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13. ABSTRACT (Maximum 200 Words)

The purpose of this study is to identify a cohort of patients with mild traumatic brain injury and follow them for one year post-injury to determine injury outcomes and identify factors that best predict long-term sequelae.

The second year has been dedicated to continued subject recruitment and follow-up. Modifications were made to the study design to enhance recruitment. Human subjects approval was obtained from both the University and Army review boards.

Data entry and validation are ongoing, a process which also includes data back-up and migration. Laboratory protocols continue for the collection, storage, and processing of blood samples for the S-100b tests. We currently have preliminary data on 60 samples. The processes by which the Balance Master data are collected and stored have been finalized. It is anticipated that within the next year, we will be able to begin preliminary data analysis as we have now begun one-year follow-up on subjects.

As of March 31, 2005, 78 subjects have been recruited. Based on a series of meetings with the PI and the co-investigators, protocol modifications were made to enhance subject enrollment and it is already apparent that these modifications have been effective in increasing enrollment.

14. SUBJECT TERMS
Mild traumatic brain injury (MTBI), injury, balance, s-100 beta protein and neuron-specific enolase

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INTRODUCTION

Each year approximately 1.5 million Americans sustain a traumatic brain injury (TBI). The most common causes of TBI are due to blunt force trauma. The goal of this research is to identify a cohort of patients with mild TBI and follow them for a period of one year (1) to determine injury outcomes and (2) to identify factors that best predict those patients with long-term sequelae. A sample of 300 subjects will be identified over the life of the study. These subjects have a baseline assessment during the initial trauma center admission, which includes biochemical markers, balance measures, clinical findings and neurometric tests. Follow-up testing is completed at 3-5 days, 7-10 days, 3 months, 6 months and 12 months post injury.

BODY

This is the annual report for year 2 of a 3-year study. The second year focused on subject recruitment and follow-up.

Human Subjects Protections / Protocol Modifications:

During year two, there were several modifications made to the protocol in an effort to enhance recruitment. **1. Changes in eligibility criteria**: Inclusion Criteria - Remove a) geographical boundaries. Exclusion Criteria - Remove a) Lower Extremity Fracture requiring greater than 3 months orthopedic management; b) Not resident in Baltimore Metro Region or specified surrounding counties; c) Brain Lesion on CT scan; d) skull fracture; e) CSF Leak; f) Lower Extremity Fracture; g) Upper extremity fracture which would prohibit balance testing; h) Chest Injuries; i) Other injury that precludes subject from being balance tested. Add a) Brain Lesion on CT scan requiring clinical intervention; b) Skull fracture requiring clinical intervention; c) CSF Leak requiring clinical intervention; d) History of psychiatric disorder requiring hospitalization or a history of hallucinations. **2. Change in procedures**: a) Balance testing is no longer mandatory for all subjects b) Telephone interviews for 3-5 and 7-10 day follow-up (if subject unable to return to the hospital) with compensation of $10.

This past year the entire research staff completed the Certified Investigator Training Initiative (CITI) as required by the University of Maryland.

New Personnel:
In addition to the two clinical research coordinators, a part-time recruiter was hired during the past year to cover non-standard working hours (evenings and weekends).

Dr. Robert Kane from the Baltimore Veterans Administration has taken over the position of Neuropsychologist as Dr. Jack Spector is unable to continue working on the study at

this time. However, Dr. Spector plans to assist with the final analysis at the end of the study.

Initially, we had one post doctorate student who was on campus everyday conducting the neuropsychological evaluations. We now have three post doctorate students that cover the neuropsychological evaluations, and this has created greater flexibility for conducting follow-up examinations.

Staffing / Training:

Because of staffing issues within the University of Maryland Medical Center Rehabilitative Services Department and concern over professional liability issues, the physical therapists are no longer involved in the examination of subjects. The two clinical coordinators and the part-time recruiter are licensed physical therapist within the state of Maryland. The study coordinator has been trained in the balance components of the study and can provide cross coverage for the clinical research coordinators as needed.

Safety:
Safety for subjects and evaluators is always a concern, and therefore we continue to provide the safest environment possible for the evaluations.

