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# **Surgical microgrippers: a survey and analysis**

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*This review article provides an overview of some challenges that arise when developing new medical robotic microgrippers. The main challenges are due to miniaturization and are present in the manufacturing and assembly processes, the types of mechanisms, the biomaterials used, the actuation principles, and the compliance with some standards and regulations. The main medical fields where these microgrippers are used are in MIS and biomedical applications. Therefore, taking these two large groups into account, this review presents a microgrippers classification according to the type of mechanism used (traditional rigid-body mechanisms and complaint mechanisms). Moreover, parameters such as applications, functionalities, DOF, sizes, range of motion, biomaterial used, and proposed methods are highlighted. The analysis of 27 microgrippers among commercial and developed by research institutes is presented.*

## NOMENCLATURE

MIS Minimally invasive surgery

MIRS minimally invasive surgical robotic systems

- DOF Degrees of freedom
- GI Gastrointestinal
- LC Laparoscopic cholecystectomy
- SAGES Society of American Gastrointestinal and Endoscopic Surgeons
- MICS Minimally invasive cardiac surgery
- CABG Coronary artery bypass grafting
- VAD ventricular assisted device
- ASD Atrial septal defect
- TVR Tricuspid valve repair
- ENT Ear, Nose, Throat-Otolaryngology
- OSA Obstructive sleep apnea
- TORS Transoral robot surgery
- FDA Food and Drug Administration
- LESS Laparoendoscopic single-site surgery
- NOTES Natural orifice transluminal endoscopic surgery
- RF radio frequency
- MEMS Microelectromechanical systems
- BioMEMS Bio-microelectromechanical systems
- CMs Compliant mechanisms
- SMA Shape memory alloys
- MDR Medical Devices Regulation
- ISO International Organization for Standardization
- MMI Medical Microinstruments
- Ni-Ti Nickel titanium
- PEEK Thermoplastic Poly-EtherEther-Ketone
- FEA finite elements analysis
- EDM micro-Electrical discharge machining
- $mm$  milimeters
- $\mu$ m micro-milimeters
- cm centimeters

N Newton deg (°) degrees  $\Omega \cdot m$  electrical resistivity unit  $J/kg$  Thermal heat capacity unit MIR Magnetic resonance imaging SOIMUMPs Silicon-On-Insulator MultiUser Micromachining Processes LVM Low carbon Vacuum melt AL Aluminum PDMS Polydimethylsiloxane IPMC Ionic polymer metal composite SMP Shape memory polymer PPF Poly(propylene fumarate) pNIPAM-AAc poly(N-isopropylacrylamide-co-acrylic acid) dc Direct current PVC Polyvinyl chloride

## 1 INTRODUCTION

The development of microscale medical devices has grown significantly in recent years. They play key roles in minimally invasive surgery (MIS) and biomedical applications. MIS uses minimally invasive surgical robotic systems (MIRS) that jointly work with micro devices such as microgrippers, scissors, knives, clamps, etc. The use of these microdevices has allowed the performing of surgical procedures by making small incisions in the human body, which represent benefits to patients and surgeons [1]. In addition, in biomedical applications, the use of microgrippers has allowed manipulating or isolating cells, microbes, and/or Oocytes.

Despite the advantages that these represent, the development of new medical devices represents a great challenge due to miniaturization. The development of these tiny medical devices involves studying and analyzing new manufacturing and assembly processes, actuation principles, functionalities, different mechanical configurations, materials used, and the fulfillment of some standards and regulations[2].

This paper offers readers a comprehensive review of the methods and approaches employed by the authors to develop new microscale medical devices. These approaches and methods are mainly linked to offer new solutions and contributions to the challenges of miniaturization.

## 2 LITERATURE SEARCH METHOD

{This paper is based on the analysis of 4 commercial microgrippers oriented for surgical applications and 23 microgrippers developed by research institutes for surgical applications and biomedical applications such as cell and microbes manipulations, drug delivery, cell excision isolating tissues, and so on. The research bibliography for the commercial microgrippers was performed on the Google research engine. The microgrippers were identified from the website of four companies dedicated to developing surgical instruments. The companies were Da Vinci®, Olympus Medical®, Medical Microinstruments SpA (MMi)®, and LIVMED®. The following keywords were used: commercial microgripper, commercial surgical tools, surgical forceps, microgrippers for surgical applications, robotic surgical tools, minimally invasive surgery, and an appropriate combination of these terms. On another hand, the research bibliography for the microgrippers developed by research institutes was performed on Web of Science®, ScienceDirect®, and Google Scholar® databases, selecting articles written only in English. In order to cover the complete proposition, there was no exclusion based on the date of publication. The following keywords were used: gripper, forceps, surgical microgrippers, robotic, surgery, surgical tools, intracorporeal surgery, compliant microgrippers, soft microgripper, self-folding microgrippers, tether-free microgrippers, piezoelectric microgrippers, hydrogel-based microgrippers, and an appropriate combination of these terms.

## 3 MEDICAL FIELDS THAT USE MICROGRIP-**PERS**

The development of different types of surgical instruments is growing significantly every day due to variety, complexity, and evolution of surgical techniques and medical applications[3]. Micro medical devices are the tools used by surgeons in different invasive procedures and by healthcare professionals in different medical applications. Basically, they are used to performing functions like cut, dissect, hold, grab, occlude, clamp, retract, suture, dilate, etc. [4]. Below, some types of surgeries and medical applications are explained, through the importance of the use of microgrippers can be noticed.

#### 3.1 Minimally invasive surgery

Minimally invasive surgery can be seen in both robotic and non-robotic surgeries. On the one hand, in non-robotic surgery, also known as laparoscopic surgery, thoracoscopy surgery, or keyhole surgery, the surgeon inserts an instrument called an endoscope. This instrument is basically a thin and flexible tube with channels for carrying video cameras and microgrippers inside the human body, through small incisions or a natural opening such as the mouth or nostrils. On the other hand, in robotic surgery, surgeons execute surgical procedures through a console that allows maneuvering of some robotic arms that lead the cameras and multiple articulating microgrippers inside the human body. In this process, the surgeons perform the incisions with the articulating microgrippers and a camera provides high-definition images to the console to see the live surgical procedure. The small incisions are called ports and their sizes vary between 3 mm, 5 mm, 10 mm, or 12 mm according to the procedure [5], [6]. Below, some surgical interventions on specific parts of the body performed within a minimally invasive approach are explained.

