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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: Ingrid Parry and Scott Dewey

RECIPIENT: The Geneva Foundation

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PREPARED FOR: U.S. Army Medical Research and Development Command (USAMRDC) Fort Detrick, Maryland 21702-5012

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14. ABSTRACT

Objective: To test a Revised Goniometry (RG) method and compare it to Standard Goniometry (SG)used to measure burn scar contracted joint angles for determine 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.

Concluding Remarks: RG method resulted in significantly greater limitation in motion than SG: 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 RG but not with SG ($R^2=.05$, $p=.0008$). This demonstrates that RG is a more appropriate method for measuring scar contracture in burn survivors.

15. SUBJECT TERMS
Goniometry, burn scar contracture, burn

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1. INTRODUCTION:

Goniometry 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 goniometry has been described as reliable in burns, scarring can affect goniometry results based on patient positioning thereby leading to questions concerning the validity of standard goniometry as a measure of patient functional outcome for patients after burn injury. The current research investigation is aimed at critically assessing standard goniometry compared to a new paradigm of revised goniometry that is 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.*

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 Y1,Q1.***

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. The core protocol at ISR closed on 8-15-19 and all sites were closed by 9-13-19.***

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.

- ***Completed Y1Q3.***

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 Y1Q1.***

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 of 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

- ***CompletedY4, Q3.***

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.

- ***CompletedY4, Q3.***

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

- ***CompletedY4, Q3.***

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 Y4, Q3.***

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 Y4, Q3.***

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 Y4, Q4.***

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.

- ***Completed Y5, Q2***

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

- ***Completed Y5,Q2 (app) and Y5,Q4 (video reference).***

<u>What was accomplished under these goals?</u>

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 and LSU were eventually 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 closed (8/15/19).
- 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; Amned#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, **lead site closure 8/15/19.**

- 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, CR 2017= 8/29/17, CR 2018=5/23/18, **study site closed 09/21/18.**
- A-18469.c for site UOI (referenced IRB #201508809), Local IRB approval: initial= 10/21/15, CR2016 8/25/16, CR2017=7/17/17. HRPO approval: initial= 11/23/2015, CR2016=9/16/16, CR 2017= 10/24/17, **study site closed 11/7/18.**
- A-18469.d for site UCD (referenced IRB #808784), Local IRB approval: initial= 10/19/15, CR2016 9/1/16, CR2017=7/18/17, CR 2018=6/6/18. HRPO approval: initial= 11/18/2015, CR2016=9/16/16, CR 2017= 8/29/17, CR 2018=8/7/18, **study site closed 9/13/19.**
- A-18469.e for site REG (referenced IRB #A13-210), Local IRB approval: initial= 11/23/15, CR2016 10/27/16, CR2017=10/3/17. HRPO approval: initial= 4/1/16, CR2016=12/15/16, CR 2017= 10/24/17, **study site closed 11/7/18.**
- A-18469.f for site HOP (referenced IRB #00080816), Local IRB approval: initial= 12/22/15, CR2016 12/7/16, **CR2017=11/28/17**. HRPO approval: initial= 4/26/16, CR2017=1/27/17, CR 2018=1/3/18, , **study site closed 3/27/19**.
- 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 site closed 8/21/18.**
- A-18469.i for site UNC (referenced IRB #16-0922), Local IRB approval: initial= 7/5/16, Amend 3/7/17, CR2017=6/29/17 **CR2018=5/8/18.** HRPO approval: initial= 10/4/16, Amend=5/25/17, CR 2017= 7/27/17, CR 2018=6/29/18, **study site closed 12/17/18.**

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, educational lectures and hands-on training prepared for presentation to investigators participating at the Training Conclave.
- Randomization Table Agenda developed and used in the study:

Goniometry Measurement Randomization Table

Body Region	Is the Patient Eligible for GM Measurement in the Body Region? Yes/No	Eligibility Status	Random Number	Body Region Order	First GM Measurement
Neck Extension	N	Non-Eligible	NA	NA	NA
Shoulder Abduction	Y	Eligible	0.447878517	4	Standard
Shoulder Flexion	N	Non-Eligible	NA	NA	NA
Elbow Flexion	N	Non-Eligible	NA	NA	NA
Elbow Extension	N	Non-Eligible	NA	NA	NA
Wrist Flexion	Y	Eligible	0.656294653	3	Revised
Wrist Extension	Y	Eligible	0.02860599	5	Revised
Knee Flexion	N	Non-Eligible	NA	NA	NA
Knee Extension	N	Non-Eligible	NA	NA	NA
Ankle Dorsiflexion	Y	Eligible	0.831524794	2	Revised
Ankle Plantarflexion	Y	Eligible	0.884784562	1	Revised

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. An example of one of the tests:

Revised Goniometry Measurement Criterion Validity

Gold Standard Measurement	Minimal Allowable Deviation
45	3

	Measurement			
Rater	1	2	3	Mean
1	44	42	43	43.0
2	44	42	40	42.0
3	49	43	41	44.3
4	48	50	45	47.7
5	43	44	44	43.7
6	48	45	44	45.7
7	44	43	44	43.7
8	42	42	44	42.7
9	44	44	43	43.7

Pass/Fail
PASS
PASS
PASS
PASS
PASS
PASS
PASS
PASS
PASS

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

3a. Begin subject screening and data submission: (ISR; UCD; CS) Month 6-43. Completed Y4,Q3.

- 7/7 centers completed screening and enrolling (ISR, ARK, UCD, UOI, REG, HOP, UNC)

Participating site	Estimated number of subjects	Actual subjects enrolled	Number of measurements achieved	Body areas tested (primary, secondary)
ISR	72	7	22	20,2
UCD	48	29	68	46,22

REG	24	2	5	4,1
UOI	25	2	5	4,1
HOP	56	8	20	18,2
ARK	36	12	35	25,10
UNC	25	6	19	15,4

3b. Begin and continue data audit: (ISR; UCD) Month 6-43. Completed Y4, Q3.

- 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. CompletedY4, Q3.

- Subjects enrolled*: **66***
- Primary body sites obtained: ***132***
- Secondary body sites obtained:***42***
- Total: ***174 (1044 measurements)*** **bold indicates primary sites**

Count of	ISR	UCD	UOI	ARK	HOP	REG	UNC	**TOTAL**
Neck Extension	3	6		1			1	**11**
Shoulder Abduction	4	10	2	5	6		4	**31**
Shoulder Flexion	6	8		5	6		6	**31**
Elbow Extension	5	3		2	2	1	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		10						**10**
Plantarflexion		1						**1**
Ankle Dorsiflexion		7						**7**
TOTAL	**22**	**68**	**5**	**35**	**20**	**5**	**19**	**174**

3d. Begin and continue on-going data analysis: (ISR; UCD; CS) 43-45. Completed Y4, Q3

- Interim data analysis was conducted Y3,Q4. 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 (*$p \leq 0.001$). 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 Y4, Q3.

