MicroSUCI: A Microsurgical Background That Incorporates Suction Under Continuous Irrigation

Theodora Papavasiliou, MD[1]   Stelios Chatzimichail, PhD[1]

Ankur Khajuria, MBBS (Hons), BSc (Hons), FHEA, FRSPH, MRCS (Eng), MAcadMEd, MFSTEd, MSc, PhD[2,3]

Joon-Pio Hong, MD, PhD, MBA[4]

[1] Research and Development Lab, Stelth, Larnaca, Cyprus
[2] Department of Surgery and Cancer, Imperial College London, White City Campus, London, United Kingdom
[3] Kellogg College, University of Oxford, Oxford, United Kingdom
[4] Department of Plastic and Reconstructive Surgery at Asan Medical Center, University of Ulsan, College of Medicine, Seoul, South Korea

Address for correspondence Theodora Papavasiliou, MD, Research and Development Lab, Stelth Ermou St, Larnaca 6020, Cyprus (e-mail: Theodora.papavasiliou@nhs.net).

Abstract

The microsurgical anastomosis is integral to the success of autologous-free tissue transfer. Successful performance of this procedure relies strongly on operator dexterity, which can be made more challenging when blood and edematous fluids obscure the field of view. Workflow is impeded by intermittent irrigation and suctioning, necessitating presence of an assistant, with risk of arterial thrombosis, from vessels being drawn into suction drains. To negate these current disadvantages and minimize the barrier of entry to microvascular operations, we designed, manufactured, and patented a novel three-dimensional printed microsurgical background device with microfluidic capabilities that allow continuous suction and irrigation as well as provide platforms that enable multiangle retraction to facilitate operator autonomy. This was validated in an ex vivo model, with the device found to be superior to the current standard. We believe that this will have major applicability to the improvement of microsurgeon

Keywords

► microsurgical
► innovation
► 3D printing
► background

Introduction

In autologous-free tissue transfer, the anastomosis step poses a high-dexterity/high-difficulty task and is integral for the success of the free flap operation. Part of this is attributed to the numerous factors that need to be optimized so that the lead surgeon can obtain a clear operating view during the operation. For optimal view of the vessels and perfect layer approximation to be achieved,[1,2] the field must be consistently irrigated to provide an ideal environment for the vessels. Currently, the assistant is required to provide suction and the contrast between the vessel and its surroundings needs to be enhanced.[3] An addition to the microsurgeon's repertoire has been the use of microvascular background sheets that provide adequate contrast of the vessel relative to its surroundings during the anastomosis technique and has been found to improve the accuracy of vessel alignment.[4]

Nambi et al provided an in-house and cost-efficient solution to alleviate some of the technical burden of the anastomosis operation by providing continuous suctioning during microvascular anastomosis with the use of a pediatric
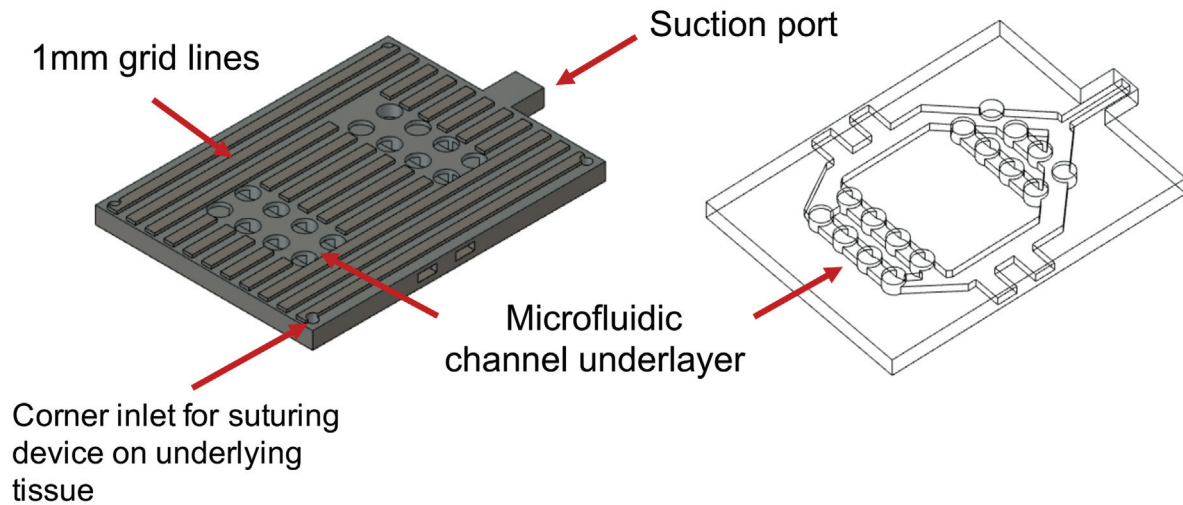
Fig. 1 Illustration of the three-dimensional printed device including the in-build microfluidic mechanism.

