MONOLITHIC SELF-SUPPORTIVE BI-DIRECTIONAL BENDING PNEUMATIC BELLOWS CATHETER

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DEDICATION

This thesis is dedicated to my beloved parents Muhammad Ali and Sardaran Bibi for prays and blessings, my wife Ammara Yousaf and children, Adil Tariq, Zoha Tariq and Hamdah Tariq for their love, caring, motivation and support.

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ABSTRACT

The minimally invasive surgery has proven to be advantageous over conventional open surgery in terms of reduction in recovery time, patient trauma, and overall cost of treatment. To perform a minimally invasive procedure, preliminary insertion of a flexible tube or catheter is crucial without sacrificing its ability to manoeuvre. Nevertheless, despite the vast amount of research reported on catheters, the ability to implement active catheters in the minimally invasive application is still limited. To date, active catheters are made of rigid structures constricted to the use of wires or on-board power supplies for actuation, which increases the risk of damaging the internal organs and tissues. To address this issue, an active catheter made of soft, flexible and biocompatible structure, driven via nonelectric stimulus is of utmost importance. This thesis presents the development of a novel monolithic self-supportive bi-directional bending pneumatic bellows catheter using a sacrificial molding technique. As a proof of concept, in order to understand the effects of structural parameters on the bending performance of a bellows-structured actuator, a single channel circular bellows pneumatic actuator was designed. The finite element analysis was performed in order to analyze the unidirectional bending performance, while the most optimal model was fabricated for experimental validation. Moreover, to attain biocompatibility and bidirectional bending, the novel monolithic polydimethylsiloxane (PDMS)-based dual-channel square bellows pneumatic actuator was proposed. The actuator was designed with an overall cross-sectional area of 5 × 5 mm^2, while the input sequence and the number of bellows were characterized to identify their effects on the bending performance. A novel sacrificial molding technique was adopted for developing the monolithic-structured actuator, which enabled simple fabrication for complex designs. The experimental validation revealed that the actuator model with a size of 5 × 5 × 68.4 mm^3 i.e. having the highest number of bellows, attained optimal bi-directional bending with maximum angles of -65° and 75°, and force of 0.166 and 0.221 N under left and right channel actuation, respectively, at 100 kPa pressure. The bending performance characterization and thermal insusceptibility achieved by the developed pneumatic catheter presents a promising implementation of flexibility and thermal stability for various biomedical applications, such as dialysis and cardiac catheterization.

ABSTRAK

Pembedahan invasif minima telah terbukti berfaedah berbanding pembedahan konvensional dari segi pengurangan masa pemulihan, trauma pesakit, dan kos rawatan secara keseluruhan. Untuk melakukan prosedur invasif yang minima, penyisipan awal tiub fleksibel atau kateter adalah penting dengan mengambil kira keupayaannya untuk mengemudi. Walaupun terdapat penyelidikan yang dilaporkan tentang kateter, keupayaan untuk melaksanakan kateter aktif dalam aplikasi invasif minima masih terhad. Sehingga kini, kateter aktif diperbuat daripada struktur tegar yang terhad kepada penggunaan wayar atau bekalan kuasa di atas talian untuk bertindak, yang meningkatkan risiko merosakkan organ-organ dan tisu-tisu dalaman. Untuk menangani masalah ini, adalah penting untuk menghasilkan kateter aktif yang diperbuat daripada struktur lembut, fleksibel dan biokompatibel, didorong melalui rangsangan bukan elektrik. Tesis ini membentangkan pembentukan kateter pneumatik lentur berbentuk silikon monolitik yang menyokong kedua-duanya dengan menggunakan teknik acuan korban. Untuk membuktikan konsep ini dan untuk memahami kesan parameter struktur pada prestasi lenturan struktur pam angin, satu saluran penggerak pam angin pneumatik berbentuk bulat telah direka. Analisis unsur habis dilakukan untuk menganalisis prestasi lentur satu arah, manakala model yang paling optimum dibuat untuk pengujian eksperimen. Selain itu, untuk mencapai biokompatibiliti dan lenturan dwiarah serta novel, sebuah penggerak pneumatik berbentuk saluran dua polimimetilsiloxane monolitik yang baru dicadangkan. Penggerak telah direka dengan luas keratan rentas keseluruhan 5×5 mm^2, manakala urutan masukan dan bilangan belos dicirikan untuk mengenal pasti kesannya terhadap prestasi lenturan. Teknik pembentuk acuan korban yang novel digunakan untuk membangunkan penggerak berstruktur monolitik, yang membolehkan fabrikasi mudah untuk reka bentuk kompleks. Pengesahan eksperimen menunjukkan bahawa model penggerak dengan saiz $5 \times 5 \times 68.4$ mm^3 iaitu mempunyai bilangan bilah yang tertinggi yang mencapai lenturan bi-arah yang optimum dengan sudut maksimum -65° dan 75°, dan daya 0.166 dan 0.221 N di bawah kiri dan pacuan saluran kanan, masing-masing, pada tekanan 100 kPa. Pencirian prestasi lentur dan ketidakupayaan haba yang dicapai oleh kateter pneumatik tersebut memberikan fleksibiliti dan kestabilan terma bagi pelbagai aplikasi bioperubatan, seperti dialisis dan kateter jantung.