- 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)

	% Limitation in motion			
Joint motion	**GM Revised**	**GM standard**	**p-value**	**Cohen's D**
Dorsiflexion	**37.9%±11.4**	**26.8±9.3**	<.0001*	3
Plantarflexion**	**52.8%±2.5**	**37.2%±4.2**	0.0054*	
Knee flexion	**28.1%±11.1**	**24.6%±12.5**	0.0224*	1.55
Knee extension	**19.0%±10.4**	**15.9%±11.0**	0.0077*	3.86
Elbow extension	**26.0%±12.4**	**20.4%±13.7**	<.0001*	.73
Elbow flexion	**24.2%±8.6**	**18.3%±7.5**	<.0001*	.72
Shoulder abduction	**43.1%±11.7**	**38.8%±11.8**	<.0001*	1.09
Shoulder flexion**	**27.0%±9.0**	**28.2%±8.4**	0.0269*	.26
Wrist extension	**47.5%±22.0**	**36.4%±20.9**	<.0001*	1.31
Wrist flexion	**45.3%±14.7**	**30.1%±10.4**	<.0001*	1.55
Neck Extension	**59.0%± 24.9**	**55.6% ±14.1**	0.2920	.42

*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 ($R^2=.05$, $p=.0008$) 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 ($R^2=.04$, $p=.0025$) suggesting that as the % CFU scarred increases, there is a greater difference between ROM results with the standard and revised GM. (Aim 3)

- Conclusions:
  Objective assessment of functional outcome after a burn injury is essential to understanding the health needs of burn survivors. Measurement of ROM to assess burn scar contracture after burn injury is a foundational and valuable outcome measure for burn survivors due to the high frequency of movement related problems as a result of burn scarring. It can provide insight into the projected rate and degree of recovery after a burn injury, help define a patient's response to treatment and influence the development or modification of a patient's plan of care related to functional recovery. The findings of this study support that standard goniometry underestimates the clinical impairment for individuals whose motion is limited by scars and that revised goniometry is a more appropriate measure of motion limitation for patients with burn scars. The revised goniometric protocol investigated considers the unique characteristics of skin impairment and the impact on functional positions and is therefore recommended for clinical use and use in research when measuring burn scar contracture in burn survivors.

Task 4. Data Reporting

4a. Begin data report organization: (GF; ISR; UCD; CS) Y3, Month 45-52. Completed Y4, Q4

- An abstract summarizing the findings was written and presented at 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 received the Andre Zagame Award.
  2) Oral presentation at the American Burn Association Annual Meeting in Las Vegas, 2019. Study was awarded the "Best of Best" abstracts and Clinical Research Award.

4b. Manuscript preparation and submission: (GF; ISR; UCD; CS) Y3, Month 46-52. Completed Y5, Q2.

Manuscript accepted for publication in Journal of Burn Care and Research: Parry I, Richard R, Aden J, Yelvington M et al. Goniometric Measurement of Burn Scar Contracture: A Paradigm Shift Challenging the Standard. J Burn Care Res 2019:40(4):377-385. Appendix C.

4c. Development of a Burn-Specific Goniometry reference manual with pictorial and narrative descriptions of the revised positions. (GF) Months 45-60. Completed Y5, Q2 and Q4.

- Smart device application developed as electronic reference for concepts and techniques of revised goniometry (Appendix D)
- Webinar on CFU concepts, background work, Goniometry study and recommended positions developed and published by the American Burn Association: www.ameriburn.org

<u>What opportunities for training and professional development has the project provided?</u>

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.
- The findings of the study support the use of the revised positions in new burn therapist training within hospitals and in physical therapy and occupational therapy graduate programs.

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. Workshops have been conducted in Iowa and Canada:
  - 6th Annual Canadian Burn Conference September 22 - 24, 2019 - Shaw Centre, Ottawa
  - Midwest Region Burn Conference, Iowa City, Iowa - October 2 - 4, 2019

How were the results disseminated to communities of interest?

1) Oral presentation at national (ABA) and international (ISBI) burn conferences.
2) Manuscript published in Journal of Burn Care and Research. (Appendix C)
3) "Scar Goniometry" application for smart devices (iOS and android). (Appendix D)
4) Educational webinar offered through American Burn Association webpage.
5) Continued presentations and workshops at local burn meetings.

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

The study is now closed.

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 that are more relevant and useful for the burn population.

What was the impact on other disciplines?

- Create awareness between burn related disciplines of the impact of burn scarring on movement and outcome.

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

Nothing to report.

Changes that had a significant impact on expenditures

This study remained within the allotted budgeted amount.

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**

Publications:

Parry I, Richard R, Aden J, Yelvington M et al. Goniometric Measurement of Burn Scar Contracture: A Paradigm Shift Challenging the Standard. J Burn Care Res 2019:40(4):377-385.

Richard R, Parry I, Santos A, Dewey S. Burn Hand or Finger Goniometric Measurements: Sum of the Isolated Parts and the Composite Whole. J Burn Care Res 2017:38(6):e960-965.

Parry I, Forbes L, Lorello D., et al. Burn Rehabilitation Therapists Competency Tool – Version 2: An Expansion to Include Long-term Rehabilitation and Outpatient Care. J Burn Care Res 2016;38:e261-e268.

Conference abstracts and presentations:

American Burn Association conference 2016: "Cutaneous Functional Units Predict ROM Recovery with Therapy." Ingrid Parry and Soman Sen from UCD. Conference abstract and podium presentation.

International Society for Burns conference 2016: "Cutaneous functional units in burn rehabilitation: A new horizon" by Reg Richard, PI from ISR. Conference abstract and podium presentation.

American Burn Association conference 2017: Burn Hand or Finger Goniometric Measurements: Sum of the Isolated Parts ≠ the Composite Whole. Conference abstract and podium presentation.

International Society for Burns conference 2018: "Measuring burn scar contracture-challenging the standard." Ingrid Parry. Conference abstract and podium presentation.

American Burn Association conference 2019: "Measuring Burn Scar Contracture: Challenging the Standard." Ingrid Parry. Conference abstract and podium presentation.

Canadian Burn Conference, Shaw Centre, Ottawa, Sept 2019: "A Cutaneokinematic Approach to Rehabilitation of Burn Scars: Revised Goniometry Techniques." Presented by Mandy Yelvington.

Midwest Region Burn Conference, Iowa City, Iowa, Oct 2019: "A Cutaneokinematic Approach to Rehabilitation of Burn Scars." Presented by Mandy Yelvington.

- **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.

Smart device application "Scar Goniometry"

- Reference application for positions of revised goniometry.
- Available for iOS and android devices.

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.

- Online webinar for ongoing education about CFUs and the Goniometry study.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

Name: Ingrid Parry, MS, PT
Project Role: Co-Investigator – Geneva Foundation
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 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: The Quad Chart (available on https://www.usamraa.army.mil) shall be updated and submitted as an appendix.

9. APPENDICES:

Appendix A – Quad chart (separate file)
Appendix B – Participating site abbreviations
Appendix C – Publication (separate file)
Appendix D – Smart device application screenshots

Appendix A

Quad chart is submitted as a separate document.

