MAYO CLINIC AND KING DEVICK

Moderator: Jim McVeigh
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News Release: Mayo and King-Devick Test Have Licensing Agreement for Sideline Concussion Test

Operator: Ladies and gentlemen, thank you for standing by. Welcome to the Mayo Clinic and King Devick Conference Call. During the presentation all participants will be in a listen-only mode.

Afterwards we will conduct and question-and-answer session. At that time if you have a question please press the 1 followed by the 4 on your telephone. If at anytime during the conference you need to reach an operator, please press Star 0.

As a reminder this conference is being recorded Tuesday, January 27, 2015. I would like to now turn the conference over to Mr. Jim McVeigh. Please go ahead.

Jim McVeigh: Thank you. Good morning, everyone. Thanks for joining us today. My name is Jim McVeigh. I'm from Public Affairs at the Mayo Clinic. We're here today for the next half-hour to share some news about the exciting collaboration to
So let's get right to it. I'd like to introduce our speakers: first, Dr. David Dodick, Professor of Neurology at Mayo Clinic and Director of the Sport and Neurology Concussion Program, and Dr. Steve Devick, who is the founder and developer of the King Devick Test. And our speakers will give a little bit of background and then we'll open it up for Q&A. So, first, Dr. Dodick?

Dr. Dodick: Thank you, Jim. Good morning everybody. Well, with this week being the Super Bowl I think all eyes will be focused on football and a lot will be said about the specter of concussion.

I think despite awareness being at an all-time high, understanding the implications of concussions is not. We're also well aware of the fact that while there may be up to 3.8 million concussions per year in the US we know from multiple survey studies that up to 50% of athletes who were surveyed indicate they do not disclose their symptoms of concussion. So many millions more are very likely undetected.

So, add to that the fact that the diagnosis of concussion can be challenging even for specialists — it's daunting for those who aren't specialized so the diagnosis of a concussion itself could be a very challenging one. So we are very excited about this collaboration with King Devick Test. I think the King Devick Test has emerged as a gold standard.

It's a very sensitive and accurate test for the sideline assessment of concussion principally because it reflects very subtle abnormalities in eye movements that would be very difficult to detect otherwise. And these eye movements occur — abnormalities in eye movements occur in the overwhelming majority of
concussions because more than half of the pathways in the brain are dedicated to eye movements. And these pathways are widely distributed throughout the brain — front to back, top to bottom. So it becomes very difficult for there to be a functional or structural brain injury that won't affect eye movements.

Not only that, it can detect concussion in those in whom it's suspected but it can also detect concussion in those in whom it may not even be suspected. So if you do a sideline King Devick test on someone who has taken a hit who isn't even reporting any symptoms they can actually document the brain injury when symptoms aren't disclosed.

So it can pick up silent concussions, if you will, which is really an advance as we see it. So we're very excited about the potential — this collaboration and the potential to detect more concussions because it's all about doc- it's all about recognizing concussion, removing that athlete from play rather than risk repeat injury because that is what leads of course to the persistent symptoms that many of these athletes suffer from and deal with for weeks, months or years.

Dr. Devick: And I'm Steve Devick and I'm happy to be here. Of course it's a big day for us to be collaborating with what is the most recognizable healthcare brand in the world, Mayo Clinic.

Just a little bit about King Devick Test, the history. It has been around for more than 30 years actually and has — it has been described in most medical books for years. It has been a saccadic function which is the micro-eye movements that are part of reading. And so for all those years it has been a tool to determine if your inability to read had something to do with your eye movements.
A few years ago there was kind of a landmark study that showed that the only physical sign of a concussion and in post-concussion syndrome was a defect in those eye movements so we took that to the leading neurologists in the country and there has been more than 25 period studies showing that this test is a quick, reliable and accurate test in screening on the sidelines to help determine 'remove from play'.

And it's really quick. Like I said, it's accurate. It's also very inexpensive; it costs less than $5 per subject per year so it's - there are no barriers of entry from a cost perspective. And it's something that a parent can perform on the sidelines or administer on the sidelines and it's — or an athletic trainer or a coach or certainly any healthcare professional. So we think it will be easily used by parents of not just football players but all sports.

Of course soccer has a lot of concussions too relative to the participation in the sports and really all contact and collision sports should probably have a test like this on the sidelines to help determine whether the athlete should be removed from the playing field and referred to a medical professional.

Jim McVeigh: All right, well, thank you, Dr. Dodick and Dr. Devick. So now we will — Moderator, can we open it up for the Q&A?

