

## **Using Telemonitoring to optimize the mobility of cancer survivors with skeletal metastases after surgery to preserve limb function**

### **1.0 Objectives:**

The primary objective of this pilot study is to develop and evaluate the feasibility of a method that enhances surveillance in cancer survivors by using mobile devices in addition to face-to-face visits following surgery for bone metastases.

The objectives of this research protocol are:

1. To evaluate how well the face-to-face follow-up format can be adapted to using mobile devices for remote surveillance.
2. Limited efficacy testing of the remote surveillance program.
3. To obtain information on acceptability of the mobile surveillance format by patients and clinicians.

### **Specific Aims:**

There are 4 specific aims in the grant.

1. To develop customized APPS and imaging technology for mobile devices for remote surveillance of late effects and functional status of cancer survivors after surgery.
2. To evaluate how well the current face-to-face follow up visit can be adapted to the innovative remote surveillance format.
3. To perform limited efficacy testing of remote surveillance by comparing data between mobile surveillance and face-to-face visits.
4. To obtain information on acceptability of the mobile surveillance format by patients and physicians.

### **2.0 Background:**

MD Anderson provides state-of-the-art, evidence-based clinical services in cancer prevention, treatment, and survivorship to over 115,000 people per year, establishing itself as one of the nation's top cancer centers <sup>[1-3]</sup>. However, only one-third of those seen are from local areas, leaving a wide gap between its services and its reach. There were 110,135 new cases of cancer in Texas in 2012, and 476,481 cancer survivors <sup>[1-3]</sup>. Cancer care for these patients can be challenging because of the large geographic size of the state, cultural diversity, the prevalence of cancer risk factors, the paucity of insurance coverage, and a substantial population of undocumented residents, estimated at 1.8 million in 2011 <sup>[3]</sup>. There are insufficient oncologists to meet the demand for cancer care, especially in rural areas <sup>[1]</sup>. Increasing access to specialized cancer care can be accomplished using telemedicine, as has been demonstrated elsewhere <sup>[4-11]</sup>. Most of these studies have explored to use telepathology, teleradiology, and videoconferencing, for patient care receiving chemotherapy <sup>[8,10]</sup>. In contrast, telesurgery clinical trials (defined as the use of communications, robotics, and information technologies, for the delivery of surgical care over a distance) have been infrequent <sup>[4,11]</sup>. MD Anderson has the opportunity to partially address these issues by increasing its outward-directed activities using telesurgery. Whatever is learned through such efforts would likely apply nationally and internationally as well.

Most of the musculoskeletal surgery performed on cancer patients is for metastatic disease [12-14]. Patients with breast cancer, prostate cancer, renal cancer, thyroid cancer, and multiple myeloma, often develop bone metastases as the disease progresses. Recent or impending pathological fractures are frequently treated by internal stabilization using an intramedullary nail [13,15]. These are metal rods which internally reinforce and splint the bone. They fit entirely on the inside of the bone, and are fixed to the bone by screws that are placed both proximal and distal to the region of the bone whose mechanical structure is compromised by the metastasis. In 2011, 2012, and 2013 respectively, 56, 77, and 91 intramedullary fixation surgeries for long bones in the lower extremity (femur, or tibia) were performed at MD Anderson, making it one of the most frequent musculoskeletal oncology surgical procedures.

The preoperative and postoperative care for these patients is standardized. The surgical procedure is minimally invasive, performed through 3-4 small incisions, usually no larger than 3cm each. The hospital inpatient recovery is typically for 3-5 days, with regular scheduled postoperative visits at 2-3, 6-7 weeks, and 12-14 weeks from surgery. The timing of this first visit is specified so that a decision can be made as to whether the patient can proceed with additional treatment, such as radiation to the operated extremity, or chemotherapy. The key parts of this assessment include inspecting the surgical wounds for signs of infection and assessing the adequacy of soft tissue healing. In addition, the radiographic studies (x-rays) of the extremity are viewed by the physician. The time required for a surgeon to make this assessment for uncomplicated cases is typically short, averaging 5-7 minutes.

The post-operative follow-up visit utilizes standardized tools to establish patient-centered outcome data with a direct impact on the individual survivor as well as contributing to a dataset for predicting functional outcomes for all bone cancer survivors. However, only one-third of those seen are from local areas, and surveillance of persistent, late effects following surgery is suboptimal. Numerous obstacles limit both the patients' ability to attend face-to-face appointments (cost of travel, impaired mobility), and the providers' ability to collect patient-centered outcome data (clinic capacity). At our clinic, data show that approximately 30% of our patients miss an appointment in the post-operative period. A missed follow-up appointment prevents medical intervention needed to enhance survivorship and reduces data collection, which in turn, makes it difficult to accurately predict outcomes over time for future bone cancer survivors.

