

NIOSH Closeout Summary with Publications

Title: Low Back Pain In Cyclic and Prolonged Occupational Activities
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Telephone: (504) 568-2251
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Program Area: Musculoskeletal Disorders: Low Back
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Final Report Abstract:

ABSTRACT

The role of spinal ligaments subjected to cyclic (repetitive) and static (prolonged) occupational activities as a source of work related musculoskeletal disorders was the objective of this investigation. It was hypothesized that ligaments subjected to cyclic and static activities develop, over time, creep (stretch) or tension-relaxation (loss of tension) and reduce the mechanical stability of the intervertebral joints. It was further hypothesized that with creep or tension-relaxation, the sensory receptors in the ligaments become de-sensitized and that in turn reduces the reflexive activation of lumbar muscles which further reduces mechanical stability and increases exposure to injury and disability. It was further anticipated that many hours of rest will be required to restore normal function.

The importance of the research to occupational safety and health is vested in the fact that epidemiologic data points out that workers exposed to daily activities requiring repetitive lumbar flexion (loading-unloading cargo, manufacturing/assembly, farm workers, etc.) and to static lumbar flexion (mechanics, brick/concrete workers, welders, roofers, etc.) report up to 10 times more episodes of low back disorders relative to other groups. The biomechanical and physiological processes active in the development of such disorders are not fully known nor are they scientifically experimentally validated. Identification of the biomechanical/physiological processes active in the development of such low back disorders will produce significant improvements in their prevention, treatment, restructuring work/rest schedules and designing optimal work conditions. Substantial financial savings could be materialized by the government and private/public sectors in reduction of medical expenses, disability payments, lost manpower and cost of manufacturing.

The approach employed in this research utilizes the "in-vivo" feline model subjected to cyclic and static loads applied to the lumbar spine to induce anterior flexion while recording creep/tension- relaxation of the ligaments (and other viscoelastic tissues) simultaneously with EMG from the multifidus muscles.

The results of the three years investigation provided new and significant insights into the biomechanical and physiological principles active in the development of a common

idiopathic low back disorder. The data obtained to date also provide experimental validation of epidemiological data pointing out that repetitive and static work activities are indeed risk factors for musculoskeletal disorders.

The major finding consist of the fact that twenty minutes (20 min) exposure to cyclic or static lumbar flexion resulted in a complex neuromuscular disorder consisting of seven components:

Substantial development of creep/tension-relaxation in the lumbar ligaments as well as other viscoelastic tissues (discs, capsule, dorsolumbar fascia) during the static or cyclic loading periods, (i.e., work period).

Sharp decrease in the reflexive activation of the posterior muscles over the same work period.

Routinely observed spasms from the posterior muscles superimposed on the decreasing EMG over the work period.

During a rest period immediately following the work period, the creep/tension- relaxation set in the ligaments did not fully recover over seven hours. The model developed predicts full recovery in 24-48 hours.

During the first hour of the rest period, muscular hyperexcitability was present in the muscles.

A delayed, often severe and prolonged muscular hyperexcitability was present in the 3rd - 7th hours of rest.

A slow recovery to normal reflexive muscular activity was present throughout the seven hours of rest.

A mathematical model was developed and fitted to the experimental data. The model describes the various components of the neuromuscular disorder as a function of work and rest time and could be used to assess, predict and prevent low back disorders by optimizing work/rest schedules. Further refinement of the model can adapt its use to prediction and prevention of Cumulative Trauma Disorders (CTD).

Overall, the research performed to date confirm experimentally that static and cyclic work activities are risk factors and delineates important biomechanical and physiological infrastructure active in the development of a transient common idiopathic low back disorder associated with repetitive and static occupational activities. Preliminary results also provide pathological and biomechanical evidence that show the same principles may be active in the development of a cumulative trauma disorder for the same work activities.

All the Specific Aims (#1 to #4) were fully met by the work accomplished over the three year period (see publication list and their relationship to the specific aims below).

