



Design, Analysis and Experimental Validation of a Novel 7-Degrees of Freedom Instrument for Laparoscopic Surgeries

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Abstract—Laparoscopic surgery is widely used for treating intra-abdominal conditions involving the gallbladder, pancreas, liver, intestines and reproductive organs. Conventional laparoscopy instruments used in manual surgeries usually have straight shafts and four degrees of freedom (DOF) plus grasping. However, these are insufficient for the complete rotation of the instrument tip. This makes it challenging to access difficult-to-reach organs inside the abdomen during the surgeries. A few robotic instruments available in the market have higher maneuverability but are expensive. Instruments incorporating cable-based mechanisms require replacement after a few sterilization cycles. This paper describes a novel, reusable and affordable multi-DOF laparoscopy instrument that provides two additional DOF: (a) wrist articulation about one axis (wristed yaw) and (b) rotation of the jaw after articulation (jaw roll). The wrist can articulate up to 45° and also roll after articulation. The additional degrees of freedom enable better maneuverability, functionality and reach than conventional laparoscopy instruments. Further, the new instrument employs only rigid links, providing better strength and minimal loss of function after multiple sterilizations. The complete design of the novel instrument, followed by its kinematic analysis and force calculations are explained in this paper, concluding with its manufacture and experimental validation.

Keywords—Laparoscopy instrument, Degree of Freedom, Kinematic analysis.

INTRODUCTION

Laparoscopic or minimally invasive surgery involves the insertion of narrow instruments into patient's abdomen and operating the internal organs by viewing them on a screen. These surgeries have many advantages, such as smaller scar size, reduced hospital stay, lower blood loss and faster recovery than open surgeries.²⁹ These instruments have a long shaft (usually 5–10 mm in diameter) and an end effector for grasping, cutting and other tasks. They pass through a cylindrical, hollow tube called a trocar. The trocars are placed through the abdominal wall and act as a portal for the subsequent placement of other instruments, such as graspers, scissors and staplers.

Conventional laparoscopy instruments have typically four degrees of freedom (DOF) as shown in Fig. 1a: (i) Translation along the axis of insertion, (ii) Rotation of the instrument about the axis of insertion (roll), and (iii) Rotation about two axes (yaw and pitch) around the pivoting point known as the remote center of motion (RCM). Due to the pivoting point, the two rotations (yaw and pitch) are usually limited to 120°, which prevents complete rotation of the end effector.²⁰ Limited maneuverability leads to smaller workspaces.¹⁶ Frequent failed attempts to hold or manipulate a tissue using non-articulating instruments can damage the tissue and waste valuable time in the operating room.¹² In case a laparoscopic surgery becomes impossible due to anatomic constraints or excessive bleeding, it is converted to open surgery. Several researchers have reported the need for addi-

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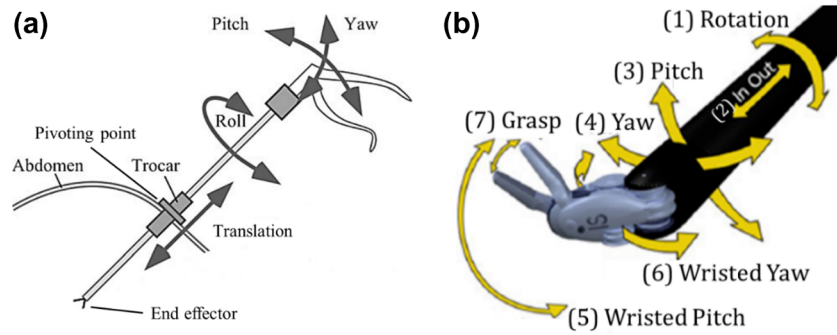


FIGURE 1. (a) DOF of a conventional laparoscopy instrument¹⁹ (b) 7-DOF of an articulating instrument.¹⁹

tional DOF in laparoscopy instruments to reach the complete workspace of a surgery.²⁴

The above gaps are overcome by robotic systems such as EndoWrist of da Vinci developed by Intuitive Surgical, USA. They have two additional DOF at the wrist (wristed yaw and wristed pitch) (Fig. 1b), permitting 360° rotation of the end effector. These allow more complex movements,⁴ and short learning curve for even non-laparoscopic surgeons.²² However, the high acquisition and maintenance costs of these systems limit their widespread use.²⁶ For example, the initial cost of a da Vinci robotic system (1.3–1.7 million USD) and annual service cost (~ 0.2 million USD) is estimated to add 1500 USD to the cost of each surgery, which is unaffordable for most patients in low and medium income countries.²⁸

In this work, a novel Multi-Use and Multi-DOF (MUMDOF) rigid-body mechanism is proposed for providing additional degrees of freedom to laparoscopic surgeons. Its complete design evolution is presented along with kinematic analysis and experimental validation. The instrument is aimed to facilitate precise control over its operation, articulation, and rotation. An innovative mechanism allows the movable and multidirectional tool head to lock at a desired angle. It is designed so that there are no restrictions on the number of usages, and is aimed to reduce the time, cost and complexity of surgeries.

MATERIALS AND METHODS

Design Requirements

There is limited information regarding the challenges and unmet needs of laparoscopy surgeons, especially those from developing countries. A study involving 93 laparoscopy surgeons across India, covering a range of demographics, medical specialties and experience revealed several valuable insights summarized in Table 1. Most surgeons participating in the study emphasized the need for articulated instruments

with surgeon-controlled camera systems. They reported similar patient outcomes of both conventional laparoscopy and robot assisted surgery (RAS). Their needs were captured in user (clinician) requirements, which were then converted into functional requirements of the proposed articulating instrument. Existing mechanisms and their limitations were studied, as described in the next section. This is followed by the design, prototyping and testing of the proposed instrument.

Existing Solutions

Most of the currently available manual instruments provide only four DOF, which induce high physical and mental stress on the surgeons. Robotic instruments overcome this difficulty but their cost is high.¹⁶ Several efforts have been made to provide additional DOF at the end effector without a significant increase in cost. For example, the FlexDex instrument (FlexDex Surgical, USA) translates the surgeon's hand, wrist and arm movements from outside the patient into the respective movements of the end effector inside the patient's body in an intuitive manner.³ This instrument is based on a mechanical design with no electrical components. At present, however, only the needle holder has been introduced in the market, limiting its applications.

A few instruments focussed on controlling the 7-DOF of the end effector by providing different mechanisms at the handle (Fig. 2). Two examples are LaproFlex by DEAM, Netherlands, and Intuitool by UNeMed Corporation, USA. The LaproFlex instrument consists of a handle that causes the end effector to bend in a reverse manner when mapped to the wrist motions of the surgeon, which is not intuitive. The shaft has a diameter of 5 mm and is attached to the handle to carry out its movements. This instrument is commercially available in Europe.²³ The Intuitool instrument, which is of 10 mm shaft diameter, comprises a handle with a trackball that can be rotated in

TABLE 1. User and functional requirements of the instrument.

User requirements		Functional requirements
1	Better articulation and maneuverability	Articulation of 45°
2	Physical and mental comfort of surgeons	Independent jaw rotation of 360° Complete rotation by 360° Pass through 10 mm trocar
3	Re-usability of the instrument	No restriction on the number of usages ¹⁷
4	Locking of the instrument at any particular orientation	Locking of the end effector in the articulated position
5	The instrument should be able to sterilize without affecting its functionality	Build the instrument using autoclavable components
6	Cost-effective for the under privileged	Affordable for mid-range hospitals

four directions, deflecting in the same way as the end effector. A trigger operates the end effector jaws in the handle, and they can be locked with a button on the handle.

Laparo-Endoscopic Single Site (or LESS) surgery allows the removal of diseased organs through a small, single incision. Collisions between instruments, lack of triangulation, and difficult retraction are some of the most significant factors that limit the use of current instruments for LESS surgery.³² Articulating instruments were designed to overcome some of these challenges and improve triangulation inside the patient. Examples include RealHand by Novare Surgical Systems, Inc., USA, Autonomy Laparo-Angle by Cambridge Endoscopic Instruments Inc., USA, and Radius r2 CURVE by Tuebingen Scientific, Germany. While the user interface slightly varies among these instruments, their overall design is similar. The Autonomy Laparo-Angle and the RealHand instruments have unique knobs to enable axial rotation of the end effector independent from angulations of the handle itself.³⁶ These are single-use disposable instruments and have 5 mm diameter shafts. The Radius r2 CURVE is 10-mm disposable instrument with a curved rotatable shaft. These instruments have the same handle design and actuation mechanism, providing a 90° deflectable and infinite rotatable end effector.³⁵ Their feasibility was tested during LESS nephrectomy in a porcine model.

The need to minimize the number of parts needed to achieve the required 7-DOF in laparoscopy instruments has been explored by a few researchers. An example of this is DragonFlex developed at bio-inspired technology (BITE) group of TU Delft, Netherlands. They employed a minimalistic design with only seven structural components and four cables, by leveraging additive manufacturing process.²¹ Another laparoscopy instrument (Maestro) was developed by a team of engineers and surgeons at Vanderbilt University. It uses the handle control method and articulates the handle relative to the shaft similar to da Vinci system.¹ This instrument featured a unique symmetric

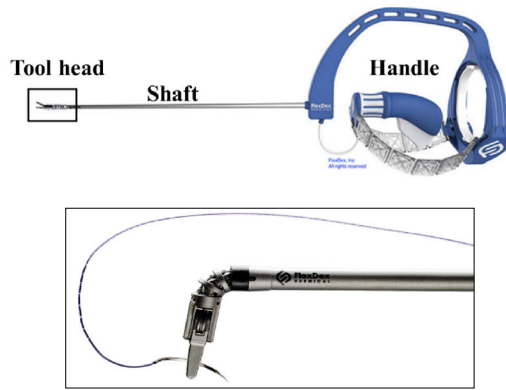
handle design that can be rotated within the user's hand to generate axial shaft rotation. These instruments are not yet available in the market.

