

**AWARD NUMBER:** W81XWH-19-2-0043

**TITLE:** STAT: Standard Therapy Plus Active Therapy to Improve Mobility, Long-Term Activity, and Quality of Life for Severely Burn-Injured Patients After Skin Graft Surgery

**PRINCIPAL INVESTIGATOR:** Soman Sen, MD

**CONTRACTING ORGANIZATION:** American Burn Association

**REPORT DATE:** October 2020

**TYPE OF REPORT:** Annual

**PREPARED FOR:** U.S. Army Medical Research and Materiel Command  
Fort Detrick, Maryland 21702-5012

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# REPORT DOCUMENTATION PAGE

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## 1. INTRODUCTION:

*This study proposes to work with participating sites (PS) to investigate the effects of a systematic and measurable rehabilitation protocol with emphasis on active components of physical therapy with severely burned patients who require skin grafting. Physical therapy is a key treatment component for severely burned patients however most rehabilitation practices are varied and do not focus on actively improving mobility, strength, conditioning and function. Additionally, many burned civilians and soldiers do not return to full work activity or full duty following a severe burn injury due to physical limitations from the burn injury. We believe implementing a systematic and measurable rehabilitation protocol (STAT) that emphasizes active therapy early in burn recovery in addition to standard therapy (ST) can improve overall outcome and return to work or active duty for burned patients. Over the next four years we propose to prove this hypothesis in the following ways:*

*Specific Aim 1: Compare the functional exercise capacity between burn patients who undergo skin grafting surgery and receive STAT rehabilitation to those who receive ST alone.*

*Specific Aim 2: Compare long-term physical activity outcomes (functional task, daily activity and gait quality) between burn patients who receive STAT rehabilitation versus ST alone.*

*Specific Aim 3: Compare Return to Work Duty and Health Related Quality of Life (HRQOL) of burn patients who receive STAT rehabilitation versus ST alone.*

*Specific Aim 4: Compare the incidence of medical and post-surgical complications between patients who receive STAT rehabilitation versus ST alone.*

## 2. KEYWORDS:

*Burn injury, Physical Therapy, Functional Outcome, Exercise, Mobilization, Activity*

3. **ACCOMPLISHMENTS:** The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.

### **What were the major goals of the project?**

*List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.*

Specific Aim 1: Compare the functional exercise capacity between burn patients who undergo skin grafting surgery and receive STAT rehabilitation to those who receive ST alone.

- **STATUS: enrollment yet to start.**

Specific Aim 2: Compare long-term physical activity outcomes (functional task, daily activity and gait quality) between burn patients who receive STAT rehabilitation versus ST alone.

- ***STATUS: enrollment yet to start.***

Specific Aim 3: Compare Return to Work Duty and Health Related Quality of Life (HRQOL) of burn patients who receive STAT rehabilitation versus ST alone.

- ***STATUS: enrollment yet to start.***

Specific Aim 4: Compare the incidence of medical and post-surgical complications between patients who receive STAT rehabilitation versus ST alone.

- ***STATUS: enrollment yet to start.***

Major Task 1: Administrative undertakings (months 1-6 and annually)

1a. Finalize study consent forms and research protocol- **completed Y1Q2.**

1b. Develop central data base - **completed Y1Q4.**

1c. Develop Case Report Forms - **completed Y1Q4.**

1d. Develop electronic collection method of data collection - **completed Y1Q4.**

1e. Finalize research contracts – **in progress, 2 of 7 complete.**

1f. Protocol regulatory review – local IRB and DoD HRPO – **in progress, lead site completed, awaiting participating site with Single IRB.**

1g. Develop standard operating procedures (SOP) manual – **completed Y1,Q4 (named MOO).**

1h. Coordinate with participating sites (PS) for annual IRB report for continuing review - **yet to start.**

Major Task 2: Establish research systems operations (months 3-7)