The use of mobile devices has the potential to improve the delivery of cost-effective, high-quality, standardized surveillance of cancer survivors. In contrast to other medical subspecialties, long-term survivorship research on post-surgical patients using mobile devices has been uncommon. This study proposes to develop and test a novel web-based mobile technology for surveillance of cancer survivors following surgery for bone metastases. The study will focus on three aspects of feasibility of the proposed new approach: adaptation, limited efficacy testing, and acceptability.<sup>84</sup> The potential economic impact includes cost savings for both patients and providers. The potential impact on survivorship care is to optimize the frequency and fidelity of outcomes research needed for the aging cancer survivor following skeletal surgery.<sup>18</sup>

The optimal surveillance system that preserves patient privacy, preserves overall fidelity, minimizes cost, and allows for requisite data quality has not yet been identified [5, 16, and 17]. In this

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study, we propose to use mobile devices to enhance the regular postoperative surveillance of cancer patients, all of whom have undergone intramedullary fixation for cancer metastases in the bone.

### **3.0 Patient Eligibility:**

Patients will be eligible to participate in this study if they:

- Have been scheduled for an Intramedullary nailing (IM) surgery with the department of Orthopaedic Oncology at UT MD Anderson Cancer Center.
- Are able to read and write English.
- Are 18 years or older.
- Are willing and able to use a smartphone or tablet comfortably.
- Have access to mobile hot spot, wireless internet, and/or cellular service.
- Must have a caregiver or assistance at home who can assist with collecting PT measures.

### **Exclusion Criteria:**

- None

### **4.0 Research Plan and Methods:**

The objectives for this protocol will be achieved in multiple steps to ensure patient safety. There are six outcome measures, including one that is completed by the patient, two by the clinician, and three assessed by the physical therapist (see **Outcomes** section below).

### **Outcomes**

Functional outcomes and quality of life will be assessed in this study via the following instruments:

1. The National Institute of Health Patient Reported Outcomes Measurement Information System for General Health (NIH PROMIS GH) <sup>87</sup> is a validated instrument widely used to assess patients' perceptions of their quality of life. The NIH PROMIS GH is completed by the patient and is composed of eight parameters that include physical functioning, physical role, bodily pain, general health perceptions, vitality, social functioning, emotional role and mental health. The physical function item bank measures self-reported capability rather than actual performance of physical activities. This includes the functioning of one's upper extremities (dexterity), lower extremities (walking or mobility), as well as instrumental activities of daily living, such as running errands. (Appendix G)
2. The Musculoskeletal Tumor Society functional score (MSTS) <sup>28</sup> is a validated instrument completed by the clinician to objectively evaluate the functional outcome of patients treated with surgery for the management of tumors of the musculoskeletal system in either the upper or lower extremity. The MSTS assigns numerical values (0-5) to six categories: in the lower extremity, pain, function, emotional acceptance, supports, walking ability, and gait pattern; and in the upper extremity, pain, function, emotional acceptance, hand positioning, manual dexterity, and lifting ability. Normal function corresponds to a score of 30. (Appendix C)

3. The Eastern Cooperative Oncology Group score (ECOG)<sup>(22)</sup> is a clinician-scored indicator of the cancer survivor's general function using categorical grades as follows: (0) fully active at pre-disease performance without restriction, (1) ambulatory and able to carry out light, non-strenuous work, (2) ambulatory, capable of self-care, up and about more than 50% of waking hours, (3) capable of limited self-care, confined to a chair or bed more than 50% of waking hours, (4) cannot perform self-care, totally confined to chair or bed, and (5) dead. (Appendix D)
4. The Timed "Up and Go" test (TUG)<sup>(23-27)</sup> is a simple test used to assess a person's mobility and requires both static and dynamic balance. The TUG is scored by a physical therapist. The survivor is asked to stand up from a standard arm chair, walk 3 meters, turn and walk back to the chair and sit. The person is expected to wear regular footwear and to use any mobility aids that they would normally require. The time in seconds is recorded for two trials and averaged. A time less than or equal to 10 seconds is normal, 11-20 seconds are within normal limits for elderly patients, and greater than 20 seconds means the person needs assistance. A score of 30 seconds or more correlates with a high fall risk. (Appendix F)
5. The Four Square Step Test (FSST)<sup>29</sup> is designed to assess dynamic standing balance and coordination by determining the person's ability to step over objects forward, sideways, and backwards. The FSST is scored by a physical therapist. The test procedure is to time the subject as they step over a four square pattern on the floor clockwise and then counterclockwise while facing forward. The better of two trials is recorded in seconds. Normal times are in the range of 17-20 seconds. (Appendix H) Note: This measure will only be used if the patient is not using an assistive device AND has been cleared in the clinic by the physical therapist to perform safely at home. Therefore, if not completed, it will not be considered a deviation
6. The Edinburg Visual Gait Score (EVGS) was originally developed as a visual gait analysis score for use in cerebral palsy patients. It is scored by a physical therapist. Videotaped sequences of patients were recorded before and after surgery as part of a three dimensional gait study. There are 17 measurements that are scored from 0-2, by observing the gait pattern recorded by video. A normal gait will have a total score of 0. (Appendix E)