Partially motorized articulating instruments have also been reported in the literature. For example, Kymerax (Terumo, Japan) uses motors within the handle to actuate the wrist.³³ Several other handhelds partially motorized, and robotic instruments for laparoscopic surgery have been developed. Incorporating motors in the handle provides additional flexibility in the mapping from the user interface to the wrist. However, the required motors increase the instrument weight and software increases their cost compared to fully mechanical instruments.

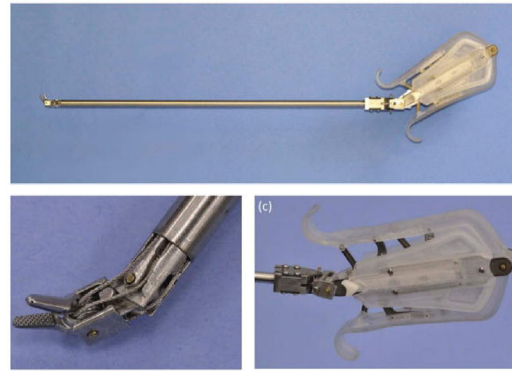
Soft robotics have many advantages over rigid body mechanisms. Known as compliant mechanisms, they utilize material compliance to provide the required deformation or articulation. However, they have known issues related to the requirements of force for various surgical applications.^{8,13} Several other concepts for articulating instruments have been published or patented, but there is little evidence of their prototyping, manufacturing and validation.^{7,9,18,34} There are a few minimally invasive surgical instruments with a pre-bent shape that does not change during use; these are outside the scope of this research work. Most of the proposed solutions to the problem of the articulating instruments do not appear to have reached practical application. The traditional manual laparoscopy instruments and da Vinci robotic system continue to be the most widely used solutions. A detailed comparison of the most prevalent laparoscopy instruments based on different parameters is presented in Table 2.

Mechanism Design and Prototyping

Various electro/mechanical systems like dial knob, cable pulleys, and power actuated flexible robotic instruments enable seven DOF. These instruments have complicated assembly of many moving parts and are difficult to sterilize. The primary goal of the current work was to develop a laparoscopy instrument with



FlexDex instrument (FlexDex Surgical, USA)
Mechanism: Universal joints with pulley & cables



Maestro instrument (Vanderbilt University, USA)
Mechanism: Cable-driven via pulley revolute joint



Radius instrument (Tuebingen Scientific, Germany)
Mechanism: Gear systems



RealHand (Novare Surgical Systems, USA)
Mechanism: Cable driven articulation

Covidien Single Incision Laparoscopic Surgery (SILS) hand instruments (Medtronic, USA)
Mechanism: Pulley and cable systems



FIGURE 2. Different articulating mechanisms for handheld instruments.³²

comparatively fewer moving parts, facilitate ease of sterilization and ensure its ease of assembly.

A systematic procedure (Fig. 3) for product development was adopted to develop critical parts of the instrument. Different concepts were generated for satisfying each functional requirement, and then eval-

uated based on the constraints to select the most suitable concept (one such example is presented in Appendix 1). This was designed in detail and then manufactured and assembled to fabricate the prototype.

TABLE 2. Summary of articulating laparoscopic instruments.^{2,32,35}

Instrument	Type	End effector lock	Shaft dia. (mm)	Handle design	Usage	Articulation mechanism	Procedures	Regulatory approval	Commercial availability
ArtiSential LIVSMED, USA	Manual	Yes	8	Pistol	Disposable	Cable & pulley driven	Laparoscopic & thoracic LESS	FDA (2019)	Available commercially
Autonomy Laparo-Angle Cambridge Endoscopic Devices Inc., USA	Manual	Yes	5	Pistol with knob	Disposable	Cable driven	LESS	Not known	Company filed bankruptcy in 2015
DragonFlex	Manual	No	5	Handle with rings	Disposable	Gear based driven by cables	Laparoscopic	Not known	Not available commercially; Developed only at lab level
Delft University of Technology, Netherlands									
EndoWrist	Robotic	No	8	Robotic control	Reusable till 10 surgeries	Cable & pulley driven	All laparoscopy	FDA (2000)	Commercially available worldwide
Intuitivrgical, USA									
FlexDex	Manual	No	8	Forearm mounted	Disposable	Gimbal based driven by cable & pulley	All laparoscopy	FDA (2016)	Currently, only the needle holder is available in market
FlexDex Surgical Inc., USA									
Intuitool	Manual	Yes	10	Pistol handle with track-ball	Not known	Ball & socket joint	Laparoscopic & LESS	Not known	Not available commercially
OneMed Corporation, USA									
Kymerax	Partially motorized	No	8.8	Pistol	Interchangeable instruments	Cable driven	Advanced laparoscopic	CE (2011)	Discontinued in Oct. 2013; Bought by Karl Storz Co. ³³
Terumo Medical Corporation, Japan									
LaproFlex	Manual	No	5	Handle with knob	Not known	Cable driven	Laparoscopic	CE (2019)	Commercially available only in Europe ²³
DEAM, Roden, Netherlands									
Maestro ¹	Manual	Yes	5	Unique symmetric handle	Disposable	Cable driven	Laparoscopic	Not known	Developed at lab level, commercially unavailable
Vanderbilt University, USA									
RealHand ³⁰	Manual	Yes	5	Handle with rings	Disposable	Cable driven	Laparoscopic hysterec-tomy LESS	FDA (2007)	No longer available in market commercially ²⁷
Novare Surgical System, USA									
Radius r2CURVE	Manual	No	10	Pistol with a knob	Reusable	Gear based mechanism	LESS	CE	Commercially available in Europe ²⁰
Tuebingen Scientific, Germany									

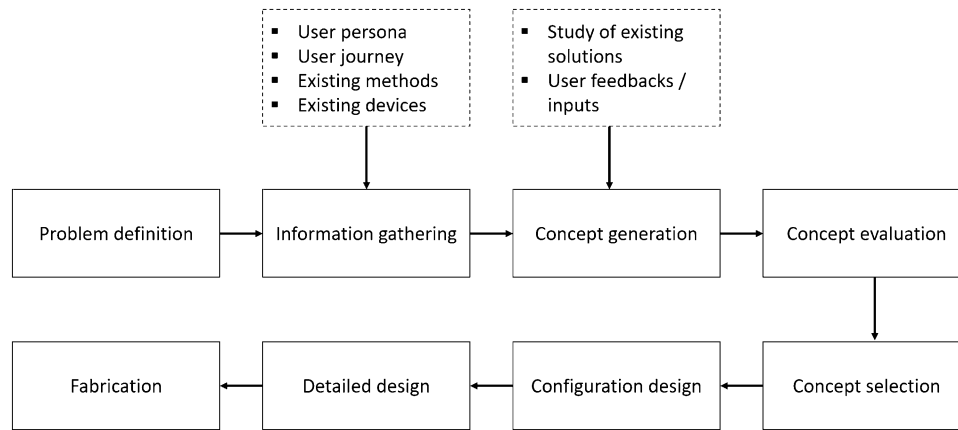


FIGURE 3. Design approach followed in developing the prototype.¹⁴

The design challenge was to transform the subtle movement of the surgeon's hand into one or more output functions at the distal tool head introduced inside the body cavity through a slender, long hollow shaft called a trocar. The articulated instruments would reduce the surgeon's mental and physical stress, thereby minimizing the possible introduction of human errors.⁸ The major components of the instrument include: (i) Tool head, (ii) Central shaft connecting the tool head and handle through links and levers, and (iii) Handle control (Fig. 2).

Tool Head

The most significant functional requirement was to design a wrist which can articulate 45° and lock in that position. This requirement came from the surgeons for reaching inaccessible regions. To fulfill this requirement, different existing mechanisms for articulation were studied (Fig. 2). The instrument should fit in a trocar of maximum 10 mm diameter leaving adequate clearance for an insulation case. The total length of the outer shaft should be around 30 cm to match the standard laparoscopic needs.

The cable and pulley mechanisms tend to lose their stiffness due to repeated heating and cooling cycles during sterilization. Such instruments (including EndoWrist of da Vinci) need to be replaced after a predetermined number of uses (usually ten).⁵ Rigid linkages are not affected in such a manner, and hence selected for further development. This allows sterilizing the instrument multiple times with minimal loss of dimensional accuracy or strength, thereby reducing the cost of surgeries.

A novel, rigid-body slider-crank mechanism was 3D modeled using SOLIDWORKS software to evaluate predefined movements generated at the tool head.³¹ The gradual up and down movements of the slider start the back and forth actions of the head portion,

respectively, triggering the opening and closing of the jaw (Fig. 4a). The entire slider-crank mechanism is placed inside a universal joint, facilitating the rotation at a certain angle.

