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Assessing Clinical Significance of the Immediate Post-Concussion Assessment and Cognitive Testing Battery When Comparing Adjusted and Unadjusted RCI Methods for Different Ranges of Baseline Scores

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ASSESSING CLINICAL SIGNIFICANCE OF THE IMMEDIATE POST-CONCUSSION ASSESSMENT AND COGNITIVE TESTING BATTERY WHEN COMPARING ADJUSTED AND UNADJUSTED RCI METHODS FOR DIFFERENT RANGES OF BASELINE SCORES

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ABSTRACT

ASSESSING CLINICAL SIGNIFICANCE OF THE IMMEDIATE POST-CONCUSSION ASSESSMENT AND COGNITIVE TESTING BATTERY WHEN COMPARING ADJUSTED AND UNADJUSTED RCI METHODS FOR DIFFERENT RANGES OF BASELINE SCORES

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The growing concern revolving around the dangers of sports-related concussions have led to the most recent implementation of neurocognitive (NC) test batteries as a means to objectively determine the presence of a cognitive defect. Whereas any other sports-related injury can be diagnosed with tools such as an x-ray or MRI, a concussion represents a metabolic disturbance that cannot be identified by these diagnostic tools. Many neurocognitive test batteries employ statistical techniques to derive cut off scores in order to represent significant or insignificant changes as compared to individual baseline scores, or pre-established normative values. If an individuals' post-injury score exceeds the pre-determined RCI, he/she is classified as impaired suggesting a cognitive defect is present. The purpose of this study was to determine the clinical significance of a widely implemented NC test battery ImPACT using adjusted and unadjusted RCI methods and comparing composite indices for both overall RCI values and RCI values for different ranges of baseline scores. Ranges consisted of the lowest (0 – 20^{th} percentile), middle (40^{th} – 60^{th} percentile), and highest (80^{th} – 100^{th}) quintile in a sample consisting of 56 NCAA Division I football players. Subjects each completed a baseline assessment at two different time points and composed a within-subjects sample.

Results of this study indicated extremely low test-retest reliability among quintile ranges when compared to the reliability that was established with the entire sample. Results also indicated different RCI values for quintile ranges compared with the overall RCI value for each composite index. Future studies are needed to evaluate the role of confounding variables that may be present when completing NC computerized assessments. This could further confirm the low reliability results of this study occurred as a result of ImPACT's poorly designed NC test battery. Future studies should also explore the implementation and use of minimal detectable change (MDC) to establish change scores as opposed to RCIs.

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DEDICATION

This is dedicated to my amazing parents. Words cannot begin to express how grateful I am for your unconditional love and support. From countless phone calls to trips clear across the country, your guidance and encouragement never goes unnoticed. Sometimes when I stop and take a look around, reflecting on what I have accomplished thus far I can't help but smile and think about you two. I would not be the person I am today without either of you, I love you!

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CHAPTER I
INTRODUCTION

Background

It is estimated that an upwards of one million traumatic brain injuries are treated in emergency departments (ED) in the United States each year,[1] resulting in approximately $56 billion in direct and indirect costs.[2] As reported by the Centers for Disease Control, there was a 62% increase in emergency room visits for sports and recreation-related concussions in persons 19 years or younger[3] with an estimated 136,000 occurring annually in high school sports between 2001 and 2009.[4–6] It is assumed that athletes participating in sports have the appropriate medical personnel to care for injuries sustained during practices or games, however, some youth organizations or secondary schools may not have such resources.[7] In the United States alone, more than 7.6 million students participate in organized secondary school athletics.[8] Many high schools and sports organizations with limited resources may rely heavily on results of computerized neuropsychological (NP) testing in making return-to-play decisions for athletes who have sustained a concussion.[9] However, NP testing has not been validated as a diagnostic tool and instead has been stressed as a monitoring tool when recovering from a head injury.[10] For the purpose of this article, the terms neurocognitive (NC) testing, and NP are used interchangeably and will be further explained at a later time.

Over time, clinicians from all realms of medicine have implemented statistical measures in attempts to quantify results of measured abnormalities.[11] Researchers have recently stressed the importance of a standardized, RCI and how the use of a standardized RCI should be meant to supplement, not replace, clinical judgment.[8,12–16] An RCI is a statistical method for developing empirically derived cutoffs that are used for evaluating meaningful differences in test scores.[9,10,12–14,16–36] When RCI differences of NC testing are the primary focus for determining

the presence or absence of a cognitive defect, there may be any increased risk of false-positive and false-negative diagnoses of sports-related concussions.[9,10,15,17,18,23,30,32,35,37,38]

Statement of Problem

When using an NC assessment such as the Immediate Post-Concussion Assessment and Cognitive Testing (ImPACT) to establish clinical significance, random variability can play a role in determining an individual's performance level.[17,23,28,30,35] Regression towards the mean theory suggests that subjects who score below average on a test tend to perform better during subsequent testing, and for those who score above average perform worse.[21,23,30,39] Consequently, when using the RCI differences of an NC assessment tool to determine a clinically significant change, measurement error may impart findings of false-positives or false-negatives. These findings at baseline can then result in a misinterpretation of data for extreme score ranges, as compared to average scorers, during subsequent testing.

A study conducted by Ikoma utilized the NC assessment tool CNS Vital Signs to establish a pre-injury cognitive level for their collegiate athlete participants.[30] After collecting baseline data, researchers separated participants' baseline scores into three quintile ranges, as described above, to determine variability in RCI ranges.[30] Clinically speaking, their results suggested the "one-size-fits-all" application of an overall RCI, which is used by many NC assessment tools, might lead to higher false-positives and false-negative rates for subgroups that score differently at baseline.[30] Therefore, a post-injury to baseline comparison of an NC assessment for those who scored in certain subgroups at baseline may require a stricter, or less strict RCI range, when compared to the overall non-quintile specific RCI range, to establish a clinically significant interpretation of scores.

Purpose

The purpose of this study was to determine the clinical significance of a widely implemented NC test battery ImPACT using adjusted and unadjusted RCI methods and comparing composite indices for both overall RCI values and RCI values for different ranges of baseline scores. Ranges consisted of the lowest (0 – 20th percentile), middle (40th – 60th percentile), and highest (80th – 100th) quintile in a sample consisting of 56 NCAA Division I football players.

Hypothesis

The null hypothesis suggests RCIs will not differ within the three selected quintile ranges of baseline scores for each of the four composite indices. The alternative hypothesis is that greater change will be observed in RCIs for each composite index within the lowest and highest quintiles when compared to the middle quintile baseline scores.

Significance and Clinical Application

When interpreting scores generated by an ImPACT assessment, licensed healthcare providers are making clinical decisions established by a computer generated overall RCI value.[9,10,12–14,16–36] RCIs are previously established based upon assessments completed by healthy subjects. Change scores can be used to determine the amount of change that can be considered measurement error compared with the amount of change that could be related to injury or true deficit. This value, in turn, dictates the presence or absence of cognitive impairment after sustaining an injury when compared to pre-established, individual baseline. In the absence of individual baseline scores, pre-existing normative scores may supplement baseline

scores.[8,14,18,21,31,37,40,41] If outlier scores are separated into their quintiles, as discussed above, there is a possibility that each of the RCI values produced could differ from the combined overall RCI value. The overall RCI, generally used as a one-size-fits-all value, may produce measurement errors that do not represent a true change for subgroups that score differently at baseline compared to average.[30,42] If the alternative hypothesis is accepted clinicians could classify the presence or absence of cognitive impairment with fewer false-positives and false-negatives.

Limitations

This study should not be generalized to the average population, as the participants were healthy, Division I NCAA football players. A small sample size my be considered a limitation and will be considered in the discussion. Also, this study was conducted retrospectively, therefore, the testing environments varied with each assessment. Additionally, lack of effort was not directly measured. Another limitation was the exclusive use of the ImPACT computer based NC assessment tool in this study.

CHAPTER II
LITERATURE REVIEW

Introduction

With media providing more coverage than ever, and clinicians and researchers worldwide continuing to ask questions, brain injuries, more specifically concussions, remain one of the most complex injuries in athletics to diagnose. Disappointedly enough, there has yet to be a universally accepted scientific definition of concussion.[6,8,14,38,43,44] To further complicate things, both diagnosis and treatment often vary from physician to physician. It is also important to note there is currently no effective equipment that prevents the occurrence of a concussion.[8,10,44] When interviewed for a local news channel, Brian Morgan, who oversees the Texas Youth Football Associated, suggested, "the game of football is organized violence."[45] Therefore, as the culture of American football continues to promote violent collisions, the number of concussions would be expected to increase as well.[46]

Although most symptoms can resolve within a few days[21], it is possible for symptoms to last weeks[47–49], months[6,49,50], or even years[49,51], further highlighting the importance of diagnosis by an appropriately trained, licensed healthcare provider.[10] Current research indicates NC deficits can linger when an athlete may report the absence of symptoms, indicating a full recovery has yet to occur.[7,14,27] This has lead to the most widely accepted method of a multidimensional approach when evaluating for a sports-related concussion.[10,15,20,31,34,37,40,42,52–56] The most recently contributed assessment tool to further enhance this multidimensional approach evaluates for cognitive impairments that are most consistently reported after concussion.[10,23,28,31,40,57–59] While at the collegiate or professional level a team physician, athletic trainer, and possibly a neuropsychologist may comprise a multidisciplinary team caring for athletes with concussions[15], high schools and youth sports groups may not have such luxuries.[9]

In a recently administered survey, 95% of athletic trainers conduct some form of NC baseline testing.[42] Also, many high schools and other institutions with limited resources may rely heavily on the results of computerized NC testing in making return-to-play decisions.[9] As indicated by the most recently published Natation Athletic Trainers' Association (NATA) Position Statement: Management of Sports Concussion, when used in isolation, NC testing does not provide clinically adequate information in regards to the sensitivity of a concussion.[8]

Current literature has established the value for detecting NC changes following a sports-related concussion. However, it has been argued that the usefulness of NP baseline testing has not been thoroughly tested and may not increase clinical utility within athletics.[19,23] Primary focus of such research revolves around confounding variables that are associated with a negative influence during the assessment of cognitive function, such as distraction, fatigue, and group testing.[13,48,52,54,56,60–63] Much less consideration has been given to the statistical techniques used to guide decisions about the presence or absence of cognitive impairment following concussion.[21,26,29,34,64]

This study aims to understand better how the method used to interpret NC scores may be impacted by an individual's baseline assessment performance. The second purpose of this study is to determine RCI values using the traditional, unadjusted, Jacobson and Truax (JT) method as well as the adjusted method produced by Chelune et al.[26] when using the overall sample as well as specific quintile ranges of the overall sample. The following information will serve to provide a comprehensive review of sports-related concussions. Literature will include current management strategies, as well as the role NP testing is currently exhibiting within the realm of sports.

Sports-Related Concussion

Definition

Throughout the years, startling ranges of definitions have been associated with a concussion. Commonly enough, these definitions focus on the nature of the signs and symptoms present at the time of injury.[65] For the past three decades, a rather popular definition proposed by the Committee on Head Injury Nomenclature of Neurological Surgeons in 1966 has been most commonly used.[14] This group defined a concussion as “a clinical syndrome characterized by the immediate and transient post-traumatic impairment of neural function such as alteration of consciousness, disturbance of vision or equilibrium, etc., due to brain stem dysfunction.”[66] With more current research providing more insight into the different aspects of concussion, further definitions have been utilized.

The American Medical Society for Sports Medicine (AMSSM) Concussion in Sport Position Statement defines a concussion as "a traumatically induced transient disturbance of brain function and is caused by a complex pathophysiological process."[10] Whereas the Centers for Disease Control and Prevention (CDC) defines a concussion, or a mild traumatic brain injury (MTBI), as "a complex pathophysiological process affecting the brain, induced by traumatic biomechanical forces secondary to direct or indirect forces to the head."[2] The CDC provides a definition that is less restricting, leaving room for interpretation by the licensed health care provider responsible for making a diagnosis. As further discussed throughout this paper, it is evident that no two concussions are alike in turn providing an explanation as to why a sports-related concussion is the most complex injury to diagnose. It is important to note that while all concussions are traumatic brain injuries (TBIs), not all TBIs are concussions.[10] An MTBI in

sports is typically referred to as a concussion.[22,41] Therefore these three terms will be used interchangeably throughout this review unless otherwise noted.

Epidemiology

As estimated by the CDC, an average 230,000 Americans are hospitalized as a result of TBI each year.[3] However, it is believed that this number underestimates actual incidences as not all sports-related concussions may be accounted for. For example, players and coaches could lack awareness or downplay symptoms of concussions. Also, the CDC statistic only incorporates those who suffered a loss of consciousness (LOC).[41] This statistics becomes much more concerning, considering 90% of concussions in sports occur without LOC.[14,44] Therefore, Langlois et al. estimated a more accurate 1.6 and 3.8 million concussive injuries occurring annually.[67] Between 2001 and 2005, approximately 207,830 of TBIs were sports and recreation related and required treatment in ED.[3] Sports and recreation–related TBI ED visits increased by 62% from 153,375 in 2001 to 248,418 in 2009 with a population consisting of 10 to 19 years old represented 70.5% of this increase.[3]

Concussions are not gender specific and can occur in all ages and all sports.[3,5,6,68,69] However, concussions have been most frequently reported among contact or collision activities.[8,17,38,47,59,68,70,71] In the United States, it is estimated that sports-related concussions are responsible for 5.8% to 6.2% of all sport-related injuries among various college sports annually.[4,72] When considering high school and collegiate sports, rates of concussions were highest among athletes participating in football and soccer.[4,5] When looking primarily at collegiate football, it is estimated that 5% to 9% of injuries each year are concussion-related.[72] Research has identified the linebacker position as displaying the highest incidence of concussion

exposure.[4,5,10,27,44,47] It has also been reported that individuals with a previous history of concussion are at a 4 to 6 times greater risk of sustaining additional concussions than those with no history.[68,73]

Pathophysiology

Contrary to popular belief, not all concussions result from a direct blow to the head. Concussions may occur from forces applied directly or indirectly to the skull that leads to the rapid acceleration and deceleration of the brain.[2,8,38,41,44,47,68] Depending on the velocity of impact, type of movement of the brain, the brain tissue can move against itself in the skull, increasing the risk for NC and neurobehavioral deficits.[41] The neurometabolic cascade of concussion represents the clinical presentation of a concussive injury. Occurring at the cellular level, the neurometabolic cascade involves a process of ionic, metabolic and pathophysiological events that are accompanied by a microscopic axonal injury.[10] Ultimately, an imbalance between energy demand and energy supply within the brain creates a cellular vulnerability that is increasingly susceptible to changes in cerebral blood flow, intracranial pressure, and apnea.[14] Until normal brain cellular function is restored, a period of increased postconcussive vulnerability is suggested. Current literature suggests a second injury during this time of vulnerability could result in second-impact syndrome.[7,8,10,14,23,44,49,68,74–76]

Symptomology

The symptoms of a concussion vary widely between injuries and individuals. A concussion can result in any combination of physical, cognitive, emotional, and sleep-related signs and symptoms.[27,77] A vast majority of research suggests headaches are the most commonly

reported symptom when sustaining a concussion.[4–6,44,47,59] A study conducted with high school football players suggested up to 70% of athletes suffered from headaches after sustaining a concussion, making it the most commonly reported symptom. The same researchers also reported concussions occurred without experiencing headaches.[14] Other symptoms commonly experienced include nausea, balance problems or dizziness,[10,14,41] change in sleep patterns, confusion, mental fogginess, memory difficulties, attention and concentration difficulties, and nervousness.[10,41] In attempts to use a system-based assessment in determining the severity of a concussion, researchers composed a study consisting of 47 concussed athletes. Results indicated that athletes who reported memory problems at follow-up had longer duration of symptoms, as well as a significantly greater symptom score and a decreased NC test performance.[14]

Several symptoms of concussion are non-specific[10] or may fall within the range of typical experiences of active participants, in the population primarily studied.[8] For example, nausea, vomiting, and headache are common when experiencing acute gastroenteritis[10], whereas symptoms produced by dehydration, fatigue, or anxiety could replicate those of a concussion.[8] Individual baseline assessments also allow for the clinician to determine if symptoms are considered normal or abnormal when evaluating for a possible concussion. The use of baseline assessments have helped to provide more objective measures with concussion assessments.[8,50,78]

It has been frequently reported that majority of athletes have symptom resolution within one week of injury.[6,47,48,79] However, symptom recovery is different from cognitive recovery and may not always occur simultaneously.[14,15,23,59,77] When comparing post-concussive symptoms and cognitive deficits, 40% of asymptomatic patients had persistent cognitive declines.[33,59] A study conducted by Field et al. found football and soccer participants displayed significant memory impairment. Interestingly enough, high school participants experienced this impairment

for at least seven days following a concussion, whereas impairment was only evident in the first 24 hours among collegiate participants.[7] Results suggest a greater cognitive recovery period is necessary for high school-aged athletes compared to college-aged athletes. Makdissi et al. defined symptom recovery as the time until all reported postconcussive symptoms had resolved and cognitive recovery as the time taken for all cognitive deficits to recover.[70] Cognitive assessments have been proven beneficial in determining decrements in the initial hours, days and weeks post-injury.[41] Several other sports-related concussion tests providing objective measurements have been developed to assist further in concussion diagnosis.[27] These tests will be discussed throughout the literature.

Long-Term Effects

The occurrence of cumulative cognitive impairment is increased if the athlete continues to participate in the activity before symptom and cognitive recovery has been established. However, the relationship between concussion and long-term cognitive health is not clear.[8] Currently, there is research to suggest chronic changes in NC functioning after concussion does not exist[48,78] and research to indicate a change in NC functioning does exist.[80] The emerging literature is expected to surface in regards to the use of functional magnetic resonance imaging (fMRI) to further promote the assessment of neural changes associated with concussions.[14] The study is intended to administer NP tests to concussed athletes during the fMRI scanning process. When this method was conducted using non-concussed individuals, results showed measurable and predictable changes in brain activity.[14]

Professional athletes are beginning to gain public attention in regards to late-life cognitive impairment, depression, and chronic traumatic encephalopathy (CTE). CTE is a

"neurodegenerative disease associated with repetitive brain trauma."[51] Symptoms of CTE include executive dysfunction, memory impairment, depression, and poor impulse control.[10] The diagnosis of CTE can only be made post-mortem, making research advances towards providing a correlation difficult to achieve.[10] While many researchers have speculated the relationship between concussions and repetitive subconcussive blows and the development of CTE, there is no current data to confirm a direct correlation.[8,71] Currently there are no direct objective measures of brain function that can definitively indicate a return to normal after concussive injuries.[7,70,77] As a result, this increases the risk of premature return-to-play and subsequently increases the risk of long-term effects.