All measures NIH PROMIS GH, MSTs, ECOG, EVGS, TUG, and FSST, are validated and have been used in orthopaedic oncology settings for years.

### Specific Aim 1 and 2: APP development and Feasibility Assessment

For Specific Aim 1, the mobile device APP used in this study will be developed by the collaborator (e-Health Technology Program). For objective 1 (Specific Aim 2), we will assess the feasibility of mobile device surveillance by comparing whether similar measurements are obtained using the mobile device format versus the established face-to-face format when performed during the same appointment on the same patient. A group of 10 patients who meet the inclusion criteria and have completed the informed consent process will be evaluated by the treating physician and physical therapist face-to-face at the normally scheduled clinic visits (2, 6, 12 and 24 weeks after surgery). After seeing the physician, the patient will then use a mobile device (provided to them with assistance and training from the study coordinator) while still at the clinic for outcome assessment videos. The mobile device data will be provided to independent evaluators (a physician and a

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physical therapist who are different from the physician and the physical therapist performing the face-to-face evaluation). The independent evaluators will not have a face-to-face visit with the patient and will use the video sequences to assess the same functional outcomes (MSTS, ECOG, TUG, EVGS, FSST, NIH PROMIS GH).

**For feasibility**, we are looking for inter-rater agreement on the physician assessed score (defined as less than 10% difference between MSTS scores evaluated using video v face-to-face) for a minimum number of patients (in this step, the MSTS score agreement for a minimum of 70% of the patients. If the feasibility criterion has been met, the research team will move forward to the limited efficacy testing. If feasibility criteria has not been met, the research team will identify the limitations and modify the process, enroll an additional 10 patients and repeat the feasibility assessment.

### *Specific Aim 3: Limited Efficacy Testing*

Once the adaptation of the face-to-face follow-up to the mobile format has been verified, we will move to the limited efficacy testing (Objective 2/Specific Aim 3). A group of 40 patients that fit the inclusion criteria and have completed the informed consent process will be enrolled in the study. Participants will be enrolled in either a control group (n=20) or to the mobile surveillance group (n=20). The control group will have face-to-face follow up visits with no mobile surveillance at the appropriate time points. The mobile surveillance group (n=20) will have both face-to-face visits and additional data obtained using mobile devices. Patients in both groups will complete the same set of outcome measures. These measures will be administered at the following time points, 2, 6, 12, and 24 weeks.

Patients in the mobile surveillance group will complete an assessment using a mobile device at home during the week after their scheduled clinic visit at 2, 6, 12 and 24 weeks (see **Table 1** below). The mobile device data is in addition to data gathered at face-to-face clinical appointments, thereby adding outcome data and enhancing surveillance overall. Participants in the mobile surveillance group will take videos using the mobile devices and upload the data over the encrypted network using the My MD Anderson secure email transmission. Participants will be provided with a mobile device (or tablet) that is enabled with a mobile hot spot for data transmission. For recovery of function, video sequences will be acquired by patients performing prescribed tasks that will be used to quantify functional status according to the MSTS, ECOG, TUG, EVGS, FSST, NIH PROMIS GH Score. The participant's surgical wound will also be photographed using the mobile device. Quality of Life questionnaires and PROMIS SF v1 (Appendix G) surveys will be sent to the group for completion on their mobile device via REDCap Software or thru My MD Anderson email.

To ensure patient safety, participants in the mobile surveillance group will also engage in videoconferences at the prescribed timepoints using Vidyo or Zoom. All patient communication will be documented as follow-up notes in Clinic Station by the clinician.