Appendix B

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

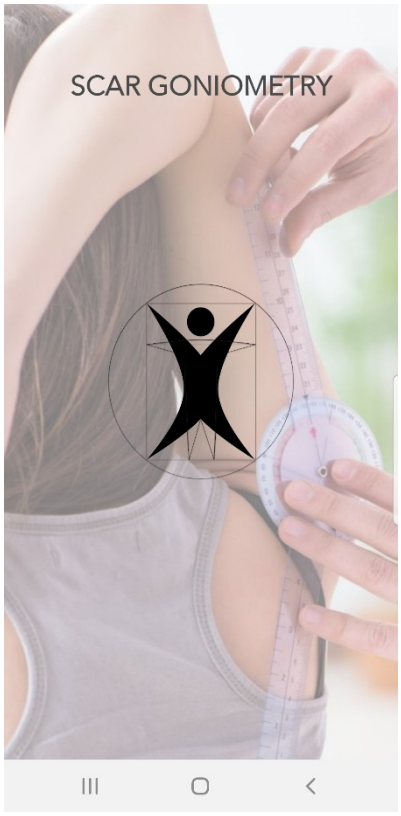
Appendix C

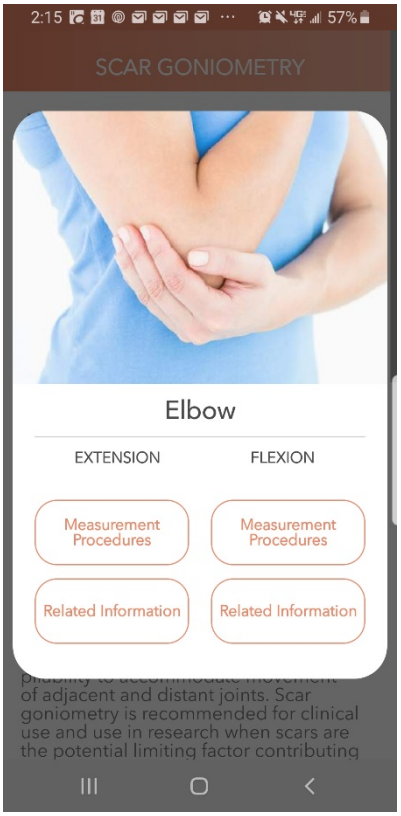
https://doi.org/10.1093/jbcr/irz038

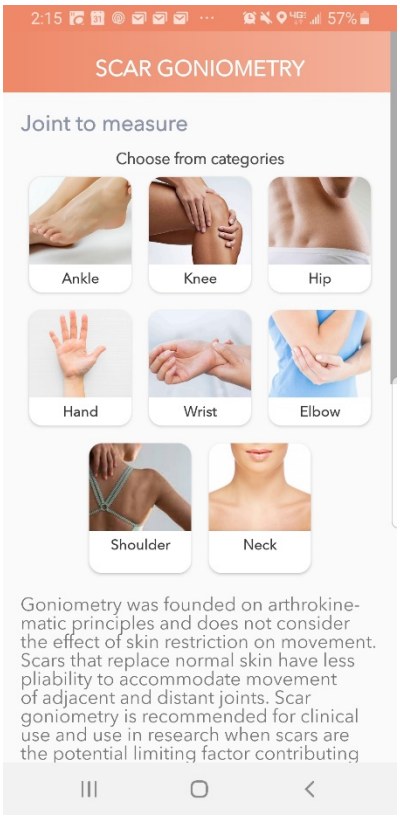
Pdf submitted as separate document.

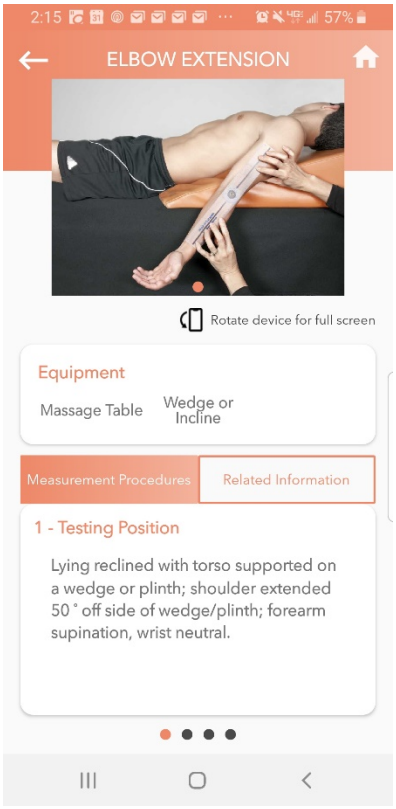
Appendix D

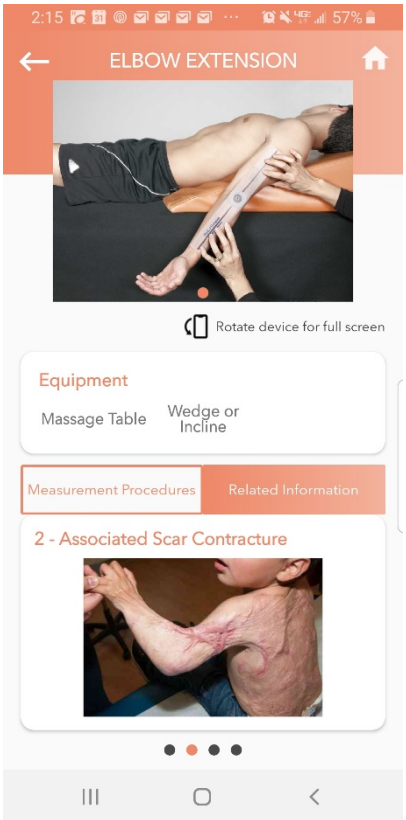
Screen shots from “Scar Goniometry” application.

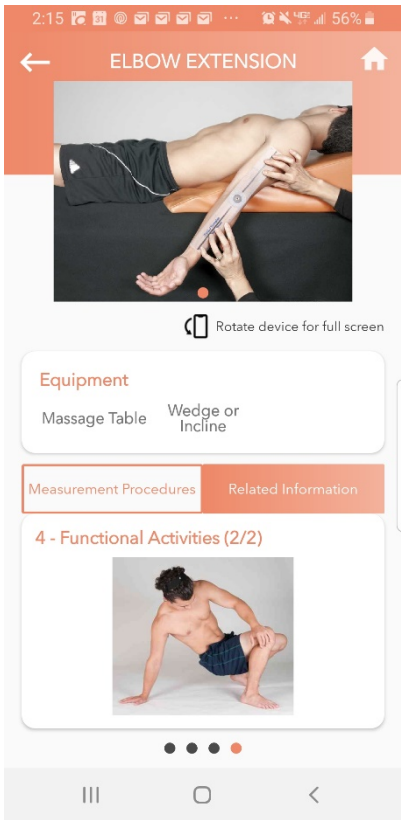












2019 CLINICAL RESEARCH PAPER AWARD WINNER, TOP 5 ABSTRACT WINNER

Goniometric Measurement of Burn Scar Contracture: A Paradigm Shift Challenging the Standard

Ingrid Parry, MS, PT, BT-C,[*] Reg Richard, MS, PT, BT-C,[†] James K. Aden, PhD,[‡] Miranda Yelvington, MS, OTR/L, BT-C, BPCR,[‖] Linda Ware, OT, CHT,[§] William Dewey PT, CHT,[¶] Keith Jacobson MPT,[**] Julie Caffrey, DO, MS,[††] and Soman Sen, MD, FACS[*]

Standard goniometry is the most commonly used method of assessing the range of motion (ROM) in patients with burn scar contracture. However, standard goniometry was founded on arthrokinematic principles and doesn't consider the cutaneous biomechanical influence between adjacent joint positions and skin pliability to accommodate motion. Therefore, the use of standard goniometry to measure burn scar contracture is called into question. This prospective, multicenter, comparative study investigated the difference between standard goniometry, based on arthrokinematics and a revised goniometry protocol, based on principles of cutaneokinematics and functional positions to measure ROM outcome in burn survivors. Data were collected for 174 joints from 66 subjects at seven burn centers totaling 1044 measurements for comparison. ROM findings using the revised protocol demonstrated significantly more limitation in motion 38.8 ± 15.2% than the standard protocol 32.1 ± 13.4% ($p < .0001$). Individual analyses of the motions likewise showed significantly more limitation with revised goniometry compared with standard goniometry for 9/11 joint motions. Pearson's correlation showed a significant positive correlation between the percentage of cutaneous functional units scarred and ROM outcome for the revised protocol ($R^2 = .05$, $p = .0008$) and the Δ between the revised and standard protocols ($R^2 = .04$, $p = .0025$) but no correlation was found with the standard goniometric protocol ($R^2 = .015$, $p = .065$). The results of this study support the hypothesis that standard goniometry underestimates the ROM impairment for individuals whose motion is limited by burn scars. Having measurement methods that consider the unique characteristics of skin impairment and the impact on functional positions is an important priority for both clinical reporting and future research in burn rehabilitation.

