Instrument Malfunction

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Abbreviations

MAUDE	Manufacturer and User Facility Device Experience
TCA	Tip cover accessory
US FDA	United States Food and Drug Administration

General Considerations

Background

Although robotic instrument malfunctions are reportedly rare, they may adversely affect clinical outcomes. The rate of reported instrument malfunctions during robotic urologic surgery ranges between 0.25% and 1.1% [1, 2]. However, many instrument malfunctions are not reported as they may go unnoticed, [3] do not result in clinical complications, [2, 4] and require that the surgical team voluntarily report incidents [3–5]. Nevertheless, depending on the specific type, severity, and timing, instrument malfunctions may increase operative costs, cause operating room delays, and even cause unintended patient injury. Despite this, the literature regarding instrument malfunctions during robotic urologic surgery is limited.

Herein, instrument malfunction refers to any intrinsic defect in a robotic instrument that limits its normal function. System-related defects that inhibit normal function of instruments and malfunctions related to linear staplers are discussed elsewhere and are thus excluded from this discussion. The purpose of this chapter is to describe the major types of instrument malfunctions during robotic urologic surgery and to review their prevention, diagnosis, and treatment.

Robotic Instruments

Currently, robotic urologic surgery generally refers to procedures performed using the da Vinci® (Intuitive Surgical, Inc., Sunnyvale, USA) surgical system. As such, our discussion of instruments and their malfunction focuses on EndoWrist® (Intuitive Surgical, Inc., Sunnyvale, USA) instruments, which are the only instruments designed for use with the da Vinci® surgical system. EndoWrist® instruments are mounted on robotic arms and introduced into the body through ports/cannulas. The instruments may be interchanged during an operation to carry out desired functions. The surgeon relays motions from the master controllers at the robotic console

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to manipulate the instruments within the patient's body. EndoWrist® instruments provide the surgeon with a range of motion greater than the human wrist through 7° of freedom, 180° of articulation, and 540° of rotation. These instruments have a preset number of uses, and most are limited to ten uses.

There are four major components to an EndoWrist® instrument. The instrument housing is the portion of the instrument that engages and disengages with the robotic arm (Figs. 4.1a and 4.2a). An instrument may be disengaged from the robotic arm by pressing on the release levers on the instrument housing. Also, for instruments capable of delivering energy, the connections for monopolar and bipolar energy are located at the instrument housing. The shaft connects the instrument housing to the wrist and acts as the rotating arm (Figs. 4.1a and 4.2a). The wrist mimics the wrist of a human hand and provides the surgeon with additional dexterity (Figs. 4.1b and 4.2b). Lastly, the end effector provides the instrument its specific function and may be used to grasp, retract, and dissect tissue; hold suture needles; apply electrocautery; and deploy clips (Figs. 4.1b and 4.2b). On the instrument housing, there are a series of discs that connect to the wrist and end effector via cables that run through the shaft. These cables allow movements to be translated from the surgeon console to the instrument via an integrated pulley system. On instruments used for the da Vinci® S and Si, the series of discs are on the back side of the instrument housing (Fig. 4.1c); on instruments used for the da Vinci® Xi (Fig. 4.2c), the series of discs are on the bottom side of the instrument housing.

