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Integration of New Technology for Research in the Emergency Department: Feasibility of Deploying a Robotic Assessment Tool for Mild Traumatic Brain Injury Evaluation

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ABSTRACT The objective of this paper is to demonstrate the effective deployment of a robotic assessment tool for the evaluation of mild traumatic brain injury (mTBI) patients in a busy, resource-constrained, urban emergency department (ED). *Methods:* Functional integration of new robotic technology for research in the ED presented several obstacles that required a multidisciplinary approach, including participation from electrical and computer engineers, emergency medicine clinicians, and clinical operations staff of the hospital. Our team addressed many challenges in deployment of this advanced technology including: 1) adapting the investigational device for the unique clinical environment; 2) acquisition and maintenance of appropriate testing space for point-of-care assessment; and 3) dedicated technical support and upkeep of the device. Upon successful placement of the robotic device in the ED, the clinical study required screening of all patients presenting to the ED with complaints of head injury. Eligible patients were enrolled and tested using a robot-assisted test battery. Three weeks after the injury, patients were contacted to complete follow-up assessments. *Results:* Adapting the existing technology to meet anticipated physical constraints of the ED was performed by engineering a mobile platform. Due to the large footprint of the device, it was frequently moved before ultimately being fully integrated into the ED. Over 14 months, 1423 patients were screened. Twenty-eight patients could not be enrolled because the device was unavailable due to operations limitations. Technical problems with the device resulted in failure to include 20 patients. A total of 66 mTBI patients were enrolled and 42 of them completed both robot-assisted testing and follow-up assessment. Successful completion of screening and enrollment demonstrated that the challenges associated with integration of investigational devices into the ED can be effectively addressed through a collaborative patient-oriented research model. *Conclusion:* Effective deployment and use of new robotic technology for research in an urban academic ED required significant planning, coordination, and collaboration with key personnel from multiple disciplines. *Clinical Impact:* A pilot clinical study on mTBI patients using the robotic device provided useful data without disrupting the ED workflow. Integration of this technology into the ED serves as an important step toward pursing active clinical research in an acute care setting.

INDEX TERMS Clinical engineering, emergency department, neurological assessment, technology integration.

I. INTRODUCTION

The Emergency Department (ED) is an integral clinical care environment within the greater health care system. In 2010, 43 per 100 US population accessed health care via the ED; US EDs provide care for approximately 130 million patient-visits per year [1]. The ED is a busy,

complex clinical environment that benefits from implementation of advanced technology that enhances clinical efficiency and effectiveness. The expansive breadth of diseases managed in the ED, the frequent time-dependent nature of the care administered, and the increasing patient volumes seen in many hospitals and EDs create obstacles to environment-specific testing and integration of advanced patient-care technology. However, advancement of care practices require exploration and research into new technologies that are infrequently designed with consideration of the patient, clinical provider, and the physical environment that are all quite unique to the ED setting.

Of the estimated 1.7 million TBIs occurring in the US every year, approximately 80% of them present to an ED [2]. The vast majority of these TBI cases (∼85%) are classified as ''mild'' [3]. Patients with mild traumatic brain injury (mTBI) require careful neurologic evaluation to identify potentially important yet often subtle clinical findings. Despite the frequency of mTBI patients presenting to the ED, there exists several widely reported challenges in care from diagnosis, management, to prognostication of mTBI [4], [5].

The descriptive title ''mild'' is misleading as these patients are at risk for precipitous neurological deterioration with potentially devastating consequences [6]; more frequently however, they experience debilitating long-term complications characterized by Post Concussive Syndrome (PCS). Indeed, up to 50% of all mTBI patients have PCS 1 month after the injury and up to one-third of all mTBI patients are functionally impaired at three months post-injury [7]. Emergency physicians currently rely on a focused clinical exam and targeted non-contrasted Head Computed Tomography (HCT) for risk stratification of the mTBI patient. However, HCT findings do not accurately predict long-term sequelae in this widely heterogeneous population [8], [9]. Thus, current clinical practice and applied technologies function only to identify structural abnormalities and important threats to life, while reliable techniques to identify the larger number of patients at risk of suffering long-term debilitating sequelae are neglected.

