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FLEXDEX™: A MINIMALLY INVASIVE SURGICAL TOOL WITH ENHANCED DEXTERITY AND INTUITIVE ACTUATION

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ABSTRACT

This paper presents the design and fabrication of a novel minimally invasive surgical (MIS) tool – *FlexDex™* – that provides enhanced dexterity, intuitive actuation, and natural force feedback in a cost-effective compact package. These attributes are accomplished by means of a fundamentally new MIS tool design paradigm that employs a tool reference attached to the surgeon’s arm, and utilizes a virtual center at the tool input that coincides with the surgeon’s wrist. The resulting physical configuration enables a highly intuitive one-to-one mapping of the surgeon’s arm and hand motions at the tool input to the end-effector motions at the tool output inside the patient’s body. Furthermore, a purely mechanical design ensures low-cost, simple construction, and natural force feedback. A functional decomposition of the proposed design paradigm and associated physical configuration is carried out to identify key modules in the system. This allows for the conceptual and detailed design of each module, followed by system-level integration. The key innovative aspects of the tool design include a three-dimensional parallel-kinematic virtual center mechanism, a decoupled 2DoF end-effector design, and the associated transmissions system.

1. INTRODUCTION AND DESIGN OVERVIEW

Minimally Invasive Surgery (MIS) is gaining widespread adoption given its numerous advantages. However, existing MIS tool technologies are prone to several practical limitations. Traditional hand-hand tools either lack the necessary dexterity needed for the increasingly complex MIS procedures, or are unintuitive to operate resulting in limited functionality and

significant surgeon training times. Robotic tools generally provide excellent dexterity and controllability, but lack haptic feedback and are exorbitantly expensive, adding to the already high costs of healthcare.

This paper describes the conceptualization, design, and development of FlexDex™ [1], a novel cost-effective hand-held MIS tool that overcomes the above-described performance limitations by employing a fundamentally new design paradigm. The FlexDex tool, shown in Fig.1, comprises a rigid frame which is secured to the surgeon’s forearm via an arm-brace. The tool frame and the surgeon’s forearm provide a common ground reference for the rest of the tool. A tool shaft, which passes through a surgical port in the patient’s body during an operation, rigidly extends from this tool frame. Thus, the surgeon’s forearm motions along four Degrees of Freedom (three translations and one roll rotation) are directly imparted to the end of the tool shaft. The surgeon holds a tool handle, which is connected to the tool frame via a virtual center (VC) mechanism. The VC mechanism creates a virtual center of rotation for the tool handle that coincides with the surgeon’s wrist. With this physical configuration, the surgeon’s hand, while holding the tool handle, can move freely and naturally about the surgeon’s wrist. A cable based transmission that runs through the hollow tool frame and tool shaft transmits these two additional wrist Degrees of Freedom (yaw and pitch rotations of the surgeon’s hand) to an end-effector attached at the tip of the tool shaft. The tool handle is equipped with a thumb lever which actuates the grasping motion of the end-effector, also via a cable transmission.

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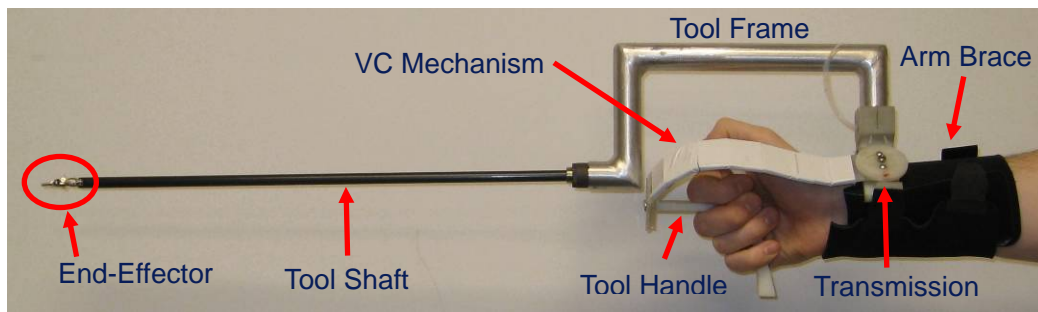


Fig. 1 FlexDex: A novel Minimally Invasive Surgical Tool with Enhanced Dexterity and Intuitive Actuation

Thus, all six Degrees of Freedom (DoF) associated with the surgeon's forearm and hand motions (three translations, one roll rotation, and two wrist rotations), in addition to a grasping action, are transmitted to the corresponding motions of the end-effector. Most importantly, attaching the tool frame to the surgeon's forearm and employing a VC mechanism to capture wrist motions, as described above, decouples these degrees of freedom, producing a one-to-one mapping from the surgeon's motion at the tool input, to the corresponding end-effector motion at the tool output. This makes FlexDex highly intuitive to use, even with minimal prior training.

In addition to its enhanced dexterity and intuitive actuation, FlexDex retains the simplicity, force-feedback capability, and cost-effectiveness of a purely mechanical tool. The cable-based transmission allows for variable motion scaling between the tool input and output, by simply adjusting pulley sizes and cable connection points. The FlexDex design also offers the additional advantage of a locally closed load-loop, which reduces reaction loads at the surgical port on the patient's body. All these attributes make FlexDex highly competitive, in terms of functionality, with current robotic surgery systems that are considerably more bulky, complex, and expensive. A video that demonstrates the functioning and advantages of FlexDex may be viewed at [2].

This paper is organized as follows. Section 2 presents an overview of the current status, emerging trends, and technology needs in MIS. Section 3 provides a comprehensive review of the present state of the art in MIS technology, including hand-held tools, conventional robotic systems, and *in vivo* robots. Section 4 highlights the need for new technology development in MIS tools and, based on this, presents the design requirements for this research. To address these, a new MIS tool design paradigm is presented in Section 5 that leads to a novel physical configuration. A functional decomposition of this physical configuration into individual modules helps pave the path for detailed design in Section 6. Section 7 presents the integration of all these modules into the present embodiment of FlexDex, followed by a summary of the design features and functionality achieved. The paper concludes in Section 8 with plans for future development and testing.

