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AWARD NUMBER: W81XWH-14-2-0148

TITLE: A Goniometry Paradigm Shift to Measure Burn Scar Contracture in Burn Patients

PRINCIPAL INVESTIGATOR: Reginald Richard

RECIPIENT: The Geneva Foundation
Tacoma, WA 98402

REPORT DATE: October 2016

TYPE OF REPORT: Annual

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

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| 14. ABSTRACT Objective: To test more extensively a recently designed Revised Goniometry (RG) method and compare it to Standard Goniometry (SG) used to measure burn scar contracted joint angles for determining disability severity and function in a burn population. Hypothesis: Significant statistical differences in patient joint angle measurements will be found between SG techniques compared to RG techniques which incorporate CKM and CFU principles. Specific Aim 1: Statistically compare SG measurements obtained using the traditional technique versus the newly designed RG measurement method at seven joints of interest with a predilection to develop burn scar contracture. Specific Aim 2: To statistically associate the severity of burn scar tissue contractures goniometrically with the extent of CFU involvement. Specific Aim 3: To statistically document the influence that adjacent joint position has on goniometric results related to patient functional outcomes. | | | | | |
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1. INTRODUCTION:

Goniometry (GM) is an accepted clinical and research practice to assess patient outcome in terms of joint range of motion (ROM). Cutaneouskinematic (CKM) research has documented that skin is recruited from areas distant to joint movement, and that adjacent joint positions also influence skin recruitment. While standard GM has been described as reliable in burns, scarring can affect GM results based on patient positioning thereby leading to questions concerning the validity of standard GM as a measure of patient functional outcome for patients after burn injury. The current research investigation is aimed at critically assessing standard GM compared to a new paradigm of revised GM based on CKM factors.

2. KEYWORDS:

Burn, Goniometry, Range of Motion, Scar, Contracture

3. ACCOMPLISHMENTS:

What were the major goals of the project?

- *All expected timelines have been updated based on additional year.*

Task 1. Administrative Undertakings

1a. Finalize research protocol: (GF; ISR; UCD; CS) Y1, Month 1-11

Resolve outstanding issues related to the study protocol at individual clinical sites.

- *Completed (8-20-15), Continuing review approval(9-18-16)*

1b. Finalize facility contracts: (GF) Y1,Month 1- Y3, Month 2

Individual contracts between The Geneva Foundation and each participating clinical site will undergo final negotiation and receive final signature by both parties.

- *In Progress: contracts 88% complete (7/8 centers)*

1c. Fabrication of foam measurement supports: (ISR) Months 1- 2

For the study, position blocks made of foam and cut to angles specific to attain positions addressed by the Revised Goniometry positions for knee flexion, knee extension and ankle dorsiflexion will be made available to all clinical sites for use in testing subjects.

- *Completed (11-14)*

1d. Protocol Regulatory Review – local and DoD: (GF; ISR; UCD; CS) Y1, Months 1- Y3, Month 2

Final approval of the protocol at both the local and secondary level will occur.

- *In progress: local approval and secondary HRPO approval for 5/8 sites. Continuing review local and HRPO approval for 4 sites*

1e. Develop Standard Operating Procedures (SOP) Manual: (ISR; UCD) Months 1 – 4

The SOP for the study detailing the procedures will be written finalized. Contents will address study and subject binders, data collection requirements including photographs of proper subject positions and goniometer placement, creation of Surface Area Graphic Evaluation diagrams, data submission, and study close-out.

- *Completed (8-12-15), now referred to as Manual of Operating Procedures (MOOP).*

1f. Test data submission mechanism: (ISR; UCD) Months 2-3

Beta testing of data submission will be trialed.

- *Completed (3-31-15)*

1g. Organize arrangements to host Study Training Conclave: (GF; ISR; UCD) Months 1 – 4

Site visits to potential host sites and negotiations between The Geneva Foundation and select host sites in San Antonio TX will be finalized.

