Towards a Procedure Optimised Steerable Microcatheter for Neurosurgical Laser Ablation

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INTRODUCTION

Minimally invasive surgery (MIS) has seen significant growth over the last two decades due to its great benefits to surgical outcomes. In MIS neurosurgical procedures such as biopsy, ablation, and fluid delivery/extractions, it is common practice to use straight catheters. The success of these procedures derives from the precision and accuracy of reaching the surgical target without damaging healthy structures, which is not often possible due to limitations of the tool design. To overcome these, researchers continue to work on improving procedural delivery via robotic steerable needles with multiple design choices [1]. Within this area of research, the first robotic ecosystem, code-name EDEN2020 (Enhanced Delivery Ecosystem for Neurosurgery in 2020), was developed to provide a clinical tool to assess the potential of Convection Enhanced Delivery (CED) of chemotherapeutics along preferential pathways that align to anisotropic brain structures [2]. This task is possible only with a flexible delivery system.

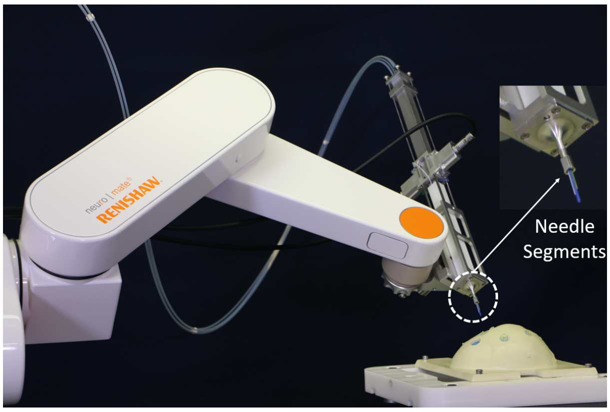

Fig. 1 EDEN2020 robotic system

The EDEN2020 robotic ecosystem shown in Fig. 1, employs a Programmable Bevel-tip Needle (PBN) with a multi-lumen design to embed sensing and drug delivery conduits for CED. Watts et al. [3] presented the first clinically viable PBN prototype with a 2.5 mm outer diameter (Fig. 2a), which was manufactured using extrusion of a medical-grade polymer. Although a diameter of 2.5 mm is clinically applicable, a further size reduction would be necessary for the application of diagnostic and therapeutic procedures involving deep-seated tissue structures, such as in Thermal Interstitial Laser Therapy (LiTT) [4]. Standard extrusion methods have limited capacity for complex geometry such as the PBN; therefore, we explored a different method to reduce the overall size of MIS tools.

This paper presents a new manufacturing method for PBNs that employs thermal drawing technology [5], which was previously applied to the manufacture of complex and irregular shapes at the micro-nano scale, with less material and lower cost. Our efforts to date have resulted in a 1.3 mm outer diameter PBN, demonstrating a 50% reduction in size but with equivalent performance to our most successful prototypes to date.