## *3.1.1 Gastroenterological surgery*

Gastrointestinal (GI) surgery or gastrointestinal laparoscopic surgery focuses on the diagnosis and treatment of some disorders of the gastrointestinal tract. Some common types of minimally invasive (GI) procedures include colon and rectal surgery, nephrectomy, adrenalectomy, foregut surgery, splenectomy, hiatal hernia repair, Bariatric surgery, pancreatic surgery, cholecystectomy, Nissen and retroperitoneum surgery. [7, 8, 9]. These types of surgeries can be performed as an open or minimally invasive procedure, depending on the patient's condition. Below we will explain in more detail cholecystectomy surgery, since it was the first laparoscopic cholecystectomy (LC) performed in 1985 but was officially recognized by the German Surgical Society in 1993 due to a skeptical mindset in the earlier years [8]. Laparoscopic cholecystectomy also known as minimally invasive cholecystectomy [10] has undergone many changes and variations since its inception. The main changes were focused on techniques to reduce the incision sizes. These reductions should not violate the principles established for this type of surgery [11, 12]. This is how it stands out, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) [13]. Minimally invasive cholecystectomy is a procedure for the removal of a diseased gallbladder and is performed through 4 small incisions using two 10 mm trocars and two 5 mm trocars along the right costal margin [14]. Through them, dissecting and grasping forceps (microgrippers) are introduced to remove the gallbladder, and cameras to visualize inside the abdomen. Trocars of 10 mm are commonly used since in most cases the gallbladder can be extracted by an incision of this size. [11]. This procedure also can be robotic cholecystectomy, in which case, the surgeon uses a surgical robot that uses articulated grasping forceps.

#### *3.1.2 Nerosurgery*

Neurosurgery is focused on the diagnosis and treatment of disorders of the brain, spine, spinal cord, and peripheral nerves [15]. This type of surgical procedure was the first one to use image-guided techniques [16] in order to see the surgical area and surgical instruments that may not be visible to the surgeon's naked eye.

Neurosurgery takes advantage of natural orifices such as nostrils to carry out the surgical process; e.g., endonasal surgery is performed through the nose by inserting an endoscope that the surgeon maneuvers to treat brain tumors. However, in some cases of complex brain tumors, when it can not be accessed through the nose, surgeons make very small incisions to directly access the brain tumor by inserting micro-instruments to perform endoscopic tumor biopsy, colloid cysts resection, and endoscopic cysts fenestration, as well as treating hydrocephalus. Another example is spinal surgery, which can also be performed using an endoscope to treat lumbar and thoracic hernias, chronic back pain, and among others [17]. In general, the instruments used in neurosurgery are taken from other endoscopic disciplines like gastroenterology. These are microforceps and microscissors for biopsy and dissection of cysts and abscess membranes; grasping forceps to remove cyst material and foreign bodies; balloon catheters for cystostomy or ventriculostomy; and monopolar RF and bipolar RF or laser energy for hemostasis [18, 19].

Although the advances in robotic neurosurgery are considerable, they are still in full development, due to the limited space of different areas for this type of surgery. One limitation, for example, is for transsphenoidal surgery because the skull area is very small. Another limitation is this procedure cannot be performed in children because the workspaces are even smaller. Generally, the main limitations are due to the size of robot arms and their surgical instruments. For this reason, many researchers are focusing on improving and developing smaller surgical instruments [20].

## *3.1.3 Cardiac surgery*

Minimally invasive cardiac surgery (MICS) is focused on treating a variety of heart conditions. The procedure consists of performing small incisions on the right side of the chest to reach the heart between the ribs rather than cutting through the breastbone, as is done in open-heart surgery [21]. Some common types of MICS include mitral valve repair/replacement, aortic valve repair/replacement, coronary artery bypass grafting (CABG), ventricular assisted device (VAD), atrial septal defect (ASD) repair, tricuspid valve repair/replacement (TVR) and MAZE procedure for atrial fibrillation [22, 23]. For instance, CABG, is a procedure performed via robotic assistance where the surgeons use robotic arms to access the heart through four small incisions made in the intercostal space. These small incisions are used to introduce robotic instruments such as forceps, needle drivers, scissors and electrocautery, and a video scope [24]. During this procedure, the surgeon uses a remote console to see inside the heart in a magnified high-definition 3D view on a video monitor and to manipulate the robotic instruments and the scope as if they were hand-held surgical instruments [21, 24]. MICS provide advantages such as, no opening of the chest or cutting of bones, less pain, faster recovery, lower risk of complications, and shorter hospital stay. Thus, improving the sizes and developing new surgical instruments in order to contribute to advances in MICS are challenges that many researchers continue working on.

## *3.1.4 Otolaryngology (ENT) surgery*

Ear, Nose, Throat (ENT) surgery is focused on treating conditions that involve benign and malignant lesions of the oropharynx, hypopharynx and larynx, microvascular reconstruction, thyroid, and parathyroid diseases, obstructive sleep apnea (OSA), and sinonasal and skull base pathologies. ENT is a MIS, usually performed with robotic devices/procedures [25]. For instance, in the transoral robot surgery (TORS) the most used surgical robot is the da Vinci Si robotic system manufactured by the Intuitive Surgical, Inc with Food and Drug Administration (FDA) approval in 2019 [26]. During this procedure, the surgeon uses three arms of the surgical robot to perform small incisions and introduces through them the endoscope, camera, and surgical instruments such as cannulas, needle drivers, round and curve scissors, and forceps recommended of 5  $mm$  [27, 26] in order to easily identify glossopharyngeal, hypoglossal and lingual nerves, as well as the lingual artery [28].

ENT surgeries greatly benefit from using robotic surgical procedures, as they allow accessing and visualizing areas with limited space. However, in some cases with TORS, many of the surgical instruments must improve in terms of flexibility and size. Further, by using other technologies such as augmented reality and haptic feedback to provide improved results [25].

