ORIGINAL ARTICLE

Precision placement of instruments for minimally invasive procedures using a "Needle Driver" robot

K Cleary, V Watson, D Lindisch, R H Taylor, G Fichtinger, S Xu, C S White, J Donlon, M Taylor, A Patriciu, D Mazilu, D Stoianovici

K Cleary, V Watson and D Lindisch
Division of Computer Aided Interventions and Medical Robotics (CAIMR), Imaging Science and Information Systems (ISIS) Center, Department of Radiology, Georgetown University Medical Center, Washington, DC, USA
R H Taylor, G Fichtinger and S Xu
Center for Computer Integrated Surgical Systems and Technology, Johns Hopkins University, Baltimore, MD, USA
C S White
Department of Diagnostic Radiology, University of Maryland Medical Center, Baltimore, Maryland, USA
J Donlon and M Taylor
ImageGuide Incorporated, Baltimore, MD, USA
A Patriciu, D Mazilu and D Stoianovici
Brady Urological Institute, Johns Hopkins University, Baltimore, MD, USA
Correspondence to: K Cleary, E-mail: cleary@georgetown.edu

Abstract

Medical practice continues to move toward less invasive procedures. Many of these procedures require the precision placement of a needle in the anatomy. Over the past several years, our research team has been investigating the use of a robotic needle driver to assist the physician in this task. This paper summarizes our work in this area. The robotic system is briefly described, followed by a description of a clinical trial in spinal nerve blockade. The robot was used under joystick control to place a 22 gauge needle in the spines of 10 patients using fluoroscopic imaging. The results were equivalent to the current manual procedure. We next describe our follow-up clinical application in lung biopsy for lung cancer screening under CT fluoroscopy. The system concept is discussed and the results of a phantom study are presented. A start-up company named ImageGuide has recently been formed to commercialize the robot. Their revised robot design is presented, along with plans to install a ceiling-mounted version of the robot in the CT fluoroscopy suite at Georgetown University.

Keywords: robotic needle driver, minimally invasive procedures, CT fluoroscopy, spinal blocks, lung biopsy

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INTRODUCTION

Medical robotics is still a relatively young field, as the first recorded use of a robot was during neurosurgery in 1985 for the positioning of a needle used in a brain biopsy [(1)]. In the nearly 20 years since then, robots have been applied to many other medical specialties, including orthopedics, urology, radiosurgery, and cardiac surgery. The goals of these robotic systems have differed according to the clinical application. For example, in orthopedics, the ROBODOC system has been used for precise milling of the femoral cavity [(2)]. In cardiac surgery, the da Vinci master/slave system provides motion scaling, as well as an ergonomic workstation for the clinician to control two laproscopic robot arms [(3)]. In radiosurgery, the Cyberknife system allows the radiation beam to be aimed from many different directions, which means that the

treatment plan can be tightly contoured around the tumor [4].

Precision placement of a needle in the anatomy, a very common, minimally invasive procedure, may benefit from medical robotics. While biopsy is the most common procedure requiring precision needle placement, there are many other related procedures that require this technique, including pain blocks, radiofrequency ablation, and brachytherapy seed placement. A typical needle placement procedure is done under an imaging modality, such as x-ray fluoroscopy or computed tomography (CT)[1]. The physician first identifies the skin entry point and then inserts the needle partially towards the desired target location. Since the physician does not want to have his hand exposed to the radiation beam used for imaging, the physician steps back, and another image is obtained. The needle path is then corrected or continued and the process is repeated until the target is reached. This process of ''advance and check'' gets the job done, but may not be optimal in terms of time or precision. The end result is also highly dependent on the skill of the physician, and regular performance of these procedures is typically required to maintain one's ability to quickly and accurately compete this task.

Because of the drawbacks of this approach, we decided several years ago to create a robotic needle driver mechanism that could help physicians with precision needle placement during minimally invasive procedures. In this article, we review and summarize our progress in this area. We begin with a description of the ''needle driver'' medical robot, designed and built at Johns Hopkins [5]. We then detail our initial clinical application in spinal nerve blocks under x-ray fluoroscopy. We next discuss our work in robotically-assisted lung biopsy under CT fluoroscopy, including a phantom study. Finally, we describe the initial prototype system under development by ImageGuide, a spin-off company recently formed to commercialize this technology.

