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3D Printed Microvascular Clamps: A safe, cheap and effective instrumentation for microsurgery training.

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Summary:

Microsurgical training involves practice in *ex-vivo* models during the early learning curve and poor instrument handling by the inexperienced microsurgeons can cause damage to microsurgical instrumentation or clamps which is particularly costly. To address this, we demonstrate the development, design, manufacturing and application of three different types of 3D printed microvascular clamps in an ex-vivo simulation training model. This report provides evidence of a low cost and easily accessible device that facilitates the process of microsurgical training. The clamps were found to provide advantages akin to normal stainless-steel microvascular clamps in training setting.

Level of evidence: V

Keywords

3D printing, microsurgery training, microvascular clamps, double clamps, innovation

Manuscript

Introduction

In microsurgery, the anastomosis is an integral surgical task to the success of a free flap. This step requires precision and dexterity that can only be acquired through deliberate practice and experience accumulation over a structured microsurgical training curriculum. Traditional curriculum involves simulation practice on the living rat training model. Though, recent ethical concerns in regards to the use of animals in research and the introduction of the 3Rs (Replacement, Reduction, Refinement) framework have shifted the barycentre of current microsurgery curriculums towards non-living models. This is especially true during the early stages of the learning curve, with hybrid approaches typically introduced in a step-ladder type training employing a combination of *ex-vivo* and *in-vivo* models. [1,2,3,4]

The minimum requirements for a basic 5-days microsurgical training course, based on International Microsurgery Simulation Society (IMSS) guidelines, is to have one microscope per trainee and instruments including two forceps (one curved), curved needle holder, microsurgical scissors, vessel dilator, 9/0 and 10/0 sutures and at least two microvascular clamps.[5] This equipment is proven to be costly especially in developing countries and during the early stages in skills acquisition can sustain damage from the interaction of untrained hands of inexperienced microsurgeons.[6] Permanent instrument damage may arise from excessive application of pressure during tissue manipulation or inappropriate use overpowering the instrument's capabilities resulting to the premature disposal of the unit. [7]

Recent developments in additive manufacturing have rendered 3D printing technologies very accessible in terms of price and functionality to institutions and individuals alike. The flexibility in design and material variety afforded by these technologies is particularly attractive for the development of surgical instrumentation, both for low-cost prototyping as well as when customised patient-precise dimensions are required.[8,9] Here, we demonstrate a 3D design and method for the production of three types of microvascular clamps which can be used by microsurgeons in training. In addition to bridging issues associated with disparity in availability and design, we show that the low-cost of production afforded by 3D printing can reduce the long term running costs of microsurgical training labs.

Device production

All microvascular clamps were designed using Autodesk's Fusion 360 software, converted to machine tool code using Ultmaker's Cura slicer and printed on an Ender 5 FDM 3-D printer (Creality, Shenzhen China) using poly-lactic acid filament (PLA 1.75 mm filament, RS-UK). This material was chosen as it proved to have sufficient tensile strength while maintaining the necessary elastic properties required for the application. Crucially this material has been found to conserve its mechanical properties after autoclave sterilization.[8] All prints were produced using a 0.4 mm diameter brass nozzle head, with the exception of supermicrosurgery clamps which were produced using a 0.2 mm diameter brass nozzle head.

Discussion

The first vascular clamp was developed by Edmund Höpfner in 1903.[10] As vascular anastomosis operations started being applied to more refined operations, so did the need for new instruments leading to Acland's first description of the microvascular clamp in 1970.[11] Microvascular clamp assemblies often include the clamp jaws and handles connected to a torsional spring, so as to produce a clamping force that is proportional to the elastic coefficient and the contraction of the spring.[12] The vessel resists the applied pressure due to the intravascular blood pressure and the resistance of the vessel against deformation. Therefore, a successful clamp ought to provide a sufficient clamping force to impede blood flow, while also being delicate enough to prevent any damage to the vessel.

For microsurgical operations, clamps ought to be in the millimetre range in order to be practical with respect to accessibility to the operating field. Given the dimension restrictions, alternative compression mechanisms to torsional springs are often sought after. Several manufacturers of microsurgical clamps provide single-piece stainless steel devices whose V-shaped design take advantage of the innate elasticity of the material.

Single-material designs are particularly suited for 3D printing as the device can be produced directly without further assembly and used directly off the build plate. Given Fusion Deposition Modelling (FDM) compatible materials offer less elastic compressibility to metal analogues, we modified the traditional V-shape design to a parabolic analogue (Figure 1) to increase the clamp jaw travel distance, whilst providing the necessary clamping force required for blood vessel occlusion. We defined the device's adequacy criterion as being able to induce vessel occlusion. (Supplementary Video 1, 2).

A set of medium double clamps including the rail can be printed in 5 minutes at a material cost of 0.01 GBP/0.013 USD. Given a relatively medium performance printer such as the one we used in this study costs in the range of 300 GBP/379 USD, an estimated turn-around period to initial equipment investment could be foreseen within the same timescale it would take to accumulate 4 S&T double-clamp (average price estimated based on quotes received from three UK suppliers) replacements for a microsurgical training lab. The reusability of the clamps was tested and found to be adequate for 25 repetition tests after use in silastic vessels and also in biological *ex-vivo* models (i.e. chicken thigh). The 3D printed clamps demonstrated occlusion capabilities akin to commercial analogues in a range of vessels varying between 0.8 - 2.4 mm in diameter. (Video supplementary 2).

