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W81XWH-19-2-0003

TITLE:

Evaluating a Portable Virtual-Reality (VR) Balance Test as a Vestibular Assessment Screen

PRINCIPAL INVESTIGATOR:

Daniel M. Merfeld

CONTRACTING ORGANIZATION:

The Ohio State University
Department of Otolaryngology
915 Olentangy River Rd.
Columbus, OH 43212

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14. ABSTRACT This is a collaborative effort between teams at The Ohio State University (OSU) and the Naval Medical Research Unit Dayton (NAMRUD). This effort proposes observational trials to evaluate a semi-portable balance test. Each installation will be equipped with the balance assessment tools and vestibular test facilities to collect data from samples for each of the aims (detailed below). Ultimately the goal is that a portable, virtual balance system will be validated for use in laboratory, clinical, and operational settings as a screening tool for vestibular insult and injury					
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1. **INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

This is a collaborative effort between teams at The Ohio State University (OSU) and the Naval Medical Research Unit Dayton (NAMRUD). This effort proposes observational trials to evaluate a semi-portable balance test. Each installation will be equipped with the balance assessment tools and vestibular test facilities to collect data from samples for each of the aims (detailed below). Ultimately the goal is that a portable, virtual balance system will be validated for use in laboratory, clinical, and operational settings as a screening tool for vestibular insult and injury

2. **KEYWORDS:** *Provide a brief list of keywords (limit to 20 words).*

Vestibular thresholds, TBI, Balance

3. **ACCOMPLISHMENTS:** *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

Major Task 1: Develop VR scenes and quiet stance balance protocol

Major Task 2: Develop dynamic posturography test protocol

Major Task 3: Quantify quiet stance balance and vestibular function in 100 healthy civilians

Major Task 4: Quantify dynamic balance function and vestibular function in 20 healthy civilians

Major Task 5: Quantify quiet stance balance function and vestibular function in 100 healthy military personnel

Major Task 6: Quantify dynamic balance function and vestibular function in 20 military personnel

Major Task 7: Quantify balance and vestibular function in between 30 and 60 patients

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

Major Activities and Specific Objectives

Activities in the preceding quarter have focused on developing required technical facilities and working to begin human data collection. These efforts relate to specific objectives regarding IRB approval (Tasks 1.1 and 2.1), implementing VR and experiment control algorithms (1.2), and collaborating with CRA on dynamic force plate development (2.2).

Our OSU Moog platform – required for proposed civilian threshold testing– is now fully operational. We demonstrate this by showing fully analyzed human subject threshold data (Figure 1). (Our first pilot study using this system is being completed. We will share these data in the next quarterly progress report.

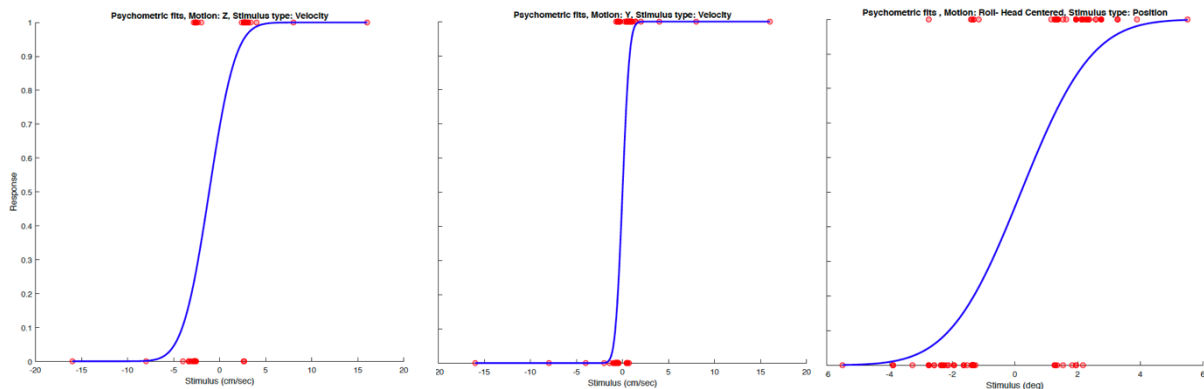


Figure 1. From left to right, the three panels show threshold data (red) and fitted psychometric function (blue) for inferior-superior translation (z-translations), inter-aural translation (y-translation) and head-centered roll tilt. Methods are identical to those we have previously published. In brief, motion was always a single cycle of sinusoidal acceleration. The frequency was 1Hz for translation and 0.2 Hz for roll tilts. Upright subjects were translated upward/downward (left panel), translated rightward/leftward (center panel), or roll tilted to their left/right (right panel). Subjects indicated whether they perceived leftward (negative) or rightward (positive) motion. While additional test conditions will be added, these are the three primary test conditions needed for our proposed study.

