ISSN: 2476-6909; Modares Mechanical Engineering. 2023;23(11):607-614

Design and Construction of a Computer-Assisted Device Applicable for Accurate Pedicle Screw Placement in Spinal Fusion Surgery

ARTICLE INFO

Article Type
Original Research

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How to cite this article
Moradihaghighat R, Rostami M, Ghasemi M.A, Kohandani Z.M. Design and Construction of a Computer-Assisted Device Applicable for Accurate Pedicle Screw Placement in Spinal Fusion Surgery. Modares Mechanical Engineering; *2023;23(11):607-614*.

ABSTRACT

The purpose of this study is to develop a new surgeon assistant device applicable in open spinal fusion surgery to improve the accuracy of the entry point for pedicle screw insertion position. We developed a new device named Surgeon Assistant Pedicle Detector (SA_PeD). SA_PeD detects and shows the accurate entry point for pedicle screw insertion to the surgeon, by using preoperative planning, registration and tracking phases. The tests were made by eight operators and each of them on five vertebrae with two holes. The results show that the average position error is 0.52±0.26mm. Repeatability and reproducibility of device is also reported which is impressive. The device is also independent of the operator and has same result for all operators. Considering that maximizing the accuracy, increases costs exponentially, so the device is cost effective in comparison to other expensive robotic and navigation systems and greatly reduces the number of errors. The device also occupies little space in the operating room and is easy to learn for the surgeon to use it.

Keywords Spinal Fusion, Pedicle Screw, Surgeon-Assistant, Computer-Assisted.

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Article History
Received: April 5, 2023
Accepted: October 29, 2023
ePublished: December 19, 2023

CITATION LINKS

1- Minimally invasive spinal surgery: a historical perspective. Neurosurgical focus. 2- Accuracy of pedicle screw insertion: a prospective CT study in 30 low back patients. 3- The use of pedicle-screw internal fixation for the operative treatment of spinal disorders. 4- Free-hand" technique for thoracolumbar pedicle screw instrumentation: critical appraisal of current" state-of-art. 5- Pedicle screw insertion accuracy with different assisted methods: a systematic review and meta-analysis of comparative studies. 6- Postoperative computed tomography assessment of pedicle screw placement accuracy. 7- Pedicle screw placement accuracy: a meta-analysis. Spine. 8- Complications of pedicle screws in lumbar and lumbosacral fusions in 105 consecutive primary operations. 9- Exploring the role of 3-dimensional simulation in surgical training: feedback from a pilot study. 10- Navigation and MIS in orthopedic surgery. 11- A miniature patient-mount navigation system for assisting needle placement in CT-guided intervention. 12- Experiments on robot-assisted navigated drilling and milling of bones for pedicle screw placement. 13- A stereotactic/robotic system for pedicle screw placement. 14- Bone-mounted miniature robot for surgical procedures: Concept and clinical applications. 15- Accuracy of robot-assisted placement of lumbar and sacral pedicle screws: a prospective randomized comparison to conventional freehand screw implantation. 16- Cooperative robotic assistant with drill-by-wire end-effector for spinal fusion surgery. 17- Design and control strategy of robotic spinal surgical system. 18- A Novel Surgeon-Assistant Device Applicable for Pedicle Detecting in Open Spine Surgery. 19- A Novel Surgeon-Assistant Device Applicable for Pedicle Detecting in Open Spine Surgery. 20- Registration techniques for computer navigation. 21- Free-hand" technique for thoracolumbar pedicle screw instrumentation: critical appraisal of current" state-of-art. 22- Morphometry of pedicle and vertebral body in a Mexican population by CT and Fluroscopy. 23- Accuracy of pedicle screw placement: a systematic review ... 24- A novel computer-assisted technique for ...

[DOI: 10.22034/mme.23.11.607]

1- Introduction

Spinal fusion, also known as Spondylodesis, is a surgical procedure whereby two or more vertebrae are joined together to stabilize the spine [1,2]. Spinal fusion is a very effective treatment for spinal pathologies with chronic pain such as degenerative disc diseases, infection, tumors, fracture and Spondylolisthesis. In this regard, stabilization of the spine is implemented to refine the deformity, release the compression and relieve the pain in traumatic, degenerative disorders, deformity corrections and oncologic conditions. Pedicle screw fixation is the most popular method for fusion of the spine since the pedicle is the strongest part of a vertebra and pedicular instrumentation provides more stability and lower risk of complication [3].