2a. Order and distribute study equipment – **completed for 2 of 7 sites.**

2b. Hire coordinators and research therapy staff – **completed Y1Q3.**

2c. Conduct onsite trainings (7 sites) – **completed for 1 of 7 sites.**

2d. Test data submission – **completed Y1Q4.**

Major Task 3: Data collection and analysis (months 6-45) – **yet to start**

3a. Begin subject screening and enrollment (month 6) -

3b. Begin and continue data submission (month 6)

3c. Conclude enrollment (month 32)

3d. Conclude outcome assessment and data submission (month 44)

3e. Conduct data analysis (month 45)

Major Task 4: Data reporting (months 46-48) – **yet to start**

4a. Data report organization

4b. Manuscript preparation and submission

### **What was accomplished under these goals?**

*For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project*

progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

Major Task 1: Administrative undertakings (months 1-6 and annually)

*The multi-site core protocol has been approved by UCD IRB and HRPO and the study has been entered into Clinicaltrials.gov (Identified: NCT04368117). Single IRB has been initiated and is in progress with all six participating sites. A central data base with all electronic CRFs has been established and tested with sample patients in REDCap. A subscription has been established with Fitabase data base for collection of activity data with Inspire Fitbits. Fitbit data collection has been trialed. Contracts between prime (ABA) and UCD, DCC and ISR have been executed. Contracts for the other five participating sites were drafted and have gone through multiple revisions. We anticipate that they will be executed in Y2Q1.*

Major Task 2: Establish research systems operations (months 3-7)

*Equipment has been ordered and delivered to UCD and ISR. When contracts are finalized for other site, equipment will be ordered for those sites. In person training with staff at UCD was conducted on September 30, 2020. Coordination for a virtual training (due to COVID-19) has been initiated with ISR. Data base has been tested by clinicians and statisticians.*

Major Task 3: Data collection and analysis (months 6-45)

- 3a. Begin subject screening and enrollment (month 6)
- 3b. Begin and continue data submission (month 6)
- 3c. Conclude enrollment (month 32)
- 3d. Conclude outcome assessment and data submission (month 44)
- 3e. Conduct data analysis (month 45)

*Enrollment is anticipated to start at UCD this month (October) by the time this report is received.*

Major Task 4: Data reporting (months 46-48)

- 4a. Data report organization
- 4b. Manuscript preparation and submission

Key Findings or Accomplishments for Specific Aim 1:  
Key Findings or Accomplishments for Specific Aim 2:  
Key Findings or Accomplishments for Specific Aim 3:  
Key Findings or Accomplishments for Specific Aim 4:

*Nothing to report.*

**What opportunities for training and professional development has the project provided?**

*If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training"*

activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

*Lead site clinical physical and occupational therapists have been trained in the use of new protocols and outcome tools (Ex. Gaitrite motion analysis walkway) thus allowing for opportunities of professional development. They underwent a day-long training to learn and practice study procedures and data entry. Clinical staff at each of the participating sites will also be given this opportunity through virtual training.*

**How were the results disseminated to communities of interest?**

*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.*

*Nothing to report.*

**What do you plan to do during the next reporting period to accomplish the goals?**

*If this is the final report, state "Nothing to Report."*

*Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.*

- 1) Receive Single IRB approval with UCD and secondary HRPO approval for 3-4 more participating sites.*
- 2) Begin screening and enrollment at lead site and 2-3 more participating sites.*
- 3) Order equipment and provide virtual study training for 2-3 more participating sites.*

4. **IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

**What was the impact on the development of the principal discipline(s) of the project?**

*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and*

research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

***The clinical therapy staff at the lead site (UCD) has been trained in research procedures thus improving the understanding and skill of physical and occupational therapists with integrating research into clinical workflows.***