2. MINIMALLY INVASIVE SURGERY BACKGROUND

Since the 1990s, surgery has benefited from advancements in materials, manufacturing techniques, and micromechanical technology [3], which have enabled the development of precise

surgical tools and robotic devices that allow a surgeon to perform increasingly complicated procedures through a few small incisions [3-6]. These procedures, variously referred to as Minimally Invasive Surgery (MIS) or Minimal Access Surgery (MAS) or laparoscopic surgery, are characterized by the use of a small camera and thin tools introduced into the body through small incisions, or ports, to perform an operation that would ordinarily require more invasive direct access through a single much larger incision (Fig.2). The benefits of MIS include reduction in trauma, blood-loss, scarring, and post-operative pain for the patient, and considerable cost-savings due to shorter hospital stays, less postsurgical pain medication, faster recovery times, and reduced risks of post-operative complications [3-6].

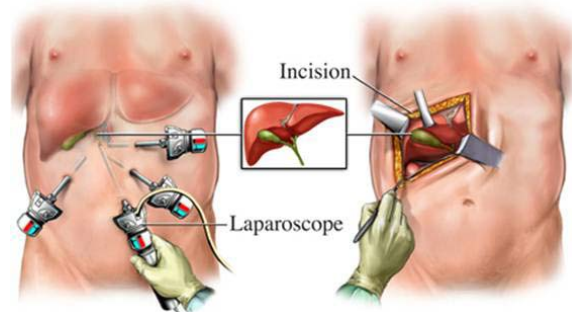


Fig. 2 Minimally Invasive vs. Traditional Surgery [9]

Due to this wide range of benefits, MIS procedures have grown significantly and now impact almost all surgical specialties including endocrine, pediatric, bariatric, urologic, abdominal, gynecological, cardiothoracic, general, and orthopedics [4]. In 2007, the minimally invasive surgery market was valued at \$19.7 billion. This market is expected to continue to expand, with a projected growth of 9% to \$30.6 billion by 2012 [4, 7]. This growth rate is driven by the desire for reduced health-care spending, a continued shift towards shorter hospital stays and more outpatient surgeries, and a greater focus on training surgeons in MIS procedures. In a report released by the Center for Disease Control in 2006 [8], an estimated 57.1 million outpatient surgical procedures were performed, which represents an approximately 66% increase in such procedures since 1996.

Given these market drivers, several new technology and procedural trends have emerged in MIS, in the recent years. Hand-held tools have been augmented to provide greater dexterity to support the increasingly complex MIS procedures

carried out by surgeons. Robotic and telerobotic surgery has grown significantly with advances in visual feedback systems [10]. Furthermore, new MIS techniques including single-port and NOTES procedures have evolved. Single-port surgeries are performed using only one incision in the body, typically at the naval, and have been successfully conducted on the gallbladder, appendix, ovary, and colon [11]. Natural Orifice Transluminal Endoscopic Surgery (NOTES), which, as the name suggests, is performed through the body's natural orifices [12]. These methods allow for even faster recovery times, zero external scarring, and generally improved patient care.

Given these trends in MIS, the key requirements that emerge for the next-generation tool technology include enhanced dexterity in terms of greater DoF at tool end-effector, intuitive actuation of these DoF, force feedback, and a cost-effective design. Collectively, these attributes can lead to a significantly wider adoption of MIS. The state-of-the-art in MIS tool technology is discussed in the following section.

3. STATE OF THE ART IN MINIMALLY INVASIVE SURGERY TOOL TECHNOLOGY

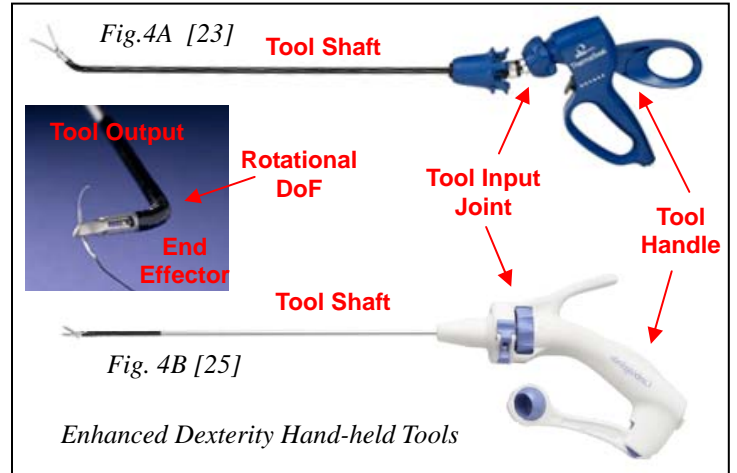
MIS tool technology can be broadly classified into three categories: Hand-held mechanical tools (traditional and enhanced-dexterity), robotic surgery systems, and internal (*in vivo*) surgical robots. The features, advantages, and disadvantages of each category are described below.

3.1 Hand-held Tools

Traditional hand-held tools represent the oldest and most common technology used in MIS. A hand-held tool typically consists of a thin, long shaft and is actuated via a scissor-like gripper at the surgeon's hand. This actuation is translated to the open/close motion of a cutting or grasping end-effector at the tool output. However, in traditional designs [13-16], the end-effector does not have any wrist-like Degrees of Freedom. (Fig.3). While such purely mechanical tools are light-weight, inexpensive, and inherently provide force feedback, their lack of wrist-like articulation at the end-effector renders them ineffective for the increasingly sophisticated MIS procedures, often requiring complex combinations of arm, forearm, hand, and wrist motions for relatively simple internal motions[17].



The most significant recent technological advance in hand-held MIS tools has been the incorporation of two additional wrist-like rotations of the end-effector with respect to the tool shaft [19-24]. With the two additional DoF, these 'enhanced-dexterity' hand-held tools are capable of greater articulation at the end-effector, while retaining the grasping action. However,



the control of these two additional two DoF remains highly unintuitive and non-ergonomic [19-24].