Management of Sports-Related Concussion

Prevention

Although a complete cessation of sports-related concussions is nearly impossible, several preventative measures can be implemented to reduce the incidence of occurrence. As of 2015, legislation addressing the need for awareness and management of concussions within the United States existed in all 50 states and the District of Columbia.[52] The NCAA has adopted guidelines that require the implementation of a concussion management protocol.[19] Professional sports organizations such as the National Hockey League (NHL)[19,81], National Football League (NFL)[19,81], Major League Soccer (MLS)[19], and Major League Baseball (MLB)[19] have developed concussion management programs as well.

While initially the primary focus was placed on educating the athlete on the different components of concussion, new trends in prevention management suggest the incorporation of a larger audience could provide increased benefits. As indicated by NATA Position Statement:

Management of Sport Concussion, it is important to ensure that not only athletes, but also parents and coaches are educated on multiple aspects of concussion including “prevention, mechanism, recognition and referral, physical and cognitive restrictions for concussed athletes, and ramifications of improper concussion management.”[8] A study was conducted to evaluate the potential benefits of implementing the CDC's "Heads Up" tool kit.[49] Researchers reported that 34% of high school coaches not only gained knowledge related to injury signs and symptoms but also indicated changes in attitude and behavior related to concussive injuries.[49] Aside from the “Heads Up” tool kit, there is a variety of other concussion material through governmental, educational and private companies.[10]

In a study containing high school aged athletes, 25.3% of concussions were associated with illegal activity.[71] Therefore, it can be implied that greater adherence to rules expressed by players, coaches, and officials may help decrease the rate of concussion. This process may require a shift in attitude, and potentially an overall culture change within contact and collision sports. A variety of sports have also enforced rule changes over the years for the benefit of the athlete. For example, spear tackling has been banned from football, elbow to head contact has been limited in soccer and no checking from behind in hockey. These rule changes have been enforced based on epidemiological data.[10]

As previously stated, professional sports organizations, as well as the NCAA, have developed concussion management programs.[19,81] As seen within these programs, preparation of care for the concussed athlete begins before participation through a pre-participation exam (PPE).[10] Such exam should provide the healthcare professional who is responsible for the care of the athlete with information that can be used to assess the risk and history of concussion. Depending on resources available, this exam may include a baseline evaluation of subjective

symptoms, as well as objective balance testing and cognitive function to serve as a pre-injury comparison level if needed later in the season. Baseline testing requires an honest effort on the part of the athlete to provide benefits with pre-injury and post-injury comparisons. Furthermore, it is of utmost importance for medical staff to be prepared with an emergency action plan if the evacuation of a critically head- or neck-injured athlete is necessary.[14]

Assessment

According to Field et al. clinicians base the diagnosis of a concussion on the following assessment criteria: any observable alteration in mental status or consciousness, presence of anterograde or retrograde amnesia, or any self-reported symptoms.[7] As indicated earlier, LOC occurs in only 10% of concussed athletes.[14,44] Therefore, the difficulty arises when initiating the assessment of a concussion, which in most cases stems from the subjective symptom report as delivered by the athlete.[10,11,18,27,33,35,44,57,59] As recommended by the most recently revised Fourth International Consensus on Concussion in Sport, an assessment should include a thorough history as well as a neurological examination including mental status, cognitive function, balance, and gait.[77]

A proper concussion evaluation is a multidimensional approach comprised of several assessments providing objective measures to identify deficits in balance or vestibular function, as well as mental status and cognitive function. Such tests include the Balance Error Scoring System (BESS), a Standardized Assessment of Concussion (SAC) or an Immediate Post-Concussion Assessment and Cognitive Testing (ImPACT) along with a symptom report using a standardized Post-Concussion Symptom Scale (PCSS). A PCSS is further implemented to allow the athlete to grade their current symptoms. Although reporting symptoms is a subjective

measure, grading of symptoms allows for comparison to baseline after an injury has been sustained. Researchers found an increased accuracy in response to symptoms reported when asked to individually grade each symptom.[27]

As with any life-threatening injury that may occur in athletics, a primary assessment involving the integrity of an airway, breathing, and heart function are performed. In this situation, an emergency transfer should occur if a cervical spine injury cannot be eliminated, or if there are signs of a more serious brain injury.[10,77] The management of such situation is beyond the scope of this paper. Once all life-threatening injuries have been ruled out, and it has been deemed safe, the athlete should be moved from the field to an area where further assessments can be performed to determine the nature and severity of the injury.

An athlete suspected of sustaining a concussion requires a thorough examination as conducted by a licensed healthcare provider trained in the evaluation and management of a concussion. A standardized approach to concussion assessment is critical to limit any potential subjectivity.[10,24,25,62,70] As stated earlier no two concussions are alike, confirming the idea of a multidimensional approach incorporating a variety of tests to provide objective measures. When dealing primarily with sideline assessments, Maddocks' questions and the SAC are the most widely used tools to assess mental status and acute cognitive function.[10] Other commonly used assessment tools include the Management of Concussion Sports Palm Card, Sideline Concussion Check, and the McGill Abbreviated Concussion Evaluation.[11]

As developed more recently by the Prague Consensus Group, the Sport Concussion Assessment Tool (SCAT) combines a variety of previously implement sideline assessment tools.[11] The SCAT originally published in 2005 has been modified and renamed twice since. The current form of this test used today, the SCAT3, was developed at the 2012 International

Summit on Concussion in Zurich.[77] It measures symptoms, orientation, memory, recall, balance and gait. The SCAT3 exam is sensitive to changes in cognition early after injury. However, its sensitivity decreases when used in the days, weeks, or months following, with respect to concussions.[11,12,82] As agreed upon by the Zurich 2012 consensus panel, the acute phase on concussion is a continuously evolving injury with individualized changes in signs and symptoms.[77] Although evaluating mental status through a SCAT exam is a primary measure of acute cognitive function, NC tools are more sensitive to prolonged cognitive deficits in the post-acute phase of a concussion and will be discussed at greater lengths in the future.[11,12]

The BESS assessment is a clinical test designed to assess postural stability on stable and unstable surfaces in 3 different stance positions.[10,27,38,50,76,77] Each stance is held for 20 seconds. Point deductions are given if the athlete opens their eyes, takes their hands off their hips, steps out of the stance, stumbles, and bends at the hips greater than 30 degrees. A maximum number of 10 errors can be recorded for each condition, with a total maximum BESS score of 60.[10,27] For most athletes, BESS performance returned to baseline levels within three to seven days post-injury.[10] With scores returning to baseline within the first week, the BESS test is much more useful as a sideline assessment, but not as useful for later follow-up evaluations.

Treatment and Return-to-Play

More than 20 concussion management guidelines have been published over the years.[14] An eye-opening consensus of the First International Symposia on Concussion in Sport Help in Vienna in 2001 deemed that no previously published concussion management guidelines were adequate for assuring proper management of every concussion.[83] As recommended by the most recently revised Fourth International Symposia on Concussion in Sport, management and return

to play (RTP) guidelines remain inadequate for assuring proper management of every concussion. Authors promote individualized management strategies and ensuring proper clinical judgment when making RTP decisions.[77] According to position statements released by the AMSSM and the NATA, the treatment of a concussion consists of relative physical and cognitive rest.[8,10] Cognitive rest requires a limited exposure to academic and cognitive stressors in activities of daily living. The goal is to keep the brain at rest by limiting mental distractions that could increase symptoms during post-concussion stage.[8] Current research supports a graduated RTP protocol[8,10,14,41,77], beginning with light aerobic exercise progressing clear through to full contact practice, and each stage separated by 24 hours.[8,10,14,77] Each treatment and management strategy should be individualized.[8,10,77]

Before RTP, an athlete should display baseline level scores for objective measures taken, for instance, PCSS, BESS, SAC, and ImPACT.[8,23] It is imperative for the athlete to be asymptomatic at rest and exertion before RTP. If an athlete develops symptoms during the supervised RTP protocol, the athlete is to return to the previous day where they can perform tasks symptom-free again. Best management practices have suggested that the managing physician is intimately involved in this process, overseeing each step.[8,10,77] Prior the final step of full RTP it is common for the athlete to participate in a full contact practice first. Best practices also suggest that the physician has the ultimate decision in allowing an athlete to return to contact participation, using his or her best clinical judgment.[8,10,14,15,21,31,35,70] Collie et al. suggest that "the cognitive function of athletes after a concussion is now commonly used to determine suitability" to RTP and rehabilitation strategies.[64] Other researchers have also suggested the use of neurocognitive tests in tracking recovery[16,22,23,33,41,55], as it can show deficits longer in athletes who are asymptomatic determined by a subjective PCSS report.[14,15,23,59,77]

Neurocognitive Testing and Sports-Related Concussion

Role and Value of Neurocognitive Testing

NP testing provides clinicians with the ability to collect objective, sensitive, and detailed neurobehavioral information about the athlete's postconcussive status.[8,14] This tool can identify impairment that would otherwise be occult.[10] A standard NP assessment consists of a variety of tests of cognitive abilities psychological functioning and testing of sensory and motor functioning.[23] Results allow neuropsychologists to make diagnoses in regards to developmental and acquired disorders of the central nervous system.[23] Although an NP assessment has been useful in detecting deficits resulting from TBI, these instruments utilize extensive, time-consuming test batteries and are not clinically applicable within athletics.[23,25]

Sports-related concussion test batteries are designed for easy implementation within athletic programs and, in turn promote the screening of a large number of athletes to establish an individual norm for each.[10,41] The NC screening portion of an NP assessment is capable of detecting transient impairments in the immediate post-injury phase of a concussion.[23] Types of cognitive impairments that are most consistently reported after concussion include deficits in memory, cognitive processing speed, and certain types of executive functions.[10,23] A range of NC deficits may be observed such as slow reaction times and increased variability in response, reduced attention and ability to process information, reduced planning and ability to switch mental set and also impaired memory and learning.[11]

NP testing was first implemented in the assessment and management of sports-related concussions in the 1980s at the University of Virginia.[10,14,25] The study supported the validity of NP testing in detecting cognitive change and recovery within one week of sustaining a concussion.[14] Initially, pencil-and-paper tests were solely available, which required training and

years of experience to both administer and interpret.[42] Such tests include the Digit Span, Controlled Oral Word Association Test, and Hopkins Verbal Learning tests.[8] It was not until the 1990s when injuries to high-profile professional athletes resulted in the widespread use of NP testing among the sport specific population.[14] Since then; several computerized NP test batteries have been developed including ImPACT, CogSport, HeadMinder Concussion Resolution Index[14,35,81], Automated Neuropsychological Assessment Metrics (ANAM).[14,81]

The implementation of computerized NP testing offers a variety of advantage, accompanied by a few disadvantages when compared to a pencil-and-paper test. For example, computerized testing allows for the evaluation of a large group and automation of data collection while requiring minimal human interaction[10,11,14,40,42,52,53,81], but this, in turn, trades face-to-face administration that could provide useful information that may not be accounted for with a computer. Also, data collected is easily stored in a central location and can be returned to at any given time.[11,81] Computerized testing also promotes an increased accuracy of measurements such as reaction time and processing speed.[10,11,14,42,53,64,81] Conversely, the test does not account for variability between computer devices used or differences between a tracking pad and a mouse. Additionally, there is an increase in randomization of test stimuli with computerized tests that may not be available for pencil-and-paper tests.[10,11,14,26,42,64,81]

Although a variety of positives with the improved methods of NC testing exist, NP testing ultimately requires a truthful symptom report as well as appropriate effort during testing periods.[53] NFL superstar Peyton Manning admitted to intentionally providing poor effort to avoid being benched if he sustained a concussion during the season.[61] Clinically speaking, it becomes difficult to determine if poor test performance is due to effects of a sports-related concussion or suboptimal effort delivered at baseline.[72] Szabo et al. reported 25% of baseline

scores suggested suboptimal effort according to the ImPACT manual.[72] Current literature both supports and rejects the validity, reliability, and clinical utility of NP tests and their role in concussion management.[14,23,40,42,53,64,72]

Neurocognitive Management Trends and Interpretation of Scores

Current trends in research suggest the use of a post-injury to baseline comparison[8,11,12,14,84], accompanied with serial evaluations conducted after the injury, to determine if and when neurocognitive deficits and clinical symptoms have subsided.[26,41,64] At a minimum, a baseline cognitive assessment should include an objective assessment of NC performance and motor control.[8] Baseline assessments act as a within-groups research design in which the athletes serve as their own control.[14,20] Guskiewicz et al. stated that "the goal of baseline testing is to provide the most reliable benchmark against which to compare post-injury performance."[84] With that being said, it is paramount to account for physiological variables such as psychological distress or fatigue, as well as environmental variables such as distractions or clarity of instructions, whenever possible.[10,25]

Studies also suggest the use of pre-collected normalized data be used in the absence of individual baseline testing.[14,42,64] Normative data currently exist for sex, age, and education level.[42] Opposing research suggests multiple errors when comparing data with population norms, as it does not account for the history of concussion, race, etc.[11] The Second International Conference on Concussion in Sport recommends using NP testing as the final step in the RTP strategy.[85] This would occur once clinical symptoms have resolved at rest and with exertion suggesting the exertional activity, but not contact drills, are encouraged before full NC recovery. However, the NATA Management of Sport Concussion Position Statement indicates a cessation

of symptoms, a restoration of motor control, and NC test results reverted to pre-injury levels before a return-to-play progression is implemented.[8]

ImPACT is one of the most widely used computer-based NC assessment tool involved in the management of sports-related concussions.[20,26,81] The test battery is comprised of 6 different test modules, which yield a total of seven composite scores. To aid in the clinical interpretation of test performance, select module scores are combined to produce composite scores. An individual symptom score is also recorded pre and post assessment and is also reported as a composite score. The ImPACT composite indices represent summary scores that provide necessary information regarding the athlete's performance in core cognitive domains.[86] Composite scores are generated to represent verbal and visual memory, visual motor speed, reaction time, impulse control, a total symptom score, and a cognitive efficiency index (CEI). ImPACT was designed to measure the speed and accuracy of responses simultaneously. As a result, athletes may decrease speed to increase accuracy and vise versa. The CEI was designed to provide an index of "tradeoff" between speed and accuracy.[86]

It has been highly recommended that a clinical neuropsychologist, who is uniquely qualified to translate results into clinically relevant recommendations, conduct interpretation of scores.[8,14,41] As indicated by Collie et al., when administered to young healthy individuals, many NP tests display floor or ceiling effects and have a restricted range within which a healthy subject usually scores.[64] ImPACT has been shown to distinguish effectively between concussed and non-concussed athletes. A study conducted by Schatz et al. using the ImPACT assessment in a sample of concussed high school football players reported sensitivity as 81.9% and specificity as 89.4%.[57] On the contrary, Mulligan et al. conducted a study in which non-concussed Division I football players were administered ImPACT 48 hours following their last

game. Results indicated 59.4% of subjects demonstrated, at least, two deficits in the test battery or more than one of the subcategories.[27] While Maerlender and Molfese reported no significant differences found when comparing baseline scores between one and three years apart, indicating good score stability over time[87], others have reported low test-retest reliability.[9,23,33]

Establishing test-retest reliability is extremely critical in determining reliable change scores for the purpose of individual decision making.[23] Reliable change scores represent a combination of true variance and error variance in a given test score.[23] Confidence intervals, as established through the overall variance of a test score, reflect the probability that a change in score results from the normally expected variance, as opposed to statistical measurement error.[23] There are multiple methods available to develop RCI scores, and even that is only one approach available for calculating the change in scores. Although ImPACT provides RCI values for detecting the change in scores, Randolph et al. suggest change-score probabilities are easier to interpret for a single overall score, which ImPACT does not provide.[23] A study conducted by Iverson et al. examined reliable change scores of ImPACT. Results indicated between 41%, and 51% of athletes across four composite scores were considered impaired. The expected false-positive rate was 10%.[16]

Echemendia et al. explored two commonly used methods for determining reliable change. The Jacobson and Traux (JT) method uses confidence intervals but does not account for regression to the mean, an adjust JT method first explored by Chelune, and the Gulliksen-Lord_Novick (GLN) method, which does account for regression to the mean. Cognitive deficits were more consistently identified with the GLN method when compared to the JT method[19] Thus while NP tests provide valuable information for some cognitive functions; the measures are not

perfect.[29] Existing literature confirms further research is needed to understand the most effective method of interpreting NC test results when managing sports-related concussions.

CHAPTER III
METHODS

Participants

This retrospective cohort study included 56 NCAA Division I collegiate football players. Data was collected in a de-identified manner. Therefore, the protocol for this study was exempt from IRB review. Before participation, each athlete underwent university-mandated concussion testing to establish an individual baseline measurement of neurocognitive function. Athletes who sustained a concussion between testing periods, or displayed an invalid baseline assessment score were excluded from the current study. Additionally, individuals who were diagnosed with a learning disability, anxiety disorders, or depression were also excluded.

Instrumentation

ImPACT is specially designed for the athletic population and is one of the most widely used computer-based NC assessment tool.[20,26,81] ImPACT consists of six different test battery modules. These tests include word memory, design memory, X's and O's, symbol match, color match, and three letters.[86] To aid in the clinical interpretation of test performance, select module scores are combined to yield composite scores. Composite scores are generated to represent verbal memory, visual memory, visual motor speed, reaction time, impulse control, a total symptom score, and a cognitive efficiency index (CEI). ImPACT was designed to measure the speed and accuracy of responses simultaneously. As a result, athletes may decrease speed to increase accuracy and vise versa. The CEI was intended to provide an index of "tradeoff" between speed and accuracy.[86] The magnitude of changes from baseline testing is assessed via the use of RC scores for the ImPACT composites. If an athlete demonstrates a change in scores

that falls outside of the range of normal score variation, the ImPACT report notes these changes in test performance.[86]

Procedures

Participants who completed two baseline assessments composed a within-subjects sample, allowing for the comparison between time one and time two.[20] Dependent measures included the verbal memory, visual memory, visual motor speed, and reaction time composite scores for each athlete as displayed in their ImPACT Clinical Report. Preseason assessments with ImPACT were collected in a group format, but individuals were separated to minimize distraction. Tests were administered by one of the several certified athletic trainers.

Statistical Analysis

Data was analyzed using SPSS for Windows. All alpha levels were set to *a priori* to p=0.05. For each composite score, the participants were categorized into one of five quintiles based on baseline scores as follows: 0-20th percentile (lowest 20%), 20-40th percentile, 40-60th percentile (‘average’ category), 60-80th percentile, and 80-100th percentile (highest 20%). Prior to determining RCI for overall and quintile specific scores of each composite index, test-retest reliability was established. Low test-retest reliability could lead to abnormally large changes scores, which may not be clinically relevant. On the other hand, high test-retest reliability would produce smaller, more realistic changes scores. Change scores accounting for measurement error and practice effects were calculated for the lowest, middle, and highest quintile of baseline scores for each composite score. Calculations of RCI were determined using the traditional,

unadjusted, Jacobson and Truax (JT) method as well as the adjusted method produced by the Chelune et al.[26] The adjusted method accounts for practice effects, where unadjusted does not.

