Journal of Visualized Experiments

Development and Implementation of a Multi-Disciplinary Technology Enhanced Care Pathway for Youth and Adults with Concussion

--Manuscript Draft--

Article Type:	Invited Methods Article - JoVE Produced Video
Manuscript Number:	JoVE58962R2
Full Title:	Development and Implementation of a Multi-Disciplinary Technology Enhanced Care Pathway for Youth and Adults with Concussion
Keywords:	value-based care, care pathway, concussion, mild traumatic brain injury, health economics, care algorithm
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Additional Information:	
Question	**Response**
Please indicate whether this article will be Standard Access or Open Access.	Standard Access (US$2,400)
Please indicate the **city, state/province, and country** where this article will be **filmed**. Please do not use abbreviations.	Cleveland, Ohio, USA

TITLE:

Development and Implementation of a Multi-Disciplinary Technology Enhanced Care Pathway for Youth and Adults with Concussion

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KEYWORDS:

value-based care, care pathway, concussion, mild traumatic brain injury, health economics, care algorithm

SUMMARY:

A multidisciplinary carepath to standardize disparate concussion care was developed and implemented at the Cleveland Clinic. The Cleveland Clinic Concussion (C3) mobile application was used to enable the carepath through biomechanical outcomes characterizing cognitive and motor function. Patient outcomes improved while cost of care was reduced following implementation.

ABSTRACT:

The evidence-informed standardization of care along disease lines is recommended to improve outcomes and reduce healthcare costs. The aim of this project is to 1) describe the development and implementation of the Concussion Carepath, 2) demonstrate the process of integrating technology in the form of a mobile application to enable the carepath and guide clinical decision-making, and 3) present data on the utility of the C3 app in facilitating decision-making throughout the injury recovery process. A multi-disciplinary team of experts in concussion care was formed to develop an evidence-informed algorithm, outlining best practices for the clinical management of concussion along three phases of recovery – acute, subacute, and post-concussive. A custom mobile application, the Cleveland Clinic Concussion

(C3) app was developed and validated to provide a platform for the systematic collection of objective, biomechanical outcomes and to provide guidance in clinical decision-making in the field and clinical environments. The Cleveland Clinic Concussion app included an electronic incident report, assessment modules to measure important aspects of cognitive and motor function, and a return to play module to systematically document the six phases of post-injury rehabilitation. The assessment modules served as qualifiers within the carepath algorithm, driving referral for specialty services as indicated. Overall, the carepath coupled with the C3 app functioned in unison to facilitate communication among the interdisciplinary team, prevent stagnant care, and drive patients to the right provider at the right time for efficient and effective clinical management.

INTRODUCTION:

The practice of medicine and the delivery of health care are undergoing a fundamental transformation from volume to value[1], driven by payers, hospitals, clinicians, and patients. Health care delivery is challenged by the lack of standardization, interoperability of systems, communication of information, and the coordination of services. These deficiencies complicate effective continuity of care that often result in unnecessary services and have been identified as primary sources of rising health care costs[1,2]. By contrast, coordinated disease- or condition-specific care has been shown to optimize outcomes while minimizing costs[2]. In a coordinated care model, patients with a given condition are managed by an experienced, interdisciplinary team according to best practice guidelines, and are referred to the right provider at the right time[2].

In efforts to transform clinical practice from a primarily volume-based to a value-based model, the Cleveland Clinic embarked on an enterprise-wide initiative to standardize clinical practice along disease lines through the development and implementation of clinical carepaths[3]. A care pathway is defined as a standardized approach for the mutual decision-making and organization of care processes for a well-defined group of patients over a well-defined time[4]. The underlying tenet of a care pathway is standardization of care. The expectation is that with evidence-based care pathways and interdisciplinary care teams, standardization and best practice will be achieved over time, venue and provider resulting in improved efficiency, effectiveness, and value[2]. With the inclusion of validated outcomes, there is a built-in mechanism for iterating the carepath over time to further refine and improve patient care. Concussion was identified as a condition in which the potential to streamline care and optimize patient management was significant. While concussive injuries are typically not life-threatening, their effects can be severe and debilitating, with direct and indirect costs estimated at $83 billion annually[5]. It is estimated that 80-90% of individuals with concussion recover within 7-14 days of injury[6,7]. However, consensus on the management of the 10-20% of individuals with persistent symptoms is lacking, and evidence supporting or refuting the efficacy of rehabilitation, medical interventions or the diagnostic value of imaging in individuals with post-concussive symptoms is sparse. Multiple consensus statements indicate that an interdisciplinary team approach is optimal to treat concussion[6,8-10]. In 2011, work on the Cleveland Clinic Concussion Carepath[11], shown in **Figure 1**, was initiated. Our primary goal was to create a standardized, evidence-informed approach to the identification, evaluation and

management of individuals with concussion. An interdisciplinary team of providers collaborated in the development of the carepath, building consensus based on available evidence in the literature and expert clinical opinion. Physician groups that were represented included: sports medicine, neurology, neurosurgery, rehabilitation medicine, neuroradiology, emergency medicine, primary care, pediatrics and family medicine. The carepath team also included athletic trainers (AT's), physical therapists (PT's), speech therapists, occupational therapists, nurses, and neuropsychologists. Finally, computer scientists and research scientists provided technical guidance and software development. The carepath algorithm, documentation template, and outcomes were developed over a course of 15 months from 2011 to 2012. To ensure appropriateness of outcome measures, the C3 application assessment modules were simultaneously being validated[12-16].

The evidence-based Cleveland Clinic concussion carepath depicted in **Figure 1** was developed to identify individuals with concussion on a trajectory of typical and delayed recovery, and specifically for the latter group, to create clear and objective criteria for referral to specialty services. Standardized outcome measures were established and proposed to be collected across disciplines. In an effort to facilitate utilization and compliance with the standardized evaluation and documentation requirements of the carepath, the Cleveland Clinic Concussion (C3) app was developed, tested, and deployed. The aim of this project is to 1) describe the development and implementation of the Concussion Carepath, 2) to demonstrate the integration of technology in the form of a mobile application to enable the carepath and guide clinical decision-making, and 3) to present preliminary data on the responsiveness of the C3 app in detecting change in neurological function post-concussion. We hypothesized that utilizing the C3 app would improve interdisciplinary communication aide in clinical decision making.

PROTOCOL:

The protocol outlined below follows the guidelines of the Cleveland Clinic human research ethics committee.

1. Administering the C3 App

1.1. Administer the C3 app to all student-athletes at baseline prior to the start of the given athletic season. Administer follow up assessments in the event of a concussive injury. Follow up assessments are reserved for the evaluation of recovery once the individual reports no more than minimal symptoms, so as to prevent symptom provocation as a result of testing. The following protocol is used when administering the C3 app.

1.2. Assess postural sway during performance of the Balance Error Scoring System (BESS) using the inertial sensors native to the digital tablet to collect biomechanical data measuring linear and angular acceleration while the student-athlete completes six 20-second balance stances.

1.3. Ensure that the volume is turned up. Ask the athlete to remove his/her shoes.

1.4. Ask and record the following information:

1.4.1. "If you were to kick a ball, what leg would you use?". Record individual's answer as their "dominant foot".

1.4.2. “Have you had an ankle or knee injury from which you haven't fully recovered in the last six months?” Record if injury affected dominant or non-dominant ankle or knee.

1.4.3. Record if the athlete is wearing any sort of brace on his/her dominant or non-dominant knee or ankle.

1.4.4. Record the surface on which the testing is being conducted.

1.4.5. Record the footwear used for testing (socks are preferred).

1.5. Affix digital tablet onto individual's sacrum using a custom belt.

1.6. Inform athlete that his/her balance will be tested. Instruct athlete to remain in the designated stance for the entire 20-second trial with his/her hands on hips and eyes closed. Instruct the athlete to get back into the correct position as quickly as possible if he/she loses his/her balance. Verify that the athlete understands the instructions, and ask him/her to stand with his/her feet together (demonstrate double limb stance, **Figure 2a**).

1.6.1. Once the athlete is in the proper stance, tap **Start** to begin the 5-second countdown that signalizes the start of the 20-second trial.

1.6.2. During the 20-second trial, count the number of errors committed. Errors include any of the following: Hands off hips; opening eyes; step, stumble, or fall; lifting toe or heel off the ground; bending more than 30 degrees at the waist; staying out of position for greater than 5 seconds.

1.6.3. Record the number of errors committed during the balance trial.

1.7. For the second trial, instruct athlete to stand on his/her non-dominant foot (**Figure 2b**). Repeat steps 1.4.1 to 1.4.3.

1.8. For the third trial, instruct athlete to stand heel to toe in tandem stance, with the non-dominant foot in the back (**Figure 2c**). Repeat steps 1.4.1 to 1.4.3.

1.9. For the fourth trial, instruct athlete to stand with feet together, identical to the first stance, but on a foam pad, (**Figure 2d**). Repeat steps 1.4.1 to 1.4.3.