feeding tube covered in a gauze layer.[5] This solved the suctioning issue, although the gauze itself did not allow for contrast improvement during operation. Indeed, in-house constructs and methods from readily available tools often found in operating theater settings have been since conceived to facilitate a smoother anastomosis process.[6–9] Kiuchi et al characterized the optimal color hue that a microsurgical background owed to exhibit. For operations described in our work (arterial and venous anastomoses), this lies in the blue-green spectrum of visible light.[3] As of now a simple device able to combine those two elements while also alleviating the technical burden of the operation has not been described.

Recent developments in additive manufacturing have rendered three-dimensional (3D) printing both a great and more accessible tool for rapid prototyping. This has, predictably, led to the adoption of the technology to the development of surgical instruments and models.[10] In this study, we demonstrate the development of a novel 3D printed continuous suctioning and irrigation background device that assists the microvascular anastomosis task and improves the autonomy of the leading surgeon. To minimize any changes to the existing operation workflow of the procedure, a microfluidic underlayer has been incorporated to the background sheet and, in essence, imbues the background device with irrigation and suctioning capabilities. We provide evidence of successful application of the device in ex vivo models and demonstrate that the device's capabilities can improve the overall efficiency of the procedure.

Idea

Device Production

All microvascular background devices (dimensions 3cmx2cm) were designed using open-source CAD software (Blender), converted to machine tool code using Ultmaker's Cura slicer software and printed on an Ender 5 FDM 3D printer (Creality, Shenzhen, China) using a flexible thermoplastic filament (1.75 mm thermoplastic elastomer [TPE] filament, eSUN, Shenzen, China; ►**Fig. 1**). This material has been found to conserve its mechanical properties after autoclave sterilization[11] and provide enough contrast on X-ray films to identify its location if required (►**Fig. 2**). All prints were produced using a 0.4-mm-diameter brass nozzle head. The dimensions of the device can be reconfigured based on the surgeon's demand and therefore the super-microsurgery backgrounds were produced using a 0.2-mm-diameter nozzle head.

Trainee Validation Study

Trainees of equal stage in their training were tasked to perform the anastomosis technique in the chicken femoral artery model using commercial backgrounds (Mercian, United Kingdom) as well as the novel devices described in this
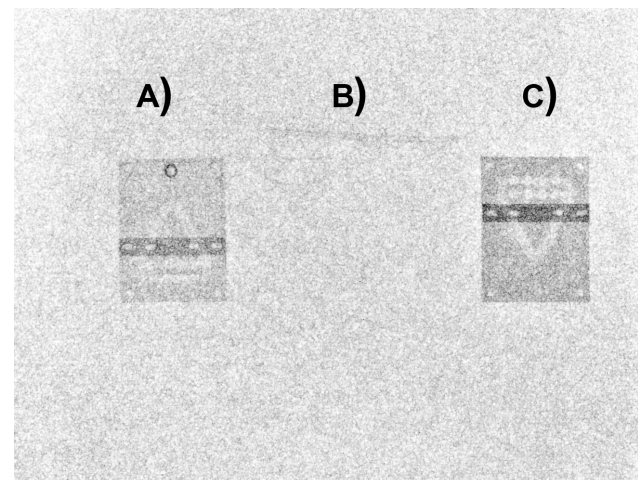

Fig. 2 Radiological comparison of the device in (**A**) thermoplastic elastomer filament and (**B**) polylactic acid filament and compared with a clear polypropylene sheet. (**C**) Increased absorbance in areas of higher thickness observed as predicted by the Beer–Lambert law ($A = \varepsilon lc$).