- *Completed (29-30 Sept 14)*

Task 2. Establish Research Systems Operations

2a. Conduct Training Conclave: (GF; ISR; UCD; CS) Month 4

Two-day Developmental Meeting with representatives from participating clinical sites. The Agenda will consist of background and supporting information for the study; explanation with rationale for the Revised Goniometry subject positions with respect to cutaneokinematics and differential diagnosis of soft tissue joint limitation of motion; practice and assessment of attendees positioning and goniometry measurement techniques.

- *Completed (18-19 Nov 14)*

2b. Conduct On-site Training: (ISR; UCD; CS) Y1, Month 5 – Y3, Month 3

One-day in-person training by either the Principal Investigator or lead Associate Investigator of all personnel at clinical sites who will be involved in the research consisting of study procedures to include goniometry techniques, instruction and practice in creating of SAGE diagrams, and data submission.

- *In progress: on-site training completed for 6/8 participating sites.*

Task 3. Data Collection / Audit / Analysis

3a. Begin subject screening and data submission: (ISR; UCD; CS) Y2, Month 3 – Y3, Month 9

Each CS is estimated to contribute 18 subjects to the data pool

Anticipated quarterly enrollment: 38 subjects

- *In Progress: data is currently being collected at 5/9 centers (including ISR).*

3b. Begin and continue data audit: (ISR; UCD) Y2, Month 3 – Y3, Month 9

Data records will be reviewed for accurateness as they are submitted in real time and in an on-going basis to detect and remedy any errors rapidly.

- *In progress: 100% of submitted records have been audited.*

3c. Conclude data submission: (ISR; UCD; CS) Y3, Month 9

- *In Progress: Data has been submitted by 6/9 centers.*

3d. Begin and continue on-going data analysis: (ISR; UCD; CS) Y3, Month 1- Y3, Month 9

Data will be monitored by concurrent audits. An interim analysis will occur after the first 163 measurement comparisons is submitted and cleared. Data collection will cease at the time that statistical significance is achieved for both the primary sites of interest and for the group aggregate. Subsequent interim analyses will occur in blocks of 45 measurement pairs. Data will be analyzed by comparing the standard to the revised goniometry measurements using repeated measures ANOVA. This process will be performed for the entire data set as well as individual joint subsets. Correlations will be performed between the severity of joint limitation and the percentage of cutaneous functional unit involvement.

- *In Progress: Data submission is 59% to interim analysis*

3e. Finish data analysis: (ISR; UCD) Y3, Month 9

With the anticipation that all needed data will be collected within the budgeted twelve months for data collection, and should statistical significance not be achieved prior to this time, final data analysis will be conducted.

Task 4. Data Reporting

4a. Begin data report organization: (GF; ISR; UCD; CS) Y3, Month 9-12

Collected and analyzed data will be collated. Study results will be shared with contributing partners in terms of interpretation and reporting. Abstract(s) will be prepared for submission to meet deadlines for presentation at appropriate professional meetings.

4b. Manuscript preparation and submission: (GF; ISR; UCD; CS) Y3, Month 9-12

A seminal manuscript will be developed and submitted to an appropriate professional burn-related journal.

What was accomplished under these goals?

Task 1. Administrative Undertakings

1a. Finalize research protocol – Completed Y1Q4

- Core protocol was approved Q4 (8-20-15) and sent to participating sites (8-21-15)
- Continuing review core protocol approval (9-18-16)

1b. Finalize facility contracts – In Progress

- Clinical Trials Agreements executed between Geneva and 7/8 participating sites, UNC in progress.
- Cooperative Research and Development Agreement (CRADA) agreements established between ISR and 8/8 participating sites.
- Extended contracts based on No Cost Extension (NCE) executed or in progress with 7/8 centers.