The RealHand™ HD from Novare [22-23] (Fig.4A) is one of the most common commercially available tools in this category. The two wrist-like rotations of the end-effector at the tool output are actuated via a universal joint at the tool input. However, because of this physical arrangement the user has to provide a complex, non-intuitive combination of multiple input motions (forearm bent down, wrist bent up) to produce a simple rotation at the tool output. During this actuation, even though the tool shaft is held in its nominal position, the user's forearm is forced out of alignment with the tool shaft. This awkward input motion is due to the fact that the tool's input joint (i.e. universal joint) is not collocated with the user's input joint (i.e. wrist). Another enhanced dexterity hand-held tool, the LaparoAngle™ from Cambridge Endo [24] (Fig.4B), provides a rotational knob at the tool input to control the end-effector rotation.

While these tools benefit from the previously stated advantages of a purely mechanical construction, both are unintuitive and non-ergonomic especially for tasks such as suturing because the surgeon has to produce the necessary level of articulation at the end-effector via a complex combination of arm, forearm, hand, and wrist motions [17]. Thus, despite their enhanced dexterity, their widespread adoption in intricate MIS procedures has been limited due to considerable surgeon training time and associated costs.

As illustrated later in Section 5, all existing hand-held tools involve an external load loop that exerts reaction forces at the surgical port, potentially causing damage to the surrounding skin and tissue of the patient.

3.2 Robotic Surgery Systems

While currently accounting for a relatively small number of procedures, robotic systems are employed for a range of surgeries and continue to grow in popularity as hospitals invest in hardware and training [3,10]. Robotic surgery systems typically comprise a user input unit that is mechanically isolated from the output, which typically comprises a sophisticated arrangement of highly articulated robotic arms

equipped with mechanical tools and end-effectors. The surgeon's hand and finger motions are captured by electronic sensors; this information is transmitted to a computer, which controls the several actuators on the robotic arms so as to translate the surgeon's input motions to the end-effector inside the patient's body. Such a computer-controlled system offers several outstanding features including high dexterity enabled by the multi-DoF robotic arms, a highly intuitive input-output motion mapping, variable motion scaling, and unprecedented hand-tremor reduction [25-27]. The da Vinci® Surgical System (Fig. 5) by Intuitive Surgical is one of the most developed robotic systems on the market in this category [26-29].

Despite the numerous advantages listed above, one of the key drawbacks of current robotic systems is the lack of force feedback. Because there is no direct or mechanical connection between the system's input and output, the surgeon receives no force feedback to gauge the forces exerted by the tool end-effector. While considerable research is being conducted to incorporate haptic feedback in robotic surgery systems [30-34], none of these technologies have yet been integrated in commercially available products, given their associated cost and complexity.

More importantly, the size and high cost of robotic systems greatly limit their widespread use. The da Vinci system initially costs \$1.5 million and each surgery uses up to \$2000 in parts [26]. Furthermore, given the relatively large size of robotic arms in these systems, the variety of surgical procedures that may be performed is restricted due to limited accessibility and maneuverability inside the patient's body. Even though some clinical reports on prostatectomy [35] indicate the benefits of robotic surgery in terms of dexterity, intuitive control, and visualization, the burden of training and additional credentialing, room setup time, and robot access remain barriers to a wider adoption of this technology.



Fig. 5 Da Vinci Surgical System [27]: Input and Output

3.3 Internal (*in vivo*) Surgical Robots

Miniature *in vivo* robots that completely enter the body through natural orifices and operate from within represent another emerging frontier in MIS technology [12, 36] that could be useful in military applications. A mobile miniature robot equipped with a camera (Fig.6) may be inserted into the body of a soldier to perform surgery, while being controlled remotely by a surgeon. However, this technology is still in the early developmental phase and is yet to be incorporated in a commercially viable product.



Fig. 6 Mobile *in vivo* Surgical Robot [12]

4. NEED FOR NEW TECHNOLOGY AND PROBLEM SPECIFICATION

As is evident from the previous section, the existing technology in MIS tools is extensive and provides a wide range of impressive functionality, but a single solution capable of all the desired attributes is currently missing. Hand-held tools are light-weight, inexpensive, and provide force feedback but either lack the necessary Degrees of Freedom or an intuitive means for actuating them. Robotic systems are highly intuitive to operate and provide excellent hand tremor reduction, but lack force feedback, prove to be too bulky for certain procedures, and are exorbitantly expensive.

To enable widespread adoption of MIS, there is clearly a need for new technology that meets all of these desired attributes simultaneously, providing high functionality at low cost. Based on the above observations and discussions with surgeons at the University of Michigan's Department of Surgery, the following list of desired attributes or *Design Requirements* (DR) in a new MIS tool was compiled.

DR1. Simple and low-cost construction: A simple and light-weight design and construction not only allows better accessibility in MIS procedures, it also provides for lower manufacturing and assembly costs. The latter is important for commercial viability and market penetration.

DR2. High Dexterity and Intuitive Actuation: In terms of functionality, high dexterity or adequate Degrees of Freedom is the first and foremost requirement. In addition to the standard four DoF (three translations and one roll rotation) plus grasping ability, it is necessary to provide wrist-like articulation at the tool end-effector via two additional DoF (pitch and yaw rotations).

Equally important, however, is a means for intuitively actuating of all these Degrees of Freedom. Such intuitive input-output motion mapping can be achieved if the DoF motions of the tool end-effector match those of the surgeon's input motions. Fig. 7 shows the three translations motions and roll rotation of the human forearm, the two rotational motions of the hand (pitch and yaw at the wrist) about the forearm, and the grasping motion using fingers/thumb. It also shows the corresponding DoF desired in an ideal MIS tool. These include three translations and roll rotation of the tool shaft, two wrist-like rotations of the end-effector about the tool shaft (pitch and yaw rotation at the output joint), and a grasping motion of the end-effector. An MIS tool that provides a one-to-one mapping

between the input motions/DoF at the user end and the output motions/DoF at end-effector, in a fashion such that these multiple DoF are largely decoupled, would greatly facilitate the intuitive actuation of the tool by a surgeon.