Despite the high importance of accurate localization of the pedicle screw, conventional methods are not very exact. The surgeon needs to use the visible anatomic landmarks and the CT-scan or MRI imaging of the patient to facilitate the precise placement of the pedicle screw. In this so-called "free-hand" technique, the surgeon evaluates the anatomical aspect of the patient and plan the surgery including sagittal and transverse angles of pedicle screw insertion for specific patient. Thereafter, during the surgery the geometrical relationship between the anatomic landmarks and the exact entry point are used intraoperatively to insert the pedicle screw correctly[4].

In the face of a huge number of studies on vertebrae anatomy and anatomic landmarks, the surgeon's skill is remained necessary to use the landmarks in the open technique to find the entry point, in other words, the efficiency of the open technique in spinal fusion depends on the surgeon's skill. According to reports, the pedicle screw misplacement rate is as high as 55% while multiple redirections of the guide hole may be required[5,6]. Furthermore, due to the intraoperative imaging required to verify the accuracy of the screw after insertion, the hazard of multiple exposures to radiation threatens the patient and the surgical staff[7,8]. So the need for a surgeon assistant device to guide the surgeon to the right entry point pose at the first try is necessary[9].

Considering the increasing interest of surgeons in implementing the computer-assisted systems in spinal fusion surgeries, a wide spectrum of computer-assisted technologies has been developed: robotics, navigation, hybrid techniques, templating and telesurgery. These technologies could be classified into many subcategories: image free or image-based, active, passive or semi-active, bone-mounted, bed-mounted or hand-held some implement in open surgery and some in MIS surgeries[10,11].

The robotic systems usually consist of preoperative planning, the robot body, tracking and registration parts and what make the difference, is the technology used in the parts[12]. In the following three different robotic system will explain.

Robotic systems were first presented by Santos-Munn et al. [13] in 1995 to improve localization. They integrated a C-arm, Puma-560 and a computer with two monitors to provide frontal and sagittal views of the CT-scan of the spine during the surgery. Shoham et al. [14] have introduced a bone mounted miniature robot, named MARS that mounted on the patient's anatomy rigidly using a special fixer called a spinous process clamp. Therefore, there is no need for tracker and dynamic reference allocation in their system. In this system, the parallel six-DOF mechanism is employed to control the drill or the guiding arm representable for holding the surgical tool and the hole is bored either automatically by the robot or manually by the surgeon. However, the attachment of this fixture to the patient's body causes injuries to the patient's vertebra and limits the working area of the robot to one vertebra. This rigid connection is also associated with a large incision.

In 2006 Mazor Surgical Technologies developed a new fixture, which was attached to the body, to avoid the large incision made by the MARS robot during the surgery. They developed two distinct fixtures, applicable in an open and percutaneous approach, carrying the MARS robot without any need for connecting the robot to the patient's body directly. Ringle et al. [15] have tested integration of the MARS robot and the new fixture, i.e. Spine Assist, and, also, compared the Spine Assist with the free-hand technique directly. The results showed the superiority of the conventional free-hand technique over the robot-assisted technique. Moreover, the intraoperative exposure was also not reduced and the surgical time was longer as well.

Lee et al. [16] presented a 6-DOF cooperative system, named CoRA applicable in tele-operation insertion. This system is a 5-DOF robot body that carries the dexterous end-effector. The end-effector is controlled by either the surgeon or automatically using a preoperative plan to hold the end-effector at the desired position. The system is cable of high-speed drilling for cortical layer gimleting that produces effective perforation and reduces the risk of screw-loosening. There are also some other robot-assisted surgical systems, which are a combination of a serial robotic manipulator, tracking system, preoperative planning and navigation system to achieve image-guided robotic surgery. For example, there is the system presented by Jin et al. [17] in 2011, in this area.

In this study we are to develop a surgeon-assistant pedicle detector device (SA_PeD), designed in a study conducted in 2014[18], to avoid the surgeon's blind exploration for the pedicle and improve the pedicle screw placement accuracy in spinal fusion surgery. The system works on the basis of end-effector tracking and intraoperative registration and is applicable to open spine surgery. The presented device is a five-DOF mechanism moved passively by the surgeon to perform the registration. In this regard, the spatial coordination of the landmarks is collected by placing the end-effector on the points selected preoperatively. After registration, the device determines the entry point of the pedicle screw intraoperatively by using a computer program on the basis of preoperative planning done by the surgeon. Our approach is close to the free-hand technique making it effortless for the surgeon to employ it in surgery. In addition to the accuracy of SA_PeD in assisting the correct placement of the pedicle screw, using the SA_PeD is more cost effective than expensive robotic and navigation systems.