Space Allocation:
Since the last report, the study office was moved to a different location within the hospital setting. The Balance Master System was moved and calibrated by the manufacturer. The move, to a smaller facility, necessitated the need for new office furniture to accommodate the needs of the subjects. This move required that the office be closed for balance testing for a few days but did not otherwise interfere with the study. The yearly biomedical check of the Balance Master was also completed by the hospital Biomedical Engineering department.

Manual of Operations:
The Manual of Operations continues to be updated as necessary.

Team Meetings:
Meetings of the study team occur at monthly intervals. We use this time to discuss issues related to recruitment, follow-up and patient recovery issues. Additional small group meetings are held as needed. These meetings focus on specific needs such as data analysis for the various components of the study.

S-100 beta testing:
The procedure to ensure timely retrieval and freezing of blood samples per testing guidelines and moving of the samples to the research lab for storage until ready for bulk processing continues. The guidelines for processing the blood samples to obtain S-100 beta values indicate that the blood samples be run in batches of thirty. Thus far we have

received preliminary results for the first 60 subjects. We plan to begin data analysis during the next year.

Data Entry and Storage:
One clinical coordinator and the part-time recruiter are responsible for all the data entry and the second clinical coordinator is responsible for auditing all the data. We continue to refine our data backup processes for the various systems on which we store data.

ANAM Proprietary Issues:
All study staff administering the ANAM or ARES are required to sign usage agreements, as the software is the proprietary information of the USAMRMC. Software usage as well as data collection, storage and analysis will be consistent with the user agreement.

Recruitment and Follow-up:

Last year we realized that recruitment had been considerably slower than anticipated, and after much discussion, we have identified several possible factors: (1) We began recruitment during the colder months of the year when overall patient enrollment is down somewhat. However, large numbers of patients were still screened but were not enrolled for various reasons related to our selection criteria, which were initially designed based on the assumption that all three aspects of the study had to be completed (i.e. the balance tests, blood test, and neuropsych testing). (2) Many patients were not eligible based on their associated injuries, such as upper and lower extremity injuries, which precluded their completing the balance test. These patients, however, are representative of the types of patients seen in trauma centers, who rarely sustain only one injury. (3) Others may have had only a mild TBI, but by the time clinical tests were completed, were unwilling to stay in the hospital longer in order to be enrolled in the research study. (4) Still others might have been eligible, were willing to participate, but expressed concern that they would be unable to return for follow-up visits.

Based on these observations, we made the following conclusions. There are adequate numbers of patients coming through the system with mild TBI, but we were losing many due to logistical considerations based on these "real world" issues. For this reason, while the goal is still to obtain testing for all three-study aspects, a more realistic approach has been adopted to obtain as much data as possible for each enrolled patient. That is, if a patient has a lower extremity injury, but is otherwise able to participate, we will enroll him, obtain the blood sample and neuropsych testing, and request that he return for follow-up visits. If a patient is eligible, willing to return for follow-ups, but unwilling to stay for the initial two-hour battery of tests, we will obtain consent, basic intake data and the blood sample, and then notify him with regard to scheduled follow-up visits. For patients who are enrolled but do not return for specified follow-up visits, we will interview them by telephone using the symptom checklist. Based on our enrollment and follow-up status, we feel this approach has proved to be beneficial, and subjects seem much more willing to participate.

Having completed one full year of recruitment and follow-up for the first group of subjects, we can now describe in more detail the complex logistics of screening, enrollment, evaluation and follow-up for this population of trauma patients with mild traumatic brain injury.

Screening: A report of admissions is run daily. This report contains all the patients that were admitted to the Shock Trauma Center for a given period of time (usually 24 hours) and may contain 25 or more entries plus anyone for whom the screening process was not completed the previous day. From this report and a review of electronic records, the research coordinator identifies potential subjects. The recruiter then proceeds to the appropriate unit, reviews the medical record and, if the subject appears to fit criteria, the recruiter obtains approval from the nurse to speak to the patient. This aspect of the process may take several hours or a full day to complete because the subject may be undergoing diagnostic or therapeutic procedures, may have been given pain medication and are unable to be approached, or it may be visiting hours and the subject does not want to be disturbed. In addition, the medical staff may be awaiting test results that would exclude the potential subject from the study. Once the recruiter determines that the subject is eligible to participate, she then begins the enrollment process.

