

AWARD NUMBER: W81XWH-14-2-0148

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

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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. <u>Specific Aim 1:</u> 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. <u>Specific Aim 2:</u> 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. <u>Specific Aim 3:</u> 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.					
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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 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), latest version with minor modifications approved 7-24-17.*

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 (9-27-16). UOC dropped from study. Agreement modifications between Geneva and participating sites are in progress to extend the period of performance with approval of a second No Cost Extension (NCE to September 2018).*

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.

- *Completed for all 8/8 sites (7-27-17).*

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 (8-29-14 and 8-30- 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 (11-18-14 and 11-19- 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.

- *Completed for all 8/8 sites (11-30-16).*

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

- *In Progress: interim analysis resulted in decision to continue enrollment for 6 more months. Data collection will resume at 8/8 centers.*

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.

- *In progress: 100% of submitted records have been audited to date. Audits will continue with additional data collection.*

3c. Conclude data submission: (ISR; UCD; CS) Month 43

- *In Progress: Data has been submitted by 7/8centers. Data submission will continue for 6 more months.*

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.

- ***In Progress: Interim analysis was conducted at Month 36. Analysis resulted in a decision to continue enrollment until Month 43 (Mar 2018) or until pre-set maximum number of measurements (based on initial power analysis) are achieved for the following body sites: ankle plantarflexion, knee extension, knee flexion, neck extension. All other measurement sites will halt enrollment.***

•

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.

- ***In Progress: Timeline for data collection was extended due to results of interim data analysis. Data analysis will conclude by Month 45.***

Task 4. Data Reporting

4a. Begin data report organization: (GF; ISR; UCD; CS) Y3, Month 45-48

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 46-48

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)
- Minor modifications approved 7-24-17

1b. Finalize facility contracts – Completed

- Clinical Trials Agreements 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.
- Extended contracts are in progress between Geneva Foundation and participating sites based on No Cost Extension (NCE approved 9-22-17).

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 Y3Q4

- Core protocol approval received (8-20-15) and continuing review core protocol approval (9-18-16).
- A-18469.a for site ISR (referenced IRB #M-10437), HRPO initial approval 8-20-15, continuing review approval local and HRPO 8-14-17,
- A-18469.b for site ARK (referenced IRB #204582), HRPO initial approval 10-23-2015, continuing

review approval local 5-15-17, secondary HRPO approval 8-29-17.

- A-18469.c for site UOI (referenced IRB #201508809), HRPO initial approval 11-23-2015, continuing review approval local 7/17/17, secondary HRPO approval pending.
- A-18469.d for site UCD (referenced IRB #808784), HRPO initial approval 11-18-2015, continuing review approval local 7/18/17, secondary HRPO approval 8-29-17.
- A-18469.e for site REG (referenced IRB #A13-210), HRPO initial approval 4-1-16, continuing review approval local 10-27-16, secondary HRPO approval 12-15-16.
- A-18469.f for site HOP (referenced IRB#00080816), HRPO initial approval 4-26-16, continuing review approval local 12-7-16, secondary HRPO approval 1-27-17.
- 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.
- A-18469.i for site UNC (referenced IRB# 16-0922), HRPO initial approval 7-5-16, continuing review approval local 6-29-17, secondary HRPO approval 7-27-17.
- 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 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: Completed Y3,Q1

- On-site training of 8/8 participating centers completed: UCD 10-8-15, ARK 10-15-15, UOI 11-20-15, UOC 1-25-16 (now removed), REG 1-26-16, HOP 2-24-16, LSU 10-11-16, UNC 11-20-16.
- 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 second No Cost Extension (NCE) has been granted to continue the study through 14 Sept 2018 due to change in PI and delays with interim analysis. Interim analysis results indicate continued enrollment is necessary.
- Interim data analysis complete. Results of analysis:
Interim analysis was conducted on 166 data points. Data was analyzed using a repeated measures ANOVA taking into account the 3 repeated measures for each GM measurement. For the interim

analysis, significance was set at $\leq .001$ using Pocock's method for adjustment of the family wise error rate.