Goniometry has been used in rehabilitation to measure joint angles and range of motion (ROM) for decades.[1] Currently in burn rehabilitation, goniometry is the most commonly used method of measuring burn scar contracture and ROM outcome.[2] Joint specific reliability has been established for goniometry with healthy populations[3] and for burn populations specifically.[4] Conventional standard goniometric methods[3] that are currently being used however, were based on an arthrokinematic model of bony segments articulating around an isolated joint and positions limbs to reduce the influence of muscles that cross two joints.[3] For burn survivors, motion is typically limited by burn scar contracture which relates to an integumentary or cutaneous model effect on joint motion. The hallmark difference between the latter model and standard goniometry is that natural skin is a single, continuous piece of tissue that envelopes the entire body like a cocoon without joints, except for a few apertures such as exists between the upper and lower eyelids. This fundamental difference served as the basis for this investigation which aims to compare ROM results found in burn survivors when using standard goniometric methods to revised goniometric methods that consider a cutaneous model of movement.

Understanding the biomechanical influence of skin and scars on joint movement is necessary to evaluate the appropriateness of a revised method of goniometry for the burn survivor. Normal skin is adapted to accommodate extreme joint flexibility and ROM of multiple joints simultaneously. Research into cutaneokinematics (CKM), defined as the biomechanical assessment of skin movement, has demonstrated that: 1) body limb segments change length as joint ROM occurs[5]; 2) movement is accommodated by fields of skin, identified as cutaneous functional units (CFUs), that are associated with

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joint ROM and are more vast in surface area than previously realized[6]; 3) adjacent joint positions impact the amount of skin recruitment necessary to permit full ROM[7,8]; and 4) skin is recruited in a serial fashion during joint ROM.[9,10]

Each of these findings adds to the pool of understanding about the influence of skin on movement and merit further explanation. As a result of skeletal arthrokinematics, limb segments or extremities change length (ie, they become longer or shorter) as they move through an arc of motion.[5] The measurable amount of length change varies depending on the anatomic segment. Shoulder abduction has been found to result in the greatest amount of segment length increase with an average of 20.3 cm difference measured along a mid-axillary line from the iliac crest to the wrist.[5] The skin encompassing the torso and extremity accommodates this length change by elongating.

Richard et al[6] identified areas of skin subsequently called CFUs that functionally contribute to the ROM of a specific joint. CFUs that contribute to motion of various joints are not only found on or immediately adjacent to the joint as would be expected, but also, due to the continuous nature of skin, have been found to extend great distances from the associated joint skin crease. The importance of this concept relative to the current study is that skin or scars, even those distant from a joint of interest, need to be considered as a source of tissue recruitment for full ROM of that joint to occur. Natural skin is known to be extensible up to 50% of its original length.[11] Burn scars, by comparison, are relatively inelastic, being extensible only up to 15% of the original length in an immature state[11] and decreasing to 4% at maturity.[12] Therefore, the greater percentage of burn scarring in a given CFU, the less ability that area has to accommodate associated movements. This principle was shown in a study where the amount of burn scar in the CFU for shoulder motion was found to negatively correlate with ROM recovery after burn injury as measured with goniometry ($p < .0004$) and with motion analysis ($p < .002$).[13]

Furthermore, skin is recruited in a serial fashion.[9,10] That is, as joint ROM increases, skin is first recruited nearest the joint within the CFU, then progressively further away from the joint to complete the movement.[6] This understanding of the ability of skin versus scar to elongate and serially recruit surrounding skin provides insight into other research that has documented the influence of adjacent joint position on ROM results with burn survivors.[7,8] Richard et al[7] demonstrated that the position of the elbow (extended or flexed) resulted in statistically more or less skin recruitment along the forearm, and consequently available wrist extension ROM ($p < .001$). Figure 1 provides a visual example of the influence of adjacent joint position. In patients with hand burns, composite finger ROM with proximal joints in maximal flexion showed significantly more limitation in motion than when the proximal joints were extended, and the tissue slackened ($p < .001$).[8] It is well established that patient position, as well as extremity or limb segment position, is a fundamental and critical factor for reliability of goniometry to measure joint ROM in a variety of different patient populations and there is wide support in the literature for standardizing patient position when performing goniometry.[4,14–16]

Burn scar contracture, defined as a lack of sufficient, extensible tissue to permit full joint ROM,[17] occurs frequently with burn survivors and often results in functional limitation. Reported incidences of burn scar contracture ranges between 18 and 50%.[18–21] The foregoing described research provides evidence which suggests that using standard goniometry to measure ROM in clinical situations where natural skin has been replaced with burn scar may not appropriately capture limitations in motion, such as those experienced by burn survivors. Standard goniometric methods do not account for the interaction of natural skin and burn scars in accommodating or restricting movement. Having reliable and valid methods of assessing ROM after a burn injury is essential for reporting the severity of a burn scar contracture because it is a primary measure of outcome in this population. Based on the results of a pilot study,[22] the aim of the following described research was to challenge the current fundamental practice of standard goniometry for measuring burn scar contracture and evaluate if a revised goniometric protocol incorporating CKM principles and functional positions is a more appropriate means to measure and document ROM outcome in burn survivors.

METHODS

Study Design

We performed a prospective, multicenter, comparative study investigating the difference between two goniometric protocols

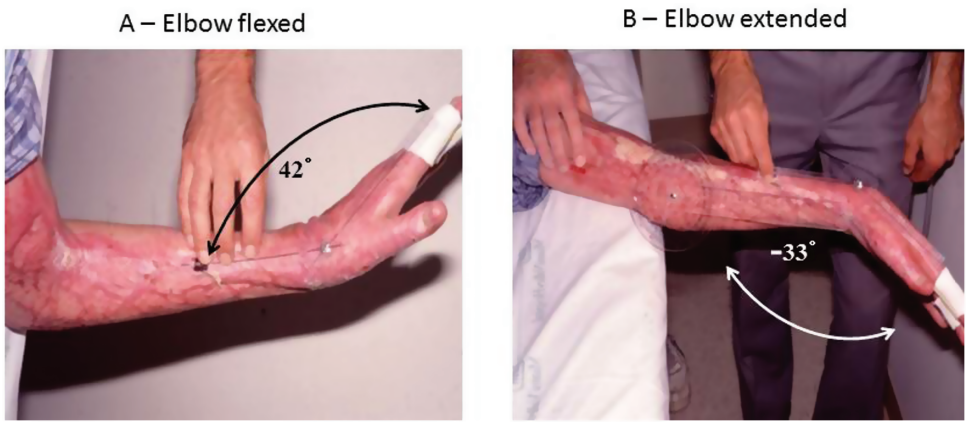

Figure 1. A visual example of the clinical difference of revised versus standard goniometric positions. A. Active wrist extension of 42° in the standard goniometric position (elbow flexed) compared with (B) active wrist extension of –33° in the revised goniometric position (elbow extended). Note that the patient is unable to fully extend the elbow in the revised position (B) due to an insufficient amount of pliable tissue to permit full ROM at either the wrist or the elbow.

