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Point-of-Care Programming for Neuromodulation: A Feasibility Study Using Remote Presence

BACKGROUND: The expansion of neuromodulation and its indications has resulted in hundreds of thousands of patients with implanted devices worldwide. Because all patients require programming, this growth has created a heavy burden on neuromodulation centers and patients. Remote point-of-care programming may provide patients with real-time access to neuromodulation expertise in their communities.

OBJECTIVE: To test the feasibility of remotely programming a neuromodulation device using a remote-presence robot and to determine the ability of an expert programmer to telementor a nonexpert in programming the device.

METHODS: A remote-presence robot (RP-7) was used for remote programming. Twenty patients were randomly assigned to either conventional programming or a robotic session. The expert remotely mentored 10 nurses with no previous experience to program the devices of patients assigned to the remote-presence sessions. Accuracy of programming, adverse events, and satisfaction scores for all participants were assessed.

RESULTS: There was no difference in the accuracy or clinical outcomes of programming between the standard and remote-presence sessions. No adverse events occurred in any session. The patients, nurses, and the expert programmer expressed high satisfaction scores with the remote-presence sessions.

CONCLUSION: This study establishes the proof-of-principle that remote programming of neuromodulation devices using telepresence and expert telementoring of an individual with no previous experience to accurately program a device is feasible. We envision a time in the future when patients with implanted devices will have real-time access to neuromodulation expertise from the comfort of their own home.

KEY WORDS: Neuromodulation, Remote presence, Robotics, Telemedicine, Telementoring

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Neuromodulation for the treatment of a rapidly expanding number of conditions has experienced an exponential growth in the past 2 decades, with hundreds of thousands of patients with implanted devices.[1-4] Spinal cord stimulation was the first neuromodulation modality extensively used for the treatment of chronic pain of neuropathic or ischemic origin.[5-7] Deep brain stimulation for movement disorders is well established[1,8,9] and is being explored for epilepsy[10,11] and psychiatric conditions such as intractable depression and obsessive-compulsive disorder.[12,13] Stimulation of the occipital nerve has been applied to the treatment of intractable occipital neuralgia and other primary headache syndromes,[14-17] and stimulation of the posterior tibial, pudendal, or sacral nerve for overactive bladder,[18,19] and may be of potential benefit in the management of fecal incontinence.[20,21]

All neuromodulation devices require programming and follow-up after implantation, and patients need to be seen at variable frequencies by clinicians experienced in programming and troubleshooting of the devices. As the indications for neuromodulation increase, the number of patients with implanted devices grows exponentially, requiring greater resources for programming and follow-up. This expansion results in a heavier

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burden on neuromodulation centers that are likely based in large urban districts and on patients who live far away from those centers. Remote point-of-care programming of neuromodulation devices makes sense because it may provide patients with implanted devices access to medical expertise in real-time in their own communities.

Advances in computer and telecommunications technology have opened the door for the development of solutions aimed at providing remote programming and follow-up of patients with implanted devices. Although increased use of Internet-based telemedicine applications has occurred in the past decade and smart cell phones, tablets, and other consumer mobile devices are progressively being used for the transmission of medical data such as laboratory reports and diagnostic imaging,[22-24] it is likely that applications such as remote programming of neuromodulation devices will require dedicated mobile medical systems capable of providing remote-presence and allowing real-time interaction with patients. Furthermore, expertise in the remote location is not needed because the expert programmer could mentor in real time a nonexpert individual in programming a device. A recent study demonstrated that nonexpert individuals can perform sophisticated diagnostic tests such as trauma ultrasound assessments with remote expert mentoring.[25]

As part of the Remote Presence Medicine Program at our institution, we have explored the feasibility of remotely programming a neuromodulation device using a remote-presence robot. Furthermore, we have examined the ability of an expert programmer to telementor a nonexpert individual in programming the device.

PATIENTS AND METHODS

Registration of Clinical Trials

This study was approved by the research ethics board of our institution, and the study is registered at http://clinicaltrials.gov (NCT01283633).

Participants

Twenty patients from our neuromodulation program signed an informed consent to participate in this study. The demographics of the patients and the type of neuromodulation device implanted are detailed in Table 1. The patients were randomly assigned to either the conventional programming session with an experienced neuromodulation programmer or the remote-presence conditions (Figure 1). Ten nurses inexperienced with neuromodulation device programming volunteered for the study and also signed an informed consent to participate in this investigation. The experienced programmer remotely mentored the nurses to program the patients assigned to the remote-presence sessions; each nurse programmed only 1 patient. A trained observer was present at all the programming sessions to ensure the safety of the patients in case of an adverse event and to record the accuracy of the programming.