Enrollment: In order to enroll a subject, the recruiter is required to complete a screening evaluation form and an evaluation to sign informed consent. The screening form includes an assessment of the subject's current cognitive status (Mini-Mental Exam), limited past medical history, and current status to confirm eligibility for the study. If the subject is unable to give informed consent, a clinical decision is made to either re-evaluate the subject or exclude them. Every attempt is made to include as many potential study subjects as possible. The consent process involves reviewing the study protocol and including the background, purpose, procedures, potential risk and discomforts, potential benefits, alternatives, subject costs and payments, rights (especially confidentiality) and the authorization to obtain, use and disclose protected health information for research (HIPAA). After reviewing all of the aspects of the study, a time for questions and answers and/or reviewing the documents is allowed. The recruiter may need to leave and return at a later time. On occasion, the subject requests that the recruiter return when a family member is available to help make the decision. Once the subject agrees to participate and signs the consent form and the HIPAA authorization, the evaluation process begins.

Evaluation: Each evaluation involves a battery of tests performed by personnel in different disciplines and is described in Table 1. The recruiter is responsible for coordinating these activities. This coordination involves not only scheduling around the clinical care of the individual subject but also the clinical responsibilities of the speech pathologists and the neuropsychologists who also treat patients outside this research setting. In the original protocol we had established a sequence for the ideal completion of the evaluations. This was abandoned shortly after the study began because of all the factors involved in

performing the evaluations. Thus, for each subject at each follow-up visit we record the order in which the evaluations were completed in the event that we need this information at the time of data analysis.

Table 1: Evaluation Components

Completed by	Test	Baseline	3-5 day	7-10 day	3 mo	6 mo	12 mo
Recruiter	S-100	X					
Recruiter	Initial Assessment	X					
Recruiter	Well-Being Rating Scale	X		X	X	X	X
Recruiter	Follow-up Assessment		X	X	X	X	X
Recruiter	ANAM Readiness Evaluation System (ARES)	X	X				
Recruiter	Mild TBI Symptom Checklist	X	X	X	X	X	X
Recruiter	Balance Master	X	X	X	X	X	X
Recruiter	Balance Error Scoring System (BESS)	X	X	X	X	X	X
Speech	Galveston Orientation & Amnesia Test (GOAT)	X					
Speech	Scales of Cognitive Ability for Traumatic Brain Injury (SCATBI)	X	X	X	X	X	X
Neuropsychology	Balance Master	X	X	X	X	X	X
Neuropsychology	Balance Error Scoring System (BESS)	X	X	X	X	X	X

Followup: Following the completion of the baseline evaluation and prior to discharge, the recruiter attempts to schedule the 3-5 day follow-up visit. As we try to schedule our follow-up appointments on the same day as the trauma clinic visits for subject convenience, this is often not possible if a clinic appointment is not confirmed before hospital discharge. In this case phone calls to schedule appointments are made over subsequent days after discharge. Also at the 3-5 day visit, the subject often does not feel well enough to return to the hospital, especially so soon after discharge, or they may not have transportation. The same issues are present at the 7-10 day follow-up. Even after scheduling the appointment and making arrangements with the study staff, the subject may not keep the appointment or arrive late. In these instances, we make an attempt to contact the subject to determine if he/she is coming to the appointment and if not, attempt to reschedule the appointment. At the end of each scheduled appointment we attempt to make the next appointment. If we are successful, we then send a reminder letter approximately one month before the appointment. For those subjects who do not schedule an appointment, we send a reminder letter one month before the appointment due date. If the subject does not respond to the letter within two weeks, we attempt to call the subject to schedule an appointment. If this effort fails then we send a letter indicating that we have been trying to contact the subject and to please call. This is the process for the 3-, 6- and 12- month follow-up visits. With all the follow-up visits, our goal is to have the subject return to the hospital for testing. As part of the continuing follow-up

process, when we contact a subject and determine they are unable to return the STC, we conduct a telephone interview that consists of the follow-up assessment and the symptom checklist. Unless a subject specifically withdraws from the study, we continue to contact him/her at each of the follow-up visits. However, to date there have been no withdraws.