for measuring ROM outcome in burn survivors: 1) a commonly used standard goniometric protocol based on arthrokinematics[3] and 2) a revised goniometric protocol developed using principles of CKM with consideration of common functional positions. Subjects between the ages of 18 and 60 years old with burn scar contracture(s) were recruited for participation. To be enrolled, subjects must have had a qualifying contracture angle of a joint (Table 1), as a result of burn scars. Subjects were evaluated to ensure the movement limitations were due to burn scar tightness and not a result of other causes such as pain, wounds, muscle tightness, joint capsular tightness, or bony deformity. Body areas with limitation of motion from causes other than burn scars and patients with prior surgically placed tissue flaps were excluded. Any joints that had a limitation in motion before the burn injury per patient report were also excluded.

Photographs were taken of the subjects' scars and an electronic body diagram using the surface area graphic evaluation (SAGE) (SageDiagram, LLC, Portland, OR) (Figure 2) program calculated the percentage of the CFU affected by scarring. The computerized SAGE program is patterned off the commonly used Lund–Browder burn body diagram but was modified to incorporate CFU modeling.[23] All bandages and clothing around the joint of interest were removed before the goniometric measurements. The subject's scar tissue was preconditioned by asking the subject to actively move through her/his available ROM multiple times before the goniometric angles were measured. Maximal active ROM was measured three times in the standard goniometric position and three times in the revised goniometric position. The series of 2 × 3 measurements was conducted in a random and successive order during the same visit as dictated by a computer-generated randomization schema specifically designed for this study. The electronic block randomization table was used to determine if the revised or standard position was measured first and to determine the order of joint motions measured (if multiple motions for the same subject qualified). A 12.5 inch, 360° clear plastic goniometer, with 2° increments of angle measurement (Prestige Medical, Northridge, CA) was used by all study investigators. After each measurement, the subjects returned to their starting position, and the goniometer was closed and reset between each measurement.

Standard and Revised Goniometry Protocols

The standard goniometric positions used were the positions defined by Norkin and White which have been shown to be commonly used in burn rehabilitation.[2,4] The majority of goniometric methods cited in burn rehabilitation studies[3,24–26] provide minimal instructions for proximal joint position during the measurements.[24–26] However, the Norkin and White reference provides more detailed instructions with pictures and has demonstrated excellent intra-rater (ICC > .99) and inter-rater (ICC > .94) with the burn population.[2–4] Therefore, this reference was selected and used as the standard goniometric protocol for comparison to the revised goniometric protocol.[3]

The revised goniometric positions were developed through analysis of the skin within a given CFU to determine if the skin was slack or taut in the measurement position. Then the relationship of the measurement position to common positions of function, adjacent joint position, and the influence of length of muscles that cross two joints was considered when developing the revised goniometry positions. The major difference between the standard and the revised goniometric methods were the positions of adjacent joint or limb segments. The standard goniometric protocol positioned the proximal adjacent joint such that the surrounding skin was slackened compared with a taut skin position for the revised goniometric protocol, in consideration of CKM principles and common functional positions. An example of the associated CFU region, standard goniometric position, revised goniometric position, and common functional task for elbow flexion is pictured in Figure 3A–D. Supplementary Figure 1 is provided with pictorial representation of all of the standard and revised positions used in the study. An effort is currently underway to make the detailed revised protocol available to all burn clinicians in the form of an electronic application.

Goniometric measurements were recorded for 11 body motions: neck extension (NE), shoulder flexion (SF), shoulder abduction (SA), elbow flexion (EF), elbow extension (EE), wrist flexion (WF), wrist extension (WE), knee flexion (KF), knee extension (KE), ankle dorsiflexion (DF), and ankle plantarflexion (PF). Hands were excluded from this study because previously published research had reported that

Table 1. Values for normal range of motion (ROM) reference, maximum allowable ROM for enrollment, and formula for calculating contracture severity

Joint Motion	ROM Normal Reference	*Maximum ROM or Contracture Angle (CA) to Be Enrolled	Formula to Determine % Contracture Severity (CS) Calculation
Neck extension	50°	34°	$CS = \frac{50-CA}{50} \times 100$
Shoulder abduction	180°	162°	$CS = \frac{180-CA}{180} \times 100$
Shoulder flexion	170°	157°	$CS = \frac{170-CA}{170} \times 100$
Elbow flexion	145°	132°	$CS = \frac{145-CA}{145} \times 100$
Elbow extension	0°	−12°	$CS = \frac{-CA}{145} \times 100$
Wrist flexion	75°	65°	$CS = \frac{75-CA}{75} \times 100$
Wrist extension	70°	59°	$CS = \frac{70-CA}{70} \times 100$
Knee flexion	135°	120°	$CS = \frac{135-CA}{135} \times 100$
Knee extension	0°	−9°	$CS = \frac{-CA}{135} \times 100$
Ankle dorsiflexion	16°	11°	$CS = \frac{-CA+15}{45+15} \times 100$
Ankle plantarflexion	45°	37°	$CS = \frac{60-CA}{45+15} \times 100$

*Determined by taking normal ROM-*SD* × 95% to account for 5% error.