Remote Presence Robot

We used the RP-7 remote-presence robot (In Touch Health Inc, Santa Barbara, California) that is controlled wirelessly by a laptop computer (control station) equipped with headphones, microphone, and a joystick to maneuver the robot in real time. The RP-7 is 165 cm in height and has a wheeled triangular base of 63 × 76 cm; its dimensions are roughly comparable to the size of a human. The robot can travel at speeds of about 3 km/h and has an 8-hour rechargeable battery (Figure 2).

The head of the RP-7 has a mobile flat-screen monitor that displays the image of the operator and a picture-in-picture window that displays the image of the person standing in front of the robot. The head of the robot is movable and fitted with 2 sophisticated digital cameras as well as audio, microphone, and amplification components, allowing for real-time 2-way audiovisual communication (Figure 1B). Connectivity between the control station and the RP-7 robot is provided by a standard 802.11 Wi-Fi Internet link.

The robot was fitted with a custom-made arm designed to hold a touch-screen programmer (N'Vision programmer; Medtronic Inc, Minneapolis, Minnesota). The arm is attached to the RP-7 robot and has shoulder and wrist joints that can be adjusted to provide optimal visualization of the N'Vision by the remote clinician (Figures 3 and 4).

The control station allows the clinician to have real-time control of the robot and visualize the remotely located N'Vision programmer, patient, and nurse (Figure 3B). The clinician operating the robot is able to telestrate using a cursor that is displayed on the robot's head monitor (Figure 4B). Telestration is important because the experienced programmer can indicate, in real time, to the nurse the buttons to touch on the screen of the N'Vision programmer. The control station is also capable of storing video and still images of the remote-presence sessions for archiving and further analysis.

Procedure

The patients were randomly assigned to either the control (no robot) or the remote-presence conditions (RP-7 robot) before the sessions. For the control condition, the clinician programmed the patient's implanted pulse generator directly using the conventional approach established in our clinic.

In the remote-presence condition, the clinician, in a separate room (but near the patient, ie, in the same building), telementored a nurse to program the patient's implanted pulse generator. The experienced programmer was in charge of the entire session and directed the nurse to perform tasks such as appropriately positioning the robot's arm or touching the buttons on the N'Vision programmer. The experienced programmer had full view of the patient, nurse, and the N'Vision touch screen at all times (Figure 3B). For both the conventional and remote-presence programming sessions, the trained observer recorded the accuracy of the remote programming performance using a checklist (see File 1, Supplemental Digital Content 1, http://links.lww.com/NEU/A507, which is a checklist to determine the accuracy of neuromodulatory device programming sessions). After each session, the patient, nurse, and experienced clinician directing the session were asked to complete a satisfaction questionnaire.

Clinician satisfaction was assessed using 6 criteria: arm setup, visual display of the session, communication with nurse, communication with patient, nurse's performance, and confidence in achieving the clinical goals of the programming session. Nurse satisfaction was assessed using 7 criteria: arm setup, visual display of the session, communication with the clinician, comfort of position (sitting/standing position with respect to the robot and the patient), clinician's performance, time of the session, and confidence in the session. Patient satisfaction was assessed using 7 criteria: visual display, communication with the clinician, absence of clinician, clinician's performance, nurse's performance, time of the session, and overall comfort. For all of the satisfaction scores, the number of questions per criterion ranged from 1 to 4, and the score for each

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TABLE 1. Demographics of Patients[a]

