

Award Number: W81XWH-14-1-0173

TITLE: "Evaluation of the King-Devick Test to Assess Eye Movements and the Performance of Rapid Number Naming in Concussed and Non-Concussed Service Members"

PRINCIPAL INVESTIGATOR: Dr. Michael L. Russell; Dr. Michael Dretsch

CONTRACTING ORGANIZATION: The Geneva Foundation
Tacoma, WA 98402

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TYPE OF REPORT: Annual

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

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14. ABSTRACT This study's objective is to determine to what extent the King-Devick Test results discriminate healthy individuals from both their pre-Combatives baseline and their post-Combatives assessment, to determine to what extent individuals diagnosed as having an mTBI event differ from their King- Devick Test pre-Combatives baseline, and to determine to what extent individuals who report a history of concussion during their pre-Combatives baseline differ from those who have not reported a prior concussive event.					
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Introduction:

The primary study objective is to determine the concurrent validity, sensitivity, and specificity of the King-Devick Test to cognitive impairment of attentional processes associated with acute mild traumatic brain injury (mTBI) in service members.

Keywords:

MTBI, concussion, neurocognitive

ACCOMPLISHMENTS:

What were the major goals of the project?

- 1) Initiate, Plan and Design Study [Months 2-3]
- 2) Execute Study (collect and analyze data) [Months 3-9]
- 3) Conclude Study [Month 10]

What was accomplished under these goals?

Transfer of study to new project PI (MAJ Dretsch).

Imaging protocol and related documents approved at Auburn University IRB.

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

Nothing to report.

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?

Modify protocol and related documents. Get expedited SRC and IRB review and approvals.

Impact

N/A

Changes/Problems

The proposal was received through the Broad Agency Announcement in FY12 with Dr. Mike Russell as the PI and the Geneva Foundation submitting on his behalf. Funding was identified for the study in FY14 and was subsequently awarded on 30 June 2014 (W81XWH-14-1-0173). During the gap between submission and award, Dr. Russell left the institution and Dr. Harvey Watson was identified as the new PI. Late summer 2014, we received word that Dr. Watson would be retiring in October 2014, hence initiating our search for yet another PI. Through consultation with subject matter experts at our Army laboratories, we were able to enlist MAJ Mike Dretsch, Ph.D. as the new PI. We then moved forward with several telecons with the on-site PI, The Geneva Foundation, the EAMC IRB representatives and others to begin the process to coordinate the switch in PI. Dr. Watson was unavailable for all of these calls and we were not able to reach him after several attempts. In early December 2014, Dr. Watson stated that he would not be retiring until Summer/Fall 2015. He continued as an ORISE fellow under OTSG. As of July 2015, MAJ Dretsch officially became the new PI. However, MAJ Dretsch was not able to get permission to access IRBNet until 21 July 2015. MAJ Dretsch made revisions to the SOW to now include an imaging component that will supplement and improve the current study that was developed by Dr. Russell and Dr. Watson. The IRB Chair at Eisenhower Army Medical Center advised MAJ Dretsch that the protocol would need a scientific review and new letters of support from brigade level commanders would be necessary prior to initiation of an IRB review.

Changes in approach and reasons for change

N/A

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

Dr. Watson maintained his position as project PI until late May 2015. MAJ Dretsch was informed he would be the new PI, but PCS'd to Fort Eustis, VA in 15 June 2015. He was unable to access IRBNet until late July 2015. During this time, the site PI at Fort Benning, GA PCS'd and was replaced.

MAJ Dretsch is working on getting required letters of support in order to submit the revised protocol.

Changes that had a significant impact on expenditures

A brain imaging component was added to the protocol. USAMRMC provided an additional \$98K to the contract with Geneva Foundation in order to carry out this component.

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

An initial brief screening for MRI eligibility is being added. Eligible subjects that volunteer for this arm of the study will also be screened for MRI contraindicators upon arrival Auburn University MRI Research Center. Subjects that participate in the imaging arm of the study will be monetarily compensated for their time.

Products

Nothing to report

Publications, conference papers, and presentations

N/A

Participants & Other Collaborating Organizations**What individuals have worked on the project?**

Name:	Dr. Michael Dretsch
Project Role:	Principal Investigator
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	3.6
Contribution to Project:	Dr. Dretsch serves as the overall study PI on this research project.

Name:	Jenifer Fauth
Project Role:	Project Director
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	9
Contribution to Project:	Jenifer Fauth serves as the Project Director and on-site lead for this research project.

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

MAJ Dretsch officially took over as the overall study PI this month (July 2015). The site PI was also recently replaced.

What other organizations were involved as partners?