We also made progress on our new NAMRUD Moog. As a major hurdle that took almost 3 months of effort, we now can remotely login to the OSU computers located at NAMRUD for running the OSU Moog platform located at NAMRUD. We were able to get the human chair attached and fully operational. We have moved the device under control of our computer but are still working on full software control implementation. Wiring is 90% completed. The remaining 10% of the wiring, which is expected to take no more than a day, awaits our ability to run the device using our Integrated Control Environment (ICE) software (expected in June 2020). In the next quarter, we hope to get this device fully operational for human studies (i.e., under control by our ICE software, perform a characterization, and complete safety testing/validation.)

Our progress implementing VR scenes and collaborating with CRA was delayed - largely due to delays in purchase order approval by OSU purchasing, which were resolved just before the most recent quarter. We now anticipate delivery of the motion platform and VR system next quarter.

Dr. Stephen Glass (the fellow working full-time on this project) obtained a faculty job sooner than expected. While great news for him, this has slowed our progress. We have met with and interviewed 3 potential fellows – one of whom will begin at NAMRUD in June. We continue our search process at OSU.

As noted in previous reports, our human subjects protocol was approved by the Ohio State University Medical Center IRB, and the NAMRU-Dayton IRB ceded review to the OSU IRB that approved the protocol. Therefore, we have accomplished our primary objectives of attaining protocol approval.

Balance Protocol Development Testing

ADVISOR – Balance Data Summary, 5/14/2020

Data Analysis

Charles River conducted quiet-standing balance testing of 25 individuals while they stood on an AMTI AccuSway force platform, under four testing conditions. All testing occurred while the study participants stood on a foam pad placed on the force platform. A virtual reality headset (Ocular Quest) was used for two of four testing conditions. Testing conditions were: Eyes Open, No Virtual Reality Headset (NVR); Eyes Open, Virtual Reality Headset worn (VR); Eyes Closed, No Virtual Reality Headset (NVR Closed); and Eyes Closed, Virtual Reality Headset Worn (VR Closed). The order of these were counterbalanced. Per confirmation with Charles River, each trial was 60 seconds in duration, collected at a sampling frequency of 50 Hz. We have

These de-identified data were shared with us for analysis. Data were first filtered using a low-pass Butterworth filter with a 5 Hz. cutoff. Data were then demeaned and resulting calculations were made to obtain a variety of commonly calculated traditional sway measures. While over 80+ postural sway parameters exist, we chose to calculate those most commonly reported, and were purposeful to include both directional and resultant measures. Our outputs were: A/P Sway Range (mm), M/L Sway Range (mm), Mean Velocity (mm/s), A/P Mean Velocity (mm/s), M/L Mean Velocity (mm/s), RMS Distance (mm), 95% Confidence Ellipse Area (mm²), and a measure known as Mean Frequency (Hz). We opted to include Mean Velocity instead of Total Excursion, as Mean Velocity (Total Excursion/Time) allows for better comparisons across studies of varying trial durations. It should be noted that some of these measures are known to be highly correlated to each other and as such, it is likely unnecessary going forward to include all of them.

RESULTS

After removing the 3 trials that were unusable, averages and standard deviations were calculated for each of the conditions, as shown below.

	Eyes Open - No VR (NVR)	Eyes Open – VR (VR)	Eyes Closed - No VR (NVR)	Eyes Closed – VR (VRC)
AP Sway Range (mm)	37.97 ± 12.69	40.09 ± 19.02	45.93 ± 22.07	45.60 ± 23.41
ML Sway Range (mm)	28.60 ± 9.94	26.64 ± 11.98	28.8 ± 11.50	28.46 ± 12.47
Mean Velocity (mm/s)	17.30 ± 5.25	15.65 ± 4.04	19.60 ± 5.58	18.57 ± 5.58
AP Mean Velocity (mm/s)	12.73 ± 4.61	11.95 ± 3.83	14.89 ± 6.22	14.10 ± 5.71
ML Mean Velocity (mm/s)	8.91 ± 3.28	7.41 ± 3.38	9.28 ± 3.30	8.83 ± 3.85
RMS Distance (mm)	8.30 ± 2.63	8.36 ± 2.83	10.05 ± 5.18	8.72 ± 3.43
95% Confidence Ellipse	371.69 ± 208.90	369.94 ±	572.86 ± 705.81	432.48 ±