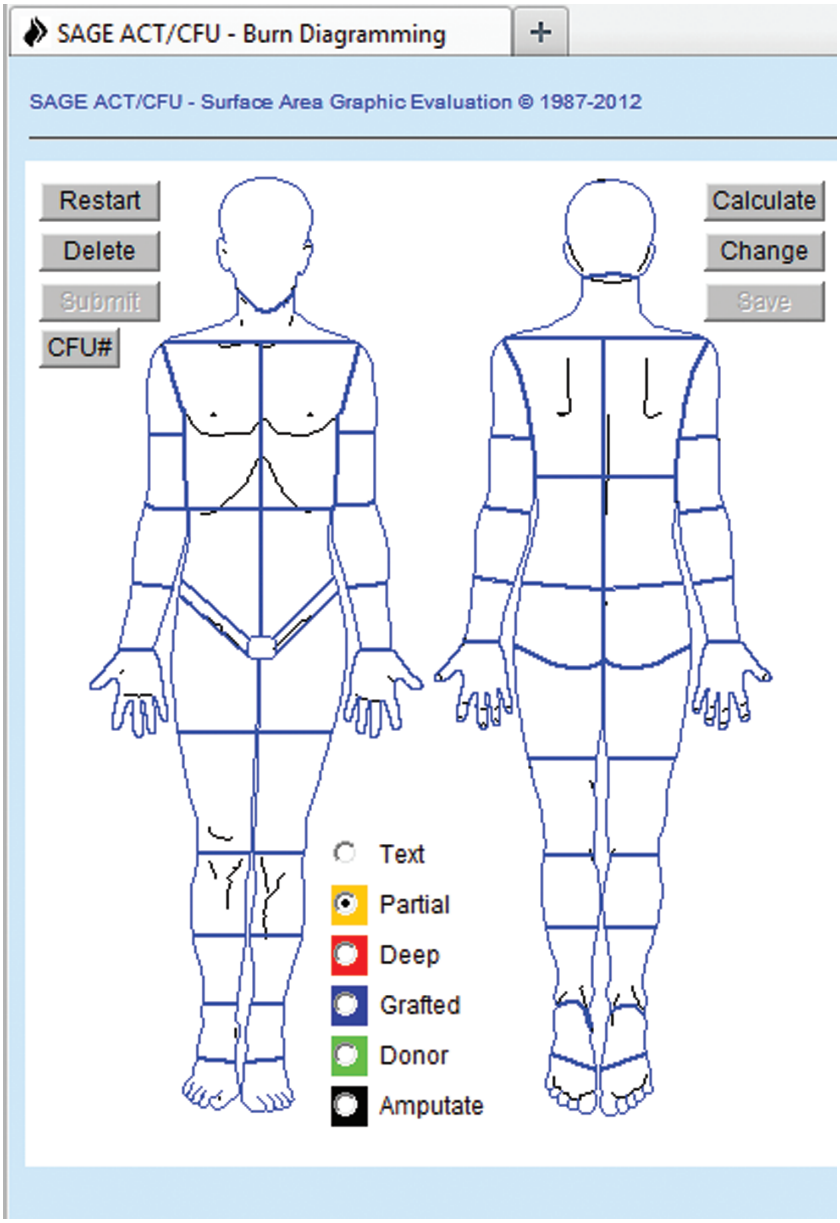

Figure 2. Surface area graphic evaluation for calculation of cutaneous functional units.

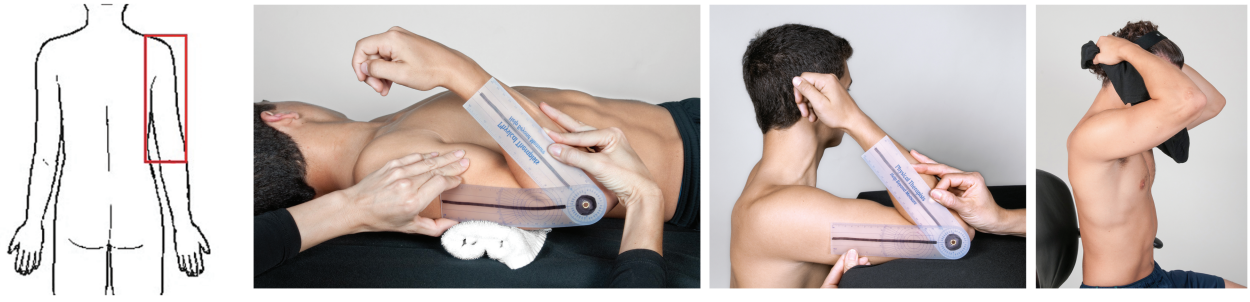

Figure 3. Example of cutaneous functional unit (CFU), standard position, revised position, and common functional task for elbow flexion. A. CFU (area of skin recruitment) when flexing elbow. B. Standard goniometry position for measuring elbow flexion: Supine with the adjacent proximal shoulder joint positioned at 0° flexion and surrounding skin in a slackened position. C. Revised goniometry position for measuring elbow flexion: Sitting with the adjacent proximal shoulder joint positioned at 90° flexion and surrounding skin in a taut position. D. Common functional position when using elbow flexion (donning a shirt).

measurement of finger ROM with adjacent joints in a composite (with skin taut) position compared with an isolated (with skin slackened) position resulted in greater limitation in motion.[8] Hip ROM was excluded from the present study due to lack of an adequate revised position model at the time the current study was conducted. It should be noted that for this study, the standard goniometric positions for two joints (SF and PF) place the surrounding tissue in a taut position. These are positions similar to what would be recommended for the revised positions therefore, for SF and PF, the revised positions were established as "proof of concept" tests. In the final data analysis, these two motions were grouped according to the test position resulting in "taut" adjacent skin (revised goniometry) instead of "slack" adjacent skin (standard goniometry).

Prestudy Training

To ensure consistent measurement of ROM between the investigators at each of the seven participating sites, in-person training on techniques for each study protocol was conducted at the outset of the study. Laminated photo cards of each of the measurement positions were provided to the investigators for reference and used throughout the study and an exercise to establish inter-rater and intra-rater reliability was conducted.

Human model manikins (SimMan® 3G, Laerdal Medical, New York and TOMMannikin, Innovative Tactical Training Solutions, Kentucky) were positioned with the study joints of interest at predetermined angles for training and reliability testing. After a period of training, blinded goniometers were given to the investigators. Each investigator measured the angle of the represented 11 joints on the manikins three times in succession and the blinded measurements were recorded by the proctor in a computerized measurement analysis program. The program assessed the measurement error based on the known joint angle and a measurement tolerance error from the reported standard deviation for measuring each joint.[3] After each measurement test, the analysis program indicated whether the investigator successfully passed or failed measuring each joint within the acceptable range. Those investigators who failed measuring any joint accurately were then retrained in the proper placement of the goniometer and underwent repeated testing until each investigator was able to measure within the measurement tolerance. At the conclusion of the training, all study investigators had successfully passed all the goniometric measurement trials ensuring a standard benchmark of reliability for study participation.

Data Analysis

Based on a previous pilot study, a power analysis was initially conducted for this study to detect a 6 ± 11° difference between the standard and modified methods.[22] This analysis showed that an overall sample size of 31 joint measurements were sufficient to establish significance with power set at 80% and alpha at 0.05. However, for the sake of research veracity, the lead investigators chose to aim for collection of 31 comparative measures of each of the 11 joints (341 total).

ROM data are reported as percent of contracture severity (Table 1) rather than absolute ROM values due to different normal ROM values for the various joints. Data were summarized for each motion using means and *SD*. The data were then analyzed by comparing the standard to the revised goniometric measurements using a mixed model ANOVA with each subject representing a random effect in the model. Cohen's *d* calculations were performed to determine the magnitude of the effect size relative to the standard deviation of the percent contracture severity per movement.

Pearson's correlations were performed between the severity of joint limitation and the percentage of CFU involvement for the standard goniometric results, revised goniometric results and the Δ between the protocols. Average within-subject variability was calculated for each joint measured to determine the repeatability of the measures within subject. The results are presented as the square root of the average within-subject variability which is the within-subject *SD*. These *SD*s were then compared using a paired *t*-test to determine if the within-subject error was different between the standard and revised methods. All analyses were performed using JMP v13.0 (SAS Corp., Cary NC).

This study was conducted under a protocol reviewed and approved by the US Army Medical Research and Materiel Command Institutional Review Board and in accordance with the approved protocol and approved by all local participating site Institutional Review Boards.