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2- *Materials and Methods*

2-1-*Problem Definition*

In this paper, construction of a surgeon assistant device, named SA_PeD has been presented. SA_PeD is applicable in open spinal fusion surgery and is an image-free device which helps the surgeon to detect the accurate position for screw insertion, at the first attempt of the surgeon to find the pedicle. This technique is based upon the idea of the free-hand technique and endeavors to remain very close to the conventional method in which the surgeon implements the preoperative planning, anatomic knowledge, and visible anatomic landmarks to find where the pedicle screw must be inserted. The SA_PeD uses preoperative planning, real time tracking of the device end-effector and intraoperative registration in order to recommend the precise location of pedicle screw placement to surgeon.

In this regard the preoperative planning using the CT image of the patient is done first. During the surgery, after the surgical site has been prepared to have an unobstructed view of the patient's anatomy, the intraoperative registration is done. The accurate entry point location of the pedicle screw is represented by SA_PeD and the pilot hole creation is performed by the surgeon. Insertion of the pedicle screws and interlocking them by rod or plates is performed by the surgeon as the final step.

The entire system consists of three main sections. The mechanical body of the device is the first section which includes the end-effector, the base which carries the manipulator passively, and the optical alarm which notifies the surgeon when the end-effector is placed in the correct position. The second section is the data acquisition system which includes the data acquisition card, the computer, and the sensors to collect the data from the mechanical joint. The last section is the computer program developed to perform calculations related to preoperative planning, tracking, registration and accurate positioning of the pedicle screw.

Figure 1 shows the block diagram of the entire system. The image of the object (the patient) is used to perform preoperative planning. During the surgery, the end-effector is controlled by the surgeon's hand and moved through the object.

The position of the end-effector is calculated real time during the movement of the end-effector. Therefore, the positions of the landmarks are calculated and recorded, from the position of the end-effector, once the surgeon puts the end-effector on the landmarks, by the computer program in the tracking section.

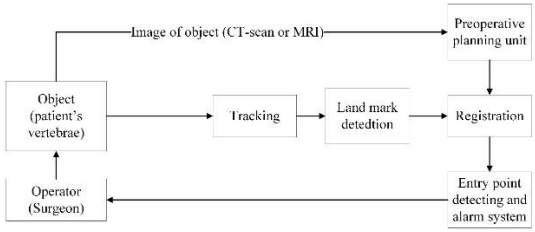

Fig. 1) Block diagram of the whole system.

Registration is done by entering the position of the landmarks that are obtained intraoperatively and with data from the preoperative planning. Entry point location is then calculated, and an alarm section alerts the surgeon when the end-effector is in the correct position. Each section plus the mechanical structure of SA_PeD is described in detail afterward in the following sections.

2-2-*Mechanical structure*

The mechanical body of the presented device is a serial mechanism featuring five degrees of freedom (DOF) and consisting of one prismatic and four revolute joints. The aforementioned joints together enable the surgeon to move the arms passively and locate the end-effector in the desired positions; the prismatic joint, which is the first joint, enables the whole structure to move along vertical axis and enables the height adjustment for each patient. Next two joints are revolute joints that moves the end-effector within the actual workspace in a horizontal place. The last two joint are placed of the device's end-effector and help the tip of end-effector move on a hemisphere surface to reach every point and direction in the space. Thus, the surgeon can perform registration intraoperatively and find the aim point precisely in the next step.

Five DOFs are considered to achieve all points and orientations in the space, due to the axisymmetric shape of the end-effector; one prismatic joint at the base of the device which enables the surgeon to freely adjust the height of the arms. Two revolute joints by vertical axis, connect two arms and the base, make the entire structure stable and the arms not drawn down. The next two revolute joints enable the end-effector to move on a hemisphere surface, the center of which is the final position of the arms. The last two joints enable the end-effector to reach all angles with respect to its center, as the end-effecter is axisymmetric. The entire mechanical structure of the designed device is shown in figure 2.

