Review Robotic Systems and Navigation Techniques in Orthopedics: A Historical Review

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Abstract: Since the da Vinci Surgical System was approved by the Food and Drug Administration 1 (FDA) in 2000, the development and deployment of various robot-assisted minimally invasive surgery 2 (MIS) systems have been largely expedited and boomed. With the rapid advancement of robotic 3 techniques in recent decades, robot-assisted systems have been widely used in various surgeries 4 including orthopedics. These robot-related techniques have been and continue to be transforming the 5 conventional ways to conduct surgical procedures. Robot-assisted orthopedic surgeries have become more and more popular due to their potential benefits of increased accuracy and precision in surgical 7 outcomes, enhanced reproducibility, reduced technical variability, decreased pain, and faster recovery 8 time. In this paper, robotic systems and navigation techniques in typical orthopedic surgeries will be 9 reviewed, especially for arthroplasty. From the perspective of robotics and engineering, the systems 10 and techniques are divided into two main categories, *i.e.*, robotic systems (RS), and computer-aided 11 navigation systems (CANS). The former will be further divided into autonomous RS, hands-on RS, 12 and teleoperated RS. For the latter, three key elements in CANS will be introduced, including 3D 13 modeling, registration, and navigation. Lastly, the potential advantages and disadvantages of the RS 14 and CANS are summarized and discussed. Future perspectives on robotics in orthopedics, as well as 15 the challenges, are presented. 16

Keywords:robot-assisted surgery;orthopedic surgery;17computer-aided navigation system;arthroscopic surgery18

1. Introduction

In 1954, Devol invented the first digitally operated and programmable robot (later 20 known as the Unimate) in the world, which has been viewed as the foundation of the 21 modern robotics industry [1]. Together with Engelberger, they founded the first robotics 22 company in the world named Unimation. The company developed the first Unimate robot 23 based on Devol's patent and sold it to General Motors in 1960 for being used to lift and 24 stack hot pieces of metal [2]. Since then, robots have been continually improved, and spread 25 their applications in the surgical field. In 1985, the first robotic surgical system, Puma 560, 26 was used for neurosurgical biopsies guided by computed tomography (CT) images [2,3]. 27 In the early 1990s, Minerva was introduced as the next-generation neurosurgical robot 28 [4]. In 1988, ROBODOC (Integrated Surgical Systems, Delaware, USA) was introduced in 29 orthopedics [4]. In the same year, PROBOT performed a clinical trial at Imperial College 30 London with the earliest robotic procedure in urology. In 1993, a robotic arm called AESOP 31 (Automated Endoscopic System for Optimal Positioning) (Computer Motion, Inc., Santa 32 Barbara, California, USA) was developed to assist in holding and positioning laparoscopic 33 camera. In 1998, both the ZEUS Robotic Surgical System (Computer Motion, Inc., Santa 34

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Barbara, California, USA) and the da Vinci Surgical System (Intuitive Surgical, Sunnyvale, California, USA) were introduced into the market for use in teleoperated surgery [4], while the latter received the Food and Drug Administration (FDA) approval in 2000 for use in general laparoscopic surgery which is considered as a legend in the field of surgical robotics. Thereafter, medical and surgical robotics started to boom in various fields.

Minimally invasive surgery (MIS) allows the surgeon to conduct surgical procedures through much smaller incisions than traditional open surgery, thus has a faster recovery rate and shorter rehabilitation time as well as lower pain for the patient [5]. Robot-assisted MIS involves a robot to improve the quality and precision of surgical procedures. Since the da Vinci Surgical System was approved by the Food and Drug Administration (FDA) in 2000, the development and deployment of various robot-assisted MIS systems have been largely expedited [6,7].

With the rapid advancement of robotic techniques in recent decades, robotic systems 47 have been widely used in various medical fields, such as neurological, laparoscopy, radio-48 surgery, prosthetics, rehabilitation, orthopedics, ophthalmology, and more beyond [5,8-10]. 49 For example, the da Vinci Surgical System (Intuitive Surgical, Sunnyvale, California, USA) 50 and RAVEN II (University of Washington, and University of California, Santa Cruz, USA) 51 for use in teleoperated laparoscopic surgery [8,11,12], the CyberKnife System (Accuray Inc., Sunnyvale, California, USA.) for use in radiosurgery [13], the JHU Steady-Hand Robot for 53 use in retinal microsurgery [14–16]. These robotic systems and techniques are transforming 54 the conventional ways to conduct surgical procedures in a large variety of fields. 55

Through decades of technique evolvements and clinical evaluations in orthopedic surgeries, plenty of studies have proven that robotic systems and navigation techniques can be beneficial in improving and enhancing surgical outcomes, such as increasing the accuracy and precision of bone cutting and component alignment, reducing operative time, and enhancing patients' satisfaction [17–19].

Numerous review papers on reviewing robots or navigation systems in orthopedics 61 can be found in the literature. Most of them focused on a meta-analysis or reviewing clinical 62 outcomes and user studies [2,19-22], or a specific field like MIS [5], or a specific feature 63 like haptic feedback [23]. Instead of those, this paper will present a historical review of 64 the robotic systems and navigation techniques that exist and have ever existed in the field 65 of orthopedics, especially on those systems still commercially available at present. And 66 the primary focus will be the historical evolvement of the systems as well as the engineer-67 ing features and techniques from the perspective of engineering. Correspondingly, two 68 main categories will be covered, *i.e.*, robotic systems (RS), and computer-aided navigation 69 systems (CANS). The RS will be further divided into autonomous RS, hands-on RS, and 70 teleoperated RS, while the CANS will be broken down into three key technical elements, 71 including 3D modeling, registration, and navigation. 72

It is worth noting that in orthopedics, computer-assisted orthopedic surgery (CAOS) divided the surgical systems into three categories, *i.e.*, autonomous (also known as active), semi-autonomous (also known as semi-active), and passive [17,24,25]. Correspondingly, the autonomous systems are equivalent to the autonomous RS used here, and the semiautonomous systems are equivalent to the hands-on RS used here, while the passive systems indicate the computer-aided navigation systems (CANS) used in this paper. A hierarchical flowchart of these categories and their components are illustrated in Fig. 1.

Common orthopedic surgeries involving RS and/or CANS may include arthroplasty, arthroscopy, and surgical interventions related to tissues in joints. Note that in orthopedics, joint replacement is equivalent to arthroplasty, and similarly total hip replacement (THR) is equivalent to total hip arthroplasty (THA), and total knee replacement (TKR) is equivalent to total knee arthroplasty (TKA). A general flowchart of surgical procedures for orthopedic surgeries is illustrated in Fig. 2. Both RS and CANS play an important role in the procedures, which will be introduced in detail in subsequent sections.

The remaining of this paper is organized as follows. Section 2 presents the robotic systems (RS) in orthopedics including their historical background, applications, main fea-

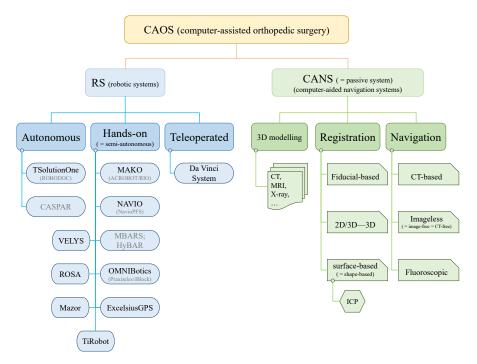


Figure 1. A hierarchical flowchart for the robotic systems and navigation techniques in orthopedics. Note: system names in gray color means either not in use anymore or upgraded with new names; The equal symbol "=" means "equivalent to".

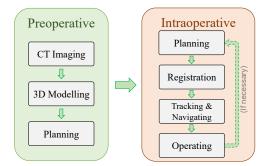


Figure 2. A general flowchart for orthopedic surgeries.

tures, and techniques. Section 3 presents CANS-related techniques including 3D modeling, registration, and navigation. Section 4 provides discussions and future perspectives on the RS and CANS in orthopedics, as well as some novel techniques. Section 5 presents a brief conclusion and future challenges.

2. Robotic Systems (RS)

In this section, the robotic systems (RS) in orthopedics are historically reviewed. For each of the RS, the background of development, the features, applications, techniques, advantages, and disadvantages will be introduced.

Robotic systems (RS) will be divided into three subcategories, *i.e.*, autonomous, hands-97 on, and teleoperated [23], as illustrated in Fig. 1. The autonomous RS indicates that the 98 robot can conduct the surgery completely on its own while the surgeon can only interrupt 99 it by using an emergency stop [26]. The hands-on RS is equivalent to semi-autonomous or 100 semi-active robots in the literature of orthopedic surgeries. It indicates that the surgeon and 101 robot cooperatively move the surgical instrument installed on the robot end-effector (EE), 102 which means it requires physical human-robot interaction (*p*HRI) [23]. The **teleoperated RS** 103 indicates a standard leader-follower teleoperation system in which two robots are required. 104

The leader robot is physically operated by the surgeon, while a follower robot on the remote 105 site (*e.g.*, on the patient side) is controlled by the leader robot via the internet or Ethernet. 105

2.1. Autonomous RS

2.1.1. **ROBODOC** → **TSolution One**

ROBODOC Surgical System (Curexo Technology Corporation, Fremont, California, USA) was a fully autonomous robotic system initially designed for total hip arthroplasty (THA) in the 1980s [9,27], and introduced to be used on patients in 1992 [26,28]. It is the first robot that was clinically used in orthopedic surgery [2]. ROBODOC had its first system installed in Germany after being approved for sale by the European Union in 1994 [2,4]. ROBOTDOC was approved by FDA¹ in 2008 for use in THA [19].

