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Using an industrial braiding machine to upscale the production and modulate the design of electrospun medical yarns

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ABSTRACT

While electrospun multifilaments have shown initial promise as medical yarns, their development has been restricted to short sections of hand-braided yarns. Integrating electrospun material into existing industrial braiding production lines would enable the modulation of yarn properties and an increased production rate to meet the demand for clinical trials. In this study, we used an industrial braiding machine to manufacture multifilament polydioxanone yarns with various filament numbers and carrier arrangements. The resulting yarns were characterized by mercury porosimetry, mechanical and pull through testing and compared to clinically used braided Vicryl and monofilament polydioxanone (PDS) sutures. Electrospun yarns were significantly more porous (67%) compared with Vicryl (28%) and PDS sutures (0%), and possessed the classic toe region reminiscent of native tissue. Pull through testing revealed that the structural configuration of electrospun yarns allowed for more energy dissipation. These findings suggest that upscaling the production of braided yarns is critical for designing medical yarns with required properties for clinical applications.

1. Introduction

Textile manufacturing is widely used in the medical market today to create dressings and medical yarns, such as sutures. Medical yarns are mostly produced by braiding, which offers some advantages over other textile methods, such as reduced fraying of the yarn, slight improvement in mechanical strength, and better control over structural properties such as porosity and pore size [1]. To date, braided medical yarns are predominantly manufactured from inert fibres, which are melt extruded from synthetic polymers, and their development is largely driven by industry. However, the recent academic interest in regenerative medicine is driving research towards 'bioactive' medical yarns that both mechanically approximate tissue, like current sutures, but also harness biophysical cues to drive cell directed repair.

For torn tissues with a poor intrinsic healing capacity, it is suggested that bioactive medical yarns made by electrospinning could be used during primary repair to better guide tissue regeneration. Electrospinning, a process by which nano- and microscale fibres are drawn out from a polymer solution using electrical charges, has received recent attention in the field of regenerative medicine [2]. Electrospun fibres mimic the extracellular matrix of soft tissues, as well as have a high surface area to volume ratio and a high porosity to promote cellular infiltration. Although densely aligned electrospun fibres collected as sheets are biologically more advantageous than randomly organized fibres [3], they present significant mechanical, structural, and production limitations, which has prevented the implementation of as-spun materials in biomedical applications, such as sutures, stents, or drug delivery devices. The production of continuous bundles of fibres, known as filaments, opens the possibility of creating multifilament braided yarns with a hierarchical structure more similar to that of native tissue [1,4–11].

Braiding electrospun filaments into multifilament yarns has shown initial promise for soft tissue applications. Braided yarns have been shown to support tenogenic differentiation of human mesenchymal stem cells (hMSCs) and displayed similar mechanical behavior to native tendons [6,8,9]. To date, braided electrospun varns have only been manufactured by hand into short sections, which limits the control over structural properties, the reproducibility of the product, and the overall production volume [1,5,6,8,9,12]. The delay in upscaling hand-made varns to an industrial machine can be partially attributed to the sensitivity of the electrospinning process and the difficulty in producing continuous filaments, thereby hindering the further processing of these filaments for use with conventional textile machinery. Moreover, electrospun fibres are delicate and sensitive to mechanical damage and environmental degradation, meaning that some textile machinery is currently not suitable for scaling up electrospinning technology.

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Together these challenges have limited the commercialization and clinical translation of many promising electrospun products in development.

We have recently developed a technique to produce sufficiently long and robust filaments, opening up the possibility of exploring braiding with an industrial machine [13,14]. Shifting the production of electrospun yarns to an industrial machine would lead to a higher degree of control over the yarn's structural properties than can be achieved with hand-braided yarns, as well as a wider variety of braiding designs to be explored by adjusting the orientation and distribution of fibres. Moreover, the use of an industrial machine can increase rate of production to meet the demand for clinical trials and later commercialisation [15]. Despite the potential of semi-automating the production of braided electrospun yarns, the use of an industrial machine has not been explored yet.

The objective of this study was two-fold: (1) to investigate the feasibility of using an industrial braiding machine with electrospun filaments, and (2) to design and manufacture yarns with various structural and mechanical properties. We hypothesized that it would be feasible to use an industrial braiding machine to modulate the properties and increase the rate of production of multifilament yarns. To demonstrate these hypotheses, electrospun polydioxanone filaments were braided using a Variation Braiding Machine into multifilament yarns with various filament numbers and carrier arrangements. The resulting yarns were characterized in terms of their porosity, mechanical behavior, and pull through properties.