Publications:

Eversull E, Solomonow M, Zhou B, Baratta RV, Zhu M: Neuromuscular Neutral Zones Sensitivity to Lumbar Displacement Rate. *Spine* 26:E314-324, 2001

Williams M, Solomonow M, Zhou B, Baratta RV, Harris M: Multifidus Spasms Elicited by Prolonged Lumbar Flexion. *Spine* 26:715-723, 2001

Solomonow M, Zhou B, Baratta RV, Zhou M, Lu Y: Neuromuscular Disorders Associated with Static Lumbar Flexion: A Feline Model. *Journal of Electromyography & Kinesiology*, in press, 2002

Jackson M, Solomonow M, Zhou B, Baratta RV, Harris M. Multifidus EMG and Tension-Relaxation Recovery After Prolonged Static Lumbar Flexion. *Spine*, 26:715-723, 2001.

Solomonow M, Eversull E, Zhou B, Baratte RV, and Zhu M. Neuromuscular Neutral Zones Associated with Viscoelastic Hysteresis During Cyclic Lumbar Flexion.

Claude L, Solomonow M, Zhou B, Baratte RV, and Zhu M. Neuromuscular Dysfunction Elicited by Cyclic Lumbar Flexion. *Muscle and Nerve*, 27:348-358-, 2003

Solomonow M, Baratte RV, Banks A, Fredenberger C, and Zhou B. Flexion-Relaxation Response to Static Lumbar Flexion in Males and Females. *Clin. Biomechanics*, 18:273-279, 2003.

Solomonow M, Hatipkarasulu S, Zhou B, Baratte RV, Aghazadeh F. Biomechanics & Electromyography of Common Idiopathic Low Back Disorder. *Spine*

Solomonow M, Baratta RV, Zhou B, Burger E, Zieske A. and Gedalia A. Muscular Dysfunction Elicited by Creep of Lumbar Viscoelastic Tissues. *J EMG & Kinesiology* (In press).



Memorandum

Date: November 20, 2003

From: Michael J. Galvin, Ph.D., Program Official 
Office of Extramural Programs, NIOSH, E-74

Subject: Final Report Submitted for Entry into NTIS for Grant 5 R01 OH004079-03.

To: William D. Bennett
Data Systems Team, Information Resources Branch, EID, NIOSH, P03/C18

The attached final report has been received from the principal investigator on the subject NIOSH grant. If this document is forwarded to the National Technical Information Service, please let us know when a document number is known so that we can inform anyone who inquires about this final report.

Any publications that are included with this report are highlighted on the list below.

Attachment

cc: Sherri Diana, EID, P03/C13

List of Publications

Solomonow M, Baratte RV, Banks A, Fredenberger C, and Zhou B. Flexion-Relaxation Response to Static Lumbar Flexion in Males and Females. *Clin. Biomechanics*, 18:273-279, 2003.

Claude L, Solomonow M, Zhou B, Baratte RV, and Zhu M. Neuromuscular Dysfunction Elicited by Cyclic Lumbar Flexion. *Muscle and Nerve*, 27:348-358-, 2003

Solomonow M, Zhou B, Baratta RV, Zhou M, Lu Y: Neuromuscular Disorders Associated with Static Lumbar Flexion: A Feline Model. *Journal of Electromyography & Kinesiology*, in press, 2002

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Williams M, Solomonow M, Zhou B, Baratta RV, Harris M: Multifidus Spasms Elicited by Prolonged Lumbar Flexion. *Spine* 26:715-723, 2001

Eversull E, Solomonow M, Zhou B, Baratta RV, Zhu M: Neuromuscular Neutral Zones Sensitivity to Lumbar Displacement Rate. *Spine* 26:E314-324, 2001

Solomonow M, Baratta RV, Zhou B, Burger E, Zieske A. and Gedalia A. Muscular Dysfunction Elicited by Creep of Lumbar Viscoelastic Tissues. *J EMG & Kinesiology* (In press).



Memorandum

Solomonow M, Hatipkarasulu S, Zhou B, Baratte RV, Aghazadeh F. Biomechanics & Electromyography of Common Idiopathic Low Back Disorder. Spine

**Final Performance Report
(Option 2)**

**Low Back Pain in Cyclic and
Prolonged Occupational Activities**

R01 - OH - 004079

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1. Summary Report

ABSTRACT

The role of spinal ligaments subjected to cyclic (repetitive) and static (prolonged) occupational activities as a source of work related musculoskeletal disorders was the objective of this investigation. It was hypothesized that ligaments subjected to cyclic and static activities develop, over time, creep (stretch) or tension-relaxation (loss of tension) and reduce the mechanical stability of the intervertebral joints. It was further hypothesized that with creep or tension-relaxation, the sensory receptors in the ligaments become de-sensitized and that in turn reduces the reflexive activation of lumbar muscles which further reduces mechanical stability and increases exposure to injury and disability. It was further anticipated that many hours of rest will be required to restore normal function.