This year, we have also been faced with issues concerning compliance with 6- and 12-month follow-ups. By this point in recovery, many subjects have returned to more normal activities and are not readily available for follow-up during 'normal' work hours. Hiring the part-time recruiter has therefore assisted with better follow-up status. The recruiter has been available for evening/weekend follow-up appointments and has been able to contact subjects in the evenings and on weekends, when the subject is more likely to be home, especially if he/she has returned to work.

An additional matter that has been addressed over the last year is the issue concerning recovery that the subjects bring to us at 3-, 6- and 12- months post injury. Many are reporting concerns about trouble thinking, trouble remembering and trouble concentrating, some even noting a significant impact on their daily lives and functioning. For some, we are the only health care professionals they have been in contact with since their last clinic visit at the Shock Trauma Center. In an effort to address the concerns of the subject but not introduce bias into the study, the team has developed the following policy. If a subject presents with symptoms that they feel are problematic, then the evaluator suggests that the subject take these concerns either to his/her primary care physician or return to the Shock Trauma Clinic. The subject is given a generic letter that states the subject has presented with symptoms that may or may not be related to his/her injury and the physician should evaluate and treat as he/she sees fit. We felt this approach would allow such concerns to be addressed appropriately and in a timely fashion.

Actual screening and recruitment was initiated on October 6, 2003. Table 2 summarizes progress to date in subject screening, recruitment and follow-up. Since October 2003, we have screened 1,254 potential subjects and have recruited 78. Because this study involves a one year follow-up period, the number of subjects due for any one follow-up varies. To be considered a complete evaluation, the subject returned to the STC and completed all components of the follow-up as indicated in Table 1. A partial evaluation means the subject returned to the STC and completed at least the follow-up assessment and the symptom check list. The telephone evaluation consists of the follow-up assessment and the symptom checklist. The total is the sum of the complete, partial and telephone evaluations, meaning we were in contact with the subject. As of March 31, 2005, the percent follow-up for the various times are as follows: 3-5 day (76%); 7-10 day (87%); 3 month (56%); 6 month (52%); 12 month (36%). At the given follow-up appointments, for those subjects contacted, the following are returning to the STC for evaluation: 3-5 day (57%); 7-10 day (72%); 3 month (85%); 6 month (82%); 12 month (100%). Even though the one-year follow-up has passed for some of the subjects, we continue to try and contact them to obtain as much information as possible.

The reasons potential subjects were not recruited in the study are also presented in Table 2. The three smallest categories: age, penetrating injury, and readmission to the trauma center can usually be determined from the daily report before the screening process even begins and therefore the numbers are so small. "Non-local resident" is no longer applicable since the geographic restrictions were removed and thus the percentage will continue to drop throughout the remainder of the study. Approximately 1/3 of those who were not recruited were because they suffered other injuries that made them ineligible. Nearly, 25% of those not recruited had extenuating circumstances (i.e., being on probation or parole, having a past medical psychiatric history, or being active military) that precluded them from being asked to participate in the study. An additional 13% were excluded because their injuries did not fit the definition of mild TBI according to our protocol. With all of our efforts to recruit every eligible subject, 103 still refused to participate. At each staff meeting, we review our progress and discuss ways in which we can improve enrollment and follow-up.