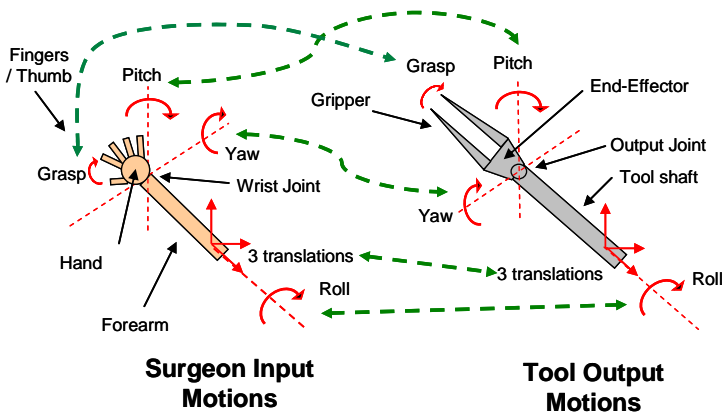


Fig. 7 One-to-one DoF mapping between the Surgeon's Input Motions and Tool Output Motions

While such one-to-one mapping is common for the standard four DoF plus grasping motion in the existing tools, a natural mapping does not exist for the additional two wrist-like rotational DoF. An ideal tool should be able to directly and exclusively translate the surgeon's natural wrist rotations (without requiring any other input motions) to the two wrist-like rotations at the end-effector. This minimizes the learning curve required to perform intricate end-effector manipulations in MIS, such as suturing.

DR3. Natural and Unrestricted Range of Motion: To provide the surgeon with a natural and intuitive feel as he/she actuates the MIS tool, it is necessary that the tool input be such that it allows large and unrestricted input motions at the surgeon's forearm, hand, wrist, fingers, and thumb.

DR4. Mechanical Force Feedback: Force feedback allows the surgeon to maintain precision and control during an MIS procedure. A mechanical or kinematic transmission of motions from the surgeon at the tool input to the end-effector at the tool output also ensures that forces at the end-effector are transmitted back to the surgeon. This is an inherent and advantageous feature of purely mechanical designs over their robotic counterparts.

DR5. Minimize Reaction Loads Exerted on the Patient's Body: Most existing hand-held tools rely on an external ground reference, typically the surgical port, to draw reaction loads so as to close the load-loop during tool actuation. This is potentially detrimental to the skin and tissues around the surgical port. An ideal MIS tool should exert minimal (ideally zero) reaction loads on the patient's body during tool actuation.

DR6. Motion Scaling: MIS procedures often involve much smaller workspaces than traditional open surgeries. A tool that could scale up or scale down the end-effector motion depending on the workspace and nature of the procedure would provide additional flexibility and utility in an operating environment. For example, translating a 30° hand rotation to a

10° end-effector rotation could provide greater precision, while doing the reverse could provide a greater work-range. Ideally, the MIS tool should provide multiple transmission ratios.

DR7. Hand Tremor Reduction: The degree of precision and scale at surgery is performed is often limited by natural tremors in the surgeon's hand. It is therefore desirable to minimize these tremors via the MIS tool design, so as to enable a wider range of MIS procedures.

DR8. Modularity and Adjustability: An ideal MIS tool should be modular; interchangeable tool tips add flexibility in application and during procedures. In addition, a modular tool adds flexibility in tool design with respect to sterility and material compatibility. It is also very important that the same size tool accommodates a range of surgeon hand sizes as well as hand preference (left or right), so as to maximize its utility in a clinic or hospital and minimize manufacturing costs.

The above list of Design Requirements (DR) provides the problem specification for the MIS tool design presented in this paper.

5. PROPOSED DESIGN PARADIGM

Given the various advantages associated with a purely mechanical construction, we choose this option from the onset since it inherently meets DR1 and DR4. However, achieving the remaining DRs in a single MIS tool design is not a trivial task and a fundamental departure from the traditional MIS tool design paradigm is needed. For reference, Fig.8A illustrates an existing enhanced dexterity MIS tool [23], which passes through a simulated surgical port and is actuated by a user to produce a single DoF pitch rotation at the end-effector.

It may be noted that the user has to provide a non-intuitive combination of multiple input motions (forearm bent down, wrist bent up) to produce a simple rotation at the tool output. This is in contrast to Fig. 7, which suggests a one-to-one mapping between the user's input DoF and the tool output DoF to ensure intuitive actuation. In Fig 8A, even though the tool shaft is held in its nominal position during the end-effector pitch rotation, the physical analog at the tool input – the user's forearm – does not stay in its nominal position. Rather, because the end-effector rotation is inverted with respect the tool handle rotation, the user's forearm is forced out of alignment with the tool shaft. This awkward input motion is due to the fact that the tool's input joint is not collocated with the user's input joint (i.e. wrist).

Moreover, such a placement of the tool input joint also makes the actuation of the tool dependent on the presence of a ground reference, which can provide reaction loads, or in other words, close the load-loop. Referring again to Fig. 8A, the user applies a torque at the tool handle, and the surgical port provides the balancing loads necessary to allow the handle to tip downwards, which then tips the end-effector downwards. The load-loop (shown by the dashed line), in this case, comprises the tool handle, tool shaft, surgical port, patient's body, the ground that the patient's body rests on, the ground that the surgeon stands on, the surgeon's body, the surgeon's

forearm, and the surgeon's hand that grips the tool handle – in that order. This implies that all the tool actuation loads necessarily flow through the surgical port and patient's body. These loads are particularly detrimental to the skin and tissue surrounding the surgical port, in the case of young or elderly patients.

All these drawbacks are interrelated and reflect a sub-optimal design paradigm employed in the physical configuration conception of existing hand-held tools. Since the tool shaft is a physical analog of the user's forearm (Fig.7), there are several advantages associated with mechanically attaching it with respect to the user's forearm.