Operator: Thank you. Ladies and gentlemen, if you would like to register a question please press the 1 followed by the 4 on your telephone. You will hear a 3-tone prompt to acknowledge your request. If your question has been answered and you would like to withdraw your registration please press the 1 followed by the 3. One moment for the first question. The first question comes (Dejure Baker). Please go ahead.
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(Dejure Baker): Oh, yes, I was just wondering, you've had it out there for 30 years but now it has come to the forefront with Mayo. I'm wanting more explanation on this timeline. If it has been around why isn't that all around that sort of time.

Dr. Devick: Well, the answer for that is that with those 30 years it was just used to help determine whether your inability to read efficiently had something to do with your eye movements. It wasn't until four years ago actually the first paper was published, just a little less than four years ago by the American Academy of Neurology in which it was determined that these same micro-eye movements that are related to your reading ability are the first physical sign of most concussions.

So nobody knew that — nobody had surmised that before the study came out of New Zealand that eye movements are an early and accurate indicator of a concussion on the sidelines.

So we took the reading tests and almost five years ago began having it tested by leading neurology departments of first (in Japan) and Mayo and NYU and that's why so many studies later have shown that this same ability to name numbers in reading is the first physical defect of a concussion and it really happens fairly immediately on the sidelines so you can test a kid right on the sidelines, and subjects and athletes.

(Dejure Baker): Oh, okay. Oh, is there — can I have a follow-up or no?

Man: Well, I guess...

Man: Fine with me.

(Dejure Baker): Are there other people? I don't know?
Jim McVeigh: Sure, go ahead.

(Dejure Baker): Yes. Why couldn't you just have a book or something like that? Is it a special piece of paper or a...

Dr. Devick: No, it actually comes in three forms, and I should have mentioned that. It's either an iPad tablet. You need an annual baseline — the subject needs an annual baseline — because your ability to name these numbers changes at least on an annual basis and so you have a baseline time. And after suspected head trauma you can check that on the King Devick Test, which comes in the form of a vinyl flipchart that's easily — you know, on the sidelines.

It also comes on an iPad or tablet version in which the baseline for the athletes are stored so immediately you'll know if there's a difference between what their baseline is and their time post-suspected head injury. That also comes in — you can also do it on a laptop or computer as well.

It has also been determined that it's an aid in determining quality of life in multiple sclerosis and Parkinson's Disease and ALS and functionality in hypoxia and extreme sleep deprivation.

So because of the widespread pathways relative to eye movements in the brain it picks up a lot of brain dysfunction and those papers have also been published relative to those other medical verticals.

(Dejure Baker): All right. Great.

Dr. Dodick: And I guess I would say that the numbers that one is reading on the three different cards the complexity increases with each card and then not the space
between the numbers horizontally and the space between the numbers vertically actually test saccadic eye movements which is what we're after here. And the test itself has been validated so that — and it has been validated and correlated with a number of other measures of concussion. So reading a book wouldn't be a substitute for reading these cards.

(Dejure Baker): All right.

Operator: The next question comes from the line of (Adam Sallet) from (KIMT TV). Please go ahead.

(Adam Sallet): Hey guys. So I was wondering I guess how do these get into a school, how can schools use these and are there any plans to get them in — for schools right now?

Dr. Dodick: Well, we're working hard in the State of Arizona — this is Dr. Dodick — to get this implemented in all schools. We've implemented it into Arizona Pop Warner League and so every kid in Arizona Pop Warner has been baselined with the King Devick Test and they get annual baselines. And so what happens is that every child, every youth athlete simply has a baseline that's stored and that's used to compare to their sideline assessment if indeed a concussion is suspected and we track that after injury in our clinics.

So we're doing everything we can to get this implemented statewide in all of the schools. We've implemented it now in more than 30 schools around the Phoenix Valley area as well as I said in Arizona Pop Warner.

So it's a matter of time, not — you know, medical discoveries take time to be implemented into clinical practice and to get implemented on a wide — in a broad scale. But once the awareness gets out there then I think this will be
picked up by most schools around the nation as it should because it's a very — as Dr. Devick says — it's very simple, valid and accurate way to detect concussion on the sidelines.

So there is no cost — there should be no cost burden to this and it literally takes less than two minutes to administer. So there's no reason for an athlete not to have an annual baseline with this.

Dr. Devick: I could add to that a couple of thousand schools and leagues already — and individuals already utilize this test on the sidelines. It has been, since the first paper that indicated that it was a valid sideline test, it has been used in schools. And elite programs like the University of Florida Football Program and (TAN) use it. And like I said a couple of thousand schools, leagues and individuals already use it since the first paper almost four years ago.

But today we're talking really about the collaboration with the Mayo Clinic and the fact that we think for the first time in probably the history of Mayo that's done somewhat a (unintelligible) like this where their name is on a product that they helped validate but was developed earlier on as a reading test.