Patient	Age, y	Sex	Diagnosis	Target	IPG	Time From Implantation, mo
1	61	M	ET	Vim	Soletra	1.5
2	64	M	PD	STN	Kinetra	18
3	69	F	ET	Vim	Soletra	24
4	31	M	ET	Vim	Soletra	6
5	50	M	ET	Vim	Soletra	36
6	49	F	FBSS	SCS	Prime Advanced	1.5
7	70	F	FBSS	SCS	Itrel 3	3
8	53	M	PD	Vim	Kinetra	1.5
9	66	F	PD	STN	Kinetra	24
10	44	M	PD	STN	Activa RC	6
11	53	M	Cervical dystonia	Gpi	Kinetra	9
12	75	M	PD	Vim	Soletra	6
13	71	F	Sciatica	SCS	Itrel 3	12
14	59	F	ET	Vim	Soletra	1.5
15	64	M	PD	STN	Kinetra	18
16	43	F	Cervical dystonia	Gpi	Kinetra	30
17	52	F	FBSS	SCS	Itrel 3	1.5
18	51	F	FBSS	SCS	Itrel 3	12
19	69	F	ET	Vim	Soletra	6
20	50	F	FBSS	SCS	Itrel 3	24

[a]IPG, implantable pulse generator; ET, essential tremor; PD, Parkinson disease; Vim, ventrointermediate nucleus; FBSS, failed back surgery syndrome; SCS, spinal cord stimulation; STN, subthalamic nucleus; Gpi, globus pallidus internus.

criterion was obtained from the mean scores of the questions that addressed that particular criterion.

The E 5 scale to measure satisfaction developed by Ware and Hays[26] was used to assess the satisfaction of participants to the different criteria. The scale ranges from the lowest score (1), reflecting poor or very dissatisfied answers, to the highest score (5), reflecting excellent or very satisfied answers.

Accuracy Measurements and Data Analysis

To quantitatively examine the accuracy of the remote-presence neuromodulation session performance, we created a checklist containing items routinely achieved in our regular clinic neuromodulation sessions (see File 1, Supplemental Digital Content 1, http://links.lww.com/NEU/A507, which is a checklist to determine the accuracy of neuromodulatory device programming sessions). Particular emphasis was given to achieving the clinical goals of the programming session. There were 16 items in the checklist that reflected the accuracy achieved during the session. In each trial for both the control and remote-presence conditions, a trained observer was asked to record the number of checklist items that were met during that session and to record any adverse event. This number was then computed to generate a percentage value.

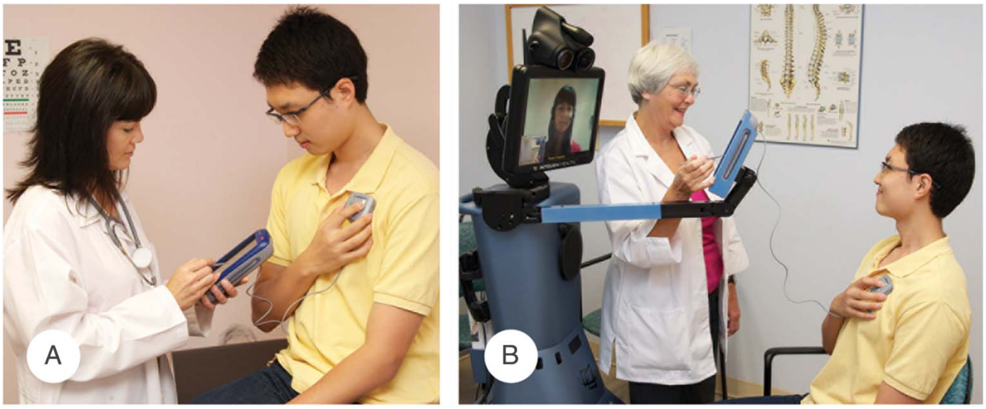

FIGURE 1. *Patients in this study were randomized to a standard direct programming session (**A**) or a remote-presence programming session using the RP-7 robot (**B**). In the remote programming session (**B**), an expert programmer clinician telementored a nurse with no previous experience in programming to program the implanted device of an patient.*

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FIGURE 2. *The RP-7 remote-presence robot was used for the remote programming session (**A**). The RP-7 is controlled wirelessly by a laptop computer (control station) equipped with headphones, microphones, and a joystick to maneuver the robot in real time (**B**). The robot was fitted with a custom-made arm designed to hold a touch-screen neurostimulator programmer (**C**; N'Vision programmer). The arm is attached to the RP-7 robot and has shoulder and wrist joints that can be adjusted to provide optimal visualization of the N'Vision by the clinician remotely programming the neuromodulation device.*

A 2-tailed independent *t* test with a .05 significance level was used to assess the statistical significance of the accuracy data. For the satisfaction measures, data interpretation involved the mean scores for the responses of each participant type (clinician, nurse, or patient) under specific criteria (different for each participant type).