Risk-stratification and triage of follow-up care of mTBI patients represents an important opportunity to improve patient safety and stream-line care by appropriate resource utilization with resulting cost-savings potential to an overextended healthcare system [10]. Furthermore, accurate and early identification of the cohort at high risk for subsequent PCS would facilitate targeted follow-up efforts, permit appropriate resource utilization, and identify an appropriate cohort for future therapeutic intervention research. Thus, there exists a profound need to develop and deploy objective methods that can guide these complex clinical decisions. We believe that the answer to this problem is most effectively addressed through the implementation of technologically advanced engineering solutions (such as a robotic assessment platform) in the ED. However, these technologies may be seen as too large, complex, and disruptive of the necessary clinical workflow in the ED. This paper will map many of the universal obstacles and solutions born of experience directly related to the ED application of advanced robotic technology for predicting neurologic sequelae among mTBI patients.

II. BACKGROUND

The Kinesiological Instrument for Normal and Altered Reaching Movement (KINARM^{TM}), developed by BKIN Technologies (Kingston, ON, Canada), is a clinical research tool that can quantitatively assess sensory, motor, and cognitive performance. It includes experimental data acquisition and control software to manage subject records, run neurological tests, perform analysis, and generate reports. The software delivers the ability to run standardized tests (KINARM Standard Tests^{TM}) as well as custom neurological tests.

The KINARM device was first developed and used for studying sensorimotor control using non-human primates [11]. With several design changes and advancements over the last decade, the device has evolved into a clinical research tool for studying neurological diseases and injuries in human subjects. Specifically, it has been widely deployed in clinical rehabilitation research to study neurological deficits as a result of stroke [12]. The technology has many favorable performance characteristics that suggested that it might perform well if adapted to function in a busy, urban ED. We proposed that, (1) this type of technology will ultimately improve clinician efficiency as the robotic assessment may be performed without the clinician at the bedside – thus freeing them to care for other patients, (2) assessment will be more detailed as multiple domains of neurologic function may be objectively and reliably assessed, and (3) due to the precision of the measurements, the device may be able to identify phenotype of patients at risk of PCS.

The KINARM device has not previously been deployed in an ED. Here, we detail our successful deployment of this device for active clinical research in an urban ED. We believe that the report of our experience will (1) encourage exploration of highly sophisticated technological solutions with applications appropriate for the ED to improve TBI care, (2) serve as a model for collaborative patient-oriented research in the ED, and (3) identify barriers and solutions to challenges that we believe are universal to busy, urban ED deployment of pre-production technological solutions.

III. METHODS

A. APPARATUS

The KINARM End-Point Robot^{TM} consists of two graspable robotic handles, a high resolution 2D virtual reality display, and a computing system (see Fig. 1).

The robotic handles provide two degrees of freedom, allowing for motion at the shoulder and elbow in a horizontal plane as well as complex mechanical environments by applying loads to the hand. A virtual reality display is created by projecting image from a flat-screen television on a semi-transparent mirror. Finally, the computing system consists of (1) a real-time computer to interface with and control the

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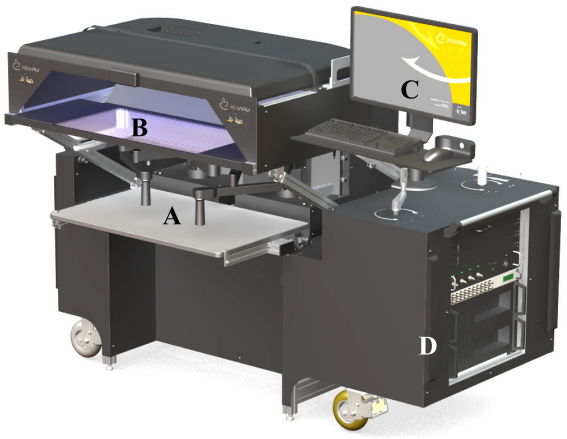


FIGURE 1. **KINARM robotic device in fully expanded/assessment state (Image Courtesy: BKIN Technologies Inc): A. Robotic handles; B. Virtual reality display; C. Operator monitor; D. Computing system.**

robots and collect analog data and (2) an operator monitor and computer for user interface purposes.