The importance of the research to occupational safety and health is vested in the fact that epidemiologic data points out that workers exposed to daily activities requiring repetitive lumbar flexion (loading-unloading cargo, manufacturing/assembly, farm workers, etc.) and to static lumbar flexion (mechanics, brick/concrete workers, welders, roofers, etc.) report up to 10 times more episodes of low back disorders relative to other groups. The biomechanical and physiological processes active in the development of such disorders are not fully known nor are they scientifically experimentally validated. Identification of the biomechanical/physiological processes active in the development of such low back disorders will produce significant improvements in their prevention, treatment, restructuring work/rest schedules and designing optimal work conditions. Substantial financial savings could be materialized by the government and private/public sectors in reduction of medical expenses, disability payments, lost manpower and cost of manufacturing.

The approach employed in this research utilizes the "in-vivo" feline model subjected to cyclic and static loads applied to the lumbar spine to induce anterior flexion while recording creep/tension-relaxation of the ligaments (and other viscoelastic tissues) simultaneously with EMG from the multifidus muscles.

The results of the three years investigation provided new and significant insights into the biomechanical and physiological principles active in the development of a common idiopathic low back disorder. The data obtained to date also provide experimental validation of epidemiological data pointing out that repetitive and static work activities are indeed risk factors for musculoskeletal disorders.

The major finding consist of the fact that twenty minutes (20 min) exposure to cyclic or static lumbar flexion resulted in a complex neuromuscular disorder consisting of seven components:

- Substantial development of creep/tension-relaxation in the lumbar ligaments as well as other viscoelastic tissues (discs, capsule, dorsolumbar fascia) during the static or cyclic loading periods, (i.e., work period).
- Sharp decrease in the reflexive activation of the posterior muscles over the same work period.
- Routinely observed spasms from the posterior muscles superimposed on the decreasing EMG over the work period.
- During a rest period immediately following the work period, the creep/tension-relaxation set in the ligaments did not fully recover over seven hours. The model developed predicts full recovery in 24-48 hours.
- During the first hour of the rest period, muscular hyperexcitability was present in the muscles.
- A delayed, often severe and prolonged muscular hyperexcitability was present in the 3rd -7th hours of rest.
- A slow recovery to normal reflexive muscular activity was present throughout the seven hours of rest.

A mathematical model was developed and fitted to the experimental data. The model describes the various components of the neuromuscular disorder as a function of work and rest time and could be used to assess, predict and prevent low back disorders by optimizing work/rest schedules. Further refinement of the model can adapt its use to prediction and prevention of Cumulative Trauma Disorders (CTD).

Overall, the research performed to date confirm experimentally that static and cyclic work activities are risk factors and delineates important biomechanical and physiological infrastructure active in the development of a transient common idiopathic low back disorder associated with repetitive and static occupational activities. Preliminary results also provide pathological and biomechanical evidence that show the same principles may be active in the development of a cumulative trauma disorder for the same work activities.

All the Specific Aims (#1 to #4) were fully met by the work accomplished over the three year period (*see publication list and their relationship to the specific aims below*).

SIGNIFICANT FINDINGS

The most significant finding of this investigation consist of new and significant insight into the biomechanical and physiological processes active in the development of a musculoskeletal disorder as a result of static or cyclic lumbar flexion. Also of significance, is experimental/biomechanical validation of epidemiological data which describes static and repetitive occupational activities as major risk factors for the development of musculoskeletal disorders. While much more research should be performed in order to provide the full picture of cumulative musculoskeletal disorders that develop over time, the presented data provide the initial biomechanical and physiological infrastructure and points out the correct direction into which additional research should be undertaken. A third significant result of the research is that a model was developed for assessment and prediction of disorders in other conditions.