1.10. For the fifth trial, instruct athlete to stand on his/her non-dominant foot, identical to the second trial, but on a foam pad (**Figure 2e**). Repeat steps 2.4.1 to 2.4.3.

1.11. For the sixth trial, instruct athlete to stand stand heel to toe in tandem stance identical to the third trial, but on a foam pad (**Figure 2f**). Repeat steps 2.4.1 to 2.4.3.

2. Assessment of Static and Dynamic Vision

2.1. Static Vision

2.1.1. Use the length of the belt to measure 5 feet to position the digital tablet and participant at the correct distance, 5 feet apart.

2.1.2. Holding the digital tablet at eye level, instruct the participant to read the 5 letters displayed from left to right (refer to instructions as shown in **Figure 3**).

2.1.3. Record the correct number of letters the participant was able to read.

2.1.4. If the participant correctly identified 3 or more letters, repeat steps 2.1.2 and 2.1.3 once smaller optotypes are presented.

2.1.5. If the participant identifies 2 or fewer correctly, proceed to step 2.2.

2.2. Dynamic Vision

2.2.1. Play the sample metronome tone and demonstrate proper head movement, rotating right to left, approximately 20 degrees of cervical rotation in each direction (envisioning movement from 10 to 2 on a horizontal clock dial). Ask the participant to demonstrate the proper head rotation, keeping with the metronome.

2.2.2. Initiate trial, ensure participant is rotating head properly while optotypes are presented. Instruct participant to read the 5 letters displayed from left to right while continuing to rotate head left to right to the beat of the metronome. If the participant stops moving his/her head to read the letters, press **Redo Trial**.

2.2.3. Record the correct number of letters the participant was able to read.

2.2.4. If the participant correctly identified 3 or more letters, repeat steps 2.2.2 and 2.2.3 once smaller optotypes are presented.

2.2.5. If the participant identifies 2 or fewer correctly, proceed to next module.

3. Assessment of Information Processing Assessment using Simple and Choice Reaction Time Paradigms[14]

3.1. Simple Reaction Time (SRT) (**Figure 4a**)

3.1.1. Display the instruction screen and instruct the participant to place his/her index finger from the dominant hand on the **Touch and Hold** button. Once the stimulus (light) turns from yellow to green, instruct the participant to release the button and touch the green light as quickly as possible.

3.1.2. Observe the participant complete the practice trial, ensuring that he/she understands the directions and is able to complete the task within the allotted time (100-500 ms).

3.1.3. Observe the participant complete 25 valid trials without errors within the allotted time (100-500 ms per trial).

3.2. Choice Reaction Time (CRT) (**Figure 4b**)

3.2.1. Display the instruction screen and ask participant to place both index fingers on **Touch and Hold** buttons.

3.2.2. After the yellow light is displayed momentarily, a green light (stimulus) and cyan light, serving as a distractor light, are displayed. Ask participant to lift the digit that corresponds with the side in which the green light was presented, and tap the green light as quickly as possible. Remind the participant to keep the digit that corresponds to the cyan distractor light on the **Touch and Hold** button.

3.2.3. Observe the participant complete practice trial, ensuring that he/she understands the directions and is able to complete task within the allotted time (100-750 ms).

3.2.4. Observe the participant complete 25 valid trials without errors within the allotted time (100-750* ms per trial).

NOTE: The 500 ms and 750 ms restrictions for SRT and CRT, respectively are lifted post-injury for follow up assessments.

4. Processing Speed Test[15]

4.1. Initiate the test and instruct the participant to read the instructions provided on the sample testing screen. Instruct the participant to use the symbol key on the top of the screen to complete the test below the symbol key. The symbol key contains symbols in the top row and corresponding digits in the bottom row. The test contains only symbols, requiring the participant to input digits that correspond to the symbol as identified in the key using the keyboard at the bottom of the screen.

4.2. Press the **Begin Practice** button and observe the participant complete the practice trial according to proper testing procedures.

4.3. Remind participant that the actual test will not provide feedback as to whether the response was "correct" or "incorrect", as it did in the practice trial.

4.4. Inform the participant that a new row of symbols will appear once he/she completes the existing row. Instruct the participant to continue to enter corresponding digits until prompted to stop and that the trial will last 2 minutes. Remind the participant that he/she cannot correct an incorrect response, and to complete each response as quickly and accurately as possible.

4.5. Press the **Begin Test** button to initiate the test. Observe the participant perform the test ensuring correct procedures are followed (**Figure 5**).

5. Assessment of Executive Function and Set Switching

5.1. Trail Making Test A

5.1.1. Instruct participant to read the instructions on the screen, describing the test as a "connect the dots" test in which 25 circles corresponding with digits 1-25 must be connected by using the stylus provided (**Figure 6a**).

5.1.2. Press **Begin Practice** and observe participant completing the practice trial, ensuring that he/she maintains contact between the digital tablet and stylus throughout the trial.

5.1.3. Proceed to test by pressing the **Begin Test** button. Observe the participant complete the test, ensuring that correct procedures are followed (**Figure 6b**).

5.2. Trail Making Test B

5.2.1. Instruct participant to read the instructions on the screen, describing the test as a "connect the dots" test in which 25 circles corresponding with digits and letters must be connected using the stylus provided. Instruct the participant to begin with the number "1", followed by the letter "A", and continue alternating between numbers and letters, in sequence, "1" followed by "A", then "2" followed by "B", then "3" followed by "C", *etc*. The test is complete when 25 dots corresponding with numbers and letters are connected.

5.2.2. Press **Begin Practice** and observe participant completing the practice trial, ensuring that he/she maintains contact between the digital tablet and stylus throughout the trial (**Figure 6c**).

5.2.3. Proceed to test by pressing **Begin Test** button. Observe the participant complete the test, ensuring that correct procedures are followed (**Figure 6d**).

6. Interpretation of C3 App to Guide Clinical Decision-Making

6.1. Administer C3 app follow-up assessment if the student-athlete is diagnosed with a concussion[20] using procedures outlined in step 1 above. Ensure clearance of cervical spine prior to administration of dynamic visual testing.

6.2. View follow-up performance on all C3 app modules as displayed in **Figure 7**.

6.3. Determine post-injury performance on radar plot by analyzing each axis (representing a given module) relative to baseline performance, represented by the perimeter of the polygon. The red, yellow, and blue polygons depict performance at various post-injury time points, representing a gradual return to baseline function.

6.4. Based on the clinical exam, performance on C3 app modules, time since injury, athlete's history, and other relevant determinants of care, refer to specialty services as outlined in carepath algorithm (**Figure 1**).

6.5. Field Validation

6.5.1. Conduct an analysis of C3 app data on a cohort of student-athletes with confirmed concussion. With Cleveland Clinic Institutional Review Board approval and waived consent, C3 app data were obtained for all incident reports completed between July, 2014 through October, 2016, and C3 baseline and follow up assessments completed on student-athletes injured between July, 2013 through December, 2014. Criteria for inclusion were as follows: 1) Presence of baseline C3 assessment, 2) Concussive injury confirmed by Cleveland Clinic physician, 3) Follow-up C3 assessment post-injury.

6.5.2. Determine post-injury performance on each module of the C3 app by comparing outcomes to baseline performance.

6.5.2.1. Analyze data as a function of post-injury phase as defined by the carepath: acute (0-7 days post-injury), subacute (8-20 days post-injury), chronic (>20 days post-injury).

6.5.2.2. Stratify student-athletes according to time to recovery (recovered within 3 weeks of injury or recovered in >3 weeks since injury).

REPRESENTATIVE RESULTS:

To investigate change in neurologic function following concussion, baseline and follow-up C3 assessments were analyzed in 181 student-athletes injured during the 2013-2014 athletic seasons. Detailed demographics of the 181 injured athletes are shown in **Table 1**. Data were stratified into two groups: those who recovered within three weeks of injury (N=92) and those who were still symptomatic three weeks after injury (N=89). When comparing the first post-injury assessments, Welch's two-sample t-tests revealed a significant difference between the two groups for the following C3 app modules: simple reaction time, ($P<0.001$); choice reaction time, ($P<0.001$); Trail Making Test B, ($P=0.01$); and for two of the six BESS stances quantifying

postural sway (double limb stance on foam, P=0.02; tandem stance on foam, P=0.04). BESS errors were not significantly different between the two groups, (P=0.26). Results of the analysis are shown in **Table 2**. These results suggest that athletes who remained symptomatic performed significantly worse on C3 modules measuring information processing, executive function, set switching, and postural stability. Importantly, athletes performed comparably on all modules at baseline (**Table 2**), and differences were only seen at follow up, suggesting that the modules are effective in detecting change in neurologic function as a result of concussive injuries. Mean performance of the 181 athletes on the C3 modules at baseline and during each post-injury phase of recovery is depicted in **Figure 8**, stratified by typical *versus* prolonged recovery.