## *3.1.5 Gynecologic surgery*

The minimally invasive gynecology surgery is focused on evaluating and treating anomalies in women's reproductive system, a wide range of noncancerous (benign) including heavy menstrual periods (menorrhagia), irregular menstrual periods (metrorrhagia), pelvic pain, endometriosis, and ovarian cysts [29].

Robotic surgery is one of the techniques that has contributed to the advancement of minimally invasive gynecologic surgery. In this procedure, the surgeons use a surgical robotic system comprised of a console that provides high-definition images during the procedure, four arms to perform the small incisions, a laparoscope, cameras, and interchangeable articulated instruments that provide the same motion range as the instrumentation used in laparotomy. The da Vinci surgical system was one of the systems approved by the FDA in 2005 to perform gynecologic surgery [30]. The emerging techniques in robotic gynecologic surgery are laparoscopic surgery which consists of introducing a laparoscope of 1.8  $mm$ to 12 mm, cameras and light through small incisions or through the umbilicus; mini laparoscopy, which uses a laparoscope of 5 mm to introduce cameras and instruments through smaller incisions than laparoscopy surgery [31]. Laparoendoscopic single-site surgery (LESS) uses a single incision to introduce all surgical instrumentation [31, 32]. The surgical instrumentation consists of trocars, graspers to manipulate tissue, a variety of scissors with coagulation capabilities, forceps to create tissue traction, and vaginal instruments [33].

Although robotic surgery has brought significant advances in MIS, there are currently many researchers focused on developing smaller surgical instrumentation to access the limited space of the pelvic area.

## *3.1.6 Natural orifice transluminal endoscopic (NOTES) surgery*

Natural orifice transluminal endoscopic surgery (NOTES) is a recent advancement in MIS [34]. This procedure takes advantage of natural orifices such as the mouth stomach, esophagus, vagina, bladder, and rectum to treat abdominal pathologies [35]. This procedure aims to eliminate abdominal incisions that are performed when using laparoscopic techniques [36]. NOTES has been applied in different procedures such as transvaginal cholecystectomy, transgastric appendectomy, transvaginal appendectomy, and transvesical peritoneoscopy. During this surgery, the surgeon uses endoscopic biopsy forceps, snares, endoscopic grasping forceps, end loops and endoscopic clips [37]. Nevertheless, the conventional surgical instrumentation that is used in NOTES was not designed exclusively for this kind of procedure; thus, this presents several limitations related to manipulation, range of motion, and size. For this reason, many researchers are developing novel articulated grasping systems to pass through the large channels of endoscopes [37] in order



Fig. 1. The main areas related to miniaturization challenges in the development of micro medical devices are the manufacturing processes, types of mechanisms, used materials, actuation principles, and standards and regulations for its commercialization.

to contribute more every day to NOTES advancements [38, 37, 34].

### 3.2 Biomedical applications

In recent years, microgrippers based on microelectromechanical systems (MEMS) have contributed to great advances in biomedical and biological fields. These fields are also known as bio-microelectromechanical systems (BioMEMS) [39]. BioMEMS technology allows developing microgrippers, which can accurately manipulate micro/nanoscale objects. Mainly these microgrippers are used to manipulate individual cells, microbes, and/or blood vessels to carry out localized cell probing, measurement of properties of biological cells [40, 41, 42, 43], manipulation of Oocytes [44], drug delivery systems, gene analysis, and some of them for surgical applications [45] [39]. Despite their enormous advances, there are many challenges regarding their sizes [46]. Mainly, these devices can crack, degrade or bend during a specific process, due to factors such as contamination, fatigue, and wear, and generally due to their manufacturing processes. For this reason, many researchers are focused on improving these shortcomings related to miniaturization.

## 4 MICROGRIPPERS' CHALLENGES AT A MI-**CROSCALE**

The development of new microscale medical devices involves many challenges related to miniaturization at various stages. These complex devices are composed of several components, and the sizes range from micrometers to millimeters. The manufacturing of these medical devices must ensure high accuracy in their sizes to facilitate their assembly. Therefore, miniaturization must consider some aspects that are strongly related, as is shown in Fig. 1. For example, when developing a new robotic medical device, the first step is to answer some questions adopted from standards and regulations for medical devices [47, 48]. From ISO 14971 we have taken three questions as an example: 1) What is the intended use/purpose, and how is the medical device to be used? 2) Is the medical device intended to be in contact with patients or other persons? 3) What materials and/or components are incorporated in, or are in contact with, the medical device? To answer these questions, it must be considered that these devices are in some cases used inside patients, often in contact with mucous membranes, tissues, bones, or blood. Therefore, the biomaterials, actuation principles, types of mechanisms, and manufacturing and assembly processes selected, must guarantee a good performance during its operating cycle. In addition, these must not affect the health of patients.

In the following subsections, each of these aforementioned aspects will be explained in more detail.

## 4.1 Manufacturing and assembly process

There are different manufacturing processes to develop functional medical devices at microscale from metals, polymers, composites, and ceramics. The challenges that these present are related to the sizes of the components, mechanical properties of the materials, type of the mechanism implemented in the devices, and moreover some modifications and adaptations in the conventional processes [49]. The key micro-manufacturing processes are micro-extrusion, micro-molding/casting, mechanical micro-machining, micro-Electrical discharge machining (EDM), excimer laser, short-pulse laser, and focused ion beam  $[50]$ .

#### 4.2 Mechanisms for microgrippers

A mechanism can be composed of several mobile components that are linked to each other through different types of joints to transfer or transform motion, force, or energy, such as in the case of traditional rigid-body mechanisms. A mechanism can also be represented by a single body, such as the case of compliant mechanisms (CMs) that allow the flexion motion through its flexible members  $[42]$ . For example, Fig. 2 (a) shows the rigid-body mechanism of a hold-down clamp composed of 18 parts and Fig. 2 (b) shows the compliant mechanism of a holddown clamp composed of 1 part [51]. Moreover, the compliant mechanisms can also be soft mechanisms represented by a single body that contains little or no rigid materials that are activated to perform pick-and-place gripping tasks [52]. There is a very broad classification of



Fig. 2. Mechanisms, (a) rigid-body mechanism of a hold-down clamp (18 parts), (b) compliant hold-down clamp concept (1 part). [51]

mechanisms that can be used for the development of new medical devices, [53, 54]. The selection of the mechanism type depends on some design requirements, for example: functionalities, workspace, range of motion, DOF, number of constitutive components, size, actuation principle, materials, and intended use. Moreover, its selection must be aligned with standards for medical devices that allow their use in medical fields, as well as its commercialization.