1c. Fabrication of foam measurement supports – Completed Y1Q1

- Foam wedges for modified positions designed, tested, fabricated and distributed to participating sites (Oct-Nov 2014)

1d. Protocol Regulatory Review – In Progress

- Core protocol approval received (8-20-15) and continuing review core protocol approval (9-18-16).
- A-18469.a for site ISR (referenced IRB #408254), HRPO initial approval 10-18-15, continuing review approval local and HRPO 8-18-16.
- A-18469.b for site ARK (referenced IRB #204582), HRPO initial approval 10-23-2015, continuing review approval local 6-14-16 and HRPO 8-24-16.
- A-18469.c for site UOI (referenced IRB #201508809), HRPO initial approval 11-23-2015, continuing review approval local 2-13-16 and HRPO 9-16-16.
- A-18469.d for site UCD (referenced IRB #808784), HRPO initial approval 11-18-2015, continuing review approval local 9-1-16 and HRPO 9-16-16.
- A-18469.e for site REG (referenced IRB #A13-210), HRPO initial approval 4-1-16
- A-18469.f for site HOP (referenced IRB#00080816), HRPO initial approval 4-26-16
- A-18469.g for site LSU (referenced IRB#00000473), HRPO initial approval pending.
- A-18469.h for site UOC (referenced IRB# 14-2306), HRPO initial approval pending
- Reference for site abbreviations in Appendix B.

1e. Develop Standard Operating Procedures (SOP) Manual – Completed Y1Q4

- The MOOP was completed Y1Q4. Submitted with last annual report.

1f. Test data submission mechanism – Completed Y1Q3

- Beta testing of data submission using the Safe Access File Exchange (SAFE) test site for submission of data between participating sites and ISR complete with 8/8 centers.

1g. Organize arrangements to host Study Training Conclave - Completed Y1Q1.

- Study materials and educational lectures were prepared for presentation to investigators participating in the Training Conclave.
- Randomization Table Agenda developed and is currently in use (submitted with Y1 annual report)

Task 2. Establish Research Systems Operations

2a. Conduct Training Conclave - Completed Y1Q2.

- A two-day developmental meeting (18-19 Nov 14) with representatives from all participating clinical sites was conducted at main site (ISR) for training and study preparation purposes. Training objectives were met and study equipment was distributed.
- Reliability testing of goniometry measurement methods within and between investigators was established (submitted with Y1 annual report).

2b. Conduct On-site Training: In Progress

- On-site training of 6/8 centers completed: UCD 10-8-15, ARK 10-15-15, UOI 11-20-15, UOC 1-25-16, REG 1-26-16, HOP 2-24-16. Awaiting secondary HRPO approval to schedule training at LSU and UNC.
- Training included protocol review, training with MOOP for study procedures, SAGE diagram training and test, review of CRFs and data submission process, review of patient positions, and evaluation of physical setting. Site training checklist developed and submitted with Y1 annual report.

Task 3. Data Collection / Audit / Analysis: In Progress

- A No Cost Extension (NCE) has been granted to continue the study through 14 Sept 2017. This will allow for continued screening, enrollment and data collection that had been delayed due to unanticipated delays in initial core protocol approval and subsequent participating site approvals.

3a. Begin subject screening and data submission: (ISR; UCD; CS): In Progress

- Subjects are currently being screen and data collected at 5/9 centers: ISR, UCD, ARK, UOI, REG,
- 35 subjects have been enrolled and 96 measurement sites have been submitted (see table).
- Data for all primary and secondary measurement sites are represented.

| | Primary Sites | Secondary Sites | Total Sites | Subjects/Allowed |
|--------------|---------------|-----------------|-------------|------------------|
| ISR | 17 | | 17 | 5/72 |
| UCD | 31 | 13 | 44 | 17/48 |
| UOI | 4 | 1 | 5 | 2/25 |
| LSU | | | | 0/13 |
| ARK | 21 | 7 | 28 | 10/60 |
| HOP | | | | 0/75 |
| REG | 1 | 1 | 2 | 1/12 |
| UNC | | | | 0/25 |
| UOC | | | | 0/50 |
| Total | 74 | 22 | 96 | 35 |

3b. Begin and continue data audit: (ISR; UCD): In Progress

- All 35 records submitted have been audited.
- 8 (22.9%) of records have been returned to investigators for revision of accuracy of completion.