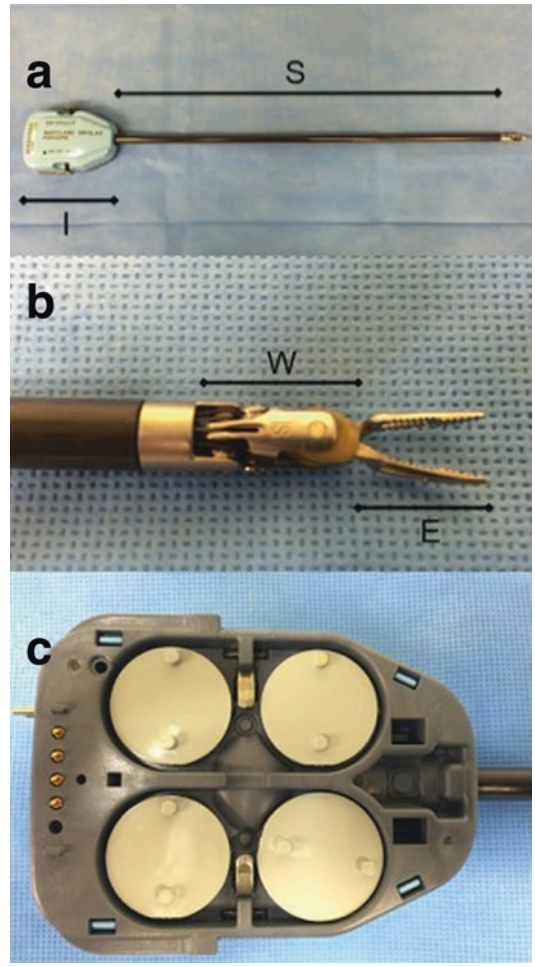

Fig. 4.1 Instrument for use in da Vinci® S and Si. (**a**) *I* instrument housing, *S* shaft. (**b**) *W* wrist, *E* end effector. (**c**) Discs on back of instrument housing that transmit motions to wrist and end effectors via cables that run through the shaft

Types of Instrument Malfunctions

There are two major types of instrument malfunctions: mechanical and electrical. A mechanical malfunction refers to a physical defect in a robotic instrument that compromises normal range of motion and/or function. Although there is a wide range of possible mechanical malfunctions, they all generally inhibit the surgeon's ability to complete an operation. For example, they may lead to an increase in operating room time as the surgical team attempts to evaluate and manage the malfunction, an increase in the cost of surgery as these malfunctions generally require that the robotic instrument be replaced, and an increase in the risk for surgical complications.

The most commonly reported sites of mechanical malfunctions are the instrument wrist and end effector. In a retrospective review of all reported robotic instrument malfunctions in the United States Food and Drug Administration (US FDA) Manufacturer and User Facility Device Experience (MAUDE) database between January 2009 and December 2010, Friedman et al. found that 285/565 (50.4%) of all reports were mechanical

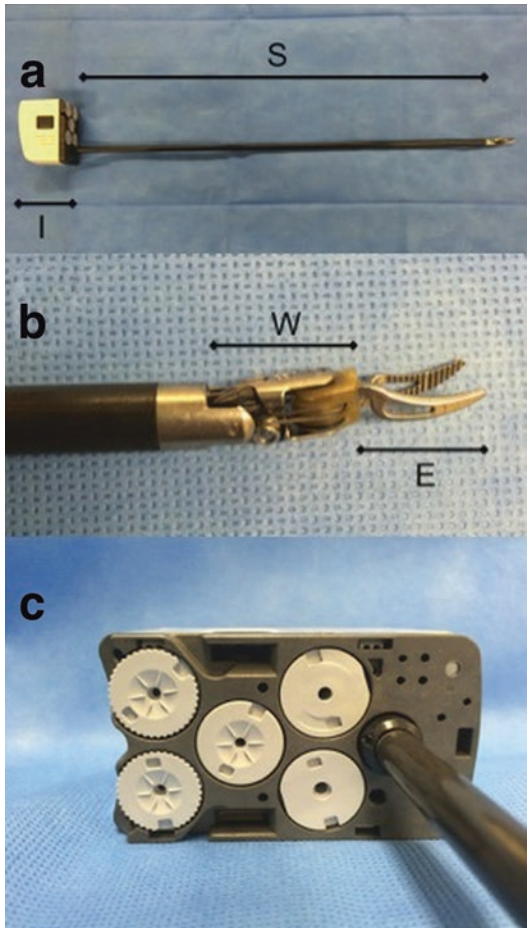

Fig. 4.2 Instrument for use in da Vinci® Xi. (**a**) *I* instrument housing, *S* shaft. (**b**) *W* wrist, *E* end effector. (**c**) Discs on bottom of instrument housing that transmit motions to wrist and end effectors via cables that run through the shaft

malfunctions at the wrist or end effector [3]. Instrument defects at the wrist generally decrease range of motion, while those at the end effector generally decrease the specific functionality of the instrument; instrument defects at both sites inhibit the surgeon's ability to operate.