RESULTS

Remote Presence Sessions

The remote-presence programming sessions were incorporated into the regular schedule of our neuromodulation clinic with no disruption to the normal clinic routine. The RP-7 robot was remotely maneuvered to the examination room by the clinician directing the session, who introduced the nurse doing the programming and the observer to the patient. All patients were programmed with no disruption of connectivity or adverse events that required the clinician to abort the session. The average time needed to program the patients was slightly shorter for the direct (26.3 minutes) than for the remote-presence (32.6 minutes) sessions. No difference in programming accuracy or achieving the clinical goals of the programming session was observed between the remote and direct conventional programming sessions (Figure 5).

Satisfaction Scores

The mean satisfaction scores for the expert clinician, nurses, and patients that participated in the study were highly consistent for the different criteria assessed. The mean scores ranged between 4 and 5 of the E 5 scale, indicating that the patients, nurses, and the expert clinician were satisfied or very satisfied with the remote-presence programming sessions (Figure 6). Additional comments on the remote-presence sessions by the participants were divided in positive and negative comments (Table 2). The negative comments by the expert clinician and nurse were mainly related to the position of the robot's arm, line of sight, and intermittent audio disruption. Interestingly, no negative comments were expressed by any of the patients.

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FIGURE 3. *A nurse without previous experience in programming is telementored, in real time, to operate the N'Vision programmer by the expert clinician (**A**). The control station screen gives the expert programmer full view of the patient, nurse, and the N'Vision touch-screen (**B**). The box on the control screen displaying the image of the expert programmer is also displayed on the head screen of the RP-7 robot.*

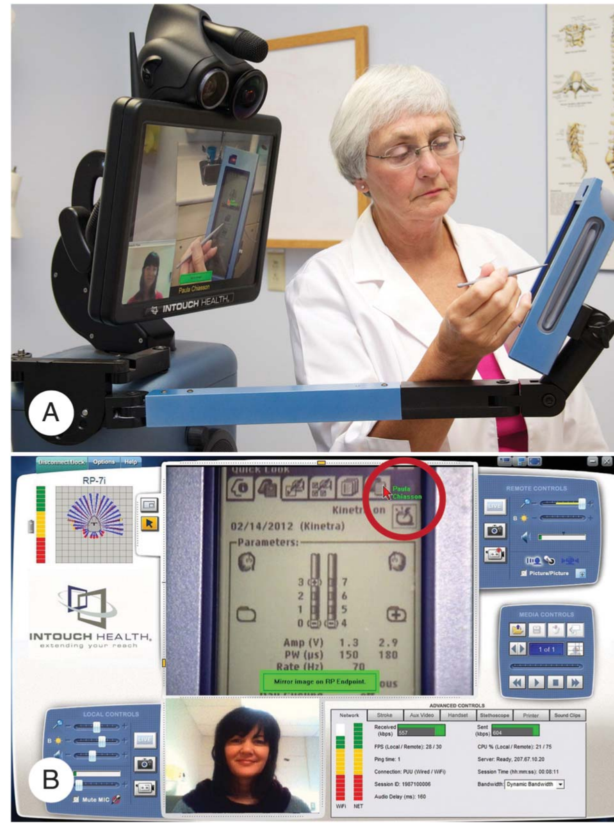

FIGURE 4. *The nurse in the remote location operates the N'Vision programmer following telestration instructions by the expert clinician telementoring the session (**A**). The control station screen (**B**) displays the touch screen of the N'Vision programmer and the telestration cursor (red circle) that is used to provide precise instructions to the nurse to operate the touch-screen controls in real time.*

DISCUSSION

This study demonstrated that remote presence can be used for point-of-care programming of neuromodulation devices. The accuracy of the programming and, in particular, achieving the clinical goals of the programming session showed no significant difference between the standard direct and remote-presence programming conditions. No adverse events occurred during the remote programming sessions. Furthermore, the patients, nurses, and the expert clinician directing and mentoring the sessions gave high satisfaction scores. A critical finding of this study is the feasibility to accurately telementor health personnel not experienced or totally inexperienced in neuromodulation programming to successfully program a device using remote presence.