- 1) All data points analyzed in aggregate found that there was a significant difference between the revised and standard measurements with the revised measurements showing greater limitation in motion ($p < .001$)

All motions	Percent limitation in motion	
	Mean	Std Error
Revised	37.783009	1.5294917
Standard	31.163631	1.5294917

- 2) Analyzing each of the eleven (11) movement direction comparing the revised position to the standard position, six (6) of the motions were found to be significant ($*p \leq 0.001$). Data collection will cease for these body sites.

		Mean % limitation in motion	Std Error
Ankle Dorsiflexion*	Revised	39.245429	4.4312934
	Standard	28.135429	4.4312934
Elbow Extension*	Revised	26.398573	3.8284624
	Standard	20.799162	3.8284624
Elbow Flexion*	Revised	24.213333	5.3482288
	Standard	18.313333	5.3482288
Shoulder Abduction*	Revised	42.654478	2.5505523
	Standard	38.317704	2.5505523
Wrist Extension*	Revised	49.885560	4.8798437
	Standard	38.779324	4.8798437
Wrist Flexion*	Revised	44.183572	2.1447436
	Standard	29.056906	2.1447436

- 3) For the five (5) sites that did not reach $p \leq 0.001$ significance, shoulder flexion was the only body site that reached terminal sample size so using the preset terminal alpha of < 0.05 , it was determined to stop enrollment for this body site:

		Mean % limitation in motion	Std Error
Shoulder Flexion * $p \leq 0.05$	Revised	27.883554	1.9266848
	Standard	26.725919	1.9266848

The other four 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 will continue for those measurement areas only. Enrollment will continue until they meet the pre-set terminal sample size or for 6 months, whichever occurs first.

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

- Subjects are currently being screened and data collected at 8/8 centers: ISR, UCD, ARK, UOI, REG, HOP, LSU, UNC
- 62 subjects have been enrolled and 166 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	19	2	21	6/72
UCD	43	18	61	26/48

UOI	4	1	5	2/25
LSU				0/13
ARK	25	10	35	12/60
HOP	18	2	20	8/75
REG	4	1	5	2/12
UNC	15	4	19	6/25
Total	128	38	166	62/330

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

- All 62 records submitted have been audited.
- 13 (21%) of the records have been returned to investigators for resubmission due to incompleteness.

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

- Interim analysis conducted during Month 36 resulted in determination to continue enrollment for neck extension, knee flexion, knee extension and plantarflexion.
- 166 data points representing 11 different measurement sites have been submitted (see table)

Count of	ISR	UCD	UOI	LSU	ARK	HOP	REG	UNC	TOTAL
Neck Extension	2	3			1			1	7
Shoulder Abduction	4	10	2		5	6		4	31
Shoulder Flexion	6	8			5	6	1	6	31
Elbow Extension	5	3			2	2		4	17
Elbow Flexion	1	1			1				3
Wrist Extension	1	9	2		12	4	3		31
Wrist Flexion	1	10	1		9	2	1	4	28
Knee Extension	1	3							4
Knee Flexion		6							6
Plantarflexion		1							1
Ankle Dorsiflexion		7							7
TOTAL	21	61	5		35	20	5	19	166

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

- Interim analysis revealed that additional enrollment is needed to provide adequate amount of data for analysis in the measurement areas: ankle plantarflexion, knee flexion, knee extension, and neck extension. We will continue to enroll for these body sites until the preset terminal sample size has been achieved. If the anticipated number of measurements is not achieved within 6 months, data collection will cease and a final analysis will be conducted at that point.

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.

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 changes in the Study PI and delays with the interim analysis, a second NCE has been requested and granted to extend the study timeframe to end on September 14, 2018. At interim analysis, it was found that analyzed in aggregate, there was a significant difference between the revised and standard goniometry positions (Aim#1). However, when analyzing the difference between the revised and standard measurements for each measurement site, only seven of the eleven sites reached statistical significance. Four sites did not reach significance and had not met terminal stopping enrollment numbers, thus further data collection is needed to determine Aim #2. Screening and enrollment will continue for these four measurement sites for 6 more months or until the pre-set maximum (31) number of measurements is achieved, whichever comes first. At that time, data collection will cease and a final analysis of the data will be conducted. We will develop a manuscript based on the results and submit for both presentation at a burn conference and publication in a burn journal. During this time, we will resume monthly meetings with participating centers to provide continued support to participating facilities for data collection and submission.