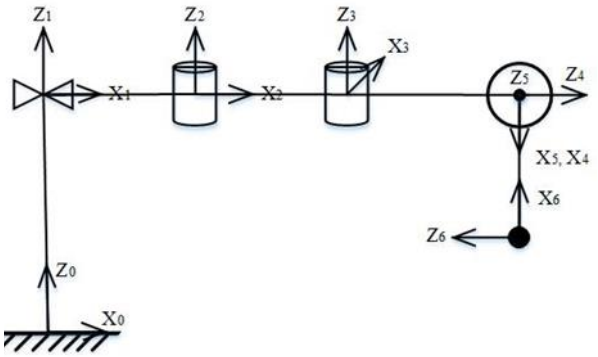

Fig. 2) The proposed system consists of 5 DOF and is a PRRRR mechanism [19].

Consequently, the proposed PRRRR mechanism provides access to all points for the end-effector using the first three joints. In addition to accessing all points of the workspace, the end-effector can be oriented in the sagittal and transverse planes by the last two revolute joints. Using Denavit-Hartenberg (D-H) convention and homogeneous matrices, the coordinate system is established, and the end-effector path is formulated (Equation 1) to analyze the device workspace.

[DOI: 10.22034/mme.23.11.607]

$$
\begin{aligned}
&l_1 + l_2 c_2 + l_3 s_{23} + l_5 c_4 c_5 c_{23} + l_5 s_5 s_{23} = p_x \\
&l_2 s_2 - l_3 c_{23} + l_5 c_4 c_5 s_{23} - l_5 s_5 c_{23} = p_y \\
&d_1 - l_5 s_4 c_5 = p_z \qquad (1) \\
&c_4 c_5 c_{23} + s_5 s_{23} = n_1 \\
&c_4 c_5 s_{23} - s_5 c_{23} = n_2
\end{aligned}
$$

Where p_x, p_y, and p_z are the end-effector coordinates, n_1 is related to the sagittal angle, n_2 is related to the transverse angle of the end-effector, c_i is shorthand for $\cos\theta_i$ and s_i is shorthand for $\sin\theta_i$. θ_1, θ_2, θ_3, θ_4, θ_5 and d_1 are the system variables. l_1, l_2, l_3, l_4 and l_5 are the device parameters.

Workspace analysis is done on the basis of the plotted areas, shown in figure 3, which is obtained from applying the presented equations. Figure 3a represents the actual workspace which is the rectangular area and the dexterous workspace which is the spotted area. As shown in figure 3a, the dexterous workspace of the mechanism covers the actual workspace. Figure 3b shows the vertical movement of the end-effector that allows for height adjustment.

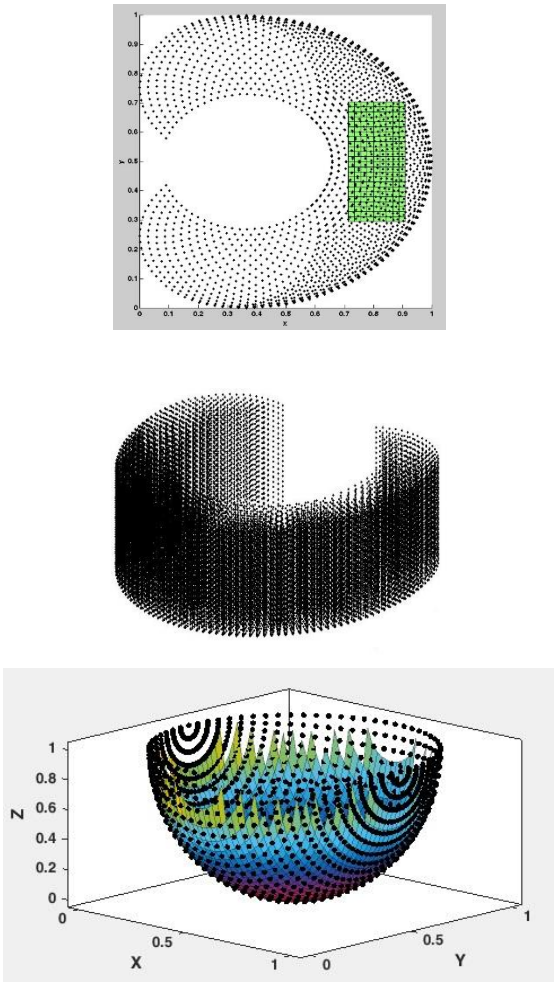

Fig. 3) (a) The actual workspace which is the rectangular area and the dexterous workspace which is the spotted area. (b) The vertical movement of the end-effector. (c) The normalized pathway of the end-effector.