RESULTS

Data were collected for 174 joints from a total of 66 subjects at seven different burn centers, resulting in 1044 goniometric measurements (522 standard, 522 revised) for comparison. Most subjects were male (75%), the average age of subjects was 39 (±11) years old and average total body surface area burned was 32% (±22%). Demographic and burn injury data are presented in Table 2. When evaluating and comparing the ROM outcome data for all motions measured, the revised goniometric protocol demonstrated significantly more limitation in motion (38.8 ± 15.2%) than the standard goniometric protocol (32.1 ± 13.4%) ($p < .0001$) (Table 3). In addition to analysis of the revised versus standard protocols that included all motions, each individual joint motion was evaluated separately to compare the revised position to the standard position. Individual joint results likewise showed significantly more limitation in motion with the revised goniometric methods compared with the standard goniometric methods for 9/11 motions (Table 3). NE showed a greater limitation with the revised goniometric protocol but the difference did not reach statistical significance. SF showed a greater limitation in the standard goniometric position but with a Cohen's *d* value of 0.26 and a difference in percent contracture of only 1.2% (Table 3), indicated need for further analysis. Because the shoulder moves in multiple planes and potentially recruits skin on both the anterior and posterior torso, a subanalysis of SF and SA combined was conducted. Results of the subanalysis demonstrated significantly greater limitation in shoulder motion in the revised (taut) position (35.04 + 10.3%) compared with the standard (slack) position (33.33 + 10.1%) ($p < .0001$) which is consistent with the other study findings.

Within-subject variability was calculated for each motion and converted to within-subject *SD* estimates to determine

Table 2. Demographic information of subjects

Subjects (*N*)	66
Males	54 (75%)
Age (mean ± *SD*)	39 ± 11 years
TBSA (mean ± *SD*)	32 ± 22%
Time from original burn (mean ± *SD*)	279 ± 563 days
Race	
Caucasian	46 (64%)
Asian	4 (6%)
African American	14 (19%)
Other/unknown	2 (1%)
Hispanic	15 (21%)

the reliability of the measurements (Table 3). These results showed that the within-subject *SD*s for percent contracture were very similar except for NE. NE had more variability with *SD* of 4.1% for the standard method and 5% for the revised method which may also have contributed to the lack of significance between the protocols for this motion. Paired *t*-test revealed no significant difference between the within-subject *SD* for the standard versus revised methods ($p = .30$) for all motions.

Pearson's correlations showed a significant, yet weak, positive correlation between the percentage of CFU affected by scarring and ROM outcome for the revised goniometric protocol ($R^2 = .05$, $p = .0008$). No correlation was found with the standard goniometric protocol ($R^2 = .015$, $p = .065$) indicating the revised goniometric method may be a more sensitive method of assessment for the burn population. In addition, a significant weak positive correlation was also found between the amount of CFU scarred and the Δ between the revised and standard goniometric protocols ($R^2 = .04$, $p = .0025$) suggesting that as the % CFU scarred increases, the greater the difference in ROM measurements found between the standard and revised goniometry methods.

DISCUSSION

Objective assessment of functional outcome after a burn injury is essential to understanding the health needs of burn survivors.[27] It can provide insight into the projected rate and degree of recovery after a burn injury, help define a patient's response to treatment and influence the development or modification of a patient's plan of care related to functional recovery. Limitation in ROM is just one measurement among many within the various domains of functional outcome as defined by the World Health Organization International Classification of Functioning (WHO ICF).[28] Yet ROM is a foundational and valuable outcome measure for burn survivors due to the high frequency of movement-related problems as a result of burn scarring.[29,30] In the burn community, there is momentum toward the development of a set of common data elements and standards for burn recovery to measure and optimize the path toward functional recovery.[27,31] Specifically, quantifying burn scar contracture is an essential component of understanding movement recovery and intuitively relates to all other levels of functional outcome such as activity limitations and participation restrictions.[32] Methods that are currently being used to assess burn scar contracture and ROM after burn injury involve measuring movement at a single, isolated joint and do not take into account the cutaneous biomechanical interaction between the position of adjacent joints and the influence of skin (or scar) to accommodate terminal positioning of two consecutive joints together. Therefore, when burn scars or other integumentary impairments are the source of movement limitation, the ability of these traditionally accepted methods of measurement to quantify true limitation of ROM is called into question.

The results of the current study demonstrate that when measuring ROM outcome for burn survivors using revised goniometric methods based on CKM, values are significantly less than when using standard goniometric methods. These findings support the notion that standard goniometry underestimates the clinical impairment for individuals whose

Table 3. Results for revised and standard goniometry (GM) protocols

		Limitation in ROM (% ± *SD*)		Repeated Measures ANOVA		Within-Subject *SD* (%)	
Joint Motion	***N***	**GM Revised**	**GM Standard**	***p* Value**	**Cohen's *d***	**Revised**	**Standard**
Dorsiflexion	7	37.9 ± 11.4	26.8 ± 9.3	<.0001*	3.0	2.8	2.6
Plantarflexion†	1	52.8 + 2.5	37.2 + 4.2	.0054*	5.2	4.2	2.5
Knee flexion	10	28.1 + 11.1	24.6 + 12.5	.0224*	1.55	1.5	1.9
Knee extension	4	19.0 + 10.4	15.9 + 11.0	.0077*	3.86	1.3	1.9
Elbow extension	17	26.0 + 12.4	20.4 + 13.7	<.0001*	0.73	1.1	1.3
Elbow flexion	3	24.2 + 8.6	18.3 + 7.5	<.0001*	0.72	0.7	1.2
Shoulder abduction	31	43.1 + 11.7	38.8 + 11.8	<.0001*	1.09	1.7	1.5
Shoulder flexion†	31	27.0 + 9.0	28.2 + 8.4	.0269*	0.26	1.9	1.2
Wrist extension	31	47.5 + 22.0	36.4 + 20.9	<.0001*	1.31	3.0	2.8
Wrist flexion	28	45.3 + 14.7	30.1 + 10.4	<.0001*	1.55	2.8	2.7
Neck extension	11	59.0 ± 24.9	55.6 + 14.1	.2920	0.42	5.0	4.1
All motions	174	38.8 ± 15.2	32.1 + 13.4	<.0001*	–	2.4	2.2

†Proof of concept motions.

motion is limited by scars. The revised goniometric protocol specifically considers the unique characteristics of skin impairment and the impact on functional positions. ROM results using the revised protocol showed a significant positive correlation with the amount of scarring in the associated CFU. This correlation was statistically weak however, CFUs did not correlate with standard methods of goniometry thus providing further evidence that revised goniometry may be a more appropriate strategy for measuring ROM outcome with burn survivors.

NE and SF deviated from the overall results when analyzed individually and merit further comment. First, although NE had a greater limitation with the revised protocol like the other motions, it did not reach statistical significance. Measurement of neck motion using a universal goniometer is complex due to the involvement of multiple vertebrae contributing to the motion as well as poorly defined anatomical landmarks for goniometer placement. NE was found to have a low Cohen's *d* statistic and a relatively higher within-subject *SD*, indicating a variation in measurement that is consistent with the broader literature and may have contributed to why NE only trended toward statistical significance in the present study. SF showed a statistical difference with the standard protocol having slightly more limitation in motion (1.2% or 2°) which was surprising given the other findings and suggests further information regarding the CFUs associated with shoulder motion is needed. Unlike other areas tested, the shoulder joint has great excursion of motion in multiple planes and potentially may recruit skin in more than just the predefined CFUs (anterior torso for SA and posterior torso for SF). This observation led to the decision to conduct a subanalysis of the two shoulder motions, SF and SA, together in subjects who had both limitations. Results of the combined analysis demonstrated significantly greater limitation in motions in the revised (taut) positions. This finding is consistent with the overall study findings and the described theoretical principles. It is unlikely that the CFUs involved with NE and SF would behave differently from other CFUs even accounting for the anisotropic nature of skin (ie, CKM varying throughout the body and between individuals). Based on the slight magnitude of their statistical failure, it would be unreasonable to think that these two skin fields, as part of a contiguous piece of tissue, would respond decidedly different in their biomechanical behavior compared with the other 9 areas. However, these findings spur the need for more detailed investigation of CKM related to movement in burn survivors, especially in the areas with larger fields of skin (eg, torso).