FIGURE AND TABLE LEGENDS:

Table 1: Demographic table outlining characteristics of 181 student-athlete diagnosed with concussion.

Table 2: Results of Welch's two-sample t-tests analyzing differences in performance at baseline (left panel) and at the first follow-up (post-injury) test (right panel) for student athletes who recovered within 21 days of injury (typical recovery) and those who recovered in greater than 21 days (prolonged recovery).

Figure 1: Cleveland Clinic Concussion Carepath algorithm depicting qualifiers guiding clinical care in the acute, subacute, and post-concussive phases post-injury. Fields with gold shading indicate points of care at which standardized, objective outcomes measured through the C3 app integrated with the carepath to guide clinical decision-making.

Figure 2: The digital tablet is affixed to the sacrum of the participant to obtain a biomechanical measure of postural sway during performance of the six stances of the Balance Error Scoring System. Double limb stance on firm surface (**Figure 2a**), Single limb stance on firm surface (**Figure 2b**), Tandem stance on firm surface (**Figure 2c**), Double limb stance on foam surface (**Figure 2d**), Single limb stance on foam surface (**Figure 2e**), Tandem stance on foam surface (**Figure 2f**).

Figure 3: Screen shot depicting instructions for administration of the static visual acuity test.

Figure 4: Screen shots depicting the simple reaction time (Figure 4a) and choice reaction time (Figure 4b) paradigms.

Figure 5: Screen shot depicting the Processing Speed Test (PST).

Figure 6: Screen shots depicting the instructions for the Trail Making Test A (Figure 6a) and the digitized Trail Making Test A (Figure 6b), in addition to the Sample Trail Making Test B (Figure 6c), and the digitized Trail Making Test B (Figure 6d).

Figure 7: Radar plot depicting baseline and post-injury performance on C3 modules for a representative athlete to aide in C3 app interpretation and guide clinical decision-making. Baseline performance is reflected by the perimeter of the polygon, while the red, yellow, and blue polygons represent performance at 2, 5, and 12 days post-injury, respectively. In the first post-injury assessment, information processing measured by the simple and choice reaction time modules did not appear to be impacted in this patient. However, deficits in balance, processing speed, and in the Trail Making Test were evident. Improvements in all aspects of function measured by the C3 app were evident over the course of recovery, as performance was at or near baseline by 12 days post-injury.

Figure 8: C3 app data for student-athletes (N=181) who incurred a concussion stratified by those who recovered within 3 weeks (typical recovery group, N=92)) and those who took longer than 3 weeks to recover (protracted recovery group, N=89). Bar plots depict mean and standard error of the mean (SEM) performance at baseline and in each phase of recovery post-injury for following C3 app modules: simple reaction time (8a), choice reaction time (8b), Trail Making Test B (8c), Processing Speed Test (8d), Cleveland Clinic Postural Stability Index during BESS double limb stance on foam surface (8e), and Cleveland Clinic Postural Stability Index during BESS tandem stance on foam surface (8f).

DISCUSSION:

The development and implementation of the concussion carepath served numerous purposes in our health system's transformation toward value-based care[1-3]. The algorithm of care was critical in guiding clinical decision-making, and was supported by standardized, biomechanical outcomes in the form of the C3 app, which was used by all members of the interdisciplinary concussion team. These standardized outcomes provided qualifiers to monitor recovery patterns in patients, helped identify individuals at risk for protracted recovery, and drove referral for specialty services for those not recovering in a timely manner. As such, the technology-enabled carepath was designed for use by the multi-disciplinary clinical team to avoid stagnant care and to funnel patients to the right provider at the right time. Care and recovery pathways have been recently developed aimed at educating the general public in concussion care[21]. While the two care pathways overlap in content, the carepath described in this manuscript was designed for use by medical personnel.

A clinical workflow was created within the carepath algorithm representing patient management at three main phases: Acute (0-7 days post-injury), Subacute (8-21 days post-injury) and Post-Concussive (>21 days post-injury). The multi-modal C3 app served to provide a set of common data elements by which clinicians characterized injury status, measured recovery, and engaged in the coordination of care across each phase of injury/recovery. For example, based on epidemiological data indicating typical time to recover from concussion[20] and modifiers/co-morbidities that often contribute to prolonged recovery[20], the carepath team recommends referral to specialty services to assist with symptom management for those individuals >8 days post-injury who demonstrated a lack of progress toward recovery (*e.g.,* no improvement in C3 modules) *and* presented with modifiers that may prolong recovery. In the absence of prognostic modifiers, referral for specialty services was recommended for

individuals who remained symptomatic >21 days post-injury and did not demonstrate improvements in performance in C3 modules relative to post-injury or did not progress toward baseline performance level if a baseline test was available. These standardized outcomes related to symptoms, neurocognitive function and postural stability using the C3 application across all members of the interdisciplinary team were incorporated into the carepath and into electronic health record (EHR) documentation templates to ensure the collection of objective clinical and subjective patient-reported outcomes to guide clinical decisions[11,17].

The C3 app metrics in combination with the carepath algorithm were critical in preventing stagnant clinical care by empowering physicians to refer patients who were not recovering in a timely manner to the right provider at the right time. Specific cut-off scores to trigger referrals were not explicitly identified in the carepath as not all outcome values had sufficient normative data. In general, if the patient was beyond one standard deviation away from an established age-gender mean value at follow-up, a referral to the next level provider was indicated.

Our preliminary analysis indicated that the assessment modules within the C3 app were responsive in detecting differences in performance between athletes who are had recovered compared to those who remained symptomatic post-concussion. A limitation to our methodology was that we cannot determine sensitivity or specificity of these modules with the current data set, as only injured athletes are represented. Correlations between baseline concussion scores and other objective outcomes have been previously reported[22], and work is under way to more precisely determine values for each module of the C3 app that indicate meaningful change. Additionally, predictive models are currently being built using clinical and C3 data to identify student-athletes at risk for protracted recovery.

Concussion care is unique in that the initial management of the injury often occurs offsite, with AT's positioned at schools and venues providing the first line of care. A limiting factor in administering medical care remotely is poor access to the EHR and limited direct interaction with other members of the interdisciplinary care team. The EIR module within the C3 app allowed for the detailed documentation of the athlete's injury, their initial disposition, and medical management provided by the AT. Thus, it facilitated hand-offs among providers by linking the care provided by the AT offsite with the medical management of the athlete in clinic and their post-injury rehabilitation. Furthermore, the electronic template eliminated the outdated paper-pencil documentation format commonly utilized in the school setting, promoting more complete documentation accessible within the EHR. Analysis of detailed injury documentation is under way to better understand circumstances surrounding concussive injuries with the aim of mitigating risk and improving outcomes.

The development and implementation of the carepath, and its enablement *via* the C3 app, served to standardize the care of concussion across the Cleveland Clinic enterprise along evidence-based best practices. Overall, the C3 app was responsive in discriminating between symptomatic and non-symptomatic athletes post-injury and guided referral to specialty services to promote active rehabilitation for athletes with prolonged symptoms. Detailed analyses quantifying the clinical and economic impact of the carepath are ongoing.

ACKNOWLEDGMENTS:

We wish to thank the Jason Cruickshank, Bob Gray, and the Cleveland Clinic Athletic Trainers for their support and assistance with data collection. This study was supported by the Edward F. and Barbara A. Bell Family Endowed Chair to JLA.

DISCLOSURES:

Drs. Alberts and Linder have filed intellectual property protecting the Cleveland Clinic Concussion mobile application. The remaining authors have nothing to disclose.