B. MULTIDISCIPLINARY INVESTIGATION MODEL FOR ED-BASED RESEARCH

The KINARM device was deployed into our urban, level I trauma center that cares from over 90,000 patients per year. There are a total of 52 ED beds (includes 14 fast track patient-care rooms) as well as a 16-bed Clinical Decision Unit (CDU). The ED is staffed with academic emergency physicians, emergency medicine residents, advanced practice providers, as well as residents from other specialties. The ED, as with most urban trauma centers, is operating under marked resource constraints specifically, physical space and support staff. Integrating and conducting research activities without hindering patient care and workflow of the ED requires dedicated support and planning at various levels of ED operation, and demands partnership and cooperation between all stakeholders. To this end, academic medical centers provide unique opportunities and support for collaboration across various clinical and non-clinical disciplines in order to facilitate active patient-oriented research. In the context of neurological diseases, such interdisciplinary collaborations are particularly important for developing and testing new neurotechnologies, and eventually translating them to clinical tools that may optimize diagnosis and treatment of neurological diseases [13].

We conducted a multidisciplinary investigation of an ED-based patient-oriented point-of-care (POC) technology. First, as shown in Fig. 2, departmental support is central to coordination of research activities in the ED as well as creating sustainable relationships between investigators and relevant ED entities. It is important to note that patient care and clinical research in the ED are viewed as separate organizational elements. Second, the clinical scientists involved in both patient-care and research play a vital role in interfacing non-clinical investigators to the ED. As a case in point, our research team consisted of two emergency medicine clinicians, two electrical/computer engineers, and two basic scientists. Together, the team is working towards developing new methods that could provide clinically relevant information regarding prognosis and recovery of mTBI patients.

C. REQUIREMENTS GATHERING AND DEVICE ACQUISITION

The KINARM platform had been designed and utilized in a clinical research environment for testing of rehabilitation patients and therefore the technology as set up would not accommodate the unique requirements of the ED setting. The first and foremost challenge, even before acquiring the device, was to ensure that the dimensions of the device met the general requirements of hospital building operations. In a typical hospital setting, 34-inch doors are to be expected, but the original KINARM design required a width of 48 inches. Furthermore, the device, as engineered,