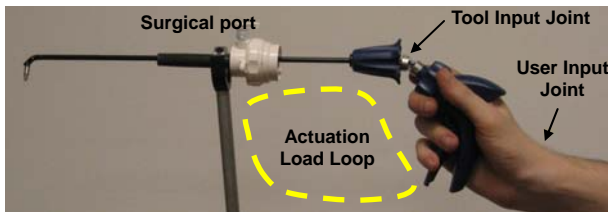


Fig. 8A. Traditional Hand-held MIS Tool Configuration

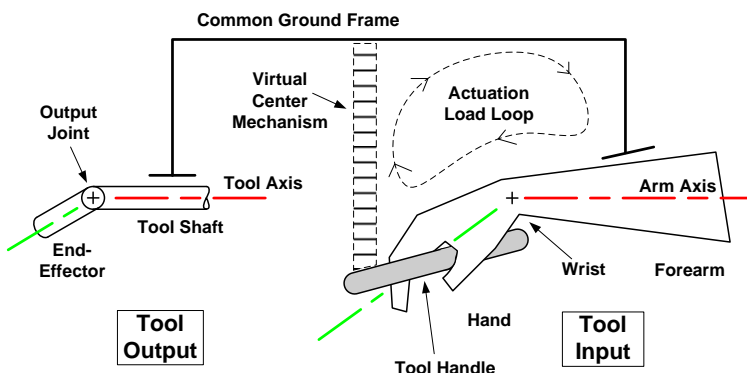


Fig. 8B. Proposed Hand-held MIS Tool Configuration

This proposed alternative design paradigm, illustrated in Fig. 8B, provides a common ground frame that bridges the tool shaft and user's forearm. One of the most obvious advantages of this configuration is that now the user's forearm motion directly guides the four DoF associated with tool shaft: three translations and one roll rotation. This leaves the user's wrist free to actuate the two end-effector rotations — cleanly decoupled from the other four DoF.

Having achieved this decoupling, the next objective is to allow the user's hand to rotate freely and naturally about the user's wrist, which requires that the tool input joint and user's input joint (i.e. wrist) be coincident. This is obviously non-trivial since it is impossible to collocate a 'real' tool input joint with a human wrist due to physical interference. However, this challenge may be overcome by employing a Virtual Center (VC) mechanism. A VC mechanism does not require the physical space occupied by the user's wrist; instead, it can be designed to project a 2DoF 'virtual' joint or center of rotation at the user's wrist.

Next, the motion of the tool handle (and therefore the user's hand) with respect to the Common Ground Frame may

be captured and transmitted to the end-effector, thus providing an entirely intuitive and natural actuation. This also ensures that when only a wrist-like rotation is needed at the end-effector, the user only actuates his/her wrist at the tool input and the user's forearm remains aligned with the tool shaft. In theory, this completes the one-to-one motion mapping of the user DoF to the corresponding end-effector DoF, as required in **DR2**.

Moreover, employing the user's forearm as a ground reference locally closes the load-loop associated with the wrist DoF actuation forces (dashed line in Fig. 8B). In marked contrast with the existing hand-held tools, this entirely eliminates the need for an external ground reference, such as the surgical port, to provide reaction loads. This greatly reduces any loads exerted on the patient's body during an MIS procedure, thus meeting **DR5**.

The MIS tool physical configuration resulting from the proposed paradigm is such that the tool simply becomes a natural extension to the user's forearm and hand, which is fundamentally different from present hand-held tool configurations. Based on this design paradigm, and associated physical configuration, we proceed to develop a novel hand-held MIS tool, referred to as FlexDex, with the objective of meeting all the **DRs** listed in the previous section. While the rationale for meeting **DR1**, **DR2**, **DR4**, and **DR5** has already been discussed, the remaining **DRs** rely on the detailed implementation of the proposed paradigm, which is described in the next section.

6. DETAILED DESIGN AND IMPLEMENTATION

The hardware implementation of the proposed design paradigm is carried out by first conducting a hierarchical functional decomposition to identify key modules in the system. These modules are individually developed while keeping in mind the overall system integration requirements. The following list is representative of the primary functions in FlexDex design and associated hardware modules to meet these functions. The reader is referred to Section 1 and Fig.1, for a brief overview of the terminology used in this section.

6.1 Tool Input

The tool input comprises a handle that surgeon grips, a Virtual Center Mechanism that connects the handle to the tool frame, a transmission system that captures the surgeon's wrist rotation, and a means for actuating the open/close motion of the end-effector.

A. Virtual Center Mechanism and Transmission: The Virtual Center (VC) Mechanism represents the most important innovation in FlexDex. Its purpose is to produce a virtual center of rotation for the tool handle that coincides with the user's wrist, thus enabling a natural and intuitive actuation of the two wrist-like rotations of the end-effector. Apart from the system-level design requirement stated earlier, the key requirements associated with the VC Mechanism are: **DR-I**. It should obviously provide a virtual center located at the user's

wrist, **DR-II**. It should create a virtual center that remains collocated with the user's wrist throughout the user's range of wrist motion. Any drift of the virtual center due to the VC mechanism kinematics can result in over-constraint and limit the user's natural motion range, **DR-III**. It must allow for a practical transmission system that can capture the user's wrist rotations and translate them to corresponding rotations of the tool end-effector, and **DR-IV**. It must be compact compared to overall tool size while avoiding any interference with other modules in the system.

The need for a VC mechanism arises because it is physically impossible to locate a joint or center of rotation at the user's wrist. However, two fixed orthogonal axes of rotation can be located such that their intersection creates a virtual center of rotation; hence, no physical structure need exist at the wrist. A VC mechanism based on this concept is illustrated in Fig. 9A. Pitch and yaw rotation axes are shown at the bottom of this figure. The tool handle is connected to a 'pitch transmission strip' and 'yaw transmission strip' oriented orthogonally with respect to each other. These two transmission strips, in turn, are pinned about respective shafts along the pitch and yaw axes. Since these two rotation axes, defined by the pin joints, are fixed with respect to the tool frame, their intersection, which is the virtual center of rotation for the tool handle, always remains stationary with respect to the tool frame. Since the tool frame, in turn, is securely attached to user's forearm, this virtual center can be provided such that it coincides with the user's wrist at all times. This helps meet **DR-I** and **DR-II** listed above.