CHAPTER IV
RESULTS

Table 1 displays total number of participants for each group, as well as values for both Pearson's correlation (*r*) and intraclass correlation coefficients (ICCs), mean and standard deviations for overall and each quintile of interest for the four composite indices. Pearson's correlation between baseline assessments ranged from 0.52 to 0.75 prior to the separation into quintile ranges. ICCs indicated greater reliability as compared to Pearson's *r*. The average time between test 1 and test 2 was 210 days ± 60 days.

Table 1: Test-Retest Reliability

		Time 1	Time 2				ICC 95% CI	
Verbal memory	n	Mean (SD)	Mean (SD)	r	p	ICC	Lower	Upper
Lowest	8	67.38 (7.50)	74.75 (12.61)	0.86	<.001	0.621	-0.054	0.911
Middle	8	84.50 (0.76)	80.00 (6.52)	0.03	0.987	0.005	-0.42	0.601
Highest	15	97.27 (1.98)	94.13 (5.62)	0.34	0.113	0.218	-0.19	0.613
		Time 1	Time 2				ICC 95% CI	
Visual memory	n	Mean (SD)	Mean (SD)	r	p	ICC	Lower	Upper
Lowest	13	60.00 (3.61)	71.15 (9.90)	0.34	0.254	0.106	-0.137	0.475
Middle	12	75.58 (1.83)	80.75 (7.94)	-0.21	0.504	-0.071	-0.443	0.435
Highest	16	89.94 (3.77)	85.50 (6.93)	0.38	0.15	0.248	-0.142	0.62
		Time 1	Time 2				ICC 95% CI	
Visual motor	n	Mean (SD)	Mean (SD)	r	p	ICC	Lower	Upper
Lowest	11	30.50 (3.71)	35.00 (4.64)	0.45	0.169	0.286	-0.138	0.701
Middle	14	38.73 (1.69)	38.06 (3.66)	-0.1	0.726	-0.076	-0.587	0.451
Highest	7	48.08 (1.67)	47.76 (2.21)	-0.06	0.904	-0.063	-0.946	0.708
		Time 1	Time 2				ICC 95% CI	
Reaction time	n	Mean (SD)	Mean (SD)	r	p	ICC	Lower	Upper
Lowest	16	0.74 (0.08)	0.66 (0.11)	0.23	0.396	0.166	-0.186	0.549
Middle	4	0.57 (0.02)	0.55 (0.04)	-0.1	0.776	-0.058	-0.533	0.491
Highest	5	0.49 (0.02)	0.56 (0.02)	-0.31	0.607	-0.066	-0.167	0.458

ICCs ranged from 0.51 to 0.74 prior to the separation into quintile ranges. The reliability of ICC for each composite index decreases when separated into quintiles, suggesting low test-

retest reliability of ImPACT. The ICC values for the middle quintile range (40-60th percentile) of each composite index displays the greatest difference from overall ICC value when compared to the lowest and highest quintiles. This could indicate a lower reliability in the middle quintile compared with the highest and lowest quintile. Figures 1-4 display scatter plots with R^2 for all subjects for each of the four composite indices. Figures 5-16 display scatter plots with R^2 for subjects within each quintile of interest for all four composite indices. Figures 1-4 differ from figures 5-16 within the respective composite index of interest. Explained variance, or R^2, decreases when subjects are placed into quintile ranges compared with the overall samples for each composite index.