Table 1. Study Design		
Control Group n = 20	Mobile Surveillance Group Patients n = 20	
<b>Postoperative clinic visits</b>	<b>Postoperative clinic visits</b>	Mobile device surveillance follow up (in week after clinic visit)
<b>2 weeks</b>	<b>2 weeks</b>	2-3 weeks
<b>6 weeks</b>	<b>6 weeks</b>	6-7 weeks
<b>12 weeks</b>	<b>12 weeks</b>	12-13 weeks
<b>24 weeks</b>	<b>24 weeks</b>	24-25 weeks
<b>Measures:</b>	<b>Measures:</b>	Measures:
<b>Completion rates</b>	Completion rates	Completion rates
<b>MSTS, TUG, ECOG, EVGS, FSST, NIH PROMIS GH</b>	<b>MSTS, TUG, ECOG, EVGS, FSST, NIH PROMIS GH</b>	MSTS, TUG, ECOG, EVGS, FSST, NIH PROMIS GH + wound image + videoconference with physician to ensure safety

Specific Aim 4: Acceptability

To assess acceptability of the mobile format by patients and physicians (Objective 3/Specific Aim 4), the data collected will be used to assess:

- Patient acceptance of mobile device surveillance for data collection.
- Clinician acceptance of data collection using mobile device surveillance.
- Ability to detect relevant outcome measures, wound complication, and/or adverse postoperative.

Patients will be included in the study until 24 weeks (6 months) after surgery. Upon completion of the study, both groups of participants will complete a survey evaluating satisfaction with care and the use of the mobile devices (Appendix J). In addition, clinicians from within the department of Orthopaedic Oncology will be recruited and asked to participate in this protocol. Surgeons, physician assistants and physical therapists that have agreed to and have participated in the telemonitoring program will complete surveys (Appendix I) created by the Orthopaedic Research

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Team. Approximately, 12 clinicians will be participating in this study. These surveys were created by the research team and were adapted from a validated survey, the RAND Health Patient Satisfaction Questionnaire (PSQ). This was originally developed by Ware, et. al. (Ware, Snyder, and Wright, 1976). PSQ-18 is a short form version that retains many characteristics of its full-length counterpart. The satisfaction surveys used for this study were modified from PSQ-18.

## **5.0 Informed Consent:**

Patients will be approached for participation for this study at their clinic visit. Potential subjects will be informed of their eligibility and asked if they would be interested in research participation. In the privacy of the exam room, surgeons and/or research nurse or research data coordinator will discuss all aspects of the study with potential subjects and answer any questions. Interested subjects will then be given the informed consent documents and will have enough time to read over and ask questions. Subjects will be given a copy of the informed consent and will be further instructed about the study and the elements of the consent document. The research staff and/or attending physician will be available to address any questions or concerns the subject may have. Subjects who agree to participate will sign the protocol-specific informed consent.

A research nurse, research data coordinator, or PI designee with appropriate training and experience sufficient to address issues raised by potential subjects may obtain the Informed Consent. Patients may withdraw from the study at any time. Once the patient has consented for the study, he or she will be trained on how to use the mobile device or tablet.

Once a patient has been assigned to group 2 in both the feasibility and limited efficacy phases, he/she will be trained in clinic on how to use the app for both videos and photographs by a licensed Physical Therapist. Reference guides and instruction manuals will be provided to the patient and contact information for the research team for any further assistance. The training session should take approximately 10-15 minutes per individual.

## **6.0 Statistics:**

### **Feasibility Assessment**

The feasibility assessment will consist of a group of 10 patients who meet the inclusion criteria. For feasibility, we are looking for inter-rater agreement on the physician assessed score (defined as less than 10% difference between MSTS scores evaluated using video v face-to-face) for a minimum number of patients (in this step, the MSTS score agreement for a minimum of 70% of the patients). If the feasibility criterion has been met, the research team will move forward to the limited efficacy testing. If feasibility criteria has not been met, the research team will identify the limitations and modify the process, enroll an additional 10 patients and repeat the feasibility assessment.

### **Limited Efficacy Testing**

There are two measurements for limited efficacy testing, completion rate and patient satisfaction/acceptability. Among the set of questionnaires the patients need to complete, MSTS,

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TUG, and PROMIS are considered the most important. A patient is considered having completed the follow-up assessment if the three outcomes are documented for the 2-, 6-, 12, and 24-week evaluations. We will then report the completion rates for each group for comparison.