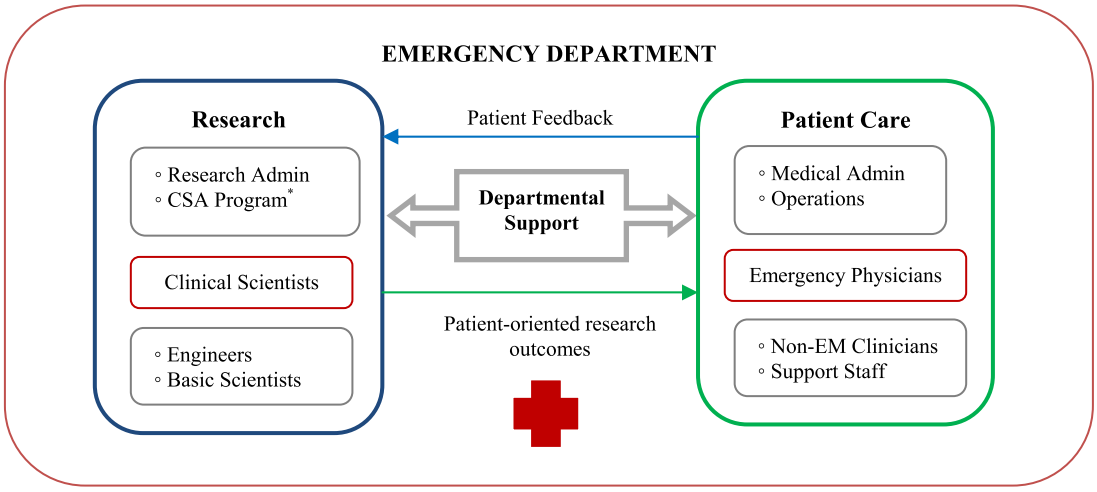


FIGURE 2. **Multidisciplinary Model for ED-based research (*Clinical Studies Assistant Program).**

was immobile, weighed approximately 800 pounds, and had multiple pieces requiring assembly/disassembly with every relocation. These engineering limitations undermine the capability of using this device in a point-of-care setting such as the ED. Therefore, the investigator team developed custom engineering requirements and worked closely with the technology provider to redesign the platform that would make the device a single assembly unit that can be mobile for practical applications such as fitting through typical hospital doorways. Through thoughtful collaboration with the company (BKIN Technologies Inc), a new "rollable" design of the KINARM that addressed minimum ED requirements was engineered. The key innovations of the new design include (1) a single self-contained unit with integrated computing resources and operator monitor, (2) a collapsible display system: Suspended by four hydraulic lifts, the virtual reality display system can be raised up (when the device is not in use) to slim the device dimensions down to a width no bigger than a hospital gurney, and (3) a pneumatic lift system that can transition the device from being on wheels to being firmly planted for operation with feet on the floor. Thus, in the "transport" mode, the display can be collapsed and the feet can be lifted so that the device is entirely on wheels. The collapsed and expanded states of the device are shown in Fig. 1 and Fig. 3 respectively. While the custom engineering of the rollable design was done by the manufacturers, it is important to note that careful assessment of research-specific needs and providing clear requirements were instrumental to efficient pre-production prototyping, and provided insights on possible ways to incorporate the technology into the ED setting.

FIGURE 3. KINARM robotic device in collapsed state (Image Courtesy: BKIN Technologies Inc).

D. ROBOT-ASSISTED EVALUATION OF mTBI IN THE ED

Upon successful integration of the device into the ED (as described in Section IV), all patients with mTBI satisfying the following enrollment criteria were screened for assessment: (1) age greater than or equal to 18 years, (2) blunt head trauma and diagnosis of mTBI within 24 hours of injury by the treating physician, (3) blood alcohol level of < 100 mg/dl, and (4) ability to give written informed consent. Patients with focal neurologic deficits or other comorbidities such as upper-limb pain or injuries that might interfere with robotic testing were excluded. During their ED stay, eligible patients were enrolled and their neurologic function was assessed (prior to ED discharge) using the following five tasks on the robotic device. Each of these tasks is briefly explained in order to highlight the technological capability of the device in quantitative assessment of neuromotor performance as compared to standard neurologic exam in the ED.

- *Upper-limb matching task:* In this task, one handle (end-point) of robot passively moves one limb and then the subject is instructed to move their other limb to the mirror-matched spatial position. This task quantifies the limb position sense component of proprioception [12].
- *Visually-guided reaching task:* This task requires the subject to make reaching movements from a central target to one of the eight targets located on the periphery of a virtual circle (Fig. 4). Parameters measured include reaction time and several movement parameters that characterize direction and accuracy of movement towards the target [14].

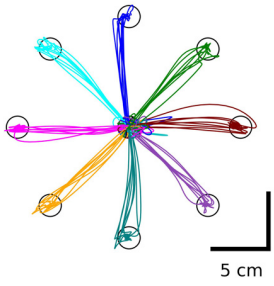
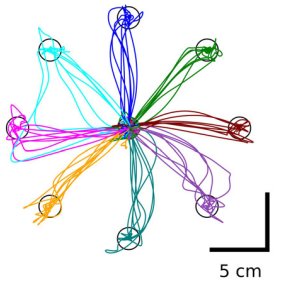
Visually-guided reaching performance of a 20-year old female mTBI patient, obtained in the ED within 24 hours of injury. This patient did not develop PCS at 3-week follow up.	
Visually-guided reaching performance of a 22-year old female mTBI patient, obtained in the ED within 24 hours of injury. This patient did have PCS at 3-week follow up.	