Figure 1: Verbal Overall

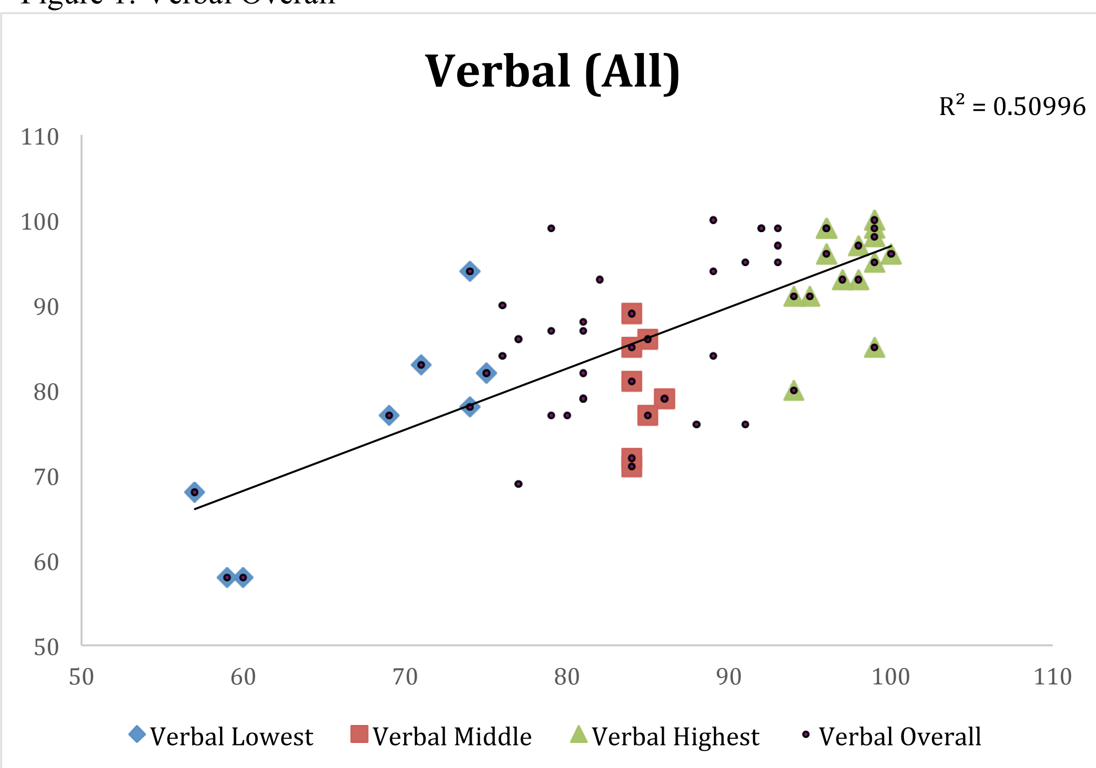


Figure 2: Visual Overall

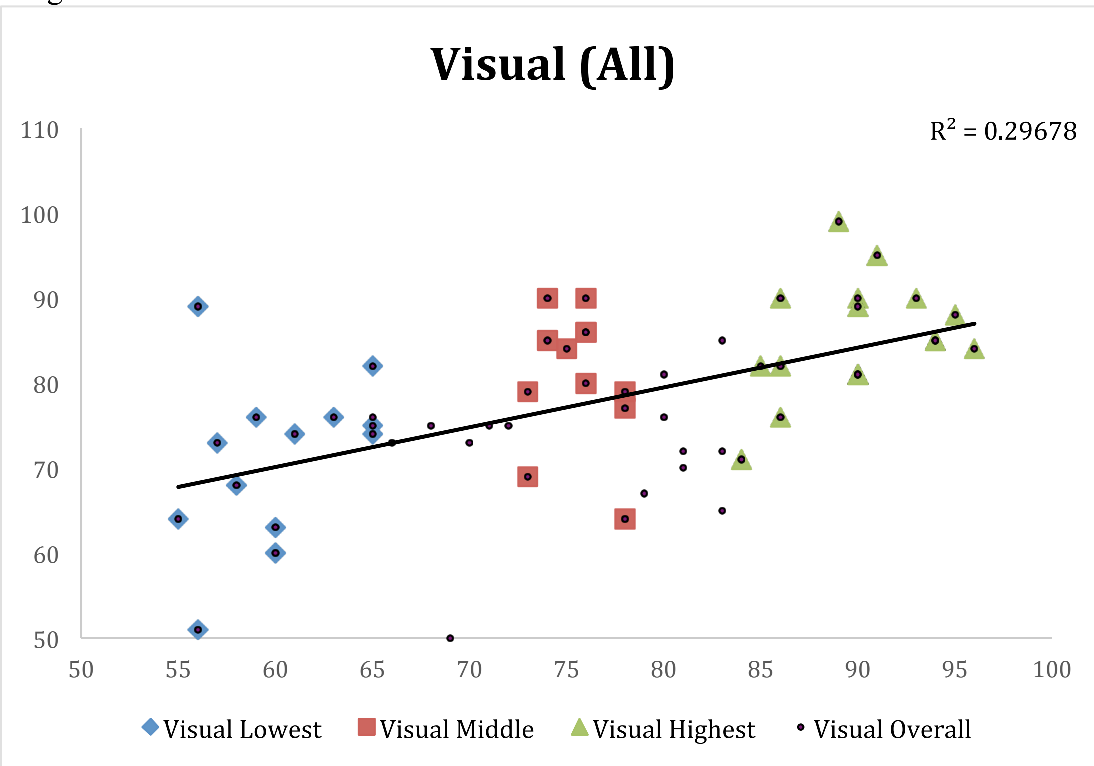


Figure 3: Visual Motor Overall

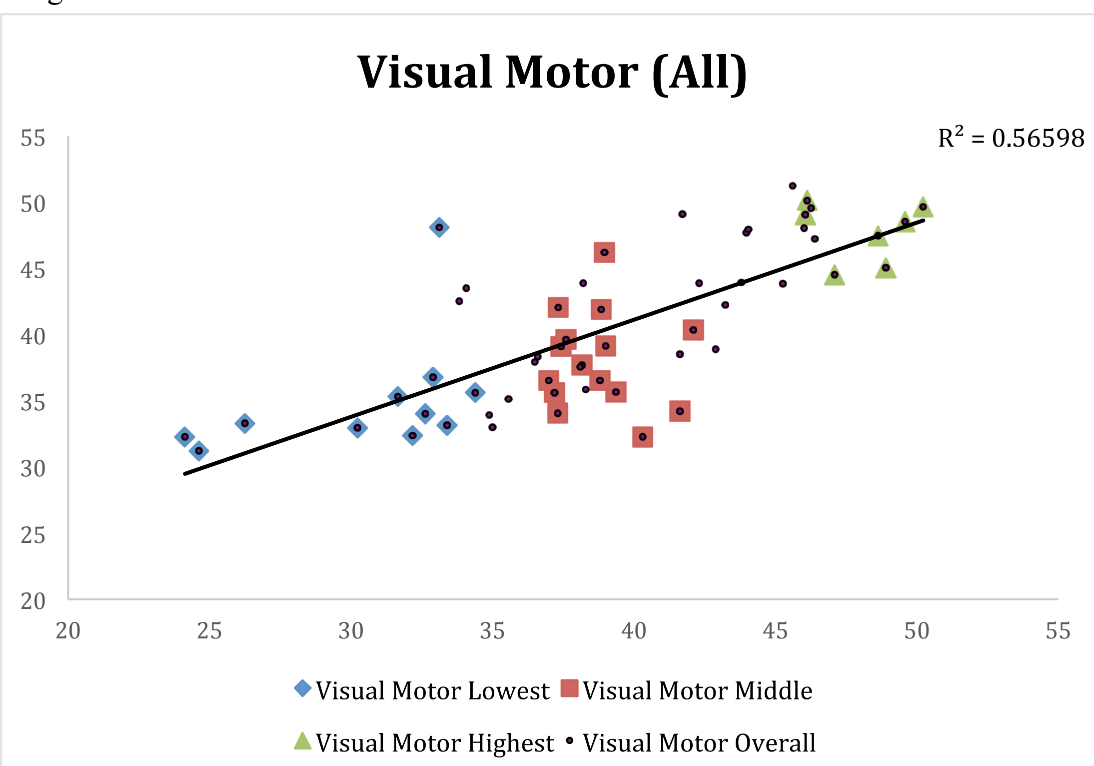


Figure 4: Reaction Time Overall

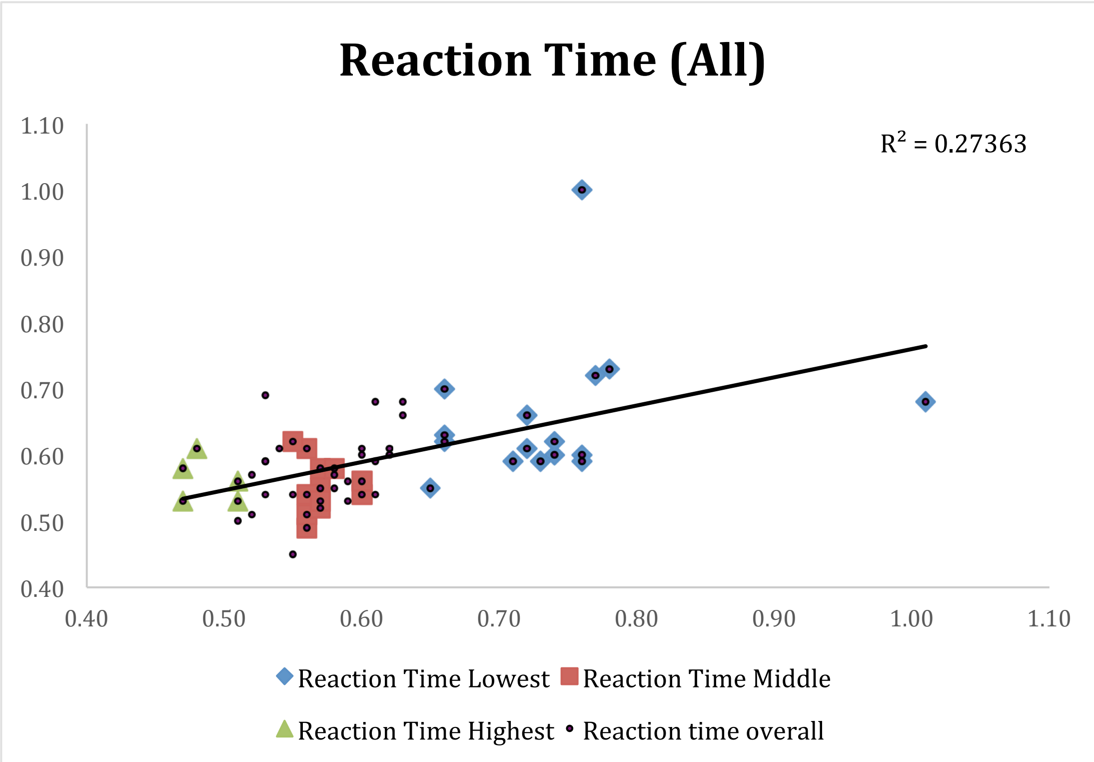


Figure 5: Verbal Lowest Quintile

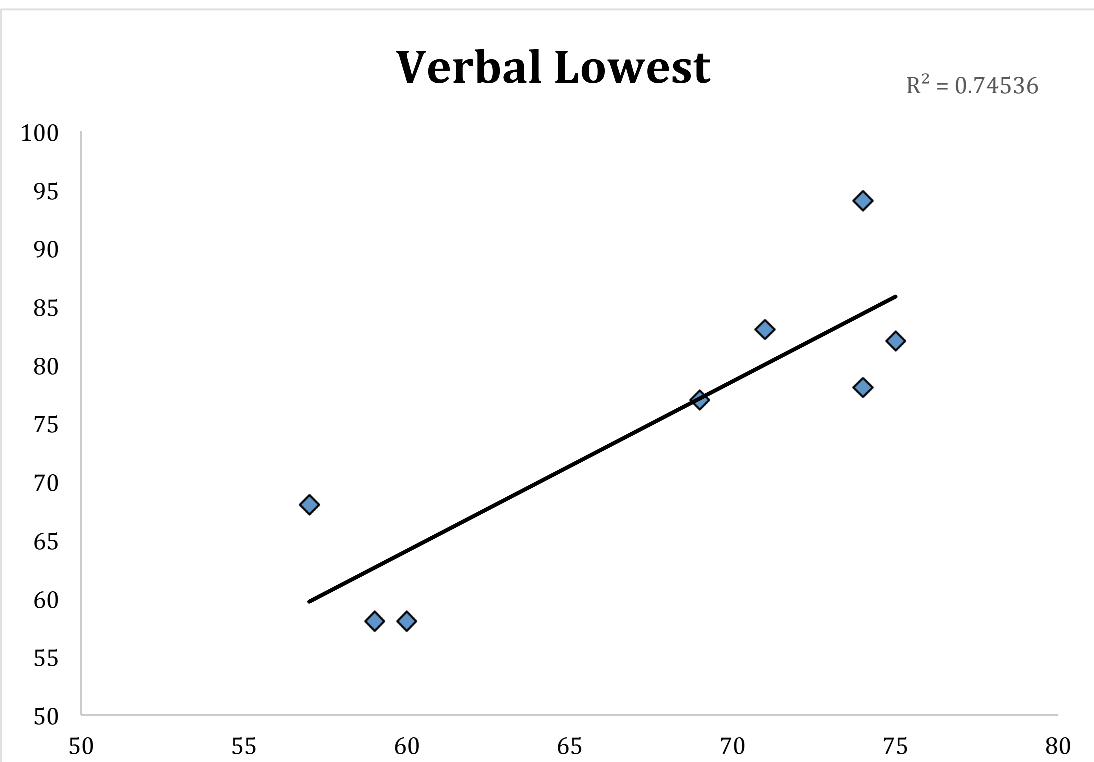


Figure 6: Verbal Middle Quintile

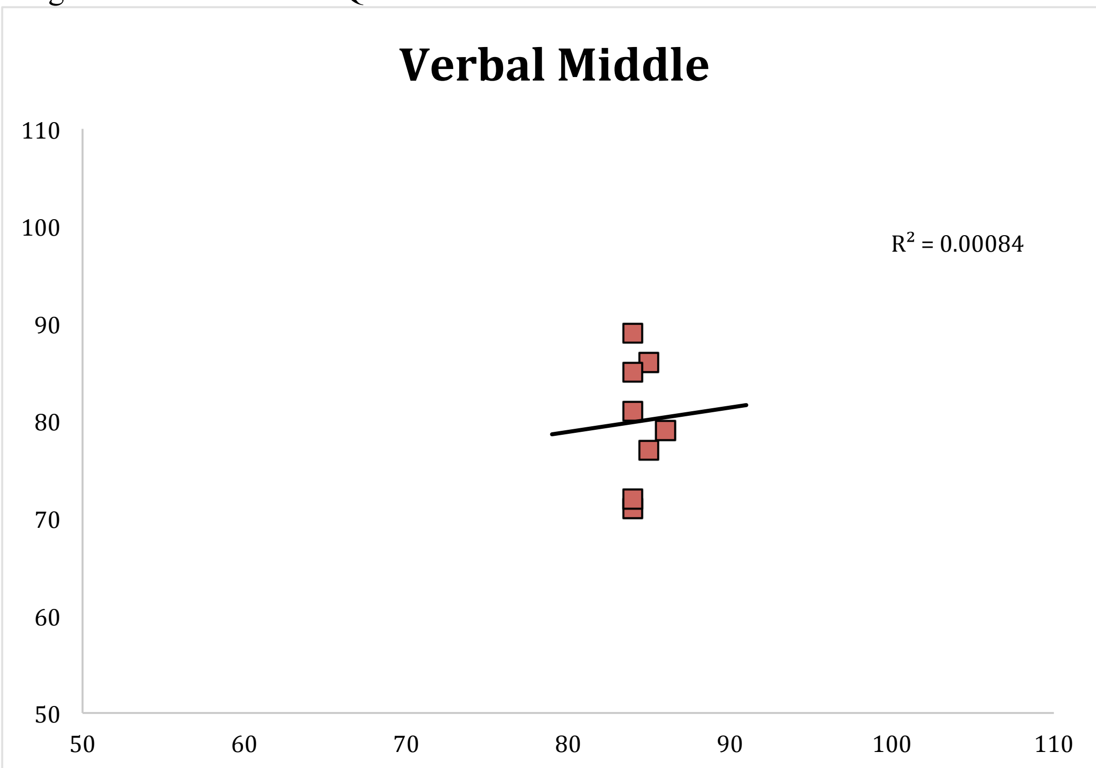


Figure 7: Verbal Highest Quintile

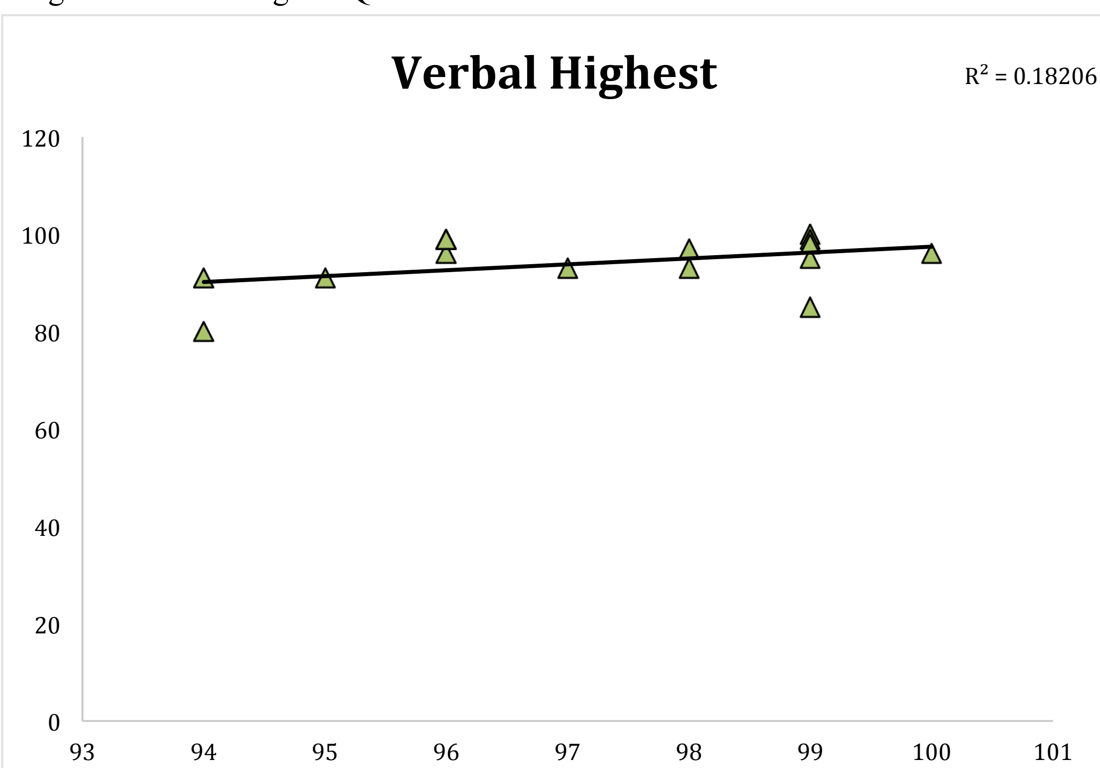


Figure 8: Visual Lowest Quintile

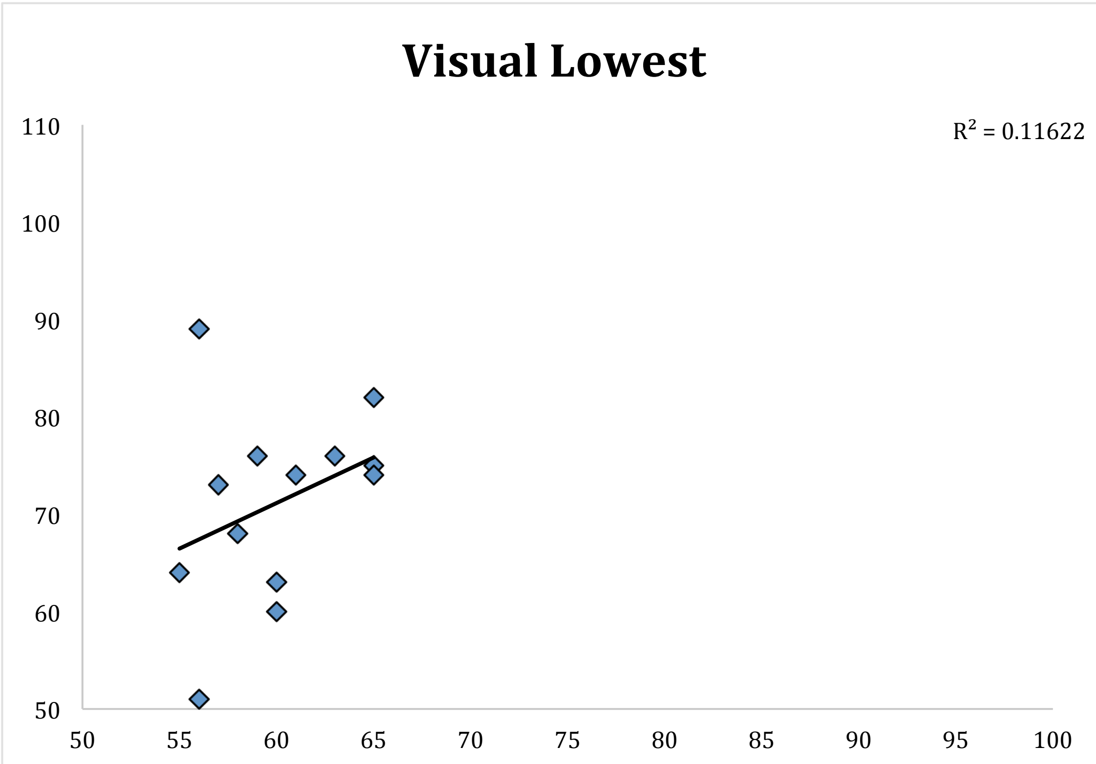


Figure 9: Visual Middle Quintile

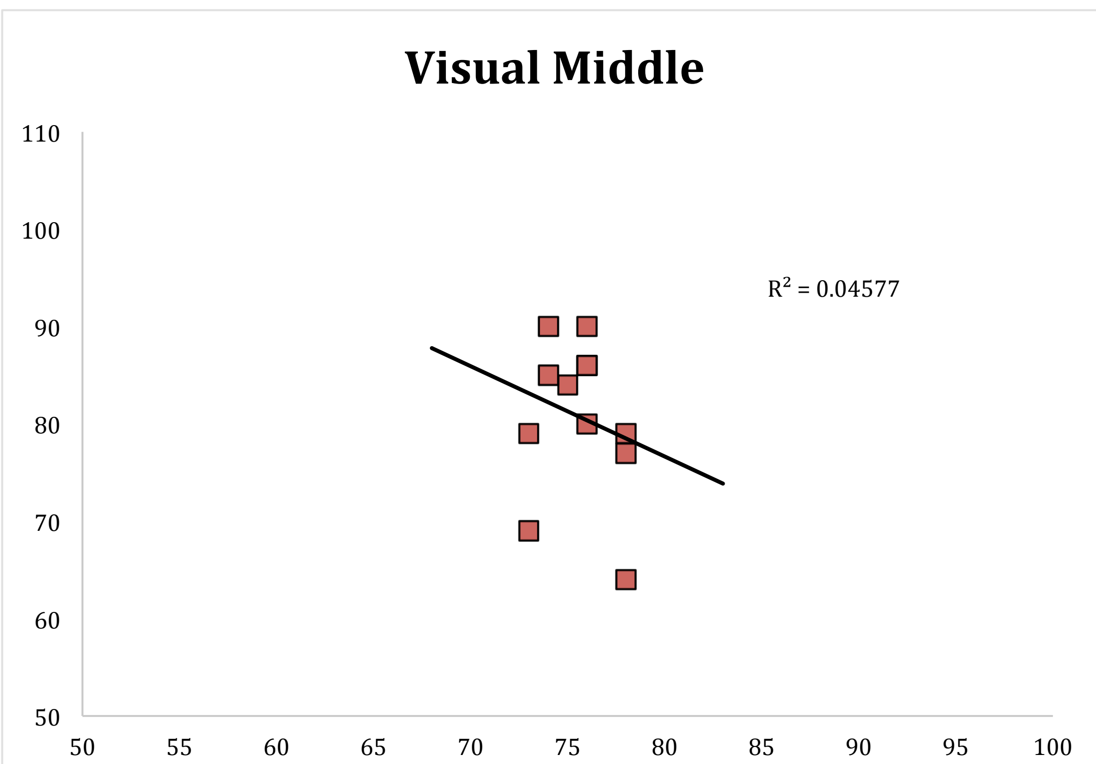


Figure 10: Visual Highest Quintile

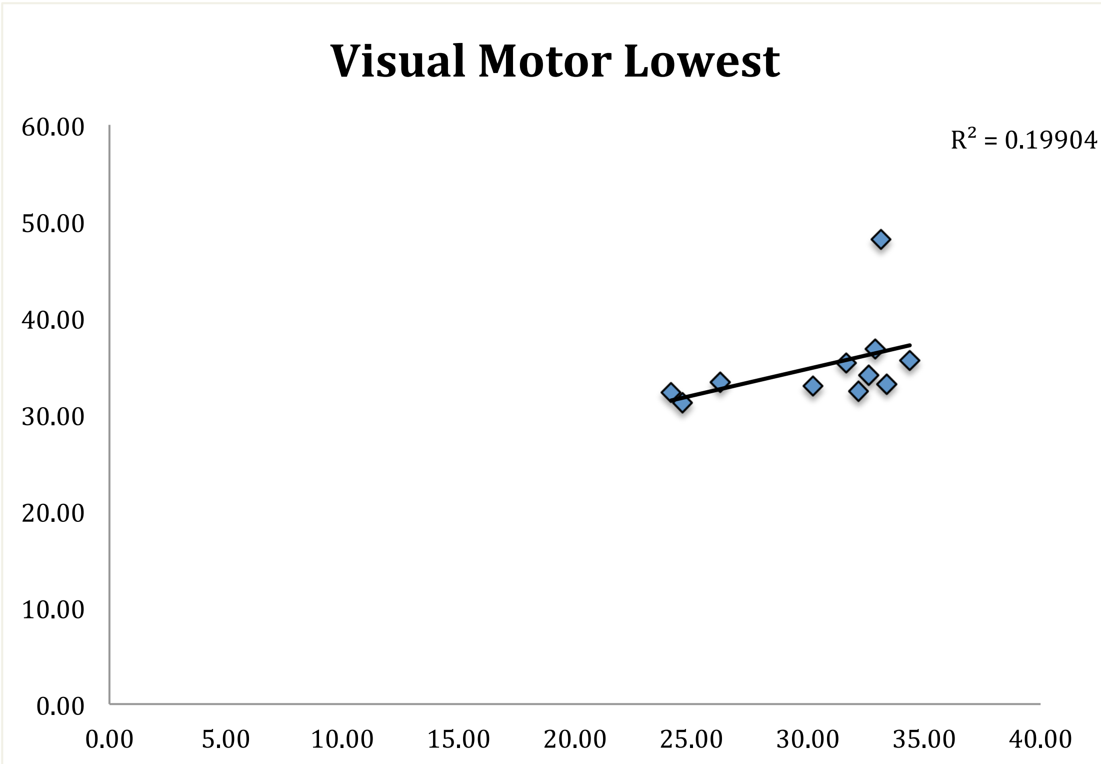


Figure 11: Visual Motor Lowest Quintile

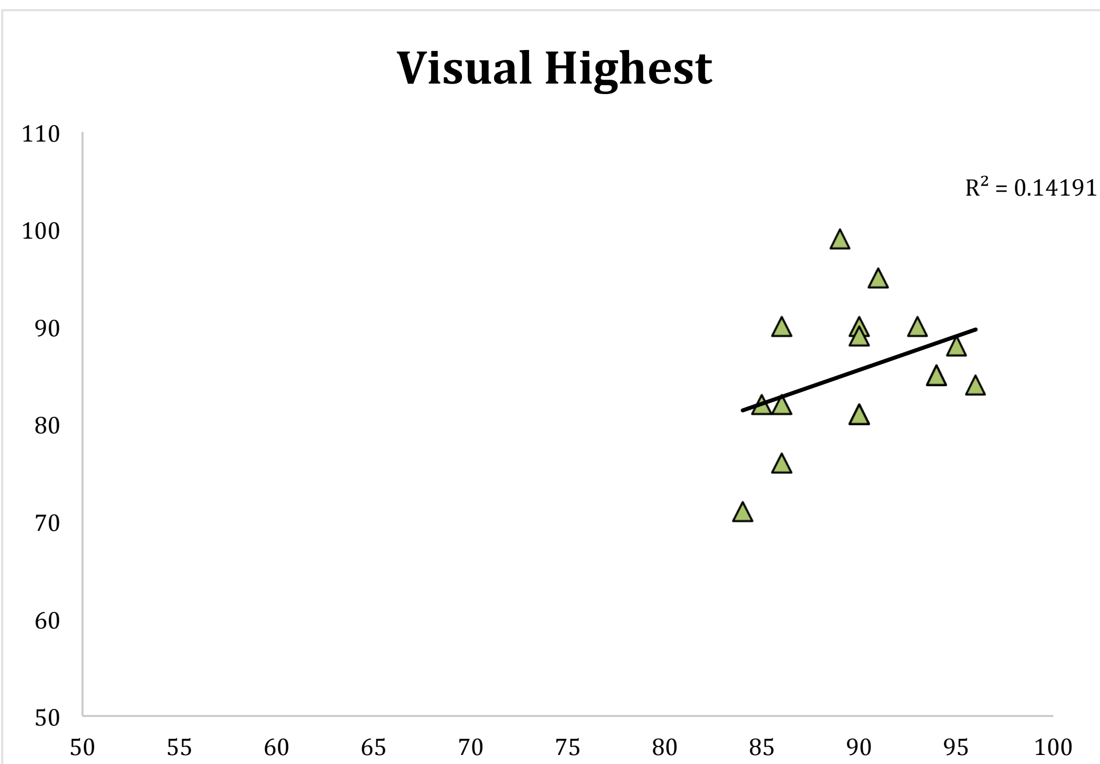


Figure 12: Visual Motor Middle Quintile

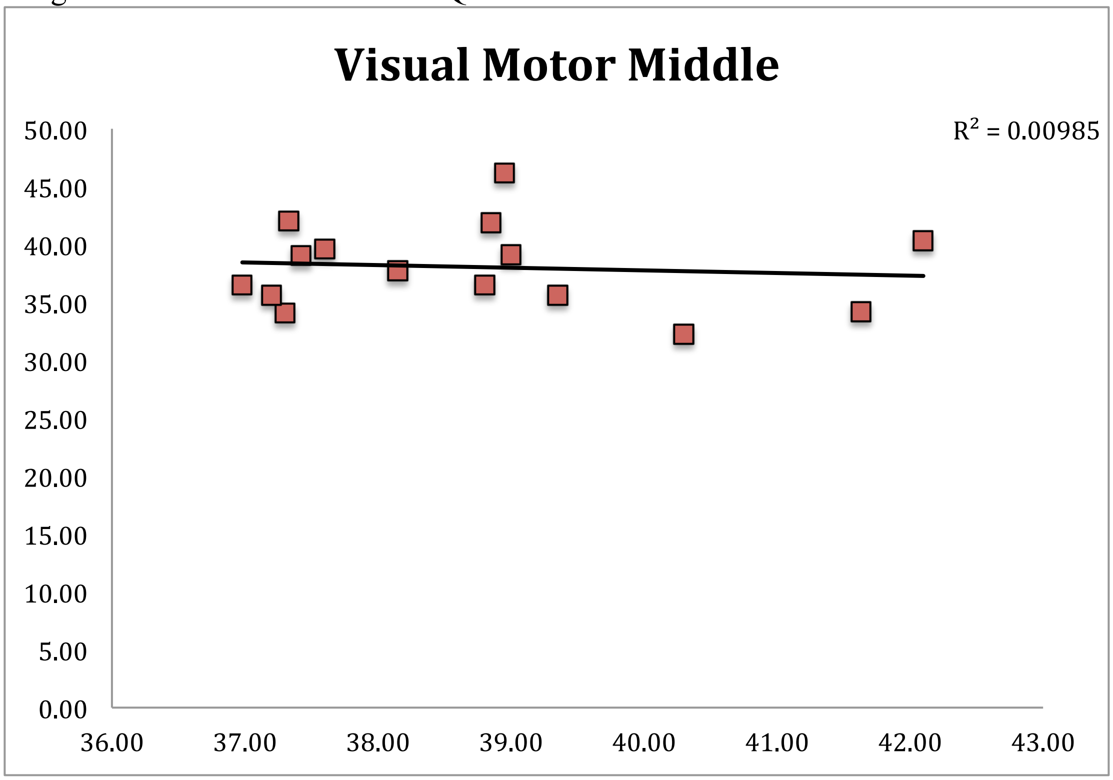


Figure 13: Visual Motor Highest Quintile

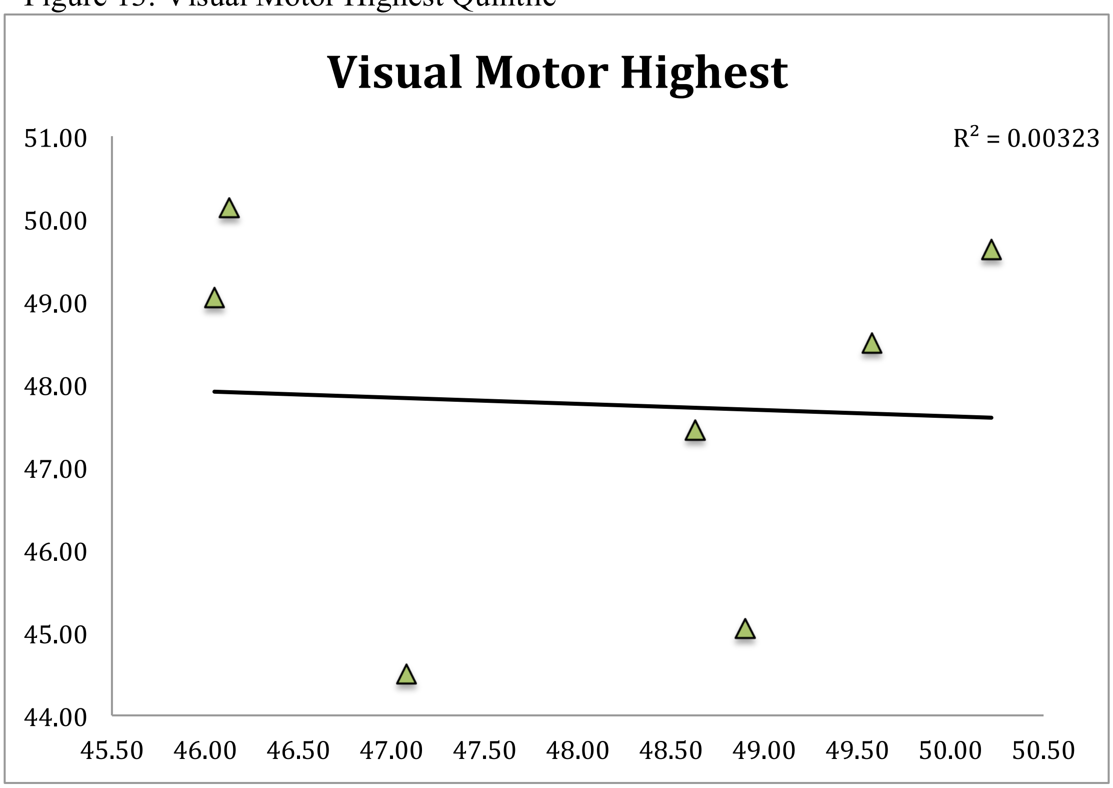


Figure 14: Reaction Time Lowest Quintile

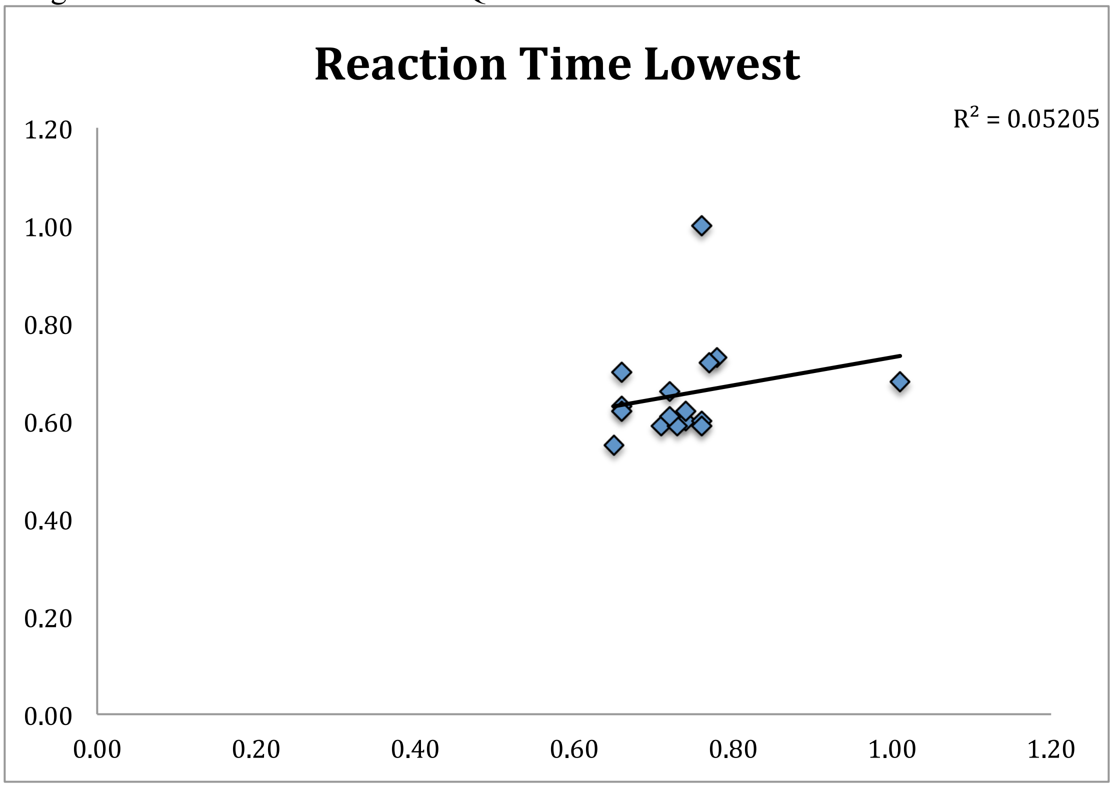


Figure 15: Reaction Time Middle Quintile

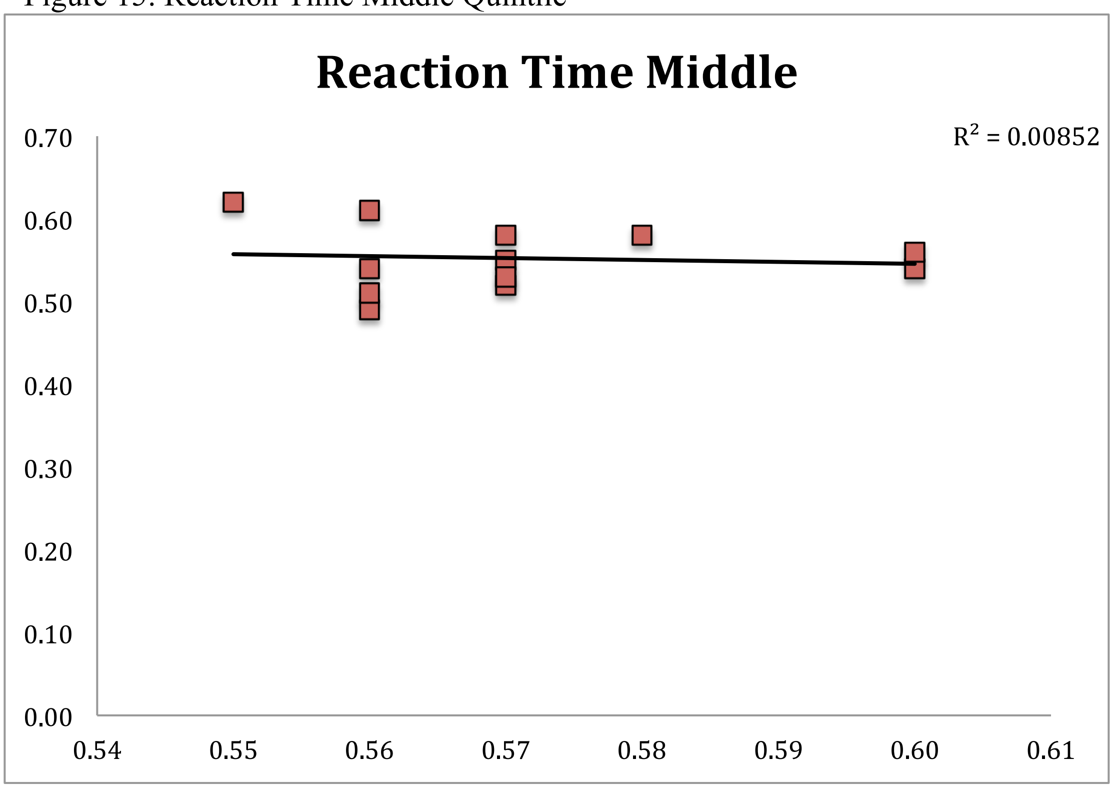


Figure 16: Reaction Time Highest Quintile

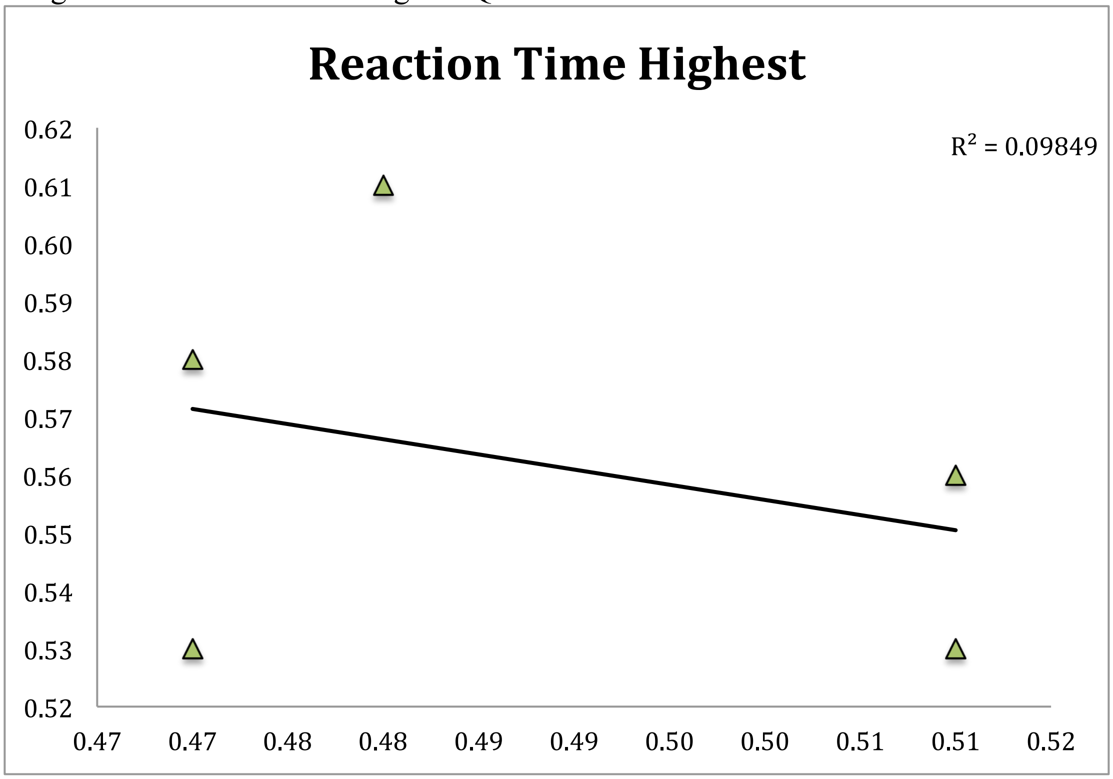


Table 2 displays adjusted and unadjusted RCI values for overall and quintile specific groups for each composite score. Quintile specific RCI values differ from the traditionally used overall RCI value. When looking at quintile ranges, the lowest and highest subgroups at baseline displayed RCI values with a greater amount of change from the overall RCI for each composite index. The smallest amount of change was observed with the middle quintile. Rates of impairment using the adjusted and unadjusted RCI methods are displayed in table 3. The number of subjects who improve or decline with the overall column differs when looking at quintile specific columns.

Table 2: Overall Composite and Quintile Specific RCI Values

Overall Composite		Time 1	Time 2	r	p	RCI (95%)	
Verbal memory	(M)	85.43	86.45	0.71	<.001	15.71	(ADJUSTED)
	(SD)	10.55	10.62			15.66	(UNADJUSTED)
Visual memory		76.02	77.63	0.54	<.001	20.36	
		11.67	10.03			21.84	
Visual motor		39.05	40.42	0.75	<.001	8.30	
		6.09	5.94			8.40	
Reaction time		0.61	0.59	0.52	<.001	0.17	
		0.10	0.08			0.20	

Verbal memory		Time 1	Time 2	r	p	RCI (95%)	
Lowest	(M)	67.38	74.75	0.86	<.001	10.59	(ADJUSTED)
	(SD)	7.50	12.61			7.66	(UNADJUSTED)
Middle		84.50	80.00	0.03	0.987	12.62	
		0.76	6.52			2.05	
Highest		97.27	94.13	0.43	0.113	8.79	
		1.98	5.62			4.14	

Visual memory		Time 1	Time 2	r	p	RCI (95%)	
Lowest	(M)	60.00	71.15	0.34	0.254	16.69	(ADJUSTED)
	(SD)	3.61	9.90			8.08	(UNADJUSTED)
Middle		75.58	80.75	-0.21	0.504	17.52	
		1.83	7.94			5.57	
Highest		89.94	85.50	0.38	0.15	12.14	
		3.77	6.93			8.2	

Visual motor		Time 1	Time 2	r	p	RCI (95%)	
Lowest	(M)	30.50	35.00	0.45	0.169	8.63	(ADJUSTED)
	(SD)	3.71	4.64			7.62	(UNADJUSTED)
Middle		38.73	38.06	-0.1	0.726	8.16	
		1.59	3.66			4.6	
Highest		48.08	47.76	-0.06	0.904	5.56	
		1.67	2.21			4.73	

Reaction time		Time 1	Time 2	r	p	RCI (95%)	
Lowest	(M)	0.74	0.66	0.23	0.396	0.23	(ADJUSTED)
	(SD)	0.08	0.11			0.2	(UNADJUSTED)
Middle		0.57	0.55	-0.1	0.776	0.09	
		0.02	0.04			0.05	
Highest		0.49	0.56	-0.31	0.607	0.09	
		0.02	0.02			0.06	

Table 3: Rates of Impairment Using Adjusted and Unadjusted RCI Methods

	Overall				Lowest				
	Subjects	Impr	Decl	Tot	Subjects	Impr	Decl	Tot	
Verbal memory		2	1	3		3	0	3	**Adjusted**
	n=56	2	1	3	n=8	5	0	5	**Unadjusted**
Visual memory		1	0	1		4	0	4	**Adjusted**