Table 1 Metrics: Modified University of Western Ontario microsurgical skills acquisition/assessment instrument (UWOMSA)

Tasks	Scoring (1–5)
Clarity of surgical field	See ►Table 2
Duration to complete task	1: >25 minutes 3: 15–25 minutes 5: <15 minutes
Preparation: Clamp placement	1: Ends set up poorly in clamps, 5: clamps applied correctly
Preparation: Dilatation	1: Forgets dilatation, 3: rough dilatation, 5: gentle dilatation
Suturing: Needle placement	1: Inaccurate needle placement3: Inconsistent needle placement, 5: accurate needle placement
Suturing: Needle passage	1: Pulls needle through roughly, 3: rough/inconsistent needle passage, 5: takes needle out on curve
Suturing: Knot tying	1: Drops suture end/inefficient knot tying, 3: knot tying loose/tight/inefficient, 5: efficient tying
Suturing: Lumen check	1: Does not look inside lumen5: Always checks inside lumen
Suturing: Movement	1: Too much movement at anastomosis with tying; 5: anastomosis stays still with tying
Final product: Outer appearance	1: Rough outer appearance, 3: outer appearance inconsistent/partially inverted, 5: smooth outer appearance
Final product: Back wall stitch	1: Back wall stitch, 3: possible back wall stitch, 5: no back wall stitch
Final product: Patency	1: Nonpatent; 5: Patent
Final product: Suture ends	1: Suture ends intraluminal, 3: some suture ends intraluminal, 5: all suture ends extraluminal
Final product: Suture spacing	1: Poor suture spacing, 3: suture spacing inconsistent, 5:appropriate suture spacing
Total scoring	Max 70 points

work. The performance of the trainees performing the anastomosis task was evaluated by two senior microsurgeons of our departments with key evaluation metrics being field clarity during performance of the technique, duration to perform the task, and quality of the repair (►Table 1). To better emulate real-world settings, the irrigation solution infused during the operation as well as to test the repair was a saline solution mixed with red food dye.

We have applied the device during the microsurgical anastomosis in 10 ex vivo chicken thigh models ($n = 10$) and evaluated the performance of the device based on a Modified University of Western Ontario microsurgical skills acquisition/assessment instrument (►Tables 1–2). The mean score when the device was used was 61.15/70 (87.36%)

compared with 47.75/70 (68.21%) when the traditional background was used proving there is significant difference between the use of the two devices in the majority of all tasks ($p < 0.01$; ►Table 3). Specifically, when measuring the operator's performance in terms of duration, the average score of trainees improved from 2.2/5 for the traditional background device to ⅘ when our device was used. We attributed this to the increased autonomy of suctioning provided by our device. The same effect was noted when comparing the clarity of field scoring which improved from ⅕ to 5/5 when our device was used. For the domains at which the participant results rejected the null hypothesis, we found that in all cases the power analysis suggested that a sample size of 10 was adequate to prove statistical significance at the

Table 2 Breakdown of surgical field clarity scale (1–5)

Score	Scale of surgical field clarity
5	Surgical field clear: the suctioning provided by the device is keeping up with the fluids collected in the anastomosis field
4	Mild surgical field impairment: operator able to continue with the task of anastomosis without the need to suction further than the capabilities of the device
3	Moderate surgical field impairment: toward the end of the anastomosis the field was not kept clear by the capabilities of the device, the operator needed to perform suction 1–3 times
2	Moderate surgical field impairment: toward the end of the anastomosis the field was not kept clear by the capabilities of the device, the operator needed to perform suction more than 3 times
1	Severe impairment of the surgical field view: the operator needs to intervene and perform suction as the device could not keep up with this task from the beginning of the anastomosis

Table 3 Average score per metric using the current background and our device

Task	Current background—average score assessor 1	Current background—average score assessor 2	MicroSUCI—average score assessor 1	MicroSUCI—average score assessor 2	*p*-Value
Clarity of surgical field	1	1	5	5	<0.01
Duration to complete task	2.1	2.3	4	4	<0.01
Preparation: Clamp placement	4	4.3	4.1	4.3	
Preparation: Dilatation	3.5	4	3.6	4.1	
Suturing: Needle placement	3	3.4	4.5	4.6	<0.01
Suturing: Needle passage	3	3.3	4	4.2	<0.01
Suturing: Knot tying	4	4.1	4.5	4.6	
Suturing: Lumen check	3	3	4.6	4.5	<0.01
Suturing: Movement	4	4.1	4.3	4.2	
Final product: Outer appearance	4	4	4.3	4.3	
Final product: Back wall stitch	3	3.2	4.5	4.5	<0.01
Final product: Patency	4.5	4.5	4.8	4.8	
Final product: suture ends	3.7	3.5	4	4	
Final product: suture spacing	4	4	4.5	4.5	<0.01
Total score	46.8/70	48.7/70	60.7/70	61.6/70	

Abbreviation: microSUCI, microsuction under continuous irrigation.