The first major finding listed above is the fact that a complex transient musculoskeletal disorder develops during and immediately after a relatively short (20 minutes) period of static or cyclic lumbar flexion in the "in-vivo" feline. The disorder consists of seven components:

- A. Development of substantial creep or tension-relaxation in the viscoelastic tissues of the lumbar spine (ligaments, discs, capsule, dorsolumbar fascia, etc.). The creep/tension-relaxation developed in an exponential fashion over the duration the lumbar spine was subjected to static or cyclic flexion. The model developed describes exponential decrease which is classical to viscoelastic tissues. The creep and tension-relaxation imply reduction in spinal stability and increased exposure to injury.
- B. During the same period that creep or tension-relaxation were developing, the reflexive muscular activity from the multifidus muscles demonstrated a substantial decrease with time. The model developed describes an exponential decrease of EMG with time. The decrease in muscular activity imply additional reduction of spinal stiffness and increased instability and exposure to injury.
- C. During the same period that creep or tension-relaxation were developing, EMG spasms were routinely present, superimposed on the exponentially decreasing multifidus EMG. Spasms are random and unpredictable events which can not be described by a model, yet indicate that tissue damage was present.
- D. During a seven hours rest period (following the 20 minutes static or cyclic loading/work period). The creep or tension-relaxation in the ligaments did not fully recover! Only 60-70% of the creep/tension-relaxation recover over seven hours of rest. The model developed predicts that 24-48 hours may be required for the exponential recovery to reach the ligaments initial resting length/tension. This indicates that up to two days of increased exposure to injury follow static or cyclic work sessions.

- E. The initial hour (of the seven hours rest) was always characterized by transient EMG hyperexcitability. This indicates that the muscles undertake the role of stiffening the spine and preventing additional damage to the ligaments until some of the creep/tension-relaxation recovered.
- F. Over the seven hours of rest, a delayed hyperexcitability, sometimes very severe, was always observed between the 3rd to the 7th hours. The model predicts a transient exponential hyperexcitability that will last from 24 hours to 48 hours. Preliminary data points out that acute inflammation is developing in the ligaments during the same period, implying that the hyperexcitability is the manifestation of inflammation.
- G. A component showing slow exponential recovery of muscular activity to its original level during the seven hours of rest. A period of 24 hours were predicted by the model as necessary rest to obtain full recovery of muscular functions.

Correlating this neuromuscular disorder with associated fragments of data from the literature results in the following updated hypothesis of idiopathic low back disorder resulting from static or cyclic work activities:

Creep developing in the lumbar viscoelastic tissues (ligaments, discs, capsule, etc) of the spine during static or cyclic loading induces microdamage in the collagen fibers of the respective tissues. The microdamage triggers the pain receptors in the tissues which in turn trigger spasms in respective muscles that control the joint. Upon initiation of rest, attempts to perform flexion and expose the ligaments to additional stretch and damage is met with hyperactivity of muscles across the joint, attempting to increase its stiffness in order to protect the damaged tissue and limit or attenuate the exposure to damage. As 50% of the creep recovers in the first hour of rest, the hyperexcitability diminishes, and/or disappears.

Yet, due to the elicited microdamage in the collagen fibers of the ligaments, discs, etc., the circulatory system mobilizes agents (neutrophils, cytokines) to the damaged tissues in order to digest and remove the damaged proteins and to deposit new proteins to reconstruct and heal the tissue. This is a well known phenomenon — acute inflammation — which signifies that a tissue healing process is under way.

Since this is a metabolic process which requires time, a time delay of several hours is required for the inflammation to manifest itself, and together with it the observed delayed hyperexcitability of the muscles which attempt to stiffen and protect the spine and its damaged tissues from repeated exposure to additional damage while the inflammation/healing is on-going.

The above hypothesis describes a transient disorder resulting from a single work session. Workers, however, are exposed to multiple work sessions over a single work day and to many sequential work days. The transient disorder associated with a single work session is therefore compounded by repeated sequential sessions and days of work. Using the findings from this research grant we can formulate a scientifically based hypothesis for the development of a Cumulative Trauma Disorder (CTD):

Creep developed in ligaments (and other viscoelastic tissues) over a single static or cyclic work session does not fully recover in a short rest period, leaving a residual creep at the start of the next work session. The residual creep accumulates over the work day, yet does not fully recover during overnight rest. This presents residual creep at the start of the next workday and so on . . . from day to day.

Similarly, the "acute inflammation" resulting from one day's work does not fully recover during an overnight rest, and persists from day to day to eventually become "chronic inflammation."