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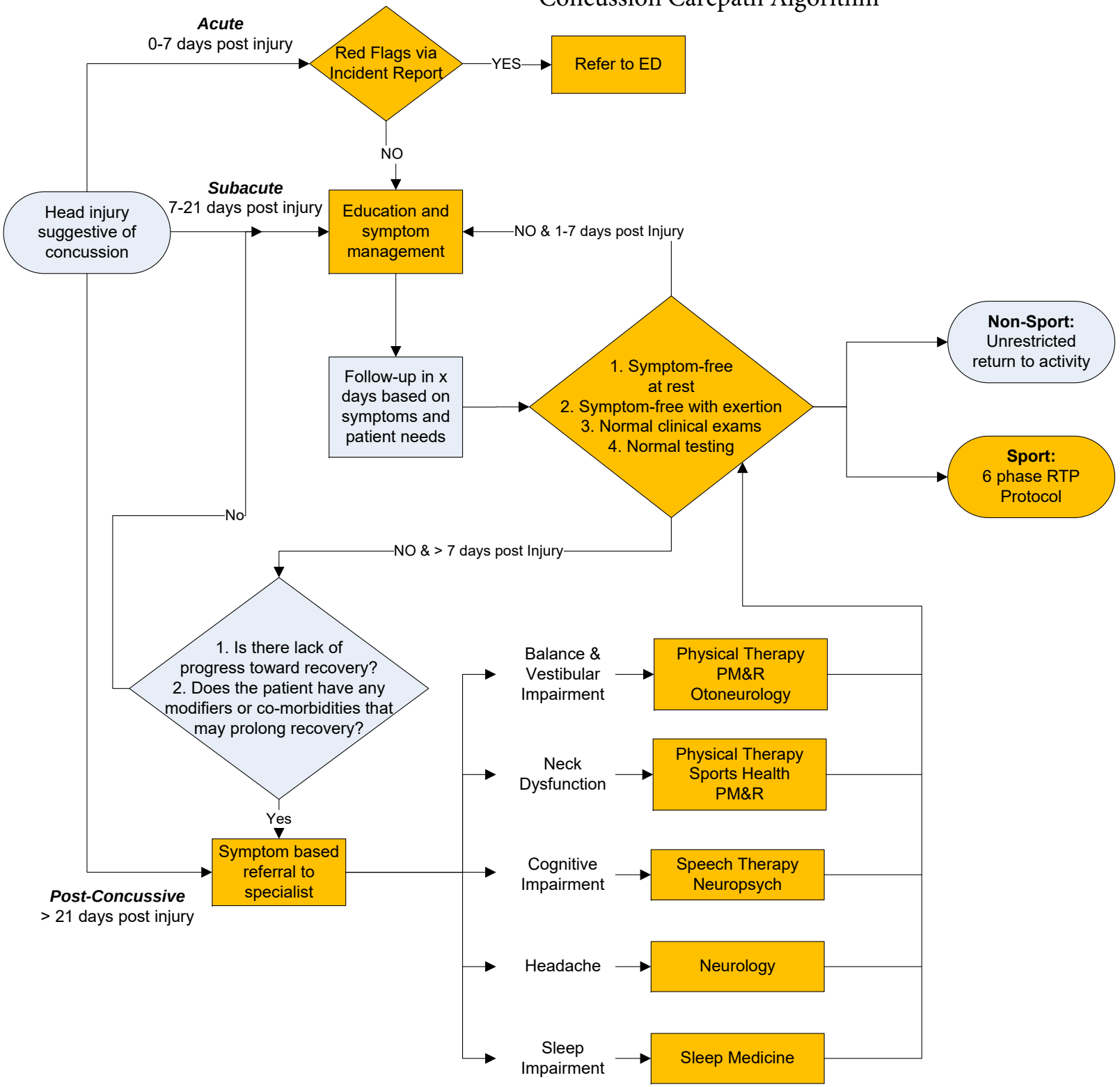
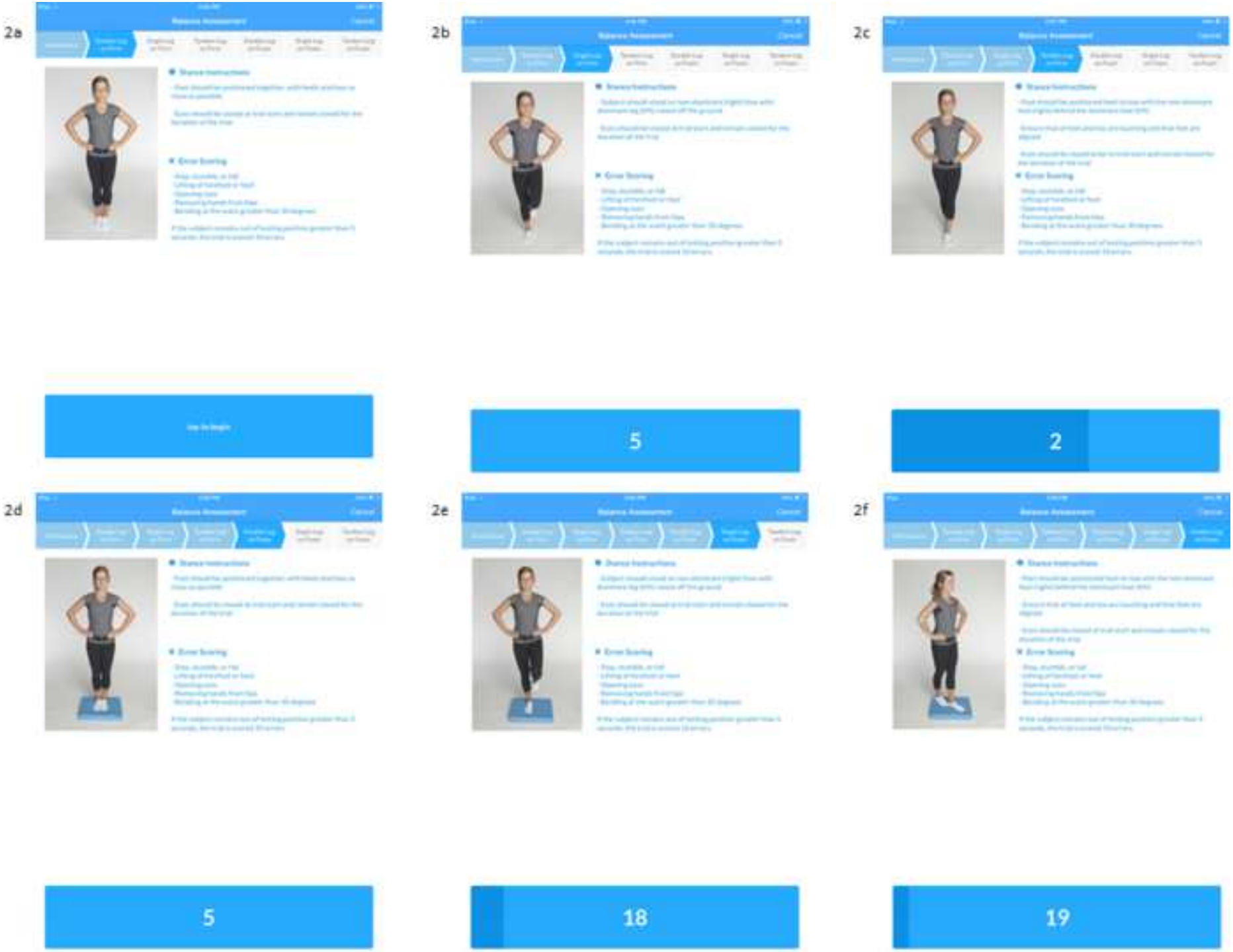
Figure

Concussion Carepath Algorithm



Figure

Click here to access/download;Figure;Figure 2.tif



Figure

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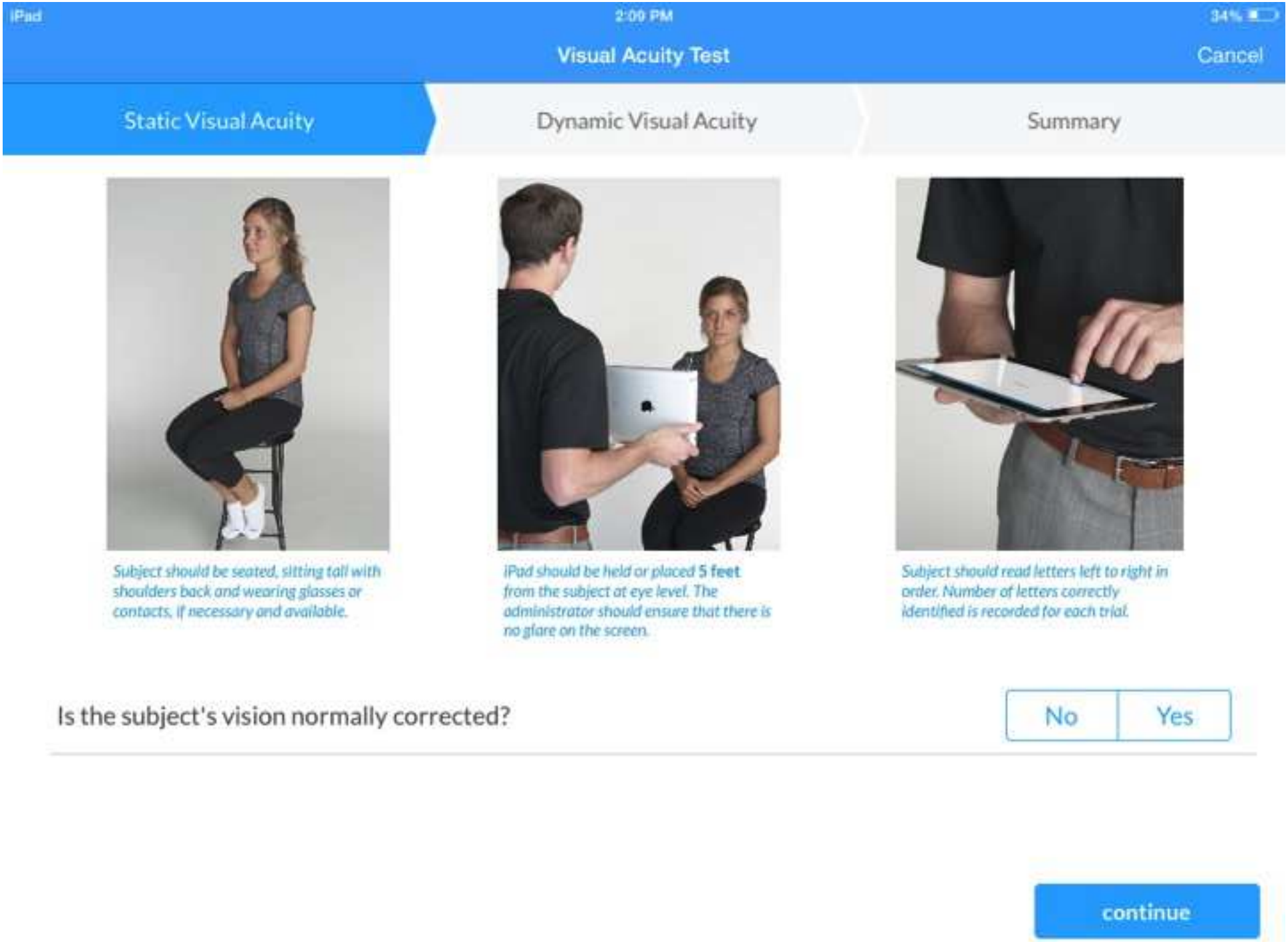

