**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, Chicago, IL

**REPORT DATE:** October 2021

**TYPE OF REPORT:** Annual

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

# REPORT DOCUMENTATION PAGE

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| **1. REPORT DATE** | **2. REPORT TYPE** | **3. DATES COVERED** |
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**4. TITLE AND SUBTITLE**
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

**5a. CONTRACT NUMBER**
W81XWH-19-2-0043

**5b. GRANT NUMBER**
MB170039

**5c. PROGRAM ELEMENT NUMBER**

**6. AUTHOR(S)**
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**5d. PROJECT NUMBER**

**5e. TASK NUMBER**

**5f. WORK UNIT NUMBER**

**7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)**
AMERICAN BURN ASSOCIATION
311 S WACKER DR STE 950
CHICAGO IL 60606-6669

**8. PERFORMING ORGANIZATION REPORT NUMBER**

**9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)**
U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

**10. SPONSOR/MONITOR'S ACRONYM(S)**

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**12. DISTRIBUTION / AVAILABILITY STATEMENT**
Approved for Public Release; Distribution Unlimited

**13. SUPPLEMENTARY NOTES**

**14. ABSTRACT**
Objective: To investigate a systematic and measureable rehabilitation protocol (STAT) that emphasizes active therapy early in burn recovery compared to standard therapy (ST) to improve overall outcome and return to work or active duty for burned patients.
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.
Major findings: None to date

**15. SUBJECT TERMS**
Burn injury, Physical Therapy, Functional Outcome, Exercise, Mobilization, Activity

| **16. SECURITY CLASSIFICATION OF:** | | | **17. LIMITATION OF ABSTRACT** | **18. NUMBER OF PAGES** | **19a. NAME OF RESPONSIBLE PERSON** |
|---|---|---|---|---|---|
| **a. REPORT** | **b. ABSTRACT** | **c. THIS PAGE** | | | USAMRDC |
| Unclassified | Unclassified | Unclassified | Unclassified | 14 | **19b. TELEPHONE NUMBER** *(include area code)* |

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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 the overall outcome and return to work or active duty for burned patients. Over the four year study period, 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:

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

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: 30 subjects enrolled (13 in ST group, 17 in STAT group). All 7 sites are enrolling.***

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: 30 subjects enrolled (13 in ST group, 17 in STAT group). All 7 sites are enrolling. Seven subjects have reached the study endpoint.***

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: 30 subjects enrolled (13 in ST group, 17 in STAT group). All 7 sites are enrolling. Seven subjects have reached the study endpoint.***

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

***STATUS: 30 subjects enrolled (13 in ST group, 17 in STAT group). All 7 sites are enrolling.***

*Major Task 1: Administrative undertakings (months 1-6 and annually)*
*1a. Finalize study consent forms and research protocol-* **completed Y1Q2**
*1b. Develop central database* **- completed Y1Q4**
*1c. Develop Case Report Forms* **- completed Y1Q4**
*1d. Develop electronic collection method of data collection* **- completed Y1Q4**
*1e. Finalize research contracts* **– completed Y2Q4**
*1f. Protocol regulatory review – local IRB and DoD HRPO* **– completed, Y2Q4**
*1g. Develop standard operating procedures (SOP) manual* **– completed Y1Q4 (named MOO)**
*1h. Coordinate with participating sites (PS) for annual IRB report for continuing review* **- CR not yet due.**

*Major Task 2: Establish research systems operations (months 3-7)*
*2a. Order and distribute study equipment –* **completed for all sites Y2Q4**
*2b. Hire coordinators and research therapy staff –* **completed Y1Q3**
*2c. Conduct onsite trainings (7 sites)* **– completed for all sites Y2Q4**
*2d. Test data submission* **–completed Y1Q4**

*Major Task 3: Data collection and analysis (months 6-45) –***enrollment in progress for all sites**
*3a. Begin subject screening and enrollment (month 6)* **- enrollment in progress for all sites**
*3b. Begin and continue data submission (month 6)-* **enrollment in progress for all sites**
*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?**

*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 approval and secondary HRPO approval have been received for all sites. A central database with all electronic CRFs using REDCap. Fitabase database has been trialed and is being used for collection of activity data with Inspire Fitbits. Contracts between prime (ABA) and all seven participating sites have been executed.***