Table 2: Screening, Recruitment, and Follow-up as of March 31, 2005

1254 Screened

78 Recruited

Follow –up Status

	Due as of 3/31/05	Complete	Partial	Telephone	Total
3-5 day	78	9	25	25	59 (76%)
7-10 day	78	23	26	19	68 (87%)
3 month	61	19	10	5	34 (56%)
6 month	42	16	2	4	22 (52%)
12 month	14	5	-	-	5 (36%)

1176 Not Recruited

Reason	n	%
Age	7	0.6
Non-local resident (*note: no longer applicable*)	34	2.9
No LOC or Mental status changes	149	12.7
Unable to give informed consent (MMS < 8/10)	14	1.2
Non-English Speaking	37	3.1
Associated Injuries	389	33.1
Discharged before enrollment completed	155	13.2
Refused	103	8.8
Penetrating Injury	6	0.5
Other (i.e., past medical history, active military, probation/parole)	277	23.6
Readmission	5	0.4

In April 2004, Dr. Dischinger presented a poster at the Department of Defense Military Health Research Forum, San Juan Puerto Rico, detailing the study overview and progress to date. A copy of the poster may be found in the appendix.

KEY RESEARCH ACCOMPLISHMENTS

There are no key research accomplishments at this time. The research is still in the recruitment phase with limited data collection completed.

REPORTABLE OUTCOMES

Abstract Submitted, Accepted and Presented:

Dischinger PC, Cooper C, Mackenzie, Romani W, Spector J: Serial Assessment of Mild Head Injury: Early Predictors of Outcome, Department of Defense Military Health Research Forum, San Juan Puerto Rico, April 25-28, 2004

CONCLUSIONS

We have completed year two of the study and have gained great insight into the logistics involved in carrying out research on mild TBI in this population. Even with the more relaxed selection criteria and in increased recruitment rate, we have found it more difficult than originally anticipated to recruit such subjects in a trauma center. Part of this difficulty may be attributable to the fact that frequently subjects, having been through a traumatic event, are not open to the suggestion of participating in a study, and are ready to go home. Another issue may be related to the fact that many patients have other injuries as well, and may not be as concerned, at that point in time, about their mild head injury. While in some sense this issue of multiple injuries may seem like a limitation, these patients represent the "real world"...i.e. people in car crashes or those who fall frequently have more than one injury, and such is probably the case in the military setting as well.

We had stated in the proposal that if enrollment lagged, we would investigate the possibility of including patients seen at the University of Maryland Emergency Department, which is adjacent to the R Adams Cowley Shock Trauma Center. However, after meeting with several of the Emergency Department physicians, it was concluded that the additional yield of eligible cases would be too low (since most would come to Shock Trauma anyway) to justify the logistical and legal issues involved in moving patients from one facility to the other for balance testing, coordination of blood drawing, etc.

In addition, we have not had staff coverage for 7 days a week, 24 hours a day, and thus may lose some eligible subjects who might be admitted on a Friday night, and discharged on Saturday, for example. However, we do have some flexibility with the current staff, who adjust their schedules as necessary to accommodate patient availability. Another factor, of course, is the seasonal variation in trauma, with higher admission rates in the spring and summer months. Overall, the experience is quite different than what we had

anticipated: i.e. patients' compliance with follow-up visits is better than expected, but overall enrollment is slower than expected.

Now that we have almost 90 subjects (six more have been enrolled since March 31st) we will begin analyses of data regarding the baseline visit, and the initial follow-up visits. As more subjects come through the "pipeline" for their one-year follow-ups, we will also begin to analyze their complete study course, as well.

REFERENCES

None at this time, research is in the recruitment phase with limited data collection completed.

APPENDIX A

ABSTRACT SUBMISSION

SERIAL ASSESSMENT OF MILD HEAD INJURY: EARLY PREDICTORS OF OUTCOME

Dischinger PC, Cooper C, Mackenzie CF, Romani W, Spector J

University of Maryland School of Medicine, Baltimore, MD 21201, USA

BACKGROUND/PURPOSE: The goal of this research endeavor is to identify a cohort of patients with mild TBI (traumatic brain injury) and follow them for a period of one year (1) to determine injury outcomes and (2) to identify those factors that best predict those patients with long-term sequelae. **METHODS:** Identify 300 patients with a mild TBI and obtain baseline measures including biochemical markers, balance measures, clinical findings and neurometric tests. Subjects will be followed at 3-5 days, 7-10 days, 3-, 6-, and 12-months post injury. **RESULTS:** We have only just begun patient recruitment and therefore have no results yet. By April, we should have preliminary findings available. **CONCLUSIONS:** The anticipated result is that biochemical and/or balance measures will add prognostic power to the prediction of long-term outcomes, and thus, could be used in the field to determine the disposition of soldiers who incur mild traumatic brain injury.