Telepresence and Telementoring

Developments in remote-presence and telecommunications technology have opened the door for potential solutions addressing issues of timely access to specialized care such as patient follow-up and programming of neuromodulation devices. There is growing evidence on the use of the RP-7 remote-presence system in clinical applications and telementoring. One of the earliest applications of

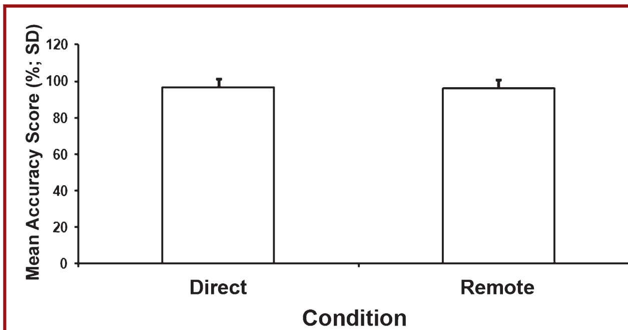

FIGURE 5. *Bar graph showing the mean (± SD) percentage of accuracy for the direct and remote-presence programming conditions. Accuracy was measured by determining the percentage of items (of 16 total items) correctly addressed during programming.*

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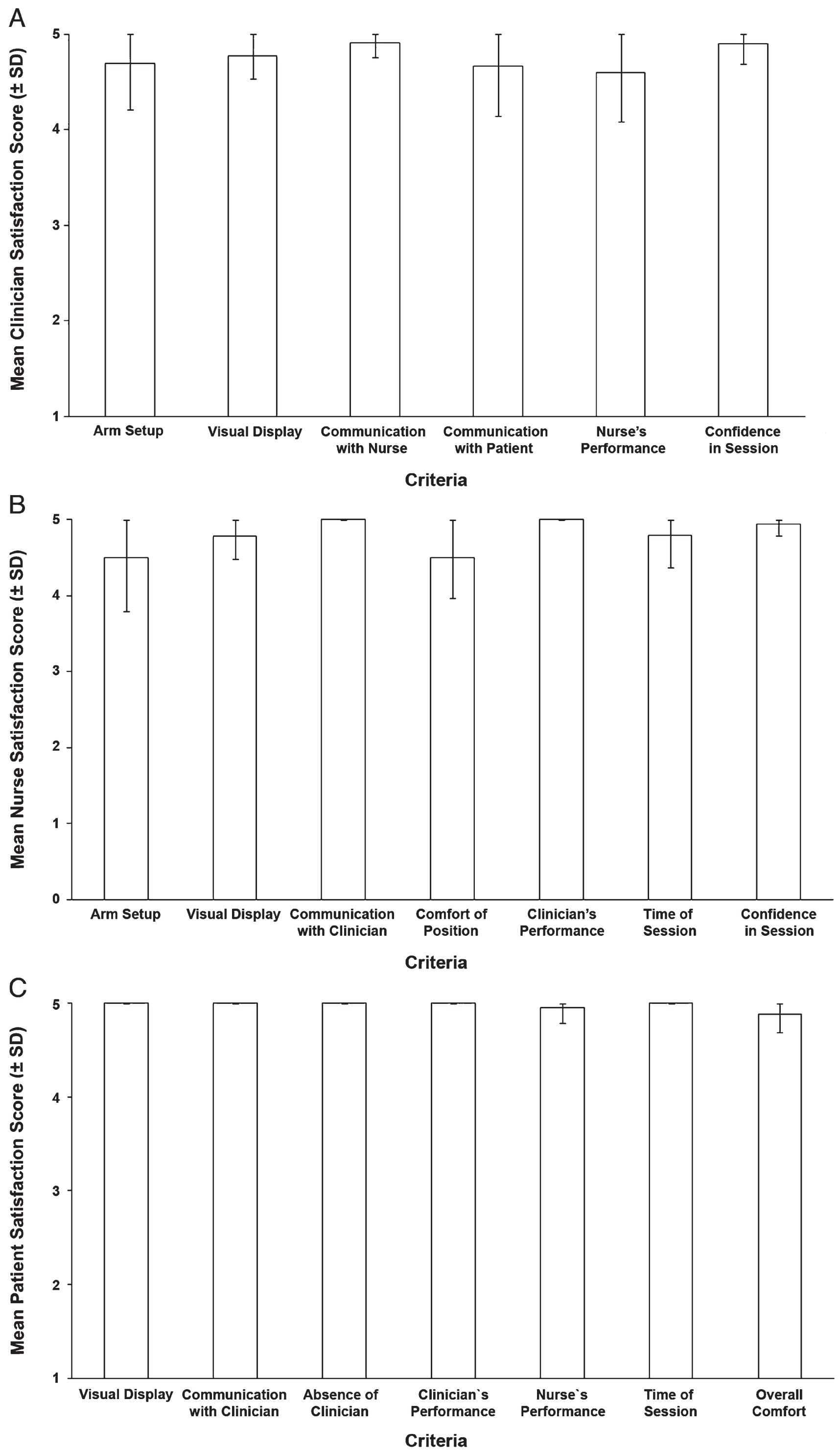