It is important to note that the pitch transmission strip is stiff about the pitch axis, but is compliant about the yaw axis. Therefore, it allows the transmission of only the pitch component of the rotation of the tool handle to the pitch transmission pulley while filtering out the yaw component by easily bending about the yaw axis. An analogous argument holds true for the yaw transmission strip, which strictly transmits only the yaw component of the handle rotation to the yaw transmission pulley, while rejecting any pitch component. This provides a mechanical filtering arrangement such that, given any random combination of yaw and pitch rotations at the tool handle made by user's hand, only the yaw component is picked up by the yaw transmission pulley and only pitch component is picked up by the pitch transmission pulley.

This greatly simplifies the input motion transmission problem since we can now deal with two entirely independent rotations of the two transmission pulleys about their respective axes that are fixed with respect to the tool frame. A pitch transmission cable and a yaw transmission cable may then be employed in conjunction with the respective pulleys to transmit the user's two wrist rotations separately to the end-effector rotations. This not only meets the system-level **DR2**, but also the module level requirement for enabling a simple and practical transmission system **DR-III**.

To further address the system-level **DR3** and module-level **DR-II**, the geometry of the blades is chosen such that they do

not impose any constraint along the tool axis. The length of the transmission strips is not dictated by the design and can be chosen to accommodate a wide range of user hand sizes, thus fulfilling system-level **DR8**. To validate the expected benefits of this 'Fixed-Axis' Virtual Center Mechanism, we first built a simple prototype (Fig. 9B), which indeed corroborated all the above-mentioned expectations.

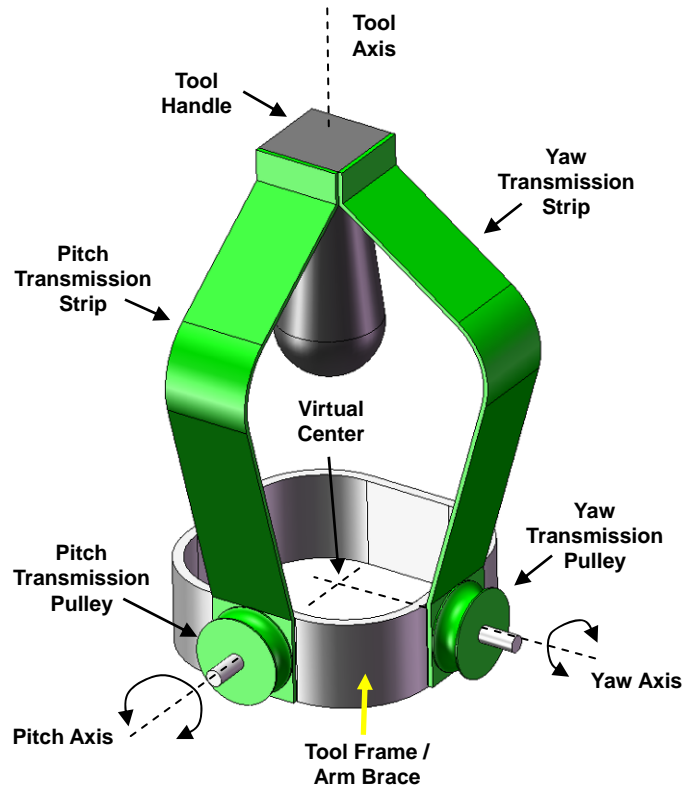


Fig.9A Fixed-Axis Virtual Center Mechanism Concept

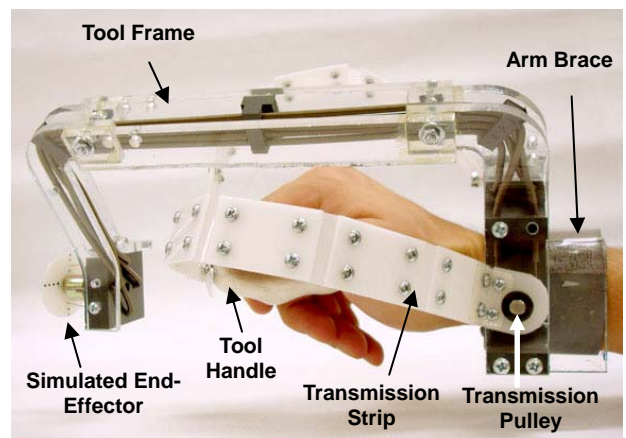


Fig.9B Fixed-Axis Mechanism Concept Validation

The key design attribute of the transmission strips is that they are compliant in bending about their thin cross-sectional dimension and highly stiff in bending along their large cross-sectional dimension. Moreover, a high stiffness in the twisting

direction is also needed to avoid any motion loss in the transmission from the tool handle to the two transmission pulleys. This may be ensured by the use of a series rigid strips interconnected by identical small length flexural pivots (Fig. 9B), as opposed to a thin continuous strip (Fig. 9A).

A cable based transmission system from the transmission pulleys to the end-effector is ideally suited for FlexDex, given the narrow bore of the shaft and the fixed axes of the pulleys. Cables threaded through cable-sheaths provide for an easy routing around the tool frame and through the tool shaft, as evident in mockup prototype of Fig. 9B. This VC mechanism and associated pulley based transmission system allows one to easily vary the pulley size to change the motion scaling from the tool input to tool output as desired in DR6. Appropriate features may be easily built into this design such that input-output motion scaling can be either discretely or continuously varied by the user.

B. Tool Handle and Gripper Actuation: The tool handle provides the interface between the user’s hand and the VC mechanisms and is designed to be comfortable and ergonomic. In addition to being a mechanical interface to the VC mechanism, the handle design must support a means for actuating the open/close motion (e.g. gripping) of the end-effector. The tool handle design employed in FlexDex is relatively simple (Fig. 10) but carefully takes into consideration ergonomics studies and guidelines for MIS tools [37-38]. The handle is slanted at a 17° angle to fit the typical natural angle of the hand at its neutral position [39].

For actuating the gripping motion of the end-effector, the handle is augmented with a thumb lever rather than the more common scissor-style actuation because the thumb tolerates higher forces and generates less tension in the wrist during use [39]. As shown in the figure, the thumb lever and tool handle are made monolithic by incorporating a thin flexure hinge that allows a simple relative motion between the two.