Area (mm ²)		287.75		372.79
Mean Frequency (Hz)	0.41 ± 0.12	0.37 ± 0.122	0.41 ± 0.12	0.43 ± 0.14

As far as general trends, prior to conducting statistical analysis, it is noted that:

- Considering the No VR conditions, and recognizing that individuals were on foam which generally increases sway measures notably (especially in the eyes closed condition), all values appear within an expected/reasonable range.
- As we have seen before, the standard deviation of the 95% Confidence Ellipse Area is nearly as large, if not larger, than the mean value. This has led us in the past to place less emphasis on this measure.
- Without the virtual reality set on, sway measures get – as expected – higher on average when eyes are closed. This is simply further confirmation that the data is as expected.
- With Eyes Open, the VR system appears to have a slightly positive effect (e.g. reduction in sway) in most measures. This is somewhat unexpected, though the differences are small and not consistent across all parameters.
- In the Eyes Closed condition, the presence or absence of the VR system does not seem to generally affect sway, with some measures again showing a slight positive effect with the headset worn.
- Based on consistency in standard deviations, and differences across conditions, mean velocity (mm/s) is standing out as a likely primary outcome to reveal if there are differences or not.

Statistical Analysis

As our primary question of interest, we examined the differences between the Eyes Open, No Virtual Reality vs. Eyes Open, Virtual Reality conditions using a Wilcoxon Signed Rank Test within IBM SPSS statistical software. Note that $p < 0.05$, without a Bonferroni correction was used due to the exploratory nature of this investigation. Also note, that because one trial had to be removed from this comparison, there were 24 study participants included in this analysis. This means that averages and standard deviations for the VR condition are slightly different than what appeared earlier in the report due to the removal of this trial pair.

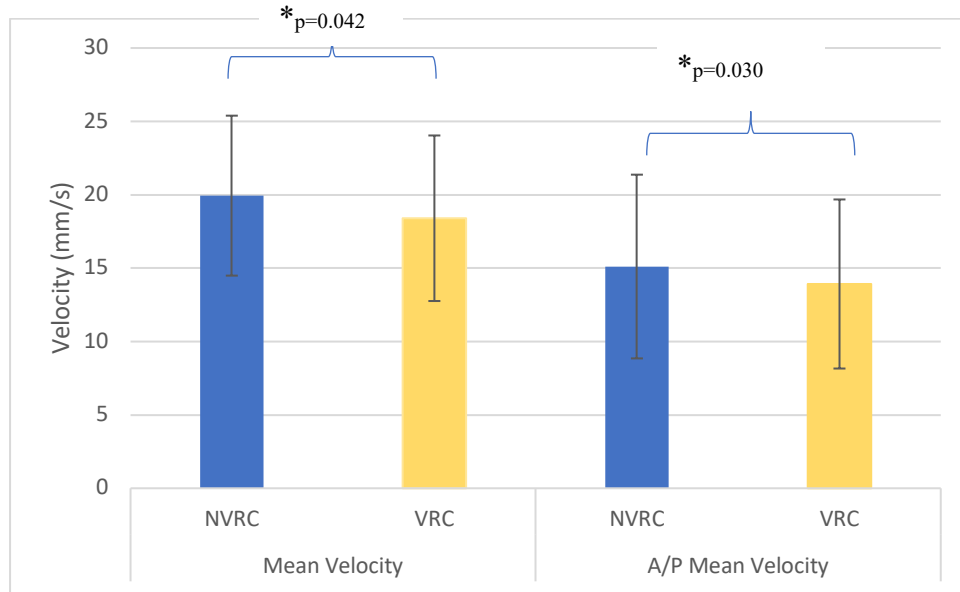
Results are as follows:

	APSR_VR - APSR_NVR	MLSR_VR - MLSR_NVR	MV_VR - MV_NVR	APMV_VR - APMV_NVR	MLMV_VR - MLMV_NVR	RMC_VR - RMS_NVR	CEA_VR - CEA_NVR	MFREQ_VR - MREQ_NVR
Z	-.514 ^b	-1.029 ^b	-2.029 ^b	-1.743 ^b	-2.171 ^b	-.971 ^b	-1.229 ^b	-1.799 ^b
Asymp. Sig. (2-tailed)	.607	.304	.042	.081	.030	.331	.219	.072

a. Wilcoxon Signed Ranks Test

b. Based on positive ranks.