FIGURE 6. *Bar graphs representing the mean (± SD) satisfaction scores provided by clinician (**A**), nurse (**B**), and patient participants (**C**). Criteria in which the participant's satisfaction was assessed are depicted on the horizontal axes. Visual display criteria refer to the display of the session viewed by the clinician at the control station (**A**), display of the clinician and programming device viewed by the nurse (**B**), and display of the clinician viewed by the patient (**C**).*

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TABLE 2. Additional Comments Left by Participants Categorized According to Participant Type and the Tone of the Comment

Participant	Positive Comments	Negative Comments
Clinician	Facility in reading labels on patient's medication bottles	Occasional audio failure
		Occasional lack of visual clarity due to natural light
		Occasional obstruction of robot's main display by nurse's head
Nurse	Experience of minimal anxiety	Slight confusion in robotic arm setup
	Acknowledgment of usefulness of clinician's introductory instructions to familiarize with the setup	Slight awkwardness of table position between robot and patient
	Comfort of interaction with clinician and nurse	Awkwardness of standing
	Acknowledgment of the importance of the nurse's position	Occasional reduced visual clarity due to electrical light
Patient	High convenience of procedure	—
	Facility and comfort in familiarizing with robotic intermediate	

the RP-7 has been in critical care, where a persistent shortage of intensivists and increasing demands results in on-site coverage challenges.[27] Several studies have demonstrated the utility of remote presence in providing critical care coverage, resulting in decreased lengths of stay in the intensive care unit, reduced unexpected events, cost savings, and high satisfaction scores by patients, intensive care unit staff, and intensivists.[28,29] Furthermore, a recent study has showed that telepresence was viewed positively by patients and their families in the intensive care unit, and they thought that the use of the RP-7 was beneficial to their care and supported its continued use.[30] The treatment of acute ischemic stroke has also been a recent application of remote presence and is gaining momentum because thrombolytic therapy has to be administered within 4.5 hours of onset of symptoms. Remote presence expert assessment of stroke patients has been crucial in reducing time to the onset of thrombolytic therapy and improving neurological outcomes.[31-33] A cost analysis of the use of the RP-7 in perioperative follow-up of patients undergoing laparoscopic gastric bypass has also showed significant savings by decreasing the length of stay.[34]

Telepresence has also been used in surgical mentoring. The RP-7 and its earlier version, the RP-6, were used in mentoring laparoscopic surgery for adult and pediatric procedures and viewed as very useful and reliable for teaching minimally invasive surgeries.[35,36] Long-distance telementoring in laparoscopic urological procedures has also been attempted with the RP-7 system.[37] Furthermore, we previously demonstrated the feasibility of using a remote robotic telecollaboration system capable of controlling the movements of a robotic arm for long-distance telementoring of cranial and spinal surgeries.[38]

There has been a dramatic increase in the use of telemedicine applications using smart cell phones, tablets, and other consumer mobile devices.[22-24] However, dedicated remote-presence medical devices are likely to be required if their use is intended to be relied on in deciding to take immediate clinical action by a health professional in a clinical situation. This higher degree of stringency has been recognized by the US Food and Drug Administration regarding Medical Device Data Systems that clearly differentiates the handling of devices for medical display or documentation purposes from active patient monitoring.[39] The RP-7 has been designated by the US Food and Drug Administration as a class II medical device and fulfills the US Food and Drug Administration requirements for its use for active patient monitoring in clinical situations in which immediate clinical action may be required.