(Adam Sallet): All right, thank you.

Operator: The next question comes from the line of Chris Maathuis with KLAS-TV. Please go ahead.

Chris Maathuis: Hi gentlemen. Appreciate you taking my time. I'm out here in Las Vegas CBS affiliate. I was doing a story a while back with the RUVO people, the brain people here in Las Vegas, and then doing some interviews and so forth with the high school kids and — or the coaches. And they were saying that here in
Nevada they actually have some tests that are kind of on the cutting edge supposedly. Have you heard any — is this the next best thing? Is Nevada already doing some stuff, do you know?

Dr. Devick: I guess I can take that. I'm not sure what tests they're talking about relative to that. There really isn't a test for 'Remove from Play' that has been validated to the extent that the King Devick Test had. As Dr. Dodick said, it's really the gold standard for this kind of testing.

They may be talking about a test that's used for 'return to play.' In other words there are many neuro-cognitive tests out there that will help you determine when an athlete should go back in the game actually he's ready to be — healed, if you will.

But this is a test that determines when an athlete on the sideline should be removed from play. So I think that they were probably referencing tests that are used and certainly there are good tests that help you determine, along with the physician or a nurse psychologist, when the athlete is okay to return to the game.

Dr. Dodick: I suspect Mr. Devick is right. They're doing a lot of work up there with regard to imaging biomarkers. They're doing very sophisticated diagnostic MRI imaging of the brain to determine the degree and extent to which there has been a brain injury and whether and to what extent that injury has recovered.

So these are after-injury diagnostic studies, if you will, that guide decision-making to determine when and whether an athlete should return to play as opposed to the King Devick Test, which is more of a remove-from-play tool. It's used on the sideline to support the diagnosis of a concussion and to get that athlete out of play.
Then a number of other diagnostic tests are used, including some likely the King Devick Test to determine return to play. So I think that's what that group up there I believe is doing, but I don't know that they've been using anything other than King Devick to determine remove from play.

Chris Maathuis: Great. Let me follow up. Are there goals for you guys to get this into all the schools? You mentioned 2000 at this point athletes, individuals in schools. Are there goals — are there — who's reaching out to, say, the Nevada people, the NIAA here in Nevada to say, 'Hey, this is the latest and greatest gold standard. You guys, got to jump on this'? Who's kind of — who's taking charge of that?

Dr. Devick: Well, I have to say that we've waited — we haven't done much marketing relative to the test in the last four years as more and more research came in with all aspects of the testing on King Devick Test. There has been more than 50 published presentations and pieces in peer-reviewed neurological and other medical publications. We've kind of waited till it was completely vetted.

And of course we feel like the Mayo collaboration is something that's important so we will begin reaching out to all areas relative to information on this test and how to incorporate it into their schools.

Chris Maathuis: I guess you're saying too it's so — it's cost-effective. I mean it's - there's no burden to the school districts, are there?

Dr. Devick: No. And actually, you know, the school district did feel it was a burden. As I said, it's as little as $5 per athlete annually and that's for unlimited testing. So there's really no cost barrier when you figure what it costs for shin guards and
things like that with soccer. This is really insignificant relative to your athlete playing sports if you're a parent if the school didn't have the budget for it.

Dr. Dodick: And there really shouldn't be a time barrier either because each of these athletes has to undergo a pre-participation physical examination. So there's absolutely no reason why this couldn't and shouldn't be part of every pre-participation physical examination because we're talking about an extra minute, minute and half to administer. So there really is no barrier in terms of time. We're not adding a burden to the examining healthcare provider when they're doing their pre-participation physical.

Chris Maathuis: Yes, well, thank you very much, gentlemen.

Dr. Dodick: Thanks.

Dr. Devick: You're welcome.

Operator: The next question comes from the line of Kenneth Reed with League of Fans. Please go ahead.

Kenneth Reed: Hello, can you hear me?

Dr. Dodick: Sure can.

Dr. Devick: I can.

Kenneth Reed: Okay, hi. I was following up the first question I had. You just answered about the cost. Is it $5 per athlete annually? Is that part of a group price for like the school or could an individual get that same cost?
Dr. Devick: It's perhaps a little more expensive, less than $10 though in all cases. But, you know, as a group for a school, if you have a five — if you have 1000 athletes in all sports in the school it would be $5 per athlete. And that's about the cost for everyone. If it's a smaller sampling it's maybe $10 an athlete but it's really insignificant.

The reason we charge on an annual basis for this as a subscription model is that you have to have a baseline every year. This test depends on having a baseline within the last 12 months and so that's why it's annual charge to remind the individuals that they do need to record a baseline every year.