Chronic inflammation is a debilitating disorder, associated with pain, muscular stiffness, reduced ranged of motion of affected joints and weakness. It is also not responsive to anti-inflammatory medication, and results in a permanent disability.

The above hypothesis for CTD, is based on rational extension of the conclusions of this research grant, but needs experimental validation which we hope to develop during future work.

A mathematical model was developed and fitted to the experimental data. The model describes all the components of the neuromuscular disorder during static or cyclic loading and during the following rest period. The model could be a highly valuable analytical tool for Ergonomists for designing optimal work/rest periods while minimizing exposure to the neuromuscular disorder associated with cyclic and static occupational activities.

The model could be further modified for use to assess and optimize work/rest schedules in order to prevent a cumulative disorder which is the long term manifestation of the transient neuromuscular disorder we described in this report.

USEFULNESS OF FINDINGS

The results of this research project delineate the biomechanical and physiological processes active in the development of low back disorder after being exposed to repetitive and static flexion.

1. The data provides scientific experimental validation of epidemiological data identifying cyclic and static occupational activities a risk factors.
2. The understanding of the biomechanical/physiological process active in the development of low back disorder could be used to prevent such disorder by restructuring work environments.
3. The same knowledge could be used by medical professionals to treat such disorders optimally.
4. Ergonomists could use the data and the developed model to design optimized work/rest schedules and work organization to prevent low back disorder.
5. The data/conclusion and the reconstructed hypothesis provided us with an insight to form a protocol for a research project extending our understanding of cumulative trauma disorders.

Overall, the results have multiple uses in various aspects of Occupational Safety and Health bringing the state-of-the-art one good step forward.

Publications

Peer Reviewed Journals

1. Williams, M., Solomonow, M., Zhou, B., Baratta, R.V., Harris, M. Multifidus Spasms Elicited by Prolonged Lumbar Flexion, *Spine*, 25:2916-2924, 2000.
2. Jackson, M., Solomonow, M., Zhou, B., Baratta, R.V., Harris, M. Multifidus EMG and Tension-Relaxation Recovery After Prolonged Static Lumbar Flexion. *Spine*, 26:715-723, 2001.
3. Eversull, E., Solomonow, M., Zhou, B., Baratta, R.V. and Zhu, M. Neuromuscular Neutral Zones Sensitivity to Lumbar Displacement Rate. *Clin. Biomechanics*, 16:102-113, 2001.
4. Solomonow, M., Eversull, E., Zhou, B., Baratta, R. and Zhu, M. Neuromuscular Neutral Zones Associated with Viscoelastic Hysteresis During Cyclic Lumbar Flexion. *Spine*, 26:E 314-324, 2001.
5. Solomonow, M., Zhou, B., Baratta, R.V., Zhu, M., Lu, Y. Neuromuscular Disorder Associated with Static Lumbar Flexion: A Feline Model. *J. EMG & Kinesiology*, 12:81-90, 2002.
6. Claude, L., Solomonow, M., Zhou, B., Baratta, R.V., And Zhu, M. Neuromuscular Dysfunction Elicited by Cyclic Lumbar Flexion. *Muscle & Nerve*, 27:348-358, 2003.
7. Solomonow, M., Baratta, R.V., Banks, A., Freudenberger, C., and Zhou, B. Flexion-Relaxation Response to Static Lumbar Flexion in Males and Females. *Clin. Biomechanics*, 18:273-279, 2003.
8. Solomonow, M., Hatipkarasulu, S., Zhou, B., Baratta, R.V., Aghazadeh, F. Biomechanics & Electromyography of Common Idiopathic Low Back Disorder. *Spine* (In Press).
9. Solomonow, M., Baratta, R.V., Zhou, B., Burger, E., Zieske, A. and Gedalia, A. Muscular Dysfunction Elicited by Creep of Lumbar Viscoelastic Tissues. *J. EMG & Kinesiology* (In Press).
10. Solomonow, M. Ligaments: A Source of Work related Musculoskeletal Disorders. *J. EMG & Kinesiology* (Submitted).
11. Lu, D., Solomonow, M., Zhou, B., Baratta, R.V. and Li, L. Frequency Dependent Changes in Neuromuscular Response to Cyclic Lumbar Flexion (In Preparation).