Figure

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Figure

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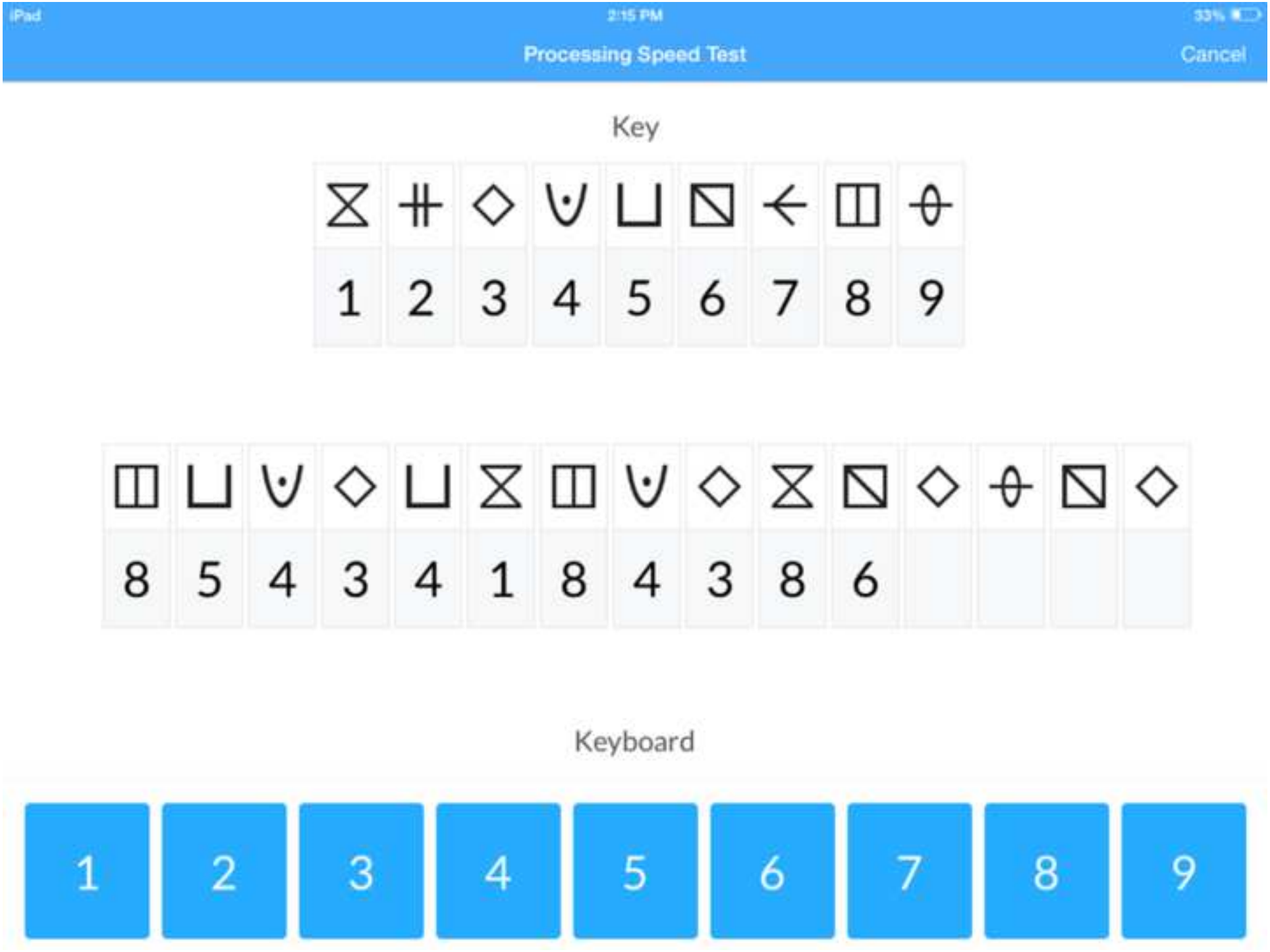

Figure

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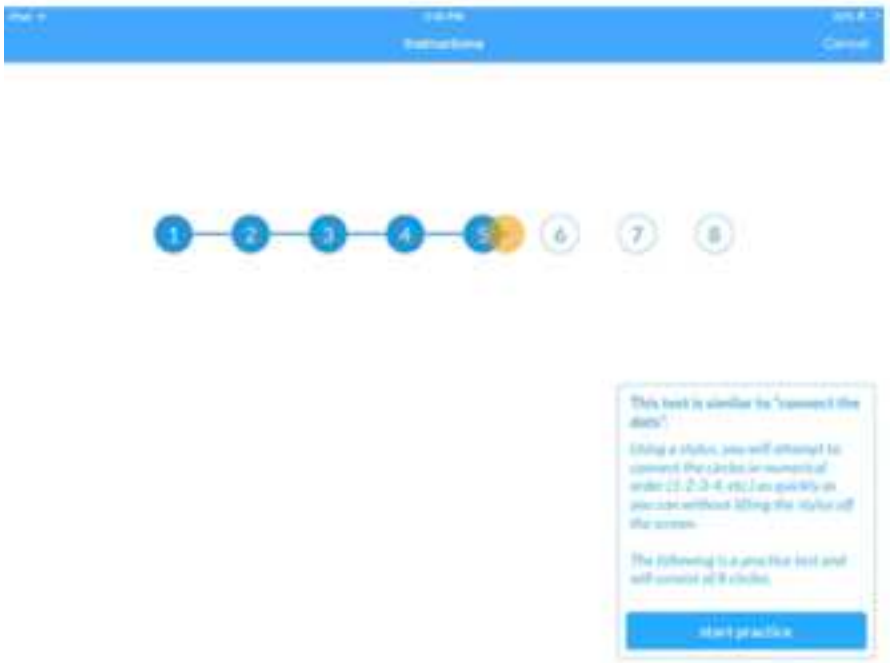
6a



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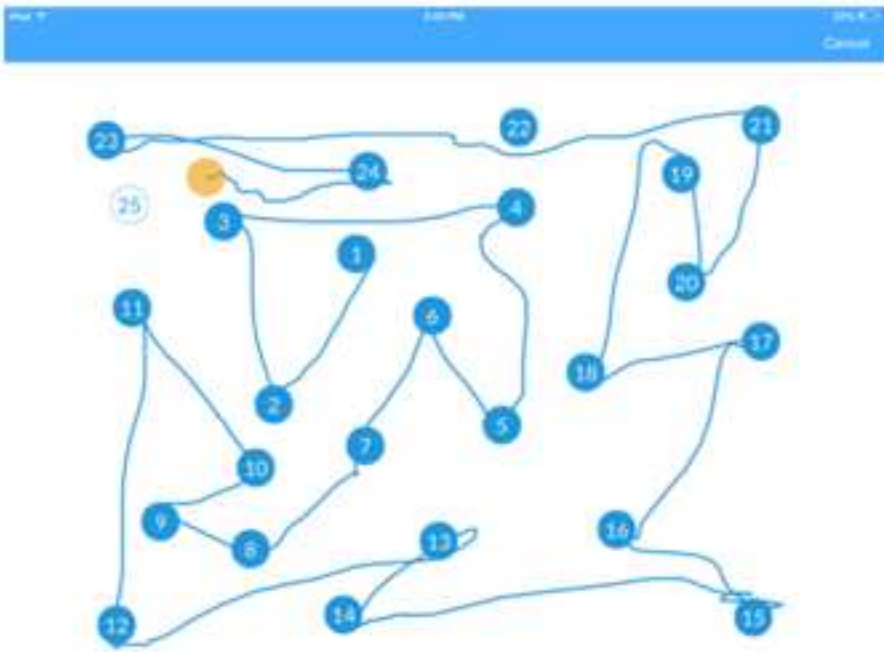