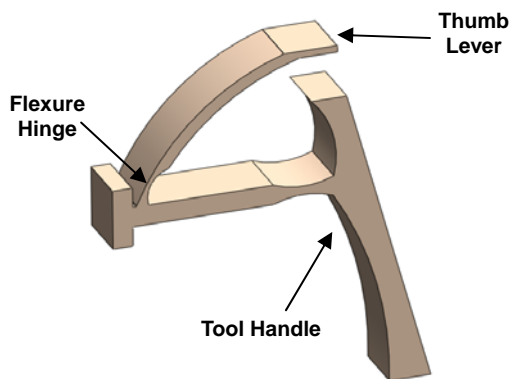


Fig.10 Tool Handle and Gripper Actuation

A cable based transmission routed around the tool frame and through the tool shaft, similar in concept to the wrist motion transmission system, is used to translate the thumb lever actuation from the tool input to the open/close motion of the end-effector.

6.2. Tool Output

The tool output in the FlexDex design comprises an end-effector, capable of open/close motion, connected to the tool shaft by means of a two-DoF rotational output joint. The end-effector and the output joint have to be integrated with the wrist motion transmission system and the gripping motion transmission system. A novel nested ring output joint concept (Fig. 11) is employed in the FlexDex to produce large and decoupled rotations (yaw and pitch) of the end-effector with respect to the tool shaft.

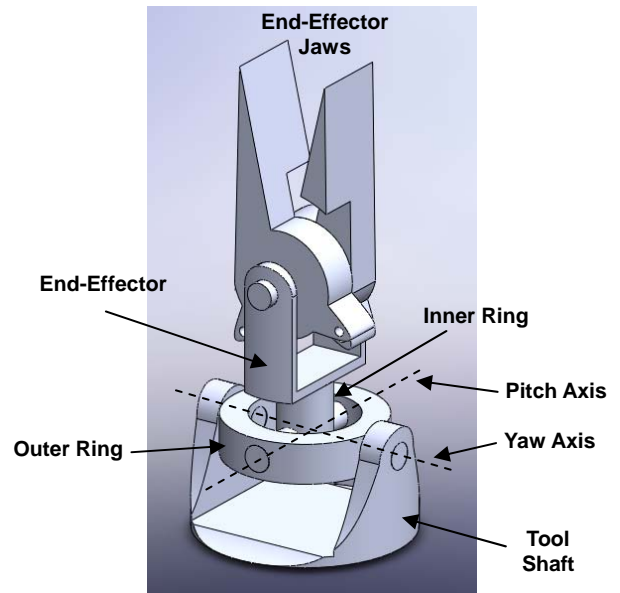


Fig. 11 Nested Ring Output Joint and End-Effector

Decoupling the two wrist-like rotational DoF at tool output is as important as doing so at the tool input, so as to meet the ultimate objective of one-to-one motion mapping between the input and output. Existing output joint designs are either based on a stacked-disk arrangement or a cascaded pair hinges.

The stacked-disk design, either flexure-based or discrete, produces very low coupling between the two DoF and can be made very thin. However, it produces a relatively large radius of curvature, and therefore large workspace, because the rotation allowed between consecutive disks is generally small. This is undesirable because it may preclude certain intricate MIS procedures that require sharp end-effector turns.

Although more expensive, cascaded hinge designs allow large rotations in very tight workspaces, along with lower friction and resistance. However, in many existing designs, such as the EndoWrist tool [27] used in da Vinci Surgical Systems, the two rotational axes are not axially collocated. This results in a coupling between the two rotational DoF at the end-effector. However, since this is a robotic system, the output coupling is easily corrected by the computer controller. This is obviously not possible in purely mechanical designs such as the FlexDex.

Therefore, to provide tight workspaces and at the same time eliminate motion coupling, the two rotational axes of the

output joint in the FlexDex are collocated in a plane (Fig.11). This is conceptually similar to the collocation of rotational axes via the VC mechanism at the tool input. An outer ring is pivoted with respect to the tool shaft about a yaw axis. An inner ring is pivoted with respect to the outer ring about a pitch axis, such that the yaw and pitch axes are orthogonal and coplanar. The inner ring is also rigidly connected to end-effector. The two ends of the yaw transmission cable are attached at two diametrically opposite points on the outer ring along the pitch axis. Similarly, the two ends of the pitch transmission cable are attached at two diametrically opposite points on the inner ring that line up along the yaw axis. Thus, the two rotational DoF as well as their associated transmissions are entirely decoupled. The gripping motion transmission cable passes through the inner ring and attaches two end-effector jaws to produce an open/close gripping motion in response to the thumb lever actuation at the tool input.

6.3 Tool Body

The tool body comprises the rigidly interconnected sections of FlexDex, including the tool frame, the arm brace, and the tool shaft.

A. Tool Frame: The tool frame is the basic structural element of FlexDex, which helps close the actuation load-loop. It is rigidly attached to the arm brace, which secures the tool to the user's forearm on one end, and is connected to the tool shaft on the other end. It provides a common ground reference for the tool handle and VC mechanism, end-effector and output joint, and the transmission systems. Additionally, it provides routing of the transmission cables from the tool handle to the tool shaft.

The tool frame design employed in the present embodiment of FlexDex is relatively straightforward (Fig.12). The frame is made of 1-inch aluminum tube, which provides a conduit for all the transmission cables. A set of 19-gauge Teflon tubes are used as low friction cable sheaths for each transmission cable. The frame is sized and oriented to avoid mechanical interference with the user's hand or transmission strips. In a more advanced prototype, the tool frame would be optimized for structural rigidity and minimal weight.

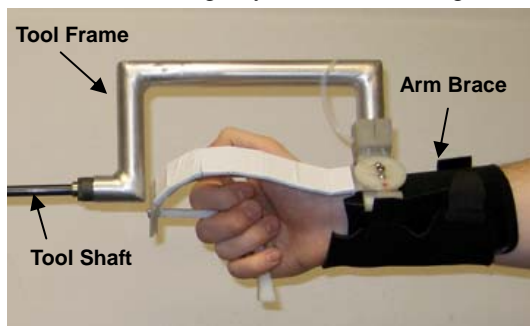


Fig. 12 Tool Frame, Arm Brace, and Tool Shaft

B. Arm Brace: An arm brace that connects the tool frame to the user's forearm is central to the proposed paradigm and its associated benefits. The arm brace should provide a secure yet comfortable interface between the tool frame and the surgeon's

forearm. Additionally, since the FlexDex may not be the only tool used during a procedure, securing the tool to the forearm and releasing it should be quick and easy.