To show the applicability afforded by this technology we designed and produced three types of simulation clamps in all six basic sizes (XXS-XL) as can be seen in Figures 2. We found our 3D printer model to be able to produce operating clamps with dimensions as small as 5 mm in length. The extra small size clamps could potentially be used in the innovative novel applications of supermicrosurgery such as lymphovenous anastomosis (LVA) and perforator flaps surgery. [13] The types designed included single, double and gamma clamps. In order to introduce our trainees to a wider range of anastomosis technique options for end to side anastomosis, we designed an adaptation to the original gamma (Γ) clamp rail format described by Baek et al. in 1980 which is currently not available by commercial vendors. [14] The gamma rail clamp employs a third clamp and a rail positioned in a direction orthogonal to the main vessel flow direction. This setting allows fine tuning of the approximation of the side vessel to the main branch and alleviates the need for surgical assistance during end to side anastomosis.

Conclusion

We designed and produced 3D printed microvascular clamps for use in training. The clamps are reusable, able to sustain multiple applications and were proven effective in ex-vivo models during microvascular anastomosis training. Traditional stainless-steel instrumentation remains the gold standard in training and practice. Nonetheless, our experience demonstrated that 3D printing can find itself in the corner of microsurgical labs as it has the ability to reduce long-term costs, especially in low-fidelity tasks training, and allow the rapid adoption of advances in instrumentation. We demonstrated the latter by restoring the designs of the commercially unavailable gamma rail clamp. This example showcased how creative applications of 3D printing can reinforce the training opportunities of trainees and may prove to facilitate the quick adoption of state-of-the-art instruments described in the literature directly to the microsurgical lab.

References:

1) Guerreschi P, Qassemyar A, Thevenet J, Hubert T, Fontaine C, Duquennoy-Martinot V Reducing the number of animals used for microsurgery training programs by using a task-trainer simulator. Laboratory animals. 2013; 48(1): 72-77

2) Kim E, Norman ICF, Myers S, Singh M, Ghanem A. The end game - A quantitative assessment tool for anastomosis in simulated microsurgery. J Plast Reconstr Aesthet Surg. 2020.

3) Onoda S, Kimata Y, Sugiyama N, Tokuyama E, Matsumoto K, Ota T, Thuzar M. Analysis of 10-Year Training Results of Medical Students Using the Microvascular Research Center Training Program. J Reconstr Microsurg. 2016; 32(5):336-41.

4) Olijnyk LD, Patel K, Brandão MR, de Morais ANL, de Carvalho RF, Severino AG, Mayor D, da Silva CE, Stefani MA. The Role of Low-Cost Microsurgical Training Models and Experience with Exercises Based on a Bovine Heart. World Neurosurg. 2019; 130:59-64.

5) Ghanem A, Kearns M, Ballestín A, Froschauer S, Akelina Y, Shurey S, Legagneux J, Ramachandran S, Cozzolino S, Ramakrishnan V, Pafitanis G, Zakaria Y, Al-Maaytah K, Komatsu S, Kimata Y, Cifuentes I, Soucacos PN, Tos P, Myers S. International microsurgery simulation society (IMSS) consensus statement on the minimum standards for a basic microsurgery course, requirements for a microsurgical anastomosis global rating scale and minimum thresholds for training. Injury. 2020; S0020-1383(20)30078-4.

(6) Chihena H.B, Pafitanis G, Mitsunaga N, Ryohei I, Minami F, Jovic G. Challenges in global reconstructive microsurgery: The sub-Saharan African Surgeon's perspective. JPRAS GO. 2019; 20;19-26.

7) Acland R. Notes on the care, restoration and repair of microsurgical instruments. Indian Journal of Plastic Surgery. 2006; 39:1

8) Alshomer F, Alhazmi B, Alowais F, Aldekhayel S. A Low-Cost 3D-Printed Tool with Multiaxial/Angular Vessel Orientation for Microvascular Anastomosis Training. Plast Reconstr Surg Glob Open. 2020; 11;8(2):e2567.

9) Papavasiliou T, Lipede C, Chatzimichail S, Sivakumar B. Development of a customized 3D printed paediatric hand retractor for patient-precise dimensions and enhanced surgical autonomy. Journal of Hand Surgery: European Volume, 2020: Online publication 21/5/20

10) Sachs M. History of surgical instruments: The development of tangentially closing vascular clamps. Chir. 1996;121(12):1085-8.

11) Fricker, Janet. "Robert Acland: Pioneer of microsurgery who forged a second career in anatomical teaching". BMJ. 2016 ;**352**: i1761.

12) Trobec R, Gersak B. Direct measurement of clamping forces in cardiovascular surgery. Medical and Biological Engineering and Computing. 1997; 35;17–20.

13) Masia J, Olivares L, Koshima I, Teo T.C, Suominen S, Landuyt K.Van, Demirtas Y, Becker C, Pons G, Garusi C, Mitsunaga N. Barcelona Consensus on Supermicrosurgery. Reconstr Microsurg 2014;30:53–58.

14) Baek SM, Jacobson J. H. A new clamp for end-to-side microvascular anastomosis. J Microsurg. 1980; 1(6):465-9.

Figure Legends

Figure 1: Illustration of the parabolic design of the microvascular clamp. Orange arrows show the force direction, when compressing the handles of the clamp the jaws are opening wide.

Figure 2: Isometric view showing all three types of 3D printed microvascular clamps: single, double and 'gamma' clamp for end to side anastomosis. Sizes shown (XXS -XL). Comparison is made on the smaller sizes (ideal for supermicrosurgery) with the classic V3 S&T metallic clamp.

Supplementary materials

Video 1- Elasticity validation test

Video 2- Occlusion validation test