ROBOTICALLY ASSISTED SPINAL BLOCKS

While the robotic needle driver was originally developed at Johns Hopkins for urological procedures [6], our initial application at Georgetown University Medical Center was for spinal blocks. The Georgetown team consisted of a medical researcher with a background in robotics (KC) and a neuroradiologist specializing in minimally invasive interventions (VW). At the time, Georgetown was developing a new research program to investigate minimally invasive techniques in computer-aided surgery and medical robotics. Spinal blocks were chosen as the initial clinical application and testbed for three reasons:

1. The procedure is done under x-ray fluoroscopy; thus the robot could benefit the physician by potentially reducing the physician's x-ray exposure.
2. It is a high volume procedure, and the required number of patients could therefore be recruited for a clinical trial.
3. A good comparison could be made regarding the accuracy of needle placement between the standard manual technique and a robotically assisted technique.

In this section, we will first describe the robotic system, then explain the clinical procedure, and conclude with a summary of the clinical trial.

Robotic system

The robotic system was developed by the Urology Robotics Group at Johns Hopkins Medical Institutions under the direction of Dan Stoianovici, PhD. The system consists of a robotic device and control computer. The robotic device is shown in Figure 1. It has a mechanical arm, a touch screen, a joystick controller, and a mounting base. The mechanical arm includes a three degree-of-freedom (DOF) translational stage, a seven DOF passive stage, a two DOF rotational stage, and a one DOF needle driver. The needle driver is radiolucent so that it will not interfere with the x-ray image. The control computer is based on an industrial PC chassis and includes several safety features such as a watchdog timer. Further details about the robot are given in the recent article by Stoianovici et al. [5].

Spinal blocks

Spinal blocks are diagnostic procedures used to localize the source of back pain. In this study, two types of spinal blocks were included: nerve blocks and facet blocks. Both procedures involve the placement of a 22-gauge needle, and the injection of a local anesthetic, into a specific location within the spinal anatomy.

[1]Needle placement can also be done under ultrasound guidance, but this approach is not as common.

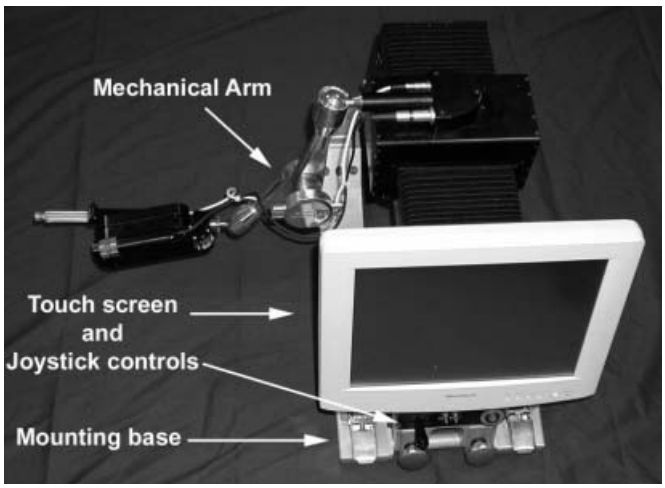

Figure 1 Robotic System.

At Georgetown University, the procedure is performed in a neuroangiography suite with biplane fluoroscopy. The patient is positioned on the table in the prone position (on the stomach). Local anesthesia is given by injecting 1% Xylocaine. Sedation is not used. A 22-gauge, 3½ or 5¼ inch needle is then placed and advanced to the target area using fluoroscopic guidance. Radio-opaque, non-ionic contrast dye (approximately 0.5 cc) may be injected during nerve blocks to visualize the nerve root.

When the needle is at the target location, the injection is done. For nerve blocks, 1.5 cc total volume containing 0.5 cc of 10 mg Kenalog and 1.0 cc of 0.25% Bipuvacaine is injected. For facet blocks, 0.75 cc total volume containing 0.25 cc of 10 mg Kenalog and 0.5 cc of 0.25% Bipuvacaine is injected. Both A/P and lateral fluoroscopy images indicating the needle position at the injection site are saved. The procedure is then complete. The patient returns to a waiting room, and after 10–15 minutes, the post procedural consultation is done, which includes the patient's assessment of their current pain level. If the procedure is successful, the patient will typically feel pain relief almost immediately.

