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Engineering mechanical gradients in next generation biomaterials – Lessons learned from medical textile design ☆

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ABSTRACT

Nonwoven and textile membranes have been applied both externally and internally to prescribe boundary conditions for medical conditions as diverse as oedema and tissue defects. Incorporation of mechanical gradients in next generation medical membrane design offers great potential to enhance function in a dynamic, physiological context. Yet the gradient properties and resulting mechanical performance of current membranes are not well described. To bridge this knowledge gap, we tested and compared the mechanical properties of bounding membranes used in both external (compression sleeves for oedema, exercise bands) and internal (surgical membranes) physiological contexts. We showed that anisotropic compression garment textiles, isotropic exercise bands and surgical membranes exhibit similar ranges of resistance to tension under physiologic strains. However, their mechanical gradients and resulting stress-strain relationships show differences in work capacity and energy expenditure. Exercise bands' moduli of elasticity and respective thicknesses allow for controlled, incremental increases in loading to facilitate healing as injured tissues return to normal structure and function. In contrast, the gradients intrinsic to compression sleeve design exhibit gaps in the middle range (1–5 N) of physiological strains and also inconsistencies along the length of the sleeve, resulting in less than optimal performance of these devices. These current shortcomings in compression textile and garment design may be addressed in the future through implementation of novel approaches. For example, patterns, fibre compositions, and fibre anisotropy can be incorporated into biomaterial design to achieve seamless mechanical gradients in structure and resulting dynamic function, which would be particularly useful in physiological contexts. These concepts can be applied further to biomaterial design to deliver pressure gradients during movement of oedematous limbs (compression garments) and facilitate transport of molecules and cells during tissue genesis within tissue defects (surgical membranes).

Statement of Significance

External and internal biomaterial membranes prescribe boundary conditions for treatment of medical disorders, from oedema to tissue defects. Studies are needed to guide the design of next generation biomaterials and devices that incorporate gradient engineering approaches, which offer great potential to enhance function in a dynamic and physiological context. Mechanical gradients intrinsic to currently implemented biomaterials such as medical textiles and surgical interface membranes are poorly understood. Here we characterise quantitatively the mechanics of textile and nonwoven biomaterial membranes for external and internal use. The lack of seamless gradients in compression medical textiles contrasts with the graded mechanical effects achieved by elastomeric exercise bands, which are designed to deliver controlled, incremental increases in loading to facilitate healing as injured tissues return to normal structure and function. Engineering textiles with a prescient choice of fibre composition/size, type of knit/weave and inlay fibres, and weave density/anisotropy will enable creation of fabrics that can deliver spatially and temporally controlled mechanical gradients to maintain force balances at tissue boundaries, *e.g.* to treat oedema or tissue defects.

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1. Introduction

Nature abounds with gradients, such as the naturally occurring spatial variations in mechanical stiffness and porosity, which are intrinsic to biological tissues and tissue bounding interfaces. Parallels can be drawn between the spatial architecture of bones and the porosity of sea sponges, as well as between interfacing biological morphologies at the tendon enthesis and those of juxtaposed biological systems in nature [1–3]. Gradient engineering provides a novel approach to engineer biomaterials that emulate the smart, emergent properties of their natural biological counterparts [1]. Such smart properties confer the capacity to adapt to the dynamic environment and thereby induce or instruct changes in biological structure and function [4]. Examples of smart biomaterials include flow-directing biomaterials that mimic the stiffness, porosity and counterintuitive flow properties of bone under mechanical loads [2], and textile weaves that mimic scaled-up three-dimensional patterns of elastin and collagen fibres comprising the fibrous layer of periosteum, a hyperelastic sleeve that exhibits strain stiffening behavior and thereby splints and strengthens bones under impact loads [5].

Recent efforts have emphasised either top-down quantification of gradients in biological materials, including the resulting smart properties intrinsic to such gradients [2], or bottom-up engineering of gradients in biomaterials using novel technological approaches [5,6]. Few published reports have used engineering methods to assess mechanical gradients intrinsic to currently implemented biomaterials such as medical textiles and surgical interface membranes. Such studies are expected to guide the design of next generation biomaterials and devices that incorporate gradient engineering approaches [7]. In addition they may speed medical translation of new design approaches, as they are implemented with processes used to manufacture current, regulatory body-approved devices (FDA-, CE Mark-, and/or TGA-approved) [8].