The mechanisms that are mentioned in this review are mechanisms used for the development of microgrippers for MIS and for medical applications. The most used mechanisms in these two applications include sliding joints for traditional rigid-body mechanisms and bending joints for complaint mechanisms [53].

#### *4.2.1 Traditional rigid-body mechanisms*

Traditional rigid-body mechanisms use sliding joints with a smooth and rather precise geometry. The principle consists of two interfacing halves that rotate about a fixed axis. This type of joint is generally resistant to transverse split, and may further be modified to be torsion-stiff and resistant to axial split [53]. Although these types of joints represent complexity in regard to miniaturization, manufacturing, and assembly, there are many researchers who use them to develop medical devices at the microscale. These types of joints enable wide ranges of motion, and when placing more than one joint in series enables to increase in the DOF number, which for MIS applications represents a great advantage.

#### *4.2.2 Compliant mechanisms*

Compliant mechanisms are widely used in the design of medical robotics and devices because of their monolithic structure and high flexibility [55]. These use the distributed compliance of their structure to transfer motion, force, or energy without the use of conventional mechanical joints or living hinges [56, 45] and their mobility is achieved through flexible members. CMs have several applications in surgical procedures since their monolithic structures provide the advantage of fewer parts as well as a reduced number of steps; thus simplifying the fabrication process [55]. However, in order to select the manufacturing process, material selection plays an important role. Depending on the manufacturing process, the material properties can be affected. In addition, in many cases, the actuation principle is strongly related to the selected material.

Research on compliant microgrippers has shown significant progress to increase the grasping force and sensing force [42].

## *4.2.3 Soft mechanisms or soft robotics*

Soft robotics is being widely used to interact with humans and environments with limited spaces [57]. The capabilities of soft mechanisms depend on their material and their structural design. Soft robots use soft sensors, soft actuators, and some springy joints to store/release elastic energy. The variety of materials used in soft robotics allows the manipulation of delicate objects and actuation with multiple DOFs. The main materials for sensor and soft actuator manufacturing include hydrogels, ionic and conducting polymers, carbon nanotubes, dielectric elastomers, shape-memory materials, and so on [58].

## 4.3 Biomaterials

Biomaterials are materials that can be used in contact with body fluids, for dental instruments, for surgical instruments used on intracorporal applications, mainly to manipulate or remove soft and hard tissues, and for biomedical applications [59, 60, 61, 62].

The criteria for choosing the material are associated with manufacturability, these materials must be ductile and malleable. The surgical instrument must maintain its shape once manufactured and must not break no matter how thin, long or small it is. This must also be capable of withstanding high temperatures when subjected to sterilization processes. Another important aspect of the biomaterials is their mechanical properties, since these materials, must be able to bear high loads, fatigue loads, and stress deformations before occurring failures. Moreover, the biocompatibility [63] with living tissues is crucial for the development of medical devices, in order to prevent tumor formation, genetic damage or blood clot formation [64], non-toxic when in contact with the body or any type of fluid [61, 65, 62]. Also, the magnetic properties, must not be affected by a magnetic field in the operating room; non-reflective and ergonomics [66]. Therefore, these biomaterial plays a very important role when an instrument is used in different surgical procedures and biomedical ap-

#### Table 1. Metals for medical devices



plications that require contact with blood, human fluids, and chemical substances [60, 61].

On the one hand, surgical instruments that do not fulfill their intended use, or can not be sterilized or decontaminated, can represent, e.g., long times during the surgical procedure, poor surgical results, patient infection, patient injury, and even the death [67]. On the other hand, proper care and handling increases the useful life of the instrument and minimizes possible failures that can represent any type of risk to patients [60].

The surgical instruments require the most stringent standards of sanitation in order to guarantee their proper operation in persons and in medical applications [59]. Failing to fulfill these ideals may affect patient safety.

Surgical instruments are carefully developed for an intended purpose. These must be easily cleaned, disinfected, maintained, durable, rigid enough for normal handling, and above all resistant to corrosion due to contact with blood, body fluids, cleaning solutions, sterilization, and the atmosphere [60].

Considering all these parameters, most surgical instruments are made of stainless steel or other metals that are detailed in Table 1, also known as biomaterials, which have characteristics such as corrosion resistance, strength, toughness, ductility [68, 64], mechanical reliability, elasticity, wear-resistance, and fatigue, toughness, and thermal and electrical conductivity [64].

Moreover, thanks to the development of new technologies there are other materials such as polymers, and plastics [60, 67].

#### 4.4 Actuation principle

In MIS and medical applications, the gripping precision and the manipulation force exerted by the microgripper are considered the key indices for selecting the actuator and its actuation principle. The actuator is a very important component for all microgrippers, since this provides the force required by the device to function as a gripper [71].

Actuation is the most important function of a microgripper as it enables to perform the grasping motions and manipulation of different objects with the proper force without causing any damage. There is a variety of actuation principles, their selection depends on the mechanism types implemented in the microgrippers [72].

For instance, the traditional rigid-body mechanisms use mechanical actuation, which consists of using mechanical components that are motion regulators such as linkages, cams, gears, racks, pinions, chains, belt drives, etc. These components are connected to a driving source, such as stepper motors, brushless motors, servo motors, universal motors, etc. in order to perform the motion. The actuation in some cases can be manual.

On the other hand, the complaint mechanisms use MEMS-based actuation principle and this is divided into two groups. In the first group, the actuation source mechanism is simply integrated with the structural body, and in the second group, the actuation source also serves as the structural body of the microgripper [73]. The actuation principle of MEMS has different approaches, the key ones are: electrostatic actuation, electrothermal actuation, electromagnetic actuation, piezoelectric actuation [74, 41, 39, 75], and shape memory alloys (SMA) actuation, and each of these can have some configurations, [76]. For example, within electrostatic actuation, the most commonly used configuration for microgrippers for medical applications is the comb-drive configuration [77, 78]. For SMA actuation, the most common configuration is using wires [79], and for piezoelectric actuation is stack, blade, bimorph and bulck (monolitic) configurations [76, 80].