Clinical trial

After successful completion of cadaver studies using the robot to precisely position a needle in the lumbar spine [7], a randomized clinical trial of 20 patients undergoing nerve and facet blocks was approved by the FDA and the local institutional review board [8]. The procedure is done in the standard manner except the robot is used to position, orient, and drive the needle under physician control. A/P fluoroscopy is used to position and orient the needle, and lateral fluoroscopy is used to monitor the depth of insertion. The robot is mounted on the interventional table using a custom-designed locking mechanism. The robot is positioned initially near the skin entry point by loosening the passive gross positioning mechanism and moving the needle driver end of the robot by hand. Once this initial position has been attained, the mechanism is locked and the robot is switched to operate by physician control.

The study was approved by the local Institutional Review Board and the Food and Drug Administration (FDA) and was conducted from August to December, 2002. The study was completed by a fellowship-trained interventional neuroradiologist at Georgetown University Hospital using a Siemens Neurostar bi-plane fluoroscopy system. The standard manual technique was used on 10 patients and the robotic device was used on 10 patients. The patients ranged in age from 30 to 70 years, and spine levels ranged from L-3 to S-1. No complications were observed in the study. One of the patients in the robotics arm group had to be converted to a manual procedure due to slippage of the needle driver. This conversion was done without difficulty or complications. A picture of the initial patient is shown in Figure 2. Patients had to sign an informed consent form and were generally receptive to the use of the robot.

There were two outcome measures: 1) accuracy of needle placement, and 2) pain relief. Accuracy of

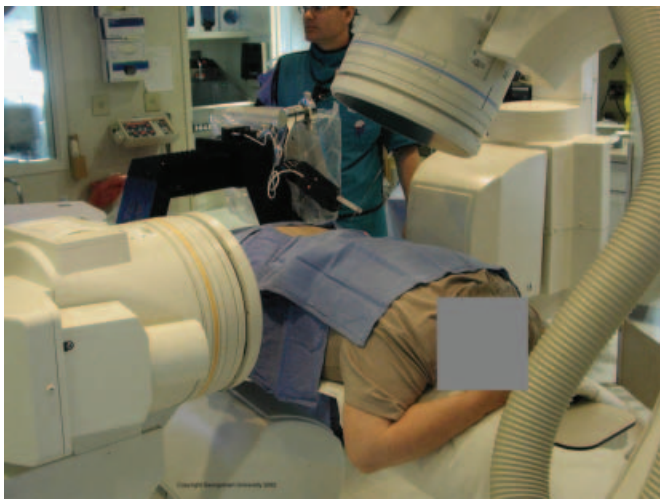

Figure 2 Nerve block clinical trial.

needle placement was determined as follows. Before the interventionalist began placing the needle, both an A/P and a lateral image of the patient were obtained. The interventionalist then annotated each image with an arrow to indicate the desired target location of the needle. After the needle was placed, an A/P and lateral image was again obtained. The two sets of images were compared to determine the distance between the intended location of the needle and the actual location of the needle. Pain relief was measured using a visual-analog scale, with 0 representing no pain and 10 representing excruciating pain. The pain scale is shown in Figure 3.

The results for the twenty patients are shown in Table 1. The table includes the patient number, age, sex, technique (manual or robot), type of block (facet or nerve), level in spine, pain before procedure, pain immediately after procedure, pain 1 week after procedure, and accuracy of needle placement on A/P and lateral images.

As noted in Table 1, there was one patient (Patient #11) who switched from the robotic method to the manual technique because the needle driver kept slipping when trying to drive the needle. The robot was then easily removed from the table, and the procedure was completed by hand (manual technique). No complications or adverse events were noted during this case, or during any of the procedures.

The results show that it is feasible to use a joystick-controlled robot for nerve and facet blocks. While this study was a pilot, and not enough data was gathered for statistical significance, some general trends can be observed. The mean accuracy of the robot method (1.105 mm) and the manual method (1.238 mm) is about the same. Therefore, it appears

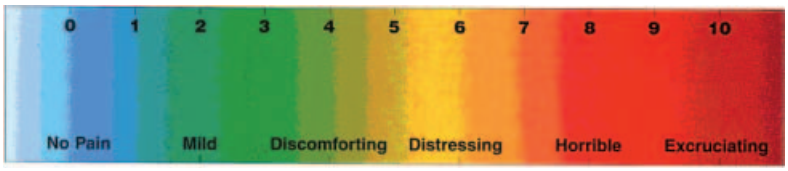

Figure 3 Pain relief was measured using a visual-analog scale from 0 to 10.