Instruments with articulating jaws, such as needle drivers, grasping retractors, and scissors, are inherently more prone to end effect malfunctions, and they may present in a variety of different ways. In a case report by Park et al., the joint bolt of a ProGrasp™ (Intuitive Surgical, Inc., Sunnyvale, California, USA) forceps became loose which decreased the ability of the instrument to grasp tissue during robotic radical prostatectomy. As the loosened bolt also prevented the ProGrasp™ forceps from being removed through the robotic trocar, the ProGrasp™ was removed with the robotic trocar en bloc. A second bedside assistant assisted with the remainder of the case in place of the ProGrasp™ forceps, and the surgical team was able to complete the procedure with no complications [6]. Also, bending of the end effectors may result in misalignment of the articulating jaws, decreasing their functionality. This may result from instrument mishandling during sterile processing, improper storage, and aggressive intraoperative use. Although reports regarding bending of the end effectors are limited, we frequently encounter this at our institution. Furthermore, there may be instances when a piece of an end effector breaks off into the operative field (Fig. 4.3a, b). Instrument fragmentation requires that the surgeon look for the broken piece and extract it from the patient's body. In another case report by Park et al., one of the jaws of a needle driver broke off into the surgical field during robotic radical prostatectomy. The surgeons were able to find the broken jaw of the needle driver and extract it from the patient using a laparoscopic grasping forceps [7].

Mechanical malfunctions also occur at the shaft. In the aforementioned study by Friedman et al., the authors found that shaft malfunctions accounted for 76/565 (13.5%) of all reported instrument malfunctions [3]. Instrument shaft defects may be caused by instrument collisions with robotic ports/cannulas and arms. While collisions with robotic ports/cannulas generally cause trauma along the vertical axis of the shaft, collisions with robotic arms generally cause trauma along the perpendicular axis of the shaft. These collisions may cause peeling, bending, cracking, or breaking of the instrument shaft [2, 3].

Furthermore, mechanical malfunctions may occur at the cables that run from the instrument housing to the wrist and end effectors. In the aforementioned study by Friedman et al., the authors found that cable malfunctions accounted for 29/565 (5.1%) of all reported instrument malfunctions. Although the cables most commonly malfunction at the instrument wrist and end effector, the cables may malfunction at any point along their length (Fig. 4.4) [3]. Movement of an

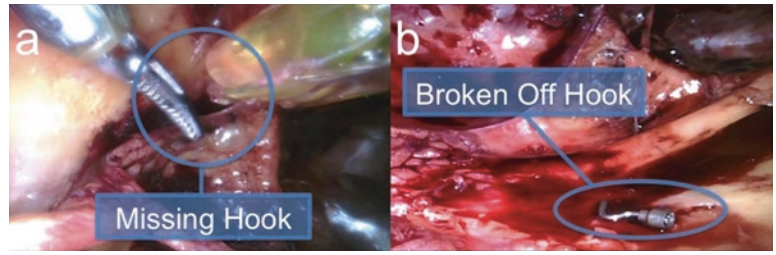

Fig. 4.3 (**a**) *Circle* highlights missing end effector on permanent cautery hook. (**b**) *Oval* highlights missing end effector of permanent cautery hook found on retroperitoneal fat

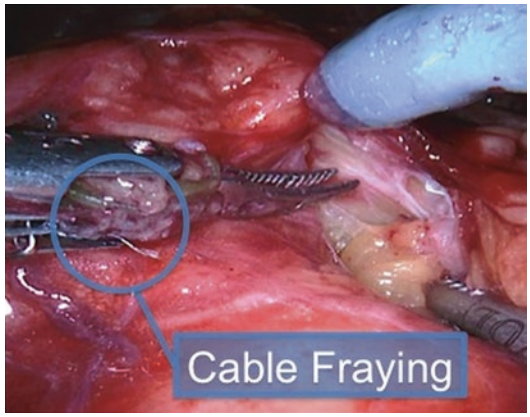

Fig. 4.4 *Circle* highlights cable fraying on Maryland bipolar forceps wrist at two locations

instrument beyond its normal range of motion or applying excessive force on the robotic instrument may cause the cables to fray, break, or become displaced from their pulleys [8]. Cable malfunctions inhibit the transmission of desired movements to the instrument.