FIGURE 4. KINARM Performance on Visually-guided reaching task of two similar mTBI patients. The patient on the top had no sequelae at 3-week follow up, and the patient on the bottom had PCS at 3 weeks.

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- *Object-hit task:* Virtual circular objects move in the horizontal plane towards the subject and the subject is instructed to hit all of the objects using virtual paddles attached to each end-point of the device. The speed and number of objects presented gradually increase with time. This task quantifies asymmetries in spatial awareness, the use of vision for action, and asymmetries in coordination of the two limbs.
- *Advanced object-hit task:* This is a variant of the object-hit task in which differently shaped objects are randomly dropped from the top of the screen. Subjects are required to remember and hit only certain 'target' shapes and avoid other 'distractor' shapes thus creating greater cognitive load on the subject.
- *Trail-making task:* This is a computerized version of the standardized trail-making task that requires alpha-numeric sequencing and is known to be valuable as a measure of frontal lobe function [15]. In this version, the device provides added capability for quantitative assessment of errors and performance changes as the task progresses.

In addition to providing a measure of a subject's performance, the task parameters can be compared to normative control group results that are based on large data sets collected from healthy control subjects. These normative comparisons account for age, gender, and/or handedness effects and are included as a part of the test battery license. Enrolled mTBI subjects completed robotic testing at baseline (within 24 hours of injury) while in the ED. The total testing time was no more than 40 minutes. Subjects were contacted three weeks later, and asked to complete the Rivermead Postconcussion Symptoms Questionnaire (RPQ) to assess presence of PCS [16]. PCS was considered present if the subject reported three or more symptoms in the RPQ as worse than pre-injury [17]. The study was reviewed and approved by the University of Cincinnati Institutional Review Board (IRB) prior to the start of the enrollment.

E. RESEARCH ADMINISTRATION AND PERSONNEL TRAINING

An integral part of the research infrastructure in the ED is the Clinical Studies Assistant (CSA) program [18] (see Fig. 2). The CSA program consists of 10-15 research assistants who work in the ED to screen patients for potential enrollment in various clinical trials and assist with various research activities. At any given time, at least two CSAs are on-duty and work under the supervision of the ED physicians while screening patients. The research administration, in consultation with the principal investigators, prioritizes various studies and allows preemption of certain high priority trials, in the event of conflicts during the screening process.

In this study, CSAs were responsible for subject identification, consenting eligible patients for the study. In addition, the CSAs were asked to contact an on-call investigator to administer the testing on the robotic device; however, as the study progressed the CSAs were formally trained in operating the device and administering the entire testing protocol.

Training and involving CSAs in the entire process was critical to our study for several reasons. First, the availability of staff dedicated only to ED-based studies at all times enabled continuous screening of patients. Second, having the CSAs perform the testing allowed the engineers to assess the performance and reliability of the device from the perspective of a human-machine interaction. Finally, it also helped in maintenance and upkeep of both the operating protocol and the device itself.

IV. RESULTS

A. DEVICE INTEGRATION INTO THE ED

On January 22, 2013, the device was delivered to the ED of University of Cincinnati Medical Center (UCMC), an urban, level 1 trauma center. Assembly, coordination, placement and operation of the device was successful due to participation from electrical/computer engineers, emergency medicine clinicians, and clinical operations staff of the hospital. Despite the newly transportable nature of the device, the size was an immediate obstacle to fluid implementation: it measures 74'' × 48'' × 53'' (L × W × H) in its fully expanded state and weighs approximately 800 lbs. Due to its large footprint and requirement for an appropriate testing environment (example, minimization of distracting stimulation), the device was relocated several times before a permanent housing solution was realized. Following assembly and internal facilities and regulatory clearance, the device was first moved into a dedicated research lab but owing to space constraints, the device was then moved into clinical area of the ED. However, the device was frequently moved to storage space when patient volume was high. As a result, it was observed that eligible patients were being identified but were unable to be enrolled because the device was unavailable. Through collaboration with departmental physician and nursing leadership, the device was ultimately located in a non-patient care area within the ED. Most recently, the device has dedicated space for testing in an ante-room adjacent to the treatment pods of the ED.