Non-woven and textile membranes have been applied both externally and internally (*cf.* Graphical Abstract) to prescribe boundary conditions for medical disorders as diverse as oedema (resulting in swelling and pushing out of normal external or internal physiologic boundaries) and tissue defects (resulting in pulling in of normal external and internal physiologic boundaries). Membranes designed for external use show the greatest range of structure, function, and resulting applications, likely due to their limited number of hurdles of obtaining regulatory approval. For example, compression sleeves for oedema treatment are designed to generate external pressure to compress the circumference and thereby to reduce swelling of oedematous limbs by facilitating lymph flow to the heart. However, the putative mechanical gradients intrinsic to such sleeves, which underpin their lymph drainage capacity, are not well established. Internal surgical membrane sleeves can also be designed to impart directed pressure gradients to tissues healing within, *e.g.* to guide differentiation of progenitor cells through transmission of mechanical and mechanically modulated biochemical cues, or to guide nutrient and/or growth factor transport to promote tissue genesis within defects [9–12]. However, surgical membrane design and implementation has been faced with a number of setbacks in the past decade, resulting in device recalls of both solid [1] and textile (mesh) surgical membrane implants [13,14]. Hence, as a first step towards engineering medical textiles that incorporate mechanical gradients and enable smart fabric properties [5], this study aims to quantify gradients in currently implemented devices used to treat oedema and tissue defects. These insights are then set in context of engineering and design of next generation medical textiles that incorporate mechanical gradients to increase functionality in both internal and external applications.

2. Materials and methods

Our working hypothesis postulates that the function of bounding membranes used for physiological purposes depends on the stiffness gradients intrinsic to both the materials from which they are made as well as their architecture when implemented in external and internal physiological contexts. Our approach was to test mechanical properties of materials from which external and internal sleeves are made, as well as to determine whether sleeve architecture affects mechanical properties and physiological function. First, we measured the mechanical properties of external, medical compression sleeves to determine potential directional dependence, *i.e.* anisotropy. We then tested compression sleeve architectures for influence on the mechanical properties of the sleeve. In a second step, we investigated mechanical properties of internal, surgical membranes. For comparison, we quantified and compared mechanical properties of external lymphoedema sleeves and internal surgical membranes with those of elastomeric exercise bands. Exercise (physio) bands were used in colour-coded series to incrementally increase loading and thereby facilitate healing as injured tissues return to normal function.

2.1. Materials

2.1.1. Compression sleeve selection

Compression sleeve design varies by class of compression needed (I–III) and size of the arm, which in turn depends on size of the patient and degree of oedema. To make the current study as generalisable as possible, we chose Class II 20–30 mmHg, FDA approved, ready-to-wear, over-the-counter compression arm sleeves as representative. The large size was chosen to maximise materials for testing. Compression sleeves are comprised of a 72% polyamide and 28% Lycra® knit.

2.1.2. Preparation of sleeves for gross analysis and mechanical testing

Compression sleeves (Da Yu Enterprise, Changhua County, Taiwan) were cut lengthwise and unfolded to resemble a trapezoidal planar surface (n = 4). The sleeves were then divided into four sections along their length, between the wrist (Section 1) and upper arm (Section 4) (1–4, Fig. 1A).

Compression sleeve weaves were imaged with a Leica M80 stereomicroscope (Leica Microsystems, CHE) at 25× magnification and characterised using image analysis. Distances between the base yarns were measured using the open source image analysis program, Fiji (Fig. 2) [15].

To assess material anisotropy, swatches of three alignments were investigated, including swatches with longitudinal alignment along the length of the sleeve, circumferential alignment around the limb, and oblique alignment at a 45° angle according to the weave bias (Fig. 1). Within each sleeve section (1–4), six swatches were cut, each measuring *circa* 50 mm × 20 mm. Swatch thickness was measured using a digital precision caliper (Mitutoyo Corp., JP), resulting in a mean thickness of 0.45 mm (n = 3).

Mechanical properties of compression textile specimens were compared with those of graded latex exercise bands (TheraBand Resistance Bands, The Hygenic Corporation, Akron, OH) and silicone elastomer surgical membranes (BioPlexus Corporation, Ventura, CA). Sections were cut to the same size as the compression sleeve swatches (50 mm × 20 mm). Surgical grade silicone membranes are manufactured to 0.05 mm thickness. Triplicates of the seven exercise band grades of the surgical membranes, represented by distinct colour, were investigated in this study.