An electrical malfunction primarily refers to arcing, when an electrical current deviates from its intended course due to an insulation defect. In the aforementioned study by Friedman et al., the authors found that arcing incidents accounted for 156/565 (27.6%) of all reported instrument malfunctions [3]. Although arching may occur with the use of any instrument that utilizes electrocautery, it primarily occurs with the use of monopolar curved scissors. Arcing is particularly problematic as it may cause unintended tissue damage. Stray electrical currents can reach temperatures between 700 and 1000 °C and cause thermal tissue injury [9]. Hollow organs, such as bowel, ureter, and blood vessels, are particularly susceptible to electrical injury as a single spark can cause an immediate or delayed perforation. Arcing may occur due to an insulation defect at the shaft [9] or at the tip cover accessory (TCA) [10, 11]. A TCA is an insulating sleeve that is applied to cover the metallic joint of monopolar curved scissors to allow electrical energy to be transmitted exclusively from the working tips of the shears to the surgical site of interest.

Mendez-Probst et al. studied instrument insulation defects by performing an in vitro study evaluating 37 robotic instruments that had reached the end of their life cycle. After confirming that all instruments did not have any visible insulation defects, the instruments were tested with monopolar current for the presence of stray electrical currents. All 37/37 (100.0%) instruments leaked electrical energy at the end of their life cycle [9]. These results suggest that microscopic insulation defects may cause electrical malfunctions. This is consistent with reports in the traditional laparoscopic literature that have suggested that visually screening instruments to predict insulation failure is limited [12, 13] and is associated with only 10% sensitivity [13].

In a case report by Lorenzo et al., arcing from TCA failure led to perforations of the right obturator and external iliac veins during robotic radical prostatectomy. Bleeding from the right obturator and external iliac veins was controlled by applying bipolar coagulation and placing a 5-mm metallic clip, respectively. Postoperatively, the authors noted two 1 mm holes on the TCA [10]. In a report by Mues et al., arcing from TCA failure occurred in 12/454 (2.6%) robotic surgeries, and 3/12 (25.0%) of arcing incidents caused significant patient injuries. Iatrogenic arcing injuries included damage to the external iliac vein, small bowel, and ureter. All patients required intraoperative repair [11].

Prevention

Preventing mechanical malfunctions involves the identification of defective instruments prior to the start of an operation and taking measures to minimize the chances of an instrument malfunction. In the preoperative setting, the surgical team should carefully inspect all instruments for broken, cracked, or worn components. Damaged instruments should not be used and should be replaced prior to the start of the procedure. Having a dedicated robotic surgical team that is trained in proper instrument handling and knowledgeable about normal instrument function may assist in the preoperative identification of instrument malfunctions [14].

Intraoperatively, it is important to keep the wrists straight when engaging and disengaging an instrument through a robotic port/cannula to prevent damage. When engaging an instrument, the bedside assistant should straighten the instrument wrists by rotating the discs on the instrument housing, rather than manipulating the wrist directly. When disengaging an instrument, the surgeon should straighten the instrument wrists using the master controls. During robotic port placement, it is important to ensure adequate spacing between ports to minimize instrument collisions. Generally, a distance of at least 8–10 cm for the da Vinci® S and Si and at least 6 cm for the da Vinci® Xi should be maintained between each port. The reason for this is because collisions between instruments, which can occur both intra-corporeally and extracorporeally, may cause physical defects.

With regard to the prevention of electrical malfunctions, the importance of proper intraoperative handling of the TCA cannot be overemphasized. Prior to the use of monopolar curved scissors, TCAs should be carefully applied using the prepackaged tip cover applicator in accordance with manufacturer specifications. The insulating TCA should cover the distal end of the instrument shaft and the entirety of the instrument wrist, leaving only the shears non-insulated. Also, similar to the prevention of mechanical malfunctions, measures should be taken to avoid physical damage to TCAs and instrument shafts. Surgeons and bedside assistants should ensure that the instrument wrists are straight prior to engaging and disengaging robotic instruments and appropriately position robotic ports to minimize intra-corporeal instrument collisions [11]. The reason for this is because defects in the TCAs and instrument shafts will compromise their insulating capacities and cause arcing.