#### 4.5 Standards and regulations

The development of new medical devices implies big challenges, mainly because these devices are destined to be used in persons, in some cases are implanted in persons, and in others are in contact with tissues or blood; for the diagnosis of disease, cure, mitigation, treatment, or prevention of disease  $[81]$ . The complexity of these devices represents some uncertainties at every process stage. These uncertainties can result from models and techniques used for the calculation of the design, the selection of one or more materials, the manufacturing process, the manufacturing ability, the assembly, and the number of components, which in many cases are usually assumed by the engineers at starting from books, data, or your own experience [82].

Complex systems are more difficult to assess, thus the likelihood of the potential failure occurring is greater, which in turn represents a greater number of risks for the users since it could further affect their health [83]. These risks can be mitigated through a risk management process, which has the intention to identify, analyze, evaluate, control, and monitor the risks and hazards associated with medical devices [47, 84] at all stages of a device's life cycle, from product design to procurement, production, and postmarked use.

Therefore, the development of medical devices must meet some regulations and standards, which provide a combination of techniques to assess the reliability and analyze the risk through their lifetime [81].

The main regulations are FDA in the United States and the Medical Devices Regulation (MDR) in Europe for commercialization, which allows getting high reliability in all phases of the design and development of medical devices. These regulations are supported by the International Organization for Standardization [ISO], mainly the ISO 14971 for medical devices [85].

#### 5 MICROGRIPPERS' DEVELOPMENT LEVEL

Below, a review of microgrippers that are both commercially available and under development is presented. Table 2 enlists some commercial microgrippers. Table 3 and Table 5 enlist microgrippers developed by research institutes. Table 3 is focused on migrogripper that use traditional rigid-body mechanisms, and Table 5 is on microgrippers that use complaint mechanisms. The main aspects that are explained in these tables are applications, functionalities, DOF, sizes, materials, actuation principles, manufacturing process, and the proposed method.

### 5.1 Commercialized grippers

The development of microgrippers presents great challenges for engineers due to their small size [6], limited workspace (inside the patient), and the loss of physical contact with the person since it limits dexterity and manipulability. These factors imply making devices with more DOF, a greater range of movement in order to get greater precision during surgery, as well as multifunctional micro-instruments that can be used during the surgical process without having to be exchanged several times. Some companies have developed surgical robot systems also known as master-slave manipulators with different DOF. Some of them have increased their DOF numbers by using the end-effectors such as microgrippers.

For example, Intuitive Surgical Inc. has developed and marketed a robotic surgical platform that contains a mobile platform and a master console, composed of four arms, each one with a capacity for 3 DOF. However, 7 DOF can be achieved with the use of the EndoWrist system that mimics the movements of the human wrist [91]. The *da EndoWrist Vinci System* diameter is about 5 mm and 8.5 mm, most of them have 7 DOF and are cable-driven [92, 91]. The main applications of Intuitive Surgical Endoscopic Instruments are urologic, general laparoscopic, gynecologic laparoscopic, general thoracoscopic, and trans-oral otolaryngology surgical procedures restricted to benign tumors and malignant tumors classified as T1 and T2, and for benign base of tongue resection procedures. The material used for these microinstruments is mainly titanium.[86].

On the one hand, the Olympus Medical System Group, [87, 93] and FlexDex [88], launched the 3D/FlexDex® laparoscopic surgical system for minimally access surgery composed of ENDOEYE FLEX 3D and the FlexDex® Needle Driver respectively. The system has technologies developed in all three axes and integrated into a conventional laparoscopic instrument, which transmits the movements of the surgeon's hand, wrist, and arm from outside the patient to an end effector inside the patient's body [94]. The FlexDex Needle Driver has a 35 cm working length, is compatible with an 8 mm trocar [95], has 7 DOF [96] and the motion of the wrist is transmitted to the tool via wires and pulleys [97, 98]. These microinstruments are destined for use in laparoscopic surgery and, including, but not limited to general surgery and gynecological specialities.

On the other hand, Medical Microinstruments SpA (MMI) developed Symani Surgical System that is composed of two arms and has the world's smallest wrist instrumentation, offering 7 DOF and dexterity beyond the reach of human hands [99]. The wristed instrumentation has an outer diameter of 3 mm and tips with 150 microns in width [89]. The main application of this small wrist is minimally invasive surgery.

LIVSMED developed Artisential® Articulating Laparoscopic instrument, which is an intuitive instrument for minimally invasive surgery. Artisential® endeffectors has a double-joint structure that allows the instrument to move 360°. The main end-effectors are Bipolar forceps, needle holders, clip appliers, monopolar hook, bipolar dissector, monopolar scissor, etc., and are designed to mimic specific capabilities of the human hand. The Artisential® end-effectors diameter is 8 mm, the shaft lengths are available from 25, 38 and 45 cm, and they have 7 DOF [90, 100]. These are the most commonly used commercial devices for MIS. In Table 4 some



Table 2. Commercial Microgrippers Table 2. Commercial Microgrippers characteristics are shown.

## 5.2 Compliant Microgrippers from research institutes

There are several researchers who have focused their work on developing or improving the microgrippers used in MIS and biomedical applications. Their contributions are different since each researcher considers parameters such as functionality, materials, manufacturing processes, action principle, diameter size for microgripper to be used in MIS and size in general for microgrippers to be used in biomedical applications.

Hardon et al. [1] built a 2-DOF detachable articulating grasper of 5 mm in diameter, a total length of 328 mm, an articulation range of 159°, (left 82°, right 77°), an articulation range for pitch of  $110^{\circ}$  (up 55°, right 55°) and a maximum tip opening between 52° and 60° for laparoscopic surgery. Due to the sizes of the devices, these are difficult to assemble and clean. Also, there are hidden elements making difficult its assembly and clean, this is the main reason that most are disposable. The authors considered these factors and focused their research on developing a grasper fully detachable and cleanable, taking the advantage of cableless steering approach. The devices were 3D printed using medical grade plastic in order to be autoclavable, and some components of the tip were Nitinol or 316 stainless steel.