In order to represent the accessible orientation merely, figure 3c illustrates the end-effector normalized pathway in space, which is accessible by the last two revolute joints, to show the accessible orientations only. As shown in figure 3c the end-effector could move on a hemisphere surface the center of which is the dexterous workspace (the spotted area) shown in figure 3a. So, the device end-effector will reach all the points in all directions in the actual workspace, that is essential for such a surgical assistant to reach all points and directions in the actual work space.

A prototype device is constructed to assess the device performance. The device's base places next to the test table while the arms move over the entire spine of the patient. Figure 4 shows the constructed prototype of SA_PeD, including the base, arms, end-effector and optical alarms.

Fig. 4) Constructed prototype of SA_PeD: the base, arms, end-effector and optical alarms.

2-3-*Preoperative planning*

The anatomical parameters of a vertebra vary considerably according to individuals and among different vertebrae. Therefore, the surgical procedure should be planned before the surgery starts to improve the surgeon's perception of the patient's anatomy and the procedure as a whole in order to achieve successful implantation. The image of object will be imported to the program and localization specification, including the exact entry point location and orientation would be calculated. The shape of a pedicle is a cylindrical and the pedicle screw should be located along the axis of this cylinder during the surgery. Therefore, the entry point location and orientation of the screw is determined by a surgeon based on the described instruction. The guide hole position and three landmarks, which are then registered with

[DOI: 10.22034/mme.23.11.607]

the real object (patient's vertebrae), are determined by the operator in this step. The results of this phase are transferred to the registration program as input for subsequent processes to register the real object with the virtual object.

2-4-*Registration technique*

Registration is the key step in any computer-assisted surgery. Time consuming and unreliable methods would not be used in computer-assisted surgeries[20]. Registration is the process of matching the virtual points selected preoperatively to the corresponding points on the real object (patient). The floating entity and the reference entity, comprising the real object frame, and the device frame respectively are considered as inputs. As a result the geometrical transformation is extracted from the registration process. Since the floating entity is rigid, the obtained transformation is a rigid transformation which is described by a rotation and a transformation. Considering the image of the object as preoperative input and the digitized landmarks as intraoperative input, a 3D/3D featured-based registration will be done.

The presented mechanical structure enables the surgeon to control the end-effector and guide it to the locations which are counterparts of the points defined in the preoperative planning, to record them. In this study, the paired point matching method produces the output of the registration stage and passes it to the computer program for entry point calculation.

2-5-*Processing and tracking*

Tool tracking is obviously an indispensable capability of a computer-assisted surgical system in implantation surgeries. The tracking section calculates the 3D position of the end-effector, that guides the surgeon to find the pilot hole location. Tracking serves to follow the end-effector accurately and achieve precise implant insertion. Previous studies commonly employed fiducial markers to locate the tool. However, in our approach, the sensors embedded in the device joints are sampled 100 times per second facilitating a predefined program to track the position of the end-effector in real time. The program applies position formula to obtain the spatial posture. The compensating coefficients are also considered to eliminate intrinsic device error and increase precision.

2-6-*Entry point detection and alarm section*

To achieve the correct pedicle screw insertion, the real time position (location and orientation) of the end-effector is permanently compared to the pre-planned position of the pilot hole while the end-effector is moved around the aim point by the surgeon during the surgery. The real time position of the end-effector is computed real-time from information of sensors in LabVIEW software according to Equation 1. The location of entry point, which is the pre-planned position, is computed according to the geometric relation between the entry point and the anatomic landmarks by Equation 2 and is shown in figure 5.

$$x = x_1$$
$$y = tan(\alpha)(x_1 - x_2) + y_2 \quad (2)$$

Where x and y are coordination's of the entry point. $x1$, $x2$ and $y2$ are the anatomic landmarks coordination, and α is determined in pre-operative step and is the slope of the line which bisects the transverse process. The orientation of entry point, however, is determined by the surgeon in cranial-caudal and medial-lateral directions. The optical alarms alert the surgeon once the end-effector is located at the correct entry point. The surgeon may then make the pilot hole and insert the pedicle screw.