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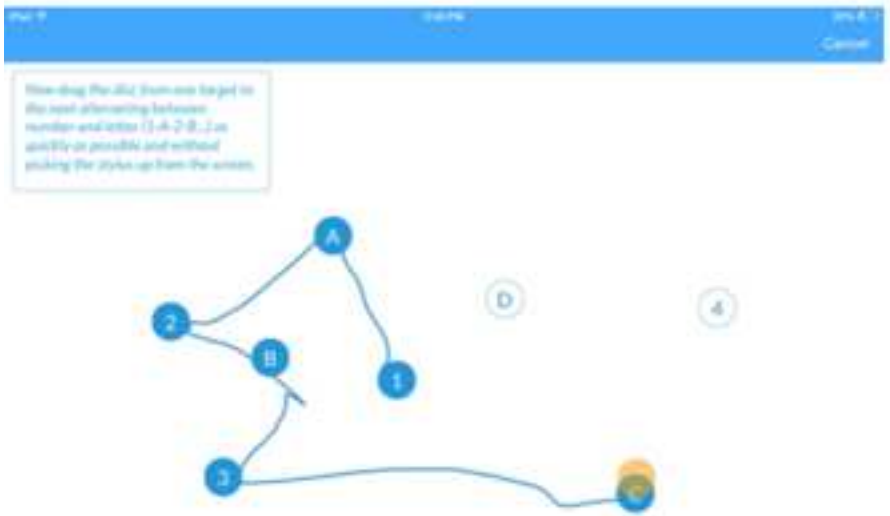

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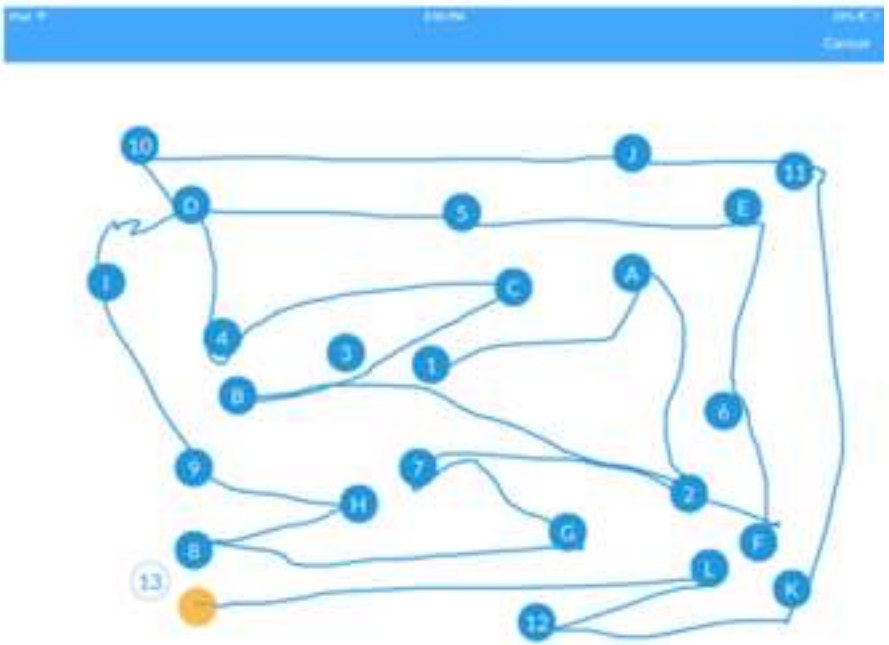
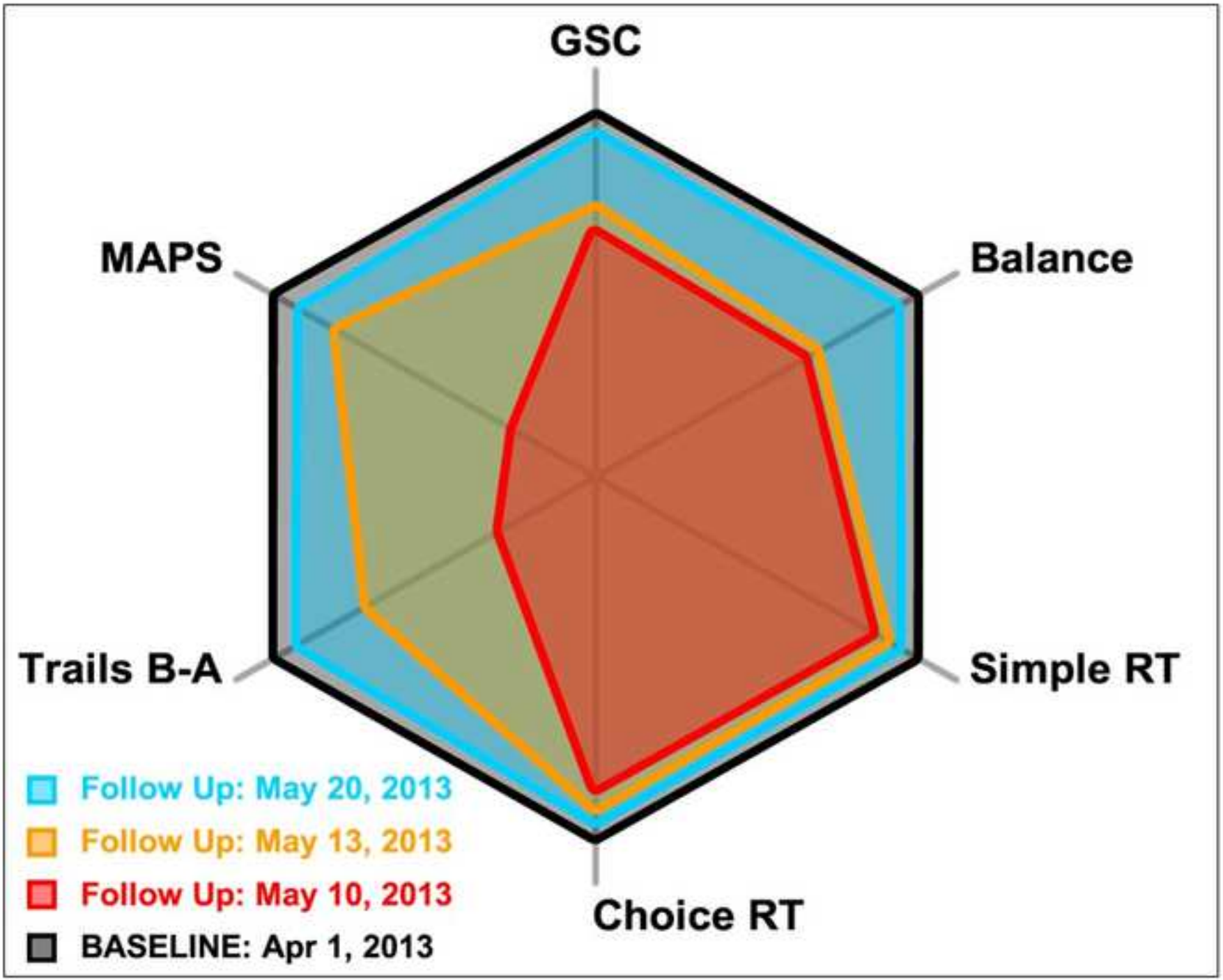