Relationship of Publications to Specific Aims

1. Publication #1 (Williams et al) directly responds to Specific Aim #1 using **displacement control (constant displacement)** of the lumbar spine/ligaments in static condition to assess flexion-relaxation development and decrease of reflexive EMG during exposure.
2. Publication #2 (Jackson et al) directly responds to Specific Aim #2 using **displacement control (constant displacement)** of the lumbar spine/ligaments in static conditions to assess the recovery of tension-relaxation and reflexive EMG with up to seven hours rest.
3. Publication #3 (Eversull et al) addresses an important technical/procedural issue of Specific Aims #1 related to the rate of which static flexion is initially induced and its effect on the changes in ligaments length-tension and associated reflexive EMG from the multifidus.
4. Publication #4 (Solomonow et al) addresses an important technical/procedural issue of Specific Aims # 3 related to the effect of the frequency of cyclic loading of lumbar ligaments on their length-tension, hysteresis and associated reflexive EMG from the multifidus.
5. Publication #5 (Solomonow et al) directly addresses Specific Aims #1 in ***Load Control*** (as opposed to displacement control used in Williams et al, above) while assessing the effect of time (duration) the static flexion was maintained. This is a direct response to the NIOSH panel recommendations in the *Summary Statement* proposing shorter exposure time.
6. Publication #6 (Claude et al) directly addresses Specific Aims #3 and #4 using ***Load Control*** (as opposed to displacement control) in order to assess viscoelastic creep of lumbar ligaments and associated reflexive EMG in cyclic flexion and during seven hours of following rest.
7. Publication #7 (Solomonow et al) addresses Specific Aim #1 ***in humans*** (as opposed to "in-vivo feline"). This was mostly supported by the Occupational Medicine Research Center Grant (HEF - 2000 - 5 - 7) but it addresses the NIOSH Summary Statement criticism regarding the need to establish relationships of data from the "in-vivo feline" to human lumbar spine. We have shown that static lumbar flexion results in a neuromuscular disorder in humans which is similar to that observed in the "in-vivo feline."
8. Publication #8 (Solomonow et al) directly addresses Specific Aims #1 and #2 assessing the development of creep and neuromuscular disorder in the lumbar spine subjected to ***load control*** (as opposed to displacement control in publications #1 and #2) static flexion and over seven hours of following rest.

9. Publication #9 (Solomonow et al) directly addresses Specific Aims #1, 2, 3 and 4. *This is an invited review paper* summarizing the findings to date.
10. Publication #10 (Solomonow) addresses Specific Aims #1, 2, 3 and 4. *This is an invited review paper* summarizing the state-of-the-art of work related disorders emerging from ligaments.
11. Publication #11 (Lu et al) directly addresses Specific Aims #3 and #4, delineating the negative impact of increased frequency of cyclic lumbar loading (under load control) on the development of creep, loss of reflexive EMG and intensification of the associated neuromuscular disorder over the following seven hours of rest.

Overall, publications 1-8 and 11 directly and fully addressed the four specific aims, whereas publications 9 and 10 are review articles of the work done to date.

INVESTIGATORS AND STUDENTS PARTICIPATING IN THIS PROJECT

CO-INVESTIGATORS

Richard V. Baratta, Ph.D.
Yun Lu, M.D.
Bing He Zhou, Msc.
Meng Ping Zhu, M.Sc.
Mitchell Harris, M.D.

COLLABORATING INVESTIGATORS

Evalina Burger, M.D.
Abraham Gedalia, M.D.
Arthur Zieske, M.D.

RESEARCH MEDICAL STUDENTS

Matthew Williams, M.D., (Presently, Orthopaedic Resident)
McLean Jackson, M.D., (Presently, Orthopaedic Resident)
Elizabeth Eversull, M.D., (Presently, Radiology Resident)

GRADUATE STUDENTS

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Selen Hatipkarasulu, M.Sc., (Presently, Ph.D. Student)
Lakiesha Claude, M.Sc., (Presently, Ph.D. Student)
Rebecca LaBry, B.Sc. (Presently, M.Sc. Student)

Ph.D. Degree:

Anthony Banks, Ph.D. (Presently, Employed by Kodak Inc.)
Michael Olson, M.Sc., (Presently, Ph.D. Student)

2. Financial Status Report

Enclosed. *See Attachment*

3. Equipment Inventory

No major equipment items were purchased with funds allocated by PHS to this project.

4. Final Invention Statement

No inventions were associated with this project.