Remote presence systems provide an expert with the ability to telementor in real time a nonexpert individual to perform sophisticated diagnostic tests. Complex ultrasound examinations under remote guidance have been conducted aboard the International Space Station, where crew members in orbit performed thoracic, vascular, and echocardiographic examinations under the guidance of an Earth-based expert.[40] A recent study showed the feasibility to telementor paramedics with no previous experience in ultrasonography to perform trauma ultrasound assessments with great accuracy.[25] In our study, 10 nurses with no previous experience in programming neuromodulation devices were able to accurately program the devices of 10 patients guided remotely by an expert programmer. Furthermore, no adverse events were recorded, and patients reported high satisfaction scores of the sessions. These results constitute the proof-of-principle that a nonexpert individual can reliably program a neuromodulation device under the remote-presence guidance of an expert. Although the sessions were conducted with the participants located in the same building, the RP-7 robot can work in any geographical location that has access to standard 802.11 Wi-Fi Internet link. We have used the RP-7 robot for neurosurgical consultations thousands of kilometers away from our center.

Potential Barriers for Remote Neuromodulation Programming

Potential barriers for the implementation of remote-presence point-of-care neuromodulation programming would not likely be technological. The rapid advances in telecommunications, robotics, and mobile device development provides a solid technological

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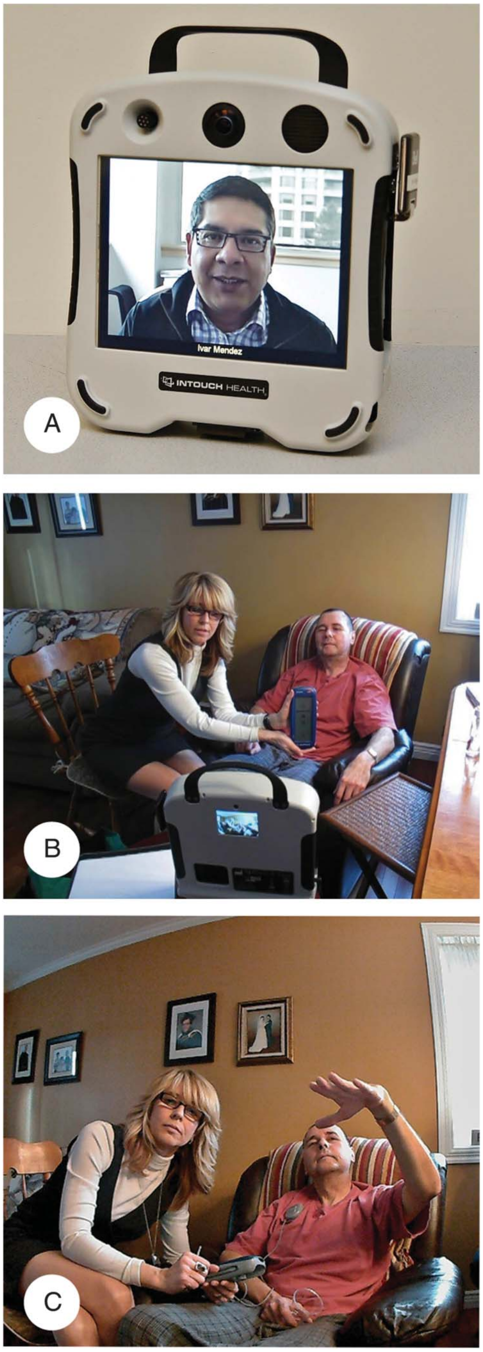

FIGURE 7. **A**, *the mobile remote-presence device, RP-Xpress, can be used for home programming of neuromodulation devices using existing local 3G cell phone networks for remote-presence transmission (***A***). A patient with an implanted neuromodulation device (deep brain stimulation for tremor control) is being programmed from our center in Halifax in his home located 1485 km away using the RP-Xpress (***B***). Snapshot of the RP-Xpress control station screen showing the results of the programming to control his left hand tremor (***C***).*

platform for point-of-care neuromodulation programming The barriers are likely to be related to issues pertaining to medical liability, jurisdictional legal considerations, provider remuneration, perceived costs of remote-presence equipment, data and patient confidentiality, competing health priorities, and lack of regional and national strategies and standards for implementation of telemedicine applications. A recent study examining barriers to implementation of robotic telemedicine has determined that the top tier barriers for adoption of telemedicine solutions in emergency and critical care medicine are regulatory barriers for physician privileges, financial barriers for billing of remote-presence services, and resistance to change established clinical paradigms for the use of telemedicine.[41] However, the explosive increase in the use of consumer mobile devices for medical applications and the decrease in the cost of the devices may force the streamlining of regulatory and remuneration issues. Although the costs of emerging technology such as the RP-7 is initially high, the RP-7 cost is approximately US$145 000, it will decrease substantially as the adoption of the technology increases. In contrast, the cost of the telecommunications is relatively minor because the RP-7 uses a standard 802.11 Wi-Fi Internet link. The cost for the remote-presence sessions was US $25 for the duration of the study.