Auburn University MRI Research Center will be providing structural brain scans as part of a tertiary arm of the study in order to assess changes in the brain associated with both combatives training and concussion.

Organization Name:

Auburn University

Location of Organization: (if foreign location list country)

Partner's contribution to the project (identify one or more)

- Financial support;
- In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);
- Facilities (e.g., project staff use the partner's facilities for project activities);
- Collaboration (e.g., partner's staff work with project staff on the project);
- Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and
- Other

Special Reporting Requirements

None

Collaborative Awards

Nothing to report

Quad Charts

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

Appendices

Evaluation of the King-Devick Test to Assess Eye Movements and the Performance of Rapid Number Naming in Concussed and Non-Concussed Service Members

Log Number 12089007

W81XWH-14-1-0173

PI: Dr. Michael Dretsch

Org: The Geneva Foundation

Award Amount: \$403,671

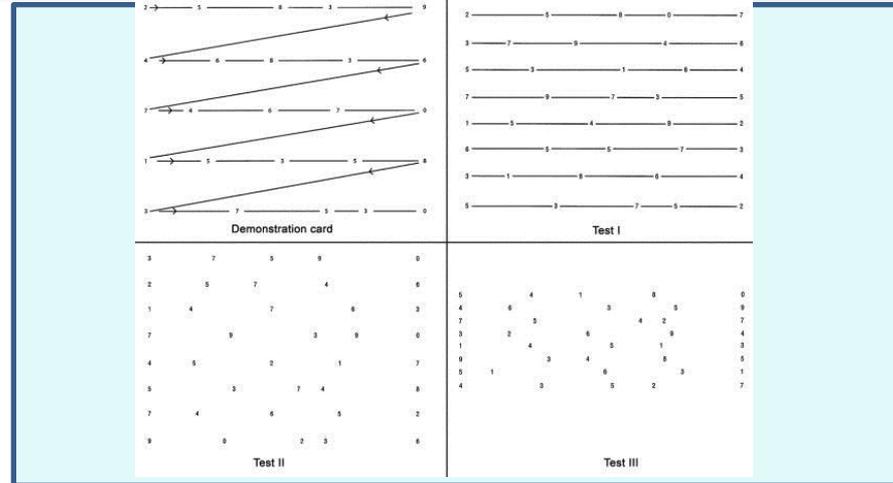


Study/Product Aim(s)

- Main Study Aim is to evaluate the ability of the King-Devick test to accurately detect concussions in Soldiers; Does the Post Incident K-D Test vary from the individual's pre-combatives baseline assessment?
- Additional Aims:
 - b. Does the** pre-combatives baseline K-D Test assessment of individuals who report a history of concussion on their baseline questionnaires vary from the pre-combatives baseline K-D Test assessment of individuals who have not reported a prior concussion event
 - c. Does the** post-combatives K-D Test assessment vary from the pre-combatives baseline assessment in healthy individuals who do not suffer a concussive event.

Approach

- Subjects will be recruited at the Fort Benning Combatives School, and other Combatives training
- Recruitment will occur on the first day of training during Soldiers' in-processing
- Any Soldier that volunteers to participate will be given the informed consent and HIPAA documents
- Any volunteers that agrees to the consent process will be given a pre-combatives questionnaire and K-D test before training begins
- Volunteers who suffer a concussive event during training will be given a post-incident questionnaire (which includes the MACE and GCS) and K-D test within 24 hours after the event occurs
- Volunteers who do not have a concussive event during training will be given a post-training questionnaire and K-D test on the last day of their training
- Recruitment and testing will be conducted until 100 concussed Soldiers have been tested



Picture above shows the King-Devick test card. Each participant will start with the demonstration card and continue through each test. Participants are instructed to read the numbers from left to right, and are informed that it is a timed event. Average test time is less than two minutes.

Timeline and Cost

Activities	CY	14	15	16
Finalizing protocol documents, training employees, meeting with post personnel, and awaiting IRB approval				
Hire additional study personnel, complete training, begin data collection				
Complete data collection and begin data analysis				
Complete data analysis, and publish findings				
Estimated Budget (\$403,671K)		\$99,540	\$201,835	\$102,295

Goals/Milestones

CY15 Goals –

- Obtain IRB approval
- Begin data collection
- Complete data collection and begin data analysis by end of fourth quarter

CY16 Goals –

- Complete data analysis
- Publish and Present Findings

Comments/Challenges/Issues/Concerns

- Initially projected that IRB approval and data collection would begin by CY14. The estimated time frame has been moved to CY15.
- If off by more than one quarter in spending, comment here.

Budget Expenditure to Date

Projected Expenditure: \$199,081

Actual Expenditure: \$64,335 as of 07.28.15

Updated: 07.28.15