Medrobotics FLEX System

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***Abstract*— Medrobotics' FLEX System is a novel endoscopic platform that has been successfully introduced in cardiovascular and more recently in oropharynx and hypopharynx procedures. Preliminary clinical experience shows promise as a surgical tool in head and neck oncology.**

Keywords—minimally invasive surgery; single port surgery; NOTES; surgery

I. INTRODUCTION

The Medrobotics' FLEX System™ (Medrobotics Inc., Raynham, MA, USA) is a highly articulated platform that features a multilink endoscope allowing minimally invasive procedures in target organs located deep within the body and otherwise difficult or previously impossible to reach through a single port. The FLEX system contains multiple open accessory channels to accept a variety of compatible flexible surgical and interventional instruments as well as on-board visualization. The platform is self-supported and enables physicians to drive and navigate through non-linear circuitous paths, and through a single access point into the body. The FLEX system's flexibility and motion is gained from its numerous mechanical linkages (>30) with two concentric mechanisms. Each mechanism can be placed into a rigid or flexible state. By employing a patented "follow-the-leader" movement strategy with these two alternate states (rigid or flexible), FLEX can be directed into any shape through the relative orientation of its linkages.

The multi-jointed FLEX System Scope component is disposable to ensure sterility, whereas the physician console and feeder unit are reusable. In addition to the core system there are a number of accessories: (i) a support stand, which attaches to the operating table and enables easy positioning of the Scope into the clinical site of interest; (ii) a camera system, incorporated into the distal tip, employs a near high-definition CMOS camera and LED lamps for high-quality visualization of the site of interest; and (iii) 3rd party hand-held compatible flexible instruments, allowing rotation and articulation, in addition to triangulation towards the site of interest. The surgeon retains tactile feedback from the instruments, enabling more efficient and safe retraction, dissection, and excision of tissue for the desired clinical application. A key distinguishing feature of the FLEX System Scope is that it contains multiple degrees of freedom distributed across its length and it is self-supporting. When compared to the 7 degrees of freedom of movement possible using the human arm, the FLEX's

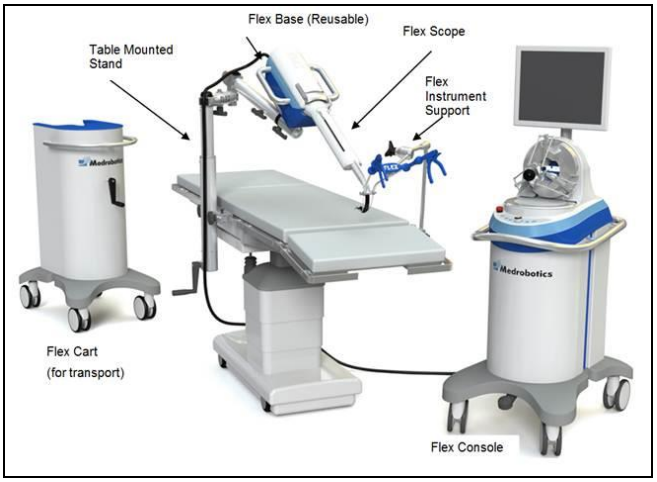

Figure 1. Medrobotics FLEX System

greater than 30 degrees of freedom enhance the physician's ability to access, visualize, and with 3rd party tool perform interventions in hard to reach anatomic targets. The FLEX system accepts an operator-defined input to generate a unique shape in 3D space. The FLEX can track along this curvilinear 3D path and return to points along the path or take a new shape as defined by the operator. One shape can be "remembered" at a time. This core property allows the FLEX to work outside the constraints of a natural lumen, such as the oropharynx, or on the surface of an organ, such as the heart. The FLEX's exact shape and location can remain static allowing it to hover in place without any tremor while delicate procedures are being performed at its distal end, and then automatically retract along the exact same path from where it came to protect the delicate anatomic structures and surrounding tissues from compression or friction damage. Additionally, the FLEX not only

supports its own weight but can support additional loads via instruments delivered through its channels for dissection or retraction. Conversely, the FLEX can become limp, allowing it to take the shape of the surrounding structures. In this state the FLEX will lie in a hand as a soft braided rope, which is an important safety feature.