The whole system includes ORTHODOC (a 3D preoperative computer modeling 115 and planning workstation) and ROBODOC surgical assistant (a 5-axis SACARA-type 116 surgical robot) [25]. The system conducted its work, e.g., bone milling and preparing 117 for stem implantation, based on preoperative computed tomography (CT) imaging. The 118 workstation will generate a 3D virtual model and produce a customized surgical plan 119 [19]. The system employed fiducials implanted about 5 mm deep in bone for bone motion 120 detection and tracking, thus the tracking accuracy is high and will not be affected by debris 121 and fluids [9]. Since ROBODOC is a fully autonomous system, once it starts to work, the 122 surgeon has only control over emergency stop [19]. 123

The company, Curexo Technology Corporation, changed its name to Think Surgical, Inc. in 2014 [2,29]. Based on ROBODOC technology, its next-generation system named TSolution One (THINK Surgical, Inc., formerly Curexo Technology Corporation, Fremont, California, USA)² was developed. Its applications have been expanded to total knee arthroplasty (TKA) [4,19]. The TSolution One was approved by the FDA³ in 2019 for use in TKA. Currently, the TSolution One system has upgraded to a computer-aided system from the earlier CT-based system [2,4].

2.1.2. CASPAR

CASPAR (computer-assisted surgical planning and robotics) (OrthoMaquet/URS, Rastatt, Germany) was another early autonomous 6-degree-of-freedom (DOF) robotic system for THA and TKA [2,9]. It was introduced by OrthoMaquet in 1997, and acquired by Getinge (Gothenburg, Sweden) in 2000, and further acquired and discontinued by Universal Robot Systems (URS, Rastatt, Germany) in 2001 [8]. One example photo of the system is shown in Fig. 3.

Similar to ROBODOC, the CASPAR also has an interactive computer system used 138 for preoperative planning based on CT images [9]. The CASPAR also has similar func-130 tions including automatically milling a bone and guiding implant position in THA [19]. 140 Therefore, it was directly competing with the ROBODOC. Although some research studies 141 showed increased accuracy of bone preparation and implant positioning in both TKA and 142 THA with CASPAR [2,30,31], many other studies showed significantly less improvement 143 in Harris Hip Scores, significantly longer procedure times and more blood loss, higher 144 rates of complications, and revision surgeries compared to ROBODOC [2,9,32]. Therefore, 145 CASPAR is no longer in use due to these drawbacks [2]. 146

2.1.3. CyberKnife

CyberKnife⁴ (Accuray Inc., Sunnyvale, California, USA) is an image-guided robotic system that is specially designed for radiosurgery and radiotherapy [33,34]. CyberKnife

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ROBODOC FDA 2008 file (accessed June 2023): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/ cfpmn/pmn.cfm?ID=K072629
TUDE Consistent of accessed June 2022): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/

² THINK Surgical website (accessed June 2023): https://thinksurgical.com/

³ TSolution One FDA 2019 file (accessed June 2023): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/ cfpmn/pmn.cfm?ID=K191369

⁴ CyberKnife website (accessed June 2023): https://cyberknife.com/cyberknife-technology/



Figure 3. CASPAR. (Reproduced with permission from J. Bellemans, Robotics in TKA, 2013, Springer Nature.)



Figure 4. ACROBOT system. (Reproduced with permission from F. Rodriguez y Baena and B. Davies, Robotic Surgery: From Autonomous Systems to Intelligent Tools, Robotica, 28(2), 163-170, 2010, Cambridge University Press.)

system can deliver stereotactic radiosurgery and radiation therapy anywhere in the body 150 including the spine and bone, although it is not a robotic system specially designed for 151 orthopedics. The system autonomously conducts the non-invasive treatment procedures 152 under the surgeons' supervision. Initially conceived in 1992 [35] and fully described in 153 1997 [36], CyberKnife received FDA approval in 1999⁵ for use in intracranial treatment 154 and in 2001⁶ for use in extracranial treatment [34]. As of 2020, CyberKnife has delivered 155 treatments to over 400,000 patients worldwide [34]. A technical overview of the CyberKnife 156 system can be found in [34]. 157

2.2. Hands-on RS

Compared with autonomous RS, hands-on RS is much more preferred by surgeons 159 due to the feature of surgeon-in-the-loop and full control by the surgeon. The following 160 ACROBOT, RIO, and MAKO have the same core system but different names at different 161 periods [37]. 162

2.2.1. ACROBOT

ACROBOT system (Acrobot Co Ltd, London, UK) is a semi-autonomous system 164 designed for robot-assisted MIS for unicompartmental knee arthroplasty (UKA) [3,26]. It 165 is the first robot-assisted system used in UKA [37]. One example photo of the ACROBOT 166 system is shown in Fig. 4 [38]. 167

The ACROBOT was named as an acronym for active-constraint robot and was initially 168 designed for knee surgeries [39]. Therefore, it employed active-constraint control, which 169 can constrain the robot's movement within a predefined zone [2,37], thus the surgeon can 170 safely cut the bone with high precision [2]. It provides haptic feedback to the surgeon and is 171

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CyberKnife FDA 1999 file (accessed June 2023): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/ cfpmn/pmn.cfm?ID=K984563

CyberKnife FDA 2001 file (accessed June 2023): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/ cfpmn/pmn.cfm?ID=K011024

considered as a prototype of modern haptic systems [37]. ACROBOT is a 6DOF robot that allows only predefined trajectories [40]. It used CT scans for preoperative planning. During the surgery, a small robot called Acrobot was mounted on a gross positioning device and operated on by the surgeon [2]. A non-invasive anatomical registration will be conducted intraoperatively, based on which the drill can be tracked. If the surgical tool is detected to be away from the predefined cutting zone, the system will actively prevent it [37].

Acrobot Co Ltd was acquired by Stanmore Implants Worldwide in 2010, and based on the ACROBOT system the Stanmore Sculptor Robotic Guidance Arm (RGA) System (Stanmore Implants, Elstree, UK) was released [37] and approved by the FDA⁷ in 2013 for use in UKA. MAKO Surgical Corp. obtained some confidential patents in 2013 as part of a patent infringement settlement [2,21]. Stryker Corporation acquired MAKO Surgical Corp. in 2013, and acquired Stanmore Implants Worldwide in 2016.

2.2.2. **RIO (**← **ACROBOT)**

The robotic arm interactive orthopedic system (RIO, previously called the Tactile Guidance System) (MAKO Surgical Corp., Fort Lauderdale, Florida, USA) is the commercialized version of the ACROBOT system [8,23], thus inherited many features from the ACROBOT [26]. It can be used for UKA [26], and TKA [23]. It received FDA approval for use in TKA⁸ in 2009 and for use in THA⁹ in 2010 [9].

The RIO system features haptic and auditory feedback, force-controlled tip, and 190 surgeon-in-the-loop. The preoperative CT images are used to construct a 3D model of 191 the patient's knee. Then the 3D model is used by the surgeon to do a preoperative plan. 192 The preoperative plan and the 3D model will be used to finalize an intraoperative plan 193 at the beginning of the operation which includes defining an exact cutting zone for the 194 robot. During the operation, the surgeon physically operates the RIO robot to perform 195 bone resection while referencing the 3D bone model on a monitor. The robot will provide 196 haptic and auditory feedback, while constraining the force-controlled tip of the tool (e.g., a 197 rotating burr) to work only within the predefined cutting zone. The robot will automatically 198 stop if the burr is outside of the predefined zone, or the computer has detected more bone 199 being resected than necessary. Therefore, the RIO robot helps to monitor the operation, 200 and provides necessary real-time data for accurate bone cutting and accurate components 201 placement, thus potentially improving the outcomes of the UKA [26]. Therefore, the RIO 202 system heavily relies on the preoperative plan and the surgeon's skill. Besides, it is reported 203 that the RIO system has a short learning curve which is beneficial to surgeons with less 204 experience in operating this system [26,41,42]. 205

2.2.3. **MAKO (**← **RIO**)

MAKO system (Stryker Corporation, Kalamazoo, Michigan, USA)¹⁰ can be viewed as a new generation of the RIO (MAKO Surgical Corp.) system, which means it is also a semi-autonomous system [10,19]. Founded in 2004, MAKO Surgical Corp., together with its most notable products, RIO (Robotic Arm Interactive Orthopedic System) and MAKOplasty (for partial knee and total hip arthroplasty), was acquired by the Stryker Corporation in 2013. MAKOplasty received FDA approval in 2014 for use in THA¹¹.