2. Materials and methods

2.1. Electrospun monofilaments

Polymer solutions were made by dissolving polydioxanone (PDO, Sigma-Aldrich; viscosity 1.5–2.2 dL/g; $T_g = -10$ to -5 °C; T_m 110-115 °C) in HFIP solvent (Apollo Scientific; 1,1,1,3,3,3, -hexafluora-2-propanol) at a 7% weight to volume ratio with a compound that changes the conductivity of the solvent, and stirred for 24 h before electrospinning. PDO is an attractive biodegradable polymer for use as a biomaterial, as it has a good safety profile with mild foreign body reaction and complete degradation between 5 months to one year, depending on manufacturing and processing conditions [13,16,17]. HFIP was chosen for its easy dissolution in the polymer and its fast evaporation in electrospinning conditions [18]. Measuring residual HFIP solvent is something that we intend to investigate more in the near future, however previous in vitro and in vivo work have shown no adverse effect and this has also been confirmed in other studies using this solvent [7,11].A custom electrospinning apparatus with a single nozzle and a stainless steel wire collector was used to fabricate continuous electrospun filaments [13]. A sketch of the electrospinning setup is given in the supplementary material as Supplementary Fig. 1. The solution feed rate was 0.8 mL/h, wire feed rate was 0.5 mm/s and the filaments spun under an electric field of 7.2 kV. The filaments were detached from the collecting wire and then manually stretched until resistance was felt (around 3.5 times their length), to increase the length and align the submicron fibres in the direction of the thread [13]. The average diameter of the electrospun fibres in the drawn filaments was 1.03 \pm 0.3 μ m and they were kept at room temperature of 25 °C in a desiccator until used for braiding.

2.2. Braided suture manufacturing

Braided multifilament sutures were made using a Variation Braiding Machine (VF 1/(4-32)-140, Herzog Braiding Machine, Oldenburg, Germany), an industrial braiding machine with manually changeable crossings, enabling the production of braids using 4 to 32 carriers. Four different braids composed of 12, 16, 20, and 24 filaments were made using 12, 8, 20, and 24 fine yarn carriers (carrier type AFDh 80, Herzog,

Oldenburg, Germany), respectively. The number of filaments for each braid was chosen based on the projected braid size falling in the desired yarn diameter range of 0.5–1 mm, a size range suitable for suture use. Following braiding assembly, the yarns were thermally annealed at 65 °C for 3 h, following previous work [14]. An optical micrometer (Keyence LS-7010MR laser with Keyence LS-7601 monitor, Milton Keynes, UK) was used to measure suture diameter by averaging 5 measurements, which was then converted to United States Pharmacopeia (USP) suture sizing standardisation. Finally, a Plugable Optical Digital Microscope (Plugable USB2-micro-250X, Redmond, WA, USA) was used to obtain images of the final yarns.

2.3. Scanning electron microscopy (SEM)

Scanning electron microscopy (Evo LS15 Variable Pressure Scanning Electron Microscope, Carl Zeiss AG, Germany) images from each braided sample were taken. The samples were washed with phosphate buffered saline (PBS, Sigma-Aldrich, St. Louis, MO, USA), cut, and coated with gold using a SC7620 Mini Sputter Coater System (Quorum Technologies Ltd, Laughton, UK) prior to mounting on the SEM machine. Samples were analysed in high vacuum mode to examine macroscopic morphology, surface texture, and braid angle of braided electrospun sutures. Images were captured at 50X and 150X magnifications and fibre diameter was determined using ImageJ software (National Institute of Health, Bethesda, MD, USA).

2.4. MicroCT analysis

Braided yarns were scanned over a length of 1 mm using microcomputed tomography (μ CT). The yarns were placed in a tube that was mounted vertically on the μ CT scanner (SkyScan 1172, SkyScan, Kontich, Belgium). The samples were scanned at an isotropic pixel size of 1.58 μ m. The scan parameters were set at a voltage of 40 kV; a current of 250 mA without filter and 900 projections were used. The images were reconstructed using NRecon software (SkyScan 1172, SkyScan, Kontich, Belgium) using the Feldkamp algorithm with a beam-hardening correction of 40% and a smoothing of 4. The reconstructed images were analysed using ImageJ software (National Institute of Health, Bethesda, MD, USA) in order to measure the yarn's surface area, diameter, and overall porosity.

2.5. Mercury porosimetry

Porosity and pore size distribution was determined by mercury intrusion technique using an Autopore IV 9500 mercury porosimeter (Micromeritics Instrument Co, Norcross, GA, USA). The porosimeter had a max pressure range of 33,000 psia and a measurable pore size range of $360 \,\mu\text{m}$ to $0.005 \,\mu\text{m}$. Electrospun sutures were cut into sections weighing 70 mg and placed in the cup of the penetrometer (s/n = 14, 3 bulb, 0.412 stem, powder). The penetrometer was first passed through both the low-pressure port where the gases are evacuated from the penetrometer and then backfilled with mercury, and then through the high-pressure port. Samples were run with a mercury filing pressure of 0.49 psia and an equilibration time of 10 s. Two experimental repeats were performed for all electrospun yarns and controls (size 2-0 PDS and Vicryl sutures).

2.6. Tensile testing

Braided yarns were tested knotless at a crosshead speed of 50 mm/ min with a 5 kN load cell until failure using a Zwick tensile testing machine (Zwick Roell Group, USA). A preliminary investigation with Pincer grips (Zwick Roell Group, USA) yielded inconsistent results and yarn pull through the grip clamps [19]. To generate more reproducible data, custom grips were designed based on tensile grips used in the textile industry for yarns and ropes [20]. These grips were Download English Version:

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