	n=56	1	0	1	n=13	10	0	10	**Unadjusted**
Visual motor		4	1	5		2	0	2	**Adjusted**
	n=56	4	1	5	n=11	4	0	4	**Unadjusted**
Reaction time		1	2	3		1	1	1	**Adjusted**
	n=56	1	1	2	n=16	1	1	1	**Unadjusted**
	Middle				**Highest**				
	Subjects	Impr	Decl	Tot	Subjects	Impr	Decl	Tot	
Verbal memory		0	2	2		0	2	2	**Adjusted**
	n=8	1	5	6	n=15	0	7	7	**Unadjusted**
Visual memory		0	0	0		0	2	2	**Adjusted**
	n=12	7	1	8	n=16	1	7	8	**Unadjusted**
Visual motor		0	1	1		0	0	0	**Adjusted**
	n=14	2	3	5	n=7	1	1	2	**Unadjusted**
Reaction time		0	0	0		2	0	2	**Adjusted**
	n=4	2	4	6	n=5	3	0	3	**Unadjusted**

CHAPTER V
DISCUSSION

This study assessed test-retest reliability in a sample of Division 1 collegiate football players with clinically relevant time periods between test sessions. Average time between test sessions was 210 days ± 60 days, which falls within the recommendations provided by the ImPACT manual.[88] The overall composite indices displayed high Pearson's *r* and ICC values and were higher than previous studies that assessed the test-retest reliability of ImPACT. Schatz et al. (2013) and Schatz (2010) evaluated test-retest reliability in two different studies, a one-month and one-year time period, and reported *r* values of .66 (verbal memory one-month), .30 (verbal memory one-year); .43 (visual memory one-month), .49 (visual memory one-year); .78 (visual motor speed one-month), .60 (processing speed one-year); and .63 (reaction time one-month), .52 (reaction time one-year).[26,89] Previous studies have used Pearson's *r* as a predictor of reliability; however Pearson's *r* establishes the correlation between two distinct variables and is not the appropriate statistic to use for repeated measurements over a period of time. Therefore ICC, which establishes the reliability of one variable over a period of time, should be used when establishing test-retest reliability.

When data from this study were divided into quintile ranges the reported reliability between testing sessions decreased, as expected. As initially indicated, the retrospective nature of this study did not allow for control over the testing environments or the status of each individual at the time of their sessions. Previous studies that have assessed reliability of this computer-based battery have done so by examining the sample as a whole, which differ from the methods of this study where the sample was divided into quintiles. The current study, which highlights the importance of individual change as opposed to group mean change, suggests that ImPACT's test-retest reliability may be deceiving.

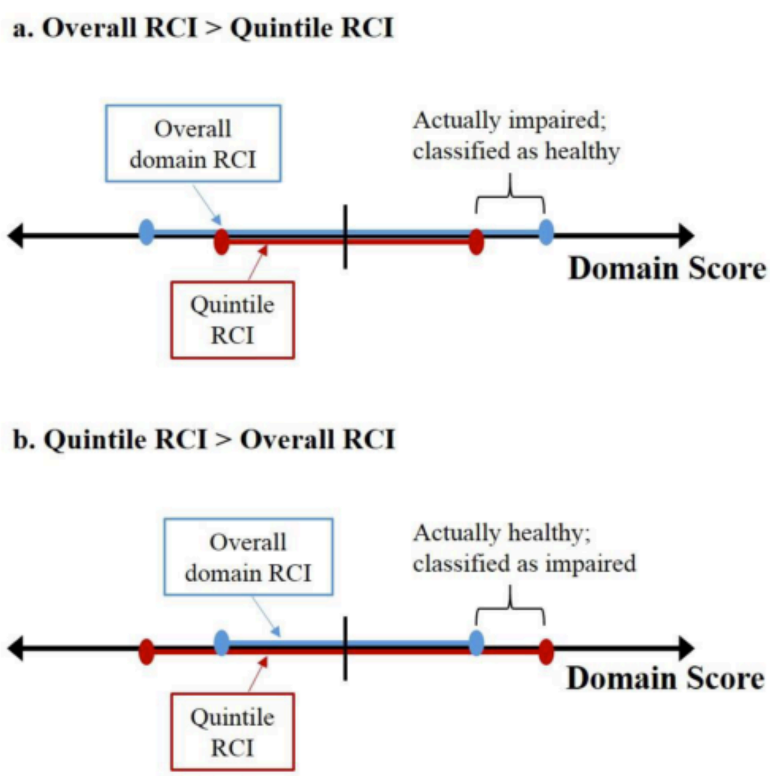
Reliability statistics use large samples of data to determine a test's reliability. Due to the nature of reliability statistics, larger samples typically lead to larger reliability coefficients, or at least statistical significance is more likely with larger samples. The utility of reliability statistics should be questioned in situations where the importance of each data point, or football player in the present study, is critical. This study revealed that the ImPACT test scores were relatively predictable, possibly due to regression to the mean, for players who scored in the high and low quintiles; however, the test was clearly not reliable for the vast majority of players in the middle quintiles who scored closer to the sample mean. Data from this study demonstrate the extremely small possibility of being able to predict test score 2 from test score 1, thus calling into question the reliability of the test.