Being further developed and rebranded from the RIO, the MAKO system is an imagebased system with haptic and auditory feedback. Preoperative CT images are acquired

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⁷ RGA FDA 2013 file (accessed June 2023): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn. cfm?ID=K121765

⁸ RIO-MCK FDA 2009 file (accessed June 2023): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/ pmn.cfm?ID=K090763

⁹ RIO-THA FDA 2010 file (accessed June 2023): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/ pmn.cfm?ID=K093425

¹⁰ MAKO SmartRobotics website (accessed June 2023): https://www.stryker.com/us/en/joint-replacement/ systems/Mako_SmartRobotics_Overview.html

¹¹ MAKOplasty FDA 2014 file (accessed June 2023): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/ cfpmn/pmn.cfm?ID=K141989

and used to do preoperative planning which will be further confirmed and adjusted intraoperatively based on the patient's true bone anatomy before executing the surgery [2]. A special feature of the MAKO system is a haptic technology named AccuStop that provides auditory beep alert, tactile vibration feedback, and visual feedback with color changes. This haptic technology can assist surgeons in making incisions, saving soft tissues and healthy bones [9]. One drawback of the MAKO system is the high purchasing and surgical costs [9].

Since 2021, the MAKO robots have been enhanced by integrating intraoperative 222 sensor technology. MAKO is integrated with a computer navigation system, and it uses 223 preoperative CT scans to generate a 3D model, then the robot arm will be guided by the 3D 224 model. MAKO is a human-robot collaboration system making use of user input and robotic 225 guidance. Besides the haptic, visual, and audio feedback, it also provides virtual fixture 226 (VF) protection and emergency auto-shutdown for safety strategy. MAKO performed its 227 first THA case in 2010 and received FDA¹² approval in 2017. MAKO has also been used for 228 UKA and TKA [19]. 229

MAKO system is gaining more popularity in clinical practice for UKA, THA, and TKA. In addition to its long history of nearly two decades, there is a large body of research literature about the MAKO system [2]. Many studies have revealed positive outcomes of using the MAKO system than manual techniques. For more clinical case study results on MAKO please refer to [2].

2.2.4. NavioPFS/NAVIO

NavioPFS (Precision Freehand Sculpting) (Blue Belt Technologies, Plymouth, Minnesota, USA) system is a computer-aided orthopedic navigation and surgical burring system, and is also a semi-autonomous, hand-held, and image-free system. It was approved by FDA¹³ in 2012 for unicondylar knee arthroplasty (uKA) [2].

The NavioPFS is a handpiece that has a cutting tool (a motorized burr) installed at 240 the robot end-effector, and the burr can extend and retract. A related safety strategy is 241 that by modulating the retraction (exposure control) and speed of the burr (speed control) 242 [27], inadvertent bone removal can be avoided although there is not haptic feedback in 243 this system. Another big advantage of this system is its imageless feature meaning that 244 preoperative CT imaging is not needed, and all the registration, planning, and navigation 245 will be performed during the surgery. Note that the imageless feature is equivalent to the 246 image-free feature in this paper. NavioPFS employs an optical-based navigation system 247 via a passive infrared (IR) tracking camera and trackers. Intraoperative data from the 248 trackers will be collected and displayed in a graphical format, and together with anatomic 240 landmarks and surface painting techniques, a 3D model of the patient's femur and tibia 250 can be created thus a surgical plan can be made by the surgeon intraoperatively [2,9]. 251

The NavioPFS system has been proven to have reduced implant position errors [43], 252 satisfied mechanical axis alignment accuracy, decreased bone cutting time, and improved Oxford Knee Scores [2]. The learning curve for operating the NavioPFS has been shown to be fairly rapid [44,45]. 255

Blue Belt Technologies Inc., a Carnegie Mellon University spin-off company that was founded in 2003, was acquired by Smith & Nephew plc (London, UK) in 2016 [10]. In 2019, Smith & Nephew acquired the orthopedic unit of Brainlab, after which Smith & Nephew's NAVIO surgical system upgraded its software to Navio 7.0. The software upgrade made a significant reduction in required data point collection and in workflow stages, faster surface modeling, and improved usability [9]. The current Smith & Nephew's NAVIO surgical 200

¹² MAKO-THA FDA 2017 file (accessed June 2023): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/ cfpmn/pmn.cfm?ID=K170593

¹³ NavioPFS FDA 2012 file (accessed June 2023): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K121936





(a) MBARS

(b) HyBAR

Figure 5. MBARS and HyBAR. (Reproduced with permission from *A. Wolf et al., MBARS: Mini Bone-Attached Robotic System for Joint Arthroplasty, International Journal of Medical Robotics and Computer Assisted Surgery, 1(2): 101-121, 2005, John Wiley and Sons; and with permission from <i>S. Song et al., HyBAR: Hybrid Bone-Attached Robot for Joint Arthroplasty, International Journal of Medical Robotics and Computer Assisted Surgery, 5: 223-231, 2009, John Wiley and Sons.*)

system¹⁴ expanded the applications to TKA and UKA, and together with its PFJ software, it can assist the surgeon in making implant plans and help them to prepare the bone for implantation [24].

2.2.5. **BRIGIT**

BRIGIT (bone resection instrument guidance by intelligent telemanipulator) system 266 [46], was developed by MedTech SA (Montpellier, France). The system was implemented 267 with a compliant control strategy aiming for more compliant and safer human-robot 268 interaction [47]. It was integrated with a computer navigation system, and can be used 269 for TKA to accurately position bone-cutting guides based on the preoperative plan [27,46]. 270 According to the initial design, the system can be operated either in cooperation mode 271 with physical human-robot interaction or in teleoperation mode with haptic feedback [46]. 272 The system was acquired by Zimmer Biomet (Warsaw, Indiana, USA) in 2006, but was not 273 commercialized [46]. 274

2.2.6. MBARS/HyBAR

MBARS (mini bone-attached robotic system) robot, as shown in Fig. 5a, is a semiautonomous robot developed at Carnegie Mellon University for TKA [48]. This type of system employed a special feature of small and bone-mounted robots, which are considered to be more efficient and cost-effective than large robotic systems [26,48].

The MBARS involves attached high-speed orthopedic tools, thus the major design issues are considered to be structural rigidity and clamping mechanism [49]. To solve this, a HyBAR (hybrid bone-attached robot), as shown in Fig. 5b, was designed for patellofemoral joint arthroplasty [49]. The HyBAR is an autonomous system with enhanced structural rigidity by using hinged prismatic joints in its novel kinematic configuration, while a new modular clamping system was introduced to enhance the robotic procedure [2,49].

2.2.7. Praxiteles \rightarrow iBlock

Praxiteles (Praxim Ltd, Grenoble, France), presented in 2005, is also a semi-autonomous system and is in the category of MBARS [50]. The Praxiteles, as shown in Fig. 6, was designed to guide the saw blade or to use a passive bone milling process, and the risk of soft tissue damage can be expected to be reduced by less-invasive exposures [27].

The OMNINAV iBlock robotic cutting guide (formerly known as Praxiteles, OMNIlife Science (now owned by Corin Group), East Taunton, MA), is a motorized, bone-mounted

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¹⁴ NAVIO Surgical System website (accessed June 2023): https://www.smithnephewlivesurgery.com/naviosurgical-system



Figure 6. Praxiteles. (Reproduced with permission from *C. Plaskos et al., Praxiteles: A Miniature Bone-Mounted Robot for Minimal Access Total Knee Arthroplasty, International Journal of Medical Robotics and Computer Assisted Surgery, 1(4): 67-79, 2005, John Wiley and Sons.)*

cutting guide for all femoral resections [51], and approved by FDA¹⁵ in 2010 for use in TKA applications [2,27]. Similar to the NAVIO system, the iBlock is also imageless. Its OmniBiotics computer station can generate a 3D digital model of the patient's knee by using patented bone morphing technology and intraoperative anatomic data [27]. Based on the 3D model, the surgeon can make the implant plan intraoperatively and see the planned bone cuts before they are executed.

Although there are limited clinical data available for this system, some studies have shown the iBlock system can obtain more efficient, accurate, and repeatable bone resections, as well as shorter bone preparation time [2,52]. The limitations of the iBlock system include no haptic feedback, only for TKA applications, a closed platform, and limited kinematic assessment after implantation [2].