The prototype was fabricated in ABS polymer (Fig. 4b) using a 3D printer based on the fused deposition method (FDM). It comprised a concentric arrangement of two cylinders and a shaft. The tool head was attached at the distal end of the main body. The slider-crank mechanism (Fig. 4c) was placed within a universal joint attached to the central shaft *via* a rotating collar. The outer cylinder encased the intricate assembly of the tool head and centrally placed shafts connecting the end effector. It also provided a place to pivot one end of the peripheral crank system, which is needed for articulation. On moving back and forth, the middle shaft produced the articulation.

Central Shaft

Once the tool head was designed, the next step was to design a central shaft which can translate all the necessary movements from the head to the handle held in surgeons' hand. There were four DOF at the head, i.e., two rotations (instrument and end effector rotation), articulation and grasping. For each degree of freedom, one shaft is used, leading to four concentric shafts (Fig. 5a). Two shafts were used for rotation and the other two for translation. The rotation of the central rigid shaft triggered axial rotational movement in the instrument through the universal joint. The backward and forward movement of the central shaft system controlled the open-close movement of the end effector through the slider-crank mechanism.

Handle

Various components in the handle assembly control the functionality of the central system. The challenge

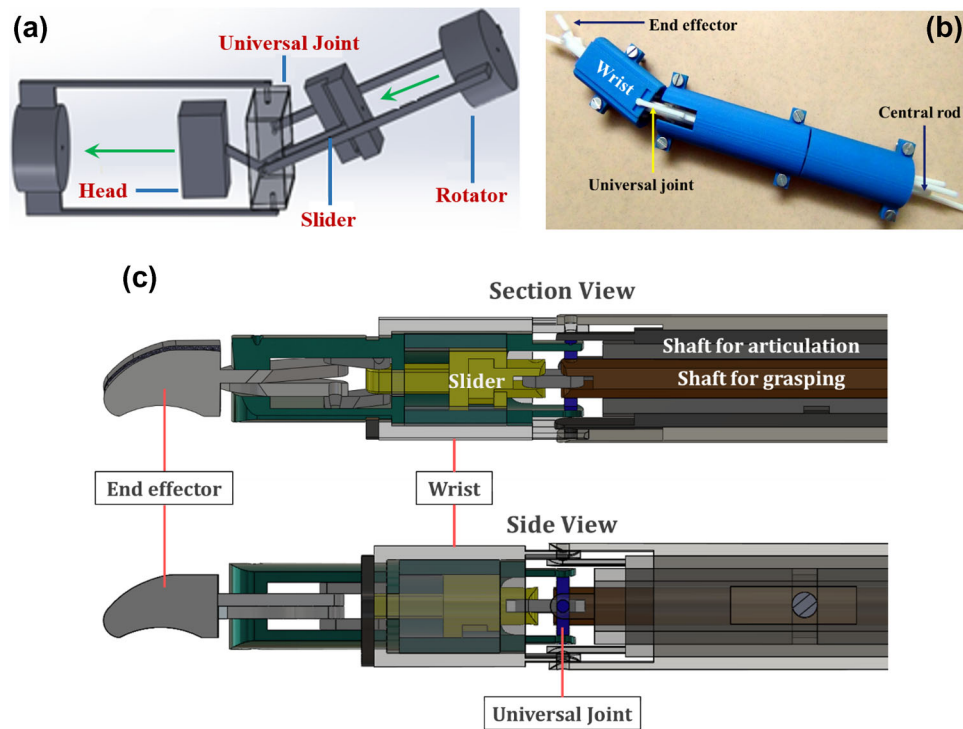


FIGURE 4. (a) Slider crank mechanism for jaw opening and closing (b) 3D printed prototype of the instrument (c) Detailed view of the articulation mechanism.

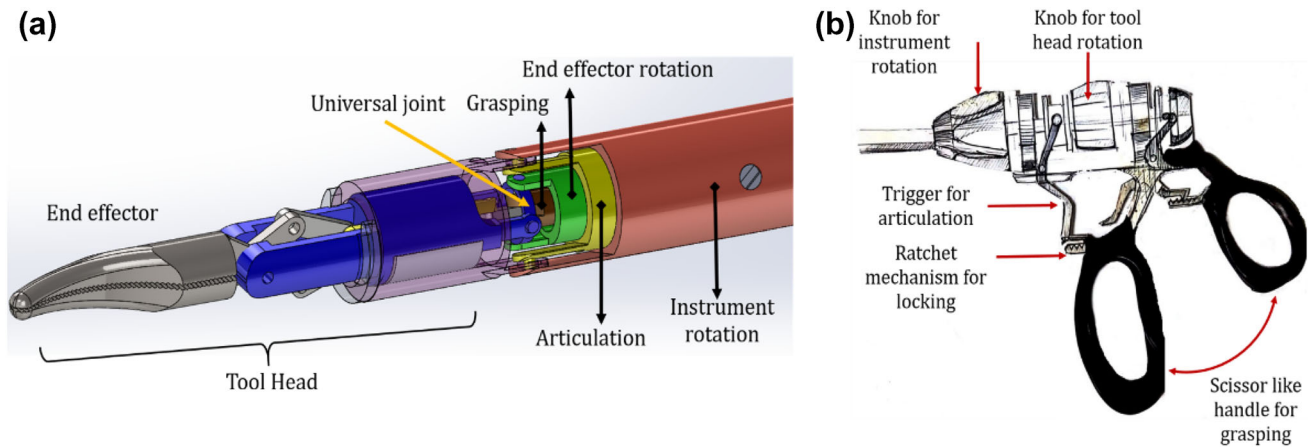


FIGURE 5. (a) Universal joint based-mechanism along with the central shaft system of the instrument (b) Concept generation for handle design.

was in designing the manipulation of the instrument at an angle, using rigid joints controlled by an ergonomic handle. It involved converting two rotations and two translations into movements that could be controlled by hand. The primary design constraint was to control four activities by a single hand.³ For this purpose, two knobs were placed on the handle to obtain the rotations of the instrument and the end effector (Fig. 5b).

A trigger was placed to translate the shaft and give the desired translation motion for wrist articulation. In addition, the mechanism needs to be locked at a par-

ticular angle as per the surgeons' requirement. A ratchet mechanism was used to address this issue. As the design evolved, the knobs were enlarged (to 30 mm diameter) to apply enough force to rotate the instrument. The ratchet mechanism was positioned near the forefinger to ensure that the surgeons did not remove their fingers from the handle and lock the instrument.

A prototype of the entire instrument was fabricated using additive manufacturing and validated by experienced surgeons at the Center of Minimal Assistive Surgery Training (CEMAST), Worli, Mumbai, for its

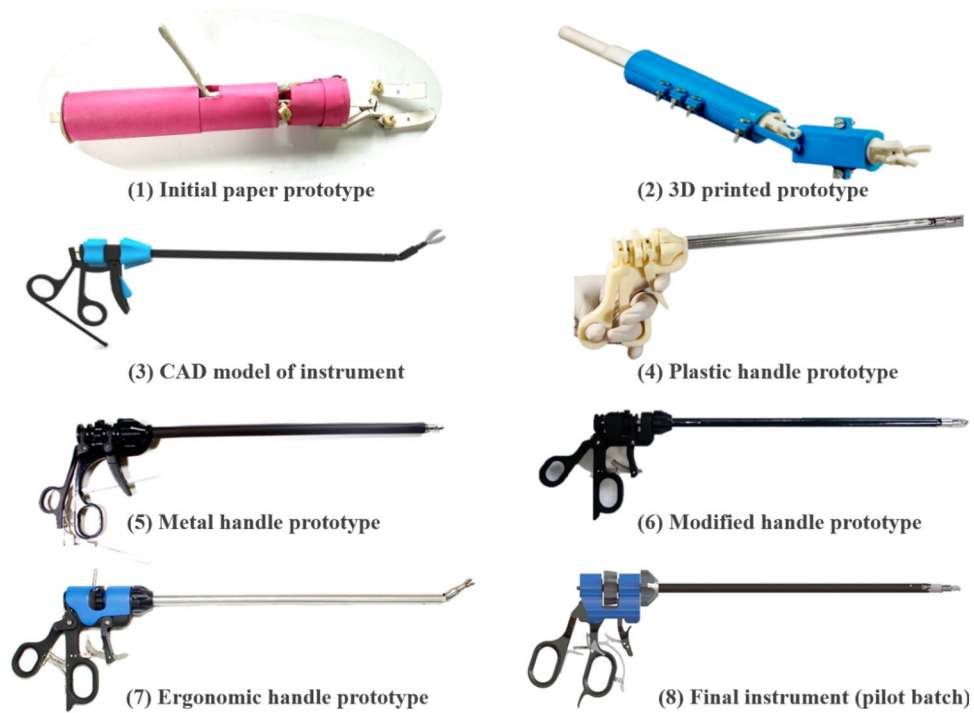


FIGURE 6. Different prototypes of the instrument.

functional movements. Various issues such as dimensional limits, tool types and handle design were reported for modifications (Appendix 2a). Based on these feedback, the MUMDOF instrument was further improved followed by manufacturing (Fig. 6). Stainless steel (SS316L) was selected for critical intricate parts such as the end effector. Stainless steel grade 304 (SS304) was selected for shafts considering its higher tensile strength. Levers, cranks and handle assembly were fabricated in SS 304.