Table 1 Results for the Twenty Patients

Patient	Age	Sex	Technique	Block	Level	Pain before	Pain After	Pain 1 week	Accuracy (mm)	
									A/P	Lateral
1	70	M	Manual	Facet	L-4	1	0	1	0.66	0.94
2	59	F	Manual	Nerve	L-5	1	0	0	0.41	0.23
3	60	M	Manual	Nerve	L-4	8	0	3	0.96	0.57
4	30	M	Manual	Nerve	L-4	9	1	2	0.69	0.81
5	55	F	Robot	Nerve	L-4	8	4	4	1.92	1.45
6	78	F	Robot	Nerve	S-1	4	3	4	0.23	0.18
7	74	F	Robot	Nerve	L-5	3	0	1	0.34	0.17
8	74	F	Robot	Nerve	L-4	4	1	2	2.00	1.44
9	60	F	Manual	Nerve	L-5	8	1	2	0.41	1.22
10	60	M	Robot	Nerve	L-4	8	0	1	0.66	0.10
11*	66	F	Robot	Facet	L-5	9	4	5	0.28	0.68
12	65	F	Manual	Facet	L-5	7	0	3	0.22	1.39
13	42	M	Manual	Facet	L-4	2	0	2	0.92	0.38
14	62	F	Robot	Nerve	L-4	5	1	2	0.40	1.01
15	69	M	Manual	Facet	L-4	8	3	7	0.53	0.57
16	70	M	Robot	Facet	L-3	8	2	7	0.90	0.97
17	65	F	Robot	Facet	L-3	6	0	0	0.63	0.42
18	42	M	Manual	Nerve	L-5	8	4	5	1.09	1.30
19	65	F	Manual	Facet	L-5	8	0	0	0.00	2.40
20	42	M	Robot	Nerve	L-5	8	3	7	0.75	0.55

*Patient 11: The needle driver kept slipping when trying to drive the needle. The robot was removed from the table and the procedure was completed by hand (manual technique). No adverse event or complications occurred. This patient was excluded from the pain scores and accuracy analysis.

that the robot is capable of accurate needle placement.

As expected, the post-treatment pain score was significantly less than the pre-treatment pain score in both the robot and manual arms. In the robot arm, pain scores fell from a mean of 6.3 pre-treatment to a mean of 1.8 post-treatment. In the manual arm, pain scores fell from a mean of 6.0 pre-treatment to a mean of 0.9 post-treatment. Since this was just an initial trial of 20 patients total, there was not enough data for statistical significance, and we have begun additional data collection as detailed in the next section.

Next steps

The data in Table 1 was reported to the FDA and the institutional review board. Based on these results, approval was obtained to continue the trial with an additional 80 patients. The trial has just resumed recently, but there is not yet sufficient new data to report.

In the future, we would like to further automate the process of needle alignment through a technique known as fluoroscopy servoing [9]. This technique would involve frame grabbing the image from the fluoroscopy monitor and using it in real-time to automatically align the needle toward the target. While the target would still be chosen by the physician, the robotic system would provide further assistance in the procedure by automatically aligning the needle. There would not be any additional risk to the patient because the needle alignment would be verified by the physician before the needle is driven into the back.

ROBOTICALLY ASSISTED LUNG BIOPSY

The spinal nerve block trial described in the last section was carried out under x-ray fluoroscopy, which provides a two-dimensional view of the anatomy. While fluoroscopy is a common imaging modality for minimally invasive procedures, there are also procedures that often use CT. A CT scan provides a three-dimensional view of the anatomy, which is typically presented to the physician as a series of axial 2D images. In recent years, CT scanners have become much faster, and now a whole chest scan can be done during a single breath hold. CT fluoroscopy has also been introduced, which combines some of the advantages of both technologies. In CT fluoroscopy, single axial images can be obtained in a continuous fashion (up to 6 frames per second on the Siemens CT scanner at Georgetown).