B. ACTIVE mTBI CLINICAL RESEARCH

Patient enrollment began March 2013 and ended April 2014. During the study period, 1423 patients were screened, 28 patients could not be enrolled because the device was unavailable due to operations limitations such as temporary lack of appropriate space to test the subject; this was solved by negotiating new space with clinical operations and successfully moving the device to current dedicated location. Twenty patients could not be enrolled because of technical problems with the device (see Fig. 5).

A total of 66 mTBI subjects were enrolled. Six of these patients withdrew from the study after consent, three of which were attributed to patients changing their minds because of problems with the device. Out of the 60 patients who

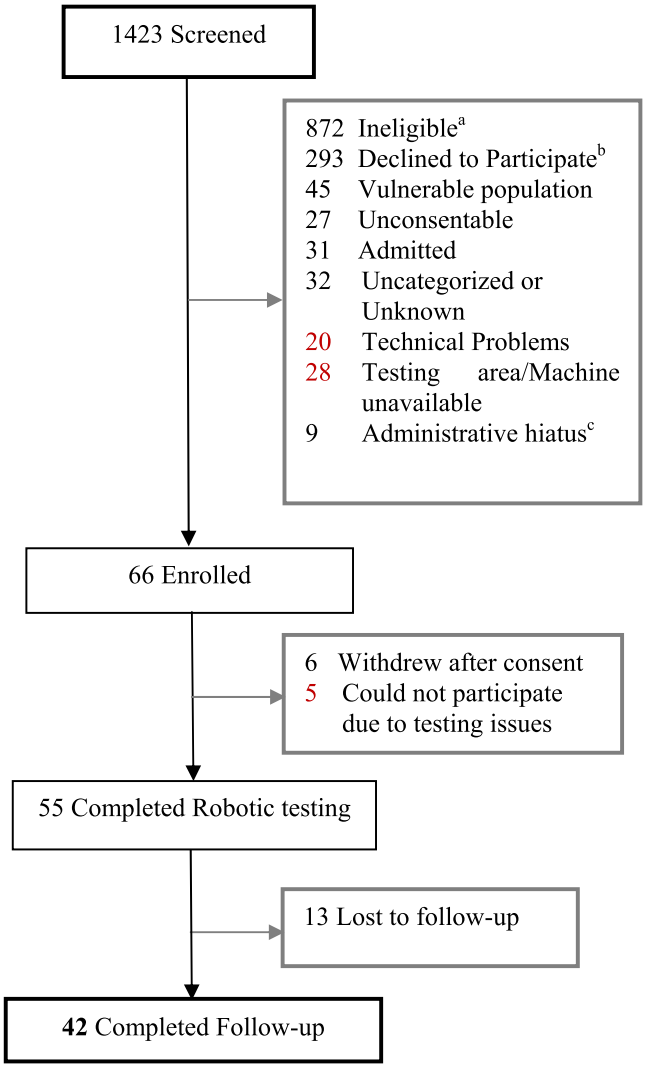

FIGURE 5. Flow of Study Participants in the pilot mTBI Robotic Assessment Study
[a]Did not meet inclusion and exclusion criteria (see Section III. D)
[b]Reasons for declining participation: no interest in the research study, the patient wanted to rest (if under observation), or the patient did not want to stay longer (if discharge was approved).
[c]Enrollment was temporarily stopped to allow for budget re-assessment.

remained in the study, five subjects could not complete robotic testing entirely due to mechanical/electrical problems with the device. Overall, 42 patients underwent robot-assisted neurologic testing and completed follow-up questionnaires, three weeks post injury.