Kinematic Analysis

Kinematic modeling was performed to understand the reach and maneuverability of the instrument. The kinematic model considers the rotations and translation of the instrument about the entry point. Since the instrument has to move in a prescribed volume of space, the position and orientation of the end effector must be controlled. Thus, it is a forward kinematics problem, which involves finding the position and orientation (pose) of the end effector relative to the base, given the positions of all of the joints and the values of all of the geometric link parameters. This is performed using the Denavit–Hartenberg parameters (also called D–H conventions).¹⁰ The base frame (Fig. 7a) is chosen at the handle end from where it enters the trocar point. In practice, the forward kinematics problem is solved by calculating the transformation between a

reference frame fixed in the end effector and another reference frame fixed in the base, i.e. between the tool and station frames. The convention (Fig. 7b) for the geometric representation of a manipulator reduces this to finding an equivalent 4×4 homogeneous transformation matrix that relates the spatial displacement of the end effector reference frame to the base reference frame.

Using the attached frames, the four parameters that locate one frame relative to another are defined as follows:

- (I) a_i —Distance from z_{i-1} to z_i along x_{i-1}
- (II) α_i —Angle from z_{i-1} to z_i along x_{i-1}
- (III) d_i —Distance from x_{i-1} to x_i along z_i
- (IV) θ_i —Angle from x_{i-1} to x_i about z_i

The equivalent homogeneous transformation is given by

$${}^{i-1}T_i = \begin{bmatrix} \cos\theta_i & -\sin\theta_i & 0 & a_i \\ \sin\theta_i\cos\alpha_i & \cos\theta_i\cos\alpha_i & -\sin\alpha_i & -\sin\alpha_id_i \\ \sin\theta_i\sin\alpha_i & \cos\theta_i\sin\alpha_i & -\cos\alpha_i & \cos\alpha_id_i \\ 0 & 0 & 0 & 1 \end{bmatrix} \quad (1)$$

The kinematic model of the MUMDOF instrument is described here (Fig. 7c). Accordingly, the homogeneous transformation matrix is calculated to obtain the position and orientation of the end effector. The transformation matrices for joint 1 to joint 7 are given

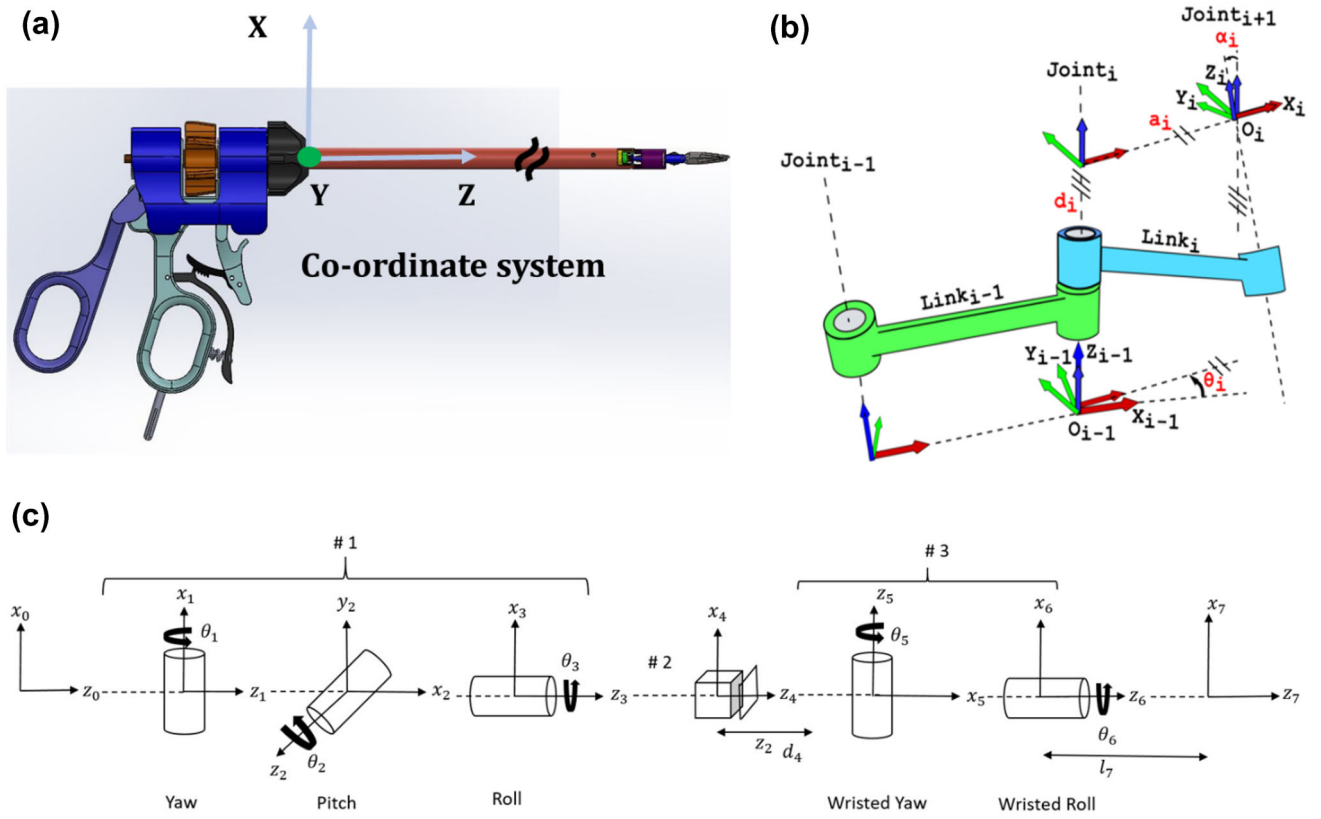


FIGURE 7. (a) Co-ordinate system for the MUMDOF laparoscopy instrument, (b) D-H parameter notation,¹⁰ (c) Kinematic model.

below, based on the values of different joint angles and link lengths (Table 3a).

$${}^0T_1 = \begin{bmatrix} c_1 & -s_1 & 0 & 0 \\ s_1 & c_1 & 0 & 0 \\ 0 & 0 & 1 & 0 \\ 0 & 0 & 0 & 1 \end{bmatrix} \quad {}^1T_2 = \begin{bmatrix} c_2 & 0 & -s_2 & 0 \\ s_2 & 0 & -c_2 & 0 \\ 0 & -1 & 0 & 0 \\ 0 & 0 & 0 & 1 \end{bmatrix}$$

$${}^2T_3 = \begin{bmatrix} c_3 & 0 & s_3 & 0 \\ s_3 & 0 & -c_3 & 0 \\ 0 & 1 & 0 & 0 \\ 0 & 0 & 0 & 1 \end{bmatrix} \quad {}^3T_4 = \begin{bmatrix} 1 & 0 & 0 & 0 \\ 0 & 1 & 0 & 0 \\ 0 & 0 & 1 & d_4 \\ 0 & 0 & 0 & 1 \end{bmatrix} \quad {}^4T_5 = \begin{bmatrix} c_5 & 0 & s_5 & 0 \\ s_5 & 0 & -c_5 & 0 \\ 0 & 1 & 0 & 0 \\ 0 & 0 & 0 & 1 \end{bmatrix}$$

$${}^5T_6 = \begin{bmatrix} c_6 & 0 & -s_6 & 0 \\ s_6 & 0 & -c_6 & 0 \\ 0 & -1 & 0 & 0 \\ 0 & 0 & 0 & 1 \end{bmatrix} \quad {}^6T_7 = \begin{bmatrix} 1 & 0 & 0 & l_7 \\ 0 & 1 & 0 & 0 \\ 0 & 0 & 1 & 0 \\ 0 & 0 & 0 & 1 \end{bmatrix}$$

The position of the end effector with respect to the fixed frame is given by:

$${}^0T_7 = {}^0T_1 \cdot {}^1T_2 \cdot {}^2T_3 \cdot {}^3T_4 \cdot {}^4T_5 \cdot {}^5T_6 \cdot {}^6T_7 \quad (2)$$

The position and orientation of the end effector is plotted in MATLAB using the values of θ_i , l and d given in Table 3b. It can be observed from Fig. 8 that the proposed MUMDOF instrument (blue points) has a higher reach than the conventional laparoscopy instruments (black dashed circle).

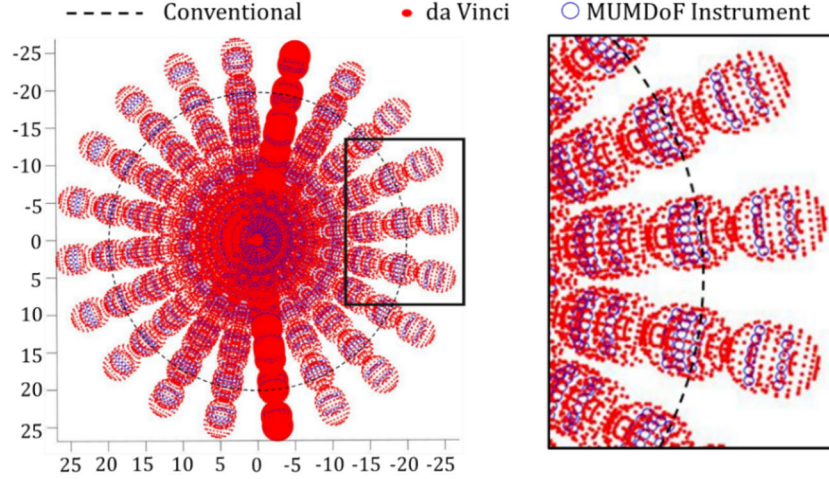
However, the EndoWrist (red points) instrument can reach farther points than the MUMDOF instrument (blue points) (by 2 cm) due to its additional two-DOF at the wrist. Given the work volume of different surgical procedures, this difference can be considered insignificant. Thus, despite being handheld, the reach of the proposed MUMDOF instrument is close to the articulating robotic instruments.