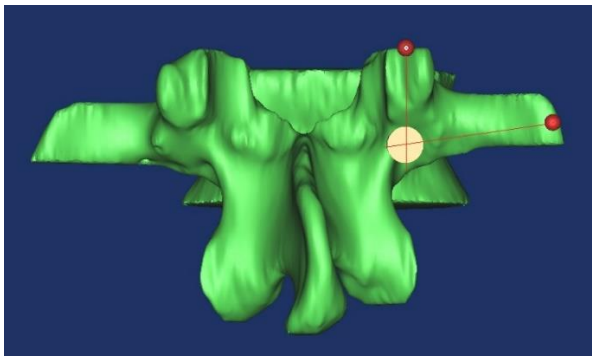

Fig. 5) Geometric relation between anatomic landmarks (shown in red points) and the entry point (light brown circle).

2-7-*Experiment setup and phantom*

Experiment setup was arranged as shown in figure 6. The setup consists of a computer for programming and calculations, a device prototype and an Advantech data acquisition board. The board collect signals from potentiometer sensors and transfers them to the computer software for further calculations.

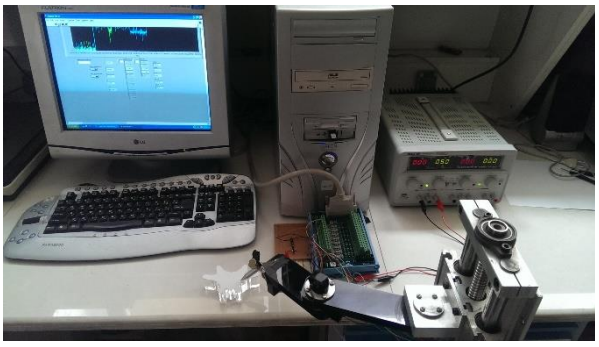

Fig. 6) The Experiment setup.

The experiment has been done on phantoms made of transparent plexiglass, with the planned holes drilled in it. During the experiment, the posterior side of the phantoms was covered by a piece of paper to avoid influencing the human operator unconsciously. If the human operator could see the planned hole entry point it might lead them to bore closer to it. The planned hole's diameter was kept small to distinguish the center of the planned entry point from the intraoperatively executed hole and measure the deviation to calculate the aforementioned criteria. Figure 7 shows the planned and created hole which are highlighted by black and white lines respectively.

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Fig. 7) The phantom made up of transparent plexiglass and shaped like the posterior view of the human lumbar vertebra with the planned holes in it. Planned holes are highlighted by black lines and created holes are highlighted by white lines.

The experiment consists of three main steps: 1) Preoperative planning: Data from the phantom was transferred to the computer. Therefore, the landmarks and the desired surgical position were determined in the preoperative planning section. 2) Registration: Counterparts of the planned points i.e. the landmarks, were specified by the device when the operator guided the end-effector toward them and by clicking on the button in the computer program, introduced them to the program. The sensor output is transferred to the computer via a data acquisition card and the coordination of real points was calculated using forward kinematics of the device. The registration calculations were then applied and the transformation between the device frame and the phantom was calculated. 3) Entry point determination: The operator then moved the end-effector around the possible entry point area. The optical alarm section informed the surgeon about the correct entry point with LED, while the surgeon sought the correct pose.

3- *Results and Discussion*

3-1-*Performance evaluation of the device*

Performance evaluation has been done measuring accuracy and precision during execution of the planned experiment in which a pilot hole in a phantom was created using SA_PeD. The experiment has also been performed by eight operators, each do the experiment ten times, to assess reproducibility and repeatability. ANOVA analysis is also done to examine the independency of the device from operator.

3-2-*Experiment results*

The experiment was done on five identical phantoms each with two planned holes, for each operator. The position error, which was the deviation of the executed position from the planned hole, was measured by a caliper. The test was done by eight operators each of them ten times. The results indicate that the mean position error of all eighty test is 0.52 mm, and the standard deviation is 0.26 mm (the error is 0.52±0.26) and the maximum error is 1.05 mm. The average position error, standard deviation of position error and maximum position error are summarized in table 1 for each operator.

Table 1) Position error in eight sets of experiments done by eight operators.