There were nine instances of device malfunction due to the following: one electronic hardware failure, two software-related problems, one mechanical problem, one human error, and four unknown/multiple issues. The majority of the problems were minor and resolved within 48 hours. Only one problem required major repair and part replacement, and resulted in a 12-day downtime. This was due to the failure of the motion controller card that controls the motors driving the robotic arms. Downtime during enrollment is described in Fig. 6.

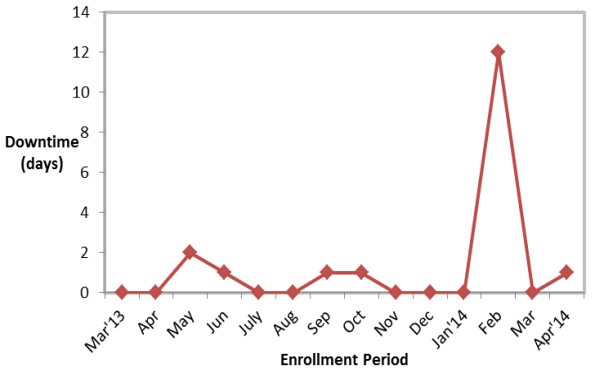

FIGURE 6. Downtime (days per month) due to device malfunction/repair during the enrollment period (March 2013 to April 2014).

V. DISCUSSION

Here, we present a comprehensive list of barriers, solutions, and lessons learned from deployment of the KINARM device in the ED. These obstacles are likely to be encountered by any implementation of new disease-specific technology and hence, we believe the solutions presented are generalizable.

- *Technology maintenance:* Experimental robotic devices and other engineering solutions deployed into clinical research require constant technical support at various levels, starting from requirements gathering through integration and maintenance. This can be solved by collaborating with engineering researchers. In the event of device malfunction or failure during the study, engineers in the investigation team play an important role in troubleshooting and repairing the device in a timely manner. They also serve as liaisons between the technology providers and clinical investigators. In systems that are heavily dependent on software for data acquisition, as in the KINARM device, it is highly critical that software updates are closely monitored and upgrades are performed only at logical points during the study period in order to preserve data integrity. To this end, engineers enabled smooth transition of data during upgrade and maintenance checkpoints.
- *Collection of supplemental baseline information:* Investigational device research often involves high start-up costs as a result of capital equipment purchase and resources needed to support the upkeep of the device while the investigators explore its clinical utility. It is therefore important to collect relevant supplemental baseline information from patients to allow for parallel (or future) observational clinical studies, targeting the same patient population. Besides time and cost savings, linking disease-specific observational studies to investigational devices research may improve the understanding of the underlying pathophysiological mechanisms. In our pilot mTBI study, blood samples were collected from the patients, providing an opportunity to explore biomarkers that may be useful for predicting outcomes in these patients.

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- *Continuous screening of study subjects:* Technical problems and malfunction may result in significant downtime and interrupt the enrollment process. Enrollment was temporarily stopped when the device was down and hence, eligible patients were missed during those time periods. Ideally, even if enrollment is held back, patients should be continuously screened for reporting purposes. If there are sufficient funds for recruitment or if other observational studies such as imaging or molecular studies are linked to the same target population, then patients can be enrolled (irrespective of technical problems) for baseline and follow-up data collection. Also, the process of screening and enrollment is considerably streamlined through an established research assistance program such as the CSA program [18], in which research assistants are already trained in regulatory aspects of clinical research and are available at all times to screen all ED patients for potential inclusion in clinical studies.
- *Point-of-Care testing:* There are several organizational and operational challenges in implementing clinical testing by the patient bedside or near the point of care delivery [19]. These challenges are even more pronounced in resource-constrained settings such as the ED. Hence, it is extremely important to establish relationships with clinical operations leadership in order to plan and coordinate facility and operational needs for clinical research. The device, while on rollers, was hardly portable due to its tremendous weight and overall size, and requires at least two people to maneuver the device in a hospital setting. Therefore, it required that subjects be taken to the testing area. This is a limitation because subjects that are symptomatic are less likely to participate owing to the fact that they may not want to get up and go to the device. However, finding a dedicated testing area that is easily accessible for patients in the emergency room will resolve this issue.
- *Device standard operating procedures:* An essential part of investigational devices research is developing, deploying, and testing Standard Operating Procedures (SOPs). Device SOPs are different from clinical procedures and workflow SOPs and require continuous improvement to reflect changing processes such as software upgrade and new (unexpected) technical problems. The KINARM device SOP in our study was regularly updated and maintained through testing by multiple operators. It is worthy to note that device SOP maintenance requires considerable time commitment and attention to subtle user interface problems that might interfere with and/or prolong patient testing.