APPENDIX B

POSTER PRESENTATION:
DOD Military Health Research Forum April 2004

SERIAL ASSESSMENT OF MILD HEAD INJURY: EARLY PREDICTORS OF OUTCOME

Dischinger PC, Cooper C, Mackenzie CF, Romani W, Spector J

University of Maryland School of Medicine, Baltimore, MD 21201, USA

Charles McC. Mathias, Jr.
National Study Center
for Trauma and Emergency Medical Systems

ABSTRACT

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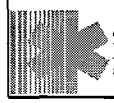

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Background: Each year approximately 1.5 million Americans sustain a TBI. The most common causes of TBI are due to motor vehicle crashes, falls and violence.

Purpose: The goal of the research project is to identify a cohort of patients with mild traumatic brain injury and follow them for a period of one year in order to determine outcomes related to their injury, and to identify baseline characteristics that best predict those with long-term sequelae. Patients selected will be those with a mild brain injury resulting from blunt trauma.

Also, to determine which of these predictors may be useful in the military setting in determining disposition of soldiers who incur mild TBI due to blunt traumatic forces.

Study Design: Prospective study of the predictors of long-term outcomes among patients with mild TBI. Predictors include clinical findings, demographic factors, neurometric measures, biochemical markers and balance tests.

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Inclusion Criteria

- 18 - 64 years of age
- Blunt mechanism of injury
- Admission GCS 13-15
- Presence of at least one of the following:
  - Loss of consciousness < 30 minutes
  - Loss of memory for events immediately before/after trauma
  - Alteration of mental state
- Acceptable Mini Mental State Examination score (8/10)
- English Speaking

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National Study Center
for Trauma and Emergency Medical Systems

Exclusion Criteria

- Presence of complication factors:
  - Brain lesion on CT requiring clinical intervention
  - Moderate or severe multiple trauma
  - Focal neurological findings
  - Skull fracture requiring clinical intervention
  - CSF leak requiring clinical intervention
  - Prior brain injury (moderate or severe)
  - Post-traumatic amnesia exceeding 24 hours
  - Seizures
- History of psychiatric disorder requiring hospitalization
- History of hallucinations
- Current probation or parole
- Lower extremity fracture requiring >3 mos orthopedic management
- Active duty military

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Standardized Evaluations

- Biochemical Marker – S-100 beta
- Interview
- Well-Being Rating Scale
- Galveston Orientation and Amnesia Test (GOAT)
- Concussion Symptom Checklist
- Scales of Cognitive Ability for Traumatic Brain Injury (SCATBI)
- Word Memory Test (WMT)
- Automated Neuropsychological Assessment Metrics (ANAM)
- ANAM Readiness Evaluation System (ARES)
- Neurocom Balance Master and Smart Equitest System
- Balance Error Scoring System (BESS)

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Concussion Symptom Checklist

- Provides objective rating of post-concussion symptoms.
- Each symptom noted as: present or absent
  number of days present in last week
  severity rated on 1 to 10 scale

- Symptoms assessed include:

Headache	Anxiety
Depression	Difficulty concentrating
Dizziness	Trouble remembering things
Blurry, double vision	Trouble thinking
Irritability	Tired, fatigue
Sensitivity to light	Sensitivity to noise

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Evaluation Components

Interview Components:

Co-morbidities
Pre-existing conditions impacting cognition and balance
Use of medical and rehabilitation services
Return to work and daily function

Galveston Orientation and Amnesia Test(GOAT):

Standardized tool used to assess current orientation and persistence of post- traumatic amnesia

Well-Being Rating Scale:

Psychological index used to measure a person's subjective well-being.
Series of 22 questions addressing dimensions of : anxiety, vitality
depression, general health, positive well-being, self-control

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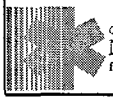
Evaluation Components

Biochemical Marker – S-100 beta test:

Protein of astroglial cells that has been identified as a marker for central nervous system damage.