Figure

Click here to access/download;Figure;Figure 7_Radar Plot.jpg



Figure

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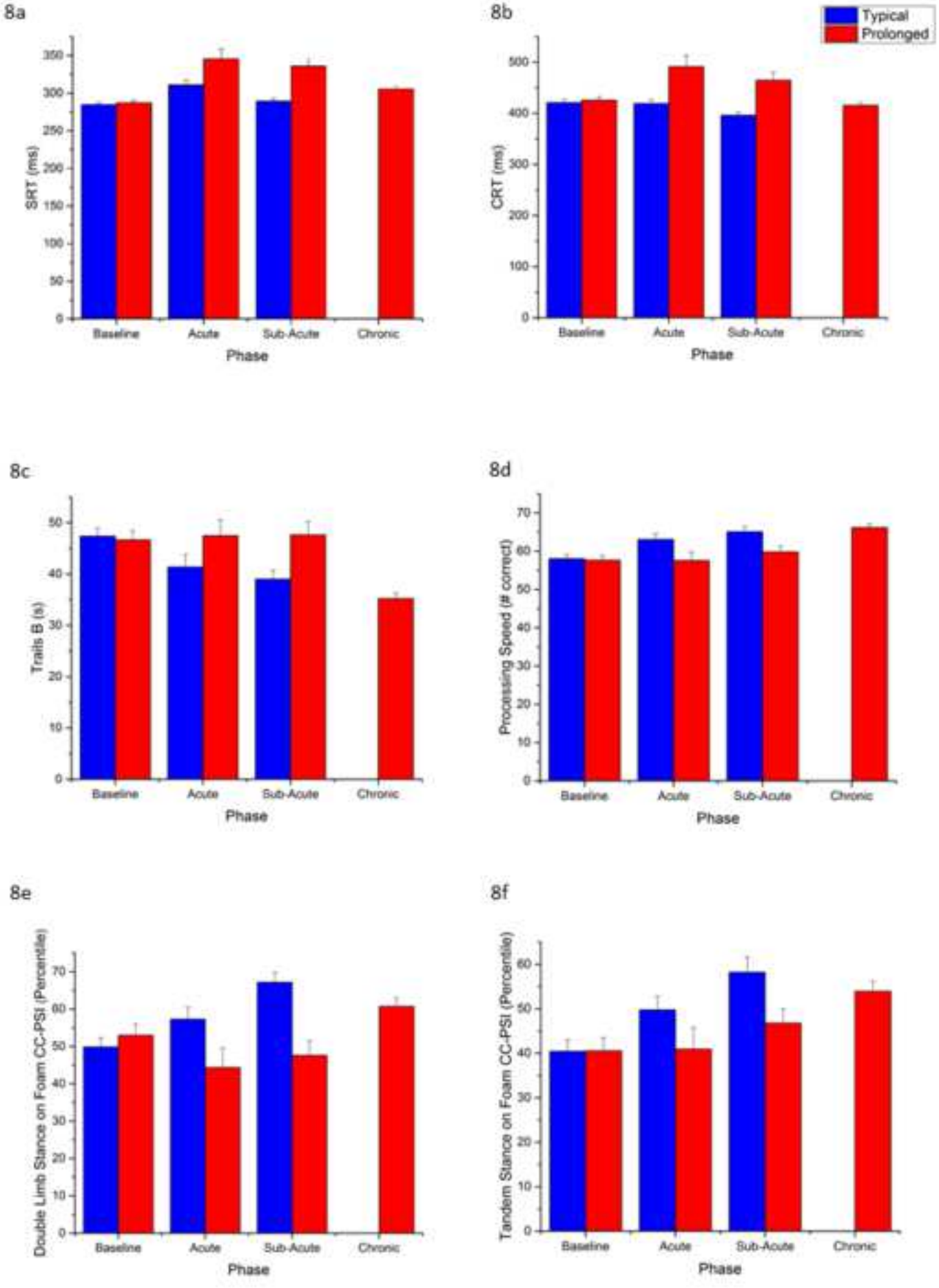

Table

	Typical	Prolonged	Total
N	92	89	181
Age (SD)	17 (1.29)	18 (1.31)	
Sex, male(%)	73 (79%)	66 (74%)	139 (76.8%)
Sport			
Football	60	46	106
Soccer	24	30	54
Baseketball	2	4	6
Volleyball	1	3	4
Wrestling	2	2	4
Hockey	1	1	2
Rugby	0	2	2
Other	2	1	3

Table

	BASELINE		
Variable, mean (SD)	**Typical**	**Prolonged**	**P-Value**
BESS (total errors)	14.5 (6.4)	14.9 (7.2)	0.65
Simple Reaction Time	284.8 (24.4)	287.6 (25.3)	0.46
Choice Reaction Time	421.1 (57.7)	425.7 (60.6)	0.61
Trail Making Test A	24.2 (8.1)	23.1 (7.0)	0.31
Trail Making Test B	47.4 (15.7)	46.7 (16.2)	0.76
Processing Speed Test	58.0 (10.5)	57.7 (10.2)	0.81
Instrumented BESS (CC-PSI percentile)			
double limb firm	46.6 (25.0)	47.5 (27.4)	0.83
single limb firm	50.0 (22.5)	53.0 (25.6)	0.44
tandem stance firm	55.6 (26.4)	54.9 (27.0)	0.87
double limb foam	52.4 (28.7)	49.7 (28.1)	0.54
single limb foam	55.6 (27.5)	50.8 (29.6)	0.29
tandem stance foam	40.8 (22.6)	40.6 (25.3)	0.96
Graded Symptom Checklist*			
Standardized Assessment of Concussion*			

*Variables only collected post-injury

Bold indicates significant at P<0.05

Abbraviations: BESS (Balance Error Scoring System); CC-PSI (Cleveland Clinic Postural Stab

FIRST POST-INJURY ASSESSMENT		
Typical	Prolonged	P-Value
10.9 (5.2)	11.9 (5.7)	0.26
294.6 (40.7)	330.1 (64.7)	**0.0003**
403.3 (60.8)	459.0 (111.9)	**0.0009**
20.6 (7.1)	23.4 (8.3)	0.05
38.4 (18.5)	46.2 (16.2)	**0.01**
65.0 (11.4)	62.0 (11.8)	0.17
51.6 (23.3)	42.2 (32.1)	0.06
64.7 (24.8)	53.4 (31.9)	**0.02**
56.7 (29.1)	50.5 (26.9)	0.18
57.2 (29.3)	56.1 (29.5)	0.82
52.9 (32.3)	46.1 (31.3)	0.21
56.7 (28.6)	47.6 (25.4)	**0.04**
4.8 (11.2)	18.4 (20.6)	0.0001
26.7 (2.5)	25.8 (4.20	0.17

ıility Index)

Table of Materials

Click here to access/download;Table of Materials;JoVE_Materials.xls

Name of Material/ Equipment	Company	Catalog Number	Comments/Description
Foam Balance Pad	Airex, Sins, Switzerland		dense foam balance pad used during balance testing
iPad Digital Table	Apple		

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Title of Article: Development and Implementation of a Technology-Enhanced Care Pathway for Concussion

Author(s): Jay Alberts, Michael Modic, Belinda Adler, Tanujit Dey, Kay Cherian, Xiaoyang Lu, Richard Figler, Andrew Rullman, Susan Linder

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CORRESPONDING AUTHOR

Name:	Jay Alberts, PhD
Department:	Biomedical Engineering
Institution:	Cleveland Clinic
Title:	Staff
Signature:	Jay Alberts
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3. Many of the Figure panels can be supplementary Figures used only for the scripting. Please remember that there will be a video component as well. Please reduce the number of Figure panels.
4. Figure 2 may be effective if only showing the picture of person in the various stances. Figure 6 is a bit cluttered and may not be clear when all the panels are included in one image file. Is there another way to present Figure 8?

   Several edits were made to the figures as follows: The number of panels was reduced for Figures 2, 3, 5, and 6 and these were placed into a single image file. We attempted to combine several outcomes from Figure 8 onto one plot, however, this was not a statistically sound approach to visualize our data as 5 of the remaining 6 plots utilize different scales. However, we eliminated three outcomes that were not as relevant and combined the remaining 6 into one image file. In all, we have reduced the original number of figures by one-third.

5. Please place the superscripted reference before the punctuation.

   This has been corrected.

6. Please use SI abbreviations for time: h, min, s, ms, etc.

   Abbreviations have been corrected.

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   For example: iPad (use tablet instead), etc.

   All references to commercial products have been removed from the manuscript and detailed in the Table of Materials and Reagents.

8. Please ensure that all text in the protocol section is written in the imperative tense as if telling someone how to do the technique (e.g., “Do this,” “Ensure that,” etc.). The actions should be described in the imperative tense in complete sentences wherever possible. Avoid usage of phrases such as “could be,” “should be,” and “would be” throughout the Protocol. Any text that cannot be written in the imperative

tense may be added as a “Note.” However, notes should be concise and used sparingly. Please include all safety procedures and use of hoods, etc.

9. The Protocol should contain only action items that direct the reader to do something. Please move the discussion about the protocol to the Discussion.
10. Please include an ethics statement before the numbered protocol steps, indicating that the protocol follows the guidelines of your institution’s human research ethics committee.
11. I have renumbered the protocol steps for clarity.
12. Step 1 and 2 of the protocol can be move to the Introduction.
13. Please remove the large paragraph of text in Step 8.

The protocol has been edited to ensure that all text are written in the imperative tense. Descriptions of the protocol have been moved to the Discussion or to the Introduction as appropriate. An ethics statement was added as suggested.

14. Please highlight 2.75 pages or less of the Protocol (including headings and spacing) that identifies the essential steps of the protocol for the video, i.e., the steps that should be visualized to tell the most cohesive story of the Protocol. Remember that non-highlighted Protocol steps will remain in the manuscript, and therefore will still be available to the reader.
15. Please ensure that the highlighted steps form a cohesive narrative with a logical flow from one highlighted step to the next. Please highlight complete sentences (not parts of sentences). Please ensure that the highlighted part of the step includes at least one action that is written in imperative tense.

Relevant steps of the protocol have been highlighted to define the visual portion of the manuscript.

16. Please spell out all journal titles.

Journal titles are now spelled out.

Reviewers' comments:

Reviewer #1:

Manuscript Summary:
the C3 application demonstrates the ability to differentiate standard recovery and prolonged recovery in student athletes. Though, further testing for sensitivity is required, the results appear to be promising.

