt more confident in their accurate assessment with the photograph (mean 67.9 to 77.0, where 0 is low and 100 is high confidence, $p < .0001$) though, in 9% of cases, they felt less confident in their assessment. There was no difference in clinical frailty scale ($p = .9048$) or ASA grade ($p = .4818$) with or without the photograph. The photograph plus other information was 72/100 representative of the patient compared to the anaesthetic documentation on admission, where 100 was 'very true'. The photograph was 76/100 where 100 was 'very helpful'.

Figure 1 Our patient's left pre-tibial wound at referral to our unit.

Case example

A 74-year-old woman sustained a left pre-tibial laceration after a mechanical fall. She was debrided to fascia at the referring hospital the following day, with antibiotics and tetanus cover (Figure 1).

She was haemophiliac (factor 12), with two previous transient ischaemic attacks, a shoulder replacement, trapeziectomy and recent *clostridium difficile* infection. She did not smoke or drink alcohol and took six medications, including aspirin. Reviewing her end-of-the-bed photograph (Figure 2) significantly reduced her perceived perioperative mortality risk (73 -> 84, $p = .0003$) with more confidence in the decision (67->84, $p = .002$), felt to be 78% representative of the patient on the day.

The cohort of patients who usually present with pre-tibial lacerations is "precariously balanced on the edge of rapid decline".[4] Surgical intervention is risky, and hospital admission is fraught with danger. Conversely, losing independence due to a chronic wound, which could be helped surgically, can be equally devastating.[2] Perceiving risks and benefit in decision making requires two parallel cognitive processes: *rationality* and *intuition*.[5] The word "intuition" comes from the Latin *intueri*: to gaze upon.[5] While it may reduce nosocomial risk and inconvenience, the problem with an outpatient system is the lack of clinical interaction for the MDT deciding whether or not to risk an operation.

We believe an end-of-the-bed patient photograph is a cheap, and effective way to bring intuition to the pre-

Figure 2 The end-of-the-bed photograph of at the referring hospital.

operative MDT. There was a statistically significant downgrading of the patient's anaesthetic risk when the end of the bed photograph was shown ($p<.0001$), with an increase in confidence in the decision ($p < .0001$), and a 75% correlation of the photograph and information to the patient on the day of surgery. This may make surgery more accessible to those who could benefit. That the ASA grade and clinical frailty scale did not significantly change may reflect limited room for manoeuvre in these grading systems.

This study was limited by its retrospective nature, and its reliance on the anaesthetic charts on the day accurately representing the clinical state of the patient. A standardised set of photographs needs to be developed. A randomised, prospective study is required to further delineate our promising findings.

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Conflict of interest

None.

Funding

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Lilli Cooper
Kirstie Forbes
Tania Cubison
Queen Victoria Hospital, East Grinstead, RH19 3DZ, United Kingdom
E-mail address: lillicooper@doctors.org.uk

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Donation to the university of bologna of the original gaspare tagliacozzi, "De curtorum chirurgia per insitionem"

Dear Sir,

Gaspare Tagliacozzi, universally considered a pioneer in reconstructive plastic surgery (the registered trademark logo of the American Board of Plastic Surgery depicts a portrait of Tagliacozzi), became a Professor of anatomy and

Figure 1 The wooden statue of Gaspare Tagliacozzi at the Archiginnasio.