Specifically, **a significant difference ($p=0.042$) was found for mean velocity, with the mean velocity being lower (“better”) with virtual reality than without (15.64 ± 4.04 mm/s vs 17.48 ± 5.29 mm/s).** However, when repeated measures are considered this was **NOT statistically significant**. It is noted that, even if significant, this difference is fairly small in magnitude. These results are shown below, with the error bars representing standard deviation. All other parameters were not significant, suggesting that the VR system does not systematically affect all aspects of sway and that, as others have found, mean velocity may be more sensitive to detecting group/condition differences.



As a secondary analysis, we examined whether the headset itself (not the virtual reality) contributed to changes in sway by comparing the Eyes Closed, No Virtual Reality vs. Eyes Closed, Virtual Reality Conditions. Note that two study participants had missing data and were removed from this comparative test, leaving 23 study participants in this Wilcoxon Signed Ranked Test. Statistical results were:

Test Statistics^a

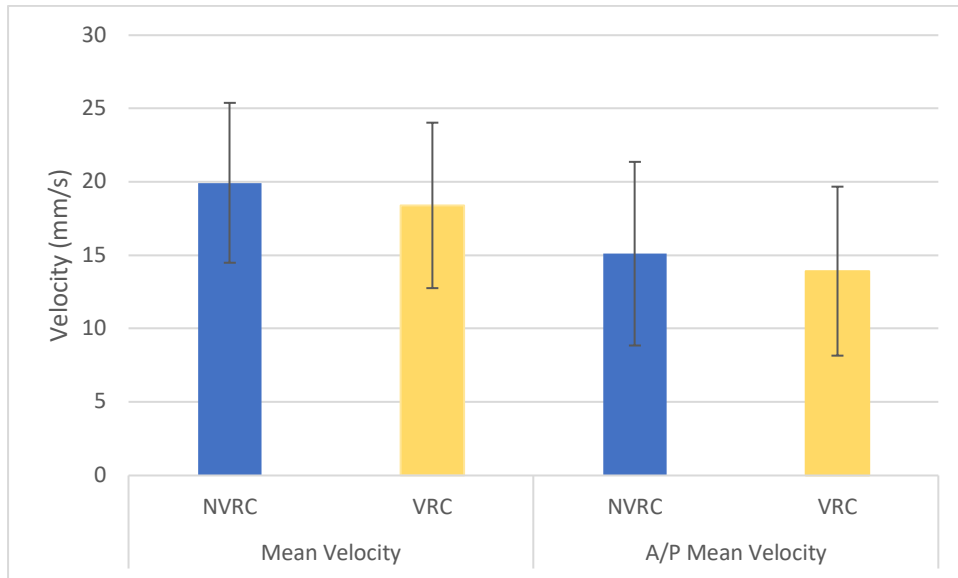
	APSR_VRC - APSR_NVRC	MLSR_VRC - MLSR_NVRC	MV_VRC - MV_NVRC	APMV_VRC - APMV_NVRC	MLMV_VRC - MLMV_NVRC	RMS_VRC - RMS_NVRC	CEA_VRC - CEA_NVRC	MFREQ_VRC - MFREQ_NVRC
Z	-.274 ^b	-1.582 ^c	-1.916 ^c	-1.825 ^c	-1.125 ^c	-1.414 ^c	-1.217 ^c	-.330 ^b
Asymp. Sig. (2-tailed)	.784	.114	.055	.068	.260	.157	.224	.741

a. Wilcoxon Signed Ranks Test

b. Based on negative ranks.

c. Based on positive ranks.

No significant differences were found ($p > 0.05$ for all parameters), suggesting that the presence of the headset did not affect postural sway, thus any differences observed in the VR condition are likely due to VR and not just wearing of the headset. It should be noted that Mean Velocity ($p = 0.055$) and A/P Mean Velocity ($p = 0.068$) did approach significance but, as above, when repeated measures are considered, this does not appear interesting. In both cases, as previously, sway slightly “improved” (mean velocity got slower) when the headset was worn (19.94 ± 5.45 mm/s vs. 18.40 ± 5.64 mm/s for mean velocity; 15.11 ± 6.26 mm/s vs. 13.92 ± 5.76 mm/s for A/P mean velocity). These results are shown below, with the error bars representing standard deviation.