Grasping Force Requirement

The kinematic model of the proposed MUMDOF instrument represents the reach of the end effector; these end effectors also have to hold tissues and manipulate them during the surgeries. As per ISO 7151 standard for laparoscopy surgical instruments, a force

TABLE 3. (a) D–H Parameters for MUMDOF instrument, (b) Range of θ_i , l and d

(a)					(b)	
Joint (i)	Joint twist angle (α_{i-1})	Link length (a_{i-1})	Joint offset (d_i)	Joint angle (θ_i)	Parameters	Values
1	0	0	0	θ_1	θ_1	120°
2	-90°	0	0	θ_2	θ_2	120°
3	90°	0	0	θ_3	θ_3	180°
4	0	0	d_4	0	$d_4(\text{cm})$	20
5	90°	0	0	θ_5	θ_5	90°
6	-90°	0	0	θ_6	θ_6	180°
7	0	l_7	0	0	$l_7(\text{cm})$	2

**FIGURE 8. Position and orientation of different instrument.**

(Fg) of approximately 10 N needs to be applied on the grasper surface to hold and manipulate tissues.⁶

The mechanism is designed to provide a mechanical advantage by giving higher gripping force as output by applying lesser input force. The kinematic diagram of the four-bar mechanism is presented to calculate this relationship between the input (F_{in}) and output forces. For simplicity, it is assumed that there is no friction in the joints of the four-bar mechanism and that the pinching force is equal on both sides of the forceps due to the symmetry of the parallelogram linkage.¹¹ It is further assumed that the friction force between the forceps and the tissue is large enough to prevent their slippage during pinching and pulling. As point O (in Fig. 9a) is a pivot point, the moment about this point is conserved.

$$F_{in} \times l_1 = F_{rod} \times l_2 \cos \theta$$

$$\Rightarrow F_{rod} = \frac{F_{in} \times l_1}{l_2 \cos \theta} \quad (3)$$

Here, α and β are the angles between the links CD, DE and the translating shaft BC (Fig. 9b). Figure 9c, d display the forces generated on the joints B, C and D

when a force is exerted on the shaft and the joints are not moving relative to each other.

The force F_a on link CD can be written as a function of F_{rod} and angle α .

$$F_{rod} = 2F_a \cos \alpha \Rightarrow F_a = \frac{F_{rod}}{2 \cos \alpha} \quad (4)$$

F_a creates an effective force F_M perpendicular to the link BC, which causes a moment about the fixed pivot point E (Fig. 9e, f).

$$F_M = F_a = F_a \cos \left(\frac{\pi}{2} - (\alpha + \beta) \right)$$

$$= F_a \sin(\alpha + \beta) \quad (5)$$

$$= \frac{F_{in} \cdot l_1 \sin(\alpha + \beta)}{2l_2 \cos \theta \cos \alpha}$$

$$\angle CDE (\gamma) = (\pi - (\alpha + \beta)) - \frac{\pi}{2} = \frac{\pi}{2} - (\alpha + \beta) \quad (6)$$

The angle between forces F_a and F_M is given by,

Taking the moment about the point E, the relationship between F_g and F_M is given by,

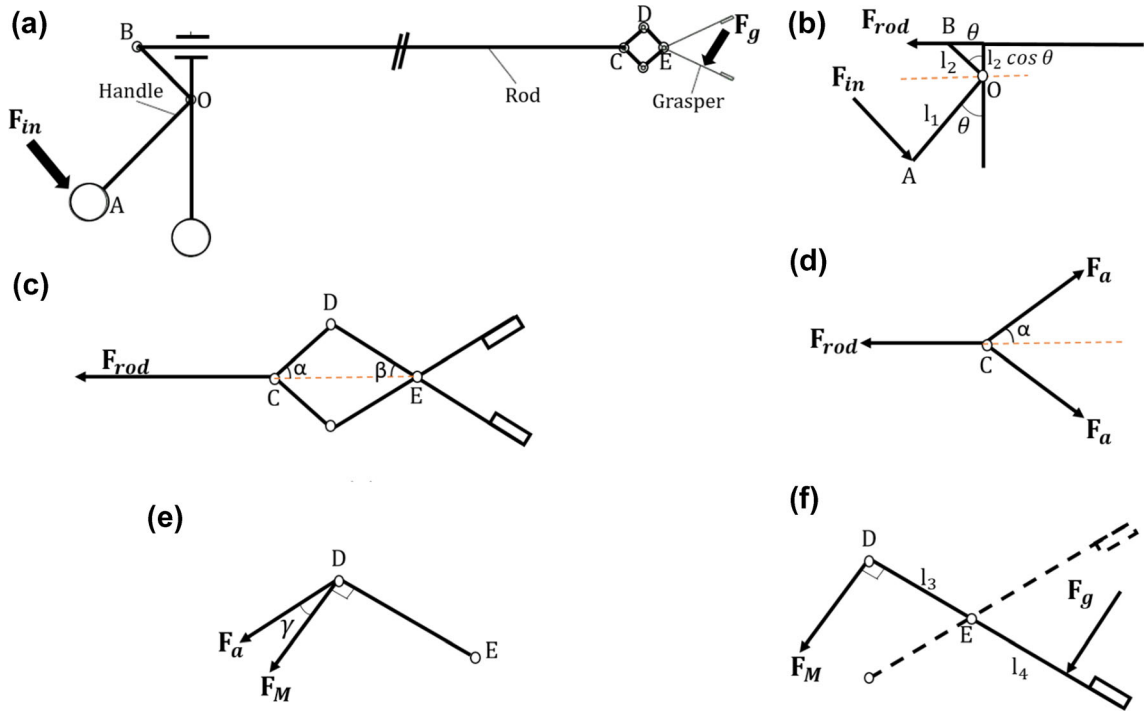


FIGURE 9. (a) Schematic representation of the grasping mechanism for the MUMDOF instrument (b, c) Kinematic diagram of four-bar mechanism, (d, e) Force propagation of four-bar mechanism (f) Force propagation to the gripper.

$$\begin{aligned} F_M \times l_3 &= F_g \times l_4 \\ \Rightarrow F_g &= \frac{F_M \times l_3}{l_4} \end{aligned} \quad (7)$$

Substituting Eq. (5) in (7), the relationship between input and output force is obtained.

$$F_g = \frac{F_{in} l_1 l_3 \sin(\alpha + \beta)}{2 l_2 l_4 \cos \theta \cos \alpha} \quad (8)$$

Putting the values of all link lengths and angles of joints as per the dimensions of the developed instrument from Table 4, the grasping force is given by

$$F_g = 1.78 \times F_{in}$$

Above relationships can be used to study the interconnections between kinematic parameters of laparoscopic instruments and the force propagation in such mechanisms. They will be used to compare the theoretical input forces required for grasping the tissues with the experimental values.

INSTRUMENT MANUFACTURE AND ASSEMBLY

The main function of the proposed MUMDOF instrument is to perform suturing, though it could also be used as scissor and as Maryland grasper. The needle

TABLE 4. Values of different variables of the MUMDOF instrument.

l_1 (mm)	l_2 (mm)	l_3 (mm)	l_4 (mm)	α	β	θ
98	15	5	8	20°	30°	20°

holder requires adequate force to hold the needle to perform suturing during laparoscopic surgeries.²⁵ The instrument contains shafts, gear-shaped profiles, and complex-shaped parts that need precision manufacturing processes to fabricate. Computer Numeric Control (CNC) turning was used to produce high-precision central shafts that are placed concentrically inside the outermost shaft. Milling, laser CNC cutting, and wire Electric Discharge Machining (EDM) were used to manufacture complex shaped parts. All the components (except handles and end effectors) were made using a bio-compatible material (stainless steel grade SS 316L).