In the present FlexDex prototype, a soft fabric-based arm brace, internally supported by rigid plates, is secured to the user's forearm using Velcro straps. This provides for a firm yet flexible mounting of the tool, and holds the tool shaft parallel and inline with the user's forearm. Such an alignment effectively captures the arm's three translational DoF and one roll DoF, and relates them to the tool shaft.

C. Tool Shaft: The tool shaft interfaces with the tool-frame on the input end and with the end-effector at the output end. It is typically a thin, long, and hollow tube, with standardized dimensions (2mm, 5mm, and 8mm) that are common across most MIS tools. The hollow tool shaft also acts as a conduit for the transmission system from the input to output and vice versa. In FlexDex, an 8mm carbon-fiber tube is chosen for its low weight and high rigidity. Future prototypes will incorporate smaller diameter shafts.

7. SYSTEM INTEGRATION AND PERFORMANCE

The detailed design, development, and validation of the above modules lead to the first fully functional prototype of the FlexDex (Fig.1). This proof-of-concept prototype corroborates the expected performance of this new MIS tool in terms of most system-level and module-level design requirements formulated earlier.

Like the traditional hand-held MIS tools, FlexDex provides a simple, light weight, and cost-effective construction, inherently capable of force feedback. In particular, the direct attachment of the tool frame to the user's forearm provides excellent feedback along the three translational and one roll DoF. Furthermore, the cable-based wrist motion transmission communicates any end-effector forces back to the user's hand.

Like other enhanced dexterity MIS tools, FlexDex provides six DoF motion plus grasping/cutting action at the end-effector. However, it provides a highly intuitive actuation, not seen in any of the other existing tools. To highlight these differences, the FlexDex is illustrated alongside Novare's RealHand™ HD tool [22] in Fig.13. Both tools are actuated to provide a pitch direction rotation at the end-effector. It is evident that to provide this single rotational DoF, the user has to generate a complex combination of input motions in case of the existing tool. Moreover, the directions of rotation of the user's wrist and end-effector are opposite and therefore counter-intuitive. Also, the user's forearm does not remain aligned with tool shaft.

With FlexDex, a single upward motion of the user's wrist produces an analogous motion of the end-effector, and the user's forearm always remains aligned with the tool shaft. This illustrates the natural and intuitive nature of actuation achieved in the proposed design.

Moreover, FlexDex allows for a full natural range of wrist motion, without imposing any mechanical constraints. It is also

important to note that while the existing tool is reliant on a surgical port, the corresponding actuation is produced by FlexDex without the presence of a surgical port. Thus, even though the FlexDex passes through a surgical port, it does not exert any significant loads on it. Furthermore, motion scaling is easily achieved via the transmission strips and pulleys employed in the design. Finally, the unique input handle and VC mechanism arrangement makes FlexDex inherently adaptable to a range of hand sizes. Because the handle is supported by flexible transmission strips, the tool does not require individual user adjustments.

By establishing all of these features in a purely mechanical design, FlexDex represents a breakthrough in MIS tool technology. It captures the positive attributes of purely mechanical hand-held tools on one end, and the enhanced functionality of robotic tools systems on the other. A video that

demonstrates the functioning and advantages of FlexDex may be viewed at [2].

8. CONCLUSION

A proof-of-concept prototype of FlexDex has been developed and has shown great promise in terms of performance, compared to other competing products and technologies. Ongoing and future plans include the development of next generation prototypes, pre-clinical and clinical trials, FDA 510K approval application, and product commercialization.

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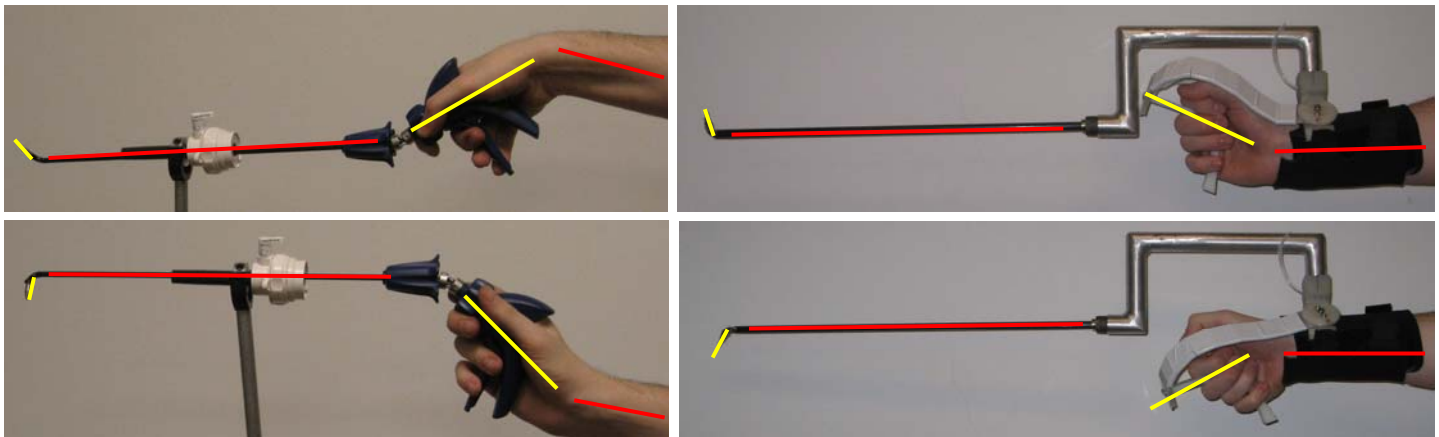


Fig. 13 Novare's RealHand™ HD MIS tool (left) vs. FlexDex (right)

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