Another important consideration for measuring movement is attention to the position of the body or adjacent limbs that are optimal for function. Many of the standard goniometric positions do not represent common functional positions (Figure 3B). This may explain why in recent literature, a correlation is lacking between ROM as measured with goniometry and ROM as measured with three-dimensional motion analysis during functional tasks.[13] In clinical situations, a patient may be able to exhibit and be measured to have acceptable ROM of an isolated joint but be unable to satisfactorily function due to a net deficit in tissue length availability through the CKM chain, as seen in Figure 1. Alternately, available ROM may be less than functionally defined limits and therefore, a patient will make significant postural compensations to complete a task.

Ultimately, the significance of scar contracture lies in its limitation on function.[33] The link between burn scar contracture, as represented by a limitation in motion, and "function" is not well established in the burn literature. Functional ROM is a term loosely used to describe a patient's ability and the ROM required to perform a functional task.[34] Functional activities incorporate the synchronous movement of multiple joints to perform a task and the ROM needed is task specific. Functional ROM of a particular joint to perform one task may be different for another functional task. When CKM are not considered, many burn survivors with severe scar contractures could be considered clinically functional.[20,35] However, burn survivors who have limitation of movement at multiple joints may perform functional tasks using poor body mechanics or significant compensation which can lead to fatigue, further injury or a less-functional modification of the task over time. This situation often complicates a disability evaluation with the intent to clear a patient to return to full unrestricted work or service. Compensatory strategies may be a result of CKM restriction, or limitations that for the burn survivor, are not explained well with standard goniometric techniques. Further complicating the reporting of scar contracture, is the variety of strategies currently used in the literature to classify the severity of scar contracture.[20,21,30] Recent studies recommend using task-specific functional ROM as a reference source.[33,34,36,37] Our revised goniometric protocol aligns with the concept of measuring and classifying burn scar contracture according to functional tasks.

Although statistically significant, it is prudent to evaluate if the difference in ROM results between the protocols investigated represent a difference that is clinically significant. This study established that there is a difference between the revised and standard goniometric methods however, the meaningfulness of the findings for each protocol and the difference between protocols, from a clinical perspective, has yet to be studied. Clinicians should use caution when making ROM judgments about what is "clinically significant or not" for patients. There is currently no consensus among clinicians or third-payer parties as to what degree of contracture merits treatment or continued treatment. Ranges of motions that result in what would be considered a minimal contracture or an acceptable contracture to clinicians can be evaluated differently from the burn survivor's perspective. There is currently no patient anchored definition of clinical significance for loss of ROM or severity of burn scar contracture. Even slight reduction of "normal" ROM can result in painful movement, movement that requires compensation or inefficient movement, all of which may influence a patient's perception of their function and quality of life. As shown in Figure 1, wrist extension ROM using the standard goniometric position would yield a "mild" clinical scar contracture according to commonly used contracture classification scheme.[20,21,30] However, using the revised goniometric position to measure ROM would result in a reclassification of the patient's contracture to "severe" using the same classification paradigm and may render a more clinically accurate picture of the patient.

To determine the potential clinical impact of the differences found between the revised and standard goniometric protocols,

we can apply our findings to a study that reports ROM outcome in a large population of burn survivors.[30] Godleski et al[30] used standard methods for measuring ROM to report average quantitative values of ROM limitation from 659 burn patients in the National Institution on Disability, Independent Living and Rehabilitation Research, Burn Model Systems database. As a practical example, we will use our findings for EF and compare to the average ROM values reported by Godelski et al to demonstrate the clinical impact of using the revised ROM protocol to measure burn scar contracture. They report that the average limitation for EF was 24% or 33° (±27°) resulting in an average of 107° of available EF. We found that when skin and scar movement is considered and the revised goniometry methods are used, subjects had 6% more limitation, which applied to the Godleski et al data would have resulted in an average available ROM for EF of 96°, 11° more limited. Oosterwijk et al[36] reported that 32 of the 45 ADL tasks evaluated, required greater than 96° of EF. Four of the tasks they evaluated fell between the range of 96° to –107°, including using one's arms to stand from a sitting position, typing on a keyboard and using a computer mouse. For individuals needing those particular tasks, using the revised goniometric methods would result in a clinically significant measurement difference. The effect of using the revised protocol will varying depending on the joint due to varying amounts of normal joint excursion, severity of existing contracture, functional tasks related to the motion, as well as size of CFU from which tissue is recruited. In our study, some motions were found to have larger differences in ROM than this example (up to 16% difference) and others had smaller differences between the protocols.

Determining a change in ROM that represents clinical significance cannot fully be determined from this example nor from the literature at this time. Because without a standard classification of burn scar contracture which is based in patient centered and functional task-specific measurement values, it is difficult to determine the true clinical significance of absolute or changes in ROM measurements. However, as clinicians, we play the role of patient advocate and, as such, it is incumbent to use the availability of "best practices" when reporting outcomes for our patients' sake. This study establishes a more appropriate means of measuring burn scar contracture than standard methods. To fully understand and interpret impairment results, which provide objective and measurable information to the clinician, future studies are needed to evaluate the relationship of ROM findings using measurement methods relevant to the burn survivor to a patient's experience and perceived impact on function.

A limitation of the current study is that all subjects had to have a qualifying burn scar contracture to participate. It is unknown if the same differences between the techniques would be found for more minor contractures. However, the CKM principles would apply regardless, so the revised goniometric positions would still be applicable in practice. In addition, all patients in this study were adults so the results cannot be generalized to pediatric patients at this time. The measurements in this study relate to impairment only, and conclusions cannot be made about outcomes other than ROM/burn scar contracture. Further investigation is needed and encouraged in order to determine the relationship between ROM outcome using the revised protocol and other outcomes that are important to the burn survivor such as function, return to work, and quality of life.

The ability to measure motion loss with valid, reliable, and appropriate techniques enables the clinician to target tissues responsible for impairment and improves their capacity to design treatment plans that are impairment specific. Enhancing treatment plan specificity can potentially reduce resolution time and enable clinicians to better project time to resolution of burn scar contracture. Burn survivors themselves, third-party payers, employers, and military medical boards alike are interested in knowing how much time patients will be out of commission or unable to work and how much therapy is needed for their recovery.

CONCLUSION

The present study addresses concerns with using standard goniometry, a commonly accepted method of measuring burn scar contracture, in burn survivors. Standard goniometric techniques are lacking consideration of the biomechanical influence of skin which can be significantly altered by scar tissue after a burn injury. Tools or methods used to measure outcome should appropriately capture influential characteristics of the specific patient population being tested. The results of this study demonstrate that a revised goniometric protocol with CKM considerations detected significantly more limitations in ROM, suggesting that the currently used standard goniometric measurement protocols may be over-reporting ROM outcome and under-representing the motion problems in burn survivors. The newly revised protocol is therefore recommended for clinical use and use in research when measuring motion in an individual with scarring.

SUPPLEMENTARY DATA

Supplementary data are available at *Journal of Burn Care & Research* online.

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