3c. Conclude data submission: (ISR; UCD; CS): In Progress

- Data submission will continue until interim analysis (and final analysis if necessary) can be conducted.
- 96 data points representing 11 different measurement sites have been submitted (see table)

| Count of | ISR | UCD | UOI | LSU | ARK | HOP | REG | UNC | UOC | TOTAL |
|--------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-------|
| Neck Extension | 2 | | | | 1 | | | | | 3 |
| Shoulder Abduction | 4 | 8 | 2 | | 5 | | | | | 19 |
| Shoulder Flexion | 5 | 8 | | | 5 | | | | | 18 |
| Elbow Extension | 4 | 3 | | | 1 | | | | | 8 |
| Elbow Flexion | | 1 | | | | | | | | 1 |
| Wrist Extension | 1 | 9 | 2 | | 9 | | 1 | | | 22 |
| Wrist Flexion | | 8 | 1 | | 7 | | 1 | | | 17 |
| Knee Extension | 1 | 2 | | | | | | | | 3 |
| Knee Flexion | | 3 | | | | | | | | 3 |
| Plantarflexion | | 1 | | | | | | | | 1 |
| Ankle Dorsiflexion | | 1 | | | | | | | | 1 |
| TOTAL | 17 | 44 | 5 | | 28 | | 2 | | | 96 |

3d. Begin and continue on-going data analysis: (ISR; UCD; CS): In Progress

- 96/163 records have been submitted which is 59% toward interim analysis.

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

Training

- Study lead investigators determined gold standard measurements during pre-conclave work to provide reliable means of determining goniometric measurements in a uniform manner.
- On-site trainings in progress to develop proficiency with the use of study tools (SAGE diagrams, goniometric techniques).
- Data audits have provided training opportunities for proper data submission

Professional Development

- The study Conclave with investigators from participating sites provided didactic and hands-on training in cutaneokinematics and goniometric techniques.
- Monthly teleconferences provide the opportunity for small group discussion regarding techniques and study procedures.
- Goniometry books – Norkin and White (FA Davis, 2009) text books were purchased for each site as a reference manual for standard goniometric techniques.

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?

Due to the protracted time for protocol approvals, significant delays have been encountered for screening, enrollment and data collection. NCE has been granted to extend the study timeframe to end on September 14, 2017. Screening and enrollment will continue until an interim analysis can be complete. Continue support and lend assistance to latent facilities to garner protocol approvals and contract settlements.

Task 3. Data Collection / Audit / Analysis

3a. Begin subject screening and data submission:

- 5/9 study sites are collecting data which will increase the data submission rate in this next reporting period. Data collection will continue at all approved sites.
- UOC, LSU and UNC are in process of receiving secondary HRPO approval with the plan that they will also be enrolling and contributing data in the next reporting period. HOP recently received secondary HRPO approval and will start screening and enrolling.

3b. Begin and continue data audit:

- Data records will continue to be reviewed for accurateness as they are submitted in real time and on an on-going basis to detect and remedy any errors.

3c. Conclude data submission.

- Pace of enrollment and results of interim data analysis will dictate the duration of data collection necessary.

3d. Begin and continue on-going data analysis:

- We are 59% toward an interim analysis which will occur when 163 records have been collected
- Data collection will cease at the time that statistical significance is achieved for both the primary sites of interest and for the group aggregate.
- Subsequent interim analyses will occur in blocks of 45 measurement pairs.
- Data will be analyzed by comparing the standard to the revised goniometry measurements using repeated measures ANOVA. This process will be performed for the entire data set as well as individual joint subsets.
- Correlations will be performed between the severity of joint limitation and the percentage of cutaneous functional unit involvement using Pearson's or Spearman's correlation coefficient.

3e. Finish data analysis:

- Completion of data analyses will be in tandem with data submission and based on periodic interim analysis. When statistical significance of the data is achieved, the study will be terminated as per the protocol.

Task 4. Data Reporting

4a. Begin data report organization:

- Collected and analyzed data will be collated.
- Study results will be shared with contributing partners in terms of interpretation and reporting.
- Abstract(s) will be prepared for submission to meet deadlines for presentation at appropriate professional meetings.