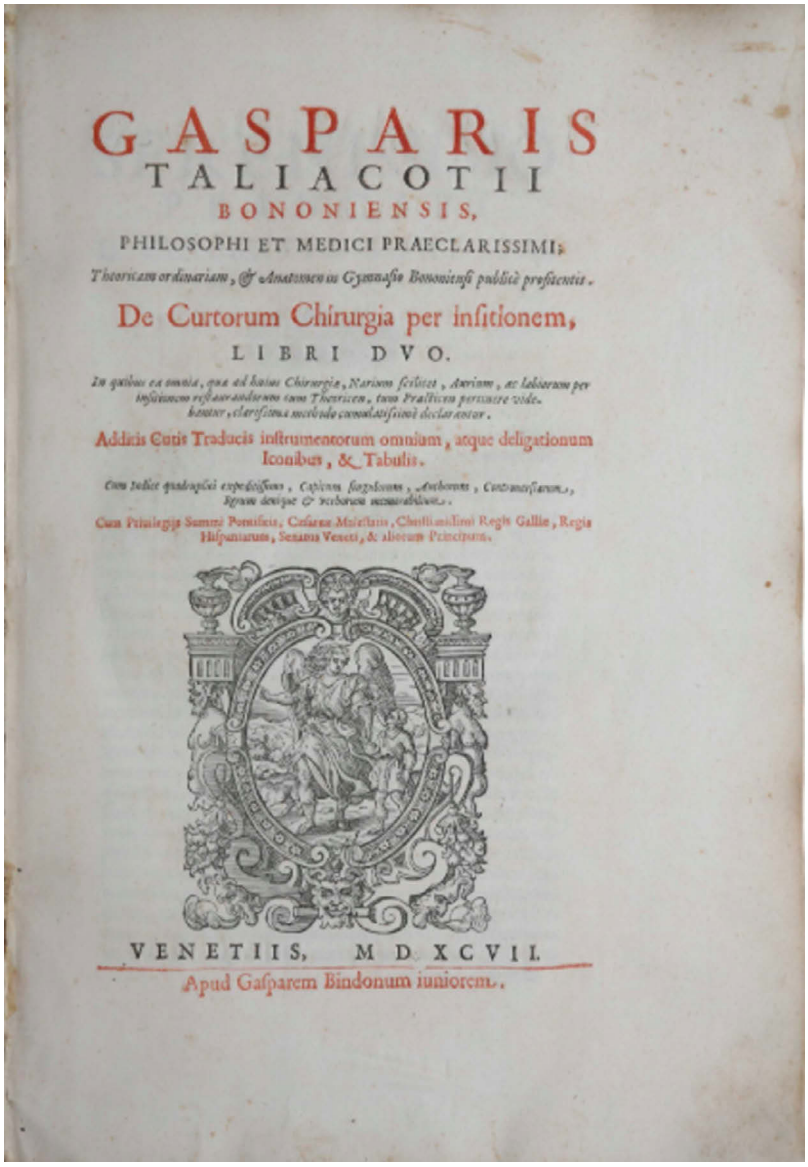
GASPARIS
TALIACOTII
BONONIENSIS,
PHILOSOPHI ET MEDICI PRAECLARISSIMI,
Theoricam ordinariam, & Anatomen in Gymnasio Bononiensi publicè profitentis.
De Curtorum Chirurgia per insitionem,
LIBRI DVO.
In quibus ea omnia, quæ ad hanc Chirurgiæ, Narium scilicet, Aurium, ac labiorum per insitionem restaurationem tum Theoricen, tum Practicen pertinere vide-
bantur, clarissima methodo copiosissimè declarantur.
Additis Cuius Tractatis instrumentorum omnium, atque deligationum Iconibus, & Tabulis.
Cum tribus quadruplici expeditissimis, Capitum sugillatorum, Authorum, Contractarum, Rerum denique & verborum memorabilium.
Cum Privilegijs Summi Pontificis, Cæsareæ Maiestatis, Christianissimi Regis Galliæ, Regis Hispaniarum, Senatus Veneti, & aliorum Principum.
VENETIIS, M D XCVII.
Apud Gasparem Bindonum iuniorem.

Figure 2 The engraved frontispiece of the first original edition of De curtorum chirurgia per insitionem.

surgery at Alma Mater Studiorum – University of Bologna from 1570.

The University of Bologna, with which Tagliacozzi professional life was intimately connected, was founded in 1088 by an organised guild of students (hence "studiorum"). It is the oldest university in the western world and, in the sixteenth century, was considered as the center of learning.

After he was appointed Professor of surgery and anatomy, Tagliacozzi taught at the Archiginnasio, the first unified seat of the University of Bologna famous for its anatomical theatre, where he procured the bodies of executed prisoners to use in dissections.[1]

Tagliacozzi conducted a long series of precise observations on the basis of which he formulated exact and detailed precepts for performance of rhinoplasty as well as various reconstructive operations on the ears and lips. Rhinoplasty was much in demand in the sixteenth century and later, both as a remedy for the grotesque deformity of saddle nose caused by syphilis, and for injuries resulting from duels.

Gaspare Tagliacozzi described his innovative surgical technique in the work that made him famous, "*De curtorum chirurgia per insitionem* (On the Surgery of Mutilations by Grafting).

The volume is divided into two parts: the first, "Theory of the art of plastic surgery," is about the structure, function, and physiology of the nose. The second part, "Practice of the art," describes and illustrates the instruments and operative procedures for restoration of the nose, lip, and ear. Tagliacozzi also fully discussed the complications, such as hemorrhage and gangrene, that often occurred during these operations.[2]

The University of Bologna held his work in such high esteem that they erected a statue to him, holding a nose, in the historical anatomical theatre in 1640 (Figure 1).

The first original edition of *De curtorum chirurgia per insitionem* published by Gaspare Bindoni the Younger in 1597 in Venice[3] (Figure 2) was donated, in the presence of the Magnifico Rettore (rector), to the University Library of Bologna on 18 june 2019. By appointment the treatise may be available for consultation to researchers, students and external visitors.

Through this donation, the profound bond between the University of Bologna and the pioneer of the modern plastic and reconstructive surgery, has been definitively strengthened.

Funding

None.

Declaration of Competing Interest

None declared.

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Ottavio Piccin
Department of Otolaryngology Head and Neck Surgery, S.Orsola-Malpighi University Hospital, Italy

Rossella Sgarzani
Department of Emergency, Burn Center, Bufalini Hospital, Azienda USL della Romagna, Cesena, Italy

Paolo G. Morselli
Department of Plastic and Reconstructive Surgery, Alma Mater Studiorum University of Bologna, via Massarenti 9, 40138 Bologna-Italy

Correspondence to: Ottavio Piccin, Department of Otolaryngology Head and Neck Surgery, S.Orsola-Malpighi University Hospital, Via Massarenti 9, 40138 Bologna Italy.
E-mail address: ottavio.piccin2@unibo.it

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Response: Augmented reality microsurgical planning with a smartphone (ARM-PS): A dissection route map in your pocket

Dear Sir,

With great interest we have read the work by Pereira et al.[1] We would like to congratulate the authors on embracing emerging technologies such as Augmented Reality (AR) and incorporating this into medical practice. The authors describe a method of using an smartphone app which loads a specified image and captures a live stream via the smartphone camera. The anatomical image and camera stream are merged semi-transparently and displayed onto the smartphone screen. However, as can be viewed from the author's supplementary video and from the app developers' demonstration video, the image is not automatically aligned to landmarks on the patient. The smartphone needs to be held stationary at a specified height and angle while drawing with a marker pen onto the patient's skin, or the patient's markings would be incorrect. Furthermore, the 3D reconstruction loaded into the AR-app is processed to display all anatomy between a certain radiodensity (Hounsfield scale), which could lead to over- or under segmenting of anatomical information. The operating surgeon would be unaware of e.g. small branching vessels or lymph nodes, as relevant anatomical information may not be presented in full.

In our hospital, we have been utilizing the VitreaAdvanced fX (Canon, Minnetonka, USA) workstation for the last five years to indicate the most favorable perforators, arteries and veins, flap size and lymph nodes to be segmented into a 3D planning.[2-4] In our endeavor to integrate digital health into clinical practice, we have developed a handheld projection device which automatically aligns and projects a 3D planning onto the human skin. Via means of laser projections we are able to visualize key anatomical structures at their anatomical correct location. This workflow does not require the usage for as smartphone screen or augmented reality glasses which interrupt the surgeon during the procedure. Furthermore, in our 3D planning, we only display relevant anatomical features for the surgeon. By pre-operatively determining the most favorable perforators and their trajectory, we found a significant time difference of 19 min during DIEP flap harvest.[5] Given the positive results in our clinic using this innovation, we have modernized our practice by incorporating the creation and projection of a 3D planning for all breast reconstruction procedures.

Technology is ever improving and being weaved more into our daily lives. Researching and combining techniques such as Augmented Reality, 3D photogrammetry, 3D printing, etc. will lead to procedure refinement we cannot yet imagine; transforming the field of plastic surgery and its medical procedures forever. We encourage all colleagues to adapt and investigate innovative techniques aimed to improve patient outcome.

Conflict of interest

N/A

Funding

N/A

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.bjps.2019.06.015.

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Stefan Hummelink*
Dietmar J.O. Ulrich
Department of Plastic Surgery, Radboudumc, Nijmegen, the Netherlands

*Correspondence to: Stefan Hummelink, Department of Plastic Surgery (hp 634), Radboud university medical center, P.O. Box 9101, 6500 HB Nijmegen, the Netherlands.
E-mail address: Stefan.Hummelink@radboudumc.nl

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Letter comments on Patient satisfaction after levator aponeurosis surgery for the treatment of involutional blepharoptosis

Dear Sir,

We read with great interest the article titled "Patient satisfaction after levator aponeurosis surgery for the treatment of involutional blepharoptosis" by Sato.[1] The authors retrospectively review patients' satisfaction rate after transcutaneous levator aponeurosis surgery for bilateral involutional blepharoptosis, concluding that, to reduce dissatisfaction rate, revision surgeries should be reduced. We congratulate with the authors for their original investigation because patients' satisfaction is a significative item to evaluate the efficacy of every surgical procedures, but we have some element to discuss. Blepharoptosis correction is a very complex procedure suffering from very sensitive aspects. The analysis of its outcomes should include objective parameters to support or advocate patients' considerations as: upper margin reflex index (uMRD), interlid uMRD difference, interlid crease difference and interlid show difference. In particular, uMRD represents the distance from the central corneal light reflection to the upper lid margin, the interlid uMRD difference represents the difference between the postoperative uMRD between the two eyes; interlid crease difference represents the postoperative difference between left and right eyelid show, which is defined as the distance between the upper lid margin and the upper lid fold; interlid show difference represents the postoperative difference in the gap between the upper and lower palpebral rim between the eyes.[2,3] In the paper authors reported asymmetry as the most common reason for complains. Since asymmetry is a very sensitive item influenced by several factors, its analysis should consider objective measurements of its real entity. To avoid bias and consequently unnecessary surgical revision, its scoring in different grade is strictly mandatory to compare surgical outcomes and perception of outcomes by the patients. Although revision surgery is inevitable, 26.3% of reoperation rate could be carefully considered. We retain that an objective quantification is strictly mandatory during preoperative planning. Intraoperative surgeon visual assessment, suffering from several factors among which edema, patient compliance, tumescent anesthesia that might strongly interfere with an effective clinical consideration, should be clearly taken into account but it could not be retained, as stated in the authors' paper, one of the main factors.

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None.

Ethical approval

All the procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and National Research Committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Conflict of interest

None.

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Alessandro Innocenti
Plastic and Reconstructive Microsurgery, Careggi University Hospital, Florence, Italy
E-mail address: innocentialessandro@alice.it

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