Also, TCA failures may occur when the electrocautery settings are above the insulating capacity of the tip covers. Intuitive Surgical recommends keeping the power settings below 3kV. However, electrical malfunctions may still occur while adhering to these recommended power settings. In the previously mentioned report by Mues et al. that detailed 12 TCA failures, all 12/12 (100.0%) failures occurred while using the manufacturer recommended power settings [11]. As such, when using electrocautery, it is important to use the lowest power setting possible for the shortest amount of time necessary to achieve the desired effect.

Risk Factors

Several risk factors are associated with instrument malfunctions. With regard to mechanical malfunctions, instruments with jaws may be at greater risk for malfunction compared to those without jaws. During surgery, these articulating jaws are used to exert considerable forces. However, given the lack of tactile sensation and force feedback during robotic surgery, the surgeon may inadvertently apply excessive force onto the jaws causing them to break [7]. In a report by Kim et al., in which all robotic instrument malfunctions that occurred during surgeries performed by 6 departments at a single institution from July 2005 to December 2008 were retrospectively reviewed, 16/19 (84.2%) instrument malfunctions occurred in instruments with jaws [2].

Also, reusing instruments increases their cumulative "wear and tear," which may increase the likelihood of mechanical malfunctions. As part of a quality control measure to minimize instrument breakdown with repetitive use, Intuitive Surgical preprograms all instruments to a limited number

of uses. Despite this, there is a paucity of literature evaluating the relationship between instrument reuse and the incidence of mechanical malfunctions. In the previously mentioned case report by Park et al., in which the joint bolt of a ProGrasp™ forceps became loose and decreased the grasping ability of the instrument during a robotic radical prostatectomy, the instrument had been used in three prior robotic radical prostatectomies [6]. Further evaluation is needed to clarify the effect of increasing instrument reuse on mechanical malfunctions.

Additionally, advancements in robotic surgical systems have been suggested to decrease the frequency of instrument pieces breaking off. Lucas et al. reviewed instrument malfunctions in the MAUDE database from 2003 to 2009 to determine whether increased robotic experience or technological improvements improved the frequency of reported instrument fragmentation complications. The year in which surgery was performed was used as a surrogate for robotic experience; and the da Vinci® S compared to the da Vinci was used as a surrogate for technological improvement. Instrument fragmentation decreased by 50% when comparing reported instrument fragmentation incidents from 2003–2006 to 2007–2009. As the frequency of fragmentation observed with the da Vinci® was two times greater than that observed for the da Vinci® S, the difference was mostly accounted for by the specific robotic system utilized [5].

Similar to mechanical malfunctions, instruments that have been reused may be more susceptible to electrical malfunctions. In the aforementioned in vitro study by Mendez-Probst et al., all 37/37 (100.0%) robotic instruments that had reached the end of their life cycle demonstrated leaking of electrical energy at the instrument shaft. However, because the testing only involved instruments that had reached the end of their life cycle, the authors were unable to determine at which specific point the insulation damage occurred. Nevertheless, the findings of this study suggest that insulation damage may occur with repetitive intraoperative uses and that instruments should not be used after they have reached the end of their life cycle [9]. Also, prolonged intraoperative use of monopolar curved scissors may cause physical defects in TCAs, which may cause arcing. In the aforementioned report by Mues et al. in which 12 TCA failures occurred in 454 robotic surgeries, all TCA failures occurred after at least 2 h of intraoperative use. The majority of defects occurred at the junction of the silicone portion and the gray plastic shaft. This finding prompted the authors to begin routinely changing TCAs after every 2 h of surgery [11].