Recent studies have hypothesized that increased levels of this protein may predict intracranial pathology and increased frequency of post-concussive symptoms



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Evaluation Components

SCATBI (Scales of Cognitive Ability for Traumatic Brain Injury):

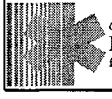
Measures cognitive processes via subtests focusing on Orientation, Organization, Recall and Reasoning.

Word Memory Test (WMT):

Assessment of verbal memory and response bias, feigning, malingering and symptom exaggeration

ANAM (Automated Neuropsychological Assessment Metrics) and ARES (ANAM Readiness Evaluation System)

Measures simple and choice reaction time, divided attention of visual and spatial skills, running memory and executive reasoning



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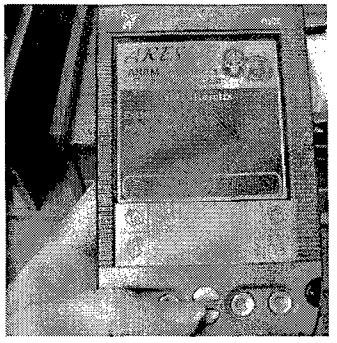
Neuropsych Evaluation

- **ANAM (Automated Neuropsychological Assessment Metrics) and ARES (ANAM Readiness Evaluation System)**
  - Measures simple and choice reaction time, divided attention of visual and spatial skills, running memory and executive reasoning



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Balance Tests

- **Balance Error Scoring System (BESS):**
  - Assess static postural stability via clinically portable means
  - Six subtests consisting of 3 positions, tested with eyes closed on a level floor surface and foam pad
  - Error points noted for any movement out of position or loss of balance with a maximum score of 10 for each subtest.

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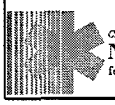
Evaluation Components

Neurocom Balance Master and Smart Equitest System
Sensory Organization Test (SOT):

Measures maintenance of postural control and sway

Three 20 second trials: Fixed and sway-referenced support with normal, absent and sway-referenced vision



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Evaluation Components

	Baseline	3-5 days	7-10 days	3 months	6 months	12 months
Instrument						
S-100b	X					
Interview	X	X	X	X	X	X
Well-Being Rating Scale	X		X	X	X	X
CAGE, CAGE-D	X					
ARES	X	X	X			
Symptom Checklist	X	X	X	X	X	X
GOAT	X					
SCATBI	X		X	X		
ANAM			X	X	X	X
WMT			X	X	X	X
Balance Master	X	X	X	X	X	X
BESS	X	X	X	X	X	X

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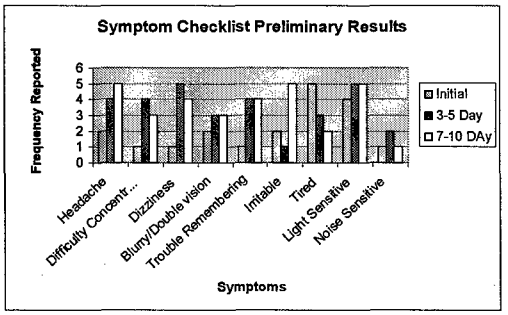
Preliminary Results

Symptom Checklist: 6 subjects completing first 3 evaluations



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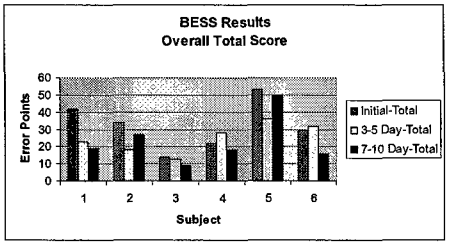
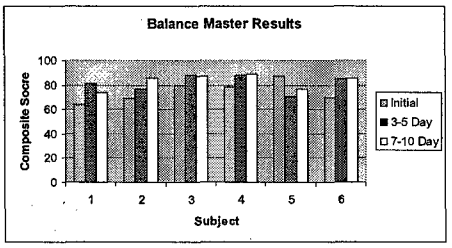
Balance results: 6 subjects completing first 3 evaluations





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