Iverson et al. have suggested that RCIs are created using the entire sample, and therefore may not be suitable for subgroups.[16] The adjusted RC scores (Table 2), were dramatically different in the quintiles when compared to the overall sample. This difference is expected due to the difference in the magnitude of the quintile scores as well as the smaller sample size in the quintiles. However, these differences call into question the accuracy of the RCI scores calculated from the entire sample. For example, the RCI for Verbal memory in the entire sample was 15.71, while the RCI's from the quintiles ranged from 8.8 to 12.6. These results further supports the findings reported by Ikoma, that a standard RCI application across all scores may lead to higher false-positive and false-negative rates for different ranges of scores at baseline.[30]

As indicated earlier, those who score relatively low or high at baseline are more likely to score closer to the sample mean during subsequent testing due to regression to the mean. This theory suggests test takers in the lower quintile require a less strict, or a greater RC score compared to the overall RC score of the sample. Also, for test takers who score relatively high at

baseline, even small change from baseline may be clinically significant. This would suggest these test takers require a stricter, or smaller RC score. Figure 17 was provided by Ikoma to further illustrate this point.[30]

Figure 17: Misclassifications From Different Overall and Quintile RCIs



When the overall composite RCI is greater than the individual quintile RCI, there could be an increase in the number of participants classified as healthy when they are actually impaired. In contrast, when the individual quintile RCI is greater than the overall composite RCI, there could be an increase in the number of participants classified as impaired when they are actually healthy. When quintile-specific RCI values are used, clinicians could make clinical decisions more specific to the athlete of interest.

Table 3 displays rates of impairment using the adjusted and unadjusted RCI methods. This table further explains the clinical significance of implementing quintile specific RC scores. When looking at overall composite scores, rates of improvements and declines do not differ between the adjusted and unadjusted RCI methods. Regression to the mean predicts a difference in RC scores is most likely to occur in the highest and lowest quintiles. Applying a stricter RCI to the highest quintile was suggested to decrease the occurrence of false negatives. Table 3 shows an increase in the number of declines for the highest quintile compared to the overall sample. If traditional application of the overall RCI was applied to this quintile, these athletes may have been classified as healthy when they were actually impaired.

Conversely, applying a less strict RCI to the lowest quintile was suggested to decrease the occurrence of false negatives. Table 3 shows an increase in the number of improvements for the lowest quintile compared with the overall sample. If traditional application of the overall RCI was applied to this quintile, these athletes may have been classified as impaired when they were actually healthy. Computer generated overall RC scores do not account for quintiles, but rather the group as a whole. Therefore, these computerized test batteries will not consider the possibility of false-positives and false-negatives when assessing cognitive function.

Returning an athlete to play after sustaining a concussion prior to full recovery could result in death. The possibility that NC test batteries could result in misclassification of impaired and non-impaired athletes greatly decreases their relevance within the realm of healthcare. High schools with scarce resources may use such NC test batteries to make return to play decisions, although this is not recommended by the ImPACT manual. The ImPACT manual clearly states that results should be used to aid in clinical decision making, and should not be used in place of an assessment performed by a properly trained healthcare provider.[88] Although ImPACT

recommends a multidimensional approach to concussion assessment, symptoms irrelevant to cognitive function may resolve, while cognitive dysfunction may linger.[27] Schools may implement NC testing prior to return to full participation for this reason, but with decreased reliability and differences among RC scores for subgroups of test takers, caution is necessary when making clinical decisions. Clinicians should use extreme caution when evaluating post injury NC scores for those test takers scoring in relatively high or relatively low subgroups at baseline. Future studies should examine the minimal detectable change (MDC) for subjects, as opposed to RCI, to establish cut off scores. Similar to RCI, MDC determines the "minimum amount of change in a patient's score that ensures the change isn't the result of measurement error."[90] Although the implementation of quintile specific RC scores could decrease the amount of false positives and false negatives, computerized NC test batteries do not employ such strategy at this time. Future studies should attempt to control for potential confounding variables during the time of assessment. In conclusion, the determination of cognitive deficit should be more heavily based on the individual at hand as opposed to numbers produced by group statistics. As indicated, previously by Ikoma[30] and more recently by the results of this study, the implementation of RC scores based on the overall sample size may produce measurement errors that do not represent true changes for those who score relatively high or low at baseline. Ultimately, the results of this study suggest clinicians should be cautious when using statistical significance to determine clinical significance.

APPENDIX

A1 – IRB Approval Form

UNLV Biomedical IRB - Administrative Review
Notice of Excluded Activity

DATE:	March 18, 2016
TO:	Kara Radzak, Ph.D
FROM:	UNLV Biomedical IRB
PROTOCOL TITLE:	[861969-1] Assessing Clinical Significance of the Immediate Post-Concussion Assessment and Cognitive Testing Battery When Comparing Two RCI Methods for Different Ranges of Baseline Scores
SUBMISSION TYPE:	New Project
ACTION:	EXCLUDED - NOT HUMAN SUBJECTS RESEARCH
REVIEW DATE:	March 18, 2016
REVIEW TYPE:	Administrative Review

Thank you for your submission of New Project materials for this protocol. This memorandum is notification that the protocol referenced above has been reviewed as indicated in Federal regulatory statutes 45CFR46.

The UNLV Biomedical IRB has determined this protocol does not meet the definition of human subjects research under the purview of the IRB according to federal regulations. It is not in need of further review or approval by the IRB.

We will retain a copy of this correspondence with our records.

Any changes to the excluded activity may cause this protocol to require a different level of IRB review. Should any changes need to be made, please submit a Modification Form.

If you have questions, please contact the Office of Research Integrity - Human Subjects at IRB@unlv.edu or call 702-895-2794. Please include your protocol title and IRBNet ID in all correspondence.

Office of Research Integrity - Human Subjects
4505 Maryland Parkway . Box 451047 . Las Vegas, Nevada 89154-1047
(702) 895-2794 . FAX: (702) 895-0805 . IRB@unlv.edu

A2 – Tables

Table 1: Test-Retest Reliability

		Time 1	Time 2				ICC 95% CI	
Verbal memory	n	Mean (SD)	Mean (SD)	r	p	ICC	Lower	Upper
Lowest	8	67.38 (7.50)	74.75 (12.61)	0.86	<.001	0.621	-0.054	0.911
Middle	8	84.50 (0.76)	80.00 (6.52)	0.03	0.987	0.005	-0.42	0.601
Highest	15	97.27 (1.98)	94.13 (5.62)	0.34	0.113	0.218	-0.19	0.613

		Time 1	Time 2				ICC 95% CI	
Visual memory	n	Mean (SD)	Mean (SD)	r	p	ICC	Lower	Upper
Lowest	13	60.00 (3.61)	71.15 (9.90)	0.34	0.254	0.106	-0.137	0.475
Middle	12	75.58 (1.83)	80.75 (7.94)	-0.21	0.504	-0.071	-0.443	0.435
Highest	16	89.94 (3.77)	85.50 (6.93)	0.38	0.15	0.248	-0.142	0.62

		Time 1	Time 2				ICC 95% CI	
Visual motor	n	Mean (SD)	Mean (SD)	r	p	ICC	Lower	Upper
Lowest	11	30.50 (3.71)	35.00 (4.64)	0.45	0.169	0.286	-0.138	0.701
Middle	14	38.73 (1.69)	38.06 (3.66)	-0.1	0.726	-0.076	-0.587	0.451
Highest	7	48.08 (1.67)	47.76 (2.21)	-0.06	0.904	-0.063	-0.946	0.708

		Time 1	Time 2				ICC 95% CI	
Reaction time	n	Mean (SD)	Mean (SD)	r	p	ICC	Lower	Upper
Lowest	16	0.74 (0.08)	0.66 (0.11)	0.23	0.396	0.166	-0.186	0.549
Middle	4	0.57 (0.02)	0.55 (0.04)	-0.1	0.776	-0.058	-0.533	0.491
Highest	5	0.49 (0.02)	0.56 (0.02)	-0.31	0.607	-0.066	-0.167	0.458

Table 2: Overall Composite and Quintile Specific RCI Values

Overall Composite		Time 1	Time 2	r	p	RCI (95%)	
Verbal memory	(M)	85.43	86.45	0.71	<.001	15.71	(ADJUSTED)
	(SD)	10.55	10.62			15.66	(UNADJUSTED)
Visual memory		76.02	77.63	0.54	<.001	20.36	
		11.67	10.03			21.84	
Visual motor		39.05	40.42	0.75	<.001	8.30	
		6.09	5.94			8.40	
Reaction time		0.61	0.59	0.52	<.001	0.17	
		0.10	0.08			0.20	

Verbal memory		Time 1	Time 2	r	p	RCI (95%)	
Lowest	(M)	67.38	74.75	0.86	<.001	10.59	(ADJUSTED)
	(SD)	7.50	12.61			7.66	(UNADJUSTED)
Middle		84.50	80.00	0.03	0.987	12.62	
		0.76	6.52			2.05	
Highest		97.27	94.13	0.43	0.113	8.79	
		1.98	5.62			4.14	

Visual memory		Time 1	Time 2	r	p	RCI (95%)	
Lowest	(M)	60.00	71.15	0.34	0.254	16.69	(ADJUSTED)
	(SD)	3.61	9.90			8.08	(UNADJUSTED)
Middle		75.58	80.75	-0.21	0.504	17.52	
		1.83	7.94			5.57	
Highest		89.94	85.50	0.38	0.15	12.14	
		3.77	6.93			8.2	

Visual motor		Time 1	Time 2	r	p	RCI (95%)	
Lowest	(M)	30.50	35.00	0.45	0.169	8.63	(ADJUSTED)
	(SD)	3.71	4.64			7.62	(UNADJUSTED)
Middle		38.73	38.06	-0.1	0.726	8.16	
		1.59	3.66			4.6	
Highest		48.08	47.76	-0.06	0.904	5.56	
		1.67	2.21			4.73	

Reaction time		Time 1	Time 2	r	p	RCI (95%)	
Lowest	(M)	0.74	0.66	0.23	0.396	0.23	(ADJUSTED)
	(SD)	0.08	0.11			0.2	(UNADJUSTED)
Middle		0.57	0.55	-0.1	0.776	0.09	
		0.02	0.04			0.05	
Highest		0.49	0.56	-0.31	0.607	0.09	
		0.02	0.02			0.06	

Table 3: Rates of Impairment Using Adjusted and Unadjusted RCI Methods

	Overall				Lowest				
	Subjects	Impr	Decl	Tot	Subjects	Impr	Decl	Tot	
Verbal memory		2	1	3		3	0	3	**Adjusted**
	n=56	2	1	3	n=8	5	0	5	**Unadjusted**
Visual memory		1	0	1		4	0	4	**Adjusted**
	n=56	1	0	1	n=13	10	0	10	**Unadjusted**
Visual motor		4	1	5		2	0	2	**Adjusted**
	n=56	4	1	5	n=11	4	0	4	**Unadjusted**
Reaction time		1	2	3		1	1	1	**Adjusted**
	n=56	1	1	2	n=16	1	1	1	**Unadjusted**
	Middle				**Highest**				
	Subjects	Impr	Decl	Tot	Subjects	Impr	Decl	Tot	
Verbal memory		0	2	2		0	2	2	**Adjusted**
	n=8	1	5	6	n=15	0	7	7	**Unadjusted**
Visual memory		0	0	0		0	2	2	**Adjusted**
	n=12	7	1	8	n=16	1	7	8	**Unadjusted**
Visual motor		0	1	1		0	0	0	**Adjusted**
	n=14	2	3	5	n=7	1	1	2	**Unadjusted**
Reaction time		0	0	0		2	0	2	**Adjusted**
	n=4	2	4	6	n=5	3	0	3	**Unadjusted**