Operator number	Average of position error (mm)	Standard deviation of position error (mm)	Maximum position error (mm)
1	0.46	0.20	0.8
2	0.64	0.31	0.95
3	0.51	0.26	1.05
4	0.56	0.33566	1
5	0.48	0.2044	0.7
6	0.5	0.27386	0.9
7	0.575	0.34095	1
8	0.445	0.23028	0.7

To examine the hypothesis that the device is independent of operator and the average error is equal for all operators the ANOVA is done and results in p-value of 0.7662 which means there is no significant evidence to reject the hypothesis that the average error for different operators are equal. So, we can say the mean error for all operators are equal. The box plot also indicates that in almost all cases the data are near the normal distribution (figure 8).

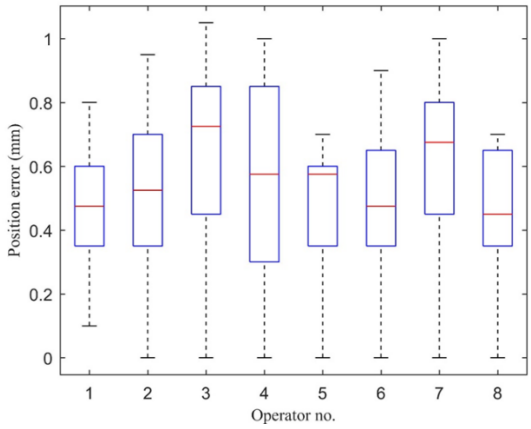

Fig. 8) The boxplot for position error for each operator.

To measure precision, repeatability and reproducibility was calculated. When a single operator does the test under the same condition, repeatability measures the variation occur for an operator during continual experiments, While reproducibility shows the ability of device to consistently reproduce constant results under the same condition when using by different operators. Total standard deviation also calculated using repeatability and reproducibility standard deviation. For SA_PeD the repeatability is 0.53 mm, reproducibility is 0.26 mm and total standard deviation for error is 0.59 mm which is an impressive result.

3-3- *Discussion*

Results show that the Surgeon-Assistant Pedicle Detector is capable of guiding the surgeon to the preplanned position accurately i.e. with an average position error of under 1 mm. Previous studies has shown that the pedicle width is an average of 10 mm[21]. The position error, recorded in table 1, shows that the SA_PeD presents acceptable performance with

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respect to the described working area. In the other words, The error is allowable with respect to the average size of the pedicle width[22].The experiment also demonstrated acceptable reproducibility with respect to multiple operators. The calculated error for SA_PeD, is the entire system error including the registration error and human error. Furthermore, due to the drilling process, the drill implementation caused additional error. Because of the reaction force between the phantom and the tool tip, the drill slightly shifted when it started to drill. To prevent egregious errors the system is designed so that the surgeon can compensate for such errors.

The considered procedure for SA_PeD is simple, without employing advanced technology it achieves its aims with low cost and is easy for surgeons to learn to use. Low cost makes the device suitable for patients who cannot afford the expensive robots and navigation methods used in similar procedures elsewhere. The presented prototype also occupies less space in the operating room.

The orientation of guide hole can be measured and introduced by SA_PeD as the position can. But testing this option is our next plan for SA_PeD. By considering a drill at end-effector and adding a guide rail to hold the drill and restrict the drill motion at desired path.

4- *Conclusion*

Pedicle screw fusion is increasingly used in spinal fusion, particularly in lumbosacral level for many spinal conditions. The free-hand technique is conventionally used for accurate placement of the instruments. Current studies have demonstrated that computer-assisted techniques, could indeed improve the accuracy and safety of pedicle screw placement[23].

In this study, we developed and evaluated the accuracy of a new surgeon assistant prototype, named SA_PeD, for spinal fusion surgery. SA_PeD is a computer-assisted orthopaedic surgery (CAOS) device which is able to introduce the exact entry point position to the surgeon. Also as the results show, SA_PeD performs consistently. To achieve accurate placement, the presented device shows the surgeon the pre-planned position when the surgeon moves the end-effector around the area of the aim point. Accurate placement lessens the need for repeated redirection and intraoperative imaging procedures, in turn, reducing the cost and stress on the patient. Consequently, the risk of damage is significantly reduced. The considered solution is similar to the conventional techniques, i.e. the free-hand technique, to reduce the training requirements of the surgeon. The presented prototype also occupies less space in the operating room due to its small framework. SA_PeD is cost effective compared to more expensive robotic and navigation systems for helping patients[24].

Conflict of interest

The authors declared that they have no conflicts of interest to this work.

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[DOI: 10.22034/mme.23.11.607]