Public expectations and pressure for cost-effective and decentralized health care provision may play a significant role in removing cultural barriers to remote-presence medicine. The acceptance by patients and their families of remote-presence solutions for health care delivery is quite favorable.[30] The health care industry is lagging behind the banking and airline industries in the implementation of decentralized consumer-center solutions that remove barriers of time and distance.

The rapid expansion of neuromodulation worldwide is likely to create an increased economic burden on the institutions that offer those programs. As the number of patients requiring programming and follow-up increases, the strain on institutional resources will increase proportionally with potential adverse consequences on timely response to the troubleshooting of devices and managing complications and emergencies in patients with implanted devices.[42] Remote point-of-care programming solutions for neuromodulation patients could provide the patient with timely and effective access to medical expertise. Neuromodulation programs are likely based in large urban centers so the use of remote-presence devices in peripheral centers makes sense because patients can be programmed and followed in their own communities; this may be clinically effective and help reduce costs for both the patient and the institution.

Future Directions and Conclusions

This study has established the feasibility of point-of-care programming of neuromodulation devices using a remote-presence system. Furthermore, we have shown that an expert can telementor a nurse with no experience in programming to accurately program a device. Although this study was conducted in the hospital setting,

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the use of portable devices that could be used to program patients in their own homes is on the horizon.

We have started a pilot study using a novel mobile remote-presence device called the RP-Xpress (In Touch Health Inc) to perform long-distance home visits for postoperative follow-up and programming of devices in patients who live more than 1000 km away from our center in Halifax (Figure 7). The RP-Xpress uses existing local 3G cell phone networks for remote-presence transmission. The use of cell phone networks for point-of-care neuromodulation programming will have a significant impact on the ability to program and follow-up with patients with neuromodulation devices in any geographic location that has cell phone signal coverage. Cellular phone networks have grown exponentially in the world. The latest survey by the International Communication Union indicates that by 2011, 90% of the world's population was covered by mobile cellular signal and that the number of mobile cell phone subscriptions was approaching 6 billion.[43] Mobile broadband continues to increase with 4G connectivity rapidly becoming the norm. In the future, remote-presence systems will incorporate in their hardware and software programming capabilities for neuromodulation devices. With such systems, the expert programmer will be able to directly interact with the neuromodulation device and the patient without additional human intervention. We envision a time, in the near future, when patients with implanted neuromodulation devices will have real-time access to an expert clinician from the comfort of their own home.

Disclosure

The authors have no personal financial or institutional interest in any of the drugs, materials, or devices described in this article.

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COMMENTS

The authors report on their findings of a feasibility study of remotely programming neuromodulation devices in patients using the RP-7 remote-presence robot. The report is timely given the rapid expansion of virtual medical care. They found high provider and patient satisfaction with the robotic programming and excellent accuracy of the programming. The application of virtual medical care in the intensive care units, telestroke programs, and rural medical clinics has been shown to be very effective.[1] The potential benefits of such technology for patients is clear. The authors correctly point out that major barriers still exist revolving around medicolegal risk, reimbursement, and regulatory hurdles. However, these obstructions should not dissuade physicians and other providers from continuing to develop technologically advanced opportunities for enhanced and more efficient medical care for patients across the globe.

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The numbers of patients fitted with neuromodulation devices is increasing. These devices and patients need to be tended to. We often talk about the burden of the disease but perhaps not enough about the burden of therapy. Often due to changes in tissue impedances, neuromodulation devices do need to be reprogrammed from time to time. Access to skilled programmers can be restricted, by geography, suitable transport availability and patient's health. Improving access through technological improvements is 1 part, but we still need the human interaction with the expert. This feasibility study shows that for current technology, this can be achieved by combining the remote presence of the expert with an untrained health worker and patient linked via a high-resolution 2-way video-conferencing device "robot."

The future may well be that the device companies incorporate technology that allows more direct remote interaction between expert and patient without the need for a third party.

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