**What was the impact on other disciplines?**

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.*

***Nothing to Report.***

**What was the impact on technology transfer?**

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:*

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

***Study therapists are being trained in the use of the Gaitrite mobile gait analysis walkway, a technology that could lead to a more clinically feasible and informative way of measuring gait after injury. Currently, gait is analyzed using expensive and space consuming laboratories with multiple cameras and is not readily accessible to clinicians. The Gaitrite walkway is portable and can quickly measure temporal and spatial parameters of a patient’s walking pattern in minutes near the bedside. Use of the Gaitrite in this study could lead to adoption of new practices in burn physical therapy. <https://www.gaitrite.com/>***

**What was the impact on society beyond science and technology?**

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:*

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

*Nothing to report.*

5. **CHANGES/PROBLEMS:** The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, “Nothing to Report,” if applicable:

**Changes in approach and reasons for change**

*Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.*

*Nothing to report.*

**Actual or anticipated problems or delays and actions or plans to resolve them**

*Describe problems or delays encountered during the reporting period and actions or plans to resolve them.*

*Due to the COVID-19 pandemic there may be delays in protocol training due to social distancing policies and the need to set up the trainings virtually. These delays may impact enrollment and may delay completion of enrollment. Our planned course of action for this possibility is to perform training remotely through video web-based training for protocol implementation.*

*Utilizing the Single IRB (sIRB) process is new for most centers and navigating this process has varied greatly between institutions. The UC Davis DCC is working closely with the UC Davis IRB and coordinators/IRBs at all centers to obtain sIRB agreements and cede review to the UC Davis IRB.*

**Changes that had a significant impact on expenditures**

*Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.*

*Some of the site contracts are still under negotiation which has resulted in a delay in the purchase of equipment items for the sites. We anticipate that all site contracts should be in place and equipment ordered during the next quarter.*

**Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**

*Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.*

**Significant changes in use or care of human subjects**

*Not applicable.*

**Significant changes in use or care of vertebrate animals.**

*Not applicable.*

**Significant changes in use of biohazards and/or select agents**

*Not applicable.*

6. **PRODUCTS:** List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state “Nothing to Report.”

- **Publications, conference papers, and presentations**

Nothing to report.

**Journal publications.**

Nothing to report.

*None.*

**Books or other non-periodical, one-time publications.**

*None.*

**Other publications, conference papers, and presentations.** *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (\*) if presentation produced a manuscript.*

*None.*

- **Website(s) or other Internet site(s)**

List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

*None.*

- **Technologies or techniques**

*Identify technologies or techniques that resulted from the research activities. In addition to a description of the technologies or techniques, describe how they will be shared.*

*None.*

- **Inventions, patent applications, and/or licenses**

*Identify inventions, patent applications with date, and/or licenses that have resulted from the research. State whether an application is provisional or non-provisional and indicate the application number. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.*

*None.*

- **Other Products**

*Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment, and/or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:*

- *data or databases;*
- *biospecimen collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other*

*The data base developed for this study will capture the quantity of therapy provided to critically ill burn patients as well as the types of therapy, response to therapy within the session, and barriers to providing the planned therapeutic interventions. To our knowledge, no*

*data base with such information currently exists. Collecting quantitative and qualitative information about physical and occupational therapy after burn injury from multiple burn centers could serve as a valuable resource for continued research beyond the aims of this study.*

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

### What individuals have worked on the project?

*Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change."*

<i>Name:</i>	Soman Sen
<i>Project Role:</i>	PI
<i>Percent effort:</i>	2%
<i>Name:</i>	Mary Beth Lawless
<i>Project Role:</i>	Director of Research Operations
<i>Percent effort:</i>	17%
<i>Name:</i>	Ingrid Parry
<i>Project Role:</i>	Co-I/ therapist
<i>Percent effort:</i>	60%
<i>Name:</i>	Michaela Canova
<i>Project Role:</i>	CRC
<i>Percent effort:</i>	25%
<i>Name:</i>	Sandy Taylor
<i>Project Role:</i>	Statistician
<i>Percent effort:</i>	10%
<i>Name:</i>	Carly Davis
<i>Project Role:</i>	Data Analyst
<i>Percent effort:</i>	25%

### Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The*

*awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.*

***Nothing to Report.***

### **What other organizations were involved as partners?**

*If there is nothing significant to report during this reporting period, state “Nothing to Report.”*

*Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.*

***There are seven (7) participating sites including the lead site:***

- ***University of California – Davis (lead) (UCD)***  
***PI: Soman Sen, MD***
- ***US Army Institute of Surgical Research (ISR)***  
***PI: Leopoldo Cancio, MD***
- ***Arizona Burn Center (ABC)***  
***PI: Kevin Foster, MD***
- ***Loyola Burn Center (LOY)***  
***PI: Anthony Baldea, MD***
- ***Eskenazi Health, Fairbanks Burn Center (IND)***  
***PI: Brett Hartman, MD***
- ***Wake Forrest (WF)***  
***PI: James Holmes, MD***
- ***Johns Hopkins Medical Center (HOP)***  
***PI: Scott Vocke, DPT***

## **8. SPECIAL REPORTING REQUIREMENTS**

### **COLLABORATIVE AWARDS:**

N/a.

### **QUAD CHARTS:**

9. **APPENDICES:** Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

**STAT: Standard Therapy plus Active Therapy To Improve Mobility, Long-Term Activity and Quality of Life for Severely Burn Injured Patients After Skin Graft Surgery**  
 W81XWH-19-2-0043



PI: Soman Sen MD FACS

Org: American Burn Association, University of California at Davis

Award Amount: \$3,473,270

**Study/Product Aim(s)**

- **Specific Aim 1:** Compare the functional exercise capacity between burn patients who undergo skin grafting surgery and receive STAT (standard therapy plus active therapy) to those who receive ST alone.
- **Specific Aim 2:** Compare long-term physical activity outcomes (functional task, daily activity and gait quality) between burn patients in the STAT versus ST groups.
- **Specific Aim 3:** Compare Return to Work Duty and Health Related Quality of Life (HRQOL) of burn patients in the STAT versus ST groups.
- **Specific Aim 4:** Compare the incidence of medical and surgical complications between the STAT versus ST groups.

**Approach**

The study is a multicenter, prospective, randomized control study comparing early standard physical therapy plus active therapy to standard therapy alone after a severe burn injury and skin grafting.

**Timeline and Cost**

Activities	FY	2019-2020	2020-2021	2021-2022	2022-2023
Facility contract negotiations/ protocol approval/ study operations established		█			
Investigator meeting/on-site training Begin enrollment/data collection		█			
Continue enrollment/data collection Begin data audit and analysis			█	█	
Complete data analysis Begin data report organization					█
Manuscript preparation/ and information dissemination					█
<b>Estimated Budget (\$3,473,270)</b>		\$1008724	\$935375	\$954794	\$574377

Updated: (9-30-2020)



**Accomplishments:** Core multisite protocol has been approved by UCD IRB and HRPO. Contracts between ABA and DCC/UCD and ISR are executed. Contracts between ABA and participating sites are in negotiation and Single IRB and secondary HRPO approval are in progress. REDCap data base has been developed and tested. Fitbase data base set up.

**Goals/Milestones**

**CY19-20 Goal – Administrative Undertakings and Research Operations**

- Finalize research protocol and study consent forms
- Develop and test central data base
- Develop Case Report Forms
- Finalize facility contracts
- Protocol regulatory review
- Develop SOP manual
- Onsite training at participating centers
- Study start-up equipment obtained
- Begin enrollment

**CYs20-22 Goals – Data Collection and analysis**

- Complete enrollment at all participating sites
- CY22-23 Goals– Data collection, analysis and reporting**
- Data analysis
- Manuscript preparation and submission

**Budget Expenditure to Date**

Projected Expenditure: 3,473,270

Actual Expenditure: \$71,004