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LIST OF ABBREVIATIONS

CBPA	-	Circular Bellows Pneumatic Actuator
SBPA	-	Square Bellows Pneumatic Actuator
MIS	-	Minimally Invasive Surgery
MEMS	-	Micro Electromechanical Systems
SMA	-	Shape Memory Alloy
DOF	-	Degree of Freedom
PDMS	-	Polydimethylsiloxane
NOTES	-	Natural Orifice Transluminal Endoscopic Surgery
FEA	-	Finite Element Analysis
TDM	-	Tendon-driven mechanism
TRP	-	Tendon-Routed Pulley
TSM	-	Tendon-Sheath Mechanism
HARP	-	Highly Articulated Robotic Probe
CTSM	-	Constrained Tendon-Driven Serpentine Manipulator
SMARLT	-	Strengthened Modularly Actuated Robotic Laparoscopic Tool
DDES	-	Direct Drive Endoscopic System
ESD	-	Endoscopic Submucosal Dissection
MINIR	-	Minimally Invasive Neurosurgical Intracranial Robot
MRI	-	Magnetic Resonance Imaging
ALICE	-	Active Locomotion Intestinal Capsule Endoscope
LMA	-	Local Magnetic Actuation
EDM	-	External Driving Magnet
IDM	-	Internal Driven Magnet
PSA	-	Pneumatic Soft Actuator
HSA	-	Hydraulic Soft Actuator
FMA	-	Flexible Micro-Actuator
CNC	-	Computer Numerical Control
ABS	-	Acrylonitrile Butadiene Styrene

LIST OF SYMBOLS

E - Young’s modulus

μ - Poisson’s ratio

θ - Bending angle of the actuator

P - Applied pressure

B - Number of bellows

BS - Bellows spacing

BW - Bellows width

WT - Actuator’s Wall-thickness

D - Actuator diameter

L_o - Initial actuator

L_{redued} - Reduced length of the actuator

L_{new} - New length of the actuator

N - Reference node

σ - Stress

ε - Strain

ΔP_i - Change in input pressure

W_e - Strain energy function

C_{ij} - Material constant

n - Model order

I_1, I_2 - Strain invariants

λ - Stretch

h_b - Bellows height

d_i - Inflation distance

F_E - Exerted force

ΔF_E - Change in exerted force

M_{d_i} - Function of d_i

L_W - Width-justified lever of F_E

CHAPTER 1

INTRODUCTION

1.1 Background of Research

In the field of medical robotics, many astonishing devices have been developed to improve the pre- and post-surgery health issues of the patients undergoing non-invasive (colonoscopy) or minimally invasive (arthroscopy) procedures. Minimally invasive surgery (MIS), started around 1987 [1], utilizes an endoscope to access the interior organs or tissue of the patient's body via three to five small incisions of about 5–15 mm in size. The MIS technique has proven to be advantageous over conventional open surgery in terms of reduction in postoperative pain, shorter hospital stays, improved cosmetics, and reduced risk of wound infection [2]. Moreover, the technical advancements in the surgical areas stimulated surgeons to apply minimally invasive tools in more advanced and complex surgical procedures, such as sigmoidectomy surgery, sigmoid colectomy, surgical aneurysm repair, coronary artery disease and carotid endarterectomy [3-5] with higher precision, flexibility, and control. For performing MIS procedures, the preliminary insertion of a small catheter is essential without sacrificing its ability to maneuver. In addition, for diagnosis and treatment of certain cardiovascular conditions via cardiac catheterization [6], a catheter is inserted in an artery or vein in the groin, neck or arm and is threaded through blood vessels to the heart as shown in Figure 1.1. Some heart disease treatments such as coronary angioplasty and coronary stenting also utilize cardiac catheterization. Considering the importance of endoscopes and catheters, many researchers have focused on improving conventional endoscopes, as well as developing new flexible endoscopes and active catheters [7]. Some of the commercially available flexible endoscopes, such as the Olympus EXERA Ill CF-Q190L and PENTAX Medical RetroView™ EC34-i10T offer an ergonomic design, however, their rigid body and large diameter limited their applications.

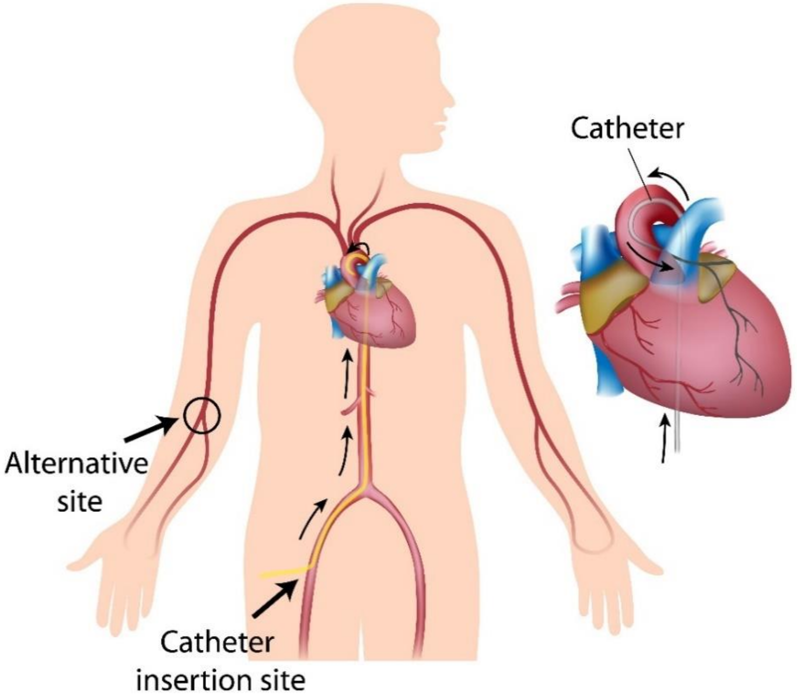

Figure 1.1 Cardiac Catheterization [8]

Initially, endoscopes were operated using a tendon-driven mechanism. Tendon-driven actuation is one of the most convenient actuation methods, which uses active or passive tendons that are passed over joints using either pulleys or sheaths. However, to develop miniature surgical tools and devices that can offer flexibility with strong manipulation force, the researchers adopt micro-electromechanical system (MEMS) actuators, such as shape memory alloys (SMA). SMA operates on 'shape-memory effect'; a phenomenon that occurs when the SMA deformed at the martensitic phase is heated up to the austenitic phase to regain its 'original' shape [9-12]. Nitinol (NiTi), a type of biocompatible SMA, has been extensively used in medical implantable devices, surgical tools and active catheters [13, 14]. Despite the various advantages offered by the SMA, its slow response and heat dissipation issues limited its application in MIS. Moreover, to increase the degree of freedom (DoF) and workspace for an end-effector, while reducing the complexity and power consumption, the researchers begun to explore magnetically actuated mechanisms. Magnetic actuators use a magnetic field based 'wireless link' to actuate the surgical tools and capsule endoscopes. Since surgical robotic systems are considered as the future of MIS, therefore, to avoid on-sight electric or magnetic interferences, the researchers took preventive measures and brought pneumatic and hydraulic-based soft actuators under consideration.

Soft actuators made from highly compliant elastomer material offer biocompatibility, high flexibility and safety, which makes them promising candidates for endoscopic application [15, 16]. The structure of a soft actuator is often reinforced with fiber to improve actuation [17], while it consists of internal channels for pneumatic or hydraulic supply. The input pressure to the actuator’s channels causes elastic deformations in its structure [18], which results in actuation. Compared to the pneumatic, a hydraulic soft actuator results in a heavier structure, limited DOF and bending motion. Soft actuators have found enormous applications in medical robotics. However, the fabrication of miniaturized soft actuators having multi-channels and complex structures becomes challenging through molding or casting techniques, which involves low repeatability and difficulty in the extraction of the channel forming mold [19].

1.2 Problem Statement

Despite the vast amount of research reported on endoscopes and active catheter to facilitate the MIS procedures, few problems still arise in the design, fabrication and actuation of these devices. The catheters are manually operated via small incisions or natural orifice at fixed positions on the patient’s body, which limit their movements in reaching the targeted areas. In addition, the maneuvering of a rigid catheter; inside an artery or vein in the groin, neck or arm for diagnosis and treatment of cardiovascular conditions, in internal jugular vein (ø15.8 ± 1.8mm) [20], or subclavian vein (ø10–20mm) or arm veins (ø3–4mm) or femoral vein (3.9–8.9mm) for removal of excess water, solutes and toxins from blood via dialysis and in urethra (ø8–9mm) for diagnosis and treatment of urethra and bladder via cystoscopy [21], might cause damage to the internal organs and tissues, which could result in life-threatening consequences. To address this issue, soft bellows actuators-based flexible and biocompatible endoscopes and active catheters are of utmost importance. Soft bellows actuators made of elastomers are fabricated by bonding an extensible half-bellows with a layer of inextensible material, as reported for the fabrication of PneuNets [22, 23]. There are many other works reported to use molding and bonding techniques to fabricate pneumatic actuators [18, 24-27]. However, these actuators suffer from leakage issue during operation. Soft actuators having complex, sophisticated and miniaturized designs can be developed using three-dimensional (3D) printing, which facilitates the formation of high-resolution molds [28-31] as well as complete 3D soft structures [32, 33]. Although emerging 3D printing technologies like digital light processing offer high theoretical resolutions, however, 3D printing of microscale voids and channels without obstruction or clogging has still been challenging. In contrast, the 3D printing technology can further facilitate the development of soft actuators via printed sacrificial molds that can eliminate the need for the bonding process.

1.3 Research Objectives

The main objective of this research is to develop a monolithic self-supportive bi-directional bending pneumatic bellows catheter that can offer a soft, flexible and biocompatible solution in contrast to the incisions or natural orifice at fixed positions on the patient’s body. The specific objectives are listed below:

1. To design single- and dual- channel CBPA and SBPA, respectively, and analyze their bending performance to highlight most optimal models feasible for MIS applications.

2. To fabricate optimal single-channel CBPA model using molding and bonding process, as a proof-of-concept uni-directional bellows-structured catheter.

3. To optimize the fabrication process for developing a small-scale monolithic-structured bi-directional bending SBPA catheter via novel sacrificial molding technique.

4. To characterize the bending performance, force exertion and thermal susceptibility of the fabricated catheters.

1.4 Scope of Research

This research focuses on the development of a biocompatible monolithic self-supportive bi-directional bending pneumatic-bellows catheter for biomedical and surgical applications. The scopes of this research work are as follows:

1. **Design and FEA-based simulation of pneumatic-bellows actuator**

   Silicone material KE-1603 A/B and RTV-3481/3081 based single-channel CBPA and polydimethylsiloxane (PDMS) based dual-channel SBPA were designed using the MARC® software. Finite element analysis (FEA) was performed to analyze the bending performance of single-channel CBPA and dual-channel SBPA against maximum pressure of 500kPa and 100kPa, respectively.

2. **Structural characterization of the pneumatic-bellows actuator**

   To analyze the bending performance of pneumatic bellows actuator, the structural parameters of single-channel CBPA were characterized in terms of bellows-width, bellows-spacing, length, diameter, wall thickness, and material to set norms for the targeted dual-channel SBPA design. In addition, the input sequence and number of bellows of dual-channel SBPA were also characterized using the MARC® software.