While we were able to successfully integrate the technology in the ED, it required significant efforts to find a physical space that did not interfere with clinical activities, and provided an environment that was conducive to neurocognitive evaluation. Despite several challenges, with clear multidisciplinary communication, an accepting clinical operations leadership, we have completed enrollment and follow-up as a part of our pilot clinical study on evaluating mTBI patients from the ED population. Results from the clinical study suggest that poor performance on robot-assisted tests obtained within 24 hours of mTBI may be associated with the presence of PCS, three weeks post injury [20], [21]. Our ability to complete screening and enrollment for the study and ultimately produce results that address clinical efficacy of the device is clear evidence that the challenges associated with deployment and utilization of robot-assisted technologies in the ED can be successfully overcome.

While the field of emergency medicine has implemented physically large technology into the ED, such as CT scanners, these devices serve a broad patient population. What is unique about this device is that it was exclusively used for assessment in the mTBI population. Given the heterogeneous nature of mTBI, the robotic tests may be able to predict delayed complications such as PCS and identify profiles of specific subpopulations of mTBI who may be at additional risk of developing PCS.

Furthermore, with the ability to objectively measure a wide variety of visual, motor, and cognitive functions, the technology has a much broader scope of application in the clinical assessment of neurological impairments [22]. To this end, we have demonstrated the technology to several clinicians in emergency medicine, neurology and rehabilitation medicine, sports medicine, and psychiatry, and formed new collaborations to expand KINARM-related research. In addition to providing a potentially cost-effective approach to clinical research and patient care, examining more patient groups using these advanced technologies, may result in important information for clinical research on neurological disorders as well as prove beneficial in the clinical setting [23].

VI. CONCLUSION

The KINARM device represents a potentially powerful technologically advanced engineering solution for risk-stratification of the mTBI patient. The pilot study demonstrated that the device could be deployed in this very challenging, yet wanting, clinical environment. Traditionally, investigators only require statistical test characteristics such as sensitivity, specificity, and negative and positive predictive value when evaluating a new test; however, a future production device would not only need to meet these typical performance requirements but it will need to be completely portable, largely self-sufficient (can be completed without requiring clinician supervision), affordable, require less than 10-20 minutes to complete, is intuitive after minimal instructions for all end-users (a particular challenge among those unfamiliar with computing systems) [24], [25]. To be successful, the device will need to be honed by a collaborative relationship between engineering, neuroscience, clinical investigators, clinical operations, and patient feedback.

The ability to integrate a new technology that can produce clinically relevant outcomes has been made possible

through effective collaboration between engineers, clinicians and medical operations staff. In particular, the evaluation of mTBI patients using a robot-assisted technology such as the KINARM device in a busy, resource-constrained, urban ED is feasible with few limitations. Additionally, operating procedures and research protocol for conducting studies using the device have also been developed and tested as a part of the pilot study.

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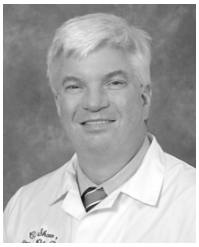

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