Lung biopsy is a typical minimally invasive procedure that often uses CT fluoroscopy. While CT fluoroscopy helps the physician visualize the target lesion and guide the biopsy needle to the lesion, the physician must be careful to minimize his exposure to the radiation source. Therefore, a robotic needle driver that could precisely hold the needle on the CT scan plane, and manipulate the needle through a joystick interface, is a possible solution to this exposure problem. We are also interested in eventually automating the entire process, so that the robotic system could track the lesion during respiration and command the needle toward the target. This section will detail our initial results in this area, starting with a discussion of lung cancer screening, proceeding with the results of a respiratory phantom study, and concluding with our plans for future work.

Lung cancer screening

The use of CT for lung cancer screening is rapidly expanding. This screening has revealed a large number of small pulmonary nodules. Most of these nodules are benign and less than 1 cm in size. They are often dismissed as clinically irrelevant, sometimes inappropriately, as some recent reports suggest that a higher portion of these nodules are malignant than previously suspected [10]. It is therefore becoming increasingly important to obtain a tissue-specific diagnosis of these small lesions.

Several methods of obtaining the tissue for histologic evaluation of these nodules are presently used, including CT-guided needle biopsy, ultrasound-guided biopsy, bronchoscopy, and video-assisted thoracoscopic surgery. Each method has its inherent advantages and disadvantages.

For example, transthoracic needle biopsy (TNB) is the procedure of choice for diagnosis of peripheral pulmonary nodules. TNB procedures are mostly performed under CT guidance. CT visualization of the biopsy needle within the lesion allows for high diagnostic yield. TNB sampling of the centrally located lesions is best performed under CT to avoid traversal of adjacent vascular structures, bronchi, or the esophagus.

However, the diagnostic accuracy of TNB is not ideal. Yankelevitz et al. state that needle misplacement probably represents the single most common cause for a false-negative biopsy. A needle trajectory

misalignment of only 3 degrees over a distance of 10 cm will result in deviation sufficient to miss a 1 cm nodule [11]. In addition, the needle bevel causes the needle to deflect as it is advanced, requiring either anticipation of the degree of deviation, or repositioning of the needle placement.

These shortcomings suggest the need for highly accurate placement of the needle tip. Moreover, CT fluoroscopy has the potential advantage of providing the real-time guidance described above. Consequently, we developed the following phantom study to address these issues.

Phantom study

The goal of this study was to evaluate the feasibility of using a joystick-controlled robotic needle driver under CT fluoroscopy to target simulated lesions in a respiratory motion phantom. The phantom is shown in Figure 4 and consists of a torso model, a rib cage, a rubber skin layer, and a synthetic lung. The lung was molded from a two-part flexible foam mix (FlexFoam II, Smooth-On, Easten, PA) using a plastic lung model. The phantom includes a one-degree-of-freedom motion platform that simulates cranial-caudal motion and can be programmed from a laptop computer.

The robot was positioned on the CT table so that the needle was aligned with the CT scan plane (Figure 5). The phantom was positioned so that the lung lesion would move in and out of the scan plane with a respiratory rate of 15 breaths per minute and an excursion of 1.5 cm. The interventional radiologist activated the CT fluoroscopy imaging mode by stepping on the foot pedal and watching the image on the in-room monitor. When the lung lesion moved into the scan plane, the respiratory motion phantom was paused for 30 seconds to simulate a breath hold, and the joystick control was used to drive the needle toward the lesion (Figure 6).

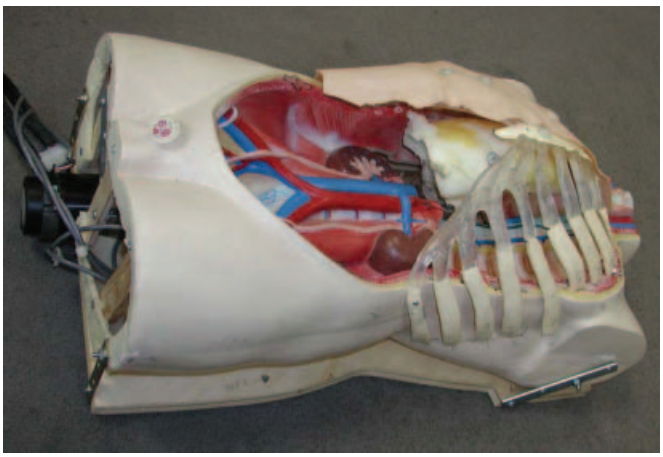

Figure 4 Respiratory motion phantom with motor at left end and lung at right end.