We will report the patient satisfaction rate using patient satisfaction surveys for both the control and the study groups. When the sample size is 20, a two-sided 95% confidence interval (CI) for completion rate or satisfaction rate using the large sample normal approximation will extend at most 0.22 from the observed rate (nQuery Advisor 7.0). When the sample size in the group is 20, the 95% CI will extend 0.30 from the observed difference in rate assuming the rate is 0.50 for one group and 0.70 for the other group. The physician satisfaction rate for using mobile devices will be reported. We will also address the economic impact for using mobile devices. Repeated measures analysis may be utilized to evaluate change over time in the completion status or questionnaire scores for each method.

## **7.0 Data Management and Security:**

All patient-reported and task performance outcomes and clinical data (including videos/photos) gathered under this protocol will be stored in a password-protected database. Data will not be transferred to laptop computers that are removed from the institution. Identifiers (name, medical record number) will be collected but will be replaced by study numbers in the analytic file. The key linking these numbers will be retained in a locked file by the investigator.

Data (including videos/photos) using mobile devices or tables will be encrypted by the IT department securely transferred using MY MD Anderson secure email to the research team.

Only MDACC personnel designated by the Principal investigator will have access to study records/data. These personnel will be fully trained to maintain the confidential nature of the patient health information. Paper records will be stored in locked files inside a locked office. External storage will be password protected.

Study data will not be shared with any individuals or entities that are not involved in the study. These data will be used only for research purposes and for this research study. Study data and paper records will be destroyed after 5 years or within one year of publication.

Study data will be collected and managed using REDCap (Research Electronic Data Capture) electronic data capture tools hosted at MD Anderson. REDCap is a secure, web-based application with controlled access designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless downloads to common statistical packages; and 4) procedures for importing data from external sources. In the case of multi-center studies REDCap uses Data Access Groups (DAGs) to ensure that personnel at each institution are blinded to the data from other institutions. REDCap (<https://redcap.mdanderson.org>) is hosted on a secure server by MD Anderson Cancer Center's Department of Research Information Systems & Technology Services.



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REDCap has undergone a Governance Risk & Compliance Assessment (05/14/14) by MD Anderson's Information Security Office and found to be compliant with HIPAA, Texas Administrative Codes 202-203, University of Texas Policy 165, federal regulations outlined in 21CFR Part 11, and UTMDACC Institutional Policy #ADM0335. Those having access to the data file include the study PI and research team personnel. Users are authenticated against MDACC's Active Directory system. External collaborators are given access to projects once approved by the project sponsor. The application is accessed through Secure Socket Layer (SSL). All protected health information (PHI) will be removed from the data when it is exported from REDCap for analysis. All dates for a given patient will be shifted by a randomly generated number between 0 and 364, thus preserving the distance between dates. Dates for each patient will be shifted by a different randomly generated number. Following publication study data will be archived in REDCap.

All data (including wound images and video sequences) will be transmitted and stored using software or programs that are compliant with HIPAA, Texas Administrative Codes 202-203, University of Texas Policy 165, federal regulations outlined in 21CFR Part 11, and UTMDACC Institutional Policy #ADM0335. All functionality of the mobile device provided by PI will be restricted so that only approved applications can be accessed by the participants.

## **8.0 Human Subjects Protection:**

**Collection of Identifiers:** Identifiers (including name, medical record number and basic information, such as demographics, type of cancer and surgical procedure) will be collected by MDACC study personnel designated by the Principal Investigator, but will be replaced by study numbers in the analytic file. This information is already documented and available in the routine medical record. The key linking these numbers and all study data will be stored on password-protected computers. Study-related documents will be retained by designated study staff in locked files. Participant-identifying information will be kept confidential and will be available only to the PI and relevant study staff who have been trained to maintain patient health information.

**Training of Personnel:** Only MDACC personnel designated by the Principal Investigator will have access to study records. These personnel will be fully trained to maintain the confidential nature of the patient health information. All of the study personnel have completed the institution's research and human subjects training.

**Data Sharing:** Study data will not be shared with any individuals or entities that are not involved in the study.

## **9.0 Reporting of Adverse Events:**

This PI initiated study is a low-risk study. The participants in both groups will continue to have regular follow-up appointments as scheduled.

The following adverse events will be tracked by the PI:

- Possible postoperative complications including wound infection, wound dehiscence, thromboembolism, and hardware failure/breakage. Adverse events and complications detected via mobile device will be addressed by instructing the patients to be seen in the emergency room or clinic. In case the participant does not submit a video or pictures at the appropriate timepoints, the study coordinator will contact the participant by phone and assess for the above adverse events.
- In the event that a patient may experience an adverse event during evaluation using a mobile device (i.e. falls while performing physical therapy assessments), he/she will be directed to call 911 or present to the local hospital for treatment. The treating surgeon will be notified.

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