2.2.8. **OMNIBotics** (\leftarrow **iBlock**)

OMNIBotics knee system¹⁶ (OMNIIife Science Inc. (acquired by Corin Group in 305 2019), Raynham, MA, USA), a new version of iBlock, is an image-free miniature bone-306 mounted robotic system for bone cutting and ligament balancing in TKA [4]. It initially 307 received FDA¹⁷ approval in 2017. The OMNIBotics system includes a bone-mounted robotic 308 cutting guide (iBlock) for guiding bone resections and a robotic ligament tensioning tool 309 (active spacer). The unique feature of integrating an active spacer allows for reproducible 310 tensioning of the soft tissues accurately before and after the bone cuts, and for adjusting 311 the interface fit between the implant and the bone intraoperatively. 312

The image-free feature does not require preoperative images. Instead, the 3D model of the patient's anatomy is reconstructed via the bone morphing technique intraoperatively, while the accuracy can be within 1 mm in all mapped areas [4]. The bone-mounted robot do not need camera-based tracking during robotic positioning and resection guidance. Once the robot is mounted and calibrated, the surgeon can perform the bone resection in sequence by operating on the robot-attached oscillating saw [4].

2.2.9. PiGalileo

PiGalileo (Plus Orthopedics AG, Switzerland, now owned by Smith & Nephew, UK), as shown in Fig. 7, is a miniaturized and bone-mounted robotic cutting jig guided by a computer-aided navigation system for TKA and THA [27,53]. The robot is clamped to the bone before surgery, and a cutting guide is accurately positioned with the help of

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¹⁵ iBlock FDA 2010 file (accessed June 2023): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/ pmn.cfm?ID=K090953

¹⁶ OMNIBotics website (accessed June 2023): https://www.coringroup.com/healthcare-professionals/solutions/ omnibotics/

¹⁷ OMNIBotics knee system FDA 2017 file (accessed June 2023): https://www.accessdata.fda.gov/scripts/cdrh/ cfdocs/cfpmn/pmn.cfm?ID=K163338



Figure 7. PiGalileo System and ligament balancer. The ligament balancer with force and distance scale is used to measure the ligament tension and gap size. (Reproduced with permission from *P. Ritschl et al., Modern Navigated Ligament Balancing in Total Knee Arthroplasty with the PiGalileo System, 2007, Springer Nature.)*

the navigation system [27]. Once the position is confirmed, the surgeon can conduct the operation. 324

Its two computer-aided navigation systems for TKA¹⁸ and THA¹⁹ are approved by FDA in 2006 and in 2007, respectively [54]. The PiGalileo's imageless navigation systems can assist the surgeon in bone cutting and implant positioning during joint replacement by collecting intraoperative data and tracking surgical tools and bone positions via stereotaxic technology and infrared (IR) markers.

The PiGalileo has been demonstrated with good surgical outcomes including high accuracy of implant positioning, improved bone cutting precision, and shorter surgical times [27].

2.2.10. **ROSA**

ROSA (robotic surgical assistant) (Zimmer Biomet Robotics, formerly MedTech SA, Montpellier, France) is a robotic system for TKA and THA [17]. The FDA approved its ROSA hip system²⁰ in 2021, and ROSA knee system²¹ in 2022.

According to the FDA documents, the ROSA hip system²² (as shown in Fig. 8a) is 338 a CT-free, fluoroscopic-guided system that can be used to assist surgeons in accurately 339 positioning and implanting hip components, while the robotic arm is used to assist in 340 the guidance of the surgical tools. Fluoroscopic images, intraoperatively acquired by a 341 C-arm, will be used to determine the surgical tools' orientation in relation to the patient's 342 anatomy and as a guide for bone component orientation. The system provides pre-, 343 intra-, and post-operative measurements relative to patient anatomy. The robotic arm is 344 maintained stationary to keep the instruments in a fixed orientation during bone component 345 implanting. 346

ROSA knee system²³ (as shown in Fig. 8b) can assist surgeons in bone resection and assessing the state of the soft tissues to facilitate implant positioning intraoperatively. This system can be either image-based or imageless. For the image-based option, a preoperative 3D virtual bone model needs to be generated preoperatively which can be used by the surgeon to make a preoperative surgical plan. For the imageless option, the landmarks

¹⁸ PiGalileo-TKR FDA 2006 file (accessed June 2023): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/ cfpmn/pmn.cfm?ID=K061362

¹⁹ PiGalileo-THR FDA 2007 file (accessed June 2023): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/ cfpmn/pmn.cfm?ID=K070731

²⁰ ROSA Hip System FDA 2021 file (accessed June 2023): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/ cfpmn/pmn.cfm?ID=K210998

²¹ ROSA Knee System FDA 2022 file (accessed June 2023): https://www.accessdata.fda.gov/scripts/cdrh/ cfdocs/cfpmn/pmn.cfm?ID=K213708

²² ROSA Hip System website (accessed June 2023): https://www.zimmerbiomet.com/en/products-andsolutions/zb-edge/robotics/rosa-hip-system.html

²³ ROSA Knee System website (accessed June 2023): https://www.zimmerbiomet.com/en/products-andsolutions/specialties/knee/rosa--knee-system.html



(a) ROSA Hip System
 (b) ROSA Knee System
 (c) ROSA ONE System
 Figure 8. ROSA systems. (Reproduced with permission from © Zimmer Biomet, Warsaw, Indiana, USA.)

data on the patient's bony anatomy will be collected intraoperatively and used to create an intraoperative surgical plan. The accuracy of resections, knee state evaluation, and soft tissue assessment will be the same between the two options since both of them are always based on intraoperative landmarks. The robotic arm can assist in precisely positioning the component relative to the implantation plan.

ROSA Spine was developed for minimally invasive spine procedures around 2015 357 [55,56] and approved by FDA²⁴ in 2016. The system includes a patient-side cart bearing 358 for a 6DOF robotic arm and a workstation, and an optical camera serving for navigation 359 purposes. In addition to pedicle screw placement, it is also promising to be used for spinal fusion, percutaneous endoscopic lumbar discectomy, intracorporeal implant posi-361 tioning, and radiofrequency ablation [55–57]. By coupling with intraoperative flat-panel 362 CT guidance, the system can perform accurate pedicle screw placement [55]. Registration 363 can be performed automatically by using a fiducial box (held by the robotic arm) and a 364 percutaneous reference pin. The robot can monitor and follow the patient's body move-365 ments in real-time by tracking the movement of the vertebrae, thus real-time robotized 366 navigation guidance can be provided by the system. Preoperative and postoperative 3D 367 CT scans can be acquired by an O'arm device and transferred to the workstation. Then, 368 by co-registration, the difference between the initial 3D planning and the actual screw 369 positions can be measured [55]. Accurate screw placement can be achieved due to the 370 robot's ability of real-time movement tracking on the vertebrae [55]. Later, the ROSA Spine 371 System is integrated into the ROSA ONE System²⁵ (as shown in Fig. 8c) and approved by 372 FDA in 2019 [57]. 373

2.2.11. **VELYS**

VELYS robotic-assisted solution (VRAS)²⁶ (DePuy Synthes, now owned by Johnson & Johnson, Warsaw, Indiana, USA), as shown in Fig. 9 [58], is a new system designed from proprietary technology developed by Orthotaxy. It performed its first TKA case in Auckland, New Zealand in 2020 [59], and was approved by FDA²⁷ in 2021.

VELYS employed a novel patient-specific TKA technique that can intraoperatively collect accurate data on both the bony anatomy and the soft tissue envelope of the knee [59]. This technique allows the surgeon to make intraoperative plan while preserving the soft tissues during the TKA surgery. The robot-assisted saw can assist in conducting the

²⁴ ROSA Spine FDA 2016 file (accessed June 2023): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/ cfpmn/pmn.cfm?ID=K151511

²⁵ ROSA ONE Spine website (accessed June 2023): https://www.zimmerbiomet.eu/en/products-and-solutions/ zb-edge/robotics/rosa-spine.html

²⁶ VELYS Robotic-Assisted Solution website (accessed June 2023): https://www.jnjmedtech.com/en-US/patient/ velys/robotic-assisted-solution

²⁷ VELYS FDA 2021 file (accessed June 2023): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K202769



Figure 9. VELYS Robotic-Assisted Solution. (Reproduced from *G.W. Doan et al., Image-Free Robotic-Assisted Total Knee Arthroplasty Improves Implant Alignment Accuracy: A Cadaveric Study, The Journal of Arthroplasty, 37*(4): 795-801, 2022, Elsevier.)

implantation plan precisely, accurately, and efficiently [59]. Early outcome results and limited data indicate favorable outcome scores and high patient satisfaction [59].

2.2.12. Mazor

Spine Assist (Mazor Robotics, Caesarea, Israel) is the first robotic system used in spine surgery and was approved by FDA²⁸ in 2004 [57]. The Spine Assist system evolved into the Renaissance system which was approved by FDA²⁹ in 2011, and then Mazor X which was approved by FDA³⁰ in 2017, and then Mazor X Stealth (Medtronic, Dublin, Ireland) which was approved by FDA³¹ in 2018. The example products of Mazor systems are shown in Fig. 10. Note that Mazor Robotics³² was acquired by Medtronic in 2018. A detailed comparison between these four versions of the Mazor systems can be found in [57]. Nowadays the robotic system is just called Mazor. A systematic review on robotics in spine surgery can be found in [60,61].

