INTRODUCTION

The prevalence of congenital hand deformities has been estimated to be 30 cases per 10,000 live births and the incidence 22.5 cases per 10,000 births, as reported by the birth registry study of Rogala et al.1 Thumb hypoplasia, in particular, is estimated to be as frequent as 1 for every 100,000 live births. The most frequently performed surgical procedure to treat the complete aplasia of a thumb is the pollicization technique.2 The technique has undergone several developments over the years. The earliest known case of pollicization was described by Guermonprez in 1885, where the middle finger was used to create a thumb.3 In 1960, Zancolli performed the first pollicization of the index finger on a 10-year-old child. In addition, he differentiated the problems of a reconstructed thumb post-trauma to that of a congenitally absent or underdeveloped thumb.4 Buck-Gramcko, based on their experience of the thalidomide incident, published his revolutionary article on his approach to the index finger’s pollicization.5

Regardless of their technique of preference, the lead-surgeon will require adequate, static positioning of the hand during the prolonged dissection as well as to exchange between positions. This makes it almost impossible for the procedure to proceed without 1 or more (often 2) assistants. In this article, we demonstrate the design, manufacturing, and application of a novel single-use customized device that provides stabilization of the hand during dissection and improves autonomy and access to the surgical field.

Production

Using patient XRs, we extracted the anatomical dimensions of the patient’s hand, and a stereolithography file (.stl) of the device was designed on Blender (Amsterdam, the Netherlands) and then manufactured on a commercial Fusion Deposition Modelling Ender 5 3-dimensional (3D) printer (Creality, Shenzhen, China) using a polylactic acid variant (PLA) sourced from RS UK (1.75-mm filament by RS, Northants, UK). (See figure, Supplemental Digital Content 1, Preoperative XRs of the 2-year-old patient with type V thumb hypoplasia. (A, B) AP and lateral XR from which we extracted...
the dimensions of the customized 3D printed device. (C) Exact measurements required for the design of the device. http://links.lww.com/PRSGO/B672.) The 4-part construct required a total of 110g of PLA material and 500 minutes of total printing time. The compression mechanism of the clamp component of the device consisted of 2 zinc-plated stainless-steel compression springs (Table 1).

**Resulting Device**

The 3D printed parts were autoclaved at 121°C under 15 psi of steam pressure for 30 minutes before the operation. During the sterilization process, biological indicators were used to confirm sterility of the instruments post-process. Approval for clinical use of the customized 3D printed retractor was subjected to a rigorous approval process as class I devices as per the UK government Medicines and Healthcare Products Regulatory Agency guidelines (Low-risk, Non-invasive, Non-implantable) and was then successfully used in vivo (Figs. 1, 2).

**DISCUSSION**

Applications of 3D printing in the healthcare sector have been described in many recent instances, including the use of customized jigs for use in orthopedic surgery during osteotomies. Chen et al have studied the different materials and patterns available for manufacturing surgical army retractors using 3D printing technologies and provide evidence for their strength tolerance being in equal range to the stainless steel instruments currently used. We ourselves, we have previously applied this technology to make customized surgical instruments for congenital hand deformities, skin preparation aiding devices, as well as simulation training tools for hand-fracture fixation training. Three-dimensional printing technologies pose an elegant toolmaking solution for low-prevalence cases such as congenital hand deformities. While techniques that lend themselves to mass-manufacturing of instruments are not economically appealing for such a small number of cases, the low-volume yet highly customized manufacturing capabilities of rapid-prototyping technologies such as those afforded by 3D printing fulfill exactly these requirements for this demographic of patients.

Here, we have developed a device for a 2-year-old patient with a left-sided radial dysplasia with congenital posterior dislocation of the radius and complete aplasia of the thumb who underwent a pollicization procedure (type V thumb hypoplasia, as classified by Blauth). The device was customized to work optimally not only to the anatomical dimensions of the patient but also to the operating setting itself where the procedure was to take place. For instance, the clamp component (component 2) of the device was attached over the drapes on the assistant’s side of the operating table (away from the leading surgeon’s field). When the surgeon was to dissect with the hand in pronation, the device was assembled with the finger retractor (component 1) as well as the wrist stabilizer (component 4) attached on the clamp (component 4 on superior and part 1 on inferior insert points). Once the patient’s hand was correctly positioned on the device, the wrist cap (component 3) was assembled to component 4 for extra stabilization of the wrist (Fig. 1A). These components can be reassembled when the hand is required to be in supination, by assembling component 1 and 4 vice versa. To minimize the risk of pressure points when the device was applied, we have reinforced component 4 with a layer of surgical gauze.

The device is lightweight (110g), radiolucent, easy to assemble and is able to provide stability throughout the pollicization operation. Using an image intensifier machine, XRs can be taken without the instrument interfering operating view. Stay sutures were also positioned to hold the soft tissue retracted as per the surgeon’s preference, using the 6 engraved channels found on the clamp and part 1 of the device. (See figure, Supplemental Digital Content 2, PolliRS device after autoclave cycle. (A) Four parts of the multi-component device. Component 1: finger retractor; component 2: spring clap; component 3: stabilizing wrist cap; component 4: wrist stabilizer. (B) The device assembled. The red arrows show the engraved channels which can be used for stay sutures that can provide automated retraction of the soft tissue. http://links.lww.com/PRSGO/B673.)

**CONCLUSIONS**

In this study, we showcased the development of a pollicization retractor for use in a patient with a type V thumb hypoplasia. We show that 3D printing technologies are ideally suited for toolmaking in these types of operations, which are low prevalence and require a high degree of customization. The bespoke retractor can provide enhanced surgical

| Table 1. Printing Parameters on Each Component of the Device |
|-----------------|-----------------|-----------------|-----------------|-----------------|
| Part 1 | Part 2 | Part 3 | Part 4 |
| Material | PLA (1.75-mm filament) | PLA (1.75-mm filament) | PLA (1.75-mm filament) | PLA (1.75-mm filament) |
| Max speed (mm/s) | 200 | 200 | 200 | 200 |
| Nozzle diameter (mm) | 0.4 | 0.4 | 0.4 | 0.4 |
| Filling density (%) | 20 | 20 | 20 | 20 |
| Infill pattern | Cubic | Cubic | Cubic | Cubic |
| Printing time (min) | 120 | 200 | 20 | 160 |
| Layer height (mm) | 0.28 | 0.28 | 0.28 | 0.28 |
| Weight (g) | 27 | 45 | 6 | 32 |
| Nozzle temperature (°C) | 210 | 210 | 210 | 210 |
| Bed temperature (°C) | 70 | 70 | 70 | 70 |
| Cost (GBP) | 0.5 | 0.9 | 0.12 | 0.64 |
| Total cost (GBP) | 2.16 |

Part 1: finger retractor, Part 2: spring clamp, Part 3: stabilizing wrist cap, Part 4: wrist stabilizer. NB: printer, software, and autoclave costs are excluded from the cost estimate.
autonomy to the lead the surgeon during the procedure and allow for more effective use of surgical assistants. The prototyping capabilities of 3D printing technologies allow for the development of cost-effective, customized and innovative surgical instrumentation solutions which can be manufactured in-house. We believe and remain hopeful that further developments of these technologies will increase both their accessibility and their adoption, and bring forth an era where customized toolmaking platforms will be a part of every surgical laboratory.  

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Fig. 1. The PolliRS Device on the patient providing evidence of good fitting. Device assembled to assist hand in (A, B) pronation and (C) supination.

Fig. 2. A, The use of the PolliRS device during fluoroscopy imaging. B, Artery clip demonstrating the shadow of our radiolucent device.