Reviewer #2:

Manuscript Summary:
Thank you for the opportunity to review your work. A multidisciplinary approach is positive. However

the target audience (users and subjects) needs to be more clearly defined. How does this technology advance what is currently available.
More references are needed to support rational for measures selected.
We appreciate these comments and have updated the manuscript to clearly communicate how this multidisciplinary approach is critical to effective management of concussion.

Major Concerns:
1. How is this protocol with technology different/similar to what is currently available ie Im PACT, NIH tool kit ? others?

While our aim is not to compete with other concussion assessment tools, we appreciate the opportunity to describe the differences in our approach to concussion assessment using the C3 app. From an assessment perspective, traditional measures including ImpACT and CNS Vital Signs only assess neuropsychological function. Yet, it is widely known that the deficits following concussion are multi-modal and may include declines in motor function, motor control, postural stability and vision. Thus, the C3 app was developed to include biomechanical measures of these additional domains of neurological function not traditionally captured using other tools. For example, the iPad is affixed onto the sacrum to provide a biomechanical measure of postural sway while individuals complete the 6 stances of the BESS. These data are converted to percentile scores based on a normative database of over 6000 student-athletes. The app also includes the assessment of static and dynamic visual acuity, which is novel compared to other assessment tools. Of note, we have further developed this iPad-based suite of visual outcomes which is beyond the scope of this manuscript, but has promising clinical implications. Also, the neuropsychological measures included in the app are not simply paper-pencil tests converted to a tablet platform. Rather, each test exploits the capacitive touch screen to provide detailed data regarding aspects of performance. For example, during the Trail Making Test, while the standard outcome is time to complete, we are able to distinguish "dwell time", or the time the individual is thinking about or searching for the next target, from "movement time", or the time required to move between targets. These detailed data provide additional information regarding the individual's deficits as related to cognitive versus motor function. Lastly, the results of the app align with the carepath and populate fields in the electronic medical record, allowing all members of the concussion management team to review this common set of data elements. While we feel these distinctions are beyond the scope of this protocol paper and have been outlined in our previous publications, should the reviewer feel that it enhances the manuscript, we are happy to add it.

2. What is the rationale and references behind the tests selected for this technology? Are they NINDS common data elements? CDC approved elements?

NINDS recommends numerous proprietary outcome measures and several non-proprietary. In collaboration with our team of neuropsychologists, we chose measures that are either recommended by NIH (ie: Trail Making Test, SAC) or are proxies that measure comparable domains of function (e.g.: assessment of static and dynamic visual acuity instead of provocation testing using the VOMS). The Processing Speed Test was developed and validated based off of the paper-pencil symbol digit modalities test. The instrumented BESS is used due to its historic role in concussion assessment and it is recommended by NINDS.

3. How does this process support more care co-ordination between health care professionals?

Prior to the development and implementation of the carepath and C3 application, the various disciplines involved in concussion care at our institution used different outcomes and different systems for documentation (ie: athletic trainers kept paper records stored in files in the training room at each school). The app combined with the carepath served three main purposes in improving care coordination: 1) unify outcomes across the multidisciplinary team, 2) standardize decision-making based on objective outcomes, and 3) enable documentation with respect to the collection of outcomes to be collected on the iPad platform which was then included in the electronic health record. The second and fourth paragraph of the discussion now outline these processes.

4. Clarify the target audience - both in terms of who will use the tool and who will be the subject of the tool/ (seems like young athletes)

We believe that our somewhat fractionated approach to concussion management, prior to the C3 app and carepath, is reflective of many approaches in hospital systems across North America and Europe. Various aspects of the tool are administered by all members of the interdisciplinary team or direct treatment to a member of the team. This includes athletic trainers, nurses, physicians (sports med, neurologists, physical medicine and rehabilitation, otoneurologists, sleep medicine, pediatricians, neuroradiologists, ED physicians), physical therapists, and speech and language pathologists. Unlike the care pathway developed by the Ontario Neurotrauma Foundation (referenced below), our carepath is designed for use by medical personnel.

The carepath was created for individuals between the ages of 12 and 50. Modules of the C3 app have been administered in individuals from 5 years to 80+, though normative values are available for individuals ages 5-24.

5. Amend title to fit target group

The title has been amended to: Development and Implementation of a Multi-Disciplinary Technology Enhanced Care Pathway for Youth and Adults with Concussion

6.What is meant by a value-based model in this context?

The first paragraph of the introduction is meant to define value-based care with respect to the context of the carepath (e.g. third- party focus on tying payments to outcomes rather than a traditional transactional fee-for-service reimbursement model). We describe perspectives regarding how disjointed care that lacks continuity contributes to overutilization and poor coordination of resources, but that "In a coordinated care model, patients with a given condition are managed by an experienced, interdisciplinary team according to best practice guidelines, and are referred to the right provider at the right time[2]."

7. What is someone has neck pain/injury - how to visual testing?

The reviewer poses an important question. Dynamic visual testing is often deferred until the athlete is asymptomatic and does not have cervicogenic dysfunction that may be worsened with testing. Dynamic visual testing can also be used as a provocative assessment in athletes to determine whether residual vestibular or cervicogenic dysfunction is present. Step 7.1 of the protocol has been amended to reflect this important detail.

8. What about those with previous concussions?

Those with previous concussions are more likely to experience protracted recovery. This "modifier" along with others (h/o migraines, ADD, anxiety, etc) is included in the carepath (see Figure 1) and in step 7.4 of the protocol when determining the timing of referral to specialty services.

9. How many times can the C3 module be repeated? reliability ? validity ?

Several of the C3 app modules have undergone reliability and validity testing both internally and externally (see references 13, 15, 17, 18, 20, and 21). A shift in post-concussion testing has occurred in the past 3-5 years, in that testing is used primarily to determine whether an individual has fully recovered and is cleared for some level of participation (school, work, sport, etc). A part of the C3 app that does not succumb to learning effect is the graded symptom checklist. This important tool, when combined with portions of the app (balance testing, for example), are often sufficient to inform the clinician regarding next steps in clinical management. Frequent administration of the entire app (ie: all modules) is discouraged to preserve the psychometric properties of the tool and to prevent unnecessary symptom provocation. While we appreciate the "standardization" of care with the carepath and the app do not take the place of sound clinical judgment in the application of these tools.

other references for the authors to consider :

a) http://concussionsontario.org/wp-content/uploads/2018/04/ONF-PatientPathway-Tearaway-WEB-1.pdf
b) Vander Vegt CB, Register-Mihalik JK et al. Baseline Concussion Clinical Measures Are Related to Sensory Organization and Balance. Med Sci Sports Exerc. 2018 Sep 19. doi: 10.1249/MSS.0000000000001789

We appreciate the recommendations and both references have been added.
Minor Concerns:
1. Are OTs and nurses not part of the multidisciplinary team?

Nurses play a prominent role in the multidisciplinary team. In our practice, very few concussion patients are referred to OT, except occasionally for vision rehabilitation, though this is primarily accomplished through an optometrist who has developed a niche in this domain. Nonetheless, both disciplines are certainly respected in the field and should be considered a part of the team. The manuscript has been edited to reflect this.

2. Explain more about being HIPPA compliant.

All assessment data are encrypted at rest and in transmission to the Amazon Web Services cloud. Further security and encryption measures are provided by ClearData before data are transmitted to an existing HIPPA compliant research database behind the Cleveland Clinic firewall. All points of access to the research database take place over Transport Layer Security/Secure Sockets Layer encrypted connections. This data collection and transmission approach has been approved by multiple groups and committees within the Cleveland Clinic: IRB, Office of Compliance, Legal, Information Technology Division (ITD) security and governance, Office of Patient Engagement, Enterprise Information Management and Analytics and Mobile Governance Committee. All iPads are enrolled in the Cleveland Clinic's Mobile Device Management (MDM) system. The Cleveland Clinic MDM has the ability to track the location of each device. Each iPad requires a double lock system – one password to get into the iPad and another to access the C3 assessment application. Should a device be lost or stolen, the MDM administratively locks and remotely wipes the device.

3. What is the definition of concussion used by the physician (line 369)

While in the carepath document we acknowledge that there is no universally agreed upon definition of concussion, we chose to use the definition based off of the 4th International Conference on Concussion in Sport: A complex pathophysiological process affecting the brain, induced by traumatic biomechanical forces. This part of the manuscript is now referenced.

4. Figure 1 does not match with the content of the manuscript- it needs a title .

Figure 1 depicts the algorithm developed with the carepath to guide clinical care in each post-injury phase. A title has been added.

5. References are not complete on the draft I have received

We are unsure if a page was omitted from the draft received by the reviewer. There are currently 23 references.

Reviewer #3:

Manuscript Summary:
The authors nicely describe the process and care pathway of use of the C3 within their system.

Major Concerns:
None, very well done.

Minor Concerns:
Figure 8, please include units on y-axis, add error bars.

Thank you for the recommendations. Figure 8 has been edited as recommended.