The Spine Assist robotic system can be used for pedicle screw placement in spine 395 surgery, but the accuracy of the screw placement is relatively low [55,57]. The updated 396 version, the Renaissance system, preserves a similar operational workflow but significant 397 software changes [57]. Finally, the latest version of the Mazor system, Mazor X Stealth, 398 has an accuracy of around 99%-100% for the screw placement. Both Spine Assist and 399 Renaissance require preoperative CT scans, based on which preoperative planning (e.g., 400 optimal implant size and trajectory) will be conducted. Nowadays, Mazor system can be 401 used in conjunction with the imaging system O-arm for 3D images, besides the use of a CT 402 scan (Scan & Plan workflow). Before the spine surgery, the robot will be mounted to the 403 patient's spine. During the surgery, intraoperative fluoroscopic images of the anatomy will 404 be acquired and matched with the preoperative CT scans in real-time, and this procedure 405 is called CT-to-Fluoro workflow. Alternatively, the Scan & Plan workflow can be used. 406 In both workflows, the robotic arm will provide guidance according to the preplanned 407 trajectory [57]. 408

As mentioned earlier, the upgraded versions of Mazor³³ do not require preoperative CT scans anymore while a feature of instrument tracking is also added [57,62]. Although preoperative CT is not mandatory, Mazor can accept preoperative or intraoperative CT

²⁸ Mazor SpineAssist FDA 2004 file (accessed June 2023): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/ cfpmn/pmn.cfm?ID=K033413

²⁹ Mazor Renaissance FDA 2011 file (accessed June 2023): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/ cfpmn/pmn.cfm?ID=K110911

³⁰ Mazor X FDA 2017 file (accessed June 2023): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K163221

³¹ Mazor X Stealth FDA 2018 file (accessed June 2023): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/ cfpmn/pmn.cfm?ID=K182077

³² Mazor Spine Robotics website (accessed June 2023): https://www.medtronic.com/ca-en/healthcareprofessionals/therapies-procedures/spinal-orthopaedic/spine-robotics.html

³³ Mazor X Stealth website (accessed June 2023): https://www.medtronic.com/ca-en/healthcare-professionals/ products/spinal-orthopaedic/spine-robotics/mazor-x-stealth-edition.html



(c) Mazor X
 (d) Mazor X Stealth Edition
 Figure 10. Mazor systems for spine surgery. (Reproduced with permission from © Medtronic, Dublin, Ireland.)

for screw planning. Before the spine surgery, the robot will be attached to a table and then mounted to the patient's spine. During the surgery, 3D images are acquired and then the intraoperative anatomy is matched with the CT scan via fluoroscopic images for intraoperative guiding purposes. The robot arm will perform procedures according to the preplanned trajectory while a 3D camera offers real-time instrument tracking [57]. The latest version of Mazor is integrated with Medtronic's Stealth navigation system which can further improve navigation accuracy.

2.2.13. ExcelsiusGPS

ExcelsiusGPS³⁴ (Globus Medical, Audubon, PA, USA), as shown in Fig. 11, is a robotic 420 system with real-time image guidance for spine surgery and was approved by FDA³⁵ in 421 2017 [57]. The robotic arm is mounted on the floor rather than the patient's bone. Preoper-422 ative CT scans are not mandatory but optional for screw trajectory planning. Optionally, 423 intraoperative CT or radiographs can also be used for the planning. The ExcelsiusGPS 424 system employed a shock-absorbing dynamic reference base and a separate surveillance 425 marker and associated surveillance software to improve the system navigation integrity 426 [57,63]. Also, the ExcelsiusGPS system employed an extremely rigid arm for its robotic 427 guidance system, which can achieve an accuracy of less than 1 mm of tool deflection under 428 a lateral disturbance force of 200 N. Additionally, the system will alert the surgeon if any 429 tool deflection is detected by the surveillance software during the surgery [57,63]. 430

2.2.14. TiRobot

TiRobot³⁶ (TINAVI Medical Technologies, Beijing, China) is a robotic system developed in China for use in spine surgery and received China FDA approval in 2016 [64]. The TiRobot platform consists of three components including a workstation, an optical tracking camera, and one 6-DOF floor-mounted robotic arm as shown in Fig. 12 [64]. The fluoroscopic-image-based registration employs a cross-referencing approach by using a

431

³⁴ ExcelsiusGPS website (accessed June 2023): https://www.globusmedical.com/musculoskeletal-solutions/ excelsiustechnology/excelsiusgps/

³⁵ ExcelsiusGPS FDA 2017 file (accessed June 2023): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/ cfpmn/pmn.cfm?ID=K171651

³⁶ TiRobot website (accessed June 2023): https://en.tinavi.com/index.php?c=article&a=type&tid=1



Figure 11. Globus ExcelsiusGPS for spine surgery. (Reproduced with permission from © Globus Medical, Inc., Audubon, PA, USA.)



Figure 12. TINAVI TiRobot for spine surgery. (Reproduced from *H. Lan et al., Intramedullary Nail Fixation Assisted by Orthopaedic Robot Navigation for Intertrochanteric Fractures in Elderly Patients, Orthopaedic Surgery, 11: 255-262, 2019, John Wiley and Sons.)*

dynamic reference base on the patient's body and another dynamic reference base on the robotic arm [60]. The TiRobot system can achieve real-time 3D navigation by tracking the relative positions of the patient and the robotic arm [60]. The workstation houses the interface for screw planning and visual feedback [64]. The robotic arm can help surgeons accurately position the surgical tools and implants. TiRobot can also be used for other surgeries like intramedullary nail fixation for intertrochanteric fractures [65].

2.3. Teleoperated RS

2.3.1. Da Vinci Surgical System

The da Vinci surgical system³⁷ (Intuitive Surgical, Sunnyvale, CA, USA), as shown 445 in Fig. 13, is the most successful teleoperated robotic system for MIS (minimally invasive 446 surgery) in the market. Initially, the system is designed for microvascular surgery [66], and 447 conducted a robot-assisted heart bypass procedure in 1998 in Germany and a robot-assisted 448 radical prostatectomy procedure in 2000 in Paris, France [4]. It received FDA³⁸ approval in 449 July 2000 for laparoscopic surgery, and since then, the system expanded its applications 450 into various surgical fields and procedures [66]. Lots of surgeries in a wide variety of 451 fields have been successfully conducted by this system, such as prostatectomies, cardiac 452 valve repair, and gynecologic surgical procedures [9]. The da Vinci surgical system further 453 received FDA approval in 2001 for use in prostate surgery, in 2002 for mitral valve repair 454 surgery, in 2005 for gynecological surgery [4]. 455

The da Vinci system is a teleoperated system, and it consists of two patient side manipulators (PSMs), one endoscopic camera manipulator (ECM), and two master tool manipulators (MTMs). The surgeon will remotely control the PSMs by physically operating on the MTMs while the remote scene on the PSM site will be presented to the surgeon via a console by using the ECM. The da Vinci system can translate the surgeon's hands

³⁷ Da Vinci website (accessed June 2023): https://www.intuitive.com/en-us/products-and-services/da-vinci

³⁸ Da Vinci FDA 2000 file (accessed June 2023): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K990144



Figure 13. Da Vinci Surgical System. (© 2023 Intuitive Surgical Operations, Inc.)

manipulation movements from MTMs to PSMs via the console in real-time, such as bending, rotating, grasping, palpating, and cutting, while providing haptic feedback to the surgeon for an immersive experience.

In orthopedics, the applications of the da Vinci surgical system can be largely limited 464 due to the fact that the system is designed more suitable for manipulating soft tissues (e.g., 465 suturing, ablation, needle insertion) than rigid bones (*e.g.*, cutting, burring). Some surgeries 466 regarding soft tissues or nerves in orthopedics have been conducted using the da Vinci 467 system. For example, da Vinci system was successfully used for ulnar nerve decompression 468 at the elbow [67] and supraclavicular brachial plexus dissection and nerve root grafting at 469 the shoulder [68]. Some cases of anterior lumbar interbody fusion (ALIF) in spine surgery 470 are also reported to be successful by using the da Vinci surgical system [69,70]. 471

2.4. RS Remarks

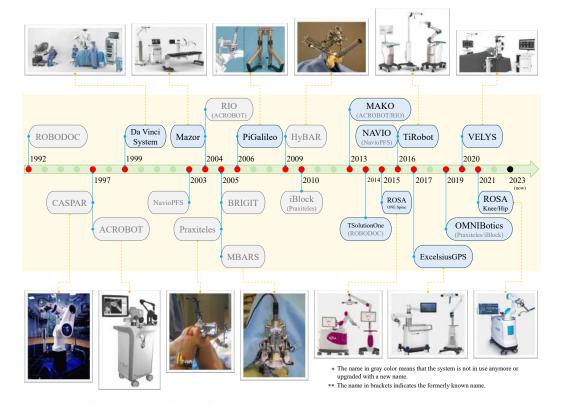


Figure 14. Robotic systems (RS) in the timeline.