Makoto [101] proposed a noninterference wrist mechanism between the pitch and yaw axes for robotassisted forceps for laparoscopic surgery. The maximum outer diameter was 7.5  $mm$ , the total length of its jaws of 14.3 mm, and a range of motion on the gripper axis of 90°. The author proposed this design in order to improve the controllability and range of motion of a slave manipulator in a patient's abdominal cavity. As actuation, Makoto considered wires-driven mechanisms using servo motor-driven and pulleys to get the motion of up/down and right/left, yaw, pitch, and grasping.

In 2019 Wu [102] developed a 2-DOF wrist mechanism of 3 mm in diameter, the length of its jaws is 7  $mm$ , and a wrist motion range of  $90^{\circ}$  to be used in robotic cleft palate repair. Wu focused this work on performing a novel design, considering the results of the characterization of the friction of the guide channels and the tension of the cable due to an exit angle of 17 degrees presented by Podoslky. For that, Wu designed a novel cam design that solved the cable path length problem and performed the characterization of the functionality of the design through motion accuracy, force capability, and fatigue tests. Moreover, the capabilities of the instrument were demonstrated by performing the suturing task using a force above 5 N which is required to cut the palatal tissue, and the tracing task using a validated cleft palate phantom. This instrument was motor-driven and cables in order to get roll, pitch, jaw and grasping motion. Some parts were manufactured through selective laser sintering out of stainless steel 316 and the gripper in 3D printed material.

Podolski et al. [103], worked on the characterization of solid surface cable guide channels of a 3-DOF wrist of 5 mm in diameter and a range of pitch motion of 90 $^{\circ}$  to be used within the infant oral cavity workspace for cleft palate repair surgery. Podolsky focused on reducing the components number of the microgripper, by replacing the pulley system to a significant modification on the link 1 (see Fig 1. shown in [103]). The authors proposed to add four guide channels in the link 1 that allowed reducing four components compared to the da Vinci Endowrist 5 mm wrist, obtaining a total of 4 components. Moreover, their proposed allow reduced the total length of the microgripper. This instrument was motor-driven and cables in order to get pitch, yaw and grip motion, and was manufactured by three-dimensionally (3D) printed using direct metal laser sintering (DMLS) in 17-stainless steel.

Yu et al. [104] presented a multi-DOF surgical type of forceps with an overall diameter of 10 mm, an overall length approximately of 27  $mm$ , and a width of 8  $mm$ for MIS. The authors focused their work on force feedback in order to reduce the risk of damage to the tissues due to the uncontrollable force magnitude. The sensing range was 0.5 N- 2.5 N to perform the grasping, stripping, and moving functionalities during the surgical procedure. For this, they developed a prototype design that includes the capability of direct force sensing through a double E-type vertical elastomer with four strain beams. The actuation principle that they considered was driven by a single rod to lead the translation into the rotation, thus the grippers are connected with the shaft of the instrument using the fastener. Their proposed prototype consists of a complaint part and a part with sliding joints that jointly avoid issues such as sudden fracture, inconvenience of disassembly, and disinfection. Moreover, the authors proved that the design met with desired requirements for strength and rigidity through the FEA results, considering the properties of the aluminum alloy 7075- T651.

Sakes et al. [105] introduced a 2-DOF steerable bipolar electrosurgical grasper of 7 mm in diameter for use in MIS. The device consists of two movable electrical jaws that meet the functionality of tissue grasping during the surgical procedure. Being a micro forceps for electrosurgery, the authors considered the following factors, the electrical resistivity lower than  $1.8 \cdot 10^{-6} \Omega m$ , the ther-



Table 3. Traditional rigid-body Microgrippers (Continued on the next page) Table 3. Traditional rigid-body Microgrippers (Continued on the next page)



Table 4. Traditional rigid-body Microgrippers (Continued from previous page) Table 4. Traditional rigid-body Microgrippers (Continued from previous page)



Table 5. Complaint microgrippers Table 5. Complaint microgrippers



Table 6. Soft and complaint microgrippers Table 6. Soft and complaint microgrippers mal capacity of the tip higher than 0.1J/Kg to prevent the tip from heating up when the current is applied and bending stiffness of at least 0.56  $N/mm$ . The microgripper was driven by two electrode cables of 0.45 mm in diameter and polymeric steering ribbons of 0.3  $mm$  thick and 4 mm wide. The electrode cable and ribbon were manufactured using conventional manufacturing methods out of PolyEther Ketone (PEEK) and the material of the two jaws was titanium. The final prototype can be opened and closed at angles up to  $170^{\circ}$  and can perform  $\pm 65^{\circ}$  for sideways, ±85° for up- and downwards movements

Kim et al. [106] presented a surgical forceps of 10  $mm$  in diameter and an overall length of 23  $mm$  for MIS. The authors focused their work on the force feedback by implementing a three-axial force sensor placed on the distal region of the surgical gripper's tip. The jaws were manufactured using the knurling process in aluminum alloy 7075. Their work aimed to preserve the gripper's shape, its minimization, and palpation function, and develop a simple design composed of 4 parts.

Haraguchi et al. [107] proposed a 3 DOF flexible wrist mechanism for forceps manipulators using a machined spring in order to get an enhanced torsional rigidity and reduce the number of parts. The forceps manipulator has a diameter of 10  $mm$ , a total length of 50  $mm$ from the gripper to the flexible joint, a bending range of  $\pm 90^\circ$  and its main use is laparoscopic surgery. The authors focused their work on design a magnetic resonance imaging (MRI)-compatible robot with pneumatics actuators, considering adding sensors and replace some metallic parts to nonmagnetic members. This instrument was pneumatically driven and used a push–pull actuation mechanism using superelastic wires for the flexible spring joint. The forceps manipulator was subjected to different test to evaluate its force, thus the performance of the force estimation was confirmed experimentally and the minimum force detectable by the forceps about 0.37 N. The biomaterials used were Ni-Ti for the superelastic wire, stainless steel 304 for the wire pipe, and pipes.

Rau [108] developed multiple functional forceps with a maximum diameter of 3 mm and an overall rigid length of the tooltip of 10 mm that contributed to MIS and NOTES. In order to meet the grasping and spreading functionalities, the author considered applying a force of 1-2 N that allows a jaw angle of 90º. Moreover, he considered two configurations for the design: compliant mechanism and traditional pinned linkages. This instrument was driven by a set of two wires to control the opening and closing movements, and it was manufactured in 316 stainless steel by wire EDM process. He proved that the design meets the requirements and performance goals of the design by iterating between predictive models, FEA, and experiments.