A3 – Figures

Figure 1: Verbal Overall

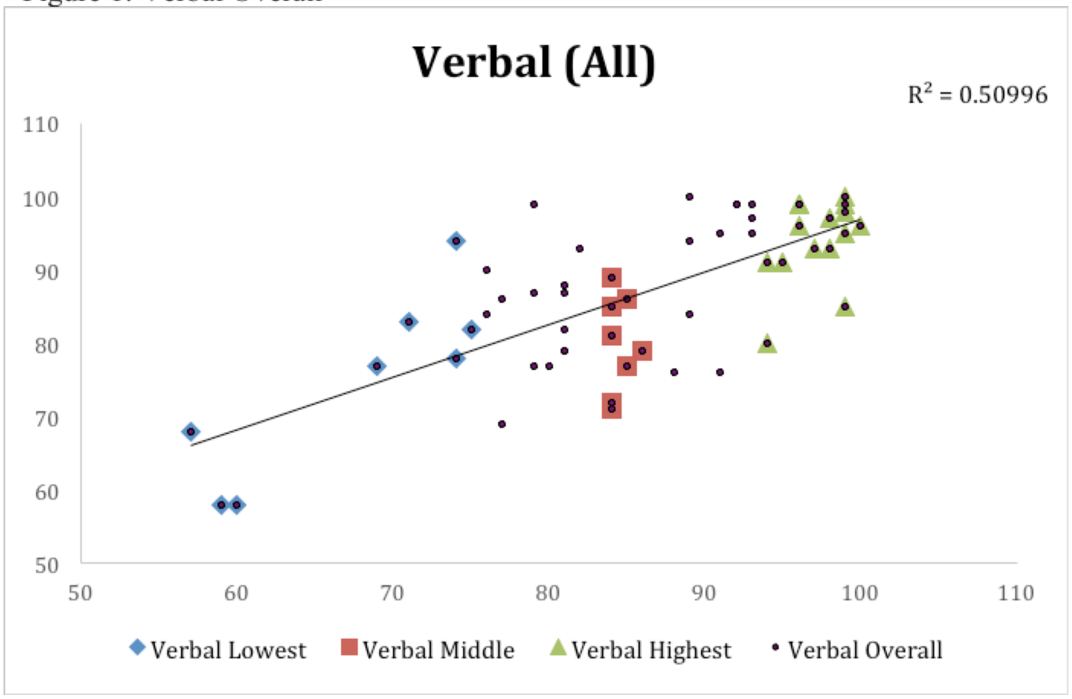


Figure 2: Visual Overall

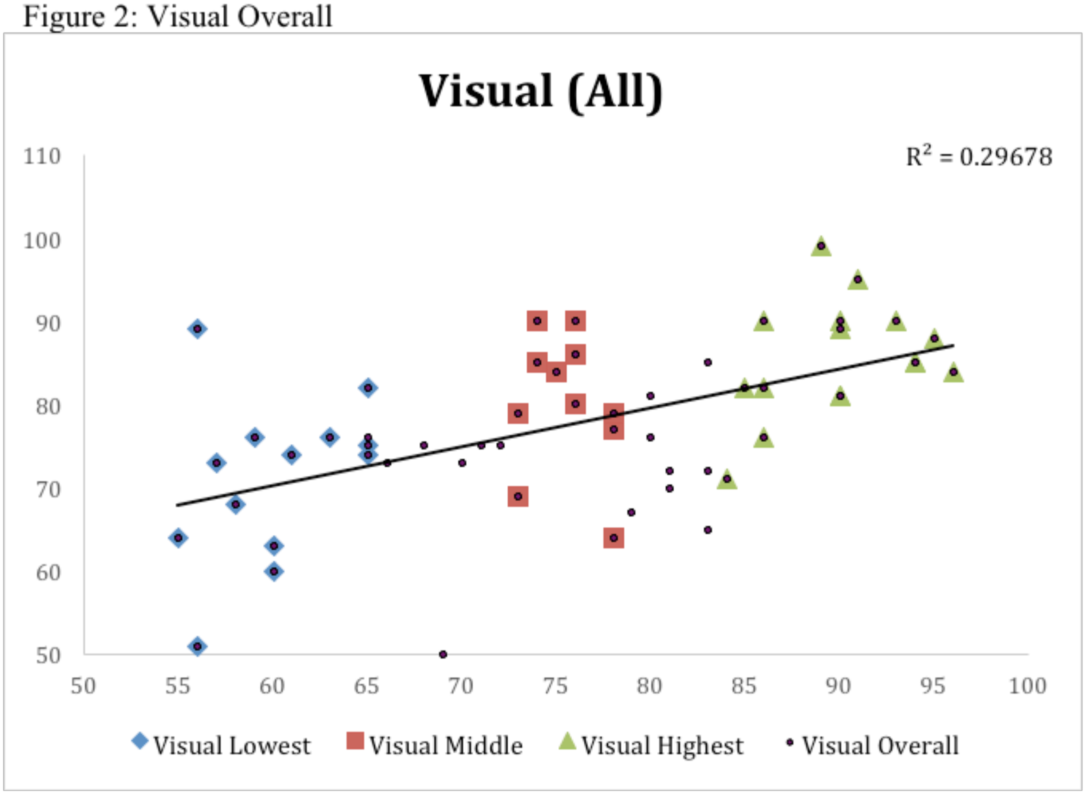


Figure 3: Visual Motor Overall

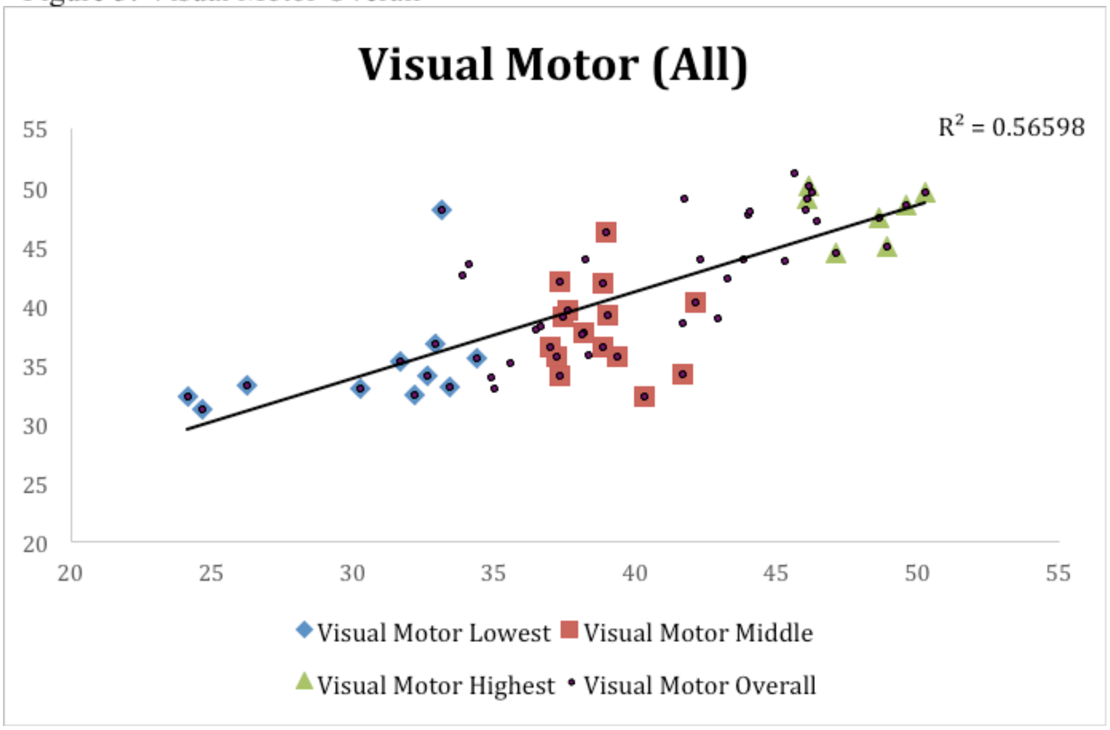


Figure 4: Reaction Time Overall

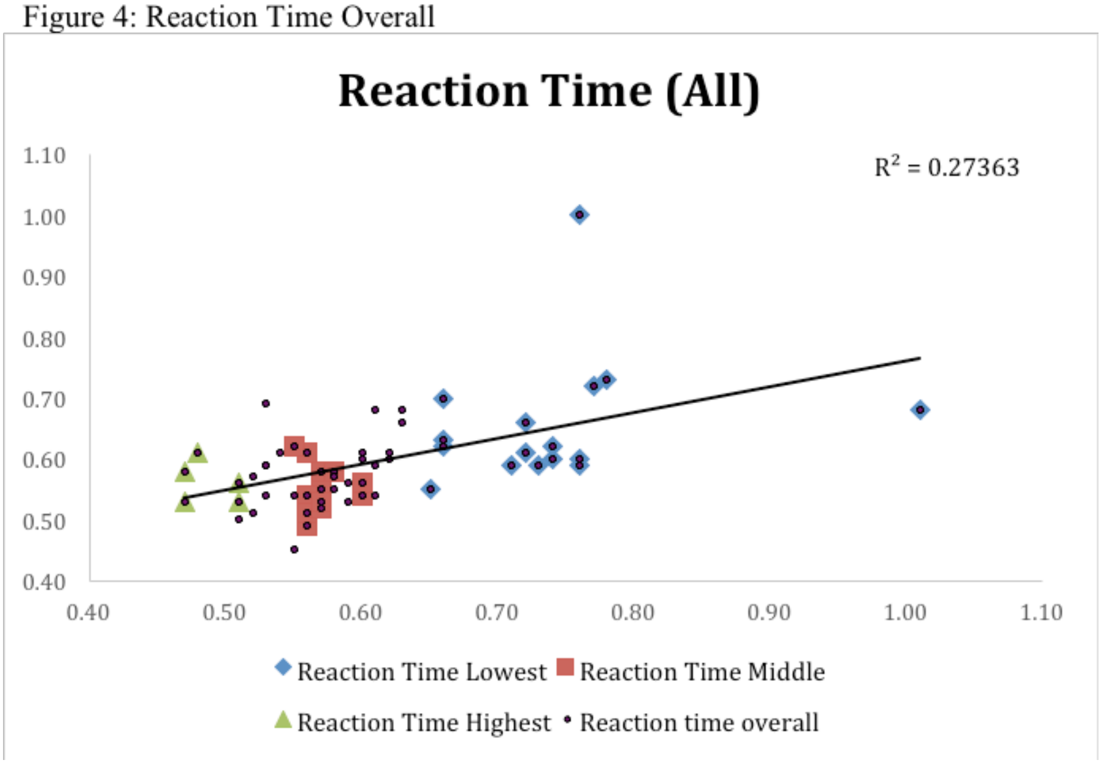


Figure 5: Verbal Lowest Quintile

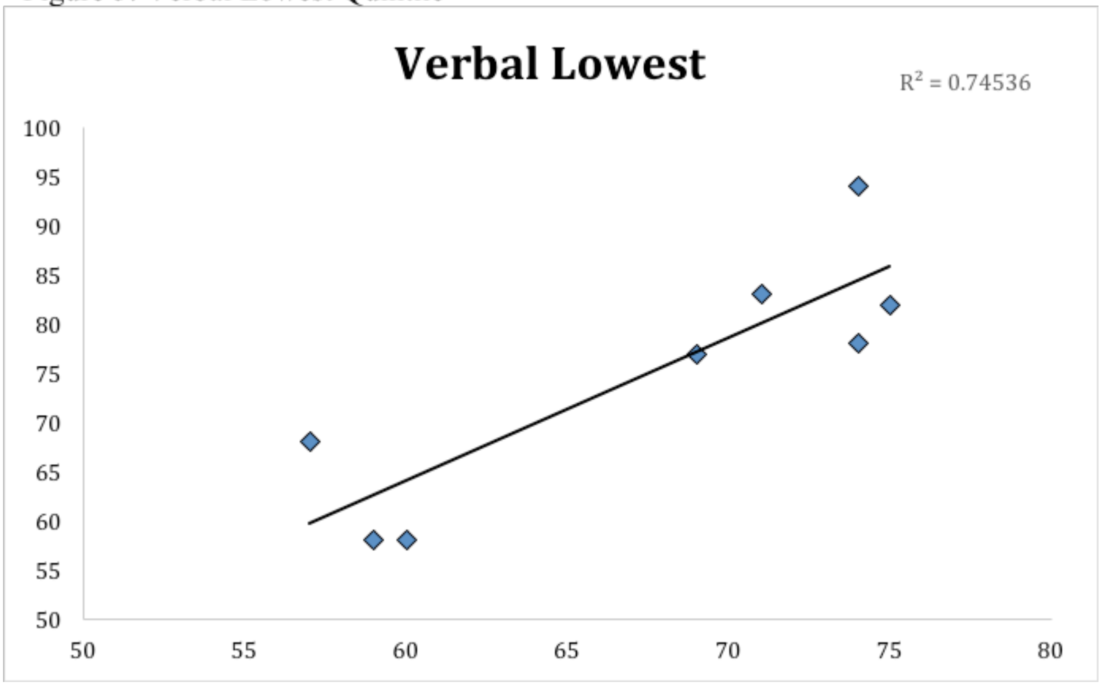


Figure 6: Verbal Middle Quintile

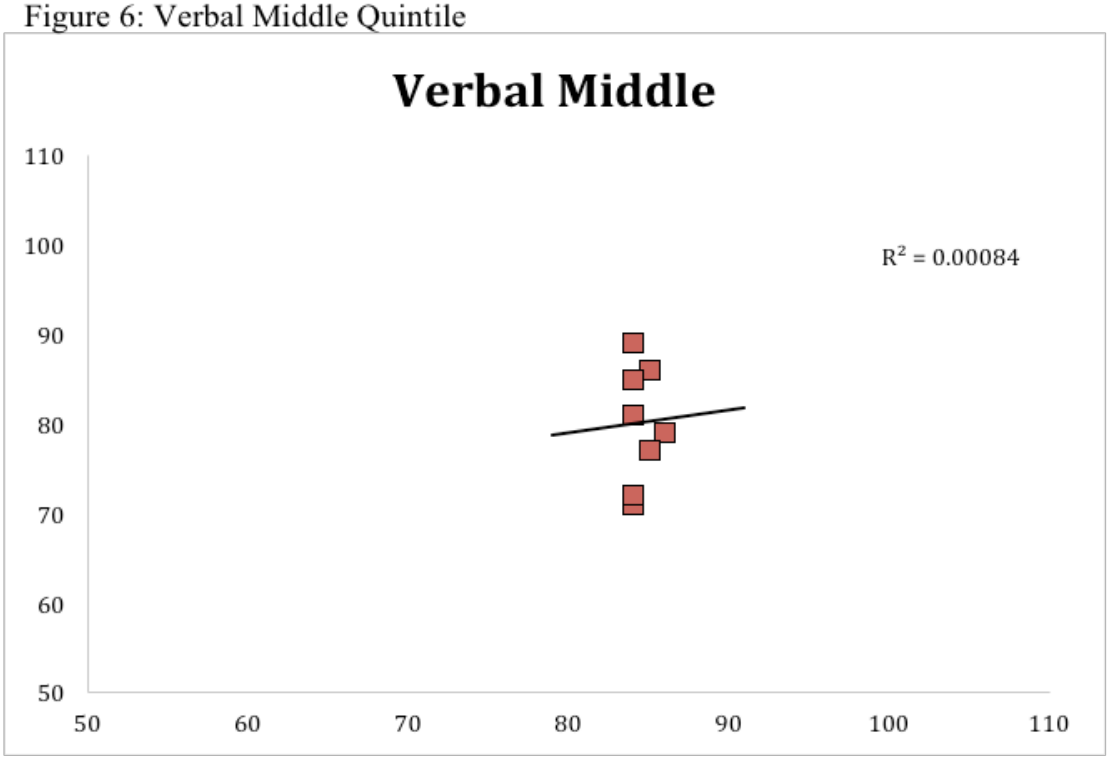


Figure 7: Verbal Highest Quintile

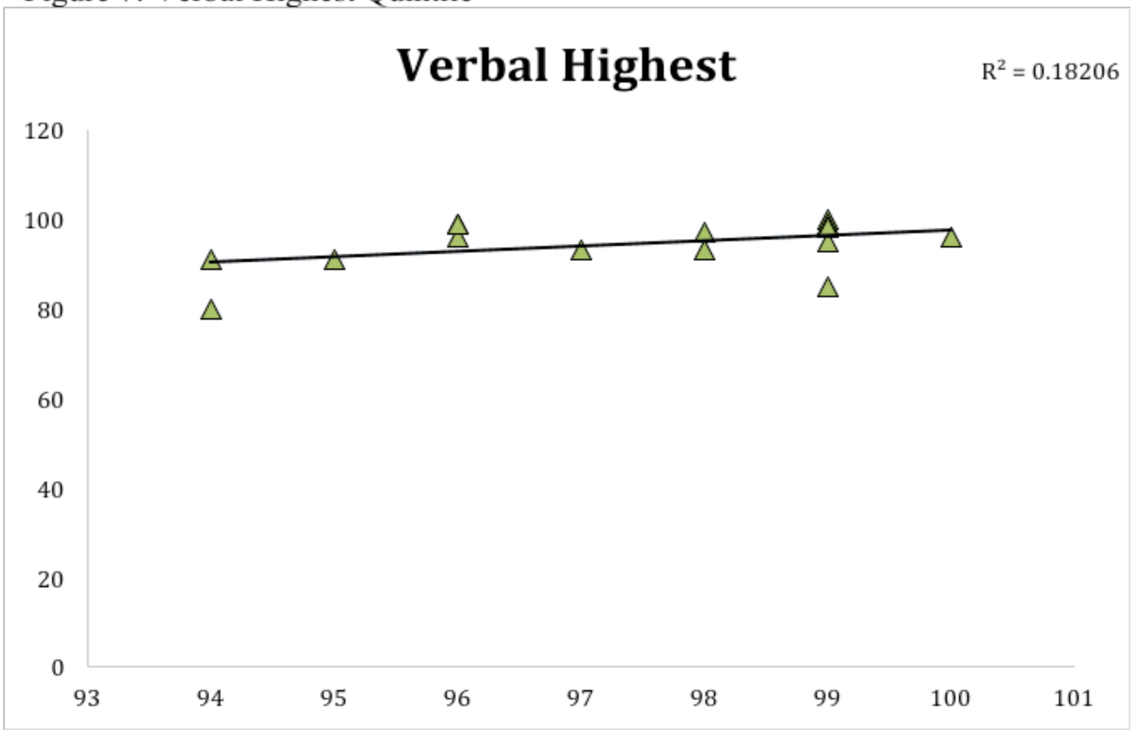


Figure 8: Visual Lowest Quintile

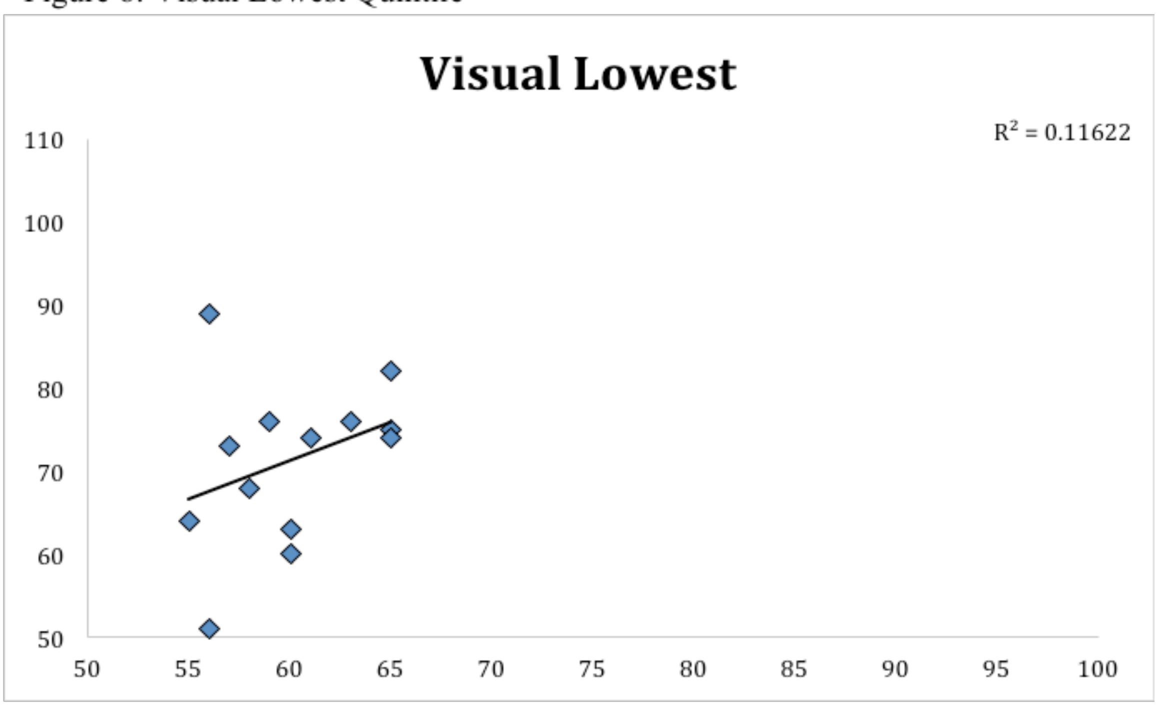


Figure 9: Visual Middle Quintile

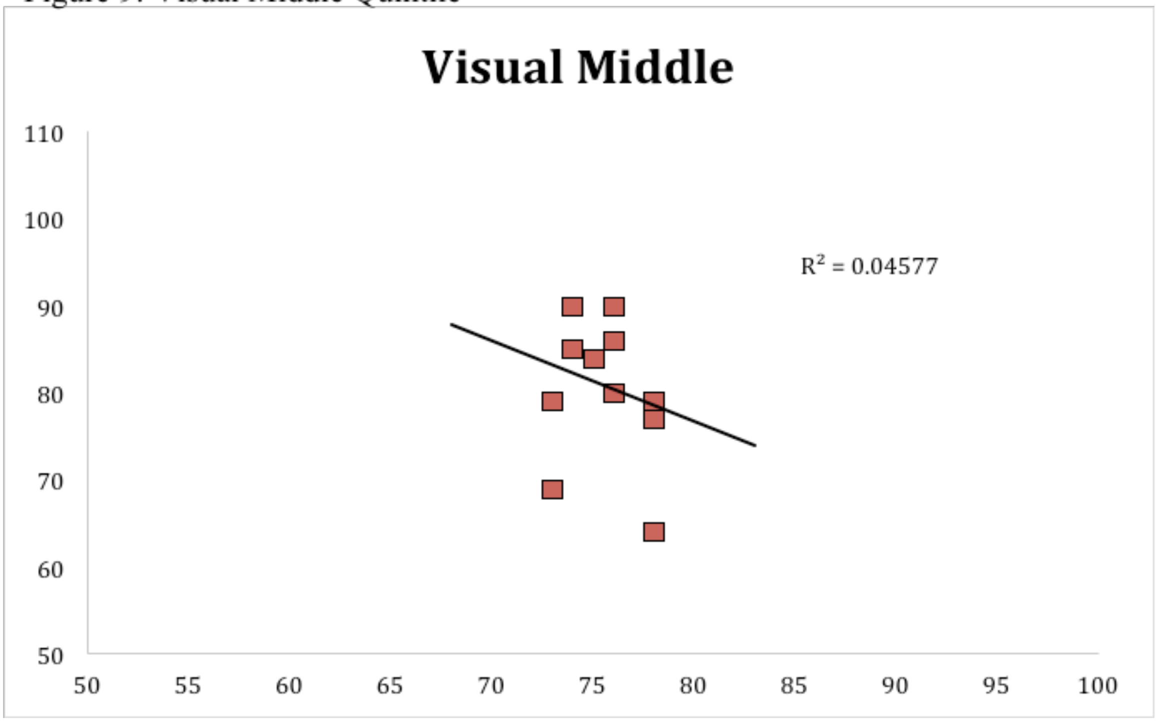


Figure 10: Visual Highest Quintile