The RS systems in the timeline are illustrated in Fig. 14. Currently, the time-honored robotic systems including TSolution One (formerly ROBODOC; THINK Surgical, Fremont, California, USA), MAKO (formerly ACROBOT/RIO; Stryker Corporation, Kalamazoo, Michigan, USA), NAVIO (Smith & Nephew plc, London, UK), and Mazor (Mazor Robotics, 476

Caesarea, Israel) are still available and continue to improve and thrive in the market. Compared to their relatively large robot body, on the other hand, MBAR represents an 478 emerging trend of mini bone-attached robots with potentially more efficiency and lower 470 cost. ROSA and VELYS are newly developed products in the market. Da Vinci Surgical 480 System represents a more versatile robot that has a large potential to be used in a large 481 variety of surgeries for the teleoperated systems used in MIS. In general, by overlooking 482 the robotic systems developed for orthopedics in the past decades, their functions are 483 mainly focusing on bone cutting, positioning, and alignment, while the precision has been 484 increasing whereas the variability has been decreasing [2]. 485

For autonomous RS, it is still cautious about using it in orthopedic surgery due to ethical issues and safety concerns on autonomous operation [26]. Typical issues and concerns include potential muscle/nerve damage and technical complications. For example, when a procedure stop occurred during the bone cutting, re-registration is required while sometimes frequent registration failures may cause the surgery to abort [25].

Compared to autonomous RS, hands-on RS may be more acceptable by surgeons due to the feature of human-in-the-loop [25]. When operating a hands-on RS, the surgeons have full control of the robot and can stop the surgical operations (*e.g.*, bone cutting) at any time they want. This can ensure the safety of the patient at the maximum.

For teleoperated RS, their applications in orthopedics are limited. The main reason is that orthopedic surgeries are more related to manipulation with rigid bone cutting and implant alignments which are not suitable for teleoperated RS. However, for those orthopedic surgeries regarding soft tissues, nerves, and vascular, the teleoperated RS could still be applicable and useful.

3. Computer-Aided Navigation Systems (CANS)

Computer-aided navigation systems (CANS) can be taken as a parallel category to RS. The CANS focuses on navigation with the help of computers. It can be either integrated with an RS or independent from an RS. When integrated together, all the coordinates of the CANS (*e.g.*, CT image frame, and external camera frame) will be registered into the coordinates of the RS, then for navigation. When independent from an RS, *i.e.*, no robots appear in surgery, all the coordinates will be registered into the digital patient's model/image or the camera frame, then for navigation.

In the category of computer-aided navigation systems (CANS), three basic elements 508 are included, *i.e.*, **3D modeling**, registration, and navigation. Strictly, the CANS are 509 computer-assisted systems rather than robot-assisted systems. However, a robot-assisted 510 system (here equivalent to RS) usually includes a CANS system implicitly or explicitly. 511 Implicitly means that an RS itself can be viewed as a special navigation system since any 512 point in the robot workspace can be tracked based on robot kinematics [17]. Explicitly 513 means that a CANS can be integrated with a robotic system to enhance the system's ability 514 (e.g., tracking and visualization). Therefore, a CANS can be used either independently or 515 integrated with an RS, which means a CANS can be an essential part of assisting surgeons in surgery, no matter whether a robot is involved or not. This also means that the CANS 517 has more wide and more general applications than RS in orthopedics and beyond.

In CAOS tripartite categories, the term of passive systems is equivalent to the CANS here [17,25]. The CANS does not perform any actions on patients thus no relevant safety concerns. Instead, the CANS only collects intraoperative data and provides visualized information and guidance to the surgeons thus helping them to better achieve their surgical objectives accurately and precisely.

A large amount of case studies have shown that the CANS can offer more accurate surgical outcomes, such as placement of the components in UKA, alignment of the femoral and tibial components, tibial slope, and the mechanical axis [17,25].

RS	System	Usage	Features	Pros/Cons (\oplus / \ominus)
Autonomous	TSolutionOne (ROBODOC)	TKA; THA.	 IBM,1980s; first patient in 1992; pre-CT based; 3D preoperative planning workstation ORTHODOC; 5-axis robot; bone milling; bone preparing. 	 ⊖ surgeon cannot intervene but stop the robot; ⊖ recovery process is complex if robot stopped during surgery.
	CASPAR	TKA; THA.	 ⊙ pre-CT based; ⊙ bone milling & preparation; ⊙ position guiding. 	\ominus problematic in many studies; \ominus thus not in use already.
Hands-on (=semi-autonomous)	ACROBOT	TKA; UKA.	 pre-CT based preop. plan; 6DOF robot; haptic feedback; bone cutting; active-constrained control. 	⊕ system actively prevents the drill from deviating the predefined cutting zone.
	RIO	TKA; THA; UKA.	 ⊙ inherited from ACROBOT; ⊙ pre-CT based; ⊙ haptic & audio feedback; ⊙ bone cutting; ⊙ force-controlled tip. 	 ⊕ system actively prevents the tool from deviating the predefined cutting zone; ⊕ short learning curve.
	МАКО	TKA; THA; UKA.	 ⊙ inherited from RIO; ⊙ pre-CT based; ⊙ bone cutting; ⊙ emergency auto shutdown; ⊙ a computer navigation system. 	 ⊕ emergency auto shutdown; ⊕ haptic & audio feedback; ⊕ VF (virtual fixture).
	NAVIO (NavioPFS)	TKA; UKA; uKA.	 ⊙ image-free system; ⊙ tool tip extend/retract; ⊙ IR optical-based navigation system; ⊙ safety strategy of modulating burr retraction and speed. 	\oplus imageless, thus no pre-CT needed. \ominus no haptic feedback.
	BRIGIT	TKA.	 ⊙ teleoperated mode available; ⊙ compliant control strategy. 	\oplus collaborative or teleoperated mode
	MBARS; HyBAR	TKA.	\odot small & bone-mounted robot; \odot can be autonomous.	\oplus more efficient; \oplus cost-effective.
	iBlock (Praxiteles)	TKA.	 ⊙ imageless system; ⊙ bone morphing technique; ⊙ computer station OmniBiotics; ⊙ intraop. anatomic data; ⊙ intraop. planning. 	 ⊕ can see the planned bone cut before execute. ⊖ no haptic feedback; ⊖ limited kinematic assessment after implantation.
	OMNIBotics	TKA.	 upgraded from iBlock; image-free system; bone morphing technique; small & bone-mounted robot; robotic tensioning tool (active spacer). 	⊕ active spacer can help to improve surgical outcomes.
	ROSA	TKA; THA; Spine.	 ⊙ either imageless or image-based; ⊙ bone resection; bone positioning; ⊙ soft tissue assessment. 	\oplus intraop. landmarks data.
	VELYS	TKA.	⊙ imageless; ⊙ patient-specific TKA technique.	 ⊕ intraop. data on both anatomy and soft tissue; ⊕ allow intraop. planning.
	Mazor	Spine.	 ⊙ SpineAssist is the 1st robot for spine; ⊙ four evolved system versions. 	 ⊕ accept preop. or intraop. CT for planning; ⊕ real-time tool tracking.
	ExcelsiusGPS	Spine.	⊙ surveillance marker;⊙ shock-absorbing.	 ⊕ accept preop. or intraop. CT, or radiographs for planning; ⊕ real-time image guidance.
	TiRobot	Spine.	\odot real-time 3D navigation.	\oplus cross-referencing registration.
Teleop.	da Vinci	MIS.	\odot applied to various MIS surgeries.	 ⊕ versatile for various MIS surgeries. ⊖ suitable for manipulating soft tissu but not rigid bones.

Table 1. Rotobic systems (RS) in orthopedics.

Note: UKA (unicompartmental knee arthroplasty); uKA (unicondylar knee arthroplasty); TKA (total knee arthroplasty); THA (total hip arthroplasty). pre-CT, preoperative CT image; preop., preoperative; intraop., intraoperative; Teleop., teleoperated; IR, infrared; MIS, minimally invasive surgery; DOF, degree of freedom. System names in gray color mean either not in use anymore or upgraded with new names.

538

3.1. Three basic elements

A complete set of CANS techniques in orthopedics includes three basic elements, *i.e.*, 528 3D modeling, registration, and navigation [10].

3.1.1. 3D modeling

3D modeling is about reconstructing a 3D digital model of the patient's bone, and then 531 the model can be further used to make preoperative planning by the surgeon. Typically, the 532 3D model is reconstructed from preoperative images (e.g., CT, X-ray, MRI). For example, 533 most of the previously introduced RSs do the 3D modeling based on preoperative CT 534 scans. Some other systems (e.g., NAVIO) generated the 3D model by using bone morphing 535 techniques and intraoperative tracking data, then visualizing the 3D model in a graphical 536 format. 537

3.1.2. Registration

Registration is a core and compulsory procedure for any CANS system or RS system 539 being used in orthopedic surgeries. The quality of registration fundamentally and directly 540 determines the accuracy and precision of the surgical outcomes [17]. It is worth mentioning 541 that both RS and CANS are heavily relying on registration, while RS is more so than an 542 independent CANS due to the fact that the surgical work is conducted by the robotic-543 attached tool in RS rather than the surgeon alone [17].