MATERIALS AND METHODS

A preform to fiber thermal drawing process is a fabrication method to produce longitudinally uniform fibers by heating the preform to its viscous liquefaction point and rolling it into meters to kilometers-long fibre while preserving cross-sectional structure [6]. Thermal drawing has been employed in several application areas in the literature, including optical communication, microfluidics, electronics, and textiles [7]. After the Additive Manufacturing methods were introduced, producing more complex and arbitrary structures with specific materials became possible. Hence, the 3D-printing thermal drawing method was chosen to produce each PBN segment. The 3D printed preform design was completed using standard Computer-Aided Design (CAD) software (SolidWorks, Dassault Systemes, France). During prototype (preform) development, several design approaches were considered and optimised attractively to reach the targeted segment dimensions and sliding performance of the interlocking mechanism by considering the effect of thermal expansion. A commercially available Ultimaker 3 Extended printer was used with PC material (Ultimaker PC Transparent, 2.85 mm filament, Netherlands) with 0.4AA print core (non-abrasive plastics) and layer thicknesses of 0.1 mm. Compared to the default speed of 250 mm/s, the print core travel speed was adjusted to 40 mm/s to create smoother surfaces. For transparent PC printing, the following temperatures were taken into account: nozzle temperature $T_n = 270\ ^{\circ}C$ and bed temperature $T_b = 107\ ^{\circ}C$. The dimensions of the 3D printed preform were 40 mm in diameter and 100 mm in length. The central lumen of the preform was 8.6 mm in diameter, and the targeted draw ratio was 40 to reach 0.21 mm central lumen. Calculation of fibre to be drawn can be done by assuming that the amount of preform fed in a radiative 3-zone furnace and drawn fibre are equal (feed-through speed $v_f = 2.5\ m/min$ and drawing speed $v_d = 1.4\ m/min$). Thus, square of draw ratio × preform length can yield for the fibre to be drawn ($40^2 \times 0.1 = 160$ m fibre). The feed-through speed was also increased and optimised to avoid the 3D printed preform shrinking during the draw due to voids in its layers. The temperature of the 3-zone furnace used for thermally drawing the fiber was as follows: top zone: 140 $^{\circ}C$, middle zone: 200 $^{\circ}C$, and bottom zone: 85 $^{\circ}C$. The thermal drawing process produced a long PBN shaped fiber segment with a radius of 0.65 mm, and afterward, the long fiber segment was trimmed to the desired length (200 mm). A complete needle assembly was created by assembling four individual shorn segments and assembly performed by hand. To compare the performance of PBN shaped fibres, the flexural stiffness and tensile stress of individual segments are tested. Additionally, the interlocking mechanism's breakout force between two assembled segments is measured.

RESULTS

The cross-section comparison between the previous segment and thermally drawn (TD) PBN segment is given in Fig. 2b. The results show that we achieved a diameter almost half the size of the current state of the art. Although there are inaccuracies in the interlocking mechanism (Fig. 2b), these do not affect the sliding behaviour or breakout strength between the segments, hence demonstrating the viability of thermal drawing as an alternative to extrusion.

TABLE I Mechanical features

	Mean Flexural Stiffness (N/mm)	*Mean Tensile Stress (MPa)*	*Mean Interlocking Breakout Force (N)*
2.5mm Extruded	0.023	13.10	5.47
2.5mm TD	0.38	53.66	18.52
1.3mm TD	0.031	51.45	10.94

The mean flexural stiffness, tensile stress, and interlocking mechanism breakout force values of the thermally drawn and extruded samples are given in Table 1. In order to have a better curvature performance, segment rigidity plays a critical role during the insertion of the segments. The thermal drawing method has higher stiffness compared to the extruded method for the same segment sizes. As a result of the increased stiffness, the catheter curvature performance is reduced, while the interlocking strength is improved. With the 1.3 mm segment prototype, the effect on steering performance is mitigated (30% worse), while interlock strength is improved (50% better). Qualitatively, the thermally drawn segments work more efficiently, moving with respect to one another without separating and more fluidly than with the extruded 2.5 mm prototype. Comparing the thermal drawing method with extrusion, the former does not need additional post-production processing (e.g., nano-coating to improve the sliding behavior), representing a marked advantage.

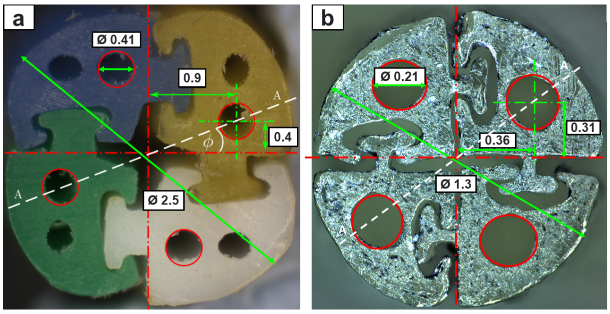

Fig. 2 a) Extruded PBN, b) Thermally Drawn PBN

DISCUSSION AND CONCLUSION

The manufacture of the PBN catheter with a 50% reduction in size to the state of the art opens door to its application to a wider range of diagnostic and therapeutic interventions. However, though our thermal drawing method is advantageous, it results in a stiffer structure compared to previous systems due to the choice of a harder material. A thorough examination of the effect of this change on the curvature performance of the needle will be part of future work. In addition, the use of different materials and molding methods will be investigated, alongside the integration of this newly developed catheter within EDEN2020's ecosystem for precision neurosurgery, paving the way for the eventual application of our needle steering technology to LiTT.

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