Figure 5 Robot, phantom, and needle on scan plane in CT fluoroscopy machine.

A total of 20 trials were done, and the radiologist was able to hit the lesion on all 20 attempts. The average time to drive the needle (after pausing the phantom) was 12.1 seconds, with a standard deviation of 3.1 seconds.

Next steps

Although we recognize that the phantom does not approach the complexity of a respiring patient, the results of this study show promise. In future work, we plan to develop software to automatically track

Figure 6 Physician watching in-room monitor and controlling robot through the joystick interface.

the lesion and drive the needle. The phantom study will then be repeated. Swine animal studies are also planned before approval for any clinical trial will be sought.

COMMERCIAL PROTOTYPE

In June of 2002 a new company, ImageGuide, Inc., was created to further develop the robotic system described here and enable a next generation in minimally invasive surgery. Through the real-time integration of advanced imaging systems, medical robotics and needle based therapies, a new interventional platform is under development that will ultimately support procedure planning activities and automate needle placement. The primary expected benefits include improved procedure workflow, greater accuracy, and reduced radiation exposure to clinicians and patients. The company's application focus is on minimally invasive cancer diagnosis and therapy.

The initial ImageGuide system will be integrated with CT and be aimed at soft tissue biopsy procedures. The system concept incorporates an overhead mounting system that is connected directly with the CT table as shown in Figure 7. The overhead system supports the needle holder/driver and translational positioning stages that will allow the needle tip to be placed and oriented at a desired skin entry point. Because the overhead system is connected directly to the CT table, the needle tip will travel with the patient as the table is advanced into the scanner. Once the patient and device are in the scanner, the clinician will be able to observe and control the needle trajectory during imaging. In a subsequent phase, the robotic device (and needle tip) will be registered directly with the scanner imaging coordinates to automate needle positioning and trajectory.

Figure 7 ImageGuide prototype undergoing testing with CT scanner.

The applications that are envisioned include ablation therapy such as radiofrequency ablation of the liver, where needle positioning accuracy is critical in determining procedure outcomes. Through the use of volumetric modeling, lesion size and needle properties can be mapped to determine the ideal needle tip location. These coordinates can then be passed to the robotic system to assist the physician in needle placement and improve the accuracy of the procedure.

The prototype system shown here is expected to begin final verification testing by the end of 2004. Three demonstration sites have also been proposed to assist in phantom based evaluations and to document system benefits.

CONCLUSIONS

This paper has described our work over the past several years in integrating a needle driver robot into the clinical environment. Our work represents a collaboration between engineers and physicians that is essential for the field to advance. The field of medical robotics is still evolving. While medical robotics holds great promise for enabling precision in minimally invasive procedures, the total installed base of medical robots is currently fairly small. However, robots do have certain advantages, such as their ability to withstand ionizing radiation, that make them ideal tools to assist the physician in certain procedures. To better understand the role of these devices, we need to continue to build prototype systems and investigate clinical applications. We hope that the work presented here is a step in this direction, and that it will ultimately lead to improved patient care.

ACKNOWLEDGEMENTS

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DISCLAIMER

Under licensing agreements between ImageGuide and the Johns Hopkins University, Dr. Stoianovici, Dr. Mazilu, and Dr. Patriciu are entitled to a share of royalty received by the University on ImageGuide's sales of products embodying the technology described in this article. Under a private license agreement between Dr. Stoianovici and ImageGuide, Dr. Stoianovici and the University own ImageGuide stock, which is subject to certain restrictions under University policy. Dr. Stoianovici is a paid consultant to Image Guide and a paid member of the company's Scientific Advisory Board. Dr. Stoianovici's participation in the study was limited to technical maintenance of the robot. Dr. Stoianovici did not interact with patients and was not involved in clinical data analysis. The terms of this arrangement are being managed by the Johns Hopkins University in accordance with its conflict of interest policies. Dr. Cleary and Dr. Watson are also consultants to Image Guide and are on the scientific advisory board of the company. Dr. Taylor is on the scientific advisory board.

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