Before the surgery in the operating room, registrations between the patient's true bone, 545 the corresponding 3D model, the robotic system (if applicable), and the surgical tool need 546 to be conducted first. Some methods may be needed to ensure accurate registration. There 547 are three typical registration methods including fiducial-based paired-point matching, surface-based, and 2D/3D–3D registration [25]. ROBODOC initially used fiducial-based 549 registration and changed to surface-based registration in 1999, while studies have proved that the surface-based registration is as accurate as the fiducial-based registration [25]. 661

Fiducial-based paired-point matching method is a modified version of the paired-552 point matching method [25]. To get a high-accuracy and reproducible registration, fiducials 553 need to be placed into the target bone before the preoperative CT scanning such that 554 these fiducials will appear in the CT images. These fiducials will be used for registration 555 by using the paired-point matching method. During the surgery, these fiducials will be 556 used as the reference points for the patient's bone, and relate it to the preoperative plan. 557 However, the fiducial-based registration requires an additional minor operation of placing 558 the fiducials into the bone before the preoperative CT scanning which brings fiducial site 559 pain or inflammation to the patients [25].

Surface-based (also known as shape-based) registration does not need fiducials. It 561 employed a widely-used iterative closest point (ICP) algorithm and the least-squares 562 method to match the points on the 3D model surface with those on the patient's bone 563 surface [71,72]. To avoid local minima, the paired-point method will be used first to do 564 a baseline registration, then a certain number of points will be used to do a refinement 565 surface-based registration [25]. An advantage of surface-based registration is that it can be 566 conducted and updated intraoperatively and in real-time, which makes it more robust than other registration methods. 568

The 2D-3D or 3D-3D registration method makes use of intraoperative fluoroscopic images [25]. Although this method has been shown to be accurate for use in robot-assisted 570 THA in a lab setting, it has not yet been widely accepted by clinical robotic surgeries [25]. 571

3.1.3. Navigation

Navigation is the kernel element and function of a navigation system. Given an 573 accurate 3D model and an accurate registration, the surgical tools and the patient's bone 574 landmarks can be precisely tracked either by a set of tracking devices or by the robot 575 coordinate system. A sensor-based navigation system usually uses optical sensors or 576 magnetic sensors to track the 3D positions of the target bones, the surgical tools, and any 577

other objects (*e.g.*, implants) needing to be tracked [25]. An optical IR-based system can track objects with high accuracy by using infrared (IR) light tracking cameras and infrared light reflecting markers [25]. However, the optical-sensor-based tracking system can be easily affected by light-sight blocking. The magnetic sensor does not have this problem, but it may be affected by metallic objects within its workspace [25]. A novel approach for active optical navigation has been proposed recently, where the optical tracking system (OTS) is installed on a robot that can actively adjust the pose of the OTS [73].

Based on the working principles, CANS includes three typical types of navigation 585 systems being used in orthopedic surgeries, *i.e.*, CT-based, imageless, and fluoroscopic 586 [25]. In 1994, two years after the ROBODOC was first used on humans, the first CT-587 based navigation system was developed and used in THA in Pittsburgh [17,74]. CT-588 based navigation is prevail among most of the previously introduced robotic systems. 589 Although CT-based navigation has the highest accuracy, a big disadvantage is that acquiring 590 preoperative CT images and making preoperative plans based on them are time-consuming 591 which may bring more cost and radiation exposure to patients [25]. 592

Imageless navigation, also known as "surgeon-defined anatomy" technology, employs some other techniques such as infrared (IR)-based tracking, stereotaxic technology, and bone morphing technology. Note that here the imageless or image-free means that no preoperative CT images are required but may still need camera-based intraoperative tracking for navigation. Together with the intraoperatively collected patient's anatomic data, an abstract of the patient's anatomy can be generated [17]. This kind of imageless technique is adopted by some robotic systems, such as the NAVIO system and Praxiteles. The accuracy of imageless navigation will depend on the techniques adopted.

Fluoroscopic navigation has a similar principle to imageless navigation but uses fluoroscopic images. The fluoroscopic navigation is good for use in trauma and spine surgeries but is limited in other orthopedic surgeries due to its cumbersome registration procedures [25].

3.2. Typical Systems

3.2.1. Stryker Navigation system

Stryker Navigation system II Cart³⁹ (Stryker, Kalamazoo, MI, USA), is an opticalbased navigation system with an optical localizer accuracy of about 0.07 mm [75]. The navigation system can reconstruct the 3D bone model by using the original CT data. Dynamic reference trackers will be placed on the patient's bone for later registration with considerations of avoiding nerve injuries and interrupting navigation pointer operations [75]. A study on validating the registration accuracy of a Stryker navigation system (Stryker II cart Navigation system) for elbow arthroscopic debridement showed that the registration accuracy can achieve to be within 1 mm [75].

3.2.2. OrthoPilot

OrthoPilot⁴⁰ (Aesculap/BBraun, Germany), as shown in Fig. 15, is a pure navigation system that conducted its first surgery in 1997 [18]. It is an imageless navigation system, and it works based on intraoperative data acquired by an optical tracking system [18]. The tracking system consists of an infrared (IR) tracking camera and IR Spectra localizer (Northern Digital Inc.). Currently, the OrthoPilot has been used in TKA, revision TKA, and THA. A detailed introduction to using OrthoPilot over two decades can be found in [18].

605

³⁹ Stryker NAV3i website (accessed June 2023): https://www.stryker.com/us/en/navigation/products/nav3i. html

⁴⁰ OrthoPilot website (accessed June 2023): https://www.bbraun.com/en/products-and-solutions/therapies/ orthopaedic-surgery/orthopilot.html





(a) Hardware (b) Multitool

(c) Software display Figure 15. OrthoPilot navigation system. (Reproduced with permission from © Aesculap AG, Tuttlingen, Germany.)



Figure 16. Brainlab Knee3. (Reproduced with permission from © Brainlab AG, Munich, Germany.)

3.2.3. Brainlab Knee3

Brainlab Knee3⁴¹ (Brainlab AG, Munich, Germany), as shown in Fig. 16, is a new imageless navigation system for use in TKA [59]. It is featured with real-time assessment 624 of the knee as a complete kinematic structure and predicting final joint stability at each 625 surgical step. It can display X-rays and templated plans during navigation. It can also 626 predict and visualize the virtual interaction between 3D kinematics, joint stability, and 627 implant alignment [76]. 628

3.3. CANS Remarks

The three basic elements of CANS, i.e., 3D modeling, registration, and navigation are 630 critical conditions to each other. 3D modeling is the necessary prerequisite for registration, 631 while registration is the necessary prerequisite for navigation. The accuracy of 3D modeling 632 directly affects the accuracy of registration, and the latter will further determine the accuracy 633 of the navigation. 634

The CANS is an independent technique that can be either used together with the 635 RS or used alone during surgical procedures. The applications of CANS are much wider 636 and more general than RS since a robot may be not demanded or applicable in some 637 surgeries while navigation can be always helpful. From another perspective, the existing 638 RS mainly focuses on hip/knee arthroplasty while the CANS has a relatively wider variety of applications, such as shoulder [22], elbow [77], and ankle. A systematic review of CT-640 based intraoperative navigation techniques used in total shoulder arthroplasty (TSA) can 641 be found in [22]. 642

4. Discussions and Future Perspectives

Both CANS and RS have been playing an increasingly critical role in modern ortho-644 pedic surgeries. According to a review study [17,78], the ratio of patents to publications 645 related to CANS and RS in knee arthroplasty increased from around 1:10 in 2004 to around 646 1:3 in 2014. The benefits brought by RS and CANS include but are not limited to augment-647 ing the surgical procedures, fine-tuning surgical plans to personalized patient profiles, and 648

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⁴¹ Brainlab Knee3 website (accessed June 2023): https://knee3.brainlab.com/#/main-menu

proving intraoperative data and real-time visualization to the surgeons for a more accurate and precise surgical outcome [17].

With decades of evolution, RS and CANS themselves have gone through critical improvement and upgrading. Without a doubt, RS and CANS will continue to thrive and play an indispensable role in orthopedics.

A critical unique feature of RS in orthopedics is that they must be capable of dealing with high forces and stiffness due to the rigid nature of their target object of bones, while the da Vinci surgical system is more suitable for soft-tissue-related procedures. The main advantages of RS applied in orthopedics include increased accuracy and precision of implant positioning, enhanced reproducibility, improved implant stability, and less resulting pain. On the other hand, the main disadvantages of RS include potential safety concerns, high economic costs, and potentially longer operative time.

CANS will continue to develop along two parallel paths. One is to integrate with robotic systems, another is to be used alone without involving RS. For the latter, CANS is capable of being used in more versatile surgeries where robots are not needed or not yet available. In that case, with the help of CANS, surgeons can perform conventional surgeries with potentially better and more accurate surgical outcomes.