Appropriate tolerances were provided to assemble the intricate parts to obtain the appropriate functionality. Tighter tolerances (± 0.1 mm) were provided for critical parts such as actuation link, whereas wider tolerances (± 0.5 mm) were provided for less complicated and non-mating parts such as the outer shaft. The components were assembled as illustrated in Fig. 10a, b. Tool head assembly consists of a slider-

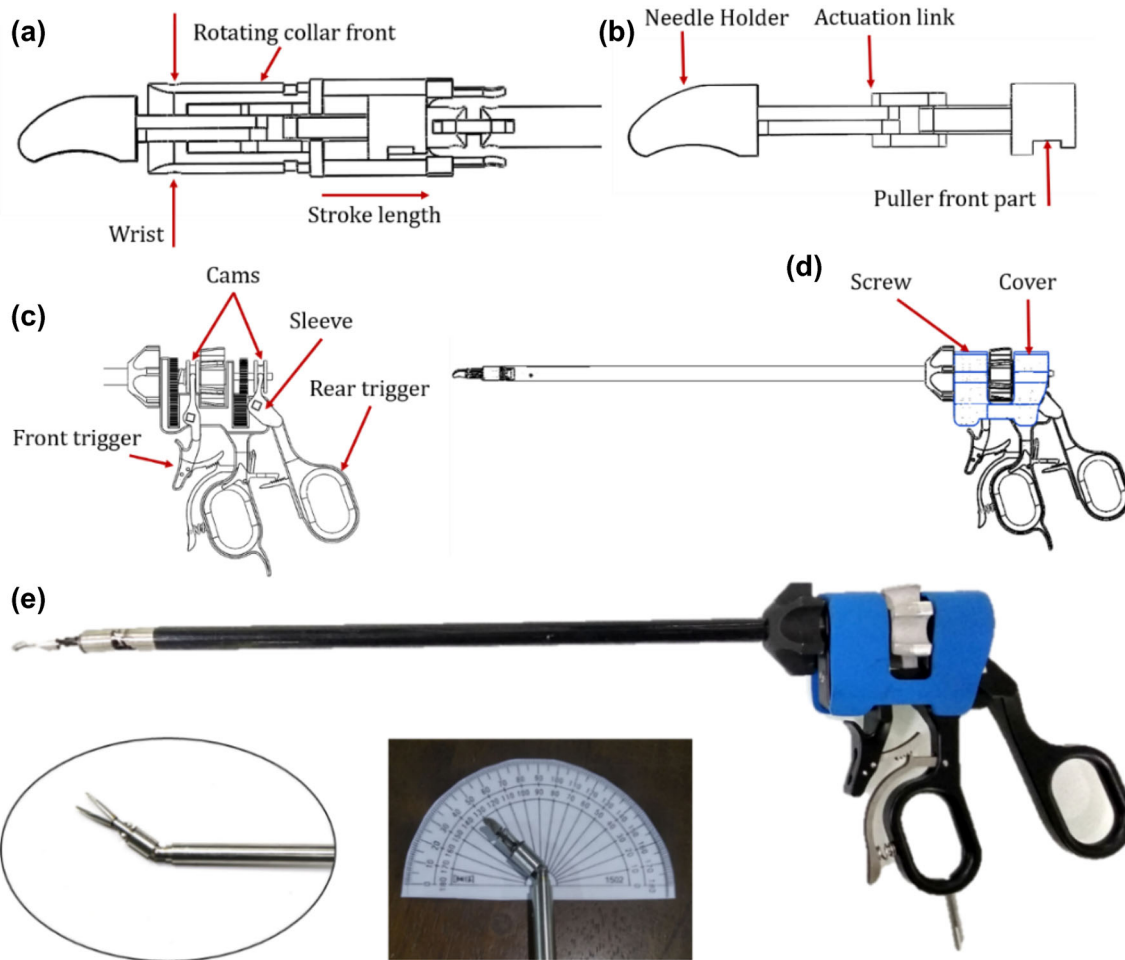


FIGURE 10. (a, b) Tool head assembly, (c) Handle Assembly, (d) Complete instrument, (e) Two additional DOF of developed instrument.

crank mechanism, jaws for grasping, connecting links between the jaws, and the slider-crank mechanism attached to the front rotating collar using riveted joints. A universal joint with four concentric shafts was connected to the tool head using the hinge joints.

The handle assembly comprises two ratchet mechanisms to lock the tool head in an articulated position and to lock the jaws in a closed position (Fig. 10c). The ratchet mechanisms were connected to the front and rear triggers using the riveted joints. Gears were used to connect the outer and the inner shaft to prevent their rotation relative to each other. The handle sub-assembly was finally attached to the four concentric shafts using grub screws to complete the assembly of the entire instrument (Fig. 10d).

MECHANICAL PERFORMANCE OF THE MUMDOF INSTRUMENT

The metal prototype could exhibit a maximum articulation of $44^\circ \pm 1.6^\circ$ with a confidence interval of 95% (shown in Fig. 10e). Considering the accuracy of EndoWrist instruments ($\pm 4.5^\circ$), the articulation values ($\pm 1.6^\circ$) of MUMDOF instrument are observed to lie in an acceptable range (Appendix 3). This can be attributed to tight tolerances in design coupled with high dimensional accuracy and surface finish obtained by manufacturing process. To verify the working of the proposed mechanism, a series of tests were conducted to evaluate the grasping force and assess the effect of sterilization on the performance of the MUMDOF instrument.

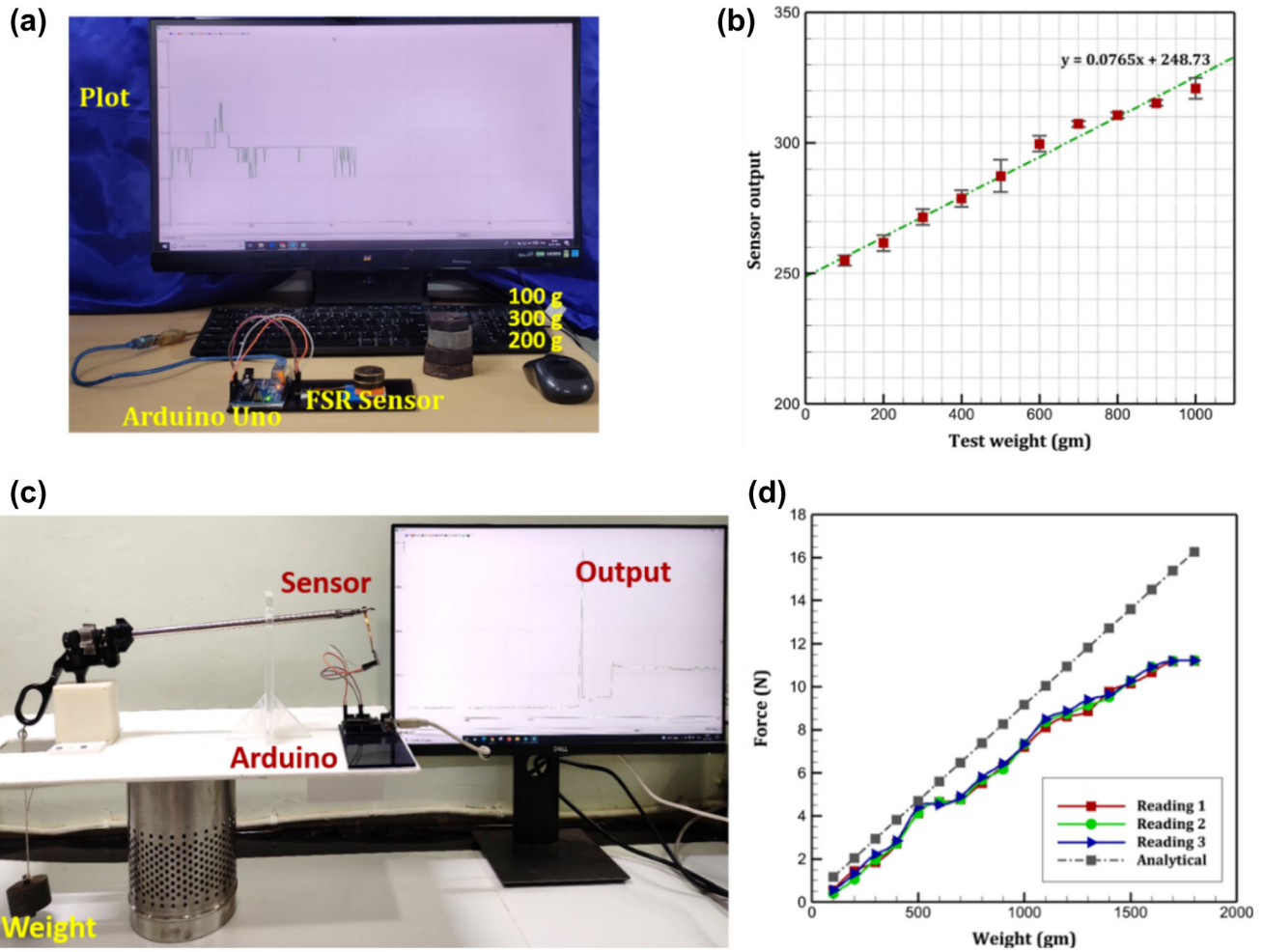


FIGURE 11. (a) Force sensor calibration experiment setup (b) Output of the sensor with the fitting linear curve (c) Test set up for grasping force measurement of developed MUMDOF instrument, (d) Comparison of experimental and analytical results.

Force Sensor Calibration

The test setup shown in Fig. 11a was used to record the output for premeasured weights. A SingleTact Force Sensor-S15-45 N (PPS UK Ltd., Glasgow, UK) was used for this purpose. Three readings were collected for different weights ranging from 100 to 1000 gm in 100 gm of increments (Appendix 4). The data were further analyzed to find the mean and the standard deviation of the readings Fig. 11b.

Gripping Force Measurement

The objective of this experiment was to assess the gripping strength of the proposed instrument. For this purpose, the instrument was mounted on a separate test rig, as shown in Fig. 11c. The force sensor was placed between the graspers, and compressive force was applied using standard weights. An input voltage of 5 V was used from an Arduino UNO microcontroller. Three trials of each weight, ranging from 100 to

1800 gm (Appendix 5), were carried out, and the maximum gripping force of the end effector was measured.

It was observed that the grasping force increased with the increase in input force. After reaching a maximum value, the curve plateaued, indicating that the maximum grasping force was reached. The maximum grasping force of the instrument was found to be 11.3 N (with a standard deviation of 0.15 N). For better repeatability, three readings were taken for each weight. It was observed that all three readings followed the same trend (with an average deviation of 2.9%) (Fig. 11d), which validated the repeatability of conducted experiments.