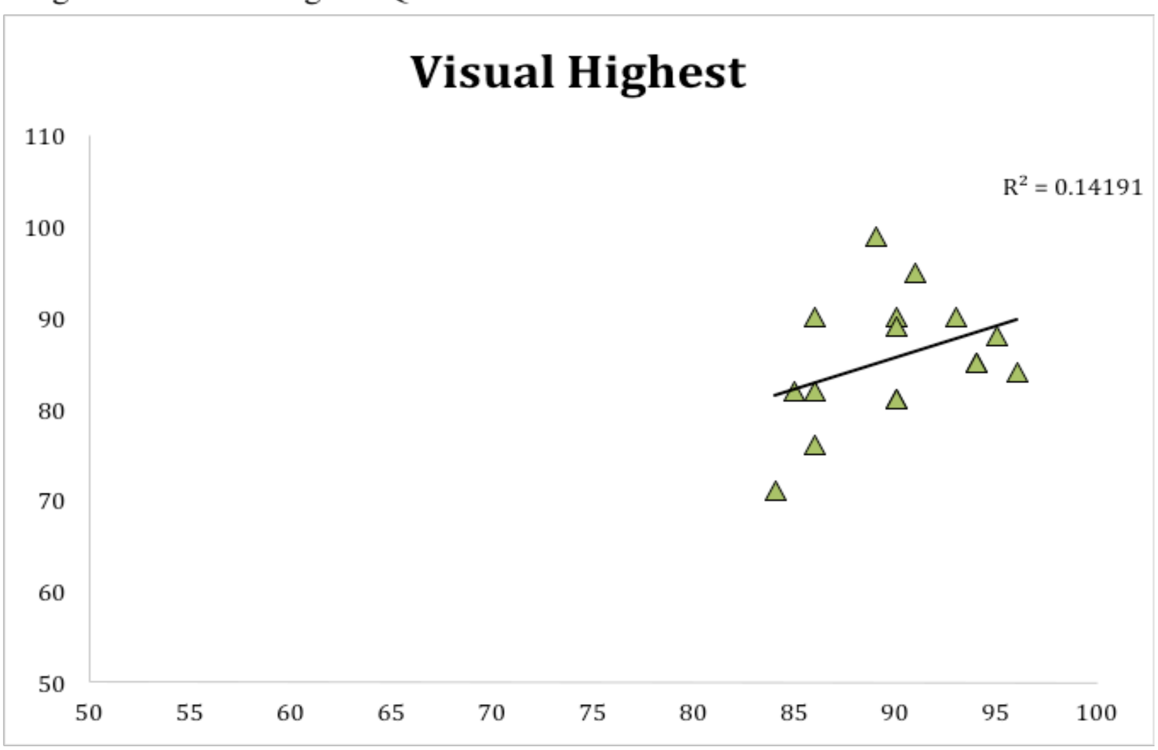


Figure 11: Visual Motor Lowest Quintile

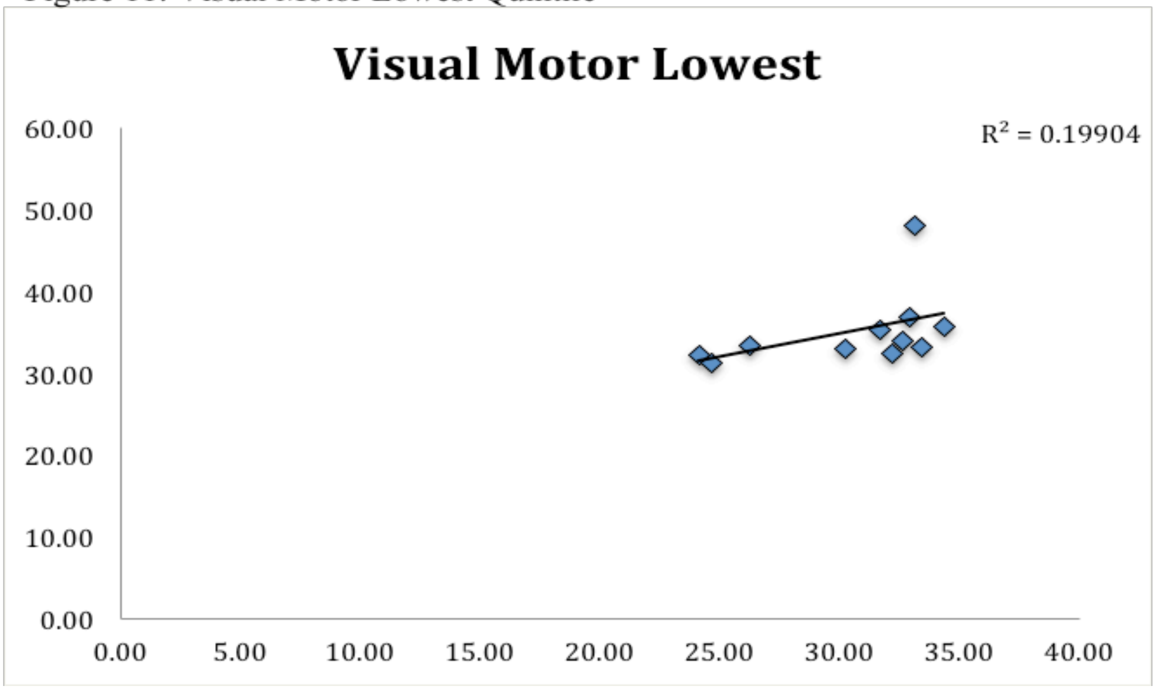


Figure 12: Visual Motor Middle Quintile

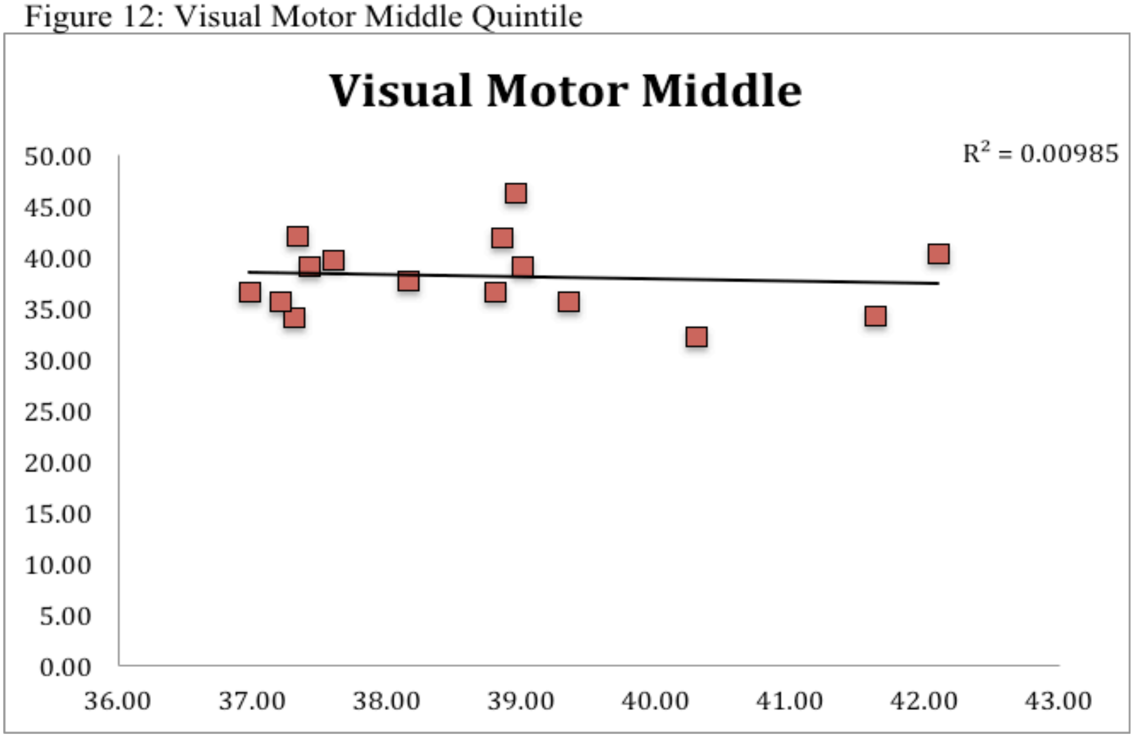


Figure 13: Visual Motor Highest Quintile

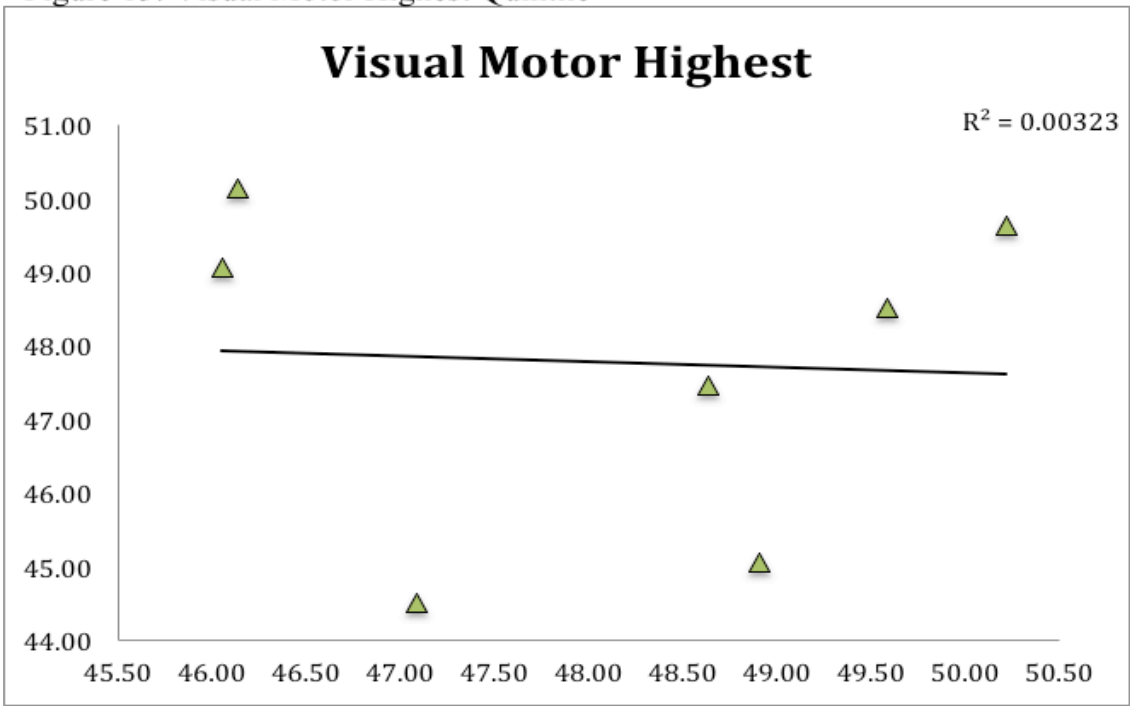


Figure 14: Reaction Time Lowest Quintile

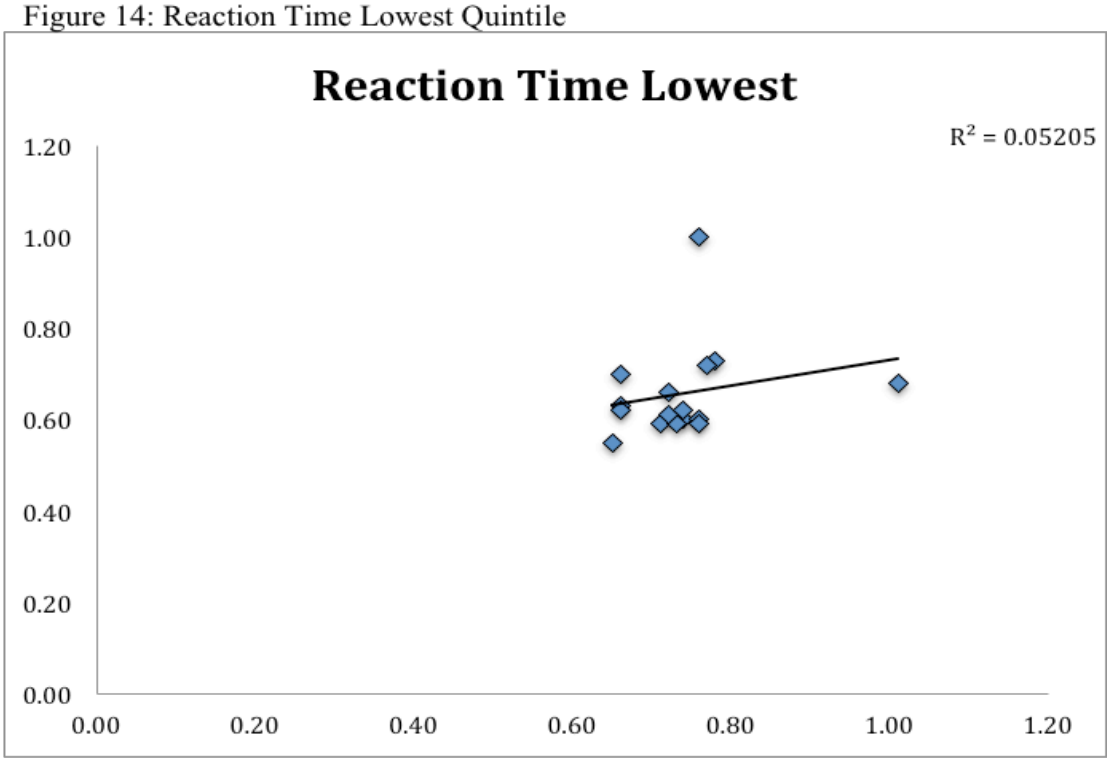


Figure 15: Reaction Time Middle Quintile

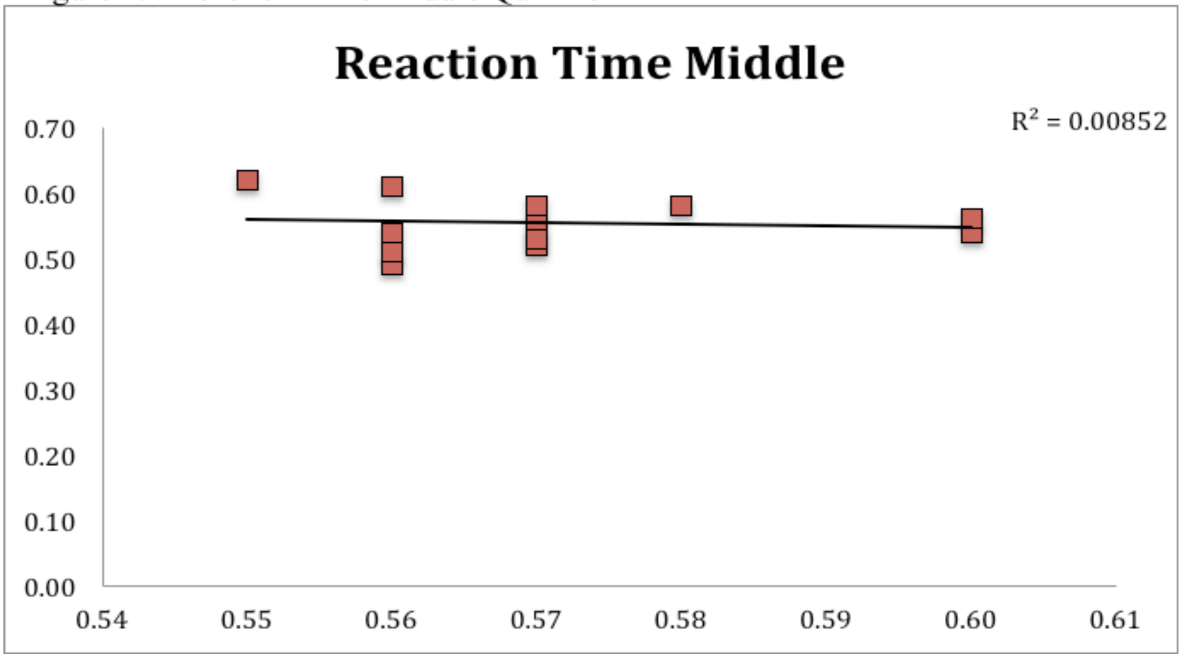


Figure 16: Reaction Time Highest Quintile

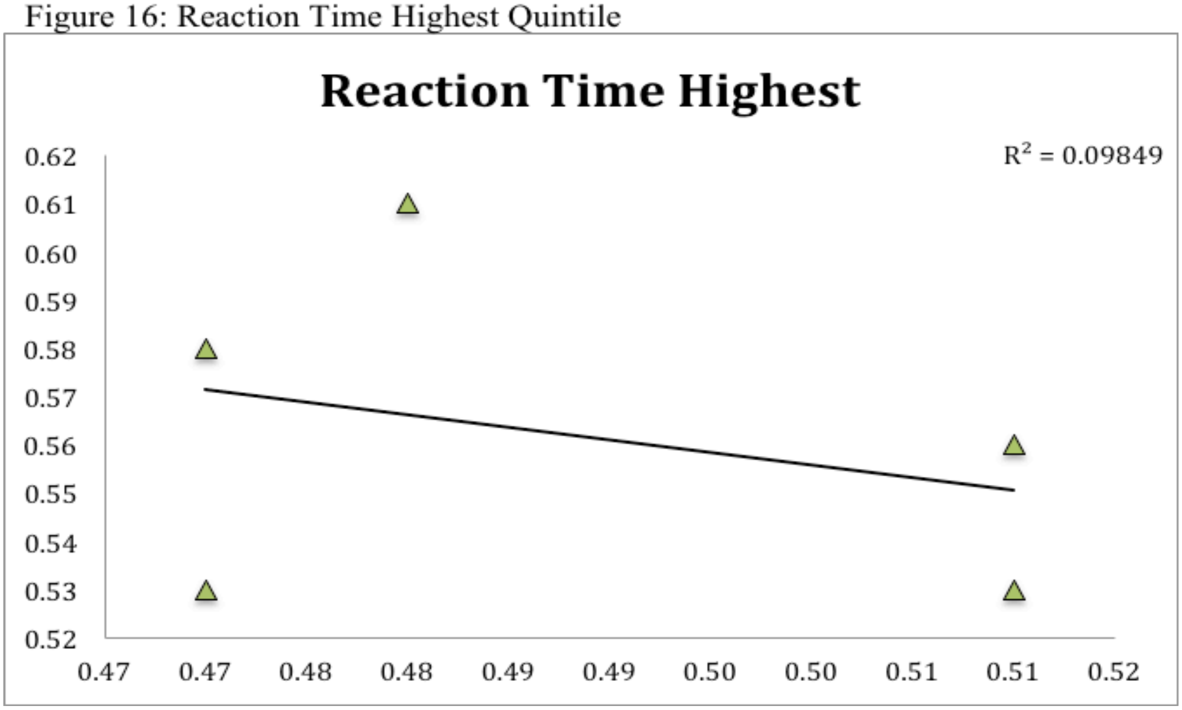
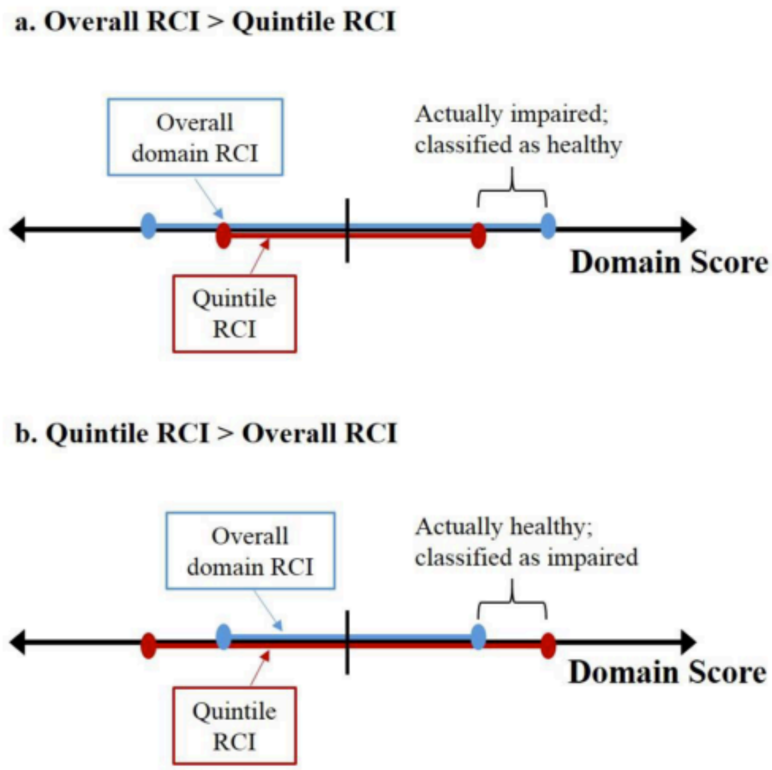


Figure 17: Misclassifications From Different Overall and Quintile RCIs



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