Salle et al. [109] presented some possibles designs of grippers of 1-DOF to be implemented in a robotic arm of 5-DOF that can be used as surgical instruments for suturing on the hearth surgery, and more precisely on CABG. The microgripper maximum diameter of the instrument was limited to 10 mm and its opening range motion was of 56°. The instrument was SMA wire-driven and some SMA wires configurations were proposed. For example parallel SMA gripper, SMA gripper with self-rotation, net SMA gripper, and helicoidal SMA gripper being the helicoidal SMA gripper the best configuration because allowed reducing the total length of the module from 37  $mm$  to 17.1  $mm$ , this configuration used 8 SMA wire of 250 microns in diameter in order to perform the opening and closing motions of the grippers. The material used for the components was thermoplastics Poly-Ether-Ether Ketone (PEEK).

Miyata et al. [110] developed a 2-DOF micro grasping forceps of 3.3  $mm$  in diameter to be used (MRI) during a neurosurgery procedure. The authors focused their research on the design of a new cam mechanism in order to meet with the requeriments such as small size and precision positioning. All the mechanisms were ultrasonic motors-driven, and they use a wire was used to perform the grasping functionality. In order to select the material they validated MR-compatibility of materials and selected aluminium and titanium for the micro grasping forceps, Be-Cu for a spring that allows the rotation of the forceps, and stainless steel for other parts set far that not interfere to magnetic field. The microgripper was subject to tests to validate the MR-compatible and to position accuracy.

Saba et al. [46] developed a complaint microgripper composed of four jaws, each exclusively designed for a specific application. The total sizes of the mechanism are, 9900  $\mu$ m and 9030  $\mu$ m. This was designed mainly to manipulate microbiological applications ranging from 300 to 700  $\mu$ m, 1 to 340  $\mu$ m, 100  $\mu$ m pool, and 1 to 120 spongy cells, respectively, however, can also be used to manipulate micro-objects, microstructures, microelectronics parts, and micro-assembly. The authors focused their work on analyzing the sensing force to manipulate biological objects, as well as a way to increase its gripping range obtaining a maximum displacement of 11.46  $\mu$ m, for that they incorporate electrostatic sensors at jaws sets. The microgripper was designed to be fabricated using commercially available Silicon-On-Insulator Multi-User Micromachining Processes (SOIMUMPs) and the actuation principle was by using thermal chevrons actuators. In addition, the authors performed FEM simulations and analytical modeling that were compared to prove the viability of the design as a microgripper.

Libu and Bharanidaran [111] developed a new multifunctional compliant mechanism forceps/scissors with an overall size of 5  $mm$  in diameter, and 15  $mm$  in length to be used in medical applications. For the actuation of the mechanism, this has an outer sheath/tube that moves towards the tip, then, the jaws of the forceps move inward as a closing position, when the sheath/tube moves in the reversed direction, the jaw is opened. In order to validate the geometrical parameters, the authors performed a FEA where the 316L stainless steel was considered. The authors opted for a complaint mechanism instead of a traditional rigid body because they focused on getting a high accuracy and controlled complex movements. The final design had a large opening of jaws of 2.98 mm and a high cutting force of 0.694 N.

Cecchi et al. developed a micro-gripper based on conjugate surfaces flexure hinge (CSFH) silicon MEMS with a dimension of 2000  $\mu$ m and 1500  $\mu$ m, and thickness of 40  $\mu$ m, to be used in medical fields as tissue and cell manipulation. The authors focused their work on designing a microgripper that solves some problems of handling cells and tissues, that can be subjected to in vivo and in vitro analysis, and that has a small dimension like those used in minimally invasive open biopsy. The manufacturing process for the microgripper was a combined surface and bulk micro-machining technique applied on silicon on insulator (SOI) wafers, thus the main materials of the microgripper were: silicon wafer, silicon oxide, photoresist and aluminum. The actuation principle was through comb-drives. The authors performed different FEA to evaluate the design requirements of the microgripper, actuation tests and in vitro observation, displacement measurements tests [119] as well as its functional characterization [77].

Mehrabi and Aminzahed [79] designed and manufactured a microgripper with SMA wire actuator with an approximate size of 12 mm long, 10 mm wide, 0.5 mm in thickness, and with a maximum deflection of 200  $\mu$ m to be used in medical applications. The authors focused their work on increasing the deflection efficiency and strength, as well as keeping the simplicity and manufacturability, thus the design was based on flexible hinge structures. This microgripper was manufactured by micro-wire EDM in aluminum AL-7075 and the actuation principle was the SMA wire. The wire which was the actuator is composed of Ni-Ti alloy with a diameter of 100 um. In order to perform the closing and opening motions of the jaws, the final design was composed of support pins, flexure joints, wires, and levers. In order to identify stress concentration, they performed a FEA, and to validate the design, they implemented and set-up microgripper and running tests.

Power et al. [80] developed a tethered force-sensing microgripper to be used in minimally invasive medical applications. The overall size of the microgripper was approximately 100  $\mu$ m in length and width. The microgripper was printed using 2-photon polymerization (22P) directly onto the tip of a single-mode of an optical fiber. The authors focused their work on integrating a forcesensing capability that allows accurate micromanipulation of fragile or soft objects. The microgripper was composed of three fingers, each based on a three-hinge mechanism consisting of four rigid links and a single compressible link length. Moreover, in order to demonstrate the manipulation capabilities, the microgripper was subjected to tests of pick-and-place to grasp, move and then release an ellipsoidal object.

Fujisawa et al. [112] proposed a 4-DOF robotic forceps based on a compliant mechanism of 3.5  $mm$  in diameter and a length of jaws of 10.35 mm, to be used in neurosurgery. The authors considered that a wire mechanism has an advantage over miniaturization in multi-DOF structures, however, the elongation, friction, and shear of the wire can affect the performance of the device, moreover, they also considered that a link mechanism has the advantages in rigidity and durability, however, the main problem is miniaturization and sterilization due to numerous components. Therefore, in order to take advantage of both, they focused their work on designing a compatible mechanism based on two types of springs joined by a pin to allow rotational movement. The actuation principle of the forceps was by using 4 linear actuators. In order to optimize the design parameters, the forceps were subjected to a series of FEA which demonstrated that the device satisfied the range motion and high rigidity.