0.01 threshold. For instance, in the case of field clarity, power analysis suggested a minimum sample size of 2.34 would be sufficient and for the duration to complete the anastomosis power analysis suggested that 4.72 participants would be adequate.

Discussion

It is important to perform the anastomosis technique without interruption. To that end, a system able to provide continuous suction while also aiding in retraction is very appealing,[12] which is why we have designed a flexible microvascular background with an in-build microfluidic underlayer that allows for continuous suctioning while anastomosis is performed (►**Fig. 1**, ►**Video 1**). The design included a 1 mm spacing ruler and a parking spot for the needle to rest in between tying of each knot and to avoid being dragged into the suctioning mechanism (►**Figs. 1** and **3**). For microsurgical operations, the ideal color for a microvascular background has been found to be in the blue-green spectrum and the TPE material of choice is flexible to allow for easy placement around the vessels to be repaired.[4] The device was attached to the traditional operating room suction machine via a 3mm tube under low pressure. Variations in the device were also produced to allow for minimal tissue handling by incorporating a threaded pole on which the suture was trapped and therefore provided upwards retraction at 12 o'clock. This allowed the lead surgeon to better visualize the two lumens without the need to manipulate the tissue. This microsurgical anastomosis technique can be seen in the electronic supplementary information

(►**Video 2**). We found applicability of this version for the early learning stage trainees.

Video 1

The continuous irrigation and suctioning mechanism of our three-dimensional printed microfluidic background device. Online content including video sequences viewable at: https://www.thieme-connect.com/products/ejournals/html/10.1055/a-1987-3338.
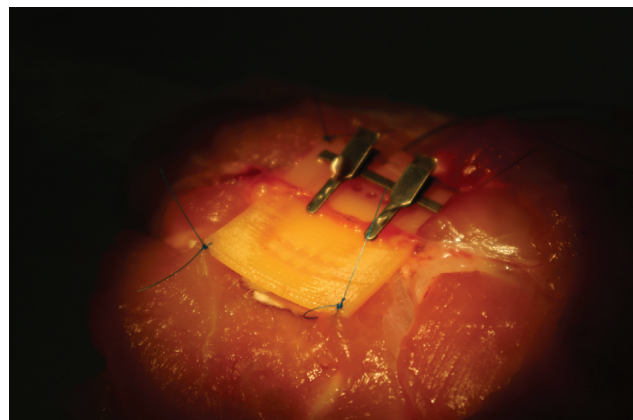

Fig. 3 Apparatus for microsurgical anastomosis simulation setup: our three-dimensional printed background device in ex vivo chicken thigh model.

Video 2

The end-to-end anastomosis performed using our three-dimensional printed microfluidic background device in the ex vivo chicken thigh model. Online content including video sequences viewable at: https://www.thieme-connect.com/products/ejournals/html/10.1055/a-1987-3338.

We have applied the device on ex vivo chicken thigh models and compared this with the traditional background in a controlled prospective study. We found that there was significant difference between the performance of the residents on the two devices ($p < 0.01$). Future work from our team is evaluating the device utility in an animal model, with subsequent first in-human application.

We designed and produced a 3D printed microvascular background device that incorporates continuous and autonomous irrigation and suctioning due to its in-build microfluidic mechanism. The device has been applied in ex vivo models and its usefulness was validated by senior microsurgeons. Creative applications of 3D printing can reinforce the current surgical instrumentation palette, as we have shown in this study, and allow the quick adoption of an idea into practice.

Authors' Contributions
TP wrote the first draft of the manuscript. All authors reviewed and edited the manuscript and approved the final version of the manuscript.

Conflict of Interest
All four authors are stakeholders in a patent (ref P68111GB) filed for the device described in this article.

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