Task 3. Data Collection / Audit / Analysis

3a. Begin subject screening and data submission:

- 8/8 study sites will continue to screen, enroll and test subjects for 6 months or until present maximum measurements are achieved in the 4 areas that did not reach significance at the interim analysis due to lack of power.

3b. Begin and continue data audit:

- Data records will continue to be reviewed and audited for completeness and accuracy by new CO-PIs as they are submitted in real time and on an on-going basis to detect and remedy any errors.

3c. Conclude data submission.

- Data collection will conclude Month 43 (March 2018) at all sites.

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

- Final data analysis will be conducted again for the aggregate set of data (Aim #1) using repeated measures ANOVA taking into account the 3 repeated measures to ensure the significance is the same as the interim analysis. In addition the final analysis will be conducted for each of the measurement sites (Aim#2) and correlation coefficients will be calculated to determine the relationship between the revised GM measurements and CFU percentage.

3e. Finish data analysis:

- Final data analysis will occur when preset maximum (31) number of measurements is achieved for each measurement site or at Month 43, whichever comes first.

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, 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

Delays have occurred due to retirement of study PI and change in personnel. The study now has a Co-PI model with Scott Dewey (ISR) serving as Lead site PI and Ingrid Parry (Geneva Foundation) as Study PI. The CO-PIs will now be responsible for study conduct. The personnel changes led to delays in the interim analysis which has now been conducted and the study is back on track with the above described goals for the next performance period. The study has been granted a second 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. All sites have resumed 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:	Ingrid Parry, MS, PT
Project Role:	Co-Investigator – Geneva Foundation
Nearest person month worked:	13
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 worked with former PI on coordinating investigator meetings and trainings and obtaining study equipment and continues to guide and support participating sites. She will monitor participating site enrollment, data audits, data analysis and writing of manuscripts for publication.

Name:	Scott Dewey MS, PT
Project Role:	Co-Investigator - ISR
Nearest 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 will monitor participating site enrollment, review data, data analysis and assist in 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?

Yes. See above. New Co-PIs: Scott Dewey and Ingrid Parry

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

See attached Quad Chart

Appendix B – Participating site abbreviations

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

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 / Scott Dewey MS, PT

Org: Geneva Foundation

Award Amount: \$368,255

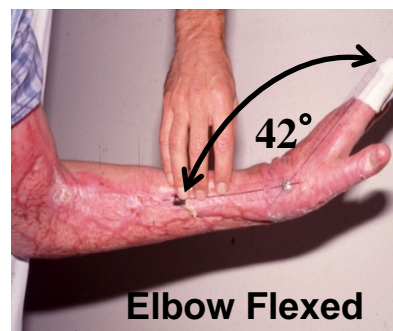
Study/Product Aim(s)

- 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.

Standard Goniometry (SG) Position to Measure Wrist Extension



Revised Goniometry (RG) Position to Measure Wrist Extension



Current enrollment- 62 subjects with 166 measurements. Interim analysis found statistically significant difference between limitation in motion with the revised and standard goniometry positions when analyzed in aggregate. Analysis of each measurement site resulted in 7 of 11 sites showing statistical significance. Enrollment will continue for four sites: neck extension, knee flexion, knee extension and plantarflexion.

Activities	FY	2014-15	2015-16	2016-17	2017-18
Quarter					
Facility contract negotiations/ system operations established					
Training conclave/on-site training					
Begin enrollment/data collection/audit/analysis					
Continue enrollment/data collection/audit/analysis					
Complete data analysis					
Begin data report organization					
Manuscript preparation/submission					
Estimated Budget (\$K)		\$219595	\$148660		

Updated: 14 Sept 17

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

- None

Budget Expenditure to Date

- Projected Expenditure: \$368K
- Actual Expenditure: \$232K