4b. Manuscript preparation and submission:

- A seminal manuscript will be developed and submitted to an appropriate professional burn- related journal.

4. IMPACT

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

Impact:

- Increase awareness of participating clinicians of the need for burn specific goniometric methods more relevant and useful for the burn population.
- Create awareness between disciplines (OT/PT) of the ways they've been taught to practice.

What was the impact on other disciplines?

Nothing to report

What was the impact on technology transfer?

Nothing to report

What was the impact on society beyond science and technology?

Nothing to report

5. CHANGES/PROBLEMS:

There have been no changes in approach.

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

Delays have occurred with core protocol and consent approval. Initially, protracted time to finalize and satisfy requirements for core protocol (including changing from a SOP to a MOOP format) and informed consent, then secondarily, delays in local and secondary HRPO submission of some of the participating sites have led to a slower pace of data collection. The study has been granted a NCE allowing the study timeframe to continue for an additional year which will allow for completion.

Changes that had a significant impact on expenditures

Spending has been delayed due to the above described circumstances. Now that additional sites are screening and enrolling, spending will increase in parallel with on-site study training and remuneration for submitted data.

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

Not applicable.

6. PRODUCTS:

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

Related abstract presentations:

American Burn Association conference 2016: “Cutaneous Functional Units Predict ROM Recovery with Therapy” by co-investigator, I Parry and S Sen from UCD. Results of related study demonstrate correlation of CFUs to ROM and lack of correlation of standard goniometric techniques to functional measures of ROM.

International Society for Burns conference 2016: “Cutaneous functional units in burn rehabilitation: A new horizon” by Reg Richard, PI from ISR. The presentation related to the study by describing the versatility of CFUs and how they have been used in the evaluation and treatment planning of patients with burn injury.

- **Technologies or techniques**

Randomization Table and Reliability Table (submitted with Y1 annual report) developed by Jud Janek PhD, statistician at ISR.

- Randomization table created to avert selection bias as well as methodological bias.
- Reliability table created to establish minimum level of acceptable goniometric measure and ensure adequacy of measurements among clinicians.

Other Products

- Prototype goniometry bolster developed for patient positioning.
- Surface Area Graphic Evaluation (SAGE) – is a computerized burn wound mapping program with an electronic diagram originally patterned and formulated based on the Lund and Browder burn diagram. It specifically was customized to calculate and report the percentage of individual cutaneous functional unit areas.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

Name: Reg Richard, MS, PT
Project Role: Principal Investigator - ISR
person month worked: 13

Contribution to Project: Mr. Richard is principle investigator and responsible for overall study conduct and study oversight. He has developed and modified all study documents including the core protocol and informed consent as needed. He co-organized the Study Conclave as well as coordinated the initiation of CRADAs, SAGE modification, development and testing and SAFE testing.

Name: Ingrid Parry, MS, PT
Project Role: Co-Investigator - UCD
person month worked: 13

Contribution to Project: Ms. Parry helped develop study protocol and appendices and formulation of the MOOP. She worked with PI on coordinating investigator meetings and trainings and obtaining study equipment. She will monitor participating site enrollment, review data, assist in data analysis and writing of manuscripts for publication.

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

James Aden, PhD – statistical analysis
Kathryn Payne, MD – PI at UOC

8. SPECIAL REPORTING REQUIREMENTS:

QUAD CHARTS: The Quad Chart (available on <https://www.usamraa.army.mil>) shall be updated and submitted as an appendix.