3. **Fabrication of pneumatic-bellows actuator**

   The optimal model of KE-1603A/B based single-channel CBPA was developed using molding and bonding technique, which set the ground for the fabrication of a biocompatible, self-supportive, monolithic, PDMS-based dual-channel SBPA using novel sacrificial molding technique.

4. **Experimental validation and performance characterization**

   An experimental setup was installed to validate the bending performance and bending force measurement of single- and dual-channel CBPA and SBPA, respectively. The thermal susceptibility of dual-channel SBPA was also characterized for possible application as surgical tool for MIS.

1.5 Potential impact of Research

Besides the tendon-driven, SMA and magnetic actuation-based mechanisms, the soft actuator delivers optimal performance to surgical robotic systems and tools. Currently, the development of minimized soft actuators with complex multichannel structures is quite difficult. The proposed bellows-structured pneumatic actuator can uniquely address these limitations and allow for implementation in a variety of potential applications. One of these promising applications is MIS, where the powering method, biocompatibility, and overall size are very crucial factors to ensure the achievement of minimal invasiveness and long-term operation. The biocompatible pneumatic bellows catheter proposed in this study would facilitate surgeons and benefit the patients undergoing endoscopic surgery by reducing the risks of damaging the internal organs and tissues. Moreover, the development of novel monolithic PDMS based dual-channel SBPA through the sacrificial molding technique would introduce a simple fabrication method, which would enable the development of multiple-channel complex soft actuator designs. The fabrication method developed to cast bellows structured actuators offers fast, reliable and cost-effective solutions through batch-fabrication processes. The proposed study contributes to multidisciplinary fields and can be utilized in several research areas. The successful outcomes of this research are expected to promote advances in soft mechanism-based technologies in biomedical fields and beyond.

1.6 Thesis Outline

This thesis presents the design, fabrication, and characterization of the bellows-structured pneumatic actuator in circular and square-shaped configurations. First, a macro-scaled single-channel CBPA was developed using the molding technique, while its bending performance was validated experimentally. To attain biocompatibility with bidirectional bending, a novel monolithic PDMS-based dual-channel SBPA was developed using the sacrificial molding technique. The bending performance of dual-channel SBPA was validated experimentally and the exerted force was measured at room temperature. Moreover, the bending performance of dual-channel SBPA was further characterized for thermal insusceptibility. The thesis comprises of six chapters. Chapter 1 has presented the background of research, followed by the problem statement, research objectives, scope and potential impact of the research.

Chapter 2 presents the critical review of the literature related to surgical robotic systems, intracorporeal tool, and devices, especially for MIS applications. A comprehensive comparison of typical actuation mechanisms including, tendon driven, SMA, magnetic, and soft pneumatic and hydraulic actuators along with their performances is elaborated.

To achieve the said research objectives, Chapter 3 presents the methodology adopted throughout this research. It covers the step-by-step workflow involved in the development of bellows-structured pneumatic actuators including; design, FEA, fabrication and performance characterization of single-channel CBPA and dual-channel SBPA, respectively.

Chapter 4 elaborates on the steps followed in the development of single-channel CBPA. Starting from the designing of the actuator, the material, and geometrical analysis, the effects of the structural characterization on the bending performance of the actuator and the bending angle calculation is presented. The fabrication of macro-scale single-channel CPBA using the molding technique and experimental validation of the bending performance and exerted force by single-channel CBPA is measured. A portion of this chapter has been published in *The International Journal of Advanced Manufacturing Technology* and *Jurnal Teknologi.*

Chapter 5 presents the steps followed in the development of dual-channel SBPA. Starting from the design configuration, the material and geometrical analysis, structural characterization and their effects on the bending performance of the actuator are elaborated. Next, the fabrication of monolithic self-supportive PDMS-based dual-channel SBPA using the sacrificial modeling technique is presented, followed by the experimental validation of bending performance and force measurement of the dual-channel SBPA. Lastly, the thermal susceptibility of dual-channel SBPA is validated and discussed. A portion of this chapter has been accepted in the *Smart Materials and Structures* journal and published in the *AsiaSim-2017* conference.

The thesis concludes with Chapter 6, which summarizes the key research findings and contributions to knowledge, followed by the directions for the future works. Lastly, the list of publications arising from the thesis is presented.

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