## 5.3 Soft and Compliant Microgrippers from research institutes

Forbrigger et al. [113] presented an end effector of 3 DOF composed of a magnet wrist and two magnets fingers for gripping, pushing, or pulling tissues in surgical applications. The wrist and the fingers were connected by compliant joints of Nitinol resulting in a total length of 21  $mm$ . Moreover, the microgripper size allows fitting through a 4  $mm$  diameter hole. The range of motion of the microgripper wrist under open-loop control was  $\pm 45^{\circ}$ . The authors mentioned that cable-driven is a common actuation method for surgical tools, however, its implementation brings many challenges since these use smaller diameter pulleys and small cables which are subjected to friction and tension and these are parameters that increase the likelihood of cable failure in the tools. For that reason,

they proposed the cable-less microgripper magnetically actuated in order to mount at the distal end of an existing surgical robot arm. The materials used were superelastic Nitinol wires for finger joints and wrist and titanium for complementary components. Moreover, the microgripper was tested to move a 5x2x2 mm cargo composed of polydimethylsiloxane (PDMS) in air under open-loop control.

Cheong et al. [114] developed a wireless-powered electroactive soft microgripper to perform gripping tasks in biomedical applications with a maximum tip displacement of 0.7 mm. The microgripper is composed of a moving finger made of ionic polymer metal composite (IPMC) with a size of 15  $mm$  in length and 2  $mm$  in height and a stationary finger made of Cu-clad polyimide. The authors highlighted that numerous soft microgripper have been developed using thermal actuation, including SU8 polymer, shape memory polymer (SMP), Parylene C polymer, and hydrogels. However, the performance of these microgrippers can be deteriorated due to a change in the environment temperature since these are highly temperature dependent. Therefore, they decided to use IPCM to activate the microgripper since this polymer can answer to small electrical signals instead of temperature. The authors tested the wireless activation by using a tuned external radio frequency (RF). The IPMC-based finger was tested by gripping fish eggs and demonstrated to have sufficient holding force to grip the fish eggs without causing any physical damage.

Al Alia et al. [115] proposed the design of two micro-piezoelectric actuated grippers able to perform clamping and grasping tasks in medical applications. Design (a) has a size of  $362x362 \mu m$  and allows a maximum opening of 43  $\mu$ m. Design (b) has a size of 940x940 nm, and allows a maximum opening of  $104$  nm. The authors chose these sizes since their purpose is to use the microgrippers for clamping cancer tumors for in vivo photodynamic therapy. They performed simulations in MAT-LAB® software to set up the electric wiring and COM-SOL® software to validate the boundary conditions. The piezoelectric material selected was zinc oxide, and the actuation principle was electric. The authors concluded that when applying a potential to the piezoelectric complaint mechanism, this offers self-actuation. Therefore, it is no need for a complex mechanism to derive and apply forces.

Rateni et al. [116] developed a soft robotic gripper composed of three fingers to grasp and manipulate soft tissues in MIS. Each finger has infinite DOFs actuated by one cable. The cross-section of each finger is  $6x2 \, mm^2$  at the distal part and 6x6  $mm^2$  at the proximal part. The total diameter of the system composed of three fingers is 17  $mm$ . The authors focused their work on exploiting specific soft robotics technologies by using a soft instrument based on an under-actuated mechanism. To achieve that, they leveraged the intrinsic compliant properties of elastomeric materials and developed a manipulator made up of silicone. The microgripper was nylon cable-driven and servomotors. The manufacturing process was additive using 3D-printed molds. Moreover, the authors performed some tests to evaluate the grasping force and wire tension.

Breger et al. [117] built self-folding thermomagnetically responsive soft microgrippers, capable of cell excision and gripping onto and isolating tissues in biological applications. The authors proposed to combine pNIPAM-AAc hydrogel polymer with PPF rigid polymer to increase the overall stiffness of the actuator. Therefore, they defined by experiments that with a PPF layer thickness of 10  $\mu$ m and pNIPAM-AAc thickness of around  $45 \mu m$  is possible to increase the overall stiffness of a soft robotic tool. Moreover, in order to incorporate the capability for magnetic direction, the authors incorporated nanoparticles into the pNIPAM-AAc layers. The polymeric grippers were fabricated using sequential photolithography and folded into 3-D structures based on the swelling/deswelling through water absorption/desorption in response to temperature. They defined that, with temperatures, above 36 °C, the pNIPAM-AAc layer excludes water and contracts and below 36 °C, the pNIPAM-AAc absorbs water and swells. This method served as an actuation mechanism.

Kuo et al. [118] presented a hydrogel-based microgripper using magnetic fields to perform the gripping, translation, and rotational motion during intravascular applications. The total length of the microgripper is approximately  $\mu$ m, the width of the gripper tip is approximately 100  $\mu$ m, and the thickness of 100  $\mu$ m. The microgripper was wirelessly actuated by using direct current (dc) and ac magnetic field. The microgripper reached a full stroke at approximately 38◦C. The material of the microgripper was biocompatible hydrogel and the manufacturing process was a simple lithography technique. The authors demonstrated the gripping, translational, and rotational motion on a PVC tube and a PDMS microfluidic channel.

#### 6 CONCLUSIONS

This paper presents a review of the main parameters to consider when developing microgrippers to be used in MIS and biomedical applications. What stands out about each of the authors are: (i) their original approaches to maintaining or reducing the sizes of these medical devices and (ii) the reduction of the number of its constituent components. Although there is a variety of biomaterials, manufacturing and assembly processes, actuation principles, and mechanical configurations, their selection will depend mainly on the intended use of the device. After reviewing the 27 microgrippers, it was identified that most of them, consider two types of mechanical configurations, which are: traditional rigid body mechanisms and complaint and soft mechanisms. In addition, it was highlighted that microgrippers using traditional rigidbody mechanisms are primarily intended for MIS, and microgrippers using complaint and soft mechanisms are mostly used for biomedical applications. Another point to highlight is that the type of mechanism used is also strongly related to the principles of action and this, in turn, with the selected biomaterials.

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