9. APPENDICES:

Appendix A – Quad chart

Appendix B – Participating site abbreviations



A Goniometry Paradigm Shift to Measure Burn Scar Contracture in Burn Patients

Log #13214017

Award #: W81XWH-14-2-0148



PI: Reg Richard, MS, PT

Org: U. S. Army Institute of Surgical Research/The Geneva Foundation

Award Amount: \$368,255

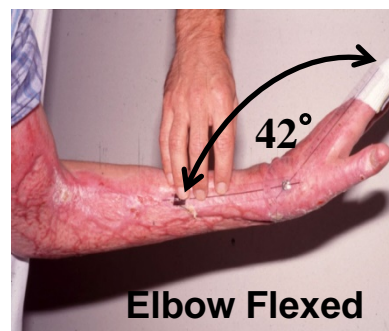
Study/Product Aim(s)

- Specific Aim 1: To statistically compare standard goniometry measurements obtained using this traditional technique versus the newly designed revised goniometry measurement method at seven joints of interest with a predilection to develop burn scar contracture.
- Specific Aim 2: To statistically associate the severity of burn scar tissue contracture goniometrically with the extent of cutaneous surface area involvement related to the joint ROM of interest.
- Specific Aim 3: To document the significant influence that adjacent joint position has on goniometric results related to patient functional outcomes.

Approach

The study is a prospective, multi-center, observational study comparing standard goniometric positions to revised goniometric positions to measure and document burn scar contracture.

Standard Goniometry (SG) Position to Measure Wrist Extension



Elbow Flexed

Revised Goniometry (RG) Position to Measure Wrist Extension



Elbow Extended

This quarter accomplishments include 5/9 centers screening and enrolling patients. Enrollment in this quarter: 35 subjects, 96 measurement sites. CRADA agreements have been executed between ISR and all 8 sites and contract agreements are in place between Geneva and 8/9 sites. A no cost extension has been granted to extend the study period to September 14, 2017.

| Activities | FY | 2014-15 | | | | 2015-16 | | | | 2016-17 | | | |
|--|----|--|--|---|---|--|---|---|---|---------|---|---|--|
| | | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| Facility contract negotiations/ system operations established | | [Bar chart showing activity from Q1 2014-15 to Q4 2015-16] | | | | | | | | | | | |
| Training conclave/on-site training | | | [Bar chart showing activity from Q3 2014-15 to Q4 2015-16] | | | | | | | | | | |
| Begin enrollment/data collection/audit/analysis | | | | | | [Bar chart showing activity from Q1 2015-16 to Q4 2016-17] | | | | | | | |
| Continue enrollment/data collection/audit/analysis | | | | | | [Bar chart showing activity from Q1 2015-16 to Q4 2016-17] | | | | | | | |
| Complete data analysis | | | | | | | | | | | | | [Bar chart showing activity in Q3 2016-17] |
| Begin data report organization | | | | | | | | | | | | | [Bar chart showing activity in Q4 2016-17] |
| Manuscript preparation/submission | | | | | | | | | | | | | [Bar chart showing activity in Q4 2016-17] |
| Estimated Budget (\$K) | | \$219595K | | | | \$148660K | | | | | | | |

Updated: 1 Oct 2016

Goals/Milestones

CY14-15 Goal – Administrative Undertakings and Research Operations

- Finalize research protocol
- Finalize facility contracts
- Study start-up equipment obtained
- Protocol Regulatory Review
- Develop SOP (MOOP)
- Study Conclave
- CRADA agreements with participating sites
- Onsite training at participating centers
- Begin enrollment

CY15-16 Goals – Data Collection, analysis and reporting

- Enrollment at all participating sites
- Data audited
- Data Analyzed
- Manuscript preparation and submission

Comments/Challenges/Issues/Concerns

- Slower than anticipated subject enrollment; protracted IRB approval at 3 sites. Expected timelines adjusted.

Budget Expenditure to Date

- Projected Expenditure: \$368K
- Actual Expenditure: \$173K

Participating Site Abbreviations:

ISR: U. S. Army Institute of Surgical Research Burn Center

UCD: University of California, Davis

HOP: Johns Hopkins Bayview Medical Center

ARK: Arkansas Children's Hospital Research Institute

UOC: University of Colorado Hospital, Denver

UOI: University of Iowa Hospital

REG: Regions Hospital

UNC: University of North Carolina Hospital- Chapel Hill

LSU: Louisiana State University Health Sciences Center