II. Pre-clinical and Clinical Experience

A. Cardiovascular Applications

The first report of pre-clinical cardiac applications of the FLEX System prototype in a porcine preparation was published by Zenati and Choset in 2006 and referred to as the "CardioARM" system [1]. The first human use (FHU) trial of the clinical prototype of the FLEX System was initiated in February 2010 and successfully completed in June 2010 with a total of three patients having been enrolled [2]. The FHU procedures were all performed in Prague, Czech Republic with approval from the local Institutional Review Board by Drs Neuzil (cardiac electrophysiologist) and Czerny (cardiac surgeon). The physicians were able to perform all elements of the clinical protocol without incident and the cases were completed in less than 5 hours from initial access to skin closure per approved protocol. All patients were discharged home 1–2 days later without any adverse events reported. During these procedures, a J&J CARTO mapping and ablation catheter was used successfully through the FLEX's instrument channel. Up to 200 recordings from the patient's beating heart surface using the CARTO mapping electrodes demonstrated that the FLEX system could be safely manipulated within the pericardial space from a small single subxiphoid port and over the heart's ventricular surfaces in a human with no induced hemodynamic changes in the heart. The clinical prototype of the FLEX was also able to integrate well with high-tech imaging modalities frequently used by interventionalists, such as intracardiac echocardiography (ICE), fluoroscopy, electroanatomic mapping (CARTO), and direct endoscopic visualization.

The portfolio of cardiovascular diagnostic and therapeutic applications of the FLEX system include epicardial beating heart atrial and ventricular mapping and ablation, epicardial injections of stem cells or tissue-engineered scaffolds for regeneration, delivery of left atrial appendage closure devices, pacing leads, etc. [3]

B. Eye, Ear & Throat (ENT) Applications

Unhindered access to the laryngopharynx is best achieved with a flexible instrument that can be introduced through the oral cavity. Although the FLEX system was originally designed for cardiac procedures, the robot has 102 degree-of-freedom and a snakelike advancement mechanism capable of steering a nonlinear, self-supported path also in other organ spaces within the body. Accordingly the FLEX Scope was modified and transformed into the Medrobotics FLEX System, developed specifically for use in applications requiring nonlinear access such as transoral surgery [4]. This flexible platform drives a chip-on-tip endoscope through nonlinear pathways, and provides a platform for the delivery of compatible flexible instruments. In a recently published study, the utility of the Medrobotics FLEX System for visualization and access to areas normally difficult to reach within the laryngopharyngeal complex was demonstrated. Feasibility of access and visualization without the use of suspension laryngoscopy, which comes with its own associated risks and disadvantages including dental injury, lingual nerve injury, and additional operative time, was confirmed. The FLEX System was also found capable to act as an appropriate platform for 3rd party compatible instruments, allowing successful surgical resections in the upper aerodigestive site.

The most recent iteration of the Medrobotics FLEX System for ENT applications consists of 50 discrete linkages that are capable of rotating 13 degrees with respect to each other. The leading linkage, that is, the most distal linkage, is controlled by the surgeon. Using the joystick-like control handle, the leading linkage is pointed in the desired direction and advanced millimeters at a time along the directed vector. The remaining linkages of the flexible Scope are also advanced, following the precise pathway of the leading linkage in a ''follow- the-leader'' fashion. The leading linkage serves as the housing for important surgical hardware including a camera, LED lamps, lens washer, and two external accessory channels. The system's two-dimensional video is captured via a specialized ''chip-on-a-stick -type'' scope embedded in the distal end of the device, and thus the camera position and orientation corresponds to the controlled position of the distal linkage of the FLEX Scope. Fixed into this linkage, the camera can be moved from side to side, up and down, and the image rotated upon its axis. The camera can also be controlled to zoom digitally. The video is then relayed to a high-definition, two-dimensional video screen. Compatible flexible instruments can be inserted through the accessory channels for tissue manipulation. Instruments are passed through the accessory channels and are manipulated manually by the surgeon with two hands without requiring instrument crossing, thus preserving instinctively and natural control.

REFERENCES

[1] A. Degani, H Choset, A. Wolf, T. Ota, M.A. Zenati. Percutaneous intrapericardial interventions using a highly articulated robotic probe. *Proceedings, First IEEE/EBIB International Conference on Biomedical Robotics and Biomechatronics* (BioRob'06) Pisa, Italy 2006, pp. 7-12 DOI 10.1109/BIOROB.2006.1639051

[2] P. Neuzil, V. Reddy, M.A. Zenati, R. Kuenzler, O. Svanidze. Single port subxiphoid access epicardial ablation using a snake robotic system. *Proceedings, International Society for Minimally Invasive Cardiac Surgery* (ISMICS), 2010 Annual Meeting, Berlin, Germany, June 2010

[3] T. Ota, et al., A highly articulated robotic surgical system for minimally invasive surgery. *Annals of Thoracic Surgery* vol 87, pp.1253-1256, 2009

[4] P.J. Johnson, C.M. Rivera Serrano, et al. Demonstration of transoral surgery in cadaveric specimens with the Medrobotics Flex system. *Laryngoscope* 123:1168-1172, 2013.