4.1. RS and CANS for Various Orthopedic Surgeries

From Table 1, it can be found that most of the robotic systems are applied for hip/knee 667 surgeries, some are for spine surgeries, and no specific robotic system is exclusively for 668 elbow/shoulder surgeries. For example, ROSA has robot-assisted systems for the hip, knee, and spine, respectively, but only has a computer-aided system for assisting in planning and 670 navigation for the shoulder. The RSs have been abundantly developed and frequently used 671 in hip/knee surgeries but not in elbow/shoulder/foot/ankle surgeries, while the latter 672 seems more favorable on CANSs [79]. The possible reason could be that there are much 673 more cases and demand for knee/hip surgery than elbow/shoulder surgery. The knee is 674 the largest hinge joint in the body while the hip is a large ball-and-socket joint. Both the 675 knee and hip joints take a lot of wear, tear, and stress from daily activities (e.g., walking, 676 running, jumping) while supporting the body weight in horizontal and vertical directions, 677 and they are more vulnerable to injury and osteoarthritis than elbow/shoulder or any other 678 ioints. 679

Technically, all joint replacement/arthroplasty surgeries are open surgeries since a 680 significant incision needs to be made in order to expose the bone for bone cutting or 681 implant positioning. It is worth noting that in joint replacement/arthroplasty, minimally invasive approach/procedure has different definitions, such as shorter incision length, 683 non-dissection of quadriceps tendon, non-eversion of the patella, or non-dislocation of 684 the tibiofemoral joint [80]. Therefore, strictly speaking, all joint replacement/arthroplasty 685 are open surgeries rather than MIS which in the latter only several trocars need to be made in order to insert the surgical instruments for performing the surgery. In this sense, 687 arthroscopic surgeries belong to the category of MIS. For arthroscopic surgeries, several portals are made to insert an arthroscope and surgical tools, and the surgical tools will be 689 used to perform the surgery with the help of the arthroscope. Arthroscopic surgeries can be used for a large variety of indications. For example, elbow arthroscopy can be used for the 691 management of stiffness related to degenerative arthritis, loose bodies, lateral epicondylitis, 692 synovitis, osteochondritis dissecans, symptomatic plica, infection, contracture, instability, 693 and fracture management [81].

Arthroscopic surgeries (*e.g.*, arthroscopic debridement) is an active field that is being transformed by techniques of RS and CANS, although there is yet no specific robotic system specially designed for them. One possible reason is that there is high demand for accuracy and precision for surgeries of joint replacement/arthroplasty but not for arthroscopic surgeries. Also, for those arthroscopic surgeries related to soft tissue manipulation rather than rigid bone cutting, laparoscopic-type robotic systems like the da Vinci surgical system can be employed [67,68]. A robotic system can be helpful in arthroscopic surgeries, such 700 as holding with the arthroscope as a robotic assistance. On the other hand, a navigation 702 system can also bring benefits, such as tracking and visualizing the real-time location of the 703 tool tip. Accompanying the wide usage of arthroscopic surgeries with the benefits of MIS, 704 RS and CANS are getting deeply involved in arthroscopic surgeries [82].

4.2. Novel Robotic Designs

In addition to traditional rigid robots, novel types of robots, instruments, and ap-707 proaches are developed for use in orthopedic surgeries [83]. A curved-drilling approach 708 has been developed by integrating curved-drilling tools with a continuum dexterous ma-709 nipulator (CDM) for use in core decompression of the femoral head osteonecrosis [84]. The 710 curved-drilling technique and bendable medical screws have been examined on cadaveric 711 specimens for minimally invasive interventions in orthopedic surgery [85]. A redundant 712 robotic system consisting of a rigid-link robot and a CDM has been proposed for the 713 treatment of pelvic osteolysis and for autonomous debridement of osteolytic bone lesions 714 in confined spaces [86,87]. A miniaturized tendon-driven articulated surgical drill was 715 designed for bone drilling which can be used in minimally invasive spine fusion [88]. Hand-716 held robotic systems have also been developed for minimally invasive orthopedic surgeries 717 [89,90]. Recently, a concentric-tube steerable drilling robot is developed for spinal fixation procedures and implanting flexible pedicle screws [91,92]. Although these novel designs 719 have not yet been applied in the clinical setting, their benefits in orthopedic surgeries can 720 be expected in the near future. 721

4.3. Surgical Simulators

In parallel to robotic systems, another promising robotic technique is surgical simula-723 tors for training novices, e.g., virtual reality (VR) arthroscopy trainer, VirtaMed ArthroS 724 Hip/Knee/Shoulder/Ankle (VirtaMed AG, Zurich, Switzerland), and insightArthroVR 725 (GMV, Madrid, Spain) [93,94]. By using surgical simulators, the surgical skills of the novice 726 can be improved before they start to conduct surgeries on human patients. This can largely 727 enhance the novice's confidence and reduce the risk of surgical mistakes in patients caused 728 by lacking practical experience and unfamiliar operations on surgical robotic systems.

4.4. Artificial Intelligence (AI)

As a prominent topic in recent years, artificial intelligence (AI) is getting extraordinarily 731 popular especially after the breakthrough made by ChatGPT (OpenAI, San Francisco, 732 California, USA), although AI itself is not a novel concept [95]. Some AI-based features 733 have already been applied in robot-assisted surgeries, for example, AI algorithms presented 734 in [95–97]. Benefiting from the huge amount of patient data available in literature and 735 hospitals, a series of reliable AI-based techniques can be expected, such as AI-based 736 diagnosis, AI-based pre- and intra-operative planning, AI-based intraoperative navigation, 737 AI-based decision-making, and AI-based control of robotic systems [95]. By appropriately 738 incorporating these AI features, the capability of the robot and navigation systems can 739 be further improved and enhanced. On the other hand, this is also an opportunity for 740 developing fully autonomous robotic systems and pushing them a step forward. One can 741 imagine that AI-powered fully automated robotic systems can be developed and accepted 742 by the public in the future. 743

The future of CANS and RS in orthopedics is promising with the rapidly advancing 744 and evolving new technologies, such as image-guided techniques, virtual reality (VR), 745 augmented reality (AR), mixed reality (MR) [98,99], advanced robotic control strategies, AI, 746 and even novel biodegradable materials [100,101]. 747

5. Conclusion and Future Challenges

As a brief conclusion, it is an unstoppable trend for the RS and CANS to be intro-749 duced into more variety of surgical scenarios besides hip/knee surgeries, and it is rapidly 750 happening. Robotics and navigation techniques have been playing increasingly impor-751

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tant roles in elbow/shoulder, foot/ankle, spine surgeries, arthroscopic surgeries, and far beyond [22,77,79,82,102,103]. With the newly emerging techniques, such as AI, VR, and soft/flexible robotics, robots and navigation systems in orthopedics will become more intelligent, more reliable, and more economical in the future.

Accompanying the increasingly thriving potential of the RS and CANS in orthopedics 756 and beyond, many challenges may emerge. First of all, fully autonomous robotic systems 757 may still face big challenges in being accepted. Safety is always of the utmost concern 758 both for surgeons and patients. To ensure safe surgery, surgeon-in-the-loop is usually a 759 preferable solution for robot-assisted surgery than fully autonomous robotic systems. In 760 return, this will slow down the development of autonomous systems. In this situation, 761 how to find a way to improve the quality and stability of autonomous systems could 762 be challenging. Artificial intelligence (AI) is increasingly popular nowadays. Another 763 challenge could be how should the developers incorporate AI features into the existing 764 robotic and navigation systems in order to enhance the capabilities of the system while 765 ensuring system stability and safety. Economic costs can be also a challenge in making 766 robotic systems widely accepted both by patients and hospitals. Without a doubt, to make 767 robot-assisted surgery affordable to patients, more efforts and collaborations need to be 768 made by manufacturers, hospitals, developers, and surgeons. Last but not least, surgeons with traditional surgical skills may face a challenging situation for operating robot-assisted 770 surgeries. Novel training approaches and strategies need to be established in order to help 773 surgeons to acquire robot-assisted surgical skills based on their own traditional surgical 772 skills.

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Abbreviations	788
The following abbreviations are used in this manuscript:	789

DC	and the state of t
RS	robotic system
CANS	computer-aided navigation system
CAOS	computer-assisted orthopedic surgery
FDA	Food and Drug Administration
CT	computed tomography
MIS	minimally invasive surgery
VF	virtual fixture
VR	virtual reality
MR	mixed reality
AR	augmented reality
AI	artificial intelligence
uKA	unicondylar knee arthroplasty
UKA	unicompartmental knee arthroplasty
UKR	unicompartmental knee replacement (=UKA)
TKA	total knee arthroplasty
TKR	total knee replacement (=TKA)
THA	total hip arthroplasty
THR	total hip replacement (=THA)
TSA	total shoulder arthroplasty
pre-CT	preoperative CT image
preop.	preoperative
intraop.	intraoperative
IR	infrared
ICP	iterative closest point
DOF	degree of freedom
CDM	continuum dexterous manipulator
pHRI	physical human-robot interaction
MTM	master tool manipulator
PSM	patient side manipulator
ECM	endoscopic camera manipulator
OTS	optical tracking system

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