Evaluation of Sterilization Effect

The surgical instruments are autoclaved after every surgery. They are kept under steam in an isolated environment to reduce the effects of harmful bacteria,

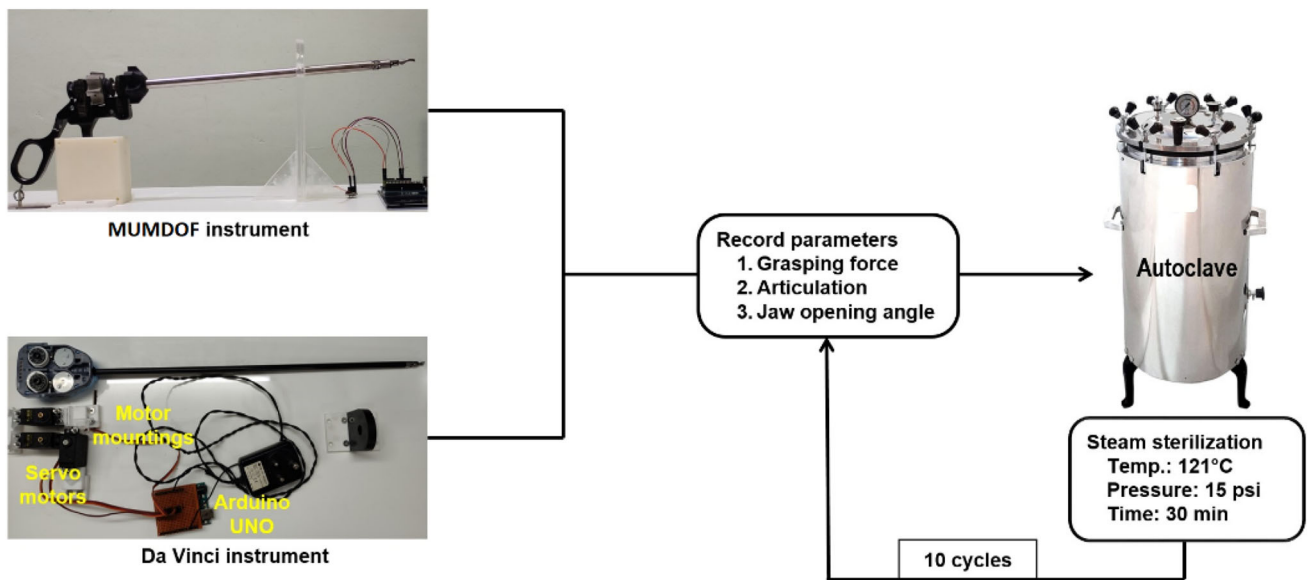


FIGURE 12. Flow chart of experimental setup for testing of life of laparoscopy instruments.

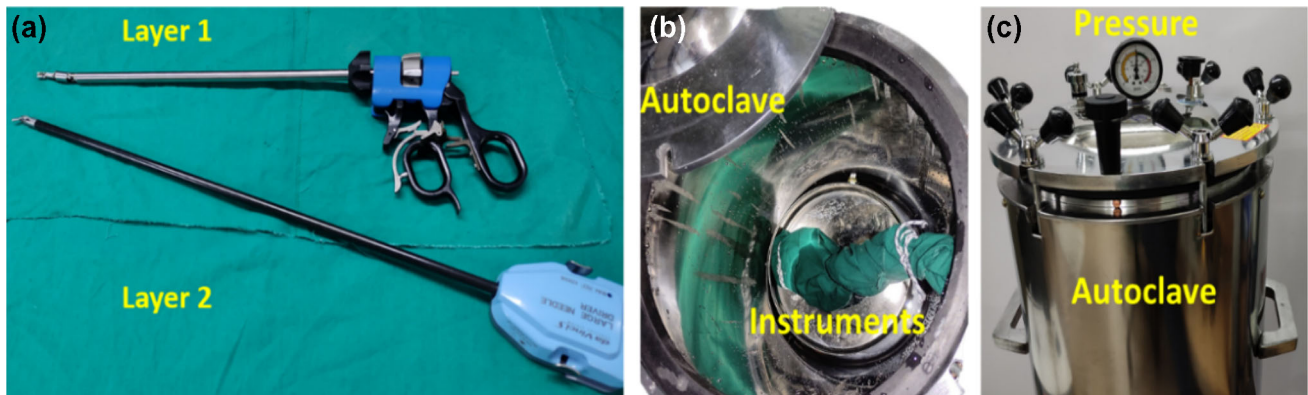


FIGURE 13. (a) Layers of wrapping of instruments before autoclave, (b) Instruments inside autoclave, and (c) Pressure generated inside autoclave.

viruses, fungi, etc. It is reported that the stiffness of the wire-driven instruments gets reduced due to the high temperatures of the autoclave.⁵ The mechanisms providing higher DOF have wire-driven mechanisms; hence they have a constraint on the number of surgeries (ten surgeries in case of EndoWrist instrument of the da Vinci robotic system).¹⁵

There is no reported literature available in which actual experiments are performed on the surgical instruments undergoing autoclave cycle. Here, both MUMDOF and EndoWrist instruments were evaluated for their response to steam sterilization. The experimental setup and the entire cycle for the sterilization process are shown in Fig. 12. The EndoWrist instrument was fixed on a test rig and then run by servo motors using Arduino UNO microcontroller.

The parameters chosen to evaluate the effect of steam sterilization were: (a) maximum grasping force,

(b) articulation (rotation about yaw axis), and (c) jaw opening angle. The instruments were wrapped in double layers of cloth (Fig. 13 (a)) and then placed inside the autoclave for steam sterilization (Fig. 13b, c). Both instruments were kept under the autoclave for 30 min at 121 °C as per the recommended standard sterilization cycle.¹⁵ After every cycle, they were taken out from the autoclave, cooled down to room temperature and then the readings were taken on the test rig (Appendix 6).

One-way Analysis of Variance (ANOVA) using Tukey criteria in Minitab software was adopted to analyze the results, since this approach is widely employed to test the statistical differences among the means of two or more groups. The test statistic for a One-Way ANOVA is denoted as F , which evaluates whether the group means are significantly different. A significance level of $\alpha = 0.05$ was selected for this experiment.

TABLE 5. Results of experiment.

	Source	DF	MUMDOF instrument				EndoWrist instrument			
			Adj SS	Adj MS	F-value	p-value	Adj SS	Adj MS	F-value	p-value
Grasping Force	Factor	9	2.13	0.24	2.23	0.06	0.65	0.072	2.28	0.06
	Error	20	2.12	0.11			0.63	0.03		
	Total	29	4.25				1.29			
Articulation	Factor	9	44.03	4.89	2.37	0.05	188.03	20.89	7.55	0.0001
	Error	20	41.33	2.07			55.33	2.77		
	Total	29	85.37				243.37			
Jaw opening angle	Factor	9	43.33	4.82	2.12	0.07	980.00	108.89	59.39	0.0001
	Error	20	45.33	2.27			36.67	1.83		
	Total	29	88.67				1016.67			

DF degrees of freedom, SS sum of squares, MS mean square.

From Table 5, it can be observed that for grasping force, the F -values are 2.23 and 2.28 for MUMDOF and EndoWrist, respectively. Since the F -values of both the instruments are less than $F_{(0.05,9,20)}$, which is 2.39, the hypothesis is accepted and concluded that the means do not differ significantly. This implies that the autoclave cycle does not affect the grasping force for both instruments. Similarly, for articulation, the F -value for the MUMDOF instrument is $2.37 < F_{(0.05,9,20)}$; hence the autoclave cycle does not significantly affect the articulation of the MUMDOF instrument.

On the other hand, for the EndoWrist instrument, the F -value (7.55) is greater than the $F_{(0.05,9,20)}$ of 2.39. This indicates that the means differ significantly, and it can be inferred that the autoclave cycle affects the articulation significantly for the EndoWrist instrument. The p -value is also calculated for this test statistic, which is very small (0.0001). For the third parameter (jaw opening angle), the F_{critical} is greater than the F -value for the MUMDOF instrument but lesser than that of the EndoWrist instrument. This implies that the autoclave cycle does not affect the jaw opening angle for the MUMDOF instrument, but it affects for EndoWrist instrument considerably.

DISCUSSION

Conventional instruments are widely used in laparoscopic surgeries, and cannot be entirely replaced with robotic systems. The requirements of better reach, dexterity, intuitive control, and reduced weight appear to be the future trends in laparoscopy instruments. This motivated the development of the Multi-Use Multi-DOF (MUMDOF) handheld instrument described in this paper. Its rigid body mechanism-based wrist-like joint can realize articulation as well as roll motions. The proposed instrument can be used in different types of laparoscopic procedures including general surgery, colorectal, bariatric, urology and

gynecology. It complies with the list of specifications identified through clinical observations and discussions with surgeons. The surgeons appreciated the novel design and gave constructive feedbacks (Appendix 2b).

The position and orientation analysis performed using the forward kinematics approach showed that the proposed instrument has a better reach compared to manual laparoscopy instruments. Despite being a handheld instrument, there is no significant difference in its reach compared with the EndoWrist instrument of da Vinci robotic system. The main components of the instrument are made of stainless steel (SS 316L), except for the handle and the end effector (which are manufactured in SS 304); both are suitable for sterilization and actual surgical interventions. Experimental results showed that the instrument has a maximum grasping force of 11.3 N (with a standard deviation of 0.15 N), which is sufficient for laparoscopic procedures. Even after ten cycles of steam sterilization, the proposed instrument did not show any loss of function in terms of grasping force, articulation and jaw opening angle. In contrast, the articulation and jaw opening angle of EndoWrist were significantly affected.