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

***Equipment has been ordered and delivered to all seven sites. In-person training with staff at UCD was conducted on 9-30-20. Virtual trainings (due to COVID-19 pandemic and restrictions with travel) were conducted for all other sites: ARZ (1-20-21 and 1-27-21), IND (3-22-21 and 4-1-21), HOP (4-1-21 and 4-22-21), WF (3-17-21 and 4-1-21), ISR (3-17-21 and 3-24-21) and LOY (8-27-21, 8-30-21 and 9-27-21). REDCap has been established and tested with sample patients and is being used for data collection.***

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

***All seven participating sites are screening and enrolling patients. Thirty patients have been enrolled with 13 randomized to ST group and 17 randomized to STAT. Data collection and entry into REDCap are ongoing. Consents have been translated to Spanish for participating sites that have requested to increase enrollment of Spanish-speaking subjects. No data analysis has been conducted due to ongoing enrollment.***

*Major Task 4: Data reporting (months 46-48)*
***Data reporting and manuscript development will begin when enrollment is complete.***

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, enrollment is in progress.***

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

***Clinical physical and occupational therapists at all sites have been trained in the use of standardized outcome tools (Ex. Gaitrite motion analysis walkway, Canadian Occupational Performance Measure, etc.) thus allowing for opportunities for professional and skill development. Clinicians underwent training on study procedures and data entry.***

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

***Nothing to report.***

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

***To date. we have met 18% of our enrollment goal due to significant delays because of the COVID-19 pandemic and its impact on hospital/ICU staffing and policies. In the next year, we plan to enroll at least half of the remaining enrollment goal (68 patients) now that all sites are enrolling.***

**4. IMPACT:**

**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."*

*The clinical therapy and research staff at all sites have been trained in research procedures thus improving the understanding and skill of these clinicians with integrating research into clinical workflows.*

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

*Implementing a structured and supervised early exercise program in a burn unit requires the entire team (burn surgeons, physiatrists, nurses, therapists, dieticians, psychologists, social workers, and others). The study has increased awareness of early exercise and the success of providing the protocol to STAT subjects indicates that team coordination has developed at the participating site.*

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

*Study therapists are now 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. The use of the Gaitrite in this study could lead to the adoption of new practices in burn physical therapy. https://www.gaitrite.com/.*

*Fitbits are being issued to ST and STAT patients to measure activity levels after discharge. Fitbits are a wearable technology that allows for monitoring of patients' exercise behaviors and the data collected could inform clinical practices regarding maintenance and/ or prevention of health issues after hospitalization from burn injury.*

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

| |
|---|
| ***Nothing to report.*** |

**5. CHANGES/PROBLEMS:**

**Changes in approach and reasons for change**

| |
|---|
| ***Nothing to report.*** |

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

| |
|---|
| ***Due to the COVID-19 pandemic, there were delays:***<br>***-trainings were postponed due to hospitals needing to shift staff from burn units to manage COVID-19 surges.***<br>***-trainings changed to virtual format due to social distancing policies and restrictions in travel.***<br>***-participating site contracts were delayed due to hospital attention to the pandemic and reduced availability of nonclinical staff for contract management.***<br>***-participating site onboarding was delayed due to the reduced availability of clinical staff at many sites for study participation.***<br>***-enrollment is slower than expected due to hospital resources and staff needing to shift to managing COVID-19 surges.***<br><br>***All sites are now trained and enrolling but enrollment at some sites is still limited by staffing shortages.*** |

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

| |
|---|
| ***Nothing to report.*** |

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

**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:

- **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)**

***None.***

- **Technologies or techniques**

***None.***

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

***None.***

- **Other Products**

***Nothing to report.***

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

**What individuals have worked on the project?**

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

*PI for LOY changed from Anthony Baldea, MD to John Kubasiak, MD*

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

*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: John Kubasiak, 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:** In addition to embedding an updated Quad Chart within this annual / final technical report, also submit a standalone copy as an attachment in PowerPoint file only (.ppt or .pptx) to CDMRP Reporting at usarmy.detrick.medcom-cdmrp.mbx.cdmrp-reporting@mail.mil and copy the assigned CDMRP Science Officer.

**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 | | | | |
| **Estimated Budget ($3,473,270)** | $1008724 | $935375 | $954794 | $574377 |

**Updated:** (10-29-2021)


**Accomplishments:** Contracts executed between ABA and 7/7 participating sites. Single IRB approved for 7/7 sites. Secondary HRPO approval for 7/7 sites. Equipment ordered and site trainings completed for 7/7 sites. Screening and enrollment initiated at 7/7 sites; 30 subjects enrolled.

**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: $698,727

## 9. APPENDICES: