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

PRINCIPAL INVESTIGATOR: Ingrid Parry

RECIPIENT: The Geneva Foundation
Tacoma, WA 98402

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**6. AUTHOR(S)**
Ingrid Parry – ingridparry@gmail.com
Scott Dewey

**7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)**
The Geneva Foundation
917 Pacific Avenue, Suite 600
Tacoma, WA 98402

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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: To compare the average reduction in joint range of motion measured with the standard GM measurements to a newly conceived set of revised GM measurements in a burn population across six (6) joints of interest in eleven (11) single directions. Specific Aim 2: To compare the average reduction in joint range of motion measured with the standard GM measurements to a newly conceived set of revised GM measurements in a burn population for each of the six (6) joints of interest in eleven (11) single directions. Specific Aim 3: To examine the association between the reduction in the joint range of motion and the extent of cutaneous surface area involvement.

*Note specific aims updated to align with core protocol.

**15. SUBJECT TERMS**
Goniometry, burn scar contracture, burn

**16. SECURITY CLASSIFICATION OF:**

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<th>a. REPORT</th>
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Prescribed by ANSI Std. Z39.18
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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). Cutaneokinematic (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 tasks and 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 Y1Q4.

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.

• Completed Y2 Q4. Upon completion of data collection, all contracts between Geneva and participating sites were closed by 8/15/18.

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 Y1Q1.

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.

• Completed Y3Q2. Upon completion of enrollment, UOI closed the protocol with their local IRB in lieu of continuing review. The remaining sites will close their protocol at the next continuing review date. The core protocol at ISR will remain open.

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 Y1Q4.

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

Beta testing of data submission will be trialed.
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 Y1Q3.

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 Y1Q1.

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 SAGE diagrams, and data submission.
• Completed Y3Q1.

Task 3. Data Collection / Audit / Analysis

3a. Begin subject screening and data submission: (ISR; UCD; CS) Month 6-43
Each CS is estimated to contribute 18 subjects to the data pool
Anticipated quarterly enrollment: 38 subjects
• Completed Y4Q3

3b. Begin and continue data audit: (ISR; UCD) Month 6-43
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.
• Completed Y4Q3 (month 43)

3c. Conclude data submission: (ISR; UCD; CS) Month 43
• Completed Y4Q3 (month 43)

3d. Begin and continue on-going data analysis: (ISR; UCD; CS) 43-45
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.
• Completed Y4Q3 (month 44)

3e. Finish data analysis: (ISR; UCD) 18-45
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.
• Completed Y4Q3 (month 45)

Task 4. Data Reporting
4a. Begin data report organization: (GF; ISR; UCD; CS) Y3, Month 45-52
   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.
• Completed Y4Q4 (month 48)

4b. Manuscript preparation and submission: (GF; ISR; UCD; CS) Y3, Month 46-52
   A seminal manuscript will be developed and submitted to an appropriate professional
   burn-related journal.
• In Progress.

4c. Development of a Burn-Specific Goniometry reference manual with pictorial and narrative
   descriptions of the revised positions. (GF) Months 45-60
• In Progress.

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)
   • Last continuing review core protocol approval (8-15-18)

1b. Finalize facility contracts – Completed Y2 Q4
   • Clinical Trials Agreements originally executed between Geneva and 8/8 sites, UOC removed from
     study.
   • Cooperative Research and Development Agreement (CRADA) agreements established between ISR
     and 7/7 participating sites.
   • Upon completion of enrollment, all contracts between Geneva and participating sites were closed.

1c. Fabrication of foam measurement supports – Completed Y1Q1
   • Foam wedges for modified positions designed, tested, fabricated and distributed to participating
     sites (Nov 2014)

1d. Protocol Regulatory Review – Completed Y3Q2
   • Core protocol approval received (8-20-15) and continuing review core protocol approval (8/15/18).
   • A-18469.a for site ISR (referenced IRB #M-10437), Local IRB approval: initial=8/19/15,
     Amend#1=10/18/15, Amend #2=2/21/16, CR2016=8/18/16, Amend#3=3/30/17,
     CR2017+Amend#4=8/14//17. HRPO initial approval 8/20/15; Amend#1=10/18/15, Amend#2=2/21/16
     CR2016=8/18/16, Amend#3= 3/30/17, CR2017+Amend#4=8/14/17, Amend #5= 2/26/18, CR 2018:
     8/15/18
   • A-18469.b for site ARK (referenced IRB #204582), Local IRB approval: initial= 9/1/15, CR2016
     6/14/16, CR2017=5/15/17, CR 2018=3/19/18. HRPO approval: initial= 10/23/2015, CR2016= 9/16/16,
A-18469.g for site LSU (referenced IRB#00000473), HRPO initial approval 9-30-16, continuing review approval local 2-15-17, secondary HRPO approval 3-16-17. Study closed = 8/21/18
Reference for site abbreviations in Appendix B.

1e. Develop Standard Operating Procedures (SOP) Manual – Completed Y1Q4
   • The MOOP was completed Y1Q4. Submitted with Y1 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 8/8 participating sites and ISR completed.

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
Y1Q1
   • 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 - Completed Y3Q1
   • 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
3a. Begin subject screening and data submission - (ISR; UCD; CS) Month 6-43. Completed Y3Q3.
   • 7/7 centers completed screening and enrolling (ISR, ARK, UCD, UOI, REG, HOP, UNC)
- Data records were audited for completeness as they were submitted in real-time.
- All 66 records were audited.
- 19/66 (29%) of the records were returned to investigators for resubmission due to incompleteness.
- All records were rectified by submitting sites.

3c. Conclude data submission – (ISR; UCD; CS) Month 43. Completed Y4Q3.
- Subjects enrolled: 66
- Primary body sites obtained: 132
- Secondary body sites obtained: 42
- Total: 174 (1044 measurements)

<table>
<thead>
<tr>
<th>Participating site</th>
<th>Estimated number of subjects</th>
<th>Actual subjects enrolled</th>
<th>Number of measurements achieved</th>
<th>Body areas tested (primary, secondary)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISR</td>
<td>72</td>
<td>7</td>
<td>22</td>
<td>20,2</td>
</tr>
<tr>
<td>UCD</td>
<td>48</td>
<td>29</td>
<td>68</td>
<td>46,22</td>
</tr>
<tr>
<td>REG</td>
<td>24</td>
<td>2</td>
<td>5</td>
<td>4,1</td>
</tr>
<tr>
<td>UOI</td>
<td>25</td>
<td>2</td>
<td>5</td>
<td>4,1</td>
</tr>
<tr>
<td>HOP</td>
<td>56</td>
<td>8</td>
<td>20</td>
<td>18,2</td>
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<tr>
<td>ARK</td>
<td>36</td>
<td>12</td>
<td>35</td>
<td>25,10</td>
</tr>
<tr>
<td>UNC</td>
<td>25</td>
<td>6</td>
<td>19</td>
<td>15,4</td>
</tr>
</tbody>
</table>

3d. Begin and continue on-going data analysis – (ISR; UCD; CS) 43-45. Completed Y4, Q3
• Interim data analysis was conducted Y3Q4. The interim analysis involved evaluation of eleven (11) movement direction comparing the revised position to the standard position, with six (6) of the motions found to be significant (*p≤0.001). Data collection for those six body sites was stopped. Four other body site measurements: neck extension, knee flexion, knee extension and plantarflexion did not reach statistical significance using the Pocock’s method for adjustment of the family wise error rate for stopping early at interim analysis. Therefore, enrollment continued for those measurement areas only until they meet the pre-set terminal sample size or for 6 more months, whichever occurred first.

3e. Finish data analysis – (ISR; UCD) 18-45. Completed Y4Q3.

• Results of final data analysis:

1) Revised goniometry (GM) protocol measured significantly more limitation in motion than standard GM protocol: 38.8 %±15.2% v. 32.1% ±13.4% (p<.0001). This suggests that the standard method of GM may be under-representing the true limitation of motion caused by burn scarring and that revised GM protocol is more valid for use when measuring ROM outcome with the burn injured population. (Aim 1)

2) Revised GM protocol showed significantly more limitation in motion than standard GM protocol for 9/11 joint motions. (Aim 2)

<table>
<thead>
<tr>
<th>Joint motion</th>
<th>% Limitation in motion</th>
<th>p-value</th>
<th>Cohen’s D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dorsiflexion</td>
<td>GM Revised: 37.9%±11.4</td>
<td>GM standard: 26.8±9.3</td>
<td>&lt;.0001*</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plantarflexion*</td>
<td>52.8%±2.5</td>
<td>37.2%±4.2</td>
<td>0.0054*</td>
</tr>
<tr>
<td></td>
<td>*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knee flexion</td>
<td>28.1%±11.1</td>
<td>24.6%±12.5</td>
<td>0.0224*</td>
</tr>
<tr>
<td>Knee extension</td>
<td>19.0%±10.4</td>
<td>15.9%±11.0</td>
<td>0.0077*</td>
</tr>
<tr>
<td>Elbow extension</td>
<td>26.0%±12.4</td>
<td>20.4%±13.7</td>
<td>&lt;.0001*</td>
</tr>
<tr>
<td></td>
<td>24.2%±8.6</td>
<td>18.3%±7.5</td>
<td>&lt;.0001*</td>
</tr>
<tr>
<td>Elbow flexion</td>
<td>43.1%±11.7</td>
<td>38.8%±11.8</td>
<td>&lt;.0001*</td>
</tr>
<tr>
<td>Shoulder abduction</td>
<td>27.0%±9.0</td>
<td>28.2%±8.4</td>
<td>0.0269*</td>
</tr>
<tr>
<td>Shoulder flexion**</td>
<td>47.5%±22.0</td>
<td>36.4%±20.9</td>
<td>&lt;.0001*</td>
</tr>
<tr>
<td>Wrist extension</td>
<td>45.3%±14.7</td>
<td>30.1%±10.4</td>
<td>&lt;.0001*</td>
</tr>
<tr>
<td>Wrist flexion</td>
<td>59.0%±24.9</td>
<td>55.6%±14.1</td>
<td>0.2920</td>
</tr>
</tbody>
</table>

* *p≤.05 ** proof of concept measurements

Shoulder flexion showed more limitation with standard GM but the Cohen’s D suggests this may be a type 1 error. Neck extension in the revised GM showed more limitation but it did not reach statistical significance.

3) A positive weak correlation between percentage of CFU affected by scarring and ROM outcome for the revised GM protocol (R²=.05, p=.0008) while no correlation was found for the standard GM protocol, indicating that the revised GM protocol may be a more sensitive method of assessment. In addition a significant positive, but weak correlation was also found between the amount of CFU scarred and the Δ in revised and standard GM protocols (R²=.04, p=.0025) suggesting that as the % CFU scarred increases, there is a greater difference between ROM results with the standard and revised GM. (Aim 3)
Task 4. Data Reporting

4a. Begin data report organization – (GF; ISR; UCD; CS) Y3, Month 45-52. Completed Y4Q4

- An abstract summarizing the findings has been written and submitted to the following burn conferences:
  1) Oral presentation at the International Society of Burn Injuries International Burn Conference in India, December 2018. It was accepted and has been selected for the Andre Zagame Award.
  2) Oral presentation and clinical research award to the American Burn Association Annual Meeting in Las Vegas, 2019. Awaiting acceptance.

4b. Manuscript preparation and submission – (GF; ISR; UCD; CS) Y3, Month 46-52. In Progress.

- Manuscript has been drafted by primary authors (Parry, Richard, Aden, Dewey) and is currently circulating for input of other authors. This manuscript will be submitted to the Journal of Burn Care and Research.


- Currently investigating format options for a paper manual, electronic manual and/or web application manual.

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 completed to develop proficiency with the use of study tools (SAGE diagrams, goniometric techniques).
- Data audits have provided training opportunities for proper data submission.
- Interim analysis revealed increased variability in neck ROM measurements offering opportunity for review of measurement procedures.

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.
- The study findings provide evidence that the revised goniometry technique is more appropriate for patients who have scar as limiting factor for motion. The revised technique should be incorporated into trainings and skill workshops for burn clinicians (occupational and physical therapists) who learn the skill of measuring goniometry.
How were the results disseminated to communities of interest?

Dissemination to clinicians who work in burn care is currently underway with the submission of abstracts for oral presentation to national and international burn conferences and development of a manuscript for submission to a burn journal. Subsequent development of a Goniometry Manual outlining the revised technique will also be disseminated to the communities of interest (ex. occupational and physical therapists working with patients who have scars).

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

During the next reporting period:

- the findings will be presented at an international burn conference
- the study manuscript will be finalized and submitted for publication
- research regarding a format for the Goniometry Manual will conclude and the appropriate and affordable format will be selected
- development of the Goniometry Manual will continue

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, specifically to measurement of ROM with goniometry.

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

There are no anticipated problems or delays.

Changes that had a significant impact on expenditures

Statistical significance was met with fewer subjects than anticipated and not all participating sites fully used
the available funds. A no cost extension has been granted to use the remaining funds for information dissemination through the development of a Goniometry Manual. The manual will guide clinicians in the newly proposed way of measuring range of motion based on the results of this study.

**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.

  International Society for Burns conference 2018: “Measuring burn scar contracture-challenging the standard.” by Ingrid Parry. The abstract has been accepted for podium presentation in Dec 2018 in the Andre Zagame awards session. The result of the study will be described.

- **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

<table>
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<tr>
<th>Name: Ingrid Parry, MS, PT</th>
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<tr>
<td>Project Role: Co-Investigator – Geneva Foundation</td>
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<tr>
<td>person month worked: 13</td>
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<tr>
<td>Contribution to Project: Ms. Parry is study PI and responsible for overall study conduct and study oversight. She helped develop study protocol and appendices and formulation of the MOOP. She</td>
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</table>
worked with former PI on coordinating investigator meetings and trainings and obtaining study equipment and continues to guide and support participating sites. She monitored participating site enrollment, data audits, data analysis and will be leading the writing of manuscripts for publication.

Name: Scott Dewey MS, PT
Project Role: Co-Investigator - ISR
person month worked: 13

Contribution to Project: Mr. Dewey is lead site PT and responsible for overall study conduct and study oversight. He is currently auditing the data submissions and communicating with participating sites regarding data accuracy. He monitored participating site enrollment, review data, data analysis and will assist in writing 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?
No.

8. SPECIAL REPORTING REQUIREMENTS:
QUAD CHARTS: Attached.

9. APPENDICES:
Appendix A – Participating site abbreviations

Appendix A

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
A Goniometry Paradigm Shift to Measure Burn Scar Contracture in Burn Patients
Log #13214017
Award #: W81XWH-14-2-0148

Co-PIs: Ingrid Parry, MS, PT / William S Dewey PT, CHT

Org: Geneva Foundation
Award Amount: $368,255

Study/Product Aim(s)

- **Specific Aim 1:** To compare the average reduction in joint range of motion measured with the standard GM measurements to a newly conceived set of revised GM measurements in a burn population across six (6) joints of interest in eleven (11) single directions.
- **Specific Aim 2:** To compare the average reduction in joint range of motion measured with the standard GM measurements to a newly conceived set of revised GM measurements in a burn population for each of the six (6) joints of interest in eleven (11) single directions.
- **Specific Aim 3:** To examine the association between the reduction in the joint range of motion and the extent of cutaneous surface area involvement.

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.


<table>
<thead>
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<th>Quarter</th>
<th>Facility contract negotiations/ system operations established</th>
<th>Training conclave/on-site training</th>
<th>Begin enrollment/data collection/audit/analysis</th>
<th>Continue enrollment/data collection/audit/analysis</th>
<th>Complete data analysis</th>
<th>Begin data report organization</th>
<th>Manuscript preparation/ and information dissemination</th>
<th>Estimated Budget ($K)</th>
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Final: 66 subjects, 174 joint sites and 1044 measurements. The revised GM method resulted in significantly greater limitation in motion than standard GM: 38.8% ±15.2% v. 32.1% ±13.4% (p<.0001) across all motions together and for 9 of 11 motions when evaluated individually. There was a significant positive weak correlation between amount of CFU scarred and ROM outcome with the revised GM method but not the standard GM method (R²=.05, p=.0008).

**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
- Study 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**
- None

**Budget Expenditure to Date**
- Projected Expenditure: $368K
- Actual Expenditure: $283K

Updated: 14 Sept 18