The key contribution of this research work lies in the novel mechanical design using rigid links to develop a reusable, articulating 7-DOF laparoscopy instrument. The use of rigid links gave the freedom to sterilize the instrument many times without any significant change in its functionality, thereby reducing the cost of surgeries. Future work involves evaluating the instrument functionalities in both *ex-vivo* and *in-vivo* procedures with different kinds of needles and sutures performed by a statistically significant population of surgeons.

SUPPLEMENTARY INFORMATION

The online version contains supplementary material available at <https://doi.org/10.1007/s10439-022-03086-w>.

APPENDIX 1 EXAMPLE OF IDEA GENERATION AND EVALUATION CRITERIA FOR A FUNCTIONAL REQUIREMENT

Functional Requirement 1. The instrument should have an articulation of 45°	
Different concepts	Evaluation criteria
Articulated instrument with 7 DOF	Feasibility
Use of compliant mechanism	Time required
Highly articulated robotic probe system	Innovative potential
Multi articulated robotic instrument	Resource availability
3 axis setup (gantry type)	Practicality
Spine/goose neck mechanism	
Gimbal mechanism	
OT light wall mounting	
Parallel manipulators	
Flexible hose/pipe	

APPENDIX 3 UNCERTAINTY ANALYSIS FOR THE MEASUREMENT OF ARTICULATION OF MUMDOF INSTRUMENT

Readings	Measured value
1	44
2	44
3	43
4	45
5	44
6	45
7	43
8	43
9	44
10	45

Mean = 44°.
Std. dev. = 0.8°.
Taking a confidence interval of 95%, uncertainty = 2*Std. dev. = 1.6°.
Hence, the measured articulation of the developed instrument is 44° ± 1.6°.

APPENDIX 2 FEEDBACKS OF SURGEONS

(a) Surgeons feedbacks during development

Sr. No	Feedback	Corrective measure
1	Needle slips when grasped at the tip of jaws; It should not slip after jaws are locked	FBD was prepared for grasping forces and then required changes in the CAD of jaws and rear trigger were performed
2	Rotation knobs have to be bigger as compared to presently designed	Rotation knob were redesigned, manufactured and replaced
3	Rear ratchet lock is unreachable; It has to be reachable to the thumb	Rear ratchet unlocking mechanism was modified and made accessible to the thumb
4	There should not be any play at distal end after the articulation and ratchet locking	The necessary actions needed to be taken while assembling the instrument
5	The jaw serrations should be such that the needle should not move after grasping	The modifications were done in the CAD and then implemented during manufacturing
6	Not able to rotate the knob easily for jaw rotation because of presence of cover on handle	The fillet was provided on the edge near rotation knob and cover design was modified and manufactured
7	The ratchets on the handle should be locked after the jaws are closed and the teeth of ratchet should be smaller	The ratchets were redesigned for fine adjustment of articulation and then manufactured

(b) Surgeon feedback after using the developed instrument

Surgeon 1 Very pleased after seeing the developed instrument. This is great for performing surgeries in intricate locations (E.g. Prostatectomy, Cholecystectomy, Hysterectomy, etc.) inside the abdominal cavity. As it is sterilisable for multiple times, it would benefit a large population. It would be also helpful if such instrument is developed for pediatric surgeries too

Surgeon 2 Conventional suturing is performed with the complete rotation of the wrist and the forearm. However, with this novel instrument, there is only one rotation of knob which makes the tissue bite action possible. This is a great advantage over the conventional instruments

Surgeon 3 The current set of instruments are good to meet our needs, but they have some limitations. The instruments with more capabilities, to reach confined spaces are the need of the hour. This instrument is capable of solving these issues. However, its handle could be further optimized to make it light weight

APPENDIX 4 FORCE SENSOR CALIBRATION READINGS

Weight (gm)	Force (N)	Reading 1	Reading 2	Reading 3	Mean	Std. Dev
100	0.98	254	256	255	255.00	1.00
200	1.96	262	263	260	261.67	1.53
300	2.94	270	272	273	271.67	1.53
400	3.92	277	279	280	278.67	1.53
500	4.9	288	284	290	287.33	3.06
600	5.88	298	300	301	299.67	1.53
700	6.86	308	307	307	307.33	0.58
800	7.84	311	310	311	310.67	0.58
900	8.82	315	315	316	315.33	0.58
1000	9.8	323	319	321	321.00	2.00

APPENDIX 5 EXPERIMENTAL READINGS OF MUMDOF INSTRUMENT GRASPING FORCE

Weight (gm)	Reading 1	Reading 2	Reading 3	Analytical
100	0.55	0.42	0.55	1.16
200	1.44	1.06	1.32	2.05
300	1.83	1.96	2.21	2.94
400	2.72	2.72	2.85	3.83
500	4.13	4.13	4.39	4.71
600	4.65	4.65	4.52	5.60
700	4.77	4.77	4.90	6.49
800	5.54	5.67	5.80	7.38
900	6.31	6.18	6.44	8.27
1000	7.21	7.34	7.34	9.16
1100	8.11	8.36	8.49	10.05
1200	8.62	8.75	8.87	10.94
1300	8.87	9.13	9.39	11.83
1400	9.77	9.51	9.64	12.72
1500	10.15	10.28	10.28	13.61
1600	10.67	10.92	10.92	14.50
1700	11.18	11.20	11.20	15.39
1800	11.20	11.22	11.22	16.28

APPENDIX 6 RESULTS OF EXPERIMENTS FOR THE EVALUATION OF STERILIZATION EFFECT

Sterilization cycle (#1–10)										
Grasping force (Newton)										
	#1	#2	#3	#4	#5	#6	#7	#8	#9	#10
MUMDOF instrument										
Reading 1	10.57	10.6	10.2	9.89	9.94	10.2	10.0	10.4	10.3	10.7
Reading 2	11.34	11.2	10.4	10.3	10.5	10.3	10.2	10.5	10.5	11.1
Reading 3	10.83	10.8	10.0	10.5	10.7	11.0	10.3	11.1	10.8	10.8
Average	10.91	10.8	10.2	10.2	10.4	10.5	10.2	10.6	10.6	10.9
da Vinci instrument										
Reading 1	7.46	7.34	7.08	7.08	7.21	7.59	7.59	7.46	7.46	7.85
Reading 2	7.59	7.46	7.34	7.21	7.59	7.21	7.46	7.59	7.21	7.46
Reading 3	7.72	7.34	7.28	7.59	7.08	7.46	7.59	7.72	7.08	7.59
Average	7.59	7.38	7.23	7.29	7.29	7.42	7.55	7.59	7.25	7.63
Articulation (degrees)										
	#1	#2	#3	#4	#5	#6	#7	#8	#9	#10
MUMDOF instrument										
Reading 1	45	46	47	50	50	48	49	48	49	48
Reading 2	47	47	46	46	46	50	50	49	48	47
Reading 3	48	45	46	46	45	50	50	48	49	50
Average	46.6	46.0	46.3	47.3	47.0	49.3	49.6	48.3	48.6	48.3
da Vinci instrument										
Reading 1	144	140	142	144	140	136	139	143	145	141
Reading 2	143	142	142	142	140	135	138	145	140	138
Reading 3	143	142	140	140	139	138	134	146	142	140
Average	143.3	141.3	141.3	142.0	139.6	136.3	137.0	144.6	142.3	139.6
Jaw opening angle (degrees)										
	#1	#2	#3	#4	#5	#6	#7	#8	#9	#10
MUMDOF instrument										
Reading 1	49	46	46	49	49	48	44	48	51	50
Reading 2	46	49	46	49	49	49	46	49	50	49
Reading 3	47	48	51	48	47	49	48	51	51	48
Average	47.3	47.7	47.7	48.7	48.3	48.7	46.0	49.3	50.7	49.0
da Vinci instrument										
Reading 1	202	207	208	209	208	208	215	218	220	220
Reading 2	206	206	209	210	208	210	215	220	223	219
Reading 3	207	207	209	210	210	208	218	218	221	221
Average	205.0	206.7	208.7	209.7	208.7	208.7	216.0	218.7	221.3	220.0

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CONFLICT OF INTEREST

This is to declare that a patent (US10828017B2: Surgical instrument with multiple degrees of freedom) related to the above work has been filed by the Indian Institute of Technology, Bombay. The authors, Rupesh Ghyar and Bhallamudi Ravi, are current employees of the institute, and Sritam Rout was an ex-employee of the same institute. These inventors collaborated with a surgeon Dr. Suresh Deshpande. As per the IP policy of the institute, a non-institute inventor, Dr. Suresh Deshpande, has significantly contributed to the invention and hence is also included as an innovator in the IP. The other authors, Prabhat Kumar and Sagar Talele, have contributed considerably to the development and testing of the invention. The patent has been licensed for commercialization to Eclipse Instrumentation Pvt. Ltd., Thane, Mumbai, and the royalty is shared by the institute and inventors.

RESEARCH INVOLVING HUMAN PARTICIPANTS AND/OR ANIMALS

This article does not contain any studies with human and/or animal's participants performed by any of the authors.

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