Your ability to name numbers as if you are reading gets better especially in the younger years. We even tell subjects that are - parents of subjects and coaches that are 6 and 7 years old that they may want to do a baseline every six months because their ability to perform this rapid number-naming test increases as they get better in reading at times.

We find that - a recent study has shown that you actually get better at this test every till you're about 40 and then of course you start to regress a little bit but the point being is that it's dependent on an annual baseline so we want to make it so that it's extremely affordable and it motivates the parents to record a new baseline every 12 months at the least.

Kenneth Reed: My big concern in like — in a concussion is quite a bit in writing about on is the sub-concussive impact and how there's a study showing now that athletes don't e- excuse me, don't even have to have a full-blown concussion to have brain damage which could eventually lead to a chronic traumatic encephalopathy and things like that. Is there any way that this test can pick up some of the sub-concussive impact damage?
Dr. Dodick: I'm glad you brought that up because one of the beauties of this test is not only can it detect the concussion when the player's symptomatic but it can also detect, we believe, the sub-concussive blows that are not symptomatic.

These are athletes who are not hiding symptoms; they simply are not experiencing any symptoms and we know that these fumbled functional and structural injuries to the brain can occur without indeed any outward symptoms.

We did a study here in Arizona with 150 high school hockey players and at the end of the season we tested every one of the players that we tested pre-season. First of all in every concussed athlete King Devick was abnormal, significantly abnormal, in every one of them. But in a handful of athletes -- 10 athletes at the end of the season — we detected individuals who were much lower than their baseline and these are athletes who never reported any symptoms and who indeed never had any symptoms.

So it appears to be sensitive for the detection of again a structural brain injury when it occurs even in the absence of symptoms which shouldn't be a surprise because, as I started with, if more than 50% of the pathways are responsible for eye movements, then if you injured the brain, even if there are no symptoms you should be able to detect abnormalities in those eye movements.

So it certainly does appear from our study and from our studies that it's sensitive to sub-concussive blows as well. So you could see a day, for example, if I was the coach of a hockey team or a football team or a any contact sport team where every athlete after the game does a King Devick Test — it literally takes, you know, a minute to two — and it would pick up any sub-concussive blows or any injuries that occur in athletes who weren't even symptomatic.
Kenneth Reed: Excellent.

Dr. Devick: Just to add to that, there was a study done in New Zealand of a rugby team, a youth rugby team, and they had doctors on the sidelines and they found in the course of a year they found five witnessed concussions where they stopped the play and they removed the athlete, he was — had a defect on his King Devick Test and they removed him from play.

But by testing every player after every game they found 17 more unwitnessed concussions and then they reviewed the game film and they found where those 17 concussions had occurred and all of them were away from the ball. So that's one of things it does. Everybody is watching the ball carrier and the ball and as a, you know, former lineman there's a big guy across from you that's going to try to beat you every play, and often concussions like that are unreported and not seen really and so perhaps the best protocol would be to do a King Devick Test quick score after every practice or game that has contact.

Kenneth Reed: Last one I had is you mentioned you could get this on a tablet. Can parents who don't usually carry around tablets, can you get it on like an iPhone or a phone of any type so it's always with you?

Dr. Devick: Well, the problem with the phone is that the size of the — it requires a tablet —sized — the test is — only fits on a tablet because you need the spacing and things for the numbers. Actually the test is, the physical test is exactly the same size as an iPad and the new androids too that have the large tablet area. So the problem with the phones is the area, the surface area of - the screen size isn't big enough.

Kenneth Reed: Okay. Thank you. Congratulations.
Dr. David Dodick: Thanks.

Dr. Devick: Thank you.

Operator: Ladies and gentlemen, as a reminder, to register a question, press the 1 followed by the 4 on your telephone. I have no further questions at this time.

Jim McVeigh: Dr. David Dodick and Dr. Steve Devick, do you have anything to add in conclusion? We have about three minutes to go.

Dr. Devick: I think that we had some great questions so I really think that the questions kind of covered anything that I would have added as a conclusion. So, Dr. David Dodick, perhaps you do but I don't.

Dr. Dodick: I just want to thank everybody for the type of questions that you did ask I would just say that again this is an exciting day for Mayo Clinic because we believe through this collaboration we're going to be keeping — we're going to be safeguarding the health and safety of athletes, both youth and professional — up to professional ranks around the country and indeed around the world. So it's exciting for Mayo Clinic to be part of this collaboration.

Dr. Devick: And for King Devick of course as well. Thank you.

Jim McVeigh: And thank you both for joining us today, and thank you everybody for being on the call. We are concluded. Thank you everyone.

Operator: Ladies and gentlemen, that does conclude the conference call for today. We thank you for your participation and ask that you please disconnect your line.

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