As a terse summary, the results suggest that VR can yield balance performance that does not differ significantly from balance when viewing “real” world visual scenes. While additional pilot studies are needed, this initial finding is positive as it supports moving forward with virtual reality for balance testing.

Results, Outcomes, and Conclusions

Other than solid preliminary data described above, we have no experimental results or conclusions to report at this time.

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

If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. “Training” activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. “Professional development” activities result in increased knowledge or skill in one’s area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

The PI attended the Vestibular Oriented Research meeting as did several other team members – both OSU team members and NAMRUD team members.

How were the results disseminated to communities of interest?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to report.

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

We hope that the COVID lockout ends soon. As soon as we can get back to the lab, we plan to finish getting our test facilities ready for testing and continue initial preliminary data collection to develop our final test protocol.

- 4. IMPACT:** *Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

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

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Since primary scientific studies have yet to begin (consistent with original plan), no impact yet.

What was the impact on other disciplines?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Since primary scientific studies have yet to begin (consistent with original plan), no impact yet.

What was the impact on technology transfer?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Since primary scientific studies have yet to begin (consistent with original plan), no impact yet.

What was the impact on society beyond science and technology?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Since primary scientific studies have yet to begin (consistent with original plan), no impact yet.

- 5. CHANGES/PROBLEMS:** *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

Charles River Analytics has yet to deliver a dynamic motion platform (Major Task 2) as they are struggling to meet acceptable specifications. We are evaluating alternatives, including use of a multi-dimensional motion platform available from NAMRUD.

COVID-19 has obviously impacted progress as we have been locked out of research labs for the past 2 months.

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

Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

COVID-19 has delayed progress. Since we were ahead of schedule prior to COVID, we are hopeful that this will have minimal impact, but a full recovery from COVID delays of nearly 3 months will likely require two or more years as we cannot make up 2-3 months of lost effort overnight.

Changes that had a significant impact on expenditures

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

None yet.

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

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

No significant changes.

Significant changes in use of biohazards and/or select agents

Not applicable.

6. PRODUCTS: *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state “Nothing to Report.”*

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

Report only the major publication(s) resulting from the work under this award.

Not applicable.

Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to report.

Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to report.

Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year*

(international, national, local societies, military meetings, etc.). Use an asterisk () if presentation produced a manuscript.*

Nothing to report.

- **Website(s) or other Internet site(s)**

List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Not applicable.

- **Technologies or techniques**

Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

None yet.

- **Inventions, patent applications, and/or licenses**

Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

None yet.

- **Other Products**

Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

- *data or databases;*
- *physical collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

Partially funded by this project, we have accomplished the following:

- a) Gotten one OSU test facility – Moog 6DOF platform – collecting data. (Data will be included in next quarterly report.)
- b) Gotten our semi-portable static balance systems nearly operational (expected to be operational first quarter of year 2).
- c) Gotten our Moog platform at NAMRUD installed and moving (expected to be operational first or second quarter of year 2).

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate “no change”.

Example:

Name:	Mary Smith
Project Role:	Graduate Student
Researcher Identifier (e.g. ORCID ID):	1234567
Nearest person month worked:	5

Contribution to Project:

Ms. Smith has performed work in the area of combined error-control and constrained coding.

Funding Support:

The Ford Foundation (Complete only if the funding support is provided from other than this award.)

Name: Merfeld, Dan

Project Role: Professor

Person Month Worked: 3.1

Name: Glass, Stephen

Project Role: Post-Doc Researcher

Nearest Person Month Worked: 1.6

Name: Shukla, Ritu

Project Role: Post-Doc Researcher

Nearest Person Month Worked: 11.5

Name: Siers, Lee

Project Role: Clinical Engineering Specialist

Nearest Person Month Worked: 3.6

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

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

As previously approved, PI support under this effort has been reduced from 20% to 10% to allow inclusion of two balance experts – Drs. Bigelow and Chaudhari – from year 2 onward.

What other organizations were involved as partners?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:

Organization Name:

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*

Organization Name: NAMRU-Dayton

Location of Organization: Wright Patterson Air Force Base, OH

Partner's contribution to the project: Facilities, data collection, and data analysis

The University of Dayton will join this project in year 2.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to <https://ers.amedd.army.mil> for each unique award.*

QUAD CHARTS: *If applicable, the Quad Chart (available on <https://www.usamraa.army.mil>) should be updated and submitted with attachments.*

- 9. APPENDICES:** *Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.*