Also, increased robotic experience has been suggested to decrease the frequency of arcing. In the aforementioned report by Lucas et al., the authors used the MAUDE database to determine whether increased robotic experience or technological improvements improved the frequency of reported arcing complications. Arcing was found to have decreased by 67% when comparing reported arcing incidents from 2003–2006 to 2007–2009. Although arcing was three times more frequent with the da Vinci® compared to the da Vinci® S, this difference was mostly accounted for by year of procedure [5].

Additionally, first-generation TCAs have been shown to be more susceptible to electrical malfunctions compared to second-generation TCAs. Intuitive Surgical released the second-generation TCA in July 2012. In a report by Engebretsen et al., 36 first-generation TCAs and 40 second-generation TCAs that had been previously used in a single urologic or gynecologic surgery were inspected for insulation defects. TCAs were examined under light microscopy for visual insulation defects and evaluated for arcing in ex vivo porcine kidney models for functional insulation defects. Visual insulation defects ranging in size from 0.5 to 2.75 mm were noted in 14/36 (39%) first-generation TCAs, while only superficial scratches were noted in 10/40 (25%) of second-generation TCAs. While arcing occurred in 12/36 (25%) first-generation TCAs, arcing did not occur in any 0/40 (0%) of the second-generation TCAs ($p < 0.001$). Furthermore, the authors found that arcing occurred more frequently with increased instrument wrist angulation ($p = 0.014$) and that higher power settings led to shorter time to insulation failure ($p = 0.048$) [15]. Although no arcing was demonstrated in second-generation TCAs in this study, extreme angulation of robotic instrument

wrists and high power settings should still be avoided when using second-generation TCAs.

Diagnosis and Identification

Diagnosis

Instrument malfunctions may occur at any point during an operation, and maintaining vigilance for diagnosing instrument malfunctions is paramount. It is the responsibility of all members of the surgical team—surgeons, bedside assistants, nurses, technicians—to identify instrument malfunctions. Diagnosing instrument malfunctions as soon as they occur is critical in minimizing potential complications that may be harmful to the patient.

As previously mentioned, the most commonly identified instrument malfunctions involve the end effector [3]. However, it is unclear whether this because end effector defects occur more frequently than defects at other locations or because instrument malfunctions at the end effector are most readily noticed. As the end effector is the portion of the instrument that provides its specific function and the surgeon is generally looking at the end effectors for the majority of the procedure, malfunctions at the end effectors may be more easily noticed than those that occur at other portions of the instrument. For example, a fragmented jaw of a needle driver is more likely to be noticed than bending of the needle driver shaft. Despite this, as all instrument malfunctions have the potential to harm patients, the operative team should maintain a high index of suspicion for malfunctions at all portions of the instrument.

There are instances when instrument malfunctions may be difficult to diagnose, especially when they do not cause any major or immediate clinical consequences. For example, in the aforementioned study by Engebretsen et al. that evaluated first- and second-generation TCAs for insulation defects in ex vivo porcine kidney models, 12/36 (33.3%) first-generation TCAs demonstrated arcing on postoperative testing for insulation defects even though there were no intraoperative arcing incidents witnessed in any of the evaluated TCAs. The authors conjectured that this could have been because defects in TCAs may have been out of the field of view during surgery, especially the surface that faces away from the surgeon [15].

Malfunction Reporting

All diagnosed instrument malfunctions, regardless of clinical consequences, should be reported to the MAUDE database, a publically available collection of medical device-related adverse event reports. The US FDA maintains the MAUDE database and uses it as a post-market surveillance system to evaluate device performance and safety. Device-related adverse event reports may be submitted by mandatory reporters such as manufacturers, importers, and device user facilities and voluntary reporters such as healthcare professionals, patients, and consumers [16].

The importance of reporting instrument malfunctions to the MAUDE database is underlined by the fact that manufacturers and the US FDA regularly monitor the MAUDE database to identify and correct device-related safety issues at the user level. Furthermore, as the MAUDE database is large, well organized, and readily accessible, it is well suited for analysis in retrospective studies to investigate reported instrument malfunctions [3, 5]. Despite this, studies that are based on the MAUDE database should be interpreted with caution as the database has several limitations. Foremost, the MAUDE database is a passive surveillance system that inherently facilitates underreporting of robotic instrument malfunctions and requires that users be proactive in reporting [3, 5]. For example, in a report by Chandler et al., only 5/64 (8%) claims made to the Physician Insurers Association of America regarding laparoscopic entry access injuries were identified in the MAUDE database over the same time period [17]. Also, the prevalence of an event cannot be determined using the MAUDE database as the numerator (number of instrument malfunctions) and the denominator (total number of instrument uses) cannot be ascertained. Nevertheless, the MAUDE database provides valuable insight into real device malfunctions. Increasing the diligence

with which instrument malfunctions are reported will not only lead to more accurate and robust research studies, but it will also allow for improved identification and correction of instrument defects.

Treatment and Control

When an instrument malfunction is realized, the surgeon should immediately pause surgery to address and resolve the instrument malfunction prior to progressing with the remainder of the operation. Promptly addressing instrument malfunctions is critical in minimizing potential intraoperative complications and ensuring that the remainder of the procedure may be safely performed. The treatment of instrument malfunctions involves two parts: first, correcting the specific instrument defect, and, second, treating the clinical consequences of the instrument defect.

With regard to mechanical malfunctions, any physical defect that compromises instrument function requires that the instrument be replaced. In the aforementioned retrospective review by Kim et al. in which 19 instrument malfunctions occurred in 1797 robotic cases, all instrument malfunctions were solved intraoperatively by replacing the instruments. After replacing the malfunctioning instruments, all operations were successfully completed [2]. Regardless of how minor the mechanical instrument malfunction may seem, the surgeon should promptly remove all instruments demonstrating mechanical malfunctions from use. The reason for this is because using a defective instrument may cause the instrument to further deteriorate and forces the surgeon to operate under suboptimal conditions. Also, attempts at manually repairing the instrument should not be pursued. As such, it is imperative that the surgeon ensures that a backup set of robotic instruments is available prior to the start of any robotic procedure in case of a mechanical malfunction.

When mechanical malfunctions are promptly diagnosed and managed, they are self-limited and do not cause clinically significant complications in most cases. However, one potentially disastrous complication resulting from a mechanical malfunction is when a piece of the instrument breaks off into the surgical field. In such cases, it is imperative that the surgeon immediately stop surgery to look for the broken piece to remove it from the patient's body as further manipulation may inadvertently push the broken piece deeper into the surgical field [18]. In most cases, a broken piece may be easily identified and retrieved with graspers [7]. If the broken piece is not readily found, fluoroscopy may be used to assist with localization. Taking fluoroscopic images in both the anterior-posterior and lateral planes is useful in pinpointing the broken piece. If the surgeon is unable to find the broken piece despite the use of fluoroscopic imaging or the use of fluoroscopy is unavailable, the surgeon must consider converting to an open procedure.

With regard to electrical malfunctions, it is important to differentiate between insulation defects at the TCA and those at the instrument itself. In cases of TCA insulation failure, the defective TCA should be replaced with a new TCA, while in cases of instrument insulation failure, the instrument should be replaced. At times, it may be unclear where the arc originated from, making localization of the insulation defect difficult to determine. In such cases, the instrument should be disengaged from the robotic arm and the instrument, and the TCA should be carefully inspected for any macroscopic insulation defects. If no visible defects are identified, the instrument and TCA should both be replaced. It is important to note that microscopic defects may be the most hazardous as the energy that is leaked has a high current density [12].

Although prompt diagnosis and management of an electrical malfunction are essential in limiting further complications, all electrical burn injuries caused by the initial arc must be fully evaluated and treated. The nature and severity of an injury caused by an electrical malfunction are variable and dependent on a multitude of factors: location and size of the insulation defect, specific power settings, and proximity to surrounding structures. Discussing the wide range of potential complications resulting from an electrical malfunction and management of each is beyond the scope of this chapter. However, when evaluating and managing arcing complications, it is important to consider

that electrical burn injuries may occur beyond the area of actual contact and the full extent of a thermal injury may take days to weeks to fully manifest [9, 19]. This occurs when thermal energy damages vascular supply beyond the area of contact, which causes delayed necrosis [19].

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